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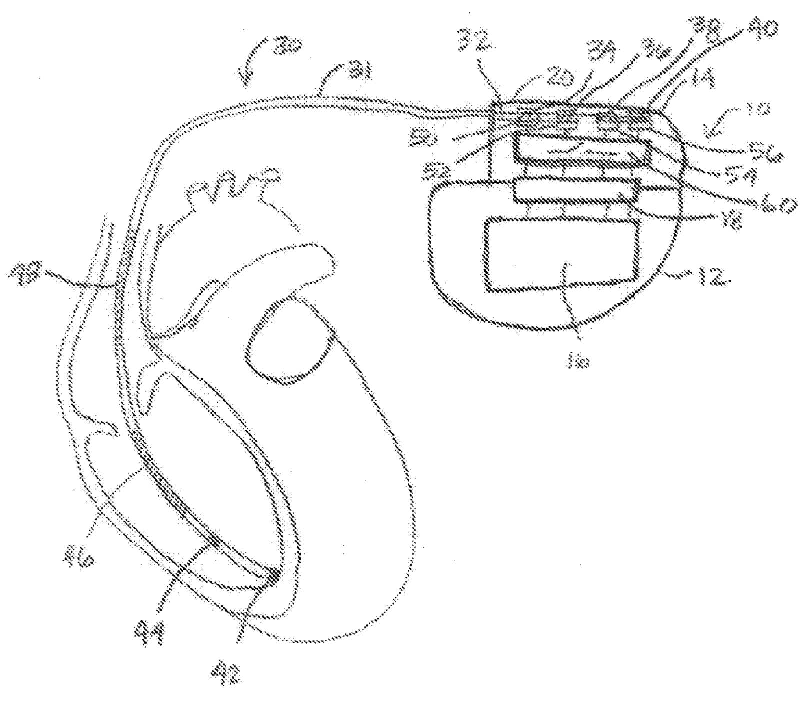
(54) **Title:** ISOLATION CIRCUITRY AND METHOD FOR GRADIENT FIELD SAFETY IN AN IMPLANTABLE MEDICAL DEVICE



(57) **Abstract:** An implantable medical device is provided for isolating an elongated medical lead from internal device circuitry in the presence of a gradient magnetic or electrical field. The device includes an isolation circuit adapted to operatively connect an internal circuit to the medical lead in a first operative state and to electrically isolate the medical lead from the internal circuit in a second operative state.

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

ISOLATION CIRCUITRY AND METHOD FOR GRADIENT FIELD SAFETY IN AN IMPLANTABLE MEDICAL DEVICE

TECHNICAL FIELD

The invention relates generally to implantable medical devices, and, in particular, to a method and apparatus for electrically isolating leads coupled to an implantable medical device from circuitry in the implantable medical device.

BACKGROUND

Numerous types of implantable medical devices (IMDs), such as cardiac pacemakers, implantable cardiovertor defibrillators (ICDs), neurostimulators, operate to deliver electrical stimulation therapies to excitable body tissue via associated electrodes. The electrodes are disposed at a targeted therapy delivery site and are commonly coupled to the IMD via conductors extending through elongated leads. Patients implanted with such IMDs are generally contraindicated for undergoing MRI procedures. The gradient magnetic fields that may be applied during an MRI procedure can induce current on the elongated lead conductors, which can be large enough to cause undesired stimulation of the excitable tissue in contact with the electrode(s) carried by the lead. As the number of patients having IMDs continues to grow, it is desirable to provide IMD systems that allow patients to safely undergo MRI procedures.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic diagram of an IMD coupled to a patient's heart via a cardiac lead.

Figure 2 is a functional block diagram of an IMD including isolation circuitry.

Figure 3 is a timing diagram illustrating IMD function during a gradient field operating mode.

Figure 4 is a flow chart summarizing one method for controlling isolation circuitry included in an IMD.

DETAILED DESCRIPTION

In the following description, references are made to illustrative embodiments for carrying out the invention. It is understood that other embodiments may be utilized without departing from the scope of the invention. The invention is generally directed toward providing an IMD and an associated method for protecting a patient from unwanted tissue stimulation due to current induced on implanted leads in the presence of time-varying magnetic or electrical fields, such as during MRI procedures involving gradient magnetic fields or in the presence of time-varying electrical fields associated with electronic article surveillance systems (EAS). As used herein, the term “gradient field” refers to any time varying magnetic or electrical field that is strong enough to induce current on an implanted lead and potentially cause tissue stimulation. As used herein, the term “module” refers to an application specific integrated circuit (ASIC), an electronic circuit, a processor (shared, dedicated, or group) and memory that execute one or more software or firmware programs, a combinational logic circuit, or other suitable components that provide the described functionality.

