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Stadler et al.

(54) **METHOD AND APPARATUS FOR DETECTING ARRHYTHMIAS IN A SUBCUTANEOUS MEDICAL DEVICE**

(71) Applicant: **Medtronic, Inc.**, Minneapolis, MN (US)

(72) Inventors: **Robert W. Stadler**, Shoreview, MN (US); **Raja N. Ghanem**, Ladera Ranch, CA (US); **Xusheng Zhang**, Shoreview, MN (US)

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A61B 5/042	(2006.01)

(52) **U.S. Cl.**

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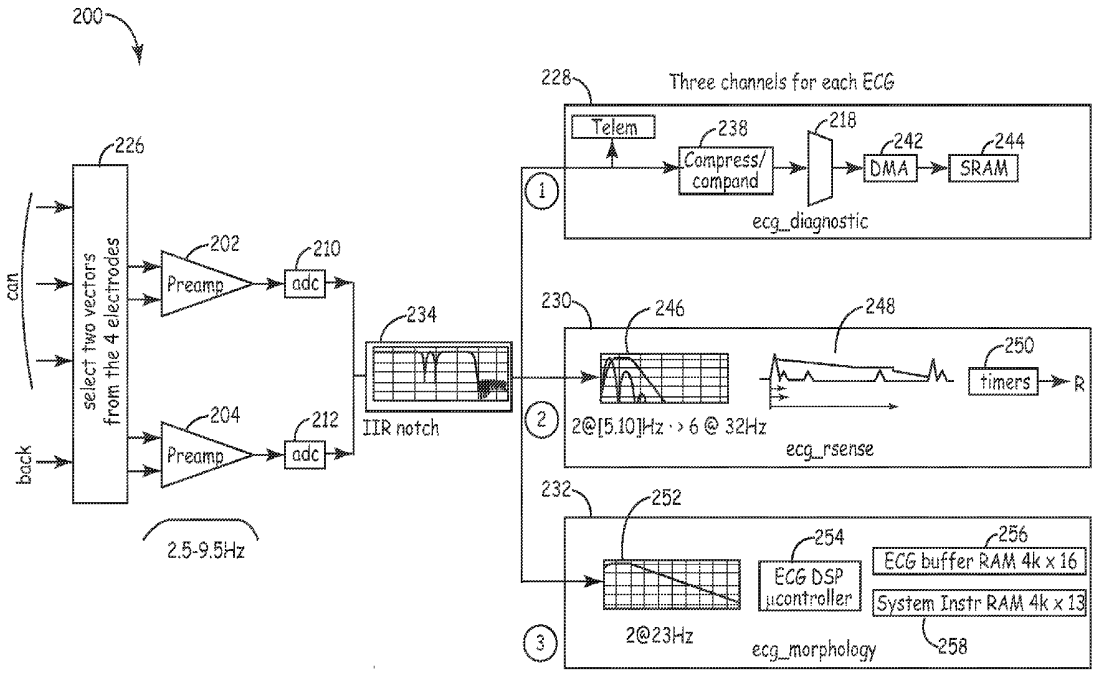
(57) **ABSTRACT**

A subcutaneously implantable cardiac medical device and a method of sensing a cardiac signal therein that includes a plurality of electrodes to sense a cardiac signal along a plurality of sensing vectors to detect a first interval and a second interval associated with a first detected event, and a processor configured to determine whether the first interval and the second interval are shorter than a predetermined threshold, determine whether the first interval and the second interval are similar, and determine, in response to the first interval and the second interval being similar, whether the sensed cardiac signal is either a noisy signal or a QRS signal.



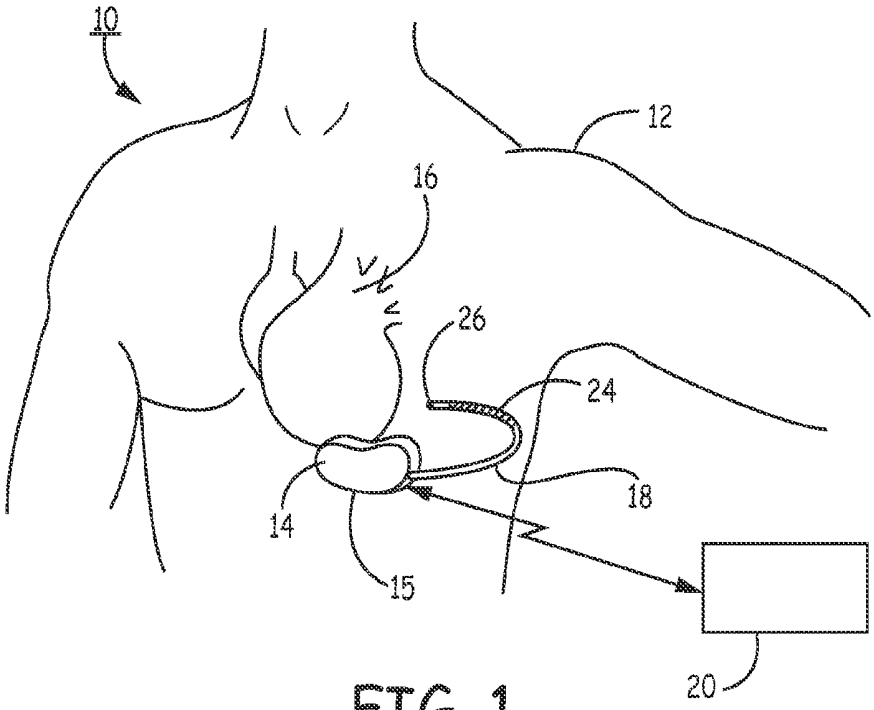


FIG. 1

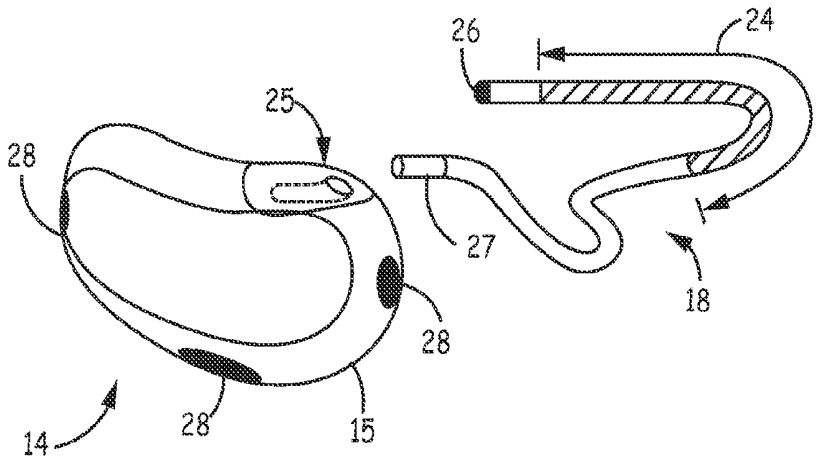


FIG. 2

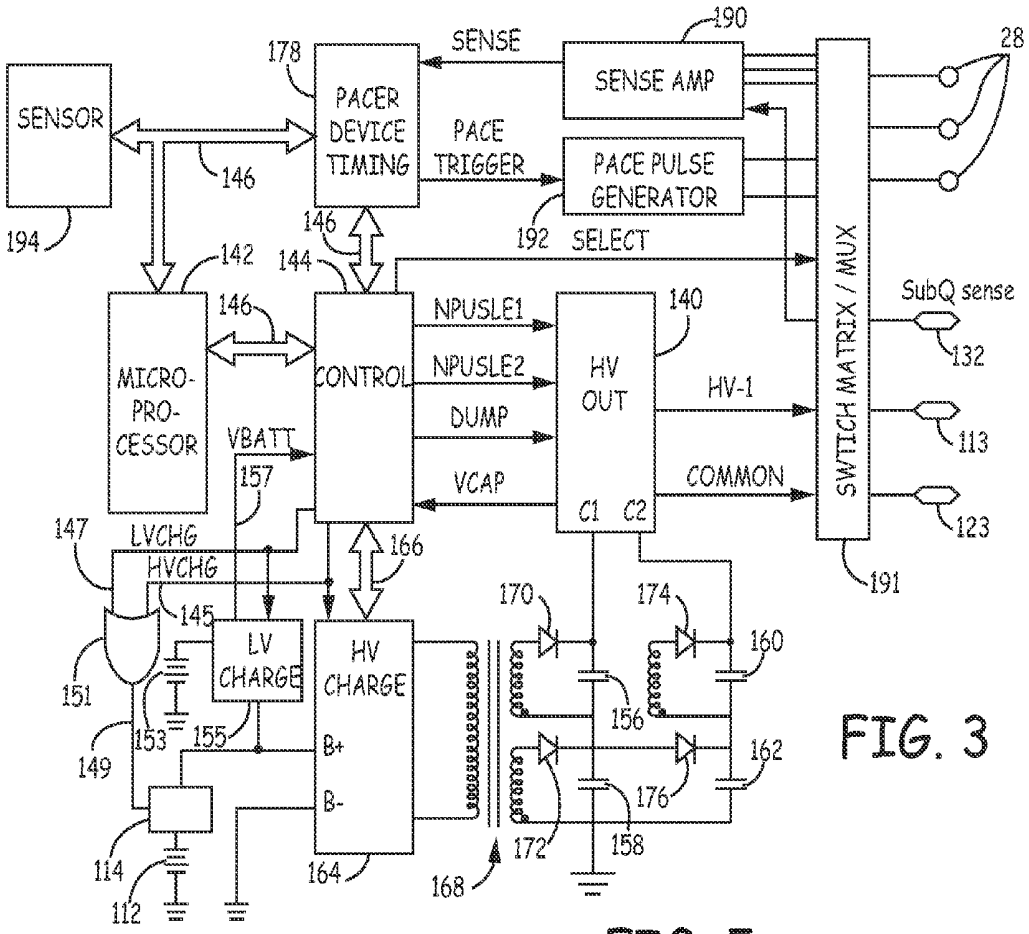
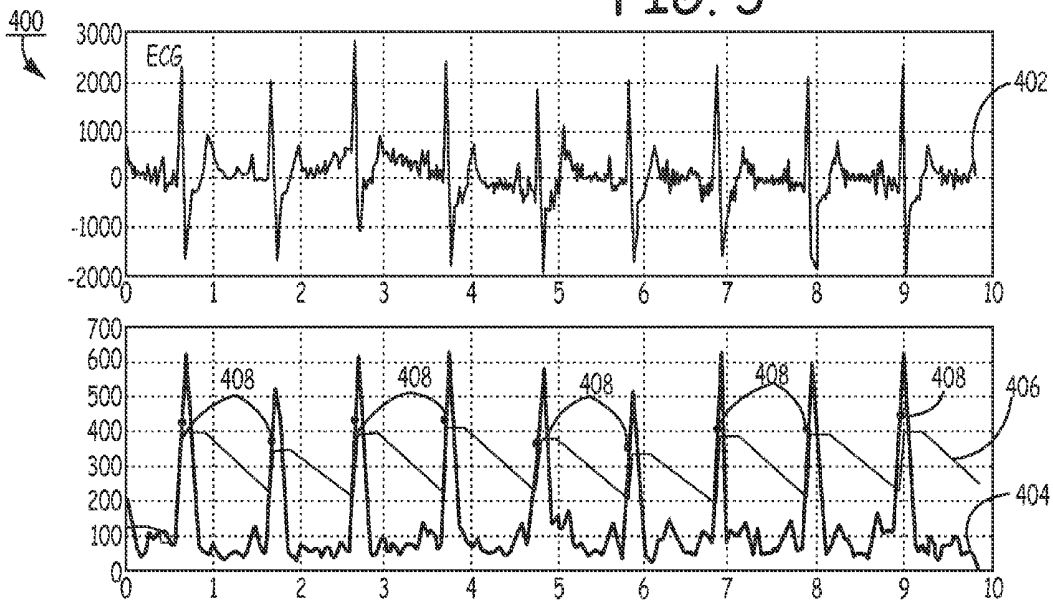

SENSOR
194
146
178
PACER DEVICE TIMING
SENSE
PACE TRIGGER
190
SENSE AMP
PACE PULSE GENERATOR
192
SELECT
28
SWITCH MATRIX / MUX
191
SubQ sense
132
113
123
142
144
MICRO-PRO-CESSOR
CONTROL
NPUSLE1
NPUSLE2
DUMP
VCAP
VBATT
157
HV OUT
140
HV-1
COMMON
C1
C2
147
LVCHG
HVCHG
166
145
LV CHARGE
HV CHARGE
B+
B-
151
153
155
149
114
112
164
168
170
172
174
156
158
160
162
176

FIG. 3

FIG. 5


400
ECG
3000
2000
1000
0
-1000
-2000
0
1
2
3
4
5
6
7
8
9
10
402
700
600
500
400
300
200
100
0
408
406
404

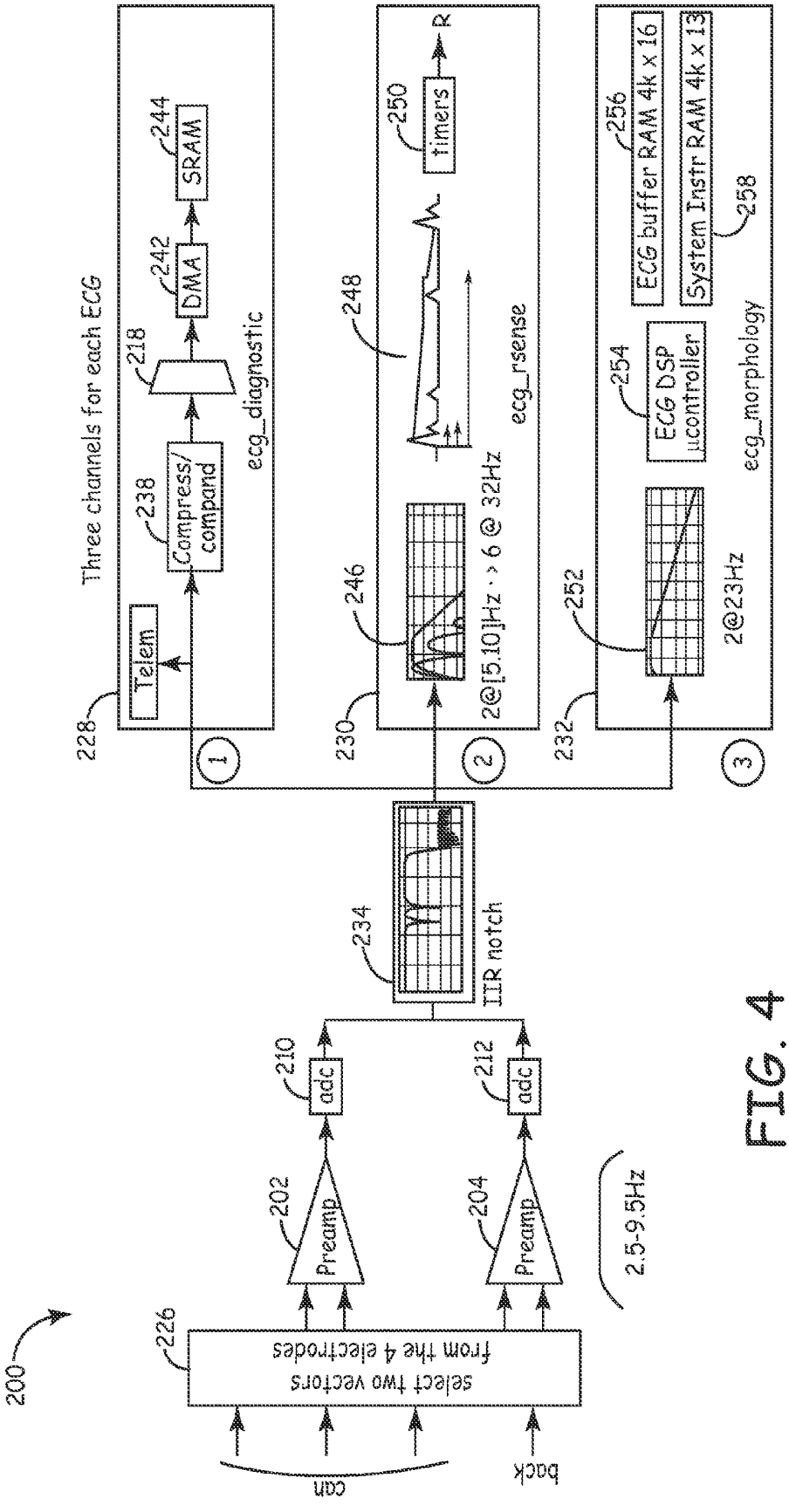

200
226
select two vectors
from the 4 electrodes
can
back
202
Preamp
204
Preamp
210
adc
212
adc
2.5-9.5Hz
234
IIR notch
Three channels for each ECG
228
Telem
238
Compress/
compand
218
242
DMA
244
SRAM
ecg_diagnostic
1
230
246
2@[5.10]Hz , 6 @ 32Hz
248
250
timers
R
ecg_rsense
2
232
252
2@23Hz
254
ECG DSP
µcontroller
256
ECG buffer RAM 4k x 16
System Instr RAM 4k x 13
258
ecg_morphology
3

FIG. 4

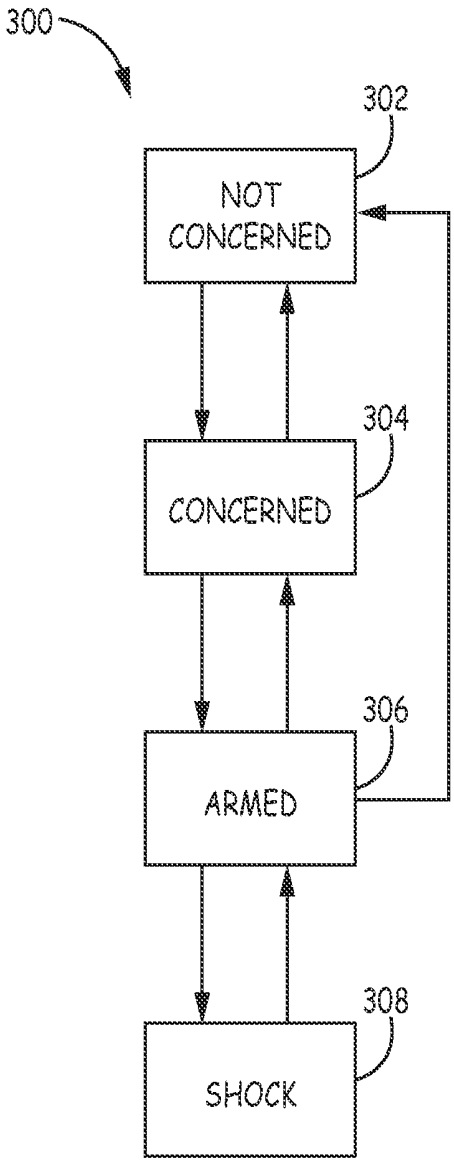


FIG. 6

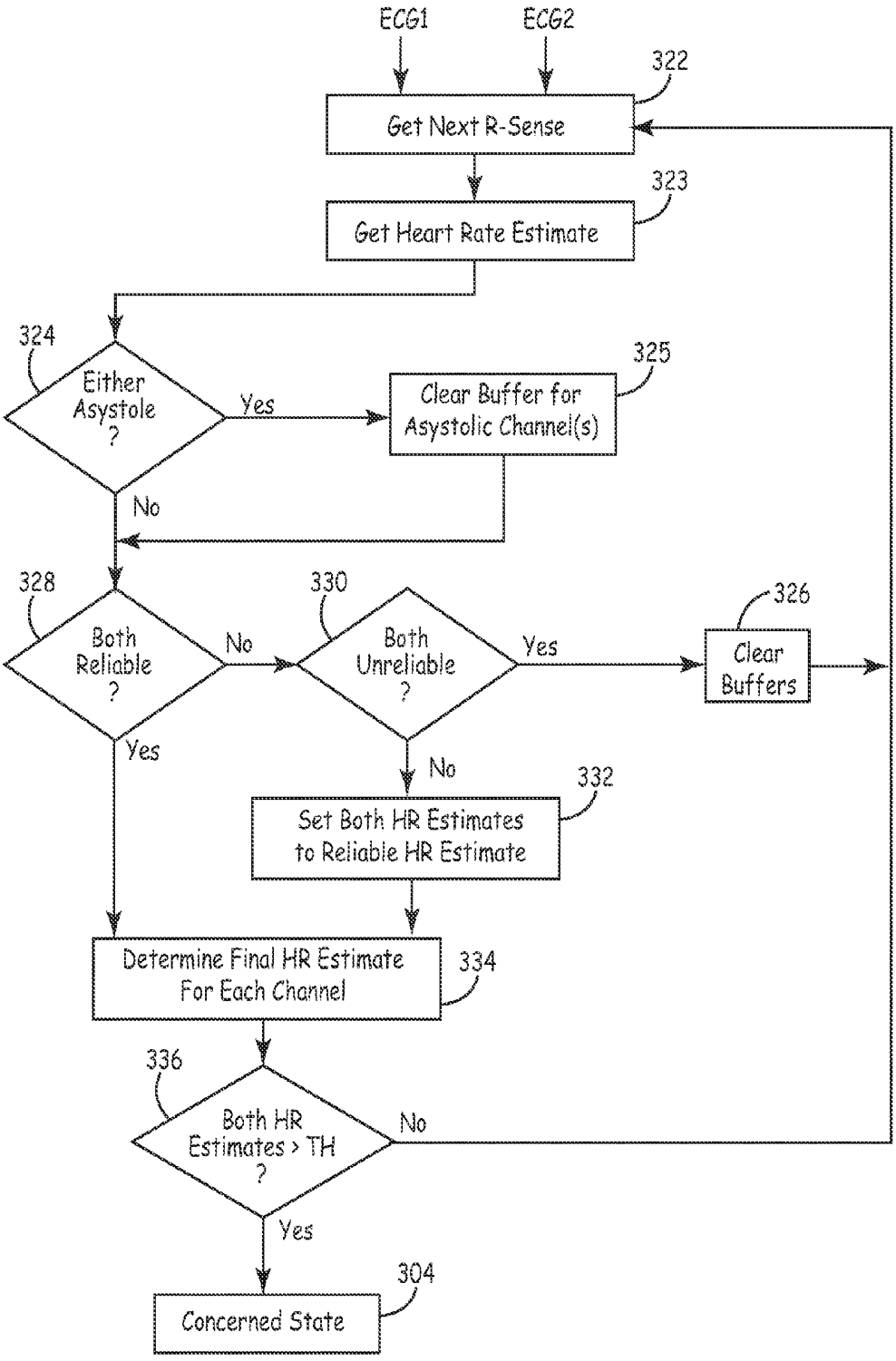

ECG1
ECG2
322
Get Next R-Sense
323
Get Heart Rate Estimate
324
Either Asystole ?
Yes
325
Clear Buffer for Asystolic Channel(s)
No
328
Both Reliable ?
No
330
Both Unreliable ?
Yes
326
Clear Buffers
Yes
No
332
Set Both HR Estimates to Reliable HR Estimate
Determine Final HR Estimate For Each Channel
334
336
Both HR Estimates > TH ?
No
Yes
304
Concerned State

