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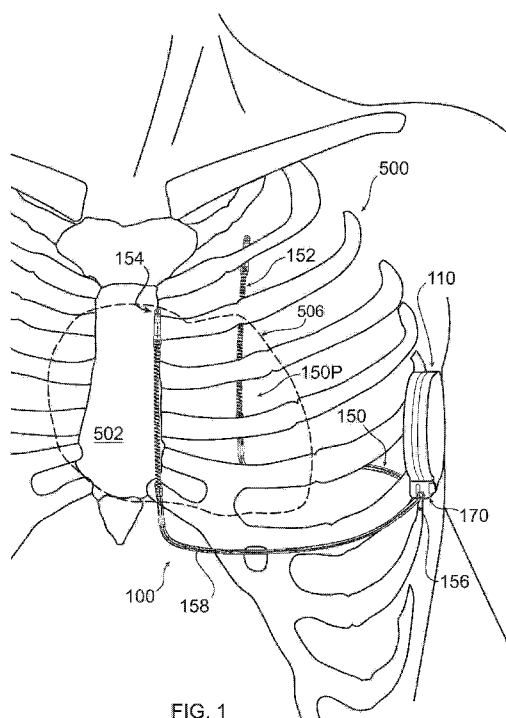
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(54) Title: SUBCUTANEOUS DEFIBRILLATION



(57) Abstract: Cardioversion or defibrillation of the heart is carried out by passing electrical energy through the heart. An electrical energy storage device, such as a battery and capacitor, are connected to an electronic processor. The energy storage device and the electronic processor are sized to be implantable within the body of the patient. Two leads are subcutaneously implanted and connected to the energy storage device under control of the processor. An electrode is connected to each lead, and are also subcutaneously implanted, the first able proximate the heart and an anterior portion of the ribcage in the patient's chest, and the second proximate the heart and a posterior portion of the ribcage in the patients back. Sensors transmit information to the processor relating to heart function, and under control of software, the processor causes the electrodes to be energized to restore normal heart function.



SUBCUTANEOUS DEFIBRILLATION

FIELD OF THE DISCLOSURE

5 The disclosure relates to a system and method for subcutaneous defibrillation, and in particular, using two subcutaneous coils positioned along anterior and posterior aspects of the body.

BACKGROUND OF THE DISCLOSURE

10 The subcutaneous implantable cardioverter defibrillator (S-ICD) can be used to prevent sudden cardiac death in patients who do not have a cardiac pacing indication. The device includes a control and power device connected to a coil, each implanted subcutaneously. Subcutaneous implantation facilitates long term lead management options which are particularly advantageous for patients at high risk for infection, while sustaining non-inferior
15 supra ventricular tachycardia discrimination compared to trans-venous systems.

By not being inserted into the vascular space, the use of an S-ICD can result in a decreased frequency of systemic infections, vascular stenosis, and significant problems of lead extraction.

20 SUMMARY OF THE DISCLOSURE

In an embodiment of the disclosure, a device for causing cardioversion or defibrillation of the heart of a patient comprises at least one electrical energy storage device; an electronic processor; the at least one electrical energy storage device and the electronic processor sized to be implantable within the body of the patient; two leads each sized to be subcutaneously
25 implantable within the body of the patient, the leads selectively connectible to one of the at least one electrical energy storage device by the electronic processor; a first electrode electrically connected to a lead and sized to be subcutaneously implantable proximate the heart and an anterior portion of the ribcage; a second electrode electrically connected to a lead and sized to be subcutaneously implantable proximate the heart and a posterior portion
30 of the ribcage; one or more sensors connected to the electronic processor to transfer information to the electronic processor relating to a physiological condition of the patient; and a data storage medium having program instructions readable by the electronic processor

to use the transferred sensor information to cause the processor to selectively connect one or both leads to at least one of the at least one electrical energy storage device.

In variations thereof, the electrical energy storage device includes at least one battery and at least one capacitor, the two leads selectively connectable to the at least one capacitor by the electronic processor; the device further includes a housing for containing the electrical energy storage device, the electronic processor, and the storage medium; the housing is sealed for implantation within the body; the housing includes at least two sockets for electrically connecting the first and second electrodes to the electrical energy storage device under control of the electronic processor; the housing has a curved shaped which corresponds to body anatomy at a site of implantation of the housing; and/or a surface of the housing forms an electrode.

In other variations thereof, the data storage medium and the processor are integrated into a single housing; at least one of the first and second electrodes includes an energy transmitting coil; the energy transmitting coil is sized to extend along an area substantially the length of the heart; the at least one electrode physically supports at least one of the one or more sensors; and/or the physiological condition of the patient is at least one of tachycardia, bradycardia, arrhythmia, flutter, lack of heartbeat.

In further variations thereof, the electrical energy storage device can produce between 10 and 18J; the one or more sensors includes a sensor for detecting a heartbeat; the device further includes one or more additional electrodes, the one or more additional electrodes cooperative with at least one of the first and second electrodes to form an electrical pathway at least one of through or proximate the heart; and/or the processor is configured to selectively assign a polarity to at least one of the first and second electrodes.

In another embodiment of the disclosure, a method for causing cardioversion or defibrillation of the heart of a patient, comprises providing at least one electrical energy storage device; an electronic processor; the at least one electrical energy storage device and the electronic processor sized to be implantable within the body of the patient; two leads each sized to be subcutaneously implantable within the body of the patient, the leads selectively connectable to one of the at least one electrical energy storage device by the electronic processor; a first electrode electrically connected to a lead and sized to be subcutaneously implantable proximate the heart and an anterior portion of the ribcage; a second electrode electrically connected to a lead and sized to be subcutaneously implantable proximate the heart and a posterior portion of the ribcage; one or more sensors connected to the electronic processor to transfer information to the electronic processor relating to a physiological

condition of the patient; and a data storage medium having program instructions readable by the electronic processor to use the transferred sensor information to cause the processor to selectively connect one or both leads to at least one of the at least one electrical energy storage device.

5 In variations thereof, the method further includes providing instructions to subcutaneously implant the first electrode proximate the heart and an anterior portion of the ribcage, and to implant the second electrode proximate the heart and a posterior portion of the ribcage; and/or the instructions detail that proximate the anterior portion of the ribcage is adjacent to the sternum, and that proximate the posterior portion of the ribcage is adjacent to
10 the spine.

In a further embodiment of the disclosure, a method for enabling subcutaneous cardioversion or defibrillation of the heart of a patient comprises subcutaneously implanting a first electrode within the chest, proximate the heart; subcutaneously implanting a second electrode within the back, proximate the heart; subcutaneously implanting a control unit
15 connected to the first and second electrode by one or more subcutaneously implanted wires, the control unit including: at least one electrical energy storage device; an electronic processor configured to selectively connect one of the first, second, or first and second electrodes to the electrical energy storage device via the one or more implanted wires; and a data storage medium connected to the processor and including program instructions readable
20 by the electronic processor to cause the processor to selectively connect one or both leads to at least one of the at least one electrical energy storage device.

In variations thereof, the method further includes using one or more sensors connected to the electronic processor to transfer information to the electronic processor relating to a physiological condition of the patient; and/or the method further includes subcutaneously
25 implanting an additional electrode that is not positioned upon the control unit.

