

(51) International Patent Classification:

A61B 5/00 (2006.01) A61B 5/0456 (2006.01)

A61B 5/0452 (2006.01) A61N 1/362 (2006.01)

A61B 5/04 (2006.01)

(21) International Application Number:

PCT/US2015/026743

(22) International Filing Date:

21 April 2015 (21.04.2015)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/983,499 24 April 2014 (24.04.2014) US

14/260,408 24 April 2014 (24.04.2014) US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))

— as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

Published:

— with international search report (Art. 21(3))

(54) Title: METHOD AND APPARATUS FOR SELECTING A SENSING VECTOR CONFIGURATION IN A MEDICAL DEVICE

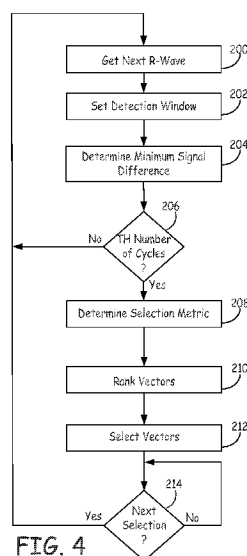


FIG. 4

(57) Abstract: A method and medical device for determining sensing vectors that includes sensing cardiac signals from a plurality of electrodes, the plurality of electrodes forming a plurality of sensing vectors, determining signal differences during a detection window in each of the plurality of sensing vectors, ranking sensing vectors of the plurality of sensing vectors in response to the determined signal differences, and selecting one or more sensing vectors of the plurality of sensing vectors in response to the determined rankings.

METHOD AND APPARATUS FOR SELECTING A SENSING VECTOR CONFIGURATION IN A MEDICAL DEVICE

TECHNICAL FIELD

5 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

10 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
15 order to detect episodes of tachycardia or fibrillation.

 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
20 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
25 effectively treating an arrhythmia and avoiding the delivery of unnecessary cardioversion/defibrillation (CV/DF) shocks, which are painful to the patient.

 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
30 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
5 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.

10 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
15 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
20 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.

25 BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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.

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

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

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

DETAILED DESCRIPTION

FIG. 1 is a conceptual diagram of a patient 12 implanted with an example extravascular cardiac defibrillation 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.

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).

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.

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.

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.

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).

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.

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
5 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
10 one or more of electrodes 18, 20 and 22 to the sensing module within ICD 14.

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
15 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
20 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.

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
25 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,
30 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
5 both electrodes 20 and 22 are illustrated as ring electrodes.

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,
10 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
15 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.

Lead 16 may also include a connector at the proximal end of lead 16, such
20 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.
25 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.

Defibrillation lead 16 may also include a suture sleeve or other fixation mechanism (not shown) located proximal to electrode 22 that is configured to
30 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.

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
5 lead in addition to defibrillation lead 16.

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
10 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
15 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
20 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.

FIG. 2 is an exemplary schematic diagram of electronic circuitry within a hermetically sealed housing of a subcutaneous device according to an
25 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 ,
30 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.

Further referring to Fig. 2, subcutaneous device 14 functions are controlled by means of software, firmware and hardware that cooperatively monitor the ECG
5 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. Patent Nos. 5,163,427 "Apparatus for Delivering Single and Multiple Cardioversion and Defibrillation Pulses" to Keimel and 5,188,105 "Apparatus and
10 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
15 the HVI output 113 of the high voltage output circuit 140.

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
20 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
25 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
30 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.

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. Patent 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.

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 EGM. 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. Patent No. 6,236,882 "Noise Rejection for Monitoring ECGs" to Lee, et al and incorporated herein by reference in its' entirety.

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.

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
5 withhold a defibrillation therapy as described generally in U.S. Patent 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
10 apparatus and method as described in U.S. Patent 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. Patent No. 4,567,892 "Implantable Cardiac Pacemaker" to
15 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. Patent 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
20 on the lead 18 to enable the sensing of contacting or near-contacting tissue oxygenation or color.

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
25 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
30 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.

5 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
10 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.

15 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
20 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
25 rendered ready to begin charging the high voltage output capacitors 156, 158, 160, and 162 with charging current from high voltage battery 112.

 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
30 113 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. Patent 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.

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.

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.

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, Minnesota.

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. Patents: 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.

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.

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.