Figure 1 is a schematic diagram of an IMD coupled to a patient’s heart via a cardiac lead. IMD 10 is shown as a single chamber cardiac device, however it is recognized that various embodiments of the present invention may be implemented in single, dual, or multi-chamber cardiac devices or single or multi-channel neurostimulators. Embodiments of the present invention include IMDs provided as monitoring devices without therapy delivery capabilities. IMDs provided with therapy delivery capabilities may include, for example, cardiac pacemakers, cardioverter/defibrillators, drug delivery devices, and neurostimulators.

IMD 10 is embodied as an implantable cardioverter defibrillator (ICD) and is coupled to lead 30 for sensing cardiac signals and delivering electrical stimulation pulses to the heart in the form of cardiac pacing pulses and cardioversion/defibrillation shock pulses. Lead 30 is provided with a tip electrode 42 and ring electrode 44 which are generally used together for bipolar sensing and/or pacing functions or in combination with IMD housing 12 for unipolar sensing and/or pacing functions. Lead 30 also includes a right ventricular coil electrode 46 and a superior vena cava coil electrode 48 used in delivering high-voltage cardioversion and defibrillation shocks.

Each of the electrodes 42, 44, 46 and 48 are coupled to individual connectors 34, 36, 38 and 40 included in a proximal lead connector assembly 32 via conductors extending through elongated lead body 31. The lead connector assembly 32 is adapted for insertion into a connector bore provided in connector header 14 of IMD 10. Electrode terminals 50, 52, 54 and 56 included in connector header 14 are electrically coupled to lead connectors 34, 36, 38 and 40 when lead connector assembly 32 is fully inserted in the connector header bore.

Electrode terminals 50, 52, 54 and 56 are electrically coupled to internal IMD circuitry 16, enclosed in hermetically sealed IMD housing 12. Electrode terminals 50, 52, 54 and 56 are coupled to internal circuitry 16 via isolation circuitry 60 and protection circuitry 18, shown schematically in FIG. 1. The actual physical location of isolation circuitry 60 and protection circuitry 18 may be anywhere between electrode terminals 50, 52, 54, and 56 and any portion of the internal circuitry 16. The functionality of isolation circuitry 60 may be implemented using dedicated components or providing dual functionality of existing switching devices included in IMD 10.

Isolation circuitry 60 provides protection to the patient against unwanted tissue stimulation due to current induced on conductors carried by lead body 31. For example, in an MRI environment involving gradient magnetic fields, current induced on lead conductors can be carried along a circuit path that includes lead 30, the IMD housing 12, and body tissue. Isolation circuitry 60 interrupts this circuit path by introducing a high-impedance element as will be described in greater detail herein. Protection circuitry 18 is generally grounded to IMD housing 12 thereby providing a path from electrode terminals 50, 52, 54, and 56 to the IMD housing 12, completing the circuit pathway through the patient's body along which induced currents may be conducted. Isolation circuitry 60 is provided to open that circuit pathway to prevent unwanted tissue stimulation in an MRI or other gradient field environment.

Protection circuitry 18 is provided for eliminating or minimizing electromagnetic interference (EMI) that may be encountered in normal operating environments. EMI can produce a potential between any of electrodes 42, 44, 46 and 48 and housing 12. Circuit elements and parasitic effects provide paths for current to flow as a result of these potentials. Protection circuitry 18 prevents EMI from being coupled to the internal circuitry 16, which may otherwise cause inappropriate IMD function. Protection circuitry 18 typically includes electrically insulated, filtered feedthroughs such that electrical connections made between electrode terminals 50, 52, 54, and 56 and internal circuitry 16 are electrically isolated from IMD housing 12. The filtered feedthroughs typically include capacitive elements for filtering EMI. Examples of protection circuitry included in IMDs are generally disclosed in U.S. Pat. No. 5,759,197 (Sawchuk, et al.) and U.S. Pat. No. 6,414,835 (Wolf et al.), both of which patents are hereby incorporated in their entirety. Protection circuitry 18 may include other noise-reduction and protection networks for static discharge and other transient voltages that may arise due to EMI.

Figure 2 is a functional block diagram of an IMD including isolation circuitry. IMD 10 generally includes timing and control circuitry 152 and an operating system that may employ microprocessor 154 or a digital state machine for timing sensing and therapy delivery functions in accordance with a programmed operating mode. Microprocessor 154 and associated memory 156 are coupled to the various components of IMD 10 via a data/address bus 155. IMD 10 includes therapy delivery unit 150 for delivering an electrical stimulation therapy, such as cardiac pacing therapies, under the control of timing and control 152. Therapy delivery unit 150 is typically coupled to two or more electrode terminals 168 via switch/multiplexer 158. Switch/MUX 158 is used for selecting which electrodes and corresponding polarities are used for delivering electrical stimulation pulses.

Electrode terminals 168 may also be used for receiving electrical signals from the body, such as cardiac signals or other electromyogram (EGM) signals, or for measuring impedance. In the case of cardiac stimulation devices, cardiac electrical signals are sensed for determining when an electrical stimulation therapy is needed and in controlling the timing of stimulation pulses.

