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(54) **SYSTEM AND METHOD FOR AUTOMATICALLY SELECTING ELECTRODE POLARITY DURING SENSING AND STIMULATION**

(57) **ABSTRACT**

An implantable multi-chamber cardiac stimulation device includes flexibly programmable electrode stimulation configurations, and is capable of precisely controlling the stimulation sequence between multiple sites. The stimulation device provides a plurality of connection ports that allow independent connection of each electrical lead associated with a particular stimulation site in the heart. Each connection port further provides a unique terminal for making electrical contact with only one electrode such that no two electrodes are required to be electrically coupled. Furthermore, each electrode, whether residing on a unipolar, bipolar or multipolar lead, may be selectively connected or disconnected through programmable switching circuitry that determines the electrode configurations to be used for sensing and for stimulating at each stimulation site. The stimulation device allows for the programmable selection of each electrode terminal connection to a relatively positive or negative battery potential. In this way, each electrode, when electrically connected, may be programmed to act as the cathode or as the anode during sensing or stimulation delivery. Thus, directionality of the depolarization wave may be controlled by programming the cathode and anode assignments of the stimulation electrodes.

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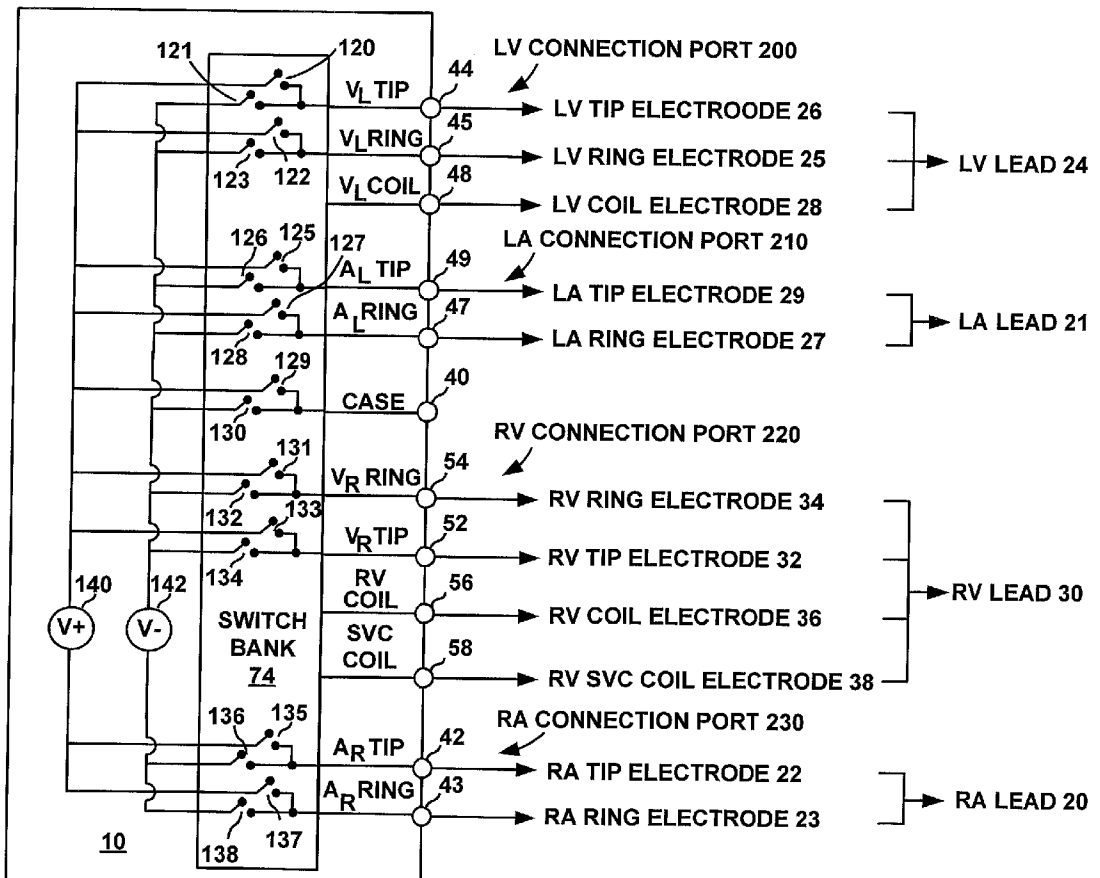
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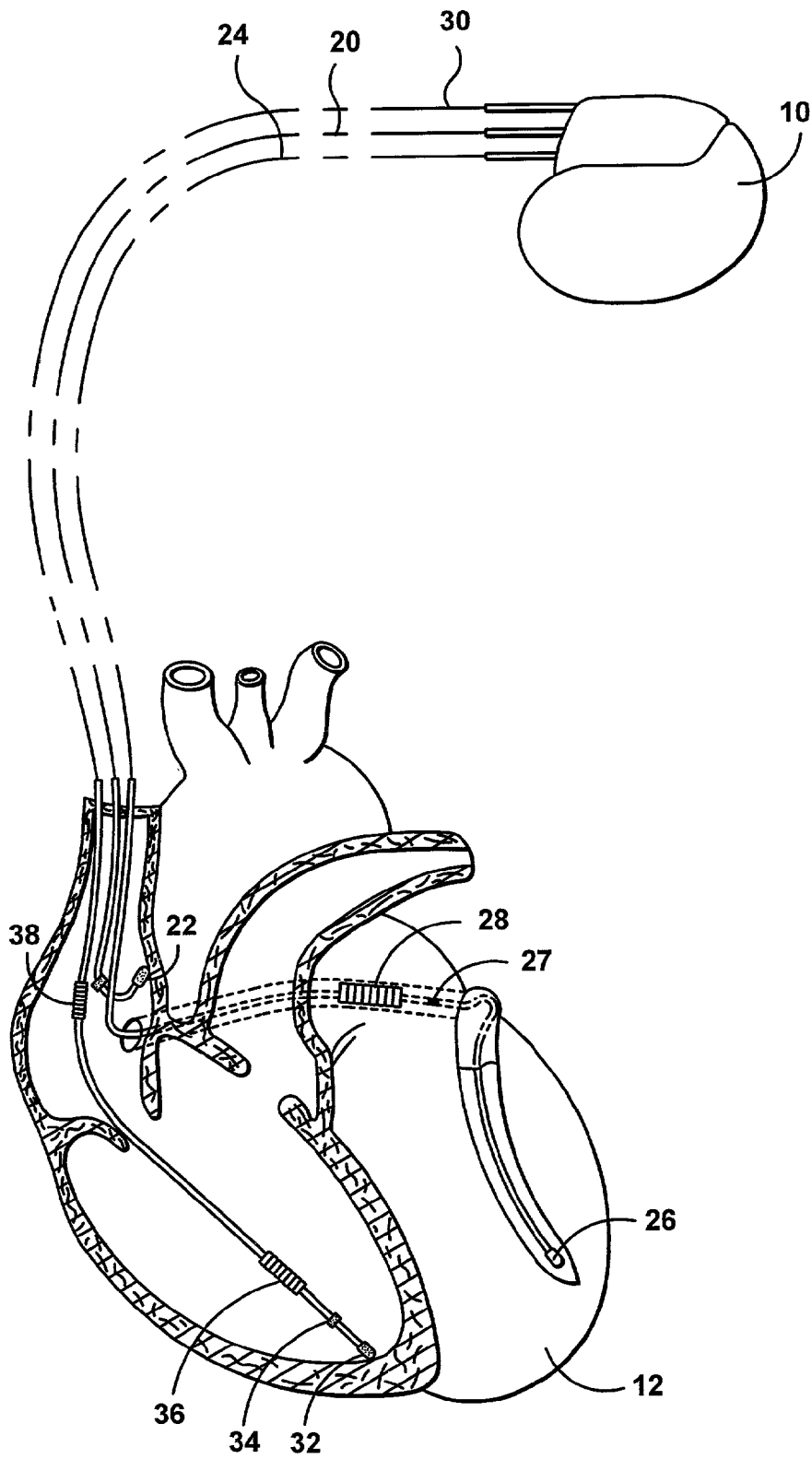


