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(54) Title: METHOD AND SYSTEM FOR DETERMINING AN ATRIAL CONTRACTION TIMING FIDUCIAL IN A LEADLESS CARDIAC PACEMAKER SYSTEM

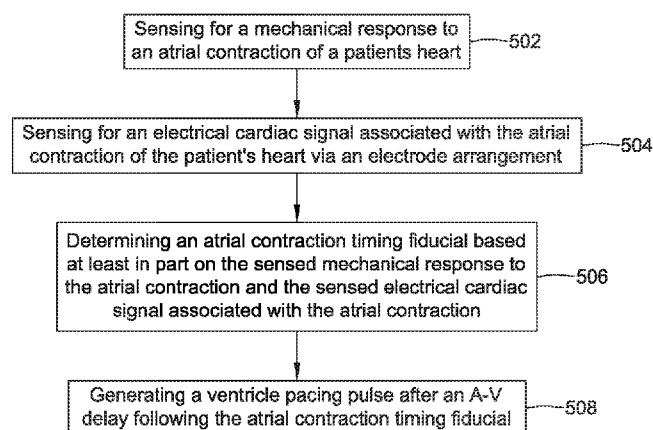


FIG. 8

(57) Abstract: Method and system for determining an atrial contraction timing fiducial in a leadless cardiac pacemaker system is disclosed. An electrical cardiac signal associated with an atrial contraction of the patient's heart and a mechanical response to the atrial contraction of a patient's heart are used to determine an atrial contraction timing fiducial. A ventricle pacing pulse may then be generated an A-V delay after the atrial contraction timing fiducial.

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METHOD AND SYSTEM FOR DETERMINING AN ATRIAL CONTRACTION TIMING FIDUCIAL IN A LEADLESS CARDIAC PACEMAKER SYSTEM

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application Serial No. 62/359,055 filed on July 6, 2016, the disclosure of which is incorporated herein by reference.

TECHNICAL FIELD

[0002] The present disclosure generally relates to implantable medical devices, and more particularly, to systems that use a leadless cardiac pacemaker for monitoring, pacing and/or defibrillating a patient's heart.

BACKGROUND

[0003] Implantable medical devices are commonly used today to monitor a patient and/or deliver therapy to a patient. For example and in some instances, pacing devices are used to 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. Such heart conditions may lead to slow, rapid, irregular, and/or inefficient heart contractions. To help alleviate some of these conditions, various medical devices (e.g., pacemakers, defibrillators, etc.) can be implanted in a patient's body. Such devices may monitor and in some cases provide electrical stimulation (e.g. pacing, defibrillation, etc.) to the heart to help the heart operate in a more normal, efficient and/or safe manner. In some cases, it is beneficial to sense and/or pace two or more chambers of the heart, such as to provide cardiac resynchronization therapy (CRT).

SUMMARY

[0004] This disclosure generally relates to implantable medical devices, and more particularly, to systems that use a leadless cardiac pacemaker for monitoring, pacing and/or defibrillating a patient's heart. In an example of the disclosure, a method for generating a ventricle pacing pulse may include sensing for a mechanical response to an atrial contraction of a patient's heart, and sensing for an electrical cardiac signal associated with the atrial contraction of the patient's heart via an electrode arrangement. An atrial contraction timing fiducial may be

determined based at least in part on the sensed mechanical response to the atrial contraction and the sensed electrical cardiac signal associated with the atrial contraction. The atrial contraction timing fiducial can be performed on a beat-by-beat basis, may be average over more than one beat, and/or may be determined in any other suitable manner. In some cases, the mechanical response to the atrial contraction of the patient's heart and the electrical cardiac signal associated with the atrial contraction of the patient's heart may be sensed by a Leadless Cardiac Pacemaker (LCP) implanted in a ventricle of the heart (e.g. at the apex of the left ventricle) and/or by a Subcutaneous Implantable Cardioverter Defibrillator (SICD) implanted subcutaneously. A ventricle pacing pulse may be generated after an A-V delay following the atrial contraction timing fiducial. The ventricle pacing pulse may be generated and delivered by an LCP.

[0005] Alternatively or additionally to any of the embodiments above, the mechanical response to the atrial contraction of the patient's heart may be sensed via an accelerometer of a Leadless Cardiac Pacemaker (LCP) and/or an accelerometer of a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD).

[0006] Alternatively or additionally to any of the embodiments above, the electrical cardiac signal associated with the atrial contraction of the patient's heart may be sensed via an electrode arrangement of a Leadless Cardiac Pacemaker (LCP) and/or an electrode arrangement of a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD).

[0007] Alternatively or additionally to any of the embodiments above, the method may further include weighting a timing associated with the sensed mechanical response to the atrial contraction with a first weight, weighting a timing associated with the sensed electrical cardiac signal associated with the atrial contraction with a second weight and determining the atrial contraction timing fiducial based at least in part on the weighted timing associated with the sensed mechanical response and the weighted timing associated with the sensed electrical cardiac signal.

[0008] Alternatively or additionally to any of the embodiments above, the sensed mechanical response to the atrial contraction of the patient's heart may be used to identify a time window in which an electrical cardiac signal is searched to identify the electrical cardiac signal associated with a subsequent atrial contraction.

[0009] Alternatively or additionally to the previous embodiment above, the sensed mechanical response includes the S3 and the S4 heart sounds, the time window is between the S3

to S4 heart sounds, and the electrical cardiac signal associated with the atrial contraction is a P-wave of an electrocardiogram signal.

[00010] Alternatively or additionally to any of the embodiments above, the sensed mechanical response to the atrial contraction of the patient's heart may have a signal-to-noise ratio (SNR) and the sensed electrical cardiac signal associated with the atrial contraction may have a signal-to-noise ratio (SNR). If the signal-to-noise ratio (SNR) of the sensed mechanical response to the atrial contraction of the patient's heart is above a SNR threshold, the atrial contraction timing fiducial may be based on the mechanical response to the atrial contraction of the patient's heart and if the signal-to-noise ratio (SNR) of the sensed mechanical response to the atrial contraction of the patient's heart is below the SNR threshold, the atrial contraction timing fiducial may be based on the electrical cardiac signal associated with the atrial contraction of the patient's heart.

[00011] Alternatively or additionally to any of the embodiments above, the method may further include detecting an ambulatory activity level of the patient. When so provided, the atrial contraction timing fiducial may be based on the mechanical response to the atrial contraction of the patient's heart if the detected ambulatory activity level is below an activity threshold and may be based on the electrical cardiac signal associated with the atrial contraction of the patient's heart if the detected ambulatory activity level is above the activity threshold.

[00012] Alternatively or additionally to any of the embodiments above, the method may further include detecting a posture of the patient. When so provided, the atrial contraction timing fiducial may be based on the mechanical response to the atrial contraction of the patient's heart if the patient is in a first posture and may be based on the electrical cardiac signal associated with the atrial contraction of the patient's heart if the patient is in a second posture that is different from the first posture.

[00013] Alternatively or additionally to any of the embodiments above, the electrode arrangement may be configured to provide two or more sense vectors for sensing electrical cardiac signals associated with the atrial contractions of the patient's heart. When so provided, the method may include sensing for the electrical cardiac signals associated with one or more atrial contractions of the patient's heart using a first sense vector of the two or more sense vectors of the electrode arrangement, and sensing for the electrical cardiac signals associated with one or more atrial contractions of the patient's heart using a second sense vector of the two or more sense vectors of the electrode arrangement. A determination may be made as to which

of the first sense vector and the second sense vector produces a higher signal-to-noise ratio (SNR) for the electrical cardiac signals associated with the one or more atrial contractions of the patient's heart. The sense vector determined to produce the higher signal-to-noise ratio (SNR) may be used when sensing electrical cardiac signals associated with subsequent atrial contractions of the patient's heart.

[00014] Alternatively or additionally to any of the embodiments above, the electrode arrangement may be configured to provide two or more sense vectors for sensing the electrical cardiac signal associated with the atrial contraction of the patient's heart. When so provided, the method may include sensing for the electrical cardiac signals associated with the atrial contractions of the patient's heart using each of two or more sense vectors of the two or more sense vectors of the electrode arrangement, determining a composite sense vector of the two or more sense vectors that increases the signal-to-noise ratio (SNR) relative to a SNR achievable by any one of the individual sense vectors, and using the composite sense vector when sensing for electrical cardiac signals associated with subsequent atrial contractions of the patient's heart.

[00015] In another example of the disclosure, a leadless cardiac pacemaker (LCP) is configured to sense cardiac activity and to pace a patient's heart and is disposable within a ventricle of the patient's heart. The LCP includes a housing, a first electrode secured relative to the housing and exposed to an environment outside of the housing and a second electrode secured relative to the housing and exposed to the environment outside of the housing, the second electrode spaced from the first electrode. A controller is disposed within the housing and is operably coupled to the first electrode and the second electrode such that the controller is capable of receiving, via the first electrode and the second electrode, electrical signals including an electrical indication of atrial contraction. An accelerometer is disposed within the housing and is operably coupled to the controller. The controller is configured to detect, via a signal from the accelerometer, a mechanical indication of atrial contraction. The controller is further configured to determine an atrial contraction timing fiducial based at least in part on the mechanical indication of atrial contraction and/or the electrical indication of atrial contraction, and to generate a ventricle pacing pulse after an A-V delay following the atrial contraction timing fiducial.

