#### Case3:11-cv-04494-WHO Document411 Filed04/18/14 Page1 of 18 Gregory L. Diskant (admitted *pro hac vice*) Eugene M. Gelernter (admitted *pro hac vice*) Maggie Wittlin (admitted *pro hac vice*) PATTERSON BELKNAP WEBB & TYLER LLP 1133 Avenue of the Americas New York, NY 10036 Telephone: (212) 336-2000 4 Facsimile: (212) 336-2222 5 E-mail: gldiskant@pbwt.com emgelernter@pbwt.com 6 mwittlin@pbwt.com 7 Charles D. Hoffmann (admitted *pro hac vice*) 8 Sean Marshall (admitted pro hac vice) HOFFMANN MARSHALL STRONG LLP 116 W 23rd Street, Suite 500 New York, NY 10011 10 Telephone: (212) 851-8403 11 Facsimile: (646) 741-4502 E-mail: charlie@hmscounsel.com 12 sean@hmscounsel.com 13 Susan Roeder (S.B. #160897) O'MELVENY & MYERS LLP 14 2765 Sand Hill Road Menlo Park, CA 94025 15 Telephone: (650) 473-2600 Facsimile: (650) 473-2601 16 E-Mail: sroeder@omm.com 17 Attorneys for Plaintiffs LIFESCAN, INC. and LIFESCAN SCOTLAND, LTD. 18 19 20 UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA 21 SAN FRANCISCO 22 LIFESCAN, INC. and Case No. 11-04494-WHO LIFESCAN SCOTLAND, LTD., 23 **DECLARATION OF MARK E.** Plaintiffs, MEYERHOFF IN SUPPORT OF 24 V. PLAINTIFFS' OPPOSITION 25 SHASTA TECHNOLOGIES, LLC, DECISION DIAGNOSTICS CORP. 26 PHARMATECH SOLUTIONS, INC., and CONDUCTIVE TECHNOLOGIES, INC., 27 Defendants. 28 MEYERHOFF DECL. CASE NO. 11-04494-WHO 6714870v.1

declare as follows:

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1. I am the Philip J. Elving Professor of Chemistry at the University of Michigan. I have been retained to testify as an expert on behalf of the Plaintiffs in the above-captioned matter.

My research at the University of Michigan is in the areas of ion-selective electrodes, biosensors,

I, Mark E. Meyerhoff, Ph.D., pursuant to 28 U.S.C. § 1746 and under penalty of perjury,

bioanalytical chemistry, immunoassay, and novel nitric oxide releasing/generating polymers. I received a Ph.D. in chemistry from the State University of New York at Buffalo in February, 1979. For the last 35+ years, I have been extensively involved in the development, research of, and

analysis of electrochemical sensors for biomedically important analytes, including glucose, lactate, ions, gases, and other species of interest. A copy of my curriculum vitae is attached to this

Declaration as Exhibit A. I am fully familiar with the matters set forth below.

2. I submit this declaration in opposition to Defendants' motion for judgment on the pleadings (D.E. 399). I have previously submitted two declarations in this case, dated December 10, 2012 and February 15, 2013, respectively, in support of LifeScan's motion for a preliminary injunction. *See* D.E. 176-2; D.E. 215-1.

3. I have been asked to provide my opinions as an expert on the essential feature or inventive aspect of the invention claimed in the '105 patent. As discussed in more detail below, it is my opinion that that LifeScan's OneTouch® Ultra® meters do not embody all or substantially all of the inventive aspects of the '105 Patent and key inventive aspects of the '105 patent are embodied in the test strip.

### I. SUMMARY OF OPINIONS

4. The steps of the methods claimed by the '105 patent that are performed by LifeScan's OneTouch® Ultra® meter (i.e., measuring two currents, comparing them, and indicating an error if they are too dissimilar) are, as I said in my first declaration (D.E. 176-2 ¶48), relatively simple. In my previous declarations, I devoted a total of one sentence to the subject. There were a

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number of issues that Defendants raised in opposition to LifeScan's motion for a preliminary injunction, and my declaration in response focused almost entirely on Defendants' invalidity arguments and the meaning of the word "proportional." I did not specifically address where the inventive features of the '105 patent lie—or whether or not the steps performed by LifeScan's OneTouch® Ultra® meter were inventive in and of themselves—in any detail in those declarations.

5. After having more time to consider this issue and having occasion to review more prior art, I would like to explain my views in more detail here and point out further evidence that supports my views. In particular, I would like to address why the steps of the '105 patent that are performed by LifeScan's meter cannot be viewed as embodying all or substantially of the inventive features of the '105 patent and that LifeScan's OneTouch® Ultra® meter does not embody all or substantially all of the inventive features of the '105 patent.

### II. THE '105 PATENT

- 6. The '105 patent is directed towards an apparatus and method "for measuring the concentration of a substance in a liquid and particularly, but not exclusively, to [an] apparatus for measuring the concentration of glucose in blood." Ex. B at 1:7-10. Glucose measuring devices function by measuring electric current "between two sensor parts [of a given test strip] called the working and reference sensor parts respectively." *Id.* at 1:28-29. The test strip's "working sensor part comprises a layer of enzyme reagent, the current being generated by the transfer of electrons from the enzyme substrate, via the enzyme and an electron mediator compound to the surface of a conductive electrode." *Id.* at 1:29-33. The current generated by the test strip's working sensor "is proportional to both the area of the sensor part and also the concentration of glucose in the test sample." *Id.* at 1:34-35.
- 7. One of the problems in the test strip art that the patent sets out to solve is "that inaccurate results are obtained if the working sensor part is not fully covered with blood since then its effective area is reduced." *Id.* at 1:39-41. If the working sensor was not covered fully, but electrical connectivity by the sample to the reference electrode still occurred, the level of glucose

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monitored would be falsely low, creating great risk to the patient using the device. Previous methods of dealing with this problem involved using an electrode downstream of the working sensor part (i.e., a trigger) to detect the presence of the sample liquid. *Id.* at 1:41-48. Another way to solve the problem of incomplete coverage of the working sensor would be simply to reduce the size of the working sensor part. *Id.* at 1:49-52. This however "tends to give a greater variability in calibrated results." *Id.* at 1:52-54.

- 8. The inventors of the '105 patent "realized that as well as incomplete coverage of the working sensor part, inaccurate results can also arise from occasional defects in the production of the test strips for such devices, in the area and/or the thickness of the working sensor part and also from accidental damage to the working sensor part e.g. by a user." *Id.* at 1:55-60. And since these type of sensors cannot be tested in advance, either by the manufacturer, or the user, the possibility of defects yielding inaccurate results are real and potentially life threatening to patients with diabetes.
- 9. The object of the invention described in the '105 patent was to create a test strip and method for analyzing such a test strip that would overcome the problems described in the previous paragraphs. *Id.* at 1:65-2:27.
- 10. The solution described in the '105 patent involves the use of a test strip that has two substantially-identical, as much as possible via manufacturing methods, working sensor parts that both generate an electric current in proportion to the concentration of a substance (e.g. glucose) in a liquid (e.g. blood). *Id.* at 2:21-27. The inventors of the '105 patent recognized that when one uses a test strip with two substantially-identical working sensors, when the blood sample is applied to the test strip, one can compare the difference in the electric current generated at each working sensor to a predetermined value and then establish whether there is an error in the measurement depending on whether or not the difference between the current measured at each working sensor is greater than the predetermined threshold value. *Id.* at 2:10-2:14.
- 11. The '105 patent teaches that by comparing the currents at each working sensor, it is possible to detect whether there is an error in the measurement. Such an error could be caused, for

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example, by one of the working sensors not properly being covered with blood or a manufacturing defect in one of the WORKING sensors or either working sensor having been damaged after manufacture. *Id.* at 2:28-39.

- 12. As the inventors describe, the '105 patent provides a test strip arrangement "whereby for a given total area of working sensor part and thus a given minimum sample volume, detection of inadequate fill and of defects in the working sensor part [is] provided by separating the area of the working sensor part into two." *Id.* at 2:51-56. Such a test strip "is self-testing for proper use, damage and certain manufacturing defects." *Id.* at 3:4-6. This is particularly beneficial in the context of test strips that are typically mass manufactured, as now "the accuracy of the final result and thus potentially the safety of a user is no longer solely dependent upon high manufacturing precision." *Id.* at 3:12-14.
- 13. In order to make the test strip most useful for detecting insufficient sample volume, the '105 patent instructs that "[m]ore preferably ... the sample liquid is constrained to flow substantially unidirectionally across the working sensor parts ... [and] the two working sensor parts are arranged one downstream of the other." *Id.* at 3:40-44. This arrangement of sensors on the test strip "makes it possible to ensure that one of the sensor parts will always be completely covered before the other begins to be covered, thus avoiding the possibility, however small, that insufficient sample liquid is applied to cover both sensor parts and furthermore that each sensor part is partially covered by the same amount." *Id.* at 3:44-50. The '105 patent also instructs that it is "preferred that both working sensor parts are downstream of the reference sensor part" on the test strip. *Id.* at 3:56-58.
- 14. The '105 patent has one independent and two dependent claims directed towards using a test strip designed as described:
  - 1. A method of measuring the concentration of a substance in a sample liquid comprising the steps of:

providing a measuring device said device comprising:

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a first working sensor part for generating charge carriers in proportion to the concentration of said substance in the sample liquid;

a second working sensor part downstream from said first working sensor part also for generating charge carriers in proportion to the concentration of said substance in the sample liquid wherein said first and second working sensor parts are arranged such that, in the absence of an error condition, the quantity of said charge carriers generated by said first working sensors part are substantially identical to the quantity of said charge carriers generated by said second working sensor part; and

a reference sensor part upstream from said first and second working sensor parts which reference sensor part is a common reference for both the first and second working sensor parts, said reference sensor part and said first and second working sensor parts being arranged such that the sample liquid is constrained to flow substantially unidirectionally across said reference sensor part and said first and second working sensor parts; wherein said first and second working sensor parts and said reference sensor part are provided on a disposable test strip;

applying the sample liquid to said measuring device;

measuring an electric current at each working sensor part proportional to the concentration of said substance in the sample liquid;

comparing the electric current from each of the working sensor parts to establish a difference parameter;

and giving an indication of an error if said difference parameter is greater than a predetermined threshold.

- 2. The method as claimed in claim 1 comprising measuring the current at each working sensor part after a predetermined time following application of the sample.
- 3. The method as claimed in claim 1 wherein the substance to be measured is glucose, and each of the working sensor parts generates charge carriers in proportion to the concentration of glucose in the sample liquid.

*Id.* at 6:51-8:12.

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### III. LIFESCAN'S METER DOES NOT EMBODY ALL OR SUBSTANTIALLY ALL OF THE INVENTIVE OR ESSENTIAL FEATURES OF THE '105 PATENT

- 15. I have been asked to consider whether the LifeScan OneTouch Ultra® family of glucose meters ("Ultra Meters") embody all or substantially all of the inventive or essential features of the '105 patent. It is my opinion that they do not.
- 16. At a high level, Ultra Meters are programmed such that they are able to apply the voltage required to oxidize/reduce mediator at the dual working and single reference/counter electrodes, measure the current traveling through two separate circuits, compare those current measurements, and provide an error message if those currents differ by more than a certain percentage. When used with a test strip with the specific characteristics detailed in the '105 patent claims (such as the LifeScan OneTouch Ultra® test strips or the Shasta GenStrips), Ultra Meters perform the "measuring," "comparing," and "giving an indication of an error" steps of claim 1 of the '105 patent.
- features of the '105 patent. Thus, the Ultra Meter, simply by having the capability to perform these steps, does not embody all or substantially all of the inventive or essential features of the '105 patent. There are at least three reasons for this. First, the '105 patent specification does not discuss these steps or the design of a meter for performing such steps in any detail, as they are trivial. Second, the steps of measuring, comparing, and error indicating, in combination and outside the context of the claimed invention, were widely known and employed prior to the time of the '105 patent; they would not have been patentable in of themselves, and are not inventive in of themselves. Finally, the Ultra meter alone does not lead one to know which type of strip to use with the meter in order to practice the '105 patent; a person of skill in the art would need to make inventive decisions with regard to the design of a test strip for use with the Ultra meter in order to use the Ultra meter in the manner claimed by the '105 patent. The novelty of the '105 patent was the realization that one could combine the straightforward step of comparing the difference of two current readings against a

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threshold with a very specific test-strip sensor arrangement to detect sample size and manufacturing problems. The arrangement of the test strip is essential to the invention of the '105 patent.

### "Measuring," "comparing" and "giving an indication of an error" or a device for performing these steps are trivial to the '105 patented invention

- 18. It is easy to misunderstand the '105 patent as requiring a specific meter or other particular piece of equipment programmed in a certain way to perform the claims. This, however, is not the case. The claims do not require a meter at all, just that a certain set of fairly straightforward steps be performed on a test strip of a specific design. Namely, all that is required is that current is measured at two sensors of this test strip to which blood has been applied, those currents are compared, and then an indication of an error is given if the currents differ by a predetermined amount.
- 19. As I explained at my deposition in Jaunary, 2013, "to practice the '105 patent, you don't need Johnson & Johnson's meter. I can do that in the laboratory and connect electrodes and subtract the two signals and compare the two signals. It's not – that's a very trivial component." Ex. C, (Meyerhoff Dep.) at 95:14-19. One could perform the method with a test strip, an ammeter, and a pencil and piece of paper to do the calculations.
- 20. A simple examination of the claim itself shows this to be the case. Claim 1 of the '105 patent is a "method of measuring." Ex. B at Claim 1. The first step of the method is "providing a measuring device." The only requirements of the measuring device being provided are that it is a comprises "a first working sensor part," "a second working sensor part," and "a reference sensor part" that have certain properties and are arranged on a disposable test strip such that liquid is constrained to flow substantially first across the reference working sensor part, then the first working sensor part, and finally the second working sensor part. Id. The measuring device itself need not include a meter of any sort or anything at all that performs the measuring, comparing, and error indicating steps of the '105 patent.
- 21. Indeed, the '105 patent's specification is focused almost entirely on the design of the test strip. While there are seven figures depicting the unique layout of the test strip, there are none

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regarding a meter. Similarly, many paragraphs are devoted to the design of the test strip and the arrangement of sensor parts, but there is nothing about the design of a meter for doing the measurements, how to do the measurements, or any components of a system for doing the measurements.

- 22. In addition, the patentee never claims that the steps of measuring, comparing, and indicating an error are inventive in of themselves. And, as far as I am aware, the '105 patent inventors made no attempt to patent the measurement, comparison, and error indication steps apart from their use with a specifically designed test strip. There is nothing from the patent that indicates to me that the patentees considered these steps to be the inventive aspects of the '105 patent. This is not surprising to me, as these steps are trivial and easy to perform by one of skill in the art.
  - B. "Measuring," "comparing," and "giving an indication of an error" are, alone, not what distinguishes the '105 patent from the prior art
- 23. It is my opinion that LifeScan would have been unable to obtain a patent on a method simply comprising the "measuring," "comparing," and "giving an indication of an error" steps of the '105 patent claims or on a device for performing those steps, and that those steps in of themselves are not what distinguish the '105 patent from the prior art.
- 24. The steps of measuring electric currents, comparing them, and giving an indication of error if they differ by a given amount are not something that was new or inventive at the time of the invention of the '105 patent. Systems that use redundancy as a reliability check have existed for a long time. As explained by U.S. Patent No. 4,337,516 to Murphy et al. (filed in 1980), "it has been known to use a pair of sensors of an identical type (redundant sensors) the output of which are compared, a failure or fault being indicated in the event that the outputs of the two sensors fail to track within a tolerance limit of each other." Ex. D, at 1:59-64.
- 25. For example, U.S. Patent No. 3,496,836 to Jenney (filed in 1968) describes use of "[a] comparator apparatus [that] is connected to receive the monitor signals and compare individual pairs thereof so as to detect any discrepancy there between. In the event of a detected discrepancy,

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switch means which is connected to the comparator means operates to disable the preselected channel which caused the discrepancy to occur." Ex. E, at 2:26-31.

- 26. Similarly, U.S. Patent No. 3,667,057 to Pfersch, Jr. et al. (filed in 1970) describes "[a] circuit [with] averaging means for providing an output corresponding to the average acceptable input signals, a comparator for comparing each input signal to the average output, and switching means controlled by the comparator for eliminating unacceptable input signal from the average when the signals differ a predetermined amount from the average output." Ex. F, at Abstract.
- 27. And again, U.S. Patent No. 3,895,223 to Neuner et al. (issued in 1975) describes "[a] circuit arrangement for enhancing the reliability of common bus outputs in redundant systems generating a plurality of at least three substantially similar outputs to a common bus signal train. Each output is separately compared to the other corresponding outputs and if a difference is determined, the output exhibiting the difference is disconnected from the common bus." Ex. G, at Abstract. These early systems did not involve the measurement of concentrations of substances in liquids, however the principals involved in measuring and comparing signals are the same as those in the '105 patent.
- 28. Simply put, the process alone of measuring and comparing signals and giving an indication of an error was widely known and not inventive as of the time of the '105 patent. *See also* U.S. Patent No. 4,327,437, Ex. H at 2:10-16 ("The detected median value signals are then compared to determine if any one of the detected median value signals exceeds the others by an amount greater than the signal level for a failed sensor. If this is the case, the detected median value signal which exceeds the others is transmitted to the control computer as the primary control signal."); U.S. Patent No. 5,570,300 Ex. I, at 1:40-46 ("[C]ontrol system designers often rely on sensor redundancy to reduce the effect of any sensor fault that may occur. If measurement data from a sensor in a group of redundant sensors is inconsistent with measurement data from other sensors in the group, a control system can designate the inconsistent data as unreliable and ignore that data."); U.S. Patent No. 5,602,732, Ex. J at 1:26-29 ("If a majority of the at least three sensors indicate substantially the same

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position, any other sensors not in agreement will be assumed to be faulty and will be excluded, at
least temporarily, from further use."); U.S. Patent No. 5,661,735, Ex. K at 1:16-19 ("When
redundant sensors are provided for measuring a quantity, it is theoretically possible to detect failures
in one or a number of such sensors by comparison of the data provided by the sensors."); U.S. Patent
No. 6,016,465, Ex. L at 1:21-25 ("This duplication of components is referred to as 'hardware
redundancy', which means that if a fault arises in one of the sensors, its presence is indicated by
virtue of the two sensors being dissimilar [T]his method is widely used"); U.S. Patent No.
6,029,524, Ex. M at 2:47-63 ("The method includes measuring an applied differential pressure using
a pressure transducer having a fluid pressure sensor comprising first and second variable pressure
sensors for providing an electrical output as a function of an applied differential fluid pressure, the
first and second pressure sensors being substantially identical; applying a differential fluid pressure
to the first and second pressure sensors via a valve; generating a first signal whose frequency is
proportional to the electrical output of the first variable pressure sensor and a second signal whose
frequency is proportional to the electrical output of the second variable pressure sensor; determining
whether the difference between the first signal and the second signal is within a preselected range;
and determining whether the sensor is damaged based upon whether the second signal is outside the
limits of the preselected range.")

29. By the time the '105 patent was filed, the steps of measuring, comparing, and providing an indication of an error had already been used in conjunction with measuring the concentration of a substance in a liquid. For example, U.S. Patent No. 5,924,794 to O'Dougherty et al., directed to a "chemical blending system for blending two or more constituent chemicals to a desired concentration," Ex. N, at Abstract, describes a method of measuring the concentration of the blended chemical: A device induces an electric current in the blended chemical that "is directly related to the conductivity, and therefore concentration of the blended chemical," *id.* at 7:43-45, two sensors measure the current and an analyzer "relates the monitored conductivity values of the blended chemical to the weight % concentration values of the blended chemical," *id.* at 7:52-54, and

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a "[m]icroprocessor [] continuously compares the concentration values generated from the sensors . . , and performs a deviation analysis to monitor the operation of the sensors," *id.* at 8:7-10. If the microprocessor "determine[s] that the concentration values are not equal (i.e., if excess deviation exists), [a] control subsystem [] will stop or discontinue the operation of [the] blending system [], and provide a corresponding error message on [the] terminal." *Id.* at 8:18-22.

- 30. Indeed, there are examples of the use of redundant sensors in the glucose monitoring field prior to the '105 patent as well. U.S. Patent No. 5,965,380 to Heller et al., for one, describes "miniature glucose sensors for subcutaneous measurement of glucose with one-point calibration." Ex. O, at 1:19-21. The Heller patent notes that "[r]edundant sensors (e.g., at least two) are preferred in the clinical application of the subcutaneous biosensors. Such redundancy permits signaling of failure of any one sensor by recognition of an increase in the discrepancy between the readings of the sensors at one time point, e.g., more than two standard deviations apart." *Id.* at 7:49:54.
- 31. It should be noted, that both the Heller and O'Dougherty references are continuous-monitoring sensors—rather than one-time use test strips. As I described in my previous declaration, continuous-monitoring sensors do not have the sample sufficiency problem that the '105 patent was setting out to solve, and the use of redundant sensors in the implantable/continuous sensor field was for a different purpose: namely, for detection of when a sensor in a real-time detection system was no longer working.
- 32. It is my opinion that if the examiner had been presented with claims directed simply to the measuring, comparing, and error indicating functions performed by LifeScan's meter, the claims would not have issued. There is nothing inventive in those steps in of themselves and they are not, in of themselves, distinguishable from the prior art. They have been known for decades if not longer. No sophisticated equipment or complicated algorithm is required for these steps. What distinguishes the '105 patent from the prior art is the arrangement of the equally sized (surface area) working and reference sensor parts on the disposable test strip that are in series with each other that allows the ultimate steps of measuring and comparing the current from the working sensors to be

indicative of an incomplete liquid (blood) fill of the sample chamber, among other possible test problems.

# C. LifeScan's Ultra Meters do not embody all or substantially all of the "essential features" of the '105 patent

- 33. As I stated earlier, at a high level, Ultra Meters are programmed such that they are able to apply an adequate potential to oxidize and reduce mediator species within the test strip, measure the current traveling through two separate circuits, compare those current measurements, and provide an error message if those currents differ by more than a certain percentage. There is nothing about the Ultra Meter, however, that requires that it be used with a test strip designed with unidirectional flow across a reference sensor part and two working sensor parts. And, further, there is nothing about the Ultra Meter's design or algorithms that makes it apparent that it should be used with a test strip of the design of the claims of the '105 patent and therefore practice the '105 patent.
- 34. For example, the '105 patent claims include the step "applying the sample liquid to said measuring device." LifeScan sells OneTouch® Ultra® control solution, which is a solution of glucose at a known concentration. The purpose of the solution is for purchasers of an Ultra Meter and Ultra test strip to be able to test the system to see if it is functioning properly and providing accurate glucose readings. The one purpose it is sold for is to be used in a method that would literally infringe the patent claim of the '105 patent. Without the control solution or some other sample liquid (e.g., blood), one could not infringe the '105 patent. However, it would be absurd in my opinion to view the control solution as embodying the "essential features" of the '105 patent. The only reason the control solution is used in a method that practices claim 1 of the '105 patent is that a person testing their Ultra Meter and test strips has both the Ultra Meter and test strips. While having a sample liquid to apply to a measuring device is essential to practice the '105 patent, the LifeScan control solution, while capable of being used in the method of the '105 patent and sold to be used in that method, does not embody the essential features of the '105 patent.
- 35. In the same way, the Ultra Meters do not embody all or substantially all of the essential features of the '105 patent. LifeScan sells the Ultra meters for the purpose of measuring

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1 glucose with the LifeScan Ultra® test strips. Its purpose is to be used with LifeScan's Ultra® test 2 strips in a manner that practices the claims of the '105 patent. But the only reason that it is used to 3 practice the '105 patent is because the test strips it is sold to be used with have the sensor 4 arrangement of the '105 patent claim. The steps that the Ultra meter performs are, as described 5 before, well known and trivial. If the '105 patent did not exist and LifeScan did not sell the Ultra test 6 strips, it would not be apparent that the Ultra meter should be used with a test strip with the specific 7 arrangement of the '105 patent claims. At most, it would be apparent that it should be used with a 8 test strip with redundant sensors. But without the sensors in the particular arrangement of the '105 9 patent claim, a system would not take full advantage of the sample size verification toward which 10 the '105 patent is directed. And while the steps of measuring, comparing, and error indicating are 11 necessary to practice the method of the '105 patent, the Ultra meters do not embody all or 12 substantially all of the "essential features" of the '105 patent, despite being capable of being used in 13 the method of the '105 patent and sold to be used in that method. A person of skill in the art would 14 need to make inventive decisions with regard to the design of a test strip for use with the Ultra meter 15 in order to use the Ultra meter in the manner claimed by the '105 patent. 16

# D. The test strip of the '105 Patent comprises inventive and essential features of the '105 patent

36. It is my opinion that inventive or essential features of the '105 patent are embodied in a test strip of the design of the '105 patent claims, such as the Shasta GenStrip or LifeScan OneTouch® Ultra® test strip.

37. As I described earlier, the only structure required of the measuring device of the '105 patent claim method is a disposable test strip with sensor parts of certain properties in a certain arrangement. Ex. B at Claim 1. These parts are arranged such that, when blood is introduced to the test strip, the blood first traverses a reference sensor part and then traverses a first working sensor part, and then the blood reaches the second working sensor part placed at the end of electrode series. This allows for a method of comparing the current at the first and second sensor parts to see if those currents are substantially the same. If they are not, an indication of an error can be given, indicating

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that either one of the sensors is defective, or not enough blood entered the sample channel or some other problem has occurred with the test strip measurement. This arrangement is, thus, essential to the invention of the '105 Patent claim.

- 38. The specification describes the inventive aspects of the '105 patent as primarily lying in a test strip having the arrangement described in the claims. The patentees wrote "the measuring device used in this method is novel and inventive in its own right ... said device comprising: a reference sensor part, a first working sensor part, comprising a working layer for generating an electric current proportional to the concentration of said substance in the sample liquid; and a second working sensor part comprising a working layer also for generating an electric current proportional to the concentration of said substance in the sample liquid." *Id.* at 2:15-27. They continued "[1]ooking at the invention another way, it provides an arrangement whereby for a given total area of working sensor part and thus a given minimum sample volume, detection of inadequate fill and of defects in the working sensor part provided by separating the area of the working sensor part into two." *Id.* at 2:51-56.
- 39. It is the test strip's specific arrangement that allows the '105 patent claim steps to be indicative of inadequate fill. This arrangement is essential to the invention, and embodied only in the test strip.

### E. The combination of test strip and meter performing the measuring, comparing, and error indicating steps is inventive

40. I am aware that the inventors of the '105 patent also attempted to obtain a patent on a test strip in a continuation patent to the '105 patent, but that those claims were ultimately abandoned and never issued. I understand that it is argued that because the patentees did not obtain a patent on a test strip itself, that the test strip therefore cannot embody inventive aspects of the '105 patent. I do not believe that the failure to obtain a patent on such a test strip indicates the opposite-that a device that performs the measuring, comparing, and error indicating steps, such as an Ultra

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meter, is therefore what embodies the inventive or essential features of the '105 patent. At most it indicates that it may only be the combination of the specifically designed test strip with a series of steps that is inventive, rather than the test strip in itself.

As I described above, the steps performed by the Ultra meter are trivial, well known, and would not have by themselves been patentable and simply cannot embody all or substantially all of the inventive features of the '105 patent by themselves. To be sure, the combination of the test strip and the Ultra meter together certainly embody all of the inventive or essential features of the '105 patent, needing only the addition of blood or some other sample liquid to practice the claimed method. It is the test strip, arranged as specified in the '105 patent, however, that allows execution of the claimed method to identify both sample size and test strip defect problems. The test strip arrangement is essential to the invention and not determined by LifeScan's Ultra meter. If the test strip does not embody all of the essential aspects itself, it must then only be the combination of test strip and the steps of measuring, comparing, and indicating error that is inventive; it is surely not the meter itself.

# IV. THE TEST STRIP IS ESPECIALLY MADE OR ESPECIALLY ADAPTED FOR USE IN AN INFRINGMENT OF THE '105 PATENT

42. I have been asked to consider whether the test strip described by the '105 patent and the Shasta Genstrip have been especially made or especially adapted for use in practicing the '105 patent, and are not staple articles or commodities of commerce suitable for noninfringing use. It is my opinion that they are especially adapted for practicing the '105 patent.

# A. The test strip of the '105 patent is especially made for use in practicing the '105 patent

43. As I have describe previously, the '105 patent provides a test strip arrangement "whereby for a given total area of working sensor part and thus a given minimum sample volume, detection of inadequate fill and of defects in the working sensor part [is] provided by separating the area of the working sensor part into two." *Id.* at 2:51-56. Such a test strip "is self-testing for proper use, damage and certain manufacturing defects." *Id.* at 3:4-6. This is particularly beneficial in the

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context of test strips that are typically mass manufactured, as now "the accuracy of the final result and thus potentially the safety of a user is no longer solely dependent upon high manufacturing precision." *Id.* at 3:12-14.

- 44. In order to make the test strip most useful for detecting insufficient sample volume, the '105 patent instructs that "[m]ore preferably ... the sample liquid is constrained to flow substantially unidirectionally across the working sensor parts ... [and] the two working sensor parts are arranged one downstream of the other." *Id.* at 3:40-44. This arrangement of sensors on the test strip "makes it possible to ensure that one of the sensor parts will always be completely covered before the other begins to be covered, thus avoiding the possibility, however small, that insufficient sample liquid is applied to cover both sensor parts and furthermore that each sensor part is partially covered by the same amount." *Id.* at 3:44-50. The '105 patent also instructs that it is "preferred that both working sensor parts are downstream of the reference sensor part" on the test strip. *Id.* at 3:56-58.
- 45. As far as I am aware, test strips designed as described by the '105 patent are not commercially available outside of those used with the LifeScan Ultra meters. They are not staple articles or commodities of commerce suitable for substantial noninfringing use, but rather are especially made or adapted for use in practicing the '105 patent claims.

### B. The Shasta Genstrip is especially made for use in practicing the '105 patent

46. As I described in a previous declaration, I have reviewed Shasta documentation describing the Shasta GenStrip and its use, including documentation submitted by Shasta to the Food and Drug Administration and correspondence related to those submissions. I have further analyzed samples of the Shasta GenStrip that have been provided to me. Shasta has not identified any uses of the Shasta GenStrip for monitoring glucose in blood samples that do not infringe claims 1, 2, and 3 of the '105 Patent, and I am unaware of any. Indeed, the only use of the Shasta GenStrip approved by the FDA infringes claims 1, 2, and 3 of the '105 patent. *See* Ex. P at 2-4. It is therefore my opinion

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1 2 3	that the Shasta GenStrip has been especially made or especially adapted for use in infringing the '105 patent, and is not a staple article or commodity of commerce suitable for noninfringing use.		
5	I declare under penalty of perjury that the foregoing is true and correct.		
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7	4/17/2014 Noch E. MINS		
8	Date Mark E. Meyerhoff, Ph.D.		
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# **EXHIBIT** A

#### **VITA**

MARK E. MEYERHOFF

Department of Chemistry The University of Michigan Ann Arbor, MI 48109-1055

Tel: 313-763-5916

PERSONAL: Born April 10, 1953, Bronx, N.Y.; Married, two children.

EDUCATION: Ph.D., State University of New York at Buffalo, conferral date: February,

1979. Thesis Director: Prof. G.A. Rechnitz

B.A., Chemistry, Herbert H. Lehman College (CUNY system), 1974.

PROFESSIONAL EXPERIENCE:

2004-present. Philip J. Elving Professor of Chemistry, The University of Michigan. Research in the areas of ion-selective electrodes, biosensors, bioanalytical chemistry, immunoassays, and novel nitric oxide

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releasing/generating polymers.

1990-05. Professor of Chemistry, The University of Michigan

1985-90. Associate Professor of Chemistry, The University of Michigan.

1979-85. Assistant Professor of Chemistry, The University of Michigan.

1978-79. Postdoctoral Fellow, Department of Chemistry, University of

Delaware, Newark, DE; Advisor, Prof. G. A. Rechnitz

PUBLICATIONS, PRESENTATIONS

AND GRANTS: see attached pages.

HONORS: -Phi Lambda Upsilon's Award for "Outstanding Teaching and

Leadership," 1982.

-Faculty Recognition Award, The University of Michigan, 1990.
-Research Award, LS&A College, The University of Michigan, 1995.
-Fellow, National Academy of Clinical Biochemistry, 2002-present
-ACS-Division of Analytical Chemistry Award in Electrochemistry, 2003.
-Society for Electroanalytical Chemistry, Charles N. Reilley Award, 2006.

-Outstanding Graduate Mentoring Award, Univ. of Michigan, 2006.

-Distinguished Faculty Achievement Award, Univ. of Michigan, 2011.

EDITORIAL/

ADVISORY
Analytical Chemistry, Clinical Chemistry, Analytica Chimica Acta,
Applied Biochemistry and Biotechnology, Biosensors & Bioelectronics,

Electroanalysis

Member, NIH Enabling Bioanalytical Tech. Study Section (2006-2010)

CONSULTANTSHIPS/

**SCIENTIFIC** 

ADVISORY *Present:* Instrumentation Laboratories Inc., Michigan Critical Care

BOARDS Consultants, Selective Technologies, EyeLab LLC.

**Past:** AngioScore Inc., Medtronic, Abbott Laboratories, GDS Technologies, Mallinckrodt Medical, Diamond Sensor Systems, Sensicore,

Bolton Medical, Eli Lilly, St. Jude Medical.

### RESEARCH FUNDING

#### **Current**:

- 1. National Institutes of Health, "Biocompatible Chemical Sensors via Nitric Oxide Release," January 1, 2010 December 31, 2013; \$1,323,679 total costs (4<sup>th</sup> renewal of grant initiated January 1, 1998).
- 2. National Institutes of Health, "Polymer Membrane Ion/Polyion Sensors: New Frontiers," April 1, 2010 to February 28, 2014; \$928,605 total costs (8th renewal of grant initiated on April 1, 1981).
- 3. National Institutes of Health, "Thrombroresistant Polymers via Catalytic Nitric Oxide Generation, May 1, 2009 March 31, 2013; \$1,348,849 total costs (2<sup>nd</sup> renewal of grant initiated May 1, 2005).
- 4. National Institutes of Health, "Extracorporeal Circulation without Anticoagulation," March 1, 2008 February 28, 2013; \$3,629135 total costs (PI: Robert H. Bartlett; MEM is co-investigator).
- 5. EyeLab Inc. "Microbiosensor for Monitoring Glucose in Tear Fluid," January 1, 2011 December 31, 2013, \$86,000 total costs.

#### **Previous:**

- 1. Petroleum Research Fund ACS, "Polymer Membrane Electrode-Based Potentiometric Gas Sensors," September 1, 1980 to August 31, 1982; \$10,000 total direct costs.
- 2. American Cancer Society, "Enzyme-Immunoassays of Diagnostically Important Enzymes," January 1, 1981 to December 31, 1981; \$4,500 total direct costs.
- 3. Rackham Foundation, "Electrode-Based Homogeneous Enzyme Immunoassay for Cyclic-AMP," January 1, 1980 to December 31, 1981; \$7,000 total direct costs.
- 4. Biomedical Research Council University of Michigan, "Interdisciplinary Projects Involving a Micro-Computer Controlled HPLC System," January, 1984; \$23,150 total direct costs for equipment acquisition.
- 5. Environmental Protection Agency, "Development of Bio-Membrane Toxicity Electrodes," September 1, 1981 to January 31, 1985; \$120,000 total direct costs; co-investigator: K. H. Mancy, School of Public Health.
- 6 Medtronics Inc., "Development of Miniature Gas Sensors Suitable for In-Vivo Monitoring," yearly unrestricted gift; \$10,000/year.
- 7. Eli Lilly and Company, unsolicited grant, yearly unrestricted gift; \$7,200/year; March 1, 1984 to February 28, 1986.
- 8. National Science Foundation, "Mechanistic Studies of Carbonate Selective Membrane Electrodes," January 1986 to June 1986, \$8,000 total costs (for sabbatical trip to ETH, Zurich).

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- Whitaker Foundation, "Enzyme-Linked Immunoelectrodes for Continuous Monitoring of Hormones and Drugs," September 1, 1984 to August 31, 1987; \$123,800 total costs; coinvestigator: W. Schramm, Department of Reproduction and Differentiation.
- 10. Eli Lilly and Company, "Studies on Immuno-Electrochemical Approaches for the Continuous Monitoring of Theophylline in Blood," February 1, 1986 to July 31, 1987; \$55,380 total costs.
- 11. Aquanautics Inc., "Gas Sensors Based on Membrane Active Organometallics," December 1, 1988 November 30, 1989; \$9,000 direct costs.
- 12. The University of Michigan President's Initiatives Grant, "Cellular Bioengineering: Positioning the University of Michigan for the 1990's and Beyond," June 1, 1987 to May 31, 1990; \$390,591 total direct costs; co-investigators: A. Rees Midgley, B.O. Palsson, and M. A. Savageau.
- 13. Mallinckrodt Sensors Inc., "Novel Biosensor Systems," July 1, 1988 to June 30, 1990; \$40,000 total costs.
- 14. Hybritech Inc., "Enzyme Activation by Tandem Sandwich Formation (EATSF) Combined with In-Situ Electrochemical Release of Substrate: A New Psuedo-Homogeneous Enzyme-Immunoassay for Rapid Detection of Proteins," October 1, 1992 to September 30, 1993; \$50,000 total costs.
- 15. National Science Foundation, "Efficient Monoclonal Antibody Production," November 15, 1990 to November 14, 1993; \$664,098; co-investigators: B. O. Palsson and M Savageau.
- 16. National Science Foundation, "Site Directed Bioreagent Immobilization for Development of Microbiosensor Arrays," September 1, 1989 to July 31, 1993; \$570,986 total costs; coinvestigator: Richard Brown.
- 17. National Science Foundation, "Immobilized Porphyrins as Versatile Stationary Phases in Liquid Chromatography," March 1, 1994 to September 30, 1995; \$50,000 direct costs.
- 18. Mallinckrodt Medical, "Planar Sensor Fabrication; A Feasibility Study," July 1, 1995 June 30, 1996; \$210,487 total costs; co-investigator: R. B. Brown (Electrical Engineering).
- 19. National Science Foundation, "New Directions for Enzyme-Linked Binding Assays" June 1, 1995 to May 31, 1999; \$312,000 total costs (continuous renewal of grant initiated on Sept. 1, 1982).
- 20. Bolton Medical Inc. "Development of Novel Nitric Oxide Release Polymeric Coatings to Reduce Risks of Thrombosis and Restenosis Associated with Placement of Metallic Coronary Artery Stents," February 1, 2001 to May 31, 2003; \$206,000.
- 21. U.S.-Polish Maria Sklodowska-Curie Joint Fund, "Anion-Selective Polymeric Membranes: Design, Optimization and Application," January 1, 1999 to June 30, 2003; \$250,000; co-investigator: Elzbieta Malinowska (Technical University of Warsaw).
- 22. Medtronic Blood Management Inc., "An Electrochemical Heparin Sensor," January 1, 2000-December 31, 2004: \$200,000 total costs; co-investigator; V. C. Yang (Pharmacy).
- 23. HandyLab Inc., "Sensitive Real-Time Measurement of PCR-DNA Analysis Using Enzyme Amplified Electrochemical Detection," August 1, 2003 to July 30, 2005; \$170,000.

- 24. Michigan Critical Care Consultants Inc., "Enhanced Nitric Oxide-Releasing Polymer Coatings," NIH SBIR Phase II, March 1, 2004 May 30, 2006; \$185,000 total costs.
- 25. Michigan Critical Care Consultants, "In Vivo Glucose Sensors with Prolonged Accuracy," subcontract for NIH-SBIR grant, July 1, 2006 May 31, 2007; \$ 23,760 total costs.
- 26. MICHR-Pilot Grant for Transitional and Clinical Research, "Thromboresistant Hemodialysis Circuits via Catalytic NO Generating Surfaces," January 1, 2008 December 31, 2008; \$100,000 direct costs (PI: Dr. Gail Annich; MEM is co-PI).
- 27. U.S. Army, "Nitric Oxide Generating Polymeric Coatings for Subcutaneous Glucose Sensors", September 15, 2005 September 14, 2009; \$300,000 total costs.
- 28. Coulter Foundation, "Rapid Sensor-Based Method To Detect S-Nitrosohemoglobin Deficiency/Stability In Red Blood Cells," July 1, 2008 June 30, 2009; \$100,000 direct costs (PI: Shu Takayama, Biomedical Engineering; MEM is co-PI).
- 29. Accord Biomaterials Inc., "Implantable Glucose Sensors with Prolonged Accuracy," September 1, 2008 August 31, 2010; \$102,000 total costs; NIH Phase II-SBIR subcontract to U of M.
- 30. State of Michigan—Michigan Initiative for Innovation and Entrepreneurship, "Intracellular Potassium Monitoring Device Development," December 1, 2008 November 30, 2009; \$32,646 total costs (co-PI: Dr. Maria Delgado).
- 31. Eli Lilly Foundation, "Analytical Graduate Program at the University of Michigan," September 1, 2008 August 31, 2010; \$50,000 (for analytical graduate student fellowships).

#### **Publications and Patents\***

- 1. M. Meyerhoff and G. A. Rechnitz, "An Activated Enzyme Electrode for Creatinine," Anal. Chim. Acta, <u>85 (2)</u>, 277-285 (1976).
- 2. M. Meyerhoff and G. A. Rechnitz, "Antibody Binding Measurements with Hapten-Selective Membrane Electrodes," Science, <u>195 (4277)</u>, 494-495 (1977).
- 3. G. A. Rechnitz, T. L. Riechel, R. K. Kobos, and M. E. Meyerhoff, "Glutamine Selective Membrane Electrode Using Living Bacterial Cells," Science, <u>199 (4327)</u>, 440-441 (1978).
- 4. Paul D'Orazio, M. E. Meyerhoff and G. A. Rechnitz, "Membrane Electrode Measurements of Lysozyme Using Living Bacterial Cells," Anal. Chem., <u>50 (11)</u>, 1531-1534 (1978).
- 5. G. A. Rechnitz, M. A. Arnold and M. E. Meyerhoff, "Bio-Selective Membrane Electrode Using Tissue Slices," Nature, <u>278 (5703)</u>, 466-467 (1979).
- 6. C. R. Gebauer, M. E. Meyerhoff, and G. A. Rechnitz, "Enzyme Electrode Based Kinetic Assays of Enzyme Activities," Anal. Biochem., <u>95</u> (2), 479-482 (1979).
- 7. M. E. Meyerhoff and G. A. Rechnitz, "Electrode Based Enzyme-Immunoassays Using Urease Conjugates," Anal. Biochem., <u>95 (2)</u>, 483-493 (1979).
- 8. M. E. Meyerhoff and G. A. Rechnitz, "Microsomal Thyroxine Measurements with Iodide Selective Membrane Electrodes," Anal. Lett. A, <u>12 (13)</u>, 1339-1346 (1979).
- 9. M. E. Meyerhoff and G. A. Rechnitz, "Electrode Based Enzyme Immunoassays Using Urease Conjugates," Meth. Enzymol., <u>70</u>, 439-454 (1980).
- 10. G. A. Rechnitz, M. A. Arnold and M. E. Meyerhoff, "Bio-Selective Electrode Probes Using Tissue Slices," U. S. Patent #4,216,065, August, 1980.
- 11. M. E. Meyerhoff, "Polymer Membrane Electrode Based Potentiometric Ammonia Gas Sensor," Anal. Chem., <u>52 (9)</u>, 1532-1534 (1980).
- 12. M. E. Meyerhoff, "Potentiometric Bio-sensors Based on Heterogeneous Catalytic Systems," in <u>Interagency Workshop on In-situ Water Quality Sensors: Biological Sensors, 2nd.</u>, PB 81-164378, NTIS, Springfield, VA, pp. 167-172.
- 13. M. E. Meyerhoff and R. H. Robins, "Disposable Potentiometric Ammonia Gas Sensors for Estimation of Ammonia in Blood," Anal. Chem. <u>52 (14)</u>, 2383-2387 (1980).
- 14. M. E. Meyerhoff, "Preparation and Response Properties of Selective Bio-Electrodes Utilizing Polymer Membrane Based Ammonia Gas Sensors," Anal. Lett. B, <u>13 (15)</u>, 1345-1357 (1980).
- 15. Y. M. Fraticelli and M. E. Meyerhoff, "Automated Ammonia Measurements Using a Potentiometric Gas Sensor with Flowing Internal Electrolyte," Anal. Chem., <u>53 (7)</u>, 992-997 (1981).
- 16. M. E. Meyerhoff and Y. M. Fraticelli, "Determination of Ammonia by Flow Injection Analysis Using a Polymer Membrane Electrode-Based Gas Sensing System," Anal. Lett. B, 14 (6), 415-432 (1981).

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- 17. Y. M. Fraticelli and M. E. Meyerhoff, "Selectivity Studies of Polymer Membrane Electrode-Based Ammonia Gas Sensing Systems," Anal. Chem., <u>53 (12)</u>, 1857-1861 (1981).
- 18. Paul M. Kovach and M. E. Meyerhoff, "Development and Application of a Histidine Selective Biomembrane Electrode," Anal. Chem., <u>54 (2)</u>, 217-220 (1982).
- 19. M. E. Meyerhoff and Y. M. Fraticelli, "Ion-Selective Electrodes-1982 Biennial Review," Anal. Chem., <u>54 (5)</u>, 27R-44R (1982).
- 20. R. K. Kobos, S. J. Parks and M. E. Meyerhoff, "Selectivity Characteristics of Potentiometric Carbon Dioxide Sensors with Various Gas Membrane Materials," Anal. Chem., 54 (12), 1976-1980 (1982).
- 21. J. Greenberg and M. E. Meyerhoff, "Response Properties, Applications and Limitations of Carbonate Selective Polymer Membrane Electrodes," Anal. Chim. Acta, <u>141</u>, 57-64 (1982).
- 22. M. E. Meyerhoff, Y. M. Fraticelli, J. A. Greenberg, J. Rosen, S. J. Parks and W. N. Opdycke, "Polymer-Membrane Electrode-Based Potentiometric Sensing of Ammonia and Carbon Dioxide in Physiological Fluids," Clin. Chem., 28 (9), 1973-1978 (1982).
- 23. Y. M. Fraticelli and M. E. Meyerhoff, "On-Line Gas Dialyzer for Automated Enzymatic Analysis Involving Potentiometric Ammonia Detection," Anal. Chem., <u>55 (2)</u>, 359-364 (1983).
- 24. Paul M. Kovach and M. E. Meyerhoff, "A Flow Injection/Ion-Selective Electrode Experiment; Direct Determination of Potassium in Blood," J. Chem. Ed., <u>60 (9)</u>, 766-768 (1983).
- 25. M. E. Meyerhoff, Y. M. Fraticelli, W. N. Opdycke, L. G. Bachas and A. D. Gordus, "Theoretical Predictions on the Response Properties of Potentiometric Gas Sensors Based on Internal Polymer Membrane Electrodes," Anal. Chim. Acta, <u>154</u>, 17-31 (1983).
- 26. W. N. Opdycke, S. J. Parks and M. E. Meyerhoff, "Polymer Membrane pH Electrodes as Internal Elements for Potentiometric Gas Sensing Systems," Anal. Chim. Acta, <u>155</u>, 11-20 (1983).
- 27. M. E. Meyerhoff and M. A. Arnold, "Ion-Selective Electrodes," Anal. Chem., <u>56 (5)</u>, 20-48 (1984).
- 28. L. G. Bachas, P. F. Lewis and M. E. Meyerhoff, "Cooperative Interaction of Immobilized Folate Binding Protein with Enzyme-Folate Conjugates An Enzyme Linked Assay for Folate," Anal. Chem., <u>56 (9)</u>, 1723-1726 (1984).
- 29. S. B. Brontman and M. E. Meyerhoff, "Homogeneous Enzyme Linked Assays Mediated by Enzyme Antibodies; A New Approach to Electrode-Based Homogeneous Immunoassays," Anal. Chim. Acta, <u>162</u>, 363-367 (1984).
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- 31. M. E. Meyerhoff, "Polymer Membrane Electrode-Based Potentiometric Gas Sensors," in <u>Proceedings of Symposium on Biosensors</u>, IEEE special publication, McGregor and Werner, Washington, 1984, pp. 51-53.

- 32. Heung L. Lee and M. E. Meyerhoff, "Comparison of Tubular Polymeric pH and Ammonium Ion Electrodes as Detectors in the Automated Determination of Ammonia," Analyst, 110 (4), 371-376 (1985).
- 33. M. C. Carter and M. E. Meyerhoff, "Instability of Succinyl Ester Linkages in O<sup>2</sup>-Monosuccinyl Cyclic AMP-Protein Conjugates at Neutral pH," J. Immunol. Meth., <u>81 (2)</u>, 245-257 (1985).
- 34. E. J. Fogt, D. Untereker, M.S. Norenberg and M. E. Meyerhoff, "Response of Ion-Selective Field Effect Transistors to Carbon Dioxide and Organic Acids," Anal. Chem., <u>57</u> (9), 1995-1998 (1985).
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- 36. L. G. Bachas, C. D. Tsalta and M. E. Meyerhoff, "Binding Proteins as Reagents in Enzyme-Linked Competitive Binding Assays of Biological Molecules," Biotechniques, <u>4 (1)</u>, 42-55 (1986).
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- 38. W. N. Opdycke and M. E. Meyerhoff, "Development and Analytical Performance of Tubular Polymer Membrane Electrode-Based pCO<sub>2</sub> Catheters," Anal. Chem., <u>58 (4)</u>, 950-956 (1986).
- 39. L. G. Bachas and M. E. Meyerhoff, "Homogeneous Enzyme-Linked Competitive Binding Assay for the Rapid Determination of Folate in Vitamin Tablets," Anal. Chem., <u>58 (4)</u>, 956-961 (1986).
- 40. G. Martin and M. E. Meyerhoff, "Membrane Dialyzer Injection Loop for Enhancing the Selectivity of Anion Responsive Liquid Membrane Electrodes in Flowing Arrangements. 1. A Sensing System for NO<sub>x</sub> and Nitrite," Anal. Chim. Acta, <u>186</u>, 71-80 (1986).
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- 43. M. E. Meyerhoff, E. Pretsch, D. Welti and W. Simon, "Role of Trifluoroacetophenone Solvents and Quaternary Ammonium Salts in Carbonate Selective Liquid Membrane Electrodes," Anal. Chem., 59 (1), 144-150 (1987).
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- 46. W. Simon, D. Ammann, B. Linderman, M. E. Meyerhoff, W.E. Morf, U. Oesch and E. Pretsch, "Sensors for Ions and Neutral Species Based on a Selective Substrate Permeation Through Membranes," in Proceedings of 1st Bioelectroanalytical Symposium,

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- 49. E. J. Fogt, M. E. Meyerhoff and D. F. Untereker, "Gas Sensor," U.S. Patent #4,694,834, Sept. 22, 1987.
- 50. J. S. Schultz and M. Meyerhoff, "Status of Monitoring in Biotechnology," Enzyme and Microb. Technol., 9 (11), 697-699 (1987).
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- 53. C. D. Tsalta, S. A. Rosario, G. S. Cha, L. G. Bachas and M. E. Meyerhoff, "A Solid-Phase Enzyme-Linked Competitive Binding Assay for Vitamin B<sub>12</sub>," Mikrochim. Acta, <u>1 (1-2)</u>, 65-73 (1989).
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## **Conference Papers Presented**

- 1. G. A. Rechnitz and M. E. Meyerhoff, "Bio-Selective Membrane Electrodes," Pittsburgh Conference, ISE Symposium, March, 1978, Cleveland, OH.
- 2. G. A. Rechnitz and M. E. Meyerhoff, "Bio-Selective Membrane Probes," Gordon Conference on Immobilized Species, August, 1978, Plymouth, NH.
- 3. M. E. Meyerhoff and G. A. Rechnitz, "Electrode Based Enzyme-Immunoassay of Cyclic-AMP Using Urease-Nucleotide Conjugates," Metrochem 1978, ACS Sectional Meeting, October 8, 1978, Fallsburgh, NY.
- 4. M. E. Meyerhoff, "A New Miniature Potentiometric Ammonia Gas Sensor," Pittsburgh Conference, March 11, 1980, Atlantic, NJ.
- 5. M. E. Meyerhoff, "Potentiometric Bio-Sensors Based on Heterogeneous Catalytic Systems," EPA-NOAA Biosensing Workshop, April 29, 1980, Pensacola, FL, <u>invited paper</u>.
- 6. M. E. Meyerhoff, "Polymer Membrane Electrodes Based Ammonia Gas Sensor," MUACC, October 2, 1980, Ames, IA.
- 7. M. E. Meyerhoff, "Potentiometric Analysis Using Heterogeneous Biocatalytic Systems," Ion-Selective Electrode Symposium, EXPO-CHEM 80, October 5, 1980, Houston, TX, invited speaker.
- 8. M. E. Meyerhoff and Y. M. Fraticelli, "Automated Ammonia Measurements Using Potentiometric Gas Sensor with Flowing Internal Electrolyte," Pittsburgh Conference, March 9, 1981, Atlantic City, NJ.
- 9. M. E. Meyerhoff, "Potentiometric Bio-Selective Electrodes; Advances in Design and Applications," Bioanalytical Methodologies Symposium, Joint Great Lakes Midwest Regional ACS Meeting, May 20, 1981, Dayton, OH, Symposium Chairman and Organizer.
- 10. M. E. Meyerhoff, "Disposable Potentiometric Gas Sensors for Clinical Analysis," FACSS Conference, September 22, 1981, Philadelphia, PA, <u>invited speaker</u>.
- 11. M. E. Meyerhoff, "Polymer Membrane Electrode-Based Carbon Dioxide Sensors," MUACC, October 2, 1981, Purdue University, W. Lafayette, IN.
- 12. M. E. Meyerhoff, "From pH to pHormones; Bioanalytical Measurements with Membrane Electrodes," MCCTA Conference, November 14, 1981, Ann Arbor, MI.
- 13. Y. M. Fraticelli and M. E. Meyerhoff, "Automated Electrode-Based Biomonitor for Inhibition and Toxin Detection," Pittsburgh Conference, March 8, 1982, Atlantic City, NJ.
- 14. S. Rivkin and M. E. Meyerhoff, "Studies of Enzyme-Labeled Competitive Binding Assays for Cyclic AMP," Pittsburgh Conference, March 8, 1982, Atlantic City, NJ.
- 15. J. A. Greenberg and M. E. Meyerhoff, "Polymer Membrane Electrode-Based Potentiometric Carbon Dioxide Sensing Systems," Pittsburgh Conference, March 9, 1982, Atlantic City, NJ.
- 16. M. E. Meyerhoff, "New Approaches for Potentiometric Sensing of Ammonia and Carbon Dioxide in Physiological Fluids," 14th Annual Symposium on Advanced Concepts for the Clinical Laboratory, April 30, 1982, Gatlinburg, TN.

- 17. S. J. Parks and M. E. Meyerhoff, "Selectivity Characteristics of Potentiometric Carbon Dioxide Sensors Using Various Gas Membrane Materials", ACS Regional Meeting, June 17, 1982, Midland, MI.
- 18. M. E. Meyerhoff, "Selectivity Characteristics of Conventional and Polymer Membrane Based Potentiometric Gas Sensors," FACSS Conference, September 20, 1982, Philadelphia, PA, invited speaker.
- 19. M. E. Meyerhoff, "Analytical Studies of Binding Protein Interactions with Enzyme-Ligand Conjugates," MUACC, October 8, 1982, Lexington, KY.
- 20. W. N. Opdycke and M. E. Meyerhoff, "Polymer Membrane-Based pH Electrodes as Internal Elements for Potentiometric Gas Sensors," Anachem 1982, October 14, 1982, Dearborn, MI.
- 21. M. E. Meyerhoff, "From pH to pHormones; Bioanalytical Measurements with Ion-Selective and Gas-Sensing Electrodes," Electrochemistry Symposium, Northwestern University, November 12, 1982, Evanston, IL, <u>invited speaker</u>.
- 22. M. E. Meyerhoff, "Potentiometric Gas Sensors; Recent Advances in Design and Bioanalytical Applications," ACS Central Regional Meeting, Symposium on Electrochemistry, May 24, 1983, Oxford, OH, <u>invited speaker</u>.
- 23. M. E. Meyerhoff, L. G. Bachas, Y. M. Fraticelli, W. N. Opdycke and A. D. Gordus, "Theoretical Predictions on the Response Properties of Polymer Membrane Electrode Based Gas Sensors," FACSS Conference, September 27, 1983, Philadelphia, PA.
- 24. M. E. Meyerhoff, P. Lewis, M. J. Carter, S. Brontman and L. G. Bachas, "Enzyme Linked Competitive Binding Assays Using Endogenous Binding Proteins," FACSS Conference, September 29, 1983, Philadelphia, PA.
- 25. M. E. Meyerhoff, "New Potentiometric Gas Sensing Systems; Clinical and Environmental Applications," Eastern Analytical Symposium, November 16, 1983, New York, NY, invited speaker.
- 26. S. J. Parks and M. E. Meyerhoff, "Automated Toxicity Biomonitor Based on Potentiometric Carbon Dioxide Detection," Pittsburgh Conference, March 6, 1984, Atlantic City, NJ.
- 27. W. N. Opdycke and M. E. Meyerhoff, "Catheter-Type Potentiometric Sensors for Ammonia and Carbon Dioxide Detection," Pittsburgh Conference, March 8, 1984, Atlantic City, NJ.
- 28. L. G. Bachas and M. E. Meyerhoff, "An Enzyme-Linked Competitive Binding Assay for Folate," Pittsburgh Conference, March 8, 1984, Atlantic City, NJ.
- 29. M. L. Carter and M. E. Meyerhoff, "Concerns in the Development of Homogeneous Enzyme Immunoassays; An Assay for Cyclic-AMP," Pittsburgh Conference, March 8, 1984, Atlantic City, NJ.
- 30. M. E. Meyerhoff, "Potentiometric Gas Sensing Systems; Recent Advances in Design and Bioanalytical Applications," Joint ACS Meeting, Symposium in Memory of Philip J. Elving, May 24, 1984, Kalamazoo, MI; invited speaker.

- 31. M. E. Meyerhoff, "Polymer Membrane Electrode-Based Potentiometric Gas Sensors; Theory, Design, and Bioanalytical Applications," International Symposium on Electrochemical Sensors, June 12, 1984, Rome, ITALY; <u>invited speaker</u>.
- 32. M. E. Meyerhoff, "Polymer Membrane Electrode-Based Potentiometric Gas Sensors," IEEE and NSF Sponsored Symposium on Biosensors, Sept. 14, 1984, Los Angeles, CA; invited speaker.
- 33. M. E. Meyerhoff, "Biodetection in Ion-Chromatography of Heavy Metals," MUACC, October 20, 1984, Madison, WI.
- 34. M. E. Meyerhoff and L. G. Bachas, "Binding Proteins as Reagents in Enzyme-Linked Competitive Binding Assays," Pittsburgh Conference, February 25, 1985, New Orleans, LA.
- 35. M. E. Meyerhoff and S. J. Yoder, "An Enzymatic-Membrane Electrode Detection System for Transition Metal Ion-Chromatography," Pittsburgh Conference, February 27, 1985, New Orleans, LA.
- 36. M. E. Meyerhoff, "Development and Environmental Applications of Gas Sensing Systems Based on Polymer Ion-Selective Electrodes," 15th Annual Symposium in the Analytical Chemistry of Pollutants, May 22, 1985, Jekyll Island, GA; <u>invited speaker</u>.
- 37. M. E. Meyerhoff, "Analyte Permeable Injection Loops for Enhancing the Selectivity and Sensitivity of Polymer Membrane Electrodes in Flowing Systems," MUACC, October 11, 1985, Iowa City, IA.
- 38. L. G. Bachas and M. E. Meyerhoff, "A Homogeneous Enzyme-Linked Competitive Binding Assay for the Rapid Determination of Folate; A Biological Gate," ACS National Meeting, New York, NY, April 17, 1986.
- 39. N. A. Chaniotakis and M. E. Meyerhoff, "Metalloporphyrins as Ion-Selective Carriers," ACS Regional Meeting, June, 1986, Bowling Green, OH.
- 40. G. Ashcom, L. G. Bachas and M. E. Meyerhoff, "An Enzyme-Linked Competitive Binding Assay for Folate Using Folate Binding Protein," ACS Regional Meeting, June, 1986, Bowling Green, OH.
- 41. M. L. C. Carter and M. E. Meyerhoff, "Concerns in the Development of Homogeneous Enzyme Immunoassays: An Assay for Cyclic AMP," ACS Regional Meeting, June, 1986, Bowling Green, OH.
- 42. M. E. Collison and M. E. Meyerhoff, "Automated Creatinine Determinations in Blood and Urine Using a Novel On-Line Gas Predialyzer and an Improved Ammonia Detection System," ACS Regional Meeting, June, 1986, Bowling Green, OH.
- 43. M. E. Meyerhoff, "Recent Progress in Polymer Membrane Based Ion and Gas Sensing Membrane Electrodes," Gordon Conference on Analytical Chemistry, August, 1986, New Hampton, NH; invited speaker.
- 44. M. E. Meyerhoff, "Recent Progress in the Design of Solvent/Polymeric Membrane Electrode Systems for Measuring Ions, Gases and Neutral Organics," FACSS Conference, Special ANACHEM Award Symposium, October 1, 1986, St. Louis, MO; <u>invited speaker</u>.

- 45. M.E. Meyerhoff, "Recent Advances in the Design of Solvent/Polymeric Membrane Electrodes for Measuring Ions, Gases, and Neutral Organics," 1986 ANACHEM Symposium, October 28, 1986, Plymouth, MI; invited speaker.
- 46. David M. Prantis and M. E. Meyerhoff, "Continuous Measurement of Atmospheric Ammonia with an ISE-Based Gas Sensor,' Pittsburgh Conference, March 10, 1987, Atlantic City, NJ.
- 47. M. E. Collison and M. E. Meyerhoff, "On-Line Ammonia Removal in Automated Electrode-Based Enzymatic Determinations of Creatinine," Pittsburgh Conference, March 10, 1987, Atlantic City, NJ.
- 48. M. E. Meyerhoff, "Polymer Membrane Based Ion and Gas Selective Bioelectrodes," International Bioanalytical Workshop, University of Kansas, June 1-3, 1987, Lawrence, KA; invited speaker.
- 49. M. E. Meyerhoff, "Interfacial Reactions of Anions with Doped Polymeric Membranes: Progress in the Design of Potentiometric Anion Selective Sensors," ACS Regional Meeting, Electrochemistry and Surface Chemistry Symposium, June 25, 1987, Columbus, OH; invited speaker.
- 50. M. E. Meyerhoff, 'New Ion and Gas Selective Biosensors Based in Polymeric Membrane Electrodes," Analytical Chemistry Summer Symposium, University of Indiana, June 30-July 2, 1987, Bloomington, IN; <u>invited speaker</u>.
- 51. M. E. Meyerhoff, "Recent Advances in the Design of Anion and Gas Selective Potentiometric Sensors," American Association of Clinical Chemists, National Meeting, Symposium on Emerging Electrochemical and Optical Technologies in Blood Gas and Electrolyte Analyses, July 23, 1987, San Francisco, CA; invited speaker.
- 52. M. E. Meyerhoff, David M. Pranitis, and Nikolas A. Chaniotakis, "Recent Advances in the Design of Anion and Gas Selective Potentiometric Sensors," Instrument Society of America 1987, Symposium on Electrochemical Analysis, Present and Future, October 6, 1987, Anaheim, CA; invited speaker.
- 53. M. E. Collison, G. Aebli, J. Petty and M. E. Meyerhoff, "Recent Progress in the Design of Ion/Gas Sensors for <u>In Vivo</u> Monitoring," FACSS <u>XIV</u>, October 6, 1987, Detroit, MI; <u>invited paper</u>.
- 54. S. A. Rosario, M. E. Meyerhoff, and C. D. Tsalta, "Solid-Phase Enzyme-Linked Competitive Binding Assay for Vitamin B<sub>12</sub>," FACSS <u>XIV</u>, October 4, 1987, Detroit, MI.
- 55. N. A. Chaniotakis and M. E. Meyerhoff, 'Potentiometric Anion Response of Polymeric Membranes Doped With Metalloporphyrins," FACSS <u>XIV</u>, October 4, 1987, Detroit, MI.
- 56. M. E. Meyerhoff, "Recent Advances in the Design of Anion and Gas Selective Polymeric Membrane Electrodes," Joint US/Japan Electrochemical Society Meeting, Symposium on Bioelectroanalytical Chemistry, October 23, 1987, Honolulu, Hawaii, invited speaker.
- 57. M. E. Meyerhoff, "Anion and Gas-Selective Membrane Electrodes: Recent Advances and Future Prospects,' 1988 Pittsburgh Conference, Special Reilly Award Symposium, February 24, 1988, New Orleans, LA; <u>invited speaker</u>.
- 58. G. S. Cha, G. S. Ashcom, and M. E. Meyerhoff, "Enzyme-Linked Competitive Binding Assays for Riboflavin," 1988 Pittsburgh Conference, February 23, 1988, New Orleans, LA.

- 59. M. E. Collison, G. Aebli, J. Petty, and M. E. Meyerhoff, 'The Design of Miniaturized Combination Ion/Gas Sensors for Continuous <u>in-vivo</u> Monitoring Applications," 1988 Pittsburgh Conference, February 24, 1988, New Orleans, LA.
- 60. M. E. Meyerhoff, "Polymer Membrane-Based Potentiometric Bioelectrodes," National ACS Meeting, Symposium on Interfacial Bioelectrochemistry, June 9, 1988, Toronto, Canada; invited speaker.
- 61. M. E. Meyerhoff, "Biosensing with Polymeric Membrane Electrodes," Gordon Conference on Bioanalytical Sensors," June 14, 1988, New London, NH; <u>invited speaker</u>.
- 62. M. E. Meyerhoff, 'New Anion and Gas Selective Potentiometric Sensors," Symposium on Chemical Sensors and Microinstrumentation, ACS National Meeting, September 28 1988, Los Angeles, CA; invited speaker.
- 63. S. C. Ma, N. A. Chaniotakis and M. E. Meyerhoff, "Response Properties of Ion-Selective Polymeric Membrane Electrodes Prepared with Aminated and Carboxylated Poly (Vinyl-Chloride)," FACSS IV, November 3, 1988, Boston, MA.
- 64. N. A. Chanitokis, S. B. Park and M. E. Meyerhoff, "Potentiometric Determination of Salicylate Using Sn[TPP]Cl<sub>2</sub> Doped Solvent Polymeric Membranes," FACSS IV, November 4, 1988, Boston, MA.
- 65. G. S. Cha and M. E. Meyerhoff, "Asymmetric Cellulose Triacetate Ion-Selective Membranes as Biosensors," FACSS XV, November 3, 1988, Boston, MA.
- 66. I. H. Lee and M. E. Meyerhoff, "Non-Equilibrium Enzyme-Linked Flow-Injection Immunoassay Using Immobilized Secondary Antibodies," FACSS XV, November 2, 1988, Boston, MA.
- 67. M. E. Meyerhoff," pH and pK Detection in Suppressed Ion Chromatography," Midwestern University Analytical Chemistry Conference, November 6, 1988, East Lansing, MI.
- 68. S. A Rosario and M. E. Meyerhoff, "Flow-Injection System for Monitoring Glutamine in Bioreactor Media," 1989 Pittsburgh Conference, March 7, 1989, Atlanta, GA.
- 69. S. C. Ma and M. E. Meyerhoff, "Ion- and Bio-Selective Membrane Electrodes Prepared with Aminated Poly(Vinyl Chloride)," 1989 Pittsburgh Conference, March 8, 1989, Atlanta GA.
- 70. I. H. Lee and M. E. Meyerhoff, "Non-Equilibrium Enzyme-Linked Flow-Injection Immunoassay System for Measurement of Proteins," 1989 Pittsburgh Conference, March 8, 1989, Atlanta, GA.
- 71. M. E. Meyerhoff, "Rapid Enzyme-Linked Competitive Binding Assays of Biomolecules; Progress and Challenges," Second International Bioanalytical Workshop, May 22, 1989, Lawrence, KA; invited speaker.
- 72. M. E. Meyerhoff, "Anion Selective Polymeric Membrane Electrodes: Progress and Challenges," Symposium on Methodology and Clinical Applications of Electrochemical and Fiber Optic Sensors, September 26, 1989, Rochester, MN; <u>invited speaker</u>.
- 73. M. Trojanowicz and M. E. Meyerhoff, "Potentiometric Detection with Membrane Electrodes in Suppressed and Replacement Ion-Chromatography," International

- Symposium on Detection in Liquid Chromatography and Flow Injection Analysis, September 22, 1989, Cordoba, Spain.
- 74. M. E. Meyerhoff, W. Matuszewski and M. Trojanowicz, "Flow-Injection Enzymatic Determination of Glucose Using Fluoride Ion-Selective Electrode," International Symposium on Detection in Liquid Chromatography and Flow Analysis, September 22, 1989, Cordoba, Spain.
- 75. M. Trojanowicz and M. E. Meyerhoff, "Potentiometric Detection with Membrane Electrodes in Suppressed and Replacement Ion-Chromatography," 11th International Symposium on Microchemical Techniques, August 28, 1989, Wiesbaden, West Germany.
- 76. M. E. Meyerhoff and M. E. Collison; "Potentiometric Ion/Gas Selective Sensors for Continuous In Vivo Measurements: Progress and Challenges," FACSS XVI, October 56, 1989, Chicago, IL; <u>invited speaker</u>.
- 77. D. V. Brown, N. A. Chaniotakis, I. H. Lee, S. C. Ma, S. B. Park and M. E. Meyerhoff, "Mn(III) Porphyrin Based Thiocyanate-Selective Membrane Electrode: Characterization and Application in Flow Injection Determination of Thiocyanate in Saliva," FACSS XVI, October 4, 1989, Chicago, IL.
- 78. M. E. Meyerhoff, "Interfacial Reactions of Anions with Doped Polymeric Membranes: Implications in the Design of Potentiometric Anion Selective Sensors", 176th Meeting of the Electrochemical Society, October 15, 1989, Hollywood, FL; invited speaker.
- 79. M. E. Meyerhoff, "Immunosensing Systems Based on Membrane Electrode Detectors," Engineering Foundation Conference on Diagnostic Genetics and Immunology, V, October 26, 1989, Santa Barbara, CA; <u>invited speaker</u>.
- 80. M. E. Meyerhoff, "New In Vitro Analytical Approaches for Measurement of Critical Care Analytes," 13th Annual Arnold O. Beckman Conference. Critical Care Medicine, Technology and Patient Management, January 23, 1990, Newport Beach, CA; invited speaker.
- 81. M. E. Meyerhoff, "Enzyme-Linked Binding Assays in Biosensing: Principles, Chemistry and Analytical Capabilities," Gordon Conference on Bioanalytical Sensors, March 12, 1990, Ventura Beach, CA; invited speaker.
- 82. M. E. Meyerhoff, "Gas Sensors Based on Ion-Selective Polymer Membrane Electrodes," Symposium on Modern Gas Sensors, ACS National Meeting, April 23, 1990, Boston, MA; invited speaker.
- 83. M. E. Meyerhoff, "Interactions of Antibodies and Binding Proteins with Enzyme-Ligand Conjugates: Implications in the Design of Homogeneous and Heterogeneous Binding Assays," Symposium on New Methods in Immunoassay, ACS National Meeting, April 23, 1990, Boston, MA; invited speaker.
- 84. M. E. Meyerhoff, "Interfacial Reactions of Anions with Doped Polymeric Membranes: Recent Progress in the Design of Potentiometric Anion Selective Sensors," Materials for Sensors and Separations, Materials Research Society National Meeting, April 16, 1990, San Francisco, CA; invited speaker.
- 85. M. E. Collison and M. E. Meyerhoff, "Development and Analytical Performance of a Potentiometric Combination Ion/pCO<sub>2</sub> Sensor for In Vivo Measurements, "Symposium on In Vivo Electroanalytical Chemistry and Biosensors," Electrochemical Society Meeting, May 10, 1990, Quebec, Canada; invited speaker.

- 86. M. E. Meyerhoff, "Interfacial Reactions of Anions with Doped Polymeric Membranes: Recent Progress in the Design of Potentiometric Anion Selective Sensors," Symposium of Electrochemical Systems and Applications, Detroit. Section of the Electrochemical Society, April 19, 1990, Bloomfield Hills, MI; invited speaker.
- 87. S. B. Park and M. E. Meyerhoff, "Anion Selective Polymeric Membrane Electrodes; Progress and Challenges," ACS National Meeting, August 27, 1990, Washington, D.C.; invited speaker.
- 88. G. S. Cha, D. V. Brown, M. E. Meyerhoff, H. C. Cantor, A. R. Midgley, H. D. Goldberg, and R. B. Brown, "Performance, Biocompatibility, and Adhesion of Various Polymeric Matrices for the Preparation of Micro-Ion/Biosensor Arrays," FACSS XVII, October 8, 1990., Cleveland, OH; invited paper.
- 89. H. S. Hyoung and M. E. Meyerhoff, "New Potentiometric Oxygen Gas Sensors," FACSS XII, October 10, 1990, Cleveland, OH.
- 90. B. Kim and M. E. Meyerhoff, "Lectin-Based Homogeneous Enzyme-Linked Binding Assays for Rapid Detection of Specific Carbohydrates and Glycoproteins," FACSS XII, October 10, 1990, Cleveland, OH.
- 91. S. B. Park and M. E. Meyerhoff, "Potentiometric Chloride Response of Polymeric Membranes Doped with In(III)-Porphyrins," FACSS XII, October 11, 1990, Cleveland, OH
- 92. D. V. Brown and M. E. Meyerhoff, "Potentiometric Psuedo Homogeneous Immunosensor for Proteins," FACSS XII, October 9, 1990, Cleveland, OH.
- 93. M. E. Meyerhoff and S. A. Rosario, "Enhancing the Selectivity and Analytical Utility of Polymer Membrane-Electrode-Based Biosensors," Biosensors Symposium, National ACS meeting, April 15, 1991, Atlanta, GA; <u>invited speaker</u>.
- 94. M. E. Meyerhoff, G. S. Cha, S. C. Ma, H. D. Goldberg, A.R. Midgley, H. Cantor and R. B. Brown, "New Polymeric Membrane Material for Fabricating Potentiometric Ion- and Bio-Selective Sensors," Symposium on Polymer Materials for Biosensors, National ACS meeting, April 18, 1991, Atlanta, GA; invited speaker.
- 95. I. Behbahani, B. Kim and M.E. Meyerhoff, "Probing the Carbohydrate Structure of Glycoproteins by a Homogeneous Enzyme-Linked Competitive Binding Assay Method," ACS Mid-West Regional Meeting, May 30, 1991, Indianapolis, IN.
- 96. M. E. Meyerhoff, "Electrochemical Sensors for Bedside Monitoring of Critically Ill Patients," Symposium on Process Monitoring, Society of Analytical Chemists of Pittsburgh, November, 2, 1991, Pittsburgh, PA.; invited speaker.
- 97. M. E. Meyerhoff, "Novel Anion and Gas Selective Potentiometric Sensors," Gordon Conference on Electrochemistry, January, 22, 1992, Ventura, CA; <u>invited speaker</u>.
- 98. M. E. Meyerhoff, "Enzyme-Linked Competitive and Non-Competitive Binding Assays," Biosensors '92, The Second World Congress on Biosensors, May 21, 1992, Geneva, Switzerland; invited speaker.
- 99. M. E. Meyerhoff, D. M. Kliza, C. E. Kibbey, H. S. Yim, S. C. Ma and S. B. Park, "Novel Anion and Gas Selective Potentiometric Sensors," Symposium on Advances in Chemical Sensors, ACS Central Regional Meeting, May 27, 1992, Cincinnati, OH; <u>invited speaker</u>.

- 100. H. S. Yim and M. E. Meyerhoff, "Copper Film-Based Potentiometric Oxygen Sensors," ACS Central Regional Meeting, May 29, 1992, Cincinnati, OH.
- 101. D. M. Kliza and M. E. Meyerhoff, "Potentiometric Anion Response of Electropolymerized Polymeric Porphyrin Film Modified Electrodes," ACS Great Lakes Regional Meeting, June 2, 1992, Milwaukee, WI.
- 102. J. M. Buckwalter, K. Pummel and M. E. Meyerhoff, "Enzyme Labels for Simultaneous Homogenous and Heterogeneous Enzyme-Linked Binding Assays," ACS Great Lakes Regional Meeting, June 3, 1992, Milwaukee, WI.
- 103. M. E. Meyerhoff, "In-Vivo Ion and Gas Sensors: Progress and Challenges," Symposium on Emergence of Critical Electrolyte and Blood Gas Monitors in Patient Care, American Association for Clinical Chemistry National Meeting, July 23, 1992, Chicago, IL.; invited speaker.
- 104. M. E. Meyerhoff, "Heparin Selective Membrane Electrode: Development, Characterization, and Biomedical Application," MUACC-92, October 23, 1992, Carbondale, IL.
- 105. M. E. Meyerhoff, "Novel Anion-Selective Membrane-Based Sensors," PITTCON-'93, March 9, 1993, Atlanta, GA; <u>invited symposium speaker</u>.
- 106. M. E. Meyerhoff, "Lectin-Based Homogeneous Enzyme-Linked Binding Assays," PITTCON-'93, March 9, 1993, Atlanta, GA; <u>invited symposium speaker</u>.
- 107. M. Telting-Diaz, M. E. Collison and M.E. Meyerhoff, "Dual Lumen pH/PCO<sub>2</sub> Catheter Electrode for In Vivo Measurements," 1993 Pittsburgh Conference, March 10, 1993, Atlanta, GA.
- 108. C. Kibbey and M. E. Meyerhoff, "Metalloporphyrins as Stationary Phases in Anion Chromatography," 1993 Pittsburgh Conference, March 11, 1993, Atlanta, GA.
- 109. E. Wang and M. E. Meyerhoff, "Metalloporphyrin Based Anion Selective Optical Sensors," 1993 Pittsburgh Conference, March 10, 1993, Atlanta, GA.
- 110. M. E. Meyerhoff, "On-Line Electrochemical Process Analysis," CCR-NICHE Conference on Process Analysis, May 17, 1993, Keystone, CO; <u>invited speaker</u>.
- 111. M. E. Meyerhoff, C. E. Kibbey, R. D. Schiller, E. Bakker and E. Wang, "Interfacial Reaction of Anions with Metalloporphyrin Doped Polymeric Membranes: Implications in the Design of Anion Selective Sensors," Symposium of Chemically Sensitive Interfaces, National ACS Meeting, August 25, 1993, Chicago, IL; invited speaker.
- 112. M. E. Meyerhoff, "Recent Advances in Chemical Sensor Technology for Near-Patient Whole Blood Testing," Mayo Medical Clinic Workshop on Near-Patient Testing, September 23, 1993, Rochester, MN; invited speaker.
- 113. M. E. Meyerhoff, "Polymer Membrane Based Electrochemical and Optical Sensor Technology in the 1990's and Beyond," Symposium on Chemical Sensing, FACSS 1993, October 18, 1993, Detroit, MI; <u>invited speaker</u>.
- 114. M. Telting-Diaz and M. E. Meyerhoff, "In Vivo Blood Gas and Electrolyte Sensors; Progress and Challenges," Symposium on Optical and Electrochemical Sensors in Clinical Chemistry, FACSS 1993, October 18, 1993, Detroit, MI; <u>invited speaker</u>.

- 115. M. E. Meyerhoff, "Novel Gas and Anion Selective Membrane Electrodes," Symposium of Electrochemical Based Sensors and Probes, Eastern Analytical Symposium 1993, November, 15, 1993, Somerset, NJ; invited speaker.
- 116. M. E. Meyerhoff, C. K. Kibbey, G. Martin, J. Xiao and M. Wilks "Immobilized Metalloporphyrins as Versatile Stationary Phases in Liquid Chromatography," Kolthoff Memorial Symposium, 1994 Pittsburgh Conference, March 1, 1994, Chicago, IL; invited speaker.
- 117. D. Liu, H. D. Goldberg, R. W. Hower, R. B. Brown and M. E. Meyerhoff, "Optimizing Screen-Printed, Microfabricated, Potentiometric Solid-State Ion/Biosensor Arrays," 1994 Pittsburgh Conference, March 1, 1994, Chicago, IL.
- 118. <u>E. Wang</u> and M. E. Meyerhoff, "Optical Sensing of Macromolecular Heparin and Other Polyanions with Thin Polymeric Films," 1994 Pittsburgh Conference, February 28, 1994, Chicago, IL.
- 119. M. E. Meyerhoff, "Advances in Chemical Sensor Technology for Whole Blood Testing," Wisconsin Association of Medical Technology, Spring Meeting, April 8, 1994, Pewaukee, WI; invited speaker.
- 120. M. E. Meyerhoff, "Novel Polymer Membrane Based Gas and Anion Sensors," Workshop on Membranes: Theory, Simulation and Experiment," April 14, 1994, Ascona, Switzerland; invited speaker.
- 121. M. E. Meyerhoff, "Polymer Membrane Based Electrochemical Sensors for Biomedical Measurements," Annual Analytical Sciences Symposium, Hercules Inc., May 17, 1994, Wilmington, DE; invited speaker.
- 122. G. B. Martin, M. E. Meyerhoff, J. Xiao, C. E. Kibbey, M. Wilks, M. R. Savina, B. K. Parseghian, J. Bai and A. H. Francis, "Efficient Separation of Fullerenes on Porphyrin-Silica Stationary Phases Using Strong Mobile Phase Solvents," Symposium on Fullerenes, Electrochemical Society Meeting, May 23, 1994, San Francisco, CA.; invited speaker.
- 123. M. E. Meyerhoff, V. C. Yang, B. Fu, J. Yun, E. Bakker, L. McCann and S. C. Ma, "Polymer Membrane-Based Polyion Sensors: Development Response Mechanism, and Bioanalytical Applications," Great Lakes/Central Joint Regional ACS Meeting, Symposium on Chemically Modified Electrodes, June 1, 1994, Ann Arbor, MI; <u>invited speaker</u>.
- 124. C. Espadas Torre, M. E. Meyerhoff and M. Telting-Diaz, "In Vivo Optical and Electrochemical Sensors; The Challenge of Achieving Biocompatible Devices," Great Lakes/Central Joint Regional ACS Meeting, Symposium on Biomaterials, June 1, 1994, Ann Arbor, MI; invited speaker.
- 125. J. Xiao, M. E. Meyerhoff, G.B. Martin, C. E. Kibbey, M. Wilkes, M. R. Savina, J. Bai and A. H. Francis, "Novel Separation of Peptides and Fullerenes on Porphyrin-Silica Stationary Phases," Joint Great Lakes/Central Regional ACS Meeting, June 2, 1994, Ann Arbor, MI.
- 126. L. C. Duan and M. E. Meyerhoff, "A Non-Separation Electrochemical Enzyme Immunoassay for Detecting Proteins in Whole Blood," Joint Great Lakes/Central Regional ACS Meeting, June 2, 1994, Ann Arbor, MI.
- 127. E. Wang and M. E. Meyerhoff, "Kinetic Response Characteristics of Heparin Optical Sensors," ACS National Meeting, August 27, 1994, Washington, D.C.

- 128. M. E. Meyerhoff, V. C. Yang, B. Fu, J. Yun, E. Wang and E. Bakker, "Polymer Membrane-based Polyion Sensors: Development, Response Mechanism, and Bioanalytical Applications," Symposium on Electrochemical Sensors, September 16, 1994, Matrufured, Hungary; invited speaker.
- 129. M. E. Meyerhoff, "Polymer Membrane-Based Polyion Sensors: Development, Response Mechanism, and Bioanalytical Applications," FACSS XXI Meeting, October 3, 1994, St. Louis, MO; invited speaker.
- 130. M. E. Meyerhoff, "A Non-Separation, Electrode-Based Sandwich Type Immunoassay System for the Detection of Proteins in Whole Blood," FACSS XXI, October 5, 1994, St. Louis, MO; invited speaker.
- 131. M. E. Meyerhoff and C. Espadas-Torre, "In Vivo Electrochemical Sensors; The Challenge of Achieving Biocompatible Devices," 41st National Symposium of the American Vacuum Society, October 26, 1994, Denver, CO; <u>invited speaker</u>.
- 132. M. E. Meyerhoff, "Advances in Polymer Membrane Based Ion/Gas Sensors; New Chemistries, Designs, and Biomedical Applications," 10th Swiss Analytical Forum, February 2, 1995, Engerken, Switzerland; invited speaker.
- 133. C. Espadas-Torre and M. E. Meyerhoff, "Approaches for Enhancing the Biocompatibility of In Vivo Ion-Selective Electrodes," 1995 Pittsburgh Conference, March 9, 1995, New Orleans, LA.
- E. Malinowska, I. Badr, and M. E. Meyerhoff, "Response Mechanism and Biological Applications of Nitrite Responsive Membrane Electrodes Based on Co(III) Tetraphenylporphyrin," 1995 Pittsburgh Conference, March 9, 1995, New Orleans, LA.
- 135. E. Bakker, B. Fu, J. H. Yung, V. C. Yang and M. E. Meyerhoff, "New Insights into the Development of Polymer Membrane Based Potentiometric Polyion Sensors," 1995 Pittsburgh Conference, March 9, 1995, New Orleans, LA.
- R. K. Meruva, D. Liu, R. C. Brown and M. E. Meyerhoff, "Enhancing Stability of Solid-State Ion-Selective Electrodes by Incorporation of Lipophilic Silver Complexes in Polymeric Films," 1995 Pittsburgh Conference, March 9, 1995, New Orleans, LA.
- 137. M. E. Meyerhoff and C. Duan, "A Novel Non-Separation Sandwich Type Electrochemical Enzyme Immunoassay System for Detecting Marker Proteins in Undiluted Blood," The Oak Ridge Conference, San Antonio, TX, April 27, 1995; invited speaker.
- 138. M. E. Meyerhoff, V. C. Yang, J. A. Wahr, L. Lee, X. Clou, J. Yun, B. Fu and E. Bakker, "Potentiometric Polyion Sensors: A New Measurement Technology for Monitoring Blood Heparin Levels During Open Heart Surgery," The Oak Ridge Conference, San Antonio, TX, April 27, 1995.
- 139. E. Malinowska, V. Oklejas, R. W. Hower, R. B. Brown and M. E. Meyerhoff, "Enhanced Electrochemical Performance of Solid-State Ion Sensors Based on Silicone Rubber Membranes," Transducers '95, June, 21, 1995, Stockholm, Sweden.
- 140. R. K. Meruva, E. Malinowska, R. W. Hower, R. B. Brown and M. E. Meyerhoff, "Improved EMF Stability of Solid-State Ion-Selective Sensors by Incorporation of Lipophilic Silver-Calix[4]arene Complexes within Polymeric Films," Transducers '95, June 22, 1995, Stockholm, Sweden.