FIG. 1

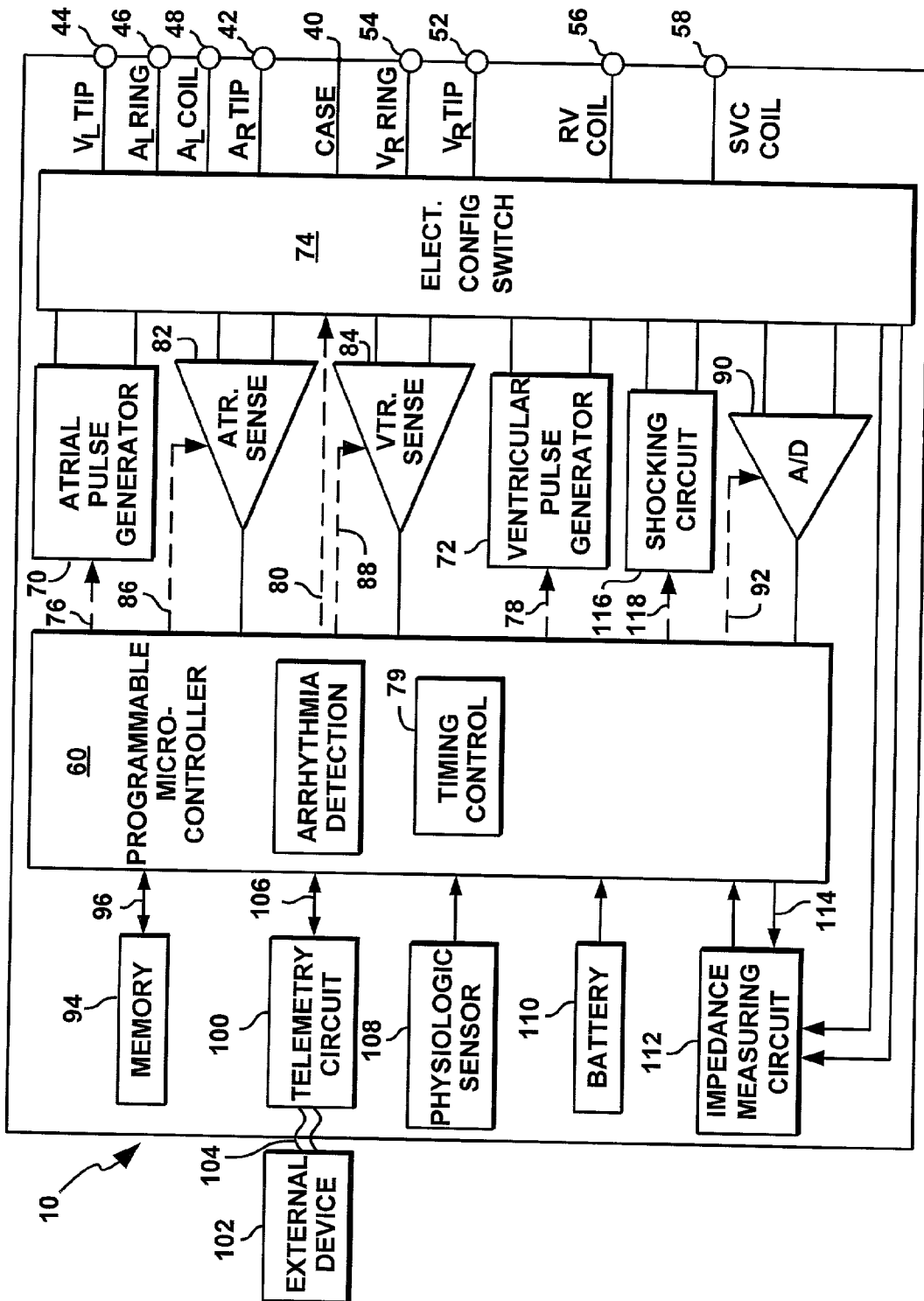


FIG. 2

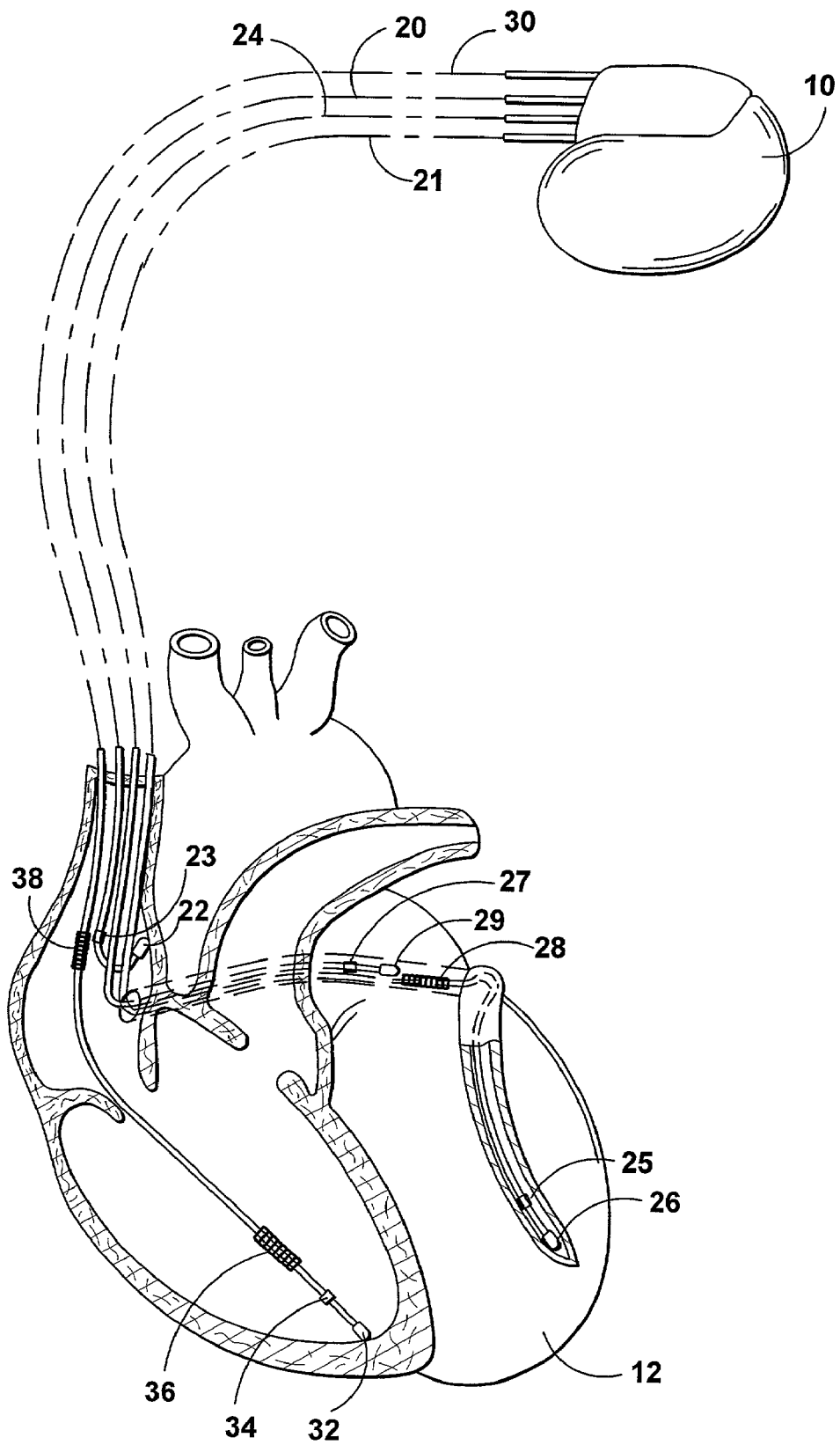


FIG. 3

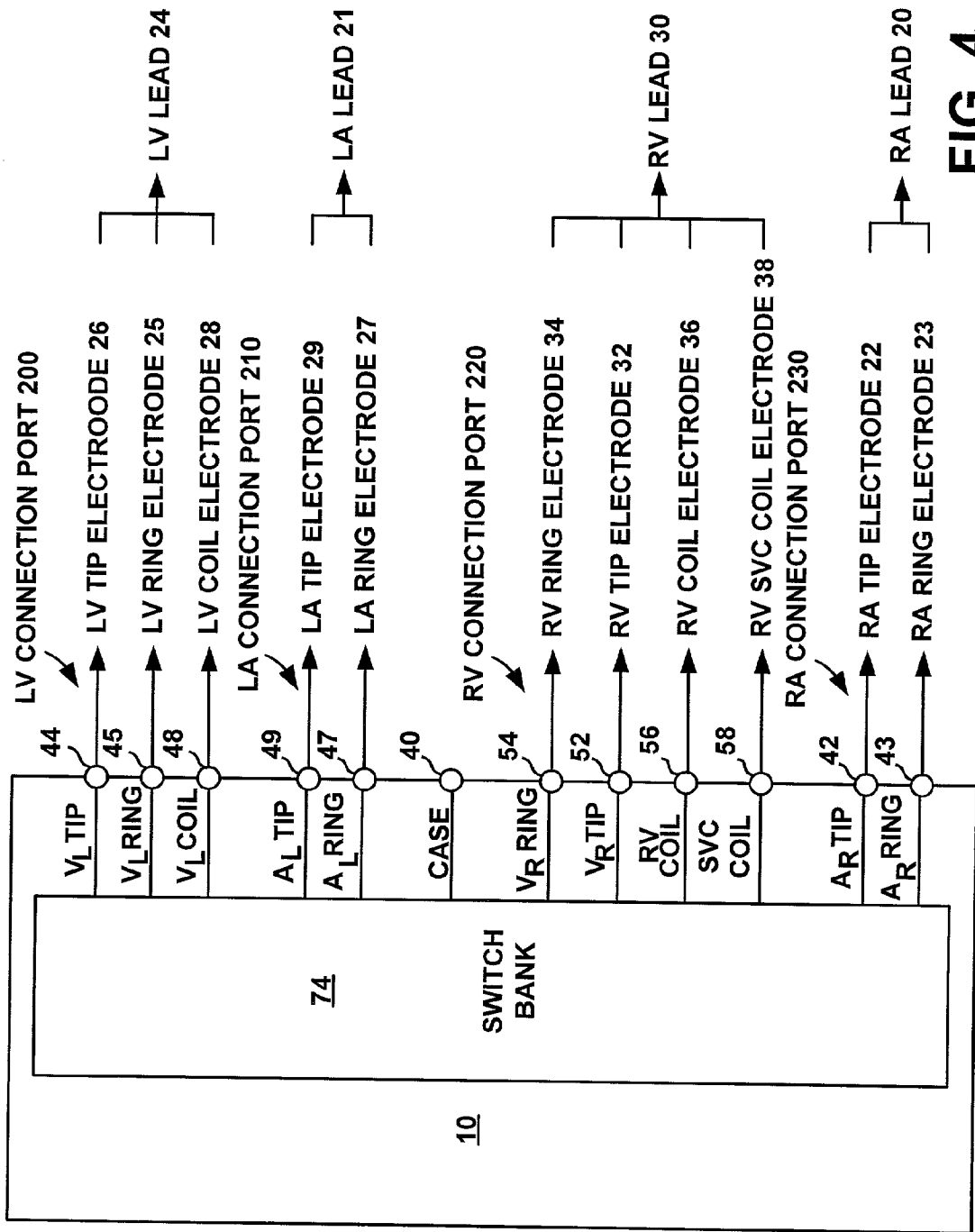


FIG. 4

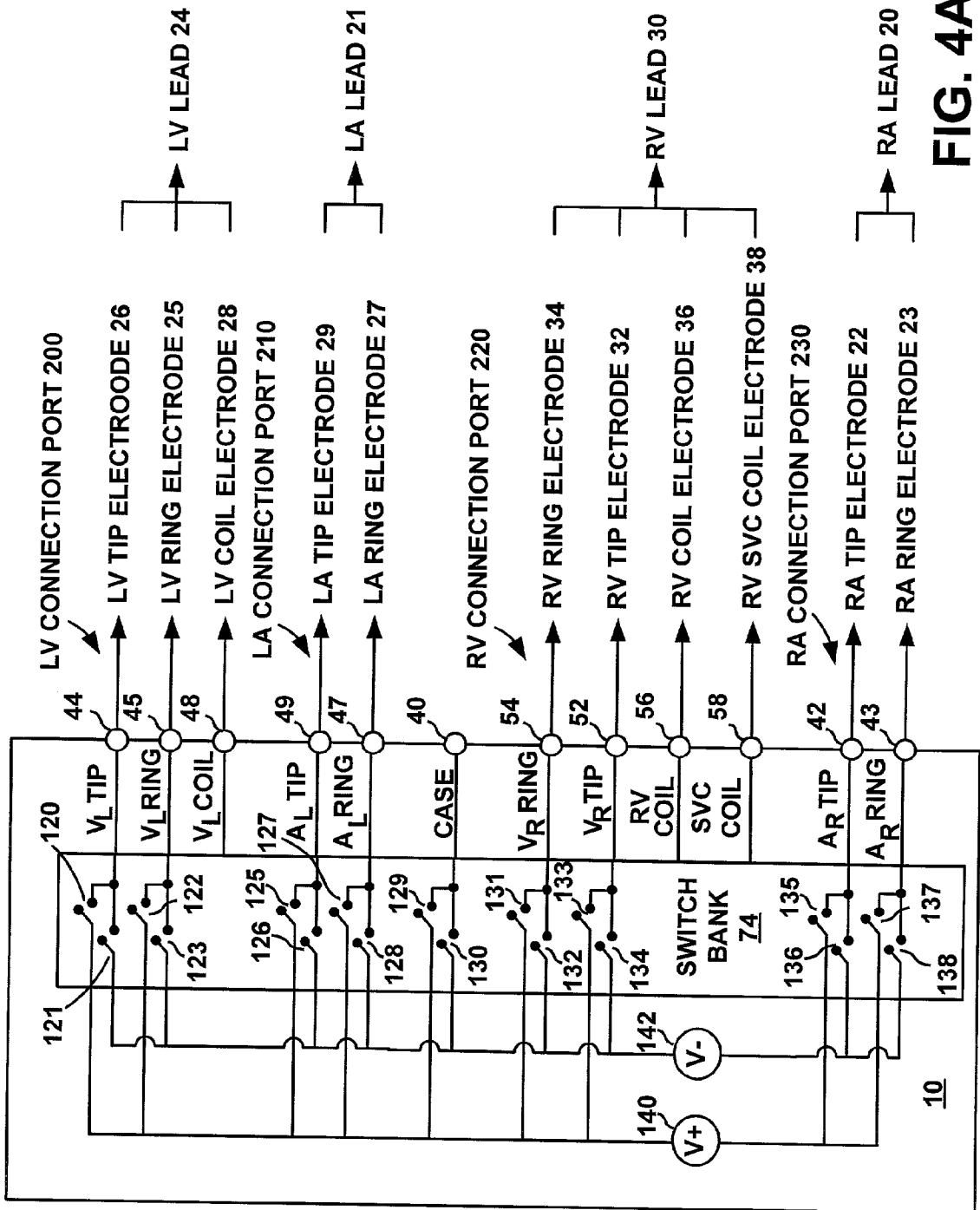


FIG. 4A

200

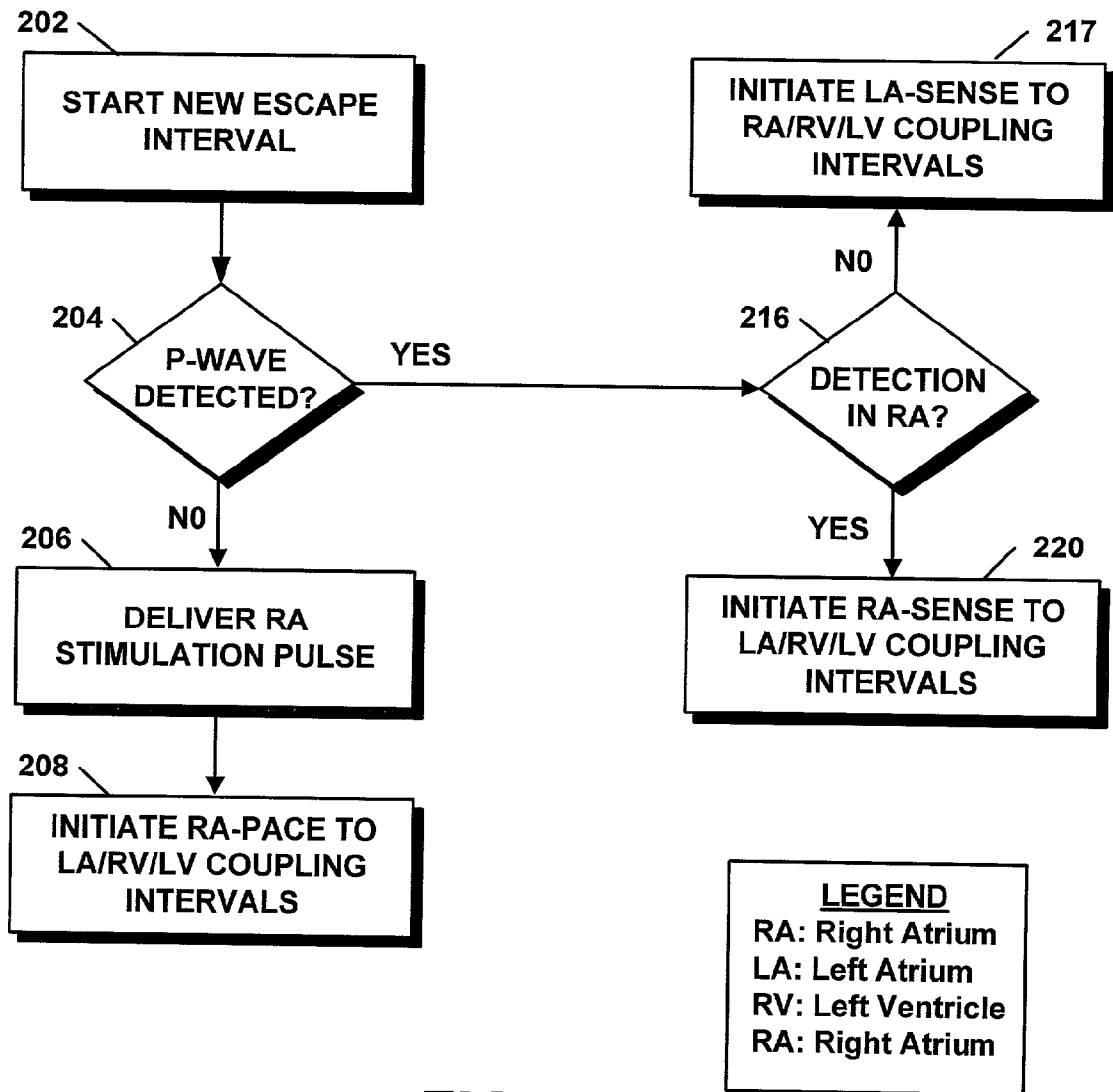


FIG. 5

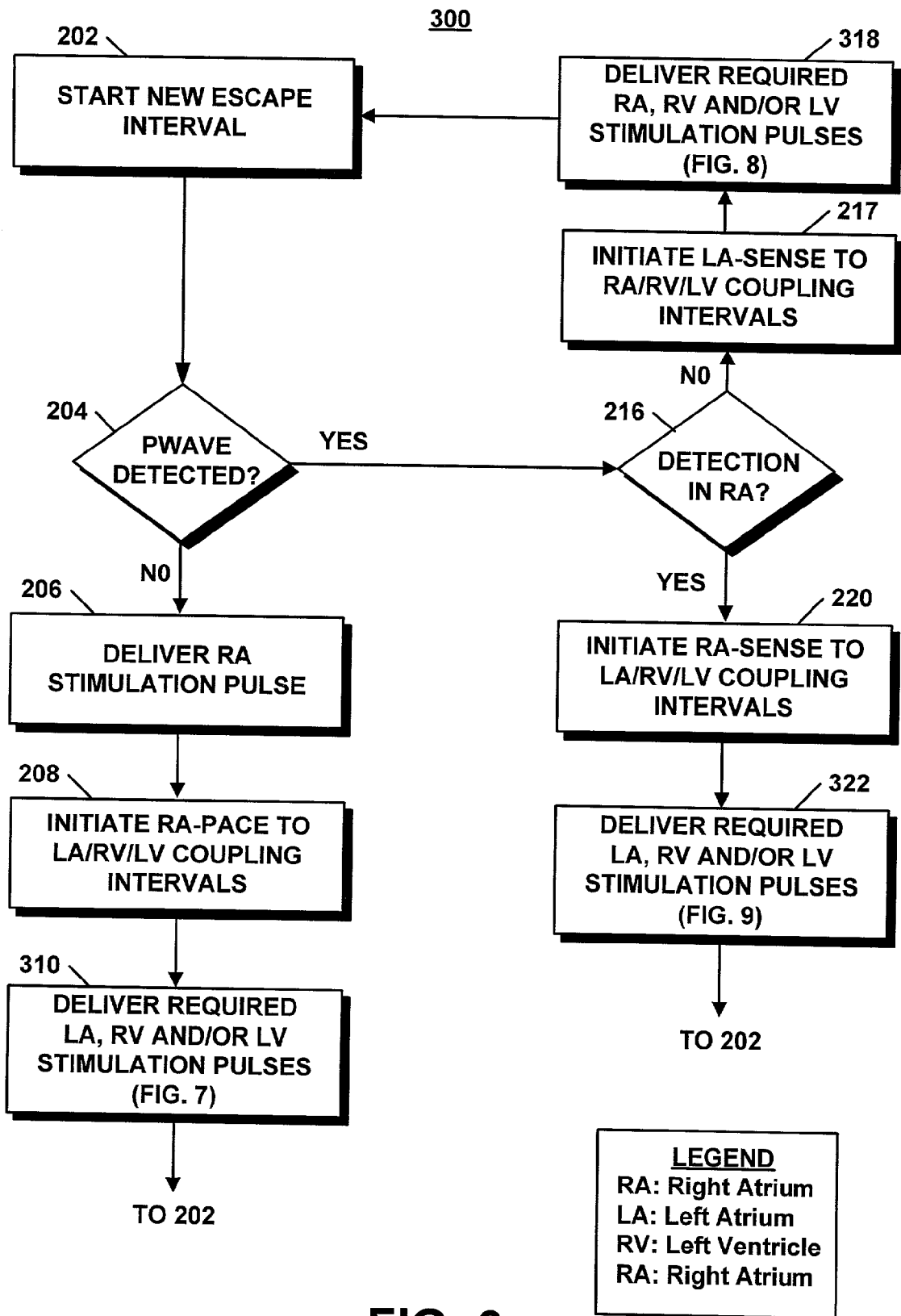


FIG. 6

310

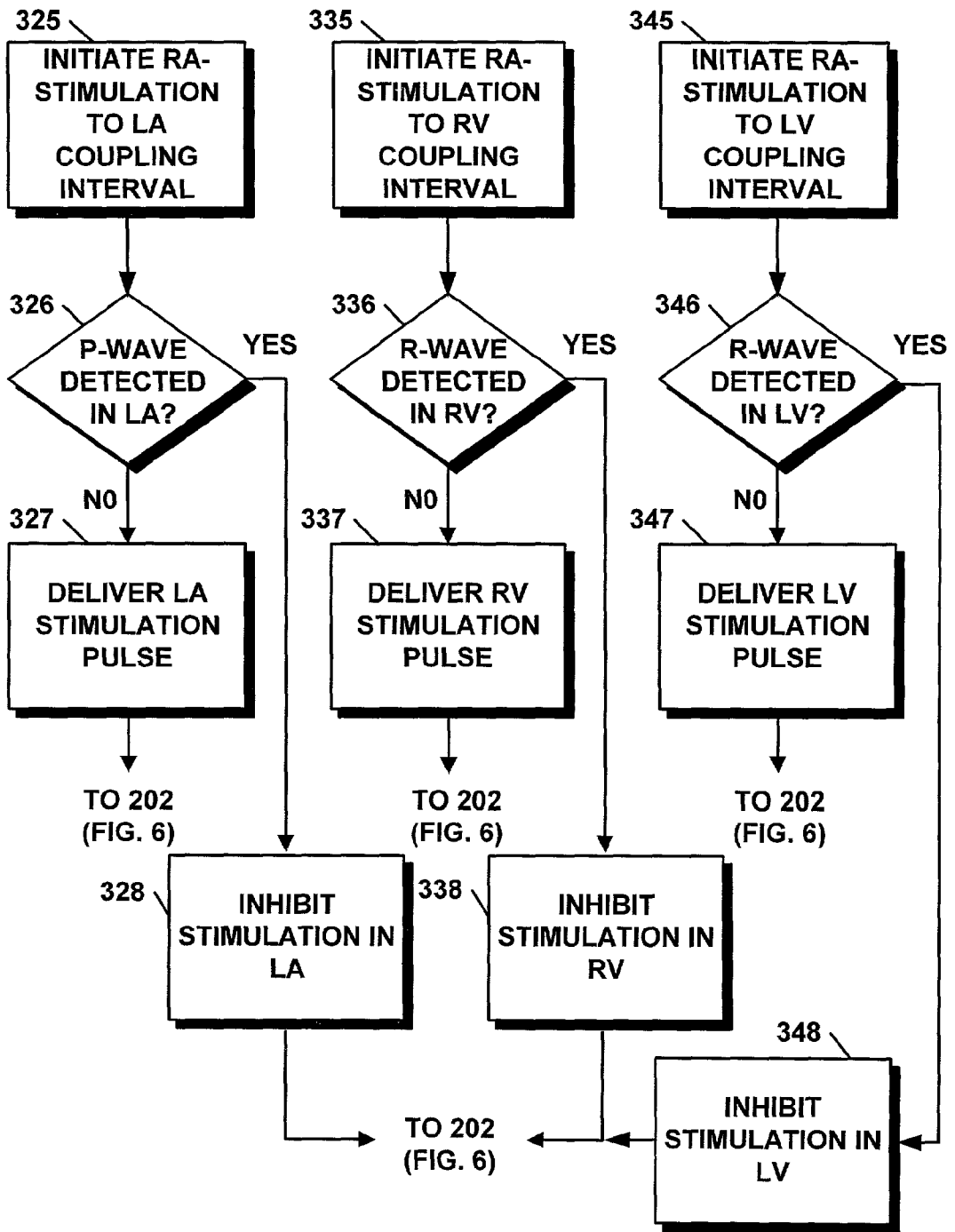


FIG. 7

318

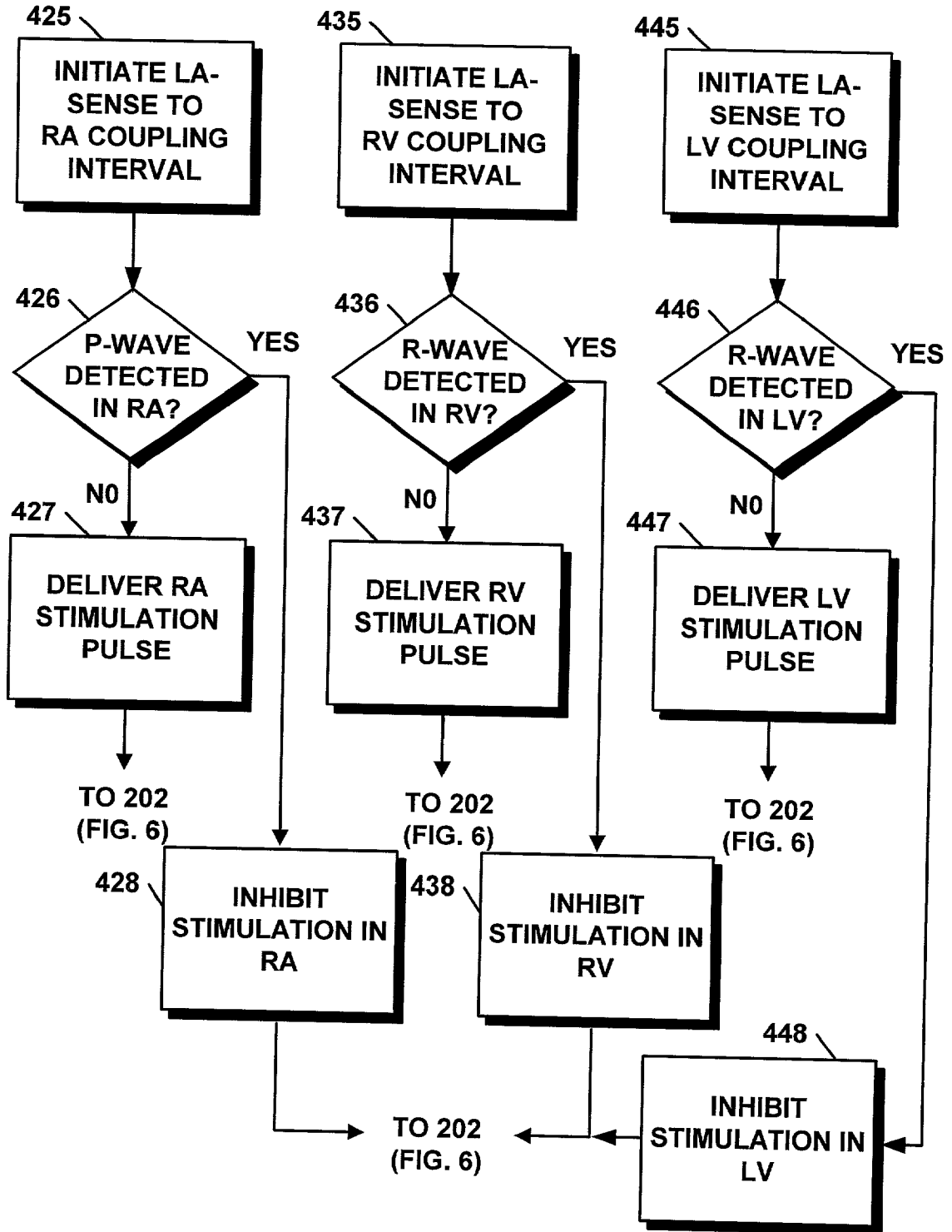


FIG. 8

322

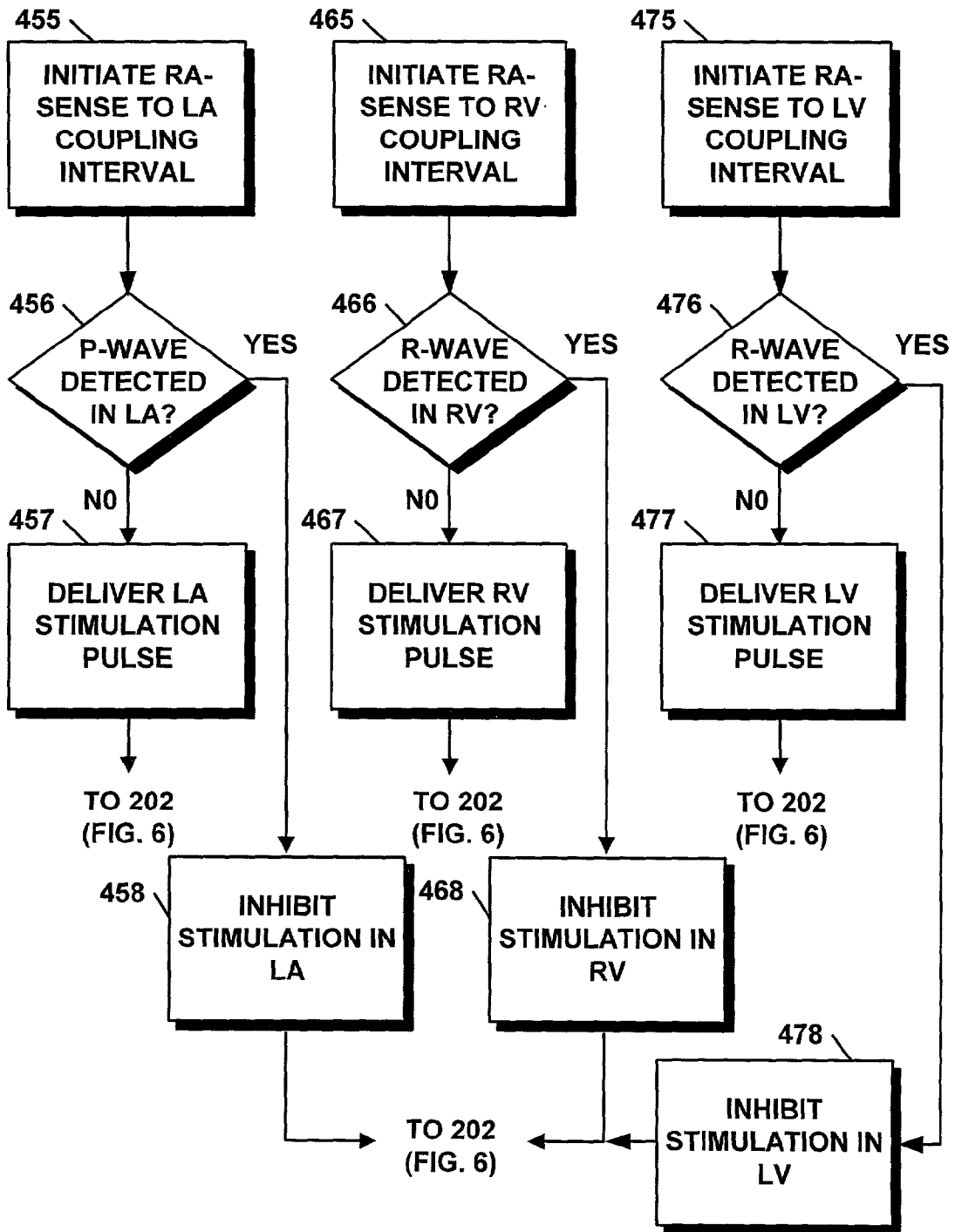


FIG. 9

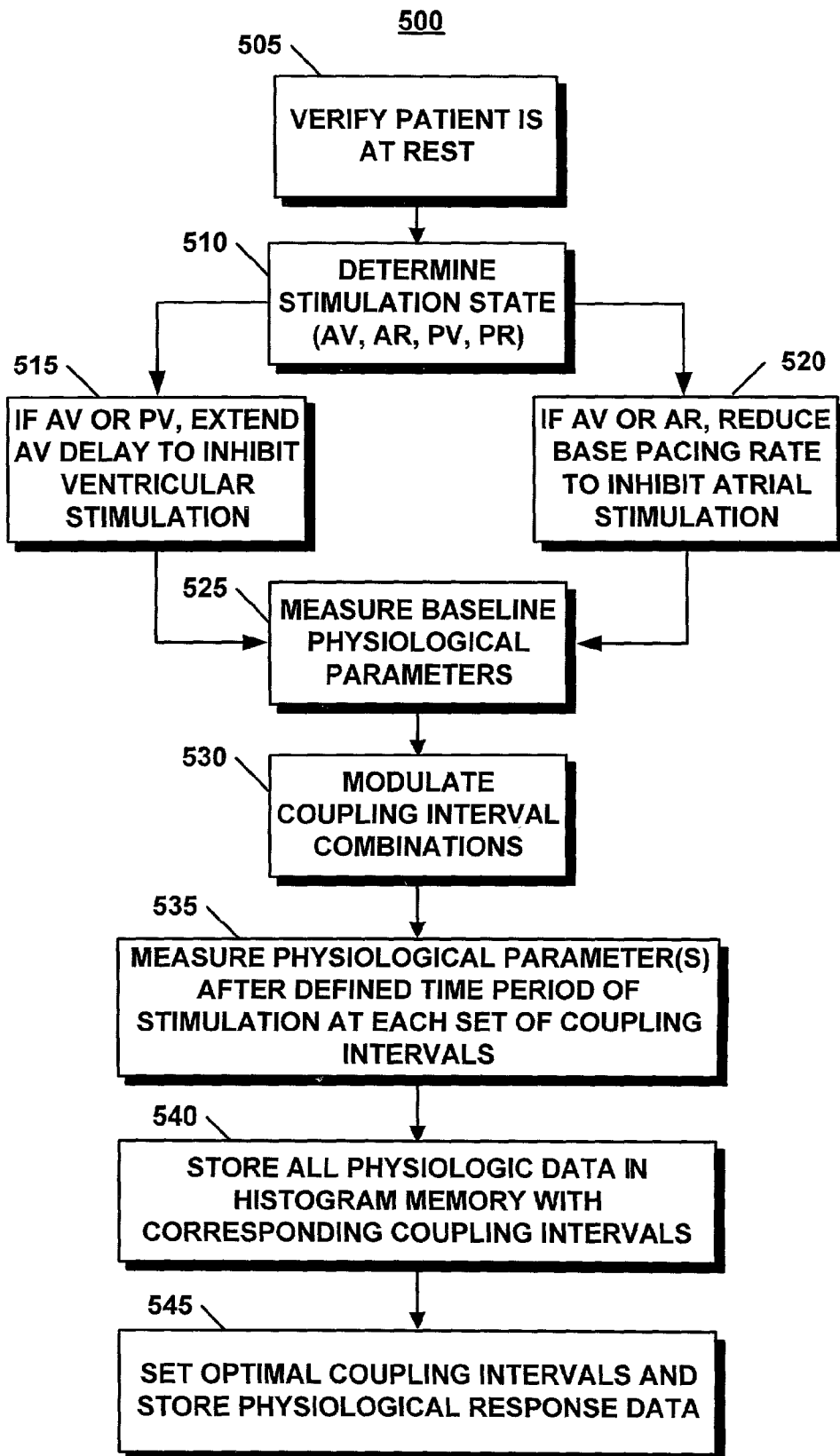


FIG. 10

SYSTEM AND METHOD FOR AUTOMATICALLY SELECTING ELECTRODE POLARITY DURING SENSING AND STIMULATION

FIELD OF THE INVENTION

[0001] This invention relates generally to programmable cardiac stimulating devices. Specifically, the present invention is directed to an implantable stimulation device and associated method for controlling the electrode sensing and stimulation configurations and the activation sequence in a multi-chamber cardiac stimulation device using noninvasive programming techniques. More particularly, the stimulation device allows for a programmable selection of each electrode terminal connection to a relatively positive or battery potential. In this way, each electrode, when electrically connected, may be programmed to act as a cathode or as an anode during sensing or stimulation delivery. Thus, directionality of the depolarization wave may be controlled by programming the cathode and anode assignments of the stimulation electrodes.

