



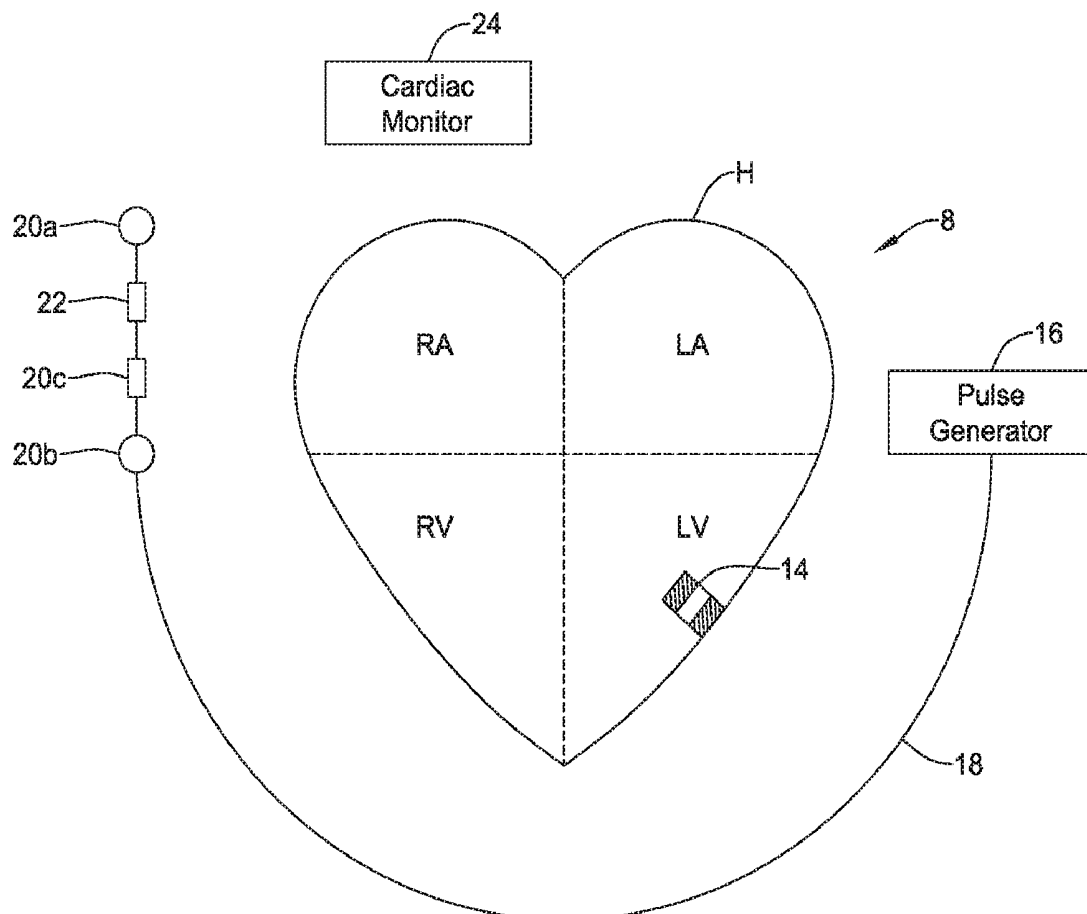
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(19) **United States**(12) **Patent Application Publication**
Koop et al.(10) **Pub. No.: US 2018/0078771 A1**(43) **Pub. Date: Mar. 22, 2018**(54) **IMPLANTABLE CARDIAC MONITOR****Publication Classification**(71) Applicant: **CARDIAC PACEMAKERS, INC.**, St. Paul, MN (US)(51) **Int. Cl.**
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A61N 1/372 (2006.01)(72) Inventors: **Brendan Early Koop**, Ham Lake, MN (US); **Lance Eric Juffer**, Lino Lakes, MN (US); **Michael J. Kane**, St. Paul, MN (US); **Benjamin J. Haasl**, Forest Lake, MN (US); **Keith R. Maile**, New Brighton, MN (US); **Arthur J. Foster**, Blaine, MN (US)(52) **U.S. Cl.**
CPC *A61N 1/37* (2013.01); *A61B 5/6886* (2013.01); *A61B 5/0402* (2013.01); *A61N 1/37211* (2013.01); *A61B 5/0031* (2013.01); *A61B 5/6869* (2013.01)(73) Assignee: **CARDIAC PACEMAKERS, INC.**, St. Paul, MN (US)(21) Appl. No.: **15/710,464**(22) Filed: **Sep. 20, 2017****Related U.S. Application Data**

(60) Provisional application No. 62/397,894, filed on Sep. 21, 2016.

(57) **ABSTRACT**

An implantable cardiac monitor (ICM) may be configured to be deployed subcutaneous, submuscular, or substernal at a position that enables the ICM to detect cardiac activity. In some cases, the ICM includes a housing that includes a body portion and a tail portion. A first electrode may be disposed adjacent a first end of the body portion, a second electrode may be disposed adjacent a second end of the body portion and a third electrode may be disposed adjacent a tail end of the tail portion. A controller may be disposed within the housing and may be operably coupled to the first electrode, the second electrode and the third electrode. The controller may be configured to select a pair of the first electrode, the second electrode and the third electrode to use for sensing cardiac electrical activity and to communicate information about the sensed activity to a second medical device.



