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(54) **METHOD AND APPARATUS FOR ATRIAL ARRHYTHMIA EPISODE DETECTION**

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A61B 5/04 (2006.01)

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See application file for complete search history.

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(57) **ABSTRACT**

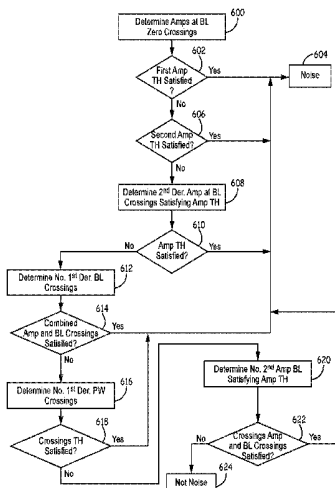
Techniques and devices for implementing the techniques for adjusting atrial arrhythmia detection based on analysis of one or more P-wave sensing windows associated with one or more R-waves. An implantable medical device may determine signal characteristics of the cardiac signal within the P-wave sensing window, determine whether the cardiac signal within the sensing window corresponds to a P-wave

(Continued)

Related U.S. Application Data

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(Continued)



based on the determined signal characteristics, determine a signal to noise ratio of the cardiac signal within the sensing window, update the arrhythmia score when the P wave is identified in the sensing window and the determined signal to noise ratio satisfies a signal to noise threshold.

19 Claims, 10 Drawing Sheets

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- A61N 1/362* (2006.01)
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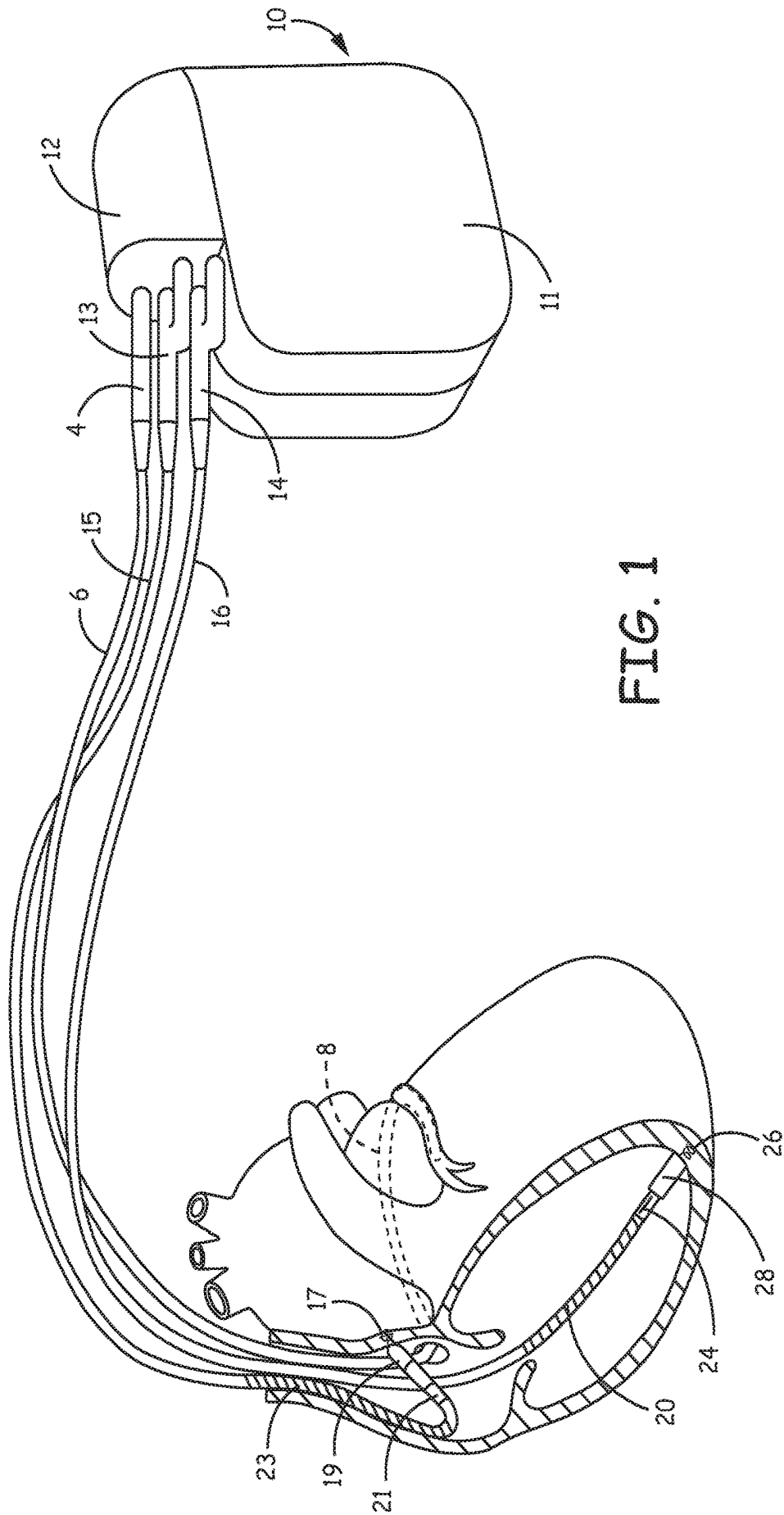


