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(54) **IMPLANTABLE MEDICAL DEVICES AND RELATED METHODS**

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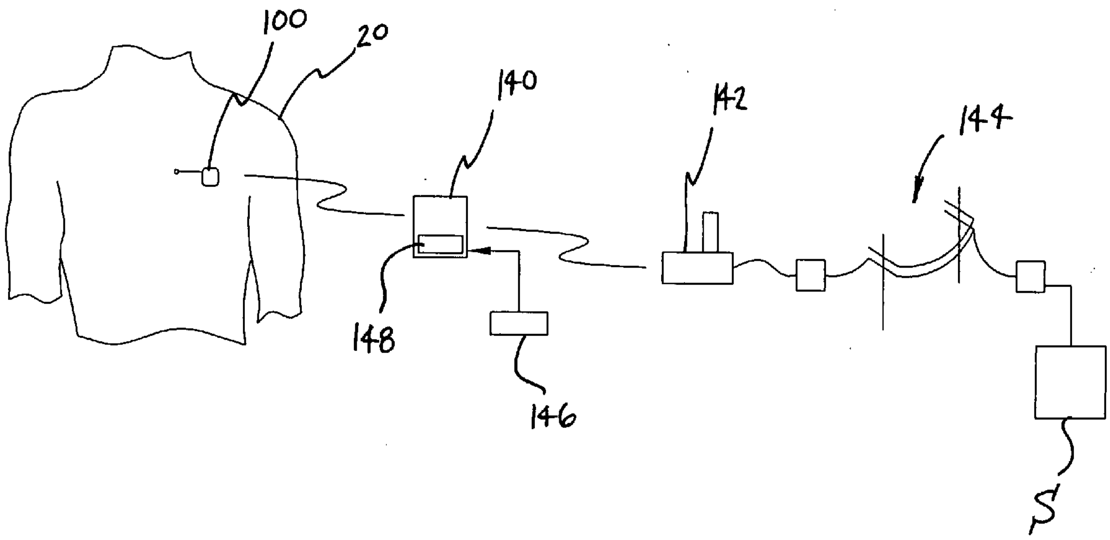
(57) **ABSTRACT**

Implantable medical devices and associated methods are disclosed. In one implementation, the implantable medical device comprises a conductive housing and a remote electrode that is mechanically coupled to the conductive housing by a lead body. An amplifier is electrically connected to the remote electrode and the conductive housing for providing a signal representative of a voltage difference between the remote electrode and the conductive housing. In some methods in accordance with the present invention, the implantable medical device is implanted in an implant site overlaying one half of a rib cage of a human body. The implantable medical device produces a signal representative of the voltage difference between the remote electrode and the conductive housing and the signal is transmitted to a receiver located outside the human body.



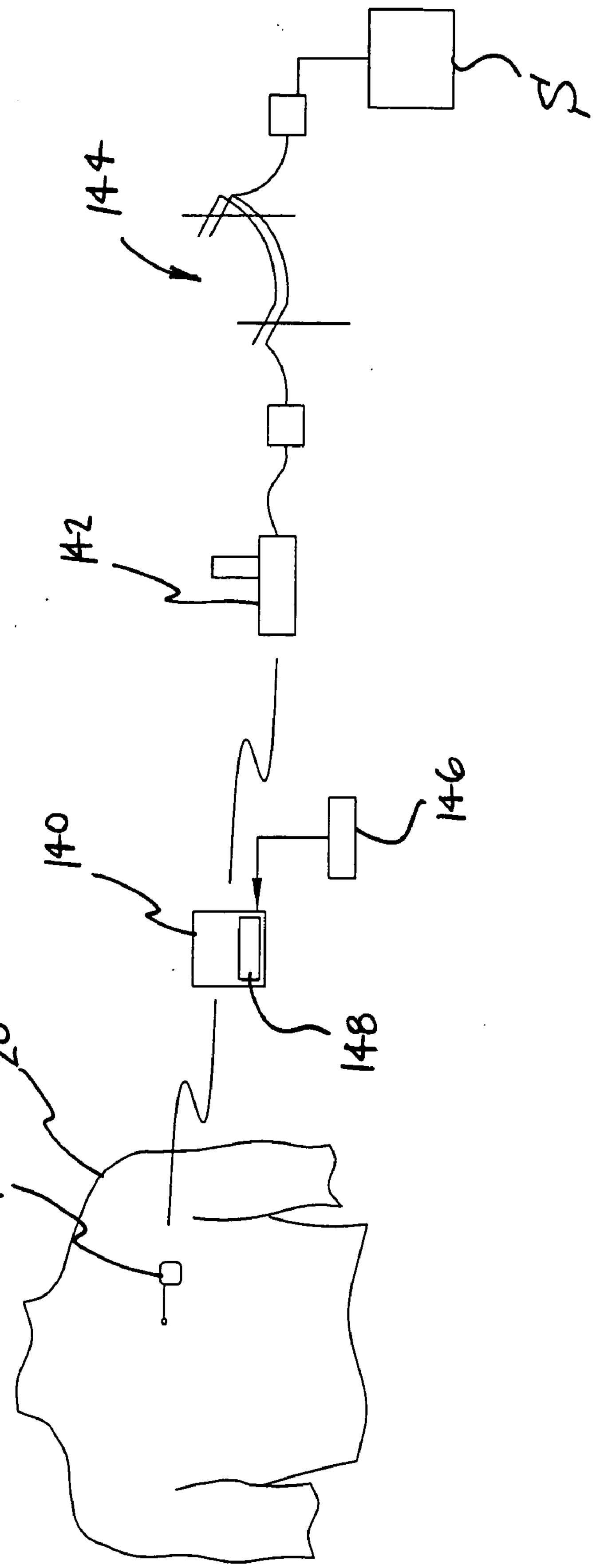
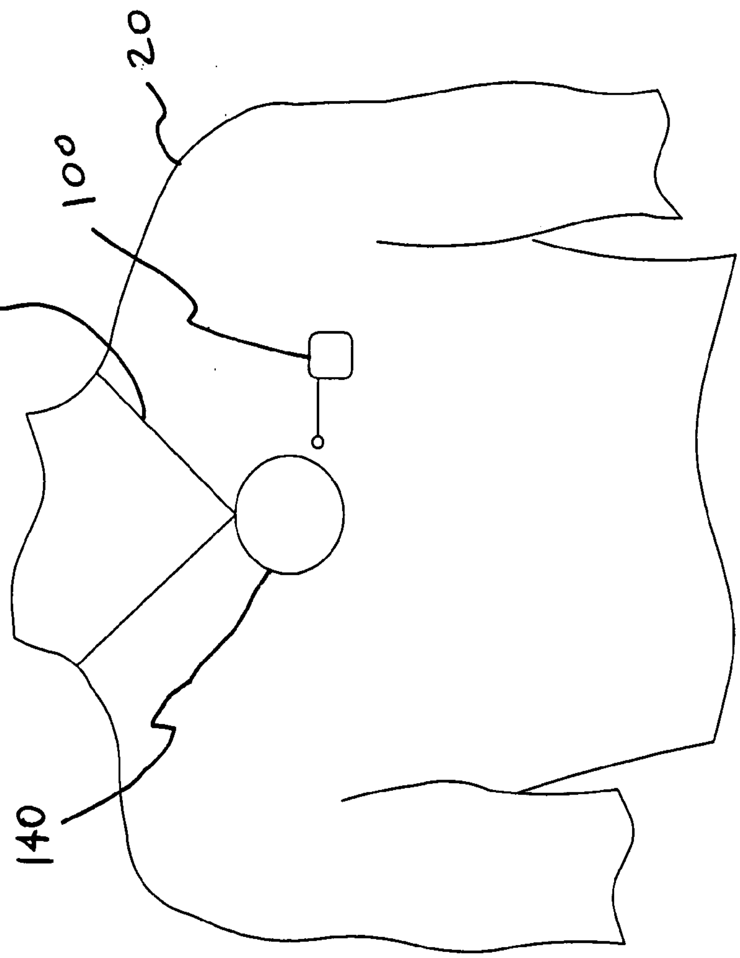


FIG. 1

FIG. 2



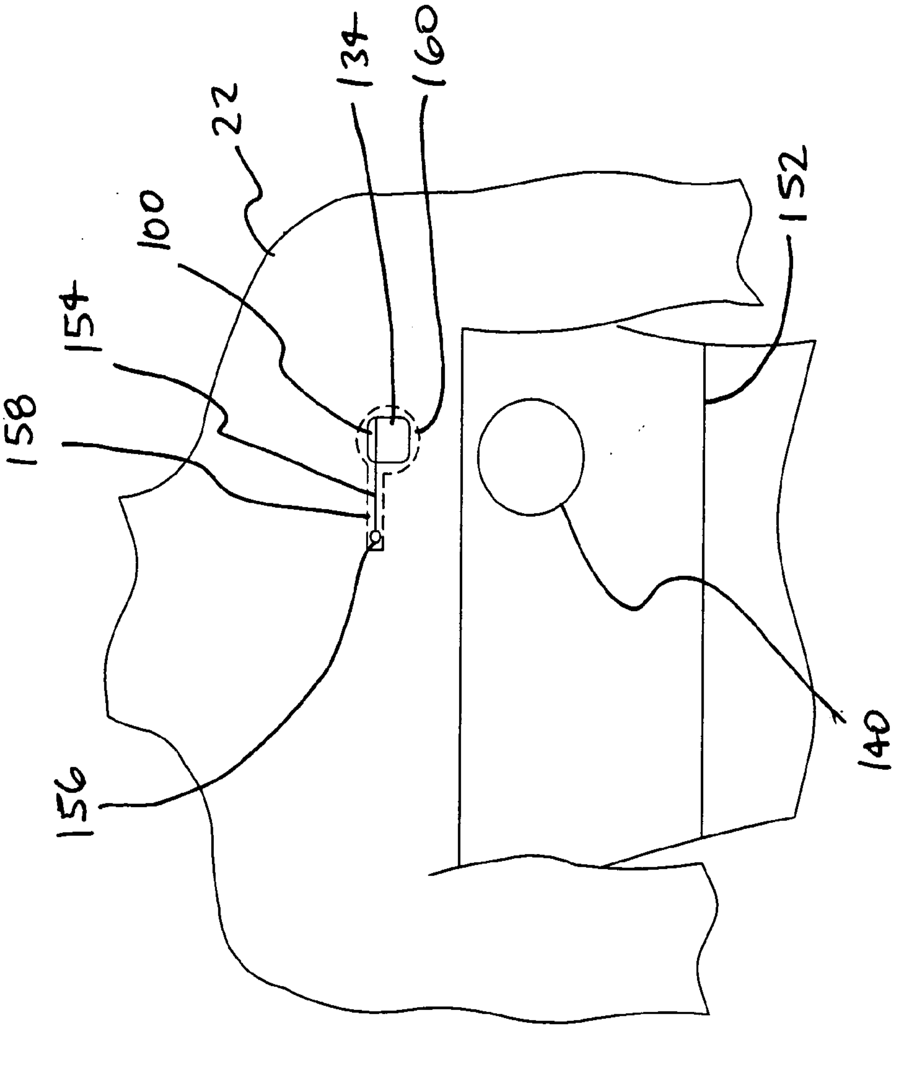


FIG. 3

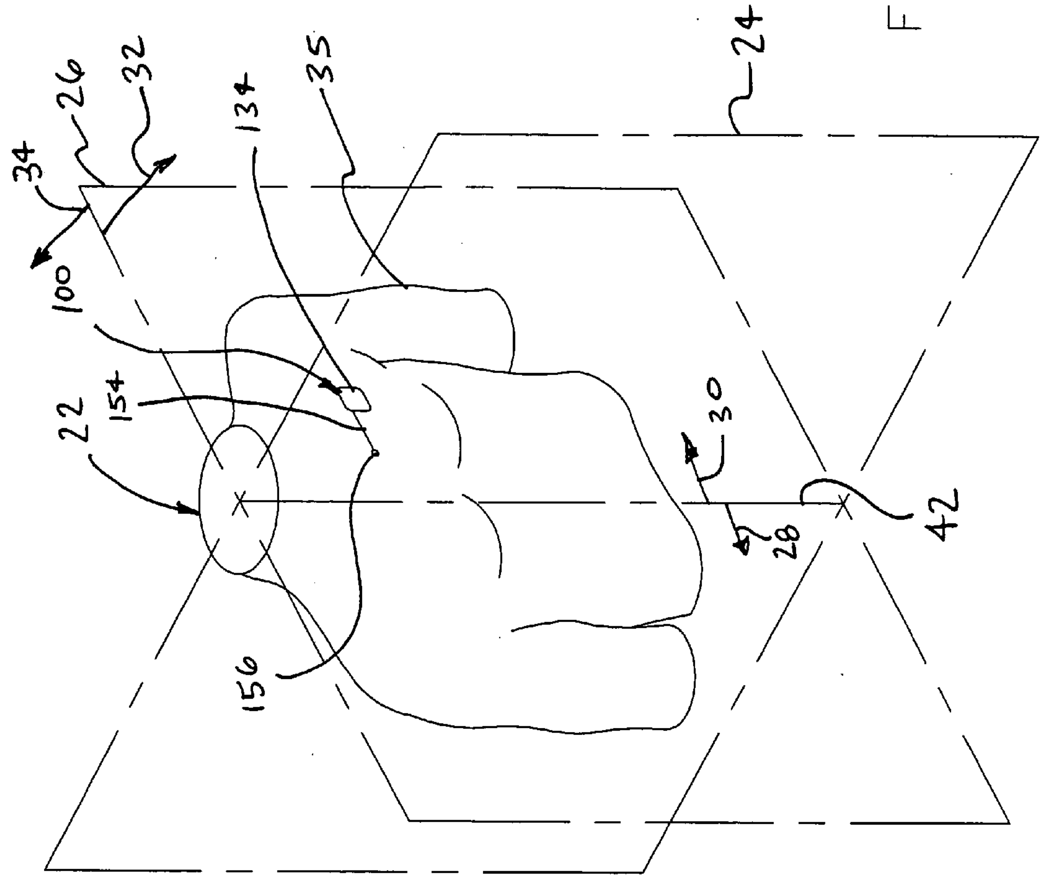


FIG. 4

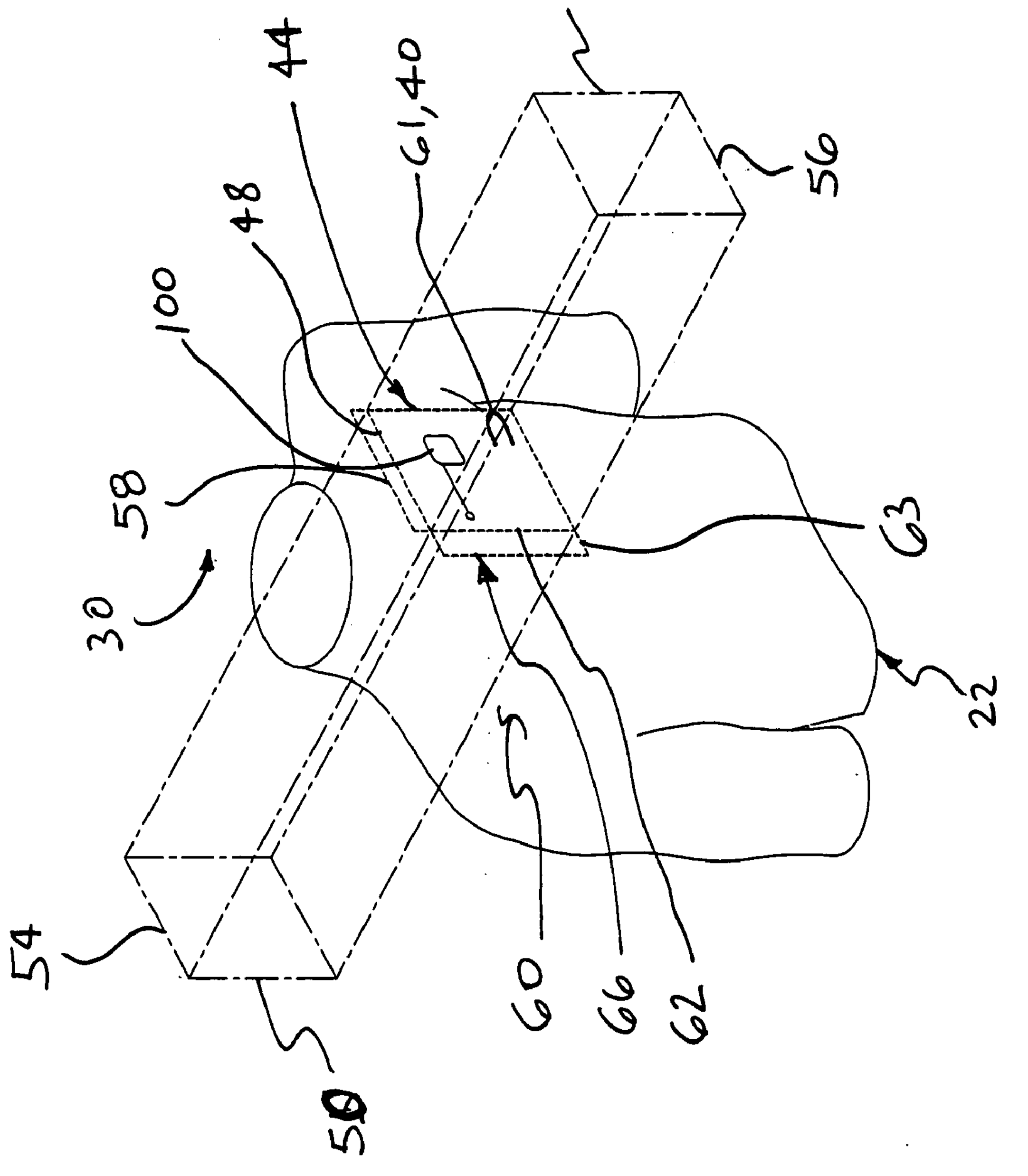
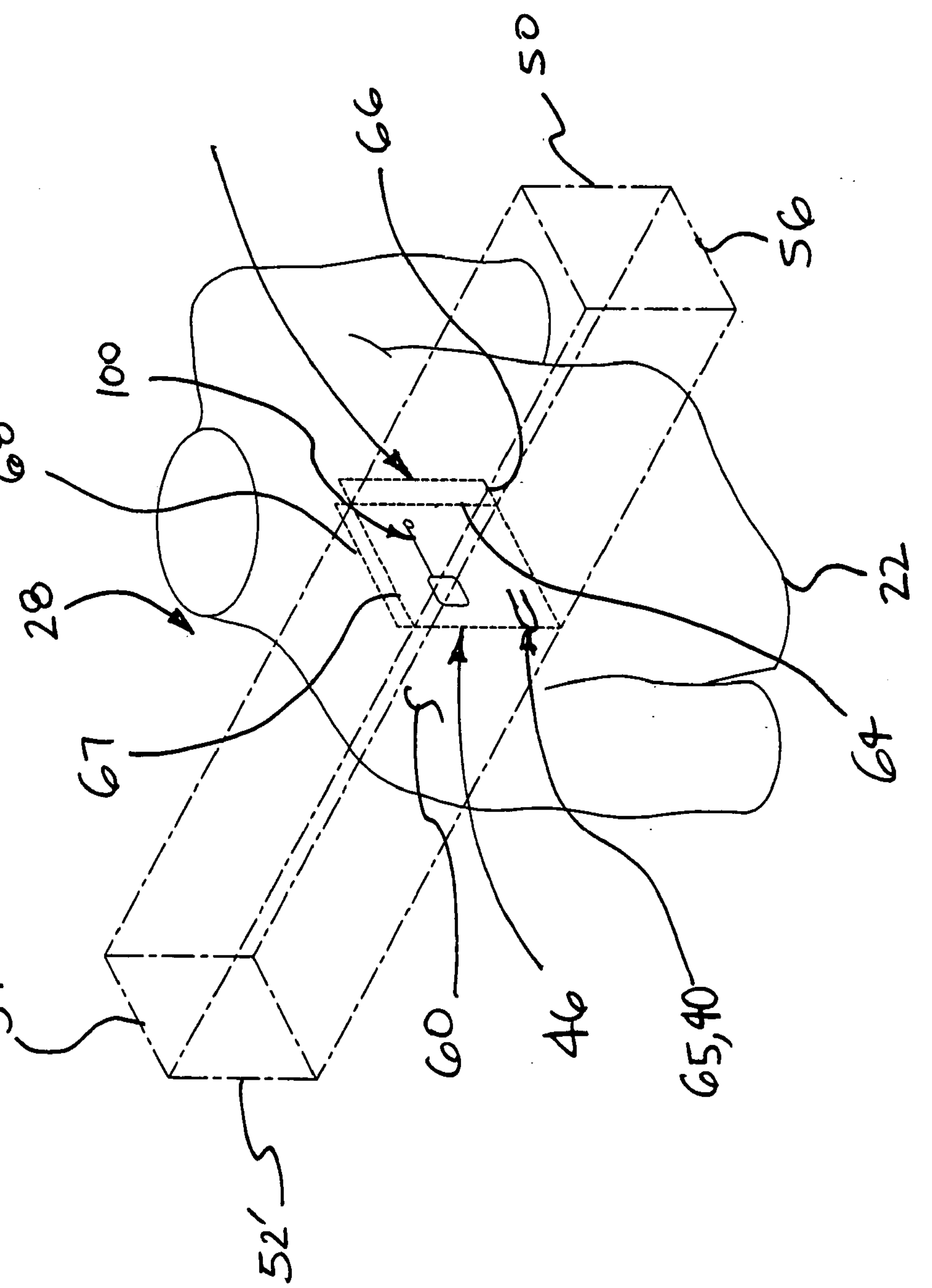


