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Brooke

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(54) **METHOD AND APPARATUS FOR PHRENIC STIMULATION DETECTION**

(58) **Field of Classification Search**
None
See application file for complete search history.

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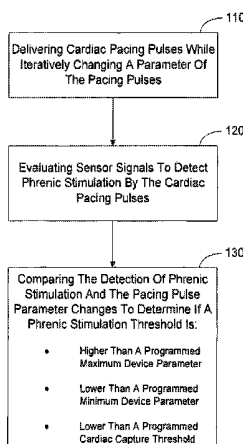
(57) **ABSTRACT**

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CPC *A61N 1/3712* (2013.01); *A61B 5/4029* (2013.01); *A61B 5/4848* (2013.01); *A61N 1/3601* (2013.01); *A61N 1/371* (2013.01); *A61N 1/36585* (2013.01); *A61B 5/04001* (2013.01); *A61B 5/042* (2013.01); *A61B 5/0488* (2013.01); *A61B 5/1107* (2013.01);

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Approaches for characterizing a phrenic stimulation threshold, a cardiac capture threshold, a maximum device parameter, and a minimum device parameter are described. A plurality of cardiac pacing pulses can be delivered by using a cardiac pacing device, a pacing parameter of the plurality of cardiac pacing pulses being changed between delivery of at least some of the pulses. One or more sensor signals can be evaluated to detect stimulation of the phrenic nerve by one or more of the plurality of cardiac pacing pulses. The evaluation of the one or more sensor signals and the pacing parameter can be compared to determine if a phrenic stimulation threshold is at least one of higher than a maximum device parameter and lower than a minimum device parameter.

20 Claims, 9 Drawing Sheets



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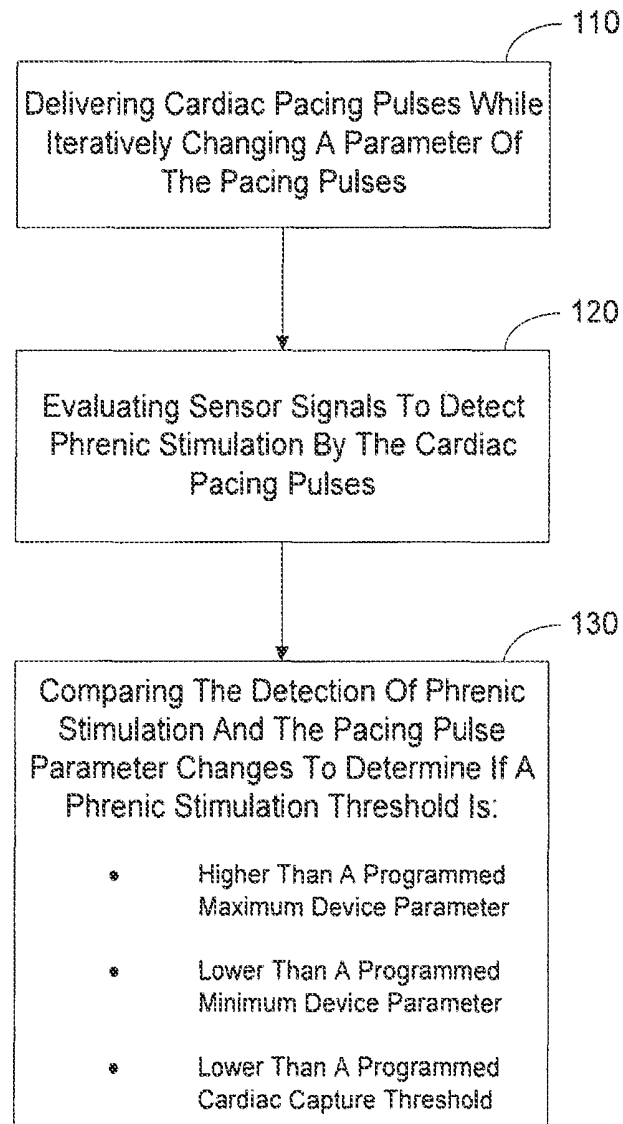
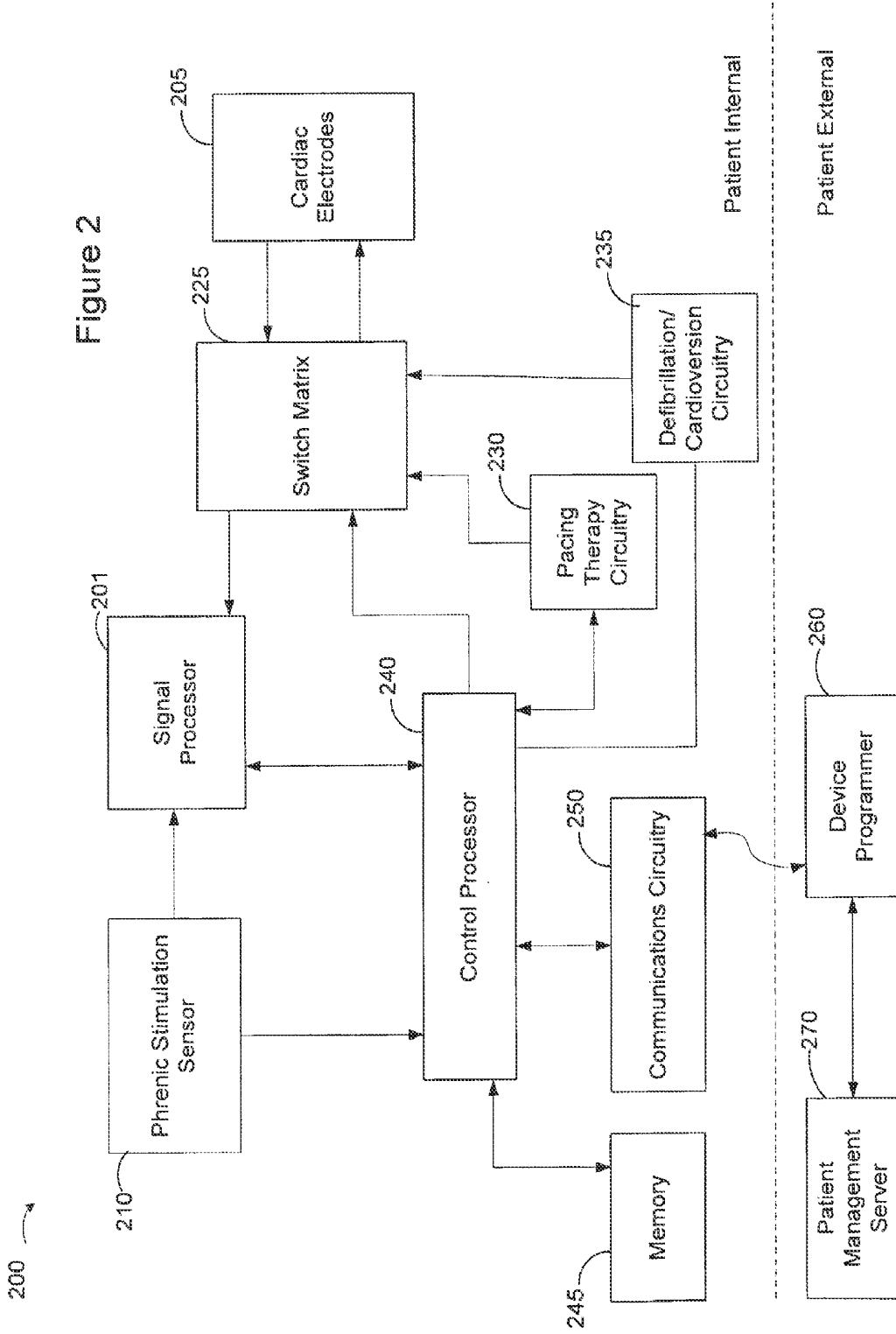


