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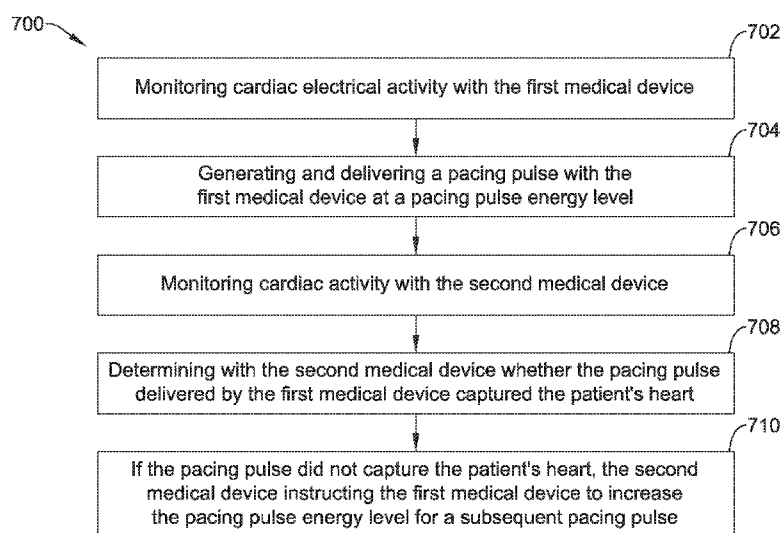


FIG. 12

(57) Abstract: A medical system may include a first medical device such as a leadless cardiac pacemaker (LCP) that is configured to pace a patient's heart and a second medical device that is configured to have a capture threshold capability. The second medical device may monitor the patient's heart to ascertain whether the pacing pulses from the first medical device are capturing the heart, and to send the first medical device instructions to alter an energy level of subsequent pacing pulses.

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USE OF A SEPARATE DEVICE IN MANAGING THE PACE PULSE ENERGY OF A CARDIAC PACEMAKER

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application Serial No. 62/413,702 filed on October 27, 2016, the disclosure of which is incorporated herein by reference.

TECHNICAL FIELD

[0002] The present disclosure generally relates to cardiac pacemakers, and more particularly, to managing the pace pulse energy of such cardiac pacemakers

BACKGROUND

[0003] Implantable medical devices are commonly used today to monitor and/or delivery therapy to a patient, including cardiac simulation therapy. Many patients suffer from heart conditions that can result in a reduced ability of the heart to deliver sufficient amounts of blood to the patient's body. Such heart conditions may lead to slow, rapid, irregular, and/or inefficient heart contractions. To help alleviate some of these conditions, various medical devices (e.g., pacemakers, defibrillators, etc.) are often implanted in a patient's body. Such devices may monitor and in some cases provide electrical stimulation (e.g. pacing, defibrillation, etc.) to the heart to help the heart operate in a more normal, efficient and/or safe manner. To extend the effective lifetime of such implanted devices, there is a desire to conserve energy while still providing effective therapy to the patient.

SUMMARY

[0004] The present disclosure generally relates to cardiac pacemakers, and more particularly, to managing the pace pulse energy of such cardiac pacemakers. In one example, a first medical device, such as a leadless cardiac pacemaker (LCP), may be configured to pace a patient's heart. A separate second medical device may be configured to have a capture threshold capability. The second medical device may monitor the patient's heart to ascertain whether the pacing pulses delivered by the first medical device are capturing the heart or not. The second medical device may be configured to help manage the pace pulse energy delivered by the first medical device

by, for example, sending instructions to the first medical device to alter the energy level of one or more subsequent pacing pulses. In some cases, the second medical device may be configured to send an instruction to increase the energy level of one or more subsequent pacing pulses when the second medical device determines that the pacing pulses delivered by the first medical device are not capturing the heart. In some cases, and if the pacing pulses are capturing the heart, the second medical device may be configured to send one or more instructions to sequentially decrease the energy level of one or more subsequent pacing pulses until the pacing pulses no longer capture the heart. The pacing energy may then be increased by a safety margin. This may be useful to help determine the current capture threshold of the heart.

[0005] In another example of the disclosure, a leadless cardiac pacemaker (LCP) may be configured to pace a patient's heart and to be disposable within a chamber of the patient's heart. The LCP may include a housing and a pair of pacing electrodes that are secured relative to the housing. A controller may be disposed within the housing and may be operably coupled to the pair of pacing electrodes. The controller may be configured to generate and deliver a plurality of pacing pulses via the pair of pacing electrodes, where each of the plurality of pacing pulses has a controllable pacing energy level. A communications module may be operably coupled to the controller and may be configured to receive a pacing energy signal from a second implantable medical device that results from an automatic capture threshold capability of the second implantable medical device. In some cases, the pacing energy signal may cause the controller of the LCP to change the pacing energy level of one or more subsequent pacing pulses of the plurality of pacing pulses.

[0006] Alternatively or additionally to any of the embodiments above, the controller may be free of a capture verification capability.

[0007] Alternatively or additionally to any of the embodiments above, the controller may be configured to change the pacing energy level by adjusting a voltage of one or more of the subsequent pacing pulses.

[0008] Alternatively or additionally to any of the embodiments above, the controller may be configured to change the pacing energy level by adjusting a pulse width of one or more of the subsequent pacing pulses.

[0009] Alternatively or additionally to any of the embodiments above, the pacing energy signal may cause the controller to increase the pacing energy level of one or more subsequent pacing pulses of the plurality of pacing pulses.

[0010] Alternatively or additionally to any of the embodiments above, the pacing energy signal may cause the controller to incrementally increase the pacing energy level of two or more subsequent pacing pulses of the plurality of pacing pulses until the communications module receives another signal from the second implantable medical device indicating that the pacing pulses are now capturing the patient's heart.

[0011] Alternatively or additionally to any of the embodiments above, the pacing energy signal may cause the controller to decrease the pacing energy level of one or more subsequent pacing pulses of the plurality of pacing pulses.

[0012] Alternatively or additionally to any of the embodiments above, the pacing energy signal may cause the controller to incrementally decrease the pacing energy level of two or more subsequent pacing pulses of the plurality of pacing pulses until the communications module receives another signal from the second implantable medical device indicating that the pacing pulses are no longer capturing the patient's heart.

[0013] Alternatively or additionally to any of the embodiments above, the controller may be configured to include a safety mode in which the controller generates and delivers pacing pulses at a predetermined energy level when the communications module is not able to receive signals from the second implantable medical device.

[0014] Alternatively or additionally to any of the embodiments above, the controller may be configured to determine when and whether to generate and deliver a pacing pulse based upon electrical cardiac signals received by the LCP.

[0015] In another example of the disclosure, a medical system for sensing and regulating cardiac activity of a patient may include a leadless cardiac pacemaker (LCP) that is configured to pace a patient's heart and to be disposable within a chamber of the patient's heart and a second medical device having an automatic capture threshold capability. The LCP may include a housing and a pair of pacing electrodes secured relative to the housing. A controller may be disposed within the housing and may be operably coupled to the pair of pacing electrodes, the controller may be configured to generate and deliver a plurality of pacing pulses to the heart via the pair of pacing electrodes, each of the plurality of pacing pulses having a controllable pacing

energy level. A communications module may be operably coupled to the controller. In the second medical device, the automatic capture threshold capability may be configured to determine whether pacing pulses generated and delivered by the LCP are capturing the heart, and to selectively generate a pacing energy signal to control the pacing energy level of one or more subsequent pacing pulses generated and delivered by the LCP. The communications module of the LCP may be configured to receive the pacing energy signal from the second medical device, and in response, the controller of the LCP may be configured to change the pacing energy level of one or more subsequent pacing pulses of the plurality of pacing pulses.

[00016] Alternatively or additionally to any of the embodiments above, the second medical device may be implantable.

[00017] Alternatively or additionally to any of the embodiments above, the second medical device may include an implantable cardioverter configured to generate and deliver shocks to the patient's heart.

[00018] Alternatively or additionally to any of the embodiments above, the pacing energy signal may cause the controller of the LCP to increase the pacing energy level of one or more subsequent pacing pulses of the plurality of pacing pulses.

[00019] Alternatively or additionally to any of the embodiments above, the pacing energy signal may cause the controller of the LCP to incrementally increase the pacing energy level of two or more subsequent pacing pulses of the plurality of pacing pulses until the communications module receives another signal from the second medical device indicating that the pacing pulses are now capturing the patient's heart.

[00020] Alternatively or additionally to any of the embodiments above, the pacing energy signal may cause the controller of the LCP to decrease the pacing energy level of one or more subsequent pacing pulses of the plurality of pacing pulses.

[00021] Alternatively or additionally to any of the embodiments above, the pacing energy signal may cause the controller of the LCP to incrementally decrease the pacing energy level of two or more subsequent pacing pulses of the plurality of pacing pulses until the communications module receives another signal from the second medical device indicating that the pacing pulses are no longer capturing the patient's heart.

[00022] In another example of the disclosure, a method of sensing and regulating cardiac activity of a patient's heart may use a first medical device that is configured to sense cardiac

electrical activity and generate and deliver pacing pulses accordingly and a second medical device that is configured to sense cardiac electrical activity and generate and deliver shocks to cardiac tissue. In some cases, cardiac electrical activity may be monitored with the first medical device. A pacing pulse may be generated and delivered with the first medical device at a pacing pulse energy level. Cardiac activity may be monitored with the second medical device and the second medical device may determine whether the pacing pulse delivered by the first medical device captured the patient's heart. If the pacing pulse did not capture the patient's heart, the second medical device may instruct the first medical device to increase the pacing pulse energy level for a subsequent pacing pulse.

[00023] Alternatively or additionally to any of the embodiments above, the method may further include, if the pacing pulse did capture the patient's heart, the second medical device instructing the first medical device to decrease the pacing pulse energy level for a subsequent pacing pulse. The first medical device may generate and deliver the subsequent pacing pulse at the decreased pacing pulse energy level and the second medical device may monitor cardiac activity to determine if the subsequent pacing pulse captured the patient's heart.

[00024] Alternatively or additionally to any of the embodiments above, the method may further include if the pacing pulse did capture the patient's heart, the second medical device continuing to instruct the first medical device to decrease the pacing pulse energy level for a subsequent pacing pulse and determining if the subsequent pacing pulse captured the patient's heart until the second medical device indicates that the subsequent pacing pulse did not capture the patient's heart.