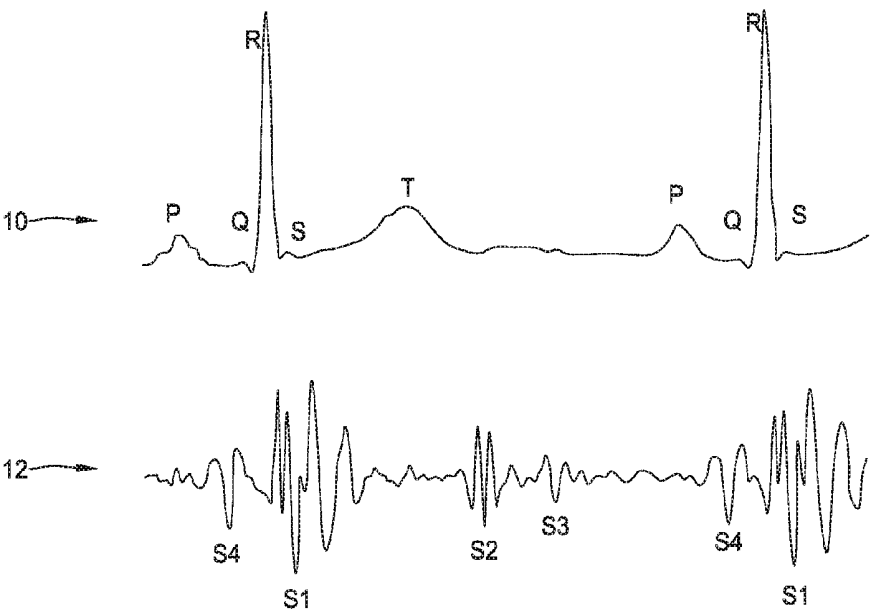


FIG. 1

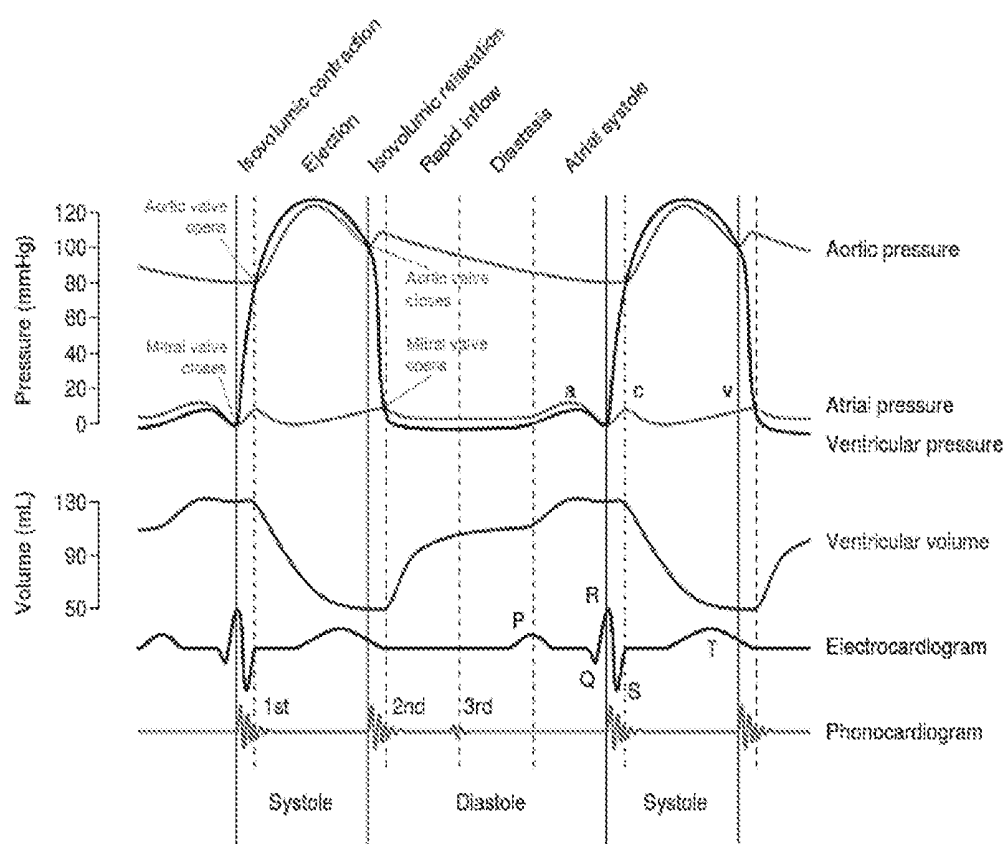


FIG. 2

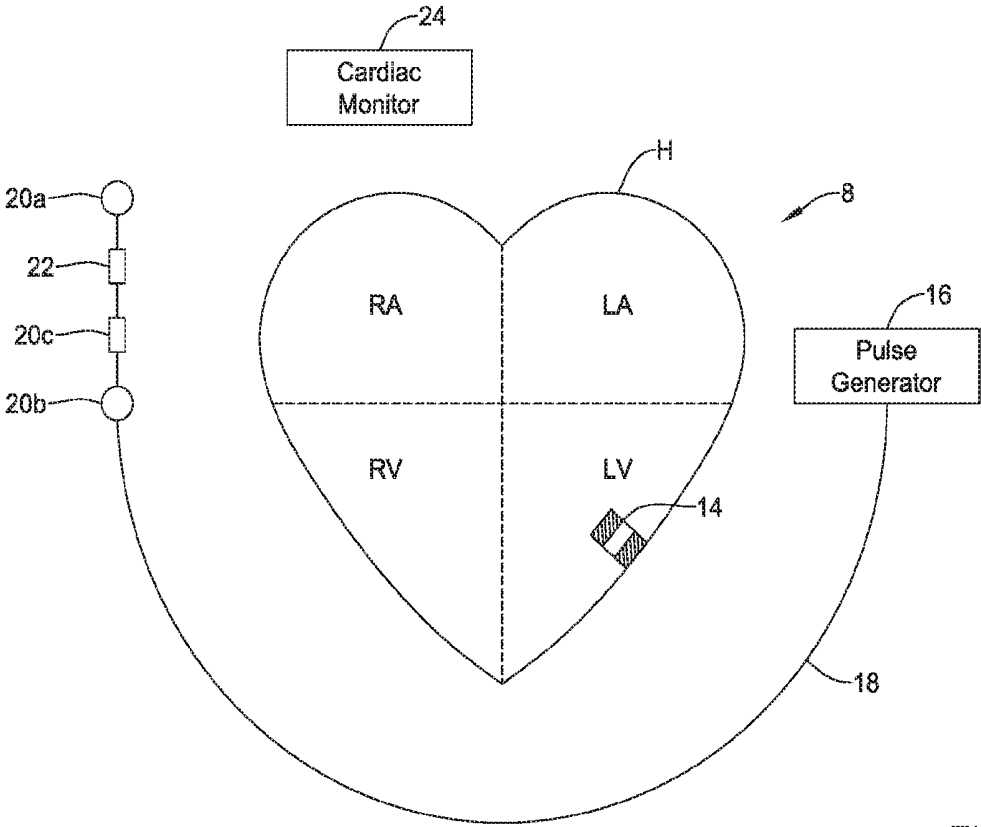


FIG. 3

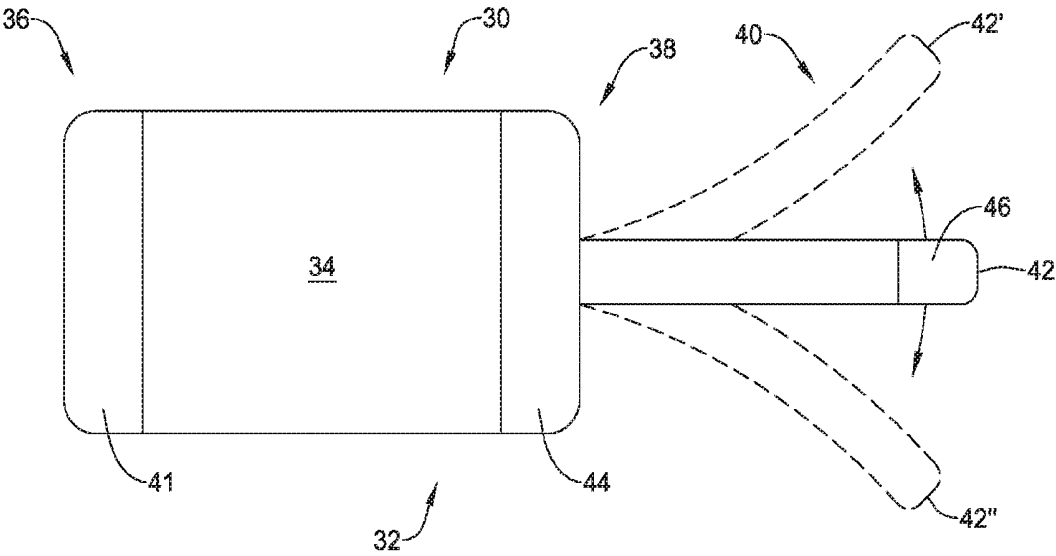


FIG. 4

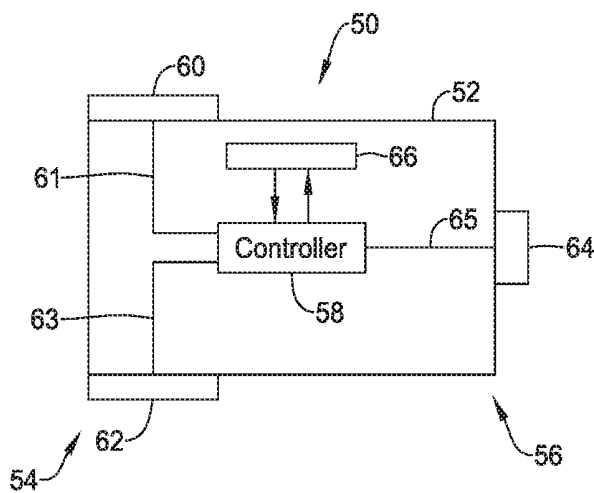


FIG. 5

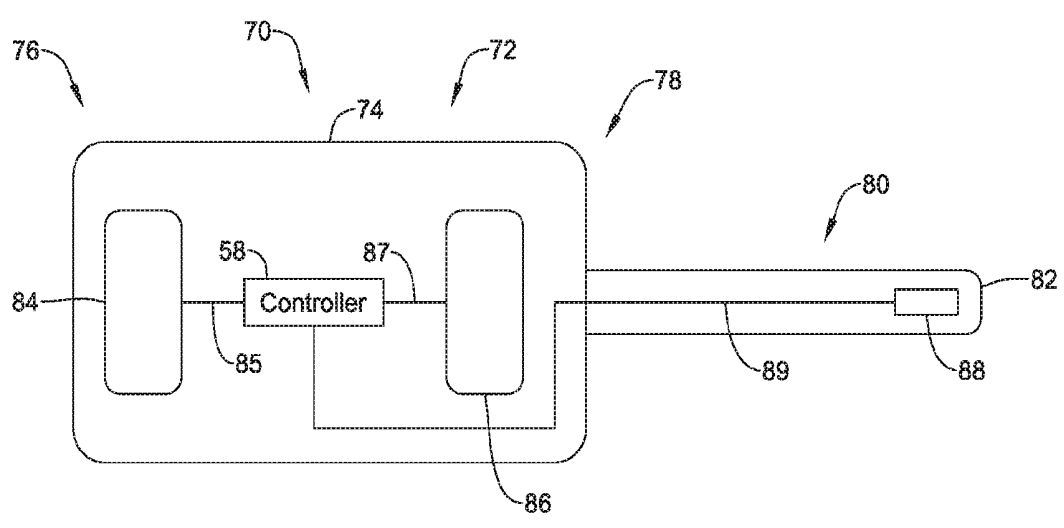


FIG. 6

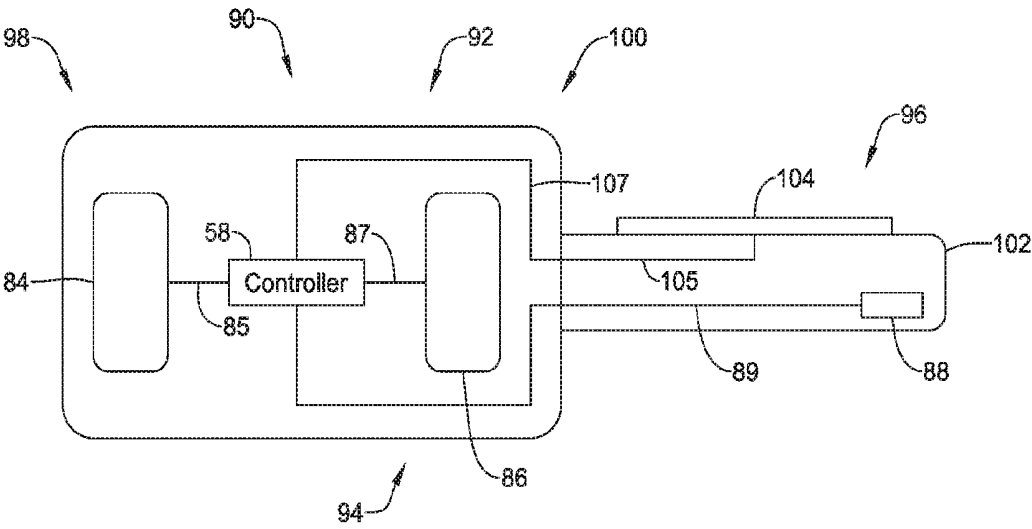


FIG. 7

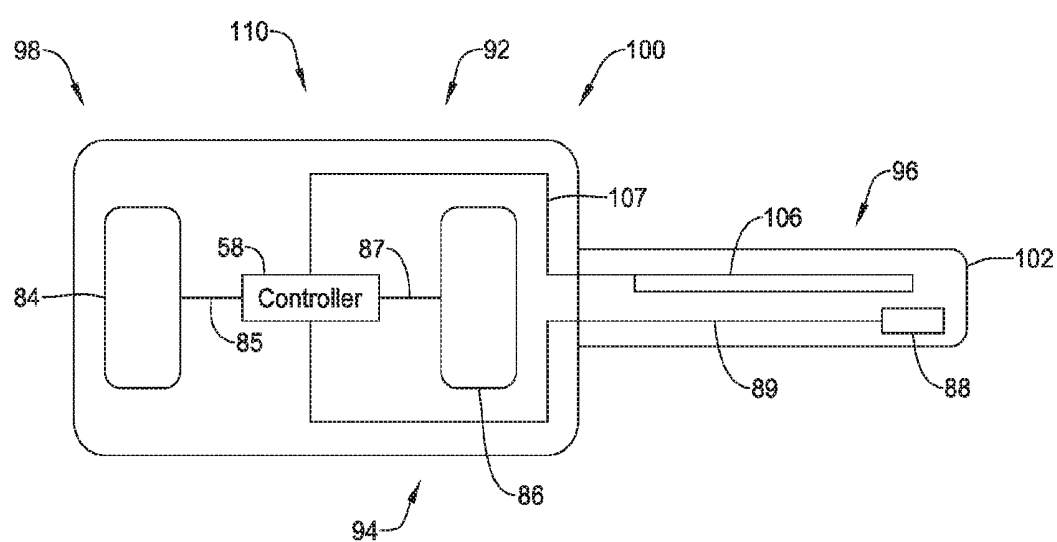


FIG. 8

