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IMPLANTABLE MEDICAL DEVICE WITH PRESSURE SENSOR

CROSS REFERENCE TO RELATED APPLICATIONS

5 This application claims the benefit of U.S. Provisional Patent Application Serial No. 62/547,458 filed on August 18, 2017, the disclosure of which is incorporated herein by reference.

TECHNICAL FIELD

10 The present disclosure generally relates to implantable medical devices and more particularly to implantable medical devices with pressure sensors

BACKGROUND

 Implantable medical devices are commonly used to perform a variety of functions, such as to monitor one or more conditions and/or delivery therapy to a patient. In some cases, an implantable medical device may deliver neurostimulation therapy to a patient. In some cases, an implantable medical device may simply monitor one or more conditions, such as pressure, acceleration, cardiac events, and may communicate the detected conditions or events to another device, such as another implantable medical device or an external programmer.

 In some cases, an implantable medical device may be configured to deliver pacing and/or defibrillation therapy to a patient. Such implantable medical devices may treat patients suffering from various heart conditions that may result in a reduced ability of the heart to deliver sufficient amounts of blood to a patient's body. In some cases, heart conditions may lead to rapid, irregular, and/or inefficient heart contractions. To help alleviate some of these conditions, various devices (e.g., pacemakers, defibrillators, etc.) may be implanted into a patient's body. When so provided, such devices can monitor and provide therapy, such as electrical stimulation therapy, to the patient's heart to help the heart operate in a more normal, efficient and/or safe manner. In some cases, a patient may have multiple implanted devices that cooperate to monitor and/or provide therapy to the patient's heart.

SUMMARY

The present disclosure generally relates to implantable medical devices and more particularly to implantable medical devices with pressure sensors.

In a first example, a leadless cardiac pacemaker (LCP) may be configured to sense cardiac activity and to deliver pacing therapy to a patient's heart. The LCP may comprise a housing having a proximal end and a distal end, a first electrode secured relative to the housing and exposed to the environment outside of the housing, a second electrode secured relative to the housing and exposed to the environment outside of the housing, a diaphragm that is exposed to the environment outside of the housing, the diaphragm is responsive to an external pressure applied to the diaphragm by the environment outside of the housing, a piezoelectric membrane having a first pressure sensor electrode and a second pressure sensor electrode, the piezoelectric membrane may be configured to generate an electrical voltage between the first pressure sensor electrode and the second pressure sensor electrode in response to a pressure change applied to the diaphragm, the electrical voltage representative of a change in external pressure applied to the diaphragm, and circuitry in the housing operatively coupled to the first electrode and the second electrode of the LCP, and also operatively coupled to the first pressure sensor electrode and the second pressure sensor electrode, the circuitry may be configured to deliver a pacing therapy to the patient's heart via the first electrode and the second electrode of the LCP, wherein the pacing therapy is dependent, at least in part, on the electrical voltage generated by the piezoelectric membrane and that is representative of the change in external pressure applied to the diaphragm.

Alternatively or additionally to any of the examples above, in another example, the circuitry may be configured to detect a pressure pulse by monitoring the electrical voltage generated between the first pressure sensor electrode and the second pressure sensor electrode by the piezoelectric membrane.

Alternatively or additionally to any of the examples above, in another example, the diaphragm may have an interior surface that faces toward an interior of the housing, and the piezoelectric may be secured to at least part of the interior surface of the diaphragm.

Alternatively or additionally to any of the examples above, in another example, the diaphragm may have an interior surface that faces toward an interior of the housing, and

the piezoelectric membrane may be spaced a distance from the interior surface of the diaphragm and may be operatively coupled to the interior surface of the diaphragm via an incompressible fluid.

Alternatively or additionally to any of the examples above, in another example, the
5 incompressible fluid may be in a fluid cavity that is at least partially defined by the interior surface of the diaphragm and may be in fluid communication with both the interior surface of the diaphragm and the piezoelectric membrane, wherein the fluid cavity may be configured to communicate a pressure applied to the incompressible fluid by the diaphragm to the piezoelectric membrane.

10 Alternatively or additionally to any of the examples above, in another example, the diaphragm may have an interior surface that faces toward an interior of the housing, and the piezoelectric membrane may be spaced a distance from the interior surface of the diaphragm and may be operatively coupled to the interior surface of the diaphragm via a mechanical linkage, wherein the mechanical linkage may be configured to translate
15 movement of the diaphragm to a pressure applied to the piezoelectric membrane.

Alternatively or additionally to any of the examples above, in another example, the diaphragm of the housing may include one or more contours.

Alternatively or additionally to any of the examples above, in another example, the circuitry may be configured to detect a change in pressure in a first chamber of the heart
20 caused by a contraction of a second chamber of the heart.

Alternatively or additionally to any of the examples above, in another example, the first chamber may be a ventricle, and the second chamber may be the corresponding atrium.

Alternatively or additionally to any of the examples above, in another example, the diaphragm may be integrally formed with the housing.

25 Alternatively or additionally to any of the examples above, in another example, the diaphragm may be hermetically sealed to the housing.

Alternatively or additionally to any of the examples above, in another example, the LCP may further comprise a fixation member at the distal end of the housing for fixing the distal end of the housing to an implant site, and wherein the diaphragm of the housing is
30 adjacent the proximal end of the housing.

Alternatively or additionally to any of the examples above, in another example, the housing may include an elongated body with a distal end surface facing distally and a proximal end surface facing proximally, wherein the diaphragm of the housing may be situated on the proximal end surface of the housing.

5 Alternatively or additionally to any of the examples above, in another example, the diaphragm and/or piezoelectric membrane may be formed to maximize the dynamic change of the diaphragm and/or piezoelectric membrane when implanted.

Alternatively or additionally to any of the examples above, in another example, the LCP may further comprise an anti-thrombogenic coating disposed over the diaphragm of
10 the housing.

In another example, a leadless cardiac pacemaker (LCP) may be configured to sense cardiac activity and to deliver pacing therapy to a patient's heart. The LCP may comprise a housing having a proximal end and a distal end, a first electrode secured relative to the housing and exposed to the environment outside of the housing, a second electrode secured
15 relative to the housing and exposed to the environment outside of the housing, a diaphragm that is exposed to the environment outside of the housing, the diaphragm is responsive to an external pressure applied to the diaphragm by the environment outside of the housing, a piezoelectric membrane having a first pressure sensor electrode and a second pressure sensor electrode, the piezoelectric membrane may be configured to generate an electrical
20 voltage between the first pressure sensor electrode and the second pressure sensor electrode in response to a pressure change applied to the diaphragm, the electrical voltage representative of a change in external pressure applied to the diaphragm, and circuitry in the housing operatively coupled to the first electrode and the second electrode of the LCP, and also operatively coupled to the first pressure sensor electrode and the second pressure
25 sensor electrode, the circuitry may be configured to deliver a pacing therapy to the patient's heart via the first electrode and the second electrode of the LCP, wherein the pacing therapy is dependent, at least in part, on the electrical voltage generated by the piezoelectric membrane and that is representative of the change in external pressure applied to the diaphragm.

30 Alternatively or additionally to any of the examples above, in another example, the circuitry may be configured to detect a pressure pulse by monitoring the electrical voltage

generated between the first pressure sensor electrode and the second pressure sensor electrode by the piezoelectric membrane.

Alternatively or additionally to any of the examples above, in another example, the diaphragm may have an interior surface that faces toward an interior of the housing, and the piezoelectric membrane may be secured to at least part of the interior surface of the diaphragm.

Alternatively or additionally to any of the examples above, in another example, the diaphragm may have an interior surface that faces toward an interior of the housing, and the piezoelectric membrane may be spaced a distance from the interior surface of the diaphragm and may be operatively coupled to the interior surface of the diaphragm via an incompressible fluid.

Alternatively or additionally to any of the examples above, in another example, the incompressible fluid may be in a fluid cavity that is at least partially defined by the interior surface of the diaphragm and may be in fluid communication with both the interior surface of the diaphragm and the piezoelectric membrane, wherein the fluid cavity may be configured to communicate a pressure applied to the incompressible fluid by the diaphragm to the piezoelectric membrane.

Alternatively or additionally to any of the examples above, in another example, the diaphragm may have an interior surface that faces toward an interior of the housing, and the piezoelectric membrane may be spaced a distance from the interior surface of the diaphragm and may be operatively coupled to the interior surface of the diaphragm via a mechanical linkage, wherein the mechanical linkage may be configured to translate movement of the diaphragm to a pressure applied to the piezoelectric membrane.

Alternatively or additionally to any of the examples above, in another example, the diaphragm of the housing may include one or more contours.

Alternatively or additionally to any of the examples above, in another example, the circuitry may be configured to detect a change in pressure in a first chamber of the heart caused by a contraction of a second chamber of the heart.

Alternatively or additionally to any of the examples above, in another example, the first chamber may be a ventricle, and the second chamber may be the corresponding atrium.

Alternatively or additionally to any of the examples above, in another example, the diaphragm may be integrally formed with the housing.

Alternatively or additionally to any of the examples above, in another example, the diaphragm may be hermetically sealed to the housing.

5 Alternatively or additionally to any of the examples above, in another example, the LCP may further comprise a fixation member at the distal end of the housing for fixing the distal end of the housing to an implant site, and wherein the diaphragm of the housing may be adjacent the proximal end of the housing.

10 Alternatively or additionally to any of the examples above, in another example, the housing may include an elongated body with a distal end surface facing distally and a proximal end surface facing proximally, wherein the diaphragm of the housing may be situated on the proximal end surface of the housing.

Alternatively or additionally to any of the examples above, in another example, the diaphragm and/or piezoelectric membrane may be formed to maximize the dynamic change
15 of the diaphragm and/or piezoelectric membrane when implanted.

In another example, a leadless cardiac pacemaker (LCP) may be configured to sense cardiac activity and to pace a patient's heart. The LCP may comprise a housing having a proximal end and a distal end, a first electrode secured relative to the housing and exposed to the environment outside of the housing, a second electrode secured relative to the
20 housing and exposed to the environment outside of the housing, the housing having a diaphragm that is exposed to the environment outside of the housing, the diaphragm is responsive to a pressure applied to the diaphragm by the environment outside of the housing, a piezoelectric material operatively coupled to the diaphragm of the housing for detecting a deflection in the diaphragm by generating charge that is representative of the
25 pressure applied to the diaphragm by the environment outside of the housing, and circuitry in the housing in operative communication with the first electrode, the second electrode and the piezoelectric material, the circuitry may be configured to deliver a pacing therapy to the patient's heart via the first electrode and the second electrode, wherein the pacing therapy is dependent, at least in part, on the charge that is generated by the piezoelectric
30 material and that is representative of the pressure applied to the diaphragm by the environment outside of the housing.

Alternatively or additionally to any of the examples above, in another example, the circuitry may be configured to detect a pressure pulse by monitoring the charge generated by the piezoelectric material.

Alternatively or additionally to any of the examples above, in another example, the
5 circuitry may be configured to detect a change in pressure in a first chamber of the heart caused by a contraction of a second chamber of the heart.

Alternatively or additionally to any of the examples above, in another example, the first chamber may be a ventricle, and the second chamber may be the corresponding atrium.

In another example, an implantable medical device (IMD) may comprise a
10 housing having a proximal end and a distal end, a first electrode secured relative to the housing and exposed to the environment outside of the housing, a second electrode secured relative to the housing and exposed to the environment outside of the housing, the housing having a diaphragm that is exposed to the environment outside of the housing, the diaphragm is responsive to a pressure applied to the diaphragm by the environment outside
15 of the housing, a piezoelectric membrane disposed on an inner surface of the diaphragm, the piezoelectric membrane generating a charge in response to the pressure applied to the diaphragm by the environment outside of the housing, and circuitry in the housing in operative communication with the first electrode, the second electrode and the piezoelectric membrane, the circuitry may be configured to deliver an electrostimulation therapy to the
20 patient's heart via the first electrode and the second electrode, wherein the therapy is dependent, at least in part, on the charge that is generated by the piezoelectric membrane and that is representative of the pressure applied to the diaphragm by the environment outside of the housing.

Alternatively or additionally to any of the examples above, in another example, the
25 piezoelectric membrane may comprise polyvinylidene fluoride (PVDF).

Alternatively or additionally to any of the examples above, in another example, the circuitry may be configured to detect a change in pressure in a first chamber of a heart caused by a contraction of a second chamber of the heart.

The above summary is not intended to describe each embodiment or every
30 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

5 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:

 Figure 1 is a schematic block diagram of an illustrative leadless cardiac pacemaker (LCP) according to one example of the present disclosure;

10 Figure 2 is a schematic block diagram of another medical device (MD), which may be used in conjunction with an LCP 100 (Figure 1) in order to detect and/or treat cardiac arrhythmias and other heart conditions;

 Figure 3 is a schematic diagram of an exemplary medical system that includes multiple LCPs and/or other devices in communication with one another;

15 Figure 4 is a schematic diagram of an exemplary medical system that includes an LCP and another medical device, in accordance with yet another example of the present disclosure;

 Figure 5 is a schematic diagram of an exemplary medical system that includes an LCP and another medical device, in accordance with yet another example of the present
20 disclosure;

 Figure 6 is a side view of an illustrative LCP;

 Figure 7A is a plan view of an example LCP implanted within a heart during ventricular filling;

 Figure 7B is a plan view of an example LCP implanted within a heart during
25 ventricular contraction;

 Figure 8 is a graph showing example pressures and volumes within the heart over time;

 Figure 9 is a schematic cross-sectional view of an illustrative LCP;

 Figure 10 is a schematic cross-sectional view of an illustrative pressure sensor for
30 use with an implantable medical device (IMD) such as an LCP;

Figure 11 is a schematic cross-sectional view of an illustrative pressure sensor for use with an IMD such as an LCP;

Figure 12 is a schematic cross-sectional view of a proximal end portion of another illustrative LCP;

5 Figure 13 is a schematic cross-sectional view of a proximal end portion of another illustrative LCP;

Figure 14 is a schematic cross-sectional view of a proximal end portion of another illustrative LCP; and

10 Figure 15 is a schematic cross-sectional view of a proximal end of another illustrative LCP.

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

DESCRIPTION

The following description should be read with reference to the drawings in which
20 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. While the present disclosure is applicable to any suitable implantable medical device (IMD), the description below uses pacemakers and more particularly leadless cardiac pacemakers (LCP) as particular examples.

25 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. This contraction forces blood out of and into the heart, providing circulation of the blood throughout the rest of the body. However, many patients suffer from cardiac conditions that affect this contractility of their hearts. For example,
30 some hearts may develop diseased tissues that no longer generate or conduct intrinsic electrical signals. In some examples, diseased cardiac tissues conduct electrical signals at

differing rates, thereby causing an unsynchronized and inefficient contraction of the heart. In other examples, a heart may initiate 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. In some cases such an abnormality can develop into a fibrillation state, where the contraction of the patient's heart chambers are almost completely de-synchronized and the heart pumps very little to no blood. Implantable medical devices, which may be configured to determine occurrences of such cardiac abnormalities or arrhythmias and deliver one or more types of electrical stimulation therapy to patient's hearts, may help to terminate or alleviate these and other cardiac conditions.

Figure 1 depicts an illustrative leadless cardiac pacemaker (LCP) that may be implanted into a patient and may operate to prevent, control, or terminate cardiac arrhythmias in patients by, for example, appropriately employing one or more therapies (e.g., anti-tachycardia pacing (ATP) therapy, cardiac resynchronization therapy (CRT), bradycardia therapy, defibrillation pulses, or the like). As can be seen in Figure 1, the LCP 100 may be a compact device with all components housed within the LCP 100 or directly on the housing 120. In the example shown in Figure 1, the LCP 100 may include a communication module 102, a pulse generator module 104, an electrical sensing module 106, a mechanical sensing module 108, a processing module 110, a battery 112, and electrodes 114. The LCP 100 may include more or less modules, depending on the application.

The communication module 102 may be configured to communicate with devices such as sensors, other medical devices, and/or the like, that are located externally to the LCP 100. Such devices may be located either external or internal to the patient's body. Irrespective of the location, remote devices (i.e., external to the LCP 100 but not necessarily external to the patient's body) can communicate with the LCP 100 via the communication module 102 to accomplish one or more desired functions. For example, the LCP 100 may communicate information, such as sensed electrical signals, data, instructions, messages, etc., to an external medical device through the communication module 102. The external medical device may use the communicated signals, data, instructions and/or messages to perform various functions, such as determining occurrences of arrhythmias, delivering electrical stimulation therapy, storing received data,

analyzing received data, and/or performing any other suitable function. The LCP 100 may additionally receive information such as signals, data, instructions and/or messages from the external medical device through the communication module 102, and the LCP 100 may use the received signals, data, instructions and/or messages to perform various functions, such as determining occurrences of arrhythmias, delivering electrical stimulation therapy, storing received data, analyzing received data, and/or performing any other suitable function. The communication module 102 may be configured to use one or more methods for communicating with remote devices. For example, the communication module 102 may communicate via radiofrequency (RF) signals, inductive coupling, optical signals, acoustic signals, conducted communication signals, and/or any other signals suitable for communication.