- 141. M. E. Meyerhoff, V. C. Yang, B. Fu, J. H. Yun and E. Bakker, "Polyion Sensitive Membrane Electrodes: Principles and Practice," FACSS XXII, October 18, 1995, Cincinnati, OH; invited speaker.
- 141. M. E. Meyerhoff, "Immobilized Metalloporphyrins as Versatile Stationary Phases in Liquid Chromatography," ANACHEM 1995, November 2, 1995, Dearborn, MI; <u>invited</u> speaker.
- 142. T. M. Ambrose and M. E. Meyerhoff, "A Novel Photopolymerizable Methacrylate-Based Membrane Matrix for Optical and Electrochemical Ion/Polyion Sensing," 1996 Pittsburgh Conference, March 4, 1996, Chicago, IL.
- 143. J. Xiao and M. E. Meyerhoff, "Metalloporphyrin-Silica Stationary Phases for HPLC Separation of Peptides and Proteins," 1996 Pittsburgh Conference, March 5, 1996, Chicago, IL.
- 144. C. Espadas-Torre, E. Bakker, S. Barker and M. E. Meyerhoff, "Influence of Nonionic Surfactants on the Potentiometric Response of Polymer Membrane pH Electrodes," 1996 Pittsburgh Conference, March 6, 1996, Chicago, IL.
- 145. U. Schaller, E. Steinle, I. Badr, M. E. Meyerhoff and E. Pretsch, "Mixed Complexation Mechanisms of Ionophores in Ion-Selective Electrode Polymeric Membranes," 1996 Pittsburgh Conference, March 6, 1996, Chicago, IL.
- 146. M. E. Meyerhoff, G. B. Martin and R. H. Smith, "Challenges in Developing Quantitative Whole Blood Immunoassays," 1996 Oakridge Conference on Emerging Technologies for the Clinical Chemistry Laboratory, April 11, 1996, San Jose, CA; <u>invited speaker</u>.
- 147. M. E. Meyerhoff, C. Duan, X. Guo, M. W. Ducey and A. M. Smith, "Novel Non-Separation Enzyme Immunoassays Using Microporous Gold Electrodes," The Sixth International Meeting on Chemical Sensors, July 23, 1996, Gaithersburg, MD; invited speaker.
- 148. M. E. Meyerhoff, "Polyion Sensitive Electrode for Heparin Analysis," Conference on Advances in Future Perfusion Techniques, September 7, 1996, Hyannis, MA; <u>invited</u> speaker.
- 149. M. W. Ducey, A. M. Smith, X. Guo and M. E. Meyerhoff, "Nonseparation Competitive Electrochemical Enzyme Binding Assays for Detection of Small Molecules, FACSS XXIII, October 1, 1996, Kansas City, MO.
- 150. R. K. Meruva and M. E. Meyerhoff, "Oxygen Sensors Based on Mixed Potential at Cobalt Electrodes for Potentiometric Determination of Oxygen in Blood," FACSS XXIII, October 1, 1996, Kansas City, MO.
- 151. S. R. Barker, R. Kopelman and M. E. Meyerhoff, "Advances in Nitric Oxide and Nitrite Sensing," FACSS XXIII, October 1, 1996, Kansas City, MO.
- 152. N. Ramamurthy, U. Schaller, V. C. Yang and M. E Meyerhoff, "Development and Biomedical Applications of an Improved Polycation-Sensitive Membrane Electrode," FACSS XIII, October 1, 1996, Kansas City, MO.
- 153. M. E. Meyerhoff, D. E. Coutant, S. Chen., U. Ruedel, J. Xiao, G. B. Martin, R. Smith and C. E. Kibbey, "Novel Solute Selectivities of Bonded Porphyrin Phases in Liquid Chromatography," Symposium on Electrochemically Modulated Liquid Chromatography, 1997 Pittsburgh Conference, March 20, 1997, Atlanta, GA; invited speaker.

- 154. A. M. Smith, M. W. Ducey and M. E. Meyerhoff, "Further Studies of a Non-Separation Enzyme Immunoassay System," 1997 Pittsburgh Conference, paper # 237, March 18, 1997, Atlanta, GA.
- 155. M. W. Ducey and M. E. Meyerhoff, "Detection of Phenols in Flowing Streams via the use of Tyrosinase Immobilized on a Mircroporous Gold Electrode," 1997 Pittsburgh Conference, March 20, 1997, Atlanta, GA.
- 156. J. M. Esson and M. E. Meyerhoff, "Polyanion-Sensitive Polymeric Membrane Electrodes for Polyphosphates, DNA, RNA, and Acidic Polypeptides," 1997 Pittsburgh Conference, March 20, 1997, Atlanta, GA.
- 157. E. D. Steinle, U. Schaller and M. E. Meyerhoff, "Investigation of Gallium(III) Porphyrins for use in Ion-Selective Polymer Membrane Electrodes," 1997 Pittsburgh Conference, March 20, 1997, Atlanta, GA.
- 158. T. M. Ambrose, R. W. Hower, R. B. Brown and M. E. Meyerhoff, "Development of a Solid-State Potentiometric Heparin Sensing Cartridge Based on Photocrosslinked Decyl Methacrylate Membranes," Transducers '97, June 6, 1997, Chicago, IL.
- 159. M. E. Meyerhoff, N. Ramamurthy, J. E. Esson, T. M. Ambrose, S. Dai, I. Badr and V. C. Yang, "Membrane Electrodes Sensitive to Biologically Important Polyions: Principles and Applications," 191st Electrochemical Society Meeting, May 2, 1997, Montreal, Canada; invited speaker.
- 160. M. E. Meyerhoff, D.E. Coutant, S. Chen, U. Ruedel, J. Xiao, G. B. Martin, A. F. Francis and R. Smith, "Immobilized Porphyrins as Versatile Stationary Phases in Liquid Chromatography," Symposium on Advances in Porphyrin Chemistry, Great Lakes Regional ACS meeting, May 30, 1997, Chicago, IL; invited speaker.
- 161. M. E. Meyerhoff, N. Ramamurthy, J. Esson, T. M. Ambrose, S. Dai, I. Badr, and V. C. Yang, "Polyion Sensitive Membrane Electrodes/Optodes: Principles and Bioanalytical Applications," Symposium on Advances in Analytical Methods for Biomolecules, 80th Canadian Society for Chemistry Conference, June, 1, 1997, Windsor, CA; <u>invited speaker</u>.
- 162. T. M. Ambrose, I. H. Badr, S. Dai, J. M. Esson, N. Ramamurthy, V. C. Yang, and M. E. Meyerhoff, "Biomedical Applications of Polyion Sensitive Membrane Electrodes," Eurosensors XI, September 22, 1997, Warsaw, Poland; invited speaker.
- 163. M. E. Meyerhoff, "Polymer Membrane Based Ion/Polyion Sensors: New Chemistries, Designs and Biomedical Applications," 20th Aniversity Symposium, Department of Chemistry, University Autonoma Metropolitana, November 17, 1997, Mexico City, Mexico; invited speaker.
- 164. S. Chen and M. E. Meyerhoff, "Effect of Surface Immobilization Chemistry on the Separation of Polycyclic Aromatic Hydrocarbons (PAHs) on Protoporphyrin-Silica Phases," 1998 Pittsburgh Conference, March 2, 1998, New Orleans, LA.
- 165. K. A. Mowery and M. E. Meyerhoff, "Thromboresistant Ion-Selective Electrodes Via Nitric Oxide Release Polymeric Membranes," 1998 Pittsburgh Conference, March 3, 1998, New Orleans, LA.; invited paper.
- 166. N. Ramamurthy, N. Baliga, T. W. Wakefield, V. C. Yang, and M. E. Meyerhoff, "Application of an Improved Polycation-Sensitive Membrane Electrode for Determination of Heparin in Whole Blood," 1998 Pittsburgh Conference, March 2, 1998, New Orleans, LA.

- 167. M. E. Meyerhoff, N. Ramamurthy, J. M. Esson, S. Dai, T. M. Ambrose, A. Frielich and V. C. Yang, "Polyion Sensitive Membrane Electrodes; Principles and Biomedical Applications," Symposium on Novel Materials and Devices Based on Electrochemical Concepts, 1998 Pittsburgh Conference, March 4, 1998, New Orleans, LA; <u>invited speaker</u>.
- 168. M. E. Meyerhoff, K. A. Mowery and M. Schoenfisch, "Improving the Biocompatibility of Intravascular Chemical Sensors via Nitric Oxide Release," IFCC 17th International Symposium on The Confluence of Critical Care Analysis and Near Patient Testing, June 7, 1998, Nice, France; invited speaker.
- 169. M. E. Meyerhoff, D. E. Coutant, S. Chen, U. Ruedel, J. Xiao and G. B. Martin, "Novel Solute Selectivities of Bonded Porphyrin Phases in Liquid Chromatography," Ohio Valley Chromatography Symposium, June 24, 1998, Hueston Woods Park, Ohio; <u>invited speaker</u>.
- 170. S. Chen and M. E. Meyerhoff, "Shape-Selective Separation of PAHs on Protoporphyrin-Silica and Metalloprotoporhyrin-Silica Phases: Effect of Immobilization Chemistry and Porphyrin Distribution on Surface," HPLC '98, May 4, 1998, St. Louis, MO.
- 171. U. Ruedel and M. E. Meyerhoff, "Redox-Modulated Liquid Chromatography on Metalloporphyrin Silica Phases," HPLC '98, May 4, 1998, St. Louis, MO.
- 172. E. Malinowska and M. E. Meyerhoff, "Study on the Effect of Nonionic Surfactants on the Performance of Cation Selective Polymeric Membrane Electrodes Designed for Clinical Applications," IFCC 17th International Symposium on The Confluence of Critical Care Analysis and Near Patient Testing, June 5, 1998, Nice, France.
- 173. M. E. Meyerhoff, A. M. Smith, M. W. Ducey and C. Duan, "Non-Separation Electrochemical Immunoassay (NEEIA) Using Porous Gold Electrodes," 5th CIMTEC meeting, Symposium on Biosensors, June 17, 1998, Florence, Italy; invited speaker.
- 174. M. E. Meyerhoff, K. Mowery, M. H. Schoenfisch, S. Peteu and C. Cole, "Improving the Biocompatibility of In-Vivo Chemical Sensors via Nitric Oxide Release," International Conference on New Trends in Electroanalytical Chemistry, September 10, 1998, Seoul, S. Korea; invited speaker.
- 175. M. E. Meyerhoff, J. Esson, N. Ramamurthy, O. Lutze, and S. Dai, "Polyion Sensitive Membrane Electrodes: Principles and Biomedical Applications," Symposium on Biochemical Sensors, 49th International Society of Electrochemistry Meeting, September 14, 1998, Kitakyushi, Japan; invited speaker.
- 176. M. E. Meyerhoff, K. A. Mowery, M. H. Schoenfisch, N. Baliga, J. E. Saavedra and L. K. Keefer, "Improving the Biocompatibility of Intravascular Chemical Sensors via In Situ Nitric Oxide Release," International Symposium on Electrochemical and Biosensors, October 16, 1998, Matrafured, Hungary; invited speaker.
- 177. J. M. Esson, N. Ramamurthy and M. E. Meyerhoff, "Polyelectrolyte-Surfactant Complexes: A Titration Based Method to Model Binding in Polyion-Sensitive Membrane Electrodes," 1999 Pittsburgh Conference, March 9, 1999, Orlando, FL.
- 178. M. H. Schoenfisch and M. E. Meyerhoff, "Thromboresistant Fluorescent Optical Sensors via Nitric Oxide Release," 1999 Pittsburgh Conference, March 10, 1999, Orlando, FL.

- 179. S. Dai, E. Wang and M. E. Meyerhoff, "Polymer Film Modified Microtiter Plates for Optical Detection of Polyions and Protease Activities," 1999 Pittsburgh Conference, March 10, 1999, Orlando, FL.
- 180. S. Chen and M. E. Meyerhoff, "Selective Preconcentration of Polycyclic Aromatic Hydrocarbons on Metalloporphyrin-Silica Phases," 1999 Pittsburgh Conference, March 10, 1999, Orlando, FL.
- 190. M. E. Meyerhoff, "In Vivo Chemical Sensors: Enhancing Blood Compatibility and Analytical Performance Via Nitric Oxide Release," Plenary Lecture, Australian International Symposium on Analytical Science, July 5, 1999, Melbourne, Australia; invited speaker.
- 191. M. E. Meyerhoff, K. A. Mowery, M. H. Schoenfisch, J. K. Politis, H. Zhang, B. Oh and M. M. Batchelor, "Enhancing the Biocompatibility and In Vivo Performance of Intravascular Chemical Sensors Using Nitric Oxide Release Polymers," Symposium on Frontiers in Chemical Instrumentation, 218th ACS National Meeting, August 24, 1999, New Orleans, LA; invited speaker.
- 192. M. E. Meyerhoff, "Novel Electrochemical Sensors for Biomedical Measurements: From Non-Equilibrium Potentiometry of Polyions to In Vivo Devices Based on Nitric Oxide Release Polymers;" Gordon Conference on Electrochemistry, January 18, 2000, Ventura, CA; invited speaker.
- 193. M. E. Meyerhoff, E. Steinle and P. Buhlmann, "Dimer-Monomer Metalloporphyrin Equilibria in Polymer Membranes; Implications for Potentiometric and Optical Anion Sensors," Symposium on Ionophore-Based Sensors: Novel Directions for a Mature Technology, 2000 Pittsburgh Conference, March 13, 2000, New Orleans, LA; invited speaker.
- 194. M. E. Meyerhoff, "Intravascular Chemical Sensors: Can In Situ Nitric Oxide Release Solve Lingering Blood Compatibility/Analytical Performance Problems?" Symposium on In Vivo Sampling—Biocompatibility Issues, 2000 Pittsburgh Conference, March 16, 2000, New Orleans, LA; invited speaker.
- 195. M. E. Meyerhoff, M. H. Schoenfisch, K. A. Mowery, M. M. Batchelor, H. Zhang, B. Oh, J. Politis and J. A. Wahr, "In Vivo Chemical Sensors: Enhancing Blood Biocompatibility and Analytical Performance Using Nitric Oxide Release Polymers," Symposium on Chemical Sensors, Central Meeting of ACS-2000, May 18, 2000, Cincinnati, OH; invited speaker.
- 196. S. Dai, L.C. Chang, V. C. Yang and M. E. Meyerhoff, "Application of Polyion Sensitive Membrane Electrodes and Optodes for Monitoring Plasminogen Activators," 2000 Pittsburgh Conference, March 13, 2000, New Orleans, LA; <u>invited paper</u>.
- 197. Q. Ye and M. E. Meyerhoff, "Surface Morphology of Thromboresistant Nitric Oxide Release Polymeric Membranes," 2000 Pittsburgh Conference, March 14, 2000, New Orleans, LA.
- 198. B. K. Oh and M. E. Meyerhoff, "Direct Electrochemical Measurement of Nitric Oxide Release Profiles from Diazeniumdiolate Doped Polymer Films," 2000 Pittsburgh Conference, March 14, 2000, New Orleans, LA.
- 199. M. M. Batchelor, J. K. Politis and M. E. Meyerhoff, "Analytical Characterization of Novel Nitric Oxide Releasing Polymer Films Containing Diazenium diolates," 2000 Pittsburgh Conference, March 16, 2000, New Orleans, LA.

- 200. M. E. Meyerhoff, "Nitric Oxide Releasing Polymers: Preparation, Characterization, and Biomedical Applications," 16<sup>th</sup> Biennial Conference on Chemical Education, August 2, 2000, Ann Arbor, MI; <u>invited speaker</u>.
- 201. M. E. Meyerhoff, K. A. Mowery, M. H. Schoenfisch, M. M. Batchelor, J. A. Wahr, J. K. Politis, B. Oh, H. Zhang, A. Yousef and C. Chen, "Intravascular Electrochemical Blood-Gas Sensors: Using Nitric Oxide Release Polymers to Enhance In-Vivo Analytical Performance," 51<sup>st</sup> International Society of Electrochemistry Meeting, September 5, 2000, Warsaw, Poland; invited keynote speaker.
- 202. M. E. Meyerhoff, K. A. Mowery, M. H. Schoenfisch, M. Batchelor, H. Zhang, J. K. Politis, B. Oh and A. Youssef, "Enhancing the Biocompatibility and In Vivo Analytical Performance of Intravascular Chemical Sensors via In Situ Nitric Oxide Release," Symposium on New Directions for Biomedical Sensors, Eastern Analytical Symposium, November 2, 2000, Atlantic City, NJ; invited speaker.
- 203. V. V. Cosofret, P. D'Orazio, M. Erdosy, T. Greco, A. Manzoni, M. E. Meyerhoff, R. Miele, P. Pamidi and S. Zanardi, "Glucose and Lactate Biosensors with Enhanced Analytical Performances for Instrumentation Laboratory Synthesis," paper #216, American Association of Clinical Chemistry National Meeting, July 25, 2000, San Francisco, CA.
- 204. V. V. Cosofret, P. D'Orazio, M. Erdosy, T. Greco, M. E. Meyerhoff, J. Moriarity and P. Pamidi, "Electrochemical Sensors for Clinical Chemistry Applications: Compatibility of Membrane Chemistry with Complex Biological Samples," paper OC-46, Euroanalysis XI, September 5, 2000, Lisbon, Portugal.
- 205. M. E. Meyerhoff, E. Steinle, P. Buhlmann, S. Amemiya, E. Malinowska and J. Niedziolka, "Origin of Super-Nernstian Potentiometric Response of Polymer Anion Selective Membrane Electrodes Based on Metal (III)-Metalloporphyrins," Symposium on Electrochemical Sciences, Pacifichem Meeting, December 18, 2000, Honolulu, HA; invited speaker.
- 206. M. E. Meyerhoff, S. Dai, Q. Ye, S. Nevins, N. Durust and N. Ramamurthy, "Polyion Sensitive Polymeric Membrane Electrodes and Optodes: Principles and Biomedical Applications," Symposium on Chemical Sensors, Pacifichem Meeting, December 17, 2000, Honolulu, HA, invited speaker.
- 207. B. K. Oh and M. E. Meyerhoff, "Study of Metal Ion Mediated Reduction of Nitrite to Nitric Oxide (NO) by Ascorbic Acid," 2001 Pittsburgh Conference, March 6, 2001, New Orleans, LA.
- 208. Q. Ye and M. E. Meyerhoff, "Rotating Polyion Sensitive Membrane Electrodes: Principles and Bioanalytical Applications," 2001 Pittsburgh Conference, March 7, 2001, New Orleans, LA.
- 209. J. Niedziolka, L. Gorski, E. Malinowska and M. E. Meyerhoff, "The Performance and Anion Response Mechanisms of Membrane Electrodes Based on Ga(III), Zr(IV), Mo(V)O, and Sn(IV) Porphyrins," 2001 Pittsburgh Conference, March 7, 2001, New Orleans, LA.
- 210. M. Frost and M. E. Meyerhoff, "Analytical Characterization of Nitric Oxide Releasing Nitrosothiol-Derivatized Fumed Silica," 2001 Pittsburgh Conference, March 8, 2001, New Orleans, LA.
- 211. M. M. Batchelor, J. K. Politis, B. K. Oh and M. E. Meyerhoff, "Synthesis of Nitric Oxide Releasing Polyurethanes," ACS National Meeting, April 3, 2001, San Diego, CA.

- 212. P. G. Parzuchowski and M. E. Meyerhoff, "Synthesis of Potentially More Blood Compatible Nitric Oxide Releasing Acrylic Copolymers," ACS National Meeting, April 2, 2001, San Diego, CA.
- 213. H. Zhang, M. M. Batchelor and M. E. Meyerhoff, "Potentially More Blood Compatible Polymers Using Nitric Oxide Release Fumed Silica as Fillers," ACS National Meeting, April 2, 2001, San Diego, CA.
- 214. M. E. Meyerhoff, S. Dai, Q. Ye, N. Ramamurthy, N. Durust and S. Nevins, "Polyion Sensitive Polymeric Membrane Electrodes and Optodes; Principles and Bioanalytical Applications," Symposium on Bioanalytical Electrochemistry, Electrochemical Society Meeting, March 27, 2001, Washington, DC. <u>invited speaker</u>.
- 215. M. C. Frost, H. Zhang, M. M. Batchelor, J. K. Politis, J. A. Green, J. A. Wahr, M. E. Meyerhoff "Improving In Vivo Biocompatibility of In Vivo Chemical Sensors Via Nitric Oxide Release," Society For Biomaterials 2001, April 27, 2001, Minneapolis, MN.
- 216. M. E. Meyerhoff, M. M. Batchelor, B. Oh, H. Zhang, M. C. Frost, J. A. Wahr and J. Green. "In Vivo Chemical Sensors: Enhancing Blood Compatibility and Analytical Performance Using Nitric Oxide Release Polymers," Symposium on Biosensors, ACS Regional Meeting, June 12, 2001, Grand Rapids, MI. invited speaker.
- 217. M. E. Meyerhoff, M. Batchelor, H. Zhang, B. Oh, M. Frost, J. Wahr and J. Green, "Chemical Sensors for Continuous In Vivo Monitoring: Enhancing Biocompatibility and Analytical Performance Using Nitric Oxide Release Polymers," Symposium on In-Situ Electrochemistry, FACSS 2001, October 8, 2001, Detroit, MI. invited speaker.
- 218. L. Gorski, E. Malinowska, and M. E. Meyerhoff, "Zr(IV)-Porphyrins as Novel Ionophores for Fluoride Selective Membrane Electrodes," 2002 Pittsburgh Conference, March 18, 2002, New Orleans, LA. <u>invited paper</u>.
- 219. S. A. Nevins, M. E. Meyerhoff, and L. Balogh, "Polyion Sensitive Membrane Electrode Response Toward Poly(amidoamine) Dendrimers," 2002 Pittsburgh Conference, March 18, 2002, New Orleans, LA. <u>invited paper</u>.
- 220. B. Oh and M. E. Meyerhoff, "Copper Complex Mediated Nitrite Reduction to Nitric Oxide (NO) at Polymer/Solution Interface by L-Ascorbate," Annual Meeting of Society for Biomaterials, April 25, 2002, Tampa, FL.
- 221. M. C. Frost and M. E. Meyerhoff, "Synthesis and Characterization of S-Nitrosothiol-Derivatized Fumed Silica for Use as Nitric Oxide Releasing Polymer Films," Annual Meeting of Society for Biomaterials, April 25, 2002, Tampa, FL.
- 222. M. E. Meyerhoff, L. M. Lee, G. Klein, S. A Nevins, N. Ramamurthy, V. C. Yang, W. P. Fay and M. J. Lim, "Rapid Measurement of Low Molecular Weight Heparins in Whole Blood via Polyion Sensitive Membrane Electrode Technology," AACC meeting on Critical Care and Point of Care Testing, September 13, 2002, Monterey, CA.
- 223. M. E. Meyerhoff, S. Nevins, G. Klein, Q. Ye, S. Dai, H. Abd-Rabboh, K. Xiao, W. Qin and N. Durust, "Polyion Sensitive Membrane Electrodes and Optodes: Recent Advances in Fundamentals and Bioanalytical Applications," Matrafured Conference on Electroanalytical Chemistry, October 13, 2002, Matrafured, Hungary; invited speaker.
- 224. Y. Lee, B. K. Oh and M. E. Meyerhoff, "Direct Measurement of Surface Nitric Oxide Release Profiles from Diazeniumdiolate Doped Polymeric Films Using Electrochemical Sensors," 2003 Pittsburgh Conference, March 12, 2003, Orlando, FL.

- 225. W. Qin, W. Zhang and M. E. Meyerhoff, "Optical Sensor for Amine Vapors Based on Dimer-Monomer Equilibrium of Indium (III) Octaethylporphyrin in Polymeric Film," 2003 Pittsburgh Conference, March 12, 2003, Orlando, FL.
- 226. M. C. Frost, S. M. Rudich, H. Zhang, M. M. Batchelor, M. A. Maraschio, and M. E. Meyerhoff, "In Vivo Biocompatibility and Analytical Performance of Intravascular Clarke-Style Amperometric Oxygen Sensors Fabricated with NO-Releasing Polymers," 2003 Pittsburgh Conference, March 13, 2003; Orlando, FL.
- W. Zhang, W. Qin, K. Xiao and M. E. Meyerhoff, "Determination of Low Molecular Weight Heparin Using Rotating Polyion-Sensitive Membrane Electrodes," 2003 Pittsburgh Conference, March 13, 2003; Orlando, FL.
- 228. M. E. Meyerhoff, "Electrochemical Sensors in Medicine: New Solutions to Old Analytical Challenges," ACS National Meeting, September 8, 2003; New York, NY. <u>invited speaker</u>.
- 229. W. Cha, Y. Lee, B. Oh and M. E. Meyerhoff, "S-Nitrosothiol Detection via Amperometric Nitric Oxide Sensor Modified with Polymer Film Containing Catalytic Lipophilic Cu(II)-Complex," 2004 Pittsburgh Conference, March 8, 2004; Chicago, IL.
- 230. Y. Lee, S. M. Rudich, J. Yang and M. E. Meyerhoff, "Direct Real-Time Measurement of Nitric Oxide Generated from Tissue Slices Using Improved Amperometric NO Sensors in the Presence of L-Arginine, Poly(L-Arginine) Peptides and Protamine," 2004 Pittsburgh Conference, March 8, 2004, Chicago, IL.
- 231. R. Gifford, G. S. Wilson, M. E. Meyerhoff, M. Batchelor, Y. Lee, "Reduction of Inflammatory Response to Subcutaneous Glucose Sensors via Nitric Oxide Release," 2004 Pittsburgh Conference, March 9, 2004; Chicago, IL
- 232. M. E. Meyerhoff, "Enhancing the Blood Compatibility and Analytical Performance of In Vivo Chemical Sensors Using Nitric Oxide Releasing/Generating Polymers," Charles N. Reilley Award Symposium, 2004 Pittsburgh Conference, March 10, 2004, Chicago, IL; invited speaker.
- 233. H. Zhang and M. E. Meyerhoff, "Gold Coated Magnetic Particles as Solid Phase for Immunoassays," 2004 Pittsburgh Conference, March 9, 2004, Chicago, IL.
- 234. Y. Kang, E. Malinowska, P. Parzuchowski, N. Rizk, <u>M. E. Meyerhoff</u>, "Study of Planar Waveguide-type Optical Sensors Based on Dimer-Monomer Equilibrium of Metalloporphyrins in thin Polymeric Films," 2004 Pittsburgh Conference, March 9, 2004, Chicago, IL; <u>invited paper</u>.
- 235. M. E. Meyerhoff, "Electrochemical Sensors in Medicine: New Solutions to Old Analytical Challenges," SensLab2 Conference, 10<sup>th</sup> Anniversary of CCS-ETH Zurich, June 17, 2004; invited keynote lecture.
- 236. M. E. Meyerhoff, "Enhancing Biocompatibility and Analytical Performance of In Vivo Chemical Sensors Using Nitric Oxide Releasing/Generating Polymers," ACS National Meeting, August 23, 2004, Philadelphia, PA; invited speaker.
- 237. M. E. Meyerhoff, "Enhancing the Biocompatibility and Analytical Performance of In Vivo Chemical Sensors Using Nitric Oxide Releasing/Generating Polymers," ACS-Miami Valley Local Section Meeting, January 19, 2005, Cincinnati, OH; <u>invited speaker</u>.

- 238. M. E. Meyerhoff, "Polyion Sensitive Membrane Electrodes and Optodes: Principles and Biomedical Applications," Eli Lilly Grantee Symposium, February 22, 2005, Indianapolis, IN; invited speaker.
- 239. W. Cha, A. Desai, J. S. Warren and M. E. Meyerhoff, "Real-Time Detection of Nitric Oxide (NO) Released from Endothelial Cells Using Microphysiometer Type Arrangement with Cells Adhered to Surface of Electrochemical NO Sensor," 2005 Pittsburgh Conference, February 28, 2005, Orlando, FL.
- 240. H. Zhang, M. Burgman, H. Yim, R. K. Franklin and M. E. Meyerhoff, "Immunosensor Based on Conducting Polymer Coated Magnetic Particles," 2005 Pittsburgh Conference, February 28, 2005, Orlando, FL.
- 241. J. T. Mitchell-Koch, I. Badr, C. Wong, E. Malinowska, L. Gorski and M. E. Meyerhoff, "Potentiometric and Optical Fluoride Selective Sensors Based on Group 13 Metallo-Porphyrin and Salophen Complexes," 2005 Pittsburgh Conference, March 3, 2005, Orlando, FL.
- 242. M. E. Meyerhoff, "Use of Nitric Oxide Releasing/Generating Polymer Coatings to Improve the Biocompatibility of Implanted Chemical Sensors," Symposium on Biosensors: Functional Polymers, ACS National Meeting, March 15, 2005; invited speaker.
- 243. M. E. Meyerhoff, "Intelligent Quality Management for Blood Gas Critical Care Testing," Michigan Society for Clinical Laboratory Science, April 22, 2005, Kalamazoo, MI; <u>invited speaker</u>.
- 244. M. E. Meyerhoff, "Highly Selective Optical and Potentiometric Fluoride Ion Sensors Based on Thin Polymeric Films Doped with Aluminum(III)- Porphyrins and Salens as Ionophores," ACS National Meeting, Division of Analytical Chemistry Awards Symposium, August 29, 2005, Washington, D.C.; invited speaker.
- 245. M. E. Meyerhoff, "Polyion Sensitive Membrane Electrodes and Optodes: Principles and Biomedical Applications," 10<sup>th</sup> International Seminar on Electroanalytical Chemistry, October 17, 2005, Changchun, China; <u>invited speaker</u>.
- 246. M. E. Meyerhoff, "Enhancing the Biocompatibility and Analytical Performance of In Vivo Electrochemical Sensors Using Nitric Oxide Releasing/Generating Polymers," 11<sup>th</sup> Beijing Conference and Exhibition on Instrumental Analysis, October 21, 2005, Beijing, China; invited speaker.
- 247. M. E. Meyerhoff, "Enzyme Amplified Electrochemical Detection of DNA and Protease Activities Using Prosthetic Group-Oligomer Conjugates," Matrafured 05; International Conference on Electrochemical Sensors, November 14, 2005, Matrafured, Hungary; invited speaker.
- 248. M. E. Meyerhoff, "Electrochemical Sensors in Medicine: Meeting Needs for the 21<sup>st</sup> Century," SEAC Reilley Award Symposiutm, 2006 Pittsburgh Conference, March 15, 2006, Orlando, FL; <u>invited speaker</u>.
- 249. Y. Wu, A. Rojas, R.H. Bartlett, M. E. Meyerhoff, "Improving Blood-compatibility of Intravascular Electrochemical Oxygen Sensors Via In Situ Generation of Nitric Oxide (NO) at the Polymer/Blood Interface." Annual Meeting on Methods in Bioengineering, Cambridge, MA, July 18, 2006.
- 250. S. Hwang, W. Cha, M. Musameh, H-S. Yim, M. E. Meyerhoff, "Nitric Oxide Generating

- Materials Based on Immobilized Catalysts for Nitrosothiol Decomposition in Blood: A Novel Approach for Creating Thromboresistant Polymers" Methods in Bioengineering Conference at MIT, July 18, 2006; Cambridge, MA.
- 251. <u>B. Wu</u>, Z. Zhou and M. E. Meyerhoff, "A Dual-Acting Biomimetic Polymeric Coating Combining Nitric Oxide Release with Surface-Bound Active Thrombomodulin," 1st Annual Meeting of Methods in Bioengineering Conference, July 17, 2006; Boston, MA.
- 252. M. E. Meyerhoff, "Sensors for Endogenous Nitrosothiols Based on Immobilized Chemical/Biochemical Catalyst," ACS National Meeting, September 12, 2006, San Francisco, CA; invited speaker.
- 253. <u>S. Hwang</u>, M. E. Meyerhoff, "Catalytic Generation of Nitric Oxide from S-Nitrosothiols Using Organotelluride-Linked Polymers" American Chemical Society National Meeting, Div. of Poly., Sept. 12, 2006; San Francisco, CA.
- 254. <u>B. Wu</u>, Z. Zhou and M. E. Meyerhoff, "Dual-Acting Biomimetic Polymeric Coatings: Combining Nitric Oxide Release with Surface-Bound Active Thrombomodulin," American Chemical Society 232nd National Meeting, September 10, 2006; San Francisco, CA.
- 255. L. Wang, H. Abd-Rabboh, M. Pietrzak, I. Badr, Y. Kang, E. Malinowska and M. E. Meyerhoff, "Further Fundamental and Applied Studies of Fluoride Sensors Based on Al(III) Porphyrin Ionophores" 2007 Pittsburgh Conference, February 27, 2007; Chicago, IL; invited speaker.
- 256. <u>Y. Wu</u>, N. Lafayette, W. Cha, M. Frost, R.H. Bartlett, M.E. Meyerhoff. "Preservation of Platelet Count and Function in Extracorporeal Circulation via Nitric Oxide Generation at Polymer/Blood Interface," Society For Biomaterials Annual Meeting, Chicago, IL, April 19, 2007.
- 257. <u>B. Wu</u> and M. E. Meyerhoff, "A Dual-Functional Polymeric Coating Combining Rapamycin and Nitric Oxide Release," 2007 Society of Materials Annual Meeting, April 18, 2007; Chicago, IL.
- 258. <u>J. Yang</u>, M. E. Meyerhoff, "Layer-by-Layer Assembly for Nitric Oxide Generation Based on Catalytic Decomposition of S-Nitrosothiols by Organoseleium Species," 2007 Annual Meeting of Society for Biomaterials, April 18, 2007, Chicago, IL.
- 259. Mark E. Meyerhoff, "Amperometric S-Nitrosothiols Sensors: Preparation, Characterization, and Potential Biomedical Applications," ETH-Zurich, Symposium Honoring Erno Pretsch, Zurich, Switzerland, June 29, 2007; invited speaker.
- 260. Mark E. Meyerhoff, "S-Nitrosothiol Sensors Based on Miniaturized Amperometric Nitric Oxide Probes: Design and Biomedical Applications," Symposium on Miniature and Micro Gas Sensors, PittCon 2008, New Orleans, March 4, 2008; invited speaker.
- 261. Mark E. Meyerhoff, "Nitric Oxide Release/Generating Polymers for Blood Contacting Medical Devices, ASAIO National Meeting, San Francisco, June 19, 2008; <u>invited speaker</u>.
- 262. Mark E. Meyerhoff, "Electrochemical Sensors for S-Nitrosothiol Species Based on Immobilized Chemical/Biochemical Catalysts: Design and Biomedical Applications," Gordon Conference on Bioanalytical Sensors, Smithfield, RI, July 1, 2008; invited speaker.
- 263. W. Cha, Y. Wu, S. Hwang and M. E. Meyerhoff, "Electrochemical Sensors for

- Nitrosothiol Species Based on Immobilized Chemical/Biochemical Catalysts: Design and Biomedical Applications", 11th ISEC & 1st SJBSEC (International & the First Sino-Japan Bilateral Symposium on Electroanalytical Chemistry) 2007 August 16-19; Changchun, China; invited speaker.
- 264. Y. Wu, W. Cha, S. Hwang, F. Zhang and M. E. Meyerhoff, "Determining S-Nitrosothiol Concentrations in Whole Blood via Electrochemical Sensors Based on Immobilized Catalysts," Second International Role of Nitrite in Physiology, Pathophysiology and Therapeutics Meeting, NIH, September 6, 2007; Bethesda, MD.
- 265. <u>J. A. Bennett</u> and M. E. Meyerhoff, "Development of Advanced Electrochemical Sensors for NO and RSNO Detection in Subcutaneous Tissue," Midwestern Universities Analytical Chemistry Conference, November 3, 2007; Champaign, IL.
- 266. <u>D. Shen</u> and M. E. Meyerhoff, "Evaluation of Pyrroloquinoline Quinone (PQQ) Doped Polymeric Micro/Nanospheres as a Sensitive Label for Binding Assays", 59th Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy, March 3, 2008; New Orleans, LA.
- 267. <u>L. Wang</u> and M. E. Meyerhoff, "Optical Nitrite Sensors Based on Co(III) Porphyrins for Potential Use in Detecting Nitrite in Biological Samples" Pittsburgh Conference, March 3, 2008; New Orleans, LA.
- 268. L. B. Zimmerman, K.D. Lee, M.E. Meyerhoff, "Sensitive Binding Assay for the Detection of Group A Streptococcus DNA Utilizing Prosthetic Group Encapsulated DNA-Tagged Liposomes," 59th Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy, March 4, 2008; New Orleans, LA.
- 269. <u>J. A. Bennett</u> and M. E. Meyerhoff, "Electrochemical Needle-Type Sensors for Subcutaneous Detection of Nitric Oxide and S-Nitrosothiols," Pittsburgh Conference, March 5, 2008; New Orleans, LA.
- 270. Q. Yan, B. Wu, W. Cha, S. Hwang, M. Reynolds, M. Frost and M. E. Meyerhoff, "Preparation and Characterization of Needle-Type Glucose/Lactate Sensors with Nitric Oxide Releasing/Generating Polymeric Coatings for Enhanced Biocompatibility," Pittcon Conference & Expo, March 3, 2008; New Orleans, LA.
- 271. Q. Yan and M. E. Meyerhoff, "Needle-Type Glucose/Lactate Sensors with Nitric Oxide Releasing/Generating Polymeric Coatings for Enhanced Biocompatibility," The Tenth World Congress on Biosensors, May 16, 2008; Shanghai, China.
- 272. <u>J. Yang</u> and M. E. Meyerhoff, "Generic Nitric Oxide Generating Antithrombotic Surface via Layer-by-Layer Assembly," 2008 World Biomaterials Congress, May 28 June 1, 2008; Amsterdam, The Netherlands.
- 273. Mark E. Meyerhoff, "Electrochemical Sensors for Measuring S-Nitrosothiol Species in Whole Blood: Design and Potential POC Applications," American Association of Clinical Chemistry Conference on Point-of-Care Technologies, Barcelona, Spain, September 19, 2008; invited speaker.
- 274. W. Cha., M. R. Anderson, F. Zhang, M. E. Meyerhoff, "Enhanced Amperometric S-Nitrosothiol Sensors by using NO Generating Cellulose Dialysis Membrane Modified with Organoselenium Catalysts", 236<sup>th</sup> ACS National Meeting 2008, September 10, 2008, Philadelphia, PA.
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- Conference on Electrochemical Sensors), October 7, 2008, Dobogókö, Hungary. <u>Invited Speaker.</u>
- 276. N. Walker and M.E. Meyerhoff, "Amperometric Detection of S-Nitrosothiols in Exhaled Breath Condensate," The 60th Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy, March 11, 2009; Chicago, IL.
- 277. <u>Mariusz D. Pietrzak</u>, Lin Wang, Russell Bornschein, Mark E. Meyerhoff, "Electrochemical and Optical Nitrite Selective Sensors Based on Rhodium(III)-Ligand Complexes as Ionophores", 60<sup>th</sup> Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy, March 11, 2009, Chicago, IL, USA.
- 278. <u>L. B. Zimmerman</u>, J.R. Brender, K.D. Lee, A. Ramamoorthy, and M.E. Meyerhoff, "Detection of Membrane Permeabilization by Antimicrobial and Amyloid Peptides Using Pyrroloquinoline Quinone (PQQ) Encapsulated Liposomes," 60th Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy, March 9, 2009; Chicago, IL.
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- 280. <u>L. Wang</u>, S. Buchanan and M. Meyerhoff, "Rapid Detection of High Charge Density Polyanion Contaminants in Biomedical Heparin Preparations Using Potentiometric Polyion Sensors," The 60th Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy, March 10, 2009; Chicago, IL.
- 281. Mark E. Meyerhoff, "Improving the Biocompatibility and Analytical Performance of In Vivo Chemical Sensors Via Nitric Oxide Release/Generating Polymer Coatings," Symposium on In Vivo Analytical Measurements, 60<sup>th</sup> Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy, Chicago, IL, March 12, 2009; invited speaker.
- 282. <u>B. Wu</u> and M. E. Meyerhoff, "Hemocompatible Polymeric Coatings with Sulfonated Polyurethanes as Matrix for Sustained Nitric Oxide." 2009 Society of Materials Annual Meeting, April 22, 2009; San Antonio, TX.
- 283. <u>B. Wu, Y. Wang, P. Roy-Chaudhury and M. E. Meyerhoff, "Combining Nitric Oxide Generation and Sirolimus Release in Polymeric Films: Potential Coatings for Stents and Other Biomedical Devices." 237<sup>th</sup> American Chemical Society National Meeting & Exposition, March 22, 2009; Salt Lake City, UT.</u>
- 284. <u>J. Yang</u>, S. Mirkazemi, and M. E. Meyerhoff, "Layer-by-Layer Assembly with Combined Nitric Oxide Generation and Surface Immobilized Heparin -- A Universal Anti-Thrombotic Coating for Cardiovascular Implants," 2009 Society for Biomaterials Annual Meeting and Exposition, April 22-25, 2009; San Antonio, Texas.
- 285. Mark E. Meyerhoff, "Nitric Oxide Releasing/Generating Polymers: Preparation, Characterization, and Biomedical Applications," 33rd Annual Symposium of the U of M Marcromolecular Science and Engineering Center, October 29, 2009; Ann Arbor, MI; invited speaker.
- 286. <u>Mark E. Meyerhoff</u>, Nitric Oxide Releasing.Generating Polymers: Preparation, Characterization, and Biomedical Applications," 11<sup>th</sup> Pacific Polymer Conference, December 9, 2009; Cairns, Australia; <u>invited speaker</u>.
- 287. <u>Mark E. Meyerhoff,</u> "Electrochemical Sensors in Medicine: Meeting Needs for the 21<sup>st</sup> Century," Annual Meeting of Electrochemical Society, Symposium on Biomedical

- Sensors, April 26, 2010; Vancouver, Canada; invited keynote speaker
- 288. <u>Kebede L. Gemene</u> and Mark E. Meyerhoff, "Rapid Detection of Protease Activities using Flash Chronopotentiometry with Polyion Sensitive Polymeric Membrane Electrodes," Midwestern Universities Analytical Chemistry Conference (MUACC), December 5, 2009; Michigan State University, East Lansing, MI.
- 289. <u>Kebede L. Gemene</u> and Mark E. Meyerhoff, "Enhancing the Selectivity of Ionophore-Based Anion-Selective Electrodes Using Pulstrode Mode of Measurement," The 61<sup>st</sup> Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy, March 1, 2010; Orlando, FL.
- 290. Q. Yan and M.E. Meyerhoff, "Optimizing Nitric Oxide Release Outer Coatings for Implantable Glucose/Lactate Sensors," The 61th Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy, March 3, 2010; Orlando, FL.
- 291. N. Walker and M.E. Meyerhoff, "Chemiluminescent Detection of S-Nitrosothiols using a Sensitive and Selective Organoselenium Catalyst," The 61st Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy, March 1, 2010; Orlando, FL.
- 292. <u>M. E. Meyerhoff,</u> "Electrochemical Sensors in Medicine: Meeting Needs for the 21<sup>st</sup> Century," Electrochemical Society Meeting, April 27, 2010; Vancouver, Canada; <u>invited</u> keynote lecture.
- 293. M. E. Meyerhoff, "Improving Blood Compatibility of Intravascular Electrochemical Sensors Using Nitric Oxide Releasing/Generating Polymeric Coatings," 161st International Society of Electrochemistry meeting, September 28, 2010; Nice, France; invited keynote speaker.
- 294. <u>M. E. Meyerhoff,</u> "Improving Blood Compatbility of Intravascular Chemical Sensors Using Nitric Oxide Releasing/Generating Polymeric Coatings," Symposium on Chemical Sensors, Pacifichem Meeting, December 18, 2010; Honolulu, Hawaii; <u>invited speaker.</u>
- 295. <u>L. Höfler</u>, C. Wenyi and M.E. Meyerhoff, "Enhancing the Sensitivity of Immobilized Organoselenium-Based Amperometric Sensors for Sub-Micromolar Detection of S-Nitrosothiols," Pittcon Conference & Expo 2011, March 15, 2011; Atlanta, GA.
- 296. <u>A. K. Bell, L. Hofler, and M. E. Meyerhoff, "Studies of High Molecular Weight Polyanion Extraction and Transport Through Plasticized Polymeric Films Doped with Tridodecylmethylammonium Chloride," Pittcon Conference and Expo 2011, March 15th, 2011; Atlanta, GA.</u>
- 297. K. L. Gemene and M. E. Meyerhoff, "Direct Detection of ProteaseActivities by Flash Chronopotentiometry with Polycation-Sensitive Polymeric Membrane Electrodes," The 62nd Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy, March 14, 2011; Atlanta, GA.
- 298. W. Cai and M. E. Meyerhoff, "Carboxyl-Ebselen-Based Layer-by-Layer Coating for Nitric Oxide Generation," Society for Biomaterials 2011 Annual Meeting & Exposition, April 13-16, 2011; Orlando, FL
- 299. A. Bell, K. Gemene, L. Höfler, L., Wang and M. E. Meyerhoff, "Polyion Sensitive Membrane Electrodes: New Applications, New Designs, and Revisiting the Origin of Potentiometric Polyion Response," Matrafured '11; International Conference on Electrochemical Sensors, Dobogokö, Hungary; June 22, 2011; invited speaker.

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- 300. Bell, K. Gemene, L. Höfler, L., Wang and M. E. Meyerhoff, "Polyion Sensitive Membrane Electrodes: New Applications, New Designs, and Revisiting the Origin of Potentiometric Polyion Response," AnaChem 2011, Livonia, MI; November 3, 2011, invited speaker.
- 301. M. E. Meyerhoff, S. Yang, N. R. Crist, K. E. Gemene, L. Hofler, "Polymeric Membrane Electrodes Selective for Nitrite and Nitrate: Current Status and Potential Biomedical/Environmental Applications," Pittsburgh Conference 2012, Orlando, FL; March 14, 2012; invited speaker.
- 302. <u>A. K. Bell and M. E. Meyerhoff, "Reversible Sensor for Detection of High Charge Density Polyanion Contaminants in Heparin Preparations," Pittsburgh Conference 2012, Orlando, FL; March 11, 2012,</u>

## **Additional Invited Lectures**:

Gelman Sciences (9/30/80); Miami University (11/14/80); Indiana University-Purdue University at Indianapolis (3/30/82); Medtronics Inc. (12/15/82); University of West Virginia (1/19/83); Society of Analytical Chemists of Pittsburgh (2/7/83); University of Pittsburgh (2/8/83); University of Colorado (2/21/83); University of Colorado at Denver (2/22/83); University of Michigan at Dearborn (4/1/83); University of Iowa (10/21/83); Michigan State University 10/27/83); Wayne State University (11/4/83); Instrumentation Laboratories, (2/10/84); Anachem Meeting (4/16/84); Eastern Michigan University (4/11/84); Allied Chemical (5/15/84); Upjohn Inc. (5/21/84); ETH in Zurich, Switzerland (6/18/84); Dow Chemical (12/9/84); University of Massachusetts (12/15/84), Purdue University (1/29/85); Michigan State University (2/15/85); Eli Lilly (6/5/85); Eli Lilly (9/19/85); Indiana University (10/1/85); University of Cincinnati (11/22/85); Dow Chemical (6/9/86); Eli Lilly (9/21/86); Miami University (11/24/86); Oakland University (10/28/87); Lehman College (11/4/87); Ohio State University (1/12/88), University of Michigan-Dearborn (1/29/88); University of Kentucky (2/25/88); University of Cincinnati (2/26/88); Pennsylvania State University (11/9/88); Hybritech Inc. (10/27/89); University of Michigan-Flint (2/19/90); Hope College (2/12/90); Calvin College (2/1/90); Beckman Instruments (1/24/90); Loyola University (9/12/90); Michigan AACC meeting (9/28/90); Univ. of Michigan Hospital (10/18/90); Lehman College (12/14/90); Dow Chemical (1/15/91); Univ. of Toledo (2/11/91); Abbott Laboratories (6/20/91); Eli Lilly (11/15/91); Univ. of Iowa (1/18/92); Dow Chemical (4/9/92); University of Ulm (5/14/92), Univ. of Warsaw (5/18/92); Kalamazoo College (10/13/92); Enzyme Discussion Group (U of M--10/7/92); University of Pittsburgh (1/4/93); Hybritech Inc. (1/15/93); Beckman Instruments (1/18/93); Baxter Healthcare (1/19/93); SUNY at Buffalo (2/4/93); University of Illinois (4/22/93); Medtronic HemoTec (3/14/94); ETH-Zurich (4/12/94); Hercules Inc. (5/15/94); University of New Hampshire (10/21/94), Univ. of Alberta (10/27/94); Univ. of Vermont (11/10/94); University of Munster (Germany) (1/27/95); ETH-Zurich (1/31/95); New Mexico State University (4/26/95); Youngstown State University (May 5, 1995); Ain Shams University (10/4/95); University of Florida (2/2/96); University of Windsor (2/23/96); Indiana University-Purdue University at Indianapolis (4/3/96); Medtronic HemoTec (4/25/96); Abbott Laboratories (10/8/96); Purdue University (10/31/96); Wayne State University (2/3/97); University of Colorado at Denver (4/23/97); Instrumentation Laboratory (Milano, Italy) (9/18/97); University of South Florida (10/23/97); Detroit Section of Electrochemical Society (1/22/98); University of Delaware (4/13/98); Dade Behring Inc. (4/14/98); St. John's University (4/17/98); Case Western Reserve University (9/28/98); Kwangwoon University (9/13/98); SUNY at Binghamton (10/2/98); University of Colorado at Denver (11/18/98); Wabash College (2/23/99); Muhlenberg College (3/17/99); College of William and Mary (3/19/99); Iowa State University (4/8/99); University of Massachusetts (4/29/99); Bowling Green State University (9/14/99); University of Michigan at Dearborn (9/24/99); Oklahoma State University (10/12/99); Medtronic Inc. (1/24/00); University of North Carolina at Chapel Hill (2/28/00); Glaxo Inc. (2/29/00); University of Toledo (2/7/00); Auburn University (3/9/00); University of Illinois (9/22/00); University of Minnesota (9/22/01); North Carolina State University (3/28/01); Medtronic Inc. (9/21/01); University of Michigan-Retirement Group (11/15/01); Southern Illinois (2/08/01); University of Indiana (4/2/02); University of Kansas (4/26/01); Oakland University (10/9/02); University of Pittsburgh (10/24/02); Medtronic (11/12/02); Hillsdale College (11/26/02); University of Illinois (10/2/03); Michigan State University (10/31/03); St. John's University (11/1/03); Transomic Inc. (10/14/04); Medtronic (10/15/04); Tufts University (10/19/04); Michigan Tech (10/29/04); University of California at Riverside (11/10/04); University of Tennessee (11/18/04); Bowling Green University (12/1/04); SUNY-Buffalo (9/30/05); Purdue University (10/6/05); Renmin University (10/20/05); Kalamazoo College (11/7/05); Pennsylvania State University (3/29/06); Arrow Inc. (3/30/06); Microchips Inc. (11/13/06); Johnson & Johnson (12/1/06); Arizona State University (3/8/07); Ohio University (4/23/07); Wayne State University (9/10/07); University of Pittsburgh (11/5/07); Bayer Diagnostics (2/15/08); Virginia Commonwealth University (3/28/08); Baxter Healthcare (6/3/08); Biomarin Inc. (6/13/08); Penn St-Erie (11/12/08); St. Jude Medical (2/27/09); University of

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Ottawa (5/21/08); University of New South Whales (12/4/09); University of Curtin (12/11/09); Stevens Institute (3/22/10); Instrumentation Laboratory Inc. (3/24/10); Dow Corning (7/8/10); University of Hamilton (11/4/10); N30 Pharmaceuticals (6/15/2011), Oakland University (2/29/12)

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## **EXHIBIT B**



US007250105B1

## (12) United States Patent Davies et al.

#### (10) Patent No.:

US 7,250,105 B1

(45) Date of Patent:

\*Jul. 31, 2007

#### (54) MEASUREMENT OF SUBSTANCES IN LIQUIDS

- (75) Inventors: Oliver W. H. Davies, Inverness (GB); Christopher P. Leach, Inverness (GB); Manuel Alvarez-Icaza, Inverness (GB)
- (73) Assignee: Lifescan Scotland Limited, Scotland (GB)
- (\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 369 days.

This patent is subject to a terminal dis-

- (21) Appl. No.: 10/431,140
- (22) Filed: May 7, 2003

#### Related U.S. Application Data

- (63) Continuation of application No. 09/521,163, filed on Mar. 8, 2000, now Pat. No. 6,733,655.
- (51) Int. Cl. G01N 27/327 (2006.01) G01N 27/333 (2006.01)

See application file for complete search history.

#### (56) References Cited

#### U.S. PATENT DOCUMENTS

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5,120,420	A	49.	6/1992	Nankai et al 204/403.11
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5.791.344	A	8/1998	Schulman et al.
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V.A. Bodner "Aviation Devices", The Machine Building Publishing House, Moscow, Russia, 1969, p. 158.
Official Action Issued by the Patent Office of the Russian Federation, mailed on or about Dec. 6, 2004, re Russuan Application No. 2002126814.

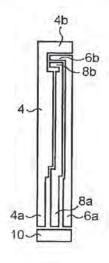
\* cited by examiner

Primary Examiner - Alex Noguerola

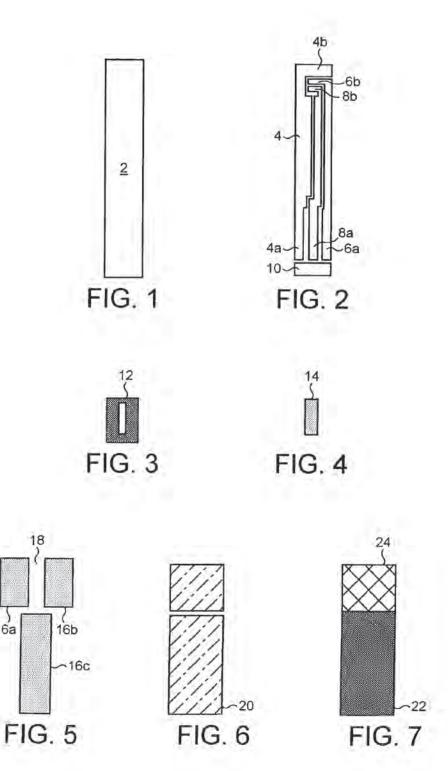
#### (57) ABSTRACT

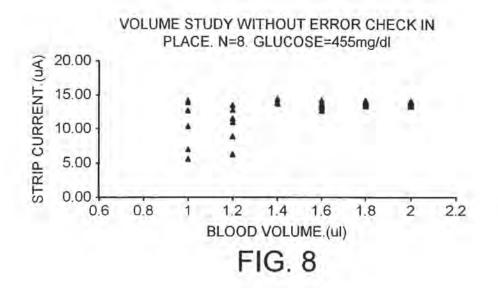
In accordance with the present invention a measuring device compares the current generated by two working sensor parts and gives an error indication if they are too dissimilar, i.e., the current at one sensor part differs too greatly from what would be expected from considering the current at the other. Not only can this method detect when one of the sensor parts has not been properly covered with sample liquid, but it can also detect if there is a manufacturing defect in either sensor part or if either has been damaged after manufacture, since even with complete coverage of the working sensor parts, an anomalous current will be generated at the affected sensor part under such circumstances.

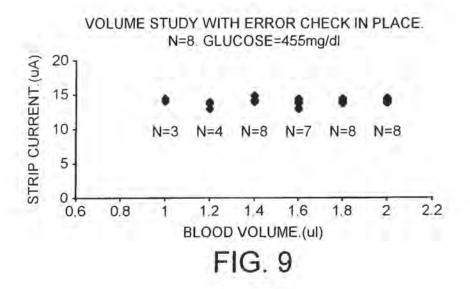
#### 3 Claims, 2 Drawing Sheets



16a







#### MEASUREMENT OF SUBSTANCES IN LIQUIDS

This application is a Continuation application of Ser. No. 09/521,163 filed Mar. 8, 2000, now U.S. Pat. No. 6,733,655, 5 which is incorporated herein by reference in its entirety.

This invention relates to apparatus for measuring the concentration of a substance in a liquid and particularly, but not exclusively, to apparatus for measuring the concentration of glucose in blood.

Devices for measuring blood glucose levels are invaluable for diabetics, especially devices that may be used by the sufferers themselves since they may then monitor their own glucose levels and take an appropriate dose of insulin. Correspondingly therefore the accuracy of such devices is 15 very important since an inaccurate reading could lead to the wrong level of insulin being administered which could be very harmful.

It is also the case that in all practical blood glucose measuring systems at least part of the device, i.e. that part 20 which comes into contact with the sample blood, is disposable. This means that it is particularly important that the cost particularly of any disposable parts can be minimised as a user will generally need large numbers of them regularly.

Known glucose measuring devices now favour an electrochemical measurement method over old colorimetric methods. The general principle is that an electric current is measured between two sensor parts called the working and reference sensor parts respectively. The working sensor part comprises a layer of enzyme reagent, the current being generated by the transfer of electrons from the enzyme substrate, via the enzyme and an electron mediator compound to the surface of a conductive electrode. The current generated is proportional to both the area of the sensor part and also the concentration of glucose in the test sample. Since the area of the working sensor part is supposedly known, the electric current should be proportional to the glucose concentration.

It has been recognised in the art that inaccurate results are obtained if the working sensor part is not fully covered with 40 blood since then its effective area is reduced. Various ways of dealing with this problem have been proposed, two of which are disclosed in U.S. Pat. No. 5,628,890 and U.S. Pat. No. 5,582,697 Both of these methods rely on a unidirectional flow of blood across the surface of the test strip and 45 both initiate the test measurement by detecting the presence of the sample liquid at an electrode or sensor part located downstream of the working sensor part.

The problem of insufficient sample liquid being present and thus the working sensor part not being completely 50 covered may of course be reduced by reducing the size of the working sensor part. However a small area for the working sensor part tends to give a greater variability in calibrated results.

The present inventors have realised that as well as incomplete coverage of the working sensor part, inaccurate results can also arise from occasional defects in the production of the test strips for such devices, in the area and/or the thickness of the working sensor part and also from accidental damage to the working sensor part e.g by a user. As far as the inventors are aware, the only practical way to deal with this problem so far has been to ensure that the printing process used to produce the test strips is as accurate as possible and to rely on adequate quality control.

It is an object of the present invention at least partially to 65 alleviate the above-mentioned disadvantages and when viewed from a first aspect the invention provides a method

of measuring the concentration of a substance in a sample liquid comprising the steps of:

providing a measuring device having a first working sensor part comprising a working layer which generates an electric current proportional to the concentration of said substance in the sample liquid, a reference sensor part and a second working sensor part comprising a working layer which also generates an electric current proportional to the concentration of said substance in the sample liquid;

applying the sample liquid to said measuring device;

comparing the electric current generated at each of the working sensor parts to establish a difference parameter; and giving an indication of an error if said difference, parameter is greater than a predetermined threshold.

Furthermore the measuring device used in this method is novel and inventive in its own right and thus from a second aspect the present invention provides a device for measuring the concentration of a substance in a sample liquid, said device comprising:

a reference sensor part.

a first working sensor part, comprising a working layer for generating an electric current proportional to the concentration of said substance in the sample liquid; and

a second working sensor part comprising a working layer also for generating an electric current proportional to the concentration of said substance in the sample liquid.

Thus it will be seen that in accordance with the invention the measuring device compares the current generated by two working sensor parts and gives an error indication if they are too dissimilar—i.e. the current at one sensor part differs too greatly from what would be expected from considering the current at the other. Not only can this method detect when one of the sensor parts has not been properly covered with sample liquid, but it can also detect if there is a manufacturing defect in either sensor part or if either has been damaged after manufacture, since even with complete coverage of the working sensor parts, an anomalous current will be generated at the affected sensor part such circumstances.

In accordance with the invention the only type of defect or damage which would not necessarily be recognised is one which affected both of the working sensor parts to the same degree. However, this is logically less likely than a defect affecting a single working sensor part and is thus an improvement over the prior art. In practice such a likelihood is considered to be negligible. In any event the invention is not limited to providing just two working sensor parts and the skilled person could therefore choose to provide three or more working sensor parts to further reduce the probability that they are all affected by an identical defect.

Looking at the invention another way, it provides an arrangement whereby for a given total area of working sensor part and thus a given minimum sample volume, detection of inadequate fill and of defects in the working sensor part provided by separating the area of the working sensor part into two.

Some or all of the sensor parts may be provided as part of an integrated device. Preferably however at least the working sensor parts are provided on a removable test member. Thus when viewed from a further aspect the present invention provides a test member for measuring the concentration of a substance in a sample liquid comprising:

a substrate; and

two working sensor parts provided on the substrate, each working sensor part comprising a working layer for generating an electric current proportional to the concentration of said substance in the sample liquid.

Preferably a reference sensor part is also provided on the

It will be appreciated by those skilled in the art that effectively what has been provided is a measuring device which is self-testing for proper use, damage and certain manufacturing defects. This is particularly beneficial in the context of a device in which the sensor parts are provided on a separate test member since this may typically be a massmanufactured test strip, e.g. for measuring blood glucose levels. Since in accordance with the invention a damaged or 10 defective test strip will be recognised, allowing it to be rejected, the accuracy of the final result and thus potentially the safety of a user is no longer solely dependent upon high manufacturing precision. Although it is of course not desirable that a large number of tests is rejected, in many 15 circumstances it is more important that inaccurate results are

The two working sensor parts may be dissimilar or different potentials may be applied to each sensor part in either of which cases the measuring device is preferably 20 arranged to apply appropriate weights to the measurements returned by one or both working sensor parts to normalise them. The difference parameter could then for example be the simple arithmetic difference between the normalised current values. Preferably however the working layer of both 25 sensor parts is of the same material and alternatively, but preferably additionally, both working sensor parts have the same area. Thus it is most preferred that the two working sensor parts are substantially identical. It is also preferred that the measuring device is arranged to apply the same 30 method in accordance with the invention; and potential to each sensor part. This allows the difference parameter to comprise a direct comparison between the respective currents at the sensor parts in order to determine whether a reliable measurement of the substance concentration can be made.

The two working sensor parts may be arranged as convenient within the device, or in accordance with the preferred embodiment, on the test member. The device or test member may be arranged to allow the sample liquid to flow freely over the working sensor parts. More preferably however the sample liquid is constrained to flow substantially unidirectionally across the working sensor parts.

It is presently preferred that the two working sensor parts are arranged one downstream of the other. This makes it possible to ensure that one of the sensor parts will always be 45 completely covered before the other begins to be covered. thus avoiding the possibility, however small, that insufficient sample liquid is applied to cover both sensor parts and furthermore that each sensor part is partially covered by the same amount. It will be appreciated however that if the 50 above-mentioned small risk is deemed acceptable, arrangements in accordance with the invention allow a much greater flexibility in the placement of the sensor parts than in known devices whilst still providing protection against an inadequate volume of sample liquid being used or other incorrect 55 product usage or damage. It is also preferred that both working sensor parts are downstream of the reference sensor part.

The threshold used to determine an inaccurate measurement may be chosen as appropriate. Typically a threshold 60 will be chosen empirically as a suitable value will depend on the inherent variability in the manufacturing process, the desired precision of results, etc. To some extent there is a trade-off between the accuracy which may be obtained by setting the threshold low and the proportion of measure- 65 ments which are disregarded as being too inaccurate. Thus the threshold might advantageously be set at a level for

example where no significant harm would be done to a patient relying on the results to administer insulin.

The difference parameter may be an absolute value—e.g. of the difference in currents measured at each sensor part, but is preferably dimensionless-e.g. a percentage of one or other of the measured currents.

The actual current value used to calculate the concentration of the substance may just be that from one of the working sensor parts, but is preferably a combination thereof, e.g. the sum or mean of the two. This gives the advantage that the maximum effective working area is utilised which further helps to increase the precision of the results obtained.

A particularly preferred embodiment of the invention is a device for measuring the concentration of glucose in blood, in which the two working sensor parts and the reference sensor part are provided on a disposable test strip.

A preferred embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

FIG. 1 shows a substrate for a test strip in accordance with the invention;

FIG. 2 shows the layout of carbon tracks applied to the substrate:

FIG. 3 shows the layer of insulation applied to the strip;

FIG. 4 shows the enzyme reagent layer;

FIG. 5 shows a layer of hydrophilic film;

FIG. 6 shows the cover layer of the strip;

FIG. 7 is a plot of the results obtained without using a

FIG. 8 is a plot similar to FIG. 7 obtained using a method in accordance with the invention.

FIG. 9 is a plot similar to FIG. 8 obtained using a method in accordance with the invention.

Turning to FIG. 1, there is shown an oblong polyester strip 2 which forms the substrate for a test strip for measuring the concentration of glucose in a sample of blood. The substrate 2 is shown in isolation although in practice an array of such strips is cut out from a large master sheet at the end of fabrication.

FIG. 2 shows the pattern of carbon ink which is applied to the substrate by screen printing. The layer of carbon comprises four distinct areas which are electrically insulated from one another. The first track 4 forms, at the distal end thereof, an electrode 4b for a reference/counter sensor part. The track 4 extends lengthwise to form a connecting terminal 4a at its proximal end. The second and third tracks 6, 8 form electrodes 6b, 8b at their distal ends for two working sensor parts and respective connecting terminals 6a, 8a at their proximal ends. The fourth carbon area is simply a connecting bridge 10 which is provided in order to close a circuit in a suitable measuring device in order to turn it on when the test strip has been properly inserted.

FIG. 3 shows the next layer to be applied also by screen printing. This is a water insoluble insulating mask 12 which defines a window over the electrodes 6b, 8b and which therefore controls the size of the exposed carbon and hence where the enzyme layer 14 (FIG. 4) will come into contact with the carbon electrodes. The size and shape of the window are set so that the two electrodes 6b, 8b have a patch of enzyme of exactly the same area printed onto them. This means that for a given potential, each working sensor part will theoretically generate the same electric current in the presence of a sample of blood.

A layer of glucose oxidase 14 (FIG. 4) is printed over the mask 12 and thus onto the electrodes 4b, 6b, 8b through the window in the mask to form the reference/counter sensor part and the two working sensor parts respectively. A 150 micron layer of adhesive is then printed onto the strip in the pattern shown in FIG. 5. This pattern has been enlarged for clarity as compared to the previous Figures. Three separate areas of adhesive 16a, b, c together define a sample chamber 5 18 between them.

Two sections of hydrophilic film 20 (FIG. 6) are laminated onto the strip and are held in place by the adhesive 16. The first section of film has the effect of making the sample chamber 18 into a thin channel which draws liquid into and along it by a capillary action. The final layer is shown in FIG. 7 and is a protective plastic cover tape 22 which has a transparent portion 24 at the distal end. This enables a user to tell instantly if a strip has been used.

Use of the strip will now be described. The test strip is inserted into the meter. The bridge portion 10 completes a circuit in the device and thus automatically turns the device on. The device also has contacts to connect to the terminals 4a, 6a, 8a on the strip. The measuring device applies a potential of 400 mV between the counter/reference sensor part and each of the two working sensor parts via the above-mentioned terminals.

A drop of blood is then placed on the distal end of the strip. Capillary action draws the blood along the sample chamber 18 and over the counter/reference sensor part and two working sensor parts.

After a predetermined time the electric current generated by each working sensor part is measured and the two measurements are compared. If they differ by more than 10% an error message is displayed on the measuring device and the test must be repeated. If they are within 10% of each other however, the two currents are added together in the device and are converted to a glucose level which is displayed on an LCD.

A comparative experiment was carried out using a strip fabricated as set out above, in order to exemplify the benefits achievable in accordance with the invention. In the experiment drops of blood increasing in volume from 1 to 2 micro liters in steps of 0.2 micro liters and with a constant glucose concentration, were applied to such strips, with each volume being repeated 8 times. The current measured at each working sensor part was measured and recorded. The results are shown in Table 1 appended to this description.

For the first part of the test the two currents were simply added together to simulate a single working sensor part having their combined area. These results are plotted in FIG. 45

In the second half of the test the two currents were first compared. Only if they differed by less than 10% were they then added together and put forward as valid results. Values differing by more than 10% were disregarded. The results of 50 this second part of the test are plotted in FIG. 9.

It is immediately apparent that the second set of results is significantly more precise, i.e. they display a much lower variation. Furthermore, since in practice the two working sensor parts will only give results consistent with one another if they are both fully covered, the second set of results is also significantly more accurate than the first since it may be safely assumed that the results are only actually given when both working sensor parts are fully covered.

Thus is will-be seen that in its preferred embodiment the forms of those present invention allows the detection and rejection of those tests that have had insufficient sample applied to the test strip i.e those in which the test strip has been incorrectly used.

It will be appreciated by those skilled in the art that many variations on what has been described above are possible 65 within the scope of the invention. For example the invention may be used to measure the level of any suitable substance

in any liquid, not just glucose in blood. Furthermore, the working sensor parts need not be provided on a test strip but may be part of an integrated device. Also the difference figure of 10% used in the embodiment described above is purely exemplary and any suitable figure may be chosen.

TABLE

Volume µL	Working 1: µA	Working 2;	% Difference	Error checked	No error check
1.	7.07	.0000	-706800		7.07
1	6.94	5,98	-16,2175732		12,92
1	5,53	0.01	-92050		5.54
1	6.99	7.09	1.42393909	14.09	14.09
1	7.34	7.02	-4.59016393	14.35	14.35
1	7.16	6.79	-5,49742078	13.94	13.94
1	7.01	3.47	-102.13441		10.48
1	7.07	5.69	-24.2578605		12.77
1.2	7.18	4.54	-58.2286847		11.72
1.2	7.00	6.78	-3.35055351	13.78	13.78
1.2	7.09	1.79	-297.032475		8.88
1.2	6.31	0.00.	-157550		6.31
1.2	6.78	6.79	0.11788977	13.56	13.56
1.2	6.95	6.59	-5,4029443	13.53	13.53
1.2	6.62	6,28	-5.36795158	12.89	12.89
1.2	7.23	3.78	-91.2721502		11.01
1.4	7.16	6.90	-3.76811594	14.06	14.06
1.4	7.14	6.94	-2.88184438	14.08	14.08
1.4	7.17	7.02	-2.13675214	14.19	14.19
1.4	7.02	6.01	-1.5918958	13.93	13.93
1.4	6.95	6.91	-0.5788712	13.86	13.86
1.4	6,93	6.88	-0.72674419	13.81	13.81
1.4	7,09	6.92	-2.4566474	14.01	14.01
1.4	7,25	7.40	2.02702703	14.65	14.65
1.6	7,808	6.59	-18.4825493		14:40
1.6	6,774	6.589	-2.80770982	13.36	13.36
1.6	6,928	6.904	-0.34762457	13.83	13.83
1.6	6,892	6.453	-6.80303735	13,35	13,35
1.6	7.087	7.314	3,10363686	14.40	14.40
1.6	7.257	6.947	-4,46235785	14.20	14.20
1.6	5.501	6,306	-3.09229305	12.81	12.81
1.6	6.811	6.755	-0.82901554	13.57	13.57
1.8	7.145	6.536	-9.31762546	13.68	13.68
1.8	7.021	6.612	-6.18572293	13.63	13.63
1.8	6.917	6.828	-1.30345636	13.75	13.75
1.8	6,971	6.78	-2.81710914	13.75	13.75
1.8	7.016	6.941	-1.08053595	13.96	13.96
1.8	6,977	7.179	2.81376236	14.16	14.16
1.8	5.946	6.794	-2.23726828	13.74	13.74
1.8	7,203	7.183	-0.27843519	14.39	14.39
2	7.145	6.536	-9.31762546	13.68	13.68
2	7.021	6.621	-6.18572293	13.63	13.63
2	5,917	6.828	-1.30345636	13.75	13.75
2	6.971	6.78	-2.81710914	13.75	13.75
2	7.016	6.941	-1.08053595	13.96	13.96
2	6,977	7,179	2.81376236	14.16	
	6,946	6.794	-2.23726818		14.16
2				13.74	13.74
4	7.203	7.183	-0.27843519	14.39	14.39

The invention claimed is:

 A method of measuring the concentration of a substance in a sample liquid comprising the steps of:

providing a measuring device said device comprising:

- a first working sensor part for generating charge carriers in proportion to the concentration of said substance in the sample liquid;
- a second working sensor part downstream from said first working sensor part also for generating charge carriers in proportion to the concentration of said substance in the sample liquid wherein said first and second working sensor parts are arranged such that, in the absence of an error condition, the quantity of said charge carriers generated by said first working sensors part are substantially identical to the quantity of said charge carriers generated by said second working sensor part; and

a reference sensor part upstream from said first and second working sensor parts which reference sensor part is a common reference for both the first and second working sensor parts, said reference sensor part and said first and second working sensor parts 5 being arranged such that the sample liquid is constrained to flow substantially unidirectionally across said reference sensor part and said first and second working sensor parts; wherein said first and second working sensor parts and said reference sensor part to stance to be measured is glucose, and each of the working are provided on a disposable test strip;

applying the sample liquid to said measuring device; measuring an electric current at each working sensor part proportional to the concentration of said substance in the sample liquid;

comparing the electric current from each of the working sensor parts to establish a difference parameter; and giving an indication of an error if said difference parameter is greater than a predetermined threshold.

- 2. The method as claimed in claim 1 comprising measuring the current at each working sensor part after a predetermined time following application of the sample.
- sensor parts generates charge carriers in proportion to the concentration of glucose in the sample liquid.

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## EXHIBIT C

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### MARK ELLIOT MEYERHOFF, PH.D. Highly Confidential - Attorneys' Eyes Only

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6	LIFESCAN SCOTLAND, LTD.,	6	EXAMINATION BY MR. MARSHALL		289
7	Plaintiffs,	7			
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9	vs Case No. 11-04494-EJD (PSG)	9	(Exhibits attached to transcript.)		
10	ndeed for greathest in count deverted until 27 1 dead or	10	Exhibit No. 1 Declaration	25	
11	SHASTA TECHNOLOGIES, LLC,	11	Exhibit No. 2 655 Patent	27	
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20	DATE: Friday, January 25, 2013	20	Exhibit No. 11 "Attention" Insert	161	
21	TIME: 9:29 a.m.	21	Exhibit No. 12 Algorithm Requirements		176
22	LOCATION: Westin Detroit Metropolitan Airport	22	Exhibit No. 13 420 Patent	187	
23	2501 Worldgateway Place	23	Exhibit No. 14 772 Patent	188	
24	Detroit, Michigan 48242	24	Exhibit No. 15 998 Patent	197	
25	REPORTER: Angela E. Broccardo, CSR 4679	25	Exhibit No. 16 752 Patent	219	
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3	SEAN R. MARSHALL	3	Exhibit No. 19 636 Patent	24	8
4	CHARLES HOFFMANN	4	Exhibit No. 20 229 Patent	25	3
5	Patterson, Belknap, Webb & Tyler, LLP	5	Exhibit No. 21 417 Patent	26	9
6	1133 Avenue of the Americas	6	Exhibit No. 22 697 Patent	27	
7	New York, New York 10036	7	Exhibit No. 23 714 Application Office A		276
8	(212) 3362000	8	ZAMBILITIES PROGRAMMENT CHIEF		
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16	Appearing on behalf of Defendant Shasta	16			
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#### MARK ELLIOT MEYERHOFF, PH.D. Highly Confidential - Attorneys' Eyes Only

January 25, 2013 93–96

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1	sensor to get the right value for glucose. Because	1 the strip design.
2	your glucose sensor is seeing both glucose, as well as	2 Q. And what is the measuring device?
3	the interferences that are present in blood.	3 A. The measuring device and the strip
	Y MR. ANDARA:	4 MR. MARSHALL: Objection. Vague, and to
5 Q	n. Right.	5 the extent it calls for a legal conclusion.
6 A		6 THE WITNESS: Rephrase state your
7	Nankai is one, and I think there are a couple of	7 question again.
8	others that talk about that design of having two	8 BY MR. ANDARA:
9	working electrodes, but the second working electrode	9 Q. What is the measuring device? You referenced
10	is not identical to the main working electrode that is	10 measuring device. I'm asking, what's the measuring
11	actually being used to give the analytical signal.	11 device?
12 (	Q. And are you aware of any system where they had used	12 A. Well, the measuring device is the meter that's used
13	the identical working electrode, there are two working	13 with the strip. But as I said, we, in our own
14	electrodes that are identical?	14 laboratory, for example you don't need to
15 A	A. Identical in size?	practice the 105 patent, you don't need Johnson &
16 (	Q. Size. They both have enzyme.	Johnson's meter. I can do that in the laboratory and
17 A		17 connect electrodes and subtract the two signals and
18	literature. There are examples where they would use a	18 compare the two signals. It's not that's a very
19	second working electrode, maybe a smaller version of	19 trivial component. You have to have the strip, and
20	it, and therefore just to to use that electrode to	20 you have to have the design of the sensors in the
21	determine whether the solution has actually reached it	right configuration and have being able to make two
22	or not, okay, in terms of, you know, to try to look	sensors that are exactly the same area, with the sam
23	for adequate sample or something, but not in the way	23 coverage of enzyme, that's the critical element, in my
24	that the 105 patent describes and the fact that both	view, of the 105 patent.
25	are exactly the same size in the 105.	25 Q. Okay.
		•
1 Q	Page 94  Now, do you understand what the term "embodiment"	Page 96
2	means?	2 literature that did that.
3 A	. I know it's used all the time by the patent lawyers.	3 Q. Do you have an understanding of the term "doctrine of
4	In one embodiment of the invention, in another	4 equivalence"? Heard that before?
5	embodiment of the invent. Like configuration, I would	5 A. You'll have to educate me on that one.
6	say, is what it means; right?	6 Q. Well, what is your understanding of "literal
	. Are you familiar are you aware of any embodiment of	7 infringement"? You use that term in your declaration.
8	the 105 patent that is being sold?	8 A. Well, literal infringement means that there that
9	MR. MARSHALL: Objection. Vague.	9 all the claims, all the claims, every element of the
10	THE WITNESS: Well, I assume the current	10 claims is practiced in the I learned that when I
11	Johnson & Johnson strips are use the 105 patent.	11 was writing the declaration or working on the
	BY MR. ANDARA:	
		declaration, that every one of the claims not every
	Q. Just the strip?	one of the claims, but all the complete claim is
	A. What do you mean?	practiced in the invention, a claim. Right?
15 16 F	MR. MARSHALL: Objection. Vague.	15 Q. Let me try this again. So the claim is basically
	BY MR. ANDARA:	several elements, and each of the elements have to b
	Q. Well, when you are saying so the strips are an	17 present
18	embodiment of the 105 patent, from your understanding?	18 A. That's correct.
19 A	·	19 Q in the product for it to infringe?
20	my opinion, okay, because even if you read the claims,	20 A. Yes.
21	the vast language of the claims relate to the strip,	21 Q. Is that your understanding? I don't want to
22	you know, in terms of the design of the strip.	22 A. Yeah, right.
23	So it's used with some measurement device,	23 Q. Okay.
24	but the strip is the main in my view, from reading	24 A. Again, yes. And so if there is a claim that says
25	the patent, that's the main elements of the patent, is	25 this, three components of that claim, each one



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## EXHIBIT D

### United States Patent [19]

Murphy et al.

[56]

[11] 4,337,516

[45] Jun. 29, 1982

[54]	SENSOR I	FAULT DETECTION BY ACTIVITY RING
[75]	Inventors:	Richard D. Murphy; Douglas H. Clelford, both of Trumbull, Conn.
[73]	Assignee:	United Technologies Corporation, Hartford, Conn.
[21]	Appl. No.:	163,445
[22]	Filed:	Jun. 26, 1980
[51] [52]	Int. Cl. <sup>3</sup> U.S. Cl	
[58]	Field of Sea	364/571 arch

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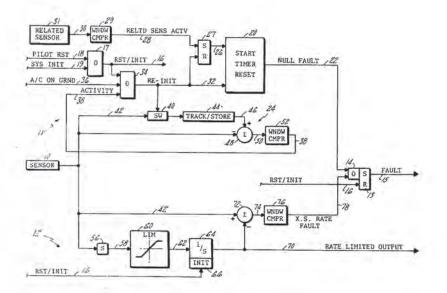
3,867,717	2/1975	Moehring et al	364/551	X
3,872,292	3/1975	Dawson, Jr.	364/551	X
4,176,396	11/1979	Howatt	364/5	51

Primary Examiner—Edward J. Wise Attorney, Agent, or Firm—M. P. Williams

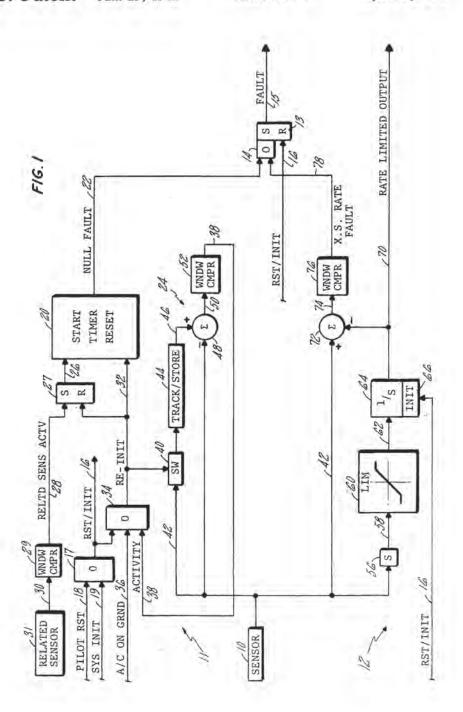
#### [57] ABSTRACT

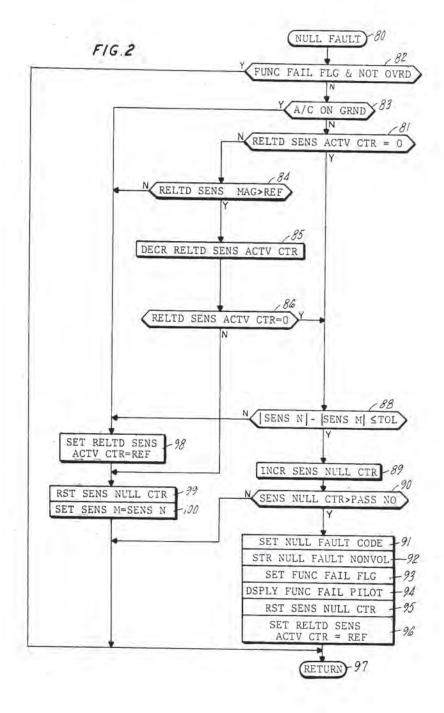
Faults in a sensor (10) are detected by excess rate fault determination by taking the differentiated (58, 107), rate limited (60, 100, 111) integral (64, 112) from the raw sensor output (72, 113) and indicating a fault (15, 117) in the event that the difference exceeds a predetermined magnitude (76, 114). A null fault (22, 91) is provided in the event that the sensor output does not show a significant change (52, 88) within a given time interval (20, 80) whenever a related sensor (31) indicates (29, 84) that the first sensor (10) should have measurable activity. Both analog (FIG. 1) and digital (FIG. 2, FIG. 3) embodiments are disclosed.

2 Claims, 3 Drawing Figures



364/432, 431

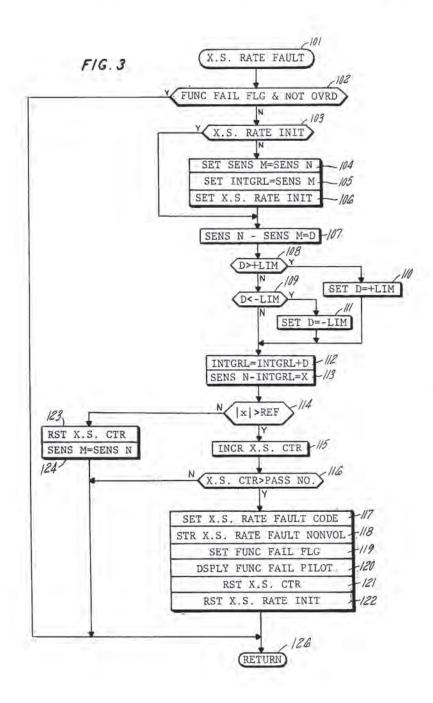




U.S. Patent Jun. 29, 1982

Sheet 3 of 3

4,337,516



#### SENSOR FAULT DETECTION BY ACTIVITY MONITORING

The Government has rights in this invention pursuant 5 to Contract No. N00019-75-C-0267 awarded by the Department of the Navy.

#### TECHNICAL FIELD

This invention relates to detecting faults in sensors, 10 such as gyros, and more particularly to sensor fault detection which does not require use of redundant sensors.

#### BACKGROUND ART

Many control systems operate in response to sensors of various types. As an example, a helicopter automatic flight control system responds to attitude and heading gyros as well as altimeters, and to attitude rate gyros and accelerometers in order to control the maneuvering 20 of the aircraft. The control of the aircraft, when an automatic flight control system is in use, is therefore dependent upon the signals provided to the flight control system by the various sensors (gyros, rate gyros and accelerometers, etc.). In the event of failure of a sensor, 25 an undesirable disturbance in the aircraft flight could result. In some cases, the disturbance may be abrupt or tumultuous, and in other cases the disturbance may be gradual. For instance, if a heading gyro failed at a given setting while the aircraft were on heading hold, the 30 effect would not be noticed until a substantial perturbation (such as a wind gust) was observed to throw the aircraft off heading, or until the pilot desired to change heading; otherwise the only observable result would be a slow drift of the aircraft off its desired heading. On 35 the other hand, if the heading gyro failed by provision of a maximum output signal, the aircraft would begin to maneuver immediately in an opposite direction as the automatic flight control tried to correct the apparent

Any sensor failure in an aircraft automatic flight control system requires pilot response to react to the change in aircraft maneuvering as well as to monitor any error-indicating alarms for disengagement of the faulty system. In many cases, the mere disengagement 45 of the faulty system can cause a reverse maneuvering effect (as a hard error in one direction is immediately converted to a zero error, or the like). Similarly, if the pilot reacts to the disturbance by introducing a countermanding input through the pilot controls, disengagement of the faulty system will leave a undesirable pilot command uncompensated, causing a further disturbance.

At times, such as hovering a few feet above the ocean, such failures in an aircraft control system can be 55 disastrous. For instance, failure of a radar altimeter in such a case could cause the aircraft to actually contact the water surface.

In order to overcome difficulties with such sensors, it has been known to use a pair of sensors of an identical 60 type (redundant sensors) the outputs of which are compared, a failure or fault being indicated in the event that the outputs of the two sensors fail to track within a tolerance limit of each other. However, this not only requires additional sensors but additional signal processing channels for each of the sensors. Furthermore, there are conditions in which two sensors of the same type are likely to fail at the same time, thereby providing the

same erroneous output signal so that they are within the prescribed tolerance of each other and therefore the comparison is not indicative of failure of either of them. Such a case can exit if the Pitot-static tube protection covers are not removed from both Pitot-static tubes of an aircraft before the beginning of a flight: both airspeed sensors would be indicating the same (zero) airspeed, and no fault would be indicated.

In an attempt to reduce the hardware required by redundant comparison, and to overcome some of the shortcomings of redundant comparisons, attempts have been made in the past to utilize a form of sensor activity monitoring. This activity monitoring known to the art has taken the derivative of a sensor's output and examined it to see if it had some amount of change on it. In the event that the rate of change of the sensor output with respect to time becomes excessive in view of the permissible aircraft maneuver in the axis which the sensor detects, a fault can be indicated. However, any spurious noise in the sensor output is amplified by virtue of differentiation of the sensor output signal, which leads to nuisance fault indications (indications of excessive rate when there really is none) due to noise. For this reason, the tolerance or sensitivity of such a fault detector has to be significantly reduced, even to the point where bonafide faults of a lesser magnitude are not even detectable. Furthermore, since many sensors are operable in normal, permissible maneuvers (such as level flight at a constant heading and speed on a calm day), such detectors cannot be monitored to sense the lack of a minimum amount of activity as an indication of fault, since zero is permissible over relatively long periods of time.

