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(54) **SYSTEMS AND METHODS FOR INFARCT DETECTION**

(71) Applicant: **Cardiac Pacemakers, Inc.**, St. Paul, MN (US)
(72) Inventors: **Michael J. Kane**, Roseville, MN (US); **Allan Charles Shuros**, St. Paul, MN (US); **Brian L. Schmidt**, White Bear Lake, MN (US); **Keith R. Maile**, New Brighton, MN (US); **Benjamin J. Haasl**, Forest Lake, MN (US)

(73) Assignee: **Cardiac Pacemakers, Inc.**, St. Paul, MN (US)

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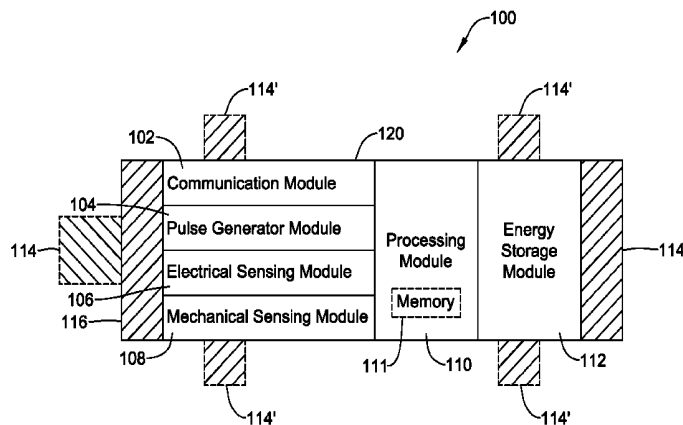
Primary Examiner — Paula J Stice

(74) *Attorney, Agent, or Firm* — Seager, Tufte & Wickhem LLP

(57) **ABSTRACT**

Systems, devices, and methods for determining occurrences of myocardial infarctions are disclosed. In one embodiment, a method of sensing for an occurrence of a myocardial infarction may include sensing a baseline accelerometer signal during a baseline, determining a baseline template based on one or more characteristics of the baseline accelerometer signal, and storing the baseline template in a memory. The method may further include sensing an accelerometer signal during a test period subsequent to the baseline, determining a test template based on one or more characteristics of the accelerometer signal during the test period, and comparing the baseline template with the test template, and based on the comparison, determining if a myocardial infarction occurred in the patient's heart. If it is determined that a myocardial infarction occurred in the patient's heart, the method may further include displaying an indication on a display that a myocardial infarction occurred.

16 Claims, 12 Drawing Sheets



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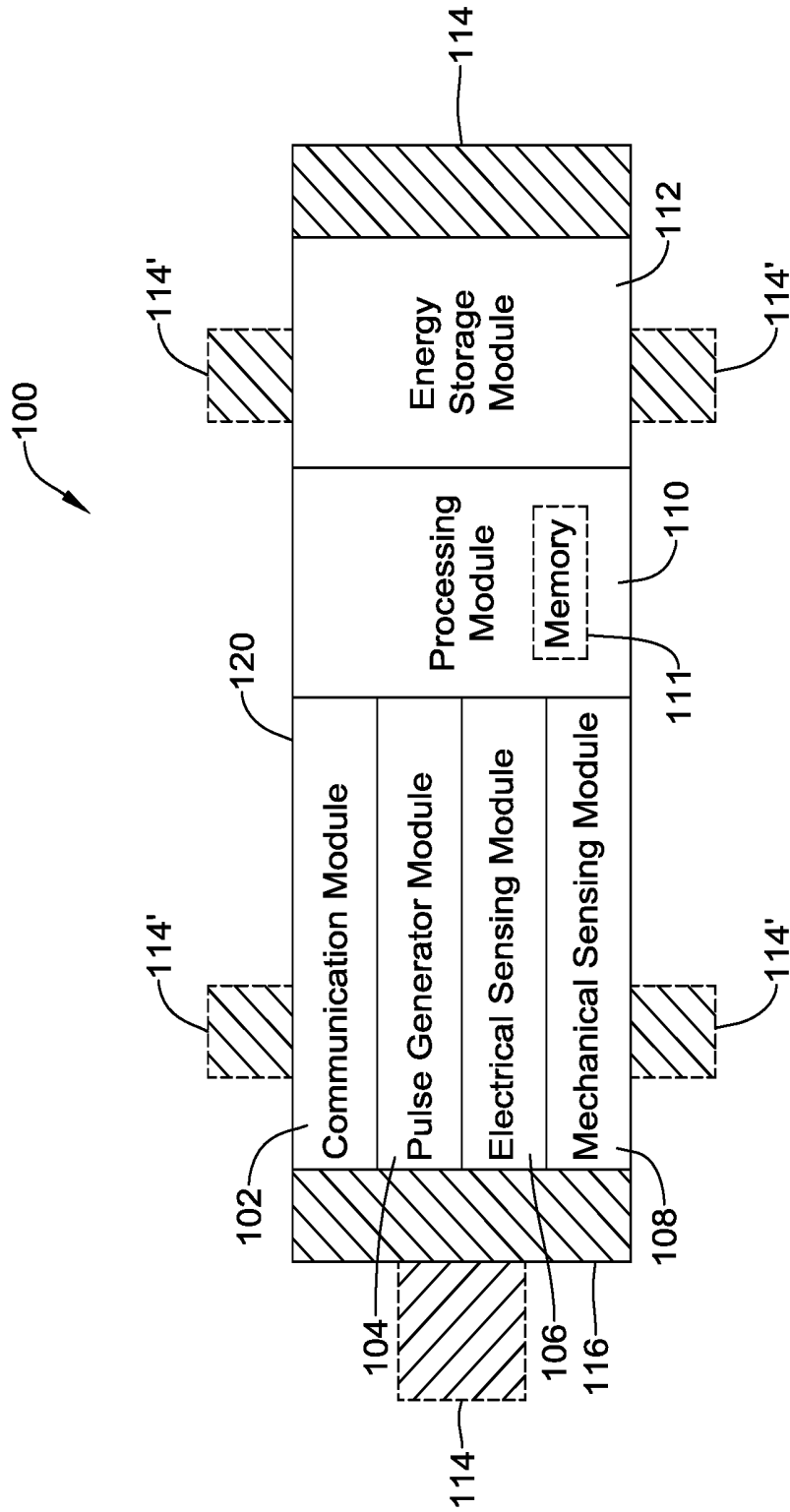