[00016] Alternatively or additionally to any of the embodiments above, the electrical indication of atrial contraction may include a P-wave of an electrocardiogram.

[00017] Alternatively or additionally to any of the embodiments above, the mechanical indication of atrial contraction may include an S4 heart sound.

[00018] Alternatively or additionally to any of the embodiments above, the electrical indication of atrial contraction may be received from a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD).

[00019] Alternatively or additionally to any of the embodiments above, the controller may be configured to preferentially use the electrical indication of atrial contraction or the mechanical indication of atrial contraction based at least in part upon a signal-to-noise ratio (SNR) associated with each.

[00020] In another example of the disclosure, a system for generating a ventricle pacing pulse may include a Subcutaneous Implantable Cardioverter Defibrillator (SICD), and a leadless cardiac pacemaker (LCP) in operative communication with the SICD. At least one of the SICD and LCP may sense for a mechanical response to an atrial contraction of a patient's heart and at least one of the SICD and LCP may sense for an electrical cardiac signal associated with the atrial contraction of the patient's heart. An atrial contraction timing fiducial is stored in the LCP, wherein the atrial contraction timing fiducial based at least in part on the sensed mechanical response to the atrial contraction and the sensed electrical cardiac signal associated with the atrial contraction. The LCP may generate a ventricle pacing pulse after an A-V delay following the atrial contraction timing fiducial.

[00021] Alternatively or additionally to any of the embodiments above, the mechanical response to the atrial contraction of the patient's heart is sensed via an accelerometer of the LCP and/or an accelerometer of the SICD.

[00022] Alternatively or additionally to any of the embodiments above, the electrical cardiac signal associated with the atrial contraction of the patient's heart is sensed via an electrode arrangement of the LCP and/or an electrode arrangement of the SICD.

[00023] Alternatively or additionally to any of the embodiments above, the sensed mechanical response to the atrial contraction of the patient's heart has a signal-to-noise ratio (SNR) and the sensed electrical cardiac signal associated with the atrial contraction has a signal-to-noise ratio (SNR). If the SNR of the sensed mechanical response to the atrial contraction of the patient's heart is above a SNR threshold, the atrial contraction timing fiducial may be based on the mechanical response to the atrial contraction of the patient's heart, and if the SNR of the sensed

mechanical response to the atrial contraction of the patient's heart is below the SNR threshold, the atrial contraction timing fiducial may be based on the electrical cardiac signal associated with the atrial contraction of the patient's heart.

[00024] The above summary is not intended to describe each embodiment or every implementation of the present disclosure. Advantages and attainments, together with a more complete understanding of the disclosure, will become apparent and appreciated by referring to the following description and claims taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[00025] 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:

[00026] Figure 1 is a highly schematic diagram of an illustrative system in accordance with an example of the disclosure;

[00027] Figure 2 is a graphical representation of an electrocardiogram (ECG) showing a temporal relationship between electrical signals of the heart and mechanical indications of contraction of the heart;

[00028] Figure 3 is a schematic block diagram of an illustrative leadless cardiac pacemaker (LCP) useable in the system of Figure 1;

[00029] Figure 4 is a schematic block diagram of an illustrative LCP in accordance with an example of the disclosure;

[00030] Figure 5 is a schematic block diagram of another illustrative medical device that may be used in conjunction with the LCP of Figure 4;

[00031] Figure 6 is a schematic diagram of an exemplary medical system that includes multiple LCPs and/or other devices in communication with one another;

[00032] Figure 7 is a schematic diagram of a system including an LCP and another medical device, in accordance with an example of the disclosure;

[00033] Figure 8 is a flow diagram showing an illustrative method in accordance with an example of the disclosure;

[00034] Figure 9 is a flow diagram showing an illustrative method in accordance with an example of the disclosure;

[00035] Figure 10 is a flow diagram showing an illustrative method in accordance with an example of the disclosure;

[00036] Figure 11 is a flow diagram showing an illustrative method in accordance with an example of the disclosure;

[00037] Figure 12 is a flow diagram showing an illustrative method in accordance with an example of the disclosure; and

[00038] Figure 13 is a flow diagram showing an illustrative method in accordance with an example of the disclosure.

[00039] 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 intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure.

DESCRIPTION

[00040] The following description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The description and the drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the disclosure.

[00041] All numbers are herein assumed to be modified by the term “about”, unless the content clearly dictates otherwise. The recitation of numerical ranges by endpoints includes all numbers subsumed within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

[00042] As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” include the plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise.

[00043] It is noted that references in the specification to “an embodiment”, “some embodiments”, “other embodiments”, etc., indicate that the embodiment described may include a particular feature, structure, or characteristic, but every embodiment may not necessarily include the particular feature, structure, or characteristic. Moreover, such phrases are not necessarily referring to the same embodiment. Further, when a particular feature, structure, or characteristic

is described in connection with an embodiment, it is contemplated that the feature, structure, or characteristic may be applied to other embodiments whether or not explicitly described unless clearly stated to the contrary.

[00044] A normal, healthy heart induces contraction by conducting intrinsically generated electrical signals throughout the heart. These intrinsic signals cause the muscle cells or tissue of the heart to contract in a coordinated manner. These contractions forces blood out of and into the heart, providing circulation of the blood throughout the rest of the body. Many patients suffer from cardiac conditions that affect the efficient operation of their hearts. For example, some hearts develop diseased tissue that no longer generate or efficiently conduct intrinsic electrical signals. In some examples, diseased cardiac tissue may conduct electrical signals at differing rates, thereby causing an unsynchronized and inefficient contraction of the heart. In other examples, a heart may generate intrinsic signals at such a low rate that the heart rate becomes dangerously low. In still other examples, a heart may generate electrical signals at an unusually high rate, even resulting in cardiac fibrillation. Implantable medical device are often used to treat such conditions by delivering one or more types of electrical stimulation therapy to the patient's heart.

[00045] Figure 1 is a schematic diagram showing an illustrative system 10 that may be used to sense and/or pace a heart H. In some cases, the system 10 may also be configured to be able to shock the heart H. The heart H includes a right atrium RA and a right ventricle. The heart H also includes a left atrium LA and a left ventricle LV. In some cases, the illustrative system 10 includes an SICD (subcutaneous implantable cardioverter defibrillator) 12. While not shown in this Figure, in some cases the SICD 12 may include a lead that may be configured to be placed subcutaneously relative to a patient's sternum and outside of the patient's heart. The SICD 12 may be configured to sense electrical activity generated by the heart H as well as provide electrical energy to the heart H in order to shock the heart H from an undesired heart rhythm to a desired heart rhythm. In some cases, the system 10 may include an LCP 14 that may be configured to sense and/or pace the heart H. While a single LCP 14 is illustrated, it will be appreciated that two or more LCPs 14 may be implanted in or on the heart H. The LCP 14 may be implanted into any chamber of the heart, such as the right atrium RA, the left atrium LA, the right ventricle RV and the left ventricle LV. When more than one LCP is provided, each LCP

may be implanted in a different chamber. In some cases, multiple LCP's may be implanted within a single chamber of the heart H.

[00046] In some cases, the SICD 12 and the LCP 14 may be implanted at the same time. In some instances, depending on the cardiac deficiencies of a particular patient, the SICD 12 may be implanted first, and one or more LCPs 14 may be implanted at a later date if/when the patient's heart decompensates and it becomes necessary to pace the heart H. In some cases, it is contemplated that one or more LCPs 14 may be implanted first, in order to sense and pace the heart H. When a need for possible defibrillation becomes evident, the SICD 12 may subsequently be implanted. Regardless of implantation order or sequence, it will be appreciated that the SICD 12 and the LCP 14 may communicate with each other using any desired communications protocol, such as conducted communication through the patient's body.

[00047] With reference to Figure 2, it will be appreciated that the heart H is controlled via electrical signals that pass through the cardiac tissue and that can be detected by implanted devices such as but not limited to the SICD 12 and the LCP 14 of Figure 1. Figure 2 includes a portion of an electrocardiogram (ECG) 16 along with a heart sounds trace 18. As can be seen in the ECG 16, a heartbeat includes a P-wave that indicates atrial depolarization. A QRS complex, including a Q-wave, an R-wave and an S-wave, represents ventricular depolarization. A T-wave indicates repolarization of the ventricles. It will be appreciated that the ECG 16 may be detected by implanted devices such as but not limited to the SICD 12 and the LCP 14 of Figure 1.

[00048] A number of heart sounds may also be detectable while the heart H beats. It will be appreciated that the heart sounds may be considered as an example of mechanical indications of the heart beating. Other illustrative mechanical indications may include, for example, endocardial acceleration or movement of a heart wall detected by an accelerometer in the LCP, endocardial acceleration or movement of a heart wall detected by an accelerometer in the SICD, a pressure, pressure change, or pressure change rate in a chamber of the heart H detected by a pressure sensor of the LCP, acoustic signals caused by heart movements detected by an acoustic sensor and/or any other suitable indication of a heart chamber beating.

[00049] An electrical signal typically causes a portion of the heart H to contract, and then there is a corresponding mechanical indication. In some cases, there may be a first heart sound that is denoted S1 and that is produced by vibrations generated by closure of the mitral and tricuspid valves during a ventricle contraction, a second heart sound that is denoted S2 and that is

produced by closure of the aortic and pulmonary valves, a third heart sound that is denoted S3 and that is an early diastolic sound caused by the rapid entry of blood from the right atrium RA into the right ventricle RV and from the left atrium LA into the left ventricle LV, and a fourth heart sound that is denoted S4 and that is a late diastolic sound corresponding to late ventricular filling during an active atrial contraction.