Electrode terminals 168 are typically included in a connector header as described in conjunction with Figure 1. Electrode terminals 168 may be electrically coupled to switch/MUX 158 via the isolation circuit 180 and any EMI protection circuitry 182. The remaining functional blocks shown in Figure 2 are typically implemented on a hybrid circuit board having contact pads for making electrical connections to protection circuitry

182. Isolation circuitry 180 may be implemented anywhere between electrode terminals 168 and the connections to the various components included on a hybrid circuit board.

Isolation circuitry 180, shown as a functional block in Figure 2, may include switching elements physically located at separate locations relative to the hybrid circuit board and IMD housing. If isolation of an associated lead from all IMD circuitry is desired, isolation circuitry 180 could be located outside the IMD housing or contained within a separate Faraday shield within the IMD housing. In other embodiments, isolation circuitry 180 may include switches used to isolate only portions of the hybrid circuitry from an associated lead and might include switching elements incorporated on the hybrid circuit board.

Switching elements already present in the IMD circuitry may be utilized to provide the isolation circuit functionality as well as other functions. For example, IMD 10 may be provided with switches used for protecting IMD circuitry from voltages produced by external defibrillation. Switches 185a through 185d may include such switches. In other words, any of switches 185a through 185d serving functionally as a part of isolation circuit 180 for protecting the patient from induced current in the presence of time-varying EM fields may be embodied as a switch already provided in IMD 10 for protecting the IMD circuitry from voltages produced by external defibrillation.

Electrodes used for sensing and electrodes used for stimulation may be selected via switch matrix 158. When used for sensing, electrode terminals 168 are coupled to signal processing circuitry 160 via switch matrix 158. Signal processor 160 includes sense amplifiers and may include other signal conditioning circuitry and an analog to digital converter. Electrical signals may then be used by microprocessor 154 for detecting physiological events, such as detecting and discriminating cardiac arrhythmias.

In some embodiments, microprocessor 154 uses signals received at electrode terminals 168 for automatically detecting induced signals associated with a gradient field, such as a time-varying magnetic field associated with MRI. Alternatively, a gradient field sensor circuit 186 may be provided for sensing external signals corresponding to a time-varying MRI or other gradient field environment. Gradient field sensor circuit 186 may be embodied according to the sensor circuit generally disclosed in U.S. Pat. No. 6,198,972 (Hartlaub et al.), hereby incorporated herein by reference in its entirety. Gradient field sensor circuit 186 may be located anywhere in a patient's body and may therefore alternatively be coupled to IMD circuitry via a sensor terminal 170. In response to a gradient field detection signal generated by gradient field sensor circuit 186, microprocessor 154 causes timing and control circuitry 152 to generate a signal on signal line 184 that opens switches 185a through 185d included in isolation circuitry 180. The circuit path through the IMD housing and the patient's body is effectively opened thereby preventing unwanted tissue stimulation due to induced currents on implanted leads coupled to IMD 10. During MRI, a sensor that detects the very strong static magnetic field may be used alone or in conjunction with other sensors to activate isolation circuitry 180.

IMD 10 may additionally or alternatively be coupled to one or more physiological sensors. As such, physiological sensor terminals 170 are provided and are electrically coupled to a sensor interface 160 via protection circuitry 182. Sensor terminals 170 may also be electrically coupled to IMD circuitry, or portions of IMD circuitry, through isolation circuitry 180 when terminals 170 are coupled to elongated leads that could carry induced currents to body tissue. Physiological sensors may include pressure sensors, accelerometers, flow sensors, blood chemistry sensors, activity sensors or other physiological sensors known for use with IMDs.

Signals received at sensor terminals 170 are received by a sensor interface 162 which provides sensor signals to signal processing circuitry 160. Sensor signals are used by microprocessor 154 for detecting physiological events or conditions. For example, IMD 10 may monitor heart wall motion, blood pressure, blood chemistry, respiration, or patient activity. Monitored signals may be used for sensing the need for delivering a therapy under control of the operating system.

The operating system includes associated memory 156 for storing a variety of programmed-in operating mode and parameter values that are used by microprocessor 154. The memory 156 may also be used for storing data compiled from sensed physiological signals and/or relating to device operating history for telemetry out on receipt of a retrieval or interrogation instruction. All of these functions and operations are known in the art, and many are generally employed to store operating commands and data for controlling device operation and for later retrieval to diagnose device function or patient condition.

IMD 10 further includes telemetry circuitry 164 and antenna 128. Programming commands or data are transmitted during uplink or downlink telemetry between IMD telemetry circuitry 164 and external telemetry circuitry included in a programmer or monitoring unit. Telemetry circuitry 164 and antenna 128 may correspond to telemetry systems known in the art. In one embodiment of the invention, a gradient field mode command is transmitted to IMD telemetry circuitry 164 by a clinician or other user using an external programmer. In response to the gradient field mode command, microprocessor 154 causes timing and control circuitry 152 to generate a signal on signal line 184 to open switches included in isolation circuitry 180.