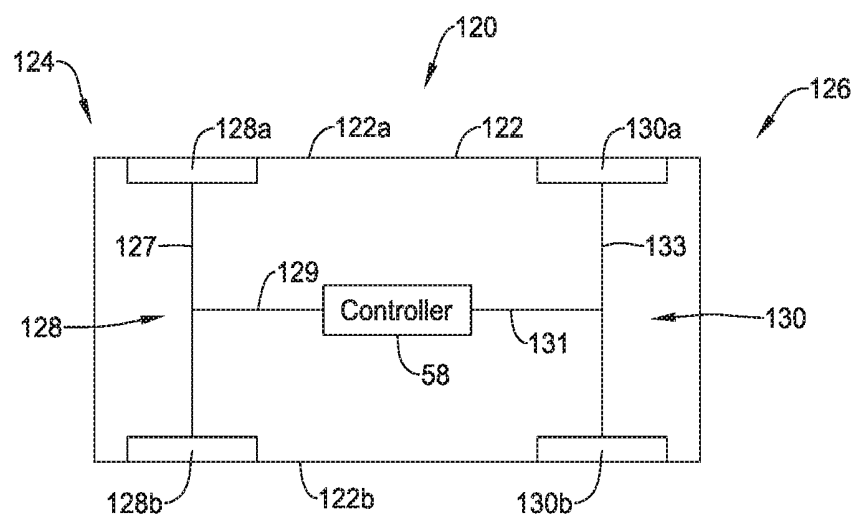


FIG. 9

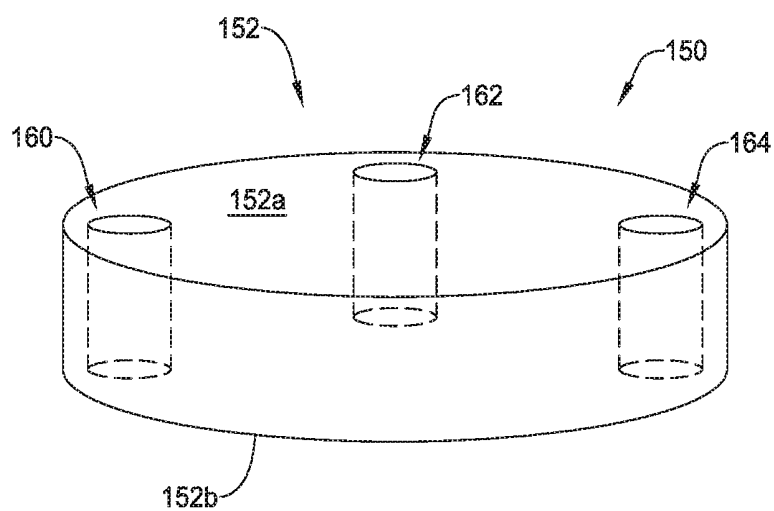


FIG. 11

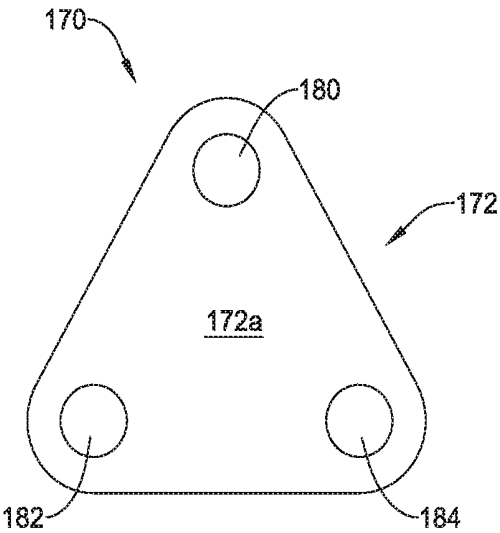


FIG. 12

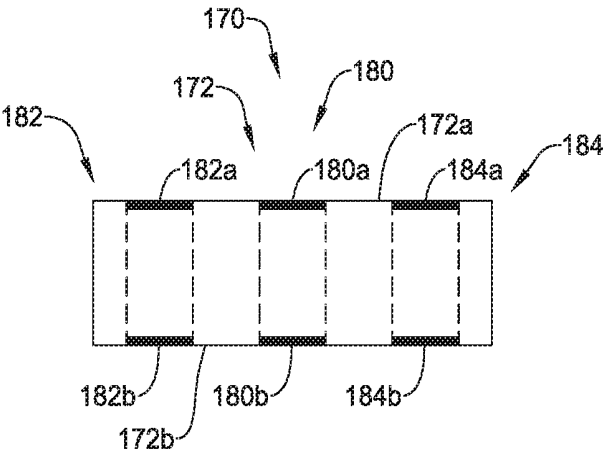


FIG. 13

IMPLANTABLE CARDIAC MONITOR

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application Ser. No. 62/397,894 filed on Sep. 21, 2016, the disclosure of which is incorporated herein by reference.

