US010561332B2

(12) **United States Patent**
Zhang et al.

(10) **Patent No.: US 10,561,332 B2**
(45) **Date of Patent: Feb. 18, 2020**

(54) **CARDIAC ELECTRICAL SIGNAL GROSS MORPHOLOGY-BASED NOISE DETECTION FOR REJECTION OF VENTRICULAR TACHYARRHYTHMIA DETECTION**

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(73) Assignee: **Medtronic, Inc.**, Minneapolis, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 238 days.

(21) Appl. No.: **15/653,969**

(22) Filed: **Jul. 19, 2017**

(65) **Prior Publication Data**

US 2018/0028085 A1 Feb. 1, 2018

Related U.S. Application Data

(60) Provisional application No. 62/367,166, filed on Jul. 27, 2016.

(51) **Int. Cl.**
A61B 5/0464 (2006.01)
A61B 5/021 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/0464*** (2013.01); ***A61B 5/02108*** (2013.01); ***A61B 5/04012*** (2013.01); ***A61B 5/04017*** (2013.01); ***A61B 5/0452*** (2013.01); ***A61B 5/7203*** (2013.01); ***A61N 1/3925*** (2013.01); *A61B 5/0245* (2013.01); *A61B 5/4836* (2013.01); *A61N 1/3704* (2013.01); *A61N 1/3956* (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC ... A61B 5/0464; A61B 5/0456; A61B 5/7203; A61B 5/04011; A61B 5/01012; A61N 1/3621; A61N 1/365; A61N 1/3702
See application file for complete search history.

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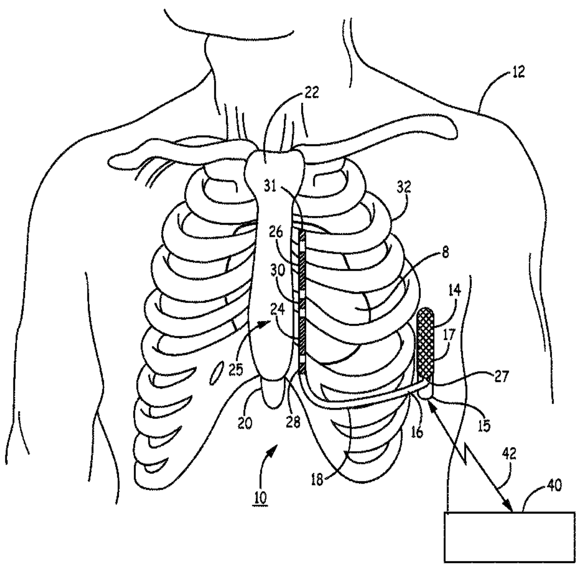
Primary Examiner — Tammie K Marlen

(57) **ABSTRACT**

A medical device system, such as an extra-cardiovascular implantable cardioverter defibrillator ICD, senses R-waves from a first cardiac electrical signal by a first sensing channel and stores a time segment of a second cardiac electrical signal in response to each sensed R-wave. The medical device system determines a morphology parameter correlated to signal noise from time segments of the second cardiac electrical signal, detects a noisy signal segment based on the signal morphology parameter; and withholds detection of a tachyarrhythmia episode in response to detecting a threshold number of noisy signal segments.

31 Claims, 21 Drawing Sheets



(51) **Int. Cl.**

A61B 5/04	(2006.01)
A61B 5/00	(2006.01)
A61N 1/39	(2006.01)
A61B 5/0452	(2006.01)
A61B 5/0245	(2006.01)
A61N 1/37	(2006.01)
H03H 21/00	(2006.01)

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

CPC *A61N 1/3962* (2013.01); *A61N 1/3987* (2013.01); *H03H 21/0012* (2013.01)

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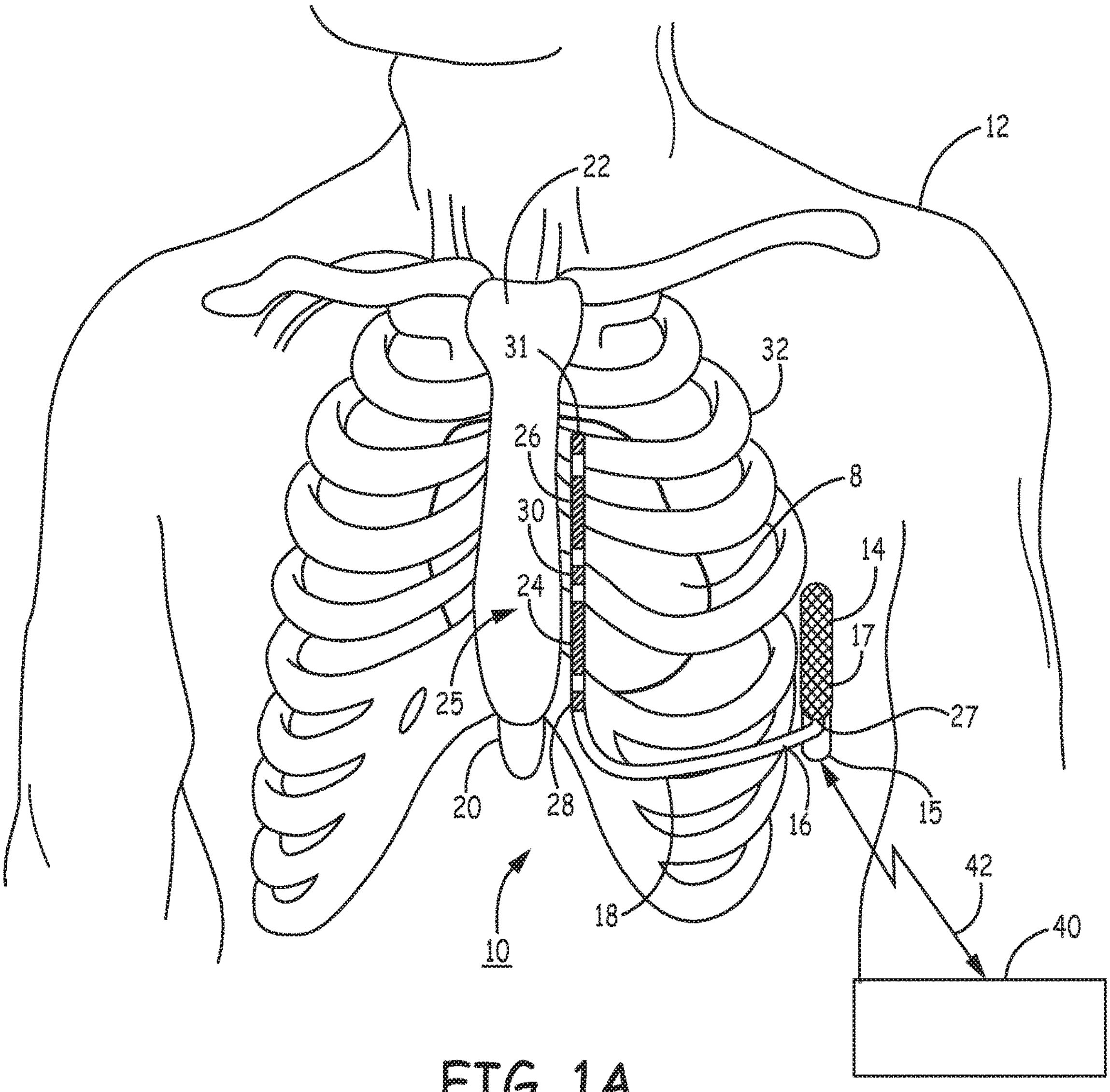