FIG. 5

FIG. 6



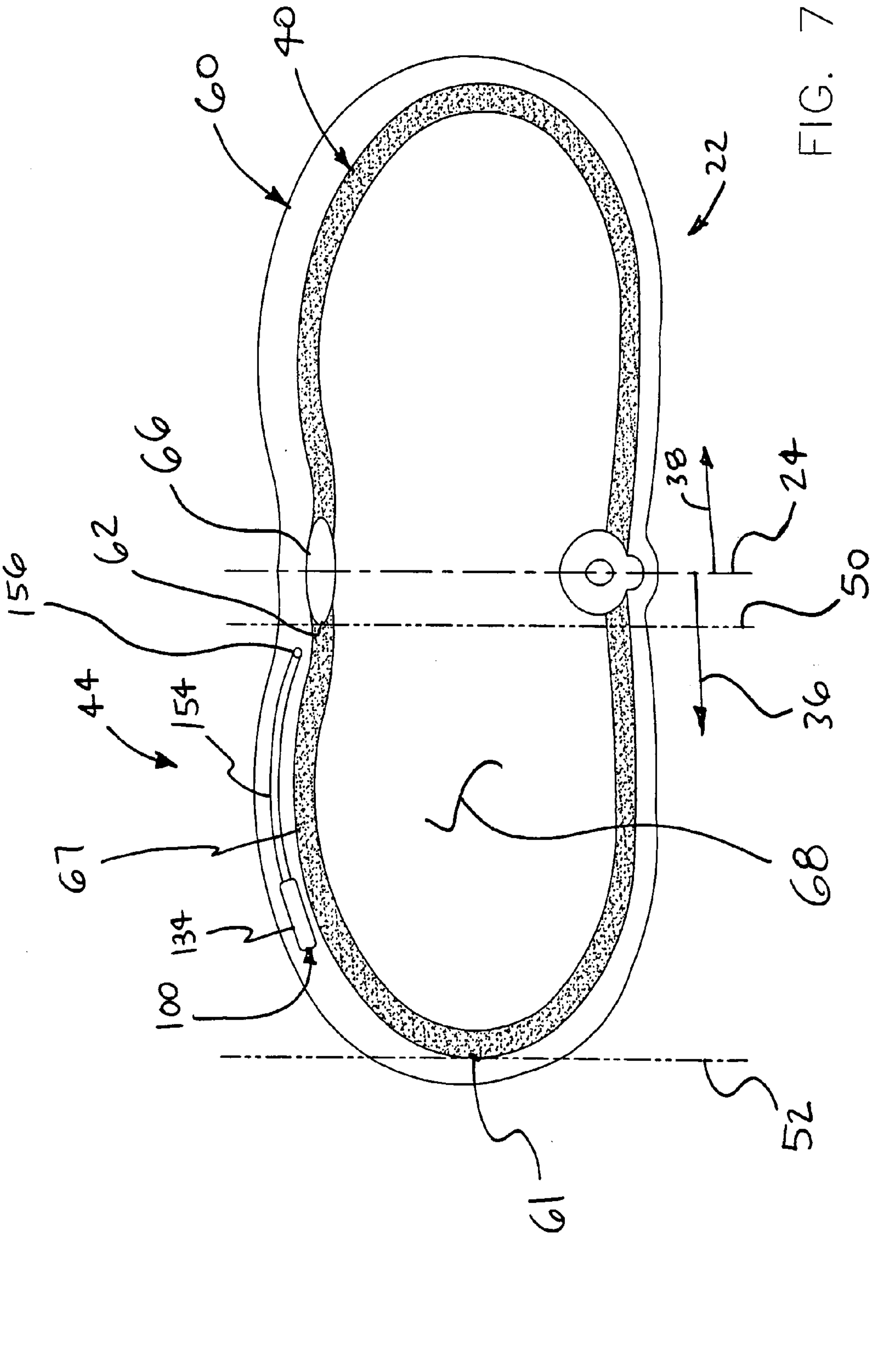


FIG. 7

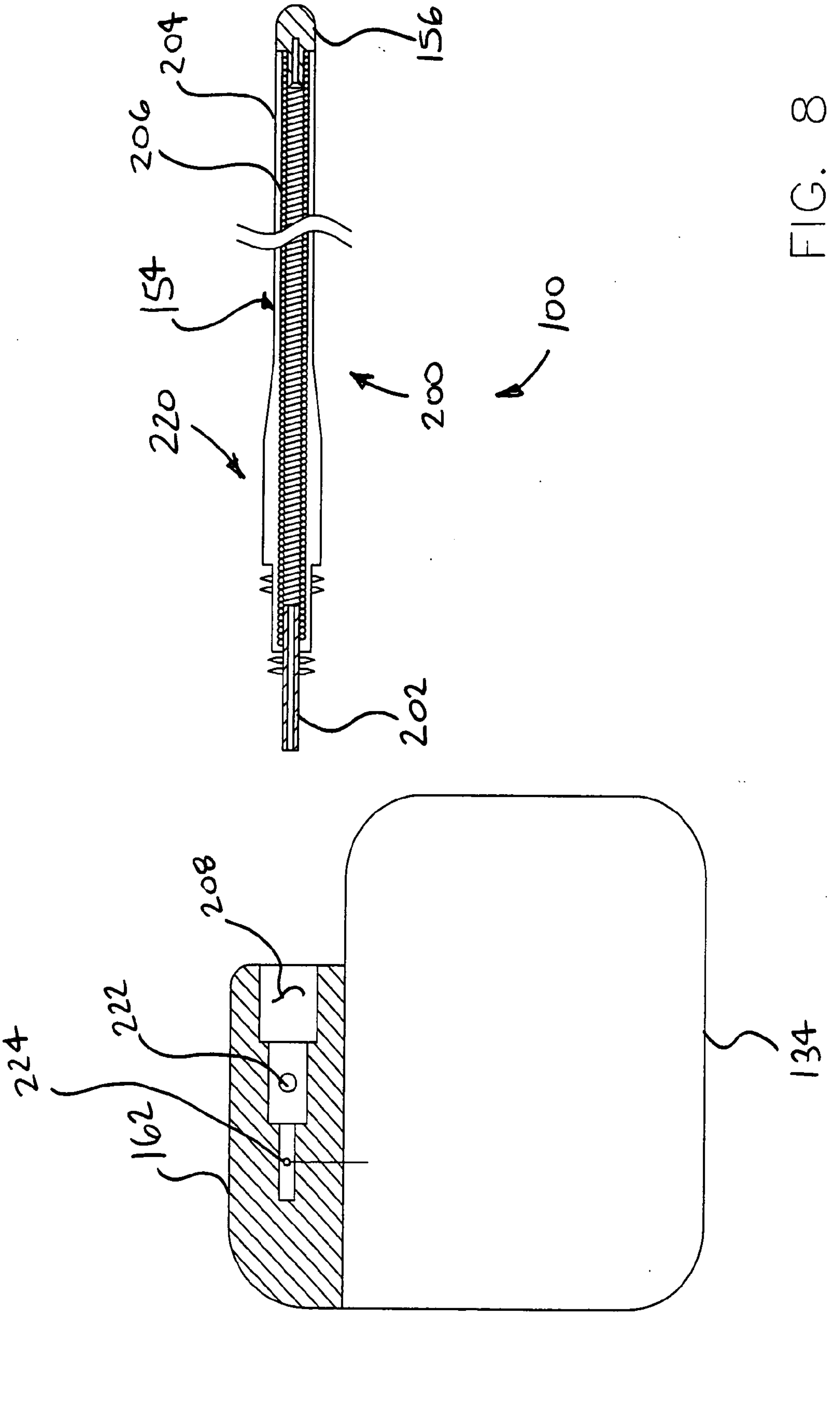


FIG. 8

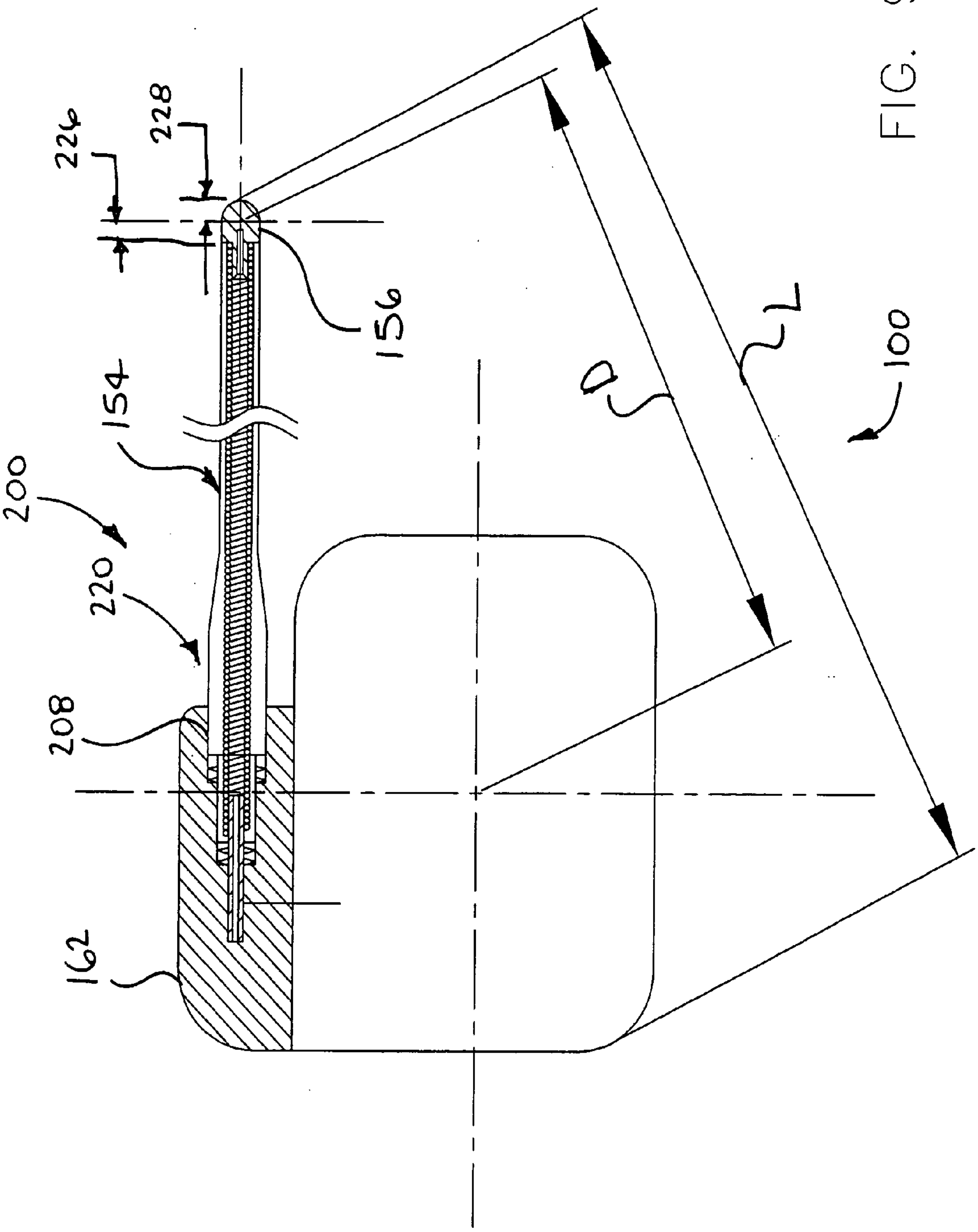


FIG. 9

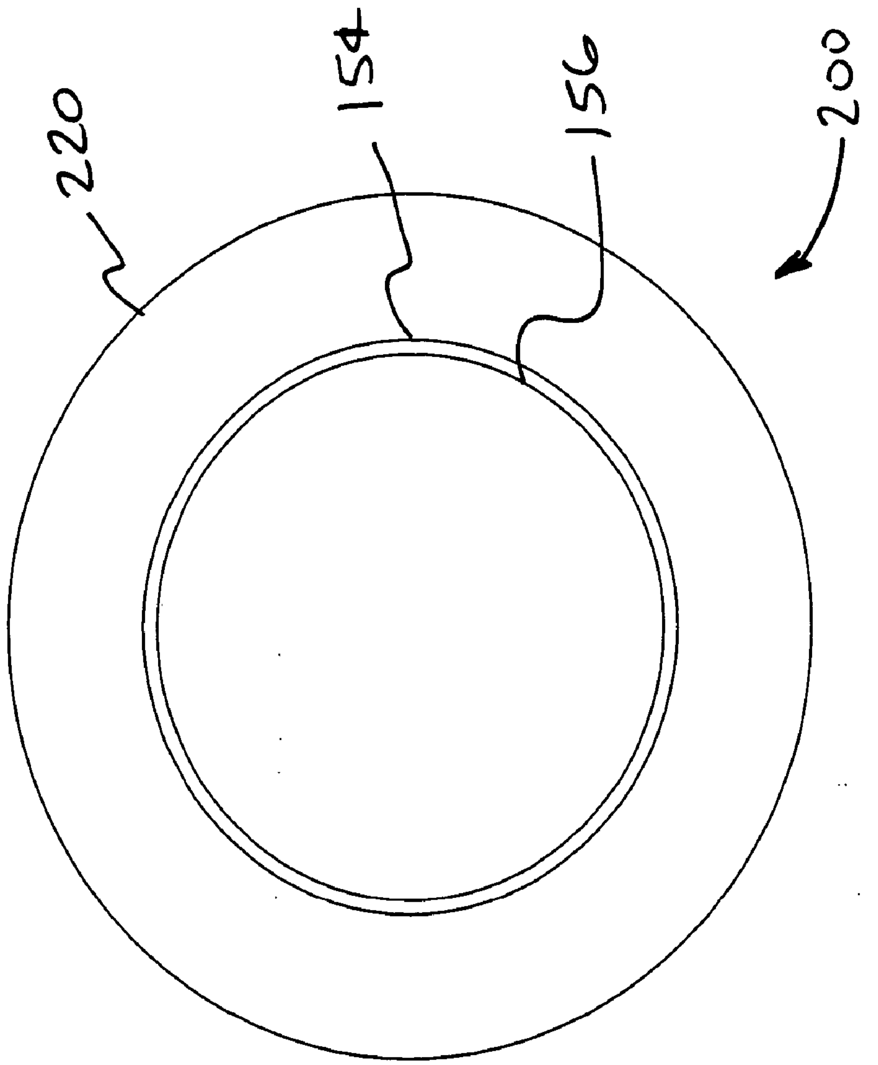


FIG. 10

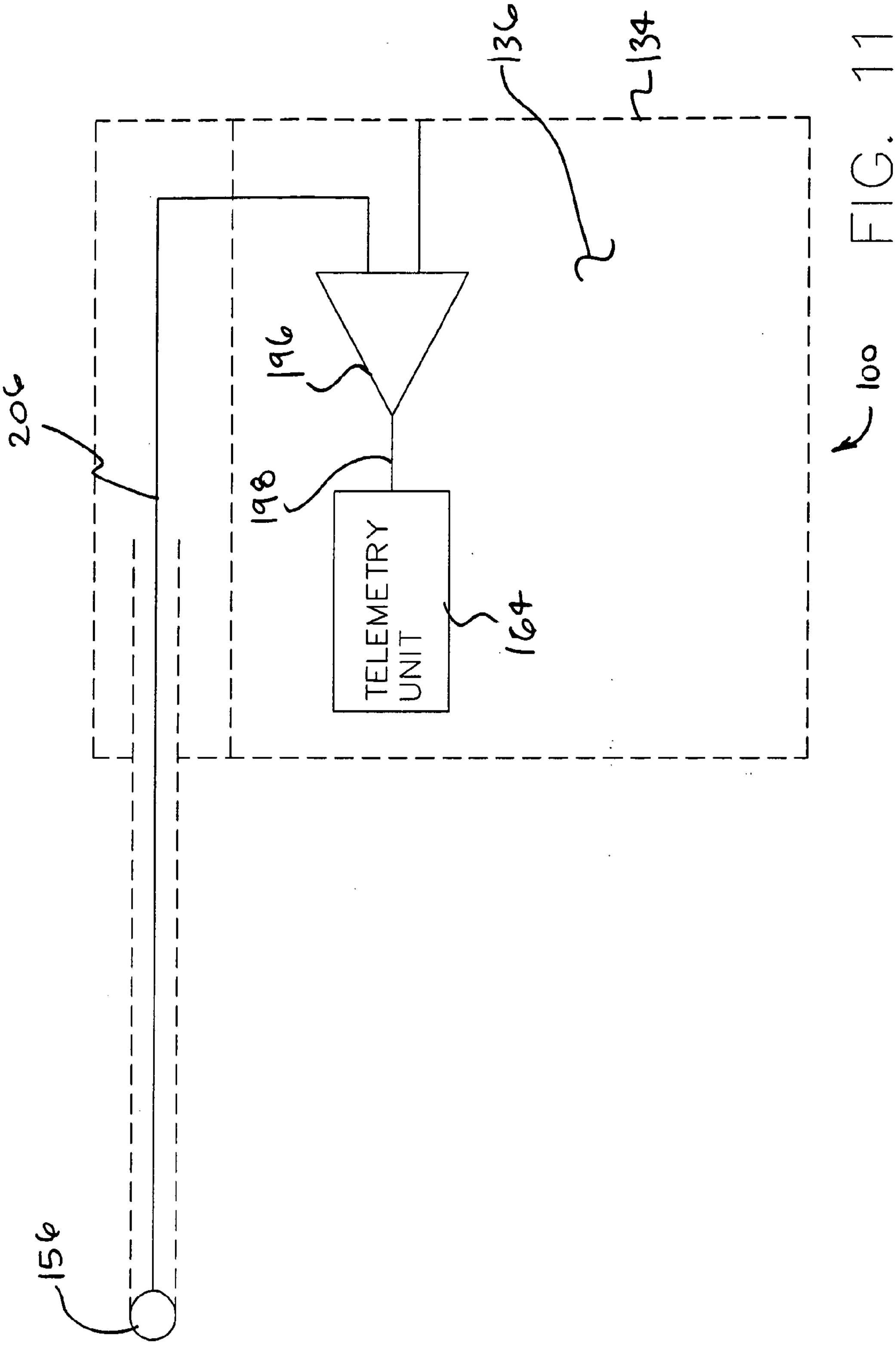


FIG. 11

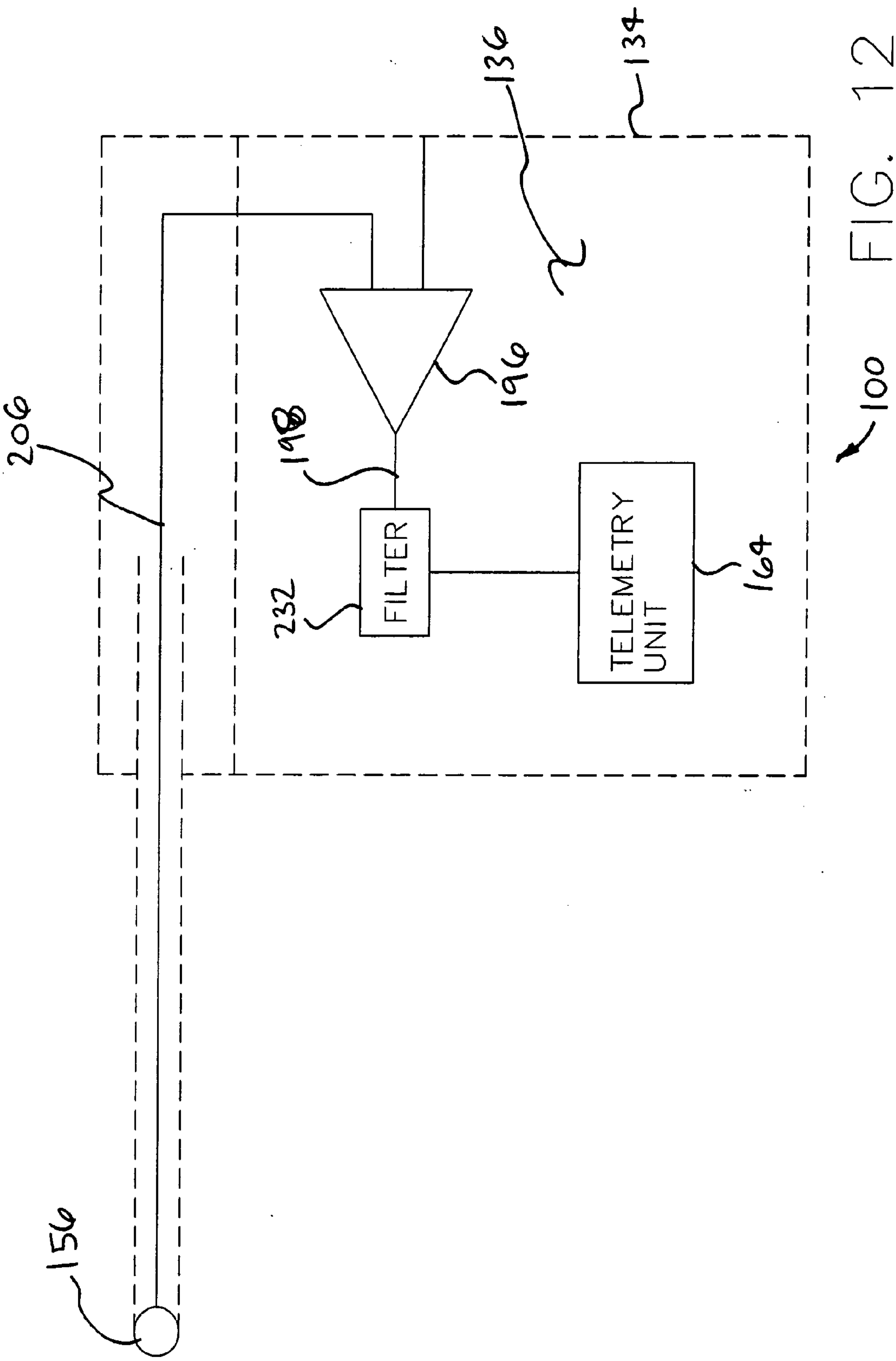


FIG. 12

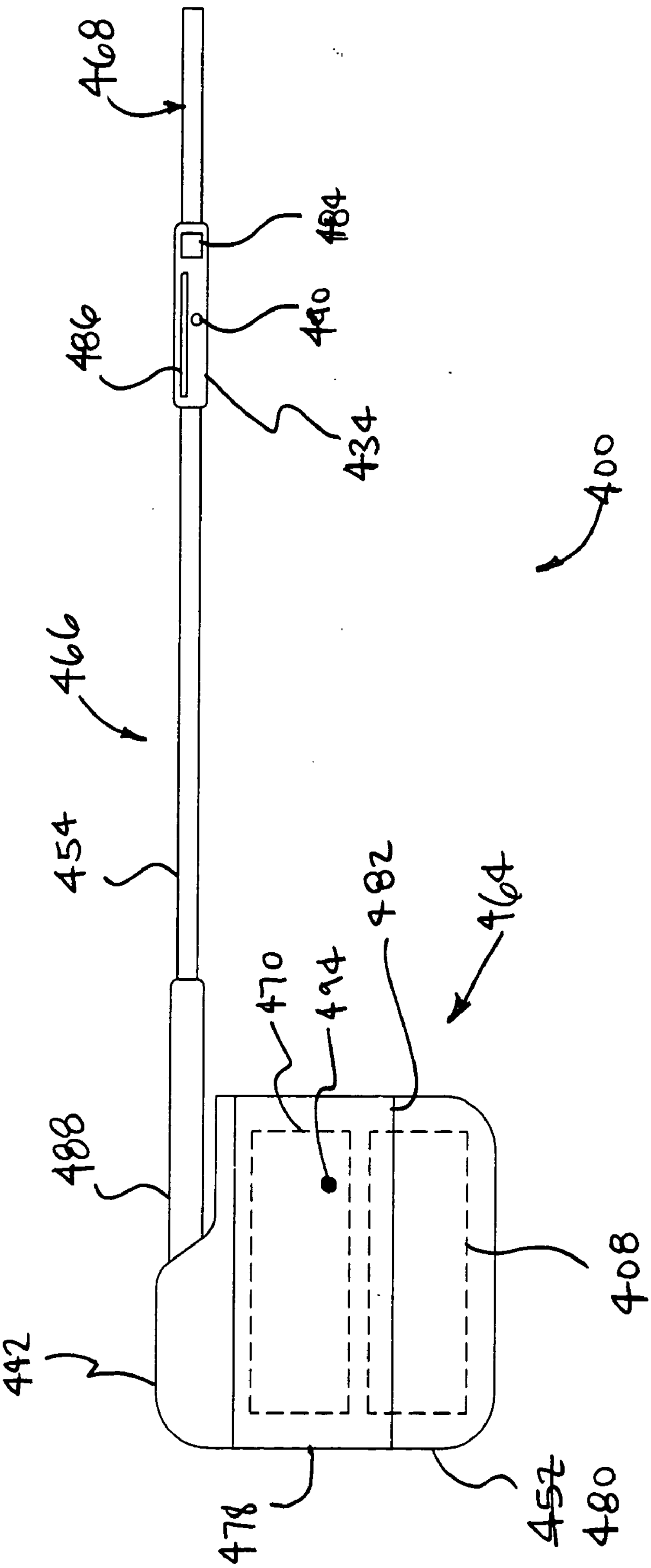

468
484
490
486
434
400
466
454
482
464
470
494