[00025] 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

[00026] 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:

[00027] Figure 1 is a highly schematic diagram of an illustrative system in accordance with an example of the disclosure;

[00028] Figure 2 is a high schematic diagram of an illustrative system in accordance with an example of the disclosure;

[00029] Figure 3 is a schematic block diagram of an illustrative leadless cardiac pacemaker (LCP) useable in the system of Figure 2;

[00030] Figure 4 is a schematic block diagram of an illustrative subcutaneous implantable cardioverter defibrillator (SICD) usable in the system of Figure 2;

[00031] Figure 5 is a schematic diagram illustrating a relationship between pacing energy level and cardiac capture status;

[00032] Figure 6 is a schematic diagram illustrating a relationship between pacing energy level and cardiac capture status;

[00033] Figure 7 is a more detailed schematic block diagram of an illustrative LCP in accordance with an example of the disclosure;

[00034] Figure 8 is a schematic block diagram of another illustrative medical device that may be used in conjunction with the LCP of Figure 7;

[00035] Figure 9 is a schematic diagram of an exemplary medical system that includes multiple LCPs and/or other devices in communication with one another;

[00036] Figure 10 is a schematic diagram of a system including an LCP and another medical device, in accordance with an example of the disclosure;

[00037] Figure 11 is a side view of an illustrative implantable leadless cardiac device;

[00038] Figure 12 is a flow diagram of an illustrative method for regulating a patient's heart using the system of Figure 1;

[00039] Figure 13 is a flow diagram of an illustrative method for regulating a patient's heart using the system of Figure 1; and

[00040] Figure 14 is a flow diagram of an illustrative method for regulating a patient's heart using the system of Figure 1.

[00041] 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

[00042] 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.

[00043] 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).

[00044] 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.

[00045] 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.

[00046] 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.

[00047] 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 RV. The heart H also includes a left atrium LA and a left ventricle LV. In some cases, the system 10 may include a medical device that provides anti-arrhythmic therapy to the heart H. In some cases, the system 10 may include a first medical device 12 and a second medical device 14. In some instances, the first medical device 12 may be implantable within the patient at a position near or even within the heart H. In some cases, the second medical device 14 may be exterior to the patient. In some cases, the second medical device 14 may be implanted within the patient but at a location that is exterior to the heart H. For example, in some cases, the second medical device 14 may be implanted at a subcutaneous position within the patient's chest.

[00048] In some cases, the first medical device 12 may be configured to sense electrical cardiac activity of the heart H and to provide pacing pulses to the heart H. In some cases, the first medical device 12 may have more than one potential pacing vector available to the first medical device 12, and the second medical device 14 may be able to determine which of several different pacing vectors are most efficient. It will be appreciated that the energy level necessary for a pacing pulse to capture the heart H may vary from patient to patient or, for a particular patient, may vary as a function of time. In some cases, the energy level necessary for a pacing pulse to capture the heart H may also vary depending on the exact location of the first medical device 12 relative to conduction pathways within the heart H, for example. Rather than always pacing at a predetermined pacing energy, which may cause the first medical device 12 to expend unnecessary energy if the pacing energy is well above the capture threshold H or fail to capture the heart H if the pacing energy is below the capture threshold of the heart H, the first medical device 12 may instead be configured to generate and deliver pacing pulses at a controllable energy level. In some cases, the pacing energy may be increased by increasing the voltage of the pacing pulse and/or increasing the pulse width of the pacing pulse. In some instances, the pacing

energy may be decreased by decreasing the voltage of the pacing pulse and/or decreasing the pulse width of the pacing pulse.

[00049] In some cases, the second medical device 14 may be configured to monitor electrical cardiac activity of the heart H, or other indications of cardiac activity, to determine whether the pacing pulses generated and delivered by the first medical device 12 are capturing the heart H. In some cases, the second medical device 14 may use motion and/or acoustic data from an accelerometer in order to differentiate capture from non-capture. Capturing the heart may be defined as one or more desired chambers of the heart H contracting in response to the pacing pulse. In some cases, the second medical device 14 may send a signal to the first medical device 12 informing the first medical device 12 that a particular pacing pulse did not capture the heart H. In response, the first medical device 12 may increase a pacing energy of one or more subsequent pacing pulses. In some cases, the first medical device 12 may not include capture verification capability but instead may rely on the second medical device 14 to perform that function. In some cases, the second medical device 14 may include capture verification capability that may be used by the second medical device 14 to verify whether the pacing pulses generated and delivered by the first medical device 12 are capturing the heart H.

[00050] In some cases, for example, the second medical device 14 may perform periodic capture threshold tests in order to minimize pacing energy. Periodic capture threshold tests may occur after every ten heart beats, or every twenty heart beats, or any other appropriate interval. In some cases, the second medical device 14 may manage pace energy on a beat to beat basis. It may be acceptable to reduce pace energy until capture is lost, then upon loss of capture, increase pace energy for the next beat, and repeat. Settings which result in capture may be used for some pre-determined number of cycles before attempting to reduce energy again, increasing the % of beats at “known good” capture settings.

[00051] In some cases, the second medical device 14, instead of informing the first medical device 12 that a particular pacing pulse did not capture the heart H, may instead instruct the first medical device 12 to change the pacing energy of one or more subsequent pacing pulses. In other words, in some cases, the first medical device 12, upon being informed that a pacing pulse did not capture the heart H, may itself determine an appropriate pacing energy for subsequent pacing pulses. In some cases, the second medical device 14 may determine an appropriate pacing energy for subsequent pacing pulses and may instruct the first medical device 12 to pace

at this appropriate pacing energy. In some cases, the second medical device 14 may use advanced understanding of the design of the first medical device 12 to optimize pace settings. For example, the first medical device 12 may have a power supply architecture with greater efficiency at a given voltage. In some cases, the second medical device 14 may, for example, target certain pace voltage and/or pulse width settings in order minimize pacing energy consumption.

[00052] By off-loading some or all of the capture verification capability from the first medical device 12 to the second medical device 14, the first medical device 12 may be configured to have less processing power, have a smaller form factor, and/or consume less energy. In some instances, for example, the first medical device 12 may not be configured to sense cardiac electrical activity and to generate and deliver pacing pulses accordingly, but rather may be configured to just generate and deliver a pacing pulse when instructed to do so by another device such as but not limited to the second medical device 14.

[00053] In some cases, for example, the second medical device 14 may be configured to maintain and/or trend pace settings and capture data for the first medical device 12 for the purposes of long-term optimization of pace settings. In some cases, the second medical device 14 may utilize additional inputs, such as posture, time of day, intrinsic rate, and the like, as inputs to a capture algorithm. For example, the second medical device 14 may be able to correlate changes in pace threshold resulting from the other inputs, and proactively adjust pace settings. In some cases, the second medical device 14 may be utilized to optimize the AV delay utilized by the first medical device 12. For example, the second medical device 14 may be able to monitor ECG morphology and/or acceleration data, such as RV or LV pace timing.

[00054] In some cases, if the second medical device 14 is implanted prior to implanting the first medical device 12, the second medical device 14 may be used to guide optimal placement of the first medical device 12, for example, by monitoring the QRS width, morphology, HRV, accelerometer signals, etc. In some cases, the second medical device 14 could provide feedback of the attempted first medical device 12's location prior to fixation or untethering of the first medical device 12. Minimizing QRS width, HRV and certain morphological parameters would be a possible goal of the clinician to obtain such an optimal site, for example. In some cases, the second medical device 14 may also be able to monitor the impedance and or heart sounds to possibly detect myocardial functional improvements as indicated by hypertrophy, or dilated

cardiomyopathy. For example, these diseases generally have increased left ventricles, thus possibly lower impedance and/or contraction changes which could be detected with wall motion during capture or loss of it.

[00055] It will be appreciated that in some cases, the first medical device 12 may have a fail-safe mode in which the first medical device 12 generates and delivers pacing pulses at a predetermined pacing voltage and pacing pulse width in the absence of communications from the second medical device 14 informing the first medical device 12 as to whether the pacing pulses generated and delivered by the first medical device 12 are capturing the heart H. In some cases, the pacing voltage and/or pulse width utilized in the fail-safe mode may be factory-set. In some cases, the pacing voltage and/or pulse width utilized in the fail-safe mode may be programmable by a physician, for example. The pacing voltage and pulse width combination utilized in the fail-safe mode may be well above the capture threshold of the heart.

[00056] Figure 2 is a schematic diagram showing an illustrative system 16 that may be used to sense and/or pace a heart H. In some cases, the system 16 may be considered as being an example of the system 10 shown in Figure 1. In some cases, the system 16 may include a leadless cardiac pacemaker (LCP) 18 and a subcutaneous implantable cardioverter defibrillator (SICD) 20. Accordingly, in some cases the LCP 18 may be considered as being an illustrative but non-limiting example of the first medical device 12 and the SICD 20 may be considered as being an illustrative but non-limiting example of the second medical device 14 described with respect to Figure 1.

[00057] In some cases, the LCP 18 may be intracardially implanted. While a single LCP 18 is illustrated, it will be appreciated that two or more LCPs 18 may be implanted in or on the heart H. The LCP 18 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.

[00058] In some cases, the SICD 12 may be extracardially implanted. While not shown in this Figure, in some cases the SICD 20 may include a lead/electrode that may be configured to be placed subcutaneously and outside of a patient's sternum. In other cases, the lead/electrode may extend around or through the sternum and may be fixed adjacent an inner surface of the sternum. In both cases, the lead/electrode is positioned extracardially (outside of the patient's heart). The

SICD 20 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.

[00059] In some cases, the LCP 18 and the SICD 20 may be implanted at the same time. In some instances, depending on the cardiac deficiencies of a particular patient, the SICD 20 may be implanted first, and one or more LCPs 18 may be implanted at a later date if/when the patient develops indications for receiving cardiac resynchronization therapy and/or it becomes necessary to pace the heart H. In some cases, it is contemplated that one or more LCPs 18 may be implanted first, in order to sense and pace the heart H. When a need for possible defibrillation becomes evident, the SICD 20 may subsequently be implanted. Regardless of implantation order or sequence, it will be appreciated that the LCP 18 and the SICD 20 may communicate with each other using any desired communications modality, such as conducted communication, inductive communication, acoustic communication, RF communication, optical communication and/or using any other suitable communication modality.

[00060] Figure 3 is a schematic diagram of an illustrative leadless cardiac pacemaker (LCP) 18. In some cases, the LCP 18 includes a housing 22 and a pair of electrodes 24, 26 that are secured relative to the housing 22. While two electrodes 24, 26 are illustrated, it will be appreciated that in some cases the LCP 18 may include three or more electrodes. A controller 28 is disposed within the housing 22 and may be operably coupled to the pair of electrodes 24, 26 via electrical connectors 25 and 27, respectively. A power supply 30 is operably coupled to the controller 28 and provides power for operation of the controller 28 as well as providing power for generating pacing pulses that can be delivered via the pair of electrodes 24, 26. In some cases, the controller 28 may be considered as being configured to generate and deliver a plurality of pacing pulses via the pair of electrodes 24, 26. In some cases, at least some of the plurality of pacing pulses have a controllable pacing energy level. In some cases, each of the plurality of pacing pulses have a controllable pacing energy that can be altered, for example, by altering the pacing voltage and/or the pacing pulse width. The controller 28 may control the pacing voltage and/or the pacing pulse width.