FIG. 7A

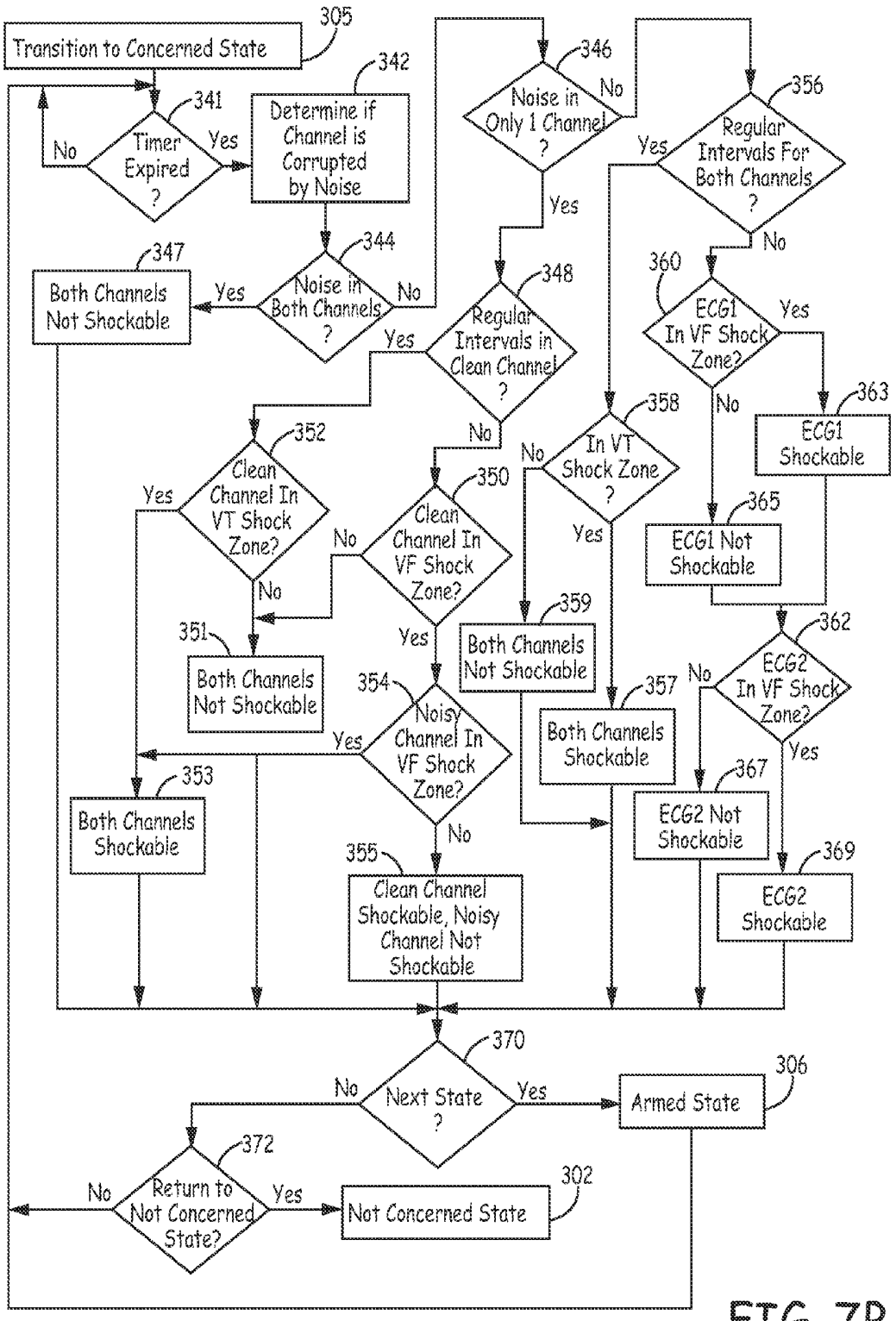

Transition to Concerned State
305
Timer Expired ?
341
No
Yes
Determine if Channel is Corrupted by Noise
342
Noise in Both Channels ?
344
Yes
No
Both Channels Not Shockable
347
Noise in Only 1 Channel ?
346
No
Yes
Regular Intervals in Clean Channel ?
348
Yes
No
Clean Channel In VT Shock Zone?
352
Yes
No
Clean Channel In VF Shock Zone?
350
No
Yes
Both Channels Not Shockable
351
Both Channels Shockable
353
Noisy Channel In VF Shock Zone?
354
Yes
No
Clean Channel Shockable, Noisy Channel Not Shockable
355
In VT Shock Zone ?
358
No
Yes
Both Channels Not Shockable
359
Both Channels Shockable
357
Regular Intervals For Both Channels ?
356
Yes
No
ECG1 In VF Shock Zone?
360
Yes
No
ECG1 Shockable
363
ECG1 Not Shockable
365
ECG2 In VF Shock Zone?
362
No
Yes
ECG2 Not Shockable
367
ECG2 Shockable
369
Next State ?
370
No
Yes
Armed State
306
Return to Not Concerned State?
372
No
Yes
Not Concerned State
302

FIG. 7B

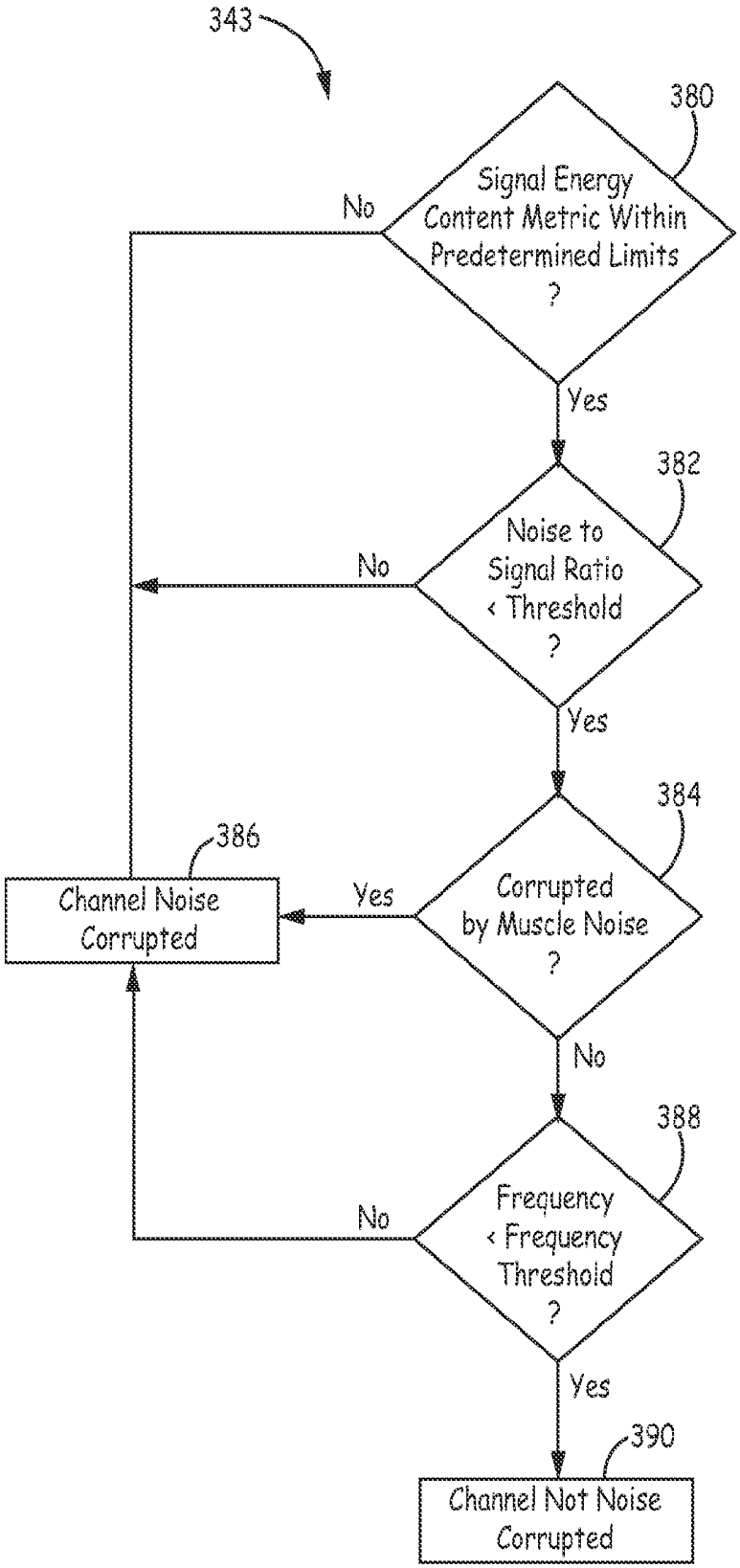

343
380
Signal Energy Content Metric Within Predetermined Limits ?
No
Yes
382
Noise to Signal Ratio < Threshold ?
No
Yes
384
Corrupted by Muscle Noise ?
Yes
386
Channel Noise Corrupted
No
388
Frequency < Frequency Threshold ?
No
Yes
390
Channel Not Noise Corrupted

FIG. 7C

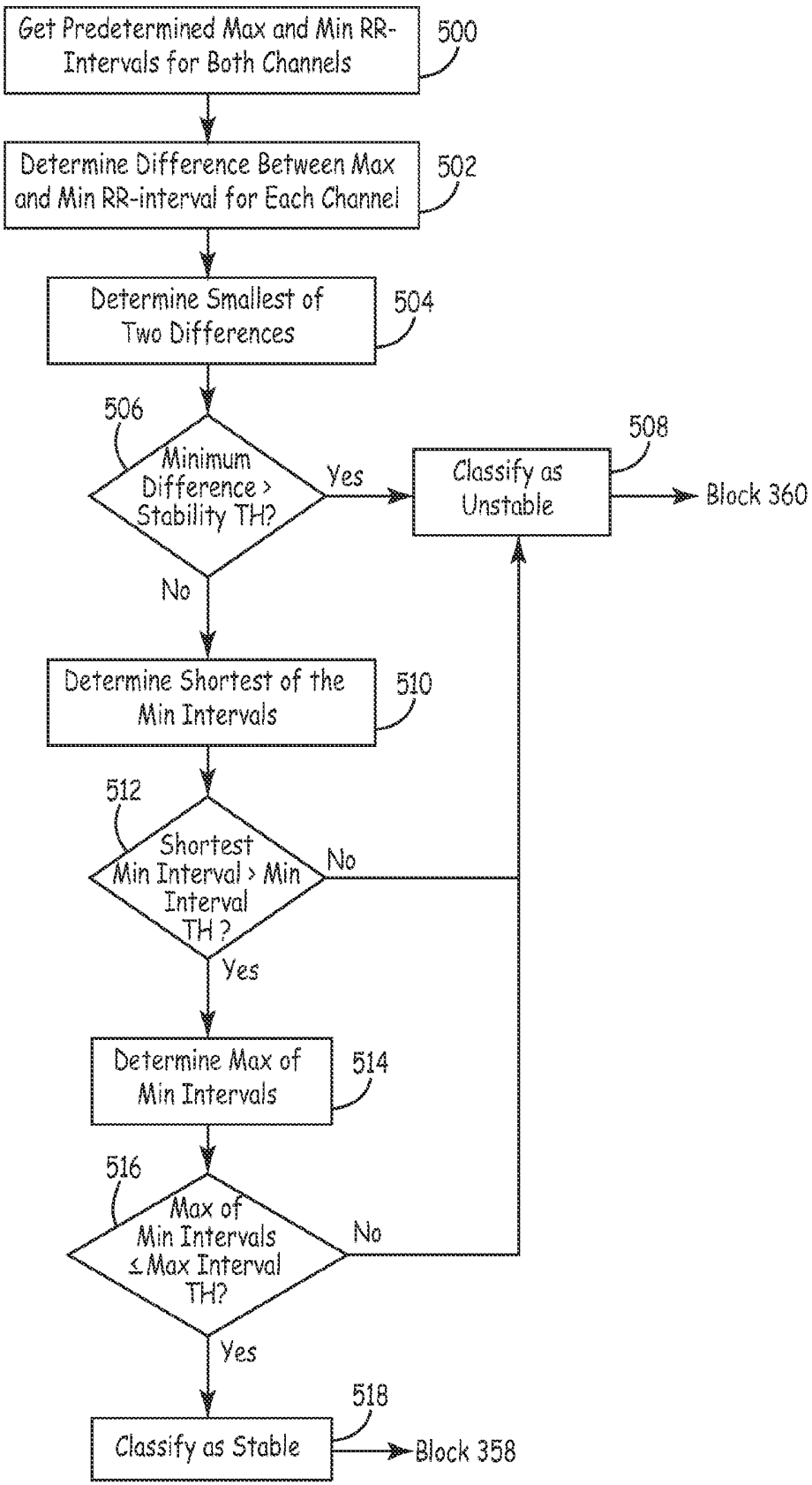

Get Predetermined Max and Min RR-Intervals for Both Channels
500
Determine Difference Between Max and Min RR-interval for Each Channel
502
Determine Smallest of Two Differences
504
506
Minimum Difference > Stability TH?
Yes
508
Classify as Unstable
Block 360
No
Determine Shortest of the Min Intervals
510
512
Shortest Min Interval > Min Interval TH ?
No
Yes
Determine Max of Min Intervals
514
516
Max of Min Intervals ≤ Max Interval TH?
No
Yes
518
Classify as Stable
Block 358

FIG. 7D

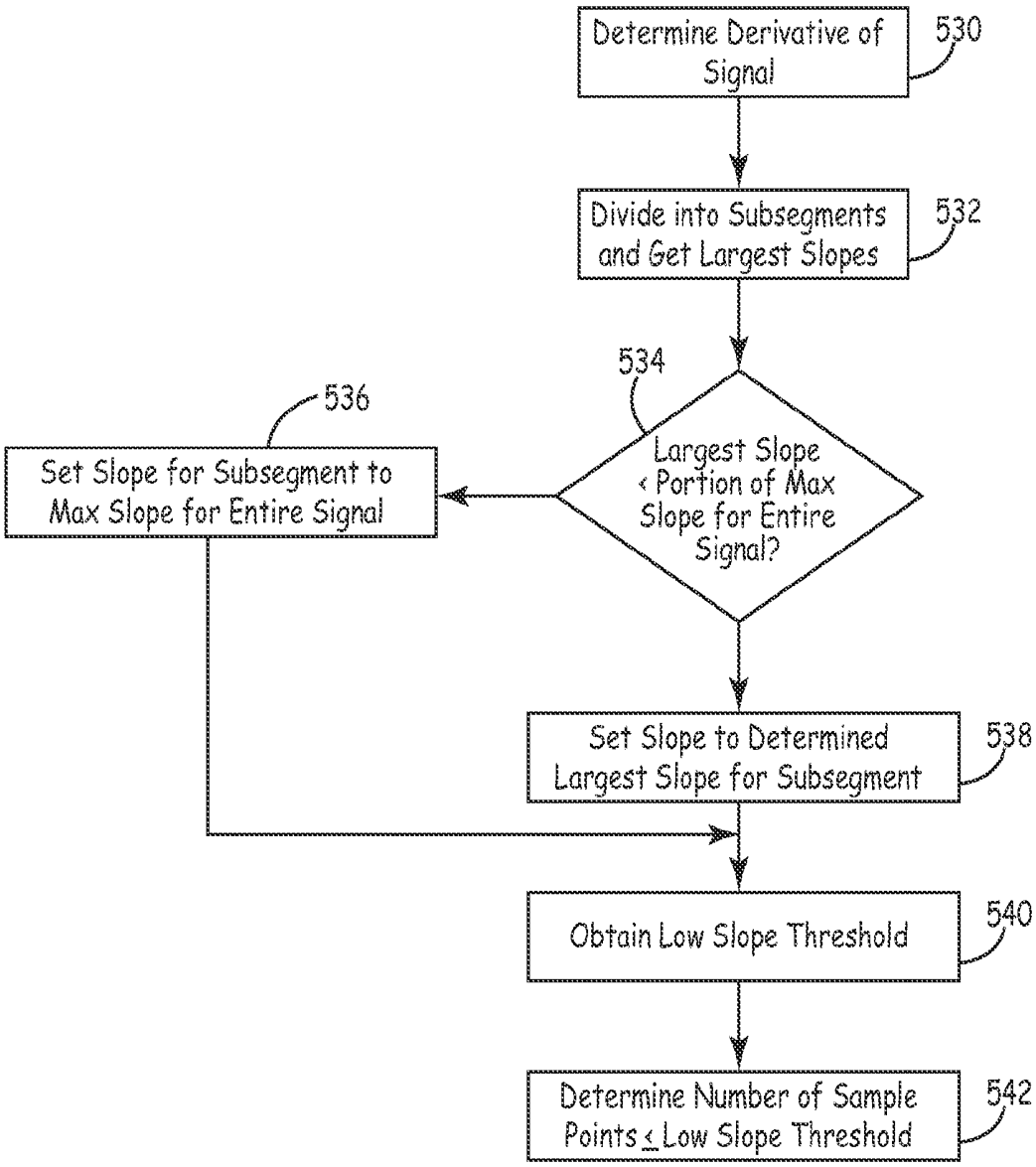

Determine Derivative of Signal
530
Divide into Subsegments and Get Largest Slopes
532
534
Largest Slope < Portion of Max Slope for Entire Signal?
536
Set Slope for Subsegment to Max Slope for Entire Signal
Set Slope to Determined Largest Slope for Subsegment
538
Obtain Low Slope Threshold
540
Determine Number of Sample Points < Low Slope Threshold
542

