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(54) **CONFIRMING SENSED ATRIAL EVENTS FOR PACING DURING RESYNCHRONIZATION THERAPY IN A CARDIAC MEDICAL DEVICE AND MEDICAL DEVICE SYSTEM**

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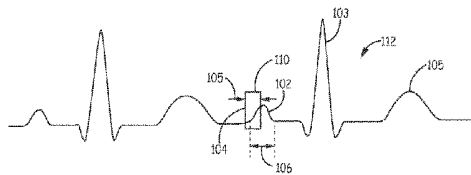
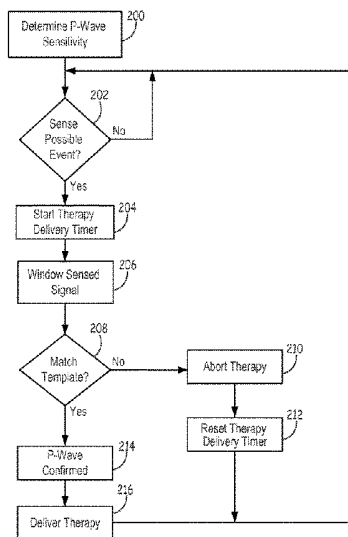
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(57) **ABSTRACT**

A medical device and medical device system for controlling delivery of therapeutic stimulation pulses that includes a sensing device to sense a cardiac signal and emit a trigger signal in response to the sensed cardiac signal, a therapy delivery device to receive the trigger signal and deliver therapy to the patient in response to the emitted trigger signal, and a processor positioned within the sensing device, the processor configured to determine whether the sensed cardiac signal exceeds a possible P-wave threshold, compare a portion of the sensed cardiac signal to a P-wave template having a sensing window having a length less than a width of the P-wave, confirm an occurrence of a P-wave signal in response to the comparing, emit the trigger signal in response to the occurrence of a P-wave signal being confirmed, and inhibit delivery of the emitting signal in response to the occurrence of a P-wave signal not being confirmed.

37 Claims, 7 Drawing Sheets



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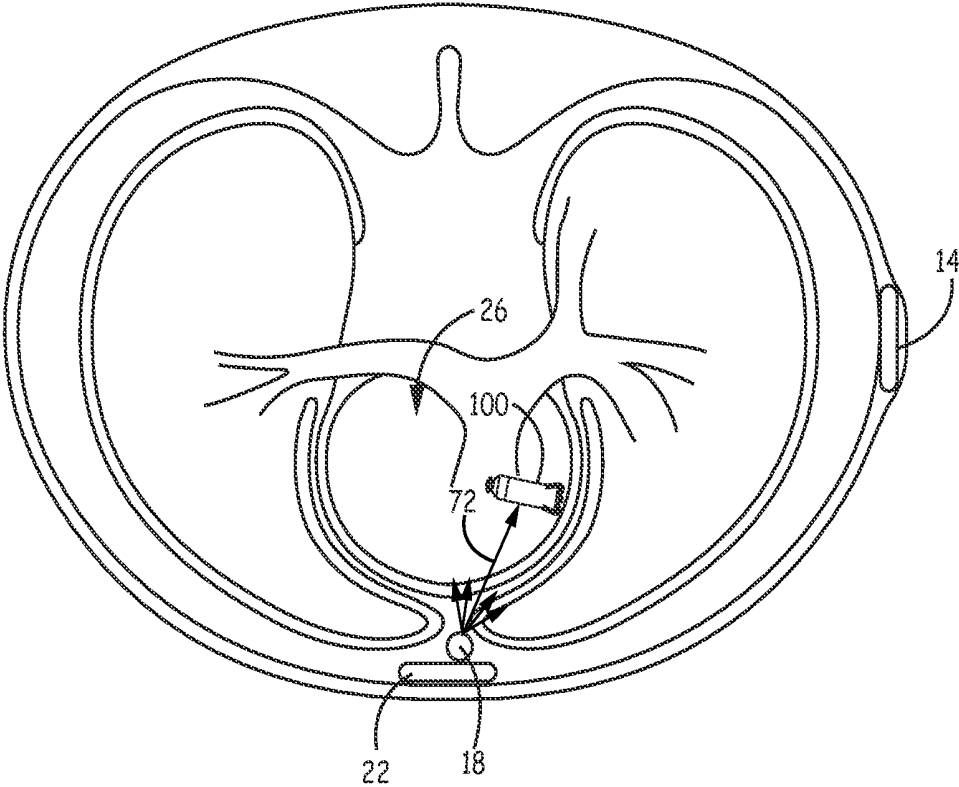