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 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 5 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 10 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.

Depending upon metric power consumption and power requirements of the 15 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 20 EMI, for example.

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 25 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 30 exercising.

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.

5 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
10 combined, or, alternatively, selected for a preferred posture.

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
15 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
20 considerations.

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,
25 using sensing techniques known in the art, such as described, for example, in U.S. Patent Application 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
30 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
5 when the sensed signal exceeds a time-dependent self-adjusting sensing threshold 110.

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
10 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-
15 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 from the detection window start point 114 to a detection
20 window end point 120, i.e., at a distance of approximately 350-380 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
25 sensing threshold 110, as described below.

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
30 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

5 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
10 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.

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
15 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
20 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
25 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.

30 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
5 process is repeated.

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
10 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
15 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.

20 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
25 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.

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
30 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
5 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.

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
10 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
15 selection process is then repeated.

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,
20 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
25 316, 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
30 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.

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.

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.

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
5 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.

10 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
15 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
20 timer in Block 408 is set as 40 seconds, for example.

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
25 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
30 the vector selection process is repeated.

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
5 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.

If the minimum signal difference 122 has been determined for the threshold
10 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
15 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
20 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
25 signal difference for that sensing vector is 0.55 millivolts.

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
30 device may generate a virtual vector signal as described in U.S. Patent 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.

In addition, while the use of a minimum signal difference is described, the
5 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
10 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.

Thus, a method and apparatus for verifying discriminating of a cardiac
15 event 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 medical device for determining sensing vectors, comprising:
 - a plurality of electrodes capable of forming a plurality of sensing vectors for sensing cardiac signals; and
 - a processor configured to determine signal differences during a detection window for each of the plurality of sensing vectors, rank sensing vectors of the plurality of sensing vectors in response to the determined signal differences, and select one or more sensing vectors of the plurality of sensing vectors in response to the determined rankings.
2. The medical device of claim 1, wherein determining signal differences during a detection window in each of the plurality of sensing vectors comprises:
 - sensing an R-wave in response to the cardiac signal exceeding a sensing threshold;
 - determining signal differences between the cardiac signal sensed during the detection window and the sensing threshold; and
 - determining a minimum signal difference of the determined signal differences.
3. The medical device of claim 2, wherein the processor is further configured to determine whether the cardiac signal exceeds the sensing threshold during the detection window, wherein the processor determines the minimum signal difference for the detection window in response to the cardiac signal not exceeding the sensing threshold during the detection window.
4. The medical device of any of claims 1-3, wherein the processor is further configured to select a vector of the plurality of vectors having the greatest determined minimum signal difference as a first sensing vector, and select a vector of the plurality of vectors having a next greatest determined minimum signal difference as a second sensing vector.

5. The medical device of any of claims 1-4, wherein the processor is further configured to sense an R-wave in response to the cardiac signal exceeding a sensing threshold, determine a maximum signal amplitude of the cardiac signal sensed during the detection window, and determine a signal difference between the maximum amplitude and the sensing threshold.
6. The medical device of claim 15, wherein the processor is further configured to select a vector of the plurality of vectors having the lowest determined signal threshold difference between the maximum amplitude and the sensing threshold as a first sensing vector, and select a vector of the plurality of vectors having the next lowest determined signal difference between the maximum amplitude and the sensing threshold as a second sensing vector.
7. The medical device of any of claims 1-6, wherein the processor is further configured to determine whether the signal differences have been determined for a threshold number of detection windows for each of the plurality of sensing vectors, and identify sensing vectors of the plurality of sensing vectors having signal differences determined for the threshold number of detection windows, wherein ranking sensing vectors of the plurality of sensing vectors comprises ranking only the identified sensing vectors.
8. The medical device of claim 7, wherein the threshold number of detection windows comprises fifteen detection windows.
9. The medical device of any of claims 5-7, wherein the processor is further configured to determine whether the cardiac signal exceeds the sensing threshold during the detection window, and update the determined number of detection windows for the sensing vector in response to the cardiac signal being determined to exceed the sensing threshold.

10. The medical device of any of claims 1-9, wherein the processor is further configured to determine whether a timer has expired, and determine whether signal differences have been determined for a predetermined number of detection windows for a predetermined number of sensing vectors of the plurality of sensing vectors in response to the timer having expired.

