(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 November 2003 (06.11.2003)

PCT

(10) International Publication Number
WO 03/090859 A1

(51) International Patent Classification[7]: A61N 1/362

(21) International Application Number: PCT/US03/12581

(22) International Filing Date: 24 April 2003 (24.04.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/131,417 25 April 2002 (25.04.2002) US

(71) Applicant: **MEDTRONIC, INC.** [US/US]; MS LC340, 710 Medtronic Parkway NE, Minneapolis, MN 55432 (US).

(72) Inventor: **KRAMM, Bethold**; Brunnsumstrasse 21a, 52074 Aachen (DE).

(74) Agents: **WALDKOETTER, Eric, R.** et al.; MS LC340, 710 Medtronic Parkway NE, Minneapolis, MN 55432 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

Published:

— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 03/090859 A1

(54) Title: VENTRICULAR SAFETY PACING IN BIVENTRICULAR PACING

(57) Abstract: A pacing method and apparatus includes providing an AV interval initiated by occurrence of either an atrial paced or sensed event. A ventricular safety pacing window is defined. In one embodiment, ventricular events are sensed at only one ventricular side and if a ventricular event is sensed during the ventricular safety pacing window, then a commitment is made to delivery of ventricular stimulus only to the one ventricular side of the patient's heart where the ventricular event is sensed. Further, in another embodiment, sensing of ventricular events may occur at both ventricular sides during the ventricular safety pacing window. If a ventricular event is sensed during the ventricular safety pacing window at a first ventricular side, then commitment is made to delivery of ventricular stimulus to at least the first ventricular side. Further, upon such sensing, modification is provided to reduce the likelihood of sensing ventricular events at the second ventricular side for a predetermined time period following the sensing of the ventricular event at the first side.

VENTRICULAR SAFETY PACING IN BIVENTRICULAR PACING

Field of the Invention

The present invention relates generally to implantable medical devices and methods of cardiac stimulus. More particularly, the present invention pertains to implantable medical pacing devices and methods that employ ventricular safety pacing (VSP) in cardiac stimulation.

Background of the Invention

Generally, in the human heart, the sinus (or sinoatrial (SA) node typically located near the junction of the superior vena cava and the right atrium) constitutes the primary natural pacemaker by which rhythmic electrical excitation is developed. The cardiac impulse arising from the sinus node is transmitted to the two atrial chambers (or atria) at the right and left sides of the heart. In response to excitation from the SA node, the atria contract, pumping blood from those chambers into the respective ventricular chambers (or ventricles). The impulse is transmitted to the ventricles through the atrioventricular (AV) node, and via a conduction system comprising the bundle of His, or common bundle, the right and left bundle branches, and the Purkinje fibers. The transmitted impulse causes the ventricles to contract with the right ventricle pumping unoxygenated blood through the pulmonary artery to the lungs, and the left ventricle pumping oxygenated (arterial) blood through the aorta and the lesser arteries to the body. The right atrium receives the unoxygenated (venous) blood. The blood oxygenated by the lungs is carried via the pulmonary veins to the left atrium.

The above action is repeated in a rhythmic cardiac cycle in which the atrial and ventricular chambers alternately contract and pump, and then relax and fill. One-way valves, between the atrial and ventricular chambers on the right and left sides of the heart, and at the exits of the right and left ventricles, prevent backflow of the blood as it moves through the heart and the circulatory system.

The sinus node is spontaneously rhythmic, and the cardiac rhythm it generates is termed sinus rhythm. This capacity to produce spontaneous cardiac impulses is called rhythmicity. Some other cardiac tissue possess rhythmicity and hence constitute secondary natural pacemakers, but the sinus node is the primary natural pacemaker because it spontaneously generates electrical pulses at a faster rate. The secondary pacemakers tend to be inhibited by the more rapid rate at which impulses are generated by the sinus node.

Disruption of the natural pacemaking and propagation system as a result of aging or disease is commonly treated by artificial cardiac pacing, by which rhythmic electrical discharges are applied to the heart at a desired rate from an artificial pacemaker. A pacemaker is a medical device which delivers electrical pulses to an electrode that is implanted adjacent to or in the patient's heart to stimulate the heart so that it will contract and beat at a desired rate. If the body's natural pacemaker performs correctly, blood is oxygenated in the lungs and efficiently pumped by the heart to the body's oxygen-demanding tissues. However, when the body's natural pacemaker malfunctions, an implantable pacemaker often is required to properly stimulate the heart.

Implantable pacemakers are typically designed to operate using various different response methodologies, such as, for example, nonsynchronous or asynchronous (fixed rate), inhibited (stimulus generated in the absence of a specified cardiac activity), or triggered (stimulus delivered in response to a specific hemodynamic parameter). Generally, inhibited and triggered pacemakers may be grouped as "demand"-type pacemakers, in which a pacing pulse is only generated when demanded by the heart. To determine when pacing is required by the pacemaker, demand pacemakers may sense various conditions such as heart rate, physical exertion, temperature, and the like. Moreover, pacemaker implementations range from the simple fixed rate, single chamber device that provides pacing with no sensing function, to highly complex models that provide fully-automatic dual chamber pacing and sensing functions. For example, such multiple chamber pacemakers are described in U.S. Patent No. 4,928,688 to Mower entitled "Method and Apparatus for Treating Hemodynamic Dysfunction," issued 29 May 1990; U.S. Patent No. 5,792,203 to Schroeppel entitled "Universal Programmable Cardiac

Stimulation Device," issued 11 August 1998; U.S. Patent No. 5,893,882 to Peterson et al. entitled "Method and Apparatus for Diagnosis and Treatment of Arrhythmias," issued 13 April 1999; and U.S. Patent No. 6,081,748 to Struble et al. entitled "Multiple Channel, Sequential Cardiac Pacing Systems," issued 27 June 2000.

For example, a DDD pacer paces either chamber (atrium or ventricle) and senses in either chamber. Thus, a pacer in DDD mode, may pace the ventricle in response to electrical activity sensed in the atrium. Further, for example, a pacer operating in VVI mode, paces and senses in the ventricle, but its pacing is inhibited by spontaneous and electrical activity of the ventricle (i.e., intrinsic ventricular activity or events, wherein the ventricle paces itself naturally).

As such, it may be desired to sense in one cardiac chamber (e.g., detect electrical activity representative of contraction of a chamber and referred to as a "sensed event") and, in response, pace (referred to as a "paced event") in the same or different chamber. It also may be desired to pace at two electrode locations following a sensed event at one of the pacing electrodes or at a different electrode. For example, patients are often treated with pacemakers that include an electrode in each of the two atrial chambers and a third electrode in the right ventricle. Both atrial chambers usually are paced following a sensed event in either chamber.

Further, bi-ventricular pacing devices are also used for treatment of patients. For example, in such a bi-ventricular pacing apparatus, multiple implantable leads having electrodes associated with a part thereof are implanted to the respective chambers of a patient's heart and coupled to respective circuitry for forming multiple channels for pacing and sensing, e.g., left ventricular channel, right atrial channel, etc. Such an exemplary implantable, four-channel cardiac pacemaker is described in U.S. Patent No. 6,070,101 to Struble et al. entitled "Multiple Channel, Sequential Cardiac Pacing Systems," issued 30 May 2000. For example, the distal end of a right atrial lead is attached to the right atrial wall and a right ventricular lead is passed through a vein into the right atrial chamber of the heart and into the right ventricle where its distal electrodes are fixed. Another lead is passed through a vein into the right atrial chamber of the heart, into the coronary sinus (CS), and then inferiorly into the great vein to extend a distal pair of left ventricular

pace/sense electrodes alongside the left ventricular chamber and leave a proximal pair of left atrial pace/sense electrodes adjacent the left atrium. With such electrode placement, pacing and sensing can be performed in each chamber of the heart, enabling bi-ventricular pacing. For example, such bi-ventricular pacing may be performed following atrial sensed events or atrial paced events.

Typically in such types of pacing apparatus, if an intrinsic or pacing pulse occurs in one of the chambers, for example, the atrium, then this activity may be erroneously sensed in the other chambers due to cross-talk. In order to eliminate this type of error, in the past, pacemakers have been provided with blanking periods for blanking the sensor in one channel after a pacing pulse occurs in the other. This blanking period is usually referred to as the cross-channel blanking period. Following the blanking period, an alert period is normally designated during which the cardiac chamber of interest is monitored for intrinsic activity. If no such activity is sensed by the end of this alert, then a pacing pulse is applied to the chamber. However, one problem with such pacemakers and the use of blanking channels has been selecting the duration of the blanking period for a particular channel properly. If the blanking period is too short, a cross-channel artifact could be interpreted as intrinsic activity and therefore pacing may be erroneously inhibited. On the other hand, if the blanking period is too long, intrinsic activity may be missed and the chamber may be paced when no such pacing is required. Either situation is undesirable physiologically.

Yet further, particularly in bi-ventricular pacing systems, e.g., systems which provide delivery of ventricular stimulus to both ventricular chambers following paced or sensed atrial events, a left ventricle lead is typically placed as described above, in a cardiac vein via the coronary sinus. Since the lead tip is in close proximity to the coronary sinus tractus, far-field coronary sinus/left atrial signals of significant amplitudes can potentially be sensed as ventricular activity and present inappropriate inhibition of bi-ventricular pacing. For example, in particular, when bipolar left ventricle leads are employed, the anode ring of the bipolar lead can be close to/or just within the coronary sinus system depending on tip-ring distance for the electrodes on the left ventricle lead. With the leads positioned in such a manner, atrial activity may be sensed using the left ventricle

electrodes, taken as an intrinsic left ventricle event, and prevent or inhibit delivery of ventricular stimulus.

Further, for example, lead dislodgment may also lead to such mistaken sensing of ventricular events. For example, a left ventricular lead may be placed via the coronary sinus with a passive lead tip fixed in a cardiac vein. Leads are typically placed 1 to 4 centimeters within the vessels (or, generally, as far as possible). Either partial lead dislodgment (e.g., gradual pullback) or permanent lead dislodgment may result in an electrode location that is undesirable and conducive to over-sensing of left atrial activity. Therefore, once again, such over-sensing of atrial activity may lead to falsely sensed ventricular activity and the inhibition of the delivery of ventricular stimulus. As such, bi-ventricular stimulation may be intermittently or may be completely lost.

In many pacing apparatus, such as, for example, dual chamber pacing devices operating in DDD mode, ventricular safety pacing (VSP) is generally available and intended to prevent inappropriate inhibition of ventricular pacing by ensuring that an atrial paced event is followed by a ventricular paced event. When this VSP feature is on, ventricular sensing within a VSP window of typically 110 milliseconds following an atrial paced event causes ventricular pacing at the end of the VSP window (e.g., the 110 millisecond period).

For example, if the pacing apparatus is programmed with a paced AV interval (PAV =100 milliseconds) (i.e., the AV interval following an atrial paced event and defined as the time between the paced event and delivery of ventricular stimulus) that is less than the VSP window (e.g., 110 milliseconds), then the delivery of ventricular stimulus would occur at the end of the programmed PAV interval when ventricular sensing occurs during the VSP window.

In another example, if the pacing apparatus is programmed with a PAV interval (PAV = 150 milliseconds) that is greater than the VSP window (VSP = 110 milliseconds), then when ventricular sensing occurs during the VSP window, the delivery of ventricular stimulus would occur at the end of the VSP interval, and not at the time out of the PAV interval.

Further, with such conventional VSP, if no ventricular events are sensed during the VSP window and the PAV is greater in length than the VSP window, if a ventricular event is sensed during the PAV but after the VSP window, delivery of ventricular stimulus would be inhibited due to the sensed intrinsic ventricular event. This VSP feature is designed to ensure ventricular output in the event of noise sensing on the ventricular lead (e.g., cross-talk) within the VSP window or 110 milliseconds after an atrial paced event and outside the programmed ventricular blanking period.

Another example of a pacemaker having safety pacing is described in U.S. Patent No. 5,782,881 to Lu et al., issued 21 July, 1998 and entitled "Pacemaker With Safety Pacing." As described therein, a monitoring window is defined during an AV delay during which signals sensed in a ventricular channel are monitored. If an abnormal signal is sensed during this window, certain features of the signal are analyzed to determine if its origin is intrinsic or due to cross-channel activity or noise. Cross-channel activity is ignored. If intrinsic cardiac activity is identified, then no pacing pulse or ventricular stimulation is applied. If no decision can be made as to the source of the cardiac activity, then delivery of stimulus is performed and ventricular pacing is not inhibited by the sensed activity.

The above-described VSP features may be inadequate in many circumstances. For example, conventional VSP features typically only occur when programmed on, and only following a paced atrial event. In other words, a VSP window is only utilized following delivery of pacing stimulus in the atrium and thus during a PAV interval. Such VSP features do not occur following atrial sensing or an atrial sensed event, where a timed sensed AV interval (SAV) is initiated.

As indicated above, ventricular safety pacing is incorporated in many dual chamber devices to avoid inhibition of ventricular pacing due to ventricular oversensing of atrial signals after an atrial pace. Ventricular signals following an atrial pace within a timing window of about, for example, 70 to 110 milliseconds (i.e., VSP window) will trigger a ventricular pace which may, for example, be delivered at the end of the PAV interval or at the end of the VSP window to ensure capture of the ventricle.

Conventional ventricular safety pacing is beneficial in many circumstances, but not necessarily in all dual chamber devices. Particularly, such conventional VSP is not necessarily advantageous in atrially triggered bi-ventricular pacing where ventricular sensing is only performed by one ventricular electrode, e.g., a right ventricular electrode. For example, this is the case for the combination of an implantable cardioverter defibrillator (ICD) and an atrially triggered bi-ventricular pacer, such as the InSync ICD (Model 7272) available from Medtronic Inc.

In such a situation, a ventricular signal being sensed in the VSP window after an atrial pace (e.g., due to a premature ventricular contraction (PVC)), may initiate a safety pace, that, as it is delivered on both ventricular leads, can fall into the late refractory period on the left ventricular side. The possibility that the safety pace may be delivered in the late refractory period on the left ventricular side is due primarily to the asymmetry of sensing and pacing. For example, the chance of this occurring is greater when the sensing of the activity or event during the ventricular safety pacing window occurs far from where the actual event takes place.

For example, as shown in Figure 7, a worst case scenario for the above situation is presented in the following illustrative case of sensing at the right ventricular side while providing bi-ventricular pacing. With sensing at the right ventricular side of the heart, there is the possibility that pacing of the left ventricular myocardium may occur as late as 220 milliseconds to 330 milliseconds after a premature ventricular contraction has occurred in the left ventricular myocardium. For example, a PVC 500 occurs on the left ventricular side of the heart. Thereafter, an atrial pace 501 is provided which initiates the ventricular safety pacing window 504. However, due to transmission delay, sensing of the PVC 500 on the right side of the heart does not occur until within the ventricular safety pacing window 504 as shown by sensed event 506. The sensing of the event 506 within the ventricular safety pacing window 504 commits to the provision of a ventricular safety pace 510 that as shown in the Figure 7 can be as much as 330 milliseconds after the PVC 500.

Thus, there is an inherent possibility of inducing tachyarrhythmias using bi-ventricular safety pacing in such a situation. This may be particularly relevant when

considering the increased rate of PVCs observed in the population having a primary incidence for an ICD together with the elevated intra-ventricular conduction delay in patients indicated for bi-ventricular pacing.

Table I below lists U.S. Patents relating to multiple chamber pacing devices and devices and methods having VSP features.