[00050] Because the heart sounds are a result of cardiac muscle contracting or relaxing in response to an electrical signal, it will be appreciated that there is a delay between the electrical signal, indicated by the ECG 16, and the corresponding mechanical indication, indicated by the heart sounds trace 18. For example, the P-wave of the ECG 16 is an electrical signal triggering an atrial contraction. The S4 heart sound is the mechanical signal caused by the atrial contraction. In some cases, it may be possible to use this relationship between the P-wave and the S4 heart sound. For example, if one of these signals may be detected, the relationship can be used as a timing mechanism to help search for the other. For example, if the P-wave can be detected, a window following the P-wave can be defined and searched to find the corresponding S4 heart sound. In some cases, detection of both signals may increase the confidence level in a detected atrial contraction. In some cases, detection of either signal may be sufficient to identify an atrial contraction. The identity of an atrial contraction may be used to identify an atrial contraction timing fiducial.

[00051] In some cases, the relationship of certain electrical signals and/or mechanical indications may be used to predict the timing of other electrical signals and/or mechanical indications within the same heartbeat. Alternatively, or in addition, the timing of certain electrical signals and/or mechanical indications corresponding to a particular heartbeat may be used to predict the timing of other electrical signals and/or mechanical indications within a subsequent heartbeat.

[00052] Returning back to Figure 1, in some cases at least one of the SICD 12 and the LCP 14 may sense for a mechanical response to an atrial contraction of the heart H. In some cases, the SICD 12 and the LCP 14 may both sense for a mechanical response. In some cases, only one of the SICD 12 and the LCP 14 may sense for a mechanical response. In some cases, at least one of the SICD 12 and the LCP 14 may sense for an electrical cardiac signal that is associated with atrial contraction. In some cases, both the SICD 12 and the LCP 14 may sense for an electrical cardiac signal while in other cases only one of the SICD 12 and the LCP 14 may do so.

[00053] In some cases, an atrial contraction timing fiducial may be stored in the LCP 14. The atrial contraction timing fiducial may be based at least in part on the sensed mechanical response to the atrial contraction and the sensed electrical cardiac signal associated with the atrial contraction. In some cases, the LCP 14 may generate a ventricle pacing pulse after an A-V delay following the atrial contraction timing fiducial. In one example, detecting at least one of the P-wave, indicating the electrical signal instructing the atria to contract, and the S4 heart sound, which is caused by atrial contraction, may be used to determine an atrial contraction timing fiducial and thus when to pace the right ventricle RV and/or the left ventricle LV.

[00054] In some cases, the mechanical response to the atrial contraction of the patient's heart H may be sensed via an accelerometer of the LCP 14 and/or an accelerometer of the SICD 12. In some cases, the SICD 12 may include an accelerometer within a lead of the SICD 12. In some instances, the SICD 12 may include an accelerometer with the main housing of the SID 12. In some cases, the LCP 14 and the SICD 12 may include accelerometers. In some instances, the electrical cardiac signal associated with the atrial contraction of the patient's heart H may be sensed via an electrode arrangement of the LCP 14 and/or an electrode arrangement of the SICD 12. Additional details regarding the SICD 12 and the LCP 14 may be discussed with respect to subsequent Figures. In some instances, the sensed mechanical response to the atrial contractions of the patient's heart may have a signal-to-noise ratio (SNR) and the sensed electrical cardiac signals associated with the atrial contractions have a signal-to-noise ratio (SNR). For example, the noise used for SNR calculating may be the electrical (for electrical SNR) or mechanical (for mechanical SNR) response during a portion of the cardiac cycle not associated with any cardiac activity (such as but not limited to the temporal window between S1 and S2). In some cases, if the SNR of the sensed mechanical response to the atrial contractions of the patient's heart is above a SNR threshold, the atrial contraction timing fiducial is based on the mechanical response to the atrial contractions of the patient's heart. In some instances, if the SNR of the sensed mechanical response to the atrial contractions of the patient's heart is below the SNR threshold, the atrial contraction timing fiducial is based on the electrical cardiac signal associated with the atrial contractions of the patient's heart.

[00055] Figure 3 is a schematic diagram of an illustrative LCP 14. In some cases, as indicated, the LCP 14 may be considered as being configured to sense cardiac activity and to pace a patient's heart H. In some cases, the LCP 14 may be disposable within a ventricle of the

heart H, such as the right ventricle RV or the left ventricle LV. The LCP 14 may be considered as including a housing 20, a first electrode 22 that is secured relative to the housing 20 and exposed to an environment outside the housing 20 (e.g. blood, tissue, etc.), and a second electrode 24 that is secured relative to the housing 20 and exposed to the environment outside of the housing 20 (e.g. blood, tissue, etc.). The second electrode 24 may be spaced from the first electrode 22. In some cases, as illustrated, the first electrode 22 may be disposed at or near a first end 26 of the housing 20 and the second electrode 24 may be disposed at or near a second end 28 of the housing 20, although this is not required in all cases.

[00056] The LCP 14 may further include a controller 30 that is disposed within the housing 20 and that is operably coupled to the first electrode 22 via a first electrical connection 32 and the second electrode 24 via a second electrical connection 34. In some cases, the controller 30 may be capable of receiving, via the first electrode 22 and the second electrode 24, electrical signals that include an electrical indication of an atrial (or other) contraction (e.g. a P-wave of an ECG 16, see Figure 2). In some cases, the controller 30 may receive the electrical signals that include an electrical indication of atrial (or other) contractions from a remote device such as the SICD 12 (Figure 1).

[00057] In some cases, the LCP 14 may include an accelerometer 36 that is disposed within the housing 20 and that is operably coupled to the controller 30 via electrical connections 38. In some cases, the controller 30 may be configured to detect, via a signal from the accelerometer 36, a mechanical indication of atrial (or other) contraction. In some cases, the mechanical indication of atrial contraction may include but is not limited to an S4 heart sound. While the LCP 14 is shown as including an accelerometer, it will be appreciated that other sensors may also be able to provide a signal representing a mechanical indication of atrial (or other) contraction. For example, in some cases the LCP 14 may include a microphone. In some cases, the LCP 14 may include a sonomicrometer, a cardiomechanical sensor that includes, for example, embedded piezoelectric material, or other piezoelectric sensors. These are just examples.

[00058] In some cases, the controller 30 may be configured to determine an atrial contraction timing fiducial based at least in part on the mechanical indication of atrial contraction and/or the electrical indication of atrial contraction. In some instances, the controller 30 may be configured to preferentially use the electrical indication of atrial contraction or the mechanical indication of

atrial contraction based at least in part upon a signal-to-noise ratio (SNR) associated with each signal. In some instances, the controller 30 may be configured to generate a ventricle pacing pulse after an A-V delay following the atrial contraction timing fiducial.

[00059] Figure 4 depicts another illustrative leadless cardiac pacemaker (LCP) that may be implanted into a patient and may operate to deliver appropriate therapy to the heart, such as to deliver anti-tachycardia pacing (ATP) therapy, cardiac resynchronization therapy (CRT), bradycardia therapy, and/or the like. As can be seen in Figure 4, the LCP 100 may be a compact device with all components housed within the or directly on a housing 120. In some cases, the LCP 100 may be considered as being an example of the LCP 14 (Figures 1 and 3). In the example shown in Figure 4, 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 an electrode arrangement 114. The LCP 100 may include more or less modules, depending on the application.

[00060] The communication module 102 may be configured to communicate with devices such as sensors, other medical devices such as an SICK, 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, external devices (i.e. external to the LCP 100 but not necessarily external to the patient's body) can communicate with the LCP 100 via 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, R-wave detection markers, etc., to an external medical device through the communication module 102. The external medical device may use the communicated signals, data, instructions, messages, R-wave detection markers, etc., to perform various functions, such as determining occurrences of arrhythmias, delivering electrical stimulation therapy, storing 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, and/or performing any other suitable function. The communication module 102 may be configured to use one or more methods for communicating with external 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.

[00061] In the example shown in Figure 4, the pulse generator module 104 may be electrically connected to the electrodes 114. In some examples, the LCP 100 may additionally include electrodes 114'. In such examples, the pulse generator 104 may also be electrically connected to the 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 the 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 synchronization, 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 anti-tachycardia pacing (ATP) therapy, cardiac resynchronization therapy (CRT), and cardioversion/defibrillation therapy.

[00062] In some examples, the LCP 100 may not include a pulse generator 104. For example, 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.

[00063] 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. In some cases, the LCP 100 may be configured to detect cardiac electrical signals from other chambers (e.g. far field), such as the P-wave from the atrium.

[00064] The mechanical sensing module 108 may include one or more sensors, such as an accelerometer, a 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/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 4 as separate sensing modules, in some cases, the electrical sensing module 206 and the mechanical sensing module 208 may be combined into a single sensing module, as desired.

[00065] 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 the 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. In some cases, one or more of the electrodes 114/114' may be provided on a tail (not shown) that extends away from the housing 120.

[00066] 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, abnormalities in the operation of the heart H. Based on any determined abnormalities, 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 abnormalities. 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 abnormality is occurring, determine a type of abnormality, 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.

[00067] 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.

[00068] 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 110 may be some other type of power source, as desired.

[00069] 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.