Figure 1

Figure 2



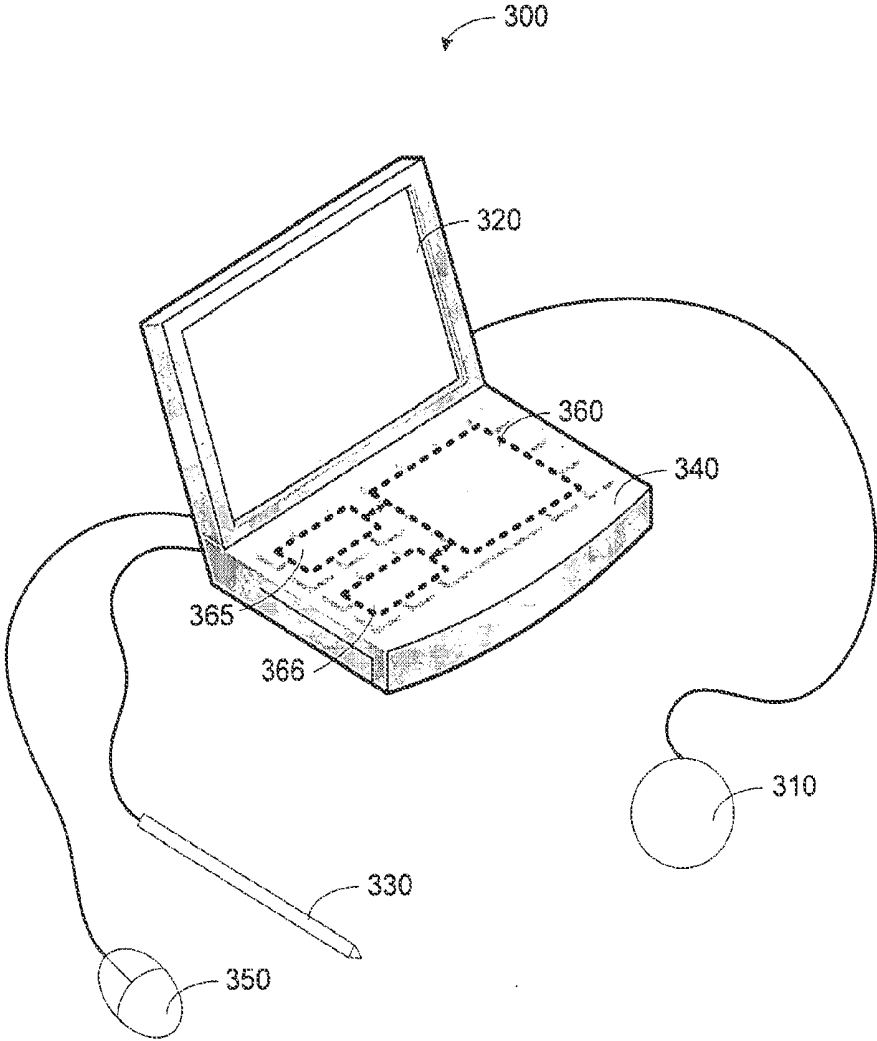


Figure 3

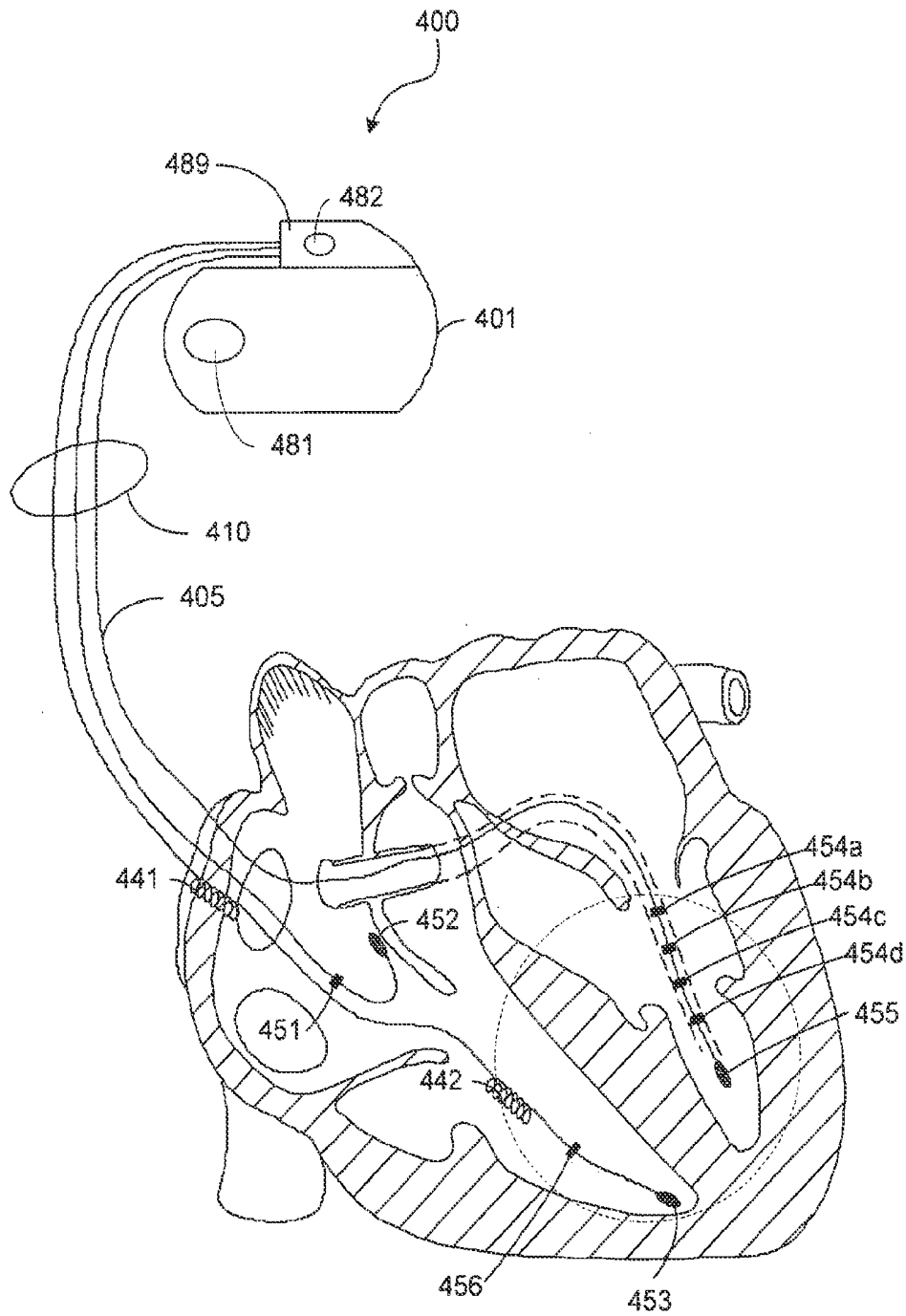


Figure 4

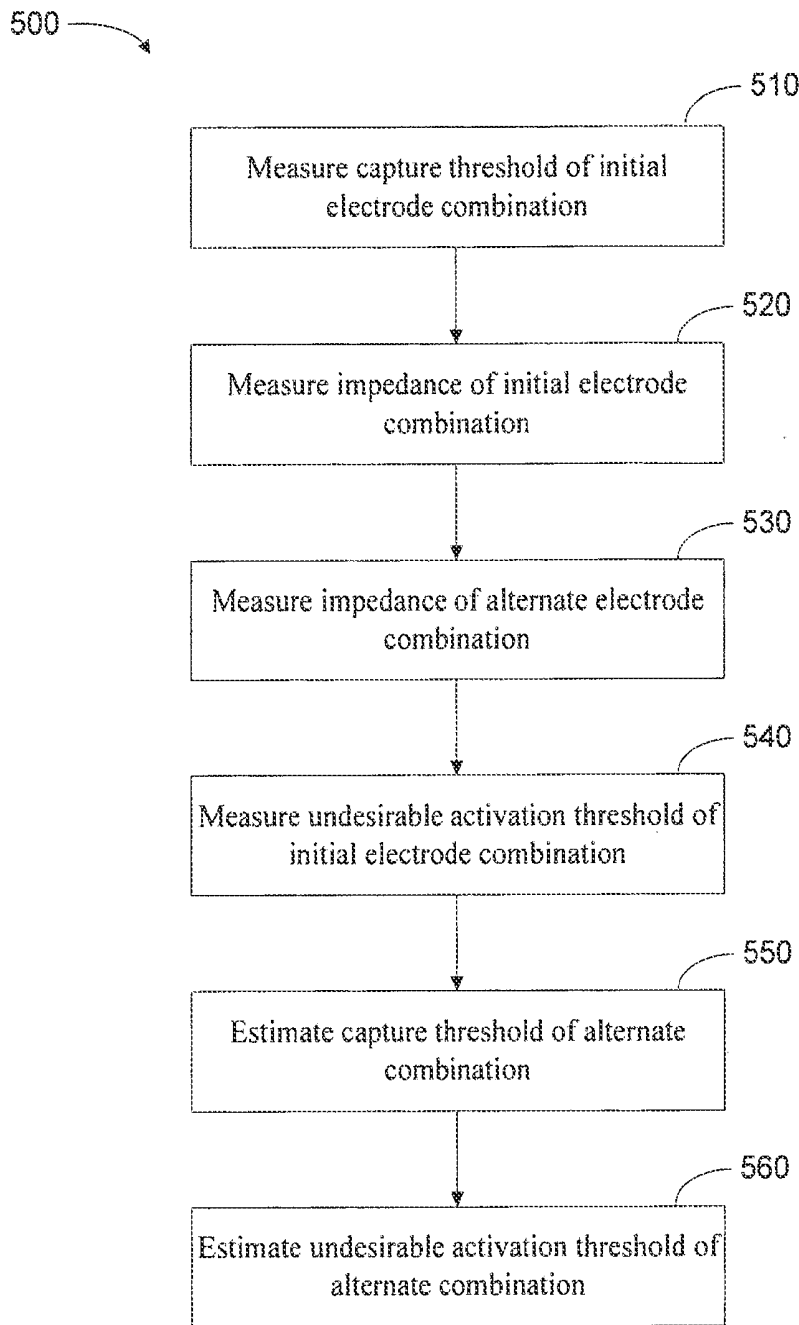


Figure 5

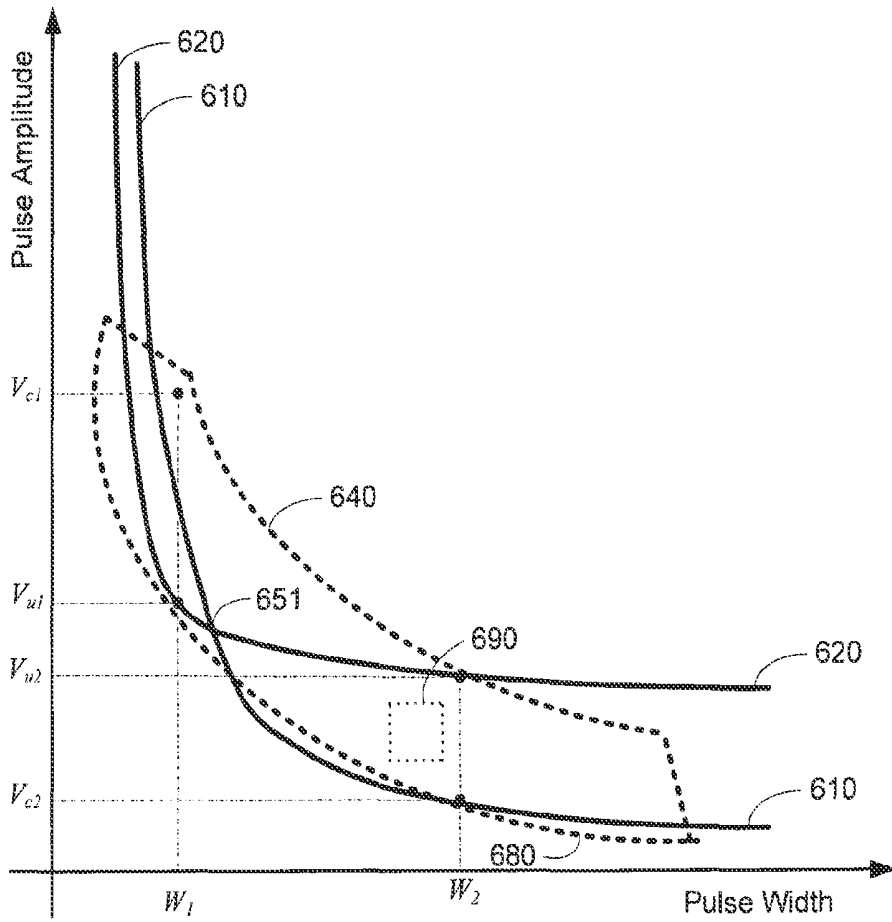


Figure 6

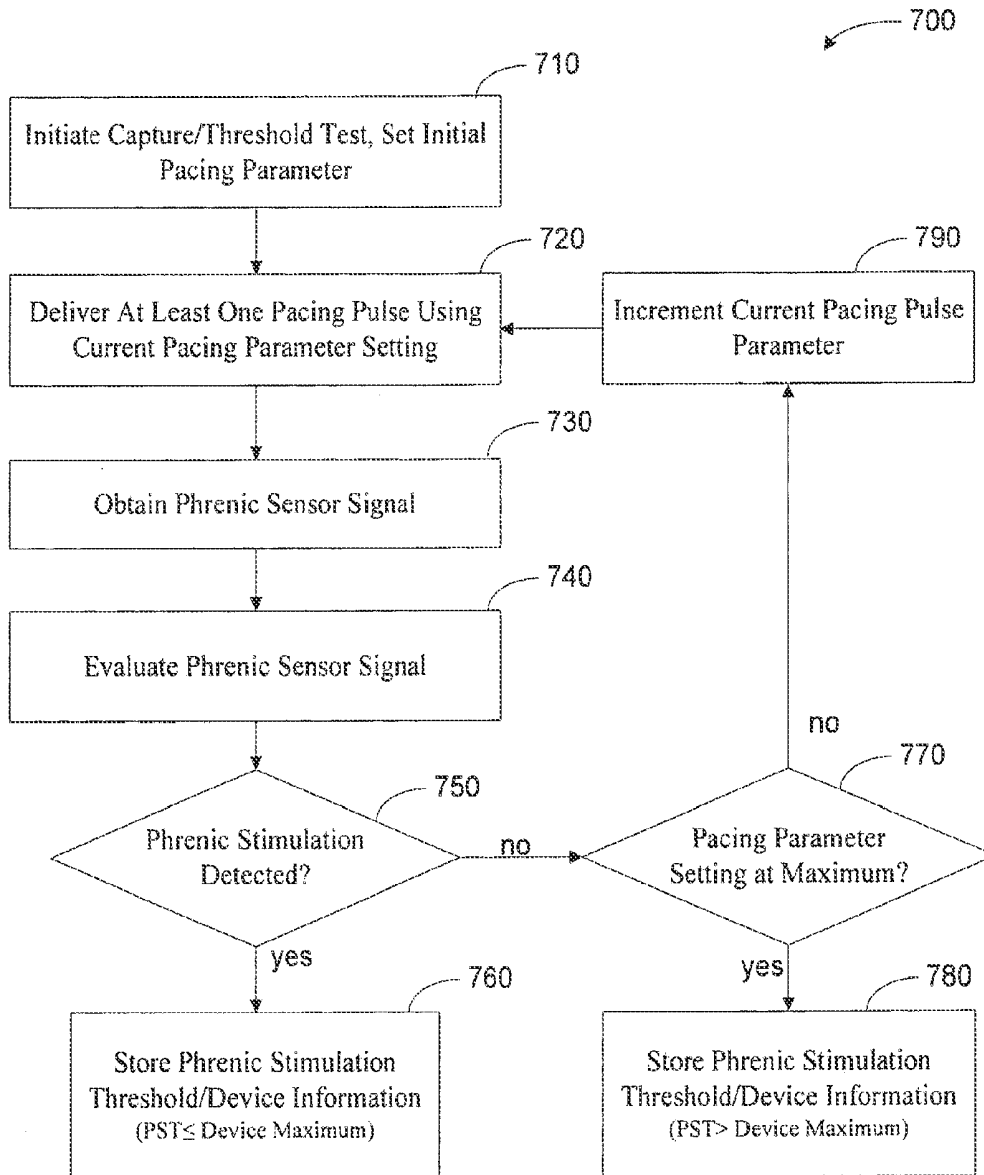


Figure 7

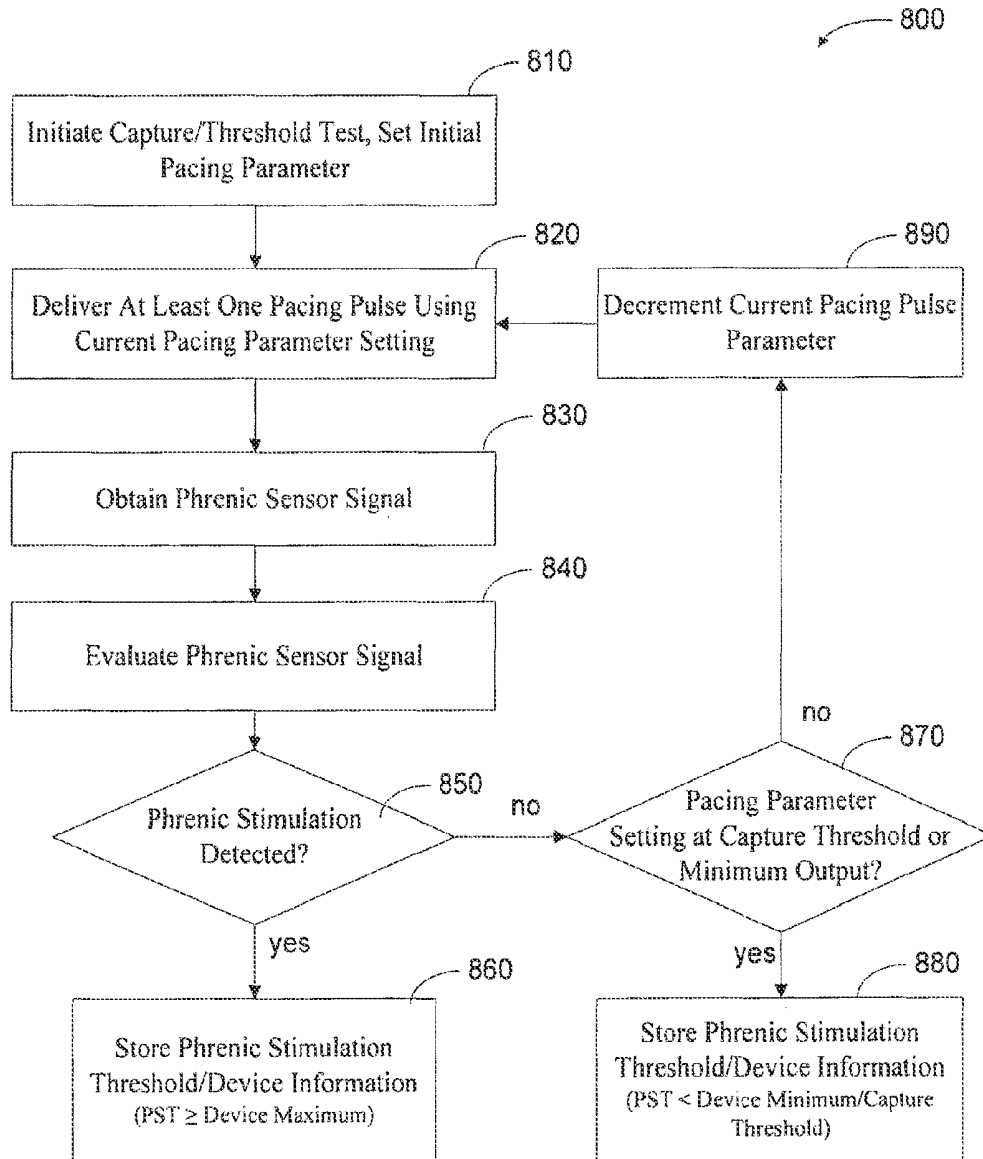


Figure 8

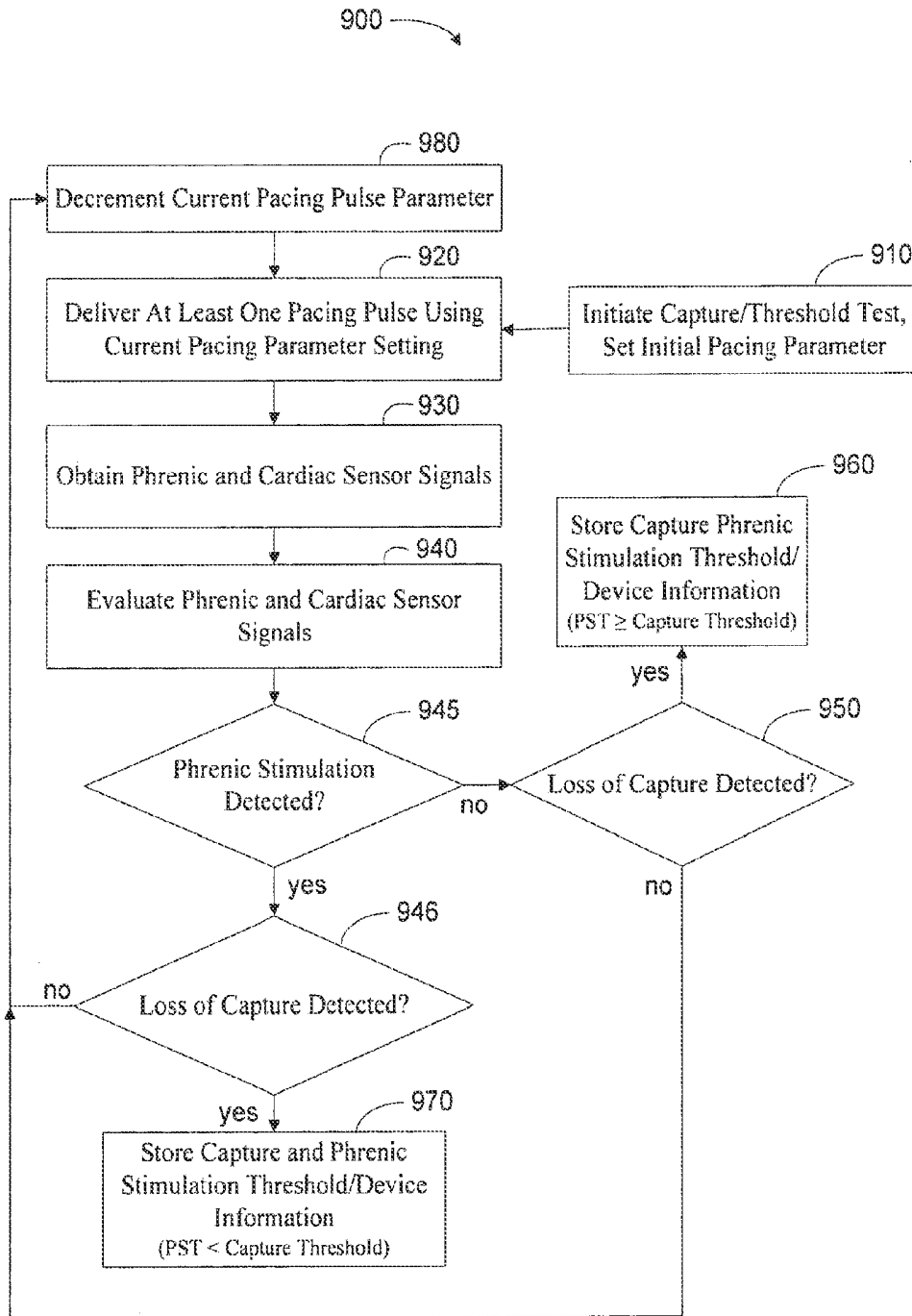


Figure 9

METHOD AND APPARATUS FOR PHRENIC STIMULATION DETECTION

This application is a continuation of co-pending U.S. patent application Ser. No. 12/368,828, filed Feb. 10, 2009, which claims the benefit of Provisional Patent Application Ser. No. 61/065,743 filed on Feb. 14, 2008, to which priority is claimed pursuant to 35 U.S.C. §119(e) and which is hereby incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

The present invention relates generally to cardiac devices and methods, and, more particularly, to characterization of capture and phrenic stimulation thresholds and device parameters.

BACKGROUND OF THE INVENTION

When functioning normally, the heart produces rhythmic contractions and is capable of pumping blood throughout the body. The heart has specialized conduction pathways in both the atria and the ventricles that enable excitation impulses (i.e. depolarizations) initiated from the sino-atrial (SA) node to be rapidly conducted throughout the myocardium. These specialized conduction pathways conduct the depolarizations from the SA node to the atrial myocardium, to the atrio-ventricular node, and to the ventricular myocardium to produce a coordinated contraction of both atria and both ventricles.

The conduction pathways synchronize the contractions of the muscle fibers of each chamber as well as the contraction of each atrium or ventricle with the opposite atrium or ventricle. Without the synchronization afforded by the normally functioning specialized conduction pathways, the heart's pumping efficiency is greatly diminished. Patients who exhibit pathology of these conduction pathways can suffer compromised cardiac output.

Cardiac rhythm management (CRM) devices have been developed that provide pacing stimulation to one or more heart chambers in an attempt to improve the rhythm and coordination of atrial and/or ventricular contractions. CRM devices typically include circuitry to sense signals from the heart and a pulse generator for providing electrical stimulation to the heart. Leads extending into the patient's heart chamber and/or into veins of the heart are coupled to electrodes that sense the heart's electrical signals and deliver stimulation to the heart in accordance with various therapies for treating cardiac arrhythmias and dyssynchrony.

Pacemakers are CRM devices that deliver a series of low energy pace pulses timed to assist the heart in producing a contractile rhythm that maintains cardiac pumping efficiency. Pace pulses may be intermittent or continuous, depending on the needs of the patient. There exist a number of categories of pacemaker devices, with various modes for sensing and pacing one or more heart chambers.