FIG. 2

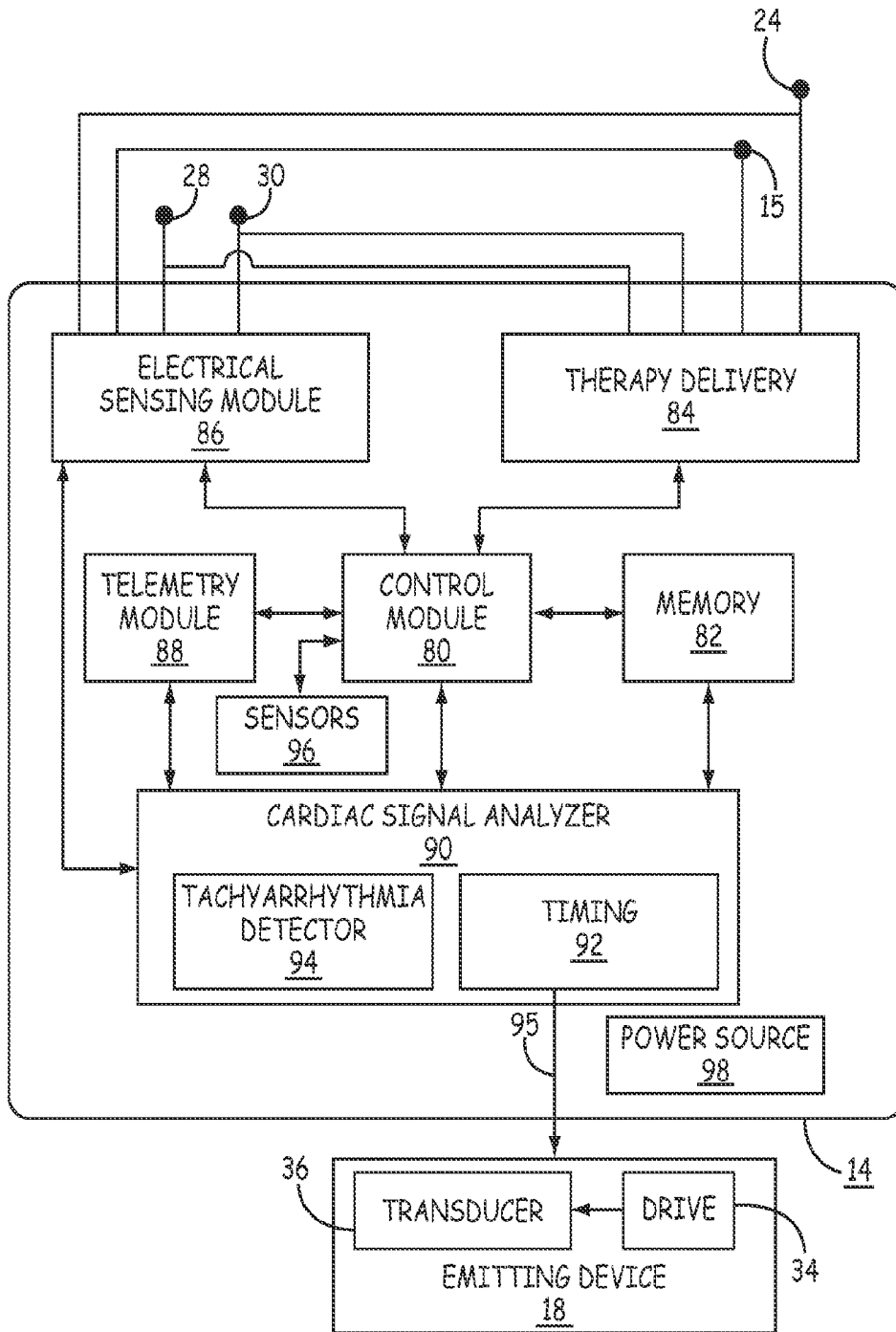


FIG. 3

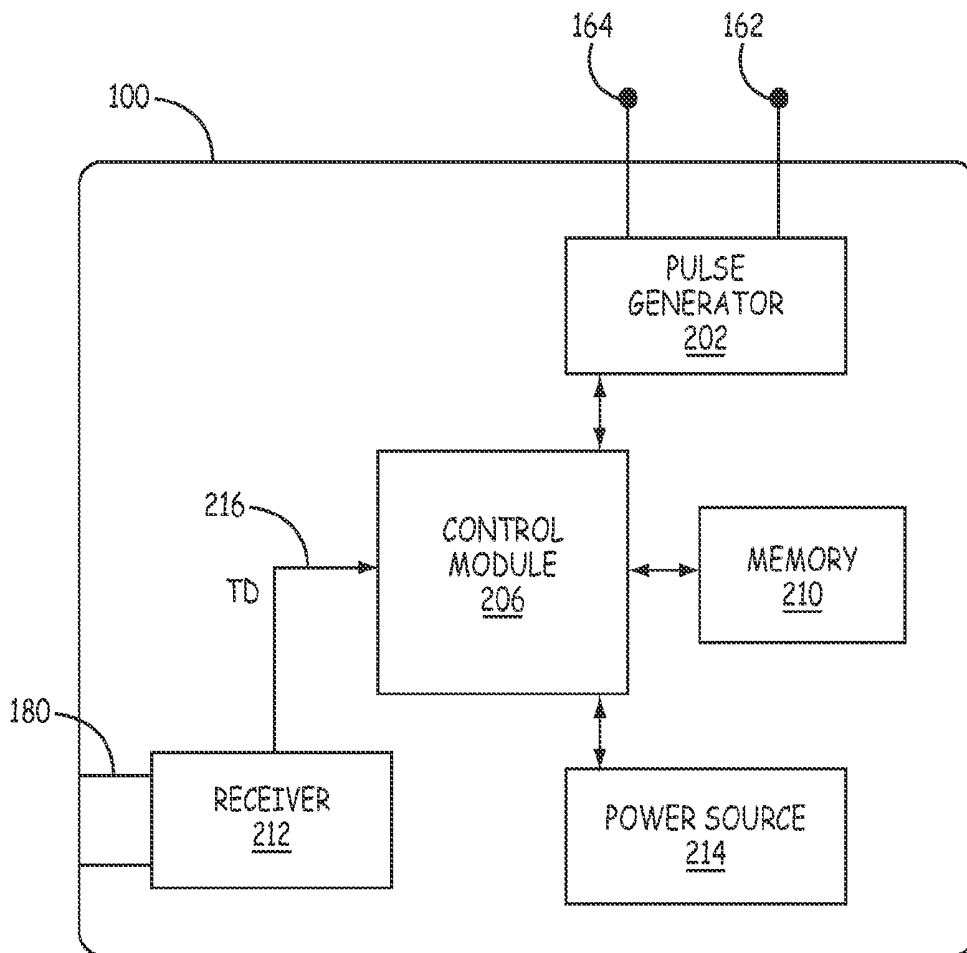


FIG. 4

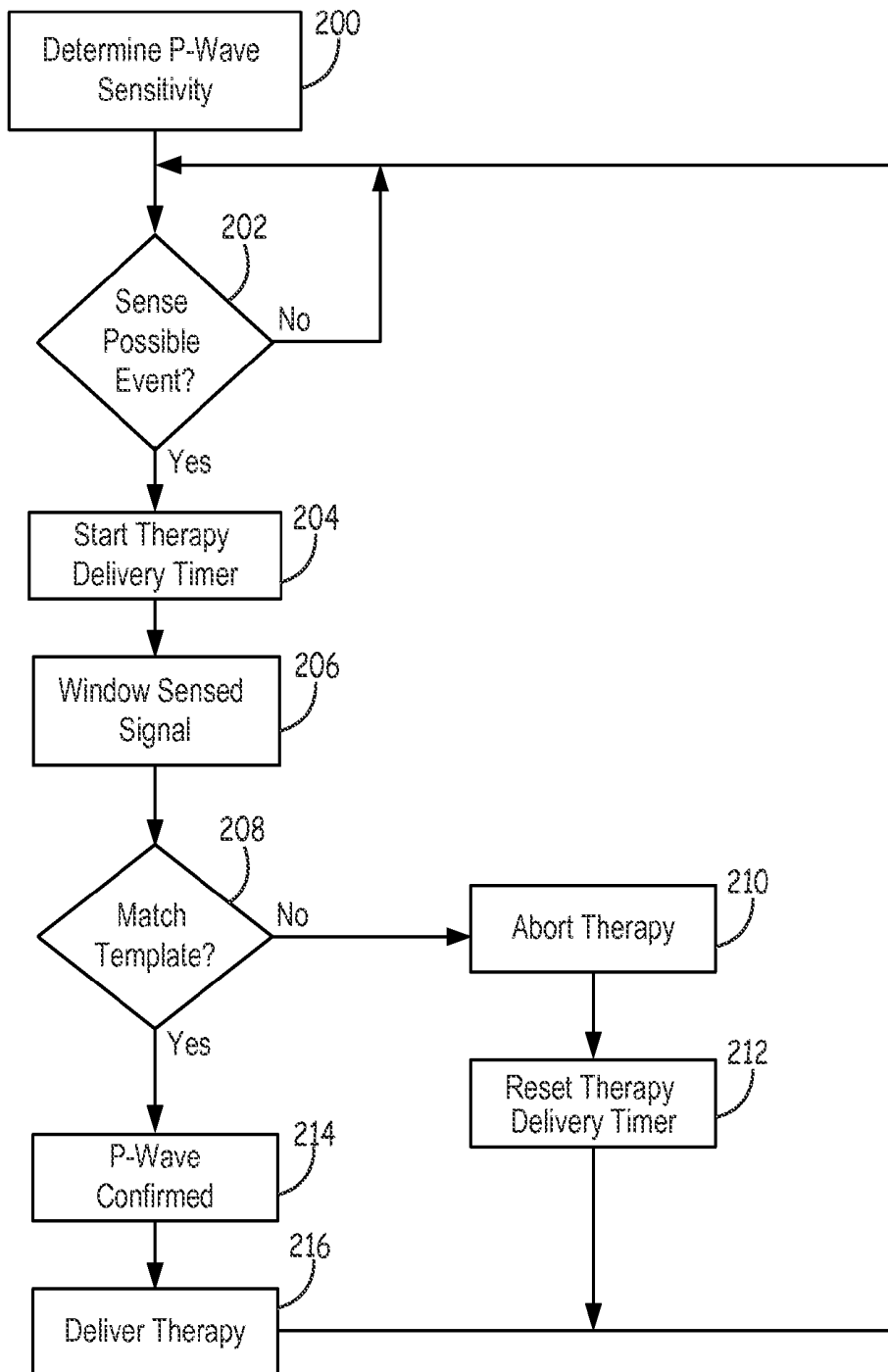


FIG. 5

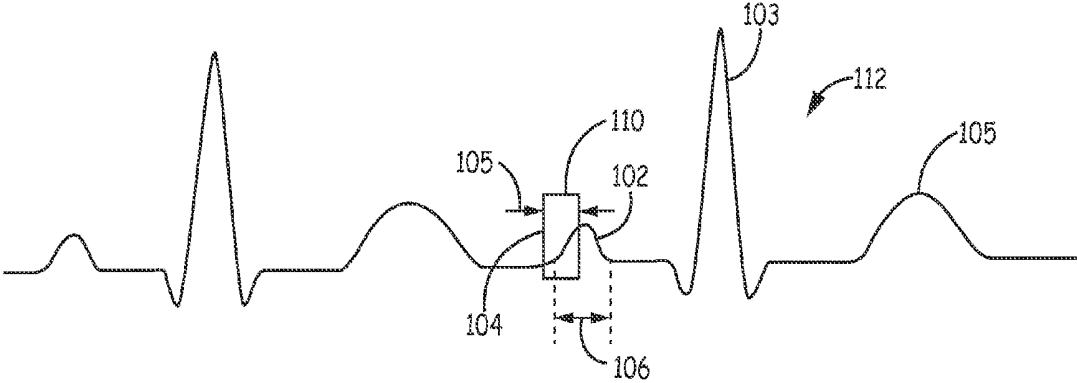


FIG. 6

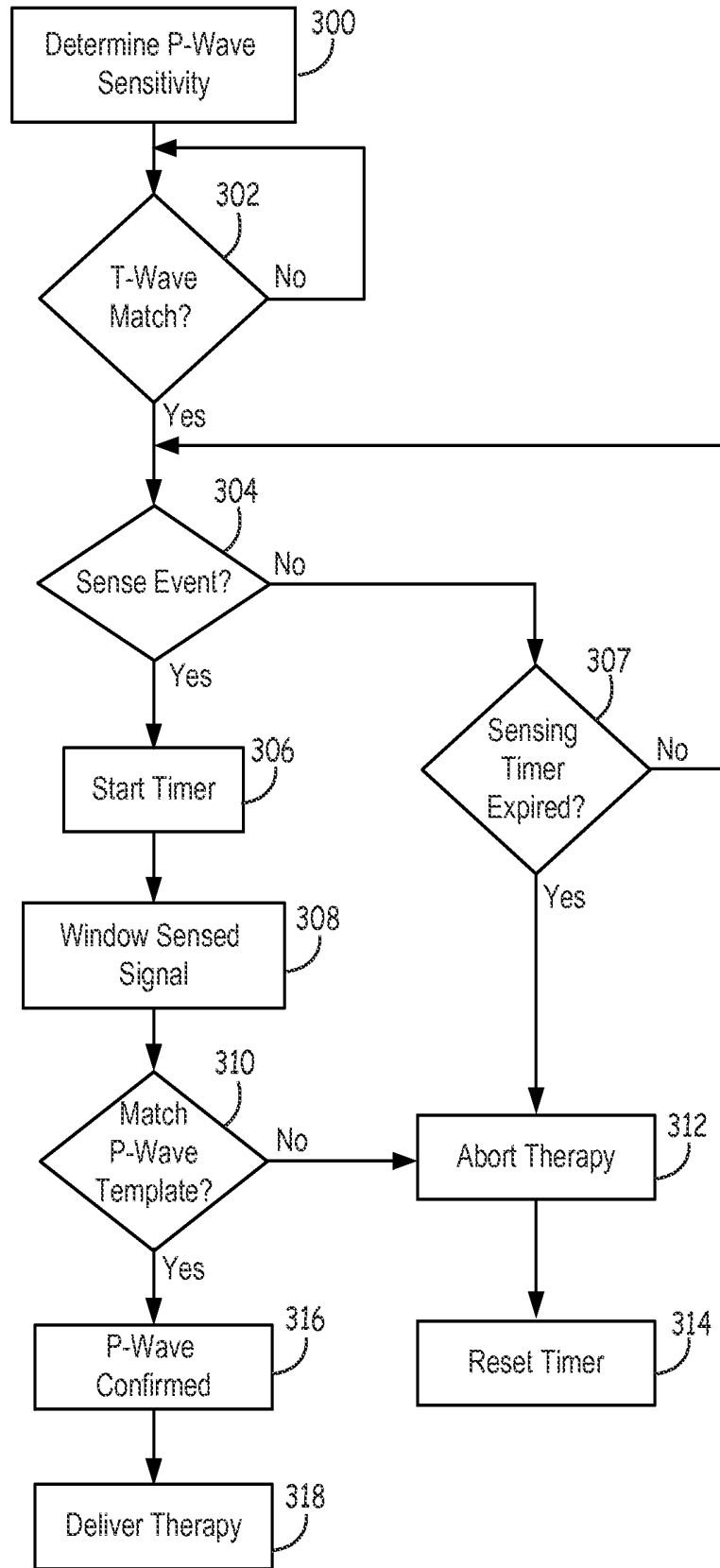


FIG. 7

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**CONFIRMING SENSED ATRIAL EVENTS
FOR PACING DURING
RESYNCHRONIZATION THERAPY IN A
CARDIAC MEDICAL DEVICE AND
MEDICAL DEVICE SYSTEM**

FIELD OF THE DISCLOSURE

The present disclosure pertains to cardiac pacing methods and systems, and, more particularly, to cardiac resyn-
chronization therapy in a cardiac medical device system.

BACKGROUND OF THE DISCLOSURE

Implantable pacemakers and cardioverter defibrillators (ICDs) are available for delivering electrical stimulation therapies to a patient's heart, such as bradycardia pacing, cardiac resynchronization therapy (CRT), anti-tachycardia pacing and cardioversion/defibrillation shocks. Medical device technology advancement has led toward smaller and smaller implantable devices. Recently, leadless intracardiac pacemakers have been introduced which can be implanted directly in a heart chamber. Elimination of transvenous, intracardiac leads has several advantages. For example, complications due to infection associated with a lead extending from a subcutaneous pacemaker pocket transvenously into the heart can be eliminated. Other complications such as "twiddler's syndrome", lead fracture or poor connection of the lead to the pacemaker are eliminated in the use of a leadless, intracardiac pacemaker.