[00070] Figure 5 depicts an example of another medical device (MD) 200, which may be used in conjunction with the LCP 100 (Figure 4) in order to detect and/or treat cardiac abnormalities. In some cases, the MD 200 may be considered as an example of the SICD 12 (Figure 1). 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 LCP 100. Additionally, the battery 218 may be similar to the battery 112 of the LCP 100. In some examples, however, the MD 200 may have a larger volume within the housing 220. 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.

[00071] While it is contemplated that the MD 200 may be another leadless device such as shown in Figure 4, 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 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 subcutaneously and outside of 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).

[00072] 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, acoustic sensors, blood pressure sensors, heart sound sensors, blood-oxygen 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.

[00073] 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.

[00074] 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 the 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. In some examples, the MD 200 may additionally be configured provide defibrillation therapy.

[00075] 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 other examples, 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 instances, the lead(s) may have one or more electrodes that are placed subcutaneously and outside of the chest cavity. In other examples, the lead(s) may have one or more electrodes that are placed inside of the chest cavity, such as just interior of the sternum.

[00076] 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 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.

[00077] Figure 6 illustrates an example of a medical device system and 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, external medical device 306, and other sensors/devices 310. The external device 306 may be any of the devices described previously with respect to the MD 200. Other sensors/devices 310 may also be any of the devices described previously with respect to the MD 200. In some instances, other sensors/devices 310 may include a sensor, such as an accelerometer, an acoustic sensor, a blood pressure sensor, or the like. In some cases, other sensors/devices 310 may include an external programmer device that may be used to program one or more devices of the system 300.

[00078] Various devices of the system 300 may communicate via 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 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. It is contemplated that the communication pathway 308 may communicate using RF signals, inductive coupling, optical signals, acoustic signals, or any other signals suitable for communication. Additionally, in at least some examples, device communication pathway 308 may comprise multiple signal types. For instance, 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). 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 other sensors/devices 310, where the LCPs 302/304 send signals to other sensors/devices 310, and other sensors/devices 310 relay the received signals to the external device 306.

[00079] 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 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 blanking period of the heart and/or may be incorporated in or modulated onto a pacing pulse, if desired.

[00080] 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.

[00081] Figure 7 shows an illustrative medical device systems. In Figure 7, an LCP 402 is shown fixed to the interior of the left ventricle of the heart 410, and a pulse generator 406 is shown coupled to a lead 412 having one or more electrodes 408a-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-408c may be positioned subcutaneously. In some cases, the one or more electrodes 408a-408c may be placed inside of the chest cavity but outside of the heart, such as just interior of the sternum.

[00082] In some cases, the LCP 402 may communicate with the subcutaneous implantable cardioverter-defibrillator (S-ICD). In some cases, the lead 412 may include an accelerometer 414 that may, for example, be configured to sense vibrations that may be indicative of heart sounds.

[00083] In some cases, the LCP 302 may be in the right ventricle, right atrium, left ventricle or left atrium of the heart, as desired. In some cases, more than one LCP 302 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 be implanted in each of the chambers of the heart.

[00084] When an LCP is placed in, for example, the left ventricle, and no LCP is placed in the left atrium, techniques of the present disclosure may be used to help determine an atrial contraction timing fiducial for the left atrium. This atrial contraction timing fiducial may then be used to determine a proper time to pace the left ventricle via the LCP, such as an AV delay after the atrial contraction timing fiducial.

[00085] Figure 8 is a flow diagram showing an illustrative method for generating a ventricle pacing pulse. As generally shown at block 502, the method begins with sensing for a mechanical response to an atrial contraction of a patient's heart. In some cases, the mechanical response to the atrial contraction of the patient's heart may be sensed via an accelerometer of a Leadless Cardiac Pacemaker (LCP) and/or an accelerometer of a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD). In one particular example, the mechanical response may be sensed by the accelerometer 36 (Figure 3) of the LCP 14, 100, or by the accelerometer 414 of the lead 412 (Figure 7).

[00086] As shown at block 504, the illustrative method includes sensing for an electrical cardiac signal associated with the atrial contraction of the patient's heart via an electrode arrangement. In some cases, the electrical cardiac signal associated with the atrial contraction of the patient's heart may be sensed via an electrode arrangement of a Leadless Cardiac Pacemaker (LCP) and/or an electrode arrangement of a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD). In one particular example, the electrical cardiac signal may be sensed by the first and second electrodes 22, 24 (LCP 14) and/or by the electrodes 114, 114' (LCP 100), or perhaps by one or more of the electrodes 408a, 408b, 408c of the lead 412.

[00087] In some cases, a sensed mechanical response to the atrial contraction of the patient's heart may be used to identify a time window in which an electrical cardiac signal is searched to identify the electrical cardiac signal associated with a subsequent atrial contraction. As an illustrative but non-limiting example, a sensed mechanical response may include the S3 and the S4 heart sounds (illustrated in the heart sounds trace 18 of Figure 2). A time window may be defined between the S3 to S4 heart sounds. A search for the P-wave may be confined to this

time window. Likewise, a sensed electrical response to an atrial contraction of the patient's heart may be used to identify a time window in which to search for a corresponding mechanical response. As an illustrative but non-limiting example, after a P-wave is sensed, a window may be defined for a period of time following the P-wave. A search for the S4 heart sound may be confined to this time window. These are just some examples.

[00088] An atrial contraction timing fiducial may be determined based at least in part on the sensed mechanical response to the atrial contraction and the sensed electrical cardiac signal associated with the atrial contraction, as seen at block 506. In some cases, the sensed mechanical response to the atrial contraction of the patient's heart has a signal-to-noise ratio (SNR) and the sensed electrical cardiac signal associated with the atrial contraction has a signal-to-noise ratio (SNR). In some cases, if the signal-to-noise ratio (SNR) of the sensed mechanical response to the atrial contraction of the patient's heart is above a SNR threshold, the atrial contraction timing fiducial may be based on the mechanical response to the atrial contraction of the patient's heart. Conversely, if the signal-to-noise ratio (SNR) of the sensed mechanical response to the atrial contraction of the patient's heart is below the SNR threshold, the atrial contraction timing fiducial is based on the electrical cardiac signal associated with the atrial contraction of the patient's heart. A ventricle pacing pulse may be generated after an A-V delay following the atrial contraction timing fiducial, as generally indicated at block 508.

[00089] Figure 9 is a flow diagram showing another illustrative method for generating a ventricle pacing pulse. As generally shown at block 502, the method begins with sensing for a mechanical response to an atrial contraction of a patient's heart. In some cases, the mechanical response to the atrial contraction of the patient's heart may be sensed via an accelerometer of a Leadless Cardiac Pacemaker (LCP) and/or an accelerometer of a lead of a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD). As shown at block 504, the method further includes sensing for an electrical cardiac signal associated with the atrial contraction of the patient's heart via an electrode arrangement. In some cases, the electrical cardiac signal associated with the atrial contraction of the patient's heart may be sensed via an electrode arrangement of a Leadless Cardiac Pacemaker (LCP) and/or an electrode arrangement of a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD).

[00090] As seen at block 510, in some cases, a timing associated with the sensed mechanical response to the atrial contraction may be weighted with a first weight. In some cases, as seen at

block 512, a timing associated with the sensed electrical cardiac signal associated with the atrial contraction may be weighted with a second weight. The atrial contraction timing fiducial may be determined based at least in part on the weighted timing associated with the sensed mechanical response and the weighted timing associated with the sensed electrical cardiac signal, as generally indicated at block 514. The first and second weights may be based on a confidence level in the corresponding signals. In some cases, the weights may be based at least in part on the Signal-To-Noise ratio (SNR) of the corresponding signals. A ventricle pacing pulse may be generated after an A-V delay following the atrial contraction timing fiducial, as generally indicated at block 508.

[00091] Figure 10 is a flow diagram showing another illustrative method for generating a ventricle pacing pulse. As generally shown at block 502, the method begins with sensing for a mechanical response to an atrial contraction of a patient's heart. In some cases, the mechanical response to the atrial contraction of the patient's heart may be sensed via an accelerometer of a Leadless Cardiac Pacemaker (LCP) and/or an accelerometer of a lead of a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD). As shown at block 504, the method further includes sensing for an electrical cardiac signal associated with the atrial contraction of the patient's heart via an electrode arrangement. In some cases, the electrical cardiac signal associated with the atrial contraction of the patient's heart may be sensed via an electrode arrangement of a Leadless Cardiac Pacemaker (LCP) and/or an electrode arrangement of a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD).

[00092] In some cases, an ambulatory activity level of the patient may be detected, as indicated at block 516. It will be appreciated that the patient's activity level may influence the confidence level in the detected electrical signals of cardiac activity and/or resultant mechanical indications of cardiac activity. At decision block 518, a determination may be made if the detected ambulatory activity level is below an activity threshold. The activity threshold may be customized for a particular patient. If the detected ambulatory activity level is below the activity threshold, control passes to block 520 and the atrial contraction timing fiducial may be based on the mechanical response to the atrial contraction of the patient's heart (or may be weighted more heavily). However, if at decision block 518 the detected ambulatory activity level is not below the activity level, control passes to block 522 and the atrial contraction timing fiducial may be based on the electrical cardiac signal associated with the atrial contraction of the patient's heart

(or may be weighted more heavily). A ventricle pacing pulse may be generated after an A-V delay following the atrial contraction timing fiducial, as generally indicated at block 508.

