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(71) Applicant *(for all designated States except US)*: **CARDIAC PACEMAKERS, INC.** [US/US]; 4100 Hamline Avenue North, Saint Paul, Minnesota 55112-5798 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **SATHAYE, Alok, S.** [US/US]; 130 Bowdoin Street #509, Boston, MA 02108 (US). **CAZARES, Shelley, M.** [US/US]; 770 5th Street NW #1001, Washington, DC 20001 (US). **KRAMER, Andrew, P.** [US/US]; 621 Walnut Street, Marine On St. Croix, MN 55047 (US). **DONG, Yanting** [US/US]; 295 Oak Hill Drive, Shoreview, MN 55126 (US). **WEI, Xuan** [US/US]; 4521 Rosewood Lane North, Plymouth, MN 55442 (US). **GARG, Ankur** [US/US]; 1400 Laurel Avenue, #W1306, Minneapolis, MN 55403 (US). **NI, Quan** [US/US]; 5812 Prairie Ridge Drive, Shoreview, MN 55126 (US).

(74) Agents: **STEFFEY, Charles, E.** et al.; Schwegman, Lundberg & Woessner, P.A., P.O. Box 2938, Minneapolis, MN 55402 (US).

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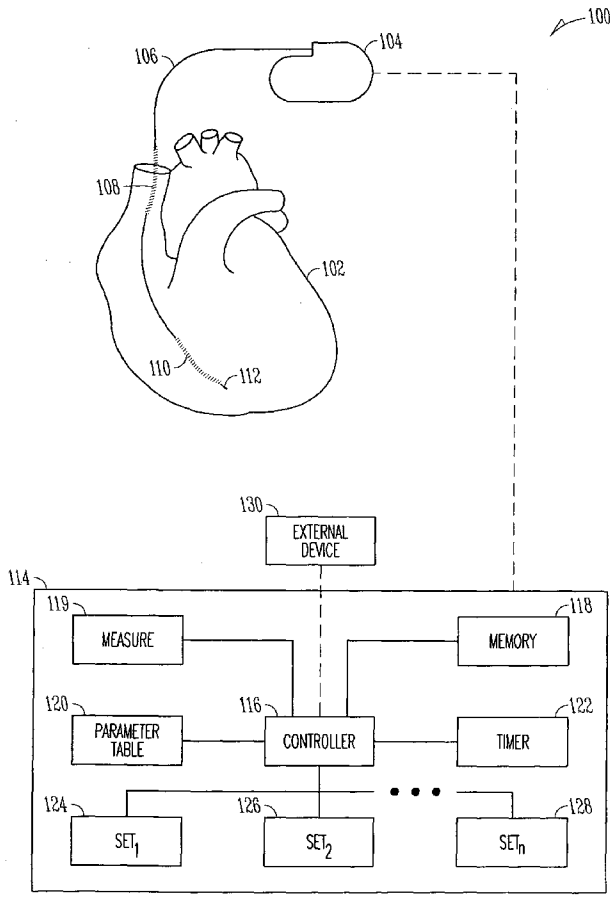
(54) Title: IMPLANTABLE DEVICE WITH MULTIPLE PARAMETER SETS



(57) Abstract: An implantable device including a programmable controller can be used to include a user-specifiable therapy control parameter set. The therapy control parameter set may then be configured to include at least one therapy control parameter that is user-configurable to automatically switch from a first parameter value to a second parameter value at a time that occurs between separate user programming sessions of the device. A remote external interface can be included that is configured to be communicatively coupled to the device. The remote external interface can be configured to perform an analysis of physiologic data received from the device in response to operation of the device using a plurality of therapy control parameter sets. The remote external interface can further be configured to select a particular therapy control parameter set using the analysis.

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IMPLANTABLE DEVICE WITH MULTIPLE PARAMETER SETS

CLAIM OF PRIORITY

Benefit of priority is hereby claimed to U.S. Patent Application No. 11/614,578, filed December 21, 2006 and entitled "METHOD AND APPARATUS TO IMPLEMENT MULTIPLE PARAMETER SETS IN AN IMPLANTABLE DEVICE", and U.S. Provisional Application No. 60/979,742, filed October 12, 2007 and entitled "METHOD AND APPARATUS TO TREND AND OPTIMIZE AN IMPLANTABLE MEDICAL DEVICE USING A PATIENT MANAGEMENT SYSTEM", which applications are both incorporated herein by reference.

TECHNICAL FIELD

This document relates generally to cardiac rhythm management (CRM) systems and particularly, but not by way of limitation, to cardiac rhythm management systems and methods that use multiple programmed parameter sets for a patient's implantable medical device, and further to cardiac rhythm management systems and methods to trend and adjust a patient's implantable medical device.

BACKGROUND

In a normal heart, the sinoatrial node, the heart's predominant natural pacemaker, generates electrical impulses, called action potentials, that propagate through an electrical conduction system to the atria and then to the ventricles of the heart to excite the myocardial tissues. The atria and ventricles contract in the normal atrio-ventricular sequence and synchrony to result in efficient blood-pumping functions indicated by a normal hemodynamic performance. These intrinsic action potentials can be sensed on a surface electrocardiogram (i.e., a "surface ECG signal") obtained from electrodes placed on the patient's skin, or from electrodes implanted within the patient's body (i.e., an "electrogram signal"). The surface ECG and electrogram waveforms, for example, include artifacts

associated with atrial depolarizations ("P-waves") and those associated with ventricular depolarizations ("QRS complexes").

When people have irregular cardiac rhythms, referred to as cardiac arrhythmias, or poor spatial coordination of heart contractions, diminished blood circulation may result. For such persons, cardiac rhythm management (CRM) systems may be used to improve these conditions. CRM systems include, among other things, pacemakers which deliver timed sequences of low energy electrical stimuli, called pace pulses, to the heart. By properly timing the delivery of pace pulses, the heart can be induced to contract in proper rhythm, improving efficiency. Another type of CRM systems include defibrillators that are capable of delivering higher energy electrical stimuli to the heart. Such defibrillators include cardioverters, which synchronize the delivery of such stimuli to sensed intrinsic heart activity signals. Defibrillators are often used to treat patients with tachyarrhythmias, which can be thought of as abnormal heart rhythms characterized by a rapid heart rate. Fibrillation is a form of tachyarrhythmia further characterized by an irregular heart rhythm.

Upon implantation, a CRM device is programmed to perform in response to detected electrical or mechanical disturbances within the heart. How the device is programmed may have a direct impact upon patient outcome. When the device is first implanted, a caregiver may rely upon historical data to determine how to set the programming parameters to be used until the next follow-up appointment, during which time results may be measured and recorded. After a specified period of time, the patient returns for a follow-up visit with the caregiver, the results are evaluated, and the device is re-programmed, if appropriate.

OVERVIEW

The present inventors have recognized that the iterative nature of the programming process, coupled with the large number of variables which may impact the functionality of the heart may delay finding an improved or optimized programmed parameter set. For these and other reasons, the present inventors have recognized a need for improved techniques of programming parameter sets.

This document describes, among other things, an implantable cardiac function management device including a programmable controller can be used to include a user-specifiable therapy control parameter set. The therapy control parameter set may then be configured to include at least one therapy control parameter that is user-configurable to automatically switch from a first parameter value to a second parameter value at a time that occurs between separate user programming sessions of the device. Various attributes of physiological measures may allow for refinement of the parameter sets to adapt to changed conditions of the subject. Methods of use are also presented.

Example 1 describes an apparatus comprising an implantable cardiac function management device. The implantable cardiac function management device includes a programmable controller. The programmable controller is configured to include a user-specifiable therapy control parameter set. The therapy control parameter set is configured to include at least one therapy control parameter that is user-configurable to automatically switch from a first parameter value to a second parameter value at a time that occurs between separate user programming sessions of the device.

In Example 2, the apparatus of Example 1 is optionally configured to obtain at least one physiological measure for each combination of parameter values of the therapy control parameter set.

In Example 3, the apparatus of at least one of Examples 1 or 2 is optionally configured such that at least one physiological measure includes information from a separate and unattached physiological sensor.

In Example 4, the apparatus of at least one of Examples 1 – 3 optionally includes the controller configured to determine which combination of parameter values contributed to a particular outcome as evidenced by at least one physiological measure.

In Example 5, the apparatus of at least one of Examples 1 – 4 optionally includes the controller configured to determine which of the first and second parameter value contributed more to the at least one physiological measure.

In Example 6, the apparatus of at least one of Examples 1 – 5 optionally includes the controller configured to suggest at least one combination of parameter values as a function of past physiological measures.

In Example 7, the apparatus of at least one of Examples 1 – 6 optionally includes the device having multiple therapy control parameter sets, wherein the device is configured to sequence through two or more of the therapy control parameter sets.

In Example 8, the apparatus of at least one of Examples 1 – 7 is optionally configured with at least one therapy control parameter set that includes at least one of a user-configurable range and a user-configurable duration.

In Example 9, the apparatus of at least one of Examples 1 – 8 is optionally configured such that the sequence occurs symmetrically from an initial parameter set to a final parameter set.

In Example 10, the apparatus of at least one of Examples 1 – 9 is optionally configured such that the duration is user-specifiable as a period of time.

In Example 11, the apparatus of at least one of Examples 1 – 10 is optionally configured such that the duration is user-specifiable as expiring upon reaching a threshold of detected events.

Example 12 includes a method comprising receiving user input to program a cardiac function management device and using the user input to automatically alter, at a time that occurs between separate user-programming sessions, a parameter value of at least one therapy control parameter.

In Example 13, the method of Example 12 is optionally performed such that it includes obtaining at least one physiological measure for each combination of parameter values of the therapy control parameter set.

In Example 14, the method of at least one of Examples 12 – 13 optionally includes determining which of the combination of parameter values contributed to a particular outcome as evidenced by at least one physiological measure.

In Example 15, the method of at least one of Examples 12 – 14 optionally includes using the user input for automatically sequencing through multiple therapy

control parameter sets at times occurring between separate user-programming sessions.

In Example 16, the method of at least one of Examples 12 – 15 optionally includes using at least one of a user-specified range and a user-specified duration for performing the sequencing.

In Example 17, the method of at least one of Examples 12 – 16 optionally includes using a user-specified duration that is user-specified as a time.

In Example 18, the method of at least one of Examples 12 – 17 optionally includes using a user-specified duration that is user-specified as a threshold number of detected events.

In Example 19, the method of at least one of Examples 12 – 18 is optionally performed such that the sequencing occurs sequentially from the initial parameter set to the final parameter set.

Example 20 describes an apparatus comprising means for receiving user input to program a cardiac function management device and means for using the user input to automatically alter, at a time that occurs between separate user-programming sessions, a parameter value of at least one therapy control parameter.

In Example 21, the apparatus of Example 20 is optionally configured such that it includes means for obtaining at least one physiological measure for each combination of parameter values of the therapy control parameter set.

In Example 22, the apparatus of at least one of Examples 20 – 21 optionally includes means for automatically sequencing, using the user input, through multiple therapy control parameter sets at times occurring between separate user-programming sessions.

In Example 23, the apparatus of at least one of Examples 20 – 22 optionally includes means for using at least one of a user-specified range and a user-specified duration for performing the sequencing.

Example 24 describes an example of an apparatus comprising a remote external interface for an implantable cardiac function management device, configured to be communicatively coupled to the implantable cardiac function management device via a network to a local external interface and via telemetry

between the local external interface and the implantable cardiac function management device, the remote external interface comprising a communication circuit, configured to communicate with the implantable cardiac function management device; and a processor circuit, configured to perform an analysis of physiologic data received from the implantable cardiac function management device in response to operation of the implantable cardiac function management device using a plurality of therapy control parameter sets, the processor circuit configured to select a particular therapy control parameter set using the analysis.

In Example 25, the apparatus of Example 24 optionally includes the implantable cardiac function management device.

In Example 26, the apparatus of Examples 24-25 optionally includes the local external interface.

In Example 27, the apparatus of Examples 24-26 optionally includes an external sensor device.

In Example 28, the apparatus of Examples 24-27 optionally includes the processor circuit being located in the network.

In Example 29, the apparatus of Examples 24-28 optionally includes the remote external interface configured to program the implantable cardiac function management device with one or more of the particular therapy control parameter set and a particular physiological response to store.

In Example 30, the apparatus of Examples 24-29 optionally includes the remote external interface configured to program the implantable cardiac function management device with an original therapy control parameter set or a default therapy control parameter set.

In Example 31, the apparatus of Examples 24-30 optionally includes the local external interface, the network, or the remote external interface configured to suggest to a third party the particular therapy control parameter set to program into the implantable cardiac function management device.