FIG. 1A

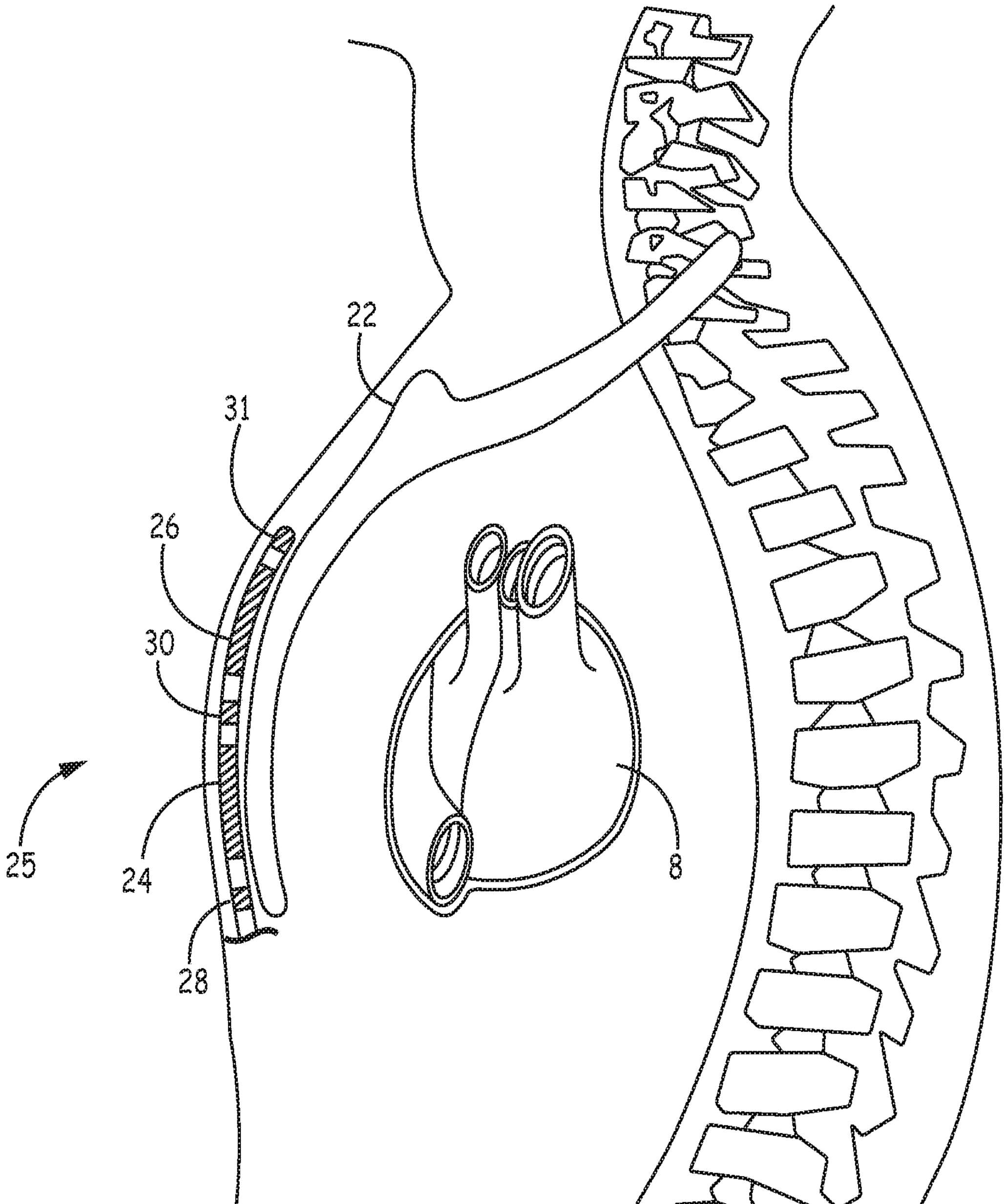


FIG. 1B

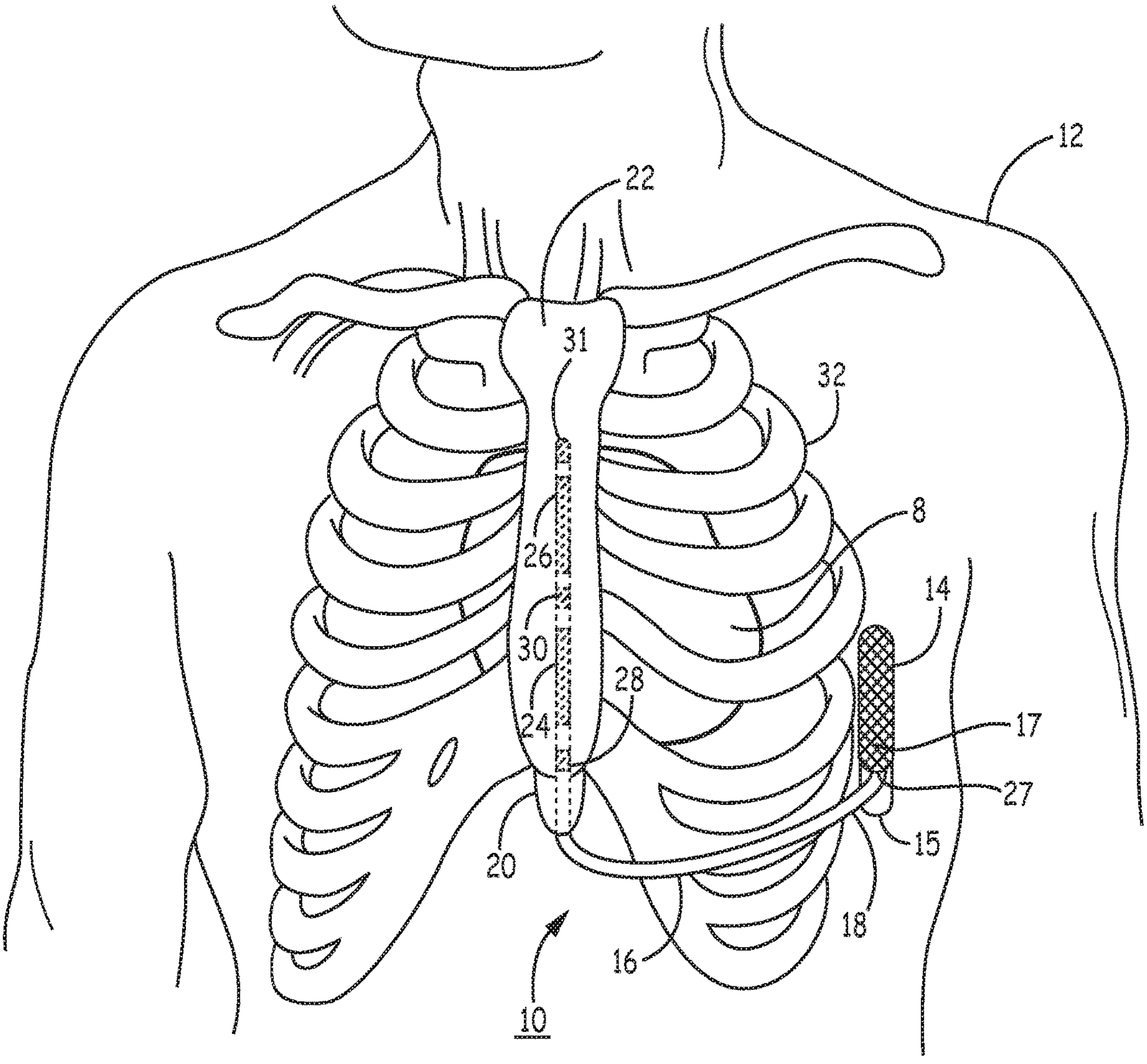


FIG. 2A

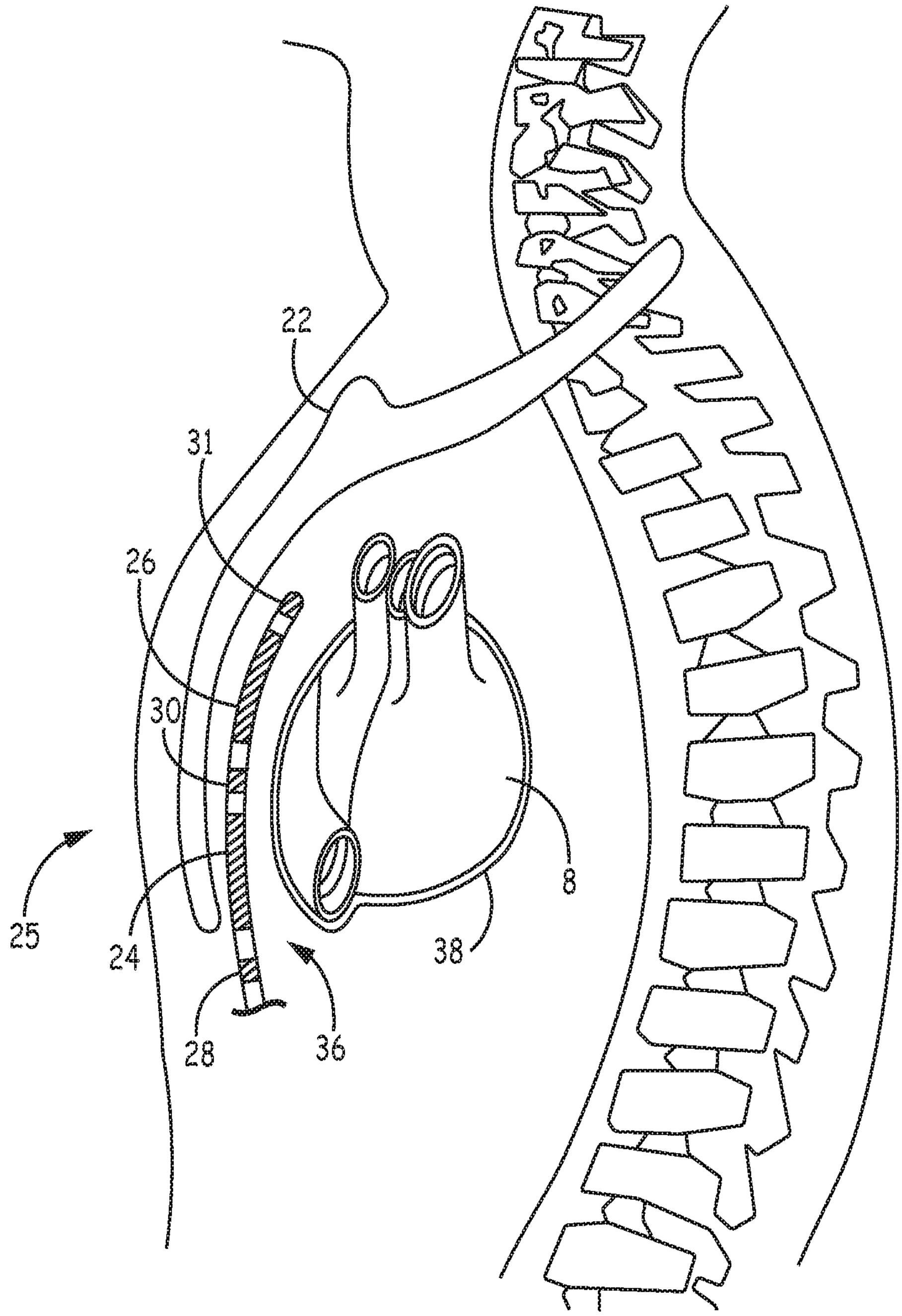


FIG. 2B

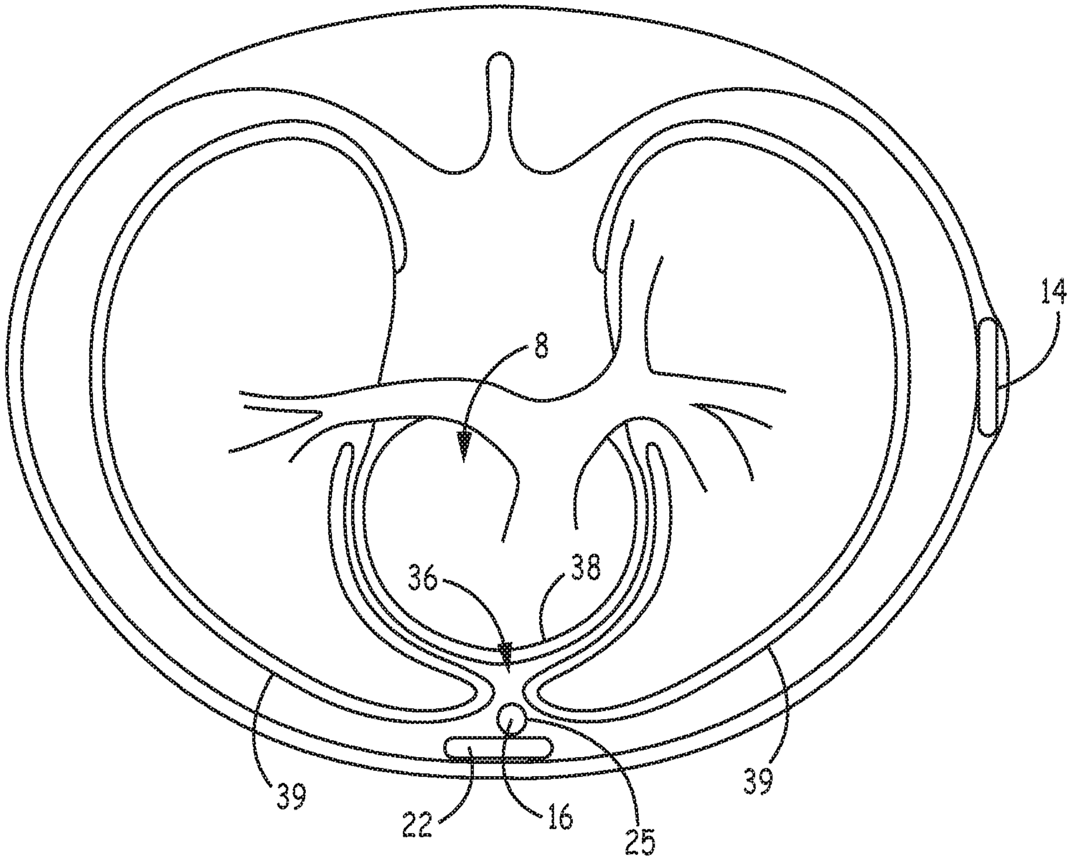


FIG. 2C

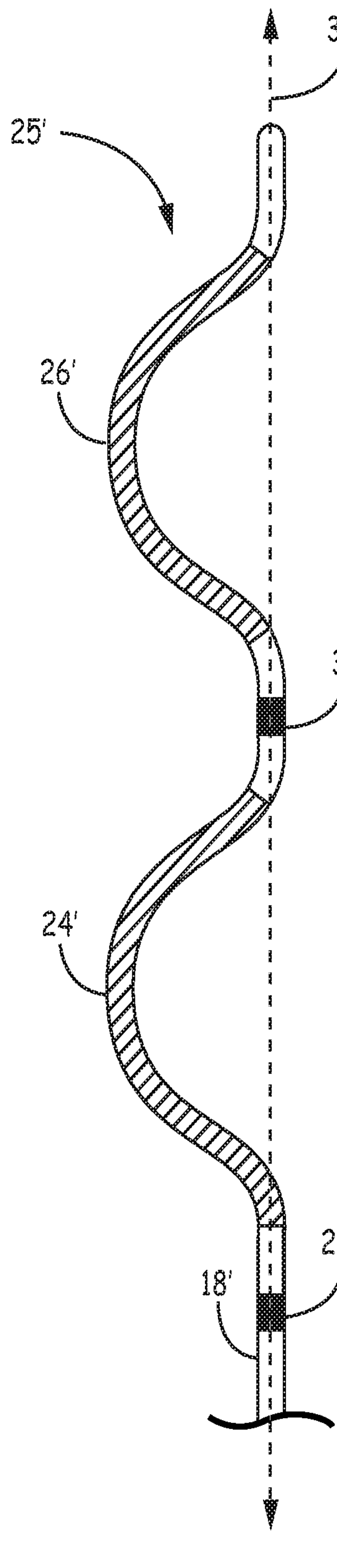


FIG. 3

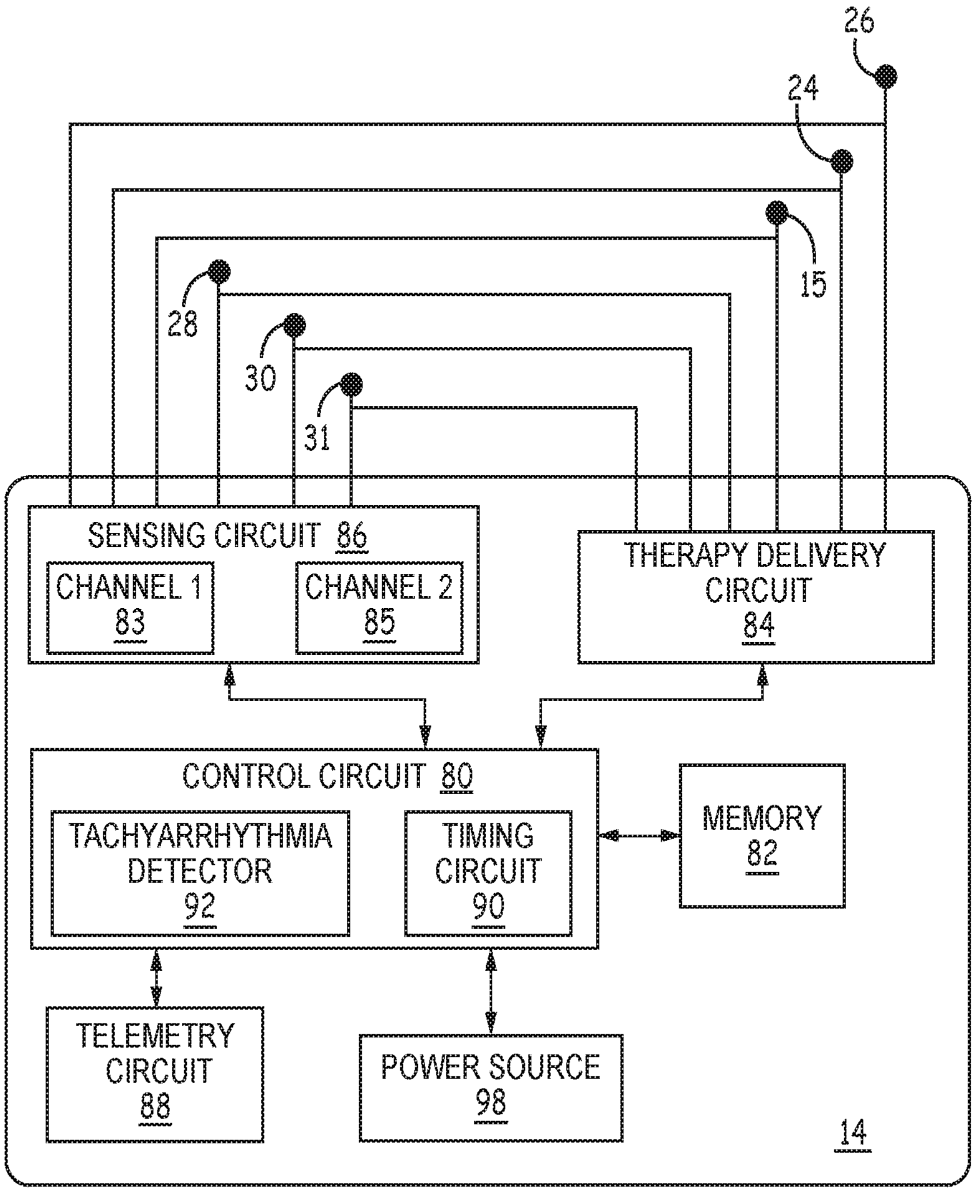

26
24
15
28
30
31
SENSING CIRCUIT 86
CHANNEL 1
83
CHANNEL 2
85
THERAPY DELIVERY
CIRCUIT
84
CONTROL CIRCUIT 80
TACHYARRHYTHMIA
DETECTOR
92
TIMING
CIRCUIT
90
MEMORY
82
TELEMETRY
CIRCUIT
88
POWER SOURCE
98
14

