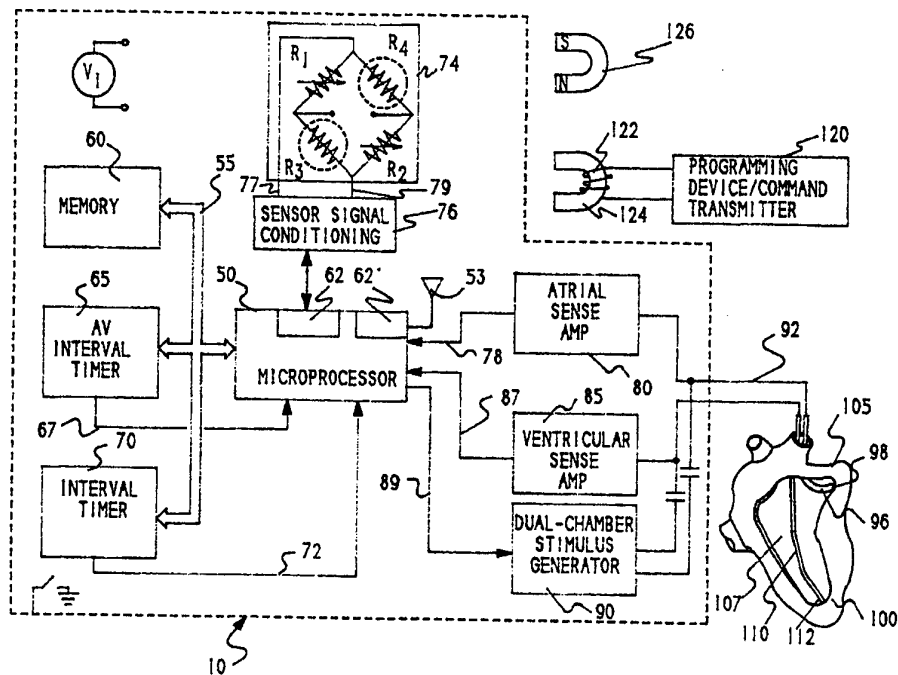




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(21) International Application Number: PCT/US96/08226 (22) International Filing Date: 31 May 1996 (31.05.96) (30) Priority Data: 08/475,491 7 June 1995 (07.06.95) US (71) Applicant: INTERMEDICS, INC. [US/US]; 4000 Technology Drive, Angleton, TX 77515 (US). (72) Inventors: PAUL, Patrick, J.; 229 Huckleberry, Lake Jackson, TX 77566 (US). PRUTCHI, David; 58 Chicory Court, Lake Jackson, TX 77566 (US). GENZER, David, G.; Route 1, Box 167, Bay City, TX 77414 (US). (74) Agents: MERKLING, John, R. et al.; Sulzermedica USA, Inc., 4000 Technology Drive, Angleton, TX 77515 (US).		(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>

(54) Title: APPARATUS AND METHOD FOR THE CONTROL OF AN IMPLANTABLE DEVICE



(57) Abstract

An implantable medical device (10) includes a giant magnetoresistance ratio (GMR) sensor (74) used to detect the presence of a magnet (124) in order to command the device to enter a predetermined mode of operation. The GMR responds to a modulated magnetic field generated by the programming of a command transmitter apparatus (120) for non-invasive programming or controlling of the implanted device. The present invention also monitors for the presence of a steady magnetic field (126) to place the implanted device in a known, safe mode.

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DescriptionApparatus and Method for the Control of an Implantable DeviceTechnical Field

The present invention relates generally to the field of implantable medical devices such as cardiac pacemakers, defibrillators, cardioverters, drug delivery devices, neural stimulators, and the like. More particularly, the present invention relates to a method and apparatus for controlling the output and mode of operation of such devices and changing the output and/or mode of operation of such devices with an external signal source, *e.g.*, without an invasive process.