TECHNICAL FIELD

[0002] The present disclosure generally relates to medical devices, and more particularly, to implantable medical devices for monitoring a patient's heart

BACKGROUND

[0003] Implantable medical devices are commonly used today to monitor and/or delivery therapy to a patient, including cardiac simulation therapy. Many patients suffer from heart conditions that can result in a reduced ability of the heart to deliver sufficient amounts of blood to the patient's body. Such heart conditions may lead to slow, rapid, irregular, and/or inefficient heart contractions. To help alleviate some of these conditions, various medical devices (e.g., pacemakers, defibrillators, etc.) are often implanted in a patient's body. Such devices may monitor and in some cases provide electrical stimulation (e.g. pacing, defibrillation, etc.) to the heart to help the heart operate in a more normal, efficient and/or safe manner. Some devices, such as implantable cardiac monitors, can be used separately or in combination with implantable stimulation devices to provide additional sensing and monitoring capability.

SUMMARY

[0004] This disclosure generally relates to implantable medical devices, and more particularly, an implantable cardiac monitor (ICM) that can be used alone or in combination with one or more implantable stimulation devices to provide a sensing and/or monitoring capability. In some cases, the ICM may provide additional sensing and/or monitoring for a leadless cardiac pacemaker (LCP) implanted in a patient's heart and/or a subcutaneous implantable cardioverter defibrillator (SICD) implanted subcutaneously in a patient. In some cases, an ICM may be configured to be deployed intravascularly at a position where the ICM may provide additional sensing and/or monitoring capability.

[0005] In one example of the disclosure, an implantable cardiac monitor (ICM) may be configured to be deployed subcutaneous, submuscular, or substernal at a position that enables the ICM to detect cardiac activity. In some cases, the ICM includes a first electrode that is secured relative to the ICM, a second electrode that is secured relative to the ICM and spaced from the first electrode and a third electrode that is secured relative to the ICM and spaced from the first electrode and the second electrode. The illustrative ICM may include a housing that is configured for subcutaneous, submuscular or substernal deployment and for supporting the first electrode, the second electrode and the third electrode. In some cases, the housing may include a body portion having a first end and a second end and a tail portion extending from the body portion to a tail end. The first electrode may be disposed adjacent the first end of the body portion, the second electrode may be disposed adjacent the second end of the body portion and the third electrode may

be disposed adjacent the tail end of the tail portion of the housing. A controller may be disposed within the housing and may be operably coupled to the first electrode, the second electrode and the third electrode. In some cases, the controller may be configured to select a pair of the first electrode, the second electrode and the third electrode to establish a vector for sensing P-waves resulting from atrial contraction and to communicate information about the sensed P-waves to a second medical device. The second medical device may be, for example, an LCP or an SICD.

[0006] Alternatively or additionally to any of the embodiments above, the tail portion may be more flexible than the body portion.

[0007] Alternatively or additionally to any of the embodiments above, the body portion may include a hermitically sealed metallic enclosure that houses the controller, and the tail portion may include a polymeric body carrying the third electrode.

[0008] Alternatively or additionally to any of the embodiments above, the ICM may further include an antenna that is embedded in the polymeric body of the tail portion.

[0009] Alternatively or additionally to any of the embodiments above, the polymeric body of the tail portion may include a biocompatible polyurethane and/or a biocompatible polyethylene.

[0010] Alternatively or additionally to any of the embodiments above, the polymeric body may be secured relative to the hermitically sealed metallic enclosure.

[0011] Alternatively or additionally to any of the embodiments above, the ICM may further include an antenna that is carried by the tail portion.

[0012] Alternatively or additionally to any of the embodiments above, the antenna may be operatively coupled to the controller and is used to communicate with an external programmer.

[0013] Alternatively or additionally to any of the embodiments above, the controller may be configured to communicate information about the sensed P-waves to the second medical device via conducted communication using two of the first electrode, the second electrode and the third electrode.

[0014] Alternatively or additionally to any of the embodiments above, the controller may be configured to select which two of the first electrode, the second electrode and the third electrode to use for conducted communication with the second medical device.

[0015] Alternatively or additionally to any of the embodiments above, the controller may be configured to communicate information about the sensed P-waves to the second medical device via conducted communication using a pair of the first electrode, the second electrode and the third electrode.

[0016] Alternatively or additionally to any of the embodiments above, the controller may be configured to select which two of the first electrode, the second electrode and the third electrode to use for conducted communication with the second medical device.

[0017] Alternatively or additionally to any of the embodiments above, the ICM may further include an accelerometer disposed within the housing, wherein the controller is configured to communicate accelerometer information.

[0018] Alternatively or additionally to any of the embodiments above, the ICM may further include a heart sound sensor, wherein the controller is configured to communicate heart sound information.

[0019] Alternatively or additionally to any of the embodiments above, the controller may be configured to provide a signal to the second medical device that is suitable for the second medical device to determine a measure of minute ventilation and/or lung fluid volume.

[0020] In another example of the disclosure, an implantable cardiac monitor (ICM) may be configured to be deployed subcutaneous, submuscular or substernal at a position that enables the ICM to detect signs of cardiac activity. The ICM may include a housing, a first electrode that is secured relative to the housing, a second electrode that is secured relative to the housing and spaced from the first electrode, and a third electrode that is secured relative to the housing and is spaced from the first electrode and the second electrode. A controller may be disposed within the housing and may be operably coupled to the first electrode, the second electrode and the third electrode. The controller may be configured to select a pair of the first electrode, the second electrode and the third electrode for sensing cardiac electrical activity and to select a pair of the first electrode, the second electrode and the third electrode for communication with a second medical device.

[0021] Alternatively or additionally to any of the embodiments above, the controller may select which electrodes to use for sensing cardiac electrical activity based on which pair of electrodes provides a satisfactory sensing vector and to select which electrodes to use for communication with a second medical device based on which pair of electrodes provides a satisfactory communications vector with the second medical device.

[0022] Alternatively or additionally to any of the embodiments above, the controller may be configured to detect an atrial contraction using the pair of electrodes selected for sensing cardiac electrical activity, and to communicate information about a detected atrial contraction to the second medical device using the pair of electrodes selected for communication with the second medical device.

[0023] Alternatively or additionally to any of the embodiments above, the controller may be configured to select a different pair of electrodes for sensing cardiac electrical activity than for communication with the second medical device.

[0024] In another example of the disclosure, an implantable cardiac monitor (ICM) may be configured to be deployed subcutaneous, submuscular, or substernal at a position that enables the ICM to detect cardiac activity. The ICM includes a first electrode secured relative to the ICM, a second electrode secured relative to the ICM and spaced from the first electrode, and a third electrode secured relative to the ICM and spaced from the first electrode and the second electrode. A controller may be operably coupled to the first electrode, the second electrode and the third electrode. The ICM may include a housing that is configured for subcutaneous, submuscular or substernal deployment and to support the first electrode, the second electrode and the third electrode. The housing may include a body portion having a first end and a second end, wherein the body portion includes a hermetically sealed metallic enclosure that houses the controller, and a flexible tail portion extending from the body portion to a tail end, the flexible tail portion including

a polymeric body carrying the third electrode. The controller may be configured to use a selected pair of the first electrode, the second electrode and the third electrode for sensing cardiac activity and to communicate information about the cardiac activity to a second medical device.

[0025] The above summary is not intended to describe each embodiment or every implementation of the present disclosure. Advantages and attainments, together with a more complete understanding of the disclosure, will become apparent and appreciated by referring to the following description and claims taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] The disclosure may be more completely understood in consideration of the following description of various illustrative embodiments in connection with the accompanying drawings, in which:

[0027] FIG. 1 is a graphical representation of an electrocardiogram (ECG) showing a temporal relationship between electrical signals of the heart and mechanical indications of contraction of the heart;

[0028] FIG. 2 is a graph showing an example ECG, various pressures, various volumes, and various heart sounds over two consecutive heart beats;

[0029] FIG. 3 is a schematic diagram of an illustrative system including an LCP and another medical device, in accordance with an example of the disclosure;

[0030] FIG. 4 is a schematic view of an illustrative implantable cardiac monitor (ICM) in accordance with an example of the disclosure;

[0031] FIG. 5 is a schematic view of an illustrative implantable cardiac monitor (ICM) in accordance with an example of the disclosure;

[0032] FIG. 6 is a schematic view of an illustrative implantable cardiac monitor (ICM) in accordance with an example of the disclosure;

[0033] FIG. 7 is a schematic view of an illustrative implantable cardiac monitor (ICM) in accordance with an example of the disclosure;

[0034] FIG. 8 is a schematic view of an illustrative implantable cardiac monitor (ICM) in accordance with an example of the disclosure;

[0035] FIG. 9 is a schematic view of an illustrative implantable cardiac monitor (ICM) in accordance with an example of the disclosure;

[0036] FIG. 10 is a schematic view of an illustrative implantable cardiac monitor (ICM) in accordance with an example of the disclosure;

[0037] FIG. 11 is a schematic view of an illustrative implantable cardiac monitor (ICM) in accordance with an example of the disclosure;

[0038] FIG. 12 is a schematic view of an illustrative implantable cardiac monitor (ICM) in accordance with an example of the disclosure; and

[0039] FIG. 13 is a side view of the ICM of FIG. 12.

