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(54) **ATRIAL ARRHYTHMIA DETECTION DURING INTERMITTENT INSTANCES OF VENTRICULAR PACING IN A CARDIAC MEDICAL DEVICE**

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(57) **ABSTRACT**

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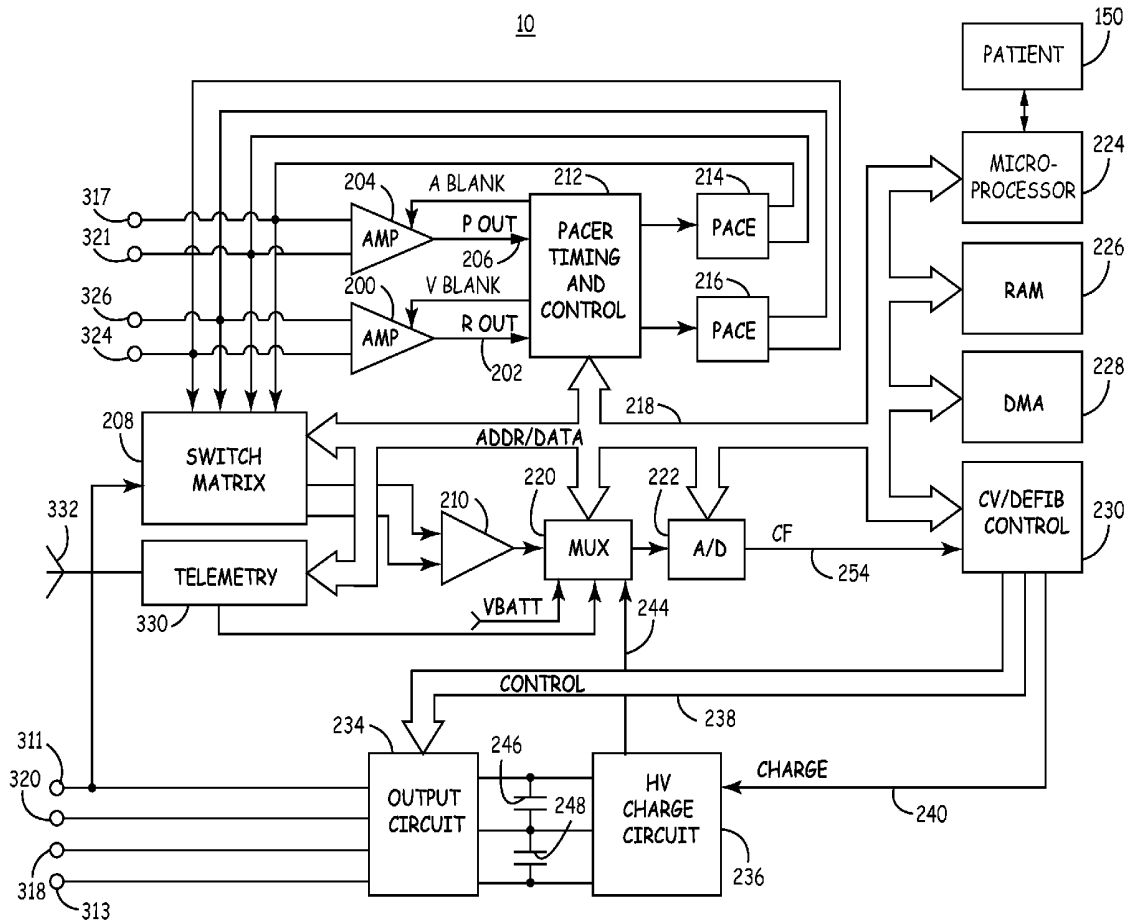
A method and medical device for determining a cardiac event that includes sensing a cardiac signal, determining a predetermined number of sensed cardiac events in response to the sensed cardiac signal, determining a plurality of sensed event windows in response to the predetermined number of the sensed cardiac events, determining, for each of the plurality of sensed event windows, whether a number of paced events is less than a paced event threshold, determining whether intervals within the sensed event windows having a number of paced events less than the paced event threshold are greater than an interval threshold, determining an interval difference factor for each of the plurality of windows having intervals less than the interval threshold, and determining the cardiac event in response to the interval difference factors determined for each of the plurality of windows.

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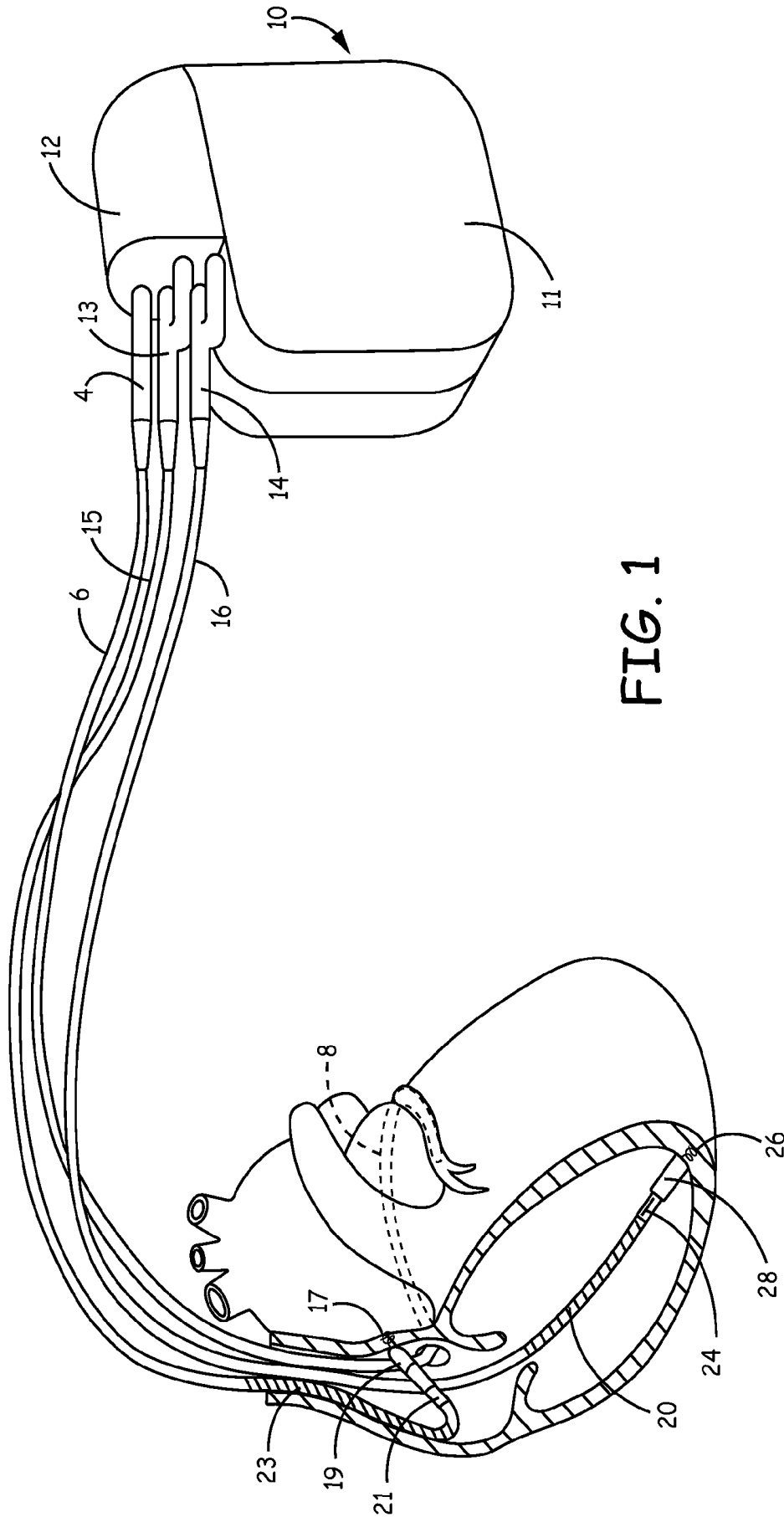


