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

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **ARCOT-KRISHNAMURTHY, Shantha** [IN/US]; 550 Sandhurst Drive West #108, Roseville, MN 55113 (US). **ZIELINSKI, John, R.** [US/US]; 4612 Weston Hills Drive, Eagan, MN 55123 (US). **PASTORE, Joseph, M.** [US/US]; 7004 Easton Way, Woodbury, MN 55125 (US). **STAHMANN, Jeffrey, E.** [US/US]; 4850 154th Lane NW, Ramsey, MN 55303 (US). **SHUROS, Allan, C.** [US/US]; 1121 Colette Place, St. Paul, MN 55116 (US). **SHIPLEY, Robert** [US/US]; 1325 Tamberwood Trail, Woodbury, MN 55125 (US).

(74) Agent: **STEFFEY, Charles, E.**; Schwegman, Lundberg & Woessner P.A, P.O Box 2938, Minneapolis, Minnesota 55402 (US).

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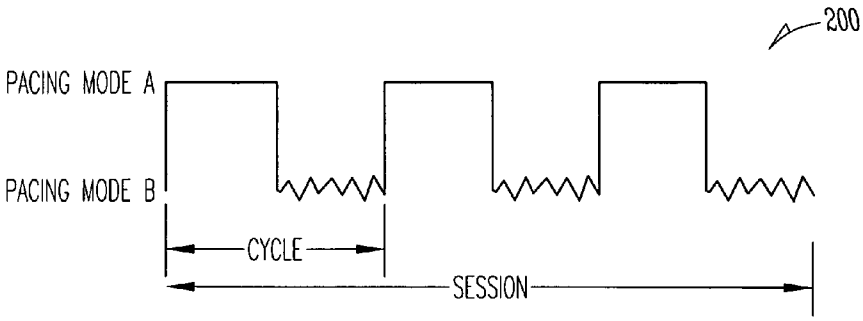

Fig. 2

(57) Abstract: This document discusses, among other things, an apparatus comprising at least one implantable cardiac depolarization sensing circuit, an electrical stimulation circuit, and a pacing mode controller. The implantable cardiac depolarization sensing circuit is configured to obtain a sensed depolarization signal from a ventricle and the electrical stimulation circuit is configured to provide pacing electrical stimulation energy to at least one implantable ventricular electrode. The pacing mode controller delivers pacing therapy according to a first pacing mode that is a normal operating mode, and delivers pacing therapy according to second and third pacing modes. The second and third pacing modes increase mechanical stress on at least a particular portion of the ventricle as compared to the pacing therapy delivered during the first pacing mode. The pacing mode controller alternates between the second and third pacing modes when switched from the normal operating mode to a stress augmentation mode.

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CONFIGURABLE INTERMITTENT PACING THERAPY

CLAIM OF PRIORITY

Benefit of priority is hereby claimed to U.S. Provisional Patent Application Serial Number 61/024,431, filed on January 29, 2008, which application is herein incorporated by reference in its entirety.

BACKGROUND

Implantable medical devices (IMDs) include devices designed to be implanted into a patient. Some examples of these devices include cardiac function management (CFM) devices such as implantable pacemakers, implantable cardioverter defibrillators (ICDs), cardiac resynchronization therapy devices (CRTs), and devices that include a combination of such capabilities. The devices can be used to treat patients using electrical or other therapy or to aid a physician or caregiver in patient diagnosis through internal monitoring of a patient's condition. The devices may include one or more electrodes in communication with one or more sense amplifiers to monitor electrical heart activity within a patient, and often include one or more sensors to monitor one or more other internal patient parameters. Other examples of implantable medical devices include implantable diagnostic devices, implantable drug delivery systems, or implantable devices with neural stimulation capability.

Sometimes patients who receive IMDs have experienced heart failure (HF) decompensation or other events associated with worsening HF. Worsening HF may cause deteriorating hemodynamic performance that could lead to the inability to carry out daily activities and even could lead to death of the patient. Symptoms associated with worsening HF may include progressive decline in ejection fraction called progressive ventricular dilatation. Electrical pacing therapy may prevent progressive ventricular dilatation.

OVERVIEW

This document relates generally to systems, devices, and methods for monitoring hemodynamic parameters of a patient or subject. An apparatus example includes at least one implantable cardiac depolarization sensing circuit, an electrical stimulation circuit, and a pacing mode controller. The implantable cardiac depolarization sensing circuit is configured to obtain a sensed depolarization signal from a ventricle and the electrical stimulation circuit is configured to provide pacing electrical stimulation energy to at least one implantable ventricular electrode. The pacing mode controller is configured to deliver pacing therapy according to a first pacing mode that is a normal operating mode, and to deliver pacing therapy according to second and third pacing modes. The second and third pacing modes increase mechanical stress on at least a particular portion of the ventricle as compared to the pacing therapy delivered during the first pacing mode. The pacing mode controller alternates between the second and third pacing modes when switched from the normal operating mode to a stress augmentation mode.

A method example includes delivering pacing therapy using an implantable device according to a first pacing mode that is a normal operating mode, and delivering pacing therapy according to a second pacing mode and a third pacing mode. The second pacing mode and the third pacing mode increase mechanical stress on at least a particular portion of the ventricle as compared to the pacing therapy delivered during the first pacing mode. The method also includes alternating between the second and third pacing modes when switched from the normal operating mode to a stress augmentation mode.

This section is intended to provide an overview of subject matter of the present patent application. It is not intended to provide an exclusive or exhaustive explanation of the invention. The detailed description is included to provide further information about the present patent application.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings, which are not necessarily drawn to scale, like numerals may describe similar components in different views. Like numerals having different letter suffixes may represent different instances of 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 is an illustration of portions of an example of a system that uses an IMD.

FIG. 2 is an illustration of a timing diagram of an example of intermittent pacing therapy provided by an IMD.

FIG. 3 is a block diagram of portions of an example of an IMD that provides intermittent pacing therapy in a stress augmentation mode.

FIG. 4 is an illustration of a timing diagram of another example of intermittent pacing therapy provided by an IMD.

FIG. 5 is a block diagram of portions of another example of an IMD that provides intermittent pacing therapy in a stress augmentation mode.

FIG. 6 is a flow diagram of an example of a method of providing intermittent pacing therapy in a stress augmentation mode.

DETAILED DESCRIPTION

An implantable medical device (IMD) may include one or more of the features, structures, methods, or combinations thereof described herein. For example, a cardiac monitor or a cardiac stimulator may be implemented to include one or more of the advantageous features and/or processes described below. It is intended that such a monitor, stimulator, or other implantable or partially implantable device need not include all of the features described herein, but may be implemented to include selected features that provide for unique structures and/or functionality. Such a device may be implemented to provide a variety of therapeutic or diagnostic functions.

FIG. 1 is an illustration of portions of a system 100 that uses an IMD 105. Examples of IMD 105 include, without limitation, a pacemaker, a cardioverter, a defibrillator, a cardiac resynchronization therapy (CRT) device,

and other cardiac monitoring and therapy delivery devices, including cardiac devices that include or work in coordination with one or more neuro-stimulating devices, drugs, drug delivery systems, or other therapies. As one example, the system 100 shown is used to treat a cardiac arrhythmia. The IMD 105 typically includes an electronics unit coupled by one or more cardiac leads 110, 115, 125, to a heart of a patient or subject. The electronics unit of the IMD 105 typically includes components that are enclosed in a hermetically-sealed canister or "can." The system 100 also typically includes an IMD programmer or other external system 190 that communicates one or more wireless signals 185 with the IMD 105, such as by using radio frequency (RF) or by one or more other telemetry methods.

