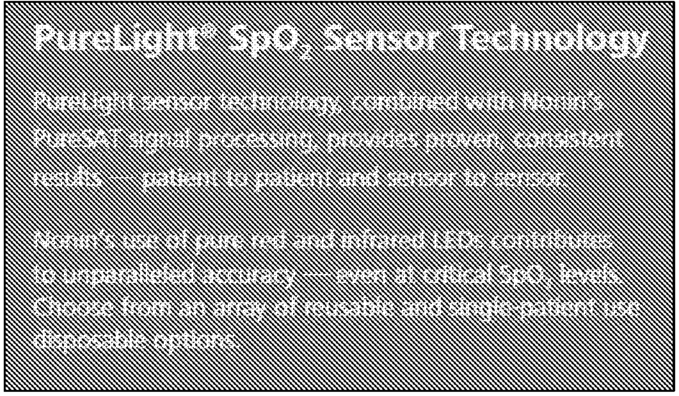
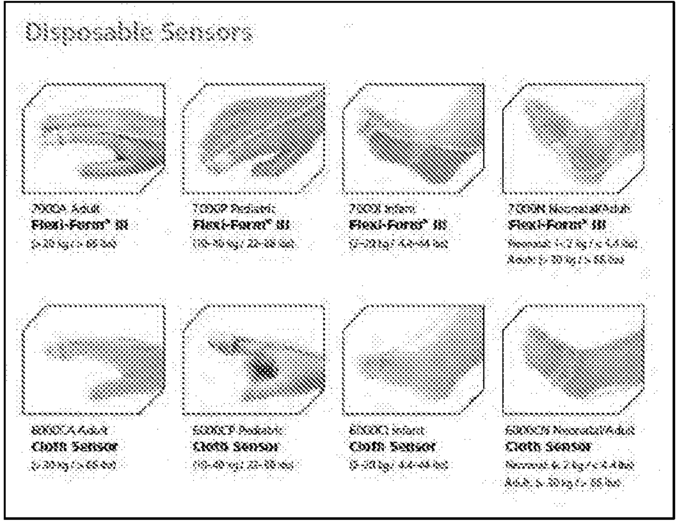
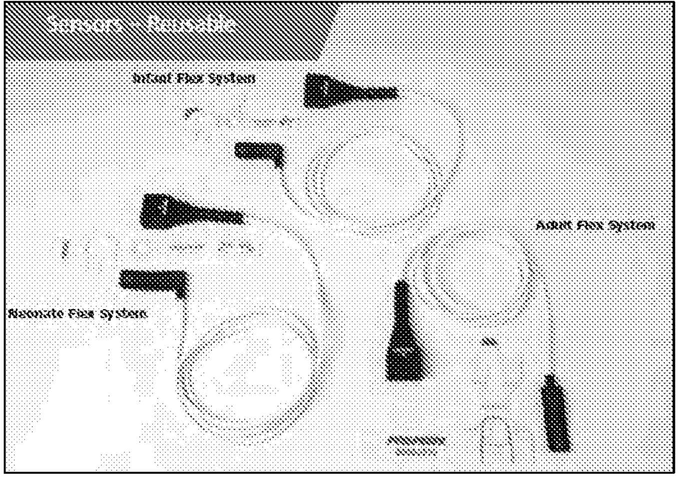
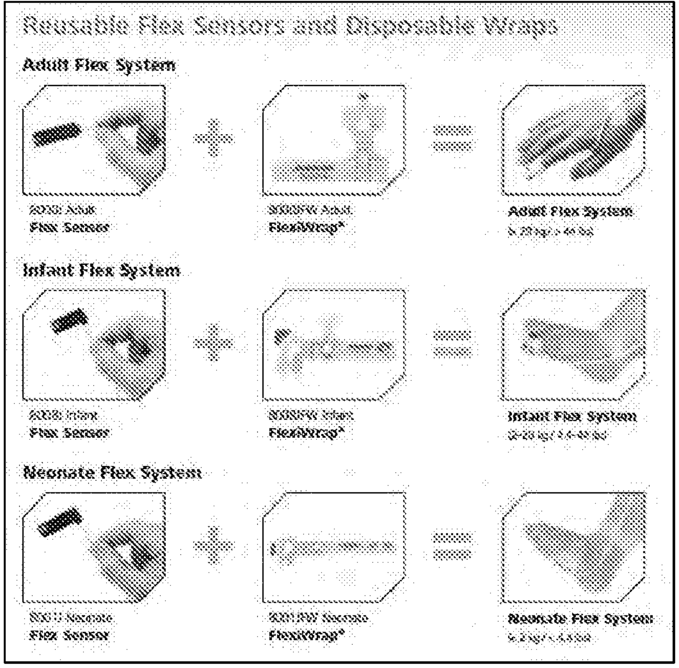
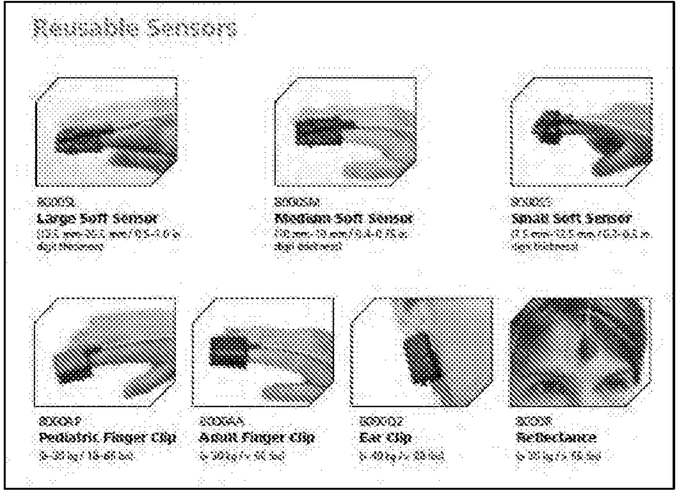
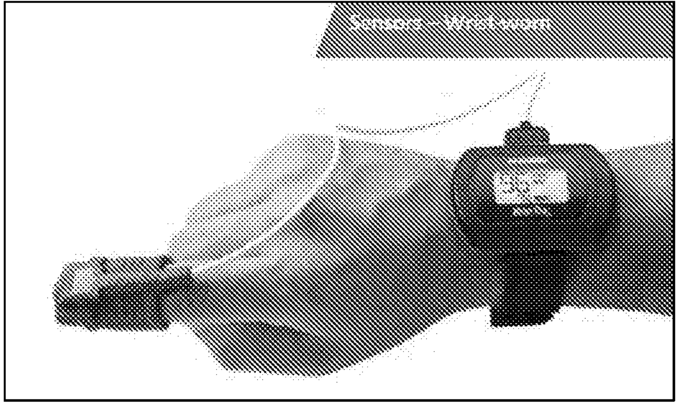
Asserted Claim of '533 Patent	Nonin Medical Pulse Oximeters
	 PureLight® SpO_2 Sensor Technology PureLight sensor technology, combined with Nonin's PureSAT signal processing, provides proven, consistent results — patient to patient and sensor to sensor. Nonin's use of pure red and infrared LEDs contributes to unparalleled accuracy — even at critical SpO_2 levels. Choose from an array of reusable and single-patient use disposable options. (Product Catalog, p. 16)

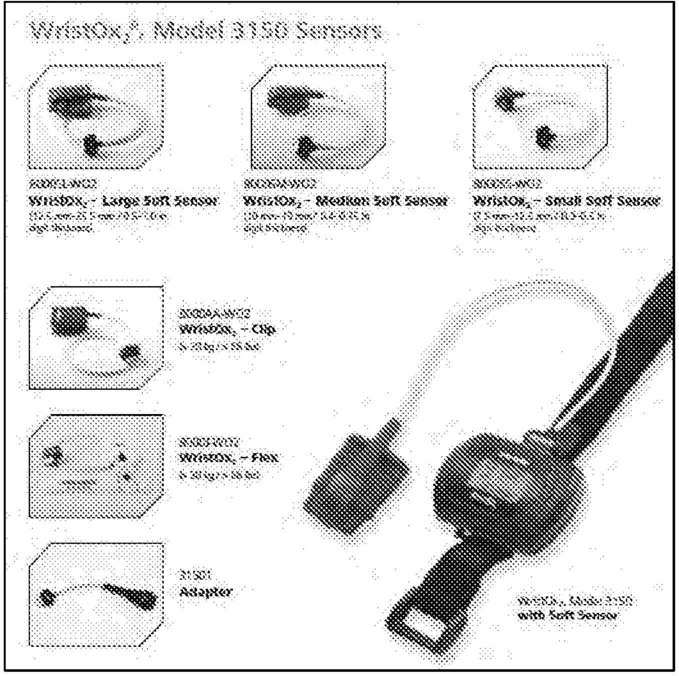
Asserted Claim of '533 Patent	Nonin Medical Pulse Oximeters
	 Disposable Sensors 7000A Adult **Flexi-Form® III** 7000P Pediatric **Flexi-Form® III** 7000I Infant **Flexi-Form® III** 7000N Neonatal/Adult **Flexi-Form® III** 8000CA Adult **Cloth Sensor** 8000CP Pediatric **Cloth Sensor** 8000CI Infant **Cloth Sensor** 8000CN Neonatal/Adult **Cloth Sensor** (Product Catalog, p. 17)

Asserted Claim of '533 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 18)

Asserted Claim of '533 Patent	Nonin Medical Pulse Oximeters
	 Reusable Flex Sensors and Disposable Wraps **Adult Flex System** [illegible] Adult **Flex Sensor** + [illegible] Adult **FlexiWrap®** = **Adult Flex System** [illegible] **Infant Flex System** [illegible] Infant **Flex Sensor** + [illegible] Infant **FlexiWrap®** = **Infant Flex System** [illegible] **Neonate Flex System** [illegible] Neonate **Flex Sensor** + [illegible] Neonate **FlexiWrap®** = **Neonate Flex System** [illegible] (Product Catalog, p. 18)

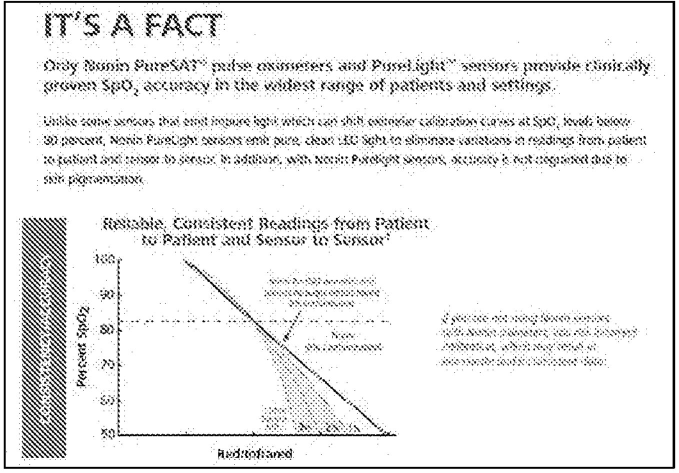
Asserted Claim of '533 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 19)

Asserted Claim of '533 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 21)

Asserted Claim of '533 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 21)

Asserted Claim of '533 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 31)

Asserted Claim of '533 Patent	Nonin Medical Pulse Oximeters
	 OEM III Module **Internal OEM Pulse Oximeter** Xpod® **External Pulse Oximeter with Mini-12 or USB Connectors** Onyx® II, Model 9560 **OEM Finger Pulse Oximeter with Bluetooth® wireless technology** Nonin 3230 Bluetooth® Smart **OEM Finger Pulse Oximeter with Bluetooth® Smart wireless technology** Nonin 3231 USB **OEM Finger Pulse Oximeter with USB Connector** WristOx2®, Model 3150 **OEM Wrist-worn Pulse Oximeter with Bluetooth® wireless technology** (Product Catalog, p. 31)

Asserted Claim of '533 Patent	Nonin Medical Pulse Oximeters
	 IT'S A FACT Only Nonin PureSAT™ pulse oximeters and PureLight™ sensors provide clinically proven SpO_2 accuracy in the widest range of patients and settings. Unlike some sensors that emit impure light which can shift oximeter calibration curves at SpO_2 levels below 80 percent, Nonin PureLight sensors emit pure, clean LED light to eliminate variations in readings from patient to patient and sensor to sensor. In addition, with Nonin PureLight sensors, accuracy is not degraded due to skin pigmentation. (Brochure, p. 2)
[13B] wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers,	Nonin Medical discloses and/or renders obvious "wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers." *See* CHART ONE: '533 Patent, Claim Element 5B above.
[13C] the light source configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least	Nonin Medical discloses and/or renders obvious "the light source configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of semiconductor sources." *See* CHART ONE: '533 Patent, Claim Element 5C above.

Asserted Claim of '533 Patent	Nonin Medical Pulse Oximeters
one of the plurality of semiconductor sources;	
[13D] the wearable measurement device comprising a plurality of lenses configured to receive a portion of the output optical beam and to deliver an analysis output beam to a sample;	Nonin Medical discloses and/or renders obvious "the wearable measurement device comprising a plurality of lenses configured to receive a portion of the output optical beam and to deliver an analysis output beam to a sample." *See* CHART ONE: '533 Patent, Claim Element 5D above.
[13E] the wearable measurement device further comprising a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal	Nonin Medical discloses and/or renders obvious "the wearable measurement device further comprising a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal." *See* CHART ONE: '533 Patent, Claim Element 5E above.
[13F] wherein the wearable measurement device receiver is configured to be synchronized to pulses of the light source;	Nonin Medical discloses and/or renders obvious "wherein the wearable measurement device receiver is configured to be synchronized to pulses of the light source." *See* CHART ONE: '533 Patent, Claim Element 5F above.
[13G] a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen,	Nonin Medical discloses and/or renders obvious "a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen." *See* CHART ONE: '533 Patent, Claim Element 5G above.

Asserted Claim of '533 Patent	Nonin Medical Pulse Oximeters
[13H] the personal device configured to receive and process at least a portion of the output signal,	Nonin Medical discloses and/or renders obvious "the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal." *See* CHART ONE: '533 Patent, Claim Element 5H above.
[13I] wherein the personal device is configured to store and display the processed output signal, and	Nonin Medical discloses and/or renders obvious "wherein the personal device is configured to store and display the processed output signal." *See* CHART ONE: '533 Patent, Claim Element 5I above.
[13J] wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link; and	Nonin Medical discloses and/or renders obvious "wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link." *See* CHART ONE: '533 Patent, Claim Element 5J above.
[13K] a remote device configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data and to store the processed data, and	Nonin Medical discloses and/or renders obvious "a remote device configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data and to store the processed data." *See* CHART ONE: '533 Patent, Claim Element 5K above.
[13L] wherein the remote device is capable of storing a history of at least a portion of the received output status over a specified period of time.	Nonin Medical discloses and/or renders obvious "wherein the remote device is capable of storing a history of at least a portion of the received output status over a specified period of time." *See* CHART ONE: '533 Patent, Claim Element 10 above.
[16] The system of claim 13, wherein the receiver is located a	Nonin Medical discloses and/or renders obvious "[t]he system of claim 13, wherein the receiver is located a first distance from a first one of the plurality of light emitting diodes and a different,

Asserted Claim of '533 Patent	Nonin Medical Pulse Oximeters
first distance from a first one of the plurality of light emitting diodes and a different, second distance from a second one of the plurality of light emitting diodes such that the receiver receives a first signal from the first light emitting diode and a second signal from the second light emitting diode.	second distance from a second one of the plurality of light emitting diodes such that the receiver receives a first signal from the first light emitting diode and a second signal from the second light emitting diode." *See* CHART ONE: '533 Patent, Claim Element 8 above.
[17] The system of claim 16, wherein the output signal is generated in part by comparing the first and second signals.	Nonin Medical discloses and/or renders obvious "[t]he system of claim 16, wherein the output signal is generated in part by comparing the first and second signals." *See* CHART ONE: '533 Patent, Claim Element 9 above.

EXHIBIT W-2

U.S. Patent No. 9,757,040 vs Nonin Medical

Priority Date/Publication Date: At least by February 2011 Prior Art Status: §§ 102(a) and (b)

Model 3150 WristOx$_2$ and certain pulse oximeters and pulse oximetry sensors manufactured by Nonin Medical ("Nonin Medical") anticipate the asserted claims of U.S. Patent No. 9,757,040 ("the '040 Patent") or renders those claims obvious alone and/or in view of at least any of the references identified in Apple's Obviousness Combinations Chart.

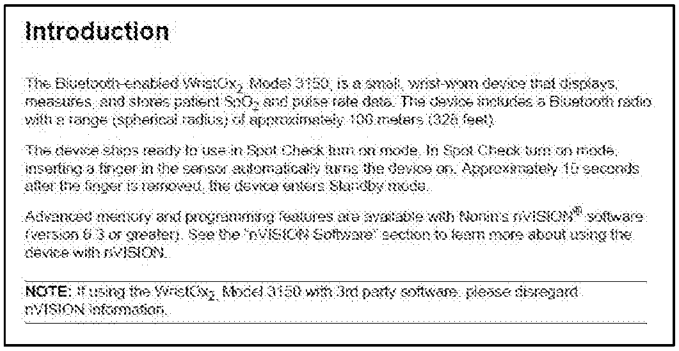
This chart is based on the following disclosures about Nonin Medical pulse oximeters:

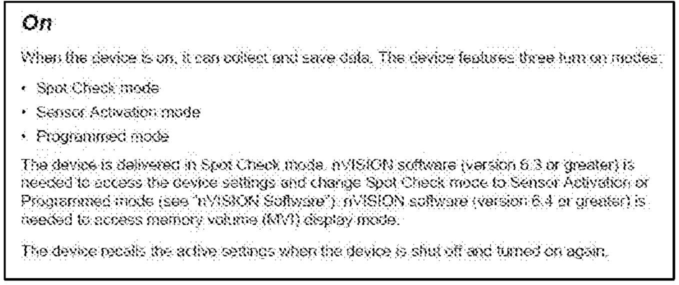
- Nonin Operator's Manual 2014 for Model 3150 WristOx$_2$ Pulse Oximeter ("Operator's Manual")
- Nonin Product Catalog 2014 ("Product Catalog")
- Nonin Brochure 2013 ("Brochure")
- Nonin Pulse Oximeter Sensor Compatibility Guide 2013 ("Compatibility Guide")

Discovery is ongoing, and Apple reserves the right to amend this chart based on new information about the Nonin Medical pulse oximeters.

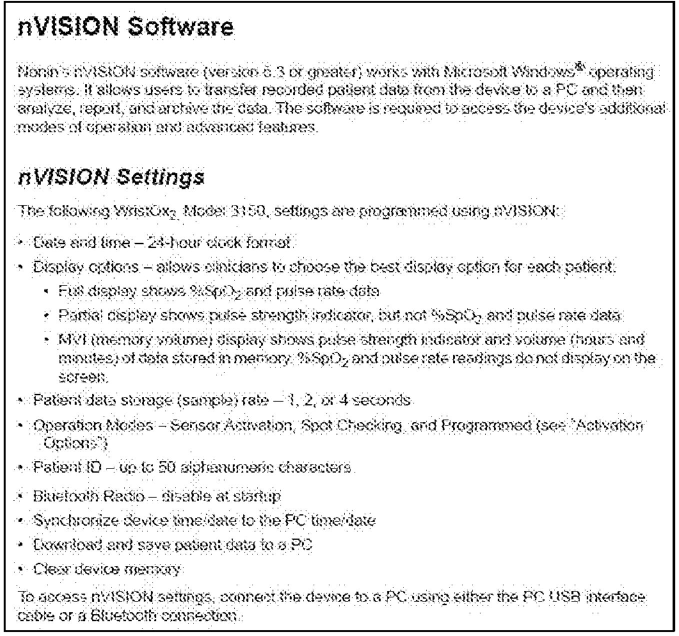
As set forth in Apple's Invalidity Contentions, the below contentions apply the prior art in part in accordance with Apple's assumption that Omni contends the claims are not invalid under 35 U.S.C. § 112. However, Apple's below contentions do not represent Apple's agreement or view as to the meaning, definiteness, written description support for, or enablement of any of the asserted claims. For each dependent claim, the disclosures cited for the claim from which it depends are incorporated by reference.

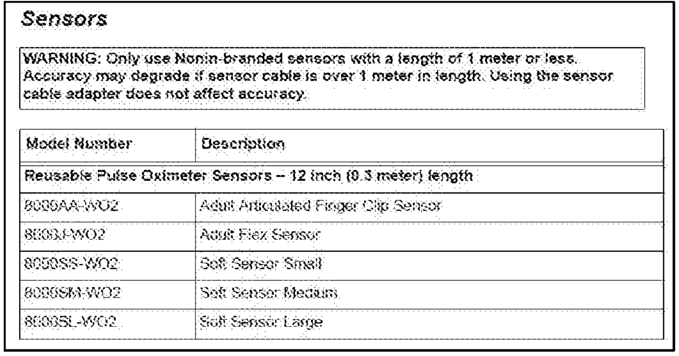
CHART TWO: U.S. Patent No. 9,757,040 vs Nonin Medical

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
[1] A wearable device for use with a smart phone or tablet, the wearable device comprising:	To the extent the preamble is limiting, Nonin Medical discloses and/or renders obvious "[a] wearable device for use with a smart phone or tablet." *See* CHART ONE: '533 Patent, Claim Elements 5, 5G, and 13A above.
[1A] a measurement device including a light source comprising a plurality of light emitting diodes (LEDs) for measuring one or more physiological parameters	Nonin Medical discloses and/or renders obvious "a measurement device including a light source comprising a plurality of light emitting diodes (LEDs) for measuring one or more physiological parameters." *See* CHART ONE: '533 Patent, Claim Element 13A above.
[1B] the measurement device configured to generate, by modulating at least one of the LEDs having an initial light intensity, an input optical beam having one or more optical wavelengths,	Nonin Medical discloses and/or renders obvious "the measurement device configured to generate, by modulating at least one of the LEDs having an initial light intensity, an input optical beam having one or more optical wavelengths."  **Introduction** The Bluetooth-enabled WristOx$_2$ Model 3150, is a small, wrist-worn device that displays, measures, and stores patient SpO$_2$ and pulse rate data. The device includes a Bluetooth radio with a range (spherical radius) of approximately 100 meters (328 feet). The device ships ready to use in Spot Check turn on mode. In Spot Check turn on mode, inserting a finger in the sensor automatically turns the device on. Approximately 10 seconds after the finger is removed, the device enters Standby mode. Advanced memory and programming features are available with Nonin's nVISION® software (version 6.3 or greater). See the "nVISION Software" section to learn more about using the device with nVISION. **NOTE:** If using the WristOx$_2$ Model 3150 with 3rd party software, please disregard nVISION information. (Operator's Manual, p. 10)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 **On** When the device is on, it can collect and save data. The device features three turn on modes: • Spot Check mode • Sensor Activation mode • Programmed mode The device is delivered in Spot Check mode. nVISION software (version 6.3 or greater) is needed to access the device settings and change Spot Check mode to Sensor Activation or Programmed mode (see "nVISION Software"). nVISION software (version 6.4 or greater) is needed to access memory volume (MVI) display mode. The device recalls the active settings when the device is shut off and turned on again. (Operator's Manual, p. 12)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters

	
	nVISION Software
	Nonin's nVISION software (version 6.3 or greater) works with Microsoft Windows® operating systems. It allows users to transfer recorded patient data from the device to a PC and then analyze, report, and archive the data. The software is required to access the device's additional modes of operation and advanced features.
	nVISION Settings
	The following WristOx$_2$ Model 3150, settings are programmed using nVISION:
	• Date and time – 24-hour clock format
	• Display options – allows clinicians to choose the best display option for each patient:
	  • Full display shows %SpO$_2$ and pulse rate data
	  • Partial display shows pulse strength indicator, but not %SpO$_2$ and pulse rate data
	  • MVI (memory volume) display shows pulse strength indicator and volume (hours and minutes) of data stored in memory. %SpO$_2$ and pulse rate readings do not display on the screen.
	• Patient data storage (sample) rate – 1, 2, or 4 seconds
	• Operation Modes – Sensor Activation, Spot Checking, and Programmed (see "Activation Options")
	• Patient ID – up to 50 alphanumeric characters
	• Bluetooth Radio – disable at startup
	• Synchronize device time/date to the PC time/date
	• Download and save patient data to a PC
	• Clear device memory
	To access nVISION settings, connect the device to a PC using either the PC USB interface cable or a Bluetooth connection.
	(Operator's Manual, p. 29)

<table>
<tr><th>Asserted Claim of '040 Patent</th><th>Nonin Medical Pulse Oximeters</th></tr>
<tr><td></td><td>
Sensors
WARNING: Only use Nonin-branded sensors with a length of 1 meter or less. Accuracy may degrade if sensor cable is over 1 meter in length. Using the sensor cable adapter does not affect accuracy.
<table>
<tr><th>Model Number</th><th>Description</th></tr>
<tr><td colspan="2">Reusable Pulse Oximeter Sensors – 12 inch (0.3 meter) length</td></tr>
<tr><td>8000AA-WO2</td><td>Adult Articulated Finger Clip Sensor</td></tr>
<tr><td>8000J-WO2</td><td>Adult Flex Sensor</td></tr>
<tr><td>8000SS-WO2</td><td>Soft Sensor Small</td></tr>
<tr><td>8000SM-WO2</td><td>Soft Sensor Medium</td></tr>
<tr><td>8000SL-WO2</td><td>Soft Sensor Large</td></tr>
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(Operator's Manual, p. 35)</td></tr>
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<table>
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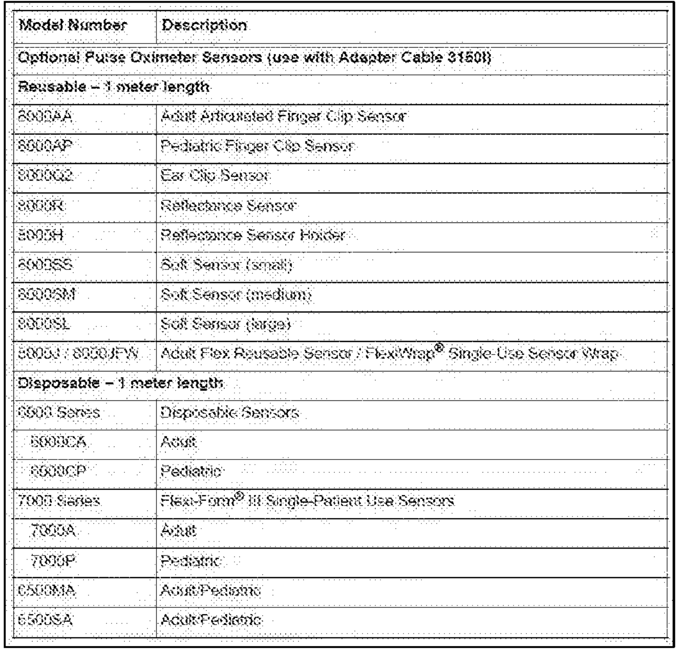
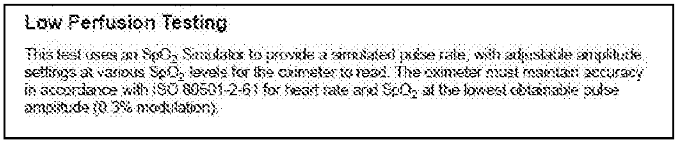
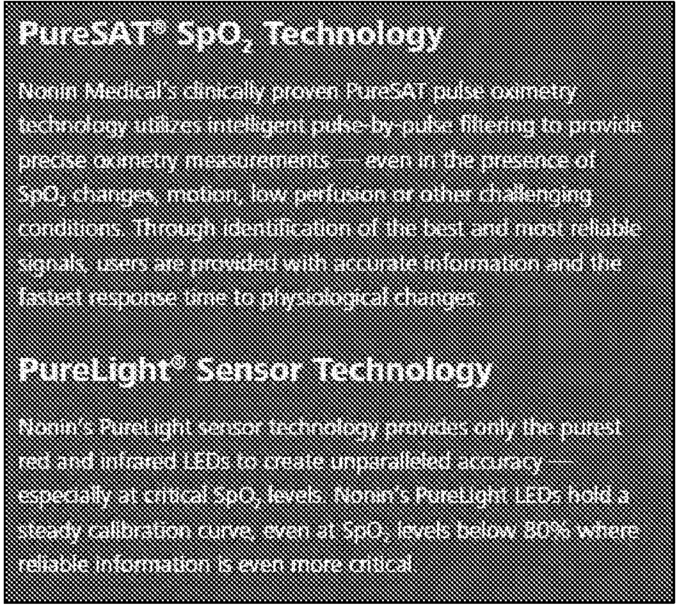
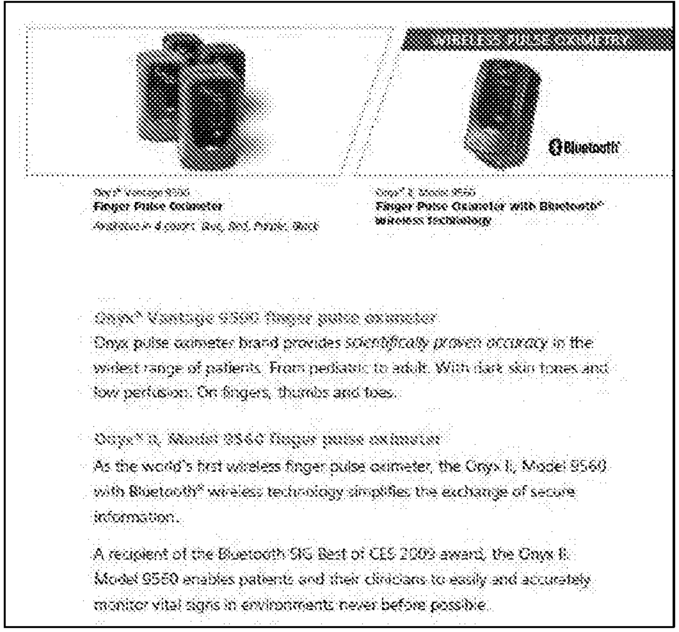

<table>
<tr><th>Model Number</th><th>Description</th></tr>
<tr><td colspan="2">Optional Pulse Oximeter Sensors (use with Adapter Cable 3150)</td></tr>
<tr><td colspan="2">Reusable – 1 meter length</td></tr>
<tr><td>8000AA</td><td>Adult Articulated Finger Clip Sensor</td></tr>
<tr><td>8000AP</td><td>Pediatric Finger Clip Sensor</td></tr>
<tr><td>8000Q2</td><td>Ear Clip Sensor</td></tr>
<tr><td>8000R</td><td>Reflectance Sensor</td></tr>
<tr><td>8000H</td><td>Reflectance Sensor Holder</td></tr>
<tr><td>8000SS</td><td>Soft Sensor (small)</td></tr>
<tr><td>8000SM</td><td>Soft Sensor (medium)</td></tr>
<tr><td>8000SL</td><td>Soft Sensor (large)</td></tr>
<tr><td>8000J / 8000JFW</td><td>Adult Flex Reusable Sensor / FlexiWrap® Single-Use Sensor Wrap</td></tr>
<tr><td colspan="2">Disposable – 1 meter length</td></tr>
<tr><td>6000 Series</td><td>Disposable Sensors</td></tr>
<tr><td>6000CA</td><td>Adult</td></tr>
<tr><td>6000CP</td><td>Pediatric</td></tr>
<tr><td>7000 Series</td><td>Flexi-Form® III Single-Patient Use Sensors</td></tr>
<tr><td>7000A</td><td>Adult</td></tr>
<tr><td>7000P</td><td>Pediatric</td></tr>
<tr><td>6500MA</td><td>Adult/Pediatric</td></tr>
<tr><td>6500SA</td><td>Adult/Pediatric</td></tr>
</table>
(Operator's Manual, p. 35)

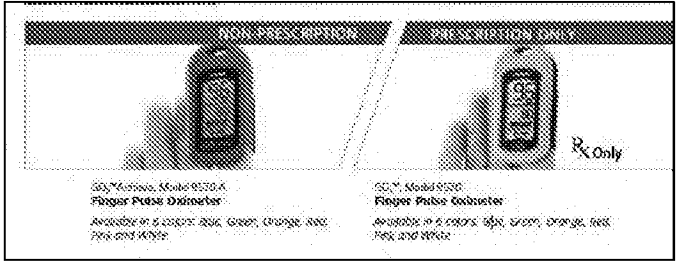

Low Perfusion Testing

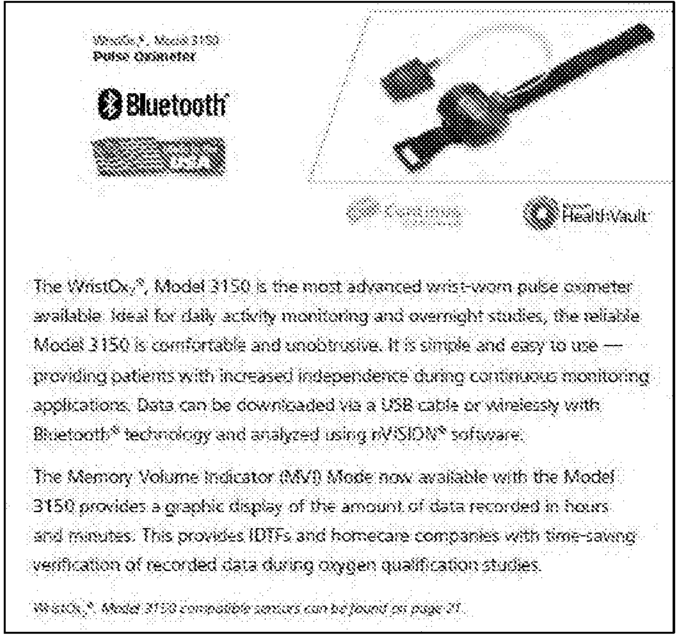
This test uses an SpO₂ Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO₂ levels for the oximeter to read. The oximeter must maintain accuracy in accordance with ISO 80601-2-61 for heart rate and SpO₂ at the lowest obtainable pulse amplitude (0.3% modulation).

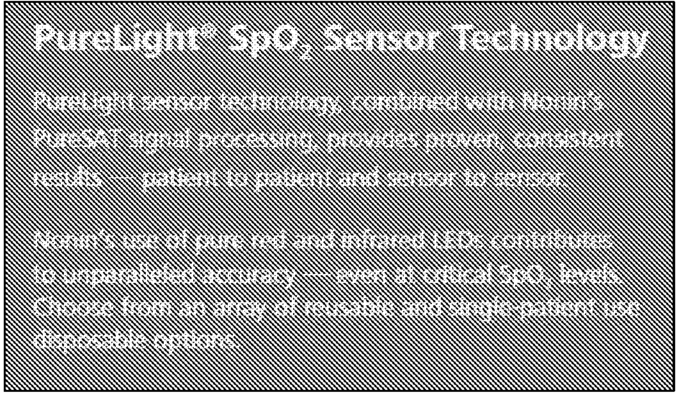
(Operator's Manual, p. 43)
</td></tr>
</table>

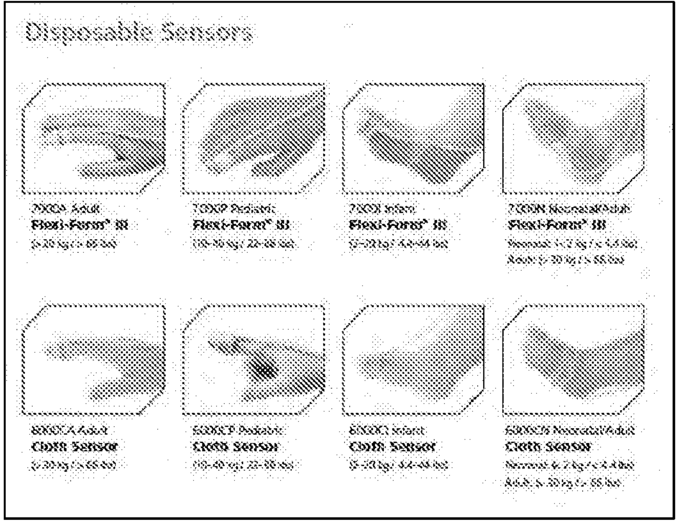
Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 **PureSAT® SpO_2 Technology** Nonin Medical's clinically proven PureSAT pulse oximetry technology utilizes intelligent pulse-by-pulse filtering to provide precise oximetry measurements — even in the presence of SpO_2 changes, motion, low perfusion or other challenging conditions. Through identification of the best and most reliable signals, users are provided with accurate information and the fastest response time to physiological changes. **PureLight® Sensor Technology** Nonin's PureLight sensor technology provides only the purest red and infrared LEDs to create unparalleled accuracy — especially at critical SpO_2 levels. Nonin's PureLight LEDs hold a steady calibration curve, even at SpO_2 levels below 80% where reliable information is even more critical. (Product Catalog, p. 4)

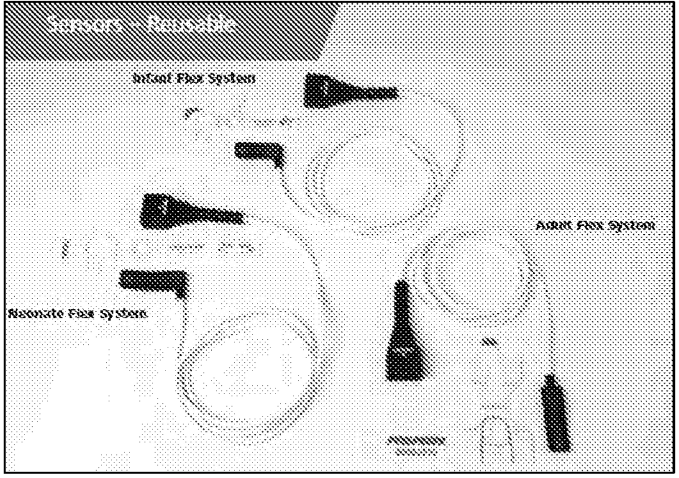
Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 Onyx® Vantage 9590 **Finger Pulse Oximeter** *Available in 4 colors: Blue, Red, Purple, Black* Onyx® II, Model 9560 **Finger Pulse Oximeter with Bluetooth® Wireless Technology** Onyx® Vantage 9590 finger pulse oximeter Onyx pulse oximeter brand provides *scientifically proven accuracy* in the widest range of patients. From pediatric to adult. With dark skin tones and low perfusion. On fingers, thumbs and toes. Onyx® II, Model 9560 finger pulse oximeter As the world's first wireless finger pulse oximeter, the Onyx II, Model 9560 with Bluetooth® wireless technology simplifies the exchange of secure information. A recipient of the Bluetooth SIG Best of CES 2009 award, the Onyx II, Model 9560 enables patients and their clinicians to easily and accurately monitor vital signs in environments never before possible. (Product Catalog, p. 7)

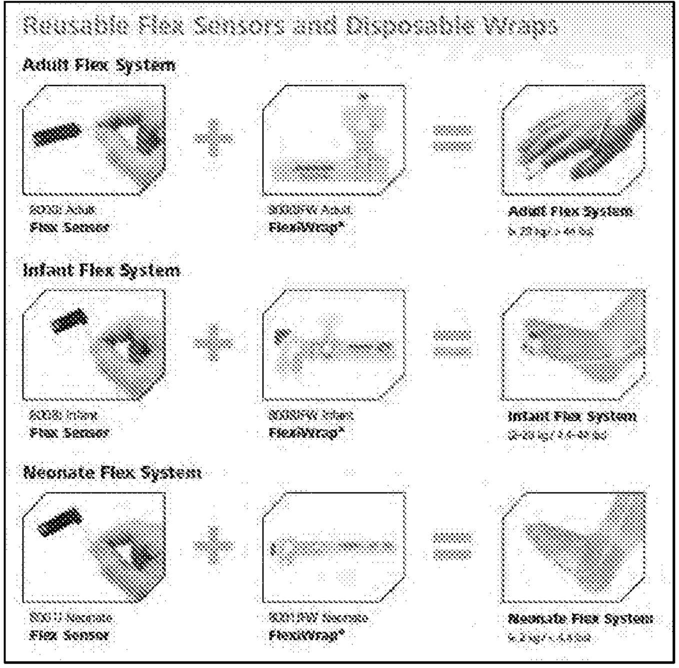
Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 9)

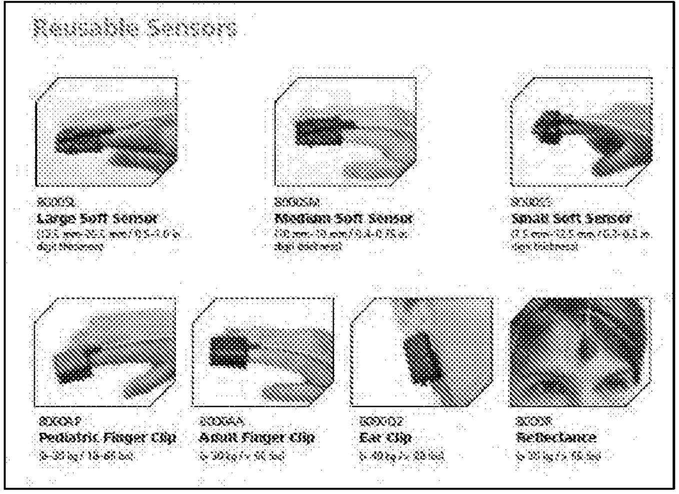
Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 WristOx$_2$®, Model 3150 Pulse Oximeter The WristOx$_2$®, Model 3150 is the most advanced wrist-worn pulse oximeter available. Ideal for daily activity monitoring and overnight studies, the reliable Model 3150 is comfortable and unobtrusive. It is simple and easy to use — providing patients with increased independence during continuous monitoring applications. Data can be downloaded via a USB cable or wirelessly with Bluetooth® technology and analyzed using nVISION® software. The Memory Volume Indicator (MVI) Mode now available with the Model 3150 provides a graphic display of the amount of data recorded in hours and minutes. This provides IDTFs and homecare companies with time-saving verification of recorded data during oxygen qualification studies. *WristOx$_2$®, Model 3150 compatible sensors can be found on page 21.* (Product Catalog, p. 11)

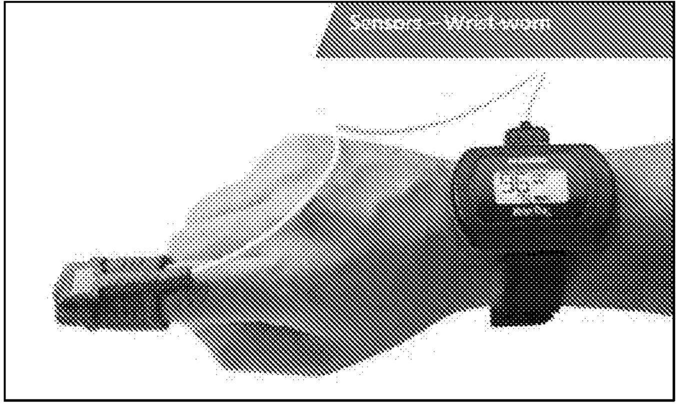
Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 **PureLight® SpO_2 Sensor Technology** PureLight sensor technology, combined with Nonin's PureSAT signal processing, provides proven, consistent results — patient to patient and sensor to sensor. Nonin's use of pure red and infrared LEDs contributes to unparalleled accuracy — even at critical SpO_2 levels. Choose from an array of reusable and single-patient use disposable options. (Product Catalog, p. 16)

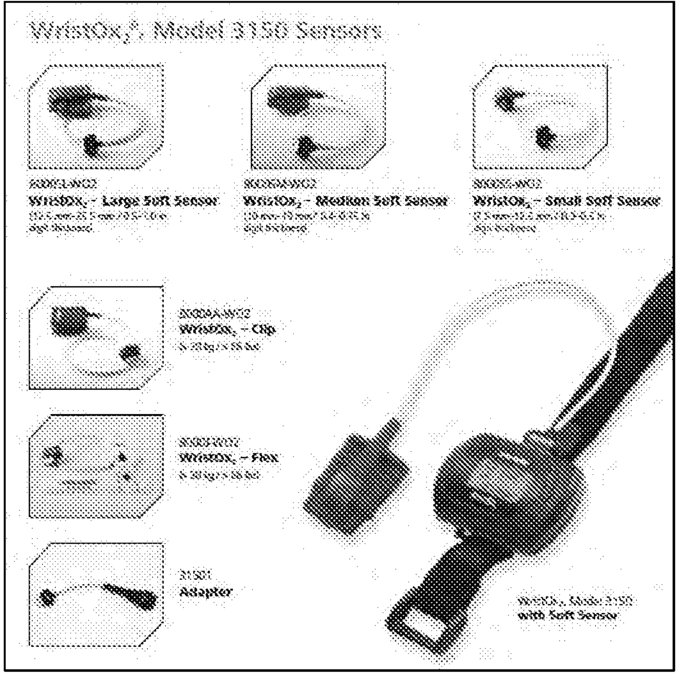
Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 Disposable Sensors 7000A Adult **Flexi-Form® III** 7000P Pediatric **Flexi-Form® III** 7000I Infant **Flexi-Form® III** 7000N Neonatal/Adult **Flexi-Form® III** 8000CA Adult **Cloth Sensor** 8000CP Pediatric **Cloth Sensor** 8000CI Infant **Cloth Sensor** 8000CN Neonatal/Adult **Cloth Sensor** (Product Catalog, p. 17)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 18)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 18)

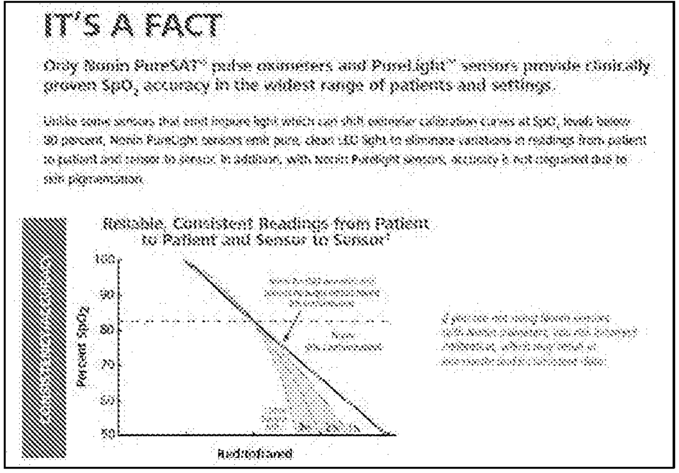
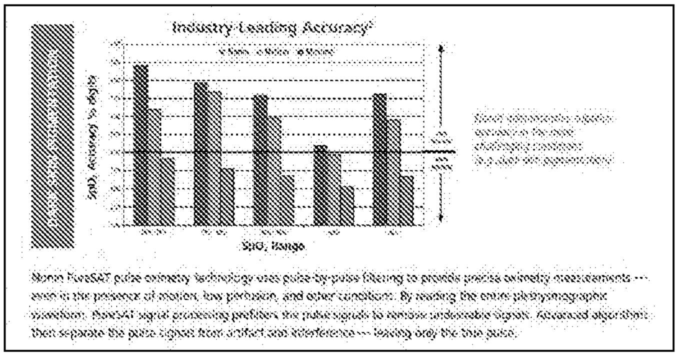
Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 Reusable Sensors 8000SL **Large Soft Sensor** 8000SM **Medium Soft Sensor** 8000SS **Small Soft Sensor** 8000AP **Pediatric Finger Clip** 8000AA **Adult Finger Clip** 8000Q2 **Ear Clip** 8000R **Reflectance** (Product Catalog, p. 19)

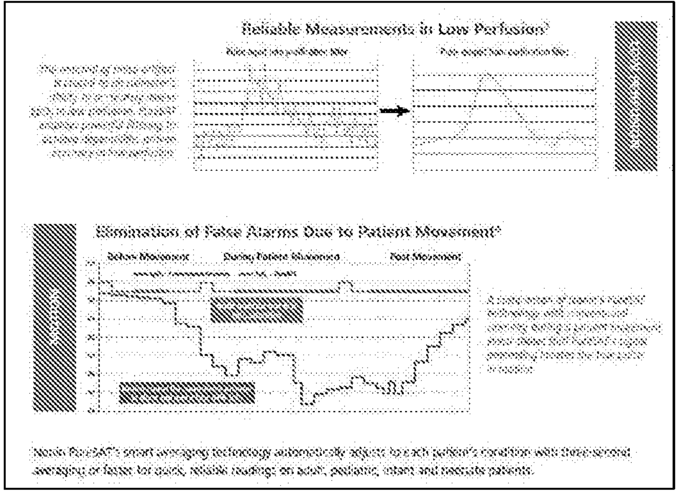
Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 21)

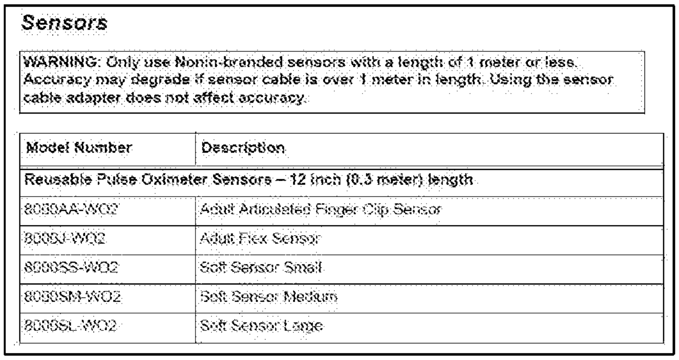
Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 WristOx$_2$®, Model 3150 Sensors **WristOx$_2$ – Large Soft Sensor** **WristOx$_2$ – Medium Soft Sensor** **WristOx$_2$ – Small Soft Sensor** **WristOx$_2$ – Clip** **WristOx$_2$ – Flex** **Adapter** WristOx$_2$, Model 3150 **with Soft Sensor** (Product Catalog, p. 21)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 31)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 OEM III Module Internal OEM Pulse Oximeter Xpod® External Pulse Oximeter with Mini-12 or USB Connectors Onyx® II, Model 9560 OEM Finger Pulse Oximeter with Bluetooth® wireless technology Nonin 3230 Bluetooth® Smart OEM Finger Pulse Oximeter with Bluetooth® Smart wireless technology Nonin 3231 USB OEM Finger Pulse Oximeter with USB Connector WristOx2®, Model 3150 OEM Wrist-worn Pulse Oximeter with Bluetooth® wireless technology (Product Catalog, p. 31)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 IT'S A FACT Only Nonin PureSAT™ pulse oximeters and PureLight™ sensors provide clinically proven SpO_2 accuracy in the widest range of patients and settings. Unlike some sensors that emit impure light which can shift oximeter calibration curves at SpO_2 levels below 80 percent, Nonin PureLight sensors emit pure, clean LED light to eliminate variations in readings from patient to patient and sensor to sensor. In addition, with Nonin PureLight sensors, accuracy is not degraded due to skin pigmentation. (Brochure, p. 1)  Nonin PureSAT pulse oximetry technology uses pulse-by-pulse filtering to provide precise oximetry measurements — even in the presence of motion, low perfusion, and other conditions. By reading the entire plethysmographic waveform, PureSAT signal processing prefilters the pulse signals to remove undesirable signals. Advanced algorithms then separate the pulse signal from artifact and interference — leaving only the true pulse. (Brochure, p. 2)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 Nonin PureSAT's smart averaging technology automatically adjusts to each patient's condition with three-second averaging or faster for quick, reliable readings on adult, pediatric, infant and neonate patients. (Brochure, p. 2)
[1C] wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers;	Nonin Medical discloses and/or renders obvious "wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers." *See* CHART ONE: '533 Patent, Claim Element 5B above.
[1D] the measurement device comprising one or more lenses configured to receive and to deliver a portion of the input optical beam to tissue, wherein the tissue reflects at least a	Nonin Medical discloses and/or renders obvious "the measurement device comprising one or more lenses configured to receive and to deliver a portion of the input optical beam to tissue, wherein the tissue reflects at least a portion of the input optical beam delivered to the tissue." *See* CHART ONE: '533 Patent, Claim Element 5D above.

<table>
<tr><th>Asserted Claim of ’040 Patent</th><th>Nonin Medical Pulse Oximeters</th></tr>
<tr><td>portion of the input optical beam delivered to the tissue;</td><td></td></tr>
<tr><td>[1E] the measurement device further comprising a reflective surface configured to receive and redirect at least a portion of light reflected from the tissue;</td><td>Nonin Medical discloses and/or renders obvious “the measurement device further comprising a reflective surface configured to receive and redirect at least a portion of light reflected from the tissue.”

<i>Sensors</i>
WARNING: Only use Nonin-branded sensors with a length of 1 meter or less. Accuracy may degrade if sensor cable is over 1 meter in length. Using the sensor cable adapter does not affect accuracy.<table>
<tr><th>Model Number</th><th>Description</th></tr>
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<tr><td>8000AA-WO2</td><td>Adult Articulated Finger Clip Sensor</td></tr>
<tr><td>8000J-WO2</td><td>Adult Flex Sensor</td></tr>
<tr><td>8000SS-WO2</td><td>Soft Sensor Small</td></tr>
<tr><td>8000SM-WO2</td><td>Soft Sensor Medium</td></tr>
<tr><td>8000SL-WO2</td><td>Soft Sensor Large</td></tr>
</table>(Operator’s Manual, p. 35)</td></tr>
</table>

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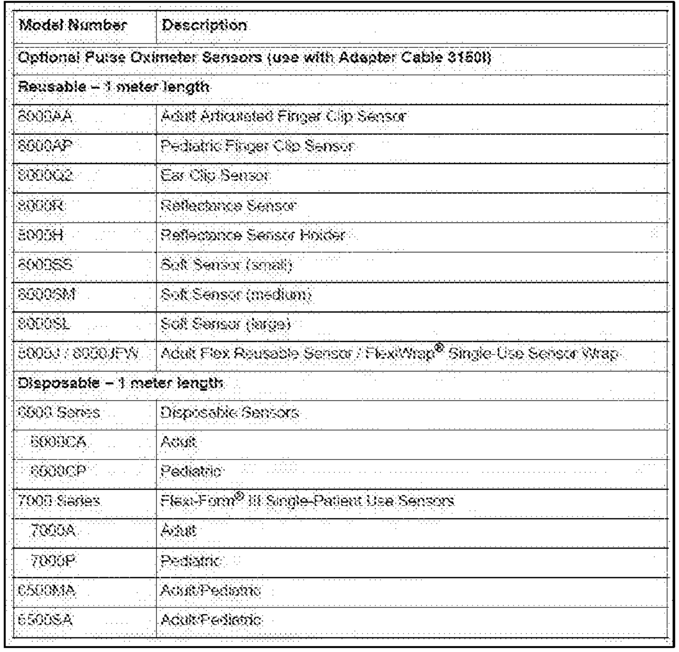
<tr><th>Asserted Claim of '040 Patent</th><th>Nonin Medical Pulse Oximeters</th></tr>
<tr><td></td><td>
<table>
<tr><th>Model Number</th><th>Description</th></tr>
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<tr><td>8000AA</td><td>Adult Articulated Finger Clip Sensor</td></tr>
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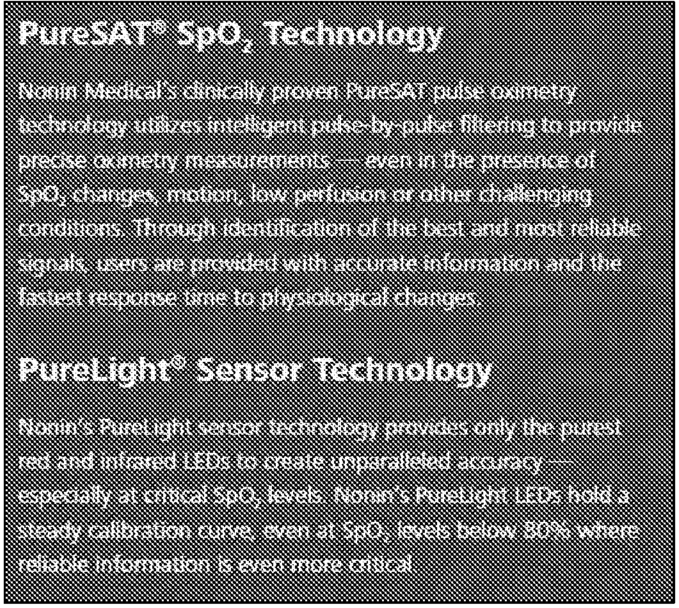
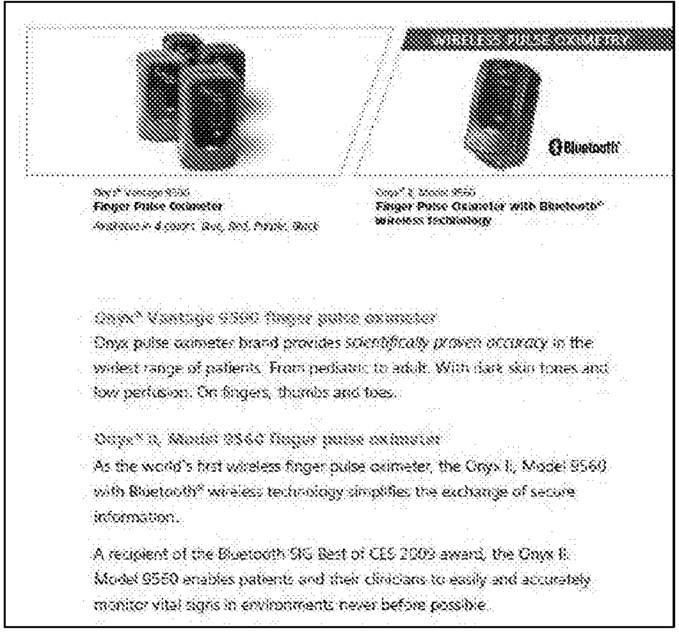
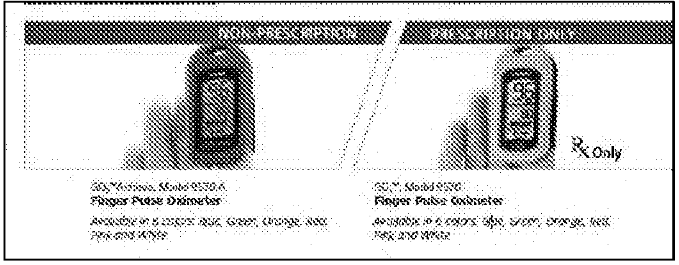
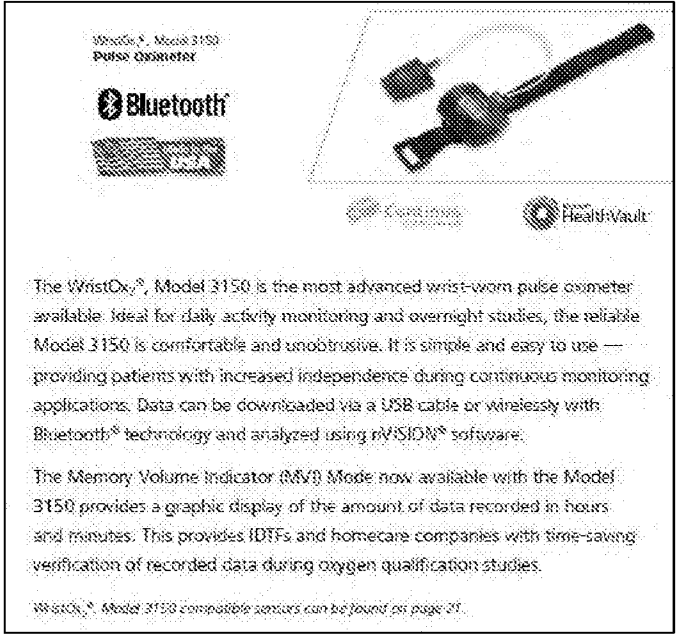
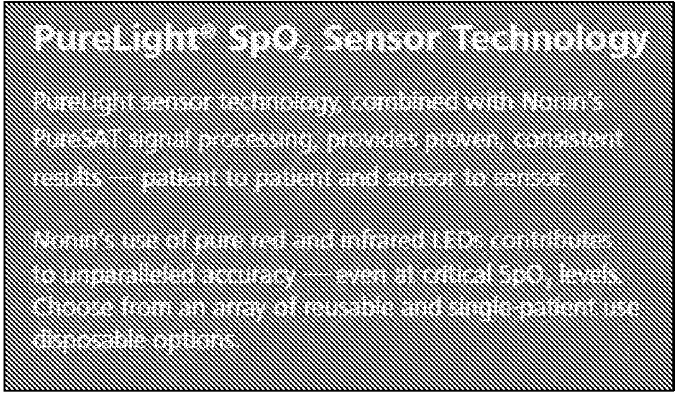
<tr><td>8000Q2</td><td>Ear Clip Sensor</td></tr>
<tr><td>8000R</td><td>Reflectance Sensor</td></tr>
<tr><td>8000H</td><td>Reflectance Sensor Holder</td></tr>
<tr><td>8000SS</td><td>Soft Sensor (small)</td></tr>
<tr><td>8000SM</td><td>Soft Sensor (medium)</td></tr>
<tr><td>8000SL</td><td>Soft Sensor (large)</td></tr>
<tr><td>8000J / 8000JFW</td><td>Adult Flex Reusable Sensor / FlexiWrap® Single-Use Sensor Wrap</td></tr>
<tr><td colspan="2">Disposable – 1 meter length</td></tr>
<tr><td>6000 Series</td><td>Disposable Sensors</td></tr>
<tr><td>6000CA</td><td>Adult</td></tr>
<tr><td>6000CP</td><td>Pediatric</td></tr>
<tr><td>7000 Series</td><td>Flexi-Form® III Single-Patient Use Sensors</td></tr>
<tr><td>7000A</td><td>Adult</td></tr>
<tr><td>7000P</td><td>Pediatric</td></tr>
<tr><td>6500MA</td><td>Adult/Pediatric</td></tr>
<tr><td>6500SA</td><td>Adult/Pediatric</td></tr>
</table>
(Operator's Manual, p. 35)</td></tr>
</table>

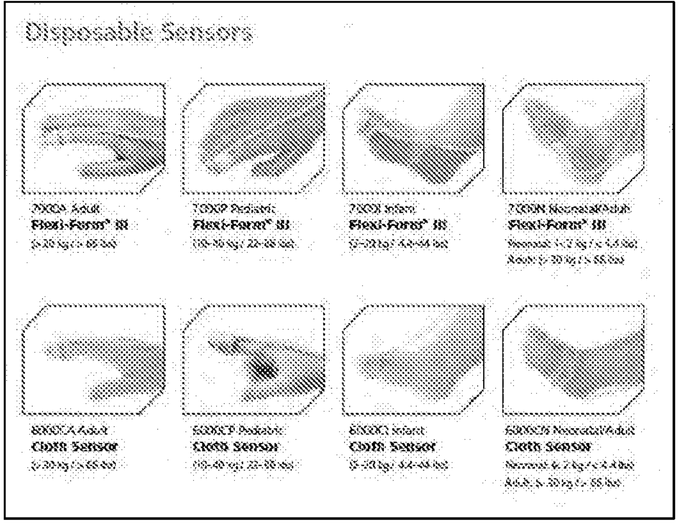
Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 **PureSAT® SpO_2 Technology** Nonin Medical's clinically proven PureSAT pulse oximetry technology utilizes intelligent pulse-by-pulse filtering to provide precise oximetry measurements — even in the presence of SpO_2 changes, motion, low perfusion or other challenging conditions. Through identification of the best and most reliable signals, users are provided with accurate information and the fastest response time to physiological changes. **PureLight® Sensor Technology** Nonin's PureLight sensor technology provides only the purest red and infrared LEDs to create unparalleled accuracy — especially at critical SpO_2 levels. Nonin's PureLight LEDs hold a steady calibration curve, even at SpO_2 levels below 80% where reliable information is even more critical. (Product Catalog, p. 4)

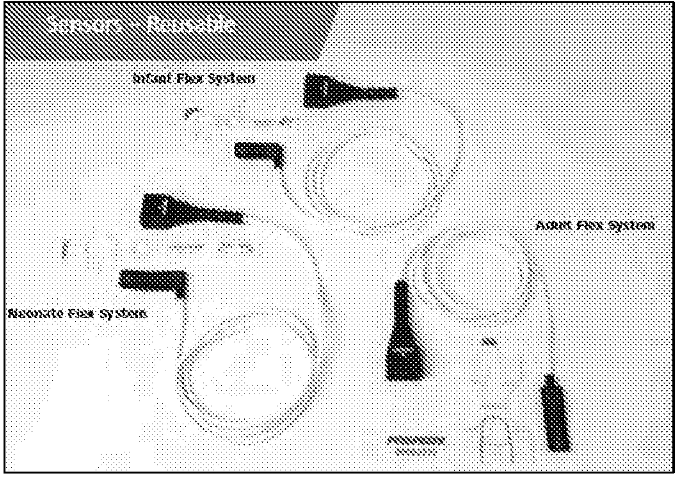
Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 Onyx® Vantage 9590 **Finger Pulse Oximeter** *Available in 4 colors: Blue, Red, Purple, Black* Onyx® II, Model 9560 **Finger Pulse Oximeter with Bluetooth® Wireless Technology** Onyx® Vantage 9590 finger pulse oximeter Onyx pulse oximeter brand provides *scientifically proven accuracy* in the widest range of patients. From pediatric to adult. With dark skin tones and low perfusion. On fingers, thumbs and toes. Onyx® II, Model 9560 finger pulse oximeter As the world's first wireless finger pulse oximeter, the Onyx II, Model 9560 with Bluetooth® wireless technology simplifies the exchange of secure information. A recipient of the Bluetooth SIG Best of CES 2009 award, the Onyx II, Model 9560 enables patients and their clinicians to easily and accurately monitor vital signs in environments never before possible. (Product Catalog, p. 7)

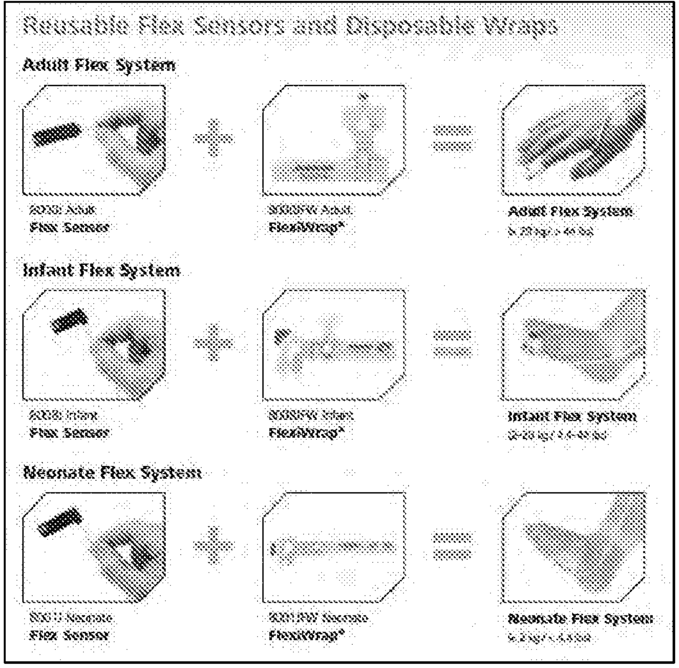
Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 9)

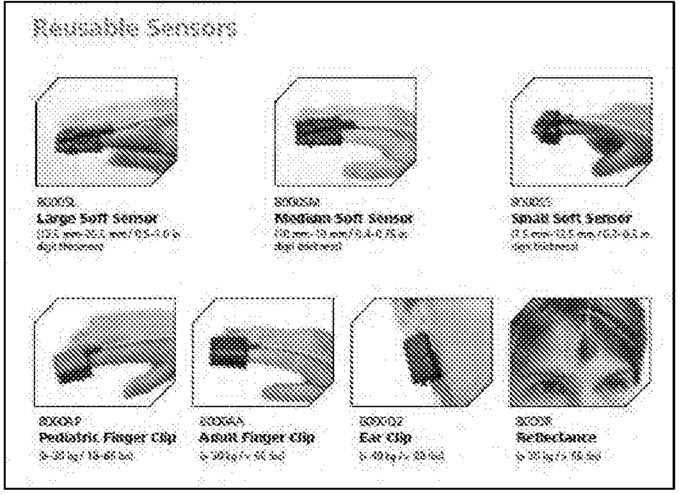
Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 WristOx$_2$®, Model 3150 Pulse Oximeter The WristOx$_2$®, Model 3150 is the most advanced wrist-worn pulse oximeter available. Ideal for daily activity monitoring and overnight studies, the reliable Model 3150 is comfortable and unobtrusive. It is simple and easy to use — providing patients with increased independence during continuous monitoring applications. Data can be downloaded via a USB cable or wirelessly with Bluetooth® technology and analyzed using nVISION® software. The Memory Volume Indicator (MVI) Mode now available with the Model 3150 provides a graphic display of the amount of data recorded in hours and minutes. This provides IDTFs and homecare companies with time-saving verification of recorded data during oxygen qualification studies. *WristOx$_2$®, Model 3150 compatible sensors can be found on page 21.* (Product Catalog, p. 11)

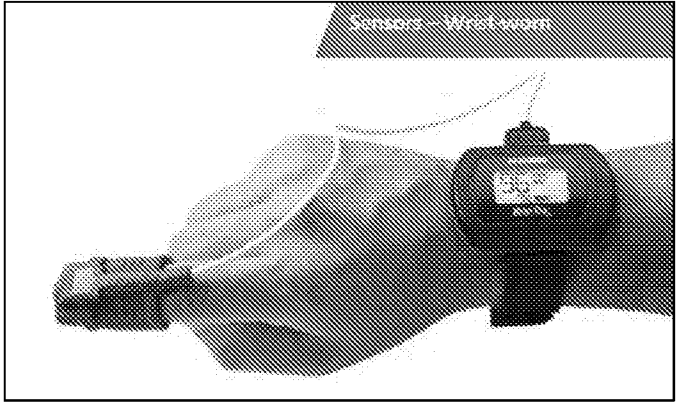
Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 PureLight® SpO_2 Sensor Technology PureLight sensor technology, combined with Nonin's PureSAT signal processing, provides proven, consistent results — patient to patient and sensor to sensor. Nonin's use of pure red and infrared LEDs contributes to unparalleled accuracy — even at critical SpO_2 levels. Choose from an array of reusable and single-patient use disposable options. (Product Catalog, p. 16)

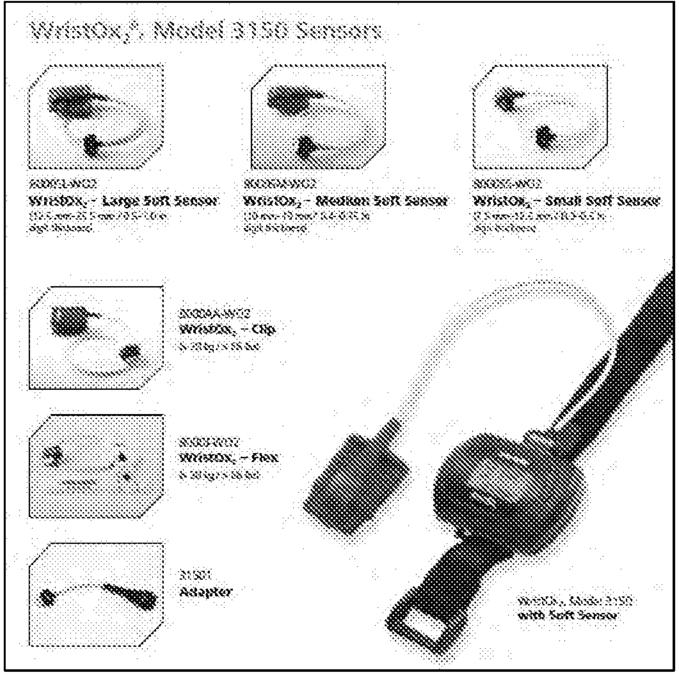
Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 Disposable Sensors 7000A Adult **Flexi-Form® III** 7000P Pediatric **Flexi-Form® III** 7000I Infant **Flexi-Form® III** 7000N Neonatal/Adult **Flexi-Form® III** 8000CA Adult **Cloth Sensor** 8000CP Pediatric **Cloth Sensor** 8000CI Infant **Cloth Sensor** 8000CN Neonatal/Adult **Cloth Sensor** (Product Catalog, p. 17)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 18)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 Reusable Flex Sensors and Disposable Wraps Adult Flex System 8000J Adult Flex Sensor + 8000JFW Adult FlexiWrap* = Adult Flex System > 20 kg / > 44 lbs Infant Flex System 8008J Infant Flex Sensor + 8008JFW Infant FlexiWrap* = Infant Flex System 2-20 kg / 4.4-44 lbs Neonate Flex System 8001J Neonate Flex Sensor + 8001JFW Neonate FlexiWrap* = Neonate Flex System < 2 kg / < 4.4 lbs (Product Catalog, p. 18)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 Reusable Sensors 8000SL **Large Soft Sensor** 8000SM **Medium Soft Sensor** 8000SS **Small Soft Sensor** 8000AP **Pediatric Finger Clip** 8000AA **Adult Finger Clip** 8000Q2 **Ear Clip** 8000R **Reflectance** (Product Catalog, p. 19)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 21)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 WristOx$_2$®, Model 3150 Sensors WristOx$_2$ – Large Soft Sensor WristOx$_2$ – Medium Soft Sensor WristOx$_2$ – Small Soft Sensor WristOx$_2$ – Clip WristOx$_2$ – Flex Adapter WristOx$_2$, Model 3150 with Soft Sensor (Product Catalog, p. 21)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 31)

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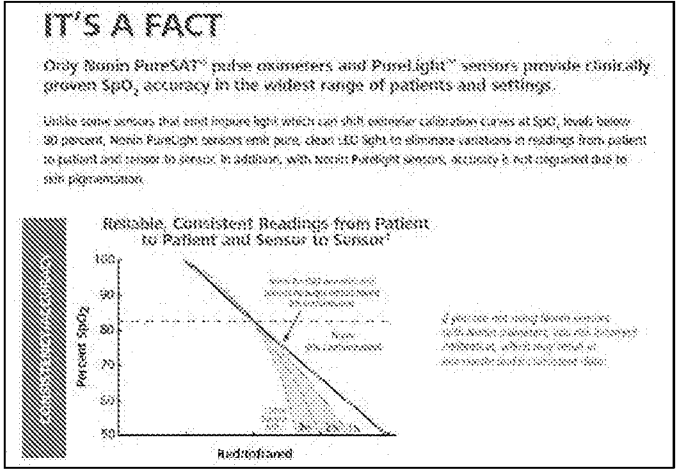
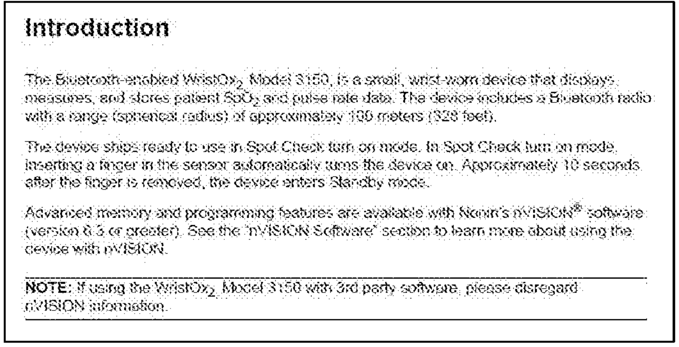
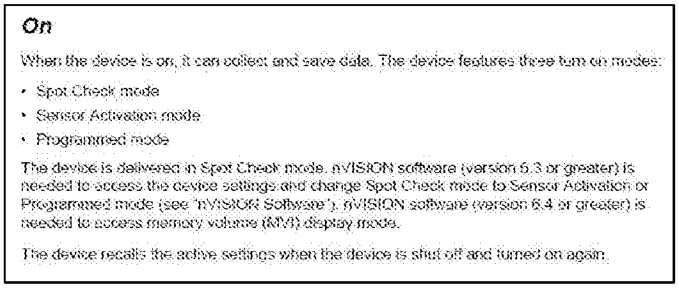
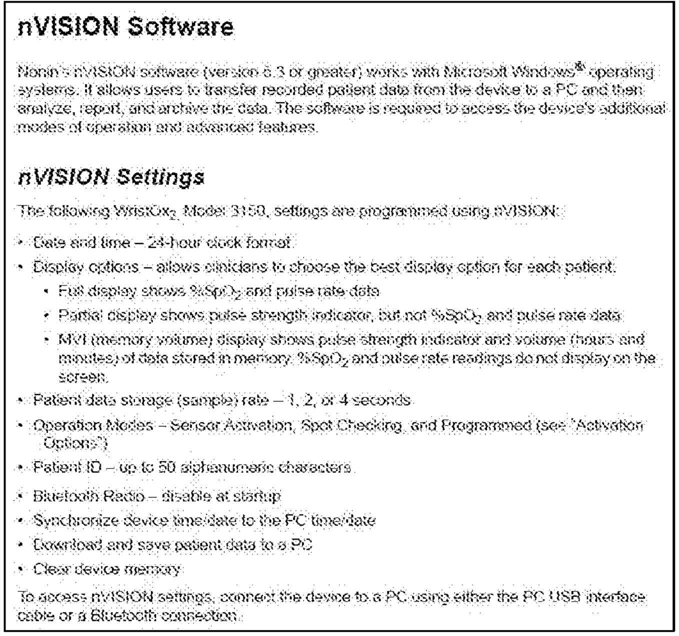
	 IT'S A FACT Only Nonin PureSAT™ pulse oximeters and PureLight™ sensors provide clinically proven SpO_2 accuracy in the widest range of patients and settings. Unlike some sensors that emit impure light which can shift oximeter calibration curves at SpO_2 levels below 80 percent, Nonin PureLight sensors emit pure, clean LED light to eliminate variations in readings from patient to patient and sensor to sensor. In addition, with Nonin PureLight sensors, accuracy is not degraded due to skin pigmentation. Reliable, Consistent Readings from Patient to Patient and Sensor to Sensor¹ (Brochure, p. 2)
[1F] the measurement device further comprising a receiver configured to: capture light while the LEDs are off and convert the captured light into a first signal and capture light while at least one of the LEDs is on and convert the captured light into a second signal, the captured light including at least a portion of the	Nonin Medical discloses and/or renders obvious "the measurement device further comprising a receiver configured to: capture light while the LEDs are off and convert the captured light into a first signal and capture light while at least one of the LEDs is on and convert the captured light into a second signal, the captured light including at least a portion of the input optical beam reflected from the tissue."

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
input optical beam reflected from the tissue;	 **Introduction** The Bluetooth-enabled WristOx$_2$ Model 3150, is a small, wrist-worn device that displays, measures, and stores patient SpO$_2$ and pulse rate data. The device includes a Bluetooth radio with a range (spherical radius) of approximately 100 meters (328 feet). The device ships ready to use in Spot Check turn on mode. In Spot Check turn on mode, inserting a finger in the sensor automatically turns the device on. Approximately 10 seconds after the finger is removed, the device enters Standby mode. Advanced memory and programming features are available with Nonin's nVISION® software (version 6.3 or greater). See the "nVISION Software" section to learn more about using the device with nVISION. **NOTE:** If using the WristOx$_2$ Model 3150 with 3rd party software, please disregard nVISION information. (Operator's Manual, p. 10)  ***On*** When the device is on, it can collect and save data. The device features three turn on modes: • Spot Check mode • Sensor Activation mode • Programmed mode The device is delivered in Spot Check mode. nVISION software (version 6.3 or greater) is needed to access the device settings and change Spot Check mode to Sensor Activation or Programmed mode (see "nVISION Software"). nVISION software (version 6.4 or greater) is needed to access memory volume (MVI) display mode. The device recalls the active settings when the device is shut off and turned on again. (Operator's Manual, p. 12)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters

	
	nVISION Software
	Nonin's nVISION software (version 6.3 or greater) works with Microsoft Windows® operating systems. It allows users to transfer recorded patient data from the device to a PC and then analyze, report, and archive the data. The software is required to access the device's additional modes of operation and advanced features.
	nVISION Settings
	The following WristOx$_2$ Model 3150, settings are programmed using nVISION:
	• Date and time – 24-hour clock format
	• Display options – allows clinicians to choose the best display option for each patient:
	  • Full display shows %SpO$_2$ and pulse rate data
	  • Partial display shows pulse strength indicator, but not %SpO$_2$ and pulse rate data
	  • MVI (memory volume) display shows pulse strength indicator and volume (hours and minutes) of data stored in memory. %SpO$_2$ and pulse rate readings do not display on the screen.
	• Patient data storage (sample) rate – 1, 2, or 4 seconds
	• Operation Modes – Sensor Activation, Spot Checking, and Programmed (see "Activation Options")
	• Patient ID – up to 50 alphanumeric characters
	• Bluetooth Radio – disable at startup
	• Synchronize device time/date to the PC time/date
	• Download and save patient data to a PC
	• Clear device memory
	To access nVISION settings, connect the device to a PC using either the PC USB interface cable or a Bluetooth connection.
	(Operator's Manual, p. 29)

<table>
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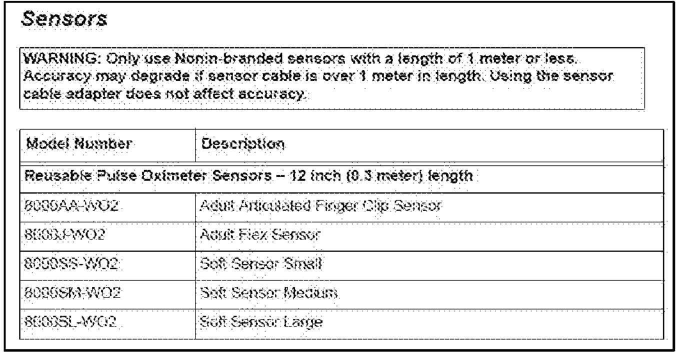
<tr><td></td><td>
<h3>Sensors</h3>
<p>WARNING: Only use Nonin-branded sensors with a length of 1 meter or less. Accuracy may degrade if sensor cable is over 1 meter in length. Using the sensor cable adapter does not affect accuracy.</p>
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<tr><th>Model Number</th><th>Description</th></tr>
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<tr><td>8000SL-WO2</td><td>Soft Sensor Large</td></tr>
</table>
<p>(Operator's Manual, p. 35)</p></td></tr>
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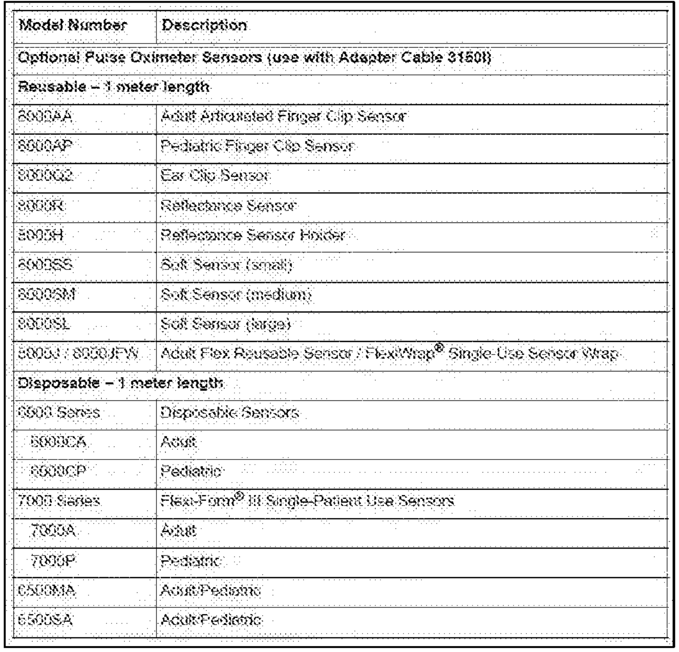
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<tr><td colspan="2">Disposable – 1 meter length</td></tr>
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<tr><td>6000CA</td><td>Adult</td></tr>
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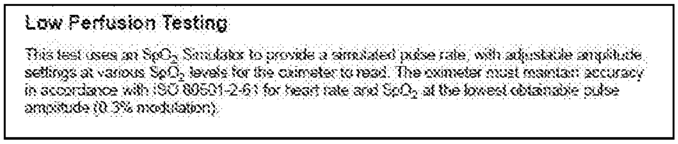
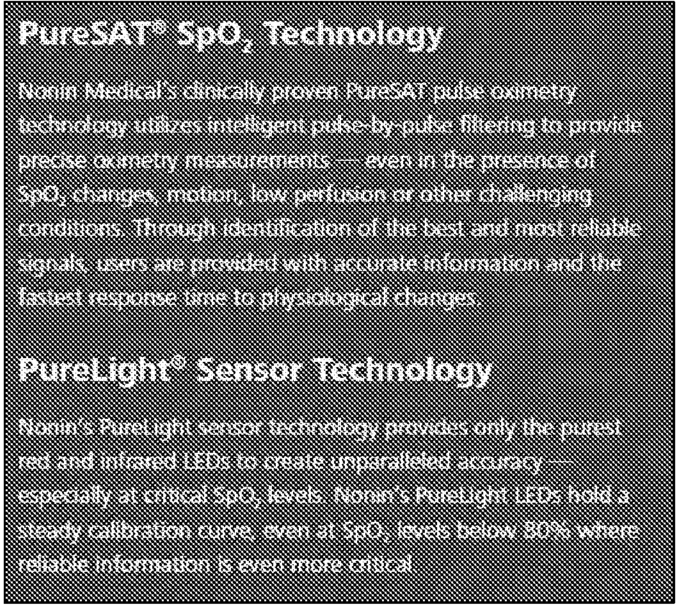
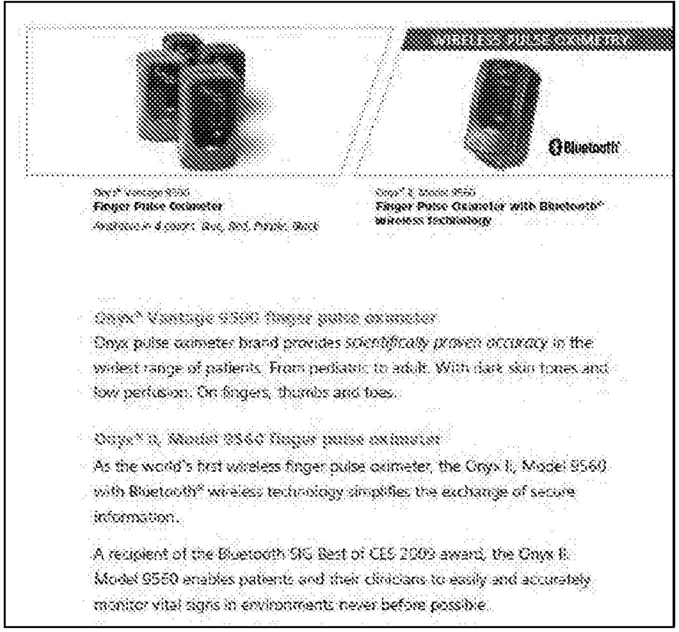
<tr><td>7000 Series</td><td>Flexi-Form® III Single-Patient Use Sensors</td></tr>
<tr><td>7000A</td><td>Adult</td></tr>
<tr><td>7000P</td><td>Pediatric</td></tr>
<tr><td>6500MA</td><td>Adult/Pediatric</td></tr>
<tr><td>6500SA</td><td>Adult/Pediatric</td></tr>
</table>
(Operator's Manual, p. 35)


Low Perfusion Testing

This test uses an SpO_2 Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO_2 levels for the oximeter to read. The oximeter must maintain accuracy in accordance with ISO 80601-2-61 for heart rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).

(Operator's Manual, p. 43)
</td></tr>
</table>

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 **PureSAT® SpO_2 Technology** Nonin Medical's clinically proven PureSAT pulse oximetry technology utilizes intelligent pulse-by-pulse filtering to provide precise oximetry measurements — even in the presence of SpO_2 changes, motion, low perfusion or other challenging conditions. Through identification of the best and most reliable signals, users are provided with accurate information and the fastest response time to physiological changes. **PureLight® Sensor Technology** Nonin's PureLight sensor technology provides only the purest red and infrared LEDs to create unparalleled accuracy — especially at critical SpO_2 levels. Nonin's PureLight LEDs hold a steady calibration curve, even at SpO_2 levels below 80% where reliable information is even more critical. (Product Catalog, p. 4)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 WIRELESS PULSE OXIMETRY Onyx® Vantage 9590 **Finger Pulse Oximeter** *Available in 4 colors: Blue, Red, Purple, Black* Onyx® II, Model 9560 **Finger Pulse Oximeter with Bluetooth® wireless technology** Bluetooth® Onyx® Vantage 9590 finger pulse oximeter Onyx pulse oximeter brand provides *scientifically proven accuracy* in the widest range of patients. From pediatric to adult. With dark skin tones and low perfusion. On fingers, thumbs and toes. Onyx® II, Model 9560 finger pulse oximeter As the world's first wireless finger pulse oximeter, the Onyx II, Model 9560 with Bluetooth® wireless technology simplifies the exchange of secure information. A recipient of the Bluetooth SIG Best of CES 2009 award, the Onyx II, Model 9560 enables patients and their clinicians to easily and accurately monitor vital signs in environments never before possible. (Product Catalog, p. 7)

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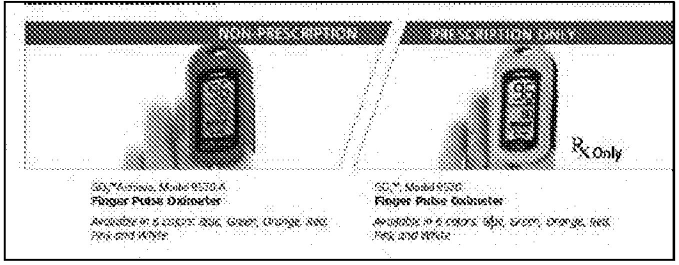
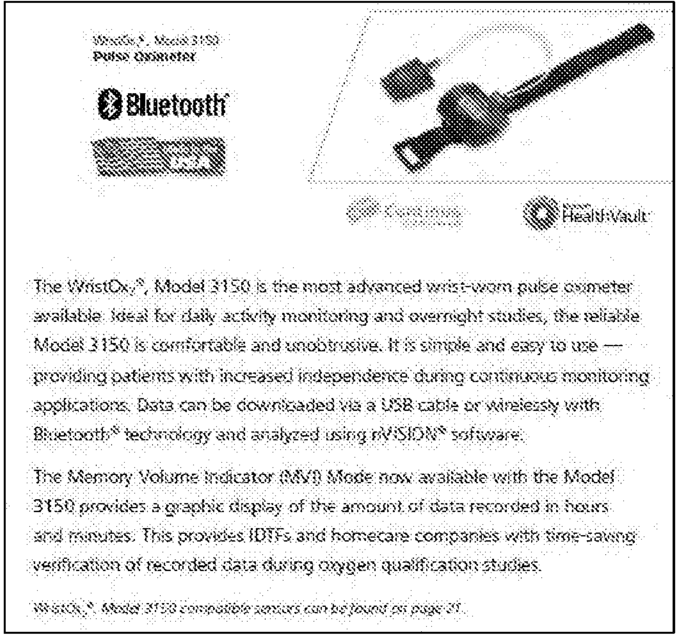
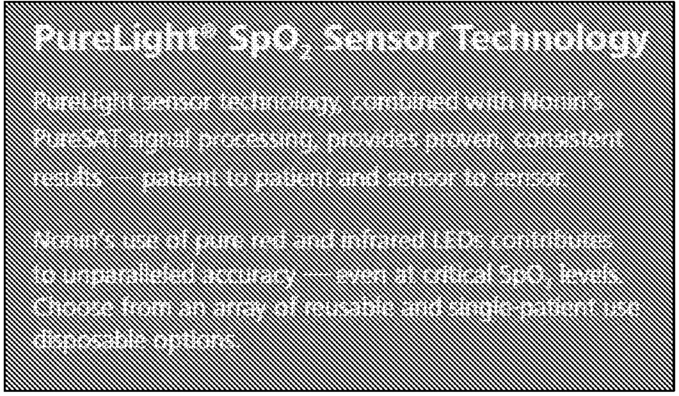
	 (Product Catalog, p. 9)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 WristOx$_2$®, Model 3150 Pulse Oximeter The WristOx$_2$®, Model 3150 is the most advanced wrist-worn pulse oximeter available. Ideal for daily activity monitoring and overnight studies, the reliable Model 3150 is comfortable and unobtrusive. It is simple and easy to use — providing patients with increased independence during continuous monitoring applications. Data can be downloaded via a USB cable or wirelessly with Bluetooth® technology and analyzed using nVISION® software. The Memory Volume Indicator (MVI) Mode now available with the Model 3150 provides a graphic display of the amount of data recorded in hours and minutes. This provides IDTFs and homecare companies with time-saving verification of recorded data during oxygen qualification studies. *WristOx$_2$®, Model 3150 compatible sensors can be found on page 21.* (Product Catalog, p. 11)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 PureLight® SpO_2 Sensor Technology PureLight sensor technology, combined with Nonin's PureSAT signal processing, provides proven, consistent results — patient to patient and sensor to sensor. Nonin's use of pure red and infrared LEDs contributes to unparalleled accuracy — even at critical SpO_2 levels. Choose from an array of reusable and single-patient use disposable options. (Product Catalog, p. 16)

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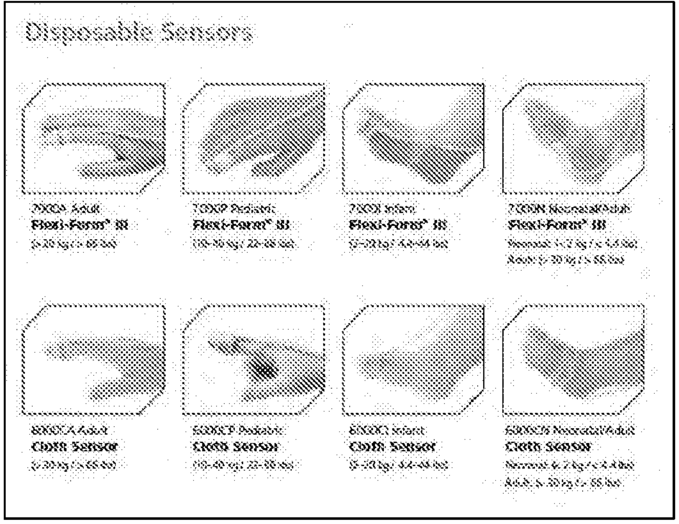
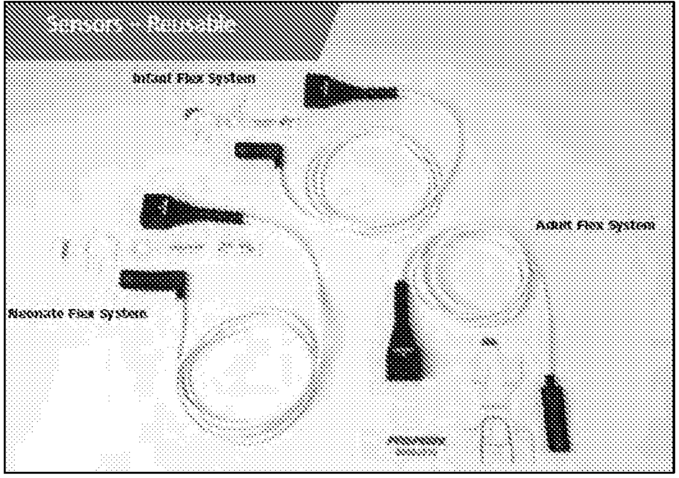
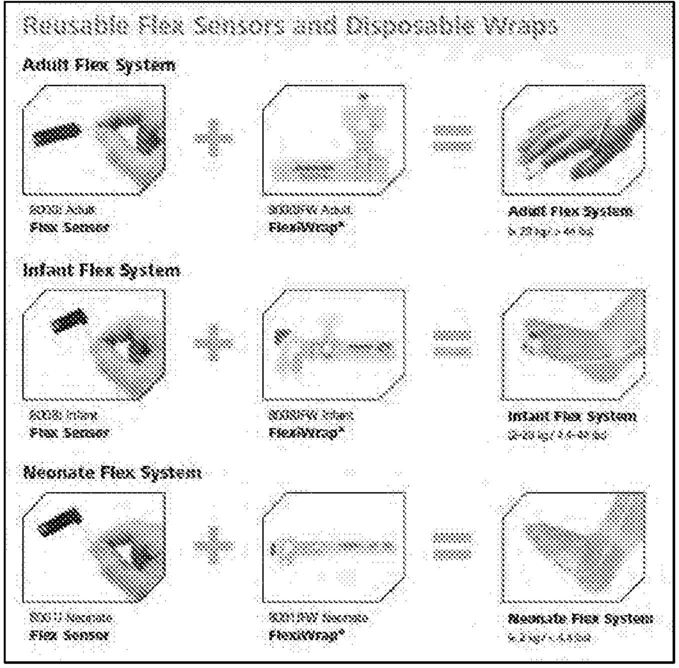
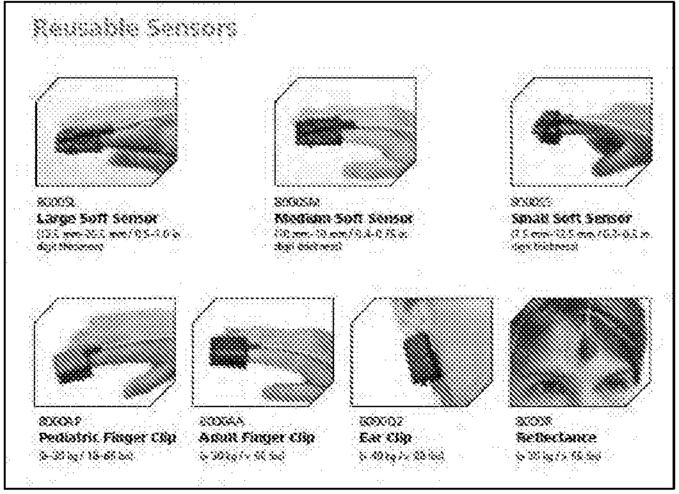
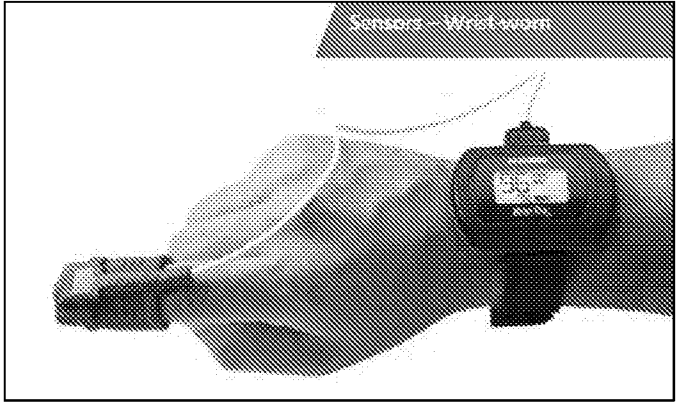
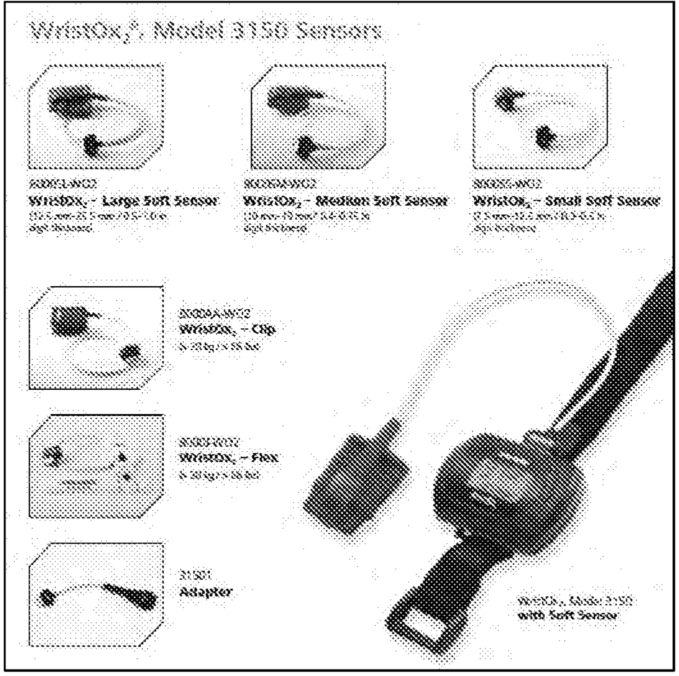
	 Disposable Sensors 7000A Adult **Flexi-Form® III** 7000P Pediatric **Flexi-Form® III** 7000I Infant **Flexi-Form® III** 7000N Neonatal/Adult **Flexi-Form® III** 8000CA Adult **Cloth Sensor** 8000CP Pediatric **Cloth Sensor** 8000CI Infant **Cloth Sensor** 8000CN Neonatal/Adult **Cloth Sensor** (Product Catalog, p. 17)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 18)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 Reusable Flex Sensors and Disposable Wraps Adult Flex System Flex Sensor FlexiWrap* Adult Flex System Infant Flex System Flex Sensor FlexiWrap* Infant Flex System Neonate Flex System Flex Sensor FlexiWrap* Neonate Flex System (Product Catalog, p. 18)

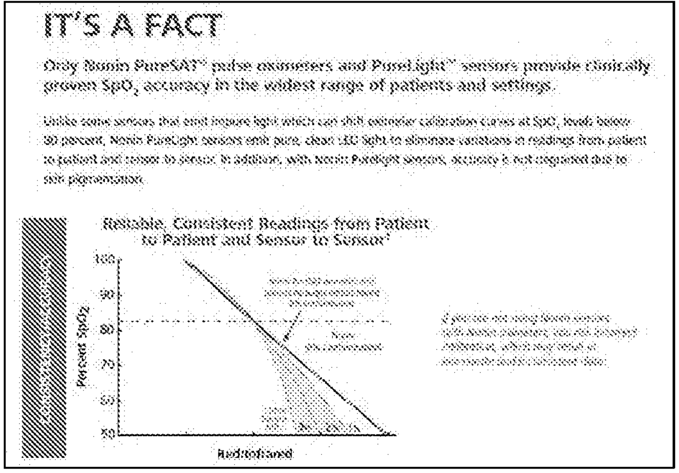
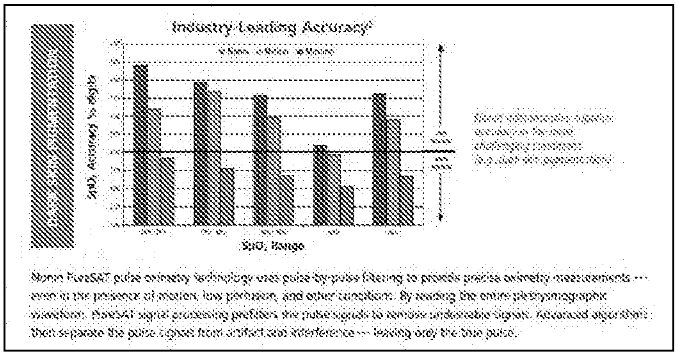
Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 Reusable Sensors 8000SL **Large Soft Sensor** 8000SM **Medium Soft Sensor** 8000SS **Small Soft Sensor** 8000AP **Pediatric Finger Clip** 8000AA **Adult Finger Clip** 8000Q2 **Ear Clip** 8000R **Reflectance** (Product Catalog, p. 19)

Asserted Claim of '040 Patent	**Nonin Medical Pulse Oximeters**
	 (Product Catalog, p. 21)

Asserted Claim of ’040 Patent	Nonin Medical Pulse Oximeters
	 WristOx2®, Model 3150 Sensors **WristOx2 – Large Soft Sensor** **WristOx2 – Medium Soft Sensor** **WristOx2 – Small Soft Sensor** **WristOx2 – Clip** **WristOx2 – Flex** **Adapter** WristOx2, Model 3150 with Soft Sensor (Product Catalog, p. 21)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 31)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 OEM III Module Internal OEM Pulse Oximeter Xpod® External Pulse Oximeter with Mini-12 or USB Connectors Onyx® II, Model 9560 OEM Finger Pulse Oximeter with Bluetooth® wireless technology Nonin 3230 Bluetooth® Smart OEM Finger Pulse Oximeter with Bluetooth® Smart wireless technology Nonin 3231 USB OEM Finger Pulse Oximeter with USB Connector WristOx2®, Model 3150 OEM Wrist-worn Pulse Oximeter with Bluetooth® wireless technology (Product Catalog, p. 31)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 IT'S A FACT Only Nonin PureSAT™ pulse oximeters and PureLight™ sensors provide clinically proven SpO_2 accuracy in the widest range of patients and settings. Unlike some sensors that emit impure light which can shift oximeter calibration curves at SpO_2 levels below 80 percent, Nonin PureLight sensors emit pure, clean LED light to eliminate variations in readings from patient to patient and sensor to sensor. In addition, with Nonin PureLight sensors, accuracy is not degraded due to skin pigmentation. (Brochure, p.  Nonin PureSAT pulse oximetry technology uses pulse-by-pulse filtering to provide precise oximetry measurements — even in the presence of motion, low perfusion, and other conditions. By reading the entire plethysmographic waveform, PureSAT signal processing prefilters the pulse signals to remove undesirable signals. Advanced algorithms then separate the pulse signals from artifact and interference — leaving only the true pulse. (Brochure, p. 2)

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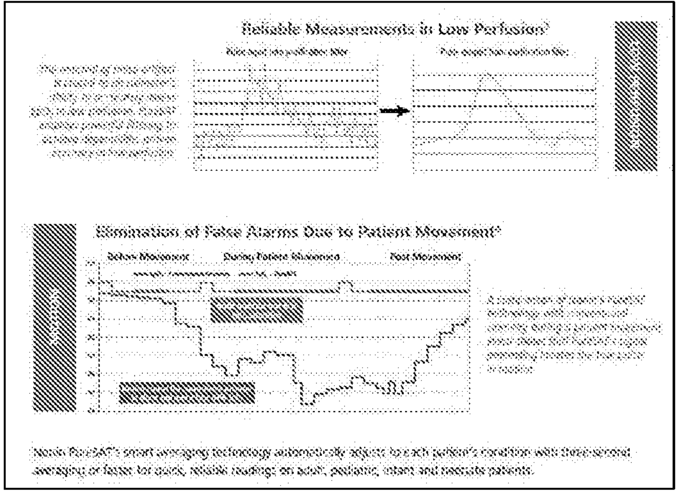
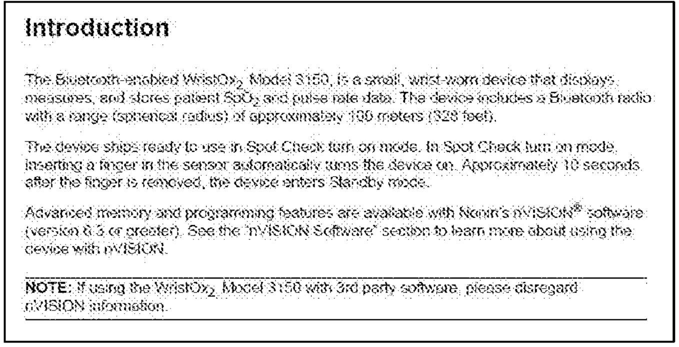
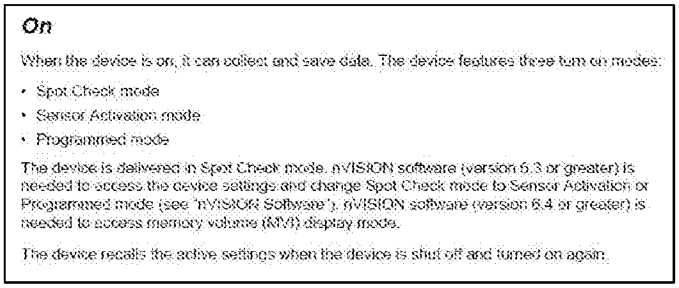
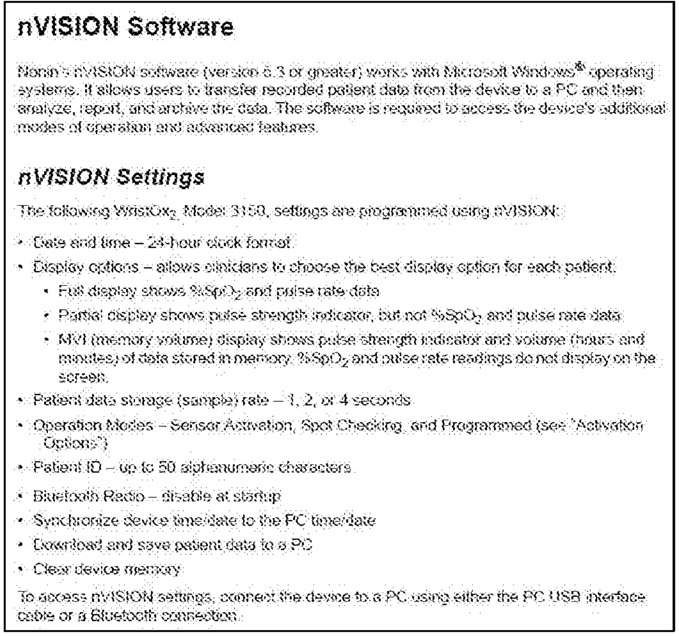
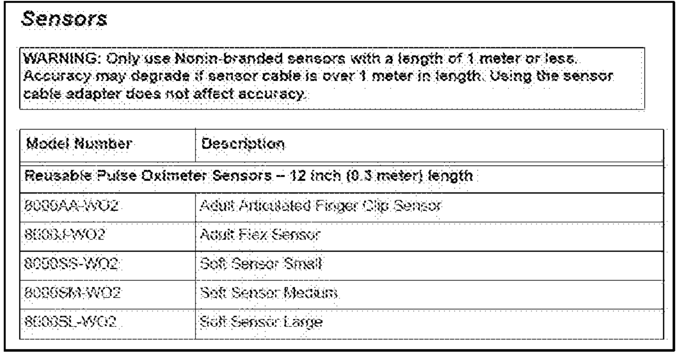
	 Nonin PureSAT's smart averaging technology automatically adjusts to each patient's condition with three-second averaging or faster for quick, reliable readings on adult, pediatric, infant and neonate patients. (Brochure, p. 2)
[1G] the measurement device configured to improve a signal-to-noise ratio of the input optical beam reflected from the tissue by differencing the first signal and the second signal;	Nonin Medical discloses and/or renders obvious "the measurement device configured to improve a signal-to-noise ratio of the input optical beam reflected from the tissue by differencing the first signal and the second signal."

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 **Introduction** The Bluetooth-enabled WristOx$_2$ Model 3150, is a small, wrist-worn device that displays, measures, and stores patient SpO$_2$ and pulse rate data. The device includes a Bluetooth radio with a range (spherical radius) of approximately 100 meters (328 feet). The device ships ready to use in Spot Check turn on mode. In Spot Check turn on mode, inserting a finger in the sensor automatically turns the device on. Approximately 10 seconds after the finger is removed, the device enters Standby mode. Advanced memory and programming features are available with Nonin's nVISION® software (version 6.3 or greater). See the "nVISION Software" section to learn more about using the device with nVISION. **NOTE:** If using the WristOx$_2$ Model 3150 with 3rd party software, please disregard nVISION information. (Operator's Manual, p. 10)  ***On*** When the device is on, it can collect and save data. The device features three turn on modes: • Spot Check mode • Sensor Activation mode • Programmed mode The device is delivered in Spot Check mode. nVISION software (version 6.3 or greater) is needed to access the device settings and change Spot Check mode to Sensor Activation or Programmed mode (see "nVISION Software"). nVISION software (version 6.4 or greater) is needed to access memory volume (MV) display mode. The device recalls the active settings when the device is shut off and turned on again. (Operator's Manual, p. 12)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters

	
	nVISION Software
	Nonin's nVISION software (version 6.3 or greater) works with Microsoft Windows® operating systems. It allows users to transfer recorded patient data from the device to a PC and then analyze, report, and archive the data. The software is required to access the device's additional modes of operation and advanced features.
	nVISION Settings
	The following WristOx_2 Model 3150, settings are programmed using nVISION:
	• Date and time – 24-hour clock format
	• Display options – allows clinicians to choose the best display option for each patient:
	  • Full display shows %SpO_2 and pulse rate data
	  • Partial display shows pulse strength indicator, but not %SpO_2 and pulse rate data
	  • MVI (memory volume) display shows pulse strength indicator and volume (hours and minutes) of data stored in memory. %SpO_2 and pulse rate readings do not display on the screen.
	• Patient data storage (sample) rate – 1, 2, or 4 seconds
	• Operation Modes – Sensor Activation, Spot Checking, and Programmed (see "Activation Options")
	• Patient ID – up to 50 alphanumeric characters
	• Bluetooth Radio – disable at startup
	• Synchronize device time/date to the PC time/date
	• Download and save patient data to a PC
	• Clear device memory
	To access nVISION settings, connect the device to a PC using either the PC USB interface cable or a Bluetooth connection.
	(Operator's Manual, p. 29)

<table>
<tr><th>Asserted Claim of '040 Patent</th><th>Nonin Medical Pulse Oximeters</th></tr>
<tr><td></td><td>


Sensors

WARNING: Only use Nonin-branded sensors with a length of 1 meter or less. Accuracy may degrade if sensor cable is over 1 meter in length. Using the sensor cable adapter does not affect accuracy.