A pace pulse must exceed a minimum energy value, or capture threshold, to "capture" the heart tissue, generating an evoked response that generates a propagating depolarization wave that results in a contraction of the heart chamber. If a pace pulse energy is too low, the pace pulses may not reliably produce a contractile response in the heart chamber and may result in ineffective pacing that does not improve cardiac function or cardiac output.

Pacing pulses can unintentionally stimulate nerves or muscles, even if the pulse energy is not sufficient to capture cardiac tissue. For example, a delivered pacing pulse may

stimulate a patient's phrenic nerve, which runs proximate the heart and innervates the diaphragm.

The present invention provides methods and systems using phrenic stimulation algorithms and provides various advantages over the prior art.

SUMMARY OF THE INVENTION

The present invention involves approaches for using phrenic stimulation algorithms for characterization of capture and phrenic stimulation thresholds and device parameters. One embodiment of the invention is directed to a method comprising delivering a plurality of cardiac pacing pulses using a cardiac pacing device, a pacing parameter of the plurality of cardiac pacing pulses being changed between delivery of the pulses. The parameter can be a pacing pulse amplitude or width, for example. The method embodiment further includes evaluating one or more sensor signals to detect activation of the phrenic nerve by one or more of the plurality of cardiac pacing pulses and comparing the evaluation of the one or more sensor signals and the pacing parameter to determine if a phrenic nerve activation threshold is at least one of higher than a maximum device parameter and lower than a minimum device parameter. The cardiac capture threshold can be a detected minimum pacing pulse amplitude that causes depolarization in targeted cardiac tissue. The maximum device parameter can be a maximum width of a pacing pulse that the cardiac pacing device is programmed to deliver. The minimum device parameter can be a minimum width of a pacing pulse that the cardiac pacing device is programmed to deliver.

Another embodiment is directed to a cardiac rhythm management system, the system comprising an implantable cardiac pacing device having a plurality of electrodes. The implantable cardiac pacing device can include circuitry configured to output a plurality of cardiac pacing pulses through the electrodes and modify one or more pacing parameters of the plurality of cardiac pacing pulses, one or more sensors configured to sense activation of the phrenic nerve by one or more of the plurality of pacing pulses and provide one or more signals based on the sensed phrenic nerve activation, a controller configured to execute program instructions stored in memory to cause the system to compare the one or more signals and the one or more pacing parameters to determine if a phrenic nerve activation threshold is at least one of higher than a maximum cardiac pacing device parameter and lower than a minimum cardiac pacing device parameter, and store information based on the determination.