BACKGROUND OF THE INVENTION

[0002] In a normal human heart, the sinus node, generally located near the junction of the superior vena cava and the right atrium, constitutes the primary natural pacemaker initiating rhythmic electrical excitation of the heart chambers. The cardiac impulse arising from the sinus node is transmitted to the two atrial chambers, causing a depolarization known as a P-wave and the resulting atrial chamber contractions. The excitation pulse is further transmitted to and through the ventricles via the atrioventricular (A-V) node and a ventricular conduction system causing a depolarization known as an R-wave and the resulting ventricular chamber contractions.

[0003] Disruption of this natural pacemaking and conduction system as a result of aging or disease can be successfully treated by artificial cardiac pacing using implantable cardiac stimulation devices, including pacemakers and implantable defibrillators, which deliver rhythmic electrical pulses or other anti-arrhythmia therapies to the heart at a desired energy and rate. One or more heart chambers may be electrically stimulated depending on the location and severity of the conduction disorder.

[0004] Cardiac pacemakers conventionally stimulate a heart chamber by applying current pulses to cardiac tissues via two electrodes, a cathode and an anode. Standard pacing leads are available in either of two configurations, unipolar leads or bipolar leads, depending on the arrangement of the electrodes of a particular lead. A unipolar pacing lead contains a single electrode, normally the cathode, which extends pervenously distal from the pacemaker in an insulating enclosure until it is adjacent to the tip of the lead where the insulation is terminated to provide for electrical contact of the cathode with the heart tissue. The anode provides a return path for the pacing electrical circuit. For a unipolar lead, the anode is the pacemaker case.

[0005] A bipolar lead contains two electrodes within an insulating sheath, an anode that extends distal from the pacemaker to a position adjacent to, but spaced from, the electrode tip, and a cathode that also extends distal from the pacemaker, but terminates a short distance distal of the anode, at the lead tip. The anode commonly takes the form

of a ring having greater surface area than the cathode tip. An insulating barrier separates the cathode and anode of a bipolar lead. In present-day pacemakers, circuits for pacing and sensing, which determine tip, ring and case electrode connections, are provided. Thus, the pacemakers can be programmed via telemetry for either bipolar or unipolar operation with respect to either sensing or pacing operations.

[0006] A single-chamber pacemaker delivers pacing pulses to one chamber of the heart, either one atrium or one ventricle, via either a unipolar or bipolar electrode. Single-chamber pacemakers can operate in either a triggered mode or a demand mode. In a triggered mode, a stimulation pulse is delivered to the desired heart chamber at the end of a defined time-out interval to cause depolarization of the heart tissue (myocardium) and its contraction. The stimulating pulse must be of sufficient energy to cause depolarization of the heart chamber, a condition known as "capture." The lowest pulse energy required to achieve capture is termed "threshold." The pacemaker also delivers a stimulation pulse in response to a sensed event arising from that chamber when operating in a triggered mode.

[0007] When operating in a demand mode, sensing and detection circuitry allow for the pacemaker to detect if an intrinsic cardiac depolarization, either an R-wave or a P-wave, has occurred within the defined time-out interval. If an intrinsic depolarization is not detected, a pacing pulse is delivered at the end of the time-out interval. However, if an intrinsic depolarization is detected, the pacing pulse output is inhibited to allow the natural heart rhythm to preside. The difference between a triggered and demand mode of operation is the response of the pacemaker to a detected native event.

[0008] Dual chamber pacemakers are now commonly available and can provide either trigger or demand type pacing in both an atrial chamber and a ventricular chamber, typically the right atrium and the right ventricle. Both unipolar or bipolar dual chamber pacemakers exist in which a unipolar or bipolar lead extends from an atrial channel of the dual chamber device to the desired atrium (e.g. the right atrium), and a separate unipolar or bipolar lead extends from a ventricular channel to the corresponding ventricle (e.g. the right ventricle). In dual chamber, demand-type pacemakers, commonly referred to as DDD pacemakers, each atrial and ventricular channel includes a sense amplifier to detect cardiac activity in the respective chamber and an output circuit for delivering stimulation pulses to the respective chamber.

[0009] If an intrinsic atrial depolarization signal (a P-wave) is not detected by the atrial channel, a stimulating pulse will be delivered to depolarize the atrium and cause contraction. Following either a detected P-wave or an atrial pacing pulse, the ventricular channel attempts to detect a depolarization signal in the ventricle, known as an R-wave. If no R-wave is detected within a defined atrial-ventricular interval (AV interval or delay), a stimulation pulse is delivered to the ventricle to cause ventricular contraction. In this way, rhythmic dual chamber pacing is achieved by coordinating the delivery of ventricular output in response to a sensed or paced atrial event.

[0010] Mounting clinical evidence supports the evolution of more complex cardiac stimulating devices capable of stimulating three or even all four heart chambers to stabilize

arrhythmias or to re-synchronize heart chamber contractions (Ref: Cazeau S. et al., "Four chamber pacing in dilated cardiomyopathy," *Pacing Clin. Electrophysiol.* 1994 17 (11 Pt 2):1974-9). Stimulation of multiple sites within a heart chamber has also been found effective in controlling arrhythmogenic depolarizations (Ref: Ramdat-Misier A., et al., "Multisite or alternate site pacing for the prevention of atrial fibrillation," *Am. J. Cardiol.*, 1999 11:83(5b):237D-240D).

[0011] In order to achieve multi-chamber or multi-site stimulation in a clinical setting, conventional dual-chamber pacemakers have now been used in conjunction with adapters that couple together two leads going to different pacing sites or heart chambers. Reference is made to U.S. Pat. No. 5,514,161 to Limousin in which a triple chamber cardiac pacemaker, with the right and left atrial combined with a right ventricular lead, is described. Cazeau et al. (*Pacing Clin. Electrophysiol.* 1994 17(11 Pt 2):1974-9) describe a four chamber pacing system in which unipolar right and left atrial leads are connected via a bifurcated bipolar adapter to the atrial port of a bipolar dual chamber pacemaker. Likewise, unipolar right and left ventricular leads are connected via a bifurcated bipolar adapter to the ventricular channel. The left chamber leads were connected to the anode terminals and the right chamber leads were connected to the cathode terminals of the dual chamber device. In this way, simultaneous bi-atrial or simultaneous bi-ventricular pacing is achieved via bipolar stimulation but with several limitations.

[0012] Firstly, this configuration of bipolar stimulation is distinctly different from a conventional bipolar lead configuration wherein both the cathode and anode are located a short distance apart, approximately one centimeter, on the same lead. In the bi-chamber pacing configuration described above, the anode and cathode are in fact located on two different leads positioned in two different locations, several centimeters apart. In addition, since the tip electrode of one lead is forced to be the anode, and this has a significantly smaller surface area than the anode of a classic bipolar lead, the relative resistance or impedance is higher with this lead system. In such a bipolar, bi-chamber pacing configuration, the threshold energy is likely to be relatively higher than in conventional bipolar stimulation in part because of the higher impedance of the electrode system. In addition, the electrode used for stimulation in the left heart chamber is usually within the coronary sinus or a cardiac vein, not making direct contact with the myocardium. As such, the energy needed to accommodate bi-chamber stimulation will usually be higher than that which is commonly required for single chamber stimulation using bipolar leads.

[0013] A potential risk that exists when higher output settings are used, as may be needed to ensure bi-chamber stimulation, is cross-chamber capture, also known as cross-stimulation (Ref: Levine PA, et al., *Cross-stimulation: the unexpected stimulation of the unpaced chamber*, *PACE* 1985; 8: 600-606). If bi-atrial stimulation is delivered in a bipolar configuration across one electrode located in the right atrium and another electrode located in the left atrium, which in actuality is the coronary sinus which lies between the left atrium and left ventricle, the stimulation energy could conceivably be high enough to inadvertently capture one or both ventricles simultaneously. Such cross-chamber capture is a highly undesirable situation in that the upper and

lower chambers would contract against each other causing severe cardiac output perturbation. This is also likely to occur with bipolar bi-ventricular stimulation with respect to cross-stimulation of the atrial chambers if the left ventricular lead located within a cardiac vein is in close anatomic proximity to the left atrium and high outputs are required to assure capture.

[0014] Another limitation of the multi-chamber stimulation systems described above is that simultaneous stimulation of left and right chambers, as required when two leads are coupled together by one adapter, is not always necessary nor desirable. For example, in some patients conduction between the two atria may be compromised, however the pacemaking function of the sinus node in the right atrium may still be normal. Hence, detection of an intrinsic depolarization in the right atrium could be used to trigger delivery of a pacing pulse in the left atrium. Since an intrinsic depolarization has occurred in one chamber, simultaneous stimulation of both chambers in this situation is unnecessary.

[0015] In another example, when inter-atrial or inter-ventricular conduction is intact, stimulation in one chamber may be conducted naturally to depolarize the second chamber. A stimulation pulse delivered in one chamber, using the minimum energy required to depolarize that chamber, will be conducted to the opposing chamber thus depolarizing both chambers. In this case, stimulation of both chambers simultaneously would be wasteful of battery energy.

[0016] Another limitation is that, in the presence of an inter-atrial or inter-ventricular conduction defect, one may want to control the interval between a sensed or paced event in one chamber and delivery of a stimulation pulse to the other chamber. If pacing is required in both chambers, the control of the sequence of the stimulation pulse delivery to each chamber, rather than the simultaneous delivery of stimulation pulses, may be desirable in order to achieve a specific activation sequence that has hemodynamic benefit.

[0017] Yet another limitation is that, once implanted, the designation of cathode and anode assignments is fixed and cannot be reassigned in order to determine the polarity that results in the lowest stimulation thresholds, to achieve a desired directionality of the stimulation delivery or to obtain the optimal sequencing of stimulation and/or sensing to optimize hemodynamic function. Typically, the electrode in the right chamber is connected to the cathode terminal and the electrode in the left chamber is connected to the anode terminal. In other cases, the electrode in the left chamber is connected to the cathode terminal while the right chamber electrode is connected to the anode. In some patients, a lower stimulation threshold or an improved excitation pattern or perhaps even hemodynamic benefit might be achieved by reversing the cathode and anode locations yet this cannot be done without operative intervention.

[0018] In the first generation of multi-chamber devices, an adapter was required to connect multiple leads to a conventional dual chamber device, a requirement that adds cost and time to the implant procedure. Adapters can be cumbersome and an additional site for potential lead breakage or discontinuity, essentially adding bulk and a "weak link" to the implanted system. In certain current devices, adapters are no longer required. The connection between leads is hardwired internally in the connector block coupling the ventricular leads to the ventricular channel and the atrial leads to the

atrial channel. While this design advantageously eliminates the need for adapters, the hardware connections preclude the potential to non-invasively adjust the polarity orientation. This also prevents introducing separate timing between stimulation pulses delivered to each chamber or responding with any programmable delays to a sensed event by delivery of an output pulse to the other chamber.

[0019] To address some of these limitations, Verboven-Nelissen proposes a method and apparatus that includes a multiple-chamber electrode arrangement having at least two electrodes placed to sense and/or pace different chambers or areas of the heart. Reference is made to U.S. Pat. No. 5,720,518. The proposed method involves switching from a bipolar to a unipolar configuration during sensing for determining the origination site of a detected depolarization signal. If the signal is determined to have arisen from the SA node in the right atrium, a conduction interval is applied to allow the cardiac signal to properly propagate to the other heart chambers. If no cardiac signal is detected in another cardiac chamber, for example, the left atrium, then pacing is initiated in that chamber at the end of the conduction interval. In this example, the interval is equal to the inter-atrial conduction time (i.e. the time required for a P-wave cardiac signal to propagate from right atrium to left atrium). However the inter-atrial conduction time may vary over time and the time for an excitation pulse to propagate from the right chamber to the left chamber may be different than the propagation time from the left chamber to the right chamber. In addition, the conduction time from the right atrium to the left atrium may vary from that required to go from the left atrium to the right atrium. Depending on the site of origin of the detected depolarization, it may be hemodynamically beneficial to control the coupling interval between the detected depolarization and the triggered output to the other chamber. U.S. Pat. No. 5,720,518 does not address the ability to control the interval between detection and stimulation within the atria or ventricles in the setting of multisite stimulation.

[0020] Reference is also made to U.S. Pat. No. 5,902,324 to Thompson et al. in which a multi-channel pacing system having two, three or four pacing channels, each including a sense amplifier and pace output pulse generator, is described. A pacing pulse or detection of a spontaneous depolarization in one of the right or left heart chambers is followed by a short conduction delay window. A pacing pulse that would otherwise be delivered at the termination of the conduction delay window in the opposing heart chamber is inhibited if the conducted depolarization wave is sensed within the conduction delay window. While the duration of the conduction delay window can be programmed, no method is provided by which to select the optimal interval between chamber depolarizations.

[0021] Patients with marked hemodynamic abnormalities may benefit from multi-site or multi-chamber pacing that controls the activation sequence of the heart chambers. Precise control of the activation sequence may improve the coordination of heart chamber contractions resulting in more effective filling and ejection of blood from the heart. Patients with hemodynamic abnormalities often have conduction defects due to dilation of the heart or other causes. Yet, even in patients with intact conduction, precise control of the timing and synchronicity of heart chamber contractions may provide hemodynamic benefit.

[0022] There remains an unmet need, therefore, for a multi-chamber or multi-site cardiac stimulation device that allows independent stimulation and sensing at multiple sites within the heart as well as flexible selection of stimulation sequence and timing intervals between these stimulation sites. It would thus be desirable to provide a multisite or multichamber cardiac stimulation device having independent sensing and output circuitry for each pacing site. It would further be desirable to allow flexible selection of sensing and stimulation polarity for each stimulation site, including the designation of cathode and anode assignment during bi-chamber stimulation. Further, it would be desirable to provide flexible programming of the stimulation sequence and timing intervals associated with multisite or multichamber pacing. Different timing intervals should be advantageously selectable depending on the origination site of a detected depolarization wave or a desired directionality of depolarization in order to achieve optimal hemodynamic or electrophysiological benefit for the patient.

SUMMARY OF THE INVENTION

[0023] The present invention addresses this need by providing an implantable multichamber or multisite cardiac stimulation device in which the electrode configurations for sensing and stimulation are flexibly programmable, and the stimulation sequence between multiple sites can be precisely controlled.

[0024] One aspect of the present invention is to provide a plurality of connection ports, preferably two through four connection ports, that allow independent connection to the stimulation device of each electrical lead associated with a particular stimulation site in the heart. Each connection port further provides a unique terminal for making electrical contact with only one electrode such that no two electrodes are required to be electrically coupled. Furthermore, each electrode, whether residing on a unipolar, bipolar or multipolar lead, may be selectively connected or disconnected through programmable switching circuitry that determines the electrode configurations to be used for sensing and for stimulating at each stimulation site.

[0025] Another aspect of the present invention is the programmable selection of each electrode terminal connection to a relatively positive or negative battery potential. In this way, each electrode, when electrically connected, may be programmed to act as the cathode or as the anode during sensing or stimulation delivery. Thus, directionality of the depolarization wave may be controlled by programming the cathode and anode assignments of the stimulation electrodes. Both electrode configuration and cathode and anode assignments may be selected so as to achieve a desired level of stimulation or sensing threshold.

[0026] Another aspect of the present invention is a unique sensing circuit associated with each stimulation site such that depolarizations occurring at each stimulation site can be detected independently of events occurring at other sites within the heart. This independent sensing advantageously allows the location of a detected depolarization to be recognized by the stimulation device. The desired electrodes to be used for sensing in a specific heart chamber or at a specific site within a heart chamber are connected to the input of the sensing circuit via programmable switching circuitry.

[0027] Still another aspect of the present invention is a unique output circuit associated with each stimulation site such that each site can be stimulated independently of other sites or on a precisely timed basis triggered by events occurring at other sites. The electrodes used for stimulation at a specific site may be different than those used for sensing at the same site.