<table>
<tr><th>Model Number</th><th>Description</th></tr>
<tr><td colspan="2">Reusable Pulse Oximeter Sensors – 12 inch (0.3 meter) length</td></tr>
<tr><td>8000AA-WO2</td><td>Adult Articulated Finger Clip Sensor</td></tr>
<tr><td>8000J-WO2</td><td>Adult Flex Sensor</td></tr>
<tr><td>8000SS-WO2</td><td>Soft Sensor Small</td></tr>
<tr><td>8000SM-WO2</td><td>Soft Sensor Medium</td></tr>
<tr><td>8000SL-WO2</td><td>Soft Sensor Large</td></tr>
</table>

(Operator's Manual, p. 35)
</td></tr>
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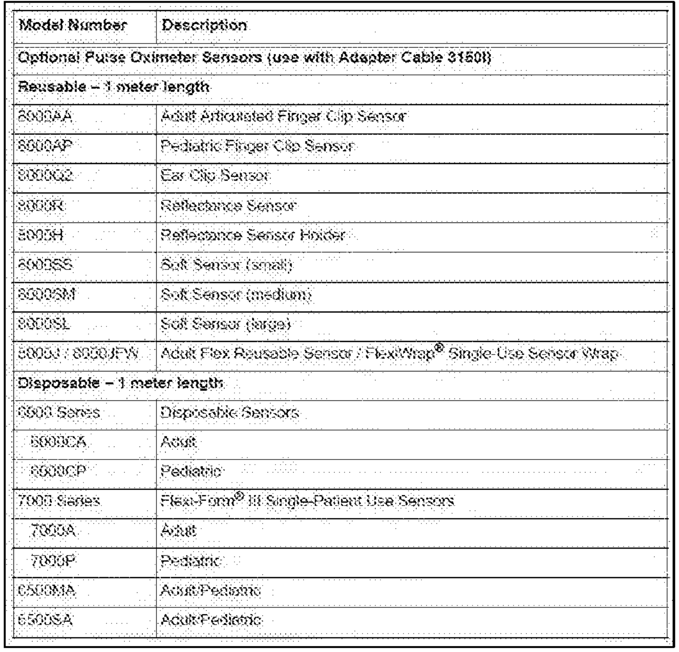
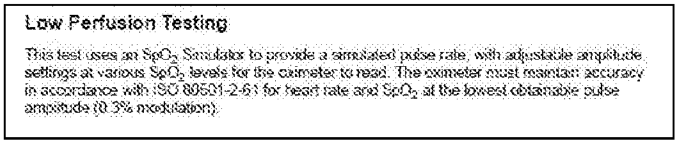
	 (Operator's Manual, p. 35)  (Operator's Manual, p. 43)

Model Number	Description
Optional Pulse Oximeter Sensors (use with Adapter Cable 3150I)	
Reusable – 1 meter length	
8000AA	Adult Articulated Finger Clip Sensor
8000AP	Pediatric Finger Clip Sensor
8000Q2	Ear Clip Sensor
8000R	Reflectance Sensor
8000H	Reflectance Sensor Holder
8000SS	Soft Sensor (small)
8000SM	Soft Sensor (medium)
8000SL	Soft Sensor (large)
8000J / 8000JFW	Adult Flex Reusable Sensor / FlexiWrap® Single-Use Sensor Wrap
Disposable – 1 meter length	
6000 Series	Disposable Sensors
6000CA	Adult
6000CP	Pediatric
7000 Series	Flexi-Form® III Single-Patient Use Sensors
7000A	Adult
7000P	Pediatric
6500MA	Adult/Pediatric
6500SA	Adult/Pediatric

Low Perfusion Testing

This test uses an SpO_2 Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO_2 levels for the oximeter to read. The oximeter must maintain accuracy in accordance with ISO 80601-2-61 for heart rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).

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	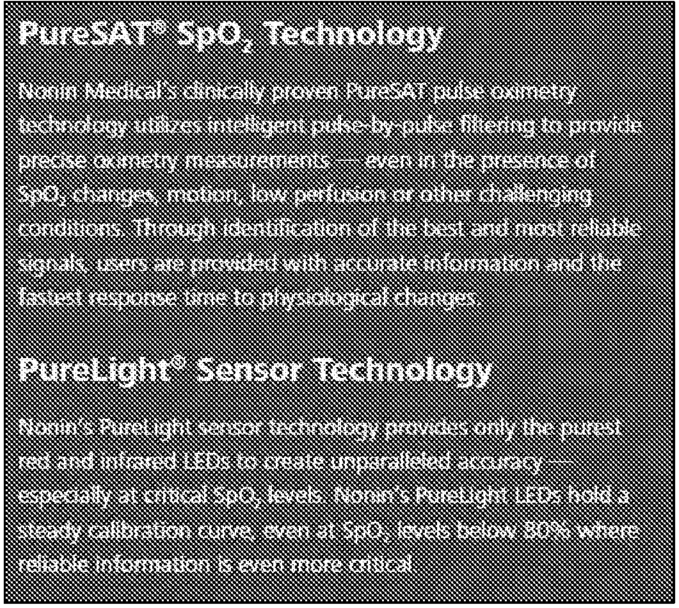 **PureSAT® SpO_2 Technology** Nonin Medical's clinically proven PureSAT pulse oximetry technology utilizes intelligent pulse-by-pulse filtering to provide precise oximetry measurements — even in the presence of SpO_2 changes, motion, low perfusion or other challenging conditions. Through identification of the best and most reliable signals, users are provided with accurate information and the fastest response time to physiological changes. **PureLight® Sensor Technology** Nonin's PureLight sensor technology provides only the purest red and infrared LEDs to create unparalleled accuracy — especially at critical SpO_2 levels. Nonin's PureLight LEDs hold a steady calibration curve, even at SpO_2 levels below 80% where reliable information is even more critical. (Product Catalog, p. 4)

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	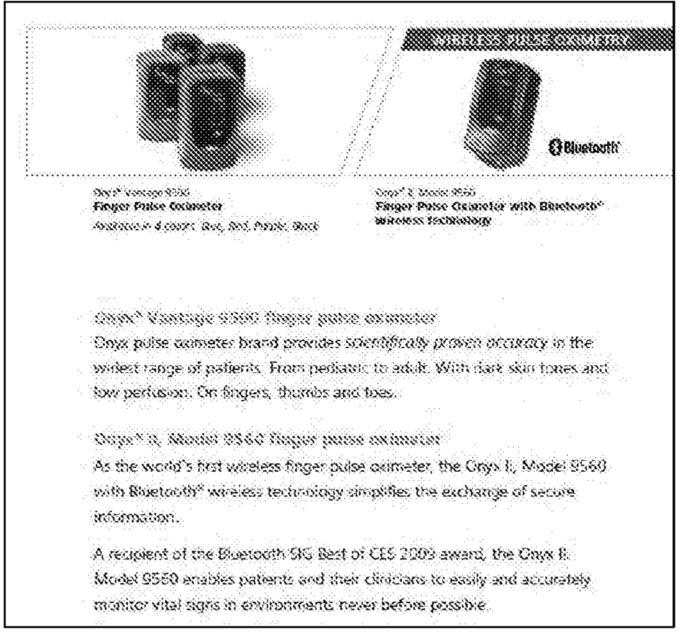 Onyx® Vantage 9590 **Finger Pulse Oximeter** *Available in 4 colors: Blue, Red, Purple, Black* Onyx® II, Model 9560 **Finger Pulse Oximeter with Bluetooth® wireless technology** Onyx® Vantage 9590 finger pulse oximeter Onyx pulse oximeter brand provides *scientifically proven accuracy* in the widest range of patients. From pediatric to adult. With dark skin tones and low perfusion. On fingers, thumbs and toes. Onyx® II, Model 9560 finger pulse oximeter As the world's first wireless finger pulse oximeter, the Onyx II, Model 9560 with Bluetooth® wireless technology simplifies the exchange of secure information. A recipient of the Bluetooth SIG Best of CES 2009 award, the Onyx II, Model 9560 enables patients and their clinicians to easily and accurately monitor vital signs in environments never before possible. (Product Catalog, p. 7)

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	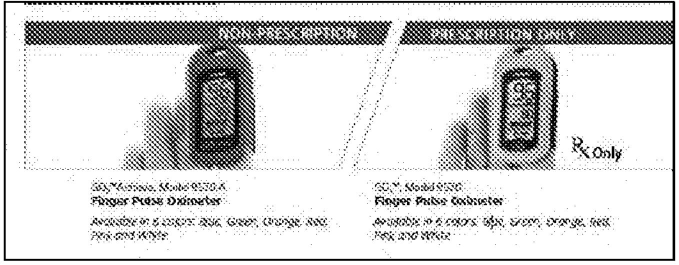 (Product Catalog, p. 9)

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	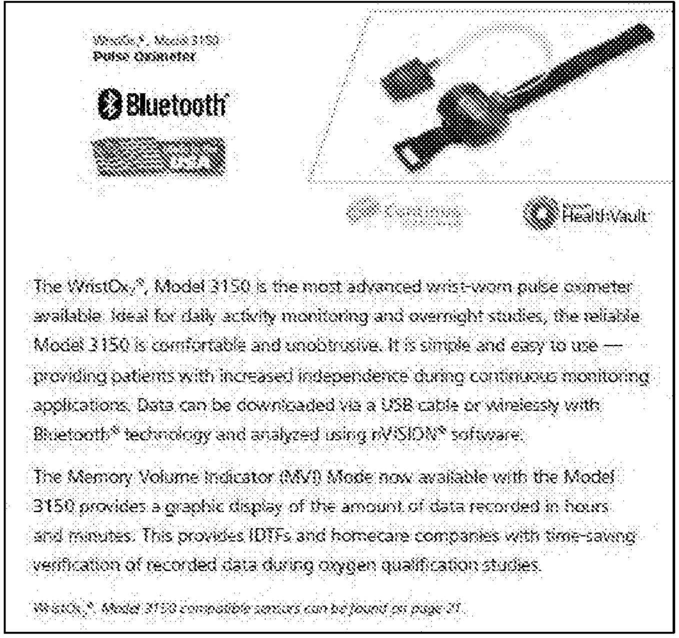 WristOx$_2$®, Model 3150 **Pulse Oximeter** The WristOx$_2$®, Model 3150 is the most advanced wrist-worn pulse oximeter available. Ideal for daily activity monitoring and overnight studies, the reliable Model 3150 is comfortable and unobtrusive. It is simple and easy to use — providing patients with increased independence during continuous monitoring applications. Data can be downloaded via a USB cable or wirelessly with Bluetooth® technology and analyzed using nVISION® software. The Memory Volume Indicator (MVI) Mode now available with the Model 3150 provides a graphic display of the amount of data recorded in hours and minutes. This provides IDTFs and homecare companies with time-saving verification of recorded data during oxygen qualification studies. *WristOx$_2$®, Model 3150 compatible sensors can be found on page 21.* (Product Catalog, p. 11)

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	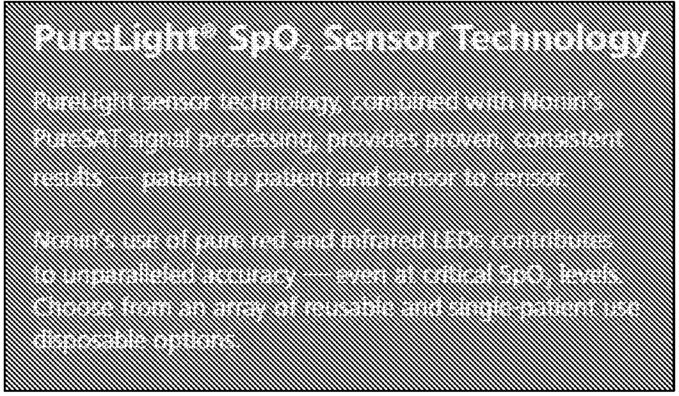 PureLight® SpO_2 Sensor Technology PureLight sensor technology, combined with Nonin's PureSAT signal processing, provides proven, consistent results — patient to patient and sensor to sensor. Nonin's use of pure red and infrared LEDs contributes to unparalleled accuracy — even at critical SpO_2 levels. Choose from an array of reusable and single-patient use disposable options. (Product Catalog, p. 16)

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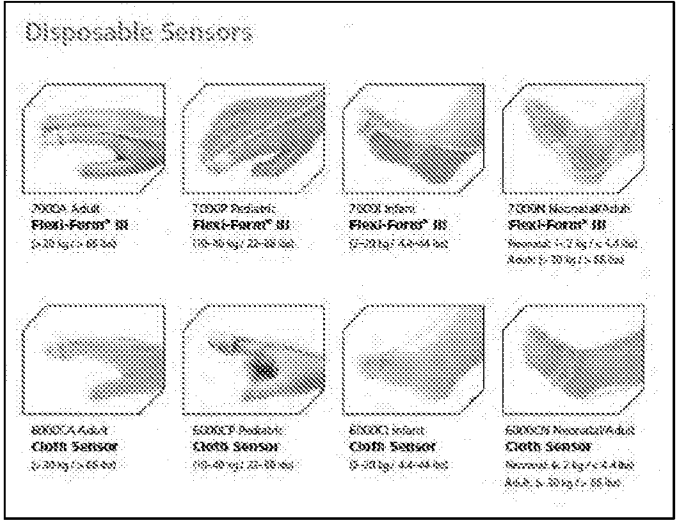
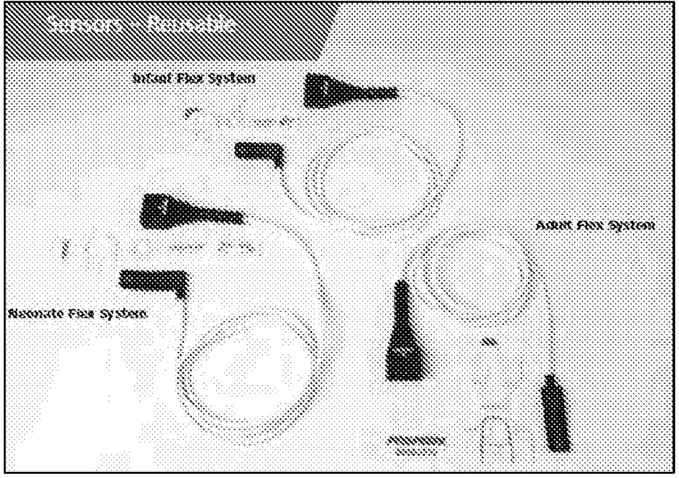
	 Disposable Sensors 7000A Adult **Flexi-Form® III** (> 30 kg / > 66 lbs) 7000P Pediatric **Flexi-Form® III** (10–40 kg / 22–88 lbs) 7000I Infant **Flexi-Form® III** (2–20 kg / 4.4–44 lbs) 7000N Neonatal/Adult **Flexi-Form® III** Neonatal: < 2 kg / < 4.4 lbs Adult: > 30 kg / > 66 lbs 8000CA Adult **Cloth Sensor** (> 30 kg / > 66 lbs) 8000CP Pediatric **Cloth Sensor** (10–40 kg / 22–88 lbs) 8000CI Infant **Cloth Sensor** (2–20 kg / 4.4–44 lbs) 8000CN Neonatal/Adult **Cloth Sensor** Neonatal: < 2 kg / < 4.4 lbs Adult: > 30 kg / > 66 lbs (Product Catalog, p. 17)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 18)

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	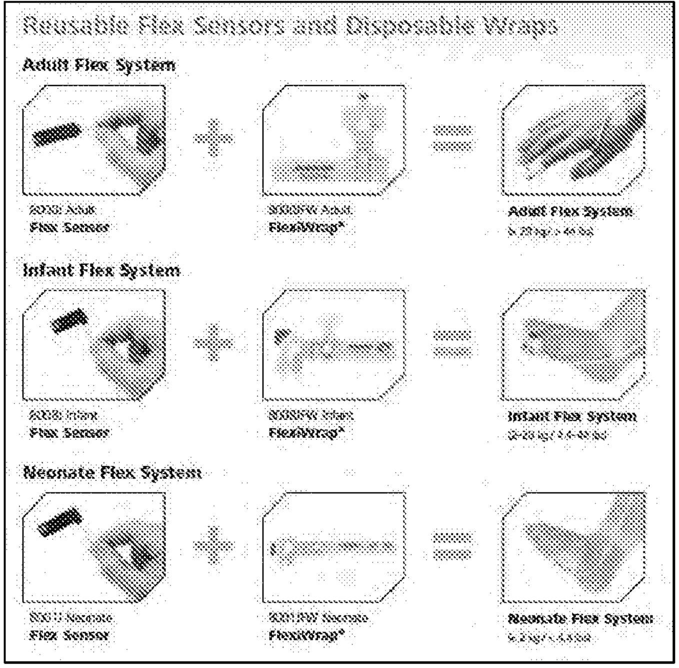 (Product Catalog, p. 18)

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	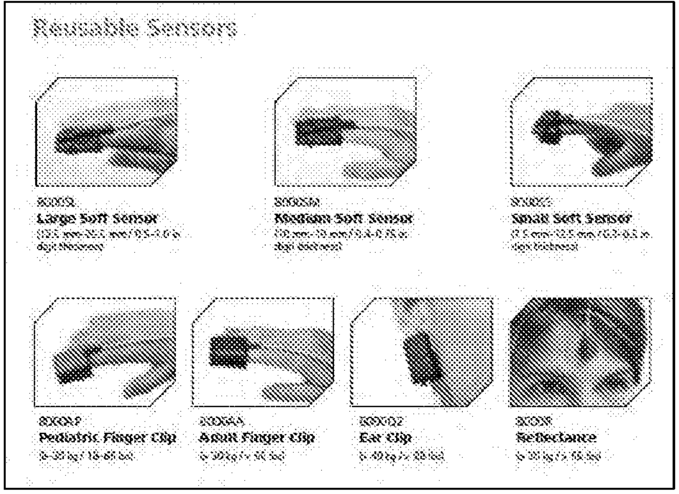 Reusable Sensors 8000SL Large Soft Sensor 8000SM Medium Soft Sensor 8000SS Small Soft Sensor 8000AP Pediatric Finger Clip 8000AA Adult Finger Clip 8000Q2 Ear Clip 8000R Reflectance (Product Catalog, p. 19)

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	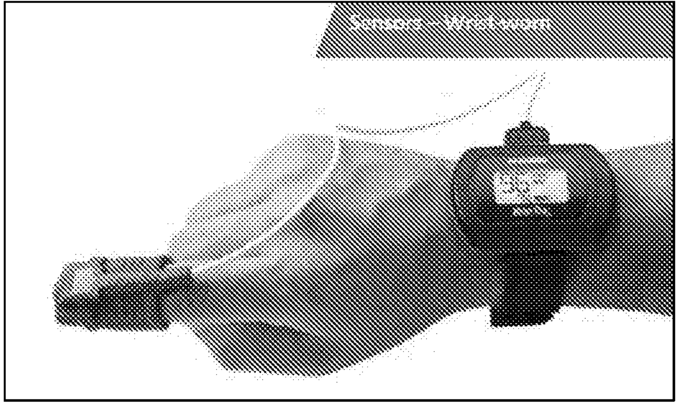 (Product Catalog, p. 21)

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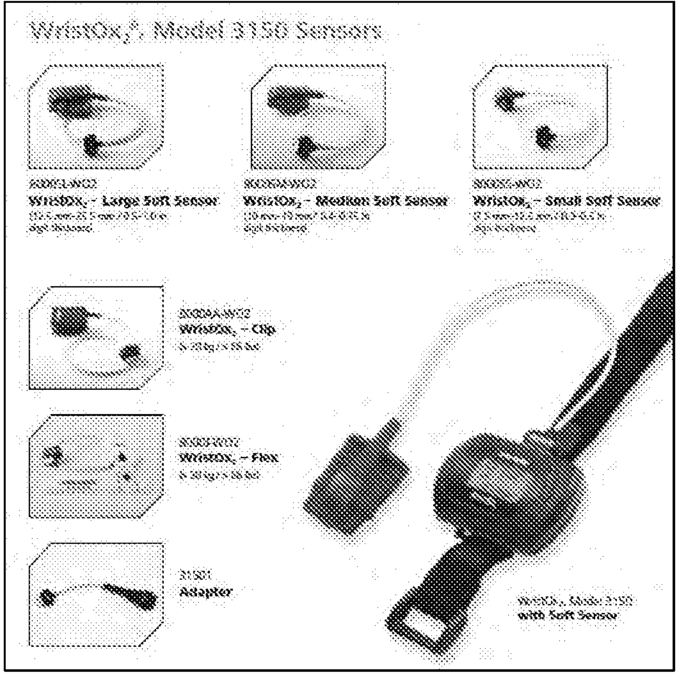
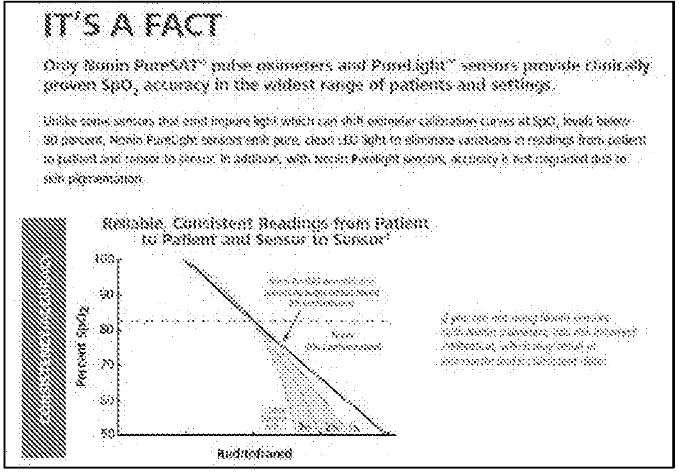
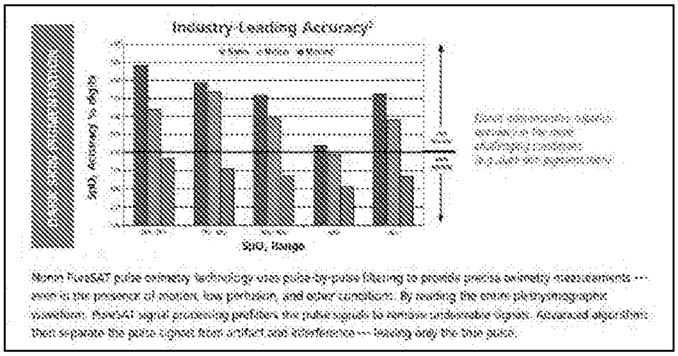
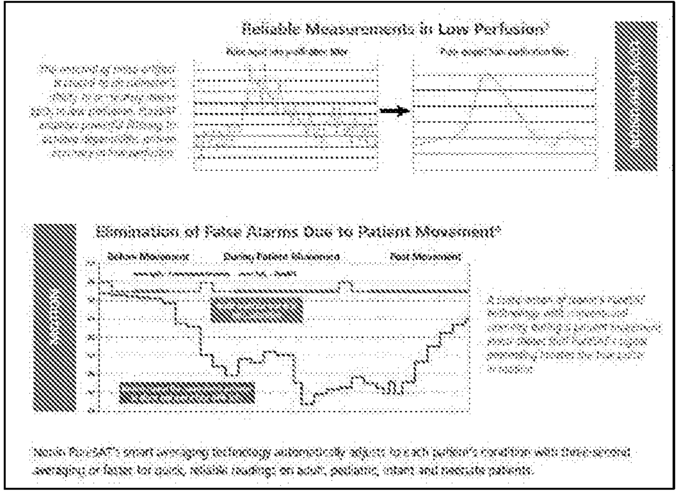
	 (Product Catalog, p. 21)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 31)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 OEM III Module **Internal OEM Pulse Oximeter** Xpod® **External Pulse Oximeter with Mini-12 or USB Connectors** Onyx® II, Model 9560 **OEM Finger Pulse Oximeter with Bluetooth® wireless technology** Nonin 3230 Bluetooth® Smart **OEM Finger Pulse Oximeter with Bluetooth® Smart wireless technology** Nonin 3231 USB **OEM Finger Pulse Oximeter with USB Connector** WristOx2, Model 3150 **OEM Wrist-worn Pulse Oximeter with Bluetooth® wireless technology** (Product Catalog, p. 31)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 IT'S A FACT Only Nonin PureSAT™ pulse oximeters and PureLight™ sensors provide clinically proven SpO$_2$ accuracy in the widest range of patients and settings. Unlike some sensors that emit impure light which can shift oximeter calibration curves at SpO$_2$ levels below 80 percent, Nonin PureLight sensors emit pure, clean LED light to eliminate variations in readings from patient to patient and sensor to sensor. In addition, with Nonin PureLight sensors, accuracy is not degraded due to skin pigmentation. (Brochure, p. 1)  Nonin PureSAT pulse oximetry technology uses pulse-by-pulse filtering to provide precise oximetry measurements — even in the presence of motion, low perfusion, and other conditions. By reading the entire plethysmographic waveform, PureSAT signal processing prefilters the pulse signals to remove undesirable signals. Advanced algorithms then separate the pulse signals from artifact and interference — leaving only the true pulse. (Brochure, p. 2)

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
	 Nonin PureSAT's smart averaging technology automatically adjusts to each patient's condition with three-second averaging or faster for quick, reliable readings on adult, pediatric, infant and neonatal patients. (Brochure, p. 2)
[1H] the light source configured to further improve the signal-to-noise ratio of the input optical beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs;	Nonin Medical discloses and/or renders obvious "the light source configured to further improve the signal-to-noise ratio of the input optical beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs." *See* CHART ONE: '533 Patent, Claim Element 5C above.
[1I] the measurement device further configured to generate an output signal representing at least in part a non-invasive	Nonin Medical discloses and/or renders obvious "the measurement device further configured to generate an output signal representing at least in part a non-invasive measurement on blood contained within the tissue."

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
measurement on blood contained within the tissue; and	*See* CHART ONE: '533 Patent, Claim Element 10 above.
[1J] the wearable device configured to communicate with the smart phone or tablet, the smart phone or tablet comprising a wireless receiver, a wireless transmitter, a display, a voice input module, a speaker, and a touch screen, the smart phone or tablet configured to receive and to process at least a portion of the output signal,	Nonin Medical discloses and/or renders obvious "the wearable device configured to communicate with the smart phone or tablet, the smart phone or tablet comprising a wireless receiver, a wireless transmitter, a display, a voice input module, a speaker, and a touch screen, the smart phone or tablet configured to receive and to process at least a portion of the output signal." *See* CHART ONE: '533 Patent, Claim Elements 5G and 5H above.
[1K] wherein the smart phone or tablet is configured to store and display the processed output signal, wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link.	Nonin Medical discloses and/or renders obvious "wherein the smart phone or tablet is configured to store and display the processed output signal, wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link." *See* CHART ONE: '533 Patent, Claim Elements 5I and 5J above.
[2] The wearable device of claim 1, wherein the receiver is configured to be synchronized to the modulation of the at least one of the LEDs.	Nonin Medical discloses and/or renders obvious "[t]he wearable device of claim 1, wherein the receiver is configured to be synchronized to the modulation of the at least one of the LEDs." *See* CHART ONE: '533 Patent, Claim Element 5F above.
[4] The wearable device of claim 1, wherein the receiver is located a first distance from a first one of the LEDs and a different distance	Nonin Medical discloses and/or renders obvious "[t]he wearable device of claim 1, wherein the receiver is located a first distance from a first one of the LEDs and a different distance from a second one of the LEDs such that the receiver can capture a third signal from the first LED and a

Asserted Claim of '040 Patent	Nonin Medical Pulse Oximeters
from a second one of the LEDs such that the receiver can capture a third signal from the first LED and a fourth signal from the second LED, and wherein the output signal is generated in part by comparing the third and fourth signals.	fourth signal from the second LED, and wherein the output signal is generated in part by comparing the third and fourth signals." *See* CHART ONE: '533 Patent, Claim Element 8 above.

EXHIBIT W-3

U.S. Patent No. 9,861,286 vs Nonin Medical

Priority Date/Publication Date: At least by February 2011 Prior Art Status: §§ 102(a) and (b)

Model 3150 WristOx$_2$ and certain pulse oximeters and pulse oximetry sensors manufactured by Nonin Medical ("Nonin Medical") anticipate the asserted claims of U.S. Patent No. 9,861,286 ("the '286 Patent") or renders those claims obvious alone and/or in view of at least any of the references identified in Apple's Obviousness Combinations Chart.

This chart is based on the following disclosures about Nonin Medical pulse oximeters:

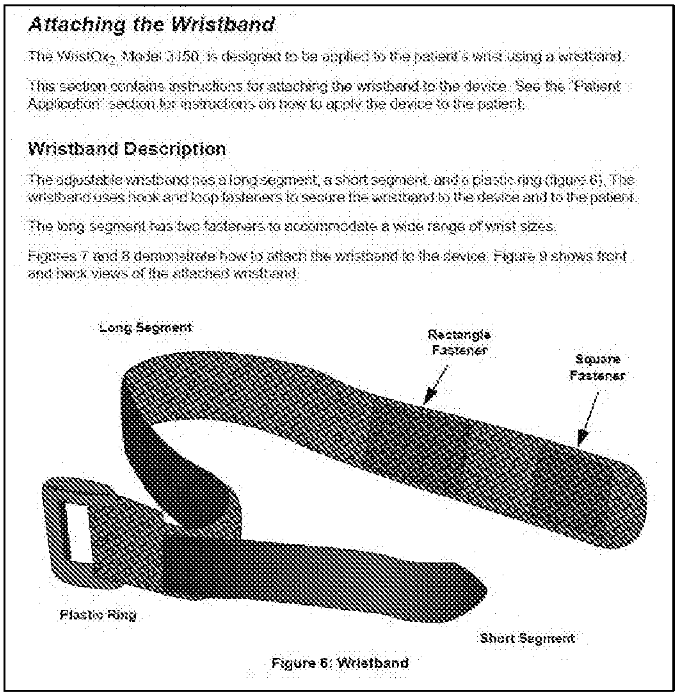
- Nonin Operator's Manual 2014 for Model 3150 WristOx$_2$ Pulse Oximeter ("Operator's Manual")
- Nonin Product Catalog 2014 ("Product Catalog")
- Nonin Brochure 2013 ("Brochure")
- Nonin Pulse Oximeter Sensor Compatibility Guide 2013 ("Compatibility Guide")

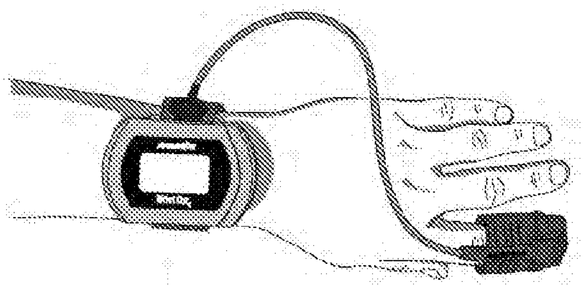
Discovery is ongoing, and Apple reserves the right to amend this chart based on new information about the Nonin Medical pulse oximeters.

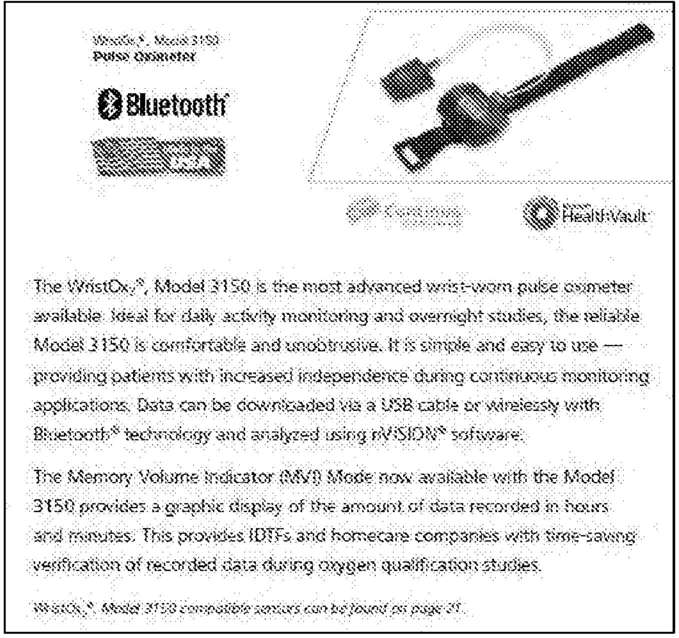
As set forth in Apple's Invalidity Contentions, the below contentions apply the prior art in part in accordance with Apple's assumption that Omni contends the claims are not invalid under 35 U.S.C. § 112. However, Apple's below contentions do not represent Apple's agreement or view as to the meaning, definiteness, written description support for, or enablement of any of the asserted claims. For each dependent claim, the disclosures cited for the claim from which it depends are incorporated by reference.

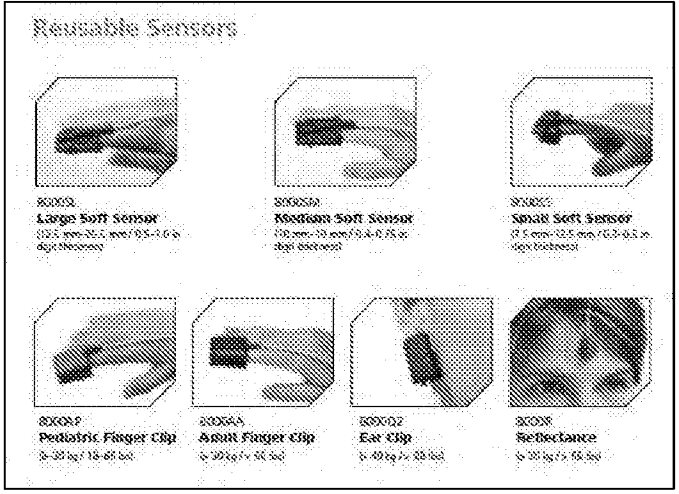
CHART THREE: U.S. Patent No. 9,861,286 vs Nonin Medical

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
[16] A wearable device for use with a smart phone or tablet, the wearable device comprising:	To the extent the preamble is limiting, Nonin Medical discloses and/or renders obvious "[a] wearable device for use with a smart phone or tablet." *See* CHART ONE: '533 Patent, Claim Elements 5, 5G, and 13A above.
[16A] a measurement device including a light source comprising a plurality of light emitting diodes (LEDs) for measuring one or more physiological parameters,	Nonin Medical discloses and/or renders obvious "a measurement device including a light source comprising a plurality of light emitting diodes (LEDs) for measuring one or more physiological parameters." *See* CHART ONE: '533 Patent, Claim Element 13A above.
[16B] the measurement device configured to generate, by modulating at least one of the LEDs having an initial light intensity, an optical beam having a plurality of optical wavelengths,	Nonin Medical discloses and/or renders obvious "the measurement device configured to generate, by modulating at least one of the LEDs having an initial light intensity, an optical beam having a plurality of optical wavelengths." *See* CHART TWO: '040 Patent, Claim Element 1B above.
[16C] wherein at least a portion of the plurality of optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers;	Nonin Medical discloses and/or renders obvious "wherein at least a portion of the plurality of optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers." *See* CHART ONE: '533 Patent, Claim Element 5B above.
[16D] the measurement device comprising one or more lenses configured to receive and to deliver a portion of the optical beam to tissue, wherein the tissue reflects at least a portion of the	Nonin Medical discloses and/or renders obvious "the measurement device comprising one or more lenses configured to receive and to deliver a portion of the optical beam to tissue, wherein the tissue reflects at least a portion of the optical beam delivered to the tissue, and wherein the measurement device is adapted to be placed on a wrist or an ear of a user." *See* CHART ONE: '533 Patent, Claim Element 5D above.

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
optical beam delivered to the tissue, and	
[16E] wherein the measurement device is adapted to be placed on a wrist or an ear of a user;	Nonin Medical discloses and/or renders obvious "wherein the measurement device is adapted to be placed on a wrist or an ear of a user."  *Attaching the Wristband* The WristOx$_2$ Model 3150, is designed to be applied to the patient's wrist using a wristband. This section contains instructions for attaching the wristband to the device. See the "Patient Application" section for instructions on how to apply the device to the patient. **Wristband Description** The adjustable wristband has a long segment, a short segment, and a plastic ring (figure 6). The wristband uses hook and loop fasteners to secure the wristband to the device and to the patient. The long segment has two fasteners to accommodate a wide range of wrist sizes. Figures 7 and 8 demonstrate how to attach the wristband to the device. Figure 9 shows front and back views of the attached wristband. Figure 6: Wristband (Operator's Manual, p. 16)

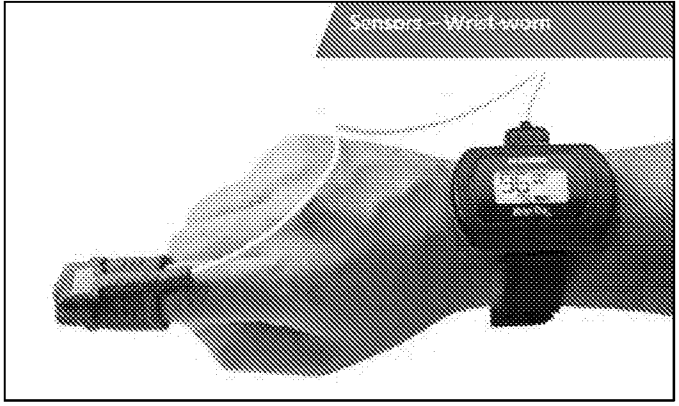
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 Figure 15: Apply Sensor to Patient (Operator's Manual, p. 22)

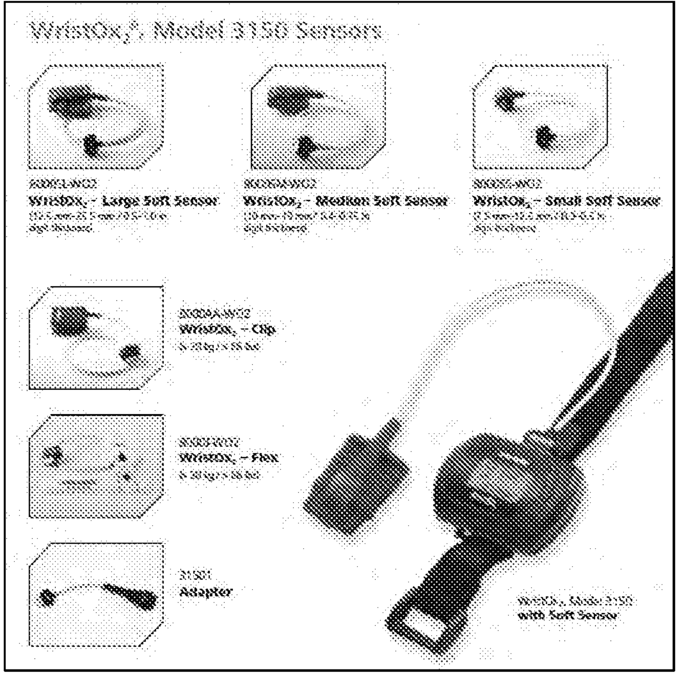
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 WristOx$_2$®, Model 3150 Pulse Oximeter Bluetooth® HealthVault The WristOx$_2$®, Model 3150 is the most advanced wrist-worn pulse oximeter available. Ideal for daily activity monitoring and overnight studies, the reliable Model 3150 is comfortable and unobtrusive. It is simple and easy to use — providing patients with increased independence during continuous monitoring applications. Data can be downloaded via a USB cable or wirelessly with Bluetooth® technology and analyzed using nVISION® software. The Memory Volume Indicator (MVI) Mode now available with the Model 3150 provides a graphic display of the amount of data recorded in hours and minutes. This provides IDTFs and homecare companies with time-saving verification of recorded data during oxygen qualification studies. *WristOx$_2$®, Model 3150 compatible sensors can be found on page 21.* (Product Catalog, p. 11)

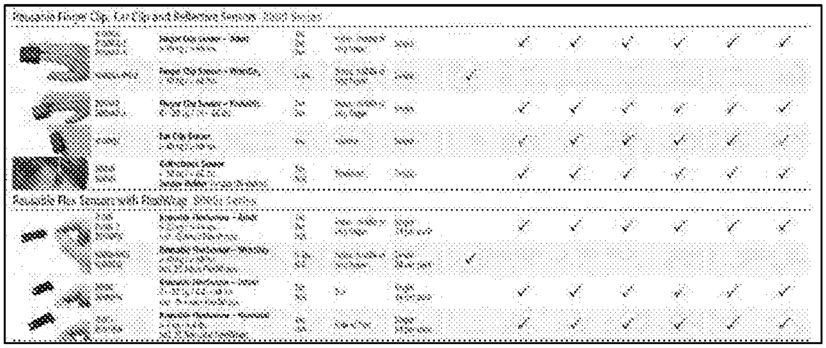
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 Reusable Sensors 8000SL **Large Soft Sensor** 8000SM **Medium Soft Sensor** 8000SS **Small Soft Sensor** 8000AP **Pediatric Finger Clip** 8000AA **Adult Finger Clip** 8000Q2 **Ear Clip** 8000R **Reflectance** (Product Catalog, p. 19)

Omni MedSci, Inc. v. Apple Inc.
Case No. 2:18-cv-134-RWS (E.D. Tex.)

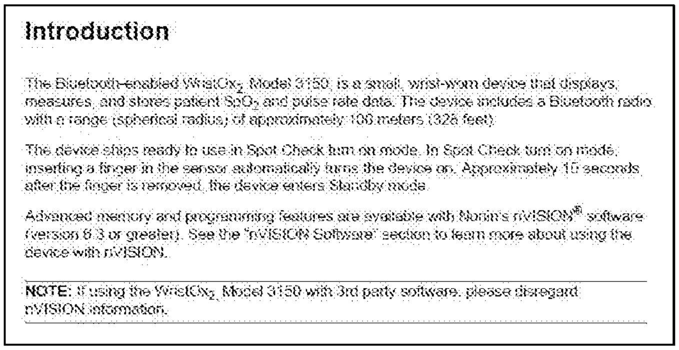
EXHIBIT W-3, p. 6

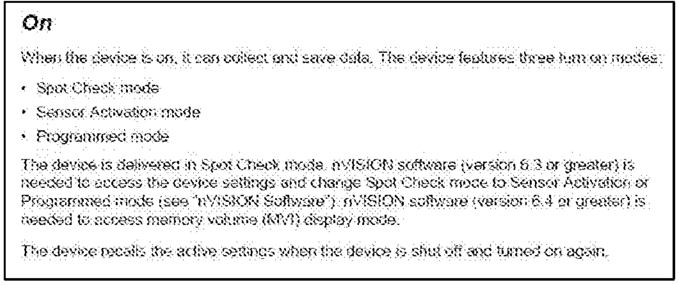
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 21)

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 21)

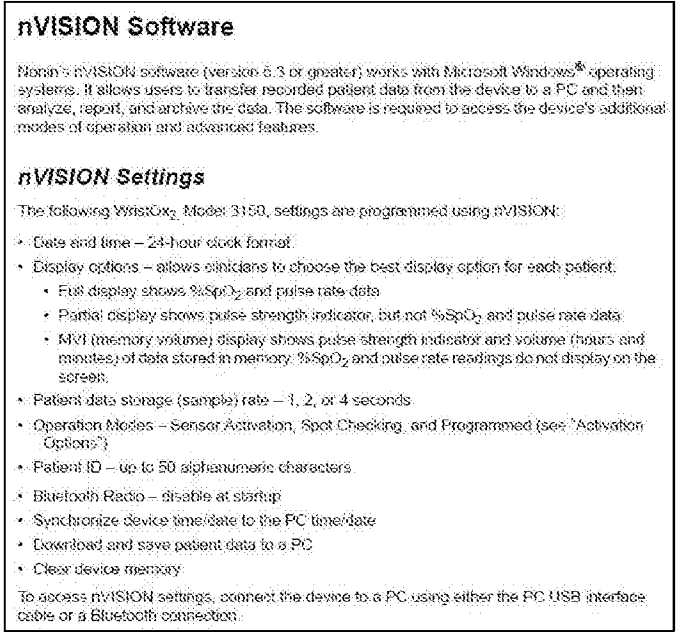
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 OEM III Module **Internal OEM Pulse Oximeter** Xpod® **External Pulse Oximeter with Mini-12 or USB Connectors** Onyx® II, Model 9560 **OEM Finger Pulse Oximeter with Bluetooth® wireless technology** Nonin 3230 Bluetooth® Smart **OEM Finger Pulse Oximeter with Bluetooth® Smart wireless technology** Nonin 3231 USB **OEM Finger Pulse Oximeter with USB Connector** WristOx2® Model 3150 **OEM Wrist-worn Pulse Oximeter with Bluetooth® wireless technology** (Product Catalog, p. 31)  (Compatibility Guide)

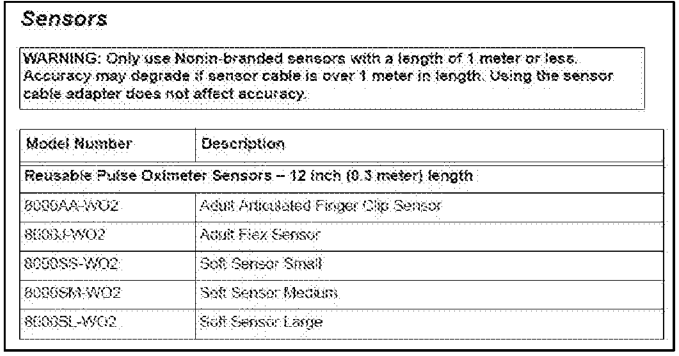
Asserted Claim of '286 Patent	**Nonin Medical Pulse Oximeters**
[16F] the measurement device further comprising a receiver configured to: capture light while the LEDs are off and convert the captured light into a first signal and capture light while at least one of the LEDs is on and convert the captured light into a second signal, the captured light including at least a portion of the optical beam reflected from the tissue;	Nonin Medical discloses and/or renders obvious "the measurement device further comprising a receiver configured to: capture light while the LEDs are off and convert the captured light into a first signal and capture light while at least one of the LEDs is on and convert the captured light into a second signal, the captured light including at least a portion of the optical beam reflected from the tissue." *See* CHART TWO: '040 Patent, Claim Element 1F above.
[16G] the measurement device configured to improve a signal-to-noise ratio of the optical beam reflected from the tissue by differencing the first signal and the second signal;	Nonin Medical discloses and/or renders obvious "the measurement device configured to improve a signal-to-noise ratio of the optical beam reflected from the tissue by differencing the first signal and the second signal." *See* CHART TWO: '040 Patent, Claim Element 1G above.
[16H] the light source configured to further improve the signal-to-noise ratio of the optical beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs;	Nonin Medical discloses and/or renders obvious "the light source configured to further improve the signal-to-noise ratio of the optical beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs." *See* CHART ONE: '533 Patent, Claim Element 5C above.

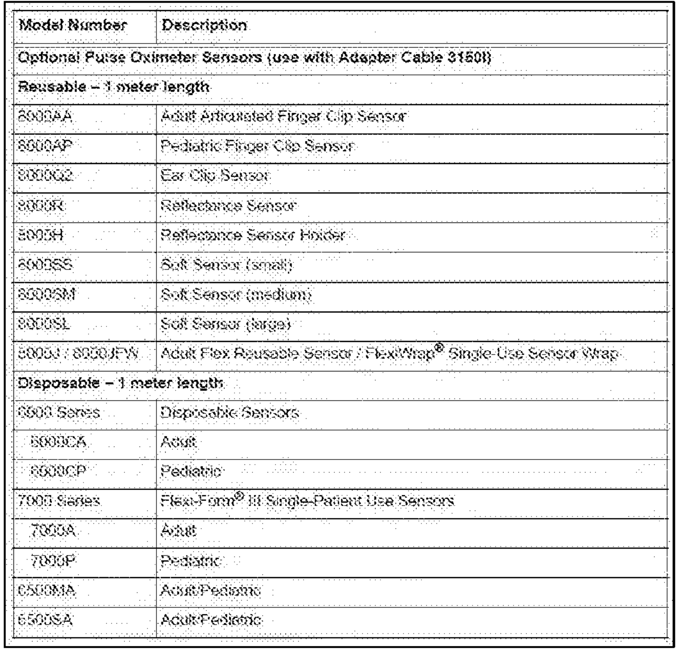
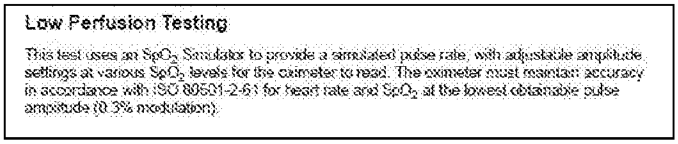
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
[16I] the measurement device further configured to generate an output signal representing at least in part a non-invasive measurement on blood contained within the tissue; and	Nonin Medical discloses and/or renders obvious "the measurement device further configured to generate an output signal representing at least in part a non-invasive measurement on blood contained within the tissue." *See* CHART ONE: '533 Patent, Claim Element 10 above.
[16J] wherein the receiver includes a plurality of spatially separated detectors,	Nonin Medical discloses and/or renders obvious "wherein the receiver includes a plurality of spatially separated detectors."  **Introduction** The Bluetooth-enabled WristOx$_2$ Model 3150, is a small, wrist-worn device that displays, measures, and stores patient SpO$_2$ and pulse rate data. The device includes a Bluetooth radio with a range (spherical radius) of approximately 100 meters (328 feet). The device ships ready to use in Spot Check turn on mode. In Spot Check turn on mode, inserting a finger in the sensor automatically turns the device on. Approximately 10 seconds after the finger is removed, the device enters Standby mode. Advanced memory and programming features are available with Nonin's nVISION® software (version 6.3 or greater). See the "nVISION Software" section to learn more about using the device with nVISION. **NOTE:** If using the WristOx$_2$ Model 3150 with 3rd party software, please disregard nVISION information. (Operator's Manual, p. 10)

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 *On* When the device is on, it can collect and save data. The device features three turn on modes: • Spot Check mode • Sensor Activation mode • Programmed mode The device is delivered in Spot Check mode. nVISION software (version 6.3 or greater) is needed to access the device settings and change Spot Check mode to Sensor Activation or Programmed mode (see "nVISION Software"). nVISION software (version 6.4 or greater) is needed to access memory volume (MV) display mode. The device recalls the active settings when the device is shut off and turned on again. (Operator's Manual, p. 12)

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters

	
	nVISION Software
	Nonin's nVISION software (version 6.3 or greater) works with Microsoft Windows® operating systems. It allows users to transfer recorded patient data from the device to a PC and then analyze, report, and archive the data. The software is required to access the device's additional modes of operation and advanced features.
	nVISION Settings
	The following WristOx$_2$ Model 3150, settings are programmed using nVISION:
	• Date and time – 24-hour clock format
	• Display options – allows clinicians to choose the best display option for each patient.
	  • Full display shows %SpO$_2$ and pulse rate data
	  • Partial display shows pulse strength indicator, but not %SpO$_2$ and pulse rate data
	  • MVI (memory volume) display shows pulse strength indicator and volume (hours and minutes) of data stored in memory. %SpO$_2$ and pulse rate readings do not display on the screen.
	• Patient data storage (sample) rate – 1, 2, or 4 seconds
	• Operation Modes – Sensor Activation, Spot Checking, and Programmed (see "Activation Options")
	• Patient ID – up to 50 alphanumeric characters
	• Bluetooth Radio – disable at startup
	• Synchronize device time/date to the PC time/date
	• Download and save patient data to a PC
	• Clear device memory
	To access nVISION settings, connect the device to a PC using either the PC USB interface cable or a Bluetooth connection.
	(Operator's Manual, p. 29)

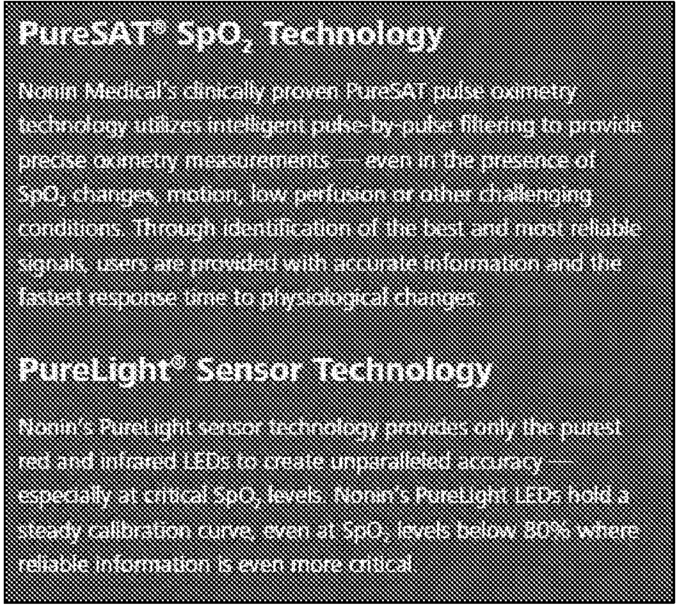
<table>
<tr><th>Asserted Claim of '286 Patent</th><th>Nonin Medical Pulse Oximeters</th></tr>
<tr><td></td><td>
Sensors
WARNING: Only use Nonin-branded sensors with a length of 1 meter or less. Accuracy may degrade if sensor cable is over 1 meter in length. Using the sensor cable adapter does not affect accuracy.
<table>
<tr><th>Model Number</th><th>Description</th></tr>
<tr><td colspan="2">Reusable Pulse Oximeter Sensors – 12 inch (0.3 meter) length</td></tr>
<tr><td>8000AA-WO2</td><td>Adult Articulated Finger Clip Sensor</td></tr>
<tr><td>8000J-WO2</td><td>Adult Flex Sensor</td></tr>
<tr><td>8000SS-WO2</td><td>Soft Sensor Small</td></tr>
<tr><td>8000SM-WO2</td><td>Soft Sensor Medium</td></tr>
<tr><td>8000SL-WO2</td><td>Soft Sensor Large</td></tr>
</table>
(Operator's Manual, p. 35)</td></tr>
</table>

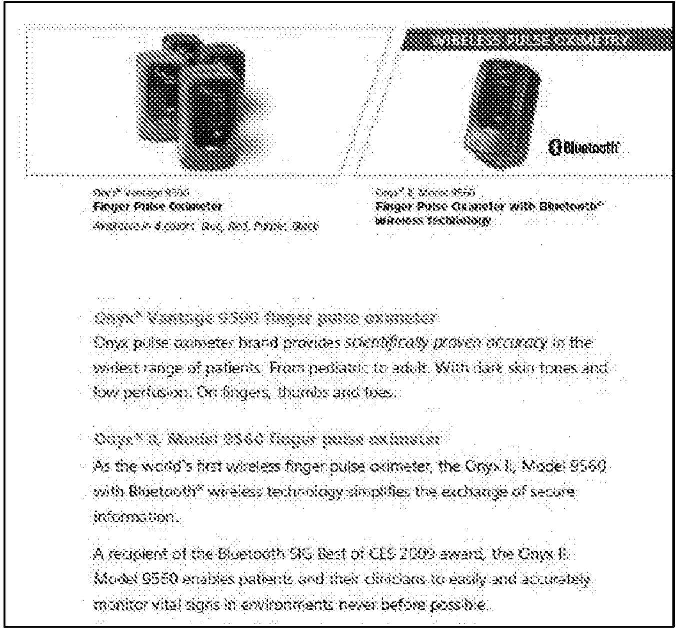
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 (Operator's Manual, p. 35)  (Operator's Manual, p. 43)

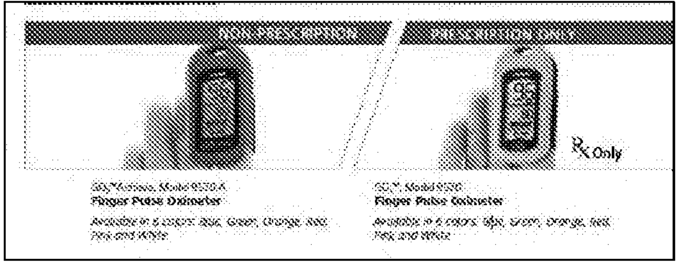
Model Number	Description
Optional Pulse Oximeter Sensors (use with Adapter Cable 3150I)	
Reusable – 1 meter length	
8000AA	Adult Articulated Finger Clip Sensor
8000AP	Pediatric Finger Clip Sensor
8000Q2	Ear Clip Sensor
8000R	Reflectance Sensor
8000H	Reflectance Sensor Holder
8000SS	Soft Sensor (small)
8000SM	Soft Sensor (medium)
8000SL	Soft Sensor (large)
8000J / 8000JFW	Adult Flex Reusable Sensor / FlexiWrap® Single-Use Sensor Wrap
Disposable – 1 meter length	
6000 Series	Disposable Sensors
6000CA	Adult
6000CP	Pediatric
7000 Series	Flexi-Form® III Single-Patient Use Sensors
7000A	Adult
7000P	Pediatric
6500MA	Adult/Pediatric
6500SA	Adult/Pediatric

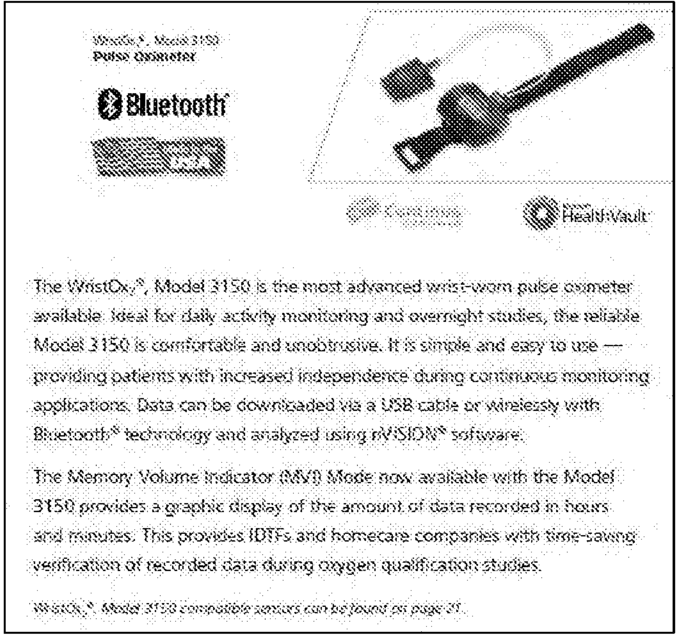
Low Perfusion Testing

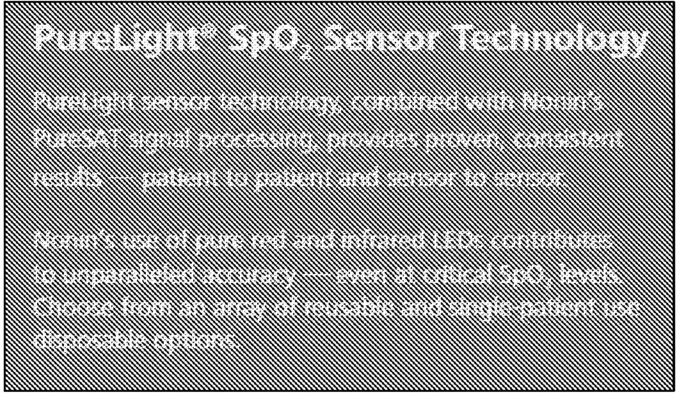
This test uses an SpO_2 Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO_2 levels for the oximeter to read. The oximeter must maintain accuracy in accordance with ISO 80601-2-61 for heart rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).

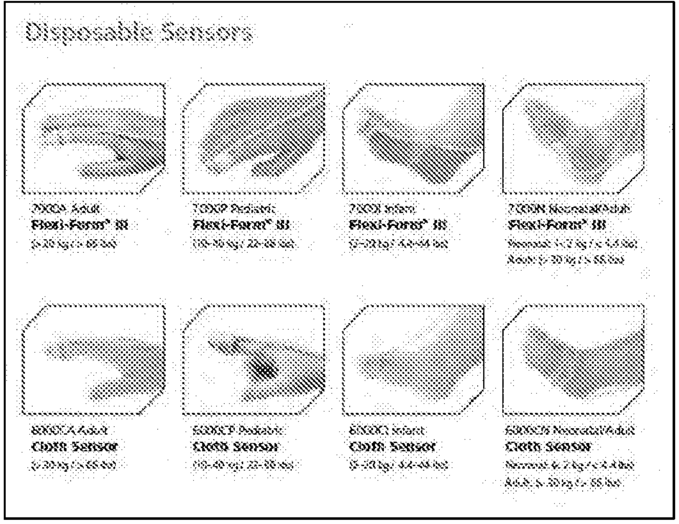
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 **PureSAT® SpO_2 Technology** Nonin Medical's clinically proven PureSAT pulse oximetry technology utilizes intelligent pulse-by-pulse filtering to provide precise oximetry measurements — even in the presence of SpO_2 changes, motion, low perfusion or other challenging conditions. Through identification of the best and most reliable signals, users are provided with accurate information and the fastest response time to physiological changes. **PureLight® Sensor Technology** Nonin's PureLight sensor technology provides only the purest red and infrared LEDs to create unparalleled accuracy — especially at critical SpO_2 levels. Nonin's PureLight LEDs hold a steady calibration curve, even at SpO_2 levels below 80% where reliable information is even more critical. (Product Catalog, p. 4)

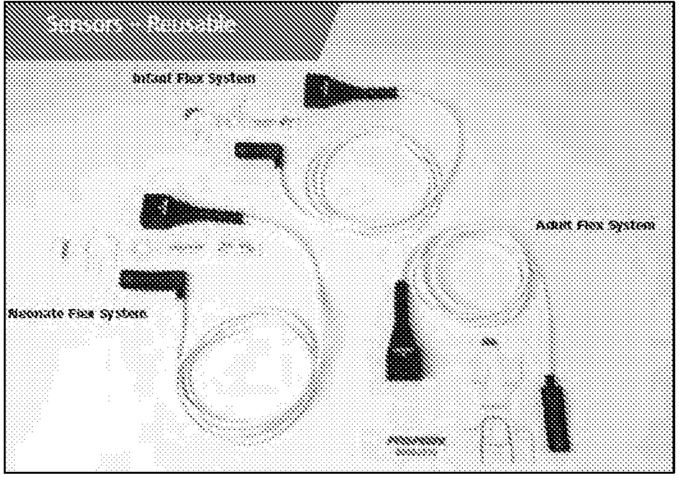
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 Onyx® Vantage 9590 **Finger Pulse Oximeter** *Available in 4 colors: Blue, Red, Purple, Black* Onyx® II, Model 9560 **Finger Pulse Oximeter with Bluetooth® Wireless Technology** Onyx® Vantage 9590 finger pulse oximeter Onyx pulse oximeter brand provides *scientifically proven accuracy* in the widest range of patients. From pediatric to adult. With dark skin tones and low perfusion. On fingers, thumbs and toes. Onyx® II, Model 9560 finger pulse oximeter As the world's first wireless finger pulse oximeter, the Onyx II, Model 9560 with Bluetooth® wireless technology simplifies the exchange of secure information. A recipient of the Bluetooth SIG Best of CES 2009 award, the Onyx II, Model 9560 enables patients and their clinicians to easily and accurately monitor vital signs in environments never before possible. (Product Catalog, p. 7)

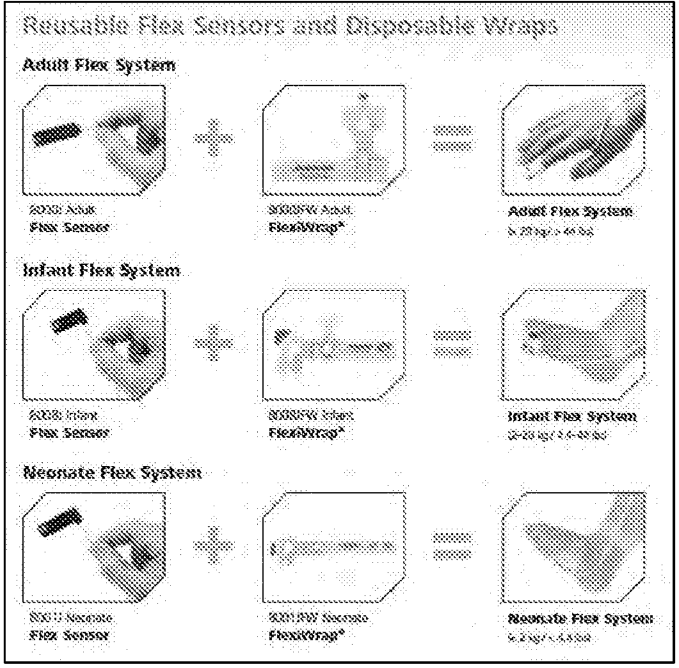
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 9)

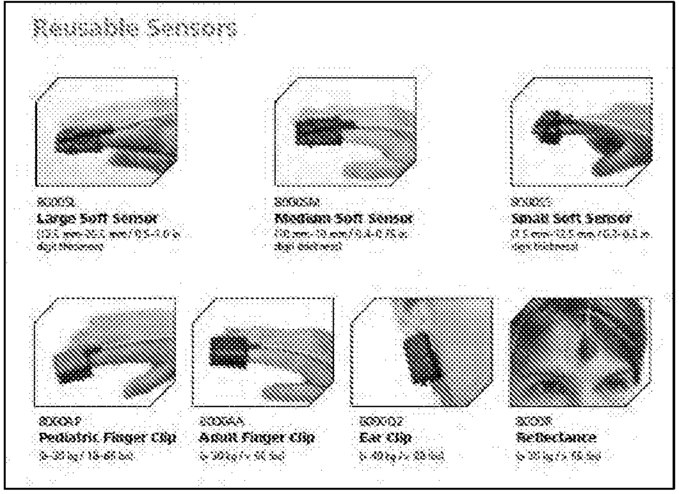
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 WristOx$_2$®, Model 3150 Pulse Oximeter Bluetooth® HealthVault The WristOx$_2$®, Model 3150 is the most advanced wrist-worn pulse oximeter available. Ideal for daily activity monitoring and overnight studies, the reliable Model 3150 is comfortable and unobtrusive. It is simple and easy to use — providing patients with increased independence during continuous monitoring applications. Data can be downloaded via a USB cable or wirelessly with Bluetooth® technology and analyzed using nVISION® software. The Memory Volume Indicator (MVI) Mode now available with the Model 3150 provides a graphic display of the amount of data recorded in hours and minutes. This provides IDTFs and homecare companies with time-saving verification of recorded data during oxygen qualification studies. WristOx$_2$®, Model 3150 compatible sensors can be found on page 21. (Product Catalog, p. 11)

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 **PureLight® SpO_2 Sensor Technology** PureLight sensor technology, combined with Nonin's PureSAT signal processing, provides proven, consistent results — patient to patient and sensor to sensor. Nonin's use of pure red and infrared LEDs contributes to unparalleled accuracy — even at critical SpO_2 levels. Choose from an array of reusable and single-patient use disposable options. (Product Catalog, p. 16)

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 17)

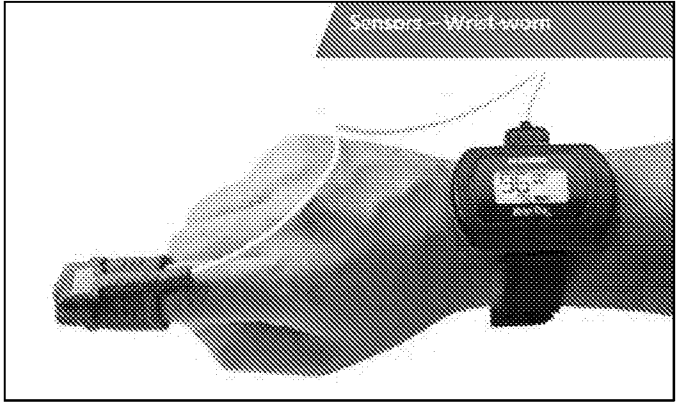
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 18)

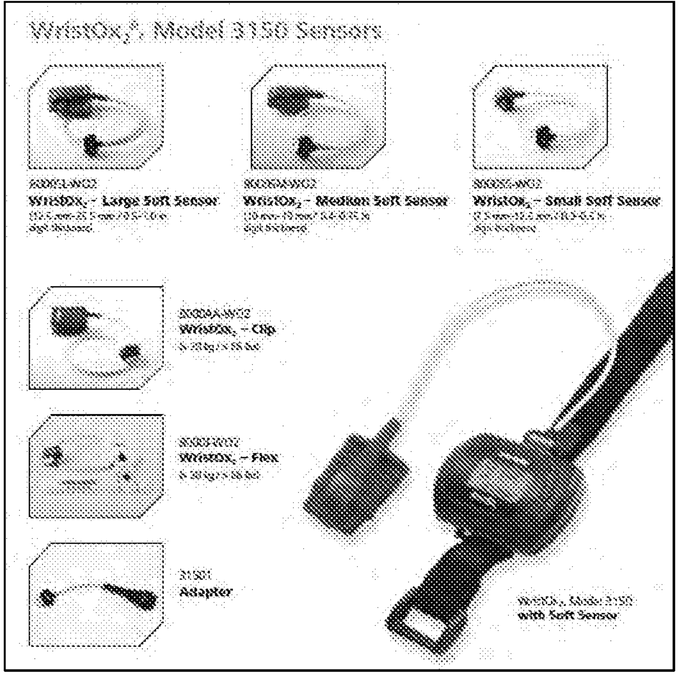
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 Reusable Flex Sensors and Disposable Wraps **Adult Flex System** [illegible] Adult **Flex Sensor** [illegible] Adult **FlexiWrap®** **Adult Flex System** **Infant Flex System** [illegible] Infant **Flex Sensor** [illegible] Infant **FlexiWrap®** **Infant Flex System** **Neonate Flex System** [illegible] Neonate **Flex Sensor** [illegible] Neonate **FlexiWrap®** **Neonate Flex System** (Product Catalog, p. 18)

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 Reusable Sensors 8000SL **Large Soft Sensor** 8000SM **Medium Soft Sensor** 8000SS **Small Soft Sensor** 8000AP **Pediatric Finger Clip** 8000AA **Adult Finger Clip** 8000Q2 **Ear Clip** 8000R **Reflectance** (Product Catalog, p. 19)

Omni MedSci, Inc. v. Apple Inc.
Case No. 2:18-cv-134-RWS (E.D. Tex.)

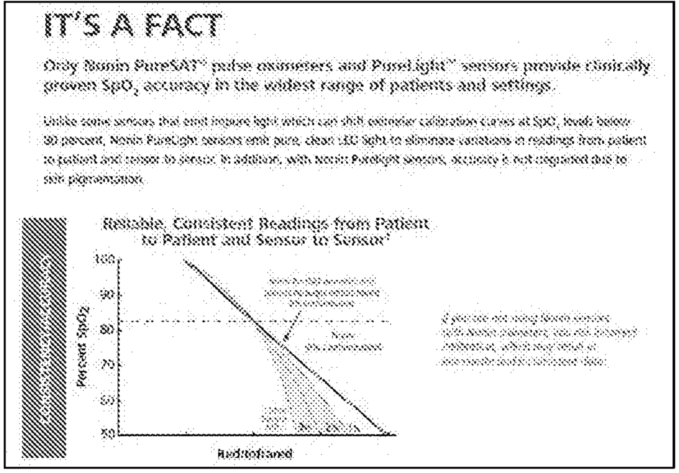
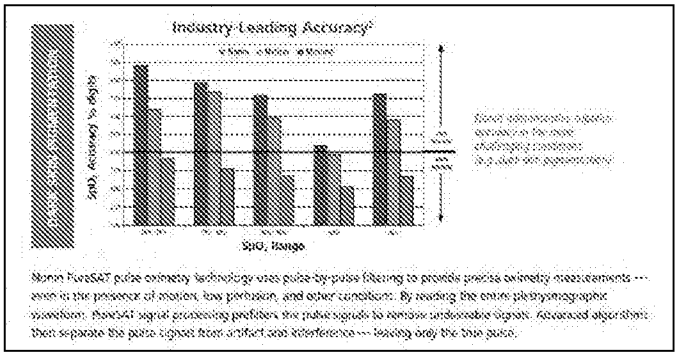
EXHIBIT W-3, p. 24

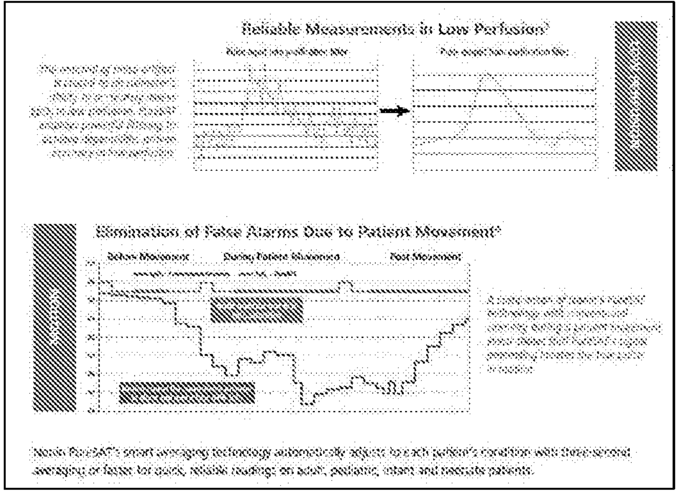
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 21)

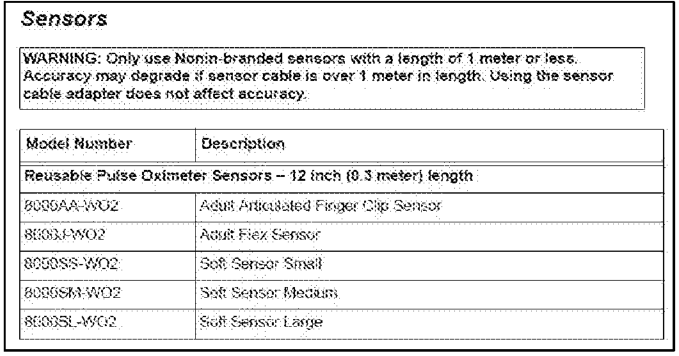
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 21)

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 31)

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 31)

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 IT'S A FACT Only Nonin PureSAT™ pulse oximeters and PureLight™ sensors provide clinically proven SpO_2 accuracy in the widest range of patients and settings. Unlike some sensors that emit impure light which can shift oximeter calibration curves at SpO_2 levels below 80 percent, Nonin PureLight sensors emit pure, clean LED light to eliminate variations in readings from patient to patient and sensor to sensor. In addition, with Nonin PureLight sensors, accuracy is not degraded due to skin pigmentation. (Brochure, p.  Nonin PureSAT pulse oximetry technology uses pulse-by-pulse filtering to provide precise oximetry measurements — even in the presence of motion, low perfusion, and other conditions. By reading the entire plethysmographic waveform, PureSAT signal processing prefilters the pulse signals to remove undesirable signals. Advanced algorithms then separate the pulse signals from artifact and interference — leaving only the true pulse. (Brochure, p. 2)

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 Reliable Measurements in Low Perfusion* Elimination of False Alarms Due to Patient Movement* Before Movement During Patient Movement Post Movement Nonin PureSAT's smart averaging technology automatically adjusts to each patient's condition with three-second averaging or faster for quick, reliable readings on adult, pediatric, infant and neonate patients. (Brochure, p. 2)
[16K] wherein at least one analog to digital converter is coupled to the spatially separated detectors.	Nonin Medical discloses and/or renders obvious "wherein at least one analog to digital converter is coupled to the spatially separated detectors."

<table>
<tr><th>Asserted Claim of '286 Patent</th><th>Nonin Medical Pulse Oximeters</th></tr>
<tr><td></td><td>


Sensors

WARNING: Only use Nonin-branded sensors with a length of 1 meter or less. Accuracy may degrade if sensor cable is over 1 meter in length. Using the sensor cable adapter does not affect accuracy.

<table>
<tr><th>Model Number</th><th>Description</th></tr>
<tr><td colspan="2">Reusable Pulse Oximeter Sensors – 12 inch (0.3 meter) length</td></tr>
<tr><td>8000AA-WO2</td><td>Adult Articulated Finger Clip Sensor</td></tr>
<tr><td>8000J-WO2</td><td>Adult Flex Sensor</td></tr>
<tr><td>8000SS-WO2</td><td>Soft Sensor Small</td></tr>
<tr><td>8000SM-WO2</td><td>Soft Sensor Medium</td></tr>
<tr><td>8000SL-WO2</td><td>Soft Sensor Large</td></tr>
</table>

(Operator's Manual, p. 35)
</td></tr>
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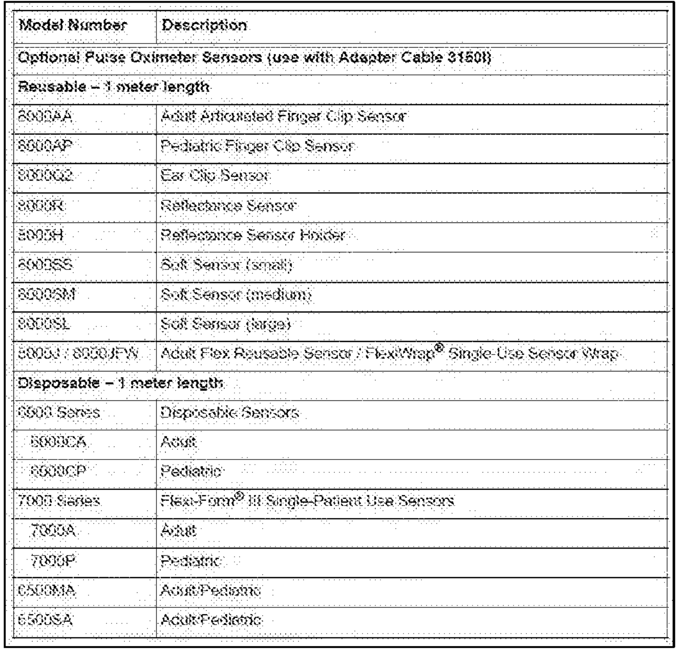
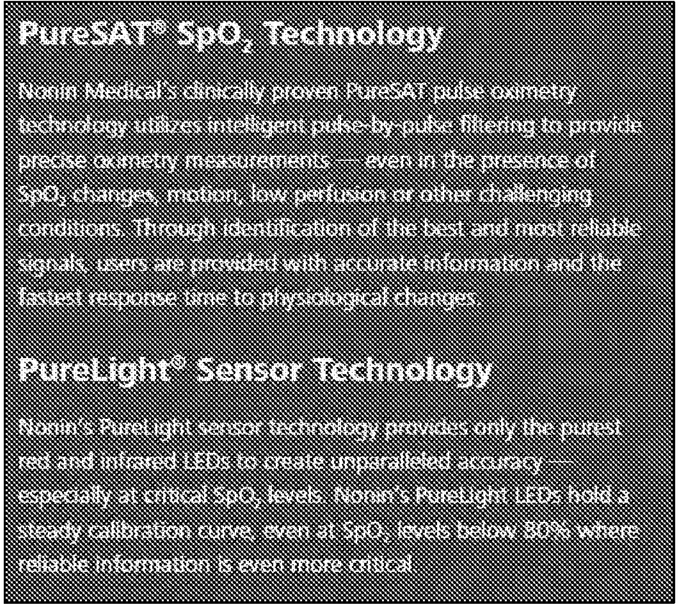
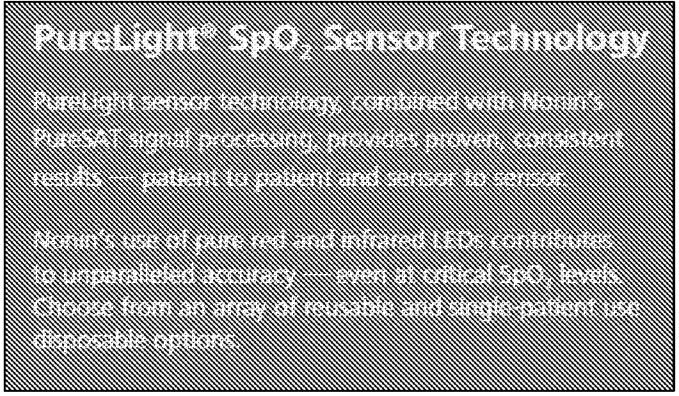
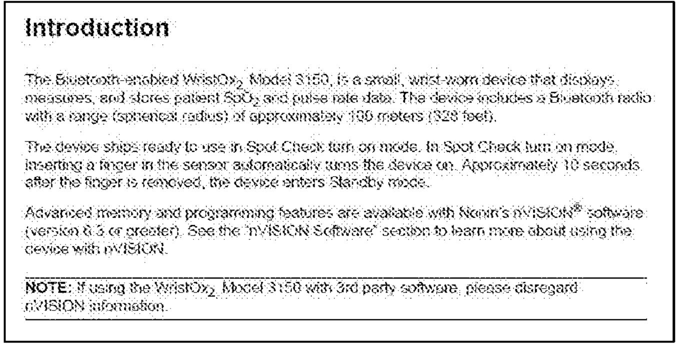
<table>
<tr><th>Asserted Claim of '286 Patent</th><th>Nonin Medical Pulse Oximeters</th></tr>
<tr><td></td><td>
<table>
<tr><th>Model Number</th><th>Description</th></tr>
<tr><td colspan="2">Optional Pulse Oximeter Sensors (use with Adapter Cable 3150)</td></tr>
<tr><td colspan="2">Reusable – 1 meter length</td></tr>
<tr><td>8000AA</td><td>Adult Articulated Finger Clip Sensor</td></tr>
<tr><td>8000AP</td><td>Pediatric Finger Clip Sensor</td></tr>
<tr><td>8000Q2</td><td>Ear Clip Sensor</td></tr>
<tr><td>8000R</td><td>Reflectance Sensor</td></tr>
<tr><td>8000H</td><td>Reflectance Sensor Holder</td></tr>
<tr><td>8000SS</td><td>Soft Sensor (small)</td></tr>
<tr><td>8000SM</td><td>Soft Sensor (medium)</td></tr>
<tr><td>8000SL</td><td>Soft Sensor (large)</td></tr>
<tr><td>8000J / 8000JFW</td><td>Adult Flex Reusable Sensor / FlexiWrap® Single-Use Sensor Wrap</td></tr>
<tr><td colspan="2">Disposable – 1 meter length</td></tr>
<tr><td>6000 Series</td><td>Disposable Sensors</td></tr>
<tr><td>6000CA</td><td>Adult</td></tr>
<tr><td>6000CP</td><td>Pediatric</td></tr>
<tr><td>7000 Series</td><td>Flexi-Form® III Single-Patient Use Sensors</td></tr>
<tr><td>7000A</td><td>Adult</td></tr>
<tr><td>7000P</td><td>Pediatric</td></tr>
<tr><td>6500MA</td><td>Adult/Pediatric</td></tr>
<tr><td>6500SA</td><td>Adult/Pediatric</td></tr>
</table>
(Operator's Manual, p. 35)</td></tr>
</table>

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 **PureSAT® SpO_2 Technology** Nonin Medical's clinically proven PureSAT pulse oximetry technology utilizes intelligent pulse-by-pulse filtering to provide precise oximetry measurements — even in the presence of SpO_2 changes, motion, low perfusion or other challenging conditions. Through identification of the best and most reliable signals, users are provided with accurate information and the fastest response time to physiological changes. **PureLight® Sensor Technology** Nonin's PureLight sensor technology provides only the purest red and infrared LEDs to create unparalleled accuracy — especially at critical SpO_2 levels. Nonin's PureLight LEDs hold a steady calibration curve, even at SpO_2 levels below 80% where reliable information is even more critical. (Product Catalog, p. 4)

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 PureLight® SpO_2 Sensor Technology PureLight sensor technology, combined with Nonin's PureSAT signal processing, provides proven, consistent results — patient to patient and sensor to sensor. Nonin's use of pure red and infrared LEDs contributes to unparalleled accuracy — even at critical SpO_2 levels. Choose from an array of reusable and single-patient use disposable options. (Product Catalog, p. 16)
[17] The wearable device of claim 16, wherein at least one LED emits at a first wavelength and at least another LED emits at a second wavelength, and wherein the first wavelength has a first penetration depth into the tissue and wherein the second wavelength has a second penetration depth into the tissue different from the first penetration depth.	Nonin Medical discloses and/or renders obvious "[t]he wearable device of claim 16, wherein at least one LED emits at a first wavelength and at least another LED emits at a second wavelength, and wherein the first wavelength has a first penetration depth into the tissue and wherein the second wavelength has a second penetration depth into the tissue different from the first penetration depth."

<table>
<tr><th>Asserted Claim of ’286 Patent</th><th>Nonin Medical Pulse Oximeters</th></tr>
<tr><td></td><td>


Introduction

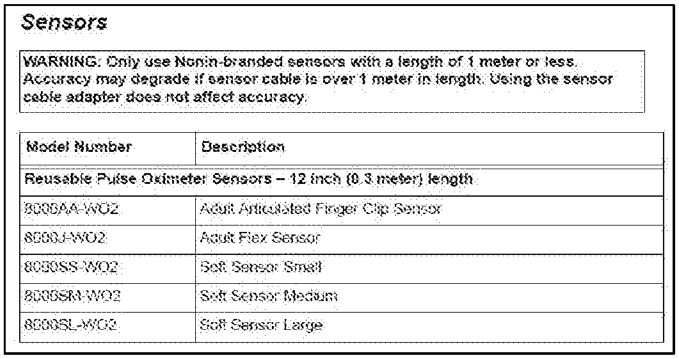
The Bluetooth-enabled WristOx$_2$ Model 3150, is a small, wrist-worn device that displays, measures, and stores patient SpO$_2$ and pulse rate data. The device includes a Bluetooth radio with a range (spherical radius) of approximately 100 meters (328 feet).

The device ships ready to use in Spot Check turn on mode. In Spot Check turn on mode, inserting a finger in the sensor automatically turns the device on. Approximately 10 seconds after the finger is removed, the device enters Standby mode.

Advanced memory and programming features are available with Nonin's nVISION® software (version 6.3 or greater). See the "nVISION Software" section to learn more about using the device with nVISION.

NOTE: If using the WristOx$_2$ Model 3150 with 3rd party software, please disregard nVISION information.

(Operator’s Manual, p. 10)



Sensors

WARNING: Only use Nonin-branded sensors with a length of 1 meter or less. Accuracy may degrade if sensor cable is over 1 meter in length. Using the sensor cable adapter does not affect accuracy.

<table>
<tr><th>Model Number</th><th>Description</th></tr>
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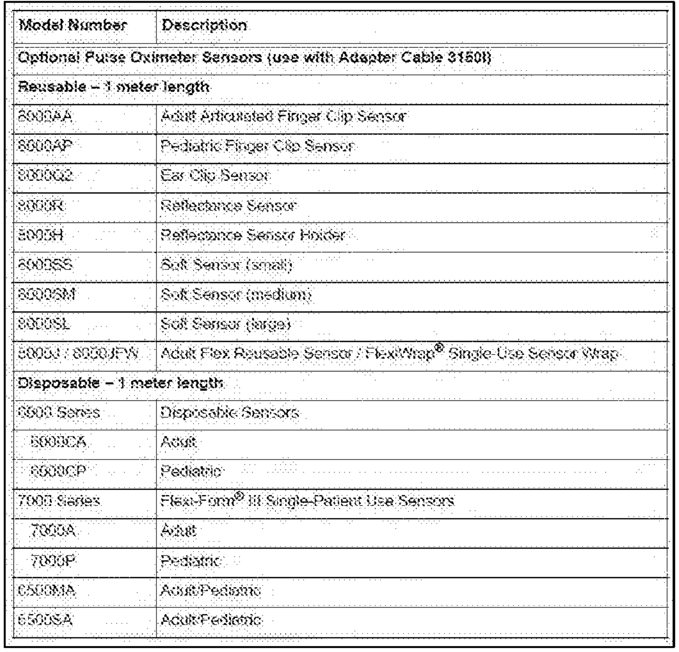
<tr><td>8000SS-WO2</td><td>Soft Sensor Small</td></tr>
<tr><td>8000SM-WO2</td><td>Soft Sensor Medium</td></tr>
<tr><td>8000SL-WO2</td><td>Soft Sensor Large</td></tr>
</table>

(Operator’s Manual, p. 35)
</td></tr>
</table>

<table>
<tr><th>Asserted Claim of ’286 Patent</th><th>Nonin Medical Pulse Oximeters</th></tr>
<tr><td></td><td>

<table>
<tr><th>Model Number</th><th>Description</th></tr>
<tr><td colspan="2">Optional Pulse Oximeter Sensors (use with Adapter Cable 3150I)</td></tr>
<tr><td colspan="2">Reusable – 1 meter length</td></tr>
<tr><td>8000AA</td><td>Adult Articulated Finger Clip Sensor</td></tr>
<tr><td>8000AP</td><td>Pediatric Finger Clip Sensor</td></tr>
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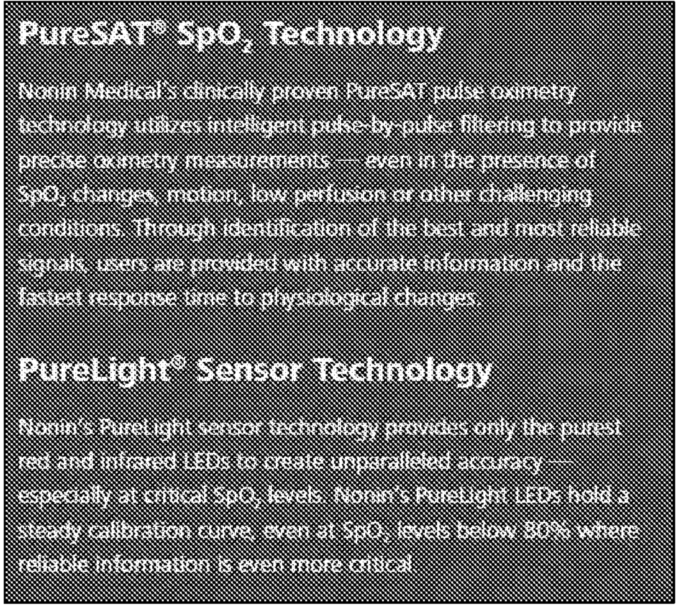
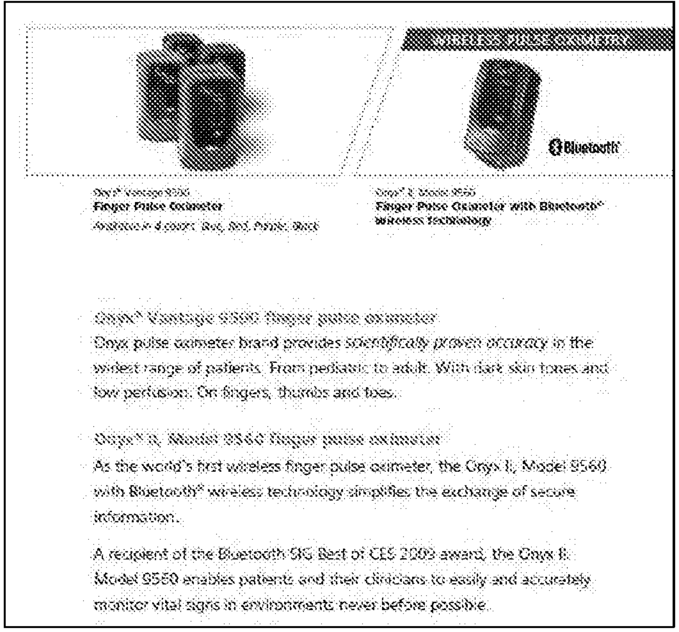
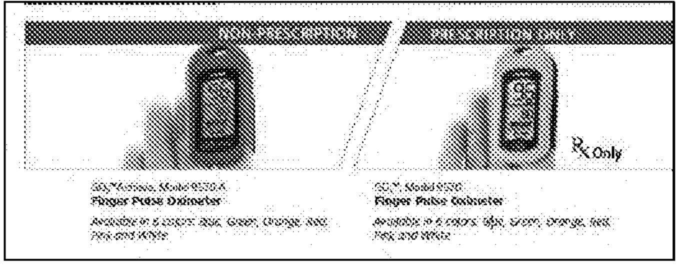
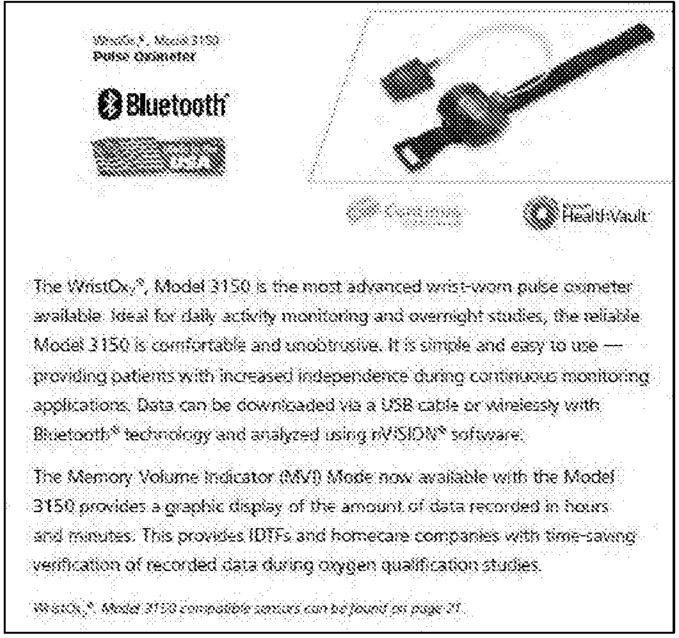
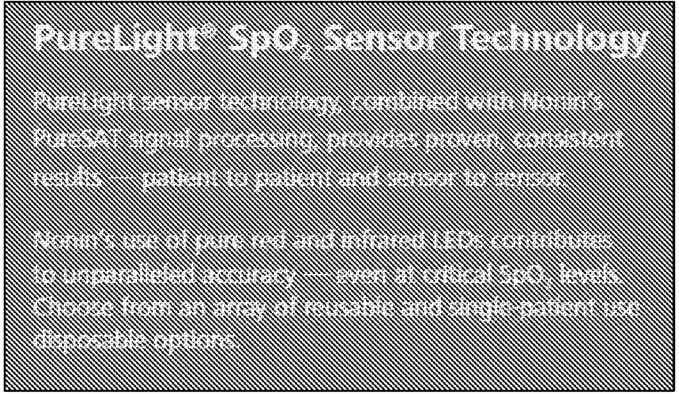
<tr><td>6500SA</td><td>Adult/Pediatric</td></tr>
</table>
(Operator’s Manual, p. 35)</td></tr>
</table>

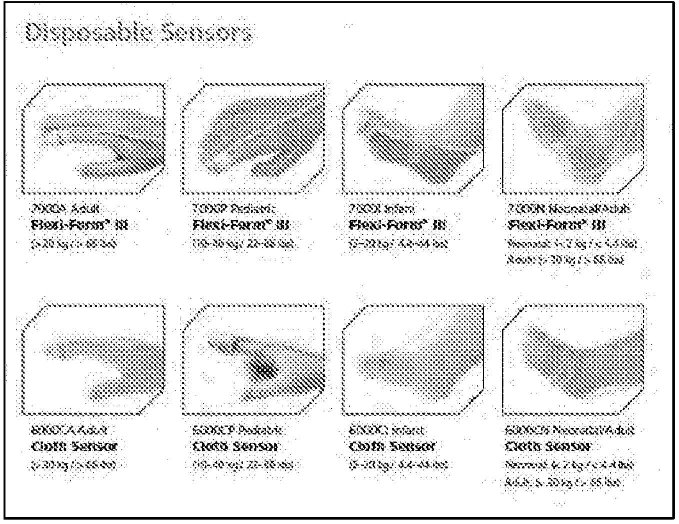
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 **PureSAT® SpO_2 Technology** Nonin Medical's clinically proven PureSAT pulse oximetry technology utilizes intelligent pulse-by-pulse filtering to provide precise oximetry measurements — even in the presence of SpO_2 changes, motion, low perfusion or other challenging conditions. Through identification of the best and most reliable signals, users are provided with accurate information and the fastest response time to physiological changes. **PureLight® Sensor Technology** Nonin's PureLight sensor technology provides only the purest red and infrared LEDs to create unparalleled accuracy — especially at critical SpO_2 levels. Nonin's PureLight LEDs hold a steady calibration curve, even at SpO_2 levels below 80% where reliable information is even more critical. (Product Catalog, p. 4)

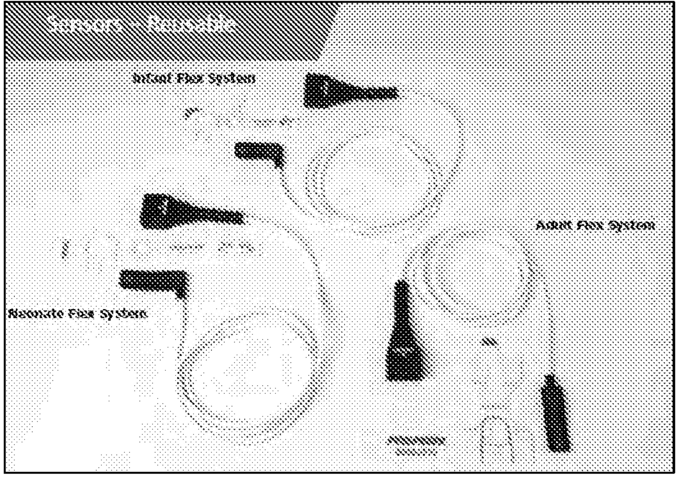
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 WIRELESS PULSE OXIMETRY Bluetooth Onyx® Vantage 9590 **Finger Pulse Oximeter** *Available in 4 colors: Blue, Red, Purple, Black* Onyx® II, Model 9560 **Finger Pulse Oximeter with Bluetooth® wireless technology** Onyx® Vantage 9590 finger pulse oximeter Onyx pulse oximeter brand provides *scientifically proven accuracy* in the widest range of patients. From pediatric to adult. With dark skin tones and low perfusion. On fingers, thumbs and toes. Onyx® II, Model 9560 finger pulse oximeter As the world's first wireless finger pulse oximeter, the Onyx II, Model 9560 with Bluetooth® wireless technology simplifies the exchange of secure information. A recipient of the Bluetooth SIG Best of CES 2009 award, the Onyx II, Model 9560 enables patients and their clinicians to easily and accurately monitor vital signs in environments never before possible. (Product Catalog, p. 7)

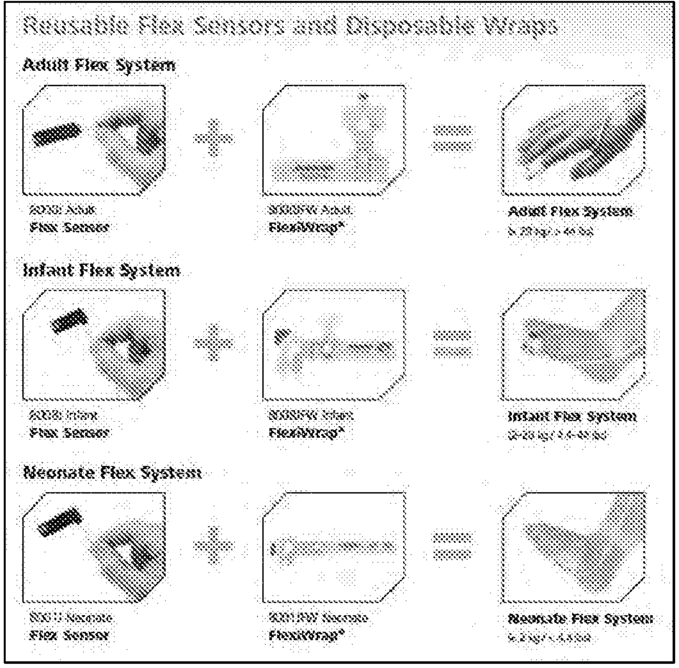
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 9)

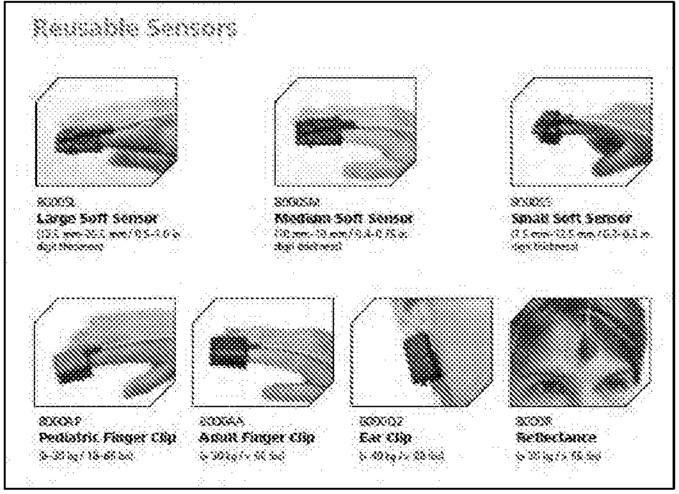
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 WristOx$_2$®, Model 3150 Pulse Oximeter The WristOx$_2$®, Model 3150 is the most advanced wrist-worn pulse oximeter available. Ideal for daily activity monitoring and overnight studies, the reliable Model 3150 is comfortable and unobtrusive. It is simple and easy to use — providing patients with increased independence during continuous monitoring applications. Data can be downloaded via a USB cable or wirelessly with Bluetooth® technology and analyzed using nVISION® software. The Memory Volume Indicator (MVI) Mode now available with the Model 3150 provides a graphic display of the amount of data recorded in hours and minutes. This provides IDTFs and homecare companies with time-saving verification of recorded data during oxygen qualification studies. *WristOx$_2$®, Model 3150 compatible sensors can be found on page 21.* (Product Catalog, p. 11)

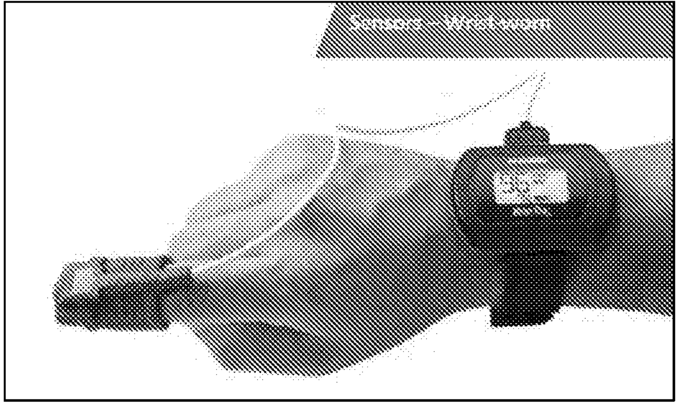
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 PureLight® SpO_2 Sensor Technology PureLight sensor technology, combined with Nonin's PureSAT signal processing, provides proven, consistent results — patient to patient and sensor to sensor. Nonin's use of pure red and infrared LEDs contributes to unparalleled accuracy — even at critical SpO_2 levels. Choose from an array of reusable and single-patient use disposable options. (Product Catalog, p. 16)

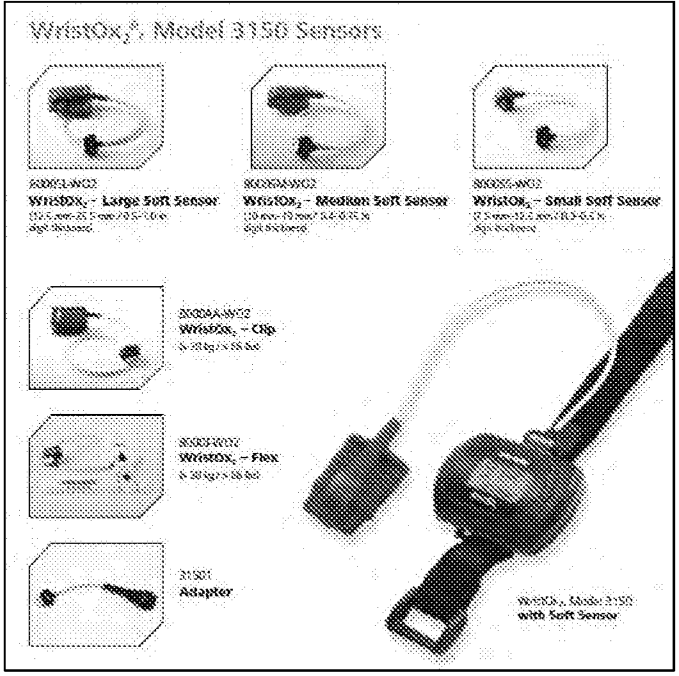
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 Disposable Sensors Adult Flexi-Form® III Pediatric Flexi-Form® III Infant Flexi-Form® III Neonatal/Adult Flexi-Form® III Adult Cloth Sensor Pediatric Cloth Sensor Infant Cloth Sensor Neonatal/Adult Cloth Sensor (Product Catalog, p. 17)

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 18)

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 18)

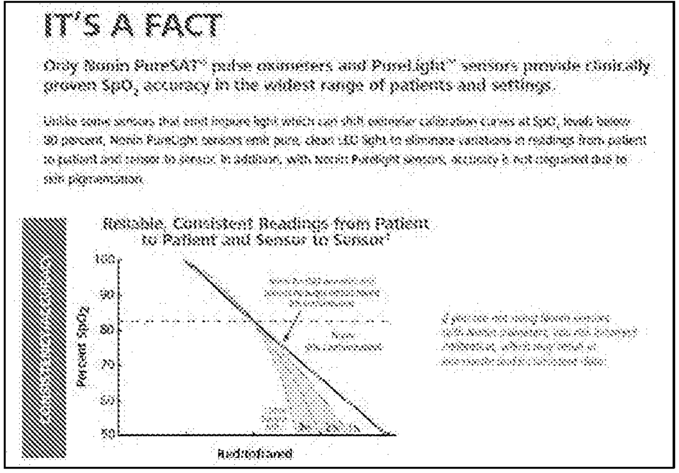
Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 Reusable Sensors 8000SL Large Soft Sensor 8000SM Medium Soft Sensor 8000SS Small Soft Sensor 8000AP Pediatric Finger Clip 8000AA Adult Finger Clip 8000Q2 Ear Clip 8000R Reflectance (Product Catalog, p. 19)

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 21)

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 WristOx$_2$®, Model 3150 Sensors **WristOx$_2$ – Large Soft Sensor** **WristOx$_2$ – Medium Soft Sensor** **WristOx$_2$ – Small Soft Sensor** **WristOx$_2$ – Clip** **WristOx$_2$ – Flex** **Adapter** WristOx$_2$, Model 3150 **with Soft Sensor** (Product Catalog, p. 21)

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 31)

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 31)

Asserted Claim of ’286 Patent	Nonin Medical Pulse Oximeters
	 IT’S A FACT Only Nonin PureSAT™ pulse oximeters and PureLight™ sensors provide clinically proven SpO_2 accuracy in the widest range of patients and settings. Unlike some sensors that emit impure light which can shift oximeter calibration curves at SpO_2 levels below 80 percent, Nonin PureLight sensors emit pure, clean LED light to eliminate variations in readings from patient to patient and sensor to sensor. In addition, with Nonin PureLight sensors, accuracy is not degraded due to skin pigmentation. Reliable, Consistent Readings from Patient to Patient and Sensor to Sensor¹ (Brochure, p. 2)
[19] The wearable device of claim 16, wherein the receiver is configured to be synchronized to the modulating of at least one of the LEDs.	Nonin Medical discloses and/or renders obvious “[t]he wearable device of claim 16, wherein the receiver is configured to be synchronized to the modulating of at least one of the LEDs.” *See* CHART ONE: ’533 Patent, Claim Element 5F above.
[20] The wearable device of claim 16, wherein the receiver is located a first distance from a first one of the LEDs and a different distance from a second one of the LEDs such that the receiver can capture a third signal from the first LED and a fourth signal from	Nonin Medical discloses and/or renders obvious “[t]he wearable device of claim 16, wherein the receiver is located a first distance from a first one of the LEDs and a different distance from a second one of the LEDs such that the receiver can capture a third signal from the first LED and a fourth signal from the second LED, and wherein the output signal is generated in part by comparing the third and fourth signals..” *See* CHART ONE: ’533 Patent, Claim Element 8 above.

Asserted Claim of '286 Patent	Nonin Medical Pulse Oximeters
the second LED, and wherein the output signal is generated in part by comparing the third and fourth signals.	

EXHIBIT W-4

U.S. Patent No. 9,885,698 vs Nonin Medical

Priority Date/Publication Date: At least by February 2011 Prior Art Status: §§ 102(a) and (b)

Model 3150 WristOx$_2$ and certain pulse oximeters and pulse oximetry sensors manufactured by Nonin Medical ("Nonin Medical") anticipate the asserted claims of U.S. Patent No. 9,885,698 ("the '698 Patent") or renders those claims obvious alone and/or in view of at least any of the references identified in Apple's Obviousness Combinations Chart.

This chart is based on the following disclosures about Nonin Medical pulse oximeters:

- Nonin Operator's Manual 2014 for Model 3150 WristOx$_2$ Pulse Oximeter ("Operator's Manual")
- Nonin Product Catalog 2014 ("Product Catalog")
- Nonin Brochure 2013 ("Brochure")
- Nonin Pulse Oximeter Sensor Compatibility Guide 2013 ("Compatibility Guide")

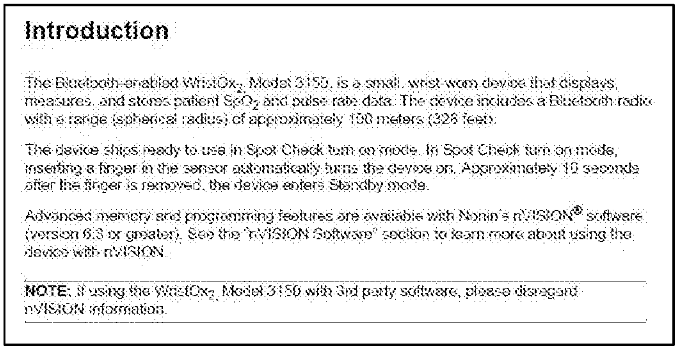
Discovery is ongoing, and Apple reserves the right to amend this chart based on new information about the Nonin Medical pulse oximeters.

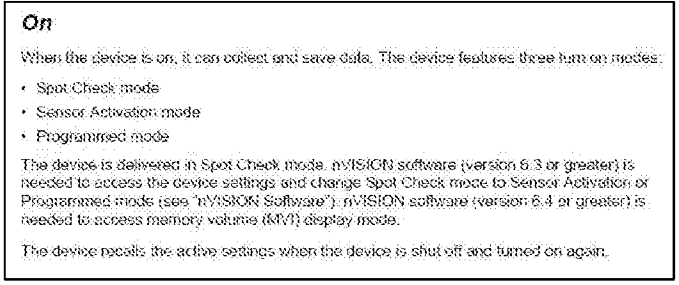
As set forth in Apple's Invalidity Contentions, the below contentions apply the prior art in part in accordance with Apple's assumption that Omni contends the claims are not invalid under 35 U.S.C. § 112. However, Apple's below contentions do not represent Apple's agreement or view as to the meaning, definiteness, written description support for, or enablement of any of the asserted claims. For each dependent claim, the disclosures cited for the claim from which it depends are incorporated by reference.

CHART FOUR: U.S. Patent No. 9,885,698 vs Nonin Medical

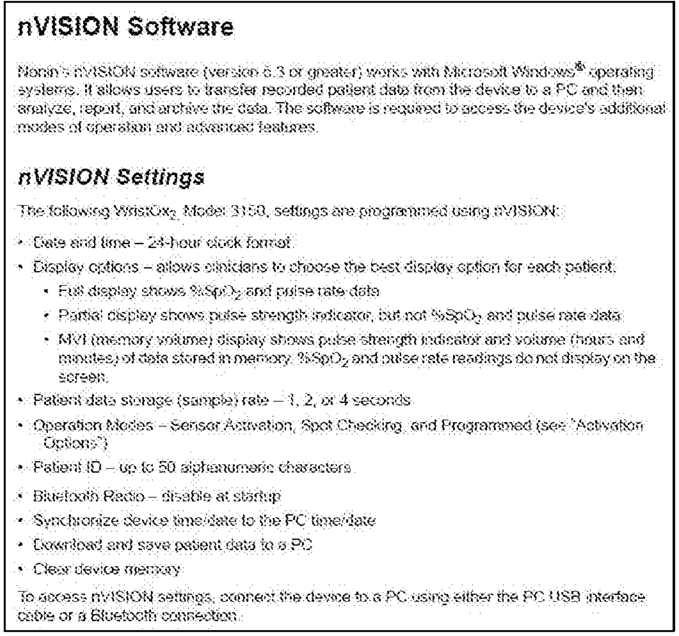
Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
[1] A wearable device, comprising:	To the extent the preamble is limiting, Nonin Medical discloses and/or renders obvious "[a] wearable device." *See* CHART ONE: '533 Patent, Claim Elements 5 and 13A above.
[1A] a measurement device including a light source comprising a plurality of light emitting diodes (LEDs) for measuring one or more physiological parameters,	Nonin Medical discloses and/or renders obvious "a measurement device including a light source comprising a plurality of light emitting diodes (LEDs) for measuring one or more physiological parameters." *See* CHART ONE: '533 Patent, Claim Element 13A above.
[1B] the measurement device configured to generate, by modulating at least one of the LEDs having an initial light intensity, an input optical beam having one or more optical wavelengths,	Nonin Medical discloses and/or renders obvious "the measurement device configured to generate, by modulating at least one of the LEDs having an initial light intensity, an input optical beam having one or more optical wavelengths." *See* CHART TWO: '040 Patent, Claim Element 1B above.
[1C] wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers;	Nonin Medical discloses and/or renders obvious "wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers." *See* CHART ONE: '533 Patent, Claim Element 5B above.
[1D] the measurement device comprising one or more lenses configured to receive and to deliver a portion of the input optical beam to tissue, wherein	Nonin Medical discloses and/or renders obvious "the measurement device comprising one or more lenses configured to receive and to deliver a portion of the input optical beam to tissue, wherein the tissue reflects at least a portion of the input optical beam delivered to the tissue." *See* CHART ONE: '533 Patent, Claim Element 5D above.