FIG. 1

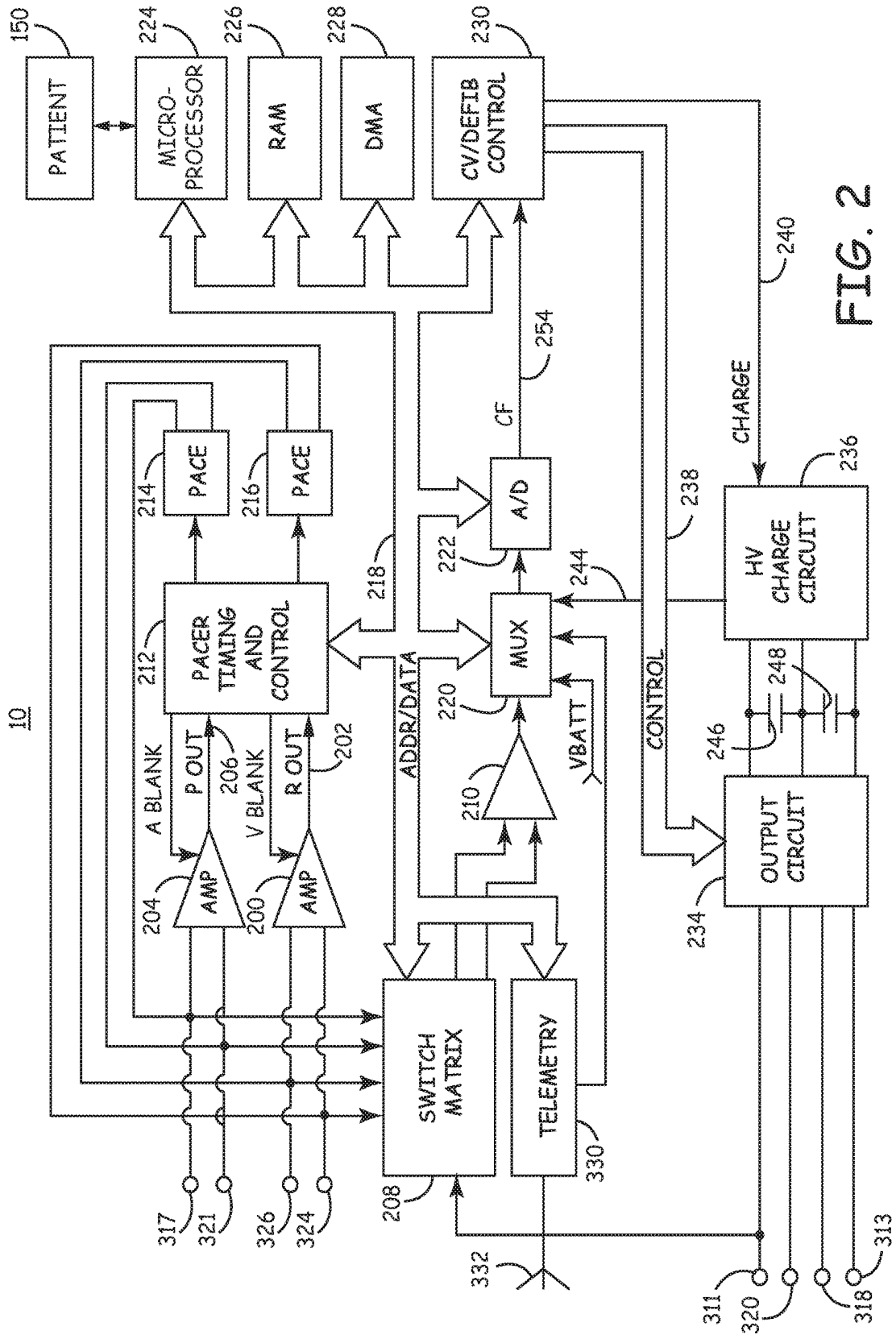


FIG. 2

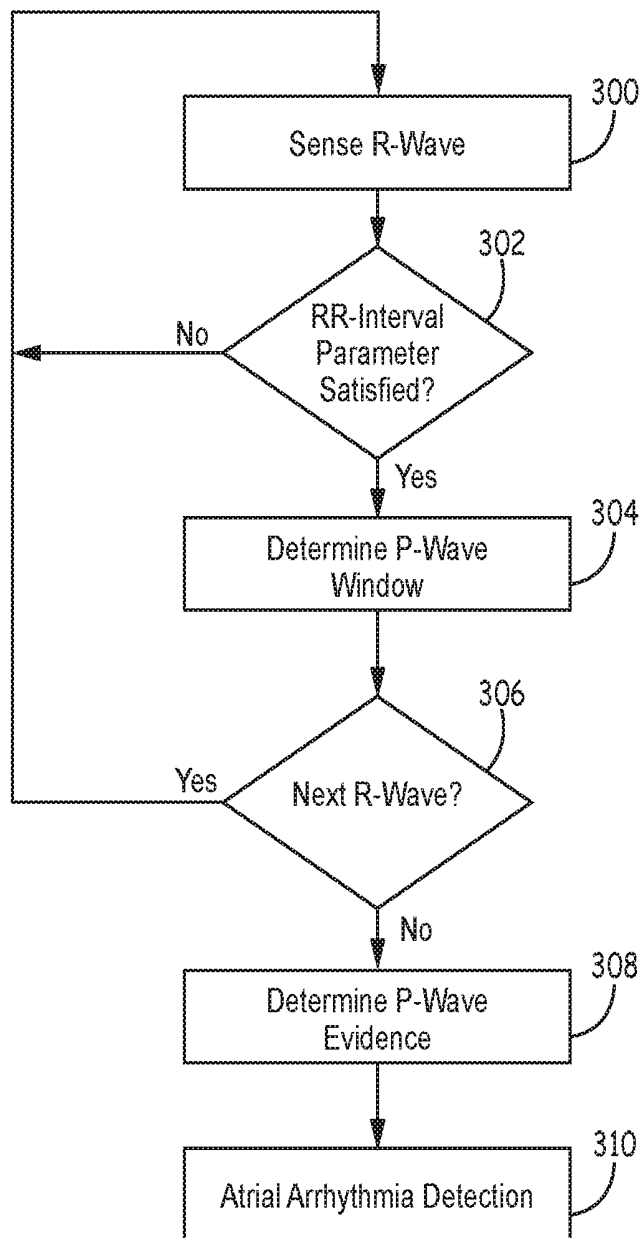


FIG. 3

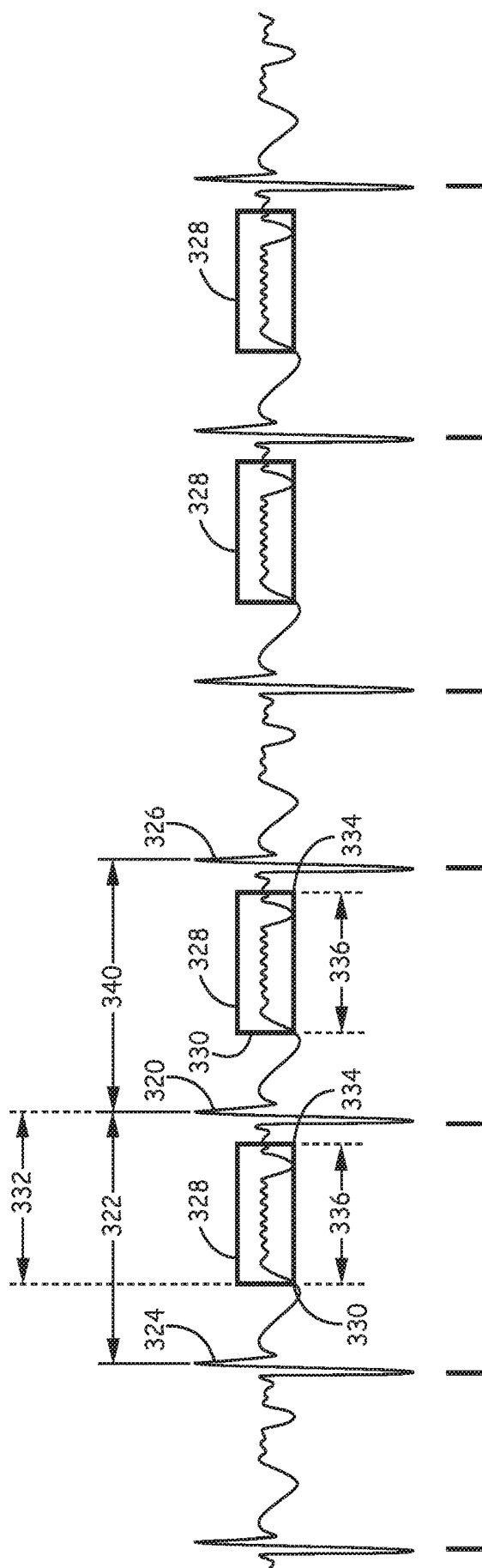


FIG. 4

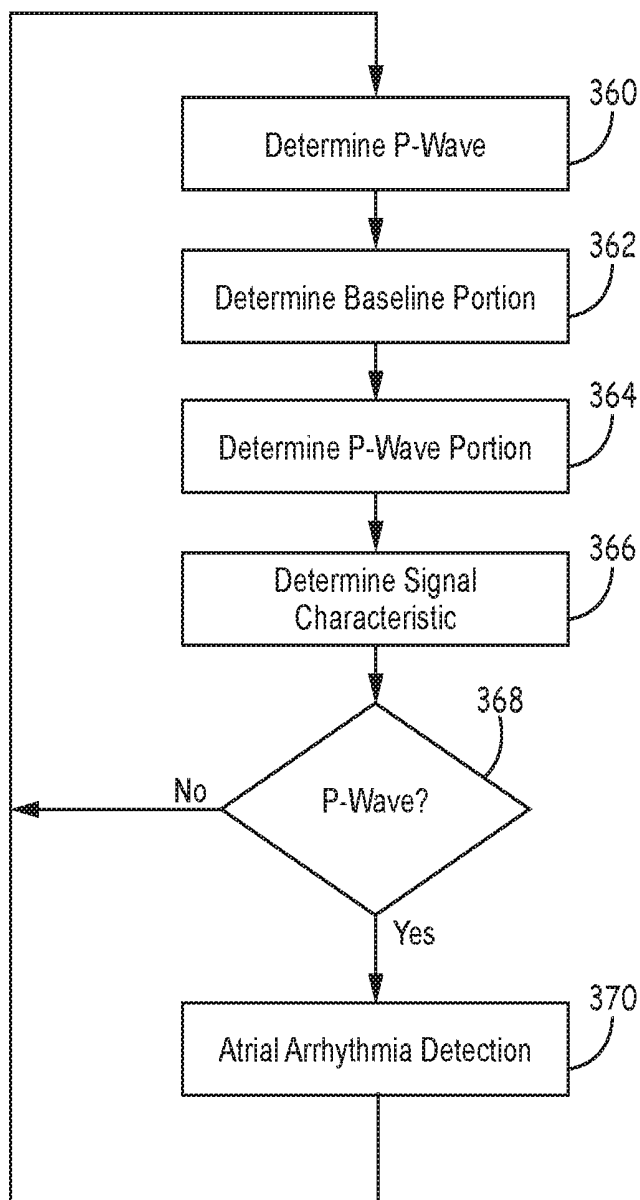


FIG. 5

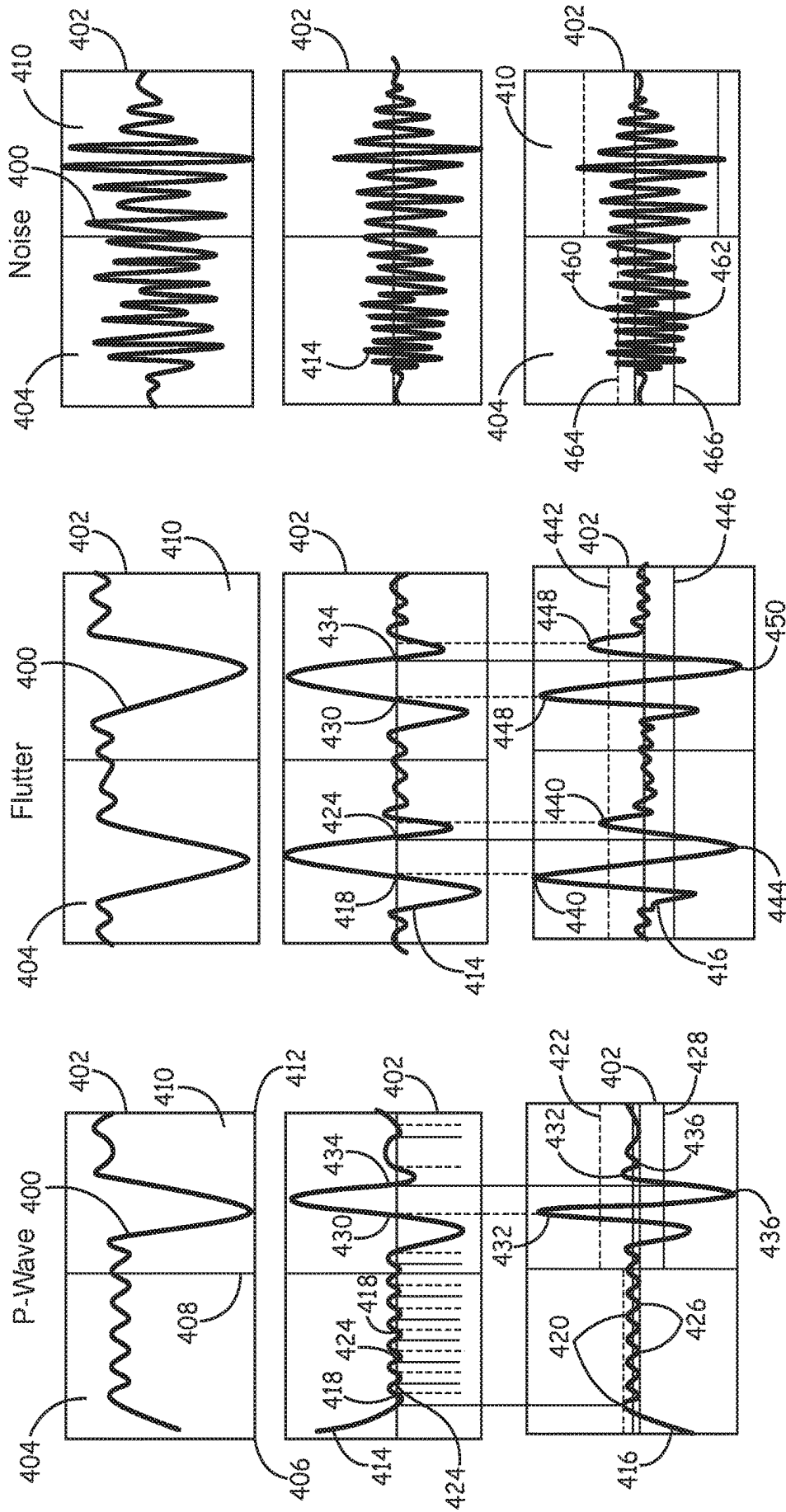


FIG. 6

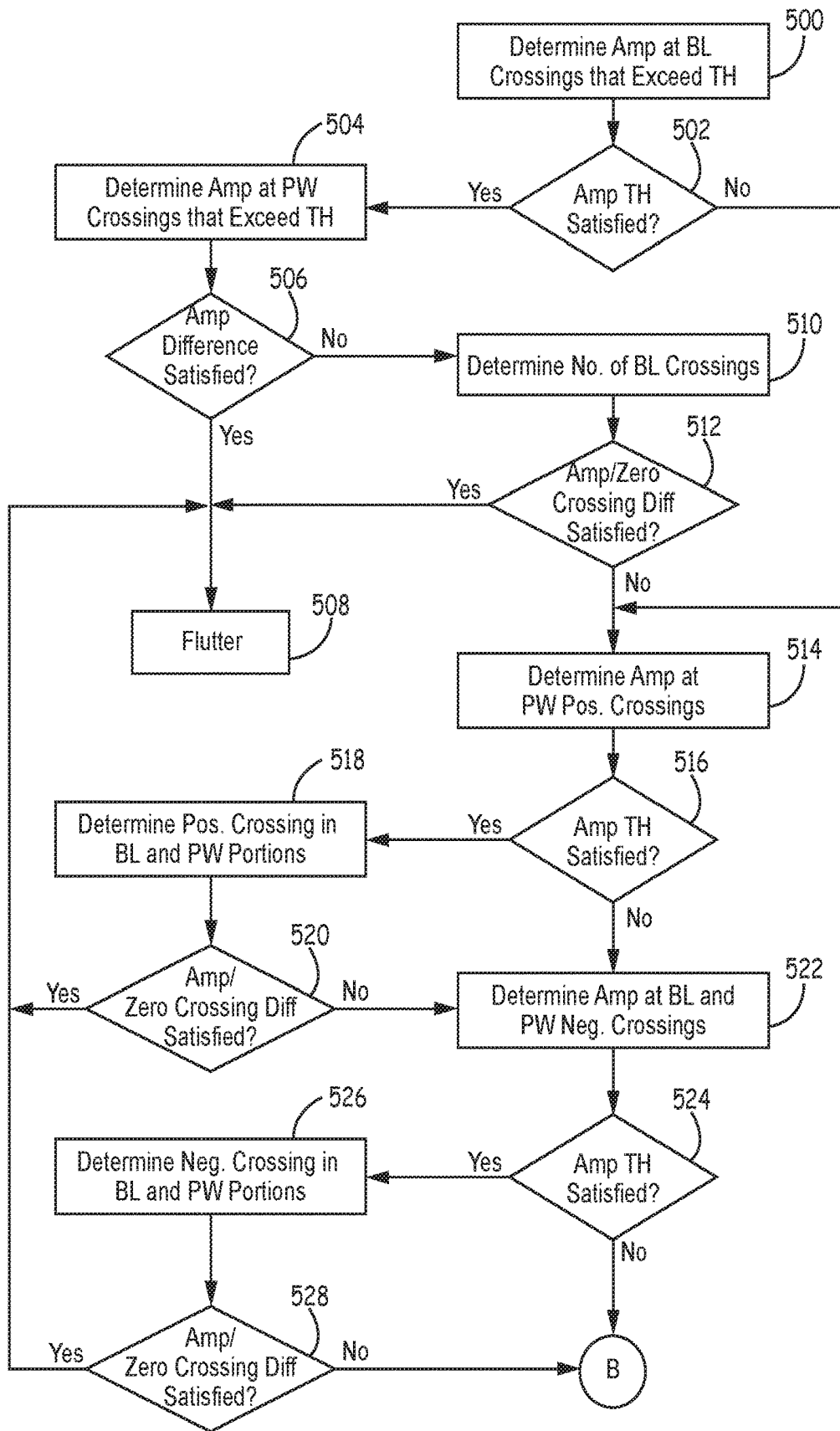


FIG. 7A

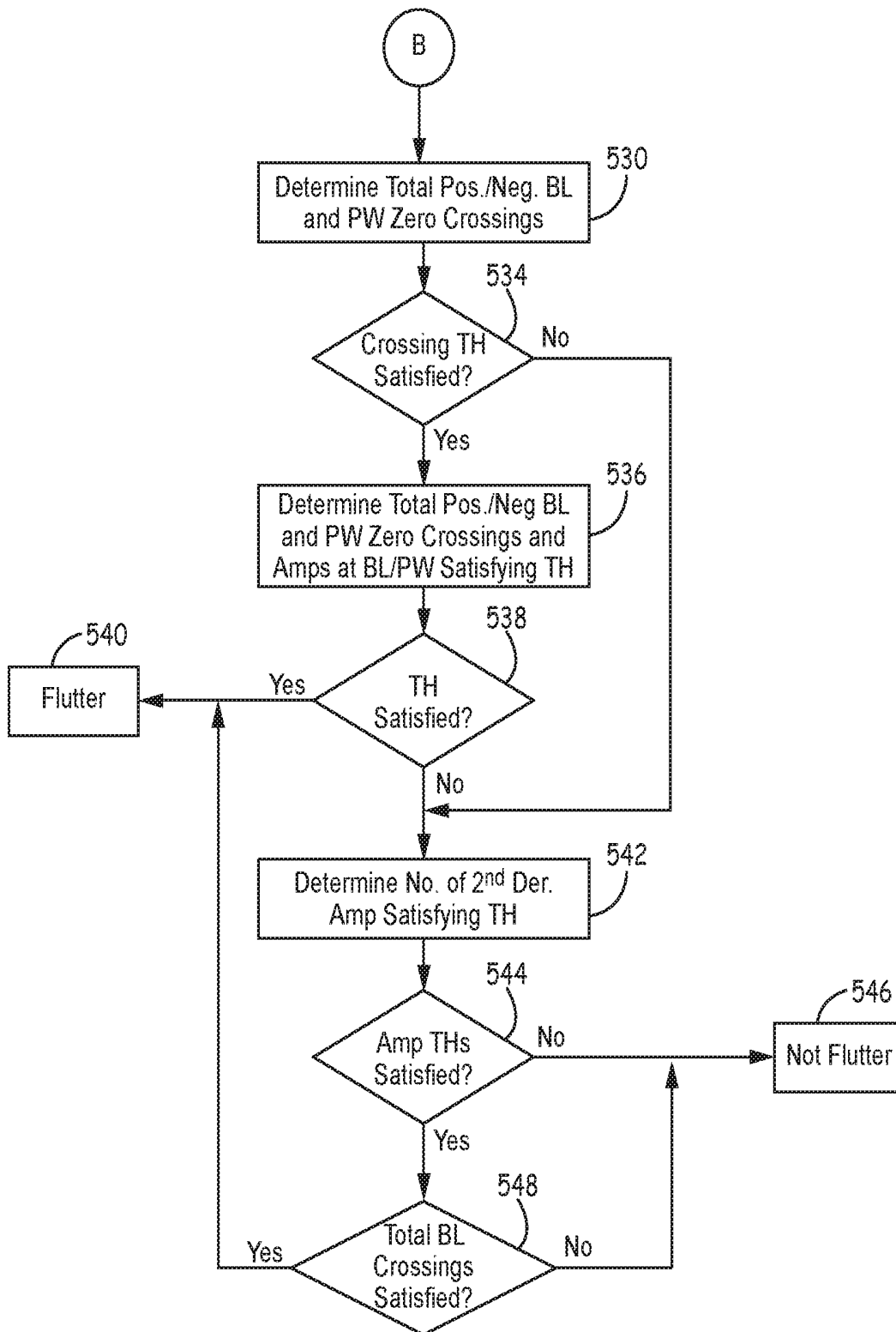


FIG. 7B

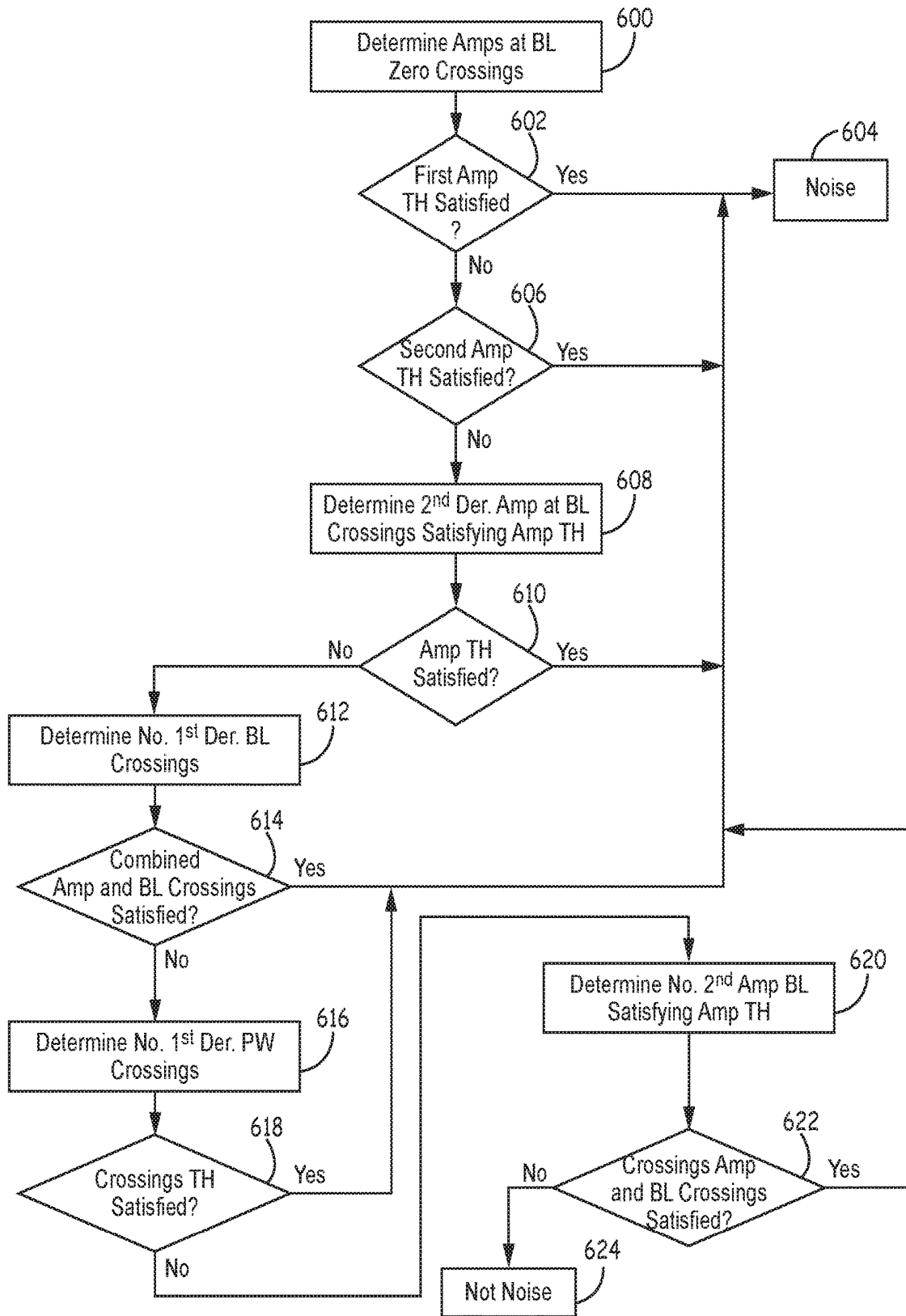


FIG. 8

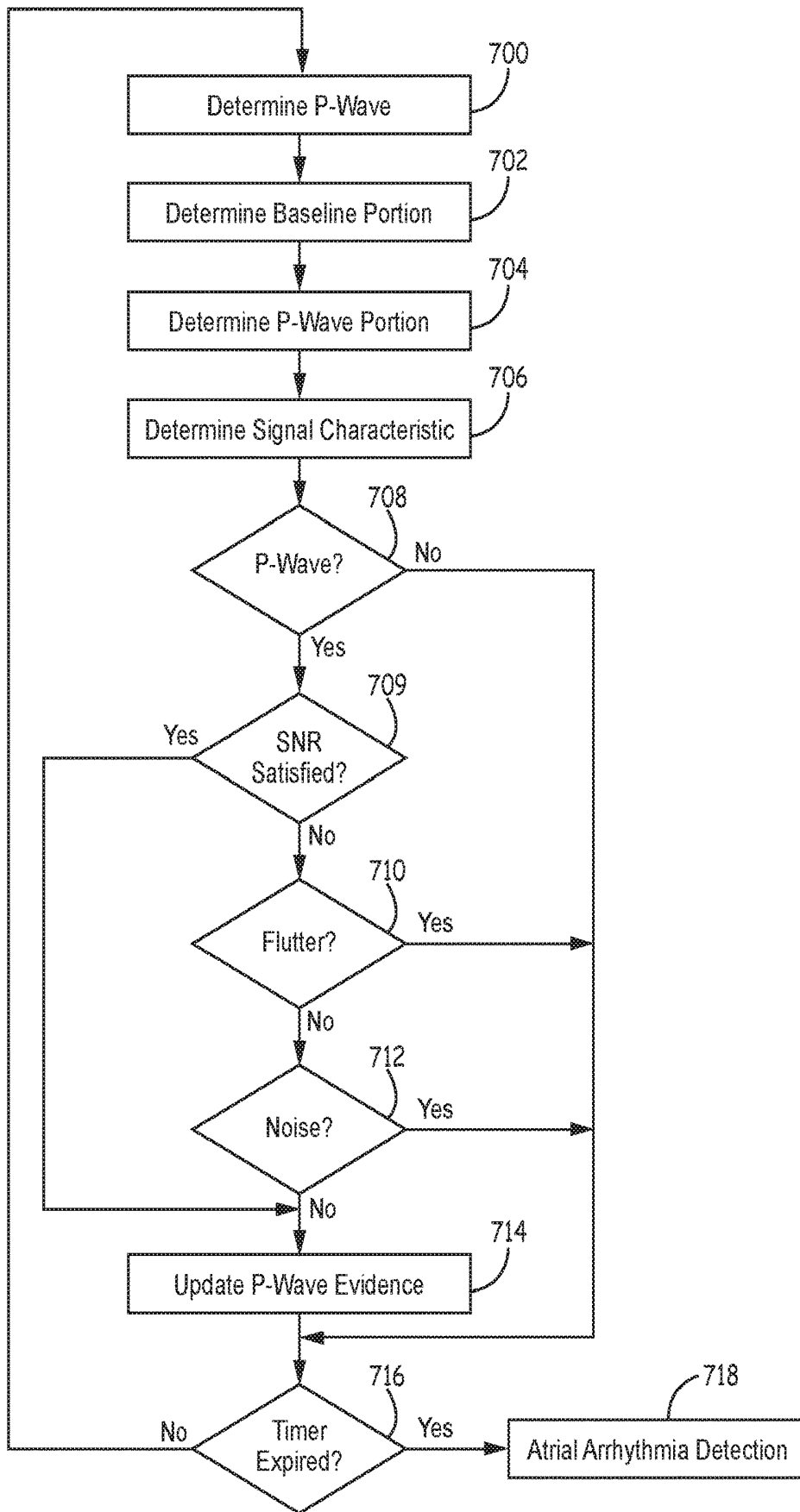


FIG. 9

METHOD AND APPARATUS FOR ATRIAL ARRHYTHMIA EPISODE DETECTION

This application is a U.S. national stage entry of International Application No. PCT/US2016/018408, filed Feb. 18, 2016, which claims the benefit of and priority from U.S. Pat. No. 9,603,543 filed Apr. 24, 2015 and U.S. Provisional Application Ser. No. 62/117,785, filed Feb. 18, 2015, the entire contents of each are incorporated herein by reference.

TECHNICAL FIELD

The disclosure relates generally to implantable cardiac medical devices and, in particular, to a method for and apparatus for detecting atrial tachyarrhythmia episodes in an implantable cardiac medical device.

BACKGROUND

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.

Atrial tachyarrhythmia includes the disorganized form of atrial fibrillation 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.

In the past, atrial arrhythmias have been largely under-treated due to the perception that these arrhythmias are relatively benign. 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.

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.

Occasionally, false detection of atrial fibrillation may occur in a subcutaneous device during runs of ectopic rhythm with irregular coupling intervals or underlying sinus

variability/sick sinus. In addition, false detection of atrial tachycardia may occur in a subcutaneous device during ectopy and regular normal sinus rhythm. Therefore, what is needed is a method for improving detection of atrial tachyarrhythmia to reduce false detection in a medical device.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic diagram of an exemplary medical device for detecting an arrhythmia according to an embodiment of the present disclosure.

FIG. 2 is a functional schematic diagram of the medical device of FIG. 1.

FIG. 3 is a flowchart of a method for detecting an atrial arrhythmia according to an embodiment of the disclosure.

FIG. 4 is a schematic diagram of detecting an atrial arrhythmia according to an embodiment of the disclosure.

FIG. 5 is a flowchart of a method of detecting an atrial arrhythmia in a medical device according to an embodiment of the disclosure.

FIG. 6 is a schematic diagram of detecting an atrial arrhythmia in a medical device, according to an embodiment of the disclosure.

FIGS. 7A and 7B are flowcharts of a method of detecting an atrial arrhythmia in a medical device according to an embodiment of the disclosure.

FIG. 8 is a flowchart of a method of determining an atrial arrhythmia according to an embodiment of the disclosure.

FIG. 9 is a flowchart of a method of detecting an atrial arrhythmia according to an embodiment of the disclosure.

DETAILED DESCRIPTION

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.

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 electrode positioned within the atrium as an atrial signal source to directly sense the atrial signal within the heart; i.e., the device may be a single chamber device having an electrode positioned only within the ventricle, or a subcutaneous device having no electrode positioned within the heart. 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.

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, including subcutaneous devices having loop recorders.