488
408
442
478
452
480

FIG. 13

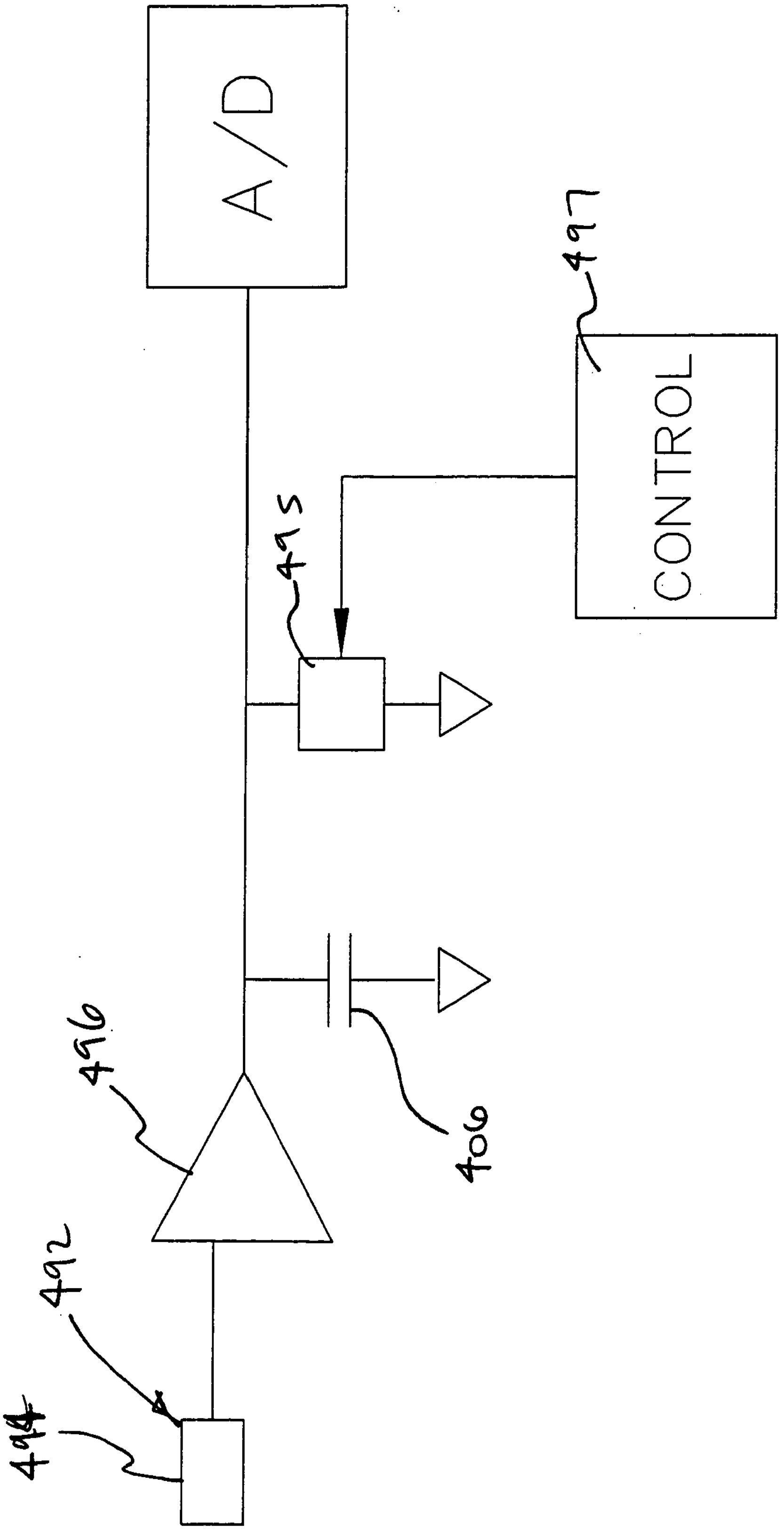


FIG. 14

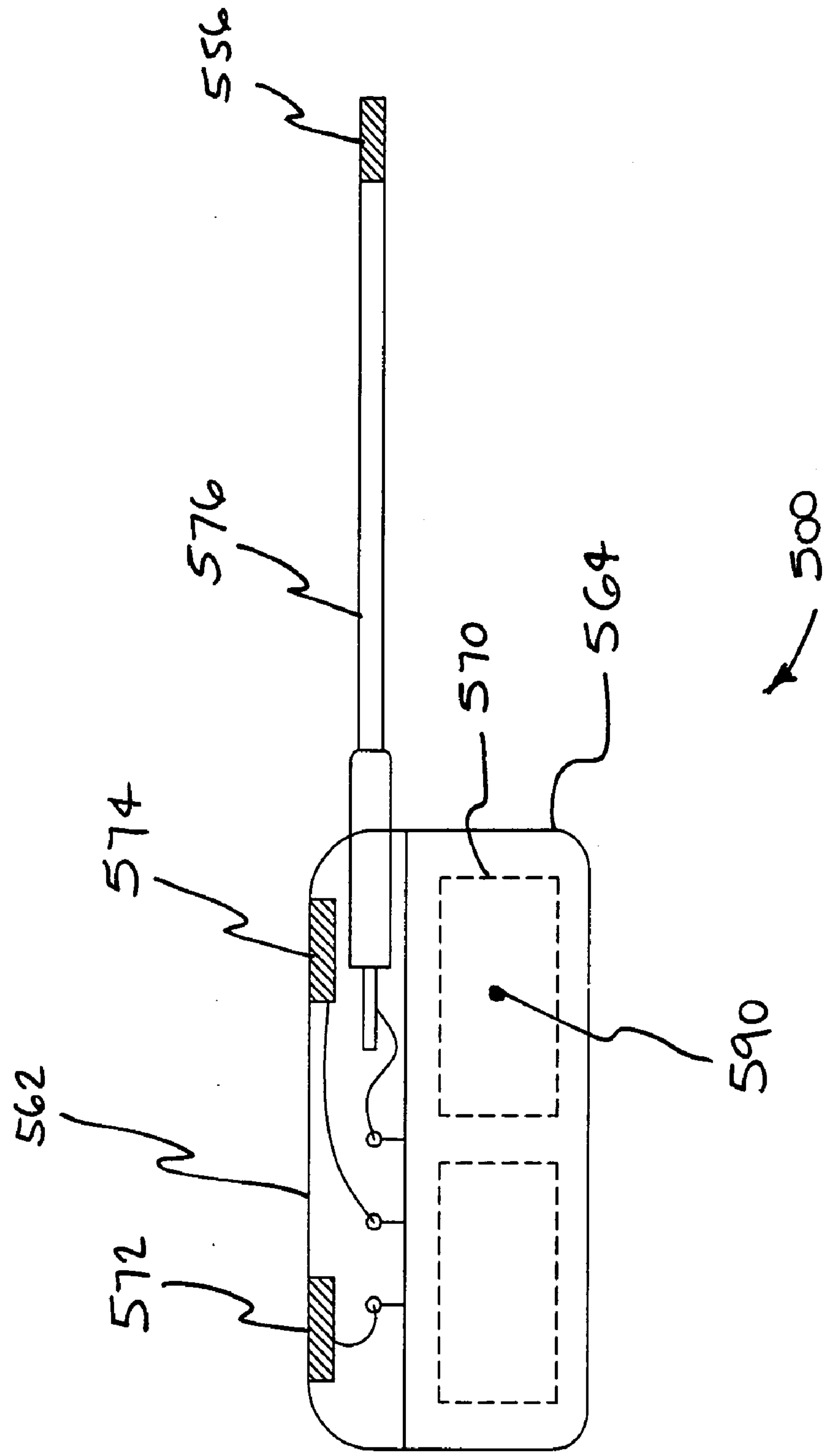


FIG. 15

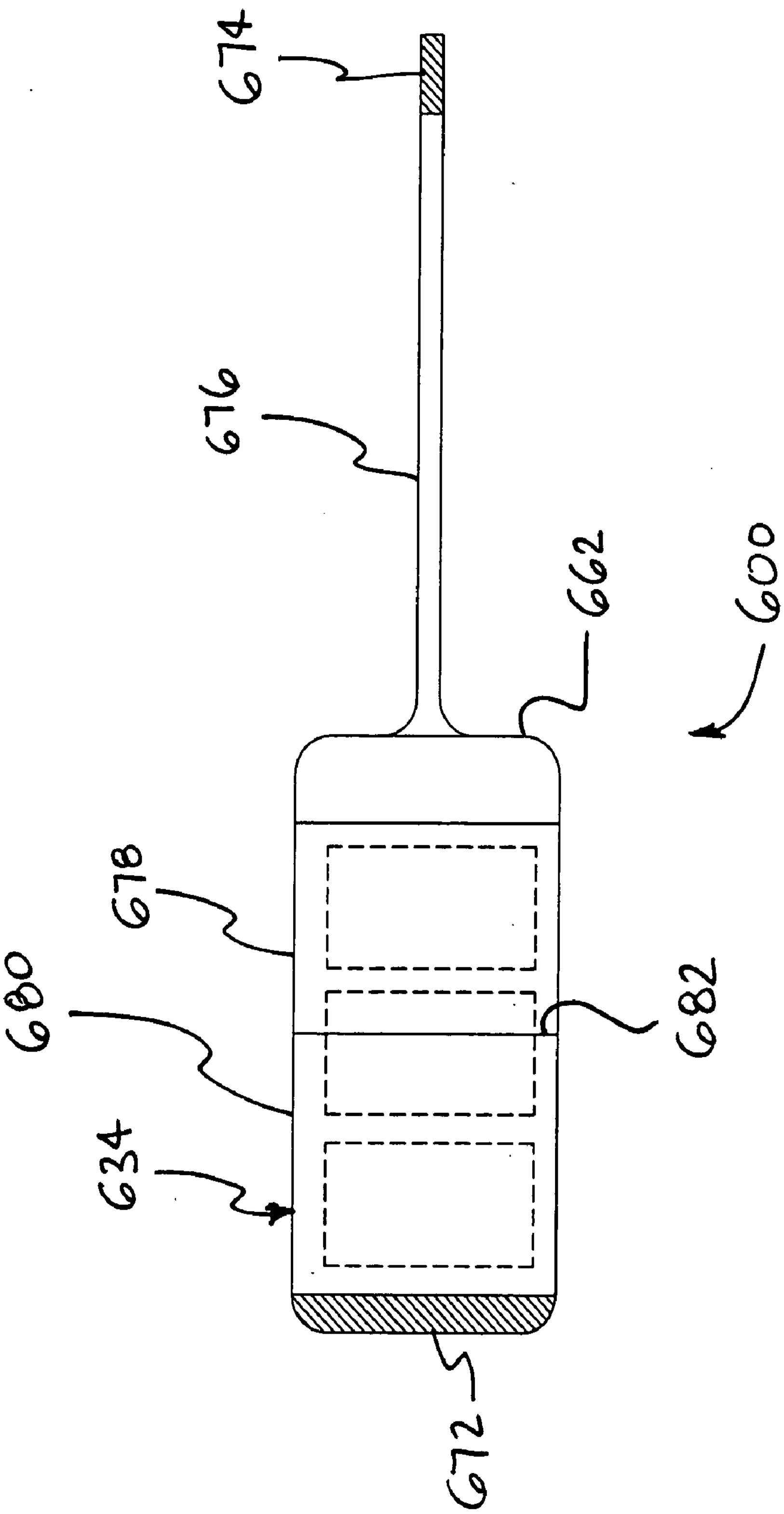


FIG. 16

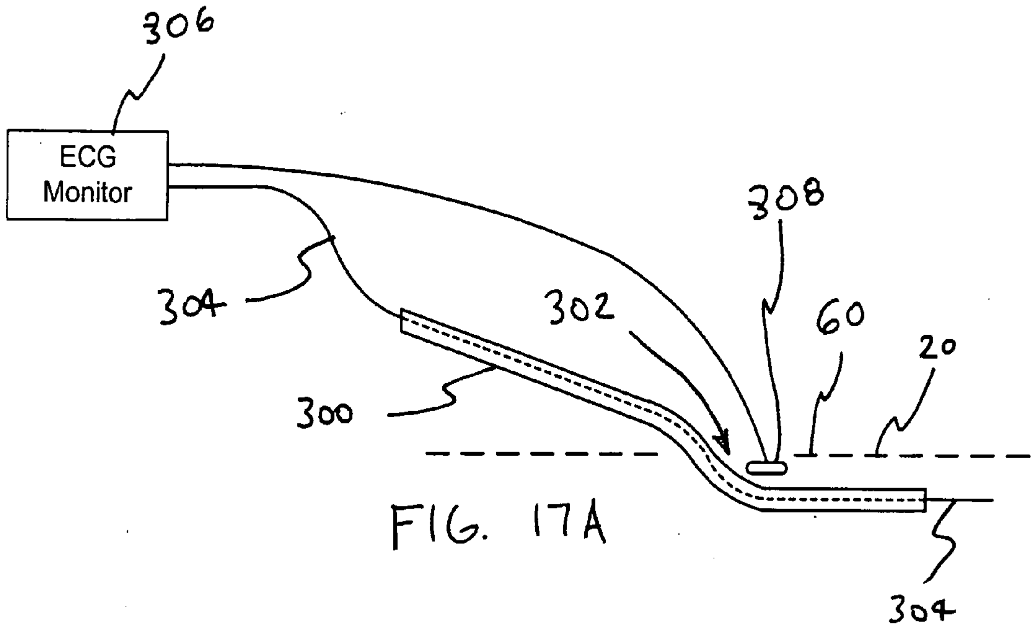


FIG. 17A

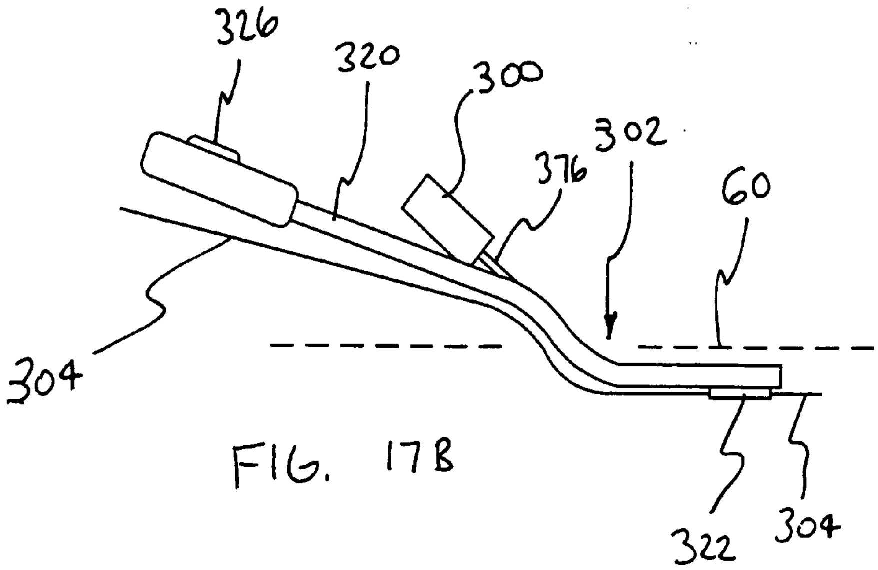


FIG. 17B

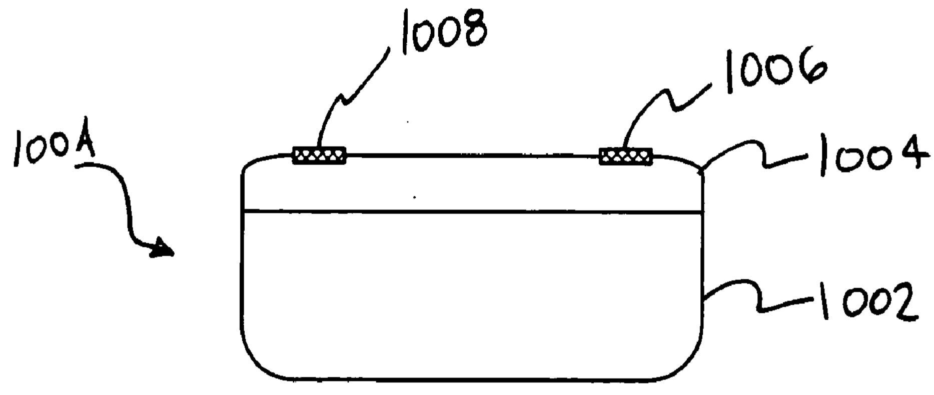


FIG. 18A

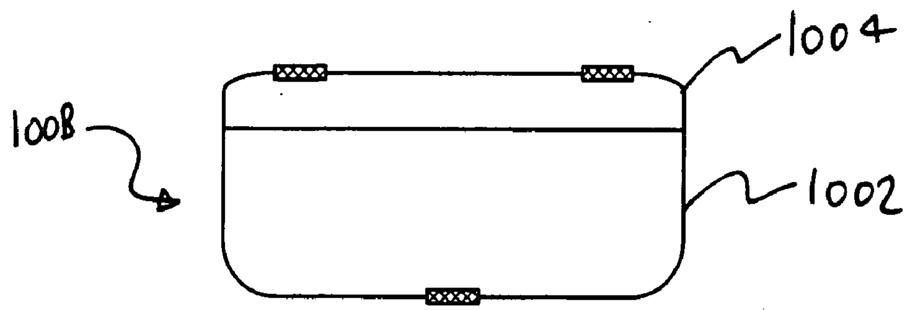


FIG. 18B