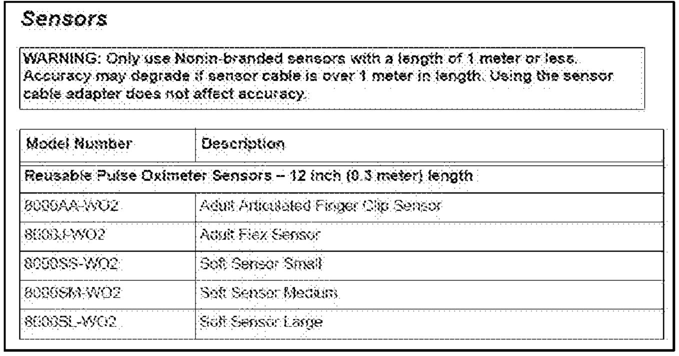
Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
the tissue reflects at least a portion of the input optical beam delivered to the tissue;	
[1E] the measurement device further comprising a receiver, wherein the receiver includes a plurality of spatially separated detectors, the detectors configured to: capture light while the LEDs are off and convert the captured light into a first signal; and capture light while at least one of the LEDs is on and convert the captured light into a second signal, the captured light including at least a portion of the input optical beam reflected from the tissue;	Nonin Medical discloses and/or renders obvious "the measurement device further comprising a receiver, wherein the receiver includes a plurality of spatially separated detectors, the detectors configured to: capture light while the LEDs are off and convert the captured light into a first signal; and capture light while at least one of the LEDs is on and convert the captured light into a second signal, the captured light including at least a portion of the input optical beam reflected from the tissue." *See* CHART TWO: '040 Patent, Claim Element 1F and CHART THREE: '286 Patent, Claim Element 16J above.
[1F] wherein at least one analog to digital converter is coupled to the spatially separated detectors and is configured to generate at least a first data signal from the first signal and at least a second data signal from the second signal;	Nonin Medical discloses and/or renders obvious "wherein at least one analog to digital converter is coupled to the spatially separated detectors and is configured to generate at least a first data signal from the first signal and at least a second data signal from the second signal." *See* CHART TWO: '040 Patent, Claim Element 1F and CHART THREE: '286 Patent, Claim Element 16K above.

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
[1G] the measurement device configured to improve a signal-to-noise ratio of the input optical beam reflected from the tissue by differencing the first data signal and the second data signal to generate an output signal representing at least in part a non-invasive measurement on blood contained within the tissue; and	Nonin Medical discloses and/or renders obvious "the measurement device configured to improve a signal-to-noise ratio of the input optical beam reflected from the tissue by differencing the first data signal and the second data signal to generate an output signal representing at least in part a non-invasive measurement on blood contained within the tissue." *See* CHART ONE: '533 Patent, Claim Element 10 and CHART TWO: '040 Patent, Claim Element 1G above.
[1H] wherein the modulating at least one of the LEDs has a modulation frequency, and wherein the receiver is configured to use a lock-in technique that detects the modulation frequency.	Nonin Medical discloses and/or renders obvious "wherein the modulating at least one of the LEDs has a modulation frequency, and wherein the receiver is configured to use a lock-in technique that detects the modulation frequency."  **Introduction** The Bluetooth-enabled WristOx$_2$, Model 3150, is a small, wrist-worn device that displays, measures, and stores patient SpO$_2$ and pulse rate data. The device includes a Bluetooth radio with a range (spherical radius) of approximately 100 meters (328 feet). The device ships ready to use in Spot Check turn on mode. In Spot Check turn on mode, inserting a finger in the sensor automatically turns the device on. Approximately 10 seconds after the finger is removed, the device enters Standby mode. Advanced memory and programming features are available with Nonin's nVISION® software (version 6.3 or greater). See the "nVISION Software" section to learn more about using the device with nVISION. **NOTE:** If using the WristOx$_2$, Model 3150 with 3rd party software, please disregard nVISION information. (Operator's Manual, p. 10)

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 *On* When the device is on, it can collect and save data. The device features three turn on modes: • Spot Check mode • Sensor Activation mode • Programmed mode The device is delivered in Spot Check mode. nVISION software (version 6.3 or greater) is needed to access the device settings and change Spot Check mode to Sensor Activation or Programmed mode (see "nVISION Software"). nVISION software (version 6.4 or greater) is needed to access memory volume (MV) display mode. The device recalls the active settings when the device is shut off and turned on again. (Operator's Manual, p. 12)

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters

	
	nVISION Software
	Nonin's nVISION software (version 6.3 or greater) works with Microsoft Windows® operating systems. It allows users to transfer recorded patient data from the device to a PC and then analyze, report, and archive the data. The software is required to access the device's additional modes of operation and advanced features.
	nVISION Settings
	The following WristOx$_2$ Model 3150, settings are programmed using nVISION:
	• Date and time – 24-hour clock format
	• Display options – allows clinicians to choose the best display option for each patient:
	  • Full display shows %SpO$_2$ and pulse rate data
	  • Partial display shows pulse strength indicator, but not %SpO$_2$ and pulse rate data
	  • MVI (memory volume) display shows pulse strength indicator and volume (hours and minutes) of data stored in memory. %SpO$_2$ and pulse rate readings do not display on the screen.
	• Patient data storage (sample) rate – 1, 2, or 4 seconds
	• Operation Modes – Sensor Activation, Spot Checking, and Programmed (see "Activation Options")
	• Patient ID – up to 50 alphanumeric characters
	• Bluetooth Radio – disable at startup
	• Synchronize device time/date to the PC time/date
	• Download and save patient data to a PC
	• Clear device memory
	To access nVISION settings, connect the device to a PC using either the PC USB interface cable or a Bluetooth connection.
	(Operator's Manual, p. 29)

<table>
<tr><th>Asserted Claim of '698 Patent</th><th>Nonin Medical Pulse Oximeters</th></tr>
<tr><td></td><td>

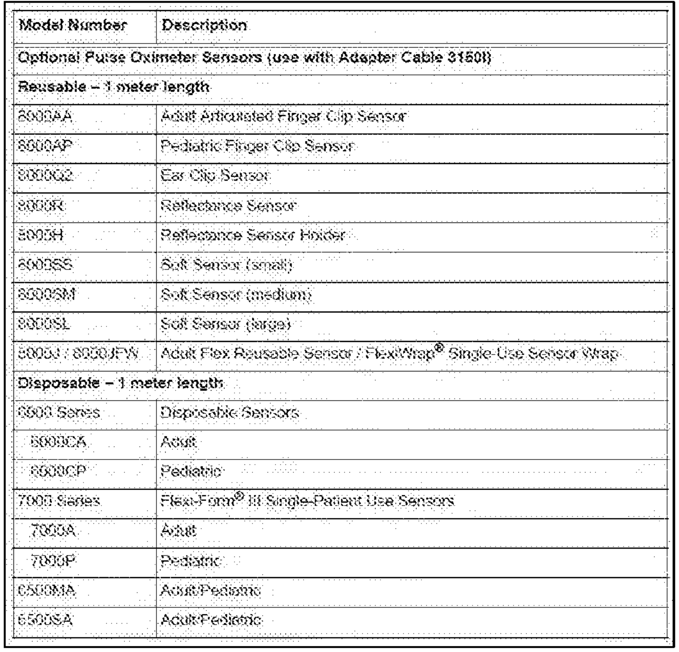
Sensors

WARNING: Only use Nonin-branded sensors with a length of 1 meter or less. Accuracy may degrade if sensor cable is over 1 meter in length. Using the sensor cable adapter does not affect accuracy.

<table>
<tr><th>Model Number</th><th>Description</th></tr>
<tr><td colspan="2">Reusable Pulse Oximeter Sensors – 12 inch (0.3 meter) length</td></tr>
<tr><td>8000AA-WO2</td><td>Adult Articulated Finger Clip Sensor</td></tr>
<tr><td>8000J-WO2</td><td>Adult Flex Sensor</td></tr>
<tr><td>8000SS-WO2</td><td>Soft Sensor Small</td></tr>
<tr><td>8000SM-WO2</td><td>Soft Sensor Medium</td></tr>
<tr><td>8000SL-WO2</td><td>Soft Sensor Large</td></tr>
</table>

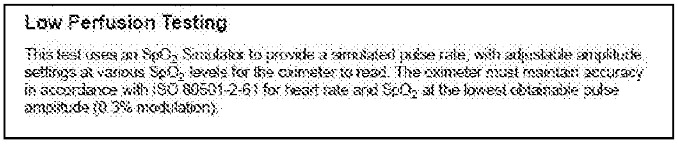
(Operator's Manual, p. 35)</td></tr>
</table>

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters



Model Number	Description
Optional Pulse Oximeter Sensors (use with Adapter Cable 3150I)	
Reusable – 1 meter length	
8000AA	Adult Articulated Finger Clip Sensor
8000AP	Pediatric Finger Clip Sensor
8000Q2	Ear Clip Sensor
8000R	Reflectance Sensor
8000H	Reflectance Sensor Holder
8000SS	Soft Sensor (small)
8000SM	Soft Sensor (medium)
8000SL	Soft Sensor (large)
8000J / 8000JFW	Adult Flex Reusable Sensor / FlexiWrap® Single-Use Sensor Wrap
Disposable – 1 meter length	
6000 Series	Disposable Sensors
6000CA	Adult
6000CP	Pediatric
7000 Series	Flexi-Form® III Single-Patient Use Sensors
7000A	Adult
7000P	Pediatric
6500MA	Adult/Pediatric
6500SA	Adult/Pediatric

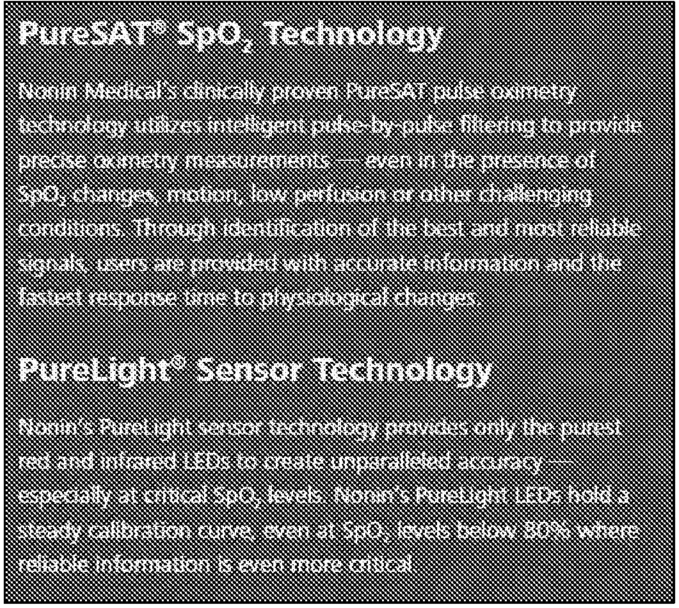
(Operator's Manual, p. 35)

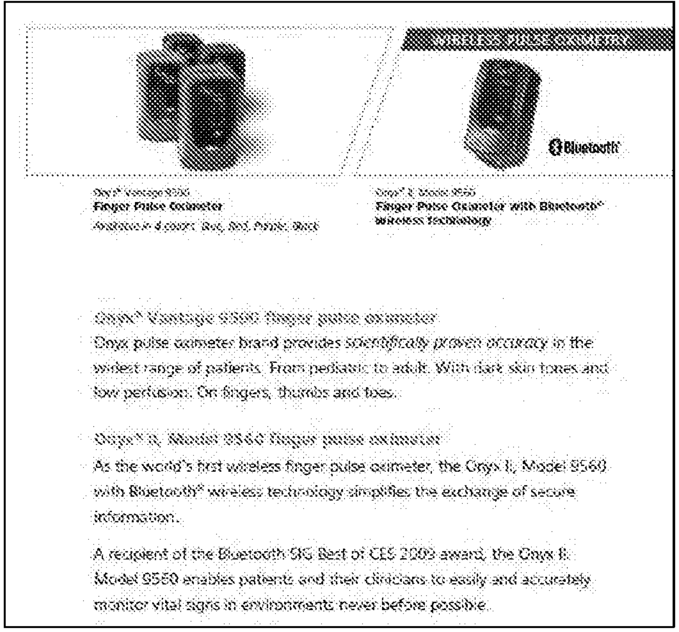


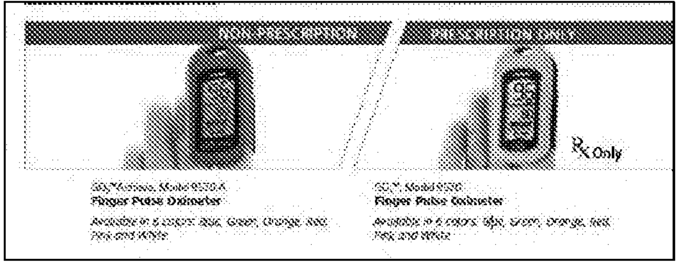
Low Perfusion Testing

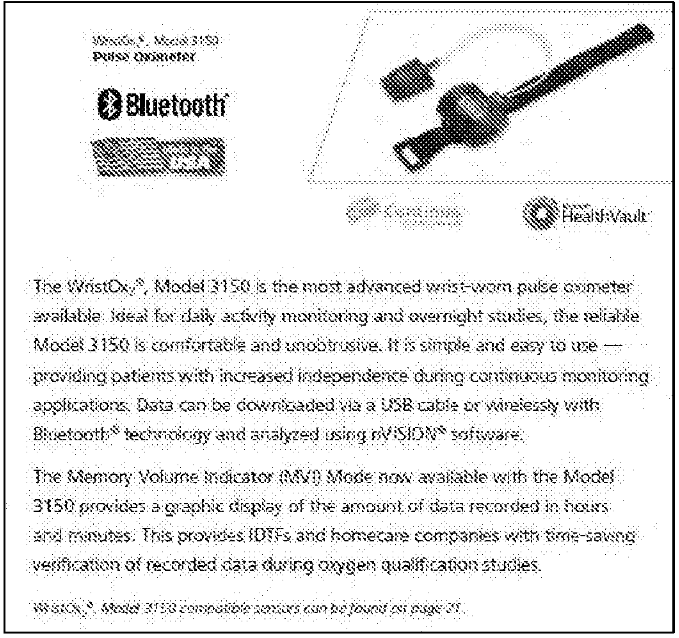
This test uses an SpO_2 Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO_2 levels for the oximeter to read. The oximeter must maintain accuracy in accordance with ISO 80601-2-61 for heart rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).

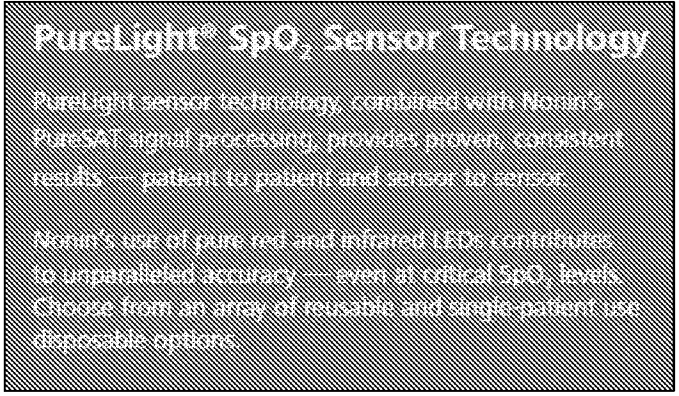
(Operator's Manual, p. 43)

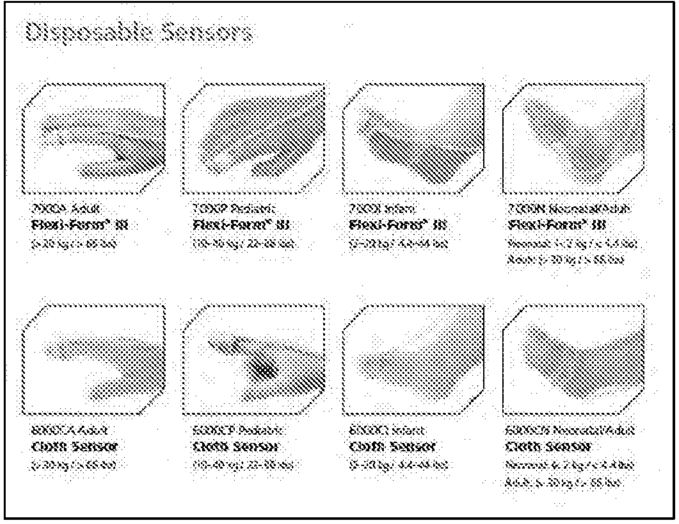
Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 **PureSAT® SpO_2 Technology** Nonin Medical's clinically proven PureSAT pulse oximetry technology utilizes intelligent pulse-by-pulse filtering to provide precise oximetry measurements — even in the presence of SpO_2 changes, motion, low perfusion or other challenging conditions. Through identification of the best and most reliable signals, users are provided with accurate information and the fastest response time to physiological changes. **PureLight® Sensor Technology** Nonin's PureLight sensor technology provides only the purest red and infrared LEDs to create unparalleled accuracy — especially at critical SpO_2 levels. Nonin's PureLight LEDs hold a steady calibration curve, even at SpO_2 levels below 80% where reliable information is even more critical. (Product Catalog, p. 4)

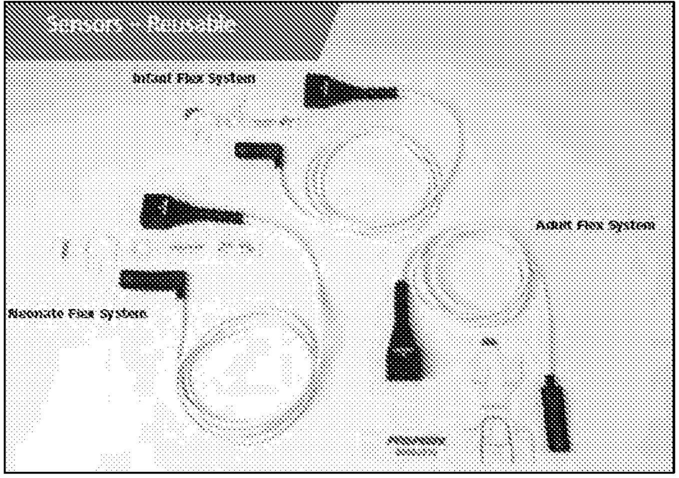
Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 WIRELESS PULSE OXIMETRY Bluetooth® Onyx® Vantage 9590 **Finger Pulse Oximeter** *Available in 4 colors: Blue, Red, Purple, Black* Onyx® II, Model 9560 **Finger Pulse Oximeter with Bluetooth® Wireless Technology** Onyx® Vantage 9590 finger pulse oximeter Onyx pulse oximeter brand provides *scientifically proven accuracy* in the widest range of patients. From pediatric to adult. With dark skin tones and low perfusion. On fingers, thumbs and toes. Onyx® II, Model 9560 finger pulse oximeter As the world's first wireless finger pulse oximeter, the Onyx II, Model 9560 with Bluetooth® wireless technology simplifies the exchange of secure information. A recipient of the Bluetooth SIG Best of CES 2009 award, the Onyx II, Model 9560 enables patients and their clinicians to easily and accurately monitor vital signs in environments never before possible. (Product Catalog, p. 7)

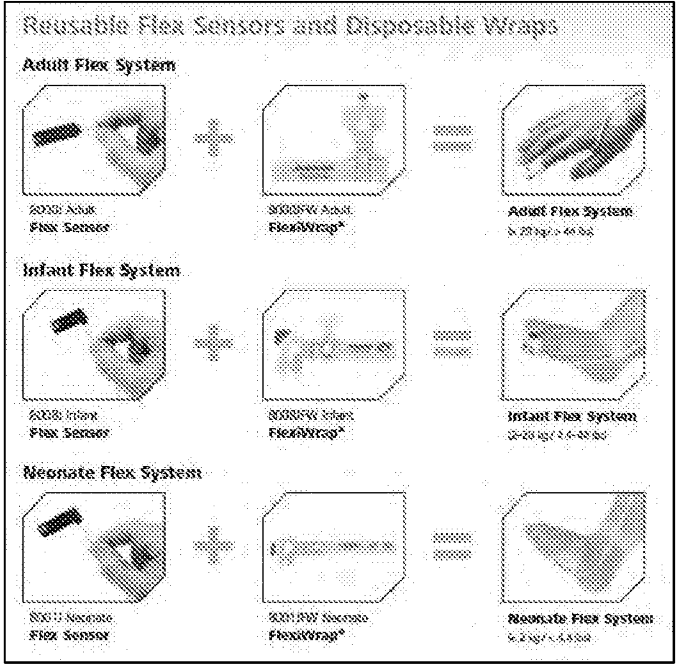
Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 9)

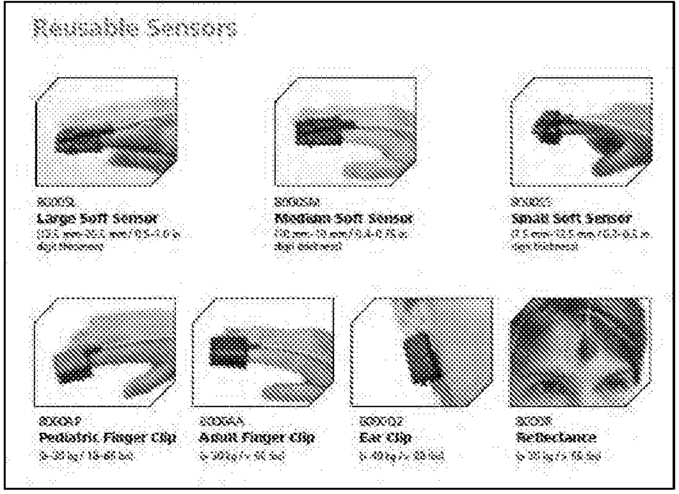
Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 WristOx$_2$®, Model 3150 Pulse Oximeter The WristOx$_2$®, Model 3150 is the most advanced wrist-worn pulse oximeter available. Ideal for daily activity monitoring and overnight studies, the reliable Model 3150 is comfortable and unobtrusive. It is simple and easy to use — providing patients with increased independence during continuous monitoring applications. Data can be downloaded via a USB cable or wirelessly with Bluetooth® technology and analyzed using nVISION® software. The Memory Volume Indicator (MVI) Mode now available with the Model 3150 provides a graphic display of the amount of data recorded in hours and minutes. This provides IDTFs and homecare companies with time-saving verification of recorded data during oxygen qualification studies. WristOx$_2$®, Model 3150 compatible sensors can be found on page 21. (Product Catalog, p. 11)

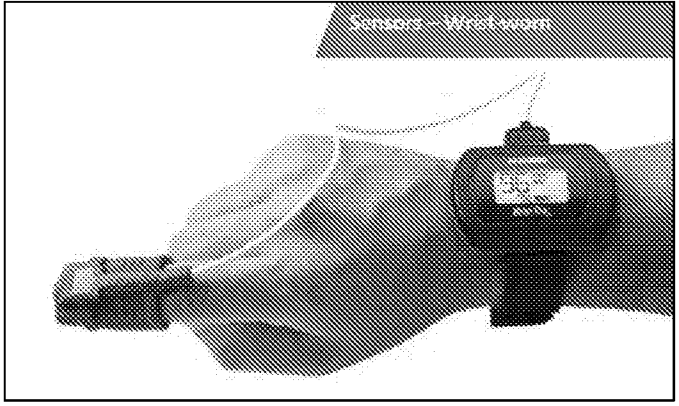
Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 **PureLight® SpO_2 Sensor Technology** PureLight sensor technology, combined with Nonin's PureSAT signal processing, provides proven, consistent results — patient to patient and sensor to sensor. Nonin's use of pure red and infrared LEDs contributes to unparalleled accuracy — even at critical SpO_2 levels. Choose from an array of reusable and single-patient use disposable options. (Product Catalog, p. 16)

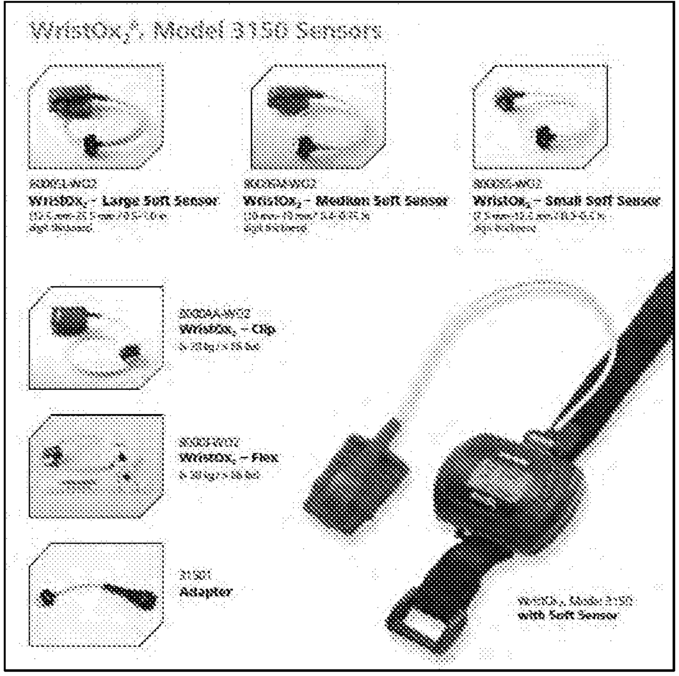
Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 Disposable Sensors 7000A Adult **Flexi-Form® III** 7000P Pediatric **Flexi-Form® III** 7000I Infant **Flexi-Form® III** 7000N Neonatal/Adult **Flexi-Form® III** 8000CA Adult **Cloth Sensor** 8000CP Pediatric **Cloth Sensor** 8000CI Infant **Cloth Sensor** 8000CN Neonatal/Adult **Cloth Sensor** (Product Catalog, p. 17)

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 18)

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 18)

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 Reusable Sensors Large Soft Sensor Medium Soft Sensor Small Soft Sensor Pediatric Finger Clip Adult Finger Clip Ear Clip Reflectance (Product Catalog, p. 19)

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 21)

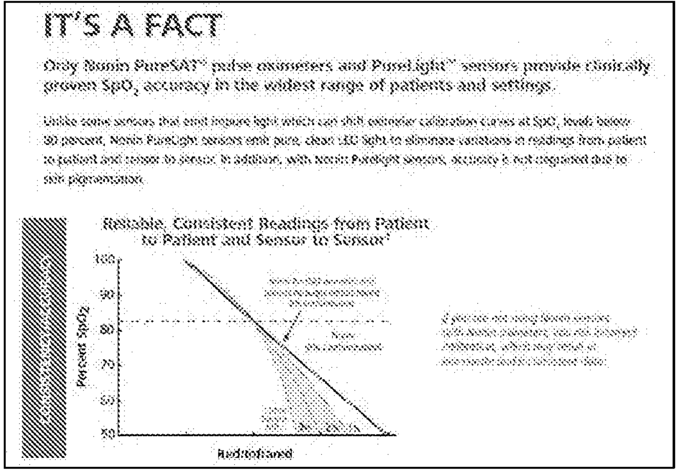
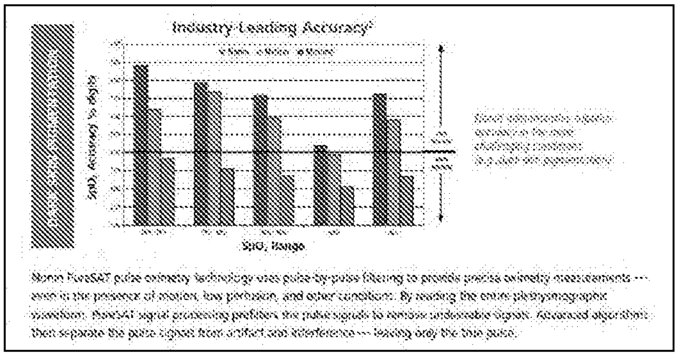
Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 21)

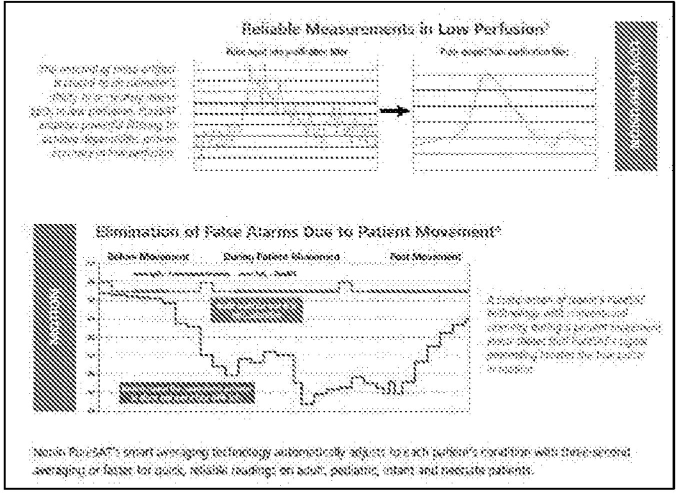
Omni MedSci, Inc. v. Apple Inc.
Case No. 2:18-cv-134-RWS (E.D. Tex.)

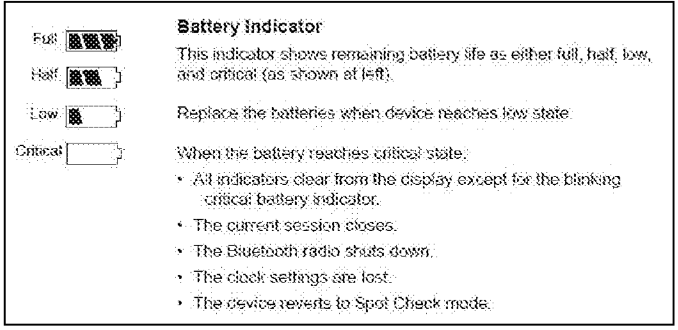
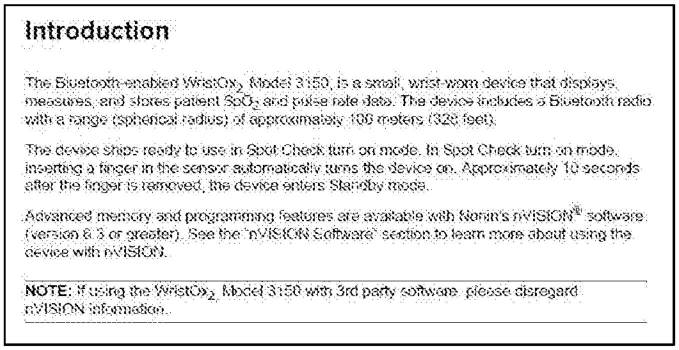
EXHIBIT W-4, p. 19

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 31)

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 31)

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 IT'S A FACT Only Nonin PureSAT™ pulse oximeters and PureLight™ sensors provide clinically proven SpO_2 accuracy in the widest range of patients and settings. Unlike some sensors that emit impure light which can shift oximeter calibration curves at SpO_2 levels below 80 percent, Nonin PureLight sensors emit pure, clean LED light to eliminate variations in readings from patient to patient and sensor to sensor. In addition, with Nonin PureLight sensors, accuracy is not degraded due to skin pigmentation. (Brochure, p.  Nonin PureSAT pulse oximetry technology uses pulse-by-pulse filtering to provide precise oximetry measurements — even in the presence of motion, low perfusion, and other conditions. By reading the entire plethysmographic waveform, PureSAT signal processing prefilters the pulse signals to remove undesirable signals. Advanced algorithms then separate the pulse signals from artifact and interference — leaving only the true pulse. (Brochure, p. 2)

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 Reliable Measurements in Low Perfusion² Elimination of False Alarms Due to Patient Movement² Nonin PureSAT's smart averaging technology automatically adjusts to each patient's condition with three-second averaging or faster for quick, reliable readings on adult, pediatric, infant and neonate patients. (Brochure, p. 2)
[2] The wearable device of claim 1, wherein the plurality of LEDs and the plurality of spatially separated detectors are mounted on a common structure, and wherein the plurality of LEDs are coupled electrically to a power supply.	Nonin Medical discloses and/or renders obvious "[t]he wearable device of claim 1, wherein the plurality of LEDs and the plurality of spatially separated detectors are mounted on a common structure, and wherein the plurality of LEDs are coupled electrically to a power supply.."

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 **Battery Indicator** This indicator shows remaining battery life as either full, half, low, and critical (as shown at left). Replace the batteries when device reaches low state. When the battery reaches critical state: • All indicators clear from the display except for the blinking critical battery indicator. • The current session closes. • The Bluetooth radio shuts down. • The clock settings are lost. • The device reverts to Spot Check mode. (Operator's Manual, p. 9)  **Introduction** The Bluetooth-enabled WristOx$_2$ Model 3150, is a small, wrist-worn device that displays, measures, and stores patient SpO$_2$ and pulse rate data. The device includes a Bluetooth radio with a range (spherical radius) of approximately 100 meters (328 feet). The device ships ready to use in Spot Check turn on mode. In Spot Check turn on mode, inserting a finger in the sensor automatically turns the device on. Approximately 10 seconds after the finger is removed, the device enters Standby mode. Advanced memory and programming features are available with Nonin's nVISION® software (version 6.3 or greater). See the "nVISION Software" section to learn more about using the device with nVISION. **NOTE:** If using the WristOx$_2$ Model 3150 with 3rd party software, please disregard nVISION information. (Operator's Manual, p. 10)

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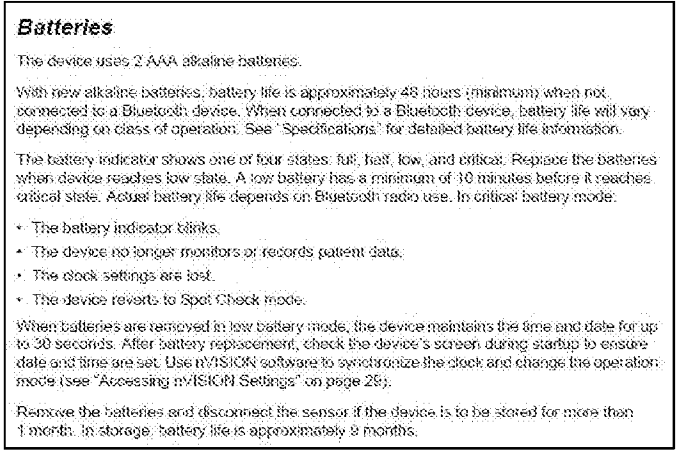
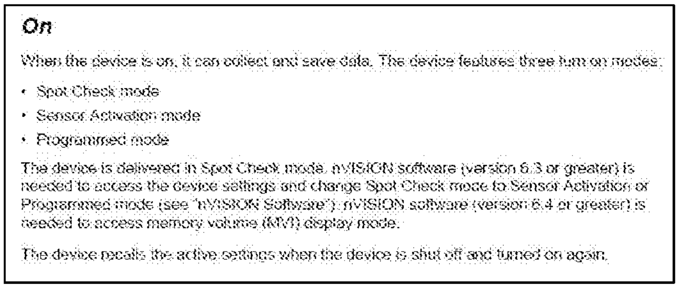
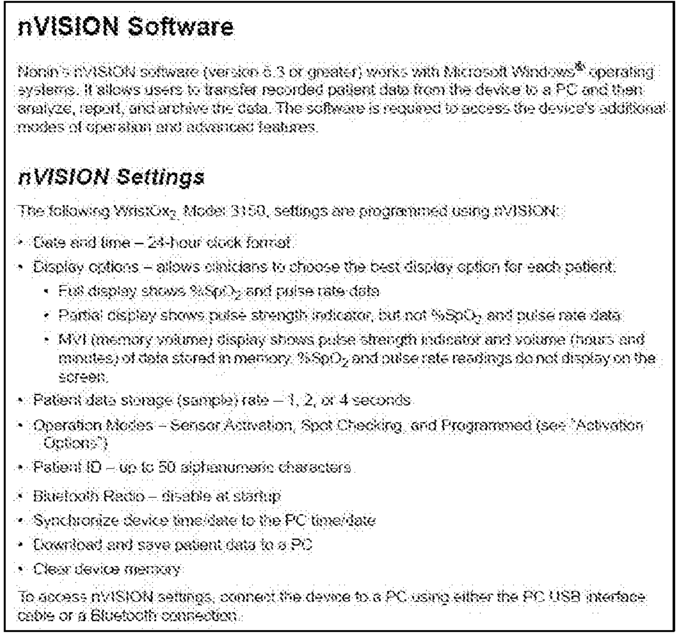
	 ***Batteries*** The device uses 2 AAA alkaline batteries. With new alkaline batteries, battery life is approximately 48 hours (minimum) when not connected to a Bluetooth device. When connected to a Bluetooth device, battery life will vary depending on class of operation. See "Specifications" for detailed battery life information. The battery indicator shows one of four states: full, half, low, and critical. Replace the batteries when device reaches low state. A low battery has a minimum of 10 minutes before it reaches critical state. Actual battery life depends on Bluetooth radio use. In critical battery mode: • The battery indicator blinks. • The device no longer monitors or records patient data. • The clock settings are lost. • The device reverts to Spot Check mode. When batteries are removed in low battery mode, the device maintains the time and date for up to 30 seconds. After battery replacement, check the device's screen during startup to ensure date and time are set. Use nVISION software to synchronize the clock and change the operation mode (see "Accessing nVISION Settings" on page 29). Remove the batteries and disconnect the sensor if the device is to be stored for more than 1 month. In storage, battery life is approximately 9 months. (Operator's Manual, p. 11)  ***On*** When the device is on, it can collect and save data. The device features three turn on modes: • Spot Check mode • Sensor Activation mode • Programmed mode The device is delivered in Spot Check mode. nVISION software (version 6.3 or greater) is needed to access the device settings and change Spot Check mode to Sensor Activation or Programmed mode (see "nVISION Software"). nVISION software (version 6.4 or greater) is needed to access memory volume (MVI) display mode. The device recalls the active settings when the device is shut off and turned on again. (Operator's Manual, p. 12)

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters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	Nonin's nVISION software (version 6.3 or greater) works with Microsoft Windows® operating systems. It allows users to transfer recorded patient data from the device to a PC and then analyze, report, and archive the data. The software is required to access the device's additional modes of operation and advanced features.
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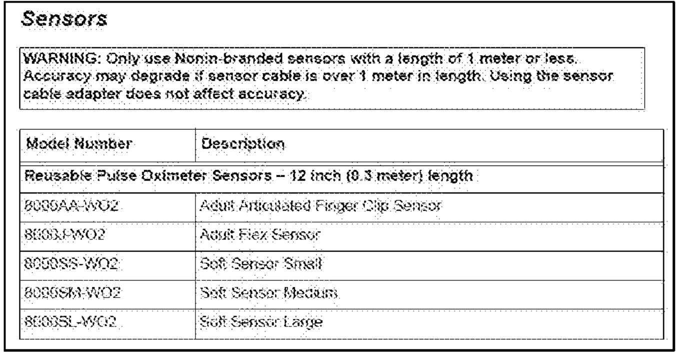
	  • Partial display shows pulse strength indicator, but not %SpO$_2$ and pulse rate data
	  • MVI (memory volume) display shows pulse strength indicator and volume (hours and minutes) of data stored in memory. %SpO$_2$ and pulse rate readings do not display on the screen.
	• Patient data storage (sample) rate – 1, 2, or 4 seconds
	• Operation Modes – Sensor Activation, Spot Checking, and Programmed (see "Activation Options")
	• Patient ID – up to 50 alphanumeric characters
	• Bluetooth Radio – disable at startup
	• Synchronize device time/date to the PC time/date
	• Download and save patient data to a PC
	• Clear device memory
	To access nVISION settings, connect the device to a PC using either the PC USB interface cable or a Bluetooth connection.
	(Operator's Manual, p. 29)

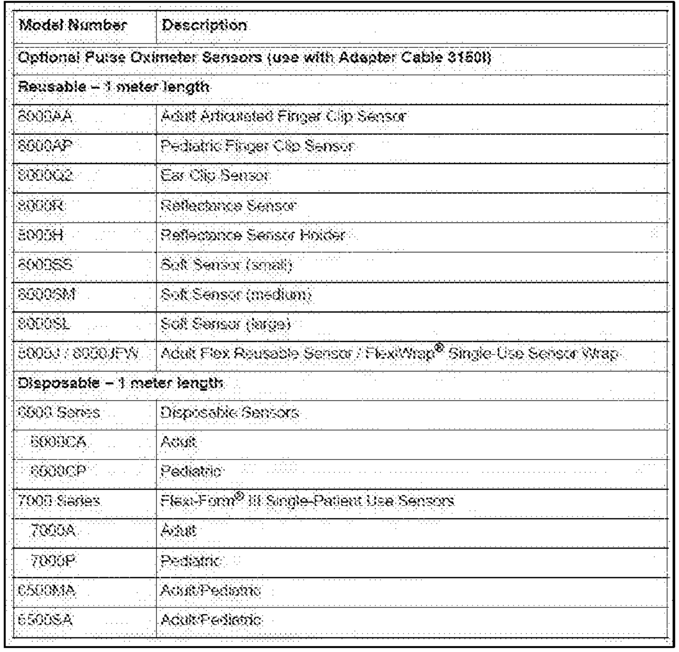
<table>
<tr><th>Asserted Claim of ’698 Patent</th><th>Nonin Medical Pulse Oximeters</th></tr>
<tr><td></td><td>

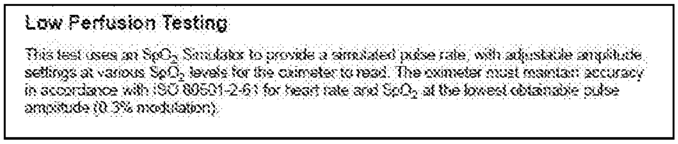
Sensors

WARNING: Only use Nonin-branded sensors with a length of 1 meter or less. Accuracy may degrade if sensor cable is over 1 meter in length. Using the sensor cable adapter does not affect accuracy.

<table>
<tr><th>Model Number</th><th>Description</th></tr>
<tr><td colspan="2">Reusable Pulse Oximeter Sensors – 12 inch (0.3 meter) length</td></tr>
<tr><td>8000AA-WO2</td><td>Adult Articulated Finger Clip Sensor</td></tr>
<tr><td>8000J-WO2</td><td>Adult Flex Sensor</td></tr>
<tr><td>8000SS-WO2</td><td>Soft Sensor Small</td></tr>
<tr><td>8000SM-WO2</td><td>Soft Sensor Medium</td></tr>
<tr><td>8000SL-WO2</td><td>Soft Sensor Large</td></tr>
</table>

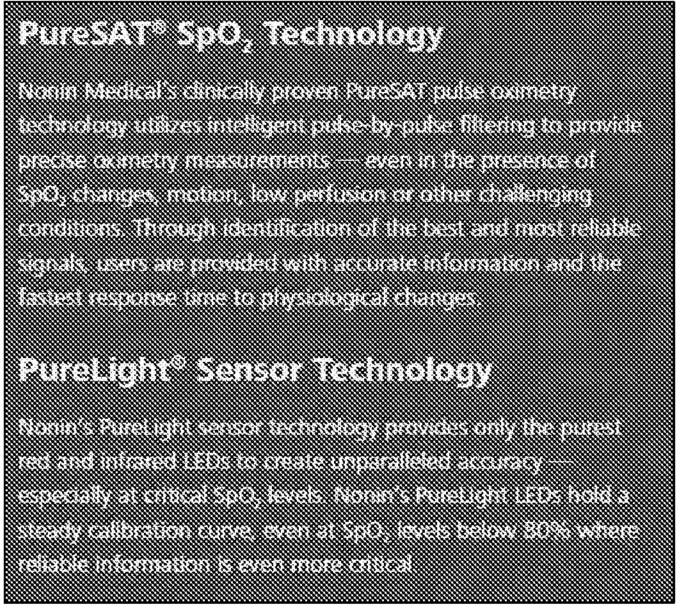
(Operator’s Manual, p. 35)</td></tr>
</table>

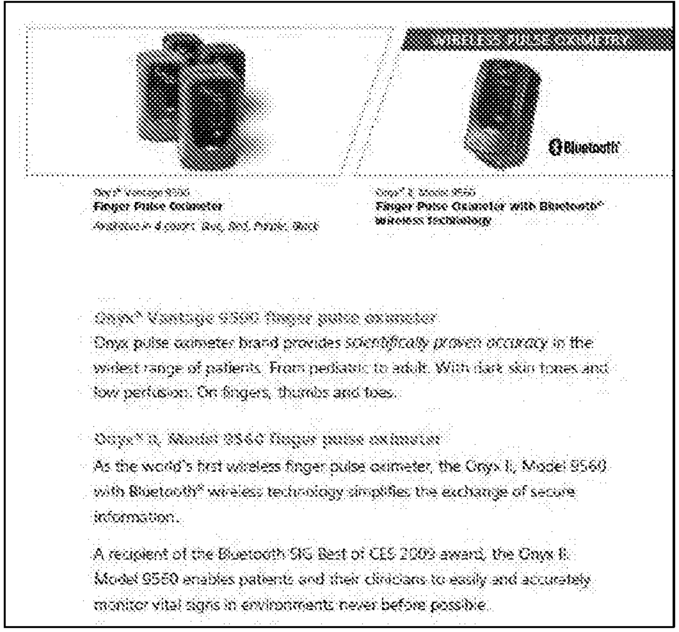
<table>
<tr><th>Asserted Claim of '698 Patent</th><th>Nonin Medical Pulse Oximeters</th></tr>
<tr><td></td><td>

<table>
<tr><th>Model Number</th><th>Description</th></tr>
<tr><td colspan="2">Optional Pulse Oximeter Sensors (use with Adapter Cable 3150I)</td></tr>
<tr><td colspan="2">Reusable – 1 meter length</td></tr>
<tr><td>8000AA</td><td>Adult Articulated Finger Clip Sensor</td></tr>
<tr><td>8000AP</td><td>Pediatric Finger Clip Sensor</td></tr>
<tr><td>8000Q2</td><td>Ear Clip Sensor</td></tr>
<tr><td>8000R</td><td>Reflectance Sensor</td></tr>
<tr><td>8000H</td><td>Reflectance Sensor Holder</td></tr>
<tr><td>8000SS</td><td>Soft Sensor (small)</td></tr>
<tr><td>8000SM</td><td>Soft Sensor (medium)</td></tr>
<tr><td>8000SL</td><td>Soft Sensor (large)</td></tr>
<tr><td>8000J / 8000JFW</td><td>Adult Flex Reusable Sensor / FlexiWrap® Single-Use Sensor Wrap</td></tr>
<tr><td colspan="2">Disposable – 1 meter length</td></tr>
<tr><td>6000 Series</td><td>Disposable Sensors</td></tr>
<tr><td>6000CA</td><td>Adult</td></tr>
<tr><td>6000CP</td><td>Pediatric</td></tr>
<tr><td>7000 Series</td><td>Flexi-Form® III Single-Patient Use Sensors</td></tr>
<tr><td>7000A</td><td>Adult</td></tr>
<tr><td>7000P</td><td>Pediatric</td></tr>
<tr><td>6500MA</td><td>Adult/Pediatric</td></tr>
<tr><td>6500SA</td><td>Adult/Pediatric</td></tr>
</table>
(Operator's Manual, p. 35)

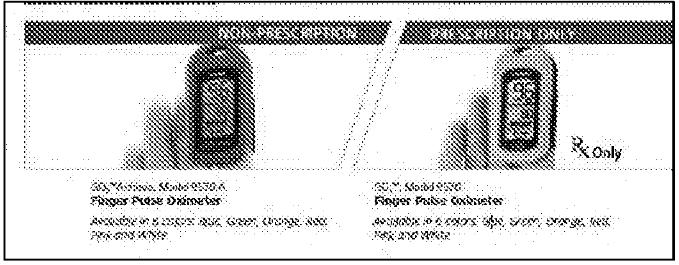

Low Perfusion Testing

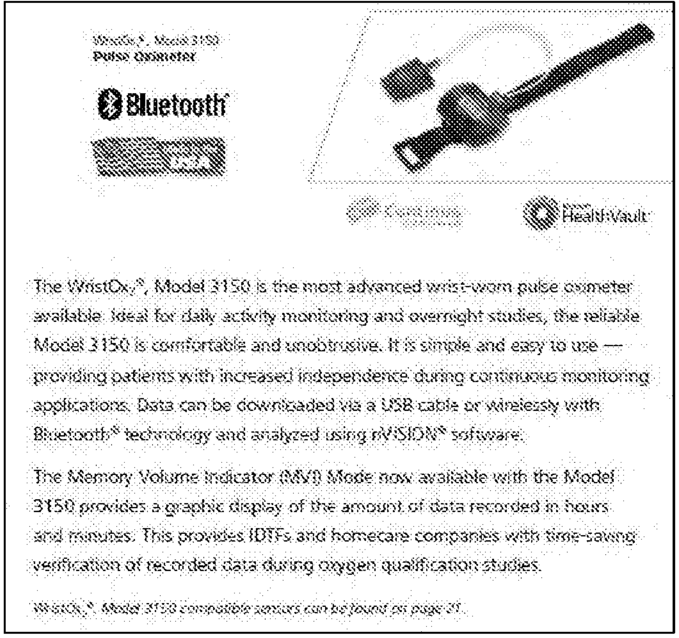
This test uses an SpO_2 Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO_2 levels for the oximeter to read. The oximeter must maintain accuracy in accordance with ISO 80601-2-61 for heart rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).

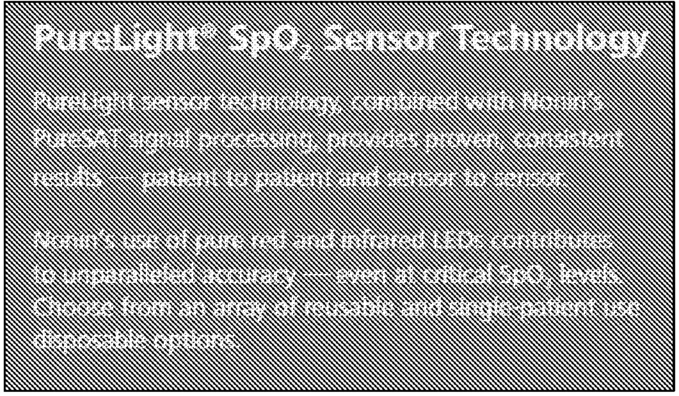
(Operator's Manual, p. 43)
</td></tr>
</table>

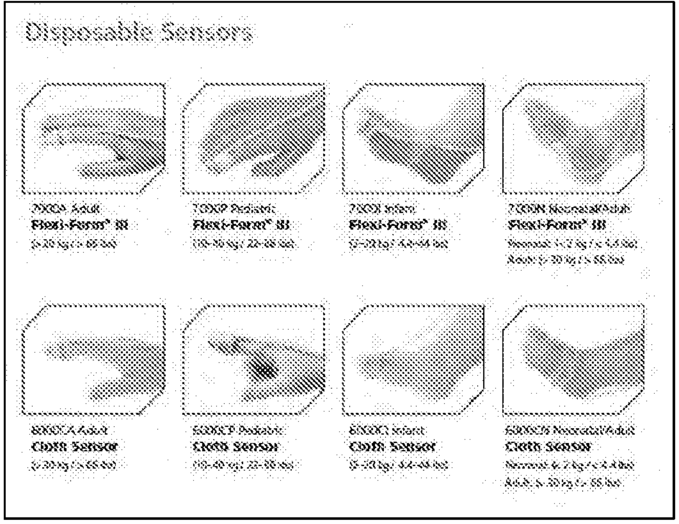
Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 **PureSAT® SpO_2 Technology** Nonin Medical's clinically proven PureSAT pulse oximetry technology utilizes intelligent pulse-by-pulse filtering to provide precise oximetry measurements — even in the presence of SpO_2 changes, motion, low perfusion or other challenging conditions. Through identification of the best and most reliable signals, users are provided with accurate information and the fastest response time to physiological changes. **PureLight® Sensor Technology** Nonin's PureLight sensor technology provides only the purest red and infrared LEDs to create unparalleled accuracy — especially at critical SpO_2 levels. Nonin's PureLight LEDs hold a steady calibration curve, even at SpO_2 levels below 80% where reliable information is even more critical. (Product Catalog, p. 4)

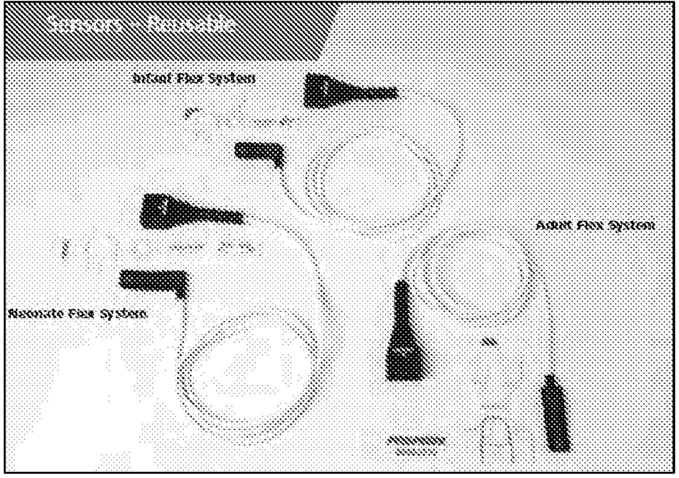
Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 Onyx® Vantage 9590 **Finger Pulse Oximeter** *Available in 4 colors: Blue, Red, Purple, Black* Onyx® II, Model 9560 **Finger Pulse Oximeter with Bluetooth® wireless technology** Onyx® Vantage 9590 finger pulse oximeter Onyx pulse oximeter brand provides *scientifically proven accuracy* in the widest range of patients. From pediatric to adult. With dark skin tones and low perfusion. On fingers, thumbs and toes. Onyx® II, Model 9560 finger pulse oximeter As the world's first wireless finger pulse oximeter, the Onyx II, Model 9560 with Bluetooth® wireless technology simplifies the exchange of secure information. A recipient of the Bluetooth SIG Best of CES 2009 award, the Onyx II, Model 9560 enables patients and their clinicians to easily and accurately monitor vital signs in environments never before possible. (Product Catalog, p. 7)

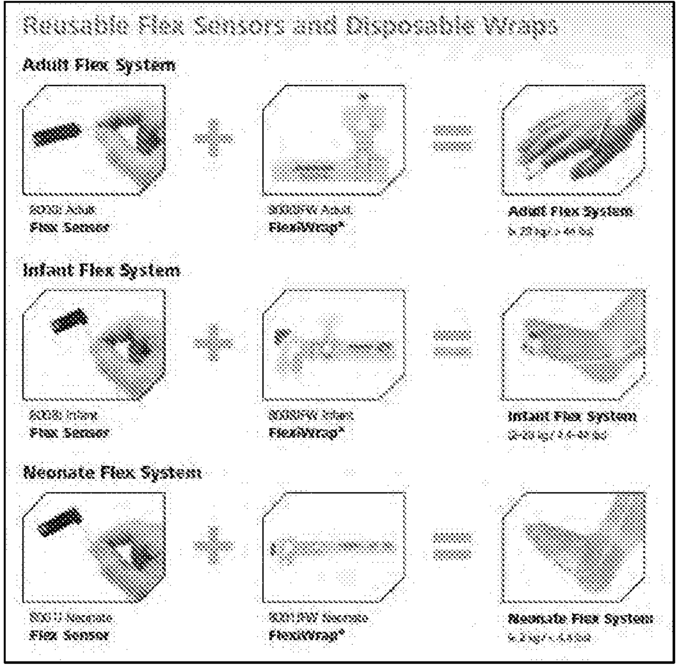
Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 9)

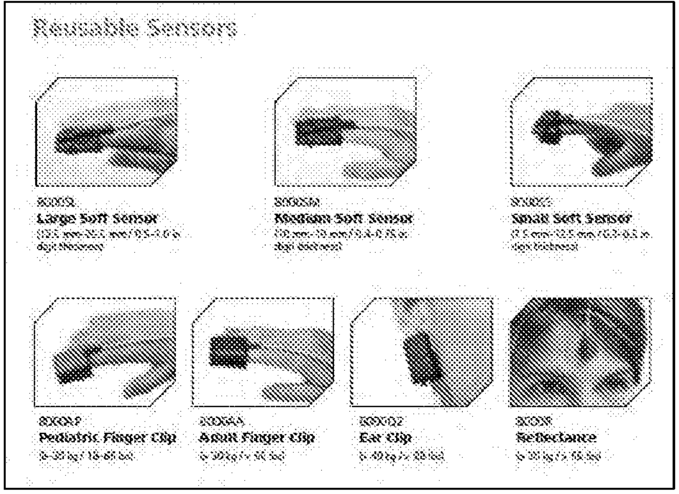
Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	WristOx$_2$®, Model 3150 Pulse Oximeter Bluetooth HealthVault The WristOx$_2$®, Model 3150 is the most advanced wrist-worn pulse oximeter available. Ideal for daily activity monitoring and overnight studies, the reliable Model 3150 is comfortable and unobtrusive. It is simple and easy to use — providing patients with increased independence during continuous monitoring applications. Data can be downloaded via a USB cable or wirelessly with Bluetooth® technology and analyzed using nVISION® software. The Memory Volume Indicator (MVI) Mode now available with the Model 3150 provides a graphic display of the amount of data recorded in hours and minutes. This provides IDTFs and homecare companies with time-saving verification of recorded data during oxygen qualification studies. *WristOx$_2$®, Model 3150 compatible sensors can be found on page 21.* (Product Catalog, p. 11)

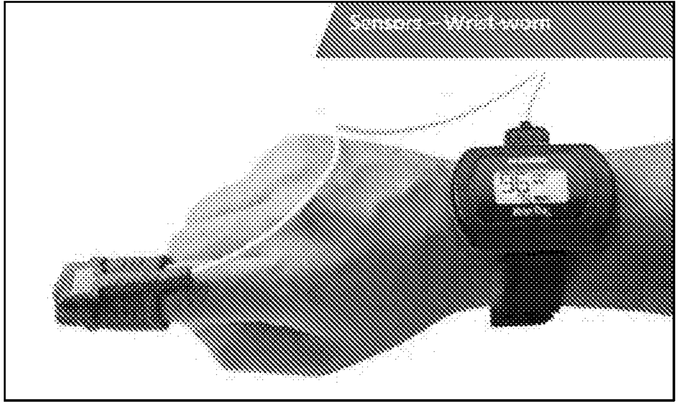
Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 PureLight® SpO_2 Sensor Technology PureLight sensor technology, combined with Nonin's PureSAT signal processing, provides proven, consistent results — patient to patient and sensor to sensor. Nonin's use of pure red and infrared LEDs contributes to unparalleled accuracy — even at critical SpO_2 levels. Choose from an array of reusable and single-patient use disposable options. (Product Catalog, p. 16)

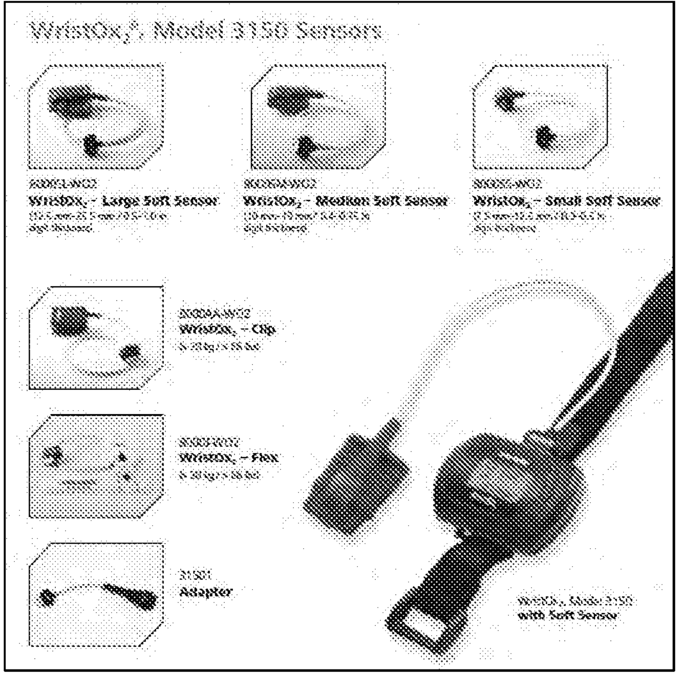
Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 Disposable Sensors 7000A Adult **Flexi-Form® III** 7000P Pediatric **Flexi-Form® III** 7000I Infant **Flexi-Form® III** 7000N Neonatal/Adult **Flexi-Form® III** 6000CA Adult **Cloth Sensor** 6000CP Pediatric **Cloth Sensor** 6000CI Infant **Cloth Sensor** 6000CN Neonatal/Adult **Cloth Sensor** (Product Catalog, p. 17)

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 18)

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 18)

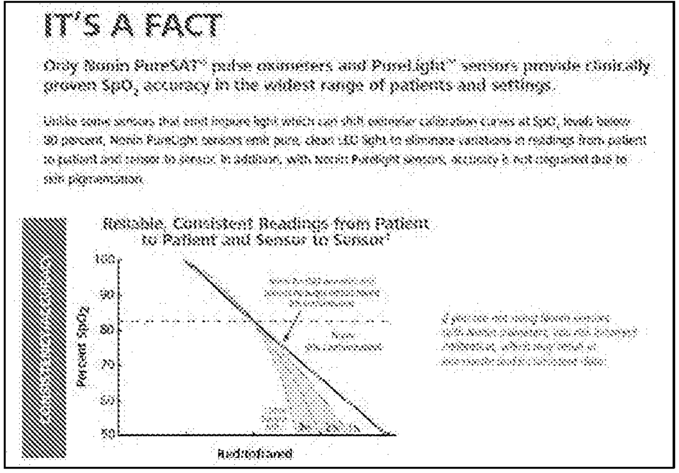
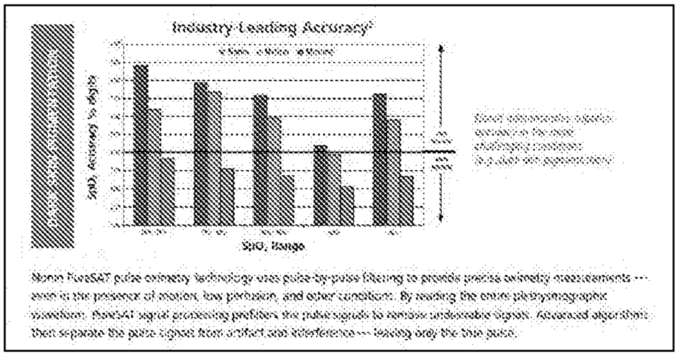
Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 19)

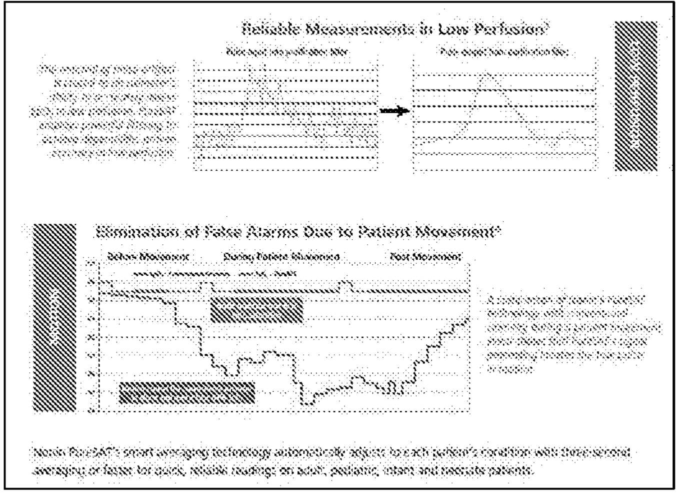
Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 21)

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 21)

Asserted Claim of '698 Patent	**Nonin Medical Pulse Oximeters**
	 (Product Catalog, p. 31)

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 (Product Catalog, p. 31)

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 IT'S A FACT Only Nonin PureSAT™ pulse oximeters and PureLight™ sensors provide clinically proven SpO_2 accuracy in the widest range of patients and settings. Unlike some sensors that emit impure light which can shift oximeter calibration curves at SpO_2 levels below 80 percent, Nonin PureLight sensors emit pure, clean LED light to eliminate variations in readings from patient to patient and sensor to sensor. In addition, with Nonin PureLight sensors, accuracy is not degraded due to skin pigmentation. Reliable, Consistent Readings from Patient to Patient and Sensor to Sensor¹ (Brochure, p.  Industry-Leading Accuracy² Nonin PureSAT pulse oximetry technology uses pulse-by-pulse filtering to provide precise oximetry measurements — even in the presence of motion, low perfusion, and other conditions. By reading the entire plethysmographic waveform, PureSAT signal processing prefilters the pulse signals to remove undesirable signals. Advanced algorithms then separate the pulse signal from artifact and interference — leaving only the true pulse. (Brochure, p. 2)

Asserted Claim of '698 Patent	Nonin Medical Pulse Oximeters
	 (Brochure, p. 2)
[3] The wearable device of claim 1, wherein the light source is configured to further improve the signal-to-noise ratio of the input beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs, and wherein the receiver is configured to be synchronized to at least one of the LEDs.	Nonin Medical discloses and/or renders obvious "[t]he wearable device of claim 1, wherein the light source is configured to further improve the signal-to-noise ratio of the input beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs, and wherein the receiver is configured to be synchronized to at least one of the LEDs." *See* CHART ONE: '533 Patent, Claim Elements 5C and 5F above.
[5] The wearable device of claim 1, wherein the wearable device is	Nonin Medical discloses and/or renders obvious "[t]he wearable device of claim 1, wherein the wearable device is configured to communicate with a smart phone or tablet, the smart phone or

Asserted Claim of '698 Patent	**Nonin Medical Pulse Oximeters**
configured to communicate with a smart phone or tablet, the smart phone or tablet comprising a wireless receiver, a wireless transmitter, a display, a voice input module, a speaker, and a touch screen, the smart phone or tablet configured to receive and to process at least a portion of the output signal, wherein the smart phone or tablet is configured to store and display the processed output signal, wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link.	tablet comprising a wireless receiver, a wireless transmitter, a display, a voice input module, a speaker, and a touch screen, the smart phone or tablet configured to receive and to process at least a portion of the output signal, wherein the smart phone or tablet is configured to store and display the processed output signal, wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link." *See* CHART ONE: '533 Patent, Claim Element 5K above.

Omni MedSci, Inc. v. Apple Inc.
Case No. 2:18-cv-134-RWS (E.D. Tex.)

DEFENDANT'S INVALIDITY CONTENTIONS
August 28, 2018

EXHIBIT X

EXHIBIT X-1

U.S. Patent No. 9,651,533 vs Nellcor

Priority Date/Publication Date: between 2001 and December 2012 Prior Art Status: §§ 102(a) and (b)

The OxiMax, NPB-40, N-550, and certain pulse oximeters and pulse oximetry sensors manufactured by Nellcor ("Nellcor") anticipate the asserted claims of U.S. Patent No. 9,651,533 ("the '533 Patent") or render those claims obvious alone and/or in view of at least any of the references identified in Apple's Obviousness Combinations Chart.

This chart is based on the following disclosures about Nellcor pulse oximeters:

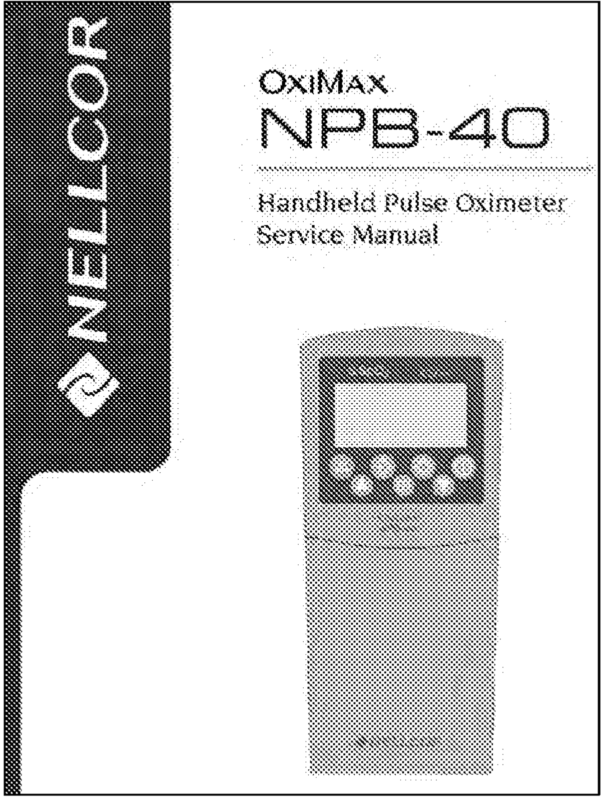
- Nellcor OxiMax NPB-40 Handheld Pulse Oximeter Service Manual 2004 ("NPB-40 Service Manual")
- Nellcor OxiMax N-550 Pulse Oximeter Service Manual 2003 ("N-550 Manual")
- Nellcor NPB-40 Handheld Pulse Oximeter Operator's Manual 2001 ("NPB-40 Operator's Manual")
- Nellcor OxiMax White Paper "A Technology Overview of the Nellcor™ OxiMax Pulse Oximetry System" 2003 ("White Paper")

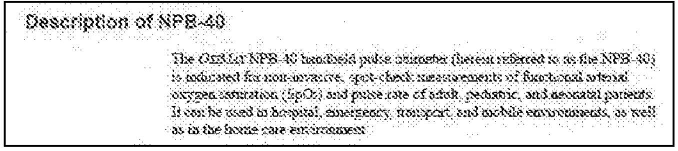
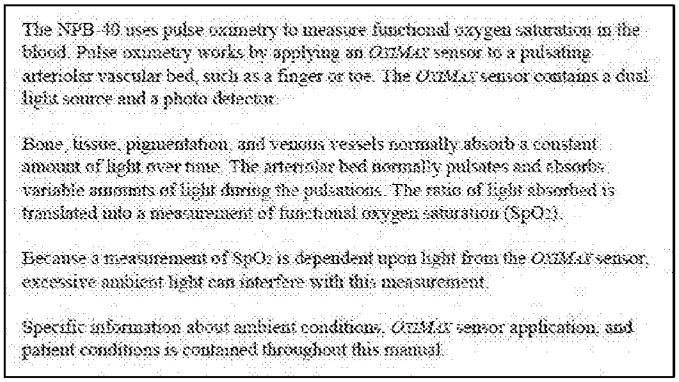
Discovery is ongoing, and Apple reserves the right to amend this chart based on new information about the Nellcor pulse oximeters.

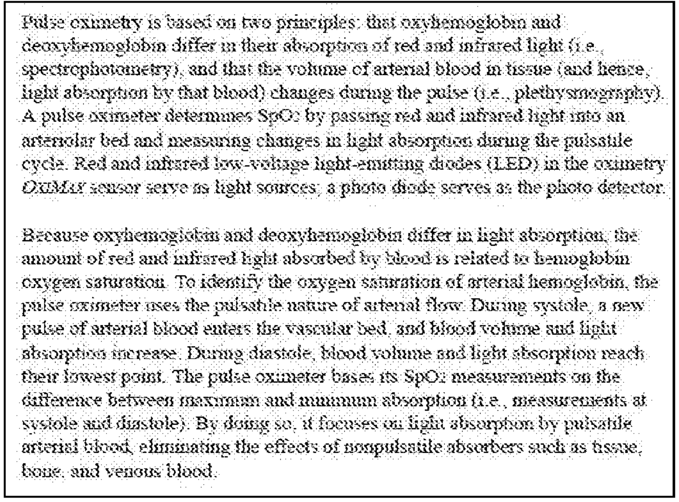
As set forth in Apple's Invalidity Contentions, the below contentions apply the prior art in part in accordance with Apple's assumption that Omni contends the claims are not invalid under 35 U.S.C. § 112. However, Apple's below contentions do not represent Apple's agreement or view as to the meaning, definiteness, written description support for, or enablement of any of the asserted claims. For each dependent claim, the disclosures cited for the claim from which it depends are incorporated by reference.

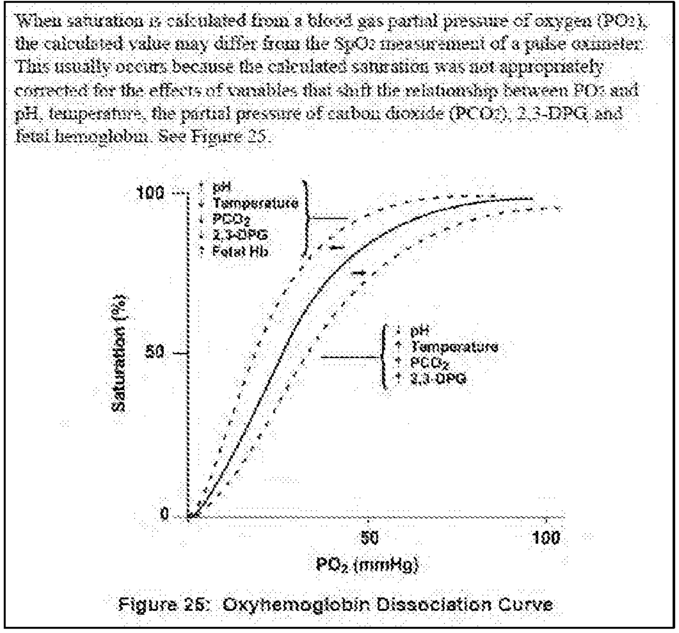
CHART ONE: U.S. Patent No. 9,651,533 vs Nellcor

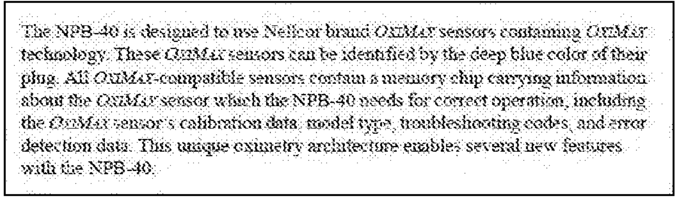
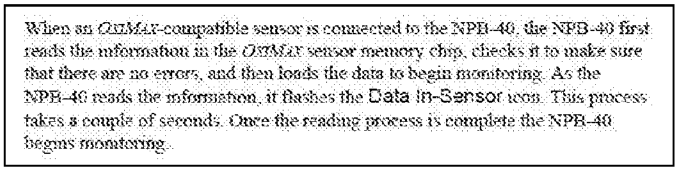
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
[5] A measurement system, comprising:	To the extent the preamble is limiting, Nellcor discloses and/or renders obvious "[a] measurement system."

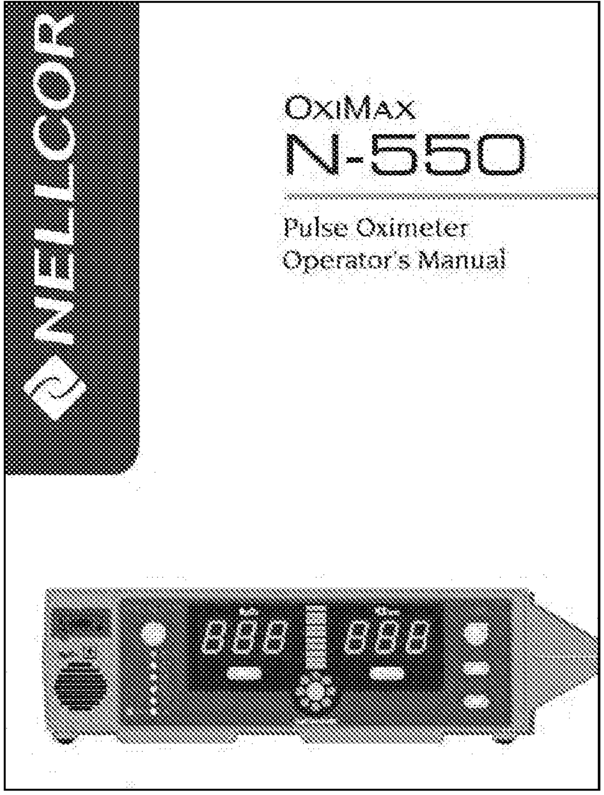
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 NELLCOR OxiMax NPB-40 Handheld Pulse Oximeter Service Manual (NPB-40 Service Manual, Cover)

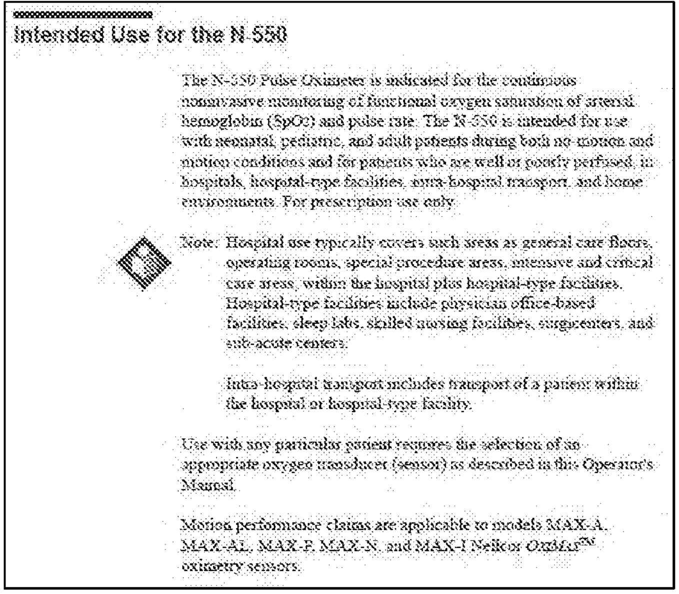
Asserted Claim of ’533 Patent	Nellcor Pulse Oximeters
	 Description of NPB-40 The *OxiMax* NPB-40 handheld pulse oximeter (herein referred to as the NPB-40) is indicated for non-invasive, spot-check measurements of functional arterial oxygen saturation (SpO_2) and pulse rate of adult, pediatric, and neonatal patients. It can be used in hospital, emergency, transport, and mobile environments, as well as in the home care environment. (NPB-40 Service Manual, p. 3)  The NPB-40 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying an *OxiMax* sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The *OxiMax* sensor contains a dual light source and a photo detector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO_2). Because a measurement of SpO_2 is dependent upon light from the *OxiMax* sensor, excessive ambient light can interfere with this measurement. Specific information about ambient conditions, *OxiMax* sensor application, and patient conditions is contained throughout this manual. (NPB-40 Service Manual, p. 75)

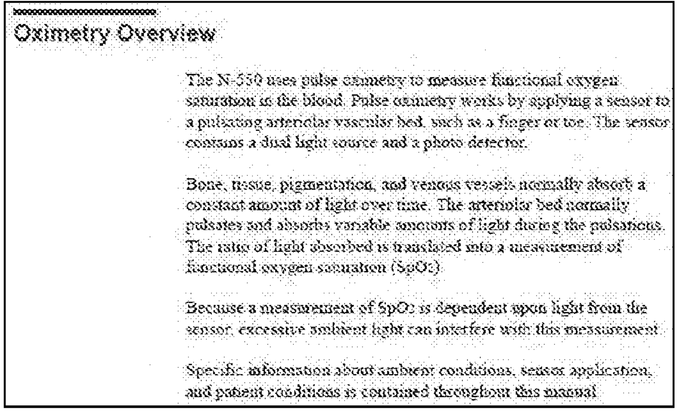
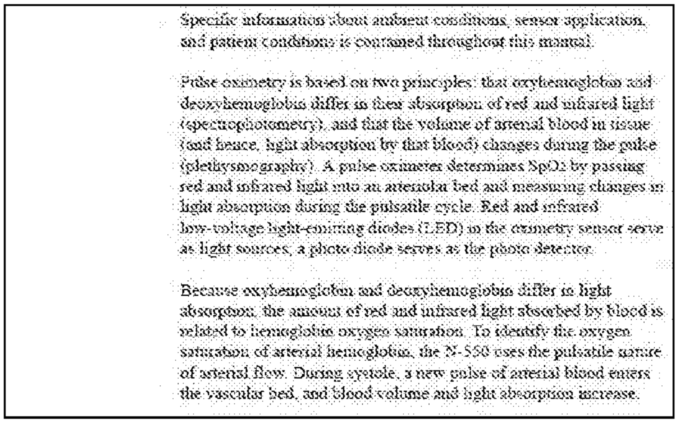
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e., spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e., plethysmography). A pulse oximeter determines SpO_2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry *OxiMax* sensor serve as light sources; a photo diode serves as the photo detector. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial hemoglobin, the pulse oximeter uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The pulse oximeter bases its SpO_2 measurements on the difference between maximum and minimum absorption (i.e., measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. (NPB-40 Service Manual, p. 75)

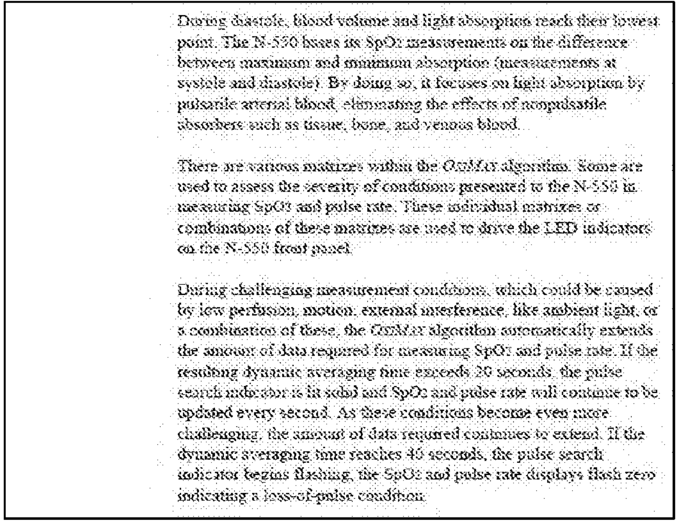
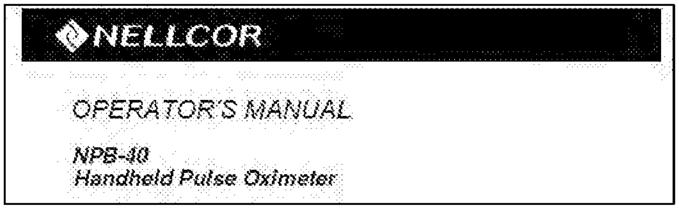
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 When saturation is calculated from a blood gas partial pressure of oxygen (PO2), the calculated value may differ from the SpO2 measurement of a pulse oximeter. This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO2 and pH, temperature, the partial pressure of carbon dioxide (PCO2), 2,3-DPG and fetal hemoglobin. See Figure 25. Figure 25: Oxyhemoglobin Dissociation Curve (NPB-40 Service Manual, p. 76)

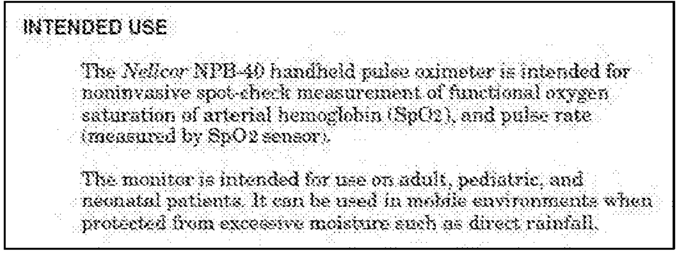
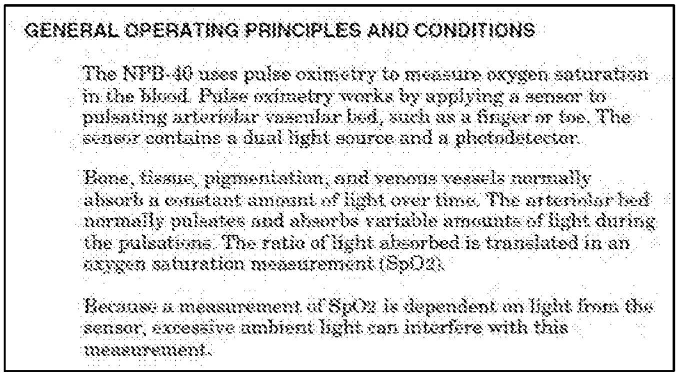
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)  When an *OxiMax*-compatible sensor is connected to the NPB-40, the NPB-40 first reads the information in the *OxiMax* sensor memory chip, checks it to make sure that there are no errors, and then loads the data to begin monitoring. As the NPB-40 reads the information, it flashes the Data In-Sensor icon. This process takes a couple of seconds. Once the reading process is complete the NPB-40 begins monitoring. (NPB-40 Service Manual, p. 77)

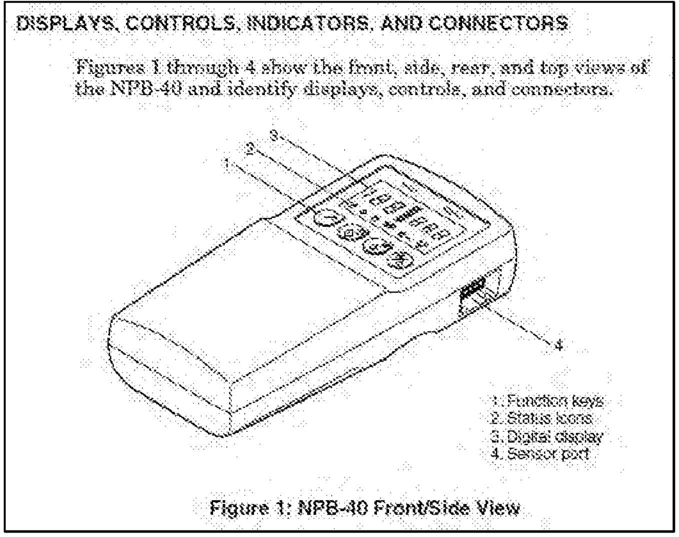
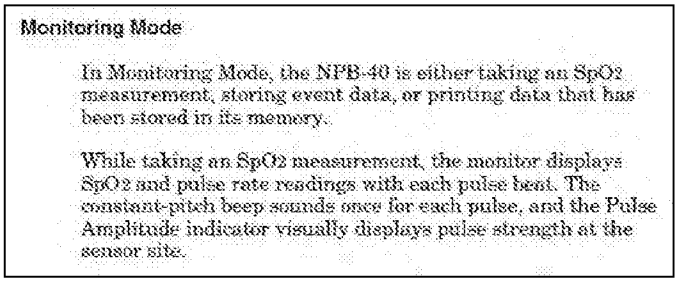
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 NELLCOR OxiMax N-550 Pulse Oximeter Operator's Manual (N-550 Manual, Cover)

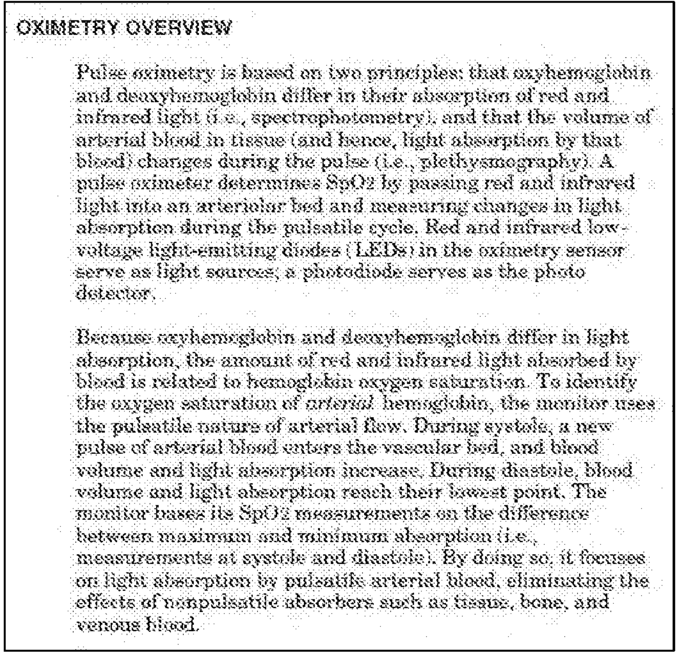
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 **Intended Use for the N-550** The N-550 Pulse Oximeter is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The N-550 is intended for use with neonatal, pediatric, and adult patients during both no-motion and motion conditions and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, intra-hospital transport, and home environments. For prescription use only. Note: Hospital use typically covers such areas as general care floors, operating rooms, special procedure areas, intensive and critical care areas, within the hospital plus hospital-type facilities. Hospital-type facilities include physician office-based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acute centers. Intra-hospital transport includes transport of a patient within the hospital or hospital-type facility. Use with any particular patient requires the selection of an appropriate oxygen transducer (sensor) as described in this Operator's Manual. Motion performance claims are applicable to models MAX-A, MAX-AL, MAX-P, MAX-N, and MAX-I Nellcor OxiMax™ oximetry sensors. (N-550 Manual, p. 5)

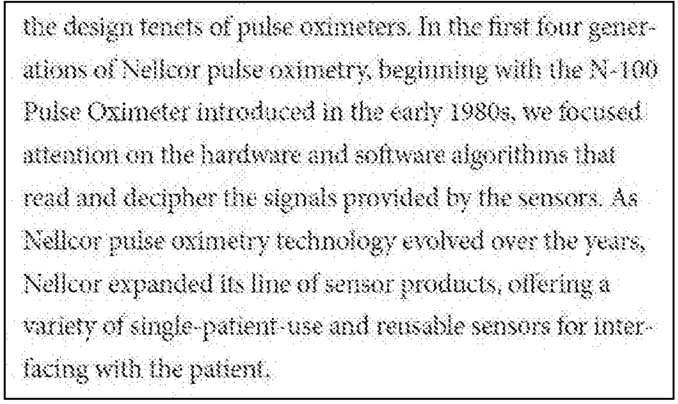
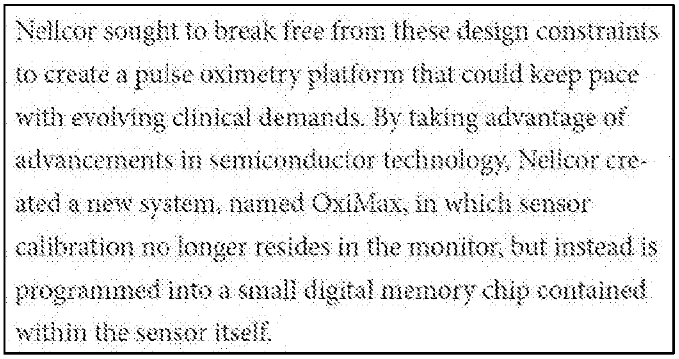
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Oximetry Overview The N-550 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photo detector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO2). Because a measurement of SpO2 is dependent upon light from the sensor, excessive ambient light can interfere with this measurement. Specific information about ambient conditions, sensor application, and patient conditions is contained throughout this manual. (N-550 Manual, p. 93)  Specific information about ambient conditions, sensor application, and patient conditions is contained throughout this manual. Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography). A pulse oximeter determines SpO2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry sensor serve as light sources; a photo diode serves as the photo detector. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial hemoglobin, the N-550 uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. (N-550 Manual, p. 93)

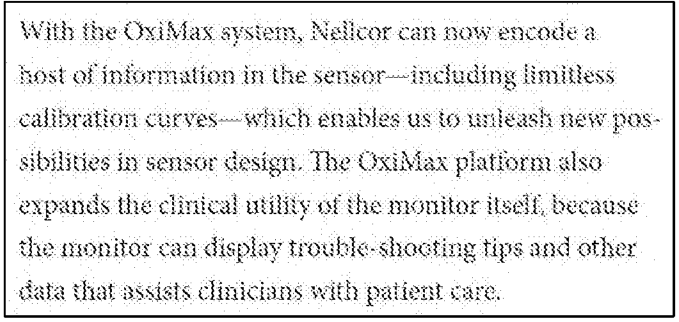
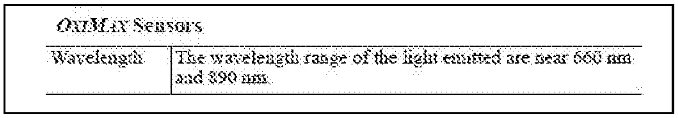
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 During diastole, blood volume and light absorption reach their lowest point. The N-550 bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. There are various matrixes within the *OxiMax* algorithm. Some are used to assess the severity of conditions presented to the N-550 in measuring SpO_2 and pulse rate. These individual matrixes or combinations of these matrixes are used to drive the LED indicators on the N-550 front panel. During challenging measurement conditions, which could be caused by low perfusion, motion, external interference, like ambient light, or a combination of these, the *OxiMax* algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate. If the resulting dynamic averaging time exceeds 20 seconds, the pulse search indicator is lit solid and SpO_2 and pulse rate will continue to be updated every second. As these conditions become even more challenging, the amount of data required continues to extend. If the dynamic averaging time reaches 40 seconds, the pulse search indicator begins flashing, the SpO_2 and pulse rate displays flash zero indicating a loss-of-pulse condition. (N-550 Manual, p. 94)  NELLCOR *OPERATOR'S MANUAL* *NPB-40* *Handheld Pulse Oximeter* (NPB-40 Operator's Manual, Cover)

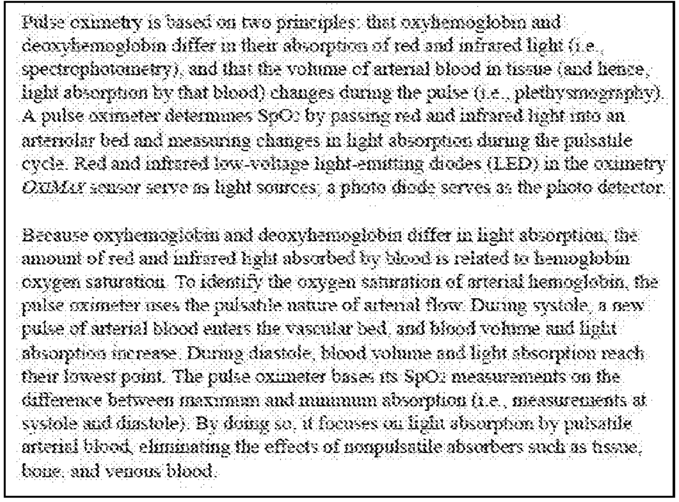
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 INTENDED USE The *Nellcor* NPB-40 handheld pulse oximeter is intended for noninvasive spot-check measurement of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate (measured by SpO2 sensor). The monitor is intended for use on adult, pediatric, and neonatal patients. It can be used in mobile environments when protected from excessive moisture such as direct rainfall. (NPB-40 Operator's Manual, p. 3)  GENERAL OPERATING PRINCIPLES AND CONDITIONS The NPB-40 uses pulse oximetry to measure oxygen saturation in the blood. Pulse oximetry works by applying a sensor to pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photodetector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated in an oxygen saturation measurement (SpO2). Because a measurement of SpO2 is dependent on light from the sensor, excessive ambient light can interfere with this measurement. (NPB-40 Operator's Manual, p. 3-4)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 DISPLAYS, CONTROLS, INDICATORS, AND CONNECTORS Figures 1 through 4 show the front, side, rear, and top views of the NPB-40 and identify displays, controls, and connectors. Figure 1: NPB-40 Front/Side View (NPB-40 Operator's Manual, p. 5)  Monitoring Mode In Monitoring Mode, the NPB-40 is either taking an SpO2 measurement, storing event data, or printing data that has been stored in its memory. While taking an SpO2 measurement, the monitor displays SpO2 and pulse rate readings with each pulse beat. The constant-pitch beep sounds once for each pulse, and the Pulse Amplitude indicator visually displays pulse strength at the sensor site. (NPB-40 Operator's Manual, p. 22)

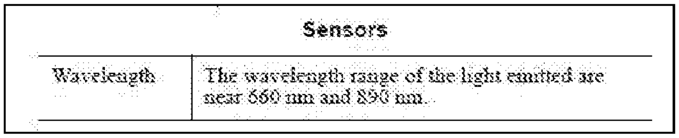
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 OXIMETRY OVERVIEW Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e., spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e., plethysmography). A pulse oximeter determines SpO2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LEDs) in the oximetry sensor serve as light sources; a photodiode serves as the photo detector. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of *arterial* hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitor bases its SpO2 measurements on the difference between maximum and minimum absorption (i.e., measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. (NPB-40 Operator's Manual, p. 41)

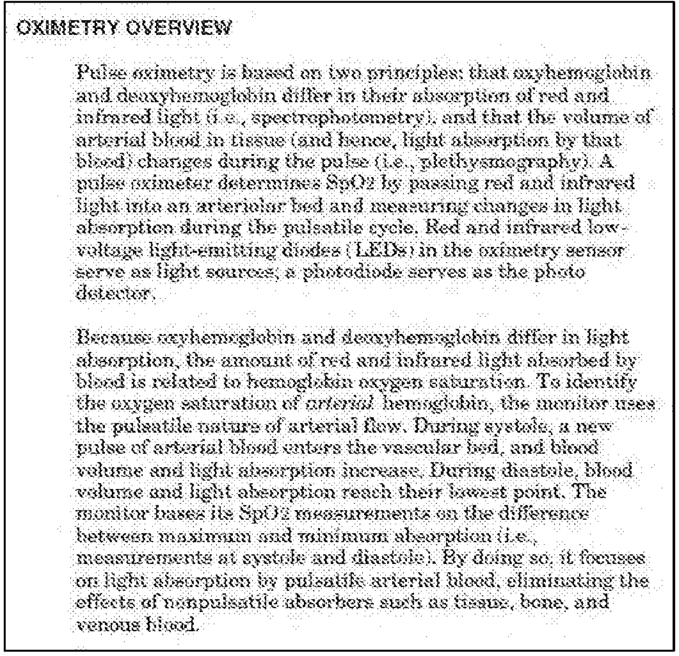
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	the design tenets of pulse oximeters. In the first four generations of Nellcor pulse oximetry, beginning with the N-100 Pulse Oximeter introduced in the early 1980s, we focused attention on the hardware and software algorithms that read and decipher the signals provided by the sensors. As Nellcor pulse oximetry technology evolved over the years, Nellcor expanded its line of sensor products, offering a variety of single-patient-use and reusable sensors for interfacing with the patient. (White Paper, p. 1) Nellcor sought to break free from these design constraints to create a pulse oximetry platform that could keep pace with evolving clinical demands. By taking advantage of advancements in semiconductor technology, Nellcor created a new system, named OxiMax, in which sensor calibration no longer resides in the monitor, but instead is programmed into a small digital memory chip contained within the sensor itself. (White Paper, p. 1)

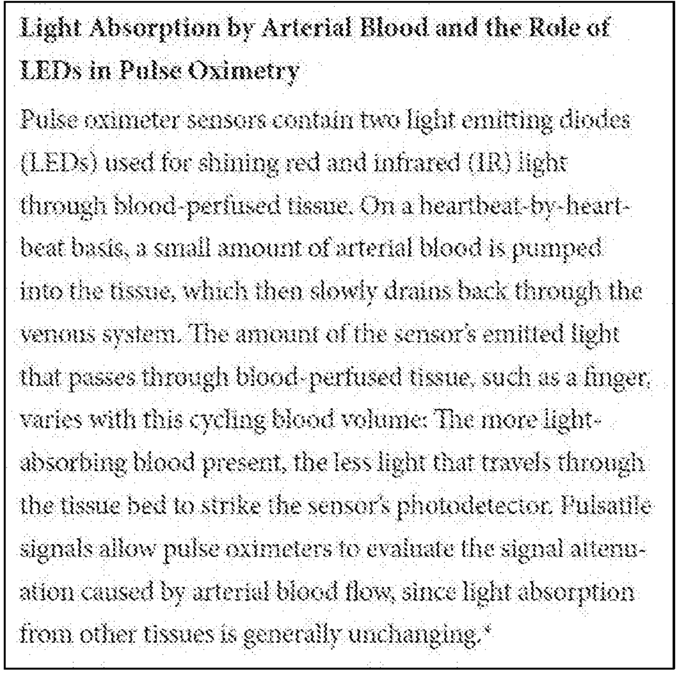
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 With the OxiMax system, Nellcor can now encode a host of information in the sensor—including limitless calibration curves—which enables us to unleash new possibilities in sensor design. The OxiMax platform also expands the clinical utility of the monitor itself, because the monitor can display trouble-shooting tips and other data that assists clinicians with patient care. (White Paper, p. 1)
[5A] a light source comprising a plurality of semiconductor sources that are light emitting diodes, the light emitting diodes configured to generate an output optical beam with one or more optical wavelengths,	Nellcor discloses and/or renders obvious "a light source comprising a plurality of semiconductor sources that are light emitting diodes, the light emitting diodes configured to generate an output optical beam with one or more optical wavelengths." *See* CHART ONE: '533 Patent, Claim Element 13A below.
[5B] wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers,	Nellcor discloses and/or renders obvious "wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers."  *OxiMax* Sensors Wavelength: The wavelength range of the light emitted are near 660 nm and 890 nm. (NPB-40 Service Manual, p. 63)

<table>
<tr><th>Asserted Claim of ’533 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>

Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e., spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e., plethysmography). A pulse oximeter determines SpO_2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry <i>OxiMax</i> sensor serve as light sources; a photo diode serves as the photo detector.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial hemoglobin, the pulse oximeter uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The pulse oximeter bases its SpO_2 measurements on the difference between maximum and minimum absorption (i.e., measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.
(NPB-40 Service Manual, p. 75)


Sensors
<table>
<tr><td>Wavelength</td><td>The wavelength range of the light emitted are near 660 nm and 890 nm.</td></tr>
</table>
(N-550 Manual, p. 102)
</td></tr>
</table>

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 OXIMETRY OVERVIEW Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e., spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e., plethysmography). A pulse oximeter determines SpO2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LEDs) in the oximetry sensor serve as light sources; a photodiode serves as the photo detector. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of *arterial* hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitor bases its SpO2 measurements on the difference between maximum and minimum absorption (i.e., measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. (NPB-40 Operator's Manual, p. 41)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 **Light Absorption by Arterial Blood and the Role of LEDs in Pulse Oximetry** Pulse oximeter sensors contain two light emitting diodes (LEDs) used for shining red and infrared (IR) light through blood-perfused tissue. On a heartbeat-by-heartbeat basis, a small amount of arterial blood is pumped into the tissue, which then slowly drains back through the venous system. The amount of the sensor's emitted light that passes through blood-perfused tissue, such as a finger, varies with this cycling blood volume: The more light-absorbing blood present, the less light that travels through the tissue bed to strike the sensor's photodetector. Pulsatile signals allow pulse oximeters to evaluate the signal attenuation caused by arterial blood flow, since light absorption from other tissues is generally unchanging.* (White Paper, p. 1)

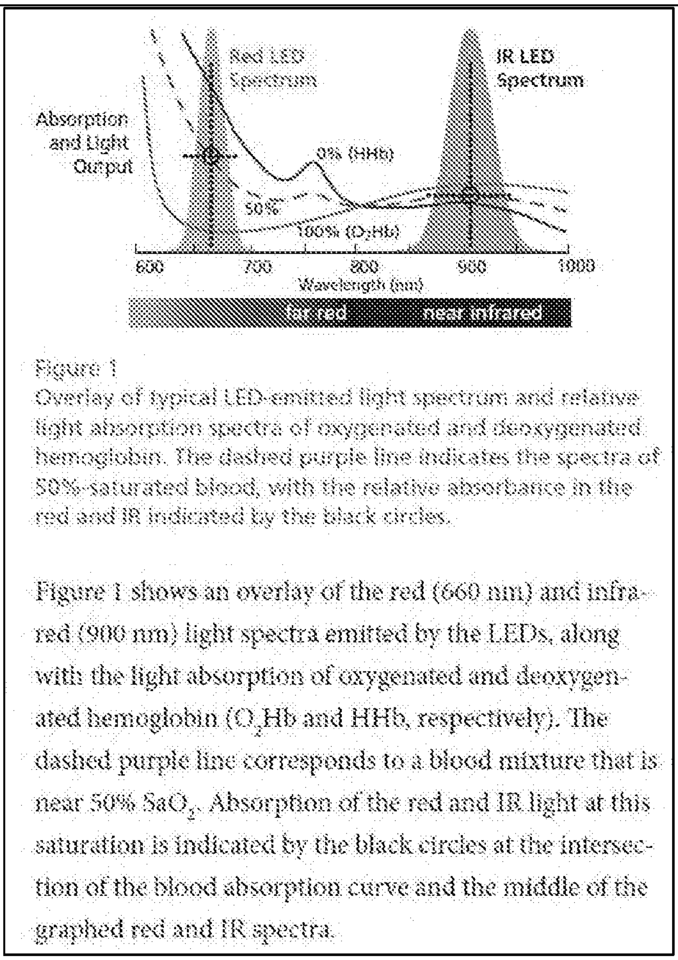
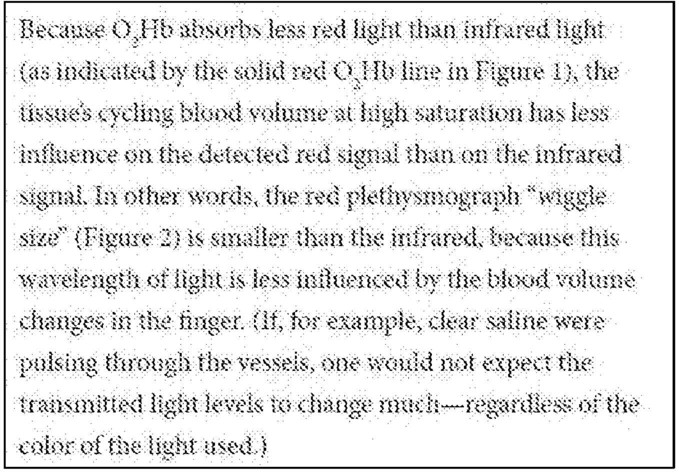
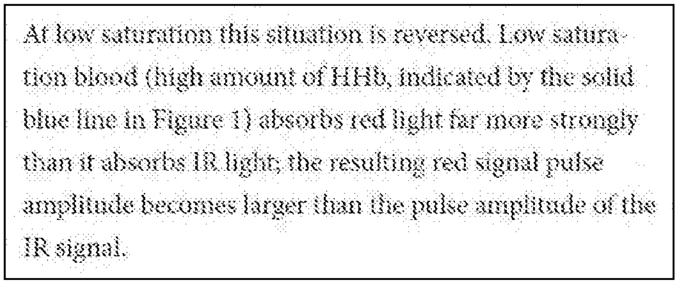
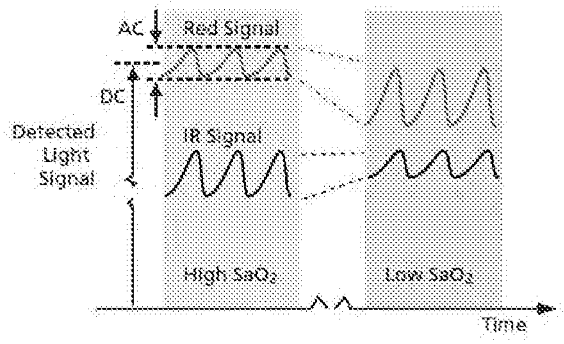


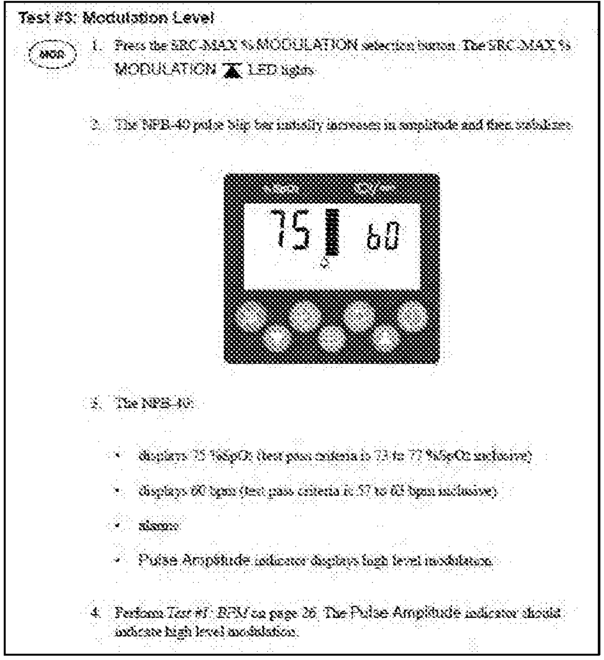
Figure 1
Overlay of typical LED-emitted light spectrum and relative light absorption spectra of oxygenated and deoxygenated hemoglobin. The dashed purple line indicates the spectra of 50%-saturated blood, with the relative absorbance in the red and IR indicated by the black circles.

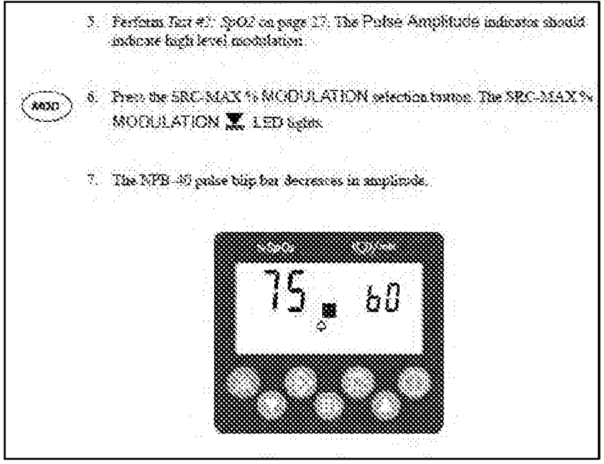
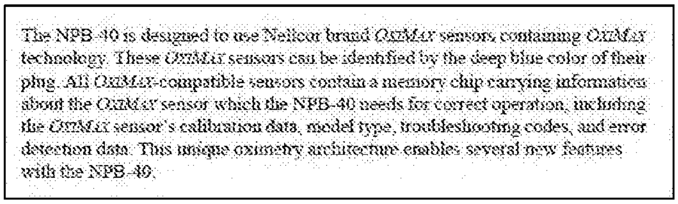
Figure 1 shows an overlay of the red (660 nm) and infrared (900 nm) light spectra emitted by the LEDs, along with the light absorption of oxygenated and deoxygenated hemoglobin (O_2Hb and HHb, respectively). The dashed purple line corresponds to a blood mixture that is near 50% SaO_2. Absorption of the red and IR light at this saturation is indicated by the black circles at the intersection of the blood absorption curve and the middle of the graphed red and IR spectra.

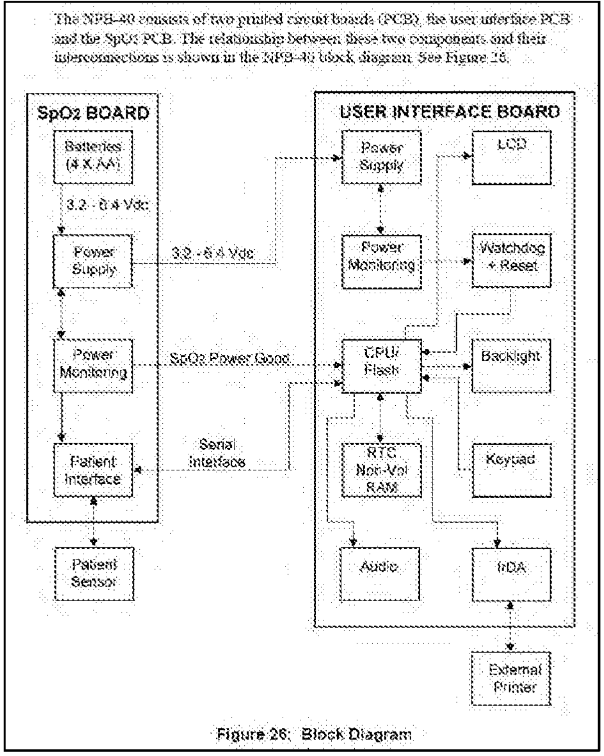
(White Paper, p. 2)

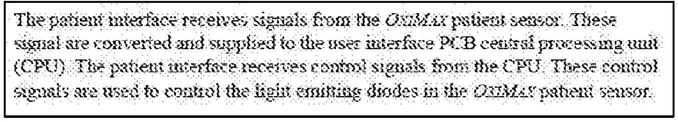
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Because O_2Hb absorbs less red light than infrared light (as indicated by the solid red O_2Hb line in Figure 1), the tissue's cycling blood volume at high saturation has less influence on the detected red signal than on the infrared signal. In other words, the red plethysmograph "wiggle size" (Figure 2) is smaller than the infrared, because this wavelength of light is less influenced by the blood volume changes in the finger. (If, for example, clear saline were pulsing through the vessels, one would not expect the transmitted light levels to change much—regardless of the color of the light used.) (White Paper, p. 2)  At low saturation this situation is reversed. Low saturation blood (high amount of HHb, indicated by the solid blue line in Figure 1) absorbs red light far more strongly than it absorbs IR light; the resulting red signal pulse amplitude becomes larger than the pulse amplitude of the IR signal. (White Paper, p. 2)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Figure 2 Red and IR light signals at high and low arterial oxygen saturation. At high saturation, the red "pulse amplitude" (AC/DC) is smaller than in the IR. At low saturation, the ratio of relative amplitudes is reversed. (White Paper, p. 2)
[5C] the light source configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of semiconductor sources;	Nellcor discloses and/or renders obvious "the light source configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of semiconductor sources."

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Test #3: Modulation Level 1. Press the SRC-MAX % MODULATION selection button. The SRC-MAX % MODULATION ▲ LED lights. 2. The NPB-40 pulse blip bar initially increases in amplitude and then stabilizes. 3. The NPB-40: - displays 75 %SpO2 (test pass criteria is 73 to 77 %SpO2 inclusive) - displays 60 bpm (test pass criteria is 57 to 63 bpm inclusive) - alarms - Pulse Amplitude indicator displays high level modulation. 4. Perform Test #1: BPM on page 26. The Pulse Amplitude indicator should indicate high level modulation. (NPB-40 Service Manual, p. 29)

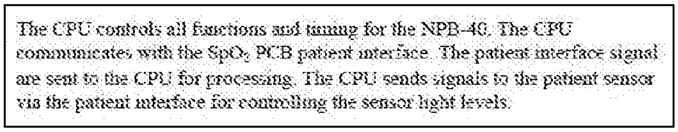
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 5. Perform Test #2: SpO2 on page 27. The Pulse Amplitude indicator should indicate high level modulation. MOD 6. Press the SRC-MAX % MODULATION selection button. The SRC-MAX % MODULATION ▼ LED lights. 7. The NPB-40 pulse blip bar decreases in amplitude. 75 60 (NPB-40 Service Manual, p. 29)  The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 The NPB-40 consists of two printed circuit boards (PCB), the user interface PCB and the SpO2 PCB. The relationship between these two components and their interconnections is shown in the NPB-40 block diagram. See Figure 26. Figure 26: Block Diagram (NPB-40 Service Manual, p. 78)

<table>
<tr><th>Asserted Claim of '533 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>


The patient interface receives signals from the *OxiMax* patient sensor. These signal are converted and supplied to the user interface PCB central processing unit (CPU). The patient interface receives control signals from the CPU. These control signals are used to control the light emitting diodes in the *OxiMax* patient sensor.