In the example shown in Figure 1, the pulse generator module 104 may be electrically connected to the electrodes 114. In some examples, the LCP 100 may include one or more additional electrodes 114'. In such examples, the pulse generator 104 may also be electrically connected to the additional electrodes 114'. The pulse generator module 104 may be configured to generate electrical stimulation signals. For example, the pulse generator module 104 may generate electrical stimulation signals by using energy stored in a battery 112 within the LCP 100 and deliver the generated electrical stimulation signals via the electrodes 114 and/or 114'. Alternatively, or additionally, the pulse generator 104 may include one or more capacitors, and the pulse generator 104 may charge the one or more capacitors by drawing energy from the battery 112. The pulse generator 104 may then use the energy of the one or more capacitors to deliver the generated electrical stimulation signals via the electrodes 114 and/or 114'. In at least some examples, the pulse generator 104 of the LCP 100 may include switching circuitry to selectively connect one or more of the electrodes 114 and/or 114' to the pulse generator 104 in order to select which of the electrodes 114/114' (and/or other electrodes) the pulse generator 104 delivers the electrical stimulation therapy. The pulse generator module 104 may generate electrical stimulation signals with particular features or in particular sequences in order to provide one or multiple of a number of different stimulation therapies. For example, the pulse generator module 104 may be configured to generate electrical stimulation signals to provide electrical stimulation therapy to combat bradycardia, tachycardia, cardiac

dyssynchrony, bradycardia arrhythmias, tachycardia arrhythmias, fibrillation arrhythmias, cardiac synchronization arrhythmias and/or to produce any other suitable electrical stimulation therapy. Some more common electrical stimulation therapies include bradycardia therapy, anti-tachycardia pacing (ATP) therapy, cardiac resynchronization therapy (CRT), and cardioversion/defibrillation therapy.

In some examples, the LCP 100 may not include a pulse generator 104 or may turn off the pulse generator 104. When so provided, the LCP 100 may be a diagnostic only device. In such examples, the LCP 100 may not deliver electrical stimulation therapy to a patient. Rather, the LCP 100 may collect data about cardiac electrical activity and/or physiological parameters of the patient and communicate such data and/or determinations to one or more other medical devices via the communication module 102.

In some examples, the LCP 100 may include an electrical sensing module 106, and in some cases, a mechanical sensing module 108. The electrical sensing module 106 may be configured to sense the cardiac electrical activity of the heart. For example, the electrical sensing module 106 may be connected to the electrodes 114/114', and the electrical sensing module 106 may be configured to receive cardiac electrical signals conducted through the electrodes 114/114'. The cardiac electrical signals may represent local information from the chamber in which the LCP 100 is implanted. For instance, if the LCP 100 is implanted within a ventricle of the heart, cardiac electrical signals sensed by the LCP 100 through the electrodes 114/114' may represent ventricular cardiac electrical signals. The mechanical sensing module 108 may include one or more sensors, such as an accelerometer, a blood pressure sensor, a heart sound sensor, a blood-oxygen sensor, a temperature sensor, a flow sensor and/or any other suitable sensors that are configured to measure one or more mechanical and/or chemical parameters of the patient. Both the electrical sensing module 106 and the mechanical sensing module 108 may be connected to a processing module 110, which may provide signals representative of the sensed mechanical parameters. Although described with respect to Figure 1 as separate sensing modules, in some cases, the electrical sensing module 106 and the mechanical sensing module 108 may be combined into a single sensing module, as desired.

The electrodes 114/114' can be secured relative to the housing 120 but exposed to the tissue and/or blood surrounding the LCP 100. In some cases, the electrodes 114 may

be generally disposed on either end of the LCP 100 and may be in electrical communication with one or more of the modules 102, 104, 106, 108, and 110. The electrodes 114/114' may be supported by the housing 120, although in some examples, the electrodes 114/114' may be connected to the housing 120 through short connecting wires such that the electrodes 114/114' are not directly secured relative to the housing 120. In examples where the LCP 100 includes one or more electrodes 114', the electrodes 114' may in some cases be disposed on the sides of the LCP 100, which may increase the number of electrodes by which the LCP 100 may sense cardiac electrical activity, deliver electrical stimulation and/or communicate with an external medical device. The electrodes 114/114' can be made up of one or more biocompatible conductive materials such as various metals or alloys that are known to be safe for implantation within a human body. In some instances, the electrodes 114/114' connected to LCP 100 may have an insulative portion that electrically isolates the electrodes 114/114' from adjacent electrodes, the housing 120, and/or other parts of the LCP 100.

The processing module 110 can be configured to control the operation of the LCP 100. For example, the processing module 110 may be configured to receive electrical signals from the electrical sensing module 106 and/or the mechanical sensing module 108. Based on the received signals, the processing module 110 may determine, for example, occurrences and, in some cases, types of arrhythmias. Based on any determined arrhythmias, the processing module 110 may control the pulse generator module 104 to generate electrical stimulation in accordance with one or more therapies to treat the determined arrhythmia(s). The processing module 110 may further receive information from the communication module 102. In some examples, the processing module 110 may use such received information to help determine whether an arrhythmia is occurring, determine a type of arrhythmia, and/or to take particular action in response to the information. The processing module 110 may additionally control the communication module 102 to send/receive information to/from other devices.

In some examples, the processing module 110 may include a pre-programmed chip, such as a very-large-scale integration (VLSI) chip and/or an application specific integrated circuit (ASIC). In such embodiments, the chip may be pre-programmed with control logic in order to control the operation of the LCP 100. By using a pre-programmed chip, the

processing module 110 may use less power than other programmable circuits (e.g., general purpose programmable microprocessors) while still being able to maintain basic functionality, thereby potentially increasing the battery life of the LCP 100. In other examples, the processing module 110 may include a programmable microprocessor. Such a programmable microprocessor may allow a user to modify the control logic of the LCP 100 even after implantation, thereby allowing for greater flexibility of the LCP 100 than when using a pre-programmed ASIC. In some examples, the processing module 110 may further include a memory, and the processing module 110 may store information on and read information from the memory. In other examples, the LCP 100 may include a separate memory (not shown) that is in communication with the processing module 110, such that the processing module 110 may read and write information to and from the separate memory.

The battery 112 may provide power to the LCP 100 for its operations. In some examples, the battery 112 may be a non-rechargeable lithium-based battery. In other examples, a non-rechargeable battery may be made from other suitable materials, as desired. Because the LCP 100 is an implantable device, access to the LCP 100 may be limited after implantation. Accordingly, it is desirable to have sufficient battery capacity to deliver therapy over a period of treatment such as days, weeks, months, years or even decades. In some instances, the battery 112 may be a rechargeable battery, which may help increase the useable lifespan of the LCP 100. In still other examples, the battery 112 may be some other type of power source, as desired.

To implant the LCP 100 inside a patient's body, an operator (e.g., a physician, clinician, etc.), may fix the LCP 100 to the cardiac tissue of the patient's heart. To facilitate fixation, the LCP 100 may include one or more anchors 116. The anchor 116 may include any one of a number of fixation or anchoring mechanisms. For example, the anchor 116 may include one or more pins, staples, threads, screws, helix, tines, and/or the like. In some examples, although not shown, the anchor 116 may include threads on its external surface that may run along at least a partial length of the anchor 116. The threads may provide friction between the cardiac tissue and the anchor to help fix the anchor 116 within the cardiac tissue. In other examples, the anchor 116 may include other structures such as barbs, spikes, or the like to facilitate engagement with the surrounding cardiac tissue.

Figure 2 depicts an example of another medical device (MD) 200, which may be used in conjunction with an LCP 100 (Figure 1) in order to detect and/or treat cardiac arrhythmias and other heart conditions. In the example shown, the MD 200 may include a communication module 202, a pulse generator module 204, an electrical sensing module 206, a mechanical sensing module 208, a processing module 210, and a battery 218. Each of these modules may be similar to the modules 102, 104, 106, 108, and 110 of the LCP 100. Additionally, the battery 218 may be similar to the battery 112 of the LCP 100. In some examples, the MD 200 may have a larger volume within the housing 220 than LCP 100. In such examples, the MD 200 may include a larger battery and/or a larger processing module 210 capable of handling more complex operations than the processing module 110 of the LCP 100.

While it is contemplated that the MD 200 may be another leadless device such as shown in Figure 1, in some instances the MD 200 may include leads such as leads 212. The leads 212 may include electrical wires that conduct electrical signals between the electrodes 214 and one or more modules located within the housing 220. In some cases, the leads 212 may be connected to and extend away from the housing 220 of the MD 200. In some examples, the leads 212 are implanted on, within, or adjacent to a heart of a patient. The leads 212 may contain one or more electrodes 214 positioned at various locations on the leads 212, and in some cases at various distances from the housing 220. Some of the leads 212 may only include a single electrode 214, while other leads 212 may include multiple electrodes 214. Generally, the electrodes 214 are positioned on the leads 212 such that when the leads 212 are implanted within the patient, one or more of the electrodes 214 are positioned to perform a desired function. In some cases, the one or more of the electrodes 214 may be in contact with the patient's cardiac tissue. In some cases, the one or more of the electrodes 214 may be positioned substernally or subcutaneously but adjacent the patient's heart. In some cases, the electrodes 214 may conduct intrinsically generated electrical signals to the leads 212, e.g., signals representative of intrinsic cardiac electrical activity. The leads 212 may, in turn, conduct the received electrical signals to one or more of the modules 202, 204, 206, and 208 of the MD 200. In some cases, the MD 200 may generate electrical stimulation signals, and the leads 212 may conduct the generated electrical stimulation signals to the electrodes 214. The electrodes 214 may then

conduct the electrical signals and delivery the signals to the patient's heart (either directly or indirectly).

The mechanical sensing module 208, as with the mechanical sensing module 108, may contain or be electrically connected to one or more sensors, such as accelerometers, blood pressure sensors, heart sound sensors, blood-oxygen sensors, acoustic sensors, ultrasonic sensors and/or other sensors which are configured to measure one or more mechanical/chemical parameters of the heart and/or patient. In some examples, one or more of the sensors may be located on the leads 212, but this is not required. In some examples, one or more of the sensors may be located in the housing 220.

While not required, in some examples, the MD 200 may be an implantable medical device. In such examples, the housing 220 of the MD 200 may be implanted in, for example, a transthoracic region of the patient. The housing 220 may generally include any of a number of known materials that are safe for implantation in a human body and may, when implanted, hermetically seal the various components of the MD 200 from fluids and tissues of the patient's body.

In some cases, the MD 200 may be an implantable cardiac pacemaker (ICP). In this example, the MD 200 may have one or more leads, for example leads 212, which are implanted on or within the patient's heart. The one or more leads 212 may include one or more electrodes 214 that are in contact with cardiac tissue and/or blood of the patient's heart. The MD 200 may be configured to sense intrinsically generated cardiac electrical signals and determine, for example, one or more cardiac arrhythmias based on analysis of the sensed signals. The MD 200 may be configured to deliver CRT, ATP therapy, bradycardia therapy, and/or other therapy types via the leads 212 implanted within the heart or in concert with the LCP by commanding the LCP to pace. In some examples, the MD 200 may additionally be configured provide defibrillation therapy.

In some instances, the MD 200 may be an implantable cardioverter-defibrillator (ICD). In such examples, the MD 200 may include one or more leads implanted within a patient's heart. The MD 200 may also be configured to sense cardiac electrical signals, determine occurrences of tachyarrhythmias based on the sensed signals, and may be configured to deliver defibrillation therapy in response to determining an occurrence of a tachyarrhythmia. In some instances, the MD 200 may be a subcutaneous implantable

cardioverter-defibrillator (S-ICD). In examples where the MD 200 is an S-ICD, one of the leads 212 may be a subcutaneously implanted lead. In at least some examples where the MD 200 is an S-ICD, the MD 200 may include only a single lead which is implanted subcutaneously, but this is not required. In some cases, the S-ICD lead may extend
5 subcutaneously from the S-ICD can, around the sternum and may terminate adjacent the interior surface of the sternum.

In some examples, the MD 200 may not be an implantable medical device. Rather, the MD 200 may be a device external to the patient's body, and may include skin-electrodes that are placed on a patient's body. In such examples, the MD 200 may be able to sense
10 surface electrical signals (e.g., cardiac electrical signals that are generated by the heart or electrical signals generated by a device implanted within a patient's body and conducted through the body to the skin). In such examples, the MD 200 may be configured to deliver various types of electrical stimulation therapy, including, for example, defibrillation therapy. The MD 200 may be further configured to deliver electrical stimulation via the
15 LCP by commanding the LCP to deliver the therapy.

Figure 3 shows an example medical device system with a communication pathway through which multiple medical devices 302, 304, 306, and/or 310 may communicate. In the example shown, the medical device system 300 may include LCPs 302 and 304, an external medical device 306, and other sensors/devices 310. The external device 306 may
20 be any of the devices described previously with respect to MD 200. In some embodiments, the external device 306 may be provided with or be in communication with a display 312. The display 312 may be a personal computer, tablet computer, smart phone, laptop computer, or other display as desired. In some instances, the display 312 may include input means for receiving an input from a user. For example, the display 312 may also include
25 a keyboard, mouse, actuatable (e.g., pushable) buttons, or a touchscreen display. These are just examples. The other sensors/devices 310 may be any of the devices described previously with respect to the MD 200. In some instances, the other sensors/devices 310 may include a sensor, such as an accelerometer or blood pressure sensor, or the like. In some cases, the other sensors/devices 310 may include an external programmer device that
30 may be used to program one or more devices of the system 300.

Various devices of the system 300 may communicate via a communication pathway 308. For example, the LCPs 302 and/or 304 may sense intrinsic cardiac electrical signals and may communicate such signals to one or more other devices 302/304, 306, and 310 of the system 300 via the communication pathway 308. In one example, one or more of the devices 302/304 may receive such signals and, based on the received signals, determine an occurrence of an arrhythmia. In some cases, the device or devices 302/304 may communicate such determinations to one or more other devices 306 and 310 of the system 300. In some cases, one or more of the devices 302/304, 306, and 310 of the system 300 may take action based on the communicated determination of an arrhythmia, such as by delivering a suitable electrical stimulation to the heart of the patient. In another example, the LCPs 302 and/or 304 may sense indications of blood pressure (e.g., via one or more pressure sensors) and indications of volume (e.g., via an impedance between the electrodes of an LCP or between LCPs via an ultrasound transducer placed within the LCP, or via strain sensors placed on the heart in communication with the LCP). In one example, one or more of the devices 302/304 may receive such signals and, based on the received signals, determine a pressure-volume loop, and in some cases may communicate such information to one or more other devices 302/304, 306, and 310 of the system 300 via the communication pathway 308.

It is contemplated that the communication pathway 308 may communicate using RF signals, inductive coupling, conductive coupling optical signals, acoustic signals, or any other signals suitable for communication. Additionally, in at least some examples, the device communication pathway 308 may comprise multiple signal types. For instance, the other sensors/device 310 may communicate with the external device 306 using a first signal type (e.g., RF communication) but communicate with the LCPs 302/304 using a second signal type (e.g., conducted communication, inductive communication). Further, in some examples, communication between devices may be limited. For instance, as described above, in some examples, the LCPs 302/304 may communicate with the external device 306 only through the other sensors/devices 310, where the LCPs 302/304 send signals to the other sensors/devices 310, and the other sensors/devices 310 relay the received signals to the external device 306.

In some cases, the communication pathway 308 may include conducted communication. Accordingly, devices of the system 300 may have components that allow for such conducted communication. For instance, the devices of the system 300 may be configured to transmit conducted communication signals (e.g., current and/or voltage pulses) into the patient's body via one or more electrodes of a transmitting device, and may receive the conducted communication signals (e.g., pulses) via one or more electrodes of a receiving device. The patient's body may "conduct" the conducted communication signals (e.g., pulses) from the one or more electrodes of the transmitting device to the electrodes of the receiving device in the system 300. In such examples, the delivered conducted communication signals (e.g., pulses) may differ from pacing or other therapy signals. For example, the devices of the system 300 may deliver electrical communication pulses at an amplitude/pulse width that is sub-threshold to the heart. Although, in some cases, the amplitude/pulse width of the delivered electrical communication pulses may be above the capture threshold of the heart, but may be delivered during a refractory period of the heart and/or may be incorporated in or modulated onto a pacing pulse, if desired.

Delivered electrical communication pulses may be modulated in any suitable manner to encode communicated information. In some cases, the communication pulses may be pulse width modulated or amplitude modulated. Alternatively, or in addition, the time between pulses may be modulated to encode desired information. In some cases, conducted communication pulses may be voltage pulses, current pulses, biphasic voltage pulses, biphasic current pulses, or any other suitable electrical pulse as desired.

In some cases, the communication pathway 308 may include inductive communication, and when so provided, the devices of the system 300 may be configured to transmit/receive inductive communication signals.

Figures 4 and 5 show illustrative medical device systems that may be configured to operate according to techniques disclosed herein. In Figure 4, an LCP 402 is shown fixed to the interior of the right ventricle of the heart 410, and a pulse generator 406 is shown coupled to a lead 412 having one or more electrodes 408a, 408b, 408c. In some cases, the pulse generator 406 may be part of a subcutaneous implantable cardioverter-defibrillator (S-ICD), and the one or more electrodes 408a, 408b, 408c may be positioned subcutaneously adjacent the heart. In some cases, the S-ICD lead may extend

subcutaneously from the S-ICD can, around the sternum and one or more electrodes 408a, 408b, 408c may be positioned adjacent the interior surface of the sternum. In some cases, the LCP 402 may communicate with the subcutaneous implantable cardioverter-defibrillator (S-ICD).

5 In some cases, the LCP 402 may be in the left ventricle, right atrium or left atrium of the heart, as desired. In some cases, more than one LCP 402 may be implanted. For example, one LCP may be implanted in the right ventricle and another may be implanted in the right atrium. In another example, one LCP may be implanted in the right ventricle and another may be implanted in the left ventricle. In yet another example, one LCP may
10 be implanted in each of the chambers of the heart.

 In Figure 5, an LCP 502 is shown fixed to the interior of the left ventricle of the heart 510, and a pulse generator 506 is shown coupled to a lead 512 having one or more electrodes 504a, 504b, 504c. In some cases, the pulse generator 506 may be part of an implantable cardiac pacemaker (ICP) and/or an implantable cardioverter-defibrillator
15 (ICD), and the one or more electrodes 504a, 504b, 504c may be positioned in the heart 510. In some cases, the LCP 502 may communicate with the implantable cardiac pacemaker (ICP) and/or an implantable cardioverter-defibrillator (ICD).