FIG. 4

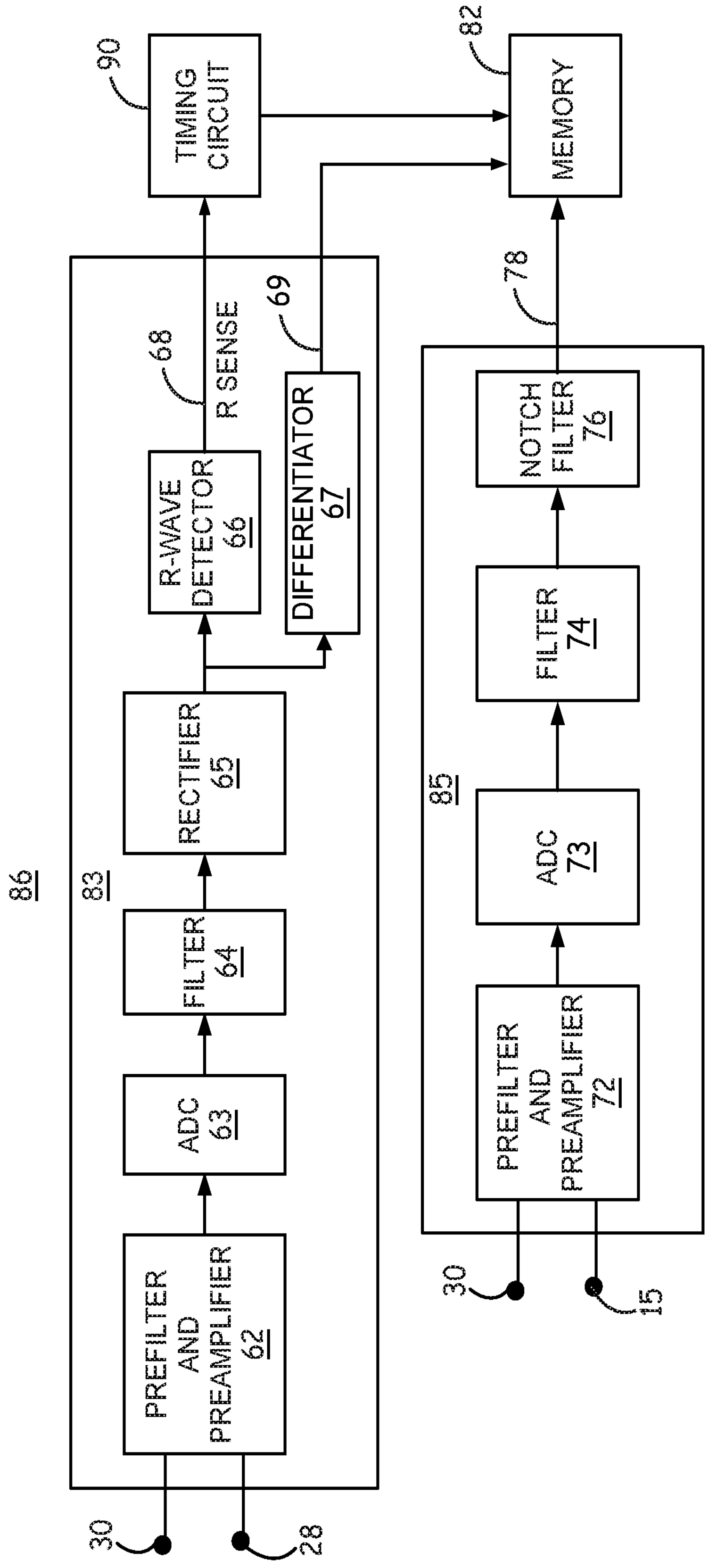

TIMING CIRCUIT
90
MEMORY
82
78
R SENSE
68
69
R-WAVE DETECTOR 66
DIFFERENTIATOR 67
NOTCH FILTER 76
FILTER 74
RECTIFIER 65
85
ADC 73
86
83
FILTER 64
PREFILTER AND PREAMPLIFIER 72
ADC 63
PREFILTER AND PREAMPLIFIER 62
30
15
30
28

FIG. 5

50

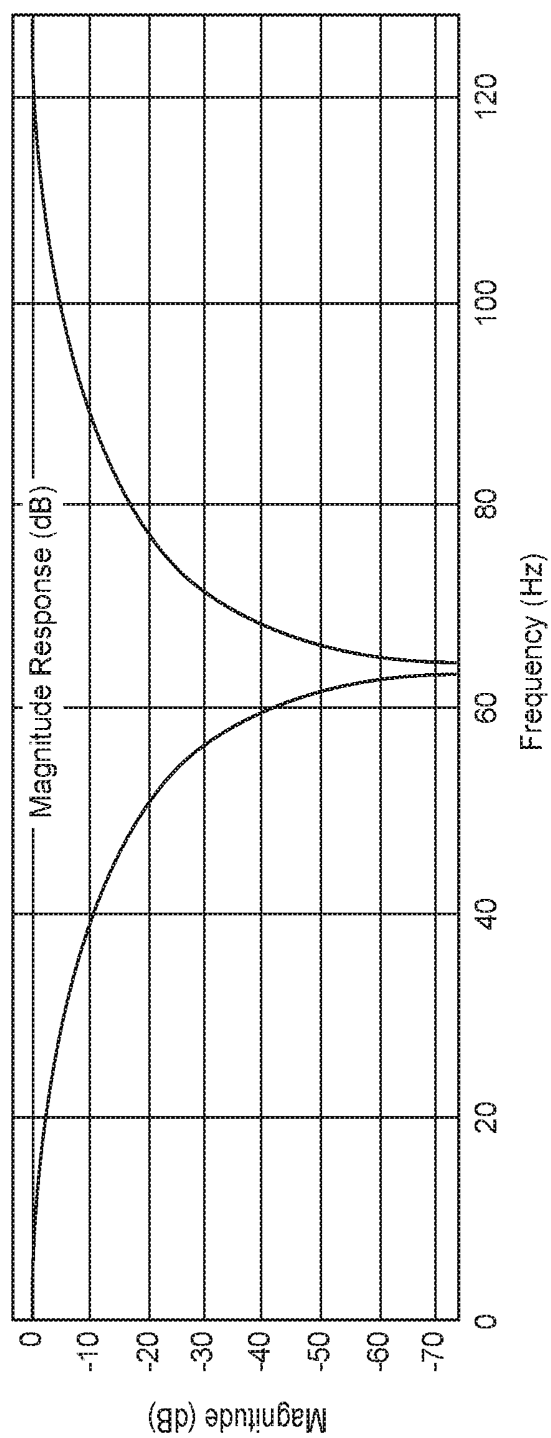

Magnitude Response (dB)
Magnitude (dB)
Frequency (Hz)
0
-10
-20
-30
-40
-50
-60
-70
0
20
40
60
80
100
120

FIG. 6

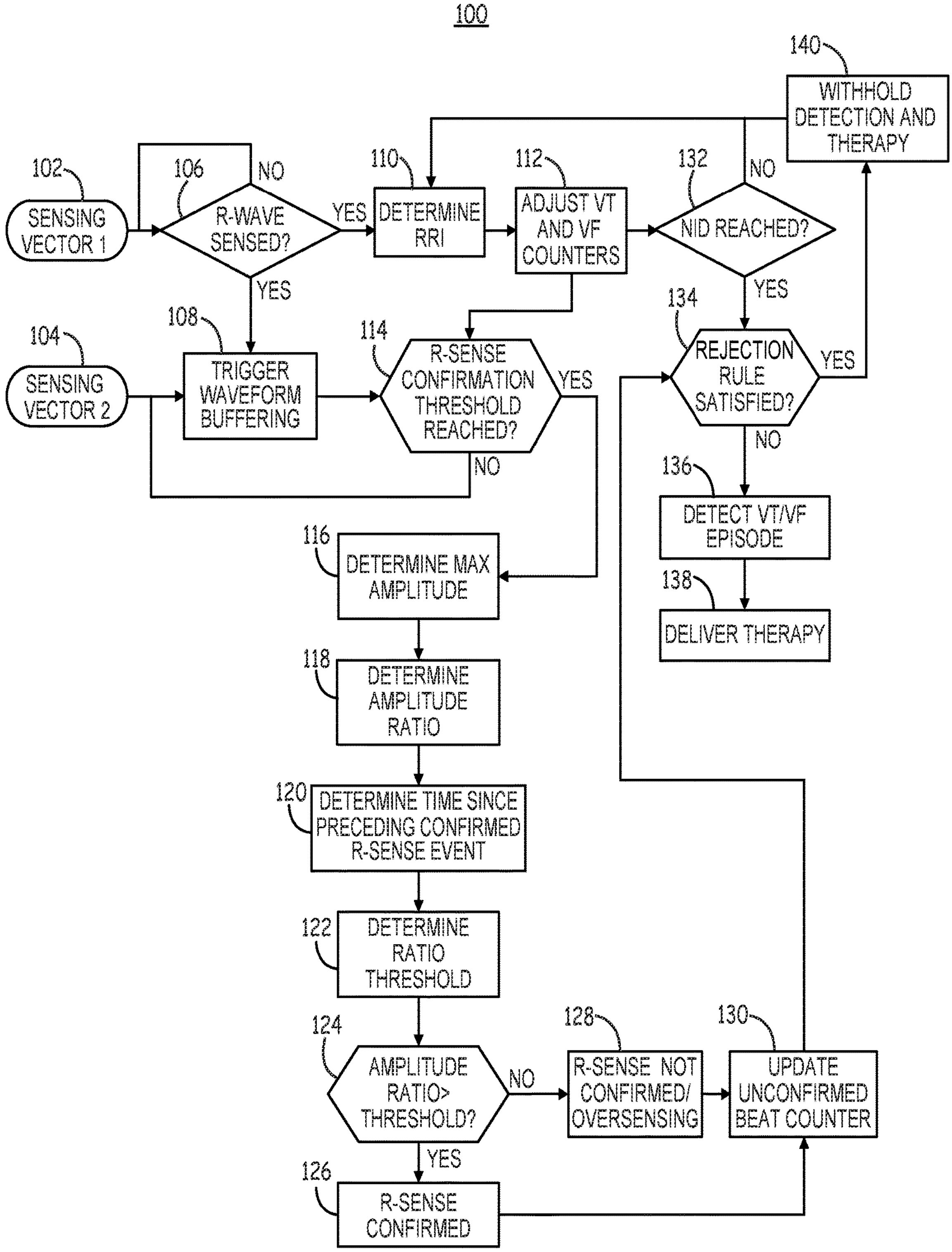

100
102
SENSING VECTOR 1
106
R-WAVE SENSED?
NO
YES
110
DETERMINE RRI
112
ADJUST VT AND VF COUNTERS
132
NID REACHED?
NO
YES
140
WITHHOLD DETECTION AND THERAPY
104
SENSING VECTOR 2
108
TRIGGER WAVEFORM BUFFERING
114
R-SENSE CONFIRMATION THRESHOLD REACHED?
YES
NO
134
REJECTION RULE SATISFIED?
YES
NO
136
DETECT VT/VF EPISODE
138
DELIVER THERAPY
116
DETERMINE MAX AMPLITUDE
118
DETERMINE AMPLITUDE RATIO
120
DETERMINE TIME SINCE PRECEDING CONFIRMED R-SENSE EVENT
122
DETERMINE RATIO THRESHOLD
124
AMPLITUDE RATIO> THRESHOLD?
NO
YES
128
R-SENSE NOT CONFIRMED/ OVERSENSING
130
UPDATE UNCONFIRMED BEAT COUNTER
126
R-SENSE CONFIRMED

FIG. 7

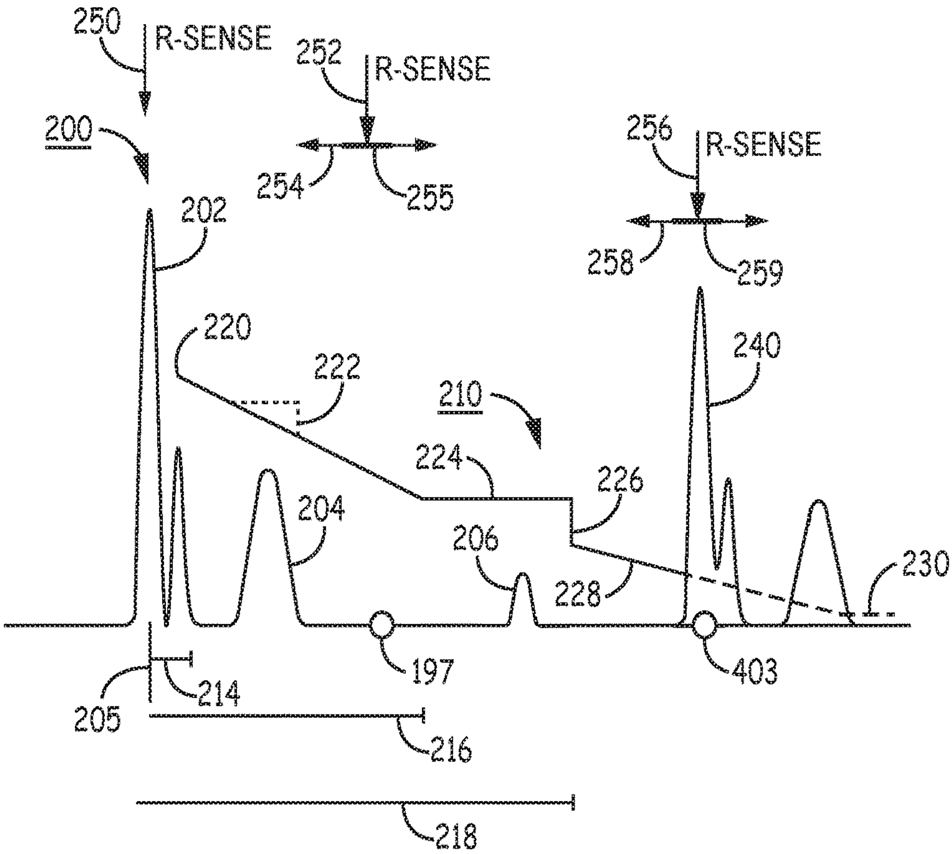


FIG. 8

300

302

304

SAMPLE POINT NUMBER	RATIO THRESHOLD
38	0.6
•	•
•	•
•	•
48	0.587
•	•
•	•
•	•
256	0.3
•	•
•	•
•	•
383	0.3
384	0.2
•	•
•	•
640	0.015