Figure 1

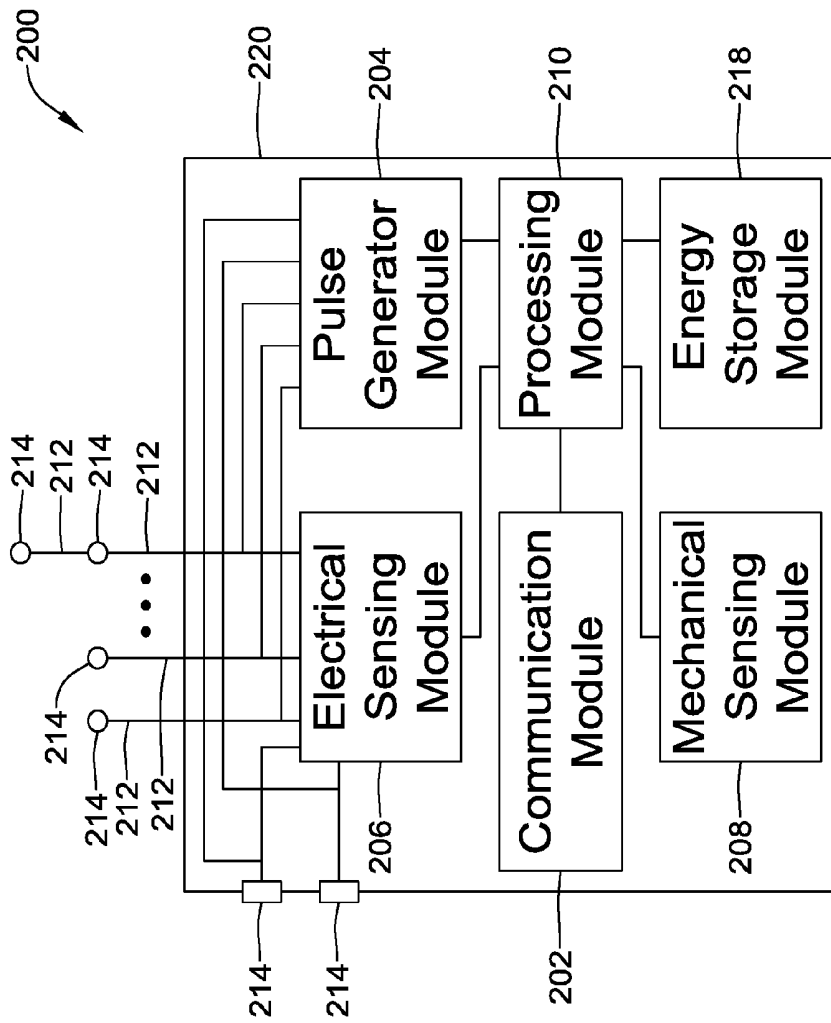


Figure 2

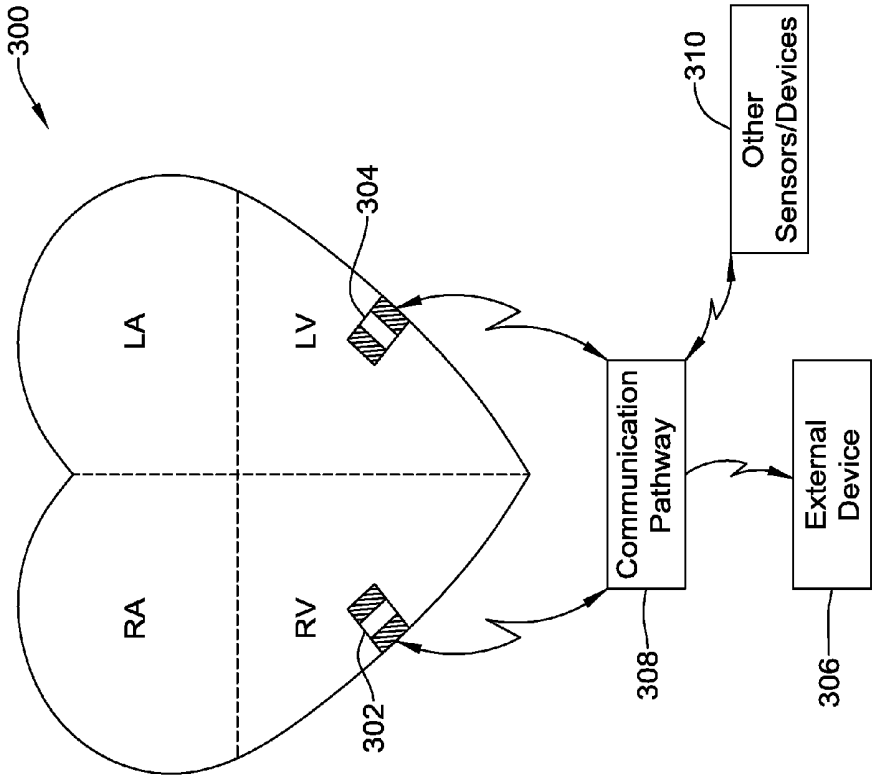


Figure 3

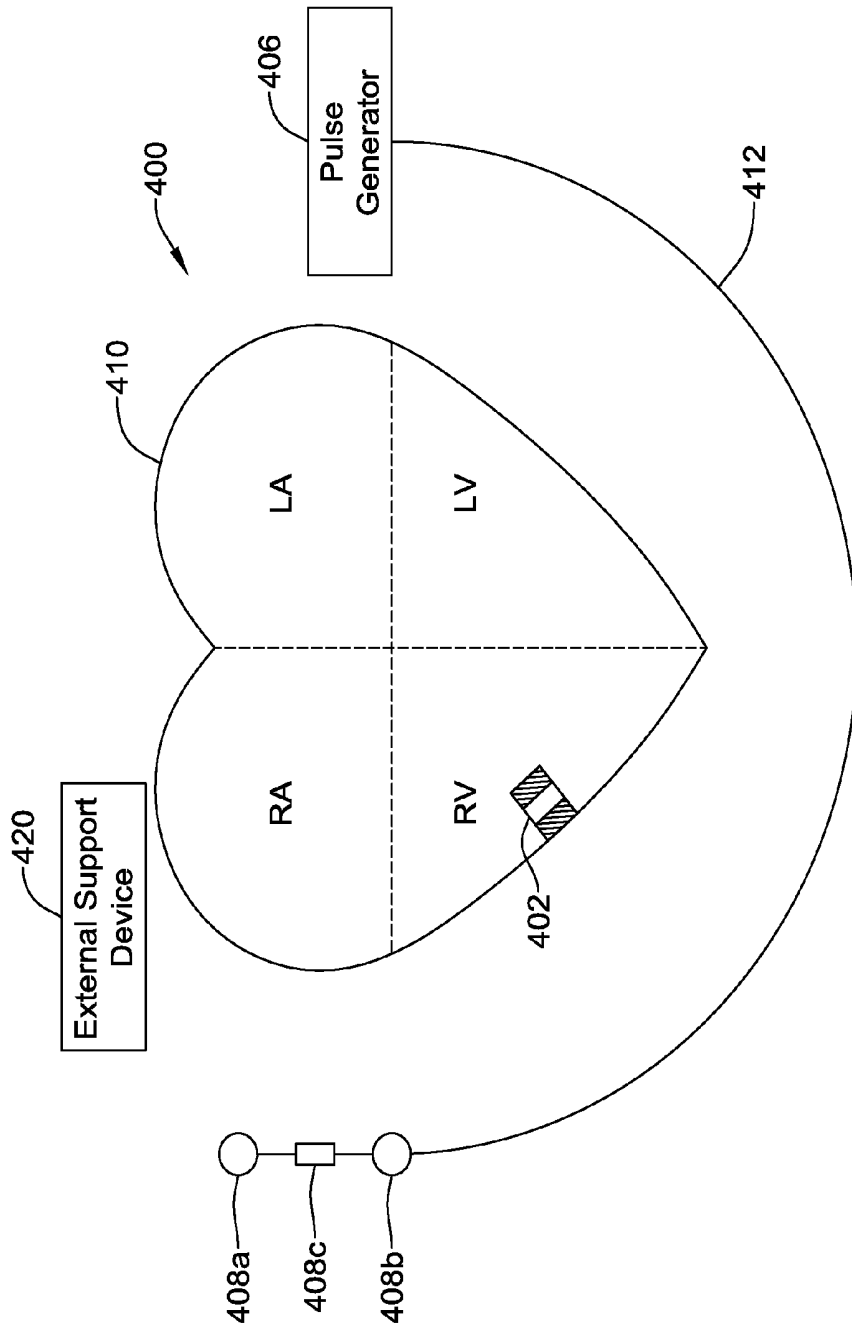


Figure 4

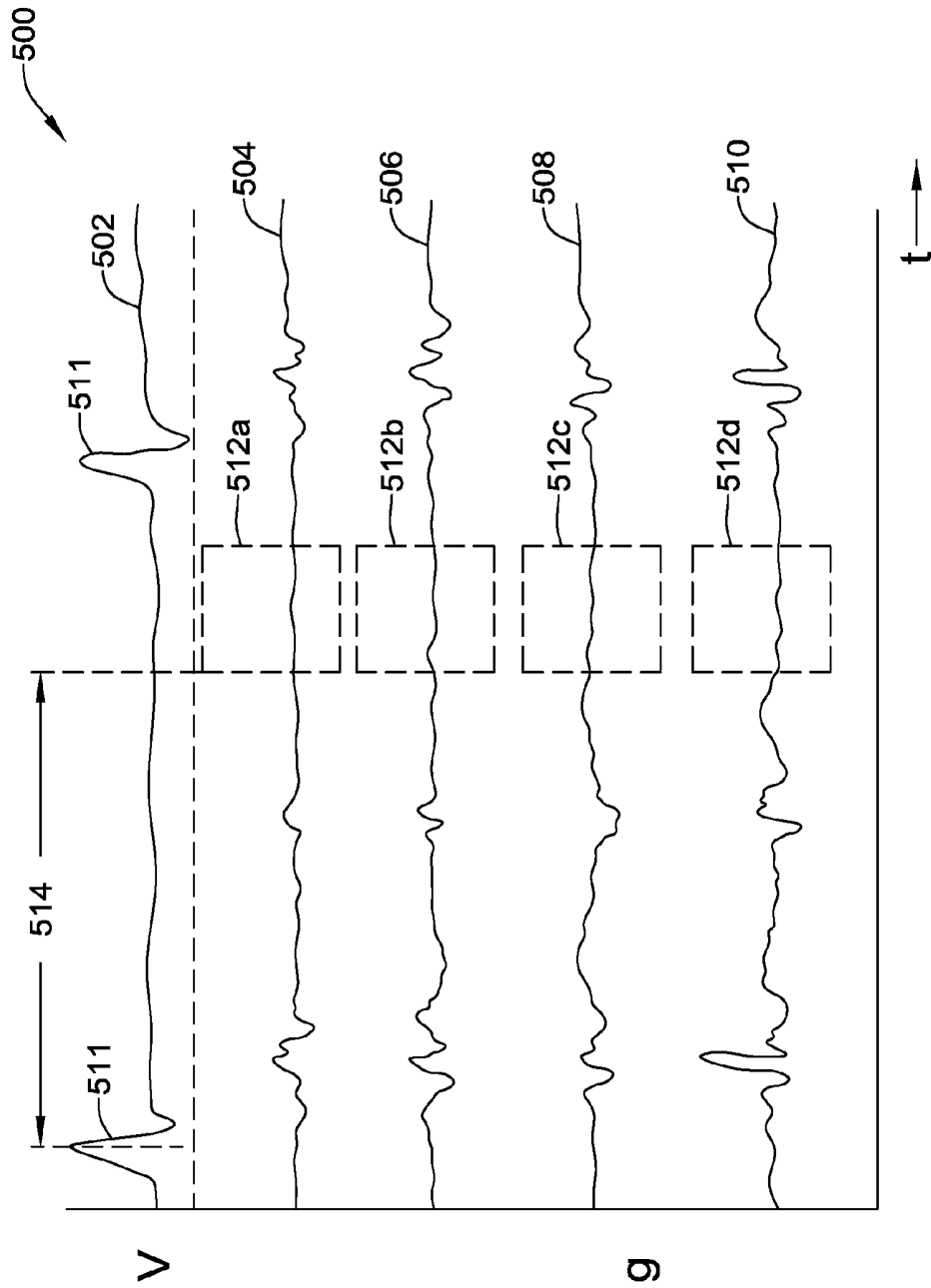


FIG. 5

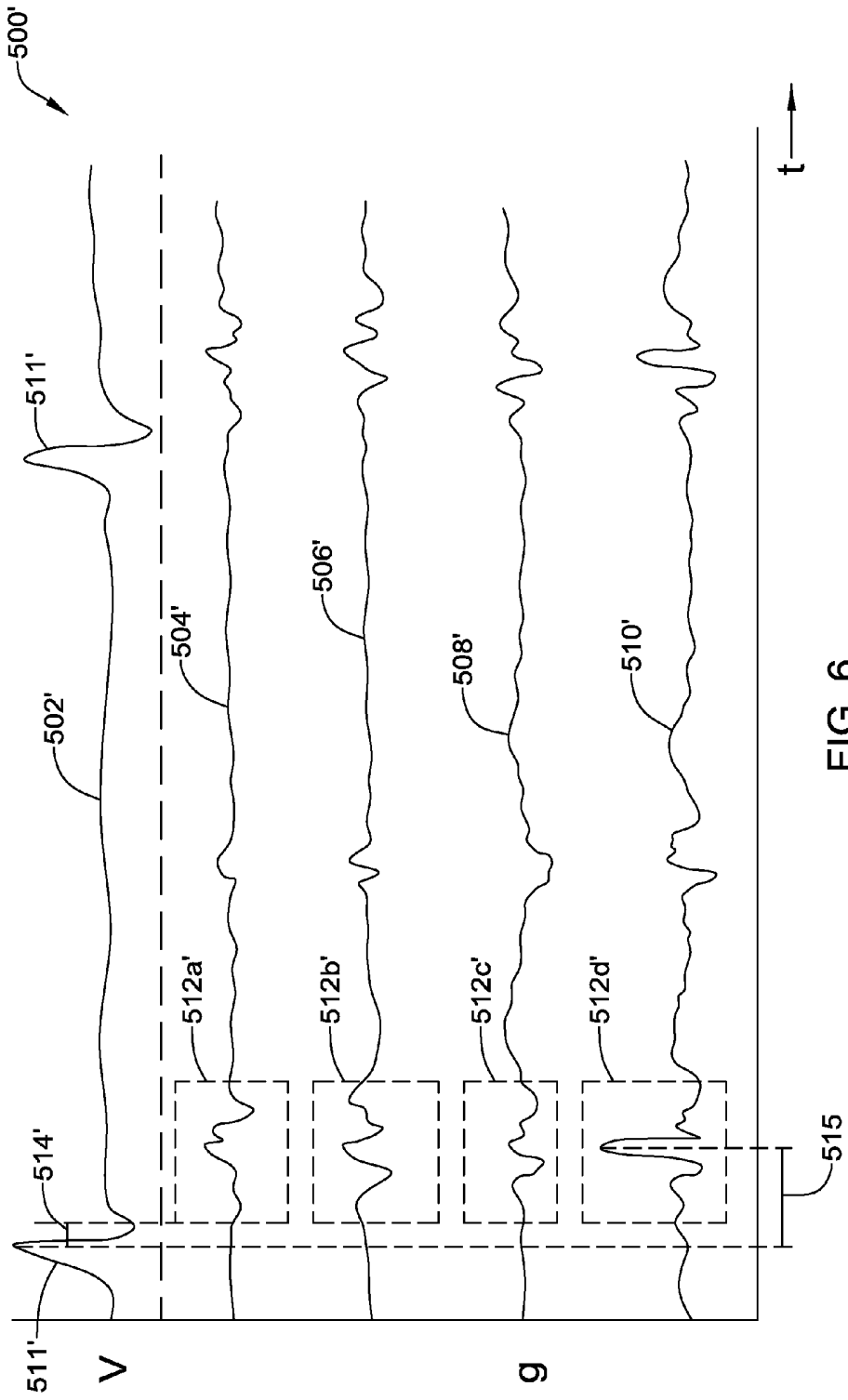


FIG. 6

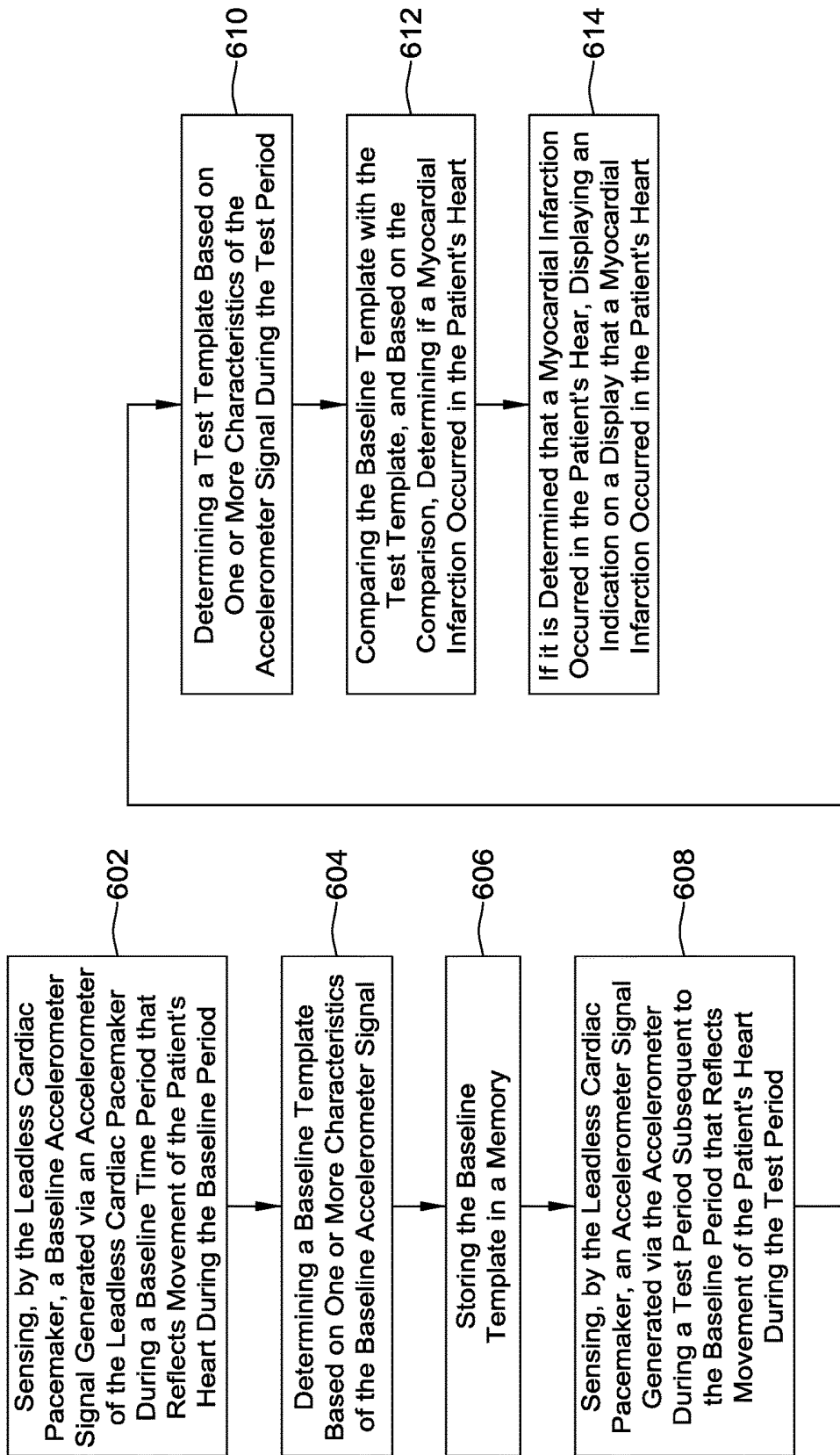


FIG. 7

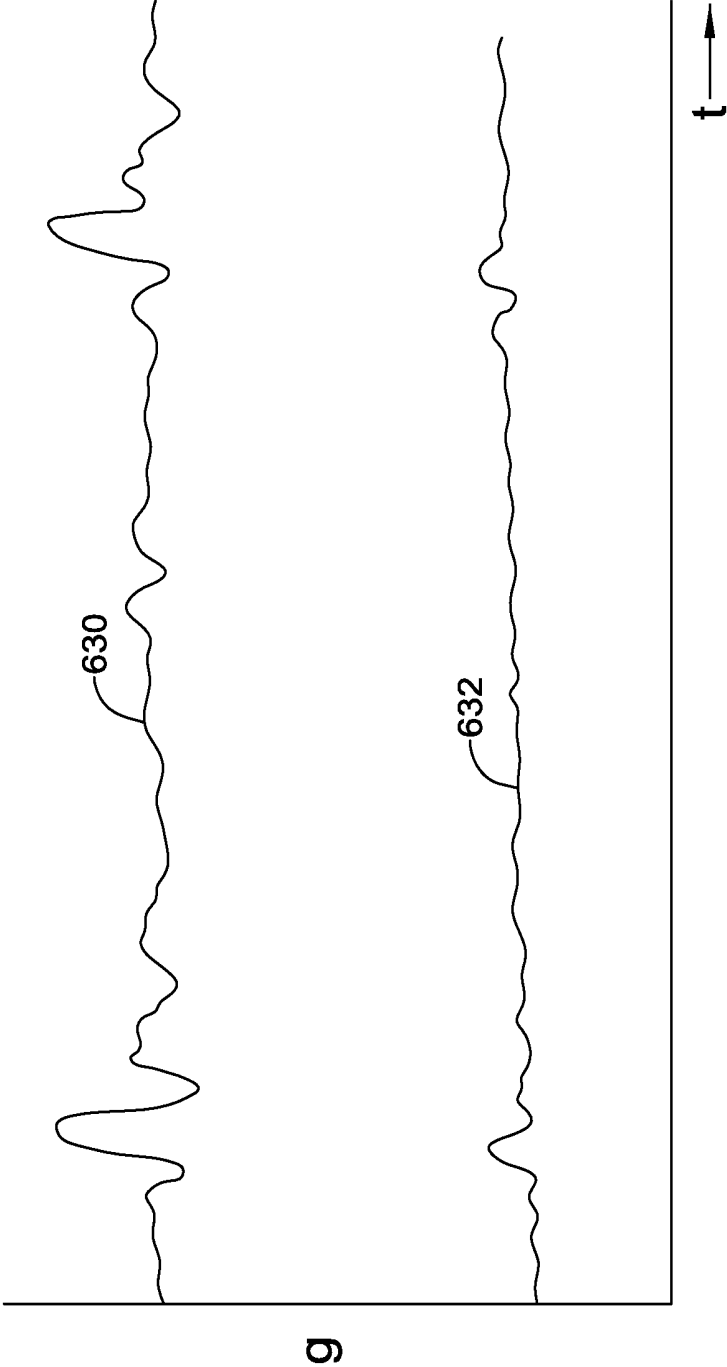


FIG. 8

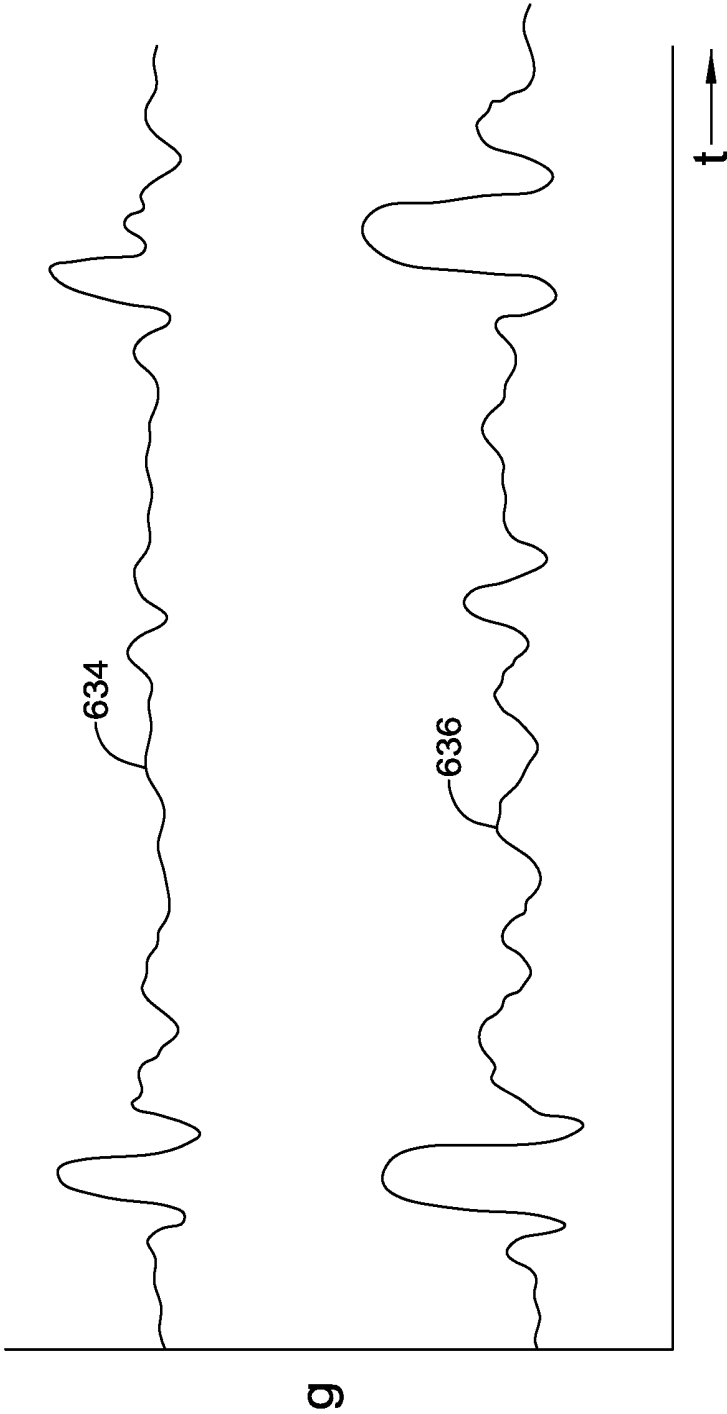


FIG. 9

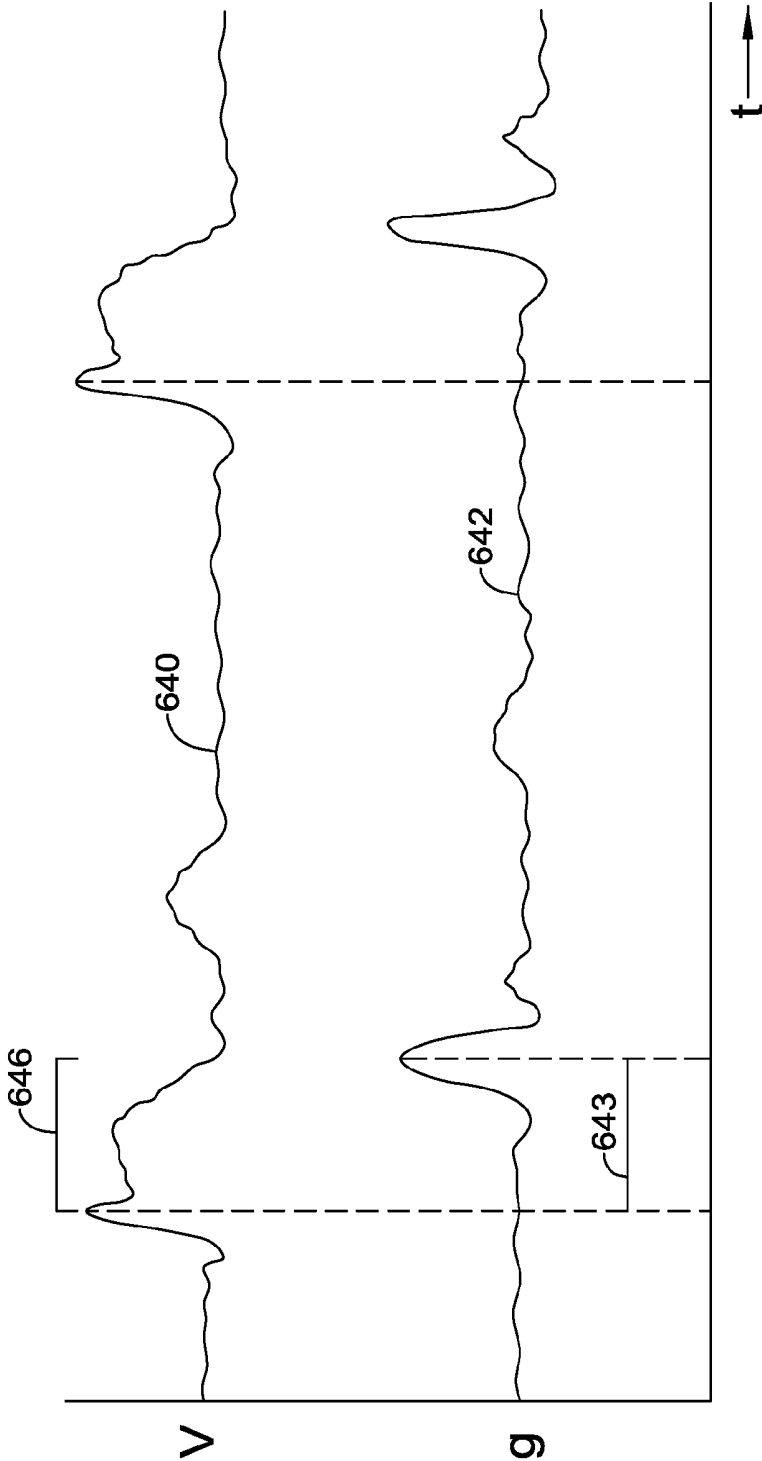


FIG. 10

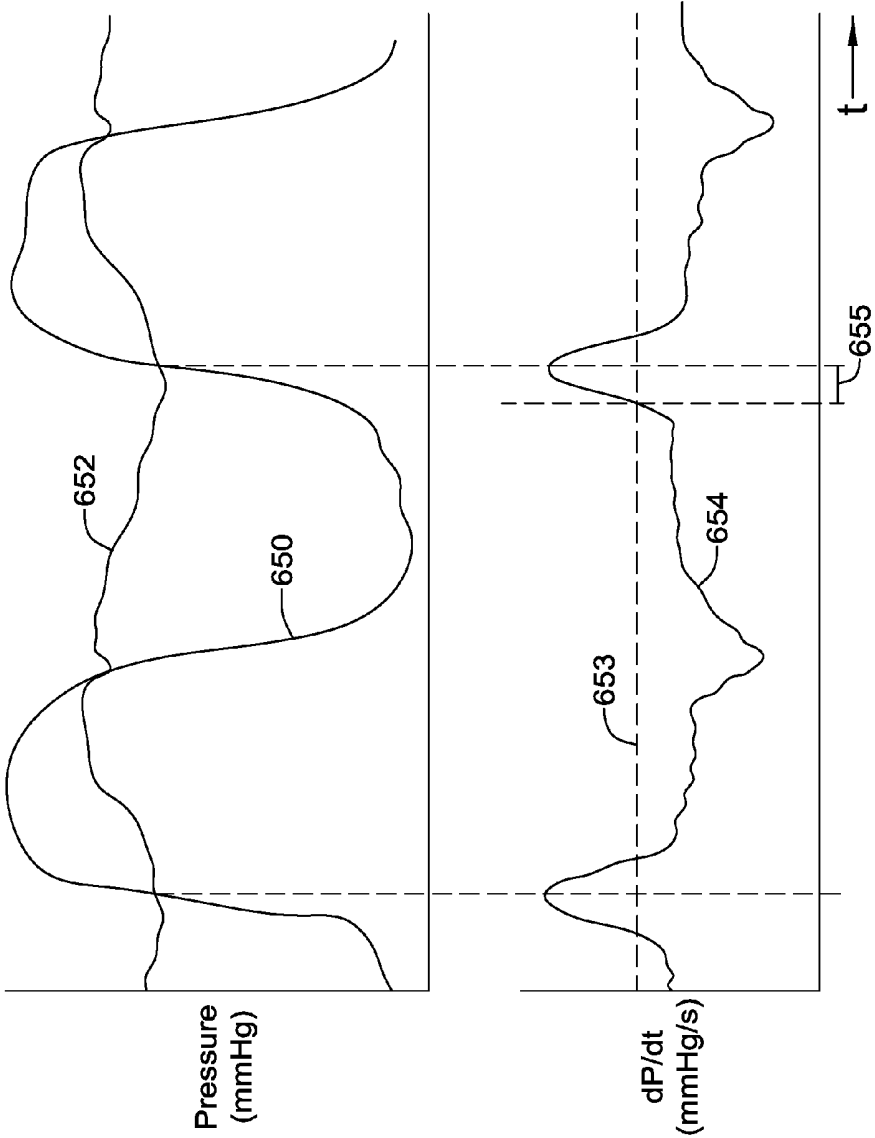


FIG. 11

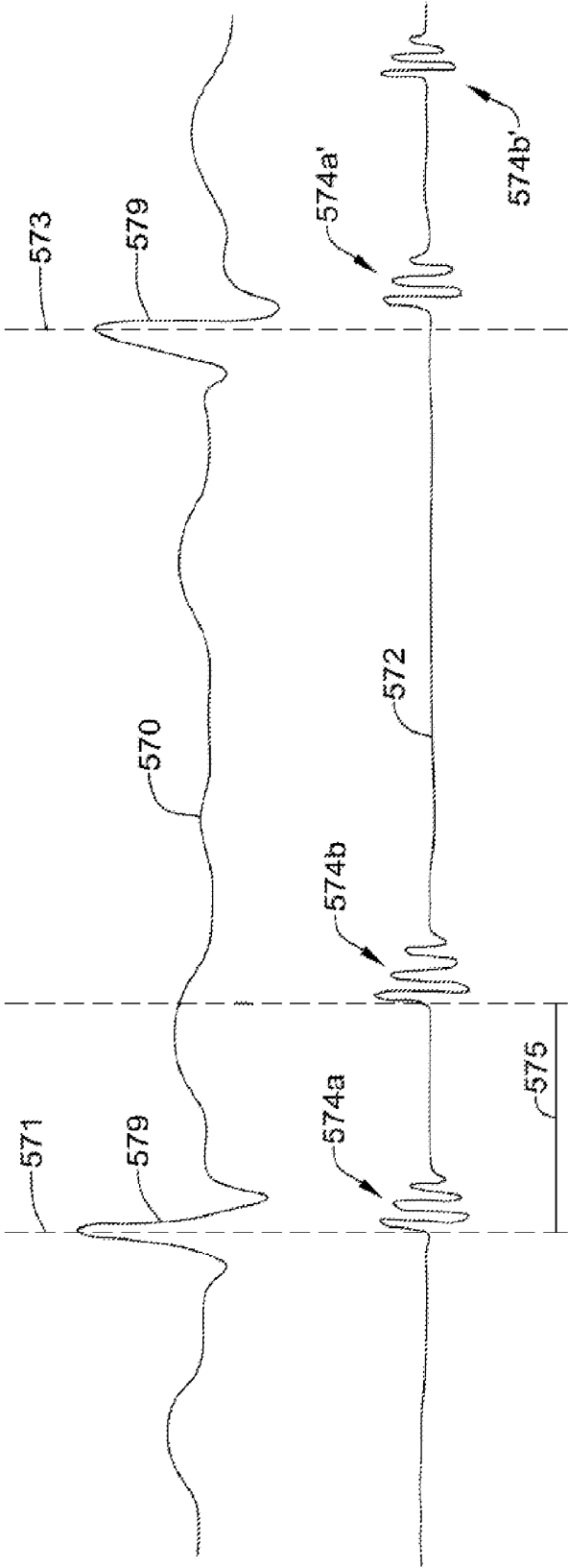


FIG. 12

SYSTEMS AND METHODS FOR INFARCT DETECTION

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Patent Application Ser. No. 62/211,397 filed on Aug. 28, 2015, the disclosure of which is incorporated herein by reference.

TECHNICAL FIELD

The present disclosure generally relates to systems, devices, and methods for detecting myocardial infarctions, and more particularly, to systems, devices, and methods for detecting myocardial infarctions using an implantable medical device such as a leadless cardiac pacemaker.

BACKGROUND

Pacing instruments can be used to treat patients suffering from various heart conditions that often result in a reduced ability of the heart to deliver sufficient amounts of blood to a patient's body. These heart conditions may lead to rapid, irregular, and/or inefficient heart contractions. To help alleviate some of these conditions, various devices (e.g., pacemakers, defibrillators, etc.) have been implanted in a patient's body. Such devices may monitor and provide electrical stimulation to the heart to help the heart operate in a more normal, efficient and/or safe manner. In some cases, blood flow to a patient's heart may be reduced or cut off, resulting in a myocardial infarction (MI). A MI can lead to a reduced ability of the heart to pump blood, and in some cases can result in serious consequences including death. It may be beneficial for an implanted device to detect occurrences of MIs in order to alert the patient and/or doctor in order to receive or alter treatment.

SUMMARY

The present disclosure generally relates to systems, devices, and methods for detecting myocardial infarctions, and more particularly, to systems, devices, and methods for detecting myocardial infarctions using an implantable medical device such as a leadless cardiac pacemaker.

In a first illustrative embodiment, a method of sensing for an occurrence of a myocardial infarction in a patient's heart using a leadless cardiac pacemaker that is affixed to the patient's heart may comprise sensing, by the leadless cardiac pacemaker, a baseline accelerometer signal generated via an patient accelerometer of the leadless cardiac pacemaker during a baseline period that reflects movement of the patient's heart during the baseline period, determining a baseline template based on one or more characteristics of the baseline accelerometer signal, and storing the baseline template in a memory. The method may further include sensing, by the leadless cardiac pacemaker, an accelerometer signal generated via the accelerometer during a test period subsequent to the baseline period that reflects movement of the patient's heart during the test period, determining a test template based on one or more characteristics of the accelerometer signal during the test period, and comparing the baseline template with the test template, and based on the comparison, determining if a myocardial infarction occurred in the patient's heart. If it is determined that a myocardial infarction has occurred in the patient's heart, the method