FIG. 1 is a schematic diagram of an exemplary medical device for detecting an arrhythmia 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 electrode 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.

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.

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.

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.

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 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.

ICD 10 may alternatively be configured as a subcutaneous device having sensing or pacing electrodes incorporated on the housing 11 of the device in which case transvenous leads are not required. A subcutaneous device may be coupled to a lead tunneled subcutaneously or submuscularly for delivering transthoracic pacing pulses and/or sensing ECG signals. An exemplary subcutaneous device is described in commonly assigned U.S. patent application Ser. Nos. 14/604,111 and 14/604,260. The techniques described herein can also be implemented in an external device, e.g. including patch electrodes and optionally another physiological sensor if desired, that can sense variable parameters as described herein.

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.

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.

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.

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. 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.

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.

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.

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. 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.

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.

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.

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.

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.

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 cardiover-

sion 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.

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.

FIG. 3 is a flowchart of a method for detecting an atrial arrhythmia according to an embodiment of the disclosure. As illustrated in FIG. 3, in order to determine whether a sensed cardiac signal is an atrial tachycardia event, the device determines whether the cardiac signal contains a P-wave portion, the results of which are utilized to augment an atrial tachycardia determination process. For example, the determination as to whether a P-wave is detected may be utilized to augment detection of atrial arrhythmias based on the irregularity of ventricular cycles having RR intervals that exhibit discriminatory signatures when plotted in a Lorenz scatter plot, such as 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. Other atrial arrhythmia determination 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.

According to one embodiment, for example, during determination of signal characteristics for augmenting atrial tachycardia detection, the device senses the cardiac signal and identifies R-waves in response to the sensed cardiac signal using any known cardiac signal sensing and detection scheme, such as that disclosed in U.S. Pat. No. 5,117,824, by Keimel, et al., for example. Upon detection of an R-wave associated with the sensed cardiac signal, Block 300, the device determines whether the R-wave satisfies one or more RR-interval parameters, Block 302, described below. If the RR-interval parameter or parameters are not satisfied, No in Block 302, the device waits for the next sensed R-wave, Block 300 and the process Block 300-302 is repeated using the next R-wave. If the RR-interval parameter or parameters are satisfied, Yes in Block 302, the device determines a P-wave window associated with the R-wave, Block 304, as described below.