New challenges arise, however, in controlling an intracardiac pacemaker to deliver pacing pulses in synchrony with paced or sensed events occurring in other heart chambers. Cardiac resynchronization therapy (CRT) is an example of a pacing therapy that includes delivering pacing pulses in a heart chamber at a predetermined time interval after a sensed or paced event in another heart chamber. CRT is a treatment for heart failure patients in whom one or more heart chambers are electrically paced to restore or improve heart chamber synchrony. Improved heart chamber synchrony is expected to alleviate symptoms of heart failure. Achieving a positive clinical benefit from CRT, however, may be dependent on several therapy control parameters, such as the timing intervals used to control pacing pulse delivery, e.g., an atrio-ventricular (AV) interval and/or an inter-ventricular (VV) interval. The AV interval controls the timing of ventricular pacing pulses relative to a preceding atrial depolarization, intrinsic or paced. The VV interval controls the timing of a pacing pulse in one ventricle relative to a paced or intrinsic sensed event in the other ventricle. Pacing may be delivered in the right ventricle (RV) and/or the left ventricle (LV) to restore ventricular synchrony.

Cardiac resynchronization utilizing cardiac pacing therapy and cardiac pacing devices operate by either delivering pacing stimulus to both ventricles or to one ventricle with the desired result of a more or less simultaneous mechanical contraction and ejection of blood from the ventricles. Ideally, each pacing pulse stimulus delivered to a ventricle evokes a response from the ventricle. In order to ensure the desired evoked response takes place, it is desirable to time the delivery of the ventricular pacing so as to be delivered at a point in time subsequent to a P-wave, resulting in the delivery of the pacing therapy coinciding with the occurrence of an R-wave of the cardiac cycle of the patient. As a result, the ability to sense P-waves is an important factor in determining timing of the ventricular pacing therapy for cardiac resynchronization therapy (CRT). Fur-

2

thermore, when either a subcutaneous device or far-field signals are utilized, the R-waves and T-waves of the cardiac cycle are often either only slightly larger or of comparable magnitudes as P-waves, making distinguishing P-waves from R-waves and T-waves even more difficult. Therefore, what is needed is an improved method of distinguishing P-waves of a cardiac cycle for timing of delivery of ventricular pacing during CRT therapy.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a conceptual diagram illustrating an implantable medical device (IMD) system that may be used to sense cardiac electrical signals in patient and provide therapy to the patient's heart.

FIG. 2 is a sectional view of the patient's anatomy depicting an alternative configuration of the implantable medical device system of FIG. 1.

FIG. 3 is a functional block diagram of electronic circuitry that is included in one embodiment of the implantable medical device system shown in FIGS. 1 and 2.

FIG. 4 is a functional block diagram of an example configuration of a therapy delivery device according to an embodiment of the present disclosure.

FIG. 5 is a flowchart of a method for sensing an atrial event for timing of delivery of therapy in an implantable medical device system, according to an embodiment of the present disclosure.

FIG. 6 is a schematic diagram of sensing of an atrial event for timing of delivery of therapy in an implantable medical device system, according to an embodiment of the present disclosure.

FIG. 7 is a flowchart of a method for sensing of an atrial event for timing of delivery of therapy in an implantable medical device system, according to an embodiment of the present disclosure.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

In the following detailed description, references are made to illustrative embodiments for carrying out methods of delivering atrial synchronous pacing with sensing of atrial activity from subcutaneous or far-field signals reflecting electrical activity of the different heart chambers. It is understood that other embodiments may be utilized without departing from the scope of the invention. For example, the invention is disclosed in detail herein in the context of a bi-ventricular or multi-electrode/multi-site cardiac resynchronization therapy (CRT) delivery.

Exemplary methods, devices, and systems shall be described with reference to FIGS. 1-7. It will be apparent to one skilled in the art that elements or processes from one embodiment may be used in combination with elements or processes of the other embodiments, and that the possible embodiments of such methods, devices, and systems using combinations of features set forth herein is not limited to the specific embodiments shown in the Figures and/or described herein. Further, it will be recognized that the embodiments described herein may include many elements that are not necessarily shown to scale.

FIG. 1 is a conceptual diagram illustrating an implantable medical device (IMD) system that may be used to sense cardiac electrical signals in patient and provide therapy to the patient's heart. As illustrated in FIG. 1, an implantable medical device (IMD) system 10 for confirming sensed atrial events for pacing and resynchronization therapy may

include a therapy delivery device **100**, such as an intracardiac pacemaker and a cardiac sensing device **14**, such as a subcutaneous cardiac defibrillator coupled to an extravascular lead **16**, such as a subcutaneous device implanted subcutaneously on the left side of a patient **12**. Such a medical device system **10** is described, for example, in commonly assigned U.S. application patent Ser. No. 14/695,004, incorporated herein by reference in its entirety. While the subcutaneous device is shown implanted subcutaneously on the left side of a patient **12**, it is understood that sensing device **14** and lead **16** may be implanted at other locations, such as the right side of patient **12**, for example. The cardiac sensing device **14** includes a defibrillation lead **16** having a defibrillation electrode **24** positioned along a proximal end of the lead **16**, which may be an elongated coil electrode, a pair of sensing electrodes **28** and **30**, illustrated as ring electrodes, although other electrode configurations may be utilized, and a trigger signal emitting device **18**. Trigger signal emitting device **18** includes a transducer that is controlled by cardiac sensing device **14** to emit trigger signals received by therapy delivery device **100** to cause therapy delivery device **100** to deliver one or more pacing pulses.

Defibrillation lead **16**, which is connected to cardiac sensing device **14**, extends medially from cardiac sensing device **14** toward sternum **22** and xiphoid process **20** of patient **12**. At a location near xiphoid process **20** defibrillation lead **16** bends or turns and extends subcutaneously superior, substantially parallel to sternum **22**. Defibrillation lead **16** may be implanted such that lead **16** is over sternum **22** or offset laterally to the left or right side of the body of sternum **22**, and may be implanted subcutaneously, e.g., between the skin and the ribs or sternum. Defibrillation lead **16** may be implanted at other locations or angles relative to sternum **22**, or positioned further superior or inferior, depending on the location of cardiac sensing device **14**, position of electrodes **24**, **28**, and **30** and trigger signal emitting device **18** along lead **16**, the location of pacemaker **100**, or other factors. In other instances, lead **16** may be implanted at other extravascular locations. In one example, lead **16** may be implanted at least partially in a substernal location or within ribcage **32**, within the thoracic cavity, and within or outside the pericardium, not necessarily in direct contact with heart **26**.

Defibrillation lead **16** is placed along sternum **22** such that a therapy vector between defibrillation electrode **24** and a second electrode (such as a portion of the housing **15** of cardiac sensing device **14** or an electrode placed on a second lead) is substantially across one or both ventricles of heart **26**. The therapy vector may, in one example, be viewed as a line that extends from a point on the defibrillation electrode **24** to a point on the housing **15** (sometimes referred to as "can electrode") of cardiac sensing device **14**. In another example, defibrillation lead **16** may be placed along sternum **22** such that a therapy vector between defibrillation electrode **24** and housing **15** of cardiac sensing device **14** (or other electrode) is substantially across an atrium of heart **26**. In this case, system **10** may be used to provide atrial therapies, such as therapies to treat atrial fibrillation.

Trigger signal emitting device **18** is positioned to establish a trigger signal transmission pathway that does not excessively attenuate the trigger signal transmitted from emitting device **18** to a receiver or detector included in intracardiac therapy delivery device **100**. For example, the location of emitting device **18** may be selected so that a direct pathway between emitting device **18** and therapy delivery device **100** avoids, as much as possible, tissues that are highly reflective,

scattering or absorbing of the type of trigger signal being used. When lead **16** is positioned extra-thoracically, emitting device **18** may be positioned inferior to the xiphoid process **20** in a position approximately as shown. Emitting device **18** is positioned relative to therapy delivery device **100** to establish an efficient trigger signal transmission pathway, which may be a direct or indirect pathway that takes into account the trigger signal properties and the transmission or attenuation properties of the surrounding and intervening tissues for the type of trigger signal being used.

Defibrillation lead **16** may include an attachment feature **29** at or toward the distal end of lead **16**. The attachment feature **29** may be a loop, link, or other attachment feature useful to aid in implantation of lead **16** and/or for securing lead **16** to a desired implant location. In some instances, defibrillation lead **16** may include a fixation mechanism in addition to or instead of the attachment feature **29**. For example, defibrillation lead **16** may include a suture sleeve or other fixation mechanism (not shown) located proximal to electrode **30** or near emitting device **18** that is configured to fixate lead **16** near the xiphoid process **20** or lower sternum location. The fixation mechanism (e.g., suture sleeve or other mechanism) may be integral to the lead or may be added by the user prior to implantation. The fixation mechanism may be used to stably locate emitting device **18** inferior to the xiphoid process **20**, along an intercostal space, or other desired location to prevent rotation or shifting of the emitting device **18** that may cause trigger signal misdirection or trigger signal loss due to interference or attenuation by body tissues.

Although cardiac sensing device **14** is illustrated as being implanted near a midaxillary line of patient **12**, cardiac sensing device **14** may also be implanted at other subcutaneous locations on patient **12**, such as further posterior on the torso toward the posterior axillary line, further anterior on the torso toward the anterior axillary line, in a pectoral region, or at other locations of patient **12**. In instances in which cardiac sensing device **14** is implanted pectorally, lead **16** would follow a different path, e.g., across the upper chest area and inferior along sternum **22**. When the cardiac sensing device **14** is implanted in the pectoral region, the system **10** may include a second lead including a defibrillation electrode, and optionally a trigger signal emitting device, that extends along the left side of the patient such that the defibrillation electrode of the second lead is located along the left side of the patient to function as an anode or cathode of the therapy vector for defibrillating heart **26**.

Cardiac sensing device **14** includes a housing **15** that forms a hermetic seal that protects components within cardiac sensing device **14**. The housing **15** of cardiac sensing device **14** may be formed of a conductive material, such as titanium or other biocompatible conductive material or a combination of conductive and non-conductive materials. Housing **15** may enclose one or more components, including processors, memories, transmitters, receivers, sensors, sensing circuitry, therapy circuitry and other appropriate components (often referred to herein as modules). In some instances, the housing **15** functions as an electrode (sometimes referred to as a housing electrode or can electrode) that is used in combination with one of electrodes **24**, **28** and **30** to deliver a therapy to heart **26** or to sense electrical activity of heart **26**.

Cardiac sensing device **14** may include a connector assembly **13** (sometimes referred to as a connector block or header) for receiving a proximal connector (not illustrated) of lead **16**. Connector assembly **13** includes electrical feedthroughs through which electrical connections are made

between conductors within defibrillation lead 16 and electronic components included within the housing 15. Depending on the intended implant location of cardiac sensing device 14, a trigger signal emitting device may be included in connector assembly 13 and/or housing 15 in addition to or in place of the emitting device 18 carried by lead 16 for transmitting trigger signals to therapy delivery device 100.