#### DISCLOSURE OF INVENTION

Objects of the invention include detecting the usual failure modes of sensors, sensor fault detection without 40 use of redundant sensors, and detection of sensor failures which result in too small a change in their outputs.

According to the present invention, the proper operation of sensors is determined by monitoring the rate of change in the sensor output, both for excessive rates of change as well as for inadequate rates of change at times when it is otherwise determined that the sensor output should be changing. According further to the invention, a sensor raw output is compared with a rate limited sensor output, and if the two are not within a tolerance limit of each other, an excess fault rate is indicated. In still further accord with the invention, the activity of a related sensor is used as an indication that the monitored sensor should have a changing output, and if the output of the monitored sensor does not have at least a minimal rate of change, a null fault is indicated.

The invention is disclosed in both analog and digital embodiments, the digital embodiment having been completely implemented and being preferred.

The invention may be readily implemented in either analog or digital systems, utilizing apparatus and techniques which are well within the skill of the art in the light of the teachings which follow herein.

Other objects, features and advantages of the present invention will become more apparent in the light of the following detailed description of exemplary embodiments thereof, as illustrated in the accompanying drawings.

#### BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 is a simplified schematic block diagram of an analog embodiment of the present invention;

FIG. 2 is a simplified logic flow diagram of an exemplary digital embodiment of the null fault detection portion of the invention; and

FIG. 3 is a simplified logic flow diagram of an exemplary digital embodiment of the excess rate fault portion of the invention.

### BEST MODE FOR CARRYING OUT THE INVENTION

Referring now to FIG. 1, a sensor 10 has its activity monitored for fault detection by a null fault portion 11 15 (in the upper half of FIG. 1) and by an excess rate fault portion 12 (in the lower half of FIG. 1), either of which can set a fault indicating bistable device 13 in response to an OR circuit 14. The output of the bistable device 13 comprises a fault signal on a line 15.

The operation of the activity monitoring system of FIG. 1 can be reset or reinitialized by a signal on a line 16 generated by an OR circuit 17 in response either to a manually activated pilot reset signal on a line 18 or an automatic flight control system initiation signal on a line 25 19, which would typically appear when an automatic flight control system is first turned on. The use of the reset/initialize signal on the line 16 is described herein-

The null fault detecting portion 11 consists mainly of 30 a timer 20 which will generate a null fault signal on a line 22 if it is allowed to time out before it is reset by a sensor activity detector 24, as described more fully hereinafter. However, the timer 20 is allowed to start only in response to a signal 26 from a bistable device 27 35 which is set by a related sensor activity signal on a line 28 from a window comparator 29 which is connected by a line 30 to a related sensor 31. By "related sensor" it is meant that the sensor bears some relationship to the parameter being sensed by the sensor 10 which the 40 circuitry herein is monitoring. For instance, the sensor 10 may be an aircraft heading gyro, and the related sensor 31 may be a yaw rate gyro; the sensor 10 may be an airspeed sensor, and the related sensor 31 may be the pitch rate gyro of a helicopter; the sensor 10 may be an 45 altimeter, in which case the related sensor 31 may be either a vertical accelerometer or a rate of climb indicator; or the sensor 10 may comprise either a pitch or roll attitude gyro and the related sensor 31 may correspondingly be either a pitch or roll rate gyro, respectively. 50 Similarly, in applications other than control of helicopters or other aircraft, other combinations of sensors may utilize the activity monitoring of the present invention. An example could be that the sensor 10 may comprise a furnace fuel flow indicator. It should be noted that the 55 particular sensor and related sensor are not significant to the invention except to the extent that the various limits and details appropriate to such sensors should be employed, in accordance with the skill of the art in the light of the teachings herein.

When the related sensor 31 is providing an output signal on a line 30 which the window comparator 29 determines to be in excess of some minimum magnitude in either a positive or negative sense, as determined by the positive and negative reference voltages utilized 65 within the window comparator 29, the signal on the line 28 will set the bistable device 27 so that the signal on the line 26 will enable the timer to start timing. Unless the

timer 20 is reset prior to time-out of the timer, the timer will provide a time-out signal, designated as a null fault signal herein, on the line 22, which will cause the OR circuit 14 to set the bistable 13 and provide the fault signal on the line 15. The bistable 13 is initially placed in the reset state by the reset/initialize signal on the line 16. The timer 20 is reset by a reinitialize signal on a line 32 which is generated by an OR circuit 34 in response to the reset/initialize signal on the line 16, or to a signal on 10 a line 36 indicating that the aircraft is on the ground, or in response to an activity signal on a line 38 which is generated by the activity detector 24. The reinitialize signal on the line 32 is utilized to open a switch 40 (such as to block a field effect transistor from conduction) that is used to connect the sensor output signal on a line 42 to a track/store circuit 44. Thereafter, the track/store circuit 44 will continue to provide on its output line 46 a signal indicative of the magnitude of the sensor output signal on the line 42 at the moment that the reinitialize signal appeared on the line 32. The signal on the line 46 is compared with the instantaneous sensor output signal on the line 42 by means of a summing junction 48 which provides a signal indicative of the difference between those two signals over a line 50 to a window comparator 52. The window comparator 52 compares the difference indicated by the signal on the line 50 with plus and minus reference signals to determine whether the difference exceeds some preestablished threshold magnitude; if it does, the window comparator 52 provides the activity signal on the line 38 which passes through the OR circuit 34 and generates the reinitialize signal on the line 32 to reset the timer. Therefore, if the instantaneous output of the sensor differs by some predetermined threshold magnitude, from the output it had when the timer was next previously reset, before the timer is allowed to time-out, there will be no null fault signal on the line 22. But if the window comparator 52 fails to detect a threshold magnitude of change in the sensor output after the timer is reset and before the timer times out, then there will be a null fault signal generated on the line 22.

A significant aspect of this part of the invention is that the sensor 10 can be tested for some minimal amount of activity, even though it may, in normal operation, have no significant output over long periods of time, because of the fact that the activity of the related sensor 31 is monitored to determine when the sensor 10 should have some measurable output. Thus utilization of a related, through not redundant sensor to determine when a particular sensor should have activity worth monitoring enables activity monitoring of a sensor for determination that it may have failed in a null, or no output condition (such as loss of a power supply to a gyro).

The output signal of the sensor 10 on the line 42 is also monitored for changing at an excessive rate, such as may occur in any hard-over type of failures. For instance, if the sensor 10 consisted of a position measuring potentiometer which is connected between divergent potentials and had a wiper that is positioned in response to the element being monitored, the loss of one of those potentials would cause the wiper to assume essentially the other potential in a rapid fashion. This would have the same effect as if the wiper were instantaneously moved from its current position to one of the extreme positions of the potentiometer. However, the excess rate fault detector portion of this invention will also test rates which are simply in excess of those that are per-

The sensor output signal on the line 42 is applied to a differentiator 56 (denoted by the Laplacian operator "s") to provide a signal on a line 58 which is a function 5 of the rate of change of the sensor output signal on the line 42. The signal is applied to a limiter 60, which may simply comprise an amplifier having both positive and negative clamps on its output, to provide a rate limited signal on a line 62 which is applied to an integrator 64. 10 The integrator 64 is capable of having an initial value set therein in response to the signal on the line 62 by means of the reset/initialize signal on the line 16 being applied

The integrator 64 is capable of having an initial value set therein in response to the signal on the line 62 by means of the reset/initialize signal on the line 16 being applied to an initialization switch 66 within the integrator 64. As an example, if the integrator 64 comprises a high gain 15 amplifier having capacitive feedback, it may be initialized by having also a resistive feedback, with electronic switching (such as a pair of complementary transistors) to cause the feedback resistor to be connected to the input when the reset/initialize signal is present on the 20 line 16, or, alternatively, to cause the capacitive feedback to be applied to the input when the reset/initialize signal is not present on the line 16. Thus, whenever operation is reestablished by means of the reset/initialize signal on the line 16, the integrator 64 is caused to 25 have its initial output value established at the value of the signal on the line 62. But when the reset/initialize signal disappears, the integrator begins to integrate as determined by the magnitude and polarity of the signal on the line 62. The output of the integrator 64 on a line 30 70 comprises a rate limited manifestation of the instantaneous sensor output signal on the line 42. Because the signal is first differentiated in the differentiator 56, and then integrated by the integrator 64, it is fully restored except to the extent that the rate of change of the signal 35 exceeded the limits established by the limiter 60. Thus if the signal on the line 70 is different from the signal on the line 42, it will be because the signal on the line 42 is changing at a rate which exceeds the predetermined rate established by the limiter 60 for the particular func- 40 tion involved. For instance, if the sensor 10 comprises an aircraft heading gyro, the heading of the aircraft could change at a rate on the order of 90° per second. If it changes faster than some predetermined permissible rate such as that, the signal on the line 58 would be of 45 such a magnitude that it would be limited by the limiter 60, and therefore the output of the integrator 64 would instantaneously differ from the magnitude of the signal

fault signal on the line 15.

If desired, the rate limited output on the line 70 may preferably be used as an output from the sensor 10 for controlling an automatic flight control system function. This provides the additional advantage that if the sensor 65 10 does experience a hard-over failure so that there is an abrupt change in the magnitude of signal on the line 42, the signal on the line 70 will not be as abrupt, but will

on the line 42. This difference is detected by a summing

difference on a line 74 to a window comparator 76 that

compares the magnitude of this signal against positive

and negative reference voltages indicative of a prede-

termined threshold difference which is determined to be

of sensor output signal on the line 42 is too fast, the

signal on the line 74 will indicate a difference which

causes the window comparator to provide an excess

fault rate signal on a line 78, which passes through the

OR circuit 14 to set the bistable 13 and generate the 60

indicative of an excessive rate fault. If the rate of change 55

junction 72 which provides a signal indicative of the 50

change only at the rate determined by the magnitude of limit in the limiter 60. Therefore, during the period of time that it takes to sense and react to the hard-over error, the function being controlled by the sensor will not be disrupted nearly as much when the rate limited output on the line 70 is utilized to control that function. This is equivalent to the use of signals which are slew rate limited in some cases to ensure that they will not exceed permissible values.

The manner of implementing the circuitry described in FIG. 1 may vary considerably utilizing various techniques and apparatus which are known to the art. For instance, the function of the timer 20 may be implemented by means of an integrator which responds to a constant input voltage when the voltage input is connected thereto, said voltage being connected only in response to closing of a switch when the related sensor activity signal is present on the line 28. The time-out of the timer in such a case is determined by the fact that the integrator output is a ramp voltage which increases linearly with time. If the integrator had a one volt per second output value for a one volt input, a ten volt signal could be subtracted therefrom and the result tested to see if it were negative, simply by passing it through a unilateral amplifier. If it were negative, that would that the timer had timed out. The comparisons performed by the window comparators 29, 52, 76 could instead be performed by taking the absolute value of the signal to be tested, subtracting a reference value from it, and passing the result through a circuit to determine the polarity of the result. The absolute value circuit can simply comprise a pair of complementary amplifiers, each having a unilateral output, so that one amplifier or the other will provide an output of a singular polarity in dependence upon the polarity of the input. The limiter 60 may simply comprise an amplifier having its output clamped in both the negative and positive directions. The integrator 56 may simply take the form of an RC integrating network, or it may take the form of any well known active differentiation feedback circuit.

The foregoing is a description of an exemplary analog embodiment of the invention. The functions performed in the circuitry of FIG. 1 may, instead, be performed by apparatus including a digital computer. A suitable computer is the type disclosed in our commonly owned, copending U.S. patent application Ser. No. 928,583, filed on Aug. 31, 1978 and entitled SELECTIVE DIS-ABLEMENT IN FAIL-OPERATIONAL, SAFE MULTI-COMPUTER CONTROL SYSTEM, now U.S. Pat. No. 4,270,168. In said copending application, two identical computers work together and each has the capability of sensing when there is disagreement between them, and if the other computer does not admit fault, one computer can disable both of them. The computers include the capability of comparing redundant sensors, and if they disagree, providing a third input signal derived from a different sensor for determining which sensor has failed. However, that action is limited to only certain sensors (the pitch rate and roll rate gyros being compared with pitch and roll rates derived from the vertical gyro). However, the present invention may be utilized in that apparatus, particularly with sensors for which an alternative is not readily derived methematically.

Referring now to FIG. 2, a simplified exemplary logic flow diagram performs the null fault detection portion similar to the portion 11 in FIG. 1. The routine is reached through a null fault entry point 80 and a first

through step 81 (counter =0). When the tests and steps 81-86 indicate that activity of the sensor 10 can be monitored, a test 88 determines 50 whether the current value of sensor output (SENS N) is within a prescribed tolerance of the preceding value of sensor output (SENS M). If it is, an affirmative result of test 88 will cause step 89 to increment a sensor null counter. This is also a pass counter of the usual type 55 which ensures that a fault has been sensed several cycles in a row before the fault is recognized. This alleviates nuisance fault indications as a result of spurious conditions which quickly go away. Then, the setting of the null counter is tested in step 90 to determine if it has advanced to a count higher than a preestablished pass number (such as on the order of three or five cycles). If the null has been detected several times in a row, so that the setting of the sensor null counter exceeds the predetermined pass number, an affirmative result of test 90 will lead to steps 91-94 in which: a null fault code is set; the null fault code is stored in a nonvolatile portion of memory (if a system of the type disclosed in said co-

of test 86 will enable the sensor test in subsequent passes

pending application is utilized); the fact that the related function has failed is registered by setting a function fail flag; and the fact of function failure is displayed to the pilot. By function failure it is meant, for instance the heading hold function of the automatic flight control system which is utilized when the aircraft is on automatic pilot. This function is lost if the heading gyro is determined to have a null fault. The pilot is interested in whether or not he has the function, rather than in what particular component failed. However, maintenance personnel are interested in what particular component failed, and thus the null fault code for the particular sensor is set and stored in nonvolatile memory to ensure that this factor will be known to maintenance personnel when the aircraft returns for repairs. The function failure flag, set in step 93, is the flag which is tested in test 82, as described hereinbefore. The function failure flag relating to a particular sensor may in fact have been set as a result of a fault in a related or other portion of the system. Thus, heading hold could be lost because of failure of a power supply used in the heading hold portion of the automatic flight control system. That would also set the same functional failure flag as that which can be set in step 93 and tested in test 82

In step 95 the sensor null counter (incremented in step 89 and tested in test 90) is reset so that following this failure it will have to count through the entire passnumber of cycles before the fault will be indicated, and in step 96 the related sensor activity counter is reset to its reference value so that it will begin decrementing from the full reference value (such as five cycles) after operation is reestablished following the present fault. Thereafter, this routine will cause return to other portions of a computer program through a return point 97.

At periods of time when there is no activity in the related attitude of the aircraft (or other related function in non-aircraft implementations of the invention), such as when the aircraft is on the ground as indicated in test 83 or when a related sensor is providing an insignificant output signal as determined in test 84, the related sensor activity counter is set to the reference in a step 98. Thus even if there has been some activity from the related sensor, so that the counter may have counted once or twice, in any cycle in which the activity falls below the requisite magnitude before the reference numbers of cycles pass, the activity counter will be reset to the reference value so that counting will have to start anew thereafter. And, in such case, the remaining portion of the program from step 85 through step 96 of the routine of FIG. 2 is bypassed. But the sensor null counter is reset in a step 99 and the sensor output value is updated in a step 100.

In cases where the related activity counter indicates that the related sensor (31, FIG. 1) has had significant activity over a required number of cycles so that the sensor (10, FIG. 1) may be activity monitored to test for a null fault, if the test 88 is a negative (eg, sensor is sufficiently active), because of the fact that the new value of the sensor output is different from the old value of the sensor output by more than the prescribed tolerance, then the remainder of the null fault program (steps 89-96) is bypassed, the related sensor activity counter is reset to the reference value in step 98, the sensor null counter is reset in step 99, and the sensor output value is updated in step 100, as described hereinbefore. In any case, however, where a null is detected in step 88 because the new value of sensor output is within tolerance of the old value of sensor output, the sensor null counter is incremented in step 89 and is tested in step 90. During the first couple of failures, test 90 will be negative because several nulls have to be sensed in a row before they will be recognized as a fault as described hereinbefore. In such case, no update takes place and the routine 5 is exited at return point 97.

Comparing the null fault detection in a digital fashion as set forth in FIG. 2 with the analog hardware shown in FIG. 1, test 83 is equivalent to the resetting activity of the aircraft on ground signal on the line 36 (FIG. 1). 10 Test 84 is equivalent to the window comparator 29 (FIG. 1). Test 88 is equivalent to window comparator 52 (FIG. 1) and step 89 and test 90 are equivalent to the time-out of the timer 20 (FIG. 1). The reinitialization signal on line 32 of FIG. 1 finds its counterpart in steps 15 98 and 99 (as well as steps 95 and 96) of FIG. 2.

Referring now to FIG. 3, the excess rate fault portion of the invention may be performed in a digital manner by a subroutine which is reached through an excess rate fault entry point 101. The first test 102 simply deter- 20 mines whether or not the routine should be performed, in the same fashion as the test 82 in FIG. 2. If test 102 is negative, a test 103 determines whether initialization of the integration function has been performed or should be performed. This is equivalent to the application of 25 the reset/initialize signal on the line 16 to initialize the setting of the integrator 64 in FIG. 1. If initialization has not previously taken place, then a step 104 will update the value of the last cycle sensor output to the current value of the sensor output, step 105 will establish an 30 initial value in the integrator (some register or memory location bearing a number which is integrated as described hereinafter) to the current value of the sensor output, and a step 106 will set the excess rate initialization flag indicating that initialization has taken place, 35 which flag will be interrogated in the subsequent pass through the routine by test 103 to cause bypassing of steps 104-106.

In FIG. 3, a step 107 takes the difference between the current value of the sensor output and the previous 40 value of the sensor output to find the difference or differential therebetween. Step 107 is equivalent to the differentiator 56 in FIG. 1. Then a pair of tests 108, 109 determine if this difference is within limits, and if it is not, it is set to an appropriate positive or negative limit 45 by corresponding steps 110, 111, which are equivalent to the limiter 60 in FIG. 1. In step 112 integration is performed by adding to the integral value established upon initialization in step 105, the difference or differential D which is found in step 107. If the difference D was 50 126 less than either of the limits so that both tests 108 and 109 were negative, and this value were not clamped to either the positive limit or the negative limit, the value D added to the integral value should equal the current value of the sensor output. If it does not, the difference 55 therebetween (C) found in step 113 will be greater than some reference value (which is preestablished in dependence upon the particular function involved) as determined in a test 114. That is to say if the difference in the present and the current value exceeds some limit, that 60 means that the sensor output is changing at too high a rate. Since the rate is too high, the difference (D) will be limited, so that it being added to the integral will not equal the current value. However, it may not exceed a reference difference utilized in test 114 sufficiently to 65 indicate a fault. But on subsequent passes, since the integral has already fallen behind, if this high rate continues, the integral will fall further behind as inadequate

amounts of D are added thereto. So, eventually, the difference in the current sensor value from the integral value will cause an affirmative result of test 114. When this happens, an excess counter is incremented in a step 115 (this is the same form of pass counter to require several faults in a row before they are recognized), and the excess counter is tested in a test 116 to see if it exceeds the preselected pass number. If it does, then the fault is recognized and housekeeping operations are performed in steps 117-122. In step 117, the excess rate fault code for the particular sensor being monitored is set, and this code may be stored in nonvolatile memory by step 118 (in a system of the type disclosed in the aforementioned copending application). In step 119, the function failure flag is set (this is the same function failure flag that is settable in step 93 in FIG. 2). And, the fact that the function has failed may be displayed to the pilot by step 120 (corresponding to step 94 in FIG. 2). Then the excess counter is reset in step 121 and the excess rate initialization flag is reset in step 122, so that, on subsequent passes through this routine (after the function failure flag is no longer set or in the event that the pilot does press an override switch so that test 102 is negative), the routine is reinitiated, in the same fashion that the reset/initialize signal on the line 16 reinitiates the excess rate fault detection in FIG. 1.

In the event that test 114 determines that the difference between the current value and the integrated value does not exceed the reference, a negative result of test 114 will cause the excess counter to be reset in a step 123 and the last cycle value of the sensor output is updated in a step 124. But notice, once failures have been detected, so that the pass counter is being incremented several times, the last cycle value of the sensor output is not updated because step 124 is bypassed. This is necessary when high rates of change are being detected because, if the sensor failed in a hard-over condition and this hard-over condition were updated to the old value. then, in all subsequent cycles, the new value and the old value of the output would be essentially equal so the pass counter would not be incremented. In other words, the fault can only be monitored for several cycles if the old value is retained so that several cycles of a hardover new value will be compared against it and provide the necessary excess over the reference in test 114. Either step 124 (in the absence of any failure), test 116 (after at least one fault has been sensed), or step 122 (after a pass number of faults have been sensed) will lead to other parts of the program through a return point

As described hereinbefore, the digital embodiment of the invention described with respect to FIGS. 2 and 3 may be practiced in apparatus of the type disclosed in the aforementioned copending application. For instance, the invention may be practiced by reading-in sensor values by means of direct memory access data moves as explained in the tables therein; and the specific subroutines disclosed herein may be performed in one of the interrupt routines RT 1-RT 4. For instance, an airspeed fault detection test can be performed in subroutine 906 (FIG. 9 therein), or a heading fault detection test can be performed in subroutines to the performed in subroutine 1304 (FIG. 13 therein).

In any utilization of the invention where a rate limited signal (such as the signal on the line 70 in FIG. 1) is already provided as a safety measure, the apparatus 56, 60 and 66 need not be employed, but such already-rate-limited signal may be applied directly to the summing

junction 72 and may be utilized as a source of the data identified in FIG. 3 as the integrator value summed with the difference or differential in step 112, such signal being applied directly for subtraction in step 113.

The invention has been disclosed and described as it 5 applies in automatic flight control systems of a helicopter or other aircraft. However, the principles herein are applicable to other systems in cases where the inactivity or hyperactivity of a sensor may be monitored in accordance with the invention to detect faults in the sensor, 10 and particularly where there is a related sensor that allows identifying periods when nulls should not be present, thereby permitting null fault detection as well as excess rate fault detection in accordance herewith. Naturally, the analog or digital embodiments will be 15 chosen in dependence upon whether the digital processing capability is otherwise to be available in any system in which the invention is to be utilized. The type of digital system which is available is irrelevant, since the functions to be performed in implementing the inven- 20 tion are simple and straightforward, and are generally capable of performance by even the smallest of microcomputers. Therefore, the functions of the digital embodiment, as described with respect to FIGS. 2 and 3 hereinbefore, are implementable utilizing ordinary 25 programming techniques suitable for virtually any type of digital processing system. The disclosed embodiments employ signal magnitude-responsive techniques, but the invention may be employed where a given parameter is characterized in a signal by frequency, pulse 30 width or other variables.

Similarly, although the invention has been shown and described with respect to exemplary embodiments thereof, it should be understood by those skilled in the art that the foregoing and various other changes, omissions and additions in the form and detail thereof may be made therein and thereto, without departing from the spirit and the scope of the invention.

We claim:

An activity-monitored sensor system comprising: 40
a first sensor providing a first output signal indicative
of a given physical parameter; and

a second sensor providing a second output signal indicative of a second parameter related to said given physical parameter so that said second output signal is also indicative of whether said first output signal should or should not be changing as a function of time;

characterized by:

signal processing means connected for response to the output signals of said first and second sensors, for providing signals indicative of first, second and third predetermined threshold signal magnitudes, responsive to said second output signal for providing a first excess signal indicative of said second parameter being in excess of a first one of said predetermined threshold signal magnitudes for providing a second excess signal indicative of a change in the magnitude of said first output signal in excess of a second one of said predetermined threshold signal magnitudes, for providing a signal indicative of null fault in response to presence of said first excess signal concurrently with absence of said second excess signal for a predetermined interval of time, for providing in response to said first output signal a rate limited signal indicative of said given physical parameter limited as to the rate of change thereof with respect to time, for comparing said rate limited signal with said first output signal. and for providing a signal indicative of excess rate fault in the event that said rate limited signal differs from said first output signal by more than a third one of said predetermined threshold signal magnitudes.

2. An activity-monitored sensor system according to claim 1 further characterized by said first sensor providing said first output signal in response to the magnitude of said given physical parameter and said second sensor providing said second output signal in response to the rate of change with time of the magnitude of said given physical parameter, said second physical parameter being the rate of change with respect to time of said given physical parameter.

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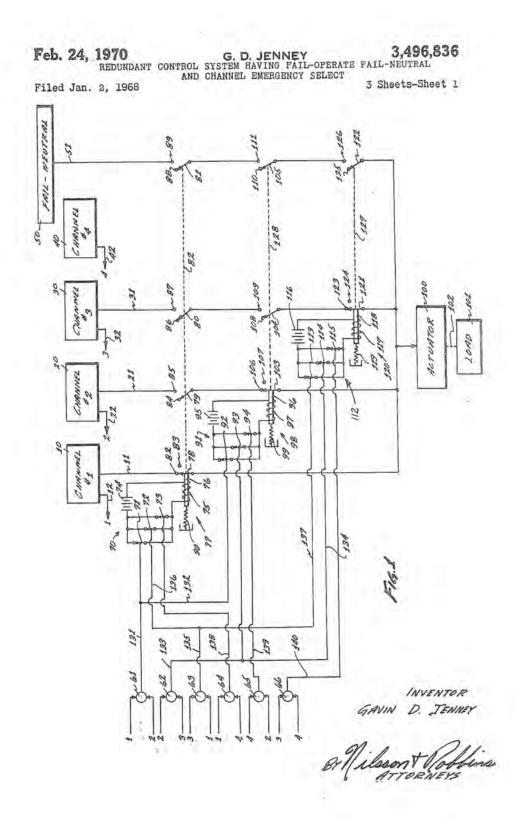
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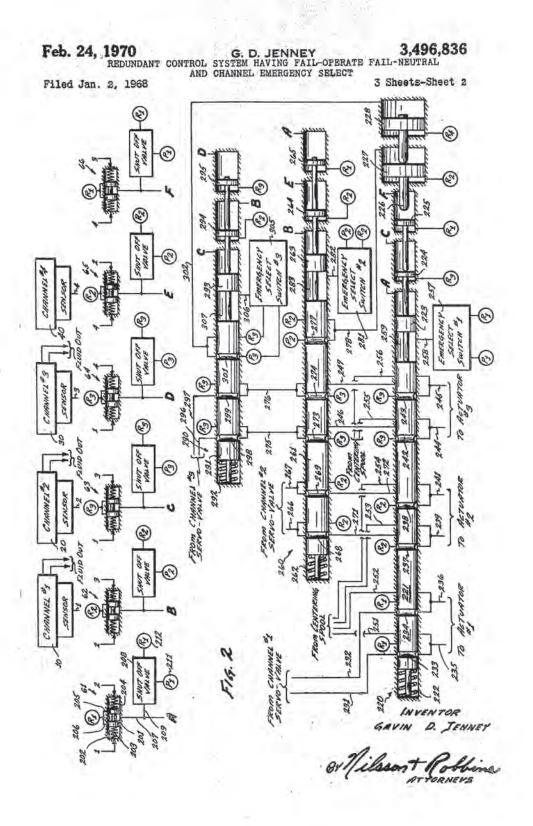
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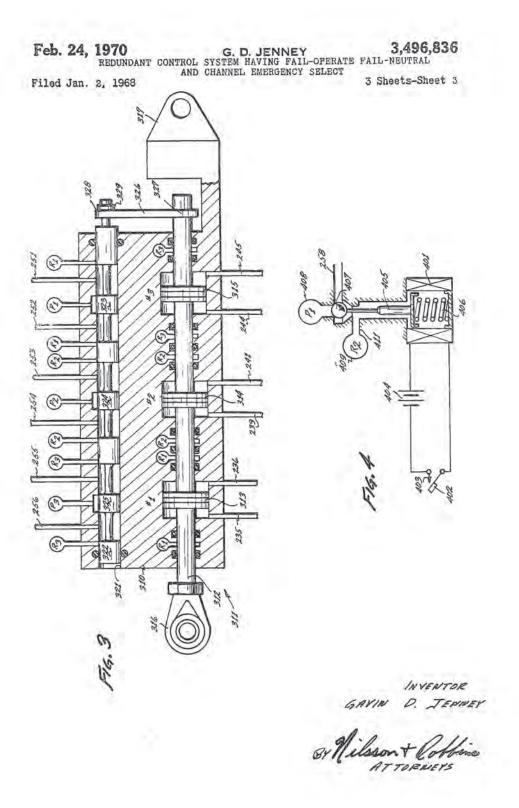
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## EXHIBIT E







3,496,836

REDUNDANT CONTROL SYSTEM HAVING FAIL-OPERATE FAIL-NEUTRAL AND CHANNEL EMERGENCY SELECT

Gavin D. Jenney, Dayton, Ohio, assignor to Bell Aero-5 space Corporation, a corporation of Delaware Filed Jan. 2, 1968, Ser. No. 695,103

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U.S. Cl. 91—411

12 Claims

#### ABSTRACT OF THE DISCLOSURE

Disclosed is a redundant control system having four channels, three of which are capable of providing working fluid to position a movable member in response to 15 input signals applied to the system. Monitor signals developed by each of the four channels are compared to ascertain discrepancies therebetween. Any discrepancy indicates a malfunction wihch is detected by comparing selected pairs of the monitor signals. Such a discrepancy actuates switch means to disable a predetermined channel in which the malfunction occurred. Two such malfunctions may occur without degradation of system performance. Upon the occurrence of a third malfunction, the controlled member is positioned to a predetermined position automatically. If desired, the operator of the sys-tem may select any one of the channels capable of positioning the movable member even though it may have been automatically disabled previously.

#### BACKGROUND OF THE INVENTION

The present invention is adaptable for use in many applications where the position of a movable member is to be controlled. One such application is to position multiple control surfaces on aircraft or similar vehicles in response to input signals applied thereto and therefore, the present invention will be described with respect to such an application.

The complexity weight and flight patterns of the present generation of aircraft necessitate the utilization of power assist to effect proper control thereof. Such power assist is further necessitated in many instances because of the inherent instability of high speed supersonic type aircraft or alternatively because of the weight and large control surfaces embodied in heavy subsonic type air-craft. In those instances where power assist is necessary, a corollary thereof is the necessity to detect failures which may occur throughout the control system and to quickly 50 eliminate the failed portions of the system from control. If such failures are not detected and properly eliminated, particularly in high speed aircraft, damage to the aircraft may result. Detection and reaction time of the human being in such aircraft is not sufficiently fast. A detection 55 and reaction time, including switching the failure out of the control system, on the order of 50 milliseconds or less is required, in aircraft of the type above referred to.

Furthermore, where the cargo or the mission of the aircraft is sufficiently important, it is often required that the aircraft control system be capable of suffering at least two consecutive similar (or dissimilar) failures while maintaining complete operability so the mission of the aircraft may be completed. The term hydraeric as used throughout the specification and claims is generic to fluid under pressure and includes both hydraulics and pneumatics.

#### BRIEF DESCRIPTION OF THE DRAWINGS

A thorough understanding of the present invention, 70 both as to its organization and method of operation will become apparent from a consideration of the following 2

description taken in conjunction with the accompanying drawings which are presented by way of example only and are not intended as a limitation upon the scope of the claims appended hereto and in which:

FIGURE 1 is a schematic illustration of one form of the present invention as it may be constructed utilizing electro-mechanical components;

FIGURE 2 is a schematic illustration of one form of the present invention as it may be embodied in hydraerically-powered apparatus;

FIGURE 3 illustrates in detail the fail-neutral mechanization utilizing one form of hydraerically powered apparatus; and

FIGURE 4 illustrates in detail a portion of the circuit illustrated in FIGURE 2.

#### BRIEF SUMMARY OF THE INVENTION

The hydraeric redundant control system in accordance with the present invention includes at least four channels, three of which are capable of providing hydraeric fluid to an actuator which is connected to position a movable member in response to input signals applied to the system. Four sensor means are connected individually to each of the four channels to provide a monitor signal which indicates the status of the particular channel at all times. A comparator apparatus is connected to receive the monitor signals and compare individual pairs thereof so as to detect any discrepancy therebetween. In the event of a detected discrepancy, switch means which is connected 30 to the comparator means operates to disable the preselected channel which caused the discrepancy to occur. In the event of the detection of three consecutive discrepancies additional apparatus is provided which positions the controlled or movable member in a predetermined position.

### DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENT

Referring now to the drawings and more particularly to FIGURE 1 thereof, there is illustrated in schematic form an electro-mechanical embodiment of the present invention. As is therein shown, there are provided four distinct channels, 1 through 4 indicated by the blocks 10, 20, 30 and 40. Channels 10, 20 and 30 are adapted to supply working fluid over lines 11, 21 and 31 respectively to an actuator 100 which is connected to a load 101 as illustrated by the dashed line 102. A fail-neutral means 50 is also connected by means of the line 51 to provide working fluid to the actuator 100. Each of the channels 10, 20, 30 and 40 includes sensor apparatus which generate monitor signals 1, 2, 3 and 4 which are indicative of the status of the respective channel. Monitor signals 1, 2, 3 and 4 are applied by lines 12, 22, 32 and 42 respectively to the comparators 61 through 66. The apparatus which is embodied in each of the channels 10, 20, 30 and 40 both for application of the working fluid and for generation of the monitor signal may, for example, be similar to that illustrated in U.S. Patent 3,338,138, and therefore no detailed illustration or description thereof will be provided herein.

As is illustrated, monitor signal 1 is applied to comparators 61, 63 and 64, monitor signal 2 is applied to comparators 61, 62 and 65, monitor signal 3 is applied to comparators 62, 63 and 66, and monitor signal 4 is applied to comparators 64, 65 and 66. The comparators 61 through 66 may take any form desired so long as they are capable of comparing the two individual monitor signals applied thereto and detecting any discrepancy which may occur therebetween. If, for example, the monitor signals are hydraeric pressure signals, the comparator apparatus may be of the type illustrated in the Patent 3,338,138. It should, however, be expressly understood that the

comparators may not be hydraeric in operation but may be electrical or electro-mechanical. The only requirement being that the comparators must be capable of detecting discrepancy between the two monitor signals applied thereto and in the event of such a discrepancy gen-

erating a signal at the output thereof.

Output signals generated by the comparators in response to discrepancy of the signals applied thereto are in turn applied to switch means, illustrated schematically in FIGURE 1, which controls the application of the working fluid over the lines 11, 21 and 31. A first such switch means is illustrated generally at 70 and includes three switches 71, 72 and 73 which are connected in parallel between a source of potential such as the battery 74 and the energizing coil 75 of a plunger 76 of a switch 15 77. The switch 77 includes movable contact arms 78, 79, 80 and 81 which are ganged together as shown by the dash line 82. Movable contact arm 78 operates between stationary contacts 82 and 83. The movable contact arm 79 operates between stationary contacts 84 and 85. The 20 movable contact arm 80 operates between stationary contacts 86 and 87 while the movable contact arm 81 operates between stationary contacts 88 and 89. Spring means 90 continuously urges the plunger 76 toward the right as viewed in FIGURE 1. The switch 77 is shown in the posi- 25 tion wherein the coil 75 is energized by the battery 74 and all of the contacts 78 through 81 have been pulled toward the left as viewed in FIGURE 1.

A similar switching arrangement is shown by the switch means 91 connected in the line 21 of channel 2. The switching means 91 includes switches 92, 93 and 94 connected in parallel between the battery 95 and the coil 97 of the switch means 98. The coil 97, upon being energized, actuates the plunger 96 against the spring means 99, so as to operate the ganged movable contact arms 35 103, 104 and 105 shown connected together by the dashed line 128. Movable contact arm 103 operates between stationary contacts 106 and 107, arm 104 between stationary contacts 108 and 109, and arm 105 between stationary contacts 110 and 111.

A switch means 112 similar to those above described is connected in the line 31 of channel 3 and includes arms 113, 114 and 115 connected in parallel between the battery 116 and the coil 117 which when energized operates the plunger 118 against the spring 119 of the switch 120. Movement of the plunger 118 moves the movable contact arms 121 and 122 which are ganged together as shown by dashed line 127. Arm 121 operates between stationary contacts 123 and 124 while the arm 122 operates between stationary contacts 125 and 126.

In the event that comparator 61 detects a discrepancy between the monitor signals 1 and 2 applied thereto, a signal is applied over lines 131 and 132 to switches 71

and 92 respectively.

In the event comparator 62 detects a discrepancy be- 55 tween the signals 2 and 3 applied thereto a signal is applied over lines 133 and 134 to switches 93 and 114 respectively. In the event comparator 63 detects a discrepancy between signals 1 and 3 applied thereto, an output signal is applied over line 135 to the interconnection with lines 136 and 137. The signal is thus applied over lines 136 and 137 to switches 72 and 113 respectively. In the event that the comparator 64 detects a discrepancy in the monitor signals 1 and 4 applied thereto a signal is applied over line 138 to switch 73. In the event that comparator 65 detects a discrepancy between monitor signals 2 and 4 applied thereto an output signal is applied over line 139 to switch 94. In the event that comparator 66 detects a discrepancy between monitor signals 3 and 4 applied thereto a signal is applied over line 140 to switch 70

During normal operation, with the switches 77, 98 and 120 in the position illustrated in FIGURE 1, input signals applied to channels 1, 2, 3 and 4 create output signals therein such that working fluid appears in lines

a

11, 21 and 31 and monitor signals 1, 2, 3 and 4 of substantially equal phase and amplitude appear on lines 12, 22, 32 and 42 respectively. Under these conditions only the working fluid in line 11 passes through the closed switch 78-82 to the actuator 100 to position the load 101.

The lines 21 and 31 are open as illustrated.

Assuming that a failure occurs in channel 1 so that the monitor signal 1 is not in agreement with monitor signals 2, 3 and 4, the following sequence of events occurs. Comparator 61 detects a discrepancy between the monitor signals 1 and 2 and applies a signal over the lines 131 and 132 to cause the switches 71 and 92 to become open. Although no mechanism is illustrated to effect the opening of the switch, any one skilled in the art will readily recognize various forms which such mechanisms may take. Likewise, comparator 63 and 64 applies output singals as a result of detected discrepancies, over the lines 135 and 138. These signals are in turn applied over the line 136 to the switch 72 to cause it to become open circuited and also to the switch 73 to cause it to become open circuited. Simultaneously, the signal from the comparator 63 would be applied over line 137 to the switch 113 to cause it to become open.

The switches 77, 98 and 120 are designed in such a way that the coils thereof remain energized and the switches remain in the positions illustrated until all of the parallel connected switches between the source of potential and the energizing coil are open. As above pointed out, the switches 71, 72 and 73 connected in parallel between the battery 74 and the energizing coil 75 are open as a result of detection of the discrepancy in the monitor signal 1. When the switches open, the coil 75 becomes de-energized and the spring 90 translates the plunger 76 toward the right as viewed in FIGURE 1. Such translation causes the line 11 carrying the working fluid from channel 1 to become open circuited by the movable arm 78 moving from stationary contact 82 to stationary contact 83. The line 21 from channel 2 becomes closed through movement of the movable arm 79 between stationary contacts 84 and 85 and since arm 103 is in engagement with stationary contact 106 of the switch 98, working fluid now passes through the line 21 to the actuator 100. Even though the movable contact arms 80 and 81 move to their closed positions the lines 31 and 51 remain open circuited because of the open contacts of switches 98 and 120.

Although this system has undergone one failure, it should be noted that two operative channels capable of supplying working fluid to the actuator 100 remain in the system. Therefore, the system is capable of sustaining a second failure without system degradation and thus is a fail-operate, fail-operate type system.

In the event of a failure occurring in channel 2, such that the monitor signal 2 is not in agreement with the monitor signals 3 and 4, the sequence of events described below would occur, assuming the previously failed channel 1 as above described. A discrepancy detection signal appears upon the lines 133 and 134 and causes switches 93 and 114 to become open circuited. A detection failure signal also appears at line 139, which is connected to the comparator 65, and operates to open circuit the switch 94. Under these circumstances (remembering that switch 92 was open circuited upon the failure signal appearing on line 32), the coil 97 becomes de-energized and the spring 99 causes the plunger 96 to move toward the right as viewed in FIGURE 2, thus, opening the switch 103 and closing the switches 104 and 105. As a result of the operation of switch 98 (and the previous operation of switch 77) line 31 now supplies working fluid from channel 3 through the closed switches 104 and 121 to the actuator 100, while the channels 1 and 2 working fluid lines 11 and 21, respectively, are open circuited by the open switches 78 and 103.

signals applied to channels 1, 2, 3 and 4 create output

As a result of two failures occurring in the system, signals therein such that working fluid appears in lines 75 there remains only one operative channel. In the event

From the foregoing description it should be recognized by those skilled in the art that in the event the first failure to occur was in channel 2, such that the monitor signal 2 was the signal which did not agree with signals 1, 3 and 4 then each of the switches 92, 93 and 94 would become open circuited thereby opening switch 103 and closing switches 104 and 105 to render channel 2 inoperative in the event of a subsequent failure. Under these circumstances, channel 1 would continue to provide working fluid to the actuator 100.

or other apparatus which is being controlled.

Similarly, in the event that channel 3 provided the signal which did not agree, switches 113, 114 and 115 would become open circuited thus causing the arm 121 to move to the open circuited position and the arm 122 to the closed circuited position, thereby rendering channel 40 3 inoperative. Under these circumstances channel 1 would remain in control as above described.

In the event channel 2 is the failed channel and a subsequent failure occurred in channel 1 it should now be obvious that control of this system would be transferred from channel 1 to channel 3. Likewise if channel 3 were the first to fail, control would be transferred in the event the subsequent failure was in channel 1 from channel 1 to channel 2.

Referring now to FIGURE 2, there is illustrated in 50 schematic form one embodiment of a system in accordance with the present invention where in the monitor signals as generated by the sensors are hydraeric pressure signals and the system functions utilizing hydraeric power, for example hydraulic fluid under pressure. Where appropriate, the same numerals utilized in FIGURE 1 are also utilized in FIGURE 2. In the embodiment of the invention as ilustrated in FIGURE 2, the channels 1, 2. 3 and 4 indicated by the numerals 10, 20, 30 and 40 along with the sensors attached thereto will take the form of an electro-hydraulic servo valve and a flapper which follows the control valve thereof positioned adjacent a nozzle to provide a monitor signal in the form of a hydraulic output signal. As illustrated in Patent 3,338,138 above referred to, the output of the electrohydraulic servo valve is designated fluid out from each of the three channels. The fluid out being applied to one of the three switching means in the form of engage valves which will be described more fully below. Since the electro-hydraulic servo valve in the sensor apparatus is fully described in Patent 3,338,138, no detailed illustration or description thereto is deemed necessary for a thorough understanding of the present invention.

The output signals from each of the sensors attached to the channels are again designated by the numerals 75 out is applied through conduits 231 and 232 from channel

1, 2, 3 and 4, respectively, for the channels 10, 20, 30 and 40. These signals are applied to the comparators 61 through 66 in the same manner as described in coniunction with FIGURE 1.

The comparators 61 through 66 are each constructed so as to include a spool valve 201 slidably disposed within a cylinder 202 and spring loaded by spring means 203 and 204 to a quiescent center position as illustrated. In the center position, the lands on the spool valve 201 block a pair of ports to which conduits 205 and 206 connect system return R1 as shown. An output conduit 207 is also connected to the cylinder 202. Under normal operating conditions system return R1 is not connected to the conduit 207. However, should there be a discrepancy between the monitor signals 1 and 2 applied to each side of the spool valve 201 (it should be noted that the end areas of the spool valve are equal), the spool valve 201 translates thus connecting system return, irrespective of the direction of the translation, to the conduit 207. Thus, system return would be applied at point A which is conected to the engage valves at the points also marked A as will be more fully described below. It should also be noted that a shut-off valve means 208 is connected by conduit 209 to conduit 207. The shut-off valve means 208 has conected to it a system pressure source P1 as shown at 211 and the system return R1 at 212. Again, under normal operating conditions the shut-off valve, when the system is normally operative, blocks system return R1 shown at 212 and applies system pressure P1 shown at 211 to the conduit 207. Details of such a shut-off valve can be obtained by reference to the patent above referred to and the function of the shut-off valve in the present structure is the same as that described in the above patent. Therefore, detailed illustration or description thereof is not deemed necessary in the present disclosure. Each of the remaining comparators 62 through 66 and the shut-off valves connected thereto are identical to the comparator 61 and the shut-off valve 208 and further description thereof will not be given herein except insofar as the function which is performed during detection of a failure in a particular channel.

As is illustrated in the remainder of FIGURE 2, three valve means in the form of slide valves are utilized to control the application of working fluid from channels 1, 2 and 3 to the actuators 1, 2 and 3 which actuators may be a single tandem ganged actuator mechanism. The first valve means 220 is a slide valve 221 having a first valve station conected to actuator 1, a second valve station connected to actuator 2 and a third valve station connected to actuator 3. The slide valve 221 is spring loaded by a spring means 222 constantly urging the slide valve 221 toward the right as viewed in FIGURE 2. Through the application of fluid pressure from the outputs A, C and F, taken at the conduits connected to comparators 61, 63 and 66, the valve 221 is urged, by the fluid presure acting against the surface of the buttons 223, 224 and 225, toward the left against the spring 222 When the slide valve 221 is in the position as illustrated in FIGURE 2, it is then in the normally operative nonfailure type position. As is illustrated, the valve 221 is a three-position valve; the first of these positions is as illustrated, the second of these positions is when the valve has translated through the loss of pressures at A, C and F toward the right so that the button 225 rests against the stop 226, which is held in place by the application of system pressure P2 against the button 227, and/or by the application of system pressure P3 so that it operates against the area of the button 228. The third position is a further translation to the righ upon the loss of system pressures P2 and P3 being applied to the buttons 227, and 228, as will be more fully explained hereinbelow.

In the first position, as illustrated in FIGURE 2, fluid

1 through the valve openings 233 and 234 and through conduits 235 and 236 to actuator 1.

In the fiirst position, as illustrated, system return R2 is connected through the valve 221 at 237 and 238 to the actuator 2 over the conduits 239 and 241. Similarly, system return R3 is connected through the valve at 242 and 243 to actuator 3 through the conduits 244 and 245 respectively.

A second valve means 260 also takes the form of a slide valve 261 which is spring loaded by a spring 262 toward the right as illustrated in FIGURE 2. Again, by application of signals from the conduits B, E and A from the outputs of comparators 62, 65 and 61 respectively, fluid pressure acting against the buttons 263, 264 and 265, respectively maintain the slide valve, during normal operation, in the position illustrated in FIGURE 2. The slide valve 261 is a two-position valve. The first position being in the operative position as illustrated and the second position being translation toward the right upon the loss of the pressures at B, E and A. In the operative position as illustrated, working fluid from channel 2, at the fluid out portion thereof, is applied to conduits 266 and 267. Such fluid passes through the slide valve 261 at 268 and 269 and is applied through the conduits 271 and 272 respectively to the slide valve 221. However, since the 25 slide valve 221 is in the operative position as illustrated, the conduits 271 and 272 are blocked thereby, and thus the working fluid from channel 2 is not applied to ac-

In the normal operational position as illustrated in 30 FIGURE 2, valve 261 at 273 ad 274 connects system return R3 to the conduits 275 and 276 respectively. Also, system pressure P2 is connected by valve 261 at 277 through the conduit 278 to act upon the button 227 of valve means 220.

Third valve means 290 also takes the form of a slide valve 291 which is spring loaded by a spring 292 urging the valve 291 toward the right as viewed in FIGURE 2. By application of pressures from C, D and B at the output conduits connected to comparators 63, 62 and 64, respectively, to operate against the buttons 293, 294 and 295 respectively, the valve 291 is maintained in the normal operational position as illustrated. In this position, the fluid out from channel 3 is applied through conduits 296 and 297 and the valve 290 at 298 and 299 to the conduits 45 275 and 276 respectively. As above pointed out, the conduits 275 and 276 are, in the normal operational position of valve means 260, connected to system return R3 and therefore the working fluid is merely returned to the system return or reservoir.

System pressure P3 is applied by valve means 290 at 301 over the line or conduit 302 to operate against the button 228 of the valve means 220.

In summary, in the normal operational position of the valve means 220, 260 and 290 as illustrated in FIGURE 2, working fluid from the channel 1 electrohydraulic servo valve is applied to actuator 1 while the working fluid from channels 2 and 3 are not applied to actuators 2 and 3. However, the working fluid is available at the valve means for application should such be necessary.

In operation of the valve means 220, 260 and 290 as illustrated in FIGURE 2, if channel 1 now mulfunctions so that the pressure signal from sensor 1 does not agree with the remainder of the signals, the slide valve in the comparators 61, 63 and 66 translates thus connecting the respective system return to the conduits connected thereto and thereby causing system return to appear at points A, C and F respectively. Upon such occurrence, the shut-off valves connected to the output of each of the comparators 61, 63 and 66 lock in the system return to those conduits so that system return remains at points A, C and F. Upon such an occurrence, the slide valve 221, in response to the force of spring 222, and the absence of pressure at positions A, C and F, causes the slide valve 221 to 75 of subsequent switching of valve means 220. At the

8 move toward the right until button 225 contacts the stop means 226. In this position, at the first valve station, system return R1 is connected through the valve at 233 and 234 to actuator 1 thus by-passing the same and rendering channel I ineffective or disabled insofar as any control of the system is concerned. Simultaneously, the working fluid from channel 2 is connected at 237 and 238 of the slide valve 221 to actuator 2 thereby causing channel 2 to assume control of the system. At the same point in time the valve 221 at 242 and 243 in valve station 3 is positioned to receive fluid through conduits 246 and 247. However, these conduits are blocked by slide valve 261, and therefore, no effect upon actuator is effected in this position. Thus, in the event the failure occurs in channel 1, command of the system is transferred from the failed channel 1 to channel 2 and the system is ready to further transfer command to channel 3 should there

be a subsequent failure in channel 2.

In the event of such a subsequent failure in channel 2 (after a previous failure in channel 1) the comparators 62 and 65 connect system return to points B and E (system return already being connected to pint A) and the slide valve 261 translates to its second position by virtue of the force of spring 262. In such second position system return R2 is connected to conduits 266 and 267 thereby rendering channel 2 ineffective to control this system, that is channel 2 is disabled. Simultaneously, the output from channel 3 is applied to actuator 3 by the valve 261 at 273 and 274 connecting conduits 275 and 276 respectively to conduits 246 and 247 respectively, it being recalled that valve 221 at 242 and 243 has connected actuator 3 to the conduits 246 and 247. Thereby control is transferred from channel 2, which is now failed, to channel 3. At the same time translation of the slide valve 261 has disconnected system pressure P2 by movement of the valve at 277 from acting against the button 227 and has connected system return R2 thereto. Such action renders the system ready to transfer to its fail-neutral capability in the event of a discrepancy between channels 3 and 4.

In the event that such does occur, translation of the spool valve in comparator 64 connects system return to point D, it being remembered that system return has already been connected to points C and B. Upon system return being connected to point D, the spring 292 forces the slide valve 291 toward the right as viewed in FIG-URE 1. Such translation connects system return R3 at points 298 and 299 to actuator 3 thereby disabling channel 3 as to any control of this system. Simultaneously, system pressure from the source P3 is disconnected by position 301 of slide valve 291 from application to the button 228 and system return R3 is connected thereto. Under these conditions slide valve 221 is translated to its third position through the actuation of the spring 222 thus moving the entire assembly of the valve means 220, including the buttons 223 through 228, their full extent toward the right, which is at that position where button 228 bottoms out against the housing. Under these conditions each of the actuators 1, 2 and 3 is connected to a centering spool apparatus which connects system pressures P1, P2 and P3 to actuators 1, 2 and 3, respectively, to cause it to move to a predetermined position thereby moving a controlled member connected to the actuator to some predetermined position. A further and thorough description of the centering spool and the matter of its operation is given hereinbelow.

In the event the first failure to occur is in channel 2 it will become apparent to those skilled in the art that system return is connected to points B, E and A and the slide valve 261 is translated to its second position. Under these circumstances, the output from channel 2 is connected through positions 268 and 269 on the slide valve 261 to system return R2, thereby rendering channel 2 incapable of any control over this system in the event

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same time channel 3 is prepared for assuming control in the event of translation of slide valve 220 by connecting the output thereof to the conduits 246 and 247 as above described. Thus, if a second failure then occurred and that failure appeared in channel 1, transfer of control of the system would go from channel 1 to channel 3.

In the event the first failure to occur is in channel 3 system return would be connected to points C, B and D and the slide valve 291 would be translated toward the right. Under these circumstances, the output from channel 3 would be blocked by the slide valve 291 and system return R3 would be connected to the points 298 and 299 thereby rendering channel 3 ineffective to ever assume control of the system. In the event the second failure to occur appeared in channel 2 the operation as im- 15 mediately above described would than occur and in those cases control would remain in channel 1 until a disagreement between channel 1 and channel 4 occurred at which point the system would immediately transfer to its fail-neutral capability.

Referring now more specifically to FIGURE 3, the fail-neutral capability is illustrated. As is shown in FIG-URE 3, an actuator includes a body 310 within which there is housed a tandem ram generally illustrated at 311 and comprising a connecting rod 312 having disposed thereon actuator pistons 313, 314 and 315 thereby forming actuators 1, 2 and 3 as designated. The rod 312 is adapted at 316 for connection to a load or to a fixed point and at the opposite end of the body is adapted as shown at 317 for connection to a load or to a fixed point as the vehicle to which the actuator is connected, as the case may be. The ram 311 operates in the well known manner by the application of working fluid from channel 1 to actuator 1, from channel 2 to actuator 2, and from channel 3 to actuator 3, depending upon the particular 35

channel which is in command. The numerals utilized in-

dicating conduits connected to each of the actuators are the same as those utilized with respect to the conduits

leading from the slide valve 221 to each of the actuators. In the event slide valve 221 (FIGURE 2) moves to 40 its third position so that the conduits 251 through 256, as illustrated in FIGURE 2, are connected from the centering spool to the actuator, the actuator is caused to return to its center position (or some predetermined position). Disposed within the body 310 is a cylinder 321 within which there is positioned a spool valve 322. System pressures P1, P2 and P3 are connected to the cylinder 321 but when the valve 322 is in its centered position as illustrated, each of the system pressures P1, P2 and P3 are blocked by lands 323, 324 and 325 respectively. The 50 position of the spool 322 is controlled by positioning the connecting rod 312 of the ram 311 by means of an adjustable linkage 326 which is affixed at one end 327 to the connecting rod and at the opposite end 328 to one end of the spool 322. As is noted by the nut 329, the position of the spool 322 with respect to the rod 312 is adjustable to obtain the desired positioning of the ram when the spool 322 is in its neutral or centered position as illus-

It should be noted that in the event the slide valve 221 60 (FIGURE 2) is in either of its first or second positions, any output from the centering spool 322 is blocked from entering the actuator ram 311 by this positioning of the slide valve 221. It is only when the slide valve 221 is in its third, or fail-neutral position, that the output of the centering spool 322 is permitted to enter the actuators 1, 2 and 3.

Assuming now that the slide valve 221 has translated to its fail-neutral position, the output of the centering spool 322 becomes effective. Under these conditions assuming 70 the ram 311 is displaced toward the right so that the lands 323, 324 and 325 are displaced toward the right, system pressure is applied from source P1 through the conduit 252, through the slide valve 221 at 234 to the conduit 236 so that fluid pressure from the source P1 is ap- 75 in the absence of energization for the coil 401 constantly

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plied to the right side of the piston 313 to cause it to move toward the lifht. Simultaneously system return R1 is connected through the conduit 251 to the conduit 235 and thereby to the opposite side of the piston 313. Similarly, system pressure from source P2 is applied through conduit 254 to valve 221 at point 238 thereof and to the conduit 241 and thus to the right side of the piston the actuator on the ram 311 toward the left. Simultaneously, system return R2 is connected to the conduit 235 and through the valve 221 to the conduit 239 on the opposite side of the piston 314. At the same time, system pressure P3 is connected through the conduit 256 and the valve 221 at point 243 thereof to the conduit 245 to the right side of the piston 315 to also assist in returning the actuator on the ram 311 toward the lifet. Simultaneously, system return is connected to the left side of the piston 315 through the conduit 244 and the valve 2211 to the conduit 255, Obviously, if the ram 311 is displaced toward the left, the connection of the fluid from the source P1, P2 and P3 will be to the opposite sides of the pistons 313, 314 and 315 respectively to move the ram in the opposite direction to its predetermined position through the centering of the spool valve 322. Those skilled in the art will recognize that additional parting may be provided in the body 310 and lands on the spool 322 to connect a fourth fluid pressure source and its return through the centering spool to a fourth actuator to insure the fail-neutral capability in the event of loss of fluid pressure sources P1, P2 and P3. Thus, it can be seen that in the event of a final discrepancy between the remaining channels in the system, then the apparatus to which the actuator is connected is caused to automatically return to a predetermined position es-tablished depending upon the apparatus to which the system is connected.

In certain missions of various apparatus which might embody a control system in accordance with the present invention it is also desirable to enable the operator to select a given channel from channels 1, 2 or 3 to provide hydraulic assist in the control of the apparatus even though that particular channel may have previously been disabled through the automatic operation of the system in the manner above described. Such a situation can occur and the operator may select a channel when it is his judgement that a particular channel was not in fact inoperative but rather it may have been the monitor channel which was at fault. Such provision is provided (referring to FIGURE 2) for channel 1 by the emergency select switch 1 illustrated at 257 which is connected by conduit 258 so as to apply either fluid pressure from source P1 or return R1 to the chamber 259 so as to operate against one end of the slide valve 221 and cause it to return to the operational position as illustrated in FIGURE 2. Similar provision is made for channel 2 by the emergency select switch 281 which by way of the conduit 282 connects system pressure  $P_2$  or return  $R_2$  to a chamber 283 to cause the slide valve 261 to return to its operational position is illustrated. Also similar provision is made by the emergency select switch 3 illustrated at 305 which connects system pressure P3 or system return R3 by way of conduit 306 to the chamber 307 to cause the slide valve 291 to be returned to its operational position as illustrated in FIGURE 2. The details of one form of emergency select switch which may be utilized is illustrated schematically in FIGURE 4 to which reference is hereby made.

In FIGURE 4, there is illustrated a solenoid operated switching apparatus which includes an energizing coil 401 which may be energized through the closing of a movable contact 402 into engagement with a stationary contact 403 to apply a source of potential such as battery 404 to the coil 401. Upon application of the electrical energy thereby energizing the coil 401, the plunger 405 is retracted against the force of the spring 406 which urges the plunger upwardly as viewed in FIGURE 4. In the absence of energization of the coil the ball valve 407 is seated in such a manner as to block the application of the source of pressure P<sub>1</sub> as shown at 408. At the same time, system return R<sub>2</sub> as shown at 409 is applied through the conduit 411 to the conduit 258 and thus the chamber 259 (FIGURE 2). If, however, the operator selects channel 1 for emergency assist purposes, and he depresses the switch 402, energizing coil 401 and retracting the plunger 405 and with it the ball 407, pressure from the source 408 then passes through the conduit 258 to the chamber 259 placing the slide valve 221 in the position illustrated in FIGURE 2 thereby connecting the output from the channel 1 electro-hydraulic servo valve into communication with actuator 1. At the same 15 time the ball 407 blocks system return R<sub>2</sub> from the conduit 258.

From the foregoing description those skilled in the art will recognize that some redundant switching is illustrated and described with respect to FIGURES 1 and 20. For example, button 265 and the connection of point A may be eliminated from valve means 260, and button 293 and point C as well as button 294 and point B may be eliminated from valve means 290 without deleteriously affecting the operation of the system.

There has thus been illustrated and described in some detail a system which may utilize the output of four (4) sensor devices to thereby provide a redundant control system which has the capability of fail-operate, fail-operate, fail-neutral and which also may have the further capability of operator selection of any desired control channel even though the same has previously been excluded automatically.

I claim:

 A hydraeric redundant control system for positioning a movable member in response to input signals applied to said system comprising;

actuator means adapted to be connected to position said movable member;

1st, 2nd, 3rd and 4th channels, three of said channels 40 being capable of delivering hydraeric fluid to said actuator means;

1st, 2nd, 3rd and 4th sensor means connected for providing an individual monitor signal indicative of the status of each of said channels, respectively;

comparator means connected to receive said monitor signals for comparing individual pairs of said monitor signals to detect discrepancy therebetween;

switch means connected to said comparator means and operative upon said detection of a discrepancy between pre-selected pairs of said monitor signals to disable a pre-selected one of said channels; and

said control system remaining operative to position said movable member without substantial system degradation until three of said four channels have been disabled.

 A redundant control system as defined in claim 1 which further includes means for automatically positioning said actuator in a predetermined position only upon detection of a third discrepancy.

3. A redundant control system as defined in claim 2 wherein said automatic positioning means is a valve means connected between a source of hydraeric fluid and said actuator means, said valve means being coupled to said actuator means and opened by movement of said actuator means from said predetermined position and closed

only by return of said actuator to said predetermined position.

4. A redundant control system as defined in claim 1 wherein said monitor signals are hydraeric signals and said comparator means includes six spool valves, each of said spool valves having a different combination of two of said monitor signals applied thereto.

5. A redundant control system as defined in claim 1 wherein said switch means includes three individual switches, each operable in response only to a discrepancy

in a predetermined monitor signal.

6. A redundant control system as defined in claim 5 wherein one of said switches is a three position switch and the others of said switches are two position switches, said one of said switches connecting hydraeric fluid from:

(a) said 1st channel to said actuator means when in its first position,

(b) said 2nd channel to said actuator means when in its second position, and

(c) said 3rd channel to said actuator means when in its second position and said others of said switches are in their second positions; and

said one of said switches disables said 1st, 2nd and 3rd channels from control of said actuator means in its third position.

7. A redundant control system as defined in claim 6 which further includes means for automatically positioning said actuator to a predetermined position connected to said actuator when said one of said switches is in its third position.

8. A redundant control system as defined in claim 7 wherein each of said switches is a slide valve and each of said slide valves is connected to operate responsive to a predetermined combination of detected discrepancies thereby to be moved to a different position in the event of a detection of a given discrepancy.

A redundant control system as defined in claim 1
which further includes select switch means connected to
each of said three channels to individually energize the
same.

10. A redundant control system as defined in claim 9 wherein said select switch means is a separate solenoid operated valve connected between a hydraeric source and each of said slide valves.

11. A redundant control system as defined in claim 8 which further includes select switch means connected to each of said three channels to individually energize the same.

12. A redundant control system as defined in claim 4 wherein said switch means includes a plurality of slide valves and each of said slide valves is connected to operate responsive to translation of a predetermined combination of said spool valves thereby to be moved to a different position in the event of a detection of a given discrepancy.

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# **EXHIBIT F**

[54]	METHOD AND MEANS FOR
	PROVIDING AN OUTPUT
	CORRESPONDING TO THE AVERAGE
	OF ACCEPTABLE INPUT SIGNALS

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[52]	U.S. Cl328/156, 307/219, 307/235,
	220/11/2 220/11/2 220/11/0 220/11/0

		328/117, 328/147, 328/148, 328/158
[51]	Int. Cl	G06g 7/14, H03k 5/20

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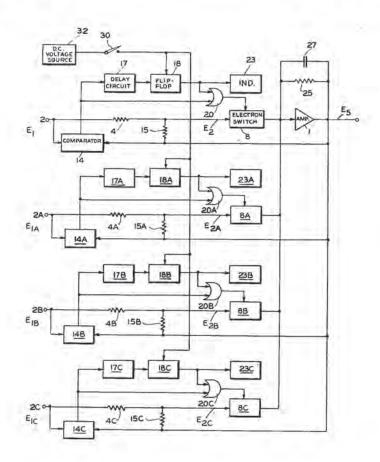
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Primary Examiner—Donald D. Forrer Assistant Examiner—L. N. Anagnos Attorney—Ronald G. Gillespie and Plante, Hartz, Smith and Thompson

#### [57] ABSTRACT

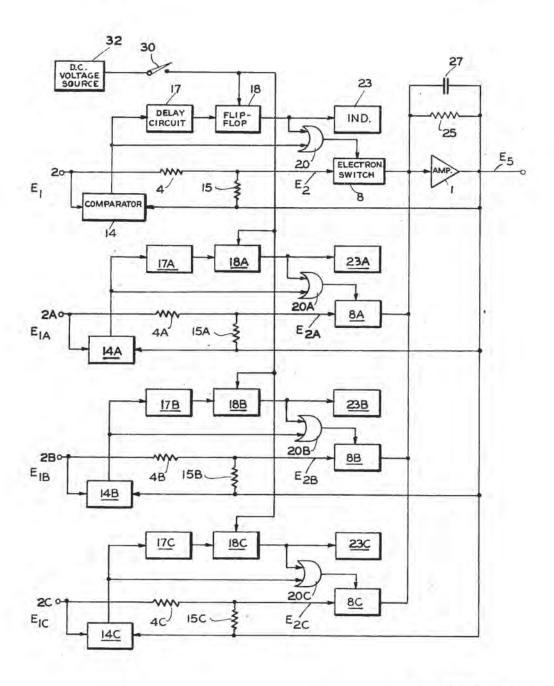
A circuit has averaging means for providing an output corresponding to the average acceptable input signals, a comparator for comparing each input signal to the average output, and switching means controlled by the comparator for eliminating unacceptable input signal from the average when the signals differ a predetermined amount from the average output.

#### 3 Claims, 1 Drawing Figure



PATENTED WAY 30 1972

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#### METHOD AND MEANS FOR PROVIDING AN OUTPUT CORRESPONDING TO THE AVERAGE OF ACCEPTABLE INPUT SIGNALS

#### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

This invention relates to signal averaging circuits in general and, more particularly, to a signal averaging network with indicating means.

#### 2. Description of the Prior Art

Heretofore, voters such as disclosed in U.S. application Ser. No. 860,315, filed on Sept. 23, 1969, now U.S. Pat. No. 3,619,791 by Harold Moreines and assigned to The Bendix Corporation, assignee of the present invention, compared the input signals with each other and passed one of the acceptable input signals to the output. The network of the present invention differs from the Moreines voter in that each input signals is compared with the output signal which has an amplitude that is the average of the acceptable input signals. The present averaging circuit provides an output signal even when there is only one acceptable input signal whereas Moreines type voters will provide an output signal selected from the majority of the input signals. Thus, a five-input voter requires at least three acceptable input signals to be operative.

#### SUMMARY OF THE INVENTION

A circuit for providing an output corresponding to the average of acceptable input signals and for eliminating from the average unacceptable input signals which differ from the average by a predetermined amount. The circuit includes a network, responsive to the input signals, for providing an output corresponding to the average of the acceptable input signals. Comparators compare each input signal to the average output and control switches to eliminate unacceptable input signals from the averaging network when the input signals differ by a predetermined amount from the average output.

I intend to provide a circuit which may be used as a voter in redundant systems and which provides an output corresponding to the average of the input signals applied to the circuit. Furthermore, if an input signal differs from the output by a predetermined amount that input signal will be isolated so as not to affect the average output. I further intend to permanently isolate an input signal which differs from the average output by a predetermined amount for a predetermined time interval. The averaging circuit is intended to include an indicator for indicating which input signal has been permanently isolated. It is intended that each input signal not differing from the average output by a predetermined amount be reduced by a factor 1/N, where N is the number of signals not differing from the average output by the predetermined amount.

The foregoing and other objects and advantages of the invention will appear more fully hereinafter from a consideration of the detailed description which follows, taken together 55 with the accompanying drawing wherein one embodiment of the invention is illustrated by way of example. It is to be expressly understood, however, that the drawing is for illustration purposes only and is not to be construed as defining the limits of the invention.

#### DESCRIPTION OF THE DRAWING

The single FIGURE of the drawing is a schematic diagram of a four-input circuit constructed in accordance with the present invention for providing an output signal having an amplitude corresponding to the average amplitude of acceptable input signals applied to the circuit.

#### DESCRIPTION OF THE INVENTION

Referring to the drawing an acceptable signal averaging circuit, constructed in accordance with the present invention, reduces acceptable input signals and sums the reduced signals to provide an output having an amplitude corresponding to the average amplitude of the acceptable input signals. An ac-

ceptable input signal is an input signal that *does not* differ from the average output by a predetermined amount. The averaging circuit includes a conventional type operational amplifier 1, and a plurality of signal processing channels which provide the reduced signals. One channel includes an input terminal 2, receiving an input signal  $E_1$ , of a group of input signals  $E_1$  through  $E_{1C}$ , connected in series with a summing resistor 4, and an electronic switch 8, which is also connected to an input of amplifier 1. The channel also includes a conventional type comparator 14 connected to switch 8 through an OR-gate 20 and connected between terminal 2 and the output of amplifier 1, and a resistor 15 connected between the output of amplifier 1 and the connection between resistor 4 and electronic switch

Terminal 2 provides signal  $E_1$  to summing resistor 4 and to comparator 14. Summing resistor 4 cooperates with resistor 15 to reduce signal  $E_1$  to provide reduced signal  $E_2$  to switch 8. Resistor 15 is connected in parallel with resistors 15A, 15B, and 15C as hereinafter explained. The parallel resistors causes signal  $E_2$  to have an amplitude corresponding to the amplitude of signal  $E_1$  divided by the number of acceptable input signals. Switch 8 passes signal  $E_2$  to amplifier 1 during the absence of a command signal from comparator 14 which occurs when signal  $E_1$  is an acceptable input signal and blocks signal  $E_2$  in response to a command signal from comparator 14 which occurs when signal  $E_1$  is in an unacceptable input signal. Amplifier 1 amplifies the sum of the reduced signals to provide an output  $E_3$  which corresponds to the average of acceptable input signals.

Comparator 14 determines if signal E<sub>1</sub> is an acceptable input signal by comparing signal E<sub>1</sub> with output E<sub>3</sub>. When the difference between signal E<sub>1</sub> and output E<sub>3</sub> does not exceed a predetermined threshold level of comparator 14, signal E<sub>1</sub> is acceptable and comparator 14 provides no command signal. Comparator 14 provides a command signal to switch 8, through an OR-gate 20, when the difference between signal E<sub>1</sub> and voltage E<sub>2</sub> exceeds the predetermined threshold level. When the difference between signal E<sub>1</sub> and output E<sub>3</sub> exceeding the threshold level is momentary, comparator 14 removes the command signal permitting switch 8 to again pass reduced signal E<sub>2</sub> when the difference between input signal E<sub>1</sub> and output E<sub>3</sub> drops below the threshold level.

Resistor 15 also operates as a feedback resistor since it connects the output of amplifier 1 to the input of amplifier 1 through electronic switch 8 when electronic switch 8 is conducting and thus is in parallel with resistors 15A, 15B, and 15C and the resistance values of resistors 4, 4A, 4B, and 4C determines the gain of amplifier 1 and the amplitudes of the reduced signals. For purpose of explanation, resistors 4, 4A, 4B, and 4C may be considered as being connected in parallel when the input signals applied to those resistors are acceptable input signals. The gain G of amplifier 1 would then be  $G = (\frac{1}{4})R_{10}/(\frac{1}{4})R_4$ 

When electronic switch 8, 8A, 8B, or 8C blocks an unacceptable signal, the electronic switch in affect disconnects one of the resistors 4, 4A, 4B, or 4C, respectively. Unless a corresponding feedback resistor 15, 15A, 15B, and 15C is also disconnected from the parallel combination of feedback resistors 15, 15A, 15B, and 15C, the gain G of amplifier 1 will decrease. By connecting feedback resistors 15, 15A, 15B, and 15C to electronic switches 8, 8A, 8B, and 8C, as shown in the FIGURE, a corresponding feedback resistor is disconnected when an electronic switch blocks an unacceptable signal so as to maintain the gain of amplifier 1.

The disconnecting of a feedback resistor 15, 15A, 15B, or 15C also causes the amplitudes of the other reduced signals being applied to amplifier 1 to increase.

Each channel also has latching means, including a delay circuit 17, having a predetermined time delay, connected to comparator 14 and a conventional type flip-flop 18 connected to delay circuit 17 and OR-gate 20. The latching means renders switch 8 non-conducting until reset when the difference between signal E<sub>1</sub> and output E<sub>5</sub> exceeds the threshold level of comparator 14 over a predetermined time interval. When the command signal from comparator 14 does not exceed the predetermined time delay of circuit 17, circuit 17 provides no output. When the command signal from comparator 14 exceeds the predetermined time delay of circuit 17, circuit 17 triggers flip-flop 18 which provides a command signal to electronic switch 8, through OR-gate 20, until flip-flop 18 is reset. An indicator 23 connected to flip-flop 18 provides an indication that the difference between signal E<sub>1</sub> and output E<sub>5</sub> has exceeded the threshold level over the predetermined time interval in response to a command signal from flip-flop 18.

Elements having the suffixes A, B, and C are connected and operate in a similar manner as elements having the same numeric designation without a suffix.

The reset circuit for flip-flop 18, 18A, 18B, and 18C include a switch 30, which may be a momentary "on" toggle switch, connected to flip-flops 18, 18A, 18B, and 18C and a source 32 of a fixed direct current voltage. Activation of switch 30 causes switch 30 to provide a direct current voltage to flip-flops 18, 18A, 18B, and 18C resetting those flip-flops.

Amplifier I also has a feedback circuit including a capacitor 27 and a bleeder resistor 25 connected between the output and the input of amplifier 1. Resistor 25 has a resistance value that is sufficiently higher than the resistors 15, 15A, 15B, and 25 15C, which are in parallel with resistor 25 when operating as feedback resistors, so that resistor 25 does not affect the gain of amplifier. Capacitor 27 provides a small time lag so that instantaneous changes between the input signals E<sub>1</sub> through E<sub>1C</sub> does not cause the signals to be removed and permits at least 30 one acceptable input signal to cause amplifier I to provide output E<sub>8</sub>.

Under a special condition where there are two unacceptable input signals, a change in one of the two remaining acceptable input signals, causing that signal to become an unacceptable input signal, can occur instantaneously or gradually. When the change is instantaneous, the changed signal will be isolated as an unacceptable input signal since output  $E_3$  will not change instantly due to capacitor 27 and resistor 25. However when the change is gradual, output  $E_3$  will have an amplitude corresponding to the average of the changed input signal and the remaining acceptable input signal which would have to be detected by other means in a system using the device of the present invention.

The signal averaging circuit heretofore described compares each input signal applied to the averaging circuit with an output from the averaging circuit. The averaging circuit of the present invention sums reduced input signals, each input signal being reduced by a factor 1/N, where N is the number of acceptable input signals. The averaging circuit isolates an input signal that differs from the output by a predetermined amount and when the difference exist over a predetermined time interval the averaging circuit permanently isolates the input signal and indicates which input signal has been permanently isolated.

What is claimed is:

1. A circuit for providing an output corresponding to the average of acceptable input signals and for eliminating unacceptable input signals which differ from the average by a predetermined amount, comprising averaging means responsive to the input signals for providing an output corresponding to the average of acceptable input signals, means connected to the output of the averaging means for comparing each input signal to the average output, switching means included in the averaging means connected to the comparing means for eliminating unacceptable input signals from the averaging means when the input signals differ a predetermined amount from the average output and said averaging means further including means receiving the input signals and connected to 70 said switching means for reducing each acceptable input signal by a factor of 1/N, where N is the number of acceptable input signals, and applying the reduced acceptable signals and the unacceptable signals to the switching means which is rendered conductive by the comparing means to pass the 75

reduced acceptable signals and rendered non-conductive by the comparing means to block the unacceptable signals; the averaging means still further including summing means connected to the switching means for summing reduced signals passed by the switching means and providing the average output; said summing means includes amplifying means for amplifying the sum signal to provide the average output; and wherein the switching means is a plurality of individual switching means for each of said input signals having first and second terminals, and the amplifying means includes an operational amplifier for amplifying the average of a number of acceptable input signals having its input terminal connected to the first terminals of all the switching means, input and output circuits for said amplifier, said input circuit comprising a first plurality of resistors, each being connected to the second terminal of its respective switching means for receiving individually a respective input signal, and said output circuit comprising a second plurality of resistors, each being connected to the output terminal of the amplifier and to the second terminal of its respective switching means to operate as a feedback resistor for said amplifier when said switching means is rendered conductive and not to operate as a feedback resistor when said switching means is rendered non-conductive to maintain the gain of said amplifier constant with varying number of acceptable input signal, and to provide in combination with a respective resistor of the first plurality of resistors a reduction in the amplitude of its respective input signal when said switching means is conductive, and an increase in the amplitude of each acceptable signal when said switching means is rendered non-conductive so as to maintain an average of acceptable signals irrespective of the number thereof.

2. A circuit for providing an output corresponding to the average of acceptable input signals and for eliminating unacceptable input signals which differ from the average by a predetermined amount, comprising averaging means responsive to the input signals for providing an output corresponding to the average of acceptable input signals, means connected to the output of the averaging means for comparing each input signal to the average output, switching means included in the averaging means connected to the comparing means for eliminating unacceptable input signals from the averaging means when the input signals differ a predetermined amount from the average output and said averaging means further including means receiving the input signals and connected to said switching means for reducing each acceptable input signal by a factor of I/N, where N is the number of acceptable input signals, and applying the reduced acceptable signals and the unacceptable signals to the switching means which is rendered conductive by the comparing means to pass the reduced acceptable signals and rendered non-conductive by the comparing means to block the unacceptable signals; the comparing means includes a plurality of comparators, each comparator being connected to the switching means and to the averaging means and receiving a different input signal and comparing the input signal with the average output from the averaging means for controlling the switching means in accordance with the comparison; and further comprising means for controlling the switching means to eliminate an input signal that was an unacceptable signal for a predetermined time interval and including a plurality of delay circuits, each delay circuit being connected to a different comparator and controlled by the comparator to provide an output when the input signal differs from the average output by a predetermined amount for a predetermined time; a plurality of flipflops, each flip-flop connecting a corresponding delay circuit to the switching means and responsive to an output from the delay circuit to control the switching means to eliminate the input signal that differed from the average output by the predetermined amount for the predetermined time, and means connected to the flip-flops for resetting the flip-flops.

A circuit of the kind described in claim 2, further com prising a plurality of indicators, each indicator being con-

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nected to a corresponding flip-flop and providing an indication when the flip-flop controls the switching means to eliminate the input signal.

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Case3:11-cv-04494-WHO Document411-7 Filed04/18/14 Page1 of 10

# EXHIBIT G

Neuner et al.

[45] July 15, 1975

1541	CIRCUIT ARRANGEMENT FOR
	ENHANCING THE RELIABILITY OF
	COMMON BUS OUTPUTS OF PLURAL
	REDUNDANT SYSTEMS

- [75] Inventors: James A. Neuner, Gibsonia, Pa.; Maurizio Traversi, Turin, Italy
- [73] Assignee: Westinghouse Electric Corporation, Pittsburgh, Pa.
- [22] Filed: Jan. 3, 1973
- [21] Appl. No.: 320,775

(521	U.S. Cl	235/153	AE;	340/	146.1	BI
1511	Int. Cl	G06f	11/0	0; G0	6f 15	5/1
1581	Field of Search	235	5/153	AE.	153	AH

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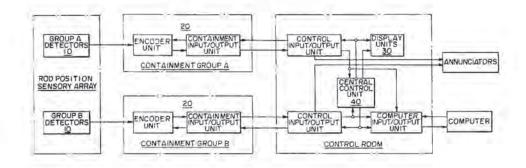
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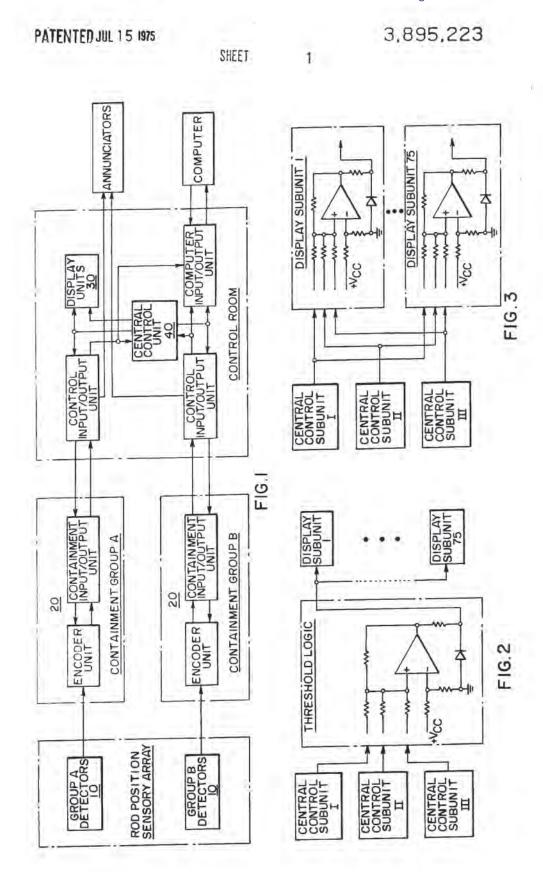
Primary Examiner—Charles E. Atkinson Attorney, Agent, or Firm—D. C. Abeles

#### [57] ABSTRACT

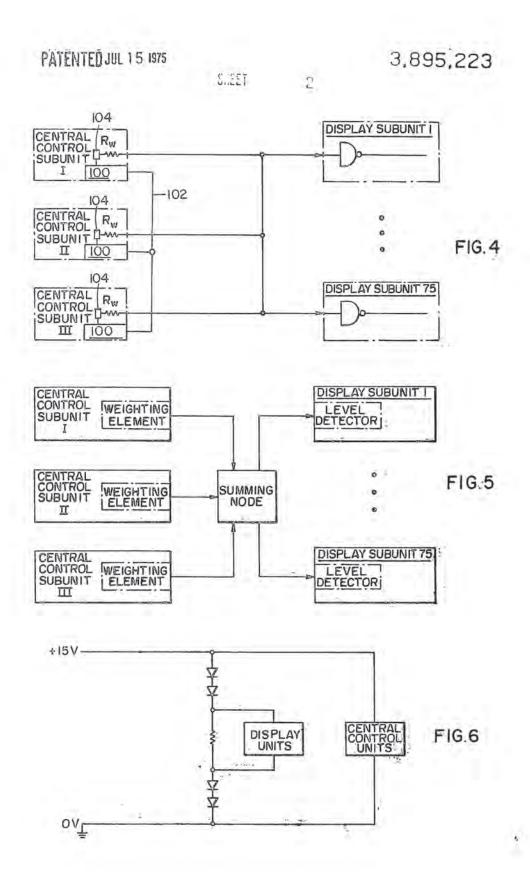
A circuit arrangement for enhancing the reliability of common bus outputs in redundant systems generating a plurality of at least three substantially similar outputs to a common bus signal train. Each output is separately compared to the other corresponding outputs and if a difference is determined, the output exhibiting the difference is disconnected from the common bus. Provision is made for a separate alarm identifying the output exhibiting the difference. In one embodiment, a second level majority vote takes place at the termination of the common bus by comparing the weighted sum voltage of the corresponding outputs applied to the common bus against a threshold voltage. Additionally, the applicability of this invention to enhance the reliability of digital position indication systems utilizing independent signal trains is specifically described. Varying degrees of redundancy are taught in the alternate embodiments to accommodate the standard of reliability desired.

8 Claims, 8 Drawing Figures





Pharmatech Solutions, Inc: EXHIBIT 1031 - 114 IPR2013-00247, U.S. Pat. No. 7,250,105



Pharmatech Solutions, Inc: EXHIBIT 1031 - 115 IPR2013-00247, U.S. Pat. No. 7,250,105

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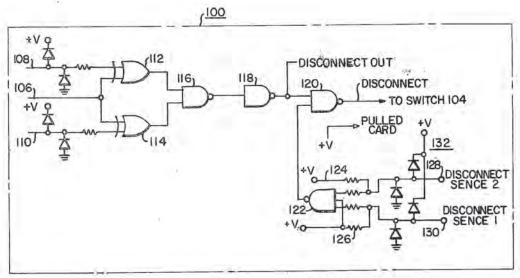


FIG.7

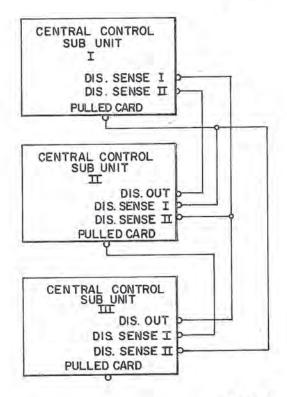


FIG.8

#### CIRCUIT ARRANGEMENT FOR ENHANCING THE RELIABILITY OF COMMON BUS OUTPUTS OF PLURAL REDUNDANT SYSTEMS

## CROSS-REFERENCE TO RELATED APPLICATIONS

The present invention is related to the invention covered by copending U.S. patent applications Ser. No. 320,776, entitled "Position Indication System" by F. T. Thompson, Frederick J. Young and D. J. Boomgaard; 10 and Ser. No. 320,792, entitled "Digital Multiplexed Position Indication and Transmission System" by J. A. Neuner, F. T. Thompson and L. Vercellotti, All of the aforementioned U.S. patent applications are assigned to the assignee of the present invention and are filed 15 concurrently herewith.

#### BACKGROUND OF THE INVENTION

This invention pertains in general to redundant systems generating a plurality of substantially similar outputs to a common bus signal train and more particularly to such systems that require a high degree of reliability through common portions of the system shared by the plurality of outputs.

In many systems utilizing a plurality of signal trains communicating substantially similar signals, mostly for redundancy, the advantage obtained is often lost in common segments of the system at the termination of the signal trains. Adding further redundancy to the common segments of the system usually degrades the maintainability of the system as well as increases the probability of single component failure.

25 drawings, in which:
FIG. 1 is a block of tem incorporating to the incorporating to the incorporating to the incorporating to the signal trains.

An exemplary system requiring redundancy to ennance system reliability is the digital multiplexed rod position indication system for nuclear reactors de- 35 scribed in copending application Ser. No. 320,776, entitled "Position Indication System" cited above. In this digital rod position indication system, redundancy is provided within the detectors, containment electronics and display area. However, a central control unit is employed to coordinate the operation of all other areas of the system, and therefore remains the common element between otherwise redundant areas. Consequently, it represents the only weak link left in the system, the overall reliability of which is primarily limited by the 45 reliability of the central control unit itself. Failure of the central control unit will probably cause a complete loss of position indication on all control rods.

Addition of a second central control unit to replace the first provides little improvement since a disagreement between the two units would prove only that one had failed but would give no indication as to which one. Due to the complexity of its functions, failure detection within each central control unit could not be reliably implemented as in the rest of the system.

Accordingly, an alternate form of redundancy is desired which will enhance the system's reliability without degrading its maintainability.

#### SUMMARY OF THE INVENTION

Briefly, this invention provides a circuit arrangement for enhancing the reliability of common bus outputs in redundant systems generating a plurality of at least three substantially similar outputs to a common bus signal train. The plurality of outputs are compared to determine the existence of a corresponding difference in signal levels. An inconsistency in corresponding signal levels is indicative of a fault in the portion of the system exhibiting the difference. If a difference is detected, the output exhibiting the difference is disconnected from the common bus, while the remaining outputs are communicated thereto.

In one embodiment, where more than one output exhibits a difference, the inconsistent outputs are disconnected from the common bus in a predetermined order of priority. Where desired, the last output within the ordered priority can be prevented from disconnecting from the common bus.