 The medical device systems 400 and 500 may also include an external support device, such as external support devices 420 and 520. The external support devices 420
20 and 520 can be used to perform functions such as device identification, device programming and/or transfer of real-time and/or stored data between devices using one or more of the communication techniques described herein. As one example, communication between the external support device 420 and the pulse generator 406 is performed via a wireless mode, and communication between the pulse generator 406 and the LCP 402 is
25 performed via a conducted mode. In some examples, communication between the LCP 402 and the external support device 420 is accomplished by sending communication information through the pulse generator 406. However, in other examples, communication between the LCP 402 and the external support device 420 may be via a communication module. In some embodiments, the external support devices 420, 520 may be provided
30 with or be in communication with a display 422, 522. The display 422, 522 may be a personal computer, tablet computer, smart phone, laptop computer, or other display as

desired. In some instances, the display 422, 522 may include input means for receiving an input from a user. For example, the display 422, 522 may also include a keyboard, mouse, actuatable buttons, or be a touchscreen display. These are just examples.

Figures 4-5 illustrate two examples of medical device systems that may be configured to operate according to techniques disclosed herein. Other example medical device systems may include additional or different medical devices and/or configurations. For instance, other medical device systems that are suitable to operate according to techniques disclosed herein may include additional LCPs implanted within the heart. Another example medical device system may include a plurality of LCPs without other devices such as the pulse generator 406 or 506, with at least one LCP capable of delivering defibrillation therapy. In yet other examples, the configuration or placement of the medical devices, leads, and/or electrodes may be different from those depicted in Figures 4 and 5. Accordingly, it should be recognized that numerous other medical device systems, different from those depicted in Figures 4 and 5, may be operated in accordance with techniques disclosed herein. As such, the examples shown in Figures 4 and 5 should not be viewed as limiting in any way.

Figure 6 is a side view of an illustrative implantable leadless cardiac pacemaker (LCP) 610. The LCP 610 may be similar in form and function to the LCP 100 described above. The LCP 610 may include any of the modules and/or structural features described herein. The LCP 610 may include a shell or housing 612 having a proximal end 614 and a distal end 616. The illustrative LCP 610 includes a first electrode 620 secured relative to the housing 612 and positioned adjacent to the distal end 616 of the housing 612 and a second electrode 622 secured relative to the housing 612 and positioned adjacent to the proximal end 614 of the housing 612. In some cases, the housing 612 may include a conductive material and may be insulated along a portion of its length. A section along the proximal end 614 may be free of insulation so as to define the second electrode 622. The electrodes 620, 622 may be sensing and/or pacing electrodes to provide electro-therapy and/or sensing capabilities. The first electrode 620 may be capable of being positioned against or may otherwise contact the cardiac tissue of the heart while the second electrode 622 may be spaced away from the first electrode 620. The first and/or second electrodes

620, 622 may be exposed to the environment outside the housing 612 (e.g., to blood and/or tissue).

It is contemplated that the housing 612 may take a variety of different shapes. For example, in some cases, the housing 612 may have a generally cylindrical shape. In other cases, the housing 612 may have a half-dome shape. In yet other embodiments, the housing 612 may be a rectangular prism. It is contemplated that the housing may take any cross sectional shape desired, including but not limited to annular, polygonal, oblong, square, etc.

In some cases, the LCP 610 may include a pulse generator (e.g., electrical circuitry) and a power source (e.g., a battery) within the housing 612 to provide electrical signals to the electrodes 620, 622 to control the pacing/sensing electrodes 620, 622. While not explicitly shown, the LCP 610 may also include a communications module, an electrical sensing module, a mechanical sensing module, and/or a processing module, and the associated circuitry, similar in form and function to the modules 102, 106, 108, 110 described above. The various modules and electrical circuitry may be disposed within the housing 612. Electrical communication between the pulse generator and the electrodes 620, 622 may provide electrical stimulation to heart tissue and/or sense a physiological condition.

In the example shown, the LCP 610 includes a fixation mechanism 624 proximate the distal end 616 of the housing 612. The fixation mechanism 624 is configured to attach the LCP 610 to a wall of the heart H, or otherwise anchor the LCP 610 to the anatomy of the patient. As shown in Figure 6, in some instances, the fixation mechanism 624 may include one or more, or a plurality of hooks or tines 626 anchored into the cardiac tissue of the heart H to attach the LCP 610 to a tissue wall. In other instances, the fixation mechanism 624 may include one or more, or a plurality of passive tines, configured to entangle with trabeculae within the chamber of the heart H and/or a helical fixation anchor configured to be screwed into a tissue wall to anchor the LCP 610 to the heart H. These are just examples.

The LCP 610 may further include a docking member 630 proximate the proximal end 614 of the housing 612. The docking member 630 may be configured to facilitate delivery and/or retrieval of the LCP 610. For example, the docking member 630 may

extend from the proximal end 614 of the housing 612 along a longitudinal axis of the housing 612. The docking member 630 may include a head portion 632 and a neck portion 634 extending between the housing 612 and the head portion 632. The head portion 632 may be an enlarged portion relative to the neck portion 634. For example, the head portion 632 may have a radial dimension from the longitudinal axis of the LCP 610 that is greater than a radial dimension of the neck portion 634 from the longitudinal axis of the LCP 610. In some cases, the docking member 630 may further include a tether retention structure (not explicitly shown) extending from or recessed within the head portion 632. The tether retention structure may define an opening configured to receive a tether or other anchoring mechanism therethrough. The retention structure may take any shape that provides an enclosed perimeter surrounding the opening such that a tether may be securably and releasably passed (e.g., looped) through the opening. In some cases, the retention structure may extend through the head portion 632, along the neck portion 634, and to or into the proximal end 614 of the housing 612. The docking member 630 may be configured to facilitate delivery of the LCP 610 to the intracardiac site and/or retrieval of the LCP 610 from the intracardiac site. While this describes one example docking member 630, it is contemplated that the docking member 630, when provided, can have any suitable configuration.

It is contemplated that the LCP 610 may include one or more pressure sensors 640 coupled to or formed within the housing 612 such that the pressure sensor(s) is exposed to and/or otherwise operationally coupled with the environment outside the housing 612 to measure blood pressures within the heart. In some cases, the one or more pressure sensors 640 may be coupled to an exterior surface of the housing 612. In other cases, the one or more pressures sensors 640 may be positioned within the housing 612 with a pressure acting on the housing and/or a port on the housing 612 to affect the pressure sensor 640. For example, if the LCP 610 is placed in the right ventricle, the pressure sensor(s) 640 may measure the pressure within the right ventricle. If the LCP 610 is placed in another portion of the heart (such as one of the atriums or the left ventricle), the pressures sensor(s) may measure the pressure within that portion of the heart. It is contemplated that the pressure sensor(s) 640 may be sensitive enough to detect a pressure change in the right atrium (e.g.

atrial kick) when the LCP is placed in the right ventricle. Some illustrative pressure sensor configurations will be described in more detail herein.

In some instances, the pressure sensor(s) 640 may include a deformable diaphragm formed in part or in whole from a piezoelectric material which does not require external power to function. In some instances, the pressure sensor(s) 640 may include a MEMS device, such as a MEMS device with a pressure diaphragm with one or more piezoelectric sensors and/or piezoresistors on the diaphragm, a capacitor-Micro-machined Ultrasonic Transducer (cMUT), a condenser, a micromanometer, a surface acoustic wave (SAW) device, and/or any other suitable sensor adapted for measuring a pressure exerted on the diaphragm. Some illustrative but non-limiting pressure sensors and configurations are describe in commonly assigned Patent Application Number 62/413,766 entitled “IMPLANTABLE MEDICAL DEVICE WITH PRESSURE SENSOR and filed on October 27, 2016, which is hereby incorporated by reference. It is contemplated that when piezoresistors are used, a piezo-resistive bridge may be operated in a low power mode (e.g., limited duty-cycle excitation) to reduce the power demand of the sensor. In some cases, the gain may be modulated to further reduce power demands.

When a piezoelectric material is used, the piezoelectric material may generate an electrical voltage (and/or electric current) between a first pressure sensor electrode and a second pressure sensor electrode in response to a pressure change applied to the piezoelectric material. The electrical voltage (and/or electric current) may be representative of the pressure change. In this instance, the piezoelectric material may not require any external power, but rather the piezoelectric material itself may convert energy extracted from the change in pressure into an electrical voltage (and/or electric current), which can then be used by the LCP to identify a pressure change. In some cases, it may not be necessary or even desirable to measure an absolute pressure value. Instead, just detecting a pressure change is all that is necessary to identify certain pressure events.

The pressures sensor(s) 640 may be part of a mechanical sensing module described herein. It is contemplated that the pressure measurements obtained from the pressures sensor(s) 640 may be used to generate a pressure curve over cardiac cycles. The pressure sensor(s) 640 may measure/sense pressure in the chamber in which the LCP 610 is implanted. For example, an LCP 610 implanted in the right ventricle (RV) could sense RV

pressure. It is further contemplated that the pressure sensor(s) 640 may be sensitive enough to detect pressure changes in other chambers as well as the chamber in which the LCP 610 is positioned. For example, when the LCP 610 is positioned within the right ventricle, the pressure sensor(s) 640 may detect pressure changes in the right atrium (e.g. atrial kick) in addition to pressure changes in the right ventricle.

In some cases, sensing atrial pressure events may allow the device 610 to detect an atrial contraction, resulting in for example an atrial kick. Such a change in atrial pressure event may be used by an LCP in the right ventricle to time a pacing pulse for the ventricle in support of treating bradycardia events. In some cases, the timing of the ventricle pacing pulse may be adjusted to maximize the amount of blood entering the right ventricle through passive filling. In some instances, this may include adjusting an AV delay relative to the atrial fiducial (e.g. atrial kick). In some cases, a measured pressure change over time may be used to support management of a CRT cardiac therapy (if placed in the left ventricle), patient health status monitoring and/or any other suitable goal. It is contemplated measuring pressure events in both the ventricle and atrium using a single LCP may replicate a dual chamber system with a single device. For example, such a system may enable a device to be positioned in the ventricle while listening to both the ventricle and the atrium and pacing accordingly (e.g., a VDD device).

The pressure sensor(s) 640 may be configured (either alone or in combination with other circuitry in the LCP 610) to derive a change in pressure over time and may be used to adjust atrium to ventricle (AV) pacing delay to optimize pacing for treating bradycardia events. In some cases, the pressure sensor(s) 640 may be configured to detect a-waves (e.g. atrial kick) and change the pacing timing of the LCP 610 for ventricular pacing in relation to the contraction of the right atrium. It is further contemplated that sensing pressure could be used during the implant procedure to optimize the placement of the LCP 610 in the chamber (e.g., RV by sampling at different implant locations and using the best location). In some cases, frequent pressure monitoring may be beneficial for management of heart failure patients. Frequent pressure monitoring may also be useful for patients with chronic heart disease, hypertension, regurgitation, valve issues, atrial contraction detection, and to aid in addressing other problems. It is further contemplated that the pressure

sensor(s) 640 may be used for monitoring respiration and associated diseases (e.g., chronic obstructive pulmonary disease (COPD), etc.). These are just examples.

In some cases, pressure readings may be taken in combination with a cardiac chamber volume measurement such as an impedance measurement (e.g., the impedance
5 between electrodes 620 and 622) to generate a pressure-impedance loop for one or more cardiac cycles. The impedance may be a surrogate for chamber volume, and thus the pressure-impedance loop may be representative of a pressure-volume loop for the heart H.

Figure 7A is a plan view of the example leadless cardiac pacing device 610 implanted within a right ventricle RV of the heart H during ventricular filling. The right
10 atrium RA, left ventricle LV, left atrium LA, and aorta A are also illustrated. Figure 7B is a plan view of the leadless cardiac pacing device 610 implanted within a right ventricle of the heart H during ventricular contraction. These figures illustrate how the volume of the right ventricle may change over a cardiac cycle. As can be seen in Figures 7A and 7B, the volume of the right ventricle during ventricular filling is larger than the volume of the right
15 ventricle of the heart during ventricular contraction.

In some cases, the processing module and/or other control circuitry may capture, at a time point within each of one or more cardiac cycles, one or more pressures within the heart (e.g., right ventricle and/or right atrium), resulting in one or more pressure data points. These one or more data points may be used, in combination with other pressure data points
20 taken at different times during the one or more cardiac cycles, to generate a pressure curve. In some cases, one or more parameters may be extracted or derived from the pressure curve. The pressure curve may be used to facilitate cardiac resynchronization therapy (CRT), patient health status monitoring, and/or the management of a non-CRT cardiac therapy.

Figure 8 is a graph 800 showing example pressures and volumes within a heart over
25 time. More specifically, Figure 8 depicts the aortic pressure, left ventricular pressure, left atrial pressure, left ventricular volume, an electrocardiogram (ECG or egram), and heart sounds of the heart H. 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.
30 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 ventricular 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
5 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. Contractions of the atria are initiated near the end of ventricular diastole. The active atrial contraction pushes or forces
10 additional volumes of blood into the ventricles (often referred to as "atrial kick") in addition to the volumes associated with passive filling. In some cases, the atrial kick contributes in the range of about 20% of the volume of blood toward ventricular preload. At normal heart rates, the atrial contractions are considered essential for adequate ventricular filling. However, as heart rates increase, atrial filling becomes increasingly important for
15 ventricular filling because the time interval between contractions for passive filling becomes progressively shorter. Cardiac pressure curves for the pulmonary artery, the right atrium, and the right ventricle, and the cardiac volume curve for the right ventricle, similar to those illustrated in Figure 8 for the left part of the heart, may be likewise generated. Typically, the cardiac pressure in the right ventricle is lower than the cardiac pressure in
20 the left ventricle.

In one example, the heart sound signals can be recorded using acoustic sensors, (for example, a microphone), which capture the acoustic waves resulted from heart sounds. In another example, the heart sound signals can be recorded using accelerometers or pressure sensors that capture the accelerations or pressure waves caused by heart sounds. The heart
25 sound signals can be recorded within or outside the heart. These are just examples.

Figure 9 is a cross-section of an illustrative implantable leadless cardiac pacemaker (LCP) 900. The LCP 900 may be similar in form and function to the LCPs 100, 610 described above. The LCP 900 may include any of the modules and/or structural features described above with respect to the LCPs 100, 610. The LCP 900 may include a shell or
30 housing 902 having a proximal end 904 and a distal end 906. In the example shown, the LCP 900 does not include a docking member. However, in some cases, a docking member

may be provided, such as a cage, a head or other feature extending proximally from adjacent the side walls of the housing 902. The illustrative LCP 900 includes a first electrode 908 secured relative to the housing 902 and positioned adjacent to the distal end 906 of the housing 902, and a second electrode (not explicitly shown) secured relative to the housing 902 and positioned adjacent to the proximal end 904 of the housing 902. In some instances, the first electrode 908 may be positioned on a distal end surface facing distally. In some cases, the housing 902 may include a conductive material and may be insulated along a portion of its length. A section along the proximal end 904 may be free of insulation so as to define the second electrode. The electrodes 908 may be sensing and/or pacing electrodes to aid in providing electro-therapy and/or sensing capabilities. The first electrode 908 may be capable of being positioned against or may otherwise contact the cardiac tissue of the heart while the second electrode may be spaced away from the first electrode 908. The first and/or second electrodes 908 may be exposed to the environment outside the housing 902 (e.g., to blood and/or tissue).

In some cases, the LCP 900 may include a pulse generator (e.g., electrical circuitry) 910 and a power source (e.g., a battery) 912 within the housing 902 to provide and/or receive electrical signals via the first and second electrodes. While not explicitly shown in Figure 9, the LCP 900 may also include a communications module, an electrical sensing module, a mechanical sensing module, and/or a processing module, and associated circuitry, similar in form and function to the modules 102, 106, 108, 110 described above. The various modules and electrical circuitry may be disposed within the housing 902. Electrical communication between the pulse generator and the electrodes may provide electrical stimulation to heart tissue and/or sense a physiological condition.

In the example shown, the LCP 900 further includes a fixation mechanism 914 proximate the distal end 906 of the housing 902. The fixation mechanism 914 is configured to attach the LCP 900 to a wall of the heart H, or otherwise anchor the LCP 900 to the anatomy of the patient. As shown in Figure 9, in some instances, the fixation mechanism 914 may include one or more, or a plurality of hooks or tines 916 anchored into the cardiac tissue of the heart H to attach the LCP 900 to a tissue wall. In other instances, the fixation mechanism 914 may include one or more, or a plurality of passive tines, configured to entangle with trabeculae within the chamber of the heart H and/or a helical fixation anchor

configured to be screwed into a tissue wall to anchor the LCP 900 to the heart H. These are just examples.

The housing 902 may include a proximal end surface 918 facing proximally (e.g., in a generally opposite direction from the distal end surface. In some instances, the proximal end surface 918 of the housing 902 may form a diaphragm 920. In some cases, the diaphragm 920 may be formed from the housing material itself. When so provided, the wall thickness of the housing in the region of the diaphragm 920 may be thinned to increase the flexibility of the diaphragm 920 to as to be responsive (e.g. sufficiently deformable) to a pressure range of interest. In other cases, the diaphragm 920 may be formed from another material, such as but not limited to titanium, titanium foil, silicone, polyimides, etc. to form a deformable or movable diaphragm 920 that is responsive to a pressure of interest applied to the diaphragm 920. In some instances, the diaphragm 920 may be titanium or titanium foil on polyvinylidene fluoride (PVDF). In some instances, the diaphragm 920 may be formed from a piezoelectric material and/or may include a piezoelectric layer.

A piezoelectric material may exhibit the piezoelectric effect, or the ability to generate a voltage (and/or current) when the material is subjected to a mechanical stress or vibration. Some illustrative piezoelectric materials may include, but are not limited to some naturally occurring crystals (e.g., quartz, sucrose, Rochelle salt, topaz, lead titanate, etc.), synthetic crystals, ceramics (e.g., barium titanate, lead zirconate titanate (PZT), zinc oxide, etc.), polymers (e.g., polyvinylidene fluoride (PVDF)), etc. This list is not intended to be exhaustive of all types of piezoelectric materials, but rather illustrative of some example materials. When used as part of the hermetic seal around the LCP, it is contemplated that the material (piezoelectric or otherwise) selected for the diaphragm 920 may be hermetic. For example, the material should be capable of preventing blood from diffusing through the diaphragm and into the interior or the LCP.

