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(54) **METHOD AND APPARATUS FOR
ADJUSTING A BLANKING PERIOD DURING
TRANSITIONING BETWEEN OPERATING
STATES IN A MEDICAL DEVICE**

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(57)

ABSTRACT

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Related U.S. Application Data

(63) Continuation of application No. 14/487,248, filed on
Sep. 16, 2014, now Pat. No. 10,252,067.

(60) Provisional application No. 61/983,499, filed on Apr.
24, 2014.

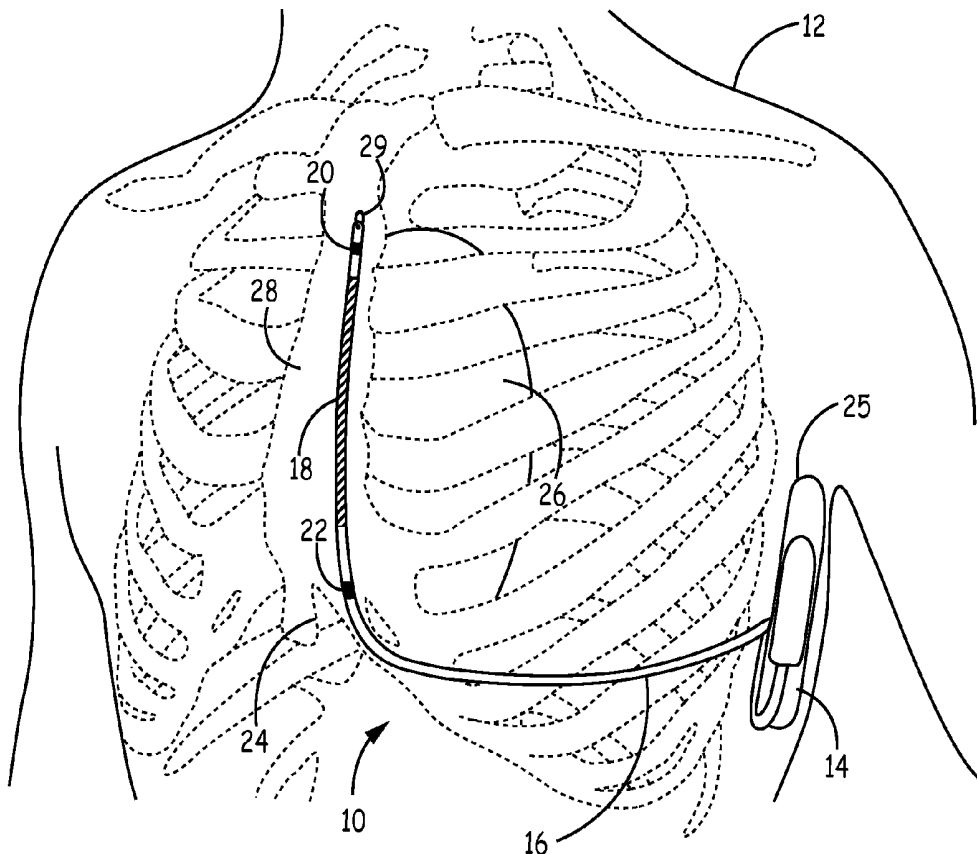
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A method and medical device for adjusting a blanking period that includes sensing cardiac signals from a plurality of electrodes, the plurality of electrodes forming a plurality of sensing vectors, determining whether to adjust a blanking period during a first operating state, advancing from the first operating state to a second operating state in response to the sensed cardiac signals, determining, while in the second operating state, whether the blanking period was adjusted while in the first operating state, and adjusting the blanking period while in the second operating state in response to the blanking period being adjusted while in the first operating state.



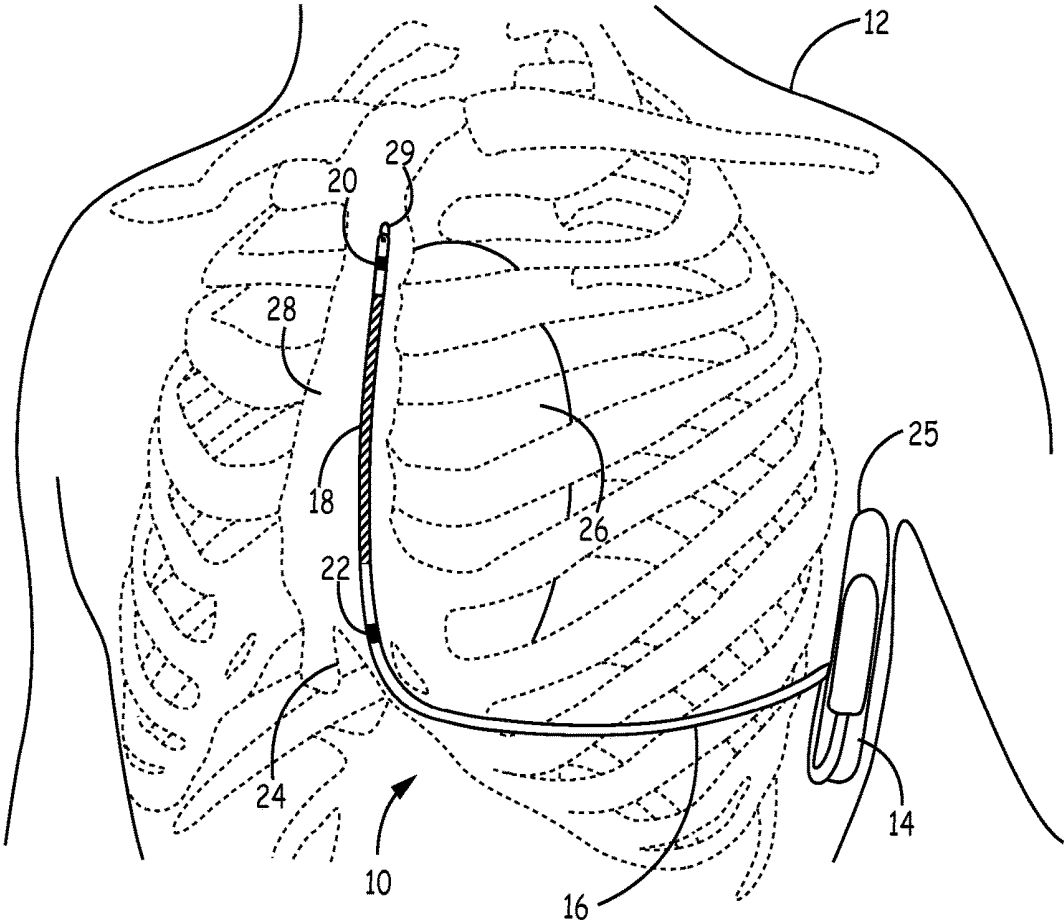


FIG. 1

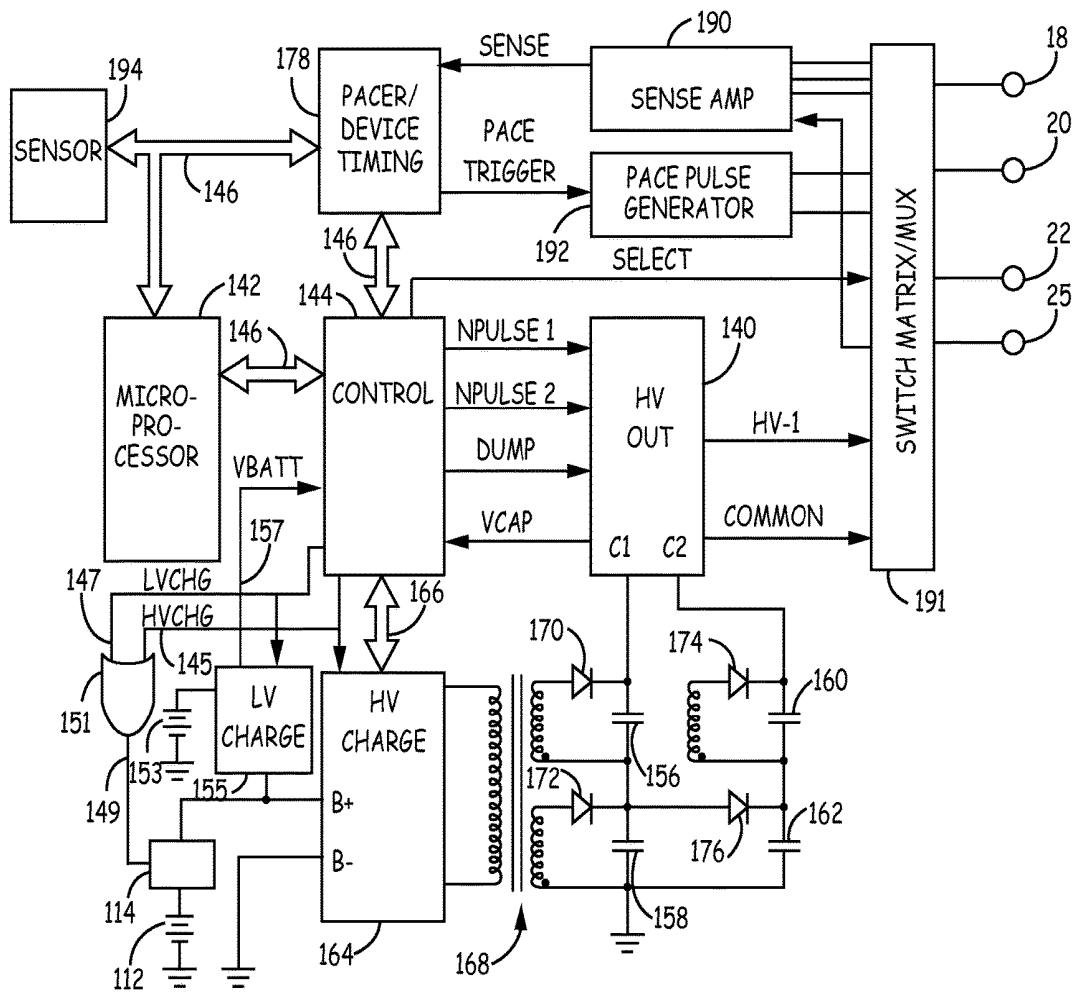
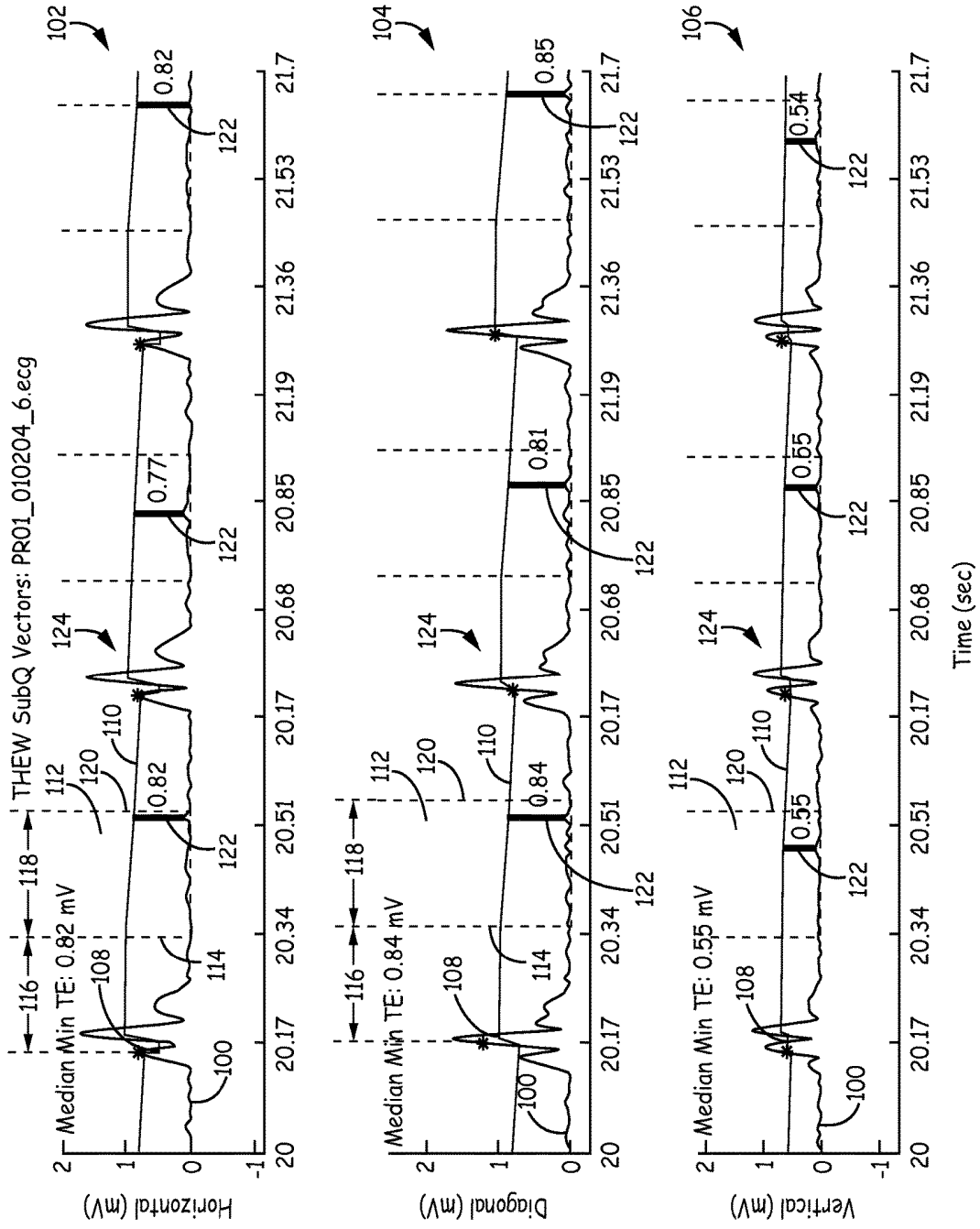