The example shown includes right atrial (RA) lead 110 having a proximal end 111 and a distal end 113. The proximal end 111 is coupled to a header connector 107 of the IMD 105. The distal end 113 is configured for placement in the RA in or near the atrial septum. The RA lead 110 may include a pair of bipolar electrodes, such as an RA tip electrode 114A and an RA ring electrode 114B. The RA electrodes 114A and 114B are incorporated into the lead body at distal end 113 for placement in or near the RA, and are each electrically coupled to IMD 105 through a conductor extending within the lead body. The RA lead is shown placed in the atrial septum, but the RA lead may be placed in or near the atrial appendage, the atrial free wall, or elsewhere.

The example shown also includes a right ventricular (RV) lead 115 having a proximal end 117 and a distal end 119. The proximal end 117 is coupled to a header connector 107. The distal end 119 is configured for placement in the RV. The RV lead 115 may include one or more of a proximal defibrillation electrode 116, a distal defibrillation electrode 118, an RV tip electrode 120A, and an RV ring electrode 120B. The defibrillation electrode 116 is generally incorporated into the lead body such as in a location suitable for supraventricular placement in the RA and/or the superior vena cava. The defibrillation electrode 118 is incorporated into the lead body near the distal end 119 such as for placement in the RV. The RV electrodes 120A and 120B may form a bipolar electrode pair and are generally incorporated into the lead body at distal end 119. The electrodes 116, 118, 120A, and 120B are each electrically

coupled to IMD 105, such as through one or more conductors extending within the lead body. The proximal defibrillation electrode 116, distal defibrillation electrode 118, or an electrode formed on the can of IMD 105 allow for delivery of cardioversion or defibrillation pulses to the heart.

The RV tip electrode 120A, RV ring electrode 120B, or an electrode formed on the can of IMD 105 allow for sensing an RV electrogram signal representative of RV depolarizations and delivering RV pacing pulses. In some examples, the IMD includes a sense amplifier circuit to provide amplification and/or filtering of the sensed signal. RA tip electrode 114A, RA ring electrode 114B, or an electrode formed on the can of IMD 105 allow for sensing an RA electrogram signal representative of RA depolarizations and allow for delivering RA pacing pulses. Sensing and pacing allows the IMD 105 to adjust timing of the heart chamber contractions. In some examples, the IMD 105 can adjust the timing of ventricular depolarizations with respect to the timing of atrial depolarizations by sensing electrical signals in the RA and pacing the RV at the desired atrial-ventricular (AV) delay time.

A left ventricular (LV) lead 125 can include a coronary pacing or sensing lead that includes an elongate lead body having a proximal end 121 and a distal end 123. The proximal end 121 is coupled to a header connector 107. A distal end 123 is configured for placement or insertion in the coronary vein. The LV lead 125 may include an LV ring or tip electrode 128A and an LV ring electrode 128B. The distal portion of the LV lead 125 is configured for placement in the coronary sinus and coronary vein such that the LV electrodes 128A and 128B are placed in the coronary vein. The LV electrodes 128A and 128B may form a bipolar electrode pair and are typically incorporated into the lead body at distal end 123. Each can be electrically coupled to IMD 105 such as through one or more conductors extending within the lead body. LV tip electrode 128A, LV ring electrode 128B, or an electrode formed on the can of the IMD 105 allow for sensing an LV electrogram signal representative of LV depolarizations and delivering LV pacing pulses.

The IMDs may be configured with a variety of electrode arrangements, including transvenous, epicardial electrodes (i.e., intrathoracic electrodes), and/or subcutaneous, non-intrathoracic electrodes, including can, header, and

indifferent electrodes, and subcutaneous array or lead electrodes (i.e., non-intrathoracic electrodes). Some IMDs are able to sense signals representative of cardiac depolarizations using electrodes without leads.

As discussed above, symptoms associated with worsening HF may include progressive ventricular dilatation or a decline in ejection fraction. Occasionally causing dyssynchrony of ventricular contractions may prevent progressive ventricular dilatation. This dyssynchrony may be provided by an intermittent pacing therapy using an IMD. The intermittent pacing therapy is designed to increase ventricular dyssynchrony to cause stress in regional areas of the myocardial wall. The stress is caused in regions that are activated later than others. Providing this intermittent regional stress may halt progression of ventricular dilatation.

FIG. 2 is an illustration of a timing diagram 200 of an example of intermittent pacing therapy provided by an IMD. The timing diagram 200 shows an intermittent pacing therapy session. Prior to and after the intermittent pacing session, the IMD provides pacing therapy in a normal operating mode that allows for regular depolarizations to occur in the heart chamber (e.g., the NASPE/BPEG-defined DDD pacing mode). The intermittent pacing session includes three cycles of alternating Pacing Mode A with Pacing Mode B. The alternating of Pacing Mode A with Pacing Mode B increases mechanical stress on at least a particular portion of a ventricle as compared to the pacing therapy delivered during the normal operating mode. This intermittent pacing therapy can be referred to as a stress augmentation mode and is designed to provide control over the progression of ventricular dilatation.

FIG. 3 is a block diagram of portions of an IMD 300 to provide intermittent pacing therapy in a stress augmentation mode. The IMD 300 includes at least one implantable cardiac depolarization sensing circuit 305, an electrical stimulation circuit 310, and a pacing mode controller 315. The cardiac depolarization sensing circuit 305 obtains a sensed depolarization signal from a ventricle such as by using a sense amplifier circuit for example. The electrical stimulation circuit provides pacing electrical stimulation energy to at least one implantable ventricular electrode.

The pacing mode controller 315 may include a digital signal processor, application specific integrated circuit (ASIC), microprocessor, or other type of processor, interpreting or executing instructions in software or firmware. In some examples, the pacing mode controller 315 may include a state machine or sequencer that is implemented in hardware circuits. The pacing mode controller 315 may include any combination of hardware, firmware, or software. The pacing mode controller 315 includes one or more circuits to perform the functions described herein. A circuit may include software, hardware, firmware or any combination thereof. For example, the circuit may include instructions in software executing on the pacing mode controller 315. Multiple functions may be performed by one or more circuits.

The pacing mode controller 315 is communicatively coupled to the cardiac depolarization sensing circuit 305 and the electrical stimulation circuit 310 (e.g., the pacing mode controller 315 is able to communicate signals with the cardiac depolarization sensing circuit 305 and the electrical stimulation circuit 310 even though there may be intervening circuitry coupled between them.

The pacing mode controller 315 delivers pacing therapy (via the cardiac depolarization sensing circuit 305 and the electrical stimulation circuit 310) according to a first mode that is a normal operating mode. The pacing mode controller 315 also delivers intermittent pacing therapy in a stress augmentation mode.

When switched from the normal operating mode to the stress augmentation mode, the pacing mode controller 315 delivers pacing therapy according to a second pacing mode and a third pacing mode. The second pacing mode and the third pacing mode increase mechanical stress on at least a particular portion of the ventricle as compared to the pacing therapy delivered during the first pacing mode. The pacing mode controller 315 alternates pacing therapy between the second and third pacing modes (e.g., between Pacing mode A and Pacing B in Fig. 2) when switched from the normal operating mode to a stress augmentation mode.