Another embodiment is directed to a cardiac rhythm management system, the system comprising an implantable cardiac pacing device having a plurality of electrodes. The implantable cardiac pacing device can include circuitry configured to output a plurality of cardiac pacing pulses through the plurality of electrodes and modify one or more pacing parameters of the plurality of cardiac pacing pulses, one or more sensors configured to sense activation of the phrenic nerve by one or more of the plurality of pacing pulses and provide one or more signals based on the sensed phrenic nerve activation, means for comparing the evaluation of the one or more sensor signals and the one or more pacing parameters to determine if a phrenic nerve activation threshold is at least one of higher than a maximum programmed device parameter and lower than a minimum programmed device parameter.

The above summary of the present invention is not intended to describe each embodiment or every implementation of the present invention. Advantages and attainments,

together with a more complete understanding of the invention, will become apparent and appreciated by referring to the following detailed description and claims taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a flowchart illustrating a method of characterizing device parameter limits, capture thresholds, and phrenic stimulation thresholds in accordance with embodiments of the invention;

FIG. 2 is a block diagram of system circuitry in accordance with embodiments of the invention;

FIG. 3 is a diagram illustrating a patient-external device that provides a user interface allowing a human analyst to interact with information and program an implantable medical device in accordance with embodiments of the invention;

FIG. 4 is a therapy device incorporating circuitry capable of implementing electrode combination selection techniques in accordance with embodiments of the invention;

FIG. 5 is a flowchart illustrating a method of estimating thresholds in accordance with embodiments of the invention;

FIG. 6 is a graph illustrating various aspects of strength-duration pacing pulse parameter and device limit curves in accordance with embodiments of the invention;

FIG. 7 is a flowchart illustrating a method characterizing device parameter limits, capture thresholds, and phrenic stimulation thresholds using a step-up scanning technique in accordance with embodiments of the invention;

FIG. 8 is a flowchart illustrating a method of characterizing device parameter limits, capture thresholds, and phrenic stimulation thresholds using a step-down scanning technique in accordance with embodiments of the invention; and

FIG. 9 is a flowchart illustrating a method of characterizing a capture threshold and phrenic stimulation threshold using a step-down scanning technique in accordance with embodiments of the invention.

While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail below. It is to be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the invention is intended to cover all modifications, equivalents, and alternatives falling within the scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF VARIOUS EMBODIMENTS

In the following description of the illustrated embodiments, references are made to the accompanying drawings forming a part hereof, and in which are shown by way of illustration, various embodiments by which the invention may be practiced. It is to be understood that other embodiments may be utilized, and structural and functional changes may be made without departing from the scope of the present invention.

Systems, devices, or methods according to the present invention may include one or more of the features, structures, methods, or combinations thereof described herein. For example, a device or system may be implemented to include one or more of the advantageous features and/or processes described below. It is intended that such a device or system need not include all of the features described herein, but may be implemented to include selected features that provide

for useful structures and/or functionality. Such a device or system may be implemented to provide a variety of therapeutic or diagnostic functions.

A wide variety of implantable cardiac monitoring and/or stimulation devices may be configured to implement phrenic stimulation algorithms of the present invention. A non-limiting, representative list of such devices includes cardiac monitors, pacemakers, cardiovertors, defibrillators, resynchronizers, and other cardiac monitoring and therapy delivery devices. These devices may be configured with a variety of electrode arrangements, including transvenous, endocardial, and epicardial electrodes (i.e., intrathoracic electrodes), and/or subcutaneous, non-intrathoracic electrodes, including can, header, and indifferent electrodes, and subcutaneous array(s) or lead electrodes (i.e., non-intrathoracic electrodes).

Bi-ventricular pacing provides therapy options for patients suffering from heart failure. However, new challenges have been presented by placement of the left-ventricular lead via the coronary sinus in bi-ventricular pacing systems. Due to the proximity of the coronary veins to the phrenic nerve, left ventricular pacing may result in phrenic nerve stimulation. The phrenic nerve innervates the diaphragm, so stimulation of the phrenic nerve can cause a patient to experience a hiccup. Electrical stimulation of the phrenic nerve can be uncomfortable for the patient, and can interfere with breathing. Therefore, phrenic stimulation from cardiac pacing may cause the patient to exhibit uncomfortable breathing patterns timed with the left-ventricular pace.

A phrenic stimulation threshold, above which the phrenic nerve will be stimulated by a pacing pulse, can be determined. One method for determining a phrenic stimulation threshold includes sensing for phrenic nerve activation and/or diaphragmic movement timed with the delivery of pacing pulses. If no phrenic stimulation is sensed using the level of electrical energy delivered, the energy level can be iteratively increased for subsequent trials of delivering electrical energy and monitoring for phrenic stimulation until phrenic stimulation is sensed. The electrical energy level at which phrenic stimulation is detected can be the phrenic stimulation threshold. In some embodiments, the level of electrical energy may be decreased or otherwise adjusted until phrenic stimulation is not detected. The energy delivered during such a scan could also be used to simultaneously perform other tests, such as searching for a capture threshold.

Methods for evaluating phrenic stimulation that maybe incorporated in embodiments of the invention are disclosed in U.S. Pat. No. 6,772,008; and Patent Application Publication No. 20060241711, filed Apr. 26, 2005, each of which are herein incorporated by reference in their respective entireties.

Programming a pacing device to avoid undesirable stimulation, such as phrenic stimulation, is not one dimensional, as many other factors can be important in setting appropriate pacing parameters. For example, a pace pulse must exceed a minimum energy value, or capture threshold, to produce an intended contraction of cardiac tissue. It is desirable for a pace pulse to have sufficient energy to stimulate capture of the heart without expending energy significantly in excess of the capture threshold. Thus, accurate determination of the capture threshold provides efficient pace energy management. If the pace pulse energy is too low, the pace pulses may not reliably produce a contractile response in the heart and may result in ineffective pacing.

A capture threshold can be determined using, among other methods, a step-down technique where a capture threshold is identified when loss of capture is detected after successive pacing cycles. A step-up technique can also be used, whereby a capture threshold is identified when capture is detected after

successive pacing cycles without capture. Capture can be detected using characteristics of an electrocardiogram indicating an intended cardiac response (e.g., a QRS complex).

Capture detection allows the cardiac rhythm management system to adjust the energy level of pace pulses to correspond to the optimum energy expenditure that reliably produces a contraction. Further, capture detection allows the cardiac rhythm management system to initiate a back-up pulse at a higher energy level whenever a pace pulse does not produce a contraction. For example, embodiments of the invention can characterize capture and phrenic stimulation thresholds and deliver a back-up pulse with a higher energy level than a standard pacing energy level set at or above the capture threshold, the back-up pulse energy level below the phrenic stimulation threshold.

Pacing devices can have pacing parameter limits, such as programmed limits and limits on device capability. For example, an implantable pacing device may be programmed to only deliver pacing pulses not exceeding a specified amplitude. Other programmed limits can include minimum pulse amplitude, minimum pulse duration, maximum pulse duration, minimum pulse frequency, maximum pulse frequency, minimum pulse current, and/or maximum pulse current, among other parameters. Devices may be programmed with these and other parameter limits for several reasons. For example, a device programmed to automatically select a pacing pulse amplitude may have a programmed limit on the amplitude to prevent the device from selecting a pulse amplitude that could be dangerous to the patient (such as in an auto-capture mode). Additionally, a device may be programmed with parameter limits to avoid operating conditions that can harm the device.

Upon implantation of a pacing device, a human analyst, such as a doctor, may establish initial capture and phrenic nerve stimulation thresholds. Based on those initial threshold determinations, the analyst may program the device with parameter range limits within which automated device features can operate. In the case of pulse amplitude, a doctor may set a voltage range having a minimum above the capture threshold and a maximum below the phrenic stimulation threshold within which an autocapture feature can operate. The maximums and minimums may each have a safety margin such that the range between the parameter minimum/maximum is less than the range between the capture and phrenic stimulation thresholds. The safety margin provides some protection from an autocapture program pacing below the capture threshold or above the phrenic stimulation threshold if either of these thresholds were to change over time.

Devices can also have capability limits associated with the hardware of the device. For example, even if no programming limits are placed on the operation of a pacing device, the device may still have limits regarding minimum pulse amplitude, maximum pulse amplitude, minimum pulse duration, maximum pulse duration, minimum pulse frequency, maximum pulse frequency, minimum pulse current, and maximum pulse current, among other parameters. Device capability limits can be related to the performance limits of the components, such as capacitors and battery, used to construct the device.

In multi-electrode pacing systems, multiple pacing electrodes may be disposed in a single heart chamber, in multiple heart chambers, and/or elsewhere in a patient's body. Electrodes used for delivery of pacing pulses may include one or more cathode electrodes and one or more anode electrodes. Pacing pulses are delivered via the cathode/anode electrode combinations, where the term "electrode combination" denotes that at least one cathode electrode and at least one

anode electrode are used. An electrode combination may involve more than two electrodes, such as when multiple electrodes that are electrically connected are used as the anode and/or multiple electrodes that are electrically connected are used as the cathode. Typically, pacing energy is delivered to the heart tissue via the cathode electrode(s) at one or more pacing sites, with a return path provided via the anode electrode(s). If cardiac capture occurs, the energy injected at the cathode electrode site creates a propagating wavefront of depolarization which may combine with other depolarization wavefronts to trigger a contraction of the cardiac muscle. The cathode and anode electrode combination that delivers the pacing energy defines the pacing vector used for pacing.

Pacing pulses maybe applied through multiple electrodes (i.e., pacing vectors defined by various electrode combinations) in a single cardiac chamber in a timed sequence during the cardiac cycle to improve contractility and enhance the pumping action of the heart chamber. It is desirable for each pacing pulse delivered via the multiple electrode combinations to capture the cardiac tissue proximate the cathode electrode. Capture of cardiac tissue depends upon, among other things, the vector used to deliver the pulse and various pulse parameters, such as the amplitude and duration of the pulse.

Stimulation characteristics of a pacing therapy are dependent on many factors, including the distance between the electrodes, proximity to targeted tissue, proximity to non-targeted tissue susceptible to unintended stimulation, type of tissue contacting and between the electrodes, impedance between the electrodes, resistance between the electrodes, and electrode type, among other factors. Such factors can influence the cardiac capture and phrenic stimulation thresholds. Stimulation characteristics can vary with physiologic changes, electrode migration, physical activity level, body fluid chemistry, hydration, and disease state, among other factors. Therefore, the stimulation characteristics for each electrode combination are unique and can change over time. As such, it can be useful to periodically determine the stimulation characteristics (e.g., cardiac capture and phrenic stimulation thresholds) for each electrode combination for optimum pacing (e.g., pacing at or just above the cardiac capture threshold and not causing undesirable stimulation).

It can be useful to consider device parameter limitations in relation to various thresholds (e.g., phrenic stimulation, cardiac capture) when programming, reprogramming, and/or operating a device. For example, if it is known that the phrenic stimulation threshold is greater than a device pulse amplitude limit, then a device may not need to consider phrenic stimulation when performing a scan to update a cardiac capture threshold. Additionally, a step-up amplitude scan of an auto-capture procedure may use larger parameter increments to facilitate faster determination of a cardiac capture threshold if it is known that the phrenic stimulation threshold is higher than the programmed device limits. In a step-down scan mode, a device may alert a physician and/or perform a reconfiguration if it is determined that the device minimum parameter limits are above the phrenic stimulation threshold (e.g., the device cannot deliver a pacing pulse having a pulse width that does not stimulate the phrenic nerve).

Devices of the present invention may facilitate characterization of pacing configurations using various phrenic stimulation algorithms. A device may determine the relationship between device parameter limits, capture threshold, and/or phrenic stimulation threshold, among other things. Embodiments may notify a doctor and/or take some other action if changes in one or more of the thresholds might change the relationship between the programmed parameter limits and

one or more of the thresholds. For example, a doctor might be notified and/or a device may be automatically reprogrammed (by itself or another system) if a phrenic stimulation threshold changes such that the threshold is lower than a programmed pacing parameter limit, where before the phrenic stimulation threshold was higher than the maximum parameter limit of the programmed range.