Background Art

Many modern pacemakers adjust pacing rate in response to a patient's intrinsic electrical cardiac activity and/or other parameters such as a patient's metabolic demand for oxygen. Most state-of-the-art pacemakers are programmable or multi-programmable, such as with an external programmer which communicates with the implanted device via radio frequency (Rf) telemetry. A pacemaker may be programmable with respect to various parameters including pacing mode, pacing rate, stimulating pulse width, refractory period, sense amplifier sensitivity, rate-responsiveness to measured physiological parameters, and other parameters.

Implantable devices, such as pacemakers, are typically programmed by broadcasting information to the device in the form of digital information identifying at least the parameter to be programmed and the desired parameter value that will be input as a result of the programming. This information is typically in the form of binary digital data which is radio-frequency modulated and transmitted to an antenna within the implanted device. In the implanted device, the signal is demodulated and the digital information decoded. Other information, such as an identification code for the implanted device, verification codes, error correction codes, access verification codes, and the like, may also be transmitted to the device during programming. In addition, the transmitted information may include initialization data to reduce the possibility of inadvertent programming (or re-programming) of the device. Alternatively, a reed switch may be provided which allows for limited external control, such as for actuation of a programming mode, by means of placing an external magnet in proximity to the switch for actuation thereof.

The disadvantages of the radio-frequency system of such devices are characterized in detail in U.S. Patent No. 5,292,342, and the present invention is intended in part to overcome those disadvantages, as well as certain shortcomings of the device disclosed in the '342 patent.

The '342 patent describes a device incorporating a MAGFET sensor in a circuit including a logic circuit for generating two signals ("magnet present" or "magnet not present"), depending upon the orientation of the magnetic field, which signals comprise essentially digital data, sensing different numbers of removal/replacement cycles of the external magnet thereby identifying the different

operating parameters of the device for programming that device. The present invention, however, adds to the programming and operating capabilities of such devices by providing additional programming options and/or input and allows marking by the patient of external stimuli and/or operating conditions. These objects of the present invention are achieved by using a so-called giant magnetoresistance ratio (GMR) sensor in the device and external magnetic fields to which that sensor is sensitive.

The device disclosed in Patent No. 5,292,342 is characterized by other disadvantages and limitations. For instance, exclusive use of that sensor and an external magnetic field for programming limits that device to receiving only communications from the outside; without radio-frequency circuitry, and thus the device is not capable of transmitting signals. Further, and perhaps more importantly, the programming options that are available for that device are limited.

In accordance with the present invention, it has been discovered that GMR sensors are adaptable for a number of control functions other than re-programming of an implantable device including a MAGFET in the manner described in U.S. Patent No. 5,292,342. Specifically, it is an object of the present invention to supplement the programming and operating modes of an implantable device such as a pacemaker by providing, in addition to radio-frequency telemetry, a second mode of communication to the implantable device which is less likely to be influenced by external electromagnetic fields and which offers greater operating and programming flexibility to the device.

It is also an object of the present invention to include in this operating and programming flexibility the opportunity for patient input for subsequent downloading by radio-frequency telemetry for diagnostic and other purposes relating to the function of the device.

Disclosure of Invention

The present invention solves these shortcomings of the prior art and provides these objects. This invention includes an implantable biomedical device in which a giant magnetoresistance ratio (GMR) sensor is used to detect the presence of a magnet in order to command the device to enter a predetermined mode of operation. Further, the GMR responds to a modulated magnetic field generated by the programming of a command transmitter apparatus for non-invasive programming or controlling of the implanted device.

The present invention also uses sensed, time varying magnetic signals which indicate low frequency electromagnetic noise. Such electromagnetic noise may adversely influence the behavior of an implantable medical device which has sensitive signal sensing circuits, as described in concurrently filed U.S. application No. 08/475,489 entitled Electromagnetic Noise Detector For Implantable Medical Devices. The GMR sensor signal, when appropriately conditioned and demodulated, may be used for the detection of extraneous low-frequency electromagnetic fields that may cause unreliable or unsafe operation of the implantable device. For example, a pulsed magnetic field from an electronic article

surveillance system (EAS) may interfere with normal operation of an implantable medical device. The implantable medical device may then activate special circuitry to enter a safe mode of operation. A plurality of spaced GMR sensors may be employed in the present invention to counteract the effects of multiple axis magnetic fields encountered by a mobile recipient of such an implantable device.