Table I

U.S. Patent No.	Inventor	Issue Date
4,890,617	Markowitz et al.	2 January 1990
4,928,688	Mower	29 May 1990
4,932,406	Berkovits	12 June 1990
4,944,298	Sholder	31 July 1990
5,144,949	Olson	8 September 1992
5,292,340	Crosby et al.	8 March 1994
5,318,594	Limousine et al.	7 June 1994
5,782,881	Lu et al.	21 July 1998
5,792,203	Schroeppel	11 August 1998
5,893,882	Peterson et al.	13 April 1999
5,902,324	Thompson et al.	11 May 1999
6,070,101	Struble et al.	30 May 2000
6,081,748	Struble et al.	27 June 2000

All references listed in Table I, and elsewhere herein, are incorporated by reference in their respective entireties. As those of ordinary skill in the art will appreciate readily upon reading the Summary of the Invention, Detailed Description of the Embodiments, and claims set forth below, at least some of the devices and methods disclosed in the references of Table I and elsewhere herein may be modified advantageously by using the teachings of the present invention. However, the listing of any such references in Table I, or elsewhere herein, is by no means an indication that such references are prior art to the present invention.

Summary of the Invention

The present invention has certain objects. That is, various embodiments of the present invention provide solutions to one or more problems existing in the prior art with respect to implantable medical device pacing techniques and, in particular, current ventricular safety pacing (VSP) techniques. One of such problems is that in various circumstances, some VSP techniques that use bi-ventricular pacing may provide safety paces that fall into late refractory periods as described above. Thus, there may be a possibility of inducing tachyarrhythmias. The risk of inducing arrhythmias may be higher when ventricular sensing of events occurs far from where the events take place in a pacing device that is only sensing on one ventricular channel, e.g., sensing on the right side when the event such as a PVC occurs on the left side.

In comparison to known VSP techniques, various embodiments of the present invention may provide one or more of the following advantages. For example, VSP according to the present invention attempts to ensure that safety paces do not occur at undesirable times. Further, such delivery of ventricular stimulation therapy according to the present invention restores symmetry of sensing and pacing intervention in certain types of pacing devices.

Some embodiments of the method of the present invention include one or more of the following features: providing a method of pacing for use in a medical device; providing a paced AV delay following an atrial paced event, wherein the paced AV delay is a predetermined time period initiated by the atrial paced event; defining a ventricular safety pacing window during at least an initial portion of the paced AV delay, wherein the paced AV delay further comprises a remainder period if the paced AV delay is longer than the ventricular safety pacing window; sensing ventricular events at only one ventricular side of a patient's heart; delivering ventricular stimulus to the at least one ventricular side of the patient's heart upon expiration of the paced AV delay if no ventricular events are sensed during the ventricular safety pacing window defined during at least the initial portion of the paced AV delay and the remainder portion of the paced AV delay; inhibiting the delivery of ventricular stimulus upon expiration of the paced AV delay if no ventricular events are sensed during the ventricular safety pacing window but a ventricular

event is sensed during the remainder portion of the paced AV delay; committing to delivery of ventricular stimulus only to the one ventricular side of the patient's heart where ventricular events are sensed if a ventricular event is sensed during the ventricular safety pacing window; providing a ventricular safety pacing window that is in the range of about 70 milliseconds to 110 milliseconds; delivering bi-ventricular stimulus if no ventricular events are sensed during the ventricular safety pacing window defined during the initial portion of the paced AV delay and a remainder portion of paced AV delay; employing the features in an implantable medical device selected from one of a pacemaker, a defibrillator, a pacemaker/cardioverter/defibrillator, and a cardioverter/defibrillator; providing an AV delay initiated by occurrence of either an atrial sensed event or an atrial paced event, wherein the AV delay is a programmed time period; and delivering ventricular stimulus to both ventricular sides of the patient's heart if no ventricular events are sensed during the AV delay or the ventricular safety pacing window.

Other embodiments of the method of the present invention include one or more of the following features: sensing ventricular events at both ventricular sides of a patient's heart during at least the ventricular safety pacing window; if a ventricular event is sensed during the ventricular safety pacing window at a first ventricular side of the patient's heart, then committing to the delivery of ventricular stimulus to at least the first ventricular side of the patient's heart; modifying at least one parameter associated with sensing at the second ventricular side of the patient's heart to reduce the likelihood of sensing ventricular events for a predetermined time period following the sensing of the ventricular event at the first side of the patient's heart; providing a predetermined time period following the sensing of the ventricular event at the first side of the patient's heart during which sensed signals at the second ventricular side are not recognized; and adjusting a sensing threshold for sensing events at the second ventricular side during a period of time following the sensing of the ventricular event at the first side of the patient's heart.

Further, some embodiments of an apparatus according to the present invention include one or more of the following features: a dual chamber pacing apparatus; atrial pacing circuitry operable to at least generate atrial pacing pulses; ventricular pacing and sensing circuitry operable to generate ventricular pacing pulses for stimulating at least one

ventricular side of a patient's heart via at least one ventricular lead; ventricular pacing and sensing circuitry for use in sensing ventricular events at only one ventricular side of the patient's heart via the at least one ventricular lead; control circuitry operable to provide a paced AV delay following an atrial paced event, wherein the paced AV delay is a predetermined time period initiated by the atrial paced event; control circuitry operable to define a ventricular safety pacing window during at least an initial portion of the paced AV delay, wherein the paced AV delay further comprises a remainder portion if the paced AV delay is longer than the ventricular safety pacing window; control circuitry operable to sense ventricular events at only one ventricle side of a patient's heart at least during the ventricular safety pacing window; control circuitry operable to control delivery of ventricular stimulus using the ventricular pacing circuitry such that if no ventricular events are sensed during the ventricular safety pacing window defined during the initial portion of the paced AV delay and the remainder portion thereof, then ventricular stimulus is delivered to at least one ventricle upon expiration of the paced AV delay; control circuitry operable to control delivery of ventricular stimulus using the ventricular pacing circuitry such that if no ventricular events are sensed during the ventricular safety pacing window but a ventricular event is sensed during the remainder portion of the paced AV delay, then inhibiting the delivery of ventricular stimulus upon expiration of the paced AV delay; control circuitry operable to control delivery of ventricular stimulus using the ventricular pacing circuitry such that if a ventricular event is sensed during the ventricular safety pacing window, committing to the delivery of a ventricular stimulus only to the ventricular side of the patient's heart where ventricular events are sensed; control circuitry operable to control delivery of ventricular stimulus using the ventricular pacing circuitry such that if no ventricular events are sensed during the ventricular safety pacing window defined during the initial portion of the paced AV delay and any remainder portion thereof, then bi-ventricular stimulus is delivered; atrial pacing and sensing circuitry operable to at least generate atrial pacing pulses and sense atrial events; and control circuitry operable to provide an AV delay initiated by occurrence of either an atrial sensed event or an atrial paced event, wherein the AV delay is a programmed time period.

Yet further, other embodiments of the apparatus may include one or more of the following features: ventricular pacing and sensing circuitry operable to generate ventricular pacing pulses for stimulating both ventricular sides of a patient's heart via one or more ventricular leads and for use in sensing ventricular events in both ventricular sides via the one or more ventricular leads; control circuitry operable to sense ventricular events at both ventricular sides of the patient's heart during at least the ventricular safety pacing window; control circuitry operable to control delivery of ventricular stimulus such that if a ventricular event is sensed during the ventricular safety pacing window at a first ventricular side of the patient's heart, then committing to delivery of ventricular stimulus to at least the first ventricular side of the patient's heart; control circuitry operable to modify at least one parameter associated with sensing at the second ventricular side of the patient's heart to reduce the likelihood of sensing ventricular events for a predetermined time period following the sensing of the ventricular event at the first side of the patient's heart; control circuitry operable to provide a predetermined time period following the sensing of the ventricular event at the first side of the patient's heart during which sensed signals at the second ventricular side are not recognized; and control circuitry operable to adjust a sensing threshold for sensing events at the second ventricular side during a period of time following the sensing of the ventricular event at the first side of the patient's heart.

The above summary of the present invention is not intended to describe each embodiment or every implementation of the present invention. Advantages, together with a more complete understanding of the invention, will become apparent and appreciated by referring to the following detailed description and claims taken in conjunction with the accompanying drawings.

Brief Description of the Drawings

The present invention will be further described with reference to the drawings, wherein:

Figure 1 is an implantable medical device (IMD) in accordance with one embodiment of the present invention, wherein the IMD is implanted within a body of a patient;

Figure 2 is an enlarged view of the IMD of Figure 1 diagrammatically illustrating coupling with the patient's heart in accordance with one embodiment of the invention;

Figure 3 is a functional block diagram of an IMD in accordance with one embodiment of the present invention;

Figure 4 is an IMD in accordance with another embodiment of the invention, wherein the IMD is an implantable pacemaker/cardioverter/defibrillator (PCD);

Figure 5 is a functional block diagram of the IMD of Figure 4;

Figure 6 is a diagram of an IMD illustrating a multiple channel bi-atrial and/or bi-ventricular pacing system coupled with a patient's heart in accordance with another embodiment of the present invention;

Figure 7 is a timing diagram illustrating potential problems using conventional ventricular safety pacing in a particular situation.

Figure 8A is a timing diagram illustrating ventricular safety pacing according to the present invention in an embodiment that includes ventricular sensing at only one side of a patient's heart;

Figure 8B is a timing diagram illustrating ventricular safety pacing according to the present invention in an embodiment that includes ventricular sensing at both sides of a patient's heart;

Figure 9A is a flow diagram for use in describing ventricular safety pacing following an atrial pace according to the present invention, wherein ventricular sensing is employed at only one ventricular side of a patient's heart;

Figure 9B is a flow diagram for use in describing ventricular safety pacing following an atrial pace according to the present invention, wherein ventricular sensing is employed at both ventricular sides of a patient's heart; and

Figures 10A-10B illustrate examples of the delivery of ventricular safety pacing stimulus corresponding respectively to each of the flow diagrams of Figures 9A and 9B.

Detailed Description of the Embodiments

Figure 1 is a simplified view of one embodiment of implantable medical device ("IMD") 10 for use in describing the present invention. IMD 10 shown in Figure 1 is a pacemaker comprising at least one of pacing and sensing leads 16 and 18 attached to hermetically sealed enclosure 14 and implanted near human or mammalian heart 8. Pacing and sensing leads 16 and 18, sense electrical signals attendant to the depolarization and re-polarization of the heart 8, and further provide pacing pulses for causing depolarization of cardiac tissue in the vicinity of the distal ends thereof. Leads 16 and 18 may have, for example, unipolar or bipolar electrodes disposed thereon, as is well known in the art. Examples of IMD 10 include implantable cardiac pacemakers disclosed in U.S. Patent No. 5,158,078 to Bennett et al., U.S. Patent No. 5,312,453 to Shelton et al. or U.S. Patent No. 5,144,949 to Olson.

Figure 2 shows connector module 12 and hermetically sealed enclosure 14 of IMD 10 located near human or mammalian heart 8. Atrial and ventricular pacing leads 16 and 18 extend from connector header module 12 to the right atrium and ventricle, respectively, of heart 8. Atrial electrodes 20 and 21 disposed at the distal end of atrial pacing lead 16 are located in the right atrium. Ventricular electrodes 28 and 29 at the distal end of ventricular pacing lead 18 are located in the right ventricle.

Figure 3 is a block diagram illustrating the constituent components of IMD 10 in accordance with one embodiment of the present invention, where IMD 10 is pacemaker having a microprocessor-based architecture. IMD 10 is shown as including activity sensor or accelerometer 11, which is preferably a piezoceramic accelerometer bonded to a hybrid circuit located inside enclosure 14. Activity sensor 11 typically (although not necessarily) provides a sensor output that varies as a function of a measured parameter relating to a patient's metabolic requirements. For the sake of convenience, IMD 10 in Figure 3 is shown with lead 18 only connected thereto; similar circuitry and connections not explicitly shown in Figure 3 apply to lead 16.

IMD 10 in Figure 3 is most preferably programmable by means of an external programming unit (not shown in the Figures). One such programmer is the commercially available Medtronic Model 9790 programmer, which is microprocessor-based and provides a series of encoded signals to IMD 10, typically through a programming head which transmits or telemeters radio-frequency (RF) encoded signals to IMD 10. Such a telemetry system is described in U.S. Patent No. 5,354,319 to Wyborny et al. The programming methodology disclosed in Wyborny et al.'s '319 patent is identified herein for illustrative purposes only. Any of a number of suitable programming and telemetry methodologies known in the art may be employed so long as the desired information is transmitted to and from IMD 10.

As shown in Figure 3, lead 18 is coupled to node 50 in IMD 10 through input capacitor 52. Activity sensor or accelerometer 11 is most preferably attached to a hybrid circuit located inside hermetically sealed enclosure 14 of IMD 10. The output signal provided by activity sensor 11 is coupled to input/output circuit 54. Input/output circuit 54 contains analog circuits for interfacing to heart 8, activity sensor 11, antenna 56 and circuits for the application of stimulating pulses to heart 8. The rate of heart 8 is controlled by software-implemented algorithms stored in microcomputer circuit 58.

Microcomputer circuit 58 preferably comprises on-board circuit 60 and off-board circuit 62. Circuit 58 may correspond to a microcomputer circuit disclosed in U.S. Patent No. 5,312,453 to Shelton et al. On-board circuit 60 preferably includes microprocessor 64, system clock circuit 66 and on-board RAM 68 and ROM 70. Off-board circuit 62 preferably comprises a RAM/ROM unit. On-board circuit 60 and off-board circuit 62 are each coupled by data communication bus 72 to digital controller/timer circuit 74. Microcomputer circuit 58 may comprise a custom integrated circuit device augmented by standard RAM/ROM components.

Electrical components shown in Figure 3 are powered by an appropriate implantable battery power source 76 in accordance with common practice in the art. For the sake of clarity, the coupling of battery power to the various components of IMD 10 is not shown in the Figures. Antenna 56 is connected to input/output circuit 54 to permit uplink/downlink telemetry through RF transmitter and receiver telemetry unit 78. By way of example, telemetry unit 78 may correspond to that disclosed in U.S. Patent No. 4,556,063 issued to

Thompson et al., or to that disclosed in the above-referenced '319 patent to Wyborny et al. It is generally preferred that the particular programming and telemetry scheme selected permit the entry and storage of cardiac rate-response parameters. The specific embodiments of antenna 56, input/output circuit 54 and telemetry unit 78 presented herein are shown for illustrative purposes only, and are not intended to limit the scope of the present invention.

V_{REF} and Bias circuit 82 (see Figure 3) most preferably generates stable voltage reference and bias currents for analog circuits included in input/output circuit 54. Analog-to-digital converter (ADC) and multiplexer unit 84 digitizes analog signals and voltages to provide "real-time" telemetry intracardiac signals and battery end-of-life (EOL) replacement functions. Operating commands for controlling the timing of IMD 10 are coupled by data bus 72 to digital controller/timer circuit 74, where digital timers and counters establish the overall escape interval of the IMD 10 as well as various refractory, blanking and other timing windows for controlling the operation of peripheral components disposed within input/output circuit 54 and for particular employing certain functionality such as ventricular safety pacing in accordance with the present invention.

Digital controller/timer circuit 74 is preferably coupled to sensing circuitry, including sense amplifier 88, peak sense and threshold measurement unit 90 and comparator/threshold detector 92. Circuit 74 is further preferably coupled to electrogram (EGM) amplifier 94 for receiving amplified and processed signals sensed by lead 18. Sense amplifier 88 amplifies sensed electrical cardiac signals and provides an amplified signal to peak sense and threshold measurement circuitry 90, which in turn provides an indication of peak sensed voltages and measured sense amplifier threshold voltages on multiple conductor signal path 67 to digital controller/timer circuit 74. An amplified sense amplifier signal is then provided to comparator/threshold detector 92. By way of example, sense amplifier 88 may correspond to that disclosed in U.S. Patent No. 4,379,459 to Stein.