11. The medical device of any of claims 1-10, wherein the medical device comprises a subcutaneous device.

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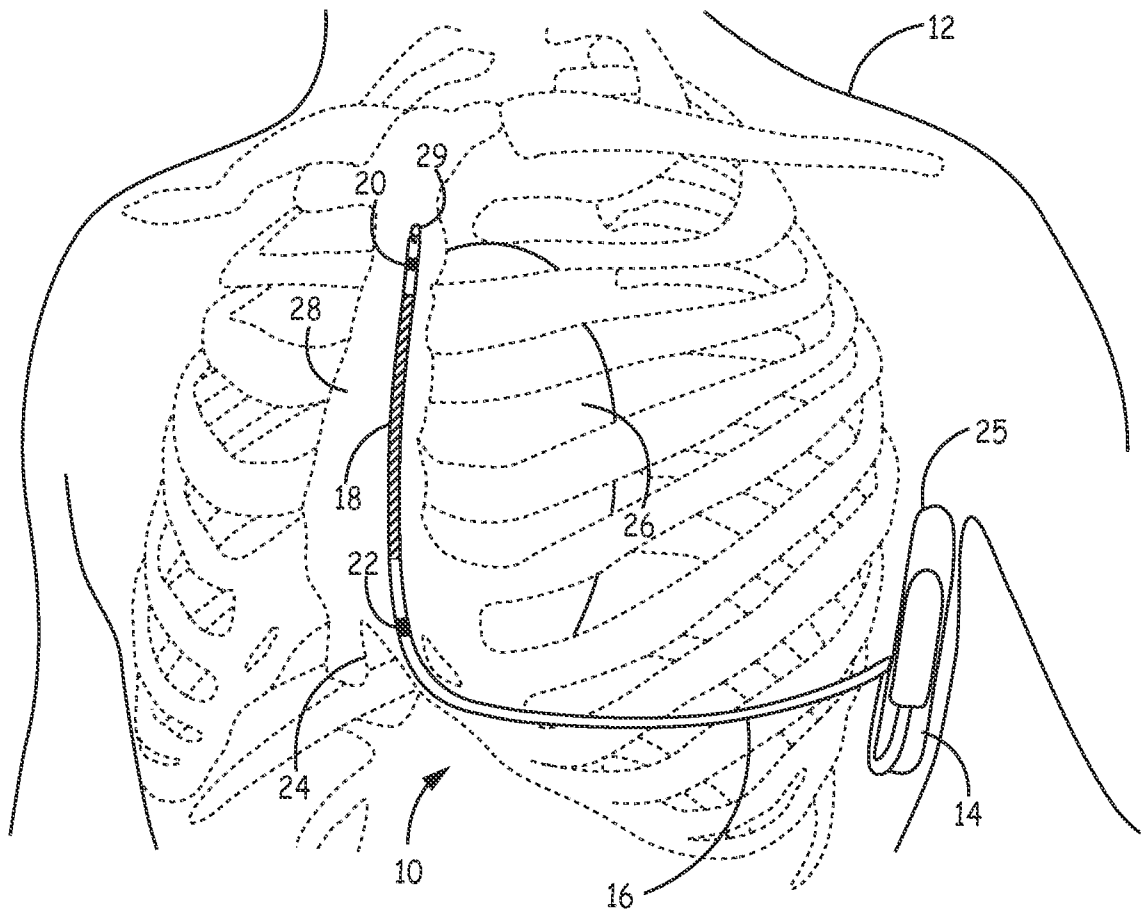