5 In the present invention, a GMR sensor is excited by an excitation voltage source. The GMR sensor develops a modulated signal in response to an applied magnetic field and provides this modulated signal to a sensor signal conditioning circuit. The sensor signal conditioning circuit amplifies and filters the GMR sensor signal such that the circuit's output is a demodulated version of the applied magnetic field. The demodulated version of the applied field is used by a command decoder
10 circuit, which decodes modulated signals into commands for the implantable device. Also, the present invention detects the application of a permanent magnet for appropriate reversion to a magnet response mode of operation.

These and other objects and advantages of the present invention will be immediately apparent to those of skill in the art from a review of the following detailed description along with the
15 accompanying drawings.

Brief Description of Drawings

Figure 1 is a block diagram of a pacemaker having circuitry for controlling the pacemaker in accordance with a preferred embodiment of the present invention.

Figure 2 is a block diagram and schematic representation of the external transmitter for
20 programming the pacemaker of Fig. 1.

Figure 3 is a plot of the operating characteristics of a typical giant magnetoresistance ratio sensor, as applied in accordance with the present invention.

Best Mode for Carrying Out the Invention

Fig. 1 is a block diagram representing a rate adaptive pacemaker **10** for control in accordance
25 with a presently preferred embodiment of the present invention. Those skilled in the art who have the benefit of this disclosure, however, will recognize that the present invention is adaptable for use in controlling other types of pacemakers and many other types of implantable, microprocessor-controlled medical devices. The pacemaker **10** is illustrated merely for purposes of exemplifying a presently preferred embodiment of the invention.

30 Briefly, U.S. Patent No. 4,967,746 describes a pacemaker controlled by a microprocessor **50** such as the microprocessor described in detail in U.S. Patent No. 4,404,972, incorporated herein in its entirety by this specific reference thereto and assigned to the Assignee of the present invention. The basic pacemaker described in the '746 patent has been modified and improved by the present invention as described below.

35 The microprocessor **50** is provided with input/output ports connected in a conventional manner

via bi-directional bus **55** to memory **60**, an A-V interval timer **65**, and a pacing interval timer **70**. In addition, the A-V timer **65** and pacing interval timer **70** each has an output connected individually to a corresponding input port of the microprocessor **50** by lines **67** and **72**, respectively.

The microprocessor **50** preferably also has an input/output port connected to a telemetry interface **62** by line **52**. The pacemaker **10** when implanted is thus able to receive pacing and rate control parameters from an external programmer (not shown) and send data to an external receiver as known in the art, and described below with regard to an antenna **53**. One such system and encoding arrangement is described in U.S. Patent No. 4,539,992, which is also assigned to the assignee of the present invention and which is incorporated herein in its entirety by this specific reference thereto. The microprocessor **50** may also be provided with a radio-frequency link through the antenna **53**. The antenna **53** is coupled to a telemetry interface **62'**, which may be the same interface as interface **62**, or it may provide a distinct interface.

The microprocessor output ports are connected to the inputs of a dual chamber stimulus pulse generator **90** by control line **89**. The microprocessor **50** transmits pulse parameter data, such as amplitude and pulse width, as well as enable/disable initiation codes to the generator **90** on control line **89**.

The microprocessor **50** also has input ports connected to outputs of an atrial sense amplifier **80** and a ventricular sense amplifier **85** by lines **78** and **87**, respectively. The atrial and ventricular sense amplifiers **80** and **85** detect occurrences of P-waves and R-waves, respectively. The atrial sense amplifier **80** outputs a signal on line **78** to the microprocessor **50** when it detects a P-wave and the ventricular sense amplifier **85** outputs a signal on line **87** to the microprocessor **50** when it detects an R-wave.