FIG. 1

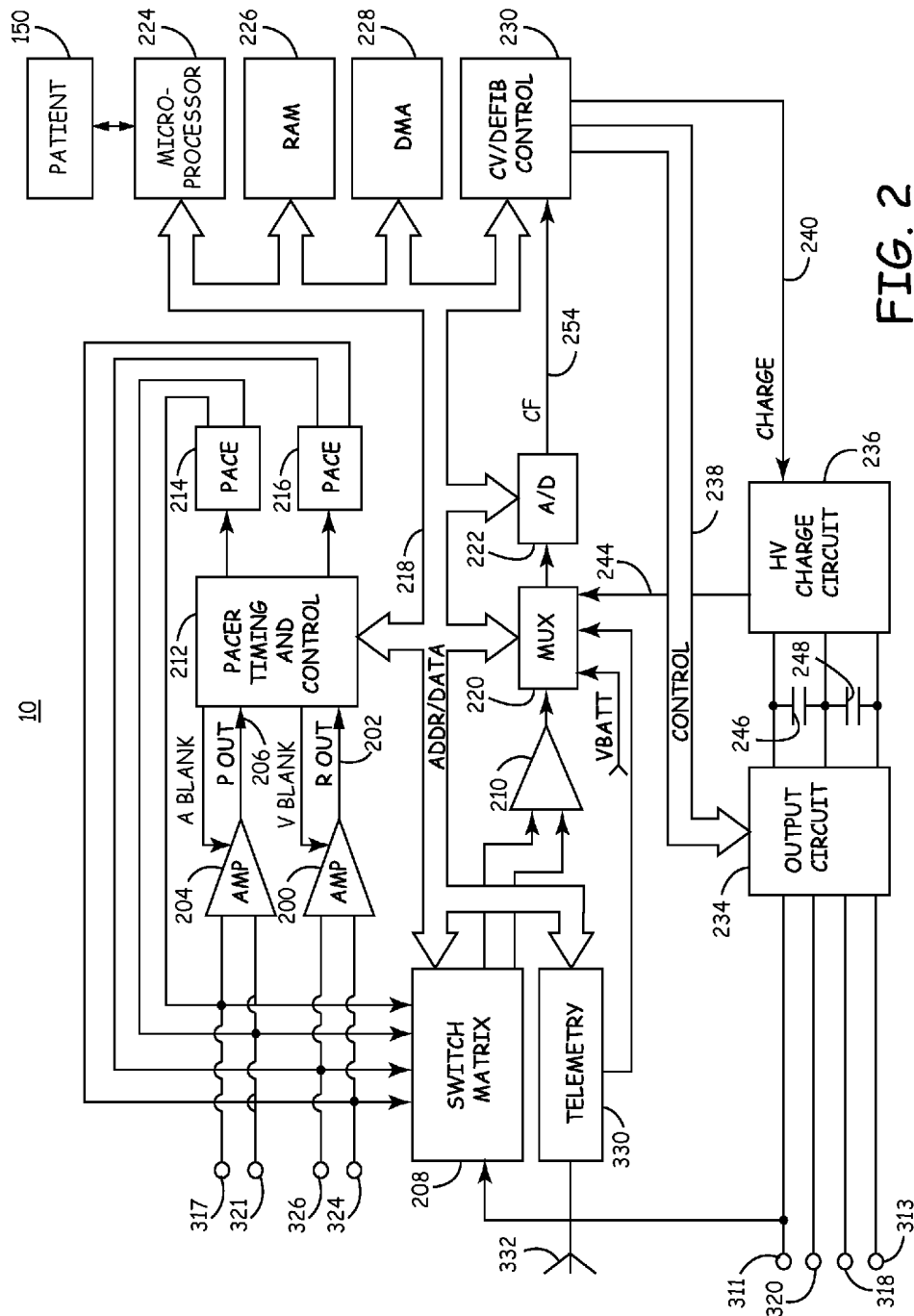


FIG. 2

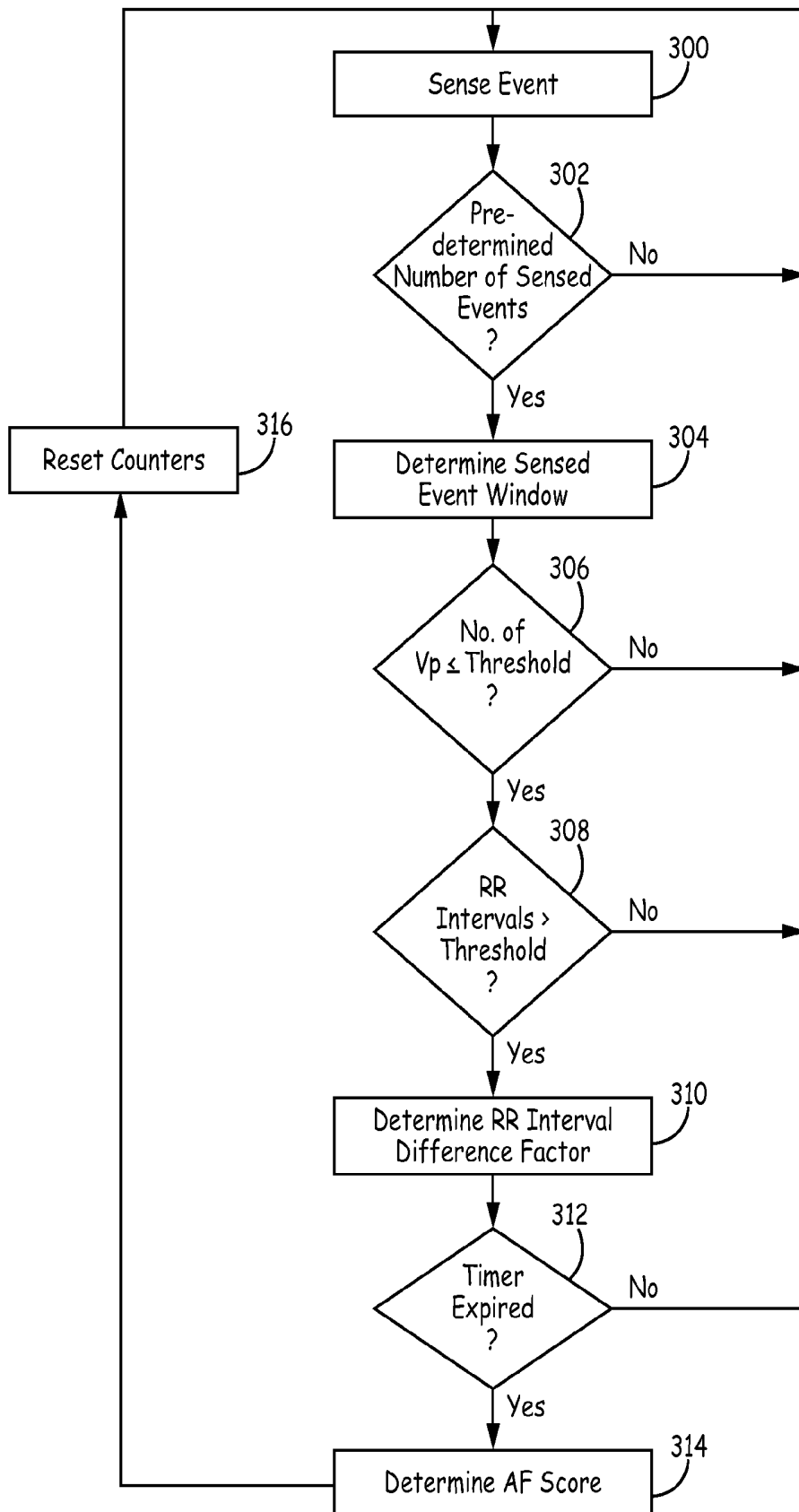


FIG. 3

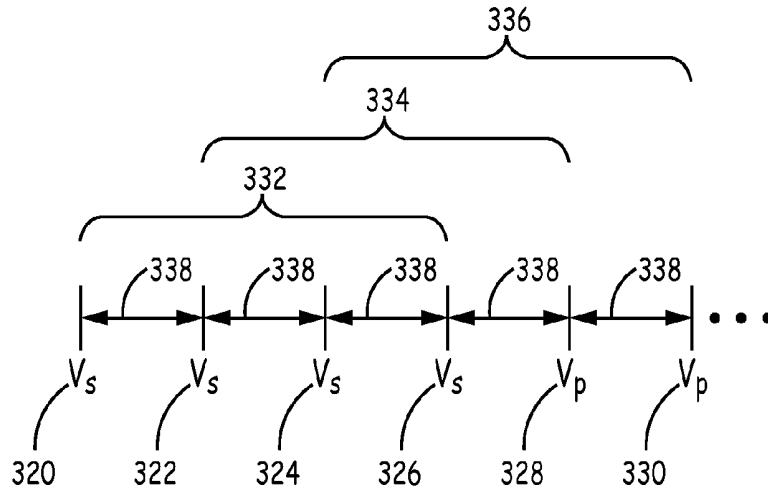


FIG. 4

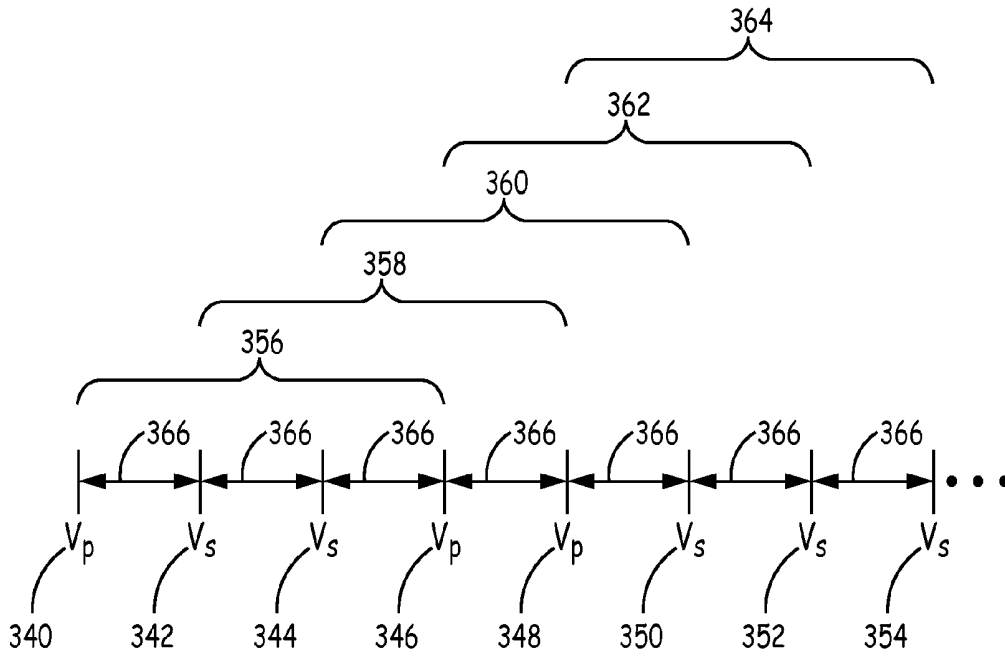


FIG. 5

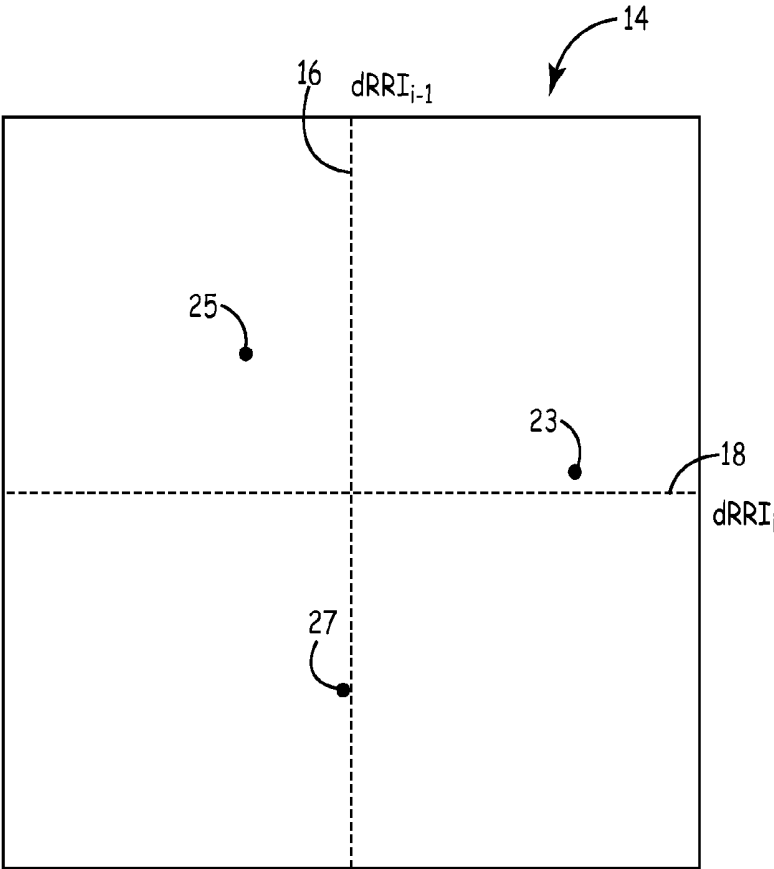


FIG. 6

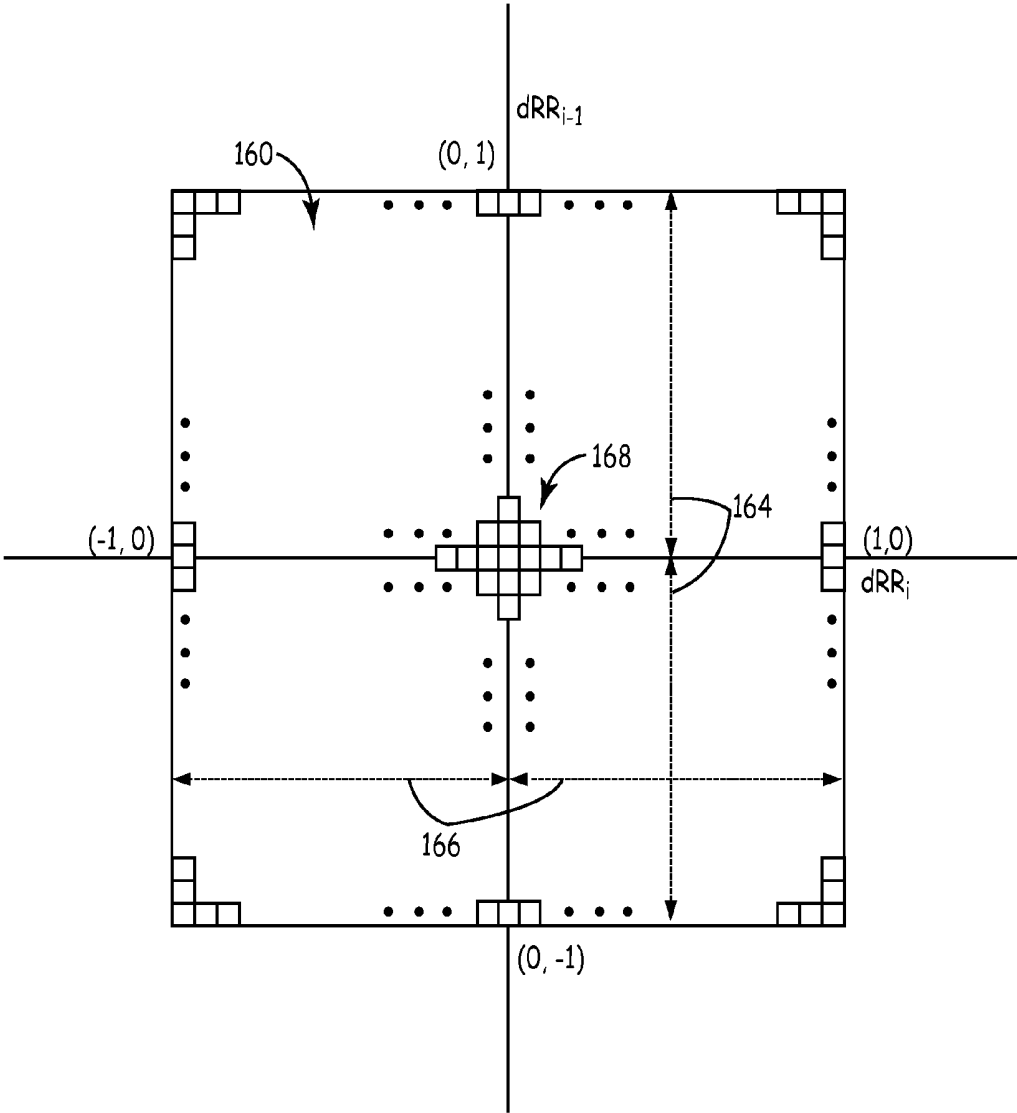


FIG. 7

**ATRIAL ARRHYTHMIA DETECTION
DURING INTERMITTENT INSTANCES OF
VENTRICULAR PACING IN A CARDIAC
MEDICAL DEVICE**

TECHNICAL FIELD

[0001] The disclosure relates generally to cardiac medical devices and, in particular, to methods for detecting atrial arrhythmias during intermittent instances of ventricular pacing in a cardiac medical device.

BACKGROUND

[0002] During normal sinus rhythm (NSR), the heart beat is regulated by electrical signals produced by the sino-atrial (SA) node located in the right atrial wall. Each atrial depolarization signal produced by the SA node spreads across the atria, causing the depolarization and contraction of the atria, and arrives at the atrioventricular (A-V) node. The A-V node responds by propagating a ventricular depolarization signal through the bundle of His of the ventricular septum and thereafter to the bundle branches and the Purkinje muscle fibers of the right and left ventricles.

[0003] Atrial tachyarrhythmia includes the disorganized form of atrial fibrillation (AF) and varying degrees of organized atrial tachycardia, including atrial flutter. Atrial fibrillation (AF) occurs because of multiple focal triggers in the atrium or because of changes in the substrate of the atrium causing heterogeneities in conduction through different regions of the atria. The ectopic triggers can originate anywhere in the left or right atrium or pulmonary veins. The AV node will be bombarded by frequent and irregular atrial activations but will only conduct a depolarization signal when the AV node is not refractory. The ventricular cycle lengths will be irregular and will depend on the different states of refractoriness of the AV-node.

[0004] As more serious consequences of persistent atrial arrhythmias have come to be understood, such as an associated risk of relatively more serious ventricular arrhythmias and stroke, there is a growing interest in monitoring and treating atrial arrhythmias.