FIG. 2



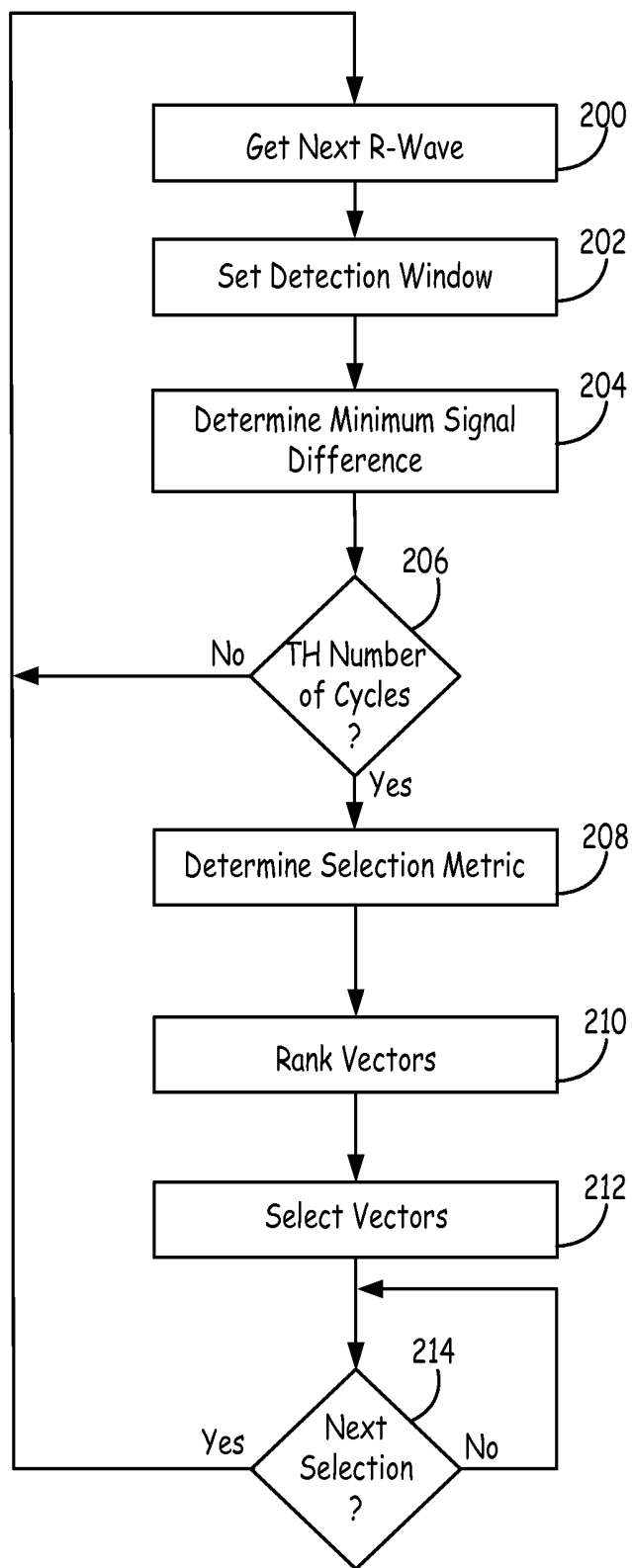


FIG. 4

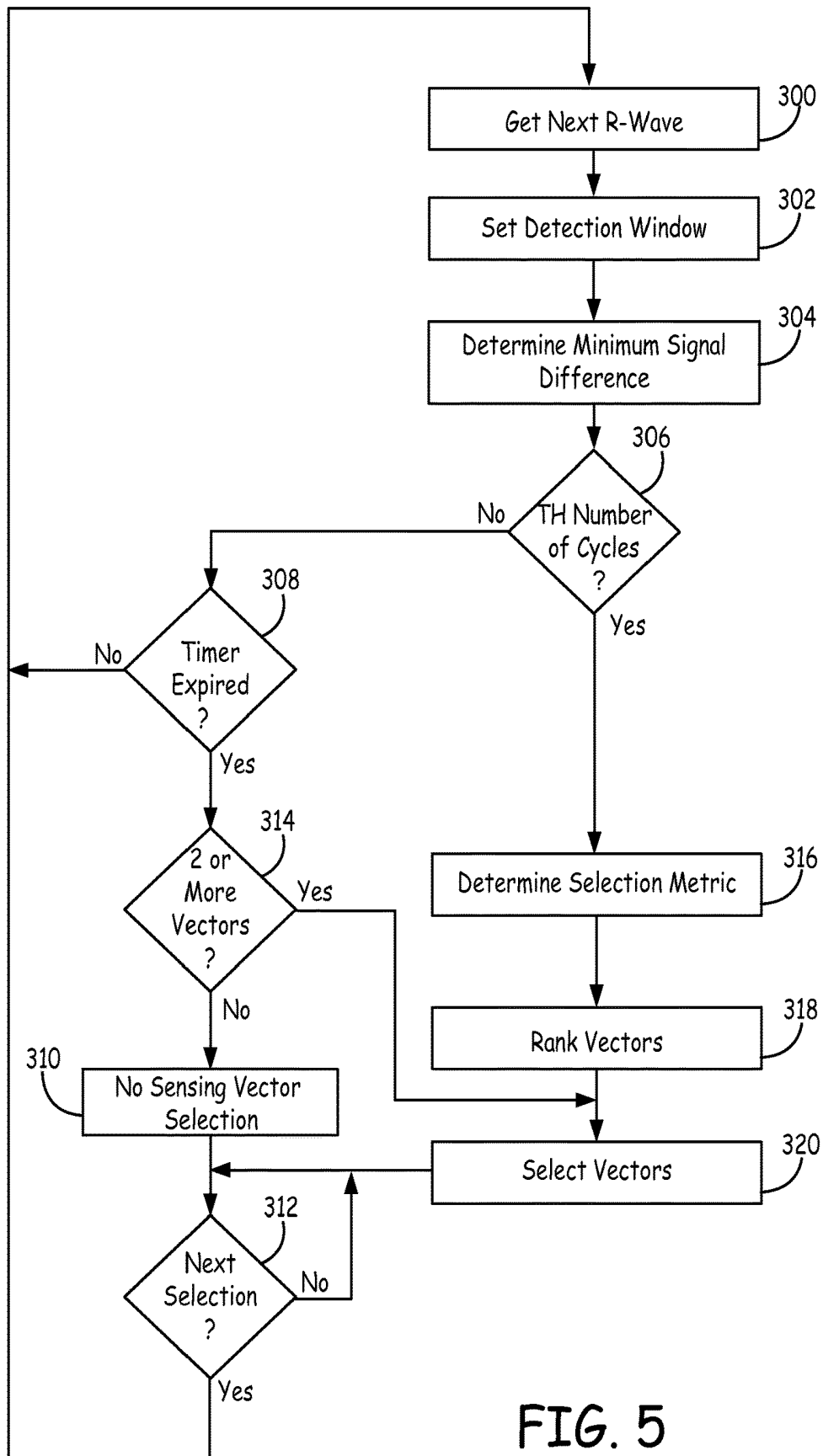


FIG. 5

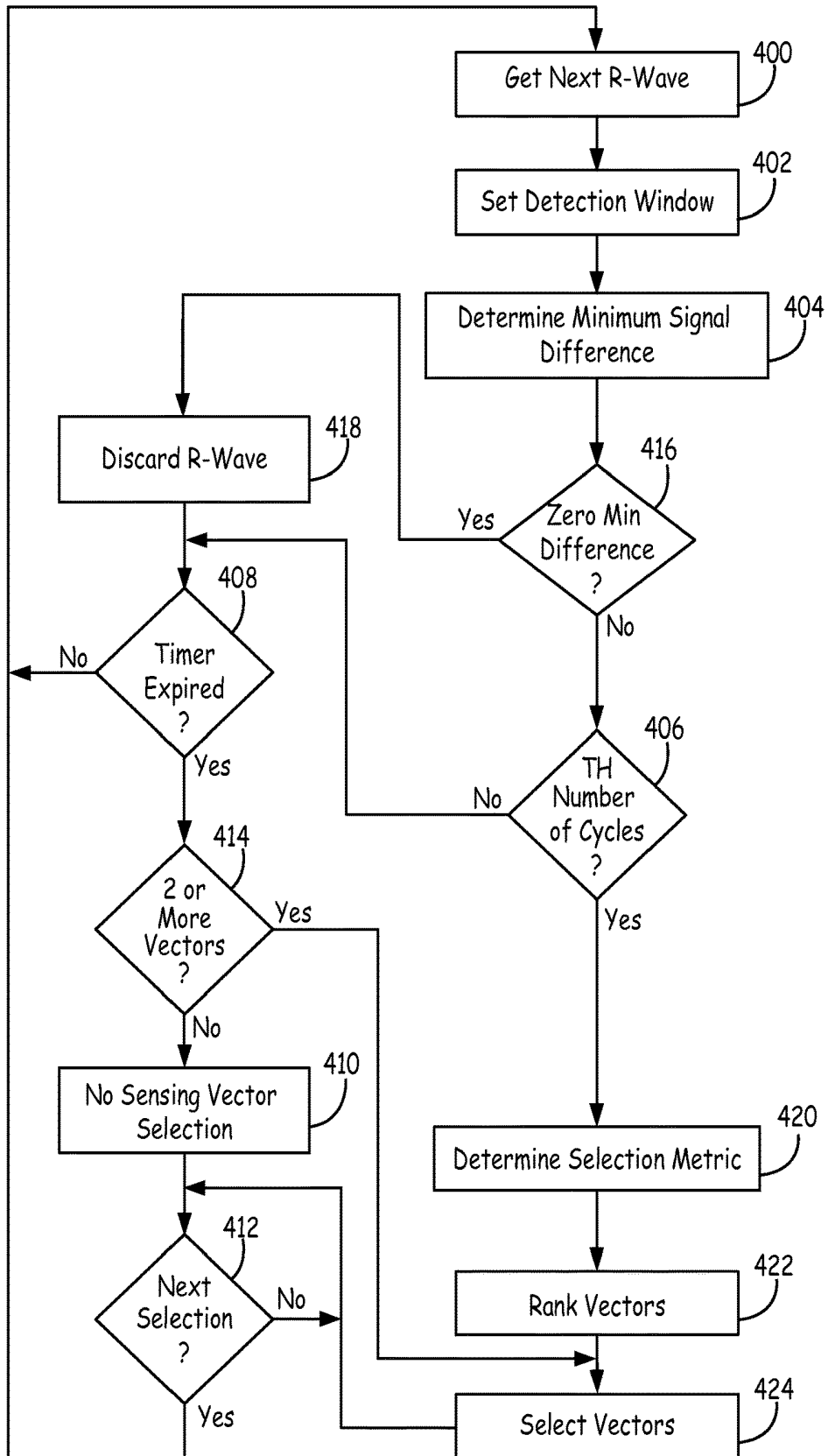


FIG. 6

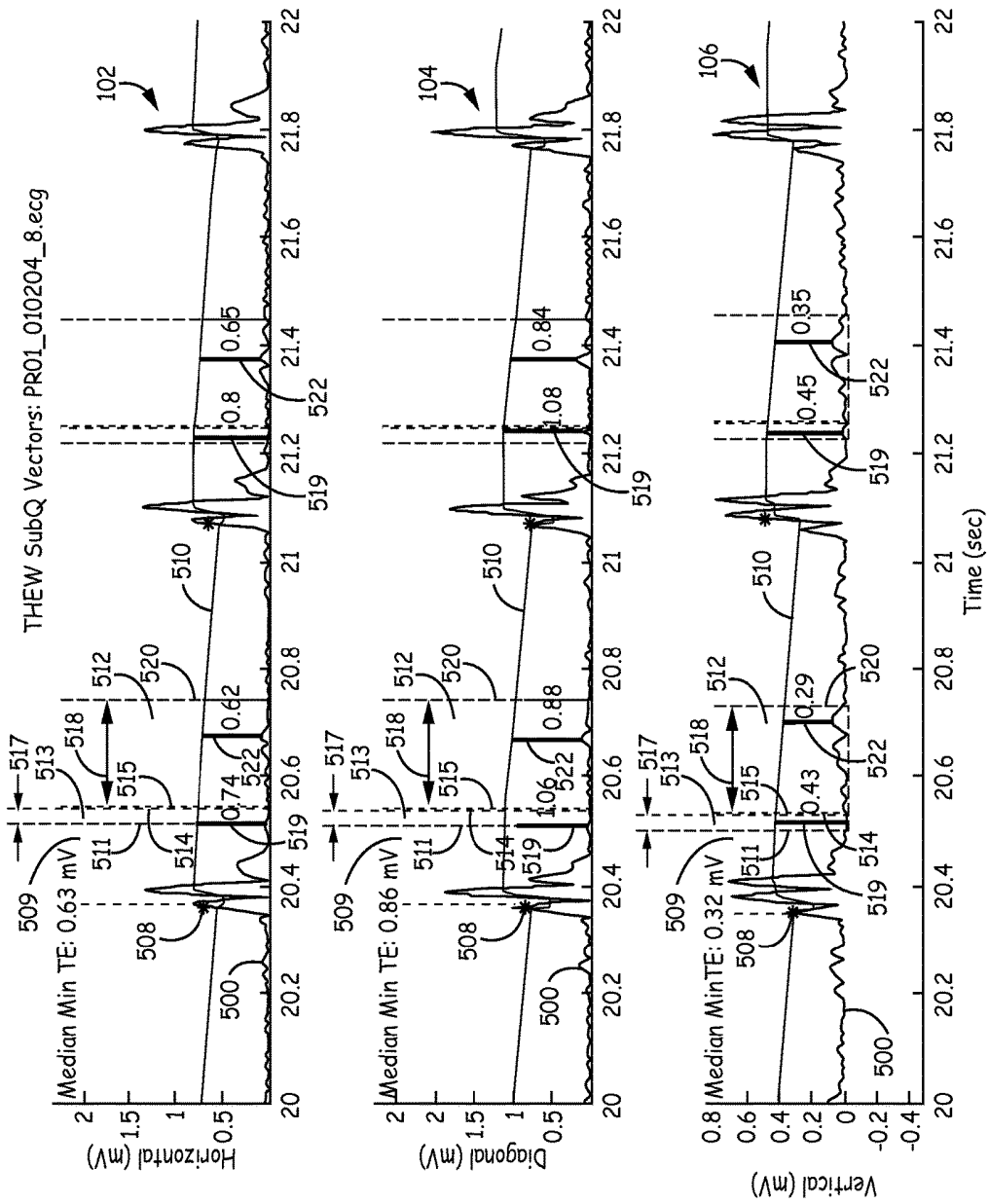


FIG. 7

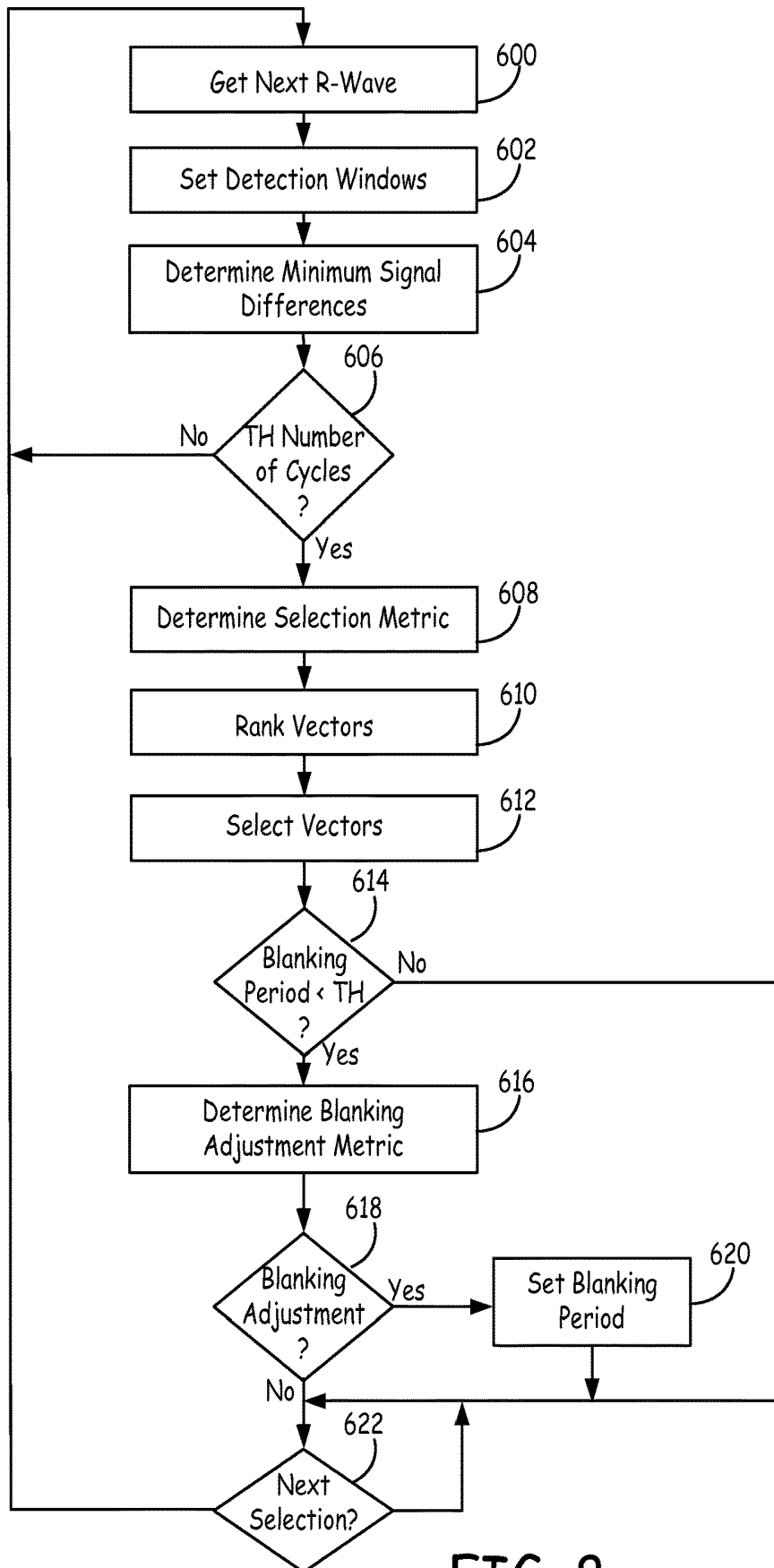


FIG. 8

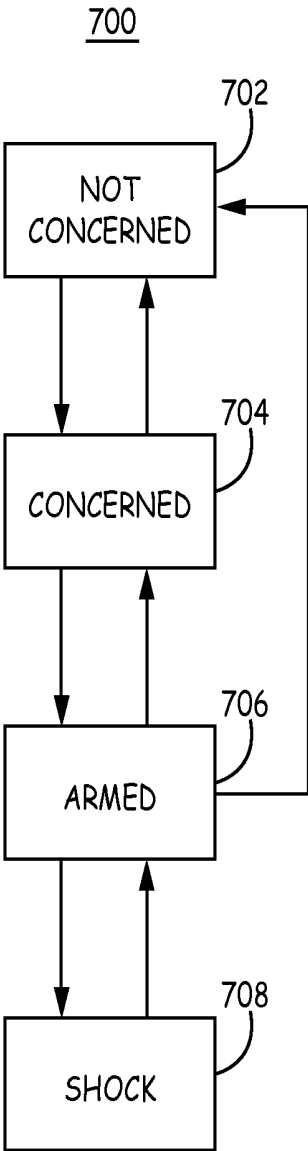


FIG. 9

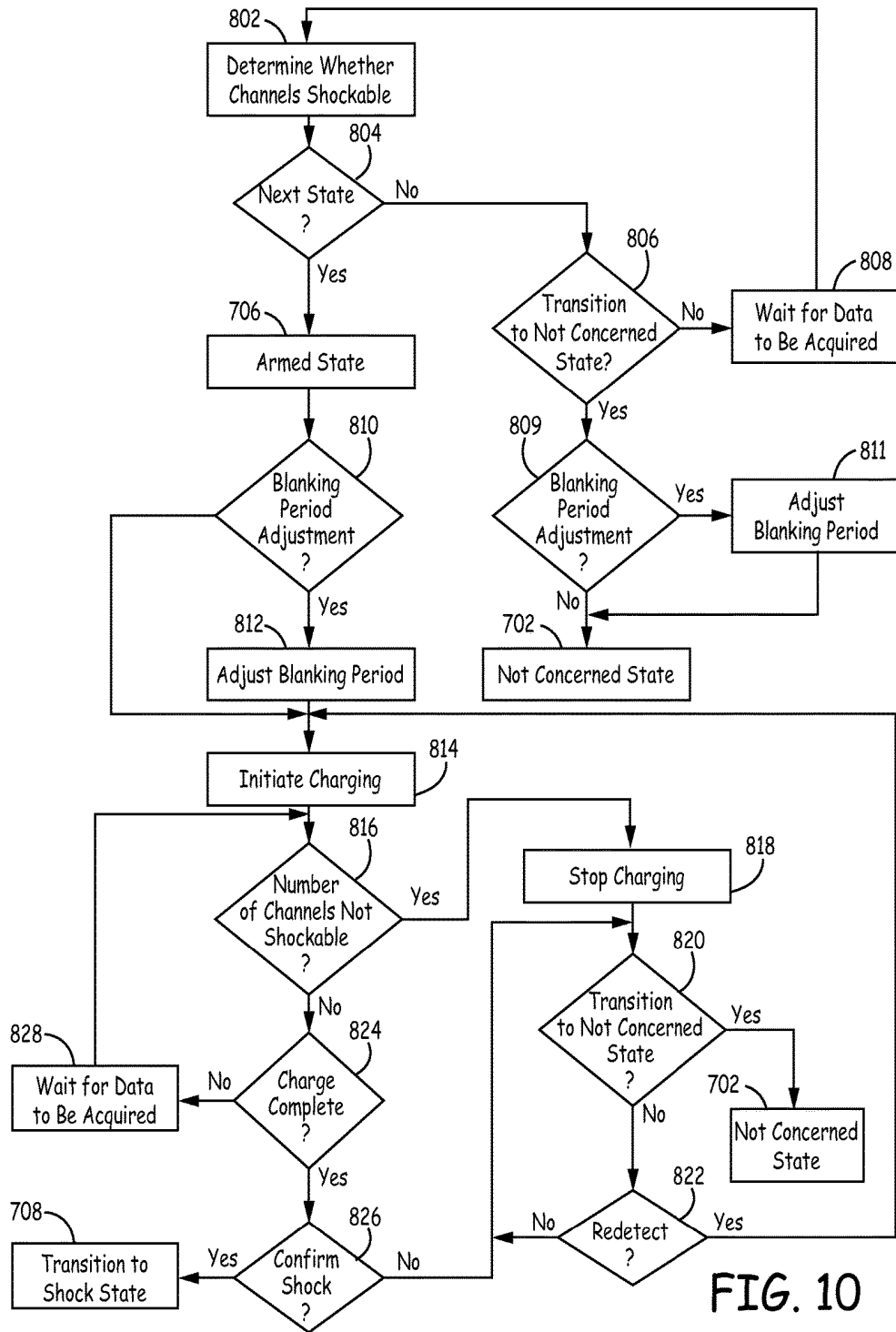


FIG. 10

**METHOD AND APPARATUS FOR
ADJUSTING A BLANKING PERIOD DURING
TRANSITIONING BETWEEN OPERATING
STATES IN A MEDICAL DEVICE**

RELATED APPLICATION

[0001] This application is a continuation of U.S. application Ser. No. 14/487,248, filed Sep. 16, 2014, entitled METHOD AND APPARATUS FOR ADJUSTING A BLANKING PERIOD DURING TRANSITIONING BETWEEN OPERATING STATES IN A MEDICAL DEVICE, which claims priority and other benefits from U.S. Provisional Patent Application Ser. No. 61/983,499, filed Apr. 24, 2014, entitled “METHOD AND APPARATUS FOR SELECTING A SENSING VECTOR CONFIGURATION IN A MEDICAL DEVICE”, both of which are incorporated herein by reference in their entirety.

TECHNICAL FIELD

[0002] The disclosure relates generally to implantable medical devices and, in particular, to an apparatus and method for selecting a sensing vector in a medical device.

BACKGROUND

[0003] Implantable medical devices are available for preventing or treating cardiac arrhythmias by delivering anti-tachycardia pacing therapies and electrical shock therapies for cardioverting or defibrillating the heart. Such a device, commonly known as an implantable cardioverter defibrillator or “ICD”, senses a patient’s heart rhythm and classifies the rhythm according to a number of rate zones in order to detect episodes of tachycardia or fibrillation.

[0004] Upon detecting an abnormal rhythm, the ICD delivers an appropriate therapy. Pathologic forms of ventricular tachycardia can often be terminated by anti-tachycardia pacing therapies. Anti-tachycardia pacing therapies are followed by high-energy shock therapy when necessary. Termination of a tachycardia by a shock therapy is commonly referred to as “cardioversion.” Ventricular fibrillation (VF) is a form of tachycardia that is a serious life-threatening condition and is normally treated by immediately delivering high-energy shock therapy. Termination of VF is commonly referred to as “defibrillation.” Accurate arrhythmia detection and discrimination are important in selecting the appropriate therapy for effectively treating an arrhythmia and avoiding the delivery of unnecessary cardioversion/defibrillation (CV/DF) shocks, which are painful to the patient.