The electrogram signal provided by EGM amplifier 94 is employed when IMD 10 is being interrogated by an external programmer to transmit a representation of a cardiac analog electrogram. See, for example, U.S. Patent No. 4,556,063 to Thompson et al. Output pulse generator 96 provides pacing stimuli to patient's heart 8 through coupling capacitor 98, for example, in response to a pacing trigger signal provided by digital controller/timer circuit 74

each time the escape interval times out, in response to an externally transmitted pacing command or in response to other stored commands as is well known in the pacing art. By way of example, output amplifier 96 may correspond generally to an output amplifier disclosed in U.S. Patent No. 4,476,868 to Thompson.

The specific embodiments of input amplifier 88, output amplifier 96 and EGM amplifier 94 identified herein are presented for illustrative purposes only, and are not intended to be limiting in respect of the scope of the present invention. The specific embodiments of such circuits may not be critical to practicing some embodiments of the present invention so long as they provide means for generating a stimulating pulse and are capable of providing signals indicative of natural or stimulated contractions of heart 8.

In some embodiments of the present invention, IMD 10 may operate in various non-rate-responsive modes, including, but not limited to, DDD, DDI, VVI, VOO and VVT modes. In other embodiments of the present invention, IMD 10 may operate in various rate-responsive modes, including, but not limited to, DDDR, DDIR, VVIR, VOOR and VVTR modes. Some embodiments of the present invention are capable of operating in both non-rate-responsive and rate-responsive modes. Moreover, in various embodiments of the present invention, IMD 10 may be programmably configured to operate so that it varies the rate at which it delivers stimulating pulses to heart 8 only in response to one or more selected sensor outputs being generated. Numerous pacemaker features and functions not explicitly mentioned herein may be incorporated into IMD 10 while remaining within the scope of the present invention.

The present invention is not limited in scope to dual-sensor pacemakers, and is not limited to IMD's comprising activity or pressure sensors only. Further, the present invention is not limited in scope to dual-chamber pacemakers, dual-chamber leads for pacemakers or single-sensor or dual-sensor leads for pacemakers. Thus, various embodiments of the present invention may be practiced in conjunction with more than two leads or with multiple-chamber pacemakers, for example. At least some embodiments of the present invention may be applied equally well in the contexts of dual-, triple- or quadruple- chamber pacemakers or other types of IMD's. See, for example, U.S. Patent No. 5,800,465 to Thompson et al.

IMD 10 may also be a pacemaker-cardioverter-defibrillator ("PCD") corresponding to any of numerous commercially available implantable PCD's. Various embodiments of the present invention may be practiced in conjunction with PCD's such as those disclosed in U.S. Patent No. 5,545,186 to Olson et al., U.S. Patent No. 5,354,316 to Keimel, U.S. Patent No. 5,314,430 to Bardy, U.S. Patent No. 5,131,388 to Pless and U.S. Patent No. 4,821,723 to Baker, Jr. et al.

Figures 4 and 5 illustrate one embodiment of IMD 10 and a corresponding lead set of the present invention, where IMD 10 is a PCD. In Figure 4, the ventricular lead takes the form of leads disclosed in U.S. Patent Nos. 5,099,838 and 5,314,430 to Bardy, and includes an elongated insulative lead body 1 carrying three concentric coiled conductors separated from one another by tubular insulative sheaths. Located adjacent the distal end of lead 1 are ring electrode 2, extendable helix electrode 3 mounted retractably within insulative electrode head 4 and elongated coil electrode 5. Each of the electrodes is coupled to one of the coiled conductors within lead body 1. Electrodes 2 and 3 are employed for cardiac pacing and for sensing ventricular depolarizations. At the proximal end of the lead is bifurcated connector 6 which carries three electrical connectors, each coupled to one of the coiled conductors. Defibrillation electrode 5 may be fabricated from platinum, platinum alloy or other materials known to be usable in implantable defibrillation electrodes and may be about 5 cm in length.

The atrial/superior vena cava (SVC) lead shown in Figure 4 includes elongated insulative lead body 7 carrying three concentric coiled conductors separated from one another by tubular insulative sheaths corresponding to the structure of the ventricular lead. Located adjacent the J-shaped distal end of the lead are ring electrode 9 and extendable helix electrode 13 mounted retractably within an insulative electrode head 15. Each of the electrodes is coupled to one of the coiled conductors within lead body 7. Electrodes 13 and 9 are employed for atrial pacing and for sensing atrial depolarizations. Elongated coil electrode 19 is provided proximal to electrode 9 and coupled to the third conductor within lead body 7. Electrode 19 preferably is 10 cm in length or greater and is configured to extend from the SVC toward the tricuspid valve. In one embodiment of the present invention, approximately 5 cm of the right atrium/SVC electrode is located in the right

atrium with the remaining 5 cm located in the SVC. At the proximal end of the lead is bifurcated connector 17 carrying three electrical connectors, each coupled to one of the coiled conductors.

The coronary sinus lead shown in Figure 4 assumes the form of a coronary sinus lead disclosed in the above cited '838 patent issued to Bardy, and includes elongated insulative lead body 41 carrying one coiled conductor coupled to an elongated coiled defibrillation electrode 21. Electrode 21, illustrated in broken outline in Figure 4, is located within the coronary sinus and great vein of the heart. At the proximal end of the lead is connector plug 23 carrying an electrical connector coupled to the coiled conductor. The coronary sinus/great vein electrode 41 may be about 5 cm in length.

The implantable PCD is shown in Figure 4 in combination with leads 1, 7 and 41, and lead connector assemblies 23, 17 and 6 inserted into connector block 12. Optionally, insulation of the outward facing portion of housing 14 of PCD 10 may be provided using a plastic coating such as parylene or silicone rubber, as is employed in some unipolar cardiac pacemakers. The outward facing portion, however, may be left uninsulated or some other division between insulated and uninsulated portions may be employed. The uninsulated portion of housing 14 serves as a subcutaneous defibrillation electrode to defibrillate either the atria or ventricles. Lead configurations other than those shown in Figure 4 may be practiced in conjunction with the present invention, such as those shown in U.S. Patent No. 5,690,686 to Min et al.

Figure 5 is a functional schematic diagram of one embodiment of an implantable PCD of the present invention. This diagram should be taken as exemplary of the type of device in which various embodiments of the present invention may be embodied, and not as limiting, as it is believed that the invention may be practiced in a wide variety of device implementations which provided pacing therapies.

The PCD is provided with an electrode system. If the electrode configuration of Figure 4 is employed, the electrode configuration correspondence may be as follows. Electrode 25 in Figure 5 includes the uninsulated portion of the housing of the PCD. Electrodes 25, 15, 21 and 5 are coupled to high voltage output circuit 27, which includes high voltage switches controlled by CV/defib control logic 29 via control bus 31.

Switches disposed within circuit 27 determine which electrodes are employed and which electrodes are coupled to the positive and negative terminals of the capacitor bank (which includes capacitors 33 and 35) during delivery of defibrillation pulses.

Electrodes 2 and 3 are located on or in the ventricle and are coupled to the R-wave amplifier 37, which preferably takes the form of an automatic gain controlled amplifier providing an adjustable sensing threshold as a function of the measured R-wave amplitude. A signal is generated on R-out line 39 whenever the signal sensed between electrodes 2 and 3 exceeds the present sensing threshold.

Electrodes 9 and 13 are located on or in the atrium and are coupled to the P-wave amplifier 43, which preferably also takes the form of an automatic gain controlled amplifier providing an adjustable sensing threshold as a function of the measured P-wave amplitude. A signal is generated on P-out line 45 whenever the signal sensed between electrodes 9 and 13 exceeds the present sensing threshold. The general operation of R-wave and P-wave amplifiers 37 and 43 may correspond to that disclosed in U.S. Pat. No. 5,117,824, to Keimel et al.

Switch matrix 47 is used to select which of the available electrodes are coupled to wide band (0.5-200 Hz) amplifier 49 for use in digital signal analysis. Selection of electrodes is controlled by the microprocessor 51 via data/address bus 53, which selection may be varied as desired. Signals from the electrodes selected for coupling to bandpass amplifier 49 are provided to multiplexer 55, and thereafter converted to multi-bit digital signals by A/D converter 57, for storage in random access memory 59 under control of direct memory access circuit 61. Microprocessor 51 may employ digital signal analysis techniques to characterize the digitized signals stored in random access memory 59 to recognize and classify the patient's heart rhythm employing any of the numerous signal processing methodologies known in the art.

The remainder of the circuitry is dedicated to the provision of cardiac pacing, cardioversion and defibrillation therapies, and, for purposes of the present invention may correspond to circuitry known to those skilled in the art. The following exemplary apparatus is disclosed for accomplishing pacing, cardioversion and defibrillation functions. Pacer timing/control circuitry 63 preferably includes programmable digital

counters which control the basic time intervals associated with DDD, VVI, DVI, VDD, AAI, DDI and other modes of single and dual chamber pacing well known to the art. Circuitry 63 also preferably controls escape intervals associated with anti-tachyarrhythmia pacing in both the atrium and the ventricle.

Intervals defined by pacing circuitry 63 include atrial and ventricular pacing escape intervals, the refractory periods during which sensed P-waves and R-waves are ineffective to restart timing of the escape intervals and the pulse widths of the pacing pulses. The durations of these intervals are determined by microprocessor 51, in response to stored data in memory 59 and are communicated to pacing circuitry 63 via address/data bus 53. Pacer circuitry 63 also determines the amplitude of the cardiac pacing pulses under control of microprocessor 51.

During pacing, escape interval counters within pacer timing/control circuitry 63 are reset upon sensing of R-waves and P-waves as indicated by signals on lines 39 and 45, and in accordance with the selected mode of pacing on time-out trigger generation of pacing pulses by pacer output circuitry 65 and 67, which are coupled to electrodes 9, 13, 2 and 3. Escape interval counters are also reset on generation of pacing pulses and thereby control the basic timing of cardiac pacing functions, including anti-tachyarrhythmia pacing. The durations of the intervals defined by escape interval timers are determined by microprocessor 51 via data/address bus 53. The value of the count present in the escape interval counters when reset by sensed R-waves and P-waves may be used to measure the durations of R-R intervals, P-P intervals, P-R intervals and R-P intervals, which measurements are stored in memory 59 and used to detect the presence of tachyarrhythmias.

Microprocessor 51 most preferably operates as an interrupt driven device, and is responsive to interrupts from pacer timing/control circuitry 63 corresponding to the occurrence of sensed P-waves and R-waves and corresponding to the generation of cardiac pacing pulses. Those interrupts are provided via data/address bus 53. Any necessary mathematical calculations to be performed by microprocessor 51 and any updating of the values or intervals controlled by pacer timing/control circuitry 63 take place following such interrupts.

Detection of atrial or ventricular tachyarrhythmias, as employed in the present invention, may correspond to tachyarrhythmia detection algorithms known in the art. For example, the presence of an atrial or ventricular tachyarrhythmia may be confirmed by detecting a sustained series of short R-R or P-P intervals of an average rate indicative of tachyarrhythmia or an unbroken series of short R-R or P-P intervals. The suddenness of onset of the detected high rates, the stability of the high rates, and a number of other factors known in the art may also be measured at this time. Appropriate ventricular tachyarrhythmia detection methodologies measuring such factors are described in U.S. Pat. No. 4,726,380 issued to Vollmann et al., U.S. Pat. No. 4,880,005 issued to Pless et al. and U.S. Pat. No. 4,830,006 issued to Haluska et al. An additional set of tachycardia recognition methodologies is disclosed in the article "Onset and Stability for Ventricular Tachyarrhythmia Detection in an Implantable Pacer-Cardioverter-Defibrillator" by Olson et al., published in Computers in Cardiology, Oct. 7-10, 1986, IEEE Computer Society Press, pages 167-170. Atrial fibrillation detection methodologies are disclosed in Published PCT Application Ser. No. US92/02829, Publication No. WO92/18198, by Adams et al., and in the article "Automatic Tachycardia Recognition", by Arzbaecher et al., published in PACE, May-June, 1984, pp. 541-547.

In the event an atrial or ventricular tachyarrhythmia is detected and an anti-tachyarrhythmia pacing regimen is desired, appropriate timing intervals for controlling generation of anti-tachyarrhythmia pacing therapies are loaded from microprocessor 51 into the pacer timing and control circuitry 63, to control the operation of the escape interval counters therein and to define refractory periods during which detection of R-waves and P-waves is ineffective to restart the escape interval counters.

Alternatively, circuitry for controlling the timing and generation of anti-tachycardia pacing pulses as described in U.S. Pat. No. 4,577,633, issued to Berkovits et al., U.S. Pat. No. 4,880,005, issued to Pless et al., U.S. Pat. No. 4,726,380, issued to Vollmann et al. and U.S. Pat. No. 4,587,970, issued to Holley et al., may also be employed.

In the event that generation of a cardioversion or defibrillation pulse is required, microprocessor 51 may employ an escape interval counter to control timing of such

cardioversion and defibrillation pulses, as well as associated refractory periods. In response to the detection of atrial or ventricular fibrillation or tachyarrhythmia requiring a cardioversion pulse, microprocessor 51 activates cardioversion/defibrillation control circuitry 29, which initiates charging of the high voltage capacitors 33 and 35 via charging circuit 69, under the control of high voltage charging control line 71. The voltage on the high voltage capacitors is monitored via VCAP line 73, which is passed through multiplexer 55 and, in response to reaching a predetermined value set by microprocessor 51, results in generation of a logic signal on Cap Full (CF) line 77 to terminate charging. Thereafter, timing of the delivery of the defibrillation or cardioversion pulse is controlled by pacer timing/control circuitry 63. Following delivery of the fibrillation or tachycardia therapy, microprocessor 51 returns the device to a cardiac pacing mode and awaits the next successive interrupt due to pacing or the occurrence of a sensed atrial or ventricular depolarization.

Several embodiments of appropriate systems for the delivery and synchronization of ventricular cardioversion and defibrillation pulses and for controlling the timing functions related to them are disclosed in U.S. Patent No. 5,188,105 to Keimel, U.S. Pat. No. 5,269,298 to Adams et al. and U.S. Pat. No. 4,316,472 to Mirowski et al. However, any known cardioversion or defibrillation pulse control circuitry is believed to be usable in conjunction with various embodiments of the present invention. For example, circuitry controlling the timing and generation of cardioversion and defibrillation pulses such as that disclosed in U.S. Patent No. 4,384,585 to Zipes, U.S. Patent No. 4,949,719 to Pless et al., or U.S. Patent No. 4,375,817 to Engle et al., may also be employed.

Continuing to refer to Figure 5, delivery of cardioversion or defibrillation pulses is accomplished by output circuit 27 under the control of control circuitry 29 via control bus 31. Output circuit 27 determines whether a monophasic or biphasic pulse is delivered, the polarity of the electrodes and which electrodes are involved in delivery of the pulse. Output circuit 27 also includes high voltage switches which control whether electrodes are coupled together during delivery of the pulse. Alternatively, electrodes intended to be coupled together during the pulse may simply be permanently coupled to one another, either exterior to or interior of the device housing, and polarity may similarly be pre-set, as

in current implantable defibrillators. Examples of output circuitry for delivery of biphasic pulse regimens to multiple electrode systems may be found in U.S. Patent No. 4,953,551 to Mehra et al. and in U.S. Patent No. 4,727,877 to Kallock.