In a modified embodiment, provision is made for a second level majority vote at the termination of the common bus. Each level of majority vote can be implemented in a redundant manner to enhance reliability without degrading systems maintainability.

An alarm provision can be included, as described, to identify the existence of a malfunctioning output as well as its location.

#### BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the invention, reference may be had to the preferred embodiment, exemplary of the invention, shown in the accompanying drawings, in which:

FIG. 1 is a block diagram of a position indication system incorporating the concepts of this invention;

FIG. 2 is a partial schematic of one embodiment of this invention:

FIG. 3 is a modification to the embodiment illustrated in FIG. 2;

FIG. 4 is an additional modification to the embodiment illustrated in FIG. 2:

FIG. 5 is an illustrative block diagram of the modification illustrated in FIG. 4;

FIG. 6 is an accessorial modification to the circuits previously illustrated;

FIG. 7 is a schematic circuitry diagram of a portion of the central control subunits illustrated in FIG. 4; and FIG. 8 is a more detailed illustration of the interconnection between control subunits illustrated in FIG. 4.

## DESCRIPTION OF THE PREFERRED EMBODIMENT

In most redundant systems the advantage obtained from redundancy is often lost in common segments of the system. This invention provides a circuit arrangement for assuring the validity and enhancing the reliability of the information processed through common portions of otherwise redundant systems. While the system contemplated by this invention will be described in conjunction with a control rod position indication system for nuclear reactors, it should be understood that this invention has analogous applicability to most redundant electrical systems employing common portions,

To provide reliable and accurate nuclear control rod position information, even under single failure conditions, for each rod, the detector coils and the associated containment electronics employed within the position indication system contemplated by this invention (more fully described in copending application Ser, No. 320,792, cited above) are divided into two separate identical groups. Each group is capable of providing redundant information on the true position of each control rod with one-half the desired resolution. Two sets of digital data are transmitted through independent

time division multiplexed channels to the reactor control room where independent error checking is performed. The two sets of verified data are sent to a central control unit and combined to determine the true position of each of the control rods with the required 5 full resolution desired.

If a failure occurs in either group, it will be automatically detected resulting in the rejection of the corresponding data so that the true rod position, determined by the remaining group, will still be displayed with reduced resolution.

Rod position information is available through independent and separate outputs including a local real time display using light emitting diodes for the reactor operator, and a plant computer which operates us a data logger. A block diagram of the overall rod position indication system is illustrated in FIG. 1. Redundancy is implemented within the detectors 10, containment electronics 20 and display area 30 as pictorially represented by groups A and B, respectively identifying the 20 separate signal trains. However, the central control unit 40, used to coordinate the operation of all other areas of the system, remains the common element between otherwise redundant areas. Consequently, it represents the only weak link in the system, the overall reliability 25 of which is primarily limited by the reliability of the central control unit itself. A failure of the central control unit will probably cause a complete loss of position information on all rods

The operation of each of the individual blocks identified by legends in FIG. 1 can better be understood by reference to the operational explanation provided in copending application Ser. No. 320,792, cited above.

The addition of a second central control unit in a redundant arrangement with the first provides little improvement since a disagreement between the two units would prove only that one had failed but would give no indication as to which one. Due to the complexity of its functions, failure detection within each central control unit could not be reliably implemented as in the rest of the system.

An excellent alternative to failure detection and correction as provided by this invention is implemented with majority voting logic (two out of three or threshold type logic). The straightforward implementation of this concept can be provided in two ways. First, a centralized majority voting scheme can be employed as illustrated in FIG. 2 or secondly, a distributive majority voting scheme can be employed as illustrated in FIG. 50

In the centralized majority voting arrangement of FIG. 2, three central redundant control units I. II and III are employed. The three corresponding output signals from the central control units I, II, and III are processed by a common majority voting circuit identified by the legend threshold logic. The resultant output from the majority voting circuit is distributed to the various display units corresponding to the number of control rods being monitored, identified by the legends display I through display 75. While, the circuit arrangement illustrated provides redundancy, it is obvious that the reliability of the system is now limited by the reliability of that common circuit (threshold logic) as it was before by the common control unit. This approach can only be implemented successfully if the reliability of the majority voting circuit is much higher than that of the control unit. Obviously, from the cir-

cuit arrangement illustrated, utilizing common electrical components, and in view of the complex nature of the functions performed by the central control unit as fully described in copending application Ser. No. 320,792, this criteria can easily be met. The desirability of this configuration is only limited by the standard of reliability required by a particular application.

In the distributive majority voting circuit arrangement illustrated in FIG. 3 the outputs from the individual control units I, II, and III are distributed to the individual display units identified by the legends display 1 through display 75, where independent majority voting takes place. This approach definitely offers greater reliability at the expense of more complex wiring and a considerable amount of additional circuitry which reduces the probability of black-out type failures by increasing the probability of individual and independent failures; thus degrading the overall maintainability and serviceability of the system. The desirability of employing either embodiment will depend upon the standard of reliability required by a particular application.

A preferred modification contemplated by this invention, which improves the reliability of the digital rod position indication system by improving the reliability of the necessarily common central control unit in the simplist possible manner, without degrading its cost, size and maintenance characteristics, is illustrated in FIG. 4.

In the system illustrated in FIG. 4, the single central control unit is replaced by three identical control units 1. If and III, which control the system as fully described in copending application Ser. No. 320,792. All control units receive the same inputs from redundant sections of the system and should then respond in an identical manner unless a failure has occurred somewhere. To provide more reliable operation, the majority vote function is implemented twice at two subsequent levels by two different methods, the first digital as set forth in application Ser. No. 320,792 and the second analog (threshold logic) as described herein. Separate outputs of identical signals are provided to redundant display sections 1 through 75 so that a failure in one section cannot affect the performance of its redundant counterpart.

The digital implementation uses an identical circuit 100 within each central control unit to control connection of the respective control unit outputs to the system as described in detail in copending application Ser. No. 320,792. The first level majority vote circuit compares each output signal from its own respective central control unit with the other outputs from the other two central control units as illustratively shown by the electrical cable ties 102. If a signal differs from both corresponding signals, the majority vote circuit will conclude that the failure exists within its own unit and automatically disconnect its output from the rest of the system by controlling analog switches generally shown by block 104 connected in series with each signal output. Detection of a failure will be alarmed both locally and by the control annunciators within the reactor control room as shown in the copending application.

The analog implementation, which represents a very efficient synthesis of the two approaches shown in FIGS. 2 and 3, is accomplished by placing a resistor Rw in series with each output signal before leaving the control units. Each signal is then tied to each of the other

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two corresponding signals before being distributed to the rest of the system as shown in FIG. 4.

As a result, the three basic functions of a threshold logic majority voting circuit (weighting of the input signals, summing of the weighted signals and comparison 5 of the summed signals against a threshold level) are shared by the various system blocks as shown in FIG. 5, which is a functional duplicate of FIG. 4. The above functions are thus accomplished in the most simple, efficient and reliable manner by respectively, the resistor 10 Rw in series with each signal output, the common bus connection of the output signals and the gate itself at the input of each display board as a result of the threshold characteristic and the high input impedance of the complementary metal oxide semiconductor logic fam- 15 ily employed, which is specifically suitable for use in this application. The voltage of the bus will follow the state presented by the majority of signals tied together and will be determined by simple resistor voltage divihave a typical threshold of one-half the power supply, the resulting threshold logic will perform the majority vote function desired. The most appealing advantage of this invention in this particular application is that it utilizes an already existing digital component (the input NAND gate as more fully illustrated in U.S. patent application Ser. No. 320,792 to perform the function usually delegated to an additional analog component such as an operational amplifier or level detector. In addition, since the NAND gates are distributed throughout 30 the system, no single active component exists which could fail and cause all displays to be lost simultaneously. The only components actually added to the system are the weighting resistors Rw which are extremely reliable and yet very inexpensive and will also 35 provide current limiting protection against voltage transients picked up on the bus line.

If the threshold of the digital component chosen varies excessively and a complete worst case design must be met, it is possible to compress the threshold band by using a lower supply voltage, floating between the supply voltages used by the central control unit to power the display units. For example, the display units could be powered by +13.5 volts and +1.5 volts derived from a +15 volt voltage supply and ground using four diodes and a resistor as shown in FIG. 6.

As previously described, if any signal output from the control unit disagrees with both corresponding signals from the other two control units, then this control unit is assumed to have failed and will be disconnected from the system leaving control to the remaining two control units. In the specific application to control rod position indication, as well as in many other applications, it is important that at no time should all central control units be disconnected from the system as would be the case under a multiple failure condition. Therefore, a priority is given to each central control unit to control the order of disconnection. The back wiring for such an ordered priority, graphically illustrated by the multiconductor electrical ties 102, as well as the individual elements comprising the majority vote circuit and the control unit circuit are illustrated in FIGS, 7 and 8 and described in copending application Ser. No. 320,792, entitled "Digital Multiplexed Position Indication and Transmission System" cited above. In the system illustrated, control unit I is given the highest priority such that if both of the two other control units disconnect or

are removed, it will continue to control the system. If control unit I is removed, then control unit II, with the second highest priority, will refuse to disconnect if control unit III has disconnected. Finally, if both control units I and II are removed, control unit III will refuse to disconnect under any circumstance. In the circuit described, all local and remote alarms will continue to function even if a unit is prevented from disconnecting, thus identifying the fault and indicating its location.

FIG. 7 provides an example of the circuitry that can be used in block 100, illustrated in FIG. 4, for providing the first level majority vote (digital implementation) and the priority of disconnection described above. The circuits illustrated in FIG. 7 are essentially the same as those illustrated in FIG. 9 of the referenced application Ser. No. 320,792; the only difference being a simplifying assumption that the control subunits of this embodiment process a single redundant signal as compared with the multitude of signals processed by the embodision. Since the NAND gates shown on the display unit 20 ment of the referenced application. Each of the control subunits operate in the same manner and for the purposes of illustration, the operation of control subunit I will be explained in detail. The processed signal from control subunit I is communicated to terminal 106 with the processed signals from the other two units being coupled respectively to terminals 108 and 110. Control subunit I's signal is compared with the other two control unit signals by the exclusive OR gates 112 and 114, which provide a digital one output if a difference is indicated. The outputs from the exclusive OR gates 112 and 114 are then processed through NAND gates 116, which provides a zero output if, and only if, control subunit I's signal disagrees with the remaining two control subunit signals indicating a malfunction within control subunit I. The output of gate 116 is processed through NAND gate 118 to provide a disconnect output (DIS. OUT), which is monitored by the other two control subunits as illustrated in FIG. 8. The output of gate 118 is also supplied to NAND gate 120, which is inhibited from passing the output signal to the switches 104 by the circuitry 132 in the event the other two control subunits have disconnected. Accordingly, if the other two control subunits have not been disconnected and a malfunction is indicated by a disagreement monitored by the exclusive ORs 112 and 114 then a zero will appear at the disconnect output actuating the switches 104 to electrically disconnect central control subunit I from passing its output. As will be well appreciated by those skilled in the art by reference to FIGS. 7 and 8, the circuitry 132 monitors the outputs from the other two central control subunits and if an indication is sensed that both of the other two central control subunits have disconnected, a one output will be provided to NAND gate 120 inhibiting the switches 104 from actuating. Considering the order of priority previously identified, it will be appreciated that the disconnect sense 2 terminal of central control subunit I monitors the disconnect out terminal of central control subunit Il as illustrated in FIG. 8 and the disconnect sense 1 terminal monitors the disconnect out of central control subunit III. Accordingly, if a one appears across both terminals 128 and 130 indicating that control subunits II and III have been disconnected, a zero will be provided to the input of gates 120 inhibiting the switches 104 from actuating. On the other hand, if a zero should appear at either terminal 128 or 130, then a one input

> Pharmatech Solutions, Inc: EXHIBIT 1031 - 119 IPR2013-00247, U.S. Pat. No. 7,250,105

will be communicated to gate 120 enabling control sub-

unit I to disconnect. However, if at a later time control subunits II and III disconnect, control subunit I will resume communicating its output in accordance with the priority affixed. Furthermore, if a control subunit circuitry card is removed from the system, the corre- 5 sponding disconnect sense terminal will assume a one voltage due to the pull-up resistors 126 and 124, providing an indication that the control unit has been removed. As will be appreciated by those skilled in the art, the order of priority is established by the pulled card terminals which provide a fixed voltage output approximately equal to the zero logical state. Therefore, as long as control subunit I is not removed from the system sense terminal 1 of control subunit II and sense terminal 2 of control subunit III will indicate that control 15 subunit I is still in operation even though analog switches 102 have activated and electrical disconnection has occurred. Therefore, control subunits II and III will disconnect from the system so long as the central control subunit circuitry card for subunit I has not been 20 physically removed. If control subunit I's circuitry card is physically removed, a reordering of priorities will occur giving control subunit II the next highest priority due to the interconnection of its pulled card terminal with the disconnect sense terminal of control subunit 25 III. Thus, the first level majority vote is obtained with an order of priorities established that control the electrical disconnection of the control subunit outputs

Accordingly, a totally redundant digital rod position indication system employing redundant signals which 30 are handled by separate sections utilizing automatic detection of most failures is described. The two groups of signals are processed by a central control unit to obtain, under most conditions, full resolution, redundant readouts. The invention describes the use of three separate control units where each digital output signal from each unit is compared with the corresponding outputs from the other two units and if the local signal exhibits a difference from both other corresponding signals, a majority condition is established for that unit whereby its outputs are disconnected (first level majority vote). A second level majority vote takes place on each input of the receiving readout units by comparing the weighted sum voltage of the corresponding outputs (from the three central control units) applied to a common bus against the logic threshold voltage of each input. By distributing the implementation of the majority vote threshold logic among three different sections of the system more reliable operation is obtained without degrading the systems maintainability. The applicability of the majority vote concept contemplated by this invention to a wide range of redundant systems utilizing similar inputs is evident. The advantages obtained in expanding the redundancy of such systems as well as in providing a method of local fault detection enhances the reliability and instills greater confidence in the validity of the information conveyed.

We claim as our invention:

1. A circuit arrangement for enhancing the reliability of common bus outputs in redundant systems generating a plurality of at least three substantially similar outputs to a common bus signal train comprising:

means for comparing the plurality of output signals and responsive to a difference in the outputs to disconnect the respective output signals exhibiting the difference from the common bus and pass the remaining outputs to the common bus, and

means responsive to a difference in more than one of the outputs to control the comparing means to disconnect the outputs exhibiting the difference from the common bus in a predetermined order of prior-

2. The circuit of claim 1 wherein when all the outputs exhibit a difference said means for controlling the comparing means prevents said comparing means from disconnecting from the common bus the last output to be 10 disconnected in accordance with the predetermined

order of priority.

3. The circuit of claim 1 wherein said means for comparing the plurality of outputs includes a plurality of comparators corresponding to and individually associated with the plurality of outputs, each of said comparators being operable to compare its corresponding output with all other outputs and disconnect its corresponding output from the common bus if a difference is exhibited thereby with respect to the remaining outputs

4. The circuit of claim 1 wherein the plurality of outputs are weighted before being distributed to the common bus, including a plurality of output circuits connected in parallel to the common bus with each of said output circuits including a threshold logic circuit responsive to the common bus input to pass the majority vote of the output signals distributed to the common

5. An improved digital position indication system for displaying the relative position of a movable element with respect to fixed known coordinates including a sensor responsive to the element's position to provide discrete electrical outputs indicative thereof; an encoder electrically coupled to said sensor and operable upon said discrete outputs to provide a digital coded output representation of the element's position; an interface electrically communicating with said encoder and operable upon said digital coded output to transmit said digital coded output upon a corresponding command address signal; a plurality of at least three redundant control systems electrically communicating with said interface for generating, sequencing and transmitting said corresponding command address signal to said interface system to effect transmission and accommodate reception of said digital coded output, each of said plurality of control systems being operable upon said digital coded output to separately provide a redundant decoded display signal output indicative of the element's position to a common bus line; and a display responsive to the display output signal provided on said common bus line to provide a visual display of the element's position, wherein the improvement comprises: means for comparing said redundant decoded display

signal outputs and responsive to a difference in the display outputs to disconnect the respective output signals exhibiting the difference from the common bus and pass the remaining outputs to the common bus; and

means responsive to a difference in more than one of the outputs to control the comparing means to disconnect the display outputs exhibiting the difference from the common bus in a predetermined order of priority.

6. The position indication system of claim 5 wherein when all the display outputs exhibit a difference said means for controlling the comparing means prevents said comparing means from disconnecting from the

common bus the last output to be disconnected in accordance with the predetermined order of priority.

7. The position indication system of claim 5 wherein said means for comparing said display outputs includes a plurality of comparators corresponding to and individually associated with said plurality of control systems, each of said comparators being operable to compare its corresponding display output with all other display outputs and disconnect its corresponding display

output from the common bus if a difference is exhibited thereby with respect to the remaining display outputs.

8. The position indication system of claim 5 wherein said common bus output is connected to a threshold logic majority vote circuit having an output consistent with the majority of said display output signals which are communicated to said display.

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# EXHIBIT H

### United States Patent [19]

Gelderloos

[11]	4,321,437
[45]	Apr. 27, 1982

[54]	RECON MANA		RING REDUNDANCY
[76]	Invento	the Ad inv	pert A. Frosch, Administrator of National Aeronautics and Space ministration, with respect to an ention of Hendrik J. C. derloos, Largo, Fla.
[21]	Appl. N	To.: 173	,518
[22]	Filed:	Jul	. 30, 1980
[51] [52]			
[58]	Field of	Search	
[56]		Re	eferences Cited
	U.	S. PAT	ENT DOCUMENTS
	3,944,974	5/1972 8/1972 3/1976	Pfersch, Jr. et al

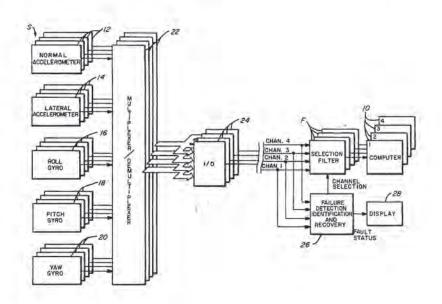
4,101,958	7/1978	Patterson et al	371/68
		Meredith et al	
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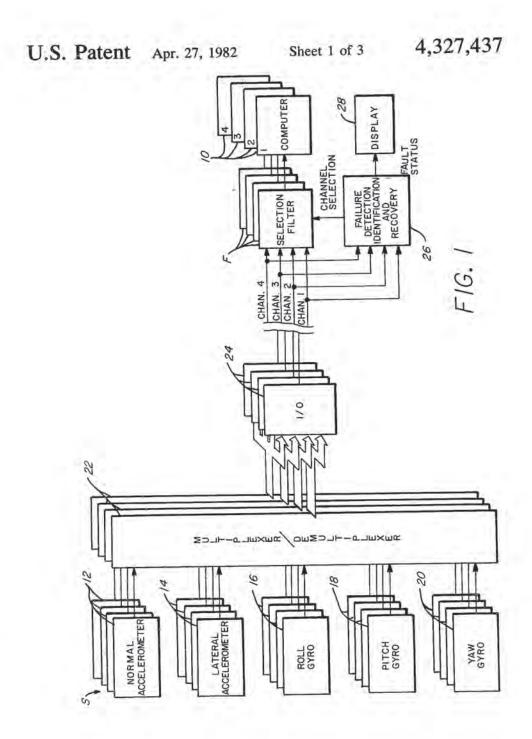
Primary Examiner—Charles E. Atkinson Attorney, Agent, or Firm—Carl O. McClenny; John R. Manning; Marvin F. Matthews

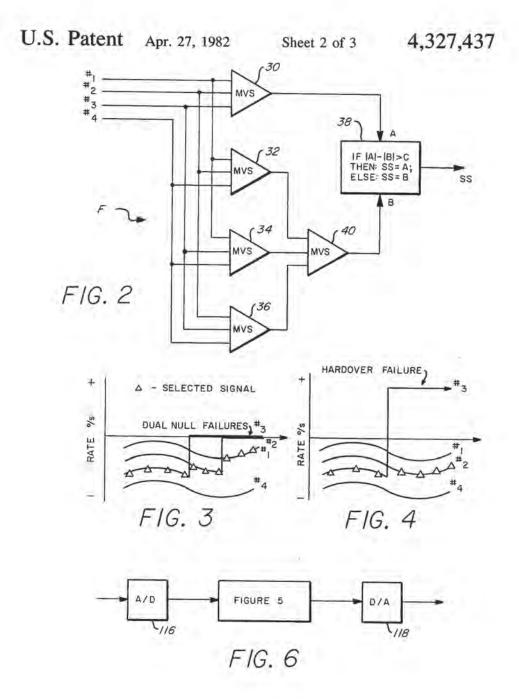
#### [57] ABSTRACT

Input signals from sensor (S) in a redundancy management system are provided redundantly in parallel so that a primary control signal may be selected. Median value signals for groups of three sensors are detected in median value selectors (30, 32, 34, 36, 40) of selection filters (F). The detected median value signals are then also compared in a subtractor/comparator (38) to determine whether any of them exceed the others by an amount greater than the signal level for a failed sensor. If so, the exceeding detected medium value signal is sent to a control computer (10) as the primary control signal. If not, the lowest level detected medium value signal is sent as the primary control signal.

18 Claims, 6 Drawing Figures







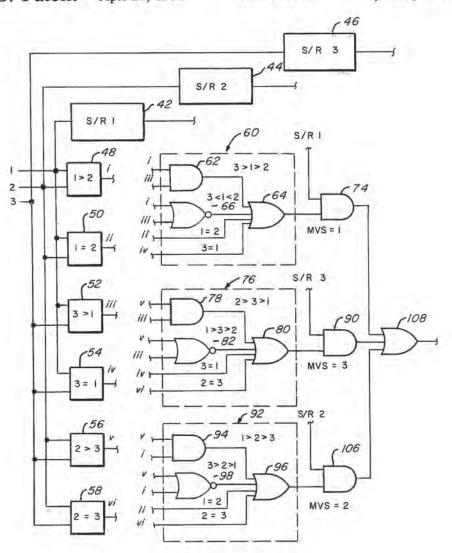


FIG. 5

#### RECONFIGURING REDUNDANCY MANAGEMENT

#### ORIGIN OF THE INVENTION

The invention described herein was made in the performance of work under a NASA contract and is subject to the provisions of Section 305 of the National Aeronautics and Space Act of 1958, Public Law 85-568 10 (72 Stat. 435; U.S.C. 2457).

#### DESCRIPTION

1. Technical Field

The present invention relates to error detection and 15 redundancy management of multiple sensors.

2. Background Art

In certain applications where reliability is critical, such as in advanced avionic systems, redundant components such as sensors, computers and actuators are used. 20 Failures of such components are detected and the system is reconfigured to compensate for the detected failure. System reliability thus becomes a function of how successfully the redundant equipment can be managed. Examples of such systems are those of U.S. Pat. 25 Nos. 3,895,223, 3,665,173 and 4,084,774.

In certain situations, sensor null failures occurred where a sensor would fail and produce a null or zero output plus or minus some specified tolerance level. Another type of sensor failure has been termed a har- 30 dover failure, where a sensor would fail and provide a full amplitude signal. For spacecraft in quiescent flight, it has been difficult to detect and identify sensor null failures, because nominal vehicle rates of close to zero degrees/second did not differ appreciably from a null 35 failure sensor reading. Additionally, during long periods of quiescent flight two separate null failures could have occurred and gone undetected.

In U.S. Pat. No. 3,639,778, voting circuits were used which operated in accordance with a truth table to select the second most positive input signal in one-half of the possible input conditions and the second most negative input signal for the other one-half of the possible inputs. However, situations existed where this selection technique would select a failed sensor input signal as the proper input signal due to the input selection

criteria

Another technique has been to form some form of weighted average value of the various input signals for 50 use as a comparison reference, such as in U.S. Pat. Nos. 3,667,057; 3,681,578 and 3,979,720. However in situations where actual sensed values are quite close in magnitude to the output of failed sensors, the desirability of weighted average comparison has been questioned.

#### DISCLOSURE OF INVENTION

Briefly, the present invention relates to the selection of a primary control signal for redundancy management in a system having a plurality of sensors providing input 60 signals redundantly in parallel to at least one control computer to provide the computer with the primary control signal representing an output from a properly operating, rather than a failed, sensor. In the preferred embodiment, the sensors are in an aircraft or spacecraft 65 avionics system and include accelerometers and gyroscopes for flight control of the craft. The present invention may be performed with analog circuitry, digital

Input signals in groups of three from the sensors are received and compared so that the median value signal of the three input signals can be detected. As used in the present invention, median value signal is defined as being the one of the input signals which is greater than or equal to one of the other two input signals while also being less than or equal to the other input signal.

The detected median value signals are then compared to determine if any one of the detected median value. signals exceeds the others by an amount greater than the signal level for a failed sensor. If this is the case, the detected median value signal which exceeds the others is transmitted to the control computer as the primary control signal. If it is not the case, the primary control signal transmitted to the control computer is the one of

lowest amplitude.

With the present invention the system continually reconfigures the redundant sensor inputs so as to minimize failure effects on system performance. Dual null failures of two sensors or a hardover failure of one sensor can be tolerated with the present invention. Further, due to the continual reconfiguration occurring prior to any attempt at detection or identification of the nature of the sensor failure, redundancy management may be performed at a later time and at a slower rate, minimizing computation load on the control computer.

#### BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 is a schematic diagram of a redundancy management system incorporating the present system

FIG. 2 is a schematic diagram of an apparatus according to the present invention;

FIGS. 3 and 4 are waveform diagrams illustrating the operation of FIG. 2; and

FIGS. 5 and 6 are schematic circuit diagrams of alternative circuitry which may be used in the apparatus of FIG. 2.

#### BEST MODE FOR CARRYING OUT THE INVENTION

In the drawings, a redundancy management system is set forth having a plurality of sensors S providing input signals redundantly in parallel to at least one control computer 10 to provide the computer 10 with a primary control signal representing the output from a properly operating, rather than a failed, sensor S. In the preferred embodiment, the sensors are in an aircraft or spacecraft avionics system, although it should be understood that the present invention may also be used in other types of redundancy management systems, if desired. As is typi-55 cal in redundancy management systems, a plurality of control computers 10 of like structure and function are provided to operate in a parallel arrangement.

In the preferred embodiment, the sensors S are arranged into a number of groups of like number to the number of control computers 10, with each sensor group including a normal accelerometer 12, a lateral accelerometer 14, a roll gyro 16, a pitch gyro 18 and a

Each of the groups of sensors S is electrically connected to an individual multiplexer/demultiplexer 22 which sequentially samples the sensors S connected thereto to determine the readings of such sensors. Since the multiplexer/demultiplexer circuits 22 are of like

structure and function, they bear like reference numerals in the drawings.

A plurality of input/output (I/O) data busses 24 of like structure and function are electrically connected to receive the readings from each group of sensors S from 5 the plural multiplexer/demultiplexers 22 to provide the computer 10 associated therewith with data readings from each of the groups of sensors in the form of multi-

ple parallel channels or data streams.

A selection filter F according to the present invention 10 receives the channels from the input/output bus 24 associated therewith and, in a manner to be set forth below, provides the computer 10 with a primary control signal SS, or selected signal, representing an output from a properly operating, rather than a failed, sensor. 15 The input/output busses 24 further provide the parallel channels of data from the sensor groups to a failure detection, identification and recovery operator 26, which may be any of several conventional types which detect failed sensors and provide fault status signals to a 20 display status indicator 28. The failure detection operator 26 further provides channel selection signals to the selection filter F in the event that a failure is detected. The failure detection technique depends, of course, on the particular type of conventional failure detection 25 operator 28 used and the number of failures detected and identified.

When all four channels are operating and no failures have been detected in the failure detection operator 26. the selection filter F of the present invention operates to 30 group the channels or input signals from the input/output busses 24 into groups of three, comparing the groups of three signals to choose the median value signal of the three input signals. As used in the present invention, median value signal is defined as being the 35 one of the input signals which is greater than or equal to one of the other two input signals while also being less than or equal to the other input signal.

In the selection filter F (FIG. 2), the detected median value signals are then compared to determine if any of the detected signals exceeds the others by an amount greater than the signal level for a failed signal. If this is the case, the detected median value signal which exceeds the others in such a manner is transmitted to the control computer 10 as the primary control signal. If no detected median value signal so exceeds the others, the primary control signal transmitted from the selection filter F to the control computer 10 is the one having the

lowest amplitude.

For example, in accordance with the present invention, for three input signals, a, b, c, the following control laws apply for definition of median value signal MVS depending upon the relative amplitude of the signals:

WHERE	b ≤ a ≤ c OR c ≤ a ≤ b	THEN MVS = a
WHERE	$a \le b \le c OR c \le b \le a$	THEN MVS = b
WHERE	$a \le c \le b ORb \le c \le a$	THEN MVS = c

The selection filter F operates in accordance with 60 these control laws to provide the control computer 10 with a proper primary control signal. The functions performed by the selection filter F may be implemented with a digital circuit, an analog circuit or may be performed in a properly programmed computer.

The operation of the present invention can more readily be understood by reference to FIG. 2, which indicates the functions performed by the selection filter

F, in whichever format. In the selection filter F, the channels of data from input/output bus 24 are provided in groups of three to four median value selector circuits or operators 30, 32, 34 and 36.

The median value selector value operator 30 forms a first selector section and receives input signals from channels 1, 2 and 3 and selects the median value signal therefrom, providing same as an input signal A to a subtractor/comparator 38. The median value selector operators 32, 34 and 36 form a first selector stage of a second selector section and receive input signals from the channels as indicated in FIG. 2, each selecting a median value signal from the three presented thereto and providing such median value signals as inputs to a median value selector operator 40 which forms a second selector stage of the second selector section. The median value selector 40 selects a median value signal from the three presented thereto from the median value selectors 32, 34 and 36 and provides the selected median value signal as an input signal B to the subtractor/comparator operator 38. Each of the median value selectors 30, 32, 34, 36 and 40 operate to indicate a median value signal from the three provided thereto in accordance with the controls laws defined above. Specific circuitry for performing this function and processing step will be set forth below.

In the subtractor/comparator operator 38, the absolute magnitude of the input signal B is subtracted from the absolute magnitude of the input signal A and the result obtained compared in a comparator with a reference level C, representing the maximum possible signal level output of a rate gyro which has failed to null. In the event that the absolute value of the input signal A to the subtractor/comparator 38 exceeds the absolute value of the input signal B by an amount greater than the reference level signal C, the subtractor/comparator operator 38 provides the signal A as the proper control signal SS to the flight control computer 10. In the event that the results of subtraction do not exceed the reference level C, the lower value input signal B is provided as the proper control signal SS to the computer 10.

From the foregoing, it can be seen that the functions performed in the subtractor/comparator operator 38 automatically selects a rate gyro output which exceeds the output of a rate gyro failed to null, and can continually reconfigure even where there are dual null failures. To illustrate, turning now to FIG. 3, the following charts represent output signals in the selection filter F at various times:

CHARI				
ALL FOUR CHANNELS OPERATING				
COMPONENT	OUTPUT (CHANNEL)			
SELECTOR 30	2			
32	2			
34	3			
36	3			
-40	3			
SUBTRACTOR/COMPARATOR 38	3			

#### CHART II

CHANNEL 3 FAILS NULL		
OUTPUT (CHANNEL)		
1		
2		
1		
2		
2		

#### CHART II-continued

NULL	
OUTPUT (CHANNEL)	
2	

#### CHART III

CHANNEL 2 NOW ALSO FAILS NULL		
COMPONENT	OUTPUT (CHANNEL)	
SELECTOR 30	NULL	
32	1	
34	1	
36	NULL	
40		
SUBTRACTOR/COMPARATOR 38	- i	

Referring now to FIG. 4, the following chart sets forth the operation of the selection filter F to detect the proper control signal in the event of a hardover failure to one of the sensors providing data in the input channel 20 thereto. Prior to the hardover failure of channel 3 illustrated in FIG. 4, the output signals from the components of the selection filter F are as set forth in Chart I above.

#### CHART IV

CHANNEL 3 FAILS H	ARDOVER
COMPONENTS	OUTPUT (CHANNEL)
SELECTOR 30	1
32	2
34	1
36	2
40	2
SUBTRACTOR/COMPARATOR 38	2

Thus, with the present invention, dual null failures or 35 one hardover failure can be tolerated while still ensuring that the control computers 10 receive a proper control signal.

#### DIGITAL IMPLEMENTATION

In FIG. 5, a digital implementation for the median value selector 30 operator in the selection filter F is set forth to implement and detect the median value signal presented thereto in accordance with the operating control laws set forth above. Other than the particular 45 channel inputs provided thereto, selectors 32, 34 and 36 and 40 are of like function and operation. Suitable power supplies and timing and control signals are, of course, provided. The input signals are first furnished to a bank of comparators by the connection indicated. The three input signals are also furnished to separate storage registers 42, 44 and 46 and are stored therein. A comparator 48 forms a logic "1" if the data on channel 1 exceeds in magnitude the data on channel 2. Should the data value on channel 2 exceed the data value on chan- 55 nel 1, the comparator 48 forms a logic "0" output signal. A comparator 50 forms a logic "1" output signal only when the data value on channel 1 equals the data value on channel 2. Otherwise, the output of the comparator

A comparator 52 forms a logic "1" output signal if the data value on channel 3 exceeds the magnitude of the data value of the data in channel 1. Should the data value on channel 1 exceed the data value on channel 3, the comparator 52 forms a logic "0" output signal. A 65 comparator 54 forms a logic "1" output signal only when the data value of the data on both channels 1 and 3 are equal. Otherwise, the output of the comparator 54

is a logic "0". Similarly, a comparator 56 forms a logic "1" if the data on channel 2 exceeds the magnitude of the data value on channel 3. If the data value on channel 3, however, exceeds the data value on channel 2, the 5 comparator 56 forms a logic "0" output signal. Finally, a comparator 58 forms a logic "1" signal only when the data value of the data on channels 2 and 3 are equal. Otherwise, the output of the comparator 58 is a logic "0" output.

The output signals from the foregoing comparators are furnished to various gating circuits shown in FIG. 5. In view of the number of such circuits and in order to preserve clarity in the drawings, the outputs from the comparators are assigned identifiers in accordance with the following chart:

COMPARATOR OUTPUT	IDENTIFIER
48	i
50	ii
52	iii
54	iv
56	V
58	VI

Other gates in FIG. 5 receiving these outputs as input signals are so designated by corresponding identifiers at their input terminals.

For example, the outputs from the comparators 48, 50, 52 and 54 are provided to a gating circuit 60 which includes AND gate 62 connected to the outputs of comparators 48 and 52 which forms a logic "1" output signal provided the conditions indicated at the output thereof are present with respect to the data magnitudes of channels 1, 2 and 3. The output from the AND gate 62 is provided as an input to an OR gate 64.

The OR gate 64 is further connected to a NOR gate 66 which receives the output signals from comparator 48 and 52 and provides a logic "1" output signal provided the conditions indicated at the output of gate 66 are fulfilled. The OR gate 64 also receives input signals from the comparators 50 and 54 and thus forms a logic "1" output signal in the event the condition detected by either of comparators 50 or 54 is fulfilled.

Analysis of the four input signals to the OR gate 64 indicate that the gating circuit 60 functions to select the signal on channel 1 as the median value signal in accordance with the control laws specified above, since the signal level of the signal on channel 1 either equals or exceeds the signal level on channel 2 and is less than or equal to the signal on channel 3, or conversely, equals or exceeds the signal level on channel 3 and is less than or equal to the signal level on channel 2. In such a situation, the OR gate 64 of the gating circuit 60 forms a logic "1" output signal which is furnished to an AND gate 74 permitting the data contents of shift register 42 containing the data value of the signals on channel 1 to pass therethrough as the median value signal.

The outputs from the comparators 52, 54, 56, and 58 are provided to a gating circuit 76 which includes AND gate 78 connected to the outputs of comparators 56 and 52 which forms a logic "1" output signal provided the conditions indicated at the output thereof are present with respect to the data magnitudes of channels 1, 2 and 3. The output from the AND gate 78 is provided as an input to an OR gate 80. The OR gate 80 is further connected to a NOR gate 82 which receives the output signals from comparator 52 and 56 and provides a logic

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"1" output signal provided the conditions indicated at the output of gate 82 are fulfilled. The OR gate 80 also receives input signals from the comparators 54 and 58 and thus forms a logic "1" output signal in the event the condition detected by either of comparators 54 or 58 is 5 fulfilled.

Analysis of the four input signals to the OR gate 80 indicates that the gating circuit 76 functions to select the signal on channel 3 as the median value signal in accordance with the control laws specified above, since the 10 signal level of the signal on channel 3 either equals or exceeds the signal level on channel 2 and is less than or equal to the signal on channel 1, or conversely, equals or exceeds the signal level on channel 1 and is less than or equal to the signal level on channel 2. In such a situation, the OR gate 80 of the gating circuit 76 forms a logic "1" output signal which is furnished to an AND gate 90 permitting the data contents of shift register 46 containing the data value of the signals on channel 3 to pass therethrough as the median value signal.

The outputs from the comparators 48, 50, 56, and 58 are provided to a gating circuit 92 which includes AND gate 94 connected to the outputs of comparators 48 and 56 which forms a logic "1" output signal provided the conditions indicated at the output thereof are present 25 with respect to the data magnitudes of channels 1, 2 and 3. The output from the AND gate 94 is provided as an input to an OR gate 96. The OR gate 96 is further connected to a NOR gate 98 which receives the output signals from comparator 48 and 56 and provides a logic 30 "1" output signal provided the conditions indicated at the output of gate 98 are fulfilled. The OR gate 96 also receives input signals from the comparators 50 and 58 and thus forms a logic "1" output signal in the event the conditions detected by either of comparators 50 or 58 is 35 fulfilled.

Analysis of the four input signals to the OR gate 96 indicate that the gating circuit 92 functions to select the signal on channel 2 as the median value signal in accordance with the control laws specified above, since the 40 signal level of the signal on channel 2 either equals or exceeds the signal level on channel 1 and is less than or equal to the signal level on channel 3 and is less than or equal to the signal level on channel 3 and is less than or equal to the signal level on channel 1. In such a situation, the OR gate 96 of the gating circuit 92 forms a logic "1" output signal which is furnished to an AND gate 106 permitting the data contents of shift register 44 containing the data value of the signals on channel 2 to pass therethrough as the median value signals.

Finally, the single output stage of the MVS selector is a triple input OR gate 108 receiving outputs from AND gates 74, 90 and 106.

As has been set forth above, each of the remaining median value selectors 32, 34 and 36 and 40 are of like 55 construction and function, with the exception of the different input channels provided thereto.

The selector 30 selects the median value signal from channels 1, 2 and 3 and provides such signal as the input signal A to the absolute value subtractor/comparator 60 38. Further, the selectors 32, 34 and 36 in the first selector stage of the second selector station each operate in a like manner to the selector set forth in FIG. 5 and select the median value signal from the three input signals provided thereto, furnishing such median value signals 65 to the second selector stage 40 which forms an output signal B representing the median value signal of the three median value signals selected in the first selector

group of the second selector stage. Further, the selector 40 provides the output signal B as as input to the subtractor/comparator 38 which functions in the manner described above.

It is evident to those skilled in the art that the new and improved operating sequence of steps above performed in the digital implementation operating in accordance with the control laws set forth above could equally as well be performed in a properly programmed general purpose digital computer which would perform comparisons to determine median value signals between two groups of the input signals, determine median value signals from each section, subtract the absolute value of the median value signals in each section and compare the subtraction results to a predetermined reference level stored in memory to select a primary control signal for provision to the control computer 10.

#### ANALOG IMPLEMENTATION

In the event that the present invention is to be performed on analog signals, input analog data would first be provided to an analog-to-digital (A/D) converter 116 which would convert the input data from each of the four channels into digital data which would be furnished as input signals to the digital selector F described above in FIGS. 2 and 5 and the proper control signal would then be furnished as an input signal to a digital-to-analog (D/A) converter 118 where it would be again converted into an analog value representing the proper control signal. Of course, analog comparators and gating circuits operating according to the principles of the control laws and in the manner of the median value selector digital circuit of FIG. 5 could as well be used.

#### OPERATION OF INVENTION

In the operation of the present invention, input data from the groups of sensors S are collected in the multiplexer slot/demultiplexer circuits 22 and provided in parallel, redundant groups through the input/output busses 24 to each of the control computers 10 through the selection filters F associated therewith. The selection filters F group the input signals into groups of three and compare the input signal so that the median value signal of the three input signals can be detected. The detected median value signals from the median value selector operators are then compared in the subtractor/comparator operator 38 to determine if any of the detected median value signals exceeds the others by an amount greater than the signal level for a failed sensor. If this is the case, the excessive detected median value signal is provided as the control signal to the control computer 10. If the converse is the case, the lowest amplitude detected median value signal is provided as the proper control signal to the control computer 10.

Since the comparison level in the comparator 38 represents the maximum possible output of a rate gyro sensor which has failed to null, with the present invention, any rate gyro output level which exceeds such a maximum possible output is logically selected. Thus, even in the event of dual null failures during quiescent operation, the selection filter F of the present invention continually reconfigures around dual null failures, instantly switching to the proper control signal at the time of the first null failure (FIG. 3) and then again at the time of the second null failure (FIG. 3). It is to be noted that with the present invention, reconfiguration by the selection filter F to the proper control signal occurs prior to detection and identification of the nature of the

failure by the failure detection operator 26. Thus, with the present invention, null failed or hardover failed sensors are disregarded in redundancy management until such time as sensor reading rates increase. At this time, the redundancy management techniques will be 5 more able to distinguish null output from proper sensor outputs and detect rate gyro null failures. Further, with the present invention, the redundancy management techniques of the present invention permit fast reconfiguration with minimal processing time required of the control computer 10 and with minimal requirements on the memory resources of the control computer 10, allowing redundancy management implementation to later detect failures at a slower processing rate.

The foregoing disclosure and description of the invention are illustrative and explanatory thereof, and various changes in the size, shape, materials, components, circuit elements, wiring connections and contacts, as well as in the details of the illustrated circuitry and construction may be made without departing 20

from the spirit of the invention.

We claim:

1. An apparatus for selecting a primary control signal for redundancy management in a system having a plurality of sensors providing input signals in parallel to a 25 control computer to provide the computer with a primary control signal representing an output from a properly operating sensor, comprising:

(a) selector means for receiving and comparing input signals in groups of three from the sensors and 30 detecting the median value signal of the three input

signals;

- (b) comparator means for comparing the detected median value signals to determine if any one of the detected median value signals exceeds the others 35 by an amount greater than the signal level for a failed sensor;
- (c) said comparator means further including means for transmitting to the control computer as the primary control signal a detector median value 40 signal which exceeds the others by an amount greater than the signal level for a failed sensor and means for transmitting to the control computer as the primary control signal the least of the detected median value signals when no detected median 45 value so exceeds the others.
- The apparatus of claim 1, wherein said comparator means comprises:
  - comparator means for comparing the detected median value signals to determine if any one of the 50 detected median value signals exceeds the others by an amount greater than the signal level for a null failed sensor.
- The apparatus of claim 1, wherein said comparator means comprises:
  - (a) means for forming a difference signal representing the difference between absolute values of the detected median value signals; and
  - (b) means for comparing the difference signal with the signal level for a failed sensor.
- The apparatus of claim 1, wherein the sensors are sensors in an avionic system.
- The apparatus of claim 4, wherein the sensors include accelerometers.
- The apparatus of claim 4, wherein the sensors in- 65 clude gyroscopes.
- 7. The apparatus of claim 1, wherein said selector means comprises:

 (a) a first selector section for receiving three input signals for detecting the median value signal of such input signals;

(b) a second selection section having:

 an initial selector stage having at least three selectors, each for detecting the median value signal of such input signals furnished thereto; and

(2) a further selector stage having as inputs the median value signals from said initial selector stage for detecting the median value signal of such input signals.

8. The apparatus of claim 7, wherein said comparator

means comprises:

- means for comparing the detected median value signals from said first selection section and said second selection section to determine if any one of the detected median value signals exceeds the others by an amount greater than the signal level for a failed sensor.
- 9. An apparatus for selecting a primary control signal for redundancy management in a system having a plurality of groups of sensors, each sensor group providing input signals in parallel to a plurality of control computer to provide the computers with primary control signals representing outputs from properly operating sensors, comprising:

(a) selector means for receiving and comparing input signals in groups of three from the sensors and detecting the median value signal of the three input

signals:

(b) comparator means for comparing the detected median value signals to determine if any one of the detected median value signals exceeds the others by an amount greater than the signal level for a failed sensor;

(c) said comparator means further including means for transmitting to the control computer as the primary control signal a detected median value signal which exceeds the others by an amount greater than the signal level for a failed sensor and means for transmitting to the control computer as the primary control signal the least of the detected median value signals when no detected median value so exceeds the others.

10. A method of selecting a primary control signal for redundancy management in a system having a plurality of sensors providing input signals in parallel to a control computer to provide the computer with a primary control signal representing an output from a properly operating sensor, comprising the steps of:

(a) receiving and comparing input signals in groups of three from the sensors and detecting the median

value signal of the three input signals;

(b) comparing the detected median value signals to determine if any one of the detected median value signals exceeds the others by an amount greater than the signal level for a failed sensor;

(c) transmitting to the control computer as the primary control signal as a detector median value signal which exceeds the others by an amount greater than the signal level for a failed sensor; and

(d) transmitting to the control computer as the primary control signal the least of the detected median value signals when no detected median value so exceeds the others.

11. The method of claim 10, wherein said step of comparing comprises: 30

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comparing the detected median value signals to determine if any one of the detected median value signals exceeds the others by an amount greater than the signal level for a null failed sensor.

12. The method of claim 10, wherein said step of 5

comparing comprises:

- (a) forming a difference signal representing the difference between absolute values of the detected median value signals; and
- (b) comparing the difference signal with the signal 10 level for a failed sensor.
- 13. The method of claim 10, wherein the sensors are sensors in an avionic system.
- 14. The method of claim 13, wherein the sensors include accelerometers.
- 15. The method of claim 13, wherein the sensors include gyroscopes.
- 16. The method of claim 10, wherein said step of receiving and comparing input signals comprises:
- (a) dividing the received signals into two groups; and 20 (b) comparing the input signals of the two groups to determine a detected median value signal in each of the two groups.
- 17. The method of claim 16, wherein said step of comparing the detected median value signals comprises: 25 comparing the detected median value signals from the first group and the second group to determine

if any one of the detected median value signals exceeds the others by an amount greater than the signal level for a failed sensor.

18. A method of selecting a primary control signal for redundancy management in a system having a plurality of groups of sensors, each sensor group providing input signals in parallel to a plurality of control computers to provide the computers with primary control signals representing outputs from properly operating sensors, comprising the steps of:

(a) receiving and comparing input signals in groups of three from the sensors and detecting the median

value signal of the three input signals;

(b) comparing the detected median value signals to determine if any one of the detected median value signals exceeds the others by an amount greater than the signal level for a failed sensor;

(c) transmitting to the control computer as the primary control signal a detector median value signal which exceeds the others by an amount greater than the signal level for a failed sensor; and

(d) transmitting to the control computer as the primary control signal the least of the detected median value signals when no detected median value so exceeds the others.

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# EXHIBIT I



#### US005570300A

### United States Patent [19]

Henry et al.

[11] Patent Number:

5,570,300

[45] Date of Patent:

Oct. 29, 1996

#### [54] SELF-VALIDATING SENSORS

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[73] Assignee: The Foxboro Company, Foxboro,

[21] Appl. No.: 406,805

[22] Filed: Mar. 20, 1995

#### Related U.S. Application Data

[63]	Continuation of Ser. No. 51,192, Apr. 21, 1993, abandoned.
[30]	Foreign Application Priority Data
Apr	22, 1992 [GB] United Kingdom 9208704
[51]	Int, Cl.6 G01B 21/00
[52]	U.S. Cl
[58]	Field of Search

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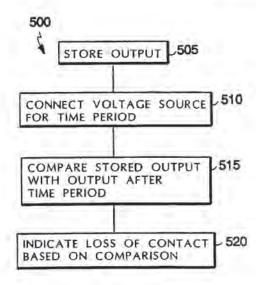
Primary Examiner—Edward R. Cosimano Attorney, Agent, or Firm—Fish & Richardson P.C.

#### 571 ABSTRACT

A sensor for provides a measurement and information about the validity of the measurement. The sensor includes a transducer for generating a data signal related to the value of a variable and a transmitter for receiving the data signal and generating output signals. The transmitter generates a first output signal related to the value of the variable. The transmitter also generates a second output signal based on a dynamic uncertainty analysis of the first output signal.

#### 21 Claims, 17 Drawing Sheets

Microfiche Appendix Included (6 Microfiche, 234 Pages)



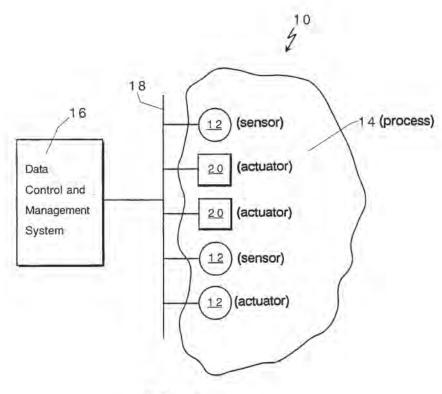
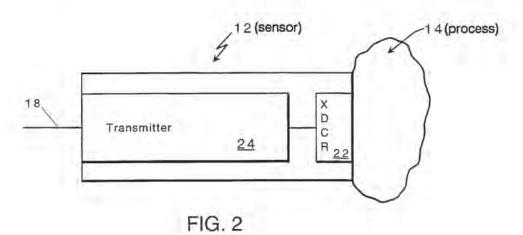


FIG. 1



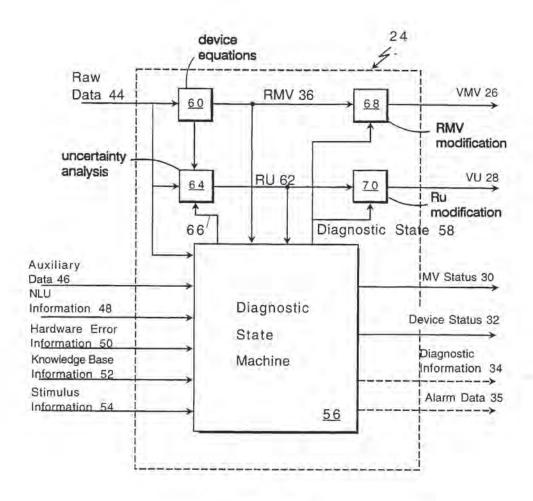
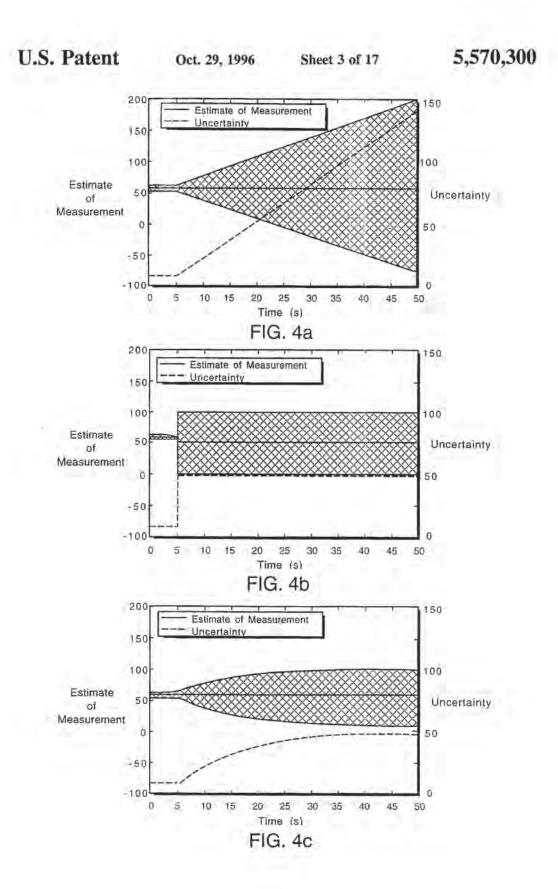


FIG. 3



Pharmatech Solutions, Inc: EXHIBIT 1031 - 137 IPR2013-00247, U.S. Pat. No. 7,250,105

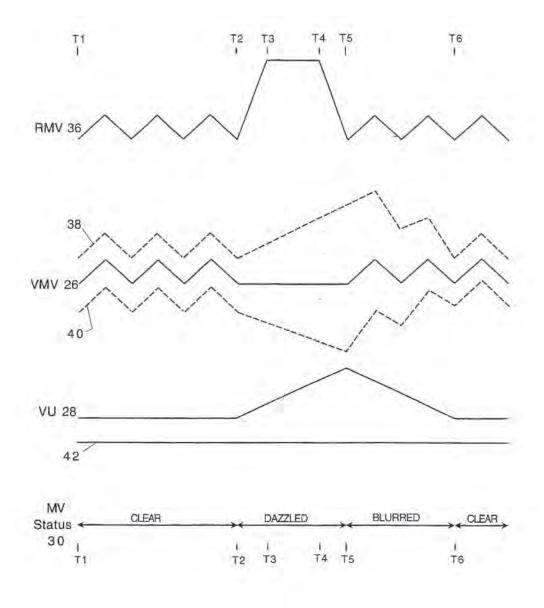


FIG. 5

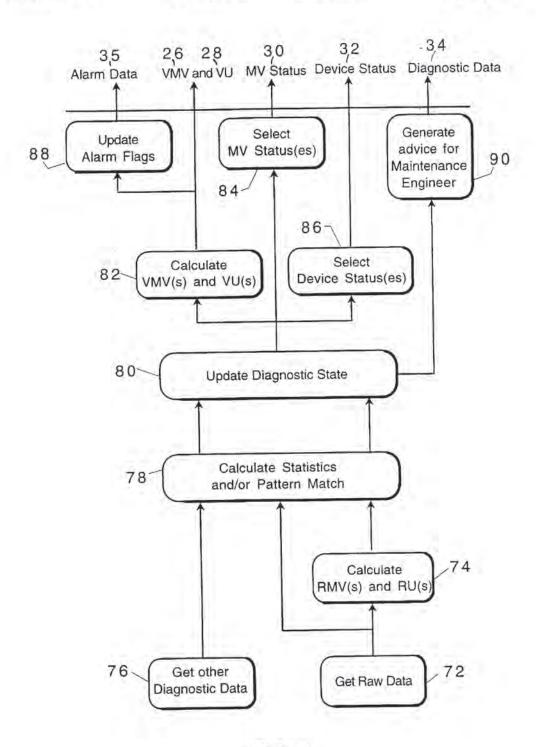
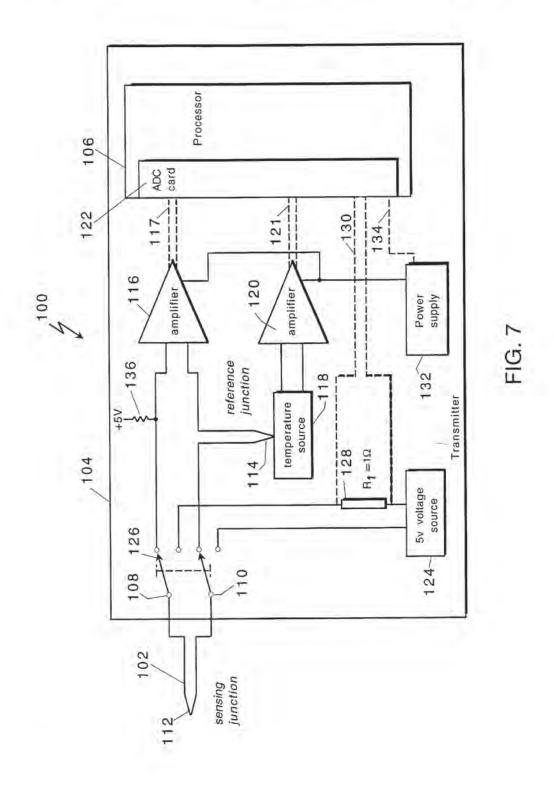
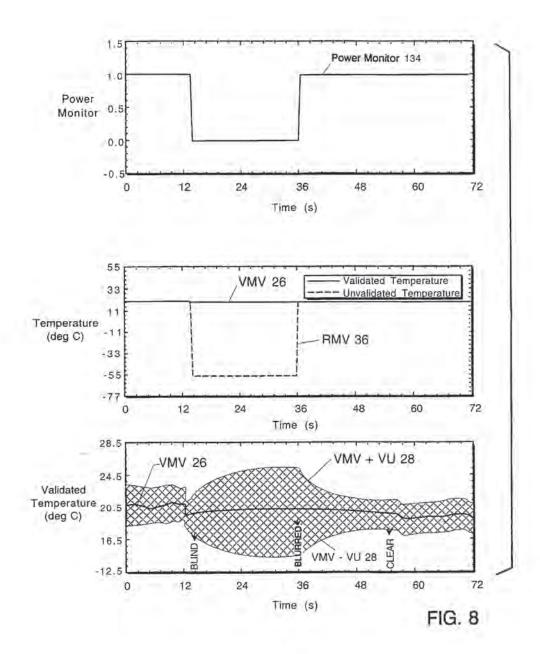
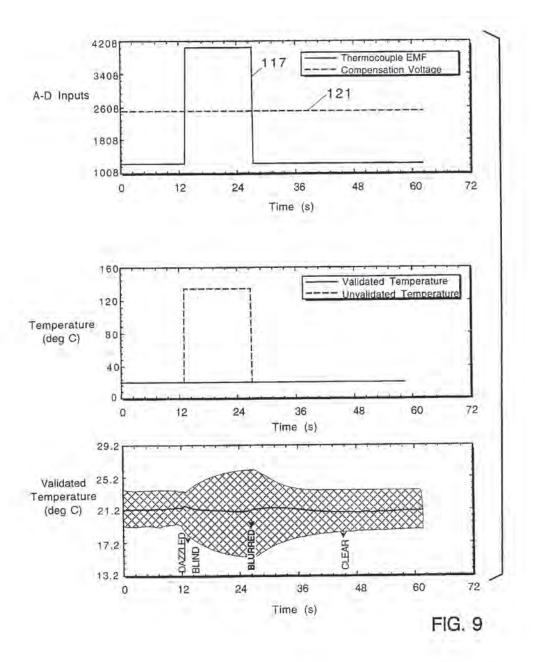


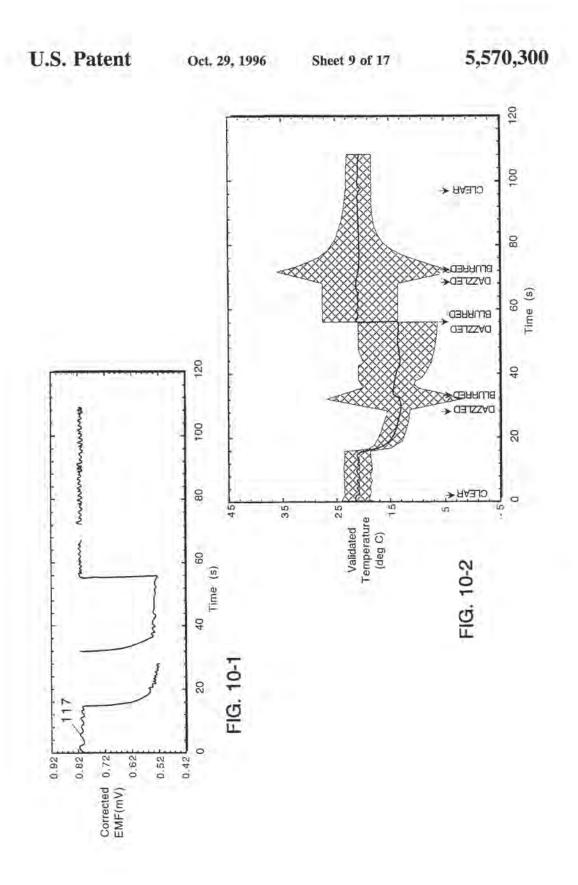
FIG. 6

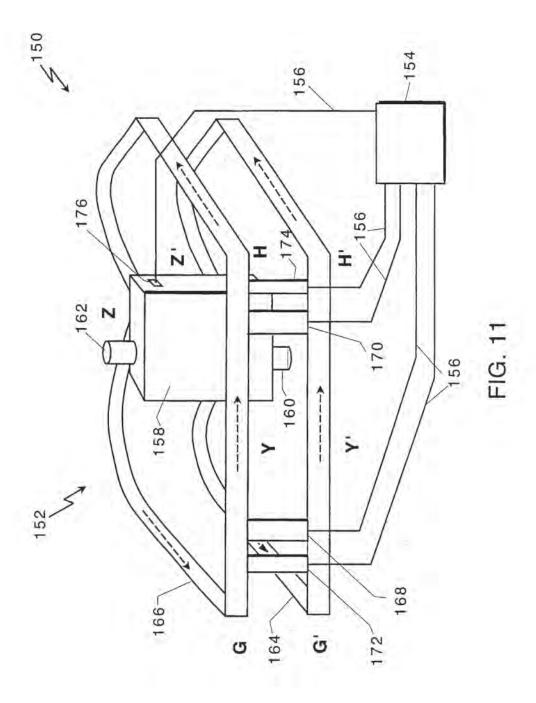
U.S. Patent Oct. 29, 1996 Sheet 6 of 17 5,570,300











Step/ (Fig. 6 step)	Action		
200 (72)	Get raw data.		
202 (74)	Calculate temperature RMV and RU.		
204 (74)	Calculate density RMV and RU.		
206 (74)	Calculate mass flow RMV and RU.		
208 (74)	Consider all inputs.		
210 (78, 80, 84, 86)	Make diagnosis.		
212 (80)	Correct all inputs.		
214 (82)	Calculate temperature VMV and VU.		
216 (82)	Calculate density VMV and VU.		
218 (82)	Calculate mass flow VMV and VU.		

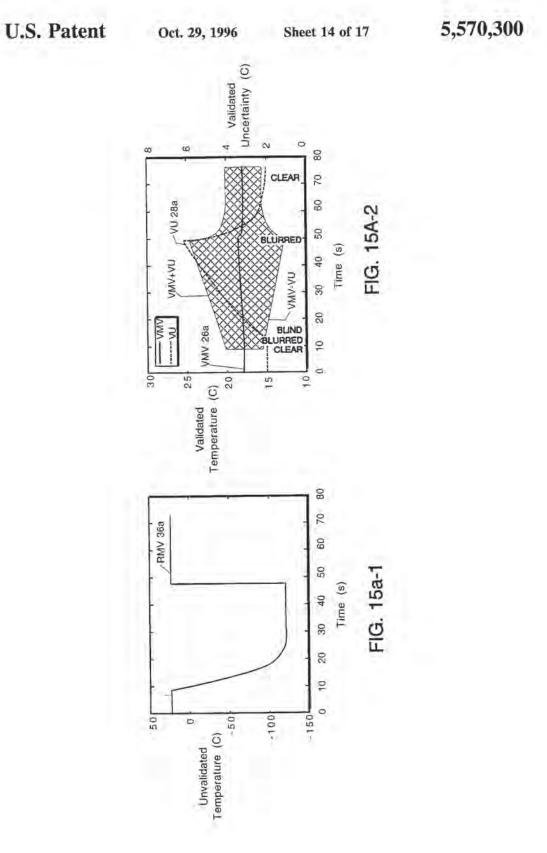
FIG. 12

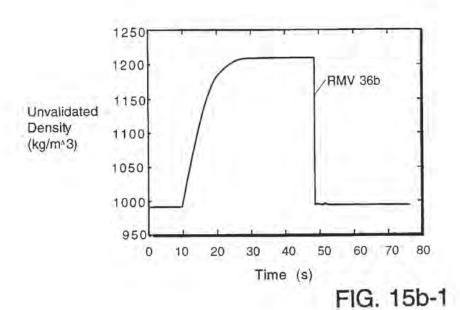
```
Step
          Action
250
          R = (RK1 * tran_temp + RK2) * f_RTD +
               RK3 * tran_temp + RK4
                [RK1-4 are calibration constants, tran_temp is
                the temperature of transmitter 154, and f_RTD
                is the frequency of the signal coming out of
                RTD temperature sensor 176.]
 252
          d_R = sqrt (
                       sqr (tran_temp * f_RTD * d_RK1) +
                       sqr (f_RTD * d_RK2) +
                          sqr (tran_temp * d_RK3) +
                          sqr (d_RK4) +
                          sqr ((RK1 * f_RTD + RK3) *
                               d_tran_temp) +
                          sqr ((RK1 * tran_temp + RK2) *
                                d_f_{RTD}
                       [d_x is the uncertainty of x.]
 254
           temperature = RTD_A * R * R + RTD_B * R + RTD_C
 256
           d_temperature = (2.0 * RTD_A * R + RTD_B) * d_R
```

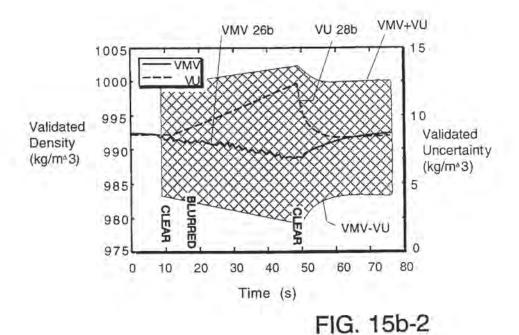
FIG. 13

Step	Action
300	Check RTD_ input_state
302	If RTD_INPUT_OK
304	If RTD_ resistance < 80.0
306	RTD_input_state = RTD_INPUT_LOST
308	If RTD_spike_state <> RTD_SPIKE_OFF
310	RTD_spike_state = RTD_SPIKE_OFF
312	If RTD_INPUT_LOST
314	If RTD_ resistance < 100.0
316	Temperature MV status = BLIND
318	Substitute historical temperature
320	Density MV status = BLURRED
322	Mass Flow MV status = BLURRED
324	Else
326	RTD_input_state = RTD_INPUT_RECOVER
328	RTD_input_count = 0
330	If RTD_INPUT_RECOVER
332	Merge past and present temperature
334	If RTD_input_count = 90
336	RTD_input_state = RTD_INPUT_OK
338	Else
340	Temperature MV status = BLURRED
342	Increment RTD_input_count

FIG. 14









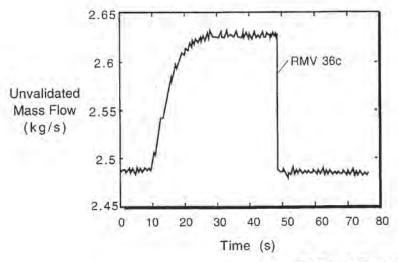


FIG. 15c-1

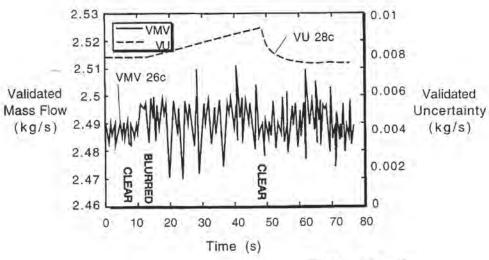
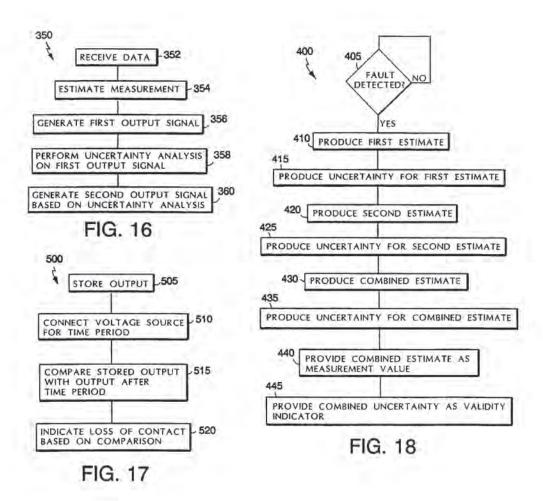


FIG. 15c-2



This application is a continuation of U.S. application Ser. No. 08/051,192, filed Apr. 21, 1993, now abandoned.

#### REFERENCE TO MICROFICHE APPENDICES

Two microfiche appendices are attached to this application, Appendix 1, which includes software for implementing a self-validating Coriolis meter according to the invention, 10 includes 125 frames on three microfiche. Appendix 2, which includes software for implementing a self-validating temperature sensor according to the invention, includes 109 frames on three microfiche.

#### BACKGROUND OF THE INVENTION

This invention relates to sensors and to control systems incorporating sensors.

A sensor generates measurement data. Typically, the measurement data is a signal that estimates the value of a process variable. In practice, the signal does not perfectly represent the value of the process variable. Instead, the signal also includes effects resulting from the sensor (such as sensor faults or distortion) and other process influences (including 25 those attributable to "faulty" process behavior).

Sensor and control system designers employ numerous techniques to increase the reliability of measurement data. For example, sensor designers try to develop improved sensor designs that minimize both the occurrence of sensor faults and the distortions occurring during normal operation. In another approach, control system designers implement rigorous programs of sensor checking, maintenance, and calibration to reduce both the frequency at which sensor faults occur and the distortion caused by poorly maintained sensors.

In conjunction with increasing the reliability of measurement data, designers employ fault detection techniques to increase a control system's ability to recognize that measurement data is unreliable. For example, control system designers often rely on sensor redundancy to reduce the effect of any sensor fault that may occur. If measurement data from a sensor in a group of redundant sensors is inconsistent with measurement data from other sensors in the group, a control system can designate the inconsistent data as unreliable and ignore that data.

In another approach to fault detection, control systems monitor information about the process and the sensor for signs of sensor faults. Until recently, sensors have been 50 limited to a single analog communication channel, normally based on the 4-20 mA convention, and, therefore, have been unable to transmit signals other than a measurement data signal. Faced with this limitation, users of process fault detection techniques have tried to extract sensor and process 55 fault information from measurement data. However, in attempting to minimize distortion of the measurement data, sensor designers have tried to eliminate, by sophisticated filtering and other means, every component of the measurement data signal that does not actually relate to the variable 60 being measured. Thus, improved sensor designs have limited the information available for extraction from the measurement signal for fault detection purposes.

Recent use of digital communications technology by control system designers has enabled sensors to transmit 65 multiple signals. This, in combination with internal diagnostics generated by microprocessors, which are now com2

monly embedded within sensors, has resulted in sensors that are able to perform fault detection analyses internally and transmit the results of these analyses as a fault information signal. Typically, the fault information signal is either a device specific error code or a single bit which indicates that the sensor is either functional or nonfunctional.

#### SUMMARY OF THE INVENTION

The invention provides a self-validating sensor for use in process control systems, A self-validating sensor provides, based on all information available to the sensor, a best estimate of the value of a parameter being monitored. Because the best estimate is based, in part, on nonmeasurement data, the best estimate does not always conform to the value indicated by the current, possibly faulty, measurement data. A self-validating sensor also provides information about the uncertainty and reliability of the best estimate, as well as information about the operational status of the sensor. Uncertainty information is derived from known uncertainty analyses and is provided even in the absence of faults.

In one aspect, generally, the invention features a sensor that includes a transducer that generates a data signal related to the value of a variable and a transmitter that receives the data signal and generates output signals in response. The transmitter generates a first output signal related to the value of the variable and a second output signal based on a dynamic uncertainty analysis of the first output signal. When the sensor experiences a fault, the transmitter modifies the first and second output signals to account for the impact of the fault. In some embodiments, the transmitter generates a third output signal that indicates a state of reliability of the first output signal.

The second output signal, which provides on line uncertainty, can be used for data quality management. A specified maximum permitted uncertainty can be used, for example, in specifying plant instrumentation, supervising feedback control, scheduling maintenance, and demonstrating adequate data quality for environmental compliance or custody transfer applications.

Generally, the invention provides a standard, deviceindependent method of communicating sensor faults and measurement quality, which eases integration into control schemes. In some cases, this avoids the cost of sensor redundancy and constant calibration programs, which, in any large or complicated process plant, are quite costly and of dubious value.

The invention also eases implementation of fault detection schemes by supplying a common set of variables in a generic form for use by control systems and requiring sensor designers, who are in the best position to recognize and define faulty behavior, to implement the actual fault detection in the sensors themselves.

#### BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a block diagram of a process control system with multiple sensors and actuators.

FIG. 2 is a block diagram of a sensor according to the invention.

FIG. 3 is a block diagram showing the flow of information in the sensor of FIG. 2.

FIGS. 4A-4C are graphs showing methods of responding to a fault in the sensor of FIG. 2.

FIG. 5 is a composite graph of various signals produced by the sensor of FIG. 2 versus time.

FIG. 6 is a block diagram showing the timing of information flow in the sensor of FIG. 2.

FIG. 7 is a block and schematic diagram of a temperature 5 sensor according to the invention.

FIG. 8 is a set of composite graphs of an auxiliary signal (upper graph), raw temperature (middle graph), and validated temperature and uncertainty (lower graph) versus time for the instrument of FIG. 7.

FIG. 9 is a set of composite graphs of raw data (upper graph), raw temperature (middle graph), and validated temperature and uncertainty (lower graph) versus time for the instrument of FIG. 7.

FIGS. 10-1 and 10-2 are graph of auxiliary data (FIG. 10-1) and validated temperature and uncertainty (FIG. 10-2) for the instrument of FIG. 7.

FIG. 11 is a schematic and block diagram of a Coriolis flow meter.

FIG. 12 is pseudocode showing steps performed by the meter of FIG. 11 during each sampling period.

FIG. 13 is pseudocode showing steps performed by the meter of FIG. 11 in determining temperature and associated uncertainty.

FIG. 14 is pseudocode showing steps performed by the meter of FIG. 11 in diagnosing a fault.

FIGS. 15a-1, 15A-2, 15b-1, 15b-2, 15c-1 and 15c-2 are a set of composite graphs showing the effect of a loss of 30 temperature on temperature (FIGS. 15a-1 and 15A-2), density (FIGS. 15b-1 and 15b-2), and mass flow rate (FIGS. 15c-1 and 15c-2) versus time for the meter of FIG. 11.

FIG. 16 is a block diagram of a procedure implemented by the sensor of FIG. 2.

FIG. 17 is a flow chart of a procedure for responding to the detection of a fault.

FIG. 18 is a flow chart of a procedure for detecting a loss of contact fault.

#### DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. 1, in a process control system 10, a plurality of sensors 12 monitor parameters of a process 14 and provide signals about the monitored parameters to a data control and management system 16 on a digital communications link 18. Digital communications link 18 allows bidirectional communication between multiple central processing units 16, sensors 12, and process actuators 20. In response to signals from sensors 12, data control and management system 16 sends process control signals to process actuators 20 on digital communications link 18. Thereafter, process actuators 20 respond to process control signals from data control and management system 16 by modifying parameters of process 14.

Because data control and management system 16 relies on measurement signals from sensors 12 in controlling process 14, measurement signals from sensors 12 need to be accurate and reliable. A given sensor 12 typically cannot guarantee complete accuracy and reliability; instead, sensor 12 provides data control and management system 16 with indications of the uncertainty (which, in turn, indicates the accuracy) and the reliability of the measurement signals.

Referring also to FIG. 2, sensor 12 includes one or more transducers 22 that monitor the values of parameters of

process 14 and provide signals to a transmitter 24. Transmitter 24 samples the signals from transducers 22 and produces measurement values for the parameters being monitored by transducers 22. Transmitter 24 validates the measurement values and provides the validated measurement values, along with an indication of the uncertainty of the validated measurement values, to data control and management system 16 via digital communications link 18. In addition, transmitter 24 generates signals indicating the reliability of the validated measurement values provided by sensor 12 and the operational status of sensor 12, and provides these signals to data control and management system 16 via digital communications link 18.

Transmitter 24 generates the signals provided to data control and management system 16 during a sample period and transmits the signals at the end of the sample period. Typically, the duration of a sample period is less than one second, but this duration can be adjusted as required by a particular application.

As shown in FIG. 3, transmitter 24 typically provides four signals to data control and management system 16:

 VMV 26—a validated measurement value of a process parameter (transmitter 24's best estimate of the value of the measured parameter),

 VU 28—a validated uncertainty associated with VMV 26.

(3) MV status 30—the status of VMV 26 (the manner in which VMV 26 was calculated), and

(4) device status 32—the operational status of the sensor. If sensor 12 measures multiple process parameters, transmitter 24 produces a version of VMV 26, VU 28, and MV status 30 for each process parameter.

In some circumstances, transmitter 24 can provide additional information. For example, upon a request by data control and management system 16, transmitter 24 provides detailed diagnostic information 34 about the status of sensor 12. Also, when a measurement has exceeded, or is about to exceed, a predetermined limit, transmitter 24 can send alarm data 35. Typically, different alarm levels can be used to indicate the severity with which the measurement has deviated from the predetermined value.

VMV 26 and VU 28 are numeric values. For example, VMV 26 could be a temperature measurement valued at 200 degrees and VU 28, the uncertainty of VMV 26, could be 9 degrees. In this case, there is a high probability (typically 95%) that the actual temperature being measured falls within an envelope around VMV 26 and designated by VU 28 (191 degrees to 209 degrees).

Transmitter 24 generates VMV 26 based on a signal produced by transducer 22. First, transmitter 24 derives RMV 36, an unvalidated image of the measured process parameter that is based on the signal generated by transducer 22. Typically, when transmitter 24 detects no abnormalities in sensor 12, transmitter 24 has nominal confidence in RMV 36 and sets VMV 26 equal to RMV 36.

As discussed in more detail below, when transmitter 24 detects an abnormality in sensor 12, transmitter 24 does not set VMV 26 equal to RMV 36. Instead, transmitter 24 sets VMV 26 to a value that transmitter 24 considers to be a better estimate of the actual parameter than RMV 36. If transmitter 24 detects a fault in sensor 12 that only partially affects the reliability of RMV 36 such that transmitter 24 has reduced confidence in RMV 36, transmitter 24 typically rederives RMV 36 by modifying the parameters used in deriving RMV 36 to account for the fault, and sets VMV 26 equal to the new value of RMV 36. Alternatively, if trans-

#### 5,570,300

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mitter 24 detects a fault in sensor 12 which indicates that RMV 36 bears no relation to the actual measured value such that transmitter 24 has zero confidence in RMV 36, transmitter 24 sets VMV 26 to a value based on past performance.

Referring also to FIGS. 4A-4C, three examples of past performance values include short term past values, long term past values, and a combination of long and short term past values. As shown in FIG. 4A, when short term past values are used, VMV 26 can equal the value of VMV 26 had immediately prior to the fault that occurs at time 5. As shown in FIG. 4B, when long term past value are used, VMV 26 can equal the average value of VMV 26. As shown in FIG. 4C, when a combination of long and short term past values is used, the long and short term past values can be combined using the following equation, which weighs each value according to its uncertainty:

$$VMV_{L6,S} = \frac{VU_L^2}{VU_L^2 + VU_S^2} + VMV_S + \frac{VU_S^2}{VU_L^2 + VU_S^2} + VMV_I$$

where  $VU_L$  and  $VU_S$  are the long and short term past values  $^{20}$  for  $VU\,28$  and  $VMV_L$  and  $VMV_S$  are the long and short term past values for  $VMV\,26$ .

Transmitter 24 generates VU 28 based on a raw uncertainty signal, RU 62, that is the result of a dynamic uncertainty analysis of RMV 36. Transmitter 24 performs this 25 uncertainty analysis during each sampling period.

Uncertainty analysis, originally described in "Describing Uncertainties in Single Sample Experiments," S. J. Kline & F. A. McClintock, Mech. Eng., 75, 3–8 (1953), has been widely applied and has achieved the status of an international standard for calibration. Essentially, an uncertainty analysis provides an indication of the "quality" of a measurement. Every measurement has an associated error, which, of course, is unknown. However, a reasonable limit on that error can often be expressed by a single uncertainty number (ANSI/ASME PTC 19.1-1985 Part 1, Measurement Uncertainty: Instruments and Apparatus).

As described by Kline & McClintock, for any observed measurement M, the uncertainty in M, w<sub>M</sub>, can be defined as follows:

where M is true ( $M_{true}$ ) with a certain level of confidence (typically 95%). This uncertainty is readily expressed in a 45 relative form as a proportion of the measurement (i.e.  $w_{sd}/M$ ).

A propagation rule exists for obtaining the uncertainties of arbitrary functions of primary measurements. For example, for an arbitrary function R of variables X, Y, and Z,

$$R=R(X,Y,Z)$$

the uncertainty of R is given by

$$|w_R/R|^2 = (\partial R/\partial X)^2 (w_x/R)^2 + (\partial R/\partial Y)^2 (w_y/R)^2 + (\partial R/\partial Z)^2 (w_y/R)^2$$

This sum of squares form is derived from the Taylor series, and assumes the independence of X, Y, and Z, that their relative uncertainties are "small", and that all uncertainties are expressed at the same probability level. For purposes of 60 this application, all uncertainties are assumed to be at 95% probability.

One of the uses of the uncertainty propagation formula is to reveal particular circumstances that can result in a higher or lower than expected level of uncertainty. For example, as 65 discussed in S. J. Kline, "The Purposes of Uncertainty Analysis", ASME Journal of Fluids Engineering, Vol. 107, 6

No. 2, pp. 153-160, 1985, if R is calculated from x and y using the equation

R=x-v

the uncertainty in R, wR, is given by

$$w_R/R = (x/(x-y)^*w_x/x)^2 + (y/(x-y)^*w_y/y)^2]^{1/2}$$

If x=1.0, y=0.98, and the uncertainty in both x and y is 1%, then the uncertainty in R is:

$$w_R/R = [(1/0.02 * 0.01)^2 + (0.98/0.02 * 0.01)^2]^{1/2}$$
  
= 0.700 = 70%.

By comparison, if R is calculated from a variable z using the equation

the uncertainty in R is given by

If z=0.1 and the uncertainty is z is 20%, then the uncertainty in R is only 0.91%.

On reflection these results should not be surprising. In the first example, two quantities of similar magnitude are being subtracted, which will increase the relative error in the result. In the second, although z has a large uncertainty, its influence on R is relatively small. Of course, for different values of x, y, and z, the impact of their uncertainties will vary. Uncertainty analysis is useful in that it can quantify these effects.

Returning to FIG. 3, VU 28 has a non-zero value even under ideal conditions (i.e., a faultless sensor operating in a controlled, laboratory environment). This is because the measurement produced by a sensor is never completely certain and there is always some potential for error.

As with VMV 26, when transmitter 24 detects no abnormalities in sensor 12, transmitter 24 sets VU 28 equal to RU 62. When transmitter 24 detects a fault in sensor 12 that only partially affects the reliability of RMV 36, transmitter 24 typically performs a new uncertainty analysis that accounts for effects of the fault and sets VU 28 equal to the results of this analysis. As with VMV 26, transmitter 24 sets VU 28 to a value based on past performance when transmitter 24 determines that RMV 36 bears no relation to the actual measured value.

FIGS. 4A-4C illustrates three exemplary techniques for adjusting VU 28 based on past performance values. First, as shown in FIG. 4A, VU 28 can be increased during each sampling period by the maximum observed rate of change of VMV 26. This technique, which tends to give good short term results, eventually produces unrealistic values for VU 28. Next, as shown in FIG. 4B, when VMV 26 is set equal to the long term average of VMV 26, VU 28 can indicate that VMV 26 can take any previous value of VMV 26. Thus, if VMV 26 always falls between 0 and 100 and VMV 26 is set to 50, VU 28 is set to 50. This technique tends to give unduly pessimistic short term results, but avoids the long term problems of method FIG. 4A. Finally, as shown in FIG. 4C, when VMV 26 is based on a combination of the long and short term past values for VMV 26, VU 28 can be calculated as follows:

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$$VU_{LikS} = \frac{VU_L \cdot V_S}{(VU_L^2 + VU_S^2)^{1/2}}$$

where VU<sub>L</sub> and VU<sub>S</sub> are the long and short term past values 5 for VU 28.

To ensure that data control and management system 16 uses VMV 26 and VU 28 properly, MV status 30 provides information about how VMV 26 and VU 28 were calculated. Transmitter 24 produces VMV 26 and VU 28 under all conditions—even when transducers 22 are inoperative. Often, data control and management system 16 needs to know whether VMV 26 and VU 28 are based on "live" or historical data. For example, if data control and management system 16 were using VMV 26 and VU 28 in feedback control and transducers 22 were inoperative, data control and management system 16 would need to know that VMV 26 and VU 28 were based on past performance.

MV status 30 is based on the expected persistence of any abnormal condition and on the confidence of transmitter 24 in RMV 36. The four primary states for MV status are generated according to Table 1.

TABLE 1

Expected Persistence	Confidence in RMV	MV Status
not applicable	nominal	CLEAR
not applicable	reduced	BLURRED
short	zero	DAZZLED
long	zero	BLIND

A CLEAR MV status 30 occurs when RMV 36 is within a normal range for given process conditions. A DAZZLED MV status 30 indicates that RMV 36 is quite abnormal, but the abnormality is expected to be of short duration. Typically, transmitter 24 sets MV status 30 to DAZZLED when there is a sudden change in the signal from transducer 22 and transmitter 24 is unable to clearly establish whether this change is due to an as yet undiagnosed sensor fault or to an abrupt change in the variable being measured. A BLURRED 40 MV status 30 indicates that RMV 36 is abnormal but reasonably related to the parameter being measured. For example, transmitter 24 may set MV status 30 to BLURRED when RMV 36 is a noisy signal. A BLIND MV status 30 indicates that RMV 36 is completely unreliable and the fault 45 is expected to persist.

Two additional states for MV status 30 are UNVALI-DATED and SECURE. MV status 30 is UNVALIDATED when transmitter 24 is not performing validation of VMV 26. MV status 30 is SECURE when VMV 26 is generated 50 from redundant measurements in which transmitter 24 has nominal confidence.

Device status 32 is a generic, discrete value summarizing the health of sensor 12 that is used primarily by fault detection and maintenance systems. Typically, device status 52 is in one of six states, each of which indicates a different operational status for sensor 12. These states are: GOOD, TESTING, SUSPECT, IMPAIRED, BAD, or CRITICAL. A GOOD device status 32 means that sensor 12 is in nominal condition. A TESTING device status 32 means that sensor 60 12 is performing a self check, and that this self check may be responsible for any temporary reduction in measurement quality. A SUSPECT device status 32 means that sensor 12 has produced an abnormal response, but transmitter 24 has no detailed fault diagnosis. An IMPAIRED device status 32 means that sensor 12 is suffering from a diagnosed fault that has a minor impact on performance. A BAD device status 32

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means that sensor 12 has seriously malfunctioned and maintenance is required. Finally, a CRITICAL device status 32 means that sensor 12 has malfunctioned to the extent that sensor 12 may cause (or have caused) a hazard such as a leak, fire, or explosion.

FIG. 5 illustrates an example of the relationship between VMV 26, VU 28, MV status 30, and RMV 36. In another aspect, FIG. 5 illustrates a preferred method of displaying the relationship between VMV 26 and VU 28 both during normal operation and when a fault has occurred: VU 28 is shown both as a separate signal and as an envelope surrounding VMV 26 (line 38 indicates the sum of VMV 26 and VU 28 and line 40 indicates the difference between VMV 26 and VU 28). When VU 28 is expressed as an envelope surrounding VMV 26, a user can, by examining the envelope, visually determine the range of probable values of the parameter represented by VMV 26 for any displayed time.