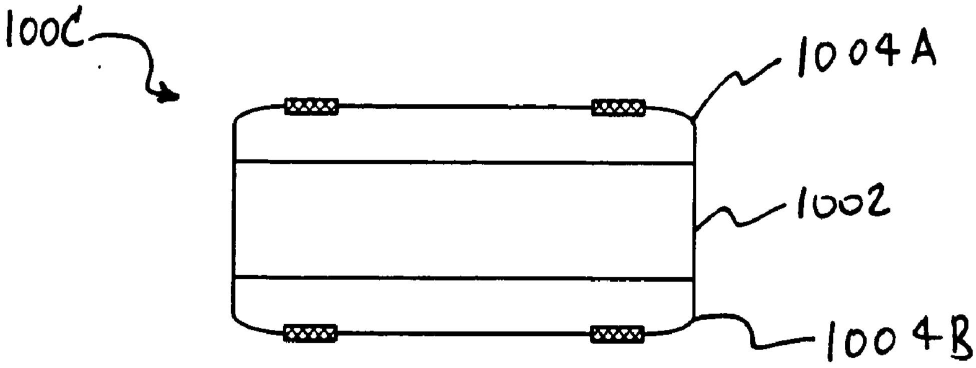


FIG. 18C

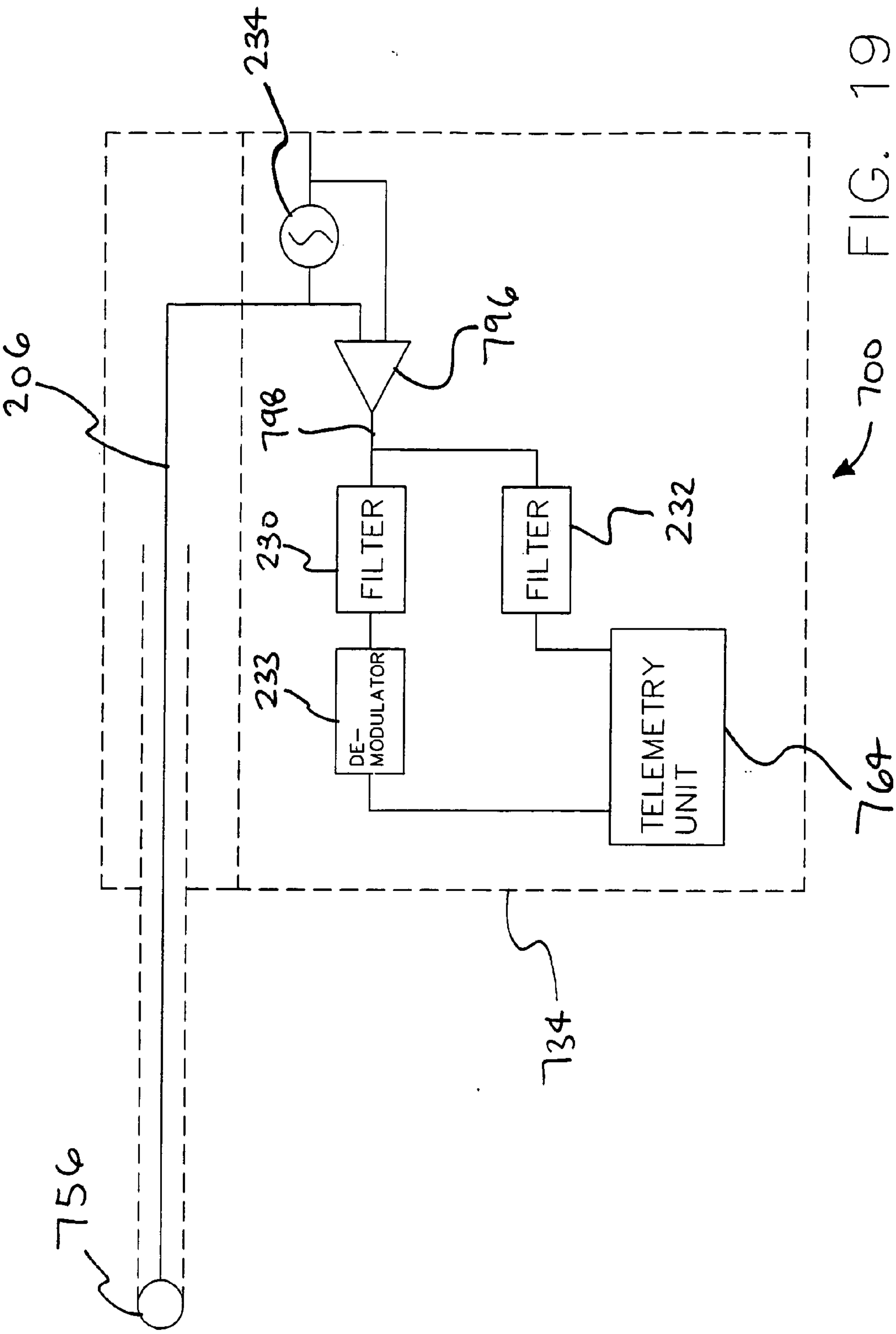

234
206
796
798
700
230
FILTER
FILTER
232
233
DE-
MODULATOR
TELEMETRY
UNIT
764
734
756

FIG. 19

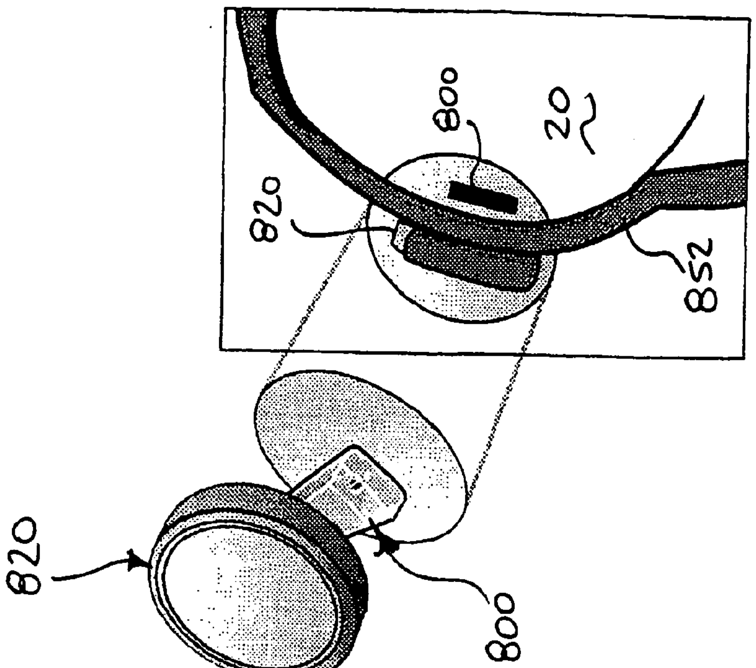


FIG. 20B

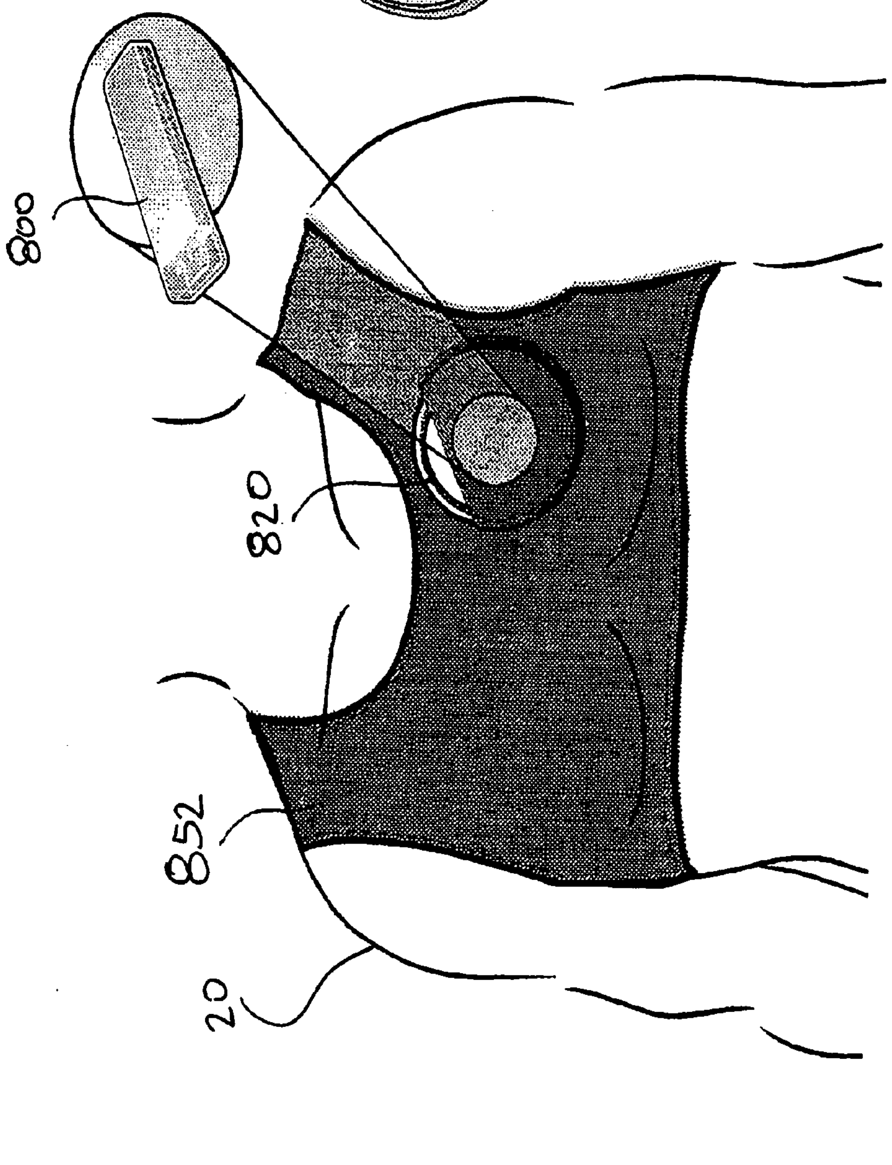


FIG. 20A

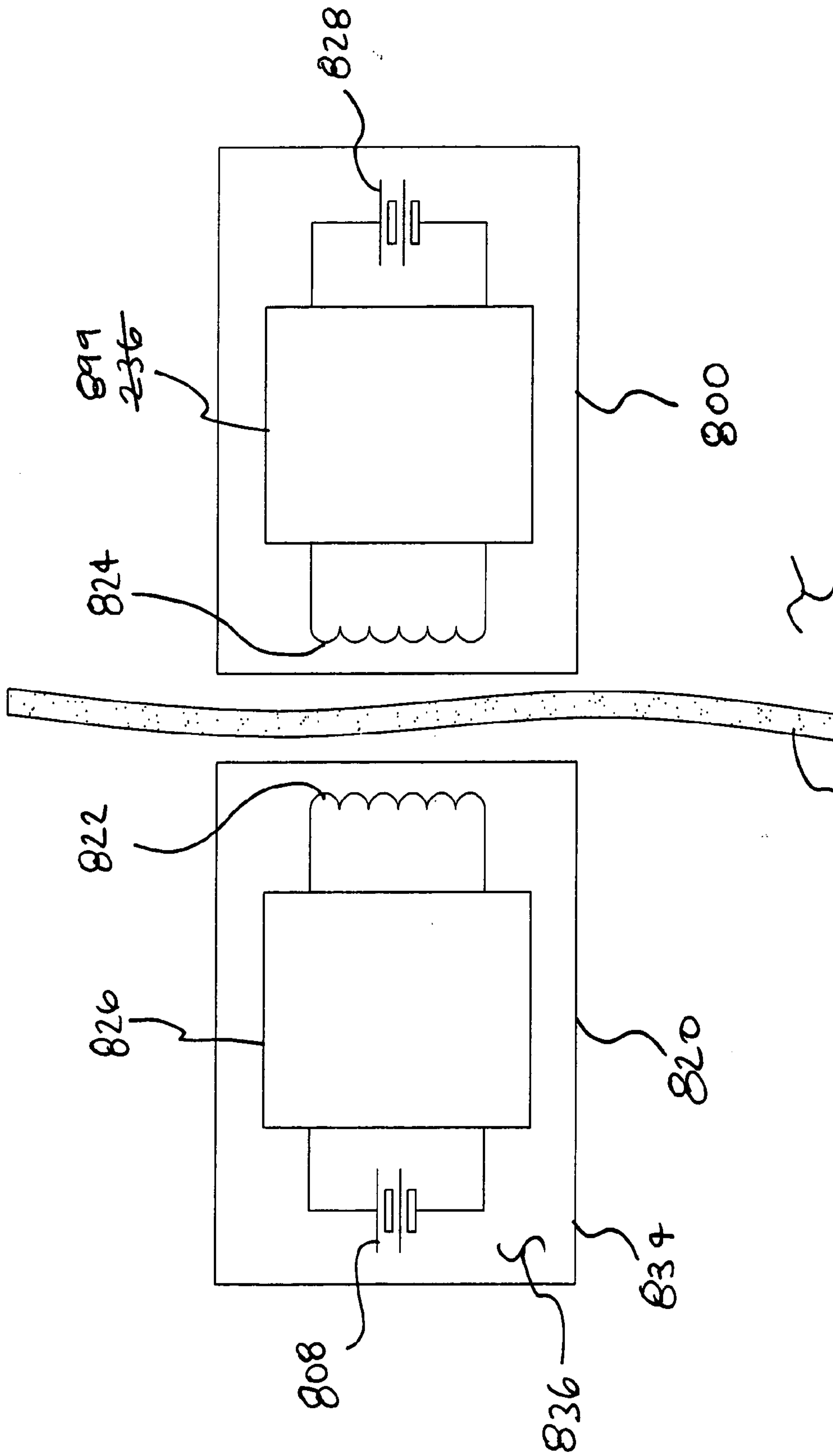


FIG. 21

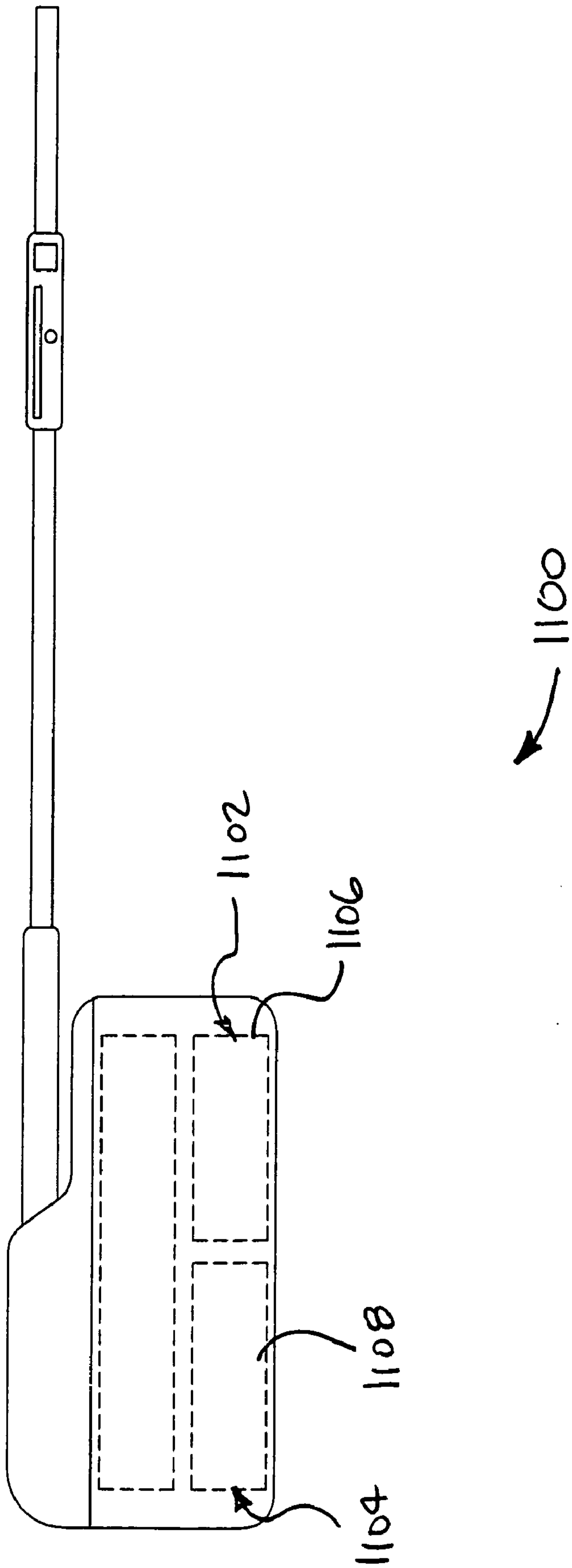
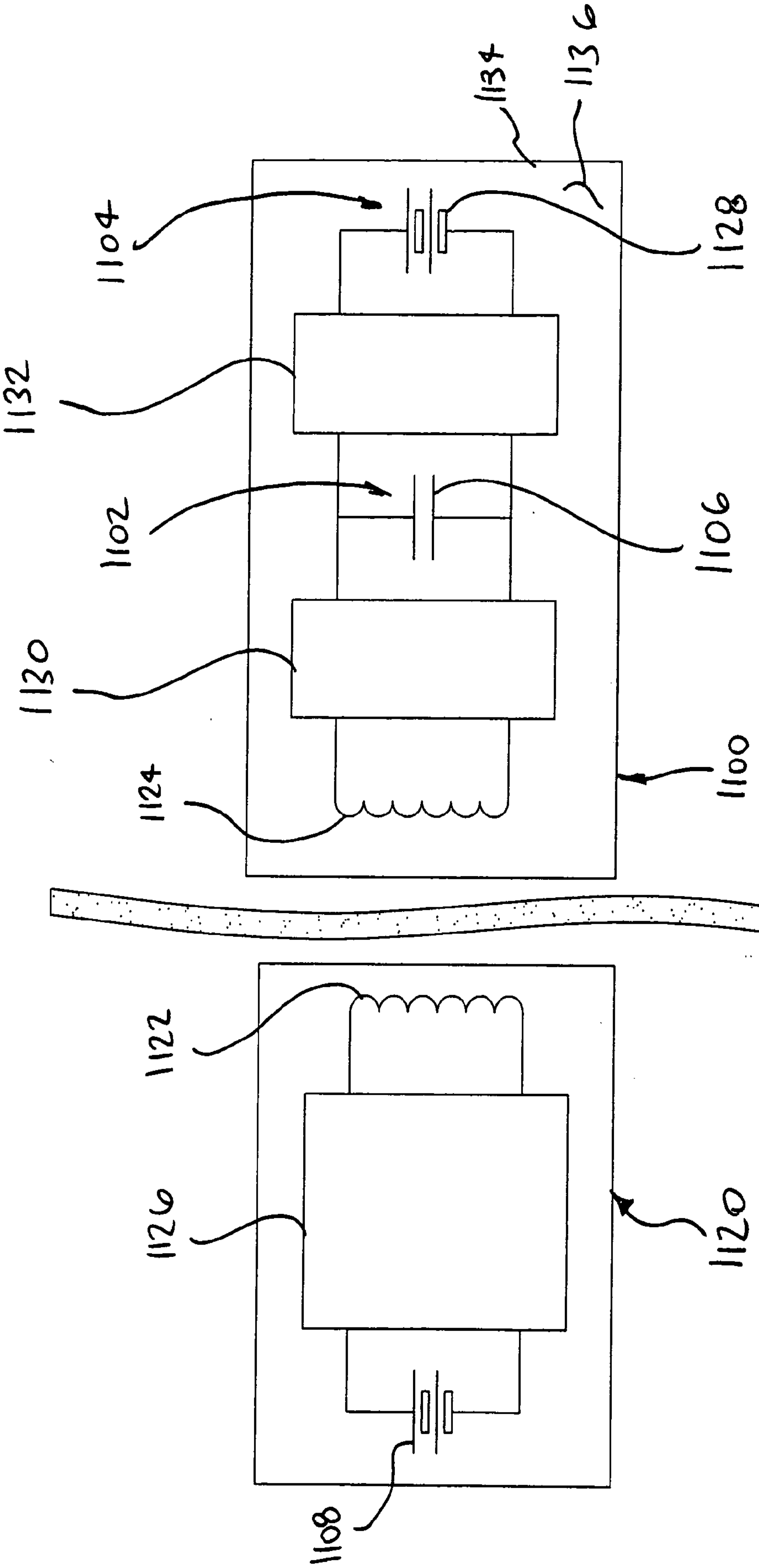