An example of circuitry which may be used to control delivery of monophasic pulses is disclosed in U.S. Patent No. 5,163,427 to Keimel. Output control circuitry similar to that disclosed in the above-cited patent issued to Mehra et al. or U.S. Patent No. 4,800,883 to Winstrom, may also be used in conjunction with various embodiments of the present invention to deliver biphasic pulses.

Figure 6 is a schematic representation of an implantable medical device (IMD) 114 that includes a four-channel cardiac pacemaker such as that described in U.S. Patent No. 6,070,101 to Struble et al. entitled "Multiple Channel, Sequential, Cardiac Pacing Systems," issued 30 May 2000. The inline connector 113 of a right atrial lead 116 is fitted into a bipolar bore of IMD connector block 112 and is coupled to a pair of electrically insulated conductors within lead body 115 that are connected with distal tip right atrial pace-sense electrode 119 and proximal ring right atrial pace-sense electrode 121. The distal end of the right atrial lead 116 is attached to the right atrial wall by a conventional attachment mechanism 117. Bipolar endocardial right ventricle lead 132 is passed through the vein into the right atrial chamber of the heart 8 and into the right ventricle where its distal ring and tip right ventricular pace-sense electrodes 138 and 140 are fixed in place in the apex by a conventional and distal attachment mechanism 141. The right ventricular lead 132 is formed with an inline connector 134 fitting into a bipolar bore of IMD connector block 112 that is coupled to a pair of electrically insulated conductors within lead body 136 and then connected with distal tip right ventricular pace-sense electrode 140 and proximal ring right ventricular pace-sense electrode 138.

In this particular illustrative embodiment, although other types of leads may be used, a quadripolar, endocardial left ventricular coronary sinus (CS) lead 152 is passed through a vein into the right atrial chamber of the heart 8, into the CS, and then inferiorly in the great vein to extend to the distal pair of left ventricular CS pace-sense electrodes 148 and 150 alongside the left ventricular chamber and leave the proximal pair of left atrial CS pace-sense electrodes 128 and 130 adjacent the left atrial chamber. The left

ventricular CS lead 152 is formed with a four-conductor lead body 156 coupled at the proximal end to a bifurcated inline connector 154 fitting into a pair of bipolar bores of IMD connector block 112. The four electrically insulated lead conductors in left ventricular CS lead body 156 are separately connected with one of the distal pair of left ventricular CS pace-sense electrodes 148 and 150 and the proximal pair of left atrial CS pace-sense electrodes 128 and 130.

The IMD 114 may comprise, for example, similar circuitry and connections as shown in Figure 3 for each of the multiple leads to establish the multiple pacing/sensing channels provided for each respective pair of pace-sense electrodes associated with each chamber of the heart as shown in Figure 6. For the sake of convenience, such circuitry is not described further. For example, channel circuitry for pacing/sensing the left atrial chamber is associated with pace-sense electrodes 128 and 130 adjacent the left atrium. One skilled in the art will recognize that each sensing/pacing channel may include a sense amplifier and pace output pulse generator coupled through the respective pacing/sensing lead. Although the pacing system shown in Figure 6, shall not be described in detail for simplicity purposes, it will be recognized that multiple chambers may be paced/sensed via respective channels for such chambers. As such, for example, bi-atrial and/or bi-ventricular pacing may be performed as would be readily apparent to one skilled in the art.

With various embodiments of medical devices, e.g., implantable medical devices, described above, it will become apparent from the description below that the present invention may be applied to any ventricular pacing system, e.g., dual chamber pacing system. For example, the present invention may be applied to a three-chamber atrial-bi-ventricular pacing apparatus, a dual chamber pacing apparatus, a dual chamber defibrillator, etc. In other words, for example, the present invention may be applied to any implantable medical device that provides bi-ventricular pacing. For example, some devices that may be modified to include the ventricular safety pacing techniques according to the present invention may include, for example, the InSync-ICD (e.g., Medtronic InSync ICD (Model 7272)), or InSync III three chamber atrial-bi-ventricular pacers; all VDD(R)/DDD(R) pacemakers including dual chamber right atrial/left ventricular pacers; Jewel DR DDD(R)-ICD; dual chamber (right atrial/left ventricular) defibrillators; three

chamber DDD(R)-ICD pacing devices available from Medtronic Inc.; and other devices such as the Medtronic InSync Model 8040.

Figures 8 and 9 shall be used to describe VSP according to the present invention. Figures 8A and 9A show a timing diagram and a VSP flow diagram for use in describing VSP when only sensing on one ventricular channel at one side of a patient's heart. In this embodiment, VSP pacing is only provided using the lead on the ventricular side where ventricular sensing occurs (e.g., right ventricular safety pacing only on the right ventricular side when sensing using the right ventricular channel).

Alternatively, Figures 8B and 9B show a timing diagram and VSP flow diagram for use in describing VSP when both ventricular channels are used for sensing ventricular events at both sides of a patient's heart (e.g., sensing of ventricular events where both ventricular lead electrodes are used for sensing). In this embodiment, VSP pacing is provided based on the first ventricular event sensed within the VSP window using a first ventricular channel. A sensing parameter modification process is used to reduce the likelihood of sensing the ventricular event using the second ventricular channel for a predetermined time period following the sensing of the ventricular event by the first ventricular channel. As such, VSP pacing is based on ventricular sensing by a first lead that is closest to the occurrence of the event, e.g., a left side PVC is recognized first by the left ventricular sensing channel and any VSP pacing is based thereon.

Generally, Figure 8A shows a timing diagram 200 that is illustrative of the ventricular safety pacing (VSP) features according to the present invention. Such features shall be described with respect to a bi-ventricular pacing and sensing system operating with only a single ventricular channel sensing ventricular events, e.g., using only one of two leads implanted for generating bi-ventricular pacing pulses. However, one skilled in the art will readily recognize that other modes and systems may utilize the present invention as described herein, e.g., combination devices such as an ICD in combination with an atrially triggered bi-ventricular pacer.

Delivery of ventricular pacing is ensured according to the present invention without such pacing being inhibited by false ventricular sensing, e.g., sensing of cross-talk, post atrial pacing ringing, etc. Such ensured delivery of ventricular pacing is

accomplished through use of a VSP window 204 as shown in timing diagram 200 of Figure 8A. Further, problems that may occur in certain circumstances, e.g., those associated with atrially triggered bi-ventricular pacing where ventricular sensing is only performed using one ventricular electrode at one ventricular side of a patient's hearts (e.g., a right ventricular electrode), are alleviated. In other words, such problems, e.g., safety pacing late in a refractory period, are addressed.

As described below in the various embodiments, ventricular safety pacing techniques are described following the occurrence of an atrial pace. However, as described in U.S. Patent Application Serial No. 09/842,884, "entitled Committed Ventricular Safety Pacing," such ventricular safety pacing may also be used in conjunction with or following the sensing of an atrial event. For simplicity, the remainder of the description shall be provided with respect to paced atrial events that generally initiate a paced AV interval. However, substantially similar techniques may be applicable with respect to sensed atrial events initiating a sensed AV interval.

Generally, the paced AV delay is somewhat longer than the sensed AV delay (e.g., about 50 milliseconds longer). The PAV delay is usually longer than SAV delay because there is a time period between delivery of pacing stimulus to the atrium and the onset (i.e., lag time) of the atrial depolarization (i.e., P-wave) which is absent when an atrial event is sensed. In sensed atrial events, the stimulus has already been delivered, and only the resulting P-wave depolarization signal is seen. This lag time is typically about 30-50 milliseconds.

Although the present method is primarily described relative to VSP following the occurrence of atrial paced events, it will be recognized that the present invention may be used following the occurrence of atrial paced and/or sensed events. In other words, a VSP feature may be turned on, programmed on, or enabled for just atrial paced events; a VSP feature may be turned on, programmed on, or enabled for just atrial sensed events; or a VSP feature may be turned on for both atrial paced and sensed events.

Further, as will be understood to one skilled in the art, the timing of delivering various pacing pulses at various times in conjunction with VSP features may vary, and the present invention is not to be taken as limited to the particular illustrative examples

provided below. For example, as described in U.S. Patent Application Serial No. 09/842,884, entitled Committed Ventricular Safety Pacing," delays in providing various pacing may be advantageous in certain circumstances. One example of such a delay that may be used is delaying the delivery of a VSP pulse until the expiration of a PAV interval when a ventricular event is sensed in the VSP window and the PAV is longer than the VSP window. Various other timing features as described therein and elsewhere may be incorporated with the VSP techniques described herein, e.g., incorporated with the delivery of VSP pacing only on the side where sensing of ventricular events is being performed.

As shown in Figure 8A, following an atrial paced event 201, a ventricular blanking period 210 occurs. This blanking period is a very brief interval initiated by the atrial paced event 201 during which ventricular sensing cannot occur. Typically, an atrial stimulus disables ventricular sensing for a 25-35 millisecond period to prevent inadvertent sensing of the atrial stimulus by a ventricular channel, thereby preventing inappropriate inhibition of delivery of ventricular stimulus. If a blanking period 210 was not used, cross-talk between the atrial and ventricular channels might lead to the undesirable inhibition of the delivery of ventricular stimulus by the pacemaker.

The blanking period 210 falls within the AV interval, e.g., paced AV (PAV) interval 202 (e.g., could also be a sensed AV (SAV) interval if the ventricular safety pacing is used with sensed atrial events). The AV interval is the interval between an atrial paced event 201 and delivery of a ventricular stimulus. For example, following an atrial paced event 201 is a PAV interval 202 extending from the atrial paced event 201 to delivery of a ventricular stimulus.

In general, the PAV interval 202 is a programmed time delay between the paced atrial event 201and when delivery of ventricular stimulus (i.e., stimulus 209 when PAV interval is shorter than the VSP window 204 and stimulus 211 for when PAV longer than the VSP window 204) is to occur thereafter (if no intrinsic ventricular activity is sensed). As such, as used hereinafter, the PAV delay represents the programmed AV interval initiated by an atrial paced event 201, respectively, and such terms "AV interval" and "AV delay" are used interchangeably herein.

If the atrium is paced, such an atrial beat will start a programmed PAV delay. For example, a programmed PAV interval, e.g., a software interval, may be initiated. One will recognize that various hardware and software may be used to implement the various timing intervals of the present invention. For example, the circuitry shown in Figure 3 may be used to implement the present invention, e.g., the processing circuitry and timing circuitry. In the case of using ventricular safety pacing with sensed atrial events, a sensed atrial event or beat, i.e., a P-wave, will start a programmed SAV delay. For example, if such depolarization of the atrium is sensed, then a SAV timer is started.

When VSP according to the present invention is turned on, programmed on, or, in other words, when this particular VSP feature is enabled, then a VSP window 204 is defined during at least an initial portion of a paced AV delay 202. The VSP window 204 is the time period, e.g., 0 to 110 milliseconds, preferably 70 milliseconds to 110 milliseconds, of the AV interval, e.g., PAV delay, during which if sensed ventricular events or activity are detected, delivery of ventricular stimulus is committed upon the expiration of the PAV delay or the ventricular safety pacing window 204, whichever is less. In other words, the VSP window 204 is defined such that upon ventricular sensing during the VSP window 204, VSP pacing at the termination of the PAV delay or ventricular safety pacing window occurs irrespective of any other signals sensed during the PAV delay.

As shown in Figure 8A, the AV interval 202, e.g., the PAV delay, may be less or greater than the VSP window. When the PAV delay 202 is less than the VSP window 204, then if ventricular events are sensed in the ventricular safety pacing window 204, delivery of ventricular stimulus 211 is committed upon the expiration of the PAV delay prior to the expiration of the VSP window 204. Likewise, when the PAV delay 202 is longer than the ventricular safety pacing window 204, then if ventricular events are sensed in the VSP window 204, delivery of ventricular stimulus is committed upon the termination of the PAV after expiration of the VSP window 204.

In other words, VSP window 204 is defined during at least an initial portion of the PAV delay 202 with a remainder portion 213 subsequent to the VSP window 203 if the PAV is longer than the VSP window. Therefore, for example, the PAV programmed

delay or interval 202 can be looked at as including an initial time period, e.g., 0-110 milliseconds, corresponding to the VSP window 204 and a remainder time period 213 before delivery of the ventricular stimulus 209 (assuming no intrinsic events are sensed in the remainder time period 213). For example, if the PAV delay 202 is programmed to 150 milliseconds, then the first 110 milliseconds may be the VSP window 204, and an additional 40 milliseconds will be the remainder portion 213 that follows the VSP window 204 prior to termination of the PAV programmed delay 202.

Preferably, VSP window 204 is 110 milliseconds. Generally, the PAV delay 202 is optimized and programmed on a patient by patient basis. Such values are set to provide optimized hemodynamic pacing delivery each individual patient. For example, an anticipated range in most patients for optimized PAV delays is about PAV 100-180 milliseconds.

As shown in Figure 8A, preferably the VSP window 204 is defined at a fixed interval for an AV delay 202. Further, as indicated above, the VSP window has a length between 70 and 110 milliseconds as, generally, any signal sensed on the ventricular channel within 110 milliseconds of any atrial event, cannot be a truly conducted intrinsic ventricular beat because such an intrinsic ventricular event would take significantly longer to occur. Therefore, this sensed signal during such an interval must be a false signal. Such a signal sensed during this time period may be, for example, post atrial ringing, EMI, PVC, etc. As a pacemaker cannot discriminate whether it is a false or intrinsic ventricular signal, ventricular inhibition based on an early (e.g., 0 to 110 millisecond) signal from any uncertain source must be prevented at all times.

Therefore, according to the present invention, if any ventricular sensing occurs at all in the VSP window 204, then a ventricular stimulus is always committed for delivery (e.g., at the termination of the PAV delay or VSP window, whichever is less), irrespective of any further sensing which might occur at a later time, e.g., in the remainder of the PAV delay if the PAV delay is longer than the VSP window. In other words, if a false signal, e.g., EMI, is sensed in the VSP window 204, then this same signal may be sensed in a later period. Such a later false sensing signal cannot be allowed to lead to ventricular pacing

inhibition. With use of committed pacing following a sensed event in the VSP window 204 as described above, inhibition based on such a false signal is prevented.

According to the present invention, use of committed pacing following a sensed event in the VSP window 204 as described above is only with respect to the ventricular side of the patient's heart at which ventricular sensing is being performing. In other words, if the ventricular sensing channel for the right side of the heart is being used (e.g., programmed on), then if a ventricular event is sensed within the VSP window, then pacing is only committed to the right ventricular side of the patient's heart. Such limited VSP pacing prohibits the problems described in the Background the Invention section herein. In other words, for example, problems that may arise from a PVC occurring in the left side of the patient's heart, but which is not sensed by the right ventricular channel until later due to conduction delays.

Figures 9A shows an illustrative flow diagram of a VSP method 320 wherein ventricular sensing is performed at only one ventricular side of a patient's heart (e.g., using a ventricular lead electrode provided in proximity thereto). As shown therein, upon the occurrence of an atrial paced event (block 322), a PAV delay 202 is initiated (block 324). In addition, as shown in block 326, a VSP window 204 is defined (e.g., during at least an initial portion of the PAV delay 202 which refers to a window that is defined during a portion or all of the PAV delay; even longer than the PAV delay).

During the PAV delay 202, sensing circuitry provides for the sensing of ventricular events (block 228). In this particular embodiment described with reference to Figure 8A, ventricular activity or ventricular sensed events 206 (which may be false sense events resulting from cross talk, lead dislodgement, etc.) are sensed during VSP window 204 at only one ventricular side of the patient's heart via a ventricular lead implanted, for example, as described previously herein (i.e., via one ventricular sensing channel). Such events are sensed based on predetermined/programmed set thresholds, e.g., an event is sensed if above a certain noise threshold).