BRIEF DESCRIPTION OF THE DRAWINGS

A more complete understanding of the present disclosure, and the attendant advantages and features thereof, will be more readily understood by reference to the following detailed
30 description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 depicts the anterior portion of the ribcage, and a cardioversion/defibrillator system of the disclosure including two electrodes, one placed alongside the sternum, and the other alongside the spine;

FIG. 2 depicts a perspective view of the ribcage, showing an alternative low profile low density cardioversion/defibrillator system of the disclosure, including two electrodes, one placed alongside the sternum, and the other alongside the spine, all in accordance with the disclosure;

5 FIG. 3 depicts a perspective view of the ribcage from the back, illustrating the device of FIG. 2;

FIG. 4 depicts a left side view of the device of FIG. 2, illustrating a curvature of the device;

FIG. 5 depicts a front view of the device of FIG. 2;

10 FIG. 6 depicts a right side view of the device of FIG. 2;

FIG. 7 depicts a top view of the device of FIG. 2, illustrating a transverse curvature of the device;

FIG. 8 depicts a back view of the device of FIG. 2, showing an electrode plate of the disclosure;

15 FIG. 9 depicts a front of the device of FIG. 2, including a socket assembly of the disclosure having two sockets;

FIG. 10 depicts a front view of the device of FIG. 2, including an alternate socket assembly of the disclosure including two sockets which accept a connection from relatively opposite directions;

20 FIG. 11 depicts a cross-sectional view of the device of FIG. 2, taken along line C-C of FIG. 5, showing internal components of a control unit of the disclosure;

FIG. 12 depicts the system of FIG. 2, further including a remote electrode; and

FIG. 13 depicts an electrical pathway of the disclosure which passes through the heart.

25 DETAILED DESCRIPTION OF THE DISCLOSURE

As required, detailed embodiments are disclosed herein; however, it is to be understood that the disclosed embodiments are merely examples and that the systems and methods described below can be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis
30 for the claims and as a representative basis for teaching one skilled in the art to variously employ the present subject matter in virtually any appropriately detailed structure and function. Further, the terms and phrases used herein are not intended to be limiting, but rather, to provide an understandable description of the concepts.

The terms “a” or “an”, as used herein, are defined as one or more than one. The term plurality, as used herein, is defined as two or more than two. The term another, as used herein, is defined as at least a second or more. The terms “including” and “having,” as used herein, are defined as comprising (i.e., open language). The term “coupled,” as used herein, is defined as “connected,” although not necessarily directly, and not necessarily mechanically.

An example of a subcutaneous ICD (implantable cardioverter-defibrillator) is the EMBLEM S-ICD model A209 of BOSTON SCIENTIFIC corporation. According to the manufacturer, this device has a Pulse Generator having a mass of 130g, a volume of 59.5 cc, a longevity of 7.3 years, a LiMnO₂ battery, and has a 3400/3401 compatible electrode. It is programmable, and automatically functions to sense a configuration, gain, rhythm discrimination, shock polarity, adaptive shock polarity, SMART charge, and internal warning system. It is programmable for a shock zone between 170 bpm and 250 bpm in steps of 10 bpm, post shock pacing, induction capability, delivered energy that is normally 80J biphasic, but is programmable in manual mode between 10J and 80J in steps of 5J, and provides up to 5 shocks per episode. It can record data for S-ECG for over 40 arrhythmic events, electrode impedance, system status including remaining battery life, and patient alerts, and a data and time stamp.

A subcutaneous electrode useable with the A209 includes the model 3401, which is shown in the illustrations. The electrode is tripolar, is 45 cm long, and has a distal tip diameter of 12 Fr/4 mm, and a defibrillation coil diameter is 9 Fr/3mm. A distal sensor having a surface area of 46 mm² is located at the tip of the electrode, and a proximal sensor having a surface area of 36 mm² is located 120 mm from the tip. The defibrillation surface area of the defibrillation coil is 750 mm², and the defibrillation coil extends between 20 to 100 mm from the tip. The insulation is polyurethane, the electrodes, conductors, and connector pins are made from MP35N, and the suture sleeve is made from silicone.

The S-ICD is termed ‘touchless’, as it does not require contact with the heart. It is a subcutaneous form of an implantable defibrillator that has the capacity to rescue a patient from cardiac arrest via defibrillation. It has one coil that senses and shocks using a vector with the capacitor. The coil is subcutaneously tunneled to a capacitor in a device which is implanted under the axilla.

With reference to FIG. 1, a subcutaneous ICD (implantable cardioverter-defibrillator), or SICD 100 of the disclosure includes a control unit 110 / 110A (generally designated as 110, herein), and at least two electrodes, in the embodiment shown designated as 150A and 150P, referred to herein generally as 150. Control unit 110 contains components providing

the functionality of a pulse generator, including a battery 112, capacitor 114, and control electronics 120 (as depicted and described further with respect to FIG. 10). The electrodes 150 can be of the type 3401 described above, or any other electrode known or hereinafter developed that can provide a subcutaneous cardioversion or defibrillation function, and which may, in various embodiments, be modified as otherwise described herein.

It should be understood that the battery 112 and capacitor 114 may be replaced with a single device able to store a sufficient charge, and to discharge at a sufficient rate, to carry out a cardioversion/defibrillation function. Alternatively, the capacitor 114 can be replaced with any device which is capable of discharging an amount of electrical energy over time sufficient to cause cardioversion and/or defibrillation. Advantageously, components of a device of the disclosure, including control unit 110/110A, electrodes, and wires, are all MRI compatible.

In FIG. 1, a ribcage 500 is shown, with the posterior portion not shown, to facilitate visualization of a second electrode 150P positioned subcutaneously within the back of a patient. For example, electrode 150P can be placed along the posterior mid-clavicular line, and placed cranio-caudally medial to the scapula, on the left side of the body. Other locations substantially to the left or right of the mid-clavicular line, or substantially superior or inferior to medial to the scapula can be used in accordance with the disclosure. Selection of a location can be made with a view to avoiding subcutaneous and visceral adipose, including epicardial and pericardial fat, which can tend to increase energy required, for example as determined during Defibrillation Threshold Testing (DFT). Without being bound to any particular theory, it is possible that improved results in accordance with the disclosure relate to most of the epicardial and pericardial fat being located anterior to the heart 506, and a posterior coil positioned according to the disclosure may circumvent this area of higher tissue impedance. This is illustrated in FIG. 13, which shows an electrical pathway or defibrillation vector "A" which passes through the heart between electrodes 150 and 150P, one of which is the cathode and the other the anode.

The implantation of electrodes 150, and the A209 and similar electrodes, is documented in the associated literature provided by Boston Scientific. Electrodes 150 and 150P are implanted using a technique similar to that described therein with respect to an electrode implanted alongside the sternum, and at a superior/inferior height corresponding to a location of the heart.