may further include displaying an indication on a display that a myocardial infarction has occurred in the patient's heart.

Additionally, or alternatively, in the first illustrative embodiment, the method may further comprise transmitting an output signal for reception by a device external to the patient indicating that a myocardial infarction occurred in the patient's heart.

Additionally, or alternatively, in the first illustrative embodiment, the method may further comprise sensing, by the leadless cardiac pacemaker, a cardiac electrical signal during the baseline period, and correlating one or more features of the sensed cardiac electrical signal with one or more features of the accelerometer signal sensed during the baseline period.

Additionally, or alternatively, in the first illustrative embodiment, the method may further comprise sensing, by the leadless cardiac pacemaker, a cardiac electrical signal during the test period, and correlating one or more features of the sensed cardiac electrical signal with one or more features of the accelerometer signal sensed during the test period, and determining that a myocardial infarction has occurred based on differences in the correlation between the cardiac electrical signal and the accelerometer signals sensed during the baseline period and the test period.

Additionally, or alternatively, in any of the above embodiments with respect to the first illustrative embodiment, the memory may be part of the leadless cardiac pacemaker.

Additionally, or alternatively, in any of the above embodiments with respect to the first illustrative embodiment, the baseline template and the test template may be compared by the leadless cardiac pacemaker.

Additionally, or alternatively, in any of the above embodiments with respect to the first illustrative embodiment, the leadless cardiac pacemaker may determine if a myocardial infarction occurred in the patient's heart.

Additionally, or alternatively, in any of the above embodiments with respect to the first illustrative embodiment, the memory may be part of an external device located external to the patient.

Additionally, or alternatively, in any of the above embodiments with respect to the first illustrative embodiment, the baseline template and the test template may be compared by an external device located external to the patient.

Additionally, or alternatively, in any of the above embodiments with respect to the first illustrative embodiment, an external device located external to the patient may determine if a myocardial infarction occurred in the patient's heart.

Additionally, or alternatively, in any of the above embodiments with respect to the first illustrative embodiment, the indication that a myocardial infarction occurred in the patient's heart may be displayed on a display of an external device located external to the patient.

Additionally, or alternatively, in any of the above embodiments with respect to the first illustrative embodiment, the external device may be a device programmer.

Additionally, or alternatively, in any of the above embodiments with respect to the first illustrative embodiment, the external device may be a cellular telephone.