In the region between time T1 and time T2, RMV 36 is a periodic signal whose amplitude falls within an expected range. In this region, VMV 26 equals RMV 36, MV status 30 is CLEAR, and VU 28 remains at a constant "normal" level that corresponds to RU 62, the uncertainty under normal operating conditions (with line 42 representing a zero value for VU 28). For purposes of this example, RU 62 is assumed to have a constant value.

At time T2, RMV 36 begins to increase at a rate that substantially exceeds an expected rate of change for RMV 36. Transmitter 24 takes a number of actions in response to this unexplained phenomenon. First, transmitter 24, which is basing VMV 26 and VU 28 on short term past performance values in this example, maintains VMV 26 at the value that VMV 26 had just before the sudden increase in RMV 36 at time T2. Finally, transmitter 24 begins to increase VU 28 at a constant rate that equals the maximum rate of increase of VMV 26 during normal operation. The progressive increase in the value of VU 28 over time reflects increasing uncertainty of the value of the measurement in the absence of up to date valid transducer data caused by sensor 12 being DAZZLED.

RMV 36 continues to increase until time T3. At time T3, RMV 36 stops increasing and remains at a constant level. Because the value of RMV 36 now exceeds expected values, transmitter 24 does not change VMV 26 or MV status 30, and continues to increase VU 28 at a constant rate. At time T4, RMV 36 begins to decrease. Because the value of RMV 36 still exceeds expected values, transmitter 24 makes no changes to VMV 26 or MV status 30, and continues to increase VU 28 at a constant rate.

At time T5, RMV 36 begins to operate as expected. In response, transmitter 24 changes MV status 30 to BLURRED and begins to merge VMV 26 with RMV 36 using, for example, the following equation:

VMV<sub>n+1</sub>=0.95\* VMV<sub>n</sub>+0.05\* RMV<sub>n+1</sub>

where  $VMV_{n+1}$  is the value of VMV 26 for the current sample,  $VMV_n$  is the value of VMV 26 generated in the previous sample, and  $RMV_{n+1}$  is the value of RMV 36 for the current sample. Next, transmitter 24 initializes a recovery timeout period. Finally, transmitter 24 begins to decrease VU 28 by merging VU 28 with RU 62 using, for example, the following equation:

 $VU_{n+1}^2 = 0.95^2 * VU_n^2 + 0.05^2 * RU_{n+1}^2$ 

where  $VU_{n+1}$  is the value of VU 28 for the current sample,  $VU_n$  is the value of VU 28 generated in the previous sample,

and  $RU_{n+1}$  is the value of RU 62 for the current sample. At time T6, transmitter 24 determines that the recovery timeout period has expired and changes MV status 30 to CLEAR. Because transmitter 24 now has nominal confidence in RMV 36, transmitter 24 sets VU 28 equal to RU 62.

If, at time T5, RMV 36 had not returned to expected levels, sensor 12 would have either maintained MV status 30 as DAZZLED or diagnosed a sensor fault and changed MV status 30 to BLIND, MV status 30 can only be DAZZLED for a limited "timeout" period. Thus, if RMV 36 remained to at unexpected levels, the timeout period would eventually expire, and transmitter 24 would change MV status 30 to BLIND.

As shown in FIG. 3, transmitter 24 uses several sources of information, each of which is discussed below, in generating VMV 26, VU 28, MV status 30, device status 32, diagnostic information 34, and alarm data 35. Raw data 44, the basic measurement information available to transmitter 24, is typically an electrical image of the output of one or more transducers 22 (e.g., the frequency of oscillation or the 20 resistance of a transducer 22). Raw data 44 contains the maximum information available about the response of transducer 22 and is therefore a rich source of information for statistical tests to detect sensor faults. However, knowledge of expected process behavior cannot be applied readily to 25 raw data 44 and is more appropriately applied to statistics based on RMV 36.

Because RMV 36 directly relates to a process parameter (e.g., temperature or mass flow rate), transmitter 24 can link the expected (no-fault) behavior of RMV 36 to the expected 30 behavior of the process parameter associated with RMV 36. Transmitter 24 derives RMV 36 from raw data 44 by conventional processing. For example, if raw data 44 corresponds to the resistance of a transducer 22 and RMV 36 corresponds to temperature, transmitter 24 derives RMV 36 based on raw data 44 in light of known effects of temperature on the resistance of transducer 22. Often, transmitter 24 filters RMV 36 to reduce the effect of sensor noise and high frequency process disturbances. When filtering occurs, RMV 36 contains less information than raw data 44.

To a certain extent, raw data 44 and RMV 36 are complementary sources of information. While raw data 44 has more information content than RMV 36, RMV 36 is more easily compared with expected process behavior. Thus, raw data 44 and RMV 36 each offer useful information to transmitter 24. 45

Auxiliary data 46 is provided by auxiliary signals within sensor 12. Auxiliary signals, though not directly related to raw data 44 or RMV 36, give useful information about the health or performance of sensor 12. For example, statistical tests to identify characteristic sensor or process behavior 50 may be associated with particular auxiliary signals. Examples of auxiliary signals include the electrical properties of components within sensor 12 (e.g., signal levels at the input or output stages of power amplifiers) and hardware error information 50. Hardware error information 50 is a special, preprocessed form of auxiliary information generated by digital components within sensor 12, requiring little or no processing or interpretation. For example, a memory checksum error in a memory component of transmitter 24 would constitute hardware error information 50.

In addition to information from within sensor 12 or from process 14, transmitter 24 uses information from data control and management system 16 in generating output signals. Data control and management system 16 is known as the "Next Level Up" ("NLU"), and information from data 65 control and management system 16 is known as NLU information 48. A difficulty associated with having trans-

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mitter 24 validate the output of sensor 12 is that transmitter 24 may have insufficient information to reach a valid conclusion. For example, transmitter 24 may be unable to distinguish between certain types of sensor faults (e.g., drift errors that cause the output of the sensor to change over time for a given input) and legitimate process changes. In these situations, transmitter 24 may refer to NLU information 48 for clarification. Data control and management system 16, which has access to additional information, including data from other sensors 12, provides transmitter 24 with the information needed to distinguish between process changes and sensor drift.

Transmitter 24 may request NLU information 48 such as anticipated process limits through standard requests to data control and management system 16. Alternatively, data control and management system 16 can provide unsolicited information, such as indications of changes in process behavior that will change the process parameters being measured by transducers 22, to transmitter 24. For example, if process 14 operates in a number of phases that each have distinct characteristics, data control and management system 16 can notify transmitter 24 when the phase of process 14 changes.

Application knowledge base information 52 allows transmitter 24 to estimate a "wear and tear" effect on sensor performance. Application knowledge base information 52 describes the relationship between signals and sensor characteristics over time. In some applications, sensors are known to degrade much more rapidly under certain conditions (e.g., at extremes of their operating range). For example, if a normal range pH probe is exposed to more than about 12 pH for as little as an hour, the probe may become alkali-conditioned and fail to respond when the solution becomes more acidic. Application knowledge base information 52 also includes factors such as the time clapsed since the last calibration or last maintenance of sensor 12.

Sensor/process stimulus information 54 provides information about a known stimulus applied to the process or part of a sensor. Sensor/process stimulus information 54 is used in implementing procedures for testing sensor 12. A known stimulus is applied to process 14 or sensor 12 and the response generated by sensor 12 is compared with an expected response. For example, sensor/process stimulus information 54 could describe a known force that has been introduced to a pressure transducer. Sensor/process stimulus information 54 is generated by transmitter 24 (i.e., as part of a self-test initiated by transmitter 24) or sent by data control and management system 16 as NLU information 48. When testing disables the measuring capability of sensor 12, transmitter 24 sets the MV status 30 of each disabled measurement to DAZZLED, bases VMV 26 and VU 28 on past performance, and sets device status 32 to TESTING.

FIG. 3 also shows the functional units of transmitter 24. A diagnostic state machine 56 processes all of the information available to transmitter 24 and determines the diagnostic state 58 of sensor 12. Diagnostic state 58 is the central piece of information used by diagnostic state machine 56 in deriving VMV 26, VU 28, MV status 30, and device status 32. Because diagnostic state 58 may itself be helpful to users performing maintenance on sensor 12, it is the basis of diagnostic information 34, which is output upon a request by data control and management system 16.

Referring also to FIG. 6, transmitter 24 performs the following operations during each sampling period. After getting raw data 44 from transducer 22 (step 72), diagnostic state machine 56 propagates raw data 44 through a set of device equations 60 to generate RMV 36 (step 74). At the

same time, transmitter 24 dynamically calculates RU 62 using an uncertainty analysis 64 based on device equations 60 and calibration data 66 in accordance with the established standards discussed above (step 74). In calculating RU 62, transmitter 24 assumes that no fault has occurred. RU 62 has a non-zero value under all operating conditions. Generally, RU 62 increases under other than ideal conditions.

Next, diagnostic state machine 56 obtains other information (step 76) and, based on the other information, raw data 44, RMV 36, and RU 62, calculates statistics or performs pattern matching to determine if sensor 12 is operating correctly (step 78). Based on the results of step 78, diagnostic state machine 56 updates diagnostic state 58 (step 80).

Next, diagnostic state machine 56 modifies (68) RMV 36 based on diagnostic state 58 to produce VMV 26. Essentially, diagnostic state machine 56 recalculates RMV 36 after modifying the parameters used in the calculation to account for diagnostic state 58 and sets VMV 26 equal to the new RMV 36 (step 82). Thus, under normal operating conditions (when diagnostic state 58 does not require modification of any parameters), VMV 26 typically equals RMV 36.

At the same time, diagnostic state machine 56 modifies (70) RU 62 based on diagnostic state 58 to produce VU 28. As with VMV 26, diagnostic state machine 56 recalculates RU 62 after modifying the parameters used in the calculation to account for diagnostic state 58 and sets VU 28 equal 25 to the new RU 62 (step 82). Thus, VU 28 typically equals RU 62 under normal operating conditions. Under other conditions, VU 28 typically exceeds RU 62.

Next, diagnostic state machine 56 selects MV status 30 (step 84) and device status 32 (step 86) based on diagnostic 30 state 58 and via either calculations or a lookup table. If necessary, diagnostic state machine 56 sends alarm data 35 by updating alarm flags (step 88). Also, if data control and management system 16 has requested it, diagnostic state machine 56 generates diagnostic information 34 based on 35 diagnostic state 58 (step 90).

Referring to FIG. 7, a self-validating temperature sensor 100 includes a thermocouple 102 and a transmitter 104 that includes a processor 106. Typically, thermocouple 102 includes two dissimilar metals in contact and produces a 40 voltage, V<sub>Diff</sub>, between two terminals 108 and 110. V<sub>Diff</sub> is proportional to the difference between the temperature of a sensing junction 112 and a reference junction 114. The sum of V<sub>Diff</sub> and V<sub>Comp</sub>, a voltage proportional to the difference between the temperature of reference junction 114 and zero 45 degrees, equals V<sub>Temp</sub>, a voltage proportional to the difference between the temperature of sensing junction 112 and zero degrees. To determine  $V_{temp}$ ,  $V_{diff}$  is amplified by amplifier 116 and  $V_{comp}$  is generated by temperature sensor 118 and amplified by amplifier 120. The output 117 of 50 amplifier 116 and the output 121 of amplifier 120 are then supplied to an analog-to-digital convertor ("ADC") 122 in processor 106. Processor 106 uses amplifier outputs 117, 121, and other available information, to generate diagnostic state 58, RMV 36, and RU 62. Based on these signals, 55 processor 106 generates VMV 26, VU 28, MV status 30, device status 32, alarm data 35, and, when requested, diagnostic information 34.

Referring to FIG. 8, self-validating temperature sensor 100 responds to a loss of power to amplifiers 116, 120 as 60 described below. During normal operation (time 0 to 15), VMV 26 equals RMV 36, which processor 106 generates based on the sum of outputs 117, 121. Similarly, VU 28 equals RU 62, and indicates the uncertainty of VMV 26. MV status 30 is CLEAR.

At time 15, the power supply 132 stops functioning and  $V_{Diff}$  and  $V_{Comp}$  (outputs 117, 121) both go to zero volts,

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which results in an RMV 36 of about negative 55° C. (for a particular transmitter design). Processor 106 detects the loss of power when power monitor 134, a digital auxiliary signal, switches from one to zero in response to the loss of power. Processor 106 then sets diagnostic state 58 to indicate that processor 106 has zero confidence in RMV 36. As a result, processor 106 sets VMV 26 and VU 28 to a combination of the long and short term past values for VMV 26 and VU 28 respectively as described above. Finally, processor 106 signals the severity and expected long term duration of the sensor fault by setting MV status 30 to BLIND.

When the power supply is restored at time 36, processor 106 detects the change in power monitor 134 from zero to one and sets MV status 30 to BLURRED. The "live" data from RMV 36 is merged with the previous value of VMV 26 as described above to give a new value for VMV 26. Similarly, RU 62 is merged with the previous value of VU 28 to give a decreasing value for VU 28. At this time, processor 106 also initializes a recovery timer.

Processor 106 generates VMV 26 and VU 28 by merging past values of VMV 26 and VU 28 with, respectively, RMV 36 and RU 62 until the recovery timer expires at time 56. (In this example, the recovery timer was set for 20 seconds.) At that time, processor 106 sets MV status to CLEAR, sets VMV 26 equal to RMV 36, and sets VU 28 equal to RU 62.

Referring now to FIG. 9, an open circuit fault occurs at time 13 when thermocouple 102 is disconnected from transmitter 104. In the presence of such a fault, RMV 36 is around 130° C., which corresponds to a normal value for output 121 but an abnormally high value for output 117 due to saturation of amplifier 116. (Pull-up resistor 136 causes saturation of amplifier 116 in the presence of an open circuit fault.) In response to the abnormally high value of output 117, processor 106 sets diagnostic state 58 to indicate zero confidence in RMV 36 and sets MV status 30 to DAZZLED. Processor 106 then generates VMV 26 and VU 28 based on a combination of the long and short term past values as described above.

Next, referring also to FIG. 7, processor 106 connects thermocouple 102 to voltage source 124 via switch 126 and monitors the voltage 130 produced across a resistor 128. Because of the open circuit, no current flows in resistor 128 and voltage 130 is zero volts. From this, processor 106 confirms the open circuit fault and sets MV status 30 to BLIND.

At time 27, the open circuit fault is corrected and output 117 returns to a normal value. Processor 106 responds by setting diagnostic state 58 to indicate reduced confidence in RMV 36 (rather than no confidence), sets MV status 30 to BLURRED, and initializes a recovery timer.

Thereafter, processor 106 generates VMV 26 and VU 28 by merging past values of VMV 26 and VU 28 with, respectively, RMV 36 and RU 62 until the recovery timer expires at time 47 (where the recovery timer was set for 20 seconds). At that time, processor 106 sets MV status to CLEAR, sets VMV 26 equal to RMV 36, and sets VU 28 equal to RU 62.

Referring to FIG. 7, a loss of contact fault occurs when sensing junction 112 loses contact with the process element of which the temperature is being measured. Because a loss of contact fault does not produce an abnormal change in RMV 36, sensor 100 cannot readily detect the fault.

As a result, sensor 100 uses current injection tests to detect loss of contact faults. In a current injection test, sensor 100 connects thermocouple 102 to voltage source 124 for a predetermined period and measures the effect on output 117. (The value of output 117 before thermocouple 102 is con-

nected to voltage source 124 is compared to the value after disconnection.)

Referring to FIGS. 10-1 and 10-2, a loss of contact fault occurs at time 12 and the measured temperature drops by about seven degrees. Because this is within normal operating parameters, sensor 100 does not immediately recognize the fault, and, instead, adjusts VMV 26 and maintains MV status 30 as CLEAR.

At time 28, processor 106 begins a current injection test. Because amplifier 116 does not read "live" data during the 10 test, processor 106 sets MV status 30 to DAZZLED and generates VMV 26 and VU 28 based on past performance as discussed above. At time 33, processor 106 determines that the fault has occurred and sets MV status 30 to BLURRED. (Processor 106 assumes that, though contact has been lost, 15 the temperature sensed by thermocouple 102 still approximates the actual temperature.)

At time 56, contact is reestablished. However, processor 106 interprets the sudden change in output 117 as a spike and temporarily sets MV status 30 to DAZZLED. When output 117 remains at the increased value, processor 106 sets MV status 30 back to BLURRED. (Processor 106 does not set MV status 30 to CLEAR because processor 106 has not detected the removal of the fault condition.)

At time 66, processor 106 begins another current injection 25 test and sets MV status 30 to DAZZLED. At time 72, processor 106 determines that contact has been reestablished and, in response, sets MV status to BLURRED and initializes a recovery timer. At time 97, the recovery timer (which was set to 25 seconds) expires and processor 106 sets MV 30 status to CLEAR.

Referring to FIG. 11, another example of a self-validating sensor according to the invention is a Coriolis flow meter 150. Flow meter 150 measures three process parameters: mass flow rate, density, and temperature. Mass flow is 35 measured directly using the principle of Coriolis acceleration, without needing to rely on external pressure, temperature, or specific gravity measurements.

Structurally, flow meter 150 consists of a flowtube 152 that is connected to a transmitter 154 by cables 156. Flow-40 tube 152 includes a body 158 to which is connected an input pipe 160 and an output pipe 162. Two parallel pipe loops 164, 166 extend from body 158. Body 158 contains passages which lead a process fluid from input pipe 160 to the beginning of loop 164, from the end of loop 164 to the 45 beginning of loop 166 and from the end of loop 166 to output pipe 162 (the broken arrows in FIG. 11 show the direction of flow in loops 164, 166).

Transmitter 154 causes loops 164, 166 to pivotally oscillate about their axes of symmetry Y'-Z' and Y-Z by supplying anti-phase sinusoidal signals to electromagnetic drivers 168, 170. Transmitter 154 uses feedback to maintain the signals to drivers 168, 170 at the resonant frequency of loops 164, 166. Transmitter 154 then detects movement of loops 164, 166 via sensors 172, 174, which each produce a voltage that is proportional to the instantaneous velocity between loops 164, 166. Transmitter 154 adjusts the amplitude of the signals to drivers 168, 170 to maintain the average amplitude of the voltages produces by sensors 172, 174 at a constant level.

Transmitter 154 measures mass flow rate, density, and temperature in the following manner. First, transmitter 154 measures the mass flow rate of the process fluid by monitoring the effect of Coriolis forces on loops 164, 166. Coriolis forces acting on sections G'-H' and G-H of oscil-65 lating loops 164, 166 cause deflections of loops 164, 166. These deflections result in a phase angle difference between

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the voltages produced by sensors 172, 174 that is proportional to the mass flow rate. Next, transmitter 154 determines the density of the process fluid from the frequency of oscillation of loops 164, 166 (which equals the frequency of the signals supplied to drivers 168, 170). The density of the process fluid is inversely proportional to the square of the drive frequency. Finally, transmitter 154 measures the temperature of the process fluid via a temperature sensor 176 located in body 158. Typically, temperature sensor 176 is an RTD device with a resistance that is temperature dependent.

In the context of flow meter 150, the raw data available are the frequency 44a of a signal coming out of temperature sensor 176 (the frequency is proportional to the resistance of temperature sensor 176), frequency 44b of the drive signals applied to drivers 168, 170, and the voltage outputs 44c of sensors 172, 174. From these signals, transmitter 154 derives three RMVs: the temperature of the process fluid 36a, the density of the process fluid 36b, and the mass flow rate 36c (derived from the phase angle between the sensor signals). In addition, transmitter 154 performs uncertainty analyses to produces three RUs (62a, 62b, 62c), each indicating the uncertainty of a corresponding RMV 36.

After generating RMVs 36a, 36b and 36c and RUs 62a, 62b and 62c, transmitter 154 determines the diagnostic state 58 of flow meter 150. This determination is based on raw data 44a, 44b and 44c, RMVs 36a, 36b and 36c, RUs 62a, 62b and 62c, and auxiliary data 46. Based on diagnostic state 58, transmitter 154 adjusts the parameters used in calculating RMVs 36a, 36b and 36c and RUs 62a, 62b and 62c and recalculates these values. Transmitter 154 then outputs the recalculated RMVs 36a, 36b and 36c and RUs 62a, 62b and 62c as VMVs 26a, 26b and 26c and VUs 28a, 28b and 28c. Transmitter 154 also outputs a MV status 30a corresponding to temperature, a MV status 30b corresponding to density, and a MV status 30c corresponding to mass flow rate. Finally, transmitter 154 outputs a single device status 32 corresponding to the status of flow meter 150.

Referring again to FIG. 6, the procedure performed by transmitter 154 during each sample period can be implemented in software. An example of software for implementing of a self-validating Coriolis meter 150 is included in microfiche appendix 1. In addition, an example of software for implementing a self-validating temperature sensor 100 as described above is included in microfiche appendix 2. The software in appendices 1 and 2 may be implemented on any processor that supports a structured programming language. In an alternative approach, the procedure could be implemented using hard-wired circuitry.

The pseudocode shown in FIG. 12 provides a simplified view of the procedure performed by transmitter 154 during each sample period. FIG. 12 also shows, in parentheses, the steps performed in FIG. 6 that correspond to the steps in FIG. 12. Initially, transmitter 154 gets raw data 44a, 44b and 44c from flowtube 152 (step 200). Transmitter 154 then calculates RMVs 36a, 36b and 36c and RUs 62a, 62b and 62c (steps 202-206). The pseudocode for calculating RMV 36a and RU 62a is shown in FIG. 13 and is discussed below. Next, transmitter 154 examines all available information (step 208) and determines diagnostic state 58, MV statuses 30a, 30b and 30c, and device status 32 (step 210). A portion of the pseudocode for determining diagnostic state 58 and MV statuses 30a, 30b and 30c is shown in FIG. 14 and discussed below. Based on diagnostic state 58, transmitter 154 corrects the parameters used in calculating RMV 36a, 36b and 36c and RU 62a, 62b and 62c (step 212). Transmitter 154 then calculates VMVs 26a, 26b and 26c and VUs

28a, 28b and 28c (steps 214-218) using the procedure with

Pharmatech Solutions, Inc: EXHIBIT 1031 - 158 IPR2013-00247, U.S. Pat. No. 7,250,105

which RMVs 36a, 36b and 36c and RUs 62a, 62b and 62c were calculated and corrected parameters.

Referring to FIG. 13, transmitter 154 calculates RMV 36a and RU 62a as follows. First, transmitter 154 calculates the resistance "R" of temperature sensor 176 (step 250). Trans- 5 mitter 154 then calculates the uncertainty "d\_R" of R based on an uncertainty analysis of the equation used to calculate R (step 252). Next, transmitter 154 calculates "temperature" (step 254), and sets RMV 36a equal to temperature. Finally, transmitter 154 calculates the uncertainty "d\_temperature" of temperature (step 256), and sets RU 62a equal to d\_temperature. Thus, as a first pass RMV 36a and RU 62a equal the measured temperature and its corresponding uncertainty, If transmitter 154 subsequently determines that it has less than nominal confidence in RMV 36a and RU 62a, transmitter 154 modifies any of the parameters, uncertainties, 15 and/or raw data (e.g., RK1, d\_RK1, f\_RTD) used in calculating temperature and d\_temperature to reflect the impact of an expected fault. Transmitter 154 then reperforms the procedure illustrated in FIG. 13 using the modified information and sets VMV 26a and VU 28a equal to the new 20 values for temperature and d temperature. Alternatively, if transmitter 154 determines that the fault is too severe, transmitter 154 may set VMV 26a and VU 28a based on historical data

FIG. 14 illustrates the procedure used by transmitter 154 25 to detect and respond to a loss of input from temperature sensor 176. Transmitter 154 maintains a variable, RTD\_input\_state, that indicates the current status of the input from temperature sensor 176. As a first step, transmitter 154 checks RTD\_input state (step 300).

If RTD\_input\_state equals RTD\_INPUT\_OK (step 302), which indicates that the input from temperature sensor 176 was functioning normally during the previous sample period, transmitter 154 checks the resistance of temperature sensor 176 (step 304). If the resistance is less than 80 ohms, 35 this indicates that the connection between transmitter 154 and temperature sensor 176 has been lost. In response, transmitter 154 sets RTD\_input\_state to RTD\_INPUT\_ LOST (step 306). Transmitter 154 then checks the value of RTD\_spike\_state, which indicates whether transmitter 154 40 had sensed a spike in the output from temperature sensor 176 during the previous sample (step 308). If RTD\_spike\_state indicates that a spike had occurred, transmitter 154 resets RTD\_input\_state to indicate no spike (step 310). (A spike is a less serious fault and is mooted by the loss of connec- 45 tion.)

If RTD\_input\_state equals RTD\_INPUT\_LOST (step 312), transmitter 154 checks the resistance of temperature sensor 176. If the resistance is less than 100 ohms (step 314), this indicates that connection with temperature sensor 176 is 50 still lost. (Different resistance values are used in steps 304 and 314 to avoid intermittent switching of RTD\_input\_ state if, for example, the resistance fluctuates between 79 and 81 ohms.) If connection is lost, transmitter 154 sets MV status 30a, which corresponds to temperature, to BLIND 55 (step 316) and substitutes historical information (step 318) about temperature for use in the recalculation steps (steps 214-218 of FIG. 12). Because density and mass flow are based, in part, on temperature, transmitter 154 sets MV statuses 30b (step 320) and 30c (step 322) to BLURRED, If 60 the resistance is greater than 100 ohms (step 324), transmitter 154 sets RTD\_input state to RTD\_INPUT\_RECOVER, to indicate that connection has been reestablished (step 326). At this time, transmitter 154 initializes a recovery timer by setting RTD\_input\_count equal to zero (step 328).

If RTD\_input\_state equals RTD\_INPUT\_RECOVER (step 330), transmitter 154 merges the past and present

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values for temperature as discussed above (step 332). Transmitter 154 then checks to see if the recovery timeout period has expired (step 334). If it has, transmitter 154 sets RTD\_input\_state to RTD\_INPUT\_OK (step 336). If it has not (step 338), transmitter 154 sets MV status 30a to BLURRED (step 340) and increments RTD\_input\_count (step 342).

FIGS. 15a-1, 15A-2, 15b-1, 15b-2, 15c-1 and 15c-2 illustrates the response of flow meter 150 to a loss of input from temperature sensor 176. At time 9, the loss of input occurs and the unvalidated temperature measurement, RMV 36a, begins to rapidly drop. At time 10, transmitter 154 sets diagnostic state 58 to indicate that a spike in the temperature input has occurred, and, in response, changes MV status 30a to DAZZLED, modifies VMV 26a and VU 28a based on past performance as discussed above, and leaves MV statuses 30b and 30c, VMVs 26b and 26c, and VUs 28b and 28c unchanged (though, because density and mass flow rate are partially dependent on temperature, VMVs 26b and 26c and VUs 28b and 28c include the changes to VMV 26a and VU 28a).

At time 12, the resistance of temperature sensor 176 drops sufficiently low that transmitter 154 sets diagnostic state 58 to indicate that a loss of temperature input has occurred, and, in response, changes MV status 30a to BLIND, continues to base VMV 26a and VU 28a on past performance, changes MV statuses 30b and 30c to BLURRED, and leaves VMVs 26b and 26c unchanged. Because the uncertainties of density and mass flow are based in part on the uncertainty of temperature, VUs 28b and 28c will increase to reflect the increase in VU 28a.

At time 48, the resistance of temperature sensor 176 increases to a sufficient level so that transmitter 154 sets diagnostic state 58 to indicates that temperature input has been recovered, and, in response, changes MV status 30a to BLURRED, initializes a recovery timer, begins merging past and present values for VMV 26a and VU 28a, and changes MV statuses 30b and 30c to CLEAR.

At time 72, the recovery timer expires, and transmitter 154 sets diagnostic state 58 to indicate that the temperature input is fully recovered, and, in response, changes MV status 30a to CLEAR and bases VMV 26a and VU 28a on RMV 36a and RU 62a.

Referring to FIG. 16, in summary, a sensor 12 according to the invention implements a procedure 350. The sensor receives a data signal related to the value of a variable (step 352), and, based on the data signal, estimates a measurement of the variable (step 354). Thereafter, the sensor generates a first output signal (step 356), which can be related to the estimated measurement of the variable. Finally, the sensor performs an uncertainty analysis on the first output signal (step 358) and generates a second output signal based on the uncertainty analysis (step 360).

Referring to FIG. 17, and as discussed above, a sensor according to the invention may respond to the detection of a fault according to a procedure 400. Initially, the sensor determines whether the occurrence of a fault has been detected in the source of a measurement (step 405). For example, as shown in FIG. 18 and discussed above, when the sensor includes a temperature transducer, the sensor may detect a loss of contact fault using a procedure 500. The sensor stores an output of the temperature transducer (step 505) and connects the temperature transducer to a voltage source for a predetermined time period (step 510). After the predetermined time period expires, the sensor compares the stored output with the current output of the temperature transducer (step 515) and indicates that a loss of contact fault has been detected based on the comparison (step 520).

Referring again to FIG. 17, if the occurrence of a fault has been detected (step 405), the sensor produces a first estimate of the measurement (step 410). The first estimate may be a mean value of the measurement during a time interval that includes a short term past value of the measurement. For example, the time interval may include a value of the measurement immediately prior to the occurrence of the fault. The sensor also produces an uncertainty measure for the first estimate (step 415). Initially, the uncertainty measure may indicate that the measurement can have any value observed for the measurement during the time interval. The sensor may also account for a reduction in reliability of the first estimate due to a time difference between the current time and a time at the end of the time interval. In particular, the sensor may adjust the uncertainty measure for the first estimate by multiplying the time difference between the current time and the time at the end of the time interval by a maximum observed rate of change of the measurement. The sensor then produces a second estimate (step 420) and a related uncertainty measure (step 425) using the approach described above for the first estimate and uncertainty measure. The second estimate may be based on long term past 20 values of the measurement.

The sensor combines the multiple estimates of the measurement to produce a combined estimate for the measurement (step 430). The sensor may combine the estimates by weighting the estimates according to their associated uncertainty measures. In particular, the sensor may multiply the first estimate by the second uncertainty measure squared divided by a sum of the second uncertainty measure squared and the first uncertainty measure squared and add a result of this multiplication to a result of multiplying the second estimate by the first uncertainty measure squared divided by a sum of the second uncertainty measure squared and the first uncertainty measure squared and the first uncertainty measure squared and the first uncertainty measure squared;

$$EST_{COM} = \frac{U_1^2}{U_1^2 + U_2^2} * EST_1 + \frac{U_2^2}{U_1^2 + U_2^2} * EST_2.$$
3:

The sensor also combines uncertainty measures for each of the multiple estimates to produce an uncertainty measure for the combined estimate for the measurement (step 435). The sensor may do so by multiplying the second uncertainty measure by the first uncertainty measure and dividing a result of the multiplication by a square root of a sum of the second uncertainty measure squared and the first uncertainty measure squared:

$$U_{COM} = \frac{U_1 * U_2}{(U_1^2 + U_2^2)^{1/2}}$$

Finally, the sensor provides the combined estimate for the measurement as a value for the measurement at a current time (step 440) and the uncertainty measure for the combined estimate as an indication of the validity of the value for the measurement at the current time (step 445).

Other embodiments are within the following claims.

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What is claimed is:

 A method of providing a measurement and an indication about the validity of the measurement when the occurrence of a fault has been detected in the source of the measurement, the method comprising:

combining multiple estimates of the measurement to produce a combined estimate for the measurement, 18

combining uncertainty measures for each of the multiple estimates to produce an uncertainty measure for the combined estimate for the measurement,

when the occurrence of a fault has been detected, providing the combined estimate for the measurement as a value for the measurement at a current time, and

when the occurrence of a fault has been detected, providing the uncertainty measure for the combined estimate for the measurement as an indication of the validity of the value for the measurement at the current time.

2. The method of claim 1, wherein the measurement comprises measurements of mass flow, density and temperature produced by a self-validating Coriolis flow meter and a source of the measurement is one or more transducers for generating a first data signal related to mass flow, a second data signal related to density, and a third data signal related to temperature.

3. The method of claim 1, wherein the measurement is a temperature measurement produced by a self-validating temperature sensor and a source of the temperature measurement is a temperature sensing transducer.

surement is a temperature sensing transducer.

4. The method of claim 3, further comprising detecting a loss of contact fault in the temperature sensing transducer

storing an output of the temperature sensing transducer, after storing the output, connecting the temperature sensing transducer to a voltage source for a predetermined time period,

comparing an output of the temperature sensing transducer after the predetermined time period to the stored output, and

detecting a loss of contact fault based on a result of the

comparing step.
5. The method of claim 1, wherein:

the step of combining multiple estimates comprises combining a first estimate that is based on short term past values of the measurement from a first time interval with a second estimate that is based on long term past values of the measurement from a second time interval that began at an earlier time than did the first time interval, and

the step of combining uncertainty measures comprises combining a first uncertainty measure for the first estimate with a second uncertainty measure for the second estimate to produce the uncertainty measure for the combined estimate.

6. The method of claim 5, wherein the first estimate corresponds to a value of the measurement immediately

prior to the occurrence of the fault.

7. The method of claim 5, wherein the step of combining the first estimate with the second estimate comprises weighting the first estimate according to the first uncertainty measure and weighting the second estimate according to the second uncertainty measure.

8. The method of claim 7, wherein the step of combining the first estimate with the second estimate comprises multiplying the first estimate by a factor that comprises the second uncertainty measure squared divided by a sum of the second uncertainty measure squared and the first uncertainty measure squared and adding a result of this multiplication to a result of multiplying the second estimate by a factor that comprises the first uncertainty measure squared divided by a sum of the second uncertainty measure squared and the first uncertainty measure squared and the first uncertainty measure squared.

9. The method of claim 1, wherein a first estimate of the measurement is associated with a time interval and is based on at least one value of the measurement during the time interval.

10. The method of claim 9, wherein the first estimate comprises a mean value of the measurement during the time interval.

#### 5,570,300

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- The method of claim 10, wherein the uncertainty measure for the first estimate indicates that the measurement can have any value observed for the measurement during the time interval.
- 12. The method of claim 11, wherein the step of combining the first uncertainty measure with the second uncertainty measure comprises multiplying the second uncertainty measure by the first uncertainty measure and dividing a result of the multiplication by a square root of a sum of the second uncertainty measure squared and the first uncertainty measure sources output.
- 13. The method of claim 9, wherein the uncertainty measure for the first estimate accounts for a reduction in reliability of the first estimate due to a time difference between the current time and a time at the end of the time interval.
- 14. The method of claim 13, wherein the uncertainty measure for the first estimate is adjusted as a function of both the time difference between the current time and the time at the end of the time interval and a maximum observed rate of change of the measurement.
- 15. The method of claim 14, wherein the uncertainty measure for the first estimate is increased by a result of multiplying the time difference between the current time and the time at the end of the time interval by the maximum observed rate of change of the measurement.
- 16. The method of claim 13, wherein the first estimate comprises a mean value of the measurement during the time interval.
- 17. The method of claim 16, wherein the uncertainty measure for the first estimate indicates that the measurement can have any value observed for the measurement during the time interval.
- 18. A temperature sensor for providing a measurement and an indication about the validity of the measurement, the temperature sensor comprising;
  - a transducer for generating a data signal related to a 35 temperature, and
  - a transmitter for receiving said data signal and generating in response thereto said temperature measurement and an uncertainty signal based on a dynamic uncertainty analysis of said temperature measurement, said transmitter being operable to detect a fault in the transducer and, upon detecting said fault, to:
  - combine multiple estimates of the temperature measurement to produce a combined estimate for the temperature measurement.
  - combine uncertainty measures for each of the multiple estimates to produce an uncertainty measure for the combined estimate for the temperature measurement,
  - provide the combined estimate for the temperature measurement as the temperature measurement at a current time, and
  - provide the uncertainty measure for the combined estimate for the temperature measurement as the uncertainty signal for the temperature measurement at the current time.
- 19. The temperature sensor of claim 18, wherein the transmitter is operable to detect a loss of contact fault in the transducer by:
  - storing a data signal produced by the transducer at a first time.
- after storing the data signal, connecting the transducer to a voltage source for a predetermined time period,
- comparing a data signal produced by the transducer after the predetermined time period to the stored data signal, and

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- detecting a loss of contact fault based on a result of the comparison.
- 20. A Coriolis flow meter for providing measurements of mass flow, density and temperature and information about the validity of the measurements, the Coriolis flow meter comprising:
  - one or more transducers for generating a first data signal related to mass flow, a second data signal related to density, and a third data signal related to temperature, and
  - a transmitter for receiving said first, second and third data signals and generating in response thereto a mass flow measurement, a first uncertainty signal based on a dynamic uncertainty analysis of said mass flow measurement, a density measurement, a second uncertainty signal based on a dynamic uncertainty analysis of said density measurement, a temperature measurement, and a third uncertainty signal based on a dynamic uncertainty analysis of said temperature measurement, said transmitter being operable to detect a fault in the one or more transducers and, upon detecting said fault, to:
  - combine multiple estimates of the temperature measurement to produce a combined estimate for the temperature measurement.
  - combine uncertainty measures for each of the multiple estimates to produce an uncertainty measure for the combined estimate for the temperature measurement,
  - provide the combined estimate for the temperature measurement as the temperature measurement at a current time, and
  - provide the uncertainty measure for the combined estimate for the temperature measurement as the third uncertainty signal at the current time.
- 21. The Coriolis flow meter of claim 20, wherein the transmitter is further operable, upon detecting a fault in the one or more transducers, to:
  - combine multiple estimates of the mass flow measurement to produce a combined estimate for the mass flow measurement,
  - combine uncertainty measures for each of the multiple estimates of the mass flow measurement to produce an uncertainty measure for the combined estimate for the mass flow measurement.
  - provide the combined estimate for the mass flow measurement as the mass flow measurement at a current time,
  - provide the uncertainty measure for the combined estimate for the mass flow measurement as the first uncertainty signal at the current time,
  - combine multiple estimates of the density measurement to produce a combined estimate for the density measurement,
  - combine uncertainty measures for each of the multiple estimates of the density measurement to produce an uncertainty measure for the combined estimate for the density measurement,
- provide the combined estimate for the density measurement as the density measurement at a current time, and
- provide the uncertainty measure for the combined estimate for the density measurement as the second uncertainty signal at the current time.

. . . . .

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Page 1 of 2

## UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT NO. : 5,570,300

DATED : October 29, 1996

INVENTOR(S) : Manus P. Henry, Wade M. Mattar, David W. Clarke

and Janice Yang

It is certified that error appears in the above-identified patent and that said Letters Patent is

hereby corrected as shown below:

On the title page:

Item [75] should read --Manus P. Henry, Oxford, England; Wade M. Mattar, Wrentham, Massachusetts; David W. Clarke, Oxford, England; Janice Yang, Hertfordshire, England--.

Item [57] Abstract, line 1, delete "for".

In the drawings, sheet 14 of 17, the legend "FIG. 15A-2" should read --FIG. 15a-2--.

Col. 3, line 16, "graph" should read --graphs--.

Col. 5, line 5, "4A-4C" should read --4a-4c--; line 8, "4A" should read --4a--; line 11, "4B" should read --4b--; line 13, "4C" should read --4c--.

Col. 6, line 25, "is" (lst. occ.) should read--in--.
line 51, "4A-4C" should read --4a-4C--;
line 51, "illustrates" should read --illustrate--;
line 53, "4A" should read --4a--;
line 57, "4B" should read --4b--;
line 64, "4A" should read --4a--;
line 64, "4C" should read --4c--.

Col. 7, lines 1-4, the equation should read:

$$VU_{L\&S} = \frac{VU_L * VU_S}{(VU_L^2 + VU_S^2)^{1/2}}$$

### Case3:11-cv-04494-WHO Document411-9 Filed04/18/14 Page31 of 31

## UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Page 2 of 2

PATENT NO. : 5,570,300

DATED : October 29, 1996

INVENTOR(S) : Manus P. Henry, Wade M. Mattar, David W. Clarke

and Janice Yang

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 13, line 59, "produces" should read --produced--.

Col. 16, line 8, "illustrates" should read --illustrate--.

Signed and Sealed this

Twelfth Day of August, 1997

Allest

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademorks

Case3:11-cv-04494-WHO Document411-10 Filed04/18/14 Page1 of 14

# EXHIBIT J

US005602732A

### United States Patent [19]

#### Nichols et al.

[56]

4,519,361

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4,718,272

[11] Patent Number:

5,602,732

[45] Date of Patent:

Feb. 11, 1997

[54]	FAULT TOLERANT DISPLACEMENT DETERMINATION METHOD
[75]	Inventors: Gary A. Nichols, Farmington Hills; James D. Yegerlehner, South Lyon, both of Mich.
[73]	Assignce: General Motors Corporation, Detroit, Mich.
[21]	Appl. No.: 361,089
[22]	Filed: Dec. 21, 1994
[51] [52]	Int. Cl. <sup>6</sup>
[58]	Field of Search 364/424.03, 424.04 364/431.07, 551.01, 571.01, 579; 123/350 352, 361, 363, 376, 377, 398, 399, 479 494; 477/906; 74/513, 514, 542; 73/118.1

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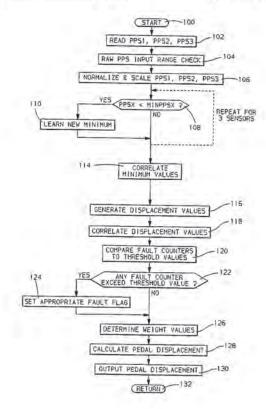
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Primary Examiner—Kevin J. Teska Assistant Examiner—Tan Nguyen Attorney, Agent, or Firm—Michael J. Bridges

#### [7] ABSTRACT

Resolution of redundant displacement sensor information to form a displacement value in an automotive electronic throttle control system provides for a varying contribution by each of a plurality of redundant sensors to the formation of the displacement value in accord with diagnosed variations in the fault status of the sensors. The number and type of fault conditions attributed to a specific sensor of the plurality over an analysis period are used to determine the relative degree by which that sensor will contribute to the displacement value formation. As an increasing number of fault conditions are attributed to a sensor, the relative degree of contribution of that sensor will gradually decrease. When severe fault conditions are attributed to a sensor, the relative degree

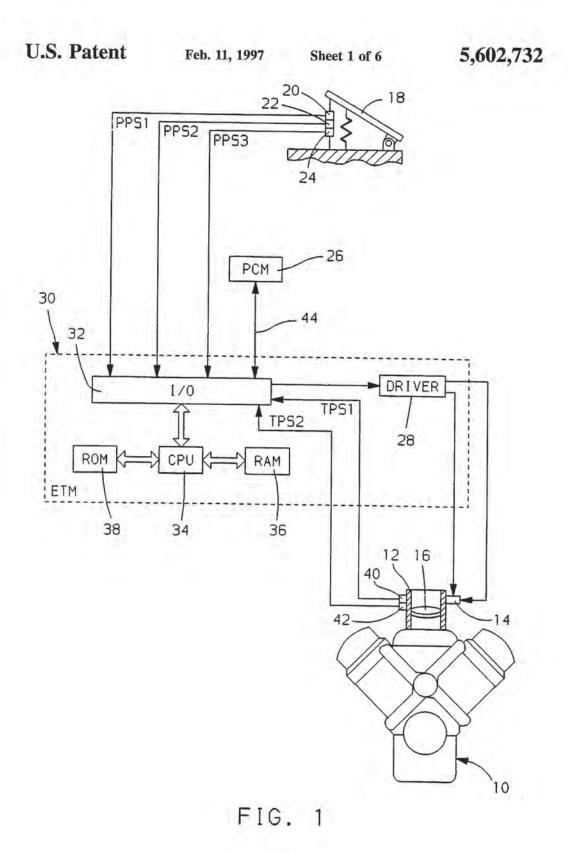
#### 12 Claims, 6 Drawing Sheets



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123/478

73/118.1



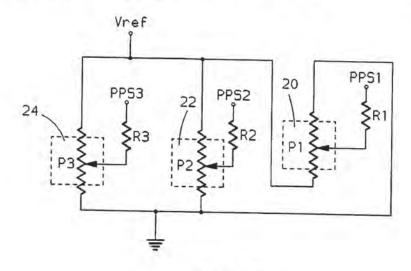


FIG. 2

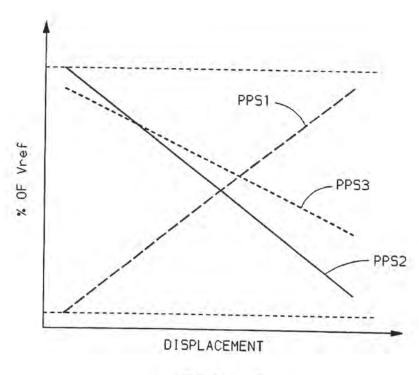
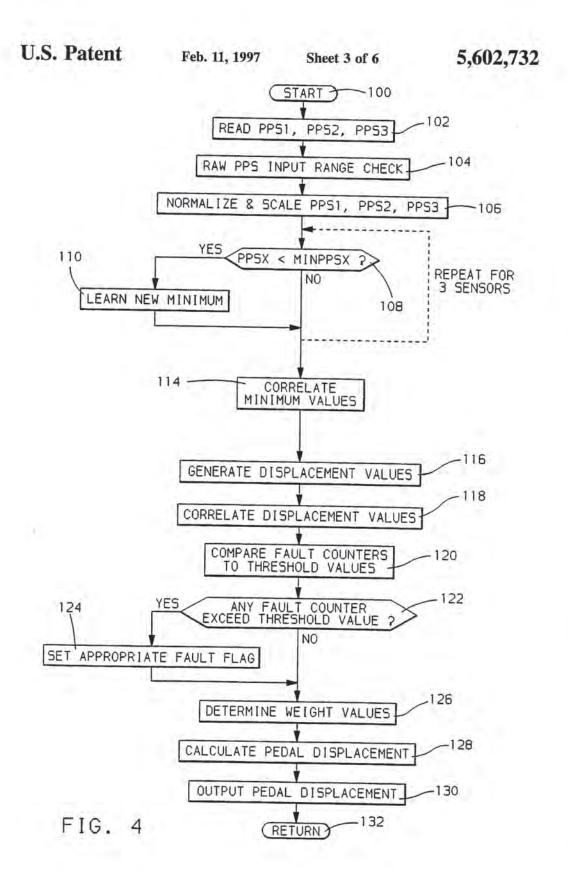


FIG. 3



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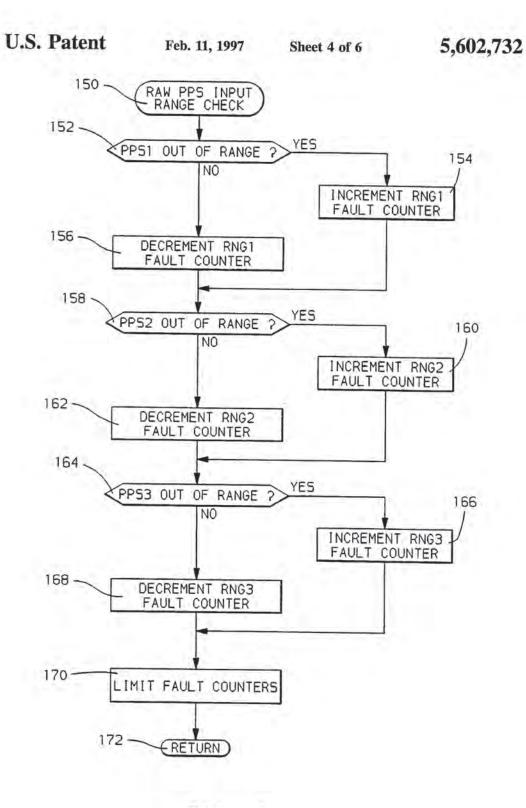
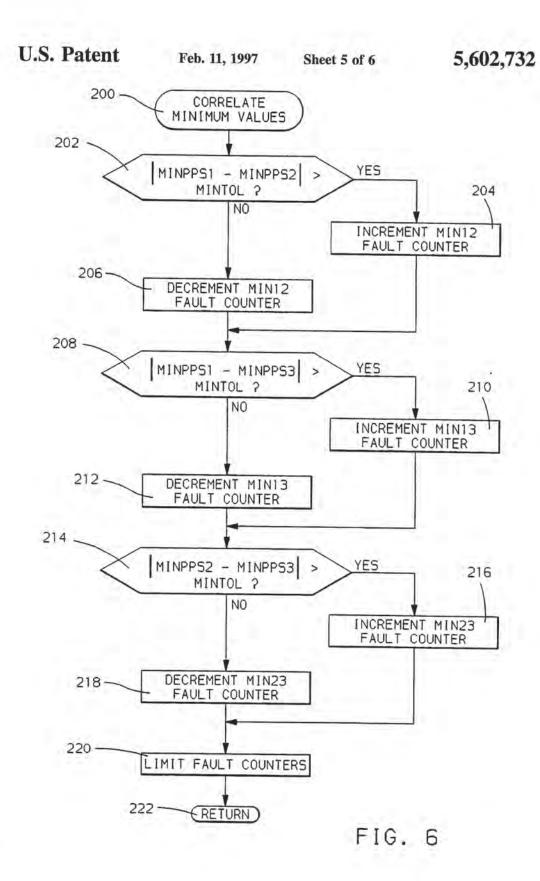


FIG. 5



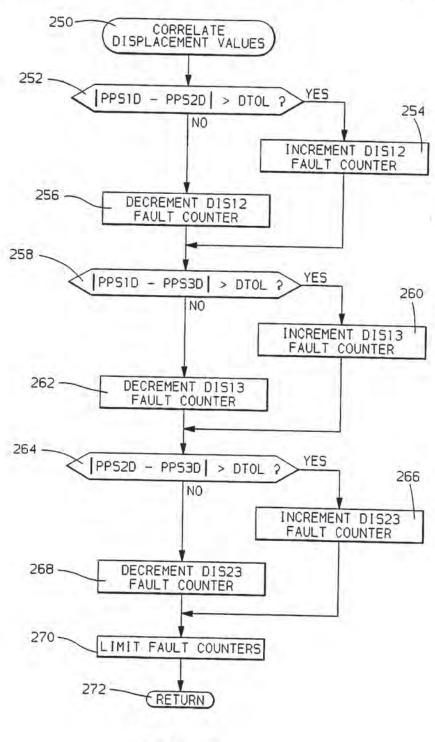


FIG. 7

#### FAULT TOLERANT DISPLACEMENT DETERMINATION METHOD

#### FIELD OF THE INVENTION

This invention relates to automotive position sensing and, more particularly, to resolving redundant sensed position input signals.

#### BACKGROUND OF THE INVENTION

Position (displacement) transducers that communicate electrical signals indicating the position or displacement of a moving part, such as an automotive vehicle accelerator 15 pedal or an engine inlet air valve are known. It is further known that redundant position indications output by multiple matched position transducers can be analyzed to improve position sensing robustness. It is still further known that a combination of at least three redundant position 20 indications provided from at least three substantially independent position transducers may be used to improve position sensing robustness by not only determining when a position transducer is providing an inaccurate position indication, but by determining which transducer is providing the 25 inaccurate position indication. If a majority of the at least three sensors indicate substantially the same position, any other sensors not in agreement will be assumed to be faulty and will be excluded, at least temporarily, from further use. The position indicated by the majority of sensors may then 30 be combined or a single position indication from the majority used as a representation of the position of the measured

Part to part variations among position transducers of reasonable cost and among typical automotive electronics components dictate that some disagreement between position indications of the plurality of processed transducers values be tolerated. Marginal transducer performance is therefore forgiven and can be reduce the accuracy of the position representation. Even minor inaccuracies can perceptibly perturb automotive vehicle performance. Until the marginal transducer performance rises to a level no longer tolerated in such conventional approaches, such inaccuracies will persist.

Accordingly, it would be desirable to provide for redundant position or displacement sensing without tolerating marginal transducer performance while avoiding the cost associated with high precision position transducers and electronic components.

#### SUMMARY OF THE INVENTION

The redundant position sensing approach of the present invention applied to automotive vehicle position or displacement sensing applications provides is desirable in that a combination of redundant position indications from inexpensive position or displacement transducers are used to resolve the position or displacement of an automotive part and the contribution of any of the combination is reduced 60 gradually in accord with its past and present fault status. Even minor fault conditions in any of the combination will be accounted for in the degree by which the transducers are permitted to contribute to the resolution of the automotive part position. Severe fault conditions attributed to a transducer may result in a more rapid decrease in its contribution to the position or displacement resolution.

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More specifically, detailed fault condition information is maintained for each of a plurality of position transducers. Each of the plurality has associated with it a weight in the form of a multiplicitive coefficient the value of which is determined as a function of the detailed fault condition information. The magnitude of the weight associated with an individual transducer is inversely proportional to the severity of any fault condition corresponding to that sensor. A transducer having no diagnosed faults will have a large weight. A sensor having a number of fault conditions from substantially independent fault analyses may have a very small weight, which can be reduced to zero. A marginal transducer may have associated with it a weight of intermediate magnitude, etc.

In a further aspect of this invention, the plurality of sensors are diagnosed in a number of fault categories including, for example, a general magnitude correlation, a minimum value correlation, and an in range correlation category. The weight associated with a transducer will decrease gradually as it appears to have failed in a greater number of such categories. The weight associated with a transducer will decrease rapidly if a severe fault condition is diagnosed for the transducer, such as a fault condition commonly associated with a significant reduction in confidence that a transducer is even reasonably accurate.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The invention may be best illustrated by reference to the preferred embodiment and to the drawings in which:

FIG. 1 is a general diagram of the automotive vehicle electronic throttle control system in which the preferred embodiment of this invention is incorporated;

FIG. 2 schematically illustrates the redundant pedal position sensor electrical configuration in accord with the preferred embodiment:

FIG. 3 diagrams relationships between pedal displacement away from a rest position and output signals of the sensors of FIG. 2; and

FIGS. 4-7 are diagrams illustrating a flow of control operations of the system of FIG, 1.

## DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. 1, inlet air is metered to internal combustion engine 10 through positioning of inlet air valve 16, such as a conventional butterfly throttle valve in engine inlet bore 12. Actuator 14 is mechanically linked to the valve 16 to rotate therewith for valve positioning. The actuator 14 is a conventional brushed DC motor in this embodiment. The rotational position of the valve 16 is transduced by a pair of rotary potentiometers 40 and 42 which output signals TPS1 and TPS2 having a voltage magnitude indicating such rotational position, in accord with well-established angular position sensing practice.

A degree of depression of an accelerator pedal 18, or equivalent means for communicating a desired engine operating level, away from a rest position is transduced by a trio of pedal position sensors 20, 22, and 24 providing respective output signals PPS1, PPS2, and PPS3 indicating such degree of depression. The sensors 20, 22, and 24 are conventional rotary potentiometers in this embodiment. An electronic throttle module ETM 30 receives the input signals TPS1, TPS2, PPS1, PPS2, ad PPS3, as well as communications from a powertrain control module PCM 26 via a bidirec-

tional communication link 44 through an input/output module I/O 32. The ETM 30 includes such standard microcontroller elements as a central processing unit CPU 34, read only memory ROM 38, and random access memory RAM 36. Through a series of control operations, the input signal information received by the ETM is processed, the processed information passed to the PCM 26 and a throttle position command generated through conventional PCM control operations. The throttle position command is returned to the ETM 30 and is passed from the CPU 34 through the I/O unit 32 to a standard DC motor driver 28, such as a full H-bridge driver configuration. The driver 28 applies drive current to throttle actuator 14 which is a DC brush motor in this embodiment, as described. The drive current excites the actuator to provide for positioning of the actuator and the valve 16 for engine inlet air metering.

The electrical configuration of the trio of pedal position sensors 20-24 in accord with this embodiment is schematically illustrated in FIG. 2. Potentiometer resistors P1, P2, and P3 are electrically connected between a reference voltage Vref, which is about five volts in this embodiment, and a ground reference voltage. The reference voltage and ground reference voltage are applied across P1 with a polarity which is the reverse of that applied across P2 and P3. The sign of the sensor output signal slope will vary between sensor 20 and the sensors 22 and 24, as will be described.

A voltage reference point varies on potentiometer resistors P1-P3 as the displacement of the accelerator pedal away from a rest position varies. Reference voltage signals PPS1, PPS2 and PPS3 are provided by passing the respective voltage reference points through respective series resistors R1, R2 and R3. The voltage difference between such signals and a reference point, such as the ground reference voltage is used as a displacement measure in this embodiment. Each of resistors R1, R2, and R3, as well as potentiometer resistors P1, P2 and P3 may be assigned distinct resistance values to provide varying sensor-to-sensor slope and offset. The varying slope and offset are valuable for sensor fault detection, as will be described.

FIG. 3 illustrates a representative set of curves for the trio of sensors 20–24 of this embodiment expressed as a function of pedal displacement. As sensor 20 is configured with a voltage polarity opposing the polarity of sensors 22 and 24 (as illustrated in FIG. 2), the voltage PPS1 corresponding to such sensor 20 will vary with inverse polarity relative to variations in the voltages PPS2 and PPS3 across respective sensors 22 and 24. The slope of the curves of FIG. 3 likewise may vary from sensor to sensor, due to resistance variations between potentiometer resistors P1–P3. Still further, offsets in the curves of FIG. 3, such as are apparent at minimum and maximum pedal displacement positions, may vary from sensor to sensor due to resistance variations between resistors R1–R3 and between potentiometer resistors P1–P3.

The described variations in slope, offset, and polarity provide fault detection advantages in that there is no sensor position for which all three sensors should have a common value. Sensor short circuit conditions to a common voltage value are thus detectable. Short circuit conditions to the ground reference or the Vref are likewise detectable, as minimum and maximum sensor voltage values corresponding to minimum and maximum pedal displacement should never be substantially the same. The rate of change in sensor voltage should also vary between the sensors for a given rate of change in pedal displacement, due to the slope variations illustrated in FIG. 3, providing yet a further fault detection opportunity. When combining the sensor voltages to resolve

pedal displacement in accord with this embodiment, the reverse sensor polarity configuration illustrated by FIGS. 2 and 3 will minimize any common increase or decrease in the sensors' output voltage, as such increase or decrease will contribute to the resolved pedal position with a reversed polarity for PPS1 than it will for PPS2 and PPS3. The different resistance values also provide for detection of internal short circuit conditions in the sensors 20–24. Such short circuit conditions will lead to a lack of correlation in sensor output values which may be detected as fault conditions. Other fault detection advantages are available through the configuration of this embodiment, as will be readily recognized through the exercise of ordinary skill in the art.

The series of steps carried out by the ETM 30 (FIG. 1) to provide for the operations of this embodiment may be stored as a series of controller instructions in ROM 38 (FIG. 1) and executed periodically while the ETM 30 is operating, such as while ignition power is applied to the ETM. In this embodiment, ignition power is applied to the ETM 30 when the ignition key of the corresponding automotive vehicle is manually rotated to its "on" position. The series of steps are generally represented by the flow of steps or controller operations detailed in FIGS. 4-7. Other operations that may be ongoing in the ETM 30 in addition to those specifically described in this embodiment, and as generally understood by those with ordinary skill in the art, including periodic reading and processing of the inlet valve position input signals TPS1 and TPS2, reading and processing of cruise control and brake control input signals (not shown), communicating diagnostic information to the PCM 26 or to other modules that may be conventionally included for vehicle diagnostics, receiving inlet air valve position command information from the PCM, verifying the PCM inlet air valve command validity, controlling the actuator 14 in accord with the received position command information, and carrying out self-diagnostic operations.

The operations pertaining specifically to pedal displacement signal processing in accord with this embodiment may be executed upon occurrence of a periodic time-based ETM interrupt. When the interrupt occurs, current CPU 34 operations, such as the above-summarized operations, are temporarily suspended, and the CPU executes specific electronic throttle control operations beginning at a step 100 of FIG. 4, and proceeding to a step 102 to read pedal position signals PPS1, PPS2, and PPS3, such as may be provided in the form of analog to digital converter output signals, indicating the voltage drop across the voltage reference points of the trio of potentiometers of FIG. 2. A fault monitoring routine is next executed at a step 104 to determine whether the position signals are within predetermined signal ranges. This routine is illustrated by the sequence of operations of FIG. 5 and, when the step 104 of FIG. 4 is executed, the sequence of FIG. 5 is carried out beginning at a step 150 and proceeding to a step 152 to compare signal PPS1 to a predetermined signal range. The signal range may be established through a conventional calibration process as the expected range of values the PPS1 sensor may output during normal operation. A corresponding range is established in this embodiment for the sensor signals PPS2 and PPS3. If PPS1 is outside the predetermined range at the step 152, a RNG1 fault counter is incremented by a calibrated increment value at a step 154 to record the sensor out of range condition. If PPS1 is not determined to be out of range at the step 152, the RNG1 fault counter is decremented by a calibrated decrement amount am step 156. After either of the steps 154 or 156, the sensor signal PPS2 is examined at a step 158. If PPS2 is outside a predetermined range of sensor values corresponding to

normal operation, such as may be determined through a conventional calibration process, a RNG2 fault counter is incremented by a calibrated increment amount at a next step 160. If no such out of range condition is determined at the step 158, the RNG2 fault counter is decremented by a 5 calibrated decrement amount at a next step 162. After either of the steps 160 or 162, the sensor signal PPS3 is analyzed at a next step 164. If PPS3 is outside a range of sensor values corresponding to normal operation, such as may be predetermined through a conventional calibration process, a RNG3 fault counter is incremented by a calibrated increment amount at a next step 166. Otherwise, if PPS3 is not outside the range at the step 164, the RNG3 fault counter is decremented by a calibrated decrement amount at a next step 168. After either of the steps 166 or 168, the routine proceeds to limit the fault counters at a step 170 to preset 15 limits. A low preset limit should be about zero to avoid counter overflow and a high preset limit should be calibrated, through a conventional calibration process, to a value preventing overflows and constraining counter values to reasonable ranges in accord with the specific requirements 20 of system in which the counters are embodied. The range of values between the low and high preset limit values then becomes the working range of the counters and any value exceeding one or the other limit will be set to that limit.

After limiting the fault counters at the step 170, the routine returns, via step 172 to the routine of FIG. 4 to continue execution of such routine at the step 106 at which the pedal position input signals are normalized and scaled to provide for direct signal comparison. For example, conventional scaling and normalization of signals PPS2 and PPS3 is carried out so that PPS2 and PPS3 signals have the same slope and offset as the signal PPS1, so that PPS2 and PPS3 may be directly compared to PPS1 to determine if the three signals generally indicate a common pedal displacement. To provide such normalization and scaling, the PPS2 and PPS3 signal values may be applied to stored lookup tables having calibrated values mapping the input signal values to values on the same scale as the PPS1 signal value.

After normalizing and scaling the pedal position input signals at the step 106, each signal is compared to a corresponding stored minimum signal value at a step 108. If the input signal is less than the corresponding stored minimum value, a step 110 is executed at which a new minimum is learned, such as by applying a conventional first order lag filter to the input signal and the stored minimum, and by limiting the learned minimum to zero. In this manner, variations in the pedal signal corresponding to a minimum pedal displacement may be learned in and used for processing subsequent pedal position signals.

After repeating the steps 108 and 110 for the three pedal position signals, so that each may learn in any new minimum value, a step 114 is next executed to correlate the sensor minimum values. The step 114 is, in this embodiment, a call to the routine illustrated in FIG. 6, to execute the steps of such routine which are responsible for determining if the minimum values of the trio of sensors are substantially the same.

Specifically, the step 114 calls for execution of the routine illustrated by the series of operations of the routine of FIG. 60, beginning at s step 200 and proceeding to a step 202 at which the difference in magnitude between MINPPS1 and MINPPS2 which are, respectively, the minimum values for signals PPS1 and PPS2 as determined at the described step 110, is compared to a calibration constant MINTOL. The 65 constant MINTOL represents a calibrated tolerance for disagreement between sensor minimum values, wherein two

pedal position sensor values are allowed to differ by a magnitude of up to MINTOL without a fault condition being assumed. The value MINTOL must be established after an analysis on sensor and analog to digital converter precision for each application, and after considering how much sensor-to-sensor variation will be tolerated in a given application before a fault condition is to be diagnosed.

Returning to the step 202, if the magnitude of difference between MINPPS1 and MINPPS2 exceeds MINTOL, a step 204 is executed to increment a MIN12 fault counter by a calibrated increment value, wherein MIN12 is provided to record such deviations. Alternatively, if the magnitude of the difference does not exceed MINTOL, the MIN12 fault counter is decremented by a calibrated decrement amount at a step 206. After either of the steps 204 or 206, a next step 208 is executed to correlate the minimum values for PPS1 and PPS3. Specifically, the magnitude of the difference between MINPPS1 and MINPPS3, which are the minimum stored sensor values for sensors PPS1 and PPS3, respectively, is compared to MINTOL. If the difference exceeds MINTOL, a MIN13 fault counter is incremented by a calibrated increment amount at a step 210, and if the difference does not exceed MINTOL, the fault counter is decremented by a calibrated decrement amount at a step 212.

After either of the steps 210 or 212, a next step 214 is executed to correlate the minimum stored values for sensors PPS2 and PPS3. Specifically, the difference between MIN-PPS2 and MINPPS3, which are, respectively, the learned minimum values for sensors PPS2 and PPS3 as determined at the described step 110, are compared to MINTOL and if the difference exceeds MINTOL, a step 216 is executed at which a MIN23 fault counter is incremented by a calibrated increment value. If the difference is not determined to exceed MINTOL at the step 214, a step 218 is next executed at which the MIN23 fault counter is decremented by a calibrated decrement value.

It should be noted that the value MINTOL may vary for each of the sensor pairs correlated through execution of the operations of the routine of FIG. 6. Specifically, MINTOL may take on a calibrated value for the comparison of the step 202 that is different than the MINTOL value for the comparison at the step 208. Further, the MINTOl used in the comparison at the step 214 may be different than either of the MINTOL values used in the steps 202 and 208. In such case, the different MINTOL values must be established through a conventional calibration process in accord with the considerations described in the text corresponding to the step 202, such as including sensor and analog to digital converter precision and a desired degree of deviation before a fault will be assumed to be present.

After either step 216 or step 218, a next step 220 is executed to limit the MIN12, MIN13, and MIN23 fault counters to a calibrated range of counter values, such to a range defined by about zero at a low counter limit and to a calibrated reasonable upper value at a high counter limit. Such range prevents counter overflows and constrains the counter values to reasonable values in accord with their intended use, to be described. The low and high counter limits define a range of counter values that MIN12, MIN13 and MIN@3 will be constrained to at the step 220, such as by setting the counter value to any limit value that it exceeds or is less than. After limiting the fault counters at the step 220, the correlation of minimum values is complete, and the routine returns, via a next step 222, to the step 114 of the routine of FIG. 4.

After correlating the minimum values through the operations executed at the step 114, a next step 116 is executed to

generate displacement values for each of the three sensor input signals. The displacement values in this embodiment represent a count of accelerator pedal displacement away from a rest position and are established as a difference between the normalized, scaled sensor input signals as provided at the step 106 of FIG. 4 and the respective sensor minimum values. The generated displacement values are designated as PPS1D, PPS2D and PPS3D for the respective sensors PPS1, PPS2 and PPS3. The determined displacement values are next correlated at a step 118, which step provides a call to a routine generally illustrated by the flow of operations of FIG. 7. The routine of FIG. 7, when called through execution of the step 118 of FIG. 4, is entered at a step 250, and proceeds to a step 252 to compare a difference between PPS1D, the displacement value corresponding to signal PPS1, and PPS2D, the displacement value corresponding to signal PPS2, to DTOL. The value DTOL is a predetermined value representing a displacement difference tolerance. DTOL may be calibrated after determining the degree of precision and signal repeatability between the 20 pedal position sensors, after examining the precision and repeatability between the analog to digital converters, and after determining how much variation will be tolerated between displacement values before a fault will be diagnosed. If the difference exceeds DTOL at the step 252, a DIS12 fault counter for storing a count of displacement value faults between displacement values corresponding to sensors PPS1 and PPS2 is incremented by a calibrated increment value at a next step 254. If the difference is determined at the step 252 to not exceed DTOL, the DIS12 fault counter is decremented by a calibrated decrement value at a next step 256.

After either of the steps 254 or 256, correlation of displacements values corresponding to PPS1 and PPS3, represented by PPS1D and PPS3D is provided by moving to 35 a next step 258 to compare the magnitude of the difference between PPS1D and PPS3D to a predetermined displacement tolerance value DTOL. DTOL may be calibrated after determining the degree of precision and signal repeatability between the pedal position sensors PPS1 and PPS3, after 40 examining the precision and repeatability between the analog to digital converters corresponding to such sensors PPS1 and PPS3, and after determining how much variation will be tolerated between the corresponding displacement values before a fault will be diagnosed. If the difference exceeds 45 DTOL at the step 258, a DIS13 fault counter for storing a count of displacement value faults between displacement values corresponding to sensors PPS1 and PPS3 is incremented by a calibrated increment value at a next step 260. Returning to the step 258, if the difference is determined to 50 not exceed DTOL, the DIS13 fault counter is decremented by a calibrated decrement value at a next step 262.

After either of the steps 260 or 262, correlation of displacements values corresponding to PPS2 and PPS3, represented by PPS2D and PPS3D is provided by moving to 55 a next step 264 to compare the magnitude of the difference between PPS2D and PPS3D to a predetermined displacement tolerance value DTOL. As described in the text corresponding to the steps 252 and 258, DTOL may be calibrated after determining the degree of precision and signal 60 repeatability between the pedal position sensors PPS2 and PPS3, after examining the precision and repeatability between the analog to digital converters corresponding to such sensors PPS2 and PPS3, and after determining how much variation will be tolerated between the corresponding 65 displacement values before a fault will be diagnosed. If the difference exceeds DTOL at the step 264, a DIS23 fault

counter for storing a count of displacement value faults between displacement values corresponding to sensors PPS2 and PPS3 is incremented by a calibrated increment value at a next step 266. Returning to the step 264, if the difference is determined to not exceed DTOL, the DIS23 fault counter is decremented by a calibrated decrement value at a next step 268. It should be pointed out that the value DTOL may vary for each of the three operations of steps 252, 258, and 264, so that varying tolerances may be made available for each of the three correlations provided through the operations of FIG. 7. The individual DTOL values may be calibrated for each of the pair of sensors correlated at the steps 252, 258,

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After either of the steps 266 or 268, the displacement fault counters are limited at a next step 270 to a range of fault counter values calibrated to prevent counter overflows and to ensure that counter values are of appropriate magnitude for use in accord with this embodiment. The calibrated counter limits are compared to the counter values at the step 270 and if a counter value exceeds either of its limit values, it is set to that limit value at the step 270.

and 264, in accord with the desired degree of magnitude

correlation between each corresponding sensor pair.

After limiting the fault counters at the step 270, a next step 272 is executed to return to the operations of FIG. 4 at the step 118, as correlation of the displacement values is complete. Following execution of the step 118, a next step 120 is executed to compare the fault counters established through execution of the routines of FIGS. 5-7 to a corresponding set of counter threshold values. The threshold values are calibrated through a conventional calibration process to maximum values tolerated for each corresponding counter before a fault condition will be flagged. Occasional small count values may be tolerated without flagging a fault condition, but when the counter values increase to a level indicating a persistent out of range condition or a persistent condition of sensor-to-sensor disagreement, such that they exceed a corresponding calibrated threshold value, a fault should be flagged.

Returning to the step 120 of FIG. 4, if any of the fault counters exceeds its corresponding threshold values as determined at a next step 122, a fault flag is set at a next step 124. The fault flag may be stored in ETM memory, such as in a non-volatile portion of RAM 36 (FIG. 1). After setting any fault flags at the step 124, or if no fault counters exceeded their corresponding threshold values at the step 122, weight values are next determined at a step 126 for weighting the trio of displacement values in accord with the fault status of the corresponding sensor. Each sensor has one weight value which may take the form of a multiplicitive coefficient applied to the displacement value corresponding to the sensor. The displacement value corresponding to PPS1, called PPS1D in this embodiment, has a weighting value W1, the displacement value corresponding to PPS2, called PPS2D in this embodiment, has a weighting value W2, and the displacement value corresponding to PPS3, called PPS3D in this embodiment, has a weighting value W3. The weighting values are determined in this embodiment as a function of the current fault flag values that may have been set at the described step 124, or which may not be set. Fault flags are initialized to zero during each ETM operating cycle in this embodiment and remain at zero unless set at the described step 124.

The weighting values are to be calibrated in this embodiment and stored in the form of a lookup table of values referenced by the status of all of the fault flags for the trio of sensors. The weighting values provide that a sensor will have a greater input into a resolved pedal position used in

electronic throttle control if it is characterized by fewer flagged fault conditions (if fewer diagnosed fault conditions are attributed to the sensor). If the fault flags indicate that a single sensor has a significant number of flagged fault conditions, or has at least one severe fault condition, it may 5 substantially be excluded from the position resolution process, as will be described. A severe fault condition is a fault condition commonly associated with a substantial degradation in sensor accuracy, such as a condition in which a sensor signal is found to be outside a reasonable signal range, as is 10 diagnosed through execution of the operations corresponding to FIG. 5. Likewise, if a sensor has few associated faults, it will have a more significant contribution to resolving pedal position.

The following logic statements are examples of fault flags 15 and corresponding weighting values in accord with this embodiment, in which the term "fcf" is "fault counter flag".

#### EXAMPLE 1:

IF: all fcf clear, THEN: W1=W2=W3=1/3.

#### **EXAMPLE 2:**

IF: all fcf set, THEN: W1=W2=W3=0.

#### EXAMPLE 3:

IF: RNG1 fcf set and
RNG2 fcf clear and
RNG3 fcf clear and
MIN23 fcf or DIS23 fcf not set,
THEN: for any MIN12, MIN13, DIS12 and DIS13 fcf,
W1=0, W2=W3=1/2.

#### EXAMPLE 4:

IF: RNG1 fcf set and
RNG2 fcf set and
RNG3 fcf clear and
THEN: for any combination of MINxx and DISxx fcf, 40
W1=W2=0, W3=1,

#### EXAMPLE 5:

IF: RNG1 fcf set and RNG2 fcf set and RNG3 fcf set and

THEN: for any MINxx and DISxx, W1=W2=W3=0.

The principles under which the above examples are established are described, for purposes of enabling extension 50 of this logic to cover all possible fault flag scenarios, as follows. If, as in example 1, no fault conditions are flagged, each sensor has an equal one third contribution (weighting) to the pedal displacement indication. If, as in example 2, all fault conditions are flagged or, as in example 5, all sensors 55 are out of range, each sensor weight will be zero, resulting in an indication of zero pedal displacement, due to an assumed severe pedal sensing fault condition.

If, as in example 4, only one of the trio of sensors is in range such that it has a clear RNGx flag, then for any 60 combination of sensor correlation fault flags, it will have a weight of one and the other two sensors will have a weight of zero, excluding such other two sensors from contributing to the displacement determination. If, as in example 3, two sensors are within range indicated by two RNGx flags being 65 clear, and the two that are within range correlate with each other, then the two correlating sensors will have a weight of

½ and the third sensor will have a weight of zero. Finally, if any combination of flags does not provide a clear indication of a "more faulty" sensor between any pair of two sensors having some flagged fault condition, the sensor with the lower indicated pedal displacement value will have a weight of one and the other two sensors will have a weight of zero.

These examples illustrate that correlation fault conditions are not relatively severe due, for example, to tolerances between sensors and between electronic components. Out of range fault conditions however, are severe. Increases in non-severe fault conditions for a sensor result in a more gradual reduction in weight values and thus in sensor contribution to displacement resolution, whereas severe fault conditions result in a more rapid reduction in the weight values.

It is to be understood that this invention is not to be limited to the specific method of weighting value determination described above for the step 126 of FIG. 1. Rather, the inventors intend that any method of varying the degree of contribution of each of a plurality of "redundant" sensors, such as the trio of sensors of this embodiment, whether gradually or more rapidly, as a function of sensor fault conditions, to the resolution of a sensed value is within the scope of this invention. For example, substantially continuous functions may be provided for each of the weighting values having fault flags or indeed fault counters as function inputs, subject to the condition that the sum of the weighting values equals one or, in the case of a severe fault condition, equals zero. Such functions may be generally expressed as

Wx=F(MINxx fault counter, DISxx fault counter, RNGx fault counter)

wherein x takes on values from 1 to 3 to cover the three weighting values and the nine different fault counter values. It should be further understood that certain values, such as counter values or weight values may be stored in non-volatile portions of ETM RAM 36 (FIG. 1) so that important sensor diagnostic information may be retained for use from one ignition cycle to the next, rather than waiting to "relearn" such information in a subsequent ignition cycle.

Returning to the routine of FIG. 4, after determining the weight values at the step 126, a pedal displacement value PD is resolved through the following calculation:

#### PD=W1\* PPS1D+W2\* PPS2D+W3\*PPS3D

so that a final resolved pedal position includes information from each of the redundant sensors with a multiplicitive weight coefficient established in accord with the determined integrity of the corresponding sensor value. Sensor values more likely to be faulty, due to a plurality of related fault conditions, will contribute less to the PD determination than will sensor values appearing less likely to be faulty, in accord with a critical aspect of this invention.

The pedal displacement value PD is next output at a step 130 to the PCM 26 (FIG. 1) via the ETM I/O hardware 32 for use in establishing a desired engine inlet air valve position in accord with well-established and generally understood principles of electronic throttle control. After outputting the pedal displacement value at the step 130, a step 132 is executed to return to any prior operations that were temporarily suspended to allow for servicing the interrupt through execution of the routines of FIGS. 4-7.

The preferred embodiment for the purpose of explaining this invention is not to be taken as limiting or restricting this invention since many modifications may be made through the exercise of ordinary skill in the art without departing from the scope of this invention.

The embodiments of the invention in which a property or privilege is claimed are described as follows:

 A method for determining displacement of a movable part, comprising the steps of:

for each of a plurality of displacement transducers, (a) providing a displacement signal from the displacement transducer, (b) diagnosing fault conditions in the displacement transducer, (c) establishing a fault severity value indicating a degree of severity of any diagnosed fault condition, and (d) calculating an adjusted displacement signal as a predetermined function of the provided displacement signal and the fault severity value; and

determining displacement of the movable part by combining the adjusted displacement signals for the plurality of displacement transducers.

The method of claim 1, further comprising, for each of the plurality of displacement transducers, the step of:

diagnosing whether a severe fault condition is present for 20 the displacement transducer;

wherein the establishing step establishes a fault severity value that gradually increases in magnitude from an initial value toward a limit value as the number of fault conditions diagnosed to be present increases and that is set to the limit value when a severe fault condition is diagnosed to be present.

and wherein the predetermined function provides for a relationship of substantially inverse proportionality between the adjusted displacement signal magnitude <sup>30</sup> and the fault severity value magnitude.

3. The method of claim 2 wherein, for any of the plurality of displacement transducers for which no severe fault condition is diagnosed to be present, the fault severity values are established subject to the condition that the sum of all of 35 such values is substantially equal to a predetermined constant.

4. The method of claim 1, further comprising, for each of the plurality of displacement transducers, the steps of:

comparing the displacement signal to the displacement 40 signals provided by the other of the plurality of displacement transducers; and

determining a correlation fault condition when the displacement signal does not substantially correspond to the displacement signals of the other of the plurality of 45 of: displacement transducers; and wherein the fault conditions diagnosed at the diagnosing step include the correlation fault condition.

5. The method of claim 1, further comprising, for each of the plurality of displacement transducers, the steps of:

establishing a range of displacement signal values over which the displacement signal of the corresponding displacement transducer may normally vary;

comparing the displacement signal provided by the corresponding displacement transducer to the established range; and

determining an out of range fault condition when the displacement signal exceeds the established range; and wherein the fault conditions diagnosed at the diagnosing step include the out of range fault condition.

 The method of claim 1, further comprising the steps of establishing, for each of the displacement transducers, a minimum displacement signal corresponding to a minimum displacement;

comparing the minimum displacement signals of the plurality of displacement transducers; and determining a minimum correlation fault condition for any of the plurality of transducers having a minimum displacement signal that does not substantially correspond to the minimum displacement signals of the other of the plurality of displacement transducers; and wherein the fault conditions diagnosed at the diagnosing step include the minimum correlation fault condition.

7. A method for resolving displacement from a plurality of displacement input signals provided by a plurality of redundant displacement sensors, comprising the steps of:

diagnosing whether any of a predetermined set of displacement sensor fault conditions are present;

attributing each fault condition diagnosed to be present to at least one of the displacement sensors;

for each displacement input signal, determining a signal weight value as a predetermined function of the fault conditions attributed to the corresponding sensor;

applying each determined signal weight value to the corresponding displacement input signal to form a weighted input signal; and

combining the weighted input signals to form a resolved displacement value.

8. The method of claim 7, wherein the predetermined set of displacement sensor fault conditions includes a predetermined subset of severe displacement sensor fault conditions, and wherein the determining step further comprises the step of:

for each of the plurality of displacement sensors, setting the corresponding signal weight value to a minimum weight value if any severe fault conditions that are diagnosed to be present are attributed to the corresponding sensor.

9. The method of claim 8 wherein, for each sensor to which no severe fault conditions are attributed, the predetermined function yields signal weight values that vary inversely with the number of diagnosed fault conditions attributed to the corresponding sensor.

10. The method of claim 9, wherein the predetermined function is subject to the condition that the sum of the signal weight values for the sensors to which no severe fault conditions are attributed is a predetermined constant.

11. The method of claim 10, further comprising the steps of:

establishing a signal range over which displacement input signals may vary under normal operating conditions;

comparing the displacement input signals to the established signal range;

and wherein the diagnosing step diagnoses a severe fault condition to be present when a displacement input signal exceeds the established signal range.

12. The method of claim 10, further comprising the steps of:

for each of the plurality of displacement sensors, establishing a signal range over which the corresponding displacement input signal may vary under normal operating conditions;

comparing each displacement input signal to its corresponding established signal range;

and wherein the diagnosing step diagnoses a severe fault condition to be present when a displacement input signal exceeds the corresponding established signal range.

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# EXHIBIT K



## United States Patent [19]

#### Fischer

5,661,735 Patent Number:

Date of Patent: Aug. 26, 1997

[54]	FDIC METHOD FOR MINIMIZING MEASURING FAILURES IN A MEASURING SYSTEM COMPRISING REDUNDANT			
	SENSORS			
1751	Inventor: Harald Fischer Preiburg Germany			

[73] Assignee: LITEF GmbH. Germany

[21] Appl. No.: 578,840

[22] Filed: Dec. 26, 1995

[30] Foreign Application Priority Data

Dec. 27, 1994 [DE] Germany ....... 

367/124; 364/560; 364/571.02

[58] Field of Search ... 371/49.1, 49.4. 371/50.1, 57.1, 64, 67.1, 25.1, 28; 395/184.01, 185.01; 376/245. 215. 216, 217; 367/124, 125; 364/560, 561, 562, 571.02, 571.03, 571.04, 571.07; 318/563, 564

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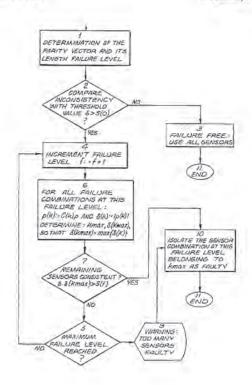
Primary Examiner-Robert W. Beausoliel, Jr. Assistant Examiner-Trinh L. Tu Attorney, Agent, or Firm-Elliott N. Kramsky

#### [57] ABSTRACT

A method for minimizing measured quantities determined from sensors affected by measuring failures and detected by a plurality of redundant sensors connected to form a measuring system by detecting and isolating the sensors affected by failures. Sensor values measured by all the sensors are mapped by a linear transformation into a vector in the parity space (parity vector). The dimension of the parity space is determined by the redundance of the measuring system (i.e., the number of sensors and the dimension of the quantity to be measured).

The subspaces at each failure level that contain the largest proportion of the measured parity vector are determined by projection of the measured parity vector onto all possible subspaces. The best sensor combination at each failure level can be determined by omitting the sensor combinations belonging to such subspaces.

