US005181902A

United States Patent [19]

Erickson et al.

[11] **Patent Number: 5,181,902**

[45] **Date of Patent: Jan. 26, 1993**

[54] **DOUBLE-TRANSDUCER SYSTEM FOR PEMF THERAPY**

[75] Inventors: **John H. Erickson**, Plano; **John C. Tepper**, Carrollton, both of Tex.

[73] Assignee: **American Medical Electronics, Inc.**, Dallas, Tex.

[21] Appl. No.: **586,505**

[22] Filed: **Sep. 21, 1990**

[51] **Int. Cl.**^{5} **A61N 1/00**

[52] **U.S. Cl.** **600/13**; 600/15

[58] **Field of Search** .... 600/9–15; 128/419 F, 802

[56] **References Cited**

U.S. PATENT DOCUMENTS

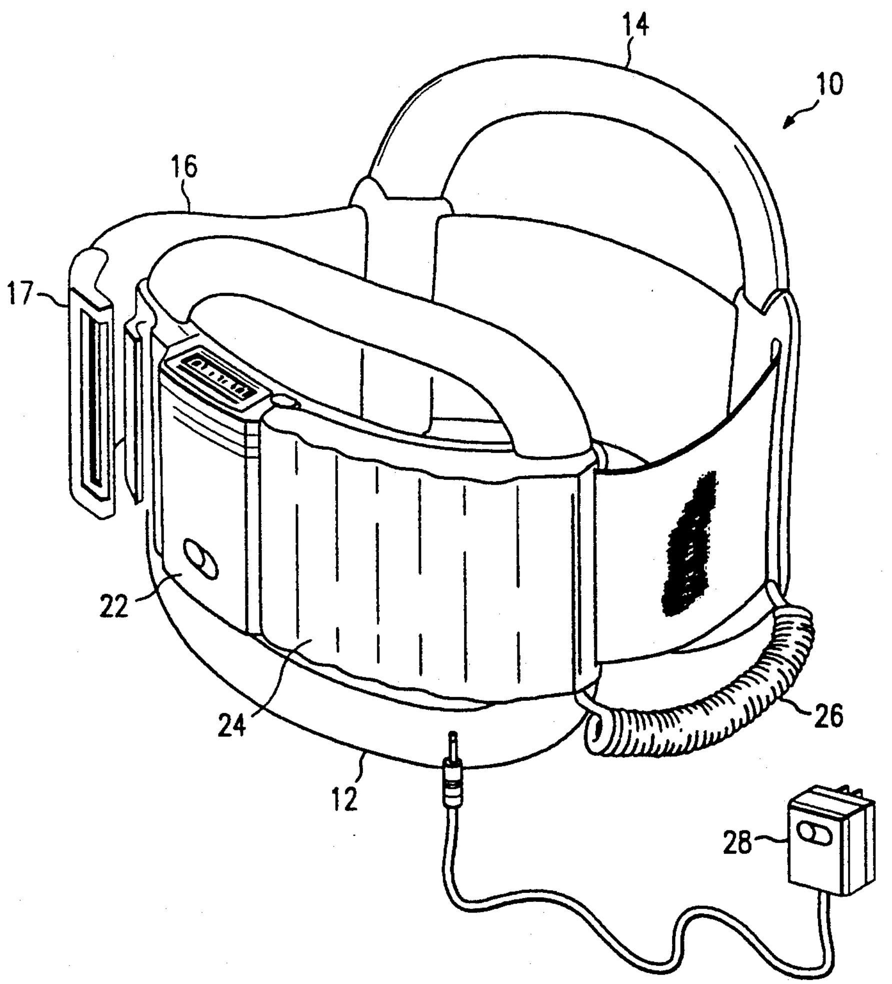
4,548,208	10/1985	Niemi	600/14
4,654,574	3/1987	Thaler	600/14
4,850,959	7/1989	Findl	600/14
5,045,050	9/1991	Liboff et al.	600/9
5,106,361	4/1992	Liboff et al.	600/15

Primary Examiner—Lee S. Cohen
Assistant Examiner—John P. Lacyk
Attorney, Agent, or Firm—Baker & Botts

[57] **ABSTRACT**

A PEMF double-transducer system (FIG. **1**) used for PEMF therapy (such as after spinal fusion) uses a two-transducer configuration for generating flux-aided electromagnetic fields. The semi-rigid transducers (**12, 14**) are comformable, anatomically contoured and flat-wound to enhance patient comfort, and incorporated with an adjustable belt (**16**) to provide bracing. The belt includes compartments for a drive electronic module (**22**), and a rechargeable battery pack (**24**), making the system portable. The drive electronics (FIG. 3) includes a PEMF processor (**41**) that executes a PEMF program for providing pulsing current to the front and back transducers at predetermined intervals, thereby activating the electromagnetic field according to a prescribed PEMF regimen.