[0028] Yet another aspect of the present invention is the ability to program unique coupling intervals for precisely controlling the activation sequence of stimulated sites. Coupling intervals may be defined in relation to the originating location of a detected depolarization or in relation to stimulus delivery at another location. Coupling intervals are advantageously selected in a way that provides optimal hemodynamic benefit to the patient by overcoming various conduction disorders or improving coordination of heart chambers in patients suffering from heart failure. One embodiment of the present invention includes a method for automatically determining the optimal coupling intervals and adjusting the programmed settings based on measurements related to the hemodynamic state of the heart.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] Further features and advantages of the present invention may be more readily understood by reference to the following description taken in conjunction with the accompanying drawings, in which:

[0030] **FIG. 1** is a simplified, partly cutaway view illustrating an implantable stimulation device in electrical communication with at least three leads implanted into a patient's heart for delivering multi-chamber stimulation and shock therapy;

[0031] **FIG. 2** is a functional block diagram of the multi-chamber implantable stimulation device of **FIG. 1**, illustrating the basic elements that provide pacing stimulation, cardioversion, and defibrillation in four chambers of the heart;

[0032] **FIG. 3** is a simplified, partly cutaway view illustrating an implantable stimulation device in electrical communication with at least four bipolar leads implanted into a patient's heart representing a preferred embodiment of the present invention;

[0033] **FIG. 4** is a block diagram of the stimulation device of **FIG. 3**, illustrating a switch with four ports for connection to four leads;

[0034] **FIG. 4A** is a block diagram illustrating a switching system for selecting the electrical polarity of each electrode terminal;

[0035] **FIG. 5** depicts a flow chart describing an overview of a method for automatically configuring sensing electrodes for use in the cardiac stimulation device of the present invention;

[0036] **FIGS. 6 through 9** depict flow chart describing a method for automatically configuring stimulation electrodes for use in the cardiac stimulation device of the present invention; and

[0037] **FIG. 10** is a flow chart describing an overview of a method implemented by the stimulation device of **FIG. 2**, for automatically adjusting the coupling intervals used in the

methods of **FIGS. 5-9**, to achieve an optimal physiological response to a multi-chamber stimulation therapy.

DETAILED DESCRIPTION OF THE INVENTION

[0038] The following description is of a best mode presently contemplated for practicing the invention. This description is not to be taken in a limiting sense but is made merely for the purpose of describing the general principles of the invention. The scope of the invention should be ascertained with reference to the issued claims. In the description of the invention that follows, like numerals or reference designators will be used to refer to like parts or elements throughout.

[0039] The present invention relates to a cardiac stimulation device capable of delivering precisely ordered stimulation pulses to multiple chambers of the heart, referred to herein as multi-chamber stimulation, or to multiple sites within a chamber of the heart, referred to herein as multi-site stimulation. As used herein, the shape of the stimulation pulses is not limited to an exact square or rectangular shape, but may assume any one of a plurality of shapes which is adequate for the delivery of an energy pulse, packet, or stimulus.

[0040] Such a stimulation device is intended for use in patients suffering from hemodynamic dysfunction, which may or may not be accompanied by conduction disorders. Precisely controlled stimulation at multiple sites or in multiple chambers is provided to intentionally make use of the pacing function of the heart in order to improve cardiac hemodynamics by re-coordinating heart chamber contractions and/or preventing arrhythmogenic depolarizations from occurring. Thus, the cardiac stimulation device is capable of delivering at least low-voltage stimulation pulses to multiple stimulation sites for providing pacing therapy, and may include high-voltage stimulation shocks for providing cardioversion therapy and defibrillation therapy.

[0041] **FIG. 1** illustrates a stimulation device **10** in electrical communication with a patient's heart **12** by way of three leads **20**, **24** and **30** suitable for delivering multi-chamber stimulation and shock therapy. To sense right atrial cardiac signals and to provide right atrial chamber stimulation therapy, the stimulation device **10** is coupled to an implantable right atrial lead **20** having at least an atrial tip electrode **22**, which typically is implanted in the patient's right atrial appendage.

[0042] To sense left atrial and/or left ventricular cardiac signals and to provide left-chamber pacing therapy, the stimulation device **10** is coupled to a "coronary sinus" lead **24** designed for placement in the "coronary sinus region" via the coronary sinus ostium so as to place a distal electrode adjacent to the left ventricle and additional electrode(s) adjacent to the left atrium. As used herein, the phrase "coronary sinus region" refers to the vasculature of the left ventricle, including any portion of the coronary sinus, great cardiac vein, left marginal vein, left posterior ventricular vein, middle cardiac vein, and/or small cardiac vein or any other cardiac vein accessible by the coronary sinus. It could also be an epicardial lead placed at the time of thoracotomy or thorascopy.

[0043] Accordingly, the coronary sinus lead **24** is designed to receive atrial and/or ventricular cardiac signals and to

deliver: left ventricular pacing therapy using at least a left ventricular tip electrode **26**, left atrial pacing therapy using at least a left atrial ring electrode **27**, and shocking therapy using at least a left atrial coil electrode **28**. For a more detailed description of a coronary sinus lead, refer to U.S. patent application Ser. No. 09/457,277, titled "A Self-Anchoring, Steerable Coronary Sinus Lead" (Pianca et al.), and U.S. Pat. No. 5,466,254, titled "Coronary Sinus Lead with Atrial Sensing Capability" (Helland), that are incorporated herein by reference.

[0044] The stimulation device **10** is also shown in electrical communication with the patient's heart **12** by way of an implantable right ventricular lead **30** having, in this embodiment, a right ventricular tip electrode **32**, a right ventricular ring electrode **34**, a right ventricular (RV) coil electrode **36**, and an SVC coil electrode **38**. Typically, the right ventricular lead **30** is transvenously inserted into the heart **12** so as to place the right ventricular tip electrode **32** in the right ventricular apex so that the RV coil electrode **36** will be positioned in the right ventricle and the SVC coil electrode **38** will be positioned in the superior vena cava. Accordingly, the right ventricular lead **30** is capable of receiving cardiac signals, and delivering stimulation in the form of pacing and shock therapy to the right ventricle.

[0045] FIG. 2 illustrates a simplified block diagram of the multi-chamber implantable stimulation device **10**, which is capable of treating both fast and slow arrhythmias with stimulation therapy, including cardioversion, defibrillation, and pacing stimulation. While a particular multi-chamber device is shown, this is for illustration purposes only, and one of skill in the art could readily duplicate, eliminate or disable the appropriate circuitry in any desired combination to provide a device capable of treating the appropriate chamber(s) with cardioversion, defibrillation and/or pacing stimulation.

[0046] The stimulation device **10** includes a housing **40** which is often referred to as "can", "case" or "case electrode", and which may be programmably selected to act as the return electrode for all "unipolar" modes. The housing **40** may further be used as a return electrode alone or in combination with one or more coil electrodes **28**, **36**, or **38**, for shocking purposes. The housing **40** further includes a connector having a plurality of terminals, **42**, **44**, **46**, **48**, **52**, **54**, **56**, and **58** (shown schematically and, for convenience, the names of the electrodes to which they are connected are shown next to the terminals). In accordance with one embodiment of the present invention, the connector will provide a unique connection port for each lead in communication with the heart so as to avoid the necessity of adapters. Furthermore, the connector will provide a unique terminal for electrical connection to each electrode(s) associated with each stimulation site within the heart **12**. In this way, coupling of more than one stimulation site using adapters, or hardwiring between terminals inside the connector, is avoided allowing independent stimulation and sensing at each stimulation site.

[0047] As such, in the embodiment of FIG. 2, the connector includes at least a right atrial tip terminal **42** adapted for connection to the atrial (A_R) tip electrode **22** in order to achieve right atrial sensing and pacing.

[0048] To achieve left chamber sensing, pacing and/or shocking, the connector includes at least a left ventricular

(V_L) tip terminal **44**, a left atrial (A_L) ring terminal **46**, and a left atrial (A_L) shocking terminal (coil) **48**, which are adapted for connection to the left ventricular tip electrode **26**, the left atrial ring electrode **27**, and the left atrial coil electrode **28**, respectively.

[0049] To support right ventricular sensing, pacing and/or shocking, the connector further includes a right ventricular (V_R) tip terminal **52**, a right ventricular (V_R) ring terminal **54**, a right ventricular (R_V) shocking terminal (coil) **56**, and an SVC shocking terminal (coil) **58**, which are adapted for connection to the right ventricular tip electrode **32**, right ventricular ring electrode **34**, the RV coil electrode **36**, and the SVC coil electrode **38**, respectively. Thus, the embodiment of FIG. 1 includes one connection port for the right atrial lead **20** and two bipolar, high-voltage connection ports for the right ventricular lead **30** and the coronary sinus lead **24**, allowing sensing and stimulation in all four chambers of the heart.

[0050] In alternative embodiments, the stimulation device **10** may include a multi-port connector capable of accommodating any combination of three, four or more uni-polar, bi-polar or multi-polar leads. The arrangement and type of leads used may vary depending on the type of stimulation therapy to be delivered and individual patient need. In a preferred embodiment, to be described later in conjunction with FIG. 3, four bipolar connection ports are provided to accommodate a programmable selection of unipolar, bipolar or combination stimulation and sensing in any or all four chambers of the heart, or at four sites within the heart **12**.

[0051] At the core of the stimulation device **10** is a programmable microcontroller **60** that controls the various modes of stimulation therapy. As is well known in the art, the microcontroller **60** typically includes a microprocessor, or equivalent control circuitry, designed specifically for controlling the delivery of stimulation therapy, and may further include RAM or ROM memory, logic and timing circuitry, state machine circuitry, and I/O circuitry. Typically, the microcontroller **60** includes the ability to process or monitor input signals (data) as controlled by a program code stored in a designated block of memory. The details of the design and operation of the microcontroller **60** are not critical to the present invention. Rather, any suitable microcontroller **60** may be used that carries out the functions described herein. The use of microprocessor-based control circuits for performing timing and data analysis functions are well known in the art.

[0052] As shown in FIG. 2, an atrial pulse generator **70** and a ventricular pulse generator **72** generate pacing stimulation pulses for delivery by the right atrial lead **20**, the right ventricular lead **30** and/or the coronary sinus lead **24**, via the switch bank **74**. It is understood that in order to provide stimulation therapy in each of the four chambers of the heart, or at multiple sites within one or more chambers, the atrial pulse generator **70** and the ventricular pulse generator **72** include dedicated, independent pulse generators, multiplexed pulse generators, or shared pulse generators. However, in order to provide independent stimulation at each stimulation site, atrial pulse generator **70** and ventricular pulse generator **72** include independent output circuits for each stimulation site that allow delivery of unique stimulation pulses to each site.

[0053] The atrial pulse generator **70** in FIG. 2 thus includes a right atrial output circuit for delivering stimula-

tion pulses to the right atrium via right atrial lead **20**, and further includes a left atrial output circuit for delivering stimulation pulses to the left atrium via coronary sinus lead **24**. The ventricular pulse generator **72** includes a right ventricular output circuit for delivering stimulation pulses to the right ventricle via right ventricular lead **30**, and further includes a left ventricular output circuit for delivering stimulation pulses to the left ventricle via the coronary sinus lead **24**. The atrial pulse generator **70** and the ventricular pulse generator **72** are controlled by the microcontroller **60** via appropriate control signals **76** and **78**, respectively, to trigger or inhibit the stimulation pulses.

[**0054**] The microcontroller **60** further includes timing control circuitry **79** which is used to control the timing of such stimulation pulses (e.g. pacing rate, atrio-ventricular (AV) delay, interatrial conduction (A-A) delay, or interventricular conduction (V-V) delay, etc.), as well as to keep track of the timing of refractory periods, PVARP intervals, noise detection windows, evoked response windows, alert intervals, marker channel timing, etc.

[**0055**] In accordance with one embodiment of the present invention, the timing control circuitry **79** is also used to control coupling intervals, which precisely control the stimulation sequence during multi-chamber or multi-site stimulation. For example, the interatrial conduction (A-A) delay may be determined by programmable selection of coupling intervals defined according to whether an intrinsic atrial depolarization is first sensed in the right atrium or in the left atrium. A right-to-left atrial coupling interval may be programmed to control the time between a right atrial detected event (P-wave) and the delivery of a left atrial stimulation pulse. A different left-to-right atrial coupling interval may be programmed to control the time between a left atrial detected P-wave and right atrial stimulation pulse delivery.

[**0056**] Furthermore, different coupling intervals may be defined in relation to paced events than detected events. Hence, the coupling interval between a right atrial paced event and a left atrial paced event may be different than the coupling interval between a right atrial detected event (intrinsic P-wave) and a left atrial paced event. In other words, for each stimulation site, a unique coupling interval between it and all other stimulation sites may be defined in relation to both paced events and detected events occurring at that site. Details regarding the application of coupling intervals as provided by the present invention will be described later in conjunction with **FIGS. 5 through 10**.

[**0057**] The switch bank **74** includes a plurality of switches for connecting the desired electrodes to the appropriate I/O circuits, thereby providing complete electrode programmability. Accordingly, the switch bank **74**, in response to a control signal **80** from the microcontroller **60**, determines the polarity of the stimulation pulses (e.g. unipolar, bipolar, combined manner, etc.) by selectively closing the appropriate combination of switches (not shown).

[**0058**] In addition to providing programmable stimulation polarity, the stimulation device **10** includes the programmable polar assignments of each electrode during bipolar or unipolar stimulation. For stimulation using a bipolar lead, either electrode of the bipolar lead may be designated as the cathode with the other electrode designated as the anode. For example, in right ventricular stimulation using the right

ventricular lead **30**, the right ventricular tip electrode **32** may be programmed to be the anode with the right ventricular ring electrode **34** programmed to be the cathode. In other cases, the right ventricular tip electrode **32** may be programmed to be the cathode with the right ventricular ring electrode **34** programmed to be the anode.

[**0059**] Bi-chamber stimulation may be achieved in a cross-chamber fashion using at least one electrode located in one chamber of the heart and another electrode in the opposite heart chamber with each electrode programmable as the cathode or the anode. For example bi-ventricular stimulation may be provided in a cross-chamber manner between the right ventricular tip electrode **32** and left ventricular tip electrode **26**, by connecting these two tip electrodes to ventricular pulse generator **72** via switch bank **74**.

[**0060**] One embodiment of the present invention further provides the programmable assignment of cathode and anode poles in the following cross-chamber biventricular stimulation configuration: The left ventricular tip electrode **26** may be selected as the cathode with the right ventricular tip electrode **32** selected as the anode to achieve one directionality and stimulation threshold.

[**0061**] Alternatively, the left ventricular tip electrode **26** may be selected as the anode and the right ventricular tip electrode **32** may be selected as the cathode, to achieve a different directionality and stimulation threshold. In this way, the selection of cathode and anode assignments may be tailored to meet the individual patient's need during bi-atrial, bi-ventricle or single-chamber combined stimulation (using electrodes located on two or more leads).

[**0062**] In some patients it may be advantageous to provide anodal stimulation rather than cathodal stimulation. Hence, it is one feature of the present invention to further allow assignment of the active electrode used in unipolar stimulation to be the anode with the housing **40** assigned as the cathode. For example, unipolar anodal stimulation of the right ventricle may be achieved by designating the right ventricular ring electrode **54** as the anode and the housing **40** as the cathode.

[**0063**] The programmable designation of electrode poles is preferably accomplished via electronic switching devices controlled by logic gates receiving high or low signals under the control of microprocessor **60**. For details regarding a switching circuitry that may be used for providing programmable selection of stimulation and sensing electrode configurations, refer to U.S. Pat. No. 4,991,583 to Silvian, hereby incorporated herein by reference.