FIG. 7E

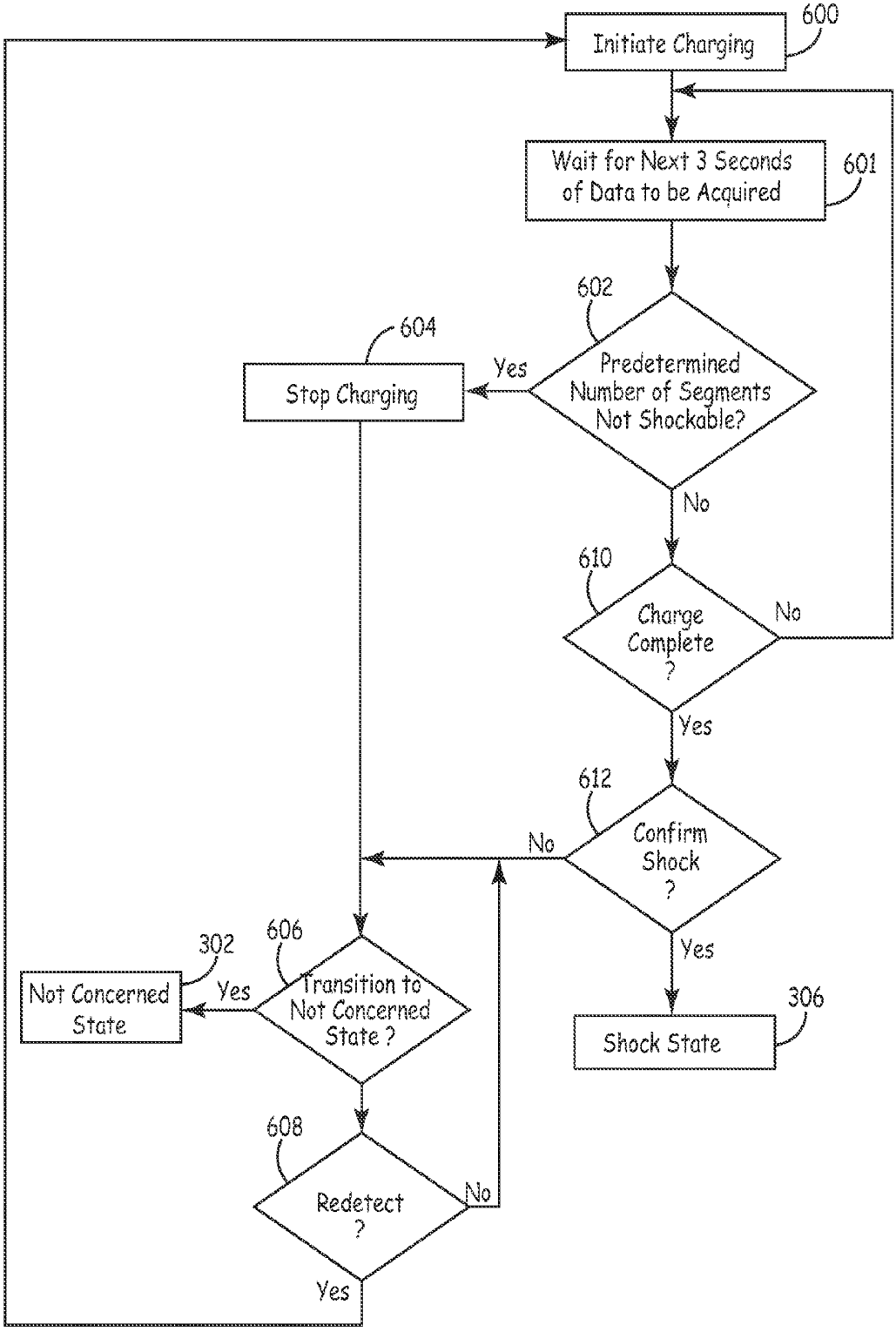

Initiate Charging
600
Wait for Next 3 Seconds of Data to be Acquired
601
602
Predetermined Number of Segments Not Shockable?
Yes
604
Stop Charging
No
610
Charge Complete ?
No
Yes
612
Confirm Shock ?
No
Yes
606
Transition to Not Concerned State ?
Yes
302
Not Concerned State
306
Shock State
608
Redetect ?
No
Yes

FIG. 7F

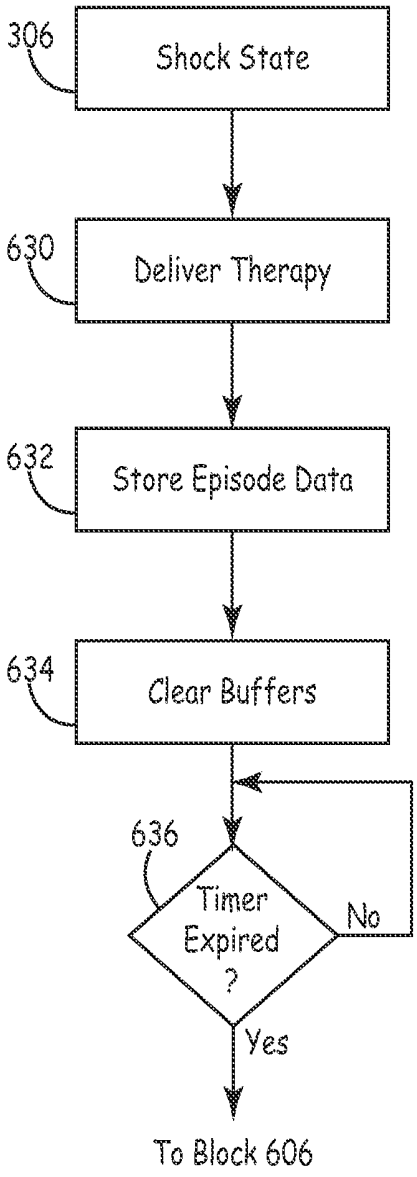

306
Shock State
630
Deliver Therapy
632
Store Episode Data
634
Clear Buffers
636
Timer Expired ?
No
Yes
To Block 606

FIG. 7G

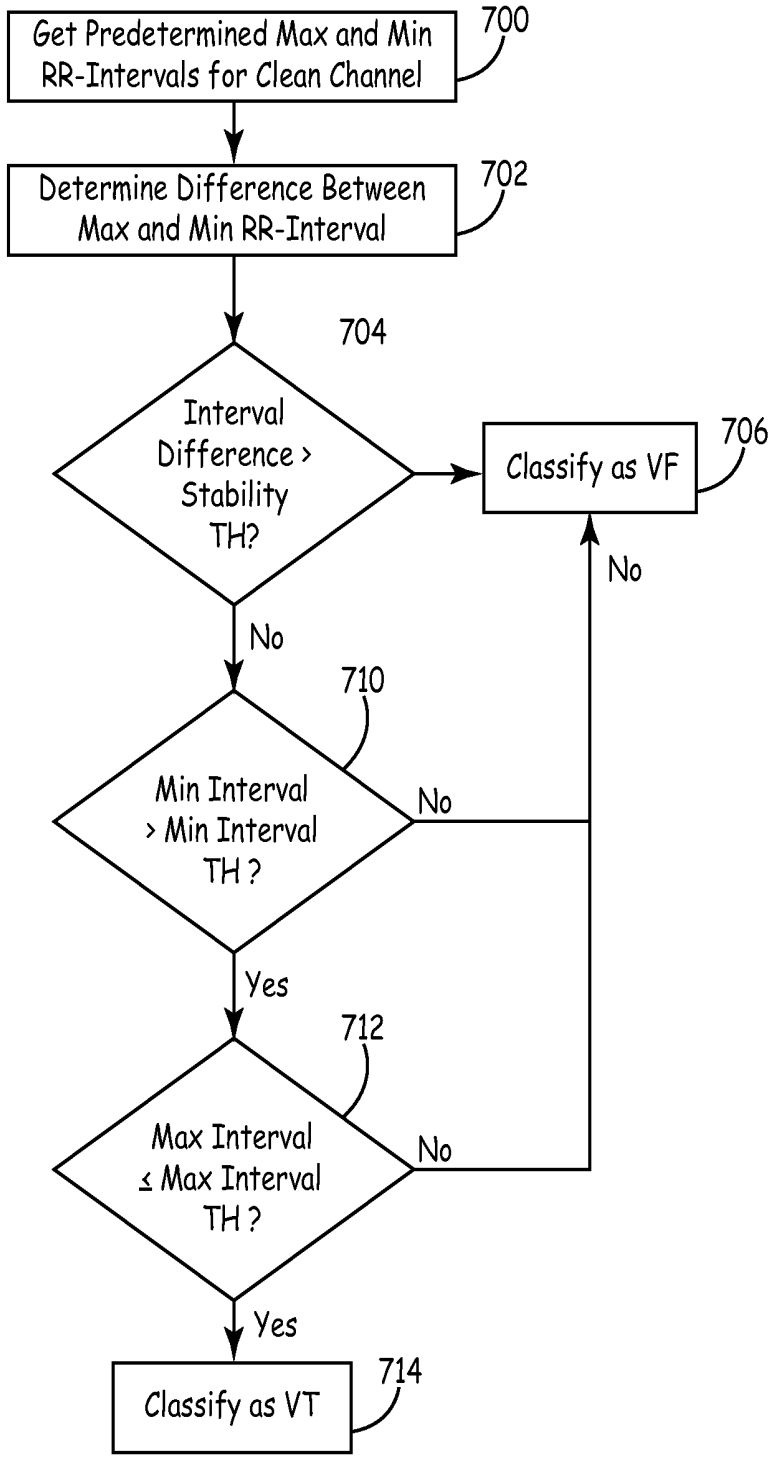

Get Predetermined Max and Min RR-Intervals for Clean Channel
700
Determine Difference Between Max and Min RR-Interval
702
704
Interval Difference > Stability TH?
Classify as VF
706
No
No
710
Min Interval > Min Interval TH ?
No
Yes
712
Max Interval ≤ Max Interval TH ?
No
Yes
Classify as VT
714

FIG. 7H

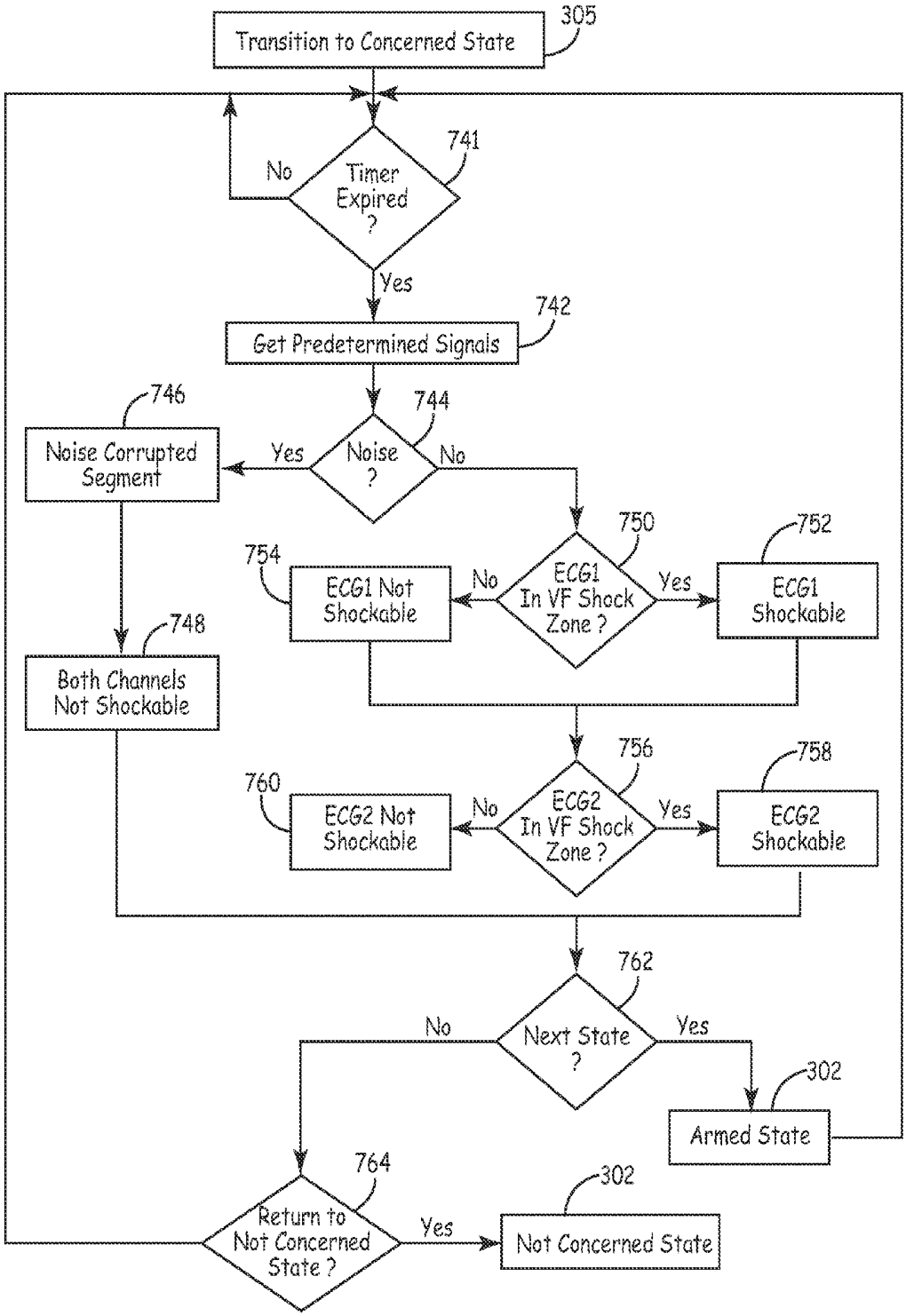

Transition to Concerned State
305
741
Timer Expired ?
No
Yes
742
Get Predetermined Signals
744
Noise ?
Yes
No
746
Noise Corrupted Segment
748
Both Channels Not Shockable
750
ECG1 In VF Shock Zone ?
No
Yes
752
ECG1 Shockable
754
ECG1 Not Shockable
756
ECG2 In VF Shock Zone ?
No
Yes
758
ECG2 Shockable
760
ECG2 Not Shockable
762
Next State ?
No
Yes
302
Armed State
764
Return to Not Concerned State ?
Yes
302
Not Concerned State

FIG. 7I

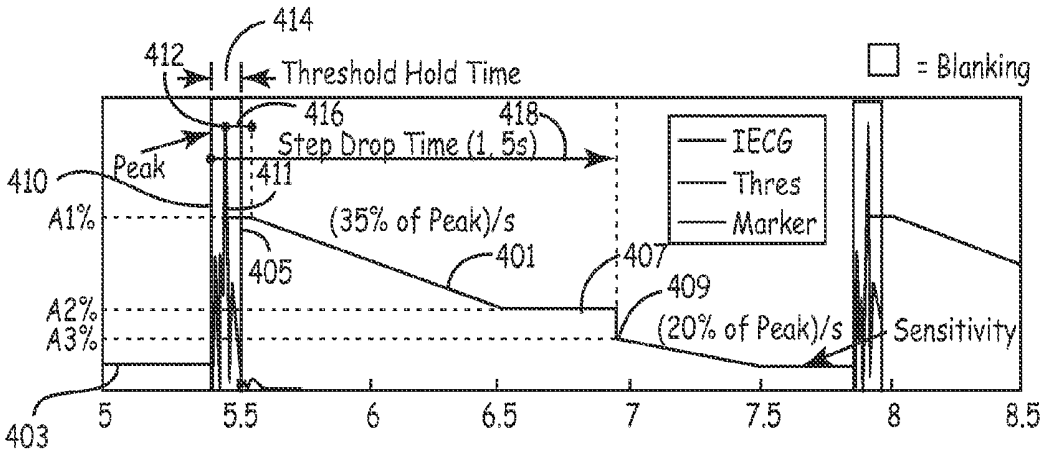

414
412
Threshold Hold Time
= Blanking
416
418
Step Drop Time (1.5s)
IECG
Thres
Marker
410
Peak
411
A1%
(35% of Peak)/s
405
401
407
409
A2%
A3%
(20% of Peak)/s
Sensitivity
403
5
5.5
6
6.5
7
7.5
8
8.5

FIG. 8

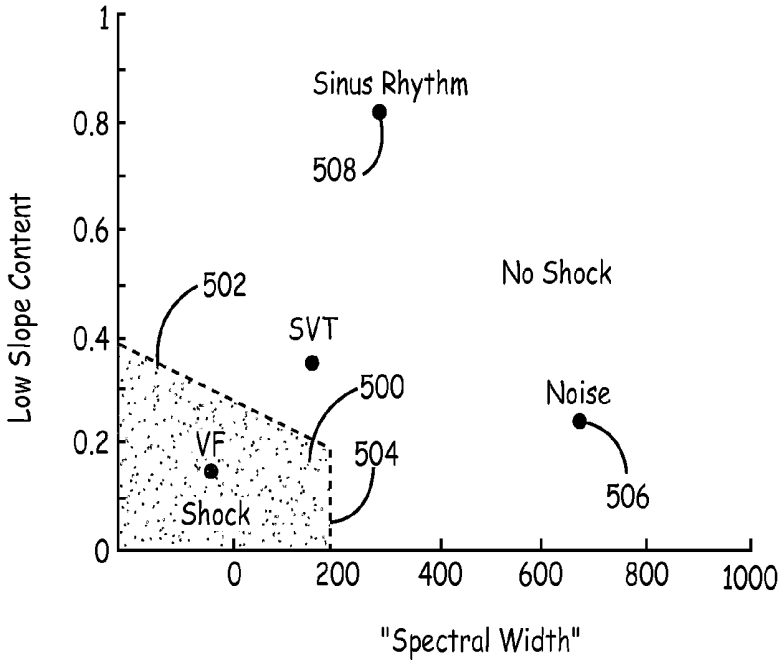

1
0.8
0.6
0.4
0.2
0
Low Slope Content
Sinus Rhythm
508
No Shock
502
SVT
500
Noise
VF
504
Shock
506
0
200
400
600
800
1000
"Spectral Width"

FIG. 10

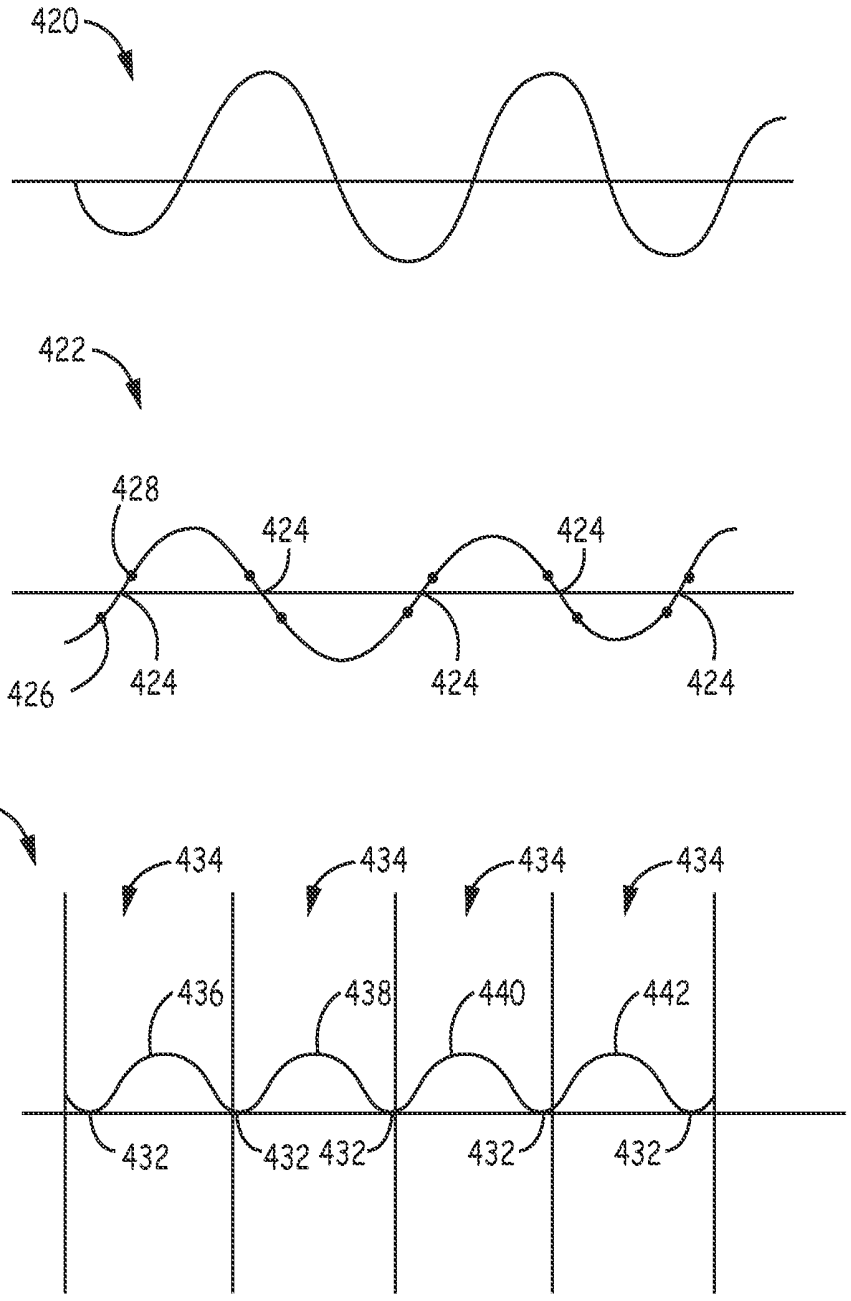

420
422
428
424
424
426
424
424
424
430
434
434
434
434
436
438
440
442
432
432
432
432
432