Upon determination of the P-wave window, the device determines whether a predetermined number of R-waves have been identified, Block 306. The predetermined number of R-waves required to satisfy the determination in Block 306 may be set as one or more R-waves, and according to one embodiment is set as four R-waves for example. If the predetermined number of R-waves have not been identified and therefore a next R-wave is needed, Yes in Block 306, the device waits for the next sensed R-wave, Block 300 and the process Block 300-306 is repeated using the next R-wave. If the predetermined number of R-waves have been identified and therefore a next R-wave is not needed, No in Block 306, the device determines P-wave evidence, Block 308, described below, and utilizes the determined P-wave evidence to augment atrial arrhythmia detection, Block 310, as described below.

FIG. 4 is a schematic diagram of detecting an atrial arrhythmia according to an embodiment of the disclosure.

As illustrated in FIGS. 3 and 4, in order to determine whether a sensed R-wave 320 satisfies the RR-interval parameters in Block 302, the device determines whether an RR interval 322 extending between the current R-wave 320 and a previous sensed R-wave 324 is greater than an interval threshold, such as 780 ms for example. If the RR interval 322 is not greater than the interval threshold, the RR-interval parameter is not satisfied, No in Block 302, and the process is repeated with the next RR interval 326. If the RR interval 322 is greater than the interval threshold, the RR interval parameter is satisfied, Yes in Block 302.

According to another embodiment, additional RR interval parameters may also be included in the determination as to whether the RR interval parameters have been satisfied in Block 302. For example, using R wave 326 as an example, in addition to the determination of whether the associated RR interval 340 satisfies the RR interval threshold, the device may also compare the RR interval 340 associated with the current R wave 326 with one or more previously determined RR intervals, such as interval 322 for example, and determine whether a relative change associated with the current RR-interval 340 is greater than a change threshold, such as 100 ms, for example. If the relative change associated with the current RR-interval is not greater than the change threshold, the RR interval parameter is not satisfied in Block 302. If the relative change associated with the current RR interval is greater than the change threshold, the RR-interval parameter is satisfied in Block 302.

In this way, if one of the RR intervals parameters are not satisfied, no P-wave window determination is made, and the process is repeated with the next R wave. If the RR interval parameter or one of the RR interval parameters are satisfied, the RR interval parameter is satisfied in Block 302, and the device determines a P wave window 328 associated with the R-wave 320 for determining whether the R wave 320 includes an associated P-wave. For example, in order to determine the P wave window 328, the device determines a P-wave window start point 330 located a predetermined distance 332 prior to the R-wave, such as 620 ms for example, and a P wave window endpoint 334 is located at a predetermined distance 336 subsequent to the P wave start point 330, such as 600 ms, for example, so that the P wave window 328 extends 600 ms between the P wave start point 330 and the P wave endpoint 334. Each time a P wave window 328 is determined, a P wave counter is updated by one, until the predetermined number of P wave windows are identified, such as four P wave windows, for example.