The input of the atrial sense amplifier **80** and the output of the stimulus pulse generator **90** are connected to a first conductor **92** which is inserted in a first conventional lead **96**. Lead **96** is inserted into the heart **100** and has an electrically conductive pacing/sensing tip **98** at its distal end which is electrically connected to the conductor **92**. The pacing/sensing tip **98** is preferably lodged in the right atrium **105**.

The input of the ventricular sense amplifier **85** and the output of stimulus pulse generator **90** are connected to a second conductor **95**. The second conductor **95** is inserted in a second conventional lead **110** which is inserted intravenously or otherwise in the right ventricle **107** of the heart **100**. The second lead **110** has an electrically conductive pacing/sensing tip **112** at its distal end. The pacing/sensing tip **112** is electrically connected to the conductor **95**. The pacing/sensing tip **112** is preferably lodged on the wall of the right ventricle.

The conductors **92** and **95** conduct the stimulus pulses generated by the stimulus pulse generator **90** to the respective pacing/sensing tips **98** and **112**. The pacing/sensing tips **98** and **112** and

corresponding conductors **92** and **95** also conduct sensed cardiac electrical signals in the right atrium appendage and right ventricle to the atrial and ventricular amplifiers **80** and **85**, respectively.

The implantable device **10** further includes a magnetic sensor **74**. The sensor **74** may be any appropriate sensor capable of sensing a time-varying magnetic field, in a manner described herein, and is preferably a GMR sensor. The sensor **74** is excited by an excitation voltage source V_1 . The GMR is preferably an integrated GMR magnetic sensor from Nonvolatile Electronics, Inc. in Eden Prairie, MN. Other resistive sensor geometries are equally applicable to the present invention, such as those described in *The Constant Current Loop: A New Paradigm for Resistance Signal Conditioning*, Anderson, K.F., *Sensors*, April 1994, so long as such resistive sensors are sensitive to a time-varying magnetic field.

As shown in Figure 1, the GMR may be arranged as a bridge circuit with bridge elements R_1 - R_4 , inclusive. The GMR sensor provides an output signal to a sensor signal conditioning circuit **76** via signal lines **77** and **79**. This signal conditioning circuit **76** demodulates the signal from the GMR sensor **74**, as well as providing filtering and signal shaping so that the signal is in condition for use by the microprocessor **50**. The sensor signal conditioning circuit provides a further feature of defining a minimum threshold level from the sensor **74** to eliminate the deleterious effects of magnetic noise.

The bridge elements R_1 - R_4 are preferably integrated circuit field effect transistors that have been biased to operate in the resistive region. Two of the bridge elements, for example R_3 and R_4 , are shielded against magnetic influence, while R_1 and R_2 are unshielded. Figure 3 illustrates typical operating characteristics of the GMR sensor **74** in the presence of a magnetic field, with the output of the sensor between lines **77** and **79**. As shown, the output voltage of the sensor is independent of the polarity of the magnetic field; that is, the voltage output depends only on the absolute value of the magnetic field.

The magnetic field is provided to the implantable device **10** from a source outside the patient. In a preferred embodiment, the magnetic signal is provided by a programming device/command transmitter **120**, shown in greater detail in Figure 2. The command transmitter **120** powers a coil **122** which is magnetically coupled to a core **124**. The command transmitter **120** develops a modulated digital data stream which is magnetically coupled to the sensor **74** for communication to the microprocessor **50**. The digital data stream may include a code sequence to define a specific parameter, which then follows the code sequence in the data stream. In this way, commands or information may be selectively directed to the microprocessor. If desired this may include re-programming the implantable device **10**, to suit the needs of the patient.

The implantable device **10** is also sensitive to the presence of a magnetic field from a permanent magnet **126**. Thus, the sensor **74** may be used to revert the operation of the implantable device to the

magnet mode of operation. In magnet mode, a predetermined, typically asynchronous, ventricular pacing rate is issued. This mode eliminates complex timing and synchronizing signals to assist in monitoring the functioning of a remotely stimulated organ. As used herein, the term "magnet mode" may also be referred to as a "known, safe mode" because this mode is dependent only on the voltage of the battery in the implanted device, and is not dependent on either heart activity or on any adapted rate factors which can alter operation of the implanted device.