FIG. 9A

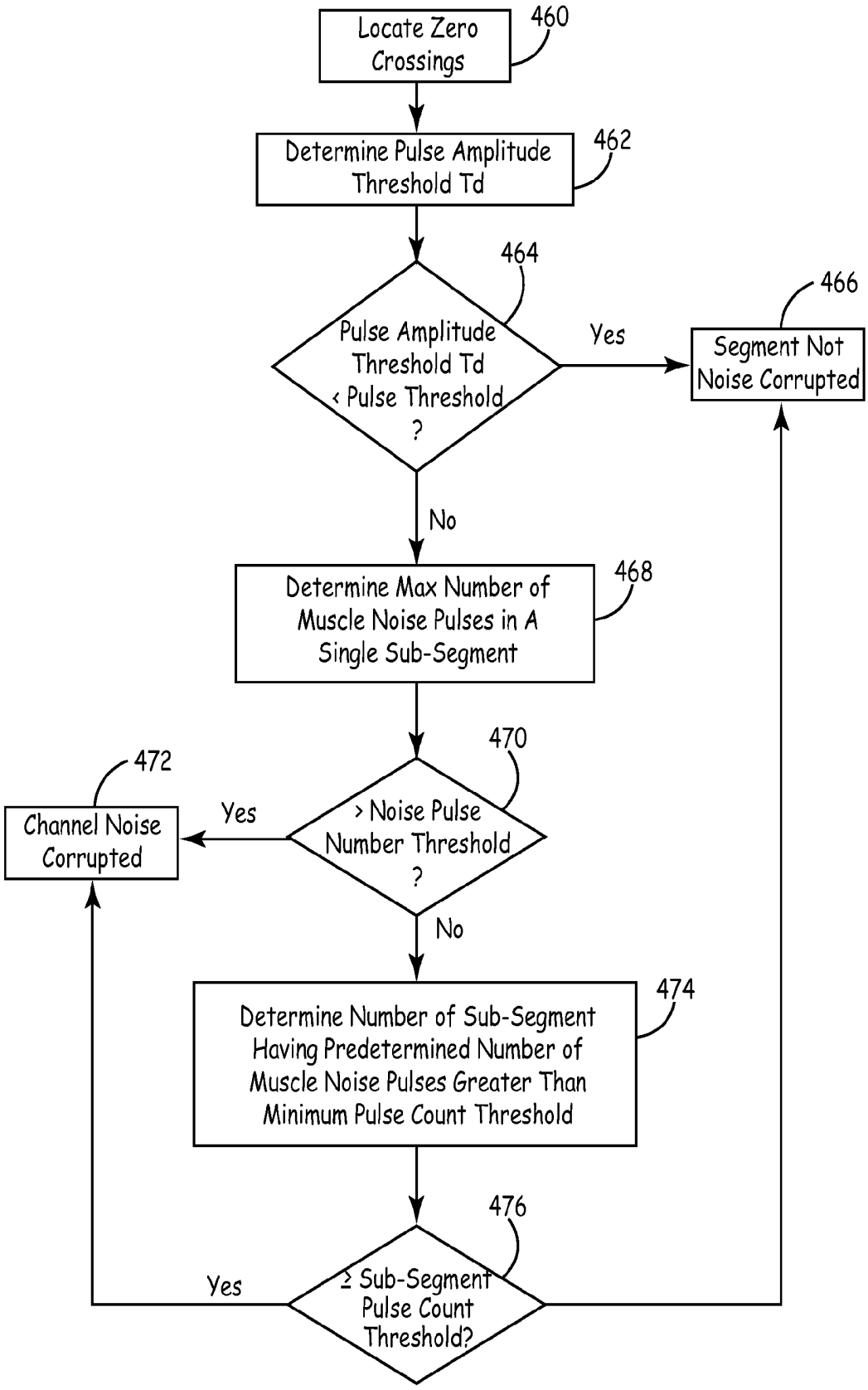

Locate Zero Crossings
460
Determine Pulse Amplitude Threshold Td
462
Pulse Amplitude Threshold Td < Pulse Threshold ?
464
Yes
Segment Not Noise Corrupted
466
No
Determine Max Number of Muscle Noise Pulses in A Single Sub-Segment
468
> Noise Pulse Number Threshold ?
470
Yes
Channel Noise Corrupted
472
No
Determine Number of Sub-Segment Having Predetermined Number of Muscle Noise Pulses Greater Than Minimum Pulse Count Threshold
474
≥ Sub-Segment Pulse Count Threshold?
476
Yes

FIG. 9B

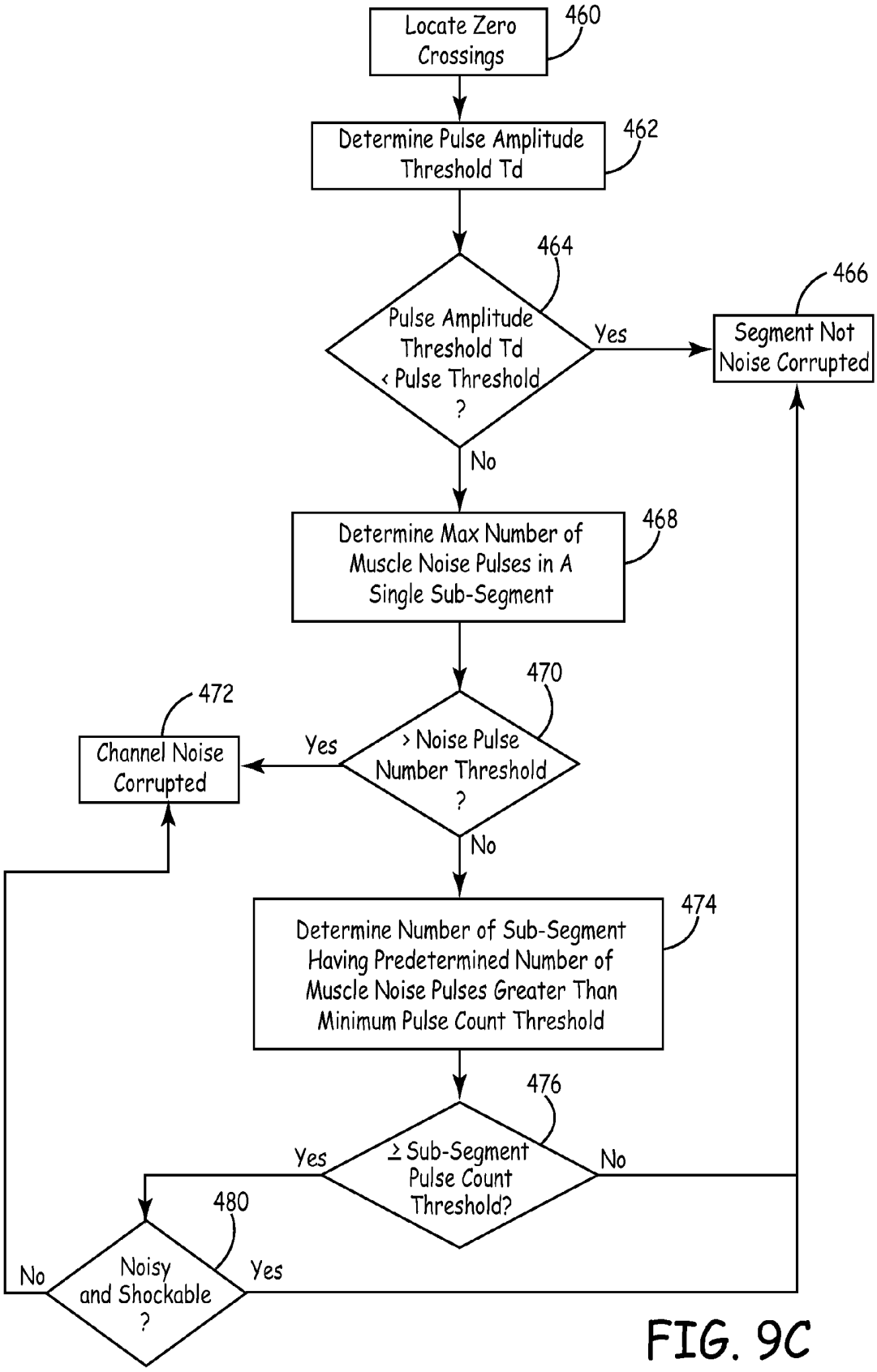

Locate Zero Crossings
460
Determine Pulse Amplitude Threshold Td
462
464
Pulse Amplitude Threshold Td < Pulse Threshold ?
Yes
466
Segment Not Noise Corrupted
No
Determine Max Number of Muscle Noise Pulses in A Single Sub-Segment
468
470
> Noise Pulse Number Threshold ?
Yes
472
Channel Noise Corrupted
No
Determine Number of Sub-Segment Having Predetermined Number of Muscle Noise Pulses Greater Than Minimum Pulse Count Threshold
474
476
≥ Sub-Segment Pulse Count Threshold?
Yes
No
480
Noisy and Shockable ?
No
Yes

FIG. 9C

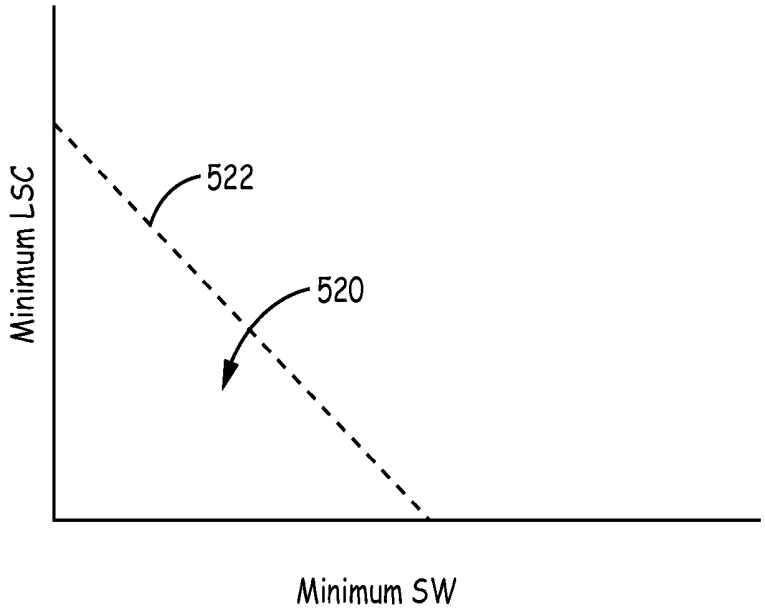


FIG. 11A

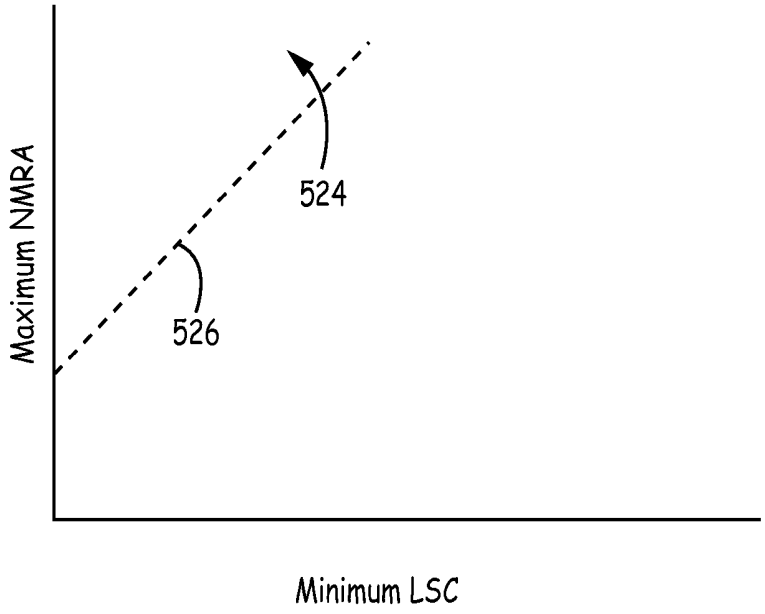


FIG. 11B

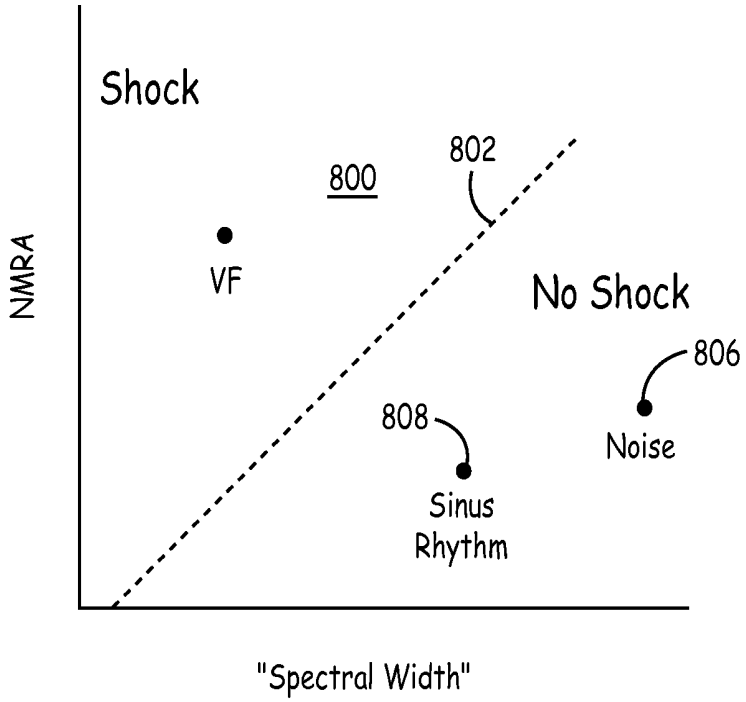

Shock
800
802
VF
No Shock
806
808
Noise
Sinus
Rhythm
NMRA
"Spectral Width"

FIG. 12

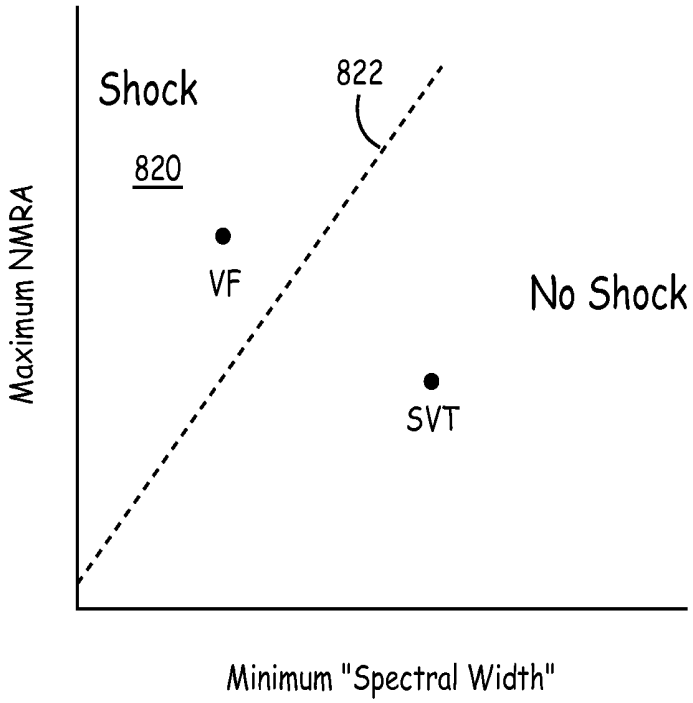

Shock
822
820
VF
No Shock
SVT
Maximum NMRA
Minimum "Spectral Width"

FIG. 13

METHOD AND APPARATUS FOR DETECTING ARRHYTHMIAS IN A SUBCUTANEOUS MEDICAL DEVICE

RELATED APPLICATION

[0001] This application is a continuation of U.S. patent application Ser. No. 11/687,094, filed Mar. 16, 2007 entitled "METHOD AND APPARATUS FOR DETECTING ARRHYTHMIAS IN A SUBCUTANEOUS MEDICAL DEVICE", which claims priority and other benefits from U.S. Provisional Patent Application Ser. No. 60/786,981, filed Mar. 29, 2006, entitled "METHOD AND APPARATUS FOR DETECTING ARRHYTHMIAS IN A SUBCUTANEOUS MEDICAL DEVICE", both of which are incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention generally relates to an implantable medical device system, and more particularly to a method and apparatus for detecting arrhythmias in a subcutaneous medical device.

BACKGROUND OF THE INVENTION

[0003] Many types of implantable medical devices (IMDs) have been implanted that deliver relatively high-energy cardioversion and/or defibrillation shocks to a patient's heart when a malignant tachyarrhythmia, e.g., ventricular tachycardia or ventricular fibrillation, is detected. Cardioversion shocks are typically delivered in synchrony with a detected R-wave when fibrillation detection criteria are met, whereas defibrillation shocks are typically delivered when fibrillation criteria are met and an R-wave cannot be discerned from the electrogram (EGM).

[0004] The current state of the art of ICDs or implantable pacemaker/cardioverter/defibrillators (PCDs) includes a full featured set of extensive programmable parameters which includes multiple arrhythmia detection criteria, multiple therapy prescriptions (for example, stimulation for pacing in the atrial, ventricular and/or both chambers, bi-atrial and/or bi-ventricular pacing, arrhythmia overdrive or entrainment stimulation, and high level stimulation for cardioversion and/or defibrillation), extensive diagnostic capabilities and high speed telemetry systems.

[0005] Current technology for the implantation of an IMD uses a transvenous approach for cardiac electrodes and lead wires. The defibrillator canister/housing is generally implanted as an active can for defibrillation and electrodes positioned in the heart are used for pacing, sensing and detection of arrhythmias.

[0006] Attempts are being made to identify patients who are asymptomatic by conventional measures but are nevertheless at risk of a future sudden death episode. Current studies of patient populations, e.g., the MADIT II and SCD-HeFT studies, are establishing that there are large numbers of patients in any given population that are susceptible to sudden cardiac death, that they can be identified with some degree of certainty and that they are candidates for a prophylactic implantation of a defibrillator (often called primary prevention).

[0007] One option proposed for this patient population is to implant a prophylactic subcutaneous implantable device (SubQ device). As SubQ device technology evolves, it may develop a clear and distinct advantage over non-SubQ devices. For example, the SubQ device does not require leads to be placed in the bloodstream. Accordingly, complications arising from leads placed in the cardiovasculature environment are eliminated. Further, endocardial lead placement is not possible with patients who have a mechanical heart valve implant and is not generally recommended for pediatric cardiac patients. For these and other reasons, a SubQ device may be preferred over an ICD.

[0008] There are technical challenges associated with the operation of a SubQ device. For example, SubQ device sensing is challenged by the presence of muscle artifact, respiration and other physiological signal sources. This is particularly because the SubQ device is limited to far-field sensing since there are no intracardial or epicardial electrodes in a subcutaneous system. Further, sensing of atrial activation from subcutaneous electrodes is limited since the atria represent a small muscle mass and the atrial signals are not sufficiently detectable transthoracically.