For example, a pocket is formed according to anatomical landmarks provided by the manufacturer, for example along the sixth rib, at the location where control unit 110 is

shown. An incision is made proximate the xyphoid, and a rod is passed subcutaneously between these first two incisions to form an access channel therebetween. A messenger line is pulled through the channel as the rod is withdrawn, and the electrode is pulled through the channel from the pocket to the xyphoid incision using the messenger line. A sleeve (not shown) is placed upon lead 158 near the incision. The electrode is positioned along the side of the sternum 502, and is used to gauge a location for a sternal incision, for example proximate the third rib. A rod is passed subcutaneously from the xyphoid incision to the sternal incision, passing a messenger line which is used to draw the electrode subcutaneously into the xyphoid incision and into a position alongside the sternum. A fixation loop 154 at the distal end of the electrode 150 is used to suture the distal end of the electrode to body tissue, to maintain a superior/inferior (hereinafter 'vertical') alignment of electrode 150. At the pocket, a connector 156 is inserted into a mating socket 170 within control unit 110, and a key (not shown) is used to lock the connector to prevent it from being pulled from socket 170. Control unit 110 is then inserted into the pocket, and the incisions are closed.

In addition to attachment at tissue fixation loop 154, lead 150 can be secured by sutures at other locations, for example near where lead 150 bends and extends laterally at an inferior end of coil 152.

In an embodiment, electrode 152P has the same general design of electrode 150, although it may be configured to transmit a larger or smaller amount of power, and could be longer or shorter, for example. A similar process as previously described is used to subcutaneously implant electrode 150P along a posterior portion of the ribcage adjacent to and to the left of the spine 504. However, maneuvering to tunnel a posterior coil can be facilitated by repositioning a sedated patient into a right lateral decubitus position, or by suspending the patient by the arms or axillae in a seated upright position. In this manner, coils 152 of both electrodes 150, 150P overlap the heart laterally and along a vertical axis. In an embodiment, an incision is made proximate each of a connection of the fourth rib and the eighth rib, although a more superior or inferior position can be used, as determined to be most efficacious by clinical results or the medical practitioner. In an embodiment, coil 150 is oriented at distance from the spine to enable coil 150 to lie at a substantially uniform distance from the ribs along the length of coil 150. Depending upon the size of the patient, this can typically be between 2 and 10 cm from a center of the spine, although a greater lateral offset can be used where the medical practitioner deems more advantageous results would be obtained.

It should be understood that the foregoing is one arrangement of the electrodes 150 in accordance with the disclosure. In another embodiment, the electrodes are each oriented to extend along a lateral axis, with either electrode 150 or 150P positioned superior with respect to the other, and with portions of the heart disposed along a path therebetween. Alternatively, the electrodes can be oriented along a superior/inferior axis, but are offset relative to each other laterally, with either electrode 150 or 150P positioned relatively more medial. Still further, an alternative is to position one electrode to be oriented laterally, and another to be oriented vertically, with the heart lying along a path therebetween. Any of the illustrated or foregoing configurations may further be configured to include one or more additional electrodes, oriented in any of the configurations described.

Control unit 110 includes the features of, for example Boston Scientific model A209, however it is adapted according to the invention to control two or more electrodes, as described herein. In an embodiment, both electrodes are connected to the same capacitor or other high discharge rate component, and are energized simultaneously. As such, control unit 110 deviates from the design of the A209, among other ways described herein, by providing an additional connector for electrode 150P. Alternatively, a splice may be made in lead 158 to branch to a second electrode.

While the presence of two electrodes can result in a synergy enabling a single electrode to be effective with a relatively reduced output relative to a single electrode configuration, it is advantageous in some configurations for the combined output of both electrodes to be greater than the total output of a single electrode configuration. Accordingly, control unit 110 can be configured to provide a larger power output than a single electrode device of the prior art. Further, one electrode can be used initially, and a second electrode can be used where the first electrode is sensed to be ineffective. Additionally or alternatively, the electrodes can alternate or be energized in various patterns, as determined to be most efficacious for the patient, or as determined to be effective by clinical studies or compiled patient data.

In an alternative embodiment of the disclosure, control unit 110 includes an electronic processor that is configured to independently control each of the more than one electrode 150, for example to phase activation of each coil 152 over time relative to each other. Software for controlling the processor can be embedded within the processor, or can be stored on computer readable media connected to the processor. Additionally or alternatively, control unit 110 can be configured to output a different power level to each coil 152. The relative timing and power levels are selected by the processor using control logic, or are

preprogrammed into the control unit, in order to achieve a likely optimal result for the patient, based upon historical data for the patient, or based upon clinical data.

FIG. 2 illustrates a perspective view of the entire ribcage, illustrating one possible location of electrode 150P in accordance with the disclosure. Control unit 110A is as described herein for control unit 110, however a thinner, lower profile shape is provided. Control unit 110A further has a larger diameter, rendering the device less dense. More particularly, as further visible in FIGS. 3-12, a housing 122 of control unit 110A is configured to have a larger peripheral dimension than the prior art, in order to achieve a slimmer height. In addition, housing 122 is curved along at least one axis, and in the embodiment illustrated, two axes, to more closely conform to patient anatomy along the side surface of the chest. The disclosure is not limited to positioning of control 110/110A in the anatomical position illustrated, however, and can include left or right prepectoral or axial locations for example, or any other location within the body, and housing 122 can be shaped to best conform to such location. Stem cell treatment and other methods of promoting angiogenesis can be used to reduce migration.

An additional advantage of a larger peripheral profile is a reduced density, which reduces a potential for migration of control unit 110 until sufficient adhesions to housing 122 are formed, and otherwise until healing takes place within the pocket formed in body tissue. The inventor has found that for some patients, and particularly obese patients, a prior art pulse generator device tended to move substantially, which caused discomfort, and eventually a displacement of the electrode. By reducing the density of control unit 110, weight is distributed over a larger region of body tissue, thereby mitigating a likelihood of migration. To further reduce the potential for migration where indicated, suture loops 188 can be provided, positioned as shown in FIG. 10, for example, and control unit 110A can be sutured to body tissue at the proper location.

As can be seen in the figures, housing 122 forms a gentle slope and a thin profile, which minimizes visibility and interference with movement. Housing 122 additionally forms low profile openings into which a connector can be inserted, which include internal insulators, fluid seals, and locking mechanisms, as known in the art. In the embodiment shown, a socket 170 is positioned along a left edge of housing 122, positioned anteriorly when housing 122 is implanted, to thereby orient a connector 156 of a lead 158 to advance anteriorly. A similar connector 170P is oriented along a posterior edge of housing 122, to thereby orient a connector 156 of a lead 158 of electrode 150P to advance posteriorly.

FIGS. 4-11 depict curved housing 112 in greater detail. Arrows “A” and “B” depict the curvature from top to bottom and side to side, respectively. The extent of curvature along arrows A and B can be different, and they may be compound curves, or only one of A and B can be curved. The curvature is selected to conform to the subcutaneous anatomy of a typical patient; to any of an age, gender, or weight of a patient; or to an individual patient.

In the embodiment shown, a grounding electrode 180 is provided upon a surface of control unit 110. In FIG. 1, electrode 180 is disposed about a periphery of control unit 110. FIG. 8 illustrates an electrode plate 182 exposed upon surface of housing 112 which faces the heart when control unit 110A is implanted. It may be seen that plate 182 is configured to occupy a substantial portion of the area of the surface, to distribute current flow over a greater portion of body tissue, to mitigate pain and potential tissue damage. In FIGS. 2-11, a peripheral electrode 180 is positioned in a similar manner to FIG. 1, and plate 182 is additionally provided. However, a single one of either electrode 180 or 182 can be provided.