The flowchart of FIG. 1 illustrates a process for using a phrenic stimulation algorithm. The process includes delivering 110 cardiac pacing pulses while iteratively changing a parameter of the pacing pulses. The parameter iteratively changed could be one or more of pulse amplitude, width, frequency, and current, among other parameters. The parameter change could be an increase or decrease. In this way, a scan can be performed for each of the one or more parameters to investigate the physiological response (e.g., capture, phrenic stimulation) across at least a portion of the available parameter spectrum.

Sensor signals are evaluated 120 to detect phrenic stimulation by the delivered 110 cardiac pacing pulses. Phrenic stimulation can be detected by the methods disclosed herein. In one embodiment, phrenic stimulation could be detected by an accelerometer signal indicating thoracic movement (e.g., an induced hiccup) shortly after the delivery 110 of a pacing pulse. Phrenic stimulation can also be detected by the detection of a short-duration deviation in the amplitude of a trans-thoracic impedance signal.

Information regarding the evaluation 120 to detect phrenic stimulation and the delivery 110 of pacing pulses can be compared 130 to determine, among other things, if a phrenic stimulation threshold is higher than a maximum programmed device parameter, lower than a minimum programmed device parameter, and/or lower than cardiac capture threshold.

For example, if the evaluation 120 did not detect phrenic stimulation corresponding to any of the delivered 110 pacing pulses, even though a pacing pulse was delivered at the maximum programmed amplitude setting for a pacing device, then it can be identified that the phrenic stimulation threshold is greater than the device's maximum programmed amplitude parameter. Additionally, it may be determined that the phrenic stimulation pulse width threshold is greater than the device's maximum programmed pulse width parameter. Similar relationships could also be identified for the other parameters disclosed herein.

If the process of FIG. 1 is employed using a step-down iterative parameter change approach, then it may be identified that the phrenic stimulation threshold is below a device's programmed minimum amplitude and/or pulse width parameter. A step-down scan according to the process of FIG. 1 may also identify that a capture threshold is below a device's minimum programmed amplitude and/or pulse width parameter, that a phrenic stimulation threshold is greater than a cardiac capture threshold, and/or that either or both of the phrenic stimulation and cardiac capture thresholds are below a maximum programmed device parameter.

In some embodiments, a device may scan only within its programmed parameter range that a particular process, such as autocapture, is allowed to operate. Such embodiments minimize testing while ensuring that a threshold has not drifted into the programmed range of the automated process.

In some embodiments, a device may scan outside of its programmed parameter range within which a particular process is allowed to operate. Such embodiments allow a device and/or doctor to recognize when thresholds have changed relative to programmed parameter limits and take appropriate action. For example, if it is identified that a capture threshold has decreased and drifted further from a minimum pro-

grammed parameter limit, then a device may be reprogrammed with a lower minimum parameter limit, which can conserve battery life. If a phrenic stimulation threshold has decreased, then a device can be reprogrammed with a lower maximum parameter limit to ensure a safety margin exists between the phrenic stimulation threshold and the maximum programmed parameter limit.

Based on the identified relationships between the phrenic stimulation threshold, the capture threshold, and the various programmed pulse parameter limits, a doctor may be notified that reprogramming of the device is needed. For example, if it is determined that a capture threshold has increased over time then embodiments of the invention can facilitate notification to the doctor that the capture threshold has increased and is nearing a device's minimum programmed pulse amplitude parameter (where a scan had been performed outside of the programmed parameter limits). In such case the doctor may reprogram the pulse parameter limits of the device by increasing the minimum programmed pulse parameter. A doctor may further increase the maximum programmed pulse parameter to allow automated functions of the device, such as an auto-capture process, adequate variability in changing a parameter. Alternatively, a device may reprogram itself or be programmed by another system to modify programmed parameter limits in response to identified changing relationships between the phrenic stimulation threshold, the capture threshold, and various programmed pulse parameter limits.

The various steps of FIG. 1, as well as the other steps disclosed herein, can be performed automatically, such that no direct human assistance (e.g., physician and/or patient) is needed to initiate or perform the various discrete steps. Alternatively, the various steps of this disclosure can be performed semi-automatically requiring some amount of human interaction to initiate or conduct one or more steps.

FIG. 2 is a block diagram of a CRM device 200 that may incorporate circuitry employing phrenic stimulation algorithms in accordance with embodiments of the present invention. The CRM device 200 includes pacing therapy circuitry 230 that delivers pacing pulses to a heart. The CRM device 200 may optionally include defibrillation/cardioversion circuitry 235 configured to deliver high energy defibrillation or cardioversion stimulation to the heart for terminating dangerous tachyarrhythmias.

The pacing pulses are delivered via multiple cardiac electrodes 205 (electrode combinations), which can be disposed at multiple locations within a heart, among other locations. Two or more electrodes may be disposed within a single heart chamber. The electrodes 205 are coupled to switch matrix 225 circuitry used to selectively couple electrodes 205 of various pacing configurations to signal processor 201 and/or other components of the CRM device 200.

The CRM device also includes a phrenic stimulation sensor 210. The phrenic stimulation sensor 210 can output a signal and/or other information to signal processor 201 and control processor 240. Phrenic stimulation sensor 210 may include an accelerometer, electrical signal sensors (e.g., EMG, impedance), pressure sensor, acoustic sensors, and/or any other sensor that can participate in the detection of phrenic stimulation. Phrenic stimulation sensor 210 may be implemented using a discrete sensor or via software executed by a processor (e.g., control processor 240) of the FRM device.

The control processor 240 can use information received from the signal processor 201, the phrenic stimulation sensor 210, memory 245, and other components to implement phrenic stimulation algorithms, as disclosed herein.

For example, the pacing therapy circuitry 230 can provide information regarding when a pacing pulse was delivered and

the parameters of the pacing pulse, the phrenic stimulation sensor **210** can provide information regarding sensed phrenic stimulation, and signal processor can provide information regarding capture of the heart. This information can be used to determine, among other things, if a phrenic stimulation threshold is higher than a maximum device parameter, lower than a minimum device parameter, and/or lower than cardiac capture threshold, among other things.

Amplitude, peak timing, and/or correlation of delivered pulses to phrenic stimulation (beat-to-beat and/or over time) can be used with a phrenic stimulation signal in either the time or frequency domain to determine whether one or more pacing pulses caused phrenic stimulation.

A CRM device **200** typically includes a battery power supply (not shown) and communications circuitry **250** for communicating with an external device programmer **260** or other patient-external device. Information, such as data, parameter information, evaluations, comparisons, data, and/or program instructions, and the like, can be transferred between the device programmer **260** and patient management server **270**, CRM device **200** and the device programmer **260**, and/or between the CRM device **200** and the patient management server **270** and/or other external system. In some embodiments, the processor **240**, memory **245**, and/or signal processor **201** may be components of the device programmer **260**, patient management server **270**, and/or other patient external system.

The CRM device **200** also includes a memory **245** for storing executable program instructions and/or data, accessed by and through the control processor **240**. In various configurations, the memory **245** may be used to store information related to thresholds, parameters, parameter limits, measured values, program instructions, and the like.

The circuitry represented in FIG. 2 can be used to perform the various methodologies and techniques discussed herein. Memory **245** can be a computer readable medium encoded with a computer program, software, firmware, computer executable instructions, instructions capable of being executed by a computer, etc. to be executed by circuitry, such as control processor **240**. For example, memory **245** can be a computer readable medium storing a computer program, execution of the computer program by control processor **240** causing delivery of pacing pulses directed by the pacing therapy circuitry, reception of one or more signals from phrenic stimulation sensors **210** and/or signal processor **201** to identify, and establish relationships between, device parameter limits, capture thresholds, and phrenic stimulation thresholds in accordance with embodiments of the invention according to the various methods and techniques made known or referenced by the present disclosure. In similar ways, the other methods and techniques discussed herein can be performed using the circuitry represented in FIG. 2.

FIG. 3 illustrates a patient external device **300** that provides a user interface configured to allow a human analyst, such as a physician or patient, to interact with an implanted medical device. The patient external device **300** is described as a CRM programmer, although the methods of the invention are operable on other types of devices as well, such as portable telephonic devices, computers, PDA's, or patient information servers used in conjunction with a remote system, for example. The programmer **300** includes a programming head **310** which is placed over a patient's body near the implant site of an implanted device to establish a telemetry link between a CRM and the programmer **300**. The telemetry link allows the data collected by the implantable device to be downloaded to the programmer **300**. The downloaded data is stored in the programmer memory **365**. In some embodiments, a commu-

nication link may be established between an implantable device and an external device via radio frequency, such that the implantable device and external device do not require relatively close proximity to facilitate transfer of data, commands, instructions, and other information.

The programmer **300** includes a graphics display screen **320**, e.g., LCD display screen, that is capable of displaying graphics, alphanumeric symbols, and/or other information. For example, the programmer **300** may graphically display information regarding pacing parameters, device limits, sensed information, and thresholds downloaded from the CRM on the screen **320**. The display screen **320** may include touch-sensitive capability so that the user can input information or commands by touching the display screen **320** with a stylus **330** or the user's finger. Alternatively, or additionally, the user may input information or commands via a keyboard **340** or mouse **350**.

The programmer **300** includes a data processor **360** including software and/or hardware for performing the methods disclosed here, using program instructions stored in the memory **365** of the programmer **300**. In one implementation, sensed data is received from a CRM via communications circuitry **366** of the programmer **300** and stored in memory **365**. The data processor **360** evaluates the sensed data, which can include information related to pacing parameters, device limits, and thresholds. The data processor **360** can also perform other method steps discussed herein, including evaluating signals, detecting phrenic stimulation, and comparing pacing parameters, device limits, and thresholds, among other things. Pacing parameters, device limits, programmed parameter limits, and thresholds, as well as other information, may be presented to a user via a display screen **320**. A notification regarding device pacing pulse parameter limits, capture threshold, and phrenic stimulation threshold can be displayed using the display screen **320** for review by a human analyst.

The therapy device **400** illustrated in FIG. 4 employs circuitry capable of implementing phrenic stimulation algorithm techniques described herein. The therapy device **400** includes CRM circuitry enclosed within an implantable housing **401**. The CRM circuitry is electrically coupled to an intracardiac lead system **410**. Although an intracardiac lead system **410** is illustrated in FIG. 4, various other types of lead/electrode systems may additionally or alternatively be deployed. For example, the lead/electrode system may comprise an epicardial lead/electrode system including electrodes outside the heart and/or cardiac vasculature, such as a heart sock, an epicardial patch, and/or a subcutaneous system having electrodes implanted below the skin surface but outside the ribcage.

Portions of the intracardiac lead system **410** are shown inserted into the patient's heart. The lead system **410** includes cardiac pace/sense electrodes **451-456** positioned in, on, or about one or more heart chambers for sensing electrical signals from the patient's heart and/or delivering pacing pulses to the heart. The intracardiac sense/pace electrodes, such as those illustrated in FIG. 4, may be used to sense and/or pace one or more chambers of the heart, including the left ventricle, the right ventricle, the left atrium and/or the right atrium. The CRM circuitry controls the delivery of electrical stimulation pulses delivered via the electrodes **451-456**. The electrical stimulation pulses may be used to ensure that the heart beats at a hemodynamically sufficient rate, may be used to improve the synchrony of the heart beats, may be used to increase the strength of the heart beats, and/or may be used for other therapeutic purposes to support cardiac function consistent with a prescribed therapy.

The lead system **410** may include defibrillation electrodes **441, 442** for delivering defibrillation/cardioversion pulses to the heart.

The left ventricular lead **405** incorporates multiple electrodes **454a-454d** and **455** positioned at various locations within the coronary venous system proximate the left ventricle. Stimulating the ventricle at multiple locations in the left ventricle or at a single selected location may provide for increased cardiac output in patients suffering from heart failure (HF), for example, and/or may provide for other benefits. Electrical stimulation pulses may be delivered via the selected electrodes according to a timing sequence and output configuration that enhances cardiac function. Although FIG. **4** illustrates multiple left ventricle electrodes, in other configurations, multiple electrodes may alternatively or additionally be provided in one or more of the right atrium, left atrium, and right ventricle.

Portions of the housing **401** of the implantable device **400** may optionally serve as one or more multiple can **481** or indifferent **482** electrodes. The housing **401** is illustrated as incorporating a header **489** that may be configured to facilitate removable attachment between one or more leads and the housing **401**. The housing **401** of the therapy device **400** may include one or more can electrodes **481**. The header **489** of the therapy device **400** may include one or more indifferent electrodes **482**. The can **481** and/or indifferent **482** electrodes may be used to deliver pacing and/or defibrillation stimulation to the heart and/or for sensing electrical cardiac signals of the heart.