In some examples, the cardiac depolarization sensing circuit 305 is configured to obtain a sensed depolarization signal from an atrium such as by

placement of an implantable electrode in or near the atrium, and the electrical stimulation circuit is configured to provide pacing electrical stimulation energy to the atrial electrode. In some examples, the pacing mode controller 315 provides the NASPE/BPEG-defined DDD pacing mode in the normal operating mode.

In some examples, when in the second pacing mode, the pacing mode controller 315 paces at least one ventricle (V), without timing the pacing of the ventricle from an atrial cardiac event, when a V-V interval exceeds a specified ventricular interval (e.g., the NASPE/BPEG-defined VVI pacing mode). In some examples, when in the third pacing mode, the pacing mode controller 315 paces an atrium and, in response to the pace in the atrium, triggers pacing of at least one ventricle after expiration of a specified fixed or dynamic AV delay without regard to any intrinsic cardiac depolarization event occurring in the ventricle (e.g., the NASPE/BPEG-defined DOO pacing mode).

The pacing mode controller 315 includes or is coupled to a memory 320. In some examples, the memory 320 includes a stress augmentation cycle memory area 325 that stores a value that specifies a programmable number of alternating cycles between the second and third pacing modes during the stress augmentation mode before returning to the first pacing mode. In other words, the stored value is the number of times the intermittent pacing alternates between Pacing Mode A and Pacing Mode B during the stress augmentation mode session.

In some examples, the memory 320 includes a second pacing mode cycle length memory area that specifies a duration of the second pacing mode before alternating to the third pacing mode, and a third pacing mode cycle length memory area that specifies the duration of the third pacing mode before alternating to the second pacing mode. The second and third pacing mode memory areas for cycle length are independently programmable to different values. Thus, in FIG. 2, the duration of time spent in Pacing Mode A can be different from the time spent in Pacing Mode B.

In some examples, the stress augmentation cycle memory area 325 specifies the duration of time spent in the stress augmentation mode before automatically switching to the normal operating mode. Thus, in FIG. 2, the

length of the stress augmentation mode session is programmable. In some examples, the stress augmentation cycle memory area 325 specifies a duration of time spent in the normal operating mode before automatically switching to the stress augmentation mode. In some examples, the stress augmentation cycle memory area 325 specifies a total number of stress augmentation mode sessions to deliver to the patient. In some examples, the stress augmentation cycle memory area 325 specifies a total number of stress augmentation mode sessions to deliver per day. In some examples, the stress augmentation cycle memory areas specifies a time of day for initiating the stress augmentation mode. In some examples, the stress augmentation cycle memory area specifies a number of days for enabling the stress augmentation mode.

According to some examples, a number of stress augmentation mode sessions as shown in FIG. 2 are delivered in a stress augmentation burst. In some examples, the stress augmentation cycle memory area 325 specifies the number of stress augmentation mode sessions in a stress augmentation burst. In some examples, the stress augmentation cycle memory area 325 specifies the number of stress augmentation bursts per day. In some examples, the stress augmentation cycle memory area 325 specifies the duration of time between stress augmentation mode sessions (e.g., the duration of the normal operating mode between the session in the burst).

FIG. 4 is an illustration of a timing diagram 400 of another example of intermittent pacing therapy provided by an IMD. In the example, there is a duration of time 405, between the switch from Pacing Mode A to Pacing Mode B, where no pacing energy is delivered by the IMD. There is also duration of time 410 between the switch from Pacing Mode B to Pacing Mode A where no pacing energy is delivered. Thus, in some examples, the stress augmentation cycle memory area 325 specifies the duration of time between the second pacing mode and the third pacing mode during which pacing electrical stimulation energy is not delivered. In some examples, the time durations 405, 410 are separately programmable.

Returning to FIG. 3, the pacing mode controller 315 delivers pacing therapy in the second and third pacing modes using independently programmable pacing parameters. In some examples, the pacing mode

controller 315 delivers a different programmable NASPE/BPEG-defined pacing mode in the second pacing mode than the programmable NASPE/BPEG-defined pacing mode in the third pacing mode. In some examples, the pacing mode controller 315 delivers pacing therapy at a different programmable rate in the second pacing mode than in the third pacing mode. In some examples, the IMD 300 includes a plurality of implantable electrodes disposed at sites in or around the heart. The pacing mode controller 315 delivers pacing in the second and/or third pacing modes to one or more different programmable pacing sites.

In some examples, the pacing mode controller 315 delivers pacing at a different programmable pacing amplitude in the second pacing mode than in the third pacing mode. In some examples, the pacing mode controller 315 delivers pacing at a different programmable pacing pulse-width in the second pacing mode than in the third pacing mode.

In some examples, at least one of the second or third pacing modes includes delivering pacing to an atrium and a ventricle. In some examples, the stress augmentation cycle memory area 325 specifies a programmable atrial-ventricular (AV) delay interval for at least one of the second and third pacing modes. In some examples, the electrical stimulation circuit 310 provides pacing electrical stimulation energy to at least one implantable ventricular electrode in the right ventricle (RV) and at least one implantable electrode in the left ventricle (LV). At least one of the second or third pacing modes includes delivering pacing to the pacing mode controller 315 delivers pacing to the RV and LV. In some examples, the stress augmentation cycle memory area 325 specifies a programmable LV offset interval for at least one of the second and third pacing modes.

According to some examples, the stress augmentation mode may be programmed to provide varying degrees of mechanical stress to the regional areas of the myocardial wall. In some examples, the change in stress is provided by the amount the AV delay interval in the stress augmentation mode is shortened from the AV delay interval in the normal mode. In certain examples, a lower level of stress is provided in the stress augmentation mode by shortening the AV delay interval by twenty percent (20%). In certain examples, a medium or nominal level of stress is provided in the stress augmentation mode by

shortening the AV delay interval by forty percent (40%). In certain examples, a high level of stress is provided in the stress augmentation mode by shortening the AV delay interval by sixty percent (60%).

In some examples, lower levels of stress may be provided for longer periods of time than higher levels of stress. In certain examples, a stress augmentation mode with a low level of stress may be provided for sixty minutes, and may be provided without cycling the stress augmentation mode on and off. This can be analogized to cardiovascular exercise training, where the intensity of the exercise is lower but the duration of the exercise is long.

In certain examples, a stress augmentation mode with a nominal level of stress may be provided for thirty minutes, and the stress augmentation mode may be cycled on and off. In some examples, cycling off the stress augmentation mode includes providing pacing therapy according to the normal pacing mode during the cycle off time. In some examples, cycling off the stress augmentation mode includes providing no pacing therapy during the cycle off time. In certain examples, a stress augmentation mode with a high level of stress may be provided for fifteen minutes, and the stress augmentation mode may be cycled on and off. This can be analogized to weight training, where the intensity of the exercise is high and the duration of the exercise is short.