FIG. 1

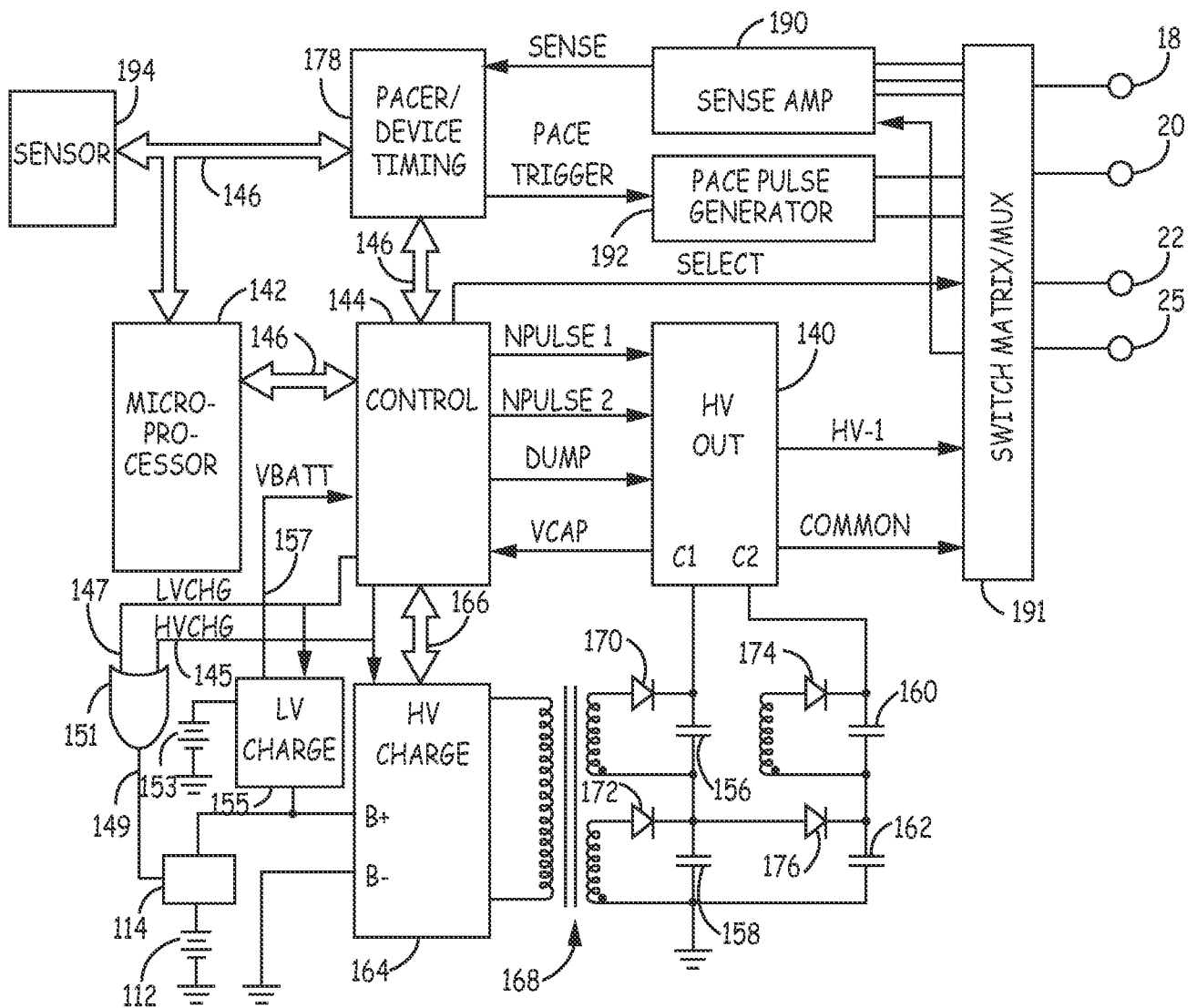
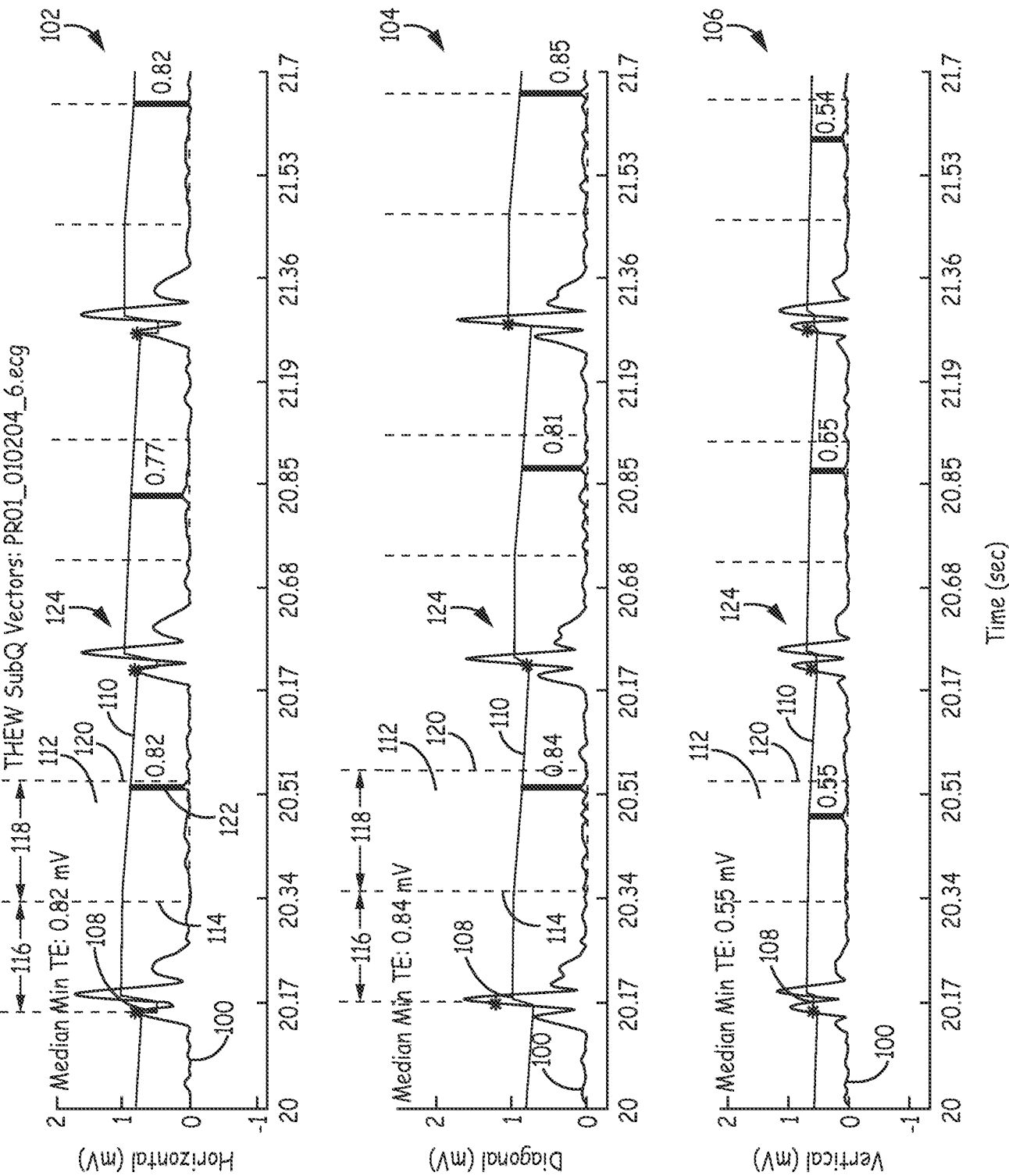