[0005] In past practice, ICD systems have employed intra-cardiac electrodes carried by transvenous leads for sensing cardiac electrical signals and delivering electrical therapies. Emerging ICD systems are adapted for subcutaneous or submuscular implantation and employ electrodes incorporated on the ICD housing and/or carried by subcutaneous or submuscular leads. These systems, referred to generally herein as “subcutaneous ICD” or “SubQ ICD” systems, do not rely on electrodes implanted in direct contact with the heart. SubQ ICD systems are less invasive and are therefore implanted more easily and quickly than ICD systems that employ intra-cardiac electrodes. However, greater challenges exist in reliably detecting cardiac arrhythmias using a subcutaneous system. The R-wave amplitude on a SubQ ECG signal may be on the order of one-tenth to one-one-

hundredth of the amplitude of intra-ventricular sensed R-waves. Furthermore, the signal quality of subcutaneously sensed ECG signals are likely to be more affected by myopotential noise, environmental noise, patient posture and patient activity than intra-cardiac myocardial electrogram (EGM) signals.

[0006] The ability of a subcutaneous ICD to detect tachyarrhythmias and reject noise depends on its ECG signal characteristics. ECG vectors with higher amplitude R-wave waves, higher frequency (high slew rate) R-waves, higher R/T wave ratios, lower frequency signal (e.g., P and T waves) around R-waves, lower susceptibility to skeletal myopotentials, and greater R-wave consistency from cycle to cycle are preferred to ECG vectors without these attributes. A subcutaneous ICD with a minimum of 2 ECG leads or vectors (using a minimum of 3 electrodes) in a plane may use these physical vectors to generate virtual ECG vectors using a linear combination of the physical vector ECGs. However, choosing the optimal vector may sometimes be a challenge given the changing environment of a subcutaneous system. As such, systems and methods that promote reliable and accurate sensing detection of arrhythmias using optimal available sensing vectors to sense ECG signals via subcutaneous electrodes are needed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIG. 1 is a conceptual diagram of a patient implanted with an example extravascular cardiac defibrillation system.