FIG. 9

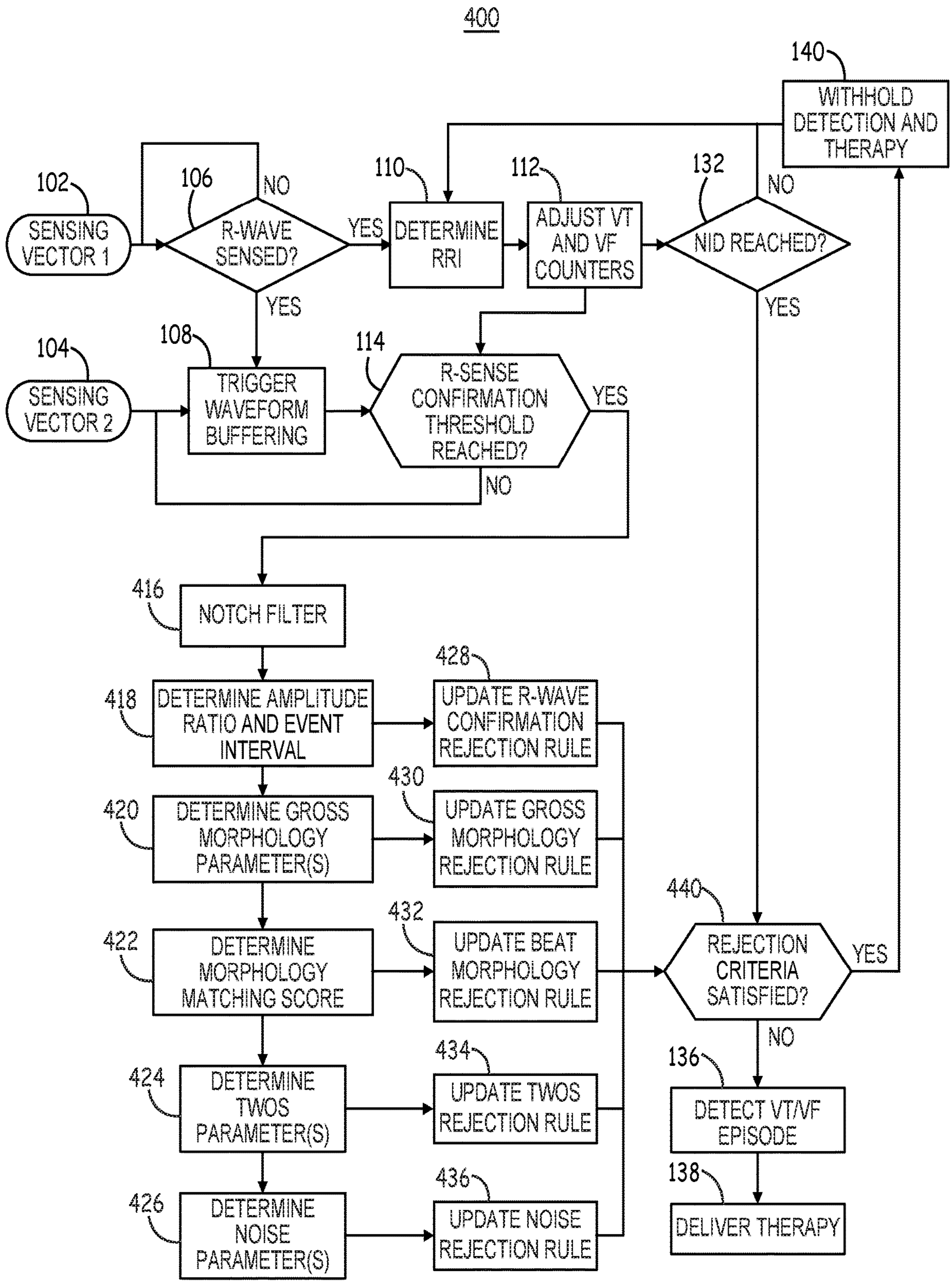

400
140
WITHHOLD DETECTION AND THERAPY
102
SENSING VECTOR 1
106
NO
R-WAVE SENSED?
YES
110
DETERMINE RRI
112
ADJUST VT AND VF COUNTERS
132
NO
NID REACHED?
YES
YES
104
SENSING VECTOR 2
108
TRIGGER WAVEFORM BUFFERING
114
R-SENSE CONFIRMATION THRESHOLD REACHED?
YES
NO
416
NOTCH FILTER
418
DETERMINE AMPLITUDE RATIO AND EVENT INTERVAL
428
UPDATE R-WAVE CONFIRMATION REJECTION RULE
420
DETERMINE GROSS MORPHOLOGY PARAMETER(S)
430
UPDATE GROSS MORPHOLOGY REJECTION RULE
440
422
DETERMINE MORPHOLOGY MATCHING SCORE
432
UPDATE BEAT MORPHOLOGY REJECTION RULE
REJECTION CRITERIA SATISFIED?
YES
NO
424
DETERMINE TWOS PARAMETER(S)
434
UPDATE TWOS REJECTION RULE
136
DETECT VT/VF EPISODE
426
DETERMINE NOISE PARAMETER(S)
436
UPDATE NOISE REJECTION RULE
138
DELIVER THERAPY

FIG. 10

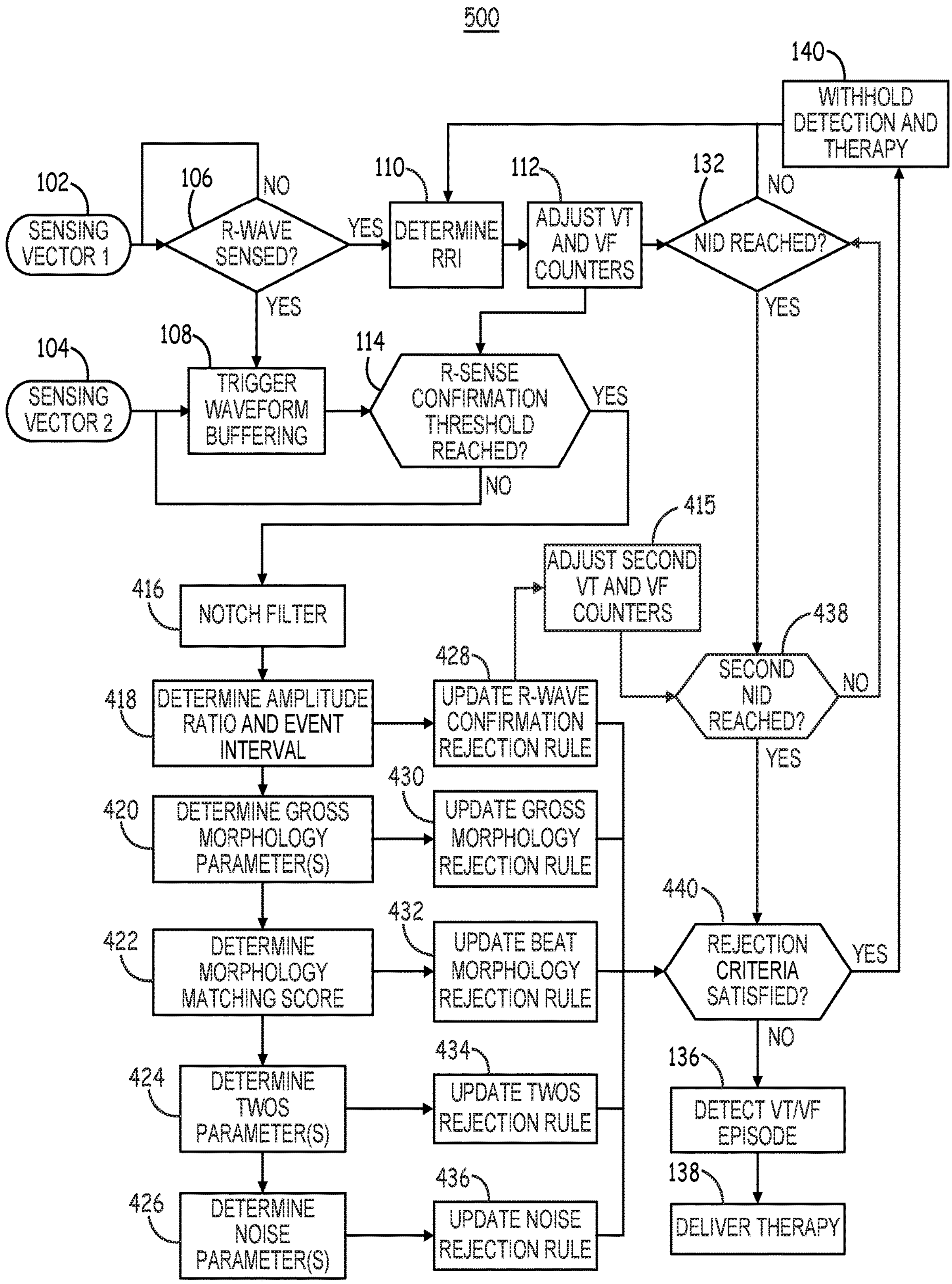

500
140
WITHHOLD DETECTION AND THERAPY
102
SENSING VECTOR 1
106
NO
R-WAVE SENSED?
YES
110
DETERMINE RRI
112
ADJUST VT AND VF COUNTERS
132
NO
NID REACHED?
YES
104
SENSING VECTOR 2
108
TRIGGER WAVEFORM BUFFERING
114
R-SENSE CONFIRMATION THRESHOLD REACHED?
YES
NO
415
ADJUST SECOND VT AND VF COUNTERS
416
NOTCH FILTER
438
SECOND NID REACHED?
NO
YES
418
DETERMINE AMPLITUDE RATIO AND EVENT INTERVAL
428
UPDATE R-WAVE CONFIRMATION REJECTION RULE
420
DETERMINE GROSS MORPHOLOGY PARAMETER(S)
430
UPDATE GROSS MORPHOLOGY REJECTION RULE
440
422
DETERMINE MORPHOLOGY MATCHING SCORE
432
UPDATE BEAT MORPHOLOGY REJECTION RULE
REJECTION CRITERIA SATISFIED?
YES
NO
424
DETERMINE TWOS PARAMETER(S)
434
UPDATE TWOS REJECTION RULE
136
DETECT VT/VF EPISODE
138
DELIVER THERAPY
426
DETERMINE NOISE PARAMETER(S)
436
UPDATE NOISE REJECTION RULE

FIG. 11

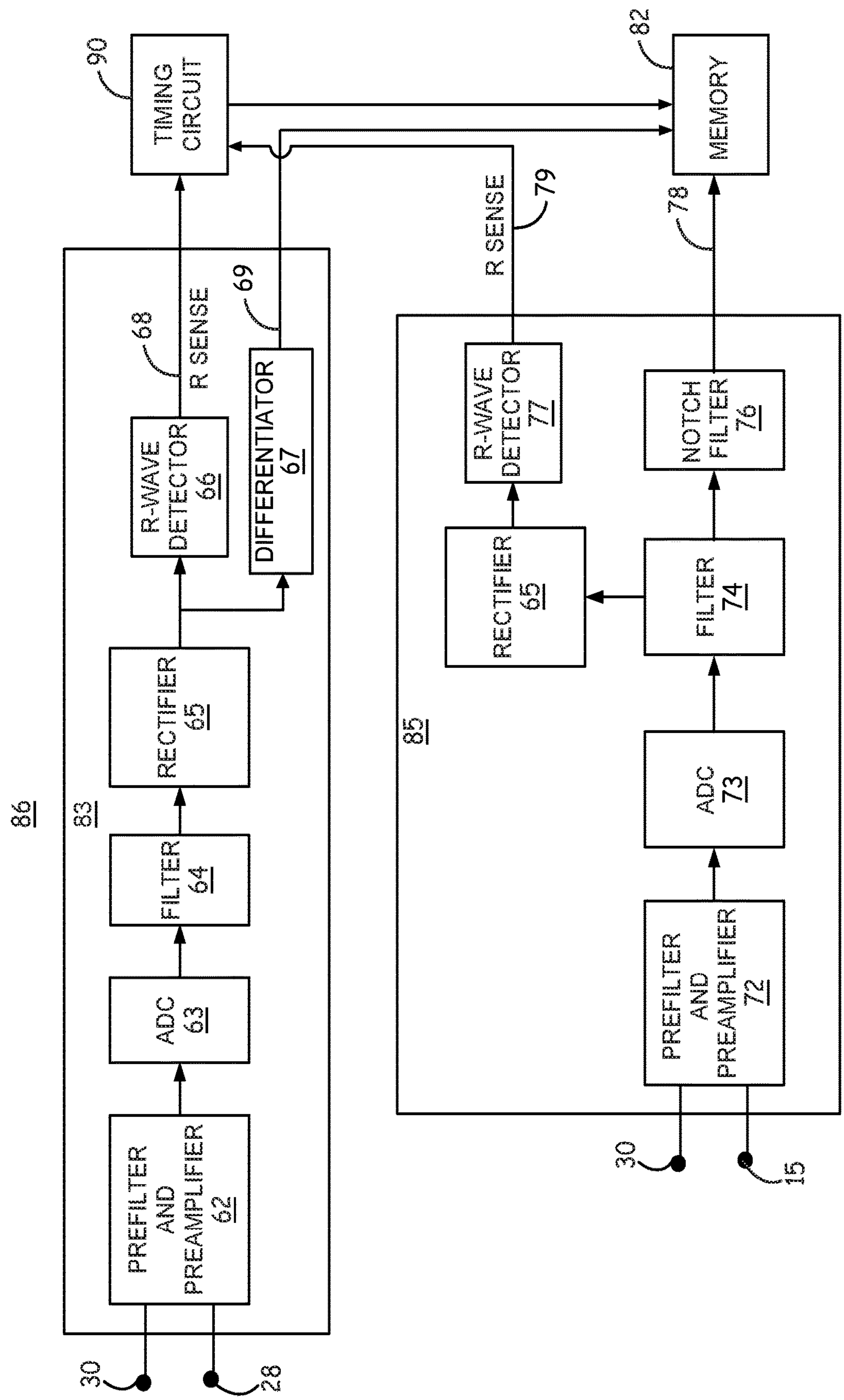

TIMING CIRCUIT
90
MEMORY
82
R SENSE
79
78
86
83
PREFILTER AND PREAMPLIFIER 62
ADC 63
FILTER 64
RECTIFIER 65
R-WAVE DETECTOR 66
DIFFERENTIATOR 67
68
R SENSE
69
30
28
85
PREFILTER AND PREAMPLIFIER 72
ADC 73
FILTER 74
RECTIFIER 65
R-WAVE DETECTOR 77
NOTCH FILTER 76
30
15