FIG. 5 is a flowchart of a method of detecting an atrial arrhythmia in a medical device according to an embodiment of the disclosure. In response to the predetermined number of P-waves being identified, No in Block 306 of FIG. 3, the device determines P-wave evidence for determining whether a P-wave is likely detected, Block 308, and utilizes the determined P-wave evidence to augment atrial arrhythmia detection, Block 310, described below. As illustrated in FIG. 5, during the determination of P-wave evidence, the device determines a characteristic P-wave in response to the current determined P-waves, Block 360. For example, according to one embodiment, the device determines an average P-wave from the four determined P-waves that is identified as the characteristic P-wave. The associated P-wave window is then divided into a baseline portion, Block 362, and a P-wave portion, Block 364, and determines signal characteristics, Block 366, for one or both of the baseline window and the P-wave window. A determination is then made,

based on the determined signal characteristics, whether the characteristic P-wave is confirmed as being a P-wave, Block 368.

If the characteristic P-wave is not confirmed as being a P-wave, No in Block 368, the device waits for the next predetermined number of P-waves to be identified, Yes in Block 306 of FIG. 3, and the process, Blocks 360-368, is repeated using the next identified P-waves. If the characteristic P-wave is confirmed as being a P-wave, Yes in Block 368, the device utilizes the determination of a P-wave being present to augment atrial arrhythmia detection, Block 370, as described below.

FIG. 6 is a schematic diagram of detecting an atrial arrhythmia in a medical device, according to an embodiment of the disclosure. As illustrated in FIGS. 5 and 6, in order to determine P-wave evidence (Block 308 of FIG. 3), the device determines a characteristic P-wave 400 having a characteristic P wave window 402 determined by averaging the determined four P-wave windows, as described above. The device divides the P-wave window 402 into a baseline portion 404, extending from the P-wave window start point 406 to a midpoint of the window 408, and a P-wave portion 410, extending from the midpoint of the window 408 to a P-wave window endpoint 412. The device determines a first derivative of the P-wave signal 414 and a second derivative of the p-wave signal 416, and determines corresponding second derivative values 420 associated with positive going zero crossings 418 of the first derivative signal 414 within the baseline portion 404 of the first derivative signal window 402. In one embodiment, the first derivative of the P wave signal can be computed as the difference between points separated by eight samples, and the second derivative can be computed as the difference between points separated by four sample in the first derivative.

The device determines the maximum amplitude of the second derivative values 420 associated with the positive going zero crossings 418, and the determined maximum amplitude value is then used to generate a first threshold 422 for evaluating the second derivative P-wave signal 416 within the P-wave portion 410 of the second derivative window 402. According to one embodiment, the threshold 422 is set as a multiple of the maximum of the second derivative values 420, such as twice the maximum of the second derivative values 420, for example.

In the same way, the device determines a corresponding second derivative value 426 for each negative going zero crossing 424 of the derivative signal 414 within the baseline portion 404 of the window 402. A minimum amplitude of the second derivative values 426 associated with the negative going first derivative zero crossings 424 is determined, and the determined minimum amplitude value is used to generate a second threshold 428 for evaluating the second derivative P-wave signal 416 within the P-wave portion 410 of the window 402. According to one embodiment, the threshold 428 is set as a multiple of the minimum of the second derivative values 426, such as twice the minimum of the second derivative values 426, for example.

Using the first threshold 422 determined in response to the determined maximum of the second derivative values 420, the device determines, for each positive going zero crossing 430 of the first derivative signal within the P-wave portion 410 of the first derivative window, a corresponding amplitude 432 of the second derivative signal within the P-wave portion 410 of the corresponding second derivative signal 416. The device compares the resulting maximum ampli-

tudes 432 of the second derivative signal 416 signal within the P-wave portion 410 of the window 402 to the first threshold 422.

Similarly, using the second threshold 422 determined in response to the determined minimum of the second derivative values 420, the device compares, for one or more negative going zero crossing 434 of the first derivative signal 414, the corresponding minimum amplitude 436 of the second derivative signal 416 signal within the P-wave portion 410 of the window 402 to the second threshold 428.

A P-wave is determined to have occurred, Yes in Block 368 of FIG. 5, if either the number of maximum amplitudes 432 determined to be greater than or equal to the first threshold 422 is equal to one, or the number of minimum amplitudes 432 determined to be less than or equal to the second threshold 428 is equal to one. If both the number of maximum amplitudes 432 determined to be greater than or equal to the first threshold 422 and the number of minimum amplitudes 432 determined to be less than or equal to the second threshold 428 is not equal to one, a P-wave is not determined to have occurred, No in Block 368 of FIG. 5. The result of the determination of whether a P-wave is identified is then used during the determination of an atrial arrhythmia event, as described below.

FIGS. 7A and 7B are flowcharts of a method of detecting an atrial arrhythmia in a medical device according to an embodiment of the disclosure. As illustrated in FIGS. 6, 7A and 7B, during detection of P-wave evidence, the device may also determine that the event is associated with other atrial events, such as an atrial flutter event, for example. During determination of signal characteristics (Block 366 of FIG. 5), the device may also determine an atrial flutter event is occurring in response to any one of a predetermined conditions being met. For example, in order to identify the event as an atrial flutter event, the device may evaluate the first derivative signal 414 and the second derivative signal 418 using the following Equation F1:

$$\text{bwinZCpThr} + \text{bwinZCnThr} = 3 \text{ AND } \text{abs} \{ \text{bwinZCpThr} + \text{bwinZCnThr} - (\text{pwinZCpThr} + \text{pwinZCnThr}) \} \leq 1$$

where bwinZCpThr is the number of the second derivative values 440 associated with each of the positive going zero crossings 418 of the first derivative signal 414 within the baseline portion 404 of the window 402 having an amplitude greater than a predetermined threshold amplitude 442, bwinZCnThr is the number of the second derivative values 444 associated with each of the negative going zero crossings 424 of the first derivative signal 414 having an amplitude less than a predetermined threshold amplitude 446, pwinZCpThr is the number of the second derivative values 448 associated with each of the positive going zero crossings 430 of the first derivative signal 414 of the P-wave portion 410 of the window 402 having an amplitude greater than a predetermined threshold amplitude 442, and pwinZCnThr is the number of the second derivative values 444 associated with each of the negative going zero crossings 424 of the first derivative signal 414 having an amplitude less than a predetermined threshold amplitude 446.

In this way, in order to identify a flutter event, the device may determine both the number of the second derivative values 440 associated with each of the positive going zero crossings 418 of the first derivative signal 414 within the baseline portion 404 of the window 402 having an amplitude greater than a predetermined threshold amplitude 442 (pwinZCpThr), and the number of the second derivative values 444 associated with each of the negative going zero cross-

ings **424** of the first derivative signal **414** having an amplitude less than a predetermined threshold amplitude **446** ($pwinZCnThr$), Block **500**. For example, according to one embodiment, the amplitude thresholds **442** and **446** may be set as 8 microvolts for the positive going zero crossings **418** and as -8 microvolts for the negative going zero crossings **424**.

The device determines whether an amplitude threshold is satisfied in response to the determined number of amplitudes **440** and **444** exceeding the thresholds **442** and **446**, Block **502**, by determining whether a total of the number of amplitudes **440** and **440** is equal to a predetermined number of amplitudes, such as three amplitudes, for example. If the number of amplitudes exceeding the thresholds **442** and **446** ($bwinZCpThr+bwinZCnThr$) is satisfied, Yes in Block **502**, the device determines both the number of the second derivative values **448** associated with each of the positive going zero crossings **430** of the first derivative signal **414** of the P-wave portion **410** of the window **402** having an amplitude greater than the threshold amplitude **442** ($pwinZCpThr$), and the number of the second derivative values **450** associated with each of the negative going zero crossings **434** of the first derivative signal **414** having an amplitude less than the threshold amplitude **446** ($pwinZCnThr$), Block **504**. A relative baseline portion **404** and P-wave portion **420** amplitude difference ($abs \{bwinZCpThr+bwinZCnThr-(pwinZCpThr+pwinZCnThr)\}$) is determined using the determined second derivative values **448** and **450** in Block **504**, and a determination is made as to whether the relative amplitude difference satisfies an amplitude threshold difference, Block **506**. For example, the amplitude threshold difference is satisfied if the relative amplitude difference is less than or equal to a predetermined threshold, such as one, for example. In this way, a flutter event may be identified in response to both the baseline portion **404** amplitude difference threshold being satisfied ($bwinZCpThr+bwinZCnThr=3$), Yes in Block **502**, and the determined relative amplitude difference ($abs \{bwinZCpThr+bwinZCnThr-(pwinZCpThr+pwinZCnThr)\} \leq 1$) being satisfied.

According to another embodiment, in order to identify the event as an atrial flutter event, the device may evaluate the first derivative signal **414** and the second derivative signal **418** using the following Equation F2:

$$bwinZCpThr+bwinZCnThr=3 \text{ AND } abs \{bwinZCpThr+bwinZCnThr-(pwinZCpThr+pwinZCnThr)\} \leq 1$$

where $bwinZCp$ is the number of positive zero crossings **418** within the baseline portion **404** of the window **402** and $bwinZCn$ is the number of negative zero crossings **424** within the baseline portion **404** of the window **402**, and the remaining variables are as described above in Equation F1.

In this way, if the amplitude difference is not satisfied, No in Block **506**, in addition to the amplitude threshold variables ($bwinZCpThr$) and ($bwinZCnThr$), the device determines both the number of positive zero crossings **418** within the baseline portion **404** of the window **402** ($bwinZCp$) and the number of negative zero crossings **424** within the baseline portion **404** of the window **402** ($bwinZCn$) and determines whether an amplitude/zero crossing threshold is satisfied, Block **512**, in response to the amplitude threshold variables ($bwinZCpThr$) and ($bwinZCnThr$), the number of positive zero crossings **418** within the baseline portion **404** of the window **402** ($bwinZCp$) and the number of negative zero crossings **424** within the baseline portion **404** ($bwinZCnThr$). For example, the amplitude/zero crossing threshold is satisfied, Yes in Block **512**, and therefore a flutter event is occurring, Block **508**, in response to both the

amplitude threshold ($bwinZCpThr+bwinZCnThr=3$) and an amplitude/zero crossing threshold ($abs \{bwinZCpThr+bwinZCnThr-(bwinZCp+bwinZCn)\} \leq 1$) being satisfied.