[**0064**] Atrial sensing circuit **82** and ventricular sensing circuit **84** may also be selectively coupled to the right atrial lead **20**, coronary sinus lead **24**, and the right ventricular lead **30**, through the switch bank **74**, for detecting the presence of cardiac activity in each of the four chambers of the heart. In order to detect events occurring within each chamber or at each stimulation site independently, the atrial and ventricular sensing circuits **82** and **84** include dedicated independent sense amplifiers associated with each stimulation site within the heart **12**. As used herein, each of the atrial sensing circuit **82** and the ventricular sensing circuit **84** includes a discriminator, which is a circuit that senses and can indicate or discriminate the origin of a cardiac signal in each of the cardiac chambers.

[0065] The inputs to each sense amplifier are programmable and may be selected in any combination of available electrode terminals in order to provide independent unipolar or bipolar sensing at each stimulation site. In this way, a detected atrial event may be distinguished as being a right atrial event or a left atrial event. Likewise, a detected ventricular event may be distinguished as a right ventricular event or a left ventricular event.

[0066] If the stimulation device **10** is being used for multisite stimulation within a chamber of the heart, one electrode might be positioned in the upper area of the chamber and a second electrode might be positioned in a lower area of the same chamber or any two distinct locations within that chamber. Unique sensing circuitry for each electrode allows discrimination of a detected event as occurring in either the upper area or the lower area of the chamber. The stimulation response provided by the device **10** may then be determined based on the location of a detected event.

[0067] Additionally, cross-chamber sensing for bi-atrial or bi-ventricular sensing during multichamber stimulation or sensing between two electrodes located on two different leads positioned within a single chamber of the heart for multisite stimulation may be selected by programming the appropriate inputs to the individual sense amplifiers. The switch bank **74** determines the sensing configuration by selectively closing the appropriate switches. In this way, the clinician may program the sensing polarity (e.g. unipolar or bipolar) independent of the stimulation polarity.

[0068] Just as the cathode and anode assignments during stimulation are programmable, one embodiment of the present invention may also provide for the programmability of the cathode and anode assignments during sensing. If the electrodes selected for sensing are the same as those for stimulation, the cathode and anode assignments during sensing may be the same as that used for stimulation or different than that used for stimulation. Thus, the sensing electrode configuration and cathode and anode assignments can be programmed to achieve a desired sensing threshold in each heart chamber, or each region of a heart chamber, in which event detection is desired.

[0069] Each of the atrial sensing circuit **82** or the ventricular sensing circuit **84** preferably employs one or more low power, precision amplifiers with programmable gain and/or automatic gain control, bandpass filtering, and a threshold detection circuit, to selectively sense the cardiac signal of interest. The automatic gain control enables the stimulation device **10** to deal effectively with the difficult problem of sensing the low amplitude signal characteristics of atrial or ventricular fibrillation. The outputs of the atrial and ventricular sensing circuits **82** and **84** are connected to the microcontroller **60** for triggering or inhibiting the atrial and ventricular pulse generators **70** and **72**, respectively, in a demand fashion, in response to the absence or presence of cardiac activity, respectively, in the appropriate chambers of the heart.

[0070] One feature of the present invention is to provide precise control of the activation sequence of stimulated. To this end, the stimulation device **10** may act only in a trigger mode thereby gaining complete control of the heart rhythm in an attempt to provide a more hemodynamically effective contraction sequence of the heart chambers than that produced by the natural heart rhythm.

[0071] Preferably, the stimulation device **10** operates in a trigger mode in controlling the timing of contraction at all the stimulation sites. Alternatively, it may operate in a demand mode in delivering or inhibiting stimulation pulses to at least one site, and may operate in a trigger mode in delivering stimulation pulses to all other stimulation sites. For example, atrial pulse generator **70** may be inhibited from delivering a right atrial stimulation pulse when atrial sensing circuit **82** detects an intrinsic P-wave in the right atrium within a given escape interval. However, this detection may cause microcontroller **60** to trigger atrial pulse generator **70** and ventricular pulse generator **72** to deliver stimulation pulses at prescribed intervals of time to the left atrium and the right and left ventricles, respectively, regardless of any events detected in these chambers. In this way, the activation sequence of all four heart chambers is precisely controlled by the natural pacemaking activity of the sinus node. Hence, in the present invention, the pacing mode of stimulation device **10**, that is demand or trigger mode, for each stimulation site is preferably programmable.

[0072] If the cardiac stimulation device **10** is also intended for delivering cardioversion and defibrillation therapy, arrhythmia detection by the stimulation device **10** utilizes the atrial and ventricular sensing circuits **82** and **84** to sense cardiac signals, for determining whether a rhythm is physiologic or pathologic. As used herein "sensing" is reserved for the noting of an electrical signal, and "detection" is the processing of these sensed signals and noting the presence of an arrhythmia. The timing intervals between sensed events (e.g. P-waves, R-waves, and depolarization signals associated with fibrillation which are sometimes referred to as "F-waves" or "Fib-waves") are then classified by the microcontroller **60** by comparing them to a predefined rate zone limit (e.g. bradycardia, normal, low rate VT, high rate VT, and fibrillation rate zones) and various other characteristics (e.g. sudden onset, stability, physiologic sensors, and morphology, etc.) in order to determine the type of remedial therapy that is needed (e.g. bradycardia pacing, anti-tachycardia pacing, cardioversion shocks or defibrillation shocks, collectively referred to as "tiered therapy").

[0073] Cardiac signals are also applied to the inputs of an analog-to-digital (A/D) data acquisition system **90**. The data acquisition system **90** is configured to acquire intracardiac electrogram (EGM) signals, convert the raw analog data into digital signals, and store the digital signals for later processing and/or telemetric transmission to an external device **102**. The data acquisition system **90** is coupled to the right atrial lead **20**, the coronary sinus lead **24**, and the right ventricular lead **30** through the switch bank **74** to sample cardiac signals across any pair of desired electrodes.

[0074] The microcontroller **60** is further coupled to a memory **94** by a suitable data/address bus **96**, wherein the programmable operating parameters used by the microcontroller **60** are stored and modified, as required, in order to customize the operation of the stimulation device **10** to suit the needs of a particular patient. Such operating parameters define, for example, pacing pulse amplitude, pulse duration, electrode polarity, rate, sensitivity, automatic features, arrhythmia detection criteria, and the amplitude, wave shape and vector of each shocking pulse to be delivered to the patient's heart **12** within each respective tier of therapy.

[0075] Advantageously, the operating parameters of the stimulation device **10** may be non-invasively programmed

into the memory 94 through a telemetry circuit 100 in telemetric communication with the external device 102, such as a programmer, transtelephonic transceiver, or a diagnostic system analyzer. The telemetry circuit 100 is activated by the microcontroller 60 by a control signal 106. The telemetry circuit 100 advantageously allows intracardiac electrograms and status information relating to the operation of the stimulation device 10 (as contained in the microcontroller 60 or memory 94) to be sent to the external device 102 through the established communication link 104.

[0076] The stimulation device 10 may further include a physiologic sensor 108, commonly referred to as a "rate-responsive" sensor because it is typically used to adjust pacing stimulation rate according to the exercise state of the patient. However, the physiological sensor 108 may further be used to detect changes in cardiac output, changes in the physiological condition of the heart, or diurnal changes in activity (e.g. detecting sleep and wake states). Accordingly, the microcontroller 60 responds by adjusting the various pacing parameters (such as rate, AV Delay, V-V Delay, etc.) at which the atrial and ventricular pulse generators 70 and 72 generate stimulation pulses.

[0077] In accordance with one feature of the present invention, coupling intervals that determine the activation sequence of stimulated chambers or sites, may be adjusted based on changes detected by the physiologic sensor 108. Preferably physiologic sensor 108 includes detection of changes related to the hemodynamic state of the patient and thereby allows adjustment of the coupling intervals to be made in a way that optimizes the hemodynamic response to multisite or multichamber stimulation. One method for accomplishing automatic adjustment of coupling intervals based on physiologic sensor 108 data will be described in detail in conjunction with FIG. 10.

[0078] While the physiologic sensor 108 is shown as being included within the stimulation device 10, it is to be understood that the physiologic sensor 108 may alternatively be external to the stimulation device 10, yet still be implanted within, or carried by the patient. A common type of rate responsive sensor is an activity sensor, such as an accelerometer or a piezoelectric crystal, which is mounted within the housing 40 of the stimulation device 10. Other types of physiologic sensors are also known, for example, sensors which sense the oxygen content of blood, cardiac output, respiration rate and/or minute ventilation, pH of blood, ventricular gradient, etc. However, any sensor may be used which is capable of sensing a physiological parameter, which corresponds to the exercise or hemodynamic state of the patient.

[0079] The stimulation device 10 additionally includes a power source such as a battery 110 that provides operating power to all the circuits shown in FIG. 2. For the stimulation device 10, which employs shocking therapy, the battery 110 must be capable of operating at low current drains for long periods of time, and also be capable of providing high-current pulses (for capacitor charging) when the patient requires a shock pulse. The battery 110 must preferably have a predictable discharge characteristic so that elective replacement time can be detected. Accordingly, the stimulation device 10 can employ, for example, lithium/silver vanadium oxide batteries.

[0080] As further shown in FIG. 2, the stimulation device 10 is shown as having an impedance measuring circuit 112

which is enabled by the microcontroller 60 by a control signal 114. The known uses for an impedance measuring circuit 120 include, but are not limited to, lead impedance surveillance during the acute and chronic phases for assessing the mechanical integrity of the lead; detecting operable electrodes and automatically switching to an operable pair if mechanical disruption occurs in one lead; measuring respiration or minute ventilation; detecting when the device has been implanted; and a variety of hemodynamic variables such as measuring stroke volume; and detecting the opening of the valves, etc. The impedance measuring circuit 120 is advantageously coupled to the switch bank 74 so that any desired electrode may be used.

[0081] The impedance measuring circuit 112 may be used advantageously in the present invention for monitoring hemodynamic indicators, such as ventricular impedance as an indication of cardiac output, to provide feedback in the selection of optimal coupling intervals. Impedance measuring circuit 112 may be used alone or in conjunction with physiological sensor 108 for providing such feedback. This data may be periodically stored in memory 94 such that a physician may then access this data during patient follow-up visits to obtain useful information in manually selecting and programming coupling intervals. Preferably, this data may be used by the stimulation device 10 to automatically adjust coupling intervals as will be described in conjunction with FIG. 10.

[0082] In cases where a primary function of the stimulation device 10 is to operate as an implantable cardioverter/defibrillator (ICD) device, it must detect the occurrence of an arrhythmia, and automatically apply an appropriate anti-tachycardia pacing (ATP) and/or electrical shock therapy to the heart aimed at terminating the detected arrhythmia. To this end, the microcontroller 60 further controls a shocking circuit 116 by way of a control signal 118. The shocking circuit 116 generates shocking pulses of low (up to 0.5 Joules), moderate (0.5-10 Joules), or high (11 to 40 Joules) energy, as controlled by the microcontroller 60. Such shocking pulses are applied to the patient's heart through at least two shocking electrodes, and as shown in this embodiment, selected from the left atrial coil electrode 28, the RV coil electrode 36, and/or the SVC coil electrode 38 (FIG. 1). As noted earlier, the housing 40 may act as an active electrode in combination with the RV electrode 36, or as part of a split electrical vector using the SVC coil electrode 38 or the left atrial coil electrode 28 (i.e., using the RV electrode as common electrode).

[0083] Cardioversion shocks are generally considered to be of low to moderate energy level (so as to minimize pain felt by the patient), and/or synchronized with an R-wave and/or pertaining to the treatment of tachycardia. Defibrillation shocks are generally of moderate to high energy level (i.e., corresponding to thresholds in the range of 5-40 Joules), delivered asynchronously (since R-waves may be too disorganized), and pertaining exclusively to the treatment of fibrillation. Accordingly, the microcontroller 60 is capable of controlling the synchronous or asynchronous delivery of the shocking pulses.

[0084] FIG. 3 illustrates a preferred embodiment of the present invention showing one bipolar lead 20 implanted in the right atrium, one bipolar lead 21 implanted in the coronary sinus region adjacent to left atrium, one bipolar

high-voltage lead **30** implanted in the right ventricle, and another bipolar high-voltage lead **31** implanted in the coronary venous region adjacent to the left ventricle. Using this electrode configuration with the stimulation device **10**, independent unipolar or bipolar stimulation and sensing of either or both atria is possible with programmable cathode and anode assignments of each electrode selected for stimulation and/or sensing. Alternatively, cross-chamber bi-atrial stimulation or sensing can be performed with the cathode assigned to an electrode located in one atrium, either the right or left atrium, and the anode assigned to an electrode located in the other atrium. In the arrangement of **FIG. 3**, the cathode may be assigned to the right atrial tip electrode **22** or the right atrial ring electrode **23** with the anode assigned to the left atrial ring electrode **27** or left atrial tip electrode **29**, or vice versa, as necessary.

[**0085**] In addition, independent unipolar or bipolar stimulation and sensing can be provided separately in the right and left ventricles with programmable cathode and anode assignments of each electrode selected for stimulation and/or sensing. Alternatively, cross-chamber bi-ventricular stimulation or sensing can be performed with the cathode assigned to an electrode located in one ventricle, either the right or left ventricle, and the anode assigned to an electrode located in the other ventricle. In the arrangement of **FIG. 3**, the cathode may be assigned to right ventricular tip electrode **32** or right ventricular ring electrode **34** and the anode assigned to the left ventricular ring electrode **25** or left ventricular tip electrode **26**, or vice versa, as necessary.

[**0086**] The programmable electrode assignments for the embodiment shown in **FIG. 3** are listed in the following TABLES I through VI. Possible electrode assignments for right ventricular unipolar or bipolar stimulation or sensing are listed in TABLE I. Possible electrode assignments for left ventricular unipolar or bipolar stimulation or sensing are listed in TABLE II. Possible electrode assignments for cross-chamber ventricular stimulation or sensing are listed in TABLE III. Possible electrode assignments for right atrial unipolar or bipolar stimulation or sensing are listed in TABLE IV. Possible electrode assignments for left atrial unipolar or bipolar stimulation or sensing are listed in TABLE V. Possible electrode assignments for cross-chamber atrial stimulation or sensing are listed in TABLE VI.