In some examples, the stress augmentation cycle memory area 325 of FIG. 3 stores an indication of a level of mechanical stress desired during at least one of the second or third pacing modes. The pacing mode controller 315 specifies an AV delay interval and a time duration of a stress augmentation mode session according to the indication of the desired level of mechanical stress. In certain examples, the AV delay interval and time duration may be included in a lookup table indexed according to desired stress level. In certain examples, the pacing mode controller 315 specifies a cycle on time and a cycle off time during the stress augmentation mode session. Pacing therapy according to the second and/or third pacing mode is provided during the cycle on time, and pacing therapy according to the normal mode or no pacing therapy is provided during the cycle off time.

The automatic specification of intermittent pacing therapy parameters according to the desired stress level may provide ease of programmability of the intermittent pacing therapy for the physician.

In some examples, the stress level for the stress augmentation mode is determined from an indication of a type of heart failure disease pathology. The stress augmentation cycle memory area 325 stores an indication of a heart failure disease pathology of the patient. The pacing mode controller 315 specifies the stress level (e.g., the AV delay interval and the time duration of a stress augmentation mode session) according to the indication of a heart failure disease pathology.

In certain examples, the pacing mode controller 315 specifies a low stress level for a long period of time if the indication is that the patient has HF but has preserved systolic function (PSF). In certain examples, the pacing mode controller 315 specifies a medium or nominal stress level for a medium period of time with on and off cycling if the indication is that the patient has had an ischemic episode. In certain examples, the pacing mode controller 315 specifies a high stress level for a short period of time with on an off cycling if the indication is that the patient has dilated cardiomyopathy (DCM).

It may be desirable to alter the NASPE/BPEG-defined pacing modes of the second and third pacing mode during the stress augmentation mode. In some examples, the pacing mode controller 315 is configured to alter the NASPE/BPEG-defined pacing mode of at least one of the second pacing mode and the third pacing mode during the stress augmentation mode. For example, either the second or third pacing mode may be changed from the NASPE/BPEG-defined VVI pacing mode to the NASPE/BPEG-defined VOO pacing mode. The pacing mode or modes may be changed between stress augmentation sessions or within a stress augmentation mode session.

According to some examples, the stress augmentation mode consists of more than the second and third pacing modes. The pacing mode controller 315 delivers pacing therapy according to at least one additional pacing mode. Like the second and third pacing mode, the additional pacing mode also increases mechanical stress on at least a particular portion of the ventricle as compared to the pacing therapy delivered during normal operating mode. The pacing mode

controller 315 alternates between the second pacing mode, third pacing mode, and the additional pacing mode when switched from the normal operating mode to a stress augmentation mode. For example, in FIG. 2, the stress augmentation mode session would alternate among Pacing Mode A, Pacing Mode B, and a Pacing Mode C.

FIG. 5 is a block diagram of portions of another IMD 500 to provide intermittent pacing therapy in a stress augmentation mode. The IMD 500 includes an implantable cardiac depolarization sensing circuit 505, an electrical stimulation circuit 510, and a pacing mode controller 515. The IMD 500 also includes a sensor circuit 530 and a signal analyzer 535 communicatively coupled to the sensor circuit 530 and the pacing mode controller 515. The sensor circuit 530 produces an electrical sensor signal indicating one or more physiologic cardiovascular events of a subject. The signal analyzer 535 detects, from information provided by the electrical sensor signal, a patient physiologic condition that contraindicates an aspect of the stress augmentation mode. In some examples, the signal analyzer 535 may detect an episode of atrial or ventricular arrhythmia using the signal provided by the electrical sensor signal. The signal analyzer 535 may include an arrhythmia detector that detects a predetermined type or types of arrhythmia. An atrial or ventricular arrhythmia is an example of a patient physiologic condition that contraindicates at least an aspect of the stress augmentation mode. In some examples, the stress augmentation may be contraindicated altogether by the physiologic condition.

In some examples, the pacing mode controller 515 inhibits the stress augmentation mode when the aspect of the stress augmentation mode is contraindicated by the signal analyzer 535. In some examples, the pacing mode controller 515 retries the stress augmentation mode after the stress augmentation mode has been inhibited for a specified time duration. In some examples, the pacing mode controller 515 retries the stress augmentation mode for a specified number of retry attempts before disabling the stress augmentation mode. In some examples, the pacing mode controller 515 automatically alters the stress augmentation mode when the aspect of the stress augmentation mode is contraindicated by the signal analyzer 535. For example, a pacing amplitude may be altered due to the detected physiologic condition.

According to some examples, the IMD 500 includes a memory 520 integral to, or communicatively coupled to, the pacing mode controller 515. The memory 520 stores a lookup table 540 of NASPE/BPEG-defined pacing modes. When the second or third pacing modes is contraindicated by the physiological condition detected using the signal analyzer 535, the pacing mode controller 515 replaces at least one of the second or third pacing modes with a different pacing mode from the lookup table 540. For example, the pacing mode controller 515 may change the third pacing mode from DOO to VOO based on the detected physiologic condition. In some examples, the look up table 540 only includes the NASPE/BPEG-defined pacing modes deemed appropriate for the patient. In other words, those NASPE/BPEG-defined pacing modes that are contraindicated are not included.

FIG. 5 also shows an external system 550 used to communicate with the IMD 500. The IMD 500 includes a communication circuit 545 coupled to the pacing mode controller 515 to communicate wirelessly with the external system 550. The external system 550 includes a user interface 555 to configure one or more parameters of the stress augmentation pacing feature. For example, the user interface 555 may display a table of parameters for a physician to fill in, or may display default parameters for the physician to alter. The external system 550 then transmits the parameters to the IMD 500 for storage in a stress augmentation cycle memory area included in the memory 520.

FIG. 6 is a flow diagram of an example of a method 600 of providing intermittent pacing therapy in a stress augmentation mode. At block 605, pacing therapy is delivered according to a first pacing mode using an IMD. The first pacing is a normal operating mode that allows for regular depolarizations to occur in the heart chamber (e.g., the NASPE/BPEG-defined DDD pacing mode).

At block 610, pacing therapy is delivered by the according to a second pacing mode using the IMD. The second pacing mode increases mechanical stress on at least a particular portion of the ventricle as compared to the pacing therapy delivered during the first pacing mode. At block 615, pacing therapy is delivered according to a third pacing mode by the IMD. The third pacing mode also increases mechanical stress on at least a particular portion of the ventricle as compared to the pacing therapy delivered during the first pacing mode.

At block 620, when the IMD is switched from the normal operating mode to a stress augmentation mode, the pacing therapy alternates between the second and third pacing modes. The intermittent pacing that alternates between the second and third pacing modes is designed to increase ventricular dyssynchrony to cause stress in regional areas of the myocardial wall. Providing this intermittent regional stress stops the deterioration of hemodynamic performance of a HF patient, such as by stopping the progression of ventricular dilatation for example.

The above 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 can be practiced. These embodiments are also referred to herein as "examples." 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.

In this document, the terms "a" or "an" are used, as is common in patent documents, to include one or more than one, independent of any other instances or usages of "at least one" or "one or more." In this document, the term "or" is used to refer to a nonexclusive or, such that "A or B" includes "A but not B," "B but not A," and "A and B," unless otherwise indicated. 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.

Method examples described herein can be machine or computer-implemented at least in part. Some examples can include a computer-readable medium or machine-readable medium encoded with instructions operable to configure an electronic device to perform methods as described in the above examples. An implementation of such methods can include code, such as microcode, assembly language code, a higher-level language code, or the like. Such code can include computer readable instructions for performing various methods. The code may form portions of computer program products. Further, the code may be tangibly stored on one or more volatile or non-volatile computer-readable media during execution or at other times. These computer-readable media may include, but are not limited to, hard disks, removable magnetic disks, removable optical disks (e.g., compact disks and digital video disks), magnetic cassettes, memory cards or sticks, random access memories (RAM's), read only memories (ROM's), and the like.