FIG. 12

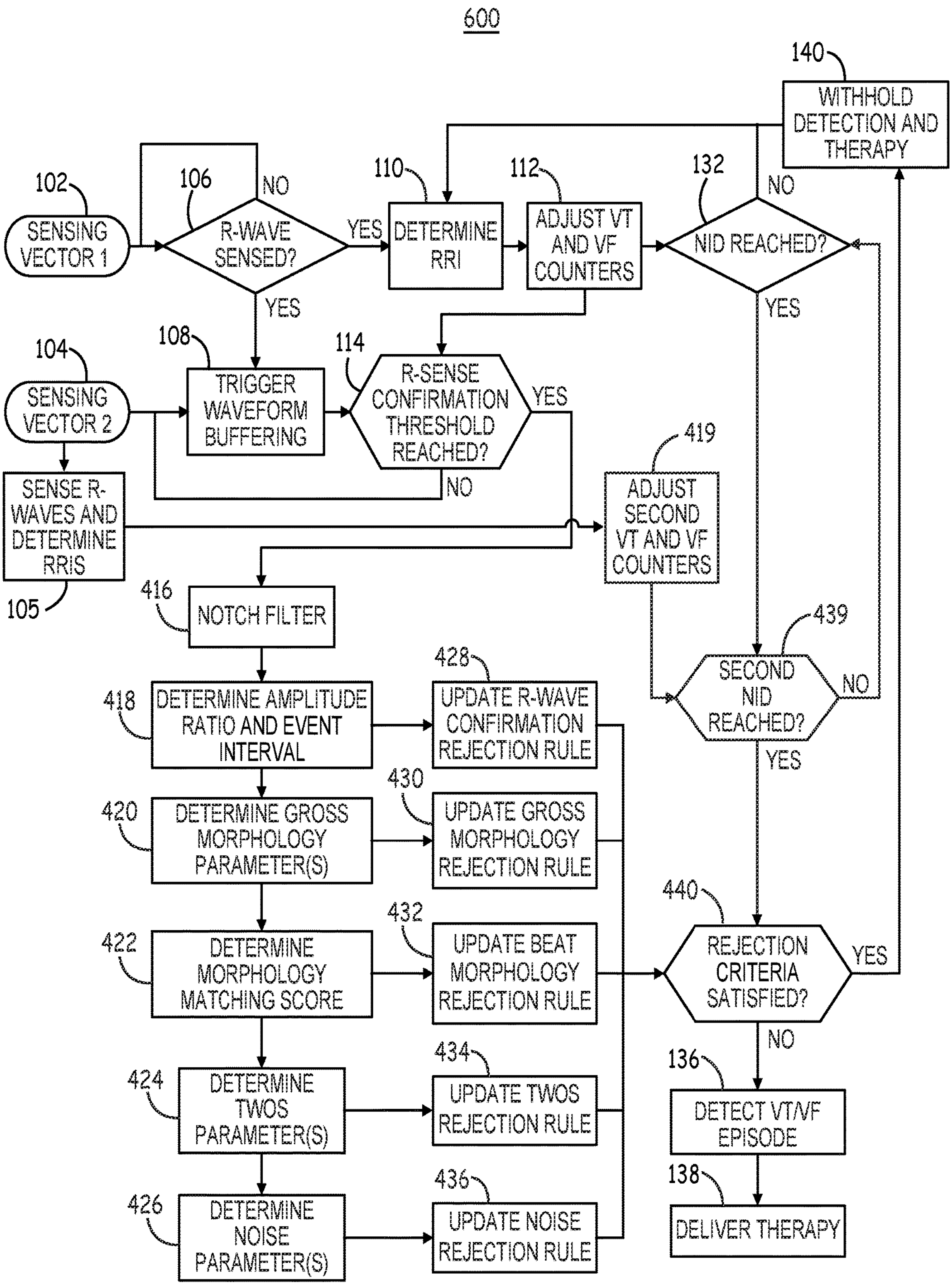

600
102
SENSING VECTOR 1
106
R-WAVE SENSED?
NO
YES
110
DETERMINE RRI
112
ADJUST VT AND VF COUNTERS
132
NID REACHED?
NO
YES
140
WITHHOLD DETECTION AND THERAPY
104
SENSING VECTOR 2
108
TRIGGER WAVEFORM BUFFERING
114
R-SENSE CONFIRMATION THRESHOLD REACHED?
YES
NO
SENSE R-WAVES AND DETERMINE RRIS
105
419
ADJUST SECOND VT AND VF COUNTERS
416
NOTCH FILTER
439
SECOND NID REACHED?
NO
YES
418
DETERMINE AMPLITUDE RATIO AND EVENT INTERVAL
428
UPDATE R-WAVE CONFIRMATION REJECTION RULE
420
DETERMINE GROSS MORPHOLOGY PARAMETER(S)
430
UPDATE GROSS MORPHOLOGY REJECTION RULE
422
DETERMINE MORPHOLOGY MATCHING SCORE
432
UPDATE BEAT MORPHOLOGY REJECTION RULE
440
REJECTION CRITERIA SATISFIED?
YES
NO
424
DETERMINE TWOS PARAMETER(S)
434
UPDATE TWOS REJECTION RULE
136
DETECT VT/VF EPISODE
138
DELIVER THERAPY
426
DETERMINE NOISE PARAMETER(S)
436
UPDATE NOISE REJECTION RULE

FIG. 13

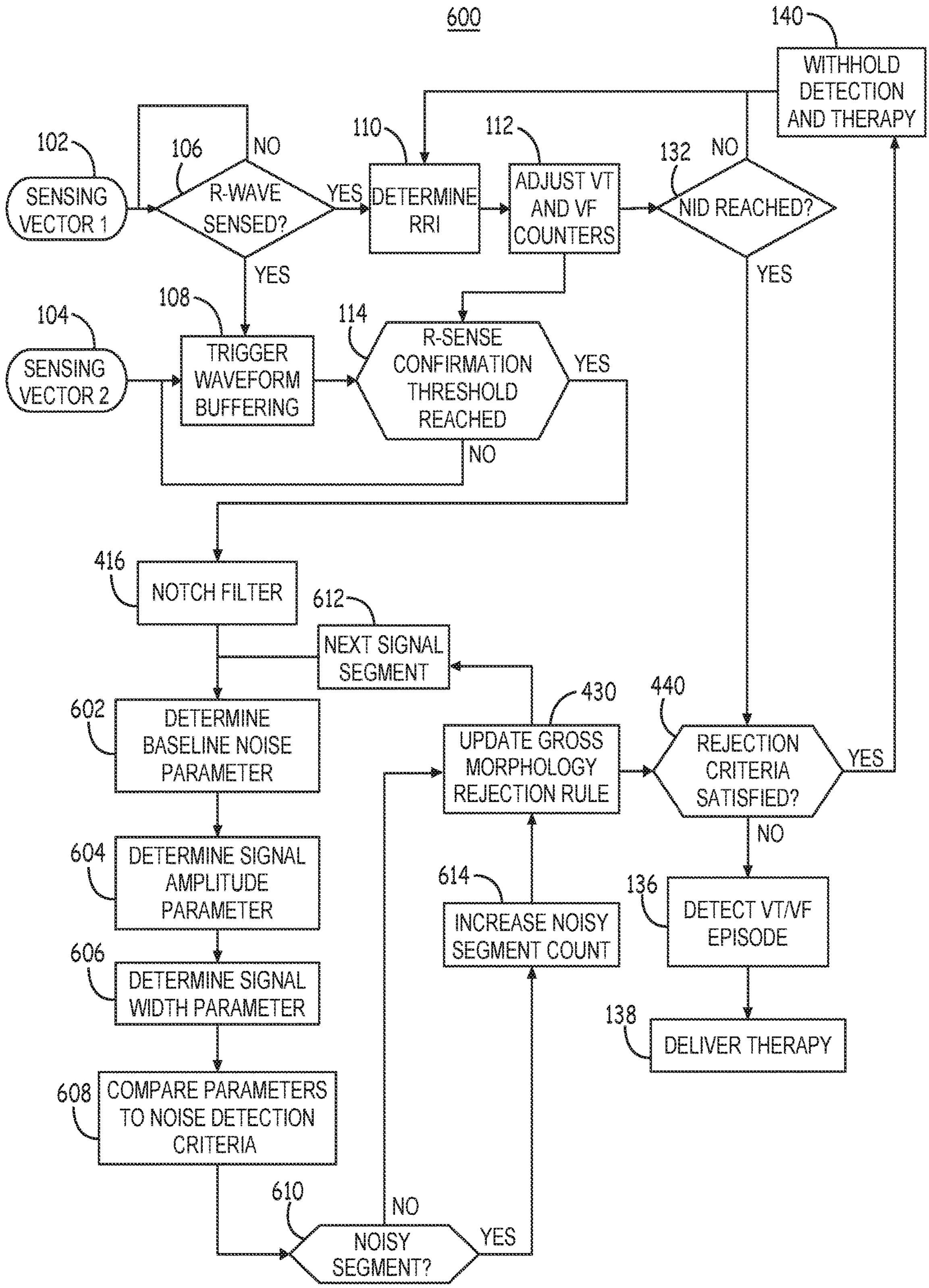

600
140
WITHHOLD DETECTION AND THERAPY
102
SENSING VECTOR 1
106
R-WAVE SENSED?
NO
YES
110
DETERMINE RRI
112
ADJUST VT AND VF COUNTERS
132
NO
NID REACHED?
YES
104
SENSING VECTOR 2
108
TRIGGER WAVEFORM BUFFERING
114
R-SENSE CONFIRMATION THRESHOLD REACHED
YES
NO
416
NOTCH FILTER
612
NEXT SIGNAL SEGMENT
602
DETERMINE BASELINE NOISE PARAMETER
430
UPDATE GROSS MORPHOLOGY REJECTION RULE
440
REJECTION CRITERIA SATISFIED?
YES
NO
604
DETERMINE SIGNAL AMPLITUDE PARAMETER
614
INCREASE NOISY SEGMENT COUNT
136
DETECT VT/VF EPISODE
606
DETERMINE SIGNAL WIDTH PARAMETER
138
DELIVER THERAPY
608
COMPARE PARAMETERS TO NOISE DETECTION CRITERIA
610
NOISY SEGMENT?
NO
YES

FIG. 14

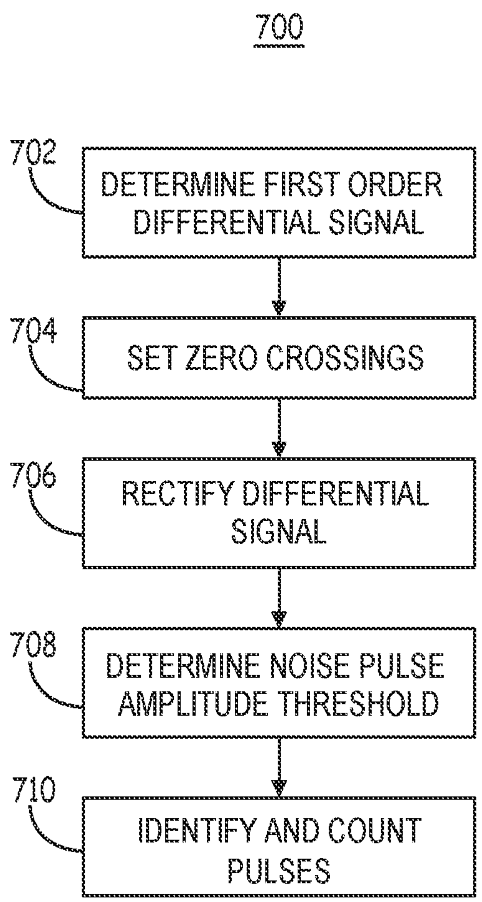

700
702
DETERMINE FIRST ORDER DIFFERENTIAL SIGNAL
704
SET ZERO CROSSINGS
706
RECTIFY DIFFERENTIAL SIGNAL
708
DETERMINE NOISE PULSE AMPLITUDE THRESHOLD
710
IDENTIFY AND COUNT PULSES

FIG. 15

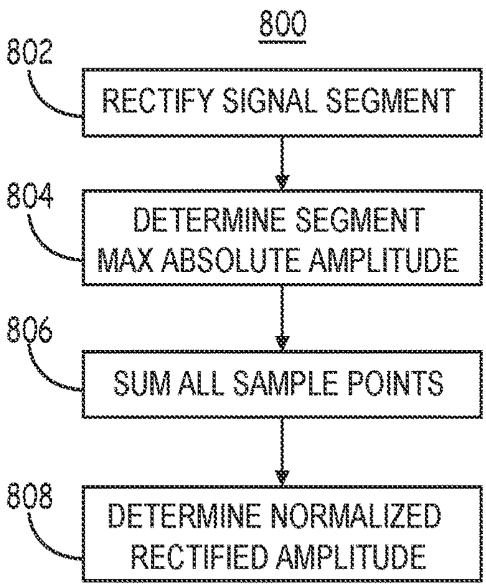

800
802
RECTIFY SIGNAL SEGMENT
804
DETERMINE SEGMENT MAX ABSOLUTE AMPLITUDE
806
SUM ALL SAMPLE POINTS
808
DETERMINE NORMALIZED RECTIFIED AMPLITUDE