[0040] While the disclosure is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit aspects of the disclosure to the particular illustrative embodiments described. On the con-

trary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure.

DESCRIPTION

[0041] The following description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The description and the drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the disclosure.

[0042] All numbers are herein assumed to be modified by the term “about”, unless the content clearly dictates otherwise. The recitation of numerical ranges by endpoints includes all numbers subsumed within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

[0043] As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” include the plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise.

[0044] It is noted that references in the specification to “an embodiment”, “some embodiments”, “other embodiments”, etc., indicate that the embodiment described may include a particular feature, structure, or characteristic, but every embodiment may not necessarily include the particular feature, structure, or characteristic. Moreover, such phrases are not necessarily referring to the same embodiment. Further, when a particular feature, structure, or characteristic is described in connection with an embodiment, it is contemplated that the feature, structure, or characteristic may be applied to other embodiments whether or not explicitly described unless clearly stated to the contrary.

[0045] A normal, healthy heart induces contraction by conducting intrinsically generated electrical signals throughout the heart. These intrinsic signals cause the muscle cells or tissue of the heart to contract in a coordinated manner. These contractions forces blood out of and into the heart, providing circulation of the blood throughout the rest of the body. Many patients suffer from cardiac conditions that affect the efficient operation of their hearts. For example, some hearts develop diseased tissue that no longer generate or efficiently conduct intrinsic electrical signals. In some examples, diseased cardiac tissue may conduct electrical signals at differing rates, thereby causing an unsynchronized and inefficient contraction of the heart. In other examples, a heart may generate intrinsic signals at such a low rate that the heart rate becomes dangerously low. In still other examples, a heart may generate electrical signals at an unusually high rate, even resulting in cardiac fibrillation. Implantable medical device are often used to treat such conditions by delivering one or more types of electrical stimulation therapy to the patient’s heart.

[0046] FIG. 1 includes a portion of an electrocardiogram (ECG) 10 along with a heart sounds trace 12. As can be seen in the ECG 10, a heartbeat includes a P-wave that indicates atrial depolarization. A QRS complex, including a Q-wave, an R-wave and an S-wave, represents ventricular depolarization. A T-wave indicates repolarization of the ventricles. It will be appreciated that the ECG 10 may be detected by a variety of implanted or wearable cutaneous devices. A number of heart sounds may be detectable while the heart H beats. It will be appreciated that the heart sounds may be

considered as on example of mechanical indications of the heart beating. Other illustrative mechanical indications may include, for example, endocardial acceleration or movement of a heart wall detected by an accelerometer in for example the LCP, acceleration or movement of a heart detected by an accelerometer in for example the SICD or ICM, a pressure, pressure change, or pressure change rate in a chamber of the heart H detected by a pressure sensor of the LCP or other intracardiac device, acoustic signals caused by heart movements detected by an acoustic sensor (e.g. accelerometer, microphone, etc.) in the LCP, SICD, ICM and/or other device, and/or other suitable indication of a heart chamber beating.

[0047] An electrical signal typically instructs a portion of the heart H to contract, and then there is a corresponding mechanical indication. In some cases, there may be a first heart sound that is denoted S1 and that is produced by vibrations generated by closure of the mitral and tricuspid valves during a ventricle contraction, a second heart sound that is denoted S2 and that is produced by closure of the aortic and pulmonary valves, a third heart sound that is denoted S3 and that is an early diastolic sound caused by the rapid entry of blood from the right atrium RA into the right ventricle RV and from the left atrium LA into the left ventricle LV, and a fourth heart sound that is denoted S4 and that is a late diastolic sound corresponding to late ventricular filling during an active atrial contraction.

[0048] Because the heart sounds are a result of cardiac muscle contracting or relaxing in response to an electrical signal, it will be appreciated that there is a delay between the electrical signal, indicated by the ECG 10, and the corresponding mechanical indication, indicated in the example shown by the heart sounds trace 12. For example, the P-wave of the ECG 10 is an electrical signal triggering an atrial contraction. The S4 heart sound is the mechanical signal caused by the atrial contraction. In some cases, it may be possible to use this relationship between the P-wave and the S4 heart sound. For example, if one of these signals may be detected, the relationship can be used as a timing mechanism to help search for the other. For example, if the P-wave can be detected, a window following the P-wave can be defined and searched in order to find and/or isolate the corresponding S4 heart sound. In some cases, detection of both signals may be an indication of an increased confidence level in a detected atrial contraction. In some cases, detection of either signal may be sufficient to identify an atrial contraction. The identity of an atrial contraction may be used to identify an atrial contraction timing fiducial (e.g. a timing marker of the atrial contraction).

[0049] In some cases, the relationship of certain electrical signals and/or mechanical indications may be used to predict the timing of other electrical signals and/or mechanical indications within the same heartbeat. Alternatively, or in addition, the timing of certain electrical signals and/or mechanical indications corresponding to a particular heartbeat may be used to predict the timing of other electrical signals and/or mechanical indications within a subsequent heartbeat. It will be appreciated that as the heart H undergoes a cardiac cycle, the blood pressures and blood volumes within the heart H will vary over time. FIG. 2 illustrates how these parameters typically match up with the electrical signals and corresponding mechanical indications in a healthy heart H.

[0050] FIG. 2 is a graph showing an example ECG, various pressures, various volumes, and various heart sounds over two consecutive beats of a heart H. More specifically, FIG. 2 shows an illustrative example of the aortic pressure, left ventricular pressure, left atrial pressure, left ventricular volume, an electrocardiogram (ECG or egram), and heart sounds of the heart H over two consecutive heart beats. A cardiac cycle may begin with diastole, and the mitral valve opens. The ventricular pressure falls below the atrial pressure, resulting in the ventricular filling with blood. During ventricular filling, the aortic pressure slowly decreases as shown. During systole, the ventricle contracts. When ventricular pressure exceeds the atrial pressure, the mitral valve closes, generating the S1 heart sound. Before the aortic valve opens, an isovolumetric contraction phase occurs where the ventricle pressure rapidly increases but the ventricle volume does not significantly change. Once the ventricular pressure equals the aortic pressure, the aortic valve opens and the ejection phase begins where blood is ejected from the left ventricle into the aorta. The ejection phase continues until the ventricular pressure falls below the aortic pressure, at which point the aortic valve closes, generating the S2 heart sound. At this point, the isovolumetric relaxation phase begins and ventricular pressure falls rapidly until it is exceeded by the atrial pressure, at which point the mitral valve opens and the cycle repeats. Cardiac pressure curves for the pulmonary artery, the right atrium, and the right ventricle, and the cardiac volume curve for the right ventricle, may be similar to those illustrated in FIG. 2. In many cases, the cardiac pressure in the right ventricle is lower than the cardiac pressure in the left ventricle.

[0051] FIG. 3 shows an illustrative medical device system 8 that includes several different implantable devices that may be implanted in and/or near a heart H. As can be seen, the heart H includes a right atrium RA, a left atrium LA, a right ventricle RV and a left ventricle LV. In FIG. 3, an LCP 14 is disposed within the LV and is attached to the ventricular wall. A pulse generator 16 is shown coupled to a lead 18 having one or more electrodes 20a, 20b, 20c. In some cases, the pulse generator 16 may be part of a subcutaneous implantable cardioverter-defibrillator (SICD), and the one or more electrodes 20a, 20b, 20c may be positioned subcutaneously and exterior of the sternum. In some cases, the one or more electrodes 20a, 20b, 20c may be placed inside of the chest cavity but outside of the heart, such as just interior of the sternum. In some cases, the LCP 14 may communicate with the subcutaneous implantable cardioverter-defibrillator (S-ICD). In some cases, the lead 18 may include an accelerometer 22 that may, for example, be configured to sense vibrations that may be indicative of heart sounds and/or other movement of the heart, chest cavity and the like.

[0052] In some cases, the LCP 14 may be in the right ventricle RV, right atrium RA, left ventricle LV or left atrium LA of the heart H, as desired. In some cases, more than one LCP 14 may be implanted. For example, one LCP may be implanted in the right ventricle RV and another may be implanted in the right atrium RA. In another example, one LCP may be implanted in the right ventricle RV and another may be implanted in the left ventricle LV. In yet another example, one LCP may be implanted in each of the chambers of the heart H.