FIG. 2



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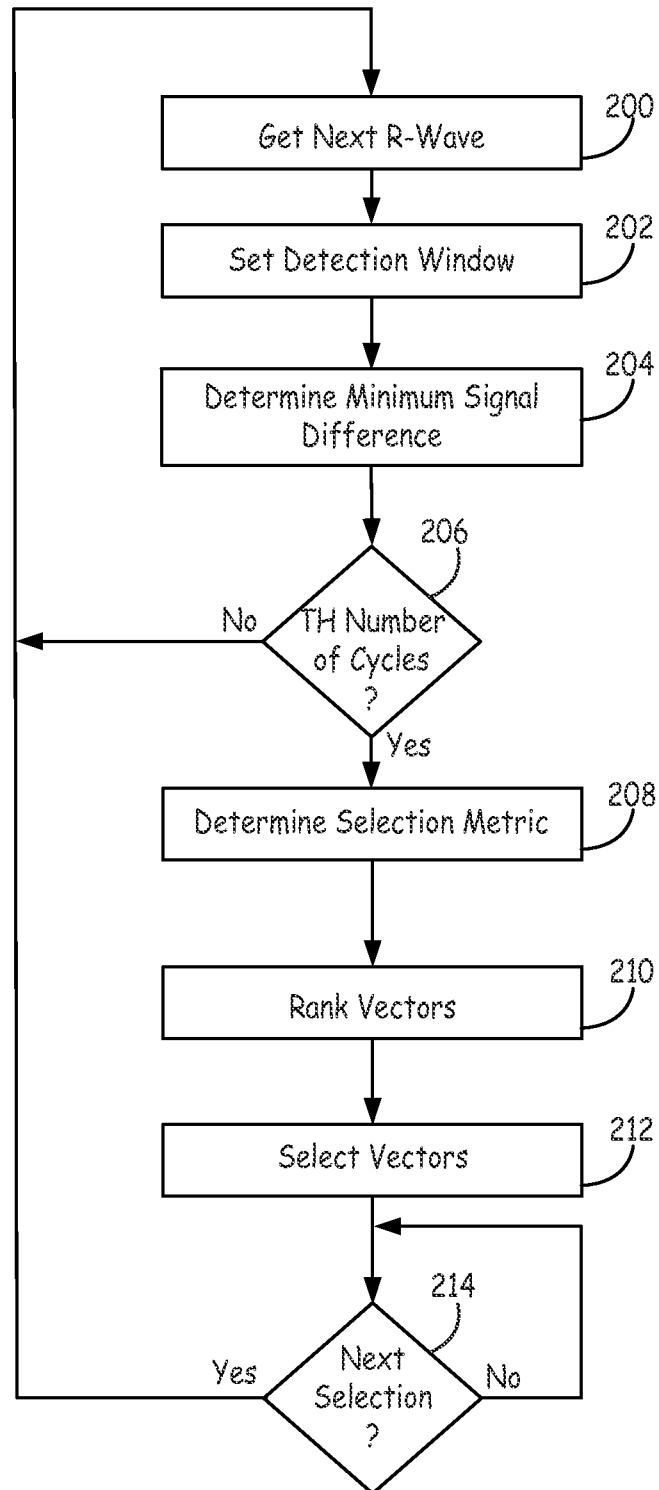