Lead 16 includes a connector at the proximal end of lead 16, such as a DF4 connector, bifurcated connector (e.g., DF-1/IS-1 connector), or other type of connector. The connector at the proximal end of lead 16 may include a terminal pin that couples to a port within the connector assembly 13 of cardiac sensing device 14. The lead body 17 of defibrillation lead 16 may be formed from a non-conductive material, including silicone, polyurethane, fluoropolymers, mixtures thereof, and other appropriate materials, and shaped to form one or more lumens within which the one or more conductors extend. However, the techniques are not limited to such constructions.

Defibrillation lead 16 includes elongated electrical conductors (not illustrated) that extend within the elongated lead body 17 from the connector on the proximal end of defibrillation lead 16 to the respective electrodes 24, 28 and 30 and emitting device 18. Although defibrillation lead 16 is illustrated as including three electrodes 24, 28 and 30, defibrillation lead 16 may include more or fewer electrodes. When the connector at the proximal end of defibrillation lead 16 is connected to connector assembly 13, the respective conductors electrically couple to circuitry of cardiac sensing device 14, such as a therapy delivery module, a sensing module, or trigger signal drive signal circuit, via connections in connector assembly 13, including associated feedthroughs.

The electrical conductors transmit electrical stimulation pulses from a therapy module within cardiac sensing device 14 to one or more of electrodes 24, 28 and 30 and transmit sensed electrical signals from one or more of electrodes 24, 28 and 30 to the sensing module within cardiac sensing device 14. An electrical conductor extending from the proximal lead connector to emitting device 18 conducts an electrical control signal to emitting device 18 to cause emitting device 18 to emit a trigger signal at appropriate times for causing intracardiac therapy delivery device 100 to deliver one or more pacing pulses to heart 26.

Cardiac sensing device 14 may sense electrical activity of heart 26 via one or more sensing vectors that include combinations of electrodes 28 and 30 and housing 15. For example, cardiac sensing device 14 may obtain cardiac electrical signals sensed using a sensing vector between electrodes 28 and 30, between electrode 28 and the conductive housing 15, between electrode 30 and the conductive housing 15, or any combination thereof. In some instances, cardiac sensing device 14 may even sense cardiac electrical signals using a sensing vector that includes defibrillation electrode 24, such as a sensing vector between defibrillation electrode 24 and one of electrodes 28 and 30, or a sensing vector between defibrillation electrode 24 and the housing 15 of cardiac sensing device 14.

Cardiac sensing device 14 determines a need for pacing therapy in response to the sensed cardiac electrical signals, which may include P-waves and R-waves for example, and controls emitting device 18 to emit trigger signals based on that determination. The need for pacing pulses may be determined according to programmed single chamber, dual chamber or multi-chamber bradycardia or CRT control parameters or other cardiac pacing therapy parameters. Cardiac sensing device 14 may also analyze the sensed

electrical signals to detect tachyarrhythmia, such as ventricular tachycardia or ventricular fibrillation, and in response to detecting tachyarrhythmia may generate and deliver an electrical stimulation therapy to heart 26. For example, cardiac sensing device 14 may deliver one or more defibrillation shocks via a therapy vector that includes defibrillation electrode 24 of defibrillation lead 16 and the housing 15.

Electrodes 24, 28, 30 and housing 50 may be used for sensing ECG signals for use in controlling the timing of an R-wave synchronized shock delivered by cardiac sensing device 14 and for controlling timing of pacing pulses delivered by therapy delivery device 100. In some instances, one or more pacing therapies may be delivered prior to or after delivery of a defibrillation shock by cardiac sensing device 14, such as anti-tachycardia pacing (ATP) or post shock pacing. In these instances, cardiac sensing device 14 may generate and deliver pacing pulses via therapy vectors that include electrodes 24, 28, 30 and/or housing 15. Alternatively, cardiac sensing device 14 causes trigger signal emitting device 18 to emit trigger signals to cause therapy delivery device 100 to deliver pacing pulses to heart 26 at appropriate times when ATP or post-shock pacing is needed as well as when bradycardia or CRT pacing therapy is needed.

The exemplary cardiac sensing device 14 illustrated in FIG. 1 is illustrative in nature and should not be considered limiting of the sensing device used in a triggered therapy delivery system and associated techniques described in this disclosure. For instance, in addition to sensing ECG signals, cardiac sensing device 14 may include shock therapy capabilities only without pacing therapy capabilities. In other examples, cardiac sensing device 14 may be coupled to more than one lead for sensing ECG signals and/or sending trigger signals to therapy delivery device 100. In still other examples, a sensing device may be substituted for cardiac sensing device 14 that is a single chamber or dual chamber subcutaneous pacemaker without cardioversion/defibrillation capabilities or a sensing-only device without therapy delivery capabilities. Any of these sensing devices may be coupled to housing-based electrodes and/or electrodes carried by a transvenous, intracardiac or extravascular, extracardiac lead for sensing a cardiac electrical signal and determining appropriate times for triggering therapy delivery device 100 to delivery therapy. In another embodiment, the sensing device may be a subcutaneously implanted leadless device, such as the leadless subcutaneous sensor device in commonly assigned U.S. patent application Ser. No. 14/695,004 to Carnet et. al, Ser. No. 14/695,013 to Cinbis et. al, for example, both incorporated by reference in their entireties.

Therapy delivery device 100 may be a transcatheter intracardiac pacemaker adapted for implantation wholly within a heart chamber, e.g., wholly within the RV, wholly within the LV, wholly within the right atrium (RA) or wholly within the left atrium (LA) of heart 26. In the example of FIG. 1, therapy delivery device 100 is positioned proximate to an inner wall of the LV to provide left ventricular pacing. In other examples, therapy delivery device 100 is positioned proximate to an inner wall of the right ventricle to provide right ventricular pacing. In other examples, therapy delivery device 100 may be positioned at any other location outside or within heart 26, including epicardial locations. For example, therapy delivery device 100 may be positioned outside or within the right atrium or left atrium, e.g., to provide respective right atrial or left atrial pacing. In other embodiments, therapy delivery device 100 may be embodied as a therapy delivery device for delivering an electrical

stimulation therapy at another body location. Therapy delivery device **100** is shown as a leadless device in FIG. **1**. It is contemplated, however that in other embodiments therapy delivery device **100** may be coupled to a lead extending from therapy deliver device **100** to position therapy delivery electrodes at a location spaced apart from therapy delivery device **100**.

Depending on the implant location, therapy delivery device **100** may be configured to deliver an electrical stimulation therapy to target therapy site(s) other than the myocardium. For example, therapy delivery device **100** may provide atrioventricular nodal stimulation, fat pad stimulation, vagal stimulation, or other types of neurostimulation. In other examples, system **10** may include a plurality of pacemakers **100**, e.g., to deliver electrical stimulation therapy at multiple sites of heart **26** such as within multiple heart chambers for multi-chamber pacing therapies.

Therapy delivery device **100** is capable of producing electrical stimulation pulses delivered to heart **26** via one or more electrodes on the outer housing of therapy delivery device **100**. Therapy delivery device **100** includes a receiving transducer for receiving a trigger signal emitted by emitting device **18**. In response to detecting the trigger signal, therapy delivery device **100** delivers one or more pacing pulses.

In one embodiment, therapy delivery device **100** includes a pulse generator configured to deliver one or more pacing pulses upon receiving the trigger signal from emitting device **18**. Cardiac signal sensing is performed by cardiac sensing device **14**. Cardiac sensing device **14** senses ECG signals through lead **16** and controls pacing delivered by therapy delivery device **100** via trigger signals emitted by emitting device **18** under the control of cardiac sensing device **14**.

Since therapy delivery device **100** may have no or limited sensing capabilities, therapy delivery device **100** may be “blinded” to intrinsic events, such as intrinsic R-waves, occurring in the same heart chamber and to paced or intrinsic events occurring in other heart chambers. Delivery of CRT, dual chamber pacing, or other multi-chamber pacing therapies may require delivering a pacing pulse at a predetermined time interval after an event, sensed or paced, in another heart chamber. As such, emitting device **18** provides a trigger signal to therapy delivery device **100** in response to ECG signals sensed by cardiac sensing device **14** to cause pacing pulses to be delivered by therapy delivery device **100** at desired time intervals relative to other heart chamber events. Therapy delivery device **100** (for generating pacing pulses) combined with cardiac sensing device **14** (for sensing physiological signals and making therapy delivery decisions) provides the functionality required to deliver various therapies that may require synchronization or coordination with cardiac events occurring in the same or a different heart chamber without physical connection between therapy delivery device **100** and cardiac sensing device **14** implanted at separate implant sites.

FIG. **1** further depicts programmer **40** in wireless communication with cardiac sensing device **14** via communication link **42**. In some examples, programmer **40** comprises a handheld computing device, computer workstation, or networked computing device. Programmer **40** includes a user interface that presents information to and receives input from a user. It should be noted that the user may also interact with programmer **40** remotely via a networked computing device.

A user, such as a physician, technician, surgeon, electrophysiologist, other caregiver, or patient, interacts with programmer **40** to communicate with cardiac sensing device **14**.

For example, the user may interact with programmer **40** to retrieve physiological or diagnostic information from cardiac sensing device **14**. A user may also interact with programmer **40** to program cardiac sensing device **14**, e.g., select values for operational parameters of the cardiac sensing device **14**, including parameters used to control trigger signal emitting device **18** for controlling therapy delivery device **100**. A user may use programmer **40** to retrieve information from cardiac sensing device **14** regarding the rhythm of heart **26**, heart rhythm trends over time, or arrhythmic episodes.

As indicated, cardiac sensing device **14** and programmer **40** communicate via wireless communication. Examples of communication techniques may include low frequency or radiofrequency (RF) telemetry, but other techniques may be used. In some examples, programmer **40** may include a programming head that is placed proximate to the patient’s body near the cardiac sensing device **14** implant site in order to improve the quality or security of communication between cardiac sensing device **14** and programmer **40**.

The embodiment illustrated in FIG. **1** is an example configuration of an IMD system **10** and should not be considered limiting of the techniques described herein. In other embodiments, cardiac sensing device **14** may be coupled to a transvenous intracardiac lead extending into the right ventricle (RV) for positioning RV sensing and pacing electrodes and a defibrillation coil electrode within the RV. An example of an RV lead that could be adapted to carry an emitting device **18** is generally disclosed in commonly-assigned, U.S. Pat. No. 5,545,186 (Olson, et al.). In this example, emitting device **18** may be positioned more distally than the position shown on lead **16** such that the emitting device **18** is positioned in the RV, opposite therapy delivery device **100** in the LV. Emitting device **18** may then be enabled to emit a trigger signal from the RV to the therapy delivery device **100** in the LV to coordinate timing of the LV pacing pulse relative to a right atrial event or a right ventricular event. It is contemplated that numerous configurations of a lead-based emitting device **18** may be conceived and emitting device **18** may be positioned along the lead body **17** at relatively more proximal or more distal locations than shown on lead **16** to position emitting device **18** at a desired location relative to therapy delivery device **100**.