In a second illustrative embodiment, a method of sensing for an occurrence of a myocardial infarction in a patient's heart using a leadless cardiac pacemaker that is affixed to the patient's heart may comprise sampling, by the leadless cardiac pacemaker, a baseline accelerometer signal generated via an accelerometer of the leadless cardiac pacemaker during a baseline period that reflects movement of the patient's heart during the baseline period and storing in a

memory one or more characteristics of the baseline accelerometer signal sensed during the baseline period. The method may further include sampling, by the leadless cardiac pacemaker, an accelerometer signal generated via the accelerometer during a test period subsequent to the baseline period that reflects movement of the patients' heart during the test period and comparing one or more characteristics of the accelerometer signal sampled during the test period with the one or more characteristics of the baseline accelerometer signal sampled during the baseline period, and based on the comparison, determining if a myocardial infarction occurred in the patients' heart. If it is determined that a myocardial infarction has occurred in the patient's heart, the method may further include displaying an indication on a display that a myocardial infarction has occurred in the patient's heart.

Additionally, or alternatively, in the second illustrative embodiment, the memory may be part of the leadless cardiac pacemaker.

Additionally, or alternatively, in any of the above embodiments with respect to the second illustrative embodiment, the one or more characteristics of the accelerometer signal sampled during the test period and the one or more characteristics of the baseline accelerometer signal sampled during the baseline period may be compared by the leadless cardiac pacemaker.

Additionally, or alternatively, in any of the above embodiments with respect to the second illustrative embodiment, the leadless cardiac pacemaker may determine if a myocardial infarction occurred in the patient's heart.

Additionally, or alternatively, in any of the above embodiments with respect to the second illustrative embodiment, an external device located external to the patient may determine if a myocardial infarction occurred in the patient's heart.

Additionally, or alternatively, in any of the above embodiments with respect to the second illustrative embodiment, the indication that a myocardial infarction occurred in the patient's heart may be displayed on a display of an external device located external to the patient.

In a third illustrative embodiment, a leadless cardiac pacemaker (LCP) may comprise a plurality of electrodes, an accelerometer, and a memory. In some instances, the LCP may further include a controller connected to the accelerometer, the plurality of electrodes, and the memory. The controller may be configured to: receive an accelerometer signal from the accelerometer; sample the accelerometer signal during a first period of time; store one or more characteristics of the sampled accelerometer signal in the memory; determine whether one or more predetermined characteristics of the accelerometer signal sampled during a second period of time differs from the stored one or more characteristics by at least a predetermined amount, and based on the result, determining if a myocardial infarction has occurred in the patient's heart; and if it is determined that a myocardial infarction has occurred in the patient's heart, transmitting an output signal for reception by a device external to the patient indicating that a myocardial infarction has occurred in the patient's heart.

Additionally, or alternatively, in the third illustrative embodiment, the one or more characteristics may comprise one or more of: an average amplitude of the accelerometer signal; an integral of the accelerometer signal; and a delay of the accelerometer signal relative to a sensed cardiac electrical signal.

Additionally, or alternatively, in any of the above embodiments with respect to the third illustrative embodiment, the controller may be further configured to determine a patient

activity level based at least in part on the received accelerometer signal, determine a heart rate of the patient's heart based on a sensed cardiac electrical signal, and use the patient activity level and heart rate, in addition to whether one or more predetermined characteristics of the accelerometer signal sampled during the second period of time differs from the stored one or more characteristics by at least a predetermined amount, when determining if a myocardial infarction occurred in the patient's heart.

In a fourth illustrative embodiment, a medical device for implantation on or within a heart may comprise a plurality of electrodes, an accelerometer, and a controller connected to the plurality of electrodes and the accelerometer. The controller may be configured to sense a baseline accelerometer signal generated via the accelerometer during a baseline period that reflects movement of the accelerometer during the baseline period, sense an accelerometer signal generated via the accelerometer during a test period subsequent to the baseline period that reflects movement of the accelerometer during the test period, and determine if a myocardial infarction has occurred. If it is determined that a myocardial infarction has occurred, the control may be further configured to cause an indication to be displayed on a display that a myocardial infarction has occurred.

Additionally, or alternatively, in the fourth illustrative embodiment, the medical device may be further configured to determine a baseline template based on one or more characteristics of the sensed baseline accelerometer signal.

Additionally, or alternatively, in the fourth illustrative embodiment, the controller may further be configured to sensing, via the plurality of electrodes, a cardiac electrical signal during the baseline period, and correlate one or more features of the sensed cardiac electrical signal with one or more features of the accelerometer signal sensed during the baseline period.

Additionally, or alternatively, in the fourth illustrative embodiment, the controller may further be configured to sense, via the plurality of electrodes, a cardiac electrical signal during the test period, correlate one or more features of the sensed cardiac electrical signal with one or more features of the accelerometer signal sensed during the test period, and determine that a myocardial infarction has occurred based on differences in the correlation between the cardiac electrical signal and the accelerometer signals sensed during the baseline period and the test period.

Additionally, or alternatively, in any of the above embodiments with respect to the fourth illustrative embodiment, the medical device may be further configured to determine a test template based on one or more characteristics of the accelerometer signal sensed during the test period.

Additionally, or alternatively, in any of the above embodiments with respect to the fourth illustrative embodiment, the controller may be further configured to store one or more determined templates in a memory of the medical device.

Additionally, or alternatively, in any of the above embodiments with respect to the fourth illustrative embodiment, the controller may be configured to determine if a myocardial infarction has occurred based on the sensed baseline accelerometer signal and the accelerometer signal sensed during the test period.

Additionally, or alternatively, in any of the above embodiments with respect to the fourth illustrative embodiment, the controller may be configured to determine if a myocardial infarction has occurred based on a comparison between the baseline template and the test template.

Additionally, or alternatively, in any of the above embodiments with respect to the fourth illustrative embodiment, to

determine if a myocardial infarction has occurred, the controller may be configured to receive an indication that a myocardial infarction has occurred from a device external to the medical device.

Additionally, or alternatively, in any of the above embodiments with respect to the fourth illustrative embodiment, the controller may be further configured to transmit the sensed baseline accelerometer signal and the sensed test accelerometer signal to a device external to the medical device.

Additionally, or alternatively, in any of the above embodiments with respect to the fourth illustrative embodiment, the controller may be further configured to determine a baseline template based on one or more characteristics of the baseline accelerometer signal, determine a test template based on one or more characteristics of the accelerometer signal during the test period, and transmit the determine baseline template and the determined test template to a device external to the medical device.

Additionally, or alternatively, in any of the above embodiments with respect to the fourth illustrative embodiment, the controller may be further configured to transmit an output signal for reception by a device external to the medical device to cause the device external to the medical device to display an indication that a myocardial infarction has occurred.

Additionally, or alternatively, in any of the above embodiments with respect to the fourth illustrative embodiment, the medical device may be a leadless cardiac pacemaker.

In a fifth illustrative embodiment, a leadless cardiac pacemaker (LCP) may comprise a plurality of electrodes, an accelerometer, a memory, and a controller connected to the accelerometer, the plurality of electrodes, and the memory. In some embodiments, the controller may be configured to receive an accelerometer signal from the accelerometer, sample the accelerometer signal during a first period of time, store one or more characteristics of the sampled accelerometer signal in the memory, and determine whether one or more predetermined characteristics of the accelerometer signal sampled during a second period of time differs from the stored one or more characteristics by at least a predetermined amount, and based on the result, determining if a myocardial infarction has occurred. If it is determined that a myocardial infarction has occurred, the controller may be further configured to transmit an output signal for reception by a device external to the LCP indicating that a myocardial infarction has occurred.

Additionally, or alternatively, in the fourth illustrative embodiment, the one or more characteristics may comprise one or more of an average amplitude of the accelerometer signal, an integral of the accelerometer signal, and a delay of the accelerometer signal relative to a sensed cardiac electrical signal.

Additionally, or alternatively, in any of the above embodiments with respect to the fourth illustrative embodiment, the output signal may cause the external device to display an indication that a myocardial infarction has occurred.

Additionally, or alternatively, in any of the above embodiments with respect to the fourth illustrative embodiment, the controller may be further configured to determine a patient activity level based at least in part on the received accelerometer signal, determine a heart rate of the patient's heart based on a sensed cardiac electrical signal, and use the patient activity level and heart rate, in addition to whether one or more predetermined characteristics of the accelerometer signal sampled during the second period of time differs from the stored one or more characteristics by at least a

predetermined amount, when determining if a myocardial infarction occurred in the patient's heart.

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

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:

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

FIG. 2 is a schematic block diagram of another illustrative medical device that may be used in conjunction with the LCP of FIG. 1;

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

FIG. 4 is a schematic diagram of a system including an LCP and another medical device, in accordance with another embodiment of the present disclosure;

FIG. 5 depicts a graph including a cardiac electrical signal and accelerometer signals tracings shown on the same time axis;

FIG. 6 depicts a graph including a cardiac electrical signal and accelerometer signals tracings shown on the same time axis;

FIG. 7 depicts a method of detecting an occurrence of a myocardial infarction (MI), in accordance with aspects of the present disclosure;

FIG. 8 depicts a graph including an accelerometer signal sensed during a baseline period and an accelerometer signal sensed during a test period after an occurrence of an MI locally to a device sensing the accelerometer signals;

FIG. 9 depicts a graph including an accelerometer signal sensed during a baseline period and an accelerometer signal sensed during a test period after an occurrence of an MI remote to a device sensing the accelerometer signals;

FIG. 10 depicts a graph including a cardiac electrical signal including elevated S-T segments and an accelerometer signal shown on the same time axis.

FIG. 11 depicts a graph of left ventricular pressure, aortic pressure, and a derivative of left ventricular pressure on the same time axis; and

FIG. 12 depicts a graph including a cardiac electrical signal and a heart sounds signal on the same time axis illustrating the timing of features between the two signals.

While the disclosure is amenable to various modifications and alternative forms, specifics thereof have been shown by way of embodiment 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

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.

FIG. 1 is a conceptual schematic block diagram of an exemplary leadless cardiac pacemaker (LCP) that may be implanted on the heart or within a chamber of the heart and may operate to sense physiological signals and parameters and deliver one or more types of electrical stimulation therapy to the heart of the patient. Example electrical stimulation therapy may include bradycardia pacing, rate responsive pacing therapy, cardiac resynchronization therapy (CRT), anti-tachycardia pacing (ATP) therapy and/or the like. As can be seen in FIG. 1, LCP 100 may be a compact device with all components housed within LCP 100 or directly on housing 120. In some instances, LCP 100 may include communication module 102, pulse generator module 104, electrical sensing module 106, mechanical sensing module 108, processing module 110, energy storage module 112, and electrodes 114.

As depicted in FIG. 1, LCP 100 may include electrodes 114, which can be secured relative to housing 120 and electrically exposed to tissue and/or blood surrounding LCP 100. Electrodes 114 may generally conduct electrical signals to and from LCP 100 and the surrounding tissue and/or blood. Such electrical signals can include communication signals, electrical stimulation pulses, and intrinsic cardiac electrical signals, to name a few. Intrinsic cardiac electrical signals may include electrical signals generated by the heart and may be represented by an electrocardiogram (ECG).

Electrodes 114 may include 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, electrodes 114 may be generally disposed on either end of LCP 100 and may be in electrical communication with one or more of modules 102, 104, 106, 108, and 110. In embodiments where electrodes 114 are secured directly to housing 120, an insulative material may electrically isolate the electrodes 114 from adjacent electrodes, housing 120, and/or other parts of LCP 100. In some instances, some or all of electrodes 114 may be spaced from housing 120 and connected to housing 120 and/or other components of LCP 100 through connecting wires. In such instances, the electrodes 114 may be placed on a tail (not shown) that extends out away from the housing 120. As shown in FIG. 1, in some embodiments, LCP 100 may include electrodes 114'. Electrodes 114' may be in addition to electrodes 114, or may replace one or more of electrodes 114. Electrodes 114' may be similar to electrodes 114 except that electrodes 114' are disposed on the sides of LCP 100. In some cases, electrodes 114' may increase the number of electrodes by which LCP 100 may deliver communication signals and/or electrical stimulation pulses, and/or may sense intrinsic cardiac electrical signals, communication signals, and/or electrical stimulation pulses.

Electrodes 114 and/or 114' may assume any of a variety of sizes and/or shapes, and may be spaced at any of a variety of spacings. For example, electrodes 114 may have an outer diameter of two to twenty millimeters (mm). In other embodiments, electrodes 114 and/or 114' may have a diameter of two, three, five, seven millimeters (mm), or any other suitable diameter, dimension and/or shape. Example lengths for electrodes 114 and/or 114' may include, for example, one, three, five, ten millimeters (mm), or any other suitable length. As used herein, the length is a dimension of electrodes 114 and/or 114' that extends away from the outer surface of the housing 120. In some instances, at least some

of electrodes 114 and/or 114' may be spaced from one another by a distance of twenty, thirty, forty, fifty millimeters (mm), or any other suitable spacing. The electrodes 114 and/or 114' of a single device may have different sizes with respect to each other, and the spacing and/or lengths of the electrodes on the device may or may not be uniform.

In the embodiment shown, communication module 102 may be electrically coupled to electrodes 114 and/or 114' and may be configured to deliver communication pulses to tissues of the patient for communicating with other devices such as sensors, programmers, other medical devices, and/or the like. Communication signals, as used herein, may be any modulated signal that conveys information to another device, either by itself or in conjunction with one or more other modulated signals. In some embodiments, communication signals may be limited to sub-threshold signals that do not result in capture of the heart yet still convey information. The communication signals may be delivered to another device that is located either external or internal to the patient's body. In some instances, the communication may take the form of distinct communication pulses separated by various amounts of time. In some of these cases, the timing between successive pulses may convey information. Communication module 102 may additionally be configured to sense for communication signals delivered by other devices, which may be located external or internal to the patient's body.

Communication module 102 may communicate to help accomplish one or more desired functions. Some example functions include delivering sensed data, using communicated data for determining occurrences of events such as arrhythmias, coordinating delivery of electrical stimulation therapy, and/or other functions. In some cases, LCP 100 may use communication signals to communicate raw information, processed information, messages and/or commands, and/or other data. Raw information may include information such as sensed electrical signals (e.g. a sensed ECG), signals gathered from coupled sensors, and the like. In some embodiments, the processed information may include signals that have been filtered using one or more signal processing techniques. Processed information may also include parameters and/or events that are determined by the LCP 100 and/or another device, such as a determined heart rate, timing of determined heartbeats, timing of other determined events, determinations of threshold crossings, expirations of monitored time periods, accelerometer signals, activity level parameters, blood-oxygen parameters, blood pressure parameters, heart sound parameters, and the like. Messages and/or commands may include instructions or the like directing another device to take action, notifications of imminent actions of the sending device, requests for reading from the receiving device, requests for writing data to the receiving device, information messages, and/or other messages commands.

In at least some embodiments, communication module 102 (or LCP 100) may further include switching circuitry to selectively connect one or more of electrodes 114 and/or 114' to communication module 102 in order to select which electrodes 114 and/or 114' that communication module 102 delivers communication pulses. It is contemplated that communication module 102 may be communicating with other devices via conducted signals, radio frequency (RF) signals, optical signals, acoustic signals, inductive coupling, and/or any other suitable communication methodology. Where communication module 102 generates electrical communication signals, communication module 102 may include one or more capacitor elements and/or other charge storage

devices to aid in generating and delivering communication signals. In the embodiment shown, communication module 102 may use energy stored in energy storage module 112 to generate the communication signals. In at least some examples, communication module 102 may include a switching circuit that is connected to energy storage module 112 and, with the switching circuitry, may connect energy storage module 112 to one or more of electrodes 114/114' to generate the communication signals.