In any event, the diaphragm 920 may be fabricated to flex or deform as the pressure (external to the housing 902) in the heart (e.g., right ventricle and/or right atrium) changes, as will be described in more detail herein. While the entire proximal end surface 918 may form the diaphragm 920, it is contemplated that only a portion of the end surface 918 may form the diaphragm 920. In some cases, the diaphragm 920 may be 1 millimeter in diameter or less. In other cases, the diaphragm 920 may be greater than 1 millimeter in

diameter. In some cases, the diaphragm 920 may have a round shape. In other cases, the diaphragm 920 may have a square, rectangular or any other suitable shape. In some cases, the diaphragm 920 may not have a uniform thickness. In some cases, the diaphragm 920 may have thicker bossed regions that provide support to, for example, increase the linearity of the deformation of the diaphragm 920 with pressure.

In some cases, the diaphragm 920 may be formed from a piezoelectric material. As the diaphragm flexes or deforms in response to an external pressure, a voltage (and/or current) may be generated by the piezoelectric material between sensor electrodes on opposing sides of the piezoelectric material. The generated voltage (and/or current) may be transferred via one or more electrical conductors 924 to the electrical circuitry 910, which may identify a pressure event and/or pressure value. In some cases, the generated voltage (and/or current) may reflect a change in pressure over time as opposed to an absolute or gauge pressure. When so provided, a reference pressure may not be required. In any event, the change in pressure over time may be sufficient to identify events such as the atrial contraction (e.g., atrial kick), ventricular filling, ventricular ejection, etc. In some instances, the electrical circuitry 910 may be configured to obtain pressure measurements at a sample rate of greater than 100 Hertz (Hz), but this is not required. This may allow for pressure measurements to be used to determine characteristics of the cardiac cycle including, but not limited to, dP/dT , dirotic notch, etc.

In some cases, the one or more electrical conductors 924 may include a first electrical conductor coupled to a first electrode on a first side of the piezoelectric material, and a second electrical conductor coupled a second electrode on a second opposite side of the piezoelectric material, such that the voltage (and/or current) generated is transmitted to the electrical circuitry 910.

The diaphragm 920 need not be placed on the proximal end surface 918 of the housing 902 such as shown in Figure 9. It is contemplated that the diaphragm 920 may be formed in any surface that is exposed to the environment outside of the housing 902. In some cases, locating the diaphragm 920 on or adjacent to the proximal end 904 of the housing 902 may orientate the diaphragm towards the heart valves (when the LCP 900 is positioned in the apex of the heart) and in-line with expected maximum pressure changes within the heart, which may achieve higher signal-to-noise (SN) levels. This may also

locate the diaphragm 920 away from the heart wall, which may reduce the likelihood that the diaphragm 920 will become fibrossed-over. In some cases, the diaphragm 920 may be coated with an anti-thrombogenic coating to help prevent tissue growth on or over the diaphragm 920.

5 In the example of Figure 9, a battery 912 is shown adjacent the diaphragm 920. However, many different configurations of the internal components of the LCP 900 are contemplated. In the example shown, the processing module (e.g., circuitry or control electronics) 910 is positioned in a distal portion 906 of the housing 902 adjacent to the distal electrode. The one or more electrical conductors 924 may be formed of a polyimide
10 or similar interconnect having a cross-sectional dimension in the range of less than 250 microns. It is contemplated that the inside surface of the housing 902 may be electrically insulated and the electrical conductors 924 (e.g., trace) may be positioned on the inside surface of the housing 902 or along the outer surface of the battery 912, as desired. Alternatively, wires or a ribbon cable may be used. These are just examples.

15 In some cases, the electrical circuitry 910 may be configured to obtain pressure measurements at predetermined intervals over one or more cardiac cycles. In other instances, the electrical circuitry 910 may be configured to obtain a pressure measurement in response to a specific cardiac event or at a specific time in a cardiac cycle. For example, the circuitry 910 may be configured to use one or more cardiac signals sensed by the first
20 electrode 908 and/or second electrode to determine when the patient's heart is in a first phase of a cardiac cycle. The circuitry 910 may be configured to determine a pressure exterior to the housing 902 based at least in part on the pressure obtained during the first phase of the cardiac cycle. In some cases, the first phase may be systole and in other cases the first phase may be diastole. The circuitry 910 may also be configured to determine a
25 pressure exterior to the housing 902 based at least in part on the pressure taken during a second phase of the cardiac cycle. It is contemplated that the circuitry 910 may be further configured to detect heart sounds of the patient's heart based at least in part on the pressure sensor output signal. For example, the first heart sound may be a timing fiducial for a sudden increase in pressure while the second heart sound may be a timing fiducial for a
30 sudden decrease in pressure.

In some cases, the circuitry 910 of the LCP 900 may be configured to obtain a plurality of pressure readings over one or more cardiac cycles. The pressure readings may be plotted (either by the circuitry 910 or an external device) to form a graph similar to the one shown in Figure 8. Various parameters related to the function of the heart can be extrapolated from the graph including but not limited to peak to peak measurements, dP/dT , time averaged values, inotropic response of the ventricle, etc. In some instances, the pressure measurements may be compared to calibration values (e.g., measurements taken at the time of implantation of the LCP 900). It is further contemplated that the diaphragm 920 may be sensitive enough to generate a voltage in response to a pressure increase in a chamber different from the chamber in which the LCP 900 is implanted. For example, when the LCP 900 is implanted in the right ventricle, the diaphragm may generate a voltage in response to a pressure increase in the right atrium (e.g. atrial kick) as well as a pressure increase in the right ventricle.

In some cases, the diaphragm 920 may be formed of the same material and of the same thickness as the remaining portion of the housing 902. For example, the housing 902 may flex or deform to transfer a pressure external to the housing 902 to a layer of piezoelectric material located within the housing 612. For example, the housing 902 may have a compliance such that the relative movement of the housing 902 in response to the external pressure may be operatively coupled to a piezoelectric material. The resulting voltage (and/or current) generated by the piezoelectric material may be calibrated relative to external pressures prior to implantation of the LCP 900 in a patient. The calibration data may be stored in the memory and/or electrical circuitry of the LCP 900. In some cases, there may be some pressure loss (e.g., in the range of 1-20% or more) between the pressure exerted on the housing 902 and the pressure applied to the piezoelectric material, depending on the placement of the piezoelectric material. This pressure loss may be compensated for (e.g., nullified) by adjusting the algorithm that converts the voltage (and/or current) generated by the piezoelectric material to a pressure using the calibration data stored in the LCP 900.

Figure 10 illustrates a proximal end portion 954 of another illustrative LCP 950 having a diaphragm 960 and a piezoelectric membrane 962. The LCP 950 may be similar in form and function to the LCPs 100, 610, 900 described above. The LCP 950 may include

any of the modules and/or structural features described above with respect to the LCPs 100, 610, 900.

The illustrative LCP 950 may include a shell or housing 952 having a proximal end portion 954 and a distal end (not explicitly shown). The housing 952 may include a proximal end surface 956 facing proximally (e.g., in a generally opposite direction from the distal end surface). In some instances, the proximal end surface 956 of the housing 952 may form a diaphragm 960. In some cases, the diaphragm 960 may be formed from the housing material itself, but this is not required. When so provided, the wall thickness of the housing in the region of the diaphragm 960 may be thinned to increase the flexibility of the diaphragm 960, although this is not required. In some cases, the diaphragm 960 may be formed from another material, such as but not limited to titanium, titanium foil, silicone, polyimides, etc. to form a deformable or movable diaphragm 960 that is responsive to a desired pressure range applied to the diaphragm 960.

In the example shown, the diaphragm 960 may flex or deform and transfer a pressure applied from external to the housing 952 to a layer of piezoelectric material 962 located within the housing 952. For example, the housing 952 may have a compliance such that the relative movement of the housing 952 and/or diaphragm 960 in response to the external pressure may deform or otherwise apply a corresponding stress to a piezoelectric material or membrane 962. In some embodiments, the piezoelectric membrane 962 may be coupled to or positioned on an interior surface of the diaphragm 960, although this is not required.

As the diaphragm 960 flexes in response an external pressure, the piezoelectric membrane 962 may also flex. The applied stress to the piezoelectric membrane 962 may generate a voltage (and/or a current) between a first sensor electrode on one side of the piezoelectric membrane 962 and a second sensor electrode on the opposing side of the piezoelectric membrane 962. The voltage (and/or current) may be transferred via one or more electrical conductors 964 to the electrical circuitry of the LCP 950 where it may be converted from a voltage (and/or current) to a pressure reading. In some cases, the one or more electrical conductors 964 may include a first electrical conductor coupled to a first side of the piezoelectric membrane 962 and a second electrical conductor coupled a second side, opposite of the first side such that the voltage (and/or current) generated is transmitted

to the electrical circuitry. In some instances, the electrical conductors may be coupled to the first and second sensor electrodes generally shown at 968.

The voltage (and/or current) generated by the piezoelectric material may be calibrated relative to external pressures applied prior to implantation of the LCP 950 in a patient. The calibration data may be stored in the memory and/or electrical circuitry of the LCP 950. In some cases, there may be some pressure loss (e.g., in the range of 1-20% or more) between the pressure exerted on the housing 952 and the pressure applied to the piezoelectric membrane 962. This pressure loss may be compensated for (e.g., nullified) by adjusting the algorithm that converts the voltage (and/or current) generated by the piezoelectric membrane 962 to a pressure using the calibration data stored in the LCP 950.

In the example of Figure 10, the battery 966 is shown adjacent the diaphragm 960. However, many different configurations of the internal components of the LCP 950 are contemplated. In the example shown, the processing module (e.g., circuitry or control electronics) may be positioned in a distal portion of the housing 952 adjacent to the distal electrode. The one or more electrical conductors 964 may be formed of a polyimide or similar interconnect having a cross-sectional dimension in the range of less than 250 microns. It is contemplated that the inside surface of the housing 952 may be electrically insulated and the electrical conductors 964 (e.g., trace) may be positioned on the inside surface of the housing 952 or along the outer surface of the battery 966, as desired. Alternatively, wires or a ribbon cable may be used. These are just examples.

Figure 11 illustrates a proximal end portion 1004 of another illustrative LCP 1000 having a diaphragm 1006 and a piezoelectric membrane 1010. The LCP 1000 may be similar in form and function to the LCPs 100, 610, 900 described above. The LCP 1000 may include any of the modules and/or structural features described above with respect to the LCPs 100, 610, 900.

The illustrative LCP 1000 may include a shell or housing 1002 having a proximal end portion 1004 and a distal end (not explicitly shown). The housing 1002 may include a proximal end surface 1018 facing proximally (e.g., in a generally opposite direction from the distal end surface). In some instances, the proximal end surface 1018 of the housing 1002 may form a diaphragm 1006. In some cases, the diaphragm 1006 may be formed from the housing material itself, although this is not required. When so provided, the wall

thickness of the housing in the region of the diaphragm 1006 may be thinned to increase the flexibility of the diaphragm 1006, although this is not required. In some cases, the diaphragm 1006 may be formed from another material, such as but not limited to titanium, titanium foil, silicone, polyimides, etc. to form a deformable or movable diaphragm 1006 that is responsive to a desired pressure range applied to the diaphragm 1006.

The diaphragm 1006 may flex or deform to transfer a pressure external to the housing 1002 to a layer of piezoelectric material or a piezoelectric membrane 1010 located within the housing 1002. For example, the housing 1002 may have a compliance such that the relative movement of the housing 1002 and/or diaphragm 1006 in response to the external pressure may be mechanically coupled to a piezoelectric material or membrane 1010. In some embodiments, the piezoelectric membrane 1010 may be coupled to the diaphragm 1006 via a mechanical linkage or arm 1008. This may allow the piezoelectric membrane 1010 to be spaced a distance from the housing 1002 while still flexing in response to an externally applied pressure 1016. In some cases, it may be desirable for a more rigid piezoelectric material to be used, and the mechanical leverage provided by the mechanical linkage or arm 1008 may allow a more modest external pressure applied to the diaphragm 1006 to suitably stress the piezoelectric membrane 1010 to produce a desired voltage (and/or current). In the example shown, as the diaphragm 1006 flexes in response to the external pressure 1016, the linkage 1008 also moves and transfers the force to the piezoelectric membrane 1010. The force applied to the piezoelectric membrane 1010 generates an voltage (and/or a current), which may be transferred via one or more electrical conductors 1012 to the electrical circuitry of the LCP 1000 where it is converted from an voltage (and/or current) to a pressure reading. In some cases, the one or more electrical conductors 1012 may include a first electrical conductor coupled to a first side of the piezoelectric membrane 1010 and a second electrical conductor coupled to a second side, opposite of the first side of the piezoelectric membrane 1010, such that the voltage (and/or current) generated across the piezoelectric membrane 1010 is transmitted to the electrical circuitry. In some instances, the electrical conductors may be coupled to first and second pressure sensor electrodes positioned on opposite sides of the piezoelectric membrane 1010.

The voltage generated by the piezoelectric membrane 1010 may be calibrated relative to external pressures prior to implantation of the LCP 1000 in a patient. The calibration data may be stored in the memory and/or electrical circuitry of the LCP 1000. In some cases, there may be some pressure loss (e.g., in the range of 1-20% or more) between the pressure exerted on the housing 1002 and the pressure applied to the piezoelectric membrane 1010, depending on the linkage or arm 1008. This pressure loss may be compensated for (e.g., nullified) by adjusting the algorithm that converts the voltage (and/or current) generated by the piezoelectric material to a pressure using the calibration data stored in the LCP 1000.

In the example shown in Figure 11, the battery 1014 is shown adjacent the piezoelectric membrane 1010. However, many different configurations of the internal components of the LCP 1000 are contemplated. In the example shown, the processing module (e.g., circuitry or control electronics) may be positioned in a distal portion of the housing 1002 adjacent to the distal electrode. The one or more electrical conductors 1012 may be formed of a polyimide or similar interconnect having a cross-sectional dimension in the range of less than 250 microns. It is contemplated that the inside surface of the housing 1002 may be electrically insulated and the electrical conductors 1012 (e.g., trace) may be positioned on the inside surface of the housing 1002 or along the outer surface of the battery 1014, as desired. Alternatively, wires or a ribbon cable may be used. These are just examples.

Figure 12 illustrates a proximal end portion 1054 of another illustrative LCP 1050 having a diaphragm 1056 and a piezoelectric membrane 1062. The illustrative LCP 1050 may be similar in form and function to the LCPs 100, 610, 900 described above. The LCP 1050 may include any of the modules and/or structural features described above with respect to the LCPs 100, 610, 900.

The illustrative LCP 1050 may include a shell or housing 1052 having a proximal end portion 1054 and a distal end (not explicitly shown). The housing 1052 may include a proximal end surface 1066 facing proximally (e.g., in a generally opposite direction from the distal end surface). In some instances, the proximal end surface 1066 of the housing 1052 may form a diaphragm 1056. In some cases, the diaphragm 1056 may be formed from the housing material itself, but this is not required. When so provided, the wall

thickness of the housing in the region of the diaphragm 1056 may be thinned to increase the flexibility of the diaphragm 1056, although this is not required. In other cases, the diaphragm 1056 may be formed from another material, such as but not limited to titanium, titanium foil, silicone, polyimides, etc. to form a deformable or movable diaphragm 1056 that is responsive to a desired pressure range applied to the diaphragm 1056.

The diaphragm 1056 may flex or deform to transfer a pressure external to the housing 1052 to a layer of piezoelectric material or a piezoelectric membrane 1062 located within the housing 1052. In the example shown, a cavity 1064 filled with a fluid 1068 may be positioned between the external diaphragm 1056 and an internal diaphragm 1058. The fluid filled cavity 1064 may be in fluid communication with the diaphragm(s) 1056, 1058 such that the fluid filled cavity 1064 may communicate a measure related to the pressure 1070 applied by the environment to the diaphragm 1056 of the housing 1052 ultimately to piezoelectric membrane 1062. The fluid filled cavity 1064 may be filled with an incompressible fluid 1068. In some cases, the fluid filled cavity 1064 may be filled with a non-conductive fluid 1068. In some cases, the fluid 1068 may be highly soluble to gases that may arise inside of the housing, particularly at body temperature (e.g., 37°C). For example, the fluid 1068 may be highly soluble to hydrogen, helium, nitrogen, argon, water, and/or other gases or liquids that might arise inside of the housing as a result of, for example, outgassing of internal components of the LCP 1050.

The diaphragms 1056, 1058 may have a compliance such that the relative movement of the housing 1052 and/or diaphragm 1056 in response to the external pressure may be coupled to the piezoelectric material or membrane 1062, sometimes through a mechanical linkage or arm 1060. In Figure 12, the piezoelectric membrane 1062 is shown mechanically coupled to the inner diaphragm 1058 via a mechanical linkage or arm 1060. However, it is contemplated that the piezoelectric material or membrane 1062 may be adhered directly to the inner diaphragm 1058, or the inner diaphragm 1058 may be made from or otherwise form the piezoelectric material or membrane 1062.

As the diaphragm 1056 flexes in response the external pressure 1070, force is transferred 1072 through the fluid filled cavity 1064 to the inner diaphragm 1058. The inner diaphragm 1058 then transfers the force to the piezoelectric material or membrane 1062, sometimes through a mechanical linkage or arm 1060. The force applied to the

piezoelectric membrane 1062 generates an voltage (and/or s current). The voltage (and/or current) may be transferred via one or more electrical conductors 1074 to the electrical circuitry of the LCP 1050 where it is converted from a voltage (and/or a current) to a pressure reading.