In Example 32, the apparatus of Examples 24-31 optionally includes the suggestion being based on at least one of an analysis of an aggregation of historic patient data or device performance data.

In Example 33, the apparatus of Examples 24-32 optionally includes the remote external interface configured to receive information about at least one of the plurality of therapy control parameter sets from a third party.

In Example 34, the apparatus of Examples 24-33 optionally includes the remote external interface configured to receive from a third party at least one of a selection of the particular therapy control parameter set or a value for a physiological parameter.

In Example 35, the apparatus of Examples 24-34 optionally includes the processor configured to perform an analysis of at least one of device performance data or patient feedback data.

In Example 36, the apparatus of Examples 24-35 optionally includes at least one of the therapy control parameter sets including at least one of an AV delay parameter, a VV offset parameter, a rate response parameter, a tachy detection parameter, a tachy therapy parameter, a pacing amplitude parameter, or a neural stimulation parameter.

In Example 37, the apparatus of Examples 24-36 optionally includes the processor configured to perform the analysis of physiologic data that includes at least one of a heart rate variability, a peripheral pressure, a blood pressure, a body weight, an activity log, a tachy conversion efficacy, a respiration rate, a posture indicator, a hemodynamic response parameter, an electrocardiogram, or a percentage of A/V pacing.

In Example 38, the apparatus of Examples 24-37 optionally includes the remote external interface configured to communicate with the implantable cardiac function management device during a real time communication session.

In Example 39, the apparatus of Examples 24-38 optionally includes the processor circuit configured to adjust therapy control parameter sets using the analysis of the physiologic data.

In Example 40, the apparatus of Examples 24-39 optionally includes the adjustment of the therapy control parameter sets uses at least one of a gradient search, an evolution algorithm, a simulated annealing method, a simplex algorithm, or a simplex algorithm.

In Example 41, a process includes receiving over a network physiologic data from an implantable cardiac function management device, the physiologic data resulting from operation of the implantable cardiac function management device using a plurality of therapy control parameter sets; analyzing the physiologic data; and selecting a particular therapy control parameter set using the analysis.

In Example 42, the process of Example 41 optionally includes programming the implantable cardiac function management device with the particular therapy control parameter set.

In Example 43, the process of Examples 41-42 optionally includes programming the implantable cardiac function management device with an original therapy control parameter set or a default therapy control parameter set.

In Example 44, the process of Examples 41-43 optionally includes providing to a third party a suggestion of the particular therapy control parameter set to program into the implantable cardiac function management device.

In Example 45, the process of Examples 41-44 optionally includes automatically adjusting the particular therapy control parameter set or a particular therapy control parameter and automatically programming the adjusted particular therapy control parameter set or the particular therapy control parameter into the implantable cardiac function management device.

In Example 46, the process of Examples 41-45 optionally includes receiving, at the remote external interface, from a third party, the one or more therapy control parameter sets.

In Example 47, the process of Examples 41-46 optionally includes receiving, at the remote external interface, an interval range for at least one parameter in the therapy control parameter sets, a time interval that the cardiac function management device is configured to operate with at least one of the therapy control parameter sets, or a value for a physiological parameter.

In Example 48, the process of Examples 41-47 optionally includes communicating with the implantable cardiac function management device in real time.

In Example 49, the process of Examples 41-48 optionally includes adjusting parameter sets using the analysis of the physiologic data.

In Example 50, the process of Examples 41-49 optionally includes adjusting the parameter search space using at least one of a gradient search, an evolution algorithm, a simulated annealing method, or a simplex algorithm.

In Example 51, an apparatus includes means for receiving over a network physiologic data from an implantable cardiac function management device, the physiologic data resulting from operation of the implantable cardiac function management device using a plurality of therapy control parameter sets; means for analyzing the physiologic data; and means for selecting a particular therapy control parameter set using the analysis.

In Example 52, an apparatus includes an implantable cardiac function management device including a programmable controller, the programmable controller configured to include a user-specifiable therapy control parameter set, wherein the therapy control parameter set is configured to include at least one therapy control parameter that is user-configurable to automatically switch from a first parameter value to a second parameter value at a time that occurs between separate user programming sessions of the device.

In Example 53, the apparatus of Example 52 is optionally configured such that the controller obtains at least one physiological measure for each combination of parameter values of the therapy control parameter set.

In Example 54, the apparatus of Examples 52-53 is optionally configured such that the at least one physiological measure includes information from a separate and unattached physiological sensor.

In Example 55, the apparatus of Examples 52-54 is optionally configured such that the controller determines which combination of parameter values contributed to a particular outcome as evidenced by at least one physiological measure.

In Example 56, the apparatus of Examples 52-55 is optionally configured such that the controller determines which of the first and second parameter value contributed more to the at least one physiological measure.

In Example 57, the apparatus of Examples 52-56 is optionally configured such that the controller suggests at least one combination of parameter values as a function of past physiological measures.

In Example 58, the apparatus of Examples 52-57 is optionally configured such that the device includes multiple therapy control parameter sets, and the device sequences through two or more of the therapy control parameter sets.

In Example 59, the apparatus of Examples 52-58 optionally includes a remote external interface for the implantable cardiac function management device, configured to be communicatively coupled to the implantable cardiac function management device via a network to a local external interface and via telemetry between the local external interface and the implantable cardiac function management device, the remote external interface comprising a communication circuit, configured to communicate with the implantable cardiac function management device, and a processor circuit, configured to perform an analysis of physiologic data received from the implantable cardiac function management device in response to operation of the implantable cardiac function management device using a plurality of the therapy control parameter sets, the processor circuit configured to select a particular therapy control parameter set using the analysis.

In Example 60, the apparatus of Examples 52-59 optionally includes one or more of the implantable cardiac function management device, the local external interface, and an external sensor device.

In Example 61, the apparatus of Examples 52-60 is optionally configured such that the remote external interface programs the implantable cardiac function management device with one or more of the particular therapy control parameter sets and a particular physiological response to store.

In Example 62, the apparatus of Examples 52-61 is optionally configured such that the remote external interface programs the implantable cardiac function management device with an original therapy control parameter set or a default therapy control parameter set.

In Example 63, the apparatus of Examples 52-62 is optionally configured such that the local external interface, the network, or the remote external interface

suggests to a third party the particular therapy control parameter set to program into the implantable cardiac function management device.

In Example 64, the apparatus of Examples 52-63 is optionally configured such that the suggestion is based on at least one of an analysis of an aggregation of historic patient data or device performance data.

In Example 65, the apparatus of Examples 52-64 is optionally configured such that the processor performs an analysis of at least one of device performance data or patient feedback data.

In Example 66, the apparatus of Examples 52-65 is optionally configured such that the processor circuit adjusts one or more therapy control parameter sets using the analysis of the physiologic data.

In Example 67, the apparatus of Examples 52-66 is optionally configured such that the adjustment of the one or more therapy control parameter sets comprises using the analysis of the physiologic data to reduce a parameter space for which the processor circuit then analyzes the physiologic data.

In Example 68, the apparatus of Examples 52-67 is optionally configured such that the optimization algorithm includes at least one of a gradient search, an evolution algorithm, a simulated annealing method, or a simplex algorithm.

In Example 69, a method includes receiving user input to program a cardiac function management device, and using the user input to automatically alter, at a time that occurs between separate user-programming sessions, a parameter value of at least one therapy control parameter.

In Example 70, the method of Example 69 optionally includes obtaining at least one physiological measure for each combination of parameter values of the therapy control parameter set.

In Example 71, the method of Examples 69-70 optionally includes determining which of the combination of parameter values contributed to a particular outcome as evidenced by at least one physiological measure.

In Example 72, the method of Examples 69-71 optionally includes using the user input for automatically sequencing through multiple therapy control parameter sets at times occurring between separate user-programming sessions.

In Example 73, the method of Examples 69-72 optionally includes receiving over a network physiologic data from the cardiac function management device, the physiologic data resulting from operation of the cardiac function management device using a plurality of therapy control parameter sets, analyzing the physiologic data, and selecting a particular therapy control parameter set using the analysis.

In Example 74, the method of Examples 69-73 optionally includes programming the implantable cardiac function management device with the particular therapy control parameter set.

In Example 75, the method of Examples 69-74 optionally includes providing to a third party a suggestion of the particular therapy control parameter set to program into the implantable cardiac function management device.

In Example 76, the method of Examples 69-75 optionally includes automatically adjusting the particular therapy control parameter set or a particular therapy control parameter and automatically programming the adjusted particular therapy control parameter set or the particular therapy control parameter into the implantable cardiac function management device.

In Example 77, the method of Examples 69-76 optionally includes receiving, at the remote external interface, from a third party, the one or more therapy control parameter sets.

In Example 78, the method of Examples 69-77 optionally includes receiving, at the remote external interface, an interval range for at least one parameter in the therapy control parameter sets, a time interval that the cardiac function management device is configured to operate with at least one of the therapy control parameter sets, or a value for a physiological parameter.

In Example 79, the method of Examples 69-78 optionally includes adjusting the therapy control parameter sets using the analysis of the physiologic data.

In Example 80, the method of Examples 69-79 optionally includes using the analysis of the physiologic data to reduce a parameter space in which the physiologic data is then analyzed.

In Example 81, an apparatus includes a means for receiving user input to program a cardiac function management device, and a means for using the user

input to automatically alter, at a time that occurs between separate user-programming sessions, a parameter value of at least one therapy control parameter.

In Example 82, the apparatus of Example 81 optionally includes a means for obtaining at least one physiological measure for each combination of parameter values of the therapy control parameter set.

In Example 83, the apparatus of Examples 81-82 optionally includes a means for automatically sequencing, using the user input, through multiple therapy control parameter sets at times occurring between separate user-programming sessions.

In Example 84, the apparatus of Examples 81-83 optionally includes a means for using at least one of a user-specified range and a user-specified duration for performing the sequencing.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings, which are not necessarily drawn to scale, like numerals describe substantially similar components throughout the several views. Like numerals having different letter suffixes represent different instances of substantially similar components. The drawings illustrate generally, by way of example, but not by way of limitation, various embodiments discussed in the present document.

FIG. 1 illustrates an example of portions of a system which utilizes a device for monitoring and controlling electrical signals of the heart.

FIG. 2 is a flow chart illustrating generally an example of portions of a technique for programming multiple parameter sets and storing responses.

FIG. 3 is a flow chart illustrating generally an example of how the results of the multiple parameter sets are evaluated and revised, such as for optimization.

FIG. 4 is a flow chart illustrating generally an example of how multiple parameter sets may operate concurrently.

FIG. 5 is a flow chart, similar to FIG. **2**, but illustrating an example of a technique in which an external device parameter is read as part of the programmed parameters.

FIG. 6 is a flow chart of an example, similar to FIG. **2**, in which the implantable cardiac function management device includes a target outcome which is later compared against the results.

FIG. 7 illustrates an example of an implantable medical device in telemetric communication with a local external system and a remote external system.

FIG. 8 illustrates an example in block diagram form of a remote external system in telemetric communication with a local external system and an implantable medical device.

FIG. 9 illustrates an example process to program an implantable medical device with a therapy control parameter set.

FIG. 10 illustrates another example process to program an implantable medical device with a therapy control parameter set.

FIG. 11 illustrates another example process to program an implantable medical device with a therapy control parameter set.

FIG. 12 is a graph illustrating an example of a process to reduce search parameter sets for CRT optimization.

DETAILED DESCRIPTION

The following detailed description includes references to the accompanying drawings, which form a part of the detailed description. The drawings show, by way of illustration, specific embodiments in which the invention may be practiced. These embodiments, which are also referred to herein as "examples," are described in enough detail to enable those skilled in the art to practice the invention. The embodiments may be combined, other embodiments may be utilized, or structural, logical and electrical changes may be made without departing from the scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims and their equivalents.

In this document, the terms "a" or "an" are used, as is common in patent documents, to include one or more than one. In this document, the term "or" is used to refer to a nonexclusive or, unless otherwise indicated. Furthermore, all

publications, patents, and patent documents referred to in this document are incorporated by reference herein in their entirety, as though individually incorporated by reference. In the event of inconsistent usages between this document and those documents so incorporated by reference, the usage in the incorporated reference(s) should be considered supplementary to that of this document; for irreconcilable inconsistencies, the usage in this document controls.