FIGS. 9 and 10 illustrate alternative socket styles. In FIG. 9, a two lead socket assembly 174 is adapted to extend from an edge of control unit 110. In FIG. 10, for socket assembly 176, one socket leads anteriorly, and the other leads posteriorly, to reduce a length of a subcutaneous travel path for at least one lead 158. With respect to socket assembly 174, a single small incision can be made to disconnect both leads for replacement of the leads. With respect to socket type 176, it is possible to manipulate control unit 110 to align each socket with the incision, or alternatively, to stretch a smaller incision to access both sides of the socket assembly. Manipulation of control unit 110 or stretching of a single incision can also be carried out for sockets 170A, 170P of the embodiment of FIG. 5, although two very small incisions can also be made.

It should be understood that any of socket assembly 174 or 176, or socket 170A or 170P, can be disposed along any edge or portion of housing 112, advantageously to minimize a subcutaneous path of any leads extending from control unit 110.

FIG. 11 illustrates a cross-section taken through line C-C of FIG. 5, diagrammatically illustrating one embodiment of a configuration of control unit 110. The relative sizes and shapes of the various components depicted in FIG. 11 are determined by available technology and the requirements of the particular application as described herein. However, it may be seen that components are packaged to best exploit the curved interior shape of housing 112. In an embodiment, the same components that are found in model A209 are positioned within housing 112, although processor or control chip logic or software programming, as well as sockets and associated wiring, at least, are modified as described herein. In the embodiment

shown, battery 112 and/or capacitor 114 can be formed to have a curved shape, or they can be comprised of one or more regular or orthogonal shapes that are interconnected. An electronics control board 120 is positioned above (or below) the battery and capacitor, and may be shaped to fit the available space. Board 120 can include the components included within model A209, and/or can include a processor 124, memory 126, and signal processing 128 components. An induction coil and related componentry can further be provided, for charging battery 112 transdermally.

With reference to FIG. 12, in a further embodiment of the disclosure, one or more additional electrodes 186 are subcutaneously implantable to be positioned remote from the control unit, between all or a portion of the heart and electrode 150/150P. Such electrodes can be positioned closer to the heart, or at locations which define a more direct path to an electrode 150 and/or 150P which passes through a desired portion of the heart. This can result in a reduced power level requirement, reducing pain and potential tissue damage to the patient, and reducing current requirements of device 100. Additional connector sockets 170 can be provided within control unit 110 to enable a connection of additional electrode 186, or a Y-connector can be used if electrode 186 is intended to be active together with another electrode.

In accordance with the disclosure, electrode plate 182 may be provided with a reverse polarity, and any of electrode 186, 150A, and 150P may be provided with the same or an opposite polarity. Further, the polarity of these various conductors can be change during defibrillation, to switch from anode to cathode or vice versa, either once, or in a pattern of alternating polarity, as is found to best restore proper cardiac function. In other embodiments, electrode plate 182 may not form part of a circuit, and control unit 110/110A thereby forms a “cold can” and does not have a surface component that forms a circuit with body tissue, for all or a part of a therapeutic application of electrical energy to the body, and electrodes 150, 150P have opposite polarities relative to each other. In one embodiment, an electrical pathway is created between electrodes 150, 150P, and an electrode 182 positioned upon housing 122. In a variation, electrodes 150 and 182 both form either the cathode or anode, and electrode 150P forms the other of the cathode and anode. Alternatively, electrode 150P and 182 can have the same polarity, and electrode 150 has a different polarity. The polarity and timing of any polarity changes can be controlled by processor 124, or by an electrical circuit within control unit 110/110A.

Electrode 150A includes proximal and distal sensor 162, 164, respectively, which provide information to control unit 110 with respect to a physiological state of the patient, for

example tachycardia, bradycardia, arrhythmia, flutter, lack of heartbeat, or any other condition relevant to a therapeutic need for cardioversion or defibrillation. It may unnecessary, therefore, to provide such sensors upon posterior electrode 150P, thereby reducing the cost and complexity of device 100. Alternatively, either all sensors can be placed upon electrode 150P, or one or more sensors can be duplicated upon electrode 150P, thereby providing redundancy, error checking, and greater reliability for the patient.

Where sensor data from both electrodes are not in accord, control unit can notify the patient or medical practitioners via an emitted sound, or via communication using a network, such as a BLUETOOTH, WIFI, IoT network, or other known or hereinafter developed means. Other error or warning conditions, or historical data, can be similarly transmitted.

Accordingly, the disclosure can be used to increase the effectiveness and reliability of cardioversion or defibrillation. A second electrode provides an increased probability of restoring a normal heart rhythm by any or all of boosting the power applied to the heart, providing an alternative current pathway through the heart, and by providing a synergistic and cooperative relationship between two electrodes. The disclosure additionally provides redundancy in events where one electrode is inoperative when needed. The disclosure can be particularly effective in cases where obesity can otherwise render a single electrode configuration ineffective, for example due to the presence of epicardial, sternal subcutaneous, and visceral fat which may increase shocking impedance causing operational failure, including failure during defibrillation threshold testing. This in turn can cause an increase in morbidity and mortality. This disclosure provides a strengthened signal, and an additional and alternate pathway for energy to pass from coils 152 to the electrical conduction system of the heart, and/or to heart muscle, to restore normal rhythm. More rapid defibrillation, and fewer required attempts, result in a reduction in pain to the patient, particularly during threshold testing, and reduces the time for such procedures.

All references cited herein are expressly incorporated by reference in their entirety. It will be appreciated by persons skilled in the art that the present disclosure is not limited to what has been particularly shown and described herein above. In addition, unless mention was made above to the contrary, it should be noted that all of the accompanying drawings are not to scale. There are many different features to the present disclosure and it is contemplated that these features may be used together or separately. Thus, the disclosure should not be limited to any particular combination of features or to a particular application of the disclosure. Further, it should be understood that variations and modifications within the spirit and scope of the disclosure might occur to those skilled in the art to which the disclosure

pertains. Accordingly, all expedient modifications readily attainable by one versed in the art from the disclosure set forth herein that are within the scope and spirit of the present disclosure are to be included as further embodiments of the present disclosure.

THE CLAIMS

What is claimed is:

1. A device for causing cardioversion or defibrillation of the heart of a patient,
5 comprising:
at least one electrical energy storage device;
an electronic processor;
the at least one electrical energy storage device and the electronic processor sized to be
implantable within the body of the patient;
10 two leads each sized to be subcutaneously implantable within the body of the patient,
the leads selectively connectable to one of the at least one electrical energy storage device by
the electronic processor;
a first electrode electrically connected to a lead and sized to be subcutaneously
implantable proximate the heart and an anterior portion of the ribcage;
15 a second electrode electrically connected to a lead and sized to be subcutaneously
implantable proximate the heart and a posterior portion of the ribcage;
one or more sensors connected to the electronic processor to transfer information to the
electronic processor relating to a physiological condition of the patient; and
a data storage medium having program instructions readable by the electronic processor
20 to use the transferred sensor information to cause the processor to selectively connect one or
both leads to at least one of the at least one electrical energy storage device.
2. The device of claim 1, wherein the electrical energy storage device includes at least
one battery and at least one capacitor, the two leads selectively connectable to the at least one
25 capacitor by the electronic processor.
3. The device of claim 1, further including a housing for containing the electrical
energy storage device, the electronic processor, and the storage medium.
- 30 4. The device of claim 3, wherein the housing is sealed for implantation within the
body.