In other words, sensing is only performed using one ventricular electrode (e.g., the right ventricular electrode) and not both ventricular leads even if available for bi-ventricular pacing. For example, in various device configurations, only one ventricular

lead is used for the sensing function (e.g., in atrially triggered bi-ventricular pacing, ventricular sensing may only be performed using the right ventricular lead).

As one ventricular side of the patient's heart is being monitored for ventricular events, if ventricular events are detected during VSP window 204 (block 330), such detected ventricular events initiate committed VSP (block 332). Once committed VSP is initiated (block 332), then upon expiration of PAV delay 202 or expiration of the VSP window 204, whichever is less, (block 342) a VSP ventricular pace is delivered via the lead used for sensing the events (block 344). In other words, if sensing is performed only by the right ventricular electrode and a ventricular event is sensed during the VSP window 204, then safety pacing stimulus is provided only to the right ventricular side of the patient's heart.

If no ventricular events are sensed during the VSP window (block 330), monitoring is still performed to sense intrinsic activity when the PAV is longer than the VSP window (i.e., shown by the dashed line extension of PAV delay 202 in Figure 8A). As such, ventricular events may be sensed during the remainder portion 213 of the PAV interval (block 334).

When the PAV 202 is shorter than the VSP window 204 (i.e., as shown by the non-dashed PAV delay 202 in Figure 8A), if a sensed ventricular event is not detected during the VSP window 204, then ventricular stimulus is provided (block 340) upon expiration of the PAV delay 202 (block 338) using at least the lead used for the sensing function. Preferably, bi-ventricular stimulus is provided in such a case since non-intrinsic events were not detected.

If a ventricular event is sensed during the remainder portion of the PAV interval (block 334) when the PAV delay 202 is longer than the VSP window 204 and no ventricular events were detected during the VSP window 204, delivery of ventricular stimulus at the termination of the PAV delay 202 is inhibited (block 336). In such a circumstance, pacing is unnecessary as proper depolarization of the ventricle has occurred intrinsically. In other words, an intrinsic ventricular event controls heart activity. Such intrinsic activity controlling the heart is desirable.

If, however, a sensed ventricular event is not detected during the remainder (i.e., time portion 213) of the PAV interval 202 (block 334) and no ventricular events were detected during the VSP window 204, then ventricular stimulus is delivered (block 340) upon expiration of the PAV delay 202 (block 338) using at least the lead used for the sensing function. However, preferably, bi-ventricular stimulus is provided since non-intrinsic events were not detected.

In summary, and with reference to Figure 8A, preferably, bi-ventricular stimulus is delivered (e.g., to both ventricular sides of the patient's heart) upon expiration of the PAV delay 202 if no ventricular events are sensed during the VSP window 204 when PAV delay 202 is shorter than the VSP window 204. Further such bi-ventricular pacing is provided upon expiration of the PAV delay 202 if no ventricular events are sensed during the VSP window 204 and the remainder portion 213 when PAV delay 202 is longer than the VSP window 204.

However, if a ventricular event is sensed during the remainder portion 213 of the PAV interval 202 and no ventricular events were detected during the VSP window 204, delivery of ventricular stimulus at the termination of the PAV delay 202 is inhibited, e.g., intrinsic activity controls.

If ventricular activity or events 206 are sensed during the VSP window, these events commit the pacemaker to the delivery of (and do not inhibit delivery of) ventricular stimulus upon expiration of the PAV delay 202 or VSP window 204, whichever is less. Of course, according to the present invention, such committed ventricular pacing is only applied to the ventricular side of the patient's heart where ventricular sensing occurs.

Generally, Figure 8B shows an illustrative timing diagram 250 (similar to diagram 200 described with reference to Figure 8A) that is illustrative of the ventricular safety pacing (VSP) features according to the present invention. However, in this particular illustrative embodiment described with reference to Figure 8B, ventricular activity or ventricular sensed events (which may be false sense events resulting from cross talk, lead dislodgement, etc.) are sensed during at least the VSP window using both ventricular leads (i.e., via bi- ventricular sensing channels). In other words, sensing is performed using both ventricular electrodes (e.g., a right and left ventricular electrode).

VSP pacing as used in this illustrative embodiment with ventricular sensing being performed on both ventricular channels, VSP pacing will always be based on the ventricular sensed event or signal which first occurs on any one of the two ventricular leads as described below. In other words, the ventricular event will be sensed by the closest lead to where the event occurs, e.g., a left side PVC will be sensed first by the left ventricular lead. However, although sensing on both channels may alleviate the problems described above wherein only one ventricular sensing channel is used, such sensing on both ventricular channels for VSP has other associated problems in certain circumstances. For example, in ICDs such sensing may impact the possibility of properly sensing arrhythmias due to the double counting (i.e., sensing) of the same ventricular event by both ventricular leads. To overcome this problem, certain modifications to parameters of the system are required. As used herein, such modification may be implemented in software, hardware, or in any manner to provide the benefits described herein, e.g., reduce the likelihood of sensing via both channels the same ventricular event that resulted in committing to the delivery of VSP paces.

As shown in Figure 8B, following an atrial paced event 251, a ventricular blanking period 260 occurs. This blanking period is a very brief interval initiated by the atrial paced event 251 such as described previously herein with reference to Figure 8A.

The blanking period 260 falls within an AV interval, e.g., paced AV (PAV) interval 252 (e.g., could also be a sensed AV (SAV) interval if the ventricular safety pacing is used with sensed atrial events) also as previously described above. In general, the PAV interval 252 is a programmed time delay between the paced atrial event 251and when delivery of ventricular stimulus is to occur thereafter (if no intrinsic ventricular activity is sensed). For example, following an atrial paced event 251 is a PAV interval 252 extending from the atrial paced event 251 to delivery of a ventricular stimulus 257, 259 (depending on the length of the PAV interval 252). When the atrium is paced, as described previously herein, such an atrial beat will start a programmed PAV delay. For example, a programmed PAV interval, e.g., a software interval, may be initiated.

When VSP according to the present invention is turned on, programmed on, or, in other words, when this particular VSP feature is enabled, then a VSP window 254 is

defined during at least an initial portion of a paced AV delay 252. The VSP window 254 is the time period, e.g., 0 to 110 milliseconds, preferably the first 70 to 110 milliseconds, of the AV interval 252 during which if sensed ventricular events or activity are detected, delivery of ventricular stimulus is committed upon the expiration of the PAV delay 252 or the ventricular safety pacing window 254, whichever is less. In other words, the VSP window 254 is defined such that upon ventricular sensing during the VSP window 254, VSP pacing at the termination of the PAV delay or ventricular safety pacing window occurs irrespective of any other signals sensed during the PAV delay.

As shown in Figure 8B, the AV interval, e.g., the PAV delay 252, may be less or greater than the VSP window 254 as shown by the dashed lined portion of PAV delay 252. When the PAV delay 252 is less than the VSP window 254, then if ventricular events are sensed in the ventricular safety pacing window 254, the delivery of ventricular stimulus 257 is committed upon the expiration of the PAV delay 252 prior to the expiration of the VSP window 254. Likewise, when the PAV delay 252 is longer than the ventricular safety pacing window 254, then if ventricular events are sensed in the VSP window 254, delivery of ventricular stimulus 258 is committed upon the expiration of the VSP window 204.

In other words, VSP window 254 is defined during at least an initial portion of the PAV delay 252 with a remainder portion 261 subsequent to the VSP window 254 if the PAV delay 252 is longer than the VSP window 254. Therefore, for example, the PAV programmed delay or interval 252 can be looked at as including an initial time period, e.g., 0-110 milliseconds, corresponding to the VSP window 254 and a remainder time period 261 before delivery of the ventricular stimulus 259 (assuming no intrinsic events are sensed in the remainder time period 261 and no ventricular events are sensed in the ventricular window 254). For example, if the PAV delay 252 is programmed to 150 milliseconds, then the first 110 milliseconds may be the VSP window 254, and an additional 40 milliseconds will be the remainder portion 261 that follows the VSP window 254 prior to termination of the PAV programmed delay 252. Preferred lengths of various time intervals have been described elsewhere herein.

As indicated above, any signal sensed on the ventricular channel within 110 milliseconds of any atrial event, cannot be a truly conducted intrinsic ventricular beat

because such an intrinsic ventricular event would take significantly longer to occur. Therefore, as previously described herein, this sensed signal during such an interval must be a false signal.

As such, according to the present invention, if any ventricular sensing occurs at all in the VSP window 254, then a ventricular stimulus is always committed at the termination of the PAV delay or VSP window, whichever is longer, irrespective of any further sensing which might occur at a later time, e.g., in the remainder of the PAV delay if the PAV delay is longer than the VSP window. In other words, if a false signal, e.g., EMI, is sensed in the VSP window 254, then this same signal may be sensed in a later period. Such a later false sensing signal cannot be allowed to lead to ventricular pacing inhibition. With use of committed pacing following a sensed event in the VSP window 254 as described above, inhibition based on such a false signal is prevented.

Figures 9B shows an illustrative flow diagram of a VSP method 450 wherein ventricular sensing is performed at both ventricular sides of a patient's heart (e.g., using both ventricular sensing channels operable with use of both ventricular leads). As shown therein, upon the occurrence of an atrial paced event (block 452), a PAV delay 252 is initiated (block 454). In addition, as shown in block 456, a VSP window 254 is defined (e.g., during at least an initial portion of the PAV delay 252).

During the PAV delay 252, sensing circuitry provides for the sensing of ventricular events at both ventricular sides of the patient's heart (block 458). As both sides of the heart are being monitored for ventricular events, if ventricular events are detected during VSP window 254 (block 460), such detected ventricular events initiate committed VSP (block 462). The first ventricular channel sensing the ventricular event in the VSP window 254 will initiate the committed VSP pulses. It is possible that such ventricular events would most likely be sensed by both ventricular sensing channels, e.g., using both leads, but at different times if parameter modification according to the present invention were not used as described herein. In other words, one sensing electrode would most likely sense the same ventricular event before the other.

Once committed VSP is initiated (block 462), then upon expiration of PAV delay 252 or VSP window 254, whichever is less (block 472), VSP ventricular paces are

delivered to at least one side of the heart via at least the lead which first sensed the ventricular event (block 474). Preferably, bi-ventricular safety paces are provided (e.g., safety paces are provided to both ventricular sides of the heart) upon expiration of PAV delay 252 or VSP window 254, whichever is less.

In other words, if sensing is performed using both right and left ventricular electrodes and a ventricular event is sensed during the VSP window 254 by the right ventricular lead prior to the event being sensed by the left ventricular lead, then VSP pacing stimulus is provided to at least the right ventricular side of the patient's heart via the right ventricular lead. However, preferably, bi-ventricular safety paces are provided (e.g., safety paces are provided to both ventricular sides of the heart).

If no ventricular events are sensed during the VSP window (block 460), monitoring is still performed to sense intrinsic activity when the PAV delay 252 is longer than the VSP window 254. As such, ventricular events may be sensed during the remainder portion 261 of the PAV interval (block 464).

When the PAV 252 is shorter than the VSP window 254, if a sensed ventricular event is not detected during the VSP window 254, then ventricular stimulus (e.g., preferably, bi-ventricular stimulus) is provided (block 470) upon expiration of the PAV delay 252 (block 468).

If a ventricular event is sensed during the remainder portion of the PAV interval (block 464) when the PAV delay 252 is longer than the VSP window 254 and no ventricular events were detected during the VSP window 254, delivery of ventricular stimulus at the termination of the PAV delay 252 is inhibited (block 466). In such a circumstance, pacing is unnecessary as proper depolarization of the ventricle has occurred intrinsically. In other words, an intrinsic ventricular event controls heart activity. Such intrinsic activity controlling the heart is desirable.

If, however, a sensed ventricular event is not detected during the remainder (i.e., time portion 261) of the PAV interval (block 464) and no ventricular events were detected during the VSP window 254 then ventricular stimulus (e.g., preferably, bi-ventricular stimulus) is delivered (block 470) upon expiration of the PAV delay 252 (block 468).

In summary, and with reference to Figure 8B, preferably, bi-ventricular stimulus is delivered (e.g., to both ventricular sides of the patient's heart) upon expiration of the PAV delay 252 if no ventricular events are sensed during the VSP window 254 when PAV delay 252 is shorter than the VSP window 254. Further such bi-ventricular pacing is provided upon expiration of the PAV delay 252 if no ventricular events are sensed during the VSP window 254 and the remainder portion 261 when PAV delay 252 is longer than the VSP window 254.

However, if a ventricular event 270 is sensed during the remainder portion 261 of the PAV interval 252 and no ventricular events were detected during the VSP window 254, delivery of ventricular stimulus at the termination of the PAV delay 252 is inhibited, e.g., intrinsic activity controls.

If ventricular activity or event 270 is sensed during the VSP window by a first lead electrode (e.g., a threshold level is met indicating an event to be sensed), these events commit the pacemaker to the delivery of (and do not inhibit delivery of) ventricular stimulus upon expiration of the PAV delay 252 or VSP window, whichever is less. According to the present invention, such committed ventricular pacing is at least applied to the ventricular side of the patient's heart where ventricular sensing first sensed the VSP committing event. However, bi-ventricular VSP paces may also be delivered.

As described above, even when VSP pacing is used in this illustrative embodiment wherein sensing is performed on both ventricular channels, other associated problems may occur, e.g., double sensing of same events. To overcome such problems, certain modifications to sensing parameters of the system are required. As shown in Figure 8B and Figure 9B, such modifications may reduce the likelihood of sensing via both channels the same ventricular event that resulted in committing to the delivery of VSP paces.

As shown in Figures 8B and 9B, if ventricular activity or event 270 is sensed during the VSP window by a first lead electrode (e.g., a threshold level is met indicating an event to be sensed), these events commit the pacer to the delivery of (and do not inhibit delivery of) ventricular stimulus upon expiration of the PAV delay 252 or VSP window 254, whichever is less. At substantially the same time as committed ventricular pacing therapy is initiated (block 462), modifications to one or more sensing parameters are made

to reduce the likelihood of sensing the same ventricular event on the second ventricular lead, e.g., not allowing recognition of the same event even if signals indicating such an event is present at the second ventricular lead.

Various modifications may be used to prevent such duplicative recognition of the same event. For example, as shown in Figure 8B, a blanking interval 282 may be used to prevent sensing on the second lead for a certain predetermined period of time. For example, such a period may be as long as 150 milliseconds to 200 milliseconds depending on the device or application. The blanking period is preferably initiated immediately after sensing of the ventricular event is sensed using the first lead electrode.

Further, for example, a threshold adjustment period 284 may be set for a predetermined period of time. During this period a threshold used for sensing events on the second lead may be adjusted such that there is a reduced likelihood that events will be sensed.

Yet further, for example, as shown by the blanking period 286 and the threshold adjustment period 288, the modifications described above may be used in combination. For example, one may follow the other with shorter time periods for each. As will be recognized, other modifications may also be used to prevent such duplicative recognition of the same event.

Figures 10A and 10B provide two illustrative examples of VSP. A single ventricular lead sensing embodiment wherein ventricular sensing is only performed on one side of the heart is shown in Figure 10A. VSP for an embodiment wherein sensing is performed on both sides of the heart using both right and left ventricular leads is shown in Figure 10B.