TABLE I

Programmable electrode assignments available for right ventricular stimulation or sensing:		
RIGHT VENTRICULAR TIP ELECTRODE 32	RIGHT VENTRICULAR RING ELECTRODE 34	DEVICE HOUSING 40
<u>UNIPOLAR CONFIGURATIONS:</u>		
Anode	Disconnected	Cathode
Cathode	Disconnected	Anode
Disconnected	Anode	Cathode
Disconnected	Cathode	Anode
<u>BIPOLAR CONFIGURATIONS:</u>		
Anode	Cathode	Disconnected
Cathode	Anode	Disconnected

[**0087**]

TABLE II

Programmable electrode assignments available for left ventricular stimulation or sensing:		
LEFT VENTRICULAR TIP ELECTRODE 26	LEFT VENTRICULAR RING ELECTRODE 25	DEVICE HOUSING 40
<u>UNIPOLAR CONFIGURATIONS:</u>		
Anode	Disconnected	Cathode
Cathode	Disconnected	Anode
Disconnected	Anode	Cathode
Disconnected	Cathode	Anode
<u>BIPOLAR CONFIGURATIONS:</u>		
Anode	Cathode	Disconnected
Cathode	Anode	Disconnected

[**0088**]

TABLE III

Programmable electrode assignments available for cross-chamber ventricular stimulation or sensing:				
RIGHT VENTRICULAR TIP ELECTRODE 32	RIGHT VENTRICULAR RING ELECTRODE 34	LEFT VENTRICULAR TIP ELECTRODE 26	LEFT VENTRICULAR RING ELECTRODE 25	DEVICE HOUSING 40
Anode	Disconnected	Cathode	Disconnected	Disconnected
Anode	Disconnected	Disconnected	Cathode	Disconnected
Cathode	Disconnected	Anode	Disconnected	Disconnected
Cathode	Disconnected	Disconnected	Anode	Disconnected
Disconnected	Anode	Cathode	Disconnected	Disconnected
Disconnected	Anode	Disconnected	Cathode	Disconnected
Disconnected	Cathode	Anode	Disconnected	Disconnected
Disconnected	Cathode	Disconnected	Anode	Disconnected

[**0089**]

TABLE IV

Programmable electrode assignments available for right atrial stimulation or sensing:		
RIGHT ATRIAL TIP ELECTRODE 22	RIGHT ATRIAL RING ELECTRODE 23	DEVICE HOUSING 40
<u>UNIPOLAR CONFIGURATIONS:</u>		
Anode	Disconnected	Cathode
Cathode	Disconnected	Anode
Disconnected	Anode	Cathode
Disconnected	Cathode	Anode
<u>BIPOLAR CONFIGURATIONS:</u>		
Anode	Cathode	Disconnected
Cathode	Anode	Disconnected

[0090]

TABLE V

Programmable electrode assignments available for left atrial stimulation or sensing:		
LEFT ATRIAL TIP ELECTRODE 29	LEFT ATRIAL RING ELECTRODE 27	DEVICE HOUSING 40
UNIPOLAR CONFIGURATIONS:		
Anode	Disconnected	Cathode
Cathode	Disconnected	Anode
Disconnected	Anode	Cathode
Disconnected	Cathode	Anode
BIPOLAR CONFIGURATIONS:		
Anode	Cathode	Disconnected
Cathode	Anode	Disconnected

[0091]

TABLE VI

Programmable electrode assignments available for cross-chamber atrial stimulation or sensing:				
RIGHT ATRIAL TIP ELEC-TRODE 22	RIGHT ATRIAL RING ELEC-TRODE 23	LEFT ATRIAL TIP ELEC-TRODE 29	LEFT ATRIAL RING ELEC-TRODE 27	DEVICE HOUSING 40
Anode	Dis-connected	Cathode	Dis-connected	Disconnected
Anode	Dis-connected	Dis-connected	Cathode	Disconnected
Cathode	Dis-connected	Anode	Dis-connected	Disconnected
Cathode	Dis-connected	Dis-connected	Anode	Disconnected
Dis-connected	Anode	Cathode	Dis-connected	Disconnected
Dis-connected	Anode	Dis-connected	Cathode	Disconnected
Dis-connected	Cathode	Anode	Dis-connected	Disconnected
Dis-connected	Cathode	Dis-connected	Anode	Disconnected

[0092] In the embodiment of FIG. 3, and as further illustrated in FIG. 4, the stimulation device 10 is illustrated to include four bipolar connection ports 299, 210, 220, 230. A left ventricular connection port (LV connection port) 200 accommodates the left ventricular lead (LV lead) 24 with terminals 44, 45, 48 that are associated with the left ventricular tip electrode (LV tip electrode) 26, the left ventricular ring electrode (LV ring electrode) 25, and the left ventricular coil electrode (LV coil electrode) 28, respectively.

[0093] A left atrial connection port (LA connection port) 210 accommodates the left atrial lead (LA lead) 21 with terminals 49, 47 that are associated with the left atrial tip electrode (LA tip electrode) 29, and the left atrial ring electrode (LA ring electrode) 27, respectively.

[0094] A right ventricular connection port (RV connection port) 220 accommodates the right ventricular lead (RV lead) 30 with terminals 52, 54, 56, 58 that are associated with the right ventricular tip electrode (RV tip electrode) 32, the right

ventricular ring electrode (RV ring electrode) 34, the right ventricular coil electrode (RVCE) 36, and the right ventricular SVC coil electrode (RV SVC coil electrode) 38, respectively.

[0095] A right atrial connection port (RA connection port) 230 accommodates the right atrial lead (RA lead) 20 with terminals that are associated with the right atrial tip electrode (RA tip electrode) 22 and the right atrial ring electrode (RA ring electrode) 23, respectively.

[0096] It is recognized that numerous variations exist in which combinations of unipolar, bipolar and/or multipolar leads may be positioned at desired locations within the heart in order to provide multichamber or multisite stimulation. The illustrated embodiments of the present invention provide for the flexibility of independent stimulation and/or sensing at multiple sites by providing a cardiac stimulation device that includes multiple connection ports with unique terminals for the electrode(s) associated with each stimulation site as well as independent sensing and output circuitry for each stimulation site. As such, stimulation and sensing sites are not obligatorily coupled together by adapters or hardwiring within the stimulation device that would otherwise preclude independent sensing and stimulation at each site during either multichamber or multisite stimulation.

[0097] Furthermore, and as indicated by Tables I through VI, above, each terminal may be selectively connected or disconnected to a desired voltage potential such that the corresponding electrode may function as either the cathode or the anode or neither during stimulation or sensing.

[0098] In the embodiment of FIG. 4A the electrode switch bank 74 of device 10 includes a plurality of paired parallel switches 120 through 138, corresponding to each electrode terminal. The paired switches, when closed one at a time, selectively connect each electrode terminal to either a positive (or relatively positive) voltage potential 140 or a negative (or relatively negative) voltage potential 142. If the paired switches are opened, the corresponding electrode terminal is electrically disconnected so that the associated electrode is unused during stimulation or sensing. The microcontroller 60 (FIG. 2) controls the opening and closing of switches 120 through 138 by sending logic commands via control signal 80 to electrode configuration switch 74 (FIG. 2).

[0099] More specifically, switches 120 and 121 connect or disconnect the left ventricular tip terminal 44; switches 122 and 123 connect or disconnect the left ventricular ring terminal 45; switches 125 and 126 connect or disconnect the left atrial tip terminal 49; switches 127 and 128 connect or disconnect the left atrial ring terminal 47; switches 129 and 130 connect or disconnect the case electrode 40; switches 131 and 132 connect or disconnect the right ventricular ring terminal 54; switches 133 and 134 connect or disconnect the right ventricular tip terminal 52; switches 135 and 136 connect or disconnect the right atrial tip terminal 42; and switches 137 and 138 connect or disconnect the right atrial ring terminal 43.

[0100] In one example, if the bipolar left ventricular stimulation or sensing is programmed with the left ventricular tip electrode 26 programmed to function as the cathode and the left ventricular ring electrode 25 programmed to function as the anode, switch 121 is closed to connect the left

ventricular tip electrode to a negative voltage potential **142**. In addition, switch **122** is closed to connect the left ventricular ring electrode **25** to a positive voltage potential **140**. Switches **120** and **123** would remain open. These anode and cathode assignments could be reversed by opening switches **121** and **122** and closing switches **120** and **123**, thereby connecting the left ventricular tip electrode **26** (now the anode) to a positive voltage potential **140** and the left ventricular ring electrode **25** (now the cathode) to a negative voltage potential **142**, respectively.

[**0101**] In another example, if cross-chamber ventricular stimulation or sensing is programmed with the right ventricular tip electrode programmed as the cathode and the left ventricular tip electrode programmed as the anode, then the right ventricular tip electrode **32** is connected to the negative voltage potential **142** by closing switch **134**, and the left ventricular tip electrode **26** is connected to the positive voltage potential **140** by closing switch **120**. Switches **133** and **121** would remain open.

[**0102**] The anode and cathode assignments in this example could be reversed by opening switches **134** and **120** and closing parallel switches **133** and **121**, thus connecting right ventricular tip electrode **32** (now the anode) to a positive voltage potential **140** and left ventricular tip electrode **26** (now the cathode) to a negative voltage potential **142**, respectively.

[**0103**] In either situation of anode and cathode assignments applied to the right ventricular tip electrode **32** and the left ventricular tip electrode **26** during this cross-chamber stimulation or sensing configuration, the right ventricular ring electrode **34** and left ventricular ring electrode **25** would be unused and therefore electrically disconnected by opening both pairs of switches (**131**, **132**), and (**122**, **123**), respectively.

[**0104**] Thus, it is seen that by selectively opening and closing switches **120** through **138**, each electrode can be electrically connected or disconnected as needed, and, when connected, selected as a cathode or as an anode.

[**0105**] **FIGS. 5 and 6** illustrate a flow chart describing methods of operation **200** and **300**, respectively, that are implemented in one embodiment of the stimulation device **10** in which defined coupling intervals are applied by microcontroller **60** for controlling the sequence of stimulation pulse delivery by the atrial pulse generator **70** and the ventricular pulse generator **72**. In this flow chart, and the other flow charts described herein, the various algorithmic steps are summarized in individual "blocks". Such blocks describe specific actions or decisions that must be made or carried out as the algorithm proceeds. Where a microcontroller (or equivalent) is employed, the flow charts presented herein provide the basis for a "control program" that may be used by such a microcontroller (or equivalent) to effectuate the desired control of the stimulation device. Those skilled in the art may readily write such a control program based on the flow charts and other descriptions presented herein.

[**0106**] The methods **200** and **300** will be described in relation to the implant configuration of **FIG. 3**, where sensing and pacing are performed in the right atrium, left atrium, right ventricle and left ventricle. It is recognized that the algorithmic steps illustrated in **FIGS. 5 and 6** may easily be modified to control the stimulation sequence during any multi-chamber or multi-site stimulation configuration.

[**0107**] At the time of implant, coupling intervals are programmed by the physician to precisely control the activation sequence of all four chambers whenever stimulation pulse delivery is required. Default nominal values stored in the stimulation device **10** may also be selected. Coupling intervals are defined in association with stimulated and sensed events occurring at each stimulation site. For example, the delivery of a right atrial stimulation pulse by the atrial pulse generator **70** will cause microcontroller **60** to initiate three coupling intervals: one associated with the left atrium; another associated with the right ventricle; and yet another associated with the left ventricle. These coupling intervals control the time between the delivery of the right atrial stimulation pulse and the delivery of the left atrial, right ventricular, and left ventricular stimulation pulses, respectively.

[**0108**] Likewise, the detection of a P-wave in the right atrium by the atrial sense circuitry **82** will also cause microcontroller **60** to initiate three coupling intervals associated with the left atrium, right ventricle, and left ventricle. However, these coupling intervals may be different than the coupling intervals initiated due to a right atrial paced event. Similarly, left atrial coupling intervals are defined for the case of a left atrial event being detected before a right atrial event for controlling the time between the left atrial detection and right atrial stimulation, right ventricular stimulation and left ventricular stimulation. In addition, the system can be configured to deliver the left atrial stimulus before the right atrial stimulus, or the left ventricular stimulus before the right ventricular stimulus.

[**0109**] The method **200** and **300** of **FIGS. 5 and 6** represent the application of these coupling intervals over one cardiac cycle. It is assumed in this example, that the stimulation device **10** is programmed to operate in a demand mode in the atrial channels and in a triggered mode in the ventricular channels although, it can be set to operate in the triggered mode in both the atrium and ventricle or the triggered mode in the atrium and the demand mode in the ventricle. The operation of device **10** is therefore programmable to be either a demand or trigger mode in each chamber or at each stimulation site.

[**0110**] Starting at step **202**, a new escape interval is initiated. The length of this escape interval is determined by the programmed base pacing (or stimulation) rate. For example, if the base pacing rate is programmed to be 60 beats per minute, then the escape interval is 1000 msec. Method **200** waits for the detection of an intrinsic P-wave by atrial sense circuit **82** prior to expiration of the escape interval.

[**0111**] If at decision step **204** the method **200** determines that the escape interval has expired before an intrinsic P-wave is detected, microprocessor **60** triggers the right atrial output circuitry in the atrial pulse generator **70** to deliver a stimulation pulse to the right atrium at step **206**, according to the programmed electrode configuration for stimulation in the right atrium.

[**0112**] The delivery of a right atrial stimulation pulse causes microprocessor **60** to trigger timing control circuitry **79** to start three separate timers simultaneously at step **208**. As it is illustrated in **FIG. 7**, one timer initiates a right atrial pace to left atrium (RAPace to LA) coupling interval at step **325**. Another timer initiates a right atrial pace to right

ventricle (RApace to RV) coupling interval at step 335. The third timer simultaneously initiates a right atrial pace to left ventricle (RApace to LV) coupling interval at step 345. Upon expiration of the coupling intervals, the stimulation device 10 delivers the required stimulation pulses at step 310.

[0113] FIG. 7 illustrates further details of step 310. Upon expiration of the right atrial pace to left atrium (RApace to LA) coupling interval (step 325), method 300 inquires, at decision step 326, if an intrinsic left atrial depolarization (P-wave) is detected. If it is, method 300 inhibits the delivery of a left atrial stimulation pulse at step 328. If an intrinsic left atrial depolarization is not detected at step 326, the microcontroller 60 triggers the left atrial output circuitry of atrial pulse generator 70 to deliver a left atrial (LA) stimulation pulse at step 327.

[0114] Similarly, upon expiration of the right atrial pace to left atrium (RApace to RV) coupling interval at step 335, method 300 inquires, at decision step 336, if an intrinsic right ventricular depolarization (R-wave) is detected. If it is, method 300 inhibits the delivery of a right ventricular stimulation pulse at step 338. If an intrinsic right ventricular depolarization is not detected at step 336, the microcontroller 60 triggers the right atrial output circuitry of the ventricular pulse generator 72 to deliver a right ventricular (RV) stimulation pulse at step 337.

[0115] In a similar manner, upon expiration of the right atrial pace to left ventricle (RApace to LV) coupling interval at step 345, method 300 inquires, at decision step 346, if an intrinsic left ventricular depolarization (R-wave) is detected. If it is, method 300 inhibits the delivery of a left ventricular stimulation pulse at step 348. If an intrinsic left ventricular depolarization is not detected at step 346, the microprocessor 60 triggers the left atrial output circuitry of the ventricular pulse generator 72 to deliver a left ventricular (LV) stimulation pulse at step 347.

[0116] With respect to steps 328, 338, and 348, if a sensed event occurs on the atrial channel or the ventricular channel, method 300 detects the chamber in which the sensed event originated and the times the delivery of the output pulse to the other chamber in accord with the automatic or physician set interval.

[0117] After the expiration of all these three coupling intervals and the delivery of triggered stimulation to the designated stimulation sites, method 300 returns to step 202 where the microprocessor 60 initiates a new escape interval to start the next cardiac pacing cycle.

[0118] Returning now to FIGS. 5 and 6, if a P-wave is detected by the atrial sense circuitry 82 prior to the expiration of the escape interval at decision step 204, methods 200 and 300 determine, at decision step 216, if this detection has been made by the right atrial sensing circuitry or the left atrial sensing circuitry of the atrial sense circuit 82.

[0119] If a P-wave is detected at step 204 and the microprocessor 60 determines that the P-wave has been detected in the left atrial sense circuitry of atrial sense circuitry 82 at decision step 216, then the coupling intervals associated with a left atrial sense event are initiated by timing the control circuitry 79 at step 217. As it is illustrated in FIG. 8, a left atrial sense to right atrial (LASense to RA) coupling interval is initiated in one timer at step 425. This coupling

interval may or may not be equal to the coupling interval between the right and left atria associated with a detected right atrial event.