[00093] Figure 11 is a flow diagram showing another illustrative method for generating a ventricle pacing pulse. As generally shown at block 502, the method begins with sensing for a mechanical response to an atrial contraction of a patient's heart. In some cases, the mechanical response to the atrial contraction of the patient's heart may be sensed via an accelerometer of a Leadless Cardiac Pacemaker (LCP) and/or an accelerometer of a lead of a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD). As shown at block 504, the method further includes sensing for an electrical cardiac signal associated with the atrial contraction of the patient's heart via an electrode arrangement. In some cases, the electrical cardiac signal associated with the atrial contraction of the patient's heart may be sensed via an electrode arrangement of a Leadless Cardiac Pacemaker (LCP) and/or an electrode arrangement of a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD).

[00094] In some cases, a posture of the patient may be detected, as indicated at block 516. It will be appreciated that the patient's posture, whether standing, sitting, laying down, etc., may influence the confidence level in the detected electrical signals of cardiac activity and/or resultant mechanical indications of cardiac activity. At decision block 526, a determination may be made as to whether the patient is in a first posture or a second posture. If the patient is in a first posture, control passes to block 528 and the atrial contraction timing fiducial may be based on the mechanical response to the atrial contraction of the patient's heart (or may be weighted more heavily). However, if at decision block 526 the patient is in the second posture, control passes to block 530 and the atrial contraction timing fiducial may be based on the electrical cardiac signal associated with the atrial contraction of the patient's heart (or may be weighted more heavily). A ventricle pacing pulse may be generated after an A-V delay following the atrial contraction timing fiducial, as generally indicated at block 508.

[00095] Figure 12 is a flow diagram showing another illustrative method for generating a ventricle pacing pulse. In some cases, the electrode arrangement used for sensing for an electrical cardiac signal associated with the atrial contraction may be configured to provide two or more sense vectors for sensing the electrical cardiac signal associated with the atrial contraction of the patient's heart. As generally shown at block 540, the method begins with sensing for the electrical cardiac signals associated with one or more atrial contractions of the

patient's heart using a first sense vector of the two or more sense vectors of the electrode arrangement. As shown at block 542, the method includes sensing for the electrical cardiac signals associated with one or more atrial contractions of the patient's heart using a second sense vector of the two or more sense vectors of the electrode arrangement. A determination may be made as to which of the first sense vector and the second sense vector produces the higher confidence level (e.g. signal-to-noise ratio (SNR)) for the electrical cardiac signal associated with the one or more atrial contractions of the patient's heart, as generally indicated at block 544. As seen at block 546, the sense vector determined to produce the confidence level (e.g. signal-to-noise ratio (SNR)) may be used when sensing electrical cardiac signal associated with subsequent atrial contractions of the patient's heart.

[00096] Figure 13 is a flow diagram showing another illustrative method for generating a ventricle pacing pulse. In some cases, the electrode arrangement used for sensing for an electrical cardiac signal associated with the atrial contraction may be configured to provide two or more sense vectors for sensing the electrical cardiac signal associated with the atrial contraction of the patient's heart. As generally seen at block 548, the method begins with sensing for the electrical cardiac signal associated with the atrial contraction of the patient's heart using each of two or more sense vectors of the two or more sense vectors of the electrode arrangement. As seen at block 550, the method includes determining a composite sense vector of the two or more sense vectors that increases the confidence level (e.g. signal-to-noise ratio (SNR)) relative to the confidence level (e.g. signal-to-noise ratio (SNR)) achievable by any one of the individual sense vectors. The composite sense vector may be used when sensing for electrical cardiac signals associated with subsequent atrial contractions of the patient's heart, as generally indicated at block 552.

[00097] 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 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 method for generating a ventricle pacing pulse, comprising:
sensing for a mechanical response to an atrial contraction of a patient's heart;
sensing for an electrical cardiac signal associated with the atrial contraction of the patient's heart via an electrode arrangement;
determining an atrial contraction timing fiducial based at least in part on the sensed mechanical response to the atrial contraction and the sensed electrical cardiac signal associated with the atrial contraction; and
generating the ventricle pacing pulse after an A-V delay following the atrial contraction timing fiducial.
2. The method of claim 1, wherein the mechanical response to the atrial contraction of the patient's heart is sensed via an accelerometer of a Leadless Cardiac Pacemaker (LCP) and/or an accelerometer of a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD).
3. The method of any one of claims 1 or 2, wherein the electrical cardiac signal associated with the atrial contraction of the patient's heart is sensed via an electrode arrangement of a Leadless Cardiac Pacemaker (LCP) and/or an electrode arrangement of a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD).
4. The method of any one of claims 1 to 3, further comprising:
weighting a timing associated with the sensed mechanical response to the atrial contraction with a first weight;
weighting a timing associated with the sensed electrical cardiac signal associated with the atrial contraction with a second weight; and
determining the atrial contraction timing fiducial based at least in part on the weighted timing associated with the sensed mechanical response and the weighted timing associated with the sensed electrical cardiac signal.

5. The method of any one of claims 1 to 4, wherein the sensed mechanical response to the atrial contraction of the patient's heart is used to identify a time window in which an electrical cardiac signal is searched to identify the electrical cardiac signal associated with a subsequent atrial contraction.

6. The method of claim 5, wherein the sensed mechanical response includes the S3 and the S4 heart sounds, the time window is between the S3 to S4 heart sounds, and the electrical cardiac signal associated with the atrial contraction is a p-wave of an electrocardiogram signal.

7. The method of any one of claims 1 to 6, wherein:
the sensed mechanical response to the atrial contraction of the patient's heart has a signal-to-noise ratio (SNR);

the sensed electrical cardiac signal associated with the atrial contraction has a signal-to-noise ratio (SNR);

wherein if the signal-to-noise ratio (SNR) of the sensed mechanical response to the atrial contraction of the patient's heart is above a SNR threshold, the atrial contraction timing fiducial is based on the mechanical response to the atrial contraction of the patient's heart; and

wherein if the signal-to-noise ratio (SNR) of the sensed mechanical response to the atrial contraction of the patient's heart is below the SNR threshold, the atrial contraction timing fiducial is based on the electrical cardiac signal associated with the atrial contraction of the patient's heart.

8. The method of any one of claims 1 to 7, wherein the electrode arrangement is configured to provide two or more sense vectors for sensing the electrical cardiac signal associated with the atrial contraction of the patient's heart, the method comprising:

sensing for the electrical cardiac signals associated with one or more atrial contractions of the patient's heart using a first sense vector of the two or more sense vectors of the electrode arrangement;

sensing for the electrical cardiac signals associated with one or more atrial contractions of the patient's heart using a second sense vector of the two or more sense vectors of the electrode arrangement;

determining which of the first sense vector and the second sense vector produces the higher signal-to-noise ratio (SNR) for the electrical cardiac signal associated with the one or more atrial contractions of the patient's heart; and

using the sense vector determined to produce the higher signal-to-noise ratio (SNR) when sensing electrical cardiac signal associated with subsequent atrial contractions of the patient's heart.

9. The method of any one of claims 1 to 7, wherein the electrode arrangement is configured to provide two or more sense vectors for sensing the electrical cardiac signal associated with the atrial contraction of the patient's heart, the method comprising:

sensing for the electrical cardiac signal associated with the atrial contraction of the patient's heart using each of two or more sense vectors of the two or more sense vectors of the electrode arrangement;

determining a composite sense vector of the two or more sense vectors that increases the signal-to-noise ratio (SNR) relative to a SNR achievable by any one of the individual sense vectors; and

using the composite sense vector when sensing for electrical cardiac signals associated with subsequent atrial contractions of the patient's heart.

10. A leadless cardiac pacemaker (LCP) configured to sense cardiac activity and to pace a patient's heart, the LCP disposable within a ventricle of the patient's heart, the LCP comprising:

a housing;

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

a second electrode secured relative to the housing and exposed to the environment outside of the housing, the second electrode spaced from the first electrode;

a controller disposed within the housing and operably coupled to the first electrode and the second electrode such that the controller is capable of receiving, via the first electrode and the second electrode, electrical signals including an electrical indication of atrial contraction;

an accelerometer disposed within the housing and operably coupled to the controller;

the controller is configured to detect, via a signal from the accelerometer, a mechanical indication of atrial contraction;

the controller further configured to determine an atrial contraction timing fiducial based at least in part on the mechanical indication of atrial contraction and/or the electrical indication of atrial contraction; and

the controller further configured to generate a ventricle pacing pulse after an A-V delay following the atrial contraction timing fiducial.

11. The LCP of claim 10, wherein the electrical indication of atrial contraction comprises a p-wave of an electrocardiogram and optionally the mechanical indication of atrial contraction comprises an S4 heart sound.

12. The LCP of any one of claims 10 or 11, wherein the electrical indication of atrial contraction is received from a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD).

13. The LCP of any one of claims 10 to 12, wherein the controller is configured to preferentially use the electrical indication of atrial contraction or the mechanical indication of atrial contraction based at least in part upon a signal-to-noise ratio (SNR) associated with each.

14. A system for generating a ventricle pacing pulse, comprising:
a Subcutaneous Implantable Cardioverter Defibrillator (SICD);
a leadless cardiac pacemaker (LCP) in operative communication with the SICD;
wherein:
at least one of the SICD and LCP senses for a mechanical response to an atrial contraction of a patient's heart;
at least one of the SICD and LCP senses for an electrical cardiac signal associated with the atrial contraction of the patient's heart;
storing an atrial contraction timing fiducial in the LCP, the atrial contraction timing fiducial based at least in part on the sensed mechanical response to the atrial contraction and the sensed electrical cardiac signal associated with the atrial contraction; and

the LCP generating a ventricle pacing pulse after an A-V delay following the atrial contraction timing fiducial.