Figure 10A shows a PAV delay 602 of 120 milliseconds initiated upon the occurrence of an atrial paced event 606. Also upon occurrence of the atrial sensed event 606, VSP window 604 of 110 milliseconds is defined. A ventricular event 608 is sensed during the VSP window 604 by a right ventricular electrode. As such, this sensed ventricular event 608 commits the pacing apparatus to deliver a VSP pulse 610 at the termination 612 of the VSP window 604 only to the right ventricular lead for stimulation of the right ventricular side of the heart.

Figure 10B, shows a PAV delay 654 of 150 milliseconds initiated upon the occurrence of an atrial paced event 652. Also upon occurrence of the atrial paced event 652, VSP window 656 of 110 milliseconds is defined. A ventricular event 658 is sensed first by the right ventricular electrode and immediately thereafter could have been sensed by the left ventricular electrode during the VSP window 656. This sensed ventricular event 658 commits the pacing apparatus to deliver at least VSP pulse 660 via the right ventricular electrode to the right side of the heart at the termination 662 of the VSP window 656 (although bi-ventricular pulses may be provided in this embodiment where sensing is performed on both ventricular sides). At the same time as commitment to deliver the VSP pulse 660, a blanking interval 680 is provided to prevent duplicative recognition by the left ventricular lead.

All patents and references cited herein are incorporated in their entirety as if each were incorporated separately. This invention has been described with reference to illustrative embodiments and is not meant to be construed in a limiting sense. As described previously, one skilled in the art will recognize that various illustrative applications including, but not limited to, pacing devices, ICD devices, etc., may utilize the VSP techniques described herein. Various modifications of the illustrative embodiments, as well as additional embodiments of the invention, will be apparent to persons skilled in the art upon reference to this description.

In the claims, means-plus-function clauses are intended to cover the structures described herein as performing the recited function and not only structural equivalents but also equivalent structures. Thus, although a nail and a screw may not be structural equivalents in that a nail employs a cylindrical surface to secure wooden parts together, whereas a screw employs a helical surface, in the environment of fastening wooden parts a nail and a screw are equivalent structures.

What is claimed is:

1. A method of pacing for use in a medical device, the method comprising:

providing a paced AV delay following an atrial paced event, wherein the paced AV delay is a predetermined time period initiated by the atrial paced event;

defining a ventricular safety pacing window during at least an initial portion of the paced AV delay, wherein the paced AV delay further comprises a remainder period if the paced AV delay is longer than the ventricular safety pacing window;

sensing ventricular events at only one ventricular side of a patient's heart;

delivering ventricular stimulus to the at least one ventricular side of the patient's heart upon expiration of the paced AV delay if no ventricular events are sensed during the ventricular safety pacing window defined during at least the initial portion of the paced AV delay and the remainder portion of the paced AV delay;

inhibiting the delivery of ventricular stimulus upon expiration of the paced AV delay if no ventricular events are sensed during the ventricular safety pacing window but a ventricular event is sensed during the remainder portion of the paced AV delay; and

if a ventricular event is sensed during the ventricular safety pacing window, committing to delivery of ventricular stimulus upon expiration of the ventricular safety pacing window or the paced AV delay, which ever is shorter, only to the one ventricular side of the patient's heart where ventricular events are sensed.

2. The method of claim 1, wherein the paced AV delay is 100 milliseconds to 180 milliseconds.

3. The method of claim 1, wherein the ventricular safety pacing window is in the range of about 70 milliseconds to 110 milliseconds.

4. The method of claim 1, wherein delivering ventricular stimulus to at least one ventricle upon expiration of the paced AV delay or ventricular safety pacing window, whichever is less, if no ventricular events are sensed during the ventricular safety pacing

window defined during the initial portion of the paced AV delay and the remainder portion of paced AV delay comprises delivering bi-ventricular stimulus.

5. The method of claim 1, wherein the medical device is an implantable medical device.

6. The method of claim 5, wherein the implantable medical device includes an implantable medical device selected from one of a pacemaker, a defibrillator, a pacemaker/cardioverter/defibrillator, and a cardioverter/defibrillator.

7. The method of claim 1, wherein sensing ventricular events at only one ventricular side of a patient's heart comprises sensing ventricular events at only the right ventricular side of the patient's heart during the ventricular safety pacing window.

8. The method of claim 7, wherein the medical device is an implantable medical device, and further wherein the implantable medical device comprises an implantable cardioverter/defibrillator.

9. A method of pacing for use in a medical device, the method comprising:

providing an AV delay initiated by occurance of either an atrial sensed event or an atrial paced event, wherein the AV delay is a programmed time period;

defining a ventricular safety pacing window during at least an initial portion of the AV delay;

sensing ventricular events at only one ventricular side of a patient's heart during at least the ventricular safety pacing window; and

if a ventricular event is sensed during the ventricular safety pacing window, then committing to delivery of ventricular stimulus only to the one ventricular side of the patient's heart where the ventricular event is sensed.

10. The method of claim 9, delivering ventricular stimulus to both ventricular sides of the patient's heart if no ventricular events are sensed during the AV delay or the ventricular safety pacing window.

11. The method of claim 9, wherein the method further comprises inhibiting delivery of ventricular stimulus upon expiration of the paced AV delay if a ventricular event is not sensed during the ventricular safety pacing window but a ventricular event is sensed during a subsequent portion of the AV interval following the ventricular safety pacing window.

12. The method of claim 9, wherein the ventricular safety pacing window is in a range of about 70 milliseconds to 110 milliseconds.

13. The method of claim 9, wherein if the ventricular event is sensed during the ventricular safety pacing window, then committing to delivery of ventricular stimulus upon expiration of the ventricular safety pacing window or the paced AV delay, which ever is less, only to the one ventricular side of the patient's heart where the ventricular event is sensed.

14. The method of claim 9, wherein the medical device is an implantable medical device.

15. The method of claim 14, wherein the implantable medical device comprises an implantable medical device selected from one of a pacemaker, a defibrillator, a pacemaker/cardioverter/defibrillator, and a cardioverter/defibrillator.

16. The method of claim 9, wherein sensing ventricular events at only one ventricular side of a patient's heart during at least the ventricular safety pacing window comprises sensing ventricular events at only the right ventricular side of a patient's heart during at least the ventricular safety pacing window.

17. The method of claim 16, wherein the medical device is an implantable medical device, and further wherein the implantable medical device comprises an implantable cardioverter/defibrillator.

18. A method of pacing for use in a medical device, the method comprising:

providing an AV delay initiated by occurrence of either an atrial sensed event or an atrial paced event, wherein the AV delay is a programmed time period;

defining a ventricular safety pacing window during at least an initial portion of the AV delay;

sensing ventricular events at both ventricular sides of a patient's heart during at least the ventricular safety pacing window;

if a ventricular event is sensed during the ventricular safety pacing window at a first ventricular side of the patient's heart, then committing to the delivery of ventricular stimulus to at least the first ventricular side of the patient's heart; and

modifying at least one parameter associated with sensing at the second ventricular side of the patient's heart to reduce the likelihood of sensing ventricular events for a predetermined time period following the sensing of the ventricular event at the first side of the patient's heart.

19. The method of claim 18, wherein modifying at least one parameter associated with sensing at the second ventricular side of the patient's heart comprises providing a predetermined time period following the sensing of the ventricular event at the first side of the patient's heart during which sensed signals at the second ventricular side are not recognized.

20. The method of claim 18, wherein modifying at least one parameter associated with sensing at the second ventricular side of the patient's heart comprises adjusting a sensing threshold for sensing events at the second ventricular side during a period of time following the sensing of the ventricular event at the first side of the patient's heart.

21. The method of claim 18, wherein modifying at least one parameter associated with sensing at the second ventricular side of the patient's heart comprises providing a time period following the sensing of the ventricular event at the first side of the patient's heart during which sensed signals at the second ventricular side are not recognized and also thereafter, adjusting a sensing threshold for sensing events at the second ventricular side during another period of time.

22. The method of claim 18, wherein the method further comprises delivering ventricular stimulus to both ventricular sides of the patient's heart if no ventricular events are sensed during the ventricular safety pacing window or the AV delay.

23. The method of claim 18, wherein the method further comprises inhibiting delivery of ventricular stimulus upon expiration of the AV delay if a ventricular event is not sensed during the ventricular safety pacing window but a ventricular event is sensed during a subsequent portion of the AV delay following the ventricular safety pacing window.

24. The method of claim 18, wherein the ventricular safety pacing window is in the range of about 70 milliseconds to 110 milliseconds.

25. The method of claim 18, wherein if the ventricular event is sensed during the ventricular safety pacing window at a first ventricular side of the patient's heart, then committing to the delivery of ventricular stimulus to at least the first ventricular side of the patient's heart upon expiration of the ventricular safety pacing window or AV delay, whichever is less.

26. The method of claim 18, wherein the medical device is an implantable medical device.

27. The method of claim 26, wherein the implantable medical device comprises an implantable medical device selected from one of a pacemaker, a defibrillator, a pacemaker/cardioverter/defibrillator, and a cardioverter/defibrillator.

28. A dual chamber pacing apparatus, the apparatus comprising:

atrial pacing circuitry operable to at least generate atrial pacing pulses;

ventricular pacing and sensing circuitry operable to generate ventricular pacing pulses for stimulating at least one ventricular side of a patient's heart via at least one ventricular lead and for use in sensing ventricular events at only one ventricle side of the patient's heart via the at least one ventricular lead; and

control circuitry operable to:

provide a paced AV delay following an atrial paced event, wherein the paced AV delay is a predetermined time period initiated by the atrial paced event;

define a ventricular safety pacing window during at least an initial portion of the paced AV delay, wherein the paced AV delay further comprises a remainder portion if the paced AV delay is longer than the ventricular safety pacing window;

sense ventricular events at only one ventricle side of a patient's heart at least during the ventricular safety pacing window;

control delivery of ventricular stimulus using the ventricular pacing circuitry such that:

if no ventricular events are sensed during the ventricular safety pacing window defined during the initial portion of the paced AV delay and the remainder portion thereof, then ventricular stimulus is delivered to at least one ventricle upon expiration of the paced AV delay;

if no ventricular events are sensed during the ventricular safety pacing window but a ventricular event is sensed during the remainder portion of the paced AV delay, then inhibiting the delivery of ventricular stimulus upon expiration of the paced AV delay; and

if a ventricular event is sensed during the ventricular safety pacing window, committing to the delivery of a ventricular stimulus only to the ventricular side of the patient's heart where ventricular events are sensed.

29. The apparatus of claim 28, wherein the control circuitry is operable to commit to the delivery of a ventricular stimulus only to the ventricular side of the patient's heart where ventricular events are sensed upon expiration of the paced AV delay or the ventricular safety pacing window, whichever is less, if the ventricular event is sensed during the ventricular safety pacing window.

30. The apparatus of claim 28, wherein the ventricular safety pacing window is in the range of 70 milliseconds to 110 milliseconds.

31. The apparatus of claim 28, wherein if no ventricular events are sensed during the ventricular safety pacing window defined during the initial portion of the paced AV delay and any remainder portion thereof, then bi-ventricular stimulus is delivered.

32. The apparatus of claim 28, wherein the dual chamber apparatus comprises an implantable medical device selected from one of a pacemaker, a defibrillator, a pacemaker/cardioverter/defibrillator, and a cardioverter/defibrillator.

33. The apparatus of claim 27, wherein the ventricular pacing and sensing circuitry is operable to sense ventricular events at the right ventricular side of the patient's heart.

34. The apparatus of claim 33, wherein the dual chamber apparatus comprises an implantable cardioverter/defibrillator.

35. A dual chamber pacing apparatus, the apparatus comprising:

atrial pacing and sensing circuitry operable to at least generate atrial pacing pulses and sense atrial events;

ventricular pacing and sensing circuitry operable to generate ventricular pacing pulses for stimulating at least one ventricular side of a patient's heart via at least one ventricular lead and for use in sensing ventricular events at only one ventricular side of the patient's heart via the at least one ventricular lead; and

control circuitry operable to:

provide an AV delay initiated by occurrence of either an atrial sensed event or an atrial paced event, wherein the AV delay is a programmed time period;

define a ventricular safety pacing window during at least an initial portion of the AV delay;

sense ventricular events at only one ventricular side of the patient's heart during at least the ventricular safety pacing window; and

control delivery of ventricular stimulus such that if a ventricular event is sensed during the ventricular safety pacing window, then committing to the delivery of ventricular stimulus only to the one ventricular side of the patient's heart where ventricular events are sensed.

36. The apparatus of claim 35, wherein the control circuitry is operable to control delivery of ventricular stimulus such that if no ventricular events are sensed during the AV delay or the ventricular safety pacing window, then ventricular stimulus is delivered to both ventricular sides of the patient's heart.

37. The apparatus of claim 35, wherein control circuitry is operable to inhibit delivery of ventricular stimulus after expiration of the ventricular safety pacing window or the AV delay if a ventricular event is not sensed during the ventricular safety pacing window but a ventricular event is sensed during a subsequent portion of the AV interval following the ventricular safety pacing window.

38. The apparatus of claim 35, wherein the ventricular safety pacing window is in the range of 70 milliseconds to 110 milliseconds.

39. The apparatus of claim 35, wherein the control circuitry is operable to control delivery of ventricular stimulus such that if the ventricular event is sensed during the ventricular safety pacing window, then committing to the delivery of ventricular stimulus after expiration of the ventricular safety pacing window or the AV delay, whichever is less, only to the one ventricular side of the patient's heart where ventricular events are sensed.

40. The apparatus of claim 35, wherein the AV delay is less than the ventricular safety pacing window.

41. The apparatus of claim 35, wherein the dual chamber apparatus comprises an implantable medical device selected from one of a pacemaker, a defibrillator, a pacemaker/cardioverter/defibrillator, and a cardioverter/defibrillator.

42. The apparatus of claim 35, wherein the ventricular pacing and sensing circuitry is operable to sense ventricular events at only the right ventricular side of a patient' heart.

43. The apparatus of claim 42, wherein the dual chamber apparatus comprises an implantable cardioverter/defibrillator.

44. A dual chamber pacing apparatus, the apparatus comprising:

atrial pacing and sensing circuitry operable to generate atrial pacing pulses and sense atrial events;

ventricular pacing and sensing circuitry operable to generate ventricular pacing pulses for stimulating both ventricular sides of a patient's heart via one or more ventricular leads and for use in sensing ventricular events in both ventricular sides via the one or more ventricular leads; and

control circuitry operable to:

provide an AV delay initiated by occurrence of either an atrial sensed event or an atrial paced event, wherein the AV delay is a programmed time period;

define a ventricular safety pacing window during at least an initial portion of the AV delay;

sense ventricular events at both ventricular sides of the patient's heart during at least the ventricular safety pacing window;

control delivery of ventricular stimulus such that if a ventricular event is sensed during the ventricular safety pacing window at a first ventricular side of the patient's heart, then committing to delivery of ventricular stimulus to at least the first ventricular side of the patient's heart; and

modify at least one parameter associated with sensing at the second ventricular side of the patient's heart to reduce the likelihood of sensing ventricular events for a predetermined time period following the sensing of the ventricular event at the first side of the patient's heart.

45. The apparatus of claim 44, wherein the control circuitry operable to modify at least one parameter associated with sensing at the second ventricular side of the patient's heart comprises means for providing a predetermined time period following the sensing of the ventricular event at the first side of the patient's heart during which sensed signals at the second ventricular side are not recognized.

46. The apparatus of claim 44, wherein the control circuitry operable to modify at least one parameter associated with sensing at the second ventricular side of the patient's heart comprises means for adjusting a sensing threshold for sensing events at the second ventricular side during a period of time following the sensing of the ventricular event at the first side of the patient's heart.