5 In some cases, the one or more electrical conductors 1024 may include a first electrical conductor coupled to a first side of the piezoelectric membrane 1062 and a second electrical conductor coupled a second side, opposite of the first side of the piezoelectric membrane 1062, such that the voltage (and/or current) generated across the piezoelectric membrane 1062 is transmitted to the electrical circuitry. In some instances, the electrical
10 conductors may be coupled to first and second pressure sensor electrodes positioned on opposite sides of the piezoelectric membrane 1062.

The voltage generated by the piezoelectric material may be calibrated relative to external pressures applied prior to implantation of the LCP 1050 in a patient. The calibration data may be stored in the memory and/or electrical circuitry of the LCP 1050.
15 In some cases, there may be some pressure loss (e.g., in the range of 1-20% or more) between the pressure exerted on the housing 1052 and the pressure applied to the piezoelectric membrane 1062. This pressure loss may be compensated for (e.g., nullified) by adjusting the algorithm that converts the voltage (and/or current) generated by the piezoelectric material to a pressure using the calibration data stored in the LCP 1050.

20 In the example of Figure 12, the battery 1076 is shown adjacent the piezoelectric membrane 1062. However, many different configurations of the internal components of the LCP 1050 are contemplated. In the example shown, the processing module (e.g., circuitry or control electronics) may be positioned in a distal portion of the housing 1052 adjacent to the distal electrode. The one or more electrical conductors 1074 may be formed
25 of a polyimide or similar interconnect having a cross-sectional dimension in the range of less than 250 microns. It is contemplated that the inside surface of the housing 1052 may be electrically insulated and the electrical conductors 1074 (e.g., trace) may be positioned on the inside surface of the housing 1052 or along the outer surface of the battery 1076, as desired. Alternatively, wires or a ribbon cable may be used. These are just examples.

30 Figure 13 illustrates a proximal end portion 1104 of another illustrative LCP 1100 having a diaphragm 1106 and a piezoelectric membrane 1108. The LCP 1100 may be

similar in form and function to the LCPs 100, 610, 900 described above. The LCP 1100 may include any of the modules and/or structural features described above with respect to the LCPs 100, 610, 900.

5 The LCP 1100 may include a shell or housing 1102 having a proximal end portion 1104 and a distal end (not explicitly shown). The housing 1102 may include a proximal end surface 1110 facing proximally (e.g., in a generally opposite direction from the distal end surface). In some instances, the proximal end surface 1110 of the housing 1102 may form a diaphragm 1106. In some cases, the diaphragm 1106 may be formed from the housing material itself, but this is not required. When so provided, the wall thickness of
10 the housing in the region of the diaphragm 1106 may be thinned to increase the flexibility of the diaphragm 1106, although this is not required. In some cases, the diaphragm 1106 may be formed from another material, such as but not limited to titanium, titanium foil, silicone, polyimides, etc. to form a deformable or movable diaphragm 1106 that is responsive to a desired pressure range applied to the diaphragm 1106.

15 The diaphragm 1106 may flex or deform to transfer a pressure external to the housing 1102 to a layer of piezoelectric material or a piezoelectric membrane 1108 located within the housing 1102. In some embodiments, a cavity 1112 filled with a fluid 1114 may be positioned between the diaphragm 1106 and the piezoelectric membrane 1108. The fluid filled cavity 1112 is shown in fluid communication with the diaphragm 1106 such
20 that the fluid filled cavity 1112 may communicate a measure related to the pressure 1116 applied by the environment to the piezoelectric membrane 1108. The fluid filled cavity 1112 may be filled with an incompressible fluid 1114. In some cases, the fluid filled cavity 1112 may be filled with a non-conductive fluid 1114. In some cases, the fluid 1114 may be highly soluble to gases that may be inside of the housing, particularly at body
25 temperature (e.g., 37°C). For example, the fluid 1114 may be highly soluble to hydrogen, helium, nitrogen, argon, water, and/or other gases or liquids that might arise inside of the housing as a result of, for example, outgassing of internal components of the LCP 1100.

The diaphragm 1106 may have a compliance such that the relative movement of the housing 1102 and/or diaphragm 1106 in response to a desired range of external
30 pressures is coupled 1118 to the piezoelectric material or membrane 1108 through the fluid 1114. The force 1118 applied to the piezoelectric membrane 1108 may generate a voltage

(and/or a current). The voltage (and/or current) may be transferred via one or more electrical conductors 1120 to the electrical circuitry of the LCP 1100 where it may be converted from a voltage (and/or current) to a pressure reading. It is contemplated that in some instances, the piezoelectric membrane 1108 may be formed from a piezoelectric material or have a piezoelectric material formed on a surface of another flexible material as described with respect to, for example, Figure 10.

In some cases, the one or more electrical conductors 1120 may include a first electrical conductor coupled to a first side of the piezoelectric membrane 1108 and a second electrical conductor coupled to a second side, opposite of the first side of the piezoelectric membrane 1108, such that the voltage (and/or current) generated by the piezoelectric material or membrane 1108 is transmitted to the electrical circuitry. In some instances, the electrical conductors may be coupled to first and second pressure sensor electrodes positioned on opposite sides of the piezoelectric membrane 1108.

The voltage (and/or current) generated by piezoelectric membrane 1108 may be calibrated relative to external pressures applied prior to implantation of the LCP 1100 in a patient. The calibration data may be stored in the memory and/or electrical circuitry of the LCP 1100. In some cases, there may be some pressure loss (e.g., in the range of 1-20% or more) between the pressure exerted on the housing 1102 and the pressure applied to the piezoelectric membrane 1108. This pressure loss may be compensated for (e.g., nullified) by adjusting the algorithm that converts the voltage (and/or current) generated by the piezoelectric membrane 1108 to a pressure using the calibration data stored in the LCP 1100.

In the example of Figure 13, the battery 1122 is shown adjacent the piezoelectric membrane 1108. However, many different configurations of the internal components of the LCP 1100 are contemplated. In the example shown, the processing module (e.g., circuitry or control electronics) may be positioned in a distal portion of the housing 1102 adjacent to the distal electrode. The one or more electrical conductors 1120 may be formed of a polyimide or similar interconnect having a cross-sectional dimension in the range of less than 250 microns. It is contemplated that the inside surface of the housing 1102 may be electrically insulated and the electrical conductors 1120 (e.g., trace) may be positioned

on the inside surface of the housing 1102 or along the outer surface of the battery 1122, as desired. Alternatively, wires or a ribbon cable may be used. These are just examples.

Figure 14 illustrates a cross-sectional view of a proximal end portion 1154 of another illustrative LCP 1150 having a diaphragm 1156 and piezoelectric membrane 1158.

5 The LCP 1150 may be similar in form and function to the LCPs 100, 610, 900 described above. The LCP 1150 may include any of the modules and/or structural features described above with respect to the LCPs 100, 610, 900.

The LCP 1150 may include a shell or housing 1152 having a proximal end portion 1154 and a distal end (not explicitly shown). In this example, the housing 1152 includes a
10 docking member 1160 extending proximally from the proximal end portion 1154. The docking member 1160 may be configured to facilitate delivery and/or retrieval of the LCP 1150. For example, the docking member 1160 may extend from the proximal end portion 1154 of the housing 1152 along a longitudinal axis of the housing 1152. The docking member 1160 may include a head portion 1162 and a neck portion 1164 extending between
15 the housing 1152 and the head portion 1162. The head portion 1162 may be an enlarged portion relative to the neck portion 1164. An access port 1166 may extend through the head portion 1162 and the neck portion 1164 to fluidly couple the diaphragm 1156 with the blood in the heart. The diaphragm 1156 may be constructed using any of the materials and/or configurations described herein. In some cases, the diaphragm 1156 may be
20 positioned at the proximal opening 1168 of the access port 1166.

It is contemplated that the docking member 1160 may be formed as a separate structure from the housing 1152 and subsequently attached to the housing 1152. For example, the docking member 1160 may be 3-D metal structure that is welded (or otherwise coupled or secured) to the housing 1152. In other embodiments, the docking
25 member 1160 and the housing 1152 may be formed as a single monolithic structure.

A piezoelectric membrane 1158 may be positioned adjacent to, but not necessarily in direct contact with the diaphragm 1156. In some cases, the piezoelectric membrane 1158 may be positioned directly on an inner surface of the diaphragm 1156, such as described with respect to Figure 10. In other embodiments, the piezoelectric membrane
30 1158 may be mechanically and/or fluidly coupled to the diaphragm 1156 through a mechanical linkage and/or a fluid filled chamber, similar to that described above. As the

diaphragm 1156 flexes in response to an external pressure, the piezoelectric membrane 1158 may also flex. The stress on the piezoelectric membrane 1158 may generate a voltage (and/or current). The voltage (and/or current) may be transferred via one or more electrical conductors 1170 to the electrical circuitry of the LCP 1150 where it is converted from a voltage (and/or current) to a pressure reading. In some embodiments, the piezoelectric membrane 1158 may be operatively connected to the housing 1152 which in turn is operatively coupled to the circuitry or control electronics.

In some cases, the one or more electrical conductors 1170 may include a first electrical conductor coupled to a first side of the piezoelectric membrane 1158 and a second electrical conductor coupled to a second side, opposite of the first side of the piezoelectric membrane 1158, such that the voltage (and/or current) generated across the piezoelectric membrane 1158 is transmitted to the electrical circuitry. In some instances, the electrical conductors may be coupled to first and second pressure sensor electrodes positioned on opposite sides of the piezoelectric membrane 1158.

Figure 14 illustrates the battery 1172 adjacent to the piezoelectric membrane 1158. However, many different configurations of the internal components of the LCP 1150 are contemplated. The one or more electrical conductors 1170 may be formed of a polyimide or similar interconnect having a cross-sectional dimension in the range of less than 250 microns. It is contemplated that the inside surface of the housing 1152 may be electrically insulated and the electrical conductors 1170 (e.g., trace) positioned on the inside surface of the housing 1152 or along the outer surface of the battery 1172, as desired. Alternatively, wires or a ribbon cable may be used. These are just examples.

Figure 15 illustrates a cross-sectional view of a proximal end portion 1204 of another illustrative LCP 1200 having a diaphragm 1206 and a piezoelectric membrane 1208. The LCP 1200 may be similar in form and function to the LCPs 100, 610, 900 described above. The LCP 1200 may include any of the modules and/or structural features described above with respect to the LCPs 100, 610, 900.

The LCP 1200 may include a shell or housing 1202 having a proximal end portion 1204 and a distal end (not explicitly shown). The housing 1202 may include a docking member 1210 extending proximally from the proximal end portion 1204. The docking member 1210 may be configured to facilitate delivery and/or retrieval of the LCP 1200.

For example, the docking member 1210 may extend from the proximal end portion 1204 of the housing 1202 along a longitudinal axis of the housing 1202. The docking member 1210 may include a head portion 1212 and a neck portion 1214 extending between the housing 1202 and the head portion 1212. The head portion 1212 may be an enlarged portion relative to the neck portion 1214. An access port 1216 may extend through the head portion 1212 and the neck portion 1214 to fluidly couple the diaphragm 1206 with the blood in the heart. The diaphragm 1206 may be constructed using any of the materials and/or configurations described herein. In some cases, the diaphragm 1206 may be positioned at the proximal opening 1168 of the access port 1216.

It is contemplated that the docking member 1210 may be formed as a separate structure from the housing 1202 and subsequently attached to the housing 1202. For example, the docking member 1210 may be 3-D metal structure that is welded (or otherwise coupled or secured) to the housing 1202. In other embodiments, the docking member 1210 and the housing 1202 may be formed as a single monolithic structure.

A piezoelectric membrane 1208 may be positioned adjacent to, but not necessarily in direct contact with the diaphragm 1206. In some embodiments, the piezoelectric membrane 1208 may be coupled to the diaphragm 1206 via a mechanical linkage or arm 1218. At least part of the piezoelectric membrane 1208 may be held in place relative to the housing 1202 such that movement of the diaphragm 1206 and mechanical linkage or arm 1218 relative to the piezoelectric membrane 1208 induces a stress in the piezoelectric membrane 1208. As the diaphragm 1206 flexes in response the external pressure 1220, the linkage 1218 moves and transfers the force to the piezoelectric membrane 1208. The force applied to the piezoelectric membrane 1208 generates a voltage (and/or current). The voltage (and/or current) may be transferred via one or more electrical conductors 1222 to the electrical circuitry of the LCP 1000 where it is converted from a voltage (and/or current) to a pressure reading.

In some cases, the one or more electrical conductors 1222 may include a first electrical conductor coupled to a first side of the piezoelectric membrane 1208 and a second electrical conductor coupled a second opposite side of the piezoelectric membrane 1208 such that the voltage (and/or current) generated across the piezoelectric membrane 1208 is transmitted to the electrical circuitry. In some instances, the electrical conductors may be

coupled to first and second pressure sensor electrodes positioned on opposite sides of the piezoelectric membrane 1208.

Figure 15 illustrates the battery 1224 adjacent to the piezoelectric membrane 1208. However, many different configurations of the internal components of the LCP 1200 are contemplated. The one or more electrical conductors 1222 may be formed of a polyimide or similar interconnect having a cross-sectional dimension in the range of less than 250 microns. It is contemplated that the inside surface of the housing 1202 may be electrically insulated and the electrical conductors 1222 (e.g., trace) positioned on the inside surface of the housing 1202 or along the outer surface of the battery 1224, as desired. Alternatively, wires or a ribbon cable may be used. These are just examples.

It is contemplated that any of the embodiments described herein may be modified to include a plurality (e.g., two or more) diaphragms and/or piezoelectric membranes to improve the sensitivity of the pressure readings. For example, it may be desirable for the diaphragm(s) to have the largest surface area possible. This may be accomplished through a single, large diaphragm or a plurality of smaller diaphragms. It should also be understood that the placement of the diaphragm and/or piezoelectric membrane is not limited to the proximal end region of the LCP. In some cases, the diaphragm and/or piezoelectric membrane may be positioned in or adjacent to a sidewall and/or near the distal end region.

In some cases, the diaphragms and/or piezoelectric membranes may include contours configured to increase the sensitivity and/or linearity of the diaphragms and/or piezoelectric membranes. Some illustrative contours may include, but are not limited to, a concave surface, a convex surface, an undulating surface, a generally convex surface having a generally concave central region, etc. It is contemplated that the contours may be tuned for the application and/or placement of the device.

Regardless of the placement location of the LCP, some static pressure may be applied to the diaphragm and/or piezoelectric membrane upon implantation of the device. This may cause the diaphragm and/or piezoelectric membrane to flex from its un-implanted configuration. The LCP may be configured to detect changes in pressure over time which are indicated by a movement of the diaphragm. As such, and in some cases, it may be desirable to pre-tune the diaphragm and/or piezoelectric membrane to optimize the pressure range of the diaphragm and/or piezoelectric membrane when the LCP is implanted. This

may be accomplished by deforming the diaphragm and/or piezoelectric membrane during manufacture in a direction opposite to the static pressure exerted by the chamber of the heart such that the diaphragm and/or piezoelectric membrane are in a neutral configuration after implantation (as opposed to flexed inwards under the static pressure of the
5 implantation chamber).

Those skilled in the art will recognize that the present disclosure may be manifested in a variety of forms other than the specific examples described and contemplated herein. For instance, as described herein, various examples include one or more modules described as performing various functions. However, other examples may include additional
10 modules that split the described functions up over more modules than that described herein. Additionally, other examples may consolidate the described functions into fewer modules. Accordingly, departure in form and detail may be made without departing from the scope and spirit of the present disclosure as described in the appended claims.

What is claimed is:

1. A leadless cardiac pacemaker (LCP) configured to sense cardiac activity and to deliver pacing therapy to a patient's heart, the LCP comprising:

a housing having a proximal end and a distal end;

a first electrode secured relative to the housing and exposed to the environment outside of the housing;

a second electrode secured relative to the housing and exposed to the environment outside of the housing;

a diaphragm that is exposed to the environment outside of the housing, the diaphragm is responsive to an external pressure applied to the diaphragm by the environment outside of the housing;

a piezoelectric membrane having a first pressure sensor electrode and a second pressure sensor electrode, the piezoelectric membrane is configured to generate an electrical voltage between the first pressure sensor electrode and the second pressure sensor electrode in response to a pressure change applied to the diaphragm, the electrical voltage representative of a change in external pressure applied to the diaphragm; and

circuitry in the housing operatively coupled to the first electrode and the second electrode of the LCP, and also operatively coupled to the first pressure sensor electrode and the second pressure sensor electrode, the circuitry is configured to deliver a pacing therapy to the patient's heart via the first electrode and the second electrode of the LCP, wherein the pacing therapy is dependent, at least in part, on the electrical voltage generated by the piezoelectric membrane and that is representative of the change in external pressure applied to the diaphragm.

2. The LCP of claim 1, wherein the circuitry is configured to detect a pressure pulse by monitoring the electrical voltage generated between the first pressure sensor electrode and the second pressure sensor electrode by the piezoelectric membrane.

3. The LCP of any one of claims 1-2, wherein the diaphragm has an interior surface that faces toward an interior of the housing, and the piezoelectric membrane is secured to at least part of the interior surface of the diaphragm.

4. The LCP of any one of claims 1-2, wherein the diaphragm has an interior surface that faces toward an interior of the housing, and the piezoelectric membrane is spaced a distance from the interior surface of the diaphragm and is operatively coupled to the interior surface of the diaphragm via an incompressible fluid.

5. The LCP of claim 4, wherein the incompressible fluid is in a fluid cavity that is at least partially defined by the interior surface of the diaphragm and is in fluid communication with both the interior surface of the diaphragm and the piezoelectric membrane, wherein the fluid cavity is configured to communicate a pressure applied to the incompressible fluid by the diaphragm to the piezoelectric membrane.