FIG. **2** is a sectional view of the patient’s anatomy depicting an alternative configuration of the implantable medical device system of FIG. **1**. Emitting device **18** is shown in a substernal position on lead **16** (not seen in the sectional view of FIG. **2**). Instead of being positioned suprasternally, inferior to the xyphoid process, emitting device **18** may be positioned substernally and relatively more superior by advancing the distal end of lead **16** to a substernal location. Emitting device **18** may be configured for directional trigger signal emission with emitting device **18** oriented to generally direct the trigger signal toward the implant position of therapy delivery device **100**, e.g., along a signal pathway to therapy delivery device **100** as represented by arrow **72**.

Lead **16** may be placed under or below the sternum in the mediastinum and, more particularly, in the anterior mediastinum. The anterior mediastinum is bounded laterally by pleurae, posteriorly by pericardium, and anteriorly by sternum. Lead **16** may be at least partially implanted in other extra-pericardial locations, i.e., locations in the region around, but not necessarily in direct contact with, the outer surface of heart **26**. These other extra-pericardial locations may include in the mediastinum but offset from sternum **22**, in the superior mediastinum, in the middle mediastinum, in

the posterior mediastinum, in the sub-xiphoid or inferior xiphoid area, near the apex of the heart, or other location not in direct contact with heart 26 and not subcutaneous. In other embodiments, lead 16 may extend within the pericardium and in direct contact with heart 26. In any of these illustrative implant locations, lead 16 may be positioned to opti-

mally position trigger signal emitting device 18 for reliably transmitting a trigger signal to therapy delivery device 100. FIG. 3 is a functional block diagram of electronic circuitry that is included in one embodiment of the implantable medical device system shown in FIGS. 1 and 2. As illustrated in FIG. 3, ICD 14 includes processing and control module 80, also referred to as "control module" 80, memory 82, therapy delivery module 84, electrical sensing module 86, telemetry module 88, and cardiac signal analyzer 90. A power source 98 provides power to the circuitry of ICD 14, including each of the modules 80, 82, 84, 86, 88, 90. Power source 98 may include one or more energy storage devices, such as one or more chargeable or non-re-chargeable bat-

teries. The functional blocks shown in FIG. 3 represent functionality that may be included in ICD 14 and may include any discrete and/or integrated electronic circuit components that implement analog and/or digital circuits capable of producing the functions attributed to ICD 14 herein. For example, the modules may include analog circuits, e.g., amplification circuits, filtering circuits, and/or other signal conditioning circuits. The modules may also include digital circuits, e.g., analog-to-digital converters, combinational or sequential logic circuits, integrated circuits, memory devices, etc. Memory 82 may include any volatile, non-volatile, magnetic, or electrical non-transitory computer readable storage media, such as a random access memory (RAM), read-only memory (ROM), non-volatile RAM (NVRAM), electrically-erasable programmable ROM (EEPROM), flash memory, or any other memory device. Furthermore, memory 82 may include non-transitory computer readable media storing instructions that, when executed by one or more processing circuits, cause control module 80 or other ICD modules to perform various functions attributed to ICD 14. The non-transitory computer readable media storing the instructions may include any of the media listed above, with the sole exception being a transitory propagating signal. The particular form of software, hardware and/or firmware employed to implement the functionality disclosed herein will be determined primarily by the particular system architecture employed in the IMD system devices. Providing software, hardware, and/or firmware to accomplish the described functionality in the context of any modern IMD system, given the disclosure herein, is within the abilities of one of skill in the art.

The functions attributed to the modules herein may be embodied as one or more processors, hardware, firmware, software, or any combination thereof. Depiction of different features as modules is intended to highlight different functional aspects and does not necessarily imply that such modules must be realized by separate hardware or software components. Rather, functionality associated with one or more modules may be performed by separate hardware or software components, or integrated within common hardware or software components. For example, arrhythmia detection operations performed by cardiac signal analyzer 90 for determining a need for therapy delivered by ICD 14 and/or therapy delivery device 100 may be implemented in processing and control module 80 executing instructions stored in memory 82.

Processing and control module 80 communicates with therapy delivery module 84, cardiac signal analyzer 90 and electrical sensing module 86 for sensing cardiac electrical activity, detecting cardiac rhythms, and generating cardiac therapies in response to sensed signals. Therapy delivery module 84 and electrical sensing module 86 are electrically coupled to electrodes 24, 28, and 30 carried by lead 16, e.g., as shown in FIG. 1, and housing 15, at least a portion of which also serves as a common or ground electrode.

Electrical sensing module 86 is coupled to electrodes 28 and 30 in order to monitor electrical activity of the patient's heart. Electrical sensing module 86 may optionally be coupled to electrodes 24 and 15 and enabled to selectively monitor one or more sensing vectors selected from the available electrodes 24, 28, 30 and 15. For example, sensing module 86 may include switching circuitry for selecting which of electrodes 24, 28, 30 and housing 15 are coupled to sense amplifiers included in sensing module 86. Switching circuitry may include a switch array, switch matrix, multiplexer, or any other type of switching device suitable to selectively couple sense amplifiers to selected electrodes. A sensing vector between electrodes 28 and 30 may be selected for sensing an ECG signal, although it is recognized that in some embodiments sensing vectors may be selected that utilize coil electrode 24 and/or housing electrode 15, e.g., from electrode 28 to housing 15 or electrode 30 and housing 15.

One or more ECG signals are received by an input of sensing module 86. Sensing module 86 includes one or more sense amplifiers or other cardiac event detection circuitry for sensing cardiac events, e.g., P-waves or R-waves, from the ECG signal(s). Sensing module 86 passes sense event signals to cardiac signal analyzer 90 in response to sensing cardiac events. For example P-wave sense event signals and R-wave sense event signals are passed to cardiac signal analyzer 90 when the ECG signal crosses a respective P-wave sensing threshold and R-wave sensing threshold, which may each be auto-adjusting sensing thresholds. Bradycardia or asystole is typically determined by a pacing escape interval timer expiring within the timing circuit 92. In response to the pacing escape interval expiring, a control signal 95 is passed to the trigger signal emitting device 18. The pacing escape interval is restarted upon a trigger signal or a sense event signal.

The control signal 95 in the illustrative examples presented herein may be referred to as a pacing control signal because it causes therapy delivery device 100 to deliver a pacing pulse to a heart chamber. In other examples, the control signal 95 may be produced by cardiac signal analyzer 90 to cause other types of therapy pulses to be delivered by therapy delivery device 100 (or another therapy delivery device). For example control signal 95 may be produced to cause therapy delivery device 100 or another therapy delivery device to deliver an ATP pulse, a vagal nerve stimulation pulse, or other type of electrical stimulation pulse.

The control signal 95 is an electrical signal that is passed to emitting device 18 along lead 16 or 60 (or another lead carrying emitting device 18) when emitting device 18 is coupled to ICD 14 in a wired connection. The control signal 95 is alternatively a wireless telemetry signal that is transmitted via telemetry module 88, to emitting device 18. Emitting device 18 may be carried by a lead but configured to wirelessly receive a control signal 95 from telemetry module 88. Alternatively, the emitting device 18 is not a lead-based emitting device and receives control signal 95 wirelessly, e.g., as an RF telemetry signal, from telemetry

module **88**. It is understood that in some embodiments, drive signal circuit **34** may be included within the housing **15** of ICD **14** and coupled to transducer **36** located external to housing **15**.

Trigger signal emitting device **18** includes a drive signal circuit **34** that receives the control signal **95**, either as a wired electrical signal or a wireless signal from telemetry module **88**. Drive signal circuit **34** passes an electrical signal to transducer **36** to enable transducer **36** to emit the trigger signal. Transducer **36** may be an optical transducer or an acoustical transducer in various examples. In other examples, the drive signal circuit **34** is coupled to an antenna for transmitting the trigger signal as an RF signal.

The trigger signal is received and detected by therapy delivery device **100** causing therapy delivery device **100** to deliver one or more pacing pulses to the patient's heart. In some examples, the trigger signal is generated according to predetermined frequency, amplitude, duration and other characteristics that are not intentionally varied by emitting device **18** under the control signal **95**. In other words, the trigger signal merely signals therapy delivery device **100** to deliver therapy without any information relating to how many pacing pulses, what pulse amplitude or pulse width or other pacing pulse control parameters. Therapy delivery device **100** is programmed to deliver a predetermined number of pacing pulses according to predefined pulse control parameters when the trigger signal is detected.

Alternatively, control signal **95** may include encoded pacing pulse control information. The control signal **95** generated by drive circuit **34** may cause transducer **36** to emit a trigger signal according to a frequency, duration, amplitude or other intentionally varied characteristics of the trigger signal to include pacing pulse control parameter information. As described below, a parameter of the trigger signal emitted by transducer **36** may be controllably varied by control signal **95** and drive circuit **34** to cause therapy delivery device **100** to adjust a pacing pulse control parameter such as pacing pulse width, pulse number, etc. Trigger signal parameters that may be varied under the control of signal **95** and drive circuit **34** include, without limitation, trigger signal amplitude, signal frequency, pulse width, pulse number and interpulse interval.

Transducer **36** may be embodied as one or more transducers configured to emit sound or light, for example, upon receiving a drive signal from circuit **34**. Transducer **36** may include any combination of one or more of a ceramic piezoelectric crystal, a polymer piezoelectric crystal, capacitive micromachined ultrasonic transducer (CMUT), piezoelectric micromachined ultrasonic transducer (PMUT), or other ultrasonic transducer, a light emitting diode (LED), a vertical cavity surface emitting laser (VCSEL) or other light source having a high quantum efficiency at a selected light wavelength. Transducer **36** may include multiple transducers arranged in an array and/or configured to emit signals in multiple directions from emitting device **18** to promote reception of the trigger signal by therapy delivery device **100** despite shifting, rotation or other changes of the relative orientations of emitting device **18** and therapy delivery device **100** with respect to each other. The multiple transducers may be selectable by drive circuit **34** such that a single one or combination of transducers producing the best signal-to-noise ratio at the pacemaker receiving transducer is selected.

In one example, transducer **36** may include multiple acoustic transducers activated by drive signal circuit **34** to emit sound waves that constructively interfere to improve the efficiency of acoustical signal transmission. Emitting

device **18** is shown as a single device but may be implemented as more than one emitting device such that transmission of the trigger signal is distributed over two or more emitting devices. When two or more emitting devices are used, emitting device **18** may include one or more lead-based emitting devices, one or more leadless emitting devices, and/or one or more emitting devices incorporated in ICD **14**. Two or more emitting devices may be activated synchronously to produce ultrasound waves that superimpose at the receiver of therapy delivery device **100** to increase transmission efficiency and/or improve signal reception. A phased array of transducers that can be independently pulsed to emit sound can be used to focus the acoustical signal toward the intended receiving transducer in therapy delivery device **100**. When multiple therapy delivery devices **100** or other therapy delivery devices are included, a phased array of transducers included in transducer **36** may be controlled by drive signal circuit **34** to pulse the transducers in a programmed time relationship to focus the trigger signal on the receiver of an intended therapy delivery device.