[0005] Methods for discriminating arrhythmias that are atrial in origin from arrhythmias originating in the ventricles have been developed for use in dual chamber implantable devices wherein both an atrial EGM signal and a ventricular EGM signal are available. Discrimination of arrhythmias can rely on event intervals (PP intervals and RR intervals), event patterns, and EGM morphology. Such methods have been shown to reliably discriminate ventricular arrhythmias from supra-ventricular arrhythmias. In addition, such methods have been developed for use in single chamber implantable devices, subcutaneous implantable devices, and external monitoring devices, where an adequate atrial EGM signal having acceptable signal-to-noise ratio is not always available for use in detecting and discriminating atrial arrhythmias. However, such single chamber devices have been designed to monitor AF during non-paced ventricular rhythm. What is needed, therefore, is a method for monitoring atrial arrhythmias during an intermittent ventricular paced rhythm.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] FIG. 1 is a schematic diagram of an exemplary medical device for detecting arrhythmia during ventricular pacing according to an embodiment of the present disclosure.

[0007] FIG. 2 is a functional block diagram of an IMD according to one embodiment.

[0008] FIG. 3 is flowchart of a method for detecting atrial arrhythmias during intermittent instances of ventricular pacing in a cardiac medical device according to an embodiment of the present disclosure.

[0009] FIG. 4 is a schematic diagram illustrating detecting atrial arrhythmias during intermittent instances of ventricular pacing in a cardiac medical device according to an embodiment of the present disclosure.

[0010] FIG. 5 is a schematic diagram illustrating detecting atrial arrhythmias during intermittent instances of ventricular pacing in a cardiac medical device according to another embodiment of the present disclosure.

[0011] FIG. 6 is a schematic diagram of classifying of cardiac events in a cardiac medical device according to an embodiment of the present disclosure.

[0012] FIG. 7 is a diagram of an exemplary two-dimensional histogram representing a Lorenz plot area for identifying cardiac events.

DETAILED DESCRIPTION

[0013] In the following description, references are made to illustrative embodiments for carrying out the methods described herein. It is understood that other embodiments may be utilized without departing from the scope of the disclosure.

[0014] In various embodiments, ventricular signals are used for determining successive ventricular cycle lengths for use in detecting atrial arrhythmias. The atrial arrhythmia detection methods do not require an atrial signal source. The methods presented herein may be embodied in software, hardware or firmware in implantable or external medical devices. Such devices include implantable monitoring devices having cardiac EGM/ECG monitoring capabilities and associated EGM/ECG sense electrodes, which may be intracardiac, epicardial, or subcutaneous electrodes.

[0015] The methods described herein can also be incorporated in implantable medical devices having therapy delivery capabilities, such as single chamber or bi-ventricular pacing systems or ICDs that sense the R-waves in the ventricles and deliver an electrical stimulation therapy to the ventricles. The atrial arrhythmia detection methods presently disclosed may also be incorporated in external monitors having ECG electrodes coupled to the patient's skin to detect R-waves, e.g. Holter monitors, or within computerized systems that analyze pre-recorded ECG or EGM data. Embodiments may further be implemented in a patient monitoring system, such as a centralized computer system which processes data sent to it by implantable or wearable monitoring devices.

[0016] FIG. 1 is a schematic diagram of an exemplary medical device for detecting arrhythmia during ventricular pacing according to an embodiment of the present disclosure. As illustrated in FIG. 1, a medical device according to an embodiment of the present disclosure may be in the form of an implantable cardioverter defibrillator (ICD) 10 a connector block 12 that receives the proximal ends of a right ventricular lead 16, a right atrial lead 15 and a coronary sinus lead 6, used for positioning electrodes for sensing and stimulation in three or four heart chambers. Right ventricular lead 16 is positioned such that its distal end is in the right ventricle for sensing right ventricular cardiac signals and delivering pacing or shocking pulses in the right ventricle. For these purposes, right ventricular lead 16 is equipped with a ring elec-

trode 24, an extendable helix electrode 26 mounted retractably within an electrode head 28, and a coil electrode 20, each of which are connected to an insulated conductor within the body of lead 16. The proximal end of the insulated conductors are coupled to corresponding connectors carried by bifurcated connector 14 at the proximal end of lead 16 for providing electrical connection to the ICD 10. It is understood that although the device illustrated in FIG. 1 is a dual chamber device, other devices such as single chamber devices may be utilized to perform the technique of the present disclosure described herein.

[0017] The right atrial lead 15 is positioned such that its distal end is in the vicinity of the right atrium and the superior vena cava. Lead 15 is equipped with a ring electrode 21 and an extendable helix electrode 17, mounted retractably within electrode head 19, for sensing and pacing in the right atrium. Lead 15 is further equipped with a coil electrode 23 for delivering high-energy shock therapy. The ring electrode 21, the helix electrode 17 and the coil electrode 23 are each connected to an insulated conductor with the body of the right atrial lead 15. Each insulated conductor is coupled at its proximal end to a connector carried by bifurcated connector 13.

[0018] The coronary sinus lead 6 is advanced within the vasculature of the left side of the heart via the coronary sinus and great cardiac vein. The coronary sinus lead 6 is shown in the embodiment of FIG. 1 as having a defibrillation coil electrode 8 that may be used in combination with either the coil electrode 20 or the coil electrode 23 for delivering electrical shocks for cardioversion and defibrillation therapies. In other embodiments, coronary sinus lead 6 may also be equipped with a distal tip electrode and ring electrode for pacing and sensing functions in the left chambers of the heart. The coil electrode 8 is coupled to an insulated conductor within the body of lead 6, which provides connection to the proximal connector 4.

[0019] The electrodes 17 and 21 or 24 and 26 may be used as true bipolar pairs, commonly referred to as a “tip-to-ring” configuration. Further, electrode 17 and coil electrode 20 or electrode 24 and coil electrode 23 may be used as integrated bipolar pairs, commonly referred to as a “tip-to-coil” configuration. In accordance with the invention, ICD 10 may, for example, adjust the electrode configuration from a tip-to-ring configuration, e.g., true bipolar sensing, to a tip-to-coil configuration, e.g., integrated bipolar sensing, upon detection of oversensing in order to reduce the likelihood of future oversensing. In other words, the electrode polarities can be reselected in response to detection of oversensing in an effort to reduce susceptibility of oversensing. In some cases, electrodes 17, 21, 24, and 26 may be used individually in a unipolar configuration with the device housing 11 serving as the indifferent electrode, commonly referred to as the “can” or “case” electrode.

[0020] The device housing 11 may also serve as a subcutaneous defibrillation electrode in combination with one or more of the defibrillation coil electrodes 8, 20 or 23 for defibrillation of the atria or ventricles. It is recognized that alternate lead systems may be substituted for the three lead system illustrated in FIG. 1. While a particular multi-chamber ICD and lead system is illustrated in FIG. 1, methodologies included in the present invention may be adapted for use with any single chamber, dual chamber, or multi-chamber ICD or pacemaker system, subcutaneous implantable device, or other internal or external cardiac monitoring device.

[0021] FIG. 2 is a functional schematic diagram of the medical device of FIG. 1. This diagram should be taken as exemplary of the type of device with which the invention may be embodied and not as limiting. The disclosed embodiment shown in FIG. 2 is a microprocessor-controlled device, but the methods of the present invention may also be practiced with other types of devices such as those employing dedicated digital circuitry.

[0022] With regard to the electrode system illustrated in FIG. 1, ICD 10 is provided with a number of connection terminals for achieving electrical connection to the leads 6, 15, and 16 and their respective electrodes. A connection terminal 311 provides electrical connection to the housing 11 for use as the indifferent electrode during unipolar stimulation or sensing. The connection terminals 320, 313, and 318 provide electrical connection to coil electrodes 20, 8 and 23 respectively. Each of these connection terminals 311, 320, 313, and 318 are coupled to the high voltage output circuit 234 to facilitate the delivery of high energy shocking pulses to the heart using one or more of the coil electrodes 8, 20, and 23 and optionally the housing 11.

[0023] The connection terminals 317 and 321 provide electrical connection to the helix electrode 17 and the ring electrode 21 positioned in the right atrium. The connection terminals 317 and 321 are further coupled to an atrial sense amplifier 204 for sensing atrial signals such as P-waves. The connection terminals 326 and 324 provide electrical connection to the helix electrode 26 and the ring electrode 24 positioned in the right ventricle. The connection terminals 326 and 324 are further coupled to a ventricular sense amplifier 200 for sensing ventricular signals. The atrial sense amplifier 204 and the ventricular sense amplifier 200 preferably take the form of automatic gain controlled amplifiers with adjustable sensitivity. In accordance with the invention, ICD 10 and, more specifically, microprocessor 224 automatically adjusts the sensitivity of atrial sense amplifier 204, ventricular sense amplifier 200 or both in response to detection of oversensing in order to reduce the likelihood of oversensing. Ventricular sense amplifier 200 and atrial sense amplifier 204 operate in accordance with originally programmed sensing parameters for a plurality of cardiac cycles, and upon detecting oversensing, automatically provides the corrective action to avoid future oversensing. In this manner, the adjustments provided by ICD 10 to amplifiers 200 and 204 to avoid future oversensing are dynamic in nature. Particularly, microprocessor 224 increases a sensitivity value of the amplifiers, thus reducing the sensitivity, when oversensing is detected. Atrial sense amplifier 204 and ventricular sense amplifier 200 receive timing information from pacer timing and control circuitry 212.