During a gradient field operating mode, electrode terminals 168 (and/or sensor terminals 170) are electrically disconnected from IMD circuitry by introducing a high-impedance element included in isolation circuitry 180. Isolation circuitry 180 generally includes switches 185a through 185d which may be embodied as electro-mechanical relays, semiconductor devices, or MEMS relays. Switches 185 included in isolation circuitry 180 may be implemented as generally described in the above-incorporated Hartlaub patent. It is recognized that each of switches 185a through 185d may include one or more electronic switches coupled in series to form a high-impedance element through isolation circuitry 180. The number of switches 185 included in isolation circuitry 180 will vary between applications and will correspond to the number of electrode terminals 168 and sensor terminals 170 that need to be electrically disconnected from the IMD ground path to prevent conduction of currents induced on elongated lead conductors during MRI procedures or in the presence of other gradient EM fields.

When microprocessor 156 determines that an electrical stimulation therapy is needed, or if an electrical stimulation therapy is in process upon initiation of the gradient field operating mode, timing and control circuitry 152 generates a transient “close” signal on signal line 184. The “close” signal is generated just prior to or contemporaneously with the generation of an electrical stimulation pulse by therapy delivery unit 150. A stimulation pulse generated by therapy delivery unit 150 is delivered to electrode terminals 168 across isolation circuitry 180. The “close” signal causes at least one switch included in isolation circuitry 180 that corresponds to a selected stimulation electrode to briefly close so that the stimulation pulse can be delivered. Other switches included in isolation circuitry 180 may remain open during stimulation pulse delivery. Accordingly, it is understood that signal line 184 may carry a multiplexed signal for operating multiple switches included in isolation circuitry 180 individually. With regard to the embodiment shown in Figure 1, a switch coupled to electrode terminal 56 corresponding to tip electrode 42 may be controlled separately from a switch coupled to electrode terminal 54, corresponding to ring electrode 44 to allow unipolar stimulation using tip electrode 42 during a gradient field operating mode.

IMD 10 may optionally be equipped with patient alarm circuitry 166 for generating audible tones, a perceptible vibration, muscle stimulation or other sensory stimulation for notifying the patient that a patient alert condition has been detected by IMD 10. In some embodiments, an alarm signal may be generated upon detection of a gradient field or upon initiating a gradient field mode of operation.

Figure 3 is a timing diagram illustrating IMD function during a gradient field operating mode. At a time 202, a gradient field mode is initiated in response to a gradient field operating mode command or the automatic detection of gradient field signals, corresponding to a time-varying MRI field or other gradient EM field, by a gradient field sensor circuit. Two biasing signals 205 and 215 are provided to individual switches, for example MOSFETs, included in isolation circuitry. Initially, prior to the initiation of gradient field operating mode at time 202, the MOSFET switches are biased with high signals 208 and 214 that maintain the switches in a closed or ON operative state. For example, a MOSFET may be biased to 5.0 volts relative to circuit common to hold the transistor in the ON state to allow normal sensing and therapy delivery functions.

Upon initiation of the gradient field operating mode at time 202, biasing signals 205 and 215 are switched to low signals 210 and 216 to open the corresponding MOSFETs to an OFF operative state. For example, the MOSFETs may be biased to 0.0 volts relative to circuit common to hold the transistor in the OFF state to prevent conduction of induced currents to excitable body tissue. A feedback or bootstrap network could be used to maintain the correct state of the MOSFET.

Pacing pulses 206a, 206b, 206c through 206n are delivered after the initiation of gradient field mode at time 202. Pacing therapy may have been in progress at the time of initiating the gradient field mode or a need for pacing therapy may be detected during the gradient field mode using other sensors or circuits that are not opened by isolation circuitry. In pacing dependent patients, initiation of the gradient field mode may include maintaining a predetermined pacing rate. Reference is made to U.S. Pat. App. Pub. No. 2003/0144705 (Funke), hereby incorporated herein by reference in its entirety. Intrinsic cardiac signals may be sensed during the gradient field operating mode through high impedance signal path sensing channels or utilize a gradient energy cancellation sensing method.

In order to deliver pacing pulses 206a through 206n, at least one switch (for unipolar pacing) included in isolation circuitry is transiently closed by generating a high biasing signal 212a, 212b, 212c, 212n at appropriate times relative to pacing pulses 206a through 206n. In order to deliver bipolar pacing pulses, two switches may be transiently closed during pacing pulse delivery. Timing and control module 152 (Figure 2) controls the alternation between high and low bias signal levels applied to isolation circuit switches to control the operative state of the switches. A switch is closed to close a pacing or electrical stimulation circuit at appropriate times during the gradient field mode to allow therapeutic stimulation to be performed, for example during MRI procedures. The switch(es) included in a pacing or electrical stimulation circuit are briefly closed for an interval of time starting just prior to or approximately the same time as a stimulation pulse and extending for a time at least equal to the stimulation pulse width. While the timing diagram shown in Figure 3 illustrates the delivery of cardiac pacing pulses, it is recognized that any type of electrical stimulation pulses may be delivered during a gradient field mode by controlling the opening and closing of switches included in isolation circuitry. For example the need for high-voltage cardioversion/defibrillation shocks may be detected based on sensing intrinsic signals using a gradient energy cancellation method and high energy therapies may be delivered based on determining a reliable sensing signal for arrhythmia detection.