Transducer **36** may include multiple transducers having different properties for emitting different frequencies of sound, light or RF signal. The different transducers are selectable by drive circuit **34** to enable transmission of different frequencies of trigger signals. For example, different frequencies or different patterns of amplitude, frequency, pulse number, etc. may be emitted for triggering different responses by therapy delivery device **100** or for triggering different intracardiac pacemakers when multiple pacemakers are implanted. As indicated above, different trigger signals may be used to cause therapy delivery device **100** to deliver pacing pulses according to different pacing pulse control parameters, such as different pulse shape, pulse amplitude, pulse width, pulse rate or pulse number.

The transducer **36** is configured to emit a trigger signal at an amplitude and frequency that is detectable by a receiving transducer of therapy delivery device **100**, after attenuation by body tissues along the pathway between the transducer **36** and the therapy delivery device **100**. In one example, transducer **36** is configured to emit sounds in the range of approximately 40 kHz to over 1 MHz. An optical trigger signal may be emitted with a wavelength greater than approximately 1000 nm. An RF signal can be radiated from an antenna at frequencies between 400 MHz and 3 GHz. The frequency of the trigger signal is selected in part based on the types and thicknesses of body tissues encountered along the signal pathway.

Timing circuit **92** may generate control signal **95** to trigger therapy delivery device **100** to provide bradycardia pacing, anti-tachycardia pacing, cardiac resynchronization therapy, AV nodal stimulation, or other pacing therapies according to pacing algorithms and timing intervals stored in memory **82**. Bradycardia pacing may be delivered by therapy delivery device **100** temporarily to maintain cardiac output after delivery of a cardioversion-defibrillation shock by ICD **14** as the heart recovers back to normal function post-shock.

Cardiac signal analyzer **90** includes a tachyarrhythmia detector **94** for detecting and discriminating supraventricular tachycardia (SVT), ventricular tachycardia (VT) and ventricular fibrillation (VF). Some aspects of sensing and processing subcutaneous ECG signals are generally disclosed in commonly-assigned U.S. Pat. No. 7,904,153 (Greenhut, et al.), hereby incorporated herein by reference in its entirety. The timing of R-wave sense event signals from sensing module **86** is used by tachyarrhythmia detector **94** to mea-

sure R-R intervals for counting RR intervals in different detection zones or determining a heart rate or other rate-based measurements for detecting ventricular tachyarrhythmia. Electrical sensing module **86** may additionally or alternatively provide digitized ECG signals to cardiac signal analyzer **90** for use in detecting tachyarrhythmia. Examples of ICDs that may be adapted for use with a triggered therapy delivery device **100** and operations that may be performed by tachyarrhythmia detector **94** for detecting, discriminating and treating tachyarrhythmia are generally disclosed in U.S. Pat. No. 7,742,812 (Ghanem, et al.), U.S. Pat. No. 8,160,684 (Ghanem, et al.), U.S. Pat. No. 5,354,316 (Keimel); U.S. Pat. No. 6,393,316 (Gillberg et al.), U.S. Pat. No. 5,545,186 (Olson, et al.), and U.S. Pat. No. 5,855,593 (Olson, et al.), all of which patents are incorporated herein by reference in their entirety.

The detection algorithms are highly sensitive and specific for the presence or absence of life threatening VT and VF. Therapy delivery module **84** includes a HV therapy delivery module including one or more HV output capacitors. When a malignant tachycardia is detected the HV capacitors are charged to a pre-programmed voltage level by a HV charging circuit. Control module **80** applies a signal to trigger discharge of the HV capacitors upon detecting a feedback signal from therapy delivery module **84** that the HV capacitors have reached the voltage required to deliver a programmed shock energy. In this way, control module **80** controls operation of the high voltage output circuit of therapy delivery module **84** to deliver high energy cardioversion/defibrillation shocks using coil electrode **24** and housing electrode **15**.

It should be noted that implemented arrhythmia detection algorithms may utilize not only ECG signal analysis methods but may also utilize supplemental sensors **96**, such as tissue color, tissue oxygenation, respiration, patient activity, heart sounds, and the like, for contributing to a decision by processing and control module **80** to apply or withhold a therapy. Sensors **96** may also be used in determining the need and timing for pacing by therapy delivery device **100**. For example, an activity sensor signal or other rate responsive sensor signal, such as a minute ventilation signal, may be used for determining a pacing rate meeting a patient's metabolic demand. Timing circuit **92** produces a control signal **95** to cause emitting device **18** to generate trigger signals that cause therapy delivery device **100** to deliver pacing pulses at an appropriate rate based on the rate responsive signal. Sensors **96** may include one or more sensors carried by a lead extending from ICD **14** or within or along housing **15** and/or connector block **13**.

Telemetry module **88** includes a transceiver and antenna for communicating with another device, such as an external programmer **40** and emitting device **18** when it is configured to receive control signal **95** wirelessly. Under the control of control module **80**, telemetry module **88** may receive downlink telemetry from and send uplink telemetry to programmer **40** or another external device. Telemetry module **88** may transmit a control signal wirelessly to emitting device **18**, e.g., as an RF signal.

FIG. 4 is a functional block diagram of an example configuration of a therapy delivery device according to an embodiment of the present disclosure. As illustrated in FIG. 4, therapy delivery device **100** includes a pulse generator **202**, an optional sensing module (not shown), a control module **206**, memory **210**, trigger signal receiver **212** and a power source **214**. Pulse generator **202** generates electrical stimulation pulses that are delivered to heart tissue via electrodes **162** and **164**. Control module **206** controls pulse

generator **202** to deliver a stimulation pulse in response to receiving a trigger detect (TD) signal **216** from receiver **212**. In other embodiments, pulse generator **202** may be configured to be enabled to deliver a stimulation pulse directly by an input signal received from receiver **212**. For example, a switch responsive to a trigger detect signal **216** produced by receiver **212** may enable pulse generator **202** to deliver a stimulation pulse to a targeted tissue via electrodes **162** and **164**.

Pulse generator **202** includes one or more capacitors and a charging circuit to charge the capacitor(s) to a pacing pulse voltage. The pacing capacitor may be charged to the pacing pulse voltage while control module **206** waits for a trigger detect signal **216** from receiver **212**. Upon detecting the trigger signal, the capacitor is coupled to pacing electrodes **162**, **164** to discharge the capacitor voltage and thereby deliver the pacing pulse. Alternatively, detection of the trigger signal initiates pacing capacitor charging and when a predetermined pacing pulse voltage is reached, the pulse is delivered. Pacing circuitry generally disclosed in U.S. Pat. No. 8,532,785 (Crutchfield), hereby incorporated herein by reference in its entirety, may be implemented in therapy delivery device **100** for charging a pacing capacitor to a predetermined pacing pulse amplitude under the control of control module **206** and delivering a pacing pulse.

Alternatively, pulse generator **202** may include a switch that connects power source **214** to pacing electrodes **162** and **164** to deliver the pacing pulse. The switch is opened by trigger detect signal **216** or by a control signal from control module **206**, and power source **214** delivers energy to pulse generator **202** for generating a pacing pulse.

As described below, control module **206** may determine a pacing pulse control parameter from the trigger detect signal **216** and use the determined pacing pulse control parameter to control pulse generator **202** to deliver one or more pacing pulses in accordance with the determined control parameter. For example, the pulse width or other aspect of the trigger signal may be determined by control module **206** and used to set the pulse width (or another aspect) of the pacing pulse.

Receiver **212** receives trigger signals through coupling member **180**. Receiver **212** includes one or more receiving transducers, which may be mounted directly along an inner surface of coupling member **180**, e.g., for receiving sound waves or light. The trigger signal causes a receiving transducer to produce a voltage signal that is passed to a comparator included in receiver **212** (or control module **206**) for comparison to a trigger signal detection threshold. If the voltage signal produced by the receiving transducer is greater than the detection threshold, a trigger detect signal **216** is passed to control module **206**, or directly to pulse generator **202**, to cause pacing pulse delivery.

The receiver **212** is configured to detect only the emitting device-generated trigger signal in some embodiments. For example, receiver **212** may be "tuned" to detect an acoustical or optical signal of a particular signal frequency or bandwidth that is outside a normal physiological range of acoustical or optical signal sensing. In some examples, receiver **212** is not configured to sense and process any physiological acoustical signals or optical signals for determining a physiological event, condition or state.

Control module **206** controls pulse generator **202** to deliver a pacing pulse according to therapy delivery control parameters such as pulse amplitude, pulse width, pulse number, etc., which may be stored in memory **210**. In some examples, pulse generator **202** is enabled to deliver a pacing pulse immediately upon receiving a trigger detect signal

216, either directly from receiver 212 or via control module 206. Alternatively, the pacing pulse may be delivered after a predetermined time delay.

Receiver 212 may include multiple receiving transducers for sensing the trigger signal. The voltage signal produced by multiple transducers may be summed, for example, for comparison to a trigger signal detection threshold. In some embodiments, multiple receiving transducers may be included that are responsive to different frequency bandwidths. Providing detection of different signal frequencies may enable different trigger signals to be transmitted for causing therapy delivery device 100 to perform different pacing functions and/or improve trigger signal detection.

Power source 214 provides power to each of the other modules and components of pacemaker 100 as required. Control module 206 may execute power control operations to control when various components or modules are powered to perform various pacemaker functions. Power source 214 may include one or more energy storage devices, such as one or more rechargeable or non-rechargeable batteries.

Circuitry represented by the block diagram shown in FIG. 4 may include any discrete and/or integrated electronic circuit components that implement analog and/or digital circuits capable of producing the functions attributed to therapy delivery device 100 herein. The functions attributed to therapy delivery device 100 herein may be embodied as one or more processors, hardware, firmware, software, or any combination thereof. Control module 206 may include any one or more of a microprocessor, a controller, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field-programmable gate array (FPGA), state machine, or equivalent discrete or integrated logic circuitry. Depiction of different features of therapy delivery device 100 as discrete modules or components is intended to highlight different functional aspects and does not necessarily imply that such modules must be realized by separate hardware or software components. Rather, functionality associated with one or more modules may be performed by separate hardware or software components, or integrated within common or separate hardware or software components, which may include combinational or sequential logic circuits, state machines, memory devices, etc.

Memory 210 may include computer-readable instructions that, when executed by control module 206, cause control module 206 to perform various functions attributed throughout this disclosure to therapy delivery device 100. The computer-readable instructions may be encoded within memory 210. Memory 210 may include any non-transitory, computer-readable storage media including any volatile, non-volatile, magnetic, optical, or electrical media, such as a random access memory (RAM), read-only memory (ROM), non-volatile RAM (NVRAM), electrically-erasable programmable ROM (EEPROM), flash memory, or other digital media with the sole exception being a transitory propagating signal. Memory 210 stores intervals, counters, or other data used by control module 206 to control the delivery of pacing pulses by pulse generator 202 in response to detection of a trigger signal received by receiver 212.