FIG. 16

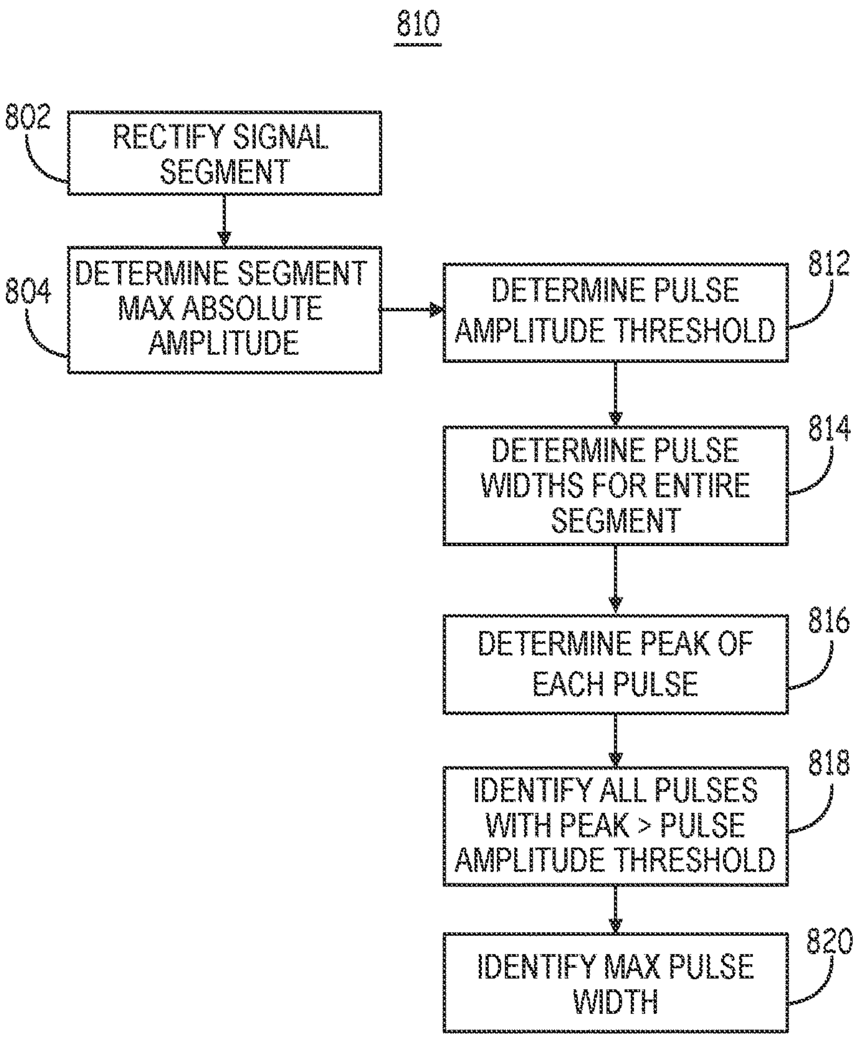

810
802
RECTIFY SIGNAL SEGMENT
804
DETERMINE SEGMENT MAX ABSOLUTE AMPLITUDE
812
DETERMINE PULSE AMPLITUDE THRESHOLD
814
DETERMINE PULSE WIDTHS FOR ENTIRE SEGMENT
816
DETERMINE PEAK OF EACH PULSE
818
IDENTIFY ALL PULSES WITH PEAK > PULSE AMPLITUDE THRESHOLD
820
IDENTIFY MAX PULSE WIDTH

FIG. 17

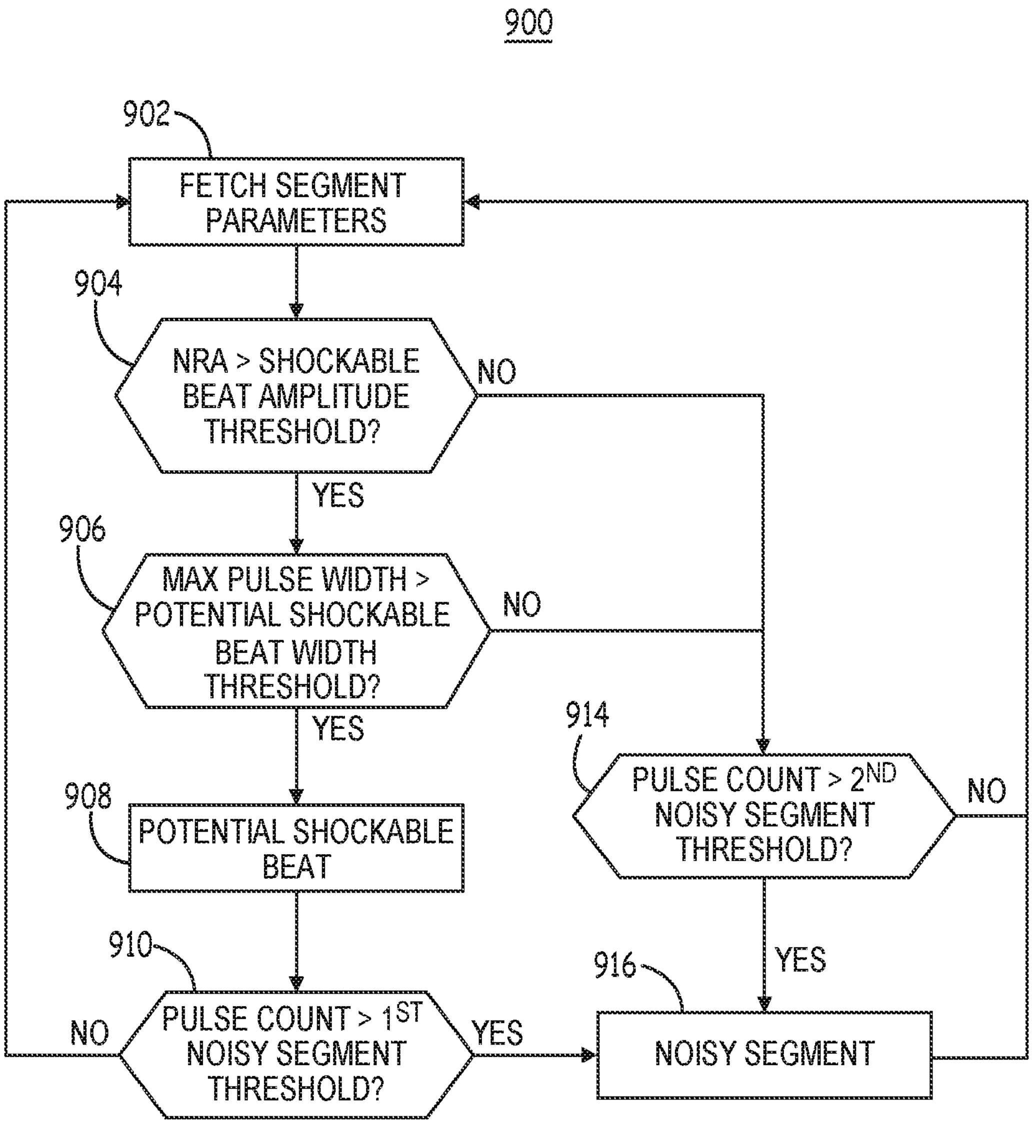

900
902
FETCH SEGMENT PARAMETERS
904
NRA > SHOCKABLE BEAT AMPLITUDE THRESHOLD?
NO
YES
906
MAX PULSE WIDTH > POTENTIAL SHOCKABLE BEAT WIDTH THRESHOLD?
NO
YES
908
POTENTIAL SHOCKABLE BEAT
914
PULSE COUNT > 2ND NOISY SEGMENT THRESHOLD?
NO
YES
910
PULSE COUNT > 1ST NOISY SEGMENT THRESHOLD?
NO
YES
916
NOISY SEGMENT

FIG. 18

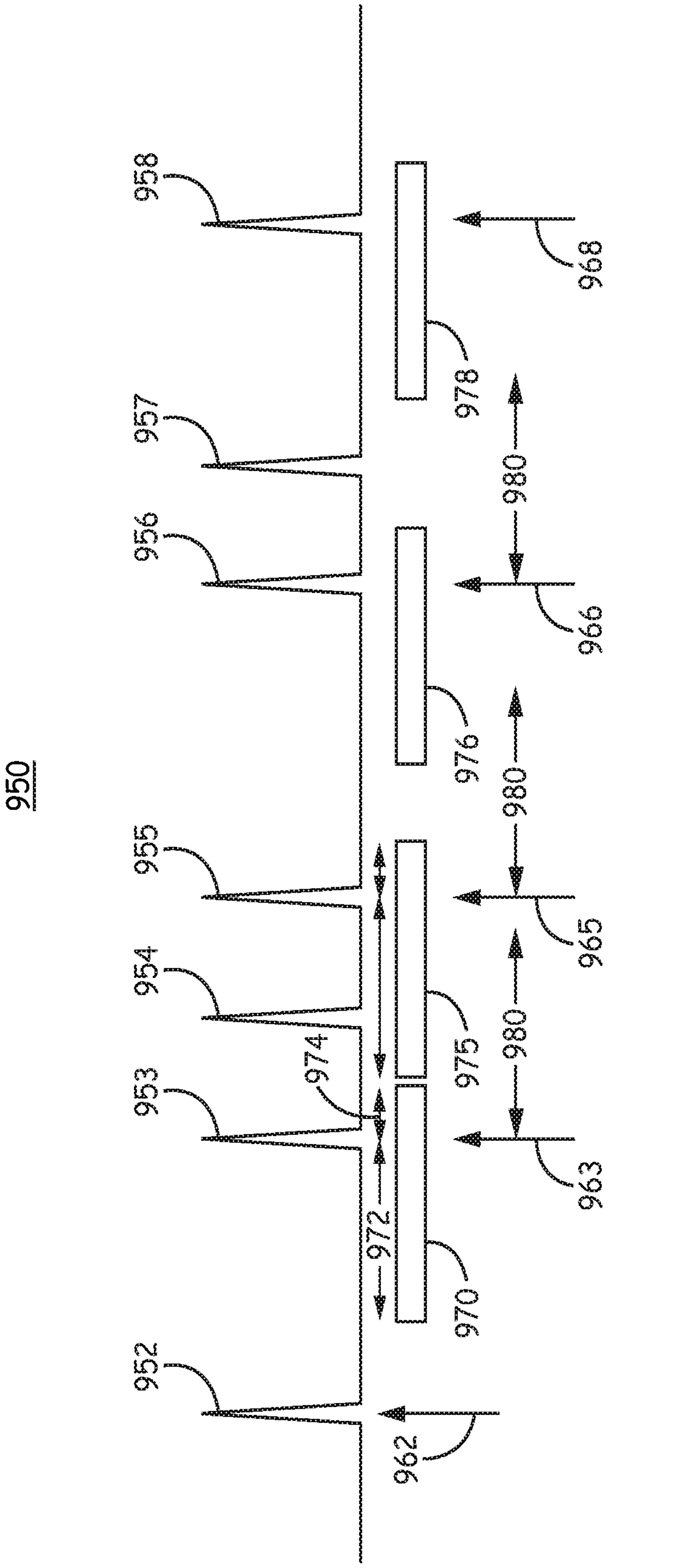
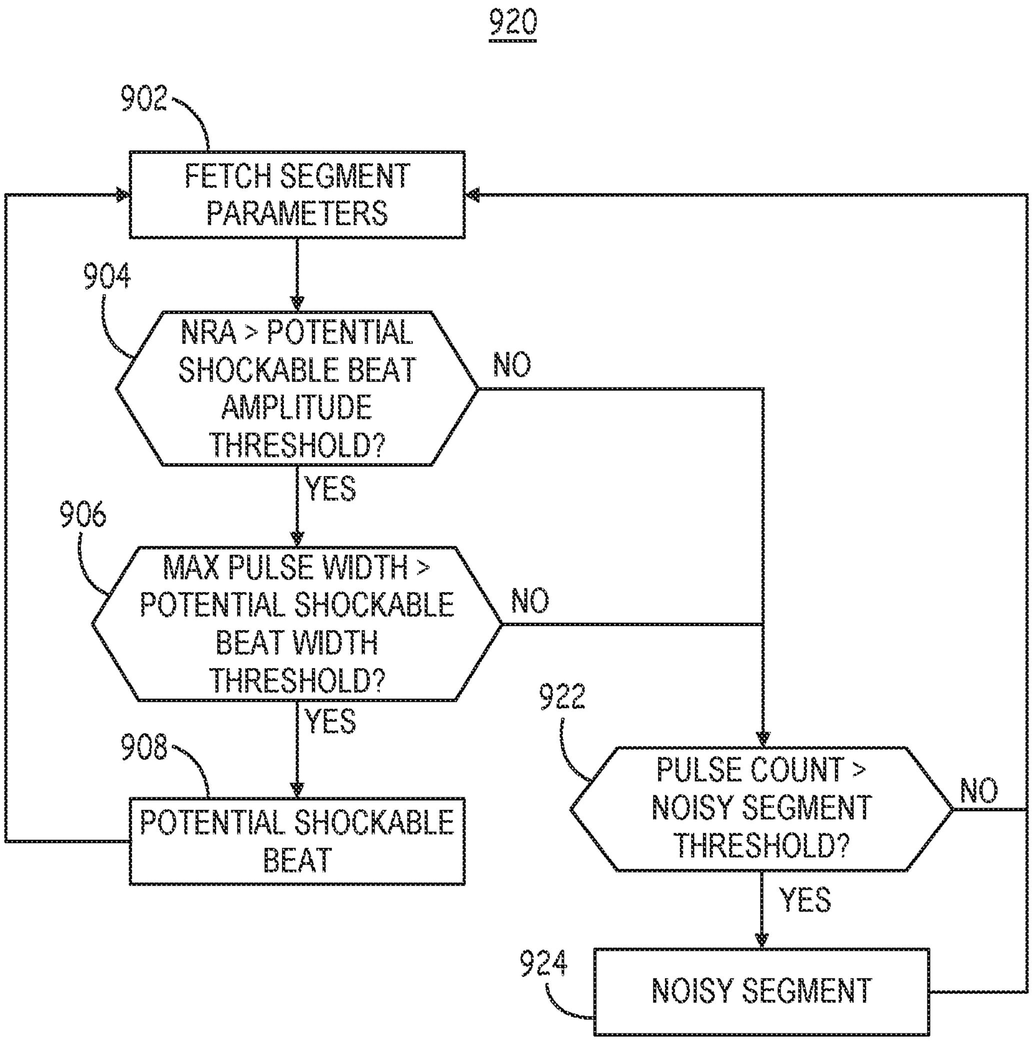

950
952
953
954
955
956
957
958
962
963
965
966
968
970
972
974
975
976
978
980
980
980

FIG. 19



920
902
FETCH SEGMENT PARAMETERS
904
NRA > POTENTIAL SHOCKABLE BEAT AMPLITUDE THRESHOLD?
NO
YES
906
MAX PULSE WIDTH > POTENTIAL SHOCKABLE BEAT WIDTH THRESHOLD?
NO
YES
908
POTENTIAL SHOCKABLE BEAT
922
PULSE COUNT > NOISY SEGMENT THRESHOLD?
NO
YES
924
NOISY SEGMENT

FIG. 20

CARDIAC ELECTRICAL SIGNAL GROSS MORPHOLOGY-BASED NOISE DETECTION FOR REJECTION OF VENTRICULAR TACHYARRHYTHMIA DETECTION

REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. Patent Application No. 62/367,166, filed provisionally on Jul. 27, 2016, the entire content of which is incorporated herein by reference.