15. The system of claim 14, wherein the mechanical response to the atrial contraction of the patient's heart is sensed via an accelerometer of the LCP and/or an accelerometer of the SICD and optionally the electrical cardiac signal associated with the atrial contraction of the patient's heart is sensed via an electrode arrangement of the LCP and/or an electrode arrangement of the SICD.

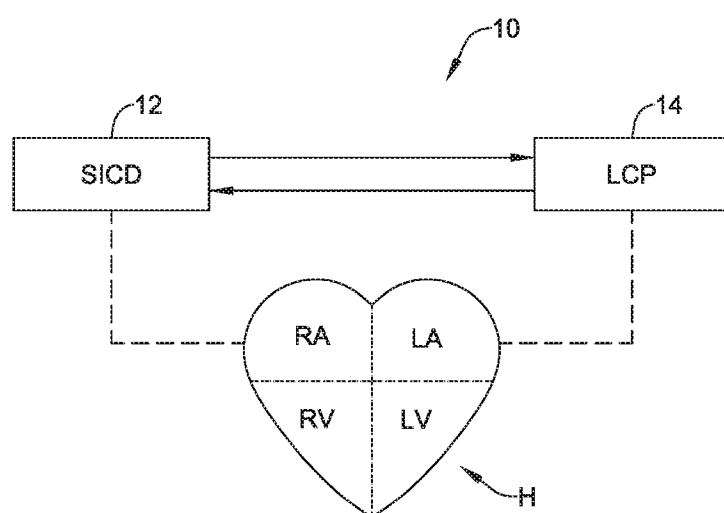


FIG. 1

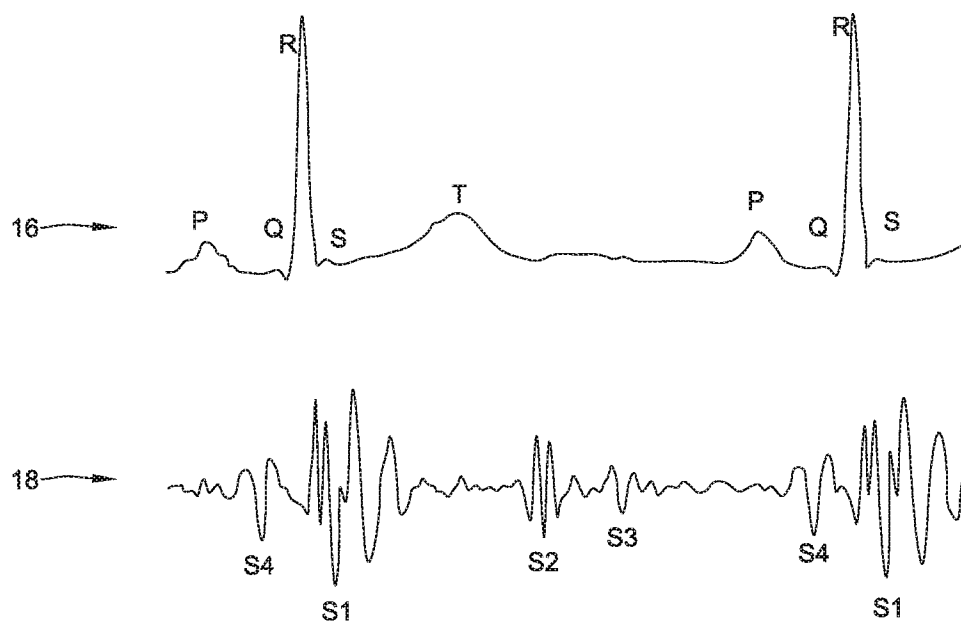


FIG. 2

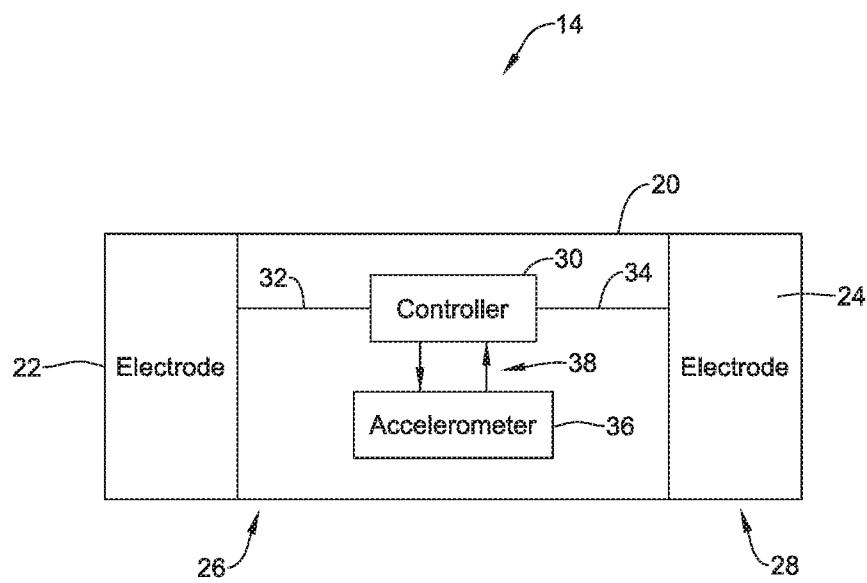


FIG. 3

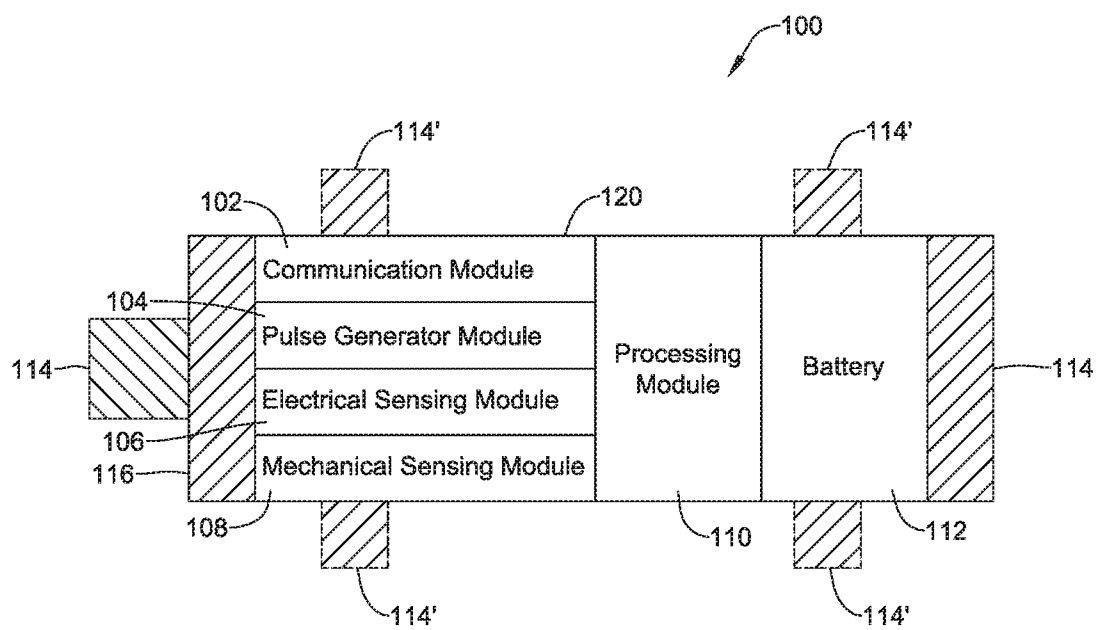


FIG. 4

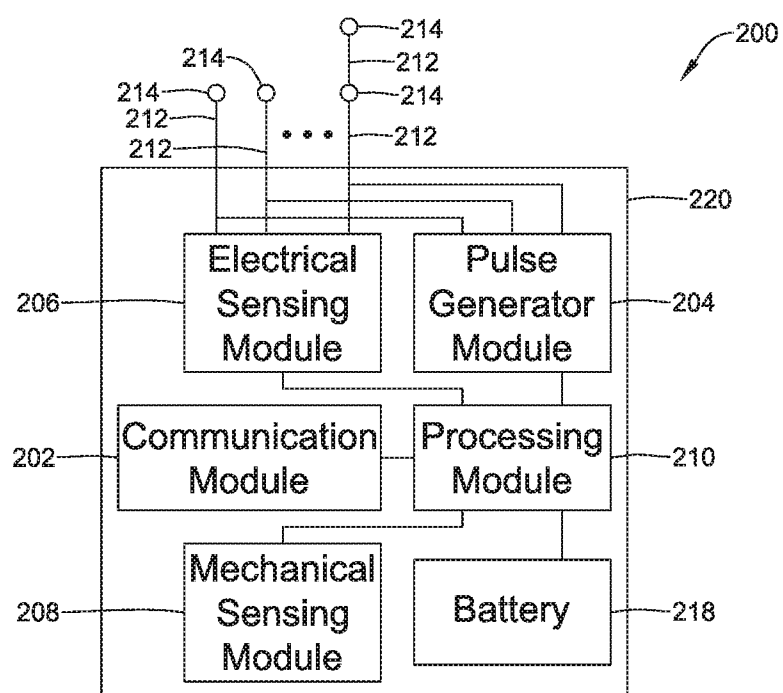


FIG. 5

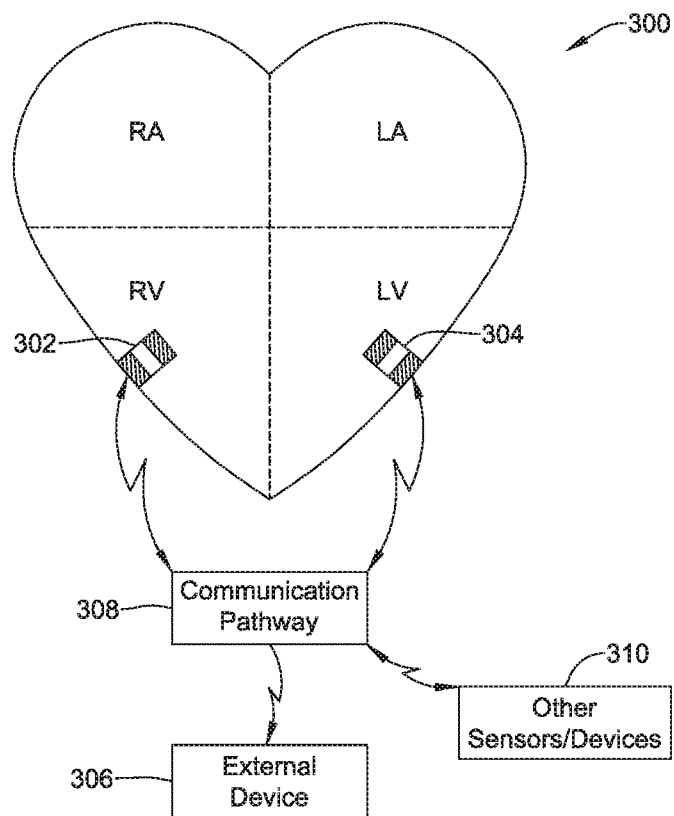


FIG. 6

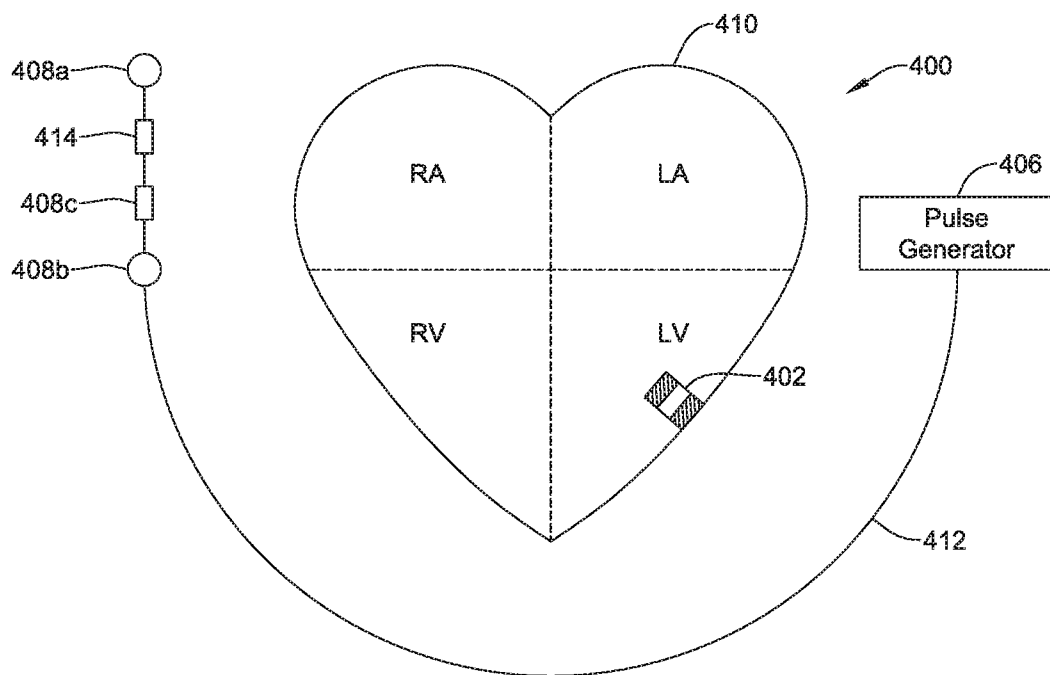


FIG. 7

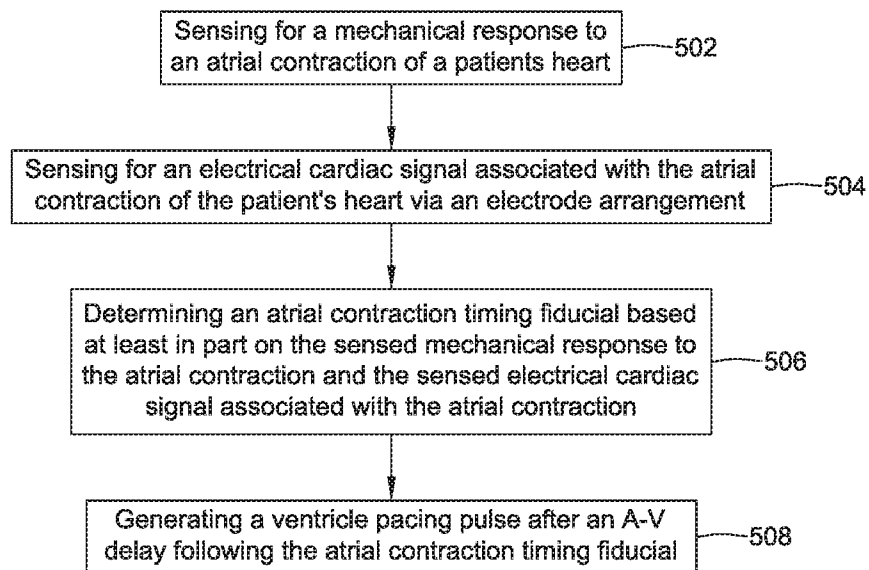


FIG. 8

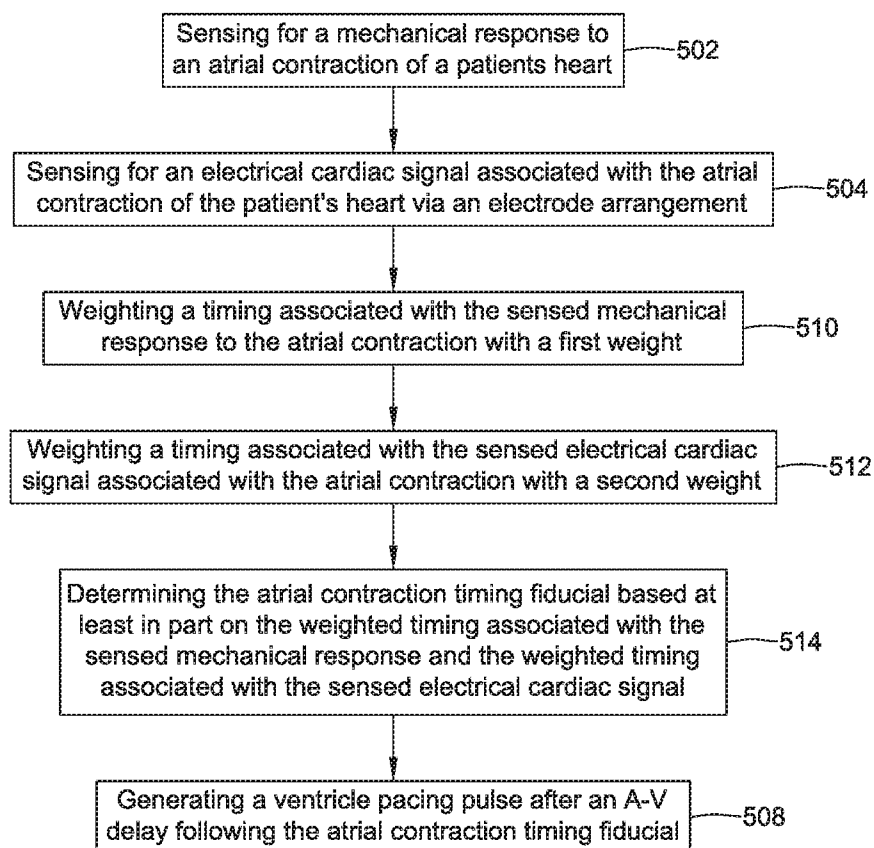


FIG. 9