[0024] Specifically, atrial sense amplifier 204 and ventricular sense amplifier 200 receive blanking period input, e.g., ABLANK and VBLANK, respectively, which indicates the amount of time the electrodes are “turned off” in order to prevent saturation due to an applied pacing pulse or defibrillation shock. As will be described, the blanking periods of atrial sense amplifier 204 and ventricular sense amplifier 200 and, in turn, the blanking periods of sensing electrodes associated with the respective amplifiers may be automatically adjusted by ICD 10 to reduce the likelihood of oversensing. The general operation of the ventricular sense amplifier 200 and the atrial sense amplifier 204 may correspond to that disclosed in U.S. Pat. No. 5,117,824, by Keimel, et al., incorporated herein by reference in its entirety. Whenever a signal

received by atrial sense amplifier **204** exceeds an atrial sensitivity, a signal is generated on the P-out signal line **206**. Whenever a signal received by the ventricular sense amplifier **200** exceeds a ventricular sensitivity, a signal is generated on the R-out signal line **202**.

[**0025**] Switch matrix **208** is used to select which of the available electrodes are coupled to a wide band amplifier **210** for use in digital signal analysis. Selection of the electrodes is controlled by the microprocessor **224** via data/address bus **218**. The selected electrode configuration may be varied as desired for the various sensing, pacing, cardioversion and defibrillation functions of the ICD **10**. Specifically, microprocessor **224** may modify the electrode configurations based on detection of oversensing due to cardiac or non-cardiac origins. Upon detection of R-wave oversensing, for example, microprocessor **224** may modify the electrode configuration of the right ventricle from true bipolar sensing, e.g., tip-to-ring, to integrated bipolar sensing, e.g., tip-to-coil.

[**0026**] Signals from the electrodes selected for coupling to bandpass amplifier **210** are provided to multiplexer **220**, and thereafter converted to multi-bit digital signals by A/D converter **222**, for storage in random access memory **226** under control of direct memory access circuit **228** via data/address bus **218**. Microprocessor **224** may employ digital signal analysis techniques to characterize the digitized signals stored in random access memory **226** to recognize and classify the patient's heart rhythm employing any of the numerous signal processing methodologies known in the art. An exemplary tachyarrhythmia recognition system is described in U.S. Pat. No. 5,545,186 issued to Olson et al, incorporated herein by reference in its entirety.

[**0027**] Upon detection of an arrhythmia, an episode of EGM data, along with sensed intervals and corresponding annotations of sensed events, are preferably stored in random access memory **226**. The EGM signals stored may be sensed from programmed near-field and/or far-field sensing electrode pairs. Typically, a near-field sensing electrode pair includes a tip electrode and a ring electrode located in the atrium or the ventricle, such as electrodes **17** and **21** or electrodes **26** and **24**. A far-field sensing electrode pair includes electrodes spaced further apart such as any of: the defibrillation coil electrodes **8**, **20** or **23** with housing **11**; a tip electrode **17** or **26** with housing **11**; a tip electrode **17** or **26** with a defibrillation coil electrode **20** or **23**; or atrial tip electrode **17** with ventricular ring electrode **24**. The use of near-field and far-field EGM sensing of arrhythmia episodes is described in U.S. Pat. No. 5,193,535, issued to Bardy, incorporated herein by reference in its entirety. Annotation of sensed events, which may be displayed and stored with EGM data, is described in U.S. Pat. No. 4,374,382 issued to Markowitz, incorporated herein by reference in its entirety.

[**0028**] The telemetry circuit **330** receives downlink telemetry from and sends uplink telemetry to an external programmer, as is conventional in implantable anti-arrhythmia devices, by means of an antenna **332**. Data to be uplinked to the programmer and control signals for the telemetry circuit are provided by microprocessor **224** via address/data bus **218**. EGM data that has been stored upon arrhythmia detection or as triggered by other monitoring algorithms may be uplinked to an external programmer using telemetry circuit **330**. Received telemetry is provided to microprocessor **224** via multiplexer **220**. Numerous types of telemetry systems known in the art for use in implantable devices may be used.

[**0029**] The remainder of the circuitry illustrated in FIG. **2** is an exemplary embodiment of circuitry dedicated to providing cardiac pacing, cardioversion and defibrillation therapies. The pacer timing and control circuitry **212** includes programmable digital counters which control the basic time intervals associated with various single, dual or multi-chamber pacing modes or anti-tachycardia pacing therapies delivered in the atria or ventricles. Pacer circuitry **212** also determines the amplitude of the cardiac pacing pulses under the control of microprocessor **224**.

[**0030**] During pacing, escape interval counters within pacer timing and control circuitry **212** are reset upon sensing of R-waves or P-waves as indicated by signals on lines **202** and **206**, respectively. In accordance with the selected mode of pacing, pacing pulses are generated by atrial pacer output circuit **214** and ventricular pacer output circuit **216**. The pacer output circuits **214** and **216** are coupled to the desired electrodes for pacing via switch matrix **208**. The escape interval counters are reset upon generation of pacing pulses, and thereby control the basic timing of cardiac pacing functions, including anti-tachycardia pacing.

[**0031**] The durations of the escape intervals are determined by microprocessor **224** via data/address bus **218**. The value of the count present in the escape interval counters when reset by sensed R-waves or P-waves can be used to measure R-R intervals and P-P intervals for detecting the occurrence of a variety of arrhythmias.

[**0032**] The microprocessor **224** includes associated read-only memory (ROM) in which stored programs controlling the operation of the microprocessor **224** reside. A portion of the random access memory (RAM) **226** may be configured as a number of recirculating buffers capable of holding a series of measured intervals for analysis by the microprocessor **224** for predicting or diagnosing an arrhythmia. In response to the detection of tachycardia, anti-tachycardia pacing therapy can be delivered by loading a regimen from microprocessor **224** into the pacer timing and control circuitry **212** according to the type of tachycardia detected. In the event that higher voltage cardioversion or defibrillation pulses are required, microprocessor **224** activates the cardioversion and defibrillation control circuitry **230** to initiate charging of the high voltage capacitors **246** and **248** via charging circuit **236** under the control of high voltage charging control line **240**. The voltage on the high voltage capacitors is monitored via a voltage capacitor (VCAP) line **244**, which is passed through the multiplexer **220**. When the voltage reaches a predetermined value set by microprocessor **224**, a logic signal is generated on the capacitor full (CF) line **254**, terminating charging. The defibrillation or cardioversion pulse is delivered to the heart under the control of the pacer timing and control circuitry **212** by an output circuit **234** via a control bus **238**. The output circuit **234** determines the electrodes used for delivering the cardioversion or defibrillation pulse and the pulse wave shape.

[**0033**] In one embodiment, the ICD **10** may be equipped with a patient notification system **150**. Any patient notification method known in the art may be used such as generating perceivable twitch stimulation or an audible sound. A patient notification system may include an audio transducer that emits audible sounds including voiced statements or musical tones stored in analog memory and correlated to a programming or interrogation operating algorithm or to a warning

trigger event as generally described in U.S. Pat. No. 6,067, 473 issued to Greeninger et al., incorporated herein by reference in its entirety.

[0034] FIG. 3 is flowchart of a method for detecting atrial arrhythmias during intermittent instances of ventricular pacing in a cardiac medical device according to an embodiment of the present disclosure. Flow chart 200 and other flow charts presented herein are intended to illustrate the functional operation of the device, and should not be construed as reflective of a specific form of software or hardware necessary to practice the invention. It is believed that the particular form of software will be determined primarily by the particular system architecture employed in the device and by the particular detection and therapy delivery methodologies employed by the device. Providing software to accomplish the present invention in the context of any modern IMD, given the disclosure herein, is within the abilities of one of skill in the art.

[0035] Methods described in conjunction with flow charts presented herein may be implemented in a computer-readable medium that includes instructions for causing a programmable processor to carry out the methods described. A “computer-readable medium” includes but is not limited to any volatile or non-volatile media, such as a RAM, ROM, CD-ROM, NVRAM, EEPROM, flash memory, and the like. The instructions may be implemented as one or more software modules, which may be executed by themselves or in combination with other software.

[0036] As illustrated in FIG. 3, during detection of atrial arrhythmias, the device senses events, such as ventricular events, for example, Block 300, and identifies the sensed ventricular event as being either an intrinsic sensed event V_s or a paced event V_p resulting from pacing being delivered by the device. Depending upon the number of RR intervals chosen for determining RR interval differences, the device determines whether a predetermined number of sensed events, either a ventricular pacing event V_p or intrinsic ventricular sensed event V_s , have been sensed, Block 302. For example, according to one embodiment, if the desired number of RR intervals for RR interval differences is three, the predetermined number of sensed events utilized in Block 302 would be four sensed events, with the four sensed events forming a sensing window, as will be illustrated below. If the predetermined number of sensed events have not been sensed, the device determines the next sensed event, Block 300, and the process is repeated.

[0037] Once the predetermined number of events are sensed, Yes in Block 302, a sensed event window is identified based on the four events, Block 304, and a determination is made as to whether the number of the sensed events in the sensed event window that are ventricular pace V_p events is less than or equal to a predetermined pacing event threshold, Block 306. For example, according to one embodiment, the pacing event threshold is set as one so that the device determines whether one or less of the sensed events in the sensed event window are ventricular pace events. If the number of the sensed events in the sensed event window that are ventricular pace V_p events is not less than or equal to, i.e., is greater than the predetermined pacing event threshold, No in Block 306, the device determines the next sensed event, Block 300, and the process is repeated.