FIG. 4

5 / 6

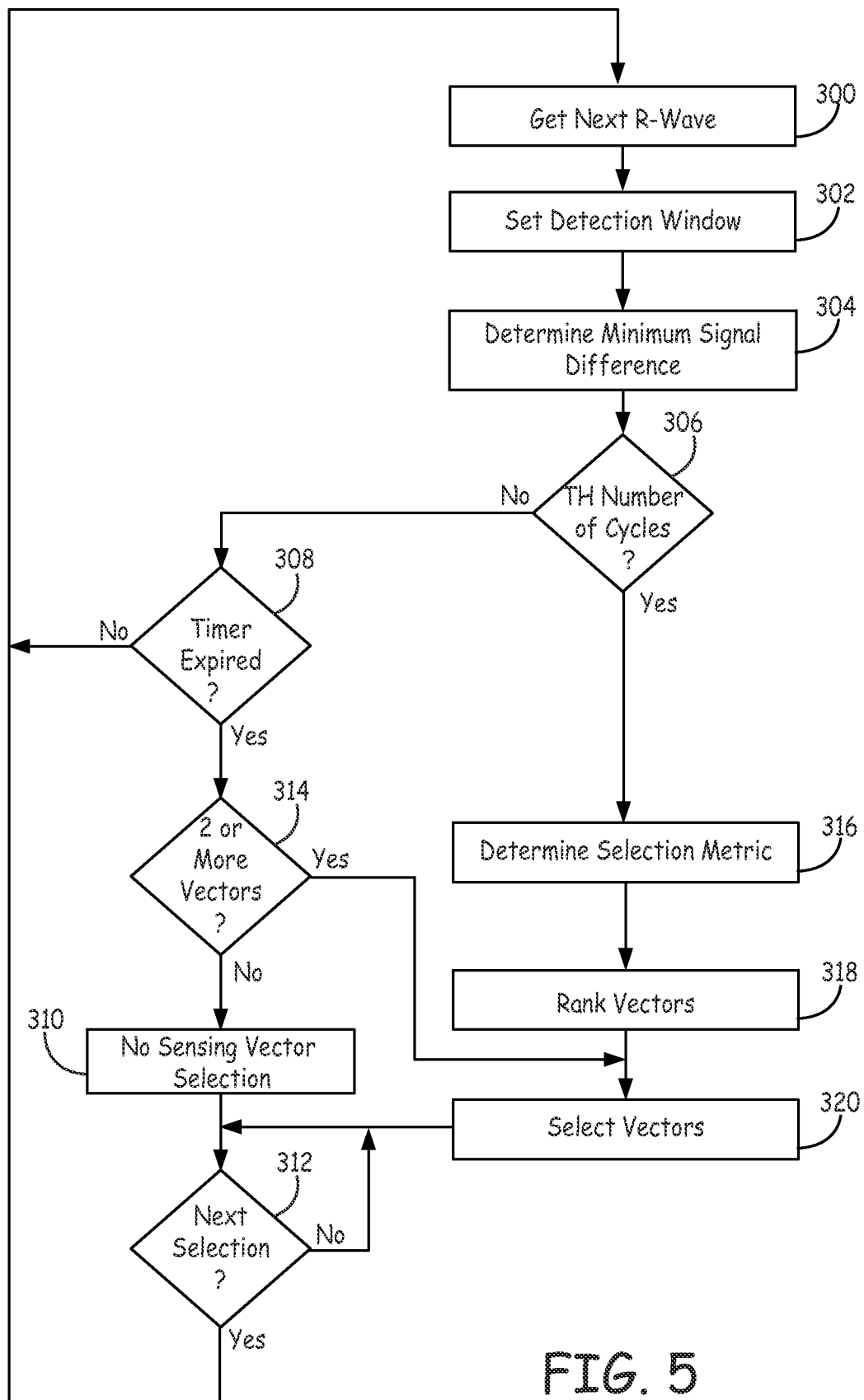


FIG. 5