[0009] Yet another challenge could occur in situations where it is desirable to combine a SubQ device with an existing pacemaker (IPG) in a patient. While this may be desirable in a case where an IPG patient may need a defibrillator, a combination implant of a SubQ device and an IPG may result in inappropriate therapy by the SubQ device, which may pace or shock based on spikes from the IPG. Specifically, each time the IPG emits a pacing stimulus, the SubQ device may interpret it as a genuine cardiac beat. The result can be over-counting beats from the atrium, ventricles or both; or, because of the larger pacing spikes, sensing of arrhythmic signals (which are typically much smaller in amplitude) may be compromised.

[0010] Therefore, for these and other reasons, a need exists for an improved method and apparatus to reliably sense and detect arrhythmias in a subcutaneous device, while rejecting noise and other physiologic signals.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Aspects and features of the present invention will be appreciated as the same becomes better understood by reference to the following detailed description of the embodiments of the invention when considered in connection with the accompanying drawings, wherein:

[0012] FIG. **1** is a schematic diagram of an exemplary subcutaneous device in which the present invention may be usefully practiced;

[0013] FIG. **2** is a schematic diagram of the implantable medical device of FIG. **1**, according to one exemplary embodiment of the invention.

[0014] FIG. **3** is an exemplary schematic diagram of electronic circuitry within a hermetically sealed housing of a subcutaneous device of the present invention;

[0015] FIG. **4** is a schematic diagram of signal processing aspects of a subcutaneous device according to an exemplary embodiment of the present invention;

[0016] FIG. **5** is a state diagram of detection of arrhythmias in a subcutaneous device according to an embodiment of the present invention;

[0017] FIG. **6** is a flow chart of a method for detecting arrhythmias in a subcutaneous device according to an embodiment of the present invention;

[0018] FIGS. **7A-7I** are flow charts of a method for detecting arrhythmias in a subcutaneous device according to an embodiment of the present invention;

[0019] FIG. **8** is a graphical representation of sensing of cardiac activity according to an embodiment of the present invention;

[0020] FIG. **9**A is a graphical representation of a determination of whether a signal is corrupted by muscle noise according to an embodiment of the present invention;

[0021] FIG. **9**B is a flowchart of a method of determining whether a signal is corrupted by muscle noise according to an embodiment of the present invention;

[0022] FIG. **9**C is a flowchart of a method of determining whether a signal is corrupted by muscle noise according to an embodiment of the present invention;

[0023] FIG. **10** is a graphical representation of a VF shock zone according to an embodiment of the present invention;

[0024] FIGS. **11**A and **11**B are graphical representations of the determination of whether an event is within a shock zone according to an embodiment of the present invention;

[0025] FIG. **12** is a graphical representation of a shock zone according to an embodiment of the present invention; and

[0026] FIG. **13** is a graphical representation of the determination of whether an event is within a shock zone according to an embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0027] FIG. **1** is a schematic diagram of an exemplary subcutaneous device in which the present invention may be usefully practiced. As illustrated in FIG. **1**, a subcutaneous device **14** according to an embodiment of the present invention is subcutaneously implanted outside the ribcage of a patient **12**, anterior to the cardiac notch. Further, a subcutaneous sensing and cardioversion/defibrillation therapy delivery lead **18** in electrical communication with subcutaneous device **14** is tunneled subcutaneously into a location adjacent to a portion of a latissimus dorsi muscle of patient **12**. Specifically, lead **18** is tunneled subcutaneously from the median implant pocket of the subcutaneous device **14** laterally and posterially to the patient's back to a location opposite the heart such that the heart **16** is disposed between the subcutaneous device **14** and the distal electrode coil **24** and distal sensing electrode **26** of lead **18**.

[0028] It is understood that while the subcutaneous device **14** is shown positioned through loose connective tissue between the skin and muscle layer of the patient, the term "subcutaneous device" is intended to include a device that can be positioned in the patient to be implanted using any non-intravenous location of the patient, such as below the muscle layer or within the thoracic cavity, for example.

[0029] Further referring to FIG. **1**, a programmer **20** is shown in telemetric communication with subcutaneous device **14** by an RF communication link **22**. Communication link **22** may be any appropriate RF link such as Bluetooth, WiFi, MICS, or as described in U.S. Pat. No. 5,683,432 "Adaptive Performance-Optimizing Communication System for Communicating with an Implantable Medical Device" to Goedeke, et al and incorporated herein by reference in its entirety.

[0030] Subcutaneous device **14** includes a housing **15** that may be constructed of stainless steel, titanium or ceramic as described in U.S. Pat. No. 4,180,078 "Lead Connector for a Body Implantable Stimulator" to Anderson and U.S. Pat. No. 5,470,345 "Implantable Medical Device with Multi-layered Ceramic Enclosure" to Hassler, et al, both incorporated herein by reference in their entireties. The electronics circuitry of SubQ ICD **14** may be incorporated on a polyimide flex circuit, printed circuit board (PCB) or ceramic substrate with integrated circuits packaged in leadless chip carriers and/or chip scale packaging (CSP).

[0031] Subcutaneous lead **18** includes a distal defibrillation coil electrode **24**, a distal sensing electrode **26**, an insulated flexible lead body and a proximal connector pin **27** (shown in FIG. **2**) for connection to the housing **15** of the subcutaneous device **14** via a connector **25**. In addition, one or more electrodes **28** (shown in FIG. **2**) are positioned along the outer surface of the housing to form a housing-based subcutaneous electrode array (SEA). Distal sensing electrode **26** is sized appropriately to match the sensing impedance of the housing-based subcutaneous electrode array.

[0032] It is understood that while device **14** is shown with electrodes **28** positioned on housing **15**, according to an embodiment of the present invention electrodes **28** may be alternatively positioned along one or more separate leads connected to device **14** via connector **25**.

[0033] Continuing with FIG. **2**, electrodes **28** are welded into place on the flattened periphery of the housing **15**. In the embodiment depicted in this figure, the complete periphery of the SubQ ICD may be manufactured to have a slightly flattened perspective with rounded edges to accommodate the placement of the electrodes **28**. The electrodes **28** are welded to housing **15** (to preserve hermaticity) and are connected via wires (not shown) to electronic circuitry (described herein below) inside housing **15**. Electrodes **28** may be constructed of flat plates, or alternatively, may be spiral electrodes as described in U.S. Pat. No. 6,512,940 "Subcutaneous Spiral Electrode for Sensing Electrical Signals of the Heart" to Brabec, et al and mounted in a non-conductive surround shroud as described in U.S. Pat. No. 6,522,915 "Surround Shroud Connector and Electrode Housings for a Subcutaneous Electrode Array and Leadless ECGs" to Ceballos, et al and U.S. Pat. No. 6,622,046 "Subcutaneous Sensing Feedthrough/Electrode Assembly" to Fraley, et al, all incorporated herein by reference in their entireties. The electrodes **28** of FIG.**2** can be positioned to form orthogonal or equilateral signal vectors, for example.

[0034] The electronic circuitry employed in subcutaneous device **14** can take any of the known forms that detect a tachyarrhythmia from the sensed ECG and provide cardioversion/defibrillation shocks as well as post-shock pacing as needed while the heart recovers. A simplified block diagram of such circuitry adapted to function employing the first and second cardioversion-defibrillation electrodes as well as the ECG sensing and pacing electrodes described herein below is set forth in FIG. **3**. It will be understood that the simplified block diagram does not show all of the conventional components and circuitry of such devices including digital clocks and clock lines, low voltage power supply and supply lines for powering the circuits and providing pacing pulses or telemetry circuits for telemetry transmissions between the device **14** and external programmer **20**.

[0035] FIG. **3** 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. **3**, 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. **3**, according to an embodiment of the present invention, the device **14** could utilize a single battery for both high and low voltage uses.

[0036] Further referring to FIG. **3**, subcutaneous device **14** functions are controlled by means of software, firmware and hardware that cooperatively monitor the ECG, 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 posterially and subcutaneously and coupled to the HVI output **113** of the high voltage output circuit **140**. Outputs **132** of FIG. **3** is coupled to sense electrode **26**.

[0037] 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 1000 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.

[0038] In FIG. **3**, 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 **24**, **26** and **28**, or, optionally, a virtual signal (i.e., a mathematical combination of two vectors) if selected. 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. Pat. No. 6,236,882 "Noise Rejection for Monitoring ECGs" to Lee, et al and incorporated herein by reference in its' entirety.

[0039] 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.

[0040] 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. 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 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.

[0041] 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**.

[0042] 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.

[0043] 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**.

[0044] High voltage output capacitors **156**, **158**, **160**, and **162** may be charged to very high voltages, e.g., **300-1000**V, 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.

[0045] 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 **113** and **123** coupled to the HV-1 and COMMON output as shown in FIG. **3**.

[0046] Thus, subcutaneous device **14** monitors the patient's cardiac status and initiates the delivery of a cardioversion-defibrillation shock through the cardioversion-defibrillation electrodes **24** and **28** 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**. Typically, the charging cycle takes only fifteen to twenty seconds, and occurs very infrequently. 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.

[0047] Subcutaneous device **14** desirably includes telemetry circuit (not shown in FIG. **3**), so that it is capable of being programmed by means of external programmer **20** via a 2-way telemetry link **22** (shown in FIG. **1**). 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.

[0048] 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.

[0049] FIG. **4** is a schematic diagram of signal processing aspects of a subcutaneous device according to an exemplary embodiment of the present invention. The transthoracic ECG signal (ECG**1**) detected between the distal electrode **26** of subcutaneous lead **18** and one of electrodes **28** positioned on the subcutaneous device **14** are amplified and bandpass filtered (2.5-105 Hz) by pre-amplifiers **202** and **206** located in Sense Amp **190** of FIG. **3**. The amplified EGM signals are directed to A/D converters **210** and **212**, which operate to sample the time varying analog EGM signal and digitize the sampled points. The digital output of ND converters **210** and **212** are applied to temporary buffers/control logic, which shifts the digital data through its stages in a FIFO manner under the control of Pacer/Device Timing block **178** of FIG. **3**. Virtual Vector block **226** selects one housing-based ECG signal (ECG**2**) from any pair of electrodes **28** as described, for example, in U.S. Pat. No. 5,331,966 "Subcutaneous Multi-Electrode Sensing System, Method and Pacer" to Bennett, et al or, alternatively, generates a virtual vector signal under control of Microprocessor **142** and Control block **144** 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. ECG**1** and ECG**2** vector selection may be selected by the patient's physician and programmed via telemetry link **22** from programmer **20**.

[0050] 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.

[0051] 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.

[0052] 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.

[0053] 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.

[0054] 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).

[0055] 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 when the noise has subsided.

[0056] 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, alternatively, selected for a preferred posture.

[0057] In the preferred embodiment, vector quality metric calculations would occur a number of times over approximately 1 minute, once per day, for each vector. These values would be averaged for each vector over the course of one week. Averaging may consist of a moving average or recursive average depending on time weighting and memory considerations. In this example, the preferred vector(s) would be selected once per week.

[0058] Continuing with FIG. **4**, a diagnostic channel **228** receives a programmable selected ECG signal from the housing based subcutaneous electrodes and the transthoracic ECG from the distal electrode **26** on lead **18**. Block **238** compresses the digital data, the data is applied to temporary buffers/control logic **218** which shifts the digital data through its stages in a FIFO manner under the control of Pacer/Device Timing block **178** of FIG. **3**, and the data is then stored in SRAM block **244** via direct memory access block **242**.

[0059] The two selected ECG signals (ECG**1** and ECG**2**) are additionally used to provide R-wave interval sensing via ECG sensing block **230**. IIR notch filter block **246** provides 50/60 Hz notch filtering. A rectifier and auto-threshold block **248** provides R-wave event detection as described in U.S. Pat. No. 5,117,824 "Apparatus for Monitoring Electrical Physiologic Signals" to Keimel, et al; publication WO2004023995 "Method and Apparatus for Cardiac R-wave Sensing in a

Subcutaneous ECG Waveform" to Cao, et al and U.S. Publication No. 2004/0260350 "Automatic EGM Amplitude Measurements During Tachyarrhythmia Episodes" to Brandstetter, et al, all incorporated herein by reference in their entireties. The rectifier of block **248** performs full wave rectification on the amplified, narrowband signal from bandpass filter **246**. A programmable fixed threshold (percentage of peak value), a moving average or, more preferably, an auto-adjusting threshold is generated as described in the '824 patent or '350 publication. In these references, following a detected depolarization, the amplifier is automatically adjusted so that the effective sensing threshold is set to be equal to a predetermined portion of the amplitude of the sensed depolarization, and the effective sensing threshold decays thereafter to a lower or base-sensing threshold. A comparator in block **248** determines signal crossings from the rectified waveform and auto-adjusting threshold signal. A timer block **250** provides R-wave to R-wave interval timing for subsequent arrhythmia detection (to be described herein below). The heart rate estimation is derived from the last 12 R-R intervals (e.g., by a mean, trimmed mean, or median, for example), with the oldest data value being removed as a new data value is added.

[0060] FIG. **5** is a schematic diagram of a rectifier and auto-threshold unit in a subcutaneous device according to an embodiment of the present invention. Waveform **402** depicts a typical subcutaneous ECG waveform and waveform **404** depicts the same waveform after filtering and rectification. A time dependant threshold **406** allows a more sensitive sensing threshold temporally with respect to the previous sensed R-wave. Sensed events **408** indicate when the rectified ECG signal **404** exceeds the auto-adjusting threshold and a sensed event has occurred.

[0061] Returning to FIG. **4**, the subcutaneous ECG signal (ECG**1**) is applied to ECG morphology block **232**, filtered by a 2-pole 23 Hz low pass filter **252** and evaluated by DSP microcontroller **254** under control of program instructions stored in System Instruction RAM **258**. ECG morphology is used for subsequent rhythm detection/determination (to be described herein below).

[0062] FIG. **6** is a state diagram of detection of arrhythmias in a medical device according to an embodiment of the present invention. As illustrated in FIG. **6**, during normal operation, the device **14** is in a not concerned state **302**, described in more detail herein below, 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 both ECG leads, indicative of an event that, if confirmed, may require the delivery of therapy, the device **14** transitions from the not concerned state **302** to a concerned state **304**, described in more detail herein below. In the concerned state **304** the device **14** 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.

[0063] If a rhythm requiring shock therapy continues to be detected while in the concerned state **304**, the device **14** transitions from the concerned state **304** to an armed state **306**, described in more detail herein below. If a rhythm requiring shock therapy is no longer detected while the device is in the concerned state **304** and the R-wave intervals are determined to no longer be short, the device **14** returns to the not concerned state **302**. However, if a rhythm requiring shock therapy is no longer detected while the device is in the concerned state **304**, but the R-wave intervals continue to be detected as being short, processing continues in the concerned state **304**.

[0064] In the armed state **306**, the device **14** 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 **14** returns to the not concerned state **302**. If the rhythm requiring shock therapy is still determined to be occurring once the charging of the capacitors is completed, the device **14** transitions from the armed state **306** to a shock state **308**, described in more detail herein below.

[0065] In the shock state **308**, the device **14** delivers a shock and returns to the armed state **306** to evaluate the success of the therapy delivered.

[0066] FIGS. **7**A-**7**I are flow charts of a method for detecting arrhythmias in a subcutaneous device according to an embodiment of the present invention. As illustrated in FIG. **7**A, device **14** continuously evaluates the two channels ECG**1** and ECG**2** associated with two predetermined electrode vectors to when sensed events occur. For example, the electrode vectors for the two channels ECG**1** and ECG**2** may include a horizontal vector selected between two of the electrodes **28** (ECG**2**) located along the housing of the device **14** as one electrode vector, while the other electrode vector is a front to back vector selected between the distal electrode **26** (ECG**1**) and one of the subcutaneous electrodes **28**, for example. The input signal from each channel ECG**1** and ECG**2** is pre-processed and rectified, and an adaptive auto-adjusting threshold is then applied. According to an embodiment of the present invention, a sensed event is determined to have occurred, for example, whenever the rising edge of the filtered ECG crosses the threshold.

[0067] FIG. **8** is a graphical representation of sensing of cardiac activity according to an embodiment of the present invention. In particular, the present invention utilizes an adaptive auto-adjusting threshold **401** during the R-wave sensing of Block **322** that includes a first threshold level **403**, a second threshold level **405**, a third threshold level **407** and a fourth threshold level **409**. An example of an auto-adjusting threshold is described, for example, in commonly assigned U.S. Patent Application Publication No. 2004/0049120, to Cao et al., filed Sep. 11, 2002, incorporated herein by reference in its entirety. Once there is a sensed event, which occurs whenever the rising edge of the rectified filtered ECG **411** crosses the threshold level, in this case threshold **403**, indicated by marker **410**, the threshold **401** is adjusted to the second threshold level **405**, which is a first predetermined percentage of a peak amplitude **412** of the rectified filtered ECG **411**, such as 65 percent, for example.

[0068] A blanking period **414** (nominally 150 ms, for example) prevents double counting of R-waves. During blanking period **414**, the threshold **401** continues to track the predetermined percentage of rectified filtered ECG **411** until peak **412** is detected. Threshold **401** is held at the second threshold level **405** during a threshold hold time period **416** (nominally 100 ms, for example) starting from the peak **412** location to prevent T-wave oversensing by delaying the linear decay. Threshold **401** then decays at a first predetermined rate, such as 35% of peak **412** per second, for example, until threshold **401** reaches the third threshold level **407**, which is

a second predetermined percentage of peak amplitude **412** (nominally 30%, for example). Threshold **401** is held at the third threshold level **407** until a step drop time **418** from the sensed event **410** (1.5 sec, for example) has expired. Once the step drop time **418** has expired, the threshold **401** is instantaneously set at the fourth threshold level **409** and begins to decay at a second predetermined rate, such as 20% of peak **412** per second, for example. The threshold **401** continues to decay linearly at the second predetermined rate until the threshold **401** reaches the first threshold level **403**. At no time can the threshold **401** become less than the first threshold level **403**.

[0069] The step drop time **418** allows abrupt adjustment of the threshold **401** in order to accommodate sensing of sudden reductions in R-wave amplitudes. The second predetermined rate associated with the linear decay is set at a rate that prevents oversensing of P-waves while maintaining adequate decay for sensing sudden drops in R-waves. If, at any time throughout this threshold adjustment process, a sensed event re-occurs outside blanking period **414**, then the threshold **401** is adjusted to the second threshold level **405**, and the threshold adjustment process is repeated.

[0070] According to an embodiment of the present invention, the nominal settings for the R-wave detector parameters may be set, for example, with the first threshold level being 25 microvolts, the second threshold level, third threshold level and fourth threshold level being set as 65, 30 and 20 percent of the peak amplitude **412**, respectively, blanking period **414** being set as 150 milliseconds, threshold hold time **416** being set as 100 milliseconds, and a maximum threshold level being 650 microvolts. These nominal settings may differ between the anterior housing-based bipolar ECG and the front to back ECG in order to account for the expected difference in amplitude and noise characteristics for those vectors.

[0071] The R-wave sensing described above is applied to each ECG channel ECG**1** and ECG**2** independently. According to the present invention, sensing of ventricular events on either channel will trigger execution of state machine in states **1** and **4**. During states **2** and **3**, R-wave sensing continues but state machine is triggered every predetermined number of seconds, as described below.

[0072] Returning to FIG. **7**A, a buffer of the most recent 12 R-R intervals obtained during R-wave processing using the sensing scheme of FIG. **8**, described above, for example, is independently maintained for each of the two sensing channels ECG**1** and ECG**2**. When the next sensed R-wave is obtained, Block **322**, which initially would be the 12^{th} R-wave interval, a heart rate estimate is determined, Block **323**, using a metric of heart rate, such as the mean, trimmed mean, or median of the RR intervals, for example. According to an embodiment of the present invention, the 9^{th} fastest beat of the 12 beats on a beat by beat basis is utilized as the heart rate metric. Using the 9^{th} fastest beat provides an estimate of heart rate that is less susceptible to oversensing while maintaining reasonable sensitivity to short R-R intervals as in the case of VT/VF. If the buffer of 12 R-R intervals contains any unknown R-R intervals (i.e., because the buffer is not yet filled) the initial estimate of heart rate is unknown.