6. The LCP of any one of claims 1-2, wherein the diaphragm has an interior surface that faces toward an interior of the housing, and the piezoelectric membrane is spaced a distance from the interior surface of the diaphragm and is operatively coupled to the interior surface of the diaphragm via a mechanical linkage, wherein the mechanical linkage is configured to translate movement of the diaphragm to a pressure applied to the piezoelectric membrane.

7. The LCP of any one of claims 1-6, wherein the diaphragm of the housing includes one or more contours.

8. The LCP of any one of claims 1-7, wherein the circuitry is configured to detect a change in pressure in a first chamber of the heart caused by a contraction of a second chamber of the heart.

9. The LCP of claim 8, wherein the first chamber is a ventricle, and the second chamber is the corresponding atrium.

10. The LCP of any one of claims 1-9, wherein the diaphragm is integrally formed with the housing.

11. The LCP of any one of claims 1-10, wherein the diaphragm is hermetically sealed to the housing.

12. The LCP of any one of claims 1-11, further comprising a fixation member at the distal end of the housing for fixing the distal end of the housing to an implant site, and wherein the diaphragm of the housing is adjacent the proximal end of the housing.

13. The LCP of any one of claims 1-12, wherein the housing includes an elongated body with a distal end surface facing distally and a proximal end surface facing proximally, wherein the diaphragm of the housing is situated on the proximal end surface of the housing.

14. The LCP of any one of claims 1-13, wherein the diaphragm and/or piezoelectric membrane are formed to maximize the dynamic change of the diaphragm and/or piezoelectric membrane when implanted.

15. The LCP of any one of claims 1-14, further comprising an anti-thrombogenic coating disposed over the diaphragm of the housing.