Figure 2 depicts a preferred embodiment of the programming device/command transmitter **120** of the present invention. An input device **130**, such as a keyboard, switch array, modem, or other means of assembling a character stream, is coupled to an encoding element **132** which develops the digital bit string. This bit string is communicated to a control logic element **134** which drives a modulator **136**. The modulator modulates the signal from the control logic to a condition to drive an output stage or amplifier **138**. The amplifier **138** matches the impedance of a conductor **140** and amplifies the signal sufficiently to drive the coil **122** and core **124** to develop a magnetic signal that is detected by the device **10**. The control logic **134** also provides monitoring of the transmitter **120** for display indicators **142**.

We claim:

1. An apparatus for communicating with a medical device (10) implanted within a human, the apparatus comprising:

- 5 a. a command transmitter (120) for generating a digital bit string;
- b. an electromagnet (124) coupled to the command transmitter to develop a series of magnetic pulses corresponding to the digital bit string;
- c. a sensor (74) in the medical device, capable of sensing a time-varying magnetic field, to receive the series of magnetic pulses and develop an output signal; and
- 10 d. a sensor signal conditioner (76) in the medical device to receive the output signal from the sensor and provide a demodulated signal to the medical device

characterized in that the sensor comprises a giant magnetoresistance ratio sensor (R_1 , R_2 , R_3 , R_4).

2. A method of altering the operating parameters of a medical device implanted within a human comprising the steps of:

- 15 a. developing a digital bit string representative of a command for communication to the medical device;
- b. driving an electromagnet to produce a digital series of magnetic pulses;
- c. receiving the series of magnetic pulses in a magnetic sensor to develop a modulated output voltage;
- 20 d. demodulating the modulated output from the sensor to produce a conditioned bit stream; and
- e. receiving the conditioned bit stream in a processor in the medical device to alter the operating parameters of the medical device

characterized in that the magnetic sensor comprises a giant magnetoresistance ratio sensor (R_1 , R_2 , R_3 , R_4).

3. An apparatus for communicating with a medical device implanted within a human, the apparatus comprising:

- a. a command transmitter (120) for generating a digital bit string;
- 30 b. a sensor (74) in the medical device, capable of sensing the presence of a steady magnetic field to develop an output command signal to place the apparatus in a known, safe mode; and
- c. a sensor signal conditioner (76) in the medical device to receive the output command signal from the sensor and issue a magnet mode signal to the medical device

characterized in that the sensor comprises a giant magnetoresistance ratio sensor (R_1 , R_2 , R_3 , R_4).