Figure 4 is a flow chart summarizing one method for controlling isolation circuitry included in an IMD. Flow chart 300 is intended to illustrate the functional operation of the device, and should not be construed as reflective of a specific form of software or hardware necessary to practice the invention. It is believed that the particular form of software will be determined primarily by the particular system architecture employed in the device and by the particular detection and therapy delivery methodologies employed by the device. Providing software and/or hardware to accomplish the present invention in the context of any modern IMD, given the disclosure herein, is within the abilities of one of skill in the art.

The IMD microprocessor initiates a gradient field operating mode at block 306. The gradient field operating mode is initiated in response to receipt of an external command provided to the IMD using a programmer or other device enabled for telemetric communication with the IMD (block 304). The gradient field operating mode is alternatively initiated in response to the detection of external or internal high level signals corresponding to an MRI or other time-varying EM environment by gradient field sensor circuit at block 302.

Upon initiation of the gradient field mode, switches included in isolation circuitry are opened at block 310. A gradient magnetic field may induce currents on implanted lead conductors large enough to cause tissue stimulation. Opening of isolation circuitry switches opens the circuit path through the capacitive feedthrough elements and the IMD housing and patient’s body, preventing conduction of induced currents and unwanted tissue stimulation.

At decision block 314, timing and control module 152 determines if a therapeutic stimulation pulse is needed based on programmed therapy delivery mode. Upon triggering the generation of a therapy stimulation pulse, timing and control 152 generates a signal to transiently close one or more isolation circuitry switches included in a stimulation circuit path in order to allow stimulation pulse delivery at block 318.

Throughout the gradient field mode, the IMD microprocessor monitors for receipt of an external command indicating that a normal operating mode should be restored at decision block 322. Additionally or alternatively, the IMD microprocessor automatically monitors for an end to the detection of gradient signals by a gradient field sensor. In other embodiments, the gradient field mode may be maintained for a fixed interval of time after gradient field mode initiation. For example, the gradient field mode may be maintained for 30 minutes, one hour, or another interval of time that is expected to extend safely beyond the completion of an MRI procedure. As long as the gradient field mode is maintained, timing and control module 152 continues to control transient closure of stimulation circuit path switches included in isolation circuitry contemporaneously with the generation of therapeutic stimulation pulses at block 318.

Upon expiration of the gradient field mode according to a predetermined time interval, receipt of an external termination command, or loss of gradient field signal detection at decision block 318, isolation circuitry switches are closed at block 326. Closure of isolation switches restores normally closed sensing and stimulation circuit paths for normal IMD operation. The gradient field operation mode is then terminated at block 330.

Thus, an IMD and associated methods for protecting a patient from unwanted tissue stimulation during exposure to time-varying electrical or magnetic fields has been presented in the foregoing description with reference to specific embodiments. It is appreciated that various modifications to the referenced embodiments may be made without departing from the scope of the invention as set forth in the following claims.

CLAIMS

1. An implantable medical device, comprising:

an internal circuit adapted to be electrically coupled to an elongated medical lead implanted in a patient's body;

an isolation circuit adapted to operatively connect the internal circuit to the medical lead in a first operative state and to electrically isolate the internal circuit from the medical lead in a second operative state;

a control module for determining a device operating mode as one of a normal operating mode and a gradient field operating mode and for controlling the operative state of the isolation circuit in the first operative state in response to determining the normal operating mode, in the second operative state in response to determining the gradient field operating mode, and transiently switching the isolation circuit from the second operative state to the first operative state during the gradient field operating mode.

2. The implantable medical device of claim 1 wherein the internal circuit includes a pulse generating circuit and wherein the control module transiently switches the isolation circuit from the second operative state to the first operative state in response to generation of a stimulation pulse by the pulse generating circuit.

3. The implantable medical device of claim 1 wherein the isolation circuit includes one of an electro-mechanical relay, a semiconductor device, and a MEMS relay.

4. The implantable medical device of claim 1 further comprising a gradient field sensor and wherein the control module determines the gradient field operating mode in response to the gradient field sensor.

5. The implantable medical device of claim 1 further comprising a telemetry circuit for receiving commands from an external programming device and wherein the control module determines the gradient field operating mode in response to a command received by the telemetry circuit.

6. The implantable medical device of claim 1 further comprising a switching element for controlling a device function and wherein the control module controls the operative state of the isolation circuit by controlling the switching element.

7. The implantable medical device of claim 6 wherein the device function includes protecting the internal circuit from external high-voltage shocks applied to a patient.