The above description is intended to be illustrative, and not restrictive. For example, the above-described examples (or one or more aspects thereof) may be used in combination with each other. Other embodiments can be used, such as by one of ordinary skill in the art upon reviewing the above description. The Abstract is provided to comply with 37 C.F.R. §1.72(b), to 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. The scope of the invention should be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

WHAT IS CLAIMED IS:

1. An apparatus comprising:

at least one implantable cardiac depolarization sensing circuit, configured to obtain a sensed depolarization signal from a ventricle;

an electrical stimulation circuit, configured to provide pacing electrical stimulation energy to at least one implantable ventricular electrode; and

a pacing mode controller communicatively coupled to the cardiac depolarization sensing circuit and the electrical stimulation circuit, wherein the pacing mode controller is configured to:

deliver pacing therapy according to a first mode, wherein the first mode is a normal operating mode;

deliver pacing therapy according to a second pacing mode, wherein the second pacing mode increases mechanical stress on at least a particular portion of the ventricle as compared to the pacing therapy delivered during the first pacing mode;

deliver pacing therapy according to a third pacing mode, wherein the third pacing mode increases mechanical stress on at least a particular portion of the ventricle as compared to the pacing therapy delivered during the first pacing mode; and

alternate between the second and third pacing modes when switched from the normal operating mode to a stress augmentation mode.

2. The apparatus of claim 1, wherein the pacing mode controller includes or is coupled to a stress augmentation cycle memory area that is configured to store a value that specifies a programmable number of alternating cycles between the second and third pacing modes during the stress augmentation mode before returning to the first pacing mode to deliver pacing therapy according to the first pacing mode.

3. The apparatus of claim 2, wherein the pacing mode controller includes or is coupled to:

a second pacing mode cycle length memory area that is configured to specify a duration of the second pacing mode before alternating to the third pacing mode;

a third pacing mode cycle length memory area that is configured to specify a duration of the third pacing mode before alternating to the second pacing mode; and

wherein the second and third pacing mode memory areas are independently programmable to different values.

4. The apparatus of any one of claims 1-3, wherein the pacing mode controller includes or is coupled to:

a stress augmentation cycle memory area that is configured to specify at least one of:

a duration of time spent in the stress augmentation mode before automatically switching to the normal operating mode;

a duration of time spent in the normal operating mode before automatically switching to the stress augmentation mode;

a number of stress augmentation mode sessions;

a number of stress augmentation mode sessions per day;

a number of stress augmentation mode sessions in a stress augmentation burst;

a number of stress augmentation bursts per day;

a duration of time between stress augmentation mode sessions;

a duration of time between the second pacing mode and the third pacing mode during which pacing electrical stimulation energy is not delivered;

a number of days for enabling the stress augmentation mode; and

a time of day for initiating the stress augmentation mode.

5. The apparatus of any one of claims 1-4, wherein the second pacing mode and the third pacing mode provide stress augmentation through one or more independently programmable pacing parameters that include at least one of: a pacing site; a NASPE/BPEG-defined pacing mode; a pacing rate; a pacing

amplitude; a pacing pulse-width; an atrial-ventricular (AV) delay interval; or left ventricular (LV) offset interval.

6. The apparatus of any one of claims 1-5, wherein the second and third pacing modes are NASPE/BPEG-defined pacing modes, and wherein the pacing mode controller is configured to alter the NASPE/BPEG-defined pacing mode of at least one of the second pacing mode and the third pacing mode during the stress augmentation mode.

7. The apparatus of any one of claims 1-6, wherein the pacing mode controller is configured to:

deliver pacing therapy according to at least one additional pacing mode, wherein the additional pacing mode increases mechanical stress on at least a particular portion of the ventricle as compared to the pacing therapy delivered during the first pacing mode; and

alternate between the second pacing mode, third pacing mode, and the additional pacing mode when switched from the normal operating mode to a stress augmentation mode.

8. The apparatus of any one of claims 1-7, comprising:

a sensor circuit, configured to produce an electrical sensor signal indicating one or more physiologic cardiovascular events of a subject; and

a signal analyzer, communicatively coupled to the sensor circuit and the pacing mode controller, the signal analyzer configured to detect, from information provided by the electrical sensor signal, a patient physiologic condition that contraindicates an aspect of the stress augmentation mode.

9. The apparatus of claim 8, wherein the pacing mode controller is configured to inhibit the stress augmentation mode when the aspect of the stress augmentation mode is contraindicated by the signal analyzer.

10. The apparatus of claim 9, wherein the pacing mode controller is configured to retry the stress augmentation mode after the stress augmentation mode has been inhibited for a specified time duration.

11. The apparatus of claim 9 or 10, wherein the pacing mode controller is configured to retry the stress augmentation mode for a specified number of retry attempts before disabling the stress augmentation mode.

12. The apparatus of any one of claims 9-11, wherein the pacing mode controller is configured to automatically alter the stress augmentation mode when the aspect of the stress augmentation mode is contraindicated by the signal analyzer.

13. The apparatus of any one of claims 9-12, including:

a memory, communicatively coupled to the pacing mode controller, to store a lookup table of NASPE/BPEG-defined pacing modes, and

wherein the pacing mode controller is configured to replace at least one of the second or third pacing modes with a different pacing mode from the lookup table when the second or third pacing modes is contraindicated by the signal analyzer.

14. The apparatus of any one of claims 1-13, wherein the implantable cardiac depolarization sensing circuit is configured to obtain a sensed depolarization signal from an atrium;

wherein the electrical stimulation circuit is configured to provide pacing electrical stimulation energy to at least one implantable atrial electrode;

wherein the second pacing mode includes pacing at least one ventricle (V), without timing the pacing of the ventricle from an atrial cardiac event, when a V-V interval exceeds a specified ventricular interval; and

wherein the third pacing mode includes pacing an atrium and, in response thereto, triggering pacing of at least one ventricle after expiration of a specified fixed or dynamic AV delay without regard to any intrinsic cardiac depolarization event occurring in the ventricle.

15. The apparatus of any one of claims 1-14, wherein the pacing mode controller includes or is coupled to a stress augmentation cycle memory area that is configured to store an indication of a level of mechanical stress desired during at least one of the second or third pacing mode, and wherein the pacing mode controller is configured to specify an AV delay interval and a time duration of a stress augmentation mode session according to the indication of the desired level of mechanical stress.

16. The apparatus of any one of claims 1-15, wherein the pacing mode controller includes or is coupled to a stress augmentation cycle memory area that is configured to store an indication of a heart failure disease pathology and wherein the pacing mode controller is configured to specify an AV delay interval and a time duration of a stress augmentation mode session according to the indication of a heart failure disease pathology.

17. A method comprising:

delivering pacing therapy according to a first pacing mode using an implantable device, wherein the first pacing mode is a normal operating mode;

delivering pacing therapy according to a second pacing mode, wherein the second pacing mode increases mechanical stress on at least a particular portion of the ventricle as compared to the pacing therapy delivered during the first pacing mode;

delivering pacing therapy according to a third pacing mode, wherein the third pacing mode increases mechanical stress on at least a particular portion of the ventricle as compared to the pacing therapy delivered during the first pacing mode; and

alternating between the second and third pacing modes, when switched from the normal operating mode to a stress augmentation mode.