(NPB-40 Service Manual, p. 78)



The CPU controls all functions and timing for the NPB-40. The CPU communicates with the SpO_2 PCB patient interface. The patient interface signal are sent to the CPU for processing. The CPU sends signals to the patient sensor via the patient interface for controlling the sensor light levels.

(NPB-40 Service Manual, p. 80)

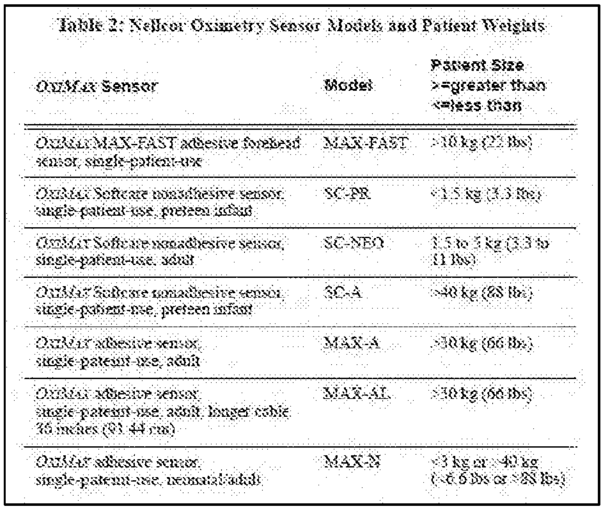


Table 2: Nellcor Oximetry Sensor Models and Patient Weights

<table>
<tr><th><i>OxiMax</i> Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td><i>OxiMax</i> MAX-FAST adhesive forehead sensor, single-patient-use</td><td>MAX-FAST</td><td>>10 kg (22 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-PR</td><td><1.5 kg (3.3 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, adult</td><td>SC-NEO</td><td>1.5 to 5 kg (3.3 to 11 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult</td><td>MAX-A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult, longer cable 36 inches (91.44 cm)</td><td>MAX-AL</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, neonatal/adult</td><td>MAX-N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
</table>

(N-550 Manual, p. 66)
</td></tr>
</table>

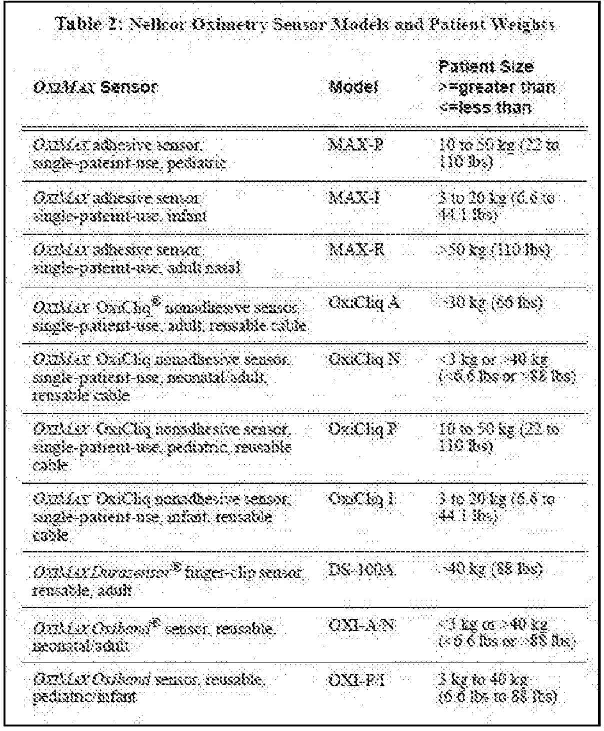
Asserted Claim of '533 Patent	**Nellcor Pulse Oximeters**
	 (N-550 Manual, p. 67)

Table 2: Nellcor Oximetry Sensor Models and Patient Weights

OxiMax Sensor	Model	Patient Size >=greater than <=less than
OxiMax adhesive sensor, single-pateint-use, pediatric	MAX-P	10 to 50 kg (22 to 110 lbs)
OxiMax adhesive sensor, single-pateint-use, infant	MAX-I	3 to 20 kg (6.6 to 44.1 lbs)
OxiMax adhesive sensor, single-pateint-use, adult nasal	MAX-R	>50 kg (110 lbs)
OxiMax OxiCliq® nonadhesive sensor, single-patient-use, adult, reusable cable	OxiCliq A	>30 kg (66 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, neonatal/adult, reusable cable	OxiCliq N	<3 kg or >40 kg (<6.6 lbs or >82 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, pediatric, reusable cable	OxiCliq P	10 to 50 kg (22 to 110 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, infant, reusable cable	OxiCliq I	3 to 20 kg (6.6 to 44.1 lbs)
OxiMax Durasensor® finger-clip sensor, reusable, adult	DS-100A	>40 kg (88 lbs)
OxiMax Oxiband® sensor, reusable, neonatal/adult	OXI-A/N	<3 kg or >40 kg (<6.6 lbs or >88 lbs)
OxiMax Oxiband sensor, reusable, pediatric/infant	OXI-P/I	3 kg to 40 kg (6.6 lbs to 88 lbs)

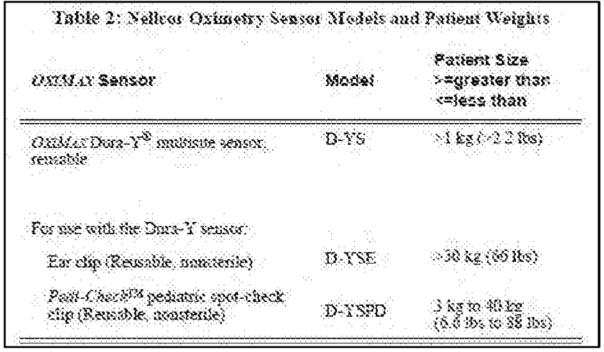
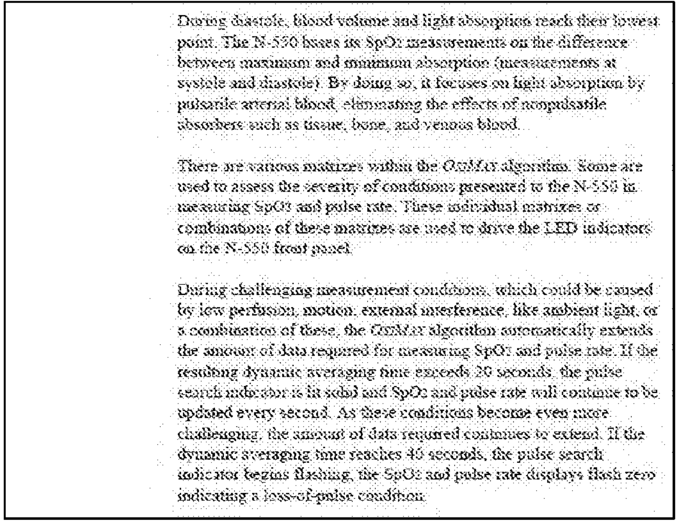
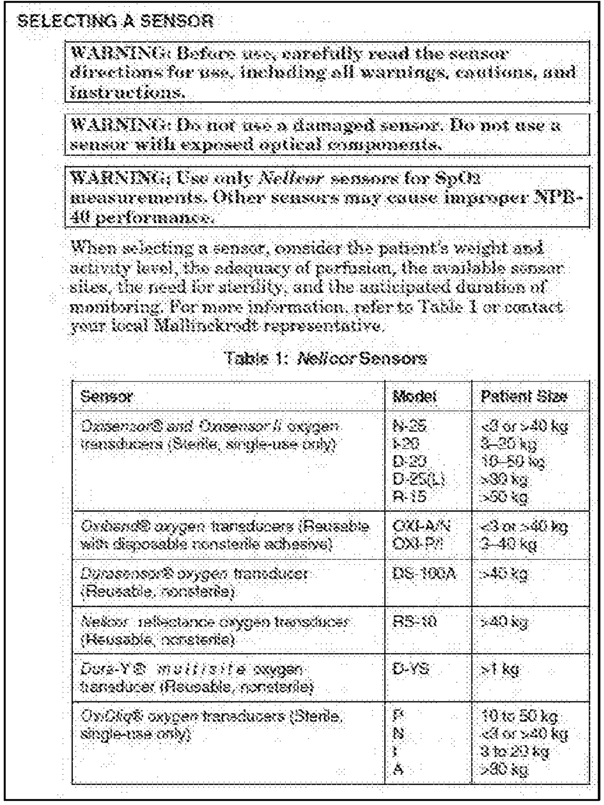
<table>
<tr><th>Asserted Claim of ’533 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>


Table 2: Nellcor Oximetry Sensor Models and Patient Weights

<table>
<tr><th><i>OxiMax</i> Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td><i>OxiMax</i> Dura-Y® multisite sensor, reusable</td><td>D-YS</td><td>>1 kg (>2.2 lbs)</td></tr>
<tr><td>For use with the Dura-Y sensor:</td><td></td><td></td></tr>
<tr><td>Ear clip (Reusable, nonsterile)</td><td>D-YSE</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>Pedi-Check</i>™ pediatric spot-check clip (Reusable, nonsterile)</td><td>D-YSPD</td><td>3 kg to 40 kg
(6.6 lbs to 88 lbs)</td></tr>
</table>

(N-550 Manual, p. 68)
</td></tr>
</table>

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 During diastole, blood volume and light absorption reach their lowest point. The N-550 bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. There are various matrixes within the *OxiMax* algorithm. Some are used to assess the severity of conditions presented to the N-550 in measuring SpO_2 and pulse rate. These individual matrixes or combinations of these matrixes are used to drive the LED indicators on the N-550 front panel. During challenging measurement conditions, which could be caused by low perfusion, motion, external interference, like ambient light, or a combination of these, the *OxiMax* algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate. If the resulting dynamic averaging time exceeds 20 seconds, the pulse search indicator is lit solid and SpO_2 and pulse rate will continue to be updated every second. As these conditions become even more challenging, the amount of data required continues to extend. If the dynamic averaging time reaches 40 seconds, the pulse search indicator begins flashing, the SpO_2 and pulse rate displays flash zero indicating a loss-of-pulse condition. (N-550 Manual, p. 94)

<table>
<tr><th>Asserted Claim of '533 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>


SELECTING A SENSOR

WARNING: Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

WARNING: Do not use a damaged sensor. Do not use a sensor with exposed optical components.

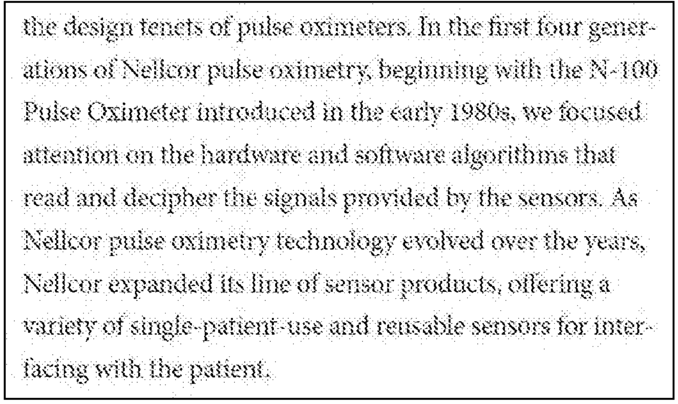
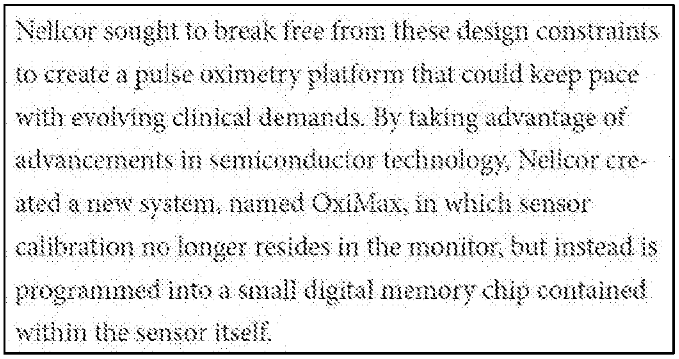
WARNING: Use only *Nellcor* sensors for SpO2 measurements. Other sensors may cause improper NPB-40 performance.

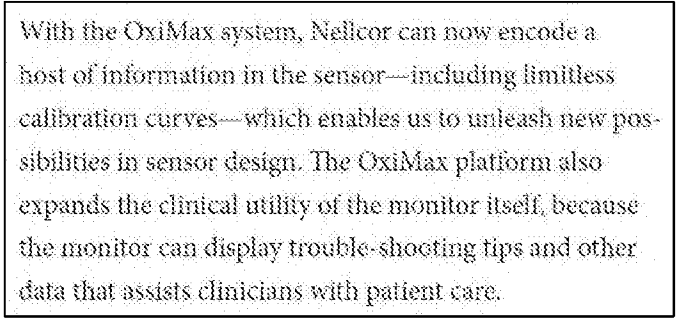
When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Mallinckrodt representative.

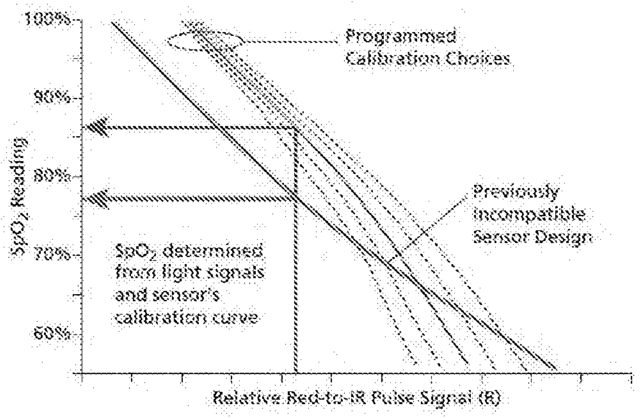
Table 1: *Nellcor* Sensors

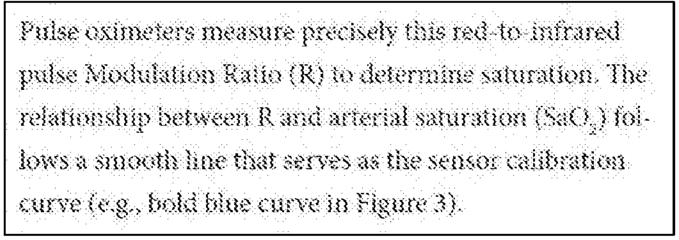
<table>
<tr><th>Sensor</th><th>Model</th><th>Patient Size</th></tr>
<tr><td><i>Oxisensor®</i> and <i>Oxisensor II</i> oxygen transducers (Sterile, single-use only)</td><td>N-25
I-20
D-20
D-25(L)
R-15</td><td><3 or >40 kg
3–20 kg
10–50 kg
>30 kg
>50 kg</td></tr>
<tr><td><i>Oxiband®</i> oxygen transducers (Reusable with disposable nonsterile adhesive)</td><td>OXI-A/N
OXI-P/I</td><td><3 or >40 kg
3–40 kg</td></tr>
<tr><td><i>Durasensor®</i> oxygen transducer (Reusable, nonsterile)</td><td>DS-100A</td><td>>40 kg</td></tr>
<tr><td><i>Nellcor</i> reflectance oxygen transducer (Reusable, nonsterile)</td><td>RS-10</td><td>>40 kg</td></tr>
<tr><td><i>Dura-Y® multisite</i> oxygen transducer (Reusable, nonsterile)</td><td>D-YS</td><td>>1 kg</td></tr>
<tr><td><i>OxiCliq®</i> oxygen transducers (Sterile, single-use only)</td><td>P
N
I
A</td><td>10 to 50 kg
<3 or >40 kg
3 to 20 kg
>30 kg</td></tr>
</table>

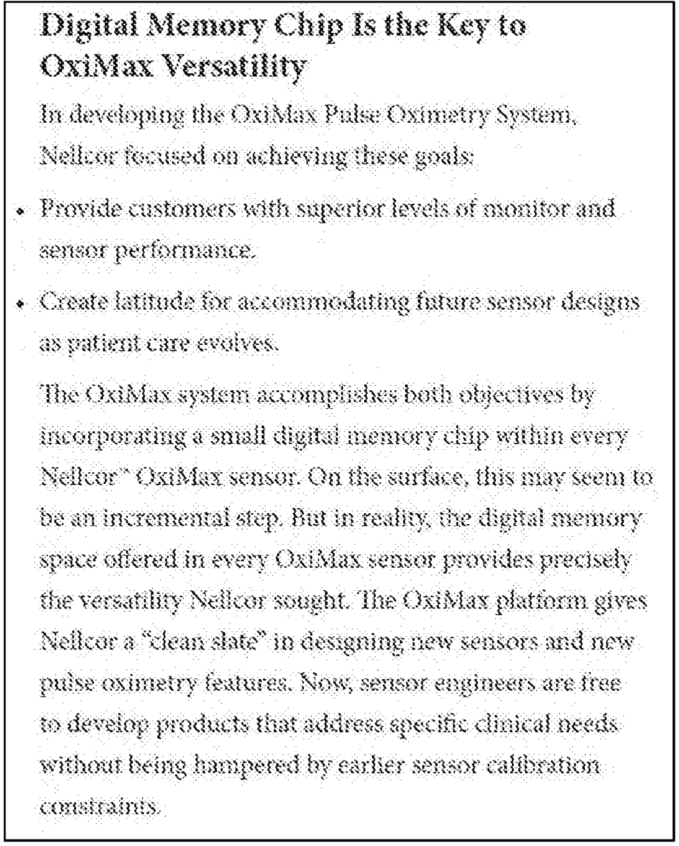
(NPB-40 Operator's Manual, p. 15)
</td></tr>
</table>

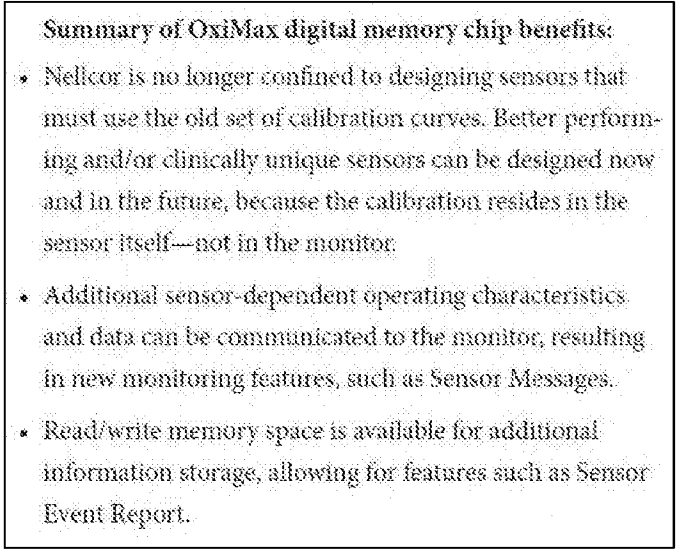
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 the design tenets of pulse oximeters. In the first four generations of Nellcor pulse oximetry, beginning with the N-100 Pulse Oximeter introduced in the early 1980s, we focused attention on the hardware and software algorithms that read and decipher the signals provided by the sensors. As Nellcor pulse oximetry technology evolved over the years, Nellcor expanded its line of sensor products, offering a variety of single-patient-use and reusable sensors for interfacing with the patient. (White Paper, p. 1)  Nellcor sought to break free from these design constraints to create a pulse oximetry platform that could keep pace with evolving clinical demands. By taking advantage of advancements in semiconductor technology, Nellcor created a new system, named OxiMax, in which sensor calibration no longer resides in the monitor, but instead is programmed into a small digital memory chip contained within the sensor itself. (White Paper, p. 1)

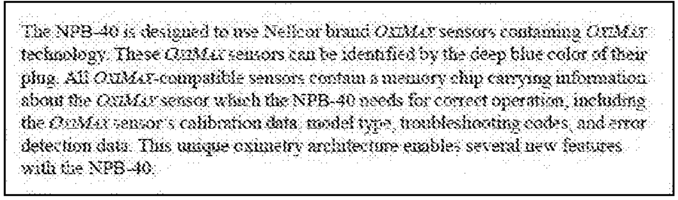
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 With the OxiMax system, Nellcor can now encode a host of information in the sensor—including limitless calibration curves—which enables us to unleash new possibilities in sensor design. The OxiMax platform also expands the clinical utility of the monitor itself, because the monitor can display trouble-shooting tips and other data that assists clinicians with patient care. (White Paper, p. 1)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Figure 3 The blue lines depict the one or more calibration curves programmed into earlier-generation monitors, while the red line indicates a calibration required of a hypothetical new sensor. Such a design would be incompatible with these earlier monitors, since none of the blue curves could provide accurate SpO_2 values for the sensor's signals. (White Paper, p. 2)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Pulse oximeters measure precisely this red-to-infrared pulse Modulation Ratio (R) to determine saturation. The relationship between R and arterial saturation (SaO_2) follows a smooth line that serves as the sensor calibration curve (e.g., bold blue curve in Figure 3). (White Paper, p. 2)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 **Digital Memory Chip Is the Key to OxiMax Versatility** In developing the OxiMax Pulse Oximetry System, Nellcor focused on achieving these goals: • Provide customers with superior levels of monitor and sensor performance. • Create latitude for accommodating future sensor designs as patient care evolves. The OxiMax system accomplishes both objectives by incorporating a small digital memory chip within every Nellcor™ OxiMax sensor. On the surface, this may seem to be an incremental step. But in reality, the digital memory space offered in every OxiMax sensor provides precisely the versatility Nellcor sought. The OxiMax platform gives Nellcor a "clean slate" in designing new sensors and new pulse oximetry features. Now, sensor engineers are free to develop products that address specific clinical needs without being hampered by earlier sensor calibration constraints. (White Paper, p. 4)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 **Summary of OxiMax digital memory chip benefits:** • Nellcor is no longer confined to designing sensors that must use the old set of calibration curves. Better performing and/or clinically unique sensors can be designed now and in the future, because the calibration resides in the sensor itself—not in the monitor. • Additional sensor-dependent operating characteristics and data can be communicated to the monitor, resulting in new monitoring features, such as Sensor Messages. • Read/write memory space is available for additional information storage, allowing for features such as Sensor Event Report. (White Paper, p. 5)
[5D] an apparatus comprising a plurality of lenses configured to receive a portion of the output optical beam and to deliver an analysis output beam to a sample	Nellcor discloses and/or renders obvious "an apparatus comprising a plurality of lenses configured to receive a portion of the output optical beam and to deliver an analysis output beam to a sample."

<table>
<tr><th>Asserted Claim of '533 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>


The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40.

(NPB-40 Service Manual, p. 76)

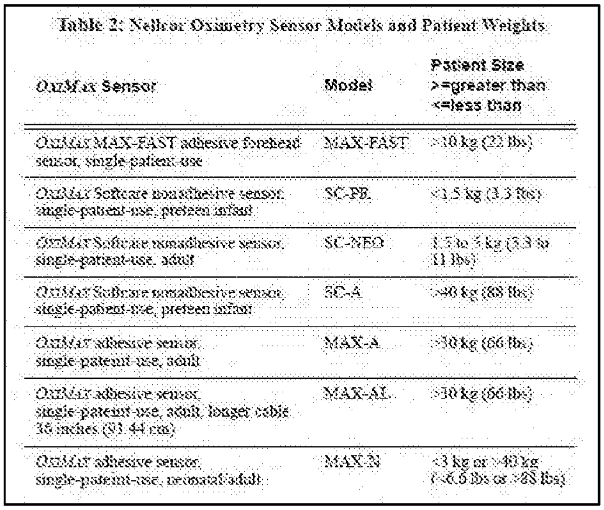


Table 2: Nellcor Oximetry Sensor Models and Patient Weights

<table>
<tr><th><i>OxiMax</i> Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td><i>OxiMax</i> MAX-FAST adhesive forehead sensor, single-patient-use</td><td>MAX-FAST</td><td>>10 kg (22 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-PR</td><td><1.5 kg (3.3 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, adult</td><td>SC-NEO</td><td>1.5 to 5 kg (3.3 to 11 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult</td><td>MAX-A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult, longer cable 36 inches (91.44 cm)</td><td>MAX-AL</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, neonatal/adult</td><td>MAX-N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
</table>

(N-550 Manual, p. 66)
</td></tr>
</table>

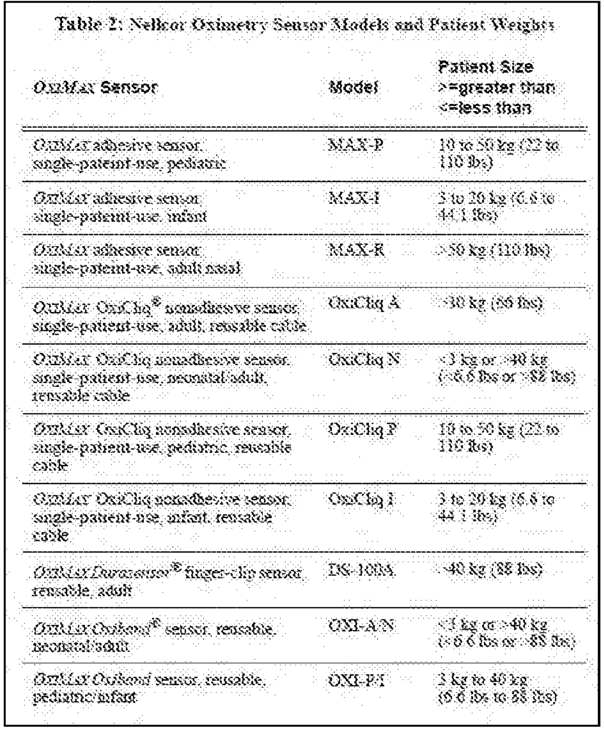
Asserted Claim of '533 Patent	**Nellcor Pulse Oximeters**
	 (N-550 Manual, p. 67)

Table 2: Nellcor Oximetry Sensor Models and Patient Weights

OxiMax Sensor	Model	Patient Size >=greater than <=less than
OxiMax adhesive sensor, single-pateint-use, pediatric	MAX-P	10 to 50 kg (22 to 110 lbs)
OxiMax adhesive sensor, single-pateint-use, infant	MAX-I	3 to 20 kg (6.6 to 44.1 lbs)
OxiMax adhesive sensor, single-pateint-use, adult nasal	MAX-R	>50 kg (110 lbs)
OxiMax OxiCliq® nonadhesive sensor, single-patient-use, adult, reusable cable	OxiCliq A	>30 kg (66 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, neonatal/adult, reusable cable	OxiCliq N	<3 kg or >40 kg (<6.6 lbs or >82 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, pediatric, reusable cable	OxiCliq P	10 to 50 kg (22 to 110 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, infant, reusable cable	OxiCliq I	3 to 20 kg (6.6 to 44.1 lbs)
OxiMax Durasensor® finger-clip sensor, reusable, adult	DS-100A	>40 kg (88 lbs)
OxiMax Oxiband® sensor, reusable, neonatal/adult	OXI-A/N	<3 kg or >40 kg (<6.6 lbs or >88 lbs)
OxiMax Oxiband sensor, reusable, pediatric/infant	OXI-P/I	3 kg to 40 kg (6.6 lbs to 88 lbs)

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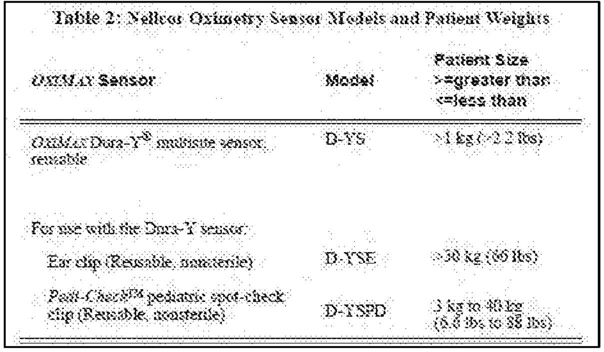
<tr><td></td><td>
Table 2: Nellcor Oximetry Sensor Models and Patient Weights
<table>
<tr><th><i>OxiMax</i> Sensor</th><th>Model</th><th>Patient Size
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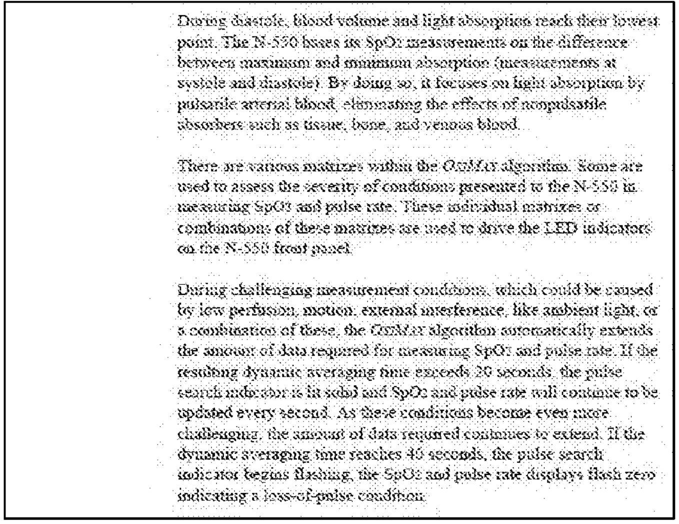
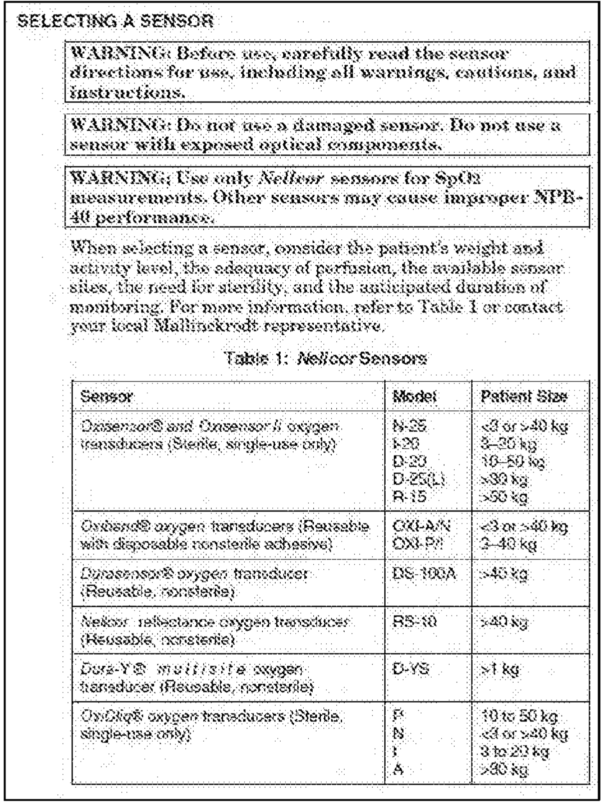
<=less than</th></tr>
<tr><td><i>OxiMax</i> Dura-Y® multisite sensor, reusable</td><td>D-YS</td><td>>1 kg (>2.2 lbs)</td></tr>
<tr><td>For use with the Dura-Y sensor:</td><td></td><td></td></tr>
<tr><td>Ear clip (Reusable, nonsterile)</td><td>D-YSE</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>Pedi-Check</i>™ pediatric spot-check clip (Reusable, nonsterile)</td><td>D-YSPD</td><td>3 kg to 40 kg
(6.6 lbs to 88 lbs)</td></tr>
</table>
(N-550 Manual, p. 68)</td></tr>
</table>

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 During diastole, blood volume and light absorption reach their lowest point. The N-550 bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. There are various matrixes within the *OxiMax* algorithm. Some are used to assess the severity of conditions presented to the N-550 in measuring SpO_2 and pulse rate. These individual matrixes or combinations of these matrixes are used to drive the LED indicators on the N-550 front panel. During challenging measurement conditions, which could be caused by low perfusion, motion, external interference, like ambient light, or a combination of these, the *OxiMax* algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate. If the resulting dynamic averaging time exceeds 20 seconds, the pulse search indicator is lit solid and SpO_2 and pulse rate will continue to be updated every second. As these conditions become even more challenging, the amount of data required continues to extend. If the dynamic averaging time reaches 40 seconds, the pulse search indicator begins flashing, the SpO_2 and pulse rate displays flash zero indicating a loss-of-pulse condition. (N-550 Manual, p. 94)

<table>
<tr><th>Asserted Claim of ’533 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>
SELECTING A SENSOR

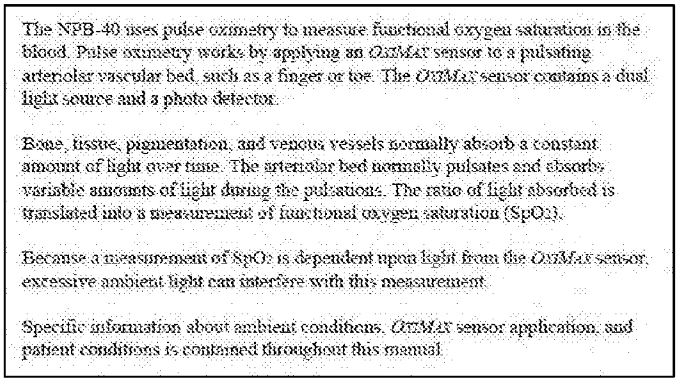
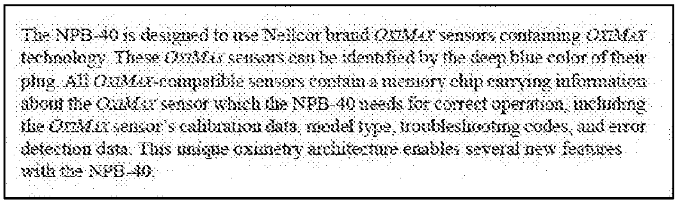
WARNING: Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

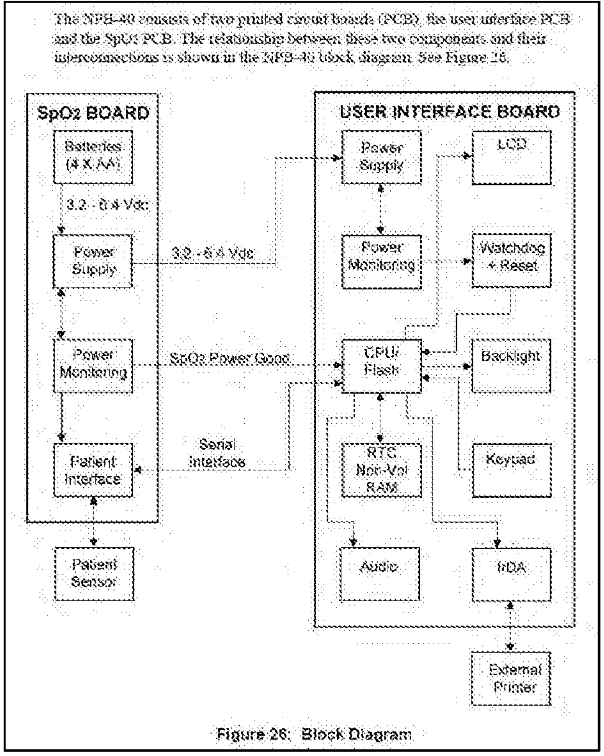
WARNING: Do not use a damaged sensor. Do not use a sensor with exposed optical components.

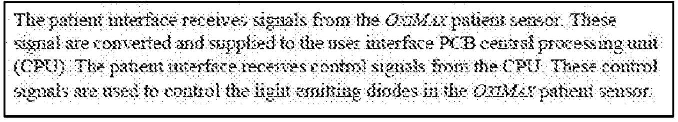
WARNING: Use only *Nellcor* sensors for SpO_2 measurements. Other sensors may cause improper NPB-40 performance.

When selecting a sensor, consider the patient’s weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Mallinckrodt representative.

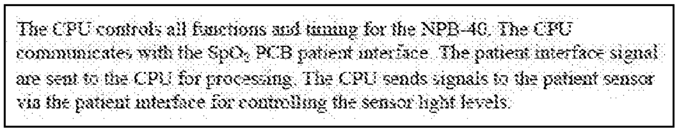
Table 1: *Nellcor* Sensors
<table>
<tr><th>Sensor</th><th>Model</th><th>Patient Size</th></tr>
<tr><td>*Oxisensor®* and *Oxisensor II* oxygen transducers (Sterile, single-use only)</td><td>N-25
I-20
D-20
D-25(L)
R-15</td><td><3 or >40 kg
3–20 kg
10–50 kg
>30 kg
>50 kg</td></tr>
<tr><td>*Oxiband®* oxygen transducers (Reusable with disposable nonsterile adhesive)</td><td>OXI-A/N
OXI-P/I</td><td><3 or >40 kg
3–40 kg</td></tr>
<tr><td>*Durasensor®* oxygen transducer (Reusable, nonsterile)</td><td>DS-100A</td><td>>40 kg</td></tr>
<tr><td>*Nellcor* reflectance oxygen transducer (Reusable, nonsterile)</td><td>RS-10</td><td>>40 kg</td></tr>
<tr><td>*Dura-Y® multisite* oxygen transducer (Reusable, nonsterile)</td><td>D-YS</td><td>>1 kg</td></tr>
<tr><td>*OxiCliq®* oxygen transducers (Sterile, single-use only)</td><td>P
N
I
A</td><td>10 to 50 kg
<3 or >40 kg
3 to 20 kg
>30 kg</td></tr>
</table>
(NPB-40 Operator’s Manual, p. 15)</td></tr>
</table>

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
[5E] a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal,	Nellcor discloses and/or renders obvious "a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal."  The NPB-40 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying an *OxiMax* sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The *OxiMax* sensor contains a dual light source and a photo detector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO2). Because a measurement of SpO2 is dependent upon light from the *OxiMax* sensor, excessive ambient light can interfere with this measurement. Specific information about ambient conditions, *OxiMax* sensor application, and patient conditions is contained throughout this manual. (NPB-40 Service Manual, p. 75)  The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)

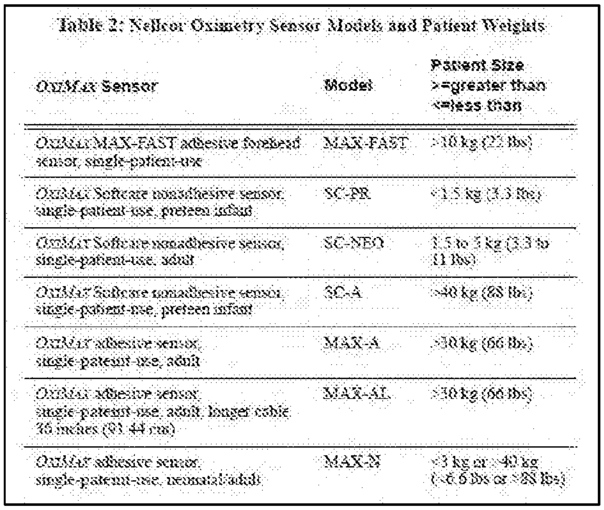
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 The NPB-40 consists of two printed circuit boards (PCB), the user interface PCB and the SpO2 PCB. The relationship between these two components and their interconnections is shown in the NPB-40 block diagram. See Figure 26. Figure 26: Block Diagram (NPB-40 Service Manual, p. 78)

<table>
<tr><th>Asserted Claim of '533 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>

The patient interface receives signals from the <i>OxiMax</i> patient sensor. These signal are converted and supplied to the user interface PCB central processing unit (CPU). The patient interface receives control signals from the CPU. These control signals are used to control the light emitting diodes in the <i>OxiMax</i> patient sensor.

(NPB-40 Service Manual, p. 78)


The CPU controls all functions and timing for the NPB-40. The CPU communicates with the SpO₂ PCB patient interface. The patient interface signal are sent to the CPU for processing. The CPU sends signals to the patient sensor via the patient interface for controlling the sensor light levels.

(NPB-40 Service Manual, p. 80)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<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, adult</td><td>SC-NEO</td><td>1.5 to 5 kg (3.3 to 11 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult</td><td>MAX-A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult, longer cable 36 inches (91.44 cm)</td><td>MAX-AL</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, neonatal/adult</td><td>MAX-N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
</table>
(N-550 Manual, p. 66)
</td></tr>
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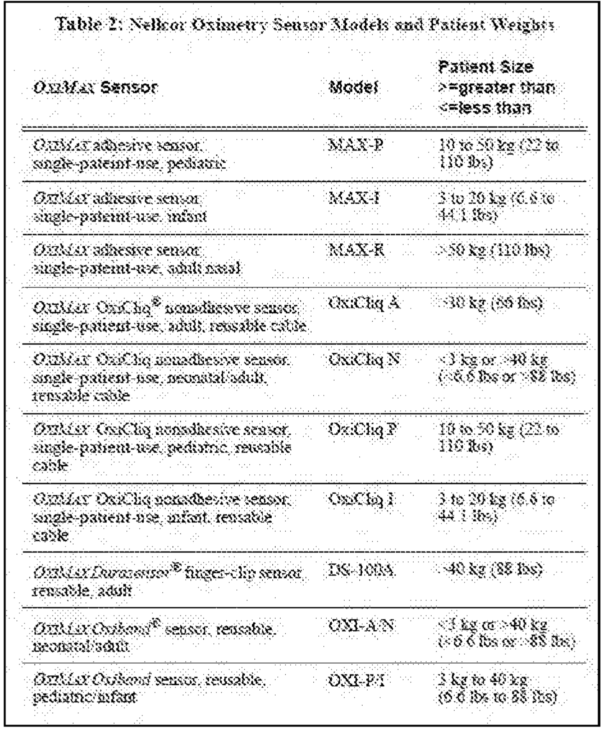
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<tr><td>OxiMax adhesive sensor, single-pateint-use, infant</td><td>MAX-I</td><td>3 to 20 kg (6.6 to 44.1 lbs)</td></tr>
<tr><td>OxiMax adhesive sensor, single-pateint-use, adult nasal</td><td>MAX-R</td><td>>50 kg (110 lbs)</td></tr>
<tr><td>OxiMax OxiCliq® nonadhesive sensor, single-patient-use, adult, reusable cable</td><td>OxiCliq A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td>OxiMax OxiCliq nonadhesive sensor, single-patient-use, neonatal/adult, reusable cable</td><td>OxiCliq N</td><td><3 kg or >40 kg (<6.6 lbs or >82 lbs)</td></tr>
<tr><td>OxiMax OxiCliq nonadhesive sensor, single-patient-use, pediatric, reusable cable</td><td>OxiCliq P</td><td>10 to 50 kg (22 to 110 lbs)</td></tr>
<tr><td>OxiMax OxiCliq nonadhesive sensor, single-patient-use, infant, reusable cable</td><td>OxiCliq I</td><td>3 to 20 kg (6.6 to 44.1 lbs)</td></tr>
<tr><td>OxiMax Durasensor® finger-clip sensor, reusable, adult</td><td>DS-100A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td>OxiMax Oxiband® sensor, reusable, neonatal/adult</td><td>OXI-A/N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
<tr><td>OxiMax Oxiband sensor, reusable, pediatric/infant</td><td>OXI-P/I</td><td>3 kg to 40 kg (6.6 lbs to 88 lbs)</td></tr>
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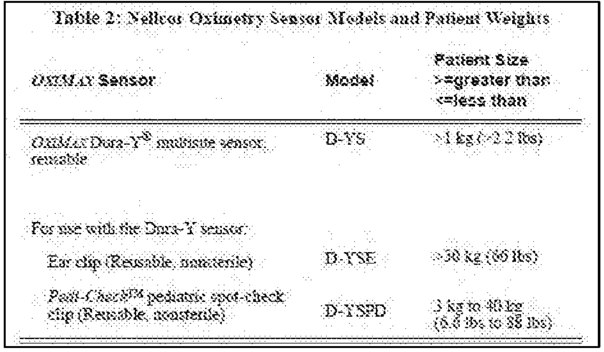
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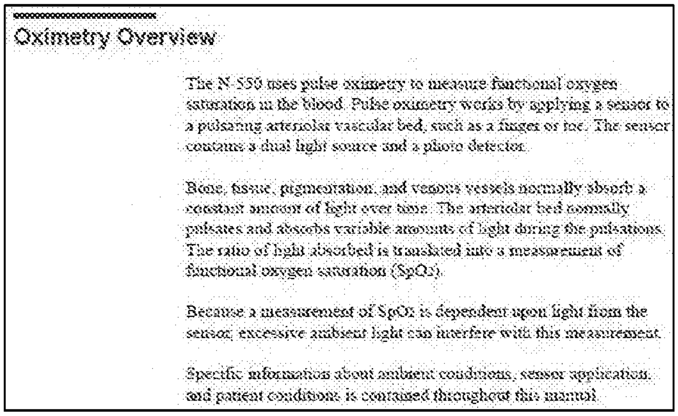
<tr><td><i>OxiMax</i> Dura-Y® multisite sensor, reusable</td><td>D-YS</td><td>>1 kg (>2.2 lbs)</td></tr>
<tr><td>For use with the Dura-Y sensor:</td><td></td><td></td></tr>
<tr><td>Ear clip (Reusable, nonsterile)</td><td>D-YSE</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>Pedi-Check</i>™ pediatric spot-check clip (Reusable, nonsterile)</td><td>D-YSPD</td><td>3 kg to 40 kg
(6.6 lbs to 88 lbs)</td></tr>
</table>
(N-550 Manual, p. 68)

Oximetry Overview

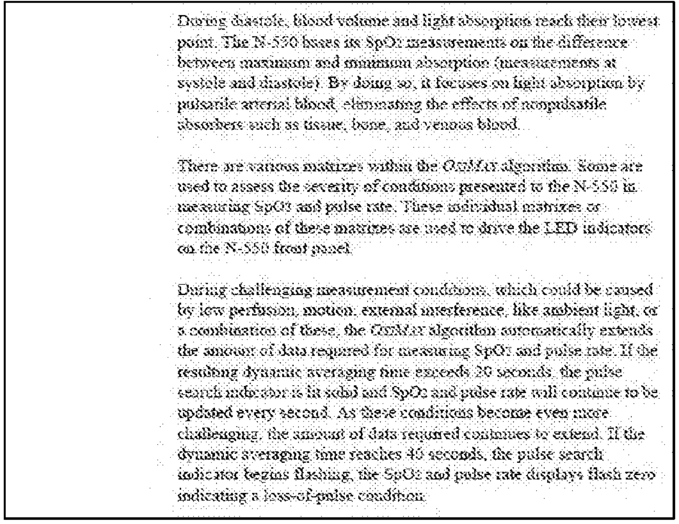
The N-550 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photo detector.

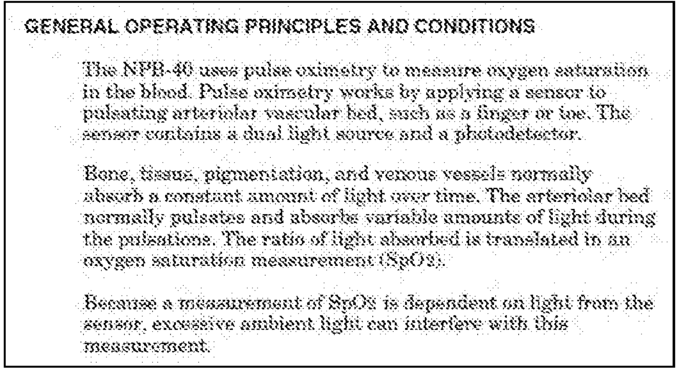
Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO2).

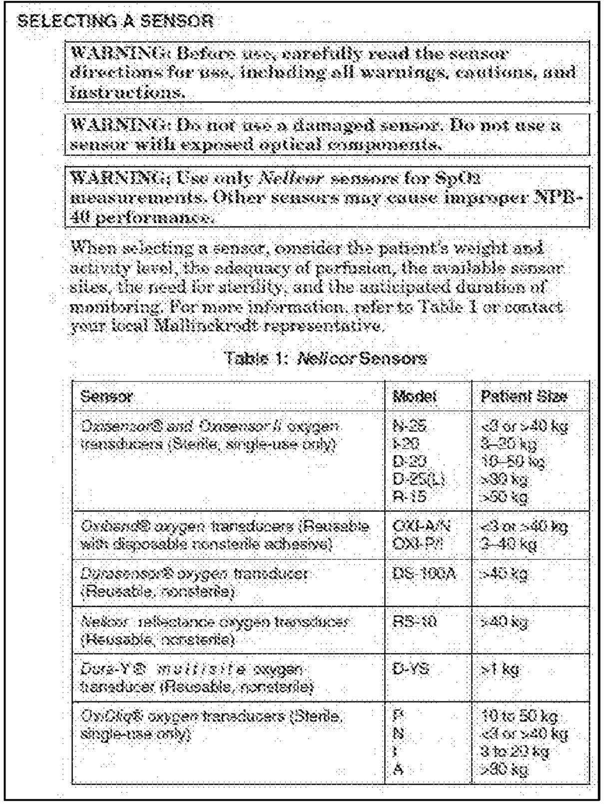
Because a measurement of SpO2 is dependent upon light from the sensor, excessive ambient light can interfere with this measurement.

Specific information about ambient conditions, sensor application, and patient conditions is contained throughout this manual.

(N-550 Manual, p. 93)
</td></tr>
</table>

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 During diastole, blood volume and light absorption reach their lowest point. The N-550 bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. There are various matrixes within the *OxiMax* algorithm. Some are used to assess the severity of conditions presented to the N-550 in measuring SpO_2 and pulse rate. These individual matrixes or combinations of these matrixes are used to drive the LED indicators on the N-550 front panel. During challenging measurement conditions, which could be caused by low perfusion, motion, external interference, like ambient light, or a combination of these, the *OxiMax* algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate. If the resulting dynamic averaging time exceeds 20 seconds, the pulse search indicator is lit solid and SpO_2 and pulse rate will continue to be updated every second. As these conditions become even more challenging, the amount of data required continues to extend. If the dynamic averaging time reaches 40 seconds, the pulse search indicator begins flashing, the SpO_2 and pulse rate displays flash zero indicating a loss-of-pulse condition. (N-550 Manual, p. 94)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 GENERAL OPERATING PRINCIPLES AND CONDITIONS The NPB-40 uses pulse oximetry to measure oxygen saturation in the blood. Pulse oximetry works by applying a sensor to pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photodetector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated in an oxygen saturation measurement (SpO2). Because a measurement of SpO2 is dependent on light from the sensor, excessive ambient light can interfere with this measurement. (NPB-40 Operator's Manual, p. 3-4)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 (NPB-40 Operator's Manual, p. 15)

SELECTING A SENSOR

WARNING: Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

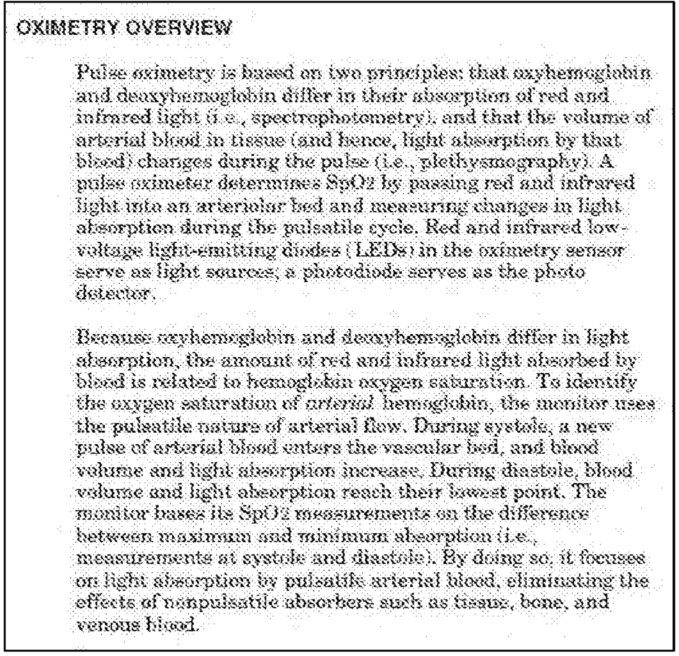
WARNING: Do not use a damaged sensor. Do not use a sensor with exposed optical components.

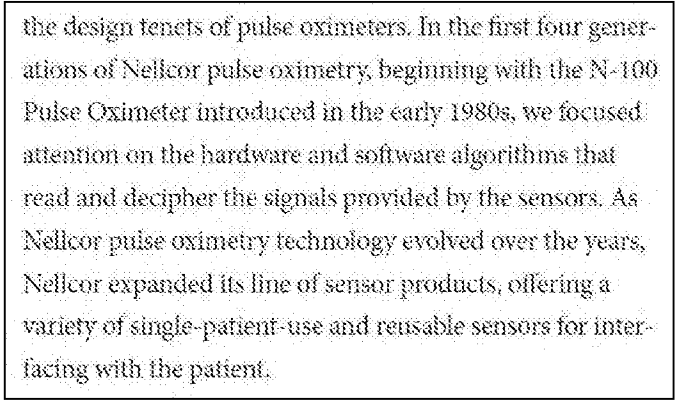
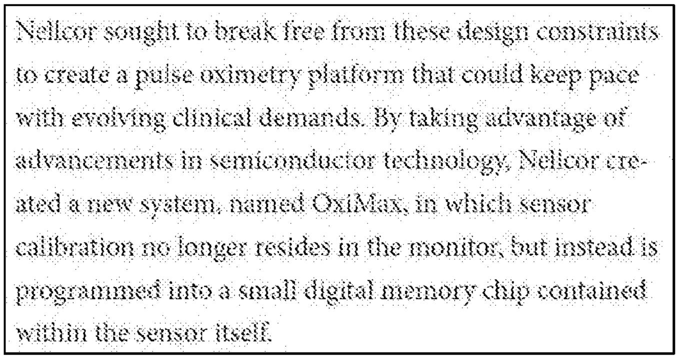
WARNING: Use only *Nellcor* sensors for SpO_2 measurements. Other sensors may cause improper NPB-40 performance.

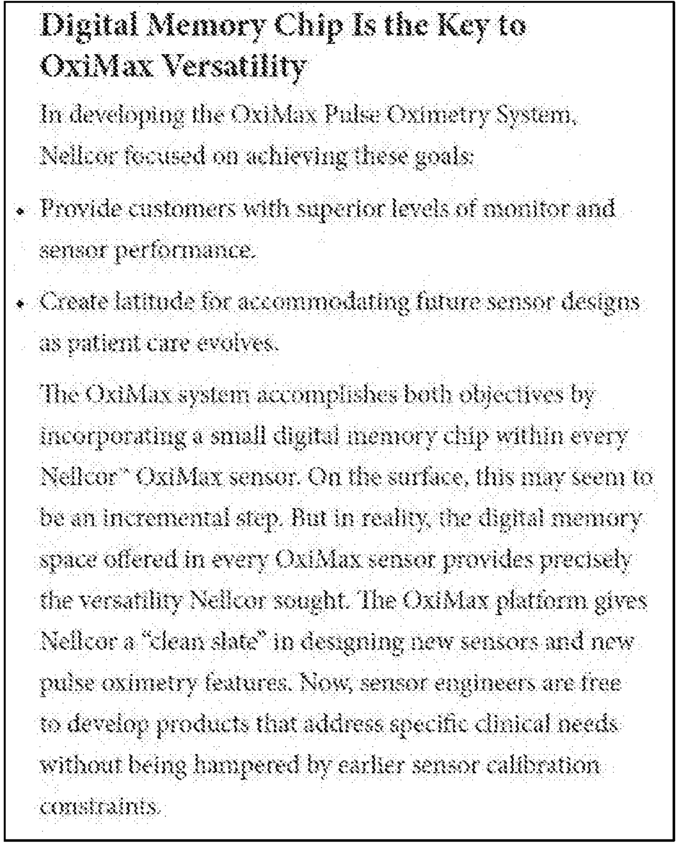
When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Mallinckrodt representative.

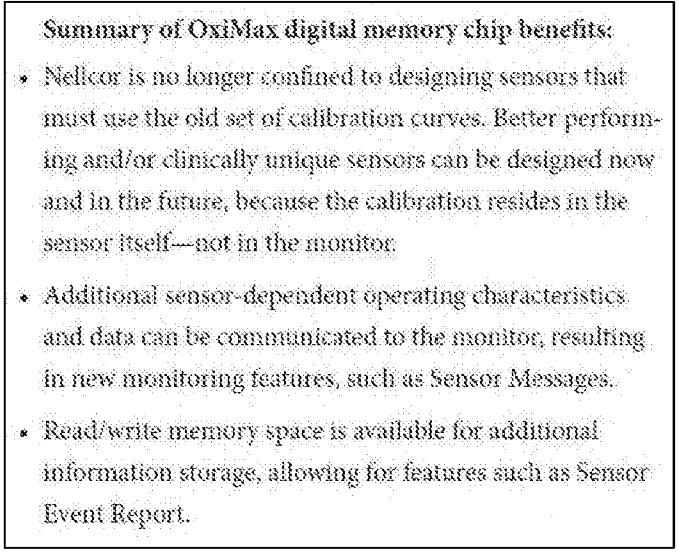
Table 1: *Nellcor* Sensors

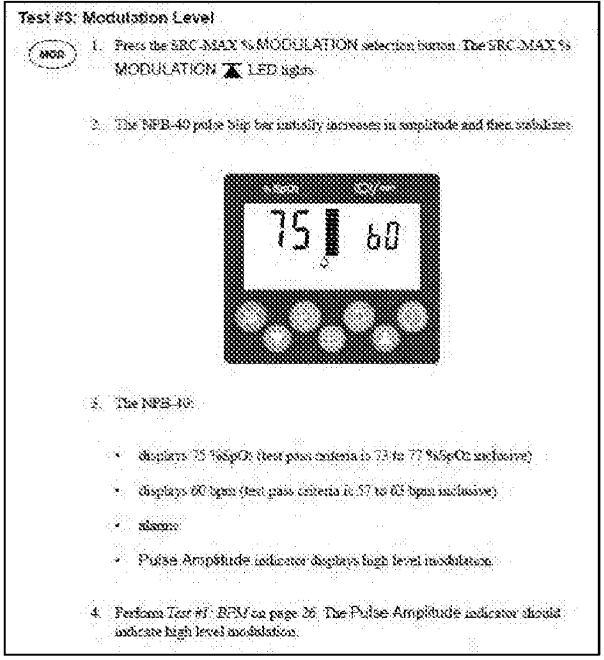
Sensor	Model	Patient Size
Oxisensor® and *Oxisensor II* oxygen transducers (Sterile, single-use only)	N-25 I-20 D-20 D-25(L) R-15	<3 or >40 kg 3–20 kg 10–50 kg >30 kg >50 kg
Oxiband® oxygen transducers (Reusable with disposable nonsterile adhesive)	OXI-A/N OXI-P/I	<3 or >40 kg 3–40 kg
Durasensor® oxygen transducer (Reusable, nonsterile)	DS-100A	>40 kg
Nellcor reflectance oxygen transducer (Reusable, nonsterile)	RS-10	>40 kg
Dura-Y® *multisite* oxygen transducer (Reusable, nonsterile)	D-YS	>1 kg
OxiCliq® oxygen transducers (Sterile, single-use only)	P N I A	10 to 50 kg <3 or >40 kg 3 to 20 kg >30 kg

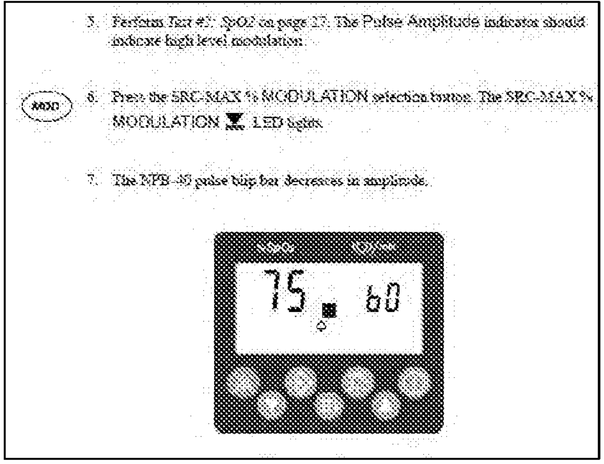
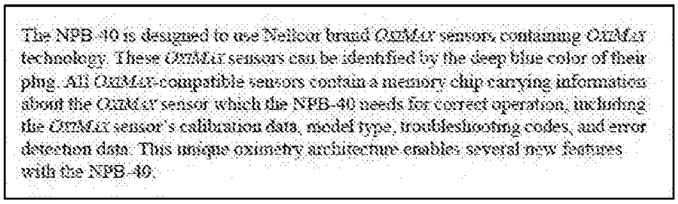
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 OXIMETRY OVERVIEW Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e., spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e., plethysmography). A pulse oximeter determines SpO2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LEDs) in the oximetry sensor serve as light sources; a photodiode serves as the photo detector. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of *arterial* hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitor bases its SpO2 measurements on the difference between maximum and minimum absorption (i.e., measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. (NPB-40 Operator's Manual, p. 41)

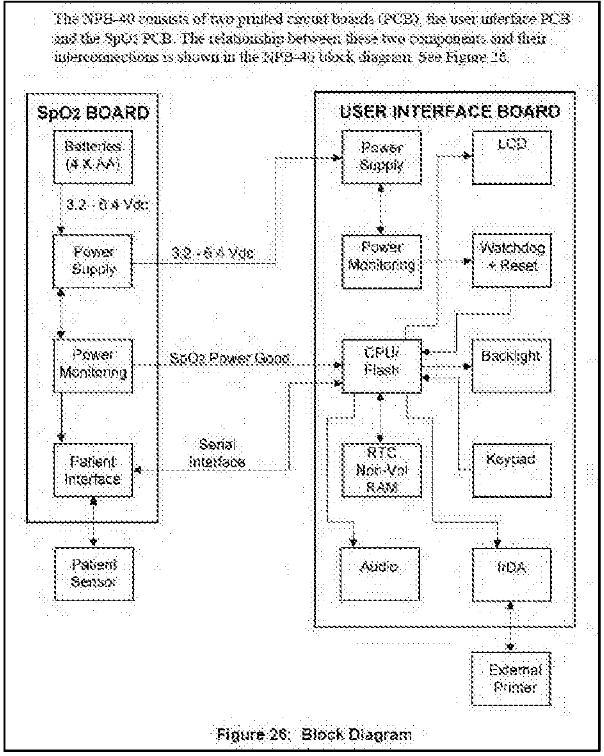
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 the design tenets of pulse oximeters. In the first four generations of Nellcor pulse oximetry, beginning with the N-100 Pulse Oximeter introduced in the early 1980s, we focused attention on the hardware and software algorithms that read and decipher the signals provided by the sensors. As Nellcor pulse oximetry technology evolved over the years, Nellcor expanded its line of sensor products, offering a variety of single-patient-use and reusable sensors for interfacing with the patient. (White Paper, p. 1)  Nellcor sought to break free from these design constraints to create a pulse oximetry platform that could keep pace with evolving clinical demands. By taking advantage of advancements in semiconductor technology, Nellcor created a new system, named OxiMax, in which sensor calibration no longer resides in the monitor, but instead is programmed into a small digital memory chip contained within the sensor itself. (White Paper, p. 1)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 **Digital Memory Chip Is the Key to OxiMax Versatility** In developing the OxiMax Pulse Oximetry System, Nellcor focused on achieving these goals: • Provide customers with superior levels of monitor and sensor performance. • Create latitude for accommodating future sensor designs as patient care evolves. The OxiMax system accomplishes both objectives by incorporating a small digital memory chip within every Nellcor™ OxiMax sensor. On the surface, this may seem to be an incremental step. But in reality, the digital memory space offered in every OxiMax sensor provides precisely the versatility Nellcor sought. The OxiMax platform gives Nellcor a "clean slate" in designing new sensors and new pulse oximetry features. Now, sensor engineers are free to develop products that address specific clinical needs without being hampered by earlier sensor calibration constraints. (White Paper, p. 4)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Summary of OxiMax digital memory chip benefits: • Nellcor is no longer confined to designing sensors that must use the old set of calibration curves. Better performing and/or clinically unique sensors can be designed now and in the future, because the calibration resides in the sensor itself—not in the monitor. • Additional sensor-dependent operating characteristics and data can be communicated to the monitor, resulting in new monitoring features, such as Sensor Messages. • Read/write memory space is available for additional information storage, allowing for features such as Sensor Event Report. (White Paper, p. 5)
[5F] wherein the receiver is configured to be synchronized to the light source;	Nellcor discloses and/or renders obvious "wherein the receiver is configured to be synchronized to the light source."

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Test #3: Modulation Level MOD 1. Press the SRC-MAX % MODULATION selection button. The SRC-MAX % MODULATION ▲ LED lights. 2. The NPB-40 pulse blip bar initially increases in amplitude and then stabilizes. 3. The NPB-40: • displays 75 %SpO2 (test pass criteria is 73 to 77 %SpO2 inclusive) • displays 60 bpm (test pass criteria is 57 to 63 bpm inclusive) • alarms • Pulse Amplitude indicator displays high level modulation. 4. Perform *Test #1: BPM* on page 26. The Pulse Amplitude indicator should indicate high level modulation. (NPB-40 Service Manual, p. 29)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 5. Perform *Test #2: SpO2* on page 27. The Pulse Amplitude indicator should indicate high level modulation. 6. Press the SRC-MAX % MODULATION selection button. The SRC-MAX % MODULATION ▼ LED lights. 7. The NPB-40 pulse blip bar decreases in amplitude. (NPB-40 Service Manual, p. 29)  The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 The NPB-40 consists of two printed circuit boards (PCB), the user interface PCB and the SpO₂ PCB. The relationship between these two components and their interconnections is shown in the NPB-40 block diagram. See Figure 26. Figure 26: Block Diagram (NPB-40 Service Manual, p. 78)

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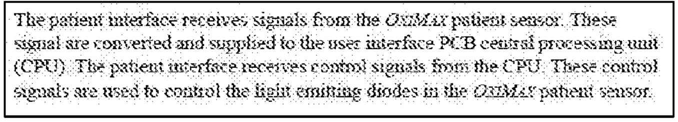
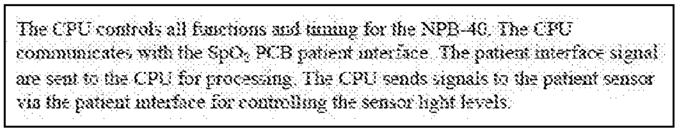
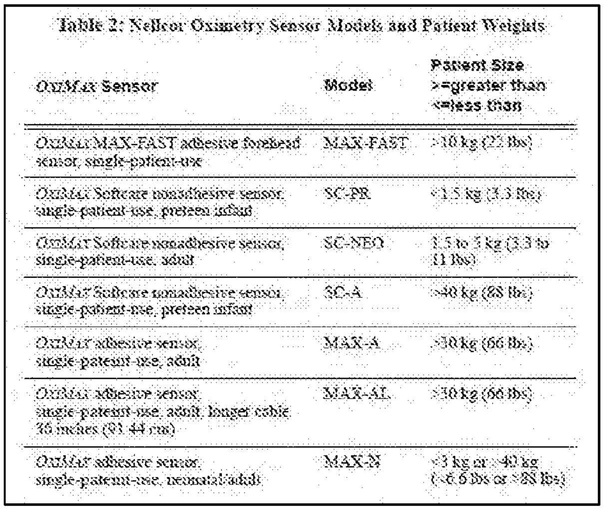

The patient interface receives signals from the <i>OxiMax</i> patient sensor. These signal are converted and supplied to the user interface PCB central processing unit (CPU). The patient interface receives control signals from the CPU. These control signals are used to control the light emitting diodes in the <i>OxiMax</i> patient sensor.

(NPB-40 Service Manual, p. 78)


The CPU controls all functions and timing for the NPB-40. The CPU communicates with the SpO_2 PCB patient interface. The patient interface signal are sent to the CPU for processing. The CPU sends signals to the patient sensor via the patient interface for controlling the sensor light levels.

(NPB-40 Service Manual, p. 80)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<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, adult</td><td>SC-NEO</td><td>1.5 to 5 kg (3.3 to 11 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult</td><td>MAX-A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult, longer cable 36 inches (91.44 cm)</td><td>MAX-AL</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, neonatal/adult</td><td>MAX-N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
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	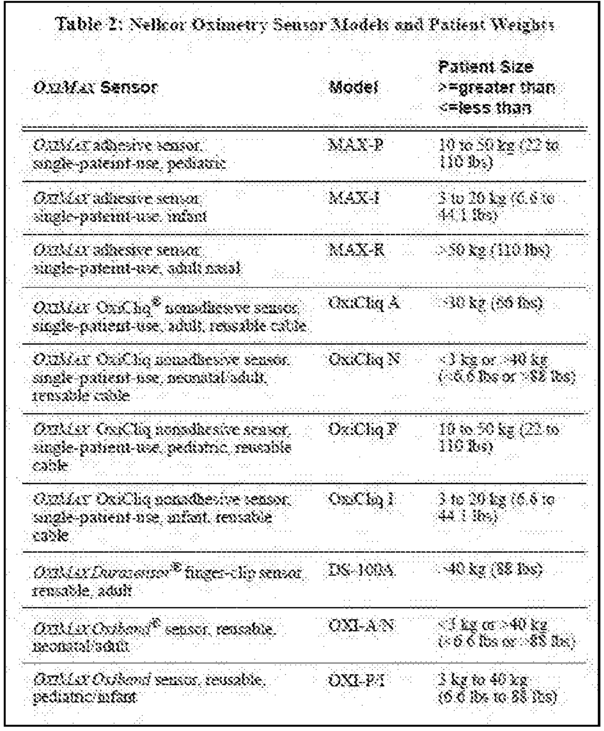 (N-550 Manual, p. 67)

Table 2: Nellcor Oximetry Sensor Models and Patient Weights

OxiMax Sensor	Model	Patient Size >=greater than <=less than
OxiMax adhesive sensor, single-pateint-use, pediatric	MAX-P	10 to 50 kg (22 to 110 lbs)
OxiMax adhesive sensor, single-pateint-use, infant	MAX-I	3 to 20 kg (6.6 to 44.1 lbs)
OxiMax adhesive sensor, single-pateint-use, adult nasal	MAX-R	>50 kg (110 lbs)
OxiMax OxiCliq® nonadhesive sensor, single-patient-use, adult, reusable cable	OxiCliq A	>30 kg (66 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, neonatal/adult, reusable cable	OxiCliq N	<3 kg or >40 kg (<6.6 lbs or >82 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, pediatric, reusable cable	OxiCliq P	10 to 50 kg (22 to 110 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, infant, reusable cable	OxiCliq I	3 to 20 kg (6.6 to 44.1 lbs)
OxiMax Durasensor® finger-clip sensor, reusable, adult	DS-100A	>40 kg (88 lbs)
OxiMax Oxiband® sensor, reusable, neonatal/adult	OXI-A/N	<3 kg or >40 kg (<6.6 lbs or >88 lbs)
OxiMax Oxiband sensor, reusable, pediatric/infant	OXI-P/I	3 kg to 40 kg (6.6 lbs to 88 lbs)

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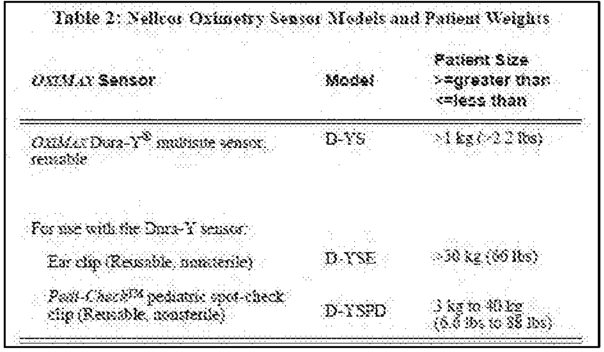
<tr><td></td><td>
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<tr><td>For use with the Dura-Y sensor:</td><td></td><td></td></tr>
<tr><td>Ear clip (Reusable, nonsterile)</td><td>D-YSE</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>Pedi-Check</i>™ pediatric spot-check clip (Reusable, nonsterile)</td><td>D-YSPD</td><td>3 kg to 40 kg
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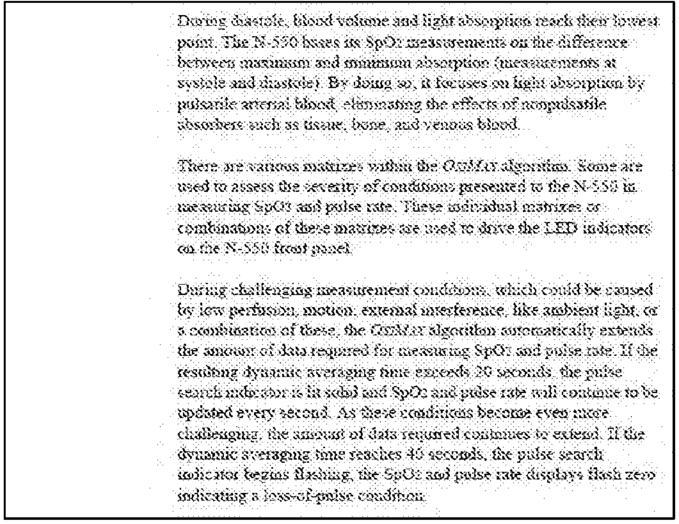
</table>

Asserted Claim of '533 Patent	**Nellcor Pulse Oximeters**
	 During diastole, blood volume and light absorption reach their lowest point. The N-550 bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. There are various matrixes within the *OxiMax* algorithm. Some are used to assess the severity of conditions presented to the N-550 in measuring SpO_2 and pulse rate. These individual matrixes or combinations of these matrixes are used to drive the LED indicators on the N-550 front panel. During challenging measurement conditions, which could be caused by low perfusion, motion, external interference, like ambient light, or a combination of these, the *OxiMax* algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate. If the resulting dynamic averaging time exceeds 20 seconds, the pulse search indicator is lit solid and SpO_2 and pulse rate will continue to be updated every second. As these conditions become even more challenging, the amount of data required continues to extend. If the dynamic averaging time reaches 40 seconds, the pulse search indicator begins flashing, the SpO_2 and pulse rate displays flash zero indicating a loss-of-pulse condition. (N-550 Manual, p. 94)

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	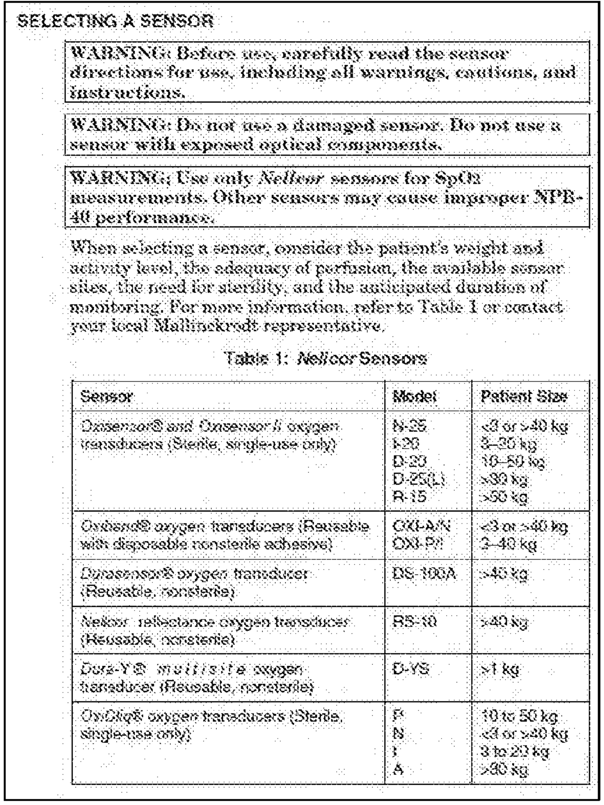 (NPB-40 Operator's Manual, p. 15)

SELECTING A SENSOR

WARNING: Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

WARNING: Do not use a damaged sensor. Do not use a sensor with exposed optical components.

WARNING: Use only *Nellcor* sensors for SpO2 measurements. Other sensors may cause improper NPB-40 performance.

When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Mallinckrodt representative.

Table 1: *Nellcor* Sensors

Sensor	Model	Patient Size
Oxisensor® and *Oxisensor II* oxygen transducers (Sterile, single-use only)	N-25 I-20 D-20 D-25(L) R-15	<3 or >40 kg 3–20 kg 10–50 kg >30 kg >50 kg
Oxiband® oxygen transducers (Reusable with disposable nonsterile adhesive)	OXI-A/N OXI-P/I	<3 or >40 kg 3–40 kg
Durasensor® oxygen transducer (Reusable, nonsterile)	DS-100A	>40 kg
Nellcor reflectance oxygen transducer (Reusable, nonsterile)	RS-10	>40 kg
Dura-Y® multisite oxygen transducer (Reusable, nonsterile)	D-YS	>1 kg
OxiCliq® oxygen transducers (Sterile, single-use only)	P N I A	10 to 50 kg <3 or >40 kg 3 to 20 kg >30 kg

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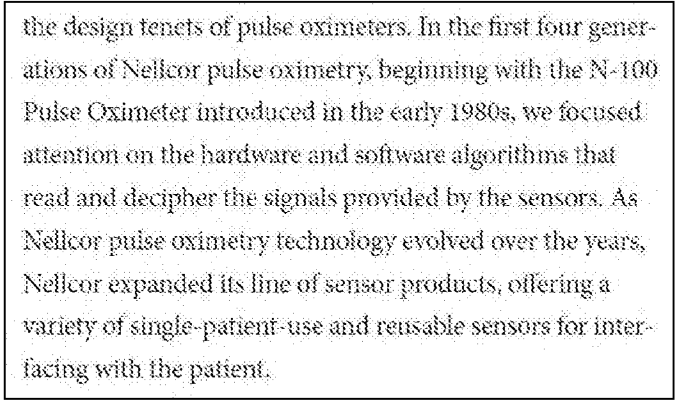
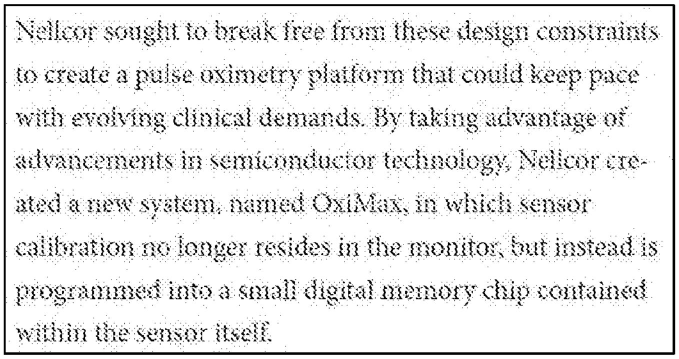
	 the design tenets of pulse oximeters. In the first four generations of Nellcor pulse oximetry, beginning with the N-100 Pulse Oximeter introduced in the early 1980s, we focused attention on the hardware and software algorithms that read and decipher the signals provided by the sensors. As Nellcor pulse oximetry technology evolved over the years, Nellcor expanded its line of sensor products, offering a variety of single-patient-use and reusable sensors for interfacing with the patient. (White Paper, p. 1)  Nellcor sought to break free from these design constraints to create a pulse oximetry platform that could keep pace with evolving clinical demands. By taking advantage of advancements in semiconductor technology, Nellcor created a new system, named OxiMax, in which sensor calibration no longer resides in the monitor, but instead is programmed into a small digital memory chip contained within the sensor itself. (White Paper, p. 1)

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	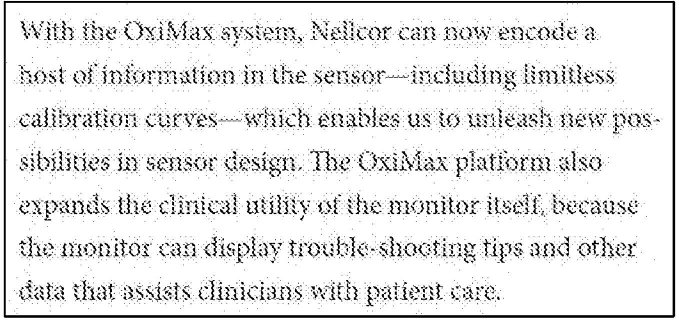 With the OxiMax system, Nellcor can now encode a host of information in the sensor—including limitless calibration curves—which enables us to unleash new possibilities in sensor design. The OxiMax platform also expands the clinical utility of the monitor itself, because the monitor can display trouble-shooting tips and other data that assists clinicians with patient care. (White Paper, p. 1)

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	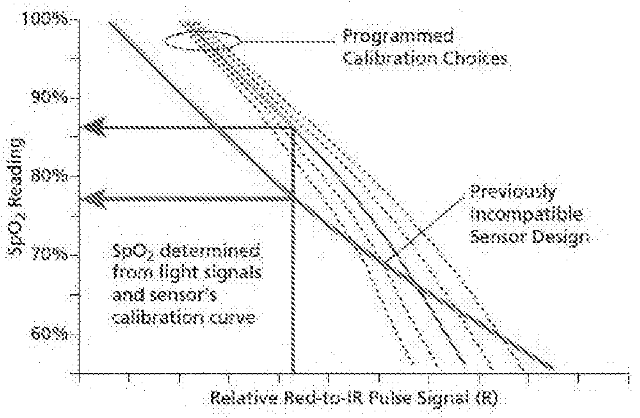 Figure 3 The blue lines depict the one or more calibration curves programmed into earlier-generation monitors, while the red line indicates a calibration required of a hypothetical new sensor. Such a design would be incompatible with these earlier monitors, since none of the blue curves could provide accurate SpO_2 values for the sensor's signals. (White Paper, p. 2)

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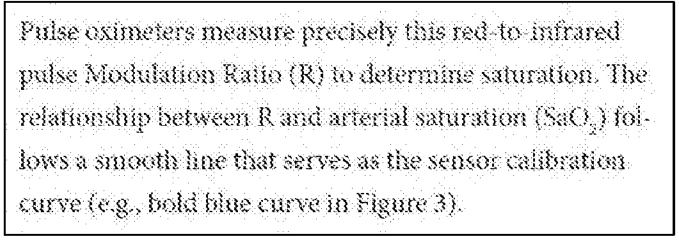
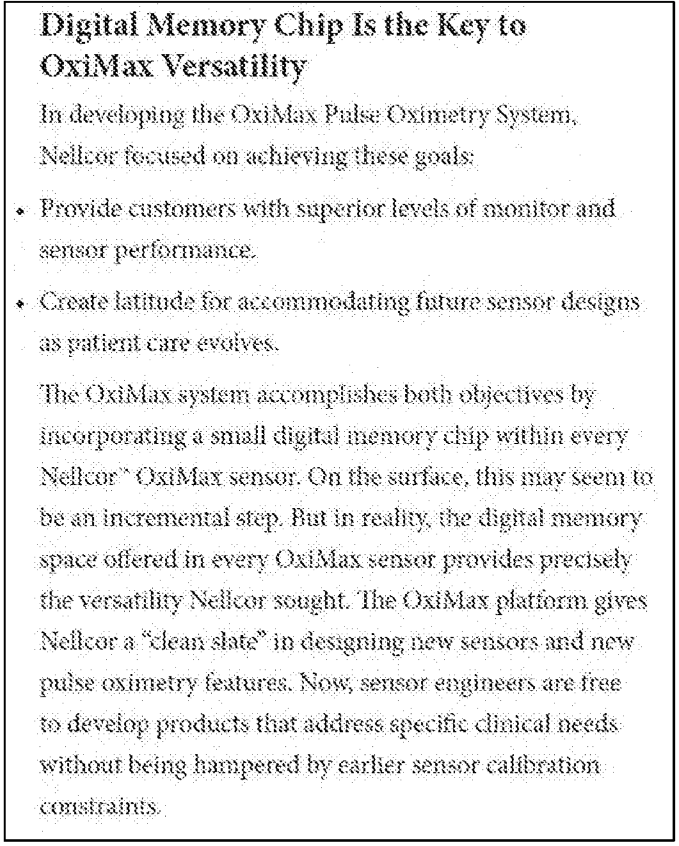
	 Pulse oximeters measure precisely this red-to-infrared pulse Modulation Ratio (R) to determine saturation. The relationship between R and arterial saturation (SaO_2) follows a smooth line that serves as the sensor calibration curve (e.g., bold blue curve in Figure 3). (White Paper, p. 2)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 **Digital Memory Chip Is the Key to OxiMax Versatility** In developing the OxiMax Pulse Oximetry System, Nellcor focused on achieving these goals: • Provide customers with superior levels of monitor and sensor performance. • Create latitude for accommodating future sensor designs as patient care evolves. The OxiMax system accomplishes both objectives by incorporating a small digital memory chip within every Nellcor™ OxiMax sensor. On the surface, this may seem to be an incremental step. But in reality, the digital memory space offered in every OxiMax sensor provides precisely the versatility Nellcor sought. The OxiMax platform gives Nellcor a "clean slate" in designing new sensors and new pulse oximetry features. Now, sensor engineers are free to develop products that address specific clinical needs without being hampered by earlier sensor calibration constraints. (White Paper, p. 4)

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	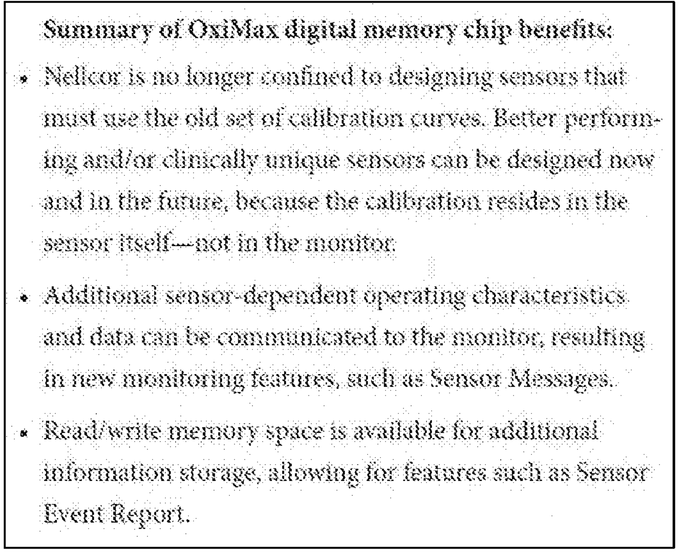 **Summary of OxiMax digital memory chip benefits:** • Nellcor is no longer confined to designing sensors that must use the old set of calibration curves. Better performing and/or clinically unique sensors can be designed now and in the future, because the calibration resides in the sensor itself—not in the monitor. • Additional sensor-dependent operating characteristics and data can be communicated to the monitor, resulting in new monitoring features, such as Sensor Messages. • Read/write memory space is available for additional information storage, allowing for features such as Sensor Event Report. (White Paper, p. 5)
[5G] a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen,	Nellcor discloses and/or renders obvious "a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen."

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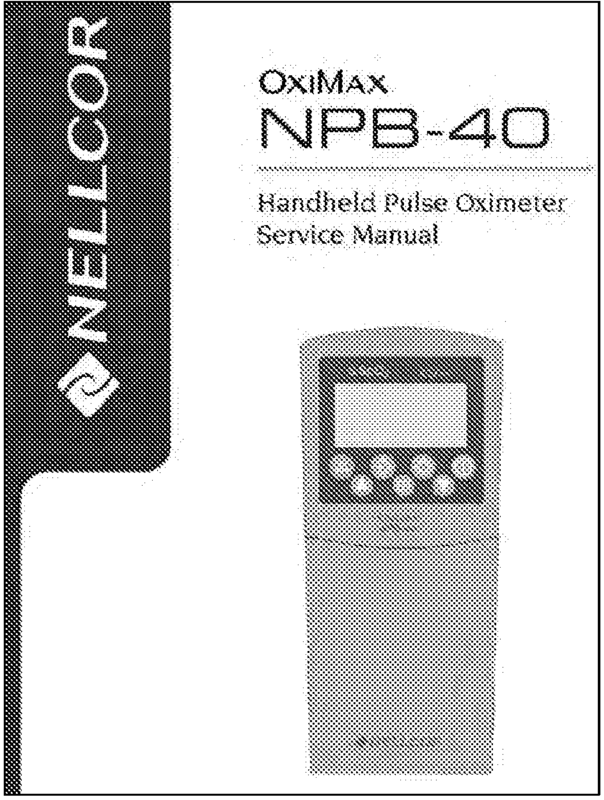
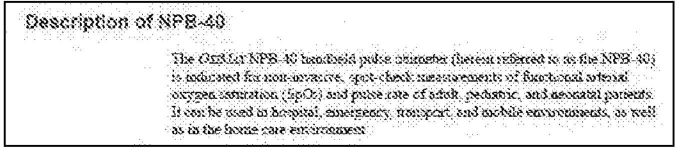
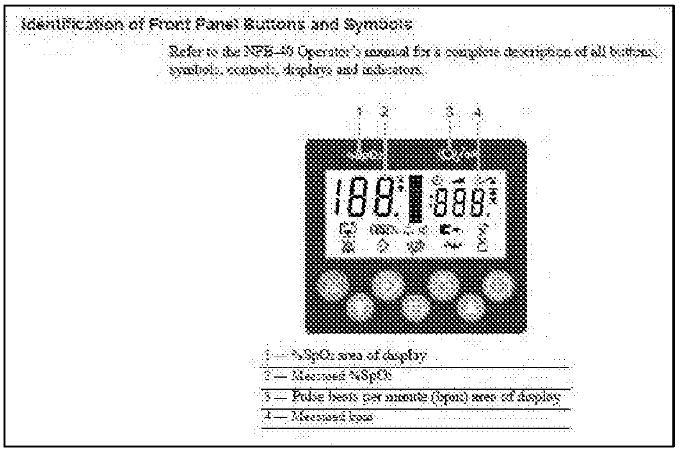
	 NELLCOR OxiMax NPB-40 Handheld Pulse Oximeter Service Manual (NPB-40 Service Manual, Cover)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Description of NPB-40 The OxiMax NPB-40 handheld pulse oximeter (herein referred to as the NPB-40) is indicated for non-invasive, spot-check measurements of functional arterial oxygen saturation (SpO2) and pulse rate of adult, pediatric, and neonatal patients. It can be used in hospital, emergency, transport, and mobile environments, as well as in the home care environment. (NPB-40 Service Manual, p. 3)  Identification of Front Panel Buttons and Symbols Refer to the NPB-40 Operator's manual for a complete description of all buttons, symbols, controls, displays and indicators. 1 — %SpO2 area of display 2 — Measured %SpO2 3 — Pulse beats per minute (bpm) area of display 4 — Measured bpm (NPB-40 Service Manual, p. 3)

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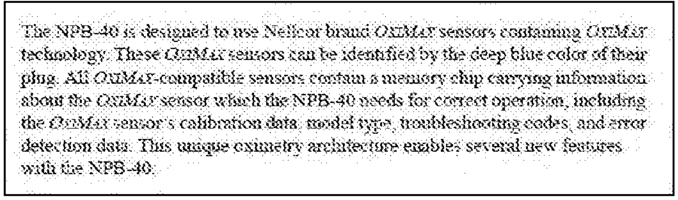
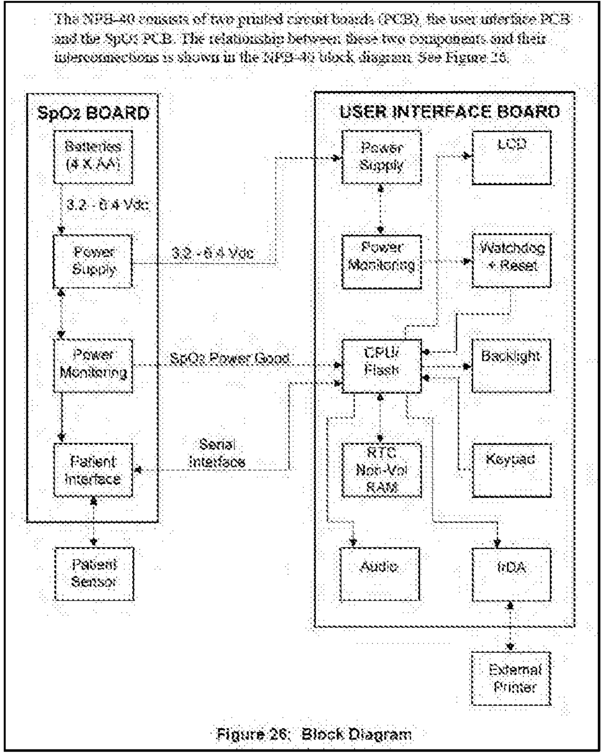
	 The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 The NPB-40 consists of two printed circuit boards (PCB), the user interface PCB and the SpO2 PCB. The relationship between these two components and their interconnections is shown in the NPB-40 block diagram. See Figure 26. Figure 26: Block Diagram (NPB-40 Service Manual, p. 78)

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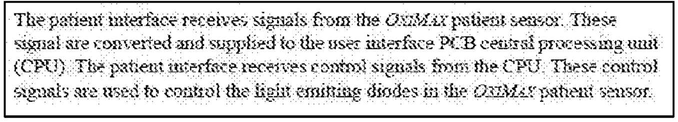
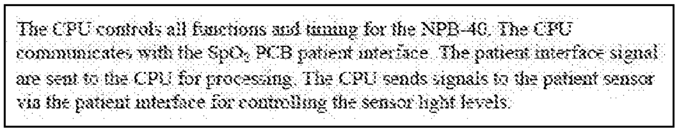
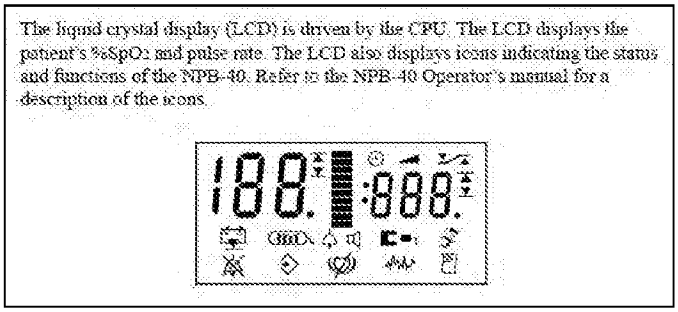
	 The patient interface receives signals from the *OxiMax* patient sensor. These signal are converted and supplied to the user interface PCB central processing unit (CPU). The patient interface receives control signals from the CPU. These control signals are used to control the light emitting diodes in the *OxiMax* patient sensor. (NPB-40 Service Manual, p. 78)  The CPU controls all functions and timing for the NPB-40. The CPU communicates with the SpO_2 PCB patient interface. The patient interface signal are sent to the CPU for processing. The CPU sends signals to the patient sensor via the patient interface for controlling the sensor light levels. (NPB-40 Service Manual, p. 80)  The liquid crystal display (LCD) is driven by the CPU. The LCD displays the patient's %SpO_2 and pulse rate. The LCD also displays icons indicating the status and functions of the NPB-40. Refer to the NPB-40 Operator's manual for a description of the icons. (NPB-40 Service Manual, p. 81)

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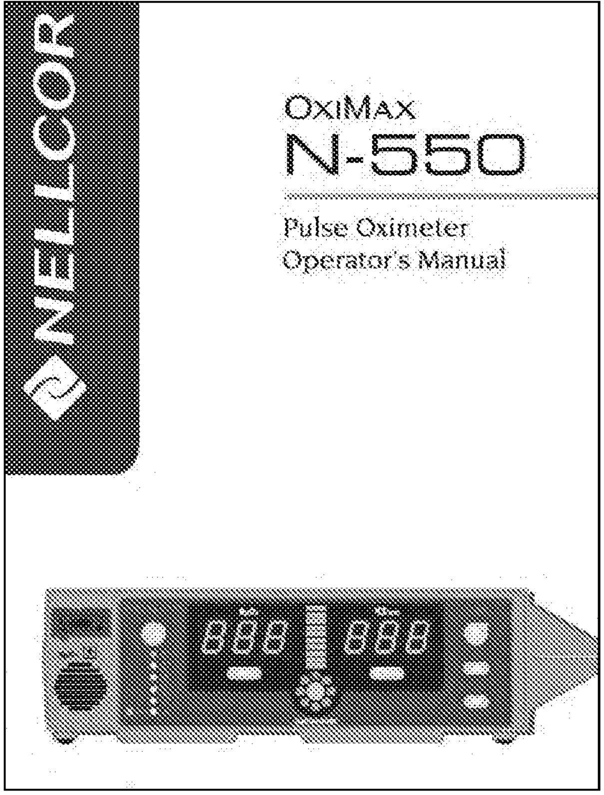
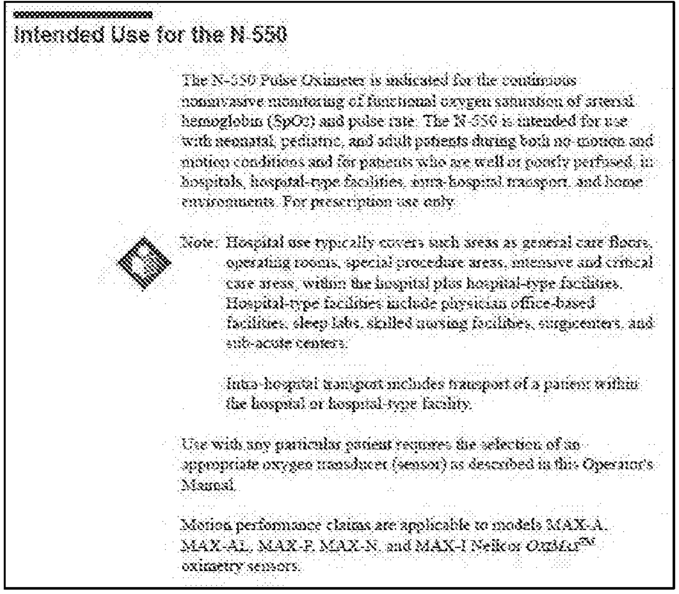
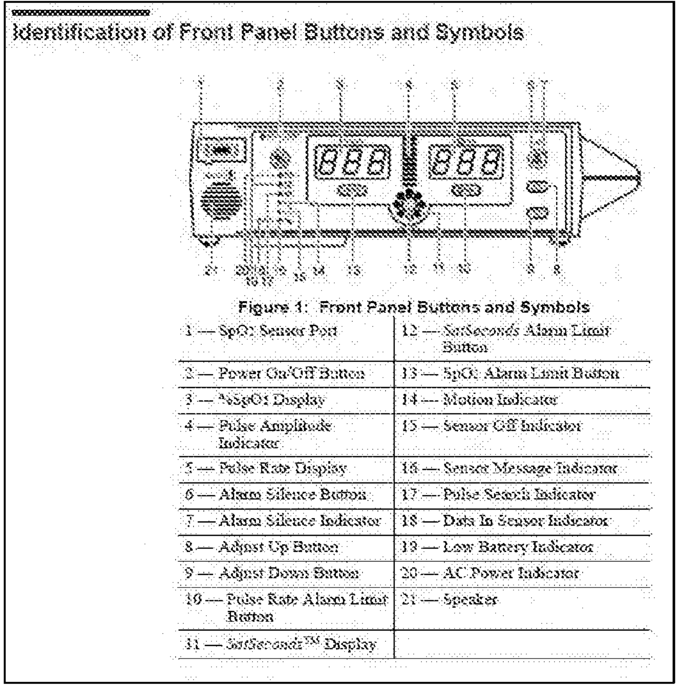
	 NELLCOR OxiMax N-550 Pulse Oximeter Operator's Manual (N-550 Manual, Cover)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 **Intended Use for the N-550** The N-550 Pulse Oximeter is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The N-550 is intended for use with neonatal, pediatric, and adult patients during both no-motion and motion conditions and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, intra-hospital transport, and home environments. For prescription use only. Note: Hospital use typically covers such areas as general care floors, operating rooms, special procedure areas, intensive and critical care areas, within the hospital plus hospital-type facilities. Hospital-type facilities include physician office-based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acute centers. Intra-hospital transport includes transport of a patient within the hospital or hospital-type facility. Use with any particular patient requires the selection of an appropriate oxygen transducer (sensor) as described in this Operator's Manual. Motion performance claims are applicable to models MAX-A, MAX-AL, MAX-P, MAX-N, and MAX-I Nellcor OxiMax™ oximetry sensors. (N-550 Manual, p. 5)

<table>
<tr><th>Asserted Claim of ’533 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>


Identification of Front Panel Buttons and Symbols

Figure 1: Front Panel Buttons and Symbols

<table>
<tr><td>1 — SpO2 Sensor Port</td><td>12 — *SatSeconds* Alarm Limit Button</td></tr>
<tr><td>2 — Power On/Off Button</td><td>13 — SpO2 Alarm Limit Button</td></tr>
<tr><td>3 — %SpO2 Display</td><td>14 — Motion Indicator</td></tr>
<tr><td>4 — Pulse Amplitude Indicator</td><td>15 — Sensor Off Indicator</td></tr>
<tr><td>5 — Pulse Rate Display</td><td>16 — Sensor Message Indicator</td></tr>
<tr><td>6 — Alarm Silence Button</td><td>17 — Pulse Search Indicator</td></tr>
<tr><td>7 — Alarm Silence Indicator</td><td>18 — Data In Sensor Indicator</td></tr>
<tr><td>8 — Adjust Up Button</td><td>19 — Low Battery Indicator</td></tr>
<tr><td>9 — Adjust Down Button</td><td>20 — AC Power Indicator</td></tr>
<tr><td>10 — Pulse Rate Alarm Limit Button</td><td>21 — Speaker</td></tr>
<tr><td>11 — *SatSeconds*™ Display</td><td></td></tr>
</table>

(N-550 Manual, p. 7)
</td></tr>
</table>

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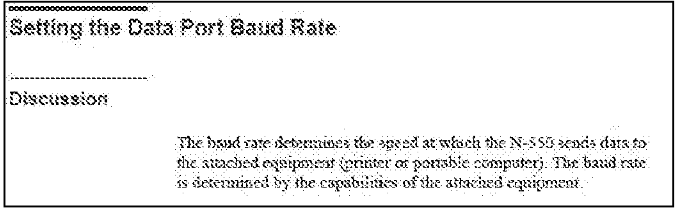
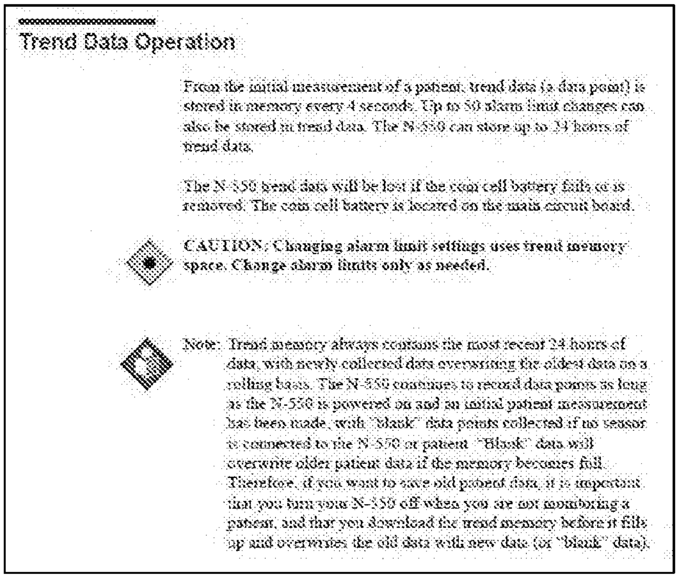
	 Setting the Data Port Baud Rate Discussion The baud rate determines the speed at which the N-550 sends data to the attached equipment (printer or portable computer). The baud rate is determined by the capabilities of the attached equipment. (N-550 Manual, p. 37)  Trend Data Operation From the initial measurement of a patient, trend data (a data point) is stored in memory every 4 seconds. Up to 50 alarm limit changes can also be stored in trend data. The N-550 can store up to 24 hours of trend data. The N-550 trend data will be lost if the coin cell battery fails or is removed. The coin cell battery is located on the main circuit board. **CAUTION: Changing alarm limit settings uses trend memory space. Change alarm limits only as needed.** Note: Trend memory always contains the most recent 24 hours of data, with newly collected data overwriting the oldest data on a rolling basis. The N-550 continues to record data points as long as the N-550 is powered on and an initial patient measurement has been made, with "blank" data points collected if no sensor is connected to the N-550 or patient. "Blank" data will overwrite older patient data if the memory becomes full. Therefore, if you want to save old patient data, it is important that you turn your N-550 off when you are not monitoring a patient, and that you download the trend memory before it fills up and overwrites the old data with new data (or "blank" data). (N-550 Manual, p. 43)

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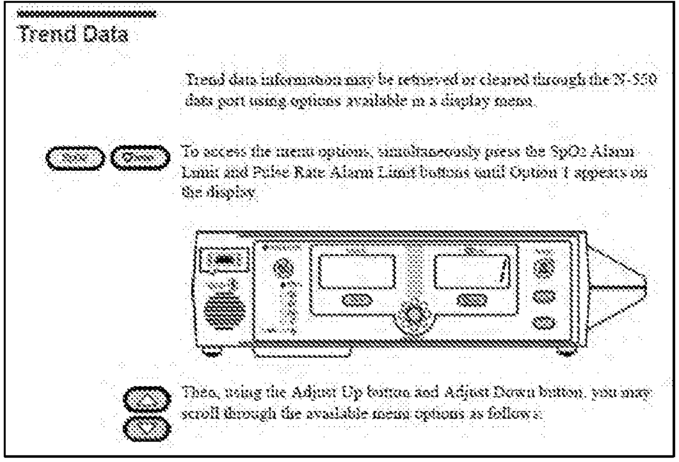
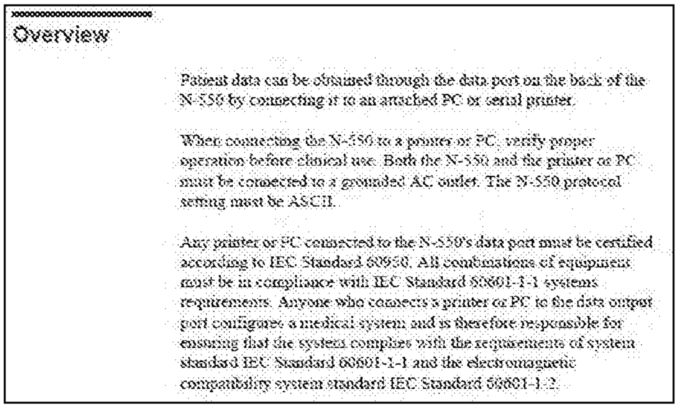
	 Trend Data Trend data information may be retrieved or cleared through the N-550 data port using options available in a display menu. To access the menu options, simultaneously press the SpO2 Alarm Limit and Pulse Rate Alarm Limit buttons until Option 1 appears on the display. Then, using the Adjust Up button and Adjust Down button, you may scroll through the available menu options as follows: (N-550 Manual, p. 43-44)  Overview Patient data can be obtained through the data port on the back of the N-550 by connecting it to an attached PC or serial printer. When connecting the N-550 to a printer or PC, verify proper operation before clinical use. Both the N-550 and the printer or PC must be connected to a grounded AC outlet. The N-550 protocol setting must be ASCII. Any printer or PC connected to the N-550's data port must be certified according to IEC Standard 60950. All combinations of equipment must be in compliance with IEC Standard 60601-1-1 systems requirements. Anyone who connects a printer or PC to the data output port configures a medical system and is therefore responsible for ensuring that the system complies with the requirements of system standard IEC Standard 60601-1-1 and the electromagnetic compatibility system standard IEC Standard 60601-1-2. (N-550 Manual, p. 47)

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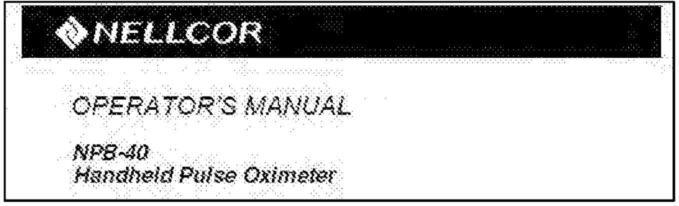
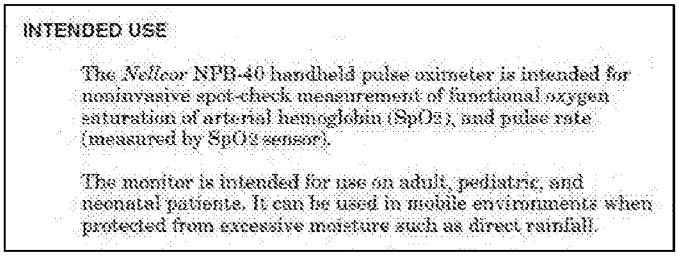
	 NELLCOR OPERATOR'S MANUAL *NPB-40* *Handheld Pulse Oximeter* (NPB-40 Operator's Manual, Cover)  INTENDED USE The *Nellcor* NPB-40 handheld pulse oximeter is intended for noninvasive spot-check measurement of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate (measured by SpO2 sensor). The monitor is intended for use on adult, pediatric, and neonatal patients. It can be used in mobile environments when protected from excessive moisture such as direct rainfall. (NPB-40 Operator's Manual, p. 3)

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	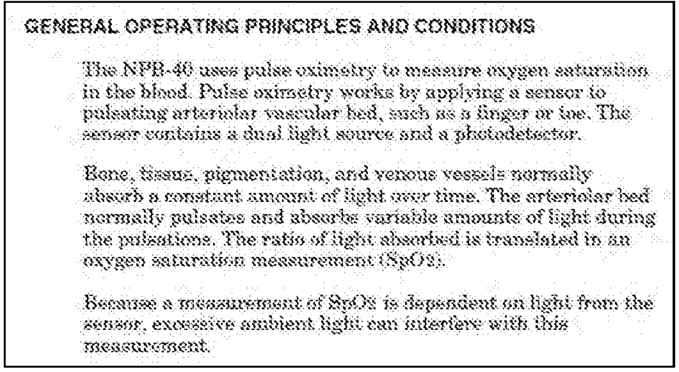 GENERAL OPERATING PRINCIPLES AND CONDITIONS The NPB-40 uses pulse oximetry to measure oxygen saturation in the blood. Pulse oximetry works by applying a sensor to pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photodetector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated in an oxygen saturation measurement (SpO2). Because a measurement of SpO2 is dependent on light from the sensor, excessive ambient light can interfere with this measurement. (NPB-40 Operator's Manual, p. 3-4)

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	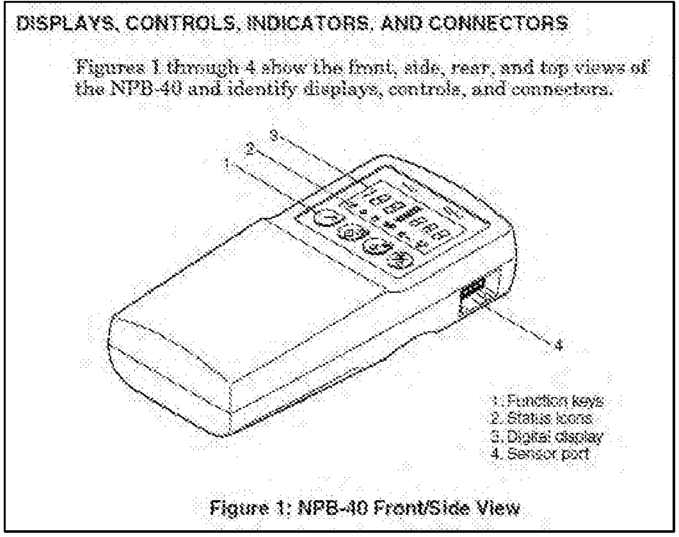 DISPLAYS, CONTROLS, INDICATORS, AND CONNECTORS Figures 1 through 4 show the front, side, rear, and top views of the NPB-40 and identify displays, controls, and connectors. 1. Function keys 2. Status icons 3. Digital display 4. Sensor port Figure 1: NPB-40 Front/Side View (NPB-40 Operator's Manual, p. 5)

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	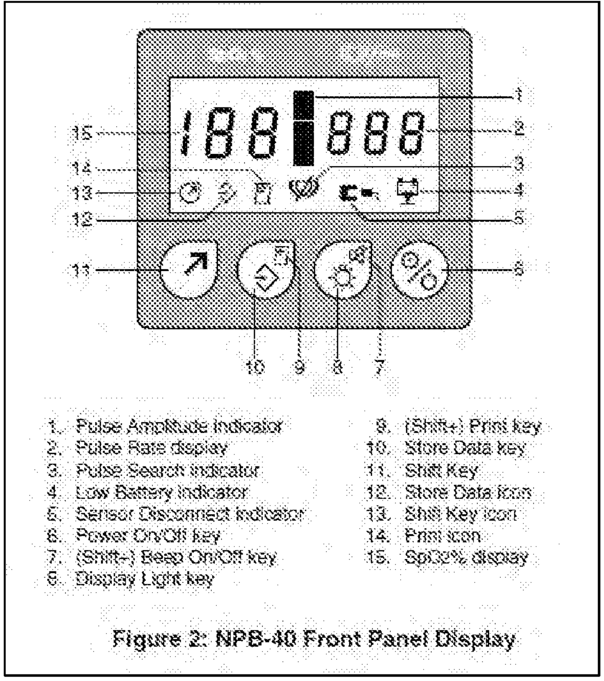 1. Pulse Amplitude indicator 2. Pulse Rate display 3. Pulse Search indicator 4. Low Battery indicator 5. Sensor Disconnect indicator 6. Power On/Off key 7. (Shift+) Beep On/Off key 8. Display Light key 9. (Shift+) Print key 10. Store Data key 11. Shift Key 12. Store Data icon 13. Shift Key icon 14. Print icon 15. SpO2% display Figure 2: NPB-40 Front Panel Display (NPB-40 Operator's Manual, p. 6)

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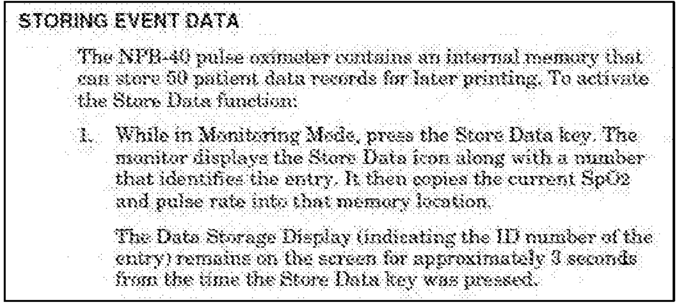
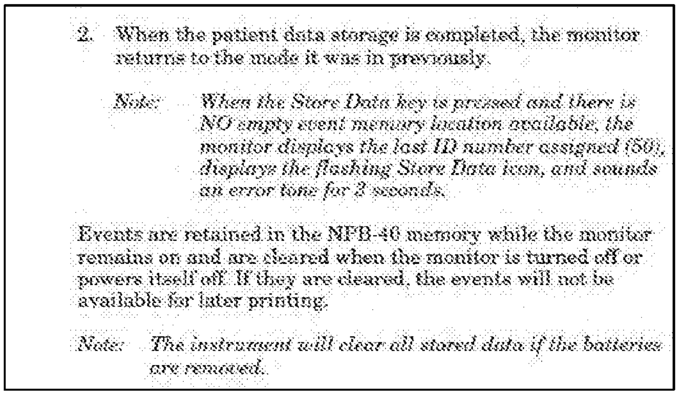
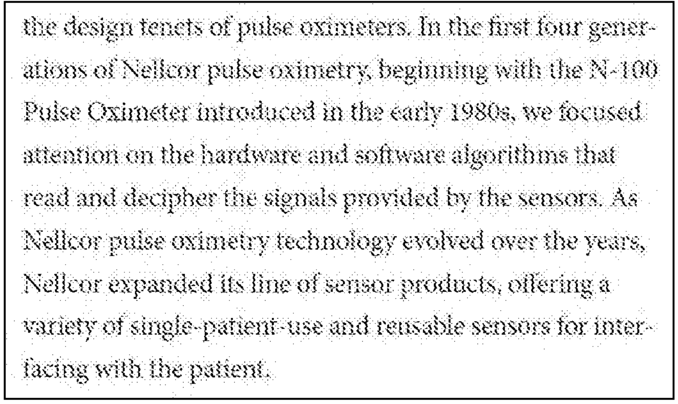
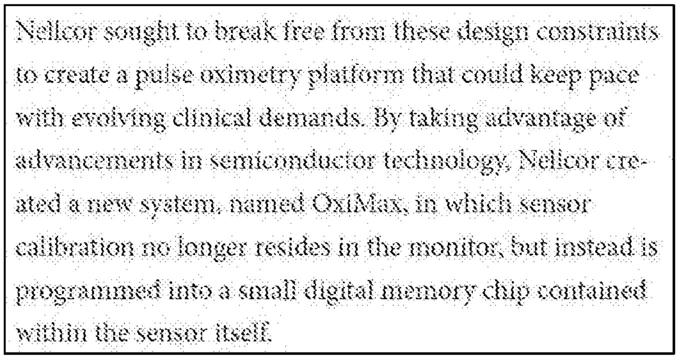
	 STORING EVENT DATA The NPB-40 pulse oximeter contains an internal memory that can store 50 patient data records for later printing. To activate the Store Data function: 1. While in Monitoring Mode, press the Store Data key. The monitor displays the Store Data icon along with a number that identifies the entry. It then copies the current SpO2 and pulse rate into that memory location. The Data Storage Display (indicating the ID number of the entry) remains on the screen for approximately 3 seconds from the time the Store Data key was pressed. (NPB-40 Operator's Manual, p. 23)  2. When the patient data storage is completed, the monitor returns to the mode it was in previously. *Note: When the Store Data key is pressed and there is NO empty event memory location available, the monitor displays the last ID number assigned (50), displays the flashing Store Data icon, and sounds an error tone for 3 seconds.* Events are retained in the NPB-40 memory while the monitor remains on and are cleared when the monitor is turned off or powers itself off. If they are cleared, the events will not be available for later printing. *Note: The instrument will clear all stored data if the batteries are removed.* (NPB-40 Operator's Manual, p. 24)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 the design tenets of pulse oximeters. In the first four generations of Nellcor pulse oximetry, beginning with the N-100 Pulse Oximeter introduced in the early 1980s, we focused attention on the hardware and software algorithms that read and decipher the signals provided by the sensors. As Nellcor pulse oximetry technology evolved over the years, Nellcor expanded its line of sensor products, offering a variety of single-patient-use and reusable sensors for interfacing with the patient. (White Paper, p. 1)  Nellcor sought to break free from these design constraints to create a pulse oximetry platform that could keep pace with evolving clinical demands. By taking advantage of advancements in semiconductor technology, Nellcor created a new system, named OxiMax, in which sensor calibration no longer resides in the monitor, but instead is programmed into a small digital memory chip contained within the sensor itself. (White Paper, p. 1)

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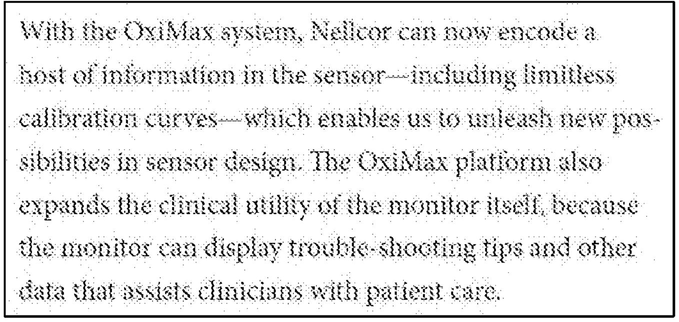
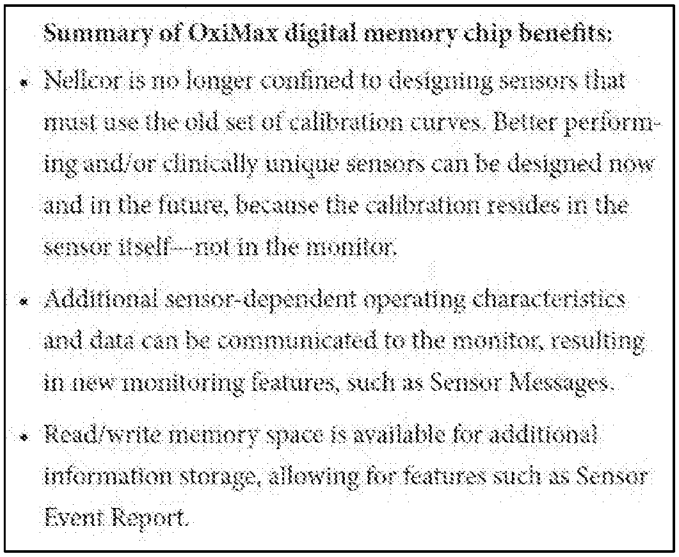
	With the OxiMax system, Nellcor can now encode a host of information in the sensor—including limitless calibration curves—which enables us to unleash new possibilities in sensor design. The OxiMax platform also expands the clinical utility of the monitor itself, because the monitor can display trouble-shooting tips and other data that assists clinicians with patient care. (White Paper, p. 1) **Summary of OxiMax digital memory chip benefits:** • Nellcor is no longer confined to designing sensors that must use the old set of calibration curves. Better performing and/or clinically unique sensors can be designed now and in the future, because the calibration resides in the sensor itself—not in the monitor. • Additional sensor-dependent operating characteristics and data can be communicated to the monitor, resulting in new monitoring features, such as Sensor Messages. • Read/write memory space is available for additional information storage, allowing for features such as Sensor Event Report. (White Paper, p. 5)

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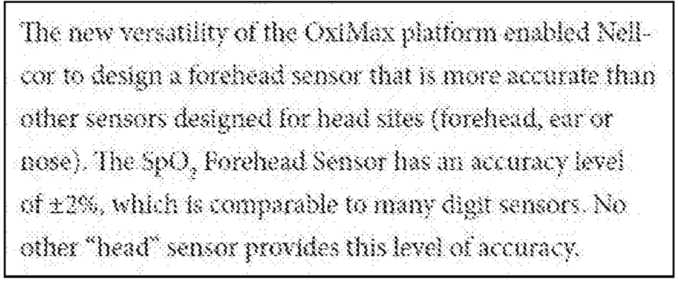
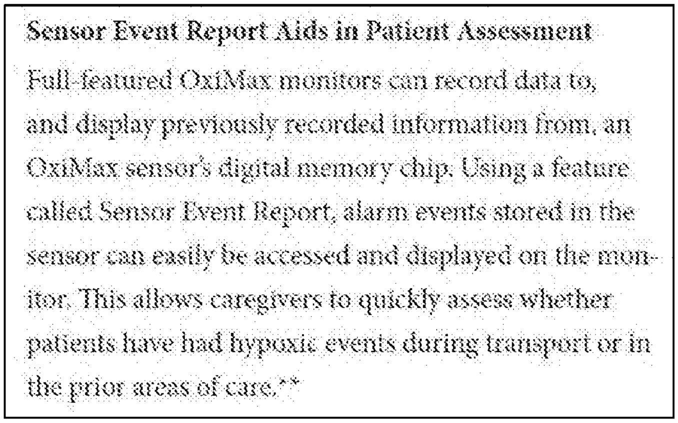
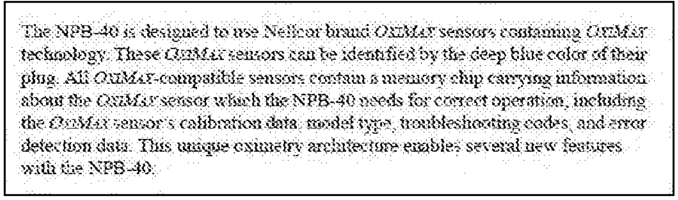
	 The new versatility of the OxiMax platform enabled Nellcor to design a forehead sensor that is more accurate than other sensors designed for head sites (forehead, ear or nose). The SpO_2 Forehead Sensor has an accuracy level of ±2%, which is comparable to many digit sensors. No other "head" sensor provides this level of accuracy. (White Paper, p. 6)  **Sensor Event Report Aids in Patient Assessment** Full-featured OxiMax monitors can record data to, and display previously recorded information from, an OxiMax sensor's digital memory chip. Using a feature called Sensor Event Report, alarm events stored in the sensor can easily be accessed and displayed on the monitor. This allows caregivers to quickly assess whether patients have had hypoxic events during transport or in the prior areas of care.** (White Paper, p. 8)
[5H] the personal device configured to receive and process at least a portion of the output signal,	Nellcor discloses and/or renders obvious "the personal device configured to receive and process at least a portion of the output signal."