[0038] If the number of the sensed events in the sensed event window that are ventricular pace V_p events is less than or equal to the predetermined pacing event threshold, Yes in Block 306, the device determines whether each of the RR

intervals associated with the sensed events in the current sensed event window are greater than a predetermined interval threshold, Block 308. For example, according to one embodiment the device determines whether each of the RR intervals associated with the sensed events in the sensed event window are greater than 220 milliseconds. If each of the RR intervals associated with the sensed events in the sensed event window are not greater than 220 milliseconds, No in Block 308, the device determines the next sensed event, Block 300, and the process is repeated using the next sensed event and the resulting next sensed event window.

[0039] If each of the RR intervals associated with the sensed events in the sensed event window are greater than 220 milliseconds, Yes in Block 308, the device determines differences or variability of the RR intervals associated with the sensed events in the sensed event window, Block 310, as will be described below. Once the RR intervals differences for the current sensed event window have been determined in Block 308, the device determines whether a predetermined cardiac event timer has expired, Block 312. If the event timer has not expired, No in Block 312, the device determines the next sensed event, Block 300, and the process is repeated using the next sensed event and the resulting next sensed event window. According to one embodiment, the cardiac event timer is set as two minutes so that once the event timer has expired, Yes in Block 312, the device determines an atrial fibrillation AF score, Block 314, based on the determined RR interval differences, Block 310, resulting from multiple sensed event windows occurring during the predetermined time period, Block 312, i.e., two minutes for example. The determination of the AF score is described below, with the device making a determining of either an atrial fibrillation AF event or a non-atrial fibrillation event occurring based on a comparison of the AF score to an AF detection threshold. The stored differences are then cleared, Block 316, and the device determines the next sensed event, Block 300, and the process is repeated for the next time period using the next sensed events and the resulting next sensed event windows.

[0040] FIG. 4 is a schematic diagram illustrating detecting atrial arrhythmias during ventricular pacing in a cardiac medical device according to an embodiment of the present disclosure. As illustrated in FIGS. 3 and 4, according to one embodiment, once the device senses the predetermined number of sensed events 320-326, Yes in Block 302, a sensed event window 332 is formed, Block 304, based on the current four sensed events 320-326. The device determines whether only one or less of the sensed events 320-326 are ventricular paced events, Block 306, and whether the RR intervals 338 formed between the sensed events 320-326 are greater than the interval threshold, Block 308. In the example illustrated in FIG. 4, all of sensed events 320-326 are ventricular sensed V_s events, and assuming all of the intervals 338 formed by the sensed events 320-326 are greater than the interval threshold, Yes in Block 308, the device determines and stores an interval difference factor associated with the intervals 338 of the current sensed events 320-326, Block 310. If all of the intervals 338 formed by the sensed events 320-326 are not greater than the interval threshold, No in Block 308, the device determines the next sensed event, Block 300, and the process is repeated using the next sensed event and the resulting next sensed event window.

[0041] Assuming the cardiac event timer has not yet expired, No in Block 312, the device senses the next event 328, Block 300, and a sensed event window 334 is formed,

Block 304, based on the current four sensed events 322-328. The device determines whether only one or less of the sensed events 322-328 are ventricular paced events, Block 306, and whether the RR intervals 338 formed between the sensed events 322-328 are greater than the interval threshold, Block 308. In the example illustrated in FIG. 4, since only one sensed event 338 of sensed events 322-328 is a ventricular paced Vp event, and assuming all of the intervals 338 formed by the sensed events 322-328 are greater than the interval threshold, Yes in Block 308, the device determines and stores an interval difference factor associated with the intervals 338 of the current sensed events 322-328, Block 310.

[0042] Assuming the cardiac event timer has not yet expired, No in Block 312, the device senses the next event 330, Block 300, and a sensed event window 336 is formed, Block 304, based on the current four sensed events 324-330. The device determines whether only one or less of the sensed events 324-330 are ventricular paced events, Block 306, and whether the RR intervals 338 formed between the sensed events 324-330 are greater than the interval threshold, Block 308. In the example illustrated in FIG. 4, since two sensed events 338 and 340 of sensed events 324-330 are ventricular paced Vp events, and therefore the number of sensed events in the sensed event window 336 that are ventricular paced Vp events is not less than or equal to the pacing event threshold, No in Block 306, an RR interval difference factor is not determined for that sensed event window 336, and the device determines the next sensed event, Block 300, and the process is repeated using the next sensed event and the resulting next sensed event window, and so on until the timer has expired, Yes in Block 312. Once the timer has expired, Yes in Block 312, the atrial fibrillation AF score for that time period is determined based on the currently stored interval difference factors, as described below.

[0043] FIG. 5 is a schematic diagram illustrating detecting atrial arrhythmias during ventricular pacing in a cardiac medical device according to another embodiment of the present disclosure. As illustrated in FIGS. 3 and 5, according to another embodiment, once the device senses the predetermined number of sensed events 340-346, Yes in Block 302, a sensed event window 356 is formed, Block 304, based on the current four sensed events 340-346. The device determines whether only one or less of the sensed events 340-346 are ventricular paced Vp events, Block 306, and whether the RR intervals 366 formed between the sensed events 340-346 are greater than the interval threshold, Block 308. In the exemplary embodiment illustrated in FIG. 5, during the determination as to whether only one or less of the sensed events 340-346 are ventricular paced Vp events, Block 306, rather than making the determination based on all of the sensed events 340-346 in the sensed event window 356, the device determines whether one or more of a predetermined number of the sensed events 340-346 are ventricular pace Vp events. For example, according to one embodiment, the device may determine whether only one or less of the most recent sensed event 346 in the sensed event window 356 and the previous two sensed events 342 and 344 are ventricular sensed Vp events, Block 306.

[0044] In the example illustrated in FIG. 5, the most recent sensed event 346 in the sensed event window 356 is a ventricular pace Vp event, and the two previous sensed events 342 and 344 are both ventricular sense VS events, resulting in there being only one ventricular pace Vp event. Therefore, the number of ventricular pace VP events is determined to be less

than or equal to the ventricular pace Vp event threshold, i.e., one ventricular pace Vp event, Yes in Block 306. As a result, similar to above, the device determines whether the RR intervals 366 associated with the current sensed events 340-346 are greater than an interval threshold, Block 308, such as 220 milliseconds, for example. If the RR intervals 366 are not greater than the interval threshold, No in Block 308, the device does not store an interval difference factor, Block 310, for the intervals 366 associated with the current sensed events 340-346, and the process is repeated using the next sensed event 348 and the resulting next sensed event window 358.

[0045] If each of the RR intervals 366 are greater than the interval threshold, Yes in Block 308, the device stores an interval difference factor, Block 310, associated with the intervals 366 formed between the current sensed events 340-346, described below, and, assuming the timer has not expired, No in Block 312, the process is repeated using the next sensed event 348 and the resulting next sensed event window 360. If the timer has expired, Yes in Block 312, the device determines an atrial fibrillation AF score, Block 314, based on the determined RR interval difference factors, Block 310, resulting from multiple sensed event windows over the predetermined time period of Block 312, such as two minutes, for example. The determination of the AF score is described below, with the device making a determining of either an atrial fibrillation AF event or a non-atrial fibrillation event occurring based on a comparison of the AF score to an AF detection threshold. The current counters are then cleared, Block 316, and the device determines the next sensed event, Block 300, and the process is repeated for the next time period using the next sensed events and the resulting next sensed event windows.

[0046] As described above, if the RR intervals are not greater than the interval threshold, No in Block 310, or if the cardiac event timer has not yet expired, No in Block 312, the device senses the next cardiac event 348, Block 300, and a sensed event window 358 is formed, Block 304, based on the most current four sensed events 342-348. The device determines whether only one or less of the most recent sensed event 348 in the sensed event window 358 and the previous two sensed events 344 and 346 are ventricular sensed Vp events, Block 306. In the example illustrated in FIG. 5, the most recent sensed event 348 and one sensed event 346 of the two previous sensed events 344 and 346 are ventricular pace Vp events, and the other previous sensed event 344 is a ventricular sense VS event, resulting in there being two ventricular pace Vp events. Therefore, since the number of ventricular pace VP events is not less than or equal to the ventricular pace Vp event threshold, No in Block 306, the device does not determine and store an interval difference factor, Block 310, for the intervals 366 formed by the current sensed events 342-348, and the process is repeated using the next sensed event 350 and the resulting next sensed event window 360.

[0047] In particular, the device determines whether only one or less of the most recent sensed event 350 in the sensed event window 360 and the previous two sensed events 346 and 348 are ventricular sensed Vp events, Block 306. In the example illustrated in FIG. 5, the most recent sensed event 350 is a ventricular sense Vs event and both of the previous two sensed events 346 and 348 are ventricular pace Vp events, resulting in there being two ventricular pace Vp events occurring during the sensed event window 360. As a result, the number of ventricular pace Vp events is not less than or equal

to the ventricular pace Vp event threshold, No in Block 306, and therefore the device does not store an interval difference factor associated with the intervals 366 formed by the current sensed events 344-350, and the process is repeated using the next sensed event 352 and the resulting next sensed event window 362.