9 Claims, 2 Drawing Sheets



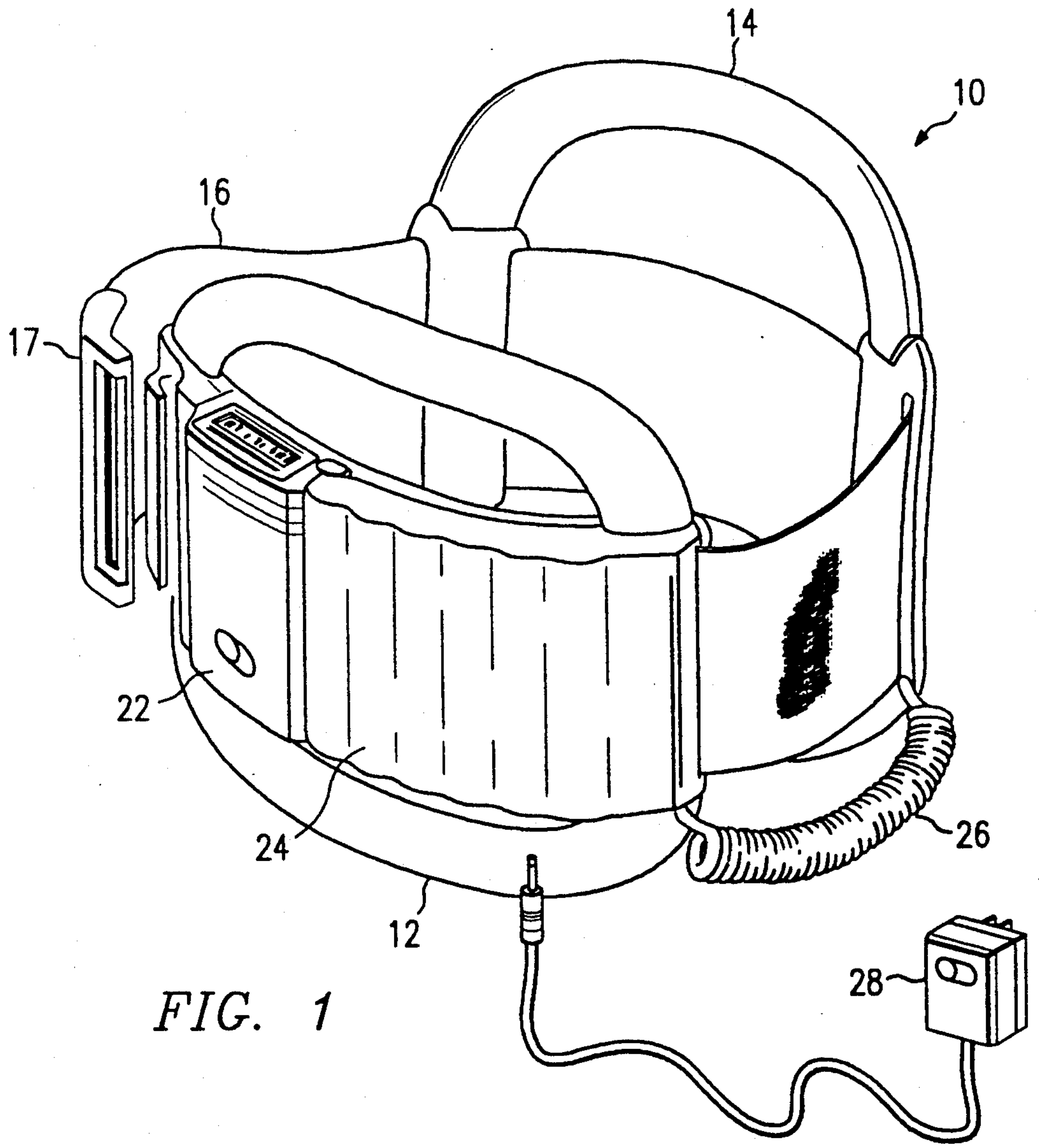


FIG. 1

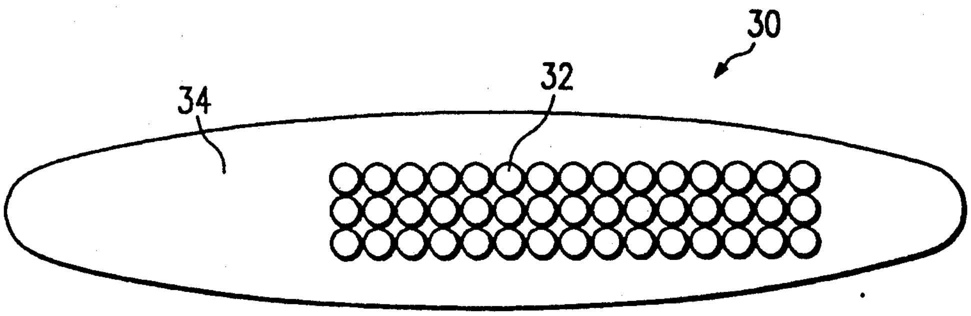


FIG. 2

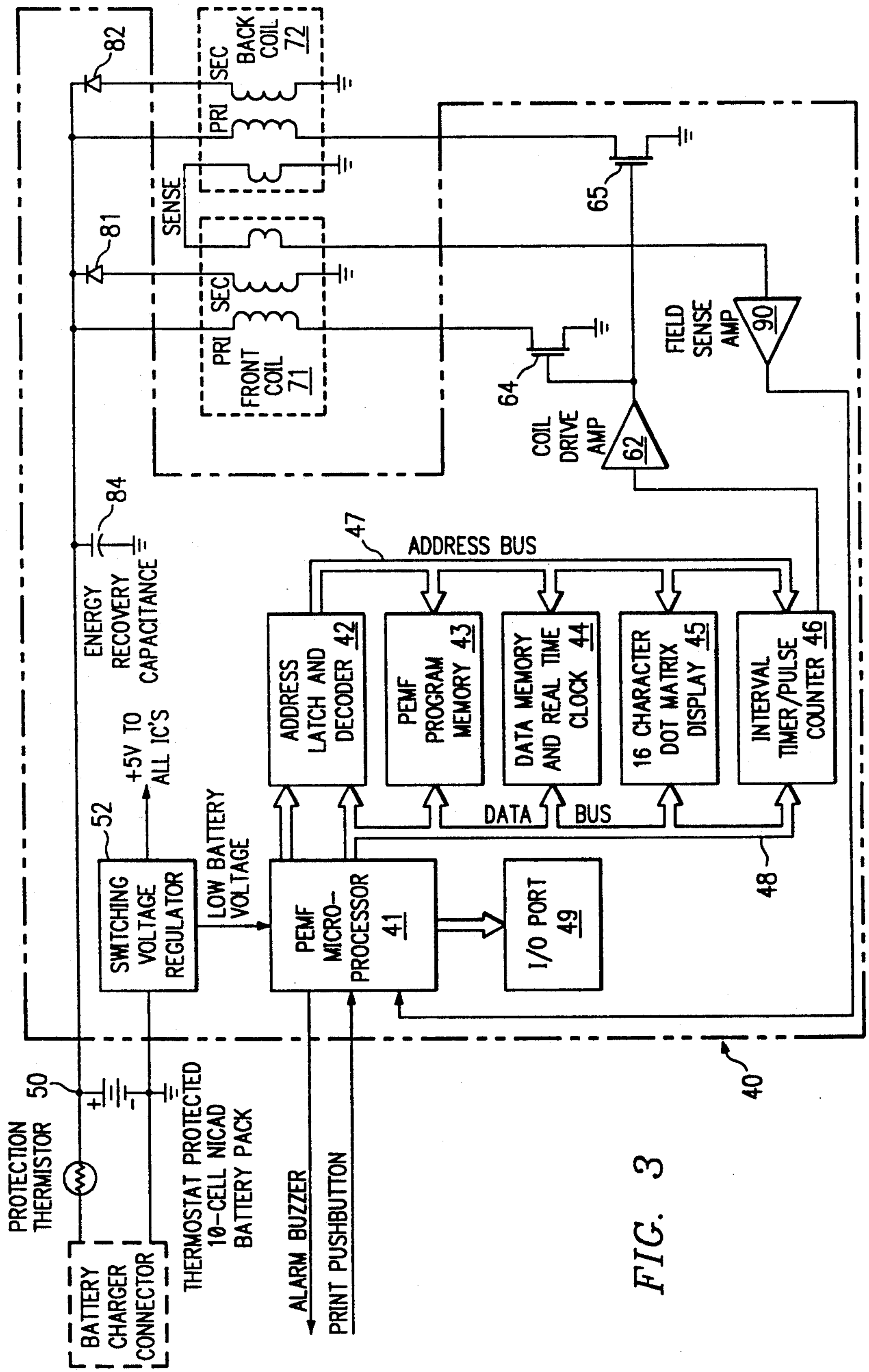

82
SEC
BACK COIL 72
PRI
SENSE
81
SEC
PRI
FRONT COIL 71
65
64
FIELD SENSE AMP
90
COIL DRIVE AMP
62
84
ENERGY RECOVERY CAPACITANCE
47
ADDRESS BUS
ADDRESS LATCH AND DECODER 42
PEMF PROGRAM MEMORY 43
DATA MEMORY AND REAL TIME CLOCK 44
16 CHARACTER DOT MATRIX DISPLAY 45
INTERVAL TIMER/PULSE COUNTER 46
DATA BUS
48
+5V TO ALL IC'S
52
SWITCHING VOLTAGE REGULATOR
LOW BATTERY VOLTAGE
PEMF MICRO-PROCESSOR 41
I/O PORT 49
PROTECTION THERMISTOR
50
THERMOSTAT PROTECTED 10-CELL NICAD BATTERY PACK
BATTERY CHARGER CONNECTOR
ALARM BUZZER
PRINT PUSHBUTTON
40

FIG. 3

DOUBLE-TRANSDUCER SYSTEM FOR PEMF THERAPY

TECHNICAL FIELD OF THE INVENTION

The invention relates generally to pulsed electromagnetic field (PEMF) therapy, and more particularly relates to a PEMF system that uses two transducers to provide PEMF therapeutic stimulation to a target area of the skeletal system (such as the spine), and a method of fabricating the system.