18. The method of claim 17, wherein alternating between the second and third pacing modes includes alternating between the second and third pacing

modes for a specified number of cycles before returning to the first pacing mode to deliver pacing therapy according to the first pacing mode.

19. The method of claim 17 or 18, including:

delivering pacing therapy according to the second pacing mode for a first specified duration before alternating to the third pacing mode; and

delivering pacing therapy according to the third pacing mode for a second specified duration before alternating to the second pacing mode, wherein the first and second durations are independently programmable to different values.

20. The method of any one of claims 17-19, including:

delivering a specified number of stress augmentation mode sessions in a stress augmentation burst; and

delivering a specified number of stress augmentation bursts per day.

21. The method of any one of claims 17-20, including altering a NASPE/BPEG-defined pacing mode of at least one of the second pacing mode and the third pacing mode during the stress augmentation mode.

22. The method of any one of claims 17-21, including:

delivering pacing therapy according to at least one additional pacing mode, wherein additional pacing mode increases mechanical stress on at least a particular portion of the ventricle as compared to the pacing therapy delivered during the first pacing mode; and

alternating between the second pacing mode, third pacing mode, and the additional pacing mode when switched from the normal operating mode to a stress augmentation mode.

23. The method of any one of claims 17-22, wherein delivering pacing therapy according to the second pacing mode and the third pacing mode includes pacing using independently programmable parameters that include at least one of: a pacing site, a NASPE/BPEG-defined pacing mode; a pacing rate, a pacing

amplitude, a pacing pulse-width, an atrial-ventricular (AV) delay interval, or a left ventricular (LV) offset interval.

24. The method of any one of claims 17-23, including detecting, using the implantable device, a patient physiologic condition that contraindicates an aspect of the stress augmentation mode.

25. The method of any one of claims 17-24, including inhibiting the stress augmentation mode when the aspect of the stress augmentation mode is contraindicated by the signal analyzer.

26. The method of claim 25, including retrying the stress augmentation mode after the stress augmentation mode has been inhibited for a specified time duration.

27. The method of claim 24, including retrying the stress augmentation mode for a specified number of retry attempts before disabling the stress augmentation mode.

28. The method of claim 24, including altering the stress augmentation mode when the aspect of the stress augmentation mode is contraindicated by the signal analyzer.

29. The method of claim 28, wherein altering the stress augmentation mode includes replacing at least one of the second pacing mode or the third pacing mode with a different pacing mode from a lookup table stored in the implantable device.

30. The method of any one of claims 17-29,

wherein delivering pacing therapy according to the second pacing mode includes pacing at least one ventricle (V), without timing the pacing of the ventricle from an atrial cardiac event, when a V-V interval exceeds a specified ventricular interval; and

wherein delivering pacing therapy according to the third pacing mode includes pacing an atrium and, in response thereto, triggering pacing of at least one ventricle after expiration of a specified fixed or dynamic AV delay without regard to any intrinsic cardiac depolarization event occurring in the ventricle.

31. The method of any one of claims 17-30, including:

receiving, into the implantable device, an indication of a desired level of mechanical stress for at least one of the second pacing mode or the third pacing mode; and

determining a decrease in AV delay and a duration of a stress augmentation mode session according to the indication.

32. An apparatus comprising:

an implantable cardiac depolarization sensing circuit, configured to obtain a sensed depolarization signal from a ventricle;

an electrical stimulation circuit, configured to provide pacing electrical stimulation energy to at least one implantable ventricular electrode and to at least one implantable atrial electrode; and

a pacing mode controller communicatively coupled to the cardiac depolarization sensing circuit and the electrical stimulation circuit, wherein the pacing mode controller is configured to:

deliver pacing therapy according to a second pacing mode, wherein the second pacing mode increases mechanical stress on at least a particular portion of the ventricle as compared to the pacing therapy delivered during the first pacing mode, wherein the second pacing mode includes pacing at least one ventricle (V), without timing the pacing of the at least one ventricle from an atrial cardiac event, when a V-V interval exceeds a specified ventricular interval;

deliver pacing therapy according to a third pacing mode, wherein the third pacing mode increases mechanical stress on at least a particular portion of the ventricle as compared to the pacing therapy delivered during the first pacing mode, wherein the third pacing mode includes pacing an atrium and, in response thereto, triggering pacing of at least

one ventricle after expiration of a specified fixed or dynamic AV delay without regard to any intrinsic cardiac depolarization event occurring in the ventricle;

alternate between the second and third pacing modes when switched from the normal operating mode to a stress augmentation mode; and

wherein the pacing mode controller is configured to deliver a programmable number of stress augmentation mode sessions as a stress augmentation burst and to deliver a programmable number of stress augmentation bursts per day.