FIG. 22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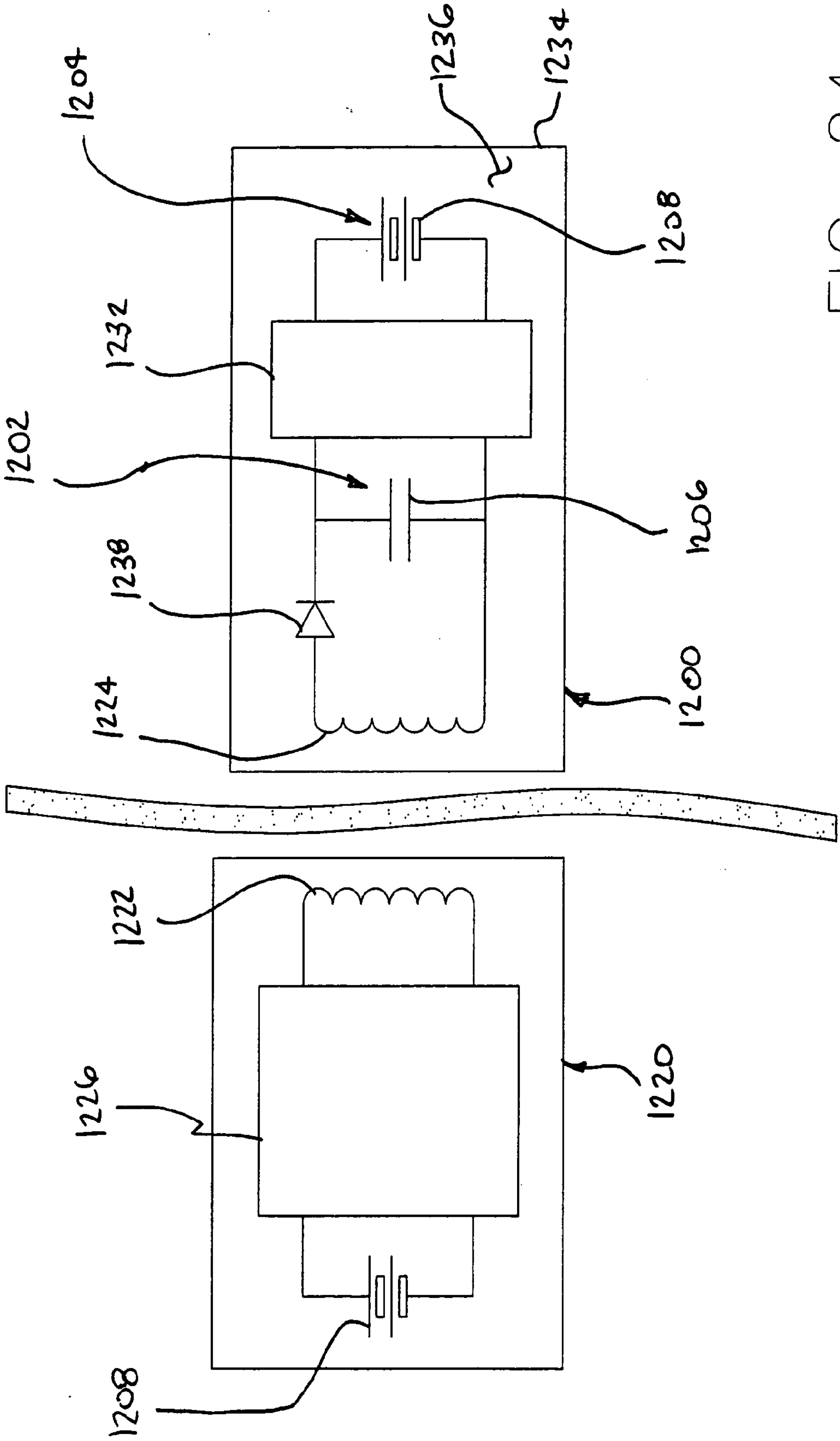
1108

FIG. 23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1234
1208
1232
1202
1206
1238
1200
1224
1222
1226
1220
1208

FIG. 24

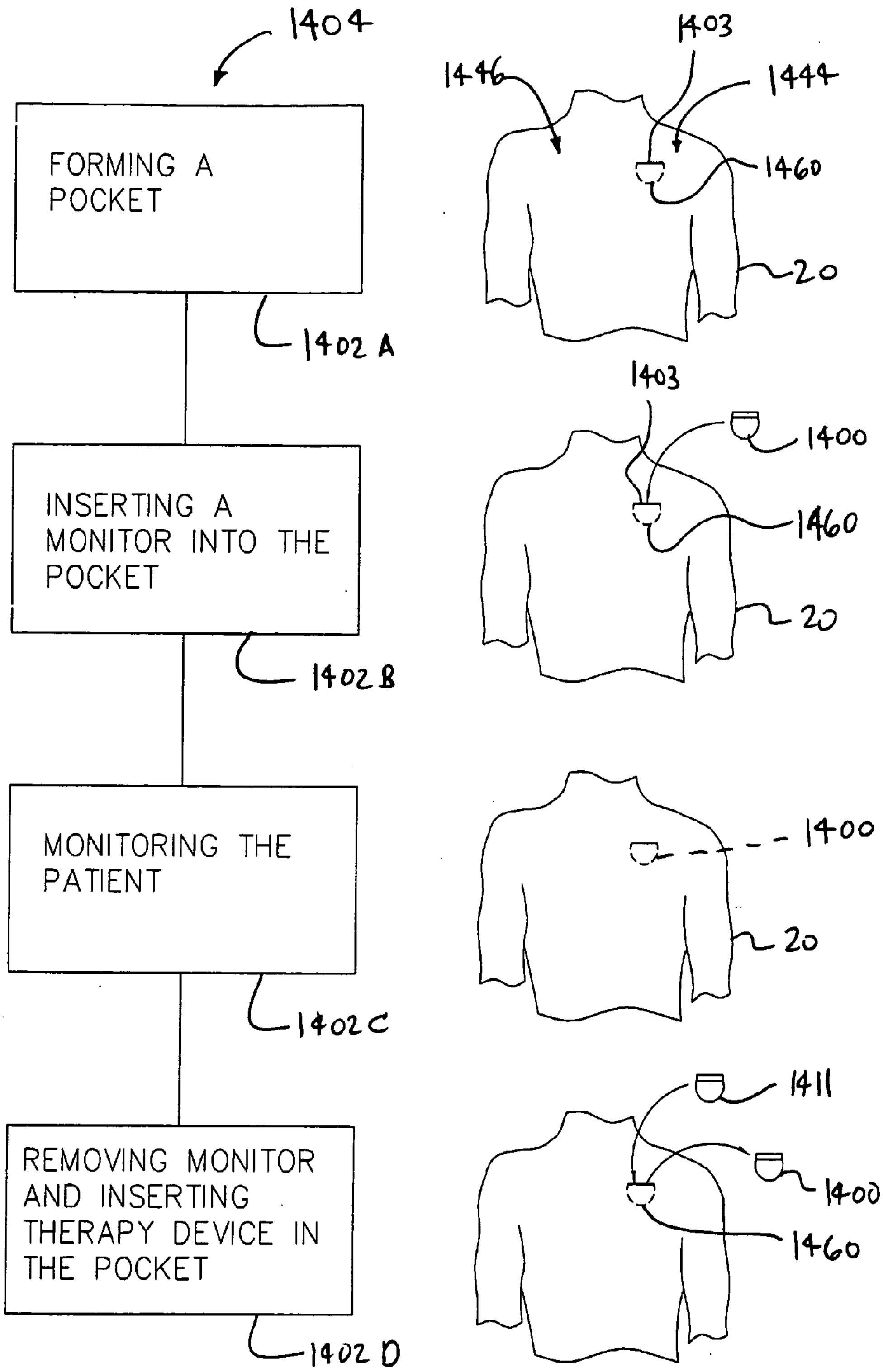
1404
FORMING A POCKET
1402 A
INSERTING A MONITOR INTO THE POCKET
1402 B
MONITORING THE PATIENT
1402C
REMOVING MONITOR AND INSERTING THERAPY DEVICE IN THE POCKET
1402 D
1403
1446
1444
1460
20
1403
1400
1460
20
1400
20
1411
1400
1460

FIG. 25

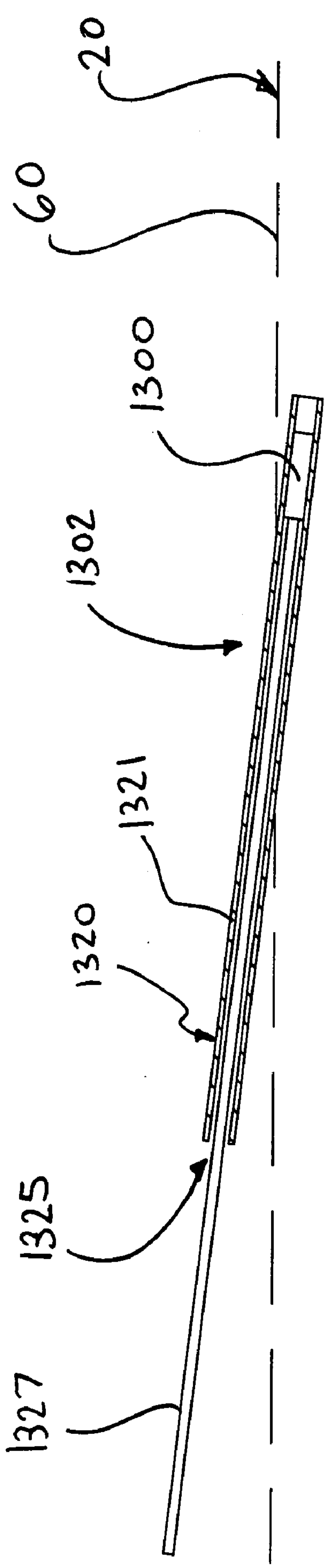

FIG. 26

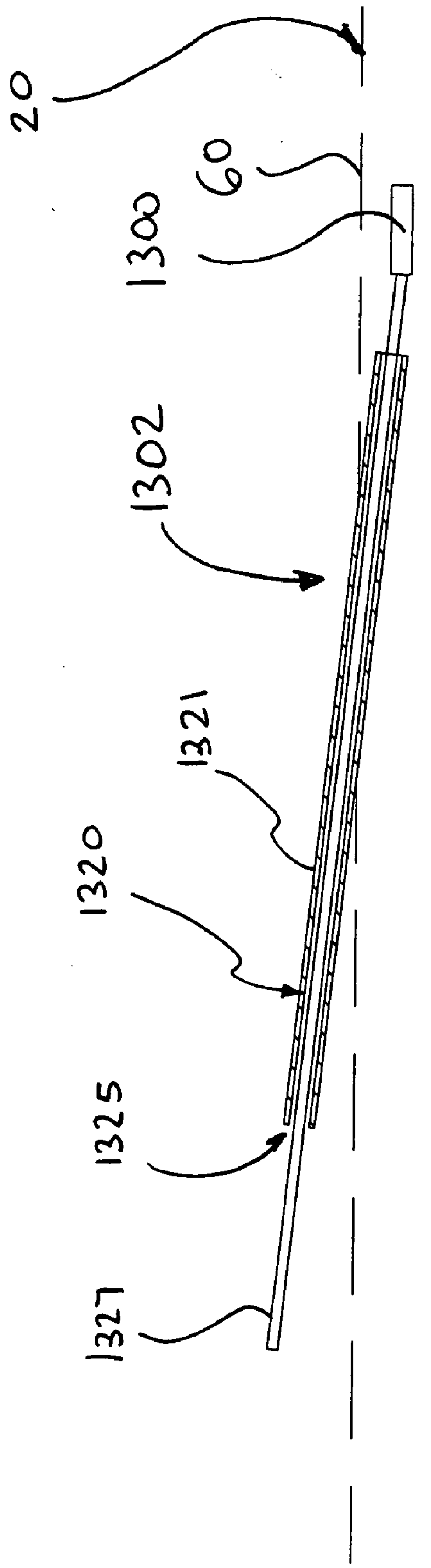

FIG. 27

IMPLANTABLE MEDICAL DEVICES AND RELATED METHODS

CROSS REFERENCE TO RELATED APPLICATION

[0001] The present application claims benefit under 35 U.S.C. §119(e) of U.S. Provisional Application No. 60/566,222, filed Apr. 28, 2004, which is hereby incorporated by reference.

BACKGROUND OF THE INVENTION

[0002] Some types of implantable devices provide for measurement of ECG and other information which may be transmitted to an external recorder and/or analysis device. The information thus recorded can be used by a physician or other medical care provider to aid in diagnosis or treatment or for alerting emergency medical services of a life-threatening event. Current systems commercially available for the same or similar purpose include the Reveal® implantable loop recorder (ILR) available from Medtronic (Minneapolis, Minn.), animal monitoring devices available from Data Sciences International (St. Paul, Minn.), mobile outpatient cardiac telemetry systems and services available from Cardionet (San Diego, Calif.), and various hardwired systems.

[0003] The Medtronic Reveal is an ECG monitor intended for diagnosis of syncope or other rhythm disturbances. This device analyzes the ECG in real time. The device detects when a rhythm disturbance occurs and stores a segment of the ECG strip before and after the time of the rhythm disturbance. Issues with this include limited signal processing capability leading to poor detection accuracy. This device is often unable to, for example, detect atrial fibrillation accurately. In addition, it often falsely detects rhythm disturbances resulting in ECG's with no useful diagnostic utility filling the memory of the device. Memory in this device is limited to about 40 minutes, and the patient must visit the clinic in order for the memory of the device to be dumped and reset. Once the memory fills, a syncopal event can no longer be recorded. Since these events can occur very infrequently, this can limit the diagnostic utility of the device. The Reveal includes ECG electrodes that are incorporated into the body of the device. One electrode is in the header and the 2nd electrodes is an uninsulated portion located at the opposite end of the metallic body of the device.

[0004] The Data Sciences International (DSI) system for monitoring animals involves an implanted ECG, temperature, and pressure transmitter that telemeters a continuous ECG. Information from this device is transmitted in real time to a receiver. The receiver forwards a signal to a computing device where the signals are analyzed (ECGs for arrhythmias, intervals; pressure for systolic, diastolic, and mean pressure, heart rate, dP/dt, etc.) The transmitter employs flexible leads for sensing that extend from the body of the device.

[0005] The Cardionet system involves surface electrodes that are placed on the patient for monitoring ECG. The ECG signal is telemetered to a computing device that analyzes the ECG and identifies rhythm abnormalities. This device can forward a real time ECG to a monitoring station, or can notify the monitoring station if an abnormal rhythm is identified. This system packetizes the telemetered signal, incorporates time synchronization, and the receiver identifies whether a particular packet was received properly. If a packet was not received properly, the computing device signals to the transmitter to resend a packet. This device requires that surface electrodes be worn. Wires from the surface electrodes are connected to the telemetry device worn by the patient. This can particularly be a problem while the patient is sleeping. Also, since surface electrodes must be worn, patient compliance is an issue. Most patients are unwilling to wear surface electrodes for more than about three to four weeks. This system provides the advantage of real time monitoring can be accomplished. If the surface electrodes come loose, this can be identified immediately by the monitoring center and the patient can be contacted to reposition the electrodes.

[0006] Hardwired systems are available to serve this purpose. A computing device connects directly to surface electrodes for recording and/or analyzing ECG for the purpose of providing diagnostic information to the physician. These devices have no telemetry link and have the disadvantage that the patient must wear surface electrodes and be connected to the recorder. This can particularly be a problem while the patient is sleeping. Also, since surface electrodes must be worn, patient compliance is an issue. Most patients are unwilling to wear surface electrodes for more than about three to four weeks. Devices are often worn for two to four weeks. If problems have occurred in the recording, it will not be noticed for quite some time.

BRIEF SUMMARY OF THE INVENTION

[0007] Implantable medical devices and associated methods are disclosed. In one implementation, the implantable medical device comprises a conductive housing and a remote electrode that is mechanically coupled to the conductive housing by a lead body. An amplifier is electrically connected to the remote electrode and the conductive housing for providing a signal representative of a voltage difference between the remote electrode and the conductive housing. In some methods in accordance with the present invention, the implantable medical device is implanted in an implant site overlaying one half of a rib cage of a human body. The implantable medical device produces a signal representative of the voltage difference between the remote electrode and the conductive housing and the signal is transmitted to a receiver located outside the human body.

BRIEF DESCRIPTION OF THE DRAWING

[0008] **FIG. 1** is a schematic illustration showing a system for monitoring one or more physiological signals telemetered from an implantable medical device implanted in a human patient.

[0009] **FIG. 2** is a plan view showing an implantable medical device that is implanted in the body of a patient and a repeater that is supported by a lanyard that extends around the neck of the patient.

[0010] **FIG. 3** is a plan view showing an implantable medical device that is implanted in a human body and a repeater that is supported by an elastic garment that extends about the human body.

[0011] **FIG. 4** is an isometric view showing a portion of a human body with an implantable medical device implanted therein.

[0012] **FIG. 5** is an isometric view showing a left implant site disposed in the left half of the human body shown in the previous figure.

[0013] **FIG. 6** is an isometric view showing a right implant site disposed in the right half of the human body shown in the previous figure.

[0014] **FIG. 7** is a transverse cross-sectional view of a human body with an implantable medical device implanted therein.

[0015] **FIG. 8** is a cross-sectional view showing an implantable medical device in accordance with an exemplary embodiment of the present invention.

[0016] **FIG. 9** is an additional cross sectional view of the implantable medical device shown in the previous figure.

[0017] **FIG. 10** is an axial view of a lead assembly in accordance with an exemplary embodiment of the present invention.

[0018] **FIG. 11** is a block diagram of an implantable medical device in accordance with an exemplary embodiment of the present invention.

[0019] **FIG. 12** is a block diagram of an implantable medical device in accordance with an additional exemplary embodiment of the present invention.

[0020] **FIG. 13** is a diagrammatic view of an implantable medical device in accordance with an exemplary embodiment of the present invention.

[0021] **FIG. 14** is a schematic diagram showing an activity sensor and associated circuitry.

[0022] **FIG. 15** is a diagrammatic view of an implantable medical device in accordance with an exemplary embodiment of the present invention.

[0023] **FIG. 16** is a diagrammatic view of an implantable medical device in accordance with an exemplary embodiment of the present invention.

[0024] **FIGS. 17A and 17B** are diagram views showing a threading tool and a placement tool that may be employed to deploy an implantable medical device in accordance with the present invention.

[0025] **FIGS. 18A-18C** show electrodes incorporated into various portions of a housing of an implantable medical device.

[0026] **FIG. 19** is a block diagram of an implantable medical device that is capable of producing a first signal that is representative of respiration and a second signal that is representative of ECG.

[0027] **FIG. 20A** and **FIG. 20B** show the recharging of an implantable medical device by transformer coupling energy from a recharging device located outside the body to a coil located inside the implantable medical device.

[0028] **FIG. 21** is a block diagram showing an implantable medical device and a recharging device.

[0029] **FIG. 22** is a diagrammatic view of an implantable medical device in accordance with an additional exemplary embodiment of the present invention.