[00061] In some cases, the LCP 18 may include a communications module 32 that is operably coupled to the controller 28. The communications module 32 may be configured to receive a pacing energy signal from a second implantable medical device such as but not limited to the

second medical device 14 (Figure 1) or the SICD 20 (Figure 2). The pacing energy signal received by the communications module 32 may, for example, result from an automatic capture threshold capability of the second implantable medical device 14. In some cases, the pacing energy signal causes the controller 28 of the LCP 18 to change the pacing energy level of one or more subsequent pacing pulses of the plurality of pacing pulses. In some cases, the pacing energy signal may merely indicate that the previous pace pulse did not capture the heart H, and the controller 28 determines the pacing energy level of the one or more subsequent pacing pulses. In other cases, the pacing energy signal may encode an energy level calculated by the second implantable medical device 14 for one or more subsequent pacing pulses, and the controller 28 of the LCP 18 may provide one or more pacing pulses with the encoded energy level. In yet other cases, the pacing energy signal may include an instruction or command that commands the LCP 18 to change the pacing energy level (e.g. pacing voltage, pacing pulse width, or both) to a commanded energy level. In some cases, the command may provide a particular pacing voltage, pulse width or both, or may instruct the LCP 18 to increment the pacing energy by an offset amount. These are just examples. It is contemplated that the pacing energy signal may take on any form that is suitable for causing the LCP 18 to change the pacing energy level in a desired manner.

[00062] In some cases, the controller 28 of the LCP 18 may not include any capture verification capability itself and thus may rely upon the second implantable medical device to provide this capability. In some cases, the controller 28 may be configured to change the pacing energy level by adjusting a voltage of one or more of the subsequent pacing pulses after receiving the pacing energy signal. In some instances, the controller 28 may be configured to change the pacing energy level by adjusting a pulse width of one or more of the subsequent pacing pulses after receiving the pacing energy signal. In some instances, the controller 28 may be configured to change the pacing energy level by adjusting a voltage and pulse width of one or more of the subsequent pacing pulses after receiving the pacing energy signal.

[00063] In some cases, the pacing energy signal received by the communications module 32 may cause the controller 28 to increase the pacing energy level of one or more of the subsequent pacing pulses. In some cases, the pacing energy signal received by the communications module 32 may cause the controller 28 to incrementally increase the pacing energy level of two or more subsequent pacing pulses of the plurality of pacing pulses until the communications module 32

receives another signal from the second implantable medical device indicating that the pacing pulses are now capturing the heart H. In some cases, once the communications module 32 receives the signal indicating capture, the controller 28 may increase the pacing energy level of a subsequent pacing pulse by a safety margin to help ensure capture. Such a routine may be periodically initiated by the second medical device as part of an automatic capture threshold capability of the second medical device.

[00064] In some cases, the pacing energy signal may cause the controller 28 to decrease the pacing energy level of one or more subsequent pacing pulses of the plurality of pacing pulses. In some cases, the pacing energy signal may cause the controller 28 to incrementally decrease the pacing energy level of two or more subsequent pacing pulses of the plurality of pacing pulses until the communications module 32 receives another signal from the second implantable medical device indicating that the pacing pulses are no longer capturing the patient's heart. In some cases, once the communications module 32 receives the signal indicating loss of capture, the controller 28 may increase the pacing energy level of a subsequent pacing pulse by a safety margin to help ensure capture. Such a routine may be periodically initiated by the second medical device as part of an automatic capture threshold capability of the second medical device.

[00065] In some cases, it will be appreciated that there may be gaps in communication between the LCP 18 and the second implantable medical device. These gaps may be short-lived, or may be of longer duration. In some instances, the controller 28 may be configured to include a safety mode in which the controller 28 generates and delivers pacing pulses at a predetermined energy level when the communications module 32 is not able to receive signals from the second implantable medical device. In some cases, the controller 28 may be configured to determine when and whether to generate and deliver a pacing pulse based upon electrical cardiac signals received by the LCP 18. In some cases, LCP 18 may be configured to determine if communications module 32 is able to receive signals by receiving an acknowledge signal in response to a communication transmitted by the LCP 18, by receiving periodic pings transmitted by the second implantable medical device, and/or in any other suitable manner.

[00066] Figure 4 is a schematic illustration of the subcutaneous implantable cardioverter defibrillator (SICD) 20. In some cases, the SICD 20 includes a housing 42 and an electrode support 44 that is operably coupled to the housing 42. In some cases, the electrode support 44 may be configured to place one or more electrodes in a position, such as subcutaneous or sub-

sternal, that enables the one or more electrodes to detect cardiac electrical activity as well as to be able to deliver electrical shocks when appropriate to the heart H. In the example shown, the housing 42 includes a controller 46, a power supply 48 and a communications module 50. As illustrated, the electrode support 44 includes a first electrode 52, a second electrode 54 and a third electrode 56. In some cases, the electrode support 44 may include fewer or more electrodes. In some cases, the SICD 20 may include one or more other sensors such as an accelerometer or a gyro, for example.

[00067] It will be appreciated that the SICD 20 may include additional components which are not illustrated here for simplicity. In the example shown, the power supply 48 is operably coupled to the controller 46 and provides the controller 46 with power to operate the controller 46, to send electrical power to the electrodes on or in the electrode support 44, and to send signals to the communications module 50, as appropriate. In some cases, the controller 46 may be configured to include an automatic capture threshold capability. In some cases, for example, the controller 46 may receive pacing pulses of the LCP 18 (Figure 3) and at least part of an electrocardiogram (ECG) via two or more of the electrodes 52, 54, 56, and may be able to determine from the ECG whether pacing pulses generated and delivered by the LCP 18 are capturing the heart H. In some cases, the controller 46 determines whether the pacing pulses are capturing the heart H, and communicates a simple CAPTURE message or a NOT CAPTURED message to the LCP 18 via the communications module 50. In some cases, the controller 46 determines whether the pacing pulses are capturing the heart H, and communicate a pacing energy level signal to the LCP 18 instructing the LCP 18 to adjust the pacing energy for subsequent pacing pulses. These are just examples.

[00068] Figure 5 shows a graph 60 that illustrates a possible relationship between pacing energy level and cardiac capture status. The graph 60 includes a pacing energy plotline 62 and a capture heart plotline 64. Initially, the pacing energy is at a level denoted by 62a and the capture heart status is NO CAPTURE, as indicated at 64a. As a result, the pacing energy is increased to a level denoted by 62b and the heart capture status is checked again. As can be seen at 64b, the capture heart status is still NO CAPTURE. The pacing energy is increased again to a level denoted by 62c and the heart capture status is checked again. As can be seen at 64c, the capture heart status is now YES. In some cases, as illustrated, the pacing energy remains at the level denoted by 62c. In some cases, while not illustrative, the pacing energy may be increased above

level 62c by a safety margin to help ensure subsequent pacing pulses capture the heart H. In some cases, while not illustrated, the pacing energy may be decreased again after a period of time, to see if capture may be achieved at a lower pacing energy level.

[00069] Figure 6 shows a graph 66 that illustrates a possible relationship between pacing energy level and cardiac capture status. The graph 66 includes a pacing energy plotline 68 and a capture heart plotline 70. Initially, the pacing energy is at a level denoted by 68a and the capture heart status is YES, as indicated at 70a. As a result, the pacing energy may be decreased to a level denoted by 68b, and the capture heart status may be checked again. As can be seen at 70b, the capture heart status remains YES, and so the pacing energy may be decreased to a level denoted by 70c and the capture heart status may be checked again. As can be seen at 70c, the capture heart status remains YES, and so the pacing energy may be decreased to a level denoted by 68d. The capture heart status has now changed to NO CAPTURE, as seen at 70d. As a result, the pacing energy may be increases to a level denoted by 68e and the capture heart status may be checked again. In some cases, the pacing energy level 68e may be equal to the pacing energy level 68c. In some cases, the pacing energy level 68e may represent a smaller change in energy level. In some cases, as illustrated, the pacing energy remains at the level denoted by 68e. In some cases, while not illustrative, the pacing energy may be increased above level 68e by a safety margin to help ensure subsequent pacing pulses capture the heart H. In some cases, while not illustrated, the pacing energy may be decreased again after a period of time, to see if capture may be achieved at a lower pacing energy level.

[00070] Figure 5 and 6 illustrate example routines that might be implemented by an automatic capture threshold capability. In some cases, the first medical device 12 may have an automatic capture threshold capability and may implement one or more of these routines. When so provided, the second medical device 14 may determine if each pacing pulse provided by the first medical device captured the heart H or not, and may communicate that information to the first medical device 12. On some cases, the automatic capture threshold capability may be distributed between the first medical device 12 and the second medical device 14. In yet other cases, the first medical device 12 may not include an automatic capture threshold capability, but rather may rely on an automatic capture threshold capability of the second medical device 14 to provide instructions to the first medical device 12 to set the pacing energy level for subsequent pacing pulses. These are just examples.

[00071] Figure 7 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 7, 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 18 (Figure 1). In the example shown in Figure 7, 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.

[00072] 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 (e.g. SICK and/or programmer) 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.

[00073] In the example shown in Figure 7, 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 and deliver 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 and deliver 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. In some cases, the pulse generator 104 may provide a controllable pulse energy. In some cases, the pulse generator 104 may allow the controller to control the pulse voltage, pulse width, pulse shape or morphology, and/or any other suitable pulse characteristic.

[00074] 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 (e.g. RV, LV), 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.

[00075] 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 chemical 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 7 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.

[00076] 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.

[00077] 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 and deliver 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.

[00078] 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.

[00079] 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.

[00080] 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.

[00081] Figure 8 depicts an example of another or second medical device (MD) 200, which may be used in conjunction with the LCP 100 (Figure 7) in order to detect and/or treat cardiac abnormalities. In some cases, the MD 200 may be considered as an example of the SICD 20 (Figure 2). 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.

[00082] While it is contemplated that the MD 200 may be another leadless device such as shown in Figure 7, 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).

[00083] 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.

[00084] 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.

[00085] 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.

[00086] 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 but outside of the heart H.

[00087] 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.

[00088] Figure 10 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.

[00089] 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 include 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.

[00090] 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-capture 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 (e.g. refractory period) and/or may be incorporated in or modulated onto a pacing pulse, if desired.

[00091] 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.

[00092] Figure 10 shows an illustrative medical device system. In Figure 10, 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.

[00093] In some cases, the LCP 402 may communicate with the subcutaneous implantable cardioverter-defibrillator (S-ICD). In some cases, the lead 412 and/or pulse generator 406 may include an accelerometer 414 that may, for example, be configured to sense vibrations that may be indicative of heart sounds.

[00094] In some cases, the LCP 402 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 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 be implanted in each of the chambers of the heart.

[00095] Figure 11 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 above with respect to the LCP 100 described above. 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).

[00096] 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 connections between the pulse generator and the electrodes 620, 622 may allow electrical stimulation to heart tissue and/or sense a physiological condition.

[00097] 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. 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.

[00098] 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 636 extending from or recessed within the head portion 632. The tether retention structure 636 may define an opening 638 configured to receive a tether or other anchoring mechanism therethrough. While the retention structure 636 is shown as having a generally “U-shaped” configuration, the retention structure 636 may take any shape that provides an enclosed perimeter surrounding the opening 638 such that a tether may be securably and releasably passed (e.g. looped) through the opening 638. In some cases, the retention structure 636 may extend though 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.