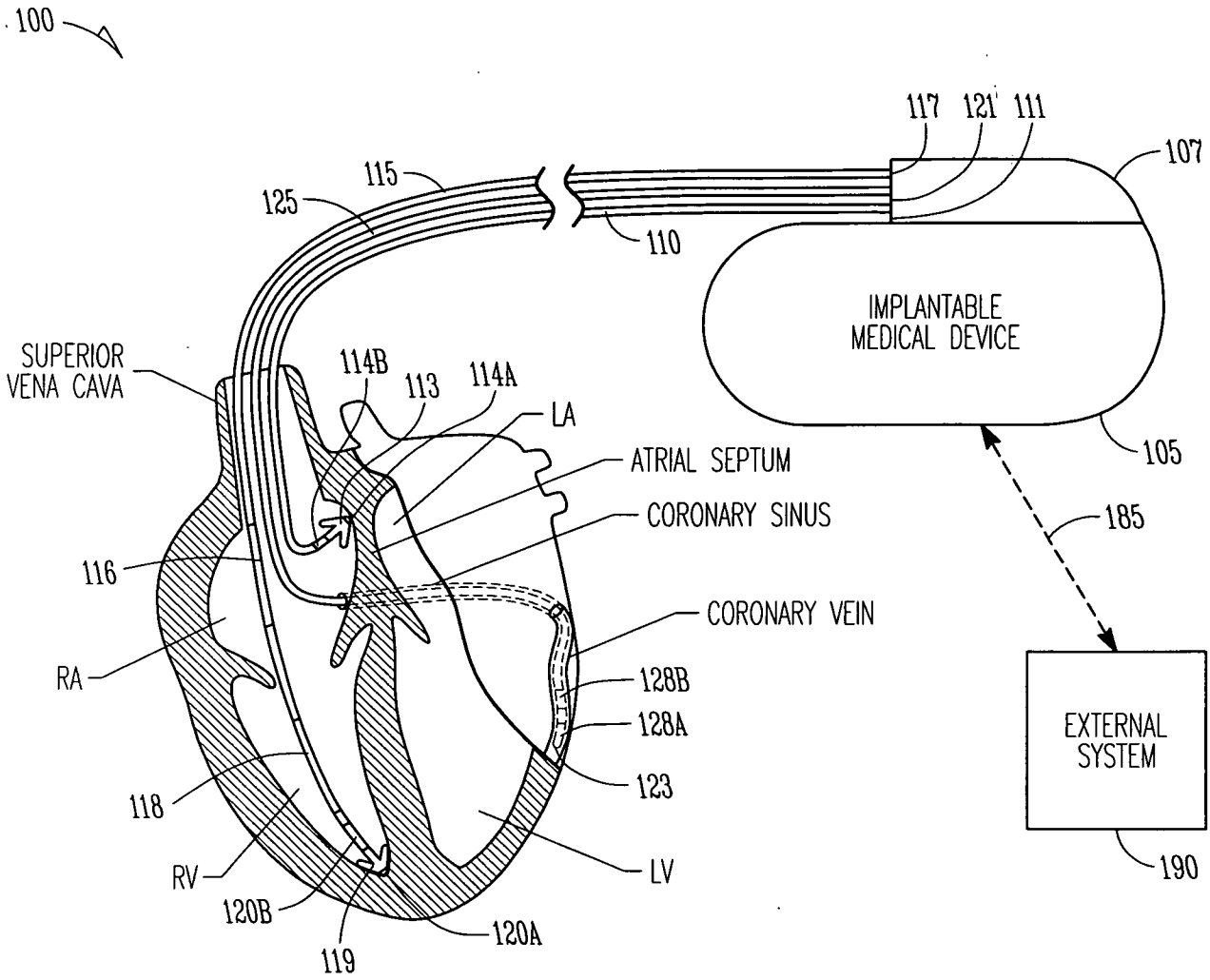
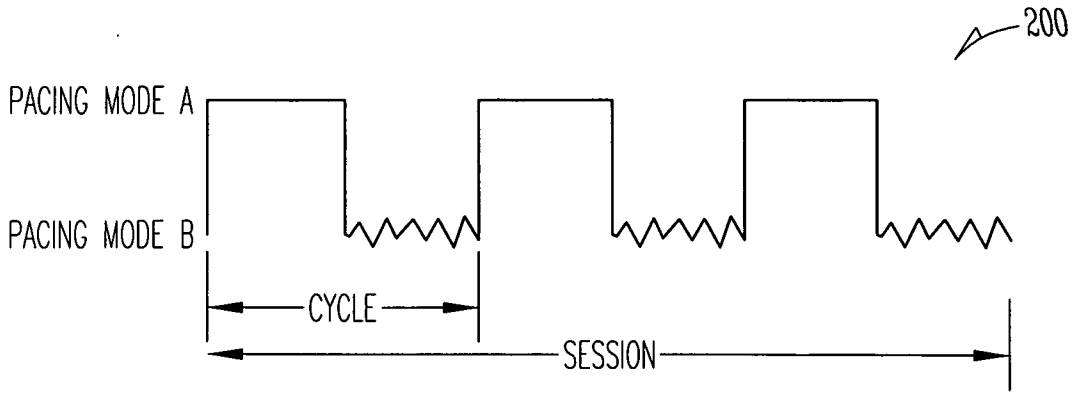

100
117
121
111
107
115
125
110
IMPLANTABLE
MEDICAL DEVICE
SUPERIOR
VENA CAVA
114B
113
114A
LA
ATRIAL SEPTUM
CORONARY SINUS
105
185
116
CORONARY VEIN
RA
128B
128A
EXTERNAL
SYSTEM
123
118
LV
RV
120B
120A
119
190

Fig. 1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PACING MODE A
PACING MODE B
CYCLE
SESSION

Fig. 2

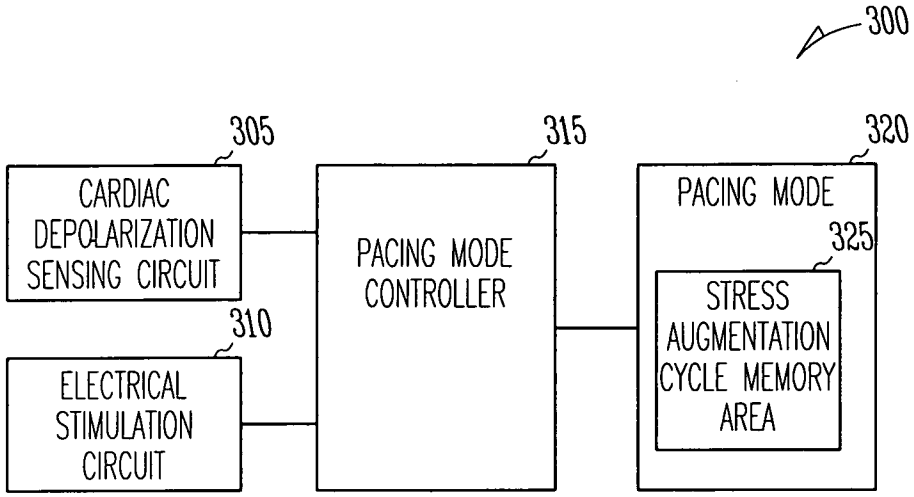
300
305
CARDIAC DEPOLARIZATION SENSING CIRCUIT
310
ELECTRICAL STIMULATION CIRCUIT
315
PACING MODE CONTROLLER
320
PACING MODE
325
STRESS AUGMENTATION CYCLE MEMORY AREA

Fig. 3

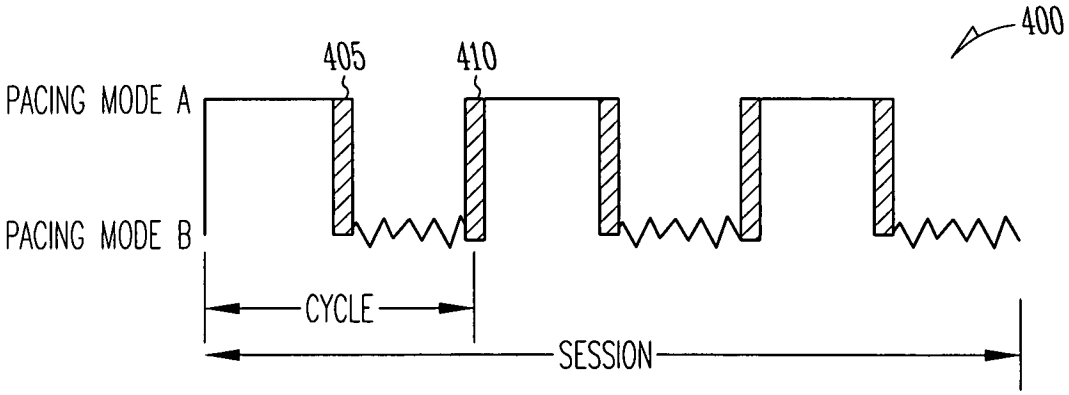
400
405
410
PACING MODE A
PACING MODE B
CYCLE
SESSION