BACKGROUND OF THE INVENTION

Pulsed electromagnetic fields (PEMF) are low-energy, time-varying magnetic fields that are used to treat therapeutically resistant problems of the musculoskeletal system. Those problems include spinal fusion, ununited fractures, failed arthrodeses, osteonecrosis, and chronic refractory tendonitis, decubitus ulcers and ligament and tendon injuries.

The specific problem to which the invention is directed is an improved PEMF spinal stimulation system for providing PEMF therapeutic stimulation to areas of the spinal column undergoing fusion or other repair (such as treatment to salvage a failed fusion).

For spinal PEMF therapy, an electromagnetic transducer is placed on the patient's back such that pulsing the transducer produces an applied or driving field that penetrates to the spinal column. The conventional approach has been to use a single flexibly packaged transducer of wires coupled to a source of driving current. The flexible transducer is conformed to the contour of the patient's back, and strapped into place. By controlling the drive electronics, an appropriate PEMF therapy can be administered.

Current spinal PEMF systems are disadvantageous in at least two respects. To allow a patient to be ambulatory during therapy, additional bracing is usually required to prevent bending that might dislodge or stress the area undergoing treatment. Also, the single transducer configuration fails to take advantage of the flux-aiding effect of a two transducer system to maximize field uniformity.

Accordingly, a need exists for an improved PEMF system that can be used without additional bracing, and provides more uniform active field to the target area than available using a single transducer configuration.

SUMMARY OF THE INVENTION

The present invention is a PEMF double-transducer system that takes advantage of flux-aiding to achieve improved field uniformity. The semi-rigid transducers are contoured and flat-wound to enhance patient comfort while obviating the need for additional bracing.