According to another embodiment, in order to identify the event as an atrial flutter event, the device may evaluate the first derivative signal **414** and the second derivative signal **418** using the following Equation F3:

$$bwinZCpThr+pwinZCpThr=3 \text{ AND } abs \{bwinZCpThr+pwinZCpThr-(bwinZCp+pwinZCp)\} \leq 1$$

where $pwinZCp$ is the number of positive going zero crossings **430** within the P-wave portion **410** of the window **402**, and the remaining variables are as described above in Equations F1 and F2. In this way, if either the number of amplitudes exceeding the thresholds **442** and **446** ($bwinZCpThr+bwinZCnThr$) is not satisfied, No in Block **502** or the amplitude/zero crossing threshold is not satisfied, No in Block **512**, in addition to the necessary previously described variables, Blocks **500**, **504**, and **510**, the device determines the number of positive going zero crossings **430** within the P-wave portion **410** of the window **402**, Block **514**. The device then determines whether an amplitude threshold is satisfied, Block **516**, by determining the sum of the number of the second derivative values **440** associated with each of the positive going zero crossings **418** of the first derivative signal **414** within the baseline portion **404** of the window **402** having an amplitude greater than a predetermined threshold amplitude **442** ($bwinZCpThr$) and the number of the second derivative values **448** associated with each of the positive going zero crossings **430** of the first derivative signal **414** of the P-wave portion **410** of the window **402** having an amplitude greater than a predetermined threshold amplitude **442** ($pwinZCpThr$) satisfies an amplitude threshold, Block **516**, such as being equal to 3, for example, ($bwinZCpThr+pwinZCpThr=3$).

If the amplitude threshold is satisfied, Yes in Block **516**, determines a sum ($bwinZCp+pwinZCp$) of the number of positive crossing points **418** in the baseline portion **404** ($bwinZCp$) and the number of positive crossings **434** in the P-wave portion **410** ($pwinZCp$), Block **518**. A determination is then made as to whether an amplitude/zero crossing difference has been satisfied, Block **520**, and if the difference has been satisfied, Yes in Block **520**, a flutter event is identified, Block **508**. According to one embodiment, for example, in order to determine whether the amplitude/zero crossing difference has been satisfied in Block **520**, the device determines whether the absolute value of the difference between the sum of the number of the second derivative values **440** associated with each of the positive going zero crossings **418** of the first derivative signal **414** within the baseline portion **404** of the window **402** having an amplitude greater than a predetermined threshold amplitude **442** ($bwinZCpThr$) and the number of the second derivative values **444** associated with each of the negative going zero crossings **424** of the first derivative signal **414** having an amplitude less than a predetermined threshold amplitude **446** ($pwinZCpThr$) and the sum of the number of positive zero crossings **418** within the baseline portion **404** of the window **402** ($bwinZCp$) and is the number of positive going zero crossings **430** within the P-wave portion **410** of the window **402** ($pwinZCp$) is less than a predetermined threshold, such as one for example.

According to another embodiment, in order to identify the event as an atrial flutter event, the device may evaluate the

first derivative signal 414 and the second derivative signal 418 using the following Equation F4:

$$\text{bwinZCnThr} + \text{pwinZCnThr} = 3 \text{ AND abs } \{ \text{bwinZCnThr} + \text{pwinZCnThr} - (\text{bwinZCn} + \text{pwinZCn}) \} \leq 1$$

where bwinZCn is the number of negative zero crossings 424 of the first derivative signal 414 within the baseline portion 404 of the window 402, pwinZCn is the number of negative going zero crossings of the first derivative signal 414 within the P-wave portion 410 of the window 402, and the remaining variables are as described above in Equations F1, F2 and F3.

In this way, if either the amplitude threshold is not satisfied, No in Block 516, or amplitude/zero crossing difference has been satisfied, No in Block 520, the device determines the number of the second derivative values 444 associated with each of the negative going zero crossings 424 of the first derivative signal 414 having an amplitude less than a predetermined threshold amplitude 446 (bwinZCnThr) and the number of the second derivative values 444 associated with each of the negative going zero crossings 424 of the first derivative signal 414 having an amplitude less than a predetermined threshold amplitude 446 (pwinZCnThr), Block 522, and determines whether an amplitude threshold is satisfied, Block 524 by determining whether a sum of the number of the second derivative values 444 associated with each of the negative going zero crossings 424 of the first derivative signal 414 having an amplitude less than a predetermined threshold amplitude 446 (bwinZCnThr) and the number of the second derivative values 444 associated with each of the negative going zero crossings 424 of the first derivative signal 414 having an amplitude less than a predetermined threshold amplitude 446 (bwinZCnThr+pwinZCnThr) is equal to a predetermined threshold, such as three for example.

If the amplitude threshold is satisfied, Yes in Block 524, the device determines the number of negative zero crossings 424 within the baseline portion 404 of the window 402 (bwinZCn) and the number of positive going zero crossings 430 within the P-wave portion 410 of the window 402 (pwinZCp), Block 562, and determines whether an amplitude/zero crossing threshold is satisfied, Block 528. For example, the device determines whether an absolute value of whether the difference between the sum of the number of the second derivative values 444 associated with each of the negative going zero crossings 424 of the first derivative signal 414 within the baseline portion 404 of the window 402 having an amplitude less than the predetermined threshold amplitude 446 (bwinZCnThr) and the number of the second derivative values 444 associated with each of the negative going zero crossings 424 of the first derivative signal 414 within the P-wave portion 410 of the window 402 having an amplitude less than the predetermined threshold amplitude 446 (pwinZCpThr) is less than or equal to a predetermined threshold, such as one, for example. If amplitude/zero crossing threshold is satisfied, Yes in Block 528, a flutter event is identified, Block 508.

According to another embodiment, in order to identify the event as an atrial flutter event, the device may evaluate the first derivative signal 414 and the second derivative signal 418 using the following Equation F5:

$$\text{bwinZCp} + \text{bwinZCn} + \text{pwinZCp} + \text{pwinZCn} \geq 6 \text{ AND } \{ \text{bwinZCp} + \text{bwinZCn} + \text{pwinZCp} + \text{pwinZCn} - (\text{bwinZCpThr} + \text{bwinZCnThr} + \text{pwinZCpThr} + \text{pwinZCnThr}) \} \leq 2$$

In this way, if either the amplitude threshold is not satisfied, No in Block 524, or amplitude/zero crossing difference has not been satisfied, No in Block 528, the device determines a sum of the total number of positive zero crossings 418 and negative zero crossings 424 of the first derivative signal 414 in the baseline portion 404 of the window 402 and the total number of positive zero crossings 430 and negative zero crossings 434 of the first derivative signal 414 in the P-wave portion 410 of the window 402 (bwinZCp+bwinZCn+pwinZCp+pwinZCn), Block 530, and determines whether sum of the total positive and negative zero crossings satisfies a zero crossing threshold, Block 534, such greater than or equal to six, for example.

If the zero crossing threshold is satisfied, Yes in Block 534, the device determines a difference between the sum of the total number of positive zero crossings 418 and negative zero crossings 424 of the first derivative signal 414 in the baseline portion 404 of the window 402 (bwinZCp+bwinZCn) and the total number of positive zero crossings 430 and negative zero crossings 434 of the first derivative signal 414 in the P-wave portion 410 of the window 402 (pwinZCp+pwinZCn) and the sum of the total number of the amplitudes 440 of the second derivative signal 416 in the baseline portion 404 of the window 402 exceeding the maximum threshold 442 (bwinZCpThr), the total number of amplitudes 444 in the baseline portion 404 of the window 402 less than the minimum threshold 446 (bwinZCnThr), the total number of the amplitudes 448 of the second derivative signal 416 in the P-wave portion 410 of the window 402 exceeding the maximum threshold 442 (pwinZCpThr), and the total number of amplitudes 450 in the P-wave portion 410 of the window 402 less than the minimum threshold 446 (pwinZCnThr), Block 536.

A determination is then made as to the whether the determined difference (bwinZCp+bwinZCn+pwinZCp+pwinZCn-(bwinZCpThr+bwinZCnThr+pwinZCpThr+pwinZCnThr) satisfies a zero crossing/amplitude difference threshold, Block 538, such as being less than or equal to 2, for example, in response to the determined difference. If the determined difference satisfies the zero crossing/amplitude difference threshold, i.e., bwinZCp+bwinZCn+pwinZCp+pwinZCn-(bwinZCpThr+bwinZCnThr+pwinZCpThr+pwinZCnThr) is less than or equal to 2, Yes in Block 538, a flutter event is identified, Block 540.

According to another embodiment, in order to identify the event as an atrial flutter event, the device may evaluate the first derivative signal 414 and the second derivative signal 418 using the following Equation F6:

$$\text{bwinPThr} + \text{bwinNThr} \geq 8 \text{ AND } \text{bwinPThr} > 0 \text{ AND } \text{bwinNThr} > 0 \text{ AND } \text{bwinZCp} + \text{bwinZCn} = 3 \text{ or } 4$$

where bwinPThr is the number of amplitudes 440 of the second derivative signal 416 within the baseline portion 404 of the window 402 that are greater than the maximum threshold 442, and bwinNThr is the number of amplitudes 444 of the second derivative signal 416 within the baseline portion 404 of the window 402 that are less than the minimum threshold 446.

In this way, if either the zero crossing threshold is not satisfied, No in Block 534, or the zero crossing/amplitude difference has not been satisfied, No in Block 538, the device determines the number of second derivative amplitudes for the baseline portion of the window that satisfy the amplitude

threshold, Block 542, by determining the number of amplitudes 440 of the second derivative signal 416 within the baseline portion 404 of the window 402 that are greater than the maximum threshold 442 (bwinPThr), and the number of amplitudes 444 of the second derivative signal 416 within the baseline portion 404 of the window 402 that are less than the minimum threshold 446 (bwinNThr). The device then determines whether amplitude thresholds are satisfied, Block 544, by determining whether the determined number of second derivative amplitudes is greater than or equal to a predetermined number of amplitudes, such as 8 amplitudes, for example (bwinPThr+bwinNThr \geq 8), and whether both the number of amplitudes 440 of the second derivative signal 416 within the baseline portion 404 of the window 402 that are greater than the maximum threshold 442 (bwinPThr), and the number of amplitudes 444 of the second derivative signal 416 within the baseline portion 404 of the window 402 that are less than the minimum threshold 446 (bwinNThr) are greater than a predetermined threshold number, such as zero, for example (bwinPThr $>$ 0 AND bwinNThr $>$ 0).

If the determined number of second derivative amplitudes does not satisfy any one of the amplitude thresholds, No in Block 544, and therefore none of the predetermined conditions Equations F1-F6 are met, a flutter event is not identified for the current characteristic P-wave 400, Block 546. If the determined number of second derivative amplitudes satisfies the amplitude thresholds, Yes in Block 544, a determination is made as to whether the sum of the total number of positive and negative zero crossings 418 and 424 of the first derivative signal 414 within the baseline portion 404 satisfy a predetermined baseline crossings threshold, Block 548, such as 3, for example (bwinZCp+bwinZCn=3 or 4).