The present systems and methods are described with respect to implantable medical devices such as neurostimulation devices, gastrointestinal stimulation devices, retinal implants, cochlear implants and including CRM devices, such as pacemakers, cardiac function management devices (CFMDs), implantable cardioverter-defibrillators (ICDs), pacer-defibrillators, and single or multi-chamber cardiac resynchronization therapy (CRT) devices that use pacing. The device may also be programmed to monitor and store one or more measured physiological parameters using a given programmed parameter set. In certain examples, the programmed parameter set contains a single parameter adjusted among one or more values within a specified range. In another example, the programmed parameter set comprises multiple parameters adjusted among one or more values within a specified range. In certain examples, the programmed parameter set is determined as a function of one or more measured physiological parameters such as by use of an algorithm to calculate a value for use in at least one programmed parameter set. In certain examples, the device may identify safe limits such that an adverse condition would prompt a stop condition for at least one parameter set. The monitored or stored information may indicate information about the patient's response to a given parameter set and thereby can sometimes be used to determine an improved programmed parameter set. For example, one measured physiological parameter may indicate how the heart reacts during one or more specific activities that, when repeated, can identify a value for a programmed parameter set or determinable condition or outcome. In another example, a "target" physiological outcome may be specified, and the stored physiological information corresponding to a particular programmed parameter set may be compared against this target such

as to determine whether any changes should be made to the programmed parameter set.

Each programmable parameter set may fit as part of a larger optimization program which uses ranges of parameter settings (e.g., AV delay range) and durations of each parameter set occurring in time (e.g., period of forty-eight hours). One example of this type of organization of variables uses a design of experiments (DOE). In DOE, a model, or series of models, can be developed to help determine what variables (e.g., parameter sets) affect a response of interest (e.g., % AV pacing). Using this method, one can determine certain variables, and can separate any dependent variables, which change in response to a change in one or more other variables, from any independent variables, which do not change in response to a change in one or more other variables. When only a few variables exist, the analysis may not need formal DOE, however, it is useful for a large number of variables or a complex interaction between variables. In certain examples, the automatic variation in one or more parameters, coupled with automatic analysis of one or more corresponding results obtained for different values of the one or more parameter, can be used to select (or to help a caregiver select) a set of parameter values that will produce a high probability of a desired response. This can reduce or eliminate clinician guess work and can obtain useful information about the effect of designed variations of one or more parameter values during the period of time between the implant of a device and the next patient follow-up,or between follow-ups. This can save time and allow much more information to be presented to the caregiver for tailoring the device for the patient.

Moreover, post-implant DOE techniques can provide data that will enable both caregivers and device manufacturers to explore performance variations resulting from parameter value variations. This information can be used to improve desirable patient outcomes earlier in the life of a particular model of device, for example. In certain examples, implanting a CRM device may involve programming a set of default parameter values based upon historical information about the subject's physiological condition before implantation. One or more parameter values can be controllably varied, and one or more specified indicators can then be

monitored until the next follow-up between the caregiver and the subject. At that point, any recorded results may be reviewed by the caregiver, who may decide to modify one or more device parameter values, or automatically evaluated by the implanted device itself or by an ancillary external device. This may provide an early indication of the subject's response to a given therapy. Considering that a single programmed parameter set over the period of time (e.g., six months) provides a limited amount of information about the subject's response, the ability to provide multiple parameter sets occurring sequentially, or in combination, may provide significantly more valuable data for the caregiver or the device to evaluate.

FIG. 1 illustrates portions of a system **100** that uses a device **104** (e.g., implantable cardiac function management device), such as for monitoring one or more electrical signals of the heart **102**. In certain examples, the device **104** may be coupled to one or more lead wires **106** having a first coil electrode **108**, a second coil electrode **110**, and a tip electrode **112**, however, a leadless implementation is also possible. An electrogram signal (EGM) may be detected from one or more intrinsic electrical signals occurring within the heart **102**, thereby providing information about heart contractions, such as an indication of heart rate, and information about how the values of the control parameters of the device **104** affect the rate. In this example, a control module **114** includes a programmable controller **116**, which may be capable of performing several functions. In certain examples, programmable controller **116** may select a user-specifiable therapy control parameter value from a parameter table **120** as a result of receiving input from a user or caregiver. The parameter table **120** may contain a listing of one or more adjustable parameters, each having specified candidate values and a duration within which each such candidate value is to be applied. A specified range of a given control parameter may limit the candidate values of a particular parameter, such as by specifying a minimum value or maximum value.

For example, one possible therapy control parameter may include an atrioventricular (AV) delay that may have a specified range of possible candidate AV delay times that may be selected for a given parameter set. The AV delay may be associated with one or more parameter sets **124**, **126** and **128**. Each parameter

set may include one or more user-specifiable therapy control parameters having a user-configurable range (or other specification of candidate values) and a user-configurable duration. For example, the duration of a specified candidate control parameter, within a particular parameter set, may include an associated period of time, such as forty eight hours, during which time a selected AV delay candidate value will be applied as part of a specified parameter set (e.g., **124**, **126** or **128**). A timer **122** may be used to count the duration for using a given parameter value or for using an entire parameter set (e.g., **124**, **126** or **128**). In certain examples, a parameter value will automatically switch from one value to another between parameter sets, such as to perform a DOE style variation in parameter values using the different parameter sets. In certain examples, the user-configurable duration may expire upon the measure module **119** reaching a threshold value. In certain examples, the device **104** cycles through various different parameter sets (e.g., **124**, **126** or **128**), such as during the period of time between an implant of the device **104** and a remote or local follow-up between a caregiver and the subject.

In the example of **FIG. 1**, an initial or first parameter set **124** (SET_1), may represent a first set of user-specified values and corresponding durations of specified device control or operating parameters from the parameter table **120**. For example, the first parameter set **124** may list an AV delay parameter with a parameter value of 5 ms to be applied for a duration of forty-eight hours from a start to an end of a period during which the first parameter set **124** is in effect. Similarly, a second parameter set **126** (SET_2), may represent a second set of specified parameters from the parameter table **120**. In certain examples the second parameter set **126**, may be automatically put into effect upon the completion of a duration of the first parameter set **124** or of one or more durations of one or more specified therapy control parameters within a first parameter set **124**. In yet another example, the second parameter set **126** may be automatically activated before the completion of the duration of the first parameter set **124**, for example, upon measuring a response that meets a particular threshold value. The second parameter set **126** may automatically alter at least one parameter value from the first parameter set **124**. A

final parameter set **128** (SET_N), may represent the last parameter set among a number of specified parameter sets.

During the application of the various parameter sets, there may be one or more physiological measures collected by the measure module **119** to be stored within memory **118**. The programmable controller **116** may obtain information about the one or more physiological measures in association with a combination of control parameter values in effect during a timer period when the physiological measure was obtained. Examples of one or more physiological measures to be monitored include but are not limited to heart rate, blood pressure, percent atrial or ventricular pacing, etc. A separate and unattached implantable or external physiological sensor may be used to obtain one or more physiological measures. Additionally, external device **130** may provide a physiological measure—and may interact with or operate independently of the programmed parameter sets. In certain examples, the external device **130** may include a weight scale, a blood pressure cuff, etc.

FIG. 2 is a flow chart illustrating generally an example of portions of a technique for programming multiple parameter sets and storing responses. In certain examples, the start of a programming cycle (or beginning of a first parameter set) follows the implant of an ICD or other implantable medical device. At **200**, a device may be implanted within the body of a subject for monitoring intrinsic cardiac signals and, at **205**, a control module (similar to control module **114** of FIG. **1**) may be programmed with more than one parameter set ($SET_1, \ldots, SET_N$). In certain examples, a program may specify a first set of parameter values for first parameter set SET_1 and an associated duration. During at least a portion of the duration of the first parameter set SET_1, one or more physiological measures may be monitored and recorded.

At **210**, the first parameter set SET_1 may be monitored for completion of its specified duration. If the duration has not yet reached completion, the control module **114** will continue to monitor. If however, at **210**, duration of the first parameter set SET_1 has reached completion, at **215**, the monitored potential outcome variables may be stored and associated with first parameter set SET_1 for

later reference or retrieval. Additionally, at **215**, the second parameter set SET_2 may be loaded by the control module **114** to begin the next phase of the programming cycle. In certain examples, the control module **114** may be programmed to delay the start of a subsequent parameter set for a specified duration, such as to establish a steady-state or reference condition before activating the next parameter set. In certain examples, this may involve returning to an interim parameter set between successive trial parameter sets. At **220**, the second parameter set (SET_2) may be monitored for completion of its specified duration. Until its duration reaches completion, the control module **114** will continue to monitor and may record one or more specified outcome variables. Upon completion of the duration, at **225**, the monitored potential outcome variables may be stored and associated with the second parameter set SET_2 for later reference or retrieval. At **215**, the final parameter set SET_N may be loaded by the control module **114** to begin the final phase of the programming cycle. At **230**, duration of the final parameter set SET_N is monitored by the control module **114** until completion of its duration. Upon completion of its duration, at **235**, the monitored potential outcome variables may be stored. At **240**, the caregiver may review the results associated with one or more parameter sets ($SET_1, \ldots, SET_N$). The caregiver may then use this information to choose, at **205**, a parameter set for subsequent operation, or to create another DOE of multiple parameter sets to be executed before another follow-up.

FIG. 3 is a flow chart illustrating generally an example of how the monitored results of the multiple parameter sets can be evaluated and parameter values improved or optimized, such as that performed at **240** of **FIG. 2**. At **300**, a follow-up may be scheduled to review the results obtained from the one or more parameter sets ($SET_1, \ldots, SET_N$). At **305**, the stored results may be evaluated to determine if a change in one or more programmed parameter values is warranted, or if further monitoring of results for different parameter sets is warranted. The caregiver may choose to have the information presented in a trended or other graphical representation to better represent the connection between a particular parameter set (or chosen therapy) and a corresponding monitored physiological measure. At **310**, the caregiver may make a determination as to the effectiveness of

the applied therapy (associated with the corresponding parameter sets). The therapy may be deemed effective if one or more parameter sets caused a desired outcome in one or more monitored physiological measures. If the caregiver determines that the therapy was effective (e.g., best outcome reached), at **315**, the identified one or more control parameter values are chosen from the one or more parameter sets (SET_1-SET_N) and at **320**, the control module **114** may be programmed to use the chosen parameter values for a subsequent specified duration or indefinitely, during which time the control module **114** may continue to monitor one or more physiological measures, if the user desires. Upon completion of the best outcome duration, at **300**, a follow-up may occur.

If, at **310**, the caregiver determines that the therapy was not effective, then at **325**, one or more programmed parameter sets can be revised, such as for further experimentation and monitoring. At **330**, the one or more parameter sets (SET_1, . . . , SET_N) are monitored until their durations have completed, thereafter, at **335**, the results associated with physiological measures are stored. At **300** a follow up is carried out.

DOE permits understanding of the effect that each variable has on a given system. As a result, multiple parameters may be concurrently varied in value, and DOE techniques used to extract the impact of a particular parameter on the resulting monitored physiological output variable. **FIG. 4** is a flow chart illustrating generally an example of how multiple parameter sets may operate concurrently. At **400**, a device may be implanted within the body of a subject for monitoring intrinsic cardiac signals. At **405**, a control module **114** (similar to control module **114** of FIG. **1**) may be programmed with more than one parameter set (SET_1, . . , SET_N). In certain examples, one or more parameter sets such as first parameter set SET_1 **410**, second parameter set SET_2 **420** and final parameter set SET_N **430** may occur concurrently or be subject to overlap of varying durations. The control module **114** may monitor physiological measures for each parameter set in combination or separately until each has completed its duration. Upon completion of the duration of the first parameter set SET_1 **410**, second parameter set SET_2 **420** and final parameter set SET_N **430**, the control module **114** will store the monitored results at

415 (SET_1), **425** (SET_2) and **435** (SET_N), respectively. At **440**, all of the results are reviewed by the caregiver at the next follow-up visit with the subject.

In certain examples, the control module **114** may collect information from an external device **130** to be used as part of the therapy for the subject and as a variable to be analyzed with the implantable cardiac rhythm management device and related specified parameter sets. In **FIG. 5**, the caregiver may implant an implantable cardiac rhythm management device at **500** and, at **505,** one or more programmable parameter sets may be programmed with a one or more parameters having a range or varying values and a duration. At **510**, the control module **114** waits for the parameter set's duration to elapse. In certain examples, the control module **114** recurrently or periodically checks for a completed duration and initiates a read operation to obtain updated information from the external device **515**, e.g., just before such completion. At **520**, the duration of one or more parameter sets has reached completion, and the monitored physiological measures may be stored and associated with the particular parameter set for future reference or retrieval. At **520**, any remaining parameter sets may be loaded by the control module **114** to begin the next phase of the programming cycle. At **525**, the results may be reviewed by a caregiver at a follow-up, such as before repeating a new cycle of parameter sets.