8. A method for use in an implantable medical device, comprising:

coupling an elongated medical lead to an internal circuit by way of an isolation circuit,

determining a device operating mode as one of a normal operating mode and a gradient field operating mode;

controlling the operative state of the isolation circuit in a first operative state in response to determining the normal operating mode and in a second operative state in response to determining the gradient field operating mode; and

transiently switching the isolation circuit from the second operative state to the first operative state during the gradient field operating mode.

9. The method of claim 8 further comprising generating therapeutic stimulation pulses and transiently switching the isolation circuit from the second operative state to the first operative state in response to generating a stimulation pulse.

10. The method of claim 8 further comprising automatically detecting a gradient field and wherein the gradient field mode is determined in response to the detected gradient field.

11. The method of claim 8 further comprising receiving an externally generated command and wherein the gradient field mode is determined in response to the command.

12. The method of claim 8 further comprising controlling a switching element state for controlling a device function and wherein controlling the operative state of the isolation circuit includes controlling the switching element state.

13. The method of claim 12 wherein the device function includes protecting of an internal circuit from external high-voltage shocks applied to a patient.

14. An implantable medical device system, comprising:

means for operatively connecting an elongated medical lead to an implantable medical device internal circuit in a first operative state and for electrically isolating the medical lead from the internal circuit in a second operative state;

means for determining a device operating mode as one of a normal operating mode or a gradient field operating mode; and

means for controlling the operative state of the means for operatively connecting and electrically isolating in the first operative state in response to determining the normal operating mode, in the second operative state in response to determining the gradient field operating mode, and transiently switching from the second operative state to the first operative state during the gradient field operating mode.

15. The implantable medical device system of claim 14 further comprising means for generating therapeutic electrical pulses and wherein the controlling means transiently switches the connecting and isolating means from the second operative state to the first operative state in response to the generation of electrical pulses by the pulse generating means.

16. The implantable medical device system of claim 13 wherein the connecting and isolating means includes any of an electro-mechanical relay, a semiconductor device, and a MEMS relay.

17. The implantable medical device system of claim 13 further comprising means for automatically detecting a gradient field.

18. The implantable medical device system of claim 13 further comprising means for receiving an externally generated gradient field operating mode command.

19. The implantable medical device system of claim 13 further comprising means for switchably controlling a device function and wherein the connecting and isolating means includes the means for switchably controlling the device function.

20. The implantable medical device of claim 18 wherein the device function includes protecting the internal circuit from external defibrillation shocks applied to a patient.