TECHNICAL FIELD

The disclosure relates generally to a medical device system and method for detecting noise in a cardiac electrical signal and withholding a ventricular tachyarrhythmia detection in response to detecting noise.

BACKGROUND

Medical devices, such as cardiac pacemakers and implantable cardioverter defibrillators (ICDs), provide therapeutic electrical stimulation to a heart of a patient via electrodes carried by one or more medical electrical leads and/or electrodes on a housing of the medical device. The electrical stimulation may include signals such as pacing pulses or cardioversion or defibrillation shocks. In some cases, a medical device may sense cardiac electrical signals attendant to the intrinsic or pacing-evoked depolarizations of the heart and control delivery of stimulation signals to the heart based on sensed cardiac electrical signals. Upon detection of an abnormal rhythm, such as bradycardia, tachycardia or fibrillation, an appropriate electrical stimulation signal or signals may be delivered to restore or maintain a more normal rhythm of the heart. For example, an ICD may deliver pacing pulses to the heart of the patient upon detecting bradycardia or tachycardia or deliver cardioversion or defibrillation shocks to the heart upon detecting tachycardia or fibrillation. The ICD may sense the cardiac electrical signals in a heart chamber and deliver electrical stimulation therapies to the heart chamber using electrodes carried by transvenous medical electrical leads. Cardiac signals sensed within the heart generally have a high signal strength and quality for reliably sensing cardiac electrical events, such as R-waves. In other examples, a non-transvenous lead may be coupled to the ICD, in which case cardiac signal sensing presents new challenges in accurately sensing cardiac electrical events.

SUMMARY

In general, the disclosure is directed to techniques for detecting noise-contaminated cardiac electrical signal segments and reject a ventricular tachyarrhythmia detection in response to detecting noisy signal segments. A medical device system operating according to the techniques disclosed herein may determine signal morphology parameters for a cardiac electrical signal segment that extends beyond an expected QRS signal width for identifying noisy signal segments based on the morphology parameters.

In one example, the disclosure provides a medical device including a sensing circuit having a first sensing channel configured to receive a first cardiac electrical signal and sense R-waves in response to crossings of a sensing amplitude threshold by the first cardiac electrical signal and having a second sensing channel configured to receive a second cardiac electrical signal. The second sensing channel receives the second cardiac electrical signal via a sensing electrode vector and different than a sensing electrode vector used by the first sensing channel. The medical device further includes a memory and a control circuit coupled to the sensing circuit and the memory. The control circuit is configured to store a time segment of the second cardiac electrical signal in the memory for each of the plurality of R-waves sensed by the first sensing channel. The control circuit is configured to, for each of a plurality of the stored time segments, determine a morphology parameter correlated to signal noise from the stored time segment and detect the stored time segment as being a noisy signal segment based on the morphology parameter determined for the respective stored time segment. The control circuit withholds detection of a tachyarrhythmia episode in response to detecting at least a threshold number of the stored time segments as noisy signal segments.

In another example, the disclosure provides a method including sensing R-waves by a first sensing channel of a sensing circuit of a medical device in response to crossings of a sensing amplitude threshold by a first cardiac electrical signal, the first cardiac electrical signal received by the first sensing channel via a first sensing electrode vector coupled to the medical device; storing a time segment of a second cardiac electrical signal in a memory of the for each of the plurality of R-waves sensed by the first sensing channel, the second cardiac electrical signal received via a second sensing electrode vector coupled to the medical device and different than the first sensing electrode vector. The method further includes, for each of a plurality of the stored time segments, determining a morphology parameter correlated to signal noise from the stored time segment; detecting the stored time segment as being a noisy signal segment based on the morphology parameter determined for the respective stored time segment, and withholding detection of a tachyarrhythmia episode in response to detecting at least a threshold number of the stored time segments as noisy signal segments

In another example, the disclosure provides a non-transitory, computer-readable storage medium comprising a set of instructions which, when executed by a control circuit of a medical device, cause the medical device to sense R-waves by a first sensing channel of a sensing circuit of the medical device in response to crossings of a sensing amplitude threshold by a first cardiac electrical signal, the first cardiac electrical signal received by the first sensing channel via a first sensing electrode vector coupled to the medical device; store a time segment of a second cardiac electrical signal in medical device memory in response to each one of the plurality of R-waves sensed by the first sensing channel, the second cardiac electrical signal received via a second sensing electrode vector by a second sensing channel of the medical device; for each one of a plurality of the stored time segments determine a morphology parameter correlated to signal noise from the stored time segment and detect the stored time segment as being a noisy signal segment based on the morphology parameter determined for the respective stored time segment; and withhold detection of a tachyarrhythmia episode in response to detecting at least a threshold number of the stored time segments as noisy signal segments.

This summary is intended to provide an overview of the subject matter described in this disclosure. It is not intended to provide an exclusive or exhaustive explanation of the apparatus and methods described in detail within the accompanying drawings and description below. Further details of

one or more examples are set forth in the accompanying drawings and the description below.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1**A and **1**B are conceptual diagrams of an extra-cardiovascular ICD system according to one example.

FIGS. **2**A-**2**C are conceptual diagrams of a patient implanted with the extra-cardiovascular ICD system of FIG. **1**A in a different implant configuration.

FIG. **3** is a conceptual diagram of a distal portion of an extra-cardiovascular lead having an electrode configuration according to another example.

FIG. **4** is a schematic diagram of the ICD of FIGS. **1**A-**2**C according to one example.

FIG. **5** is diagram of circuitry included in the sensing circuit of FIG. **4** according to one example.

FIG. **6** is a plot of the attenuation characteristics of a notch filter that may be included in the sensing circuit of FIG. **5**.

FIG. **7** is a flow chart of a method performed by the ICD of FIGS. **1**A-**2**C for sensing and confirming R-waves for use in tachyarrhythmia detection according to one example.

FIG. **8** is a diagram of a filtered cardiac electrical signal and an amplitude ratio threshold that may be applied for confirming R-wave sensed events.

FIG. **9** is an example of a look-up table of amplitude ratio threshold values that may be stored in memory of the ICD of FIGS. **1**A-**2**C for use in confirming R-wave sensed events.

FIG. **10** is a flow chart of a method for detecting tachyarrhythmia by an ICD according to one example.

FIG. **11** is a flow chart of a method for detecting tachyarrhythmia by an ICD according to another example.

FIG. **12** is a diagram of circuitry included in the sensing circuit of FIG. **4** according to another example.

FIG. **13** is a flow chart of a method for detecting tachyarrhythmia by an ICD according to yet another example.

FIG. **14** is a flow chart of a method performed by an ICD for withholding a ventricular tachyarrhythmia detection in response to a gross morphology rejection rule.

FIGS. **15**, **16** and **17** are flow charts of illustrative methods for determining gross morphology parameters of a cardiac electrical signal that may be used in detecting a noisy signal segment.

FIG. **18** is a flow chart of a method for comparing the gross morphology parameters of FIGS. **15**, **16** and **17** to noisy segment detection criteria and detecting a cardiac electrical signal segment as a noisy segment.

FIG. **19** is a timing diagram depicting time segments over which a morphology parameter correlated to baseline noise, an amplitude parameter and a signal width parameter may be determined for determining whether the respective time segment is a noisy segment.

FIG. **20** is a flow chart of a method for comparing the gross morphology parameters to noise detection criteria and detecting the segment as a noisy segment according to another example.

DETAILED DESCRIPTION

In general, this disclosure describes techniques for detecting noise contamination of a cardiac electrical signal in a medical device system and withholding detection of a ventricular tachyarrhythmia in response to detecting noise. The medical device system may be any implantable or external medical device enabled for sensing cardiac electrical signals, including implantable pacemakers, implantable cardioverter-defibrillators (ICDs), cardiac resynchronization therapy (CRT) devices, or cardiac monitors coupled to extra-cardiovascular, transvenous, epicardial or intrapericardial leads carrying sensing electrodes; leadless pacemakers, ICDs or cardiac monitors having housing-based sensing electrodes; and external pacemakers, defibrillators, or cardiac monitors coupled to external, surface or skin electrodes.

However, the techniques are described in conjunction with an implantable medical lead carrying extra-cardiovascular electrodes. As used herein, the term "extra-cardiovascular" refers to a position outside the blood vessels, heart, and pericardium surrounding the heart of a patient. Implantable electrodes carried by extra-cardiovascular leads may be positioned extra-thoracically (outside the ribcage and sternum) or intra-thoracically (beneath the ribcage or sternum) but generally not in intimate contact with myocardial tissue. The techniques disclosed herein provide a method for detecting noisy signals acquired using extra-cardiovascular electrodes and withhold detection of ventricular tachycardia (VT) and ventricular fibrillation (VF) when signal noise is identified.

FIGS. **1**A and **1**B are conceptual diagrams of an extra-cardiovascular ICD system **10** according to one example. FIG. **1**A is a front view of ICD system **10** implanted within patient **12**. FIG. **1**B is a side view of ICD system **10** implanted within patient **12**. ICD system **10** includes an ICD **14** connected to an extra-cardiovascular electrical stimulation and sensing lead **16**. FIGS. **1**A and **1**B are described in the context of an ICD system **10** capable of providing defibrillation and/or cardioversion shocks and pacing pulses.

ICD **14** includes a housing **15** that forms a hermetic seal that protects internal components of ICD **14**. The housing **15** of ICD **14** may be formed of a conductive material, such as titanium or titanium alloy. The housing **15** may function as an electrode (sometimes referred to as a can electrode). Housing **15** may be used as an active can electrode for use in delivering cardioversion/defibrillation (CV/DF) shocks or other high voltage pulses delivered using a high voltage therapy circuit. In other examples, housing **15** may be available for use in delivering unipolar, low voltage cardiac pacing pulses in conjunction with lead-based cathode electrodes and for sensing cardiac electrical signals in conjunction with lead-based electrodes. In other instances, the housing **15** of ICD **14** may include a plurality of electrodes on an outer portion of the housing. The outer portion(s) of the housing **15** functioning as an electrode(s) may be coated with a material, such as titanium nitride.

ICD **14** includes a connector assembly **17** (also referred to as a connector block or header) that includes electrical feedthroughs crossing housing **15** to provide electrical connections between conductors extending within the lead body **18** of lead **16** and electronic components included within the housing **15** of ICD **14**. As will be described in further detail herein, housing **15** may house one or more processors, memories, transceivers, electrical cardiac signal sensing circuitry, therapy delivery circuitry, power sources and other components for sensing cardiac electrical signals, detecting a heart rhythm, and controlling and delivering electrical stimulation pulses to treat an abnormal heart rhythm.

Lead **16** includes an elongated lead body **18** having a proximal end **27** that includes a lead connector (not shown) configured to be connected to ICD connector assembly **17** and a distal portion **25** that includes one or more electrodes. In the example illustrated in FIGS. **1**A and **1**B, the distal portion **25** of lead **16** includes defibrillation electrodes **24** and **26** and pace/sense electrodes **28**, **30** and **31**. In some cases, defibrillation electrodes **24** and **26** may together form a defibrillation electrode in that they may be configured to be activated concurrently. Alternatively, defibrillation electrodes **24** and **26** may form separate defibrillation electrodes in which case each of the electrodes **24** and **26** may be activated independently. In some instances, defibrillation electrodes **24** and **26** are coupled to electrically isolated conductors, and ICD **14** may include switching mechanisms to allow electrodes **24** and **26** to be utilized as a single defibrillation electrode (e.g., activated concurrently to form a common cathode or anode) or as separate defibrillation electrodes, (e.g., activated individually, one as a cathode and one as an anode or activated one at a time, one as an anode or cathode and the other remaining inactive with housing **15** as an active electrode).

Electrodes **24** and **26** (and in some examples housing **15**) are referred to herein as defibrillation electrodes because they are utilized, individually or collectively, for delivering high voltage stimulation therapy (e.g., cardioversion or defibrillation shocks). Electrodes **24** and **26** may be elongated coil electrodes and generally have a relatively high surface area for delivering high voltage electrical stimulation pulses compared to low voltage pacing and sensing electrodes **28**, **30** and **31**. However, electrodes **24** and **26** and housing **15** may also be utilized to provide pacing functionality, sensing functionality or both pacing and sensing functionality in addition to or instead of high voltage stimulation therapy. In this sense, the use of the term "defibrillation electrode" herein should not be considered as limiting the electrodes **24** and **26** for use in only high voltage cardioversion/defibrillation shock therapy applications. For example, electrodes **24** and **26** may be used in a pacing electrode vector for delivering extra-cardiovascular pacing pulses such as ATP pulses and/or in a sensing vector used to sense cardiac electrical signals and detect VT and VF.

Electrodes **28**, **30** and **31** are relatively smaller surface area electrodes for delivering low voltage pacing pulses and for sensing cardiac electrical signals. Electrodes **28**, **30** and **31** are referred to as pace/sense electrodes because they are generally configured for use in low voltage applications, e.g., used as either a cathode or anode for delivery of pacing pulses and/or sensing of cardiac electrical signals. In some instances, electrodes **28**, **30** and **31** may provide only pacing functionality, only sensing functionality or both.

In the example illustrated in FIGS. **1**A and **1**B, electrode **28** is located proximal to defibrillation electrode **24**, and electrode **30** is located between defibrillation electrodes **24** and **26**. A third pace/sense electrode **31** may be located distal to defibrillation electrode **26**. Electrodes **28** and **30** are illustrated as ring electrodes, and electrode **31** is illustrated as a hemispherical tip electrode in the example of FIGS. **1**A and **1**B. However, electrodes **28**, **30** and **31** may comprise any of a number of different types of electrodes, including ring electrodes, short coil electrodes, hemispherical electrodes, directional electrodes, segmented electrodes, or the like, and may be positioned at any position along the distal portion **25** of lead **16** and are not limited to the positions shown. Further, electrodes **28**, **30** and **31** may be of similar type, shape, size and material or may differ from each other.