Asserted Claim of '533 Patent	**Nellcor Pulse Oximeters**
	 The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)

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	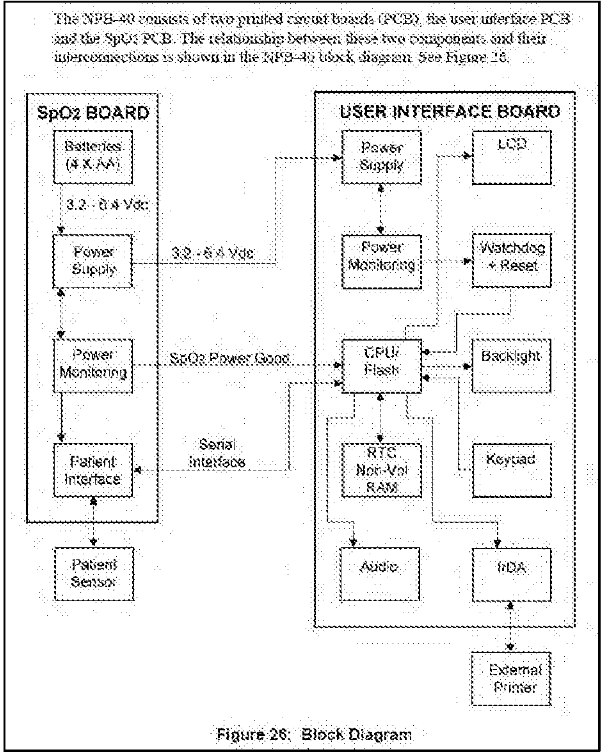 The NPB-40 consists of two printed circuit boards (PCB), the user interface PCB and the SpO2 PCB. The relationship between these two components and their interconnections is shown in the NPB-40 block diagram. See Figure 26. Figure 26: Block Diagram (NPB-40 Service Manual, p. 78)

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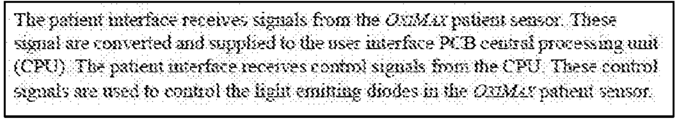
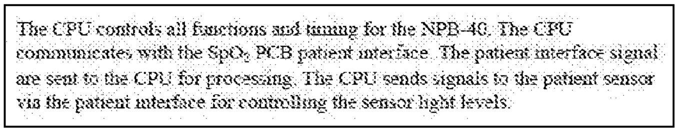
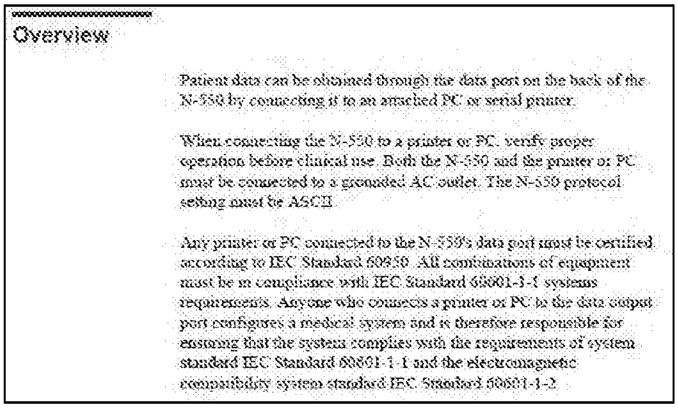
	 The patient interface receives signals from the *OxiMax* patient sensor. These signal are converted and supplied to the user interface PCB central processing unit (CPU). The patient interface receives control signals from the CPU. These control signals are used to control the light emitting diodes in the *OxiMax* patient sensor. (NPB-40 Service Manual, p. 78)  The CPU controls all functions and timing for the NPB-40. The CPU communicates with the SpO_2 PCB patient interface. The patient interface signal are sent to the CPU for processing. The CPU sends signals to the patient sensor via the patient interface for controlling the sensor light levels. (NPB-40 Service Manual, p. 80)  Overview Patient data can be obtained through the data port on the back of the N-550 by connecting it to an attached PC or serial printer. When connecting the N-550 to a printer or PC, verify proper operation before clinical use. Both the N-550 and the printer or PC must be connected to a grounded AC outlet. The N-550 protocol setting must be ASCII. Any printer or PC connected to the N-550's data port must be certified according to IEC Standard 60950. All combinations of equipment must be in compliance with IEC Standard 60601-1-1 systems requirements. Anyone who connects a printer or PC to the data output port configures a medical system and is therefore responsible for ensuring that the system complies with the requirements of system standard IEC Standard 60601-1-1 and the electromagnetic compatibility system standard IEC Standard 60601-1-2. (N-550 Manual, p. 47)

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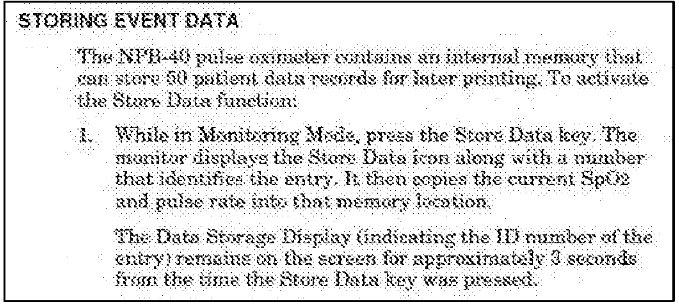
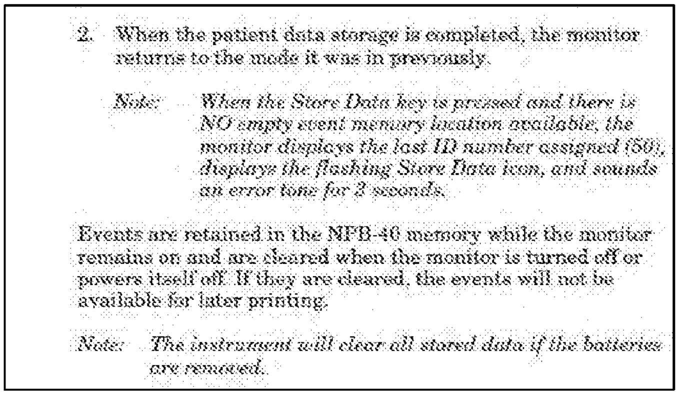
	 STORING EVENT DATA The NPB-40 pulse oximeter contains an internal memory that can store 50 patient data records for later printing. To activate the Store Data function: 1. While in Monitoring Mode, press the Store Data key. The monitor displays the Store Data icon along with a number that identifies the entry. It then copies the current SpO2 and pulse rate into that memory location. The Data Storage Display (indicating the ID number of the entry) remains on the screen for approximately 3 seconds from the time the Store Data key was pressed. (NPB-40 Operator's Manual, p. 23)  2. When the patient data storage is completed, the monitor returns to the mode it was in previously. *Note: When the Store Data key is pressed and there is NO empty event memory location available, the monitor displays the last ID number assigned (50), displays the flashing Store Data icon, and sounds an error tone for 3 seconds.* Events are retained in the NPB-40 memory while the monitor remains on and are cleared when the monitor is turned off or powers itself off. If they are cleared, the events will not be available for later printing. *Note: The instrument will clear all stored data if the batteries are removed.* (NPB-40 Operator's Manual, p. 24)

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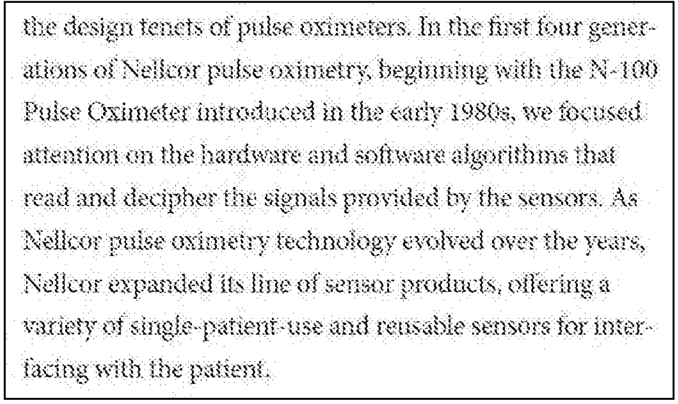
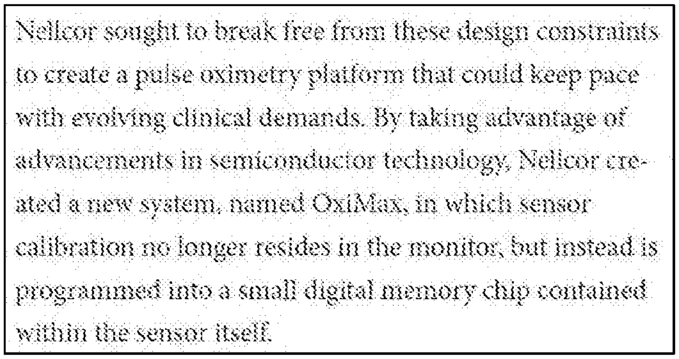
	 the design tenets of pulse oximeters. In the first four generations of Nellcor pulse oximetry, beginning with the N-100 Pulse Oximeter introduced in the early 1980s, we focused attention on the hardware and software algorithms that read and decipher the signals provided by the sensors. As Nellcor pulse oximetry technology evolved over the years, Nellcor expanded its line of sensor products, offering a variety of single-patient-use and reusable sensors for interfacing with the patient. (White Paper, p. 1)  Nellcor sought to break free from these design constraints to create a pulse oximetry platform that could keep pace with evolving clinical demands. By taking advantage of advancements in semiconductor technology, Nellcor created a new system, named OxiMax, in which sensor calibration no longer resides in the monitor, but instead is programmed into a small digital memory chip contained within the sensor itself. (White Paper, p. 1)

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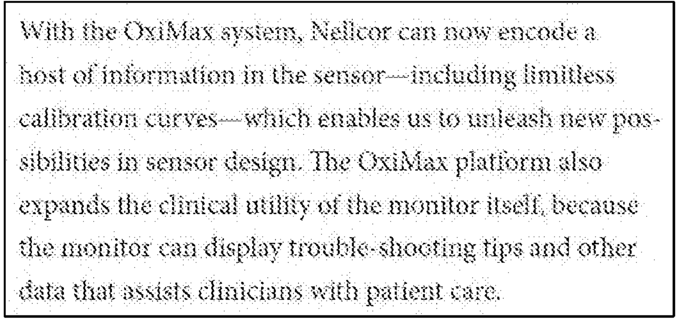
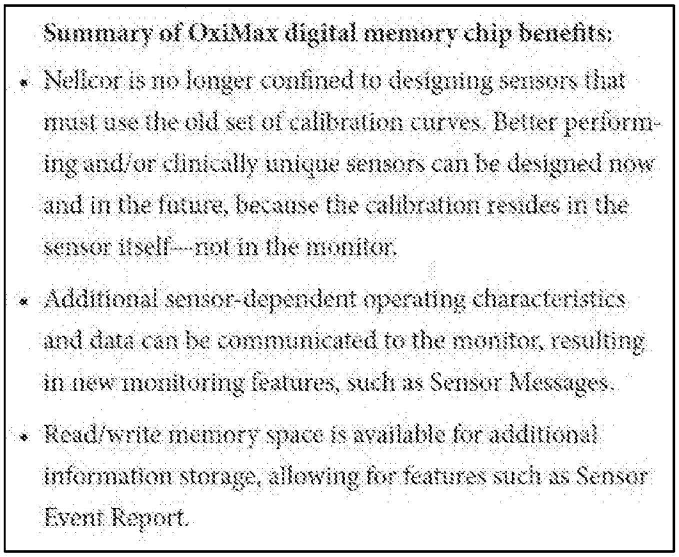
	 With the OxiMax system, Nellcor can now encode a host of information in the sensor—including limitless calibration curves—which enables us to unleash new possibilities in sensor design. The OxiMax platform also expands the clinical utility of the monitor itself, because the monitor can display trouble-shooting tips and other data that assists clinicians with patient care. (White Paper, p. 1)  **Summary of OxiMax digital memory chip benefits:** • Nellcor is no longer confined to designing sensors that must use the old set of calibration curves. Better performing and/or clinically unique sensors can be designed now and in the future, because the calibration resides in the sensor itself—not in the monitor. • Additional sensor-dependent operating characteristics and data can be communicated to the monitor, resulting in new monitoring features, such as Sensor Messages. • Read/write memory space is available for additional information storage, allowing for features such as Sensor Event Report. (White Paper, p. 5)

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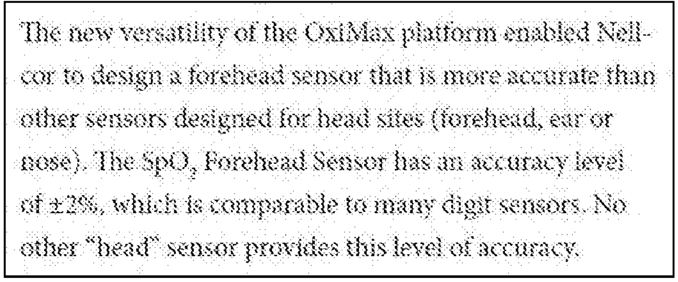
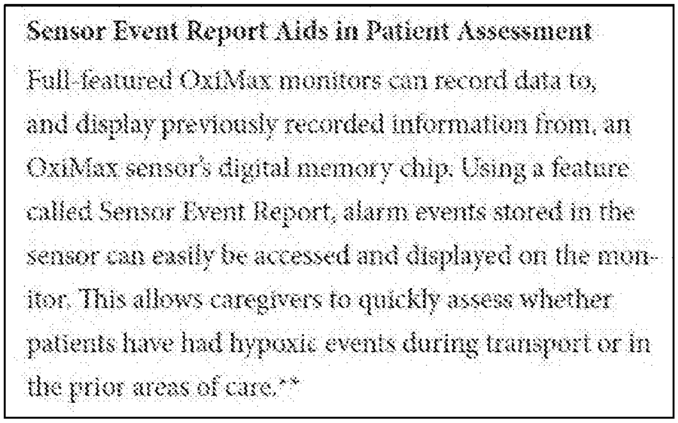
	 The new versatility of the OxiMax platform enabled Nellcor to design a forehead sensor that is more accurate than other sensors designed for head sites (forehead, ear or nose). The SpO_2 Forehead Sensor has an accuracy level of ±2%, which is comparable to many digit sensors. No other "head" sensor provides this level of accuracy. (White Paper, p. 6)  **Sensor Event Report Aids in Patient Assessment** Full-featured OxiMax monitors can record data to, and display previously recorded information from, an OxiMax sensor's digital memory chip. Using a feature called Sensor Event Report, alarm events stored in the sensor can easily be accessed and displayed on the monitor. This allows caregivers to quickly assess whether patients have had hypoxic events during transport or in the prior areas of care.** (White Paper, p. 8)
[5I] wherein the personal device is configured to store and display the processed output signal,	Nellcor discloses and/or renders obvious "wherein the personal device is configured to store and display the processed output signal."

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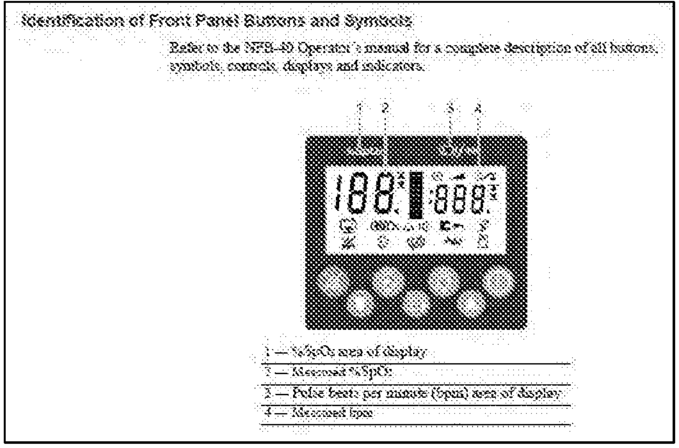
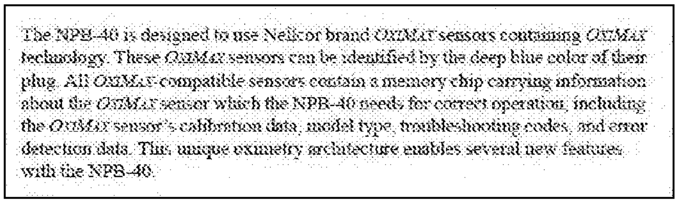
	 Identification of Front Panel Buttons and Symbols Refer to the NPB-40 Operator's manual for a complete description of all buttons, symbols, controls, displays and indicators. 1 — %SpO$_2$ area of display 2 — Measured %SpO$_2$ 3 — Pulse beats per minute (bpm) area of display 4 — Measured bpm (NPB-40 Service Manual, p. 3)  The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)

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	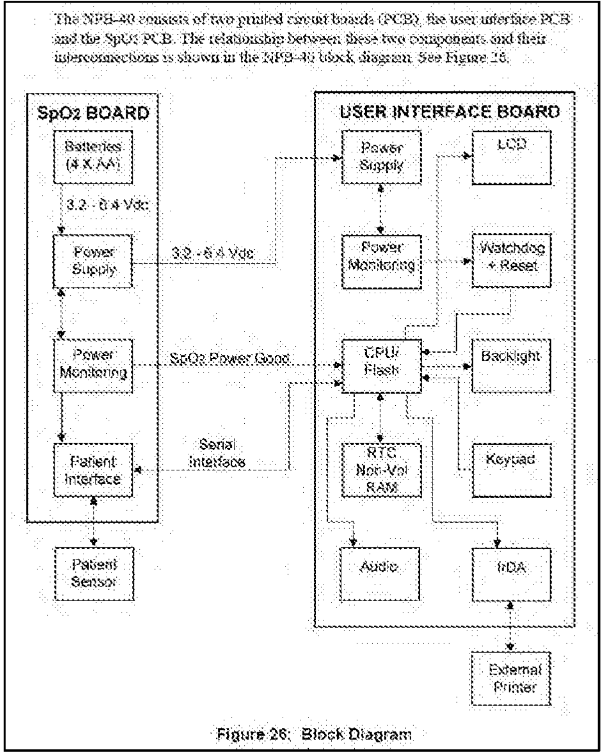 The NPB-40 consists of two printed circuit boards (PCB), the user interface PCB and the SpO2 PCB. The relationship between these two components and their interconnections is shown in the NPB-40 block diagram. See Figure 26. Figure 26: Block Diagram (NPB-40 Service Manual, p. 78)

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	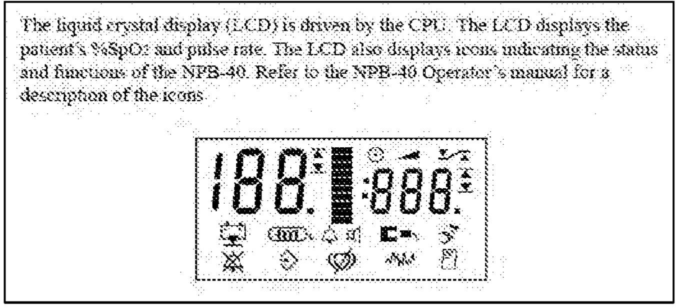 The liquid crystal display (LCD) is driven by the CPU. The LCD displays the patient's %SpO$_2$ and pulse rate. The LCD also displays icons indicating the status and functions of the NPB-40. Refer to the NPB-40 Operator's manual for a description of the icons. (NPB-40 Service Manual, p. 81)

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	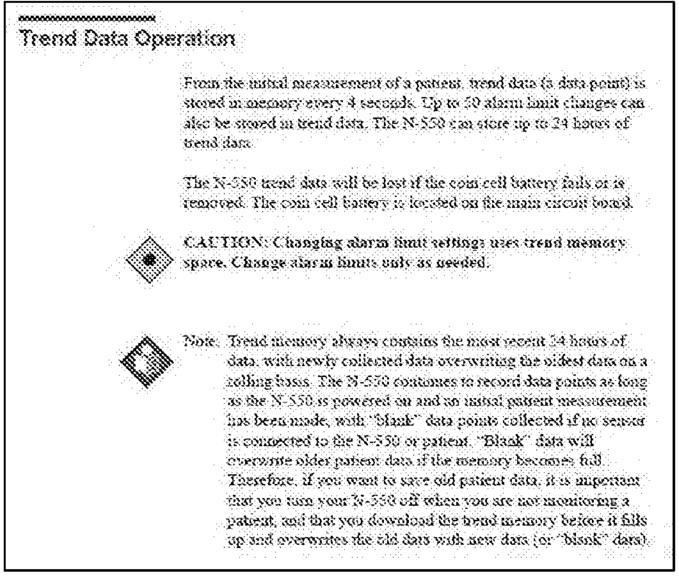 Trend Data Operation From the initial measurement of a patient, trend data (a data point) is stored in memory every 4 seconds. Up to 50 alarm limit changes can also be stored in trend data. The N-550 can store up to 24 hours of trend data. The N-550 trend data will be lost if the coin cell battery fails or is removed. The coin cell battery is located on the main circuit board. **CAUTION: Changing alarm limit settings uses trend memory space. Change alarm limits only as needed.** Note: Trend memory always contains the most recent 24 hours of data, with newly collected data overwriting the oldest data on a rolling basis. The N-550 continues to record data points as long as the N-550 is powered on and an initial patient measurement has been made, with "blank" data points collected if no sensor is connected to the N-550 or patient. "Blank" data will overwrite older patient data if the memory becomes full. Therefore, if you want to save old patient data, it is important that you turn your N-550 off when you are not monitoring a patient, and that you download the trend memory before it fills up and overwrites the old data with new data (or "blank" data). (N-550 Manual, p. 43)

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	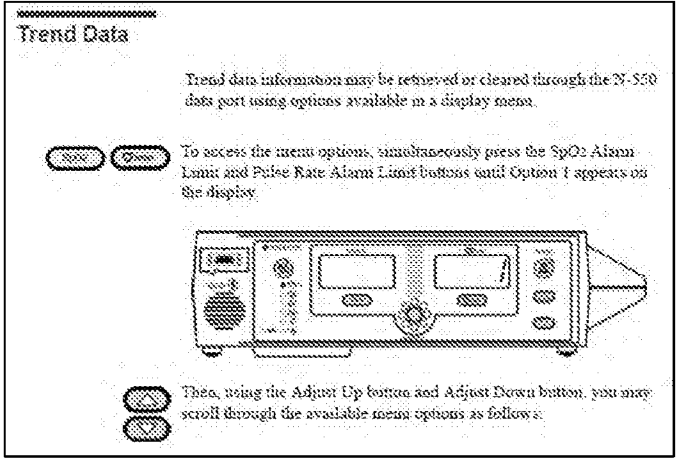 Trend Data Trend data information may be retrieved or cleared through the N-550 data port using options available in a display menu. To access the menu options, simultaneously press the SpO_2 Alarm Limit and Pulse Rate Alarm Limit buttons until Option 1 appears on the display. Then, using the Adjust Up button and Adjust Down button, you may scroll through the available menu options as follows: (N-550 Manual, p. 43-44)

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	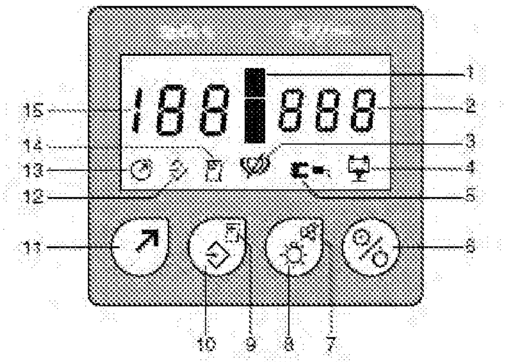 1. Pulse Amplitude indicator 2. Pulse Rate display 3. Pulse Search indicator 4. Low Battery indicator 5. Sensor Disconnect indicator 6. Power On/Off key 7. (Shift+) Beep On/Off key 8. Display Light key 9. (Shift+) Print key 10. Store Data key 11. Shift Key 12. Store Data icon 13. Shift Key icon 14. Print icon 15. SpO2% display Figure 2: NPB-40 Front Panel Display (NPB-40 Operator's Manual, p. 6)

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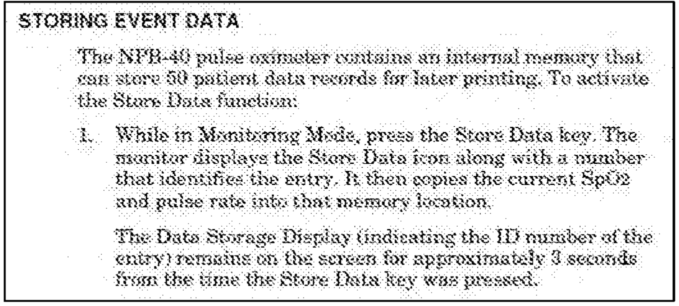
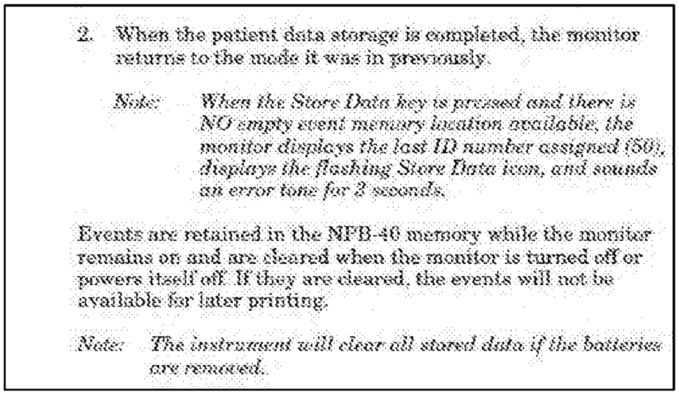
	 STORING EVENT DATA The NPB-40 pulse oximeter contains an internal memory that can store 50 patient data records for later printing. To activate the Store Data function: 1. While in Monitoring Mode, press the Store Data key. The monitor displays the Store Data icon along with a number that identifies the entry. It then copies the current SpO2 and pulse rate into that memory location. The Data Storage Display (indicating the ID number of the entry) remains on the screen for approximately 3 seconds from the time the Store Data key was pressed. (NPB-40 Operator's Manual, p. 23)  2. When the patient data storage is completed, the monitor returns to the mode it was in previously. *Note: When the Store Data key is pressed and there is NO empty event memory location available, the monitor displays the last ID number assigned (50), displays the flashing Store Data icon, and sounds an error tone for 2 seconds.* Events are retained in the NPB-40 memory while the monitor remains on and are cleared when the monitor is turned off or powers itself off. If they are cleared, the events will not be available for later printing. *Note: The instrument will clear all stored data if the batteries are removed.* (NPB-40 Operator's Manual, p. 24)

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	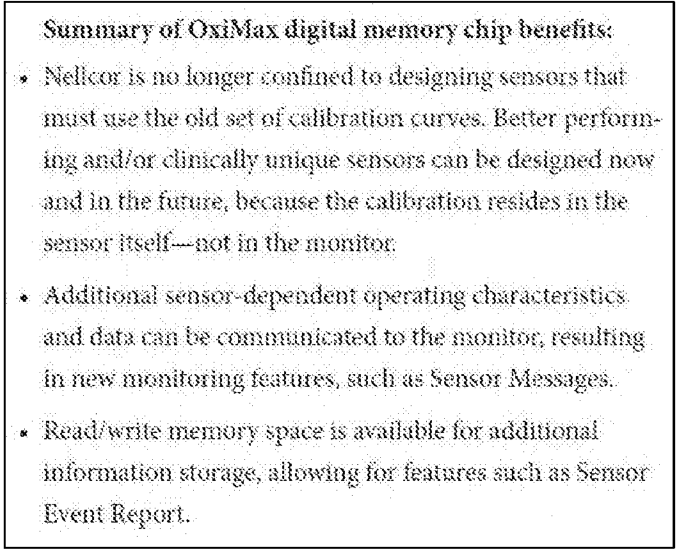 **Summary of OxiMax digital memory chip benefits:** • Nellcor is no longer confined to designing sensors that must use the old set of calibration curves. Better performing and/or clinically unique sensors can be designed now and in the future, because the calibration resides in the sensor itself—not in the monitor. • Additional sensor-dependent operating characteristics and data can be communicated to the monitor, resulting in new monitoring features, such as Sensor Messages. • Read/write memory space is available for additional information storage, allowing for features such as Sensor Event Report. (White Paper, p. 5)

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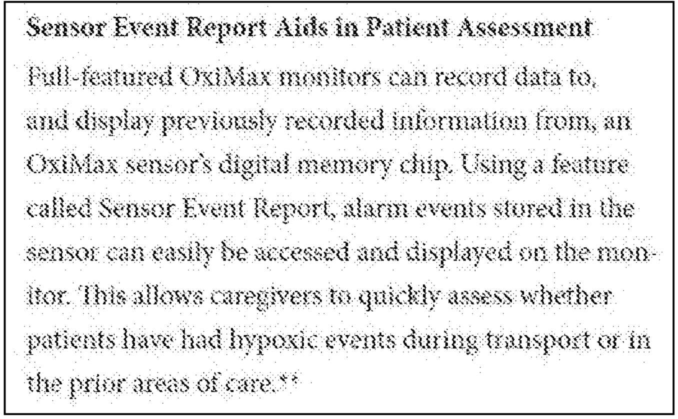
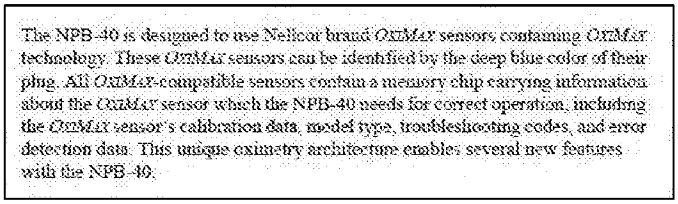
	 **Sensor Event Report Aids in Patient Assessment** Full-featured OxiMax monitors can record data to, and display previously recorded information from, an OxiMax sensor's digital memory chip. Using a feature called Sensor Event Report, alarm events stored in the sensor can easily be accessed and displayed on the monitor. This allows caregivers to quickly assess whether patients have had hypoxic events during transport or in the prior areas of care.** (White Paper, p. 8)
[5J] and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link; and	Nellcor discloses and/or renders obvious "and wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link."  The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)

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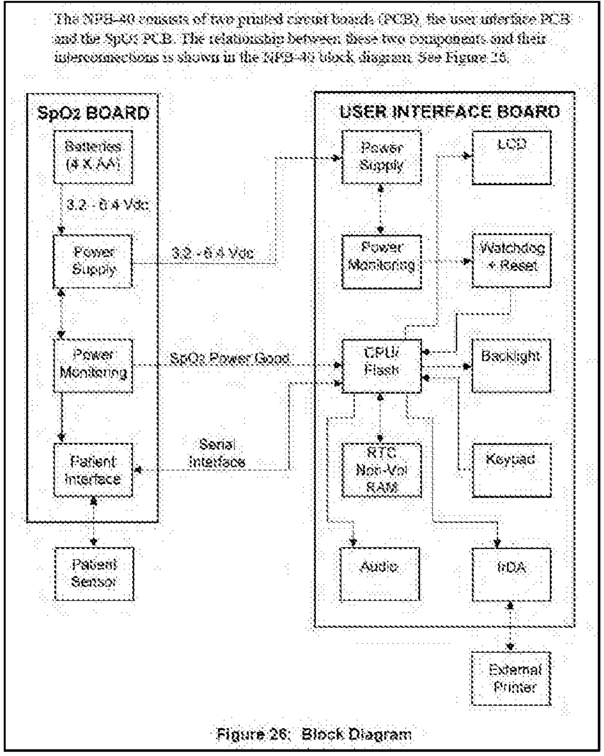
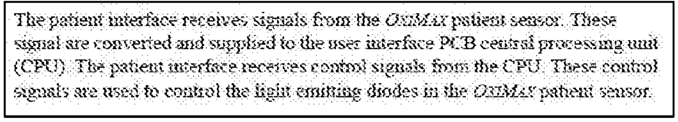
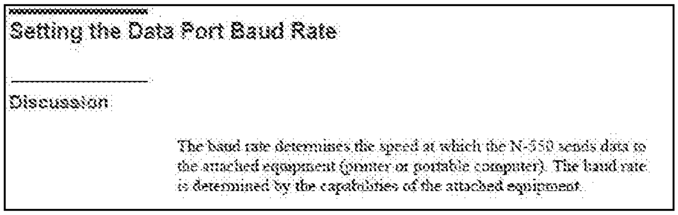
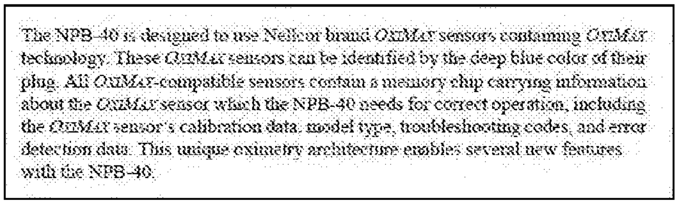
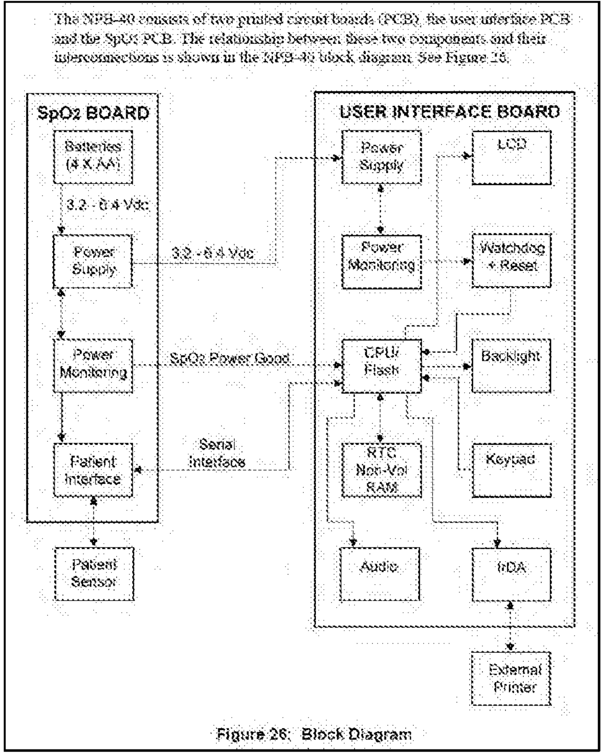
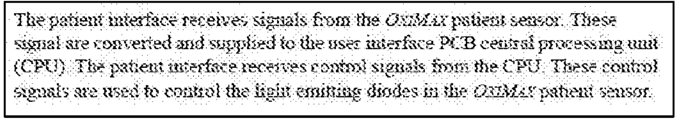
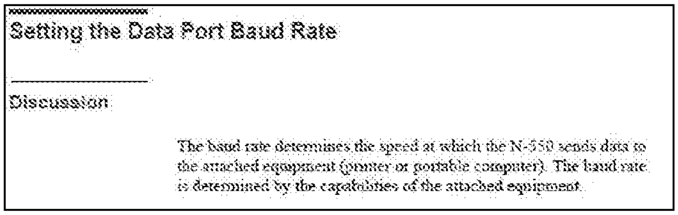
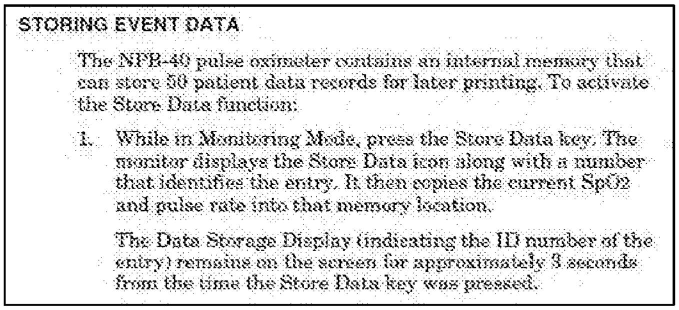
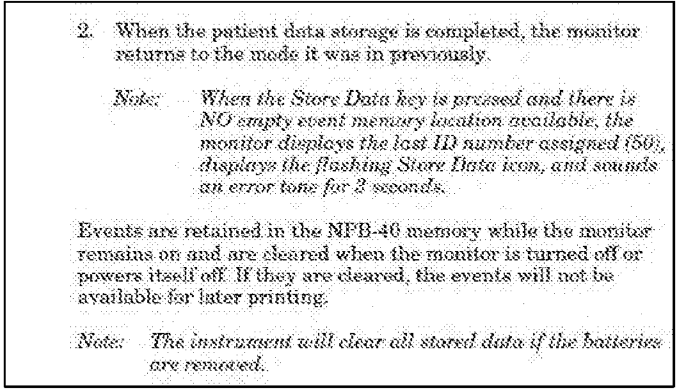
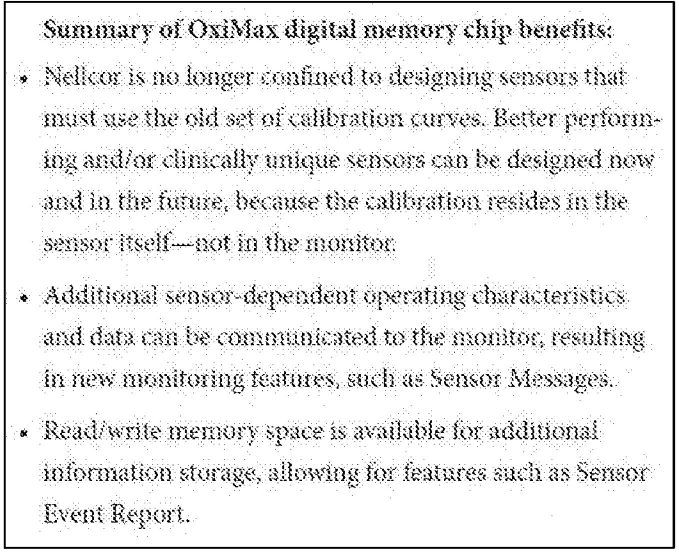
	 The NPB-40 consists of two printed circuit boards (PCB), the user interface PCB and the SpO2 PCB. The relationship between these two components and their interconnections is shown in the NPB-40 block diagram. See Figure 26. Figure 26: Block Diagram (NPB-40 Service Manual, p. 78)

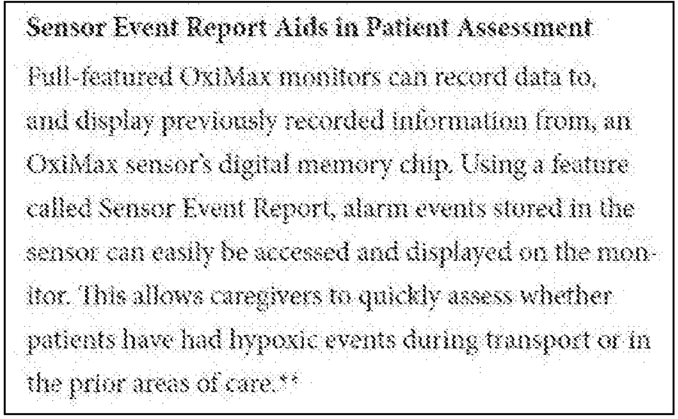
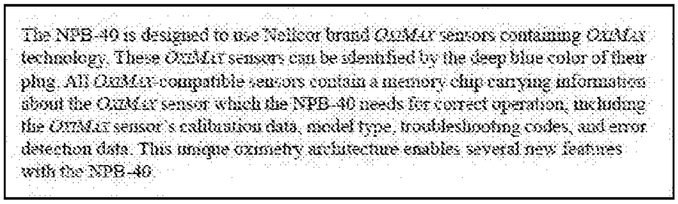
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 The patient interface receives signals from the *OxiMax* patient sensor. These signal are converted and supplied to the user interface PCB central processing unit (CPU). The patient interface receives control signals from the CPU. These control signals are used to control the light emitting diodes in the *OxiMax* patient sensor. (NPB-40 Service Manual, p. 78)  Setting the Data Port Baud Rate Discussion The baud rate determines the speed at which the N-550 sends data to the attached equipment (printer or portable computer). The baud rate is determined by the capabilities of the attached equipment. (N-550 Manual, p. 37)
[5K] a remote device configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data and to store the processed data.	Nellcor discloses and/or renders obvious "a remote device configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data and to store the processed data."  The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)

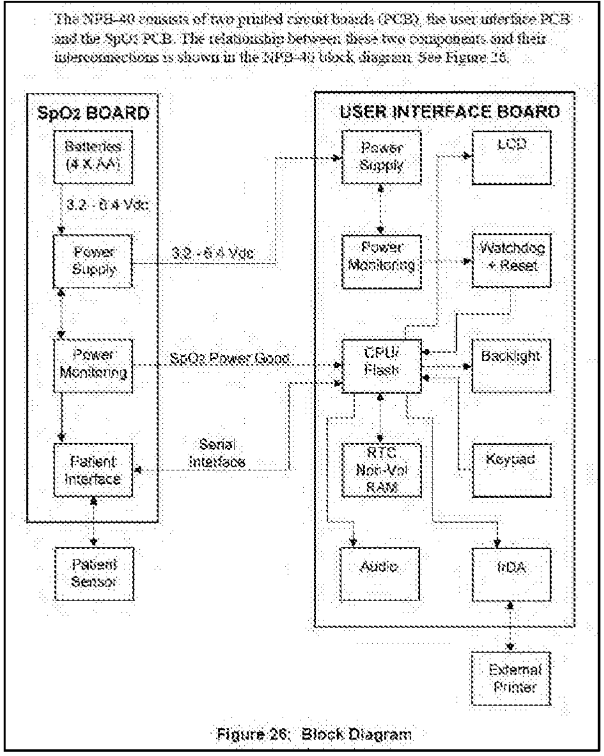
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 The NPB-40 consists of two printed circuit boards (PCB), the user interface PCB and the SpO2 PCB. The relationship between these two components and their interconnections is shown in the NPB-40 block diagram. See Figure 26. Figure 26: Block Diagram (NPB-40 Service Manual, p. 78)

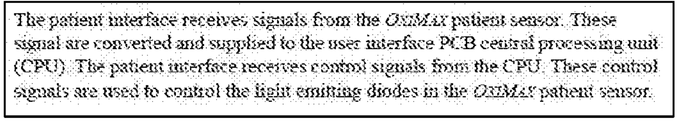
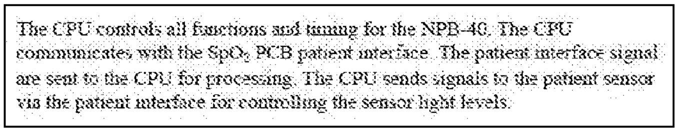
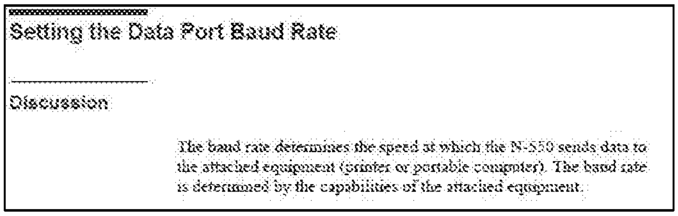
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 The patient interface receives signals from the *OxiMax* patient sensor. These signal are converted and supplied to the user interface PCB central processing unit (CPU). The patient interface receives control signals from the CPU. These control signals are used to control the light emitting diodes in the *OxiMax* patient sensor. (NPB-40 Service Manual, p. 78)  Setting the Data Port Baud Rate Discussion The baud rate determines the speed at which the N-550 sends data to the attached equipment (printer or portable computer). The baud rate is determined by the capabilities of the attached equipment. (N-550 Manual, p. 37)  STORING EVENT DATA The NPB-40 pulse oximeter contains an internal memory that can store 50 patient data records for later printing. To activate the Store Data function: 1. While in Monitoring Mode, press the Store Data key. The monitor displays the Store Data icon along with a number that identifies the entry. It then copies the current SpO2 and pulse rate into that memory location. The Data Storage Display (indicating the ID number of the entry) remains on the screen for approximately 3 seconds from the time the Store Data key was pressed. (NPB-40 Operator's Manual, p. 23)

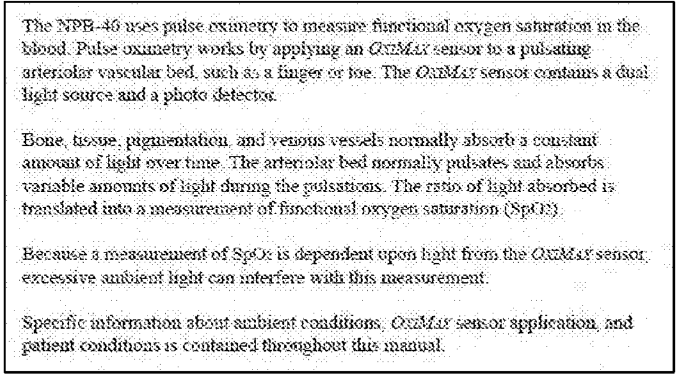
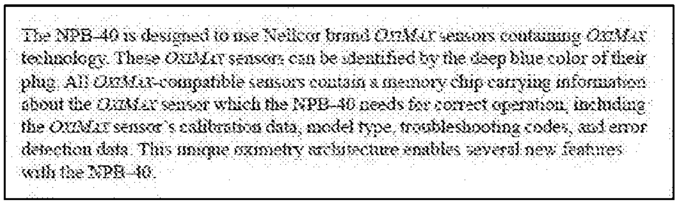
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 2. When the patient data storage is completed, the monitor returns to the mode it was in previously. *Note: When the Store Data key is pressed and there is NO empty event memory location available, the monitor displays the last ID number assigned (50), displays the flashing Store Data icon, and sounds an error tone for 2 seconds.* Events are retained in the NPB-40 memory while the monitor remains on and are cleared when the monitor is turned off or powers itself off. If they are cleared, the events will not be available for later printing. *Note: The instrument will clear all stored data if the batteries are removed.* (NPB-40 Operator's Manual, p. 24)

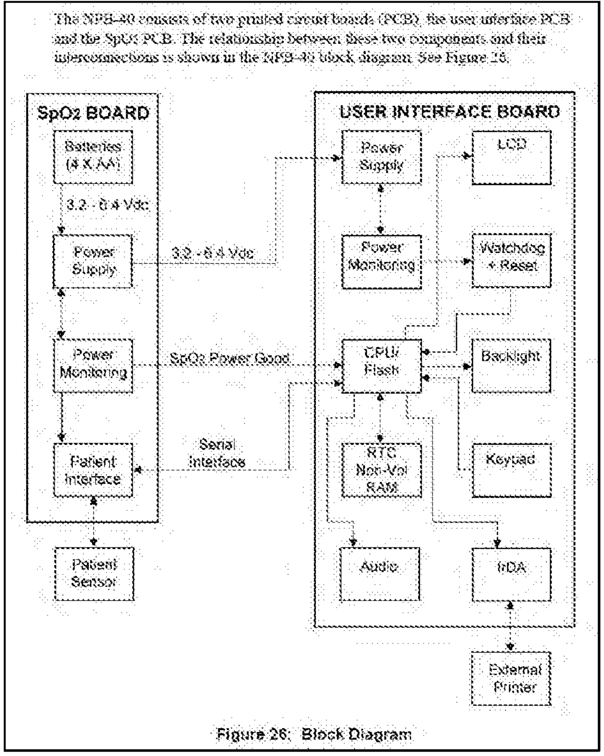
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 **Summary of OxiMax digital memory chip benefits:** • Nellcor is no longer confined to designing sensors that must use the old set of calibration curves. Better performing and/or clinically unique sensors can be designed now and in the future, because the calibration resides in the sensor itself—not in the monitor. • Additional sensor-dependent operating characteristics and data can be communicated to the monitor, resulting in new monitoring features, such as Sensor Messages. • Read/write memory space is available for additional information storage, allowing for features such as Sensor Event Report. (White Paper, p. 5)

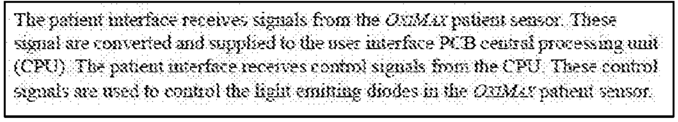
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 **Sensor Event Report Aids in Patient Assessment** Full-featured OxiMax monitors can record data to, and display previously recorded information from, an OxiMax sensor's digital memory chip. Using a feature called Sensor Event Report, alarm events stored in the sensor can easily be accessed and displayed on the monitor. This allows caregivers to quickly assess whether patients have had hypoxic events during transport or in the prior areas of care.** (White Paper, p. 8)
[7] The system of claim 5, wherein the remote device is further configured to transmit at least a portion of the processed data to one or more other locations, wherein the one or more other locations is selected from the group consisting of the personal device, a doctor, a healthcare provider, a cloud-based server and one or more designated recipients, and wherein the remote device is capable of transmitting information related to a time and a position associated with the at	Nellcor discloses and/or renders obvious "[t]he system of claim 5, wherein the remote device is further configured to transmit at least a portion of the processed data to one or more other locations, wherein the one or more other locations is selected from the group consisting of the personal device, a doctor, a healthcare provider, a cloud-based server and one or more designated recipients, and wherein the remote device is capable of transmitting information related to a time and a position associated with the at least a portion of the processed data."  The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
least a portion of the processed data.	 The NPB-40 consists of two printed circuit boards (PCB), the user interface PCB and the SpO2 PCB. The relationship between these two components and their interconnections is shown in the NPB-40 block diagram. See Figure 26. Figure 26: Block Diagram (NPB-40 Service Manual, p. 78)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 The patient interface receives signals from the *OxiMax* patient sensor. These signal are converted and supplied to the user interface PCB central processing unit (CPU). The patient interface receives control signals from the CPU. These control signals are used to control the light emitting diodes in the *OxiMax* patient sensor. (NPB-40 Service Manual, p. 78)  The CPU controls all functions and timing for the NPB-40. The CPU communicates with the SpO_2 PCB patient interface. The patient interface signal are sent to the CPU for processing. The CPU sends signals to the patient sensor via the patient interface for controlling the sensor light levels. (NPB-40 Service Manual, p. 80)  Setting the Data Port Baud Rate Discussion The baud rate determines the speed at which the N-550 sends data to the attached equipment (printer or portable computer). The baud rate is determined by the capabilities of the attached equipment. (N-550 Manual, p. 37)
[8] The system of claim 5, wherein the receiver is located a first distance from a first one of the plurality of light emitting diodes and a different, second distance from a second one of the plurality of light emitting diodes such that the receiver receives a first signal from the first light emitting diode and a second	Nellcor discloses and/or renders obvious "[t]he system of claim 5, wherein the receiver is located a first distance from a first one of the plurality of light emitting diodes and a different, second distance from a second one of the plurality of light emitting diodes such that the receiver receives a first signal from the first light emitting diode and a second signal from the second light emitting diode."

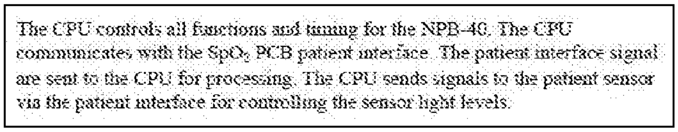
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
signal from the second light emitting diode.	 The NPB-40 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying an *OxiMax* sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The *OxiMax* sensor contains a dual light source and a photo detector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO_2). Because a measurement of SpO_2 is dependent upon light from the *OxiMax* sensor, excessive ambient light can interfere with this measurement. Specific information about ambient conditions, *OxiMax* sensor application, and patient conditions is contained throughout this manual. (NPB-40 Service Manual, p. 75)  The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 The NPB-40 consists of two printed circuit boards (PCB), the user interface PCB and the SpO2 PCB. The relationship between these two components and their interconnections is shown in the NPB-40 block diagram. See Figure 26. Figure 26: Block Diagram (NPB-40 Service Manual, p. 78)

<table>
<tr><th>Asserted Claim of '533 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>


The patient interface receives signals from the *OxiMax* patient sensor. These signal are converted and supplied to the user interface PCB central processing unit (CPU). The patient interface receives control signals from the CPU. These control signals are used to control the light emitting diodes in the *OxiMax* patient sensor.

(NPB-40 Service Manual, p. 78)



The CPU controls all functions and timing for the NPB-40. The CPU communicates with the SpO_2 PCB patient interface. The patient interface signal are sent to the CPU for processing. The CPU sends signals to the patient sensor via the patient interface for controlling the sensor light levels.

(NPB-40 Service Manual, p. 80)

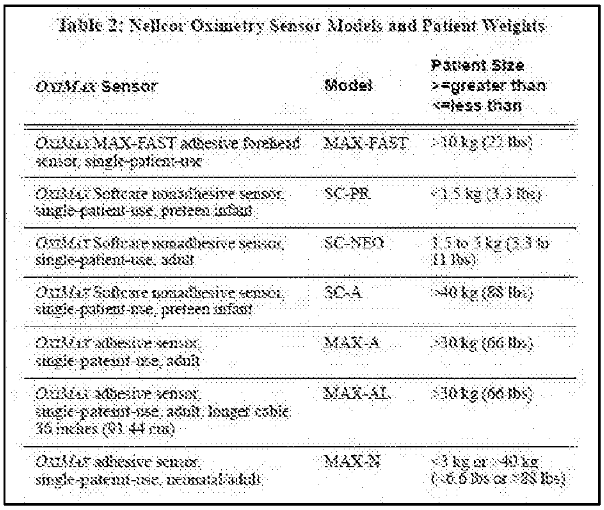


Table 2: Nellcor Oximetry Sensor Models and Patient Weights

<table>
<tr><th><i>OxiMax</i> Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td><i>OxiMax</i> MAX-FAST adhesive forehead sensor, single-patient-use</td><td>MAX-FAST</td><td>>10 kg (22 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-PR</td><td><1.5 kg (3.3 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, adult</td><td>SC-NEO</td><td>1.5 to 5 kg (3.3 to 11 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult</td><td>MAX-A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult, longer cable 36 inches (91.44 cm)</td><td>MAX-AL</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, neonatal/adult</td><td>MAX-N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
</table>

(N-550 Manual, p. 66)
</td></tr>
</table>

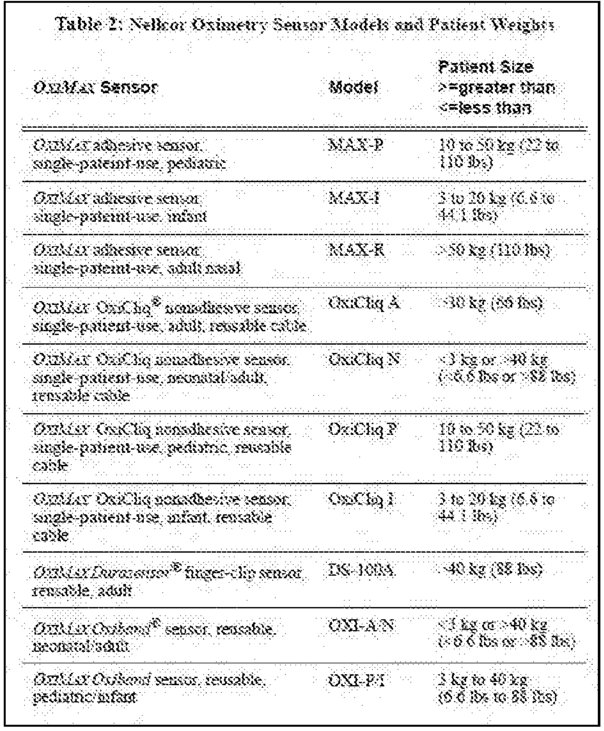
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 (N-550 Manual, p. 67)

Table 2: Nellcor Oximetry Sensor Models and Patient Weights

OxiMax Sensor	Model	Patient Size >=greater than <=less than
OxiMax adhesive sensor, single-pateint-use, pediatric	MAX-P	10 to 50 kg (22 to 110 lbs)
OxiMax adhesive sensor, single-pateint-use, infant	MAX-I	3 to 20 kg (6.6 to 44.1 lbs)
OxiMax adhesive sensor, single-pateint-use, adult nasal	MAX-R	>50 kg (110 lbs)
OxiMax OxiCliq® nonadhesive sensor, single-patient-use, adult, reusable cable	OxiCliq A	>30 kg (66 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, neonatal/adult, reusable cable	OxiCliq N	<3 kg or >40 kg (<6.6 lbs or >88 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, pediatric, reusable cable	OxiCliq P	10 to 50 kg (22 to 110 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, infant, reusable cable	OxiCliq I	3 to 20 kg (6.6 to 44.1 lbs)
OxiMax Durasensor® finger-clip sensor, reusable, adult	DS-100A	>40 kg (88 lbs)
OxiMax Oxiband® sensor, reusable, neonatal/adult	OXI-A/N	<3 kg or >40 kg (<6.6 lbs or >88 lbs)
OxiMax Oxiband sensor, reusable, pediatric/infant	OXI-P/I	3 kg to 40 kg (6.6 lbs to 88 lbs)

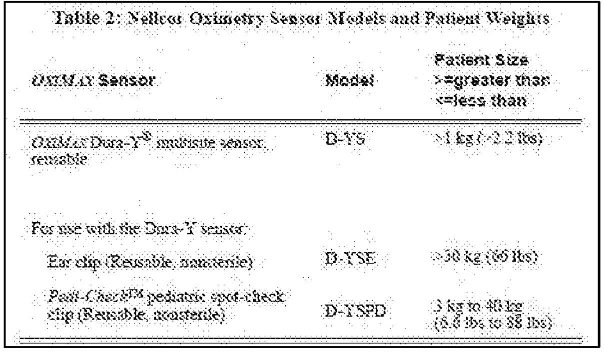
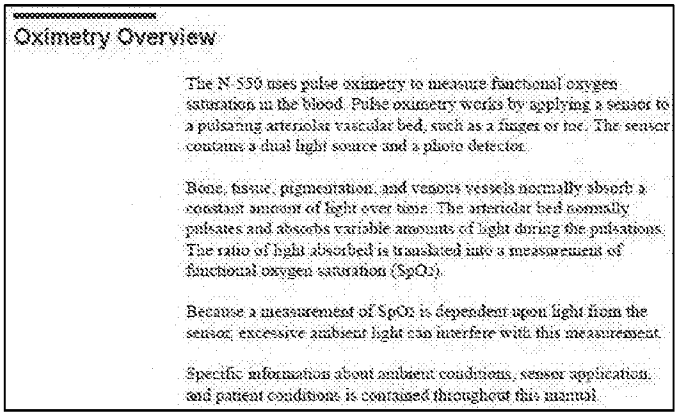
<table>
<tr><th>Asserted Claim of ’533 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>


Table 2: Nellcor Oximetry Sensor Models and Patient Weights

<table>
<tr><th>OXIMAX Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td>OXIMAX Dura-Y® multisite sensor, reusable</td><td>D-YS</td><td>>1 kg (>2.2 lbs)</td></tr>
<tr><td>For use with the Dura-Y sensor:</td><td></td><td></td></tr>
<tr><td>Ear clip (Reusable, nonsterile)</td><td>D-YSE</td><td>>30 kg (66 lbs)</td></tr>
<tr><td>Pedi-Check™ pediatric spot-check clip (Reusable, nonsterile)</td><td>D-YSPD</td><td>3 kg to 40 kg
(6.6 lbs to 88 lbs)</td></tr>
</table>

(N-550 Manual, p. 68)



Oximetry Overview

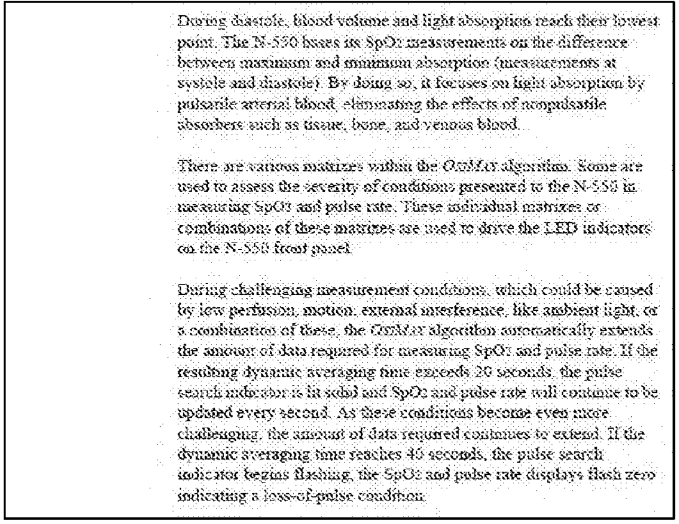
The N-550 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photo detector.

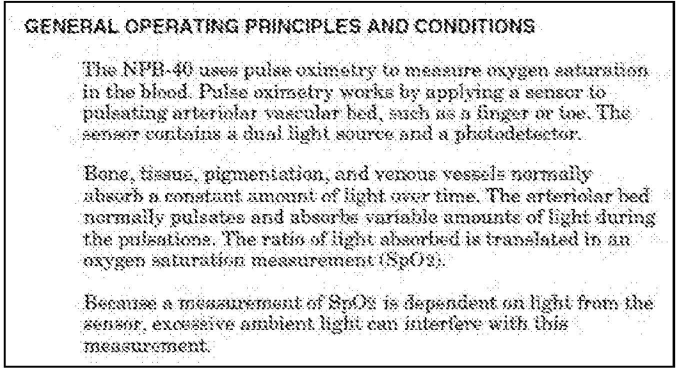
Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO2).

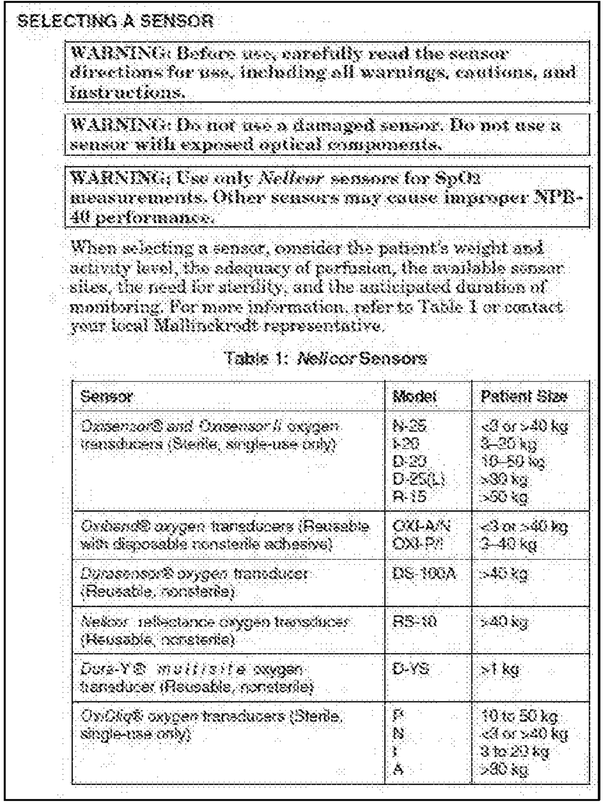
Because a measurement of SpO2 is dependent upon light from the sensor, excessive ambient light can interfere with this measurement.

Specific information about ambient conditions, sensor application, and patient conditions is contained throughout this manual.

(N-550 Manual, p. 93)
</td></tr>
</table>

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 During diastole, blood volume and light absorption reach their lowest point. The N-550 bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. There are various matrixes within the *OxiMax* algorithm. Some are used to assess the severity of conditions presented to the N-550 in measuring SpO3 and pulse rate. These individual matrixes or combinations of these matrixes are used to drive the LED indicators on the N-550 front panel. During challenging measurement conditions, which could be caused by low perfusion, motion, external interference, like ambient light, or a combination of these, the *OxiMax* algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate. If the resulting dynamic averaging time exceeds 20 seconds, the pulse search indicator is lit solid and SpO_2 and pulse rate will continue to be updated every second. As these conditions become even more challenging, the amount of data required continues to extend. If the dynamic averaging time reaches 40 seconds, the pulse search indicator begins flashing, the SpO_2 and pulse rate displays flash zero indicating a loss-of-pulse condition. (N-550 Manual, p. 94)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 GENERAL OPERATING PRINCIPLES AND CONDITIONS The NPB-40 uses pulse oximetry to measure oxygen saturation in the blood. Pulse oximetry works by applying a sensor to pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photodetector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated in an oxygen saturation measurement (SpO2). Because a measurement of SpO2 is dependent on light from the sensor, excessive ambient light can interfere with this measurement. (NPB-40 Operator's Manual, p. 3-4)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 (NPB-40 Operator's Manual, p. 15)

SELECTING A SENSOR

WARNING: Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

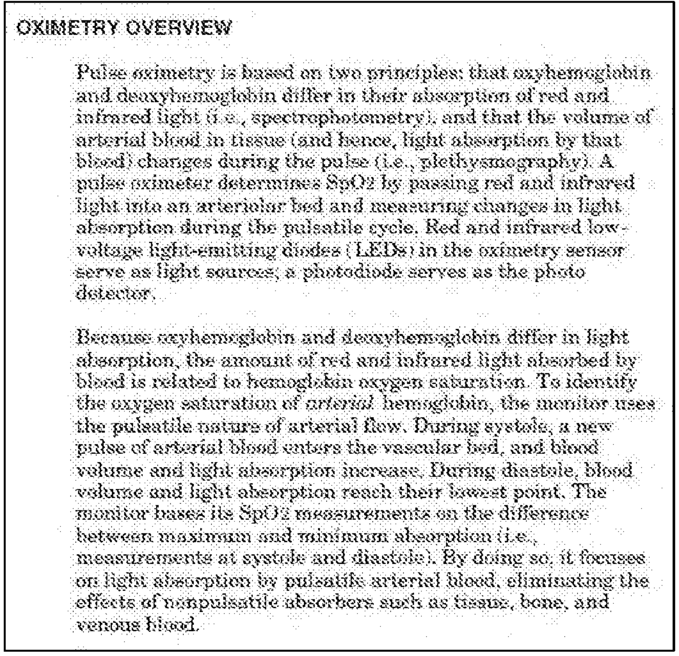
WARNING: Do not use a damaged sensor. Do not use a sensor with exposed optical components.

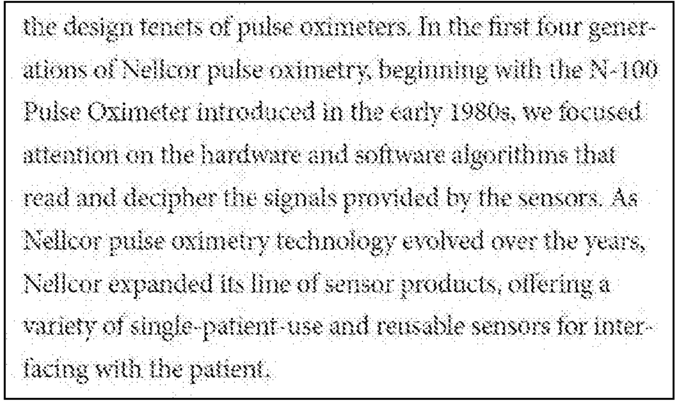
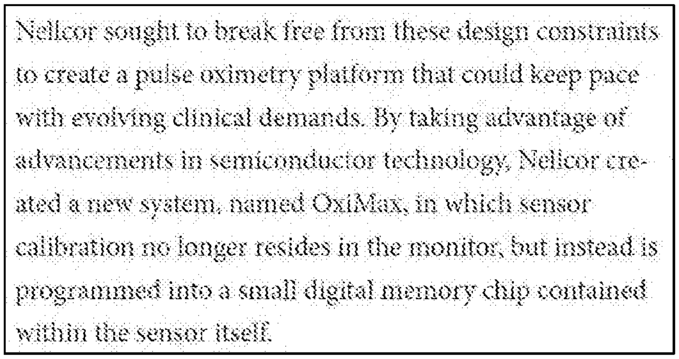
WARNING: Use only *Nellcor* sensors for SpO2 measurements. Other sensors may cause improper NPB-40 performance.

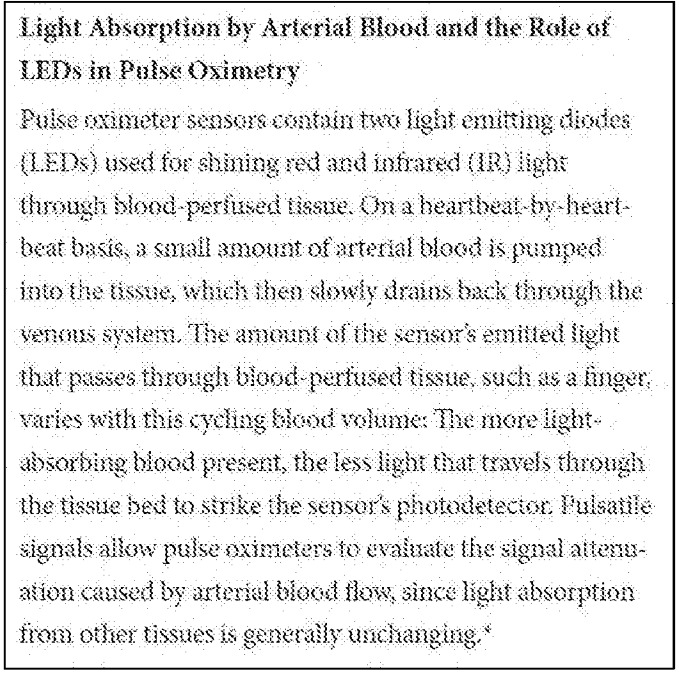
When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Mallinckrodt representative.

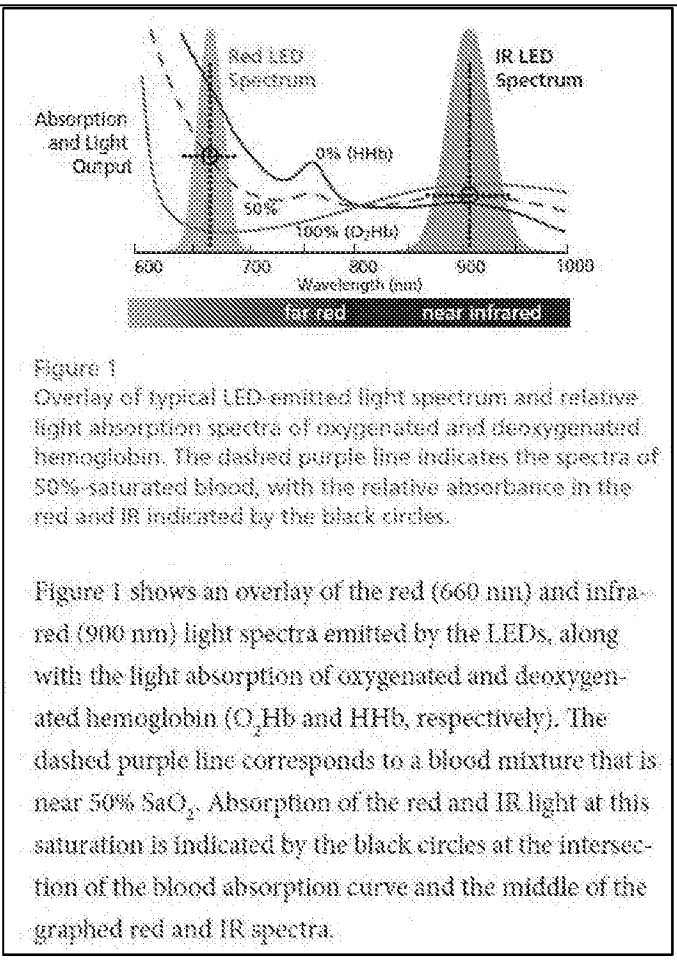
Table 1: *Nellcor* Sensors

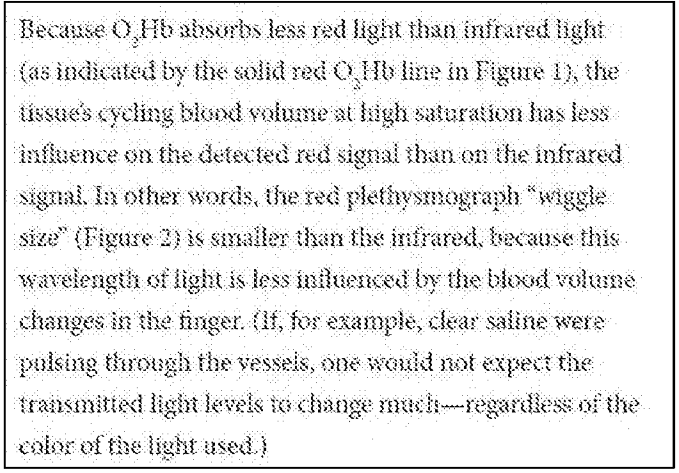
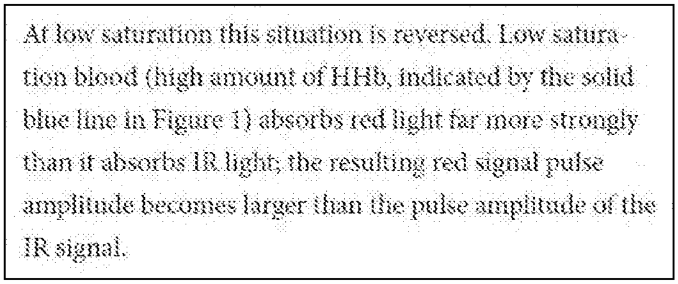
Sensor	Model	Patient Size
Oxisensor® and *Oxisensor II* oxygen transducers (Sterile, single-use only)	N-25 I-20 D-20 D-25(L) R-15	<3 or >40 kg 3–20 kg 10–50 kg >30 kg >50 kg
Oxiband® oxygen transducers (Reusable with disposable nonsterile adhesive)	OXI-A/N OXI-P/I	<3 or >40 kg 3–40 kg
Durasensor® oxygen transducer (Reusable, nonsterile)	DS-100A	>40 kg
Nellcor reflectance oxygen transducer (Reusable, nonsterile)	RS-10	>40 kg
Dura-Y® *multisite* oxygen transducer (Reusable, nonsterile)	D-YS	>1 kg
OxiCliq® oxygen transducers (Sterile, single-use only)	P N I A	10 to 50 kg <3 or >40 kg 3 to 20 kg >30 kg

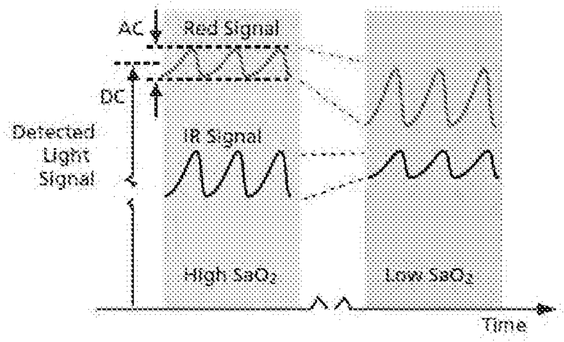
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 OXIMETRY OVERVIEW Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e., spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e., plethysmography). A pulse oximeter determines SpO2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LEDs) in the oximetry sensor serve as light sources; a photodiode serves as the photo detector. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of *arterial* hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitor bases its SpO2 measurements on the difference between maximum and minimum absorption (i.e., measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. (NPB-40 Operator's Manual, p. 41)

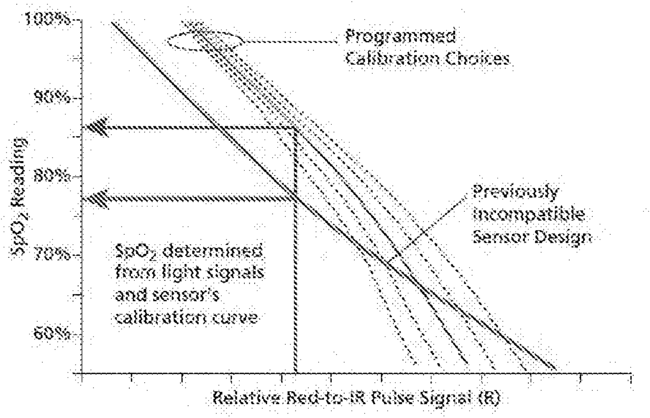
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 the design tenets of pulse oximeters. In the first four generations of Nellcor pulse oximetry, beginning with the N-100 Pulse Oximeter introduced in the early 1980s, we focused attention on the hardware and software algorithms that read and decipher the signals provided by the sensors. As Nellcor pulse oximetry technology evolved over the years, Nellcor expanded its line of sensor products, offering a variety of single-patient-use and reusable sensors for interfacing with the patient. **(White Paper, p. 1)**  Nellcor sought to break free from these design constraints to create a pulse oximetry platform that could keep pace with evolving clinical demands. By taking advantage of advancements in semiconductor technology, Nellcor created a new system, named OxiMax, in which sensor calibration no longer resides in the monitor, but instead is programmed into a small digital memory chip contained within the sensor itself. **(White Paper, p. 1)**

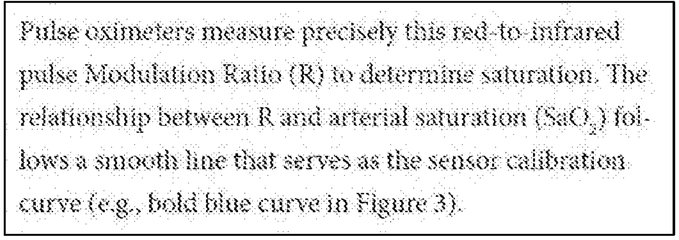
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 **Light Absorption by Arterial Blood and the Role of LEDs in Pulse Oximetry** Pulse oximeter sensors contain two light emitting diodes (LEDs) used for shining red and infrared (IR) light through blood-perfused tissue. On a heartbeat-by-heartbeat basis, a small amount of arterial blood is pumped into the tissue, which then slowly drains back through the venous system. The amount of the sensor's emitted light that passes through blood-perfused tissue, such as a finger, varies with this cycling blood volume: The more light-absorbing blood present, the less light that travels through the tissue bed to strike the sensor's photodetector. Pulsatile signals allow pulse oximeters to evaluate the signal attenuation caused by arterial blood flow, since light absorption from other tissues is generally unchanging.* (White Paper, p. 1)

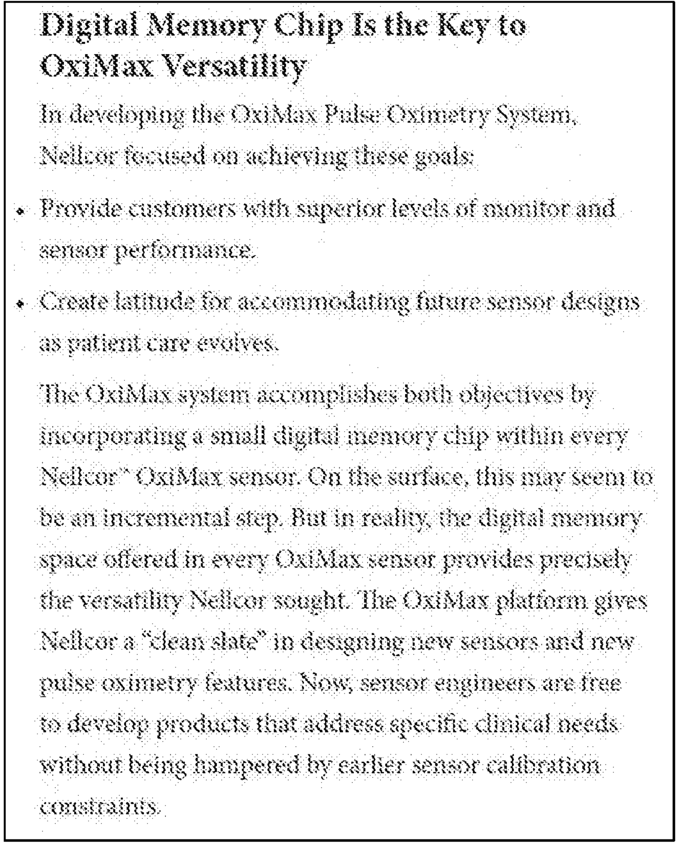
	 Figure 1 Overlay of typical LED-emitted light spectrum and relative light absorption spectra of oxygenated and deoxygenated hemoglobin. The dashed purple line indicates the spectra of 50%-saturated blood, with the relative absorbance in the red and IR indicated by the black circles. Figure 1 shows an overlay of the red (660 nm) and infrared (900 nm) light spectra emitted by the LEDs, along with the light absorption of oxygenated and deoxygenated hemoglobin (O_2Hb and HHb, respectively). The dashed purple line corresponds to a blood mixture that is near 50% SaO_2. Absorption of the red and IR light at this saturation is indicated by the black circles at the intersection of the blood absorption curve and the middle of the graphed red and IR spectra. (White Paper, p. 2)

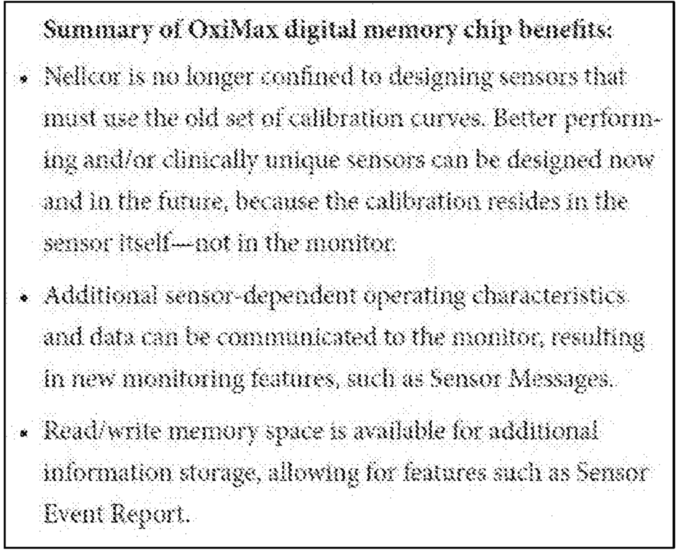
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Because O_2Hb absorbs less red light than infrared light (as indicated by the solid red O_2Hb line in Figure 1), the tissue's cycling blood volume at high saturation has less influence on the detected red signal than on the infrared signal. In other words, the red plethysmograph "wiggle size" (Figure 2) is smaller than the infrared, because this wavelength of light is less influenced by the blood volume changes in the finger. (If, for example, clear saline were pulsing through the vessels, one would not expect the transmitted light levels to change much—regardless of the color of the light used.) (White Paper, p. 2)  At low saturation this situation is reversed. Low saturation blood (high amount of HHb, indicated by the solid blue line in Figure 1) absorbs red light far more strongly than it absorbs IR light; the resulting red signal pulse amplitude becomes larger than the pulse amplitude of the IR signal. (White Paper, p. 2)

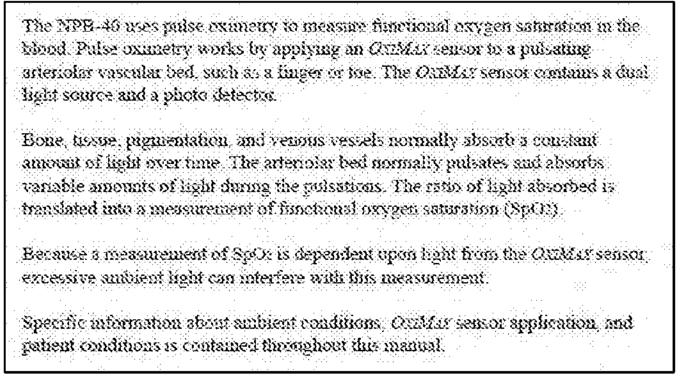
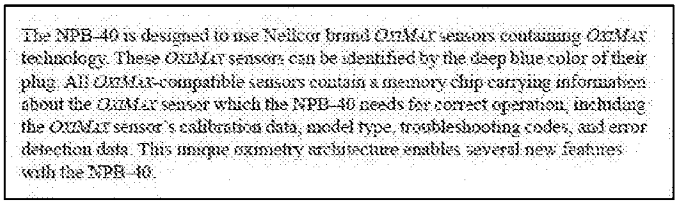
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Figure 2 Red and IR light signals at high and low arterial oxygen saturation. At high saturation, the red "pulse amplitude" (AC/DC) is smaller than in the IR. At low saturation, the ratio of relative amplitudes is reversed. (White Paper, p. 2)

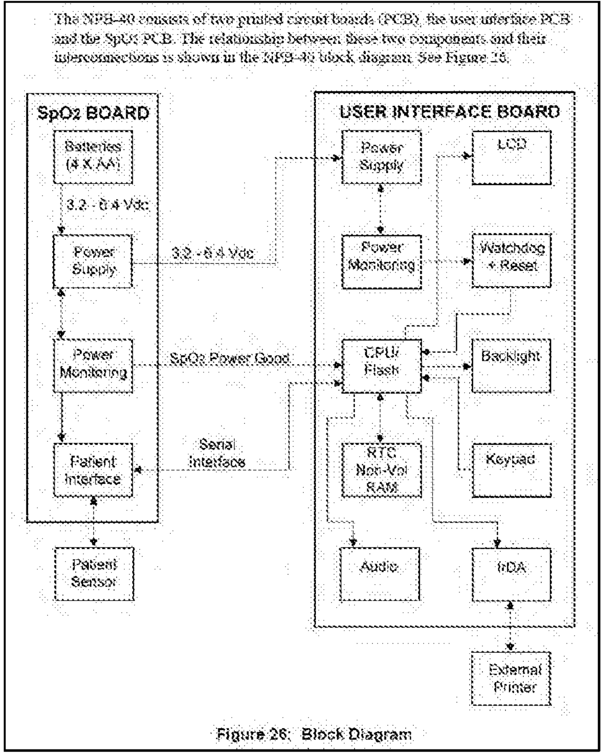
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Figure 3 The blue lines depict the one or more calibration curves programmed into earlier-generation monitors, while the red line indicates a calibration required of a hypothetical new sensor. Such a design would be incompatible with these earlier monitors, since none of the blue curves could provide accurate SpO_2 values for the sensor's signals. (White Paper, p. 2)

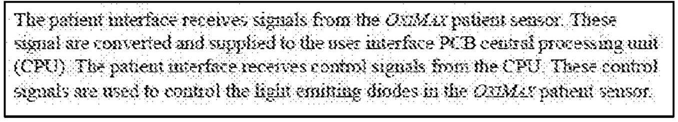
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Pulse oximeters measure precisely this red-to-infrared pulse Modulation Ratio (R) to determine saturation. The relationship between R and arterial saturation (SaO_2) follows a smooth line that serves as the sensor calibration curve (e.g., bold blue curve in Figure 3). (White Paper, p. 2)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 **Digital Memory Chip Is the Key to OxiMax Versatility** In developing the OxiMax Pulse Oximetry System, Nellcor focused on achieving these goals: • Provide customers with superior levels of monitor and sensor performance. • Create latitude for accommodating future sensor designs as patient care evolves. The OxiMax system accomplishes both objectives by incorporating a small digital memory chip within every Nellcor™ OxiMax sensor. On the surface, this may seem to be an incremental step. But in reality, the digital memory space offered in every OxiMax sensor provides precisely the versatility Nellcor sought. The OxiMax platform gives Nellcor a "clean slate" in designing new sensors and new pulse oximetry features. Now, sensor engineers are free to develop products that address specific clinical needs without being hampered by earlier sensor calibration constraints. (White Paper, p. 4)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 **Summary of OxiMax digital memory chip benefits:** • Nellcor is no longer confined to designing sensors that must use the old set of calibration curves. Better performing and/or clinically unique sensors can be designed now and in the future, because the calibration resides in the sensor itself—not in the monitor. • Additional sensor-dependent operating characteristics and data can be communicated to the monitor, resulting in new monitoring features, such as Sensor Messages. • Read/write memory space is available for additional information storage, allowing for features such as Sensor Event Report. (White Paper, p. 5)
[9] The system of claim 8, wherein the output signal is generated in part by comparing the first and second signals	Nellcor discloses and/or renders obvious "[t]he system of claim 5, wherein the output signal is generated in part by comparing the first and second signals."

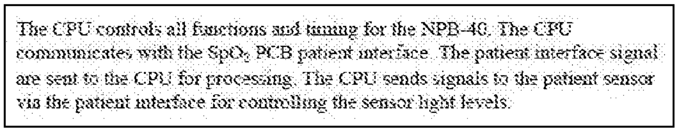
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 The NPB-40 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying an *OxiMax* sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The *OxiMax* sensor contains a dual light source and a photo detector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO_2). Because a measurement of SpO_2 is dependent upon light from the *OxiMax* sensor, excessive ambient light can interfere with this measurement. Specific information about ambient conditions, *OxiMax* sensor application, and patient conditions is contained throughout this manual. (NPB-40 Service Manual, p. 75)  The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 The NPB-40 consists of two printed circuit boards (PCB), the user interface PCB and the SpO2 PCB. The relationship between these two components and their interconnections is shown in the NPB-40 block diagram. See Figure 26. Figure 26: Block Diagram (NPB-40 Service Manual, p. 78)

<table>
<tr><th>Asserted Claim of ’533 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>


The patient interface receives signals from the *OxiMax* patient sensor. These signal are converted and supplied to the user interface PCB central processing unit (CPU). The patient interface receives control signals from the CPU. These control signals are used to control the light emitting diodes in the *OxiMax* patient sensor.

(NPB-40 Service Manual, p. 78)



The CPU controls all functions and timing for the NPB-40. The CPU communicates with the SpO_2 PCB patient interface. The patient interface signal are sent to the CPU for processing. The CPU sends signals to the patient sensor via the patient interface for controlling the sensor light levels.

(NPB-40 Service Manual, p. 80)

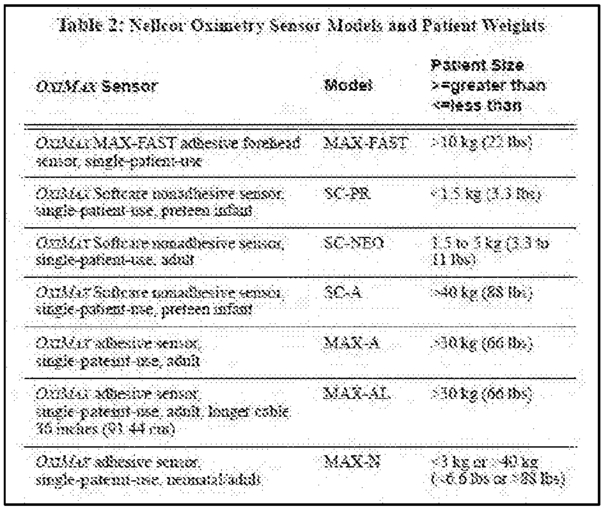


Table 2: Nellcor Oximetry Sensor Models and Patient Weights

<table>
<tr><th><i>OxiMax</i> Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td><i>OxiMax</i> MAX-FAST adhesive forehead sensor, single-patient-use</td><td>MAX-FAST</td><td>>10 kg (22 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-PR</td><td><1.5 kg (3.3 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, adult</td><td>SC-NEO</td><td>1.5 to 5 kg (3.3 to 11 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult</td><td>MAX-A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult, longer cable 36 inches (91.44 cm)</td><td>MAX-AL</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, neonatal/adult</td><td>MAX-N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
</table>

(N-550 Manual, p. 66)
</td></tr>
</table>

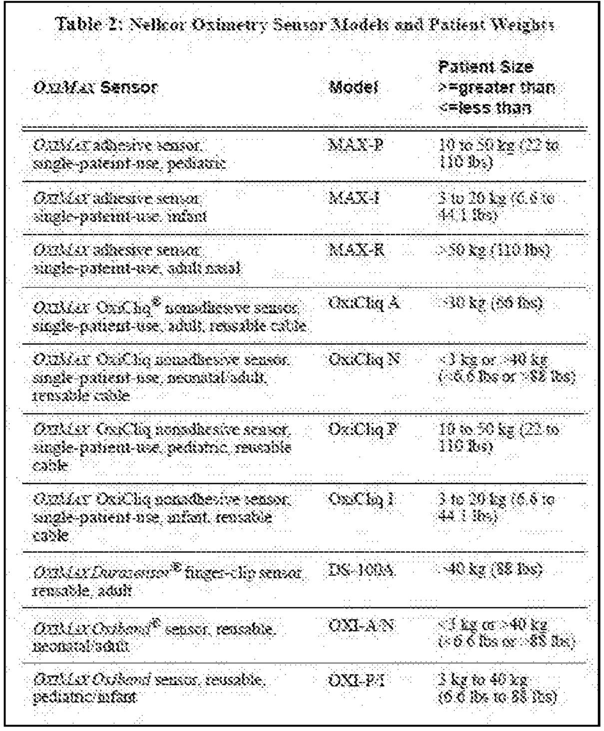
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 (N-550 Manual, p. 67)

Table 2: Nellcor Oximetry Sensor Models and Patient Weights

OxiMax Sensor	Model	Patient Size >=greater than <=less than
OxiMax adhesive sensor, single-pateint-use, pediatric	MAX-P	10 to 50 kg (22 to 110 lbs)
OxiMax adhesive sensor, single-pateint-use, infant	MAX-I	3 to 20 kg (6.6 to 44.1 lbs)
OxiMax adhesive sensor, single-pateint-use, adult nasal	MAX-R	>50 kg (110 lbs)
OxiMax OxiCliq® nonadhesive sensor, single-patient-use, adult, reusable cable	OxiCliq A	>30 kg (66 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, neonatal/adult, reusable cable	OxiCliq N	<3 kg or >40 kg (<6.6 lbs or >88 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, pediatric, reusable cable	OxiCliq P	10 to 50 kg (22 to 110 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, infant, reusable cable	OxiCliq I	3 to 20 kg (6.6 to 44.1 lbs)
OxiMax Durasensor® finger-clip sensor, reusable, adult	DS-100A	>40 kg (88 lbs)
OxiMax Oxiband® sensor, reusable, neonatal/adult	OXI-A/N	<3 kg or >40 kg (<6.6 lbs or >88 lbs)
OxiMax Oxiband sensor, reusable, pediatric/infant	OXI-P/I	3 kg to 40 kg (6.6 lbs to 88 lbs)

<table>
<tr><th>Asserted Claim of '533 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>

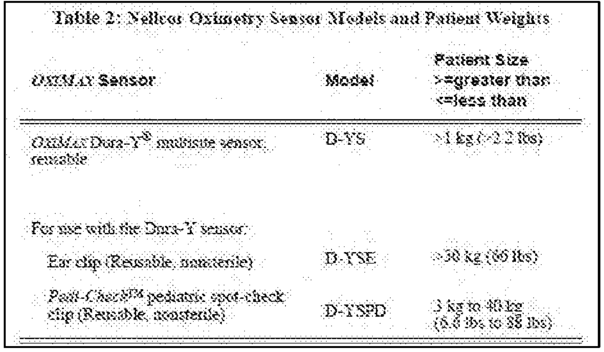
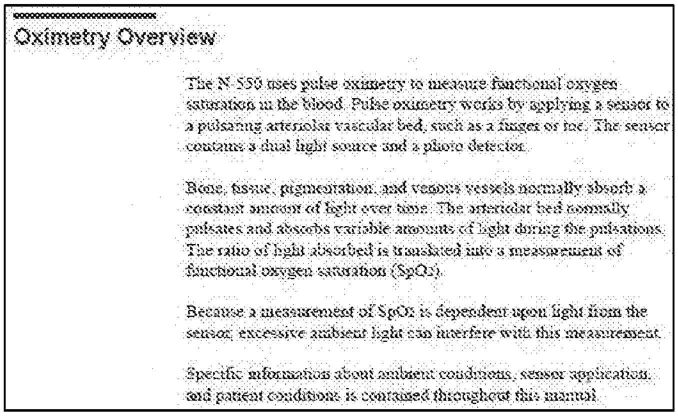



Table 2: Nellcor Oximetry Sensor Models and Patient Weights
<table>
<tr><th><i>OXIMAX</i> Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td><i>OXIMAX</i> Dura-Y® multisite sensor, reusable</td><td>D-YS</td><td>>1 kg (>2.2 lbs)</td></tr>
<tr><td>For use with the Dura-Y sensor:</td><td></td><td></td></tr>
<tr><td>Ear clip (Reusable, nonsterile)</td><td>D-YSE</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>Pedi-Check</i>™ pediatric spot-check clip (Reusable, nonsterile)</td><td>D-YSPD</td><td>3 kg to 40 kg
(6.6 lbs to 88 lbs)</td></tr>
</table>
(N-550 Manual, p. 68)

Oximetry Overview

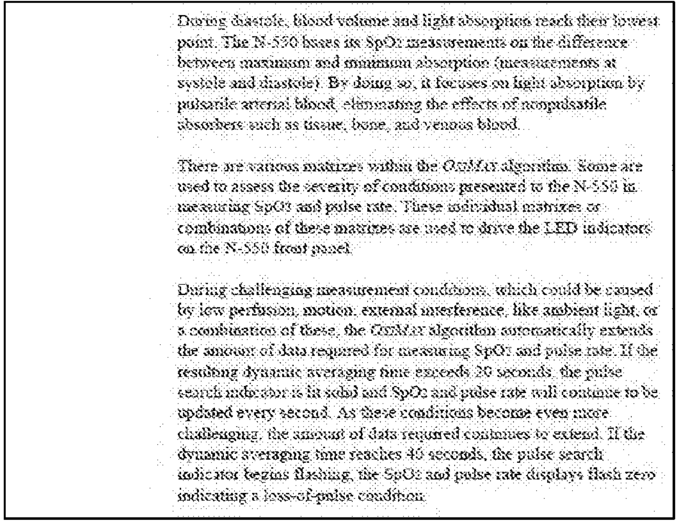
The N-550 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photo detector.

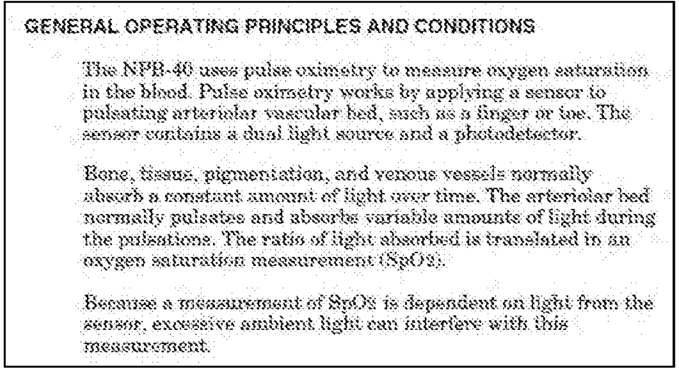
Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO2).

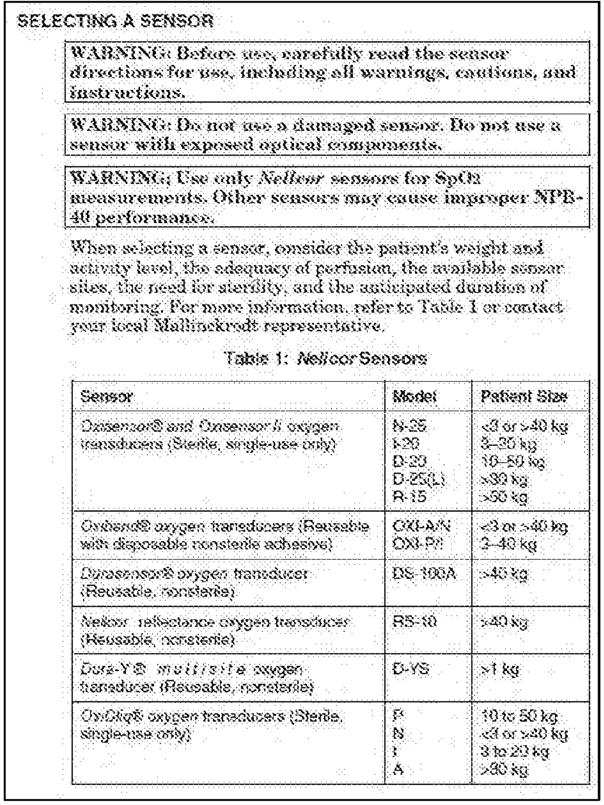
Because a measurement of SpO2 is dependent upon light from the sensor, excessive ambient light can interfere with this measurement.

Specific information about ambient conditions, sensor application, and patient conditions is contained throughout this manual.

(N-550 Manual, p. 93)
</td></tr>
</table>

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 During diastole, blood volume and light absorption reach their lowest point. The N-550 bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. There are various matrixes within the *OxiMax* algorithm. Some are used to assess the severity of conditions presented to the N-550 in measuring SpO_2 and pulse rate. These individual matrixes or combinations of these matrixes are used to drive the LED indicators on the N-550 front panel. During challenging measurement conditions, which could be caused by low perfusion, motion, external interference, like ambient light, or a combination of these, the *OxiMax* algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate. If the resulting dynamic averaging time exceeds 20 seconds, the pulse search indicator is lit solid and SpO_2 and pulse rate will continue to be updated every second. As these conditions become even more challenging, the amount of data required continues to extend. If the dynamic averaging time reaches 40 seconds, the pulse search indicator begins flashing, the SpO_2 and pulse rate displays flash zero indicating a loss-of-pulse condition. (N-550 Manual, p. 94)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 GENERAL OPERATING PRINCIPLES AND CONDITIONS The NPB-40 uses pulse oximetry to measure oxygen saturation in the blood. Pulse oximetry works by applying a sensor to pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photodetector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated in an oxygen saturation measurement (SpO2). Because a measurement of SpO2 is dependent on light from the sensor, excessive ambient light can interfere with this measurement. (NPB-40 Operator's Manual, p. 3-4)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 (NPB-40 Operator's Manual, p. 15)

SELECTING A SENSOR

WARNING: Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

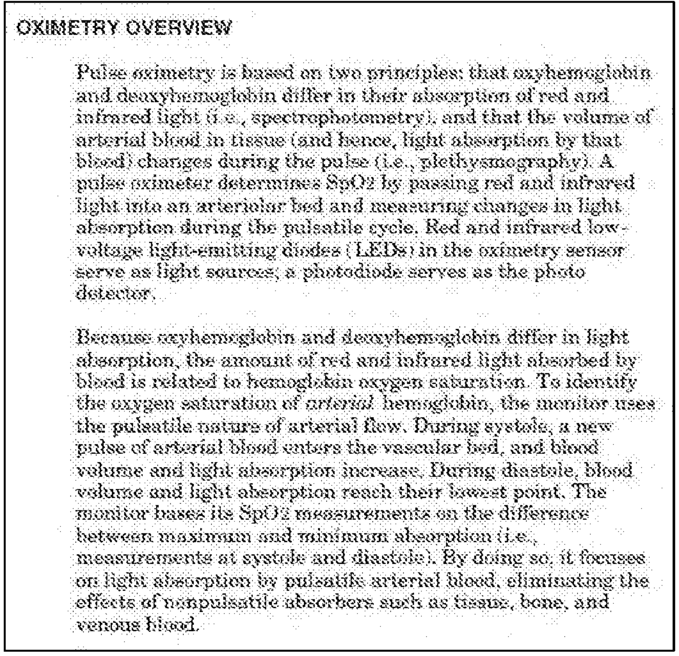
WARNING: Do not use a damaged sensor. Do not use a sensor with exposed optical components.