In one aspect of the invention, the PEMF double-transducer system includes front and back transducers, both including at least a primary winding with a selected number of turns encased in a shell that is at least semi-rigid. The transducers are anatomically contoured, and are physically coupled for releasably securing the transducers on either side of a target area for PEMF therapy. Drive electronics are coupled to the primary winding of both transducers for selectively generating electromagnetic fields, thereby implementing a prescribed PEMF therapy program.

In more specific aspects of the invention, each transducer includes both primary and secondary windings, and the drive electronics includes an energy recovery circuit. The secondary windings and the energy recovery circuit are active during a deenergization cycle to recover energy to conserve battery power—the secondary windings are also used to tailor the electromagnetic field.

In an exemplary embodiment, the PEMF double-transducer system is used for spinal PEMF therapy, such as for post fusion repair. For both transducers, primary, secondary and sense windings are flat wound, permitting the shell to be formed with a substantially flat cross sectional profile. The shell is a semi-rigid formable polyurethane elastomer.

The drive electronics includes a PEMF processor that executes a PEMF program for controlling the activation of the electromagnetic fields (field strength and duty cycle). In addition to implementing the PEMF therapy program, the PEMF processor collects appropriate data in memory to enable the attending health care professional to monitor the course of the therapy.

The transducers are incorporated with a belt that permits the transducers to be placed around a patient and secured in place in front and back of the patient. The belt includes compartments for a drive electronics module and (rechargeable) battery pack.

Each transducer is fabricated as follows. Primary, secondary and sense windings of adhesive coated magnet wire are wound around a flat mandrel with an appropriate anatomical shape for the transducer. The windings are bonded by heat curing the adhesive to obtain a flat-wound flexible winding bundle. The winding bundle is placed in a mold, and encapsulated in a semi-rigid shell. A bending fixture is used to configure the transducer with the selected anatomical contour.

The technical advantages of the invention include the following. The PEMF double-transducer system includes two transducers, a Helmholtz design that is magnetic flux-aiding to optimize the electromagnetic field available for stimulating the target area, and to reduce system power consumption. The transducers are configured with an anatomical contour, and with a substantially flat cross sectional profile that provides a broad contact area, thereby enhancing patient comfort. The transducers are formable with a selected degree of rigidity, and with a selected anatomical contour and profile, providing a conformable brace without any special conforming assembly or process (such as heat). The transducers can be incorporated into a belt or other securing means to provide an integrated semi-bracing design for the PEMF device. Programmable drive electronics implement a PEMF program to control electromagnetic field activation according to a predetermined PEMF therapeutic regimen, and store and provide appropriate data for monitoring the progress of the PEMF therapy. The transducers are incorporated with a belt that includes compartments for a drive electronics module and a rechargeable battery pack to provide a integrated, portable PEMF system.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the invention, and for further features and advantages, reference is now made to the following Detailed Description of an exemplary embodiment of the invention, taken in conjunction with the accompanying Drawings, in which:

FIG. 1 illustrates an exemplary spinal PEMF double-transducer system according to the invention;

FIG. 2 is a cross sectional view of a transducer showing the flat-wound bundle of windings, and the encapsulating shell; and

FIG. 3 is a schematic block diagram of the drive electronics.

DETAILED DESCRIPTION OF THE INVENTION

The Detailed Description of an exemplary embodiment of the PEMF double-transducer system of the invention is organized as follows:

1. Spinal PEMF System
2. Transducer Fabrication
3. Drive Electronics Module
4. Conclusion

The exemplary embodiment is a self-contained portable PEMF system for providing PEMF therapy to the spinal column, such as for fusion repair.

1. Spinal PEMF System. FIGURE illustrates an exemplary spinal PEMF double-transducer system **10**. The system includes front and back transducers **12** and **14** incorporated with an adjustable belt **16**.

Transducers **12** and **14** are anatomically contoured to enhance patient comfort, with a substantially flat cross sectional profile that provides a broad contact area, thereby enhancing patient comfort . The transducers are semi-rigid to maintain the selected contour and profile, and to provide bracing support as a fully integrated PEMF system. As described in Section **2**, the transducers include flat-wound primary, secondary and sense windings encapsulated in a shell of a plasticized elastomer material (such as polyurethane) with a selected degree of rigidity.