In certain examples, a caregiver may indicate a desired outcome or target value for a particular physiological measure, in anticipation of reaching the target value during implementation of one or more control parameters or among one or more parameter sets. In certain examples, one or more quantitative criteria based upon one or more monitored physiological parameters may prompt the control module **114** to select one or more parameter sets. For example, a system **100** may include one or more sensors to measure right and left ventricular pressure and a target value that can be specified by a user or caregiver. In certain examples, this target value may represent an increase in ventricular pressure over time (dP/dt), an increase in stroke volume, or a decrease in mechanical dyssynchrony. In such examples, the control module **114** may determine which parameter set resulted in reaching the target value and may further select a next parameter set based upon this determination. In such cases, there may be a need to store a target result within the

control module **114** and later compare a monitored result to the target value. The target may be representative of one or a combination of multiple physiological measures. Similarly, the control module **114** may be configured to identify which parameter set produces a target result and to store that information. For example, this may include identifying and storing the parameter set associated with the largest increase in ventricular pressure or a largest decrease in mechanical dyssynchrony.

In **FIG. 6**, at **600**, the caregiver implants an implantable cardiac device within the body of a subject. At **605**, the caregiver specifies a target value for one or more physiological measures. At **610**, the control module **114** may be programmed with one or more parameter sets, as discussed above. At **615**, one or more physiological quantities corresponding to a parameter set may be monitored by the control module **114** until a completed duration is reached. At such time, at **620**, the monitored results may be stored by the control module **114**. Then, at **625**, the results of at least one parameter set associated with past physiological measures may be reviewed and compared against the one or more targets at **605**. At **610**, the next parameter set may be loaded, or alternatively, based upon the comparison of the results from the prior parameter set, a modified parameter set may be programmed by the control module **114** to run next. In this manner, the caregiver may have a specified range within which the program may operate and refine a parameter set with the goal of reaching a specified target without additional follow-ups. Alternatively, a proposed set of parameter settings may be suggested at **610**, to be reviewed by the caregiver at the next follow-up. In certain examples, the device may use one or more search techniques to explore measured physiological parameters and improve or optimize a programmed parameter set. For example search techniques may include, but are not limited to hill climbing, genetic search, heuristic search, A* ("A star") search, simulated annealing, or min-max.

FIG. 7 is a block diagram illustrating an example of a medical device system **700**, and portions of an environment in which it is used. The environment includes a body **702** with a heart **705**. In this example, system **700** can include an implantable medical device **710**, a lead system **715**, an external sensor device **717**, a local external system **720**, and a remote external system **725**. The local external

system **720** is coupled to the implantable medical device **710** via a telemetry link **730**, and the remote external system **725** is coupled to the local external system **720** via a telemetry link **740**. The external sensor device **717** senses electrical, vibration, or other physiological information from the body **702**. The external sensor device **717** is coupled to the local external system **720** via telemetry link **730**.

FIG. 8 illustrates an example of the remote external system **725** including a remote external interface **810**. The remote external interface **810** can include one or more of a processor, a server, and a display unit. The remote external interface **810** is configured to be coupled to the implantable medical device **710** via the communication link **740** (such as a wireless link or a network connection) to the local external interface or system **720**, and via the telemetry link **730** between the local external interface **720** and the implantable medical device **710**. The remote external system **725** can include a communication circuit **815** and a processor circuit **820**.

The communication circuit **815** is configured to communicate with the implantable medical device **710**. This communication can be in real time. As noted above, this communication can use the links **730** and **740** and the local external interface **720**. The processor circuit **820** is configured to perform an analysis of physiologic data that is received from the implantable medical device **710**. This data is captured by the implantable medical device **710** in response to operation of the implantable medical device **710** using a plurality of therapy control parameter sets. The processor circuit **820** is further configured to select a particular therapy control parameter set based on its analysis of the physiologic data.

In an example, a particular therapy control parameter set may include one or more of an AV delay parameter, a VV offset parameter, a rate response parameter, a tachy detection parameter, a tachy therapy parameter, a pacing amplitude parameter, or a neural stimulation parameter. The physiologic data received by the remote external interface **725** can include one or more of a heart rate, a heart rate variability, a peripheral pressure, a blood pressure, a body weight, an activity log, a tachy conversion efficacy, a respiration rate, a posture indicator, a hemodynamic

response parameter, an electrocardiogram, or a percentage of atrial or ventricular pacing.

A dual sensor adaptive-rate pacing system, such as one with an accelerometer and a minute ventilation sensor, typically requires a parameter search of response factors for both of the sensors. Given that each sensor may have a range of response factor settings, for example 1 through 16 for both sensors, the combinations of the parameter settings rise to 256 possibilities, providing a difficult task for a clinician to accomplish. However, using one of the parameter search algorithms, such as a gradient search, an evolution algorithm, a simulated annealing method, or a simplex algorithm, only a limited combination are needed to reach an optimal response factor combination for the two sensors.

In an example of optimizing AV delay and VV delay settings for bi-ventricular pacing, both delay settings have a range of timing intervals that can be programmed. A parameter search algorithm can be used with consideration of patient response through measurements from both internal or external sensors. A convergence to the optimal combination of AV and VV delay settings can be found more quickly than the a step-wise search through every possible combination of the two parameters.

FIG. 9 illustrates an example of a process **900** to program an implantable medical device with a particular therapy control parameter set. At **910**, physiologic data is received from an implantable medical device. The physiologic data can be transmitted from an implantable medical device such as device **710** through a network such as the local external system **720**, the telemetry links **730** and **740**, and received at the remote external system **725**. The physiologic data can result from operation of the implantable medical device using a plurality of therapy control parameter sets. At **920**, the physiologic data is analyzed. This analysis can be performed by a processor such as processor circuit **820**. At **930**, the processor circuit selects one of the particular therapy control parameter sets based on its analysis of the plurality of the sets. At **940**, the implantable medical device is programmed with the particular therapy control parameter set selected by the processor circuit.

FIG. 10 illustrates another example of a process **1000** to program an implantable medical device with a particular therapy control parameter set. As in process **900** of **FIG. 9**, physiologic data is received at **910**. At **915**, a check is made to determine if the system is set for an active programming mode. If the system is set for active programming mode, then at **920**, the physiologic data is analyzed. In an example, device performance data or patient feedback data can also be analyzed. For example, if a patient indicates that he did not feel well when a particular therapy control parameter set was in place and executing, then a health care provider can decide not to use that therapy control parameter set again. At **925**, the processor circuit determines if one or more of the therapy control parameter sets are acceptable. If the processor circuit determines that one or more therapy control parameter sets are acceptable, then at **940**, the implantable medical device is programmed with the particular therapy control parameter set selected by the processor circuit. If the processor circuit determines at **925** that none of the therapy control parameter sets are acceptable, then at **927**, the implantable medical device is programmed to its original or default therapy control parameter set. At **929**, a health care provider is informed of the results, and suggestions are provided to the health care provider. An example suggestion would be to change a particular parameter in the parameter set to a certain value, and resubmit the altered parameter set to the implantable medical device via the remote external system **725**.

At **915**, if the processor circuit determines that the system is not set to an active programming mode, then at **950**, the device is first reprogrammed back to its original therapy control parameter set. At **955**, a health care provider examines the data resulting from the use of the plurality of therapy control parameter sets. At **960**, the health care provider determines if any of the plurality of therapy control parameter sets produced acceptable results. If the health care provider determines that one or more therapy control parameter sets produced acceptable results, than at **965**, the health care provider programs the implantable medical device with his or her choice of a therapy control parameter set. This determination can be based on one or more suggestions or other information provided by the remote external system **725**. Such suggestions can be based on the patient's historic data maintained

at the remote external system, or an aggregation of historic data from a plurality of patients. If no acceptable results are found, then at **970**, a new plurality of therapy control parameter sets can be transmitted to the implantable medical device. The new therapy control parameter sets can be provided by the health care provider via the remote external interface **810**, and may or may not be based on suggestions provided by the remote external system **725**.

In connection with the processes **900** and **1000**, a health care provider can provide an interval range for one or more parameters in a parameter set. This can be input at the remote external interface **810**. A health care provider can also provide at the remote external interface **810** a time interval that the implantable medical device can operate with at least one of the therapy control parameter sets. A health care provider can also provide a particular value for a physiological parameter in the therapy control parameter set.

In an example, the processor circuit **820** can adjust a parameter search space based on the analysis of the physiologic data. For example, the A-V delay can be altered based on the results generated with other known values of the A-V delay. The parameter search space can be adjusted using one or more of a gradient search, an evolution algorithm, a simulated annealing method, or a simplex algorithm.

FIG. 11 illustrates another example process **1100** to program an implantable medical device with a therapy control parameter set. At **1110,** a physician determines a number of parameter sets 1 through N (or a range of a parameter to be evaluated) to be used in the implantable medical device. In an example, the external interface can provide to a physician one or more recommended parameter sets to be investigated based on data from a large patient data base. At **1120,** the processor circuit on the remote external system programs the implantable medical device with the parameter set 1, and informs the implantable medical device which physiological response to monitor and store. The processor circuit can also perform an analysis of the physiological response and adjust the parameter sets accordingly. The processor circuit can also serve as storage of the physiological responses for different parameter sets. The physician can make the decision as to what parameter set to use. At **1130,** the processor circuit retrieves the physiological response

corresponding to the parameter set 1 via the communication circuit. The retrieval of these physiological responses can be performed at physician-determined intervals. At **1140,** the processor circuit serially programs the implantable medical device with the other parameter sets, and retrieves the physiological responses generated during the device operation with each of these parameter sets. At **1150,** the processor circuit analyzes the physiological response and selects a particular parameter set as a preferred configuration for the implantable medical device. At **1150,** the processor transmits a message to the external interface informing a physician that the results are ready for review.

FIG. 12 is a graph illustrating an example of a process to reduce a search parameter space for CRT optimization. A search parameter space can include a number of parameter sets or a number of parameters and parameter values within one or more parameter sets. Referring specifically to **FIG. 12,** for CRT AV and VV delay optimization, to reach optimized value, all combinations of AV and VV delay need to be examined. In **FIG. 12**, 6 AV delay and 5 VV delays are investigated. This results in a total of 30 possible AV and VV combinations. However, by using optimization algorithms, the search parameter sets can be significantly reduced. The simplex optimization algorithm is used as an example in **FIG. 12**. First, 3 AV and VV combinations within a physician determined range are chosen by the processor circuit. The physiological response, in this case, blood pressure (SBP_{rel} (mmHg)), corresponding to each of the 3 AV and VV combinations (point 1, 2, 3 on **FIG. 12**) is measured. In **FIG. 12**, the AV and VV combination at point 1 produces the least desirable response. A new parameter set 4 is then generated by reflection into the parameter space opposite the undesirable result. Similarly, parameter set 5 is generated by comparing the response from AV and VV combinations at points 2, 3, and 4, and reflecting into the parameter space opposite the least desirable combination at point 2. Then parameter set represented by point 6 is generated by comparing a response from parameter sets at points 3, 4, and 5, and the physiological response from the parameter set at point 6 is collected. The parameter set at point 7 is then chosen based on comparing the responses from parameter sets at points 4, 5, and 6, and reflecting into the parameter space opposite the least

desirable parameter set, that is, set 4. The physiological response from the parameter set at point 7 is then collected. However, since the physiological response from the parameter set at point 7 does not exceed that of the parameter set at point 6, the search is stopped and the parameter set at point 6 is chosen as the optimal AV and VV combination. From this example, it can be seen that by using optimization algorithms, the parameter search sets can be significantly reduced, from 30 to 7 in this example.

It is to be understood that the above description is intended to be illustrative, and not restrictive. For example, the above-described embodiments (and/or aspects thereof) may be used in combination with each other. Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. In the appended claims, the terms "including" and "in which" are used as the plain-English equivalents of the respective terms "comprising" and "wherein." Also, in the following claims, the terms "including" and "comprising" are open-ended, that is, a system, device, article, or process that includes elements in addition to those listed after such a term in a claim are still deemed to fall within the scope of that claim. Moreover, in the following claims, the terms "first," "second," and "third," etc. are used merely as labels, and are not intended to impose numerical requirements on their objects.

The Abstract is provided to comply with 37 C.F.R. §1.72(b), which requires that it allow the reader to quickly ascertain the nature of the technical disclosure. It is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims. Also, in the above Detailed Description, various features may be grouped together to streamline the disclosure. This should not be interpreted as intending that an unclaimed disclosed feature is essential to any claim. Rather, inventive subject matter may lie in less than all features of a particular disclosed embodiment. Thus, the following claims are hereby incorporated into the Detailed Description, with each claim standing on its own as a separate embodiment.