FIG. 5 is a flowchart of a method for sensing an atrial event for timing of delivery of therapy in an implantable medical device system, according to an embodiment of the present disclosure. According to one embodiment, in order to determine whether a P-wave event is occurring, a template generated from average P-wave morphologies determined from a predetermined patient population may be utilized, using known template generation schemes. In another embodiment, since P-wave morphologies may vary

from patient to patient, a P-wave template may be generated either at implant by the implanting physician based on determined P-wave morphologies of the patient and using known template generation schemes, or may be automatically generated by the implanted device.

FIG. 6 is a schematic diagram of sensing of an atrial event for timing of delivery of therapy in an implantable medical device system, according to an embodiment of the present disclosure. As illustrated in FIG. 6, the sensing device 14 sensing a cardiac signal 112 to monitor the signal 112, including a identifying a P-wave 102, an R-wave 103, and a T-wave 105, and determine the occurrence of a cardiac event. During delivery of cardiac resynchronization pacing therapy, in order to ensure that the ventricular pacing stimulus is delivered in synchrony with atrial activity to maintain atrioventricular synchrony, and that the delivered pacing therapy results in an appropriate evoked response from the ventricle, delivery of the pacing therapy is typically timed off of a sensed P-wave 102. During delivery of the cardiac resynchronization pacing therapy, a sensed atrioventricular (SAV) delay, which is a time period between a sensed atrial event and a paced ventricular event, is typically nominally set as 100 ms, so that the amount of time in which the confirmation of a P-wave 102 must occur in order to time the delivery of the pacing therapy must occur within 100 ms of sensing the P-wave 102. However, the typical duration of a P-wave exceeds 100 ms, making timing of the delivery of therapy problematic. Therefore, as illustrated in FIG. 6, according to an embodiment of the present disclosure, in order to reduce the time required to confirm the occurrence of a P-wave 102, a P-wave template 110 is generated having a P-wave window 104 whose length 105 is less than a width 106 of a P-wave 102 of the sensed cardiac signal 112. For example, the length 105 of the P-wave window 104 may be set as a predetermined percentage of width 106 of the P-wave 102, such as 50%, for example, that still enables the essential morphologic characteristics of the P-wave 102 to be identified, depending on specific patient tendencies. It is understood that, while the SAV delay is nominally set as 100 ms, other values may be utilized, depending on certain patient requirements, and may be within a range of approximately 80-300 ms. In addition, the P-wave template may be periodically updated to address changes in P-wave morphology/features over time.

As illustrated in FIGS. 5 and 6, as described above, the P-wave template 110 is generated corresponding to a desired P-wave sensitivity, such as 50% for example, either during implant by a physician or post-implant by the implanted device, Block 200. The sensing device 14 senses the cardiac signal 112 of the patient and, based on the sensed cardiac signal 112, determines whether a possible P-wave event, i.e., a cardiac event not yet confirmed as a P-wave event, is sensed, Block 202. The basis of determination of a possible P-wave event being sensed is based on comparing a pre-specified time-window of the signal around the time-point of sensing to a template. For the comparison, specific signal characteristics like amplitude, slope, polarity may be used or more global template matching measures like correlation coefficient or wavelet match scores may be used. For example if the correlation coefficient between the windowed signal and the P-wave template exceeds a certain amplitude threshold (e.g. 0.6, 0.65, 0.7, 0.75, 0.8, 0.85, 0.9, 0.95) the sensed signal is determined to be a possible P-wave event. In addition, according to one embodiment, the template matching may be performed using a matching scheme that is insensitive to amplitude, such as correlation waveform analysis (CWA), for example, in combination with a match-

ing scheme that is sensitive to amplitude, such as difference of area (DOA). For example, the amplitude insensitive template matching (CWA) is applied, and if a match is determined, then the amplitude sensitive template matching scheme (DOA) is subsequently applied. If a match is again determined, using the amplitude sensitive matching scheme, the waveform is considered to match the template, and if a match is not again determined, using the amplitude sensitive matching scheme, the waveform is not considered to match the template.

Once a possible P-wave event is determined to have occurred, Yes in Block 202, the sensing device 14 initiates a ventricular pace delivery timer, Block 204, and windows the sensed signal 112 using the generated P-wave template 110, Block 206, to determine whether the cardiac signal 112 matches the P-wave template 110, Block 208. A P-wave template match may be determined, for example, by calculating a correlation coefficient based on a point-by-point comparison of the sampled signal and the stored P-wave template 110. Calculation of a correlation coefficient may be performed as generally described in U.S. Pat. No. 5,193,550 issued to Duffin, incorporated herein by reference in its entirety.

If a P-wave match is not determined to occur, No in Block 208, the possible P-wave is not confirmed as being a P-wave and delivery of the pacing therapy is aborted, Block 210. As a result, the therapy deliver timer is reset, Block 212, and the sensing device 14 waits for the next sensed possible P-wave event to occur, Block 202. If a P-wave match is determined to occur, Yes in Block 208, the possible P-wave is confirmed as being a P-wave, Block 214, and the sensing device 14 emits the trigger signal which is received by the therapy delivery device 100, which then initiates delivery of the pacing therapy, Block 216, utilizing the confirmed sensed P-wave 102 for timing of the delivered therapy.

FIG. 7 is a flowchart of a method for sensing of an atrial event for timing of delivery of therapy in an implantable medical device system, according to an embodiment of the present disclosure. In some circumstances, a T-wave portion of the cardiac signal may be mistakenly identified as being a P-wave portion of the signal. Therefore, according to another embodiment, a T-wave template, generated using known T-wave template generation schemes, is used to identify the occurrence of the T-wave. For example, as illustrated in FIG. 7, as described above, the P-wave template 110 is generated corresponding to a desired P-wave sensitivity, such as 50% for example, either during implant by a physician or post-implant by the implanted device, Block 300. The sensing device 14 senses the cardiac signal and determines whether a T-wave match occurs, Block 302, using a known T-wave template matching scheme. For example, a T-wave template match may be determined, for example, by calculating a correlation coefficient based on a point-by-point comparison of the sampled signal and the stored T-wave template. Other known T-wave matching schemes may be utilized, such as described in U.S. Pat. No. 7,831,304 to Cao, et al., for example, or in U.S. Patent Publication No 2006/0116592 to Zhou et al., both incorporated herein by reference in their entireties.

Once a T-wave match is determined to occur, Yes in Block 302, the sensing device 14 determines, based on the sensed cardiac signal 112, whether a possible P-wave event is sensed, Block 304, as described above. The sensing device 14 continues to determine whether a possible P-wave is sensed, Block 304 for a predetermined period of time after sensing of the T-wave, such as between 200 and 500 ms, for example. Therefore, during the determination of whether a

possible P-wave event is present in Block 304, the device monitors whether a determination is made as to whether a predetermined time period has expired, Block 307, so that if the device 14 is unable to determine that a possible P-wave event has been sensed after sensing of the T-wave within the predetermined time period, Yes in Block 307, the possible P-wave is not confirmed as being a P-wave and delivery of the pacing therapy is aborted, Block 312. As a result, the therapy deliver timer is reset, Block 314, and the sensing device 14 waits for the next T-wave to be sensed, Block 302. Once the sensing device 14 determines a possible P-wave event has occurred, Yes in Block 304, the sensing device 14 initiates a ventricular pace delivery timer, Block 306, and windows the sensed cardiac signal 112 using the generated P-wave template 110, Block 308, to determine whether the signal matches the P-wave template 110, Block 310, as described above.

If a P-wave match is not determined to occur, No in Block 310, the possible P-wave is not confirmed as being a P-wave and delivery of the pacing therapy is aborted, Block 312. As a result, the therapy deliver timer is reset, Block 314, and the sensing device 14 waits for the next T-wave to be sensed, Block 302. If a P-wave match is determined to occur, Yes in Block 310, the possible P-wave is confirmed as being a P-wave, Block 316, and the sensing device 14 emits the trigger signal to the therapy delivery device 100, which then initiate delivery of the pacing therapy via the therapy delivery device 100, Block 318, utilizing the confirmed sensed P-wave for timing of the delivered therapy.

The techniques described in this disclosure, including those attributed to the IMD, the programmer, or various constituent components, may be implemented, at least in part, in hardware, software, firmware, or any combination thereof. For example, various aspects of the techniques may be implemented within one or more processors, including one or more microprocessors, DSPs, ASICs, FPGAs, or any other equivalent integrated or discrete logic circuitry, as well as any combinations of such components, embodied in programmers, such as physician or patient programmers, stimulators, image processing devices, or other devices. The term "module," "processor," or "processing circuitry" may generally refer to any of the foregoing logic circuitry, alone or in combination with other logic circuitry, or any other equivalent circuitry.

Such hardware, software, and/or firmware may be implemented within the same device or within separate devices to support the various operations and functions described in this disclosure. In addition, any of the described units, modules, or components may be implemented together or separately as discrete but interoperable logic devices. Depiction of different features as modules or units is intended to highlight different functional aspects and does not necessarily imply that such modules or units must be realized by separate hardware or software components. Rather, functionality associated with one or more modules or units may be performed by separate hardware or software components, or integrated within common or separate hardware or software components.

When implemented in software, the functionality ascribed to the systems, devices and techniques described in this disclosure may be embodied as instructions on a computer-readable medium such as RAM, ROM, NVRAM, EEPROM, FLASH memory, magnetic data storage media, optical data storage media, or the like. The instructions may be executed by one or more processors to support one or more aspects of the functionality described in this disclosure.

This disclosure has been provided with reference to illustrative embodiments and is not meant to be construed in a limiting sense. As described previously, one skilled in the art will recognize that other various illustrative applications may use the techniques as described herein to take advantage of the beneficial characteristics of the apparatus and methods described herein. Various modifications of the illustrative embodiments, as well as additional embodiments of the disclosure, will be apparent upon reference to this description.

What is claimed:

1. A medical device system for controlling delivery of therapeutic stimulation pulses, the medical device system comprising:

- a sensing device configured to:
 - sense a cardiac signal of a patient; and
 - emit a trigger signal in response to the sensed cardiac signal;
- a therapy delivery device configured to:
 - receive the trigger signal; and
 - deliver therapy to the patient in response to the emitted trigger signal; and
- a processor positioned within the sensing device, the processor being configured to:
 - determine whether the sensed cardiac signal exceeds a P-wave candidate threshold;
 - compare, in response to a determination that the sensed cardiac signal exceeds the P-wave candidate threshold, a portion of the sensed cardiac signal to a P-wave template, the P-wave template comprising a sensing window having a length less than a width of a P-wave with a predetermined P-wave morphology, the sensing window corresponding to a time window that ends prior to an end of the P-wave with the predetermined P-wave morphology;
 - confirm an occurrence of a P-wave in the sensed cardiac signal in response to the comparison between the portion of the sensed cardiac signal and the P-wave template;
 - generate, in response to the occurrence of the P-wave in the sensed cardiac signal being confirmed, the trigger signal emitted by the sensing device; and
 - inhibit delivery of the trigger signal in response to the occurrence of the P-wave in the sensed cardiac signal not being confirmed.