As shown in FIG. 1, a pulse generator module 104 may be electrically connected to one or more of electrodes 114 and/or 114'. Pulse generator module 104 may be configured to generate electrical stimulation pulses and deliver the electrical stimulation pulses to tissues of a patient via one or more of the electrodes 114 and/or 114' in order to effectuate one or more electrical stimulation therapies. Electrical stimulation pulses as used herein are meant to encompass any electrical signals that may be delivered to tissue of a patient for purposes of treatment of any type of disease or abnormality. For example, when used to treat heart disease, the pulse generator module 104 may generate electrical stimulation pacing pulses for capturing the heart of the patient, i.e. causing the heart to contract in response to the delivered electrical stimulation pulse. In some of these cases, LCP 100 may vary the rate at which pulse generator 104 generates the electrical stimulation pulses, for example in rate adaptive pacing. In other embodiments, the electrical stimulation pulses may include defibrillation/cardioversion pulses for shocking the heart out of fibrillation or into a normal heart rhythm. In yet other embodiments, the electrical stimulation pulses may include anti-tachycardia pacing (ATP) pulses. It should be understood that these are just some examples. When used to treat other ailments, the pulse generator module 104 may generate electrical stimulation pulses suitable for neurostimulation therapy or the like. Pulse generator module 104 may include one or more capacitor elements and/or other charge storage devices to aid in generating and delivering appropriate electrical stimulation pulses. In at least some embodiments, pulse generator module 104 may use energy stored in energy storage module 112 to generate the electrical stimulation pulses. In some particular embodiments, pulse generator module 104 may include a switching circuit that is connected to energy storage module 112 and may connect energy storage module 112 to one or more of electrodes 114/114' to generate electrical stimulation pulses.

LCP 100 may further include an electrical sensing module 106 and mechanical sensing module 108. Electrical sensing module 106 may be configured to sense intrinsic cardiac electrical signals conducted from electrodes 114 and/or 114' to electrical sensing module 106. For example, electrical sensing module 106 may be electrically connected to one or more electrodes 114 and/or 114' and electrical sensing module 106 may be configured to receive cardiac electrical signals conducted through electrodes 114 and/or 114' via a sensor amplifier or the like. In some embodiments, the cardiac electrical signals may represent local information from the chamber in which LCP 100 is implanted. For instance, if LCP 100 is implanted within a ventricle of the heart, cardiac electrical signals sensed by LCP 100 through electrodes 114 and/or 114' may represent ventricular cardiac electrical signals. Mechanical sensing module 108 may include, or be electrically connected to, various sensors, such as accelerometers, including multi-axis accelerometers such as two-axis or three-axis accelerometers, gyroscopes, including multi-axis gyroscopes such as two-axis or three-axis gyroscopes, blood pressure sensors, heart sound sen-

sors, piezoelectric sensors, blood-oxygen sensors, and/or other sensors which measure one or more physiological parameters of the heart and/or patient. Mechanical sensing module 108, when present, may gather signals from the sensors indicative of the various physiological parameters. Both electrical sensing module 106 and mechanical sensing module 108 may be connected to processing module 110 and may provide signals representative of the sensed cardiac electrical signals and/or physiological signals to processing module 110. Although described with respect to FIG. 1 as separate sensing modules, in some embodiments, electrical sensing module 106 and mechanical sensing module 108 may be combined into a single module. In at least some examples, LCP 100 may only include one of electrical sensing module 106 and mechanical sensing module 108. In some cases, any combination of the processing module 110, electrical sensing module 106, mechanical sensing module 108, communication module 102, pulse generator module 104 and/or energy storage module may be considered a controller of the LCP 100.

Processing module 110 may be configured to direct the operation of LCP 100 and may, in some embodiments, be termed a controller. For example, processing module 110 may be configured to receive cardiac electrical signals from electrical sensing module 106 and/or physiological signals from mechanical sensing module 108. Based on the received signals, processing module 110 may determine, for example, occurrences and types of arrhythmias and other determinations such as whether LCP 100 has become dislodged. Processing module 110 may further receive information from communication module 102. In some embodiments, processing module 110 may additionally use such received information to determine occurrences and types of arrhythmias and/or other determinations such as whether LCP 100 has become dislodged. In still some additional embodiments, LCP 100 may use the received information instead of the signals received from electrical sensing module 106 and/or mechanical sensing module 108—for instance if the received information is deemed to be more accurate than the signals received from electrical sensing module 106 and/or mechanical sensing module 108 or if electrical sensing module 106 and/or mechanical sensing module 108 have been disabled or omitted from LCP 100.

After determining an occurrence of an arrhythmia, processing module 110 may control pulse generator module 104 to generate electrical stimulation pulses in accordance with one or more electrical stimulation therapies to treat the determined arrhythmia. For example, processing module 110 may control pulse generator module 104 to generate pacing pulses with varying parameters and in different sequences to effectuate one or more electrical stimulation therapies. As one example, in controlling pulse generator module 104 to deliver bradycardia pacing therapy, processing module 110 may control pulse generator module 104 to deliver pacing pulses designed to capture the heart of the patient at a regular interval to help prevent the heart of a patient from falling below a predetermined threshold. In some cases, the rate of pacing may be increased with an increased activity level of the patient (e.g. rate adaptive pacing). For instance, processing module 110 may monitor one or more physiological parameters of the patient which may indicate a need for an increased heart rate (e.g. due to increased metabolic demand). Processing module 110 may then increase the rate at which pulse generator 104 generates electrical stimulation pulses. Adjusting the rate of delivery of the electrical stimulation pulses based on the one or more physiological parameters may extend the battery life of LCP

100 by only requiring higher rates of delivery of electrical stimulation pulses when the physiological parameters indicate there is a need for increased cardiac output. Additionally, adjusting the rate of delivery of the electrical stimulation pulses may increase a comfort level of the patient by more closely matching the rate of delivery of electrical stimulation pulses with the cardiac output need of the patient.

For ATP therapy, processing module 110 may control pulse generator module 104 to deliver pacing pulses at a rate faster than an intrinsic heart rate of a patient in attempt to force the heart to beat in response to the delivered pacing pulses rather than in response to intrinsic cardiac electrical signals. Once the heart is following the pacing pulses, processing module 110 may control pulse generator module 104 to reduce the rate of delivered pacing pulses down to a safer level. In CRT, processing module 110 may control pulse generator module 104 to deliver pacing pulses in coordination with another device to cause the heart to contract more efficiently. In cases where pulse generator module 104 is capable of generating defibrillation and/or cardioversion pulses for defibrillation/cardioversion therapy, processing module 110 may control pulse generator module 104 to generate such defibrillation and/or cardioversion pulses. In some cases, processing module 110 may control pulse generator module 104 to generate electrical stimulation pulses to provide electrical stimulation therapies different than those examples described above.

Aside from controlling pulse generator module 104 to generate different types of electrical stimulation pulses and in different sequences, in some embodiments, processing module 110 may also control pulse generator module 104 to generate the various electrical stimulation pulses with varying pulse parameters. For example, each electrical stimulation pulse may have a pulse width and a pulse amplitude. Processing module 110 may control pulse generator module 104 to generate the various electrical stimulation pulses with specific pulse widths and pulse amplitudes. For example, processing module 110 may cause pulse generator module 104 to adjust the pulse width and/or the pulse amplitude of electrical stimulation pulses if the electrical stimulation pulses are not effectively capturing the heart. Such control of the specific parameters of the various electrical stimulation pulses may help LCP 100 provide more effective delivery of electrical stimulation therapy.

In some embodiments, processing module 110 may further control communication module 102 to send information to other devices. For example, processing module 110 may control communication module 102 to generate one or more communication signals for communicating with other devices of a system of devices. For instance, processing module 110 may control communication module 102 to generate communication signals in particular pulse sequences, where the specific sequences convey different information. Communication module 102 may also receive communication signals for potential action by processing module 110.

In further embodiments, processing module 110 may control switching circuitry by which communication module 102 and pulse generator module 104 deliver communication signals and/or electrical stimulation pulses to tissue of the patient. As described above, both communication module 102 and pulse generator module 104 may include circuitry for connecting one or more electrodes 114 and/114' to communication module 102 and/or pulse generator module 104 so those modules may deliver the communication signals and electrical stimulation pulses to tissue of the

patient. The specific combination of one or more electrodes by which communication module 102 and/or pulse generator module 104 deliver communication signals and electrical stimulation pulses may influence the reception of communication signals and/or the effectiveness of electrical stimulation pulses. Although it was described that each of communication module 102 and pulse generator module 104 may include switching circuitry, in some embodiments, LCP 100 may have a single switching module connected to the communication module 102, the pulse generator module 104, and electrodes 114 and/or 114'. In such embodiments, processing module 110 may control the switching module to connect modules 102/104 and electrodes 114/114' as appropriate.

In some embodiments, processing module 110 may include a pre-programmed chip, such as a very-large-scale integration (VLSI) chip 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 LCP 100. By using a pre-programmed chip, processing module 110 may use less power than other programmable circuits while able to maintain basic functionality, thereby potentially increasing the battery life of LCP 100. In other instances, processing module 110 may include a programmable microprocessor or the like. Such a programmable microprocessor may allow a user to adjust the control logic of LCP 100 after manufacture, thereby allowing for greater flexibility of LCP 100 than when using a pre-programmed chip. In still other embodiments, processing module 110 may not be a single component. For example, processing module 110 may include multiple components positioned at disparate locations within LCP 100 in order to perform the various described functions. For example, certain functions may be performed in one component of processing module 110, while other functions are performed in a separate component of processing module 110.

Processing module 110, in additional embodiments, may include a memory circuit 111 and processing module 110 may store information on and read information from the memory circuit 111. In other embodiments, LCP 100 may include a separate memory circuit (not shown) that is in communication with processing module 110, such that processing module 110 may read and write information to and from the separate memory circuit. The memory circuit 111, whether part of processing module 110 (as shown in FIG. 1) or separate from processing module 110, may be volatile memory, non-volatile memory, or a combination of volatile memory and non-volatile memory.

Energy storage module 112 may provide a power source to LCP 100 for its operations. In some embodiments, energy storage module 112 may be a non-rechargeable lithium-based battery. In other embodiments, the non-rechargeable battery may be made from other suitable materials. In some embodiments, energy storage module 112 may include a rechargeable battery. In still other embodiments, energy storage module 112 may include other types of energy storage devices such as capacitors or super capacitors.

To implant LCP 100 inside a patient's body, an operator (e.g., a physician, clinician, etc.), may fix LCP 100 to the cardiac tissue of the patient's heart. To facilitate fixation, LCP 100 may include one or more anchors 116. The one or more anchors 116 are shown schematically in FIG. 1. The one or more anchors 116 may include any number of fixation or anchoring mechanisms. For example, one or more anchors 116 may include one or more pins, staples, threads, screws, helix, tines, and/or the like. In some embodiments,

although not shown, one or more anchors **116** may include threads on its external surface that may run along at least a partial length of an anchor member. The threads may provide friction between the cardiac tissue and the anchor to help fix the anchor member within the cardiac tissue. In some cases, the one or more anchors **116** may include an anchor member that has a cork-screw shape that can be screwed into the cardiac tissue. In other embodiments, anchor **116** may include other structures such as barbs, spikes, or the like to facilitate engagement with the surrounding cardiac tissue.

In some examples, LCP **100** may be configured to be implanted on a patient's heart or within a chamber of the patient's heart. For instance, LCP **100** may be implanted within any of a left atrium, right atrium, left ventricle, or right ventricle of a patient's heart. By being implanted within a specific chamber, LCP **100** may be able to sense cardiac electrical signals originating or emanating from the specific chamber that other devices may not be able to sense with such resolution. Where LCP **100** is configured to be implanted on a patient's heart, LCP **100** may be configured to be implanted on or adjacent to one of the chambers of the heart, or on or adjacent to a path along which intrinsically generated cardiac electrical signals generally follow. In these examples, LCP **100** may also have an enhanced ability to sense localized intrinsic cardiac electrical signals and deliver localized electrical stimulation therapy. In embodiments where LCP **100** includes an accelerometer, LCP **100** may additionally be able to sense the motion of the cardiac wall to which LCP **100** is attached.

FIG. 2 depicts an embodiment of another device, medical device (MD) **200**, which may operate to sense physiological signals and parameters and deliver one or more types of electrical stimulation therapy to tissues of the patient. In the embodiment shown, 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 an energy storage module **218**. Each of modules **202**, **204**, **206**, **208**, and **210** may be similar to modules **102**, **104**, **106**, **108**, and **110** of LCP **100**. Additionally, energy storage module **218** may be similar to energy storage module **112** of LCP **100**. However, in some embodiments, MD **200** may have a larger volume within housing **220**. In such embodiments, MD **200** may include a larger energy storage module **218** and/or a larger processing module **210** capable of handling more complex operations than processing module **110** of LCP **100**.

While MD **200** may be another leadless device such as shown in FIG. 1, in some instances MD **200** may include leads, such as leads **212**. Leads **212** may include electrical wires that conduct electrical signals between electrodes **214** and one or more modules located within housing **220**. In some cases, leads **212** may be connected to and extend away from housing **220** of MD **200**. In some embodiments, leads **212** are implanted on, within, or adjacent to a heart of a patient. Leads **212** may contain one or more electrodes **214** positioned at various locations on leads **212** and various distances from housing **220**. Some leads **212** may only include a single electrode **214**, while other leads **212** may include multiple electrodes **214**. Generally, electrodes **214** are positioned on leads **212** such that when 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 other cases, the one or more of the electrodes **214** may be positioned subcutaneously but adjacent the patient's heart. The elec-

trodes **214** may conduct intrinsically generated electrical cardiac signals to leads **212**. Leads **212** may, in turn, conduct the received electrical cardiac signals to one or more of the modules **202**, **204**, **206**, and **208** of MD **200**. In some cases, MD **200** may generate electrical stimulation signals, and leads **212** may conduct the generated electrical stimulation signals to electrodes **214**. Electrodes **214** may then conduct the electrical stimulation signals to the cardiac tissue of the patient (either directly or indirectly). MD **200** may also include one or more electrodes **214** not disposed on a lead **212**. For example, one or more electrodes **214** may be connected directly to housing **220**.

Leads **212**, in some embodiments, may additionally contain one or more sensors, such as accelerometers, blood pressure sensors, heart sound sensors, blood-oxygen sensors, and/or other sensors which are configured to measure one or more physiological parameters of the heart and/or patient. In such embodiments, mechanical sensing module **208** may be in electrical communication with leads **212** and may receive signals generated from such sensors.

While not required, in some embodiments MD **200** may be an implantable medical device. In such embodiments, housing **220** of MD **200** may be implanted in, for example, a transthoracic region of the patient. 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 MD **200** from fluids and tissues of the patient's body. In such embodiments, leads **212** may be implanted at one or more various locations within the patient, such as within the heart of the patient, adjacent to the heart of the patient, adjacent to the spine of the patient, or any other desired location.

In some embodiments, MD **200** may be an implantable cardiac pacemaker (ICP). In these embodiments, MD **200** may have one or more leads, for example leads **212**, which are implanted on or within the patient's heart. The one or more leads **212** may include one or more electrodes **214** that are in contact with cardiac tissue and/or blood of the patient's heart. 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. MD **200** may be configured to deliver CRT, ATP therapy, bradycardia therapy, and/or other therapy types via leads **212** implanted within the heart. In some embodiments, MD **200** may additionally be configured to provide defibrillation/cardioversion therapy.