[0030] **FIG. 23** is a block diagram showing an implantable medical device and a recharging device that may be used to recharge the implantable medical device.

[0031] **FIG. 24** is a block diagram showing an implantable medical device and a recharging device that may be used to recharge the implantable medical device.

[0032] **FIG. 25** is a flowchart illustrating an exemplary method in accordance with the present invention.

[0033] **FIG. 26** is a diagram view showing a placement tool and an associated method that may be employed to deploy an implantable medical device in accordance with the present invention.

[0034] **FIG. 27** is an additional diagram view showing a placement tool and an associated method that may be employed to deploy an implantable medical device in accordance with the present invention.

DETAILED DESCRIPTION

[0035] The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

[0036] **FIG. 1** is a schematic illustration showing a system for monitoring one or more physiological signals telemetered from implantable medical device **100** implanted in a human patient **20**. In this illustrative embodiment, the system measures physiological signals such as ECG, pressure and/or temperature, and transmits (e.g., wirelessly) the waveforms of these signals to repeater **140** worn by or kept near patient **20**. Repeater **140** receives the transmitted signals from implantable medical device **100** and retransmits (e.g., wirelessly) the signals to receiver/analyzer/storage buffer, RASB **142**. Implantable medical device **100**, repeater **140** and RASB **142** allow patient **20** to be monitored when lying in bed sleeping or going about normal daily activities. The RASB **142** may transmit the physiological data to a physician monitoring station S via a network **144**. Network **144** may comprise various networks without deviating from the spirit and scope of the present invention. Examples of networks that may be suitable in some applications include the Internet and modem communication via telephone lines. Various communication techniques are described in the following U.S. Pat. Nos.: 5,113,869; 5,336,245; 6,409,674; 6,347,245; 6,577,901; 6,804,559; 6,820,057. The entire disclosures of the above-mentioned U.S. Patents are hereby incorporated herein by reference. Various communication techniques are described in the following U.S. patent applications: US2002/0120200 and US2003/0074035. The entire disclosures of the above-mentioned U.S. patent applications are also hereby incorporated herein by reference.

[0037] Implantable medical device **100** may be dedicated to patient monitoring, or it may alternatively include a therapeutic function (e.g., pacing, defibrillation, etc.) as well. Repeater **140** may comprise a barometric pressure sensor **146** that measures barometric pressure and communicates the measurement to computing device **148**. Computing device **148** subtracts barometric pressure from pressure measured by implantable medical device **100** to provide a gauge pressure measurement of internal body pressure. This gauge pressure signal is then retransmitted by repeater **140** to RASB **142**, or it may be communicated back to a medical device implanted in patient **20** to aid in controlling delivery of a therapy. The therapeutic function may be contained within a separate implantable device that is in communication with repeater **140** or/and implantable medical device **100**. This therapeutic function may be controlled in part by information derived separately or in combination from repeater **140** or/and medical device.

[0038] Implantable medical device **100** may transmit signals in real time or pseudo real time (slightly delayed from real time). If the transmissions occur in true real time, and if the waveforms were to be transmitted either continuously or frequently, in order to achieve satisfactory battery life, the transmitter may employ a modulation scheme such as Pulse Interval Modulation (PIM) and use a relatively low transmit carrier frequency (for example, tens or hundreds of kHz). Another approach to conserving power might be to process the signals within the medical device to extract the useful information. If the volume of data comprising the useful information is much less than the signals from which it was derived, the useful information may then be stored for later transmission, or it may then be transmitted in real time or pseudo real time to a receiver located outside the body. One limitation that is apparent in the Medtronic REVEAL device (Minneapolis, Minn.) is that the device often fills memory with false positive strips of what it perceives to be aberrant rhythms. By transmitting the raw data to a processor located outside the body, the useful information contained in the signals can be more precisely extracted

[0039] A limitation of using PIM and a low carrier frequency is that the transmit range is relatively short and the signal transmission is subject to interference. This limitation can be overcome by locating repeater **140** in close proximity to implantable medical device **100**. This can be accomplished by wearing repeater **140** in close proximity to implantable medical device **100** by attaching it to lanyard or clip, or by securing it to a strap or elastic garment worn on patient **20**.

[0040] **FIG. 2** is a plan view showing an implantable medical device **100** that is implanted in the body of a patient **20**. A repeater **140** is supported by a lanyard **150** that extends around the neck of patient **20**. Use of lanyard **150** allows repeater **140** to be carried in close proximity to implantable medical device **100**.

[0041] **FIG. 3** is a plan view showing an implantable medical device **100** that is implanted in a human body **22**. A repeater **140** is supported by an elastic garment **152** that extends about the human body **22**. In the embodiment of **FIG. 3**, implantable medical device **100** comprises a housing **134**, a lead body **154**, and a remote electrode **156**. With reference to **FIG. 3**, it will be appreciated that housing **134** is disposed in a pocket **160** that has been formed in the tissue of human body **22**. With continuing reference to **FIG. 3**, it will be appreciated that remote electrode **156** is disposed in a channel **158** that has been formed in the tissue of human body **22**.

[0042] In some methods in accordance with the present invention, pocket **160** and channel **158** are formed within a pre-selected implant site inside human body **22**. Pocket **160** may be formed, for example, by making an incision with a cutting tool and pushing a blunt object through the incision to displace tissue and form pocket **160**. For example, pocket **160** may be formed by pushing gloved fingers through the incision. Channel **158** may be formed, for example, by inserting a stylet into a lumen of lead body **154** and advancing lead body **154** into the body so that tissue is displaced and channel **158** is formed in the tissue. By way of a second example, channel **158** may be formed by inserting a groove director into pocket **160** and advancing the groove director into the body so that tissue is displaced and channel **158** is formed in the tissue. One groove director that may be suitable in some applications is commercially available from Universal Surgical Instruments of Glen Cove, N.Y., USA which identifies it by the part number 88-42-2695.

[0043] **FIG. 4** is an isometric view showing a portion of a human body **22** with an implantable medical device **100** implanted therein. In **FIG. 4**, a central sagital plane **24** and a frontal plane **26** are shown intersecting human body **22**. In the embodiment of **FIG. 4**, central sagital plane **24** and frontal plane **26** intersect one another at a median axis **42** of human body **22**. With reference to **FIG. 4**, it will be appreciated that central sagital plane **24** bisects human body **22** into a right half **28** and a left half **30**. Also with reference to **FIG. 4**, it will be appreciated that frontal plane **26** divides human body **22** into an anterior portion **32** and a posterior portion **34**. In the embodiment of **FIG. 4**, central sagital plane **24** and a frontal plane **26** are generally perpendicular to one another.

[0044] With reference to **FIG. 4**, it will be appreciated that implantable medical device **100** is implanted in tissue proximate a left arm **35** of human body **22**. In the embodiment of **FIG. 4**, implantable medical device **100** comprises a housing **134**, a remote electrode **156** and a lead body **154** that mechanically couples remote electrode **156** to housing **134**.

[0045] **FIG. 5** is an isometric view showing a left implant site **44** disposed in the left half **30** of the human body **22** shown in the previous figure. With reference to **FIG. 5**, it will be appreciated that an implantable medical device **100** is disposed in the left implant site **44**. As shown in **FIG. 5**, left implant site **44** may be defined by reference to a plurality of planes. A first sagittal plane **50** is shown contacting a left-most extent **62** of a sternum **66** of human body **22**. A second sagittal plane **52** is shown contacting a left-most extent **61** of a rib cage **40**. In the embodiment of **FIG. 5**, left implant site **44** extends laterally between first sagittal plane **50** and second sagittal plane **52**. A superior transverse plane **54** is shown contacting a lower surface **48** of a left clavicle **58** of human body **22**. An inferior transverse plane **56** is shown contacting a lower extent **63** of sternum **66**. In the embodiment of **FIG. 5**, left implant site **44** extends between superior transverse plane **54** and inferior transverse plane **56**. Some methods in accordance with the present invention, include the step of implanting implantable medical device **100** within left implant site **44**. In some methods in accordance with the present invention, implantable medical device **100** is implanted between the skin **60** of the human body **22** and a front extent of rib cage **40**.

[0046] **FIG. 6** is an isometric view showing a right implant site **46** disposed in the right half **28** of the human body **22** shown in the previous figure. With reference to **FIG. 6**, it will be appreciated that an implantable medical device **100** is disposed in the right implant site **46**. As shown in **FIG. 6**, right implant site **46** may be defined by reference to a plurality of planes. A first sagittal plane **50'** is shown contacting a right-most extent **64** of a sternum **66** of human body **22**. A second sagittal plane **52'** is shown contacting a right-most extent **65** of a rib cage **40**. In the embodiment of **FIG. 6**, right implant site **46** extends laterally between first sagittal plane **50'** and second sagittal plane **52'**. A superior transverse plane **54** is shown contacting a lower surface **67** of a right clavicle **68** of human body **22**. An inferior transverse plane **56** is shown contacting a lower extent sternum **66**. In the embodiment of **FIG. 6**, right implant site **46** extends between superior transverse plane **54** and inferior transverse plane **56**. Some methods in accordance with the present invention, include the step of implanting implantable medical device **100** within right implant site **46**. In some methods in accordance with the present invention, implantable medical device **100** is implanted between the skin **60** of the human body **22** and a front extent of rib cage **40**.

[0047] **FIG. 7** is a transverse cross-sectional view of a human body **22** with an implantable medical device **100** implanted therein. The skin **60** and rib cage **40** of human body **22** are visible in this cross-sectional view. With reference to **FIG. 7**, it will be appreciated that implantable medical device **100** is disposed in a left implant site **44** of human body **22**. Central sagital plane **24** is also shown in **FIG. 7**. With reference to **FIG. 7**, it will be appreciated that central sagital plane **24** bisects rib cage **40** into a right half **38** and a left half **36**. With reference to **FIG. 7**, it will be appreciated that left implant site **44** generally overlays left half **36** of rib cage **40**.

[0048] With reference to **FIG. 7**, it will be appreciated that implantable medical device **100** is disposed between skin **60** of human body **22** and a frontal extent **67** of the rib cage **40** of human body **22**. In the embodiment of **FIG. 7**, left implant site **44** extends between a first sagittal plane **50** and a second sagittal plane **52**. In **FIG. 7**, first sagittal plane **50** is shown contacting a left-most extent **62** of a sternum **66** of human body **22**. Also in **FIG. 7**, second sagittal plane **52** is shown contacting a left-most extent **61** of rib cage **40**.

[0049] In the embodiment of **FIG. 7**, implantable medical device **100** comprises a housing **134**, a lead body **154**, and a remote electrode **156**. In **FIG. 7**, lead body **154** is shown assuming a generally curved shape. In some useful embodiments of the present invention, lead body **154** has sufficient lateral flexibility to allow lead body **154** to conform to the contour of left implant site **44**. Also in some useful embodiments of the present invention, lead body **154** has sufficient lateral flexibility to allow lead body **154** to flex in compliance with muscle movements of human body **22**. With reference to **FIG. 7**, it will be appreciated that lead body **154** does not extend into a chest cavity **68** of human body **20**. Accordingly, it will be appreciated that lead **154** does not extend into a cavity of the heart of human body **20**.

[0050] **FIG. 8** is a cross-sectional view showing an implantable medical device **100** in accordance with an exemplary embodiment of the present invention. Implantable medical device **100** comprises a conductive housing **134**, a header **162**, and a lead assembly **200**. Lead assembly **200** comprises a remote electrode **156** and a connector pin **202**. Remote electrode **156** and connector pin **202** are mechanically coupled to one another by a lead body **154** of lead assembly **200**. Lead body **154** comprises a coiled conductor **206** and an outer sheath **204**. In some useful embodiments, outer sheath comprises a flexible material. Examples of flexible materials that may be suitable in some applications include silicone rubber and polyurethane.

[0051] Remote electrode **156** and connector pin **202** are also electrically connected to one another by coiled conductor **206**. Coiled conductor **206** may comprise one or more filars wound in a generally helical shape. For example, coiled conductor **206** may comprise four helically wound filars. Remote electrode **156** may comprise various materials without deviating from the spirit and scope of the present invention. Examples of materials that may be suitable in some applications include stainless steel, Elgiloy, MP-35N, titanium, gold and platinum. Remote electrode **156** may also comprise a coating. Examples of coatings that may be suitable in some applications include carbon black, platinum black, and iridium oxide.

[0052] Header **162** defines a socket **208** that is dimensioned to receive a connecting portion **220** of lead assembly **200**. Remote electrode **156** may be detachably attached to conductive housing **134** by inserting connecting portion **220** of lead assembly **200** into socket **208**. In the embodiment of **FIG. 8**, a set screw **222** is disposed in a threaded hole defined by header **162**. Set screw may be used to selectively lock connecting portion **220** of lead assembly **200** in socket **208**. An electrical contact **224** is also shown in **FIG. 8**. Electrical contact **224** may make contact with connector pin **202** when connecting portion **220** of lead assembly **200** is disposed in socket **208**.

[0053] **FIG. 9** is an additional cross sectional view of implantable medical device **100** shown in the previous figure. In the embodiment of **FIG. 9**, connecting portion **220** of lead assembly **200** is disposed in socket **208** defined by header **162**. In the embodiment of **FIG. 9**, remote electrode **156** comprises a generally cylindrical body portion **226** having a generally circular lateral cross section. With reference to **FIG. 9** it will be appreciated that remote electrode **156** also comprises a general rounded tip portion **228**. In the embodiment of **FIG. 9**, tip portion **228** has a generally hemispherical shape.

[0054] With reference to **FIG. 9**, it will be appreciated that remote electrode **156** and lead body **154** are both free of anchors. In some applications, providing a remote electrode that is free of anchors may facilitate removal of the remote electrode from the human body. Additionally, providing a lead body that is free of anchors may facilitate removal of the lead from the human body.

[0055] With reference to **FIG. 9**, it will be appreciated that lead body **154** separates remote electrode **156** and conductive housing **134** by a center-to-center distance D. In some useful embodiments, distance D is selected to be relatively large so that a voltage differential between conductive housing **134** and remote electrode **156** is relatively large. In some useful embodiments of the present invention, distance D is greater than about 4.0 centimeters and less than about 10.0 centimeters. In some particularly useful embodiments, distance D is greater than about 5.0 centimeters and less than about 7.0 centimeters.

[0056] With continuing reference to **FIG. 9**, it will be appreciated that implantable medical device **100** has an overall length L. In some useful embodiments of the present invention, overall length L is selected so that conductive housing **134**, remote electrode **156**, and lead body **154** will all be received in an implant site overlaying one half of a rib cage of a human body. In some useful embodiments of the present invention, overall length L is greater than about 4.0 centimeters and less than about 13.0 centimeters. In some particularly useful embodiments, overall length L is greater than about 5.0 centimeters and less than about 10.0 centimeters.

[0057] Conductive housing **134** may comprise various materials without deviating from the spirit and scope of the present invention. Examples of materials that may be suitable in some applications include stainless steel, Elgiloy, MP-35N, titanium, gold and platinum. Conductive housing **134** may also comprise a conductive coating. Examples of conductive coatings that may be suitable in some applications include carbon black, platinum black, and iridium oxide. In the embodiment of **FIG. 9**, conductive housing **134** is free of insulating coatings so that the entire outer surface of conductive housing **134** is available to make electrical connection with body tissue. Embodiments of the present invention are possible in which a portion of conductive housing **134** is covered with an insulating coating, for example, PARYLENE.

[0058] **FIG. 10** is an axial view of lead assembly **200** shown in the previous figure. With reference to **FIG. 10**, it will be appreciated that remote electrode **156**, lead body **154**, and connecting portion **220** are all generally circular in cross section. In some applications, providing a remote electrode having a circular transverse cross-section may facilitate removal of the remote electrode from the human body. Additionally, providing a lead body having a circular transverse cross-section may facilitate removal of the lead from the human body.

[0059] **FIG. 11** is a block diagram of an implantable medical device **100** in accordance with an exemplary embodiment of the present invention. Implantable medical device **100** of **FIG. 11** comprises a conductive housing **134** defining a cavity **136**. In **FIG. 11**, an amplifier **196** is shown disposed in a cavity **136**. A remote electrode **156** is electrically connected to amplifier **196** via a conductor **206**. Amplifier **196** is also electrically connected to conductive housing **134**. In the embodiment of **FIG. 11**, amplifier **196** is capable of detecting a voltage difference between conductive housing **134** and remote electrode **156**. Amplifier **196** is also capable of producing a signal **198** that is representative of the voltage difference between conductive housing **134** and remote electrode **156**. In **FIG. 11**, a telemetry unit **164** is shown connected to amplifier **196**. In some useful embodiments of the present invention, implantable medical device **100** is disposed inside a human body and telemetry unit **164** is capable of transmitting signal **198** to a receiver located outside of the body.

[0060] **FIG. 12** is a block diagram of an implantable medical device **100** in accordance with an additional exemplary embodiment of the present invention. Implantable medical device **100** of **FIG. 12** comprises a conductive housing **134** that is electrically connected to an amplifier **196**. In the embodiment of **FIG. 12**, amplifier **196** is disposed within a cavity **136** defined by conductive housing **134**. A remote electrode **156** is electrically connected to amplifier **196** via a conductor **206**. In the embodiment of **FIG. 12**, amplifier **196** is capable of detecting a voltage difference between conductive housing **134** and remote electrode **156**. Amplifier **196** is also capable of producing a signal **198** that is representative of the voltage difference between conductive housing **134** and remote electrode **156**.

[0061] In the embodiment of **FIG. 12**, a filter **232** is electrically connected to amplifier **196**. Filter **232** may be capable of filtering signal **198**. Filter **232** may comprise, for example, a band-pass filter. When this is the case, filter **232** may pass a portion of signal **198** having frequency's between about 0.5 Hz and about 80.0 Hz. Filter **232** is electrically connected to a telemetry unit **164**. In some useful embodiments of the present invention, implantable medical device **100** is disposed inside a human body and telemetry unit **164** is capable of transmitting at least a portion of signal **198** to a receiver located outside of the body.

[0062] **FIG. 13** is a diagrammatic view of an implantable medical device **400** in accordance with an exemplary embodiment of the present invention. Implantable medical device **400** may be used to measure a number of signals. In the embodiment of **FIG. 13**, for example, implantable medical device **400** is capable of measuring ECG, pressure, patient activity, patient posture, impedance, respiratory rate, respiratory effort, glucose, and temperature. In the embodiment of **FIG. 13**, implantable medical device **400** includes a telemetry unit **464** and remote sensing lead **466**. Remote sensing lead **466** is capable of sensing pressure from an artery or vein, and communicating such signal to telemetry unit **464** for transmission. Remote sensing lead **466** may also contain one or more electrodes for sensing ECG as well as a pressure sensor.

[0063] Remote sensing lead **466** may employ one of a variety of pressure sensing means such as fiberoptic sensors, resonant sensor, piezoresistive sensors, capacitive sensors, and other sensors that can be fabricated in a diameter small enough to be safely introduced and reside within a vessel. In the preferred embodiment, the pressure sensing means may comprise a pressure transmission catheter (PTC **468**), as described in U.S. Pat. No. 4,846,494 that can be introduced into an artery or vein. The entire disclosure of the above-mentioned U.S. patent is hereby incorporated by reference herein. The PTC approach as described in the '494 patent is advantageous in that it can be fabricated in a very small diameter. This is beneficial because the small size is less likely to damage the endothelial lining of the vessel and also because accidental pullout of the sensing catheter will result in far lesser complications.

[0064] PTC **468** refers the pressure signal to pressure sensor **484**. Signal processing electronics **486** converts the signal from pressure sensor **484** to a signal that can be communicated to telemetry unit **464** via flexible lead body **454** and connector **488**.

[0065] Remote sensing lead **466** may also incorporate a temperature sensor **490**. Temperature sensor **490** would preferably be located within conductive housing **434** and the signal from temperature sensor **490** would be processed by signal processing electronics **486**. The temperature signal would preferably be multiplexed with the pressure signal for communication to telemetry unit **464** via flexible lead body **454** and connector **488**.

[0066] The housing of telemetry unit **464** may be constructed of three parts: a metallic portion **480** fabricated of a metallic material (e.g., titanium), an RF transparent portion **478** fabricated of ceramic, and a header **442**. In the embodiment of **FIG. 13**, metallic portion **480** and RF transparent portion **478** are joined together at a seam **482**. In **FIG. 13**, a battery **408** can be seen disposed in metallic portion **480**.

[0067] Remote sensing lead **466** may also contain ECG sensing electrodes. In some embodiments, for example, conductive housing **434** of implantable medical device **400** may serve as one ECG sensing electrode while metallic portion **480** of the housing of telemetry unit **464** may serve as another ECG sensing electrode. Alternately, the second ECG sensing electrode could be incorporated into flexible lead body **454**. This arrangement provides for sufficient spacing between the two ECG sensing electrodes to obtain adequate ECG signal amplitude and sensing of important features of the ECG such as p-waves for detection of atrial fibrillation. Flexible lead body **454** includes a conductor to connect the second ECG sensing electrode to signal processing electronics **486**. The ECG signal is preferably multiplexed with the pressure and temperature signal for communication to telemetry unit **464** via flexible lead body **454** and connector **488**.