[0008] FIG. 2 is an exemplary schematic diagram of electronic circuitry within a hermetically sealed housing of a subcutaneous device according to an embodiment of the present invention.

[0009] FIG. 3 is a graphical representation of cardiac signals sensed along multiple sensing vectors during selection of a sensing vector in a medical device according to one embodiment.

[0010] FIG. 4 is a flowchart of a method for selecting one or more sensing vectors according to an exemplary embodiment.

[0011] FIG. 5 is a flowchart of a method for selecting one or more sensing vectors according to another exemplary embodiment.

[0012] FIG. 6 is a flowchart of a method for selecting one or more sensing vectors according to another exemplary embodiment.

[0013] FIG. 7 is a graphical representation of cardiac signals sensed along multiple sensing vectors during selection of a sensing vector in a medical device according to another embodiment.

[0014] FIG. 8 is a flowchart of a method for selecting one or more sensing vectors according to another exemplary embodiment.

[0015] FIG. 9 is a state diagram of detection of arrhythmias in a medical device according to an embodiment of the present invention.

[0016] FIG. 10 is a flowchart of a method for adjusting a blanking period during transitioning between operating states, according to an embodiment of the present disclosure.

DETAILED DESCRIPTION

[0017] FIG. 1 is a conceptual diagram of a patient 12 implanted with an example extravascular cardiac defibrilla-

tion system 10. In the example illustrated in FIG. 1, extravascular cardiac defibrillation system 10 is an implanted subcutaneous ICD system. However, the techniques of this disclosure may also be utilized with other extravascular implanted cardiac defibrillation systems, such as a cardiac defibrillation system having a lead implanted at least partially in a substernal or submuscular location. Additionally, the techniques of this disclosure may also be utilized with other implantable systems, such as implantable pacing systems, implantable neurostimulation systems, drug delivery systems or other systems in which leads, catheters or other components are implanted at extravascular locations within patient 12. This disclosure, however, is described in the context of an implantable extravascular cardiac defibrillation system for purposes of illustration.

[0018] Extravascular cardiac defibrillation system 10 includes an implantable cardioverter defibrillator (ICD) 14 connected to at least one implantable cardiac defibrillation lead 16. ICD 14 of FIG. 1 is implanted subcutaneously on the left side of patient 12. Defibrillation lead 16, which is connected to ICD 14, extends medially from ICD 14 toward sternum 28 and xiphoid process 24 of patient 12. At a location near xiphoid process 24, defibrillation lead 16 bends or turns and extends subcutaneously superior, substantially parallel to sternum 28. In the example illustrated in FIG. 1, defibrillation lead 16 is implanted such that lead 16 is offset laterally to the left side of the body of sternum 28 (i.e., towards the left side of patient 12).

[0019] Defibrillation lead 16 is placed along sternum 28 such that a therapy vector between defibrillation electrode 18 and a second electrode (such as a housing or can 25 of ICD 14 or an electrode placed on a second lead) is substantially across the ventricle of heart 26. The therapy vector may, in one example, be viewed as a line that extends from a point on the defibrillation electrode 18 to a point on the housing or can 25 of ICD 14. In another example, defibrillation lead 16 may be placed along sternum 28 such that a therapy vector between defibrillation electrode 18 and the housing or can 25 of ICD 14 (or other electrode) is substantially across an atrium of heart 26. In this case, extravascular ICD system 10 may be used to provide atrial therapies, such as therapies to treat atrial fibrillation.

[0020] The embodiment illustrated in FIG. 1 is an example configuration of an extravascular ICD system 10 and should not be considered limiting of the techniques described herein. For example, although illustrated as being offset laterally from the midline of sternum 28 in the example of FIG. 1, defibrillation lead 16 may be implanted such that lead 16 is offset to the right of sternum 28 or more centrally located over sternum 28. Additionally, defibrillation lead 16 may be implanted such that it is not substantially parallel to sternum 28, but instead offset from sternum 28 at an angle (e.g., angled lateral from sternum 28 at either the proximal or distal end). As another example, the distal end of defibrillation lead 16 may be positioned near the second or third rib of patient 12. However, the distal end of defibrillation lead 16 may be positioned further superior or inferior depending on the location of ICD 14, location of electrodes 18, 20, and 22, or other factors.

[0021] Although ICD 14 is illustrated as being implanted near a midaxillary line of patient 12, ICD 14 may also be implanted at other subcutaneous locations on patient 12, such as further posterior on the torso toward the posterior axillary line, further anterior on the torso toward the anterior

axillary line, in a pectoral region, or at other locations of patient 12. In instances in which ICD 14 is implanted pectorally, lead 16 would follow a different path, e.g., across the upper chest area and inferior along sternum 28. When the ICD 14 is implanted in the pectoral region, the extravascular ICD system may include a second lead including a defibrillation electrode that extends along the left side of the patient such that the defibrillation electrode of the second lead is located along the left side of the patient to function as an anode or cathode of the therapy vector of such an ICD system.

[0022] ICD 14 includes a housing or can 25 that forms a hermetic seal that protects components within ICD 14. The housing 25 of ICD 14 may be formed of a conductive material, such as titanium or other biocompatible conductive material or a combination of conductive and non-conductive materials. In some instances, the housing 25 of ICD 14 functions as an electrode (referred to as a housing electrode or can electrode) that is used in combination with one of electrodes 18, 20, or 22 to deliver a therapy to heart 26 or to sense electrical activity of heart 26. ICD 14 may also include a connector assembly (sometimes referred to as a connector block or header) that includes electrical feedthroughs through which electrical connections are made between conductors within defibrillation lead 16 and electronic components included within the housing. Housing may enclose one or more components, including processors, memories, transmitters, receivers, sensors, sensing circuitry, therapy circuitry and other appropriate components (often referred to herein as modules).

[0023] Defibrillation lead 16 includes a lead body having a proximal end that includes a connector configured to connect to ICD 14 and a distal end that includes one or more electrodes 18, 20, and 22. The lead body of defibrillation lead 16 may be formed from a non-conductive material, including silicone, polyurethane, fluoropolymers, mixtures thereof, and other appropriate materials, and shaped to form one or more lumens within which the one or more conductors extend. However, the techniques are not limited to such constructions. Although defibrillation lead 16 is illustrated as including three electrodes 18, 20 and 22, defibrillation lead 16 may include more or fewer electrodes.

[0024] Defibrillation lead 16 includes one or more elongated electrical conductors (not illustrated) that extend within the lead body from the connector on the proximal end of defibrillation lead 16 to electrodes 18, 20 and 22. In other words, each of the one or more elongated electrical conductors contained within the lead body of defibrillation lead 16 may engage with respective ones of electrodes 18, 20 and 22. When the connector at the proximal end of defibrillation lead 16 is connected to ICD 14, the respective conductors may electrically couple to circuitry, such as a therapy module or a sensing module, of ICD 14 via connections in connector assembly, including associated feedthroughs. The electrical conductors transmit therapy from a therapy module within ICD 14 to one or more of electrodes 18, 20 and 22 and transmit sensed electrical signals from one or more of electrodes 18, 20 and 22 to the sensing module within ICD 14.

[0025] ICD 14 may sense electrical activity of heart 26 via one or more sensing vectors that include combinations of electrodes 20 and 22 and the housing or can 25 of ICD 14. For example, ICD 14 may obtain electrical signals sensed using a sensing vector between electrodes 20 and 22, obtain

electrical signals sensed using a sensing vector between electrode 20 and the conductive housing or can 25 of ICD 14, obtain electrical signals sensed using a sensing vector between electrode 22 and the conductive housing or can 25 of ICD 14, or a combination thereof. In some instances, ICD 14 may sense cardiac electrical signals using a sensing vector that includes defibrillation electrode 18, such as a sensing vector between defibrillation electrode 18 and one of electrodes 20 or 22, or a sensing vector between defibrillation electrode 18 and the housing or can 25 of ICD 14.

[0026] ICD may analyze the sensed electrical signals to detect tachycardia, such as ventricular tachycardia or ventricular fibrillation, and in response to detecting tachycardia may generate and deliver an electrical therapy to heart 26. For example, ICD 14 may deliver one or more defibrillation shocks via a therapy vector that includes defibrillation electrode 18 of defibrillation lead 16 and the housing or can 25. Defibrillation electrode 18 may, for example, be an elongated coil electrode or other type of electrode. In some instances, ICD 14 may deliver one or more pacing therapies prior to or after delivery of the defibrillation shock, such as anti-tachycardia pacing (ATP) or post shock pacing. In these instances, ICD 14 may generate and deliver pacing pulses via therapy vectors that include one or both of electrodes 20 and 22 and/or the housing or can 25. Electrodes 20 and 22 may comprise ring electrodes, hemispherical electrodes, coil electrodes, helix electrodes, segmented electrodes, directional electrodes, or other types of electrodes, or combination thereof. Electrodes 20 and 22 may be the same type of electrodes or different types of electrodes, although in the example of FIG. 1 both electrodes 20 and 22 are illustrated as ring electrodes.

[0027] Defibrillation lead 16 may also include an attachment feature 29 at or toward the distal end of lead 16. The attachment feature 29 may be a loop, link, or other attachment feature. For example, attachment feature 29 may be a loop formed by a suture. As another example, attachment feature 29 may be a loop, link, ring of metal, coated metal or a polymer. The attachment feature 29 may be formed into any of a number of shapes with uniform or varying thickness and varying dimensions. Attachment feature 29 may be integral to the lead or may be added by the user prior to implantation. Attachment feature 29 may be useful to aid in implantation of lead 16 and/or for securing lead 16 to a desired implant location. In some instances, defibrillation lead 16 may include a fixation mechanism in addition to or instead of the attachment feature. Although defibrillation lead 16 is illustrated with an attachment feature 29, in other examples lead 16 may not include an attachment feature 29.

[0028] Lead 16 may also include a connector at the proximal end of lead 16, such as a DF4 connector, bifurcated connector (e.g., DF-1/IS-1 connector), or other type of connector. The connector at the proximal end of lead 16 may include a terminal pin that couples to a port within the connector assembly of ICD 14. In some instances, lead 16 may include an attachment feature at the proximal end of lead 16 that may be coupled to an implant tool to aid in implantation of lead 16. The attachment feature at the proximal end of the lead may separate from the connector and may be either integral to the lead or added by the user prior to implantation.

[0029] Defibrillation lead 16 may also include a suture sleeve or other fixation mechanism (not shown) located proximal to electrode 22 that is configured to fixate lead 16

near the xiphoid process or lower sternum location. The fixation mechanism (e.g., suture sleeve or other mechanism) may be integral to the lead or may be added by the user prior to implantation.

[0030] The example illustrated in FIG. 1 is exemplary in nature and should not be considered limiting of the techniques described in this disclosure. For instance, extravascular cardiac defibrillation system 10 may include more than one lead. In one example, extravascular cardiac defibrillation system 10 may include a pacing lead in addition to defibrillation lead 16.

[0031] In the example illustrated in FIG. 1, defibrillation lead 16 is implanted subcutaneously, e.g., between the skin and the ribs or sternum. In other instances, defibrillation lead 16 (and/or the optional pacing lead) may be implanted at other extravascular locations. In one example, defibrillation lead 16 may be implanted at least partially in a substernal location. In such a configuration, at least a portion of defibrillation lead 16 may be placed under or below the sternum in the mediastinum and, more particularly, in the anterior mediastinum. The anterior mediastinum is bounded laterally by pleurae, posteriorly by pericardium, and anteriorly by sternum 28. Defibrillation lead 16 may be at least partially implanted in other extra-pericardial locations, i.e., locations in the region around, but not in direct contact with, the outer surface of heart 26. These other extra-pericardial locations may include in the mediastinum but offset from sternum 28, in the superior mediastinum, in the middle mediastinum, in the posterior mediastinum, in the sub-xiphoid or inferior xiphoid area, near the apex of the heart, or other location not in direct contact with heart 26 and not subcutaneous. In still further instances, the lead may be implanted at a pericardial or epicardial location outside of the heart 26.

[0032] FIG. 2 is an exemplary schematic diagram of electronic circuitry within a hermetically sealed housing of a subcutaneous device according to an embodiment of the present invention. As illustrated in FIG. 2, subcutaneous device 14 includes a low voltage battery 153 coupled to a power supply (not shown) that supplies power to the circuitry of the subcutaneous device 14 and the pacing output capacitors to supply pacing energy in a manner well known in the art. The low voltage battery 153 may be formed of one or two conventional LiCF_x , LiMnO_2 or LiI_2 cells, for example. The subcutaneous device 14 also includes a high voltage battery 112 that may be formed of one or two conventional LiSVO or LiMnO_2 cells. Although two both low voltage battery and a high voltage battery are shown in FIG. 2, according to an embodiment of the present invention, the device 14 could utilize a single battery for both high and low voltage uses.

[0033] Further referring to FIG. 2, subcutaneous device 14 functions are controlled by means of software, firmware and hardware that cooperatively monitor the ECG signal, determine when a cardioversion-defibrillation shock or pacing is necessary, and deliver prescribed cardioversion-defibrillation and pacing therapies. The subcutaneous device 14 may incorporate circuitry set forth in commonly assigned U.S. Pat. No. 5,163,427 "Apparatus for Delivering Single and Multiple Cardioversion and Defibrillation Pulses" to Keimel and U.S. Pat. No. 5,188,105 "Apparatus and Method for Treating a Tachyarrhythmia" to Keimel for selectively delivering single phase, simultaneous biphasic and sequential biphasic cardioversion-defibrillation shocks typically

employing ICD IPG housing electrodes **28** coupled to the COMMON output **123** of high voltage output circuit **140** and cardioversion-defibrillation electrode **24** disposed posteriorly and subcutaneously and coupled to the HVI output **113** of the high voltage output circuit **140**.