In some instances, MD **200** may be an implantable cardioverter-defibrillator (ICD). In such embodiments, MD **200** may include one or more leads implanted within a patient's heart. MD **200** may also be configured to sense electrical cardiac signals, determine occurrences of tachyarrhythmias based on the sensed electrical cardiac signals, and deliver defibrillation and/or cardioversion therapy in response to determining an occurrence of a tachyarrhythmia (for example by delivering defibrillation and/or cardioversion pulses to the heart of the patient). In other embodiments, MD **200** may be a subcutaneous implantable cardioverter-defibrillator (SICD). In embodiments where MD **200** is an SICD, one of leads **212** may be a subcutaneously implanted lead. In at least some embodiments where MD **200** is an SICD, MD **200** may include only a single lead which is implanted subcutaneously but outside of the chest cavity, however this is not required.

In some embodiments, MD **200** may not be an implantable medical device. Rather, MD **200** may be a device external to the patient's body, and electrodes **214** may be skin-electrodes that are placed on a patient's body. In such

embodiments, MD 200 may be able to sense surface electrical signals (e.g. electrical cardiac 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). MD 200 may further be configured to deliver various types of electrical stimulation therapy, including, for example, defibrillation therapy via skin-electrodes 214.

FIG. 3 illustrates an embodiment of a medical device system and a communication pathway through which multiple medical devices 302, 304, 306, and/or 310 of the medical device system may communicate. In the embodiment shown, medical device system 300 may include LCPs 302 and 304, external medical device 306, and other sensors/devices 310. External device 306 may be a device disposed external to a patient's body, as described previously with respect to MD 200. In at least some examples, external device 306 may represent an external support device such as a device programmer, as will be described in more detail below. Other sensors/devices 310 may be any of the devices described previously with respect to MD 200, such as ICPs, ICDs, and SICDs. Other sensors/devices 310 may also include various diagnostic sensors that gather information about the patient, such as accelerometers, blood pressure sensors, 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 system 300.

Various devices of system 300 may communicate via communication pathway 308. For example, 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 system 300 via communication pathway 308. In one embodiment, one or more of devices 302/304 may receive such signals and, based on the received signals, determine an occurrence of an arrhythmia. In some cases, device or devices 302/304 may communicate such determinations to one or more other devices 306 and 310 of system 300. In some cases, one or more of devices 302/304, 306, and 310 of 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. One or more of devices 302/304, 306, and 310 of system 300 may additionally communicate command or response messages via communication pathway 308. The command messages may cause a receiving device to take a particular action whereas response messages may include requested information or a confirmation that a receiving device did, in fact, receive a communicated message or data.

It is contemplated that the various devices of system 300 may communicate via pathway 308 using RF signals, inductive coupling, optical signals, acoustic signals, or any other signals suitable for communication. Additionally, in at least some embodiments, the various devices of system 300 may communicate via pathway 308 using multiple signal types. For instance, other sensors/device 310 may communicate with external device 306 using a first signal type (e.g. RF communication) but communicate with LCPs 302/304 using a second signal type (e.g. conducted communication). Further, in some embodiments, communication between devices may be limited. For instance, as described above, in some embodiments, LCPs 302/304 may communicate with external device 306 only through other sensors/devices 310, where LCPs 302/304 send signals to other sensors/devices 310, and other sensors/devices 310 relay the received signals to external device 306.

In some cases, the various devices of system 300 may communicate via pathway 308 using conducted communi-

cation signals. Accordingly, devices of 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. a voltage and/or current waveform punctuated with current and/or voltage pulses, referred herein as electrical communication pulses) into the patient's body via one or more electrodes of a transmitting device, and may receive the conducted communication signals via one or more electrodes of a receiving device. The patient's body may "conduct" the conducted communication signals from the one or more electrodes of the transmitting device to the electrodes of the receiving device in the system 300. In such embodiments, the delivered conducted communication signals may differ from pacing pulses, defibrillation and/or cardioversion pulses, or other electrical stimulation therapy signals. For example, the devices of system 300 may deliver electrical communication pulses at an amplitude/pulse width that is sub-threshold. That is, the communication pulses have an amplitude/pulse width designed to not capture the heart. In some cases, the amplitude/pulse width of the delivered electrical communication pulses may be above the capture threshold of the heart, but may be delivered during a refractory period of the heart and/or may be incorporated in or modulated onto a pacing pulse, if desired.

Additionally, unlike normal electrical stimulation therapy pulses, the electrical communication pulses may be delivered in specific sequences which convey information to receiving devices. For instance, 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 and/or amplitude modulated. Alternatively, or in addition, the time between pulses may be modulated to encode desired information. In some cases, a predefined sequence of communication pulses may represent a corresponding symbol (e.g. a logic "1" symbol, a logic "0" symbol, an ATP therapy trigger symbol, etc.). 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.

FIG. 4 depicts an illustrative medical device system 400 that may be configured to operate together. For example, system 400 may include multiple devices that are implanted within a patient and are configured to sense physiological signals, determine occurrences of cardiac arrhythmias, and deliver electrical stimulation to treat detected cardiac arrhythmias. In some embodiments, the devices of system 400 may be configured to determine occurrences of dislodgment of one or more devices of system 400. In FIG. 4, an LCP 402 is shown fixed to the interior of the right ventricle of the heart 410, and a pulse generator 406 is shown coupled to a lead 412 having one or more electrodes 408a-408c. In some cases, pulse generator 406 may be part of a subcutaneous implantable cardioverter-defibrillator (SICD), and the one or more electrodes 408a-408c may be positioned subcutaneously adjacent the heart. LCP 402 may communicate with the SICD, such as via communication pathway 308. The locations of LCP 402, pulse generator 406, lead 412, and electrodes 408a-c depicted in FIG. 4 are just exemplary. In other embodiments of system 400, LCP 402 may be positioned in the left ventricle, right atrium, or left atrium of the heart, as desired. In still other embodiments, LCP 402 may be implanted externally adjacent to heart 410 or even remote from heart 410.

Medical device system 400 may also include external support device 420. External support device 420 can be used

to perform functions such as device identification, device programming and/or transfer of real-time and/or stored data between devices using one or more of the communication techniques described herein, or other functions involving communication with one or more devices of system 400. As one example, communication between external support device 420 and pulse generator 406 can be performed via a wireless mode, and communication between pulse generator 406 and LCP 402 can be performed via a conducted communication mode. In some embodiments, communication between LCP 402 and external support device 420 is accomplished by sending communication information through pulse generator 406. However, in other embodiments, communication between the LCP 402 and external support device 420 may be via a communication module.

FIG. 4 only illustrates one example embodiment of a medical device system that may be configured to operate according to techniques disclosed herein. Other example medical device systems may include additional or different medical devices and/or configurations. For instance, other medical device systems that are suitable to operate according to techniques disclosed herein may include additional LCPs implanted within the heart. Another example medical device system may include a plurality of LCPs with or without other devices such as pulse generator 406, with at least one LCP capable of delivering defibrillation therapy. Still another example may include one or more LCPs implanted along with a transvenous pacemaker and with or without an implanted SCD. In yet other embodiments, the configuration or placement of the medical devices, leads, and/or electrodes may be different from those depicted in FIG. 4. Accordingly, it should be recognized that numerous other medical device systems, different from system 400 depicted in FIG. 4, may be operated in accordance with techniques disclosed herein. As such, the embodiment shown in FIG. 4 should not be viewed as limiting in any way.

In some embodiments, LCP 100 may be configured to operate in one or more modes. Within each mode, LCP 100 may operate in a somewhat different manner. For instance, in a first mode, LCP 100 may be configured to sense certain signals and/or determine certain parameters. In a second mode, LCP 100 may be configured to sense at least some different signals and/or determine at least some different parameters than in the first mode. In at least one mode, LCP 100 may be configured to determine whether a patient has suffered from a myocardial infarction (MI). For ease of description, a mode that includes LCP 100 being configured to determine whether a patient has suffered from an MI may be called an MI mode. Other modes may include one or more programming and/or therapy modes, and it may be possible for LCP 100 to be engaged in multiple modes concurrently.

When LCP 100 is in an MI mode, LCP 100 may be configured to sense one or more different signals, or one or more signals in a different manner, than when not in an MI mode. As one example, when not in an MI mode, LCP 100 may be configured to sense signals from an accelerometer of mechanical sensing module 108 at first time periods in relation to a cardiac cycle. When in an MI mode, LCP 100 may be configured to sense accelerometer signals at different or additional time periods in relation to a cardiac cycle, or at a higher sampling rate, than when not in an MI mode. In other embodiments, when in an MI mode, LCP 100 may be configured to process sensed signals in a different or additional manner than when not in an MI mode.

When part of a system, LCP 100 may enter an MI mode based on a signal communicated from another device, for

example external support device 420 or pulse generator 406. In other embodiments, LCP 100 may be configured to enter an MI mode periodically, intermittently, after a triggering event such as detection of another parameter exceeding a threshold, or the like. In some cases, LCP 100 may be configured to enter an MI mode once an hour, once every six hours, once a day, once every other day, or once a week, or any other suitable time period. In another example, LCP 100 may be configured to enter an MI mode based on one or more characteristics of a sensed signal, as will be described in more detail below.

Throughout this description, LCP 100 is described as sensing signals, determining parameters, and determining whether the patient has suffered from an MI. However, where LCP 100 is part of a system, such as system 400 as one example, the sensing of signals, determining parameters, and determining a whether the patient has suffered from an MI may be split up in any manner between any combinations of the devices of the system. For instance, LCP 100 may sense one or more signals and communicate those signals to another device, such as pulse generator 406. Pulse generator 406, then, may determine one or more parameters and/or and determining whether the patient has suffered from an MI based on the signals received from LCP 100. In other embodiments, pulse generator 406 may determine whether the patient has suffered from an MI on its own, for instance based off of signals sensed by pulse generator 406, and communicate an indication to LCP 100. LCP 100 may then use its own sensed signals to determine whether the patient has suffered from an MI. However, these are only a few examples contemplated by this disclosure of how the sensing, determining, and modulating processes may be split up amongst the devices of a system.

In some embodiments, LCP 100 may include an accelerometer and may be configured to enter an MI mode based on signals received from the accelerometer. For instance, LCP 100 may be configured to sense both cardiac electrical signals and signals generated by the accelerometer. In some instances, the accelerometer may be a three-axis accelerometer, but this is not required. Other contemplated embodiments include accelerometers having one or two axes.

FIG. 5 depicts a graph 500 that includes a number of signal tracings shown on the same time axis. The signal tracings of graph 500 may represent signals sensed or generated by LCP 100 during a time period where LCP 100 is attached to a wall of a patient's heart. In the example shown, signal 502 represents a cardiac electrical signal sensed by LCP 100. Signals 504, 506, and 508 all represent signals from different axes generated by a three-axis accelerometer of LCP 100. Signal 510 represents an accelerometer magnitude signal, which may be determined by summing signals 504, 506, and 508 or summing the absolute values of signals 504, 506, and 508. In other embodiments, signal 510 may represent a different signal generated by another combinations of signals 504, 506, and 508, such as a root-mean-square or root-sum-square of signals 504, 506, and 508, or any other derivation of signals 504, 506, and 508 as desired.

LCP 100 may be configured to sense one or more of signals 504, 506, 508 and/or 510, or generate one or more of signals 504, 506, 508 and/or 510 via the accelerometer, during predetermined time periods. For instance, to sense signals 504, 506, 508 and/or 510, LCP 100 may be configured to receive signals 504, 506, 508 and/or 510 at processing module 110. In some embodiments, LCP 100 may connect an output of the accelerometer to processing module 110 during the time periods where LCP 100 is sensing

signals **504**, **506**, **508** and/or **510**. In other embodiments, the accelerometer may be configured to actively output signals **504**, **506**, **508** and/or **510** during the time periods where LCP **100** is sensing signals **504**, **506**, **508** and/or **510**, for example using a communication link connecting processing module **110**. Where processing module **110** is a digital device, sensing signals **504**, **506**, **508** and/or **510** may be sampled signals **504**, **506**, **508** and/or **510**. In other embodiments, LCP **100** may control the generation of signals **504**, **506**, **508** and/or **510** by the accelerometer. For instance, LCP **100** may control when power is delivered to the accelerometer, and the accelerometer may only generate signals **504**, **506**, **508** and/or **510** when power is delivered to the accelerometer, or the accelerometer may only provide a substantial signal at an output during times where power is delivered to the accelerometer. In some cases, LCP **100** may switch the accelerometer from a lower-power state to a higher-power state during time periods where LCP **100** senses the accelerometer signal. During the lower-power state, the accelerometer may not provide an appreciable signal at an output for LCP **100** to sense.

As mentioned, LCP **100** may be configured to sense one or more signals during predetermined time periods. Such predetermined time periods may be represented by sensing periods **512a-512d** in FIG. 5. Sensing periods **512a-512d** may occur at regular intervals, such as every five seconds, every second, every eight hundred milliseconds, every seven hundred milliseconds, or any other suitable interval. Alternatively, LCP **100** may initiate sensing periods **512a-512d** after every beat, once every other beat, once every five beats, or at any other suitable frequency. In at least some cases, LCP **100** may adjust the timing of the intervals according to a heart rate of the patient such that sensing periods **512a-512d** occur during the same portion of each successive cardiac cycle.

In some cases, LCP **100** may implement sensing periods **512a-512d** based on one or more detected features of cardiac electrical signal **502**. For instance, LCP **100** may detect one or more features of cardiac electrical signal **502**, such as cardiac electrical events **511**. Cardiac electrical events **511** may, in some cases, represent R-waves or other morphological features that may be detected by LCP **100**. Upon detection of a cardiac electrical event **511**, LCP **100** may initiate a time delay, such as time delay **514**. Upon expiration of time delay **514**, LCP **100** may initiate sensing periods **512a-512d**, during which LCP **100** may sense one or more of signals **504**, **506**, **508** and **510**. In some cases, LCP **100** may adjust time delay **514** based on the heart rate of the patient. For instance, when the heart rate is at a relatively higher rate, LCP **100** may shorten time delay **514**, and when the heart rate is at a relatively lower rate, LCP **100** may lengthen time delay **514**. This may help to ensure that LCP **100** consistently initiates sensing periods **512a-512d** during the same or similar portion of each cardiac cycle.

In some embodiments, the length of time delay **514** may be chosen to align with a portion of the cardiac cycle where the heart is relatively mechanically inactive, such as shown in FIG. 5. For instance, time delay **514** may be chosen so that it expires between about fifty milliseconds to about one-hundred fifty milliseconds before the beginning of a next cardiac electrical event **511**. During this portion of the cardiac cycle, the heart muscle may be in a relatively relaxed state while filling with blood. Accordingly, during this portion of the cardiac cycle, the orientation of LCP **100**, and hence the accelerometer within LCP **100**, may be disposed at relatively consistent position. This may allow LCP **100** to

more accurately detect a posture of the patient and/or an activity level of the patient by minimizing movement caused by contraction of the heart.

To determine a posture of the patient, LCP **100** may compare the accelerometer signal captured during a sensing period with a stored template accelerometer signal. For example, LCP **100** may be initially programmed by orienting a patient in a first posture and sensing the accelerometer signal (relative to gravity) during one or more sensing periods while the patient is in the first posture. LCP **100** may store the sensed accelerometer signal in memory. In some cases, this may be repeated several times. In either cases, the LCP may generate an accelerometer signal template. This process may be repeated for different postures. LCP **100** may then compare current sensed accelerometer signals to the stored accelerometer signal templates to determine the current posture of the patient.

In some additional or alternative embodiments, LCP **100** may track a patient activity parameter using the accelerometer signal sensed during the sensing periods **512a-512d**. To determine a patient activity parameter, LCP **100** may determine a difference between the sensed or sampled current accelerometer signal and a previously sensed or sampled accelerometer signal. LCP **100** may generate an activity parameter based at least in part on this determined difference. In some cases, LCP **100** may store the determined difference and may generate new determined differences on a rolling basis as LCP **100** sensed or samples new current accelerometer signals. When so provided, LCP **100** may determine a patient activity parameter from multiple of these determined differences. For instance, LCP **100** may sum the differences together over a rolling period of time to produce a patient activity parameter. LCP **100** may then compare the patient activity parameter to one or more thresholds to determine an activity level of the patient.