[00099] 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 the environment outside the housing 612 to measure blood pressure within the heart. For example, if the LCP 610 is placed in the left ventricle, the pressure sensor(s) 640 may measure the pressure within the left ventricle. If the LCP 610 is placed in another portion of the heart (such as one of the atriums or the right ventricle), the pressures sensor(s) may measure the pressure within that portion of the heart. The pressure sensor(s) 640 may include a MEMS device, such as a MEMS

device with a pressure diaphragm and piezoresistors on the diaphragm, a piezoelectric sensor, a capacitor-Micro-machined Ultrasonic Transducer (cMUT), a condenser, a micro-monometer, or any other suitable sensor adapted for measuring cardiac pressure. 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 readings may be taken in combination with impedance measurements (e.g. the impedance between electrodes 620 and 622) to generate a pressure-impedance loop for one or more cardiac cycles as will be described in more detail below. The impedance may be a surrogate for chamber volume, and thus the pressure-impedance loop may be representative for a pressure-volume loop for the heart H.

[000100] In some embodiments, the LCP 610 may be configured to measure impedance between the electrodes 620, 622. More generally, the impedance may be measured between other electrode pairs, such as the additional electrodes 114' described above. In some cases, the impedance may be measure between two spaced LCP's, such as two LCP's implanted within the same chamber (e.g. LV) of the heart H, or two LCP's implanted in different chambers of the heart H (e.g. RV and LV). The processing module of the LCP 610 and/or external support devices may derive a measure of cardiac volume from intracardiac impedance measurements made between the electrodes 620, 622 (or other electrodes). Primarily due to the difference in the resistivity of blood and the resistivity of the cardiac tissue of the heart H, the impedance measurement may vary during a cardiac cycle as the volume of blood (and thus the volume of the chamber) surrounding the LCP changes. In some cases, the measure of cardiac volume may be a relative measure, rather than an actual measure. In some cases, the intracardiac impedance may be correlated to an actual measure of cardiac volume via a calibration process, sometimes performed during implantation of the LCP(s). During the calibration process, the actual cardiac volume may be determined using fluoroscopy or the like, and the measured impedance may be correlated to the actual cardiac volume.

[000101] In some cases, the LCP 610 may be provided with energy delivery circuitry operatively coupled to the first electrode 620 and the second electrode 622 for causing a current to flow between the first electrode 620 and the second electrode 622 in order to determine the impedance between the two electrodes 620, 622 (or other electrode pair). It is contemplated that the energy delivery circuitry may also be configured to deliver pacing pulses via the first and/or

second electrodes 620, 622. The LCP 610 may further include detection circuitry operatively coupled to the first electrode 620 and the second electrode 622 for detecting an electrical signal received between the first electrode 620 and the second electrode 622. In some instances, the detection circuitry may be configured to detect cardiac signals received between the first electrode 620 and the second electrode 622.

[000102] When the energy delivery circuitry delivers a current between the first electrode 620 and the second electrode 622, the detection circuitry may measure a resulting voltage between the first electrode 620 and the second electrode 622 (or between a third and fourth electrode separate from the first electrode 620 and the second electrode 622, not shown) to determine the impedance. When the energy delivery circuitry delivers a voltage between the first electrode 620 and the second electrode 622, the detection circuitry may measure a resulting current between the first electrode 620 and the second electrode 622 (or between a third and fourth electrode separate from the first electrode 620 and the second electrode 622) to determine the impedance.

[000103] In some instances, the impedance may be measured between electrodes on different devices and/or in different heart chambers. For example, impedance may be measured between a first electrode in the left ventricle and a second electrode in the right ventricle. In another example, impedance may be measured between a first electrode of a first LCP in the left ventricle and a second LCP in the left ventricle. In yet another example, impedance may be measured from an injected current. For example, a medical device (such as, but not limited to an SICD such as the SICD 12 of Figure 1), may inject a known current into the heart and the LCP implanted in the heart H may measure a voltage resulting from the injected current to determine the impedance. These are just some examples.

[000104] Figure 12 is a flow diagram showing an illustrative method 700 of sensing and regulating cardiac activity of a patient's heart using a first medical device (such as but not limited to the first medical device 12 of Figure 1) that is configured to sense cardiac electrical activity and generate and deliver pacing pulses accordingly, and a second medical device (such as but not limited to the second medical device 14 of Figure 1) that is configured to sense cardiac electrical activity. The illustrative method 700 includes monitoring cardiac electrical activity with the first medical device, as generally seen at block 702. At block 704, a pacing pulse is generated and delivered with the first medical device at a pacing pulse energy level. Cardiac activity may be monitored with the second medical device, as indicated at block 706. At block

708, a determination may be made via the second medical device as to whether the pacing pulse delivered by the first medical device captured the patient's heart. As seen at block 710, if the pacing pulse did not capture the patient's heart, the second medical device may instruct the first medical device to increase the pacing pulse energy level for a subsequent pacing pulse.

[000105] Figure 13 is a flow diagram showing an illustrative method 712 of sensing and regulating cardiac activity of a patient's heart using a first medical device (such as but not limited to the first medical device 12 of Figure 1) that is configured to sense cardiac electrical activity and generate and deliver pacing pulses accordingly, and a second medical device (such as but not limited to the second medical device 14 of Figure 1) that is configured to sense cardiac electrical activity. The illustrative method 712 includes monitoring cardiac electrical activity with the first medical device, as generally seen at block 702. At block 704, a pacing pulse is generated and delivered with the first medical device at a pacing pulse energy level. Cardiac activity may be monitored with the second medical device, as indicated at block 706. At block 708, a determination may be made via the second medical device as to whether the pacing pulse delivered by the first medical device captured the patient's heart.

[000106] As seen at block 714, if the pacing pulse did capture the patient's heart, the second medical device may instruct the first medical device to decrease the pacing pulse energy level for a subsequent pacing pulse. The first medical device may generate and deliver the subsequent pacing pulse at a decreased pacing pulse energy level, as seen at block 716. The second medical device may monitor cardiac activity to determine if the subsequent pacing pulse captured the patient's heart, as generally seen at block 718.

[000107] Figure 14 is a flow diagram showing a method 720 of sensing and regulating cardiac activity of a patient's heart using a first medical device (such as but not limited to the first medical device 12 of Figure 1) that is configured to sense cardiac electrical activity and generate and deliver pacing pulses accordingly, and a second medical device (such as but not limited to the second medical device 14 of Figure 1) that is configured to sense cardiac electrical activity. The method 720 includes monitoring cardiac electrical activity with the first medical device, as generally seen at block 702. At block 704, a pacing pulse is generated and delivered with the first medical device at a pacing pulse energy level. Cardiac activity may be monitored with the second medical device, as indicated at block 706. At block 708, a determination may be made with the second medical device as to whether the pacing pulse delivered by the first medical

device captured the patient's heart. As seen at block 722, if the pacing pulse did capture the patient's heart, the second medical device may continue to instruct the first medical device to decrease the pacing pulse energy level for a subsequent pacing pulse and determines if the subsequent pacing pulse captured the patient's heart until the second medical device indicates that the subsequent pacing pulse did not capture the patient's heart. In some cases, at this point, the pacing energy may be increased by a safety margin for a subsequent pacing pulse.

[000108] It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the disclosure. This may include, to the extent that it is appropriate, the use of any of the features of one example embodiment being used in other embodiments.

What is claimed is:

1. A leadless cardiac pacemaker (LCP) configured to pace a patient's heart, the LCP disposable within a chamber of the patient's heart, the LCP comprising:

a housing;

a pair of pacing electrodes secured relative to the housing;

a controller disposed within the housing and operably coupled to the pair of pacing electrodes, the controller configured to generate and deliver a plurality of pacing pulses via the pair of pacing electrodes, wherein each of the plurality of pacing pulses has a controllable pacing energy level; and

a communications module operably coupled to the controller, the communications module configured to receive a pacing energy signal from a second implantable medical device that results from an automatic capture threshold capability of the second implantable medical device, wherein the pacing energy signal causes the controller of the LCP to change the pacing energy level of one or more subsequent pacing pulses of the plurality of pacing pulses.

2. The LCP of claim 1, wherein the controller is configured to change the pacing energy level by adjusting a voltage and/or a pulse width of one or more of the subsequent pacing pulses.

3. The LCP of any one of claims 1 or 2, wherein the pacing energy signal causes the controller to increase the pacing energy level of one or more subsequent pacing pulses of the plurality of pacing pulses.

4. The LCP of any one of claims 1 to 3, wherein the pacing energy signal causes the controller to incrementally increase the pacing energy level of two or more subsequent pacing pulses of the plurality of pacing pulses until the communications module receives another signal from the second implantable medical device indicating that the pacing pulses are now capturing the patient's heart.

5. The LCP of any one of claims 1 to 3, wherein the pacing energy signal causes the controller to decrease the pacing energy level of one or more subsequent pacing pulses of the plurality of pacing pulses.

6. The LCP of claim 5, wherein the pacing energy signal causes the controller to incrementally decrease the pacing energy level of two or more subsequent pacing pulses of the plurality of pacing pulses until the communications module receives another signal from the second implantable medical device indicating that the pacing pulses are no longer capturing the patient's heart.

7. The LCP of any one of claims 1 to 6, wherein the controller is configured to include a safety mode in which the controller generates and delivers pacing pulses at a predetermined energy level when the communications module is not able to receive signals from the second implantable medical device.

8. The LCP of any one of claims 1 to 7, wherein the controller is configured to determine when and whether to generate and deliver a pacing pulse based upon electrical cardiac signals received by the LCP.

9. A medical system for sensing and regulating cardiac activity of a patient, the medical system comprising:

a leadless cardiac pacemaker (LCP) configured to pace a patient's heart, the LCP disposable within a chamber of the patient's heart, the LCP comprising:

a housing;

a pair of pacing electrodes secured relative to the housing;

a controller disposed within the housing and operably coupled to the pair of pacing electrodes, the controller configured to generate and deliver a plurality of pacing pulses to the heart via the pair of pacing electrodes, wherein each of the plurality of pacing pulses has a controllable pacing energy level;

a communications module operably coupled to the controller;

a second medical device having an automatic capture threshold capability, wherein the automatic capture threshold capability is configured to determine whether pacing pulses generated and delivered by the LCP are capturing the heart, and to selectively generate a pacing energy signal to control the pacing energy level of one or more subsequent pacing pulses generated and delivered by the LCP; and

the communications module of the LCP is configured to receive the pacing energy signal from the second medical device, and in response, the controller of the LCP is configured to change the pacing energy level of one or more subsequent pacing pulses of the plurality of pacing pulses.

10. The medical system of claim 9, wherein the second medical device is implantable.

11. The medical system of any one of claims 9 or 10, wherein the second medical device comprises an implantable cardioverter configured to generate and deliver shocks to the patient's heart.

12. The medical system of any one of claims 9 to 11, wherein the pacing energy signal causes the controller of the LCP to increase the pacing energy level of one or more subsequent pacing pulses of the plurality of pacing pulses.