Communications circuitry is disposed within the housing **401** for facilitating communication between the CRM circuitry and a patient-external device, such as an external programmer or advanced patient management (APM) system. The therapy device **400** may also include sensors and appropriate circuitry for sensing a patient's metabolic need and adjusting the pacing pulses delivered to the heart to accommodate the patient's metabolic need.

In some implementations, an APM system may be used to perform some of the processes discussed here, including evaluating, estimating, comparing, detecting, selecting, and updating, among others. Methods, structures, and/or techniques described herein, may incorporate various APM related methodologies, including features described in one or more of the following references: U.S. Pat. Nos. 6,221,011; 6,270,457; 6,277,072; 6,280,380; 6,312,378; 6,336,903; 6,358,203; 6,368,284; 6,398,728; and 6,440,066, which are hereby incorporated herein by reference in each of their respective entireties.

In certain embodiments, the therapy device **600** may include circuitry for detecting and treating cardiac tachyarrhythmia via defibrillation therapy and/or anti-tachyarrhythmia pacing (ATP). Configurations providing defibrillation capability may make use of defibrillation coils **441, 442** for delivering high energy pulses to the heart to terminate or mitigate tachyarrhythmia.

CRM devices using multiple electrodes, such as illustrated herein, are capable of delivering pacing pulses to multiple sites of the atria and/or ventricles during a cardiac cycle. Certain patients may benefit from activation of parts of a heart chamber, such as a ventricle, at different times in order to distribute the pumping load and/or depolarization sequence to different areas of the ventricle. A multi-electrode pacemaker has the capability of switching the output of pacing pulses between selected electrode combinations within a heart chamber during different cardiac cycles.

Commonly owned U.S. Pat. No. 6,772,008, which is incorporated herein by reference, describes methods and systems

that may be used in relation to detecting undesirable tissue stimulation. Muscle stimulation may be detected, for example, through the use of an accelerometer and/or other circuitry that senses accelerations indicating muscle movements that coincide with the output of the stimulation pulse.

Other methods of measuring tissue stimulation may involve, for example, the use of an electromyogram sensor (EMG), microphone, and/or other sensors. For example, stimulation of the laryngeal muscles may be automatically detected using a microphone to detect the patient's expiration response to undesirable diaphragmic activation due to electrical phrenic stimulation.

Undesirable nerve or muscle stimulation may be detected by sensing a parameter that is directly or indirectly responsive to the stimulation. Undesirable nerve stimulation, such as stimulation of the vagus or phrenic nerves, for example, may be directly sensed using electroneurogram (ENG) electrodes and circuitry to measure and/or record nerve spikes and/or action potentials in a nerve. An ENG sensor may comprise a neural cuff and/or other type or neural electrodes located on or near the nerve of interest. For example, systems and methods for direct measurement of nerve activation signals are discussed in U.S. Pat. Nos. 4,573,481 and 5,658,318 which are incorporated herein by reference in their respective entireties. The ENG may comprise a helical neural electrode that wraps around the nerve (e.g., phrenic nerve) and is electrically connected to circuitry configured to measure the nerve activity. The neural electrodes and circuitry operate to detect an electrical activation (action potential) of the nerve following application of the electrical stimulation pulse.

Neural activation can be detected by sensing a surrogate parameter that is indirectly responsive to nerve stimulation. Lung pressure, pleural pressure, thoracic pressure, airway pressure, and thoracic impedance are examples of parameters that change responsive to stimulation of the phrenic nerve. In some embodiments, a patient's airway pressure may be measured during and/or closely following delivery of electrical stimulation. The detected change in pressure may be related to stimulation of the phrenic nerve.

Undesirable stimulation threshold measuring may be performed by iteratively increasing, decreasing, or in some way changing a voltage, current, duration, energy level, and/or other therapy parameter between a series of test pulses. One or more sensors can monitor for undesirable activation immediately after each test pulse is delivered. Using these methods, the point at which a parameter change causes undesirable stimulation can be identified as an undesirable stimulation threshold.

By way of example and not by way of limitation, the undesirable stimulation threshold for a particular electrode combination may be measured by delivering first test pulse using the initial electrode combination. During and/or after each test pulse is delivered, sensors can monitor for undesirable stimulation. For example, an accelerometer may monitor for movement of the diaphragm indicating that the test pulse stimulated the phrenic nerve and/or diaphragm muscle. If no phrenic nerve and/or diaphragm muscle stimulation is detected after delivery of a test pulse, then the test pulse is increased a predetermined amount and another test pulse is delivered. This scanning process of delivering, monitoring, and incrementing is repeated until phrenic nerve and/or diaphragm muscle stimulation is detected. One or more of the test pulse parameters at which the first undesirable stimulation is detected can be considered to be the undesirable stimulation threshold.

Although methods to measure cardiac capture and phrenic stimulation thresholds are disclosed herein, it is contemplated

that various thresholds can be estimated instead of directly measured, as demonstrated in FIG. 5.

The flowchart of FIG. 5 illustrates a process 500 for estimating thresholds, such as a cardiac capture threshold or phrenic stimulation threshold. The process 500 includes measuring 510 a capture threshold of an initial electrode combination. The procedure for measuring 510 a capture threshold for the initial electrode combination can be done according to any capture threshold measuring methods disclosed herein or known in the art.

The process 500 of FIG. 5 further includes measuring 520 the impedance of the initial electrode combination. The impedance of the initial electrode combination may be measured with the capture threshold measurement of the initial electrode combination.

Any method for measuring impedance for one or more electrode combinations may be used. One illustrative example of techniques and circuitry for determining the impedance of an electrode combination is described in commonly owned U.S. Pat. No. 6,076,015 which is incorporated herein by reference in its entirety.

In accordance with this approach, measurement of impedance involves an electrical stimulation source, such as an exciter. The exciter delivers an electrical excitation signal, such as a strobed sequence of current pulses or other measurement stimuli, to the heart between the electrodes. In response to the excitation signal provided by an exciter, a response signal, e.g., voltage response value, is sensed by impedance detector circuitry. From the measured voltage response value and the known current value, the impedance of the electrode combination may be calculated.

The process 500 of FIG. 5 further includes measuring 530 the impedance of an alternate electrode combination. The measuring step 530 could be repeated for a plurality of different alternate electrode combinations.

The process 500 of FIG. 5 further includes measuring 540 an undesirable activation threshold (e.g., phrenic stimulation threshold) of the initial electrode combination. The procedure for measuring 540 the undesirable activation threshold of the initial electrode combination may be similar to the procedure for measuring 510 the capture threshold of the initial electrode combination, and may be done concurrently with the measuring 510 of the capture threshold of the initial electrode combination.

The process 500 of FIG. 5 further includes estimating 550 a capture threshold of the alternate electrode combination. Estimating 550 the capture threshold of the alternate electrode combination can be performed by using the capture threshold and the impedance of the initial electrode combination and the impedance of the alternate electrode combination.

Estimation of the capture threshold of the alternate electrode combination in accordance with some embodiments described herein, is based on the assumption that for a given pulse width, the capture threshold voltage for the initial electrode combination and the capture threshold voltage for the alternate electrode combination require an equal amount of current, energy or charge. The relationship between the capture threshold voltage and current for each electrode combination can be defined by Ohm's law as follows:

$$V_{th} = I_{th} Z, \quad [1]$$

where V_{th} is the capture threshold voltage of the electrode combination, I_{th} is the capture threshold current of the electrode combination, and Z is the impedance of the electrode combination.

For the initial electrode combination, the relationship between the capture threshold voltage and current may be expressed as:

$$V_{th-in} = I_{th-in} Z_{in} \quad [2]$$

where, V_{th-in} is the capture threshold voltage of the initial electrode combination, I_{th-in} is the capture threshold current of the initial electrode combination, and Z_{in} is the impedance of the initial electrode combination.

For the alternate electrode combination, the relationship between the capture threshold voltage and current may be expressed as:

$$V_{th-ex} = I_{th-ex} Z_{ex} \quad [3]$$

where, V_{th-ex} is the capture threshold voltage of the alternate electrode combination, I_{th-ex} is the capture threshold current of the alternate electrode combination, and Z_{ex} is the impedance of the alternate electrode combination.

As previously stated, in some embodiments, the capture threshold current of two electrode combinations having a common electrode is assumed to be about equal, or, $I_{th-in} = I_{th-ex}$.

The relationship between the alternate and initial capture threshold voltages may then be expressed as:

$$V_{th-ex} = \frac{V_{th-in}}{Z_{in}} Z_{ex} \quad [4]$$

By the processes outlined above V_{th-in} , Z_{in} , and, Z_{ex} are measured parameters, and the capture threshold voltage may be estimated based on these measured parameters.

The accuracy of an estimation calculation of a capture threshold for a particular electrode combination may be increased if the measured electrode combination has the same polarity as the electrode combination for which the capture threshold is being estimated. Methods for parameter estimation, including capture threshold estimation, are disclosed in U.S. patent application Ser. No. 11/505,645, filed on Aug. 17, 2006, herein incorporated by reference in its entirety.

The process 500 of FIG. 5 further includes estimating 560 an undesirable activation threshold of the alternate electrode combination. The undesirable activation threshold can be a phrenic stimulation threshold, for example. Estimating 560 the undesirable activation threshold of the alternate electrode combination can be performed by using the undesirable activation threshold and the impedance of the initial electrode combination and the impedance of the alternate electrode combination. Estimating 550 the undesirable activation threshold of the alternative electrode combination can be performing using methods similar to estimating a capture threshold, as discussed and referenced herein.

Estimating a threshold, such as estimating a capture threshold and/or an undesirable activation threshold, instead of measuring the same, can provide several advantages. For example, in some circumstances, measuring and estimating of some thresholds for a plurality of electrode combinations can be done faster than measuring the threshold for each electrode combination of a plurality of electrode combinations, as one or more test pulses do not need to be delivered for each electrode combination. Additionally, a test pulse can be uncomfortable for a patient to experience, and therefore minimizing the number of test pulses can be preferable.

The methods and devices disclosed herein can employ strength-duration relationship information measured or otherwise provided.

Capture is produced by pacing pulses having sufficient energy to produce a propagating wavefront of electrical depolarization that results in a contraction of the heart tissue. Generally speaking, the energy of the pacing pulse is a product of two energy parameters—the amplitude of the pacing pulse and the duration of the pulse. Thus, the capture threshold voltage over a range of pulse widths may be expressed in a capture strength-duration plot **610** as illustrated in FIG. 6.

Undesirable activation by a pacing pulse is also dependent on the pulse energy. The phrenic stimulation strength-duration plot **620** for undesirable activation may have a different characteristic from the capture strength-duration and may have a relationship between pacing pulse voltage and pacing pulse width.

A CRM device, such as a pacemaker, may have the capability to adjust the pacing pulse energy by modifying either or both the pulse width and the pulse amplitude to produce capture. Identical changes in pacing pulse energy may cause different changes when applied to identical therapies using different electrode combinations. Determining a capture strength-duration plot **610** can aid in characterizing the relationships between device parameter limits, capture threshold, and/or phrenic stimulation threshold, among other things.

FIG. 6 provides graphs illustrating a capture strength-duration plot **610** associated and a phrenic stimulation strength-duration plot **620** associated with an undesirable diaphragmatic activation. A pacing pulse having a pulse width of W_1 requires a pulse amplitude of V_{c1} to produce capture. A pacing pulse having pulse width W_1 and pulse amplitude V_{c1} exceeds the voltage threshold, V_{u1} , for an undesirable diaphragmatic activation. If the pulse width is increased to W_2 , the voltage required for capture, V_2 , is less than the voltage required for undesirable diaphragmatic activation, V_{u2} . Therefore, pacing pulses can be delivered at the pacing energy associated with W_2 , V_{c2} to provide capture of the heart without causing the phrenic stimulation.

The area to the right of the intersection **651** of the capture and phrenic stimulation strength-duration plots **610**, **620**, between the phrenic stimulation strength-duration **620** and capture strength-duration **610** plots, defines a set of energy parameter values that produce capture while avoiding phrenic stimulation. Pacing pulses within this region produce the most ideal therapy response (capture without undesirable stimulation).