47. The apparatus of claim 44, wherein the control circuitry operable to modify at least one parameter associated with sensing at the second ventricular side of the patient's heart comprises means for providing a time period following the sensing of the ventricular event at the first side of the patient's heart during which sensed signals at the second ventricular

side are not recognized and also means for adjusting a sensing threshold for sensing events at the second ventricular side during another period of time.

48. The apparatus of claim 44, wherein the control circuitry is operable to deliver ventricular stimulus to both ventricles if no ventricular events are sensed during the ventricular safety pacing window or the AV delay.

49. The apparatus of claim 44, wherein the control circuitry is operable to inhibit delivery of ventricular stimulus upon expiration of the AV delay if a ventricular event is not sensed during the ventricular safety pacing window but a ventricular event is sensed during a subsequent portion of the AV delay following the ventricular safety pacing window.

50. The apparatus of claim 44, wherein the ventricular safety pacing window is in the range of 70 milliseconds to 110 milliseconds.

51. The apparatus of claim 44, wherein the control circuitry is operable to control delivery of ventricular stimulus such that if the ventricular event is sensed during the ventricular safety pacing window at a first ventricular side of the patient's heart, then committing to delivery of ventricular stimulus to at least the first ventricular side of the patient's heart upon expiration of the ventricular safety pacing window or AV delay, whichever is longer.

52. The apparatus of claim 44, wherein the dual chamber apparatus comprises an implantable medical device selected from one of a pacemaker, a defibrillator, a pacemaker/cardioverter/defibrillator, and a cardioverter/defibrillator.

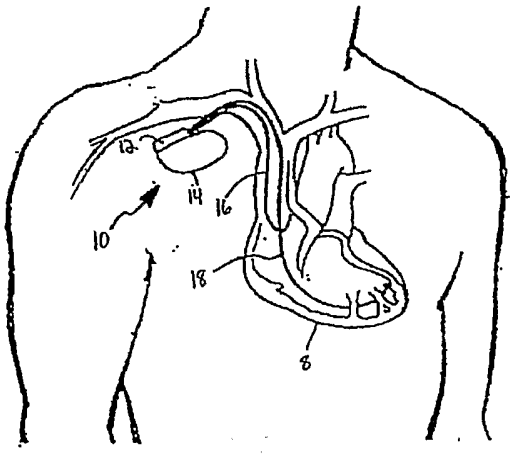

FIG . 1

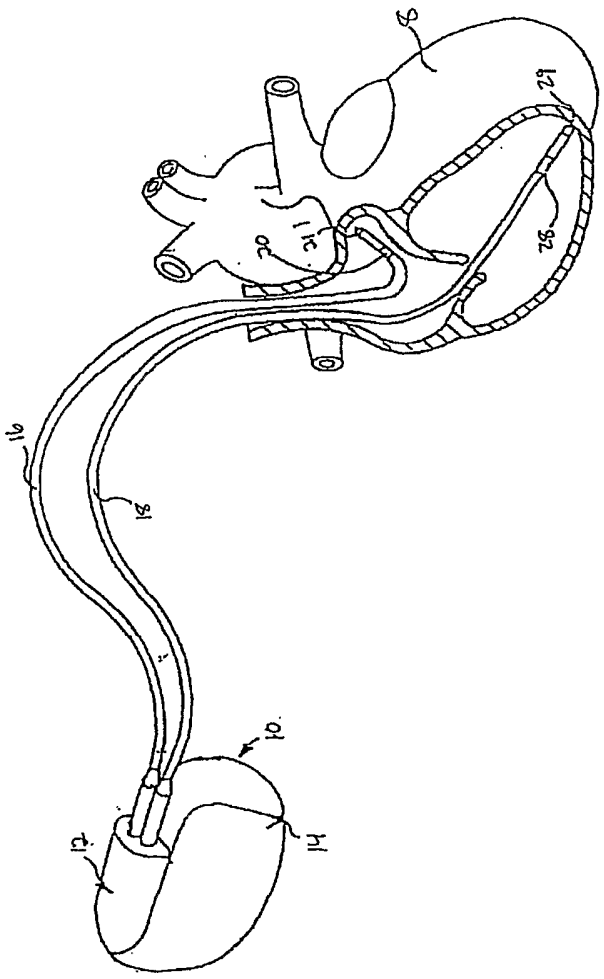

FIG. 2

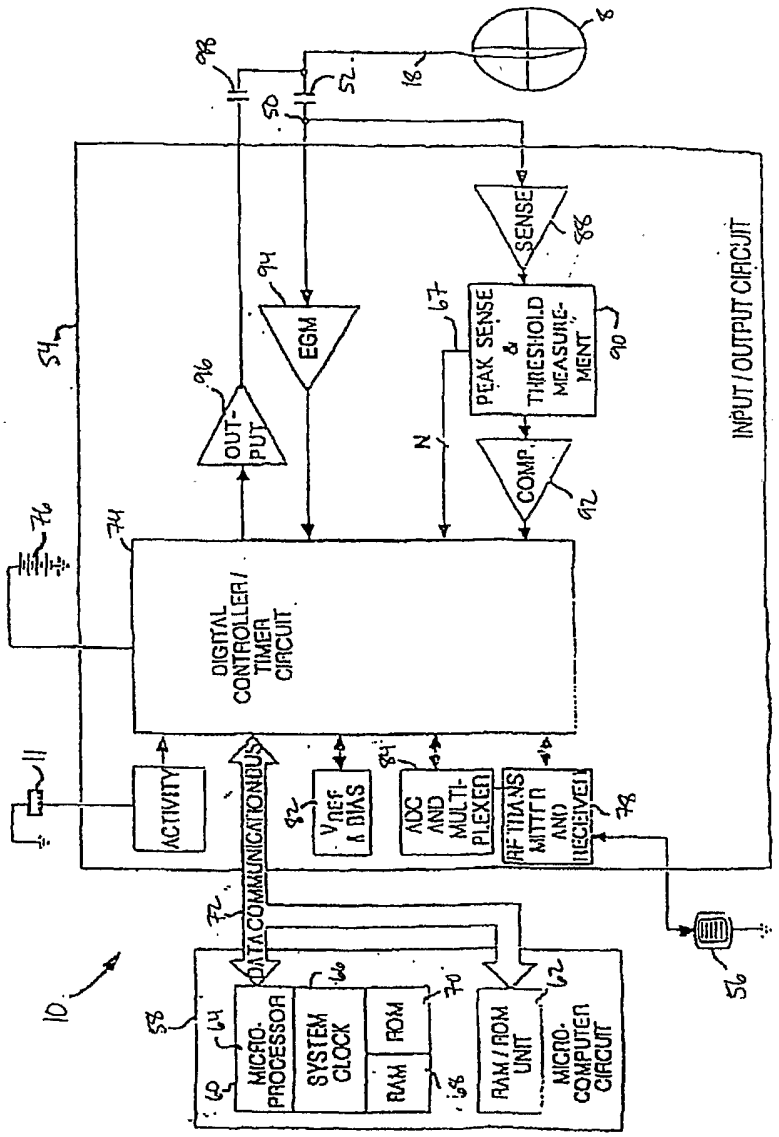
INPUT / OUTPUT CIRCUIT
SENSE
EGM
OUT-PUT
PEAK SENSE & THRESHOLD MEASURE-MENT
COMP.
DIGITAL CONTROLLER / TIMER CIRCUIT
ACTIVITY
V REF & BIAS
ADC AND MULTI-PLEXER
RF TRANS MITTER AND RECEIVER
DATA COMMUNICATIONS BUS
MICRO-PROCESSOR
SYSTEM CLOCK
ROM
RAM
RAM / ROM UNIT
MICRO-COMPUTER CIRCUIT

FIG. 3

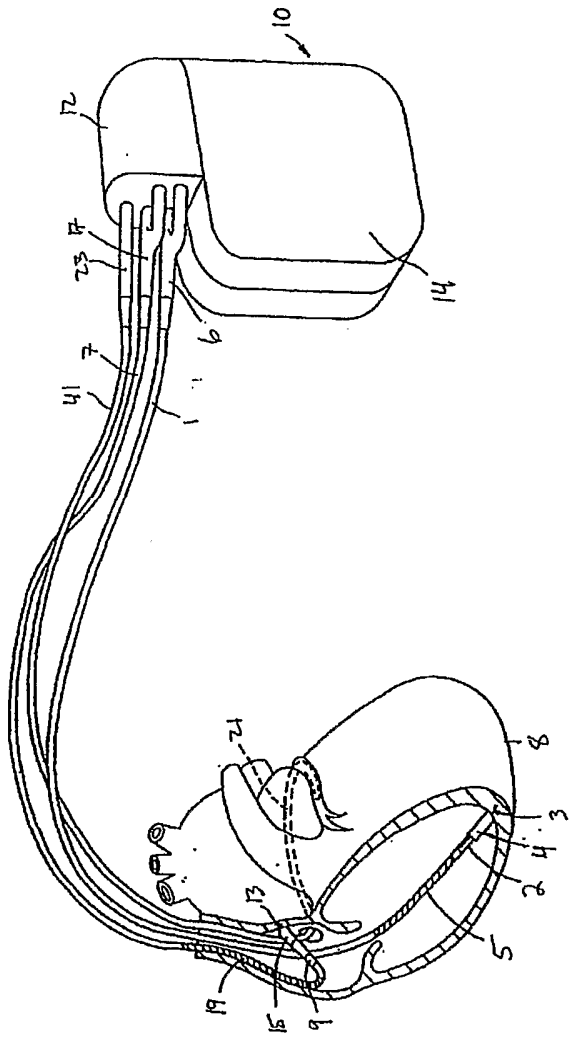

FIG.4

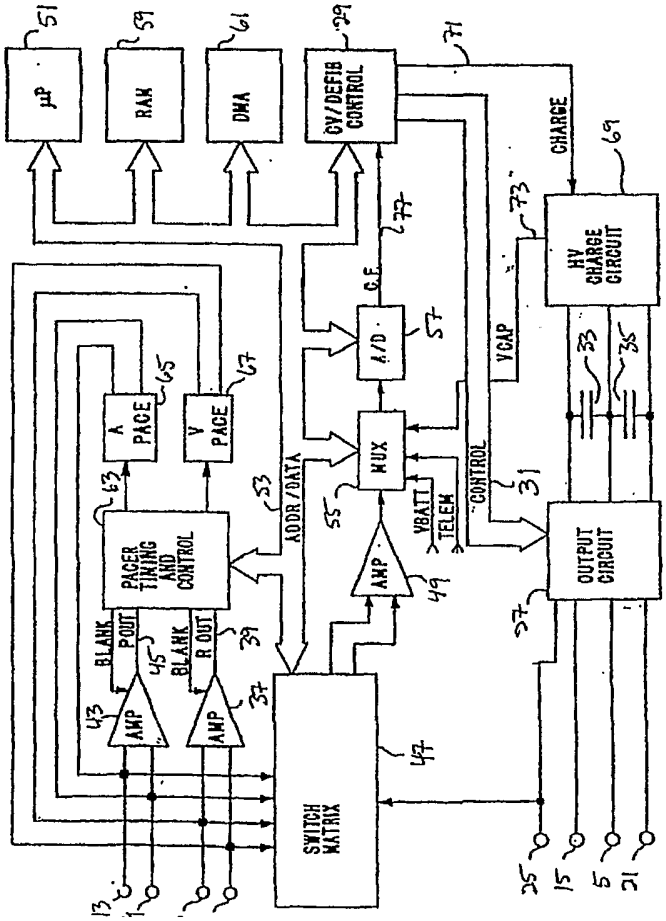
μP
RAM
DMA
CV/DEFIB CONTROL
CHARGE
HV CHARGE CIRCUIT
A/D
G.E.
MUX
VCAP
A PACE
V PACE
PACER TIMING AND CONTROL
ADDR/DATA
CONTROL
VBATT
TELEM
AMP
BLANK
P OUT
R OUT
OUTPUT CIRCUIT
SWITCH MATRIX

FIG.5

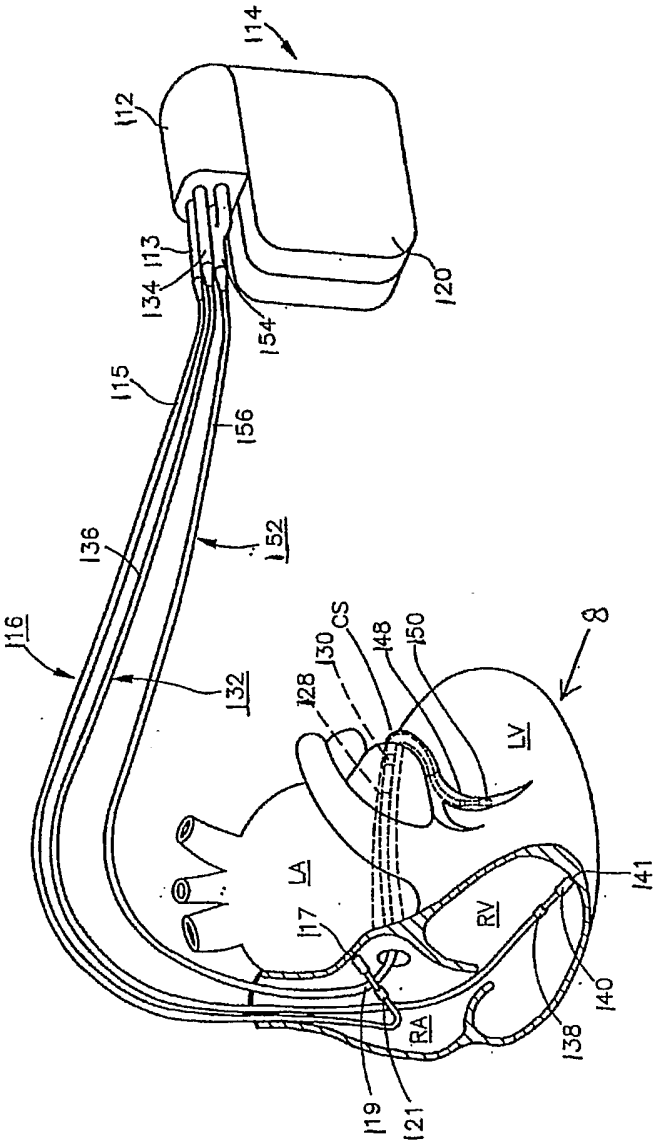
114
112
113
134
154
120
115
156
136
152
116
132
128
130
CS
148
150
8
LV
LA
117
RV
141
140
138
RA
119
121

FIG. 6

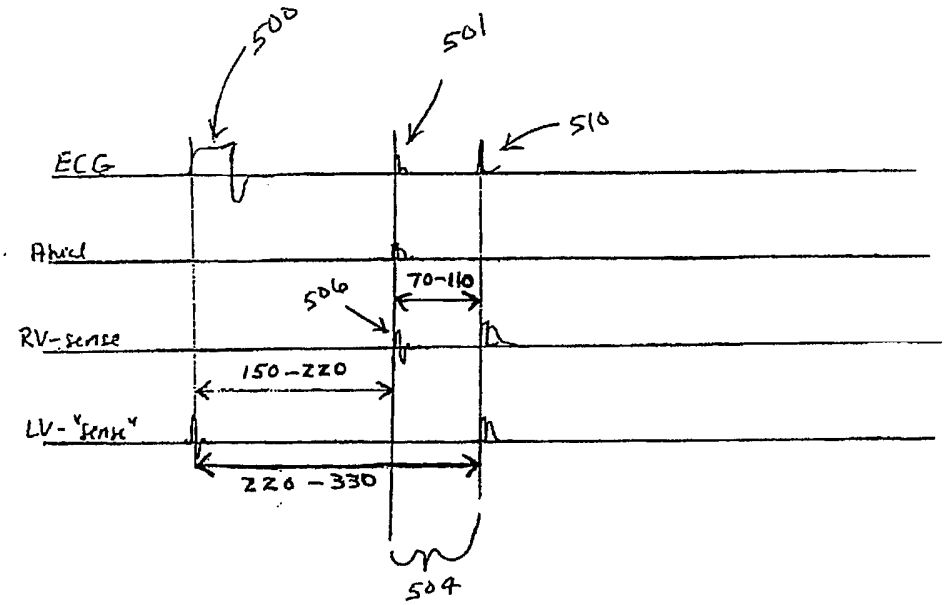
500
501
510
ECG
Atrial
70-110
506
RV-sense
150-220
LV-"sense"
220-330
504