[0073] Once the heart rate estimate is obtained using the heart rate metric, a determination is made as to whether asystole is detected for either channel, ECG**1** or ECG**2**, Block **324**. According to an embodiment of the present invention, asystole is detected for the channel, for example, either by determining whether one of the 12 R-R intervals is greater than a predetermined time period, such as three seconds, for example, or if the time since the most recently sensed R wave exceeds a predetermined time period, such as three seconds, for example. The latter can occur if an R-wave is sensed, for example, in one channel ECG**1**, but the other channel ECG**2** has not had an R-wave sense in three or more seconds. If asystole is detected for either of the two channels ECG**1** or ECG**2**, the current 12 R-R intervals for channels that are determined to be in asystole are cleared from the buffers, Block **325**, and the process continues by determining whether the current heart rate estimate is reliable for both channels ECG**1** and ECG**2**, Block **328**, described below.

[0074] If asystole is not detected for either channel ECG**1** and ECG**2**, NO in Block **324**, a determination is made independently for both channels ECG**1** and ECG**2** as to whether the current heart rate estimate for both channels ECG**1** and ECG**2** is reliable, Block **328**. According to an embodiment of the present invention, the current heart rate estimate for each of the two channels ECG**1** and ECG**2** is determined not to be reliable, No in Block **328**, if either there are unknown or cleared entries in the buffer for that channel, or if a predetermined number of the sensed R-waves associated with the current 12 R-R intervals for that channel was sensed at the minimum sensing threshold level, i.e., the first threshold level **403** of FIG. **8**, for example, and if the current heart rate estimate for the channel is less than the programmed heart rate threshold. According to one embodiment, the predetermined number of sensed R-waves that must be sensed at the minimum threshold is set at two, for example. In addition, the programmed heart rate threshold may be within a range of 150 to 240 beats per minute, and is nominally set at 180 beats per minute, for example. It is understood that while the processing is described using a buffer of 12 R-R intervals, any number of intervals and predetermined number of sensed R-waves that must be sensed at the minimum threshold may be utilized.

[0075] If the above analysis does not determine that both of the channels are reliable, No in Block **328**, a determination is made as to whether just one of the channels was unreliable or if both channels were unreliable, Block **330**. If both channels are determined to be unreliable, the current 12 R-R intervals for both channels ECG**1** and ECG**2** are cleared from the buffers, Block **326**, and the next R-sense is obtained for each channel, Block **322** using the sensing scheme of FIG. **8**, described above, so that a new heart rate estimate is determined, Block **323**, based on the new R-R intervals.

[0076] If only one channel is determined to unreliable, the value for the heart rate estimate for both channels is set to the current heart rate estimate for the channel determined to be reliable, Block **332**. Once either both channels are determined to be reliable, YES in Block **328**, or only one of the two channels is determined to be unreliable and therefore the heart rate estimate for both channels is set to the current heart rate estimate for the channel determined to be reliable, Block **332**, the final heart rate estimate is determined for each channel ECG**1** and ECG**2** based on those results, Block **334**, i.e., the heart rate estimate for each channel is set equal to their respective heart rate estimates determined in Block **323**, or both are set equal to the heart rate estimate associated with the channel determined to be reliable, Block **332**. A determination is then made as to whether the final heart rate estimates for both channels is greater than a predetermined VT/VF threshold, Block **336**. According to an embodiment of the present invention, the predetermined VT/VF threshold of

Block **336** is set at 180 bpm, for example, although any desired threshold could be utilized.

[0077] If the final heart rate estimates for one or both channels is not greater than the predetermined VT/VF threshold, the buffer containing the 12 R-R intervals for the channel not greater than the predetermined VT/VF threshold is updated by removing the first R-sense, shifting the remaining eleven R-sense samples back so that the second R-sense becomes the first R-sense, and so forth, and inserting the next detected R-sense, Block **322**, as the twelfth R-sense for each corresponding channel ECG**1** and ECG**2**. A new current heart rate estimate is then determined, Block **323**. Once the final heart rate estimates for both channels is greater than the predetermined VT/VF threshold, Yes in Block **336**, the process transitions from the not concerned state **302** to the concerned state **304**.

[0078] According to the present invention, upon transition from the not concerned state **302** to the concerned state **304**, Block **305**, a most recent window of ECG data from both channels ECG**1** and ECG**2** are utilized, such as three seconds, for example, so that processing is triggered in the concerned state **304** by a three-second timeout, rather than by the sensing of an R-wave, which is utilized when in the not concerned state **302**, described above. It is understood that while the processing is described as being triggered over a three second period, other times 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 ECG**1** and ECG**2** when in the concerned state **304**, and the buffer of 12 R-R intervals continues to be updated, the opportunities for changing from the concerned state **304** to another state and the estimates of heart rate only occur once the three-second timer expires. Upon initial entry to the concerned state **304**, 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 **304**. This requires a continuous circular buffering of the most recent three seconds of ECG data even while in the not concerned state **302**.

[0079] As described in detail below, while in the concerned state **304**, the present invention determines how sinusoidal and how noisy the signals 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. As illustrated in FIG. **7**B, once the device transitions from the not concerned state **302** to the concerned state **304**, Block **305**, a buffer for each of the two channels ECG**1** and ECG**2** for storing classifications of 3-second segments of data as "shockable" or "non-shockable" is cleared. Processing of signals of the two channels ECG**1** and ECG**2** while in the concerned state **304** is then triggered by the three second time period, rather than by the sensing of an R-wave utilized during the not concerned state **302**, described above.

[0080] Once the three second time interval has expired, YES in Block **341**, morphology characteristics of the signal during the three second time interval for each channel are utilized to determine whether the signals are likely corrupted by noise artifacts and to characterize the morphology of the signal as "shockable" or "not shockable". For example, using the signals associated with the three second time interval, a determination is made for each channel ECG**1** and ECG**2** as to whether the channel is likely corrupted by noise, Block **342**, and a determination is then made as to whether both channels ECG**1** and ECG**2** are corrupted by noise, Block **344**.

[0081] As illustrated in FIG. **7**C, the determination as to whether the signal associated with each of the channels ECG**1** and ECG**2** is likely corrupted by noise, Block **342** of FIG. **7**B, includes multiple sequential noise tests that are performed on each channel ECG and ECG**2**. During a first noise test, for example, a determination is made as to whether a metric of signal energy content of the signal for the channel is within predetermined limits, Block **380**. For example, the amplitude of each sample associated with the three second window is determined, resulting in N sample amplitudes, from which a mean rectified amplitude is calculated as the ratio of the sum of the rectified sample amplitudes to the total number of sample amplitudes N for the segment. If the sampling rate is 256 samples per second, for example, the total number of sample amplitudes N for the three-second segment would be N=768 samples.

[0082] Once the mean rectified amplitude is calculated, a determination is made as to whether the mean rectified amplitude is between an upper average amplitude limit and a lower average amplitude limit, the lower average amplitude limit being associated with asystole episodes without artifact and the upper average amplitude limit being associated with a value greater than what would be associated with ventricular tachycardia and ventricular fibrillation events. According to an embodiment of the present invention, the upper average amplitude limit is set as 1.5 mV, and the lower average amplitude limit is set as 0.013 mV. While the metric of signal energy content is described above as the mean rectified amplitude, it is understood that other signal of energy contents could be utilized.

[0083] If the determined mean rectified amplitude is not between the upper average amplitude limit and the lower average amplitude limit, the three second segment for that channel is identified as being likely corrupted with noise, Block **386**, and no further noise tests are initiated for that channel's segment.

[0084] If the determined mean rectified amplitude is located between the upper average amplitude limit and the lower average amplitude limit, a noise to signal ratio is calculated and a determination is made as to whether the noise to signal ratio is less than a predetermined noise to signal threshold, Block **382**. For example, the amplitude of each sample associated with the three second window is determined, resulting in N raw sample amplitudes. The raw signal is lowpass filtered, resulting in L lowpass sample amplitudes. The raw mean rectified amplitude is determined as the average of the absolute values of the raw sample amplitudes. The lowpass mean rectified amplitude is determined as the average of the absolute values of the lowpass sample amplitudes. Next, a highpass mean rectified amplitude is then calculated as the difference between the raw mean rectified amplitude and the lowpass mean rectified amplitude. The noise to signal ratio is then determined as the ratio of the highpass mean rectified amplitude to the lowpass mean rectified amplitude. If the noise to signal ratio is greater than a predetermined threshold, such as 0.0703, for example, the three second segment for that channel is identified as being likely corrupted with noise, Block **386**, and no further noise tests are initiated for the segment.

[0085] If the noise to signal ratio is less than or equal to the predetermined threshold, a determination is made as to

whether the signal is corrupted by muscle noise, Block **384**. According to an embodiment of the present invention, the determination as to whether the signal is corrupted by muscle noise is made by determining whether the signal includes a predetermined number of signal inflections indicative of the likelihood of the signal being corrupted by muscle noise, using a muscle noise pulse count that is calculated to quantify the number of signal inflections in the three second interval for each channel ECG**1** and ECG**2**. The presence of a significant number of inflections is likely indicative of muscle noise.

[0086] FIG. **9**A is a graphical representation of a determination of whether a signal is corrupted by muscle noise according to an embodiment of the present invention. FIG. **9**B is a flowchart of a method of determining whether a signal is corrupted by muscle noise according to an embodiment of the present invention. For example, as illustrated in FIGS. **9**A and **9**B, in order to determine a muscle noise count for the three second interval, the raw signal **420** is applied to a first order derivative filter to obtain a derivative signal **422**, and all of the zero-crossings **424** in the derivative signal **422** are located, Block **460**. A data pair corresponding to the data points immediately prior to and subsequent to the zero crossings **424**, points **426** and **428** respectively, for each crossing is obtained. The value of the data point in each data pair with smaller absolute value is zeroed in order to allow a clear demarcation of each pulse when a rectified signal **430** is derived from the derivative signal **422** with zeroed zero-crossing points **432**.

[0087] A pulse amplitude threshold Td, for determining whether the identified inflection is of a significant amplitude to be identified as being associated with muscle noise, is determined, Block **462**, by dividing the rectified signal from the three second segment into equal sub-segments **434**, estimating a local maximum amplitude **436**-**442** for each of the sub-segments **434**, and determining whether the local amplitudes **436**-**442** are less than a portion of the maximum amplitude, which is maximum amplitude **440** in the example of FIG. **9**, for the whole three second segment. If the local maximum amplitude is less than the portion of the maximum amplitude for the whole three second segment, the local maximum amplitude is replaced by the maximum for the whole three second segment for the sub-segment corresponding to that local maximum amplitude.

[0088] It is understood that while only two or less zero-crossing points are shown as being located within the sub-segments in the illustration of FIG. **9** for the sake of simplicity, in fact each of the sub-segments **434**, which have a length of approximately 750 milliseconds, will contain many inflections, such as every 25 milliseconds, for example.

[0089] According to an embodiment of the present invention, the three second segment is divided into four sub-segments and the local maximum amplitudes are replaced by the maximum amplitude for the whole segment if the local maximum amplitude is less than one fifth of the maximum amplitude for the whole segment. Once the determination of whether to replace the local maximum amplitudes for each of the sub-segments with the maximum amplitude for the whole segment is completed, the pulse amplitude threshold Td for the segment is set equal to a predetermined fraction of the mean of the local maximum amplitudes for each of the sub-segments. According to an embodiment of the present invention, the pulse amplitude threshold Td for the three second segment is set equal to one sixth of the mean of the local maximum amplitudes **436**-**440**.

[0090] Once the pulse amplitude threshold Td has been determined, the inflections associated with the signal for the three second segment is classified as being of significant level to be likely indicative of noise by determining whether the pulse amplitude threshold Td is less than a pulse threshold, Block **464**. According to an embodiment of the present invention, the pulse threshold is set as 1 microvolt. If the pulse amplitude threshold Td is less than the pulse threshold, the signal strength is too small for a determination of muscle noise, and therefore the signal is determined to be not likely corrupted by noise and therefore the channel is determined to be not noise corrupted, Block **466**.

[0091] If the pulse amplitude threshold Td is greater than or equal to the pulse threshold, the three second segment is divided into twelve sub-segments of 250 ms window length, the number of muscle noise pulses in each sub-segment is counted, and both the sub-segment having the maximum number of muscle noise pulses and the number of sub-segments having 6 or more muscle noise pulses that are greater than a predetermined minimum threshold is determined. Muscle noise is determined to be present in the signal if either the maximum number of muscle noise pulses in a single sub-segment is greater than a noise pulse number threshold or the number of sub-segments of the twelve sub-segments having 6 or more muscle noise pulses greater than the minimum threshold is greater than or equal to a sub-segment pulse count threshold. According to an embodiment of the present invention, the noise pulse number threshold is set equal to eight and the sub-segment pulse count threshold is set equal to three.

[0092] For example, if the pulse amplitude threshold Td is greater than or equal to the pulse threshold, No in Block **464**, the maximum number of muscle noise counts in a single sub-segment is determined, Block **468**. If the maximum number of muscle noise counts is greater than the noise pulse number threshold, Yes in Block **470**, the channel is determined to be noise corrupted, Block **472**. If the maximum number of muscle noise counts for the channel is less than or equal to the noise pulse number threshold, No in Block **470**, the number of sub-segments of the twelve sub-segments having 6 or more muscle noise pulses greater than the minimum threshold is determined, Block **474**, and if the number is greater than or equal to a sub-segment pulse count threshold, Yes in Block **476**, the channel is determined to be noise corrupted, Block **472**. If the number is less than the sub-segment pulse count threshold, No in Block **476**, the channel is determined not to be noise corrupted, Block **466**.

[0093] FIG. **9**C is a flowchart of a method of determining whether a signal is corrupted by muscle noise according to an embodiment of the present invention. Since muscle noise can be present during an episode of ventricular tachycardia, the width of the overall signal pulse waveform is determined in order to distinguish between signals that are determined likely to be purely noise related and signals that are both shockable events and determined to include noise. Therefore, as illustrated in FIG. **9**C, according to an embodiment of the present invention, once muscle noise is determined to be present as a result of the muscle noise pulse count being satisfied, No in Block **470** and Yes in Block **476**, a determination is made as to whether the signal is both noise corrupted and shockable, Block **480**.

[0094] According to an embodiment of the present invention, the determination in Block **480** as to whether the signal is both noisy and shockable is made, for example, by dividing the rectified signal, having 768 data points, into four sub-

segments and determining a maximum amplitude for each of the four sub-segments by determining whether a maximum amplitude for the sub-segment is less than a portion of the maximum amplitude for the entire rectified signal in the three second segment. For example, a determination is made for each sub-segment as to whether the maximum amplitude for the sub-segment is less than one fourth of the maximum amplitude for the entire rectified signal. If less than a portion of the maximum amplitude for the entire rectified signal in the three second segment, the maximum amplitude for the sub-segment is set equal to the maximum amplitude for the entire rectified signal.

[0095] A mean rectified amplitude for each of the sub-segments is determined by dividing the sum of the rectified amplitudes for the sub-segment by the number of samples in the sub-segment, i.e., 768÷4. Then the normalized mean rectified amplitude for each sub-segment is determined by dividing the mean rectified amplitude for each of the sub-segments by the peak amplitude for the sub-segment. The normalized mean rectified amplitude for the three second segment is then determined as the sum of the normalized mean rectified amplitudes for each sub-segment divided by the number of sub-segments, i.e., four.

[0096] Therefore, once muscle noise is suspected as a result of the determination of the muscle noise pulse count, the determination of Block **480** based on whether the normalized mean rectified amplitude for the three second segment is greater than a predetermined threshold for identifying signals that, despite being indicative of a likelihood of being associated with noise, nevertheless are associated with a shockable event. For example, according to an embodiment of the present invention, a determination is made as to whether the normalized mean rectified amplitude for the three second segment is greater than 18 microvolts. If the normalized mean rectified amplitude for the three second segment is less than or equal to the predetermined threshold, the channel is likely corrupted by muscle noise and not shockable, No in Block **480**, and is therefore identified as being corrupted by noise, Block **472**. If the normalized mean rectified amplitude for the three second segment is greater than the predetermined threshold, the channel is determined to be likely corrupted by muscle noise and shockable, Yes in Block **480**, and is therefore identified as not to be likely corrupted by muscle noise, Block **478**.

[0097] Returning to FIG. **7**C, when the signal is determined to be not likely corrupted by muscle noise, a determination is made as to whether the mean frequency of the signal associated with the channel is less than a predetermined mean frequency threshold, Block **388**, such as 11 Hz for example. The mean frequency of the signal during the 3 second segment for each channel ECG**1** and ECG**2** is generated, for example, by calculating the ratio of the mean absolute amplitude of the first derivative of the 3 second segment to the mean absolute amplitude of the 3 second segment, multiplied by a constant scaling factor. If the mean frequency is determined to be greater than or equal to the predetermined mean frequency threshold, No in Block **388**, the three second segment for that channel is identified as being likely corrupted with noise, Block **386**. If the mean frequency is determined to be less than the predetermined mean frequency threshold, Yes in Block **388**, the three second segment for that channel is identified as being not noise corrupted, Block **390**.

[0098] According to an embodiment of the present invention, since the mean spectral frequency tends to be low for true ventricular fibrillation events, moderate for organized rhythms such as sinus rhythm and supraventricular tachycardia, for example, and high during asystole and noise, the determination in Block **388** includes determining whether the mean frequency is less than a predetermined upper mean frequency threshold, such as 11 Hz (i.e., mean period T of approximately 91 milliseconds) for example, and whether the mean frequency is less than a predetermined lower mean frequency, such as 3 Hz for example. If the mean frequency is below a second, lower threshold, such as 3 Hz, for example, the signal is also rejected as noise and no further noise tests are initiated. This comparison of the mean frequency to a second lower threshold is intended to identify instances of oversensing, resulting in appropriate transition to the concerned state. If the mean frequency of the signal is less than 3 Hz, it is generally not possible for the heart rate to be greater than 180 beats per minute. In practice, it may be advantageous to set the lower frequency threshold equal to the programmed VT/VF detection rate, which is typically approximately 3 Hz.

[0099] Therefore, in the determination of Block **388**, if the mean frequency is determined to be either greater than or equal to the predetermined upper mean frequency threshold or less than the lower threshold, the three second segment for that channel is identified as being likely corrupted with noise, Block **386**. If the mean frequency is determined to be both less than the predetermined upper mean frequency threshold and greater than the lower threshold, the three second segment for that channel is identified as not being noise corrupted, Block **390**.

[0100] Returning to FIG. **7**B, once the determination as to whether the channels ECG**1** and ECG**2** are corrupted by noise is made, Block **342**, a determination is made as to whether both channels are determined to be noise corrupted, Block **344**. If the signal associated with both channels ECG**1** and ECG**2** is determined to likely be corrupted by noise, both channels are classified as being not shockable, Block **347**, and therefore a buffer for each channel ECG**1** and ECG**2** containing the last three classifications of the channel is updated accordingly. If both channels ECG**1** and ECG**2** are not determined to be likely corrupted by noise, No in Block **344**, the device distinguishes between either one of the channels being not corrupted by noise or both channels being not corrupted by noise by determining whether noise was determined to be likely in only one of the two channels ECG**1** and ECG**2**, Block **346**.

[0101] If noise was likely in only one of the two channels, a determination is made whether the signal for the channel not corrupted by noise, i.e., the clean channel, is more likely associated with a VT event or with a VF event by determining, for example, whether the signal for that channel includes R-R intervals that are regular and the channel can be therefore classified as being relatively stable, Block **348**. If the R-R intervals are determined not to be relatively stable, NO in Block **348**, the signal for that channel is identified as likely being associated with VF, which is then verified by determining whether the signal is in a VF shock zone, Block **350**, described below. If R-R intervals for that channel are determined to be stable, YES in Block **348**, the signal is identified as likely being associated with VT, which is then verified by determining whether the signal is in a VT shock zone, Block **352**, described below.

[0102] If noise was not likely for both of the channels, No in Block **346**, i.e., both channels are determined to be clean channels, a determination is made whether the signal for both

channels is more likely associated with a VT event or with a VF event by determining whether the signal for both channels includes R-R intervals that are regular and can be therefore classified as being relatively stable, Block **356**. If the R-R intervals are determined not to be relatively stable, NO in Block **356**, the signal for both channels is identified as likely being associated with VF, which is then verified by determining whether the signal for each channel is in a VF shock zone, Block **360**, described below. If R-R intervals for both channels are determined to be stable, YES in Block **356**, the signal is identified as likely being associated with VT, which is then verified by determining, based on both channels, whether the signal is in a VT shock zone, Block **352**.