[0053] In some cases, the medical device system 8 may include an implantable cardiac monitor (ICM) 24. While one ICM 24 is shown, it will be appreciated that in some cases

multiple ICMs may be implanted. In some cases, the ICM 24 may be implanted at a subcutaneous position, a submuscular position or a substernal position. In some cases, the ICM 24 may instead be disposed within the patient's vascular system at a location where the ICM 24 may sense aspects of the cardiac cycle. For example, the ICM 24 may be deployed within the internal thoracic vein. It will be appreciated that this location is merely illustrative. In some cases, the exact location may be driven at least in part by what particular aspects of the cardiac cycle the ICM 24 is configured or otherwise intended to sense. For example, if the ICM 24 is intended to sense atrial activity, such as but not limited to detecting P-waves, the ICM 24 may be implanted at a location relatively close to the top of the heart H in order to place the ICM 24 at a location where P-waves may be more easily detected. If the ICM 24 is intended to sense heart sounds, the ICM 24 may be implanted at a location relatively close to the ventricles of the heart H. If the ICM 24 is intended to sense respiration, the ICM 24 may be implanted at a pectoral or other location that provides a good vector across the lungs of the patient. These are just examples.

[0054] In some cases, one or more ICMs 24 may be implanted at particular locations to better sense localized cardiac activity, as discussed above. In some cases, using one or more ICMs 24, which include particular electrode combinations and/or various sensors configured to sense cardiac electrical activity and/or to detect mechanical indications of cardiac activity, may enable other devices such as the LCP 14 to be made smaller, as the LCP 14 may not need to include particular sensors, for example, if the ICM 24 provides the information that would otherwise be provided by one or more sensors on board the LCP 14. This may be of particular advantage, for example, if there are multiple LCPs implanted within the heart H. In addition, or alternatively, using one or more ICMs 24 may enable other devices such as the LCP 14 to use less power, as the LCP 14 may not need to sense for particular signals or events if the ICM 24 provides the desired information. In addition, or alternatively, using one or more ICMs 24 may enable other devices such as the LCP 14 to monitor signals that are otherwise hard to sense from the location of the other device. For example, an LCP 14 implanted in the left ventricle may find it difficult to sense the P-wave emanating from the atrium.

[0055] FIG. 4 is a schematic view of an illustrative implantable cardiac monitor (ICM) 30 that may, for example, be considered as being an example of the ICM 24 (FIG. 3). The illustrative ICM 30 includes a housing 32 that may be configured for subcutaneous, submuscular or substernal deployment. In some cases, the housing 32 may include a body portion 34 that extends from a first end 36 to a second end 38. In some cases, the housing 32 may include a tail portion 40 that extends from the body portion 34 to a tail end 42. In some cases, the tail portion 40 may be flexible, as indicated by the phantom tail portions including a tail end 42' and a tail end 42". In some cases, the body portion 34 may be a hermitically sealed metallic enclosure that encloses a controller, as will be illustrated in subsequent Figures. In some cases, the tail portion 40 may include a polymeric material and may be made flexible. In some cases, for example, the tail portion 40 may include or otherwise be formed of a biocompatible polyurethane and/or a biocompatible polyethylene. The tail portion 40 may be secured relative to the hermitically sealed metallic enclosure. The

tail portion 40 may be flexible such that the tail end 42 can be moved about and implanted in a desired configuration.

[0056] In some cases, the ICM 30 may include a first electrode 41 that is secured relative to the ICM 30, a second electrode 44 that is secured relative to the ICM 30 and is spaced from the first electrode 41, and a third electrode 46 that is secured relative to the ICM 30 and is spaced from the first electrode 41 and the second electrode 44. In some cases, the first electrode 41 may be disposed adjacent the first end 36 of the body portion 34. In some cases, the second electrode 44 may be secured adjacent the second end 38 of the body portion 34. The third electrode 46 may, for example, be disposed adjacent the tail end 42 of the tail portion 40. By moving the tail end 42 off axis relative to the other two fixed electrodes, the three electrodes 41, 44 and 46 may be oriented non co-axially when implanted. When so provided, the ability to select two of the three electrodes for sensing and/or communication provide a number of different off-axis sensing and/or communication vectors to choose from.

[0057] FIG. 5 is a schematic view of an illustrative implantable cardiac monitor (ICM) 50 that may, for example, be considered as being an example of the ICM 24 (FIG. 3). The illustrative ICM 50 includes a housing 52 that may be configured for subcutaneous, submuscular or sub-sternal deployment. In some cases, the housing 52 may extend from a first end 54 to a second end 56 and may house a controller 58. The controller 58 may be operably coupled with a first electrode 60, a second electrode 62 and a third electrode 64 via electrical connections 61, 63 and 65, respectively. In some cases, the ICM 50 may include fewer electrodes. In some cases, the ICM 50 may include additional electrodes (not illustrated). As shown, the first electrode 60 and the second electrode 62 are disposed at or near the first end 54 of the housing 52 while the third electrode 64 is disposed at or near the second end 56 of the housing 52. It will be appreciated that the relative locations of the electrodes 60, 62, 64 are merely illustrative.

[0058] In some cases, the controller 58 may be configured to select a pair of electrodes of the first electrode 60, the second electrode 62 and the third electrode 64 to use for sensing cardiac activity. In an example, the controller 58 may be configured for selecting a pair of electrodes of the first electrode 60, the second electrode 62 and the third electrode 64 to use for sensing P-waves resulting from atrial contraction. The controller 58 may, for example, use the first electrode 60 and the second electrode 62 as a pair, or the first electrode 60 and the third electrode 64 as a pair, or the second electrode 62 and the third electrode 64 for sensing cardiac electrical activity. In some cases, the controller 58 may be configured to communicate information about the sensed cardiac electrical activity, including but not limited to sensed P-waves to a second medical device such as, for example, the LCP 14 or the pulse generator 16 shown in FIG. 3.

[0059] In some cases, the controller 58 may be configured to communicate information about the sensed P-waves to the second medical device via conducted communication using two of the first electrode 60, the second electrode 62 and the third electrode 64. In some cases, the controller 58 may be configured to select which two of the first electrode 60, the second electrode 62 and the third electrode 64 to use for conducted communication with the second medical device. In some cases, the controller 58 may be configured to

communicate information about the sensed P-waves to the second medical device via conducted communication using a pair of the first electrode 60, the second electrode 62 and the third electrode 64.

[0060] The controller 58 may, for example, be configured to select which two of the first electrode 60, the second electrode 62 and the third electrode 64 to use for conducted communication with the second medical device. In some cases, the controller 58 may be configured to select which electrodes of the electrodes 60, 62, 64 to use for communication with a second medical device based on which pair of electrodes provides a satisfactory communications vector with the second medical device. In some cases, the controller 58 may select a first electrode pair for sensing and a different electrode pair for communication. In some cases, the controller 58 may select the same electrode pair for both sensing and communication. As an example, if the ICM 50 is being used to sense atrial activity such as sensed P-waves, the controller 58 may be configured to detect an atrial contraction using the pair of electrodes selected for sensing cardiac electrical activity and to communicate information about the detected atrial contraction to the second medical device using the pair of electrodes selected for communication with the second medical device.

[0061] In some cases, the ICM 50 may include a sensor 66 that is operably coupled with the controller 58. In some instances, the sensor 66 may be or otherwise include an accelerometer, and the controller 58 may be configured to communicate accelerometer information. In some instances, the sensor 66 may be or otherwise include a heart sound sensor, and controller 58 may be configured to communicate heart sound information. In some cases, the controller 58 may be configured to provide a signal to the second medical device that is suitable for the second medical device to determine a measure of minute ventilation and/or lung fluid volume.

[0062] FIG. 6 is a schematic view of an illustrative implantable cardiac monitor (ICM) 70 that may, for example, be considered as being an example of the ICM 24 (FIG. 3). The illustrative ICM 70 includes a housing 72 that may be configured for subcutaneous, submuscular or sub-sternal deployment. In some cases, the housing 72 may include a body portion 74 that extends from a first end 76 to a second end 78. The housing 72 may include a tail portion 80 that extends from the body portion 74 to a tail end 82. In some cases, the tail portion 80 may be flexible. In some cases, the body portion 74 may be a hermitically sealed metallic enclosure that encloses the controller 58. In some cases, the tail portion 80 may be formed of a polymeric material. In some cases, for example, the tail portion 80 may include or otherwise be formed of a biocompatible polyurethane and/or a biocompatible polyethylene. The tail portion 80 may be secured relative to the hermitically sealed metallic enclosure, for example.