5. The device of claim 4, wherein the housing includes at least two sockets for electrically connecting the first and second electrodes to the electrical energy storage device under control of the electronic processor.

5 6. The device of claim 3, the housing having a curved shaped which corresponds to body anatomy at a site of implantation of the housing.

7. The device of claim 3, wherein a surface of the housing forms an electrode.

10 8. The device of claim 1, wherein the data storage medium and the processor are integrated into a single housing.

9. The device of claim 1, wherein at least one of the first and second electrodes includes an energy transmitting coil.

15

10. The device of claim 9, wherein the energy transmitting coil is sized to extend along an area substantially the length of the heart.

11. The device of claim 1, wherein the at least one electrode physically supports at least
20 one of the one or more sensors.

12. The device of claim 1, wherein the physiological condition of the patient is at least one of tachycardia, bradycardia, arrhythmia, flutter, lack of heartbeat.

25 13. The device of claim 1, wherein the electrical energy storage device can produce between 10 and 18J.

14. The device of claim 1, wherein the one or more sensors includes a sensor for detecting a heartbeat.

30

15. The device of claim 1, further including one or more additional electrodes, the one or more additional electrodes cooperative with at least one of the first and second electrodes to form an electrical pathway at least one of through or proximate the heart.

16. The device of claim 1, wherein the processor is configured to selectively assign a polarity to at least one of the first and second electrodes.

17. A method for causing cardioversion or defibrillation of the heart of a patient,
5 comprising:
providing:

at least one electrical energy storage device;

an electronic processor;

10 the at least one electrical energy storage device and the electronic processor
sized to be implantable within the body of the patient;

two leads each sized to be subcutaneously implantable within the body of the
patient, the leads selectively connectible to one of the at least one electrical energy
storage device by the electronic processor;

15 a first electrode electrically connected to a lead and sized to be
subcutaneously implantable proximate the heart and an anterior portion of the
ribcage;

a second electrode electrically connected to a lead and sized to be
subcutaneously implantable proximate the heart and a posterior portion of the
ribcage;

20 one or more sensors connected to the electronic processor to transfer
information to the electronic processor relating to a physiological condition of the
patient; and

a data storage medium having program instructions readable by the electronic
processor to use the transferred sensor information to cause the processor to
25 selectively connect one or both leads to at least one of the at least one electrical
energy storage device.

18. The method of claim 17, further including providing instructions to subcutaneously
implant the first electrode proximate the heart and an anterior portion of the ribcage, and to
30 implant the second electrode proximate the heart and a posterior portion of the ribcage.

19. The method of claim 17, wherein the instructions detail that proximate the anterior
portion of the ribcage is adjacent to the sternum, and that proximate the posterior portion of
the ribcage is adjacent to the spine.

20. A method for enabling subcutaneous cardioversion or defibrillation of the heart of a patient, comprising:

subcutaneously implanting a first electrode within the chest, proximate the heart;

5 subcutaneously implanting a second electrode within the back, proximate the heart;

subcutaneously implanting a control unit connected to the first and second electrode by one or more subcutaneously implanted wires, the control unit including:

at least one electrical energy storage device;

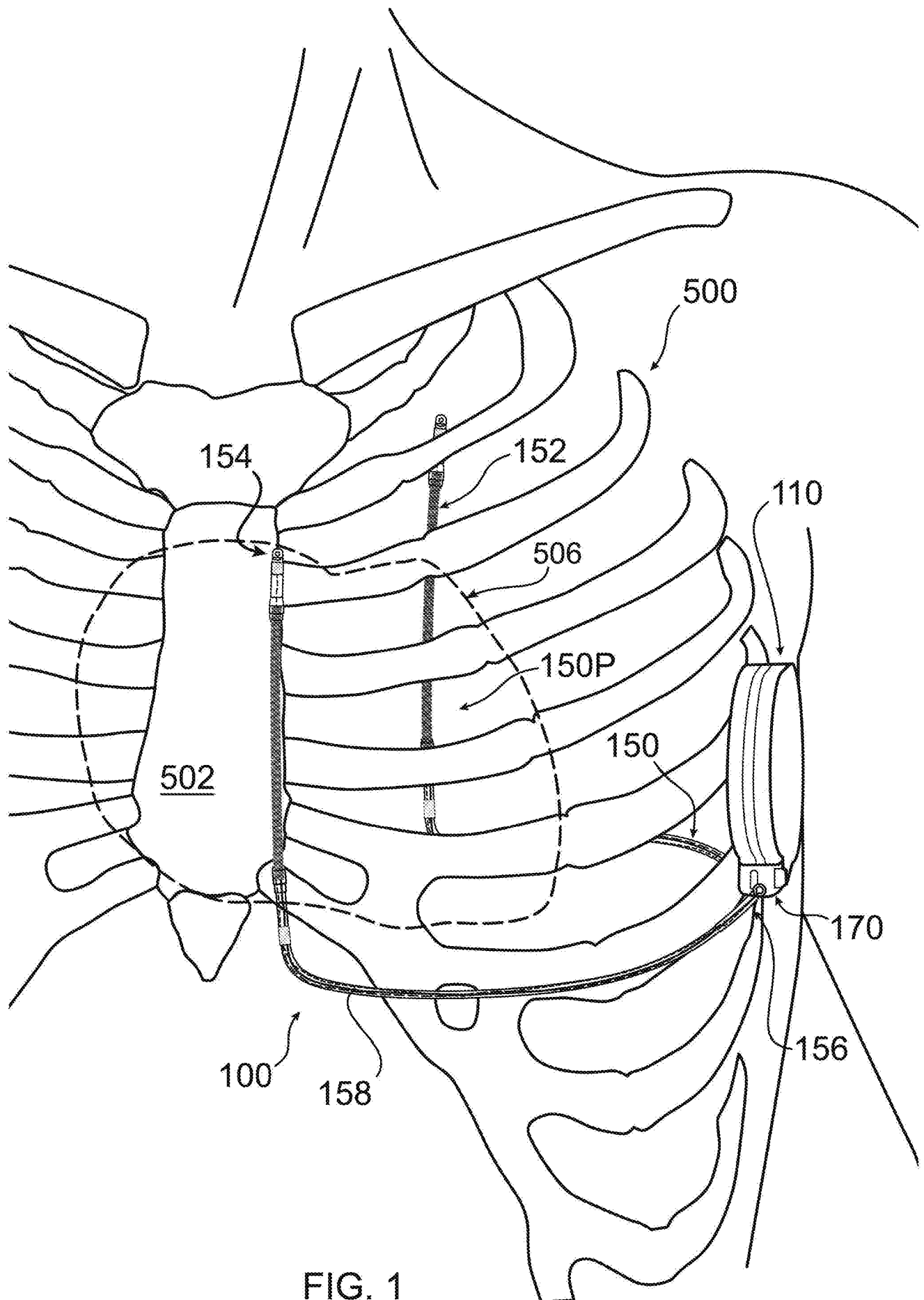
10 an electronic processor configured to selectively connect one of the first, second, or first and second electrodes to the electrical energy storage device via the one or more implanted wires; and

15 a data storage medium connected to the processor and including program instructions readable by the electronic processor to cause the processor to selectively connect one or both leads to at least one of the at least one electrical energy storage device.