[0103] As illustrated in FIG. **7**D, according to an embodiment of the present invention, in order to determine whether the signal for both channels includes R-R intervals that are regular and the channels can be therefore classified as being relatively stable, Block **356**, predetermined maximum and minimum intervals for each channel ECG**1** and ECG**2** are identified, Block **500**, from the updated buffer of 12 RR-intervals, Block **342**. According to one embodiment of the present invention, the largest RR-interval and the sixth largest RR-interval of the twelve RR-intervals are utilized as the maximum interval and the minimum interval, respectively.

[0104] The difference between the maximum RR-interval and the minimum RR-interval of the 12 RR-intervals is calculated for each channel ECG**1** and ECG**2**, Block **502**, to generate a first interval difference associated with the first channel ECG**1** and a second interval difference associated with the second channel ECG**2**. The smallest of the first interval difference and the second interval difference is then identified, Block **504**, and a determination is made as to whether the minimum of the first interval difference and the second interval difference is greater than a predetermined stability threshold, Block **506**, such as 110 milliseconds, for example.

[0105] If the minimum of the first interval difference and the second interval difference is greater than the stability threshold, the event is classified as an unstable event, Block **508**, and a determination is made for each channel as to whether the signal associated with the channel is within a predetermined VF shock zone, Blocks **360** and **362** of FIG. **7**B, described below. If the minimum of the first interval difference and the second interval difference is less than or equal to the stability threshold, No in Block **506**, the device determines which one of the minimum RR-interval associated with the first channel ECG**1** and the minimum RR-interval associated with the second channel ECG**2** is shortest, Block **510**, and determines whether the shortest minimum interval is greater than a minimum interval threshold, Block **512**, such as 200 milliseconds, for example.

[0106] If the shortest of the two minimum intervals is less than or equal to the minimum interval threshold, the event is classified as an unstable event, Block **508**, and a determination is made for each channel as to whether the signal associated with the channel is within a predetermined VF shock zone, Blocks **360** and **362** of FIG. **7**B, described below. If the shortest of the two minimum intervals is greater than the minimum interval threshold, the device determines which one of the minimum RR-interval associated with the first channel ECG**1** and the minimum RR-interval associated with the second channel ECG**2** is the greatest, Block **514**, and determines whether the maximum of the two minimum intervals is less than or equal to a maximum interval threshold, Block **516**, such as 333 milliseconds for example. If the maximum of the two minimum intervals is greater than the maximum interval threshold, the event is classified as an unstable event, Block **508**, and a determination is made for each channel as to whether the signal associated with the channel is within a predetermined VF shock zone, Blocks **360** and **362** of FIG. **7**B, described below. If the maximum of the two minimum intervals is less than or equal to the maximum interval threshold, the event is classified as a stable event, Block **518**, and a determination is made, based on both channels ECG**1** and ECG**2**, as to whether the signal is within a predetermined VT shock zone, Block **358**, described below.

[0107] Returning to FIG. **7**B, according to an embodiment of the present invention, during the determination of whether the signal associated with each of the channels ECG**1** and ECG**2** is within the VF shock zone, Blocks **360** and **362**, the VF shock zone is defined based upon a low slope content metric and a spectral width metric for each of the two channels ECG**1** and ECG**2**. The low slope content metric is calculated as the ratio of the number of data points with low slope to the total number of samples in the 3-second segment. For example, according to an embodiment of the present invention, the difference between successive ECG samples is determined as an approximation of the first derivative (i.e, the slope) of the ECG signal. In particular, as illustrated in FIG. **7**E, the raw signal for each channel is applied to a first order derivative filter to obtain a derivative signal for the three-second segment, Block **530**. The derivative signal is then rectified, divided into four equal sub-segments, and the largest absolute slope is estimated for each of the four sub-segments, Block **532**.

[0108] A determination is made as to whether the largest absolute slopes are less than a portion of the overall largest absolute slope for the whole three-second segment, Block **534**, such as one-fifth of the overall absolute slope, for example. If the largest absolute slope is less than the portion of the overall slope, then the slope value for that sub-segment is set equal to the overall largest absolute slope, Block **536**. If the largest absolute slope is not less than the portion of the overall slope, then the slope value for that sub-segment is set equal to the determined largest absolute slope for the sub-segment, Block **538**.

[0109] Once the slope value for each of the sub-segments has been determined and updated by being set equal to the largest slope for the three second segment, if necessary, the average of the four slopes is calculated and divided by a predetermined factor, such as 16 for example, to obtain a low slope threshold, Block **540**. The low slope content is then obtained by determining the number of sample points in the three-second segment having an absolute slope less than or equal to the low slope threshold, Block **542**.

[0110] According to an embodiment of the present invention, if, during the determination of the low slope threshold in Block **540**, the low slope threshold is a fraction, rather than a whole number, a correction is made to the low slope content to add a corresponding fraction of the samples. For example, if the threshold is determined to be 4.5, then the low slope content is the number of sample points having an absolute slope less than or equal to 4 plus one half of the number of sample points with slope equal to 5.

[0111] The spectral width metric, which corresponds to an estimate of the spectral width of the signal for the three-second segment associated with each channel ECG**1** and ECG**2**, is defined, for example, as the difference between the

mean frequency and the fundamental frequency of the signal. According to an embodiment of the present invention, the spectral width metric is calculated by determining the difference between the most recent estimate of the RR-cycle length and the mean spectral period of the signal for that channel. As is known in the art, the mean spectral period is the inverse of the mean spectral frequency.

[0112] It is understood that R-R cycle length utilized in the concerned state and armed state can be different than that used in the not concerned state. For example, according to an embodiment of the present invention, the 9^{th} longest R-R interval is utilized in the not concerned state and the mean of the 7^{th} to the 10^{th} R-R interval is utilized in the concerned state and the armed state.

[0113] FIG. **10** is a graphical representation of a VF shock zone according to an embodiment of the present invention. As illustrated in FIG. **10**, a VF shock zone **500** is defined for each channel ECG**1** and ECG**2** based on the relationship between the calculated low slope content and the spectral width associated with the channel. For example, the shock zone is defined by a first boundary **502** associated with the low slope content set for by the equation:

$$\text{Low slope content} = -0.0013 \times \text{spectral width} + 0.415 \qquad \text{Equation 1}$$

[0114] and a second boundary **504** associated with the spectral width set forth by the equation:

$$\text{spectral width} = 200 \qquad \text{Equation 2}$$

[0115] As can be seen in FIG. **10**, since noise **506** tends to have a relatively higher spectral width, and normal sinus rhythm **508** tends to have a relatively higher low slope content relative to VF, both noise **506** and normal sinus rhythm **508** would be located outside the VF shock zone **500**.

[0116] A determination is made for each channel ECG**1** and ECG**2** as to whether the low slope content for that channel is less than both the first boundary **502** and the spectral width is less than the second boundary **504**, i.e., the low slope content is less than −0.0013×spectral width+0.415, and the spectral width is less than 200. For example, once the event is determined to be associated with VF, i.e., the intervals for both channels are determined to be irregular, No in Block **356**, a determination is made that channel ECG**1** is in the VF shock zone, Yes in Block **360**, if, for channel ECG**1**, both the low slope content is less than the first boundary **502** and the spectral width is less than the second boundary **504**. The three second segment for that channel ECG**1** is then determined to be shockable, Block **363** and the associated buffer for that channel is updated accordingly. If either the low slope content for the channel is not less than the first boundary **502** or the spectral width is not less than the second boundary, the channel ECG**1** is determined not to be in the VF shock zone, No in Block **360**, the three second segment for that channel ECG**1** is then determined to be not shockable, Block **365**, and the associated buffer is updated accordingly.

[0117] Similarly, a determination is made that channel ECG**2** is in the VF shock zone, Yes in Block **362**, if, for channel ECG**2**, both the low slope content is less than the first boundary **502** and the spectral width is less than the second boundary **504**. The three second segment for that channel ECG**2** is then determined to be shockable, Block **369** and the associated buffer for that channel is updated accordingly. If either the low slope content for the channel is not less than the first boundary **502** or the spectral width is not less than the second boundary, the channel ECG**2** is determined not to be in the VF shock zone, No in Block **362**, the three second segment for that channel ECG**2** is then determined to be not shockable, Block **367**, and the associated buffer is updated accordingly.

[0118] According to an embodiment of the present invention, rather than being defined by Equation 1, the shock zone may be defined so that the first boundary **502** associated with the low slope content is set forth by the following equation:

$$\text{Low slope content} = -0.005 \times \text{spectral width} + 1.1 \qquad \text{Equation 1A}$$

[0119] so that the VF shock zone **500** is defined, as described above, using Equation 1A and Equation 2.

[0120] FIGS. **11**A and **11**B are graphical representations of the determination of whether an event is within a shock zone according to an embodiment of the present invention. During the determination of whether the event is within the VT shock zone, Block **358** of FIG. **7**B, the low slope content and the spectral width is determined for each channel ECG**1** and ECG**2**, as described above in reference to determining the VF shock zone. A determination is made as to which channel of the two signal channels ECG**1** and ECG**2** contains the minimum low slope content and which channel of the two signal channels ECG**1** and ECG**2** contains the minimum spectral width. A first VT shock zone **520** is defined based on the relationship between the low slope content associated with the channel determined to have the minimum low slope content and the spectral width associated with the channel determined to have the minimum spectral width. For example, according to an embodiment of the present invention, the first VT shock zone **520** is defined by a boundary **522** associated with the minimum low slope content and the minimum spectral width set forth by the equation:

$$\text{LSC} = -0.004 \times \text{SW} + 0.93 \qquad \text{Equation 3}$$

[0121] A second VT shock zone **524** is defined based on the relationship between the low slope content associated with the channel determined to have the minimum low slope content and the normalized mean rectified amplitude associated with the channel determined to have the maximum normalized mean rectified amplitude. The normalized mean rectified amplitudes for the two channels ECG**1** and ECG**2** utilized during the VT shock zone test is the same as described above in reference to the noise determination of Block **343**. For example, according to an embodiment of the present invention, the second VT shock zone **524** is defined by a second boundary **526** associated with the relationship between the minimum low slope count and the maximum normalized mean rectified amplitude set forth by the equation:

$$\text{NMRA} = 68 \times \text{LSC} + 8.16 \qquad \text{Equation 4}$$

[0122] If both the minimum low slope count is less than the first boundary **522**, i.e., −0.004×minimum spectral width+0.93, and the maximum normalized mean rectified amplitude is greater than the second boundary **526**, i.e., 68×minimum low slope count+8.16, the event is determined to be in the VT shock zone, YES in Block **358**, and both channels ECG**1** and ECG**2** are determined to be shockable, Block **357**, and the associated buffers are updated accordingly. If either the minimum low slope count is not less than the first boundary **522** or the maximum normalized mean rectified amplitude is not greater than the second boundary **526**, the event is determined to be outside the VT shock zone, NO in Block **358**, and both channels ECG**1** and ECG**2** are determined to be not shockable, Block **359**.

[0123] As described, during both the VF shock zone test, Blocks **360** and **362**, and the VT shock zone test, Block **358**,

the test results for each channel ECG**1** and ECG**2** as being classified as shockable or not shockable are stored in a rolling buffer containing the most recent eight such designations, for example, for each of the two channels ECG**1** and ECG**2** that is utilized in the determination of Block **356**, as described below.

[0124] If only one of the two channels ECG**1** and ECG**2** is determined to be corrupted by noise, Yes in Block **346**, a determination is made whether the signal for the channel not corrupted by noise, i.e., the "clean channel", is more likely associated with a VT event or with a VF event by determining whether the signal for the clean channel includes R-R intervals that are regular and can be therefore classified as being relatively stable, Block **348**. If the R-R intervals are determined not to be relatively stable, NO in Block **348**, the signal for the clean channel is identified as likely being associated with VF, which is then verified by determining whether the signal for the clean channel is in a VF shock zone, Block **350**, described below. If R-R intervals for the clean channel are determined to be stable, YES in Block **348**, the signal is identified as likely being associated with VT, which is then verified by determining whether the signal for the clean channel is in a VT shock zone, Block **352**.

[0125] According to an embodiment of the present invention, in order to determine whether the signal for the clean channel includes R-R intervals that are regular and the clean channel can be therefore classified as being either relatively stable, Yes in Block **348**, or relatively unstable, No in Block **348**, the device discriminates VT events from VF events in Block **348** by determining whether the relative level of variation in the RR-intervals associated with the clean channel is regular. For example, as illustrated in FIG. **7**H, predetermined maximum and minimum intervals for the clean channel are identified, Block **700**, from the updated buffer of 12 RR-intervals, Block **342** of FIG. **7**B. According to an embodiment of the present invention, the largest RR-interval and the sixth largest RR-interval of the twelve RR-intervals are utilized as the maximum interval and the minimum interval, respectively.

[0126] The difference between the maximum RR-interval and the minimum RR-interval of the 12 RR-intervals is calculated to generate an interval difference associated with the clean channel, **702**. A determination is then made as to whether the interval difference is greater than a predetermined stability threshold, Block **704**, such as 110 milliseconds, for example.

[0127] If the interval difference is greater than the stability threshold, the event is classified as an unstable event, Block **706**, and therefore the clean channel is determined not to include regular intervals, No in Block **348**, and a determination is made as to whether the signal associated with the clean channel is within a predetermined VF shock zone, Block **350** of FIG. **7**B, described below. If the interval difference is less than or equal to the stability threshold, No in Block **704**, the device determines whether the minimum RR interval is greater than a minimum interval threshold, Block **710**, such as 200 milliseconds, for example.

[0128] If the minimum interval is less than or equal to the minimum interval threshold, No in Block **710**, the event is classified as an unstable event, Block **706**, and therefore the clean channel is determined not to include regular intervals, No in Block **348**, and a determination is made as to whether the signal associated with the clean channel is within a predetermined VF shock zone, Block **350** of FIG. **7**B, described below. If the minimum interval is greater than the minimum interval threshold, Yes in Block **710**, the device determines whether the maximum interval is less than or equal to a maximum interval threshold, Block **712**, such as 333 milliseconds for example. If the maximum interval is greater than the maximum interval threshold, the event is classified as an unstable event, Block **706**, and therefore the clean channel is determined not to include regular intervals, No in Block **348**, and a determination is made as to whether the signal associated with the clean channel is within a predetermined VF shock zone, Block **350** of FIG. **7**B, described below. If the maximum interval is less than or equal to the maximum interval threshold, the event is classified as a stable event, Block **714**, and therefore the clean channel is determined to include regular intervals, Yes in Block **348**, and a determination is made as to whether the signal associated with the clean channel is within a predetermined VT shock zone, Block **352** of FIG. **7**B, described below.

[0129] Returning to FIG. **7**B, according to an embodiment of the present invention, the determination of whether the clean channel is within the VF shock zone, Block **350**, is made based upon a low slope content metric and a spectral width metric, similar to the VF shock zone determination described above in reference to Blocks **360** and **362**, both of which are determined for the clean channel using the method described above. Once the low slope content metric and a spectral width metric are determined for the clean channel, the determination of whether the clean channel is in the VF shock zone is made using Equations 1 and 2, so that if either the low slope content for the clean channel is not less than the first boundary **502** or the spectral width is not less than the second boundary **504**, the clean channel is determined not to be in the VF zone, No in Block **350** and both channels are classified as not shockable, Block **351**, and the associated buffers are updated accordingly.

[0130] If the low slope content for the clean channel is less than the first boundary **502** and the spectral width is less than the second boundary **504**, the clean channel is determined to be in the VF zone, Yes in Block **350**. A determination is then made as to whether the channel determined to be corrupted by noise, i.e., the "noisy channel", is within the VF shock zone, Block **354**. If either the low slope content for the noisy channel is not less than the first boundary **502** or the spectral width is not less than the second boundary **504**, the noisy channel is determined not to be in the VF zone, No in Block **354**, the clean channel is classified as shockable and the noisy channel is classified as not shockable, Block **355**, and the associated buffers are updated accordingly.

[0131] If the low slope content for the noisy channel is less than the first boundary **502** and the spectral width is less than the second boundary **504**, the noisy channel is determined to be in the VF zone, Yes in Block **354**, both the clean channel and the noisy channel are classified as being shockable, Block **353**, and the associated buffers are updated accordingly.

[0132] Similar to the VT shock zone determination described above in reference to Block **358**, during the determination as to whether the clean channel is within the VT shock zone in Block **352**, the low slope content and the spectral width is determined for the clean channel as described above in reference to determining the VF shock zone. The first VT shock zone **520** is defined based on the relationship between the low slope content and the spectral width associated with the clean channel according to Equation 3, for example, and the second VT shock zone **524** is

defined based on the relationship between the low slope count and the normalized mean rectified amplitude associated with the clean channel. The normalized mean rectified amplitudes for the clean channel is the same as described above in reference to the noise detection tests of Block **344**. For example, according to an embodiment of the present invention, the second VT shock zone **524** is defined by a second boundary **526** associated with the relationship between the low slope count and the normalized mean rectified amplitude of the clean channel using Equation 4.

[0133] If both the low slope count is less than the first boundary **522**, i.e., −0.004×spectral width of clean channel+0.93, and the normalized mean rectified amplitude is greater than the second boundary **526**, i.e., 68×low slope count of clean channel+8.16, the clean channel is determined to be in the VT shock zone, Yes in Block **352**, both channels are classified as being shockable, Block **353**, and the associated buffers are updated accordingly.

[0134] If either the low slope count is not less than the first boundary **522** or the maximum normalized mean rectified amplitude is not greater than the second boundary **526**, the clean channel is determined to be outside the VT shock zone, No in Block **352**, both channels are classified as being not shockable, Block Block **351**, and the associated buffers are updated accordingly.

[0135] FIG. **12** is a graphical representation of a shock zone according to an embodiment of the present invention. According to an embodiment of the present invention, during the determination of whether the signal associated with each of the channels ECG**1** and ECG**2** is within the VF shock zone, Blocks **360** and **362**, the VF shock zone is defined based upon a normalized mean rectified amplitude metric and a spectral width metric for each of the two channels ECG**1** and ECG**2**, both of which may be generated, for example, as described above. In particular, according to the embodiment of FIG. **12**, a VF shock zone **800** is defined for each channel ECG**1** and ECG**2**, during a given three second sensing window, based on the relationship between the calculated normalized mean rectified amplitude and the spectral width associated with the channel, with the shock zone **800** being defined by a boundary **802** associated with the normalized mean rectified amplitude by the equation:

$$\text{Normalized Mean Rectified Amplitude} = 0.2 \times \text{spectral width} + 3 \qquad \text{Equation. 5}$$

[0136] As can be seen in FIG. **12**, since noise **806** tends to have a relatively higher spectral width, and normal sinus rhythm **808** tends to have a relatively lower normalized mean rectified amplitude relative to VF, both noise **806** and normal sinus rhythm **808** are located outside the VF shock zone **800**. Therefore, a determination is made for each channel ECG**1** and ECG**2**, during a given three second sensing window, as to whether the normalized mean rectified amplitude for that channel is greater than or equal to the boundary **802**, i.e., the normalized mean rectified amplitude is greater than or equal to 0.2×spectral width+3. For example, once the event is determined to be associated with VF, i.e., the intervals for both channels are determined to be irregular, No in Block **356**, a determination is made that channel ECG**1** is in the VF shock zone, Yes in Block **360**, if, for channel ECG**1**, the normalized mean rectified amplitude is greater than or equal to the boundary **802**. The three second segment for that channel ECG**1** is then determined to be shockable, Block **363** and the associated buffer for that channel is updated accordingly. If the normalized mean rectified amplitude for the channel is less than the boundary **802**, the channel ECG**1** is determined not to be in the VF shock zone, No in Block **360**, the three second segment for that channel ECG**1** is then determined to be not shockable, Block **365**, and the associated buffer is updated accordingly.

[0137] Similarly, a determination is made that channel ECG**2** is in the VF shock zone, Yes in Block **362**, if, for channel ECG**2**, the normalized mean rectified amplitude is greater than or equal to the boundary **802**. The three second segment for that channel ECG**2** is then determined to be shockable, Block **369** and the associated buffer for that channel is updated accordingly. If the normalized mean rectified amplitude for the channel is less than the boundary **802**, the channel ECG**2** is determined not to be in the VF shock zone, No in Block **362**, the three second segment for that channel ECG**2** is then determined to be not shockable, Block **367**, and the associated buffer is updated accordingly.