[0048] In particular, the device determines whether only one or less of the most recent sensed event 352 in the sensed event window 362 and the previous two sensed events 348 and 350 are ventricular sensed Vp events, Block 306. In the example illustrated in FIG. 5, the most recent sensed event 352 and one sensed event 350 of the two previous sensed events 348 and 350 are ventricular sense Vs events, and the other previous sensed event 348 is a ventricular pace Vp event, resulting in only one ventricular pace Vp event occurring during the sensed event window 362. As a result, the number of ventricular pace VP events is less than or equal to the ventricular pace Vp event threshold, Yes in Block 306, and therefore the device determines whether the RR intervals 366 associated with the current sensed events 346-352 are greater than the interval threshold, Block 308. If the RR intervals 366 are not greater than the interval threshold, No in Block 308, the device does not store an interval difference factor, Block 310, associated with the intervals 366 formed by the current sensed events 346-352, and the process is repeated using the next sensed event 354 and the resulting next sensed event window 364.

[0049] If each of the RR intervals 366 are greater than the interval threshold, Yes in Block 308, the device stores an interval difference factor, Block 310, associated with the intervals 366 formed between the current sensed events 346-352, described below. Assuming the timer has not expired, No in Block 312, the process is then repeated using the next sensed event 354 and the resulting next sensed event window 364. If the timer has expired, Yes in Block 312, the device determines an atrial fibrillation AF score, Block 314, based on the determined RR interval difference factors, Block 310, resulting from multiple sensed event windows over the predetermined time period of Block 312, i.e., two minutes for example. The determination of the AF score is described below, with the device making a determining of either an atrial fibrillation AF event or a non-atrial fibrillation event occurring based on a comparison of the AF score to an AF detection threshold. The counters are then cleared, Block 316, and the device determines the next sensed event, Block 300, and the process is repeated for the next time period using the next sensed events and the resulting next sensed event windows, and so on.

[0050] In the example illustrated in FIG. 5, the most recent sensed event 354 and both of the two previous sensed events 350 and 352 are ventricular sense Vs events, resulting in the number of ventricular pace VP events being less than or equal to the ventricular pace Vp event threshold, Yes in Block 306. Assuming that each of the RR intervals 366 are greater than the interval threshold, Yes in Block 308, the device determines and stores an interval difference factor, Block 310, associated with the intervals 366 formed between the current sensed events 348-354, described below. In this way, assuming the timer has expired, Yes in Block 312, in the example of FIG. 5, the device determines and stores an interval difference factor, Block 310, only for intervals formed in sensed event windows 356, 362 and 364, and not for intervals formed in sensed event windows 358 and 360. The determination of the atrial fibrillation AF score, Block 314, described below, is

therefore made based on the interval difference factor, Block 310, determined only for intervals formed in sensed event windows 356, 362 and 364, and therefore does not include intervals formed in sense event windows 358 and 360 having more than the predetermined number of ventricular pace Vp events therein.

[0051] FIG. 6 is a schematic diagram of classifying of cardiac events in a cardiac medical device according to an embodiment of the present disclosure. As illustrated in FIG. 6, according to one embodiment, in order to determine the atrial fibrillation AF score based on the determined RR interval difference factors resulting from multiple sensed event windows, described above, the determined RR interval difference factors calculated for the RR intervals formed by the sensed events for each sensed event window, described above, are used to plot single points on a Lorenz plot 14.

[0052] The Lorenz plot 14 is a Cartesian coordinate system defined by δRR_i along the x-axis 18 and δRR_{i-1} along the y-axis 16. As such, each plotted point in a Lorenz plot is defined by an x-coordinate equaling δRR_i and a y-coordinate equaling δRR_{i-1} . δRR_i is the difference between the i^{th} RR interval and the previous RR interval, RR_{i-1} . δRR_{i-1} is the difference between RR_{i-1} and the previous RR interval, RR_{i-2} . As such, each data point plotted on the Lorenz plot 14 represents a ventricular cycle length VCL pattern relating to three consecutive VCLs: RR_i , and RR_{i-2} , measured between the four consecutively sensed R-waves associated with a sensing event window.

[0053] In order to plot each point on the Lorenz plot area 14, a $(\delta RR_i, \delta RR_{i-1})$ point is identified based on the RR interval difference determined for the intervals formed by the sensed events in each single sensed event window during the two minute time period having one or less ventricular pace Vp events, described above. The atrial fibrillation AF score for each two minute time period is then determined based on the relative position of the resulting plotted points on the plot area 14. For example, using the example illustrated in FIG. 5, a first data point 23 is plotted based on the RR interval difference factor determined for intervals 366 formed in sensed event window 356, a second data point 25 is plotted based on the RR interval difference factor determined for intervals 366 formed in sensed event window 362, and a third data point 27 is plotted based on the RR interval difference factor determined for intervals 366 formed in sensed event window 364, and so forth.

[0054] In particular, for example, δRR_i for the first data point 23 is determined as the difference between the RR interval 366 between sense 346 and sense 344 and the RR interval 366 between sense 344 and sense 342, and δRR_{i-1} is determined as the difference between the RR interval 366 between sense 344 and sense 342 and the RR interval 366 between sense 342 and sense 340. In the same way, the corresponding $(\delta RR_i, \delta RR_{i-1})$ point is identified for sensed event windows 362 and 364, and so on until the timer has expired.

[0055] The plotted $(\delta RR_i, \delta RR_{i-1})$ points over a two minute time period are then used to identify the event as either an atrial fibrillation event or a non-atrial fibrillation. Methods have been developed for detecting atrial arrhythmias based on the irregularity of ventricular cycles measured by RR intervals that exhibit discriminatory signatures when plotted in a Lorenz scatter plot such as the plot shown in FIG. 6. One such method is generally disclosed by Ritscher et al. in U.S. Pat. No. 7,031,765, or in U.S. Pat. No. 8,639,316 to Sarkar, both

incorporated herein by reference in their entireties. Other methods are generally disclosed by Sarkar, et al. in U.S. Pat. No. 7,623,911 and in U.S. Pat. No. 7,537,569 and by Houben in U.S. Pat. No. 7,627,368, all of which patents are also incorporated herein by reference in their entirety.

[0056] FIG. 7 is a diagram of an exemplary two-dimensional histogram representing a Lorenz plot area for identifying cardiac events. Generally, the Lorenz plot area **14** shown in FIG. 7 is numerically represented by a two-dimensional histogram **160** having predefined ranges **166** and **164** in both positive and negative directions for the δRR_i and δRR_{i-1} coordinates, respectively. The two-dimensional histogram is divided into bins **168** each having a predefined range of δRR_i and δRR_{i-1} values. In one example, the histogram range might extend from -1200 ms to $+1200$ ms for both δRR_i and δRR_{i-1} values, and the histogram range is divided into bins extending 7.5 ms in each of the two dimensions resulting in a 160 bin \times 160 bin histogram. The successive RRI differences determined over a detection time interval are used to populate the histogram **160**. Each bin stores a count of the number of (δRR_i , δRR_{i-1}) data points falling into the bin range. The bin counts may then be used in determining RRI variability metrics and patterns for determining a cardiac rhythm type.

[0057] An RRI variability metric is determined from the scatter plot. Generally, the more histogram bins that are occupied, i.e. the more sparse the distribution of (δRR_i , δRR_{i-1}) points, the more irregular the VCL during the data acquisition time period. As such, a metric of the RRI variability can be used for detecting atrial fibrillation, which is associated with highly irregular VCL. In one embodiment, an RRI variability metric for detecting AF, referred to as an AF score is computed as generally described in the above-incorporated '911 patent. Briefly, the AF score may be defined by the equation:

$$\text{AF Evidence} = \text{Irregularity Evidence} - \text{Origin Count} - \text{PAC Evidence}$$

[0058] wherein Irregularity Evidence is the number of occupied histogram bins outside a Zero Segment defined around the origin of the Lorenz plot area. During normal sinus rhythm or highly organized atrial tachycardia, nearly all points will fall into the Zero Segment because of relatively small, consistent differences between consecutive RRIs. A high number of occupied histogram bins outside the Zero segment is therefore positive evidence for AF.

[0059] The Origin Count is the number of points in a "Zero Segment" defined around the Lorenz plot origin. A high Origin Count indicates regular RRIs, a negative indicator of atrial fibrillation, and is therefore subtracted from the Irregularity Evidence term. In addition, a regular PAC evidence score may be computed as generally described in the above-incorporated '911 patent. The regular PAC evidence score is computed based on a cluster signature pattern of data points that is particularly associated with PACs that occur at regular coupling intervals and present regular patterns of RRIs, e.g. associated with bigeminy (short-short-long RRIs) or trigeminy (short-short-short-long RRIs).

[0060] In other embodiments, an AF score or other RRI variability score for classifying an atrial rhythm may be computed as described in any of the above-incorporated '765, '316, '911, '569 and '368 patents.