[0068] Remote sensing lead **466** may further incorporate one or more conductors in flexible lead body **454** to serve as a transmitting and/or receiving antenna. Telemetry unit **464** may contain an activity sensor. The activity sensor may also comprise, for example, an accelerometer **494**. As the patient moves about, g-forces placed on the accelerometer **494** by the patient may create an electrical signal that is representative of patient activity.

[0069] TU circuitry **470** contained in telemetry unit **464** is responsible for controlling power to remote sensing lead **466** and for transmitting the signals to repeater **440**. In one exemplary embodiment, telemetry unit **464** has two operating states, on and off. When on, telemetry unit **464** transmits a PIM signal with a carrier frequency of about three hundred kHz. In another exemplary embodiment telemetry unit **464** compresses the signals to reduce the volume of data to be telemetered to reduce the power required by the transmitter. Power consumption can be further reduced by storing either the raw or compressed data in memory for a period of time, a few seconds for example, and then transmitting data at multiples of real time to repeater **440** or to RASB **442**. In this approach, the transmitter is a high frequency transmitter operating at about nine hundred MHz, for example. Although such a high frequency transmitter consumes significantly more power when operating, it also provides for a much faster data transmission rate and therefore needs to operate for a much shorter period of time. It therefore allows several seconds of data stored in memory to be transmitted in a fraction of a second. Such an approach also allows the transmitter to employ more reliable communication means. For example, instead of using PIM, this approach allows for the use of frequency shift keying (FSK) modulation, a more robust modulation scheme compared to PIM. Further, transmitted data can be divided into packets and error correction codes (ECC) can be added to each packet. When a transmitted data packet is received at RASB **442**, the ECC can be evaluated to determine if the packet was received correctly. RASB can either ignore such a corrupt packet, or it can be equipped with bi-directional communication such that it signals back to implantable medical device **400** that the packet was not received correctly and request that it be retransmitted by implantable medical device **400**.

[0070] **FIG. 14** is a schematic diagram showing an activity sensor **492** and associated circuitry. Telemetry unit **464** (shown in the previous figure) may contain activity sensor **492** and it's associated circuitry. Activity sensor **492** may comprise, for example, an accelerometer **494**. As the patient moves about, g-forces placed on the accelerometer **494** by the patient's movement create an electrical signal that is amplified by an amplifier **496**. The output of amplifier **496** is a current source that charges capacitor **406** with a fixed amount of charge. Once that level of charge is reached, a pulse is triggered and the charge on capacitor **406** is dumped, indicating that a quantum of patient activity has occurred. Pulses are counted over a unit time, a few minutes for example, to indicate the degree of patient activity. In the embodiment of **FIG. 14**, a switch **495** and a controller **497** cooperate to dump the charge on capacitor **406**.

[0071] **FIG. 15** is a diagrammatic view of an implantable medical device **500** in accordance with an additional exemplary embodiment of the present invention. In the embodiment of **FIG. 15**, implantable medical device **500** is used to monitor ECG, activity, and temperature. In this embodiment, since pressure is not necessarily being measured, the need for a remote sensing lead including a pressure sensor is eliminated. A temperature sensor **590** is contained within telemetry unit **564**. Telemetry unit **564** includes TU circuitry **570**. Data transmission approaches in this embodiment are similar in function to those previously described.

[0072] In the embodiment of **FIG. 15**, a first ECG electrode **572** and a second ECG electrode **574** are integral to header **562**. A remote electrode **556** is contained at the distal end of flexible lead **576**. Flexible lead **576** allows for remote electrode **556** to be directed to a site at the time of implantation that allows for a high quality ECG. By proper placement of telemetry unit **564** under the skin, it is possible to obtain two ECG channels using remote electrode **556** as a common electrode, allowing for measurement of two different ECG vectors. Further, if implantable medical device **500** were only capable of transmitting a single ECG channel, remote electrode **556** could be selectively paired by TU circuitry **570** to serve as a common electrode for either first ECG electrode **572** or second ECG electrode **574**. This would allow fine-tuning of the ECG signal following implantation via a programmable function incorporated into TU circuitry **570**. Such fine-tuning would allow the physician to select that electrode pair that provided, for example, the highest amplitude p-wave, or the least amount of muscle noise. Flexible lead **576** could also incorporate additional conductive elements to accommodate a transmitting and/or receiving antenna for the transmitter contained in telemetry unit **564**.

[0073] **FIG. 16** is a diagrammatic view of an implantable medical device **600** in accordance with an additional exemplary embodiment of the present invention. In the embodiment of **FIG. 16**, implantable medical device **600** comprises a first electrode **672** and a second electrode **674**. By placing one electrode at the distal end of flexible lead **676**, sufficient spacing can be obtained between the two electrodes to detect a good quality ECG signal. In addition, placing an electrode on the end of flexible lead **676** provides for a greater degree of flexibility in placement of the electrodes relative to each other. This has the potential to improve the diagnostic quality of the ECG vector because flexibility in positioning could allow the physician to adjust the relative location of electrodes to improve the amplitude of the p-wave, t-wave, or other clinically significant features of the ECG waveform. The housing **634** of implantable medical device **600** may be constructed of three parts: a metallic portion **680** fabricated of a metallic material (e.g., titanium:; an RF transparent portion **678** fabricated of ceramic, and a header **662**. The metallic portion **680** and RF transparent portion **678** are joined together at a seam **682**. Metallic portion **680** is electrically insulated with parylene, except for the portion comprising first electrode **672**. Flexible lead **676** may extend approximately four to ten centimeters distal to header **662**.

[0074] **FIGS. 17A and 17B** are diagram views showing a threading tool **300** and a placement tool **320** that may be employed to deploy an implantable medical device **300** in accordance with the present invention. To implant implantable medical device **300**, an incision **302** is made where the device is to be inserted under the skin **60** of patient **20** and a pocket is formed under the skin **60** distal to the incision to accommodate the housing of implantable medical device. Threading tool **300** has a hollow lumen and is directed through the incision **302** and under the skin **60** to the desired location for a remote electrode of the implantable medical device. Once in location, a guidewire **304** is inserted into the lumen and threading tool **300** is extracted. Guidewire **304** is electrically insulated with the exception of a distal portion thereof. To evaluate a location for the remote electrode of the implantable medical device, the proximal end of guidewire **304** can be connected to an ECG monitoring instrument **306** while the other input to the ECG monitoring instrument **306** is connected to a temporary electrode **308** placed in the incision **302** at the approximate location where housing of the implantable medical device will be placed when the implantable medical device is implanted. If the result is satisfactory, the housing of the implantable medical device **300** and the flexible lead **376** of the implantable medical device **300** are attached to a placement tool **320**. Placement tool **320** contains a guide **322** through which guidewire **304** is inserted. Placement tool **320** is then directed along guidewire **304** until guide **322** has reached the end of guidewire **304**. Release **326** is then triggered, the housing of implantable medical device **300** and flexible lead **376** from placement tool **320**. Placement tool **320** may then be extracted, leaving the housing of implantable medical device **300** and flexible lead **376** in position. The housing of implantable medical device **300** is positioned within the pocket adjacent to the incision and the incision is closed.

[0075] Various alternative lead-less embodiments of implantable medical device **100** are contemplated. For example, as shown in **FIGS. 18A-18C**, electrodes may be incorporated into various portions of the housing of the device **100**. In each of these embodiments, the housing may include a case portion **1002** made of ceramic for example, and header portion **1004** made of a polymeric material. The electrodes **1006, 1008, 1010, 1012** may comprise a conductive material embedded in the header **1004** and/or case **1002**, and the orientation of the electrodes and the distance between the electrodes may be maintained by the non-conductive portions of the housing, such as the ceramic case **1002** and/or the polymeric header **1004**, in order to fix orientation for best signal capture. The housing holds and orientates one or more sensing electrodes **1006, 1008, 1010, 1012** for purposes of measuring ECG signals or other bio-potential signals such as EEG, EMG, ECG etc., or respiratory effort and/or cardiac stroke volume via impedance. These signals may be transmitted and or recorded as described previously.

[0076] The electrodes **1006, 1008, 1010, 1012** may be made from any suitable sensor electrode material (e.g., Stainless Steel, Elgiloy, MP-35N, Titanium, etc.) and may be coated to increase sensing capability (i.e.: carbon black, platinum black, iridium oxide, etc). The electrode surface may be smooth or porous coated, again to increase sensing capability. The electrodes may be located in-line or orthogonally opposed to increase the relative distance between them for improved capability. The macroscopic surface area of each electrode may vary depending on the application and the microscopic surface finish. The electrodes may be disposed in or on (e.g., embedded or coated) the header **1004** or the case **1002**, and provided that they remain electrically isolated from each other and the rest of the structure. This may be accomplished by fabricating the case **1002** and/or header **1004** of a non-conductive material, or if a conductive material is used for the case **1002**, by isolating the electrodes from the case with an insulating material.

[0077] A single header arrangement may be used as shown in **FIGS. 18A and 10B**, or a double header arrangement may be used as shown in **FIG. 18C**. With any one of these arrangements, two, three, four or more electrodes may be used depending on the number of electrical channels the device electronics allows for, the surface area required for each electrode and the signal to be measured in a given application. Additional electrodes may be provided via a flexible or semi-flexible wire lead arrangement as described previously herein, which would allow for further electrode spacing for increased signal resolution.

[0078] For measuring respiratory effort/respiratory rate, a constant current carrier signal may be injected between two electrodes. The carrier signal may be amplitude modulated by the changing impedance between the electrodes due to respiratory effort. The amplitude modulated signal may be demodulated and band-passed filtered for respiratory signals producing a changing voltage proportional to respiratory effort which can then be transmitted and or recorded. Cardiac stroke volume can be attained using similar methods but with a band pass tailored to the cardiac signal. An intra-cardiac electrode as one of the electrodes in the configuration would provide an improved measurement of cardiac stroke volume. Each of these techniques could be accomplished using a four electrode method, as Well, with one electrode pair providing the constant current, and another electrode pair to provide the measurement. This results in a more accurate measurement by eliminating the electrode impedance. All four electrodes could be configured in the header of the device, in the body of the device, via a flexible or semi-flexible wire arrangement, or in any combination of these electrode types.

[0079] **FIG. 19** is a block diagram of an implantable medical device **700** that is capable of producing a first signal that is representative of respiration and a second signal that is representative of ECG. Implantable medical device **700** of **FIG. 19** comprises a conductive housing **734** that is electrically connected to a current source **234**. A remote electrode **756** is also electrically connected to current source **234** via a conductor **206**. In the embodiment of **FIG. 19**, current source **234** provides a substantially constant current traveling between conductive housing **734** and remote electrode **756**.

[0080] In the embodiment of **FIG. 19**, an amplifier **796** is arranged to detect a voltage difference between conductive housing **734** and remote electrode **756**. Amplifier **796** is also capable of producing a signal **798** that is representative of the voltage difference between conductive housing **734** and remote electrode **756**. In the embodiment of **FIG. 19**, a first filter **230** and a second filter **232** are both connected to amplifier **796**.

[0081] First filter **230** may comprise, for example, a band-pass filter that passes a portion of signal **798** that is related to the respiration of a human patient. For example, first filter **230** may pass a portion of signal **798** having frequency's between about 0.2 Hz and about 2.0 Hz. A de-modulator **233** is provided for demodulating the respiration related portion of signal **798**.

[0082] Second filter **232** may comprise, for example, a band-pass filter that passes a portion of signal **798** that is related to ECG. For example, second filter **232** may pass a portion of signal **798** having frequency's between about 0.2 Hz and about 80.0 Hz. First filter **230** and second filter **232** are both electrically connected to a telemetry unit **764**. In some useful embodiments of the present invention, implantable medical device **700** is disposed inside a human body and telemetry unit **764** is capable of transmitting at least a portion of signal **798** to a receiver located outside of the body.

[0083] To extend the useful life, an implantable medical device **800** in accordance with the present invention may contain a rechargeable battery. As shown in **FIG. 20A** and **FIG. 20B**, recharging may be performed by transferring energy into implantable medical device **800** by transformer coupling energy from a recharging device **820**, located outside the body, to a coil located in implantable medical device **800**. The secondary of the transformer coil, located in implantable medical device **800**, would drive circuitry that would create a charging current for the rechargeable battery.

[0084] For convenience, the charging device may be battery powered and portable and could be worn by patient **20** in an elastic garment **852** when necessary for recharging. The use of an elastic garment **852** would assure the device were held stably in proper position for charging. Alternately, recharging device **820** could contain a replaceable adhesive surface such that it could be located on the skin in close proximity to implantable medical device **800**. In order to make it easy for the patient to place the recharging device properly, an indicator would tell the patient when the device was aligned properly, as measured by current being transferred into implantable medical device **800**. A second indicator may tell the patient when the rechargeable battery is fully charged based on information transmitted from the implantable device to the recharging device.

[0085] **FIG. 21** is a block diagram showing an implantable medical device **800** and a recharging device **820**. In the embodiment of **FIG. 21**, implantable medical device **800** is disposed inside a human body **22** and recharging device **820** is disposed outside of the human body **22**. The skin **60** of the human body **22** is shown extending between implantable medical device **800** and recharging device **820** in **FIG. 21**.

[0086] In the embodiment of **FIG. 21**, recharging device comprises a first coil **822** and a first battery **808** coupled to first coil **822** for exciting first coil **822**. A control circuit **826** is connected between first coil **822** and first battery **808**. Control circuit **826** is capable of generating the oscillating current necessary to inductively couple first coil **822** of recharging device **820** with a second coil **824** of implantable medical device **800**.

[0087] Implantable medical device comprises a second battery **828** and a second coil **824** coupled to second battery **828** for charging second battery **828**. A charging circuit **899** is connected between second coil **824** and second battery. Charging circuit **899** may comprise, for example, a voltage regulator that is capable of controlling the magnitude of the voltage that is applied to second battery **828** during charging. Charging circuit **899** may also comprise, for example, a current regulator that is capable of controlling the magnitude of the current that is applied to second battery **828** during charging.

[0088] In the embodiment of **FIG. 21**, first coil **822** and second coil **824** are inductively coupled to one another so that second battery **828** is charged while first battery **808** is depleted. With reference to **FIG. 21**, it will be appreciated that recharging device **820** comprises a housing **834** defining a cavity **836**. In the embodiment of **FIG. 21**, first battery **808** is disposed within cavity **836** defined by housing **834**. In some useful embodiments of the present invention, first battery **808** is capable of satisfying the power requirements of recharging device **820**. For example, first battery **808** may have sufficient capacity to fully charge second battery **828** and while, at the same time, compensating for energy lost during the charging of the second battery. In such embodiments, first battery **808** may be larger than second battery **828**. Also in such embodiments, first battery **808** may be the sole source of power for recharging device **820**. This arrangement may allow the user of implantable medical device to remain ambulatory during the charging process.

[0089] Various charging techniques are described in the following U.S. Pat. Nos.: 3,454,012; 3,824,129; 3,867,950; 3,492,535; 4,014,346; 4,057,069; 4,082,097; 4,096,866; 4,172,459; 4,441,210; 4,562,840; 4,679,560; 4,741,339; 5,279,292; 5,350,413; 5,411,537; 5,690,693; 5,702,431; 5,991,665; 6,067,474; 6,154,677; 6,324,431; 6,505,077; 6,516,227; 6,549,807; and 6,850,803. The entire disclosures of the above-mentioned U.S. Patents are hereby incorporated herein by reference.

[0090] In another embodiment, battery **828** of implantable medical device **828** may be recharged by deriving power from an implanted power source. Such an implanted power source may derive power from a human body by mechanical, thermal and/or chemical means. Examples of implantable power sources that derive power from a human body by thermal means include those described in U.S. Pat. No. 6,470,212 and U.S. Pat. No. 6,640,137. Examples of implantable power sources that derive power from a human body by mechanical means include those described in U.S. Pat. Nos. 3,943,936; 5,431,694; and 6,822,343 and U.K. Patent Application Number GB 2350302. The entire disclosure of each of the above-mentioned patents and patent application is hereby incorporated by reference herein. The implantable power source may be connected to charging circuit **899** and/or second battery **828** by a first wire and a second wire.

[0091] In some useful embodiments of the present invention, implantable medical device **800** may include a charge counter to track the amount of charge that has been consumed from the battery. In addition, implantable medical device **800** also incorporates a counter to track the amount of charge that has been depleted from battery **828**. By tracking charge added and charge depleted, remaining battery life can be determined and communicated to an external receiver. When battery **828** is fully charged, both the charge added and charge depleted counters are reset to zero. The circuits used to count charge have some inherent error. If this error were allowed to accumulate through multiple charges and discharges of battery **828**, the remaining charge in the battery as indicated by the charge added and charge depleted counters battery life indicator may have limited value. To address this problem, implantable medical device **800** contains a circuit that measures charging current to battery **828**. When the charging current present indicates that battery **828** has reached full charge, both the charge depleted and charge added counters are reset.

[0092] **FIG. 22** is a diagrammatic view of an implantable medical device **1100** in accordance with an additional exemplary embodiment of the present invention. Implantable medical device **1100** comprises a first energy storage element **1102** and a second energy storage element **1104**. In the embodiment of **FIG. 22**, first energy storage element **1102** comprises a capacitor **1106** and second energy storage element **1104** comprises a battery **1108**. In the embodiment of **FIG. 22**; implantable medical device **1100** employs a first energy storage element **1102**, such as capacitor **1106**, that can store a smaller amount of charge than can be stored in battery **1108**, but can store charge at a much faster rate than battery **1108**. By placing a charging device near implantable medical device **1100** for a short period of time, first energy storage element **1102** is fully charged. Once first energy storage element **1102** is fully charged, additional charge coupled into implantable medical device **1100** from the charging device may be directed toward charging battery **1108**. Once the charging device is pulled away and is no longer coupling energy into implantable medical device **1100**, the charge stored in first energy storage element **1102** is transferred into battery **1108**.

[0093] This architecture, employing a fast charging element and a slower charging element (e.g., a battery) may have advantages in certain situations. For example, suppose that battery **1108** had a charge capacity equal to about one hundred and fifty days of operation of implantable medical device **1100** and first energy storage element **1102** had a capacity of about seven days of operation. Normal charging time for battery **1108** may be about two hours, while charge time for first energy storage element **1102** was only about thirty seconds. In this scenario, the patient could obtain a charge equal to about one full week of operation in about thirty seconds. Many patients may find this protocol more convenient than wearing a vest holding a recharging device for two hours every three months.

[0094] **FIG. 23** is a block diagram showing an implantable medical device **1100** and a recharging device **1120** that may be used to recharge implantable medical device **1100**. In the embodiment of **FIG. 23**, recharging device **1120** comprises a first coil **1122** and a first battery **1108** coupled to first coil **1122** for exciting first coil **1122**. A control circuit **1126** is connected between first coil **1122** and first battery **1108**. Control circuit **1126** is capable of generating the oscillating current necessary to inductively couple first coil **1122** of recharging device **1120** with a second coil **1124** of implantable medical device **1100**.

[0095] Implantable medical device **1100** comprises a first energy storage element **1102** and a second energy storage element **1104**. In the embodiment of **FIG. 23**, first energy storage element **1102** comprises a capacitor **1106** and second energy storage element **1104** comprises a second battery **1128**. A second coil **1124** and a first regulator **1130** are connected to first energy storage element **1102**.

[0096] In the embodiment of **FIG. 23**, second coil **1124** and first regulator **1130** can cooperate to charge first energy storage element **1102**. First regulator **1130** is capable of controlling the flow of current and the magnitude of voltage applied to first energy storage element so that first energy storage element **1102** is charged at a first charging rate. First regulator **1130** may comprise, for example, a current regulator and/or a voltage regulator.

[0097] In the embodiment of **FIG. 23**, a second regulator **1132** is interposed between the first energy storage element **1102** and second energy storage element **1104**. Second regulator **1132** is capable of controlling the flow of current and the magnitude of voltage applied to second energy storage element so that second energy storage element **1104** is charged at a second charging rate. Second regulator **1132** may comprise, for example, a current regulator and/or a voltage regulator.

[0098] In the embodiment of **FIG. 23**, capacitor **1106** is capable of being charged at a faster rate than battery **1108**. Accordingly, the second charging rate is slower than the first charging rate. Although one capacitor **1106** is illustrated in **FIG. 23**, it will be appreciated that embodiments are possible in which capacitor **1106** comprises a plurality of capacitors.

[0099] As shown in **FIG. 23**, implantable medical device **1100** comprises a housing **1134** defining a cavity **1136**. Housing **1134** may comprise various materials without deviating from the spirit and scope of the present invention. Examples of materials that may be suitable in some applications include titanium and stainless steel. With reference to **FIG. 23**, it will be appreciated that second coil **1124**, first regulator **1130** and first battery **1108** are disposed in cavity **1136** defined by housing **1134**.