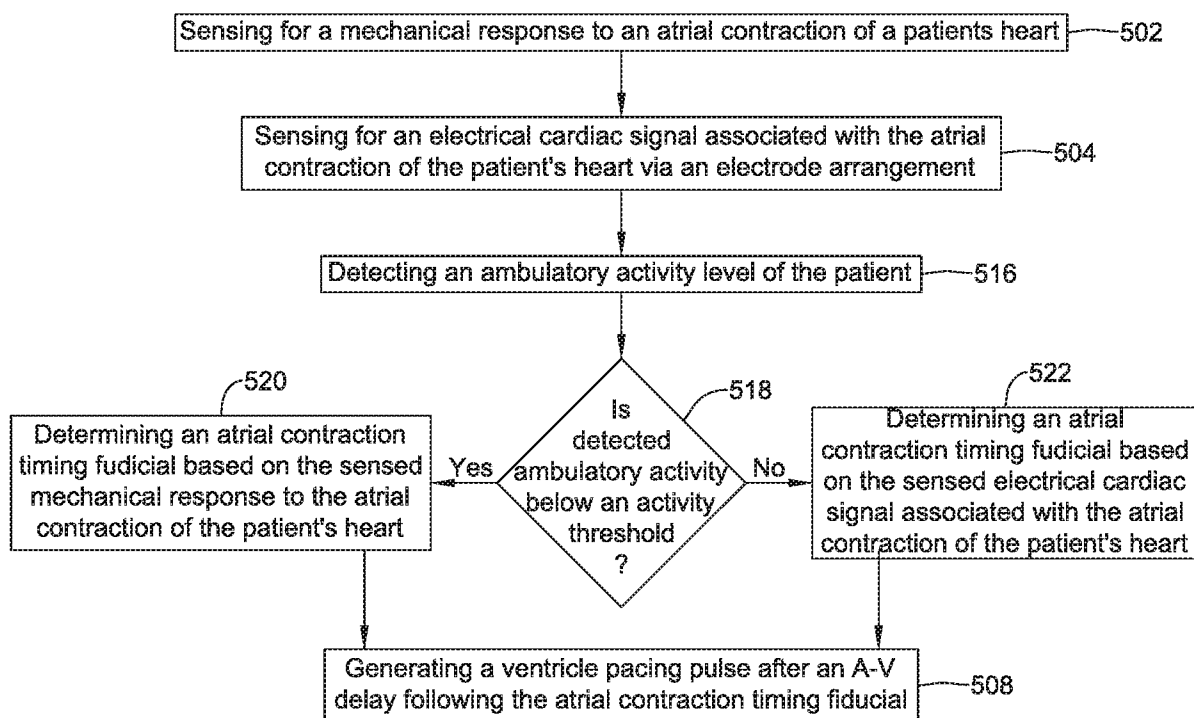


FIG. 10

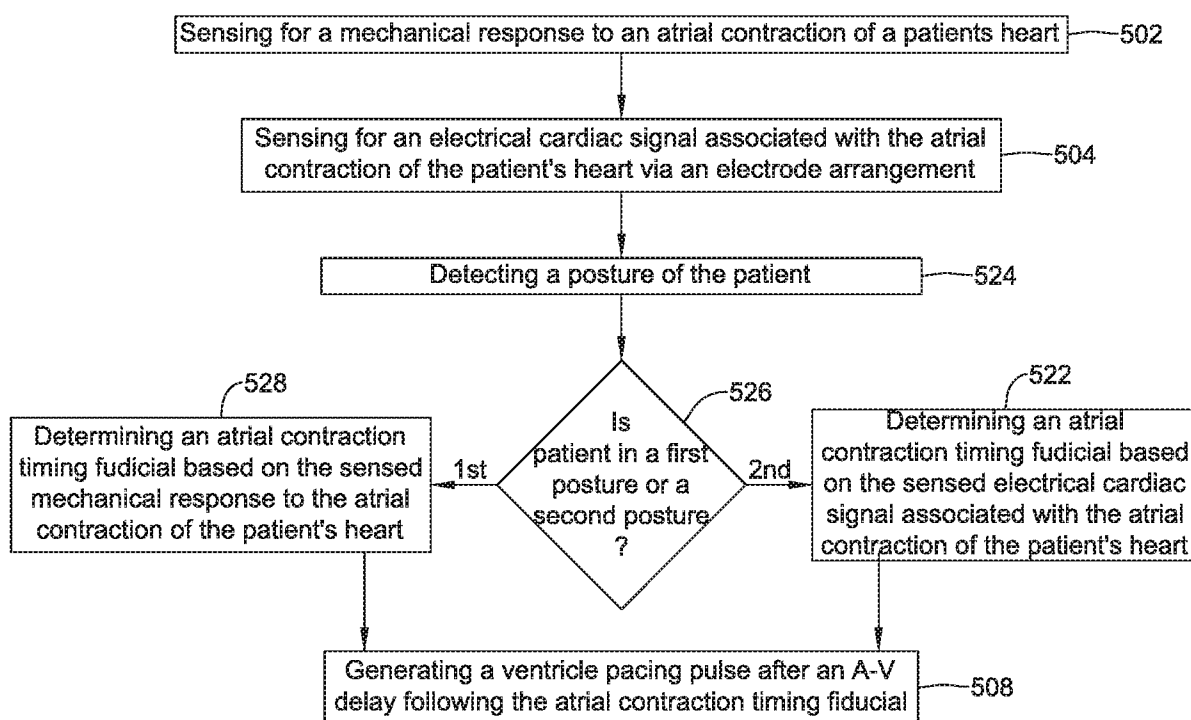


FIG. 11

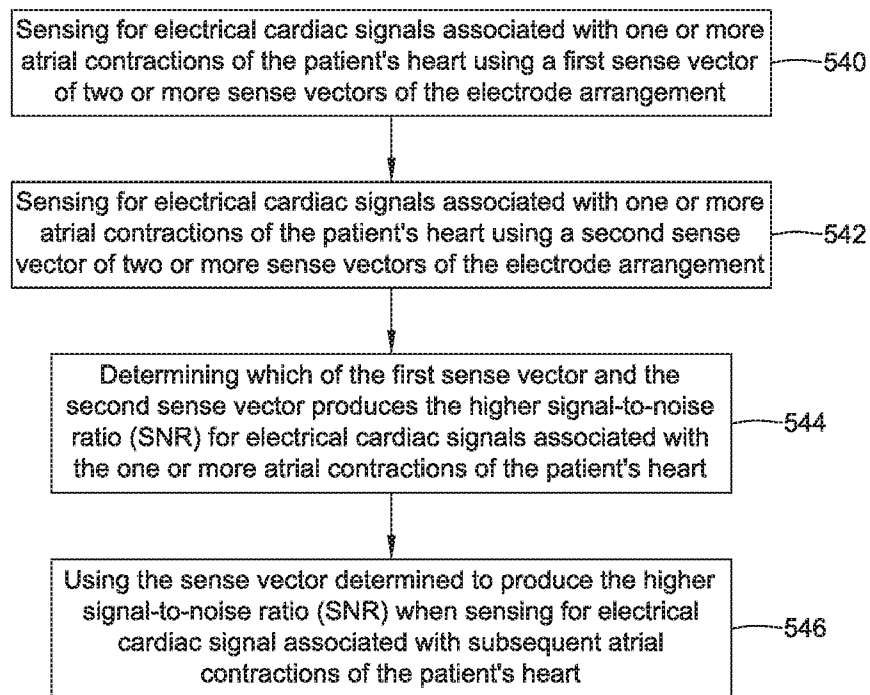


FIG. 12

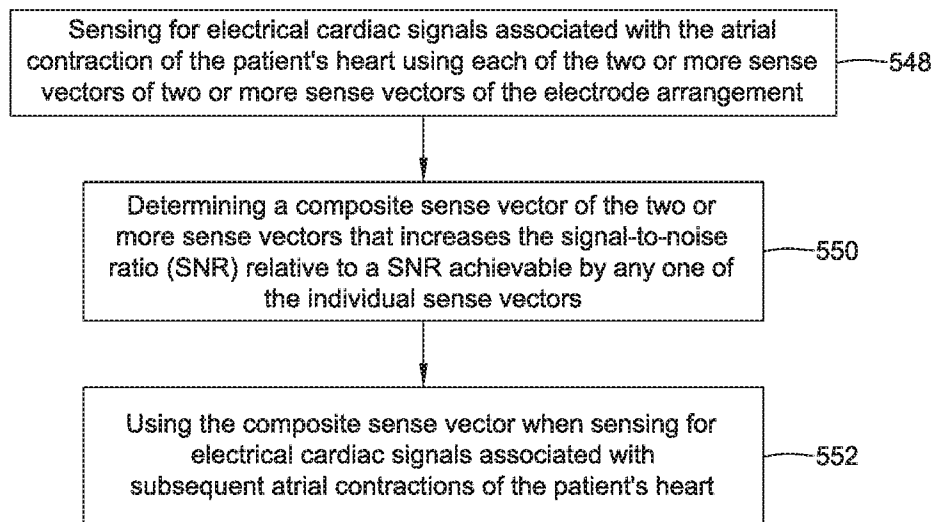


FIG. 13

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/040754

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61N1/372 A61N1/375 A61N1/39
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)

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)

EP0-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 2016/023000 A1 (CHO YONG K [US] ET AL) 28 January 2016 (2016-01-28)	10,11,13
Y	the whole document	12
A	-----	14,15
X	US 2015/142069 A1 (SAMBELASHVILI ALEKSANDRE T [US]) 21 May 2015 (2015-05-21)	14,15
Y	the whole document	12
A	-----	10-15
	US 2013/079861 A1 (REINERT MICHAEL A [US] ET AL) 28 March 2013 (2013-03-28) the whole document	

☐

Further documents are listed in the continuation of Box C.

☒

See patent family annex.

* Special categories of cited documents :

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

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

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

5 September 2017

Date of mailing of the international search report

12/09/2017

Name and mailing address of the ISA/

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Authorized officer

Schöffmann

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/040754

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-9
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2017/040754

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			EP	2760541 A1	06-08-2014
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			WO	2013049265 A1	04-04-2013