[0063] In some cases, the ICM 70 may include a first electrode 84 that is secured relative to the ICM 70, a second electrode 86 that is secured relative to the ICM 70 and is spaced from the first electrode 84, and a third electrode 88 that is secured relative to the ICM 70 and is spaced from the first electrode 84 and the second electrode 86. In some cases, the first electrode 84 may be disposed adjacent the first end 76 of the body portion 74. In some cases, the second electrode 86 may be secured adjacent the second end 78 of the body portion 74. The third electrode 88 may, for

example, be disposed adjacent the tail end **82** of the tail portion **80**. In some cases, the controller **58** may be operably coupled with the first electrode **84**, the second electrode **86** and the third electrode **88** via electrical connectors **85**, **87** and **89**, respectively.

[0064] FIG. 7 is a schematic view of an illustrative implantable cardiac monitor (ICM) **90** that may, for example, be considered as being an example of the ICM **24** (FIG. 3). The illustrative ICM **90** includes a housing **92** that may be configured for subcutaneous, submuscular or substernal deployment. In some cases, the housing **92** may include a body portion **94** and a tail portion **96**. The body portion **94** extends from a first end **98** to a second end **100**. The tail portion **96** extends from the body portion **94** to a tail end **102**. In some cases, the tail portion **96** may be flexible. In some cases, the body portion **94** may be a hermitically sealed metallic enclosure that encloses the controller **58**. In some cases, the tail portion **96** may be formed of a polymeric material. In some cases, for example, the tail portion **96** may include or otherwise be formed of a biocompatible polyurethane and/or a biocompatible polyethylene. The tail portion **96** may be secured relative to the hermitically sealed metallic enclosure, for example.

[0065] In some cases, the ICM **90** may include the first electrode **84**, the second electrode **86** and the third electrode **88** that are operably coupled to the controller **58** via the electrical connectors **85**, **87** and **89**, respectively. In some cases, the ICM **90** may include an antenna **104** that is operably coupled to the controller **58** via an electrical connector **105**. The antenna **104** may, for example, be carried by the tail portion **96**. In some cases, the antenna **104** may be secured to an outer surface of the tail portion **96**, or may be embedded in the flexible polymeric material of the tail portion **96**. In some cases, the antenna may be an RF antenna, an inductive antenna (i.e. coil), and/or any other suitable antenna suitable for communication with a second medical device. In some cases, the antenna **104** may be used to communicate with an external programmer.

[0066] FIG. 8 is a schematic view of an illustrative implantable cardiac monitor (ICM) **110** that may, for example, be considered as being an example of the ICM **24** (FIG. 3). The illustrative ICM **110** includes a housing **92** that may be configured for subcutaneous, submuscular or substernal deployment. In some cases, the housing **92** may include a body portion **94** and a tail portion **96**. The body portion **94** extends from a first end **98** to a second end **100**. The tail portion **96** extends from the body portion **94** and to a tail end **102**. In some cases, the tail portion **96** may be flexible. In some cases, the body portion **94** may be a hermitically sealed metallic enclosure that encloses the controller **58**. In some cases, the tail portion **96** may be formed of a polymeric material. In some cases, for example, the tail portion **96** may include or otherwise be formed of a biocompatible polyurethane and/or a biocompatible polyethylene. The tail portion **96** may be secured relative to the hermitically sealed metallic enclosure, for example.

[0067] In some cases, the ICM **110** may include the first electrode **84**, the second electrode **86** and the third electrode **88** that are operably coupled to the controller **58** via the electrical connectors **85**, **87** and **89**, respectively. In some cases, the ICM **110** may include an antenna **106** that is embedded in the flexible polymeric material of the tail portion **96** and is operably coupled to the controller **58** via an electrical connector **107**. In some cases, the antenna may

be an RF antenna, an inductive antenna (i.e. coil), and/or any other suitable antenna suitable for communication with a second medical device. In some cases, the antenna **106** may be used to communicate with an external programmer.

[0068] FIG. 9 is a schematic view of an illustrative implantable cardiac monitor (ICM) **120** that may, for example, be considered as being an example of the ICM **24** (FIG. 3). The illustrative ICM **120** includes a housing **122** that may be configured for subcutaneous, submuscular or substernal deployment and that includes a first side **122a** and a second opposing side **122b**. In some cases, the housing **122** may extend from a first end **124** to a second end **126** and may house the controller **58** within the housing **122**. In some cases, the ICM **120** may include a first electrode **128** that is disposed at or near the first end **124** of the housing **122** and a second electrode **130** that is disposed at or near the second end **126** of the housing **122**. It will be appreciated that in some instances, the ICM **120** may be inserted in an orientation that is 180 degrees from its final deployment orientation. In some cases, for example, there may be a desire to test a possible location before inverting the ICM **120** for its final deployment in the patient's body.

[0069] Accordingly, the first electrode **128** may include a first electrode portion **128a** that is disposed on the first side **122a** and a second electrode portion **128b** that is disposed on the opposing second side **122b**. Similarly, the second electrode **130** may include a first electrode portion **130a** that is disposed on the first side **122a** and a second electrode portion **130b** that is disposed on the opposing second side **122b**. Accordingly, the controller **58** is configured to be electrically coupled to the first electrode **128** and the second electrode **130**, with the first electrode **128** and the second electrode **130** in contact with a desired tissue region independent of orientation of the first side **122a** and the second side **122b**. For example, if the first side **122a** is in contact with the desired tissue location prior to inversion, the first electrode portions **128a**, **130a** are in contact with the desired tissue location. After device inversion, the second side **122b** would be in contact with the desired tissue location, and thus the second electrode portions **128b**, **130b** would be in contact with the desired tissue location.

[0070] FIG. 10 is a schematic view of an illustrative implantable cardiac monitor (ICM) **140** that may, for example, be considered as being an example of the ICM **24** (FIG. 3). The illustrative ICM **140** includes a housing **122** that may be configured for subcutaneous, submuscular or substernal deployment and that includes a first side **122a** and an opposing second side **122b**. In some cases, the housing **122** may extend from a first end **124** to a second end **126** and may house the controller **58** within the housing **122**. In some cases, the ICM **120** may include a first electrode **128** that is disposed at or near the first end **124** of the housing **122** and a second electrode **130** that is disposed at or near the second end **126** of the housing **122**. It will be appreciated that in some instances, the ICM **140** may be inserted in an orientation that is 180 degrees from its final deployment orientation. In some cases, for example, there may be a desire to test a possible location before inverting the ICM **140** for its final deployment.

[0071] Accordingly, the first electrode **128** may include a first electrode portion **128a** that is disposed on the first side **122a**, and a second electrode portion **128b** that is disposed on the opposing second side **122b**. Similarly, the second electrode **130** may include a first electrode portion **130a** that

is disposed on the first side **122a**, and a second electrode portion **130b** that is disposed on the opposing second side **122b**. Accordingly, the controller **58** may be able to be electrically coupled to the first electrode **128** and the second electrode **130**, with the first electrode **128** and the second electrode **130** in contact with a desired tissue location independent of orientation or the first side **122a** and the second side **122b**. For example, if the first side **122a** is in contact with the desired tissue location prior to inversion of the ICM **140**, the first electrode portions **128a**, **130a** are in contact with the desired tissue location. After device inversion, the second side **122b** will be in contact with the desired tissue location, and thus the second electrode portions **128b**, **130b** will be in contact with the desired tissue location.

[0072] In some cases, there may be a desire to not electrically couple the first electrode portion **128a** to the second electrode portion **128b**, or to not electrically couple the first electrode portion **130a** to the second electrode portion **130b**. While the first electrode **128** is coupled to the controller **58** via electrical connectors **127** and **129**, it can be seen that the electrical connector **127** schematically includes a switch **127a** and a switch **127b**. While shown separate from the controller **58**, it will be appreciated that the switches **127a** and **127b** may be incorporated into the controller **58** and thus may be under the control of the controller **58**. Similarly, the electrical connector **133** coupling the second electrode **130** to the controller **58** may include a switch **133a** and a switch **133b**. In some cases, the controller **58** can selectively electrically connect or disconnect to any of the first electrode portion **128a**, the second electrode portion **128b**, the first electrode portion **130a** and/or the second electrode portion **130b**.

[0073] In one example, when the ICM **140** is implanted subcutaneous and is intended to sense P-waves of the heart, it may be desirable to connect the electrode portions that face away from the heart to the controller **58** for sensing P-waves, and disconnect and even ground the electrode portions that face toward the heart. In some instances, muscle activity adjacent the side of the ICM **140** facing the heart can introduce unwanted noise at the electrode portions that face toward the heart.