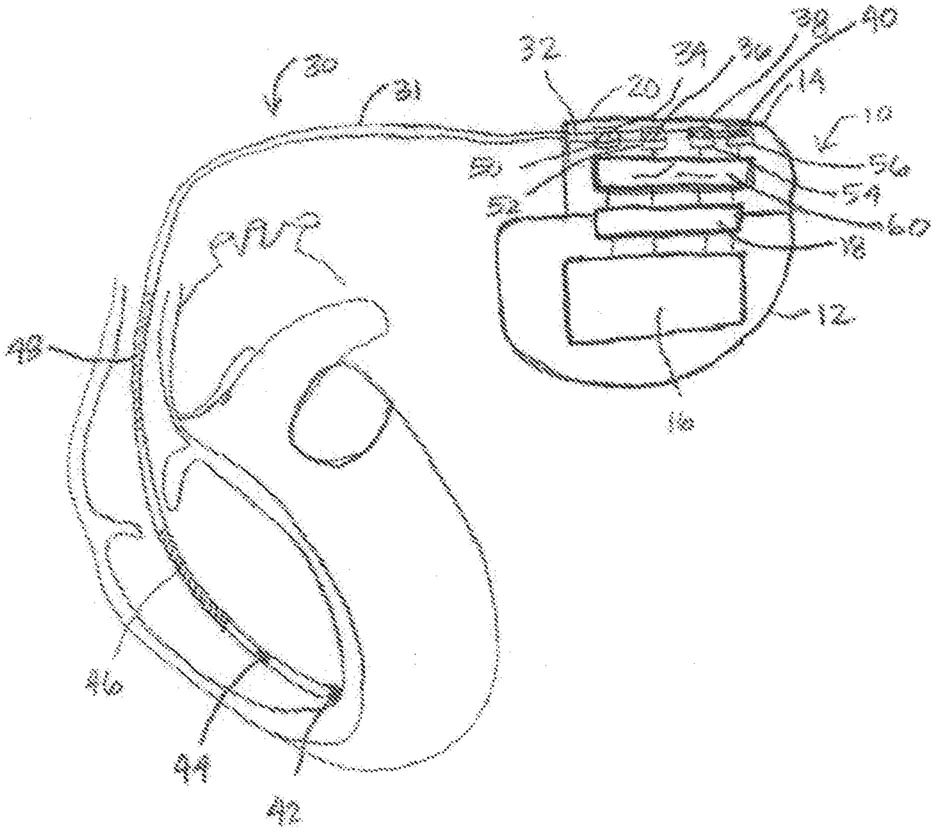

FIG. 1

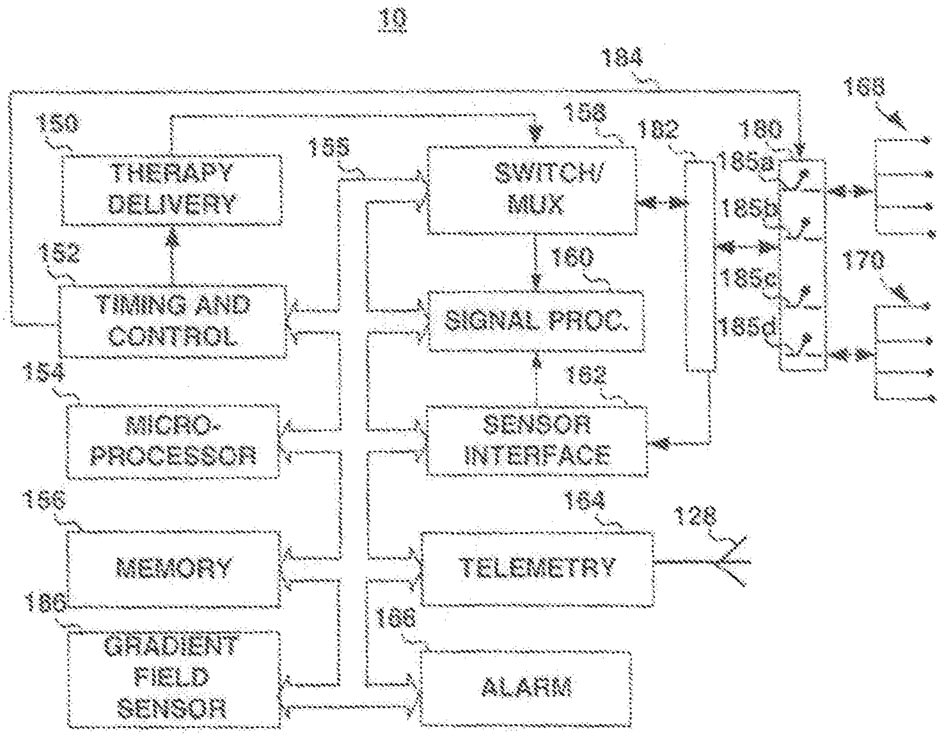
10
184
168
150
158
182
180
THERAPY DELIVERY
188
SWITCH/ MUX
185a
185b
152
160
170
185c
TIMING AND CONTROL
SIGNAL PROC.
185d
154
162
MICRO-PROCESSOR
SENSOR INTERFACE
156
164
128
MEMORY
TELEMETRY
186
166
GRADIENT FIELD SENSOR
ALARM

FIG. 2

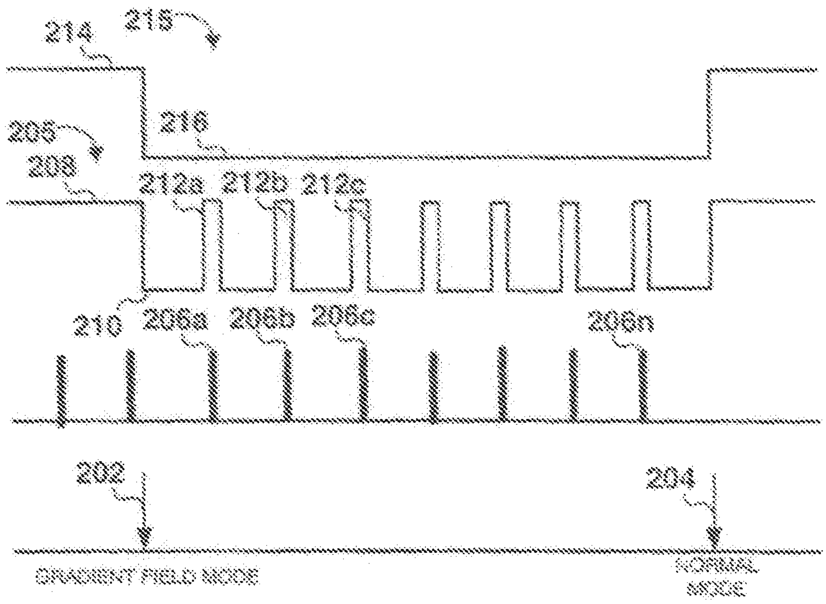
214
215
216
205
208
212a
212b
212c
210
206a
206b
206c
206n
202
204
GRADIENT FIELD MODE
NORMAL MODE