WHAT IS CLAIMED IS:

1. An apparatus comprising:

an implantable cardiac function management device including a programmable controller, the programmable controller configured to include a user-specifiable therapy control parameter set, wherein the therapy control parameter set is configured to include at least one therapy control parameter that is user-configurable to automatically switch from a first parameter value to a second parameter value at a time that occurs between separate user programming sessions of the device.

2. The apparatus of claim 1, wherein the controller is configured to obtain at least one physiological measure for each combination of parameter values of the therapy control parameter set.

3. The apparatus of claim 2, wherein the at least one physiological measure includes information from a separate and unattached physiological sensor.

4. The apparatus of claim 2, wherein the controller is configured to determine which combination of parameter values contributed to a particular outcome as evidenced by at least one physiological measure.

5. The apparatus of claim 4, wherein the controller is configured to determine which of the first and second parameter value contributed more to the at least one physiological measure.

6. The apparatus of claim 4, wherein the controller is configured to suggest at least one combination of parameter values as a function of past physiological measures.

7. The apparatus of claim 1, wherein the device includes multiple therapy control parameter sets, and wherein the device is configured to sequence through two or more of the therapy control parameter sets.

8. The apparatus of claim 1, comprising:

a remote external interface for the implantable cardiac function management device, configured to be communicatively coupled to the implantable cardiac function management device via a network to a local external interface and via telemetry between the local external interface and the implantable cardiac function management device, the remote external interface comprising:

a communication circuit, configured to communicate with the implantable cardiac function management device; and

a processor circuit, configured to perform an analysis of physiologic data received from the implantable cardiac function management device in response to operation of the implantable cardiac function management device using a plurality of the therapy control parameter sets, the processor circuit configured to select a particular therapy control parameter set using the analysis.

9. The apparatus of claim 8, comprising one or more of the implantable cardiac function management device, the local external interface, and an external sensor device.

10. The apparatus of claim 8, wherein the remote external interface is configured to program the implantable cardiac function management device with one or more of the particular therapy control parameter sets and a particular physiological response to store.

11. The apparatus of claim 8, wherein the remote external interface is configured to program the implantable cardiac function management device with an original therapy control parameter set or a default therapy control parameter set.

12. The apparatus of claim 8, wherein the local external interface, the network, or the remote external interface is configured to suggest to a third party the particular therapy control parameter set to program into the implantable cardiac function management device.

13. The apparatus of claim 12, wherein the suggestion is based on at least one of an analysis of an aggregation of historic patient data or device performance data.

14. The apparatus of claim 8, wherein the processor is configured to perform an analysis of at least one of device performance data or patient feedback data.

15. The apparatus of claim 8, wherein the processor circuit is configured to adjust one or more therapy control parameter sets using the analysis of the physiologic data.

16. The apparatus of claim 15, wherein the adjustment of the one or more therapy control parameter sets comprises using the analysis of the physiologic data to reduce a parameter space for which the processor circuit then analyzes the physiologic data.

17. The apparatus of claim 16, wherein the optimization algorithm includes at least one of a gradient search, an evolution algorithm, a simulated annealing method, or a simplex algorithm.

18. A method comprising:

receiving user input to program a cardiac function management device; and

using the user input to automatically alter, at a time that occurs between separate user-programming sessions, a parameter value of at least one therapy control parameter.

19. The method of claim **18**, comprising obtaining at least one physiological measure for each combination of parameter values of the therapy control parameter set.

20. The method of claim **18**, comprising determining which of the combination of parameter values contributed to a particular outcome as evidenced by at least one physiological measure.

21. The method of claim **18**, comprising using the user input for automatically sequencing through multiple therapy control parameter sets at times occurring between separate user-programming sessions.

22. The method of claim **18**, comprising:

receiving over a network physiologic data from the cardiac function management device, the physiologic data resulting from operation of the cardiac function management device using a plurality of therapy control parameter sets;

analyzing the physiologic data; and

selecting a particular therapy control parameter set using the analysis.

23. The method of claim **22**, comprising programming the implantable cardiac function management device with the particular therapy control parameter set.

24. The method of claim **22**, comprising providing to a third party a suggestion of the particular therapy control parameter set to program into the implantable cardiac function management device.

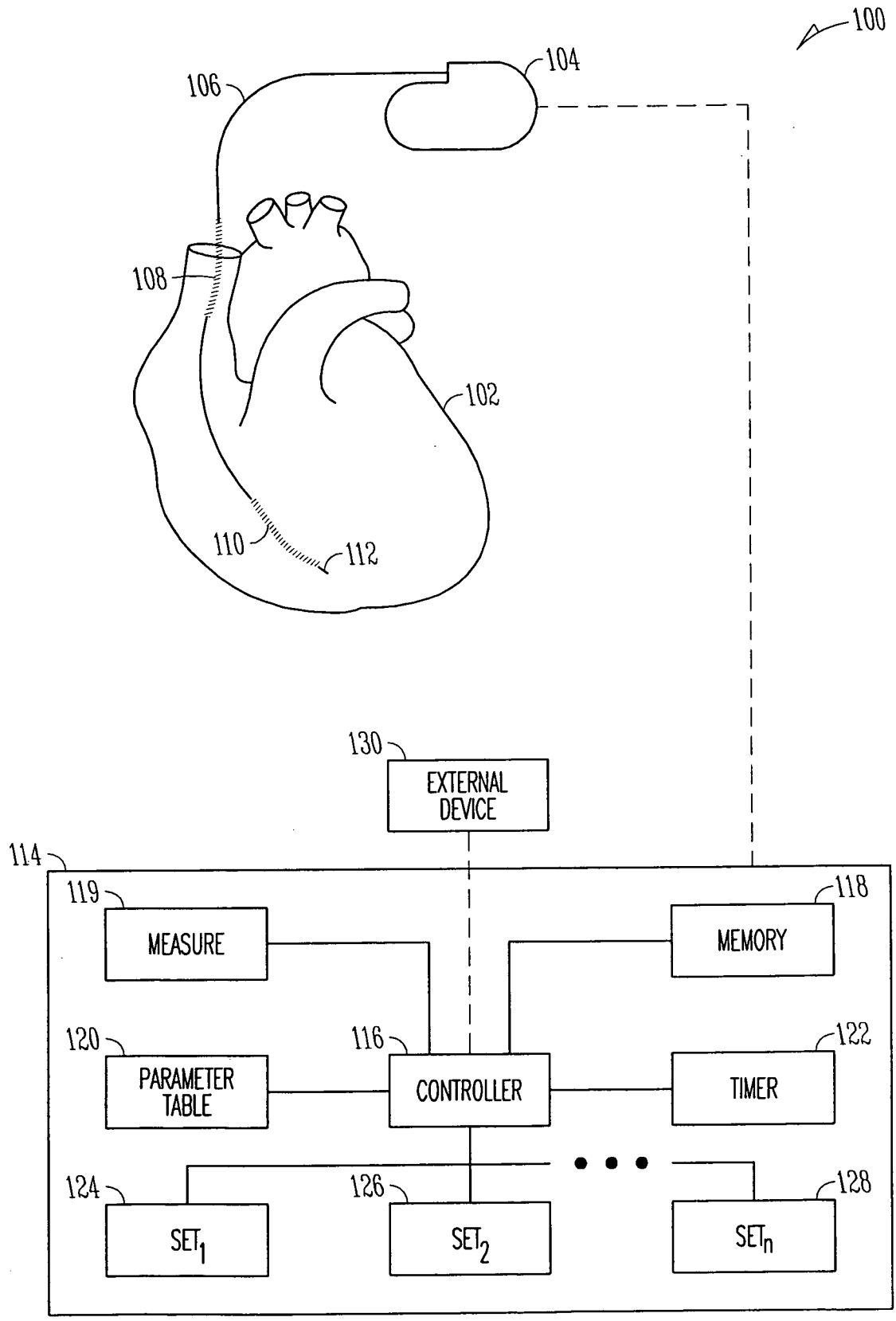
25. The method of claim **22**, comprising automatically adjusting the particular therapy control parameter set or a particular therapy control parameter and automatically programming the adjusted particular therapy control parameter set or the particular therapy control parameter into the implantable cardiac function management device.

26. The method of claim **22**, comprising receiving, at the remote external interface, from a third party, the one or more therapy control parameter sets.

27. The method of claim **22**, comprising receiving, at the remote external interface, an interval range for at least one parameter in the therapy control parameter sets, a time interval that the cardiac function management device is configured to operate with at least one of the therapy control parameter sets, or a value for a physiological parameter.

28. The method of claim **22**, comprising adjusting the therapy control parameter sets using the analysis of the physiologic data.

29. The method of claim **22**, comprising using the analysis of the physiologic data to reduce a parameter space in which the physiologic data is then analyzed.


100
104
106
108
102
110
112
130
EXTERNAL DEVICE
114
119
MEASURE
118
MEMORY
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PARAMETER TABLE
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CONTROLLER
122
TIMER
124
SET1
126
SET2
128
SETn

FIG. 1

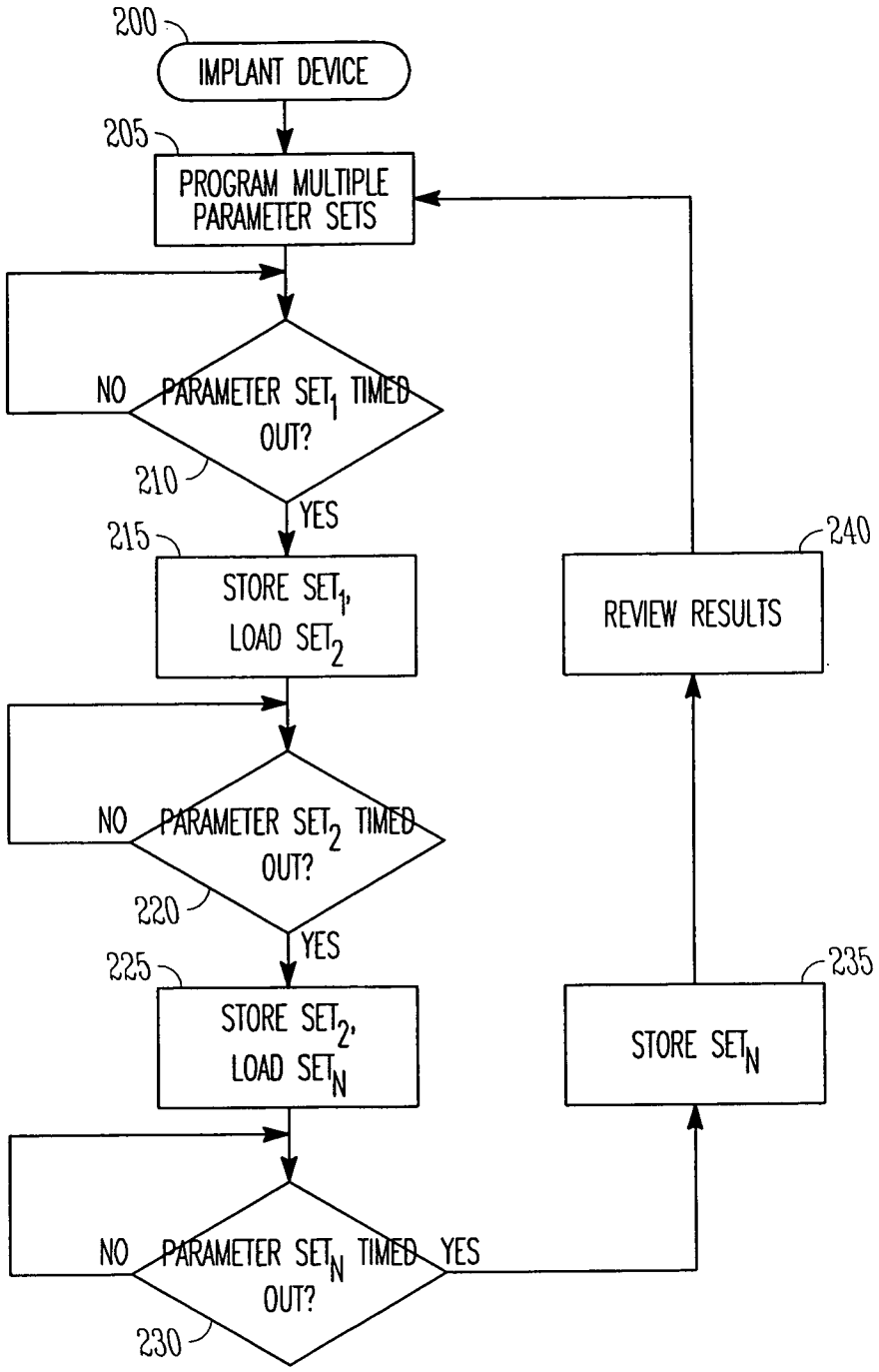
200
IMPLANT DEVICE
205
PROGRAM MULTIPLE PARAMETER SETS
NO
PARAMETER SET1 TIMED OUT?
210
YES
215
STORE SET1, LOAD SET2
NO
PARAMETER SET2 TIMED OUT?
220
YES
225
STORE SET2, LOAD SETN
NO
PARAMETER SETN TIMED OUT?
230
YES
235
STORE SETN
240
REVIEW RESULTS