[0074] FIG. **11** is a schematic view of an illustrative implantable cardiac monitor (ICM) **150** that may, for example, be considered as being an example of the ICM **24** (FIG. **3**). The illustrative ICM **150** includes a housing **152** that may be configured for subcutaneous, submuscular or substernal deployment and that includes a first side **152a** and a second side **152b**. In some cases, the housing **152** may have an ovoid or circular profile. In some cases, the first side **152a** may include a first electrode **160**, a second electrode **162** and a third electrode **164**. In some cases, the ICM **150** may include fewer electrodes. In some cases, the ICM **150** may include additional electrodes. In some cases, the first electrode **160** may include a first electrode portion **160a** on the first side **152a** and a second electrode portion **160b** on the opposing second side **152b**. The second electrode **162** may include a first electrode portion **162a** on the first side **152a** and a second electrode **162b** on the opposing second side **152b**. The third electrode **164** may include a first electrode portion **164a** on the first side **152a** and a second electrode portion **164b** on the opposing second side **152b**. It is contemplated that the first electrode **160**, the second electrode **162** and the third electrode **164** may optionally be

individually switched into or out of electrical contact with the controller **58** (not shown).

[0075] FIG. **12** is a schematic view of an illustrative implantable cardiac monitor (ICM) **170** and FIG. **13** is a side view thereof that may, for example, be considered as being an example of the ICM **24** (FIG. **3**). The illustrative ICM **170** includes a housing **172** that may be configured for subcutaneous, submuscular or substernal deployment and that includes a first side **172a** and an opposing second side **172b**. In some cases, the housing **172** may have a triangular shape, sometimes with rounded corners. In some cases, the ICM **170** may include a first electrode **180**, a second electrode **182** and a third electrode **184**. In some cases, the ICM **170** may include fewer electrodes. In some cases, the ICM **170** may include additional electrodes. In some cases, the first electrode **180** may include a first electrode portion **180a** on the first side **172a** and a second electrode portion **180b** on the opposing second side **172b**. The second electrode **182** may include a first electrode portion **182a** on the first side **172a** and a second electrode **182b** on the opposing second side **172b**. The third electrode **184** may include a first electrode portion **184a** on the first side **172a** and a second electrode portion **184b** on the opposing second side **172b**. The first electrode **180**, the second electrode **182** and the third electrode **184** may each be positioned adjacent a corresponding corner of the triangular shaped housing **172**. In some cases, the first electrode **180**, the second electrode **182** and the third electrode **184** may optionally be individually switched into or out of electrical contact with the controller **58** (not shown).

[0076] It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the disclosure. This may include, to the extent that it is appropriate, the use of any of the features of one example embodiment being used in other embodiments.

What is claimed is:

1. An implantable cardiac monitor (ICM) configured to be deployed subcutaneous, submuscular, or substernal at a position that enables the ICM to detect cardiac activity, the ICM comprising:

- a first electrode secured relative to the ICM;
- a second electrode secured relative to the ICM and spaced from the first electrode;
- a third electrode secured relative to the ICM and spaced from the first electrode and the second electrode;
- a housing that is configured for subcutaneous, submuscular or substernal deployment and to support the first electrode, the second electrode and the third electrode, the housing comprising:
 - a body portion having a first end and a second end;
 - a tail portion extending from the body portion to a tail end;
- the first electrode disposed adjacent the first end of the body portion;
- the second electrode disposed adjacent the second end of the body portion;
- the third electrode disposed adjacent the tail end of the tail portion;
- a controller disposed within the housing and operably coupled to the first electrode, the second electrode and the third electrode;

the controller configured to select a pair of the first electrode, the second electrode and the third electrode to use for sensing P-waves resulting from atrial contraction; and

the controller configured to communicate information about the sensed P-waves to a second medical device.

2. The ICM of claim 1, wherein the tail portion is more flexible than the body portion.

3. The ICM of claim 2, wherein the body portion comprises a hermitically sealed metallic enclosure that houses the controller, and the tail portion comprises a polymeric body carrying the third electrode.

4. The ICM of claim 3, further comprises an antenna wherein the antenna is embedded in the polymeric body of the tail portion.

5. The ICM of claim 3, wherein the polymeric body of the tail portion comprises a biocompatible polyurethane and/or a biocompatible polyethylene.

6. The ICM of claim 3, wherein the polymeric body is secured relative to the hermitically sealed metallic enclosure.

7. The ICM of claim 2, further comprises an antenna wherein the antenna is carried by the tail portion.

8. The ICM of claim 7, wherein the antenna is operatively coupled to the controller and is used to communicate with an external programmer.

9. The ICM of claim 1, wherein the controller is configured to communicate information about the sensed P-waves to the second medical device via conducted communication using two of the first electrode, the second electrode and the third electrode.

10. The ICM of claim 9, wherein the controller is configured to select which two of the first electrode, the second electrode and the third electrode to use for conducted communication with the second medical device.

11. The ICM of claim 11, wherein the controller is configured to communicate information about the sensed P-waves to the second medical device via conducted communication using a pair of the first electrode, the second electrode and the third electrode.

12. The ICM of claim 12, wherein the controller is configured to select which two of the first electrode, the second electrode and the third electrode to use for conducted communication with the second medical device.

13. The ICM of claim 1, further comprising an accelerometer disposed within the housing, wherein the controller is configured to communicate accelerometer information.

14. The ICM of claim 1, further comprising a heart sound sensor, wherein the controller is configured to communicate heart sound information.

15. The ICM of claim 1, wherein the controller is configured to provide a signal to the second medical device that is suitable for the second medical device to determine a measure of minute ventilation and/or lung fluid volume.

16. An implantable cardiac monitor (ICM) configured to be deployed subcutaneous, submuscular or substernal at a position that enables the ICM to detect signs of cardiac activity, the ICM comprising:

a housing;

a first electrode secured relative to the housing;

a second electrode secured relative to the housing and spaced from the first electrode;

a third electrode secured relative to the housing and spaced from the first electrode and the second electrode;

a controller disposed within the housing and operably coupled to the first electrode, the second electrode and the third electrode;

the controller configured to select a pair of the first electrode, the second electrode and the third electrode for sensing cardiac electrical activity; and

the controller configured to select a pair of the first electrode, the second electrode and the third electrode for communication with a second medical device.

17. The ICM of claim 16, wherein:

the controller selects which electrodes to use for sensing cardiac electrical activity based on which pair of electrodes provides a satisfactory sensing vector; and

the controller selects which electrodes to use for communication with a second medical device based on which pair of electrodes provides a satisfactory communications vector with the second medical device.

18. The ICM of claim 16, wherein the controller is configured to detect an atrial contraction using the pair of electrodes selected for sensing cardiac electrical activity, and is further configured to communicate information about a detected atrial contraction to the second medical device using the pair of electrodes selected for communication with the second medical device.

19. The ICM of claim 16, wherein the controller is configured to select a different pair of electrodes for sensing cardiac electrical activity than for communication with the second medical device.

20. An implantable cardiac monitor (ICM) configured to be deployed subcutaneous, submuscular, or substernal at a position that enables the ICM to detect cardiac activity, the ICM comprising:

a first electrode secured relative to the ICM;

a second electrode secured relative to the ICM and spaced from the first electrode;

a third electrode secured relative to the ICM and spaced from the first electrode and the second electrode;

a controller operably coupled to the first electrode, the second electrode and the third electrode;

a housing that is configured for subcutaneous, submuscular or substernal deployment and to support the first electrode, the second electrode and the third electrode, the housing comprising:

a body portion having a first end and a second end, wherein the body portion comprises a hermitically sealed metallic enclosure that houses the controller;

a flexible tail portion extending from the body portion to a tail end, the flexible tail portion comprises a polymeric body carrying the third electrode;

the controller configured to use a selected pair of the first electrode, the second electrode and the third electrode for sensing cardiac activity; and

the controller configured to communicate information about the cardiac activity to a second medical device.

* * * * *

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摘要(译)

可植入心脏监测器 (ICM) 可以被配置为使ICM能够检测心脏活动的位置处部署皮下，肌肉下或胸骨下。在一些情况下，ICM包括壳体，壳体包括主体部分和尾部。第一电极可以设置在主体部分的第一端附近，第二电极可以设置在主体部分的第二端附近，第三电极可以设置在尾部的尾端附近。控制器可以设置在壳体内，并且可以可操作地连接到第一电极，第二电极和第三电极。控制器可以被配置为选择一对第一电极，第二电极和第三电极以用于感测心脏电活动并且将关于感测到的活动的信息传送到第二医疗设备。