The capture and phrenic stimulation strength-duration plots **610**, **620** of FIG. 6 may be generated by delivering a number of test pulses at various amplitudes and pulse widths and evaluating whether cardiac capture and undesirable stimulation occurred. The capture and phrenic stimulation strength-duration plots **610**, **620** curves can then be completed by interpolation and extrapolation based on, for example, an exponential fit. Such methods can minimize the number of test pulses required to fully characterize the relationships between pulse parameters and stimulation, thereby minimizing battery consumption and uncomfortable testing.

Extrapolation and interpolation can also allow the relationships between pulse parameters and stimulation for a particular device configuration to be characterized beyond what the device itself is programmed to, or capable of, performing.

Dashed line curves **640** and **680** illustrate device capability pacing parameter limits. Maximum curve **640** illustrates the maximum energy output (based on pulse amplitude and width parameters) that the device is capable of delivering. Maximum curve **640** demonstrates a pulse parameter tradeoff for a particular device when attempting to deliver the maximum amount of energy possible—pulse amplitude is sacrificed for greater pulse width.

Minimum curve **680** illustrates the minimum energy output (based on pulse amplitude and width parameters) that the device is capable of delivering. A device can be capable of delivering pulses having amplitudes and pulse widths parameters within the area between the curves **640** and **680**.

As demonstrated in FIG. 6, a particular device may not be capable of delivering a pacing pulse having any particular amplitude/width parameters that will capture the targeted cardiac tissue without causing undesirable stimulation.

It is generally desirable to have the greatest amount of overlap between the ranges of pacing pulse parameters that capture targeted cardiac tissue without causing undesirable stimulation and the ranges of pacing pulse parameters that a particular device is actually capable of delivering, as the amount of overlap reflects the relative amount of variation in parameters that can be used to achieve an intended therapy outcome.

The methods and devices discussed herein can facilitate understanding the relationships between device parameter limits, capture threshold, and/or phrenic stimulation threshold and optimizing a therapy. For example, the generation of the plots of FIG. 6 can allow for a comparison of overlap between the ranges of pulse parameters that capture targeted cardiac tissue without causing undesirable stimulation and the ranges of pulse parameters that a particular device is actually capable of delivering for different device configurations. A physician (or program) may elect to use the device configuration (e.g., electrode combination corresponding to a vector) having the greatest amount of overlap, as this configuration would likely correspond to the configuration having the greatest amount of flexibility in operation as the possible parameter ranges that achieve a desired therapy outcome are greatest.

Establishing the relationships between device parameter limits, capture threshold, and/or phrenic stimulation threshold can also aid in selecting pacing parameters. For example, when selecting a pulse width parameter, a physician may view a plot similar to that of FIG. 6 to select the pulse width that has the greatest amplitude range, the range being limited by the maximum device parameter curve **640**, the minimum device parameter curve **680**, the undesirable activation threshold curve **620**, and/or the capture threshold curve **610**. Likewise, a pulse amplitude parameter may be selected based on which pulse amplitude corresponds to the greatest pulse width range within the maximum device parameter curve **640**, the minimum device parameter curve **680**, the undesirable activation threshold curve **620**, and/or the capture threshold curve **610**. Parameter selection in this way may be performed by a human or automatically by a processor executing program instructions.

Methods and systems for determining and using strength-duration relationships are described in United States Patent Application Publication No. 2008/0071318, filed Sep. 14, 2006, which is incorporated herein by reference in its entirety.

FIG. 6 also illustrates programmed parameter limits **690** defining maximum and minimum pulse widths and amplitudes within which a device is programmed to operate. Various automated device features can automatically change pulse parameters to adjust to various conditions, such as with an autocapture program. A doctor may implement programmed parameter limits **690** to ensure that a device does not automatically adjust a parameter to a level that could be detrimental to patient care, such as to a level that prematurely runs down a battery or risks causing undesirable stimulation.

Programmed parameter limits **690** may be preprogrammed or set at device implantation based on detected threshold levels. If embodiments of the invention identify changing

relationships between programmed parameter limits **690**, the capture strength-duration plot **610**, and the phrenic stimulation strength-duration plot **620**, the programmed parameter limits **690** may be adjusted, either automatically or after a doctor is notified of the change, for example. Adjustment of programmed parameter limits **690** may increase a maximum pulse amplitude, decrease a maximum pulse amplitude, increase a minimum pulse amplitude, decrease a minimum pulse amplitude, increase a maximum pulse duration, decrease a maximum pulse duration, increase a minimum pulse duration, and/or decrease a minimum pulse duration. In such a way, a programmed parameter limit range, such as amplitude range, may be widened, narrowed, and/or shifted within the parameter limits **640** and **680** that the device is capable of delivering by reprogramming. Other pulse parameters limits of other pulse parameters discussed herein or otherwise made known may be similarly reprogrammed.

In some embodiments of the invention, identification of changing relationships between thresholds and programmed pulse limits may cause the device to modify automated processes that use pulse parameter increments and/or scanning techniques, such as autocapture. For example, if the phrenic stimulation strength-duration plot **620** was to decrease over time corresponding to a detected decrease in phrenic stimulation threshold, then an autocapture program may employ smaller parameter increments when operating within the programmed parameter limits **690**. Alternatively, if the phrenic stimulation strength-duration plot **620** was to increase over time corresponding to a detected increase in phrenic stimulation threshold, then autocapture parameter increments may be increased. Increases in increments can facilitate faster identification of thresholds and the like while minimizing the delivery of test pulses. Decreases in increments can allow for more cautious and thorough scanning. Increasing or decreasing pulse increments in response to changes in relationships between programmed parameter limits and thresholds can quickly optimize automated device functions while balancing safety, efficacy, and battery consumption considerations. Changes in parameter increments may be made automatically by a device upon detection of a change in relationship between programmed parameter limits and thresholds and/or implemented by a doctor upon reviewing information regarding the identified change in relationship.

In some embodiments, a capture threshold and/or phrenic stimulation threshold may be periodically identified and updated. If some amount of parameter separation exists between the programmed parameter limits and one or both of the thresholds then a device may retest to identify the capture threshold and/or phrenic stimulation threshold less frequently. The separation can be a preprogrammed safety margin between thresholds and programmed parameter limits. If a detected threshold is identified as within the parameter separation (e.g., exceeding the safety margin) then a device may increase the frequency with which it tests the thresholds. Increasing and/or decreasing the frequency of testing based on proximity of detected thresholds to programmed parameter limits can minimize battery consumption and uncomfortable testing while balancing safety and efficacy considerations (i.e., testing is done more frequently when it is likely that a threshold will drift into the programmed parameter limits and less frequently when a large margin exists between a threshold and the programmed limits).

The flowchart of FIG. 7 illustrates a process **700** for using phrenic stimulation algorithms for identifying, and characterizing the relationships between, device parameter limits, capture threshold, and/or phrenic stimulation threshold, among other things. The process **700** includes initiating **710** a cap-

ture/threshold test and setting an initial pacing parameter. The initial pacing parameter setting can be, for example, a device minimum amplitude, a device minimum pulse width, a device minimum pulse current, a previously determined capture threshold, or some combination thereof. The process **700** further includes delivering **720** at least one pacing pulse using the current pacing parameter setting. The current pacing parameter setting can be the initial pacing parameter setting if step **720** is being performed for the first time. Otherwise, the current pacing parameter setting can be a parameter value (e.g., pulse amplitude) different from that of the initial setting value.

After delivery **720** of the at least one pacing pulse, a phrenic sensor signal can be obtained **730**. Such a phrenic sensor signal can be any signal produced by any sensor that is capable of detecting phrenic stimulation. The phrenic sensor signal is then evaluated **740**. The evaluation **740** can be used to determine whether a delivered **720** pacing pulse stimulated the phrenic nerve or otherwise cause diaphragmic movement. If phrenic stimulation is detected **750**, then phrenic stimulation threshold/device information is stored **760**. Such information can reflect that the phrenic stimulation threshold (PST) is less than a device maximum parameter value, and may be equal to the device parameter minimum value or capture threshold, if the parameter value had been accordingly set and increased.

If phrenic stimulation is not detected **750**, then it is determined whether the pacing parameter setting is set at a maximum value **770**. During the first few iterations of the process **700**, it is unlikely that the pacing parameter setting is set at a maximum value **770**, and in which case the process **700** increments **790** the current pacing pulse parameter and returns to delivering **720** at least one more pacing pulse using the current pacing parameter setting. In this way, the process **700** can repeat steps **720-730-740-750-770-790**, increasing the pacing pulse parameter each iteration in a scanning fashion until a phrenic stimulation threshold is identified **750-760** or the pacing parameter setting reaches a maximum **770**.

If the pacing parameter setting is incremented **790** to a maximum **770**, then the process **700** stores **780** phrenic stimulation threshold/device information. Such phrenic stimulation threshold/device information could reflect that the PST is greater than the maximum device parameter setting.

The capture threshold and/or PST for a particular electrode combination may change over time due to various physiological effects. Testing the capture threshold and PST for a particular electrode combination may be implemented periodically or on command to ensure that the information regarding relationships between device parameter limits, capture threshold, and/or phrenic stimulation threshold is current.

The flowchart of FIG. 8 illustrates a process **800** for using phrenic stimulation algorithms for identifying, and characterizing the relationships between, device parameter limits, capture threshold, and/or phrenic stimulation threshold, among other things. The process **800** includes initiating **810** a capture/threshold test and setting an initial pacing parameter. The initial pacing parameter setting can be, for example, a device maximum amplitude, a device maximum pulse width, a device maximum pulse current, a previously determined threshold, or some combination thereof. The process **800** further includes delivering **820** at least one pacing pulse using the current pacing parameter setting. The current pacing parameter setting can be the initial pacing parameter setting if step **820** is being performed for the first time. Otherwise, the current pacing parameter setting can be a parameter value (e.g., pulse amplitude) different from that of the initial setting value.

After delivery **820** of the at least one pacing pulse, a phrenic sensor signal can be obtained **830**. Such a phrenic sensor signal can be any signal produced by any sensor that is capable of detecting phrenic stimulation. The phrenic sensor signal is then evaluated **840**. The evaluation **840** can be used to determine whether a delivered **820** pacing pulse stimulated the phrenic nerve. If phrenic stimulation is detected **850** then phrenic stimulation threshold/device information is stored **860**. Such information can reflect that the PST is greater than or equal to a device maximum parameter value.

If phrenic stimulation is not detected **850**, then it is determined whether the pacing parameter setting is set at a minimum value and/or capture threshold **870**. During the first few iterations of the process **800**, it is unlikely that the pacing parameter setting is set at a minimum value or capture threshold **870**, and in which case the process **800** decrements **890** the current pacing pulse parameter and returns to delivering **820** at least one more pacing pulse using the current pacing parameter setting. In this way, the process **800** can repeat steps **820-830-840-850-870-890**, decreasing the pacing pulse parameter each iteration in a scanning fashion until a phrenic stimulation threshold is identified **850-860** or the pacing parameter setting reaches a device minimum and/or capture threshold **870**. In some embodiments, it may be desirable to not scan for the phrenic stimulation threshold below the capture threshold as it could be dangerous to lose capture of cardiac tissue during the test.

If the pacing parameter setting is decremented **890** to a device minimum and/or capture threshold **870**, then the process **800** stores **880** phrenic stimulation threshold/device information. Such phrenic stimulation threshold/device information could reflect that the PST is less than the minimum device parameter setting and/or cardiac capture threshold. If the testing fails to identify pacing parameters that produce capture and avoids phrenic stimulation, then an alert may be communicated to the external device via communication circuitry to alert a system or physician.

The flowchart of FIG. **9** illustrates a process **900** for using phrenic stimulation algorithms for identifying, and characterizing the relationships between, device parameter limits, capture threshold, and/or phrenic stimulation threshold, among other things. The process **900** includes initiating **910** a capture/threshold test, and setting an initial pacing parameter. The initial pacing parameter setting can be, for example, a device maximum amplitude, a device maximum pulse width, a device maximum pulse current, a previously determined threshold, or some combination thereof. The process **900** further includes delivering **920** at least one pacing pulse using the current pacing parameter setting. The current pacing parameter setting can be the initial pacing parameter setting if step **920** is being performed for the first time. Otherwise, the current pacing parameter setting can be a parameter value (e.g., pulse amplitude) different from that of the initial setting value.