[0100] **FIG. 24** is a block diagram showing an implantable medical device **1200** and a recharging device **1220** that may be used to recharge implantable medical device **1200**. In the embodiment of **FIG. 24**, recharging device **1220** comprises a first coil **1222** and a first battery **1208** coupled to first coil **1222** for exciting first coil **1222**. A control circuit **1226** is connected between first coil **1222** and first battery **1208**. Control circuit **1226** is capable of generating the oscillating current necessary to inductively couple first coil **1222** of recharging device **1220** with a second coil **1224** of implantable medical device **1200**.

[0101] Second coil **1224** of implantable medical device **1200** is coupled to a first energy storage element **1202** by a diode **1238**. Implantable medical device **1200** also includes a second energy storage element **1204**. In the embodiment of **FIG. 24**, second coil **1224** and diode **1238** can cooperate to charge first energy storage element **1202**. In the embodiment of **FIG. 24**, a regulator **1232** is interposed between the first energy storage element **1202** and second energy storage element **1204**. Regulator **1232** is capable of controlling the flow of current and the magnitude of voltage applied to second energy storage element so that second energy storage element **1204** is charged at a controlled charging rate. Regulator **1232** may comprise, for example, a current regulator and/or a voltage regulator.

[0102] In the embodiment of **FIG. 24**, first energy storage element **1202** comprises a capacitor **1206** and second energy storage element **1204** comprises a battery **1208**. In this embodiment, capacitor **1206** is capable of being charged at a faster rate than battery **1208**. Accordingly, regulator **1232** may be used to charge battery **1208** at a second charging rate is slower than a first charging rate that capacitor **1206** is capable of. Although one capacitor **1206** is illustrated in **FIG. 24**, it will be appreciated that embodiments are possible in which capacitor **1206** comprises a plurality of capacitors.

[0103] As shown in **FIG. 24**, implantable medical device **1200** comprises a housing **1234** defining a cavity **1236**. Housing **1234** may comprise various materials without deviating from the spirit and scope of the present invention. Examples of materials that may be suitable in some applications include titanium and stainless steel. With reference to **FIG. 24**, it will be appreciated that second coil **1224**, first regulator **1230** and first battery **1208** are disposed in cavity **1236** defined by housing **1234**.

[0104] **FIG. 25** shows a flowchart **1404** illustrating an exemplary method in accordance with the present invention. Block **1402**A of flowchart **1404** illustrates the step of forming a pocket **1460** in a left implant site **1444** in the body of a patient **20**. In should be noted that pocket **1460** may be formed in a right implant site **1446** of the body of patient **20** without deviating from the spirit and scope of the present invention. Pocket **1460** may be formed, for example, by making an incision **1403** with a cutting tool and pushing a blunt object through the incision **1403** to displace tissue and form pocket **1460**. Pocket **1460** may also be formed by pushing gloved fingers through incision **1403**.

[0105] Block **1402**B of flowchart **1404** illustrates the step of inserting an implantable monitoring device **1400** in pocket **1460**. Implantable monitoring device may comprise, for example, the implantable medical devices described herein. Implantable monitoring device **1400** may be inserted through incision **1403** so that the housing of implantable monitoring device **1400** is positioned within pocket **1460** adjacent to incision **1403**. Incision **1403** may then be closed and the patient may be allowed to go about a normal daily routine.

[0106] Block **1402**C of flowchart **1404** illustrates the step of monitoring the patient. Implantable monitoring device **1400** may detect various physiological parameters such as, for example, ECG, pressure and temperature. Implantable monitoring device **1400** may transmit (e.g., wirelessly) signals related to these parameters to a repeater worn by or kept near patient **20**. Patient **20** may be monitored during normal daily activity for a period of weeks, months and/or years.

[0107] A method in accordance with the present invention may include, for example, the steps of placing an implantable monitoring device comprising a conductive housing and a remote electrode in a left implant site **1444** and detecting a voltage difference between the remote electrode and the conductive housing. This method may further include the step of producing a signal representative of the voltage difference between the remote electrode and the conductive housing. The signal may be transmitted to a receiver located outside the human body. Information obtained during the monitoring step may be analyzed to determine what type of implantable therapy device may be appropriate for patient **20**.

[0108] Block **1402**D of flowchart **1404** illustrates the steps of removing implantable monitoring device **1400** from pocket **1460** and inserting an implantable therapy device **1411** in pocket **1460**. In some useful methods in accordance with the present invention, implantable monitoring device **1400** is removed from pocket **1460** and implantable therapy device **1411** is inserted in pocket **1460** during a single surgical procedure. In the embodiment of **FIG. 25**, implantable monitoring device **1400** and implantable therapy device **1411** have similar shapes and a similar in size.

[0109] Implantable therapy device **1411** may comprise various elements without deviating from the spirit and scope of the present invention. Examples of implantable therapy devices that may be suitable in some applications include pacemakers, defibrillators, and/or cardioverters. In some useful methods in accordance with the present invention, pocket **1460** is disposed in a location which will allow leads connected to implantable therapy device **1411** to travel through the vasculature of patient **20** to the heart of patient **20**.

[0110] **FIGS. 26 and 27** are diagram views showing a placement tool **1320** that may be employed to deploy an implantable medical device **1300** in accordance with the present invention. Placement tool **1320** comprises a wall **1321** defining a lumen **1325**. A shaft **1327** has been inserted into the lumen **1325** of placement tool **1320**. To implant implantable medical device **1300**, an incision **1302** is made where the device is to be inserted under the skin **60** of patient **20**. Placement tool **1320** is directed through the incision **1302** and under the skin **60** until the distal end of placement tool **1320** is proximate a desired location for implantable medical device **1300**. Shaft **1327** is moved distally so that implantable medical device **1300** exits the distal end of placement tool **1320**. Placement tool **1320** may then be extracted, leaving implantable medical device **1300** in the desired position.

[0111] It should be recognized to those skilled in the art that the devices described here can be applied for monitoring of other physiological signals such as those which can be measured on or within the heart, brain, bladder, transplanted organs, arteries, veins, and other body tissues.

[0112] Those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described herein. Accordingly, departures in form and detail may be made without departing from the spirit and scope of the present invention as described in the appended claims.

What is claimed is:

1. A method comprising the steps of:

forming a pocket in an implant site overlaying a rib cage of a human body;

inserting an implantable monitoring device into the pocket;

removing the implantable monitoring device from the pocket; and

inserting an implantable therapy device into the pocket.

2. The method of claim 1, wherein the implantable monitoring device has a size and shape that is similar to a size and shape of the implantable therapy device.

3. The method of claim 2, further including the steps of:

detecting a voltage difference between a conductive housing of the heart monitor and a remote electrode of the heart monitor.

producing a signal representative of the voltage difference between the remote electrode and the conductive housing; and

transmitting the signal to a receiver located outside the human body.

4. The method of claim 1, wherein the implant site extends between a skin and a rib cage of the human body.

5. The method of claim 1, wherein the implant site extends between a left-most extent of a sternum of the human body and a left-most extent of a rib cage of the human body.

6. The method of claim 1, wherein the implant site extends between a right-most extent of a sternum of the human body and a right-most extent of a rib cage of the human body.

7. The method of claim 1, wherein the implant site extends between a lower-most surface of a clavicle of the human body and a lower-most extent of a sternum of the human body.

8. The method of claim 1, wherein the heart monitor is placed between a skin and a rib cage of the human body.

9. The method of claim 1, wherein the heart monitor is placed between a left-most extent of a sternum of the human body and a left-most extent of a rib cage of the human body.

10. The method of claim 1, wherein the heart monitor is placed between a right-most extent of a sternum of the human body and a right-most extent of a rib cage of the human body.

11. The method of claim 1, wherein the heart monitor is placed between a lower-most surface of a clavicle of the human body and a lower-most extent of a sternum of the human body.

12 A method comprising the steps of:

placing an implantable medical device comprising a conductive housing and a remote electrode in an implant site proximate a left arm of a human body;

detecting a voltage difference between the remote electrode and the conductive housing;

producing a signal representative of the voltage difference between the remote electrode and the conductive housing; and

transmitting the signal to a receiver located outside the human body.

13. The method of claim 12, wherein the step of placing the implantable medical device in the implant site comprises the steps of:

forming a pocket in the implant site; and

inserting the conductive housing into the pocket.

14. The method of claim 13, further including the steps of:

removing the implantable medical device from the pocket; and

inserting a heart therapy device into the pocket.

15. The method of claim 12, wherein the step of placing the remote electrode and the conductive housing in the implant site comprises the steps of:

forming a pocket in the implant site;

forming a channel in the implant site such that the channel communicates with the pocket;

placing the remote electrode in the channel;

connecting the remote electrode to the conductive housing; and

placing the conductive housing in the pocket.

16. The method of claim 12, wherein the implant site extends between a skin and a rib cage of the human body.

17. The method of claim 12, wherein the implant site extends between a left-most extent of a sternum of the human body and a left-most extent of a rib cage of the human body.

18. The method of claim 12, wherein the implant site extends between a right-most extent of a sternum of the human body and a right-most extent of a rib cage of the human body.

19. The method of claim 12, wherein the implant site extends between a lower-most surface of a clavicle of the human body and a lower-most extent of a sternum of the human body.

20. The method of claim 12, wherein the remote electrode and the conductive housing are both placed between a skin and a rib cage of the human body.

21. The method of claim 12, wherein the remote electrode and the conductive housing are both placed between a left-most extent of a sternum of the human body and a left-most extent of a rib cage of the human body.

22. The method of claim 12, wherein the remote electrode and the conductive housing are both placed between a right-most extent of a sternum of the human body and a right-most extent of a rib cage of the human body.

23. The method of claim 12, wherein the remote electrode and the conductive housing are both placed between a lower-most surface of a clavicle of the human body and a lower-most extent of a sternum of the human body.

24. The method of claim 12, wherein the remote electrode and the conductive housing are placed so that the remote electrode and the conductive housing are separated by a center-to center distance that is pre-selected for fitting the remote electrode and the conductive housing within the implant site.

25. The method of claim 24, wherein the pre-selected distance is greater than about 4.0 centimeters and less than about 10.0 centimeters.

26. The method of claim 25, wherein the pre-selected distance is greater than about 5.0 centimeters and less than about 7.0 centimeters.

27. The method of claim 12, wherein the remote electrode and the conductive housing are placed so that the remote electrode and the conductive housing define an overall length of the implantable medical device that is pre-selected for fitting the remote electrode and the conductive housing within the implant site.

28. The method of claim 27, wherein the overall length is greater than about 4.0 centimeters and less than about 13.0 centimeters.

29. The method of claim 25, wherein the overall length is greater than about 5.0 centimeters and less than about 10.0 centimeters.

30. The method of claim 12, further comprising the steps of receiving the transmitted signal and re-transmitting the signal.

31. The method of claim 30, further comprising the steps of receiving the re-transmitted signal and communicating the signal over a network.

32. The method of claim 31, wherein the network comprises the internet.

33. The method of claim 31, further including the step of analyzing the signal.

34. The method of claim 33, wherein the signal is analyzed after the signal is communicated over the network.

35. The method of claim 12, wherein the signal is transmitted substantially in real time.

36. The method of claim 12, wherein the signal transmitted at a given point in time is representative of the voltage difference being detected at the given point time.

37. The method of claim 12, wherein the signal is a function of the voltage difference between the remote electrode and the conductive housing.

38. The method of claim 12, wherein the step of producing a signal representative of the voltage difference between the remote electrode and the conductive housing comprises the step of amplifying the voltage difference between the remote electrode and the conductive housing.

39. The method of claim 12, further comprising the step of filtering the signal.

40. An implantable medical device, comprising:

a conductive housing;

a remote electrode mechanically coupled to the conductive housing by a lead body;

an amplifier electrically connected to the remote electrode and the conductive housing for providing a signal representative of a voltage difference between the remote electrode and the conductive housing.

41. The implantable medical device of claim 40, wherein further including a battery disposed in the conductive housing.

42. The implantable medical device of claim 41, wherein further including a battery disposed in the conductive housing.

43. The implantable medical device of claim 42, wherein the implantable power source comprises a means for generating power from a human body.

44. The implantable medical device of claim 40, wherein the lead body separates remote electrode and the conductive housing by a center to center distance that is selected so that the conductive housing, the remote electrode, and the lead body will all be received in an implant site overlaying one half of a rib cage of a human body.

45. The implantable medical device of claim 44, wherein the implant site extends between a skin and a rib cage of the human body.

46. The implantable medical device of claim 44, wherein the implant site extends between a left-most extent of a sternum of the human body and a left-most extent of a rib cage of the human body.

47. The implantable medical device of claim 44, wherein the implant site extends between a right-most extent of a sternum of the human body and a right-most extent of a rib cage of the human body.

48. The implantable medical device of claim 44, wherein the implant site extends between a lower-most surface of a clavicle of the human body and a lower-most extent of a sternum of the human body.

49. The implantable medical device of claim 44, wherein the pre-selected distance is greater than about 4.0 centimeters and less than about 10.0 centimeters.

50. The implantable medical device of claim 44, wherein the pre-selected distance is greater than about 5.0 centimeters and less than about 7.0 centimeters.

51. The implantable medical device of claim 40, wherein the remote electrode is detachably attached to the conductive housing by the lead body.

52. The implantable medical device of claim 40, further comprising a transmitter for transmitting a signal produced by the amplifier.

53. The implantable medical device of claim 40, wherein the lead body has sufficient lateral flexibility to allow relative motion between the electrode and the conductive housing in response to muscle movements of the human body.

54. The implantable medical device of claim 40, wherein the lead body has sufficient longitudinal stiffness to maintain spacing between the electrode and the conductive housing.

55. The implantable medical device of claim 40, wherein the remote electrode has a generally circular lateral cross section.

56. The implantable medical device of claim 40, wherein the remote electrode comprises a generally cylindrical body portion.

57. The implantable medical device of claim 40, wherein the remote electrode comprises a rounded tip portion.

58. The implantable medical device of claim 57, wherein the remote electrode comprises a generally hemispherical tip portion.

59. The implantable medical device of claim 40, wherein the remote electrode is free of anchors.

60. The implantable medical device of claim 40, wherein the lead body is free of anchors.

61. In combination:

a charging device comprising a first coil and a first battery coupled to the first coil for exciting the first coil;

an implantable medical device comprising a second battery and a second coil coupled to the second battery for charging the second battery;

the first coil and the second coil being inductively coupled to one another so that the second battery is charged while the first battery is depleted.

62. The combination of claim 61, wherein the implantable medical device is disposed inside a human body and the charging device is disposed outside of the human body.

63. The combination of claim 61, wherein the charging device comprises a housing defining a cavity.

64. The combination of claim 63, wherein the first battery is disposed within the cavity defined by the housing of the charging device.

65. The combination of claim 61, wherein the first battery is capable of satisfying the power requirements of the charging device.

66. The combination of claim 61, wherein the first battery is larger than the second battery.

67. The combination of claim 66, wherein the first battery is sufficiently larger than the second battery so that the first battery has sufficient capacity for fully charging the second battery and compensating for energy lost during the charging of the second battery.

68. The combination of claim 61, wherein the first battery is the sole source of power for the charging device.

69. The combination of claim 61, further comprising a garment for holding the charging device proximate the implanted medical device.

70. The combination of claim 69, wherein the garment comprises a pocket that is dimensioned to receive the charging device.

71. An implantable medical device, comprising:

a first energy storage element;

a first coil and a first regulator coupled to the first energy storage element for charging the first energy storage element at a first charging rate;

a second energy storage element coupled to the first energy storage element; and

a second regulator interposed between the first energy storage element and the second energy storage element for charging the second energy storage element at a second charging rate.

72. The implantable medical device of claim 71, wherein the second charging rate is different from the first charging rate.

73. The implantable medical device of claim 72, wherein the second charging rate is slower than the first charging rate.

74. The implantable medical device of claim 71, wherein the first energy storage element comprises one or more capacitors.

75. The implantable medical device of claim 71, further comprising a housing defining a cavity.

76. The implantable medical device of claim 75, wherein the housing comprises a metallic material.

77. The implantable medical device of claim 76, wherein the metallic material comprises titanium.

78. The implantable medical device of claim 75, wherein the first coil is disposed in the cavity defined by the housing.

79. The implantable medical device of claim 71, wherein the second energy storage element comprises a battery.

80. An implantable medical device, comprising:

a first energy storage element;

a coil coupled to the first energy storage element for charging the first energy storage element;

a second energy storage element coupled to the first energy storage element; and

a regulator interposed between the first energy storage element and the second energy storage element for charging the second energy storage element at a second charging rate.

81. The implantable medical device of claim 80, further including a diode connected between the coil and the first energy storage element.

82. The implantable medical device of claim 80, wherein the first energy storage element comprises one or more capacitors.

83. The implantable medical device of claim 80, further comprising a housing defining a cavity.

84. The implantable medical device of claim 83, wherein the housing comprises a metallic material.

85. The implantable medical device of claim 85, wherein the metallic material comprises titanium.

86. The implantable medical device of claim 83, wherein the first coil is disposed in the cavity defined by the housing.

87. The implantable medical device of claim 80, wherein the second energy storage element comprises a battery.

88. A method for placing an implantable medical device in a body, comprising the steps of:

providing an implantable medical device disposed in a lumen defined by a placement tool;

inserting a distal end of the placement tool into the body; and

moving a shaft distally within the lumen of the placement tool for urging the implantable medical device to exit the distal end of the placement tool.

89. In combination:

a placement tool having a proximal end, a distal end, and a lumen extending therebetween;

a shaft disposed in sliding engagement with the lumen of the placement tool;

the shaft being partially disposed within the lumen of the placement tool; and

an implantable medical device disposed in the lumen of the delivery tool.

90. The combination of claim 89, wherein a distal end of the shaft is disposed in the lumen of the placement tool and a proximal end of the shaft is disposed outside of the lumen of the placement tool.

91. The combination of claim 89, wherein the implantable medical device is disposed proximate a distal end of the placement tool.

92. The combination of claim 89, wherein the implantable medical device is disposed proximate a distal end of the shaft.

93. The combination of claim 92, wherein a distal end of the shaft contacts the implantable medical device.

94. The combination of claim 89, wherein the implantable medical device comprises a first electrode, a second electrode, and an amplifier electrically connected to the first electrode and the second electrode for providing a signal representative of a voltage difference between the first electrode and the second electrode.

95. The combination of claim 94, wherein the first electrode and the second electrode are capable of contacting a tissue of a body.

96. The combination of claim 89, wherein the implantable medical device is capable of detecting a physiological parameter of a human body.

97. The combination of claim 96, wherein the physiological parameter is selected from the group consisting of ECG, pressure, patient activity, patient posture, impedance, respiratory rate, respiratory effort, and glucose.

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patsnap

专利名称(译)	植入式医疗器械和相关方法		
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[标]申请(专利权)人(译)	布罗克韦BRIAN P MILLS佩里 FOSTER ARTHURĴ LAMBERT SCOTT SHERWOOD KATHY大号		
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当前申请(专利权)人(译)	布罗克韦BRIAN P MILLS佩里 FOSTER ARTHURĴ LAMBERT SCOTT SHERWOOD KATHY大号		
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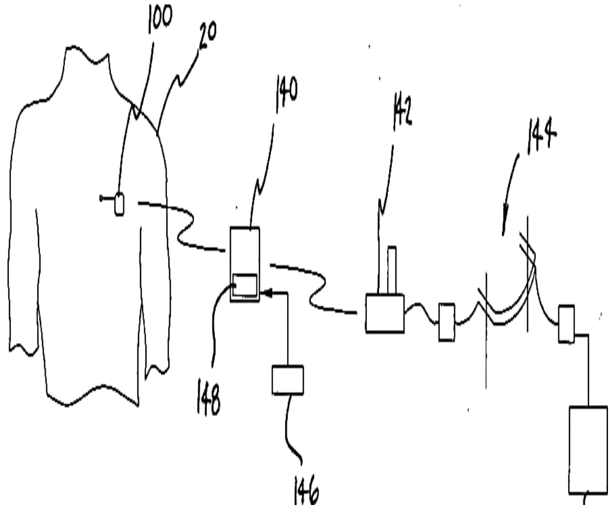
摘要(译)

公开了可植入的医疗装置和相关方法。在一个实施方式中，可植入医疗装置包括导电壳体和远程电极，远程电极通过引线体机械地耦合到导电壳体。放大器电连接到远程电极和导电壳体，用于提供表示远程电极和导电壳体之间的电压差的信号。在根据本发明的一些方法中，将可植入医疗装置植入覆盖人体肋骨的一半的植入部位。可植入医疗设备产生表示远程电极和导电外壳之间的电压差的信号，并且信号被传输到位于人体外部的接收器。



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