[0034] The cardioversion-defibrillation shock energy and capacitor charge voltages can be intermediate to those supplied by ICDs having at least one cardioversion-defibrillation electrode in contact with the heart and most AEDs having cardioversion-defibrillation electrodes in contact with the skin. The typical maximum voltage necessary for ICDs using most biphasic waveforms is approximately 750 Volts with an associated maximum energy of approximately 40 Joules. The typical maximum voltage necessary for AEDs is approximately 2000-5000 Volts with an associated maximum energy of approximately 200-360 Joules depending upon the model and waveform used. The subcutaneous device **14** of the present invention uses maximum voltages in the range of about 300 to approximately 1500 Volts and is associated with energies of approximately 25 to 150 joules or more. The total high voltage capacitance could range from about 50 to about 300 microfarads. Such cardioversion-defibrillation shocks are only delivered when a malignant tachyarrhythmia, e.g., ventricular fibrillation is detected through processing of the far field cardiac ECG employing the detection algorithms as described herein below.

[0035] In FIG. 2, sense amp **190** in conjunction with pacer/device timing circuit **178** processes the far field ECG sense signal that is developed across a particular ECG sense vector defined by a selected pair of the subcutaneous electrodes **18**, **20**, **22** and the can or housing **25** of the device **14**, or, optionally, a virtual signal (i.e., a mathematical combination of two vectors) if selected. For example, the device may generate a virtual vector signal as described in U.S. Pat. No. 6,505,067 "System and Method for Deriving Virtual ECG or EGM Signal" to Lee, et al; incorporated herein by reference in its entirety. In addition, vector selection may be selected by the patient's physician and programmed via a telemetry link from a programmer.

[0036] The selection of the sensing electrode pair is made through the switch matrix/MUX **191** in a manner to provide the most reliable sensing of the ECG signal of interest, which would be the R wave for patients who are believed to be at risk of ventricular fibrillation leading to sudden death. The far field ECG signals are passed through the switch matrix/MUX **191** to the input of the sense amplifier **190** that, in conjunction with pacer/device timing circuit **178**, evaluates the sensed ECG. Bradycardia, or asystole, is typically determined by an escape interval timer within the pacer timing circuit **178** and/or the control circuit **144**. Pace Trigger signals are applied to the pacing pulse generator **192** generating pacing stimulation when the interval between successive R-waves exceeds the escape interval. Bradycardia pacing is often temporarily provided to maintain cardiac output after delivery of a cardioversion-defibrillation shock that may cause the heart to slowly beat as it recovers back to normal function. Sensing subcutaneous far field signals in the presence of noise may be aided by the use of appropriate denial and extensible accommodation periods as described in U.S. Pat. No. 6,236,882 "Noise Rejection for Monitoring ECGs" to Lee, et al and incorporated herein by reference in its entirety.

[0037] Detection of a malignant tachyarrhythmia is determined in the Control circuit **144** as a function of the intervals

between R-wave sense event signals that are output from the pacer/device timing **178** and sense amplifier circuit **190** to the timing and control circuit **144**. It should be noted that the present invention utilizes not only interval based signal analysis method but also supplemental sensors and morphology processing method and apparatus as described herein below.

[0038] Supplemental sensors such as tissue color, tissue oxygenation, respiration, patient activity and the like may be used to contribute to the decision to apply or withhold a defibrillation therapy as described generally in U.S. Pat. No. 5,464,434 "Medical Interventional Device Responsive to Sudden Hemodynamic Change" to Alt and incorporated herein by reference in its entirety. Sensor processing block **194** provides sensor data to microprocessor **142** via data bus **146**. Specifically, patient activity and/or posture may be determined by the apparatus and method as described in U.S. Pat. No. 5,593,431 "Medical Service Employing Multiple DC Accelerometers for Patient Activity and Posture Sensing and Method" to Sheldon and incorporated herein by reference in its entirety. Patient respiration may be determined by the apparatus and method as described in U.S. Pat. No. 4,567,892 "Implantable Cardiac Pacemaker" to Plicchi, et al and incorporated herein by reference in its entirety. Patient tissue oxygenation or tissue color may be determined by the sensor apparatus and method as described in U.S. Pat. No. 5,176,137 to Erickson, et al and incorporated herein by reference in its entirety. The oxygen sensor of the '137 patent may be located in the subcutaneous device pocket or, alternatively, located on the lead **18** to enable the sensing of contacting or near-contacting tissue oxygenation or color.

[0039] Certain steps in the performance of the detection algorithm criteria are cooperatively performed in microcomputer **142**, including microprocessor, RAM and ROM, associated circuitry, and stored detection criteria that may be programmed into RAM via a telemetry interface (not shown) conventional in the art. Data and commands are exchanged between microcomputer **142** and timing and control circuit **144**, pacer timing/amplifier circuit **178**, and high voltage output circuit **140** via a bi-directional data/control bus **146**. The pacer timing/amplifier circuit **178** and the control circuit **144** are clocked at a slow clock rate. The microcomputer **142** is normally asleep, but is awakened and operated by a fast clock by interrupts developed by each R-wave sense event, on receipt of a downlink telemetry programming instruction or upon delivery of cardiac pacing pulses to perform any necessary mathematical calculations, to perform tachycardia and fibrillation detection procedures, and to update the time intervals monitored and controlled by the timers in pacer/device timing circuitry **178**.

[0040] When a malignant tachycardia is detected, high voltage capacitors **156**, **158**, **160**, and **162** are charged to a pre-programmed voltage level by a high-voltage charging circuit **164**. It is generally considered inefficient to maintain a constant charge on the high voltage output capacitors **156**, **158**, **160**, **162**. Instead, charging is initiated when control circuit **144** issues a high voltage charge command HVCHG delivered on line **145** to high voltage charge circuit **164** and charging is controlled by means of bi-directional control/data bus **166** and a feedback signal VCAP from the HV output circuit **140**. High voltage output capacitors **156**, **158**, **160** and **162** may be of film, aluminum electrolytic or wet tantalum construction.

[0041] The negative terminal of high voltage battery 112 is directly coupled to system ground. Switch circuit 114 is normally open so that the positive terminal of high voltage battery 112 is disconnected from the positive power input of the high voltage charge circuit 164. The high voltage charge command HVCHG is also conducted via conductor 149 to the control input of switch circuit 114, and switch circuit 114 closes in response to connect positive high voltage battery voltage EXT B+ to the positive power input of high voltage charge circuit 164. Switch circuit 114 may be, for example, a field effect transistor (FET) with its source-to-drain path interrupting the EXT B+ conductor 118 and its gate receiving the HVCHG signal on conductor 145. High voltage charge circuit 164 is thereby rendered ready to begin charging the high voltage output capacitors 156, 158, 160, and 162 with charging current from high voltage battery 112.

[0042] High voltage output capacitors 156, 158, 160, and 162 may be charged to very high voltages, e.g., 300-1500V, to be discharged through the body and heart between the electrode pair of subcutaneous cardioversion-defibrillation electrodes 113 and 123. The details of the voltage charging circuitry are also not deemed to be critical with regard to practicing the present invention; one high voltage charging circuit believed to be suitable for the purposes of the present invention is disclosed. High voltage capacitors 156, 158, 160 and 162 may be charged, for example, by high voltage charge circuit 164 and a high frequency, high-voltage transformer 168 as described in detail in commonly assigned U.S. Pat. No. 4,548,209 "Energy Converter for Implantable Cardioverter" to Wielders, et al. Proper charging polarities are maintained by diodes 170, 172, 174 and 176 interconnecting the output windings of high-voltage transformer 168 and the capacitors 156, 158, 160, and 162. As noted above, the state of capacitor charge is monitored by circuitry within the high voltage output circuit 140 that provides a VCAP, feedback signal indicative of the voltage to the timing and control circuit 144. Timing and control circuit 144 terminates the high voltage charge command HVCHG when the VCAP signal matches the programmed capacitor output voltage, i.e., the cardioversion-defibrillation peak shock voltage.

[0043] Control circuit 144 then develops first and second control signals NPULSE 1 and NPULSE 2, respectively, that are applied to the high voltage output circuit 140 for triggering the delivery of cardioverting or defibrillating shocks. In particular, the NPULSE 1 signal triggers discharge of the first capacitor bank, comprising capacitors 156 and 158. The NPULSE 2 signal triggers discharge of the first capacitor bank and a second capacitor bank, comprising capacitors 160 and 162. It is possible to select between a plurality of output pulse regimes simply by modifying the number and time order of assertion of the NPULSE 1 and NPULSE 2 signals. The NPULSE 1 signals and NPULSE 2 signals may be provided sequentially, simultaneously or individually. In this way, control circuitry 144 serves to control operation of the high voltage output stage 140, which delivers high energy cardioversion-defibrillation shocks between the pair of the cardioversion-defibrillation electrodes 18 and 25 coupled to the HV-1 and COMMON output as shown in FIG. 2.

[0044] Thus, subcutaneous device 14 monitors the patient's cardiac status and initiates the delivery of a cardioversion-defibrillation shock through the cardioversion-defibrillation electrodes 18 and 25 in response to detection of a tachyarrhythmia requiring cardioversion-defibrillation.

The high HVCHG signal causes the high voltage battery 112 to be connected through the switch circuit 114 with the high voltage charge circuit 164 and the charging of output capacitors 156, 158, 160, and 162 to commence. Charging continues until the programmed charge voltage is reflected by the VCAP signal, at which point control and timing circuit 144 sets the HVCHG signal low terminating charging and opening switch circuit 114. The subcutaneous device 14 can be programmed to attempt to deliver cardioversion shocks to the heart in the manners described above in timed synchrony with a detected R-wave or can be programmed or fabricated to deliver defibrillation shocks to the heart in the manners described above without attempting to synchronize the delivery to a detected R-wave. Episode data related to the detection of the tachyarrhythmia and delivery of the cardioversion-defibrillation shock can be stored in RAM for uplink telemetry transmission to an external programmer as is well known in the art to facilitate in diagnosis of the patient's cardiac state. A patient receiving the device 14 on a prophylactic basis would be instructed to report each such episode to the attending physician for further evaluation of the patient's condition and assessment for the need for implantation of a more sophisticated ICD.

[0045] Subcutaneous device 14 desirably includes telemetry circuit (not shown in FIG. 2), so that it is capable of being programmed by means of external programmer 20 via a 2-way telemetry link (not shown). Uplink telemetry allows device status and diagnostic/event data to be sent to external programmer 20 for review by the patient's physician. Downlink telemetry allows the external programmer via physician control to allow the programming of device function and the optimization of the detection and therapy for a specific patient. Programmers and telemetry systems suitable for use in the practice of the present invention have been well known for many years. Known programmers typically communicate with an implanted device via a bi-directional radio-frequency telemetry link, so that the programmer can transmit control commands and operational parameter values to be received by the implanted device, so that the implanted device can communicate diagnostic and operational data to the programmer. Programmers believed to be suitable for the purposes of practicing the present invention include the Models 9790 and CareLink® programmers, commercially available from Medtronic, Inc., Minneapolis, Minn.

[0046] Various telemetry systems for providing the necessary communications channels between an external programming unit and an implanted device have been developed and are well known in the art. Telemetry systems believed to be suitable for the purposes of practicing the present invention are disclosed, for example, in the following U.S. Pat. No. 5,127,404 to Wyborny et al. entitled "Telemetry Format for Implanted Medical Device"; U.S. Pat. No. 4,374,382 to Markowitz entitled "Marker Channel Telemetry System for a Medical Device"; and U.S. Pat. No. 4,556,063 to Thompson et al. entitled "Telemetry System for a Medical Device". The Wyborny et al. '404, Markowitz '382, and Thompson et al. '063 patents are commonly assigned to the assignee of the present invention, and are each hereby incorporated by reference herein in their respective entireties.

[0047] According to an embodiment of the present invention, in order to automatically select the preferred ECG vector set, it is necessary to have an index of merit upon

which to rate the quality of the signal. "Quality" is defined as the signal's ability to provide accurate heart rate estimation and accurate morphological waveform separation between the patient's usual sinus rhythm and the patient's ventricular tachyarrhythmia.

[0048] Appropriate indices may include R-wave amplitude, R-wave peak amplitude to waveform amplitude between R-waves (i.e., signal to noise ratio), low slope content, relative high versus low frequency power, mean frequency estimation, probability density function, or some combination of these metrics.

[0049] Automatic vector selection might be done at implantation or periodically (daily, weekly, monthly) or both. At implant, automatic vector selection may be initiated as part of an automatic device turn-on procedure that performs such activities as measure lead impedances and battery voltages. The device turn-on procedure may be initiated by the implanting physician (e.g., by pressing a programmer button) or, alternatively, may be initiated automatically upon automatic detection of device/lead implantation. The turn-on procedure may also use the automatic vector selection criteria to determine if ECG vector quality is adequate for the current patient and for the device and lead position, prior to suturing the subcutaneous device 14 device in place and closing the incision. Such an ECG quality indicator would allow the implanting physician to maneuver the device to a new location or orientation to improve the quality of the ECG signals as required. The preferred ECG vector or vectors may also be selected at implant as part of the device turn-on procedure. The preferred vectors might be those vectors with the indices that maximize rate estimation and detection accuracy. There may also be an a priori set of vectors that are preferred by the physician, and as long as those vectors exceed some minimum threshold, or are only slightly worse than some other more desirable vectors, the a priori preferred vectors are chosen. Certain vectors may be considered nearly identical such that they are not tested unless the a priori selected vector index falls below some predetermined threshold.

[0050] Depending upon metric power consumption and power requirements of the device, the ECG signal quality metric may be measured on the range of vectors (or alternatively, a subset) as often as desired. Data may be gathered, for example, on a minute, hourly, daily, weekly or monthly basis. More frequent measurements (e.g., every minute) may be averaged over time and used to select vectors based upon susceptibility of vectors to occasional noise, motion noise, or EMI, for example.