13. The medical system of claim 12, wherein the pacing energy signal causes the controller of the LCP to incrementally increase the pacing energy level of two or more subsequent pacing pulses of the plurality of pacing pulses until the communications module receives another signal from the second medical device indicating that the pacing pulses are now capturing the patient's heart.

14. The medical system of any one of claims 9 to 11, wherein the pacing energy signal causes the controller of the LCP to decrease the pacing energy level of one or more subsequent pacing pulses of the plurality of pacing pulses.

15. The medical system of claim 14, wherein the pacing energy signal causes the controller of the LCP to incrementally decrease the pacing energy level of two or more subsequent pacing pulses of the plurality of pacing pulses until the communications module receives another signal from the second medical device indicating that the pacing pulses are no longer capturing the patient's heart.

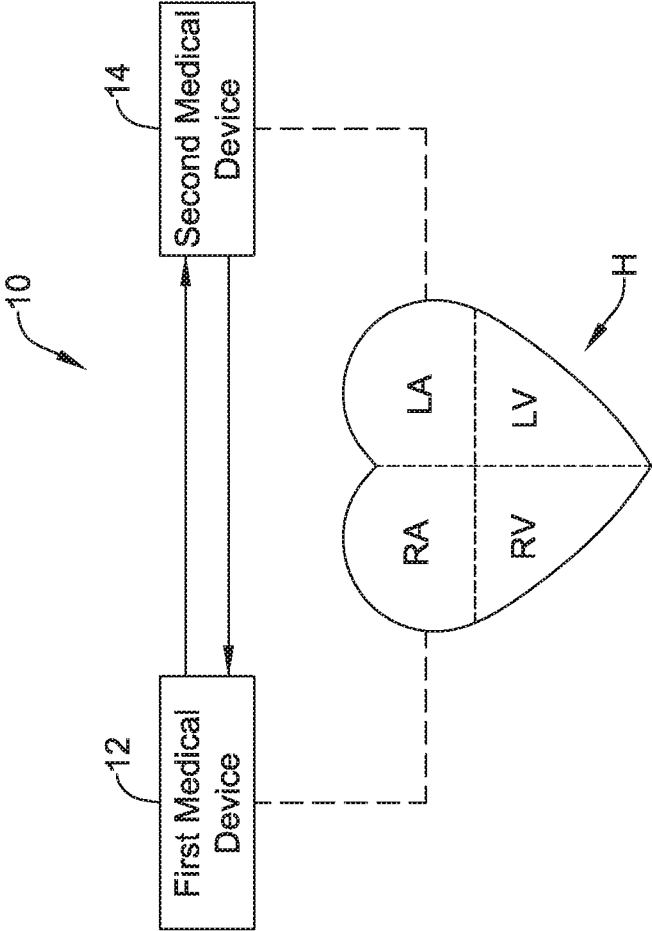


FIG. 1

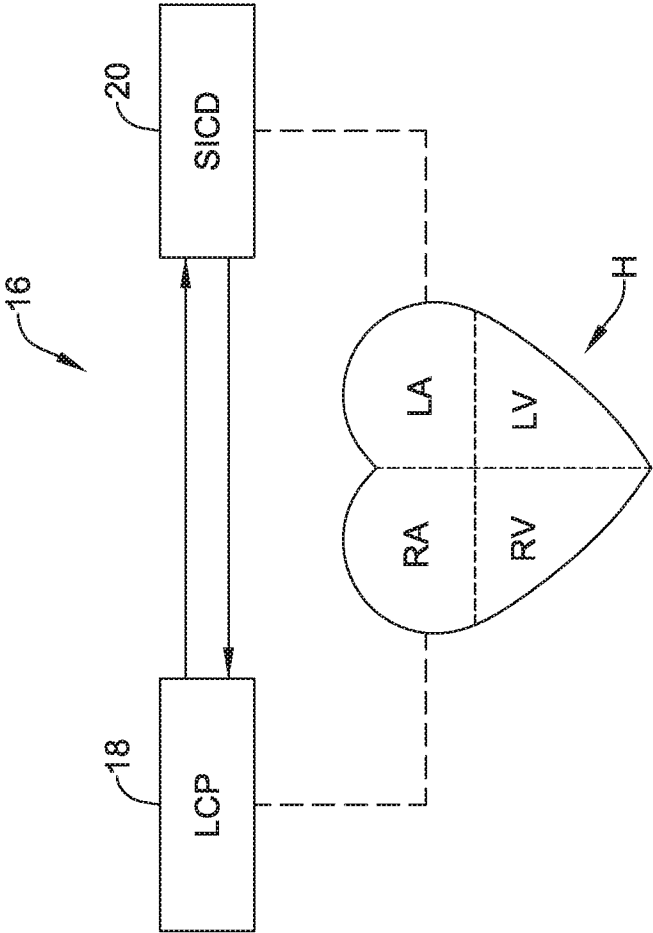


FIG. 2

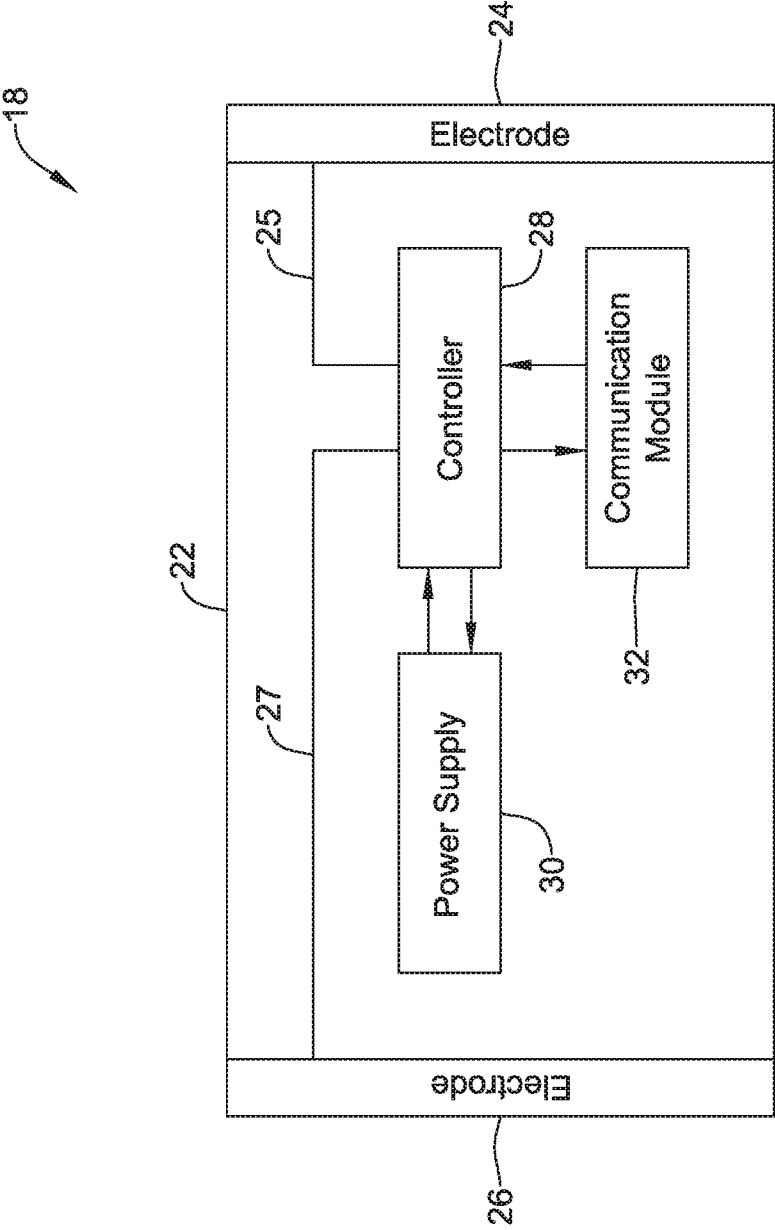


FIG. 3

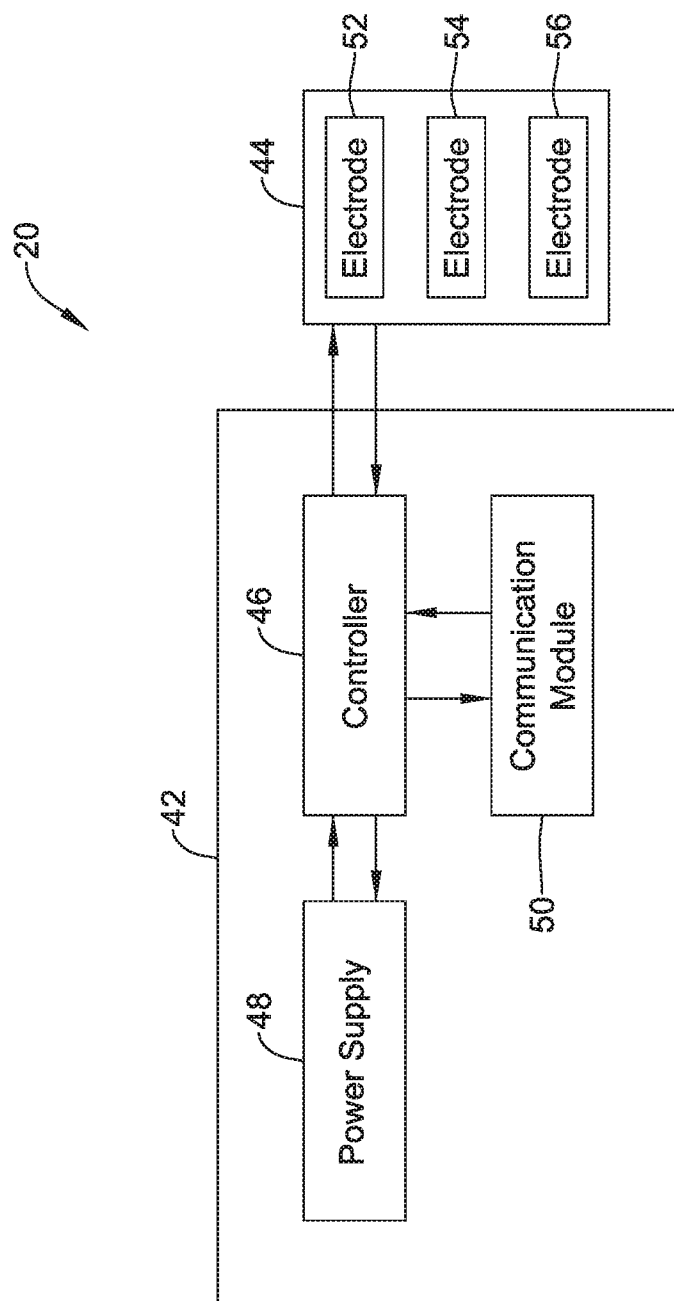


FIG. 4

60

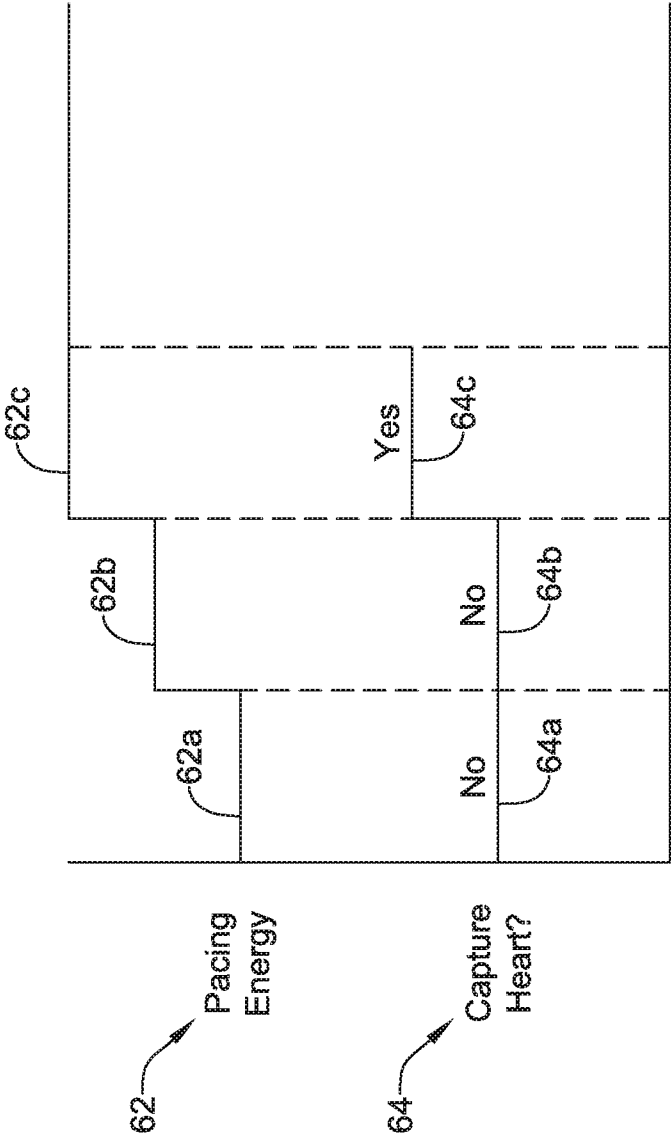


FIG. 5

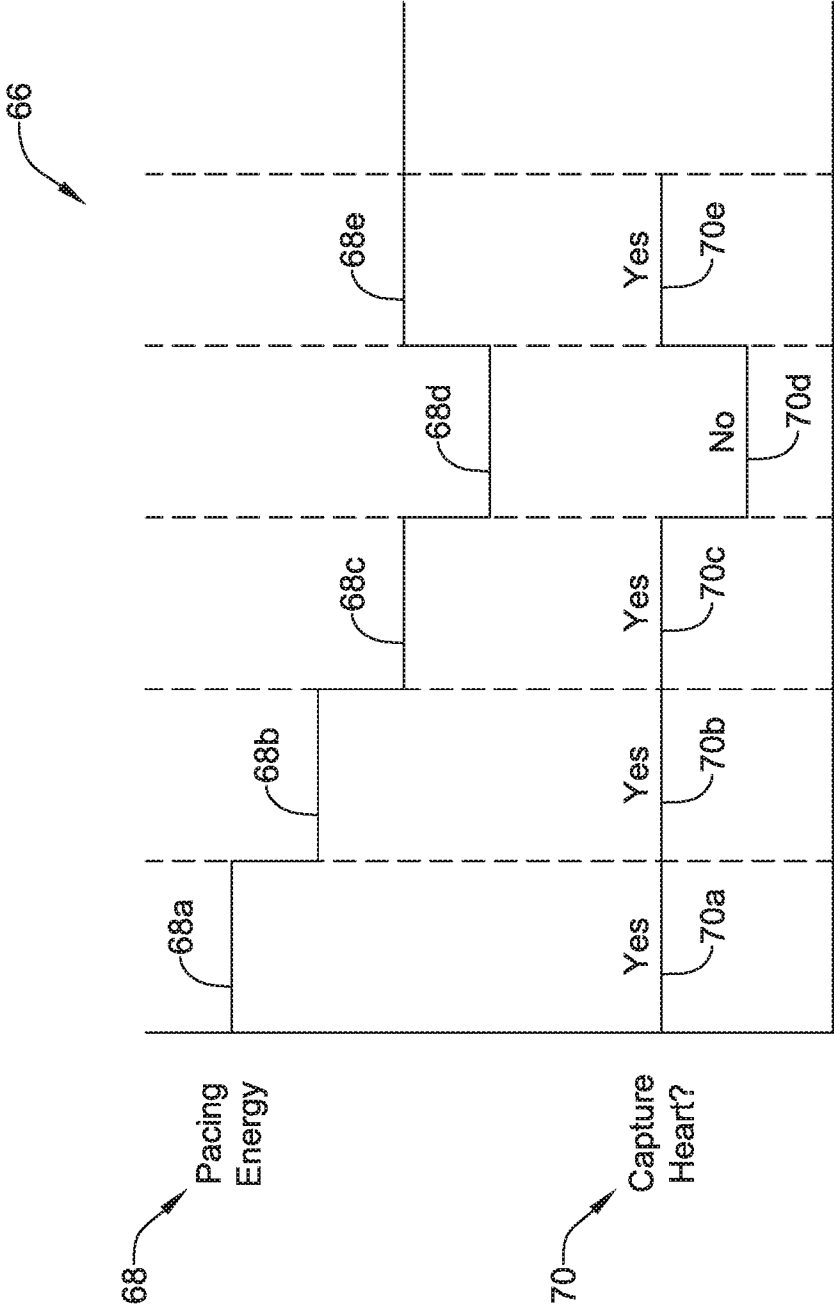


FIG. 6

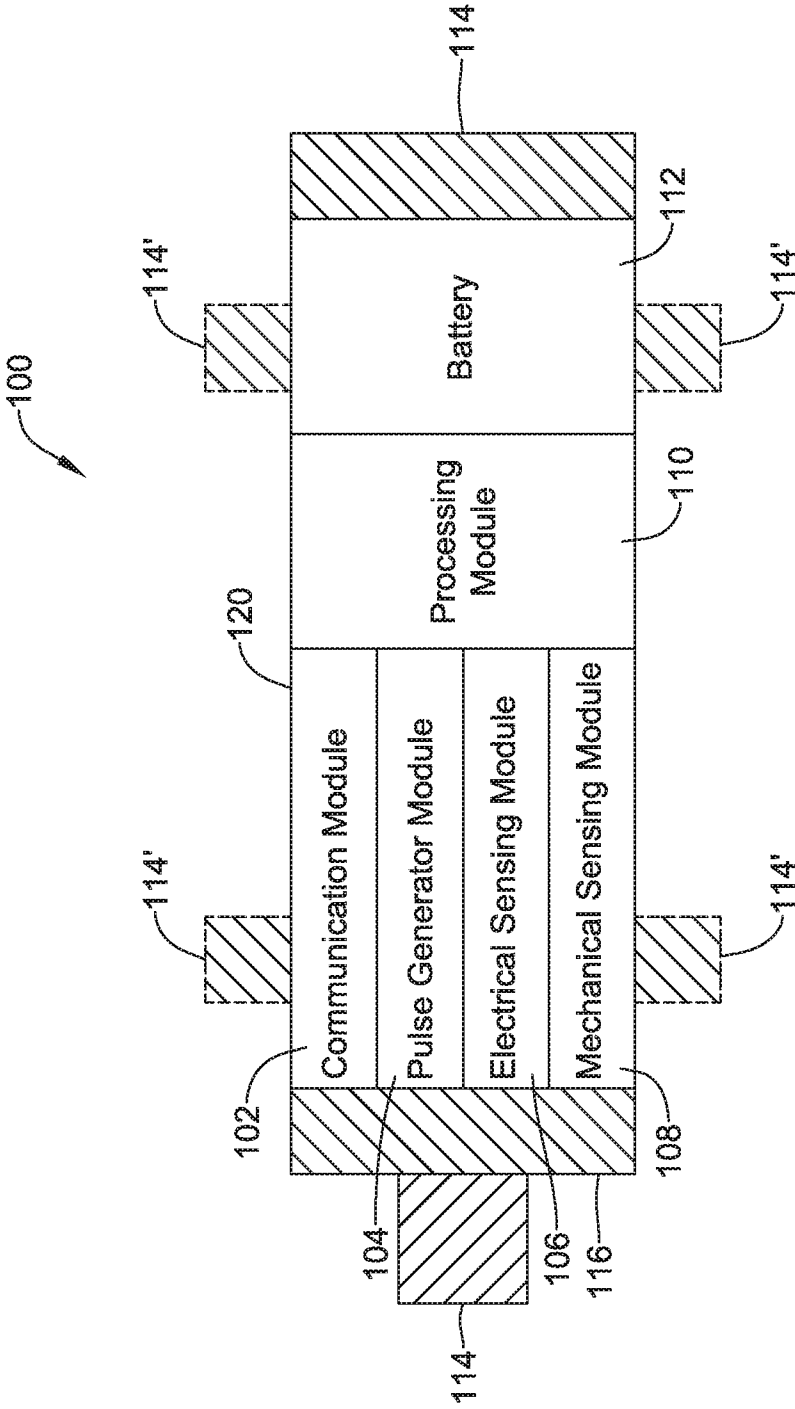


FIG. 7

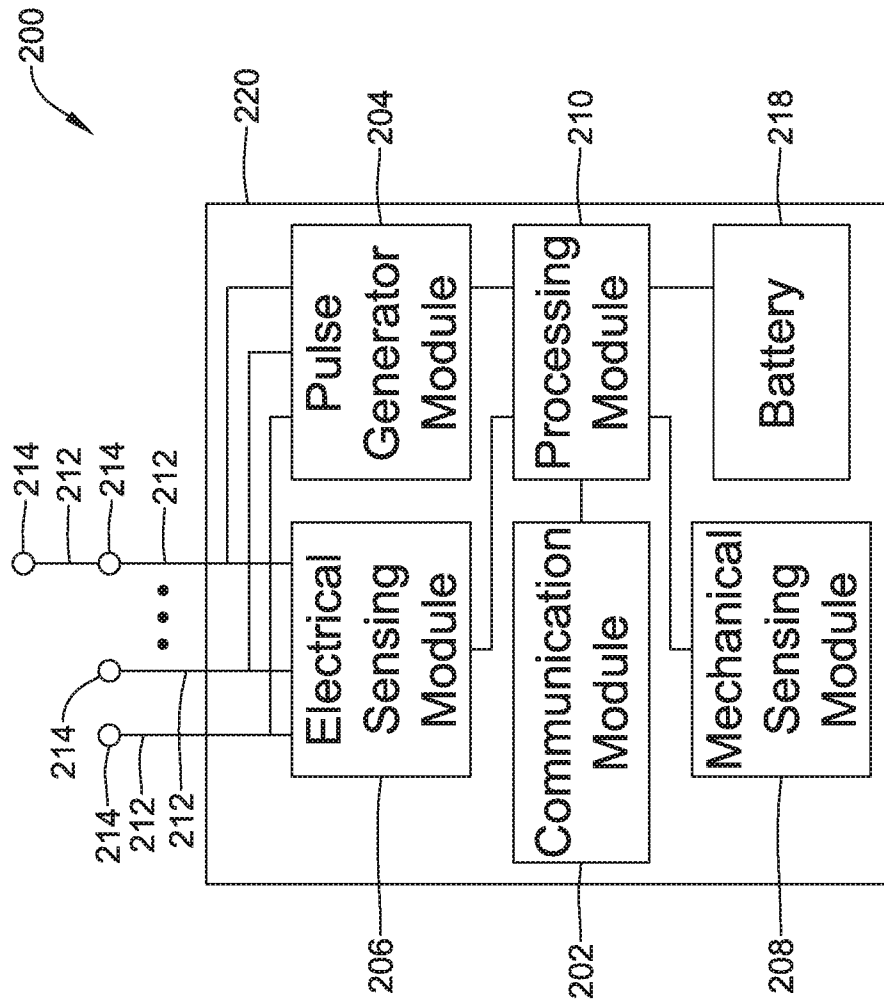


FIG. 8

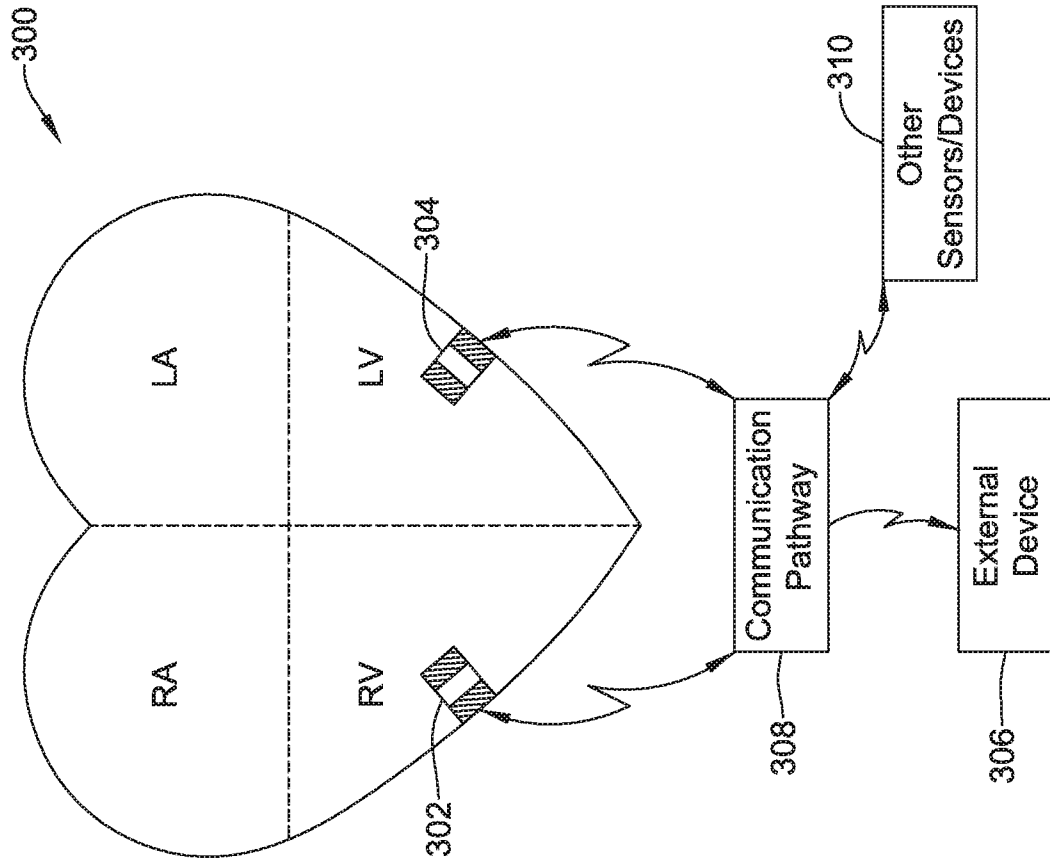


FIG. 9

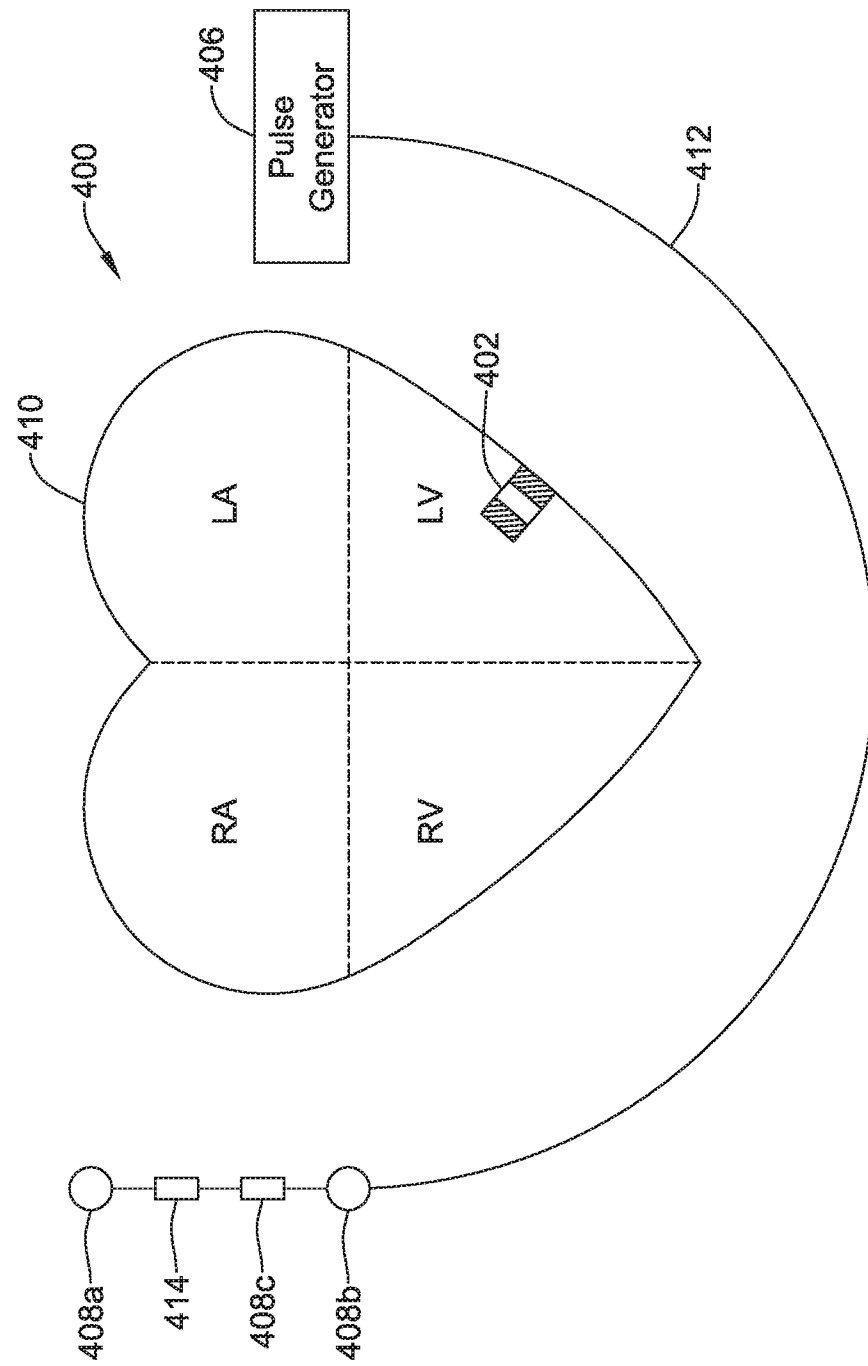