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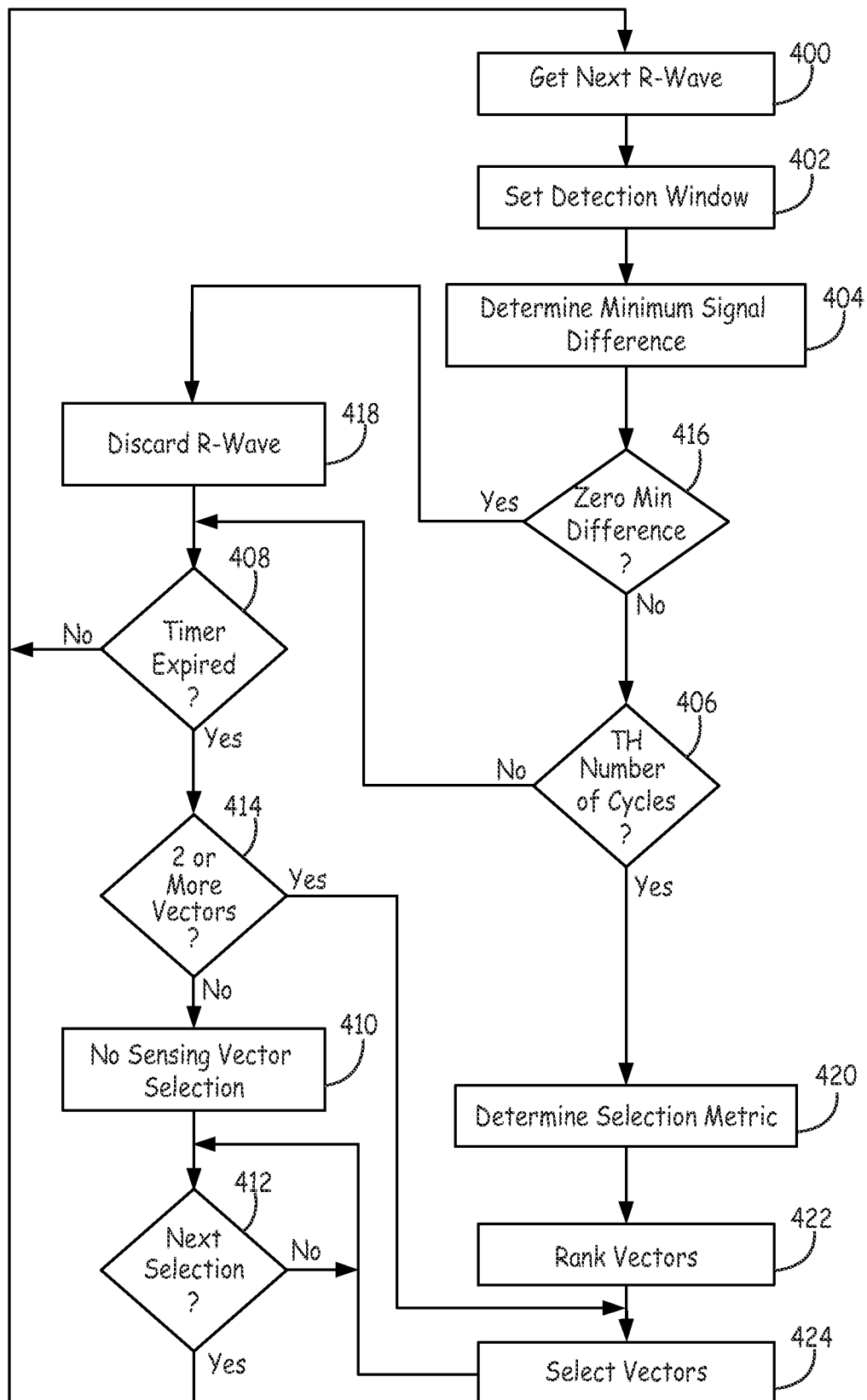