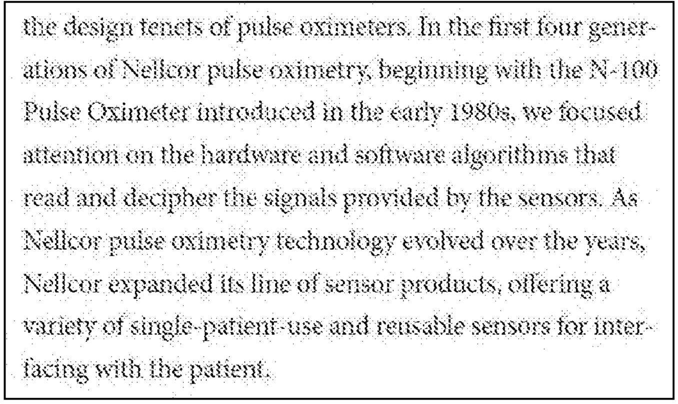
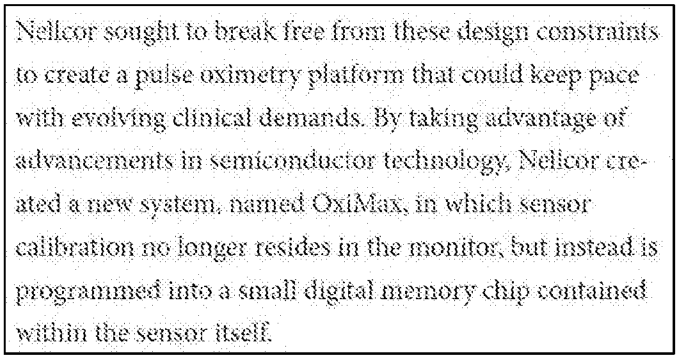
WARNING: Use only *Nellcor* sensors for SpO2 measurements. Other sensors may cause improper NPB-40 performance.

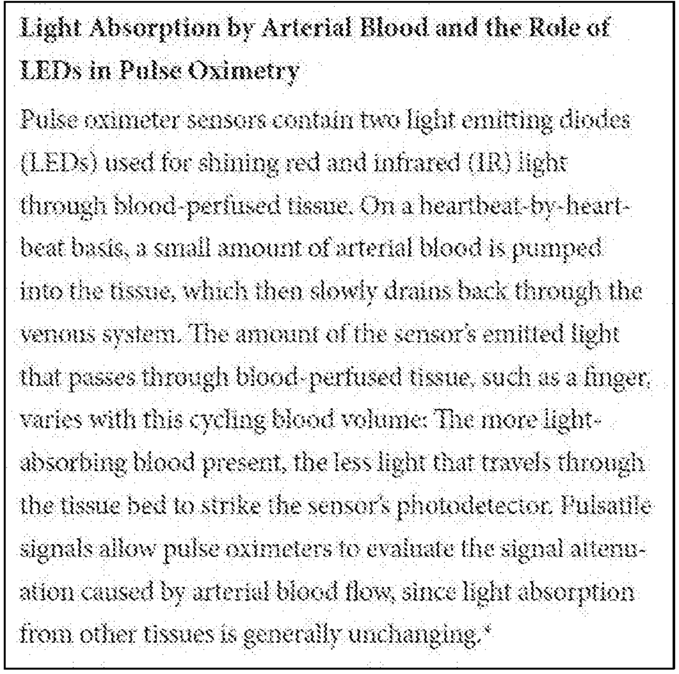
When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Mallinckrodt representative.

Table 1: *Nellcor* Sensors

Sensor	Model	Patient Size
Oxisensor® and *Oxisensor II* oxygen transducers (Sterile, single-use only)	N-25 I-20 D-20 D-25(L) R-15	<3 or >40 kg 3–20 kg 10–50 kg >30 kg >50 kg
Oxiband® oxygen transducers (Reusable with disposable nonsterile adhesive)	OXI-A/N OXI-P/I	<3 or >40 kg 3–40 kg
Durasensor® oxygen transducer (Reusable, nonsterile)	DS-100A	>40 kg
Nellcor reflectance oxygen transducer (Reusable, nonsterile)	RS-10	>40 kg
Dura-Y® *multisite* oxygen transducer (Reusable, nonsterile)	D-YS	>1 kg
OxiCliq® oxygen transducers (Sterile, single-use only)	P N I A	10 to 50 kg <3 or >40 kg 3 to 20 kg >30 kg

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 OXIMETRY OVERVIEW Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e., spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e., plethysmography). A pulse oximeter determines SpO2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LEDs) in the oximetry sensor serve as light sources; a photodiode serves as the photo detector. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of *arterial* hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitor bases its SpO2 measurements on the difference between maximum and minimum absorption (i.e., measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. (NPB-40 Operator's Manual, p. 41)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 the design tenets of pulse oximeters. In the first four generations of Nellcor pulse oximetry, beginning with the N-100 Pulse Oximeter introduced in the early 1980s, we focused attention on the hardware and software algorithms that read and decipher the signals provided by the sensors. As Nellcor pulse oximetry technology evolved over the years, Nellcor expanded its line of sensor products, offering a variety of single-patient-use and reusable sensors for interfacing with the patient. (White Paper, p. 1)  Nellcor sought to break free from these design constraints to create a pulse oximetry platform that could keep pace with evolving clinical demands. By taking advantage of advancements in semiconductor technology, Nellcor created a new system, named OxiMax, in which sensor calibration no longer resides in the monitor, but instead is programmed into a small digital memory chip contained within the sensor itself. (White Paper, p. 1)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 **Light Absorption by Arterial Blood and the Role of LEDs in Pulse Oximetry** Pulse oximeter sensors contain two light emitting diodes (LEDs) used for shining red and infrared (IR) light through blood-perfused tissue. On a heartbeat-by-heartbeat basis, a small amount of arterial blood is pumped into the tissue, which then slowly drains back through the venous system. The amount of the sensor's emitted light that passes through blood-perfused tissue, such as a finger, varies with this cycling blood volume: The more light-absorbing blood present, the less light that travels through the tissue bed to strike the sensor's photodetector. Pulsatile signals allow pulse oximeters to evaluate the signal attenuation caused by arterial blood flow, since light absorption from other tissues is generally unchanging.* (White Paper, p. 1)

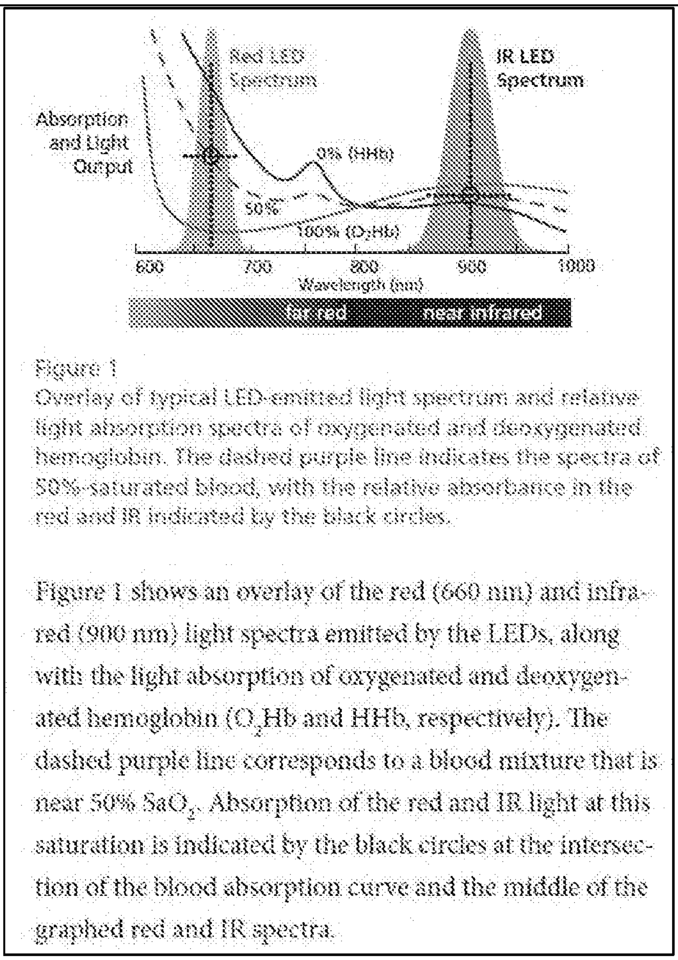
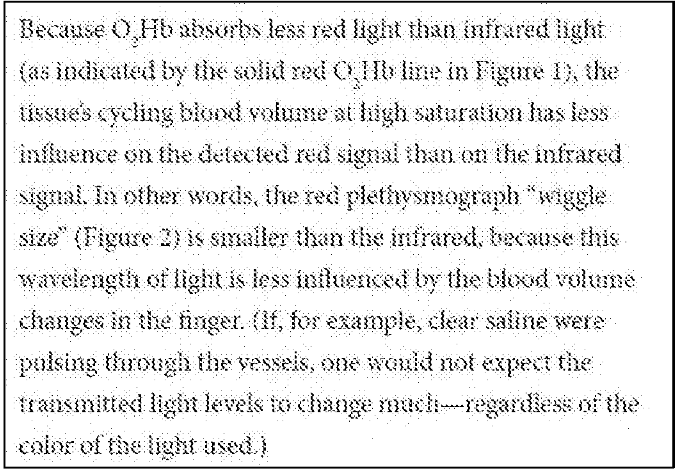
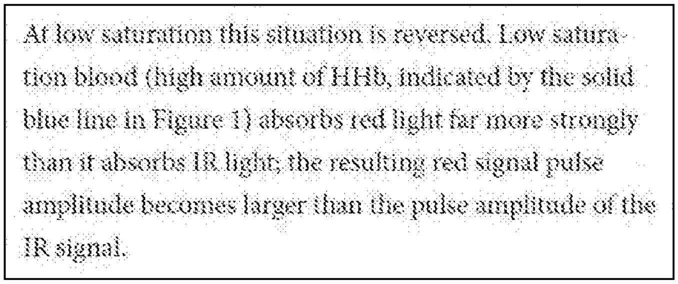
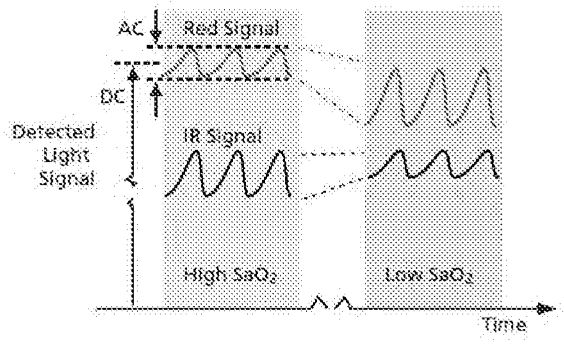


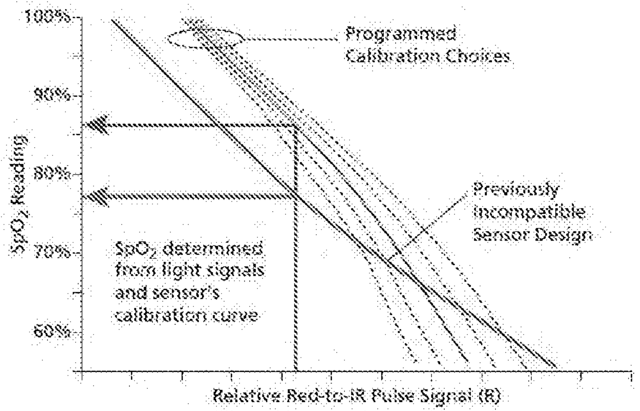
Figure 1
Overlay of typical LED-emitted light spectrum and relative light absorption spectra of oxygenated and deoxygenated hemoglobin. The dashed purple line indicates the spectra of 50%-saturated blood, with the relative absorbance in the red and IR indicated by the black circles.

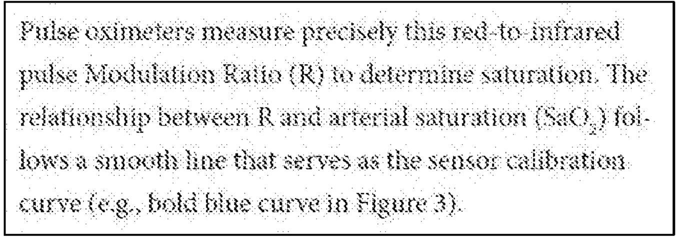
Figure 1 shows an overlay of the red (660 nm) and infrared (900 nm) light spectra emitted by the LEDs, along with the light absorption of oxygenated and deoxygenated hemoglobin (O_2Hb and HHb, respectively). The dashed purple line corresponds to a blood mixture that is near 50% SaO_2. Absorption of the red and IR light at this saturation is indicated by the black circles at the intersection of the blood absorption curve and the middle of the graphed red and IR spectra.

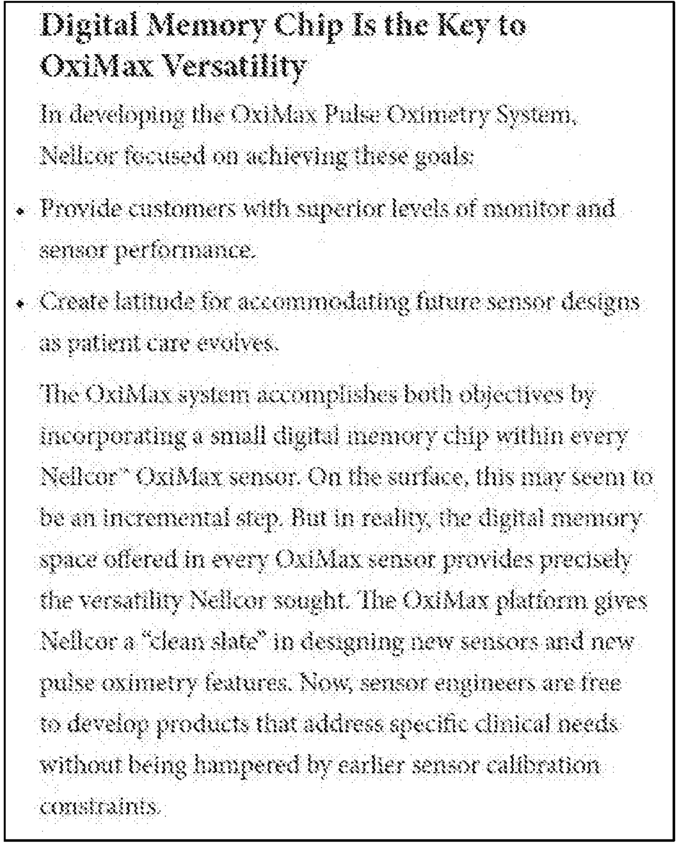
(White Paper, p. 2)

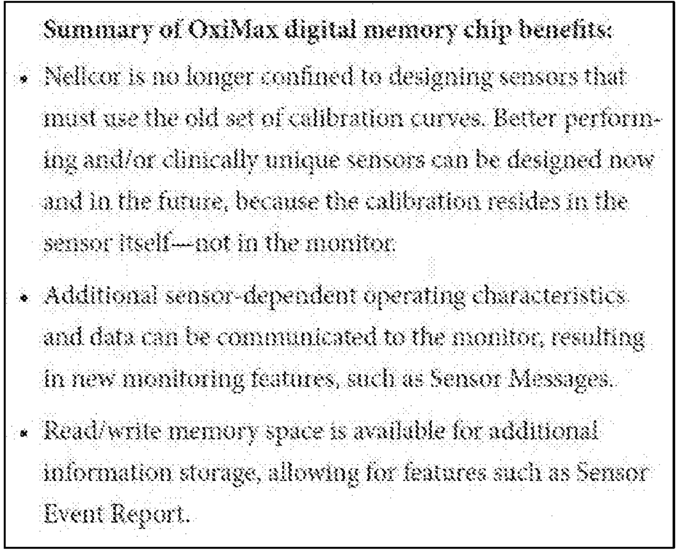
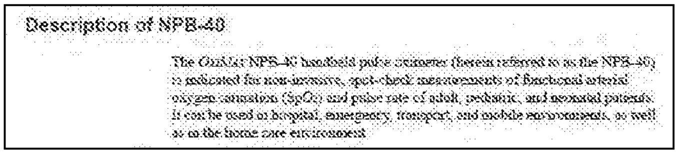
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Because O_2Hb absorbs less red light than infrared light (as indicated by the solid red O_2Hb line in Figure 1), the tissue's cycling blood volume at high saturation has less influence on the detected red signal than on the infrared signal. In other words, the red plethysmograph "wiggle size" (Figure 2) is smaller than the infrared, because this wavelength of light is less influenced by the blood volume changes in the finger. (If, for example, clear saline were pulsing through the vessels, one would not expect the transmitted light levels to change much—regardless of the color of the light used.) (White Paper, p. 2)  At low saturation this situation is reversed. Low saturation blood (high amount of HHb, indicated by the solid blue line in Figure 1) absorbs red light far more strongly than it absorbs IR light; the resulting red signal pulse amplitude becomes larger than the pulse amplitude of the IR signal. (White Paper, p. 2)

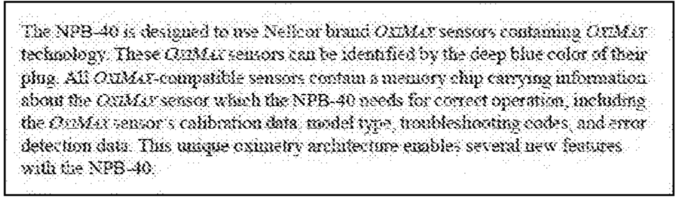
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Figure 2 Red and IR light signals at high and low arterial oxygen saturation. At high saturation, the red "pulse amplitude" (AC/DC) is smaller than in the IR. At low saturation, the ratio of relative amplitudes is reversed. (White Paper, p. 2)

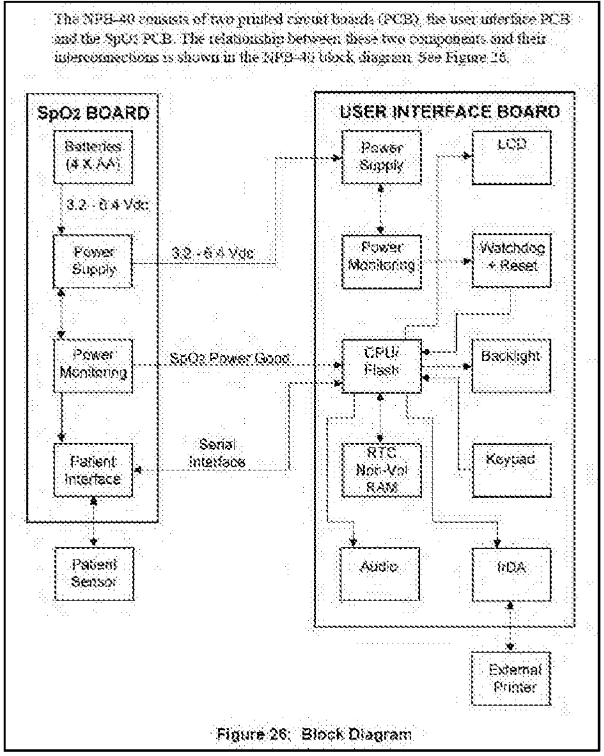
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Figure 3 The blue lines depict the one or more calibration curves programmed into earlier-generation monitors, while the red line indicates a calibration required of a hypothetical new sensor. Such a design would be incompatible with these earlier monitors, since none of the blue curves could provide accurate SpO_2 values for the sensor's signals. (White Paper, p. 2)

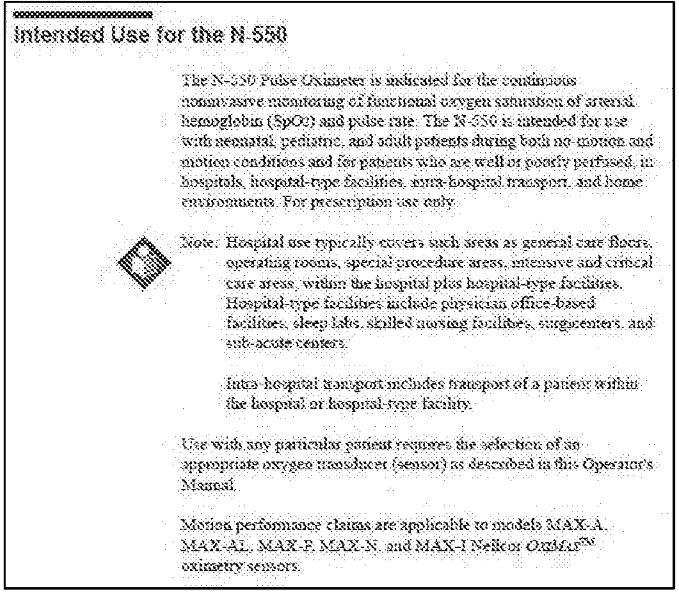
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Pulse oximeters measure precisely this red-to-infrared pulse Modulation Ratio (R) to determine saturation. The relationship between R and arterial saturation (SaO_2) follows a smooth line that serves as the sensor calibration curve (e.g., bold blue curve in Figure 3). (White Paper, p. 2)

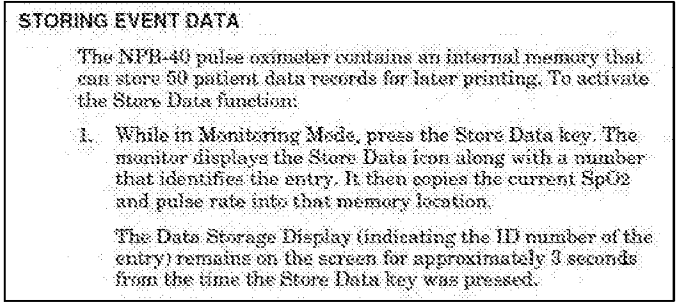
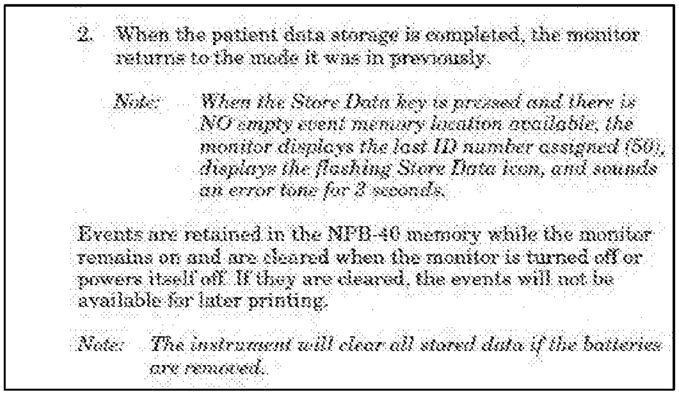
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 **Digital Memory Chip Is the Key to OxiMax Versatility** In developing the OxiMax Pulse Oximetry System, Nellcor focused on achieving these goals: • Provide customers with superior levels of monitor and sensor performance. • Create latitude for accommodating future sensor designs as patient care evolves. The OxiMax system accomplishes both objectives by incorporating a small digital memory chip within every Nellcor™ OxiMax sensor. On the surface, this may seem to be an incremental step. But in reality, the digital memory space offered in every OxiMax sensor provides precisely the versatility Nellcor sought. The OxiMax platform gives Nellcor a "clean slate" in designing new sensors and new pulse oximetry features. Now, sensor engineers are free to develop products that address specific clinical needs without being hampered by earlier sensor calibration constraints. (White Paper, p. 4)

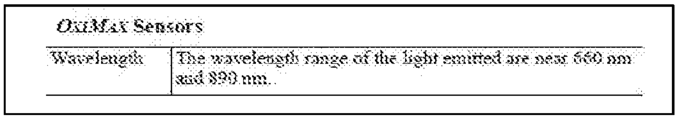
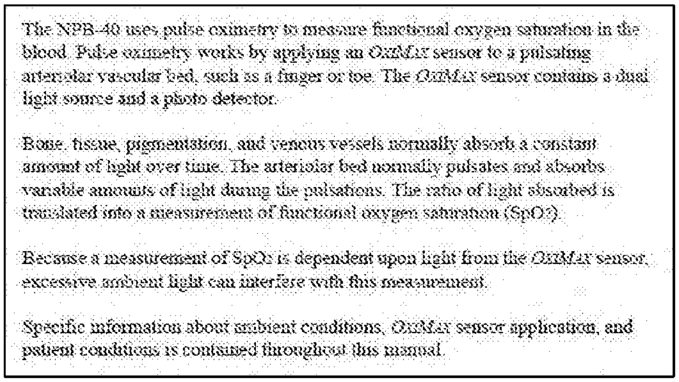
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 **Summary of OxiMax digital memory chip benefits:** • Nellcor is no longer confined to designing sensors that must use the old set of calibration curves. Better performing and/or clinically unique sensors can be designed now and in the future, because the calibration resides in the sensor itself—not in the monitor. • Additional sensor-dependent operating characteristics and data can be communicated to the monitor, resulting in new monitoring features, such as Sensor Messages. • Read/write memory space is available for additional information storage, allowing for features such as Sensor Event Report. (White Paper, p. 5)
[10] The system of claim 5, wherein the output signal comprises one or more physiological parameters, and the remote device is capable of storing a history of at least a portion of the one or more physiological parameters over a specified period of time.	Nellcor discloses and/or renders obvious "[t]he system of claim 5, wherein the output signal comprises one or more physiological parameters, and the remote device is capable of storing a history of at least a portion of the one or more physiological parameters over a specified period of time."  Description of NPB-40 The OxiMax NPB-40 handheld pulse oximeter (herein referred to as the NPB-40) is indicated for non-invasive, spot-check measurements of functional arterial oxygen saturation (SpO2) and pulse rate of adult, pediatric, and neonatal patients. It can be used in hospital, emergency, transport, and mobile environments, as well as in the home care environment. (NPB-40 Service Manual, p. 3)

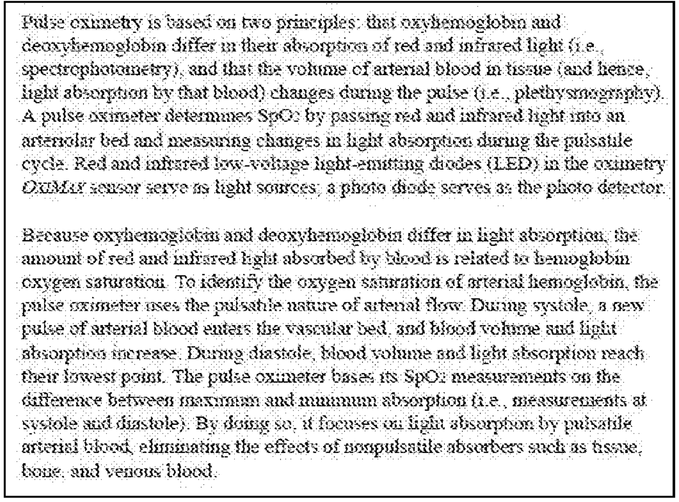
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)

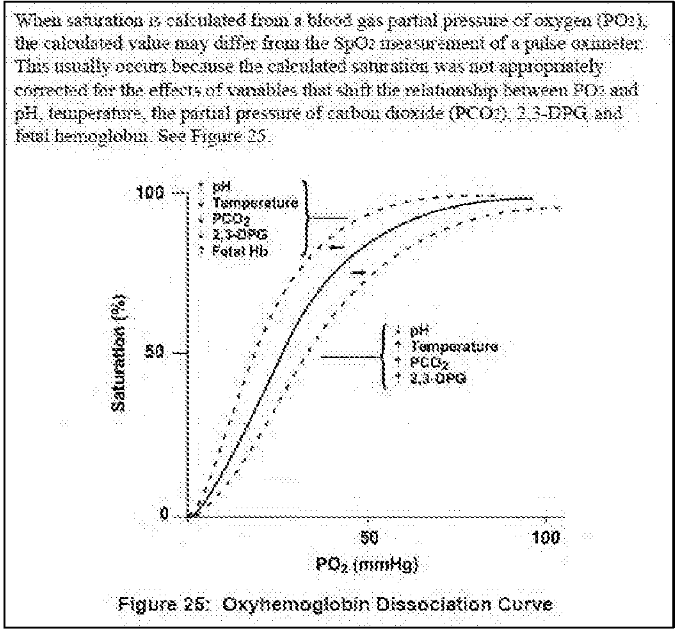
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 The NPB-40 consists of two printed circuit boards (PCB), the user interface PCB and the SpO2 PCB. The relationship between these two components and their interconnections is shown in the NPB-40 block diagram. See Figure 26. Figure 26: Block Diagram (NPB-40 Service Manual, p. 78)

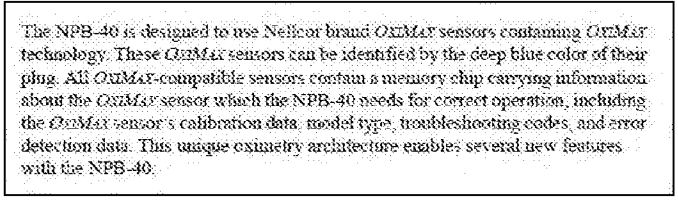
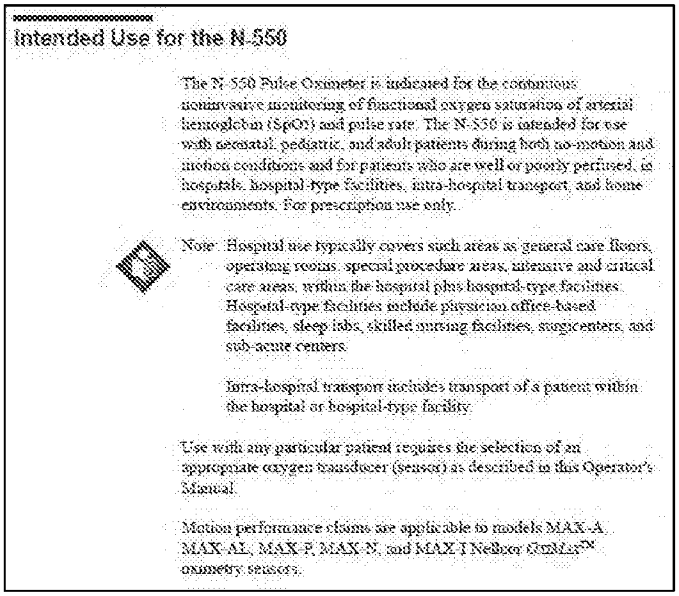
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 **Intended Use for the N-550** The N-550 Pulse Oximeter is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO$_2$) and pulse rate. The N-550 is intended for use with neonatal, pediatric, and adult patients during both no-motion and motion conditions and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, intra-hospital transport, and home environments. For prescription use only. Note: Hospital use typically covers such areas as general care floors, operating rooms, special procedure areas, intensive and critical care areas, within the hospital plus hospital-type facilities. Hospital-type facilities include physician office-based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acute centers. Intra-hospital transport includes transport of a patient within the hospital or hospital-type facility. Use with any particular patient requires the selection of an appropriate oxygen transducer (sensor) as described in this Operator's Manual. Motion performance claims are applicable to models MAX-A, MAX-AL, MAX-P, MAX-N, and MAX-I Nellcor OxiMax™ oximetry sensors. (N-550 Manual, p. 5)

Asserted Claim of '533 Patent	**Nellcor Pulse Oximeters**
	 STORING EVENT DATA The NPB-40 pulse oximeter contains an internal memory that can store 50 patient data records for later printing. To activate the Store Data function: 1. While in Monitoring Mode, press the Store Data key. The monitor displays the Store Data icon along with a number that identifies the entry. It then copies the current SpO2 and pulse rate into that memory location. The Data Storage Display (indicating the ID number of the entry) remains on the screen for approximately 3 seconds from the time the Store Data key was pressed. (NPB-40 Operator's Manual, p. 23)  2. When the patient data storage is completed, the monitor returns to the mode it was in previously. *Note: When the Store Data key is pressed and there is NO empty event memory location available, the monitor displays the last ID number assigned (50), displays the flashing Store Data icon, and sounds an error tone for 3 seconds.* Events are retained in the NPB-40 memory while the monitor remains on and are cleared when the monitor is turned off or powers itself off. If they are cleared, the events will not be available for later printing. *Note: The instrument will clear all stored data if the batteries are removed.* (NPB-40 Operator's Manual, p. 24)
[13] A measurement system comprising	To the extent the preamble is limiting, Nellcor discloses and/or renders obvious "a measurement system."

Asserted Claim of '533 Patent	**Nellcor Pulse Oximeters**
	See CHART ONE: '533 Patent, Claim Element 5 above.
[13A] a wearable measurement device for measuring one or more physiological parameters, including a light source comprising a plurality of semiconductor sources that are light emitting diodes, the light emitting diodes configured to generate an output optical beam with one or more optical wavelengths,	Nellcor discloses and/or renders obvious "a wearable measurement device for measuring one or more physiological parameters, including a light source comprising a plurality of semiconductor sources that are light emitting diodes, the light emitting diodes configured to generate an output optical beam with one or more optical wavelengths."  *OxiMax* Sensors Wavelength The wavelength range of the light emitted are near 660 nm and 890 nm. (NPB-40 Service Manual, p. 67)  The NPB-40 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying an *OxiMax* sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The *OxiMax* sensor contains a dual light source and a photo detector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO_2). Because a measurement of SpO_2 is dependent upon light from the *OxiMax* sensor, excessive ambient light can interfere with this measurement. Specific information about ambient conditions, *OxiMax* sensor application, and patient conditions is contained throughout this manual. (NPB-40 Service Manual, p. 75)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e., spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e., plethysmography). A pulse oximeter determines SpO_2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry *OxiMax* sensor serve as light sources; a photo diode serves as the photo detector. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial hemoglobin, the pulse oximeter uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The pulse oximeter bases its SpO_2 measurements on the difference between maximum and minimum absorption (i.e., measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. (NPB-40 Service Manual, p. 75)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 When saturation is calculated from a blood gas partial pressure of oxygen (PO_2), the calculated value may differ from the SpO_2 measurement of a pulse oximeter. This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO_2 and pH, temperature, the partial pressure of carbon dioxide (PCO_2), 2,3-DPG, and fetal hemoglobin. See Figure 25. Figure 25: Oxyhemoglobin Dissociation Curve (NPB-40 Service Manual, p. 76)

Asserted Claim of '533 Patent	**Nellcor Pulse Oximeters**
	 The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)  Intended Use for the N-550 The N-550 Pulse Oximeter is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The N-550 is intended for use with neonatal, pediatric, and adult patients during both no-motion and motion conditions and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, intra-hospital transport, and home environments. For prescription use only. Note: Hospital use typically covers such areas as general care floors, operating rooms, special procedure areas, intensive and critical care areas, within the hospital plus hospital-type facilities. Hospital-type facilities include physician office-based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acute centers. Intra-hospital transport includes transport of a patient within the hospital or hospital-type facility. Use with any particular patient requires the selection of an appropriate oxygen transducer (sensor) as described in this Operator's Manual. Motion performance claims are applicable to models MAX-A, MAX-AL, MAX-P, MAX-N, and MAX-I Nellcor *OxiMax*™ oximetry sensors. (N-550 Manual, p. 5)

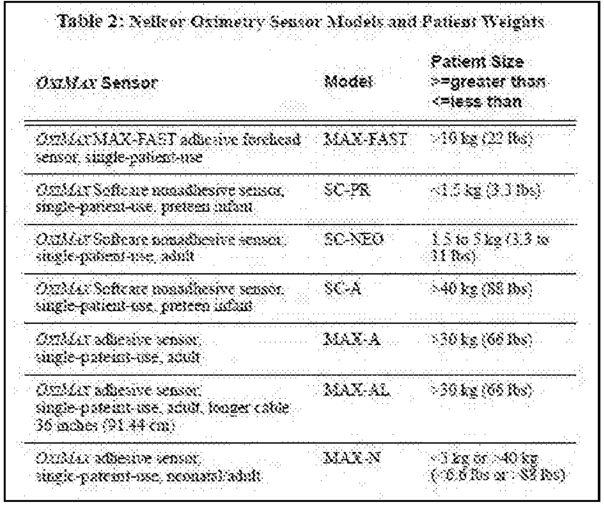
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 (N-550 Manual, p. 66)

Table 2: Nellcor Oximetry Sensor Models and Patient Weights

OxiMax Sensor	Model	Patient Size >=greater than <=less than
OxiMax MAX-FAST adhesive forehead sensor, single-patient-use	MAX-FAST	>10 kg (22 lbs)
OxiMax Softcare nonadhesive sensor, single-patient-use, preteen infant	SC-PR	<1.5 kg (3.3 lbs)
OxiMax Softcare nonadhesive sensor, single-patient-use, adult	SC-NEO	1.5 to 5 kg (3.3 to 11 lbs)
OxiMax Softcare nonadhesive sensor, single-patient-use, preteen infant	SC-A	>40 kg (88 lbs)
OxiMax adhesive sensor, single-pateint-use, adult	MAX-A	>30 kg (66 lbs)
OxiMax adhesive sensor, single-pateint-use, adult, longer cable 36 inches (91.44 cm)	MAX-AL	>30 kg (66 lbs)
OxiMax adhesive sensor, single-pateint-use, neonatal/adult	MAX-N	<3 kg or >40 kg (<6.6 lbs or >88 lbs)

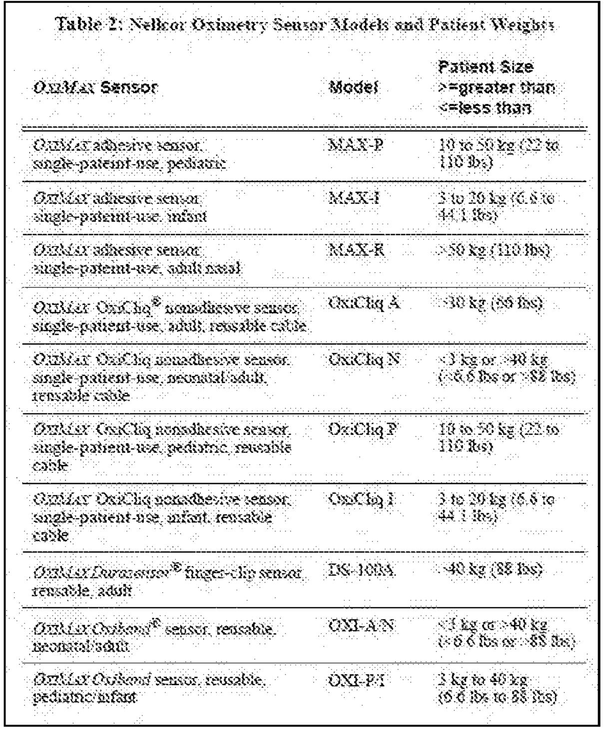
Asserted Claim of '533 Patent	**Nellcor Pulse Oximeters**
	 (N-550 Manual, p. 67)

Table 2: Nellcor Oximetry Sensor Models and Patient Weights

OxiMax Sensor	Model	Patient Size >=greater than <=less than
OxiMax adhesive sensor, single-pateint-use, pediatric	MAX-P	10 to 50 kg (22 to 110 lbs)
OxiMax adhesive sensor, single-pateint-use, infant	MAX-I	3 to 20 kg (6.6 to 44.1 lbs)
OxiMax adhesive sensor, single-pateint-use, adult nasal	MAX-R	>50 kg (110 lbs)
OxiMax OxiCliq® nonadhesive sensor, single-patient-use, adult, reusable cable	OxiCliq A	>30 kg (66 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, neonatal/adult, reusable cable	OxiCliq N	<3 kg or >40 kg (<6.6 lbs or >82 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, pediatric, reusable cable	OxiCliq P	10 to 50 kg (22 to 110 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, infant, reusable cable	OxiCliq I	3 to 20 kg (6.6 to 44.1 lbs)
OxiMax Durasensor® finger-clip sensor, reusable, adult	DS-100A	>40 kg (88 lbs)
OxiMax Oxiband® sensor, reusable, neonatal/adult	OXI-A/N	<3 kg or >40 kg (<6.6 lbs or >88 lbs)
OxiMax Oxiband sensor, reusable, pediatric/infant	OXI-P/I	3 kg to 40 kg (6.6 lbs to 88 lbs)

<table>
<tr><th>Asserted Claim of '533 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>

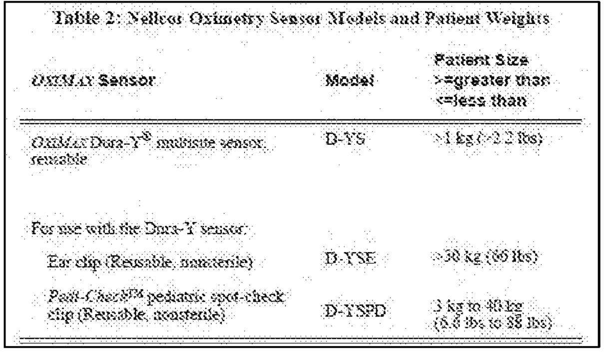
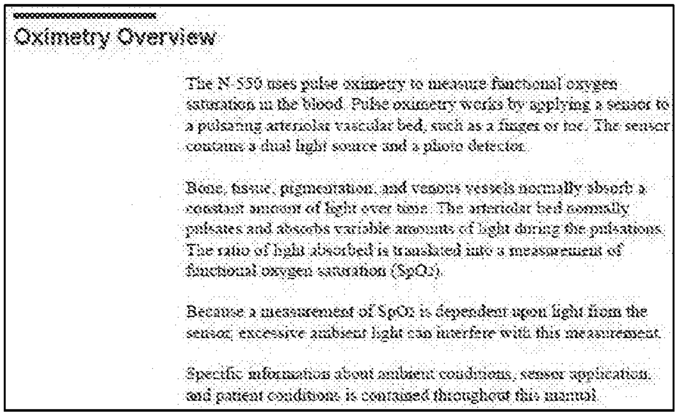
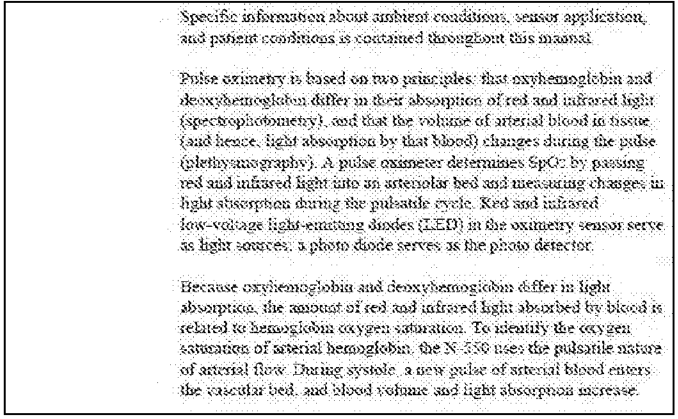
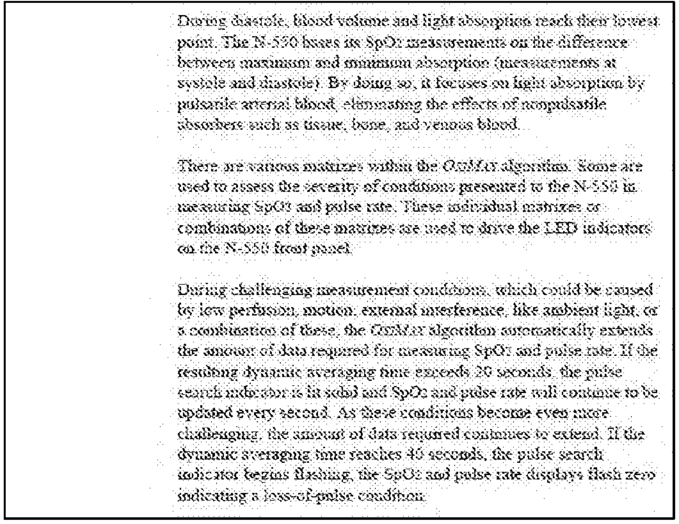



Table 2: Nellcor Oximetry Sensor Models and Patient Weights
<table>
<tr><th><i>OxiMax</i> Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td><i>OxiMax</i> Dura-Y® multisite sensor, reusable</td><td>D-YS</td><td>>1 kg (>2.2 lbs)</td></tr>
<tr><td>For use with the Dura-Y sensor:</td><td></td><td></td></tr>
<tr><td>Ear clip (Reusable, nonsterile)</td><td>D-YSE</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>Pedi-Check</i>™ pediatric spot-check clip (Reusable, nonsterile)</td><td>D-YSPD</td><td>3 kg to 40 kg
(6.6 lbs to 88 lbs)</td></tr>
</table>
(N-550 Manual, p. 68)

Oximetry Overview
The N-550 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photo detector.
Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO2).
Because a measurement of SpO2 is dependent upon light from the sensor, excessive ambient light can interfere with this measurement.
Specific information about ambient conditions, sensor application, and patient conditions is contained throughout this manual.
(N-550 Manual, p. 93)
</td></tr>
</table>

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Specific information about ambient conditions, sensor application, and patient conditions is contained throughout this manual. Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography). A pulse oximeter determines SpO_2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry sensor serve as light sources; a photo diode serves as the photo detector. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial hemoglobin, the N-550 uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. (N-550 Manual, p. 93)

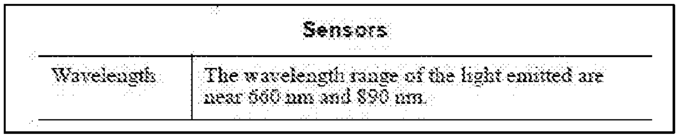
<table>
<tr><th>Asserted Claim of '533 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>


During diastole, blood volume and light absorption reach their lowest point. The N-550 bases its SpO2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

There are various matrixes within the *OxiMax* algorithm. Some are used to assess the severity of conditions presented to the N-550 in measuring SpO2 and pulse rate. These individual matrixes or combinations of these matrixes are used to drive the LED indicators on the N-550 front panel.

During challenging measurement conditions, which could be caused by low perfusion, motion, external interference, like ambient light, or a combination of these, the *OxiMax* algorithm automatically extends the amount of data required for measuring SpO2 and pulse rate. If the resulting dynamic averaging time exceeds 20 seconds, the pulse search indicator is lit solid and SpO2 and pulse rate will continue to be updated every second. As these conditions become even more challenging, the amount of data required continues to extend. If the dynamic averaging time reaches 40 seconds, the pulse search indicator begins flashing, the SpO2 and pulse rate displays flash zero indicating a loss-of-pulse condition.

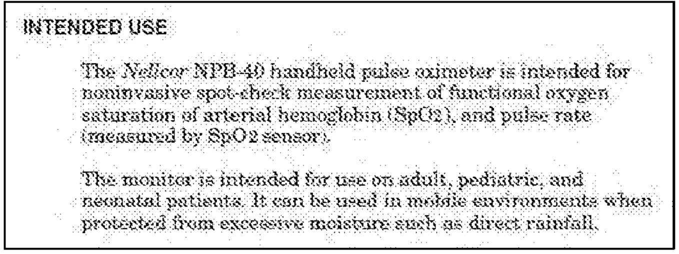
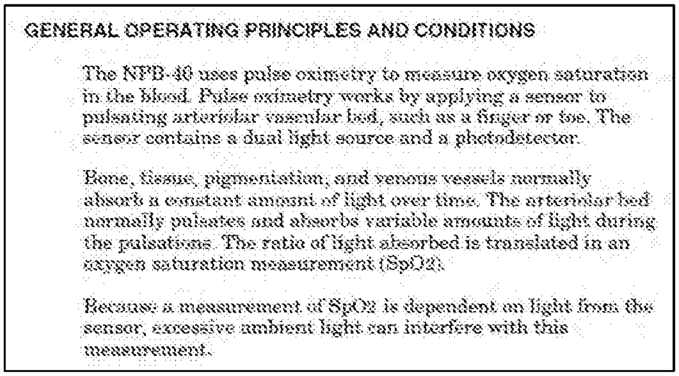
(N-550 Manual, p. 94)

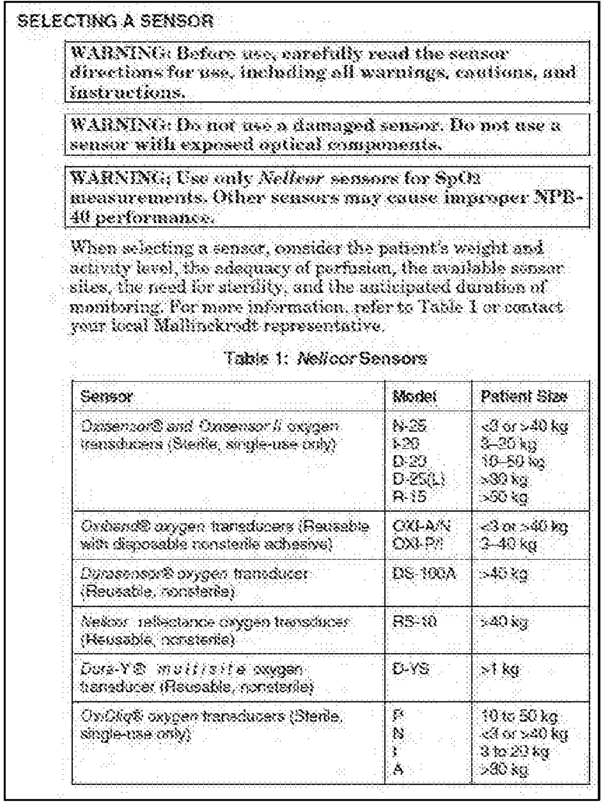


Sensors

<table>
<tr><td>Wavelength</td><td>The wavelength range of the light emitted are near 660 nm and 890 nm.</td></tr>
</table>

(N-550 Manual, p. 102)
</td></tr>
</table>

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 INTENDED USE The *Nellcor* NPB-40 handheld pulse oximeter is intended for noninvasive spot-check measurement of functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate (measured by SpO2 sensor). The monitor is intended for use on adult, pediatric, and neonatal patients. It can be used in mobile environments when protected from excessive moisture such as direct rainfall. (NPB-40 Operator's Manual, p. 3)  GENERAL OPERATING PRINCIPLES AND CONDITIONS The NPB-40 uses pulse oximetry to measure oxygen saturation in the blood. Pulse oximetry works by applying a sensor to pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photodetector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated in an oxygen saturation measurement (SpO2). Because a measurement of SpO2 is dependent on light from the sensor, excessive ambient light can interfere with this measurement. (NPB-40 Operator's Manual, p. 3-4)

<table>
<tr><th>Asserted Claim of '533 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>

SELECTING A SENSOR

WARNING: Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

WARNING: Do not use a damaged sensor. Do not use a sensor with exposed optical components.

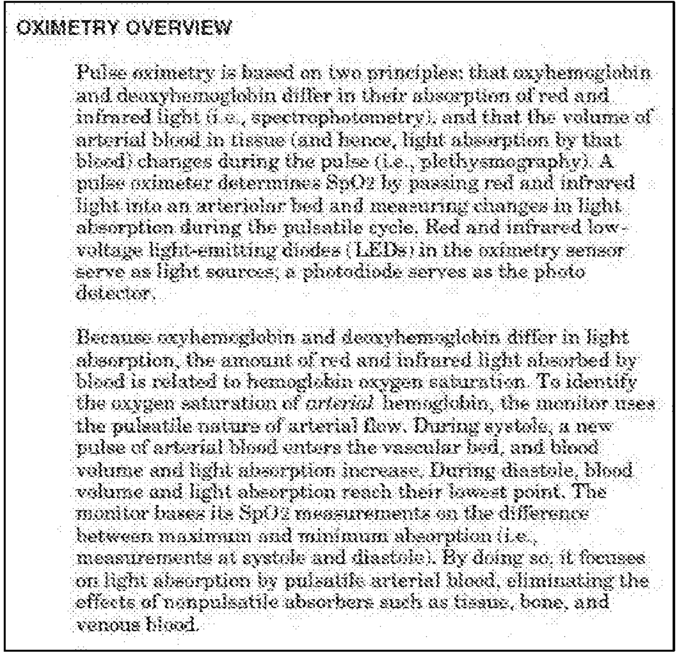
WARNING: Use only *Nellcor* sensors for SpO2 measurements. Other sensors may cause improper NPB-40 performance.

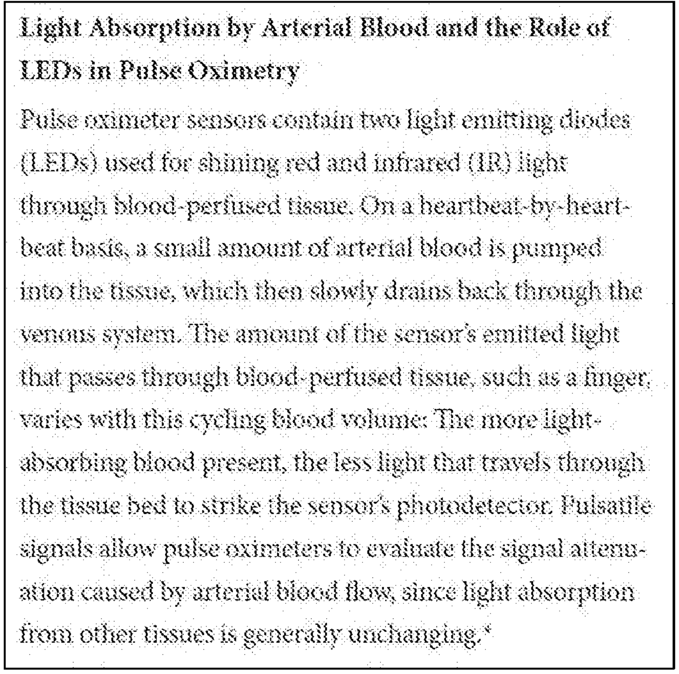
When selecting a sensor, onsider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Mallinckrodt representative.

Table 1: *Nellcor* Sensors

<table>
<tr><th>Sensor</th><th>Model</th><th>Patient Size</th></tr>
<tr><td><i>Oxisensor</i>® and <i>Oxisensor II</i> oxygen transducers (Sterile, single-use only)</td><td>N-25
I-20
D-20
D-25(L)
R-15</td><td><3 or >40 kg
3–20 kg
10–50 kg
>30 kg
>50 kg</td></tr>
<tr><td><i>Oxiband</i>® oxygen transducers (Reusable with disposable nonsterile adhesive)</td><td>OXI-A/N
OXI-P/I</td><td><3 or >40 kg
3–40 kg</td></tr>
<tr><td><i>Durasensor</i>® oxygen transducer (Reusable, nonsterile)</td><td>DS-100A</td><td>>40 kg</td></tr>
<tr><td><i>Nellcor</i> reflectance oxygen transducer (Reusable, nonsterile)</td><td>RS-10</td><td>>40 kg</td></tr>
<tr><td><i>Dura-Y</i>® <i>multisite</i> oxygen transducer (Reusable, nonsterile)</td><td>D-YS</td><td>>1 kg</td></tr>
<tr><td><i>OxiCliq</i>® oxygen transducers (Sterile, single-use only)</td><td>P
N
I
A</td><td>10 to 50 kg
<3 or >40 kg
3 to 20 kg
>30 kg</td></tr>
</table>

(NPB-40 Operator's Manual, p. 15)</td></tr>
</table>

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 OXIMETRY OVERVIEW Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e., spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e., plethysmography). A pulse oximeter determines SpO2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LEDs) in the oximetry sensor serve as light sources; a photodiode serves as the photo detector. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of *arterial* hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitor bases its SpO2 measurements on the difference between maximum and minimum absorption (i.e., measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. (NPB-40 Operator's Manual, p. 41)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 **Light Absorption by Arterial Blood and the Role of LEDs in Pulse Oximetry** Pulse oximeter sensors contain two light emitting diodes (LEDs) used for shining red and infrared (IR) light through blood-perfused tissue. On a heartbeat-by-heartbeat basis, a small amount of arterial blood is pumped into the tissue, which then slowly drains back through the venous system. The amount of the sensor's emitted light that passes through blood-perfused tissue, such as a finger, varies with this cycling blood volume: The more light-absorbing blood present, the less light that travels through the tissue bed to strike the sensor's photodetector. Pulsatile signals allow pulse oximeters to evaluate the signal attenuation caused by arterial blood flow, since light absorption from other tissues is generally unchanging.[4] (White Paper, p. 1)

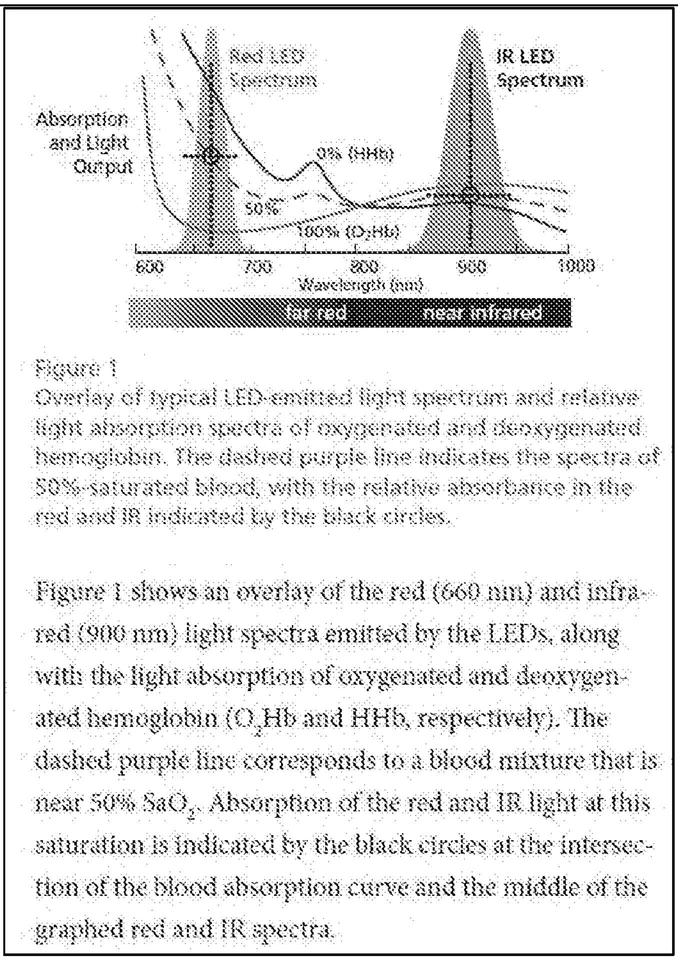
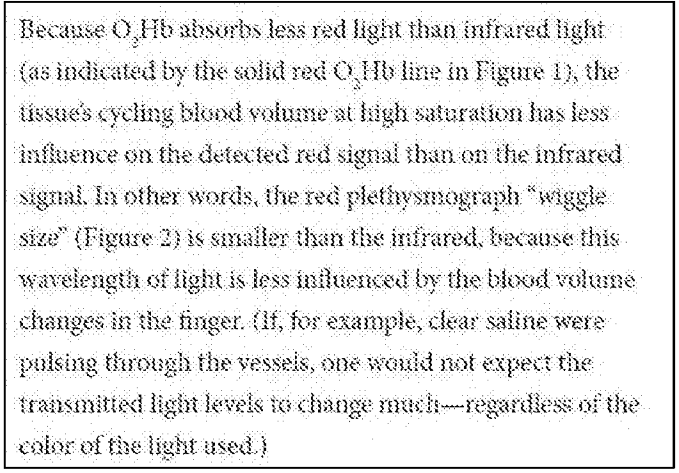
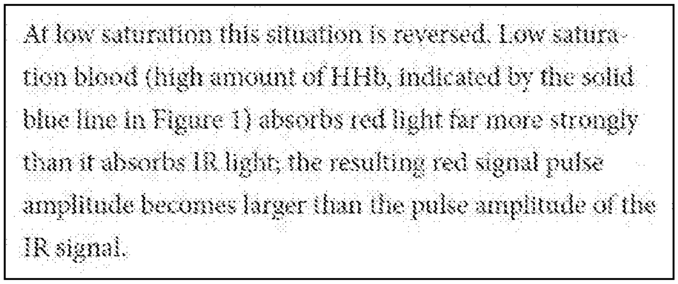
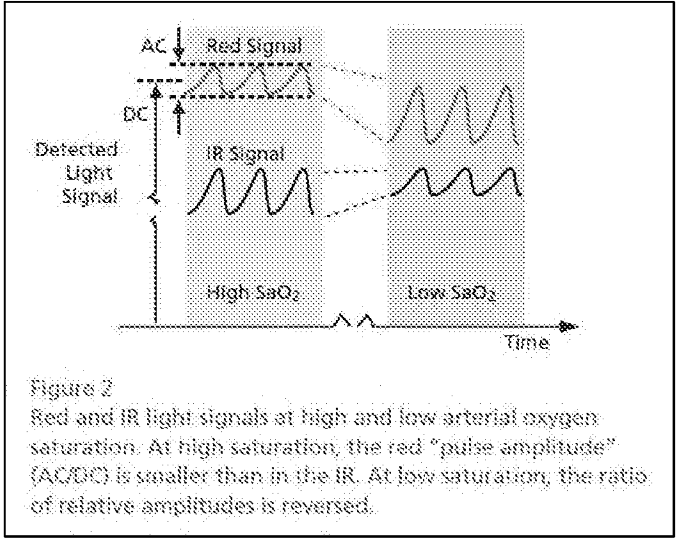


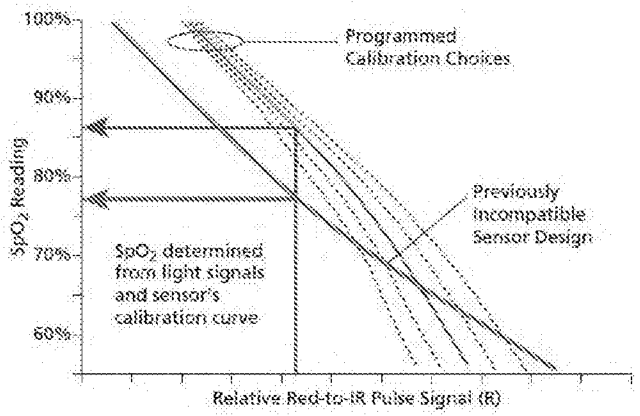
Figure 1
Overlay of typical LED-emitted light spectrum and relative light absorption spectra of oxygenated and deoxygenated hemoglobin. The dashed purple line indicates the spectra of 50%-saturated blood, with the relative absorbance in the red and IR indicated by the black circles.

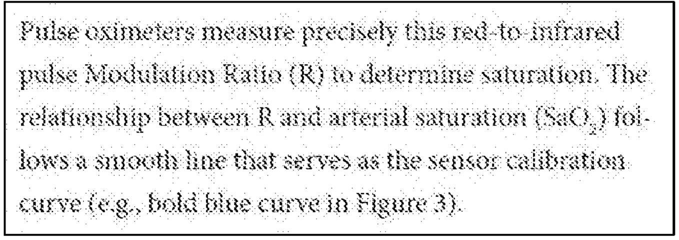
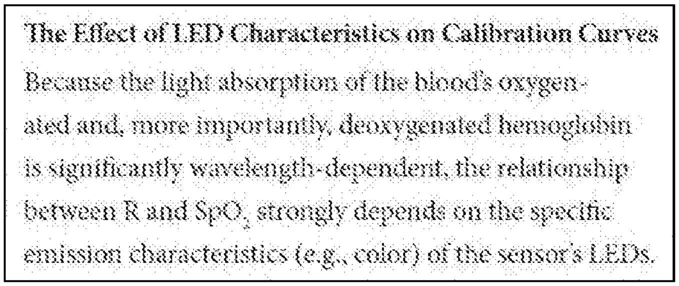
Figure 1 shows an overlay of the red (660 nm) and infrared (900 nm) light spectra emitted by the LEDs, along with the light absorption of oxygenated and deoxygenated hemoglobin (O_2Hb and HHb, respectively). The dashed purple line corresponds to a blood mixture that is near 50% SaO_2. Absorption of the red and IR light at this saturation is indicated by the black circles at the intersection of the blood absorption curve and the middle of the graphed red and IR spectra.

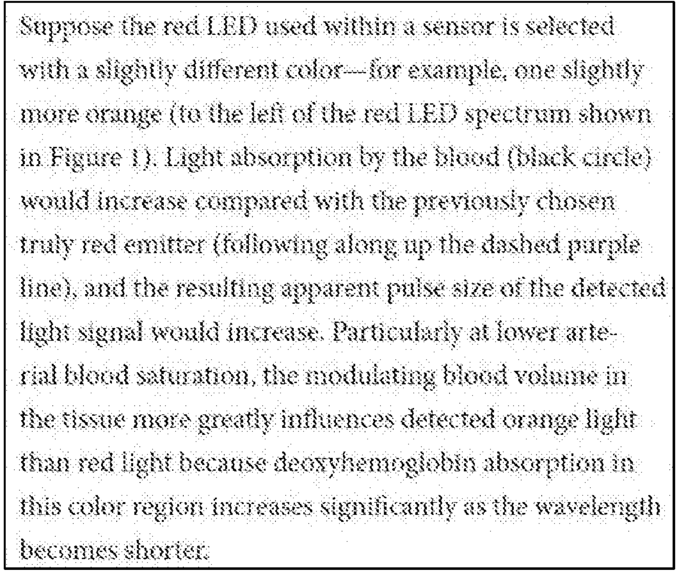
(White Paper, p. 2)

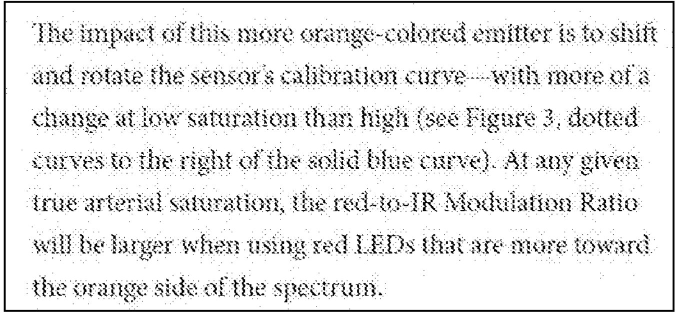
Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Because O_2Hb absorbs less red light than infrared light (as indicated by the solid red O_2Hb line in Figure 1), the tissue's cycling blood volume at high saturation has less influence on the detected red signal than on the infrared signal. In other words, the red plethysmograph "wiggle size" (Figure 2) is smaller than the infrared, because this wavelength of light is less influenced by the blood volume changes in the finger. (If, for example, clear saline were pulsing through the vessels, one would not expect the transmitted light levels to change much—regardless of the color of the light used.) (White Paper, p. 2)  At low saturation this situation is reversed. Low saturation blood (high amount of HHb, indicated by the solid blue line in Figure 1) absorbs red light far more strongly than it absorbs IR light; the resulting red signal pulse amplitude becomes larger than the pulse amplitude of the IR signal. (White Paper, p. 2)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Figure 2 Red and IR light signals at high and low arterial oxygen saturation. At high saturation, the red "pulse amplitude" (AC/DC) is smaller than in the IR. At low saturation, the ratio of relative amplitudes is reversed. (White Paper, p. 2)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Figure 3 The blue lines depict the one or more calibration curves programmed into earlier-generation monitors, while the red line indicates a calibration required of a hypothetical new sensor. Such a design would be incompatible with these earlier monitors, since none of the blue curves could provide accurate SpO_2 values for the sensor's signals. (White Paper, p. 2)

Asserted Claim of '533 Patent	**Nellcor Pulse Oximeters**
	 Pulse oximeters measure precisely this red-to-infrared pulse Modulation Ratio (R) to determine saturation. The relationship between R and arterial saturation (SaO_2) follows a smooth line that serves as the sensor calibration curve (e.g., bold blue curve in Figure 3). (White Paper, p. 2)  **The Effect of LED Characteristics on Calibration Curves** Because the light absorption of the blood's oxygenated and, more importantly, deoxygenated hemoglobin is significantly wavelength-dependent, the relationship between R and SpO_2 strongly depends on the specific emission characteristics (e.g., color) of the sensor's LEDs. (White Paper, p. 3)

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	 Suppose the red LED used within a sensor is selected with a slightly different color—for example, one slightly more orange (to the left of the red LED spectrum shown in Figure 1). Light absorption by the blood (black circle) would increase compared with the previously chosen truly red emitter (following along up the dashed purple line), and the resulting apparent pulse size of the detected light signal would increase. Particularly at lower arterial blood saturation, the modulating blood volume in the tissue more greatly influences detected orange light than red light because deoxyhemoglobin absorption in this color region increases significantly as the wavelength becomes shorter. (White Paper, p. 3)

Asserted Claim of '533 Patent	**Nellcor Pulse Oximeters**
	 The impact of this more orange-colored emitter is to shift and rotate the sensor's calibration curve—with more of a change at low saturation than high (see Figure 3, dotted curves to the right of the solid blue curve). At any given true arterial saturation, the red-to-IR Modulation Ratio will be larger when using red LEDs that are more toward the orange side of the spectrum. (White Paper, p. 3)
[13B] wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers,	Nellcor discloses and/or renders obvious "wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers." *See* CHART ONE: '533 Patent, Claim Element 5B above.
[13C] the light source configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of semiconductor sources;	Nellcor discloses and/or renders obvious "the light source configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of semiconductor sources." *See* CHART ONE: '533 Patent, Claim Element 5C above.
[13D] the wearable measurement device comprising a plurality of lenses configured to receive a portion of the output optical beam	Nellcor discloses and/or renders obvious "the wearable measurement device comprising a plurality of lenses configured to receive a portion of the output optical beam and to deliver an analysis output beam to a sample." *See* CHART ONE: '533 Patent, Claim Element 5D above.

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
and to deliver an analysis output beam to a sample;	
[13E] the wearable measurement device further comprising a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal	Nellcor discloses and/or renders obvious "the wearable measurement device further comprising a receiver configured to receive and process at least a portion of the analysis output beam reflected or transmitted from the sample and to generate an output signal." *See* CHART ONE: '533 Patent, Claim Element 5E above.
[13F] wherein the wearable measurement device receiver is configured to be synchronized to pulses of the light source;	Nellcor discloses and/or renders obvious "wherein the wearable measurement device receiver is configured to be synchronized to pulses of the light source." *See* CHART ONE: '533 Patent, Claim Element 5F above.
[13G] a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen,	Nellcor discloses and/or renders obvious "a personal device comprising a wireless receiver, a wireless transmitter, a display, a microphone, a speaker, one or more buttons or knobs, a microprocessor and a touch screen." *See* CHART ONE: '533 Patent, Claim Element 5G above.
[13H] the personal device configured to receive and process at least a portion of the output signal,	Nellcor discloses and/or renders obvious "the personal device configured to receive and process at least a portion of the output signal, wherein the personal device is configured to store and display the processed output signal." *See* CHART ONE: '533 Patent, Claim Element 5H above.
[13I] wherein the personal device is configured to store and display the processed output signal, and	Nellcor discloses and/or renders obvious "wherein the personal device is configured to store and display the processed output signal."

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
	See CHART ONE: '533 Patent, Claim Element 5I above.
[13J] wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link; and	Nellcor discloses and/or renders obvious "wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link." *See* CHART ONE: '533 Patent, Claim Element 5J above.
[13K] a remote device configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data and to store the processed data, and	Nellcor discloses and/or renders obvious "a remote device configured to receive over the wireless transmission link an output status comprising the at least a portion of the processed output signal, to process the received output status to generate processed data and to store the processed data." *See* CHART ONE: '533 Patent, Claim Element 5K above.
[13L] wherein the remote device is capable of storing a history of at least a portion of the received output status over a specified period of time.	Nellcor discloses and/or renders obvious "wherein the remote device is capable of storing a history of at least a portion of the received output status over a specified period of time." *See* CHART ONE: '533 Patent, Claim Element 10 above.
[16] The system of claim 13, wherein the receiver is located a first distance from a first one of the plurality of light emitting diodes and a different, second distance from a second one of the plurality of light emitting diodes such that the receiver receives a first signal from the first light emitting diode and a second	Nellcor discloses and/or renders obvious "[t]he system of claim 13, wherein the receiver is located a first distance from a first one of the plurality of light emitting diodes and a different, second distance from a second one of the plurality of light emitting diodes such that the receiver receives a first signal from the first light emitting diode and a second signal from the second light emitting diode." *See* CHART ONE: '533 Patent, Claim Element 8 above.

Asserted Claim of '533 Patent	Nellcor Pulse Oximeters
signal from the second light emitting diode.	
[17] The system of claim 16, wherein the output signal is generated in part by comparing the first and second signals.	Nellcor discloses and/or renders obvious "[t]he system of claim 16, wherein the output signal is generated in part by comparing the first and second signals." *See* CHART ONE: '533 Patent, Claim Element 9 above.

EXHIBIT X-2

U.S. Patent No. 9,757,040 vs Nellcor

Priority Date/Publication Date: between 2001 and December 2012 Prior Art Status: §§ 102(a) and (b)

The OxiMax, NPB-40, N-550, and certain pulse oximeters and pulse oximetry sensors manufactured by Nellcor ("Nellcor") anticipate the asserted claims of U.S. Patent No. 9,651,533 ("the '533 Patent") or render those claims obvious alone and/or in view of at least any of the references identified in Apple's Obviousness Combinations Chart.

This chart is based on the following disclosures about Nellcor pulse oximeters:

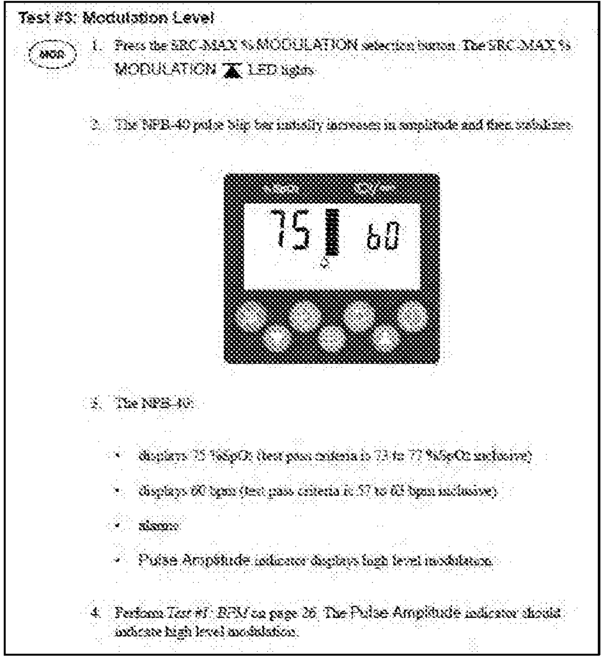
- Nellcor OxiMax NPB-40 Handheld Pulse Oximeter Service Manual 2004 ("NPB-40 Service Manual")
- Nellcor OxiMax N-550 Pulse Oximeter Service Manual 2003 ("N-550 Manual")
- Nellcor NPB-40 Handheld Pulse Oximeter Operator's Manual 2001 ("NPB-40 Operator's Manual")
- Nellcor OxiMax White Paper "A Technology Overview of the Nellcor™ OxiMax Pulse Oximetry System" 2003 ("White Paper")

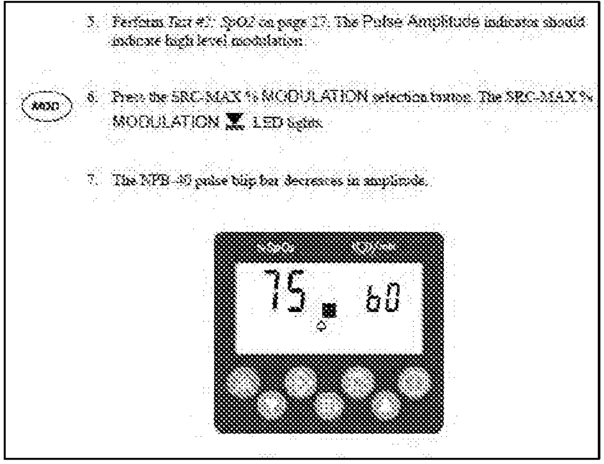
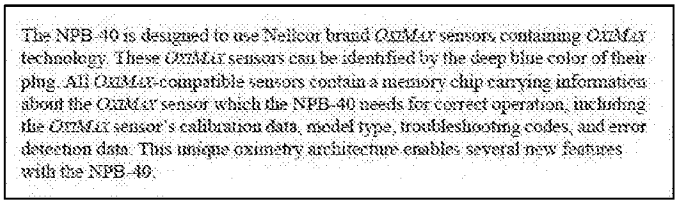
Discovery is ongoing, and Apple reserves the right to amend this chart based on new information about the Nellcor pulse oximeters.

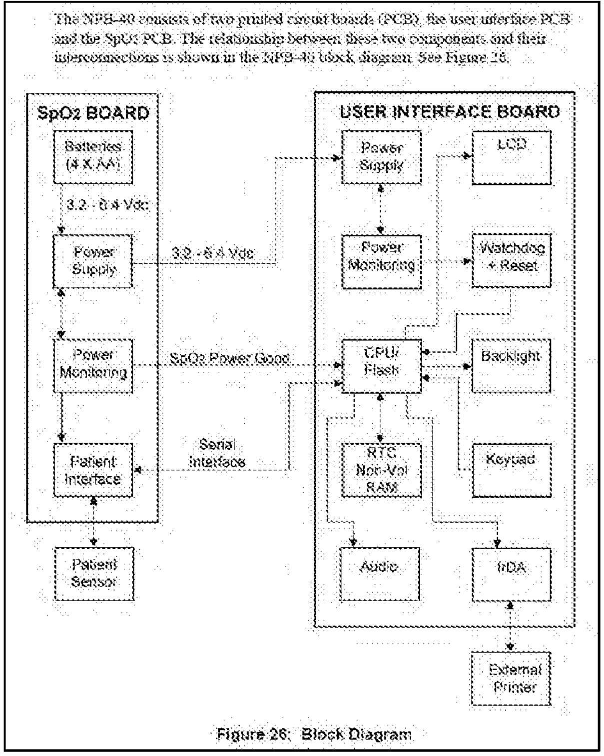
As set forth in Apple's Invalidity Contentions, the below contentions apply the prior art in part in accordance with Apple's assumption that Omni contends the claims are not invalid under 35 U.S.C. § 112. However, Apple's below contentions do not represent Apple's agreement or view as to the meaning, definiteness, written description support for, or enablement of any of the asserted claims. For each dependent claim, the disclosures cited for the claim from which it depends are incorporated by reference.

CHART TWO: U.S. Patent No. 9,757,040 vs Nellcor

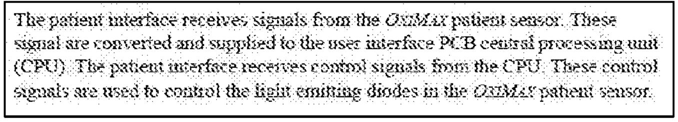
Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
[1] A wearable device for use with a smart phone or tablet, the wearable device comprising:	To the extent the preamble is limiting, Nellcor discloses and/or renders obvious "[a] wearable device for use with a smart phone or tablet." *See* CHART ONE: '533 Patent, Claim Elements 5, 5G, and 13A above.
[1A] a measurement device including a light source comprising a plurality of light emitting diodes (LEDs) for measuring one or more physiological parameters	Nellcor discloses and/or renders obvious "a measurement device including a light source comprising a plurality of light emitting diodes (LEDs) for measuring one or more physiological parameters." *See* CHART ONE: '533 Patent, Claim Element 13A above.
[1B] the measurement device configured to generate, by modulating at least one of the LEDs having an initial light intensity, an input optical beam having one or more optical wavelengths,	Nellcor discloses and/or renders obvious "the measurement device configured to generate, by modulating at least one of the LEDs having an initial light intensity, an input optical beam having one or more optical wavelengths."

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 Test #3: Modulation Level MOD 1. Press the SRC-MAX % MODULATION selection button. The SRC-MAX % MODULATION ▲ LED lights. 2. The NPB-40 pulse blip bar initially increases in amplitude and then stabilizes. 3. The NPB-40: • displays 75 %SpO2 (test pass criteria is 73 to 77 %SpO2 inclusive) • displays 60 bpm (test pass criteria is 57 to 63 bpm inclusive) • alarms • Pulse Amplitude indicator displays high level modulation. 4. Perform Test #1: BPM on page 26. The Pulse Amplitude indicator should indicate high level modulation. (NPB-40 Service Manual, p. 29)

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 5. Perform *Test #3: SpO2* on page 27. The Pulse Amplitude indicator should indicate high level modulation. 6. Press the SRC-MAX % MODULATION selection button. The SRC-MAX % MODULATION ⧗ LED lights. 7. The NPB-40 pulse blip bar decreases in amplitude. (NPB-40 Service Manual, p. 29)  The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)

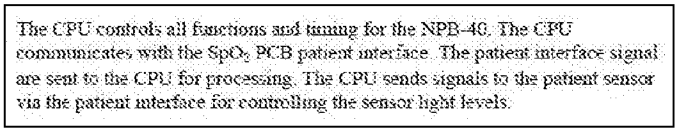
Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 The NPB-40 consists of two printed circuit boards (PCB), the user interface PCB and the SpO2 PCB. The relationship between these two components and their interconnections is shown in the NPB-40 block diagram. See Figure 26. Figure 26: Block Diagram (NPB-40 Service Manual, p. 78)

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters



The patient interface receives signals from the *OxiMax* patient sensor. These signal are converted and supplied to the user interface PCB central processing unit (CPU). The patient interface receives control signals from the CPU. These control signals are used to control the light emitting diodes in the *OxiMax* patient sensor.

(NPB-40 Service Manual, p. 78)



The CPU controls all functions and timing for the NPB-40. The CPU communicates with the SpO_2 PCB patient interface. The patient interface signal are sent to the CPU for processing. The CPU sends signals to the patient sensor via the patient interface for controlling the sensor light levels.

(NPB-40 Service Manual, p. 80)

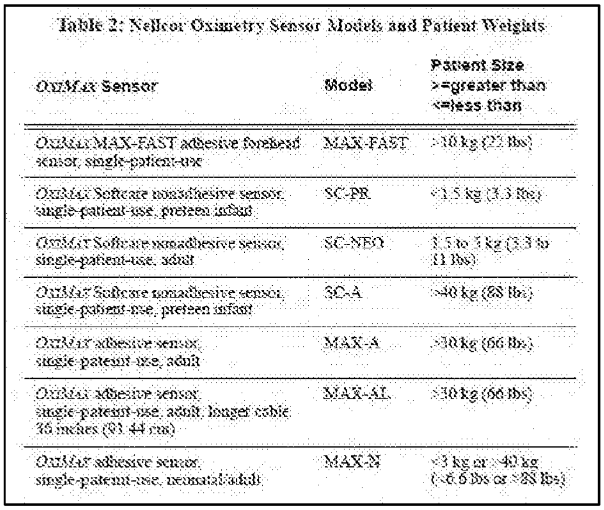


Table 2: Nellcor Oximetry Sensor Models and Patient Weights

OxiMax Sensor	Model	Patient Size >=greater than <=less than
OxiMax MAX-FAST adhesive forehead sensor, single-patient-use	MAX-FAST	>10 kg (22 lbs)
OxiMax Softcare nonadhesive sensor, single-patient-use, preteen infant	SC-PR	<1.5 kg (3.3 lbs)
OxiMax Softcare nonadhesive sensor, single-patient-use, adult	SC-NEO	1.5 to 5 kg (3.3 to 11 lbs)
OxiMax Softcare nonadhesive sensor, single-patient-use, preteen infant	SC-A	>40 kg (88 lbs)
OxiMax adhesive sensor, single-pateint-use, adult	MAX-A	>30 kg (66 lbs)
OxiMax adhesive sensor, single-pateint-use, adult, longer cable 36 inches (91.44 cm)	MAX-AL	>30 kg (66 lbs)
OxiMax adhesive sensor, single-pateint-use, neonatal/adult	MAX-N	<3 kg or >40 kg (<6.6 lbs or >88 lbs)

(N-550 Manual, p. 66)

<table>
<tr><th>Asserted Claim of '040 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>

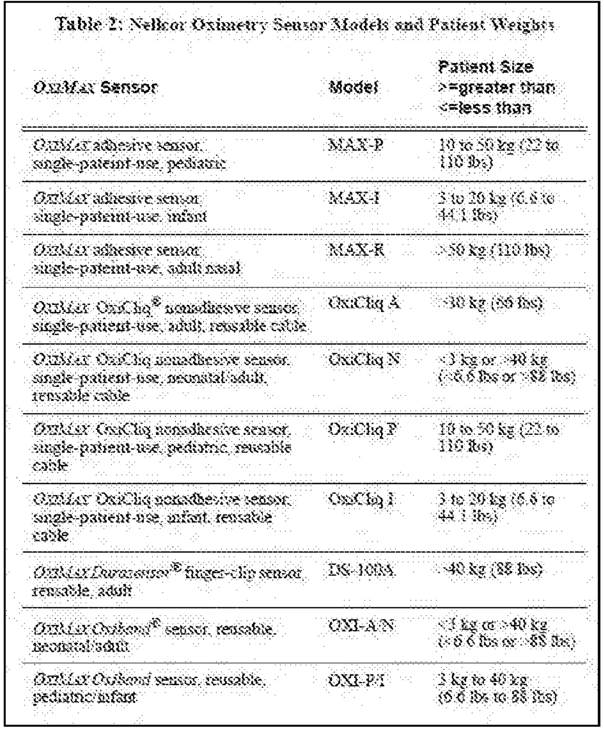
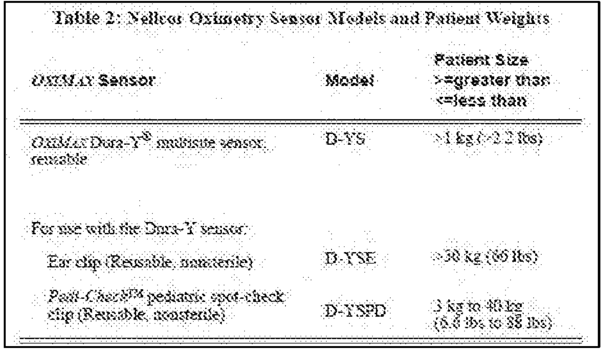
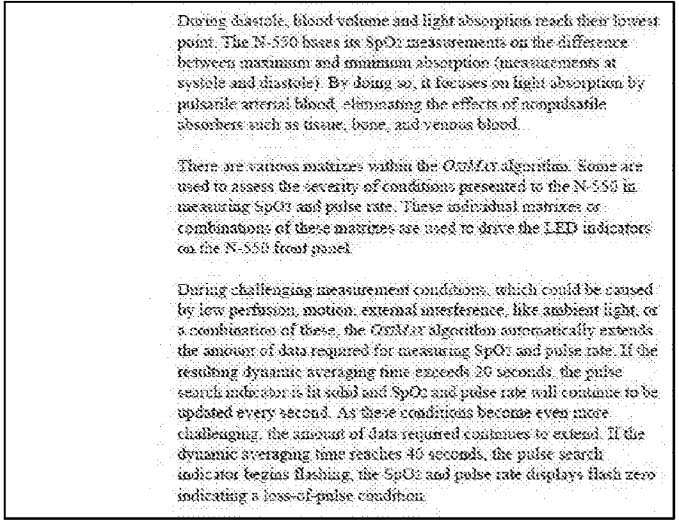
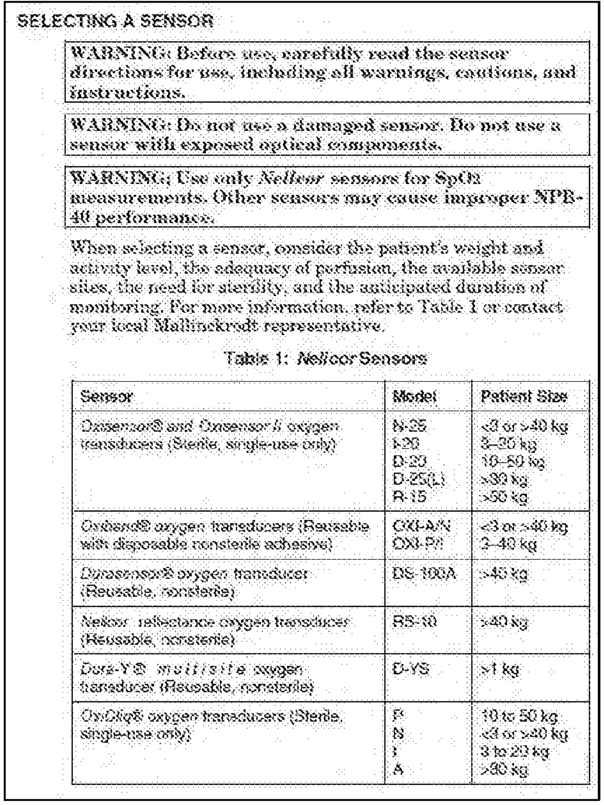



Table 2: Nellcor Oximetry Sensor Models and Patient Weights
<table>
<tr><th>*OxiMax* Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td>*OxiMax* adhesive sensor, single-pateint-use, pediatric</td><td>MAX-P</td><td>10 to 50 kg (22 to 110 lbs)</td></tr>
<tr><td>*OxiMax* adhesive sensor, single-pateint-use, infant</td><td>MAX-I</td><td>3 to 20 kg (6.6 to 44.1 lbs)</td></tr>
<tr><td>*OxiMax* adhesive sensor, single-pateint-use, adult nasal</td><td>MAX-R</td><td>>50 kg (110 lbs)</td></tr>
<tr><td>*OxiMax* OxiCliq® nonadhesive sensor, single-patient-use, adult, reusable cable</td><td>OxiCliq A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td>*OxiMax* OxiCliq nonadhesive sensor, single-patient-use, neonatal/adult, reusable cable</td><td>OxiCliq N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
<tr><td>*OxiMax* OxiCliq nonadhesive sensor, single-patient-use, pediatric, reusable cable</td><td>OxiCliq P</td><td>10 to 50 kg (22 to 110 lbs)</td></tr>
<tr><td>*OxiMax* OxiCliq nonadhesive sensor, single-patient-use, infant, reusable cable</td><td>OxiCliq I</td><td>3 to 20 kg (6.6 to 44.1 lbs)</td></tr>
<tr><td>*OxiMax Durasensor*® finger-clip sensor, reusable, adult</td><td>DS-100A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td>*OxiMax Oxiband*® sensor, reusable, neonatal/adult</td><td>OXI-A/N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
<tr><td>*OxiMax Oxiband* sensor, reusable, pediatric/infant</td><td>OXI-P/I</td><td>3 kg to 40 kg (6.6 lbs to 88 lbs)</td></tr>
</table>
(N-550 Manual, p. 67)</td></tr>
</table>

<table>
<tr><th>Asserted Claim of '040 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>
<table>
<tr><th colspan="3">Table 2: Nellcor Oximetry Sensor Models and Patient Weights</th></tr>
<tr><th><i>OxiMax</i> Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td><i>OxiMax</i> Dura-Y® multisite sensor, reusable</td><td>D-YS</td><td>>1 kg (>2.2 lbs)</td></tr>
<tr><td>For use with the Dura-Y sensor:</td><td></td><td></td></tr>
<tr><td>Ear clip (Reusable, nonsterile)</td><td>D-YSE</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>Pedi-Check</i>™ pediatric spot-check clip (Reusable, nonsterile)</td><td>D-YSPD</td><td>3 kg to 40 kg
(6.6 lbs to 88 lbs)</td></tr>
</table>
(N-550 Manual, p. 68)</td></tr>
</table>

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 During diastole, blood volume and light absorption reach their lowest point. The N-550 bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. There are various matrixes within the OxiMax algorithm. Some are used to assess the severity of conditions presented to the N-550 in measuring SpO_2 and pulse rate. These individual matrixes or combinations of these matrixes are used to drive the LED indicators on the N-550 front panel. During challenging measurement conditions, which could be caused by low perfusion, motion, external interference, like ambient light, or a combination of these, the OxiMax algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate. If the resulting dynamic averaging time exceeds 20 seconds, the pulse search indicator is lit solid and SpO_2 and pulse rate will continue to be updated every second. As these conditions become even more challenging, the amount of data required continues to extend. If the dynamic averaging time reaches 40 seconds, the pulse search indicator begins flashing, the SpO_2 and pulse rate displays flash zero indicating a loss-of-pulse condition. (N-550 Manual, p. 94)

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 (NPB-40 Operator's Manual, p. 15)

SELECTING A SENSOR

WARNING: Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

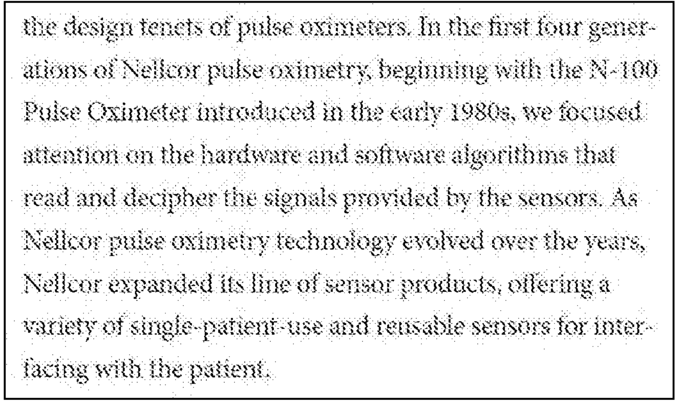
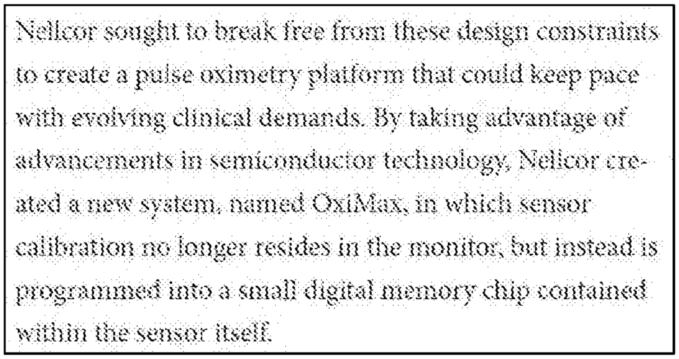
WARNING: Do not use a damaged sensor. Do not use a sensor with exposed optical components.

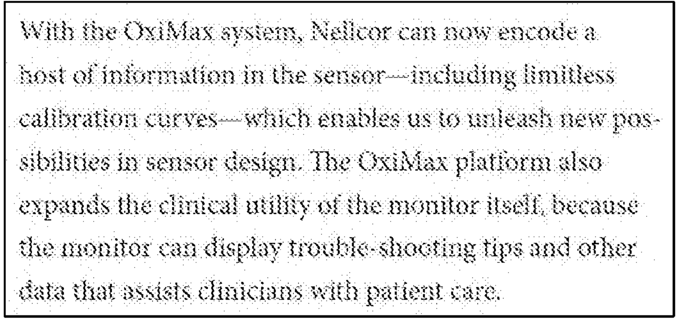
WARNING: Use only *Nellcor* sensors for SpO2 measurements. Other sensors may cause improper NPB-40 performance.

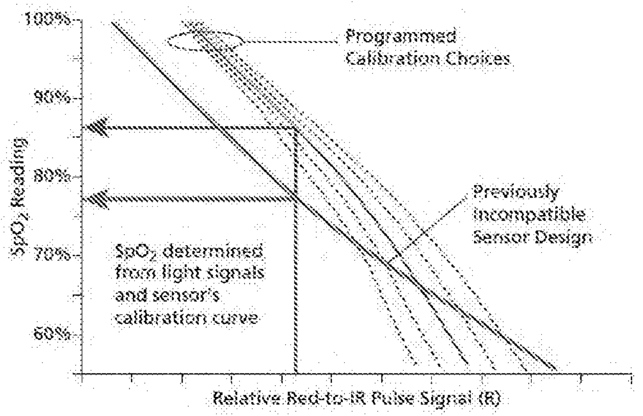
When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Mallinckrodt representative.

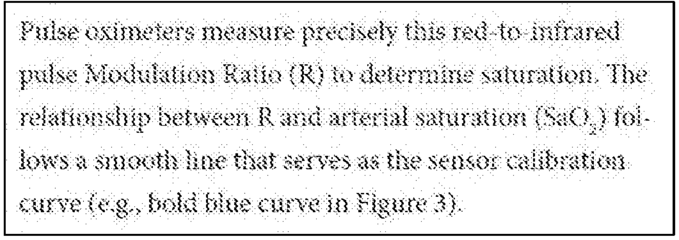
Table 1: *Nellcor* Sensors

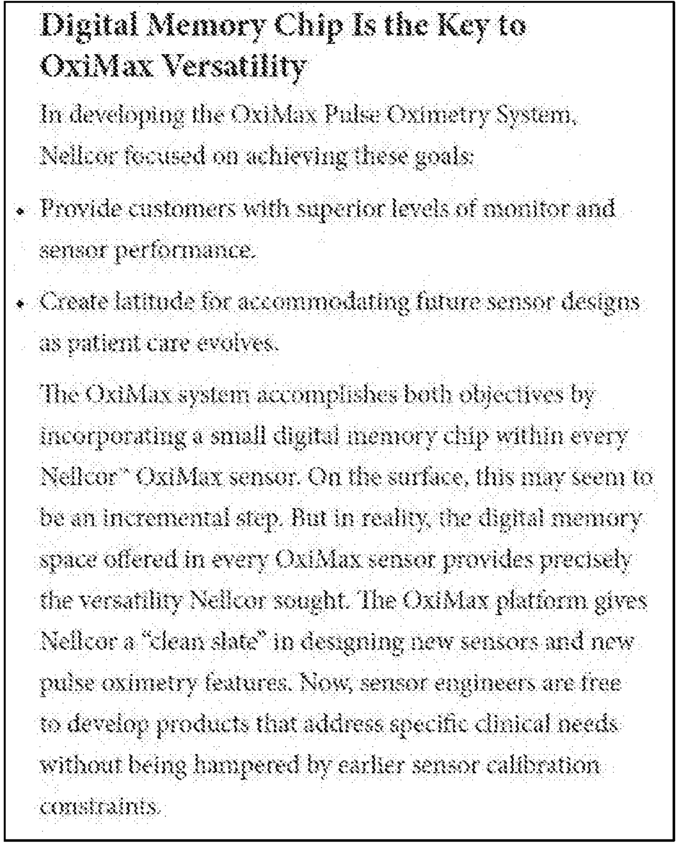
Sensor	Model	Patient Size
Oxisensor® and *Oxisensor II* oxygen transducers (Sterile, single-use only)	N-25 I-20 D-20 D-25(L) R-15	<3 or >40 kg 3–20 kg 10–50 kg >30 kg >50 kg
Oxiband® oxygen transducers (Reusable with disposable nonsterile adhesive)	OXI-A/N OXI-P/I	<3 or >40 kg 3–40 kg
Durasensor® oxygen transducer (Reusable, nonsterile)	DS-100A	>40 kg
Nellcor reflectance oxygen transducer (Reusable, nonsterile)	RS-10	>40 kg
Dura-Y® *multisite* oxygen transducer (Reusable, nonsterile)	D-YS	>1 kg
OxiCliq® oxygen transducers (Sterile, single-use only)	P N I A	10 to 50 kg <3 or >40 kg 3 to 20 kg >30 kg

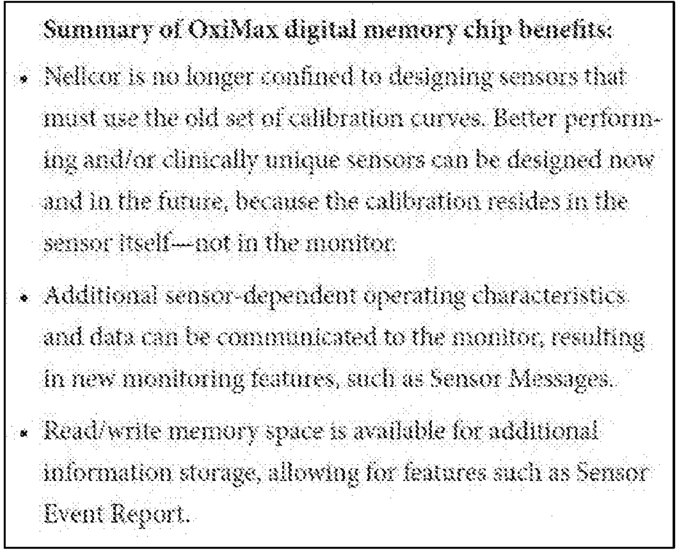
Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 the design tenets of pulse oximeters. In the first four generations of Nellcor pulse oximetry, beginning with the N-100 Pulse Oximeter introduced in the early 1980s, we focused attention on the hardware and software algorithms that read and decipher the signals provided by the sensors. As Nellcor pulse oximetry technology evolved over the years, Nellcor expanded its line of sensor products, offering a variety of single-patient-use and reusable sensors for interfacing with the patient. (White Paper, p. 1)  Nellcor sought to break free from these design constraints to create a pulse oximetry platform that could keep pace with evolving clinical demands. By taking advantage of advancements in semiconductor technology, Nellcor created a new system, named OxiMax, in which sensor calibration no longer resides in the monitor, but instead is programmed into a small digital memory chip contained within the sensor itself. (White Paper, p. 1)

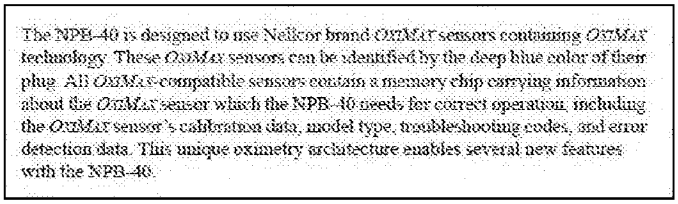
Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 With the OxiMax system, Nellcor can now encode a host of information in the sensor—including limitless calibration curves—which enables us to unleash new possibilities in sensor design. The OxiMax platform also expands the clinical utility of the monitor itself, because the monitor can display trouble-shooting tips and other data that assists clinicians with patient care. (White Paper, p. 1)

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 Figure 3 The blue lines depict the one or more calibration curves programmed into earlier-generation monitors, while the red line indicates a calibration required of a hypothetical new sensor. Such a design would be incompatible with these earlier monitors, since none of the blue curves could provide accurate SpO$_2$ values for the sensor's signals. (White Paper, p. 2)

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 Pulse oximeters measure precisely this red-to-infrared pulse Modulation Ratio (R) to determine saturation. The relationship between R and arterial saturation (SaO_2) follows a smooth line that serves as the sensor calibration curve (e.g., bold blue curve in Figure 3). (White Paper, p. 2)

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 **Digital Memory Chip Is the Key to OxiMax Versatility** In developing the OxiMax Pulse Oximetry System, Nellcor focused on achieving these goals: • Provide customers with superior levels of monitor and sensor performance. • Create latitude for accommodating future sensor designs as patient care evolves. The OxiMax system accomplishes both objectives by incorporating a small digital memory chip within every Nellcor™ OxiMax sensor. On the surface, this may seem to be an incremental step. But in reality, the digital memory space offered in every OxiMax sensor provides precisely the versatility Nellcor sought. The OxiMax platform gives Nellcor a "clean slate" in designing new sensors and new pulse oximetry features. Now, sensor engineers are free to develop products that address specific clinical needs without being hampered by earlier sensor calibration constraints. (White Paper, p. 4)

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 Summary of OxiMax digital memory chip benefits: - Nellcor is no longer confined to designing sensors that must use the old set of calibration curves. Better performing and/or clinically unique sensors can be designed now and in the future, because the calibration resides in the sensor itself—not in the monitor. - Additional sensor-dependent operating characteristics and data can be communicated to the monitor, resulting in new monitoring features, such as Sensor Messages. - Read/write memory space is available for additional information storage, allowing for features such as Sensor Event Report. (White Paper, p. 5)
[1C] wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers;	Nellcor discloses and/or renders obvious "wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers." *See* CHART ONE: '533 Patent, Claim Element 5B above.
[1D] the measurement device comprising one or more lenses configured to receive and to deliver a portion of the input optical beam to tissue, wherein the tissue reflects at least a	Nellcor discloses and/or renders obvious "the measurement device comprising one or more lenses configured to receive and to deliver a portion of the input optical beam to tissue, wherein the tissue reflects at least a portion of the input optical beam delivered to the tissue." *See* CHART ONE: '533 Patent, Claim Element 5D above.

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
portion of the input optical beam delivered to the tissue;	
[1E] the measurement device further comprising a reflective surface configured to receive and redirect at least a portion of light reflected from the tissue;	Nellcor discloses and/or renders obvious "the measurement device further comprising a reflective surface configured to receive and redirect at least a portion of light reflected from the tissue."  The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)

<table>
<tr><th>Asserted Claim of '040 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
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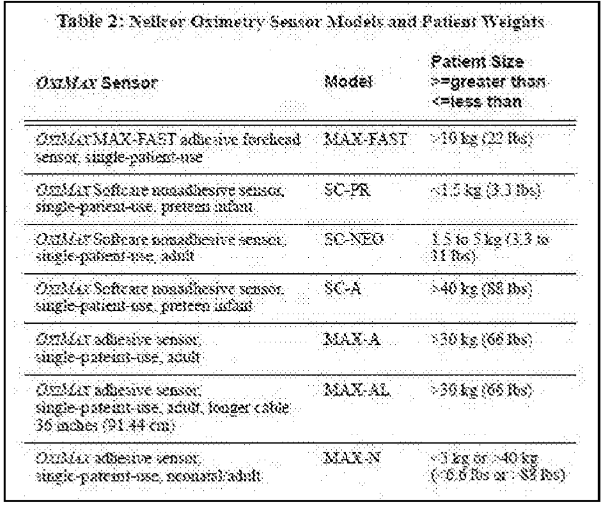

Table 2: Nellcor Oximetry Sensor Models and Patient Weights

<table>
<tr><th><i>OxiMax</i> Sensor</th><th>Model</th><th>Patient Size
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<=less than</th></tr>
<tr><td><i>OxiMax</i> MAX-FAST adhesive forehead sensor, single-patient-use</td><td>MAX-FAST</td><td>>10 kg (22 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-PR</td><td><1.5 kg (3.3 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, adult</td><td>SC-NEO</td><td>1.5 to 5 kg (3.3 to 11 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult</td><td>MAX-A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult, longer cable 36 inches (91.44 cm)</td><td>MAX-AL</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, neonatal/adult</td><td>MAX-N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
</table>

(N-550 Manual, p. 66)
</td></tr>
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<table>
<tr><th>Asserted Claim of '040 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
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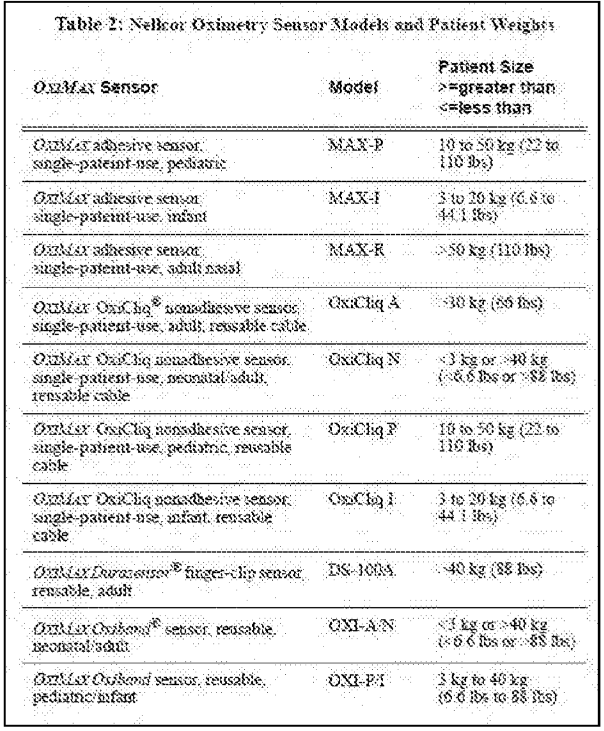


Table 2: Nellcor Oximetry Sensor Models and Patient Weights

<table>
<tr><th><i>OxiMax</i> Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, pediatric</td><td>MAX-P</td><td>10 to 50 kg (22 to 110 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, infant</td><td>MAX-I</td><td>3 to 20 kg (6.6 to 44.1 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult nasal</td><td>MAX-R</td><td>>50 kg (110 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq® nonadhesive sensor, single-patient-use, adult, reusable cable</td><td>OxiCliq A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq nonadhesive sensor, single-patient-use, neonatal/adult, reusable cable</td><td>OxiCliq N</td><td><3 kg or >40 kg (<6.6 lbs or >82 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq nonadhesive sensor, single-patient-use, pediatric, reusable cable</td><td>OxiCliq P</td><td>10 to 50 kg (22 to 110 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq nonadhesive sensor, single-patient-use, infant, reusable cable</td><td>OxiCliq I</td><td>3 to 20 kg (6.6 to 44.1 lbs)</td></tr>
<tr><td><i>OxiMax Durasensor</i>® finger-clip sensor, reusable, adult</td><td>DS-100A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td><i>OxiMax Oxiband</i>® sensor, reusable, neonatal/adult</td><td>OXI-A/N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
<tr><td><i>OxiMax Oxiband</i> sensor, reusable, pediatric/infant</td><td>OXI-P/I</td><td>3 kg to 40 kg (6.6 lbs to 88 lbs)</td></tr>
</table>

(N-550 Manual, p. 67)</td></tr>
</table>

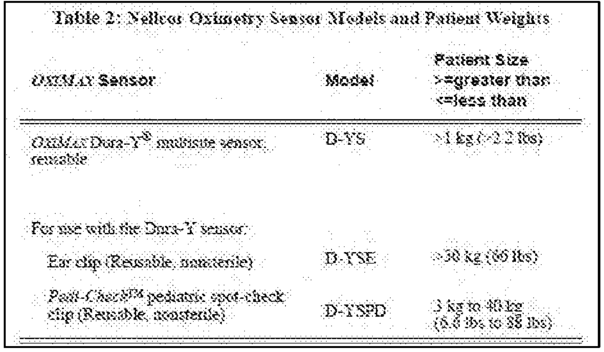
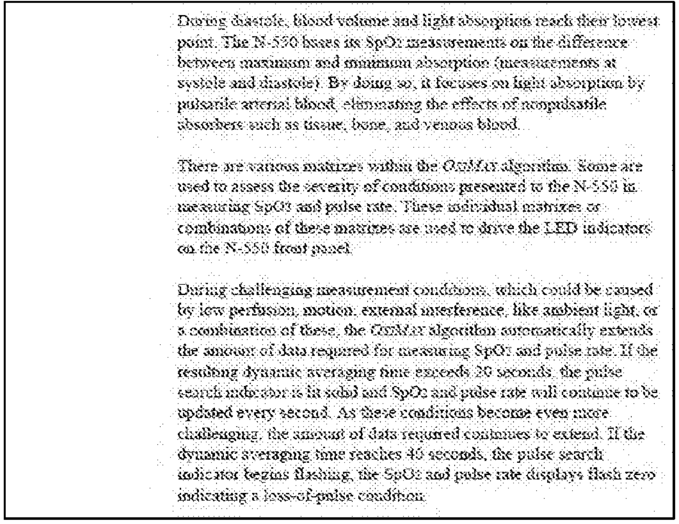
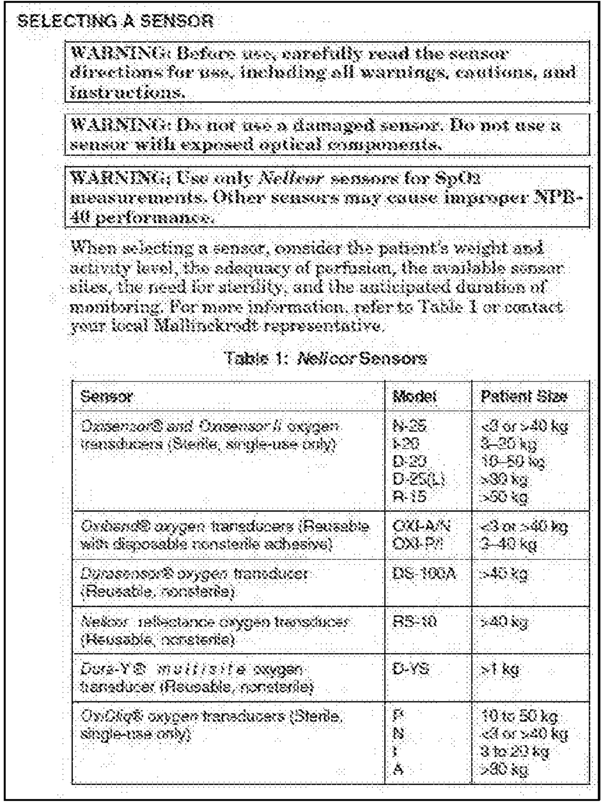
Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 (N-550 Manual, p. 68)

Table 2: Nellcor Oximetry Sensor Models and Patient Weights

OXIMAX Sensor	Model	Patient Size >=greater than <=less than
OXIMAX Dura-Y® multisite sensor, reusable	D-YS	>1 kg (>2.2 lbs)
For use with the Dura-Y sensor:		
Ear clip (Reusable, nonsterile)	D-YSE	>30 kg (66 lbs)
Pedi-Check™ pediatric spot-check clip (Reusable, nonsterile)	D-YSPD	3 kg to 40 kg (6.6 lbs to 88 lbs)

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 During diastole, blood volume and light absorption reach their lowest point. The N-550 bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. There are various matrixes within the *OxiMax* algorithm. Some are used to assess the severity of conditions presented to the N-550 in measuring SpO_2 and pulse rate. These individual matrixes or combinations of these matrixes are used to drive the LED indicators on the N-550 front panel. During challenging measurement conditions, which could be caused by low perfusion, motion, external interference, like ambient light, or a combination of these, the *OxiMax* algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate. If the resulting dynamic averaging time exceeds 20 seconds, the pulse search indicator is lit solid and SpO_2 and pulse rate will continue to be updated every second. As these conditions become even more challenging, the amount of data required continues to extend. If the dynamic averaging time reaches 40 seconds, the pulse search indicator begins flashing, the SpO_2 and pulse rate displays flash zero indicating a loss-of-pulse condition. (N-550 Manual, p. 94)

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 (NPB-40 Operator's Manual, p. 15)

SELECTING A SENSOR

WARNING: Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

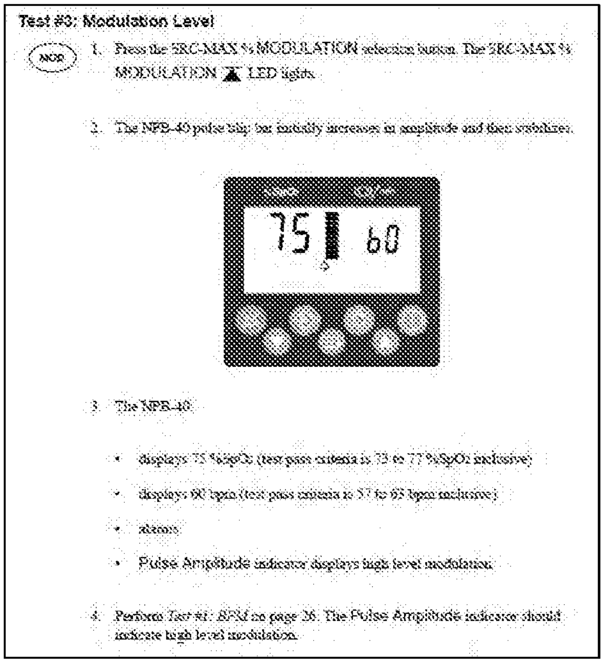
WARNING: Do not use a damaged sensor. Do not use a sensor with exposed optical components.