[0138] FIG. **13** is a graphical representation of the determination of whether an event is within a shock zone according to an embodiment of the present invention. According to another embodiment of the present invention, during the determination of whether the event is within the VT shock zone, Block **358** of FIG. **7**B, the normalized mean rectified amplitude and the spectral width are determined for each channel ECG**1** and ECG**2** during a given three second sensing window, as described above in reference to determining the VF shock zone. A determination is made as to which channel of the two signal channels ECG**1** and ECG**2** contains the maximum normalized mean rectified amplitude and which channel of the two signal channels ECG**1** and ECG**2** contains the minimum spectral width. A VT shock zone **820** is defined based on the relationship between the normalized mean rectified amplitude associated with the channel determined to have the maximum normalized mean rectified amplitude and the spectral width associated with the channel determined to have the minimum spectral width. For example, according to an embodiment of the present invention, the VT shock zone **820** is defined, for a given three second sensing window, by a boundary **822** associated with the maximum normalized mean rectified amplitude and the minimum spectral width set forth by the equation:

$$\text{NMRA} = 0.3636 \times \text{SW} - 15 \qquad \text{Equation 6}$$

[0139] If the maximum normalized mean rectified amplitude is greater than or equal to the boundary **822**, i.e., 0.3636× minimum spectral width−15, the event is determined to be in the VT shock zone, YES in Block **358**, and the three second segment for both channels ECG**1** and ECG**2** are determined to be shockable, Block **357**, and the associated buffers are updated accordingly. If the maximum normalized mean rectified amplitude is less than the boundary **822**, the event is determined to be outside the VT shock zone, NO in Block **358**, and both channels ECG**1** and ECG**2** are determined to be not shockable, Block **359**.

[0140] Returning to FIG. **7**B, according to another embodiment of the present invention, the determination of whether the clean channel is within the VF shock zone, Block **350**, is made based upon a normalized mean rectified amplitude metric and a spectral width metric, similar to the VF shock zone determination described above in reference to Blocks **360** and **362**, both of which are determined for the clean channel using the VF shock zone described above in reference to FIG. **12**. In particular, once the normalized mean rectified amplitude metric and a spectral width metric are determined for the clean

channel, the determination of whether the clean channel is in the VF shock zone is made using Equation 5, so that if the normalized mean rectified amplitude for the clean channel is less than the boundary **802**, the clean channel is determined not to be in the VF zone, No in Block **350** and both channels are classified as not shockable, Block **351**, and the associated buffers are updated accordingly.

[0141] If the normalized mean rectified amplitude for the clean channel is greater than or equal to the boundary **802**, the clean channel is determined to be in the VF zone, Yes in Block **350**. A determination is then made as to whether the channel determined to be corrupted by noise, i.e., the "noisy channel", is within the VF shock zone, Block **354**. If the normalized mean rectified amplitude for the noisy channel is less than the boundary **802**, the noisy channel is determined not to be in the VF zone, No in Block **354**, the clean channel is classified as shockable and the noisy channel is classified as not shockable, Block **355**, and the associated buffers are updated accordingly.

[0142] If the normalized mean rectified amplitude for the noisy channel is greater than or equal to the boundary **802**, the noisy channel is determined to be in the VF zone, Yes in Block **354**, both the clean channel and the noisy channel are classified as being shockable, Block **353**, and the associated buffers are updated accordingly.

[0143] Similar to the VT shock zone determination described above in Block **358** using the VT shock zone of FIG. **13**, during the determination as to whether the clean channel is within the VT shock zone in Block **352**, the normalized mean rectified amplitude and the spectral width are determined for the clean channel as described above in reference to determining the VF shock zone. The VT shock zone **820** is then defined based on the relationship between the normalized mean rectified amplitude and the spectral width associated with the clean channel according to Equation 6. If the maximum normalized mean rectified amplitude for the clean channel is greater than or equal to the boundary **822**, i.e., 0.3636×minimum spectral width−15, the clean channel is determined to be in the VT shock zone, YES in Block **352**, and both channels ECG**1** and ECG**2** are determined to be shockable, Block **353**, and the associated buffers are updated accordingly. If the maximum normalized mean rectified amplitude for the clean channel is less than the boundary **822**, the clean channel is determined to be outside the VT shock zone, NO in Block **352**, and both channels ECG**1** and ECG**2** are determined to be not shockable, Block **351**.

[0144] Once the classification of both of the channels ECG**1** and ECG**2** is made subsequent to the determination of whether the clean channel or channels is in the VT shock zone, Block **352** and **358**, or the VF shock zone, Blocks **350** and Blocks **360** and **362** in combination, a determination is made as to whether the device should transition from the concerned state **304** to the armed state **306**, Block **370**. For example, according to an embodiment of the present invention, the transition from the concerned state **304** to the armed state **306** is confirmed if a predetermined number, such as two out of three for example, of three-second segments for both channels ECG**1** and ECG**2** have been classified as being shockable. If the predetermined number of three-second segments in both channels ECG**1** and ECG**2** have been classified as shockable, the device transitions from the concerned state **304** to the armed state **306**, Yes in Block **370**. If the predetermined number of three-second segments in both channels ECG**1** and ECG**2** have not been classified as shockable, the device does not transition from the concerned state **304** to the armed state **306**, no in Block **370**, and a determination as to whether to transition back to the not concerned state **302** is made, Block **372**. The determination as to whether to transition from the concerned state **304** back to the not concerned state **302** is made, for example, by determining whether the heart rate estimate is less than a heart rate threshold level in both of the two channels ECG**1** and ECG**2**. If it is determined that the device should not transition to the not concerned state **302**, i.e., both of the two heart rate estimates are greater than the heart rate threshold, the process is repeated using the signal generated during a next three-second window, Block **341**.

[0145] According to an embodiment of the present invention, the heart rate threshold level is set as 180 bpm, for example, and a single estimate of heart rate (that occurs every three seconds) in at least one of the two channels ECG**1** and ECG**2** that is less than the heart rate threshold level will suffice to cause the device to transition from the concerned state **304** to the not concerned state **302**, Yes in Block **372**.

[0146] When the device transitions from the concerned state **304** to the armed state **306**, Yes in Block **370**, processing continues to be triggered by a three-second time out as is utilized during the concerned state **304**, described above. As illustrated in FIG. **7**F, once the device transitions from the concerned state **302** to the armed state **306**, charging of the capacitors is initiated, Block **600**. During the charging of the capacitors, the classification of segments for each channel ECG**1** and ECG**2** as being either shockable or not shockable generated during the shock zone tests described above continues and once the next three seconds of data has been acquired, Block **601**, a determination is made as 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 ECG**1** and ECG**2** as not shockable, Block **602**. 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 **602**, the charging of the capacitors is stopped, Block **604**, and a determination is made as to whether to transition to the not concerned state **302**, Block **606**.

[0147] According to an embodiment of the present invention, the device will transition from the armed state **306** to the not concerned state **302**, Yes in Block **606**, if certain termination requirements are met. For example, return to the not concerned state **302** occurs if, for both channels ECG**1** and ECG**2** 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 **302** is the observation of 4 consecutive not shockable classifications in both channel ECG**1** and ECG**2** simultaneously.

[0148] 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 **403**, and capacitor charging must not in progress. If each of these requirements are satisfied, Yes in Block **606**, the device transitions from the armed state **306** to the not concerned state **302**.

[0149] 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 **606**, and a determination is then made

as whether the shockable rhythm is redetected, Block **608**, 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 ECG**1** and ECG**2**, 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 **608**, the determination of whether to terminate delivery of the therapy, Block **606**, is repeated so that the processing switches between the determination of whether to terminate delivery of therapy, Block **606** and the determination as to whether the shockable event is redetected, Block **608**, until either the event has terminated and the device transitions from the armed state **306** to the not concerned state **302** or the event is redetected. If the predetermined redetection requirements are met, Yes in Block **608**, charging is re-initiated, Block **600**, and the process is repeated.

[0150] If, during the charging of the capacitors, the predetermined number of three second segments have not been classified as not shockable, No in Block **602**, a determination is made as to whether the charging of the capacitors is completed, Block **610**. As long as the predetermined number of three second segments continue to be classified as shockable, No in Block **602**, charging of the capacitors continues until charging is completed. Once the charging of the capacitors is completed, Yes in Block **610**, a determination is made as to whether delivery of the therapy is still appropriate, Block **612**, 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 ECG**1** and ECG**2**, 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 ECG**1** and ECG**2**.

[0151] If the predetermined therapy delivery requirements have not been satisfied, and therefore the delivery of the therapy is not confirmed, No in Block **612**, the determination of whether to transition from the armed state **306** to the not concerned state **302**, Block **606**, is repeated. If the predetermined therapy delivery requirements are satisfied, and therefore the delivery of the therapy is confirmed, Yes in Block **612**, the device transitions from the armed state **306** to the shock state **308**.

[0152] As illustrated in FIG. **7**G, once the device transitions from the armed state **306** to the shock state **308**, the therapy is delivered upon observation of the first sensed R-wave, Block **630**, the episode data is stored, Block **632**, and the buffers for storing the eight three second segments are cleared, Block **634**. Once a post shock timer, such as three seconds for example, has expired, Yes in Block **636**, the device transitions from the shock state **308** to Block **606** of the armed state **306**. Since, as described above, classification of at least three subsequent three-second segments is required before the termination decision can be made in Block **606** subsequent to the delivery of therapy in the shock state **308**, a determination based on the termination requirements cannot be initiated until at least twelve seconds after the initial shock therapy was delivered. The termination and redetection requirements are then reviewed until one of the two requirements are satisfied, i.e., the event is determined to have terminated, Yes in Block **606**, or the event is redetected, Yes in Block **608**. If the redetection requirements are satisfied, the charging of the capacitors is again initiated, Block **600**, and processing in the armed state **306** continues as described above until all available therapies have been exhausted.

[0153] It will be apparent from the foregoing that while particular embodiments of the invention have been illustrated and described, various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims. For example, as illustrated in FIG. **71**, during the noise determination of Block **744**, the determination is made for each channel ECG**1** and ECG**2** as to whether the channel is corrupted by noise as described above. However, according to an embodiment of the present invention, once noise is determined to be present in either channel, No in Blocks **380**, **382** or **388**, Yes in Block **384** of FIG. **7**C, both channels are classified as being not shockable, Block **748**.

[0154] If noise is not present in either channel ECG**1** and ECG**2**, No in Block **744**, a determination is made as for each channel ECG**1** and ECG**2** as to whether the channel is in a VF shock zone using the one of the methods described above. For example, according to an embodiment of the present invention, a determination is made that channel ECG**1** is in the VF shock zone, Yes in Block **748**, if, for channel ECG**1**, both the low slope content is less than the first boundary **502** and the spectral width is less than the second boundary **504**, as described above. The three second segment for that channel ECG**1** is then determined to be shockable, Block **750** and the associated buffer for that channel is updated accordingly. If either the low slope content for the channel is not less than the first boundary **502** or the spectral width is not less than the second boundary, the channel ECG**1** is determined not to be in the VF shock zone, No in Block **748**, the three second segment for that channel ECG**1** is then determined to be not shockable, Block **752**, and the associated buffer is updated accordingly.

[0155] Similarly, a determination is made that channel ECG**2** is in the VF shock zone, Yes in Block **754**, if, for channel ECG**2**, both the low slope content is less than the first boundary **502** and the spectral width is less than the second boundary **504**, as described above. The three second segment for that channel ECG**2** is then determined to be shockable, Block **756** and the associated buffer for that channel is updated accordingly. If either the low slope content for the channel is not less than the first boundary **502** or the spectral width is not less than the second boundary, the channel ECG**2** is determined not to be in the VF shock zone, No in Block **754**, the three second segment for that channel ECG**2** is then determined to be not shockable, Block **758**, and the associated buffer is updated accordingly.

[0156] According to another embodiment of the present invention, a determination is made that channel ECG**1** is in the VF shock zone, Yes in Block **748**, if, for channel ECG**1**, the normalized mean rectified amplitude is greater than or equal to the boundary **802**, as described above. The three second segment for that channel ECG**1** is then determined to be shockable, Block **750** and the associated buffer for that channel is updated accordingly. If the normalized mean rectified amplitude for the channel is less than the boundary **802**, the channel ECG**1** is determined not to be in the VF shock

zone, No in Block **748**, the three second segment for that channel ECG**1** is then determined to be not shockable, Block **752**, and the associated buffer is updated accordingly.

[0157] Similarly, a determination is made that channel ECG**2** is in the VF shock zone, Yes in Block **754**, if, for channel ECG**2**, the normalized mean rectified amplitude is greater than or equal to the boundary **802**, as described above. The three second segment for that channel ECG**2** is then determined to be shockable, Block **756** and the associated buffer for that channel is updated accordingly. If the normalized mean rectified amplitude for the channel is less than the boundary **802**, the channel ECG**2** is determined not to be in the VF shock zone, No in Block **754**, the three second segment for that channel ECG**2** is then determined to be not shockable, Block **758**, and the associated buffer is updated accordingly.

[0158] Once the classification of both of the channels ECG**1** and ECG**2** as being either shockable, Block **752** and **758**, or not shockable, Blocks **748**, **754** and **760**, a determination is made as to whether the device should transition from the concerned state **304** to the armed state **306**, Block **762**. The determination of whether the device should transition from the concerned state **304** to the armed state **306** in Block **762**, in addition to the subsequent determination of whether to transition from the concerned state **304** to the not concerned state **302** in Block **764** are similar to the determination of whether the device should transition from the concerned state **304** to the armed state **306** in Block **370**, and to the determination of whether to transition from the concerned state **304** to the not concerned state **302** in Block **372** in FIG. **7**B described above, and therefore will not be repeated for the sake of brevity.

[0159] Some of the techniques described above may be embodied as a computer-readable medium comprising instructions for a programmable processor such as microprocessor **142**, pacer/device timing circuit **178** or control circuit **144** shown in FIG. **3**. The programmable processor may include one or more individual processors, which may act independently or in concert. A "computer-readable medium" includes but is not limited to any type of computer memory such as floppy disks, conventional hard disks, CR-ROMS, Flash ROMS, nonvolatile ROMS, RAM and a magnetic or optical storage medium. The medium may include instructions for causing a processor to perform any of the features described above for initiating a session of the escape rate variation according to the present invention.

[0160] While a particular embodiment of the present invention has been shown and described, modifications may be made. It is therefore intended in the appended claims to cover all such changes and modifications, which fall within the true spirit and scope of the invention.

We claim:

1. A subcutaneously implantable cardiac medical device, comprising:

a plurality of electrodes to sense a cardiac signal along a plurality of sensing vectors to detect a first interval and a second interval associated with a first detected event; and

a processor configured to determine whether the first interval and the second interval are shorter than a predetermined threshold, determine whether the first interval and the second interval are similar, and determine, in response to the first interval and the second interval being similar, whether the sensed cardiac signal is either a noisy signal or a QRS signal.

2. The subcutaneously implantable cardiac medical device of claim **1**, wherein determining whether the first interval and the second interval are similar comprises determining whether both the first interval and the second interval comprise regular intervals.

3. The subcutaneously implantable cardiac medical device of claim **1**, wherein the processor is configured to perform an amplitude analysis in response to the first interval and the second interval being similar, and characterize the sensed cardiac signal is either a noisy signal or a QRS signal in response to the amplitude analysis.

4. The subcutaneously implantable cardiac medical device of claim **3**, wherein the processor is configured to characterize the first detected event as a noisy signal and a subsequent second detected event as a QRS signal in response to the amplitude analysis.

5. The subcutaneously implantable cardiac medical device of claim **3**, wherein the processor is configured to characterize the first detected event as a QRS signal and a subsequent second detected event as a noisy signal in response to the amplitude analysis.

6. The subcutaneously implantable cardiac medical device of claim **5**, wherein the processor is configured to characterize the first detected event as a noisy signal and the subsequent second detected event as a QRS signal in response to the amplitude analysis.

7. A method of sensing a cardiac signal in a subcutaneously implantable cardiac medical device, comprising:

sensing the cardiac signal along a plurality of sensing vectors to detect a first interval and a second interval associated with a first detected event;

determining whether the first interval and the second interval are shorter than a predetermined threshold;

determining whether the first interval and the second interval are similar; and

determining, in response to the first interval and the second interval being similar, whether the sensed cardiac signal is either a noisy signal or a QRS signal.

8. The method of claim **7**, wherein determining whether the first interval and the second interval are similar comprises determining whether both the first interval and the second interval comprise regular intervals.

9. The method of claim **7**, further comprising:

performing an amplitude analysis in response to the first interval and the second interval being similar; and

characterizing the sensed cardiac signal is either a noisy signal or a QRS signal in response to the amplitude analysis.

10. The method of claim **9**, further comprising characterizing the first detected event as a noisy signal and a subsequent second detected event as a QRS signal in response to the amplitude analysis.

11. The method of claim **9**, further comprising characterizing the first detected event as a QRS signal and a subsequent second detected event as a noisy signal in response to the amplitude analysis.

12. The method of claim **11**, further comprising characterizing the first detected event as a noisy signal and the subsequent second detected event as a QRS signal in response to the amplitude analysis.

13. A computer-readable medium storing a set of instructions which cause a processor of an implantable medical device to perform a method of sensing a cardiac

signal in a subcutaneously implantable cardiac medical device, comprising:

sensing the cardiac signal along a plurality of sensing vectors to detect a first interval and a second interval associated with a first detected event;

determining whether the first interval and the second interval are shorter than a predetermined threshold;

determining whether the first interval and the second interval are similar; and

determining, in response to the first interval and the second interval being similar, whether the sensed cardiac signal is either a noisy signal or a QRS signal.

14. The computer-readable medium of claim **13**, wherein determining whether the first interval and the second interval are similar comprises determining whether both the first interval and the second interval comprise regular intervals.

15. The computer-readable medium of claim **13**, the method further comprising:

performing an amplitude analysis in response to the first interval and the second interval being similar; and

characterizing the sensed cardiac signal is either a noisy signal or a QRS signal in response to the amplitude analysis.

16. The computer-readable medium of claim **15**, the method further comprising characterizing the first detected event as a noisy signal and a subsequent second detected event as a QRS signal in response to the amplitude analysis.

17. The computer-readable medium of claim **15**, the method further comprising characterizing the first detected event as a QRS signal and a subsequent second detected event as a noisy signal in response to the amplitude analysis.

18. The computer-readable medium of claim **17**, the method further comprising characterizing the first detected event as a noisy signal and the subsequent second detected event as a QRS signal in response to the amplitude analysis.

* * * * *

专利名称(译)	用于检测皮下医疗设备中的心律失常的方法和设备		
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当前申请(专利权)人(译)	美敦力公司，INC.		
[标]发明人	STADLER ROBERT W GHANEM RAJA N ZHANG XUSHENG		
发明人	STADLER, ROBERT W. GHANEM, RAJA N. ZHANG, XUSHENG		
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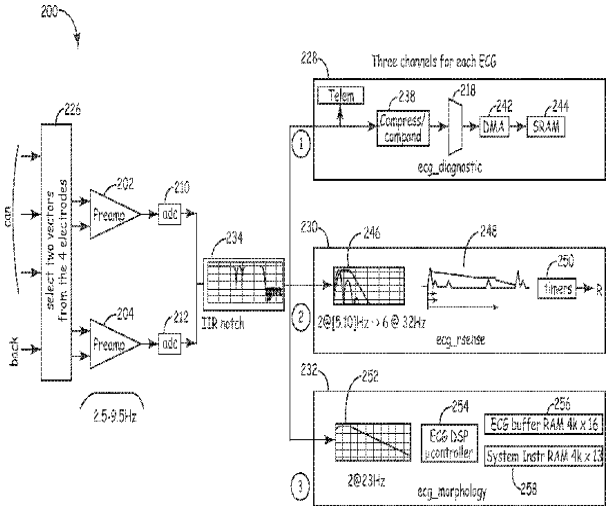
一种皮下植入式心脏医疗装置及其中感测心脏信号的方法，其包括多个电极以沿多个感测向量感测心脏信号以检测与第一检测到的事件相关联的第一间隔和第二间隔，以及处理器，被配置为确定第一间隔和第二间隔是否短于预定阈值，确定第一间隔和第二间隔是否相似，并且响应于第一间隔和第二间隔相似，确定是否感测到心脏信号是噪声信号或QRS信号。