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2015/026743

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/00 A61B5/0452 A61B5/04 A61B5/0456 A61N1/362
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2013/197381 A1 (CHARLTON SANDRA B [US] ET AL) 1 August 2013 (2013-08-01) paragraphs [0044], [0076], [0114], [0115], [0116]; figures 3,5,8 -----	1,11
X	US 2004/088018 A1 (SAWCHUK ROBERT T [US] ET AL) 6 May 2004 (2004-05-06) paragraphs [0012], [0055], [0056], [0068], [0069], [0070]; figures 1,8 paragraphs [0060], [0061], [0064], [0081] - [0084], [0058] -----	1-10
A	US 2007/276445 A1 (SANGHERA RICK [US] ET AL) 29 November 2007 (2007-11-29) the whole document -----	1-11
A	US 2007/233196 A1 (STADLER ROBERT W [US] ET AL) 4 October 2007 (2007-10-04) the whole document -----	1-11



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

21 July 2015

Date of mailing of the international search report

29/07/2015

Name and mailing address of the ISA/

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Authorized officer

Monogyiou, Efstratia

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2015/026743

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2013197381	A1	01-08-2013	NONE
US 2004088018	A1	06-05-2004	AU 2003286860 A1 25-05-2004
		CA 2501954 A1	13-05-2004
		EP 1578490 A1	28-09-2005
		JP 4423201 B2	03-03-2010
		JP 2006504474 A	09-02-2006
		US 2004088018 A1	06-05-2004
		WO 2004039447 A1	13-05-2004
US 2007276445	A1	29-11-2007	CN 101522258 A 02-09-2009
		US 2007276445 A1	29-11-2007
		US 2014296932 A1	02-10-2014
US 2007233196	A1	04-10-2007	NONE

专利名称(译)	用于在医疗设备中选择感测矢量配置的方法和装置		
公开(公告)号	EP3133981A1	公开(公告)日	2017-03-01
申请号	EP2015721920	申请日	2015-04-21
[标]申请(专利权)人(译)	美敦力公司		
申请(专利权)人(译)	美敦力公司, INC.		
当前申请(专利权)人(译)	美敦力公司, INC.		
[标]发明人	GREENHUT SAUL E STADLER ROBERT W ZHANG XUSHENG		
发明人	GREENHUT, SAUL E. STADLER, ROBERT W. ZHANG, XUSHENG		
IPC分类号	A61B5/00 A61B5/0452 A61B5/04 A61B5/0456 A61N1/362		
CPC分类号	A61B5/0031 A61B5/0422 A61B5/0456 A61B5/046 A61B5/0464 A61B5/686 A61B5/7203 A61B5/7221 A61B5/7264 A61B2560/0468 A61N1/3621 G16H50/20		
优先权	61/983499 2014-04-24 US 14/260408 2014-04-24 US		
外部链接	Espacenet		

摘要(译)

一种用于确定感测矢量的方法和医疗设备, 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, 确定所述多个感测矢量中的每一个中的检测窗口期间的信号差异, 对感测矢量进行排序多个感测矢量响应于所确定的信号差异, 并响应于所确定的排序选择多个感测矢量中的一个或多个感测矢量。