FIG. 2

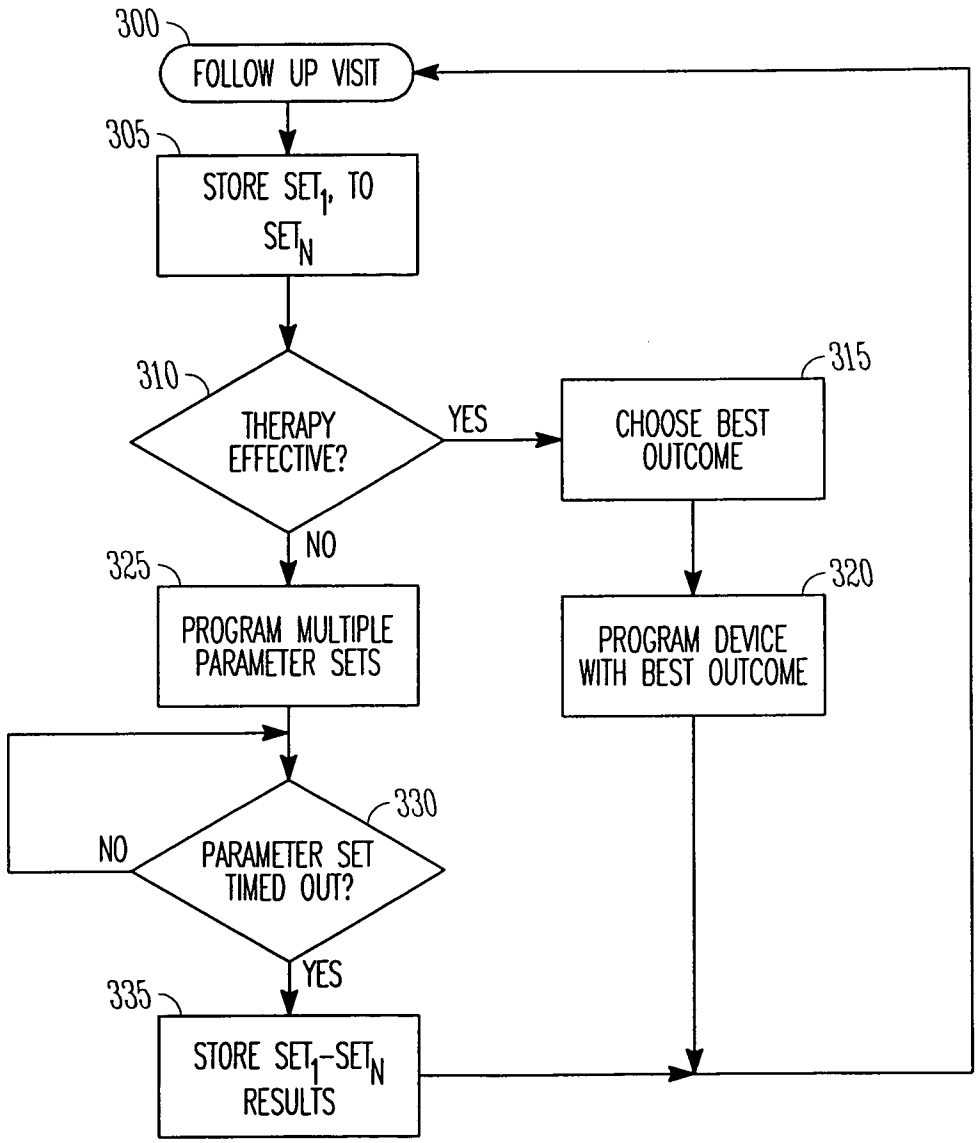
300
FOLLOW UP VISIT
305
STORE SET1 TO SETN
310
THERAPY EFFECTIVE?
YES
315
CHOOSE BEST OUTCOME
NO
325
PROGRAM MULTIPLE PARAMETER SETS
320
PROGRAM DEVICE WITH BEST OUTCOME
330
NO
PARAMETER SET TIMED OUT?
YES
335
STORE SET1-SETN RESULTS

FIG. 3

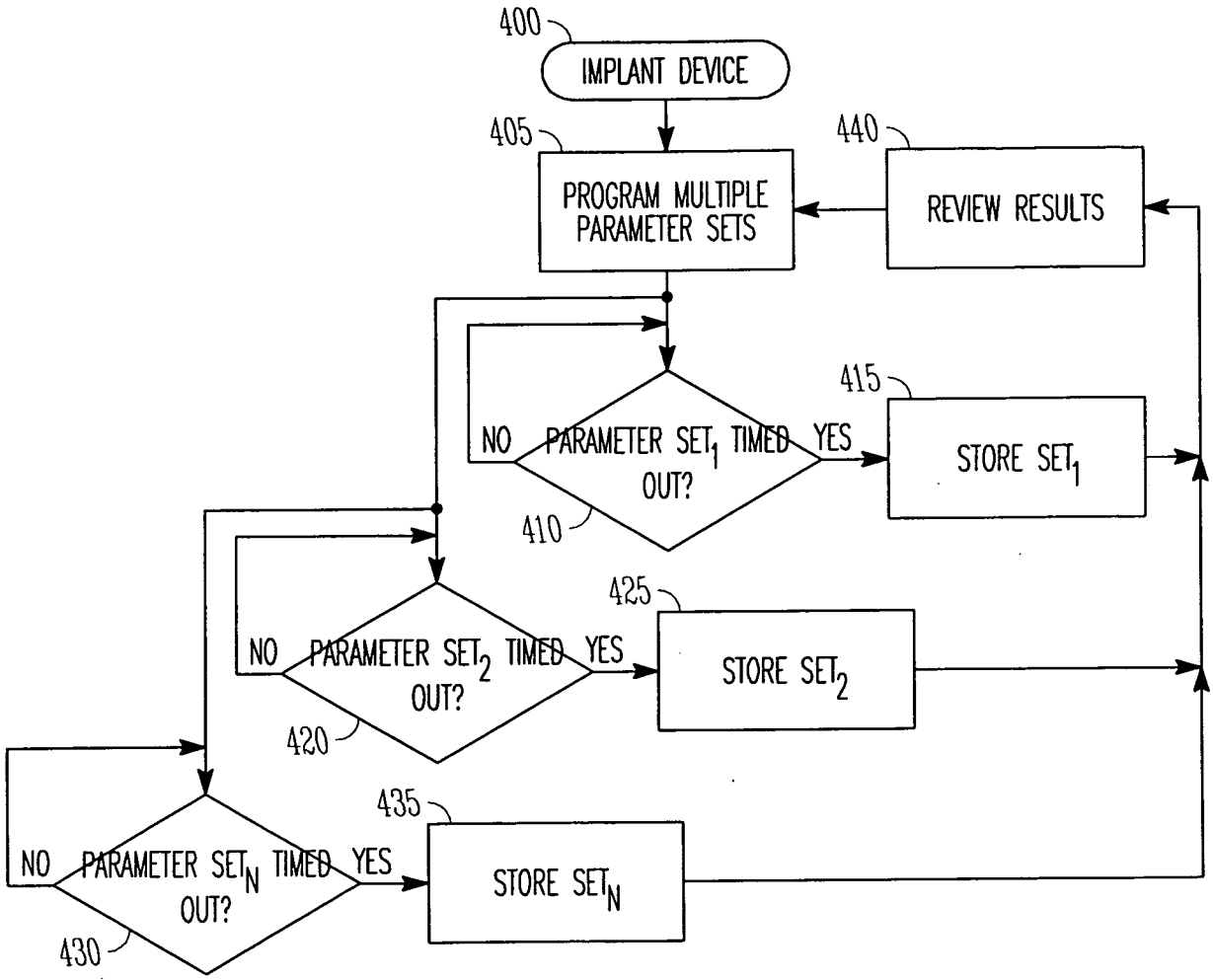
400
IMPLANT DEVICE
405
PROGRAM MULTIPLE PARAMETER SETS
440
REVIEW RESULTS
415
NO PARAMETER SET1 TIMED OUT? YES
STORE SET1
410
425
NO PARAMETER SET2 TIMED OUT? YES
STORE SET2
420
435
NO PARAMETER SETN TIMED OUT? YES
STORE SETN
430

FIG. 4

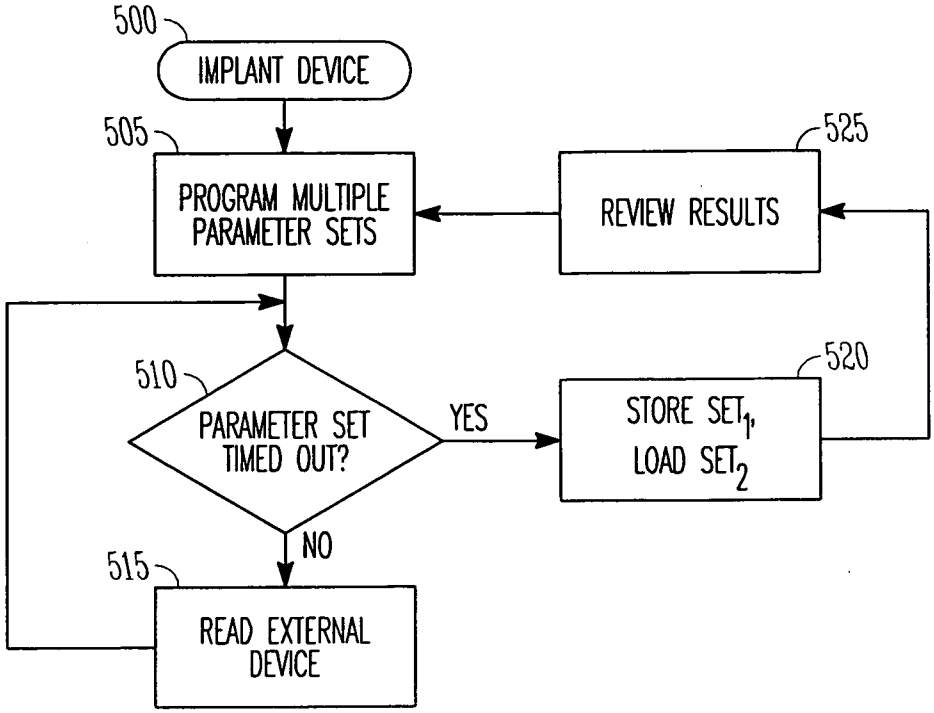
500
IMPLANT DEVICE
505
PROGRAM MULTIPLE PARAMETER SETS
525
REVIEW RESULTS
510
PARAMETER SET TIMED OUT?
YES
520
STORE SET1, LOAD SET2
NO
515
READ EXTERNAL DEVICE

FIG. 5

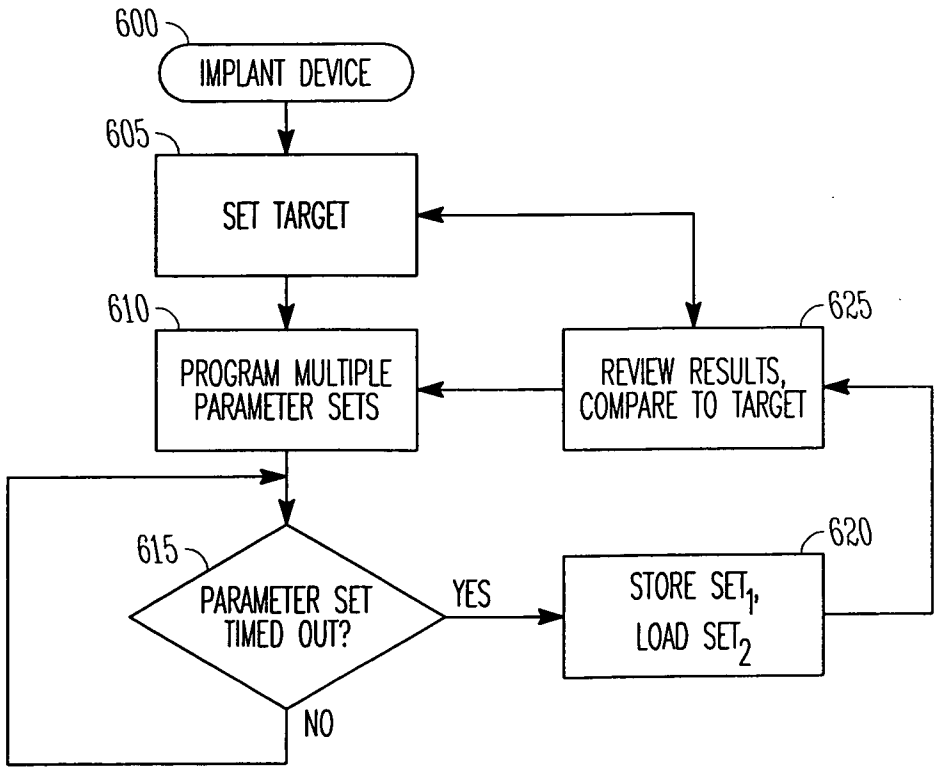
600
IMPLANT DEVICE
605
SET TARGET
610
PROGRAM MULTIPLE PARAMETER SETS
625
REVIEW RESULTS, COMPARE TO TARGET
615
PARAMETER SET TIMED OUT?
YES
620
STORE SET1, LOAD SET2
NO