[0061] The AF score is compared to an AF threshold for detecting atrial fibrillation to determine whether the AF score corresponds to an AF event. The AF threshold may be selected and optimized based on historical clinical data of selected patient populations or historical individual patient

data, and the optimal threshold setting may vary from patient to patient. If the metric crosses a detection threshold, AF detection occurs. A response to AF detection is made, either in response to a classification of a single two second time interval as being AF, i.e., being greater than the AF threshold, or in response to a predetermined number of two second intervals being classified as being an AF event by each being greater than the AF threshold. Such response to the AF detection may include withholding or altering therapy, such as a ventricular therapy, for example, storing data that can be later retrieved by a clinician, triggering an alarm to the patient or that may be sent remotely to alert the clinician, delivering or adjusting a therapy, and triggering other signal acquisition or analysis.

[0062] The RRI measurements may continue to be performed after an AF detection to fill the histogram during the next detection time interval. After each detection time interval, the RRI variability metric is determined and the histogram bins are re-initialized to zero for the next detection time interval. The new RRI variability metric determined at the end of each data acquisition interval may be used to determine if the AF episode is sustained or terminated.

[0063] Thus, an apparatus and method have been presented in the foregoing description with reference to specific embodiments. It is appreciated that various modifications to the referenced embodiments may be made without departing from the scope of the invention as set forth in the following claims.

We claim:

1. A method of determining a cardiac event in a medical device, comprising:

- sensing a cardiac signal;
- determining a predetermined number of sensed cardiac events in response to the sensed cardiac signal;
- determining a plurality of sensed event windows in response to the predetermined number of the sensed cardiac events;
- determining, for each of the plurality of sensed event windows, whether a number of paced events is less than a paced event threshold;
- determining whether intervals within the sensed event windows having a number of paced events less than the paced event threshold are greater than an interval threshold;
- determining an interval difference factor for each of the plurality of windows having intervals less than the interval threshold; and
- determining the cardiac event in response to the interval difference factors determined for each of the plurality of windows.

2. The method of claim 1, wherein determining the cardiac event in response to the RR interval difference factor determined for each of the plurality of windows comprises determining a relative distribution of the interval difference factors.

3. The method of claim 1, wherein the predetermined number of sensed cardiac events comprises four sensed cardiac events, the paced event threshold comprises one paced event, and the interval threshold comprises 220 milliseconds.

4. The method of claim 1, further comprising determining, for each sensed event window of the plurality of sensed event windows, whether one or less of a most recent sensed event and two sensed events occurring prior to the most recent sensed event are paced events.

5. The method of claim 1, wherein each of the plurality of sensed event windows comprise four sensed cardiac events, and wherein all of the plurality of sensed event windows combined occur during a two minute time period.

6. The method of claim 5, wherein the four sensed events comprise a first sensed event, a second sensed event subsequent to the first sensed event, a third sensed event subsequent to the second sensed event and a fourth sensed event subsequent to the third sensed event, and wherein determining the cardiac event in response to the interval factors comprises:

populating a two dimensional histogram for the two minute time period with data points each having an x-coordinate and a y-coordinate, wherein the x-coordinate comprises the difference between a first interval and a second interval, the first interval being between the fourth sensed event and the third sensed event and the second being interval between the third sensed event and the second sensed event, and the y-coordinate comprises the difference between the second interval and a third interval, the third interval being between the second sensed event and the first sensed event;

determining an atrial fibrillation evidence score in response to the populated histogram; and

identifying the cardiac event as an atrial fibrillation event in response to the atrial fibrillation score being greater than an atrial fibrillation threshold.

7. The method of claim 6, further comprising determining, for each sensed event window of the plurality of sensed event windows, whether one or less of a most recent sensed event and two sensed events occurring prior to the most recent sensed event are paced events.

8. The method of claim 6, wherein one of the first sensed event, the second sensed event, the third sensed event and the fourth sensed event are paced events.

9. The method of claim 1, wherein the sensed events comprise a first sensed event, a second sensed event subsequent to the first sensed event, a third sensed event subsequent to the second sensed event and a fourth sensed event subsequent to the third sensed event, and wherein determining an interval difference factor comprises determining a difference between a first interval and a second interval, the first interval being between the fourth sensed event and the third sensed event and the second being interval between the third sensed event and the second sensed event, and the y-coordinate comprises the difference between the second interval and a third interval, the third interval being between the second sensed event and the first sensed event.

10. A medical device for determining a cardiac event, comprising:

a sensor sensing a cardiac signal; and

a processor configured to determine a predetermined number of sensed cardiac events in response to the sensed cardiac signal, determine a plurality of sensed event windows in response to the predetermined number of the sensed cardiac events, determine, for each of the plurality of sensed event windows, whether a number of paced events is less than a paced event threshold, determine whether intervals within the sensed event windows having a number of paced events less than the paced event threshold are greater than an interval threshold, determine an interval difference factor for each of the plurality of windows having intervals less than the interval threshold, and

determine the cardiac event in response to the interval difference factors determined for each of the plurality of windows.

11. The device of claim 10, wherein determining the cardiac event in response to the RR interval difference factor determined for each of the plurality of windows comprises determining a relative distribution of the interval difference factors.

12. The device of claim 10, wherein the predetermined number of sensed cardiac events comprises four sensed cardiac events, the paced event threshold comprises one paced event, and the interval threshold comprises 220 milliseconds.

13. The device of claim 10, wherein the processor is configured to determine, for each sensed event window of the plurality of sensed event windows, whether one or less of a most recent sensed event and two sensed events occurring prior to the most recent sensed event are paced events.

14. The device of claim 10, wherein each of the plurality of sensed event windows comprise four sensed cardiac events, and wherein all of the plurality of sensed event windows combined occur during a two minute time period.

15. The device of claim 9, wherein the four sensed events comprise a first sensed event, a second sensed event subsequent to the first sensed event, a third sensed event subsequent to the second sensed event and a fourth sensed event subsequent to the third sensed event, and wherein the processor is configured to populate a two dimensional histogram for the two minute time period with data points each having an x-coordinate and a y-coordinate, wherein the x-coordinate comprises the difference between a first interval and a second interval, the first interval being between the fourth sensed event and the third sensed event and the second being interval between the third sensed event and the second sensed event, and the y-coordinate comprises the difference between the second interval and a third interval, the third interval being between the second sensed event and the first sensed event, determine an atrial fibrillation evidence score in response to the populated histogram, and identify the cardiac event as an atrial fibrillation event in response to the atrial fibrillation score being greater than an atrial fibrillation threshold.

16. The device of claim 15, wherein the processor is configured to determine, for each sensed event window of the plurality of sensed event windows, whether one or less of a most recent sensed event and two sensed events occurring prior to the most recent sensed event are paced events.

17. The device of claim 15, wherein one of the first sensed event, the second sensed event, the third sensed event and the fourth sensed event are paced events.

18. The device of claim 10, wherein the sensed events comprise a first sensed event, a second sensed event subsequent to the first sensed event, a third sensed event subsequent to the second sensed event and a fourth sensed event subsequent to the third sensed event, and wherein the processor is configured to determine a difference between a first interval and a second interval, the first interval being between the fourth sensed event and the third sensed event and the second being interval between the third sensed event and the second sensed event, and the y-coordinate comprises the difference between the second interval and a third interval, the third interval being between the second sensed event and the first sensed event.

19. A computer-readable medium storing a set of instructions which cause a processor of an implantable medical device to perform a method comprising:

sensing a cardiac signal;
determining a predetermined number of sensed cardiac events in response to the sensed cardiac signal;
determining a plurality of sensed event windows in response to the predetermined number of the sensed cardiac events;
determining, for each of the plurality of sensed event windows, whether a number of paced events is less than a paced event threshold;
determining whether intervals within the sensed event windows having a number of paced events less than the paced event threshold are greater than an interval threshold;
determining an interval difference factor for each of the plurality of windows having intervals less than the interval threshold; and
determining the cardiac event in response to the interval difference factors determined for each of the plurality of windows.

20. The computer-readable medium of claim **19**, the method further comprising determining, for each sensed event window of the plurality of sensed event windows, whether one or less of a most recent sensed event and two sensed events occurring prior to the most recent sensed event are paced events.

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专利名称(译)	在心脏医疗设备中间歇性心室起搏期间检测房性心律失常		
公开(公告)号	US20160113534A1	公开(公告)日	2016-04-28
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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.		
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摘要(译)

一种用于确定心脏事件的方法和医疗设备, 包括感测心脏信号, 响应于感测的心脏信号确定预定数量的感测的心脏事件, 响应于感测的心脏的预定数量确定多个感测的事件窗口事件, 为多个感测事件窗口中的每一个确定多个起搏事件是否小于起搏事件阈值, 确定感测事件窗口内具有小于起搏事件阈值的多个起搏事件的间隔是否更大比间隔阈值确定具有小于间隔阈值的间隔的多个窗口中的每个窗口的间隔差异因子, 并且响应于针对多个窗口中的每个窗口确定的间隔差异因子确定心脏事件。