21. The method of claim 20, further including one or more sensors connected to the electronic processor to transfer information to the electronic processor relating to a physiological condition of the patient.

20

22. The method of claim 20, further including subcutaneously implanting an additional electrode that is not positioned upon the control unit.



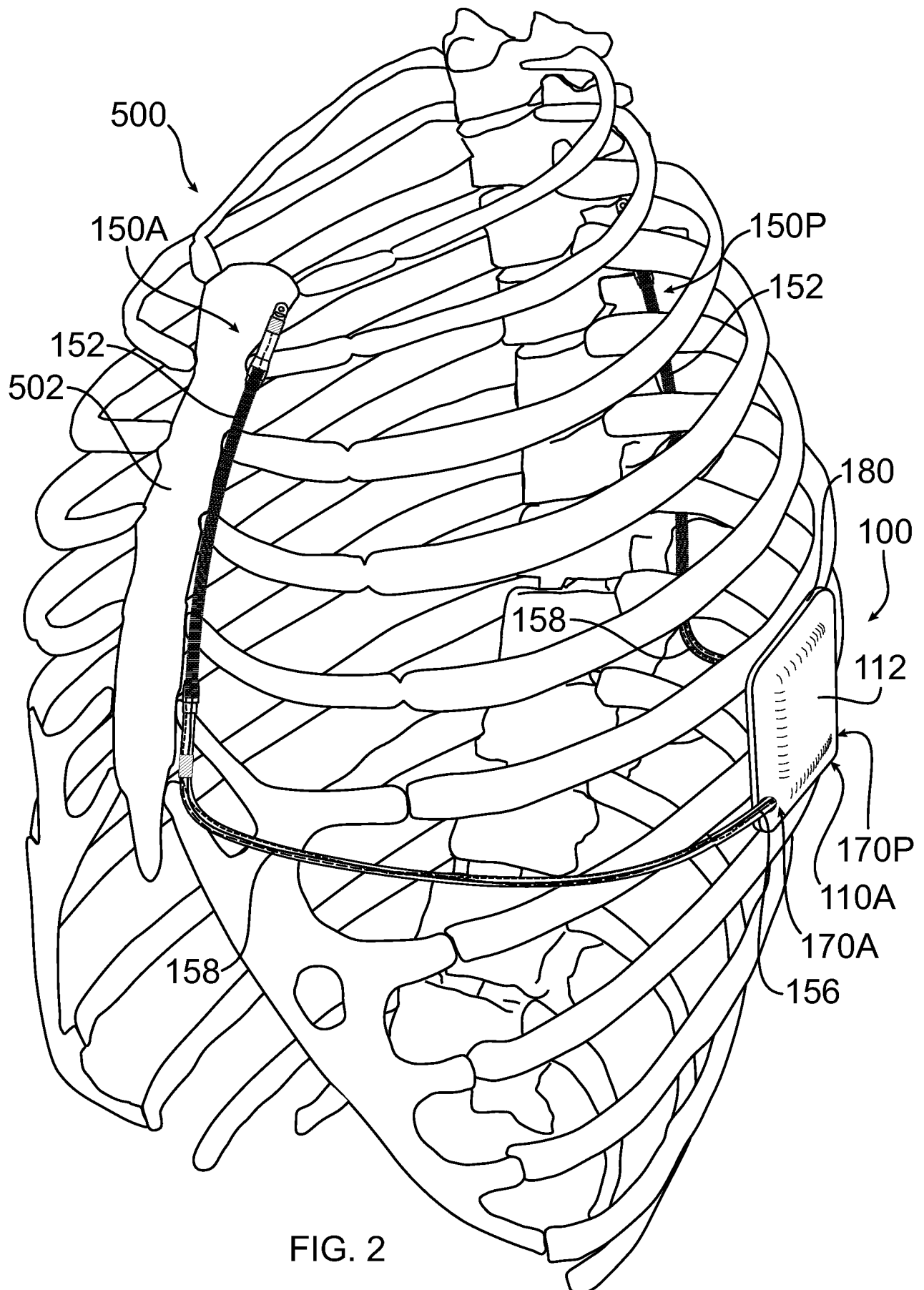