#### 5 Claims, 5 Drawing Sheets

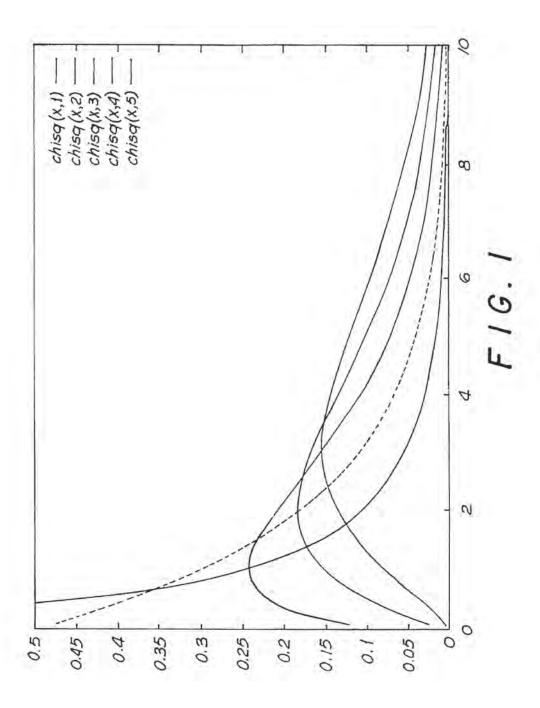


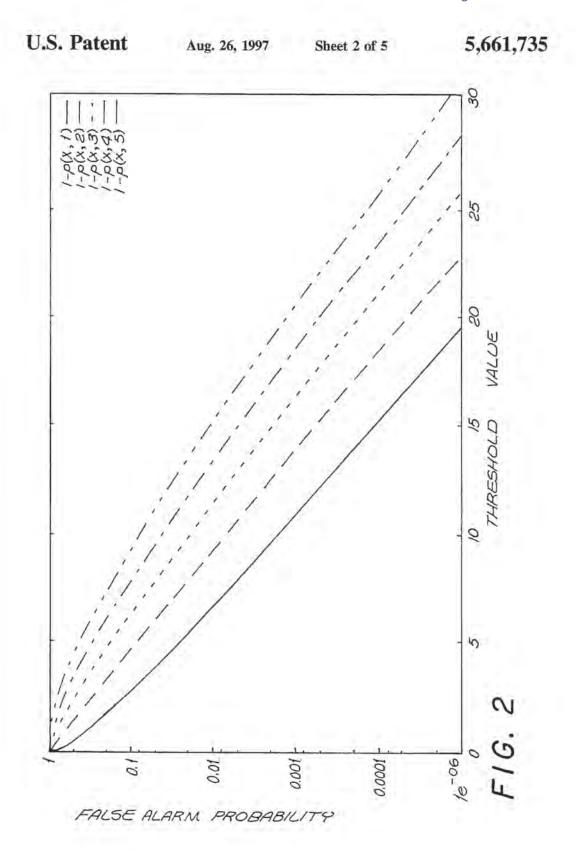
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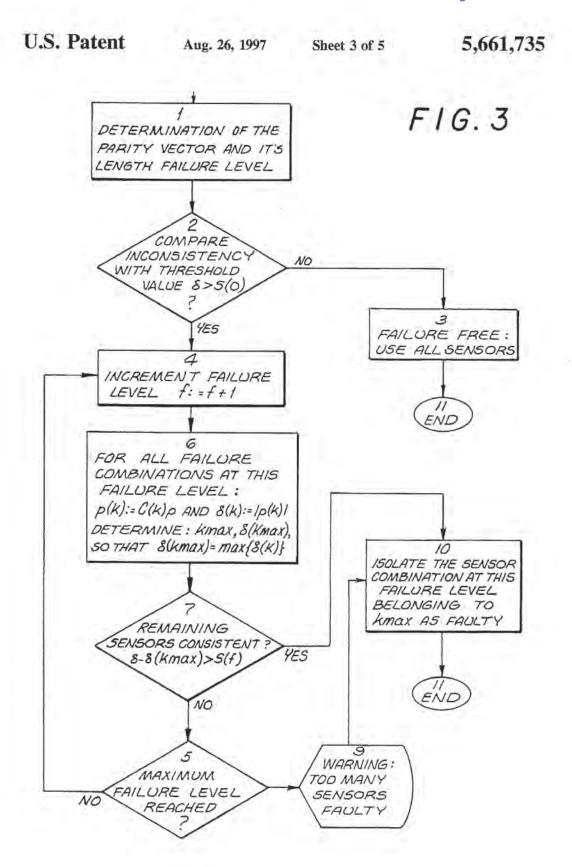
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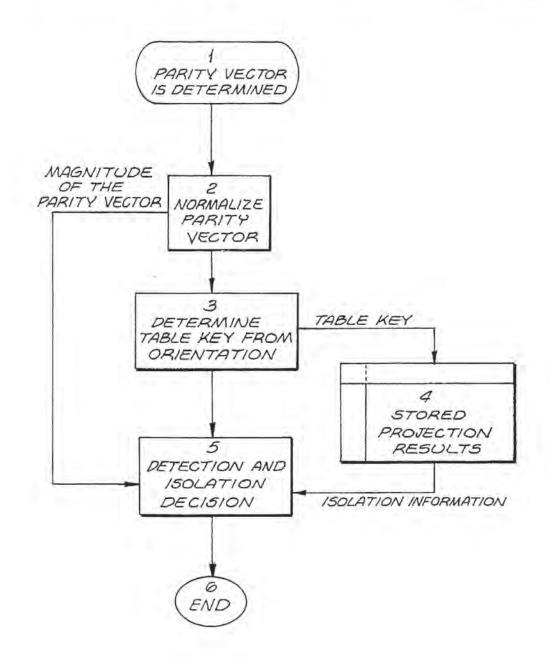
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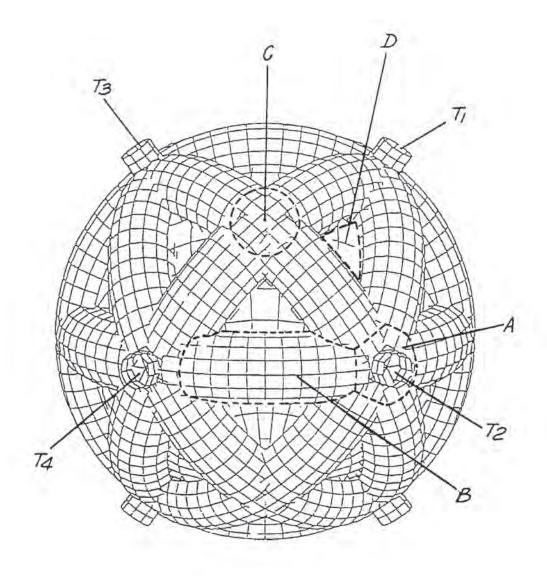




Aug. 26, 1997



F1G. 4



F1G. 5

#### FDIC METHOD FOR MINIMIZING MEASURING FAILURES IN A MEASURING SYSTEM COMPRISING REDUNDANT SENSORS

#### BACKGROUND

#### 1. Field of the Invention

The present invention relates to a method for minimizing the contributions of failed sensors in a measurement system comprising a plurality of redundant interconnected sensors.

More particularly, this invention is directed to minimizing measurement errors in such a system by detecting and isolating the faulty sensors employing failure detection, isolation and correction ("FDIC") methods.

#### 2. Description of the Prior Art

When redundant sensors are provided for measuring a quantity, it is theoretically possible to detect failures in one or a number of such sensors by comparison of the data provided by the sensors. If the faulty sensors are additionally isolated, then it is possible to eliminate the measuring failure by omitting the sensors determined to be faulty.

This general problem occurs in a multiplicity of applications including, for example, measurement of movement with inertial systems containing redundant inertial sensors 25 (e.g. gyroscopes and accelerometers possibly possessing nonparallel sensing axes), and position determination in satellite navigation systems having redundant satellite configurations. The existing methods for solving the problem can be broadly divided into two categories. These are (i) grouping of the system into sensor combinations of minimal redundance by determining all individual combinations and employing combinatorial logic to determining the largest possible failure-free sensor combination (i.e. "parity methods") and (ii) isolating the individual sensor that contributes most to the overall discrepancy (Chi-square criterion) followed by elimination of that sensor ("maximum likelihood" methods).

The known disadvantages of such methods are, in the case of parity methods:

- (a) The number of individual combinations of minimal redundance required to be taken into account grows combinatorially (i.e. as n!) with the number of sensors. Since the parity of each combination must be evaluated, cost increases commensurately.
- (b) Each individual parity is evaluated discretely as either "good" or "bad" by comparison with predetermined threshold values. A parity that only barely violates a threshold value is indistinguishable from a large threshold-value violation. The same is true of 50 threshold-value undershoots. The resulting total pattern of the parity violations does not, therefore, permit unambiguous interpretation over a comparatively wide range of sensor failures, leaving interpretation to heuristic means. This can lead to unnecessary misinterpretations as the additional introduction of various ("large" and "small") threshold values can only party ameliorate the problem while increasing cost.
- (c) Since the selection of threshold values is generally fixed, an unexpectedly high noise level of all the sensor of values leads to complete failure as it is then possible that all individual combinations will exceed the threshold values with discrimination no longer taking place beyond them. The threshold values must be matched to the worst possible case to avoid this problem. This is leads to undesirably high insensitivity of the method in "normal operation".

(d) As the individual parities are broadly divided into higher/lower than the threshold value, singularities (i.e. sensor data combinations that do not, in principle, permit unambiguous isolation of failure) can only be roughly detected and partly distinguished from unambiguous situations. The result of this is that either (1) singularities remain undiscovered or (2) cases that are actually unambiguous are treated as singularities. Failure to discover singularities can lead to incorrect decisions. Treating unambiguous cases as singularities can impair the integrity of the method since a less reliable information is generally relied upon in the treatment of singularities.

"Maximum likelihood" methods are subject to the fol-15 lowing disadvantages:

- (a) False isolation decisions can occur when multiple failures take place simultaneously since these methods are based upon the assumption that, at any particular given time, only one sensor delivers faulty data.
- (b) After the occurrence and isolation of an individual failure, it is necessary to reconfigure the parameters of the method in real time to the corresponding (n-1) sensor configuration to detect and further isolate lateroccurring individual failures. The subsequent faulty behavior of the previously-isolated sensors is no longer included in the new configuration. Possible "recovery" of such sensors can only be detected by parallel processing of a plurality of configurations. This correspondingly increases the processing costs.

#### SUMMARY AND OBJECTS OF THE INVENTION

It is therefore an object of the invention to provide an improved FDIC method that is free of the described short-comings of prior art parity and maximum likelihood methods.

The present invention addresses the aforesaid object by providing a method for minimizing the contributions of sensors affected by possible measuring failures detected by a plurality of redundant interconnected sensors forming a measuring system by detecting and isolating the sensors affected by failures. The method is begun by mapping the sensor values measured by all of the sensors, which are combined to form a measured vector by means of a linear transformation, into a vector in a parity space (parity vector). The dimension of the vector space is determined by the redundance of the system.

Thereafter, the absolute magnitude of the parity vector is determined and compared with a first detection threshold. A failure-free state is concluded when the first detection threshold is not exceeded. In the event that the threshold is exceeded, the measured parity vector is projected onto all subspaces characteristic of possible failure states. The dimensions of the subspaces are determined by the number of possible faulty sensors associated with the respective failure state. In order to isolate the failures, the projection of the parity vector onto a subspace, respectively belonging to the relevant failure determination level, which provides the largest proportion of the measured parity vector, is established.

It is then tested to determine whether the remaining residual failure exceeds a second detection threshold. When the second detection threshold has not been exceeded, the best sensor combination is determined by omitting the sensor value combination belonging to the respective subspaces with the largest proportion of the parity vector at the

relevant failure determination level. When the second detection threshold is exceeded, the measured parity vector is projected onto all subspaces characteristic of the possible failure states, the projection of the parity vector onto a subspace that provides the largest proportion of the measured parity vector established as before and the remaining residual failure tested to determine whether the next detection threshold is exceeded. This process continues until a detection threshold is not exceeded in which case the best sensor combination is determined by omitting the sensor value combination belonging to the respective subspaces with the largest proportion of the parity vector at the relevant failure determination level.

The method according to the invention essentially differs from the known parity and maximum likelihood methods in 15 the following regards:

geometrical interpretation of the properties of the parity space and their consequent use for isolating simultaneously occurring multiple failures;

off-line analysis of the directions in the parity space and the provision of the isolation results in a precalculated table.

optionally possible adaptive matching of the detection thresholds to the general noise level of the failure-free sensors.

The sensor values (measurement vector) measured by all the sensors are mapped by a linear transformation into a vector in the parity space. The dimension of the parity space is determined by the redundance of the measuring system, which is to say by the number of sensors and the dimension of the quantity to be measured. For example, with 8 non-parallel measuring axes for measuring a 3-dimensional movement quantity (for example speed of rotation or acceleration), the dimension of the associated parity space is equal to 5. A number of subspaces can be defined in this parity space, each of which is characteristic of a particular combination of sensor failures. In the case of the abovementioned example of 8 individual sensor axes for measuring a 3-dimensional quantity, these subspaces are:

- 8 one-dimensional subspaces (lines) for characterizing uniaxial failures
- 28 two-dimensional subspaces (planes) for characterizing biaxial failures
- 56 three-dimensional subspaces for characterizing triaxial 45 failures
- 70 four-dimensional subspaces for characterizing fouraxis failures

(Note: five-axis failures can still be detected, but not isolated, and failures relating to a larger number of axes 50 cannot even be detected using the sensor system of this example.)

The subspaces characterize failure combinations in such a way that, when a particular failure combination is present, the resulting parity vector lies fully within the relevant 55

The principle of the method consists in determining, by projection of the measured parity vector onto all possible subspaces, which of the subspaces for each failure level (uniaxial, biaxial, ...) involves the greatest portion of the 60 measured parity vector. By omitting the sensor combinations associated with these subspaces, the best sensor combination can then be determined at each failure level. The result of this failure isolation is independent of any threshold values, since it is not determined by the magnitude (length) of the 65 measured parity vector, but only by its direction. The magnitude of the parity vector, or of the projection of the

parity vector onto the subspaces, is only employed for failure detection; that is to decide whether a failure is present at all, or whether a single, double, triple failure, etc., should be assumed. (This decision, too, can be made without "a priori" threshold values, if the projections onto the subspaces with minimal redundance are optionally employed as a measure for these threshold values.)

Measures to improve efficiency are essential for actual practice of the principle in real-time processing. Since the failure isolation depends only on the direction of the parity vector, it is possible to calculate the projections of the parity vector onto the characteristic subspaces off line, outside the real-time application, and to provide the result of the failure isolation in a table. The cost to be expended in real time is then restricted to calculation of the parity vector and of a table key from the direction of the parity vector. By using the key, the results of the failure isolation are then called up from the table. In order to minimize the required table size, use may be made of the symmetries in the parity space, which are given from the symmetry of the sensor axial arrangement.

The preceding and other objects and advantages of the present invention will become further apparent from the detailed description that follows. Such description is accompanied by a set of drawing figures. Numerals of the drawing figures, corresponding to those of the written description, point to the features of the invention. Like numerals refer to like features throughout both the written description and the drawing figures.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a graph of the statistical (Chi-square) density distributions of the resulting lengths of parity vectors for 1 degrees to 5 degrees of freedom;

 FIG. 2 is a graph of false-alarm probability as a function of predeterminable threshold values for various degrees of freedom;

FIG. 3 is a flow chart for illustrating the method of the invention;

FIG. 4 is a flow chart of the method of the invention in accordance with an alternative embodiment that includes stored isolation detection; and

FIG. 5 is an illustration of the parity space in which four sensors are provided to measure a scalar quantity.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The method of the invention is described below in three sections ("A", "B" and "C"). Section A describes basic principles. The implementation of the failure-detection method is described in section B with the aid of flow charts. Finally, two applications are presented in section C. A. BASIC PRINCIPLES

The basic principle underlying the invention is the existence of a linear or linearized relationship in the failure-free case between quantities to be determined and sensor values measured. Thus,

Where s indicates the sensor values combined to form measurement vectors, x is the quantity to be measured and e indicates a sensor failure. The matrix A describes the relationship between the two for the failure-free case.

The estimated value of the quantity to be measured is given by the measured sensor values according to the following:

In particular,

$$f=H\bar{s}$$

$$H=(A^TA)^{-1}A$$
(2)

Where H, pseudoinverse of the matrix A, provides the linear least squares fit. It is assumed below that the relevant inverse exists (i.e., the measured quantity can be determined).

With regard to "residues" (i.e., deviations between actual sensor values (affected by failures) and the sensor values 10 associated with the estimated measured value), the following equation applies;

$$r = s - A\hat{x}$$

$$= \langle 1 - AH \rangle s$$

$$= R s$$
(3)

The magnitude of the residue vector r is a measure of the consistency of the sensor data. That is, with fully consistent sensor data, r is equal to zero, while it differs from zero when the sensor data are affected by failures. In principle, the value of r allows conclusions to be drawn regarding the failure. For efficient analysis of sensor data consistency, r is not directly taken as a starting point. Rather, R is firstly diagonalized according to

$$R = V^2$$

$$\begin{pmatrix}
\lambda_1 & 0 & \cdots & 0 \\
0 & \lambda_2 & \cdots & 0 \\
- & & \cdots & \cdots \\
0 & \cdots & 0 & \lambda_n
\end{pmatrix} V$$
(4)

R is by definition real and symmetrical, so that diagonalization is always possible. In addition, it is a property of the eigenvalues λ, that they can only assume the values of 0 and 1. The degeneracy of the eigenvalue 0 is determined by the dimension of the measured quantity while that of the eigenvalue 1 is determined by the number of redundant sensors. For the decomposition of R according to equation 4, this means that, in the matrix V, only the rows with the eigenvalues 1 contribute to R. Let m be the dimension of the quantity to be measured and n be the number of sensors, then the dimension of the matrix V is (n-m)×m, and the (n-m) rows of V can be constructed from an orthonormalized set of eigenvectors of R with the eigenvalue 1.

The matrix V has the following properties

The mapping

defines, for a measured vector s. a parity vector p that 65 contains all the information regarding the failure state of the sensor value.

$$\mathbf{r}^{T}\mathbf{r}=\mathbf{p}^{T}\mathbf{p}$$
 (7

that is, the length of the residue vector r is equal to the length of the parity vector p and serves as a measure of the consistency of the sensor combination containing all sensors.

A conclusion can be drawn from the direction of p as to which sensors contribute how much to the overall failure. If, for example, a single failure is present in sensor i, then the parity vector determined according to equation 6 lies wholly in the direction defined by the ith column of V. In the event of a double failure (i.e., in the sensors i and j), the resulting parity vector lies in the plane spanned by the ith and jth columns of V. The column vectors of the matrix V thus define characteristic subspaces containing the resulting parity vector for particular failure combinations. The assignment of subspaces of the parity space to failure combinations can be continued with an increasing number of sensors affected by failures for as long as the number of associated column vectors does not yet span the entire parity space. In the case of n sensors and an m-dimensional measured quantity, the dimension of the parity space is (n-m) and the matrix V consists of n characteristic column vectors. Only (n-m) column vectors are required to span the parity space fully (i.e., it is possible to isolate failures in up to (n-m-1) sensors).

In order to test the hypothesis that failures are present in a particular combination k of sensors, one of the projections

$$p_A=C_Ap$$

$$o_A=O_Ap$$
(8)

with the property

$$o_k^T o_k + p_k^T p_k = p^T p$$
 (9)

is formed, the rows of the transformation matrix  $C_k$  being formed by orthonormalization of the column vectors of V involved in the combination k. The corresponding transformation  $O_k$  projects onto the respective orthogonal subspace. The relationship of equation 9 can be used to determine only the projection onto the subspace with smaller dimensionality. As a result, the processing cost is reduced.

The following consistency criteria are satisfied:

The quantities

$$c_k = p_k^T p_k$$
  
 $\delta_k = p^T p_- p_k^T p_k$  (10)

are a measure of which portion of the observed inconsistency is due to the sensors involved in the combination k, or still remains if these sensors are omitted.

The total number K of sensor combinations whose failtotal ures can, in principle, be isolated is given by

$$K = \sum_{f=0}^{n-m-1} {n \choose f}$$
(11)

The summand in each case describes the number of combinations (f of n) associated with a failure level f. The summation runs from the failure-free case (f=0) to the minimum required residual redundance (f=n-m-1). For

each of these sensor failure combinations, the consistency of the remaining sensors can be determined according to equation 8, and, by comparison with a threshold value dependent on the failure level, a decision can be made as to whether the sensor combination remaining in each case affords acceptable consistency. In particular, it is also possible to sort the sensor combination at each failure level in order of increasing inconsistency, and at each failure level to determine the combination with the best consistency. An important property of the parity vector, which is used in a practical embodiment of the method, is that the relative magnitudes of the inconsistencies for the various sensor combinations are determined solely by the orientation of the parity vector in the parity space. The absolute magnitude is given by a common factor from the magnitude of the parity vector. The 15 latter does not, however, have any influence on the order of the sensor combinations sorted according to inconsistencies.

Under particular failure conditions it is possible for a plurality of different sensor combinations to give an accept- 20 able consistency for one failure level or for the best consistency not to be determined unambiguously, in such a way that two different sensor combinations provide consistency values which are very close to the maximum. In the geometrical interpretation of the parity space, this case corresponds to the situation that the parity vector determined from the measured vector lies at the intersection of two (or more) characteristic subspaces. Should this occur at the maximum failure level, then there is a singularity, and unambiguous failure isolation only on the basis of the 30 currently measured sensor values is not possible. An isolation decision may then possibly be made using the data of earlier processing cycles, for example such that an earlier, unambiguously made isolation decision is retained, if this also delivers an acceptable consistency for the current 35 singularity case. Otherwise, additionally available status information regarding the individual sensors is employed to resolve singularities.

#### Threshold Value Determination:

In the establishment of detection thresholds as acceptance 40 criteria for the inconsistencies of the remaining sensor combinations at the various failure levels ("threshold values"), account must be taken of the fact that even failure-free sensors do not deliver absolutely consistent measured data, but they are affected by some inaccuracies. 45 The inaccuracies of the failure-free sensors establish a lower limit for the threshold values to be selected, it also being possible to take into account a safety factor to avoid false alarms. The safety factor is determined by the statistical distribution of the inaccuracies of failure-free sensors and 50 The effect of selection of the threshold values is that, even the required maximum false alarm rate.

An upper limit for the threshold values to be selected is given by the external accuracy requirements of the application. Such requirements establish which failures in the measured quantity to be determined can still be accepted or at what rate missed detection is permissible

A prerequisite of a technically meaningful application is that the inaccuracies of the failure-free sensors permit a sufficiently accurate determination of the measured quantity. That is, the upper limit of the threshold values must lie considerably above the abovementioned lower limit.

If an independent, statistical normal distribution (with variance 1, to which the threshold values are then related) is in each case assumed for the inaccuracies of the failure-free sensors, then a Chi-square distribution with degree of freedom v=(n-m) results from equation 7 for the statistical 65 density distribution of the resulting length of the parity vector.

$$f(x,v) = \frac{x^{r/2-1} \exp(-x/2)}{2^{r/2}\Gamma(v/2)}$$
(12)

This density distribution is represented in FIG. 1 for various degrees of freedom. In the case of failure-free sensors, this corresponds to the statistical distribution of the remaining inconsistencies o, at the various failure levels. For each degree of freedom they are respectively equal to the degree of freedom. The lower limits for the threshold values S' for a predetermined, maximum permissible false alarm rate P, are determined by

$$P_f = 1 - \int_{0}^{S_f^{MGZ}} f(x, \nu) dx \qquad (13)$$

and the upper limits for the threshold values Smax can, with a maximum permissible failure Ax, of the ith component of the measured quantity to be determined, be estimated as

$$S_{\pi}^{\text{nea}} = \frac{\Delta x_i^2}{\sum_{i=1}^{n} H_{\pi}^2}$$
(14)

Where Hij are the elements of the least squares transformation matrix. The graph of FIG. 2 gives the relationship between selected threshold value (in units of  $\sigma^2$  of the sensor inaccuracy) and the resulting false alarm probability.

Under nominal conditions (i.e., if the sensor inaccuracy of the failure-free sensors has the assumed distribution), then the threshold values determined in this way affect the desired false alarm rate and failure limits for the measured quantity. However, under circumstances in which (temporarily) all of the sensors exhibit larger inaccuracies than assumed, undesired failure detections can occur. To avoid this, the threshold values can be dynamically matched to the lowest inconsistency of the highest failure level (i.e., to the inconsistency of the best sensor combination) with the minimum number of redundant sensors. Instead of the above-described threshold values Snom, threshold values of the form

$$S_*=\max[S_*^{hom},a\cdot\min[\delta_k]]$$
 (15)

are then selected, where a is chosen as a function of the failure level, or of the degree of freedom, for example such

with unexpectedly high inaccuracy of all sensors, the method accepts the best sensor combination, at the latest, at the maximum failure level. Even failures at the lower failure levels are only detected when individual sensors are actually significantly less accurate.

## B. IMPLEMENTATION OF THE METHOD

It is not generally required to evaluate respectively all sensor combinations or sensor failure combinations to carry out the failure detection and isolation method. Rather, the method schematically represented in the flow chart of FIG. 3 can be employed. In this, the parity vector is first determined (box 1) and the consistency of the overall sensor combination calculated therefrom.

Whether the consistency of the overall sensor combination is acceptable is detected (box 2) by comparison with a threshold value which is selected specifically for the failure level f (here f=0). If acceptable, then all sensors are sufficiently failure-free and can be employed to determine the measured quantity (box 3). The method (for the current processing cycle) is then terminated. Otherwise, the sensor combinations of the failure level 1, which result from omission of one sensor in each case, are first evaluated (box 5 6), and the best sensor combination at this failure level is determined. Should this best sensor combination be acceptable (i.e., the remaining inconsistency lies below a threshold value (dependent on the failure level) (box 5)), then the combination at this failure level (box 10).

Otherwise, a test is carried out as to whether the maximum failure level has already been reached (box 5), and, if this is not the case, such method is continued for the next higher failure level (box 4). If the maximum failure level is 15 measured value T, is reached without sufficient consistency determined in the remaining sensors at the maximum failure level, it is assumed that too many sensors are faulty. The best sensor combination at the maximum failure level is isolated as an "emergency solution". This case can only occur if the 20 threshold values of the individual failure level are rigidly predetermined and are not dynamically matched.

For applications in which the geometry of the sensor system, and therefore also the geometry of the characteristic subspaces in the parity space, do not change at all or only 25 slowly compared to the required processing frequency, a method in accordance with FIG. 4 can be selected to increase the efficiency further.

After the parity vector has been determined from the sensor values (box 1), the norm of the parity vector is 30 determined and the parity vector is suitably normalized (box 2). A normalization particularly suitable for these purposes consists of normalizing the component with maximum magnitude to the value +1 by multiplication of all components by a factor. The index of the maximum component serves as a 35 first element in the table key. The remaining portion of the table key is then obtained from the remaining components of the parity vector by quantizing the respective value range [-1, +1] into q equal sections. A table formed in this way then has, in the case of a d-dimensional parity space and a 40 quantization of the components into q sections,

entries, which respectively code for one direction of the 45 parity vector. This number gives an upper limit, which can be further reduced by exploiting possible applicationspecific symmetries in the parity space.

After the table key has been determined from the components of the parity vector (box 3), isolation information 50 stored under this key is called up (box 4). At each table key (direction of the parity vector), the f respective best sensor combinations are provided in order of increasing inconsistency for each failure level f.

For the detection and isolation decision (box 5), only 55 these respective best sensor combinations are then evaluated, by projection of the parity vector onto the associated subspaces, at each failure level. In this case, the sequence of the above-described stepped method can then again be used.

The sensor combination to be used is then selected independent of the method used to establish the consistency of the sensor combinations. Each sensor combination has its own least squares transformation matrix H, in which the sensors to be omitted are no longer taken into account, and 65 the value of the quantity to be measured is given from the measured vector according to equation 2.

#### C. APPLICATION EXAMPLES

Four thermometers:

In this example, the application for a particularly simple case is demonstrated. In it redundant sensors are used for measuring a scalar (1-dimensional) measured quantity. In the example, 4 sensors were chosen, so that it is even possible to isolate simultaneously occurring double failures and, on the other hand, the parity space, which, in this case, isolation decision can be terminated with the best sensor 10 is three-dimensional, still gives clear ideas regarding the geometry in the parity space. Instead of the thermometers, mentioned here, for measuring temperature, it is equally possible to consider any other scalar measured quantities/ sensors. The relationship between the temperature and the

$$\begin{cases} T_1 \\ T_2 \\ T_3 \\ T_4 \end{cases} = \begin{pmatrix} \frac{1}{4} \\ \frac{1}{4} \\ \frac{1}{4} \end{pmatrix}, r$$
Then
$$H = \begin{pmatrix} \frac{1}{4} & \frac{1}{4} & \frac{1}{4} & \frac{1}{4} \\ -\frac{1}{4} & \frac{3}{4} & -\frac{1}{4} & -\frac{1}{4} \\ -\frac{1}{4} & -\frac{1}{4} & \frac{3}{4} & -\frac{1}{4} \\ -\frac{1}{4} & -\frac{1}{4} & -\frac{1}{4} & \frac{3}{4} \end{cases}$$
with a
$$V = \begin{pmatrix} -\frac{1}{2} & \frac{1}{2} & -\frac{2}{2} & \frac{1}{2} \\ -\frac{1}{2} & \frac{1}{2} & -\frac{1}{2} & -\frac{1}{2} \\ -\frac{1}{2} & \frac{1}{2} & \frac{1}{2} & -\frac{1}{2} \end{pmatrix}$$

The number of possible, isolatable failure combinations is K-11, and the corresponding combinations, with the associated projection matrices, are given in the following table. A projection onto the subspace of smaller dimension is chosen in each case.

TABLE 1

		for the characteristic remometer example.
Number of faulty sensors	Faulty sensor(s)	Projection matrices
1	1	$C_k = \frac{1}{\sqrt{3}} \cdot (-11 - 1)$
1	2	$C_k = \frac{1}{\sqrt{3}} \cdot (1 \ 1 \ 1)$
4	3	$C_k = \frac{1}{\sqrt{1-k}} \cdot (-1-k)$

TABLE 1-continued

		for the characteristic hermometer example.
Number of faulty sensors	Faulty sensor(s)	Projection matrices
1	4	$C_k = \frac{1}{\sqrt{3}} \cdot (1 - i \rightarrow 1)$
2	1,2	$O_k = \frac{1}{\sqrt{2}} \cdot (10 - 1)$
2	1,3	$O_k = \frac{1}{\sqrt{2}} \cdot (0 \text{ I } 1)$
2	1,4	$Q_k = \frac{1}{\sqrt{2}} - (1 \ 1 \ 0)$
2	2,3	$O_k = \frac{1}{\sqrt{2}} \cdot (1-1.0)$
2	2,4	$O_k = \frac{1}{\sqrt{2}} \cdot (0.1 - 1)$
2	3,4	$O_k = \frac{1}{\sqrt{2}} * (1 \cdot 0 \cdot 1)$

FIG. 5 illustrates the geometrical conditions in the threedimensional parity space for the preceding example including four thermometers. The four characteristic directions for individual failures lie along the space diagonals (regions A) defined by the four thermometers T1 to T4. Six planes in all are spanned by the four directions, and the planes correspond to the double failures (regions B), the width of the indicated "bulge" specifying the magnitude of the permissible establishable inaccuracies of failure-free sensors. The intersections of the planes define the singularity regions in which unambiguous double failure isolation is not possible (regions C). If the direction of the parity vector lies in the remaining regions of the represented sphere (regions D), then there exists a failure in more than two thermometers. which can no longer be isolated. The width of the regions depends on the inaccuracy assumed for failure-free sensors. In the representation of FIG. 5 only a typical region is represented, by bold interrupted bordering, for each region. Position determination by measuring the pseudodistance to navigation satellites:

In this case, position determination from measured "pseudodistances" is considered. The measurement equation is of the form (after conventional linearization by a known approximated value for the position), in the case of n observed satellites

$$s = Ax$$

$$\begin{pmatrix} s_1 \\ \vdots \\ s_n \end{pmatrix} = \begin{pmatrix} a_{1x} & a_{1y} & a_{1x} & 1 \\ \vdots \\ a_{xx} & a_{xy} & a_{xx} & 1 \end{pmatrix} \begin{pmatrix} x \\ y \\ z \\ c \cdot \delta t \end{pmatrix}$$

$$s_0$$

$$s_0$$

$$s_1$$

$$s_2$$

$$s_3$$

$$s_4$$

$$s_4$$

$$s_4$$

$$s_5$$

$$s_6$$

$$s_7$$

$$s$$

The components  $s_i$  of the measured vector characterize the 65 measured pseudodistances to the individual satellites, x, y, z and  $\delta t$  characterize the components of the positional

correction, or the failure in the receiver clock. The first three elements of each row of the measured matrix are the direction cosines of the connecting line between the satellite and the approximated position. Since, in this case, the measured matrix A changes as a function of the respective satellite constellation, further procedures must be dynamically carried out for failure detection and isolation, i.e., for calculation of the parity transformation V. In this case, however, it is substantially possible to resort to quantities already determined for the position determination.

In any case, the transformation matrix

 $H=(A^TA)^{-1}A$ 

is determined, from which the residue matrix R can be determined, by

R=I-AH

An orthonormal set of eigenvectors of R with eigenvalue 1 can be determined by means of standard numerical methods. The eigenvectors, as row vectors, respectively form the rows of the matrix V. The parity vector determined by

p=V s

is then projected onto the characteristic subspaces, determined by the permissible satellite combinations, and an optimally consistent satellite combination is determined. When determining the permissible satellite combinations, care should be taken to consider only such combinations with a sufficient DOP value.

Because of the changing satellite constellation, there is no possibility of an off-line precalculation of a decision table, in which an isolation decision for all directions of the parity vector is stored. However, such a calculation can be carried out by a background task, since the satellite constellation only changes slowly.

The improvements which can be achieved with this method are:

Failure isolation takes place without threshold values, which is to say that it can take place without "a priori" assumptions regarding the actual noise of the failurefree sensors.

During isolation of the failure, apparent singularities are avoided and actual singularities are detected as such.

In contrast to existing parity methods, the processing cost needed in real time for failure detection and isolation is in principle determined only by the dimension of the parity space, and is independent of the number of possible sensor combinations. Thus, for example, the 163 possible combinations of 8 uniaxial accelerometers, arranged with nonparallel axes, can be isolated with the same cost as the 11 possible combinations of 4 biaxial gyroscopes arranged with nonparallel axes.

In contrast to existing "maximum likelihood" methods, it is in addition always possible, within the bounds of intrinsic limits, to detect and isolate simultaneously occurring multiple failures correctly. While this invention has been described with reference to its presently-preferred embodiment, it is not limited thereto. Rather, the present invention is limited only insofar as it is defined by the following set of patent claims and includes within its scope all equivalents thereof.

While this invention has been described with reference to its presently-preferred embodiment, it is not limited thereto. Rather, the present invention is limited only insofar as it is defined by the following set of patent claims and includes within its scope all equivalents thereof.

What is claimed is:

- 1. A method for minimizing a contributions of sensors affected by possible measuring failures detected by a plurality of redundant interconnected sensors forming a measuring system by detecting and isolating said sensors affected by failures comprising the steps of:
  - a) mapping the sensor values measured by all of said sensors such that the sensor values are combined to form a measured vector by means of a linear transformation into a measured parity vector; and
  - b) determining a dimension of said vector space by redundance of the measuring system; then
  - determining an absolute magnitude of said parity vector; and
  - d) comparing said magnitude with a first detection threshold; and
  - c) concluding a failure-free state when said magnitude does not exceed said first detection threshold; and
  - f) if said magnitude exceeds said first detection threshold, projecting said measured parity vector onto all subspaces characteristic of the possible failure states wherein dimensions of said subspaces are determined by the number of possible faulty sensors associated with the respective failure state; and
- g) establishing which projection of the parity vector onto a subspace, respectively belonging to relevant failure determination level, providing the largest proportion of the measured parity vector, in order to isolate said failures: then

- h) testing whether a residual failure exceeds a second detection threshold; and
- i) proceeding to step j) when said residual failure does not exceed said second detection threshold while carrying out steps f) and g) with the next failure determination level if said residual failure exceeds said second detection threshold; and then
- j) determining the best sensor combination by omitting a sensor value combination belonging to the respective subspaces with the largest proportion of the parity vector at the relevant failure determination level.
- 2. A method as recited in claim 1 further characterized in
- a) failure isolation is carried out off-line by calculating all
  possible projections of the parity vectors onto the
  characteristic subspaces; and
- a calculated result is stored in a table whose elements are employed via a correspondingly coded direction of the parity vector as a table key,
- A method as recited in claim I wherein said detection thresholds are selected by external guidelines.
- 4. A method as recited in claim 1 wherein at least said first detection threshold is determined by possible noise values and permissible inaccuracies of said sensors.
- 5. A method as recited in claim 3 wherein a number of sensors is taken into account in the guidelines for the detection thresholds.

\* \* \* \* \*

Case3:11-cv-04494-WHO Document411-12 Filed04/18/14 Page1 of 14

# EXHIBIT L



# United States Patent [19]

#### Kelly

### Patent Number:

## 6,016,465

Date of Patent:

Jan. 18, 2000

#### [54] SENSOR FAULT DETECTION SYSTEM

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- Assignee: The Secretary of State for Defence,
  - Farnborough, United Kingdom
- [21] Appl. No.: 09/005,547
- [22] Filed: Jan. 12, 1998

#### Related U.S. Application Data

- [63] Continuation of application No. PCT/GB96/01596, Jul. 4,
- [30] Foreign Application Priority Data Jul. 10, 1995 [GB] United Kingdom

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[:	51]	Int. Cl.7	
F	521	TIS CI	702/116: 702/60: 702/170

702/189; 702/191; 376/215 ...... 702/116, 60-69, [58] Field of Search 702/179, 189, 191, 193, 195; 376/215-217; 345/914, 915

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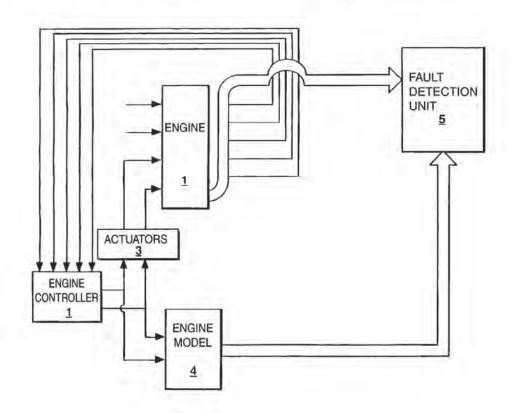
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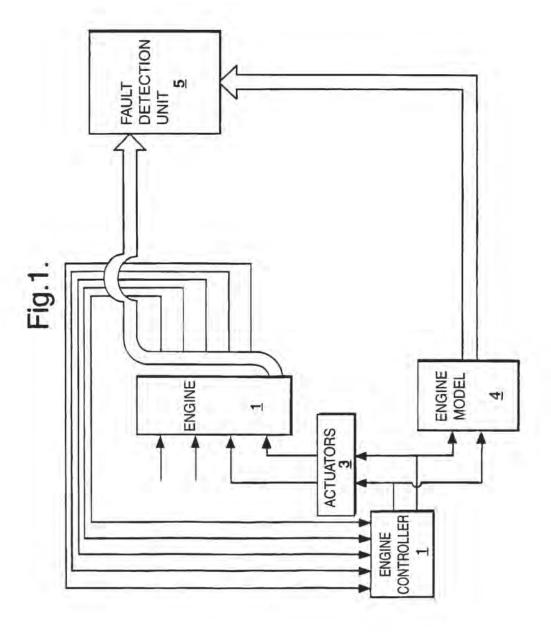
Primary Examiner-Kamini Shah Attorney, Agent, or Firm-Nixon & Vanderhye P.C.

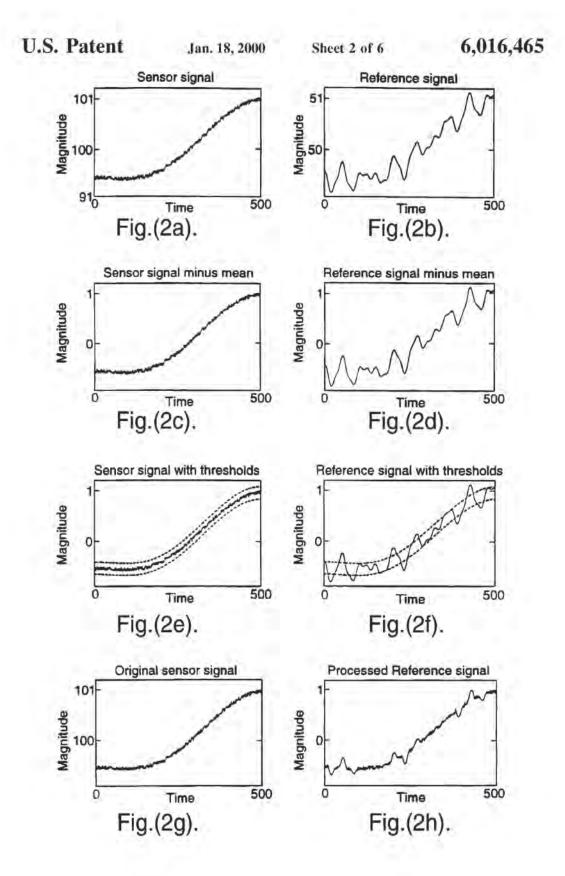
ABSTRACT

The sensor fault detector is one in which each sensor signal is compared with a reference signal provided by e.g. a model of the system being monitored. Prior art sensor fault detectors subtract the output of the sensor and the corresponding reference signal from each other, and a fault is declared when the residual difference exceeds a prescribed threshold. However, modelling errors (such as scaling discrepancies), die bias and noise mean that faults are often wrongly declared, or alternatively that only large faults can be detected. These problems are overcome according to the invention by comparing the "shape" of the sensor signal with that of the corresponding reference signal (i.e. comparing the signal outlines) over a finite time window, using e.g. correlation techniques. A fault is declared when the shapes differ by a prescribed amount.

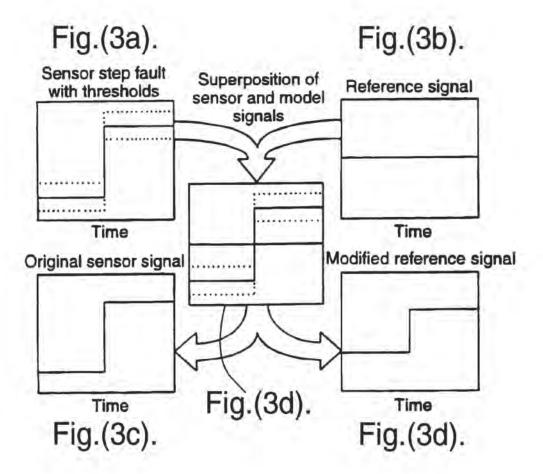
#### 8 Claims, 6 Drawing Sheets



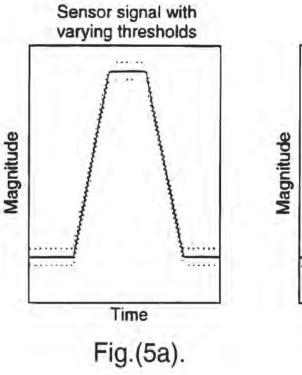


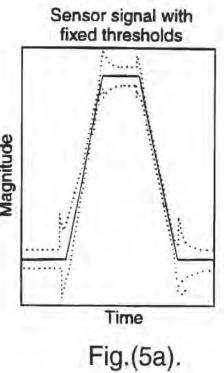


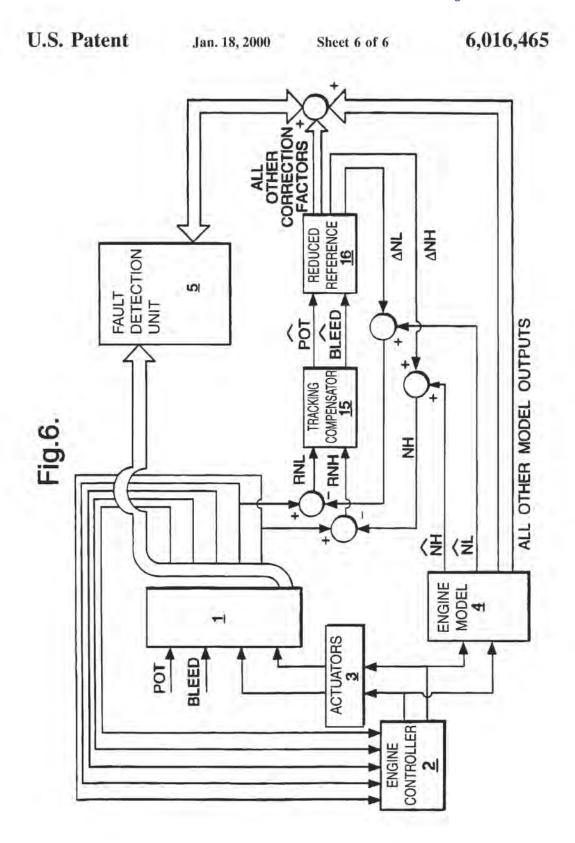
Pharmatech Solutions, Inc: EXHIBIT 1031 - 195 IPR2013-00247, U.S. Pat. No. 7,250,105



Jan. 18, 2000







#### SENSOR FAULT DETECTION SYSTEM

This is a continuation of PCT application No. PCT/ GB96/01596, filed Jul. 4, 1996.

#### BACKGROUND OF THE INVENTION

#### 1, Field of the Invention

This invention relates to an improved system for detecting, sensor faults in systems which rely on sensors for monitoring and control purposes. An example of this is the detection of faults in sensors used to control gas turbine engines.

#### 2. Discussion of Prior Art

Sensors which measure gas turbine engine parameters have been shown to be one of the most fault prone components in such engine control systems. Attempts to improve sensor integrity have concentrated on maintaining correct sensor readings, even in the event of one or more sensor faults. It is known in the art to overcome the problem of sensor faults by doubling or even trebling the number of sensors. This duplication of components is referred to as "hardware redundancy", which means that if a fault arises in one of the sensors, its presence is indicated by virtue of the two sensor signals being dissimilar. Although this method is widely used, it is not only costly, but more importantly in aerospace applications, results in extra weight of the sensors and associated electronics.

To avoid these disadvantages, "analytical redundancy" has been studied as a means of reducing the number of sensors whilst still retaining the required degree of integrity. Analytical redundancy detects the presence of a sensor fault by comparing the sensor reading with a reference signal provided by a software model for example, rather than from a duplicate sensor. Such software models must accurately follow the characteristics of the system being monitored or controlled, and must be able to run in real time. Most model-based systems use some sort of observer or Kalman filter to continuously correct the reference states, using information from the engine sensors, such that they mirror the actual outputs.

Once the reference outputs are obtained they are subtracted from the actual sensor outputs. The difference between these two signals is often referred to as the residual signal. In prior art fault detection systems which use this method, a fault is declared if the residual exceeds a prescribed threshold value; if no faults are present, the residual signal would ideally be zero.

In most applications, however, it is impossible to obtain a model of a complicated system such as a gas turbine engine which can run in real time and which still matches the system sensor outputs over the system's entire operating range. This is especially true when sensor noise is taken into consideration. Filtering can help reduce noise but will not entirely eliminate it. In practice, therefore, allowance must be made for the fact that the amplitude of the reference outputs will always be different from the amplitude of the sensor outputs.

Methods which only compare the amplitude of the engine and reference outputs are very susceptible to modelling 60 errors. When a system is in steady state, modelling errors will cause d.c. biases between the system and reference outputs. These biases will not only vary under different operating conditions of the engine but also between different systems of the same type. Prior art fault detection systems 65 which compare the difference in amplitudes between system and reference outputs generate residual signals which are at

least as large as these d.c. biases and so the fault detection thresholds have to be increased accordingly. This in turn means that only faults which are larger than these d.c. biases can be detected. Another problem is that the dynamic modelling errors are usually larger than the steady state errors. This means that during engine manoeuvres where the engine state is chaoging rapidly, the sensor fault detection thresholds have to be increased. Because of these problems it has been difficult to determine effective threshold values which allow differences in signals due to small faults to be distinguished from those arising from modelling errors, noise and d.c. biases. This often results in sensor faults being wrongly declared. Practical application of the above techniques has therefore been largely confined to the detection of large, catastrophic faults.

UK patent application GB 212156A describes a method for detecting errors in a control system by comparing model and actual outputs from the system. Error signals above a pre-set deadband are integrated and a fault signal is generated if the integral exceeds a pre-set value. The integral is set to zero when the discrepency dissappears. Although this helps to show slow incipient errors, problems remain. Firstly one has to choose the appropriate deadband which is often a "hit or miss" exercise because many modelling errors or d.c. biases which may occur are indeterminate, especially when one considers that each sensor is different. Another problem concerns scaling; both reference and actual signals have to be of the same scale otherwise the integral method will always register a fault.

The problem with such systems are that when the system is running at as steady state, the only characteristics of the sensor and artificial reference signals will be due to noise which will be different for both signals, often causing a faults to be erroneously indicated.

#### SUMMARY OF THE INVENTION

It is therefore an object of the invention to provide a sensor fault detection system which overcomes these problems.

According to the invention is provided a method of detecting sensor faults in a system having at least one sensor for monitoring or controlling system parameters, the method comprising the following steps:

- (a) generating reference sensor signals of the system;
- (b) recording the value of the or each sensor signal and the corresponding reference sensor signals at regular intervals:
- (c) comparing the shape characteristics of a series of values of the or each sensor signal with the shape characteristics of a series of corresponding modified reference signals by means of a correlation coefficient;
- (d) continuously updating the respective series of signals with the most recent values, and;
- (e) declaring a fault when the correlation coefficient fails outside a prescribed range, characterised in that the modified reference signal is generated by:
- (f) multiplying the reference signal by a scaling factor to convert the or each sensor signal and its corresponding reference signal
- (g) calculating the mean values of the or each sensor signal and its corresponding reference signal;
- (h) subtracting the respective mean values from the or each sensor signal and its corresponding reference signal to obtain new values for the or each sensor signal and its corresponding reference signal;
- (i) applying deviation thresholds to either side of the new values for the or each sensor signal;

(j) superimposing the value of the or each reference signal over the thresholds around the new value of its corresponding sensor signal, and

(k) formulating a modified reference signal from a hybrid of values of the new sensor signal and the new reference signal.

It is a further object of the invention to provide a sensor fault detection method which is insensitive to unmeasured disturbances acting on the system. These unmeasured disturbances are in effect inputs which, in an open loop system, will affect the system output but not reference outputs. In the case of aero engines for example, unmeasured disturbances would be typified by power off-take or bleed. Power off-take describes the process by which power is drawn from the engine to supply energy for various airborne systems such as to actuate control surfaces. The magnitude of these disturbances is unmeasured and therefore unknown. In a closed loop control system engine output are fed back to provide information to the model. The effects of unmeasured disturbances on the system outputs and reference outputs will 20 generally be different. Compensation for the effects of unmeasured disturbances is performed according to an aspect of the invention by detecting the level of such unmeasured disturbances and by incorporating an additional model of these to allow correction factors to be applied to 25 the reference outputs used in the comparison stage.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described by way of example only with reference to the following figures of which:

FIG. 1 shows in block diagram form an arrangement of the sensor fault detection system.

FIGS. 2(a)-2(h) show diagrammatic representation of the generation of a modified reference signal which is 35 preferably compared with the actual sensor signal.

FIG. 3 and FIGS. 3(a) to 3(d) shows a problem of detecting step faults in the one of the embodiments of the invention.

FIG. 4(a)-4(i) show how the problem described in FIG. 3 is overcome by a further refinement

FIG. 5(a)-5(b) show sensor signals onto which fixed or varying thresholds may be added.

FIG. 6 shows a block diagram of the sensor fault detector configured to compensate for conditions when unmeasured disturbances are acting.

# DETAILED DISCUSSION OF PREFERRED EMBODIMENTS

FIG. 1 shows an embodiment of the sensor fault detector applied to an aero-engine. The complete system comprises the aero-engine (1) which is to be monitored and controlled and to which various sensors are fitted for measuring parameters such as high pressure spool speed, low pressure spool speed, high pressure compressor temperature, high pressure compressor pressure etc. Some of the signals from these sensors, including low and high pressure spool speeds, are input into an engine controller (2). In addition, the engine controller has three inputs arising from outside manual 60 control: fuel flow, nozzle area and intermediate pressure blow-off valve position. The engine controller dictates the operating conditions of the engine by giving signals to actuators (3) which act on the engine. The engine controller signals are also delivered to an engine model (4) which is a software model of the engine characteristics. This engine model provides reference signal values, these being deter-

mined by the operating conditions of the engine. The general arrangement described thus far is known from prior art systems. It is in the final unit, fault detection unit (5), that the invention is embodied. The fault detection unit (5) receives all the outputs from actual engine sensors as well as the corresponding reference signals provided by the engine model. This unit is used to compare actual engine sensor output signals with corresponding reference signals.

The sensor fault detector according to the invention detects the presence of a sensor fault by comparing the shapes of the actual sensor signals and those provided by the reference signal. Comparing shapes eliminates any complications that would otherwise be encountered where the reference sensor signal is differently scaled or may have a different offset value from the actual sensor value. Shapes are compared by comparing values of actual and reference sensor signals over a period of time, the so-called time window, the duration of which is chosen to suit requirements. This is achieved according to the invention by taking samples of the actual and reference sensor signals at time intervals and analysing the differences in shape characteristics of the last 2 or more samples in order to determine the degree of similarity/difference between the actual and reference sensor signals. This is done by calculation of a correlation coefficient which determines whether a sensor fault is to be declared.

The time window extends from the time when the last pair of values is sampled to a preset time beforehand, all sampled values within this time window being used for shape comparison purposes. Using the most recent values means that the fault detection system may be run in "real time" and allows faults to be detected quickly. In other words, the values of the last N samples of reference and actual sensor signals are used for comparison purposes, where N can be 2 or more. If, for example, the time window chosen is 10 seconds and samples of the actual and reference sensor signals are taken every 0.1 seconds, then the last 100 sample pairs are used to perform the comparison exercise. After each comparison, i.e. after every 0.1 seconds, new samples of the actual and reference sensor values are taken and the oldest pair of reference and signal values is rejected from the set of samples used for shape comparison.

The correlation coefficient is used as a measure of how similar the shapes are and is preferably calculated using the formula below:

Correlation coefficient = 
$$\frac{\displaystyle\sum_{n=1}^{N}(x_n-x)(y_n-y)}{\sqrt{\displaystyle\sum_{n=1}^{N}(x_n-x)^2\sum_{n=1}^{N}(y_n-y)^2}}$$

5 Where

x is the nth sample of the sensor signal;

y the nth sample of the reference signal;

x is the mean value of the sensor signal taken over N samples.

y is the mean value of the reference signal taken over N samples.

Not all the samples of the reference and sensor signals are used but only the latest N samples, extending along the chosen time window, As each new sample is taken the oldest sample is deleted and the correlation coefficient is recalculated.

The correlation coefficient calculated from the above equation will always lie between -1 and +1. This value is then squared to give a revised correlation coefficient such that the value thereof lies between zero and 1. If both the sensor and reference signal have exactly the same shape then the revised correlation coefficient will be unity and as the shapes become more and more dissimilar the revised correlation coefficient drops to zero. In this embodiment, the sensor is declared to be faulty if the revised correlation coefficient falls below a predetermined value e.g. 0.95.

The above equation for the correlation coefficient in a preferred embodiment is modified to prevent any possible system crash by division by zero. This situation would occur if either of the reference or sensor signals remain exactly constant; the denominator of the above equation would be zero. An alternative correlation coefficient which overcomes this problem is shown below:

Correlation coefficient = 
$$\frac{\displaystyle\sum_{n=1}^{N}(x_n-x)(y_n-y)}{\sqrt{\displaystyle\sum_{n=1}^{N}(x_n-x)^2\sum_{n=1}^{N}(y_n-y)^2+a}}$$

where a is a constant e.g. 0.001 which ensures the denominator is never zero. x, x, y, y, and N are as before.

As mentioned previously, any d.c. biases between the sensor and reference outputs are ignored by the technique. Because this method uses the sensor and reference signals without simply looking at their differences, large similarities in the shape of the two signals mask any small dissimilarities due to modelling errors. A further advantage of the above method is that the effects of different scaling between actual and reference signals do not affect the result.

A preferred refinement of the technique will now be described. In practice, both the sensor and the reference output signals will be corrupted by noise. When the engine is in steady state the sensor and reference signals will consist of d.c. values plus signal and reference noise. The noise signals are generally uncorrelated and so the correlation coefficient will fall to zero in the case of steady state conditions, indicating that the signal shapes are totally dissimilar and that the sensor is faulty, even though both the sensor and reference signals are behaving in the same manner. Incorporation of a filter is an impractical solution to this problem as it does not eliminate noise completely and it would also introduce time delays.

The way in which a preferred refinement of the invention overcomes this problem is by generating a modified refer- 50 ence signal which is then compared with the actual sensor signal by means of a correlation coefficient. The modified reference is made to only differ from the sensor signal by the amount by which the reference signal lies outside the thresholds applied to the sensor signal. The modified reference signal is produced by the following steps: Firstly the actual sensor signal is taken and deviation thresholds are either side of it These sensor deviation threshold levels are then applied to the reference signal. Those portions of the reference signal which lie outside the deviation thresholds have the threshold value subtracted from them if the reference signal lies above the threshold or added to it if it lies below the threshold. The portion of the reference signal which lies within the signal deviation thresholds is substituted with the sensor signal values. In this way a modified 65 (hybrid) reference signal is produced which only differs from the sensor signal by the amount by which the model

signal lies outside the thresholds. The modified reference signal thus obtained is the same as the actual sensor signal only when the variations between the actual and reference signals are small (due to noise). When the signals are undergoing larger magnitude changes e.g. due to a sensor fault, the modified reference signal is the same as the parent reference signal, except that the deviation thresholds are removed or added. The modified reference signal, which is in effect a hybrid of the actual sensor and reference signals, is then compared with the original sensor signal.

FIG. 2 shows in more detail how this is implemented. FIG. 2a shows an example of a sensor signal, and FIG. 2b shows the corresponding reference signal. Both signals are shown over a prescribed time window of 500 seconds. Firstly, the mean values are subtracted from the original sensor signal and the parent reference signal to produce two new signals, FIGS. 2c and 2d. Prescribed threshold levels are placed on either side of the new sensor signal, shown in FIG. 2e by broken lines. These threshold values are chosen to suit the requirements of the sensor fault detection system. The same threshold curves are then applied against the reference signal, as shown in FIG. 2f. This determines which portions of the reference signal are to be replaced with the sensor signal. Every portion of the reference signal which lies within these threshold limits is regarded as being the same as the sensor signal, but where the reference signal falls outside the thresholds it is regarded as being different from the example sensor signal by the amount which it falls outside the thresholds. A modified reference signal 2h is thus generated which is a hybrid of the sensor signal and the reference signal (with the threshold value added or subtracted), in which the sensor signal is replaced with the reference signal in those portions where the reference signal values exceed the sensor signal thresholds. The new hybrid 35 signal is then correlated with the original sensor signal to assess sensor reliability. The threshold levels can be chosen to suit requirements, but in any case should be larger than the amplitude of the noise.

The above method prevents the correlation coefficient from falling due to noise in steady state operation. However this adversely affects the detection of step faults. The reason for this is illustrated in FIG. 3, in which the engine is running at a constant operating condition and therefore the reference signal is constant (FIG. 3b), and a step fault suddenly appears on the sensor signals (FIG. 3c). The reference signal will remain constant and always lies outside the sensor signal thresholds (FIG. 3a). The modified reference signal thus is made to differ from the sensor signal by the amount in which the reference signal lies outside the sensor signal thresholds. In this way the modified sensor signal (FIG. 3d) comprises a small step equal to twice the threshold value. The modified reference and sensor signals are now both the same shape and so produce a perfect correlation even though a fault is present.

In order to prevent this situation two preferred modifications can be incorporated as explained hereinafter. The first is simply to produce the modified reference signal by the same steps as above except that where the reference signal is outside the sensor signal thresholds, the modified reference signal comprises the reference signal without any threshold values added or subtracted.

This simplification is not ideal in all situations. The reason why when the reference signal lies outside the sensor signal threshold, the modified reference signal is made up of the reference signal minus or plus the threshold value is because it is preferred to ignore any difference between the sensor and reference signals which is less than or equal to the

threshold value, not just when the reference signal lies within the sensor signal thresholds.

A second preferred alternative will now be described which overcomes a problem of undesired correlation of step faults, by means of scaling up the signal with the smallest area, and which is described with reference to FIG. 4. Thresholds are applied to the sensor signal which, in the example a step fault, as described before (FIG. 4a). The reference signal which in the example is a continuous level, is assumed comprise a noise signal but if felt that the noise signal is too small in order to calculate an area, a dither signal (small triangular waveform) can be applied to the reference signal (FIG. 4b). The next step is to calculate the areas of the sensor signal and reference signal (FIGS. 4c and 4d respectively). The signal with the smallest area is then scaled up by the ratio of the largest area to the smallest area (FIG. 4f). In this example the reference signal is scaled up by this ratio. This scaled up reference signal is then superposed on the sensor signal deviation threshold values as described before. For the time that the scaled reference signal lies within the sensor signal thresholds the modified reference signal comprises the sensor signal and where the scaled reference signal lies outside the sensor signal thresholds, the modified reference signal comprises the scaled reference signals with the threshold value either 25 added or subtracted such that the modified reference signal only differs from the sensor signal by the amount by which the scaled reference signal lies outside the deviation thresholds. The modified reference signal (FIG. 4i) is then correlated as described before with the sensor signal (FIG. 4h) 30 and a correlation coefficient determined.

FIG. 5 shows yet a further enhancement of the invention whereby the magnitude of the threshold values placed around the sensor signal are allowed to vary in order to compensate for increased modelling errors during transient behaviour. Some differences between engine and model may be due to time delays e.g. which are large relative to steady state errors. FIG. 5a shows how the thresholds applied to the sensor signal may vary. The magnitude of the increase in the thresholds may be determined buy factors such as size and rate of change of the signal. In the example once the thresholds have been increased at the beginning and end of a transient they are then allowed to decrease back to their normal values in an exponential fashion.

FIG. 6 shows a further embodiment in which the fault 45 detection system is additionally configured to compensate for two conditions of unmeasured disturbance, namely power off-take and service bleed. For each unmeasured disturbance for which compensation is required, a sensor output is taken in order to determine the level of disturbance. The complete system comprises the engine (1), the engine controller (2), actuators (3) and the engine model (4) as before. In the embodiment described here, two additional modules are included: a tracking compensator (15) and a reduced reference (16). The reason for these two extra 55 modules is to accommodate for conditions when the unmeasured disturbances are acting. The function provided by the final two modules is to ensure that perturbations of the engine outputs caused by variations in power off-take and service bleed are mirrored by similar correction factors added to the reference outputs. This is done by taking two of the sensor outputs which respond differently to power offtake and service bleed and forcing the corresponding engine reference outputs to track these signals.

In the example which follows, the two sensor signals 65 which are used to compensate for unmeasured disturbances are high pressure spool speed and low pressure spool speed,

respectively designated as NH and NL in the text which follows. The reference signals of these two sensor signals (designated NH and NL) are corrected by the addition of correction factors NH and NL via summing junctions 7 and 8 respectively. The actual sensor outputs NH and NL are compared with these corrected values at junctions 9 and 10 and the differences between them (the residual signals RNH and RNL) are fed into a tracking compensator 15. Levels of power off-take (POT) and service bleed (BLEED) are calculated by the tracking compensator and fed into a reduced model 16.

The reduced model is a software model having information on the characteristics of the two unmeasured disturbances at various operating conditions. It is a two state model which models the effects of power off-take and service bleed on all the outputs of interest. In order to produce this software model, the dynamic responses of the engine to the two unmeasured disturbances applied individually to a number of running conditions must be identified. Correction factors are then computed which are added to the reference outputs via junction 11, such that they reflect the true output values. The corrected reference signal outputs are then fed into the fault detection system 5 where they are compared with the actual output signals. Correction factors NH and NL are also output from the reduced reference and added to the original reference signals at junctions 7 and 8 as described previously.

The above solution assumes that the NH and NL sensor outputs are correct and not prone to faults themselves. If either of them were faulty then incorrect estimates of power off-take and bleed would be obtained and this would affect all the other reference outputs, possibly causing faults to be flagged erroneously on all the sensors. It is therefore a requirement that the sensors used to determine levels of unmeasured disturbances are high integrity and do not suffer from faults themselves. They may therefore have to be duplicated or even triplicated to provide the required degree of confidence. Although this increases cost of these particular sensors, overall savings result by removing hardware redundancy from other areas.

Although in the embodiment described here the sensor fault detection system is configured to compensate for the effects of two kinds of unmeasured disturbance, it will be clear to persons skilled in the art that the invention may be extended to compensate for any number of unmeasured disturbances. This can be achieved if the reduced model incorporates the characteristics of the unmeasured disturbance and its effects on all the other sensor values at all operating points. For each type of unmeasured disturbance one actual sensor signal and the corresponding reference signal needs to be taken to provide estimates of the unmeasured disturbance acting.

It is a requirement that the sensors used to estimate unmeasured disturbances respond differently to the different kinds of unmeasured for which compensation is required. If the sensors respond in an identical manner to the different kinds of unmeasured disturbance, it is not possible to detect which type of disturbance is acting. In practice, where compensation is required for two types of unmeasured disturbance, it is unlikely that the two chosen sensors, which measure different engine parameters, will respond in an identical fashion to both kinds of unmeasured disturbance. A knowledge of the control system and the particular unmeasured disturbance should enable a person skilled in the art to identify two suitable sensors.

Although the present invention has been described in terms of a sensor fault detection system for use in a control system of a gas turbine engine it will be appreciated by those skilled in the art that the sensor fault detection system can be applied to any system which possesses sensors for monitoring, measuring or control purposes.

I claim:

1. A method of detecting sensor faults in a system having at least one sensor providing a sensor signal for monitoring or controlling system parameters, the method comprising the following steps:

- (a) generating reference signals of the system;
- (b) recording the value of each sensor signal and the corresponding reference signals at time intervals;
- (c) comparing the shape of an outline formed from a series of values of each sensor signal with the shape of an outline formed from a series of corresponding modified reference signals by means of a correlation coefficient;
- (d) continuously updating the respective series of signals with the most recent values and
- (e) declaring a fault when the correlation coefficient falls 20 Where outside a prescribed range, wherein the modified reference signal is generated by:
- (f) multiplying the reference signal by a scaling factor to convert each sensor signal and its corresponding reference signal;
- (g) calculating the mean values of each sensor signal and its corresponding reference signal;
- (h) subtracting the respective mean values from each sensor signal and its corresponding reference signal to obtain new values for each sensor signal and its corresponding reference signal;
- (i) applying deviation thresholds to either side of the new values for each sensor signal;
- (j) superimposing the value of each reference signal over 35 the thresholds around the new value of its corresponding sensor signal, and
- (k) formulating a modified reference signal from a hybrid of values of the new sensor signal and the new reference signal.
- 2. A method of detecting sensor faults in a system having at least one sensor providing a sensor signal for monitoring or controlling system parameters, the method comprising the following steps:
  - (a) generating reference sensor signals of the system;
  - (b) recording the value of each sensor signal and the corresponding reference sensor signals at regular intervals;
  - (c) comparing the shape characteristics of a series of values of each sensor signal with the shape character- 50 istics of a series of corresponding modified reference signals by means of a correlation coefficient;
  - (d) continuously updating the respective series of signals with the most recent values and
  - (e) declaring a fault when the correlation coefficient falls 55 outside a prescribed range, wherein the modified reference signal is generated by:
  - (f) multiplying the reference signal by a scaling factor to convert each sensor signal and its corresponding reference signal;
  - (g) calculating the mean values of each sensor signal and its corresponding reference signal:
  - (h) subtracting the respective mean values from each sensor signal and its corresponding reference signal to 65 obtain new values for each sensor signal and its corresponding reference signal;

- (i) applying deviation thresholds to either side of the new values for each sensor signal;
- (j) superimposing the value of each reference signal over the thresholds around the new value of its corresponding sensor signal, and
- (k) formulating a modified reference signal from a hybrid of values of the new sensor signal and the new reference signal, wherein said correlation coefficient is of the form

$$\begin{aligned} \text{Correlation coefficient} &= \frac{\displaystyle\sum_{n=1}^{N} (x_n - x)(y_n - y)}{\sqrt{\displaystyle\sum_{n=1}^{N} (x_n - x)^2 \sum_{n=1}^{N} (y_n - y)^2}} \end{aligned}$$

x, is the nth sample of the sensor signal;

- y, the nth sample of the reference signal;
- x is the mean value of the sensor signal taken over N samples and
- y is the mean value of the reference signal taken over N
- 3. A method of detecting sensor faults in a system having 30 at least one sensor providing a sensor signal for monitoring or controlling system parameters, the method comprising the following steps:
  - (a) generating reference sensor signals of the system;
  - (b) recording the value of each sensor signal and the corresponding reference sensor signals at regular inter-
  - (c) comparing the shape characteristics of a series of values of each sensor signal with the shape characteristics of a series of corresponding modified reference signals by means of a correlation coefficient;
  - (d) continuously updating the respective series of signals with the most recent values and
  - (e) declaring a fault when the correlation coefficient falls outside a prescribed range, wherein the modified reference signal is generated by:
  - (f) multiplying the reference signal by a scaling factor to convert each sensor signal and its corresponding reference signal;
  - (g) calculating the mean values of each sensor signal and its corresponding reference signal;
  - (h) subtracting the respective mean values from each sensor signal and its corresponding reference signal to obtain new values for each sensor signal and its corresponding reference signal;
  - (i) applying deviation thresholds to either side of the new values for each sensor signal:
  - (j) superimposing the value of each reference signal over the thresholds around the new value of its corresponding sensor signal, and
  - (k) formulating a modified reference signal from a hybrid of values of the new sensor signal and the new reference signal, wherein said correlate coefficient is of the

$$\begin{aligned} & & \sum_{n=1}^{N} (x_n - x)(y_n - y) \\ & & & \sqrt{\sum_{n=1}^{N} (x_n - x)^2 \sum_{n=1}^{N} (y_n - y)^2 + a} \end{aligned}$$

Where

 $x_n$  is the nth sample of the sensor signal;

y, the nth sample of the reference signal;

x is the mean-value of the sensor signal taken over N samples and

y is the mean value of the reference signal taken over N 15 samples

a is a constant.

4. A method of detecting sensor faults as claimed in claim 1 wherein in step (k) the modified reference signal comprises values of the new sensor signal where the new reference signal fails within said deviation thresholds, and those values of the new reference signal itself where the new reference signal fails outside said deviation thresholds. 5. A method of detecting sensor faults as claimed in claim 4 wherein in step (k) the modified reference comprises the new sensor signal values when the new reference signal lies within said deviation thresholds and comprising the new reference signal with the deviation threshold value added or subtracted therefrom when the new reference signal lies outside said deviation thresholds, such that the modified reference signal only differs from the sensor signal by the amount the new reference signal lies outside the deviation thresholds.

6. A method of detecting sensor faults as claimed in claim 1 comprising the additional step between steps (h) and (i) of calculating the areas under the new reference signal and new sensor signal and scaling that signal of them with smallest area by the ratio of the largest area to the smallest area.

7. A method for detecting sensor faults as claimed in claim 6 comprising the additional step of applying a dither signal to the either the new reference signal or the new sensor signal.

8. A method of detecting sensor faults as claimed in claim 1 wherein the deviation thresholds are allowed to vary in magnitude during operation of sensor fault detection.

\* \* \* \* \*

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# EXHIBIT M



#### US006029524A

## United States Patent [19]

#### Klauder et al.

### [11] Patent Number:

6,029,524

[45] Date of Patent:

\*Feb. 29, 2000

#### [54] TRANSDUCER HAVING REDUNDANT PRESSURE SENSORS

- [75] Inventors: Philip R. Klauder, Ambler; James O. Moore, Worcester; Christopher J. O'Brien, New Britain, all of Pa.
- [73] Assignee: Moore Products Co., Springhouse, Pa.
- [\*] Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C.

154(a)(2).

- [21] Appl. No.: 08/889,707
- [22] Filed: Jul. 8, 1997

#### Related U.S. Application Data

[62] Division of application No. 08/661,851, Jun. 11, 1996, Pat. No. 5,672,808.

[51]	Int. CL G01L 9/12
[52]	U.S. Cl. 73/718
[58]	Field of Search
	73/718, 719, 720, 721, 724, 725, 726, 727,
	861.44, 702, 703; 361/283.1

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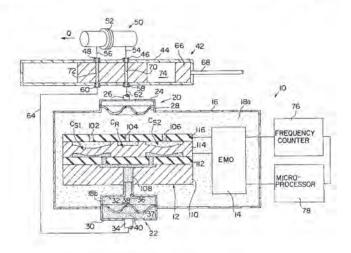
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Primary Examiner—William Ocu Attorney, Agent, or Firm—Seidel, Gonda, Lavorgna & Monaco, PC

#### [57] ABSTRACT

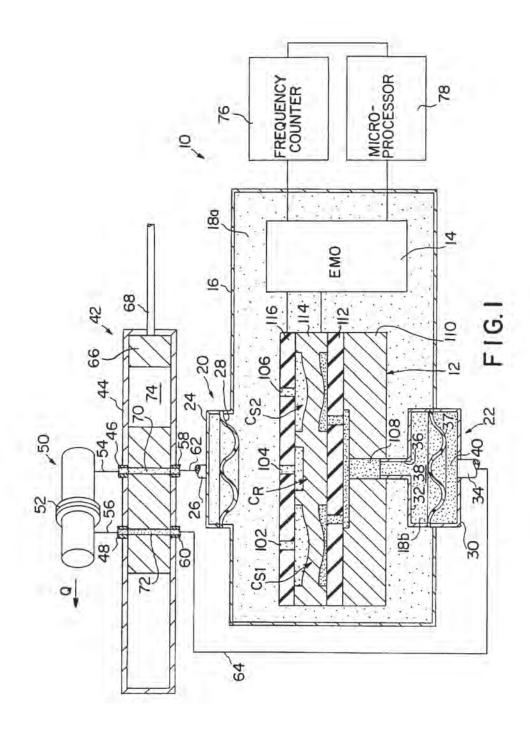
A pressure transducer having a redundant fluid pressure sensor can be used to determine if the pressure transducer needs to be recalibrated. The pressure transducer comprises a fluid pressure sensor for measuring differential pressure. The fluid pressure sensor includes a pair of substantially identical pressure sensors for providing a variable electrical output as a function of a differential fluid pressure and a reference sensor for providing an electrical output independent of the differential fluid pressure. A conditioning circuit is provided for generating a frequency-based signal whose frequency is a function of the electrical output for each fluid pressure sensor. The electrical output of the first and second pressure sensors can be compared to determine whether the pressure transducer needs to be calibrated. In one embodiment, the pressure sensors comprise variable capacitors. The first and second capacitors each have one fixed plate and one movable plate responsive to differential fluid pressure across the movable plate. The reference capacitor has two fixed plates. The first variable, second variable, and reference capacitors are all located in proximity to one another and in communication with the differential fluid pressure. The pressure transducer also includes a switching network connected to the capacitors for selectable connecting at least one of the capacitors to an electronic circuit.

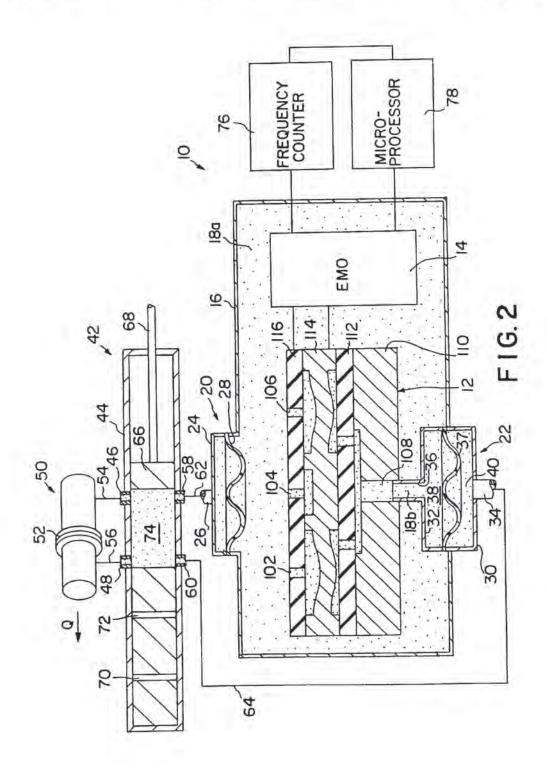
#### 7 Claims, 10 Drawing Sheets



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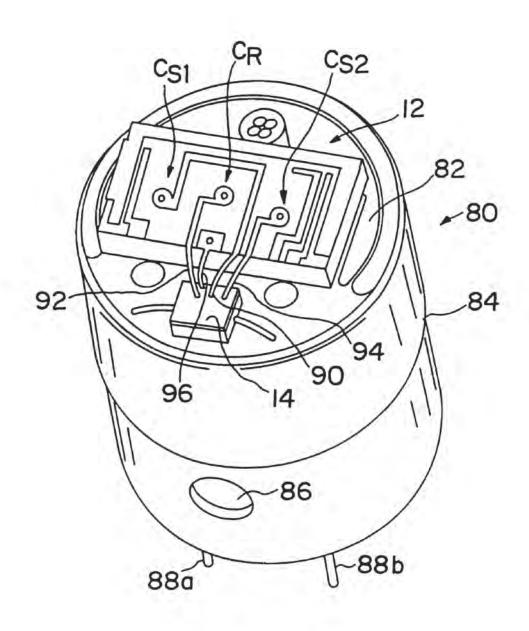




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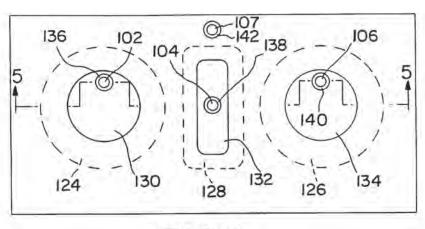


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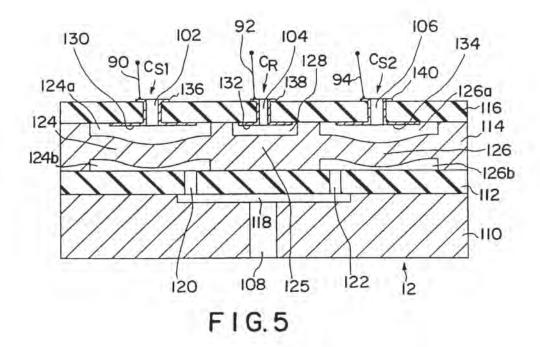
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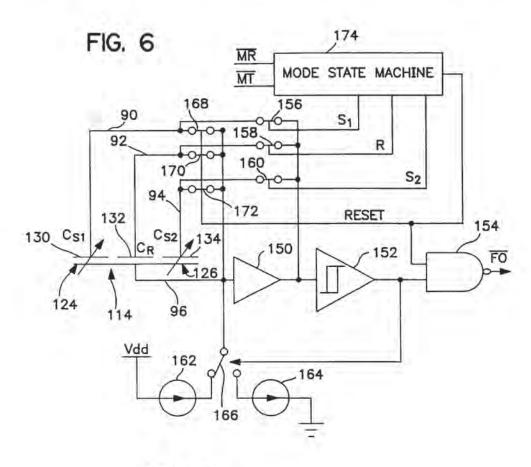
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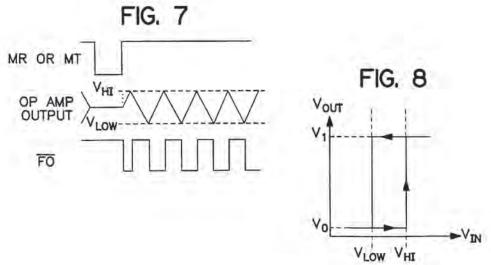
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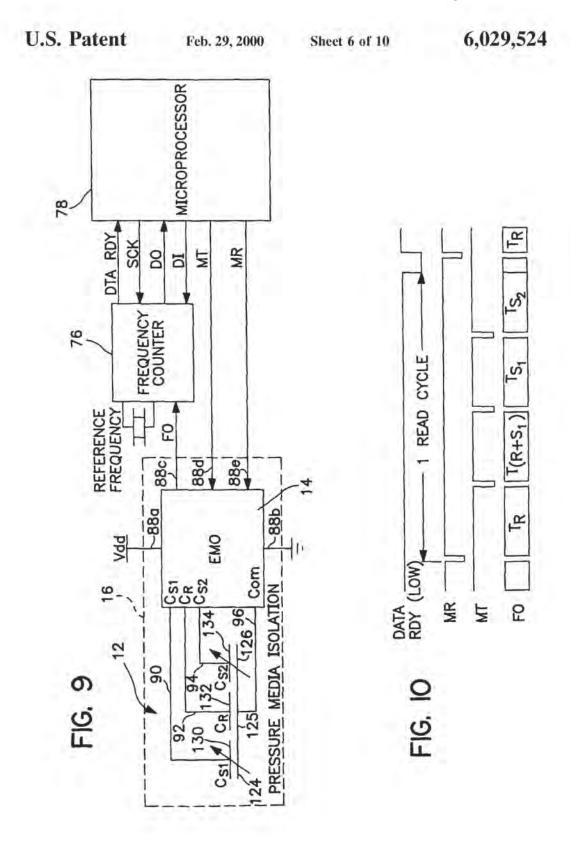


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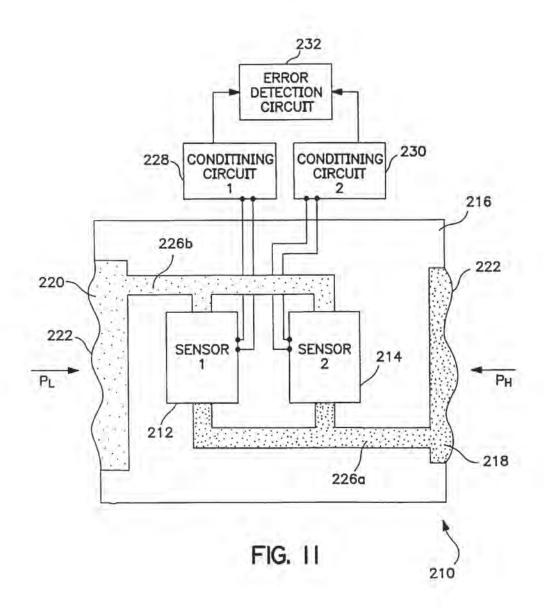
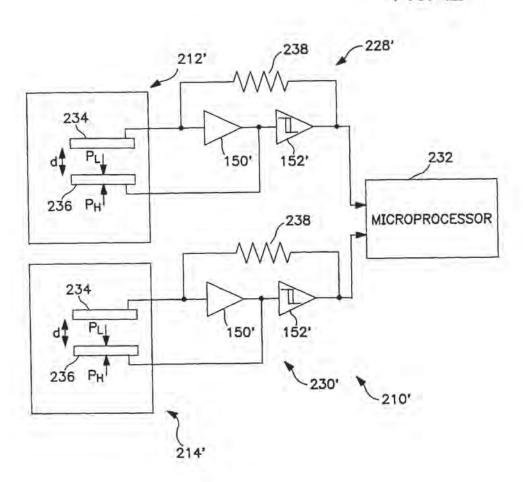
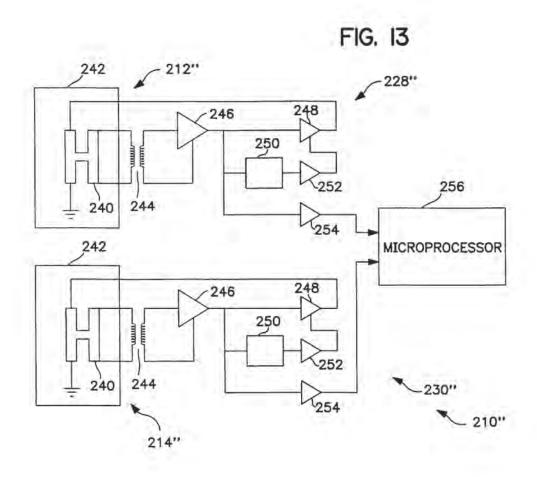
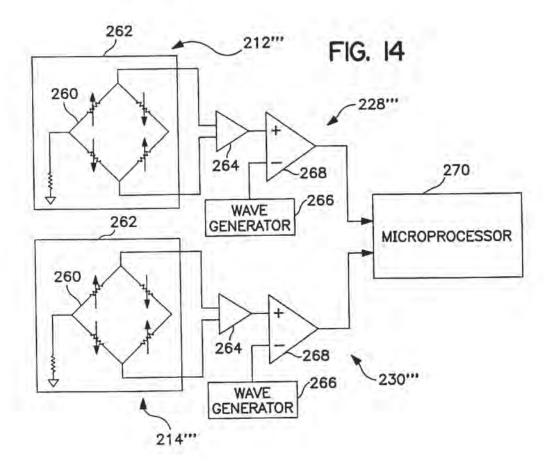


FIG. 12







# TRANSDUCER HAVING REDUNDANT PRESSURE SENSORS

This is a divisional of application Ser. No. 08/661,851, filed on Jun. 11, 1996 now U.S. Pat. No. 5,672,808.

# BACKGROUND OF THE INVENTION

# 1. Field of the Invention

The present invention relates to a pressure transducer system including a pressure sensor for accurately measuring such parameters as temperature, differential, absolute, and gauge pressures, and which is capable of detecting defects in the pressure sensor. The system includes a redundant pressure sensor and its associated circuitry.

## 2. Background of the Invention

Pressure transducers used to measure the pressure of a process fluid flowing through a pipe are known in the art. Pressure transducers are used in high sensitive environments such as refineries, the aerospace industry and power plants. The accurate detection of flow conditions is critical in ensuring the operation and safety of the processes in these and other industries.

Most pressure transducers are generally contained in a housing containing an inert transfer medium which isolates the process fluid being measured from the pressure sensor itself. The housing provides the sensor With resistance to corrosion which may be caused by the process fluid. Pressure is transmitted via the transfer medium to the isolated pressure sensor through diaphragms located on the housing. The diaphragms separate the process fluid from the transfer medium while permitting pressure to be transmitted to the sensor.

Pressure transducers are typically required to have their stability verified at periodic intervals to ensure that their calibration has not changed, especially in critical applications. The most likely calibration problems affecting pressure transducers are span shift and zero shift. Span shift occurs when the pressure sensitivity of the pressure sensor is no longer accurate within the normal range of operating pressures. Usually, the pressure sensitivity of the affected pressure sensor varies within the operating range. Typically, a "five valve" or a "three valve" manifold, known in the art, is used to verify the accuracy of a pressure sensor affected by span shift.

In contrast, zero shift occurs when all of the pressure sensor readings are off by some constant error value. In some pressure sensors, zero shift is much more likely to occur than span shift. Therefore, for these pressure sensors it is acceptable to check the pressure sensor only at the zero condition and compensate for any detected error shift. For example, if the pressure sensor has a reading of 1 psi at the zero condition, recalibrating the sensor would only require subtracting 1 psi from all future readings of the pressure

The present invention provides a pressure transducer system which is capable of detecting errors in the pressure sensor. Upon detection of an error, a "three valve" manifold can be used to pinpoint the cause of the error and compensate for it.

# SUMMARY OF THE INVENTION

The present invention relates to a pressure transducer having a redundant pressure sensor. The redundant pressure sensor is used to sense the differential pressure of a process 65 fluid and to determine whether the pressure transducer needs to be recalibrated due to the presence of a zero shift

condition. The pressure sensor includes first and second variable pressure sensors each for providing a variable electrical output as a function of a differential fluid pressure.

A conditioning circuit is used for generating a first frequency based signal whose frequency is a function of the electrical output of the first variable pressure sensor and a second frequency based signal whose frequency is a function of the electrical output of the second variable pressure sensor. A microprocessor or error detecting circuit can be provided for determining whether the difference between the first signal and the second signal is within a preselected range.

The pressure sensors can be formed either as a single monolithic structure or as separate structures. The sensors are contained in a housing which isolates the process fluid, which is being measured by the pressure sensor, from the sensor itself. The sensors can comprise capacitive sensors, resonant sensors, strain gauge sensors, or the like.

In one embodiment, the first and second variable pressure sensors are variable capacitors. The first and second capacitors each have one fixed plate and one movable plate responsive to differential fluid pressure across the movable plate. A reference capacitor can also be provided. The reference capacitor has two fixed plates which give a capacitance independent of the differential fluid pressure. The first variable, second variable, and reference capacitors are all located in proximity to one another and in communication with the differential fluid pressure.

The pressure transducer can also include a switching network connected to the pressure sensors for selectably connecting at least one of the sensors to an interface circuit. The interface circuit has inputs connected to the switching network for generating a frequency-based signal whose frequency, is a function of the electrical output of the at least one pressure sensor connected to the interface circuit through the switching network.

The number of cycles in the frequency based signal transmitted from the interface circuit is counted by a frequency counter which transmits the number to a controller. The capacitance of the first and second capacitors, as reflected in the frequency based signal, are compared by the controller to determine whether the pressure transducer needs to be calibrated. A "three valve" manifold can be provided to apply a zero differential pressure to the pressure sensor. In this manner, the precise condition of the pressure sensor can be determined without taking the pressure transducer out of service.

A method for detecting defects in a fluid pressure sensor is also comprehended by the invention. The method includes measuring an applied differential pressure using a pressure transducer having a fluid pressure sensor comprising first and second variable pressure sensors for providing an electrical output as a function of an applied differential fluid pressure, the first and second pressure sensors being substantially identical; applying a differential fluid pressure to the first and second pressure sensors via a valve; generating a first signal whose frequency is proportional to the electrical output of the first variable pressure sensor and a second signal whose frequency is proportional to the electrical output of the second variable pressure sensor; determining whether the difference between the first signal and the second signal is within a preselected range; and determining whether the sensor is damaged based upon whether the second signal is outside the limits of the preselected range.

# BRIEF DESCRIPTION OF THE DRAWINGS

For the purpose of illustrating the invention, there is shown in the drawings a form which is presently preferred; it being understood, however, that this invention is not limited to the precise arrangements and instrumentalities shown.

FIG. 1 is a schematic view, shown partially in crosssection, of a pressure transducer system having a "three valve" manifold in a first position in accordance with the present invention.