FIG. 7

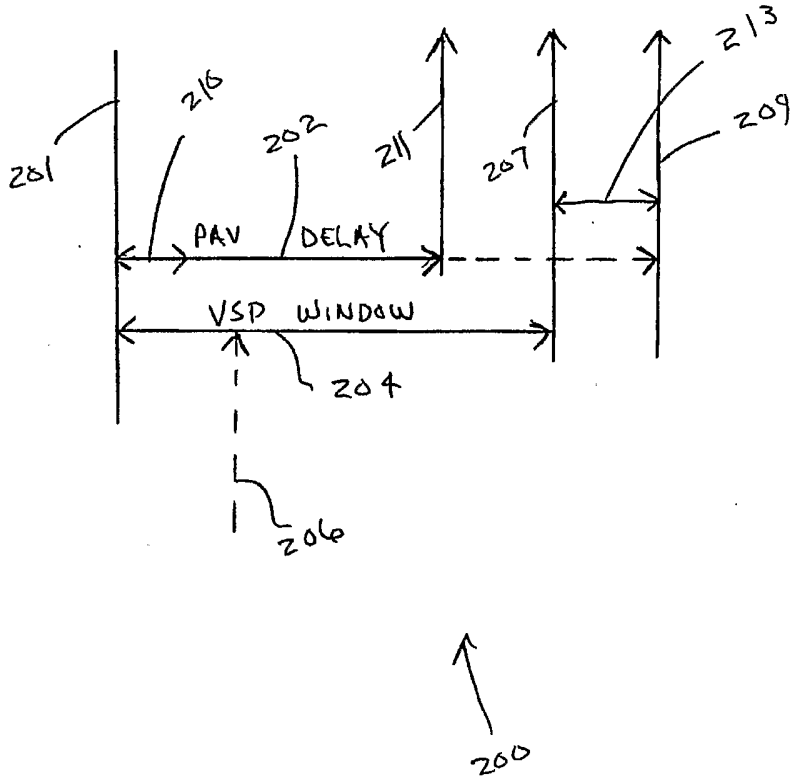

FIG. 8 A

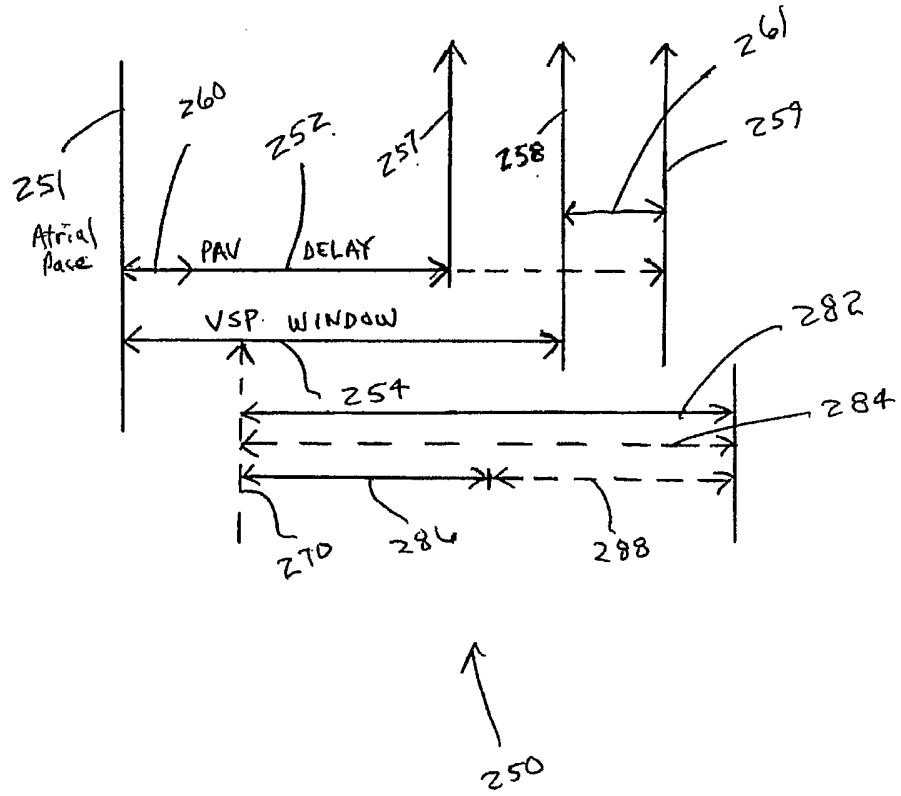
251
Atrial Pace
260
252
257
258
259
261
PAV
DELAY
VSP WINDOW
254
282
284
270
286
288
250

FIG. 8 B

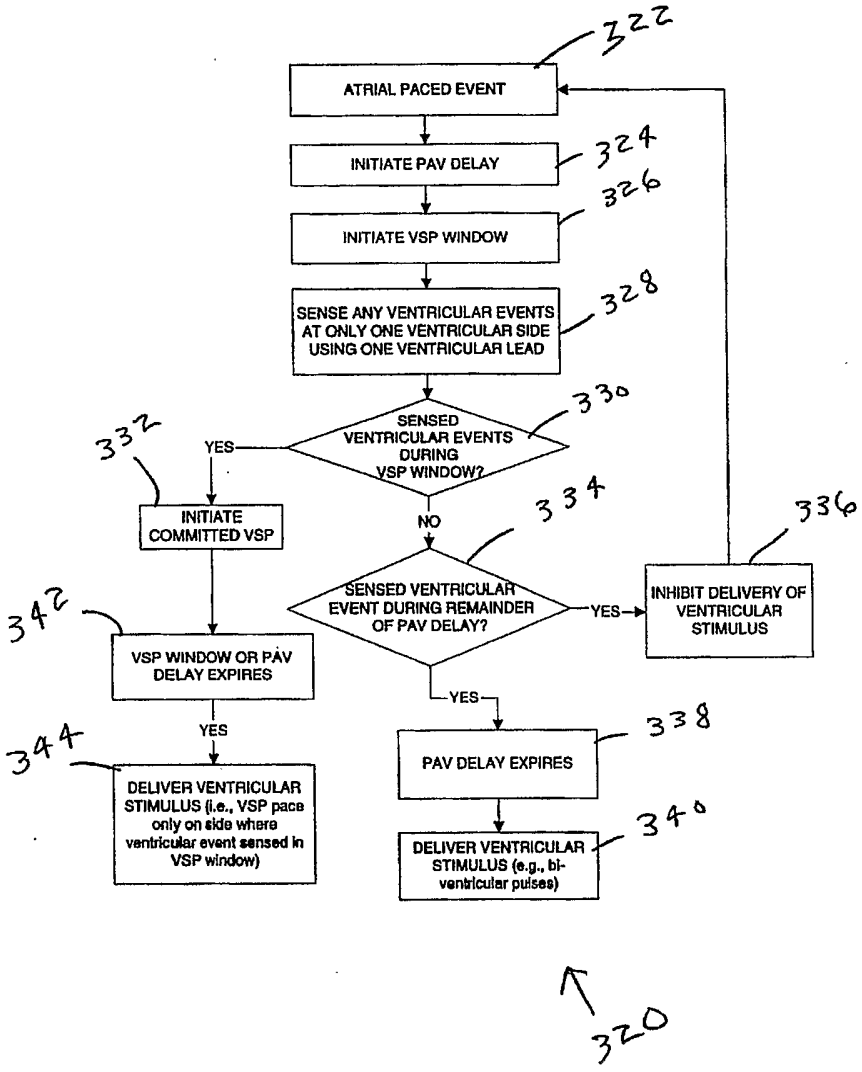
322
ATRIAL PACED EVENT
INITIATE PAV DELAY
324
INITIATE VSP WINDOW
326
SENSE ANY VENTRICULAR EVENTS AT ONLY ONE VENTRICULAR SIDE USING ONE VENTRICULAR LEAD
328
SENSED VENTRICULAR EVENTS DURING VSP WINDOW?
330
YES
332
INITIATE COMMITTED VSP
NO
334
SENSED VENTRICULAR EVENT DURING REMAINDER OF PAV DELAY?
YES
336
INHIBIT DELIVERY OF VENTRICULAR STIMULUS
342
VSP WINDOW OR PAV DELAY EXPIRES
YES
344
DELIVER VENTRICULAR STIMULUS (i.e., VSP pace only on side where ventricular event sensed in VSP window)
YES
338
PAV DELAY EXPIRES
340
DELIVER VENTRICULAR STIMULUS (e.g., bi-ventricular pulses)
320

FIG. 9 A

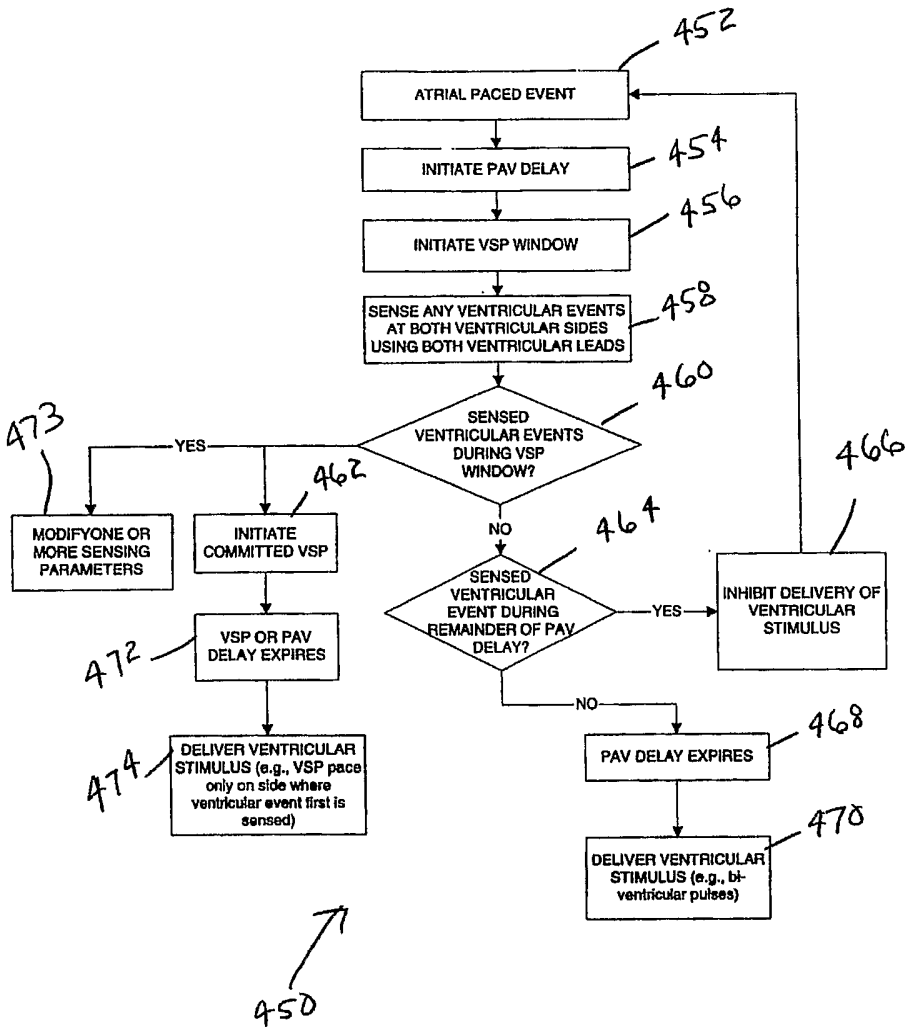
452
ATRIAL PACED EVENT
454
INITIATE PAV DELAY
456
INITIATE VSP WINDOW
458
SENSE ANY VENTRICULAR EVENTS AT BOTH VENTRICULAR SIDES USING BOTH VENTRICULAR LEADS
460
SENSED VENTRICULAR EVENTS DURING VSP WINDOW?
YES
NO
473
MODIFYONE OR MORE SENSING PARAMETERS
462
INITIATE COMMITTED VSP
464
SENSED VENTRICULAR EVENT DURING REMAINDER OF PAV DELAY?
YES
466
INHIBIT DELIVERY OF VENTRICULAR STIMULUS
472
VSP OR PAV DELAY EXPIRES
NO
468
PAV DELAY EXPIRES
474
DELIVER VENTRICULAR STIMULUS (e.g., VSP pace only on side where ventricular event first is sensed)
470
DELIVER VENTRICULAR STIMULUS (e.g., bi-ventricular pulses)
450

FIG. 9 B

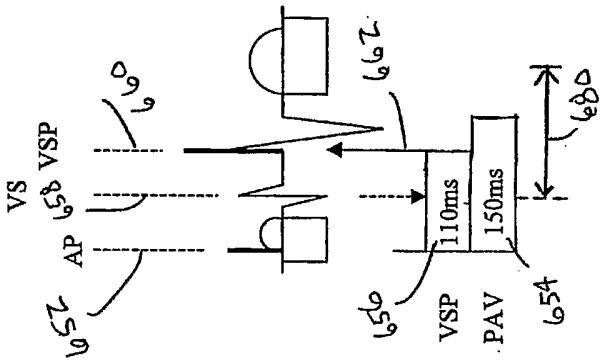

FIG. 10 B

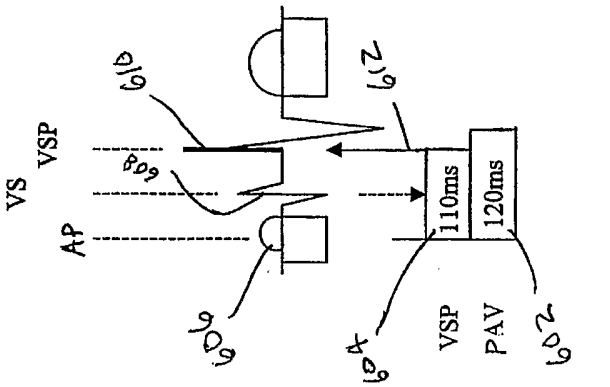

FIG. 10 A

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/12581

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 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)
IPC 7 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,P	FR 2 816 218 A (ELA MEDICAL SA) 10 May 2002 (2002-05-10) the whole document	28,44
A	EP 1 142 607 A (MEDTRONIC INC) 10 October 2001 (2001-10-10) abstract	28-52

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

☒ Patent family members are listed in 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 July 2003	05/08/2003

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	Gaillard, A

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/12581

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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.: 1-27
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 II Observations where unity of invention is lacking (Continuation of item 2 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 all searchable claims.

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

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers 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.

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

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/12581

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR 2816218 A	10-05-2002	FR 2816218 A1	10-05-2002
		EP 1205214 A1	15-05-2002
		US 2002095183 A1	18-07-2002
EP 1142607 A	10-10-2001	US 6507756 B1	14-01-2003
		EP 1142607 A2	10-10-2001