If the baseline zero crossings threshold is satisfied, Yes in Block 548, a flutter event is identified, Block 540, and if the baseline zero crossings threshold is not satisfied, No in Block 548, and therefore none of the predetermined conditions Equations F1-F6 are met, a flutter event is not identified for the current characteristic P-wave 400, Block 546. It is understood that any single one or combination and order of the predetermined conditions F1-F6 may be utilized in determining whether a flutter event is identified, and therefore numerous combinations of the conditions F1-F6, or single ones of the conditions F1-F6 may be utilized in determining a flutter event, and therefore the disclosure is not limited to the combination and order of the conditions as illustrated in FIGS. 7A and 7B. In this way, a flutter event may be determined in response to one of any of the conditions of Equations F1-F6.

FIG. 8 is a flowchart of a method of determining an atrial arrhythmia according to an embodiment of the disclosure. As illustrated in FIGS. 6 and 8, during detection of P-wave evidence, the device may also determine that the event is associated with other events, such as noise, for example. During determination of signal characteristics (Block 366 of FIG. 5), the device may also determine a noise event is occurring in response to any one of a predetermined conditions being met. For example, in order to determine whether a noise event is occurring, the device may determine the amplitudes of the second derivative signal located at both the positive going zero crossing and the negative going zero crossings of the first derivative signal 414 within the baseline portion 404 of the window 402, Block 600, and determine whether both a maximum amplitude 460 of the second derivative signal 416 at a positive zero crossing of the first derivative signal 414 within the baseline portion 404 of the

window 402 and a minimum amplitude 462 of the second derivative signal 416 at a negative zero crossing of the first derivative signal 414 within the baseline portion 404 of the window 402 satisfy a first amplitude threshold, Block 602, such as the maximum amplitude being greater than 16 microvolts and the minimum amplitude being less than -16 microvolts, for example.

If the first amplitude threshold is satisfied, Yes in Block 602, noise is identified for the characteristic P-wave 400, Block 604. If the first amplitude threshold is not satisfied, No in Block 602, the device may determine other conditions for indicating noise, such as determining whether either a maximum amplitude 460 of the second derivative signal 416 at a positive zero crossing of the first derivative signal 414 within the baseline portion 404 of the window 402 or a minimum amplitude 462 of the second derivative signal 416 at a negative zero crossing of the first derivative signal 414 within the baseline portion 404 of the window 402 satisfy a second amplitude threshold, Block 606, such as the maximum amplitude being greater than 49 microvolts or the minimum amplitude being less than -49 microvolts, for example.

If the second amplitude threshold is satisfied, Yes in Block 606, noise is identified for the characteristic P-wave 400, Block 604. If the second amplitude threshold is not satisfied, No in Block 606, the device may determine the number of positive going zero crossings of the first derivative signal 414 within the baseline portion 404 of the window 402 whose corresponding amplitude 460 of the second derivative signal 416 is greater than a maximum amplitude threshold 464, such as 16 microvolts, for example, and the number of negative going zero crossings of the first derivative signal 414 within the baseline portion 404 of the window 402 whose corresponding minimum amplitude 462 of the second derivative signal 416 is less than a minimum amplitude threshold 466, such as -16 microvolts for example, Block 608. A determination is then made as to whether an amplitude threshold is satisfied, Block 610, and if the amplitude threshold is satisfied, Yes in Block 610, noise is identified, Block 604. For example, according to one embodiment, the device determines whether the amplitude threshold is satisfied in Block 610 by determining whether a sum of both the number of positive going zero crossings of the first derivative signal 414 within the baseline portion 404 of the window 402 whose corresponding amplitude 460 of the second derivative signal 416 is greater than the maximum amplitude threshold 464 and the number of negative going zero crossings of the first derivative signal 414 within the baseline portion 404 of the window 402 whose corresponding minimum amplitude 462 of the second derivative signal 416 is less than the minimum amplitude threshold 466 being equal to a predetermined number, such as 3 for example.

If the amplitude threshold is not satisfied, No in Block 610, the device may determine the number of positive zero crossings within the baseline portion 404 of the window 402 and the number of negative zero crossings within the baseline portion 404 of the window 402, Block 612. A determination is made as to whether a combined amplitude threshold and a baseline crossing threshold is satisfied, Block 614, by determining, for example, whether both the sum of the number of positive going zero crossings of the first derivative signal 414 within the baseline portion 404 of the window 402 whose corresponding amplitude 460 of the second derivative signal 416 is greater than the maximum amplitude threshold 464 and the number of negative going zero crossings of the first derivative signal 414 within the baseline portion 404 of the window 402 whose correspond-

ing minimum amplitude **462** of the second derivative signal **416** is less than the minimum amplitude threshold **464** is equal to a predetermined number, such as three for example, and the sum of the number of positive zero crossings within the baseline portion **404** of the window **402** and the number of negative zero crossings within the baseline portion **404** of the window **402** is within a predetermined range, such as greater than four and less than ten, for example.

If the combined amplitude threshold and baseline crossing threshold is satisfied, Yes in Block **614**, a noise event is identified, Block **604**. If the combined amplitude threshold and a baseline crossing threshold is satisfied, No in Block **614**, the device may determine the number of positive going zero crossings and the number of negative going zero crossings of the first derivative signal **414** within the P-wave portion **410** of the window **302**, Block **616**, and determine whether a zero crossings threshold has been satisfied, Block **618**, by determining whether a sum of the determined number of positive going zero crossings and the number of negative going zero crossings of the first derivative signal **414** is greater than four, for example.

If the zero crossings threshold has been satisfied, Yes in Block **618**, a noise event is determined, Block **604**. If the zero crossings threshold has not been satisfied, No in Block **618**, the device may determine the number of amplitudes **460** of the second derivative signal **416** within the baseline portion **404** of the window **402** that are greater than the maximum threshold **464**, and the number of amplitudes **462** of the second derivative signal **416** within the baseline portion **404** of the window **402** that are less than the minimum threshold **466**, Block **620**.

A determination is made as to whether a combined amplitude and baseline crossings threshold has been satisfied, Block **622**, by determining both whether a sum of the number of positive zero crossings within the baseline portion **404** of the window **402** and the number of negative zero crossings within the baseline portion **404** of the window **402** is greater than a baseline crossing threshold, such as four for example, and whether a sum of the number of amplitudes **460** of the second derivative signal **416** within the baseline portion **404** of the window **402** that are greater than the maximum threshold **464**, and the number of amplitudes **462** of the second derivative signal **416** within the baseline portion **404** of the window **402** that are less than the minimum threshold **466** is greater than an amplitude threshold, such as 10 samples or 16 microvolts for example.

If the combined amplitude and baseline crossings threshold has been satisfied, Yes in Block **622**, a noise event is determined, Block **604**. If the combined amplitude and baseline crossings threshold has not been satisfied, No in Block **622**, and therefore none of the predetermined conditions, Blocks **602**, **606** **610**, **614**, **618** and **622** are met, a noise event is not identified for the current characteristic P-wave **400**, Block **624**.

It is understood that any single one or combination and order of the predetermined conditions, Blocks **602**, **606** **610**, **614**, **618** and **622**, may be utilized in determining whether a noise event is identified, and therefore numerous combinations of the conditions, or single ones of the conditions may be utilized in determining a noise event, and therefore the disclosure is not limited to the combination and order of the conditions as illustrated in FIG. **8**. In this way, a noise event may be determined in response to one of any of the conditions of Blocks **602**, **606** **610**, **614**, **618** and **622**.

Therefore, the characteristic signal **400** may be determined to be a noise event if any one of the following noise conditions are met:

N1. $bwinZC_{max} > 156 \text{ ms}$ AND $bwinZC_{min} < -156 \text{ ms}$ (Block **602**)

N2. $bwinZC_{max} > 468 \text{ ms}$ OR $bwinZC_{min} < -468 \text{ ms}$ (Block **606**)

N3. $bwinZC_pThr + bwinZC_nThr > 3$ (Block **610**)

N4. $bwinZC_pThr + bwinZC_nThr = 3$ AND $\{4 < (bwinZC_p + bwinZC_n) < 10\}$ (Block **614**)

N5. $pwinZC_p + pwinZC_n > 4$ (Block **618**)

N6. $bwinZC_p + bwinZC_n > 4$ AND $bwinPThr + bwinNThr > 10$ (Block **622**)

where $bwinZC_{max}$ is the maximum amplitude **460** of the second derivative signal **416** at a positive zero crossing of the first derivative signal **414** within the baseline portion **404** of the window **402**, $bwinZC_{min}$ is the minimum amplitude **462** of the second derivative signal **416** at a negative zero crossing of the first derivative signal **414** within the baseline portion **404** of the window **402**, and the remaining conditions are as described above.

FIG. **9** is a flowchart of a method of detecting an atrial arrhythmia according to an embodiment of the disclosure. As described above, in response to the predetermined number of P-waves being identified, Yes in Block **306** of FIG. **3**, the device determines P-wave evidence, Block **308**, and utilizes the determined P-wave evidence to augment atrial arrhythmia detection, Block **310**, described below. As described above, according to another embodiment, during the determination of P-wave evidence, the device determines a characteristic P-wave in response to the current determined P-waves, Block **700**. For example, according to one embodiment, the device determines an average P-wave from the four determined P-waves that is identified as the characteristic P-wave. The associated P-wave window is then divided into a baseline portion, Block **702**, and a P-wave portion, Block **704**, and signal characteristics are determined, Block **706**, for one or both of the baseline window and the P-wave window. A determination is then made, based on the determined signal characteristics, whether the characteristic P-wave is confirmed as being a P-wave, Block **708**.

If the characteristic P-wave is not confirmed as being a P-wave, No in Block **708**, the device determines whether a timer, such as a two minute timer, for example, has expired, Block **716**. If the timer has expired, P-wave evidence is used to augment an atrial arrhythmias scheme, as described below, during atrial arrhythmia detection, Block **718**, such as the determination of an atrial detection score determined based on the irregularity of ventricular cycles having RR intervals that exhibit discriminatory signatures when plotted in a Lorenz scatter plot, for example, which 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. Other atrial arrhythmia determination methods that may be utilized 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. If the timer has not expired, No in Block **716**, the device waits for the next predetermined number of P-waves to be identified, and the process, Blocks **700-708**, is repeated using the next identified P-waves.

If the characteristic P-wave is confirmed as being a P-wave, Yes in Block **708**, the device determines whether a maximum signal to noise ratio is greater than a signal to noise ratio SNR threshold, Block **709**. If the maximum signal to noise ratio is greater than the SNR threshold, Yes in Block **709**, the device updates a P-Wave evidence counter, Block **714**, and either repeats the process if the timer has not expired, No in Block **716**, or utilizes the updated P-wave evidence counter Block **714** to augment the atrial arrhythmia

detection score, Block 718, generated based on the irregularity of ventricular cycles, described above.