FIG. 6

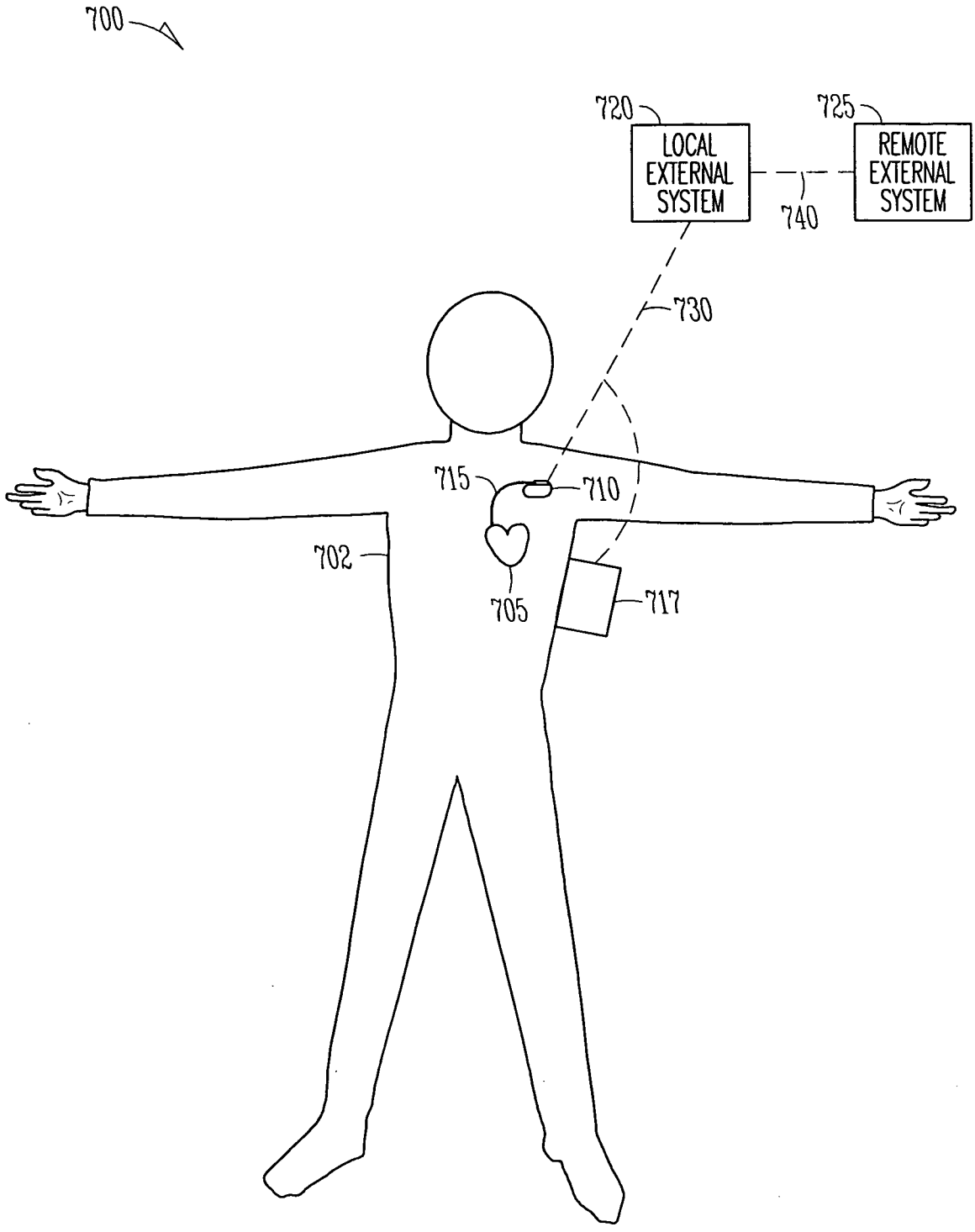
700
720
LOCAL EXTERNAL SYSTEM
725
REMOTE EXTERNAL SYSTEM
740
730
715
710
702
705
717

FIG. 7

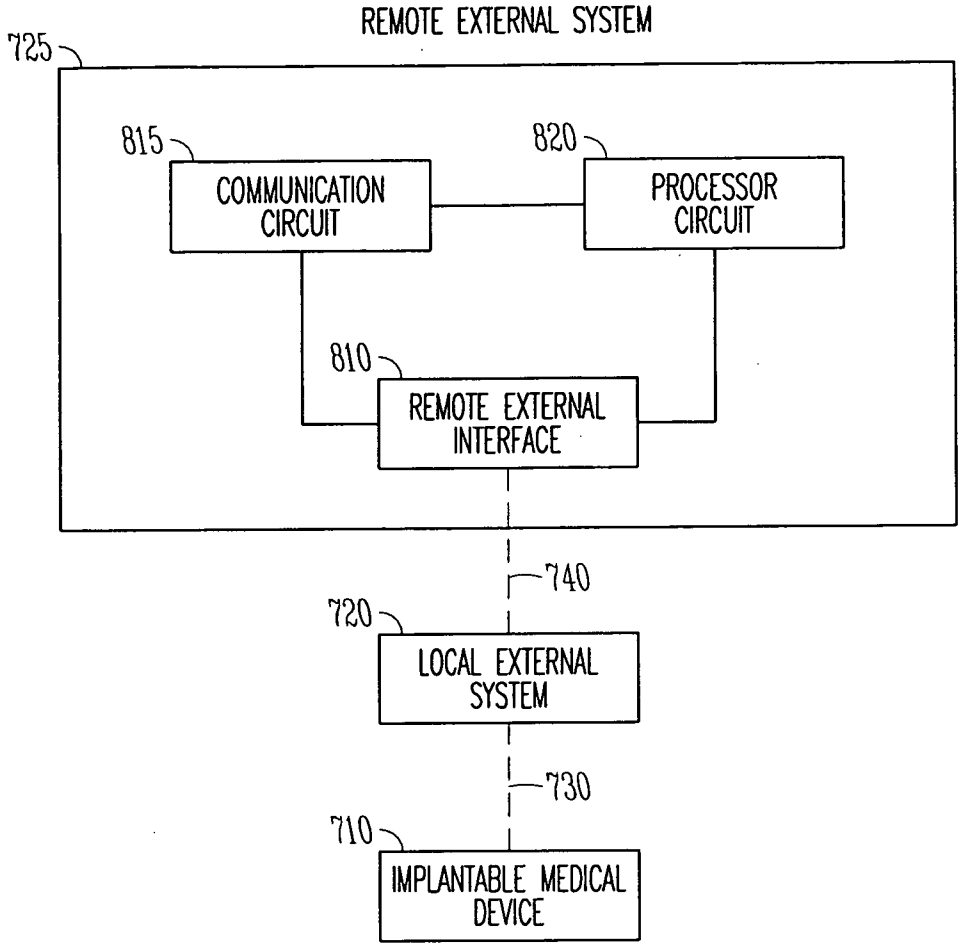
REMOTE EXTERNAL SYSTEM
725
815
COMMUNICATION CIRCUIT
820
PROCESSOR CIRCUIT
810
REMOTE EXTERNAL INTERFACE
740
720
LOCAL EXTERNAL SYSTEM
730
710
IMPLANTABLE MEDICAL DEVICE

FIG. 8

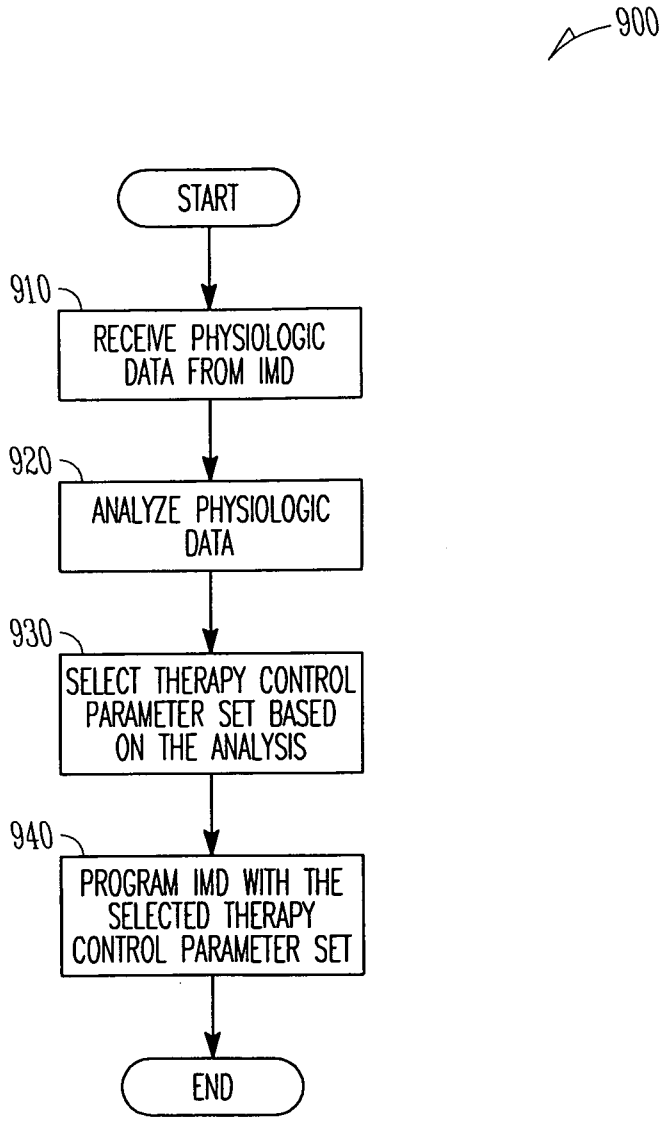
900
START
910
RECEIVE PHYSIOLOGIC DATA FROM IMD
920
ANALYZE PHYSIOLOGIC DATA
930
SELECT THERAPY CONTROL PARAMETER SET BASED ON THE ANALYSIS
940
PROGRAM IMD WITH THE SELECTED THERAPY CONTROL PARAMETER SET
END