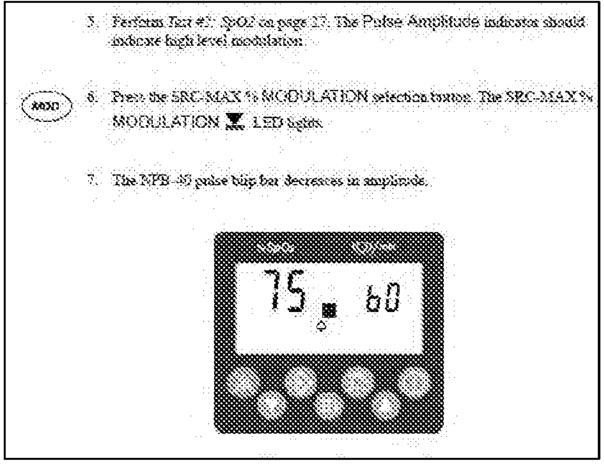
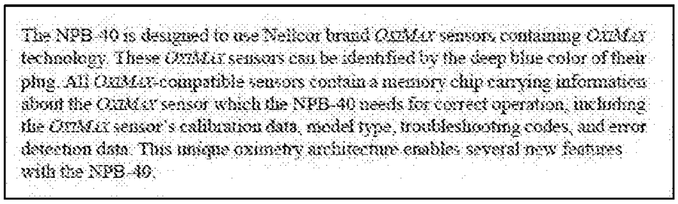
WARNING: Use only *Nellcor* sensors for SpO2 measurements. Other sensors may cause improper NPB-40 performance.

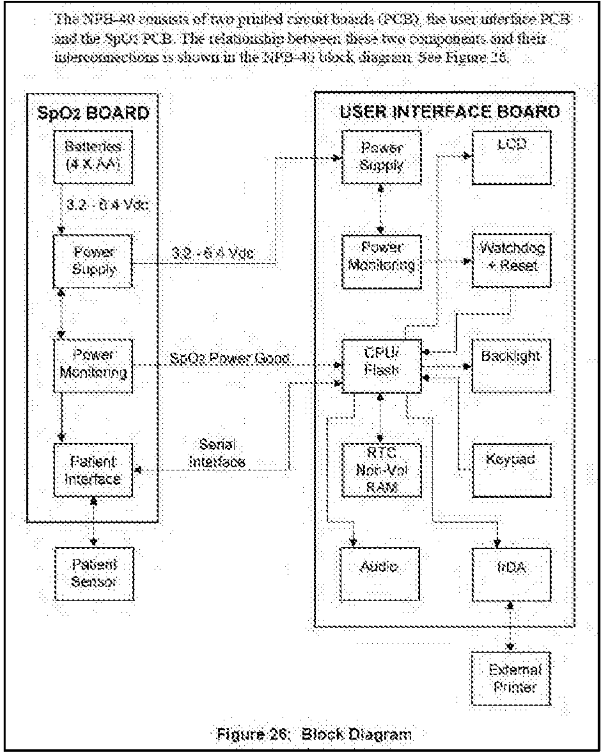
When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Mallinckrodt representative.

Table 1: *Nellcor* Sensors

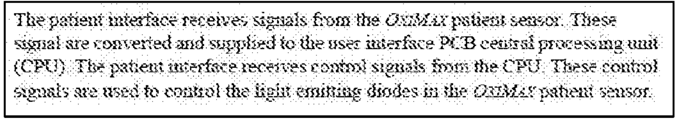
Sensor	Model	Patient Size
Oxisensor® and *Oxisensor II* oxygen transducers (Sterile, single-use only)	N-25 I-20 D-20 D-25(L) R-15	<3 or >40 kg 3–20 kg 10–50 kg >30 kg >50 kg
Oxiband® oxygen transducers (Reusable with disposable nonsterile adhesive)	OXI-A/N OXI-P/I	<3 or >40 kg 3–40 kg
Durasensor® oxygen transducer (Reusable, nonsterile)	DS-100A	>40 kg
Nellcor reflectance oxygen transducer (Reusable, nonsterile)	RS-10	>40 kg
Dura-Y® *multisite* oxygen transducer (Reusable, nonsterile)	D-YS	>1 kg
OxiCliq® oxygen transducers (Sterile, single-use only)	P N I A	10 to 50 kg <3 or >40 kg 3 to 20 kg >30 kg

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
[1F] the measurement device further comprising a receiver configured to: capture light while the LEDs are off and convert the captured light into a first signal and capture light while at least one of the LEDs is on and convert the captured light into a second signal, the captured light including at least a portion of the input optical beam reflected from the tissue;	Nellcor discloses and/or renders obvious "the measurement device further comprising a receiver configured to: capture light while the LEDs are off and convert the captured light into a first signal and capture light while at least one of the LEDs is on and convert the captured light into a second signal, the captured light including at least a portion of the input optical beam reflected from the tissue."  Test #3: Modulation Level 1. Press the SRC-MAX % MODULATION selection button. The SRC-MAX % MODULATION ▲ LED lights. 2. The NPB-40 pulse blip bar initially increases in amplitude and then stabilizes. 3. The NPB-40: - displays 75 %SpO2 (test pass criteria is 73 to 77 %SpO2 inclusive) - displays 60 bpm (test pass criteria is 57 to 63 bpm inclusive) - alarms - Pulse Amplitude indicator displays high level modulation 4. Perform Test #1: BPM on page 26. The Pulse Amplitude indicator should indicate high level modulation. (NPB-40 Service Manual, p. 29)

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 5. Perform Test #2: SpO2 on page 27. The Pulse Amplitude indicator should indicate high level modulation. 6. Press the SRC-MAX % MODULATION selection button. The SRC-MAX % MODULATION ▼ LED lights. 7. The NPB-40 pulse blip bar decreases in amplitude. (NPB-40 Service Manual, p. 29)  The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)

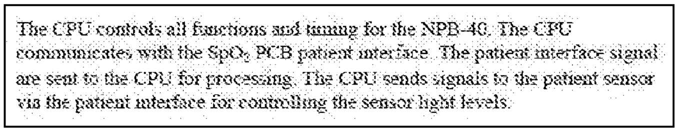
Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 The NPB-40 consists of two printed circuit boards (PCB), the user interface PCB and the SpO2 PCB. The relationship between these two components and their interconnections is shown in the NPB-40 block diagram. See Figure 26. Figure 26: Block Diagram (NPB-40 Service Manual, p. 78)

<table>
<tr><th>Asserted Claim of '040 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>



The patient interface receives signals from the *OxiMax* patient sensor. These signal are converted and supplied to the user interface PCB central processing unit (CPU). The patient interface receives control signals from the CPU. These control signals are used to control the light emitting diodes in the *OxiMax* patient sensor.

(NPB-40 Service Manual, p. 78)



The CPU controls all functions and timing for the NPB-40. The CPU communicates with the SpO_2 PCB patient interface. The patient interface signal are sent to the CPU for processing. The CPU sends signals to the patient sensor via the patient interface for controlling the sensor light levels.

(NPB-40 Service Manual, p. 80)

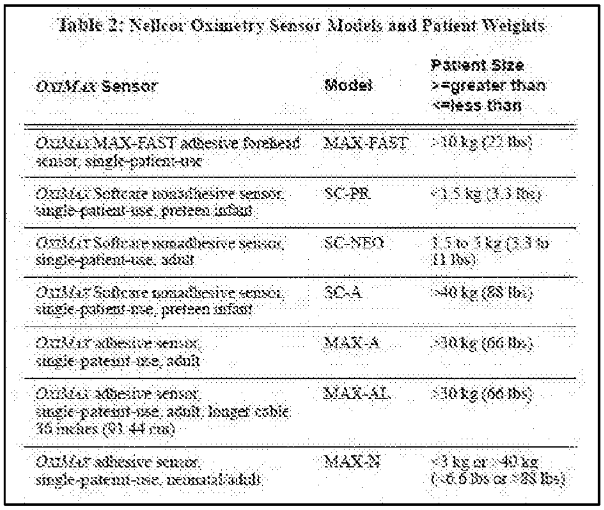
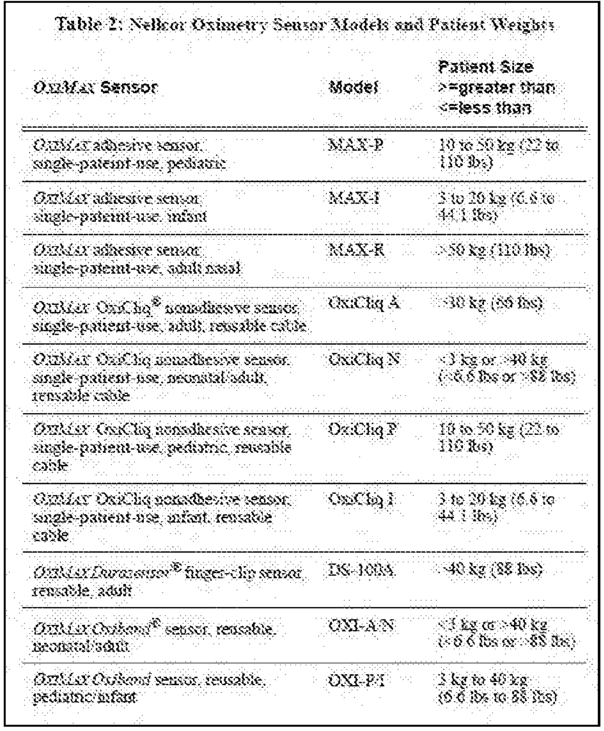


Table 2: Nellcor Oximetry Sensor Models and Patient Weights

<table>
<tr><th><i>OxiMax</i> Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td><i>OxiMax</i> MAX-FAST adhesive forehead sensor, single-patient-use</td><td>MAX-FAST</td><td>>10 kg (22 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-PR</td><td><1.5 kg (3.3 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, adult</td><td>SC-NEO</td><td>1.5 to 3 kg (3.3 to 11 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult</td><td>MAX-A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult, longer cable 36 inches (91.44 cm)</td><td>MAX-AL</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, neonatal/adult</td><td>MAX-N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
</table>

(N-550 Manual, p. 66)

</td></tr>
</table>

<table>
<tr><th>Asserted Claim of ’040 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>
<table>
<tr><th colspan="3">Table 2: Nellcor Oximetry Sensor Models and Patient Weights</th></tr>
<tr><th><i>OxiMax</i> Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, pediatric</td><td>MAX-P</td><td>10 to 50 kg (22 to 110 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, infant</td><td>MAX-I</td><td>3 to 20 kg (6.6 to 44.1 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult nasal</td><td>MAX-R</td><td>>50 kg (110 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq® nonadhesive sensor, single-patient-use, adult, reusable cable</td><td>OxiCliq A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq nonadhesive sensor, single-patient-use, neonatal/adult, reusable cable</td><td>OxiCliq N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq nonadhesive sensor, single-patient-use, pediatric, reusable cable</td><td>OxiCliq P</td><td>10 to 50 kg (22 to 110 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq nonadhesive sensor, single-patient-use, infant, reusable cable</td><td>OxiCliq I</td><td>3 to 20 kg (6.6 to 44.1 lbs)</td></tr>
<tr><td><i>OxiMax Durasensor</i>® finger-clip sensor, reusable, adult</td><td>DS-100A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td><i>OxiMax Oxiband</i>® sensor, reusable, neonatal/adult</td><td>OXI-A/N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
<tr><td><i>OxiMax Oxiband</i> sensor, reusable, pediatric/infant</td><td>OXI-P/I</td><td>3 kg to 40 kg (6.6 lbs to 88 lbs)</td></tr>
</table>
(N-550 Manual, p. 67)</td></tr>
</table>

<table>
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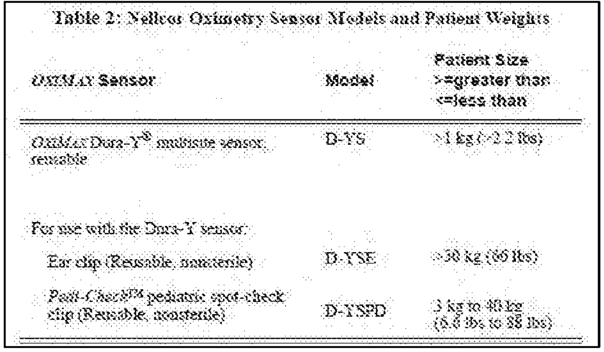
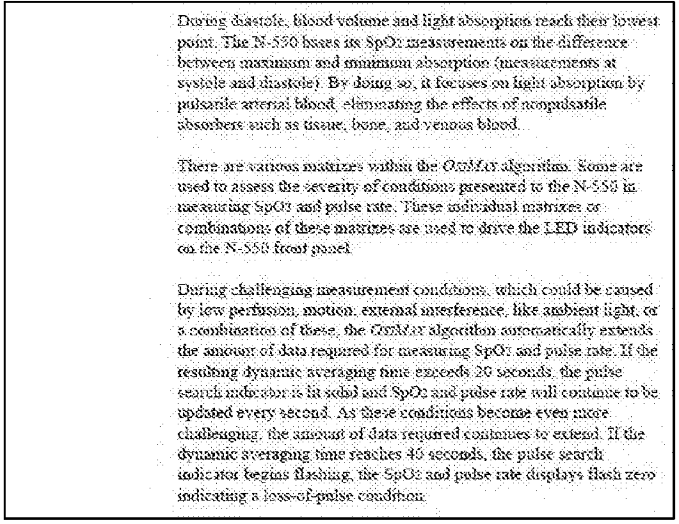
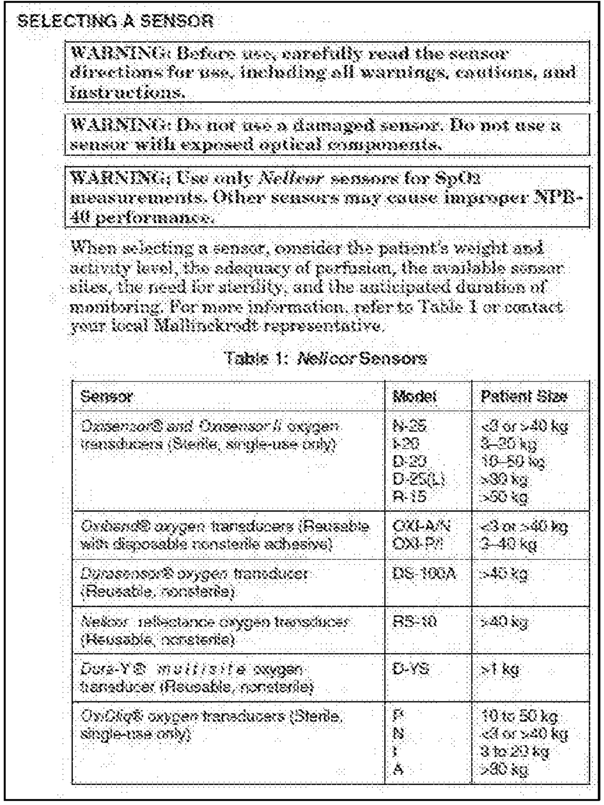


Table 2: Nellcor Oximetry Sensor Models and Patient Weights

<table>
<tr><th>OXIMAX Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td>OXIMAX Dura-Y® multisite sensor, reusable</td><td>D-YS</td><td>>1 kg (>2.2 lbs)</td></tr>
<tr><td>For use with the Dura-Y sensor:</td><td></td><td></td></tr>
<tr><td>Ear clip (Reusable, nonsterile)</td><td>D-YSE</td><td>>30 kg (66 lbs)</td></tr>
<tr><td>Pedi-Check™ pediatric spot-check clip (Reusable, nonsterile)</td><td>D-YSPD</td><td>3 kg to 40 kg (6.6 lbs to 88 lbs)</td></tr>
</table>

(N-550 Manual, p. 68)
</td></tr>
</table>

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 During diastole, blood volume and light absorption reach their lowest point. The N-550 bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. There are various matrixes within the *OxiMax* algorithm. Some are used to assess the severity of conditions presented to the N-550 in measuring SpO_2 and pulse rate. These individual matrixes or combinations of these matrixes are used to drive the LED indicators on the N-550 front panel. During challenging measurement conditions, which could be caused by low perfusion, motion, external interference, like ambient light, or a combination of these, the *OxiMax* algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate. If the resulting dynamic averaging time exceeds 20 seconds, the pulse search indicator is lit solid and SpO_2 and pulse rate will continue to be updated every second. As these conditions become even more challenging, the amount of data required continues to extend. If the dynamic averaging time reaches 40 seconds, the pulse search indicator begins flashing, the SpO_2 and pulse rate displays flash zero indicating a loss-of-pulse condition. (N-550 Manual, p. 94)

<table>
<tr><th>Asserted Claim of '040 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>


SELECTING A SENSOR

WARNING: Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

WARNING: Do not use a damaged sensor. Do not use a sensor with exposed optical components.

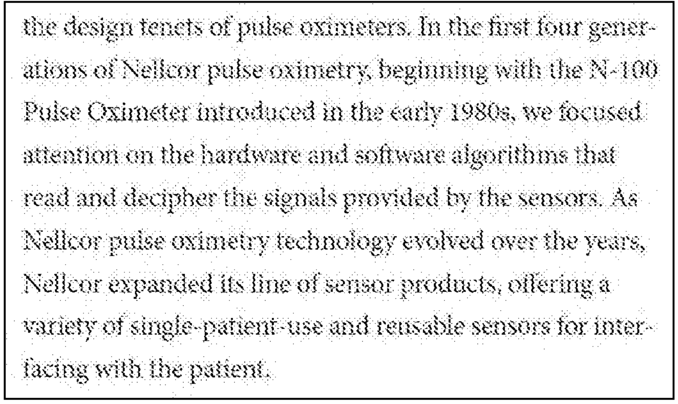
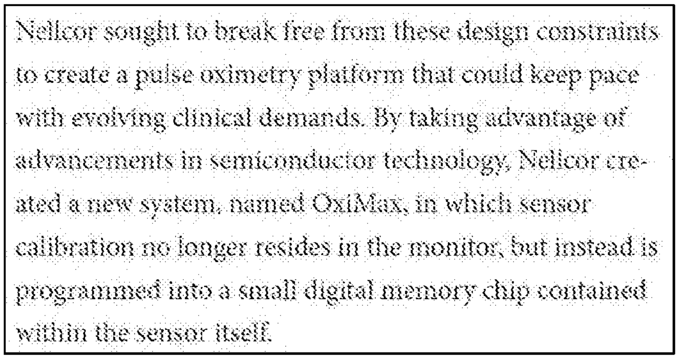
WARNING: Use only *Nellcor* sensors for SpO2 measurements. Other sensors may cause improper NPB-40 performance.

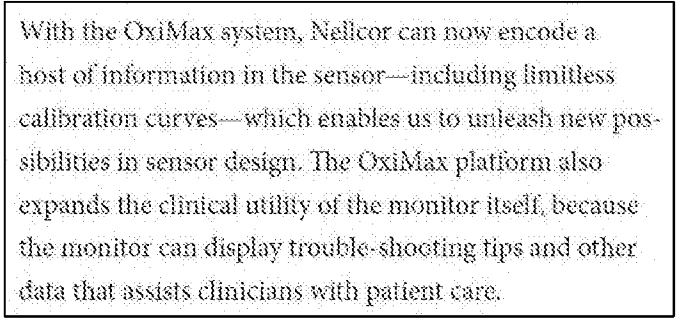
When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Mallinckrodt representative.

Table 1: *Nellcor* Sensors

<table>
<tr><th>Sensor</th><th>Model</th><th>Patient Size</th></tr>
<tr><td><i>Oxisensor</i>® and <i>Oxisensor II</i> oxygen transducers (Sterile, single-use only)</td><td>N-25
I-20
D-20
D-25(L)
R-15</td><td><3 or >40 kg
3–20 kg
10–50 kg
>30 kg
>50 kg</td></tr>
<tr><td><i>Oxiband</i>® oxygen transducers (Reusable with disposable nonsterile adhesive)</td><td>OXI-A/N
OXI-P/I</td><td><3 or >40 kg
3–40 kg</td></tr>
<tr><td><i>Durasensor</i>® oxygen transducer (Reusable, nonsterile)</td><td>DS-100A</td><td>>40 kg</td></tr>
<tr><td><i>Nellcor</i> reflectance oxygen transducer (Reusable, nonsterile)</td><td>RS-10</td><td>>40 kg</td></tr>
<tr><td><i>Dura-Y</i>® <i>multisite</i> oxygen transducer (Reusable, nonsterile)</td><td>D-YS</td><td>>1 kg</td></tr>
<tr><td><i>OxiCliq</i>® oxygen transducers (Sterile, single-use only)</td><td>P
N
I
A</td><td>10 to 50 kg
<3 or >40 kg
3 to 20 kg
>30 kg</td></tr>
</table>

(NPB-40 Operator's Manual, p. 15)
</td></tr>
</table>

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 the design tenets of pulse oximeters. In the first four generations of Nellcor pulse oximetry, beginning with the N-100 Pulse Oximeter introduced in the early 1980s, we focused attention on the hardware and software algorithms that read and decipher the signals provided by the sensors. As Nellcor pulse oximetry technology evolved over the years, Nellcor expanded its line of sensor products, offering a variety of single-patient-use and reusable sensors for interfacing with the patient. **(White Paper, p. 1)**  Nellcor sought to break free from these design constraints to create a pulse oximetry platform that could keep pace with evolving clinical demands. By taking advantage of advancements in semiconductor technology, Nellcor created a new system, named OxiMax, in which sensor calibration no longer resides in the monitor, but instead is programmed into a small digital memory chip contained within the sensor itself. **(White Paper, p. 1)**

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 With the OxiMax system, Nellcor can now encode a host of information in the sensor—including limitless calibration curves—which enables us to unleash new possibilities in sensor design. The OxiMax platform also expands the clinical utility of the monitor itself, because the monitor can display trouble-shooting tips and other data that assists clinicians with patient care. (White Paper, p. 1)

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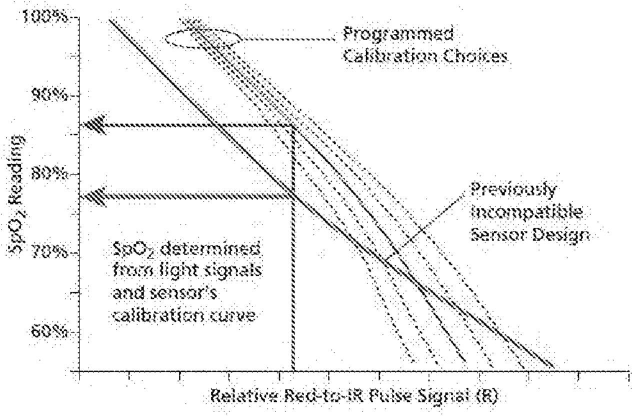
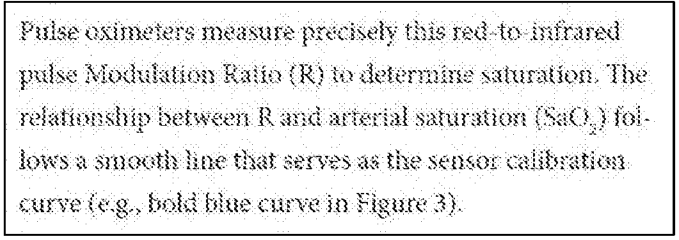
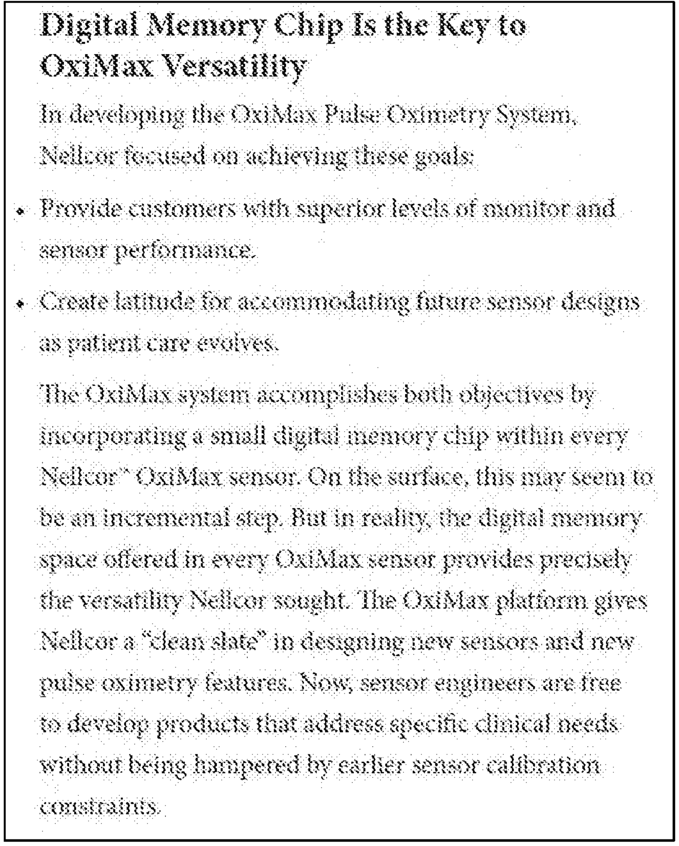
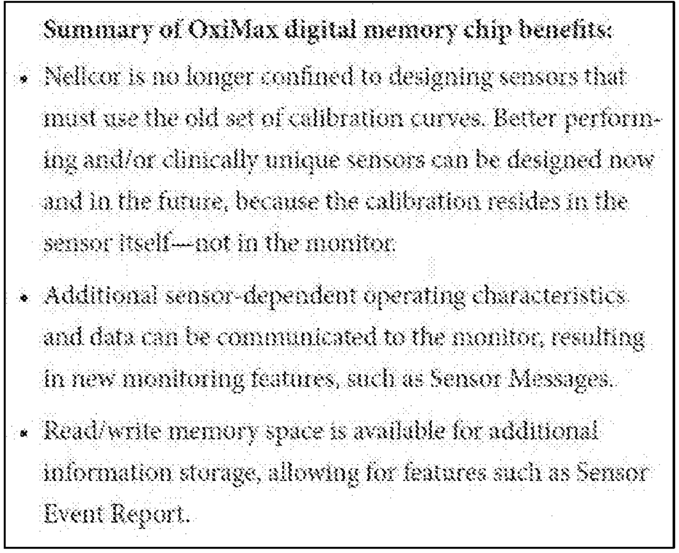
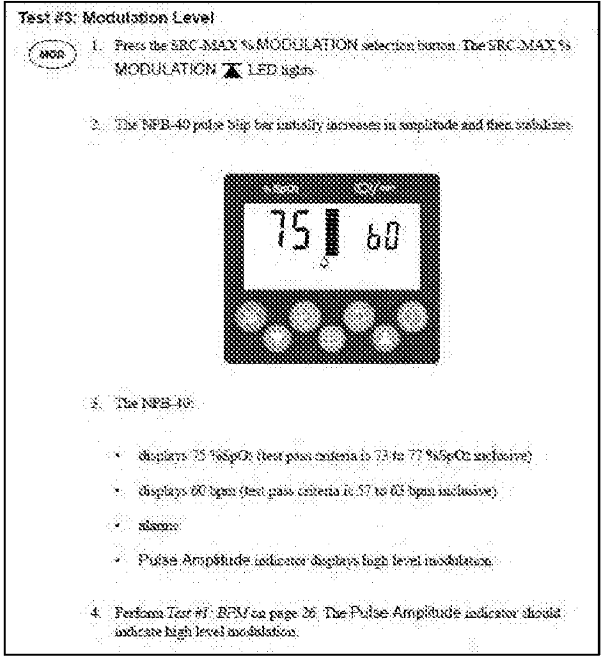
	 Figure 3 The blue lines depict the one or more calibration curves programmed into earlier-generation monitors, while the red line indicates a calibration required of a hypothetical new sensor. Such a design would be incompatible with these earlier monitors, since none of the blue curves could provide accurate SpO_2 values for the sensor's signals. (White Paper, p. 2)

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 Pulse oximeters measure precisely this red-to-infrared pulse Modulation Ratio (R) to determine saturation. The relationship between R and arterial saturation (SaO$_2$) follows a smooth line that serves as the sensor calibration curve (e.g., bold blue curve in Figure 3). (White Paper, p. 2)

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 **Digital Memory Chip Is the Key to OxiMax Versatility** In developing the OxiMax Pulse Oximetry System, Nellcor focused on achieving these goals: • Provide customers with superior levels of monitor and sensor performance. • Create latitude for accommodating future sensor designs as patient care evolves. The OxiMax system accomplishes both objectives by incorporating a small digital memory chip within every Nellcor™ OxiMax sensor. On the surface, this may seem to be an incremental step. But in reality, the digital memory space offered in every OxiMax sensor provides precisely the versatility Nellcor sought. The OxiMax platform gives Nellcor a "clean slate" in designing new sensors and new pulse oximetry features. Now, sensor engineers are free to develop products that address specific clinical needs without being hampered by earlier sensor calibration constraints. (White Paper, p. 4)

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 Summary of OxiMax digital memory chip benefits: • Nellcor is no longer confined to designing sensors that must use the old set of calibration curves. Better performing and/or clinically unique sensors can be designed now and in the future, because the calibration resides in the sensor itself—not in the monitor. • Additional sensor-dependent operating characteristics and data can be communicated to the monitor, resulting in new monitoring features, such as Sensor Messages. • Read/write memory space is available for additional information storage, allowing for features such as Sensor Event Report. (White Paper, p. 5)
[1G] the measurement device configured to improve a signal-to-noise ratio of the input optical beam reflected from the tissue by differencing the first signal and the second signal;	Nellcor discloses and/or renders obvious "the measurement device configured to improve a signal-to-noise ratio of the input optical beam reflected from the tissue by differencing the first signal and the second signal."

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 Test #3: Modulation Level 1. Press the SRC-MAX % MODULATION selection button. The SRC-MAX % MODULATION ▲ LED lights. 2. The NPB-40 pulse blip bar initially increases in amplitude and then stabilizes. 3. The NPB-40: - displays 75 %SpO2 (test pass criteria is 73 to 77 %SpO2 inclusive) - displays 60 bpm (test pass criteria is 57 to 63 bpm inclusive) - alarms - Pulse Amplitude indicator displays high level modulation. 4. Perform *Test #1: BPM* on page 26. The Pulse Amplitude indicator should indicate high level modulation. (NPB-40 Service Manual, p. 29)

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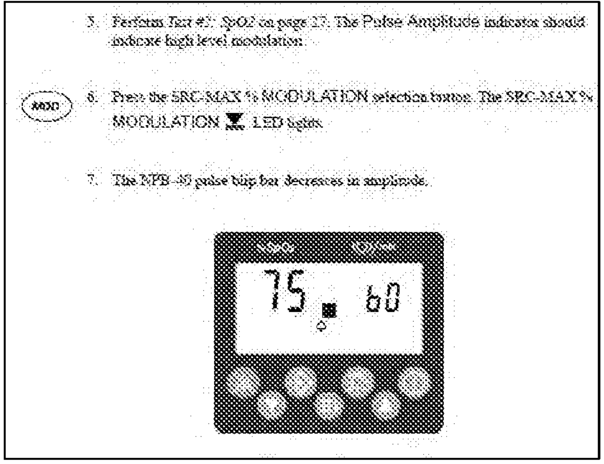
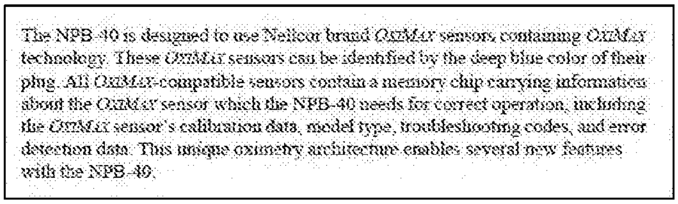
	 5. Perform *Test #2: SpO2* on page 27. The Pulse Amplitude indicator should indicate high level modulation. MOD 6. Press the SRC-MAX % MODULATION selection button. The SRC-MAX % MODULATION ▼ LED lights. 7. The NPB-40 pulse blip bar decreases in amplitude. (NPB-40 Service Manual, p. 29)  The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)

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	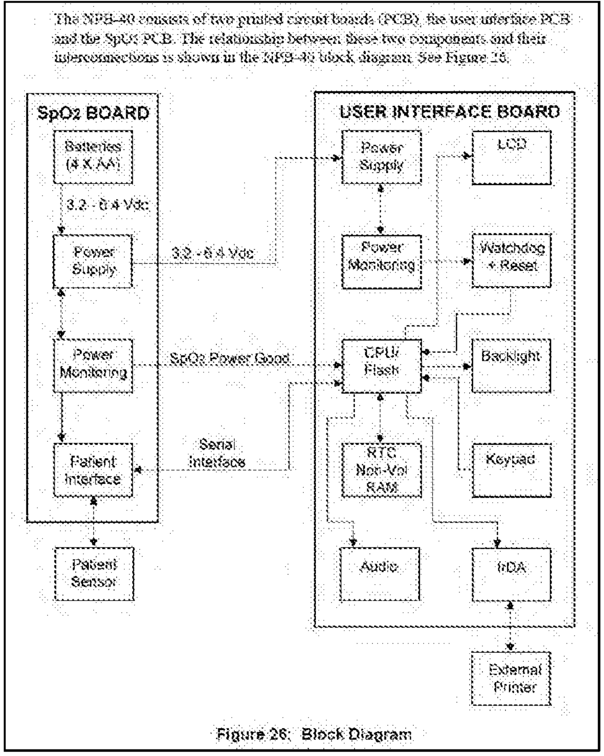 The NPB-40 consists of two printed circuit boards (PCB), the user interface PCB and the SpO2 PCB. The relationship between these two components and their interconnections is shown in the NPB-40 block diagram. See Figure 26. Figure 26: Block Diagram (NPB-40 Service Manual, p. 78)

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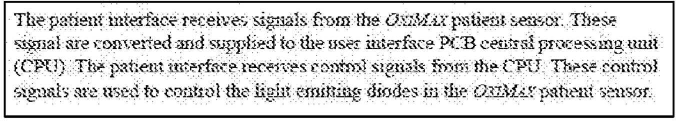
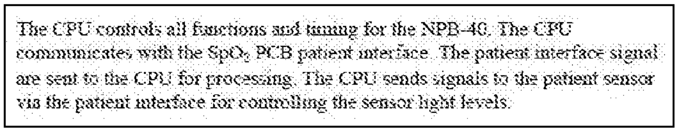


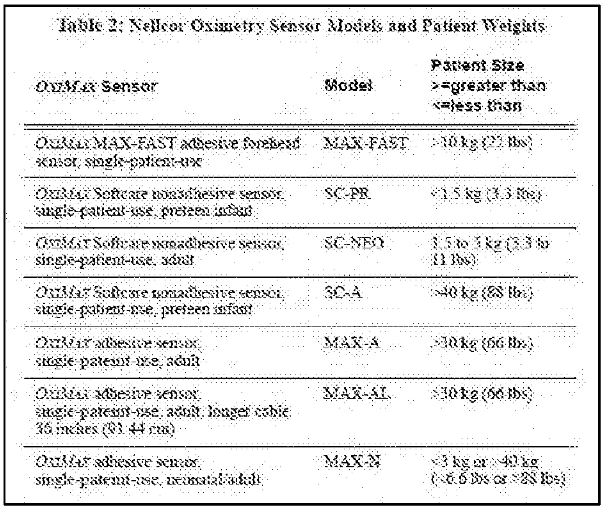
The patient interface receives signals from the OxiMax patient sensor. These signal are converted and supplied to the user interface PCB central processing unit (CPU). The patient interface receives control signals from the CPU. These control signals are used to control the light emitting diodes in the OxiMax patient sensor.

(NPB-40 Service Manual, p. 78)



The CPU controls all functions and timing for the NPB-40. The CPU communicates with the SpO₂ PCB patient interface. The patient interface signal are sent to the CPU for processing. The CPU sends signals to the patient sensor via the patient interface for controlling the sensor light levels.

(NPB-40 Service Manual, p. 80)



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<tr><td>OxiMax Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-PR</td><td><1.5 kg (3.3 lbs)</td></tr>
<tr><td>OxiMax Softcare nonadhesive sensor, single-patient-use, adult</td><td>SC-NEO</td><td>1.5 to 5 kg (3.3 to 11 lbs)</td></tr>
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<tr><td>OxiMax adhesive sensor, single-pateint-use, neonatal/adult</td><td>MAX-N</td><td><3 kg or >40 kg
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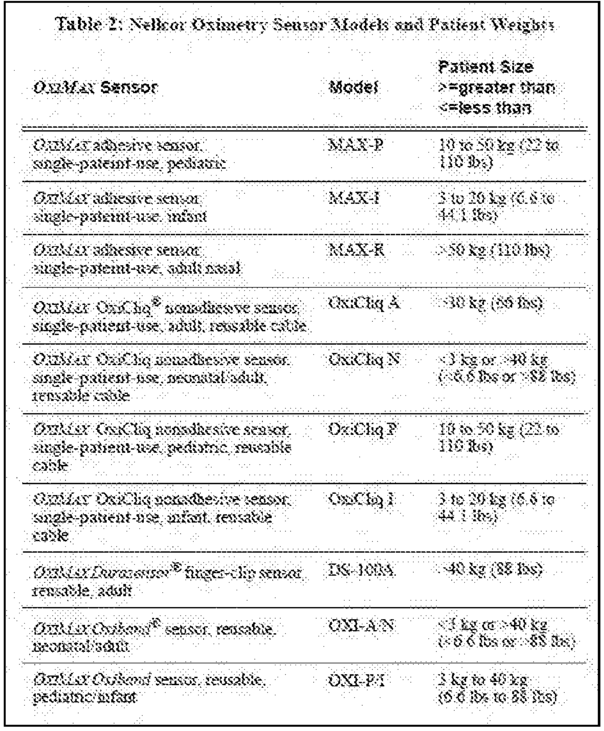

Table 2: Nellcor Oximetry Sensor Models and Patient Weights

<table>
<tr><th>OxiMax Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td>OxiMax adhesive sensor, single-pateint-use, pediatric</td><td>MAX-P</td><td>10 to 50 kg (22 to 110 lbs)</td></tr>
<tr><td>OxiMax adhesive sensor, single-pateint-use, infant</td><td>MAX-I</td><td>3 to 20 kg (6.6 to 44.1 lbs)</td></tr>
<tr><td>OxiMax adhesive sensor, single-pateint-use, adult nasal</td><td>MAX-R</td><td>>50 kg (110 lbs)</td></tr>
<tr><td>OxiMax OxiCliq® nonadhesive sensor, single-patient-use, adult, reusable cable</td><td>OxiCliq A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td>OxiMax OxiCliq nonadhesive sensor, single-patient-use, neonatal/adult, reusable cable</td><td>OxiCliq N</td><td><3 kg or >40 kg (<6.6 lbs or >82 lbs)</td></tr>
<tr><td>OxiMax OxiCliq nonadhesive sensor, single-patient-use, pediatric, reusable cable</td><td>OxiCliq P</td><td>10 to 50 kg (22 to 110 lbs)</td></tr>
<tr><td>OxiMax OxiCliq nonadhesive sensor, single-patient-use, infant, reusable cable</td><td>OxiCliq I</td><td>3 to 20 kg (6.6 to 44.1 lbs)</td></tr>
<tr><td>OxiMax Durasensor® finger-clip sensor, reusable, adult</td><td>DS-100A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td>OxiMax Oxiband® sensor, reusable, neonatal/adult</td><td>OXI-A/N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
<tr><td>OxiMax Oxiband sensor, reusable, pediatric/infant</td><td>OXI-P/I</td><td>3 kg to 40 kg (6.6 lbs to 88 lbs)</td></tr>
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(N-550 Manual, p. 67)
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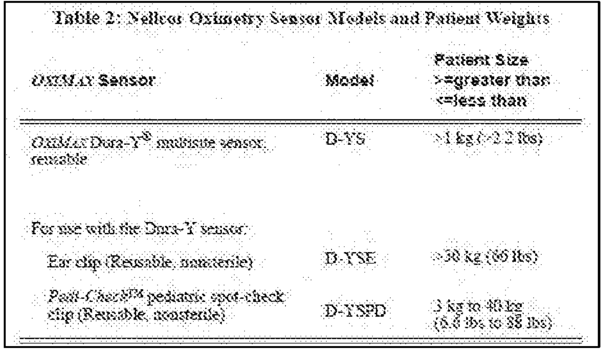
<tr><td></td><td>
Table 2: Nellcor Oximetry Sensor Models and Patient Weights
<table>
<tr><th>OxiMax Sensor</th><th>Model</th><th>Patient Size
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<tr><td>OxiMax Dura-Y® multisite sensor, reusable</td><td>D-YS</td><td>>1 kg (>2.2 lbs)</td></tr>
<tr><td>For use with the Dura-Y sensor:</td><td></td><td></td></tr>
<tr><td>Ear clip (Reusable, nonsterile)</td><td>D-YSE</td><td>>30 kg (66 lbs)</td></tr>
<tr><td>Pedi-Check™ pediatric spot-check clip (Reusable, nonsterile)</td><td>D-YSPD</td><td>3 kg to 40 kg
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	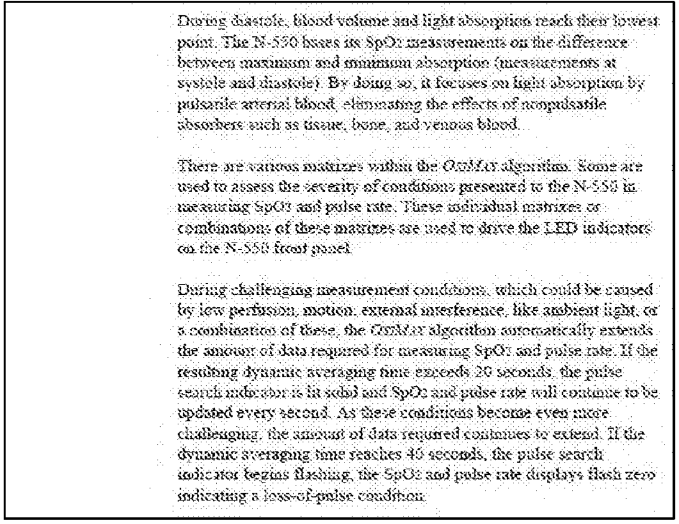 During diastole, blood volume and light absorption reach their lowest point. The N-550 bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. There are various matrixes within the *OxiMax* algorithm. Some are used to assess the severity of conditions presented to the N-550 in measuring SpO_2 and pulse rate. These individual matrixes or combinations of these matrixes are used to drive the LED indicators on the N-550 front panel. During challenging measurement conditions, which could be caused by low perfusion, motion, external interference, like ambient light, or a combination of these, the *OxiMax* algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate. If the resulting dynamic averaging time exceeds 20 seconds, the pulse search indicator is lit solid and SpO_2 and pulse rate will continue to be updated every second. As these conditions become even more challenging, the amount of data required continues to extend. If the dynamic averaging time reaches 40 seconds, the pulse search indicator begins flashing, the SpO_2 and pulse rate displays flash zero indicating a loss-of-pulse condition. (N-550 Manual, p. 94)

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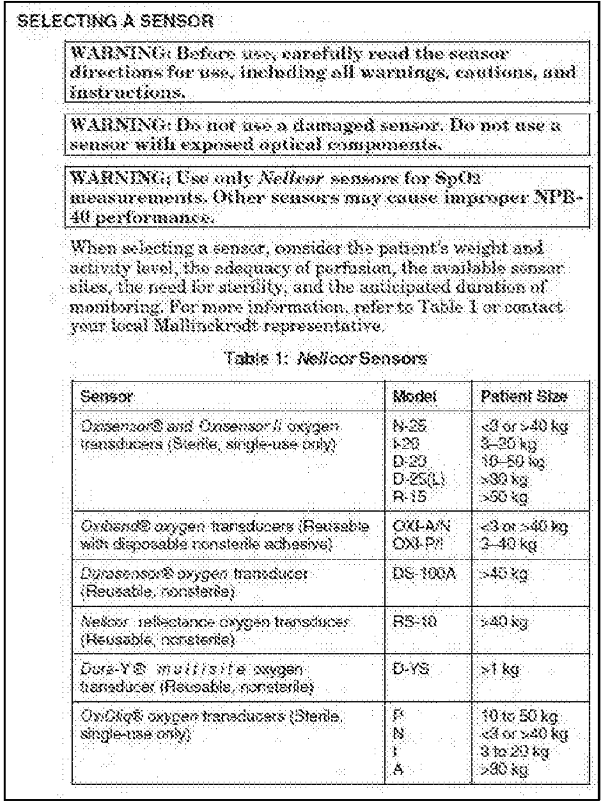
	 (NPB-40 Operator's Manual, p. 15)

SELECTING A SENSOR

WARNING: Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

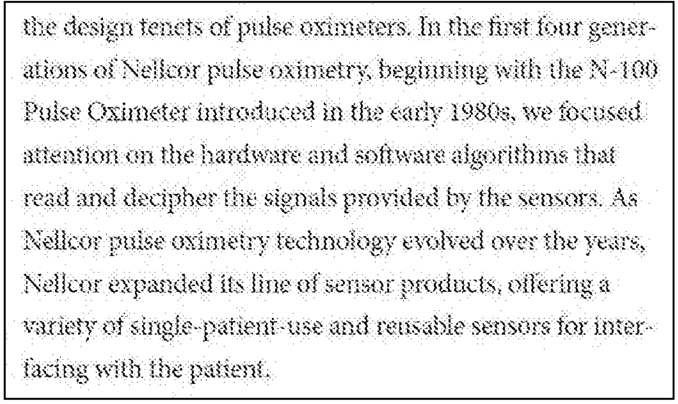
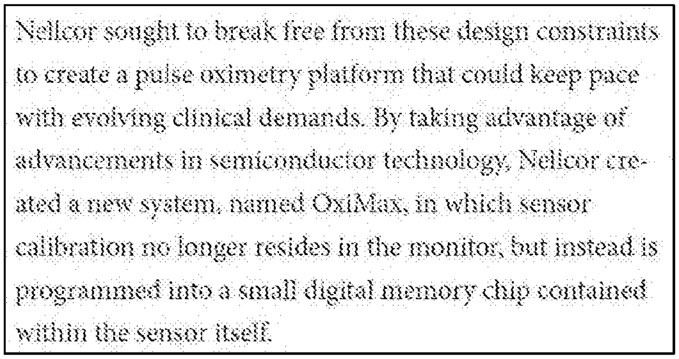
WARNING: Do not use a damaged sensor. Do not use a sensor with exposed optical components.

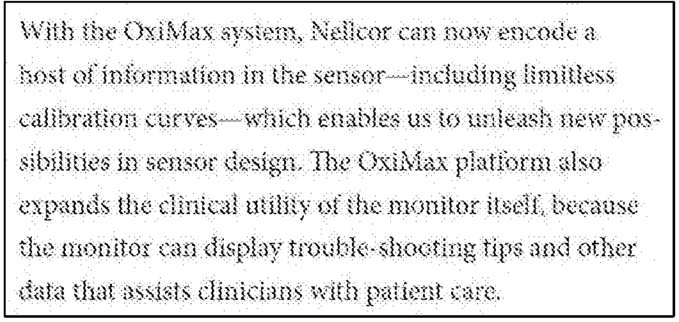
WARNING: Use only *Nellcor* sensors for SpO2 measurements. Other sensors may cause improper NPB-40 performance.

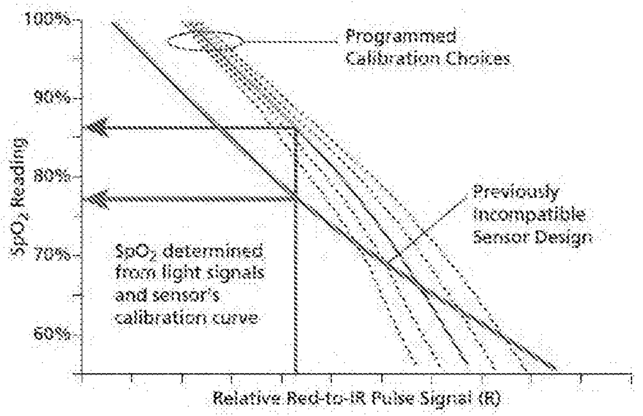
When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Mallinckrodt representative.

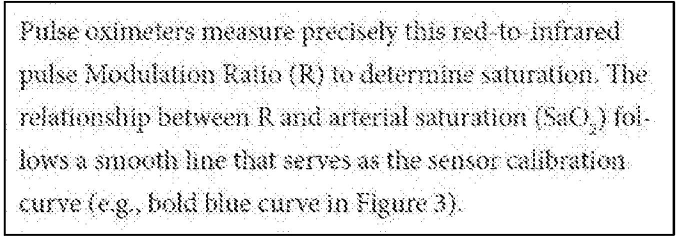
Table 1: *Nellcor* Sensors

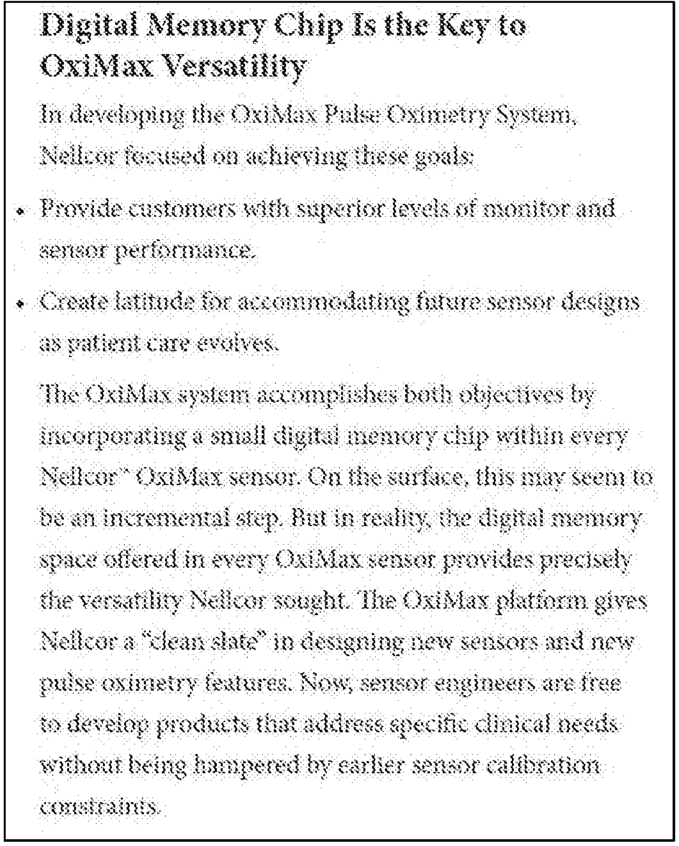
Sensor	Model	Patient Size
Oxisensor® and *Oxisensor II* oxygen transducers (Sterile, single-use only)	N-25 I-20 D-20 D-25(L) R-15	<3 or >40 kg 3–20 kg 10–50 kg >30 kg >50 kg
Oxiband® oxygen transducers (Reusable with disposable nonsterile adhesive)	OXI-A/N OXI-P/I	<3 or >40 kg 3–40 kg
Durasensor® oxygen transducer (Reusable, nonsterile)	DS-100A	>40 kg
Nellcor reflectance oxygen transducer (Reusable, nonsterile)	RS-10	>40 kg
Dura-Y® *multisite* oxygen transducer (Reusable, nonsterile)	D-YS	>1 kg
OxiCliq® oxygen transducers (Sterile, single-use only)	P N I A	10 to 50 kg <3 or >40 kg 3 to 20 kg >30 kg

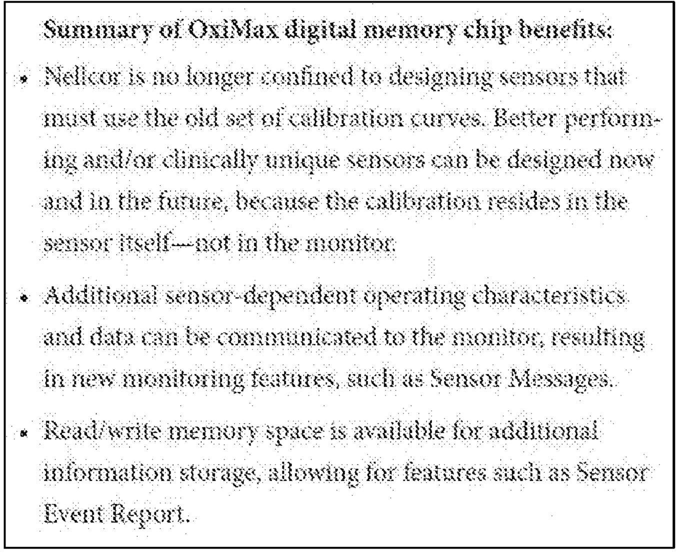
Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 the design tenets of pulse oximeters. In the first four generations of Nellcor pulse oximetry, beginning with the N-100 Pulse Oximeter introduced in the early 1980s, we focused attention on the hardware and software algorithms that read and decipher the signals provided by the sensors. As Nellcor pulse oximetry technology evolved over the years, Nellcor expanded its line of sensor products, offering a variety of single-patient-use and reusable sensors for interfacing with the patient. (White Paper, p. 1)  Nellcor sought to break free from these design constraints to create a pulse oximetry platform that could keep pace with evolving clinical demands. By taking advantage of advancements in semiconductor technology, Nellcor created a new system, named OxiMax, in which sensor calibration no longer resides in the monitor, but instead is programmed into a small digital memory chip contained within the sensor itself. (White Paper, p. 1)

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 With the OxiMax system, Nellcor can now encode a host of information in the sensor—including limitless calibration curves—which enables us to unleash new possibilities in sensor design. The OxiMax platform also expands the clinical utility of the monitor itself, because the monitor can display trouble-shooting tips and other data that assists clinicians with patient care. (White Paper, p. 1)

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 Figure 3 The blue lines depict the one or more calibration curves programmed into earlier-generation monitors, while the red line indicates a calibration required of a hypothetical new sensor. Such a design would be incompatible with these earlier monitors, since none of the blue curves could provide accurate SpO$_2$ values for the sensor's signals. (White Paper, p. 2)

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 Pulse oximeters measure precisely this red-to-infrared pulse Modulation Ratio (R) to determine saturation. The relationship between R and arterial saturation (SaO_2) follows a smooth line that serves as the sensor calibration curve (e.g., bold blue curve in Figure 3). (White Paper, p. 2)

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 **Digital Memory Chip Is the Key to OxiMax Versatility** In developing the OxiMax Pulse Oximetry System, Nellcor focused on achieving these goals: • Provide customers with superior levels of monitor and sensor performance. • Create latitude for accommodating future sensor designs as patient care evolves. The OxiMax system accomplishes both objectives by incorporating a small digital memory chip within every Nellcor™ OxiMax sensor. On the surface, this may seem to be an incremental step. But in reality, the digital memory space offered in every OxiMax sensor provides precisely the versatility Nellcor sought. The OxiMax platform gives Nellcor a "clean slate" in designing new sensors and new pulse oximetry features. Now, sensor engineers are free to develop products that address specific clinical needs without being hampered by earlier sensor calibration constraints. (White Paper, p. 4)

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
	 Summary of OxiMax digital memory chip benefits: • Nellcor is no longer confined to designing sensors that must use the old set of calibration curves. Better performing and/or clinically unique sensors can be designed now and in the future, because the calibration resides in the sensor itself—not in the monitor. • Additional sensor-dependent operating characteristics and data can be communicated to the monitor, resulting in new monitoring features, such as Sensor Messages. • Read/write memory space is available for additional information storage, allowing for features such as Sensor Event Report. (White Paper, p. 5)
[1H] the light source configured to further improve the signal-to-noise ratio of the input optical beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs;	Nellcor discloses and/or renders obvious "the light source configured to further improve the signal-to-noise ratio of the input optical beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs." *See* CHART ONE: '533 Patent, Claim Element 5C above.

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
[1I] the measurement device further configured to generate an output signal representing at least in part a non-invasive measurement on blood contained within the tissue; and	Nellcor discloses and/or renders obvious "the measurement device further configured to generate an output signal representing at least in part a non-invasive measurement on blood contained within the tissue." *See* CHART ONE: '533 Patent, Claim Element 10 above.
[1J] the wearable device configured to communicate with the smart phone or tablet, the smart phone or tablet comprising a wireless receiver, a wireless transmitter, a display, a voice input module, a speaker, and a touch screen, the smart phone or tablet configured to receive and to process at least a portion of the output signal,	Nellcor discloses and/or renders obvious "the wearable device configured to communicate with the smart phone or tablet, the smart phone or tablet comprising a wireless receiver, a wireless transmitter, a display, a voice input module, a speaker, and a touch screen, the smart phone or tablet configured to receive and to process at least a portion of the output signal." *See* CHART ONE: '533 Patent, Claim Elements 5G and 5H above.
[1K] wherein the smart phone or tablet is configured to store and display the processed output signal, wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link.	Nellcor discloses and/or renders obvious "wherein the smart phone or tablet is configured to store and display the processed output signal, wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link." *See* CHART ONE: '533 Patent, Claim Elements 5I and 5J above.
[2] The wearable device of claim 1, wherein the receiver is configured to be synchronized to the modulation of the at least one of the LEDs.	Nellcor discloses and/or renders obvious "[t]he wearable device of claim 1, wherein the receiver is configured to be synchronized to the modulation of the at least one of the LEDs." *See* CHART ONE: '533 Patent, Claim Element 5F above.

Asserted Claim of '040 Patent	Nellcor Pulse Oximeters
[4] The wearable device of claim 1, wherein the receiver is located a first distance from a first one of the LEDs and a different distance from a second one of the LEDs such that the receiver can capture a third signal from the first LED and a fourth signal from the second LED, and wherein the output signal is generated in part by comparing the third and fourth signals.	Nellcor discloses and/or renders obvious "[t]he wearable device of claim 1, wherein the receiver is located a first distance from a first one of the LEDs and a different distance from a second one of the LEDs such that the receiver can capture a third signal from the first LED and a fourth signal from the second LED, and wherein the output signal is generated in part by comparing the third and fourth signals." *See* CHART ONE: '533 Patent, Claim Element 8 above.

EXHIBIT X-3

U.S. Patent No. 9,861,286 vs Nellcor

Priority Date/Publication Date: between 2001 and December 2012 Prior Art Status: §§ 102(a) and (b)

The OxiMax, NPB-40, N-550, and certain pulse oximeters and pulse oximetry sensors manufactured by Nellcor ("Nellcor") anticipate the asserted claims of U.S. Patent No. 9,651,533 ("the '533 Patent") or render those claims obvious alone and/or in view of at least any of the references identified in Apple's Obviousness Combinations Chart.

This chart is based on the following disclosures about Nellcor pulse oximeters:

- Nellcor OxiMax NPB-40 Handheld Pulse Oximeter Service Manual 2004 ("NPB-40 Service Manual")
- Nellcor OxiMax N-550 Pulse Oximeter Service Manual 2003 ("N-550 Manual")
- Nellcor NPB-40 Handheld Pulse Oximeter Operator's Manual 2001 ("NPB-40 Operator's Manual")
- Nellcor OxiMax White Paper "A Technology Overview of the Nellcor™ OxiMax Pulse Oximetry System" 2003 ("White Paper")

Discovery is ongoing, and Apple reserves the right to amend this chart based on new information about the Nellcor pulse oximeters.

As set forth in Apple's Invalidity Contentions, the below contentions apply the prior art in part in accordance with Apple's assumption that Omni contends the claims are not invalid under 35 U.S.C. § 112. However, Apple's below contentions do not represent Apple's agreement or view as to the meaning, definiteness, written description support for, or enablement of any of the asserted claims. For each dependent claim, the disclosures cited for the claim from which it depends are incorporated by reference.

CHART THREE: U.S. Patent No. 9,861,286 vs Nellcor

Asserted Claim of '286 Patent	Nellcor Pulse Oximeters
[16] A wearable device for use with a smart phone or tablet, the wearable device comprising:	To the extent the preamble is limiting, Nellcor discloses and/or renders obvious "[a] wearable device for use with a smart phone or tablet." *See* CHART ONE: '533 Patent, Claim Elements 5, 5G, and 13A above.
[16A] a measurement device including a light source comprising a plurality of light emitting diodes (LEDs) for measuring one or more physiological parameters,	Nellcor discloses and/or renders obvious "a measurement device including a light source comprising a plurality of light emitting diodes (LEDs) for measuring one or more physiological parameters." *See* CHART ONE: '533 Patent, Claim Element 13A above.
[16B] the measurement device configured to generate, by modulating at least one of the LEDs having an initial light intensity, an optical beam having a plurality of optical wavelengths,	Nellcor discloses and/or renders obvious "the measurement device configured to generate, by modulating at least one of the LEDs having an initial light intensity, an optical beam having a plurality of optical wavelengths." *See* CHART TWO: '040 Patent, Claim Element 1B above.
[16C] wherein at least a portion of the plurality of optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers;	Nellcor discloses and/or renders obvious "wherein at least a portion of the plurality of optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers." *See* CHART ONE: '533 Patent, Claim Element 5B above.
[16D] the measurement device comprising one or more lenses configured to receive and to deliver a portion of the optical beam to tissue, wherein the tissue reflects at least a portion of the	Nellcor discloses and/or renders obvious "the measurement device comprising one or more lenses configured to receive and to deliver a portion of the optical beam to tissue, wherein the tissue reflects at least a portion of the optical beam delivered to the tissue, and wherein the measurement device is adapted to be placed on a wrist or an ear of a user." *See* CHART ONE: '533 Patent, Claim Element 5D above.

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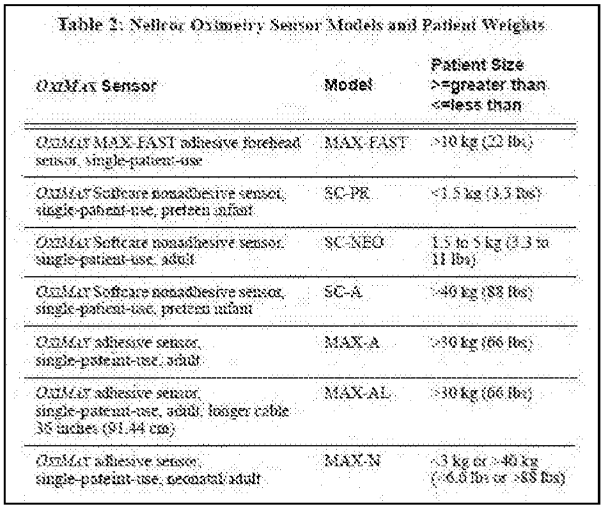
<tr><td>optical beam delivered to the tissue, and</td><td></td></tr>
<tr><td>**[16E]** wherein the measurement device is adapted to be placed on a wrist or an ear of a user;</td><td>Nellcor discloses and/or renders obvious "wherein the measurement device is adapted to be placed on a wrist or an ear of a user."

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<=less than</th></tr>
<tr><td>OxiMax MAX-FAST adhesive forehead sensor, single-patient-use</td><td>MAX-FAST</td><td>>10 kg (22 lbs)</td></tr>
<tr><td>OxiMax Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-PR</td><td><1.5 kg (3.3 lbs)</td></tr>
<tr><td>OxiMax Softcare nonadhesive sensor, single-patient-use, adult</td><td>SC-NEO</td><td>1.5 to 5 kg (3.3 to 11 lbs)</td></tr>
<tr><td>OxiMax Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td>OxiMax adhesive sensor, single-pateint-use, adult</td><td>MAX-A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td>OxiMax adhesive sensor, single-pateint-use, adult, longer cable 36 inches (91.44 cm)</td><td>MAX-AL</td><td>>30 kg (66 lbs)</td></tr>
<tr><td>OxiMax adhesive sensor, single-pateint-use, neonatal/adult</td><td>MAX-N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
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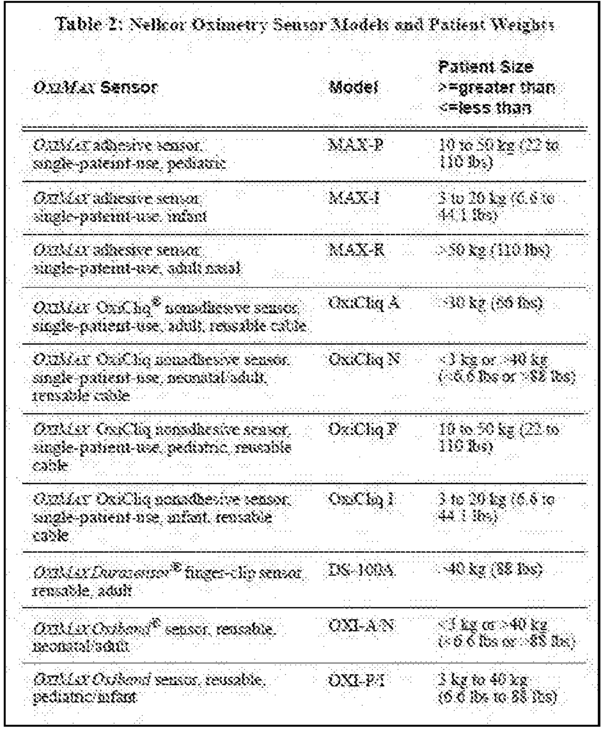

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<tr><td>OxiMax adhesive sensor, single-pateint-use, adult nasal</td><td>MAX-R</td><td>>50 kg (110 lbs)</td></tr>
<tr><td>OxiMax OxiCliq® nonadhesive sensor, single-patient-use, adult, reusable cable</td><td>OxiCliq A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td>OxiMax OxiCliq nonadhesive sensor, single-patient-use, neonatal/adult, reusable cable</td><td>OxiCliq N</td><td><3 kg or >40 kg (<6.6 lbs or >82 lbs)</td></tr>
<tr><td>OxiMax OxiCliq nonadhesive sensor, single-patient-use, pediatric, reusable cable</td><td>OxiCliq P</td><td>10 to 50 kg (22 to 110 lbs)</td></tr>
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<tr><td>OxiMax Oxiband sensor, reusable, pediatric/infant</td><td>OXI-P/I</td><td>3 kg to 40 kg (6.6 lbs to 88 lbs)</td></tr>
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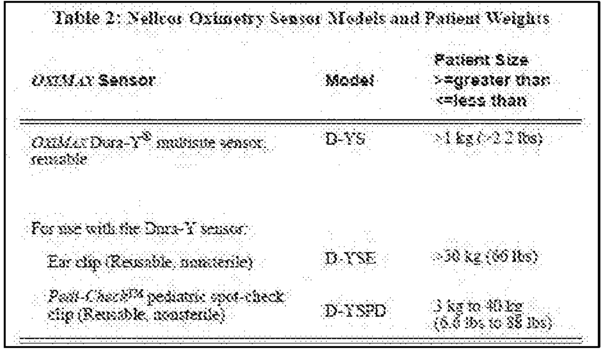
<tr><td></td><td>
<table>
<tr><td colspan="3">Table 2: Nellcor Oximetry Sensor Models and Patient Weights</td></tr>
<tr><th><i>OXIMAX</i> Sensor</th><th>Model</th><th>Patient Size
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<=less than</th></tr>
<tr><td><i>OXIMAX</i> Dura-Y® multisite sensor, reusable</td><td>D-YS</td><td>>1 kg (>2.2 lbs)</td></tr>
<tr><td>For use with the Dura-Y sensor:</td><td></td><td></td></tr>
<tr><td>Ear clip (Reusable, nonsterile)</td><td>D-YSE</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>Pedi-Check</i>™ pediatric spot-check clip (Reusable, nonsterile)</td><td>D-YSPD</td><td>3 kg to 40 kg (6.6 lbs to 88 lbs)</td></tr>
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(N-550 Manual, p. 68)</td></tr>
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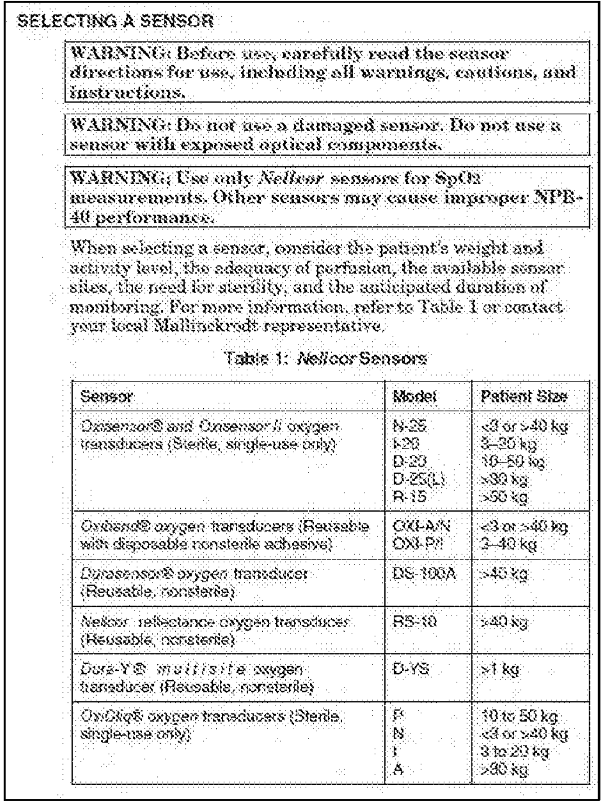
Asserted Claim of '286 Patent	Nellcor Pulse Oximeters
	 (NPB-40 Operator's Manual, p. 15)

SELECTING A SENSOR

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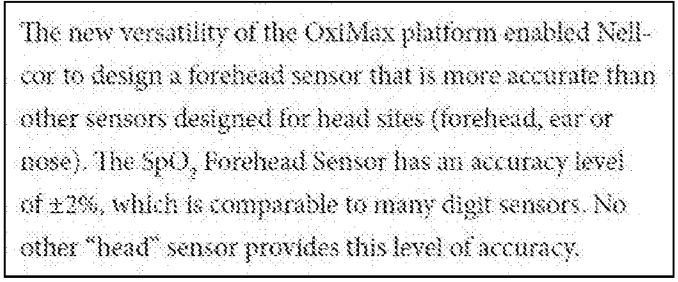
WARNING: Do not use a damaged sensor. Do not use a sensor with exposed optical components.

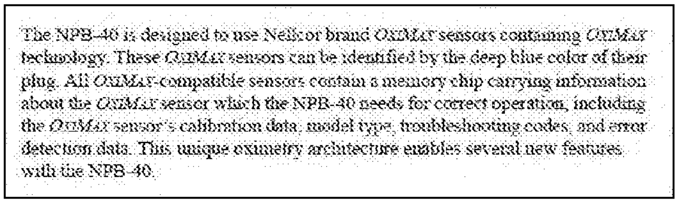
WARNING: Use only *Nellcor* sensors for SpO2 measurements. Other sensors may cause improper NPB-40 performance.

When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Mallinckrodt representative.

Table 1: *Nellcor* Sensors

Sensor	Model	Patient Size
Oxisensor® and *Oxisensor II* oxygen transducers (Sterile, single-use only)	N-25 I-20 D-20 D-25(L) R-15	<3 or >40 kg 3–20 kg 10–50 kg >30 kg >50 kg
Oxiband® oxygen transducers (Reusable with disposable nonsterile adhesive)	OXI-A/N OXI-P/I	<3 or >40 kg 3–40 kg
Durasensor® oxygen transducer (Reusable, nonsterile)	DS-100A	>40 kg
Nellcor reflectance oxygen transducer (Reusable, nonsterile)	RS-10	>40 kg
Dura-Y® multisite oxygen transducer (Reusable, nonsterile)	D-YS	>1 kg
OxiCliq® oxygen transducers (Sterile, single-use only)	P N I A	10 to 50 kg <3 or >40 kg 3 to 20 kg >30 kg

Asserted Claim of '286 Patent	Nellcor Pulse Oximeters
	 The new versatility of the OxiMax platform enabled Nellcor to design a forehead sensor that is more accurate than other sensors designed for head sites (forehead, ear or nose). The SpO_2 Forehead Sensor has an accuracy level of ±2%, which is comparable to many digit sensors. No other "head" sensor provides this level of accuracy. (White Paper, p. 6)
[16F] the measurement device further comprising a receiver configured to: capture light while the LEDs are off and convert the captured light into a first signal and capture light while at least one of the LEDs is on and convert the captured light into a second signal, the captured light including at least a portion of the optical beam reflected from the tissue;	Nellcor discloses and/or renders obvious "the measurement device further comprising a receiver configured to: capture light while the LEDs are off and convert the captured light into a first signal and capture light while at least one of the LEDs is on and convert the captured light into a second signal, the captured light including at least a portion of the optical beam reflected from the tissue." *See* CHART TWO: '040 Patent, Claim Element 1F above.
[16G] the measurement device configured to improve a signal-to-noise ratio of the optical beam reflected from the tissue by	Nellcor discloses and/or renders obvious "the measurement device configured to improve a signal-to-noise ratio of the optical beam reflected from the tissue by differencing the first signal and the second signal." *See* CHART TWO: '040 Patent, Claim Element 1G above.

Asserted Claim of '286 Patent	**Nellcor Pulse Oximeters**
differencing the first signal and the second signal;	
[16H] the light source configured to further improve the signal-to-noise ratio of the optical beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs;	Nellcor discloses and/or renders obvious "the light source configured to further improve the signal-to-noise ratio of the optical beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs." *See* CHART ONE: '533 Patent, Claim Element 5C above.
[16I] the measurement device further configured to generate an output signal representing at least in part a non-invasive measurement on blood contained within the tissue; and	Nellcor discloses and/or renders obvious "the measurement device further configured to generate an output signal representing at least in part a non-invasive measurement on blood contained within the tissue." *See* CHART ONE: '533 Patent, Claim Element 10 above.
[16J] wherein the receiver includes a plurality of spatially separated detectors,	Nellcor discloses and/or renders obvious "wherein the receiver includes a plurality of spatially separated detectors."  The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)

<table>
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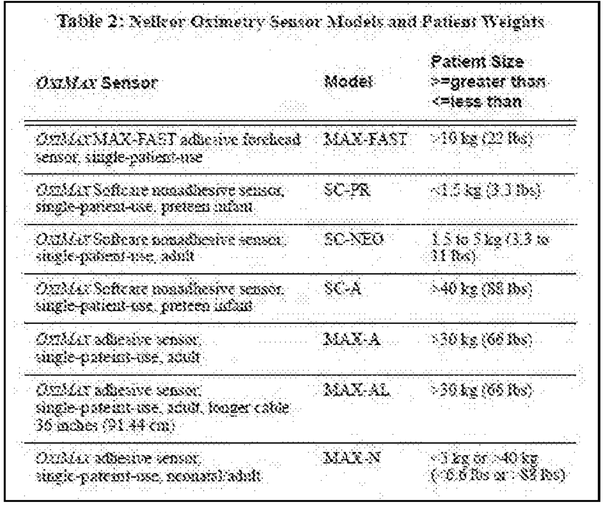

Table 2: Nellcor Oximetry Sensor Models and Patient Weights

<table>
<tr><th>*OxiMax* Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td>*OxiMax* MAX-FAST adhesive forehead sensor, single-patient-use</td><td>MAX-FAST</td><td>>10 kg (22 lbs)</td></tr>
<tr><td>*OxiMax* Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-PR</td><td><1.5 kg (3.3 lbs)</td></tr>
<tr><td>*OxiMax* Softcare nonadhesive sensor, single-patient-use, adult</td><td>SC-NEO</td><td>1.5 to 5 kg (3.3 to 11 lbs)</td></tr>
<tr><td>*OxiMax* Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td>*OxiMax* adhesive sensor, single-pateint-use, adult</td><td>MAX-A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td>*OxiMax* adhesive sensor, single-pateint-use, adult, longer cable 36 inches (91.44 cm)</td><td>MAX-AL</td><td>>30 kg (66 lbs)</td></tr>
<tr><td>*OxiMax* adhesive sensor, single-pateint-use, neonatal/adult</td><td>MAX-N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
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(N-550 Manual, p. 66)
</td></tr>
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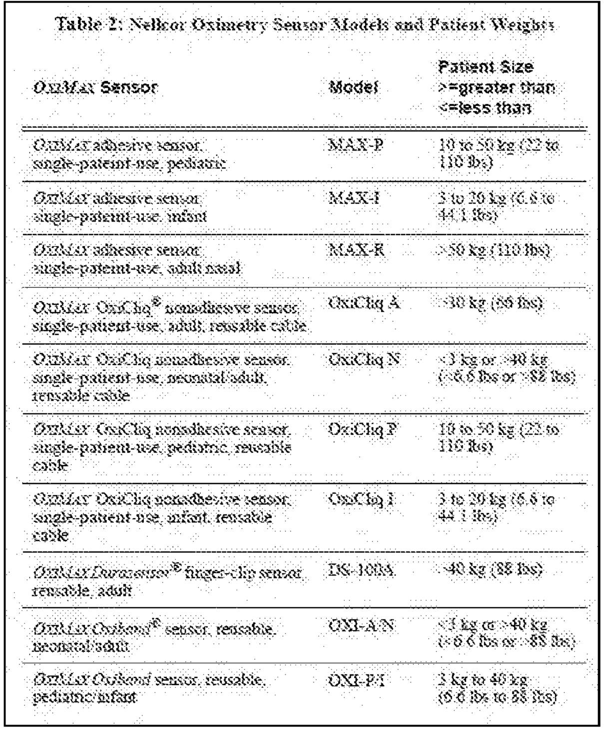
<tr><td></td><td>
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<tr><th><i>OxiMax</i> Sensor</th><th>Model</th><th>Patient Size
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<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, pediatric</td><td>MAX-P</td><td>10 to 50 kg (22 to 110 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, infant</td><td>MAX-I</td><td>3 to 20 kg (6.6 to 44.1 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult nasal</td><td>MAX-R</td><td>>50 kg (110 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq® nonadhesive sensor, single-patient-use, adult, reusable cable</td><td>OxiCliq A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq nonadhesive sensor, single-patient-use, neonatal/adult, reusable cable</td><td>OxiCliq N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq nonadhesive sensor, single-patient-use, pediatric, reusable cable</td><td>OxiCliq P</td><td>10 to 50 kg (22 to 110 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq nonadhesive sensor, single-patient-use, infant, reusable cable</td><td>OxiCliq I</td><td>3 to 20 kg (6.6 to 44.1 lbs)</td></tr>
<tr><td><i>OxiMax Durasensor</i>® finger-clip sensor, reusable, adult</td><td>DS-100A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td><i>OxiMax Oxiband</i>® sensor, reusable, neonatal/adult</td><td>OXI-A/N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
<tr><td><i>OxiMax Oxiband</i> sensor, reusable, pediatric/infant</td><td>OXI-P/I</td><td>3 kg to 40 kg (6.6 lbs to 88 lbs)</td></tr>
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<p>(N-550 Manual, p. 67)</p></td></tr>
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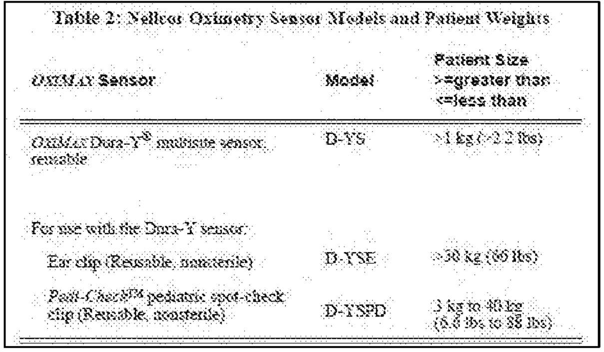
<tr><td></td><td>
Table 2: Nellcor Oximetry Sensor Models and Patient Weights
<table>
<tr><th>OXIMAX Sensor</th><th>Model</th><th>Patient Size
>=greater than
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<tr><td>OXIMAX Dura-Y® multisite sensor, reusable</td><td>D-YS</td><td>>1 kg (>2.2 lbs)</td></tr>
<tr><td>For use with the Dura-Y sensor:</td><td></td><td></td></tr>
<tr><td>Ear clip (Reusable, nonsterile)</td><td>D-YSE</td><td>>30 kg (66 lbs)</td></tr>
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(N-550 Manual, p. 68)</td></tr>
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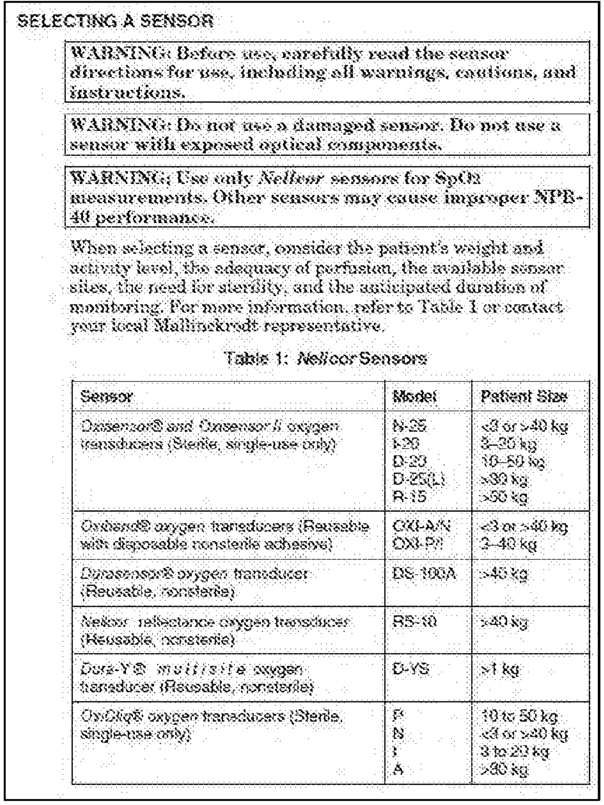
Asserted Claim of '286 Patent	Nellcor Pulse Oximeters
	 (NPB-40 Operator's Manual, p. 15)

SELECTING A SENSOR

WARNING: Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

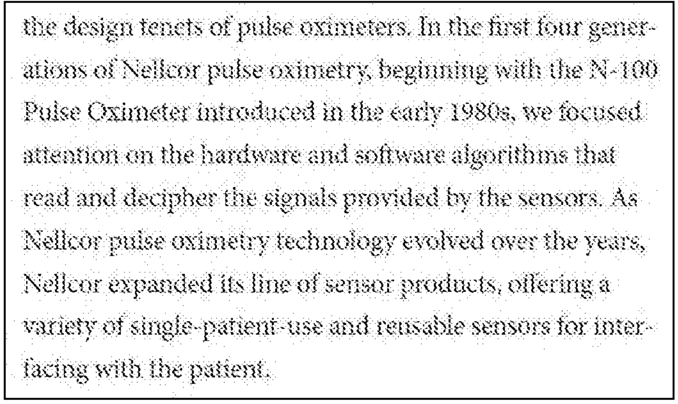
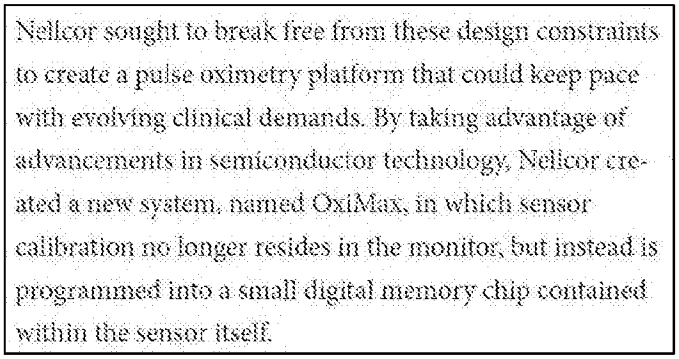
WARNING: Do not use a damaged sensor. Do not use a sensor with exposed optical components.

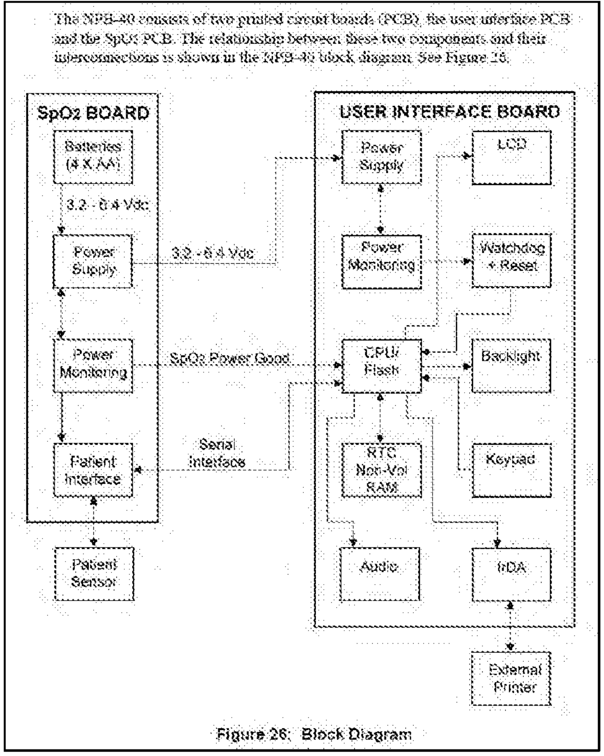
WARNING: Use only *Nellcor* sensors for SpO_2 measurements. Other sensors may cause improper NPB-40 performance.

When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Mallinckrodt representative.

Table 1: *Nellcor* Sensors

Sensor	Model	Patient Size
Oxisensor® and *Oxisensor II* oxygen transducers (Sterile, single-use only)	N-25 I-20 D-20 D-25(L) R-15	<3 or >40 kg 3–20 kg 10–50 kg >30 kg >50 kg
Oxiband® oxygen transducers (Reusable with disposable nonsterile adhesive)	OXI-A/N OXI-P/I	<3 or >40 kg 3–40 kg
Durasensor® oxygen transducer (Reusable, nonsterile)	DS-100A	>40 kg
Nellcor reflectance oxygen transducer (Reusable, nonsterile)	RS-10	>40 kg
Dura-Y® multisite oxygen transducer (Reusable, nonsterile)	D-YS	>1 kg
OxiCliq® oxygen transducers (Sterile, single-use only)	P N I A	10 to 50 kg <3 or >40 kg 3 to 20 kg >30 kg

Asserted Claim of '286 Patent	Nellcor Pulse Oximeters
	 the design tenets of pulse oximeters. In the first four generations of Nellcor pulse oximetry, beginning with the N-100 Pulse Oximeter introduced in the early 1980s, we focused attention on the hardware and software algorithms that read and decipher the signals provided by the sensors. As Nellcor pulse oximetry technology evolved over the years, Nellcor expanded its line of sensor products, offering a variety of single-patient-use and reusable sensors for interfacing with the patient. (White Paper, p. 1)  Nellcor sought to break free from these design constraints to create a pulse oximetry platform that could keep pace with evolving clinical demands. By taking advantage of advancements in semiconductor technology, Nellcor created a new system, named OxiMax, in which sensor calibration no longer resides in the monitor, but instead is programmed into a small digital memory chip contained within the sensor itself. (White Paper, p. 1)
[16K] wherein at least one analog to digital converter is coupled to the spatially separated detectors.	Nellcor discloses and/or renders obvious "wherein at least one analog to digital converter is coupled to the spatially separated detectors."

Asserted Claim of '286 Patent	Nellcor Pulse Oximeters
	 The NPB-40 consists of two printed circuit boards (PCB), the user interface PCB and the SpO2 PCB. The relationship between these two components and their interconnections is shown in the NPB-40 block diagram. See Figure 26. Figure 26: Block Diagram (NPB-40 Service Manual, p. 78)

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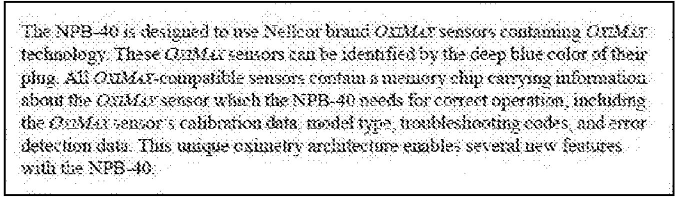
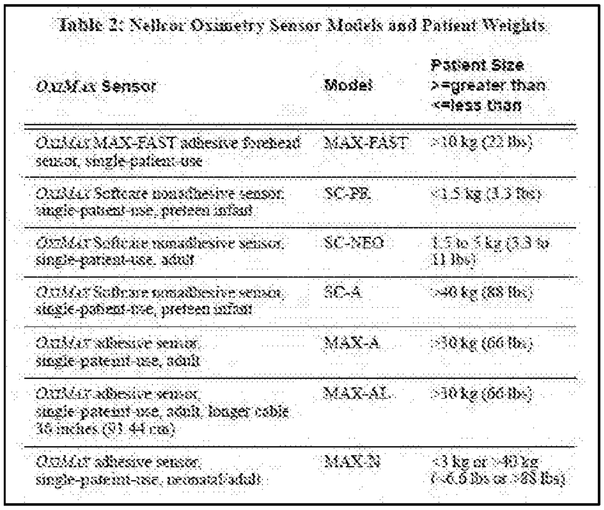


The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40.

(NPB-40 Service Manual, p. 76)



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<tr><td>OxiMax Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-A</td><td>>40 kg (88 lbs)</td></tr>
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(N-550 Manual, p. 66)

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	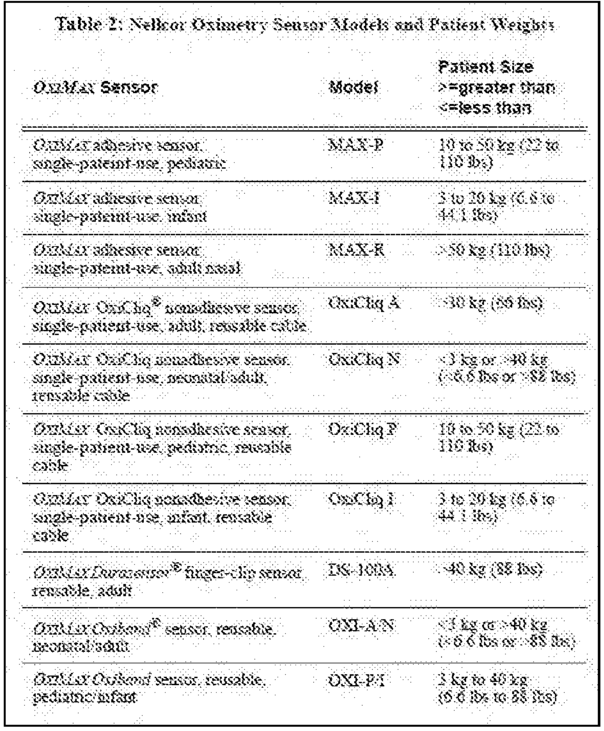 (N-550 Manual, p. 67)

Table 2: Nellcor Oximetry Sensor Models and Patient Weights

OxiMax Sensor	Model	Patient Size >=greater than <=less than
OxiMax adhesive sensor, single-pateint-use, pediatric	MAX-P	10 to 50 kg (22 to 110 lbs)
OxiMax adhesive sensor, single-pateint-use, infant	MAX-I	3 to 20 kg (6.6 to 44.1 lbs)
OxiMax adhesive sensor, single-pateint-use, adult nasal	MAX-R	>50 kg (110 lbs)
OxiMax OxiCliq® nonadhesive sensor, single-patient-use, adult, reusable cable	OxiCliq A	>30 kg (66 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, neonatal/adult, reusable cable	OxiCliq N	<3 kg or >40 kg (<6.6 lbs or >82 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, pediatric, reusable cable	OxiCliq P	10 to 50 kg (22 to 110 lbs)
OxiMax OxiCliq nonadhesive sensor, single-patient-use, infant, reusable cable	OxiCliq I	3 to 20 kg (6.6 to 44.1 lbs)
OxiMax Durasensor® finger-clip sensor, reusable, adult	DS-100A	>40 kg (88 lbs)
OxiMax Oxiband® sensor, reusable, neonatal/adult	OXI-A/N	<3 kg or >40 kg (<6.6 lbs or >88 lbs)
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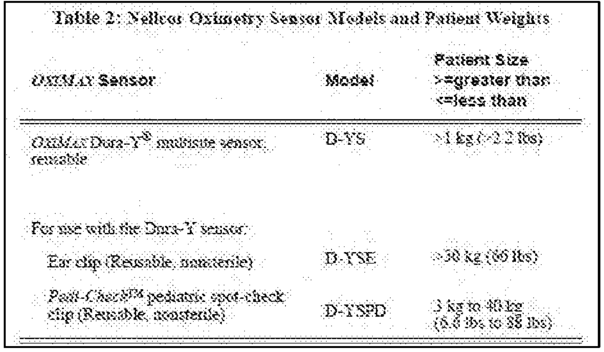

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<tr><td>For use with the Dura-Y sensor:</td><td></td><td></td></tr>
<tr><td>Ear clip (Reusable, nonsterile)</td><td>D-YSE</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>Pedi-Check</i>™ pediatric spot-check clip (Reusable, nonsterile)</td><td>D-YSPD</td><td>3 kg to 40 kg
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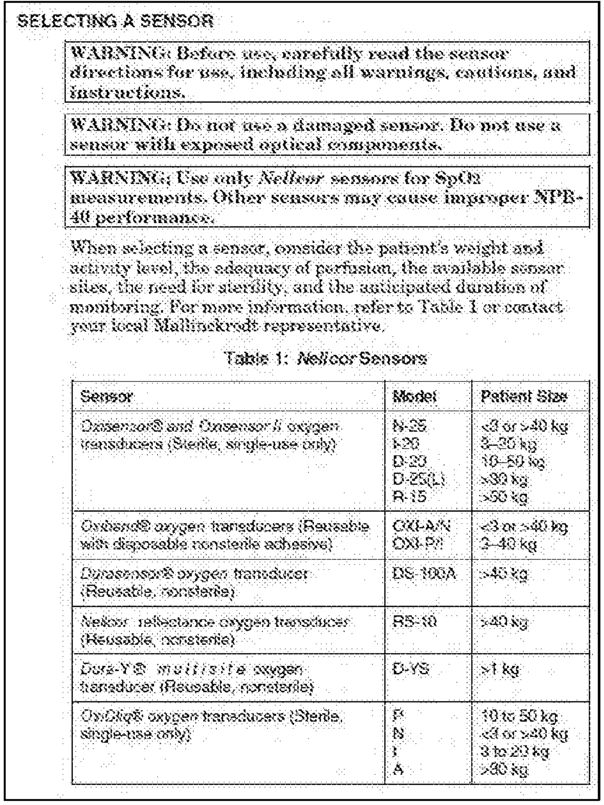

SELECTING A SENSOR

WARNING: Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

WARNING: Do not use a damaged sensor. Do not use a sensor with exposed optical components.

WARNING: Use only *Nellcor* sensors for SpO2 measurements. Other sensors may cause improper NPB-40 performance.

When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Mallinckrodt representative.

Table 1: *Nellcor* Sensors

<table>
<tr><th>Sensor</th><th>Model</th><th>Patient Size</th></tr>
<tr><td><i>Oxisensor</i>® and <i>Oxisensor II</i> oxygen transducers (Sterile, single-use only)</td><td>N-25
I-20
D-20
D-25(L)
R-15</td><td><3 or >40 kg
3–20 kg
10–50 kg
>30 kg
>50 kg</td></tr>
<tr><td><i>Oxiband</i>® oxygen transducers (Reusable with disposable nonsterile adhesive)</td><td>OXI-A/N
OXI-P/I</td><td><3 or >40 kg
3–40 kg</td></tr>
<tr><td><i>Durasensor</i>® oxygen transducer (Reusable, nonsterile)</td><td>DS-100A</td><td>>40 kg</td></tr>
<tr><td><i>Nellcor</i> reflectance oxygen transducer (Reusable, nonsterile)</td><td>RS-10</td><td>>40 kg</td></tr>
<tr><td><i>Dura-Y</i>® <i>multisite</i> oxygen transducer (Reusable, nonsterile)</td><td>D-YS</td><td>>1 kg</td></tr>
<tr><td><i>OxiCliq</i>® oxygen transducers (Sterile, single-use only)</td><td>P
N
I
A</td><td>10 to 50 kg
<3 or >40 kg
3 to 20 kg
>30 kg</td></tr>
</table>

(NPB-40 Operator's Manual, p. 15)
</td></tr>
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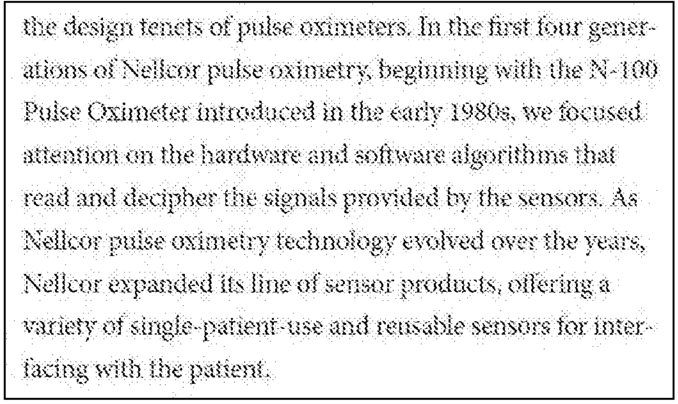
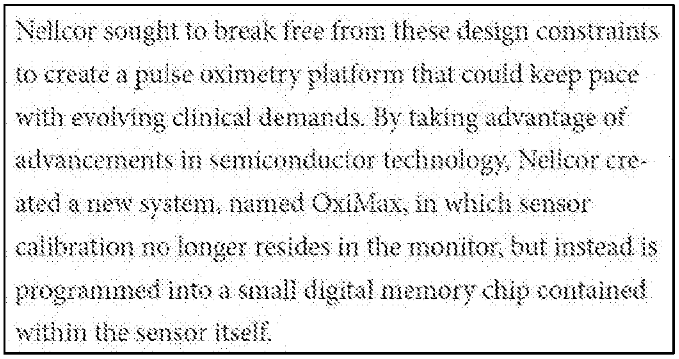
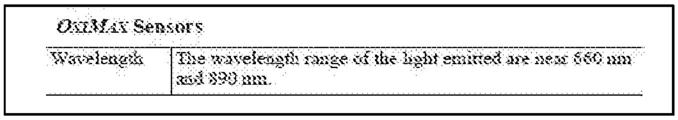
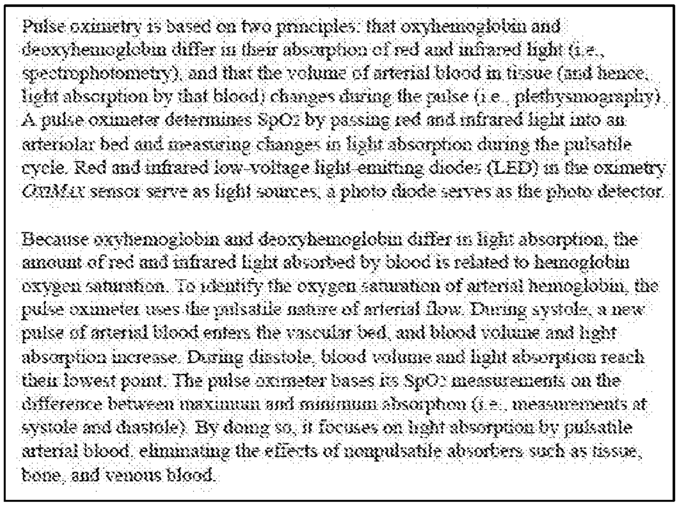
Asserted Claim of '286 Patent	Nellcor Pulse Oximeters
	 the design tenets of pulse oximeters. In the first four generations of Nellcor pulse oximetry, beginning with the N-100 Pulse Oximeter introduced in the early 1980s, we focused attention on the hardware and software algorithms that read and decipher the signals provided by the sensors. As Nellcor pulse oximetry technology evolved over the years, Nellcor expanded its line of sensor products, offering a variety of single-patient-use and reusable sensors for interfacing with the patient. (White Paper, p. 1)  Nellcor sought to break free from these design constraints to create a pulse oximetry platform that could keep pace with evolving clinical demands. By taking advantage of advancements in semiconductor technology, Nellcor created a new system, named OxiMax, in which sensor calibration no longer resides in the monitor, but instead is programmed into a small digital memory chip contained within the sensor itself. (White Paper, p. 1)
[17] The wearable device of claim 16, wherein at least one LED emits at a first wavelength	Nellcor discloses and/or renders obvious "[t]he wearable device of claim 16, wherein at least one LED emits at a first wavelength and at least another LED emits at a second wavelength, and wherein the first wavelength has a first penetration depth into the tissue and wherein the second

<table>
<tr><th>Asserted Claim of ’286 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td>and at least another LED emits at a second wavelength, and wherein the first wavelength has a first penetration depth into the tissue and wherein the second wavelength has a second penetration depth into the tissue different from the first penetration depth.</td><td>wavelength has a second penetration depth into the tissue different from the first penetration depth..”

<i>OxiMax</i> Sensors
<table><tr><td>Wavelength</td><td>The wavelength range of the light emitted are near 660 nm and 890 nm.</td></tr></table>
(NPB-40 Service Manual, p. 67)

Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e., spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e., plethysmography). A pulse oximeter determines SpO2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry <i>OxiMax</i> sensor serve as light sources; a photo diode serves as the photo detector.
Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial hemoglobin, the pulse oximeter uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The pulse oximeter bases its SpO2 measurements on the difference between maximum and minimum absorption (i.e., measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.
(NPB-40 Service Manual, p. 75)</td></tr>
</table>

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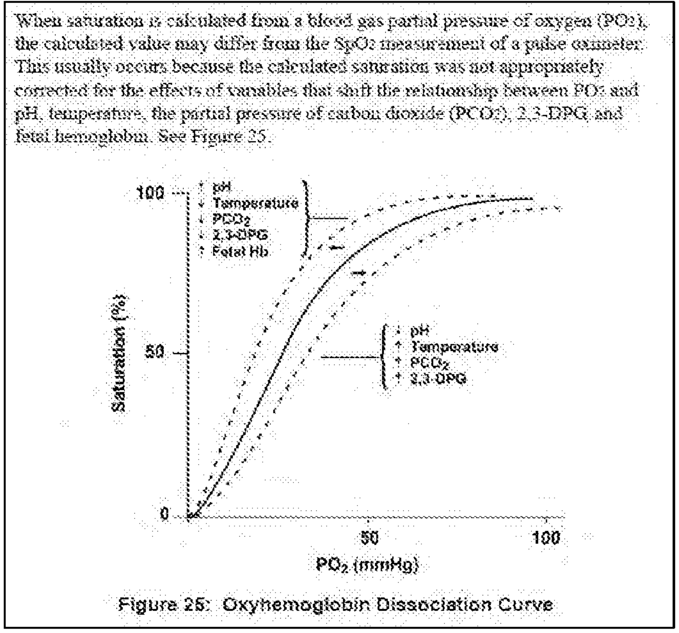
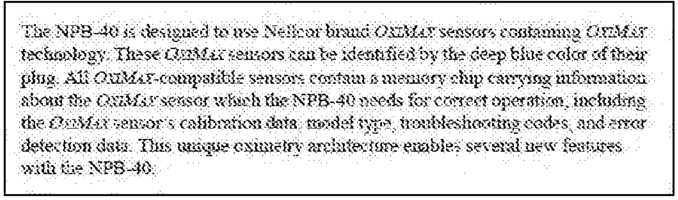
	 When saturation is calculated from a blood gas partial pressure of oxygen (PO2), the calculated value may differ from the SpO2 measurement of a pulse oximeter. This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO2 and pH, temperature, the partial pressure of carbon dioxide (PCO2), 2,3-DPG and fetal hemoglobin. See Figure 25. Figure 25: Oxyhemoglobin Dissociation Curve (NPB-40 Service Manual, p. 76)

<table>
<tr><th>Asserted Claim of '286 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>


The NPB-40 is designed to use Nellcor brand <i>OxiMax</i> sensors containing <i>OxiMax</i> technology. These <i>OxiMax</i> sensors can be identified by the deep blue color of their plug. All <i>OxiMax</i>-compatible sensors contain a memory chip carrying information about the <i>OxiMax</i> sensor which the NPB-40 needs for correct operation, including the <i>OxiMax</i> sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40.

(NPB-40 Service Manual, p. 76)

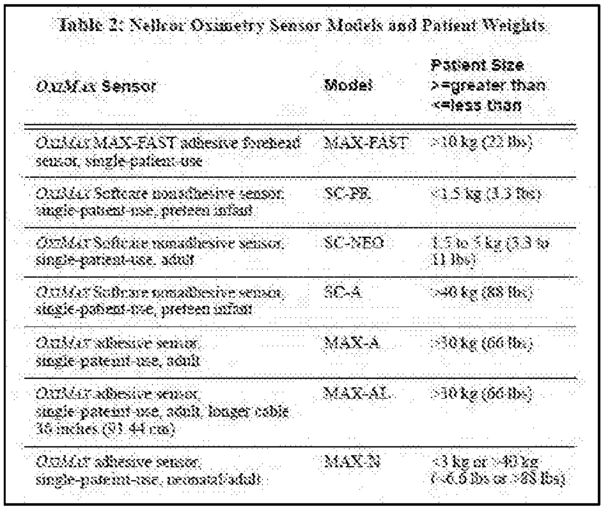
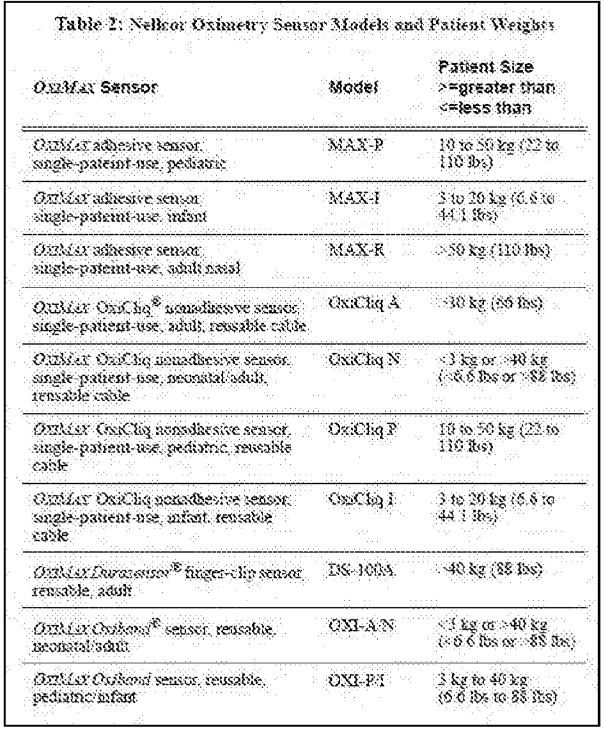


Table 2: Nellcor Oximetry Sensor Models and Patient Weights

<table>
<tr><th><i>OxiMax</i> Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td><i>OxiMax</i> MAX-FAST adhesive forehead sensor, single-patient-use</td><td>MAX-FAST</td><td>>10 kg (22 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-PR</td><td><1.5 kg (3.3 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, adult</td><td>SC-NEO</td><td>1.5 to 5 kg (3.3 to 11 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult</td><td>MAX-A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult, longer cable 36 inches (91.44 cm)</td><td>MAX-AL</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, neonatal/adult</td><td>MAX-N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
</table>

(N-550 Manual, p. 66)
</td></tr>
</table>

<table>
<tr><th>Asserted Claim of '286 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>
Table 2: Nellcor Oximetry Sensor Models and Patient Weights
<table>
<tr><th><i>OxiMax</i> Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, pediatric</td><td>MAX-P</td><td>10 to 50 kg (22 to 110 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, infant</td><td>MAX-I</td><td>3 to 20 kg (6.6 to 44.1 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult nasal</td><td>MAX-R</td><td>>50 kg (110 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq® nonadhesive sensor, single-patient-use, adult, reusable cable</td><td>OxiCliq A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq nonadhesive sensor, single-patient-use, neonatal/adult, reusable cable</td><td>OxiCliq N</td><td><3 kg or >40 kg (<6.6 lbs or >82 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq nonadhesive sensor, single-patient-use, pediatric, reusable cable</td><td>OxiCliq P</td><td>10 to 50 kg (22 to 110 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq nonadhesive sensor, single-patient-use, infant, reusable cable</td><td>OxiCliq I</td><td>3 to 20 kg (6.6 to 44.1 lbs)</td></tr>
<tr><td><i>OxiMax Durasensor</i>® finger-clip sensor, reusable, adult</td><td>DS-100A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td><i>OxiMax Oxiband</i>® sensor, reusable, neonatal/adult</td><td>OXI-A/N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
<tr><td><i>OxiMax Oxiband</i> sensor, reusable, pediatric/infant</td><td>OXI-P/I</td><td>3 kg to 40 kg (6.6 lbs to 88 lbs)</td></tr>
</table>
(N-550 Manual, p. 67)</td></tr>
</table>

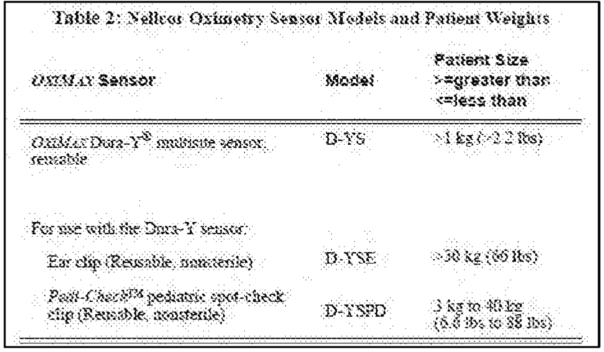
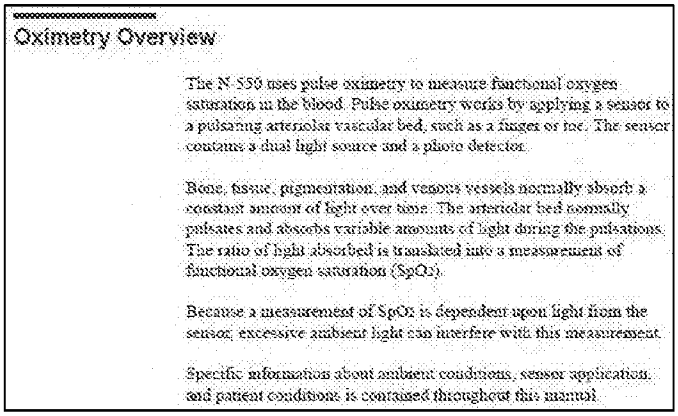
<table>
<tr><th>Asserted Claim of '286 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>


Table 2: Nellcor Oximetry Sensor Models and Patient Weights

<table>
<tr><th><i>OxiMax</i> Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td><i>OxiMax</i> Dura-Y® multisite sensor, reusable</td><td>D-YS</td><td>>1 kg (>2.2 lbs)</td></tr>
<tr><td>For use with the Dura-Y sensor:</td><td></td><td></td></tr>
<tr><td>Ear clip (Reusable, nonsterile)</td><td>D-YSE</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>Pedi-Check</i>™ pediatric spot-check clip (Reusable, nonsterile)</td><td>D-YSPD</td><td>3 kg to 40 kg
(6.6 lbs to 88 lbs)</td></tr>
</table>

(N-550 Manual, p. 68)



Oximetry Overview

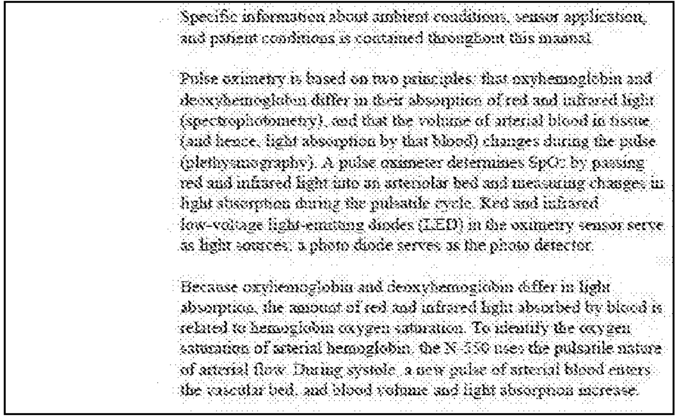
The N-550 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photo detector.