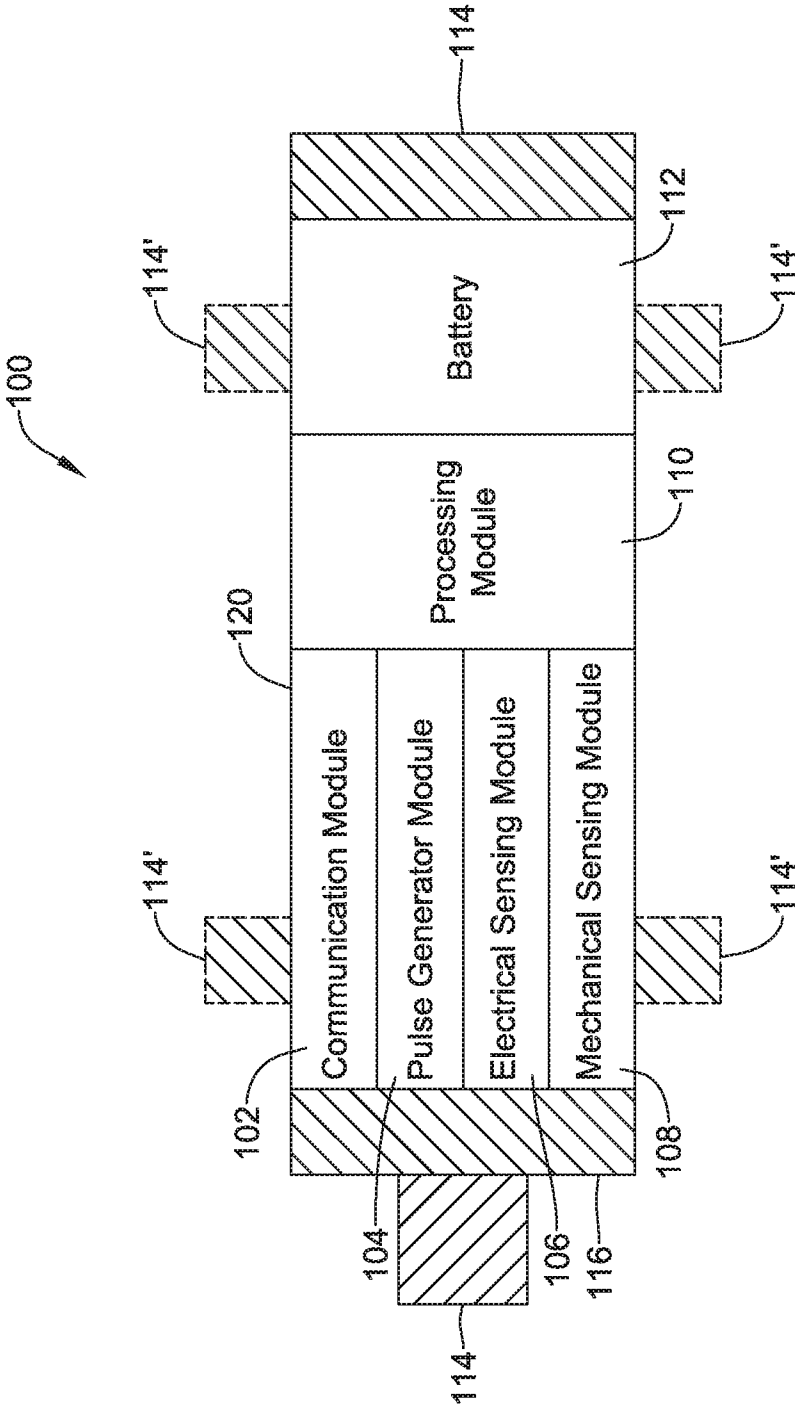


FIG. 1

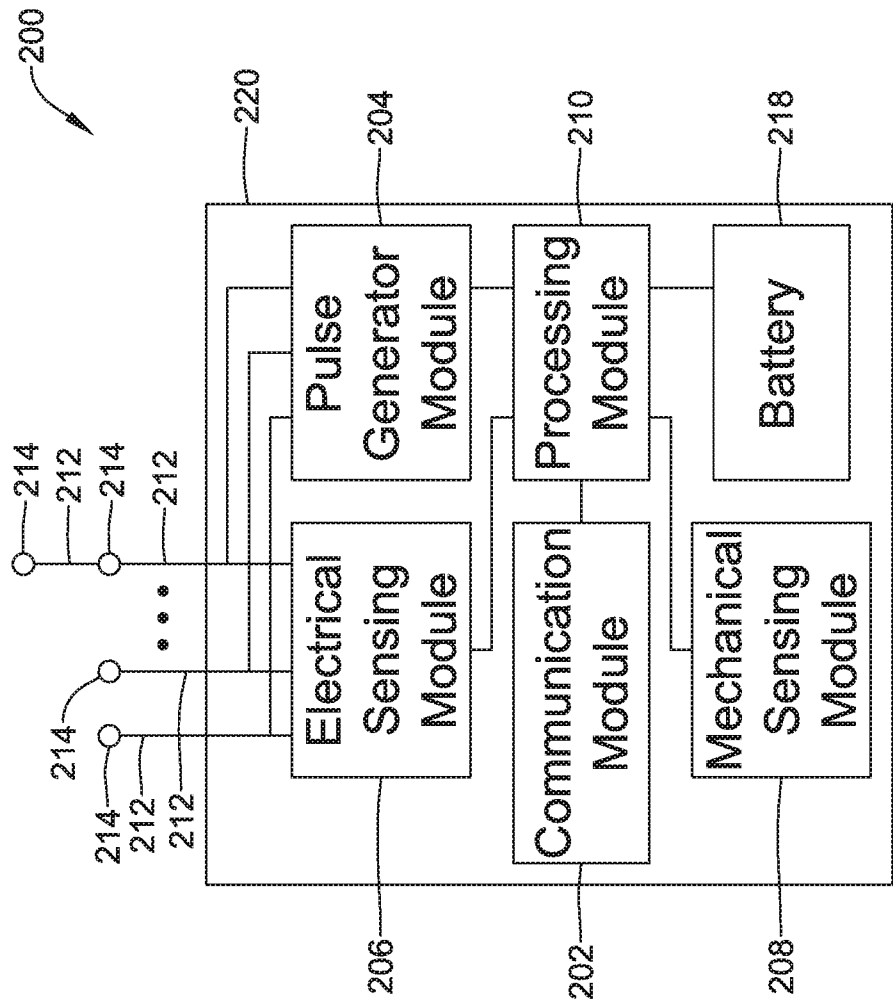


FIG. 2

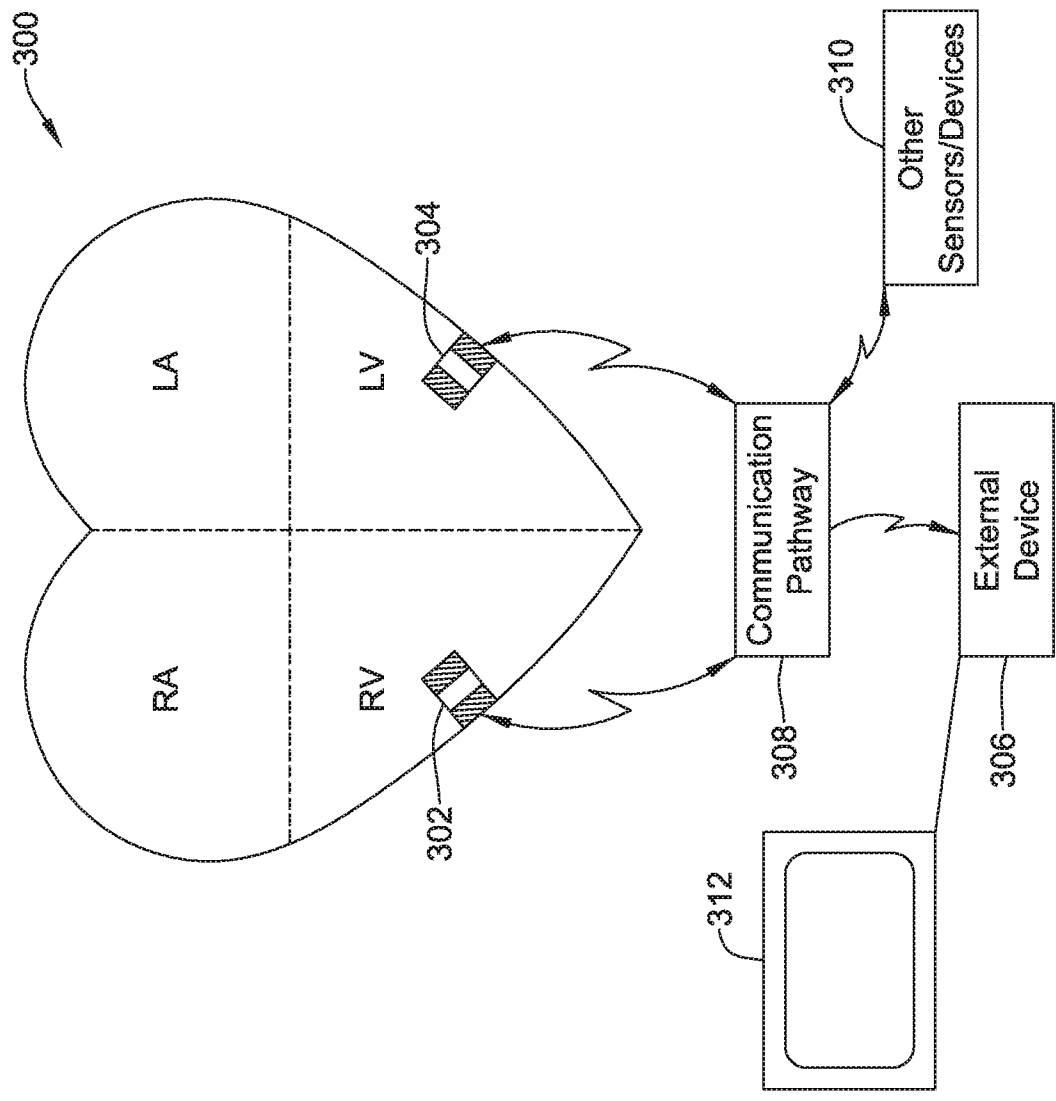


FIG. 3

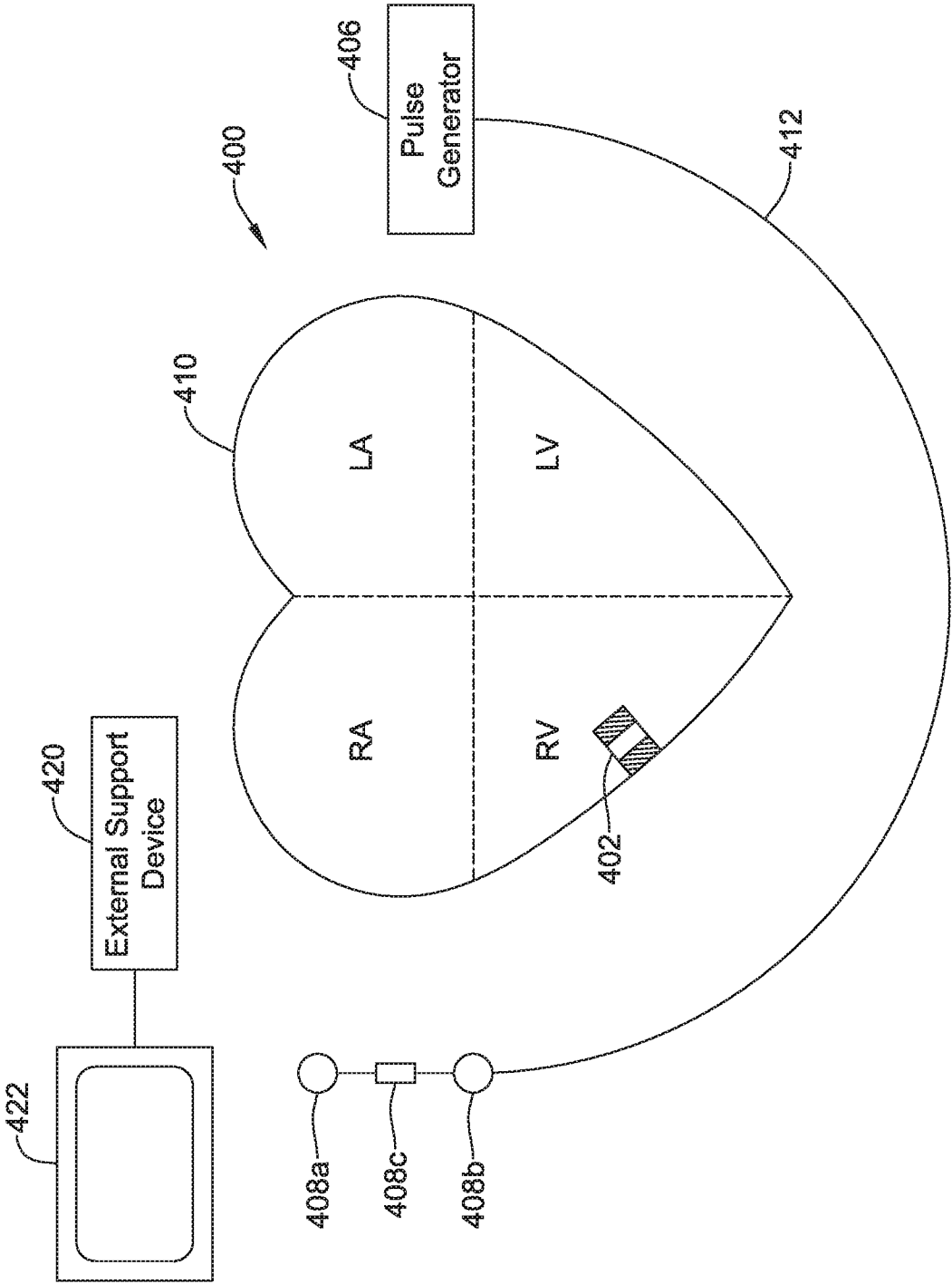


FIG. 4

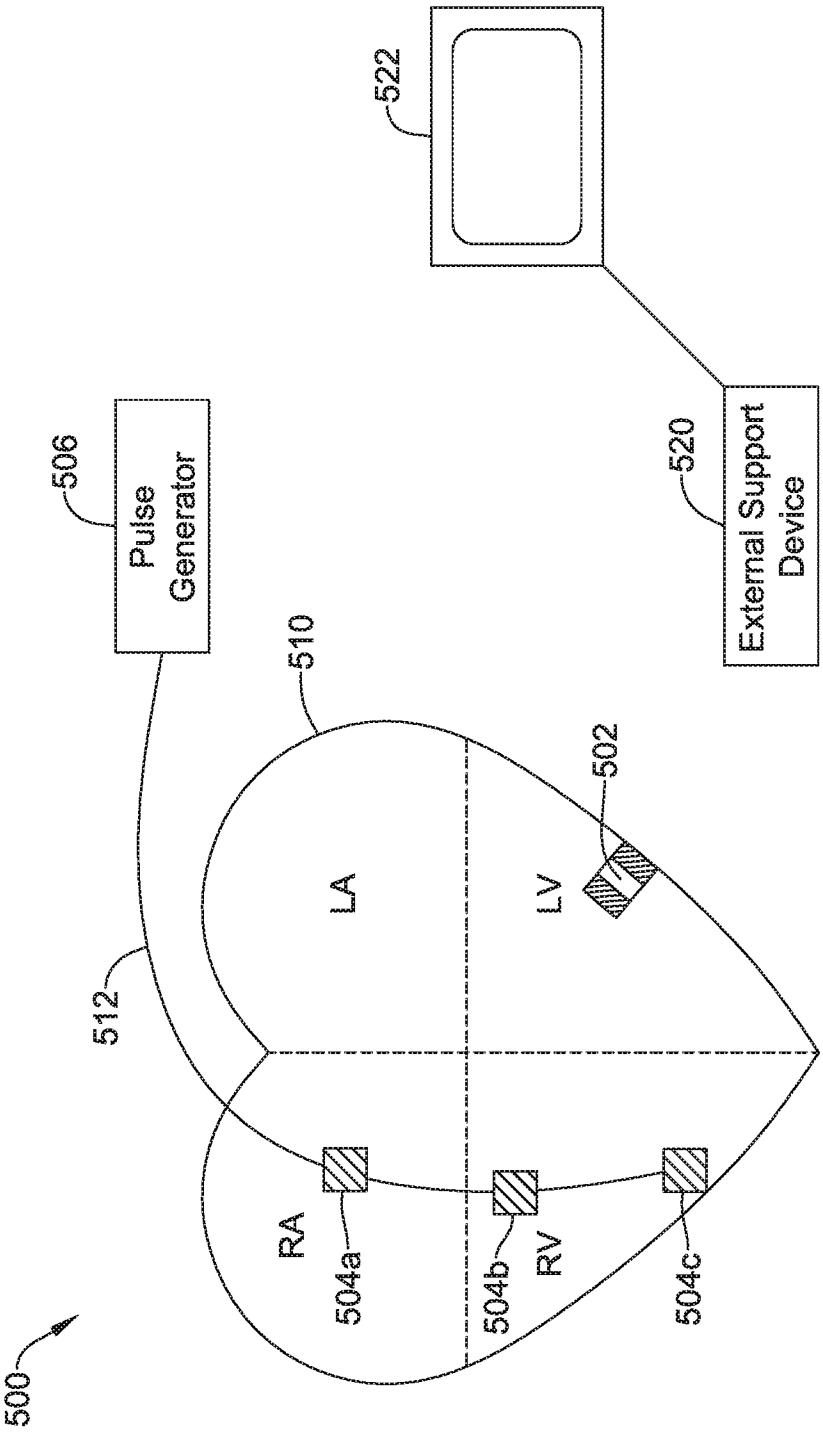


FIG. 5

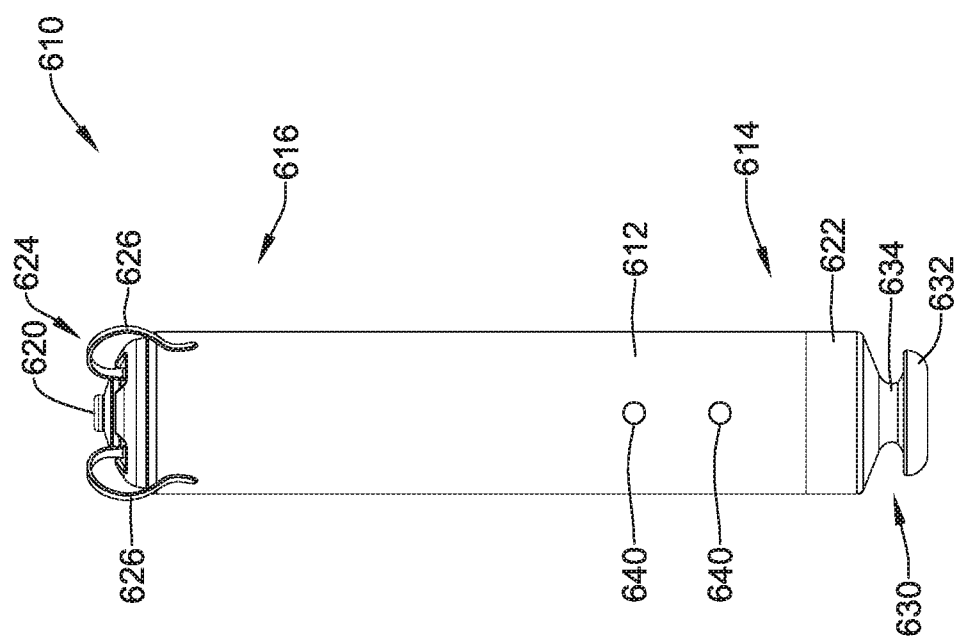


FIG. 6

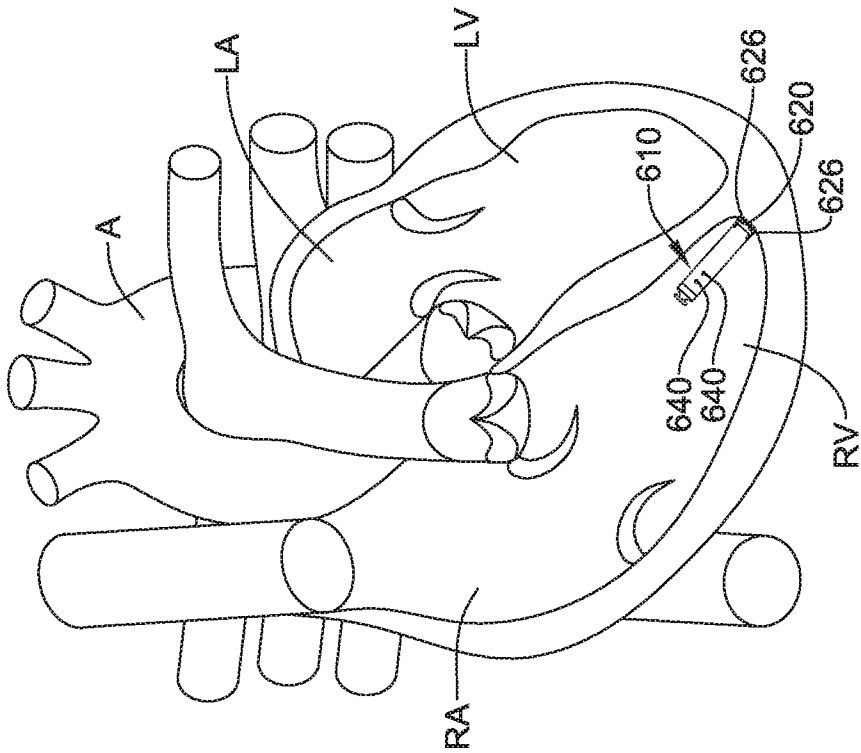


FIG. 7A

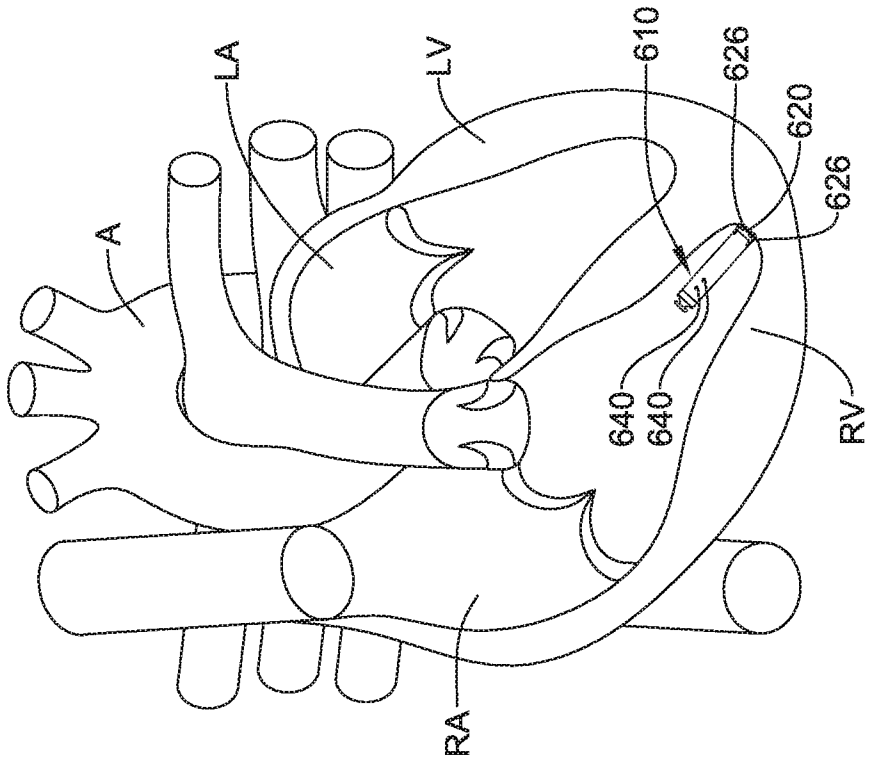


FIG. 7B

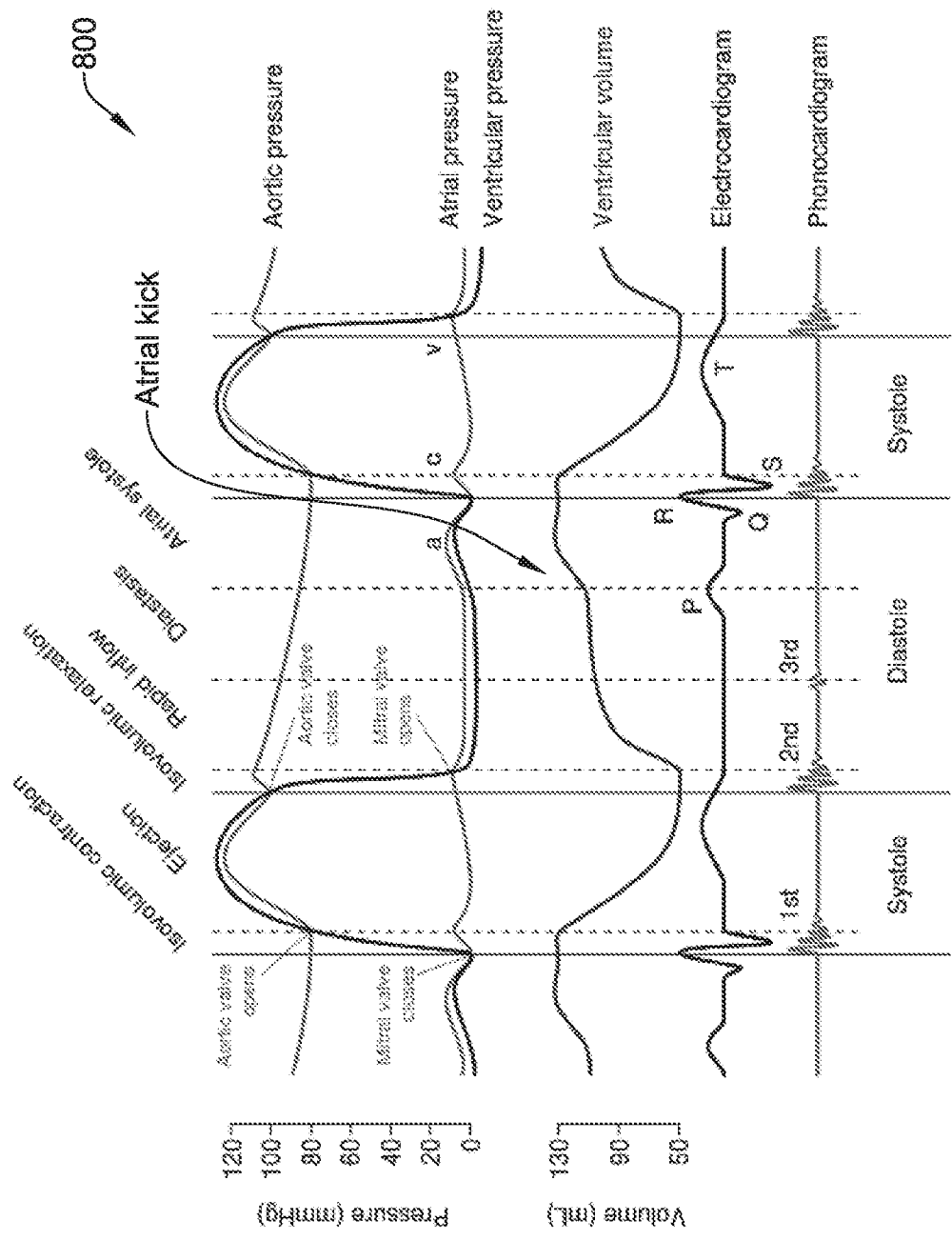


FIG. 8

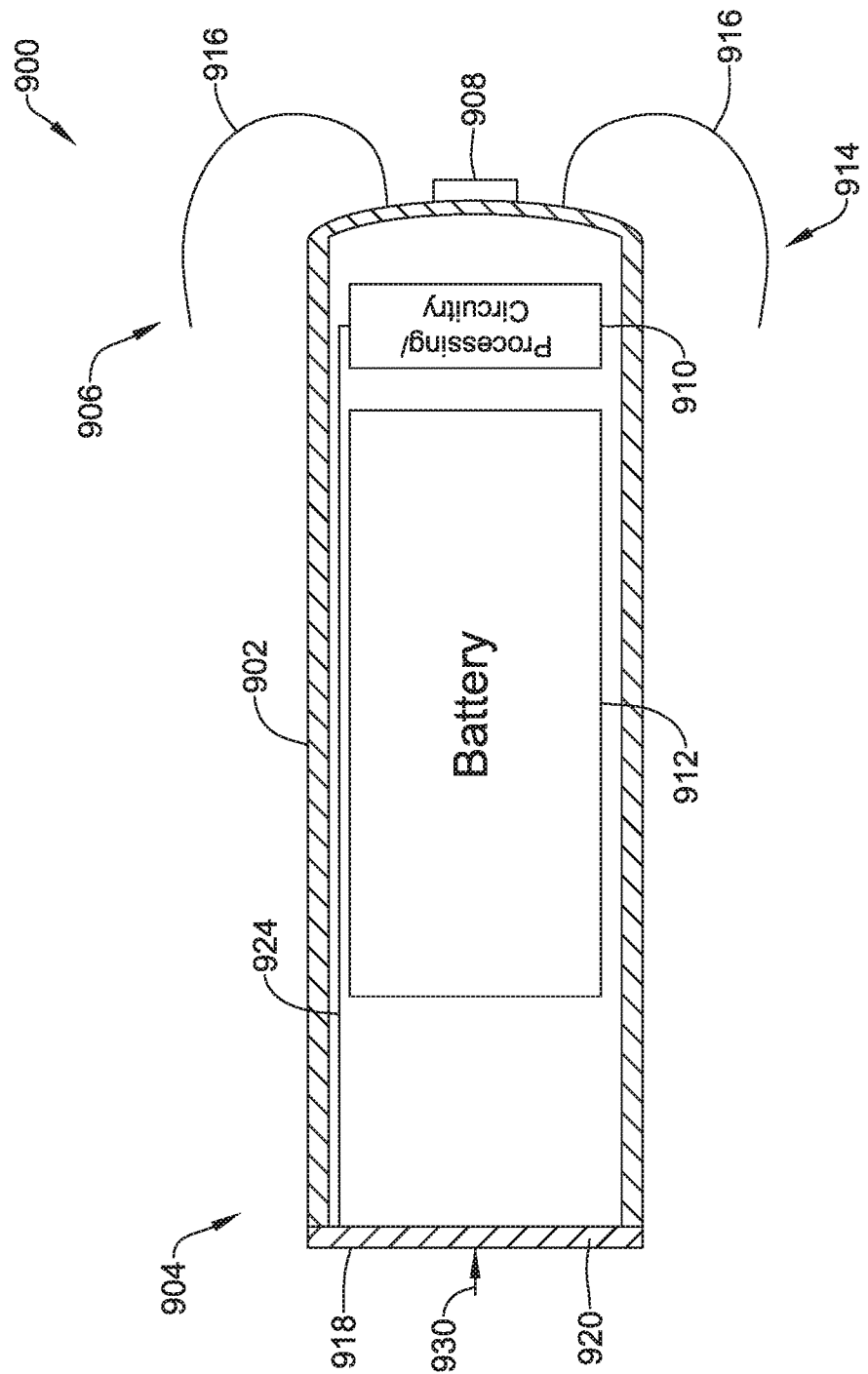


FIG. 9

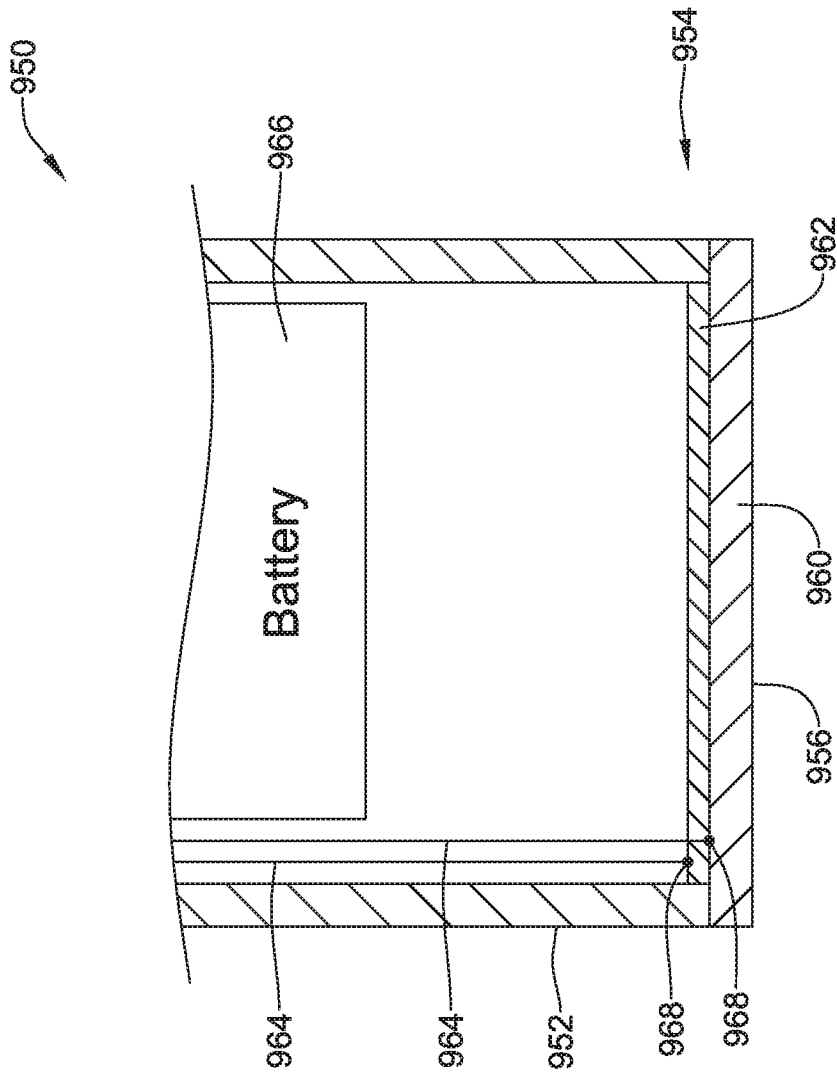


FIG. 10

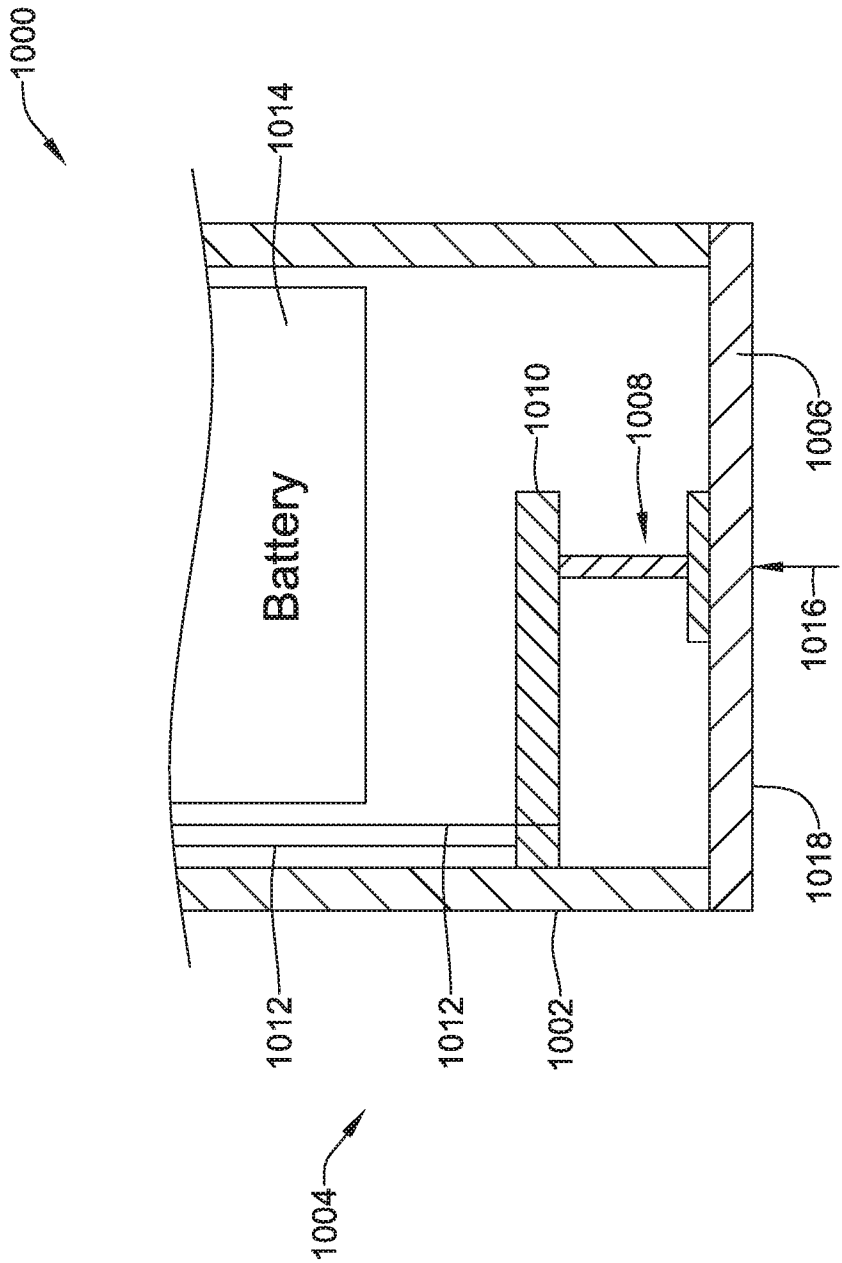


FIG. 11

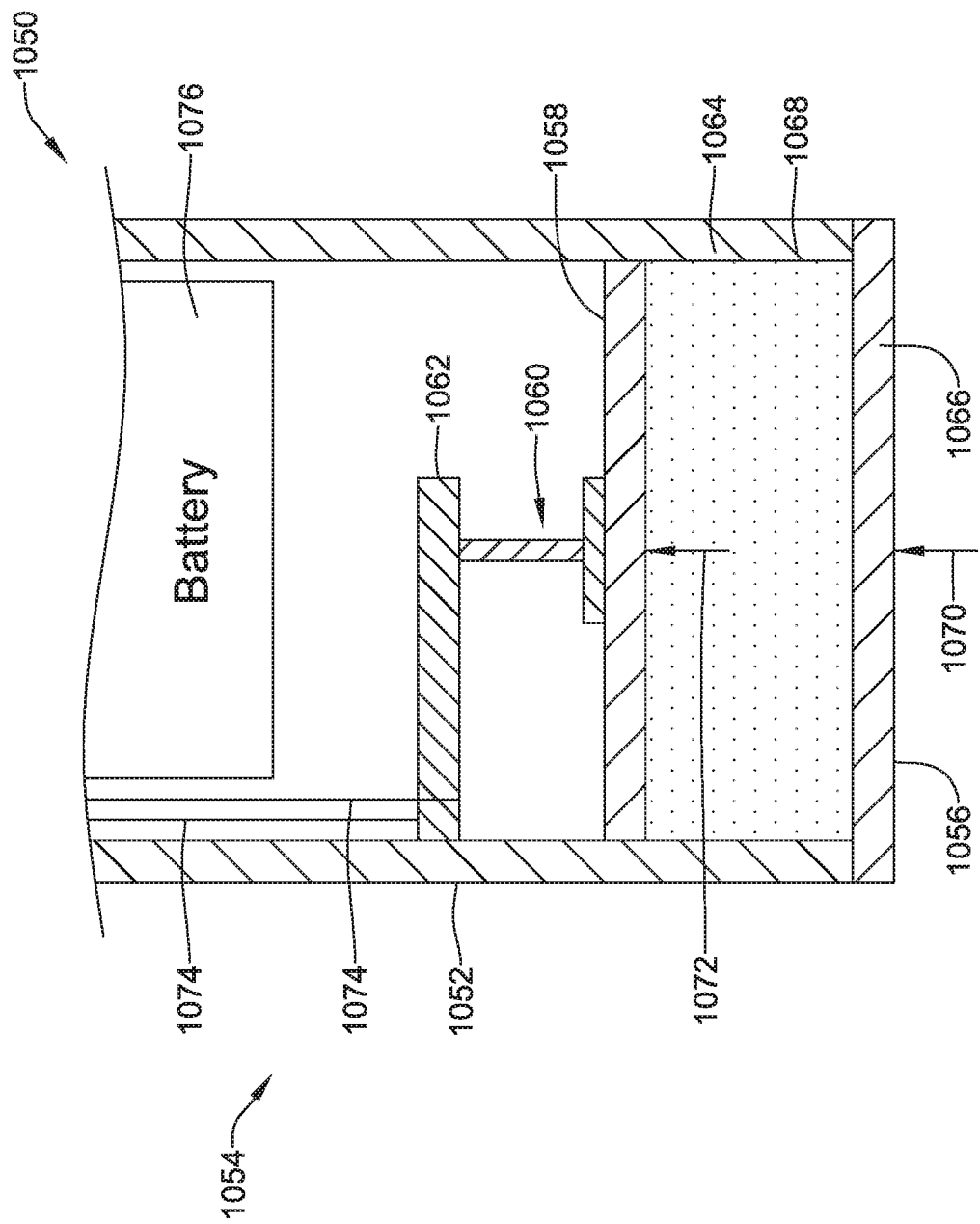
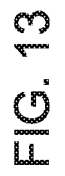


FIG. 12



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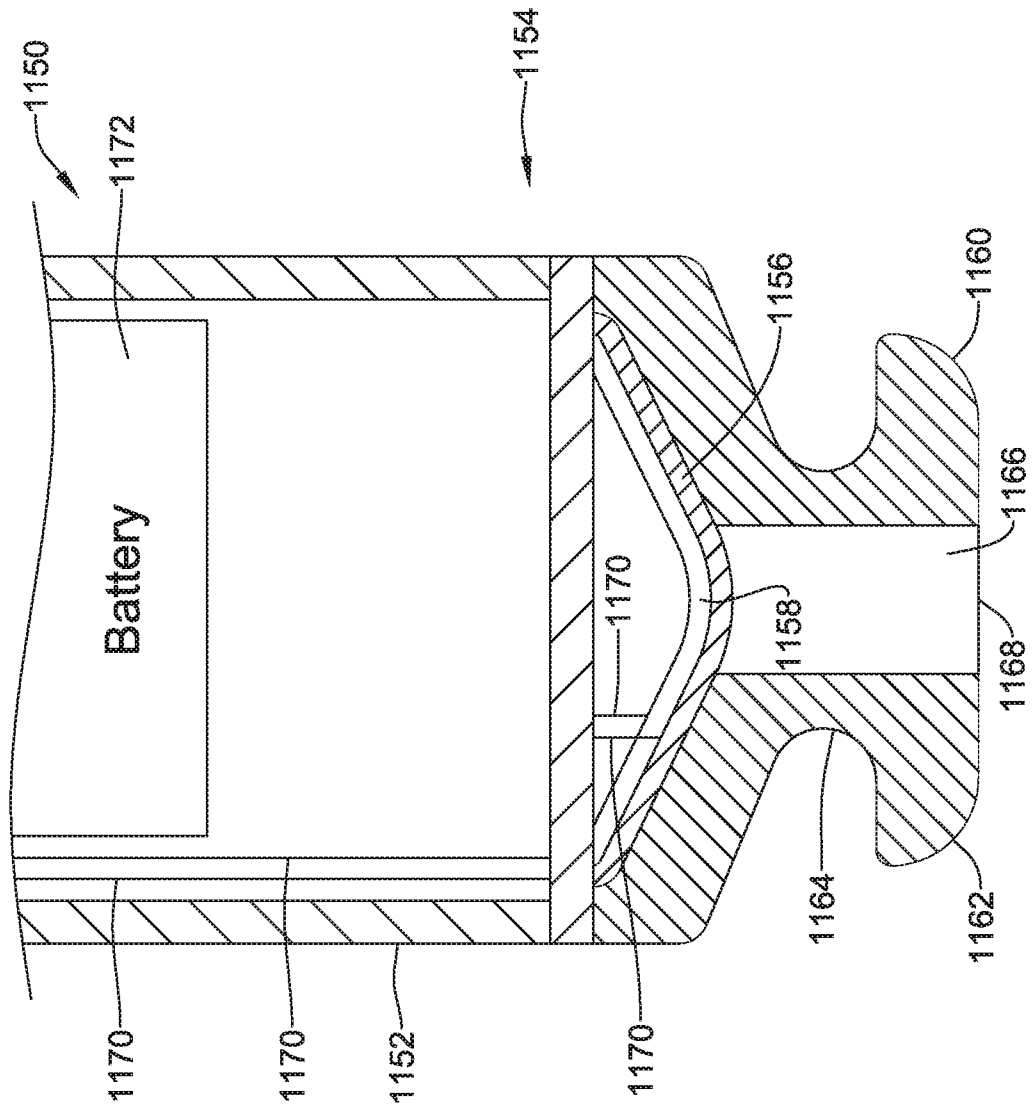


FIG. 14

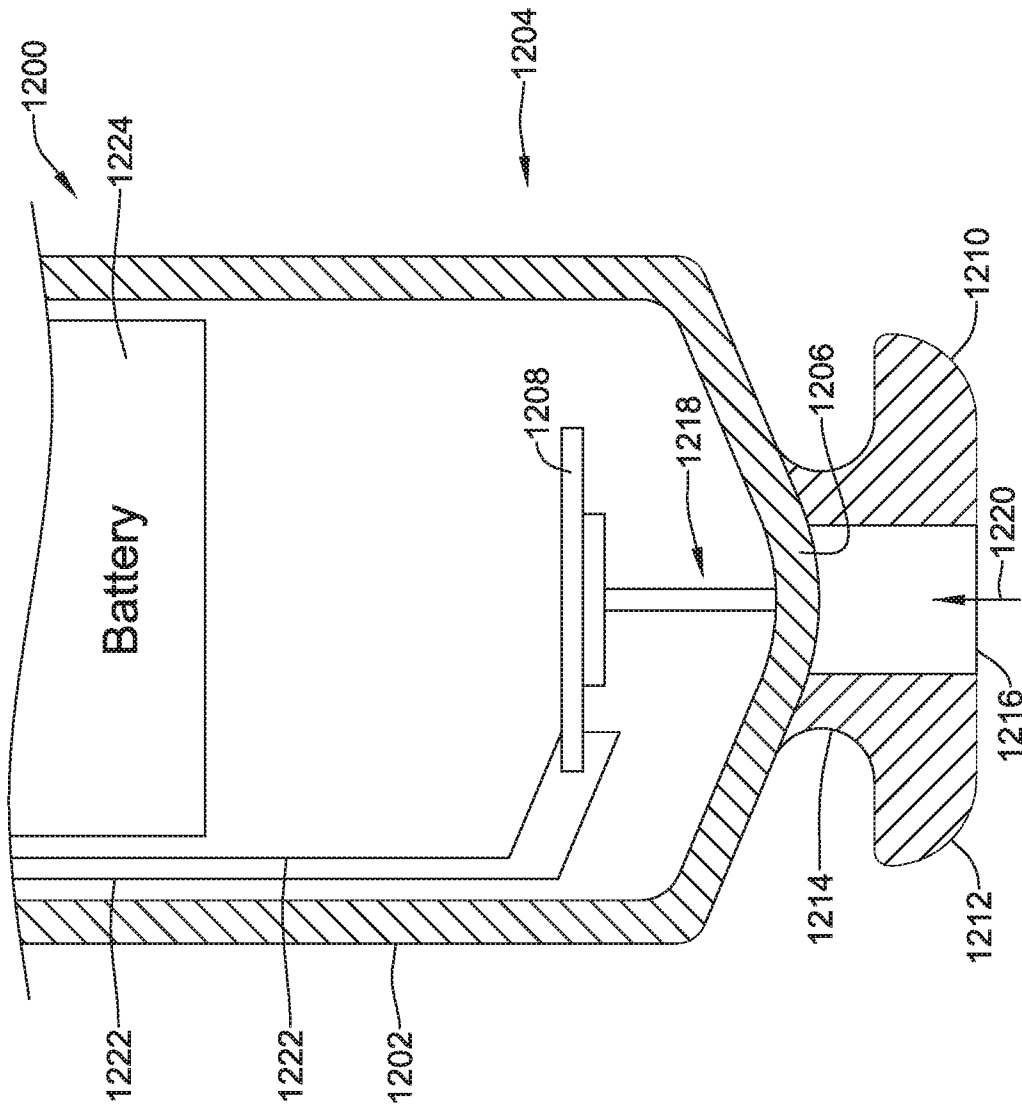


FIG. 15

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2018/046885

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61N1/375 A61N1/365 A61B5/00 A61B5/042 A61B5/0452
 ADD.

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)

A61B A61N

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/317978 A1 (MAILE KEITH R [US] ET AL) 16 December 2010 (2010-12-16) paragraphs [0086] - [0106]; figures 8-10,13-14	1-10, 13-15
A	----- EP 2 030 564 A2 (PACESETTER INC [US]) 4 March 2009 (2009-03-04) paragraph [0038]; figure 2A	1-15
A	----- EP 2 639 845 A1 (SORIN CRM SAS [FR]) 18 September 2013 (2013-09-18) figures 9A-9C	1-15



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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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