FIG. 9

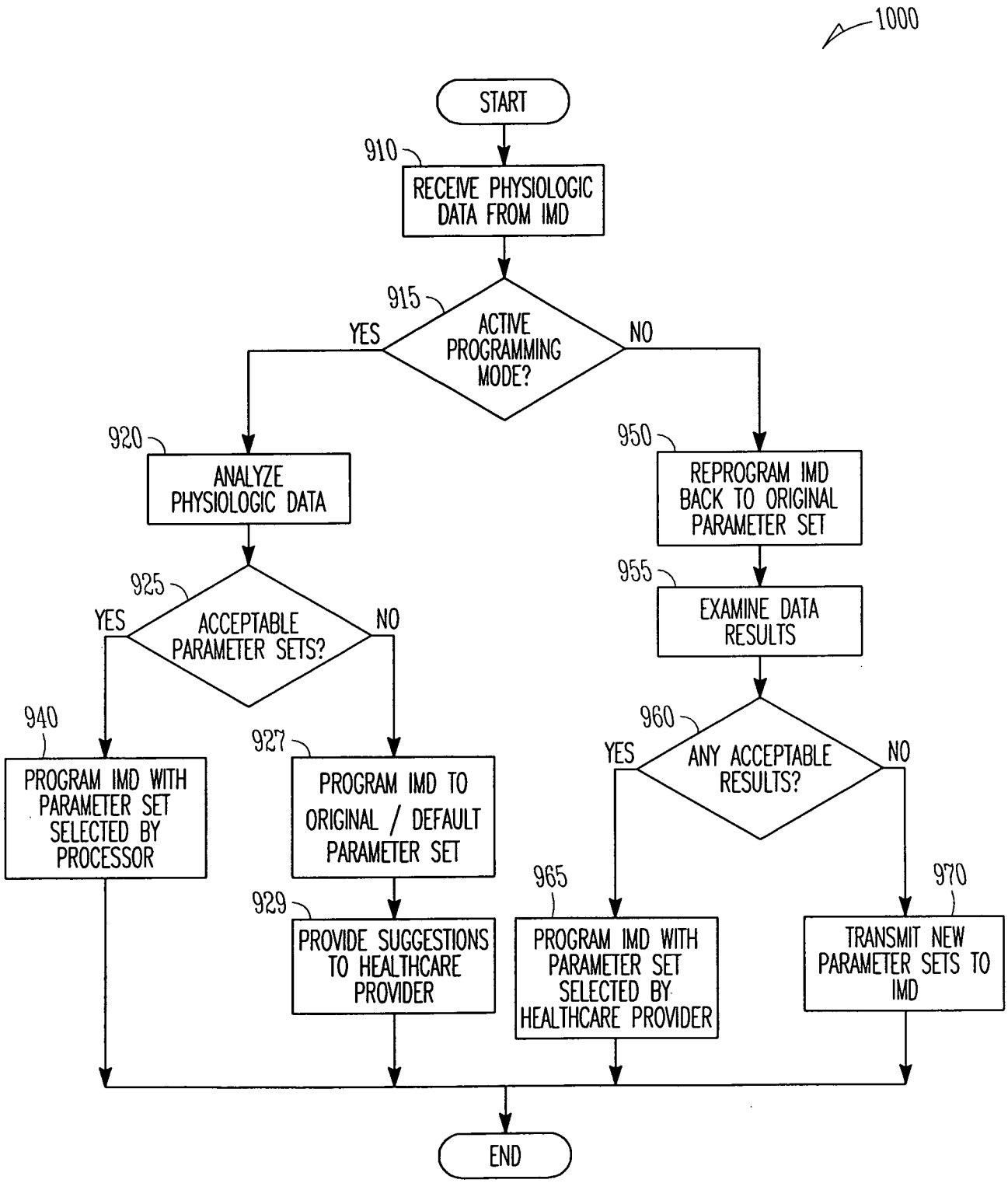
1000
START
910
RECEIVE PHYSIOLOGIC DATA FROM IMD
915
ACTIVE PROGRAMMING MODE?
YES
NO
920
ANALYZE PHYSIOLOGIC DATA
925
ACCEPTABLE PARAMETER SETS?
YES
NO
940
PROGRAM IMD WITH PARAMETER SET SELECTED BY PROCESSOR
927
PROGRAM IMD TO ORIGINAL / DEFAULT PARAMETER SET
929
PROVIDE SUGGESTIONS TO HEALTHCARE PROVIDER
950
REPROGRAM IMD BACK TO ORIGINAL PARAMETER SET
955
EXAMINE DATA RESULTS
960
ANY ACCEPTABLE RESULTS?
YES
NO
965
PROGRAM IMD WITH PARAMETER SET SELECTED BY HEALTHCARE PROVIDER
970
TRANSMIT NEW PARAMETER SETS TO IMD
END

FIG. 10

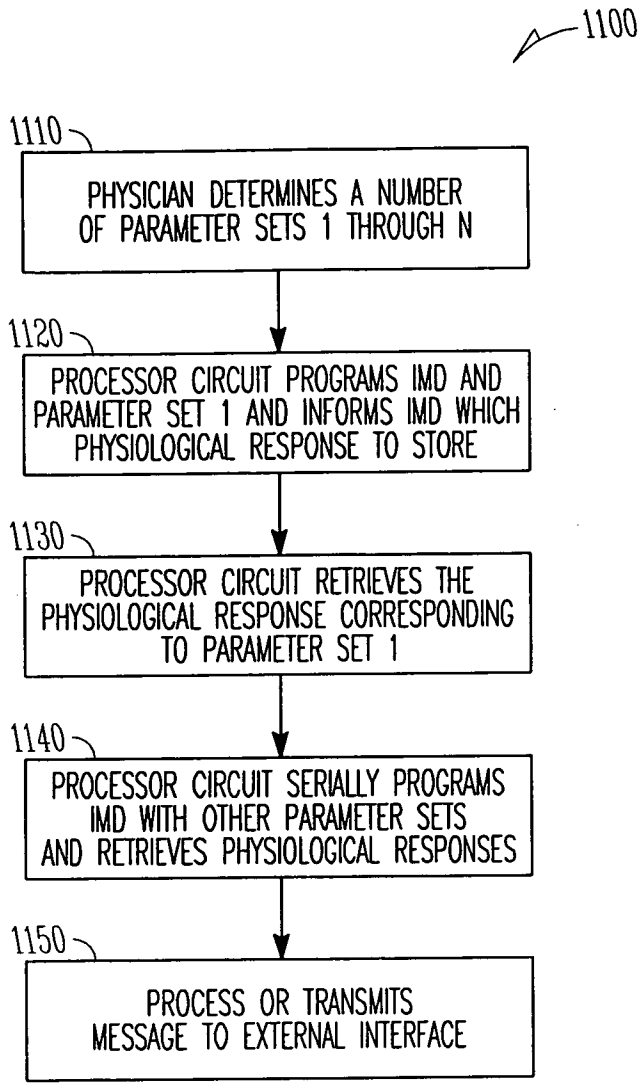
1100
1110
PHYSICIAN DETERMINES A NUMBER OF PARAMETER SETS 1 THROUGH N
1120
PROCESSOR CIRCUIT PROGRAMS IMD AND PARAMETER SET 1 AND INFORMS IMD WHICH PHYSIOLOGICAL RESPONSE TO STORE
1130
PROCESSOR CIRCUIT RETRIEVES THE PHYSIOLOGICAL RESPONSE CORRESPONDING TO PARAMETER SET 1
1140
PROCESSOR CIRCUIT SERIALLY PROGRAMS IMD WITH OTHER PARAMETER SETS AND RETRIEVES PHYSIOLOGICAL RESPONSES
1150
PROCESS OR TRANSMITS MESSAGE TO EXTERNAL INTERFACE

FIG. 11

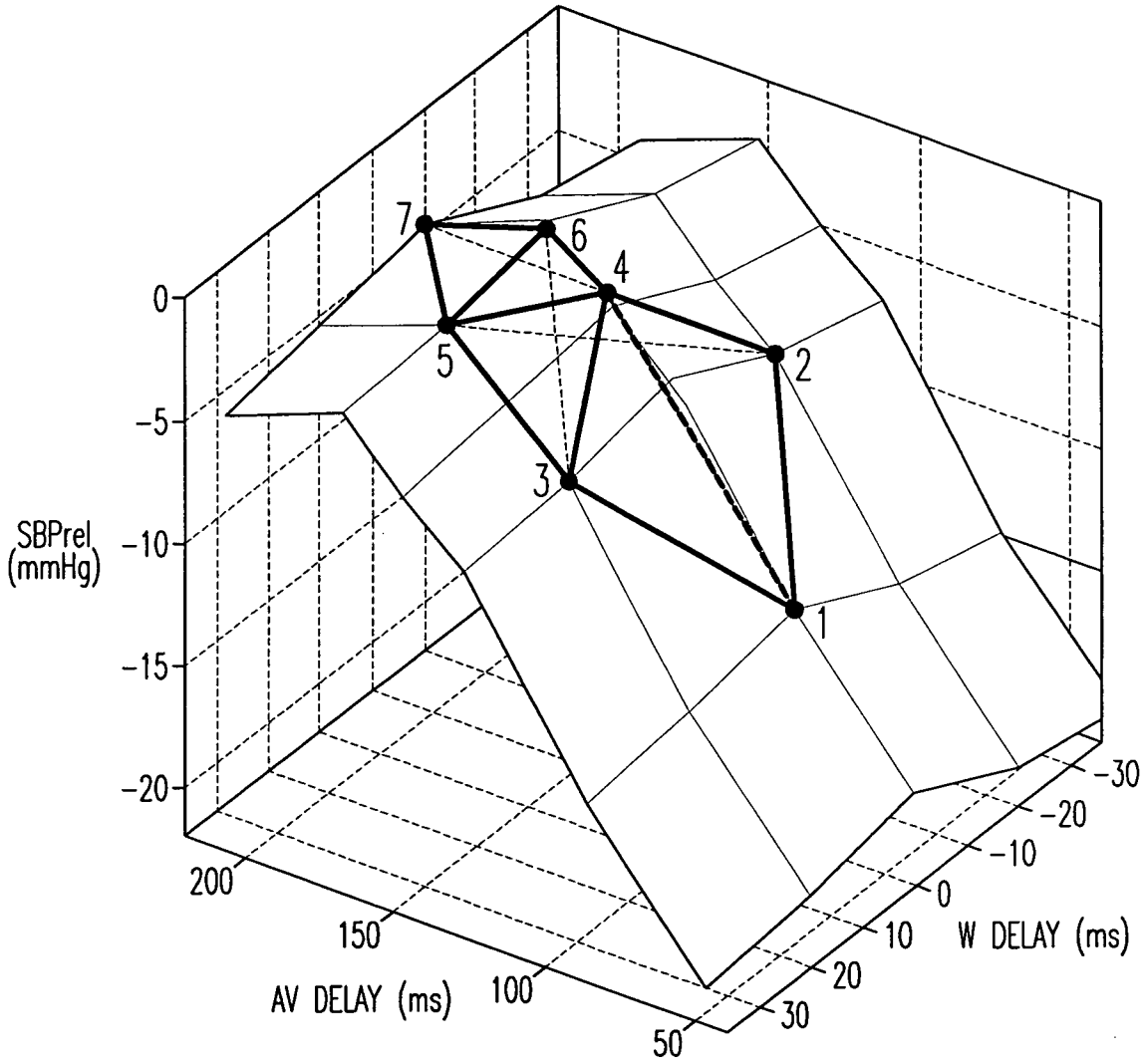
SBPrel
(mmHg)
0
-5
-10
-15
-20
7
6
4
5
2
3
1
200
150
100
50
AV DELAY (ms)
-30
-20
-10
0
10
20
30
W DELAY (ms)

FIG. 12

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/026191

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/365 A61N1/372 G06F19/00
ADD. A61N1/37

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61N G06F

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2005/122902 A (CARDIAC PACEMAKERS INC [US]; BROCKWAY MARINA [US]; LINCOLN WILLIAM C [) 29 December 2005 (2005-12-29)	1-8,10
Y	page 16, lines 19,30; figure 5 page 13, line 30 - page 15, line 15 page 18, lines 4-7,9 page 4, lines 5-7 page 3, lines 17,18	9,11-17
Y	EP 1 484 083 A (CARDIODYNAMICS INTERNAT CORP [US]) 8 December 2004 (2004-12-08) abstract; figure 2 paragraphs [0038] - [0045], [0052]	9,11-17

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 May 2008	28/05/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Pfeiffer, Uwe

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/026191

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/037428 A (MEDTRONIC INC [US]). 8 May 2003 (2003-05-08) abstract	1-7
A	page 45, line 18 - page 46, line 5 page 11, lines 12-19	8-17
X	EP 1 350 539 A (OSYPKA MEDICAL GMBH [DE]) 8 October 2003 (2003-10-08) paragraphs [0023] - [0025]	1-7
X	US 2004/106960 A1 (SIEJKO KRZYSZTOF Z [US] ET AL) 3 June 2004 (2004-06-03) paragraphs [0049], [0066], [0032], [0052], [0055]; figure 2	1-7
X	US 2006/111751 A1 (CAZARES SHELLEY M [US] CAZARES SHELLEY MARIE [US]) 25 May 2006 (2006-05-25) abstract; figure 9 paragraphs [0001], [0097], [0100], [0102] - [0104]	1-17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/026191

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

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

1. [X] Claims Nos.: 18-29
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2007/026191

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2005122902 A	29-12-2005	EP 1768566 A1	04-04-2007
		JP 2008502444 T	31-01-2008
		US 2007162080 A1	12-07-2007
		US 2006020294 A1	26-01-2006
EP 1484083 A	08-12-2004	AT 362780 T	15-06-2007
		US 2004243192 A1	02-12-2004
WO 03037428 A	08-05-2003	CA 2460227 A1	08-05-2003
		EP 1455896 A2	15-09-2004
		JP 2005507721 T	24-03-2005
		US 2005027323 A1	03-02-2005
EP 1350539 A	08-10-2003	AT 342752 T	15-11-2006
		DE 60215458 T2	23-08-2007
		US 2004030356 A1	12-02-2004
US 2004106960 A1	03-06-2004	US 2004106961 A1	03-06-2004
US 2006111751 A1	25-05-2006	US 2007239217 A1	11-10-2007