FIG. 2 is a schematic view of the pressure transducer system of FIG. 1 having the "three valve" manifold in a second position.

FIG. 3 is a perspective view of a pressure transducer in accordance with the present invention, showing constructional features.

FIG. 4 is a top view of a pressure sensor in accordance 15 with the present invention.

FIG. 5 is a sectional view taken along line 5—5 of FIG. 4.

FIG. 6 is a schematic wiring diagram of the pressure transducer.

FIG. 7 is a timing diagram of the signals of an interface circuit of the present invention.

FIG. 8 is a curve showing the input and output voltages of the interface circuit.

FIG. 9 is a schematic view of the external connections to the pressure transducer.

FIG. 10 is a timing diagram of one read cycle of the interface circuit.

FIG. 11 is a schematic view of an alternate embodiment <sup>30</sup> of the pressure transducer system having separate generic pressure sensors.

FIG. 12 is a schematic view of a first specific embodiment of the pressure transducer system of FIG. 11 having capacitive pressure sensors.

FIG. 13 is a schematic view of a second specific embodiment of the pressure transducer system of FIG. 11 having resonant pressure sensors.

FIG. 14 is a schematic view of a third specific embodiment of the pressure transducer system of FIG. 11 having a strain gauge pressure sensors.

### DESCRIPTION OF THE PREFERRED EMBODIMENT

In the drawings, where like numerals identify like elements, there is shown a form of the present invention which is presently preferred. In FIG. 1 there is schematically shown a pressure transducer device 10 for accurately measuring differential, absolute, and gauge pressures and temperature of a process fluid. The device 10 includes a capacitive pressure sensor 12 and an inter-face circuit 14 electrically connected to the sensor 12. In the embodiment shown, the sensor 12 is a redundant dual silicon capacitor sensor. By using a redundant sensor, the device is able to detect the presence of sensor defects, or damage, which could cause measurement inaccuracies without taking the pressure transducer out of service

The sensor 12 is in fluid communication with a process fluid stream 50 and includes a plurality of capacitors  $C_{S1}$ , 60  $CS_2$ , and  $C_R$  for measuring the pressure and temperature of the fluid in the processes stream 50. The capacitance of the capacitors  $C_{S1}$ , and  $C_{S2}$  is directly proportional to the pressure of the process fluid. The interface circuit 14, called an extended mode oscillator (EMO) circuit, is connected to 65 the sensor 12 and converts the capacitance of each capacitor  $C_{S1}$ ,  $C_{S2}$ , and  $C_R$  into a signal whose frequency is propor-

tional to the pressure of the process fluid. In the embodiment shown, the EMO circuit 14 is interfaced directly to an external frequency counter 76, which samples the signal transmitted by the EMO circuit 14, and an external controller 78, such as a microprocessor or the like, which calculates the actual pressure of the process fluid.

The sensor 12 and the EMO circuit 14 are mounted within a scaled housing 16 which isolates the sensor 12 from the possibly corrosive effects of the process fluid stream 50. The housing 16 is filled with inert pressure transfer media 18a and 18b which transfer the pressure of the process fluid to the sensor 12. The transfer media 18a and 18b typically comprise silicon oil, which allows the entire assembly to exhibit virtually no mechanical hysteresis.

A first chamber 20 and a second chamber 22 are formed in the walls of the housing 16. The first chamber 20 has an outer wall 24 and an inlet port 26 formed thereon. A seal diaphragm 28 is secured within the first chamber 20 and functions as an inner surface of the first chamber 20.

The second chamber 22 includes an outer wall portion 30 and an inner wall portion 32. An inlet 34 is formed on the outer wall portion 30 and a conduit 36 extends from the inner wall portion 32. A seal diaphragm 37 is secured within the second chamber 22 and separates the second chamber 22 into an inner second chamber 38 and an outer second chamber 40.

The seal diaphragms 28 and 37 are preferably fabricated from Hastelloy®, Monel® metal, tantalum, stainless steel, or the like.

The sensor 12 includes a base plate 110, an intermediate plate 112, an intermediate plate 114, and a cap plate 116. A plurality of openings 102, 104, and 106 are formed in the cap plate 116 and permit fluid communication with a portion of the interior of the sensor 12 between plates 116 and 114. As such, the fluid 18a contained in the housing 16 fills the portion of the sensor between plates 116 and 114 through the openings 102, 104, and 106.

Similarly, an opening 108 is formed in the base plate 110 and permits fluid communication with a portion of the interior of the sensor 12 between plates 110 and 114. The sensor 12 is mounted in the housings 16 so that conduit 36 is received in the opening 108. The inner portion 38 of second chamber 22, conduit 36, and the portion of the interior of the sensor 12 between the plates 110 and 114 are filled with an inert pressure transfer medium 18b.

The pressure transducer device 10 is also provided with a "three valve" manifold 42 which allows the pressure transducer 10 to be calibrated and remotely zeroed without taking it out of service. The valve manifold 42 comprises a housing 44 having a first inlet port 46 and a second inlet port 48 fluidly connected in the usual manner to a process fluid, such as across an orifice plate 52 of a process fluid stream 50, as shown in FIG. 1, by fluid lines 54 and 56, respectively. It is understood that the process fluid may be used in any fluid process such as gas or liquid storage tank, gas or liquid pipe, pitot tube, a calibrated restriction for measuring flow, or the like.

The valve manifold 42 is also provided with a first outlet port 58 and a second outlet port 60 aligned with the first inlet port 46 and second inlet port 48, respectively. The first outlet port 58 is in fluid communication with the first inlet 26 via fluid line 62. Similarly, the second outlet port 60 is in fluid communication with the second inlet 34 via fluid line 64.

A movable inner valve member 66 is disposed within the valve manifold housing 44. An external actuator 68 is connected to the valve member 66 for moving the valve

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member 66 between a first position, shown in FIG. 1, and a second position, shown in FIG. 2. The valve member 66 is provided with a first bore 70 and a second bore 72 extending through valve member 66. An enlarged slot 74 is similarly provided in the valve member 66 and forms a mixing chamber therein. It is contemplated that the valve manifold 42 be automated and remotely controlled from the pressure transducer 10 via a controller (not shown) connected to the external actuator 68.

When the valve member 66 is in the first position (FIG. 10), the first bore 70 is aligned with both the first inlet 46 and the first outlet 58. forming a passageway from the process fluid stream 50 through the housing 44 and the valve member 66 to inlet port 26 of first chamber 20. At the same time, the second bore 72 is aligned with both the second inlet 48 and the second outlet 60, forming a passageway from the process fluid stream 50 to inlet 34 of second chamber 22. When the valve member 66 is in the second position (FIG. 2), the enlarged radial slot 74 is aligned with both the first inlet and outlet 46 and 58 and also the second inlet and outlet 58 and 60, forming a common mixing chamber within the valve manifold 42.

The operation of the pressure transducer system 10 will now be described for measuring the pressure differential across the orifice plate 52 of the fluid process stream 50 25 exemplified in FIGS. 1 and 2.

In fluid process stream 50, fluid flowing in the direction indicated by arrow Q creates a pressure drop across the orifice plate 52. On the upstream side of the orifice plate 52, the fluid has a high pressure,  $P_H$ , while on the downstream side, the fluid has a lower pressure,  $P_L$ .

When the valve member 66 is in the first, or normal, position (FIG. 1), the first passageway 70 interconnects the fluid line 54 (connected to the upstream side of the orifice plate 52) and the first chamber 20. Similarly, the second passageway 72 interconnects the fluid line 56 (connected to the downstream side of the orifice plate 52) and the outer portion 40 of the second chamber 22. The fluid in the upstream circuit 54, 70, 62 will exert the upstream pressure, P<sub>11</sub>, on the seal diaphragm 28 of the first chamber 20, which transmits the upstream pressure, PH, to the inert pressure transfer medium 18a contained in the housing 16. Similarly, the fluid in the downstream circuit 56, 72, 64 will exert the downstream pressure, P., on the seal diaphragm 37 of the second chamber 22, which transmits the downstream pressure, PL, to the inert pressure transfer medium 18b contained in the inner chamber portion 38. Thus, the upstream pressure, PH, is transmitted to the interior of the pressure sensor 12 through openings 102 and 104, and the downstream pressure, P1, is transmitted to the interior of the pressure sensor 12 through opening 108. Therefore, as is more fully described below in connection with FIGS, 4 and 5, the differential pressure, PH-PL, is exerted on the flexible plates of capacitors  $C_{s_1}$ , and  $C_{s_2}$ .

The capacitance of the capacitors  $C_{S1}$ , and  $C_{S2}$  is proportional to the differential pressure,  $P_H$ – $P_L$ . The EMO circuit 14 converts this capacitance to a square-wave signal whose period (and frequency) is proportional to the differential pressure,  $P_H$ – $P_L$ .

The controller 78 then calculates the true pressure differential across the orifice plate 52 based on the number of pulses counted by the frequency counter 76. The complete operation of the pressure transducer 10 is described in detail below in connection with the FIGS. 6–10.

When the valve member 66 is in the second, or test, position (FIG. 2) the enlarged slot 74 connects the fluid lines 6

54 and 56, and the pressure of the fluid in the slot 74 is at the same pressure,  $P_E$  (i.e.,  $P_H$  is equal to  $P_L$ ). Since the slot 74 is connected to the fluid lines 62 and 64, the fluid contained therein exerts the pressure,  $P_E$ , on both seal diaphragms 28 and 37. Therefore, the pressure transmitted to the pressure sensor 12 through the openings 102, 104, 106, and 108 is the pressure,  $P_E$ . Thus, when the valve member 66 is in the second position, there is a zero differential pressure exerted on the pressure sensor 12 and, the pressure differential calculated by the controller 78 is therefore also zero. The second position (FIG. 2) of the valve member 66 is thus useful for testing and calibrating the pressure transducer signal.

In FIG. 3, a preferred physical embodiment of the capacitive pressure sensor 12 and EMO circuit 14 is shown mounted to a header assembly 80. The header assembly 80 includes a header plate 82 and a header body 84 for mounting or bonding the sensor 12 and the EMO circuit 14 to the housing 16 (not shown). The EMO circuit 14 is preferably mounted proximate the sensor 12 on the header plate 82 to reduce the physical size of the header assembly 80, limit any undesirable capacitor fluctuations (e.g., parasitic capacitances due to the length of environmentally exposed leads), and minimize the effects caused by temperature gradients, so that temperature variations will affect all the capacitors equally. The header body 84 is preferably fabricated from a stainless steel material or the like which provides corrosion resistance and weldability, and functions to isolate the sensor 12 and EMO circuit 14 from mechanical stresses and external electrical interference.

The capacitors  $C_{s1}$ ,  $C_{R}$ , and  $C_{s2}$  of the sensor 12 are electrically connected to the EMO circuit 14 by leads 90, 92, 94, and 96, respectively. The header assembly 80 typically has five leads 88a–e (only leads 88a and 88b are shown in FIG. 3) extending from the header body 84. As seen in FIG. 9, lead 88a connects to the power line  $V_{dd}$ , lead 88b connects to the ground line, lead 88c connects to line FO, lead 88d connects to line MT, and lead 88e connects to line MR. An opening 86 is also formed on a side wall of the header body 84 and provides fluid communication with the opening 108 of the sensor 12.

The capacitive pressure sensor 12 is shown in more detail in FIGS. 4 and 5. In the embodiment shown, the sensor 12 has a monolithic structure similar to a semiconductor chip and is manufactured by a batch process which creates sensors having closely matching characteristics. The sensor 12, however, is a passive device. The monolithic structure permits the use of a common capacitor plate 114 for all three the capacitors  $C_{S1}$ ,  $C_{S2}$ , and  $C_R$ . Additionally, the proximity of the capacitors to each other and their construction on a common plate reduces the effect of temperature gradients because temperatures affects all the capacitors equally. The monolithic structure also reduces the manufacturing cost of the sensor 12 and the marginal cost of adding additional capacitors.

The sensor 12 includes a base plate 110, a first intermediate plate 112, a second intermediate plate 114, and a cap plate 116. The base plate 110 has an opening 108 extending therethrough and a channel 118 formed in one face of the plate 110, which communicates with the opening 108. The base plate 110 is attached to the header plate 82, preferably by anodic bonding. The plate 110 is preferably composed of a semiconductor substrate, such as doped silicon material, which reduces thermal stress on the plate 114 and provides a electrical shielding for the sensor 12.

The intermediate plate 112 is attached to the base plate 110, preferably by anodic bonding. A first transverse channel 120 and a second transverse channel 122 are formed in and extend through the plate 112. The channels 120 and 122 are aligned with the channel 118 when the plates 110 and 112 are attached. The plate 112 is preferably a dielectric material, such as Pyrex® glass or borosilicate glass, which allows the plate 112 to be anodically bonded to the silicon plate 110, provides electrical isolation between plate 110 and plate 114. The plate 112 has a preferable thickness of approximately 10 mils.

The intermediate plate 114 is attached to the plate 112, preferably by anodic bonding. The plate 114 has a plurality of flexible circular portions 124 and 126 formed therein and an elongated slot 128 formed in one surface of portion 125 of the plate 114. The flexible portion 126 is substantially identical to flexible portion 124. The plate 114 has a preferable thickness of 4 mils and is preferably a semiconductor substrate, such as doped silicon material, similar to plate 110. The flexible portions 124 and 126 are formed by thinning (e.g., etching or micro-machining) both faces of the plate 114.

The plate 114 forms a common capacitor plate for the variable capacitors  $C_{S1}$  and  $C_{S2}$  and fixed reference capacitor  $C_R$ . As such, the flexible portions 124 and 126 and fixed portion 125 are electrically connected, since they are formed from the same silicon semiconductor material of plate 114. The flexible portion 124 comprises one of the movable plates of capacitor  $C_{S1}$ , the flexible portion 126 comprises one of the movable plates of capacitor  $C_{S2}$ , and the fixed portion 125 comprises one of the fixed plates of capacitor  $C_R$ . The thickness and diameter of the flexible plates 124 and 126 are selected depending upon the desired sensitivity of the variable capacitors  $C_{S1}$ , and  $C_{S2}$ .

The thinned flexible portion 124 creates an upper cavity 124a above the flexible portion 124 and a lower cavity 124b below the flexible portion 124. Similarly, the thinned flexible portion 126 creates an upper cavity 126a above the flexible portion 126 and a lower cavity 126b below the flexible portion 126. The lower cavity 124b is aligned with the channel 120, and the lower cavity 126b is aligned with the channel 122 when the plate 114 is positioned on the plate 112.

The cap plate 116 is attached to the common plate 114, preferably by anodic bonding. The transverse openings 102, 104, and 106 are formed in and extend through the plate 116. The openings 102, 104, 106 are aligned with the upper cavity 124a, the groove 128, and the upper cavity 126a, respectively when the plate 116 is positioned on the plate 114. Another transverse opening 107 is formed in plate 116 adjacent one side edge. The plate 116 is preferably composed of a dielectric material, such as pyrex® glass or borosilicate glass, which allows the plate 116 to be anodically bonded to the silicon plate. The plate 116 has a preferable thickness of approximately 15 mils.

A metal terminal 142 is formed on the outer surface of plate 116 on opening 107. The terminal 142 is electrically connected to the EMO circuit 14 through a lead line 96 (FIG. 6). Opening 107 is metalized to connect the common capacitor plate 114 to terminal 142, providing electrical contact with the EMO circuit 14, and forms a common electrode for all three capacitors.

Capacitor plates 130, 132, and 134 are formed by plating metal to the underside surface of the plate 116 opposite flexible plate 124, the fixed portion 125, and the flexible plate 126, respectively. Openings 102, 104, and 106 are metalized to connect plates 130, 132, and 134 to terminals 136. 138, and 140, respectively on the top surface of plate

116. The terminals 130, 132, and 134 are connected to the EMO circuit 14 through leads 90, 92, and 94, respectively (FIG. 3). Thus, the capacitor plates 130, 132, and 134 form the second capacitor plates of capacitors  $C_{S1}$ ,  $C_R$ , and  $C_{S2}$ , respectively.

Fluid 18a entering through openings 102 and 106 fills chambers 124a and 126a and exerts a pressure  $P_{IP}$  on the top side of flexible plates 124 and 126 respectively, Similarly, fluid 18b entering opening 108, channel 118, and channels 120 and 122 fills chambers 124b and 126b and exerts a pressure  $P_L$ , on the bottom side of movable plates 124 and 126, respective. The flexible plates 124 and 126 deflect under the influence of the two pressures,  $P_H$  and  $P_L$ . Since the flexible plates 124 and 126 form one of the plates of capacitors  $C_{S1}$  and  $C_{S2}$ , respectively, the deflection of the flexible plates 124 and 126 changes the distance between the plates of the variable capacitors  $C_{S1}$  and  $C_{S2}$ .

The capacitance of each capacitor is related to the distance between the plates of each capacitor by:

$$C = \frac{kA}{d}$$

where

C is the capacitance,

k is a constant,

A is the area of the plate, and

d is the distance between the plates.

Thus, the capacitance C of each capacitor is inversely proportional to the distance, d, between the plates of each capacitor. That distance is proportional to the differential pressure, P<sub>H</sub>-P<sub>L</sub>.

The EMO circuit 14 detects the capacitance across the top plate 130 and bottom plate 124 of capacitor  $C_{S1}$  and across the top plate 134 and bottom plate 126 of capacitor  $C_{S2}$ . The capacitance of capacitors  $C_{S3}$  and  $C_{S2}$  should be substantially the same because the structure of the capacitors and the pressures exerted on each are substantially identical. If the capacitance, detected by the EMO circuit 14, of each capacitor  $C_{S1}$  and  $C_{S2}$  is not the same, then it is reasonable to conclude that one of the capacitors is probably damaged.

In a similar manner, fluid 18a entering through opening 104 fills groove 128. However, since the fixed portion 125 of the common capacitor plate 114 directly across from the top plate 132 is solid and inflexible (as compared to flexible plates 124 and 126), the fluid 18a in groove 128 does not cause portion 125 of the silicon plate 114 to deflect. Therefore, the capacitance of the fixed capacitor CR is constant regardless of the pressure of fluid 18a, Thus, capacitor CR can be used to compensate for temperature variations and static pressure effects which affect the operation of the sensor 12, reducing analog sensing errors. Since all the capacitors are affected equally by static pressure and temperature effects and only the capacitors  $C_{81\ und\ CS2}$  are affected by differential pressure, these effects can be compensated for by comparing the ratio of each capacitor C<sub>S1</sub> and C<sub>S2</sub> against the capacitor C<sub>R</sub>. In FIG. 6, a schematic block diagram of the EMO

In FIG. 6, a schematic block diagram of the EMO interface circuit 14 and sensor 12 is shown. The EMO circuit 14 is capable of oscillating over a wide frequency range, with the actual frequency depending of the amount of frequency-controlling capacitance actively connected in the circuit. The actual frequency is governed by:

$$f = \frac{1}{RC}$$

where

f is the frequency of the signal,

R is the fixed resistance of the circuit,

C is the capacitance of the capacitor,

Thus, the output signal of the  $\dot{\text{EMO}}$  circuit I4 has a period (and frequency) which is proportional to the differential pressure,  $P_{H}$ – $P_{L}$ .

More particularly, the EMO circuit 14 converts the capacitance of whichever of the capacitors,  $C_{S1}$ ,  $C_{S2}$ , and  $C_R$  are actively connected in the EMO circuit 14 to a square wave FO (frequency output) signal. The resulting FO signal has a frequency which is proportional to the capacitance of the actively connected capacitor or capacitors and is transmitted to the frequency counter 76

The EMO circuit 14 is preferably an application-specific 20 CMOS integrated circuit. The EMO circuit 14 comprises an inverting operational amplifier 150, a bistable hysteresis amplifier 152 connected to the output of the op-amp 150, and a NAND gate 154 connected to the output of the bistable amplifier 152. The feedback circuit of the op-amp 150 is 25 connected to the plates 130, 132, and 134 of the capacitors Cs1, CR, and Cs2 via leads 90, 92 and 94, respectively. The feedback circuit of the bistable amplifier 152 controls a current source selecting switch 166. A current source 162 and an opposing current source 164 are alternately connected in the circuit depending upon the position of the selecting switch 166. The selected current source (162 or 164) is connected to the plates 130, 132, and 134 of capacitors Cs1, CR, and Cs2. The common plate 114 of the sensor 12 is connected to the inverting input terminal of the 35

The amount of frequency controlling capacitance actively connected in the EMO circuit 14 is controlled by independent single-pole switches 156, 158, and 160 in lines 90, 92, and 94, respectively. When closed, the switches 156, 158, and 160 connect the plates 130, 132, and 134, respectively to the output of the op-amp 150. By selectively closing switches 156, 158, and 160, any combination of the capacitors C<sub>S1</sub>, C<sub>R</sub>, and C<sub>S2</sub> can be actively connected in the EMO circuit 14 to determine the frequency of the circuit.

The operation of the switches 156, 158, and 160 is performed by an electronic switching network operated by a switch controller, such as a dedicated mode state machine 174 or a programmable controller. The mode state machine 174 is responsive to control signals MR (master reset) and MT (master toggle) sent from the controller 78. The switching device 174, through lines S<sub>1</sub>, R, and S<sub>2</sub>, can selectively close any combination of the switches 156, 158, and 160 to connect to the output of the inverting amplifier 150 any combination of the capacitors C<sub>S1</sub>, C<sub>R</sub>, and C<sub>S2</sub>. Any capacitor not connected to the output of the op-amp 150 is inactive so far as affecting frequency is concerned.

Independent single-pole switches 168, 170, and 172 are provided between capacitors  $C_{S1}$ ,  $C_{R}$ , and  $C_{S2}$ , respectively, and the common capacitor plate 114. When closed, the switches 168, 170, and 172 connect the respective plates to the common capacitor plate. The mode state machine 174, via the RESET line, closes the switches 168, 170 and 172 to discharge the capacitors after every occurrence of signal MR and MT sent by the controller 78 as described below.

The mode state machine 174 is also connected to a first input of the NAND gate 154 by the RESET line. The second input of the NAND gate 154 is connected to the output of the bistable amplifier 152. When activated by the mode state machine 174, the NAND gate 154 inverts the output signal from the bistable amplifier 152.

The EMO circuit 14 operates as follows. The controller 78 sends a control signal MR to the mode state machine 174 which momentarily closes switches 168, 170, and 172 via the RESET line, discharging capacitors C<sub>S1</sub>, C<sub>R</sub>, and C<sub>S2</sub>. After switches 168, 170, and 172 are opened again, the capacitors are then charged by the current source 162. The first input of the NAND gate 154 is set high via the RESET line.

Switch 158 is closed, actively connecting capacitor  $C_R$  into the oscillating circuit (i.e., to the output of the op-amp 150). Upon switching the capacitor  $C_R$  into the EMO circuit 12, the op-amp 150 will begin integrating the capacitance of the capacitor  $C_R$ .

As shown in FIGS. 7 and 8, the input voltage of the bistable amplifier 152 (and output voltage of the op-amp 150) is labelled  $V_{IN}$  and the output voltage is labelled  $V_{OUT}$ . In normal operation,  $V_{IN}$  ranges from a minimum of  $V_{LOW}$  and a maximum of  $V_{III}$ . These are the trigger voltages of the bistable amplifier 152. The output voltage.  $V_{OUT}$  ranges from  $V_0$  to Vand is initially equal to  $V_0$ . Since the current source 162 is initially switched into the circuit, the integrating op-amp 150 will cause  $V_{IV}$  to increase, or ramp up, until it reaches  $V_{III}$ .

When  $V_{IN}$  equals  $V_{IH}$ ,  $V_{OUT}$  goes high to Vand the opposing current source 164 is switched into the circuit via switch 166 by the output of the amplifier 152. Consequently, the integrating op-amp 150 causes  $V_{IN}$  to decrease, or ramp down, until it reaches  $V_{LOW}$ . When  $V_{IN}$  equals  $V_{LOW}$  the bistable amplifier 154 triggers to its opposite state which causes  $V_{OUT}$  to go low to  $V_0$ , and the current source 162 is switched back into the circuit via switch 166.

Thus, the output of the op-amp 150 is a triangular wave which ranges from VLOW to VHI and the output of the bistable amplifier 154 is a rectangular wave which ranges from Vo to V1. The NAND gate 154 serves to invert the output of the amplifier 152. The frequency (and period) of oscillation of the square wave output of the NAND gate 154 and the triangular wave output of the op-amp 150 is a function of the capacitance of the capacitor that is switched into the circuit. The greater the capacitance, the faster the rate of change of the output voltage of the op-amp 150, VIN Therefore, for larger capacitance values, the EMO circuit 14 will oscillate more rapidly between the trigger voltages, V<sub>HI</sub> and Viow, and the frequency of the FO signal will be higher. 10 The controller 78 next sends a signal MT to the mode state machine 174. In response, the RESET signal is again asserted, discharging the capacitors. The mode state machine 174 closes switch 156, placing the capacitor  $C_{S1}$  into the circuit along with the capacitor  $C_R$ . The op-amp 150 causes the circuit to oscillate at a frequency proportional to the capacitance of both the capacitors  $C_R$  and  $C_{S1}$ . Another control signal MT is sent to the mode state machine 174 which again asserts the RESET signal and opens the switch 158, removing the capacitor C<sub>R</sub> from the circuit. This causes the circuit to oscillate at a frequency proportional to the capacitance of the capacitor C51. A last signal MF is sent to the mode state machine 174 which asserts the RESET signal and opens the switch 156 and closes the switch 160. At this point, only the capacitor  $C_{S2}$  is connected in the circuit, which thus oscillates at a frequency proportional to the capacitance of the capacitor Cs2. Each of the resulting square wave signals  $FO_{CR}$ ,  $FO_{CS1+CR}$ ,  $FO_{CS1}$ , and  $FO_{CS2}$  are transmitted to the frequency counter 76 for further processing.

The external connections of the EMO circuit 14 are shown in FIG. 9. The controller 78 sends digital control signals MR and MT to the EMO circuit 14 to select which capacitors to actively connect in the EMO circuit. The output signal FO for each operating mode is sampled by the external frequency counter 76 and converted to a digital number representing the period of the signal FO. The frequency counter 76 typically measures the period of the signal FO by employing a reference frequency, typically 2 to 10 MHz, which is much higher than the signal FO, so that the period of FO can be measured with sufficient resolution. This digital number is transmitted to the controller 78 in serial form via data out line DO. The data in line DI is used to read data to set up the frequency counter 76 in its preferred mode of operation. The data ready line DTA RDY indicates to the controller 78 that the information has been received by the frequency counter 76. The serial clock line SCK provides the timing for the transfer of information between the frequency counter 76 and the controller 24.

Pressure transducers typically require data rates of about 10 samples per second. In order to provide this data rate at a high resolution, the frequency counter 76 is preferably a gate frequency counter with a resolution of 2<sup>17</sup> counts. The period of the signal FO is determined as follows. A gate time is sent to the frequency counter 76 via the serial data lines DO and DI, establishing the minimum gate time. The gate is opened by the falling edge of the first frequency output signal FO received by the frequency counter 76. The gate is closed on the first negative edge of FO after the minimum gate time has elapsed. This results in an integer number D of frequency output FO pulses. The resulting gate time is measured by the N clock pulses of the reference frequency (typically at the rate of 10 MHz). The measured period, T, is proportional to N/D.

For example, if the applied differential pressure  $(P_H - P_L)$  is 0 psi, the frequency output  $FO_{CR}$  transmitted when capacitor  $C_R$  is actively connected is 2 kHz or 0.5 ms and the frequency output FO due to capacitors  $C_{S1}$ , and  $C_{S2}$  would be substantially the same. For a differential pressure of 16 psi, which might typically represent full scale, the frequency output FO due to capacitor  $C_R$  would remain the same but the frequency output FO due to capacitors  $C_{S1}$  and  $C_{S2}$  would increase to 3 kHz.

The operation of one complete read cycle of the present device is as follows. As shown in FIG. 10, the data ready signal DTA RDY is first sent to the controller 78 indicating that the frequency counter is ready. In response, the controller transmits the MR signal to the EMO circuit 14. The 45 switching network actively connects the capacitor  $C_R$  in the EMO circuit and transmits the output frequency FO to the frequency counter 76.

The frequency counter 76 counts the number of 10 MHz reference frequency pulses in D pulses of frequency output  $FO_{CR}$ . Thus, if the frequency counter 76 is configured by data sent via the data in line DI to count reference frequency pulses for 10 FO pulses, D would be equal to 10 and the period of  $FO_{CR}$  would be represented by a count of 10 times 10 MHz/2 kHz, or 50,000 and represent a resolution of 1 part in 50,000. The resulting period  $T_R$  is sent to the controller 78 via the data output line DO.

The controller **78** then sends a control signal MT which advances the EMO circuit **14** to its next state, actively connecting capacitors  $C_{S1}$  and  $C_R$  in the EMO circuit **14**. The resulting frequency output  $FO_{CS1+CR}$  is measured and the period  $T_{S1+R}$  transmitted to the controller **78** by the frequency counter **76** in the same manner. The next control signal MT causes the switching network to actively connect the capacitor  $C_{S1}$  in the EMO circuit **14**, followed by a third control signal MT Which connects the capacitor  $C_{S2}$ . Thus, 65 after one complete cycle, the four periods  $T_R$ ,  $T_{S1+R}$ ,  $T_{S1}$ , and  $T_{S2}$  are transmitted and stored in the controller **78**.

In order to get a redundant signal representative of the differential pressure ( $P_{H-PL}$ ) and the compensated ratio used to calculate the pressure reading, the controller uses the four stored periods  $T_R$ ,  $T_{S1+R}$ ,  $T_{S1}$ , and  $T_{S2}$ . Since these periods are also sensitive to temperature, it is necessary to minimize or eliminate any parasitic capacitance caused by the temperature. An algorithm has been developed to reduce these parasitic capacitance effects and is set forth in U.S. Pat. No. 4,794,320 to Chang, the disclosure of which is hereby incorporated by reference herein.

The signal representative of differential pressure  $(P_H - P_L)$  is calculated in the controller 78 according to the Chang algorithm by computing the ratio:

$$R = \frac{(T_{S_1+R} - T_{S_1})}{(T_{S_1+R} - T_R)} \approx \frac{T_R}{T_{S_1}}$$

The capacitors by their nature have systematic pressure nonlinearity caused by their geometry. Thus, the differential pressure reading, P, is determined from the ratio R, by using a polynomial to correct for the nonlinearities, and is given by:

$$P=a_0+a_1R+a_2R^2+a_3R^3$$
...

The above equation is typically a fifth order polynomial which can be used to correct for nonlinearities of the sensor 12 to within 0.01% of full scale. The measured pressure  $P_x$  is a function of the capacitance of the capacitors  $C_R$  and  $C_{S1}$ . The error,  $\epsilon$ , substantially uninfluenced by temperature and pressure, is calculated by:

$$\varepsilon = \frac{T_R}{T_{S_1}} - \frac{T_R}{T_{S_2}}$$

The error term  $\epsilon$  allows the performance of the pressure transducer 10 to be verified with a high degree of certainty by comparing the compensated capacitance of both the capacitor  $C_{S1}$  and the capacitor  $C_{S2}$ . If the capacitors  $C_{S1}$  and  $C_{S2}$  are free of defects, such as particulate contamination, and have not been damaged by overstress, the error term  $\epsilon$  would be close to the same value under all conditions of pressure and temperature within the specified operating range.

Using the above equations, the controller 78 consults the following diagnostic table, preferably programmed into a memory, to determine the status of the redundant pressure transducer 10.

Condition	Position of Valve 42	P	e	Status of Sensor
1	first	Px	~()	OK
2	first	PN	*()	Sensor damaged/drifted
3	second	0		sensor and process diaphragms OK
4	second	0	*()	Cs. damaged/drifted - ignore
5	second	×()	~U	process diaphragms damaged - service
6	second	<b>≠</b> ()	*()	swap $C_{S1}$ for $C_{S2}$ ; if $P = 0$ then $C_{S1}$ is damaged; otherwise, service

The first condition in the diagnostic table is a properly functioning pressure transmitter 10. The transmitter is indicating a measured pressure  $P_X$  of the process fluid and the error term,  $\epsilon$ , is within tolerance. In the second condition,  $\epsilon$  is not within tolerance, indicating a possible error condition. To determine the possible problems, the valve manifold 42

14

is moved to the second position. If the pressure transmitter is functioning properly, the differential pressure across the capacitors should now be equal to zero and error ∈ should be within tolerance. This state is shown in the third condition.

The fourth condition shows that the differential pressure,  $P_s$  is accurately indicated as zero, but error  $\varepsilon$  is not within tolerance. In this case the capacitor  $C_{S2}$  has been damaged or has drifted because P is a function of the capacitance of capacitor  $C_{S1}$  only, while error  $\varepsilon$  is a function of the capacitance of both capacitors  $C_{S1}$  and  $C_{S2}$ . The fifth condition shows an inaccurate pressure indication but an error  $\varepsilon$  which is within tolerance. When this is the case, both capacitors  $C_{S1}$  and  $C_{S2}$  are giving inaccurate readings, indicating that the process diaphragms 28 and 37 are damaged and that service is required.

The sixth condition shows an inaccurate pressure reading and also an error  $\epsilon$  which is not within tolerance. This indicates that at least capacitor in  $C_{s1}$  is damaged. The capacitor  $C_{s2}$  is swapped for  $C_{s1}$  via software in the microprocessor and a pressure reading is determined as a function of  $C_{s2}$ . If the resulting pressure reading is correct then  $C_{s2}$  is the only damaged component. Otherwise, there is a more serious problem and the entire pressure transmitter 10 must be serviced.

The above test is sufficient because the probability of multiple defects or damage affecting each of the capacitors 25  $C_{S1}$  and  $C_{S2}$  in exactly, the same manner under all operating conditions is extremely small. Therefore, if the error  $\epsilon$  remains very small under varying conditions of temperature and pressure, it can be assumed that the sensor's characterization is unchanged from the time of initial manufacture.

Additionally, the three valve manifold 42 in conjunction with the redundant sensor 12 provides a way to assure accurate and reliable operation without the need for service personnel to have access to the pressure transducer 16. Since damage or leaks in the process diaphragms 28 and 37 cause errors undetectable by the redundant sensor 12, the problem can be isolated to the process diaphragms 28 and 37 if the error  $\epsilon$  is within tolerance yet there is a nonzero differential pressure reading when the valve manifold is placed in the second position (FIG. 2).

It is understood that the present invention can also be practiced with two separate substantially identical pressure sensors housed in a single transducer instead of with a monolithic sensor. In addition, a separate interface or conditioning circuit can be used with each pressure sensor to 45 transform the output of the pressure sensor to a frequency based signal, instead of a single interface/conditioning circuit and a switching network. FIG. 11 schematically shows such an arrangement.

In FIG. II there is schematically shown a generic embodiment of a pressure transducer device 210 which includes a pair of separate substantially identical pressure sensors 212 and 214 mounted within a sealed housing 216. A first chamber 218 and a second chamber 220 are formed in the walls of the housing 216. The first chamber 218 is filled with an inert pressure transfer medium 226a and is in fluid communication with pressure sensors 212 and 214. Similarly, the second chamber 220 is filled with an inert pressure transfer medium 226b and is in fluid communication with pressure sensors 212 and 214. Each chamber has a seal diaphragm outer wall 222 for transferring an applied pressure to the inert transfer media therein. Thus an applied differential pressure PH-PL is transmitted to the pressure sensors 212 and 214 by the seal diaphragms 222 and transfer media 226a and 226b.

Each sensor 212 and 214 generates an output which is proportional to the applied differential pressure  $P_H - P_L$ . A first conditioning circuit 228 is electrically connected to the first sensor 212 for transforming the output of the first sensor 212 into a discrete signal. Similarly, a second conditioning circuit 230 is electrically connected to the second sensor 214 for transforming the output of the second sensor 214 into a discrete signal. The signals from each conditioning circuit 228 and 230 are compared in an error detection circuit or microprocessor 232. A significant deviation between the two signals indicates the presence of sensor defects or damage.

Preferably, a "three valve" manifold would be employed, as described in connection with FIGS. 1–11, to pinpoint the source of any error.

The sensors 212 and 214 can be any type of pressure sensor responsive to applied differential pressure. Suitable pressure sensors are capacitive sensors, resonant sensors, strain gauge sensors, or the like. In addition, each sensor could also include a reference sensor to compensate for non-linearities caused by temperature variations and parasitic effects.

In FIG. 12 there is schematically illustrated a first embodiment of the pressure transducer device 210°. The pressure sensors of device 210° are capacitive pressure sensors 212° and 214°. Each capacitor 212° and 214° has a fixed plated 234 and a movable plate 236. The differential pressure,  $P_{IF}$   $P_{LS}$  is applied to each movable plate 236, deflecting each. The change in distance d, between the plates of the capacitors 212° and 214′ causes a change in capacitance proportional to the differential pressure,  $P_{IF}$   $P_{LS}$ 

Each capacitor 212' and 214' is electrically connected to a separate conditioning circuit 228' and 230', respectively. The conditioning circuits 228' and 230' are similar to the EMO circuit 14 (without the switching network) and function in a similar manner.

The conditioning circuits 228' and 230' each comprise an inverting operational amplifier 150 and a bistable hysteresis amplifies 152 connected to the output of the op-amp 150. The feedback circuit of the op-amp 150 is connected to the movable plate 236 of each respective capacitor 212' and 214'. The output of the bistable amplifier is fed back through a feedback resistance 238 to the input of the op-amp 150. The fixed plate 234 of each capacitor 212' and 214' is connected to the inverting input terminal of the respective op-amp 150. In this way, circuit 228' oscillates at a frequency proportional to the capacitance of capacitor 212' and circuit 230' oscillates at a frequency proportional to the capacitance of capacit

FIG. 13 schematically shows a second specific embodiment of the pressure transducer device 210". The pressure sensors of device 210" are resonant pressure sensors 212" and 214". Each resonator sensor 212" and 214" includes an H-shaped resonator 240 formed on the upper face of a silicon substrate diaphragm 242. A magnetic field is horizontally applied by a permanent magnet (not shown) adjacent the resonator 240. The resonator oscillates according to the principle of electromagnetic induction. One component of the differential pressure,  $P_H - P_L$  is applied to each face of the diaphragm 242, elastically deforming it. This generates a strain in the resonator 240, changing its resonant frequency in proportion to the differential pressure,  $P_H - P_L$ .

The relationship between the applied differential pressure  $P_H$ – $P_L$  and the resonant frequency f of the resonator 240 is given by the following equations:

$$\epsilon = \frac{Kr^2}{t^2(\Delta P)}$$
 
$$f = \frac{4.73^2h}{2\pi l} \sqrt{\frac{E}{12\hat{\rho}} \left(1 + 0.2366 \left(\frac{1}{h}\right)^2 \epsilon\right)}$$

where

€ is the strain in the resonator

K is a constant

r, 1 are diaphragm radius and thickness

 $\Delta P$  is the applied differential pressure  $(P_H - P_L)$ 

f is the resonant frequency

h, I are the resonator thickness and length

E is Young's modulus for silicon

p is the density of silicon

Conditioning circuits 228" and 230" are electrically connected to each resonator sensor 212" and 214", respectively. The conditioning circuit excites the resonator 240 and detects its resonant frequency. Preferably the conditioning circuit is implemented as a dedicated application specific integrated circuit.

The conditioning circuits, 228" and 230" each comprise a transformer 244 for separating the resonator 240 output DC voltage component. The AC component of the resonator 240 output is amplified by a preamplifier 246. The preamplifier 246 output is fed back to the resonator 240 input terminal via a variable voltage-current circuit (amplifier) 248.

The output of the preamplifier 246 is also branched to an automatic gain control circuit 250. The output of the automatic gain control circuit 250 is amplified by amplifier 252 and fed into the amplifier 248. This results in stable oscillation of the resonator 240 at a constant amplitude.

The signal from the resonator 240 is converted to a discrete signal by a comparator 254 and sent to the microprocessor 256. The microprocessor 256 compares the signals from each circuit 212" and 214" to monitor for drift or damage.

It is understood that the resonator sensors 212" and 214" can also be formed as a redundant monolithic sensor on a 40 single substrate.

FIG. 14 schematically shows a third embodiment of the pressure transducer device 210<sup>m</sup>. The sensors of device 210<sup>m</sup> are strain gauge sensors 212<sup>m</sup> and 214<sup>m</sup>. Each strain gauge sensor 212<sup>m</sup> and 214<sup>m</sup> includes a strain gauge 260 45 attached to a diaphragm 262.

One component of the differential pressure,  $P_H$ – $P_L$  is applied to each face of the diaphragm 262, elastically deforming it. This causes the strain to change in the strain gauge 260, causing a change in the resistance in each resistor of the strain gauge 260. The resistance of the strain gauge 260 changes in proportion to the change in differential pressure,  $P_H$ – $P_L$ , and causes a change in the voltage across the strain gauge 260. The voltage across each strain gauge 260, which is also proportional to the differential pressure,  $p_H$ – $p_L$ , is output to a conditioning circuit.

Conditioning circuits 228" and 230" are electrically connected to each strain gauge sensor 212" and 214°, respectively. The output from the strain gauge 260 is amplified by a preamplifier 264. The output of the preamplifier 264 is converted to a discrete signal by a wave generator 266 and a comparator 268. The microprocessor 270 compares the discrete signals from each circuit 228" and 230" to monitor for drift or damage.

It is understood that the strain gauge sensors 212" and 65 214" can also be formed as a redundant monolithic sensor on a single substrate.

The present invention may be embodied in other specific forms without departing front the spirit or essential attributes thereof and, accordingly, reference should be made to the appended claims, rather than to the foregoing specification, as indicating the scope of the invention.

We claim:

1. A pressure transducer comprising:

- a fluid pressure sensor comprising a first variable pressure sensor for providing an electrical output as a function of a differential fluid pressure, the first and second variable sensors being located in proximity to each other and in communication with the differential fluid pressure, the first variable pressure sensor being substantially identical to the second variable pressure sensor;
- a conditioning circuit for generating a first frequencybased signal whose frequency is a function of the electrical output of the first variable sensor and a second frequency-based signal whose frequency is a function of the electrical output of the second variable sensor; and

means for determining whether the difference between the first signal and the second signal is within a preselected range.

- The pressure transducer according to claim 1, wherein the first and second variable sensors comprise capacitive sensors, resonant sensors, or strain gauge sensors.
- 3. The pressure transducer according to claim I, wherein the fluid pressure sensor further comprises a reference sensor for providing an electrical output independent of the differential fluid pressure, the reference sensor being located in proximity to the first and second variable sensors and being in communication with the differential fluid pressure.
- 4. The pressure transducer according to claim 2, wherein the first and second variable sensors are formed on a common semiconductor substrate.
- This pressure transducer according to claim 2, wherein the first and second variable sensors are separate and independent.
- 6. This pressure transducer according to claim 1, wherein the first and second pressure sensors are resonant pressure sensors comprising a stilicon substrate, a flexible diaphragm in communication with the differential fluid pressure formed in the substrate, and an H-shaped resonator formed on the flexible diaphragm which resonates at a resonant frequency proportional to the differential pressure; and wherein the conditioning circuit excites tile resonator of the first and second resonant pressure sensors, and generates a first frequency-based signal whose frequency is a function of the resonant frequency based signal whose frequency is a function of the resonant frequency of the first resonant pressure sensor and a second frequency based signal whose frequency is a function of the resonant frequency of the second resonant pressure sensor.
- 7. The pressure transducer according to claim I, wherein the first and second pressure sensors are strain gauge sensors comprising a silicon substrate, a flexible diaphragm in communication with the differential fluid pressure, and a strain gauge located on the flexible diaphragm and whose resistance is proportional to the differential pressure; wherein the conditioning circuit generates a first frequency-based signal whose frequency is a function of the voltage output of the first strain gauge sensor and a second frequency-based signal whose frequency is a function of the voltage output of the second strain gauge sensor.

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# **EXHIBIT N**



US005924794A

# United States Patent [19]

O'Dougherty et al.

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5,924,794

[45] Date of Patent:

\*Jul. 20, 1999

# [54] CHEMICAL BLENDING SYSTEM WITH TITRATOR CONTROL

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- [73] Assignee: FSI International, Inc., Chaska, Minn.
- [\*] Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C.

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- [21] Appl. No.: 08/395,374
- [22] Filed: Feb. 21, 1995

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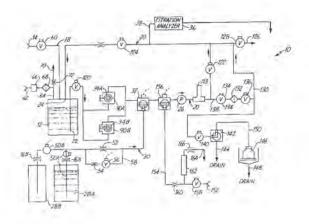
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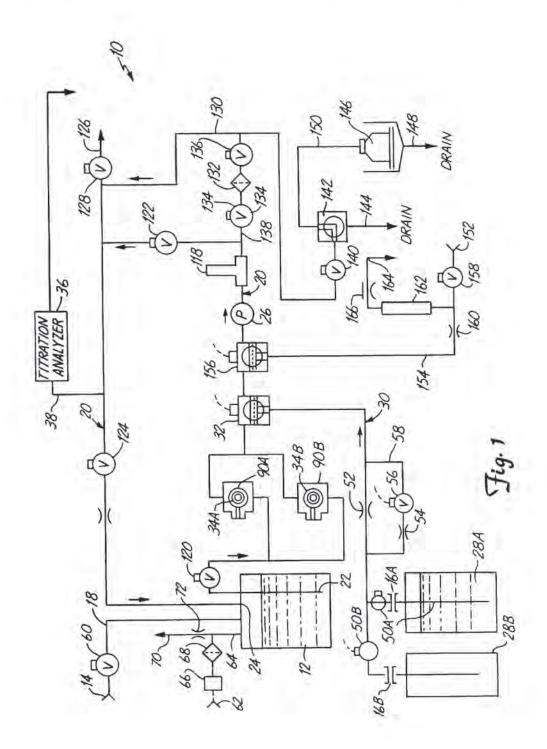
Primary Examiner—Tony G. Sooboo Autorney, Agent, or Firm—Faegre & Benson LLP

# 57] ABSTRACT

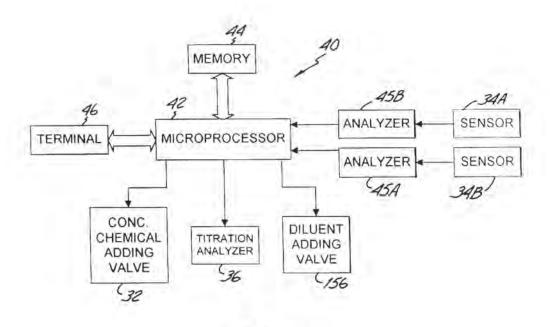
A chemical blending system for blending two or more constituent chemicals to a desired concentration. One embodiment of the system includes a mix tank, a recirculation line having an inlet and an outlet in the tank, and a pump in the recirculation line for recirculating and mixing the blended chemical. A source of diluent is fluidly coupled to the mix tank through a diluent inlet and supply line. A source of concentrated chemical is fluidly coupled to the recirculation line through a concentrated chemical inlet, supply line, and an adding valve located in the recirculation line between the inlet and pump. A conductivity-type sensor in the recirculation line provides continuous measurements of the blended chemical concentration. A titration analyzer is coupled to the recirculation line to provide periodic blended chemical concentration measurements. A programmable logic control system including a processor and associated memory is coupled to the adding valve, conductivitytype sensor and titration analyzer. A blending control program and process control values are stored in the memory. The processor executes the blending control program and controls the concentrate adding valve as a function of the concentration measurements provided by the conductivity-type sensor and titration analyzer to blend the chemical to the desired concentration.

# 40 Claims, 6 Drawing Sheets

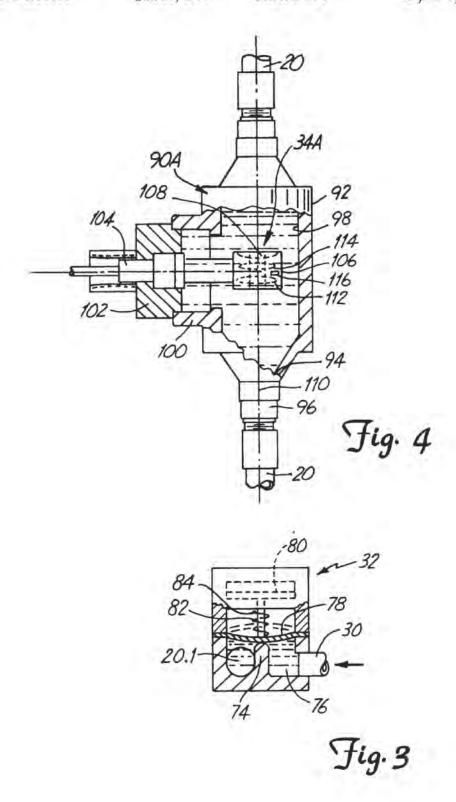


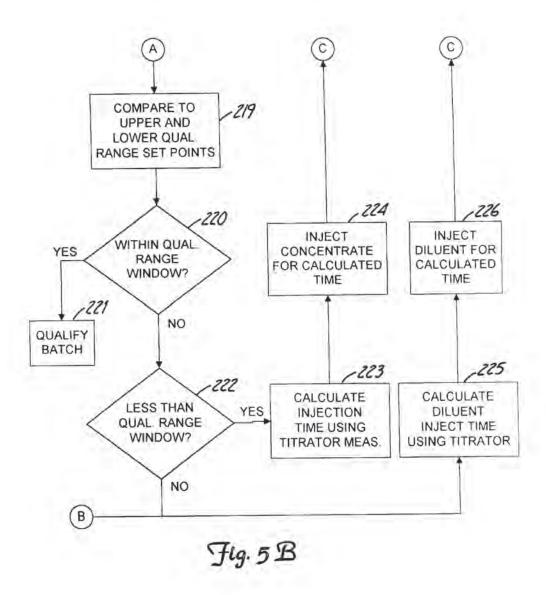


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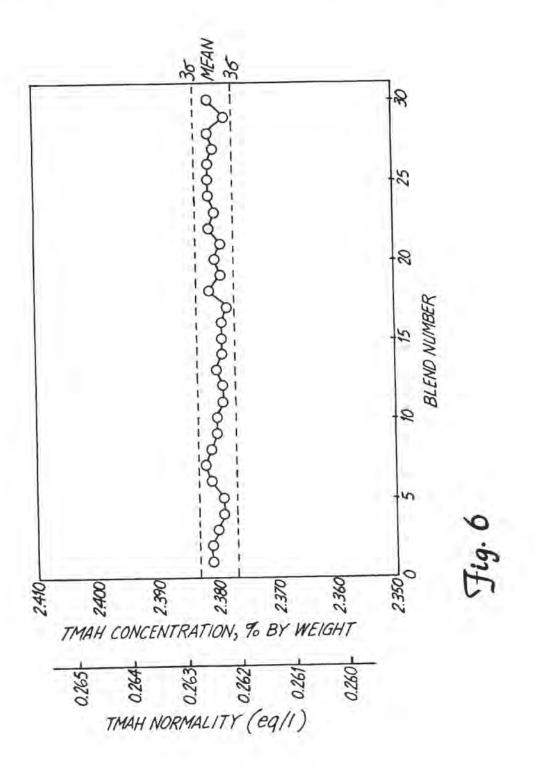


Flg. 2





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# CHEMICAL BLENDING SYSTEM WITH TITRATOR CONTROL

### BACKGROUND OF THE INVENTION

# 1. Field of the Invention

The present invention is a chemical blending system. In particular, the present invention is a computer-controlled system for blending batches of concentrated chemicals from two or more chemical components for subsequent use in semiconductor fabrication facilities.

### 2. Description of the Related Art

Chemical generation or blending systems are used in a variety of industrial applications to blend two or more components or constituents to a desired concentration. In semiconductor fabrication facilities, for example, concentrated chemicals (which are usually provided by commercial chemical suppliers in solution with water) are mixed or diluted with DI (deionized) water before being sprayed on or otherwise applied to semiconductor wafers. Table 1 below lists a number of chemicals used in semiconductor fabrication facilities, and the concentration (in weight %) in which these chemicals are typically provided by suppliers.

TABLE 1

Chemical	Symbol	Percentage Concentrate in Water
Hydrofluoric Acid	HF	49%
Acetic Acid	HAC	99.7%
Nitrie Acid	HNO,	71%
Phosphoric Acid	H <sub>2</sub> PO <sub>4</sub>	80%
Potassium Hydroxide	KOH	30%
Tetramethyl Ammonium Hydroxide	TMAH	25%
Hydrochloric Acid	HCI	37%
HF and Ammonium Fluoride Mixtures	BOEs	-
Ammonium Hydroxide	NH,OH	28-30%
Sulfuric Acid	H-SO <sub>4</sub>	93-98%

When used in semiconductor fabrication facilities, the concentrated chemicals described above are commonly diluted with DI water (i.e., a diluent) to desired concentrations or assays. Concentrations in these applications are typically described in terms of weight % (weight percent) of concentrated or pure chemical in water. Hydrofluoric Acid (HF), for example, is often diluted with high purity water to concentrations ranging from about 0.5%–5% HF by weight when used for etching and cleaning processes. Tetramethyl Ammonium Hydroxide (TMAH) is often diluted to about 2.38 weight % for use as a positive photoresist developer. Non-aqueous blended chemicals, and blended chemicals with three or more components, can also be generated.

Chemical blending systems blend the chemicals to a desired concentration which is sometimes known as the 55 nominal or qualification concentration. A high degree of accuracy is also required. The range or window of acceptable concentrations surrounding the qualification concentration is known as the qualification range, and can be defined as a weight % error with respect to the qualification of concentration, or by upper and lower qualification range concentrations.

A known chemical blending system which is commercially available from FSI International of Chaska, Minn., the assignee of the present invention, is disclosed generally in commonly assigned application Ser. No. 08/355,671, filed Dec. 14, 1994 and entitled "Apparatus For Blending Chemi-

cal And Diluent Liquids". This chemical blending system includes a mix tank for the blended chemical, a recirculation line having an inlet and outlet in the mix tank, and a pump in the recirculation line. A source of a first constituent of the blended chemical, such as DI water which is used as a diluent, is coupled to the mix tank through an inlet and supply line. A source of a second constituent of the blended chemical, such as the concentrated chemical to be diluted, is coupled to the recirculation line through an inlet, source line and adding valve. The adding valve is located in the recirculation line on the suction side of the pump (i.e., between the pump and the inlet of the recirculation line), and is controlled by a microprocessor-based control system. When the pump is operating and the adding valve is open, concentrated chemical is drawn into the recirculation line. Recirculation of the blended chemical through the recirculation line causes the blended chemical and added concentrate to be thoroughly mixed.

Concentration of the blended chemical is monitored by conductivity-type sensors in the recirculation line between the pump and inlet. The sensors are coupled to the control system through analyzers that convert the conductivity readings provided by the sensors to concentration values used by the control system.

The control system initiates a chemical blending cycle by filling the mix tank with a desired quantity of DI water and activating the pump to recirculate the blended chemical within the tank and recirculation line. The concentrate adding valve is then opened to provide a continuous flow of 30 concentrated chemical into the recirculation line. During this continuous injection phase of the blending cycle the concentration of the blended chemical is monitored continuously and compared to a coarse blend setpoint. The coarse blend setpoint can be empirically determined, and represents a concentration which is sufficiently less than the qualification concentration that the continuous addition of concentrated chemical will approach, but not exceed or overshoot, the qualification concentration if the addition of concentrated chemical is stopped when the measured concentration has increased to the coarse blend setpoint. Once the control system determines that the measured blended chemical concentration has reached the coarse blend setpoint, it closes the concentrate adding valve.

The control system then periodically opens and closes the concentrate adding valve during a periodic injection phase. Relatively small quantities of the concentrated chemical are added during the time periods that the valve is open, and the added concentrated chemical is mixed with the blended chemical while the valve is closed. The concentration of the blended chemical is continuously measured and compared to the qualification concentration during this periodic injection phase. To ensure that the concentration measurements are made in homogeneous and thoroughly blended chemical, the duty cycle of the period during which the concentrate adding valve is open is relatively short compared to the duty cycle of the time period during which the valve is closed. Furthermore, to minimize the chances that the concentration will exceed the qualification range, the duty cycle of the time period during which the valve is open is relatively short so as to increase the concentration in relatively small increments. In one embodiment, for example, the open valve duty cycle is about six seconds while the closed valve duty cycle is about twenty-four seconds. When the measured concentration reaches the qualification concentration, the control system qualifies the blended chemical batch and ceases further concentrated chemical addition. The blended chemical can then be pumped to its point of use.

The conductivity-type sensors used in the chemical blending system described above are capable of providing continuous and almost instantaneous measurements of the blended chemical concentration. The accuracy of the measurements provided by the conductivity-type sensors is also good. Nonetheless, blended chemical concentration variations within the range of accuracy that can be provided through the use of conductivity-type sensors can result in semiconductor fabrication process variations. These process variations can detrimentally affect the physical and electrical characteristics of the semiconductor wafers being processed. The problems associated with these process variations will become even more critical as the circuit geometries on the wafers become smaller and the circuit patterns more complex. Chemical blending systems capable of blending chemicals to higher concentration accuracy levels or tolerances are therefore needed to keep pace with other advances in semiconductor fabrication processes.

The use of titration analyzers to measure the concentration of blended chemicals produced by chemical blending systems is also known. Titration analyzers are commercially available from a number of suppliers including Applikon Dependable Instruments of the Netherlands, through its North American distributer Applikon Analyzers, Inc. of Kingwood Tex. When actuated, analyzers of this type draw a sample of the blended chemical. The sample is then titrated with reagents and its pH or pH inflection point measured to determine the concentration of the blended chemical. Titration analyzers are capable of providing concentration measurements to a higher degree of accuracy than conductivity-type sensors (e.g., to less than about 0.10% relative error (i.e., error/setpoint) at three standard deviations or three sigma (30)).

For a number of reasons including the minimization of storage container space, the propensity of containers to contaminate chemicals during prolonged storage and the tendency of concentration values to change with time, chemicals are typically blended relatively frequently and in relatively small batches. The batches of blended chemical are then used relatively soon after they are produced. Chemical blending systems must therefore be capable of quickly blending the batches of chemical to the desired concentration. Unfortunately, titration analyzers have a relatively slow measurement response time (about 3-5 minutes per measurement) compared to the nearly instantaneous response of conductivity-type sensors. Since a number of concentration measurements are typically required before a batch of blended chemical can be qualified, the use of titration analyzers can increase the length of time required to blend a batch of chemical.

It is evident that there is a need for improved chemical blending systems. In particular, there is a need for chemical blending systems capable of quickly blending batches of chemical to a very high degree of accuracy. To be commercially viable, the chemical blending system must also be highly reliable.

# SUMMARY OF THE INVENTION

The present invention is a chemical blending system 60 capable of quickly and accurately blending chemicals to a desired concentration. One embodiment of the chemical blending system includes a concentrated chemical inlet for receiving concentrated chemical, a diluent inlet for receiving diluent, and a blending tank coupled to the concentrated 65 chemical inlet and the diluent inlet for receiving and blending the concentrated chemical. A flow control mechanism

responsive to concentration control signals controls the flow of diluent from the diluent inlet into the blending tank. The system also includes first and second concentration measuring instruments. The first concentration measuring instrument has first operating characteristics and provides first instrument readings as a function of the measurements. The second concentration measuring instrument has second operating characteristics different than the first operating characteristics, and provides second instrument readings as a function of the measurements. A programmable logic controller including a processor and memory are coupled to the first and second concentration measuring instruments and to the flow control mechanism. Information stored in the memory includes concentration data, fine setpoint data and qualification setpoint data. The concentration data is representative of the relationship between the concentration control signals and blended chemical concentration changes induced by actuation of the flow control mechanism. The fine setpoint data is representative of a first chemical concentration which is less than the desired chemical concentration. The qualification setpoint data is representative of a chemical concentration within a qualification range of the desired concentration. The blending control program executed by the processor includes:

5 (a) monitoring first instrument readings of blended chemical concentration measurements provided by the first concentration measuring instrument;

(b) generating concentration control signals as a function of the concentration data and the first instrument readings, to actuate the flow control mechanism and attempt to increase the blended chemical concentration to the desired concentration if the first monitored instrument reading is less than or equal to the fine concentration setpoint;

(c) monitoring second instrument readings of blended chemical concentration measurements provided by the second concentration measuring instrument if the first monitored instrument reading is greater than the fine concentration setpoint;

(d) generating concentration control signals as a function of the concentration data and the second instrument readings, to actuate the flow control mechanism and attempt to increase the blended chemical concentration to the desired concentration if the second monitored instrument reading is greater than the fine concentration set point and less than the qualification setpoint; and

(e) repeating functions (c)-(d) until the second instrument reading is within the qualification range.

# BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a diagrammatic illustration of a chemical blending system in accordance with the present invention.

FIG. 2 is a block diagram of a programmable logic control (PLC) subsystem for operating the chemical blending system shown in FIG. 1 in accordance with the present invention.

FIG. 3 is a partial cross-sectional view of the adding valves shown in FIG. 1.

FIG. 4 is a partial cross-sectional view of the conductivity-type sensors and associated housings shown in FIG. 1.

FIGS. 5A and 5B are flow diagrams of a chemical blending program executed by the control subsystem shown in FIG. 2.

FIG. 6 is a graph of TMAH concentrations obtained during thirty blend cycle tests of a prototype of the present invention.

The programmable logic control subsystem 40 used to control the operation of chemical blending system 10 is illustrated generally in FIG. 2. As shown, control subsystem 35 40 includes a microprocessor 42 and associated memory 44. Conductivity sensors 34A and 34B are interfaced to microprocessor 42 through analyzers 45A and 45B. Adding valves 32 and 156 and titration analyzer 36 are interfaced directly to the microprocessor 42. An operator can interface with 40 control subsystem 40 through a terminal 46. Data representing information including concentration setpoints, process control values and a chemical blending control program is stored in memory 44. Microprocessor 42 executes the chemical blending control program as a function of the concentration setpoints, process control values and the concentration measurements made by titration analyzer 36 and sensors 34A and 34B, and in response actuates concentrate adding valve 32 and diluent adding valve 156 to regulate the flow of concentrated chemical and diluent into recirculation 50 line 20. The chemical constituents can be quickly blended to the desired concentration with a high degree of accuracy.

The embodiment of chemical blending system 10 shown in FIGS. 1 and 2 is configured to produce blended chemicals used in semiconductor fabrication facilities. For example, 55 concentrated tetramethyl ammonium hydroxide (TMAH) can be blended with DI water by system 10 for use as photoresist developer. In applications such as these the concentrated chemical is typically available from commercial suppliers in fifty-five gallon (about 200 liter) drums such as containers 28A and 28B. Containers 28A and 28B can be attached to and disconnected from inlets 16A and 16B, respectively, by conventional couplers (not shown). Inlets 16A and 16B are each independently connected to concentrated chemical supply line 30 through on-off solenoid 5 valves 50A and 50B, respectively. The flow rate of concentrated chemical through supply line 30 can be regulated by

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orifices 52 and 54. Orifice 54 and on-off solenoid valve 56 are connected in series with one another and in a shunt line 58 around orifice 52. Orifice 54 is configured to regulate a different and typically larger flow of concentrated chemical than orifice 52. Blending system 10 can therefore be quickly reconfigured for blending different constituent chemicals and different concentration ranges of the same chemical. Additional shunt lines (not shown) can also be included to expand the concentration ranges over which system 10 can operate.

Mixing and storage tank 12 is fabricated from a material such as Teflon® PFA (perfluoroalkoxy) or ultra high molecular weight polyethylene which is resistant to corrosion by the blended chemical. The flow of diluent into tank 12 through supply line 18 is controlled by on-off solenoid valve 60. Inlet 62 is configured to be coupled to a source of process nitrogen which is used as inert tank makeup gas and to provide a blanket which separates the blended chemical from air and prevents evaporation that would result in concentration variations. Process nitrogen inlet 62 is coupled to tank 12 through a supply line 64 having a regulator 66 and filter 68. An exhaust line 70 having an orifice 72 extends from tank 12 to vent excess gas from the tank. Tank 12 has a capacity of about thirty gallons (about 110 liters) in one embodiment, although the size can vary depending upon the application of blending system 10.

Concentrated chemical adding valve 32 connects concentrated chemical supply line 30 to recirculation line 20. As shown in FIG. 1, adding valve 32 is located in recirculation line 20 between tank 12 and the suction side of pump 26. Adding valve 32 is a sample valve in the illustrated embodiment, and enables concentrated chemical to be added directly from supply line 30 into duct portion 20.1 of the valve. As shown in greater detail in FIG. 3, duct portion 20.1 of valve 32 functions as an unobstructed flow-through portion of recirculation line 20, and extends along a weir 74 which separates the duct portion from an inlet chamber 76 to which supply line 30 is connected. A diaphragm 78 is biased downwardly toward weir 74 by spring 84. An actuator such as pneumatic piston 80 is connected by a stem 82 to the diaphragm 78. Spring 84 biases diaphragm 78 to a closed position separating inlet chamber 76 from duct portion 20.1, thereby sealing concentrated chemical supply line 30 from recirculation line 20. When actuated by control subsystem 40, piston 80 lifts diaphragm 78 off the weir 74 to allow the flow of concentrated chemical from supply line 30 into recirculation line 20 where it will mix with the blended chemical then present in the recirculation line and tank 12. Adding valve 32 is capable of accurately regulating the flow of concentrated chemical into recirculation line 20 when opened, and the rate of this flow can be empirically determined. The adding valve 32 described herein is similar to that disclosed in U.S. Pat. No. 4,977,929, but modified to be actuated by a pneumatic piston to reduce dead spots that can otherwise result in quiescent quantities of concentrated chemical.

Conductivity sensors 34A and 34B are mounted within flow housings 90A and 90B, respectively, and are connected in recirculation line 20 in a parallel hydraulic circuit between tank 12 and adding valve 32. Concentration sensor 34A, which can be identical to sensor 34B, is described in greater detail with reference to FIG. 4. As shown, sensor 34A is mounted within a housing 90A formed of PFA, PVDF or other material resistant to corrosion by the blended chemical. Housing 90A has a generally cylindrical outer wall 92, and tapered end walls 94 providing fittings to couple the housing to recirculation line 20. The nature of the

material from which housing 90A is fabricated and the smooth inner surfaces 98 of wall 92 tend to minimize the collection of gas bubbles on the housing as the blended chemical flows therethrough.

Sensor 34A includes a stem 104 extending through a mounting plug 102. Mounting plug 102 is welded or otherwise secured to a T-shaped opening 100 in housing 90A. Sensor 34A also includes a sensing head 106 on the end of stem 104 within housing 90A. Sensing head 106 is annular in shape and has a central opening 108 axially aligned with the centerline 110 of housing 90A. Blended chemical flowing through housing 90A therefore flows through the central opening 108 of sensor 34A as well. Sensor 34A also includes a temperature sensor 116 which is coupled to control subsystem 40 to provide a temperature signal representative of the temperature of the blended chemical flowing through the sensor.

Sensing head 106 and stem 104 can be molded as an integral unit from PFA, PVDF or other corrosion-resistant material. A pair of coils 112 and 114 and associated lead wires which extend from stem 104 (not shown in FIG. 4) are embedded within head 106 and the stem while they are being molded. Coils 112 and 114 surround the central opening 108 of head 106. As with housing 90A, the material from which stem 104 and head 106 are fabricated and the smooth surfaces of these components minimizes the collection of gas bubbles on sensor 34A as the blended chemical flows through and by the sensor.

As shown in FIG. 2, sensors 34A and 34B are interfaced to microprocessor 42 through analyzers 45A and 45B, 30 respectively. Analyzers 45A and 45B drive sensors 34A and 34B, and process signals received from the sensors to generate digital concentration values representative of the weight % concentration of the blended chemical flowing past the sensors. Analyzers such as 45A and 45B are well 35 known and commercially available from a number of manufacturers such as Great Lakes Instruments of Milwaukee, Wis. Briefly, and with reference to sensor 34A illustrated in FIG. 4, coil 112 is energized by an AC drive signal from analyzer 45A to create an inductive field. The inductive field establishes an electric current in the blended chemical flowing by sensor head 106. The magnitude of the electric current established in the blended chemical is directly related to the conductivity, and therefore concentration, of the blended chemical. The current established in the blended 45 chemical induces a sense current signal in coil 114, and the magnitude of the sense current signal is also directly related to the conductivity and concentration of the blended chemical. The sense current signal is digitized by analyzer 45A to produce an uncompensated digital conductivity value.

Analyzer 45A includes stored conductivity-concentration data (e.g., in the form of lookup table) which relates the monitored conductivity values of the blended chemical to the weight % concentration values of the blended chemical at a predetermined temperature (e.g., 25° C.). The relationship between the conductivity values generated by sensor 34A and the actual concentration of the blended chemical is also dependant upon the temperature of the blended chemical. Analyzer 45A therefore also includes temperature compensation data characterizing the relationship between conductivity values at the temperature for which the conductivity-concentration data is established, and the actual temperature of the blended chemical. The uncompensated digital conductivity value is processed by analyzer 45A as a function of the measured temperature of the blended chemical and the temperature compensation data to generate compensated digital conductivity values. Using the

compensated digital conductivity value as an input, analyzer 45A then accesses the conductivity-concentration data to generate a compensated digital concentration value in units of weight %. The compensated digital concentration values generated by analyzer 45A are provided to microprocessor 42.

Microprocessor 42 continuously compares the concentration values generated from the sensors 34A and 34B, and performs a deviation analysis to monitor the operation of the sensors. If sensors 34A and 34B are both operating properly, the concentration values generated by these sensors will be equal to one another within a predetermined range of deviation. If the concentration measurements based upon the conductivity readings from sensors 34A and 34B are equal to one another within the predetermined range of deviation, microprocessor 42 will use one of the concentration measurements to control the operation of blending system 10. If at any time microprocessor 42 determined that the concentration values are not equal (i.e., if excess deviation exists), control subsystem 40 will stop or discontinue the operation of blending system 10, and provide a corresponding error message on terminal 46. Blending system 10 and/or control subsystem 40 can then be serviced to identify and repair the

Referring back to FIG. 1, a surge suppressor 118 can be included in recirculation line 20 immediately downstream from pump 26. On-off solenoid valves 120, 122 and 124 are also included in recirculation line 20 in the illustrated embodiment of blending system 10. Valve 120 is located between the intake end 22 of recirculation line 20 and sensors 34A and 34B. Valves 122 and 124 are in series with one another between surge suppressor 118 and the discharge end 24 of the recirculation line 20.

Blended chemical from system 10 is delivered to its point of use through discharge line 126. In the embodiment shown, discharge line 126 is coupled to recirculation line 20 at a point between valves 122 and 124. An on-off solenoid valve 128 can be used to control the discharge of blended chemical through line 126.

A filter line 130 is connected in parallel with valve 122. As shown, filter line 130 includes a filter 132, and on-off solenoid valves 134 and 136. Valves 134 and 136 are positioned on opposite sides of filter 132.

A drain and sample collecting line 138 is connected to the recirculation line 20 between valves 122 and 124, and includes on-off solenoid valve 140 and two-way valve 142. A first outlet port of two-way valve 142 is connected to drain line 144. A second outlet port of valve 142 is coupled to sample bottle 146 and associated drain line 148 through sample line 150. When actuated by control subsystem 40, two-way valve 142 can connect the drain and sample collecting line 138 to either drain line 144 or sample line 150.

As described above, diluent inlet 152 is coupled to recirculation line 20 through diluent line 154 and adding valve 156. Adding valve 156 can be identical to valve 32 described above and is located in recirculation line 20 between concentrate adding valve 32 and pump 26 in the embodiment shown. Since diluent adding valve 156 is positioned adjacent to the suction side of pump 26, diluent from supply line 154 will be drawn into recirculation line 20 when the diluent adding valve is open. Adding valve 156 is capable of accurately regulating the flow of diluent into recirculation line 20 when opened, and the rate of this flow can be empirically determined.

On-off solenoid valve 158 and orifice 160 are included in diluent line 154 to control and regulate the flow of diluent to valve 156. The embodiment of blending system 10 shown in FIG. 1 also includes a column 162 coupled to line 154 between valve 158 and orifice 160. Column 162 is connected to a drain line 164 through orifice 166. In practice, column 162 can be periodically replenished with diluent by opening 5 valve 158, thereby maintaining a fresh supply of diluent within the column for subsequent addition to the blended chemical in recirculation line 20 through the diluent adding valve. Alternatively, DI water can be continuously added to column 162, and allowed to overflow, to minimize bacteria 10 growth.

Titration analyzers such as 36 arc well known and commercially available from a number of sources such as Applikon Dependable Instruments by of the Netherlands, through its North American distributer Applikon Analyzers, Inc. of Kingwood Tex. When actuated by control subsystem 40, titration analyzer 36 initiates an analysis cycle by drawing a sample of blended chemical from recirculation line 20. The sample is then titrated with reagents and its pH or pH inflection point measured to determine the concentration of the blended chemical sample. Analyzers such as 36 can also implement other titration techniques to measure concentrations of various components of the sample. A signal representative of the concentration of the blended chemical is provided to control subsystem 40 by titration 25 analyzer 36 at the end of the titration analysis cycle. Titration analyzers such as 36 have a relatively slow response time (e.g., 3-5 minutes) compared to the nearly instantaneous concentration measurements that can be obtained through the use of conductivity sensors 34A and 34B, but are 30 capable of providing concentration measurements to a higher degree of accuracy than those obtained from the conductivity sensors (e.g., less than about 0.10% relative error at three standard deviations or 30).

The manner by which control subsystem 40 operates 35 blending system 10 to blend diluent with concentrated chemical to obtain blended chemical having the desired concentration can be described generally with reference to FIGS. 2 and 5. The blending control program executed by microprocessor 42 to control the operation of concentrate adding valve 32, diluent adding valve 156 and titration analyzer 36 is stored in memory 44. Also stored in memory 44 is data characterizing a number of setpoints and process control values used by the blending control program. The setpoints and process control values are dependant on the specific type and concentration of blended chemical being produced by blending system 10 (e.g., on the type of diluent and concentrated chemical) and the blending algorithm being implemented by the blending control program. In the embodiment described herein, blended chemical concentration is described in terms of weight percent (weight %) of concentrated chemical in the blended chemical. Accordingly, the setpoints and process control values are referenced to units of weight %. The blending control program executed by the embodiment of control subsystem 40 described herein makes use of the following setpoints and process control values.

- 1. Desired Qualification Setpoint
- 2. Upper Qualification Range Setpoint
- 3, Lower Qualification Range Setpoint
- 4. Coarse Blend Setpoint
- 5. Fine Blend Setpoint
- 6. Concentrate Injection Constant
- 7. Diluent Injection Constant

The Desired Qualification Setpoint is a value representing the desired or nominal blended chemical concentration. An operator will typically enter the Desired Qualification Setpoint into control subsystem 40 through terminal 46. The
Upper and Lower Qualification Range Setpoints are blended
chemical concentrations above and below the Desired Qualification Setpoint, respectively, that represent an acceptable
window or range of final blended chemical concentrations.
The Upper and Lower Qualification Range Setpoints can be
programmed directly into control subsystem 40 through
terminal 46. Alternatively, a percent composition error value
or other specification describing a range of acceptable
blended chemical concentrations can be programmed into
control subsystem 40, and used by the control subsystem,
along with the Desired Qualification Setpoint, to compute
the Upper and Lower Qualification Range Setpoints.

The Coarse Blend Setpoint is a value representing a blended chemical concentration that is used to control the initial injection or addition of concentrated chemical into the recirculation line 20. As is described in greater detail below. during the initial operation of blending system 10, concentrated chemical is continuously added to the recirculation line 20 to quickly increase the concentration of the blended chemical as long as the concentration measurements provided by conductivity sensors 34A and 34B indicate that the blended chemical concentration is less than the Coarse Blend Setpoint. The Coarse Blend Setpoint therefore represents a concentration which is sufficiently less than the Desired Qualification Setpoint that the actual blended chemical concentration will approach, but not exceed or overshoot, the Desired Qualification Setpoint if the addition of concentrated chemical is stopped when the concentration measurements provided by sensors 34A and 34B indicate that the blended chemical concentration has increased to the Coarse Blend Setpoint. The Coarse Blend Setpoint can be empirically determined by observing the operation of blending system 10, and programmed into control subsystem 40 through terminal 46.

The Fine Blend Setpoint is a value representing a blended chemical concentration which is greater than the Coarse Blend Setpoint, but less than the Lower Qualification Range Setpoint. The Fine Blend Setpoint is used to determine whether concentration measurements based on conductivity sensors 34A and 34B or titration analyzer 36 will be used for subsequent process control operations implemented by control subsystem 40. The Fine Blend Setpoint can be empirically determined and programmed into control subsystem 40 through terminal 46.

The Concentrate Injection Constant is a process value characterizing the relationship between a parameter of blending system 10 that can be controlled by control subsystem 40, and corresponding changes to the concentration of the blended chemical. In the embodiment of blending system 10 described herein, the concentrate Injection Constant is representative of the relationship between the length of time that concentration adding valve 32 is actuated and associated changes (increases) in the blended chemical concentration. In particular, the Concentrate Injection Constant is a value characteristic of weight % increases in blended chemical concentration per second that adding valve 32 is open (i.e., in units of wt %/sec). The Concentrate Injection Constant can be empirically determined and programmed into control subsystem 40 through terminal 46. As described in greater detail below, control subsystem 40 can also update the Concentration Injection Constant on the basis of monitored changes in concentration to increase the accuracy of blending system 10.

The Diluent Injection Constant is also a process value characterizing the relationship between a parameter of blending system 10 that can be controlled by subsystem 40, and corresponding changes to the concentration of the blended chemical. In the embodiment of blending system 10 described herein, the Diluent Injection Constant is representative of the relationship between the length of time that diluent adding valve 156 is actuated and associated changes (decreases) in the blended chemical concentration. In particular, the Diluent Injection Constant is a value characteristic of weight % decreases in blended chemical concentration per second that adding valve 156 is open (i.e., in units of wt %(sec))

FIG. 5 is a flow diagram of the method by which blending system 10 is operated by control subsystem 40 to quickly and accurately mix diluent and concentrated chemical in tank 12 and recirculation line 20, and generate blended chemical having a concentration between the Upper and Lower Qualification Range Setpoints. When used in semiconductor fabrication applications, blending system 10 will typically produce blended chemicals having less concentrated chemical than diluent (i.e., a relatively low weight % of concentrated chemical). As shown at step 200, microprocessor 42 therefore begins the blending process by opening valve 60 to fill tank 12 with a desired amount of diluent. Once tank 12 has been filled, valve 60 is closed. Pump 26 is then actuated to continually recirculate the diluent through tank 12 and recirculation line 20. Before initiating subsequent steps of the blending method shown in FIG. 5, pump 26 is allowed to recirculate the blended chemical (or initially only the diluent) for a predetermined length of time to thoroughly mix the diluent and concentrated chemical and generate a homogeneous blended chemical. This mixing step is shown at 201 in FIG. 5.

After the mixing operation at step 201, the concentration of the blended chemical within tank 12 and recirculation line 20 is continuously measured by microprocessor 42 using 35 readings provided by conductivity sensors 34A and 34B. This measurement is shown at step 202. The measured concentration is then compared to the setpoints including the Desired Qualification Setpoint, Upper and Lower Qualification Range Setpoints, and the Coarse and Fine Blend 40 Setpoints. This comparison is indicated by step 203 in FIG. 5

If the comparison performed at step 203 indicates that the blended chemical concentration is less than the Coarse Blend Setpoint (decision step 204) (e.g. at the beginning of the blend cycle), microprocessor 42 either opens concentrate adding valve 32, or keeps the valve open, to continuously inject or add concentrated chemical to recirculation line 20. This step is shown at 205 in FIG, 5 and results in the mixture of the added concentrate with the blended chemical within the recirculation line 20. Steps 202–205 are then continuously repeated as shown in FIG. 5 until the measured concentration of the blended chemical reaches the Coarse Blend Setpoint. The continuous injection of concentrated chemical in this manner will cause the concentration of the blended chemical to relatively quickly increase to the value represented by the Coarse Blend Setpoint.

After the comparison performed at step 203 indicates that the concentration of the blended chemical has increased to a value which is greater than or equal to the Coarse Blend 60 Setpoint, but less than or equal to the Fine Blend Setpoint (decision step 206), microprocessor 42 closes the concentrate adding valve 32. Microprocessor 42 then calculates the length of time that concentrate adding valve 32 should be opened to inject or add enough concentrated chemical to recirculation line 20 to increase the blended chemical concentration to the Fine Blend Setpoint. These steps are shown

generally at 207 and 208 in FIG. 5. In particular, at step 207 microprocessor 42 computes the difference between the Fine Blend Setpoint and the most recent measurement of the blended chemical concentration at step 202. This difference, in weight % of concentrated chemical, is then divided by the Concentrate Injection Constant to compute the length of time that the concentrate adding valve 32 should be opened. As shown at step 208, microprocessor 42 then opens concentrate adding valve 32 for the computed concentrate inject time in an attempt to increase the concentration of the blended chemical to the Fine Blend Setpoint. Upon the completion of step 208, the blending procedure described above is repeated beginning with step 201.

If the comparison performed at step 203 indicates that the measured concentration is greater than the Fine Blend Setpoint but less than or equal to the Upper Qualification Range Setpoint as shown at decision step 209, microprocessor 42 actuates titration analyzer 36, thereby causing the titration analyzer to take a sample and measure the concentration of the blended chemical. This action of the titration analyzer 36 is shown at step 218 in FIG. 5. Microprocessor 42 then compares the blended chemical concentration value provided by titration analyzer 36 to the Upper and Lower Qualification Range Setpoints at step 219. If the comparison performed at step 219 indicates that the concentration is within the qualification range window (decision step 220) (e.g., greater than or equal to the Lower Qualification Range Setpoint but less than or equal to the Upper Qualification Range Setpoint), the blending process is complete and the batch of blended chemical is qualified for subsequent use as indicated by step 221.

If the comparison performed at step 219 indicates that the blended chemical concentration is still less than the Lower Qualification Range Setpoint (decision step 222), microprocessor 42 will calculate the length of time that concentrate adding valve 32 should be opened to inject or add enough concentrated chemical to recirculation line 20 to increase the blended chemical concentration to the Desired Qualification Setpoint. These steps are shown generally at 223 and 224 in FIG. 5. In particular, at step 223 microprocessor 42 computes the difference between the Desired Qualification Setpoint and the most recent measurement of the blended chemical concentration at step 218. This difference, in weight %, is then divided by the Concentrate Injection Constant to compute the length of time that the concentrate adding valve 32 should be opened. As shown at step 224, microprocessor 42 then opens concentrate adding valve 32 for the computed concentrate inject time in an attempt to increase the concentration of the blended chemical to the Desired Qualification Setpoint. Upon completion of step 224, the blended chemical is recirculated and mixed for a predetermined length of time (step 217), and the blending procedure described above is repeated beginning with step

Concentration measurements provided by titration analyzer 36 are very accurate. The Concentrate Injection Constant also accurately characterizes the changes in blended chemical concentration that can be obtained by actuating concentrate adding valve 32. For these reasons, blending control subsystem 40 will typically need to perform concentrated chemical additions based on concentration measurements provided by titration analyzer 36 (steps 223 and 224) only once before the batch of blended chemical is qualified at step 221. If for any reason, however, the comparison performed at step 219 indicates that the measured concentration is greater than the Upper Qualification Range Setpoint, microprocessor 42 will calculate the length of time

that diluent adding valve 156 should be opened to inject or add enough diluent to recirculation line 20 to decrease the blended chemical concentration to the Desired Qualification Setpoint. These steps are shown generally at 225 and 226 in FIG. 5. In particular, at step 225 microprocessor 42 computes the difference between the Desired Qualification Setpoint and the most recent measurement of the blended chemical concentration at step 218. This difference, in weight %, is then divided by the Diluent Injection Constant to compute the length of time that the diluent adding valve 156 should be opened. As shown at step 226, microprocessor 42 then opens diluent adding valve 32 for the computed diluent inject time in an attempt to decrease the concentration of the blended chemical to the Desired Qualification Setpoint. Upon completion of step 226, the blending procedure described above is repeated beginning with step 217, until the blended chemical is qualified at step 221.

The accuracy of the chemical blending procedure performed by system 10 and control subsystem 40 can be increased by updating the Concentrate Injection Constant and/or the Diluent Injection Constant as a function of the actual blended chemical concentration changes induced by the injection of concentrated chemical at steps 208 and 224 or the injection of diluent at step 226. By way of example, both before and after the injection of concentrated chemical at step 224, the concentration of the blended chemical will be measured at step 218. Control subsystem 40 can therefore compute an effective concentrate injection constant by taking the difference between the measured concentration values before and after the injection of concentrated chemical at the associated step 224, and dividing this difference by the length of time that concentrate adding valve 32 was opened to achieve that concentration change during the associated step 224. The current value of the Concentrate Injection Constant stored in memory 44 can then be updated by 35 control system 40 as a function of the currently stored value and the just-computed effective concentrate injection constant. This update calculation can be performed as a function of running and/or weighted averages of the just-calculated effective concentrate injection constant, the currently stored 40 value of the Concentrate Injection Constant, and any number of previous concentrate injection constants. Procedures of this type can also be used to update the Concentrate Injection Constant after the performance of step 208, and to update the Diluent Injection Constant after the performance of step 45

An alternative embodiment of blending system 10 (not shown) does not include diluent adding valve 156 or other associated elements such as inlet 152 and supply line 154 which enable the controlled addition of diluent. Accordingly, 50 the control subsystem 40 in this embodiment is not programmed to decrease the blended chemical concentration by performing steps 225 and 226. In this embodiment the control subsystem 40 can calculate the concentration injection time at steps 207 and 223 using a "target" concentration 55 less than the Desired Qualification Setpoint by a predetermined amount. This approach minimizes the chances that control subsystem 40 will "overshoot" the Upper Qualification Range Setpoint when performing concentrated chemical addition steps 208 and 224 in this embodiment, 60 and therefore be incapable of subsequently reducing the blended chemical concentration to qualify the batch at step

Chemical blending system 10 and the associated control subsystem 40 offer considerable advantages. In particular, 65 the system and subsystem are capable of quickly blending constituents to the desired degree of concentration. The

control subsystem can be programmed to blend these constituents to any of a wide range of concentrations. Furthermore, these batches of chemical can be blended to a very high degree of accuracy. By way of example, a prototype of chemical blending system 10 that did not include diluent adding valve 156 or the capability of injecting diluent to reduce concentration was configured to blend concentrated TMAH (25% by weight) with DI water to a nominal or desired concentration of 2.38 weight percent. Thirty twenty-five gallon batches of TMAH were blended. FIG. 6 is a graph of the final blend concentrations that were achieved. The relative error of this blending system at three standard deviations is ±0.13%.

Although the present invention has been described with reference to preferred embodiments, those skilled in the art will recognize that changes can be made in form and detail without departing from the spirit and scope of the invention. In particular, although described as a system for blending two constituents, the invention can also be used to quickly and accurately blend three or more constituents to desired concentrations. Also, although described in connection with a system for blending water with chemicals, the invention can also be used to blend non-aqueous constituents.