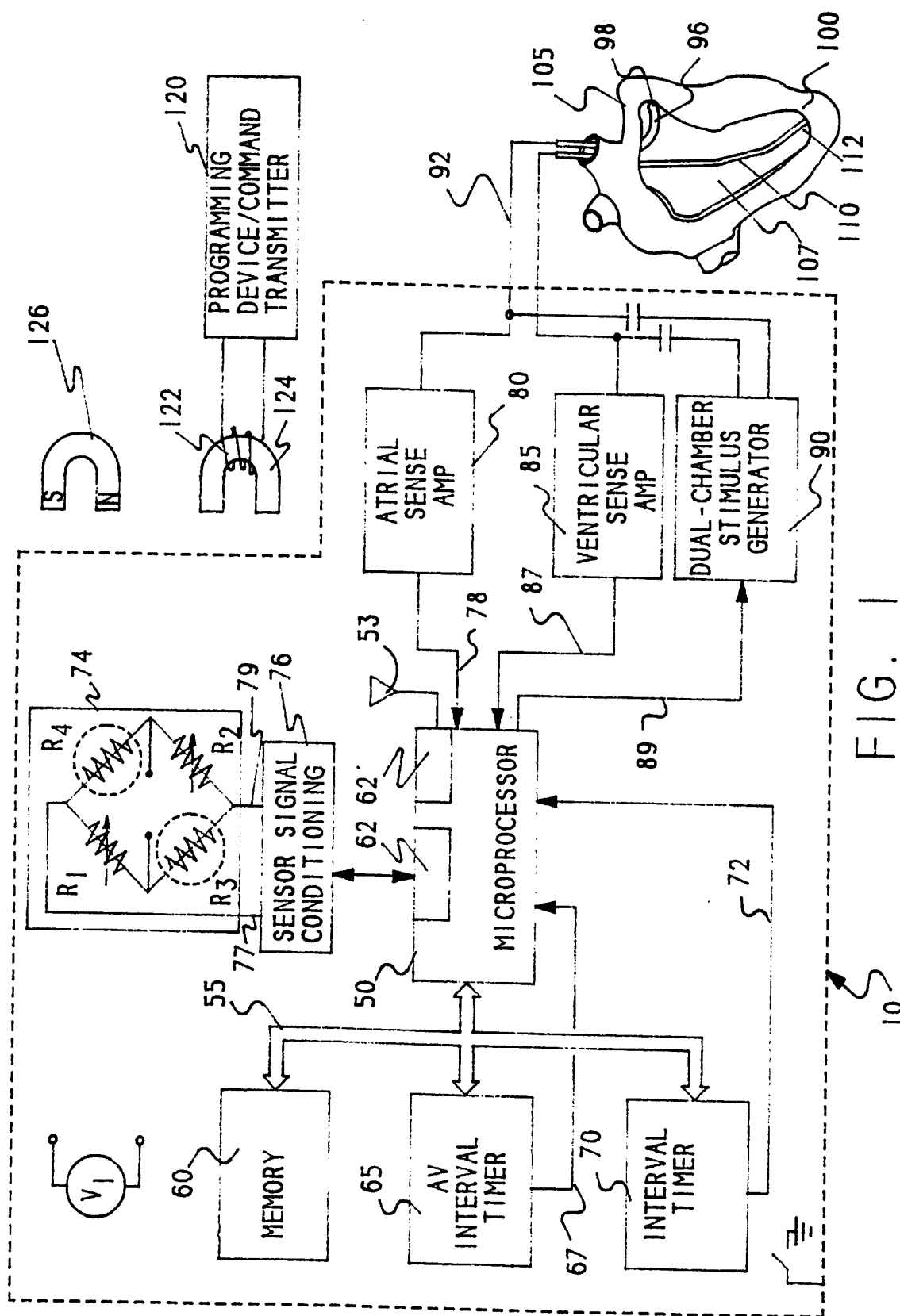


FIG. 1

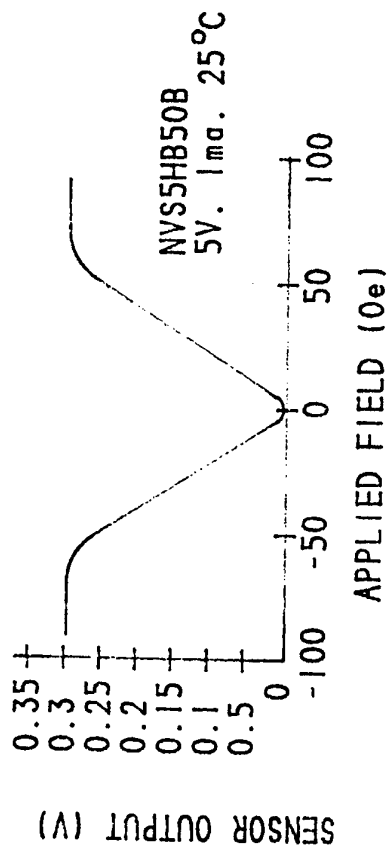
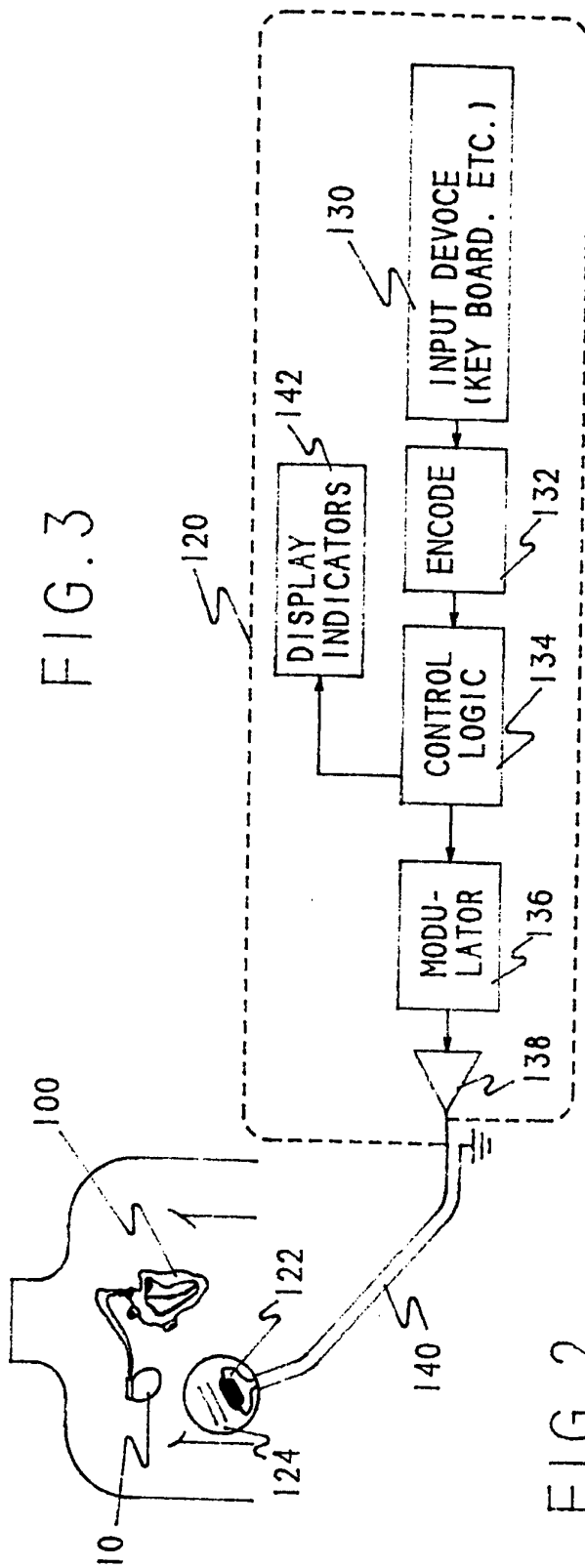


FIG. 3



INTERNATIONAL SEARCH REPORT

International application No
PCT/US 96/08226

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N1/372

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61N A61F A61B H04B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP,A,0 443 496 (SIEMENS) 28 August 1991 see column 3, line 53 - column 4, line 29 ---	1-3
A	WO,A,91 11063 (BERTIN) 25 July 1991 see page 10, line 1 - page 12, line 30 ---	1-3
A	WO,A,91 16696 (SIEMENS-ELEMA AB) 31 October 1991 see page 8, line 23 - page 10, line 34; claim 6 ---	1-3
A	WO,A,93 16757 (ZMD CORPORATION) 2 September 1993 see page 16, line 6 - page 17, line 31 ---	1-3
A	WO,A,94 12238 (MEDTRONIC) 9 June 1994 see page 11, line 3 - line 14 ---	1-3
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

12 September 1996

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INTERNATIONAL SEARCH REPORT

International Application No.
PCT/US 96/08226

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO,A,94 16769 (MEDTRONIC) 4 August 1994 see claim 1	1-3
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INTERNATIONAL SEARCH REPORT

Information on patent family members

Application No

PCT/US 96/08226

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