FIG. 10

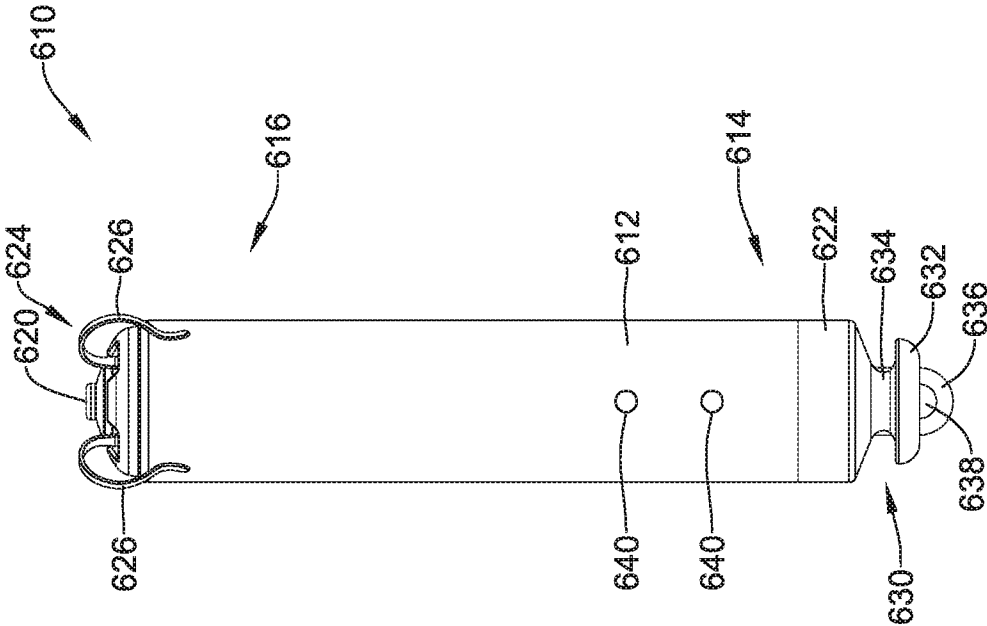


FIG. 11

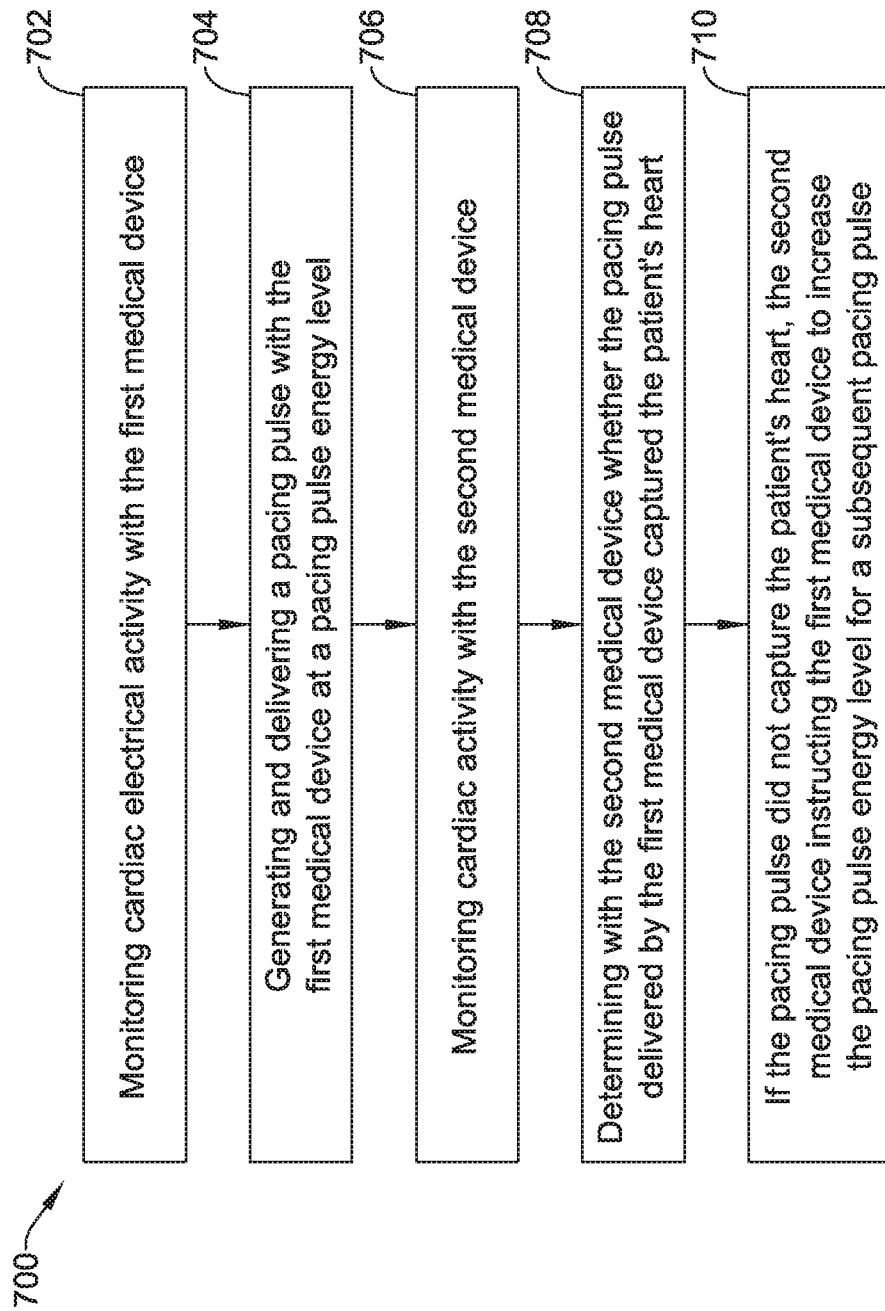


FIG. 12

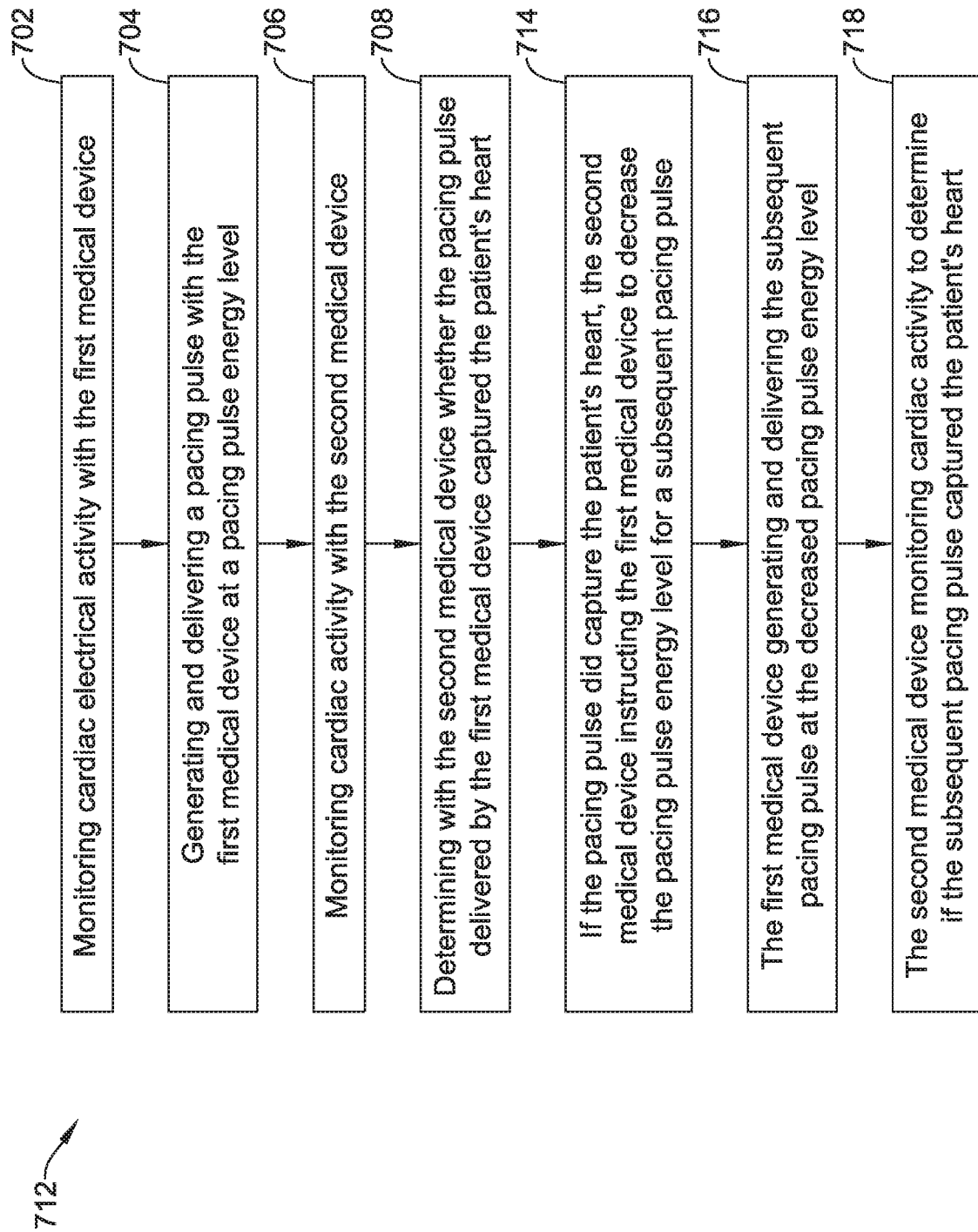


FIG. 13

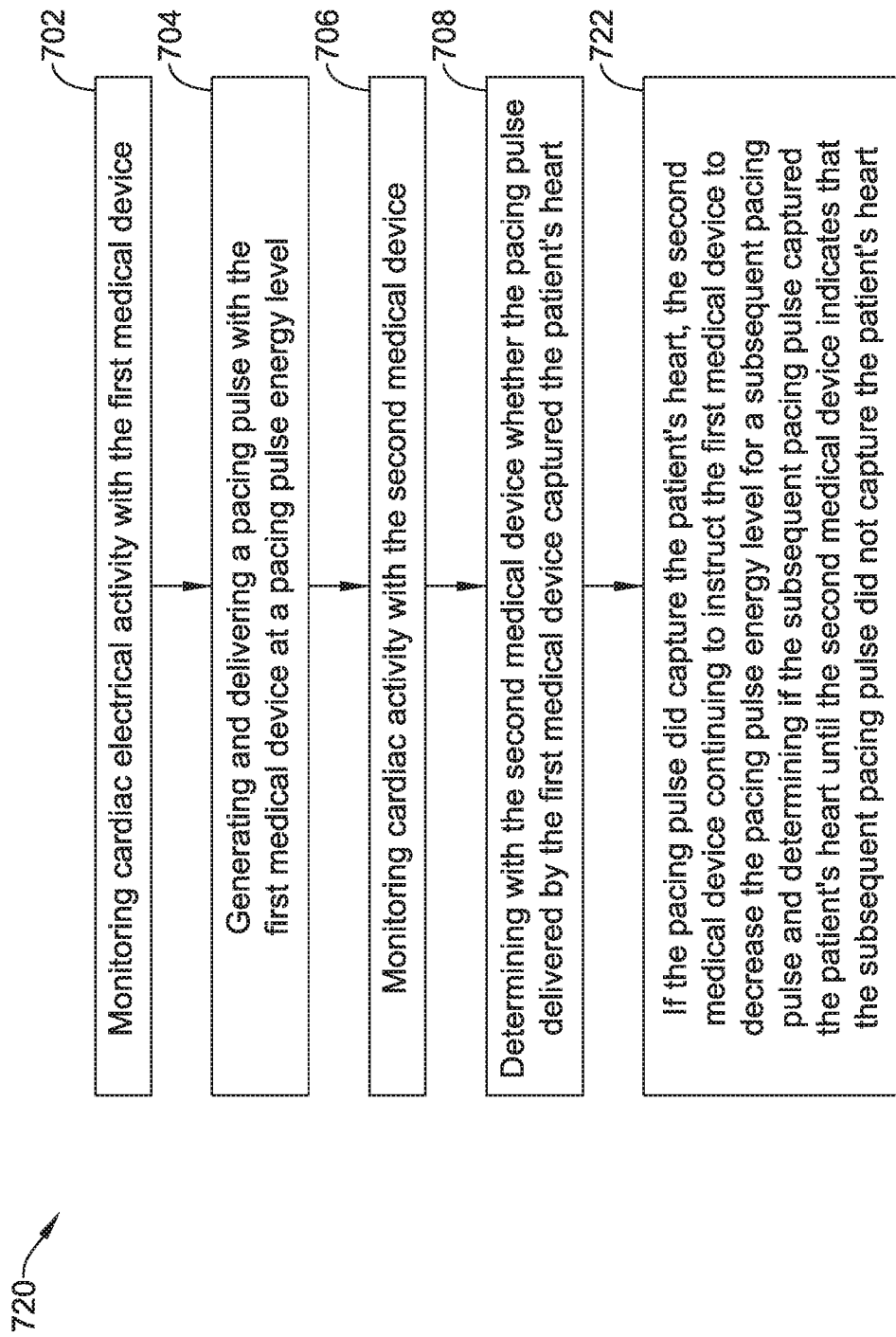


FIG. 14

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/058242

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/375 A61N1/37 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)

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 2014/107723 A1 (HOU WENBO [US] ET AL) 17 April 2014 (2014-04-17) paragraphs [0127] - [0144]; figure 8 -----	1-15
A	US 2016/059022 A1 (STAHMANN JEFFREY E [US] ET AL) 3 March 2016 (2016-03-03) the whole document -----	1-15
A	US 2016/038742 A1 (STAHMANN JEFFREY E [US] ET AL) 11 February 2016 (2016-02-11) the whole document -----	1-15
A	US 2012/290025 A1 (KEIMEL JOHN G [US]) 15 November 2012 (2012-11-15) the whole document -----	1-15
A	US 2015/238768 A1 (BORNZIN GENE A [US]) 27 August 2015 (2015-08-27) the whole document -----	1-15



Further documents are listed in the continuation of Box C.



See patent family annex.

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

11 January 2018

Date of mailing of the international search report

22/01/2018

Name and mailing address of the ISA/

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Authorized officer

Smit, Jos

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2017/058242

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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