[0051] Alternatively, the subcutaneous device 14 may have an indicator/sensor of patient activity (piezo-resistive, accelerometer, impedance, or the like) and delay automatic vector measurement during periods of moderate or high patient activity to periods of minimal to no activity. One representative scenario may include testing/evaluating ECG vectors once daily or weekly while the patient has been determined to be asleep (using an internal clock (e.g., 2:00 am) or, alternatively, infer sleep by determining the patient's position (via a 2- or 3-axis accelerometer) and a lack of activity). In another possible scenario, the testing/evaluating ECG vectors may be performed once daily or weekly while the patient is known to be exercising.

[0052] If infrequent automatic, periodic measurements are made, it may also be desirable to measure noise (e.g.,

muscle, motion, EMI, etc.) in the signal and postpone the vector selection measurement until a period of time when the noise has subsided.

[0053] Subcutaneous device 14 may optionally have an indicator of the patient's posture (via a 2- or 3-axis accelerometer). This sensor may be used to ensure that the differences in ECG quality are not simply a result of changing posture/position. The sensor may be used to gather data in a number of postures so that ECG quality may be averaged over these postures, or otherwise combined, or, alternatively, selected for a preferred posture.

[0054] In one embodiment, vector quality metric calculations may be performed by the clinician using a programmer either at the time of implant, during a subsequent visit in a clinic setting, or remotely via a remote link with the device and the programmer. According to another embodiment, the vector quality metric calculations may be performed automatically for each available sensing vector by the device a predetermined number of times, such multiple times daily, once per day, weekly or on a monthly basis. In addition, the values could be averaged for each vector over the course of one week, for example. Averaging may consist of a moving average or recursive average depending on time weighting and memory considerations.

[0055] FIG. 3 is a graphical representation of cardiac signals sensed along multiple sensing vectors during selection of a sensing vector in a medical device according to one embodiment. As illustrated in FIG. 3, during the vector selection process, the device senses a cardiac signal for each available sensing vector, using sensing techniques known in the art, such as described, for example, in U.S. patent application Ser. No. 14/250,040, incorporated herein by reference in its entirety, and based on the result of the sensed signals, ranks the available sensing vectors and determines one or more desired sensing vectors based on the resulting ranking of sensing vectors 102-106. For example, as illustrated in FIG. 3, according to one embodiment, the device senses an ECG signal 100 from each of the available sensing vectors, including a horizontal sensing vector 102 extending between the housing or can 25 and electrode 22, a diagonal sensing vector 104 extending between the housing or can 25 and electrode 20, and a vertical sensing vector 106 extending between electrodes 20 and 22. The device determines a sensed R-wave 108 for each sensing vector 102-106 as occurring when the sensed signal exceeds a time-dependent self-adjusting sensing threshold 110.

[0056] Once the R-wave 108 is sensed, the device sets a vector quality metric detection window 112 based on the sensed R-wave 108 for each of the sensing vectors 102-106, for determining a vector quality metric associated with the sensing vectors 102-106. According to an embodiment, the device sets a quality metric detection window 112 to start at a start point 114 located a predetermined distance 116 from the R-wave 108, and having a detection window width 118 so as to allow an analysis of the signal 100 to be performed in an expected range of the signal 100 where a T-wave of the QRS signal associated with the sensed R-wave 108 is likely to occur. For example, the device sets the quality metric detection window 112 as having a width 118 of approximately 200 ms, with a start point 114 of the quality metric detection window 112 located between approximately 150-180 milliseconds from the sensed R-wave 108, and the width 118 extending 200 ms, for example, from the detection window start point 114 to a detection window end point 120,

i.e., at a distance of approximately 350-380 ms from the detected R-wave **108**. According to another embodiment, the width **118** extends 270 ms, for example, from the detection window start point **114** to a detection window end point **120**, i.e., at a distance of approximately 420-450 ms from the detected R-wave **108**. Once the quality metric detection window **112** is set, the device determines a minimum signal difference **122** between the sensed signal **100** and the sensing threshold **110** within the quality metric detection window **112**, i.e., the minimum distance extending between the sensed signal **100** and the sensing threshold **110**, as described below.

[0057] FIG. 4 is a flowchart of a method for selecting one or more sensing vectors according to an exemplary embodiment. As illustrated in FIGS. 3 and 4, for each cardiac signal **100** obtained from the respective sensing vectors **102-106**, the device obtains the sensed R-wave **108** of the cardiac signal **100**, Block **200**, and sets the quality metric detection window **112**, Block **202**, based on the sensed R-wave **108** for that sensing vector **102-106**. Once the quality metric detection window **112** is located, the device determines the minimum signal difference **122** between the sensed cardiac signal **100** and the sensing threshold **110** within the quality metric detection window **112** for each of the sensing vectors, Block **204**. The determined minimum signal difference **122** is stored, and the device determines whether the minimum signal difference **122** has been determined for a predetermined threshold number of cardiac cycles for each of the sensing vectors **102-106**, Block **206**. If the minimum signal difference has not been determined for the predetermined threshold number of cardiac cycles for each sensing vector **102-106**, No in Block **206**, the device gets the next R-wave **108** for each sensing vector **102-106**, and the process is repeated for a next sensed cardiac cycle for each of the sensing vectors **102-106**. According to one embodiment, the minimum signal difference **122** is determined for 15 cardiac cycles, for example.

[0058] Once the minimum signal difference **122** has been determined for all of the predetermined threshold number of cardiac cycles, Yes in Block **206**, the device determines a vector selection metric for each vector **102-106** based on the 15 minimum signal differences **122** determined for that vector, Block **208**. For example, according to an embodiment, the device determines the median of the 15 minimum signal differences **122** for each sensing vector and sets the vector selection metric for that sensing vector equal to the determined median of the associated minimum signal differences **122**. Once a single vector selection metric is determined for each of the sensing vectors **102-106** in Block **208**, the device ranks the vector selection metrics for the sensing vectors **102-106**, Block **210**. For example, the device ranks the determined vector selection metrics from highest to lowest, so that in the example of FIG. 3, the diagonal sensing vector **104** would be ranked highest since the median minimum signal difference for that vector was 0.84 millivolts, the horizontal sensing vector **102** would be ranked second, since the median minimum signal difference for that vector is 0.82 millivolts, and the vertical sensing vector **106** would be ranked third, since the median minimum signal difference for that sensing vector is 0.55 millivolts.

[0059] Once the sensing vectors have been ranked in Block **210**, the device selects the sensing vector(s) to be utilized during subsequent sensing and arrhythmia detection

by the device, Block **212**. Depending on the amount of time programmed to occur between updating of the sensing vectors **102-106**, i.e., an hour, day, week or month, for example, the device waits until the next scheduled vector selection determination, Block **214**, at which time the vector selection process is repeated.

[0060] FIG. 5 is a flowchart of a method for selecting one or more sensing vectors according to another exemplary embodiment. As illustrated in FIGS. 3 and 5, according to another embodiment, for each cardiac signal **100** obtained from the respective sensing vectors **102-106**, the device obtains the sensed R-wave **108** of the cardiac signal **100**, Block **300**, and sets the quality metric detection window **112**, Block **302**, based on the sensed R-wave **108** for that sensing vector **102-106**, as described above. Once the quality metric detection window **112** is located, the device determines the minimum signal difference **122** between the sensed cardiac signal **100** and the sensing threshold **110** within the quality metric detection window **112** for each of the sensing vectors **102-106**, Block **304**. The determined minimum signal difference **122** is stored, and the device determines whether the minimum signal difference **122** has been determined for a predetermined threshold number of cardiac cycles for each sensing vector **102-106**, Block **306**, i.e., such as 15 cardiac cycles, for example.

[0061] If the minimum signal difference **122** has not been determined for the threshold number of cardiac cycles for each sensing vector **102-106**, No in Block **306**, the device determines whether a predetermined timer has expired, Block **308**. If the timer has not expired, No in Block **308**, the device gets the next R-wave **108** for each sensing vector **102-106**, and the process is repeated for a next sensed cardiac cycle for each of the sensing vectors **102-106**. According to one embodiment, the timer in Block **308** is set as 40 seconds, for example.

[0062] In some instances, the device may have not been able to obtain the required number of minimum signal differences **122** for one or more of the sensing vectors, and therefore if the timer has expired, Yes in Block **308**, the device determines whether the required number of minimum signal differences was obtained for at least 2 of the sensing vectors **102-106**, Block **314**. If the required number of minimum signal differences was not obtained for at least 2 of the sensing vectors, i.e., for only one or none of the sensing vectors **102-106**, No in Block **314**, the device determines no sensing vector selection can be made, Block **310**, and depending on the amount of time programmed to occur between updating of the sensing vectors **102-106**, i.e., an hour, day, week or month, for example, the device waits until the next scheduled vector selection determination, Block **312**, at which time the vector selection process is repeated.

[0063] If the required number of minimum signal differences was obtained for at least 2 of the sensing vectors **102-106**, Yes in Block **314**, the device selects those two sensing vectors in Block **320** to be utilized during subsequent sensing and arrhythmia detection by the device. As described above, depending on the amount of time programmed to occur between updating of the sensing vectors **102-106**, i.e., an hour, day, week or month, for example, the device waits until the next scheduled vector selection determination, Block **312**, at which time the vector selection process is then repeated.

[0064] If the minimum signal difference **122** has been determined for the predetermined number of cardiac cycles for each sensing vector **102-106**, Yes in Block **306**, the device determines a vector selection metric for each vector **102-106** based on the **15** minimum signal differences **122** determined for that vector, Block **316**. For example, according to an embodiment, the device determines the median of the **15** minimum signal differences **122** for each sensing vector and sets the vector selection metric for that sensing vector equal to the determined median of the associated minimum signal differences **122**. Once a single vector selection metric is determined for each of the sensing vectors **102-106** in Block **316**, the device ranks the vector selection metrics for the sensing vectors **102-106**, Block **318**. For example, the device ranks the determined vector selection metrics from highest to lowest, so that in the example of FIG. 3, the diagonal sensing vector **104** would be ranked highest since the median minimum signal difference for that vector was 0.84 millivolts, the horizontal sensing vector **102** would be ranked second, since the median minimum signal difference for that vector is 0.82 millivolts, and the vertical sensing vector **106** would be ranked third, since the median minimum signal difference for that sensing vector is 0.55 millivolts.

[0065] Once the sensing vectors have been ranked in Block **318**, the device selects the sensing vector(s) to be utilized during subsequent sensing and arrhythmia detection by the device, Block **320**. According to another embodiment, the results of the ranking may be displayed, such as on a programmer, to enable a user to select the sensing vector (s). Depending on the amount of time programmed to occur between updating of the sensing vectors **102-106**, i.e., an hour, day, week or month, for example, the device waits until the next scheduled vector selection determination, Block **312**, at which time the vector selection process is repeated. In addition, according to another embodiment, the user may manually initiate the vector selection process, so that the device would wait until the user input is received, and which point the next scheduled vector selection process would be repeated.

[0066] FIG. 6 is a flowchart of a method for selecting one or more sensing vectors according to another exemplary embodiment. As described above, in some instances, the device may have not been able to obtain the required number of minimum signal differences **122** for one or more of the sensing vectors. In addition, there may be instances where the minimum signal difference **122** for one or more of the cardiac cycles in one or more of the sensing vectors **102-106** is equal to zero when the ECG signal is greater than or equal to the sensing threshold in one or more cardiac cycles or throughout the quality metric sensing window **112**. Such instances of zero minimum signal differences may likely reflect either T-wave oversensing, frequent premature ventricular contractions, high rate sensing (greater than 150 beats per minute) or noise occurring in the sensing vector.

[0067] Therefore, according to one embodiment, as illustrated in FIGS. 3 and 6, for each cardiac signal **100** obtained from the respective sensing vectors **102-106**, the device obtains the sensed R-wave **108** of the cardiac signal **100**, Block **400**, and sets the quality metric detection window **112**, Block **402**, based on the sensed R-wave **108** for that sensing vector **102-106**, as described above. Once the quality metric detection window **112** is located, the device determines the minimum signal difference **122** between the

sensed cardiac signal **100** and the sensing threshold **110** within the quality metric detection window **112** for each of the sensing vectors **102-106**, Block **404**. In addition, the device determines, for each sensing vector **102-106**, whether a zero minimum signal difference occurred during the detection window **112**, Block **416**. If a zero minimum signal difference occurred during the detection window **112**, Yes in Block **416**, the R-wave associated with that vector is discarded, Block **418**, and a determination is made as to whether a timer has expired, as described below.

[0068] If a zero minimum signal difference did not occur during the detection window **112**, No in Block **416**, the device determines whether the minimum signal difference **122** has been determined for a predetermined threshold number of cardiac cycles, Block **406**, i.e., such 15 cardiac cycles, for example. If the minimum signal difference **122** has not been determined for the threshold number of cardiac cycles for each sensing vector **102-106**, No in Block **406**, the device determines whether the predetermined timer has expired, Block **408**. If the timer has not expired, No in Block **408**, the device gets the next R-wave **108** for each sensing vector **102-106**, and the process is repeated for a next sensed cardiac cycle for each of the sensing vectors **102-106**. According to one embodiment, the timer in Block **408** is set as 40 seconds, for example.

[0069] If the timer has expired, Yes in Block **408**, the device determines whether the required number of minimum signal differences was obtained for at least 2 of the sensing vectors **102-106**, Block **414**. If the required number of minimum signal differences was not obtained for at least 2 of the sensing vectors, i.e., for only one or none of the sensing vectors **102-106**, No in Block **414**, the device determines no sensing vector selection can be made, Block **410**, and depending on the amount of time programmed to occur between updating of the sensing vectors **102-106**, i.e., an hour, day, week or month, for example, the device waits until the next scheduled vector selection determination, Block **412**, at which time the vector selection process is repeated.

[0070] If the required number of minimum signal differences was obtained for at least 2 of the sensing vectors **102-106**, Yes in Block **414**, the device selects those two sensing vectors in Block **320** to be utilized during subsequent sensing and arrhythmia detection by the device. As described above, depending on the amount of time programmed to occur between updating of the sensing vectors **102-106**, i.e., an hour, day, week or month, for example, the device waits until the next scheduled vector selection determination, Block **412**, at which time the vector selection process is then repeated.