The transducers include both primary and secondary windings, with the secondary windings being used to provide energy recovery, and as a collateral function, to assist in tailoring the electromagnetic field output from the transducers. Alternatively, the advantages of the PEMF double-transducer system of the invention for implementing a PEMF therapy could be obtained using a pair of transducers, each with only a primary winding (i.e., with no energy recovery windings, but preferably with an alternative efficient programmed energy format).

Adjustable belt **16** can be fastened by means of a buckle **17**. The belt includes compartments for a drive electronics module **22**, and a rechargeable battery pack **24**.

The drive electronics module includes a PEMF processor for providing pulsing current to the front and back transducers at predetermined intervals, thereby activating the electromagnetic field according to a prescribed preprogrammed PEMF regimen. The drive electronics is coupled to the back transducer **14** by a cord **26**.

The battery pack can be recharged using an AC adapter **28**.

In operation, a health care professional determines a PEMF therapy that includes a regimen of PEMF stimulation of a target area of the spine. The prescribed PEMF therapy regimen is translated into a PEMF program, which is programmed into a PEMF memory in the drive electronics, either during manufacture or subsequently.

To commence a PEMF therapy session, the patient arranges the contoured front and back transducers for comfort, and engages the buckle (adjusting the belt to control snugness). Once the PEMF system is in place,

the patient starts the PEMF program by turning on the drive electronics module.

In accordance with the stored PEMF therapy program, the PEMF processor correspondingly control the activation current supplied to the transducers, thereby controlling the electromagnetic fields in terms of energization time, deenergization time and duty cycle (repetition rate). In addition to controlling the PEMF therapy, the PEMF processor maintains treatment data that is available on request to the patient (through a small display), and to a health care professional (via an I/O port) for monitoring and analysis.

2. Transducer Fabrication. For an exemplary embodiment, the front and back flat-wound contoured transducers are fabricated as follows.

FIG. **2** is a cross sectional view of a transducer (front or back) **30** that includes primary, secondary and sense windings **32** encapsulated in a semi-rigid shell **34**. The primary, secondary and sense windings are not shown differentiated in the FIG., nor is the total number of windings shown meant to be accurate—the FIG. is illustrative only.

For the exemplary embodiment, a transducer includes two parallel primary windings of about 7 turns each, a secondary winding of about 35 turns, and a sense winding of at least 1 turn. For the primary and secondary windings, 18 gauge wire can be used, while 22 gauge wire can be used for the sense winding. The approximate dimensions of the winding bundle are 0.75 by 0.12 inches, while the approximate dimensions of the shell are 1.50 by 0.31 inches.

The winding material is a commercially available magnet wire that includes an overcoat of an adhesive, such as polyurethane adhesive coated wire. The shell is a polyurethane-type elastomer material, also available commercially. Other shell materials can be used to provide different degrees of transducer-shell rigidity, thereby providing different bracing rigidity characteristics.

The adhesive-coated primary, secondary and sense windings are wound simultaneously in a winding machine around a flat mandrel of the appropriate shape for the transducer. The windings are maintained in the flat-wound position shown in the FIG. by parallel sideplates. Once wound, the start and finish wire ends for each winding are cut to provide leads for coupling to the drive electronics, and the winding assembly—winding bundle, mandrel and sideplates—is removed from the winding machine.

The winding assembly is then placed in an oven for heat curing at the appropriate curing temperature. Heat curing activates the adhesive coating, and the windings are bonded together to form the winding bundle **32**. The winding assembly is removed from the oven and, after cooling, a sideplate is removed, allowing the bonded winding bundle to be removed. The winding bundle is now in a flexible, bonded unit.

The winding bundle **32** is placed in a substantially flat mold of the appropriate shape, with the winding leads running out of the mold fill slot. The polyurethane type elastomer material is then introduced into the mold to form the shell **34**.

For the exemplary embodiment, a two component polyurethane elastomer is used: an isocyanate and a polyol. In a vacuum, the two components are mixed, and then poured into the mold, covering the winding bundle. These steps are performed in a vacuum to eliminate entrapped air which can cause voids that reduce

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

WHAT WILL YOU BUILD? | sales@docketalarm.com | 1-866-77-FASTCASE

fastcase® Smarter legal research.