After delivery **920** of the at least one pacing pulse, a phrenic sensor signal and cardiac sensor signal can be obtained **930**. Such phrenic and cardiac sensor signals can be any of the signals produced by sensors that are capable of detecting phrenic stimulation or detecting cardiac capture. The phrenic sensor signal and cardiac sensor signal are then evaluated **940**. The evaluation **940** can be used to determine **945** whether a delivered **920** pacing pulse stimulated the phrenic nerve. If phrenic stimulation is detected **945** then the process **900** determines whether capture was lost **946** during the delivery **920** of the one or more pacing pulses.

If phrenic stimulation **945** and loss of cardiac capture **946** are both detected then cardiac capture and phrenic stimula-

tion threshold/device information can be stored **970**. Such information can reflect that the phrenic stimulation threshold PST is less than the capture threshold.

If phrenic stimulation is detected **945** and loss of capture is not detected **946** then the current pacing pulse parameter is decremented **980**. For example, if the pacing pulse parameter is pulse width, then the current pulse width can be decremented **980** to a shorter pulse width. Pulse amplitude, frequency, and/or current pulse parameters can be similarly decremented (or incremented, in step-up embodiments).

If phrenic stimulation is not detected **945**, the process **900** determines whether loss of capture was detected **950**. If no phrenic stimulation is detected **945** and loss of capture is detected **950**, then capture and phrenic stimulation threshold/device information is stored **960**. Such information can indicate that the phrenic stimulation threshold is greater than or equal to the capture threshold.

In this way, the process **900** can repeat steps **920-930-940-945-946-980**, or steps **920-930-940-945-950**, decreasing the pacing pulse parameter each iteration in a scanning fashion until a relationship between phrenic stimulation threshold is the capture threshold is identified (e.g., $PST > \text{capture threshold}$ or $PST < \text{capture threshold}$). Such a process allows for the simultaneous scanning for both a phrenic stimulation threshold and the cardiac capture threshold. Searching for these parameters together minimizes the number of pulses that need to be delivered, as compared to doing the tests separately, preserving battery energy and minimizing patient discomfort. Simultaneous scanning in this way also minimizes the total time necessary for a device to test to establish these thresholds.

The processes **700**, **800**, and **900**, as well as other methods discussed herein, can be initiated upon implant, by a physician, upon detection of a change in condition, and/or periodically. Condition changes that could initiate the processes include loss of capture, change in posture, change in disease state, detection of non-therapeutic activation, and/or short or long term change in patient activity state, for example.

The device parameter limits of FIGS. **700**, **800**, and **900**, and well as others discussed herein, can be programmed parameter limits or parameter limits corresponding to maximum/minimum pulse parameter values that a pacing system is capable of delivering.

Periodic and/or condition initiated testing to update capture threshold, phrenic stimulation threshold, and device relationship information can be useful to monitor for certain conditions that might not otherwise be readily apparent but warrant attention and/or a therapy change. Device and/or physiologic changes may alter the effect of pacing pulses. For example, device component defects, lead migration, electrode encapsulation, and/or physiologic changes may increase the pacing pulse amplitude needed to reliably produce capture and/or decrease the pacing pulse amplitude needed to stimulate the phrenic nerve, leading to uncomfortable and ineffective pacing therapy. Updated capture threshold, phrenic stimulation threshold, and device relationship information can be used to automatically reprogram the therapy device and/or alert a physician to reconfigure the therapy device.

The various processes illustrated and/or described herein (e.g., the processes of FIGS. **1, 5, 7, 8**, and **9** and those associated with FIG. **6**) can be performed using a single device embodiment (e.g., device of FIGS. **2** and **4**) configured to perform each of the processes discussed herein.

The components, functionality, and structural configurations depicted herein are intended to provide an understanding of various features and combination of features that may

be incorporated in an implantable pacemaker/defibrillator. It is understood that a wide variety of cardiac monitoring and/or stimulation device configurations are contemplated, ranging from relatively sophisticated to relatively simple designs. As such, particular cardiac device configurations may include particular features as described herein, while other such device configurations may exclude particular features described herein.

Various modifications and additions can be made to the preferred embodiments discussed hereinabove without departing from the scope of the present invention. Accordingly, the scope of the present invention should not be limited by the particular embodiments described above, but should be defined only by the claims set forth below and equivalents thereof.

What is claimed is:

1. A method for operating a cardiac pacing device, comprising:

determining if a phrenic stimulation threshold of the cardiac pacing device is greater than a device limit;

if it is determined that the phrenic stimulation threshold is greater than the device limit, perform a capture threshold test without performing a phrenic stimulation threshold test; and

if it is determined that the phrenic stimulation threshold is not greater than the device limit, perform a capture threshold test and a phrenic stimulation threshold test.

2. The method of claim 1, wherein the device limit is a device capability limit.

3. The method of claim 1, wherein the device limit is a programmed limit.

4. The method of claim 1, wherein the cardiac pacing device includes a plurality of electrode combinations where each electrode combination defines a pacing vector, the method comprising performing the method for each of two or more pacing vectors.

5. The method of claim 1, wherein the capture threshold test comprises:

delivering a plurality of cardiac pacing pulses;

changing a pacing parameter for one or more of the plurality of cardiac pacing pulses between delivery of at least some of the plurality of cardiac pacing pulses until a capture threshold is detected.

6. The method of claim 5, wherein the pacing parameter comprises an amplitude and/or width of a cardiac pacing pulse, and wherein the pacing parameter is reduced between delivery of at least some of the plurality of cardiac pacing pulses until the capture threshold is detected.

7. The method of claim 5, wherein the phrenic stimulation threshold test comprises:

delivering a plurality of cardiac pacing pulses;

changing a pacing parameter for one or more of the plurality of cardiac pacing pulses between delivery of at least some of the plurality of cardiac pacing pulses until the phrenic stimulation threshold is detected.

8. The method of claim 7, wherein at least some of the plurality of cardiac pacing pulses are part of both the capture threshold test and the phrenic stimulation threshold test.

9. The method of claim 1, wherein the phrenic stimulation threshold test comprises:

delivering a plurality of cardiac pacing pulses;

changing a pacing parameter for one or more of the plurality of cardiac pacing pulses between delivery of at least some of the plurality of cardiac pacing pulses until the phrenic stimulation threshold is detected.

10. The method of claim 9, wherein the pacing parameter comprises an amplitude and/or width of a cardiac pacing

pulse, and wherein the pacing parameter is reduced between delivery of at least some of the plurality of cardiac pacing pulses until the phrenic stimulation threshold is detected.

11. The method of claim 9, wherein the pacing parameter comprises an amplitude and/or width of a cardiac pacing pulse, and wherein the pacing parameter is increased between delivery of at least some of the plurality of cardiac pacing pulses until the phrenic stimulation threshold is detected.

12. A method, comprising:

delivering a plurality of cardiac pacing pulses using a cardiac pacing device, a pacing parameter of the plurality of cardiac pacing pulses being changed between delivery of at least some of the cardiac pacing pulses;

evaluating one or more sensor signals to detect stimulation of the phrenic nerve by one or more of the plurality of cardiac pacing pulses;

comparing the evaluation of the one or more sensor signals and the pacing parameter of one or more of the plurality of cardiac pacing pulses to determine if a phrenic stimulation threshold is at least one of higher than a maximum device parameter and lower than a minimum device parameter; and

altering an operation of the cardiac pacing device if it is determined that the phrenic stimulation threshold is at least one of higher than the maximum device parameter and lower than the minimum device parameter.

13. The method of claim 12, wherein the maximum device parameter is a maximum amplitude and/or width of a pacing pulse that the cardiac pacing device is programmed to deliver and the minimum device parameter is a minimum amplitude and/or width of a pacing pulse that the cardiac pacing device is programmed to deliver.

14. The method of claim 12, wherein delivering the plurality of cardiac pacing pulses comprises increasing a pacing pulse amplitude and/or width parameter for one or more of the plurality of cardiac pacing pulses between delivery of the at least some pulses until at least one of the phrenic stimulation threshold is detected and a cardiac pacing pulse is delivered at maximum amplitude and/or width that the cardiac pacing device is programmed to deliver.

15. The method of claim 12, wherein delivering the plurality of cardiac pacing pulses comprises decreasing a pacing pulse amplitude and/or width parameter for one or more of the plurality of cardiac pacing pulses between delivery of the at least some pulses until:

at least one of the phrenic stimulation threshold is detected and a cardiac pacing pulse is delivered at minimum amplitude and/or width that the cardiac pacing device is programmed to deliver; or

a cardiac pacing pulse reaches a capture threshold.

16. The method of claim 12, wherein delivering the plurality of cardiac pacing pulses comprises delivering an initial pacing pulse having an amplitude and/or width parameter at or above the cardiac capture threshold and increasing the pacing pulse amplitude and/or width parameter for one or more of the plurality of cardiac pacing pulses between delivery of the at least some pacing pulses until at least one of the phrenic stimulation threshold is detected and a cardiac pacing pulse is delivered at maximum amplitude and/or width that the cardiac pacing device is programmed to deliver.

17. The method of claim 12, wherein delivering the plurality of cardiac pacing pulses comprises delivering an initial pacing pulse having an amplitude and/or width parameter at or above the cardiac capture threshold and decreasing the pacing pulse amplitude and/or width parameter for one or

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more of the plurality of cardiac pacing pulses between delivery of the at least some pacing pulses until:

- at least one of the phrenic stimulation threshold is detected and a cardiac pacing pulse is delivered at minimum amplitude and/or width that the cardiac pacing device is programmed to deliver; or
- a cardiac pacing pulse reaches a capture threshold.

18. A method of operating a cardiac pacing device, wherein the cardiac pacing device includes a plurality of electrode combinations where each electrode combination defines a pacing vector, the method, comprising:

- delivering a plurality of cardiac pacing pulses using a selected pacing vector of the cardiac pacing device, a pacing parameter of the plurality of cardiac pacing pulses being changed between delivery of at least some of the pulses;
- evaluating one or more sensor signals to detect stimulation of the phrenic nerve by one or more of the plurality of cardiac pacing pluses;
- evaluating one or more sensor signals to detect whether the heart was captured by one or more of the plurality of cardiac pacing pluses;

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comparing the evaluation of the one or more sensor signals and the pacing parameter of one or more of the plurality of cardiac pacing pulses to determine if a phrenic stimulation threshold is higher than a maximum device parameter, and if not, higher than a capture threshold; and

delivering pacing therapy to the heart via a plurality of cardiac pacing pulses that are above the capture threshold but below the phrenic stimulation threshold if it is determined that the phrenic stimulation threshold is higher than the maximum device parameter, and if not, higher than the capture threshold.

19. The method of claim 18, further comprising performing the delivering, evaluating and comparing steps of claim 1 for each of two or more vectors of the cardiac pacing device.

20. The method of claim 18, wherein the pacing parameter of the plurality of cardiac pacing pulses is decreased between delivery of at least some of the pulses.

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专利名称(译)	用于膈刺激检测的方法和设备		
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[标]申请(专利权)人(译)	心脏起搏器股份公司		
申请(专利权)人(译)	心脏起搏器, INC.		
当前申请(专利权)人(译)	心脏起搏器, INC.		
[标]发明人	BROOKE M JASON		
发明人	BROOKE, M. JASON		
IPC分类号	A61N1/18 A61B5/00 A61B5/04 A61B5/042 A61B5/0488 A61B5/11 A61N1/36 A61N1/365 A61N1/368 A61N1/37 A61N1/372		
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摘要(译)

描述了用于表征膈刺激阈值, 心脏捕获阈值, 最大装置参数和最小装置参数的方法。可以通过使用心脏起搏设备来递送多个心脏起搏脉冲, 在递送至少一些脉冲之间改变多个心脏起搏脉冲的起搏参数。可评估一个或多个传感器信号以检测多个心脏起搏脉冲中的一个或多个刺激膈神经。可以比较一个或多个传感器信号和起搏参数的评估以确定膈刺激阈值是否是高于最大设备参数和低于最小设备参数中的至少一个。