[0071] If the minimum signal difference **122** has been determined for the threshold number of cardiac cycles for each sensing vector **102-106**, Yes in Block **406**, the device determines a vector selection metric for each vector **102-106** based on the **15** minimum signal differences **122** determined for that vector, Block **420**. For example, according to an embodiment, the device determines the median of the **15** minimum signal differences **122** for each sensing vector and sets the vector selection metric for that sensing vector equal to the determined median of the associated minimum signal differences **122**. Once a single vector selection metric is determined for each of the sensing vectors **102-106** in Block **420**, the device ranks the vector selection metrics for the sensing vectors **102-106**, Block **422**. For example, the

device ranks the determined vector selection metrics from highest to lowest, so that in the example of FIG. 3, the diagonal sensing vector 104 would be ranked highest since the median minimum signal difference for that vector was 0.84 millivolts, the horizontal sensing vector 102 would be ranked second, since the median minimum signal difference for that vector is 0.82 millivolts, and the vertical sensing vector 106 would be ranked third, since the median minimum signal difference for that sensing vector is 0.55 millivolts.

[0072] FIG. 7 is a graphical representation of cardiac signals sensed along multiple sensing vectors during selection of a sensing vector in a medical device according to another embodiment. As illustrated in FIG. 7, during the vector selection process, the device senses a cardiac signal 500 for one or more of the available sensing vector, as described above. When the signal 500 exceeds a time-dependent, self-adjusting sensing threshold 510, an R-wave 508 is sensed. Once an R-wave 508 is sensed, the device sets a predetermined blanking period 509 and a quality metric window 512 based on the sensed R-wave 508 for each of sensing vectors 102-106, for determining a vector quality metric associated with the sensing vectors 102-106. According to one embodiment, the device sets the blanking period 509 as extending a predetermined period of time starting from the sensed R-wave 508 and extending to a blanking period endpoint 511. For example, the blanking period 509 may be set as 150 ms, although any initial setting may be used, typically between 150 and 180 ms. A blanking period adjustment window 513 is set, extending from the blanking period endpoint 511 to a blanking period adjustment endpoint 514. A width 517 of the blanking period adjustment window 513 will be dependent upon the current setting of the blanking period. Since, according to one embodiment, the blanking period is typically set between 150 and 180 ms, if the blanking period was 150 ms, the blanking period adjustment window 513 would be 30 ms. In this way, the width 517 of the blanking period adjustment window 513 is dependent upon the selected blanking period range.

[0073] In addition, the device sets the quality metric window 512 to start at the blanking period adjustment endpoint 514 and having a detection window width 518 so as to allow an analysis of the signal 500 to be performed in an expected range of the signal 500 where a T-wave of the QRS signal associated with the sensed R-wave 508 is likely to occur. For example, the device sets the quality metric detection window 512 as having a width 518 of approximately 200 ms, with a start point 515 of the quality metric detection window 512 located at the blanking period endpoint 514 and the width 518 extending 200 ms from the detection window start point 515 to a detection window endpoint 520, i.e., at a distance of approximately 350 ms from the detected R-wave 508 when the blanking period 509 is set at 150 ms. Once the blanking period adjustment window 513 and quality metric detection window 512 are set, the device determines a minimum signal difference 519 between the sensed signal 500 and the sensing threshold 510 within the blanking period adjustment window 513, and a minimum signal difference 522 between the sensed signal 500 and the sensing threshold 510 within the quality metric detection window 512, as described below.

[0074] FIG. 8 is a flowchart of a method for selecting one or more sensing vectors according to another exemplary embodiment. As illustrated in FIGS. 7 and 8, for each

cardiac signal 500 obtained from the respective sensing vectors 102-106, the device obtains a sensed R-wave 508 of the cardiac signal 500, Block 600, and sets the blanking period adjustment window 513 and the quality metric detection window 512, Block 602, based on the sensed R-wave 508 for that sensing vector 102-106. Once the blanking period adjustment window 513 and the quality metric detection window 512 is located, the device determines the minimum signal difference 519 between the sensed cardiac signal 500 and the sensing threshold 510 within the blanking period adjustment window 513 and the minimum signal difference 522 between the sensed cardiac signal 500 and the sensing threshold 510 within the quality metric detection window 512 for each of the sensing vectors, Block 604. The determined minimum signal differences 519 and 522 are stored, and the device determines whether the minimum signal differences 519 and 522 have been determined for a predetermined threshold number of cardiac cycles for each of the sensing vectors 102-106, Block 606.

[0075] If the minimum signal differences 519 and 522 have not been determined for the predetermined threshold number of cardiac cycles for each sensing vector 102-106, No in Block 606, the device gets the next R-wave 508 for each sensing vector 102-106, and the process is repeated for a next sensed cardiac cycle for each of the sensing vectors 102-106. According to one embodiment, the minimum signal differences 519 and 522 are determined for 15 cardiac cycles, for example.

[0076] Once the minimum signal differences 519 and 522 have been determined for all of the predetermined threshold number of cardiac cycles, Yes in Block 606, the device determines a vector selection metric for each vector 102-106 based on the 15 minimum signal differences 522 determined for that vector, Block 608. For example, according to an embodiment, the device determines the median of the 15 minimum signal differences 522 for each sensing vector and sets the vector selection metric for that sensing vector equal to the determined median of the associated minimum signal differences 522. Once a single vector selection metric is determined for each of the sensing vectors 102-106 in Block 608, the device ranks the vector selection metrics for the sensing vectors 102-106, Block 610. For example, the device ranks the determined vector selection metrics from highest to lowest, so that in the example of FIG. 7, the diagonal sensing vector 104 would be ranked highest since the median minimum signal difference for that vector was 0.86 millivolts, the horizontal sensing vector 102 would be ranked second, since the median minimum signal difference for that vector is 0.63 millivolts, and the vertical sensing vector 106 would be ranked third, since the median minimum signal difference for that sensing vector is 0.32 millivolts.

[0077] Once the sensing vectors have been ranked in Block 610, the device selects the sensing vector(s) to be utilized during subsequent sensing and arrhythmia detection by the device, Block 612. In addition, the device may determine whether the current set blanking period is less than a predetermined blanking period threshold corresponding to a desired maximum time period, i.e., 180 ms as described above, Block 614. Depending on the amount of time programmed to occur between updating of the sensing vectors 102-106, i.e., an hour, day, week or month, for example, if the current blanking is not less than the blanking period threshold, No in Block 614, the device waits until the

next scheduled vector selection determination, Block 622, at which time the vector selection process is repeated.

[0078] If the current blanking is less than the blanking period threshold, Yes in Block 614, the device determines a blanking period adjustment metric for each vector 102-106 based on the 15 minimum signal differences 519, Block 616. For example, according to an embodiment, the device determines the median of the 15 minimum signal differences 519 for each sensing vector and sets the blanking period adjustment metric for that sensing vector equal to the determined median of the associated minimum signal differences 519. Once a single blanking period adjustment metric is determined for each of the sensing vectors 102-106 in Block 616, the device determines whether an adjustment to the blanking period is to be made for the sensing vectors 102-106, Block 618. One reason for increasing the blanking period is to avoid double counting of R-waves. According to one embodiment, in order to determine whether to adjust the blanking period from the current setting, the device determines, for each of the two highest ranked vectors from Block 610, whether the corresponding determined blanking period adjustment metric is less than a proportion of the corresponding determined vector selection metric and less than a predetermined minimum blanking period threshold.

[0079] For example, using the results of FIG. 7, where the diagonal sensing vector 104 would be ranked highest since the median minimum signal difference for that vector was 0.86 millivolts, and the horizontal sensing vector 102 would be ranked second, since the median minimum signal difference for that vector is 0.63 millivolts, the device determines whether the blanking period adjustment metric determined for the diagonal sensing vector 104 is both less than one half of the vector selection metric for that sensing vector, i.e., 0.86 millivolts, and less than 0.05 millivolts, and whether the blanking period adjustment metric determined for the horizontal sensing vector 102 is both less than one half of the vector selection metric for that sensing vector, i.e., 0.63 millivolts, and less than 0.05 millivolts.

[0080] If the blanking period adjustment metric is not less than the predetermined proportion of one of the two highest ranked vectors or is not less than the predetermined minimum blanking period threshold, No in Block 618, the device waits until the next scheduled vector selection determination, Block 622, at which time the vector selection process is repeated. Depending on the amount of time programmed to occur between updating of the sensing vectors 102-106, the next scheduled updating of the vectors may occur in an hour, a day, a week or a month, for example.

[0081] If the blanking period adjustment metric is less than the predetermined proportion of one of the two highest ranked vectors and less than a predetermined minimum blanking period threshold, Yes in Block 618, the blanking period is updated, Block 620. For example, the blanking period may be increased to 180 ms, or may be increased by a predetermined amount, such as 10 ms. In addition, according to another embodiment, rather than automatically increasing the blanking period, the device may generate an alarm or other stored indication to indicate to the attending medical personnel that the blanking period should be increased so that the increase in the blanking period can be adjusted manually, using a programmer or other input device.

[0082] FIG. 9 is a state diagram of detection of arrhythmias in a medical device according to an embodiment of the

present invention. As illustrated in FIG. 9, according to an embodiment, the device transitions between a Not Concerned State 702, a Concerned State 704, an Armed State 706 and a Shock State 708, as described for example, in U.S. Pat. No. 7,894,894 to Stadler et al., incorporated herein by reference in its entirety. For example, during normal operation, the device is in the Not Concerned State 702, during which R-wave intervals are being evaluated to identify periods of rapid rates and/or the presence of asystole. Upon detection of short R-wave intervals simultaneously in two separate ECG sensing vectors, indicative of an event that, if confirmed, may require the delivery of therapy, the device transitions from the Not Concerned State 702 to the Concerned State 704. While in the Concerned State 704, the device evaluates a predetermined window of ECG signals to determine the likelihood that the signal is corrupted with noise and to discriminate rhythms requiring shock therapy from those that do not require shock therapy, using a combination of R-wave intervals and ECG signal morphology information, as described, for example, in U.S. patent application Ser. No. 14/250,040, to Zhang and in U.S. Pat. No. 7,894,894 to Stadler et al., both incorporated herein by reference in their entireties.

[0083] If a rhythm requiring shock therapy continues to be detected while in the Concerned State 704, the device transitions from the Concerned State 704 to the Armed State 706. If a rhythm requiring shock therapy is no longer detected while the device is in the Concerned State 704 and the R-wave intervals are determined to no longer be short, the device returns to the Not Concerned State 702. However, if a rhythm requiring shock therapy is no longer detected while the device is in the Concerned State 704, but the R-wave intervals continue to be detected as being short, processing continues in the Concerned State 704.

[0084] In the Armed State 706, the device charges the high voltage shocking capacitors and continues to monitor R-wave intervals and ECG signal morphology for spontaneous termination. If spontaneous termination of the rhythm requiring shock therapy occurs, the device returns to the Not Concerned State 702. If the rhythm requiring shock therapy is still determined to be occurring once the charging of the capacitors is completed, the device transitions from the Armed State 706 to the Shock State 708. In the Shock State 708, the device delivers a shock and returns to the Armed State 706 to evaluate the success of the therapy delivered.

[0085] FIG. 10 is a flowchart of a method for adjusting a blanking period during transitioning between operating states, according to an embodiment of the present disclosure. As illustrated in FIG. 10, according to an embodiment of the present disclosure, while in the Concerned State 704, the device determines whether the sensing channels ECG1 and ECG2 are shockable, Block 802, using the method for determining whether the sensing channels are shockable or not shockable, as described, for example, in U.S. patent application Ser. No. 14/250,040, to Zhang and in U.S. Pat. No. 7,894,894 to Stadler et al., both incorporated herein by reference in their entireties. For example, according to one embodiment, while the device is in the Concerned State 704 a most recent window of ECG data from both channels ECG1 and ECG2 are utilized, such as three seconds, for example, so that processing is triggered in the Concerned State 704 by a three-second timeout. It is understood that while the processing is described as being triggered over a three second period, other time periods for the processing

time utilized when in the Concerned State **304** may be chosen, but should preferably be within a range of 0.5 to 10 seconds. As a result, although sensing of individual R-waves continues to occur in both channels ECG1 and ECG2 when in the Concerned State **704**, the opportunities for changing from the Concerned State **704** to another state only occur once the three-second timer expires. Upon initial entry to the Concerned State **704**, it is advantageous to process the most recent three-seconds of ECG data, i.e., ECG data for the three seconds leading up to the transition to the Concerned State **704**. This requires a continuous circular buffering of the most recent three seconds of ECG data even while in the Not Concerned State **702**.

[0086] While in the Concerned State **704**, the device determines how sinusoidal and how noisy the signals in the two sensing channels are in order to determine the likelihood that a ventricular fibrillation (VF) or fast ventricular tachycardia (VT) event is taking place, since the more sinusoidal and low noise the signal is, the more likely a VT/VF event is taking place. Based on this analysis, the device classifies the sensing channels as being one of either shockable or not shockable. According to one embodiment, the device may identify both of the channels ECG1 and ECG2 as being either shockable or not shockable as described in commonly assigned U.S. application Ser. No. 14/250,040, entitled "Method and Apparatus for Discriminating Tachycardia Events in A Medical Device Using Two Sensing Vectors", to Zhang, incorporated herein by reference in its entirety. Based on whether the sensing channels for the current vectors are classified as being shockable or not shockable, a determination is made as to whether the device should transition from the Concerned State **704** to another state, Block **804**.