FIG. 2

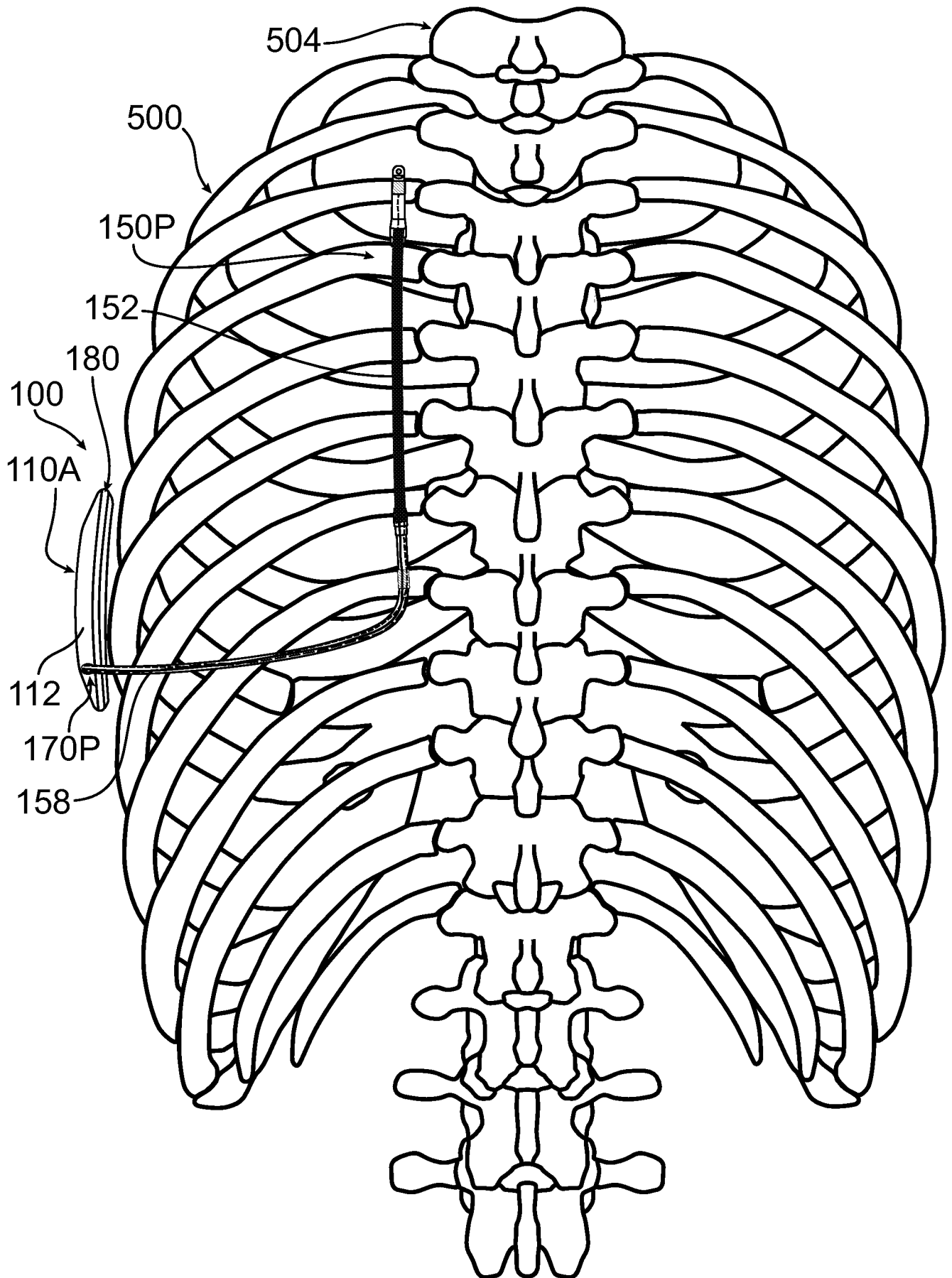
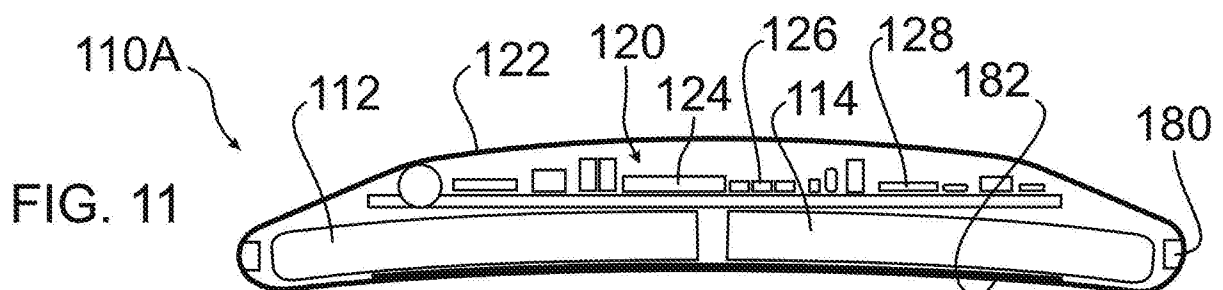
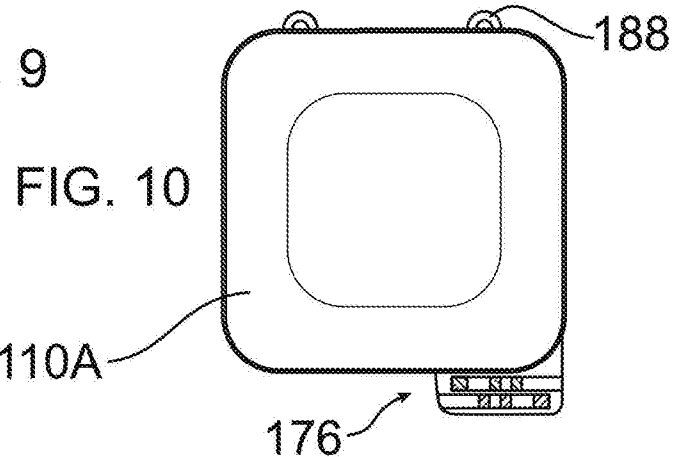
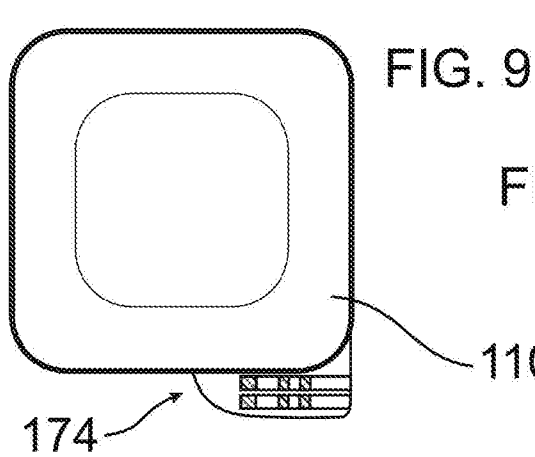
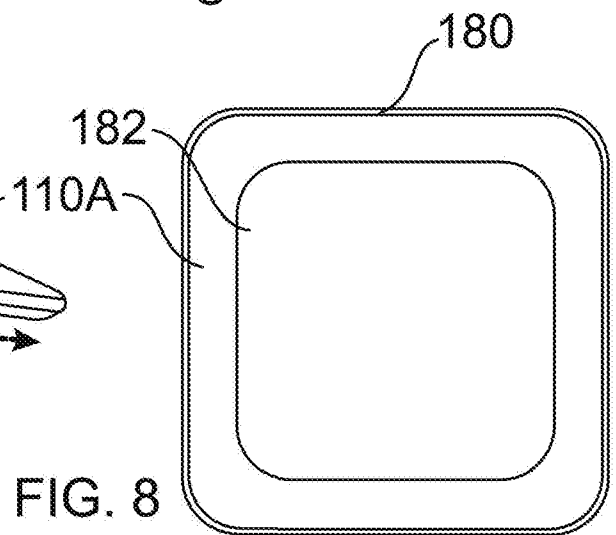
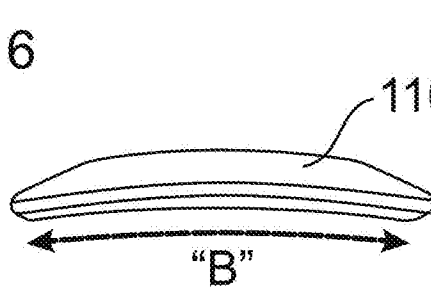
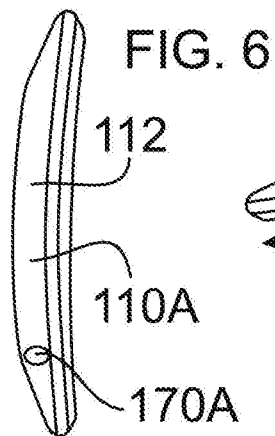
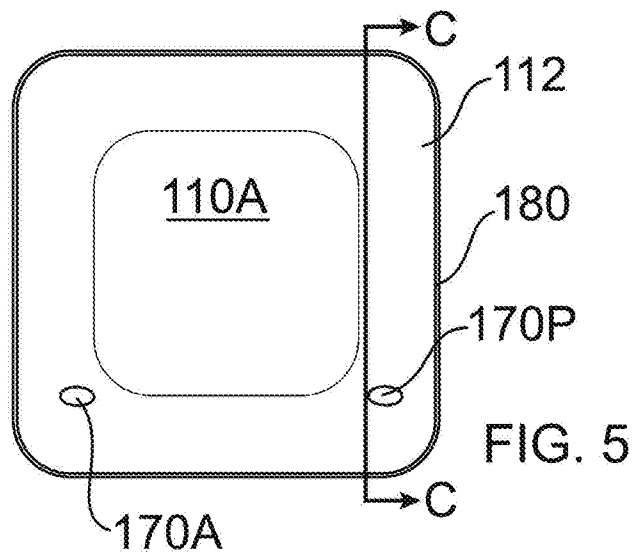
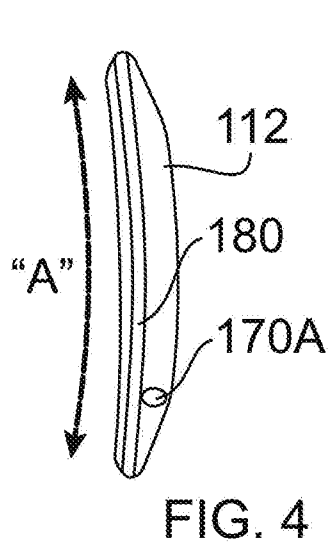