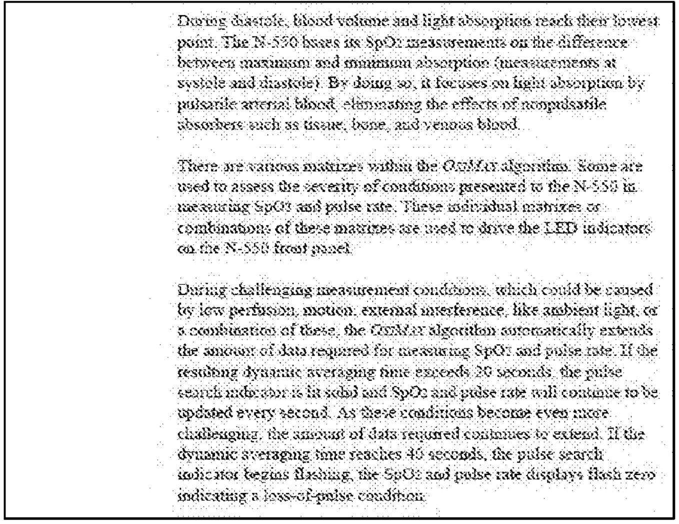
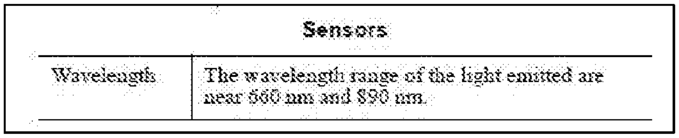
Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO2).

Because a measurement of SpO2 is dependent upon light from the sensor, excessive ambient light can interfere with this measurement.

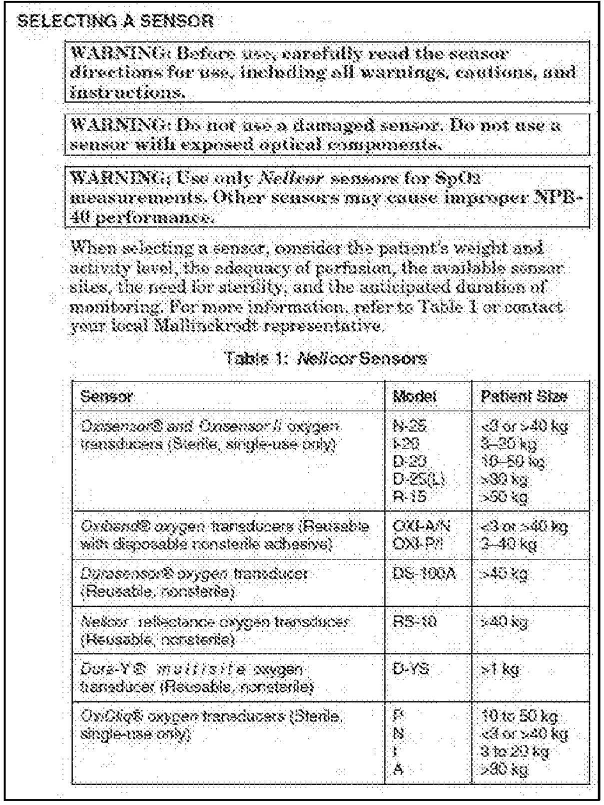
Specific information about ambient conditions, sensor application, and patient conditions is contained throughout this manual.

(N-550 Manual, p. 93)
</td></tr>
</table>

Asserted Claim of '286 Patent	Nellcor Pulse Oximeters
	 Specific information about ambient conditions, sensor application, and patient conditions is contained throughout this manual. Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography). A pulse oximeter determines SpO_2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry sensor serve as light sources; a photo diode serves as the photo detector. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial hemoglobin, the N-550 uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. (N-550 Manual, p. 93)

<table>
<tr><th>Asserted Claim of '286 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>

<p>During diastole, blood volume and light absorption reach their lowest point. The N-550 bases its SpO2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.</p>
<p>There are various matrixes within the <i>OxiMax</i> algorithm. Some are used to assess the severity of conditions presented to the N-550 in measuring SpO2 and pulse rate. These individual matrixes or combinations of these matrixes are used to drive the LED indicators on the N-550 front panel.</p>
<p>During challenging measurement conditions, which could be caused by low perfusion, motion, external interference, like ambient light, or a combination of these, the <i>OxiMax</i> algorithm automatically extends the amount of data required for measuring SpO2 and pulse rate. If the resulting dynamic averaging time exceeds 20 seconds, the pulse search indicator is lit solid and SpO2 and pulse rate will continue to be updated every second. As these conditions become even more challenging, the amount of data required continues to extend. If the dynamic averaging time reaches 40 seconds, the pulse search indicator begins flashing, the SpO2 and pulse rate displays flash zero indicating a loss-of-pulse condition.</p>
<p>(N-550 Manual, p. 94)</p>

<p>Sensors</p>
<table>
<tr><td>Wavelength</td><td>The wavelength range of the light emitted are near 660 nm and 890 nm.</td></tr>
</table>
<p>(N-550 Manual, p. 102)</p>
</td></tr>
</table>

<table>
<tr><th>Asserted Claim of '286 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>



SELECTING A SENSOR

WARNING: Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

WARNING: Do not use a damaged sensor. Do not use a sensor with exposed optical components.

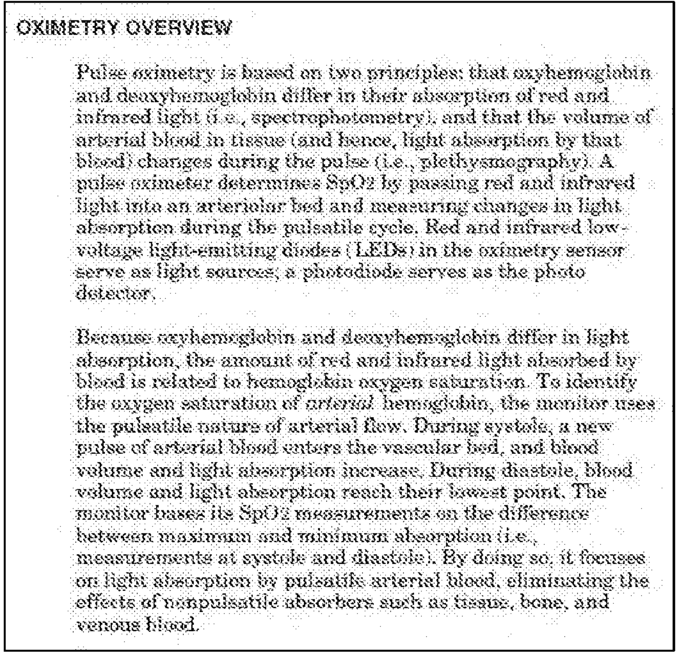
WARNING: Use only *Nellcor* sensors for SpO_2 measurements. Other sensors may cause improper NPB-40 performance.

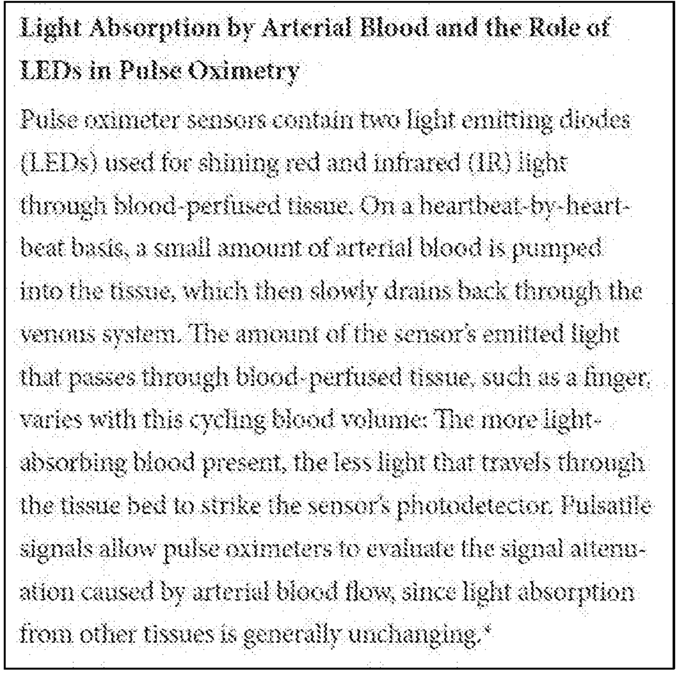
When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Mallinckrodt representative.

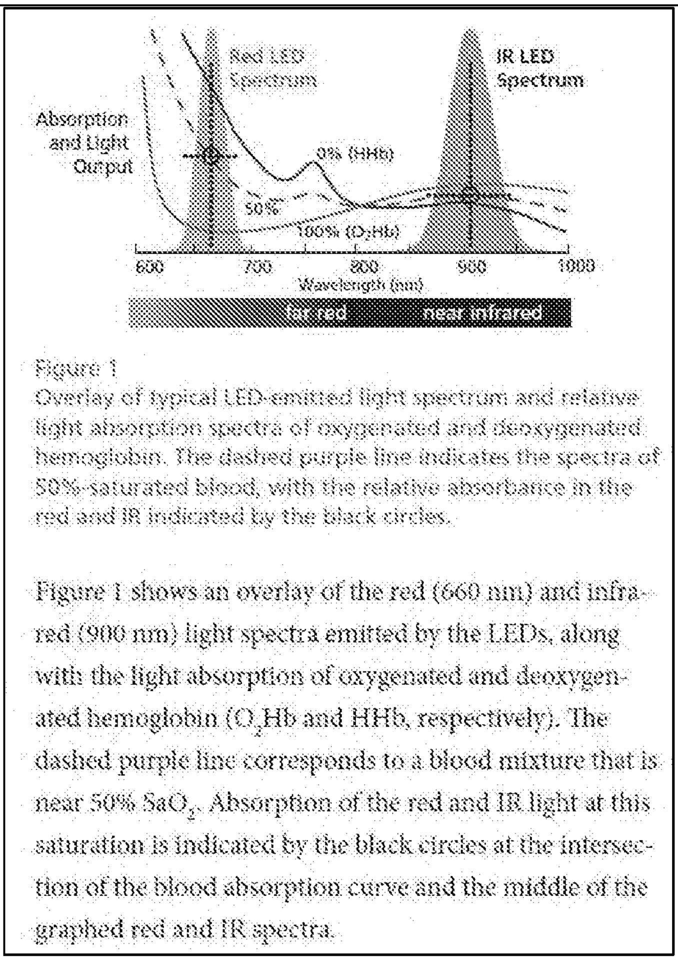
Table 1: *Nellcor* Sensors

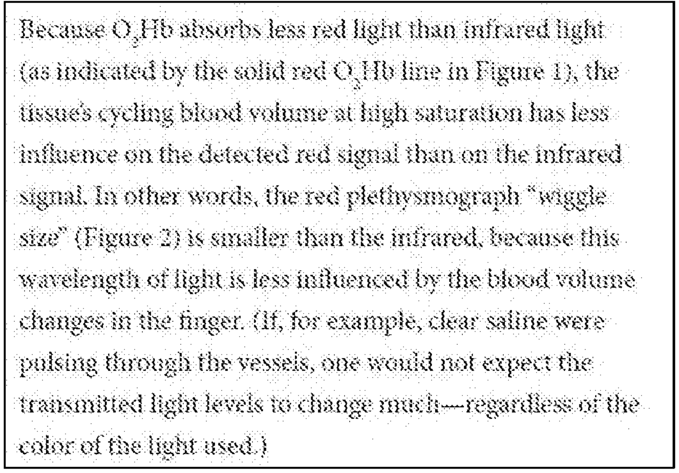
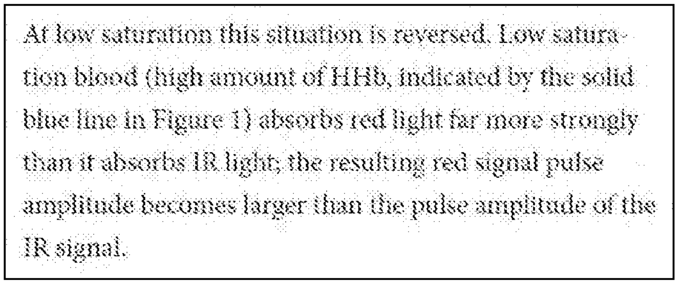
Sensor	Model	Patient Size
Oxisensor® and *Oxisensor II* oxygen transducers (Sterile, single-use only)	N-25 I-20 D-20 D-25(L) R-15	<3 or >40 kg 3–20 kg 10–50 kg >30 kg >50 kg
Oxiband® oxygen transducers (Reusable with disposable nonsterile adhesive)	OXI-A/N OXI-P/I	<3 or >40 kg 3–40 kg
Durasensor® oxygen transducer (Reusable, nonsterile)	DS-100A	>40 kg
Nellcor reflectance oxygen transducer (Reusable, nonsterile)	RS-10	>40 kg
Dura-Y® multisite oxygen transducer (Reusable, nonsterile)	D-YS	>1 kg
OxiCliq® oxygen transducers (Sterile, single-use only)	P N I A	10 to 50 kg <3 or >40 kg 3 to 20 kg >30 kg

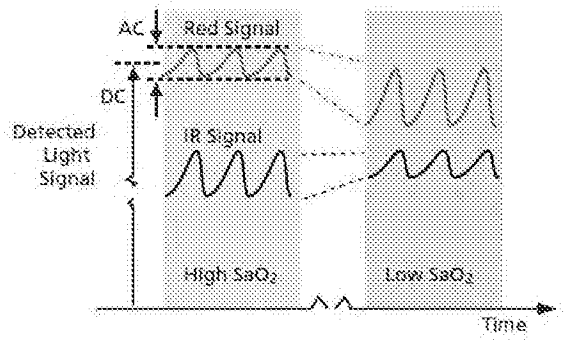
(NPB-40 Operator's Manual, p. 15)
</td></tr>
</table>

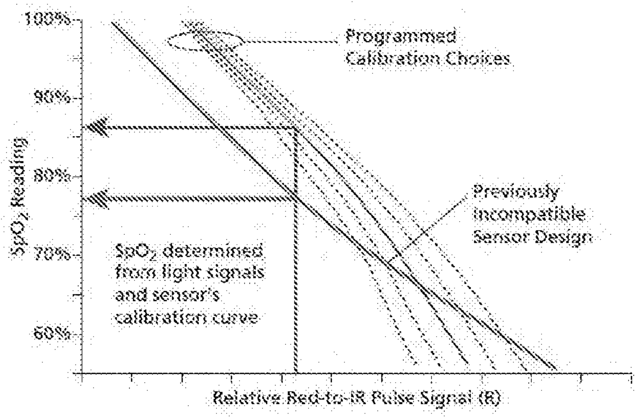
Asserted Claim of '286 Patent	**Nellcor Pulse Oximeters**
	 OXIMETRY OVERVIEW Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e., spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e., plethysmography). A pulse oximeter determines SpO2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LEDs) in the oximetry sensor serve as light sources; a photodiode serves as the photo detector. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of *arterial* hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitor bases its SpO2 measurements on the difference between maximum and minimum absorption (i.e., measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. (NPB-40 Operator's Manual, p. 41)

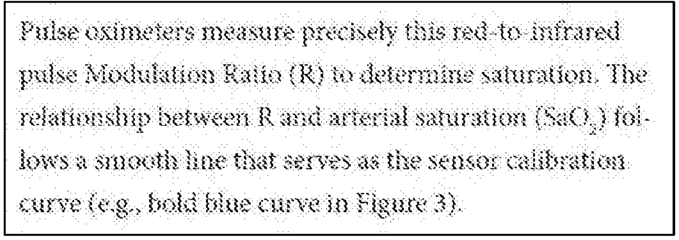
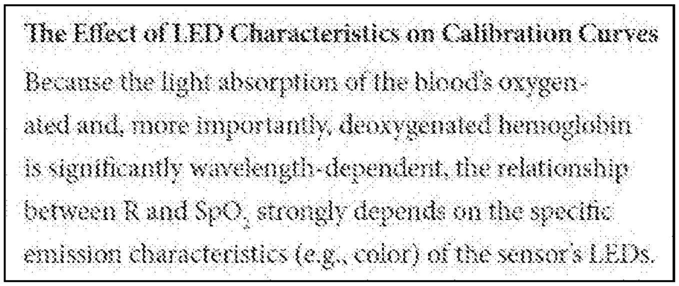
Asserted Claim of '286 Patent	Nellcor Pulse Oximeters
	 **Light Absorption by Arterial Blood and the Role of LEDs in Pulse Oximetry** Pulse oximeter sensors contain two light emitting diodes (LEDs) used for shining red and infrared (IR) light through blood-perfused tissue. On a heartbeat-by-heartbeat basis, a small amount of arterial blood is pumped into the tissue, which then slowly drains back through the venous system. The amount of the sensor's emitted light that passes through blood-perfused tissue, such as a finger, varies with this cycling blood volume: The more light-absorbing blood present, the less light that travels through the tissue bed to strike the sensor's photodetector. Pulsatile signals allow pulse oximeters to evaluate the signal attenuation caused by arterial blood flow, since light absorption from other tissues is generally unchanging.* (White Paper, p. 1)

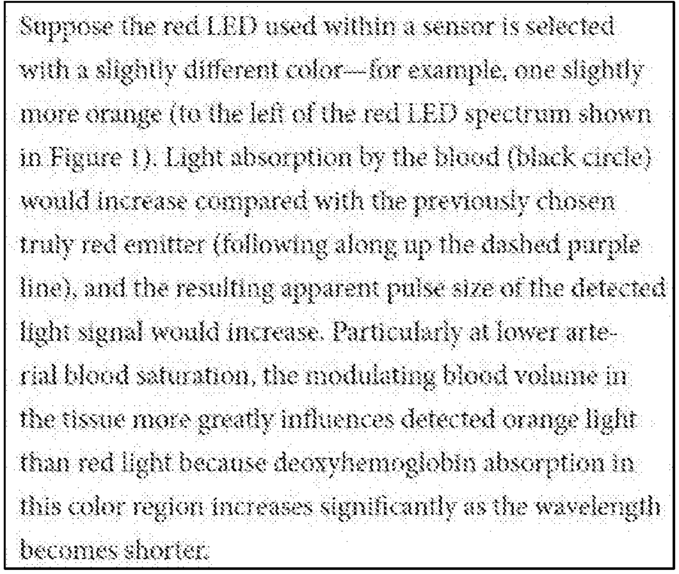
	 Figure 1 Overlay of typical LED-emitted light spectrum and relative light absorption spectra of oxygenated and deoxygenated hemoglobin. The dashed purple line indicates the spectra of 50%-saturated blood, with the relative absorbance in the red and IR indicated by the black circles. Figure 1 shows an overlay of the red (660 nm) and infrared (900 nm) light spectra emitted by the LEDs, along with the light absorption of oxygenated and deoxygenated hemoglobin (O_2Hb and HHb, respectively). The dashed purple line corresponds to a blood mixture that is near 50% SaO_2. Absorption of the red and IR light at this saturation is indicated by the black circles at the intersection of the blood absorption curve and the middle of the graphed red and IR spectra. (White Paper, p. 2)

Asserted Claim of '286 Patent	Nellcor Pulse Oximeters
	 Because O_2Hb absorbs less red light than infrared light (as indicated by the solid red O_2Hb line in Figure 1), the tissue's cycling blood volume at high saturation has less influence on the detected red signal than on the infrared signal. In other words, the red plethysmograph "wiggle size" (Figure 2) is smaller than the infrared, because this wavelength of light is less influenced by the blood volume changes in the finger. (If, for example, clear saline were pulsing through the vessels, one would not expect the transmitted light levels to change much—regardless of the color of the light used.) (White Paper, p. 2)  At low saturation this situation is reversed. Low saturation blood (high amount of HHb, indicated by the solid blue line in Figure 1) absorbs red light far more strongly than it absorbs IR light; the resulting red signal pulse amplitude becomes larger than the pulse amplitude of the IR signal. (White Paper, p. 2)

Asserted Claim of '286 Patent	Nellcor Pulse Oximeters
	 Figure 2 Red and IR light signals at high and low arterial oxygen saturation. At high saturation, the red "pulse amplitude" (AC/DC) is smaller than in the IR. At low saturation, the ratio of relative amplitudes is reversed. (White Paper, p. 2)

Asserted Claim of '286 Patent	Nellcor Pulse Oximeters
	 Figure 3 The blue lines depict the one or more calibration curves programmed into earlier-generation monitors, while the red line indicates a calibration required of a hypothetical new sensor. Such a design would be incompatible with these earlier monitors, since none of the blue curves could provide accurate SpO$_2$ values for the sensor's signals. (White Paper, p. 2)

Asserted Claim of '286 Patent	Nellcor Pulse Oximeters
	 Pulse oximeters measure precisely this red-to-infrared pulse Modulation Ratio (R) to determine saturation. The relationship between R and arterial saturation (SaO_2) follows a smooth line that serves as the sensor calibration curve (e.g., bold blue curve in Figure 3). (White Paper, p. 2)  **The Effect of LED Characteristics on Calibration Curves** Because the light absorption of the blood's oxygenated and, more importantly, deoxygenated hemoglobin is significantly wavelength-dependent, the relationship between R and SpO_2 strongly depends on the specific emission characteristics (e.g., color) of the sensor's LEDs. (White Paper, p. 3)

Asserted Claim of '286 Patent	Nellcor Pulse Oximeters
	 Suppose the red LED used within a sensor is selected with a slightly different color—for example, one slightly more orange (to the left of the red LED spectrum shown in Figure 1). Light absorption by the blood (black circle) would increase compared with the previously chosen truly red emitter (following along up the dashed purple line), and the resulting apparent pulse size of the detected light signal would increase. Particularly at lower arterial blood saturation, the modulating blood volume in the tissue more greatly influences detected orange light than red light because deoxyhemoglobin absorption in this color region increases significantly as the wavelength becomes shorter. (White Paper, p. 3)

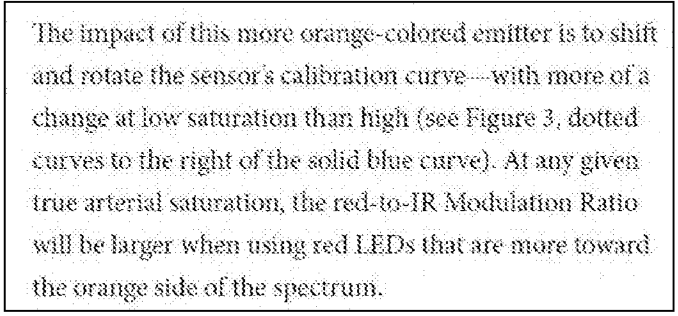
Asserted Claim of '286 Patent	Nellcor Pulse Oximeters
	 The impact of this more orange-colored emitter is to shift and rotate the sensor's calibration curve—with more of a change at low saturation than high (see Figure 3, dotted curves to the right of the solid blue curve). At any given true arterial saturation, the red-to-IR Modulation Ratio will be larger when using red LEDs that are more toward the orange side of the spectrum. (White Paper, p. 3)
[19] The wearable device of claim 16, wherein the receiver is configured to be synchronized to the modulating of at least one of the LEDs.	Nellcor discloses and/or renders obvious "[t]he wearable device of claim 16, wherein the receiver is configured to be synchronized to the modulating of at least one of the LEDs." *See* CHART ONE: '533 Patent, Claim Element 5F above.
[20] The wearable device of claim 16, wherein the receiver is located a first distance from a first one of the LEDs and a different distance from a second one of the LEDs such that the receiver can capture a third signal from the first LED and a fourth signal from the second LED, and wherein the output signal is generated in part by comparing the third and fourth signals.	Nellcor discloses and/or renders obvious "[t]he wearable device of claim 16, wherein the receiver is located a first distance from a first one of the LEDs and a different distance from a second one of the LEDs such that the receiver can capture a third signal from the first LED and a fourth signal from the second LED, and wherein the output signal is generated in part by comparing the third and fourth signals.." *See* CHART ONE: '533 Patent, Claim Element 8 above.

EXHIBIT X-4

U.S. Patent No. 9,885,698 vs Nellcor

Priority Date/Publication Date: between 2001 and December 2012 Prior Art Status: §§ 102(a) and (b)

The OxiMax, NPB-40, N-550, and certain pulse oximeters and pulse oximetry sensors manufactured by Nellcor ("Nellcor") anticipate the asserted claims of U.S. Patent No. 9,651,533 ("the '533 Patent") or render those claims obvious alone and/or in view of at least any of the references identified in Apple's Obviousness Combinations Chart.

This chart is based on the following disclosures about Nellcor pulse oximeters:

- Nellcor OxiMax NPB-40 Handheld Pulse Oximeter Service Manual 2004 ("NPB-40 Service Manual")
- Nellcor OxiMax N-550 Pulse Oximeter Service Manual 2003 ("N-550 Manual")
- Nellcor NPB-40 Handheld Pulse Oximeter Operator's Manual 2001 ("NPB-40 Operator's Manual")
- Nellcor OxiMax White Paper "A Technology Overview of the Nellcor™ OxiMax Pulse Oximetry System" 2003 ("White Paper")

Discovery is ongoing, and Apple reserves the right to amend this chart based on new information about the Nellcor pulse oximeters.

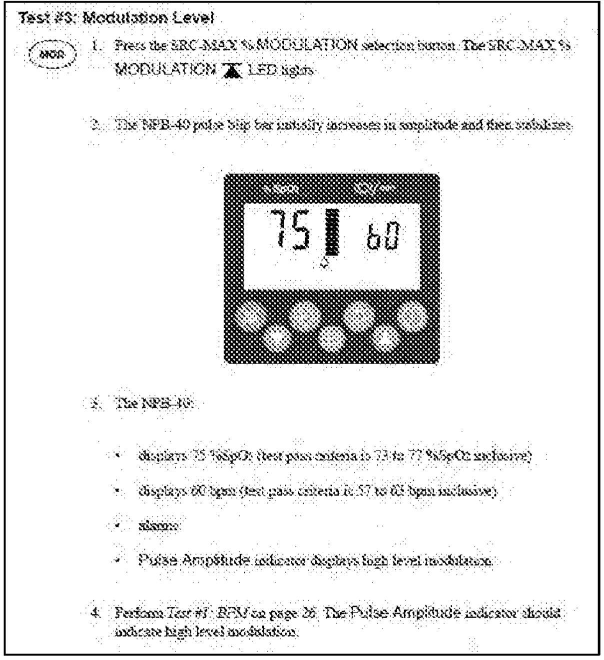
As set forth in Apple's Invalidity Contentions, the below contentions apply the prior art in part in accordance with Apple's assumption that Omni contends the claims are not invalid under 35 U.S.C. § 112. However, Apple's below contentions do not represent Apple's agreement or view as to the meaning, definiteness, written description support for, or enablement of any of the asserted claims. For each dependent claim, the disclosures cited for the claim from which it depends are incorporated by reference.

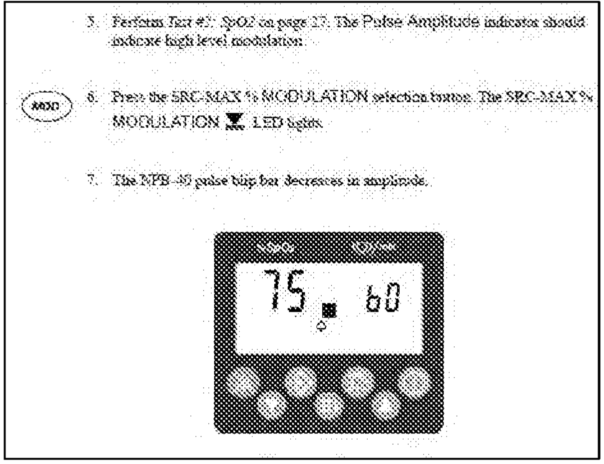
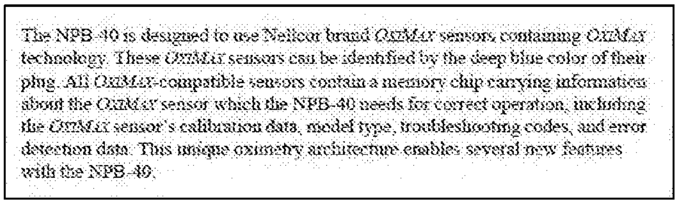
CHART FOUR: U.S. Patent No. 9,885,698 vs Nellcor

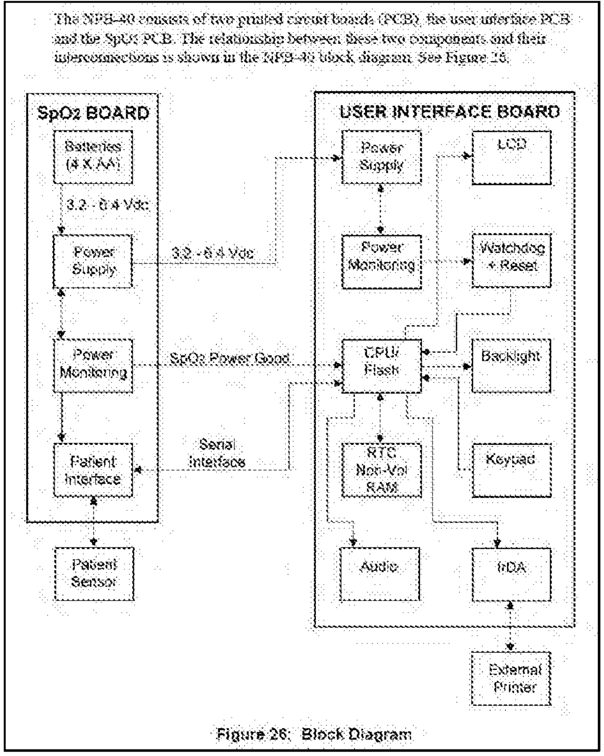
Asserted Claim of '698 Patent	Nellcor Pulse Oximeters
[1] A wearable device, comprising:	To the extent the preamble is limiting, Nellcor discloses and/or renders obvious "[a] wearable device." *See* CHART ONE: '533 Patent, Claim Elements 5 and 13A above.
[1A] a measurement device including a light source comprising a plurality of light emitting diodes (LEDs) for measuring one or more physiological parameters,	Nellcor discloses and/or renders obvious "a measurement device including a light source comprising a plurality of light emitting diodes (LEDs) for measuring one or more physiological parameters." *See* CHART ONE: '533 Patent, Claim Element 13A above.
[1B] the measurement device configured to generate, by modulating at least one of the LEDs having an initial light intensity, an input optical beam having one or more optical wavelengths,	Nellcor discloses and/or renders obvious "the measurement device configured to generate, by modulating at least one of the LEDs having an initial light intensity, an input optical beam having one or more optical wavelengths." *See* CHART TWO: '040 Patent, Claim Element 1B above.
[1C] wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers;	Nellcor discloses and/or renders obvious "wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers." *See* CHART ONE: '533 Patent, Claim Element 5B above.
[1D] the measurement device comprising one or more lenses configured to receive and to deliver a portion of the input optical beam to tissue, wherein	Nellcor discloses and/or renders obvious "the measurement device comprising one or more lenses configured to receive and to deliver a portion of the input optical beam to tissue, wherein the tissue reflects at least a portion of the input optical beam delivered to the tissue." *See* CHART ONE: '533 Patent, Claim Element 5D above.

Asserted Claim of '698 Patent	Nellcor Pulse Oximeters
the tissue reflects at least a portion of the input optical beam delivered to the tissue;	
[1E] the measurement device further comprising a receiver, wherein the receiver includes a plurality of spatially separated detectors, the detectors configured to: capture light while the LEDs are off and convert the captured light into a first signal; and capture light while at least one of the LEDs is on and convert the captured light into a second signal, the captured light including at least a portion of the input optical beam reflected from the tissue;	Nellcor discloses and/or renders obvious "the measurement device further comprising a receiver, wherein the receiver includes a plurality of spatially separated detectors, the detectors configured to: capture light while the LEDs are off and convert the captured light into a first signal; and capture light while at least one of the LEDs is on and convert the captured light into a second signal, the captured light including at least a portion of the input optical beam reflected from the tissue." *See* CHART TWO: '040 Patent, Claim Element 1F and CHART THREE: '286 Patent, Claim Element 16J above.
[1F] wherein at least one analog to digital converter is coupled to the spatially separated detectors and is configured to generate at least a first data signal from the first signal and at least a second data signal from the second signal;	Nellcor discloses and/or renders obvious "wherein at least one analog to digital converter is coupled to the spatially separated detectors and is configured to generate at least a first data signal from the first signal and at least a second data signal from the second signal." *See* CHART TWO: '040 Patent, Claim Element 1F and CHART THREE: '286 Patent, Claim Element 16K above.

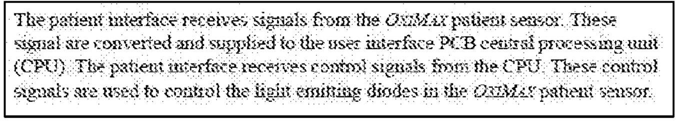
Asserted Claim of '698 Patent	Nellcor Pulse Oximeters
[1G] the measurement device configured to improve a signal-to-noise ratio of the input optical beam reflected from the tissue by differencing the first data signal and the second data signal to generate an output signal representing at least in part a non-invasive measurement on blood contained within the tissue; and	Nellcor discloses and/or renders obvious "the measurement device configured to improve a signal-to-noise ratio of the input optical beam reflected from the tissue by differencing the first data signal and the second data signal to generate an output signal representing at least in part a non-invasive measurement on blood contained within the tissue." *See* CHART ONE: '533 Patent, Claim Element 10 and CHART TWO: '040 Patent, Claim Element 1G above.
[1H] wherein the modulating at least one of the LEDs has a modulation frequency, and wherein the receiver is configured to use a lock-in technique that detects the modulation frequency.	Nellcor discloses and/or renders obvious "wherein the modulating at least one of the LEDs has a modulation frequency, and wherein the receiver is configured to use a lock-in technique that detects the modulation frequency."

Asserted Claim of '698 Patent	Nellcor Pulse Oximeters
	 Test #3: Modulation Level 1. Press the SRC-MAX % MODULATION selection button. The SRC-MAX % MODULATION ▲ LED lights. 2. The NPB-40 pulse blip bar initially increases in amplitude and then stabilizes. 3. The NPB-40: • displays 75 %SpO2 (test pass criteria is 73 to 77 %SpO2 inclusive) • displays 60 bpm (test pass criteria is 57 to 63 bpm inclusive) • alarms • Pulse Amplitude indicator displays high level modulation. 4. Perform Test #1: BPM on page 26. The Pulse Amplitude indicator should indicate high level modulation. (NPB-40 Service Manual, p. 29)

Asserted Claim of '698 Patent	Nellcor Pulse Oximeters
	 5. Perform *Test #2: SpO2* on page 27. The Pulse Amplitude indicator should indicate high level modulation. 6. Press the SRC-MAX % MODULATION selection button. The SRC-MAX % MODULATION ▼ LED lights. 7. The NPB-40 pulse blip bar decreases in amplitude. (NPB-40 Service Manual, p. 29)  The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)

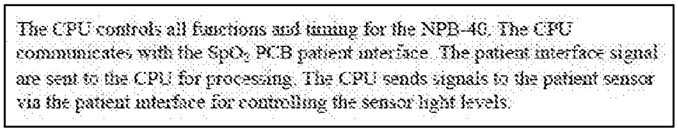
Asserted Claim of '698 Patent	Nellcor Pulse Oximeters
	 The NPB-40 consists of two printed circuit boards (PCB), the user interface PCB and the SpO2 PCB. The relationship between these two components and their interconnections is shown in the NPB-40 block diagram. See Figure 26. Figure 26: Block Diagram (NPB-40 Service Manual, p. 78)

Asserted Claim of '698 Patent	Nellcor Pulse Oximeters



The patient interface receives signals from the *OxiMax* patient sensor. These signal are converted and supplied to the user interface PCB central processing unit (CPU). The patient interface receives control signals from the CPU. These control signals are used to control the light emitting diodes in the *OxiMax* patient sensor.

(NPB-40 Service Manual, p. 78)



The CPU controls all functions and timing for the NPB-40. The CPU communicates with the SpO_2 PCB patient interface. The patient interface signal are sent to the CPU for processing. The CPU sends signals to the patient sensor via the patient interface for controlling the sensor light levels.

(NPB-40 Service Manual, p. 80)

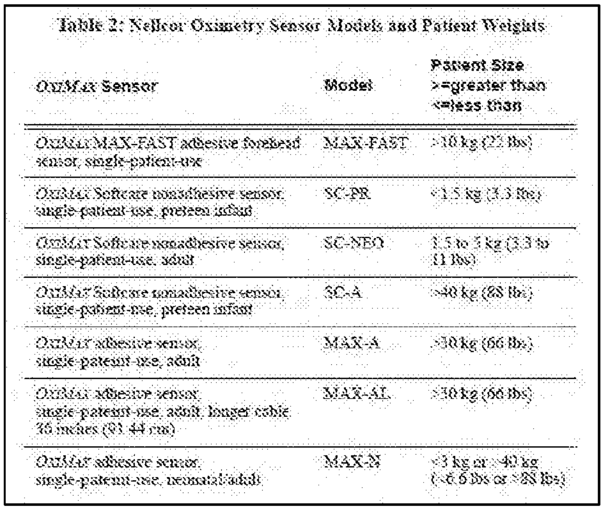


Table 2: Nellcor Oximetry Sensor Models and Patient Weights

OxiMax Sensor	Model	Patient Size >=greater than <=less than
OxiMax MAX-FAST adhesive forehead sensor, single-patient-use	MAX-FAST	>10 kg (22 lbs)
OxiMax Softcare nonadhesive sensor, single-patient-use, preteen infant	SC-PR	<1.5 kg (3.3 lbs)
OxiMax Softcare nonadhesive sensor, single-patient-use, adult	SC-NEO	1.5 to 3 kg (3.3 to 11 lbs)
OxiMax Softcare nonadhesive sensor, single-patient-use, preteen infant	SC-A	>40 kg (88 lbs)
OxiMax adhesive sensor, single-pateint-use, adult	MAX-A	>30 kg (66 lbs)
OxiMax adhesive sensor, single-pateint-use, adult, longer cable 36 inches (91.44 cm)	MAX-AL	>30 kg (66 lbs)
OxiMax adhesive sensor, single-pateint-use, neonatal/adult	MAX-N	<3 kg or >40 kg (<6.6 lbs or >88 lbs)

(N-550 Manual, p. 66)

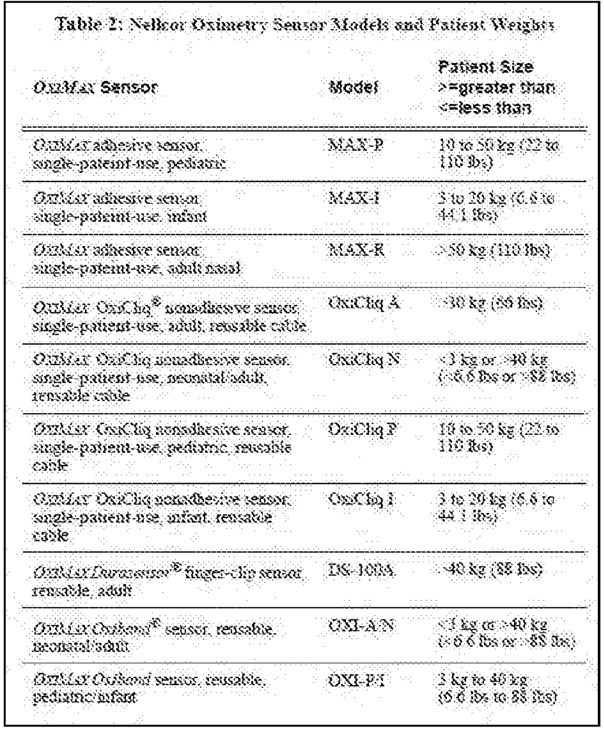
<table>
<tr><th>Asserted Claim of '698 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>


Table 2: Nellcor Oximetry Sensor Models and Patient Weights

<table>
<tr><th><i>OxiMax</i> Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, pediatric</td><td>MAX-P</td><td>10 to 50 kg (22 to 110 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, infant</td><td>MAX-I</td><td>3 to 20 kg (6.6 to 44.1 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult nasal</td><td>MAX-R</td><td>>50 kg (110 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq® nonadhesive sensor, single-patient-use, adult, reusable cable</td><td>OxiCliq A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq nonadhesive sensor, single-patient-use, neonatal/adult, reusable cable</td><td>OxiCliq N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq nonadhesive sensor, single-patient-use, pediatric, reusable cable</td><td>OxiCliq P</td><td>10 to 50 kg (22 to 110 lbs)</td></tr>
<tr><td><i>OxiMax</i> OxiCliq nonadhesive sensor, single-patient-use, infant, reusable cable</td><td>OxiCliq I</td><td>3 to 20 kg (6.6 to 44.1 lbs)</td></tr>
<tr><td><i>OxiMax Durasensor</i>® finger-clip sensor, reusable, adult</td><td>DS-100A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td><i>OxiMax Oxiband</i>® sensor, reusable, neonatal/adult</td><td>OXI-A/N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
<tr><td><i>OxiMax Oxiband</i> sensor, reusable, pediatric/infant</td><td>OXI-P/I</td><td>3 kg to 40 kg (6.6 lbs to 88 lbs)</td></tr>
</table>

(N-550 Manual, p. 67)
</td></tr>
</table>

<table>
<tr><th>Asserted Claim of '698 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>

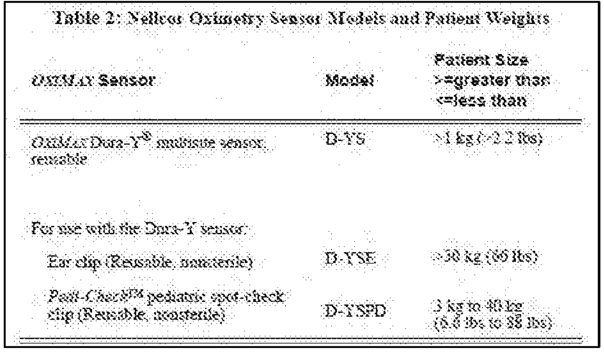
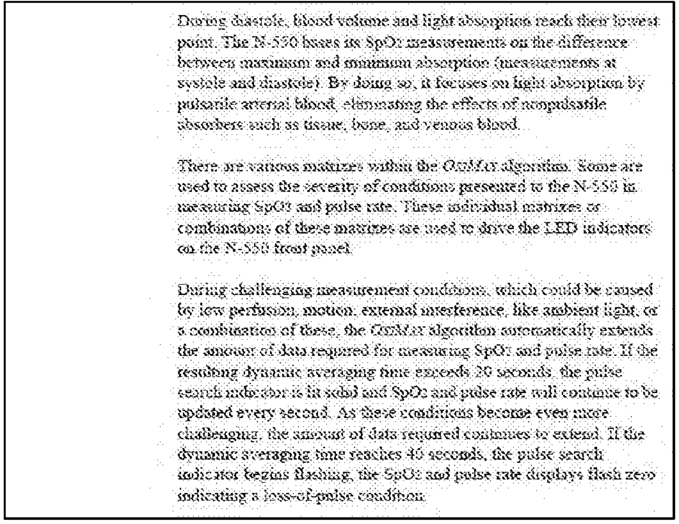
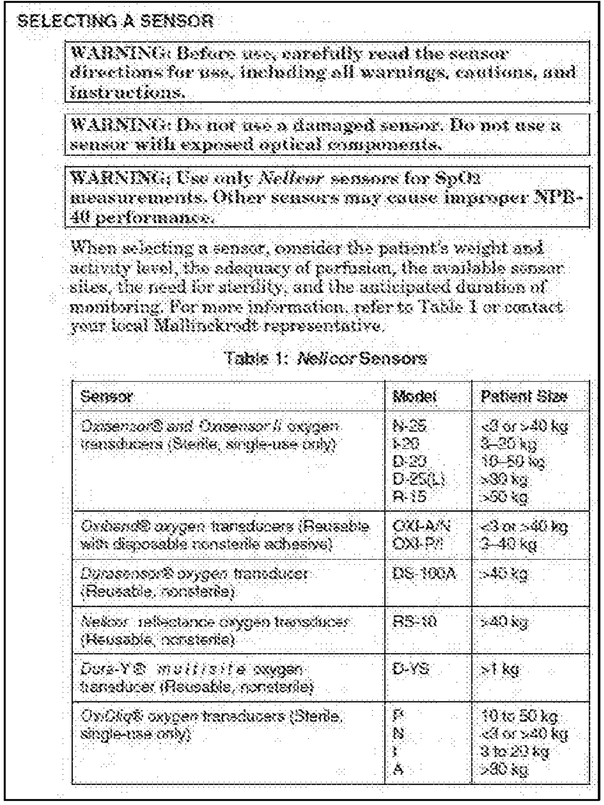



Table 2: Nellcor Oximetry Sensor Models and Patient Weights
<table>
<tr><th><i>OxiMax</i> Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td><i>OxiMax</i> Dura-Y® multisite sensor, reusable</td><td>D-YS</td><td>>1 kg (>2.2 lbs)</td></tr>
<tr><td>For use with the Dura-Y sensor:</td><td></td><td></td></tr>
<tr><td>Ear clip (Reusable, nonsterile)</td><td>D-YSE</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>Pedi-Check</i>™ pediatric spot-check clip (Reusable, nonsterile)</td><td>D-YSPD</td><td>3 kg to 40 kg
(6.6 lbs to 88 lbs)</td></tr>
</table>
(N-550 Manual, p. 68)
</td></tr>
</table>

Asserted Claim of '698 Patent	Nellcor Pulse Oximeters
	 During diastole, blood volume and light absorption reach their lowest point. The N-550 bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood. There are various matrixes within the *OxiMax* algorithm. Some are used to assess the severity of conditions presented to the N-550 in measuring SpO_2 and pulse rate. These individual matrixes or combinations of these matrixes are used to drive the LED indicators on the N-550 front panel. During challenging measurement conditions, which could be caused by low perfusion, motion, external interference, like ambient light, or a combination of these, the *OxiMax* algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate. If the resulting dynamic averaging time exceeds 20 seconds, the pulse search indicator is lit solid and SpO_2 and pulse rate will continue to be updated every second. As these conditions become even more challenging, the amount of data required continues to extend. If the dynamic averaging time reaches 40 seconds, the pulse search indicator begins flashing, the SpO_2 and pulse rate displays flash zero indicating a loss-of-pulse condition. (N-550 Manual, p. 94)

Asserted Claim of '698 Patent	**Nellcor Pulse Oximeters**
	 (NPB-40 Operator's Manual, p. 15)

SELECTING A SENSOR

WARNING: Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

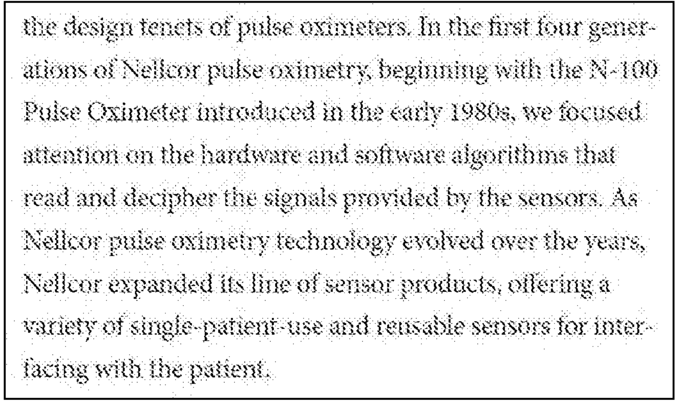
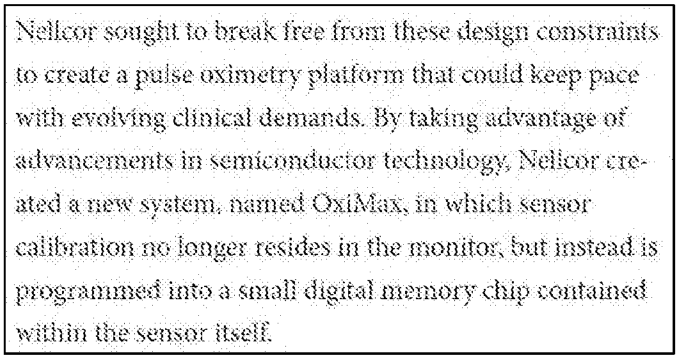
WARNING: Do not use a damaged sensor. Do not use a sensor with exposed optical components.

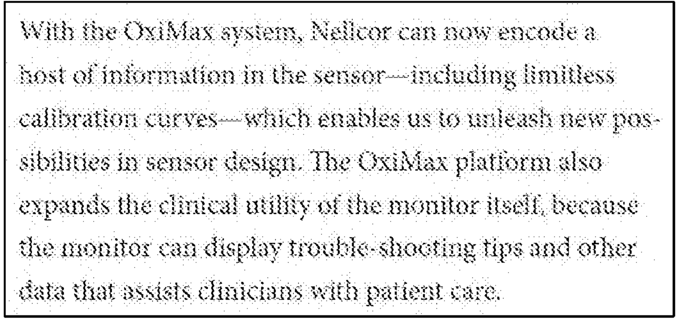
WARNING: Use only *Nellcor* sensors for SpO2 measurements. Other sensors may cause improper NPB-40 performance.

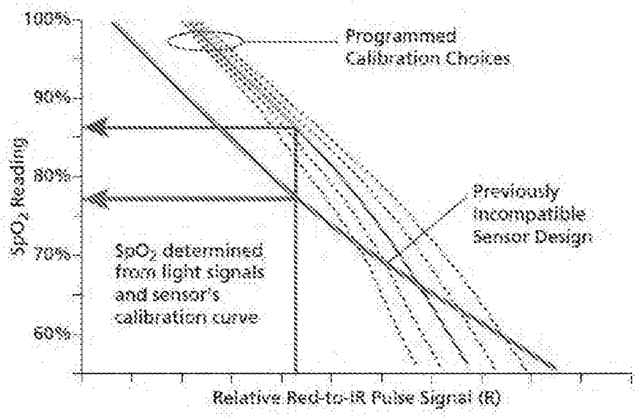
When selecting a sensor, consider the patient's weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Mallinckrodt representative.

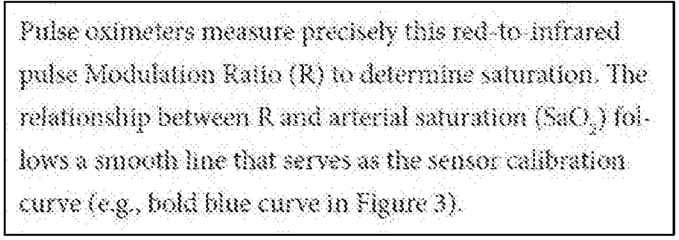
Table 1: *Nellcor* Sensors

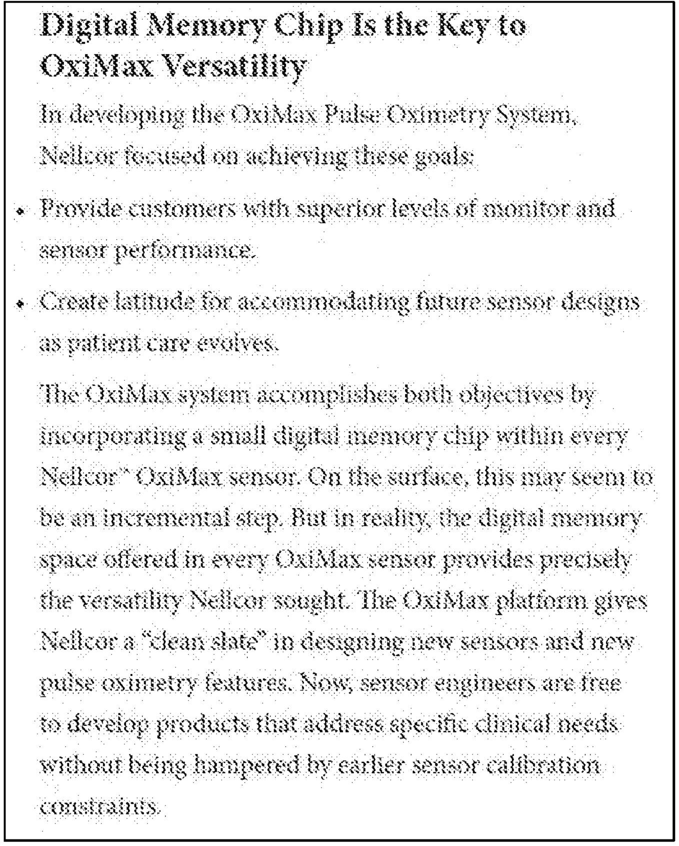
Sensor	Model	Patient Size
Oxisensor® and *Oxisensor II* oxygen transducers (Sterile, single-use only)	N-25 I-20 D-20 D-25(L) R-15	<3 or >40 kg 3–20 kg 10–50 kg >30 kg >50 kg
Oxiband® oxygen transducers (Reusable with disposable nonsterile adhesive)	OXI-A/N OXI-P/I	<3 or >40 kg 3–40 kg
Durasensor® oxygen transducer (Reusable, nonsterile)	DS-100A	>40 kg
Nellcor reflectance oxygen transducer (Reusable, nonsterile)	RS-10	>40 kg
Dura-Y® *multisite* oxygen transducer (Reusable, nonsterile)	D-YS	>1 kg
OxiCliq® oxygen transducers (Sterile, single-use only)	P N I A	10 to 50 kg <3 or >40 kg 3 to 20 kg >30 kg

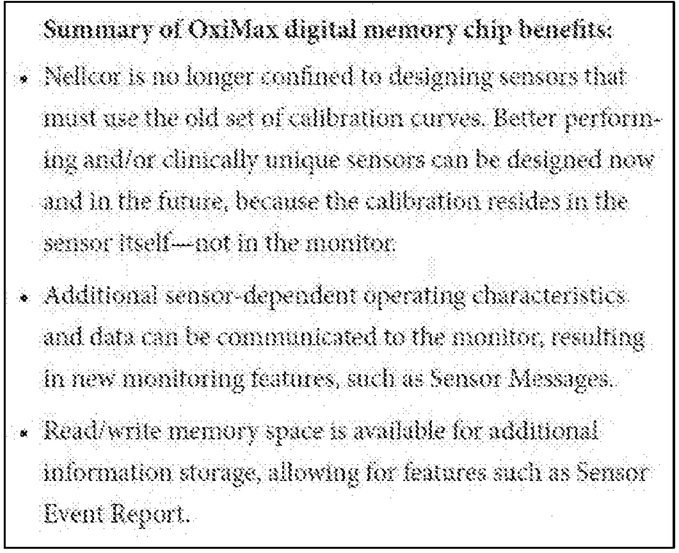
Asserted Claim of '698 Patent	Nellcor Pulse Oximeters
	 the design tenets of pulse oximeters. In the first four generations of Nellcor pulse oximetry, beginning with the N-100 Pulse Oximeter introduced in the early 1980s, we focused attention on the hardware and software algorithms that read and decipher the signals provided by the sensors. As Nellcor pulse oximetry technology evolved over the years, Nellcor expanded its line of sensor products, offering a variety of single-patient-use and reusable sensors for interfacing with the patient. (White Paper, p. 1)  Nellcor sought to break free from these design constraints to create a pulse oximetry platform that could keep pace with evolving clinical demands. By taking advantage of advancements in semiconductor technology, Nellcor created a new system, named OxiMax, in which sensor calibration no longer resides in the monitor, but instead is programmed into a small digital memory chip contained within the sensor itself. (White Paper, p. 1)

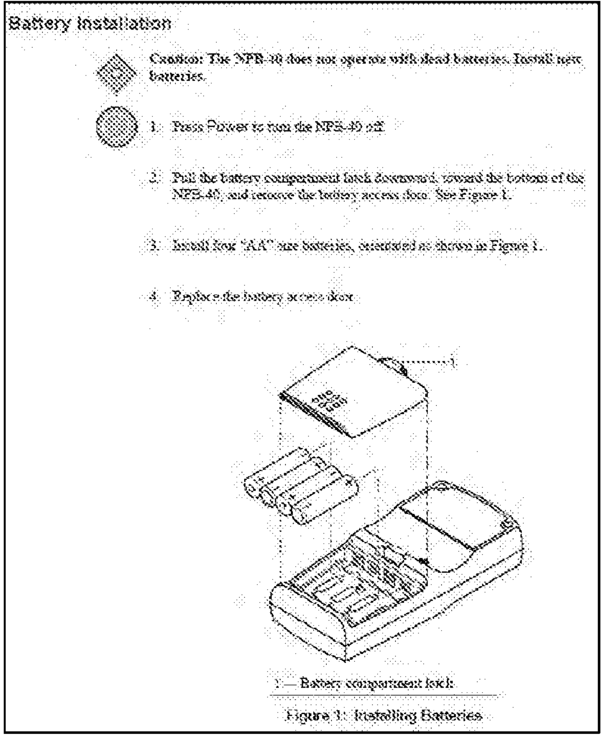
Asserted Claim of '698 Patent	Nellcor Pulse Oximeters
	 With the OxiMax system, Nellcor can now encode a host of information in the sensor—including limitless calibration curves—which enables us to unleash new possibilities in sensor design. The OxiMax platform also expands the clinical utility of the monitor itself, because the monitor can display trouble-shooting tips and other data that assists clinicians with patient care. (White Paper, p. 1)

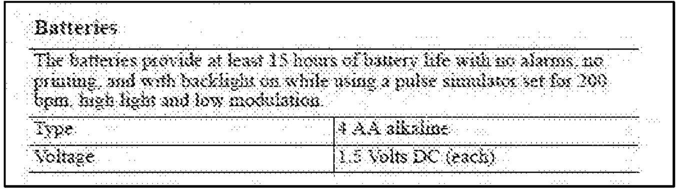
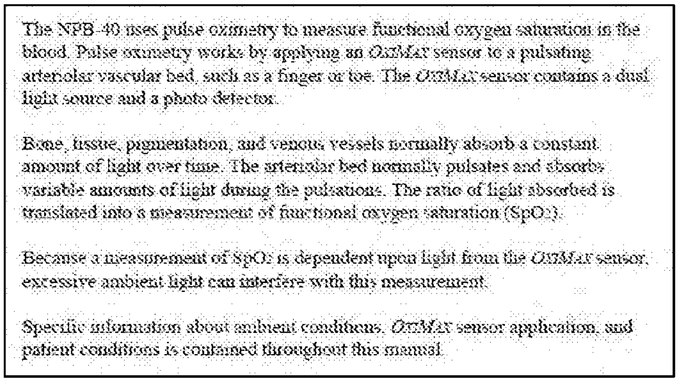
Asserted Claim of '698 Patent	Nellcor Pulse Oximeters
	 Figure 3 The blue lines depict the one or more calibration curves programmed into earlier-generation monitors, while the red line indicates a calibration required of a hypothetical new sensor. Such a design would be incompatible with these earlier monitors, since none of the blue curves could provide accurate SpO_2 values for the sensor's signals. (White Paper, p. 2)

Asserted Claim of '698 Patent	Nellcor Pulse Oximeters
	 Pulse oximeters measure precisely this red-to-infrared pulse Modulation Ratio (R) to determine saturation. The relationship between R and arterial saturation (SaO_2) follows a smooth line that serves as the sensor calibration curve (e.g., bold blue curve in Figure 3). (White Paper, p. 2)

Asserted Claim of '698 Patent	Nellcor Pulse Oximeters
	 **Digital Memory Chip Is the Key to OxiMax Versatility** In developing the OxiMax Pulse Oximetry System, Nellcor focused on achieving these goals: • Provide customers with superior levels of monitor and sensor performance. • Create latitude for accommodating future sensor designs as patient care evolves. The OxiMax system accomplishes both objectives by incorporating a small digital memory chip within every Nellcor™ OxiMax sensor. On the surface, this may seem to be an incremental step. But in reality, the digital memory space offered in every OxiMax sensor provides precisely the versatility Nellcor sought. The OxiMax platform gives Nellcor a "clean slate" in designing new sensors and new pulse oximetry features. Now, sensor engineers are free to develop products that address specific clinical needs without being hampered by earlier sensor calibration constraints. (White Paper, p. 4)

Asserted Claim of '698 Patent	Nellcor Pulse Oximeters
	 Summary of OxiMax digital memory chip benefits: • Nellcor is no longer confined to designing sensors that must use the old set of calibration curves. Better performing and/or clinically unique sensors can be designed now and in the future, because the calibration resides in the sensor itself—not in the monitor. • Additional sensor-dependent operating characteristics and data can be communicated to the monitor, resulting in new monitoring features, such as Sensor Messages. • Read/write memory space is available for additional information storage, allowing for features such as Sensor Event Report. (White Paper, p. 5)
[2] The wearable device of claim 1, wherein the plurality of LEDs and the plurality of spatially separated detectors are mounted on a common structure, and wherein the plurality of LEDs are coupled electrically to a power supply.	Nellcor discloses and/or renders obvious "[t]he wearable device of claim 1, wherein the plurality of LEDs and the plurality of spatially separated detectors are mounted on a common structure, and wherein the plurality of LEDs are coupled electrically to a power supply.."

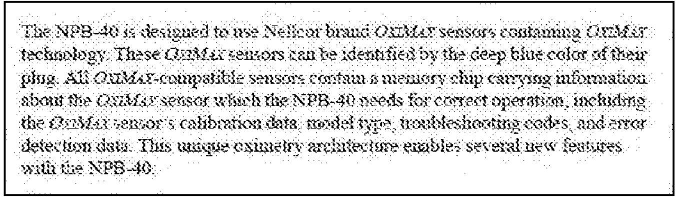
Asserted Claim of '698 Patent	Nellcor Pulse Oximeters
	 Battery Installation Caution: The NPB-40 does not operate with dead batteries. Install new batteries. 1. Press Power to turn the NPB-40 off. 2. Pull the battery compartment latch downward, toward the bottom of the NPB-40, and remove the battery access door. See Figure 1. 3. Install four "AA" size batteries, oriented as shown in Figure 1. 4. Replace the battery access door. 1 — Battery compartment latch Figure 1: Installing Batteries (NPB-40 Service Manual, p. 12)

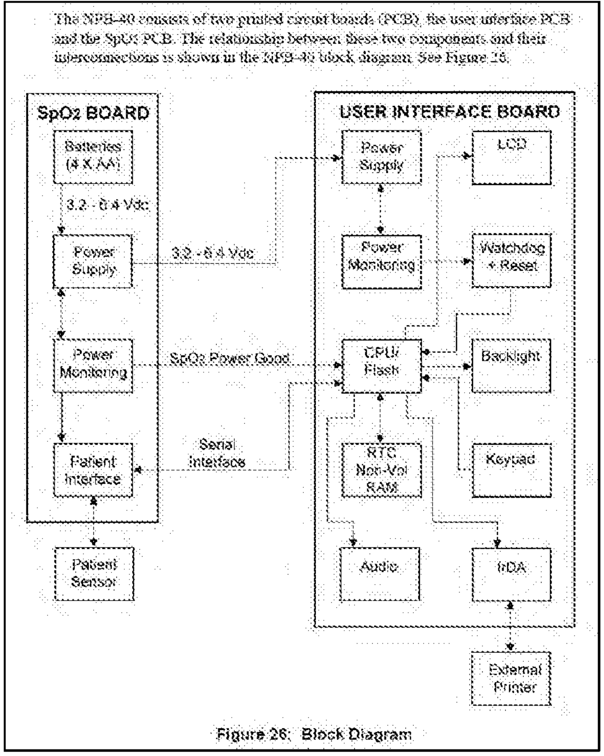
<table>
<tr><th>Asserted Claim of '698 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>
Batteries
The batteries provide at least 15 hours of battery life with no alarms, no printing, and with backlight on while using a pulse simulator set for 200 bpm, high light and low modulation.<table><tr><td>Type</td><td>4 AA alkaline</td></tr><tr><td>Voltage</td><td>1.5 Volts DC (each)</td></tr></table>(NPB-40 Service Manual, p. 67)

The NPB-40 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying an *OxiMax* sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The *OxiMax* sensor contains a dual light source and a photo detector.

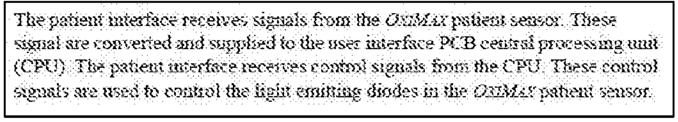
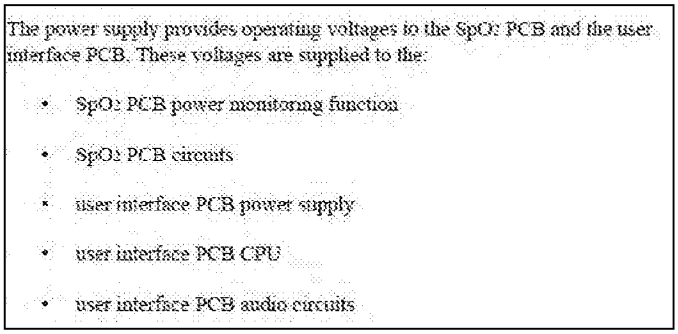
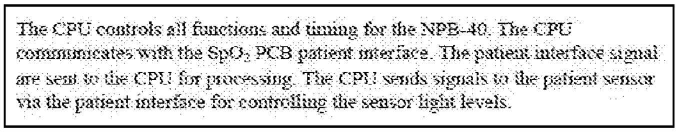
Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO2).

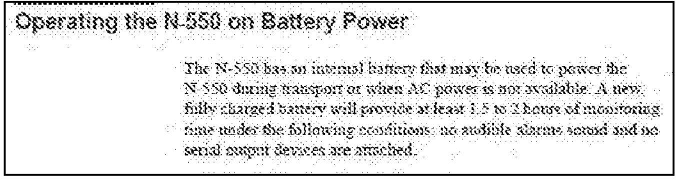
Because a measurement of SpO2 is dependent upon light from the *OxiMax* sensor, excessive ambient light can interfere with this measurement.

Specific information about ambient conditions, *OxiMax* sensor application, and patient conditions is contained throughout this manual.
(NPB-40 Service Manual, p. 75)</td></tr>
</table>

Asserted Claim of '698 Patent	**Nellcor Pulse Oximeters**
	 The NPB-40 is designed to use Nellcor brand *OxiMax* sensors containing *OxiMax* technology. These *OxiMax* sensors can be identified by the deep blue color of their plug. All *OxiMax*-compatible sensors contain a memory chip carrying information about the *OxiMax* sensor which the NPB-40 needs for correct operation, including the *OxiMax* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the NPB-40. (NPB-40 Service Manual, p. 76)

Asserted Claim of '698 Patent	Nellcor Pulse Oximeters
	 The NPB-40 consists of two printed circuit boards (PCB), the user interface PCB and the SpO2 PCB. The relationship between these two components and their interconnections is shown in the NPB-40 block diagram. See Figure 26. Figure 26: Block Diagram (NPB-40 Service Manual, p. 78)

Asserted Claim of '698 Patent	Nellcor Pulse Oximeters
	 The patient interface receives signals from the *OxiMax* patient sensor. These signal are converted and supplied to the user interface PCB central processing unit (CPU). The patient interface receives control signals from the CPU. These control signals are used to control the light emitting diodes in the *OxiMax* patient sensor. (NPB-40 Service Manual, p. 78)  The power supply provides operating voltages to the SpO2 PCB and the user interface PCB. These voltages are supplied to the: • SpO2 PCB power monitoring function • SpO2 PCB circuits • user interface PCB power supply • user interface PCB CPU • user interface PCB audio circuits (NPB-40 Service Manual, p. 79)  The CPU controls all functions and timing for the NPB-40. The CPU communicates with the SpO_2 PCB patient interface. The patient interface signal are sent to the CPU for processing. The CPU sends signals to the patient sensor via the patient interface for controlling the sensor light levels. (NPB-40 Service Manual, p. 80)

<table>
<tr><th>Asserted Claim of '698 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>


Operating the N-550 on Battery Power

The N-550 has an internal battery that may be used to power the N-550 during transport or when AC power is not available. A new, fully charged battery will provide at least 1.5 to 2 hours of monitoring time under the following conditions: no audible alarms sound and no serial output devices are attached.

(N-550 Manual, p. 19)

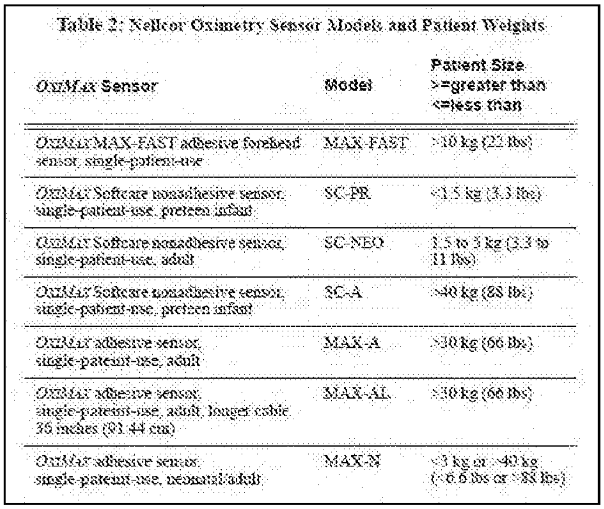
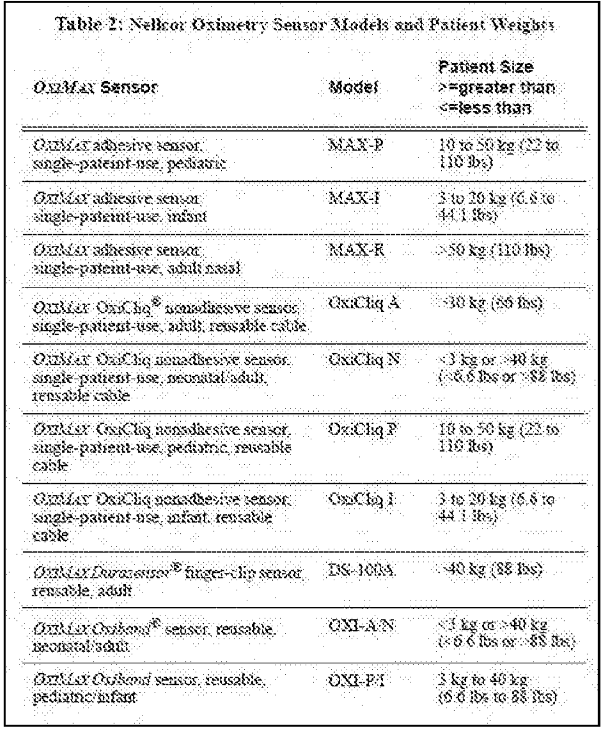


Table 2: Nellcor Oximetry Sensor Models and Patient Weights

<table>
<tr><th><i>OxiMax</i> Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td><i>OxiMax</i> MAX-FAST adhesive forehead sensor, single-patient-use</td><td>MAX-FAST</td><td>>10 kg (22 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-PR</td><td><1.5 kg (3.3 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, adult</td><td>SC-NEO</td><td>1.5 to 5 kg (3.3 to 11 lbs)</td></tr>
<tr><td><i>OxiMax</i> Softcare nonadhesive sensor, single-patient-use, preteen infant</td><td>SC-A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult</td><td>MAX-A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, adult, longer cable 36 inches (91.44 cm)</td><td>MAX-AL</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>OxiMax</i> adhesive sensor, single-pateint-use, neonatal/adult</td><td>MAX-N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
</table>

(N-550 Manual, p. 66)
</td></tr>
</table>

<table>
<tr><th>Asserted Claim of '698 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>
Table 2: Nellcor Oximetry Sensor Models and Patient Weights
<table>
<tr><th>OxiMax Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td>OxiMax adhesive sensor, single-pateint-use, pediatric</td><td>MAX-P</td><td>10 to 50 kg (22 to 110 lbs)</td></tr>
<tr><td>OxiMax adhesive sensor, single-pateint-use, infant</td><td>MAX-I</td><td>3 to 20 kg (6.6 to 44.1 lbs)</td></tr>
<tr><td>OxiMax adhesive sensor, single-pateint-use, adult nasal</td><td>MAX-R</td><td>>50 kg (110 lbs)</td></tr>
<tr><td>OxiMax OxiCliq® nonadhesive sensor, single-patient-use, adult, reusable cable</td><td>OxiCliq A</td><td>>30 kg (66 lbs)</td></tr>
<tr><td>OxiMax OxiCliq nonadhesive sensor, single-patient-use, neonatal/adult, reusable cable</td><td>OxiCliq N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
<tr><td>OxiMax OxiCliq nonadhesive sensor, single-patient-use, pediatric, reusable cable</td><td>OxiCliq P</td><td>10 to 50 kg (22 to 110 lbs)</td></tr>
<tr><td>OxiMax OxiCliq nonadhesive sensor, single-patient-use, infant, reusable cable</td><td>OxiCliq I</td><td>3 to 20 kg (6.6 to 44.1 lbs)</td></tr>
<tr><td>OxiMax Durasensor® finger-clip sensor, reusable, adult</td><td>DS-100A</td><td>>40 kg (88 lbs)</td></tr>
<tr><td>OxiMax Oxiband® sensor, reusable, neonatal/adult</td><td>OXI-A/N</td><td><3 kg or >40 kg (<6.6 lbs or >88 lbs)</td></tr>
<tr><td>OxiMax Oxiband sensor, reusable, pediatric/infant</td><td>OXI-P/I</td><td>3 kg to 40 kg (6.6 lbs to 88 lbs)</td></tr>
</table>
(N-550 Manual, p. 67)</td></tr>
</table>

<table>
<tr><th>Asserted Claim of '698 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>

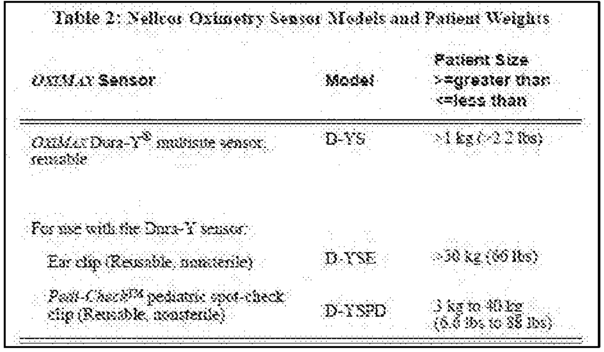
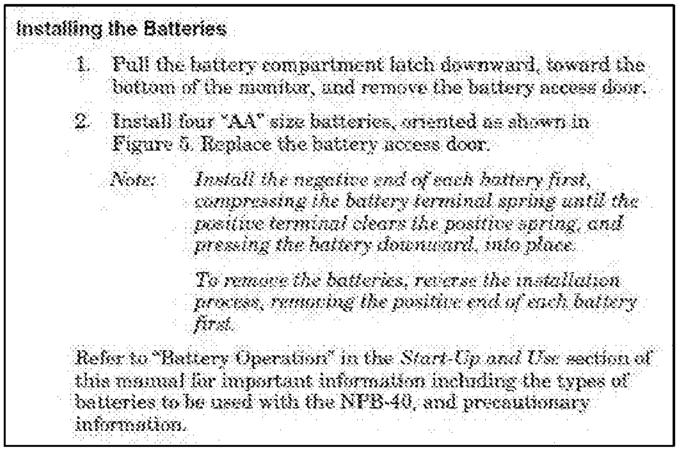
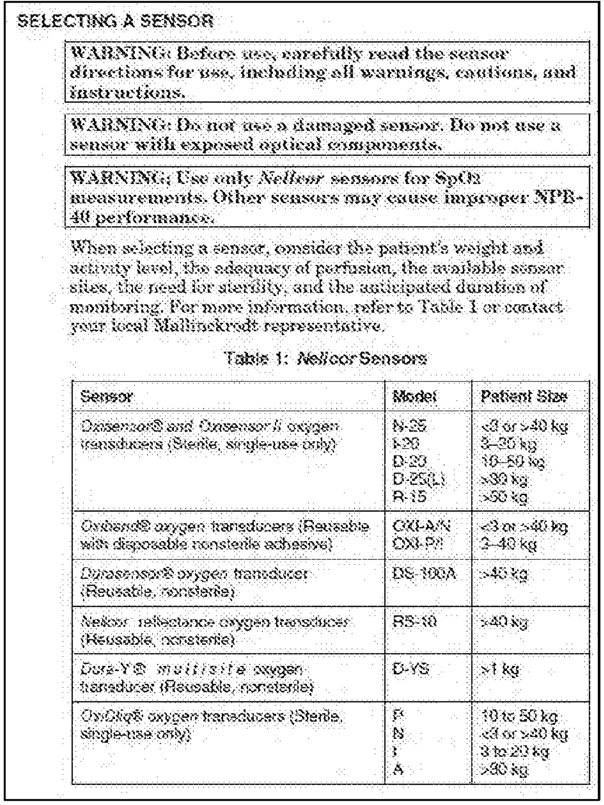



Table 2: Nellcor Oximetry Sensor Models and Patient Weights
<table>
<tr><th><i>OXIMAX</i> Sensor</th><th>Model</th><th>Patient Size
>=greater than
<=less than</th></tr>
<tr><td><i>OXIMAX</i> Dura-Y® multisite sensor, reusable</td><td>D-YS</td><td>>1 kg (>2.2 lbs)</td></tr>
<tr><td>For use with the Dura-Y sensor:</td><td></td><td></td></tr>
<tr><td>Ear clip (Reusable, nonsterile)</td><td>D-YSE</td><td>>30 kg (66 lbs)</td></tr>
<tr><td><i>Pedi-Check</i>™ pediatric spot-check clip (Reusable, nonsterile)</td><td>D-YSPD</td><td>3 kg to 40 kg
(6.6 lbs to 88 lbs)</td></tr>
</table>
(N-550 Manual, p. 68)

Installing the Batteries

Pull the battery compartment latch downward, toward the bottom of the monitor, and remove the battery access door.
Install four "AA" size batteries, oriented as shown in Figure 5. Replace the battery access door.

Note: <i>Install the negative end of each battery first, compressing the battery terminal spring until the positive terminal clears the positive spring, and pressing the battery downward, into place.</i>
<i>To remove the batteries, reverse the installation process, removing the positive end of each battery first.</i>
Refer to "Battery Operation" in the <i>Start-Up and Use</i> section of this manual for important information including the types of batteries to be used with the NPB-40, and precautionary information.
(NPB-40 Operator's Manual, p. 12)
</td></tr>
</table>

<table>
<tr><th>Asserted Claim of ’698 Patent</th><th>Nellcor Pulse Oximeters</th></tr>
<tr><td></td><td>


SELECTING A SENSOR

WARNING: Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

WARNING: Do not use a damaged sensor. Do not use a sensor with exposed optical components.

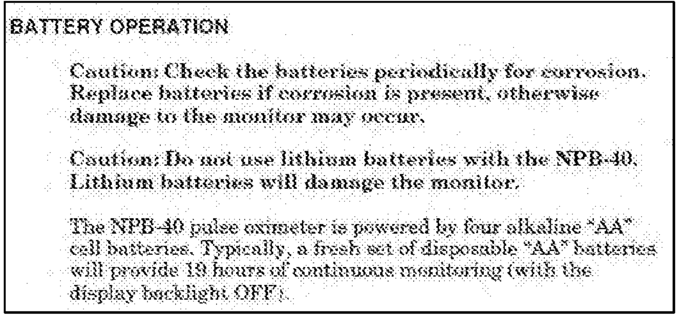
WARNING: Use only *Nellcor* sensors for SpO2 measurements. Other sensors may cause improper NPB-40 performance.

When selecting a sensor, consider the patient’s weight and activity level, the adequacy of perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact your local Mallinckrodt representative.

Table 1: *Nellcor* Sensors

<table>
<tr><th>Sensor</th><th>Model</th><th>Patient Size</th></tr>
<tr><td><i>Oxisensor® and Oxisensor II</i> oxygen transducers (Sterile, single-use only)</td><td>N-25
I-20
D-20
D-25(L)
R-15</td><td><3 or >40 kg
3–20 kg
10–50 kg
>30 kg
>50 kg</td></tr>
<tr><td><i>Oxiband®</i> oxygen transducers (Reusable with disposable nonsterile adhesive)</td><td>OXI-A/N
OXI-P/I</td><td><3 or >40 kg
3–40 kg</td></tr>
<tr><td><i>Durasensor®</i> oxygen transducer (Reusable, nonsterile)</td><td>DS-100A</td><td>>40 kg</td></tr>
<tr><td><i>Nellcor</i> reflectance oxygen transducer (Reusable, nonsterile)</td><td>RS-10</td><td>>40 kg</td></tr>
<tr><td><i>Dura-Y®</i> <i>multisite</i> oxygen transducer (Reusable, nonsterile)</td><td>D-YS</td><td>>1 kg</td></tr>
<tr><td><i>OxiCliq®</i> oxygen transducers (Sterile, single-use only)</td><td>P
N
I
A</td><td>10 to 50 kg
<3 or >40 kg
3 to 20 kg
>30 kg</td></tr>
</table>

(NPB-40 Operator’s Manual, p. 15)
</td></tr>
</table>

Asserted Claim of '698 Patent	Nellcor Pulse Oximeters
	 BATTERY OPERATION Caution: Check the batteries periodically for corrosion. Replace batteries if corrosion is present, otherwise damage to the monitor may occur. Caution: Do not use lithium batteries with the NPB-40. Lithium batteries will damage the monitor. The NPB-40 pulse oximeter is powered by four alkaline "AA" cell batteries. Typically, a fresh set of disposable "AA" batteries will provide 19 hours of continuous monitoring (with the display backlight OFF). (NPB-40 Operator's Manual, p. 28)
[3] The wearable device of claim 1, wherein the light source is configured to further improve the signal-to-noise ratio of the input beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs, and wherein the receiver is configured to be synchronized to at least one of the LEDs.	Nellcor discloses and/or renders obvious "[t]he wearable device of claim 1, wherein the light source is configured to further improve the signal-to-noise ratio of the input beam reflected from the tissue by increasing the light intensity relative to the initial light intensity from at least one of the LEDs, and wherein the receiver is configured to be synchronized to at least one of the LEDs." *See* CHART ONE: '533 Patent, Claim Elements 5C and 5F above.
[5] The wearable device of claim 1, wherein the wearable device is configured to communicate with a smart phone or tablet, the smart phone or tablet comprising a wireless receiver, a wireless transmitter, a display, a voice	Nellcor discloses and/or renders obvious "[t]he wearable device of claim 1, wherein the wearable device is configured to communicate with a smart phone or tablet, the smart phone or tablet comprising a wireless receiver, a wireless transmitter, a display, a voice input module, a speaker, and a touch screen, the smart phone or tablet configured to receive and to process at least a portion of the output signal, wherein the smart phone or tablet is configured to store and display the

Asserted Claim of '698 Patent	Nellcor Pulse Oximeters
input module, a speaker, and a touch screen, the smart phone or tablet configured to receive and to process at least a portion of the output signal, wherein the smart phone or tablet is configured to store and display the processed output signal, wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link.	processed output signal, wherein at least a portion of the processed output signal is configured to be transmitted over a wireless transmission link." *See* CHART ONE: '533 Patent, Claim Elements 5G, 5H, 5I, and 5J above.

Omni MedSci, Inc. v. Apple Inc.
Case No. 2:18-cv-134-RWS (E.D. Tex.)

DEFENDANT'S INVALIDITY CONTENTIONS
August 28, 2018

EXHIBIT Y

EXHIBIT Y-1

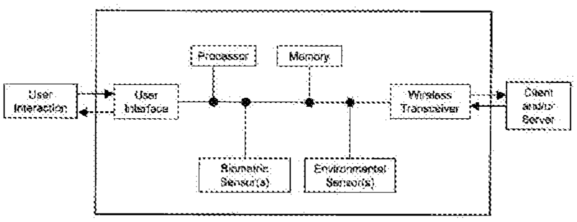
U.S. Patent No. 9,651,533 vs Park

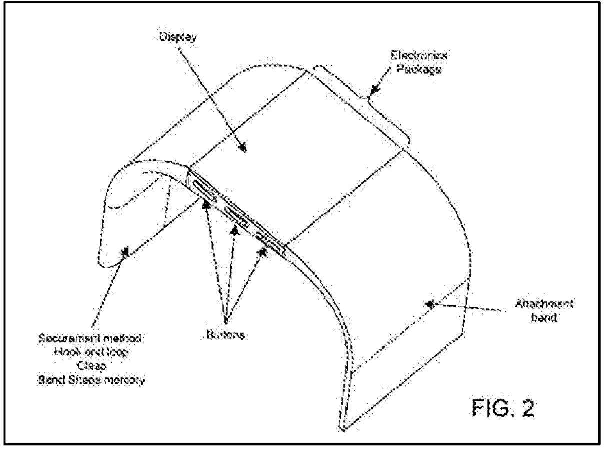
Priority Date/Publication Date:	June 24, 2013/Nov. 6, 2013/Mar. 21, 2017	Prior Art Status:	§§ 102(a), (b), (e) (Pre-AIA) §§102(a), (b), (d)

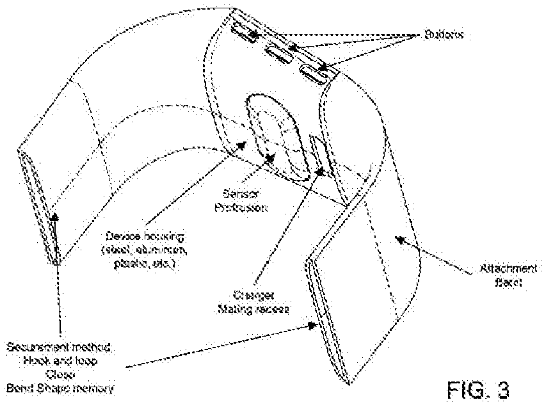
U.S. Patent No. 9,596,990 B2 to Park et al. ("Park") anticipates the asserted claims of U.S. Patent No. 9,651,533 ("the '533 Patent") or renders those claims obvious alone and/or in view of at least any of the references identified in Apple's Obviousness Combinations Chart.

As set forth in Apple's Invalidity Contentions, the below contentions apply the prior art in part in accordance with Apple's assumption that Omni contends the claims are not invalid under 35 U.S.C. § 112. However, Apple's below contentions do not represent Apple's agreement or view as to the meaning, definiteness, written description support for, or enablement of any of the asserted claims. For each dependent claim, the disclosures cited for the claim from which it depends are incorporated by reference.

CHART ONE: U.S. Patent No. 9,651,533 vs Park

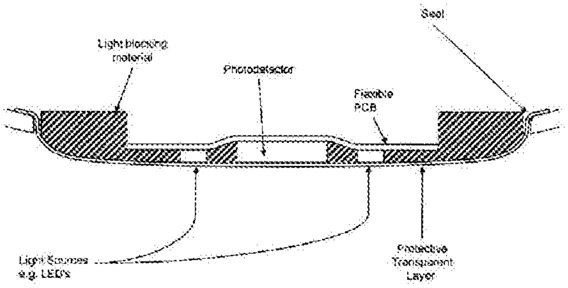
Asserted Claim of '533 Patent	U.S. Patent No. 9,596,990 B2 to Park et al. ("Park")
[5] A measurement system, comprising:	To the extent the preamble is limiting, Park discloses and/or renders obvious "[a] measurement system." "The present inventions, in one aspect, are directed to portable biometric monitoring device including a housing having a physical size and shape that is adapted to couple to the user's body, at least one band to secure the monitoring device to the user, a physiological sensor, disposed in the housing, to generate data which is representative of a physiological condition of the user data. The physiological sensor may include a light source to generate and output light having at least a first wavelength, and a photodetector to detect scattered light (e.g., from the user). A light pipe is disposed in the housing and optically coupled to the light source directs/transmits light therefrom along a predetermined path to an outer surface of the housing. Processing circuitry calculates a heart rate of the user using data which is representative of the scattered light." (Park, Abstract)  FIG. 1 (Park, Fig. 1)

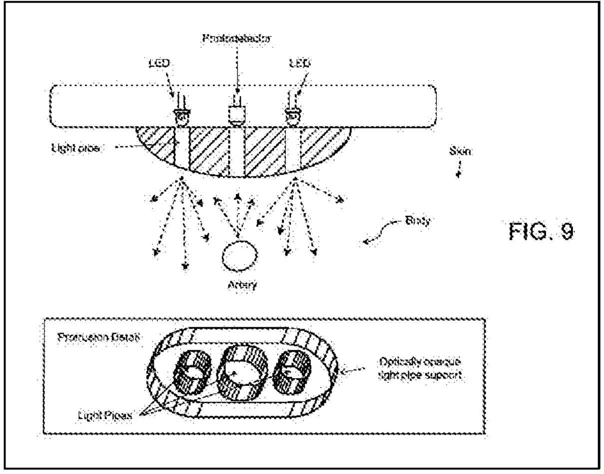
Asserted Claim of '533 Patent	U.S. Patent No. 9,596,990 B2 to Park et al. ("Park")
	 FIG. 2 (Park, Fig. 2)

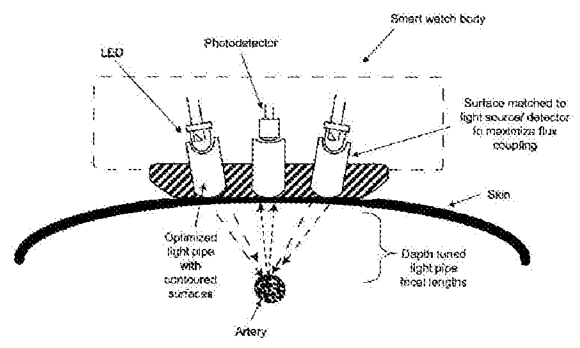
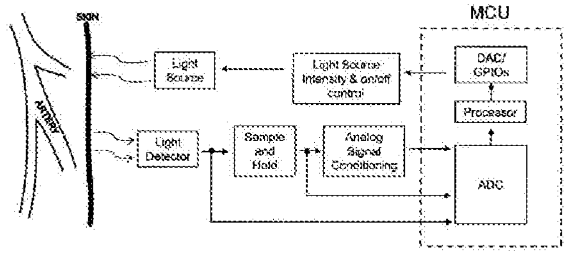
Asserted Claim of '533 Patent	U.S. Patent No. 9,596,990 B2 to Park et al. ("Park")
	 FIG. 3 (Park, Fig. 3)

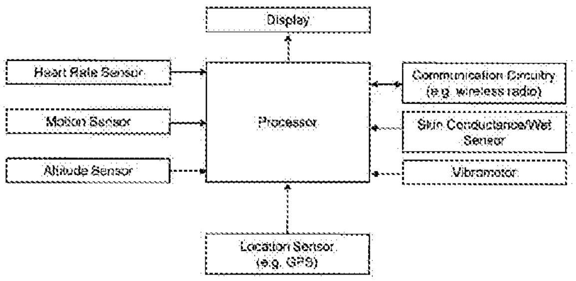
Omni MedSci, Inc. v. Apple Inc.
Case No. 2:18-cv-134-RWS (E.D. Tex.)

EXHIBIT Y-1, p. 4

Asserted Claim of '533 Patent	U.S. Patent No. 9,596,990 B2 to Park et al. ("Park")
	 FIG. 5 (Park, Fig. 5)

Asserted Claim of '533 Patent	U.S. Patent No. 9,596,990 B2 to Park et al. ("Park")
	 FIG. 9 (Park, Fig. 9)

Asserted Claim of '533 Patent	U.S. Patent No. 9,596,990 B2 to Park et al. ("Park")
	 FIG. 10 (Park, Fig. 10)  FIG. 18 (Park, Fig. 18)

Asserted Claim of '533 Patent	U.S. Patent No. 9,596,990 B2 to Park et al. ("Park")
	 FIG. 25 (Park, Fig. 25) "The present inventions relate to a biometric monitoring device and methods and techniques to collect one or more types of physiological and/or environmental data from embedded or resident sensors and/or external devices and communicates or relays such information to other devices or other internet-viewable sources. (See, for example, FIG. 1). While the user is wearing or manipulating the biometric monitoring device, through one or a plurality of sensors, the device may detect one or many of physiological metrics including, but not limited to, the user's heart rate." (Park, 1:34-43) "The device may have a user interface directly on the device that indicates the state of one or more of the data types available and/or being tracked/acquired. The user interface may also be used to display data from other devices or Internet sources." (Park, 1:44-48) "The device may implement wireless communications so that when the user and device comes within range of a wireless base station or access point, the stored data automatically uploads to an internet viewable source such as a website." (Park, 1:49-53)

Asserted Claim of '533 Patent	U.S. Patent No. 9,596,990 B2 to Park et al. ("Park")
	"FIG. 1 illustrates an exemplary portable monitoring device which enables user interaction via a user interface, wherein the portable monitoring device may have a user interface, processor, biometric sensor(s), memory, environmental sensor(s) and/or a wireless transceiver which may communicate with an external device (for example, a client and/or server);" (Park, 2:19-25) "FIG. 2 illustrates an exemplary portable biometric monitoring device which may be secured to the user through the use of a band; the exemplary portable biometric monitoring device may have a display, button(s), electronics package, and/or a band or an attachment band; notably, the band or attachment band is employed to secure the portable biometric monitoring device to the user, for example, an appendage of the user, for example, via hooks and loops (e.g., Velcro), a clasp, and/or a band having memory of its shape (e.g. through the use of, for example, a spring metal band, elastic band, a "rubber" band, and/or a watch-like band);" (Park, 2:26-36) "FIG. 3 illustrates a view of the skin facing portion of the portable biometric monitoring device of, for example, FIG. 2; notably, in this embodiment, the portable monitoring device includes a sensor protrusion and recess for mating a charger and/or data transmission cable; notable, the protrusion may more firmly maintain the sensor in contact with the skin of the user (for example, predetermined or fixed relational contact with the skin of the user);" (Park, 2:37-44) "FIG. 5 illustrates a cross sectional view of a sensor protrusion of an exemplary portable biometric monitoring device; notably, two light sources (e.g. LED's) may be located on one or more sides of the photodetector (for example, either side or opposing sides of a photodetector) to enable photoplethysmography (PPG) sensing wherein light blocking material may be placed between the light sources and the photodetector to prevent any light from the light sources from going through the device body and being detected by the photodetector (in one embodiment, the light sources and photodetector are placed on a flexible PCB); a flexible transparent layer may be placed on the lower surface of the sensor protrusion to form a seal wherein the transparent layer may provide other functions such as preventing liquid from entering the device where the light sources or photodetectors are disposed or placed; notably, the transparent layer may be formed through in-mold labeling or "IML";" (Park, 2:48-64)

Asserted Claim of '533 Patent	U.S. Patent No. 9,596,990 B2 to Park et al. ("Park")
	"FIG. 9 illustrates an exemplary PPG sensor having a photodetector and two LED light sources which may be disposed or located in a portable biometric monitoring device having a protrusion; notably, in this embodiment, light pipes are optically connected the LED's and photodetector to the surface of the user's skin, wherein, in operation, the light from the light sources scatters/reflects off of blood in the body, some of which reaches the photodetector via the light pipes; notably, the light pipes preferentially direct or transmit light along a predetermined path, for example, defined by the geometry and/or material of the light pipe;" (Park, 3:17-27) "FIG. 10 illustrates an exemplary PPG detector having a protrusion with curved sides to reduce and/or minimize any discomfort to the user during operation and/or to more firmly maintain the sensor in contact with the skin of the user (for example, predetermined or fixed relational contact with the skin of the user); in this embodiment, the surface of light pipes are connect the photodetector and LEDs to the user's skin and are contoured to enhance and/or maximize light flux coupling between the LEDs and photodetectors to the light pipes; notably, the end of the light pipes which face the user's skin may also contoured wherein this contour may provide focusing or defocusing to enhance and/or optimize the PPG signal (for example, the contour may focus light to a certain depth and location which coincides with an area where blood flow is likely to occur); in addition, the vertex of these foci overlap or are very close together so that the photodetector may receive, for example, the maximum possible amount of scattered/reflected light;" (Park, 3:28-45) "FIG. 18 illustrates an exemplary PPG sensor which is similar to the embodiment illustrated in FIG. 17; in this embodiment, however, the sensor employs a sample and hold circuit as well as analog signal conditioning;" (Park, 4:28-31) "FIG. 25 illustrates certain circuitry/elements of an exemplary portable biometric monitoring device having a heart rate or PPG sensor, motion sensor, display, vibromotor/vibramotor, location sensor, altitude sensor, skin conductance/wet sensor and communication circuitry which is connected to a processor;" (Park, 4:55-60)

Asserted Claim of '533 Patent	U.S. Patent No. 9,596,990 B2 to Park et al. ("Park")
[5A] a light source comprising a plurality of semiconductor sources that are light emitting diodes, the light emitting diodes configured to generate an output optical beam with one or more optical wavelengths,	Park discloses and/or renders obvious "a light source comprising a plurality of semiconductor sources that are light emitting diodes, the light emitting diodes configured to generate an output optical beam with one or more optical wavelengths." *See* CHART ONE: '533 Patent, Claim Element 13A below.
[5B] wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers,	Park discloses and/or renders obvious "wherein at least a portion of the one or more optical wavelengths is a near-infrared wavelength between 700 nanometers and 2500 nanometers." "The source(s) may emit light having one or more wavelengths which are specific or directed to a type of physiological data to be collected. The optical detectors may sample, measure and/or detect one or more wavelengths that are also specific or directed to a type of physiological data to be collected and physiological parameter (of the user) to be assessed or determined. For instance, in one embodiment, a light source emitting light having a wavelength in the green spectrum (for example, an LED that emits light having wavelengths corresponding to the green spectrum) and photodiode positioned to sample, measure and/or detect a response or reflection may provide data used to determine or detect heart rate. In contrast, a light source emitting light having a wavelength in the red spectrum (for example, an LED that emits light having wavelengths corresponding to the red spectrum) and a light source emitting light having a wavelength in the infrared spectrum (for example, an LED that emits light having wavelengths corresponding to the IR spectrum) and photodiode positioned to sample, measure and/or detect a response or reflection may provide data used to determine or detect SpO2." (Park, 10:50-11:3) "Indeed, in one embodiment, the color or wavelength of the light emitted by the LED (or set of LEDs) may be modified, adjusted and/or controlled in accordance with a predetermined type of physiological data being acquired or conditions of operation. Here, the wavelength of the light emitted by the LED is adjusted and/or controlled to optimize and/or enhance the "quality" of the physiological data obtained and/or sampled by the detector. For example, the color of the light emitted by the LED may be switched from infrared to green when the user's skin temperature or

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	the ambient temperature is cool in order to enhance the signal corresponding to cardiac activity. (See, for example, FIG. 20)." (Park, 11:4-16) "The biometric monitoring device, in one embodiment, includes a window (for example, a visually opaque window) in the housing to facilitate optical transmission between the optical sensors and the user. Here, the window may permit light (for example, a substantial portion of a selected wavelength) to be emitted by, for example, one or more LEDs, onto the skin of the user and a response or reflection to pass into the housing to be sampled, measured and/or detected by, for example, one or more photodiodes. In one embodiment, the circuitry related to emitting and receiving light may be disposed in the interior of the device housing and underneath a plastic or glass layer (for example, painted with infrared ink) or an infrared lens which permits infrared light to pass but not light in the human visual spectrum. In this way, the light transmission is invisible to the human eye." (Park, 11:17-31) "The biometric monitoring device, in one embodiment, may employ light pipes or other light transmissive structures. (See, for example, FIGS. 8-10). In this regard, in one embodiment, light is directed from the light source to the skin of the user through light pipes or other light transmissive structures. Scattered or reflected light from the user's body may be directed back to and detected by the optical circuitry through the same or similar structures. Indeed, the transmissive structures may employ a material and/or optical design to facilitate low light loss (for example, a lens) thereby improving SNR of the photo detector and/or reducing power consumption of the light emitter(s) and/or light detector(s). In one embodiment, the light pipes or other light transmissive structures may include a material that selectively transmits light having one or more specific or predetermined wavelengths with higher efficiency than others, thereby acting as a bandpass filter. This bandpass filter may be tuned to improve the signal of a specific physiological data type. For example, in one embodiment, an In-Mold-Labeling or "IML" light transmissive structure may be implemented wherein the structure uses a material with predetermined or desired optical characteristics to create a specific bandpass characteristic, for example, to pass infrared light with greater efficiency than light of other wavelengths (for example, light having a wavelength in human visible spectrum)." (Park, 11:32-57)

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	"As intimated above, the portable biometric monitoring device may include a material disposed on the skin or interior side which includes high reflectivity characteristic—for example, polished stainless steel, reflective paint, and polished plastic. In this way, light scattered/reflected off the skin side of the device may be scattered/reflected back into the skin in order to, for example, improve the SNR. Indeed, this effectively increases the input light signal as compared with a device body back that is non-reflective. Notably, in one embodiment, the color of the skin or interior side of the biometric monitoring device is selected to provide certain optical characteristics (for example, reflect certain or predetermined wavelengths of light), in order to improve the signal of certain physiological data types. For example, where the skin or interior side of the biometric monitoring is green, the measurements of the heart rate may be enhanced due to the preferential emission of a wavelength of the light corresponding to the green spectrum. Where the skin or interior side of the biometric monitoring is red, the measurements of the SpO2 may be enhanced due to the emission preferential of a wavelength of the light corresponding to the red spectrum. In one embodiment, the color of the skin or interior side of the biometric monitoring device may be modified, adjusted and/or controlled in accordance with a predetermined type of physiological data being acquired." (Park, 15:49-16:7)
[5C] the light source configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of semiconductor sources;	Park discloses and/or renders obvious "the light source configured to increase signal-to-noise ratio by increasing a light intensity from at least one of the plurality of semiconductor sources and by increasing a pulse rate of at least one of the plurality of semiconductor sources."

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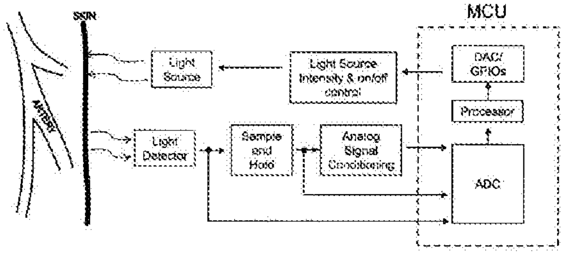
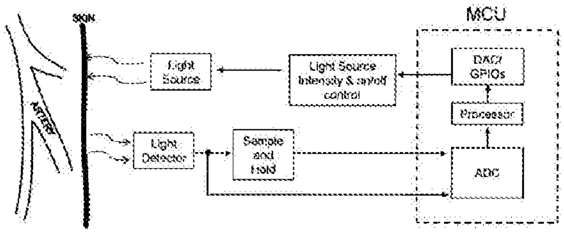
	 FIG. 18 (Park, Fig. 18)  FIG. 19 (Park, Fig. 19)

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	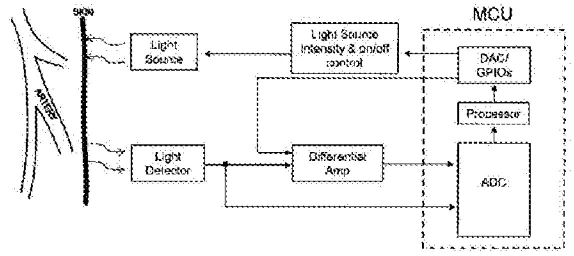 FIG. 22 (Park, Fig. 22) "In another embodiment, the biometric monitoring device of the present inventions may employ data indicative of user activity or motion (for example, from one or more motion sensors) to adjust or modify characteristics of triggering, acquiring and/or obtaining desired heart rate measurement or data (for example, to improve robustness to motion artifact). For instance, data indicative of user activity or motion may be employed to adjust or modify the sampling rate and/or resolution mode of sensors which acquire heart rate data (for example, where the amount of user motion exceeds a certain threshold, the biometric monitoring device may increase the sampling rate and/or increase the sampling resolution mode of sensors employed to acquire heart rate measurement or data). Moreover, the biometric monitoring device may adjust or modify the sampling rate and/or resolution mode of the motion sensor(s) during such periods of user activity or motion (for example, periods where the amount of user motion exceeds a certain threshold). In this way, when the biometric monitoring device determines or detects such user activity or motion, the motion sensor(s) may be placed into a higher sampling rate and/or higher sampling resolution mode to, for example, enable more accurate adaptive filtering on the heart rate signal. (See, for example, FIG. 15)." (Park, 7:7-30) "FIG. 17 depicts an exemplary schematic block diagram of an optical sensor where light is emitted from a light source toward the user's skin and the reflection is sensed by a light detector, wherein

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	the output of the detector is subsequently digitized by an analog to digital converter (ADC). The intensity of the light source may be modified (e.g., through a light source intensity control module) to maintain a desirable scattered/reflected intensity signal. For example, the intensity of the output of the light source may be reduced to avoid saturation of the output signal from the light detector. As another example, the light source intensity may be increased to maintain the output signal from the light detector within a desired range of output values. Notably, the active control of the sensor device may be achieved through linear or nonlinear control methods such as proportional-integral-derivative (PID) control, fixed step control, predictive control, neural networks, hysteresis, and the like, and may also employ information derived from other sensors in the device such as motion, galvanic skin response, etc. FIG. 17 is provided for illustration and does not limit the implementation of such a system to, for instance, an ADC integrated within a MCU, or the use of a MCU for that matter. Other possible implementations include the use of one or more internal or external ADCs, FPGAs, ASICs, etc." (Park, 16:8-31) "In another embodiment, the sensor device may incorporate the use of a sample and hold circuit (or equivalent) to maintain the output of the light detector while the light source is turned off or attenuated to save power. In embodiments of the present inventions where relative changes in the light detector output are of primary importance (e.g., heart rate measurement), the sample and hold circuit may not have to maintain an accurate copy of the output of the light detector. In such cases, the sample and hold circuitry may be, for example, a diode (e.g., Schottky diode) and capacitor. The output of the sample and hold may be presented to an analog signal conditioning circuit (e.g., a Sallen-Key bandpass filter, level shifter, and/or gain circuit) to condition and amplify the signal within frequency bands of interest (e.g., 0.1 Hz to 10 Hz for cardiac or respiratory function) which is then digitized by the ADC. (See, for example, FIG. 18)." (Park, 16:32-47) "In another embodiment, the sensor device may incorporate a differential amplifier to amplify the relative changes in the output of the light detector output. (See, for example, FIG. 22). In one embodiment, a digital average or digital lowpass filtered signal is subtracted from the output of the light detector output and amplified before it is digitized by the ADC. In another embodiment, an analog average or analog lowpass filtered signal is subtracted from the output of the light detector through, for example, the use of a sample and hold circuit and analog signal conditioning circuitry. The power provided to the light source, light detector, and differential amplifier may be controlled

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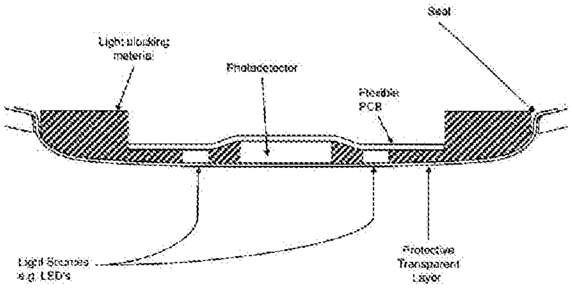
	separately from the power provided to the analog signal conditioning circuit to improve power savings." (Park, 17:12-25) "In one embodiment, the light detector module may incorporate a transimpedance amplifier stage with variable gain. Such a configuration may avoid or minimize saturation from bright ambient light and/or bright emitted light from the light source. For example, the gain of the transimpedance amplifier may be automatically adjusted and/or reduced with a variable resistor and/or multiplexed set of resistors in the negative feedback path of the transimpedance amplifier. In embodiment of the present inventions, the device may incorporate little to no optical shielding from ambient light by amplitude modulating the intensity of the light source and demodulating the output of the light detector (e.g., synchronous detection). (See, for example, FIG. 21). In other aspects, if the ambient light is of sufficient brightness to obtain a heart rate signal, the light source may be reduced in brightness and/or turned off completely." (Park, 17:26-41)
[5D] an apparatus comprising a plurality of lenses configured to receive a portion of the output optical beam and to deliver an analysis output beam to a sample	Park discloses and/or renders obvious "an apparatus comprising a plurality of lenses configured to receive a portion of the output optical beam and to deliver an analysis output beam to a sample."  FIG. 5 (Park, Fig. 5)

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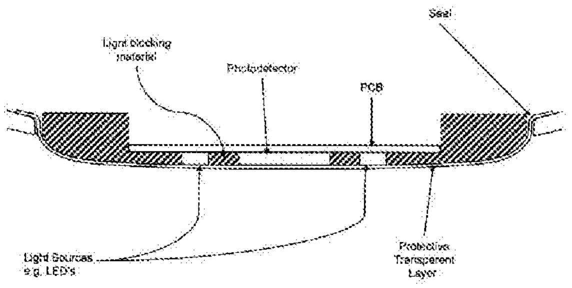
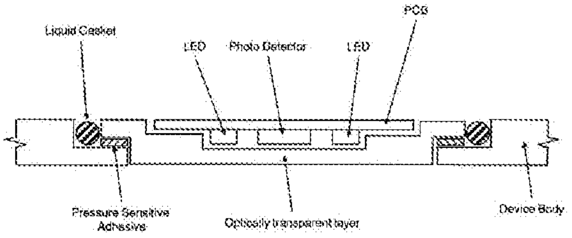
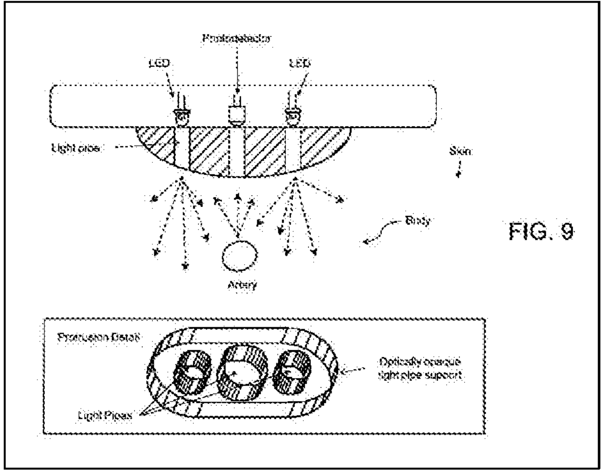
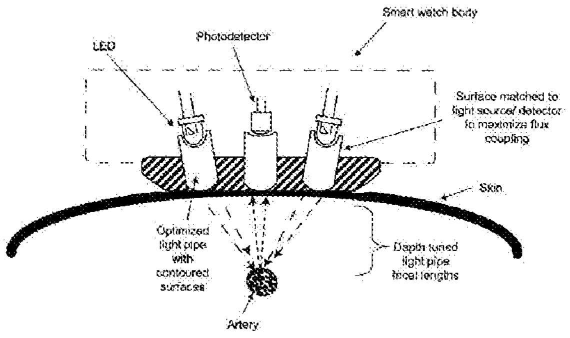
	 FIG. 6 (Park, Fig. 6)  FIG. 7 (Park, Fig. 7)

Asserted Claim of '533 Patent	U.S. Patent No. 9,596,990 B2 to Park et al. ("Park")
	 FIG. 9 (Park, Fig. 9)

Asserted Claim of '533 Patent	U.S. Patent No. 9,596,990 B2 to Park et al. ("Park")
	 FIG. 10 (Park, Fig. 10) "Where optical sensors are disposed or arranged on the skin side of the biometric monitoring device, in operation, a light source emits light upon the skin of the user and, in response, a light detector samples, acquires and/or detects a response or scattered/reflected light from the skin (and/or from inside the body). The one or more sources and detectors may be arranged in an array or pattern that enhances or optimizes the SNR and/or reduces or minimizes power consumption by light sources and detectors. These optical detectors sample, acquire and/or detect physiological data which may then be processed or analyzed (for example, by resident processing circuitry) to obtain data which is representative of, for example, a user's heart rate, respiration, heart rate variability, oxygen saturation (SpO2), blood volume, blood glucose, skin moisture and/or skin pigmentation level." (Park, 10:34-49) "The source(s) may emit light having one or more wavelengths which are specific or directed to a type of physiological data to be collected. The optical detectors may sample, measure and/or detect one or more wavelengths that are also specific or directed to a type of physiological data to be collected and physiological parameter (of the user) to be assessed or determined. For instance, in one embodiment, a light source emitting light having a wavelength in the green spectrum (for

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	example, an LED that emits light having wavelengths corresponding to the green spectrum) and photodiode positioned to sample, measure and/or detect a response or reflection may provide data used to determine or detect heart rate. In contrast, a light source emitting light having a wavelength in the red spectrum (for example, an LED that emits light having wavelengths corresponding to the red spectrum) and a light source emitting light having a wavelength in the infrared spectrum (for example, an LED that emits light having wavelengths corresponding to the IR spectrum) and photodiode positioned to sample, measure and/or detect a response or reflection may provide data used to determine or detect SpO2." (Park, 10:50-11:3) "The biometric monitoring device, in one embodiment, includes a window (for example, a visually opaque window) in the housing to facilitate optical transmission between the optical sensors and the user. Here, the window may permit light (for example, a substantial portion of a selected wavelength) to be emitted by, for example, one or more LEDs, onto the skin of the user and a response or reflection to pass into the housing to be sampled, measured and/or detected by, for example, one or more photodiodes. In one embodiment, the circuitry related to emitting and receiving light may be disposed in the interior of the device housing and underneath a plastic or glass layer (for example, painted with infrared ink) or an infrared lens which permits infrared light to pass but not light in the human visual spectrum. In this way, the light transmission is invisible to the human eye." (Park, 11:17-31) "The biometric monitoring device, in one embodiment, may employ light pipes or other light transmissive structures. (See, for example, FIGS. 8-10). In this regard, in one embodiment, light is directed from the light source to the skin of the user through light pipes or other light transmissive structures. Scattered or reflected light from the user's body may be directed back to and detected by the optical circuitry through the same or similar structures. Indeed, the transmissive structures may employ a material and/or optical design to facilitate low light loss (for example, a lens) thereby improving SNR of the photo detector and/or reducing power consumption of the light emitter(s) and/or light detector(s). In one embodiment, the light pipes or other light transmissive structures may include a material that selectively transmits light having one or more specific or predetermined wavelengths with higher efficiency than others, thereby acting as a bandpass filter. This bandpass filter may be tuned to improve the signal of a specific physiological data type. For example, in one embodiment, an In-Mold-Labeling or "IML" light transmissive structure may be