According to one embodiment, in order to determine whether a maximum signal to noise ratio is satisfied, Block 709, the device determines whether either the maximum amplitude 432 of the second derivative signal 416 within the P-wave portion 410 of the window 402 is greater than four times the maximum amplitude 420 of the second derivative signal 416 within the baseline portion 404 of the window 402, or whether the minimum amplitude 436 of the second derivative signal 416 within the P-wave portion 410 of the window 402 is greater than four times the minimum amplitude 426 of the second derivative signal 416 within the baseline portion 404 of the window 402. If either is determined to occur, the maximum SNR threshold is satisfied, Yes in Block 709. If neither of the two is determined to occur, the maximum SNR threshold is not satisfied, No in Block 709, and the device determines whether the characteristic P-wave 400 is identified as a flutter event, Block 710, using the flutter conditions described above. If a flutter event is identified, Yes in Block 710, the device determines whether the timer, Block 716 as described above. If a flutter event is not identified, No in Block 710, the device determines whether the characteristic P-wave 400 is identified as a noise event, Block 712, using the conditions described above. If a noise event is identified, Yes in Block 712, the device determines whether the timer, Block 716 as described above. If a noise event is not identified, No in Block 712, the device updates a P-wave evidence counter, Block 714, either repeats the process if the timer has not expired, No in Block 716, or utilizes the updated P-wave evidence counter Block 714 to augment the atrial arrhythmia detection score, Block 718, generated based on the irregularity of ventricular cycles, described above.

According to one embodiment, each time a P-wave is determined to occur and the P-wave evidence is updated, Block 714, the device increases a P-wave evidence counter for AF detection by two and increases an P-wave evidence counter for AT detection by one, for example, and once the timer has expired, Yes in Block 716, the total, or a multiple of the total, of the respective P-wave evidence counters is used to withhold AT detection based on regularity evidence if P-wave evidence counter for AT is greater than a threshold, 4 as an example, or are subtracted from an AF evidence score and a AT evidence score generated as described in commonly assigned U.S. Patent Publication No. 2012/0238891, to Sarkar et al., for example. The respective P-wave evidence counters can also be used to withhold the AF or AT detection respectively based on AF or AT evidence score.

In another embodiment, the amount of increase of P-wave evidence counters for AF and AT detection in Block 714 can depend on user choice of the mode of operation and on meeting a high SNR condition. In order to determine whether a high signal to noise ratio is satisfied the device determines whether either the maximum amplitude 432 of the second derivative signal 416 associated with a positive going zero crossing of the first derivative signal 414 within the P-wave portion 410 of the window 402 is greater than four times the maximum amplitude 420 of the second derivative signal 416 associated with a positive going zero crossing of the first derivative signal 430 within the baseline portion 404 of the window 402, or whether the minimum amplitude 436 of the second derivative signal 416 associated with a negative going zero crossing of the first derivative signal within the P-wave portion 410 of the window 402 is greater than four times the minimum amplitude 426 of the

second derivative signal 416 associated with a negative going zero crossing of the first derivative signal within the baseline portion 404 of the window 402. If either is determined to occur, the high SNR threshold is satisfied, which will then lead to a higher increase of P-wave evidence counters for AF and AT detection in Block 714.

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.

The invention claimed is:

1. An implantable medical device for determining an atrial arrhythmia event within a cardiac signal, comprising:
 - a plurality of electrodes configured to sense the cardiac signal; and
 - a processor configured to identify one or more R-waves within the sensed cardiac signal, determine an atrial arrhythmia score for identifying the arrhythmia event based at least on the one or more R-waves, determine a sensing window associated with the one or more R-waves, determine signal characteristics of the cardiac signal within the sensing window, determine whether the cardiac signal within the sensing window corresponds to a P-wave based on the determined signal characteristics, determine a signal to noise ratio of the cardiac signal within the sensing window, update the arrhythmia score when the P-wave is identified in the sensing window and the determined signal to noise ratio satisfies a signal to noise threshold.
2. The medical device of claim 1, wherein the processor is further configured to determine whether to deliver an arrhythmia therapy based on the updated arrhythmia score.
3. The medical device of claim 1, wherein the processor is further configured to determine a second derivative signal of the cardiac signal within the sensing window, determine a first maximum amplitude of the second derivative signal within the first portion of the sensing window and a second maximum amplitude of the second derivative signal within the second portion of the sensing window, compare the first maximum amplitude with the second maximum amplitude, and determine whether the signal to noise ratio satisfies the signal to noise threshold based on the comparison.
4. The medical device of claim 3, wherein the comparing comprises determining whether the second maximum amplitude is greater than a multiple of the first maximum amplitude and the signal to noise ratio satisfies the signal to noise ratio threshold when the second maximum amplitude is greater than the multiple of the first maximum amplitude.
5. The medical device of claim 1, wherein the processor is further configured to determine a second derivative signal of the cardiac signal within the sensing window, determine a first minimum amplitude of the second derivative signal within the first portion of the sensing window and a second minimum amplitude of the second derivative signal within the second portion of the sensing window, compare the first minimum amplitude with the second minimum amplitude, determine whether the signal to noise ratio satisfies the signal to noise threshold based on the comparison.
6. The medical device of claim 5, wherein the comparing comprises determining whether the second minimum amplitude is less than a multiple of the first minimum amplitude and the signal to noise ratio satisfies the signal to noise ratio threshold when the second minimum amplitude is less than the multiple of the first minimum amplitude.

7. The medical device of claim 1, wherein the processor is further configured to determine, in response to the P-wave being identified in the sensing window and the signal to noise ratio not satisfying the signal to noise threshold, whether the cardiac signal within the sensing window corresponds to one of a flutter event and a noise event, and update the arrhythmia score in response to the cardiac signal within the sensing window not corresponding to one of a flutter event and a noise event.

8. The medical device of claim 1, wherein the atrial arrhythmia event comprises one of an atrial tachycardia event and an atrial fibrillation event, the processor is further configured to increase, in response to the cardiac signal within the sensing window corresponding to a P-wave, a P-wave evidence counter for atrial fibrillation by a first predetermined amount and increase a P-wave evidence counter for atrial tachycardia by a second predetermined amount not equal to the first predetermined amount.

9. The medical device of claim 8, wherein the processor is further configured to update the arrhythmia score by at least one of withholding atrial arrhythmia detection based on at least one of the P-wave evidence counter for atrial tachycardia being greater than a first threshold or the P-wave evidence counter for atrial fibrillation being greater than a second threshold.

10. The medical device of claim 8, wherein at least one of a value of the P-wave evidence counter for atrial fibrillation, a value of the P-wave evidence counter for atrial tachycardia, a multiple of the value of the P-wave evidence counter for atrial fibrillation, or a multiple of the value of the P-wave evidence counter for atrial tachycardia is subtracted from the atrial arrhythmia score.

11. The medical device of claim 1, wherein the medical device comprises a subcutaneous device.

12. The medical device of claim 1, wherein the sensing window includes a first portion and a second portion, the first portion of the sensing window is a baseline portion and the second portion of the sensing window is a P-wave portion.

13. The medical device of claim 1, wherein the processor is further configured to, in response to the P-wave being identified in the sensing window and the signal to noise ratio not satisfying the signal to noise threshold, determine whether the cardiac signal within the sensing window corresponds to an atrial flutter event, determine whether the cardiac signal within the sensing window corresponds to a noise event, and update the arrhythmia score in response to the cardiac signal within the sensing window not corresponding to an atrial flutter event and not corresponding to a noise event.

14. A method comprising:
 sensing a cardiac signal on a plurality of electrodes;
 identifying one or more R-waves within the sensed cardiac signal;
 determining an atrial arrhythmia score for identifying an arrhythmia event based at least on the one or more R-waves;
 determining a sensing window associated with the one or more R-waves;
 determining signal characteristics of the cardiac signal within the sensing window;
 determining whether the cardiac signal within the sensing window corresponds to a P-wave based on the determined signal characteristics;
 determining a signal to noise ratio of the cardiac signal within the sensing window;

increasing, when the cardiac signal within the sensing window is determined to correspond to a P-wave and the determined signal to noise ratio satisfies a signal to noise threshold, a P-wave evidence counter for atrial fibrillation by a first predetermined amount;

increasing, when the cardiac signal within the sensing window is determined to correspond to a P-wave and the determined signal to noise ratio satisfies a signal to noise threshold, a P-wave evidence counter for atrial tachycardia by a second predetermined amount not equal to the first predetermined amount; and

updating the arrhythmia score based on at least one of the P-wave evidence counter for atrial fibrillation and the P-wave evidence counter for atrial tachycardia.

15. The method of claim 14, wherein updating the arrhythmia score comprises withholding atrial arrhythmia detection based on at least one of the P-wave evidence counter for atrial tachycardia being greater than a first threshold or the P-wave evidence counter for atrial fibrillation being greater than a second threshold.

16. The method of claim 14, wherein updating the arrhythmia score comprises subtracting at least one of a value of the P-wave evidence counter for atrial fibrillation, a value of the P-wave evidence counter for atrial tachycardia, a multiple of the value of the P-wave evidence counter for atrial fibrillation, or a multiple of the value of the P-wave evidence counter for atrial tachycardia from the atrial arrhythmia score.

17. The method of claim 14, further comprising:
 in response to the P-wave being identified in the sensing window and the signal to noise ratio not satisfying the signal to noise threshold, determining whether the cardiac signal within the sensing window corresponds to one of a flutter event and a noise event; and
 updating the arrhythmia score in response to the cardiac signal within the sensing window not corresponding to one of a flutter event and a noise event.

18. The method of claim 14, further comprising:
 in response to the P-wave being identified in the sensing window and the signal to noise ratio not satisfying the signal to noise threshold, determining whether the cardiac signal within the sensing window corresponds to an atrial flutter event;
 determining whether the cardiac signal within the sensing window corresponds to a noise event; and
 updating the arrhythmia score in response to the cardiac signal within the sensing window not corresponding to an atrial flutter event and not corresponding to a noise event.

19. The method of claim 14, further comprising:
 identifying a first, baseline portion of the sensing window; and
 identifying a second, P-wave portion of the sensing window,
 wherein determining signal characteristics of the cardiac signal comprises determining signal characteristics of the cardiac signal within each of the first, baseline portion and the second, P-wave portion of the sensing window,
 further wherein determining whether the cardiac signal within the sensing window corresponds to a P-wave comprises determining whether the cardiac signal within the sensing window corresponds to a P-wave based on the determined signal characteristics of each

of the first, baseline portion and the second, P-wave
portion of the sensing window.

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摘要(译)

用于基于对与一个或多个R波相关联的一个或多个P波感测窗的分析来实施用于调节房性心律不齐检测的技术的技术和设备。植入式医疗设备可确定P波感测窗口内的心脏信号的信号特性，基于确定的信号特性确定感测窗口内的心脏信号是否对应于P波，确定心电图的信噪比。当在感测窗口中识别出P波并且确定的信噪比满足信噪比阈值时，在感测窗口内的心脏信号更新心律失常评分。