What is claimed is:

- A chemical blending system for blending at least first and second chemical constituents to obtain blended chemical having a desired chemical concentration, including:
  - a first constituent inlet for receiving a first chemical constituent;
  - a second constituent inlet for receiving a second chemical constituent;
  - a blending tank fluidly coupled to the first and second constituent inlets, for receiving the chemical constituents and holding the blended chemical;
- a recirculation line having an inlet and an outlet in the blending tank;
- pump means having a suction end and a pressure end in the recirculation line, for recirculating blended chemical from the blending tank through the recirculation line to blend the chemical constituents;
- at least a first regulating mechanism coupling the first constituent inlet to the recirculation line between the recirculation line inlet and the suction end of the pump means, for regulating the amount of at least the first chemical constituent supplied to the recirculation line;
- a first concentration measuring instrument having first operating characteristics, for measuring concentration of the blended chemical in the blending tank;
- a second concentration measuring instrument having second operating characteristics different than the first operating characteristics, for measuring concentration of the blended chemical in the blending tank;

memory for storing digital data representative of:

- a blending control program; and
- a concentration qualification range representative of chemical concentrations within a qualification range of the desired chemical concentration; and
- a digital processor coupled to the memory, first and second concentration measuring instruments and to the first regulating mechanism, for executing the blending control program and controlling at least the first regulating mechanism as a function of the concentration measurements provided by the first and second concentration measuring instruments to blend the first and second chemical constituents to a concentration within the qualification range.

2. The chemical blending system of claim 1 wherein:

the system further includes a second regulating mechanism coupling a source of the second chemical constituent to the recirculation line between the recirculation line inlet and the suction end of the pump means, for regulating the amount of the second chemical constituent supplied to the recirculation line; and

the digital processor is coupled to the second regulating mechanism, and controls the first and second regulating mechanisms as a function of the concentration measurements provided by the first and second concentration measuring instruments to blend the first and second chemical constituents to a concentration within the qualification range.

3. The chemical blending system of claim 1 wherein:

the memory further includes memory for storing digital data representative of first constituent injection information characterizing the relationship between a controlled parameter of the first regulating mechanism and expected corresponding changes in the concentration of the blended chemical; and

the digital processor controls the first regulating mechanism as a function of the first constituent injection information and differences between the concentration measurements provided by the first and second concentration measuring instruments and the desired chemical concentration.

4. The chemical blending system of claim 3 wherein:

the system further includes a second regulating mechanism coupling a source of the second chemical constituent to the recirculation line between the recirculation line inlet and the suction end of the pump means, for regulating the amount of the second chemical constituent supplied to the recirculation line;

the memory further includes memory for storing digital data representative of second constituent injection information characterizing the relationship between a controlled parameter of the second regulating mechanism and expected corresponding changes in the concentration of the blended chemical; and

the digital processor is coupled to the second regulating mechanism, and controls the second regulating mechanism as a function of the second constituent injection information and differences between the concentration measurements provided by the first and second concentration measuring instruments and the desired chemical concentration to blend the first and second chemical constituents to a concentration within the qualification range.

5. The chemical blending system of claim 4 wherein the 50 digital processor further includes:

first update means for updating the first constituent injection information as a function of the difference between expected changes in blended chemical concentrations caused by control of the first regulating mechanism, and actual changes in the blended chemical concentrations caused by control of the first regulating mechanism; and

second update means for updating the second constituent injection information as a function of the difference 60 between expected changes in blended chemical concentrations caused by control of the second regulating mechanism, and actual changes in the blended chemical concentrations caused by control of the second regulating mechanism.

The chemical blending system of claim 3 wherein the digital processor further includes means for updating the first constituent injection information as a function of the difference between expected changes in blended chemical concentrations caused by control of the first regulating mechanism, and actual changes in the blended chemical concentrations caused by control of the first regulating mechanism.

7. The chemical blending system of claim 1 wherein the first concentration measuring instrument includes measurement means for providing a relatively fast measurement response time with respect to the response time operating characteristics of the second concentration measuring instrument.

8. The chemical blending system of claim 7 wherein the first concentration measuring instrument includes measurement means for providing a substantially instantaneous measurement response time.

 The chemical blending system of claim 7 wherein the first concentration measuring instrument includes a conductivity-type measuring instrument.

10. The chemical blending system of claim 1 wherein the second concentration measuring instrument includes measurement means for providing a relatively high degree of measurement accuracy with respect to the degree of measurement accuracy operating characteristics of the first concentration measuring instrument.

11. The chemical blending system of claim 10 wherein the second concentration measuring instrument includes a titration analyzer measuring instrument.

12. A chemical blending system for blending at least first and second chemical constituents to produce blended chemical having a desired chemical concentration within a qualification range, including:

a first constituent inlet for receiving the first chemical constituent:

a second constituent inlet for receiving the second chemical constituent;

blending apparatus fluidly coupled to the first and second constituent inlets, for receiving and blending the first and second chemical constituents to produce the blended chemical:

 a first regulating mechanism for regulating the amount of at least one of the chemical constituents received by the blending apparatus;

a first concentration measuring instrument having first operating characteristics, for measuring concentration of the blended chemical in the blending apparatus;

a second concentration measuring instrument having second operating characteristics different than the first operating characteristics, for measuring concentration of the blended chemical in the blending apparatus; and

a control system coupled to the first and second concentration measuring instruments for controlling the first regulating mechanism, including:

first control means for actuating the first regulating mechanism to control chemical blending as a function of concentration measurements from the first concentration measuring instrument when the measured concentration is less than a first blend concentration set point which is less than the qualification range;

second control means for actuating the first regulating mechanism to control chemical blending as a function of concentration measurements from the second concentration measuring instrument when the measured concentration is greater than the first blend concentration setpoint and less than a lower qualification range setpoint of the qualification range; and third control means for qualifying the blended chemical by causing the first regulating mechanism to discontinue the receipt of the chemical constituents when the concentration measurements from the second concentration measuring instrument are within the qualification range.

13. The chemical blending system of claim 12 and further including fourth control means for actuating the first regulating mechanism as a function of concentration measurements from the first concentration measuring instrument when the measured concentration is less than a second blend concentration setpoint which is less than the first blend concentration setpoint.

14. The chemical blending system of claim 12 wherein:

the control system further includes stored first constituent injection information characterizing a relationship between a controlled parameter of the first regulating mechanism and expected corresponding changes in the concentration of the blended chemical;

the first control means includes means for actuating the first regulating mechanism as a function of the first constituent injection information and the difference between the concentration measurements from the first measuring instrument and the desired concentration, to add a finite quantity of the chemical constituent to the blending apparatus in an attempt to increase the blended chemical concentration to a concentration within the qualification range; and

the second control means includes means for actuating the first regulating mechanism as a function of the first constituent injection information, and the difference between the concentration measurements from the second measuring instrument and the desired concentration, to add a finite quantity of the chemical constituent to the blending apparatus in an attempt to increase the blended chemical concentration to a concentration within the qualification range.

15. The chemical blending system of claim 14 wherein the control system further includes first update means for updating the first constituent injection information as a function of the difference between expected changes in blended chemical concentration caused by control of the first regulating mechanism, and actual changes in the blended chemical concentration caused by control of the first regulating mechanism.

16. The chemical blending system of claim 14 and further including fourth control means for actuating the first regulating mechanism to continuously add the chemical constituent to the blending apparatus when the measured concentration is less than a second blend concentration setpoint which is less than the first blend concentration setpoint, in an attempt to increase the blended chemical concentration to a concentration which is greater than or equal to the second blend concentration setpoint.

17. The chemical blending system of claim 12 and further 55 including:

a second regulating mechanism for regulating the amount of a second chemical constituent received by the blending apparatus; and

second regulating mechanism control means for actuating 60
the second regulating mechanism to control chemical
blending as a function of concentration measurements
from at least one of the first and second measuring
instruments when the measured concentration is greater
than the qualification range.

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18. The chemical blending system of claim 17 wherein the control system further includes stored second constituent injection information characterizing a relationship between a controlled parameter of the second regulating mechanism and expected corresponding changes in the concentration of the blended chemical, and the second regulating mechanism control means includes means for actuating the second regulating means as a function of second constituent injection information and the difference between the concentration measurements from the measuring instrument and the desired concentration, to add a finite quantity of the second chemical constituent to the blending apparatus in an attempt to decrease the blended chemical concentration to a concentration within the qualification range.

19. The chemical blending system of claim 18 and further including second update means for updating the second constituent injection information as a function of the difference between expected changes in blended chemical concentration caused by control of the second regulating mechanism, and measured changes in the blended chemical concentration caused by control of the second regulating mechanism.

20. The chemical blending system of claim 12 wherein the first concentration measuring instrument includes measurement means for providing a relatively fast measurement response time with respect to the response time operating characteristics of the second concentration measuring instrument.

21. The chemical blending system of claim 20 wherein the first concentration measuring instrument includes measurement means for providing a substantially instantaneous measurement response time.

22. The chemical blending system of claim 12 wherein the first concentration measuring instrument includes a conductivity-type measuring instrument.

23. The chemical blending system of claim 12 wherein the second concentration measuring instrument includes measurement means for providing a relatively high degree of measurement accuracy with respect to the degree of measurement accuracy operating characteristics of the first concentration measuring instrument.

24. The chemical blending system of claim 12 wherein the second concentration measuring instrument includes a titration analyzer measuring instrument.

25. The chemical blending system of claim 12 wherein: the blending apparatus includes;

a blending tank fluidly coupled to the first and second constituent inlets, for receiving the chemical constituents and holding the blended chemical;

a recirculation line having an inlet and an outlet in the blending tank; and

pump means having a suction end and a pressure end in the recirculation line, for recirculating blended chemical from the blending tank through the recirculation line to blend the chemical constituents; and

the first regulating mechanism couples the first constituent inlet to the recirculation line between the recirculation line inlet and the suction end of the pump means.

26. The chemical blending system of claim 25 wherein the first regulating mechanism includes a valve.

27. The chemical blending system of claim 12 wherein the first control means, second control means and third control means include digital control means and associated memory.

28. A chemical blending system for blending concentrated chemical with a diluent to obtain blended chemical having a desired chemical concentration within a qualification 5 range, including:

a concentrated chemical inlet for receiving concentrated

- a diluent inlet for receiving diluent;
- a blending tank fluidly coupled to the concentrated chemical inlet and the diluent inlet, for receiving and blending the concentrated chemical and diluent to produce the blended chemical;
- a concentrate flow regulating mechanism responsive to concentrate control signals, for controlling the flow of concentrated chemical from the concentrated chemical inlet into the blending tank;
- a first concentration measuring instrument having first operating characteristics, for measuring concentration of the blended chemical in the blending tank and providing first instrument readings as a function of the measurements;
- a second concentration measuring instrument having second operating characteristics different than the first operating characteristics, for measuring concentration of the blended chemical in the blending tank and providing second instrument readings as a function of the measurements;

memory for storing data representative of:

- concentrate injection information representative of the relationship between the concentrate control signals 25 and blended chemical concentration changes induced by actuation of the concentrate flow regulating mechanism;
- a fine blend setpoint concentration which is less than the qualification range; and
- qualification range setpoint concentrations representative of chemical concentrations within a qualification range of the desired chemical concentration; and
- a digital processor coupled to the memory, first and second concentration measuring instruments and the 35 concentrate flow regulating mechanism, and including means for:
  - (a) monitoring first instrument readings of blended chemical concentration measurements provided by the first concentration measuring instrument;
  - (b) generating concentrate control signals as a function of the concentrate injection information and the first instrument readings, to actuate the concentrate flow regulating mechanism and add a finite quantity of the chemical concentrate in an attempt to increase the blended chemical concentration to the desired concentration if the monitored first instrument reading is less than or equal to the fine blend setpoint concentration;
  - (c) monitoring second instrument readings of blended 50 chemical concentration measurements provided by the second concentration measuring instrument if the monitored first instrument reading is greater than the fine blend setpoint concentration;
  - (d) generating concentrate control signals as a function of the concentrate injection information and the second instrument readings, to actuate the concentrate flow regulating mechanism and add a finite quantity of the chemical concentrate in an attempt to increase the blended chemical concentration to the desired concentration if the monitored second instrument reading is greater than the fine blend setpoint concentration and less than the qualification range setpoint concentrations;
  - (e) repeating functions (a)-(d) until the second instrument reading is within the qualification range setpoint concentrations.

- 29. The chemical blending system of claim 28 wherein:
- the memory further includes data representative of a coarse blend setpoint concentration which is less than the fine blend setpoint concentration; and
- the digital processor further includes means for:
  - (f) generating concentrate control signals to actuate the concentrate flow regulating mechanism and continuously add chemical concentrate to increase the blended chemical concentration if the monitored first instrument reading is less than the coarse blend setpoint concentration; and
  - (g) repeating functions (a)—(d) and (f), but not (e), until the second instrument reading is within the qualification range setpoint concentrations.
- 30. The chemical blending system of claim 29 wherein:
- the system further includes a recirculation line having an inlet and an outlet in the blending tank;
- the system further includes pump means having a suction end and a pressure end in the recirculation line, for recirculating blended chemical from the blending tank through the recirculation line to blend the chemical constituents; and
- the concentrate flow regulating mechanism couples the concentrated chemical inlet to the recirculation line between the recirculation line inlet and the suction end of the pump means.
- 31. The chemical blending system of claim 29 wherein the digital processor further includes concentrate injection information update means for updating the concentrate injection information as a function of the difference between expected changes in blended chemical concentration caused by functions (b) and (d), and actual changes in blended chemical concentration caused by functions (b) and (d).
  - 32. The chemical blending system of claim 29 wherein:
  - the system further includes a diluent flow regulating mechanism responsive diluent control signals, for controlling the flow of diluent into the blending tank;
  - the memory further includes data representative of diluent injection information representative of the relationship between the diluent control signals and blended chemical concentration changes induced by actuation of the diluent flow regulating mechanism; and
- the digital processor further includes means for:
  - (h) generating diluent control signals as a function of the diluent injection information and at least one of the first and second instrument readings, to actuate the diluent flow regulating mechanism and add a finite quantity of the diluent in an attempt to decrease the blended chemical concentration to the desired concentration if the monitored instrument reading is greater than the qualification range setpoint concentrations; and
  - (i) repeating functions (a)-(d), (f) and (h), but not (e) or (g), until the second instrument reading is within the qualification range setpoint concentrations.
- 33. The chemical blending system of claim 32 wherein the digital processor further includes:
  - concentrate injection information update means for updating the concentrate injection information as a function of the difference between expected changes in blended chemical concentration caused by functions (b) and (d), and actual changes in blended chemical concentration caused by functions (b) and (d); and
  - diluent injection information update means for updating the concentrate injection information as a function of

the difference between expected changes in blended chemical concentration caused by function (h), and actual changes in blended chemical concentration caused by function (h).

34. The chemical blending system of claim 33 wherein: 5 the system further includes a recirculation line having an inlet and an outlet in the blending tank;

the system further includes pump means having a suction end and a pressure end in the recirculation line, for recirculating blended chemical from the blending tank through the recirculation line to blend the chemical constituents; and

the concentrate flow regulating mechanism couples the concentrated chemical inlet to the recirculation line between the recirculation line inlet and the suction end of the pump means.

35. The chemical blending system of claim 28 wherein the first concentration measuring instrument includes measurement means for providing a relatively fast measurement response time with respect to the response time operating characteristics of the second concentration measuring instrument.

36. The chemical blending system of claim 35 wherein the first concentration measuring instrument includes measurement means for providing a substantially instantaneous measurement response time.

37. The chemical blending system of claim 28 wherein the first concentration measuring instrument includes a conductivity-type measuring instrument.

38. The chemical blending system of claim 28 wherein the second concentration measuring instrument includes mea-

surement means for providing a relatively high degree of measurement accuracy with respect to the degree of measurement accuracy operating characteristics of the first concentration measuring instrument.

39. The chemical blending system of claim 28 wherein the second concentration measuring instrument includes a titration analyzer measuring instrument.

40. The chemical blending system of claim 28 wherein:

the concentrate flow regulating mechanism includes a concentrate flow regulating valve;

the memory for storing concentrate injection includes a concentrate injection constant representative of chemical concentration changes as a function of the length of time that the valve is actuated; and

the digital processor means for performing function (b) includes means for:

(b<sub>1</sub>) determining the difference in concentration between the concentration reading provided by the first concentration measuring instrument and the desired concentration;

(b<sub>2</sub>) accessing the memory and determining a concentrate flow regulating valve actuation time as a function of the concentration difference determined by function b<sub>1</sub> and the concentration injection constant; and

(b<sub>3</sub>) actuating the concentrate flow regulating valve for the actuation time determined by function b<sub>2</sub>.

\* \* \* \* \*

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# **EXHIBIT O**



# United States Patent [19]

Heller et al.

Patent Number: [11]

5,965,380

Date of Patent:

Oct. 12, 1999

[54] SUBCUTANEOUS GLUCOSE ELECTRODE

Inventors: Adam Heller; Michael V. Pishko, both of Austin, Tex.

Assignee: E. Heller & Company, Alameda, Calif.

Appl. No.: 09/229,235

[22] Filed: Jan. 12, 1999

# Related U.S. Application Data

Continuation of application No. 08/767,110, Dec. 4, 1996, which is a continuation of application No. 08/70/,110, 19ec. 4, 1996, which is a continuation of application No. 08/299,526, Sep. 1, 1994, Pat. No. 5,593,852, which is a continuation-in-part of application No. 08/161,682, Dec. 2, 1993, Pat. No. 5,356,786.

C12Q 1/26

435/14; 435/4; 435/25; 435/28; 435/24; 435/817; 435/962

435/14, 4, 25, [58] Field of Search ..... 435/28, 24, 817, 962

[56] References Cited

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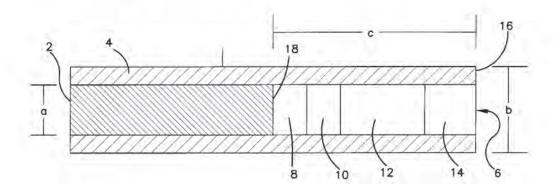
1/1997 Heller et al. .....

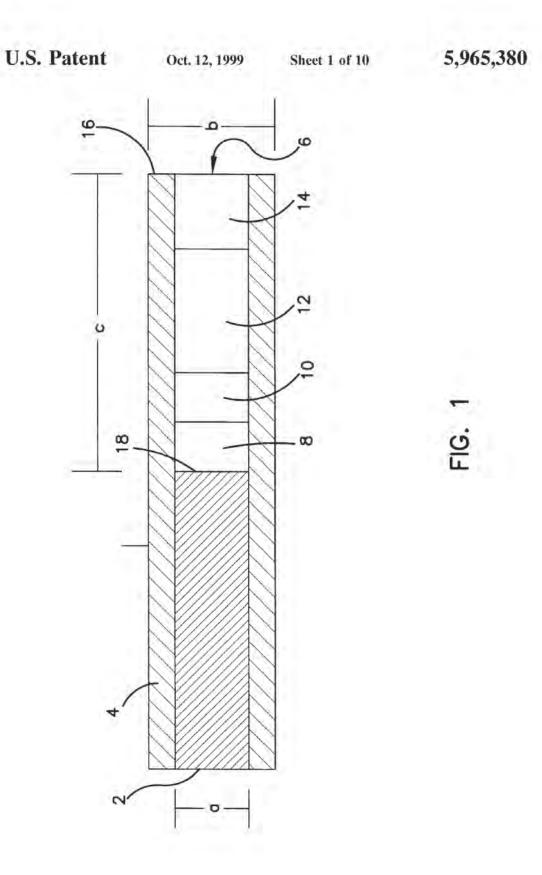
Primary Examiner-Louise N. Leary Attorney, Agent, or Firm-Merchant & Gould P.C.

ABSTRACT [57]

A small diameter flexible electrode designed for subcutaneous in vivo amperometric monitoring of glucose is described. The electrode is designed to allow "one-point" in vivo calibration, i.e., to have zero output current at zero glucose concentration, even in the presence of other electroreactive species of serum or blood. The electrode is preferably three or four-layered, with the layers serially deposited within a recess upon the tip of a polyamide insulated gold wire. A first glucose concentration-to-current transducing layer is overcoated with an electrically insulating and glucose flux limiting layer (second layer) on which, optionally, an immobilized interference-eliminating horseradish peroxidase based film is deposited (third layer). An outer (fourth) layer is biocompatible.

# 36 Claims, 10 Drawing Sheets





Oct. 12, 1999

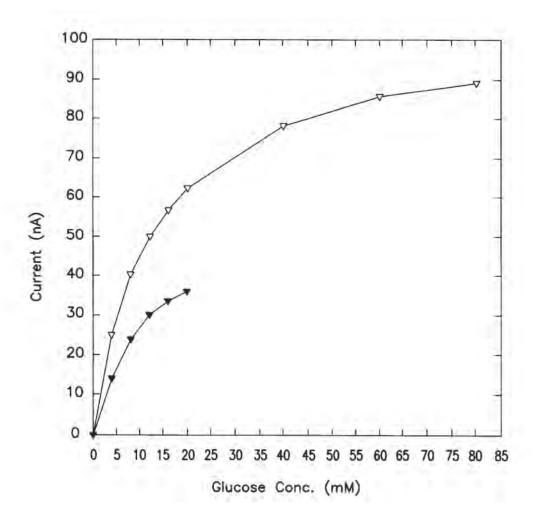


FIG. 2

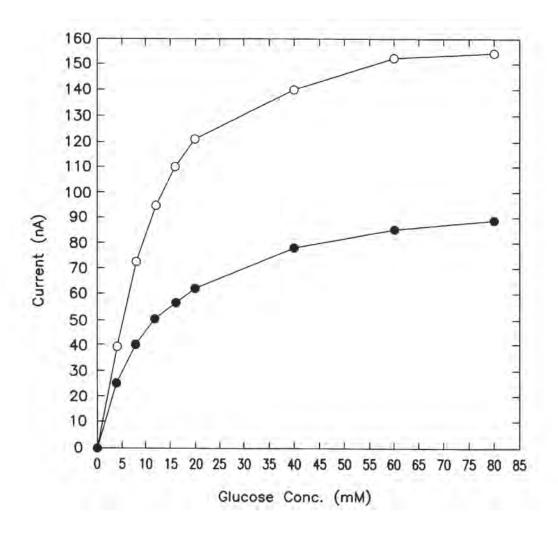


FIG. 3

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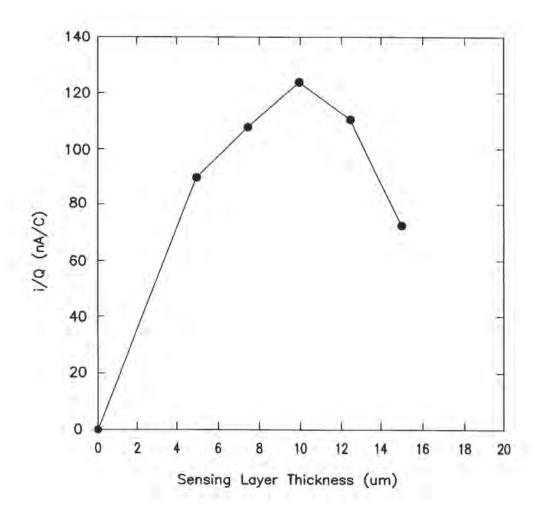


FIG. 4

Oct. 12, 1999

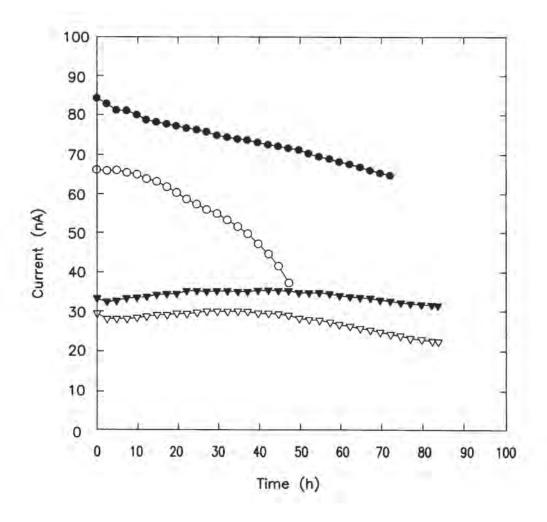


FIG. 5

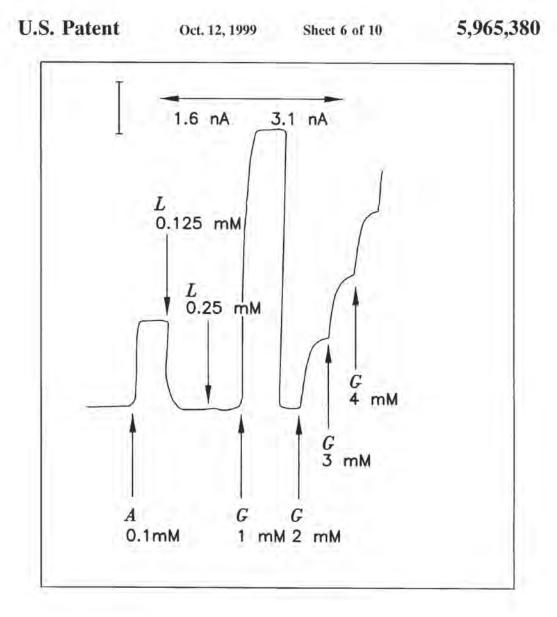


FIG. 6

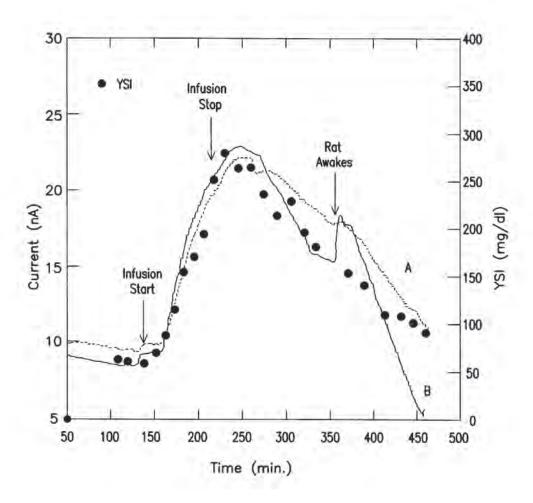


FIG. 7

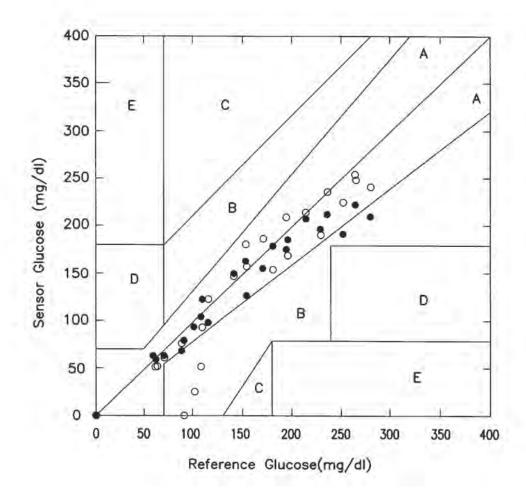


FIG. 8

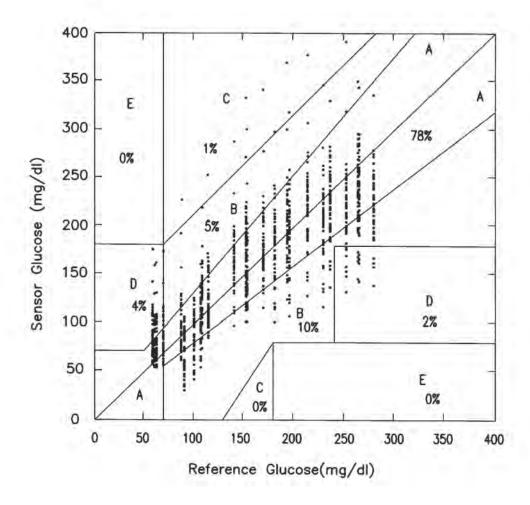


FIG. 9

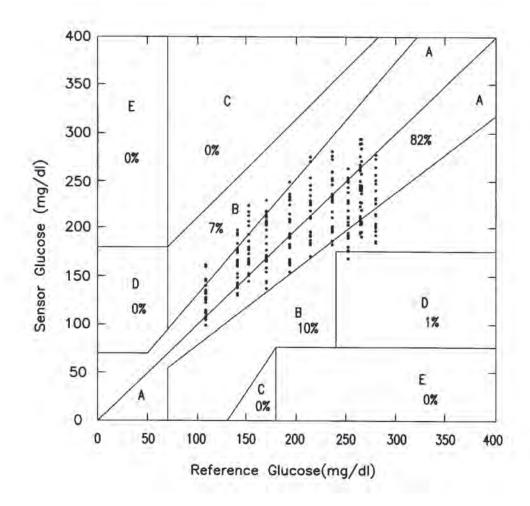


FIG. 10

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#### SUBCUTANEOUS GLUCOSE ELECTRODE

This application is a Continuation of application Ser. No. 08/767,110, filed Dec. 4, 1996, which is a Continuation of application Ser. No. 08/299,526, filed Sep. 1, 1994, now U.S. Pat. No. 5,593,852, which is a Continuation-in-Part of application Ser. No. 08/161,682, filed Dec. 2, 1993, now U.S. Pat. No. 5,356,786, which application(s) are incorporated herein by reference.

This is a continuation in part of copending U.S. patent application Ser. No. 08/161,682 which is hereby incorporated by reference for all purposes.

This work was supported in part by the National Institutes of Health (DK42015). Accordingly, the U.S. government may have rights in this invention.

#### FIELD OF THE INVENTION

The present invention relates to in vivo enzyme biosensors and more specifically to miniature glucose sensors for subcutaneous measurement of glucose with one-point calibration.

#### BACKGROUND

In response to the need for frequent or continuous in vivo monitoring of glucose in diabetics, particularly in brittle diabetes, a range of possible in vivo glucose electrodes have been studied. The desired characteristics of these electrodes include safety, clinical accuracy and reliability, feasibility of in vivo recalibration, stability for at least one hospital shift of eight hours, small size, ease of insertion and removal, and a sufficiently fast response to allow timely intervention. The in vivo recalibration should be based upon withdrawal of a single sample of body fluid, e.g., blood, and measuring its glucose concentration. This is termed "one point calibration"

Keys to safety are absence of leachable components, biocompatibility, and limiting of the potentially hazardous foreign matter introduced into the body to an amount that is inconsequential in a worst case failure. The clinical accuracy 40 must be such that even when the readings are least accurate, the clinical decisions based on these be still correct. Feasibility of prompt confirmation of proper functioning of the sensors and of periodic in vivo recalibration is of essence if a physician is to allow the treatment of a patient to depend on the readings of the sensor. This one-point calibration, relying on the signal at zero glucose concentration being zero and measuring the blood glucose concentration at one point in time, along with the signal, is of essence, but has heretofore been clusive. The sensitivity must be sufficiently 50 stable for the frequency of required in vivo recalibration to not be excessive. The sensor must be small enough to be introduced and removed with minimal discomfort to the patient and for minimal tissue damage. It is preferred that the sensor be subcutaneous and that it be inserted and removed 55 by the patient or by staff in a physician's office. Finally, its response time must be fast enough so that corrective measures, when needed, can be timely.

In response to some of these needs, needle type and other subcutaneous amperometric sensors were considered. The 60 majority of these utilized platinum-iridium, or platinum black to electrooxidize H<sub>2</sub>O<sub>2</sub> generated by the glucose oxidase (GOX) catalyzed reaction of glucose and oxygen. In these sensors, the GOX was usually in large excess and immobilized, often by crosslinking with albumin and glutaraldehyde. To exclude electrooxidizable interferants, membranes of cellulose acetate and sulfonated polymers includ-

ing Nafion™ were used. Particular attention was paid to the exclusion of the most common electrooxidizable interferants: ascorbate, urate and acetaminophen. Also to cope with the interferants, two-electrode differential measurements were used, one electrode being sensitive to glucose and electrooxidizable interferants and the other only to interferants. One strategy for overcoming the problem of interferants, applicable also to the present invention, involves their preoxidation. Another strategy involves shifting, through chemical changes, the redox potential of the polymer in the sensing layer to more reducing potentials. When the redox potential of the polymer is in the region between about -0.15 V and +0.15 V versus the standard calomel electrode (SCE), and the electrodes are poised in their in vivo operation between about -0.10 and +0.25 V, the rate of electrooxidation of interferants such as ascorbate, urate, and acetaminophen is very slow relative to that of glucose through its physiological concentration range. Thus, also the currents from electrooxidation of interferants are small relative to those of glucose.

To make the electrodes more biocompatible, hydrophilic polyurethanes, poly(vinyl alcohol) and polyHEMA membranes have been used.

Several researchers tested GOX-based glucose sensors in vivo and obtained acceptable results in rats, rabbits, dogs, pigs, sheep and humans. These studies validated the subcutaneous tissue as an acceptable glucose sensing site. Good correlation was observed between intravascular and subcutaneous glucose concentrations. They also demonstrated the need for in vivo sensor calibration. Another approach to in vivo glucose monitoring was based on coupling subcutaneous microdialysis with electrochemical detection. To control and adjust the linear response range, electrodes have been made glucose-diffusion limited, usually through glucose transport limiting membranes.

Diffusional mediators, through which the O2 partial pressure dependence of the signals is reduced, are leached from sensors. Such leaching introduces an unwanted chemical into the body, and also leads to loss in sensitivity, particularly in small sensors. In microsensors, in which outward diffusion of the mediator is radial, the decline in sensitivity is rapid. This problem has been overcome in "wired" enzyme electrodes, i.e., electrodes made by connecting enzymes to electrodes through crosslinked electronconducting redox hydrogels ("wires"). Glucose oxidase has been "wired" with polyelectrolytes having electron relaying [Os(bpy),Cl]+/2+ redox centers in their backbones. Hydrogels were formed upon crosslinking the enzyme and its wire on electrodes. These electrodes had high current densities and operated at a potential of 0.3V vs. SCE. The electrooxidizable interferants are eliminated through peroxidasecatalyzed preoxidation in a second, nonwired, hydrogen peroxide generating layer on the "wired" enzyme electrode.

#### SUMMARY OF THE INVENTION

A small (e.g., 0.29 mm), recessed, non-corroding metal (e.g., gold, platinum, palladium) or carbon wire electrode for subcutaneous in vivo glucose monitoring, approaching in its performance all of the above listed requirements, including in vivo one-point calibration, has been produced. The electrode was constructed by depositing active polymer layers into a recess formed by etching away gold from an insulated gold wire.

The active polymer layers, including a sensing layer, a glucose flux-limiting layer, a biocompatable layer, and optionally a peroxidase-based interferant eliminating layer, were protected within the recess against mechanical damage. (The peroxidase-based interferant eliminating layer is not required when a lower redox potential polymer is used, as described above.) The recess and its polymer layers also reduced the transport of glucose to the wire electrode 5 contacting sensing layer.

By limiting the glucose flux, the desired linear response range, spanning the clinically relevant glucose concentration range was obtained. The inventive biosensors are able to accurately measure, for example, approximately 2–30 m $\mu$  glucose and approximately 0.5–10 m $\mu$  lactate, in vivo. The sensor has no leachable components, and its four crosslinked polymer layers contain only about 5  $\mu$ g of immobilized material, and only a few nanograms of polymer-bound osmium. Preoxidation of the interferants in one of the four layers makes possible one-point in vivo calibration of the sensor.

#### BRIEF DESCRIPTION OF THE PIGURES

FIG. 1 is a schematic drawing of an electrode of the present invention.

FIG. 2 is a graphical representation of data generated comparing current density of glucose electrooxidation on electrodes made with PVI<sub>3</sub>-Os (open triangles) with those made with PVI<sub>3</sub>-Os (filled triangles).

FIG. 3 is a graphical representation of data generated comparing dependency of current generated on the depth of the recess.

FIG. 4 is a graphical representation of data generated 30 comparing dependency of the ratio of the current generated and the charge required to electoreduce or oxidize the polymer redox centers in the sensing layer on the thickness of the sensing layer.

FIG. 5 is a graphical representation of data generated comparing variation of current generated by electrodes having sensing layers of differing thickness and diffusion limiting layers of different compositions and thickness. Solid circles: 7.5 μm thick sensing layer of PVL<sub>5</sub>-Os (52%), rGOX (35%), PEGDGE (13%), coated with 4 μm PAL/PAZ (1:1 ratio). Open circles: 5.0 sensing layer. Solid triangles: 12.5 μm sensing layer and 7 μm PAL/PAZ (1:2 ratio). Open triangles: 7.5 μm sensing layer and 4.5 μm PAL/PAZ (1:2 ratio).

FIG. 6 is a graphical representation of data generated comparing dependency of current generated on the presence of ascorbate, in the absence and presence of lactate and glucose. The concentrations of ascorbate (A), lactate (L) and glucose (G) are shown. Ascorbate is an electrooxidzable interferant. Upon addition of lactate its electrooxidation current is suppressed while that of glucose is not suppressed.

FIG. 7 is a graphical representation of data showing current density and corresponding subcutaneous glucose concentration measured with the subcutaneously implanted electrodes of the present invention in a rat animal model. Large solid circles show blood glucose concentrations measured on withdrawn blood samples using a YSI analyzer.

FIG. 8 is a Clarke-type clinical grid analyzing the clinical relevance of the blood glucose measurements of FIG. 7.

FIG. 9 is a Clarke-type clinical grid of all possible correlations obtained when each of the 24 glucose analyses of FIG. 7 were used for single point calibration of either implanted electrode.

FIG. 10 is a Clarke-type clinical grid testing improvement 65 of the single point calibration through redundant electrodes, the readings of which were within the standard deviation

calculated for all differences between simultaneous readings by a pair of implanted electrodes.

# DETAILED DESCRIPTION OF THE INVENTION

The present invention includes an insulated, noncorroding conducting metal (e.g., gold, platinum, palladium) or carbon wire-based small (e.g., 290 µm) O.D. subcutaneous glucose sensor, allowing one-point calibration in vivo. As shown in FIG. 1, its construction involves coating a small (e.g., 250 µm) diameter non-corroding metal or carbon wire 2 with an electrically insulating material 4, e.g., a polyimide, and, layering in a recess 6 formed by etching or removing a portion of the metal or carbon, the following active polymeric layers: an immobilized, "wired," glucose oxidase layer 8; an electrically insulating and glucose diffusion limiting layer 10 formed, for example, by crosslinking a polyallylamine (PAL) with a polyaziridine (PAZ); optionally, an interference eliminating layer 12, e.g., of crosslinked horseradish-peroxidase and lactate oxidase; and a biocompatible film 14 e.g., of poly(ethylene oxide) (PEO) derivatized to allow its photo-crosslinking. The outside diameter a of the wire 2 is preferably about 0.25 mm or less, and the outside diameter b of the insulated wire is preferably about 0.3 mm or less. The recess 6 in the insulated electrode extends from the tip 16 of the electrode which is open to the surrounding environment, to the top 18 of the wire 2 in the insulating sheath, generally for a length c of less than about 0.150 mm, and preferably about 0.125 mm.

The electrodes have no leachable components. The total amount of polymers and enzymes is preferably about 5 µg. The glucose response through the physiologically relevant 2–20 mM concentration range is close to linear. The electrodes do not respond to ascorbate, urate or acetaminophenol for at least about 36 hours. Their 10–90% response time is about 90 seconds at 2 mM glucose and about 30 seconds at 20 mM glucose. Their sensitivity, after about 30 minutes equilibration, is stable for about 72 hours at 37° C. in 10 mM glucose, the current deviating from the average by less than ±5%. The electrodes have substantially no signal output, e.g., current, charge, or potential, when the concentration of the analyte to be measured is zero.

Two electrodes implanted subcutaneously in a rat tracked blood glucose levels, and their absolute, uncorrected current output was proportional to the blood glucose concentration. Analysis of the correlation between the blood glucose levels in the tail vein and the current output of the sensors in the subcutaneous regions of the thorax and between the scapulae of the same rat showed that even when the probed sites and organs differed in the extreme, one point in vivo calibration was valid. The analysis also showed the value of implanting redundant sensors. Had clinical decisions been made based on individual sensor readings, calibrated at one point, 94% would have been clinically correct. By using redundant sensors and accepting only those pairs of readings that were within one standard deviation, the percentage of the clinically correct decisions was increased to 99%.

It is understood that one of skill in the art may substitute various components of the biosensor described above with known materials to obtain an modified biosensor using the principles outlined herein. For example, the following substitutions are contemplated:

Base electrode: The base electrode of the inventive sensor may be formed of a non-corroding metal or carbon wire, for example vitreous carbon, graphite, platinum, palladium, or gold. Gold is preferred, and is used in the following illustrative examples of the invention.

2,7 02,2

Insulator: The conductive metal or carbon wire is coated with an electrically insulating material, which also forms a wall about the recess which houses the active polymeric components. The insulating material may be, for example, polyurethane, teflon (fluorinated polymers), polyethylene-terephthalate (PET, Dacron) or polyimide. The insulating material is preferably a biocompatible polymer containing less than about 5% water when in equilibrium with physiological body fluids, e.g., subcutaneous tissue.

Recess: In general, the recess at the tip of the electrode is approximately 20 to 150  $\mu m$  in length c, and preferably is approximately 50 to 125  $\mu m$ .

Etching method: The method for etching metal from the tip of the electrode described herein may utilize chloride, bromide or iodide in the bath in lieu of cyanide as described. Bromide is preferred, because it is less toxic and, like Au(CN)<sub>2</sub>-, AuBr<sub>4</sub>- is a water soluble anion. Thus, in aqueous HBR, the metal, e.g., gold, an be etched by applying a sufficiently oxidizing potential where gold is electrolytically dissolved:

#### Au+4HBr-+HAuBr<sub>4</sub>+3/2H<sub>2</sub>

Wired Enzyme Layer; In the sensing enzyme-containing 25 layer, glucose oxidase may be substituted with other redox enzymes to measure other relevant clinical compounds. For example, lactate oxidase may be used for the in vivo detection of lactate, important in determining if an organ is receiving sufficient oxygen through the blood.

Useful redox polymers and methods for producing the sensing layer are described, for example, in U.S. Pat. Nos. 5,264,104; 5,356,786; 5,262,035; and 5,320,725. Additional redox polymers include, for example, poly(1-vinyl imidazole); poly(4-vinyl pyridine); or copolymers of 1-vinyl imidazole) such as poly (acrylamide co-1-vinyl imidazole) where the imidazole or pyridine complexes with [Os (bpy)<sub>2</sub> CI]\*\*<sup>2+</sup>; [Os (4,4'-dimethyl bipyridine)<sub>2</sub>CI]\*\*<sup>2+</sup>; [Os (4,4'-dimethyl phenanthroline)<sub>2</sub>CI]\*\*<sup>2+</sup>; and [Os (4,4'-dimethoxy 40 bipyridine)<sub>2</sub>CI]\*\*\* to imidazole rings. The imidazole ring compounds are preferred because their complexes have more reducing redox potentials, i.e., closer to that of the SCE potential. At these more reducing potentials, the rate of electrooxidation of interferants and the current generated 45 thereby.

Barrier Layer: The polymeric barrier layer is electrically insulating and limits diffusion of glucose through to the sensing layer. It may be formed, for example, by crosslinking a polyallylamine (PAL) with a polyaziridine (PAZ). Alternatively, PAL may be replaced wholly or in part with a zwitterionic polymer obtained by quaternizing poly (vinylpyridine) with bromoacetate and dialyzing against 0.15M NaCl or by a polyanion such as a polysulfonic acid.

The barrier layer may contain a polyanionic polymer, in which the rate of permeation of anionic interferants such as ascorbate and urate is slowed. This layer may also contain a polycation that enhances the retention of the polyanion by electrostatic bonds and improves wetting by the biocompatable layer.

Interference Eliminating Layer: As described above, this layer is optional, in that it is not required when a redox polymer having a more reducing potential is used, such as PVI<sub>15</sub>-dmeOs (Ohara et al.: Analytical Chemistry, 1994, 64:2451-2457). At operating potentials of approximately 65 –0.10 to +0.25 for the glucose biosensor, the rate of electrooxidation of interferants such as ascorbate, urate and

acetaminophen is very slow relative to that of glucose through its physiological concentration range.

When a separate interferant eliminating layer is used, it preferably contains a peroxidase enzyme which may or may not be preactivated. Such interferant eliminating layers are disclosed, for example, in U.S. Pat. No. 5,356,786 which discloses and U.S. patent application No. 08/161,682 which disclose the structure and function of interferant eliminating biosensors. The glucose biosensor preferably contains lactate oxidase (LOX) in combination with peroxidase in the interferant eliminating layer. However, for biosensors used to detect lactate, glucose oxidase would be used with peroxidase. In a similar manner, the enzyme composition of the interferant eliminating layer may be altered for a specified function.

Biocominatable Layer: In general, the biocompatable layer is comprised of hydrogels, e.g., polymeric compositions which contain more than about 20% by weight of water when in equilibrium with a physiological environment such as living tissue or blood. An example is crosslinked poly (ethylene oxide), e.g., poly(ethylene oxide) tetraacrylate. The polymeric compositions must be non-toxic and compatible with living systems.

Method for making multi-layered recessed biosensors:

Insulated non-corroding metal or carbon wires that have been etched as described above to contain a recess at the tip, are placed in a block that serves as an X-Y positioner. The wires vertically traverse the block and are held in place, e.g., by pressure. The blocks with the wires can be formed of elements, each element having multiple half-cylinder grooves running vertically. The wires are placed in these grooves and the elements are assembled into the block using screws. For example, the block may be formed of aluminum having equally spaced holes, (900 for a 30×30 array of wires), each hole to contain one wire. The block is positioned under a fixed micronozzle that ejects a fluid in to the recess of the insulated wire.

To reduce the requirement of precision in the positioning of the block and the micronozzle, the nozzle is electrically charged, with the wire having an opposite charge, or the wire being grounded or at least having a potential such that there is a potential difference between the nozzle and the wire. Because the nozzle is charged, the microdroplets it ejects are also charged with the same type of charge (positive or negative) as the nozzle. The higher the potential on the nozzle (e.g., versus ground potential), the higher the charge on the ejected microdroplets. If the tip of the wire to be coated is at ground potential or has a charge of the opposite type, the charged microdroplets are guided into the recess to deposit on the electrode, even if the jet of microdroplets is not vertical, i.e., even if the micronozzle is not precisely aligned above the wire's tip.

Furthermore, the higher the electrical potential on the nozzle (relative to ground) the greater the charge on the ejected microdroplet. When the charge is high enough, the droplet breaks up into two or more smaller droplets because of electrostatic repulsion of charges on the droplet. Thus, the very small droplets all "drift" (drift meaning transport assisted by an electrical field) to the recessed electrode surface and are collected on it, even if they did not originate in a nozzle precisely aligned with the electrode.

This coating method is useful in making any small biosensor, not only those in recessed zones. Clinical Use of the Recessed Biosensors

5 The recessed biosensors of the present invention have sufficient sensitivity and stability to be used as very small, subcutaneous biosensors for the measurement of clinically relevant compounds such as glucose and lactate. The electrodes accurately measure glucose in the range of about 2-30 µM and lactate in the range of about 0.5-10 mM. One function of the implanted biosensor is to sound an alarm when, for example, a patient's glucose concentration is too low or too high. When pairs of implanted electrodes are used, there are three situations in which an alarm is triggered: low glucose concentration, high glucose concentration; sensor malfunction as determined by a discrepancy between paired readings of the two sensors. A discrepancy sufficient to trigger the alarm may be, for example more than two or three times the standard deviation persisting for a defined period, e.g., not less than ten minutes. Such a system may be useful in sleeping patients, and also in emergency and intensive care hospital rooms, where vital functions are continuously monitored.

Another function of the inventive biosensors in to assist diabetics in maintaining their blood glucose levels near normal. Many diabetics now maintain higher than normal blood glucose levels because of danger of coma and death in severe hypoglycemia. However, maintaining blood glucose levels substantially, e.g., approximately 40% or more above normal leads to retinopathy and blindness as well as to kidney failure. Use of the subcutaneous biosensors to frequently, if not continuously, monitor glucose concentrations is desirable so that glucose concentrations can be maintained closer to an optimum level.

The subcutaneous biosensors can be used to measure the rate of rise and decline of glucose concentrations after a meal or the administration of glucose (e.g., a glucose tolerance test). The sensors are also useful in feedback loops for automatic or manually controlled maintenance of glucose concentrations within a defined range. For example, when used in conjunction with an insulin pump, a specified amount of insulin is delivered from the pump if the sensor 35 glucose reading is above a set value.

In all of these applications, the ability to promptly confirm that the implanted sensor reading is accurate is essential. Prompt confirmation and rapid recalibration are possible only when one-point calibration is valid. Generally, even if a sensor's response is linear through the relevant concentration range, calibration requires at least two blood or fluid samples, withdrawn from the patient at times when the glucose concentration differs. It usually takes several hours for the glucose concentration to change sufficiently to validate proper functioning by two-point calibration. The ability to confirm and recalibrate using only one point is thus a highly desirable feature of the present invention.

Redundant sensors (e.g., at least two) are preferred in the clinical application of the subcutaneous biosensors. Such 50 redundancy permits signaling of failure of any one sensor by recognition of an increase in the discrepancy between the readings of the sensors at one time point, e.g., more than two standard deviations apart. The redundant sensors may be implanted near each other or at remote sites.

It is preferred that the biosensors be implanted in subcutaneous tissue so as to make the sensor relatively unobtrusive, and at a site where they would not be easily dislodged, e.g., with turning or movement. It is also preferred, when readings are not corrected for temperature 60 (which they generally are) that the sensors be implanted where they are likely to be at body temperature, e.g., near 37° C., and preferably covered by clothing. Convenient sites include the abdomen, inner thigh, arm.

Although we describe here continuous current measurement for assaying glucose, the electrical measurement by which the glucose concentration is monitored can be con-

tinuous or pulsed. It can be a current measurement, a potential measurement or a measurement of charge. It can be a steady state measurement, where a current or potential that does not substantially change during the measurement is monitored, or it can be a dynamic measurement, e.g., one in which the rate of current or potential change in a given time period is monitored. These measurements require at least one electrode in addition to the sensing electrode. This second electrode can be placed on the skin or can be implanted, e.g., subcutaneously. When a current is measured it is useful to have a potentiostat in the circuit connecting the implanted sensing electrode and the second electrode, that can be a reference electrode, such as an Ag/AgCl electrode. When a current is measured the reference electrode may serve also as the counter electrode. The counter electrode can also be a separate, third electrode, such as a platinum, carbon, palladium or gold electrode.

In addition to implanting the sending electrode in the body, fluid from the body, particularly fluid from the subcutaneous region, can be routed to an external sensor. It is preferred in this case to implant in the subcutaneous region a microfiltration giver and pull fluid to an evacuated container, the fluid traversing a cell containing the sensing electrode. Preferably this cell also contains a second electrode, e.g., a reference electrode which may serve also as a counter electrode. Alternatively, the reference and counter electrodes may be separate electrodes. In coulometric measurements only two electrodes, the sensing electrode and the counter electrode are required. The flow of body fluid may be pulsed or continuous. Other than an implanted microfiltration fiber, also a microdialysis fiber may be used, preferably in conjunction with a pump. Increased Stability of the Biosensors

To increase the stability and useful life of the inventive biosensors, it is advantageous to use intrinsically more stable enzymes and redox polymers. However, even if the enzyme and redox polymer degrade in the glucose electrooxidation process by which the signal (current) is generated, it is possible to greatly extend the useful life of the implanted electrodes and reduce the frequency of their

required recalibration after implantation.

A simple measure by which the life of the implanted electrodes can be extended and the frequency of their required recalibration reduced involves turning the electrodes "on" by applying a bias, i.e., a potential, only during the period of measurement, then turning the biasing potential off or reducing it, so that a lesser current will flow. It is generally sufficient to perform only one measurement every five or even ten minutes, or longer, because glucose concentrations do not change abruptly.

Another measure is to lower the glucose flux to the sensing layer much as possible, consistent with maintaining adequate sensitivity and detectivity. Reduction of the glucose flux to the sensing layer reduces the current. Therefore, even though this stabilizes the electrodes, i.e., slows the loss in sensitivity, the flux dependent current must not be excessively reduced. Usually a current of 3–5 nA at 2 mM glucose concentration is adequate. When the glucose flux is lowered by using one or more glucose-flux reducing polymer slayers, such as the PAL/PAZ layer, the lifetime of the sensor is increased.

### EXAMPLES

#### Example 1

Electrode Preparation

Electrodes were made of a polyamide-insulated 250 µm diameter gold wire, having an outer diameter (O.D.) of 290 um (California Fine Wire Co., Grover City, Calif.). Heat shrinkable tubing (RNF 100 %4" BK and ½16" BK, Thermofit®, Raychem, Menlo Park, Calif.) and a two component silver epoxy (Epo-tek H<sub>2</sub>OE; Epoxy Tech, Inc., Billerica, Mass.) were used for electrode preparation.

The glucose sensing layer was made by crosslinking a genetically engineered glucose oxidase (rGOX) (35% purity, Chiron Corp., Emeryville, Calif.) with a polymer derived of poly(vinylimidazole) (PVI), made by complexing part of the imidazoles to [Os(bpy)\_Ct]\*/2+. The resulting redox polymer, termed PVI-Os, was synthesized according to a previously published protocol. (Ohara et al., 1993, Anal. Chem., 65:24). Poly(ethylene glycol) diglycidyl ether 400 (PEDGE; Polysciences, Warrington, Pa.) was used as the crosslinker.

The barrier layer between the sensing and interferenceeliminating layers was made of polyallylamine (PAL; Polysciences) crosslinked with a polyfunctional aziridine (PAZ) (XAMA-7; Virginia Chemicals, Portsmouth, Va.).

The interference-eliminating layer was prepared by co-immobilizing horseradish peroxidase (HRP) type VI 20 (Cat. no. P-8375, 310 U/mg, denoted herein as HRP-VI, Sigma, St. Louis, Mo.) and HRP for immunological assay (No. 814407, min 1000 U/mg, denoted HRP-BM, Boehringer-Mannheim, Indianapolis, Ind.) with lactate oxidase from Pediococcus sp. (Cat. No. 1361, 40 U/mg denoted LOX, Genzyme, Cambridge, Mass.) and a recombinant microbial source (Cat. No. 1381 denoted rLOX, Genzyme). Co-immobilization was performed using sodium periodate (Cat. No. S-1147, Sigma) according to the methods described in Maidan and Heller, 1992, Anal. Chem. 30 64:2889–2896.

The biocompatible layer was made of 10% aqueous poly(ethylene oxide) tetraacrylate (PEO-TA). To form the photocrosslinkable polymer, PEO was acrylated by reaction with acryloyl chloride. The 18,500 g/mol PEO (Polysciences) is a tetrahydroxylated compound by virtue of two hydroxyl groups on a bisphenol A bisepoxide that linked two α, ω-hydroxy-terminated 9,000 g/mol PEO units. Acryloyl chloride (Aldrich, Milwaukee, Wis.) in a 2 to 5 molar excess was used to acrylate the polymer (10% w/v PEO in benzene). Triethylamine (Mallinkrodt, Paris, Ky.) was used as a proton acceptor equimolar with theacryloyl chloride.

Other chemicals used were bovine serum albumin (BSA) fraction V (Cat. No. A-2153), BSA, ascorbic acid, uric acid, 4-acetaminophenol, L(+)=lactic acid, and hydrogen peroxide 30%, all from Sigma. All chemicals were used as received. Solutions (if not otherwise specified) were made with distilled, deionized water. Glucose monitoring was performed in buffer, in bovine serum (Sigma, Cat. No. S-6648) containing antibiotic-antimycotic solution (Sigma, 50 Cat. No. A-8909) at 37° C. and in rats.

Instrumentation

In making the recessed gold electrodes, a potentiostal/galvanostat (PAR Model 173, Princeton Applied Research, Princeton, N.J.) operated in a galvanostatic mode, and a sonicator (Fisher Scientific, Pittsburgh, Pa.) were used. Cyclic voltammograms were recorded with a potentiostat (PAR Model 273A) and a conventional electrochemical cell having a Pt wire counter and a SCE reference electrode and were evaluated with PAR 270 software. Glucose signals were monitored with a bipotentiostat (Biometra EP 30) and a two channel strip-chart recorder. The recessed electrodes were coated under a microscope (Bausch & Lomb) using a micromanipulator (Narisbige, Seacliff, N.Y.). The micropipettes were pulled with a micropipette puller (Narisbige). Temperature was controlled with an isothermal circulator (Fisher Scientific).

Electrode Preparation

Five cm lengths of polyamide insulated gold wire were cut with a sharp razor blade. Electrical contact was made at one end with silver epoxy to an insulated stainless steel wire and the junction was covered with insulating heat shrinkable tubing. The recess forming electrochemical etching process was carried out in 10 ml of 3M potassium cyanide, with the gold wire as the working electrode and a platinum or gold wire as the counter electrode. The wires were placed in contact with the bottom of the beaker, all electrodes being equidistant from the counter electrode. The beaker was sonicated during the etching procedure. The ends of the gold wires were bent upwards, so that agitation by the sonicator caused the oxygen bubbles formed during the etching process to rise and escape. The electrodes were then thoroughly washed and immersed in water for 30 minutes.

A recess 6, i.e., channel, in a polyamide insulated gold wire 2 is formed by electrochemical etching of the gold under galvanostatic control. By controlling the charge, the total amount of gold electrooxidized and dissolved as Au(CN), is defined. When the conditions were set so that the CN-transport into the channel and the Au(CN)2-transport out of it are not rate limiting, (e.g., sonicated bath and high concentration of potassium cyanide, at least approximately 0.2M, and preferably 3M), a flat gold wire surface is produced at the bottom of channels with aspect ratios of 0.5 to 2.0. Thus, when the CN-concentration is high enough and the wires are ultrasonically vibrated, the tips of gold wires are flat. Passage of 1.5 coulombs per electrode at 8 mA current produced approximately 125 µm deep cavities or channels. At theoretical efficiency for one-electron oxidation, 3.08 mg of gold would have been etched. The amount of gold actually etched was only 0.076 mg, showing significant CN- or water oxidation. Nevertheless, the process is reproducible, accurate and fast with 20 electrodes being processed in each batch in less than five minutes. The recess-forming procedure was highly reproducible, with a deviation of ±10 µm found (using an objective micrometer) for a batch of 30 recessed electrodes. Before coating, the electrodes were examined under a microscope for flatness of the gold surface and correct depth.

FIG. 1 shows a schematic side view in cross-section of an electrode of the present invention, showing the gold wire 2, insulating coating 4, and recess or channel 6. The recessed gold surfaces were coated by filling of the cavities or channels 6 with aqueous solutions containing the crosslinkable components of the different layers, and their crosslinkers. The solutions were introduced under a microscope with a micropipette (connected to a microsyringe by polyethylene tubing and shrink tubing), using a micromanipulator. After application of each of the individual layers, the electrodes were cured overnight at room temperature, in air. Electrode Structure

The electrodes were prepared by sequentially depositing four layers within the recess or channel 6. The layers were: the sensing layer 8, the insulating layer 10, the interference-eliminating layer 12 and the biocompatible layer 14. The sensing layer, containing "wired" redox enzyme is positioned adjacent to and in contact with the gold wire 2. The insulating layer 10 is positioned between the sensing layer 8 and the peroxidase-based interferant-eliminating layer 12. The biocompatible layer 14 fills the remaining space in the recess 6 and is in contact with the environment outside the electrode. The thin polymer layers are well protected by containment within the polyamide sleeve 4.

The sensing layer 8 was made by "wiring" rGOX to the gold electrode through a redox hydrogel to which the

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enzyme was covalently bound. The electrodes were prepared as follows: 10 mg/ml solutions were made from

the PVI-Os redox polymer in water,

2. the crosslinker, PEGDGE, in water, and

the enzyme, rGOX, in a 10 mM HEPES solution adjusted to pH 8.15.

A redox hydrogel was formed by mixing the three solutions so that the final composition (by weight) was 52% redox polymer, 35% enzyme and 13% crosslinker.

The insulating layer 10 prevented electrical contact between the redox hydrogel and the interference eliminating enzymes (HRP and LOX). PAL:PAZ was used as the insulating material. The film was deposited from a solution obtained by mixing in volume ratio of ½, ½ or ⅓, a PAL solution (4.5 mg in 100 mM HEPES buffer at pH 7.0) and a freshly prepared PAZ solution (30 mg/ml). The PAZ solution was used within 15 minutes of preparation.

The interference-eliminating layer 12 was prepared according to a previously published protocol, Maidan and Heller, 1992, Anal. Chem., 64:2889–2896. 50 µl of a 12 mg/ml freshly prepared sodium periodate solution was added to 100 µl of a solution containing 20 mg/ml HRP (HRP-VI or HRP-BM) and 100 mg/ml LOX (LOX or rLOX) in 0.1 M sodium bicarbonate and the mixture was incubated in the dark for two hours. Alternatively, the oxidation of HRP could be carried out prior to adding LOX and crosslinking.

The biocompatible layer 14 films were photocrosslinked by exposure to UV light (UVP, Inc., San Gabriel, Calif.; Blak-Ray; spectral peak at 360 nM, UV irradiance at the sample 200 mW/cm²) for one minute, The initiator used was 2,2-dimethoxy-2-phenylacetophenone (Aldrich). A solution of 300 mg/ml of the initiator in 1-vinyl-2-pyrrolidinone (Aldrich) was added to the prepolymer mixtures. Approximately 30 µl of the initiator solution was added per ml of 10% w/w aqueous solution of the tetraacrylated PEO. The prepolymers were crosslinked in situ inside the recess of the electrode. The films were prepared by filling the recess with the prepolymer solution twice and exposing the electrode to the UV light source after each time the cavity was filled. In vitro Testing of Electrodes

In vitro experiments were carried out in batch fashion at 40 250 and 37° C., using a conventional three electrode electrochemical cell with the enzyme-modified gold wire as the working electrode, a platinum wire as the counter electrode and a saturated calomel reference electrode (SCE). The electrolyte was a 20 mM phosphate buffered-saline solution 45 containing 0.15 M NaCl at pH 7.15. Experiments in serum were performed at 37° C., adding 100 µL antibiotic-antimycotic solution to 10 ml serum. Phosphate buffered-saline and serum were agitated during the experiments. The working potential was +0.3 V versus SCE for experiments 50 with the PVI-Os polymers.

Structure and Performance: The depth e of the channel 6 and the thickness of the polymer layers in it controls the mass transport, i.e., flux of glucose, to the sensing layer. By controlling these parameters, the apparent Michaelis constant (K<sub>m</sub>) is adjusted to about 20-30 mM glucose. The polyimide wall 4 of the channel 6 also protects the four polymer and polymer/enzyme layers 8, 10, 12, 14 against mechanical damage and reduces the hazard of their loss in the body. Because the glucose electrooxidation current is limited by glucose mass transport through the recess 16 and its polymer films 8, 10, 12, 14, rather than by mass transport to the tissue-exposed tip 16, the current is practically insensitive to motion. Evidently, the electrooxidation rate of glucose in the recessed sensing layer 8 is slower than the rate of glucose diffusion to the channel's outer fluid contacting interface.

PVI<sub>5</sub>-Os is preferred as the "wire" of the sensing layer when an interference eliminating layer of HRP and LOX is used, but not in the absence of this layer, i.e., when redox polymers with more reducing redox potential are preferred. The subscript (5) is used to indicate that, on the average, every fifth vinylimidazole mer carries an electron-relaying osmium center. Use of electrodes formed with PVI<sub>5</sub>-Os and PVI<sub>3</sub>-Os (every third 1-vinylimidazole mer carrying an osmium center) are compared in FIG. 2, and show higher current density of glucose electrooxidation on electrodes made with PVI<sub>5</sub>-Os (open triangle) than on those made with PVI<sub>3</sub>-Os (filled triangles).

Depth of the recess and the sensing layer: Channels of 125, 250, and 500 µm depth, were investigated to assess the dependence of the current on the depth of the recess (FIG. 3), with the total amount of PVI5-Os and rGOX being kept constant. Much of the loss in current in the deeper cavities resulted not from reduced plucose mass transport, but from adsorptive retention of part of the enzyme and polymer on the polyamide wall when microdrops of the component solutions were introduced into the recess in the process of making the electrodes. Through repeated rinsing with water, some of the adsorbed polymer and enzyme on the walls were washed onto the electrode surface, increasing the current. The highest currents were seen after five washings. When the thickness of the sensing layer was increased through increasing the number of coatings (FIG. 4) the ratio of current to charge required to electroreduce or electrooxidize the redox polymer in the sensing layer reached a maximum, then dropped. For the preferred 125 µm recess, 10 coatings, producing an approximately 13 µm thick wired-rGOX sensing layer, yielded sensors that had the desired characteristics for in vivo use.

The insulating layer: This layer electrically insulates the redox enzymes of the interference eliminating layer (HRP and LOX) from the "wired" rGOX layer and limits the glucose flux to the sensing layer, thereby extending the useful life of the electrode. PAL crosslinked with PAZ, forming a polycationic network at pH 7.09 is preferred. The best results, i.e., best stability of current outputs, were obtained using 1:2 PAL:PAZ (FIG. 5), with three coatings applied to form an approximately 7 µm thick crosslinked film.

The interference eliminating layer: Interferants, particularly ascorbate, urate, and acetaminophenol, are oxidized in the third layer, containing LOX and HRP. In this layer, lactate, the typical concentration of which in blood is 1 mM, reacts with O2 to form H2O2 and pyruvate, H2O2, in the presence of HRP, oxidizes ascorbate, urate, and acetaminophenol, being reduced to water. The preferred coimmobilization process involved two separate steps: periodate oxidation of oligosaccharide functions of HRP to aldehydes, followed by mixing with LOX and formation of multiple Schiff bases between HRP-aldehydes and LOX amines (e.g. lysines) and between HRP aldehydes and amines. The thickness of the interference eliminating layer is approximately 85 µm and is made by applying successive coatings, e.g., about six coatings. FIG. 6 shows that electrooxidizable interferants were eliminated in the presence of lactate at physiological levels. LOX slowly lost its activity in the crosslinked HRP-LOX layer. This led to degradation of the ability of the layer to eliminate interferants. After 36 hours of operation at 37° C., a measurable current increment was noted when enough ascorbate was added to produce a 0.1 mM concentration.

The biocompatible layer: A preferred biocompatible layer consists, for example, of photocrosslinked tetraacrylated

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18,500 Da poly(ethylene oxide) (Pathak et al., 1993, J. Am. Chem. Soc., 114:8311–8312). The thickness of this layer, made by sequential photo-crosslinking of two coatings, is about 20  $\mu$ m. One minute UV exposure required for the photocrosslinking process reduced the sensitivity by  $16\pm2\%$ .

#### Example 2

In vivo Use of Sensor

The objective of this experiment was to establish the validity of a one-point in vivo calibration. Two sensors were simultaneously implanted subcutaneously in a rat, one on the thorax, the second between the scapulae. To make the difference between the blood sampled and the subcutaneous fluid proved with the sensors as extreme as possible, i.e., to probe whether the one-point calibration holds even if the organs sampled are different and the sampling sites are remote, blood was withdrawn from the tail vein. Blood glucose levels were periodically measured in withdrawn samples, while the absolute uncorrected sensor current output was continuously monitored.

In vivo experiments (6-10 hours) were carried out in 300 20 g male Sprague-Dawley rats. The rats were fasted overnight and prior to the experiment were anaesthetized with an intraperitoneal (i.p.) injection of sodium pentobarbital (65 mg/kg rat wt). An i.p. injection of atropine sulfate (166 mg/kg rat wt) was then administered to suppress respiratory 25 depression. Once the rat was anaesthetized, a portion of the rat's abdomen was shaved, coated with a conductive gel, and an Ag/AgCl surface skin reference electrode was attached. This electrode served also as the counter electrode. Sensors were then implanted subcutaneously using a 22 gauge Per-Q-Cath Introducer (Gesco International, San Antonio, Tex.) on the rat's thorax, or subcutaneously in the intrascepular area through a small surgical incision. The sensors were taped to the skin to avoid sensor movement. The sensors, along with the reference electrode, were connected to an in-house built bipotentiostat. The operating potential of the sensors was 0.3 V vs. Ag/AgCl, with the Ag/AgCl electrode serving as both the reference counter electrode. Sensor readings were collected using a data logger (Rustrak Ranger, East Greenwich, R.I.) and at the end of the experi- 40 ment were transferred to a computer. During the experiment, the rat's body temperature was maintained at 37° C. by a homeostatic blanket. The sensors were allowed to reach a basal signal level for at least one hour before blood sampling was started. Blood samples were obtained from the tail vein 45 and all blood samples were analyzed using a glucose analyzer (YSI, Inc., Yellow Springs, Ohio; Model 23A).

Approximately thirty minutes after the start of blood sampling, an i.p. glucose infusion was started using a syringe pump (Harvard Apparatus, South Natick, Mass.) at a rate of 120 mg glucose/min kg rat wt. The glucose infusion was maintained for approximately one bour.

As seen in FIG. 7, at 410 min the current dropped precipitously. Such a drop was observed in other measurements with subcutaneously implanted electrodes between 400 and 600 min, but was never observed in electrodes operated in buffer at 37° C. When the failed electrodes were withdrawn and retested in buffer, most of their original sensitivity was found to be intact. The cause for this apparent deactivation was failure of the counter/reference Ag/AgCl electrode on the rat's skin to make good electrolytic contact, and was not due to any failure of the implanted sensor. Using an arbitrarily chosen point to calculate a calibration curve for each electrode, i.e., one blood glucose level determination and one current measurement to establish the scales, all the data from FIG. 7 were plotted in a Clarke-type, (Clarke et al., 1987, Diabetes Care, 5:622–627) clinical grid (FIG.

8), without further correction. In this analysis, points falling in region A of the grid are considered clinically accurate, while those in region B are considered clinically correct. Points falling in region C are not correct, but would not lead to improper treatment. Points in regions D and E are incorrect and if treatment would rely on these, it would be improper.

All of the points, from both electrodes, were in regions A and B, with 43 of the 48 points being in region A. The three points in region B near 100 mg/dl glucose, for the electrode implanted between the scapulae, were the last three points of the experiment, at about 410 min. Notwithstanding the failure mode at 400–600 min because of poor electrolytic contact of the counter/reference electrode with the skin and failure after 36 hours by deactivation of the lactate oxidase, resulting in loss of interference elimination, one-point calibration is shown here to be practical. After such calibration, the readings of the subcutaneous sensors provide, without any correction, clinically useful estimates of blood glucose levels.

FIG. 9 shows the distribution of all possible correlations obtained when each of the 24 glucose analyses was used for single point calibration of either implanted electrode. There are 2×24×24=1152 points in the distribution. Of these, 78% are in region A, 15% are in region B, 1% in region C, 6% are in region D, and no points are in region E.

In FIG. 10, we tested for the improvement of the single point calibration through using redundant electrodes. First, the readings of electrode A were normalized with respect to those of electrode B by multiplying each reading by the average output of electrode B divided by the average output of electrode A. Next the standard deviation was calculated for the differences between the 24 sets of readings of implanted electrode B and corrected readings of implanted electrode A. Then, all those sets of readings that differed by more than the standard deviation were rejected. The number of sets was reduced thereby from 24 to 11; 82% of the points were in region A, 17% in region B, it in region D, and no points in regions C and E. The distribution demonstrates that the sensors can be calibrated through a single independent measurement of the glucose concentration in a withdrawn blood sample. They also demonstrate the improvement in clinical accuracy resulting from the use of redundant subcutaneous sensors. The selection of those data points that differed by less than the standard deviation for the entire set led to a sixfold reduction in the probability of clinically erring in a decision based on readings of the implanted

Stability and Other Characteristics

In order to improve the stability, more thermostable recombinant GOX, (rGOX; Heller, 1992, J. Phys. Chem., 96:3579–3587) rather than GOX is used in the sensor and glucose transport is reduced to make the sensor current diffusion, not enzyme turnover, limited. The glucose flux is attenuated by the three outer layers and the sensing layer itself. Because the sensing layer contains a large excess of glucose oxidase, its activity greatly exceeds that needed for electrooxidizing the attenuated glucose flux, and the sensor's stability is improved.

The stability can be tested by methods known, for example, tested in the presence of 0.1 mM ascorbate in 10 mM glucose at 37° C. The current output of a typical optimized electrode was about 35 nA and the apparent K<sub>m</sub>, derived from an Eadie-Hofstee plot, was about 20 mM (Table 1). The 10–90% response time was approximately one minute.

As expected, and as can be seen in FIG. 5, with thinner films the glucose mass transport was increased, i.e., the current was higher, while for thicker films the stability was improved. Because of the high sensitivity of thin sensing film (approximately 1 µm) electrodes (less than 10<sup>-2</sup> Å cm<sup>-2</sup> M<sup>-1</sup>), an order of magnitude decrease in sensitivity could be raded for stability, while the currents remained high enough to be easily measured.

As seen in FIG. 5, the sensitivity of the stabilized sensors does not change by more than ±5% for 72 hours of operation at 37° C. After a small initial decrease in sensitivity, it increased to a maximum after 40 hours and the final 72 hour sensitivity was almost identical with the initial.

The characteristics of the electrodes of the present invention are summarized in Table 1. Each entry represents an average value for five tested electrodes. Baseline currents are typically less than 0.5 nA and the noise less than 10 pA. The currents observed throughout the physiological glucose concentration range (2–20 mM) exceed the noise equivalent current by at least a factor of 100. The apparent  $K_m$  is 20 mM, and the 10% to 90% response time is, for aged electrodes, about 90 seconds at the lowest physiologically relevant glucose concentration (2 mM) and 20 seconds at the highest (20 nM).

The baseline of nil at 0 mM glucose is stable for 36 hours in the presence of 0.1 mM ascorbate. The stability observed and the existence of a valid zero-point in the presence of interferants suggest that the sensor can be used in vivo for 72 hours and tested/recalibrated in vivo through a single point calibration, i.e., by withdrawing only a single sample of blood for independent analysis.

TABLE 1

	-	SENSOR CHA	RACIERISTICS	S	
l(nA)	j(µA/cm²)	K <sub>M</sub> <sup>app</sup> (mM) EH	$K_M^{spp}(mM)$ LB	t,(8)	Current Variance (%)
33.9	69.1	18.5	33.4	30-90	5.0

where

i is the current measured at 37° C, and at 10 mM glucose concentration j is the current density measured at 37° C, at 10 mM glucose concentration K<sub>M</sub>\*\*pop is the apparent Michaelis-Menten coefficient determined from an electrochemical Eadie-Hoffstee (EH) or Lineweaver-Burk (LB) plot t, is the 30-90% risetime, 90s for 2 mM and 30 s for 20 mH glucose concentration. Current Variance is the maximum deviation from

Current Variance is the maximum deviation for the mean value, measured during the 72 hour test, conducted in 10 mM glucose in the presence of interferants. The current was continuously monitored at 37° C.

The foregoing examples are designed to illustrate certain aspects of the present invention. The examples are not intended to be comprehensive of all features and all embodiments of the present invention, and should not be construed as limiting the claims presented herein.

We claim:

A method of calibrating an electrochemical sensor, 60 comprising steps of:

withdrawing only a single calibration sample from an animal;

assaying a concentration of an analyte in the single calibration sample; and

correlating the assayed concentration to at least one signal generated by at least one working electrode implanted in the animal to provide a single point, in vivo calibration of the electrochemical sensor, wherein an analyteresponsive sensing layer is disposed on at least one working electrode.

The method of claim 1, wherein the sensing layer comprises a non-leachable redox mediator.

3. The method of claim 2, wherein the non-leachable redox mediator comprises a redox polymer.

 The method at claim 2, wherein the sensing layer further comprises an enzyme.

The method of claim 4, wherein the enzyme is bound to the redox mediator.

The method of claim 1, wherein the sensing layer comprises analyte-responsive enzyme.

7. The method of claim 6, wherein the analyte-responsive enzyme comprises glucose oxidase, glucose dehydrogenase, lactate oxidase, or mixtures thereof.

The method of claim 6, wherein the analyte-responsive enzyme is non-leachable.

9. The method of claim 1, wherein at least one working electrode further comprises a barrier layer disposed over the sensing layer to at least slow a rate of permeation of interferents.

 The method of claim 9, wherein the barrier layer comprises a polyanionic polymer.

 The method of claim 1, wherein at least one working electrode further comprises an interferent eliminating layer disposed over the sensing layer.

12. The method of claim 11, wherein the interferent eliminating layer comprises a peroxide-generating enzyme.

13. The method of claim 1, wherein at least one working electrode further comprises, disposed over the sensing layer, an analyte flux limiting layer to limit diffusion of the analyte.

14. The method of claim 1, wherein at least one working electrode further comprises a biocompatible layer disposed over the sensing layer.

 The method of claim 14, wherein the biocompatible layer is bound to the sensing layer.

16. The method of claim 15, wherein the biocompatible layer is indirectly bound to the sensing layer via an intermediate layer between the biocompatible layer and the sensing layer.

17. The method of claim 16, wherein the intermediate layer comprises at least one of an interferent eliminating layer and an analyte flux limiting layer.

18. The method of claim 15, wherein the biocompatible 45 layer is chemically bound to the sensing layer.

 The method of claim 15, wherein the biocompatible layer is crosslinked with the sensing layer.

The method of claim 14, wherein the biocompatible layer comprises a hydrogel.

21. The method of claim 14, wherein the biocompatible layer comprises at least one material selected from the group consisting of hydrophilic polyurethanes, poly(vinyl alcohol), and polyHEMA membranes.

 The method of claim 14, wherein the biocompatible layer comprises polyethylene oxide.

23. The method of claim 1, wherein at least one working electrode is configured and arranged to provide a substantially constant signal output in absence of the analyte.

24. The method of claim 1, wherein at least one working electrode is configured and arranged to have a baseline current of less than 0.5 nA in absence of the analyte.

25. The method of claim 1, wherein at least one working electrode is configured and arranged to have a noise level of less than 10 pA.

26. The method of claim 1, wherein at least one working electrode is configured and arranged to generate a signal of at least 3 nA at 2 mM glucose. 17

- 27. The method of claim 1, wherein the analyte-responsive sensing layer defines, on the working electrode, a working surface having an area of no more than 0.05 mm².
- 28. The method of claim 1, wherein correlating the assayed analyte concentration comprises correlating the 5 assayed analyte concentration to signals generated by at least two working electrodes implanted in the animal to provide a single point, in vivo calibration of the electrochemical sensor.
- 29. The method of claim 28, further comprising comparing signals generated at each of the working electrodes and accepting those signals that do not differ by more than a predetermined degree.
- 30. The method of claim 1, further comprising disposing a reference or counter/reference electrode on the skin of the animal.
- The method of claim 1, further comprising subcutaneously implanting the at least one working electrode in the animal.
- 32. The method of claim 31, wherein withdrawing only a single calibration sample comprises withdraw only a single calibration sample of blood from the animal.
- 33. The method of claim 31, further comprising waiting a period of time until a basal signal level is reached before withdraw the single calibration sample.
- 34. The method of claim 31, wherein the working electrode is poised at a potential between about -0.10 to about +0.25 relative to a standard calomel electrode.
- 35. A method of measuring the concentration of a biochemical in an animal comprising:
  - implanting at least one working electrode of an electrochemical sensor into an animal, each working electrode

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- having a sensing layer comprising an analyte responsive enzyme disposed on the working electrode;
- withdrawing a single calibration sample from the animal; assaying an analyte concentration of the single calibration sample;
- correlating the assayed analyte concentration to a signal generated at the at least one working electrode implanted in the animal to provide a single point in vivo calibration of the electrochemical sensor;
- contacting body fluid of the animal with the electrochemical sensor to generate an electrical signal; and
- determining from the generated electrical signal the concentration of a biochemical in the body fluid.
- 36. A method of calibrating an electrochemical sensor, comprising steps of:
  - withdrawing only a single calibration sample from an animal:
  - assaying a concentration of an analyte in the single calibration sample; and
  - correlating the assayed concentration to at least one signal generated by at least one working electrode implanted in the animal to provide a single point, in vivo calibration of the electrochemical sensor, wherein the electrochemical sensor further comprises a means for reducing diffusion of interferents to at lent one working electrode.

\* \* \* \* \*

### CERTIFICATE OF CORRECTION

PATENT NO. : 5,965,380 DATED : October 12, 1999 INVENTOR(S) : Heller et al. Page 1 of 18

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

#### Title page

Item [56], References Cited, U.S. PATENT DOCUMENTS, insert the following references:

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PATENT NO. : 5,965,380 Page 3 of 18 DATED : October 12, 1999

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PATENT NO. : 5,965,380 Page 5 of 18

DATED : October 12, 1999 INVENTOR(S) : Heller et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

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### CERTIFICATE OF CORRECTION

PATENT NO. : 5,965,380 DATED : October 12, 1999 INVENTOR(S) : Heller et al. Page 6 of 18

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

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DATED : October 12, 1999 INVENTOR(S) : Heller et al.

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DATED : October 12, 1999 INVENTOR(S) : Heller et al.

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PATENT NO. : 5,965,380 : October 12, 1999 DATED INVENTOR(S) : Heller et al.

Page 15 of 18

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Poitout, V. et al., "Calibration in dogs of a subcutaneous miniaturized glucose sensor using a glucose meter for blood glucose determination," Biosensors & Bioelectronics, 7:587-592 (1992).

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PATENT NO. : 5,965,380 Page 16 of 18

DATED : October 12, 1999 INVENTOR(S) : Heller et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Sternberg, R. et al., "Covalent Enzyme Coupling on Cellulose Acetate Membranes for Glucose Sensor Development," *Analytical Chemistry*, **60**(24):2781-2786 (December 15, 1988).

Sternberg, R. et al., "Study and Development of Multilayer Needle-type Enzyme-based Glucose Microsensors," *Biosensors*, 4:27-40 (1988).

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### UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT NO. : 5,965,380 : October 12, 1999 DATED

INVENTOR(S) : Heller et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Vreeke, M. S. et al., "Chapter 15: Hydrogen Peroxide Electrodes Based on Electrical Connection of Redox Centers of Various Peroxidases to Electrodes through a Three-Dimensional Electron-Relaying Polymer Network," Diagnostic Biosensor Polymers, 7 pgs. (July 26, 1993).

Vreeke, M. et al., "Hydrogen Peroxide and β-Nicotinamide Adenine Dinucleotide Sensing Amperometric Electrodes Based on Electrical Connection of Horseradish Peroxidase Redox Centers to Electrodes through a Three-Dimensional Electron Relaying Polymer Network," Analytical Chemistry, 64(24):3084-3090 (December 15, 1992).

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PATENT NO. : 5,965,380 DATED : October 12, 1999 INVENTOR(S) : Heller et al. Page 18 of 18

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Zamzow, K. et al., "New Wearable Continuous Blood Glucose Monitor (BGM) and Artificial Pancreas (AP), *Diabetes*, **39**:5A(20) (May 1990). Zhang, Y. et al., "Application of cell culture toxicity tests to the development of implantable biosensors," *Biosensors & Bioelectronics*, **6**:653-661 (1991). Zhang, Y. et al., "Elimination of the Acetaminophen Interference in an Implantable Glucose Sensor," *Anal. Chem.* **66**:1183-1188 (1994). --

Column 11, Line 41, "250" should read -- 25° --

Column 14, Line 37, "it" should read — 1% —

Signed and Sealed this

Ninth Day of April, 2002

Attest:

Attesting Officer

JAMES E. ROGAN

Director of the United States Patent and Trudemark Office

Case3:11-cv-04494-WHO Document411-16 Filed04/18/14 Page1 of 7

# Exhibit P

ignostics Corp. > GenStrip

# **Decision Diagnostics Corp.**

# Introducing Genstrip

## **Blood Glucose Test Strip**

For use with Lifescan One Touch® Ultra®, Ultra 2®, Ultra Smart® and Ultra Mini® meters

Frequent and accurate testing of blood glucose is essential to the treatment of diabetes. Unfortunately, high costs of testing supplies puts regular monitoring out of reach for many diabetics.

Shasta's GenStrip® Blood Glucose Test Strips make blood glucose testing fast, easy, convenient, and more affordable for anyone living with diabetes. This new diagnostic product will be comparable to the existing consumable provided by the platform manufacturer, but priced significantly (50%) lower.

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#### DEPARTMENT OF HEALTH & HUM AN SERVICES

Public Health Service

Food and Drug Administration 10903 New Hampshire Award Document Control Cansts - WO66-G609 Silver Spring, MD 20993-002

November 30, 2012

Shasta Technologies, LLC c/o Mr. Mark DuVal 1820 Medical Arts Building 825 Nicollet Mall Minneapolis, MN 55402

Re: k103542

Trade/Device Name: Gen Strip Test Strips Regulation Number: 21 CFR §862.1345 Regulation Name: Glucose Test System

Regulatory Class: Class II Product Code: NBW, CGA Dated: November 7, 2012 Received: November 8, 2012

Dear Mr. DuVal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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Page 2 - DuVal

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarker notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <a href="http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm">http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</a> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/edrlv/industrv/support/index.html.

Sincerely yours,

Carol C. Benson

for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

### Case3:11-cv-04494-WHO Document411-16 Filed04/18/14 Page5 of 7

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### Indications for Use

510(k) Number (if known): k103542

Device Name: GenStrip™ Test Strip

Indications for Use:

GenStrip<sup>TM</sup> Test Strips with calibration codes 4, 10, and 13 are for use with OneTouch<sup>®</sup> Ultra<sup>®</sup>, Ultra<sup>®</sup>2 and UltraMini<sup>®</sup> Meters purchased before July 2010. They are used to quantitatively measure glucose in fresh capillary whole blood samples taken from the finger, forearm or palm. Testing is done outside the body (in vitro diagnostic use). They are indicated for use by people with diabetes in their home as an aid to monitor the effectiveness of diabetes control. The system is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

Prescription Use \_\_\_\_\_ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use \_xx. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE: CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostic Device

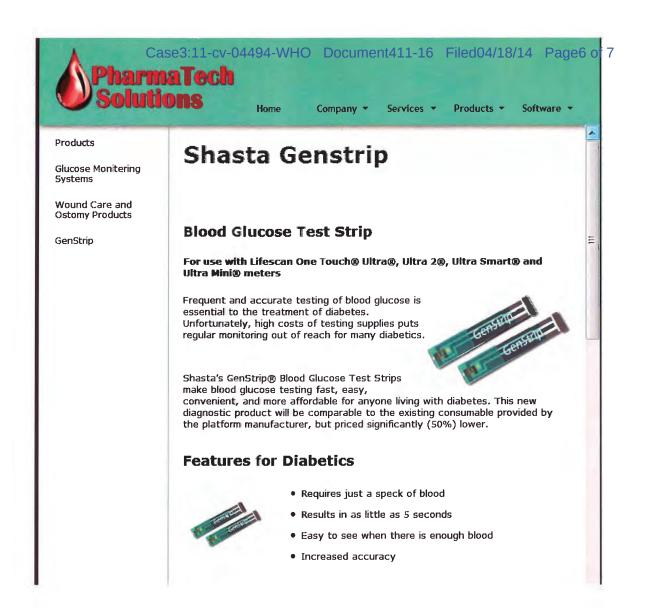
**Evaluation and Safety** 

510(k) k103542

Page 1 of \_\_\_\_

Site Map

4



### **Proof**

An estimated 20.8 million people in the United States are living with diabetes.

- A rising population of people diagnosed with diabetes – an estimated 6 million are unaware they have the disease!
- Individuals with diabetes need to test frequently to maintain a healthy lifestyle
- Increasing demand for low-cost alternatives for diabetic testing supplies



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