[0120] On a separate timer, the timing control circuitry 79 simultaneously initiates a left atrial sense to right ventricle (LASense to RV) coupling interval at step 435. Another timer starts the left atrial sense to left ventricle (LASense to LV) coupling interval at step 445. If a sensed event occurs within the designated coupling intervals, the timing of the stimulus output to the other chamber is based on the sensed event and not the output pulse in the atrium. Upon expiration of the coupling intervals, the stimulation device 10 delivers the required stimulation pulses at step 318.

[0121] FIG. 8 illustrates further details of step 318. Upon expiration of the left atrial sense to right atrial (LASense to RA) coupling interval at step 425, method 300 inquires, at decision step 426, if an intrinsic right atrial depolarization (P-wave) is detected. If it is, method 300 inhibits the delivery of a right atrial stimulation pulse at step 428. If an intrinsic left atrial depolarization is not detected at step 426, the microprocessor 60 triggers the right atrial output circuitry of the atrial pulse generator 70 to deliver a stimulation pulse to the right atrium at step 427.

[0122] Similarly, upon expiration of the left atrial to right ventricular (LASense to RV) coupling interval at step 435, method 300 inquires, at decision step 436, if an intrinsic right ventricular depolarization (R-wave) is detected. If it is, method 300 inhibits the delivery of a right ventricular stimulation pulse at step 438. If an intrinsic right ventricular depolarization is not detected at step 436, the microcontroller 60 triggers right ventricular output circuitry of the ventricular pulse generator 72 to deliver a stimulation pulse to the right ventricle at step 437.

[0123] In a similar manner, upon expiration of the left atrial to left ventricular (LASense to LV) coupling interval at step 445, method 300 inquires, at decision step 446, if an intrinsic left ventricular depolarization (R-wave) is detected. If it is, method 300 inhibits the delivery of a left ventricular stimulation pulse at step 348. If an intrinsic left ventricular depolarization is not detected at step 446, the microprocessor 60 triggers the left ventricular output circuit of the ventricular pulse generator 72 to deliver a stimulation pulse to the left ventricle at step 447.

[0124] Returning now to FIGS. 5 and 6, if the P-wave detection has been made in the right atrium, the microprocessor 60 commands the timing control circuitry 79 to simultaneously initiate three different timers at step 220. As it is illustrated in FIG. 9, one timer starts the right atrial sense to left atrium (RASense to LA) coupling interval (step 455). Another timer simultaneously starts the right atrial sense to right ventricle (RASense to RV) coupling interval (step 465). The third timer starts the right atrial sense to left ventricle (RASense to LV) coupling interval (step 475). These coupling intervals triggered by a right atrial sense event may be different than the coupling intervals triggered by a right atrial pace event as described above in conjunction with steps 425, 435, and 445. Upon expiration of the coupling intervals, the stimulation device 10 delivers the required stimulation pulses at step 322.

[0125] FIG. 9 illustrates further details of step 322. Upon expiration of the right atrial sense to left atrium (RASense to

LA) coupling interval at step 455, method 300 inquires, at decision step 456, if an intrinsic right atrial depolarization (P-wave) is detected. If it is, method 300 inhibits the delivery of a left atrial stimulation pulse at step 457. If an intrinsic left atrial depolarization is not detected at step 456, the microprocessor 60 triggers the left atrial output circuitry of the atrial pulse generator 70 to deliver a left atrial (LA) stimulation pulse at step 457.

[0126] Similarly, upon expiration of the right atrial pace to right ventricular (RApace to RV) coupling interval at step 465, method 300 inquires, at decision step 466, if an intrinsic right ventricular depolarization (R-wave) is detected. If it is, method 300 inhibits the delivery of a right ventricular stimulation pulse at step 468. If an intrinsic right ventricular depolarization is not detected at step 436, the microcontroller 60 triggers the ventricular pulse generator 72 to deliver a right ventricular (RV) stimulation pulse at step 467.

[0127] In a similar manner, upon expiration of the right atrial sense to left ventricular (RASense to LV) coupling interval at step 475, method 300 inquires, at decision step 476, if an intrinsic left ventricular depolarization (R-wave) is detected. If it is, method 300 inhibits the delivery of a left ventricular stimulation pulse at step 478. If an intrinsic left ventricular depolarization is not detected at step 476, the microprocessor 60 triggers the left atrial output circuitry of the ventricular pulse generator 72 to deliver a left ventricular (LV) stimulation pulse. After the expiration of these three coupling intervals and the delivery of triggered stimulation to the designated stimulation sites, method 300 returns to step 202 (FIG. 6) where the microprocessor 60 initiates a new escape interval to start the next cardiac cycle.

[0128] In this way, the sequential delivery of stimulation pulses to all four chambers of the heart is precisely controlled in order to provide coordinated depolarization of the cardiac chambers. In this example, the stimulation device 10 essentially operates in a demand pacing mode in the right and left atria and in a triggered pacing mode in the right and left ventricles, though other possibilities are similarly feasible, as described herein. Sensing within all of these chambers is still provided, however, in order to accommodate the tachycardia detection features of the stimulation device 10, and to utilize its ability to deliver shocking therapy in addition to pacing therapy as needed.

[0129] The programmed settings of the coupling intervals described in conjunction with FIG. 5 are preferably selected in a way that provides optimal hemodynamic benefit to the patient. A medical practitioner may manually program these settings based on clinical measurements of cardiac performance. It is recognized that the selection and programming of numerous coupling intervals associated with numerous stimulation sites could become a time-consuming task. Therefore, the selection of coupling intervals may be semi-automatic or completely automatic. For example, after manual programming of the most critical coupling intervals, the microprocessor 60 might calculate other coupling intervals based on mathematical relationships or patient's history stored in memory 90, or apply default values to other coupling intervals.

[0130] In an alternative embodiment of the present invention, the optimal coupling intervals may be selected automatically based on measurements of cardiac function or other physiological parameters that relate to the clinical

condition of the patient as measured by physiological sensor 108 and/or impedance measuring circuit 112.

[0131] FIG. 10 illustrates a method 500 for automatically adjusting the coupling intervals. The method 500 may be performed upon delivery of an external command, or on a programmed periodic basis, for example, daily. Method 500 starts at step 505 by verifying that the patient is at rest. Preferably, physiological measurements made for comparing cardiac state during different pacing modalities is performed only at rest in order to avoid confounding variables that may occur if the patient is engaged in varying levels of activity during the test. Various methods may be used to verify resting state, such as heart rate or other physiological sensor 108 measured parameters. For details regarding one method for verifying resting state reference is made to U.S. Pat. No. 5,476,483 to Bornzin.

[0132] At step 510, the microprocessor 60 determines the present pacing state of the stimulation device 10. If the device 10 is programmed to be operating in a demand mode in both the atrial and ventricular chambers, it may be in one of four pacing states: atrial pacing and ventricular pacing (AV pacing state), atrial pacing and ventricular sensing (AR pacing state), atrial sensing and ventricular pacing (PV pacing state) or atrial sensing and ventricular sensing (PR pacing state).

[0133] If the stimulation device 10 is pacing in the ventricle, that is in either the AV or PV pacing states, an attempt is made to inhibit ventricular pacing by extending the atrial-ventricular (AV) delay to allow more time for an intrinsic R-wave to occur at step 515. If the stimulation device 10 is pacing in the atrium, that is in either the AV or AR pacing states, an attempt is made to inhibit atrial pacing by reducing the base pacing rate in order to allow the natural heart rate to predominate at step 520.

[0134] Preferably, all pacing is inhibited in order to obtain a baseline physiologic measurement during the natural resting state of the heart. If ventricular pacing cannot be inhibited, even at the maximum AV delay setting, such as in the situation of total AV block, no further attempt is made to inhibit ventricular pacing. Atrial pacing may also not be inhibited even at a minimum pacing rate due to sinus node dysfunction with either too slow a native sinus rate or an unstable native sinus rate. In such cases, the minimum base pacing rate and a nominal AV delay are applied.

[0135] At step 525, a measurement is made using the physiological sensor 108 and/or impedance measurement circuit 112 to establish a baseline cardiac function. At step 530, the coupling intervals are modulated in a way that allows testing of numerous combinations of coupling intervals, thus altering the activation sequence, in order to determine the activation sequence and timing that allows optimal improvement in cardiac state. Initially, coupling intervals between the atria and coupling intervals between the ventricles may be modulated. Next, the AV delay, herein referred to as the atrial to ventricular coupling intervals, may be modulated. Pacing should be sustained for any given set of "test" coupling intervals for a defined minimum time period, such as one minute, to allow the functional state of the heart to stabilize under the "test" conditions before making physiological measurements at step 535.

[0136] Preferably, the stimulation device 10 operates in a trigger mode throughout this test in order to provide a steady

cardiac rhythm at each set of coupling intervals. The physiological measurement made by the sensor **108** and/or the impedance measurement made by impedance measuring circuit **112** are stored in memory **94** (**FIG. 2**) with codes indicating the corresponding coupling interval settings at step **540**.

[**0137**] The coupling interval settings resulting in the greatest improvement in cardiac function based on sensor **108** measurements and/or impedance circuit **112** measurements are selected as the final settings. At step **545**, the optimal coupling interval settings are automatically reprogrammed. The physiologic sensor **108** measurement and/or the impedance measuring circuit **112** measurement at these final settings should be stored in histogram memory **94** to be recalled and displayed graphically over time during patient follow-up visits.

[**0138**] Thus, a multichamber or multisite cardiac stimulation device has been provided which allows independent sensing and stimulation at multiple sites within the heart according to programmed electrode configurations and polar assignments. Furthermore, a method by which the activation sequence of the stimulated sites may be precisely controlled using programmable coupling intervals has been provided. Thus, greater flexibility in sensing and stimulation during multisite or multichamber stimulation therapies may be achieved whereby stimulation therapies may be individually tailored to patient need so that optimal hemodynamic or electrophysiological results may be realized.

[**0139**] While detailed descriptions of specific embodiments of the present invention have been provided, it would be apparent to those reasonably skilled in the art that numerous variations of multi-site or multi-chamber stimulation configurations are possible in which the concepts and methods of the present invention may readily be applied. The descriptions provided herein, therefore, are for the sake of illustration and are no way intended to be limiting.

What is claimed is:

1. A method of automatically selecting sensing or stimulation polarities of a plurality of sensing and stimulation electrodes that are positioned in multiple cardiac chambers, for use with a multi-site cardiac stimulation device, the method comprising the steps of:

defining a plurality of sensing electrode configurations and a plurality of stimulation electrode configurations;

detecting the presence of a cardiac signal in any one of the multiple cardiac chambers with a sensing electrode configuration that corresponds to a first sensing electrode positioned in a right cardiac chamber and a second sensing electrode positioned in a left cardiac chamber;

selectively delivering a stimulus, on demand, to a cardiac chamber with a stimulation electrode configuration that corresponds to a first stimulation electrode positioned in a right cardiac chamber and a second stimulation electrode positioned in a left cardiac chamber; and

independently selecting the polarities of the first sensing electrode, the second sensing electrode, the first stimulation electrode, and the second stimulation electrode.

2. The method of claim 1, further including switching the polarities of the first sensing electrode and the second sensing electrode.

3. The method of claim 1, further including switching the polarities of the first stimulation electrode and the second stimulation electrode.

4. The method of claim 2, further including switching the polarities of the first stimulation electrode and the second stimulation electrode in response to the step of switching the polarities of the first sensing electrode and the second sensing electrode.

5. The method of claim 1, wherein the step of selectively delivering the stimulus includes delivering the stimulus by means of the first and second sensing electrodes.

6. The method of claim 5, wherein the step of selectively delivering the stimulus includes delivering the stimulus by means of at least a third sensing electrode that is different from the first and second sensing electrodes.

7. The method of claim 1, further including controlling a directionality of a depolarization wave by selecting a cathodic assignment and an anodic assignment of the first and second stimulation electrodes.

8. A multi-site cardiac stimulation device capable of automatically selecting sensing or stimulation polarities of a plurality of sensing and stimulation electrodes that are positioned in multiple cardiac chambers, from among a plurality of sensing electrode configurations and a plurality of stimulation electrode configurations, the stimulation device comprising:

a discriminator, coupled to the plurality of sensing electrodes and to the plurality of stimulation electrodes, that detects the presence of a cardiac signal in any one of the multiple cardiac chambers with a sensing electrode configuration that corresponds to a first sensing electrode positioned in a right cardiac chamber and a second sensing electrode positioned in a left cardiac chamber;

a pulse generator, connected to the stimulation electrodes, to selectively deliver a stimulus, on demand, to a cardiac chamber with a stimulation electrode configuration that corresponds to a first stimulation electrode positioned in a right cardiac chamber and a second stimulation electrode positioned in a left cardiac chamber; and

control circuitry, connected to the sensing electrodes, the stimulation electrodes, the pulse generator, and the discriminator to independently select the polarities of the first sensing electrode, the second sensing electrode, the first stimulation electrode, and the second stimulation electrode.

9. The stimulation device of claim 8, wherein the control circuitry includes a programmable switching system that switches the polarities of the first sensing electrode and the second sensing electrode.

10. The stimulation device of claim 8, wherein the control circuitry includes a programmable switching system that switches the polarities of the first stimulation electrode and the second stimulation electrode.

11. The stimulation device of claim 9, wherein the switching system that switches the polarities of the first stimulation electrode and the second stimulation electrode in response to a switch in the polarities of the first sensing electrode and the second sensing electrode.

12. The stimulation device of claim 8, wherein the pulse generator delivers the stimulus by means of the first and second sensing electrodes.

13. The stimulation device of claim 8, wherein the pulse generator delivers the stimulus by means of at least a third sensing electrode that is different from the first and second sensing electrodes.

14. The stimulation device of claim 8, wherein the sensing electrode configuration includes any of a right ventricular or left ventricular unipolar sensing configuration.

15. The stimulation device of claim 8, wherein the sensing electrode configuration includes any of a right atrial unipolar or left atrial sensing configuration.

16. The stimulation device of claim 8, wherein the sensing electrode configuration includes a cross-chamber sensing configuration.

17. The stimulation device of claim 8, wherein the stimulation electrode configuration includes any of a right ventricular or left ventricular unipolar stimulation configuration.

18. The stimulation device of claim 8, wherein the stimulation electrode configuration includes any of a right atrial unipolar or left atrial stimulation configuration.

19. The stimulation device of claim 8, wherein the stimulation electrode configuration includes a cross-chamber stimulation configuration.

20. The stimulation device of claim 8, wherein the sensing electrode configuration includes any one or more of: a right ventricular or left ventricular unipolar sensing configuration; a right atrial unipolar or left atrial sensing configuration; and a cross-chamber sensing configuration; and

wherein the stimulation electrode configuration includes any one or more of: a right ventricular or left ventricular unipolar stimulation configuration; a right atrial

unipolar or left atrial stimulation configuration; or a cross-chamber stimulation configuration.

21. A multi-site cardiac stimulation device capable of automatically selecting sensing or stimulation polarities of a plurality of sensing and stimulation electrodes that are positioned in multiple cardiac chambers, the stimulation device comprising:

means for detecting the presence of a cardiac signal with a sensing electrode configuration;

means for selectively delivering a stimulus, on demand, to a cardiac chamber with a stimulation electrode configuration;

means for independently selecting the polarities of the sensing electrodes and the stimulation electrodes;

means for switching the polarities of the sensing electrodes on demand; and

means for switching the polarities of the stimulation electrodes on demand.

22. The stimulation device of claim 21, wherein the sensing electrode configuration includes any one or more of: a right ventricular or left ventricular unipolar sensing configuration; a right atrial unipolar or left atrial sensing configuration; or a cross-chamber sensing configuration; and

wherein the stimulation electrode configuration includes any one or more of: a right ventricular or left ventricular unipolar stimulation configuration; a right atrial unipolar or left atrial stimulation configuration; or a cross-chamber stimulation configuration.

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