Fig. 4

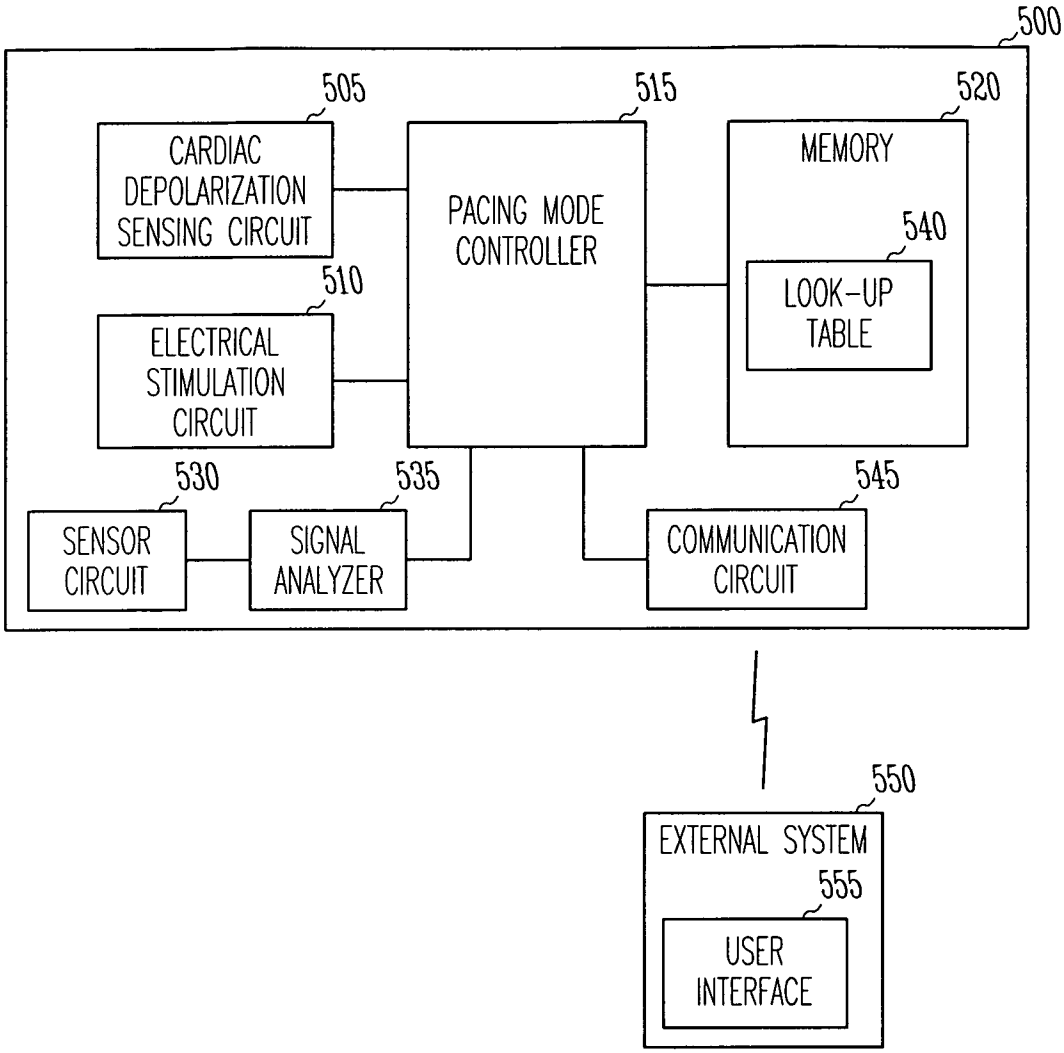
500
505
CARDIAC DEPOLARIZATION SENSING CIRCUIT
515
PACING MODE CONTROLLER
520
MEMORY
540
LOOK-UP TABLE
510
ELECTRICAL STIMULATION CIRCUIT
530
SENSOR CIRCUIT
535
SIGNAL ANALYZER
545
COMMUNICATION CIRCUIT
550
EXTERNAL SYSTEM
555
USER INTERFACE

Fig. 5

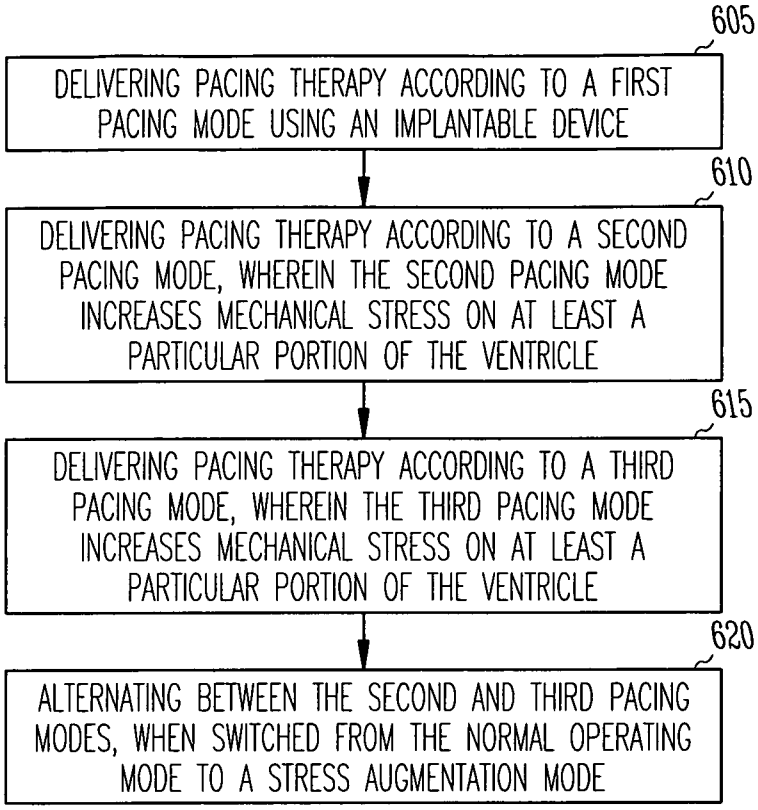
605
DELIVERING PACING THERAPY ACCORDING TO A FIRST PACING MODE USING AN IMPLANTABLE DEVICE
610
DELIVERING PACING THERAPY ACCORDING TO A SECOND PACING MODE, WHEREIN THE SECOND PACING MODE INCREASES MECHANICAL STRESS ON AT LEAST A PARTICULAR PORTION OF THE VENTRICLE
615
DELIVERING PACING THERAPY ACCORDING TO A THIRD PACING MODE, WHEREIN THE THIRD PACING MODE INCREASES MECHANICAL STRESS ON AT LEAST A PARTICULAR PORTION OF THE VENTRICLE
620
ALTERNATING BETWEEN THE SECOND AND THIRD PACING MODES, WHEN SWITCHED FROM THE NORMAL OPERATING MODE TO A STRESS AUGMENTATION MODE

Fig. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/000552

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/362

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2006/287684 A1 (BAYNHAM TAMARA C [US] ET AL) 21 December 2006 (2006-12-21) the whole document	1,4-9, 14,32 2,3, 10-13, 15,16
Y	US 2006/149326 A1 (PRINZEN FRITS [NL] ET AL) 6 July 2006 (2006-07-06) paragraphs [0020] - [0027]	2,3, 10-13, 15,16
A	US 2007/260284 A1 (PASTORE JOSEPH M [US] ET AL) 8 November 2007 (2007-11-08) paragraphs [0045] - [0048], [0051]	1-16,32

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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

"E" earlier 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
21 April 2009	04/05/2009

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, Fax: (+31-70) 340-3016	Schöffmann

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/000552

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.: 17-31
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/US2009/000552

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2006287684 A1	21-12-2006	EP 2024023 A2	18-02-2009
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		US 2007021789 A1	25-01-2007
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US 2007260284 A1	08-11-2007	EP 2012874 A2	14-01-2009
		WO 2007130774 A2	15-11-2007