When LCP **100** is in the MI mode, LCP **100** may adjust how LCP **100** senses the accelerometer signal(s). For example, FIG. 6 depicts an example cardiac electrical signal **502'**, accelerometer signals **504'**, **506'**, **508'** and **510'**, and sensing periods **512a'-512d'** during which LCP **100** may sense the accelerometer signals. As can be seen, time delay **514'** of FIG. 6 is relatively shorter than time delay **514** of FIG. 5. The length of time delay **514'** may be chosen to generally align with the contraction of the heart. This may help LCP **100** sense the accelerometer signals during sensing periods **512a'-512d'** that correspond to when the heart is actually contracting. Although not shown in FIG. 6, in some cases when in an MI mode, LCP **100** may also sense accelerometer signals **504'**, **506'**, **508'** and **510'** during sensing periods **512a-512d** in order to still obtain information related to patient posture and/or activity.

In some instances, time delay **514'** may be about ten milliseconds, about fifteen milliseconds, about twenty milliseconds, about twenty-five milliseconds, about thirty milliseconds, about thirty-five milliseconds, or any other suitable period of time following a detected R-wave. In general, time delay **514'** may have a value that is less than an electromechanical delay of the heart, which is the delay between when LCP **100** detects a cardiac electrical event **511'** (e.g. R-wave) and an onset of cardiac wall motion or a threshold amount of cardiac wall motion. Sensing periods **512a'-512d'** may have a duration of about twenty-five milliseconds, about thirty milliseconds, about forty milliseconds, or about fifty milliseconds. However, in other embodiments, sensing periods **512a'-512d'** may be substantially longer, for instance, about half of a cardiac cycle of the patient, about three quarters of the cardiac cycle of the

patient, or may span an entire cardiac cycle of the patient. In some additional or alternative embodiments, time delay 514' and/or sensing periods 512a'-512d' may have lengths that change along with the heart rate of the patient. As one example, for relatively higher heart rates, time delay 514' and/or sensing periods 512a'-512d' may be shorter than for relatively lower heart rates.

In general, LCP 100 may be able to use accelerometer signals sensed during a portion of the cardiac cycle that corresponds to sensing periods 512a'-512d' to determine whether a patient has suffered from an MI. For example, an MI may cause permanent damage to muscle cells of the heart in one or more localized areas of the heart. Accordingly, an MI may cause a change in the cardiac wall motion of the heart during a contraction. The area or areas of the heart affected by the MI may not contract at all, or may contract at a reduced level, while other areas of the heart may contract more forcefully in an attempt to make up for the damaged portions of the heart. Using an accelerometer, LCP 100, attached to the wall of the heart, may be used to detect these changes.

FIG. 7 depicts a flow diagram of an illustrative method 600 of determining whether an MI has occurred. In the example shown, LCP 100 is configured to sense an accelerometer signal generated via an accelerometer of the LCP 100 during a baseline period that reflects movement of the patient's heart during the baseline period, as at 602. The baseline period may be a period where it is known that the patient has not suffered from an MI or has suffered from a known number of MIs. During this baseline period, LCP 100 may sense accelerometer signals during portions of the cardiac cycle corresponding to sensing periods 512a'-512d'. In some additional or alternative embodiments, LCP 100 may also sense one or more cardiac electrical signal during the baseline period.

The method may further include determining a baseline template based on one or more characteristics of the baseline accelerometer signal, as shown at 604. In some embodiments, the baseline template may simply be the accelerometer signals sensed during the sensing periods, resulting in baseline accelerometer signal templates. Where LCP 100 also senses the cardiac electrical signal, the sensed cardiac signal may form a baseline cardiac signal template.

In additional or alternative embodiments, the baseline template may include one or more determined characteristics. For instance, LCP 100 may determine one or more baseline characteristics based on the sensed accelerometer signals and/or the sensed cardiac electrical signal. One example baseline characteristic may include the average amplitude of the sensed accelerometer signal during the sensing period. Another example baseline characteristic may include the maximum amplitude of the sensed accelerometer signal during the sensing period. Additional or alternative baseline characteristics may include the integral of the sensed accelerometer signal during the sensing period, the relative phase of the sensed accelerometer signals, a delay parameter, and/or a vector map.

The delay parameter, represented by delay period 515 in FIG. 6, may represent the time delay between detection of a cardiac electrical event 511' (e.g. R-wave) and a peak of the accelerometer signal or where the accelerometer signal crosses an amplitude threshold. In some cases, an MI may cause the delay period 515 to lengthen for one or more of the sensed accelerometer signals 504'-510'. For instance, delay period 515 of FIG. 6 for signal 510' may be shorter than

delay period 643 of FIG. 10 showing an example cardiac electrical signal and accelerometer signal after an MI has occurred.

The vector map may include a series of vectors determined based on the sensed accelerometer signals. For instance, where LCP 100 uses a three-axis accelerometer, LCP 100 may use accelerometer signals 504', 506', 508' and/or 510' sensed during sensing periods 512a'-512d' over time to determine a series of three-dimensional vectors forming a vector map.

In general, the baseline template may include any one of these determined baseline characteristics or any combination of these characteristics.

When developing the baseline template(s), it is contemplated that the accelerometer signals 504', 506', 508' and 510' may be repeatedly sensed over multiple heartbeats, and the resulting accelerometer signals 504', 506', 508' and 510' may be used to derive the baseline template(s). For example, the accelerometer signals 504', 506', 508' and 510' may be sensed over ten heartbeats, and then may be averaged, sometimes with a standard deviation or the like, when deriving the baseline template(s). This is just one example.

As described, LCP 100 may be the device that determines the baseline template. For instance, LCP 100 may determine one or more of the baseline characteristics based on the sensed accelerometer signals and/or the sensed cardiac electrical signal. However, in other embodiments, LCP 100 may communicate the sensed accelerometer signals and/or the sensed cardiac electrical signals to another device, such as pulse generator 406 and/or external support device 420. Pulse generator 406 and/or external support device 420, then, may determine the baseline template based on the received signals.

After the baseline template has been determined, the baseline template may be stored in a memory, as shown at 606. In some embodiments, LCP 100 may store the determined baseline template in its own memory. In alternative embodiments, LCP 100 may communicate the determined baseline template to another device, such as pulse generator 406 or external support device 420, and the receiving device may store the determined baseline template in its own memory.

Once the baseline template has been stored in a memory, LCP 100 may sense a signal generated by the accelerometer during a test period subsequent to the baseline period that reflects movement of the patient's heart during the test period, as shown at 607. For example, during a time period that occurs after the baseline time period, LCP 100 may sense the accelerometer signals and/or the cardiac electrical signal(s), which can be used to determine if the patient has suffered from an MI. During the test period, as during the baseline period, LCP 100 may be configured to sense the accelerometer signals and/or the cardiac electrical signal(s) during portions of the cardiac cycle corresponding to sensing periods 512a'-512d'.

In some cases, the method may include determining a test template based on one or more characteristics of the accelerometer signals during the test period, as at 610. LCP 100, pulse generator 406, and/or external support device 420 (or other devices that may be a part of system 400, such as implantable loop recorder) may determine the test template in a similar manner to how the baseline template is determined. In examples where the test template includes a delay parameter, the determining device may further utilize a cardiac electrical signal sensed during the test period. In some cases, the test template may simply be the sensed

accelerometer signals themselves, and/or an average of the sensed accelerometer signals over a plurality of heartbeats.

A device may compare the baseline template with the test template and determine if an MI has occurred in the patient's heart based on the comparison, as shown at **612**. In some instances, it may be LCP **100** doing the determining, pulse generator **406** doing the determining, or external support device **420** doing the determining. In some cases, the determining may be split among the various devices.

In some embodiments, the comparison may include performing one or more correlation analyses. For instance, where the baseline template and the test template include the accelerometer signals themselves, the comparison may include a cross-correlation analysis between the baseline accelerometer signal template or templates and the test accelerometer signal template or templates, resulting in a correlation parameter. Where the baseline template and the test template include one or more determined characteristics, the comparison may include a comparison of the differences between one or more of the determined characteristics of the baseline template and the test template.

As used herein, determining a difference between two values may include subtracting either value from the other. The process may further include determining an absolute value of the difference. Accordingly, comparison of determined differences to thresholds may correspond to comparing the absolute value of the determined difference to a threshold. In other embodiments, however, the determined difference may be directly compared to a threshold. In some of these embodiments, the threshold may have a negative value.

In embodiments where the comparison includes producing a correlation parameter, the comparing device may compare the correlation parameter to a threshold. If the correlation parameter is below the threshold, the device may determine that the patient has suffered from an MI. Where the comparison includes comparing a difference between the baseline template and the test template, e.g. comparing a difference between one or more of the determined characteristics of the baseline template and the test template, the difference may be compared to one or more thresholds. As one example, the comparing device may compare the difference between the baseline average amplitude of the accelerometer signal or signals and the test average amplitude of the accelerometer signal or signals to a threshold. If the difference is greater than the threshold, the device may determine that an MI has occurred.

In some embodiments, the comparing device may be able to distinguish between MIs that have occurred locally to LCP **100** within the heart or remote from LCP **100** within the heart. For instance, an MI that occurs locally to LCP **100** within the heart may cause the average amplitude of the accelerometer signal or signals to be relatively lower than the baseline average amplitude of the accelerometer signal or signals, as the infarcted tissue may contract to a lesser extent during contraction. However, an MI that occurs remote to LCP **100** within the heart may cause the average amplitude of the accelerometer signal or signals to be relatively higher than the baseline average amplitude of the accelerometer signal or signals, as the heart tissue locally to LCP **100** may contract to a greater extent to make up for the lower relative contraction of the infarcted tissue. Accordingly, in some embodiments, the comparing device may compare the difference between the baseline and the test average amplitude of the accelerometer signal or signals (e.g. the test average amplitude of the accelerometer signal or signals subtracted from the baseline average amplitude of

the accelerometer signal or signals) to multiple thresholds, such as a high threshold and a low threshold. In these embodiments, the comparing device may determine that an MI has occurred if the difference is either above the high threshold or below the low threshold. In some additional embodiments, the comparing device may further determine that the MI occurred remotely to LCP **100** if the difference is below the low threshold and determine the MI occurred locally to LCP **100** if the difference is above the high threshold.

FIG. **8** is a graph depicting an example accelerometer signal **630** sensed during the baseline period and an example accelerometer signal **632** sensed during a test period. Example accelerometer signal **632** represents an example accelerometer signal after the heart has experienced an MI locally to LCP **100**. FIG. **9** is a graph depicting an example accelerometer signal **634** sensed during the baseline period and an example accelerometer signal **636** sensed during a test period. Example accelerometer signal **636** represents an example accelerometer signal after the heart has experienced an MI remote to LCP **100**. As can be seen, accelerometer signal **632** has a relatively lower maximum amplitude and lower average amplitude than accelerometer signal **630**. Additionally, accelerometer signal **636** has a relatively higher maximum amplitude and average amplitude than accelerometer signal **634**.

In a similar manner, the comparing device may use the determined baseline maximum amplitude, integral, and/or phase compared to the test maximum amplitude, integral, and/or phase to determine whether an MI has occurred. For instance, the comparing device may compare differences between determined characteristics in the baseline template and determined characteristics in the test template to one or more thresholds to determine whether an MI has occurred.

Where the comparing device uses a vector map, the comparing device may compare differences in baseline vectors and test vectors that were determined at the same time within a sensing period. For instance, the comparing device may compare a baseline vector determined ten milliseconds into a sensing period with a test vector determined ten milliseconds into a sensing period. If the comparing device determines that the difference between the two vectors exceeds a threshold difference, the device may determine that an MI has occurred. In additional embodiments, the device may compare baseline and test vectors determined at multiple locations within a sensing period. For instance, the comparing device may compare five, eight, ten, fifteen, twenty, or any other suitable number of determined baseline and test vectors across the sensing period. In some of these embodiments, the comparing device may determine that an MI has occurred if any of the comparisons between the baseline and test vectors exceeds a threshold difference. In other embodiments, the comparing device may determine that an MI has occurred if a threshold number of the comparisons between baseline and test vectors exceed the threshold difference. In additional or alternative embodiments, the comparing device may track a total difference parameter that sums the differences between the baseline and test vectors. The comparing device may compare the total difference parameter to a threshold value and determine that an MI occurred if the total difference parameter exceeds the threshold value. These are just some examples.

In any of these manners, the comparing device may determine that an MI has occurred. Once the device has determined that an MI has occurred, the comparing device may cause an indication to be displayed on a display indicating that an MI has occurred in the patient's heart, as

shown at 614. For instance, where the comparing device is LCP 100 or pulse generator 420, the device may generate an alarm signal and communicate the alarm signal to a device that is external to the patient and includes a display for viewing by a user, such as external support device 420 as one example. Upon receipt of the alarm signal, the external device may cause an indication to be displayed on the display alerting a user that an MI has occurred. Where the comparing device is the external device, the external device may simply cause an indication to be displayed on its own display alerting a user that an MI has occurred. In at least some embodiments, the external device may be a cellular telephone.

Other contemplated embodiments include variations on the above described method for determining whether an MI has occurred. For instance, in some embodiments, the baseline template and the test template may include multiple determined characteristics, and the comparing device may compare multiple of the determined characteristics to determine whether an MI has occurred. In some of these embodiments, the comparing device may not determine that an MI has occurred unless multiple of the determined characteristics indicate that an MI has occurred. As one example, the comparing device may only determine that an MI has occurred after determining that differences between two determined characteristics of the baseline and test templates fall above or below respective threshold values. For instance, the correlation parameter and the difference between average amplitudes of the baseline and test templates may need to fall above or below respective threshold values. However, more generally, the comparing device may use any two of the disclosed determined characteristics and the correlation parameter to make the determination about whether an MI has occurred. In other embodiments, the determining device may use three, four, or five of the determined characteristics and/or the correlation parameter, or all of the determined characteristics and/or the correlation parameter in determining that an MI has occurred.

In some instances, the method used to determine whether an MI has occurred may include creating separate baseline and test templates based on intrinsic cardiac electrical events and paced cardiac electric events. For instance, the response of the heart, and hence the accelerometer signal or signals and/or the cardiac electrical signal sensed by LCP 100, may be different depending on whether the a cardiac electrical event is an intrinsic cardiac electrical event or is in response to delivered pacing pulse. In these embodiments, the device that determines the baseline templates and the test templates may determine a baseline template and a test template using signals sensed after an intrinsic cardiac electrical event and a baseline template and a test template using signals sensed after a paced cardiac electrical event. In some cases, the device that determines whether an MI has occurred may determine that an MI has occurred based on comparisons between either of the determined baseline and test templates. In some cases, the comparing device may only determine that an MI has occurred after comparisons between baseline and test templates determined using signals sensed after an intrinsic cardiac electrical event and comparisons between baseline and test templates determined using signals sensed after a paced cardiac electrical event indicate that an MI has occurred.

In some cases, determining that a difference between a baseline template and a test template falls above or below a threshold may only be one step in the process to determine whether an MI has occurred. For instance, a method may further include analysis of one or more other sensed signals,

as signals other than the sensed accelerometer signals may change after an MI has occurred. FIG. 10 depicts an example graph including cardiac electrical signal 640 and accelerometer signal 642, both sensed after an MI has occurred. The device that determines whether an MI has occurred may use cardiac electrical signal 640 itself to determine whether an MI has occurred. For instance, the specific morphology of a sensed cardiac electrical signal may differ before and after an MI. One difference that commonly occurs is an elongated and/or elevated S-T segment, as depicted in region 646 of cardiac electrical signal 640. In some embodiments, the determining device may compare a baseline cardiac electrical signal template with a test cardiac electrical signal or signal template, for instance using one or more correlation analyses, and determine one or more correlation parameters. The determining device may then compare the one or more determined correlation parameters to a threshold and, based on this comparison, determine whether an MI has occurred. In some instances, the template and the test signal may only include a portion of the sensed cardiac electrical signal, such as the portion encompassing the S-T segment of the cardiac electrical signal within region 646. However, it should be understood that this is only one example in which the comparing device may determine an occurrence of an elevated S-T segment.