2. The medical device system of claim 1, wherein the sensing device comprises a subcutaneous device capable of being implanted subcutaneously within a patient and the therapy delivery device comprises a transcatheter intracardiac pacemaker adapted for implantation wholly within a heart chamber.

3. The medical device system of claim 1, wherein the sensing device comprises subcutaneously implanted electrodes to sense the cardiac signal.

4. The medical device system of claim 1, wherein the sensing device comprises a subcutaneously implanted leadless device.

5. The medical device system of claim 1, wherein the length of the sensing window of the P-wave template corresponds to a predetermined percentage of the width of the P-wave with the predetermined P-wave morphology.

6. The medical device system of claim 5, wherein the predetermined percentage is fifty percent (50%).

7. The medical device system of claim 1, wherein the therapeutic stimulation pulses comprise cardiac resynchronization therapy pacing pulses.

8. The medical device system of claim 1, wherein the P-wave candidate threshold comprises at least one of an amplitude or a slope.

9. A medical device system for controlling delivery of therapeutic stimulation pulses, the medical device system comprising:

- a sensing device configured to:
 - sense a cardiac signal of a patient; and
 - emit a trigger signal in response to the sensed cardiac signal;
- a therapy delivery device configured to:
 - receive the trigger signal; and
 - deliver therapy to the patient in response to the emitted trigger signal; and
- a processor positioned within the sensing device, the processor being configured to:
 - determine whether the cardiac signal comprises a T-wave;
 - determine, in response to a determination that the cardiac signal comprises a T-wave, whether the sensed cardiac signal exceeds a P-wave candidate threshold;
 - compare, in response to a determination that the sensed cardiac signal exceeds the P-wave candidate threshold, a portion of the sensed cardiac signal to a P-wave template, the P-wave template comprising a sensing window having a length less than a width of a P-wave with a predetermined P-wave morphology, the sensing window corresponding to a time window that ends prior to an end of the P-wave with the predetermined P-wave morphology;
 - confirm an occurrence of a P-wave in the sensed cardiac signal in response to the comparison between the portion of the sensed cardiac signal and the P-wave template;
 - generate, in response to the occurrence of a P-wave in the sensed cardiac signal being confirmed, the trigger signal emitted by the sensing device; and
 - inhibit delivery of the trigger signal in response to one of the T-wave not occurring and the occurrence of the P-wave in the sensed cardiac signal not being confirmed.

10. The medical device system of claim 9, wherein the sensing device comprises a subcutaneous device capable of being implanted subcutaneously within a patient and the therapy delivery device comprises a transcatheter intracardiac pacemaker adapted for implantation wholly within a heart chamber.

11. The medical device system of claim 9, wherein the sensing device comprises subcutaneously implanted electrodes to sense the cardiac signal.

12. The medical device system of claim 9, wherein the sensing device comprises a subcutaneously implanted leadless device.

13. The medical device system of claim 9, wherein the length of the sensing window of the P-wave template corresponds to a predetermined percentage of the width of the P-wave with the predetermined P-wave morphology.

14. The medical device system of claim 13, wherein the predetermined percentage is fifty percent (50%).

15. The medical device system of claim 9, wherein the therapeutic stimulation pulses comprise cardiac resynchronization therapy pacing pulses.

16. The medical device system of claim 9, wherein the P-wave candidate threshold comprises at least one of an amplitude or a slope.

17. A method of delivering therapeutic stimulation pulses, the method comprising:
 sensing a cardiac signal of a patient;
 receiving a trigger signal;
 delivering therapy to the patient via a therapy delivery device in response to the emitted trigger signal;
 determining whether the sensed cardiac signal exceeds a P-wave candidate threshold;
 comparing, in response to determining that the sensed cardiac signal exceeds the P-wave candidate threshold, a portion of the sensed cardiac signal to a P-wave template, the P-wave template comprising a sensing window having a length less than a width of a P-wave with a predetermined P-wave morphology, the sensing window corresponding to a time window that ends prior to an end of the P-wave with the predetermined P-wave morphology;
 confirming an occurrence of a P-wave in the sensed cardiac signal in response to the comparison between the portion of the sensed cardiac signal and the P-wave template;
 generating the trigger signal in response to the occurrence of the P-wave in the sensed cardiac signal being confirmed; and
 inhibiting delivery of the trigger signal in response to the occurrence of the P-wave in the sensed cardiac signal not being confirmed.

18. The method of claim 17, wherein the sensing device comprises a subcutaneous device capable of being implanted subcutaneously within a patient and the therapy delivery device comprises a transcatheter intracardiac pacemaker adapted for implantation wholly within a heart chamber.

19. The method of claim 17, wherein the sensing device comprises subcutaneously implanted electrodes to sense the cardiac signal.

20. The method of claim 17, wherein the sensing device comprises a subcutaneously implanted leadless device.

21. The method of claim 17, wherein the length of the sensing window of the P-wave template corresponds to a predetermined percentage of the width of the P-wave with the predetermined P-wave morphology.

22. The method of claim 21, wherein the predetermined percentage is fifty percent (50%).

23. The method of claim 17, wherein the therapeutic stimulation pulses comprise cardiac resynchronization therapy pacing pulses.

24. The method of claim 17, wherein the P-wave candidate threshold comprises at least one of an amplitude or a slope.

25. A method of delivering therapeutic stimulation pulses, the method comprising:

sensing a cardiac signal of a patient;
 receiving a trigger signal;
 delivering therapy to the patient via a therapy delivery device in response to the emitted trigger signal;
 determining whether the cardiac signal comprises a T-wave;
 determining, in response to a T-wave occurring, whether the sensed cardiac signal exceeds a P-wave candidate threshold;
 comparing, in response to determining that the sensed cardiac signal exceeds the P-wave candidate threshold, a portion of the sensed cardiac signal to a P-wave template, the P-wave template comprising a sensing window having a length less than a width of a P-wave with a predetermined P-wave morphology, the sensing

window corresponding to a time window that ends prior to an end of the P-wave with the predetermined P-wave morphology;

confirming an occurrence of a P-wave in the sensed cardiac signal in response to the comparison between the portion of the sensed cardiac signal and the P-wave template;

generating the trigger signal in response to the occurrence of the P-wave in the sensed cardiac signal being confirmed; and

inhibiting delivery of the trigger signal in response to one of the T-wave not occurring and the occurrence of the P-wave in the sensed cardiac signal not being confirmed.

26. The method of claim 25, wherein the sensing device comprises a subcutaneous device capable of being implanted subcutaneously within a patient and the therapy delivery device comprises a transcatheter intracardiac pacemaker adapted for implantation wholly within a heart chamber.

27. The method of claim 25, wherein the sensing device comprises subcutaneously implanted electrodes to sense the cardiac signal.

28. The method of claim 25, wherein the sensing device comprises a subcutaneously implanted leadless device.

29. The method of claim 25, wherein the length of the sensing window of the P-wave template corresponds to a predetermined percentage of the width of the P-wave with the predetermined P-wave morphology.

30. The method of claim 29, wherein the predetermined percentage is fifty percent (50%).

31. The method of claim 25, wherein the therapeutic stimulation pulses comprise cardiac resynchronization therapy pacing pulses.

32. The method of claim 25, wherein the possible P-wave threshold comprises at least one of an amplitude or a slope.

33. A medical device for controlling delivery of therapeutic stimulation pulses, the medical device comprising:

a subcutaneous sensing device comprising subcutaneously implanted electrodes configured to sense a cardiac signal of a patient;

an emitting device configured to emit a trigger signal to deliver the therapeutic stimulation pulses in response to the sensed cardiac signal; and

a processor positioned within the subcutaneous sensing device, the processor configured to:

determine whether the sensed cardiac signal exceeds a P-wave candidate threshold,

compare, in response to a determination that the sensed cardiac signal exceeds the P-wave candidate threshold, a portion of the sensed cardiac signal to a P-wave template, the P-wave template comprising a sensing window having a length less than a width of a P-wave with a predetermined P-wave morphology, the sensing window corresponding to a time window that ends prior to an end of the P-wave with the predetermined P-wave morphology;

confirm an occurrence of a P-wave in the sensed cardiac signal in response to the comparison between the portion of the sensed cardiac signal and the P-wave template;

generate, in response to the occurrence of the P-wave in the sensed cardiac signal being confirmed, the trigger signal emitted by the emitting device; and

inhibit delivery of the trigger signal in response to the occurrence of the P-wave in the sensed cardiac signal not being confirmed.

34. The medical device of claim 33, wherein the length of the sensing window of the P-wave template corresponds to a predetermined percentage of the width of the P-wave with the predetermined P-wave morphology.

35. The medical device of claim 34, wherein the predetermined percentage is fifty percent (50%).

36. The medical device of claim 33, wherein the therapeutic stimulation pulses comprise cardiac resynchronization therapy pacing pulses.

37. The medical device of claim 33, wherein the P-wave candidate threshold comprises at least one of an amplitude or a slope.

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专利名称(译)	在心脏医疗设备和医疗设备系统中的再同步治疗期间确认感测的心房事件以进行起搏		
公开(公告)号	US10004906	公开(公告)日	2018-06-26
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[标]申请(专利权)人(译)	美敦力公司		
申请(专利权)人(译)	美敦力公司, INC.		
当前申请(专利权)人(译)	美敦力公司, INC.		
[标]发明人	GHOSH SUBHAM DU JUAN GREENHUT SAUL E HEMMING MICHAEL T		
发明人	GHOSH, SUBHAM DU, JUAN GREENHUT, SAUL E HEMMING, MICHAEL T		
IPC分类号	A61B5/00 A61N1/365 A61N1/368 A61B5/0452 A61N1/375 A61B5/042 A61N1/362		
CPC分类号	A61N1/3682 A61B5/0422 A61B5/0452 A61B5/04525 A61B5/7285 A61N1/36507 A61N1/3756 A61B5/7246 A61N1/3627		
其他公开文献	US20170014629A1		
外部链接	Espacenet		

摘要(译)

一种用于控制治疗刺激脉冲的输送的医疗装置和医疗装置系统，包括感测装置以感测心脏信号并响应于感测到的心脏信号发出触发信号，治疗递送装置接收触发信号并将治疗递送至响应于发射的触发信号的患者和位于感测装置内的处理器，处理器配置成确定感测的心脏信号是否超过可能的P波阈值，将感测的心脏信号的一部分与P波进行比较具有长度小于P波宽度的感测窗口的模板，响应于比较确认P波信号的发生，响应于P波信号的发生而发出触发信号并且，响应于未确认的P波信号的发生，抑制发射信号的传送。