FIG. 3

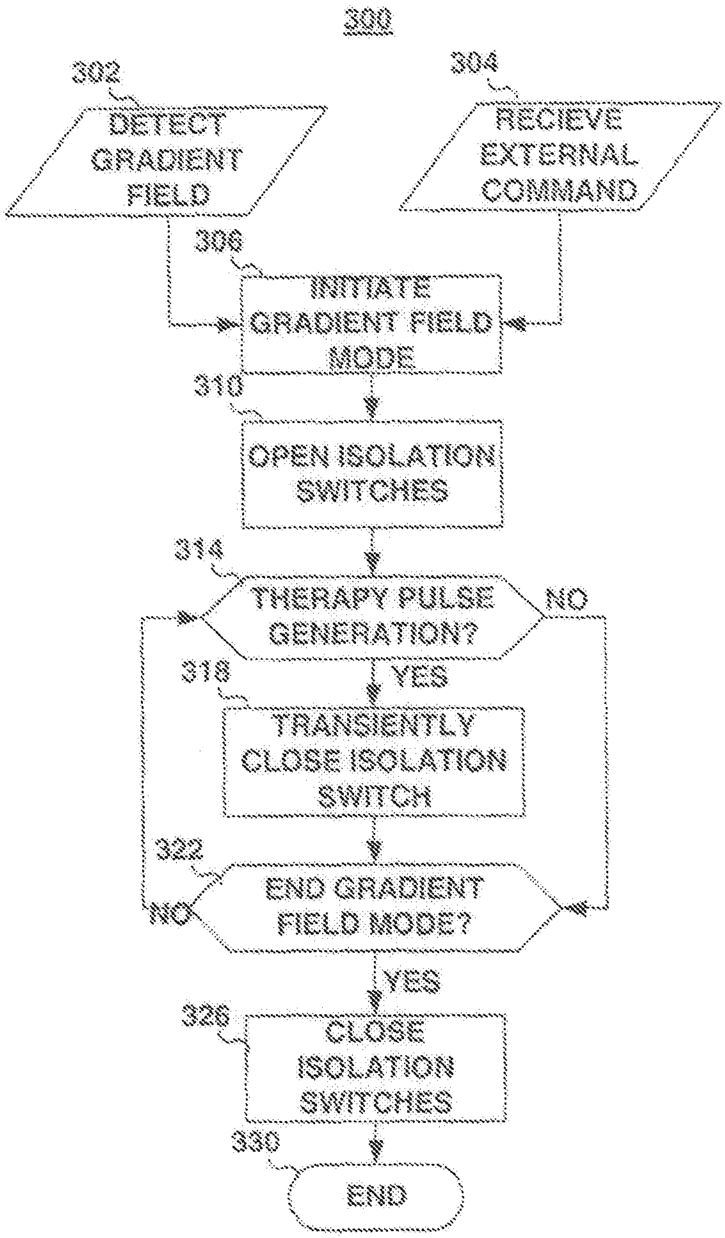
300
302
DETECT GRADIENT FIELD
304
RECIEVE EXTERNAL COMMAND
306
INITIATE GRADIENT FIELD MODE
310
OPEN ISOLATION SWITCHES
314
THERAPY PULSE GENERATION?
NO
YES
318
TRANSIENTLY CLOSE ISOLATION SWITCH
322
END GRADIENT FIELD MODE?
NO
YES
326
CLOSE ISOLATION SWITCHES
330
END

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/067254

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/372
ADD. A61N1/37

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)
A61N

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)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 901 292 B2 (HRDLICKA GREGORY [US] ET AL HRDLICKA GREGORY ANTHONY [US] ET AL) 31 May 2005 (2005-05-31) column 4, line 66 - column 6, line 54; figures 6-8	1-20
X	US 2003/036776 A1 (FOSTER THOMAS H [US] ET AL) 20 February 2003 (2003-02-20) paragraphs [0041] - [0043], [0046], [0047], [0062], [0076], [0083]; figures 2a,b,5	1-20
X	US 6 198 972 B1 (HARTLAUB JEROME T [US] ET AL) 6 March 2001 (2001-03-06) the whole document	1-20

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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Date of the actual completion of the international search	Date of mailing of the international search report
23 August 2007	10/09/2007

Name and mailing address of the ISA/	Authorized officer
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/267233 A1 (GINGGEN ALEC [CH]) 30 December 2004 (2004-12-30) paragraphs [0027], [0029]; figure 1	1-4,6,7
X	US 2004/088012 A1 (KROLL MARK W [US] ET AL) 6 May 2004 (2004-05-06) paragraphs [0013], [0014]	1,8,14
X	US 2006/064149 A1 (BELACAZAR HUGO A [US] ET AL) 23 March 2006 (2006-03-23) paragraphs [0059], [0060]	1,5,8, 13,14,20

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2007/067254

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
US 6901292	B2	31-05-2005	US	2002133204	A1	19-09-2002
US 2003036776	A1	20-02-2003	US	2002038135	A1	28-03-2002
US 6198972	B1	06-03-2001	US	6209764	B1	03-04-2001
US 2004267233	A1	30-12-2004	EP	1493460	A1	05-01-2005
			JP	2005021688	A	27-01-2005
US 2004088012	A1	06-05-2004	NONE			
US 2006064149	A1	23-03-2006	WO	2006036667	A1	06-04-2006