In some additional or alternative embodiments, the determining device may further use a determined isovolumic contraction period to determine whether an MI has occurred. For instance, LCP 100 may include a pressure sensor and may sense intra-ventricular pressure. FIG. 11 depicts intra-ventricular pressure signal 650 along with intra-aorta pressure 652. FIG. 11 further depicts dp/dt signal 654 representing a derivative of the intra-ventricular pressure signal, which may be determined by LCP 100 or another device based on receipt of intra-ventricular pressure signal 650 transmitted by LCP 100. Based on sensed intra-ventricular pressure signal 650, a device may determine an isovolumic contraction period during the baseline time period and a test time period. In the example of FIG. 11, period 655 may represent the isovolumic contraction period. Illustrative period 655 is the period of time after dp/dt signal 654 rises above threshold 653 until dp/dt signal 654 reaches a peak. After an MI, the length of the isovolumic contraction period, e.g. period 655, may lengthen. Accordingly, the determining device may compare the isovolumic contraction period determined during the baseline time period along with an isovolumic contraction period determined during a test period. If the difference between these two parameters is greater than a threshold amount, the device may determine that an MI has occurred.

In some cases, the determining device may use the comparison between the isovolumic contraction period determined during the baseline time period and the isovolumic contraction period determined during a test period as a basis for determining that the heart is experiencing ischemic conditions. For instance, lengthening of the isovolumic contraction period may indicate ischemia as opposed to an occurrence of an MI. Accordingly, a device may determine that the heart is experiencing ischemic conditions if the difference between the isovolumic contraction period determined during the baseline time period and the isovolumic contraction period determined during a test period is greater than a threshold amount. In some embodiments, the threshold amount for determining that the heart is experiencing ischemic conditions may be less than the threshold amount for determining whether there has been an occurrence of an MI. In other embodiments, however, the thresholds may be

the same. In some embodiments where the thresholds are the same, the device may determine that the heart is experiencing ischemic conditions rather than determining an occurrence of an MI when no other signals (e.g. cardiac and/or accelerometer signals) or signal characteristics indicate that an MI has occurred. Where the device determines that the heart is experiencing ischemic conditions, the device may output an alarm signal indicating that the heart is experiencing ischemic conditions.

In some cases, the determining device may use heart sounds to help determine whether an MI has occurred. For instance, a device, using the accelerometer signal or signals sensed by LCP 100, may be able to determine a heart sounds signal (e.g. first heart sound, second heart sound). FIG. 12 depicts sensed cardiac electrical signal 570 along with heart sounds signal 572. Similar to the accelerometer signal or signals and the cardiac electrical signal, heart sounds signal 572 may differ before and after an MI. For instance, heart sounds signal 572 may have a different morphology before and after an MI. Additionally, or alternatively, one or more features of heart sounds signal 572 may occur at different times in relation to each other, or in relation to one or more features of cardiac electrical signal 570. As one example, in a healthy heart, heart sound features 574a and 574a' may begin in close relation to peaks of cardiac electrical events 579, represented by lines 571 and 573. However, after an MI, there may be a delay between a peak of a cardiac electrical event and the beginning of a heart sound feature, such as features 574a or 574a'. Another indication may be the time between heart sound features 574a and 574b or 574a' and 574b', represented by time period 575. For instance, after an MI, time period 575 may become shorter or longer.

Accordingly, the device that determines whether an MI has occurred may alternatively or additionally use differences in a heart sounds signal template determined during the baseline period, e.g. a baseline heart sounds signal template, and a heart sounds signal template determined during a test period, e.g. a test heart sounds signal template, to determine whether an MI has occurred. For instance, the determining device may compare the heart sounds signal templates using a correlation analysis to produce a correlation parameter. The device may compare the correlation parameter to a threshold, and determine that an MI has occurred if the parameter is lower than the threshold. Additionally, or alternatively, the determining device may determine one or more characteristics or timings of the heart sounds signal templates, such as a timing between a peak of a cardiac electrical event and a beginning of a heart sounds feature or the timing between two heart sounds features. The determining device may then compare the one or more determined timings to one or more thresholds to determine whether an MI has occurred. For instance, the device may determine an MI has occurred if the difference between the timing of the peak of a cardiac electrical event and a beginning of a heart sounds feature or the timing between two heart sounds features is greater than a threshold.

In some embodiments, the device that determines whether an MI has occurred may determine that an MI has occurred after any of the accelerometer signals, the cardiac electrical signals, the heart sounds signals, and/or the isovolumic contraction period indicate that an MI has occurred. However, in other embodiments, the determining device may only determine that an MI has occurred if multiple of the accelerometer signals, the cardiac electrical signals, the heart sounds signals, and the isovolumic contraction period indicate that an MI has occurred. For instance, the deter-

mining device may determine that an MI has occurred after determinations made based on the accelerometer signals and the cardiac electrical signals indicate that an MI has occurred. However, this is just one example. In other embodiments, the determining device may only determine that an MI has occurred after any two of the accelerometer signals, the cardiac electrical signals, the heart sounds signals, and the isovolumic contraction period indicate that an MI has occurred. In still other embodiments, the determining device may only determine that an MI has occurred after any three of the accelerometer signals, the cardiac electrical signals, the heart sounds signals, and the isovolumic contraction period, or all of the accelerometer signals, the cardiac electrical signals, the heart sounds signals, and the isovolumic contraction period, indicate that an MI has occurred.

In some cases, the determining device may employ a cascading scheme for determining whether an MI has occurred. For example, the determining device may initially monitor only one (or a few) of the accelerometer signals, the cardiac electrical signals, the heart sounds signals, and/or the isovolumic contraction period to determine whether an MI has occurred. After the determining device has determined that the initially monitored signal(s) or period indicate that an MI has occurred, the determining device may use a second one of the accelerometer signals, the cardiac electrical signals, the heart sounds signals, and/or the isovolumic contraction period to determine whether an MI has occurred. If the second one of the accelerometer signals, the cardiac electrical signals, the heart sounds signals, and/or the isovolumic contraction period also indicates that an MI has occurred, the determining device may ultimately determine that an MI has occurred and generate an alarm signal. In some cases, the determining device may switch to using a third one of accelerometer signals, the cardiac electrical signals, the heart sounds signals, and/or the isovolumic contraction period to determine whether an MI has occurred before generating an alarm signal. In some cases, the determining device may also use the fourth of the accelerometer signals, the cardiac electrical signals, the heart sounds signals, and/or the isovolumic contraction period to determine whether an MI has occurred before generating an alarm signal. In general, the determining device may use the accelerometer signals, the cardiac electrical signals, the heart sounds signals, and/or the isovolumic contraction period in any order or combination to determine whether an MI has occurred and to generate an alarm signal.

In another example, the determining device may initially monitor a cardiac electrical signal and look for an elongated and/or elevated ST segment of the cardiac electrical signal. For instance, the determining device may compare a portion of the cardiac electrical signal containing the ST segment to one or more templates of an elongated and/or elevated ST segment and determine that the portion of the cardiac electrical signal contains an elongated and/or elevated ST segment based on a threshold fit to the one or more templates. Once an elongated and/or elevated ST segment is detected, the determining device may turn on the accelerometer of the LCP to monitor the accelerometer signals to confirm whether or not an MI has occurred. In any event, it is contemplated that the determining device may save some energy by only monitoring or using a single or small number of signals to initially detect if an MI occurred, and then monitor other signals to confirm whether an MI occurred.

Another variation to the disclosed methods may include, before determining whether an MI has occurred, determining an activity level, heart rate, and/or posture of the patient.

For instance, during the baseline period, LCP 100 may be configured to determine and store a baseline activity level, a baseline heart rate, and a baseline posture. In these examples, before switching into an MI mode, LCP 100 may determine a test activity level, a test heart rate, and a test posture. If any one of these test parameters differs from their corresponding baseline parameter by more than a threshold amount, LCP 100 may skip entering the MI mode. For instance, as described, LCP 100 may be configured to enter an MI mode based periodically, intermittently or based on a trigger. Once the period expires or LCP 100 receives a trigger, LCP 100 may determine one or more of the test activity level, a test heart rate, and a test posture.

LCP 100 may skip entering the MI mode and wait for another trigger or a next scheduled time period if LCP 100 determines that one of activity level, heart rate, or posture test parameters differ from their corresponding baseline parameter by more than a threshold amount. In some cases, it may be desirable to operate in this manner because the signals used to determine whether an MI has occurred may differ based on the activity level of the patient, the heart rate of the patient, and/or the posture of the patient. Accordingly, where any of these parameters differ by greater than a threshold amount from their corresponding baseline parameter, the signals sensed during the test period may differ due to the differences in activity level, the heart rate, and/or the posture rather than because of an occurrence of an MI. LCP 100 may then reduce or eliminate false positive determinations of occurrences of MI by only entering MI mode when a detected activity level, heart rate, and/or posture are similar to the activity level, heart rate, and/or posture during the baseline period. Rather than operating in this manner, the LCP 100 may be configured to compensate for the different activity level, heart rate, or posture test parameters when determining whether an MI occurred.

Those skilled in the art will recognize that the present disclosure may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. For instance, as described herein, various embodiments include one or more modules described as performing various functions. However, other embodiments may include additional modules that split the described functions up over more modules than that described herein. Additionally, other embodiments may consolidate the described functions into fewer modules.

Although various features may have been described with respect to less than all embodiments, this disclosure contemplates that those features may be included on any embodiment. Further, although the embodiments described herein may have omitted some combinations of the various described features, this disclosure contemplates embodiments that include any combination of each described feature. Accordingly, departure in form and detail may be made without departing from the scope and spirit of the present disclosure as described in the appended claims.

What is claimed is:

1. A method of sensing for an occurrence of a myocardial infarction in a patient's heart using a leadless cardiac pacemaker that is affixed to the patient's heart, the method comprising:

sensing, by the leadless cardiac pacemaker, a baseline first sensor signal generated via a first sensor of the leadless cardiac pacemaker during a baseline period, the first sensor comprising one or more of a cardiac electrical signal sensor, a heart sound sensor, and an isovolumic contraction period sensor;

sensing, by the leadless cardiac pacemaker, a baseline accelerometer signal generated via an accelerometer of the leadless cardiac pacemaker during the baseline period that reflects movement of the patient's heart during the baseline period;

determining a baseline template based on one or more characteristics of the baseline first sensor signal and the baseline accelerometer signal;

storing the baseline template in a memory;

sensing, by the leadless cardiac pacemaker, the baseline first sensor signal generated via the first sensor during a first test period subsequent to the baseline period;

determining a first test template based on one or more characteristics of the first sensor signal during the test period;

comparing the first test template with the baseline template, and based on the comparison, determining if a myocardial infarction may have occurred in the patient's heart;

when it is determined that a myocardial infarction may have occurred in the patient's heart, then:

sensing, by the leadless cardiac pacemaker, the accelerometer signal generated via the accelerometer during a second test period subsequent to the first test period that reflects movement of the patient's heart during the second test period;

determining a second test template based on one or more characteristics of the accelerometer signal during the second test period;

comparing the second test template with the baseline template, and based on the comparison, determining if a myocardial infarction occurred in the patient's heart;

communicating information from the leadless cardiac pacemaker to an external device; and

when it is determined that a myocardial infarction occurred in the patient's heart based on the comparison of the second test template with the baseline template, displaying an indication on a display of the external device that a myocardial infarction occurred in the patient's heart.

2. The method of claim 1, further comprising:

transmitting an output signal for reception by the external device that is located external to the patient indicating that a myocardial infarction occurred in the patient's heart.

3. The method of claim 2, wherein the external device is a device programmer.

4. The method of claim 2, wherein the external device is a cellular telephone.

5. The method of claim 1, wherein the memory is part of the leadless cardiac pacemaker.

6. The method of claim 1, wherein the baseline template and the first test template are compared by the leadless cardiac pacemaker.

7. The method of claim 1, wherein the leadless cardiac pacemaker determines if a myocardial infarction occurred in the patient's heart.

8. The method of claim 1, wherein the memory is part of the external device that is located external to the patient.

9. The method of claim 1, wherein the baseline template and the first test template are compared by the external device that is located external to the patient.

10. The method of claim 1, wherein the external device is located external to the patient and determines if a myocardial infarction occurred in the patient's heart.

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11. A method of sensing for an occurrence of a myocardial infarction in a patient's heart using a leadless cardiac pacemaker that is affixed to the patient's heart, the method comprising:

determining when one or more baseline conditions exist; 5
 when the one or more baseline conditions exist, then:
 sampling, by the leadless cardiac pacemaker, a baseline accelerometer signal generated via an accelerometer of the leadless cardiac pacemaker during a baseline period that reflects movement of the patient's heart during the baseline period; 10
 storing in a memory one or more characteristics of the baseline accelerometer signal sensed during the baseline period;
 after storing in the memory the one or more characteristics of the baseline accelerometer signal sensed during the baseline period, determining when the one or more baseline conditions again exist; 15
 when the one or more baseline conditions again exist:
 sampling, by the leadless cardiac pacemaker, an accelerometer signal generated via the accelerometer that reflects movement of the patients' heart during a test period; 20
 comparing one or more characteristics of the accelerometer signal sampled during the test period with the one or more characteristics of the baseline accelerometer signal sampled during the baseline period, 25

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and based on the comparison, determining if a myocardial infarction occurred in the patients' heart; communicating information from the leadless cardiac pacemaker to an external device; and
 when it is determined that a myocardial infarction occurred in the patient's heart, displaying an indication on a display of the external device that a myocardial infarction occurred in the patient's heart.

12. The method of claim 11, wherein the memory is part of the leadless cardiac pacemaker.

13. The method of claim 11, wherein the one or more characteristics of the accelerometer signal sampled during the test period and the one or more characteristics of the baseline accelerometer signal sampled during the baseline period are compared by the leadless cardiac pacemaker.

14. The method of claim 11, wherein the leadless cardiac pacemaker determines if a myocardial infarction occurred in the patient's heart.

15. The method of claim 11, wherein the external device is located external to the patient and determines if a myocardial infarction occurred in the patient's heart.

16. The method of claim 11, wherein the one or more baseline conditions comprises one or more of a baseline activity level condition, a baseline heart rate condition, and a baseline posture condition.

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当前申请(专利权)人(译)	心脏起搏器, INC.		
[标]发明人	KANE MICHAEL J SHUROS ALLAN CHARLES SCHMIDT BRIAN L MAILE KEITH R HAASL BENJAMIN J		
发明人	KANE, MICHAEL J. SHUROS, ALLAN CHARLES SCHMIDT, BRIAN L. MAILE, KEITH R. HAASL, BENJAMIN J.		
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摘要(译)

公开了用于确定心肌梗塞发生的系统, 装置和方法。在一个实施例中, 感测心肌梗塞发生的方法可包括在基线期间感测基线加速度计信号, 基于基线加速度计信号的一个或多个特征确定基线模板, 以及将基线模板存储在存储器中。该方法还可以包括在基线之后的测试时段期间感测加速度计信号, 基于测试时段期间加速度计信号的一个或多个特性确定测试模板, 以及将基线模板与测试模板进行比较, 并且基于比较, 确定患者心脏是否发生心肌梗塞。如果确定患者心脏中发生心肌梗塞, 则该方法可以进一步包括在显示器上显示心肌梗塞发生的指示。