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"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

7 November 2018

Date of mailing of the international search report

15/11/2018

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
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 Fax: (+31-70) 340-3016

Authorized officer

Gentil, Cédric

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2018/046885

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2010317978	A1	16-12-2010	NONE

EP 2030564	A2	04-03-2009	EP 2030564 A2 04-03-2009
		US 2009062667	A1 05-03-2009
		US 2012108987	A1 03-05-2012

EP 2639845	A1	18-09-2013	EP 2639845 A1 18-09-2013
		US 2013238072	A1 12-09-2013

专利名称(译)	带有压力传感器的可植入医疗设备		
公开(公告)号	EP3668592A1	公开(公告)日	2020-06-24
申请号	EP2018782224	申请日	2018-08-17
[标]申请(专利权)人(译)	心脏起搏器股份公司		
申请(专利权)人(译)	心脏起搏器，INC.		
当前申请(专利权)人(译)	心脏起搏器，INC.		
[标]发明人	MAILE KEITH R LINDER WILLIAM J SWEENEY MOIRA B KANE MICHAEL J KOOP BRENDAN EARLY		
发明人	MAILE, KEITH R. LINDER, WILLIAM J. SWEENEY, MOIRA B. KANE, MICHAEL J. KOOP, BRENDAN EARLY		
IPC分类号	A61N1/375 A61N1/365 A61B5/00 A61B5/042 A61B5/0452		
CPC分类号	A61B5/02158 A61B5/042 A61B5/0464 A61B5/686 A61B2560/0462 A61B2562/0247 A61N1/36564 A61N1/3756 A61B5/0215 A61B5/0422 A61B5/0452 A61B5/6869 A61B5/0031 A61B5/1107 A61B5/ /4836 A61B2560/0219 A61N1/3627 A61N1/3655 A61N1/36571 A61N1/36578 A61N1/3682 A61N1/ /3684 A61N1/3702 A61N1/37276 A61N1/37512		
优先权	62/547458 2017-08-18 US		
外部链接	Espacenet		

摘要(译)

植入式医疗设备 (IMD) 配置有压力传感器。 IMD包括外壳和在外壳外部暴露于环境的隔膜。 隔膜构造成将压力从壳体外部的环境传递到压电膜。 作为响应，压电膜产生电压和/或电流，该电压和/或电流代表施加到壳体隔膜上的压力变化。 在某些情况下，仅使用压力随时间的变化，而不使用绝对压力或表压。