FIG. 3



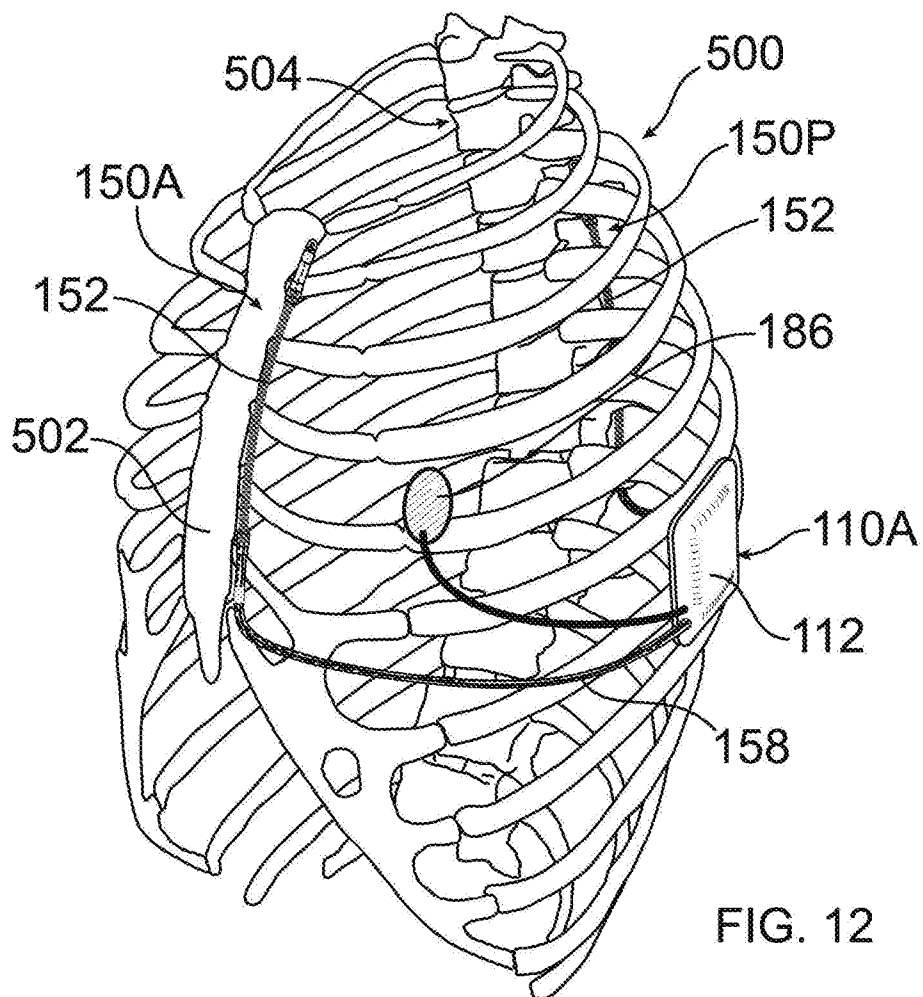


FIG. 12

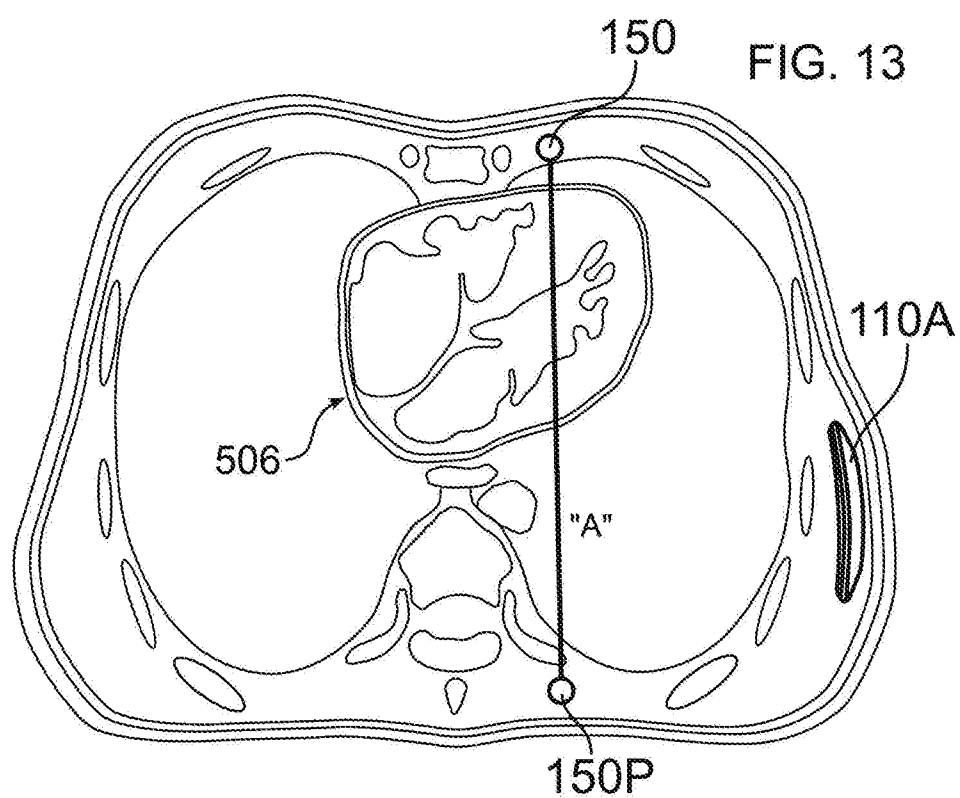


FIG. 13

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2017/026751

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61N 1/05; A61N 1/372; A61N 1/375; A61N 1/39 (2017.01)

CPC - A61N 1/0504; A61N 1/0563; A61N 1/3956 (2017.02)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

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

USPC - 607/5; 607/7; 607/9; 607/36; 607/119 (keyword delimited)

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2013/0211205 A1 (HAVEL et al) 15 August 2013 (15.08.2013) entire document	1-4, 6-9, 11-14, 17-21
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Y		5, 10, 15, 16, 22
Y	US 8,532,779 B2 (KRAUSE et al) 10 September 2013 (10.09.2013) entire document	5, 15, 16, 22
Y	US 2016/0121130 A1 (MEDTRONIC INC) 05 May 2016 (05.05.2016) entire document	10

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

31 May 2017

Date of mailing of the international search report

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