[0087] For example, according to an embodiment of the present disclosure, the transition from the Concerned State **704** to the Armed State **706** is confirmed if a predetermined number, such as two out of three for example, of three-second segments for both channels ECG1 and ECG2 have been classified as being shockable. If the predetermined number of three-second segments in both channels ECG1 and ECG2 have been classified as shockable, Yes in Block **804**, the device transitions from the Concerned State **704** to the Armed State **706**. If the predetermined number of three-second segments in both channels ECG1 and ECG2 have not been classified as shockable, No in Block **804**, the device does not transition from the Concerned State **704** to the Armed State **706**, and a determination as to whether to transition back to the Not Concerned State **702** is made, Block **806**.

[0088] The determination as to whether to transition from the Concerned State **704** back to the Not Concerned State **702** is made, for example, by determining whether a heart rate estimate is less than a heart rate threshold level in at least one of the two channels ECG1 and ECG2, as described in U.S. patent application Ser. No. 14/250,040, to Zhang and in U.S. Pat. No. 7,894,894 to Stadler et al., both incorporated herein by reference in their entireties. If it is determined that the device should not transition to the Not Concerned State **702**, i.e., both of the two heart rate estimates are greater than the heart rate threshold, No in Block **806**, the process is repeated using the signal generated during a next three-second window, Block **808**. If it is determined that the device should transition to the Not Concerned State **702**, i.e., both of the two heart rate estimates are greater than the heart

rate threshold, Yes in Block **806**, a determination is made as to whether a blanking period adjustment, described above, was made while in the Concerned State, Block **809**. If an adjustment to the blanking period was made, Yes in Block **809**, the device adjusts the blanking period, Block **811**. For example, according to one embodiment the device may reduce the blanking period by a predetermined amount, or according to another example, the device may adjust the blanking period back to the initial or nominal blanking period setting utilized prior to the adjustment occurring while the device was in the Concerned State. For example, once operation of the device transitions from the Concerned State **704** to the Not Concerned State **702**, if the blanking period was adjusted from 150 ms to 180 ms while the device was in the Concerned State, Yes in Block **809**, the device adjusts the blanking to period to the initial 150 ms setting, Block **811**. If an adjustment to the blanking period was not made, No in Block **809**, or once the device adjusts the blanking period back to the nominal or initial setting when in the Not Concerned State, Block **811**, operation of the device is in the Not Concerned State, Block **702**.

[0089] When the device transitions from the Concerned State **704** to the Armed State **706**, Yes in Block **804**, processing continues to be triggered by a three-second time out as is utilized during the Concerned State. Once in the Armed State **706**, a determination is made as to whether a blanking period adjustment, described above, was made while in the Concerned State **704**, Block **810**. If an adjustment to the blanking period was made, Yes in Block **810**, the device adjusts the blanking period, Block **812**. For example, according to one embodiment the device may reduce the blanking period by a predetermined amount, or according to another example, the device may adjust the blanking period back to the initial or nominal blanking period setting utilized prior to the adjustment occurring while the device was in the Concerned State **704**. For example, once operation of the device transitions from the Concerned State **704** to the Armed State **706**, if the blanking period was adjusted from 150 ms to 180 ms while the device was in the Concerned State **704**, Yes in Block **810**, the device adjusts the blanking to period to the initial 150 ms setting, Block **812**. If an adjustment to the blanking period was not made, No in Block **810**, or once the device adjusts the blanking period back to the nominal or initial setting when in the Armed State **706**, Block **812**, charging of the capacitors is initiated, Block **814**.

[0090] During the charging of the capacitors, the classification of segments for each channel ECG1 and ECG2 as being either shockable or not shockable continues, and once the next three seconds of data has been acquired using the adjusted blanking period, Block **812**, a determination is made as to whether the event continues to be a shockable event by determining whether a predetermined number of segments, such as the most recent two segments for example, have been classified in both of the two channels ECG1 and ECG2 as not shockable, Block **816**. If the predetermined number of three second segments have been classified as not shockable, indicating that the event may possibly no longer be a shockable event, Yes in Block **816**, the charging of the capacitors is stopped, Block **818**, and a determination is made as to whether to transition to the Not Concerned State **702**, Block **820**.

[0091] According to an embodiment of the present invention, the device will transition from the Armed State **706** to

the Not Concerned State **702**, Yes in Block **820**, if certain termination requirements are met. For example, return to the Not Concerned State **702** occurs if, for both channels ECG1 and ECG2 simultaneously, less than two out of the last three three-second segments are classified as shockable, less than three out of the last eight three-second segments are classified as shockable, and the most recent three second segment is classified as not shockable. Another possible criteria for returning to the Not Concerned State **702** is the observation of 4 consecutive not shockable classifications in both channel ECG1 and ECG2 simultaneously.

[0092] In addition to the two criteria described above, at least one of the current heart rate estimates must be slower than the programmed rate threshold, and capacitor charging must not be in progress. If each of these requirements are satisfied, Yes in Block **820**, the device transitions from the Armed State **706** to the Not Concerned State **702**.

[0093] If one or more of these requirements are determined not to be satisfied, return to the Not Concerned State is not indicated, No in Block **820**, and a determination is then made as to whether the shockable rhythm is redetected, Block **822**, by determining whether predetermined redetection requirements have been satisfied. For example, a determination is made as to whether a predetermined number of three-second segments in both of the two channels ECG1 and ECG2, such as two out of the most recent three for example, have been classified as being shockable. If the predetermined redetection requirements are not satisfied, No in Block **822**, the determination of whether to terminate delivery of the therapy, Block **820**, is repeated so that the processing switches between the determination of whether to terminate delivery of therapy, Block **820** and the determination as to whether the shockable event is redetected, Block **822**, until either the event has terminated and the device transitions from the Armed State **706** to the Not Concerned State **702** or the event is redetected. If the predetermined redetection requirements are met, Yes in Block **822**, charging is re-initiated, Block **814**, and the process is repeated.

[0094] If, during the charging of the capacitors, the predetermined number of three second segments have not been classified as not shockable, No in Block **816**, a determination is made as to whether the charging of the capacitors is completed, Block **824**. As long as the capacitor charging continues to occur, No in Block **816**, the process is repeated using the signal generated during a next three-second window, Block **828**, and once the charging of the capacitors is completed, Yes in Block **824**, a determination is made as to whether delivery of the therapy is still appropriate, Block **826**, by determining whether predetermined therapy delivery confirmation requirements have been satisfied. For example, according to an embodiment of the present invention, the predetermined therapy delivery confirmation requirements include determining whether, for both channels ECG1 and ECG2, at least five out of the last eight three-second segments are classified as being shockable, and at least two of the last three three-second segments are classified as being shockable. In addition, a determination is made as to whether the most recent three-second segment has been classified as being shockable for at least one of the two channels ECG1 and ECG2.

[0095] If the predetermined therapy delivery requirements have not been satisfied, and therefore the delivery of the therapy is not confirmed, No in Block **826**, the determination

of whether to transition from the Armed State **706** to the Not Concerned State **702**, Block **820**, is repeated. If the predetermined therapy delivery requirements are satisfied, and therefore the delivery of the therapy is confirmed, Yes in Block **826**, the device transitions from the Armed State **706** to the Shock State **708**.

[0096] It is understood that in addition to the three sensing vectors **102-16** described above, optionally, a virtual signal (i.e., a mathematical combination of two vectors) may also be utilized in addition to, thus utilizing more than three sensing vectors, or in place of the sensing vectors described. For example, the device may generate a virtual vector signal as described in U.S. Pat. No. 6,505,067 "System and Method for Deriving Virtual ECG or EGM Signal" to Lee, et al; both patents incorporated herein by reference in their entireties. In addition, vector selection may be selected by the patient's physician and programmed via a telemetry link from a programmer.

[0097] In addition, while the use of a minimum signal difference is described, the device may utilize other selection criteria for ranking vectors. For example, according one embodiment, the device may determine, for each vector, a maximum signal amplitude within the detection window for each R-wave, determine the difference between the maximum amplitude and the sensing threshold for each of the maximum amplitudes, and determine a median maximum amplitude difference for each sensing vector over 15 cardiac cycles. The device would then select the vector(s) having the greatest median maximum amplitude difference as the sensing vector(s) to be utilized during subsequent sensing and arrhythmia detection by the device. According to another embodiment, the maximum amplitude in the quality metric window may be subtracted from the maximum R-wave amplitude, or the maximum amplitude in the quality metric window is subtracted from the sense threshold at the time of the maximum amplitude.

[0098] Thus, a method and apparatus for selecting a sensing vector configuration in a medical device 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 disclosure as set forth in the following claims.

We claim:

1. A method of adjusting a blanking period in a medical device, comprising:

sensing cardiac signals from a plurality of electrodes, the plurality of electrodes forming a plurality of sensing vectors;

determining whether to adjust a blanking period during a first operating state;

advancing from the first operating state to a second operating state in response to the sensed cardiac signals;

determining, while in the second operating state, whether the blanking period was adjusted while in the first operating state; and

adjusting the blanking period while in the second operating state in response to the blanking period being adjusted while in the first operating state.

2. The method of claim 1, further comprising:

increasing the blanking period from a first setting to a second setting while in the first state; and

- decreasing the blanking period from the second setting to the first setting while in the second operating state.
3. The method of claim 1, further comprising:
 increasing the blanking period a first predetermined amount while in the first state; and
 decreasing the blanking period a second predetermined amount not equal to the first predetermined amount while in the second operating state.
4. The method of claim 1, further comprising:
 adjusting the blanking period while in the second state if the blanking period was adjusted while in the first state; and
 not adjusting the blanking period while in the second state if the blanking period was not adjusted while in the first state.
5. The method of claim 1, wherein the first state comprises determining whether a shockable event is occurring and the second state comprises charging of a therapy delivery device for delivering therapy.
6. The method of claim 1, wherein determining whether to adjust a blanking period during a first operating state comprises:
 setting a blanking period and a blanking period adjustment window for the plurality of sensing vectors in response to the sensed cardiac signals;
 determining first signal differences during the blanking period adjustment window; and
 adjusting the blanking period in response to the determined first signal differences.
7. The method of claim 6, wherein determining first signal differences comprises:
 determining signal differences between the cardiac signal sensed during the blanking period adjustment window and the sensing threshold; and
 determining a minimum signal difference of the determined signal differences.
8. The method of claim 7, further comprising:
 increasing the blanking period from a first setting to a second setting while in the first state; and
 decreasing the blanking period from the second setting to the first setting while in the second operating state.
9. The method of claim 7, further comprising:
 increasing the blanking period a first predetermined amount from a first setting while in the first state; and
 decreasing the blanking period a second predetermined amount not equal to the first predetermined amount while in the second operating state.
10. The method of claim 7, further comprising:
 adjusting the blanking period while in the second state if the blanking period was adjusted while in the first state; and
 not adjusting the blanking period while in the second state if the blanking period was not adjusted while in the first state, wherein the first state comprises determining whether a shockable event is occurring and the second state comprises charging of a therapy delivery device for delivering therapy.
11. A medical device, comprising:
 a plurality of electrodes capable of forming a plurality of sensing vectors for sensing cardiac signals; and
 a processor configured to determine whether to adjust a blanking period during a first operating state, advance from the first operating state to a second operating state in response to the sensed cardiac signals, determine, while in the second operating state, whether the blanking period was adjusted while in the first operating state, and adjust the blanking period while in the second operating state in response to the blanking period being adjusted while in the first operating state.
12. The device of claim 11, wherein the processor is further configured to increase the blanking period from a first setting to a second setting while in the first state, and decrease the blanking period from the second setting to the first setting while in the second operating state.
13. The device of claim 11, wherein the processor is further configured to increase the blanking period a first predetermined amount while in the first state, and decrease the blanking period a second predetermined amount not equal to the first predetermined amount while in the second operating state.
14. The device of claim 11, wherein the processor is further configured to adjust the blanking period while in the second state if the blanking period was adjusted while in the first state, and not adjust the blanking period while in the second state if the blanking period was not adjusted while in the first state.
15. The device of claim 11, wherein the first state comprises determining whether a shockable event is occurring and the second state comprises charging of a therapy delivery device for delivering therapy.
16. The device of claim 11, wherein determining whether to adjust a blanking period during a first operating state comprises:
 setting a blanking period and a blanking period adjustment window for the plurality of sensing vectors in response to the sensed cardiac signals;
 determining first signal differences during the blanking period adjustment window; and
 adjusting the blanking period in response to the determined first signal differences.
17. The device of claim 16, wherein determining first signal differences comprises:
 determining signal differences between the cardiac signal sensed during the blanking period adjustment window and the sensing threshold; and
 determining a minimum signal difference of the determined signal differences.
18. The device of claim 17, wherein the processor is further configured to increase the blanking period from a first setting to a second setting while in the first state, and decrease the blanking period from the second setting to the first setting while in the second operating state.
19. The device of claim 17, wherein the processor is further configured to increase the blanking period a first predetermined amount from a first setting while in the first state, and decrease the blanking period a second predetermined amount not equal to the first predetermined amount while in the second operating state.
20. The device of claim 17, wherein the processor is further configured to adjust the blanking period while in the second state if the blanking period was adjusted while in the first state, and not adjust the blanking period while in the second state if the blanking period was not adjusted while in the first state, wherein the first state comprises determining whether a shockable event is occurring and the second state comprises charging of a therapy delivery device for delivering therapy.

专利名称(译)	用于在医疗设备中的操作状态之间转换期间调整消隐时段的方法和装置		
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当前申请(专利权)人(译)	美敦力公司, INC.		
[标]发明人	GREENHUT SAUL E STADLER ROBERT W ZHANG XUSHENG		
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摘要(译)

一种用于调整消隐时段的方法和医疗设备，包括感测来自多个电极的心脏信号，所述多个电极形成多个感测矢量，确定是否在第一操作状态期间调整消隐时段，从第一操作前进响应于所感测的心脏信号，状态到第二操作状态，在第二操作状态下确定在第一操作状态期间是否调整了消隐时段，并且在第二操作状态中响应于第二操作状态调整消隐时段。在第一操作状态下调整消隐期。