Lead **16** extends subcutaneously or submuscularly over the ribcage **32** medially from the connector assembly **27** of ICD **14** toward a center of the torso of patient **12**, e.g., toward xiphoid process **20** of patient **12**. At a location near xiphoid process **20**, lead **16** bends or turns and extends superior subcutaneously or submuscularly over the ribcage and/or sternum, substantially parallel to sternum **22**. Although illustrated in FIGS. **1**A and **1**B as being offset laterally from and extending substantially parallel to sternum **22**, lead **16** may be implanted at other locations, such as over sternum **22**, offset to the right or left of sternum **22**, angled laterally from sternum **22** toward the left or the right, or the like. Alternatively, lead **16** may be placed along other subcutaneous or submuscular paths. The path of extra-cardiovascular lead **16** may depend on the location of ICD **14**, the arrangement and position of electrodes carried by the lead distal portion **25**, and/or other factors.

Electrical conductors (not illustrated) extend through one or more lumens of the elongated lead body **18** of lead **16** from the lead connector at the proximal lead end **27** to electrodes **24**, **26**, **28**, **30** and **31** located along the distal portion **25** of the lead body **18**. Lead body **18** may be tubular or cylindrical in shape. In other examples, the distal portion **25** (or all of) the elongated lead body **18** may have a flat, ribbon or paddle shape. The lead body **18** of lead **16** may be formed from a non-conductive material, including silicone, polyurethane, fluoropolymers, mixtures thereof, and other appropriate materials, and shaped to form one or more lumens within which the one or more conductors extend. However, the techniques disclosed herein are not limited to such constructions or to any particular lead body design.

The elongated electrical conductors contained within the lead body **18** are each electrically coupled with respective defibrillation electrodes **24** and **26** and pace/sense electrodes **28**, **30** and **31**, which may be separate respective insulated conductors within the lead body. The respective conductors electrically couple the electrodes **24**, **26**, **28**, **30** and **31** to circuitry, such as a therapy delivery circuit and/or a sensing circuit, of ICD **14** via connections in the connector assembly **17**, including associated electrical feedthroughs crossing housing **15**. The electrical conductors transmit therapy from a therapy delivery circuit within ICD **14** to one or more of defibrillation electrodes **24** and **26** and/or pace/sense electrodes **28**, **30** and **31** and transmit sensed electrical signals from one or more of defibrillation electrodes **24** and **26** and/or pace/sense electrodes **28**, **30** and **31** to the sensing circuit within ICD **14**.

ICD **14** may obtain electrical signals corresponding to electrical activity of heart **8** via a combination of sensing vectors that include combinations of electrodes **28**, **30**, and/or **31**. In some examples, housing **15** of ICD **14** is used in combination with one or more of electrodes **28**, **30** and/or **31** in a sensing electrode vector. ICD **14** may even obtain cardiac electrical signals using a sensing vector that includes one or both defibrillation electrodes **24** and/or **26**, e.g., between electrodes **24** and **26** or one of electrodes **24** or **26** in combination with one or more of electrodes **28**, **30**, **31**, and/or the housing **15**.

ICD **14** analyzes the cardiac electrical signals received from one or more of the sensing vectors to monitor for abnormal rhythms, such as bradycardia, VT or VF. ICD **14** may analyze the heart rate and/or morphology of the cardiac electrical signals to monitor for tachyarrhythmia in accordance with any of a number of tachyarrhythmia detection techniques. One example technique for detecting tachyarrhythmia is described in U.S. Pat. No. 7,761,150 (Ghanem, et al.), incorporated by reference herein in its entirety.

ICD **14** generates and delivers electrical stimulation therapy in response to detecting a tachyarrhythmia (e.g., VT or VF). ICD **14** may deliver ATP in response to VT detection, and in some cases may deliver ATP prior to a CV/DF shock or during high voltage capacitor charging in an attempt to avert the need for delivering a CV/DF shock. ATP may be delivered using an extra-cardiovascular pacing electrode vector selected from any of electrodes **24**, **26**, **28**, **30**, **31** and/or housing **15**. The pacing electrode vector may be different than the sensing electrode vector. In one example, cardiac electrical signals are sensed between pace/sense electrodes **28** and **30** and between one of pace/sense electrodes **28** or **30** and housing **15**, and ATP pulses are delivered between pace/sense electrode **30** used as a cathode electrode and defibrillation electrode **24** used as a return anode electrode. In other examples, pacing pulses may be delivered between pace/sense electrode **28** and either (or both) defibrillation electrode **24** or **26** or between defibrillation electrode **24** and defibrillation electrode **26**. These examples are not intended to be limiting, and it is recognized that other sensing electrode vectors and pacing electrode vectors may be selected according to individual patient need.

If ATP does not successfully terminate VT or when VF is detected, ICD **14** may deliver one or more cardioversion or defibrillation (CV/DF) shocks via one or both of defibrillation electrodes **24** and **26** and/or housing **15**. ICD **14** may deliver the CV/DF shocks using electrodes **24** and **26** individually or together as a cathode (or anode) and with the housing **15** as an anode (or cathode). ICD **14** may generate and deliver other types of electrical stimulation pulses such as post-shock pacing pulses or bradycardia pacing pulses using a pacing electrode vector that includes one or more of the electrodes **24**, **26**, **28**, **30** and **31** and the housing **15** of ICD **14**.

FIGS. **1**A and **1**B are illustrative in nature and should not be considered limiting of the practice of the techniques disclosed herein. In other examples, lead **16** may include less than three pace/sense electrodes or more than three pace/sense electrodes and/or a single defibrillation electrode or more than two electrically isolated or electrically coupled defibrillation electrodes or electrode segments. The pace/sense electrodes **28**, **30** and/or **31** may be located elsewhere along the length of lead **16**. For example, lead **16** may include a single pace/sense electrode **30** between defibrillation electrodes **24** and **26** and no pace/sense electrode distal to defibrillation electrode **26** or proximal defibrillation electrode **24**. Various example configurations of extra-cardiovascular leads and electrodes and dimensions that may be implemented in conjunction with the extra-cardiovascular pacing techniques disclosed herein are described in U.S. Publication No. 2015/0306375 (Marshall, et al.) and U.S. Publication No. 2015/0306410 (Marshall, et al.), both of which are incorporated herein by reference in their entirety.

ICD **14** is shown implanted subcutaneously on the left side of patient **12** along the ribcage **32**. ICD **14** may, in some instances, be implanted between the left posterior axillary line and the left anterior axillary line of patient **12**. ICD **14** may, however, be implanted at other subcutaneous or submuscular locations in patient **12**. For example, ICD **14** may be implanted in a subcutaneous pocket in the pectoral region. In this case, lead **16** may extend subcutaneously or submuscularly from ICD **14** toward the manubrium of sternum **22** and bend or turn and extend inferiorly from the manubrium to the desired location subcutaneously or submuscularly. In yet another example, ICD **14** may be placed abdominally. Lead **16** may be implanted in other extra-cardiovascular locations as well. For instance, as described with respect to FIGS. **2**A-**2**C, the distal portion **25** of lead **16** may be implanted underneath the sternum/ribcage in the substernal space.

An external device **40** is shown in telemetric communication with ICD **14** by a communication link **42**. External device **40** may include a processor, display, user interface, telemetry unit and other components for communicating with ICD **14** for transmitting and receiving data via communication link **42**. Communication link **42** may be established between ICD **14** and external device **40** using a radio frequency (RF) link such as BLUETOOTH®, Wi-Fi, or Medical Implant Communication Service (MICS) or other RF or communication frequency bandwidth.

External device **40** may be embodied as a programmer used in a hospital, clinic or physician's office to retrieve data from ICD **14** and to program operating parameters and algorithms in ICD **14** for controlling ICD functions. External device **40** may be used to program R-wave sensing parameters, cardiac rhythm detection parameters and therapy control parameters used by ICD **14**. Data stored or acquired by ICD **14**, including physiological signals or associated data derived therefrom, results of device diagnostics, and histories of detected rhythm episodes and delivered therapies, may be retrieved from ICD **14** by external device **40** following an interrogation command. External device **40** may alternatively be embodied as a home monitor or hand held device.

FIGS. **2**A-**2**C are conceptual diagrams of patient **12** implanted with extra-cardiovascular ICD system **10** in a different implant configuration than the arrangement shown in FIGS. **1**A-**1**B. FIG. **2**A is a front view of patient **12** implanted with ICD system **10**. FIG. **2**B is a side view of patient **12** implanted with ICD system **10**. FIG. **2**C is a transverse view of patient **12** implanted with ICD system **10**. In this arrangement, extra-cardiovascular lead **16** of system **10** is implanted at least partially underneath sternum **22** of patient **12**. Lead **16** extends subcutaneously or submuscularly from ICD **14** toward xiphoid process **20** and at a location near xiphoid process **20** bends or turns and extends superiorly within anterior mediastinum **36** in a substernal position.

Anterior mediastinum **36** may be viewed as being bounded laterally by pleurae **39**, posteriorly by pericardium **38**, and anteriorly by sternum **22**. In some instances, the anterior wall of anterior mediastinum **36** may also be formed by the transversus thoracis muscle and one or more costal cartilages. Anterior mediastinum **36** includes a quantity of loose connective tissue (such as areolar tissue), adipose tissue, some lymph vessels, lymph glands, substernal musculature, small side branches of the internal thoracic artery or vein, and the thymus gland. In one example, the distal portion **25** of lead **16** extends along the posterior side of sternum **22** substantially within the loose connective tissue and/or substernal musculature of anterior mediastinum **36**.

A lead implanted such that the distal portion **25** is substantially within anterior mediastinum **36** may be referred to as a "substernal lead." In the example illustrated in FIGS. **2**A-**2**C, lead **16** is located substantially centered under sternum **22**. In other instances, however, lead **16** may be implanted such that it is offset laterally from the center of sternum **22**. In some instances, lead **16** may extend laterally such that distal portion **25** of lead **16** is underneath/below the ribcage **32** in addition to or instead of sternum **22**. In other examples, the distal portion **25** of lead **16** may be implanted in other extra-cardiovascular, intra-thoracic locations, including the pleural cavity or around the perimeter of and adjacent to but typically not within the pericardium **38** of heart **8**. Other implant locations and lead and electrode arrangements that may be used in conjunction with the cardiac pacing techniques described herein are generally disclosed in the above-incorporated patent applications.

FIG. **3** is a conceptual diagram illustrating a distal portion **25'** of another example of extra-cardiovascular lead **16** of FIGS. **1**A-**2**C having a curving distal portion **25'** of lead body **18'**. Lead body **18'** may be formed having a curving, bending, serpentine, or zig-zagging shape along distal portion 25'. In the example shown, defibrillation electrodes 24' and 26' are carried along curving portions of the lead body 18'. Pace/sense electrode 30' is carried in between defibrillation electrodes 24' and 26'. Pace/sense electrode 28' is carried proximal to the proximal defibrillation electrode 24'. No electrode is provided distal to defibrillation electrode 26' in this example.

As shown in FIG. 3, lead body 18' may be formed having a curving distal portion 25' that includes two "C" shaped curves, which together may resemble the Greek letter epsilon, "ε" Defibrillation electrodes 24' and 26' are each carried by one of the two respective C-shaped portions of the lead body distal portion 25', which extend or curve in the same direction away from a central axis 33 of lead body 18'. In the example shown, pace/sense electrode 28' is proximal to the C-shaped portion carrying electrode 24', and pace/sense electrode 30' is proximal to the C-shaped portion carrying electrode 26'. Pace/sense electrodes 28' and 30' may, in some instances, be approximately aligned with the central axis 33 of the straight, proximal portion of lead body 18' such that mid-points of defibrillation electrodes 24' and 26' are laterally offset from electrodes 28' and 30'. Other examples of extra-cardiovascular leads including one or more defibrillation electrodes and one or more pacing and sensing electrodes carried by curving, serpentine, undulating or zig-zagging distal portion of the lead body that may be implemented with the pacing techniques described herein are generally disclosed in U.S. Pat. Publication No. 2016/0158567 (Marshall, et al.), incorporated herein by reference in its entirety.

FIG. 4 is a schematic diagram of ICD 14 according to one example. The electronic circuitry enclosed within housing 15 (shown schematically as an electrode in FIG. 4) includes software, firmware and hardware that cooperatively monitor cardiac electrical signals, determine when an electrical stimulation therapy is necessary, and deliver therapies as needed according to programmed therapy delivery algorithms and control parameters. The software, firmware and hardware are configured to detect tachyarrhythmias and deliver anti-tachyarrhythmia therapy, e.g., detect ventricular tachyarrhythmias and in some cases discriminate VT and VF for determining when ATP or CV/DF shocks are required. ICD 14 is coupled to an extra-cardiovascular lead, such as lead 16 carrying extra-cardiovascular electrodes 24, 26, 28, 30 and 31 (if present), for delivering electrical stimulation pulses to the patient's heart and for sensing cardiac electrical signals.

ICD 14 includes a control circuit 80, memory 82, therapy delivery circuit 84, sensing circuit 86, and telemetry circuit 88. A power source 98 provides power to the circuitry of ICD 14, including each of the components 80, 82, 84, 86, and 88 as needed. Power source 98 may include one or more energy storage devices, such as one or more rechargeable or non-rechargeable batteries. The connections between power source 98 and each of the other components 80, 82, 84, 86 and 88 are to be understood from the general block diagram of FIG. 4, but are not shown for the sake of clarity. For example, power source 98 may be coupled to a low voltage (LV) charging circuit and to a high voltage (HV) charging circuit included in therapy delivery circuit 84 for charging low voltage and high voltage capacitors, respectively, included in therapy delivery circuit 84 for producing respective low voltage pacing pulses, such as bradycardia pacing, post-shock pacing or ATP pulses, or for producing high voltage pulses, such as CV/DF shock pulses. In some examples, high voltage capacitors are charged and utilized for delivering ATP, post-shock pacing or other pacing pulses instead of low voltage capacitors. Power source 98 is also coupled to components of sensing circuit 86, such as sense amplifiers, analog-to-digital converters, switching circuitry, etc. as needed.

The functional blocks shown in FIG. 4 represent functionality included in ICD 14 and may include any discrete and/or integrated electronic circuit components that implement analog and/or digital circuits capable of producing the functions attributed to ICD 14 herein. The various components may include an application specific integrated circuit (ASIC), an electronic circuit, a processor (shared, dedicated, or group) and memory that execute one or more software or firmware programs, a combinational logic circuit, state machine, or other suitable components or combinations of components that provide the described functionality. The particular form of software, hardware and/or firmware employed to implement the functionality disclosed herein will be determined primarily by the particular system architecture employed in the ICD and by the particular detection and therapy delivery methodologies employed by the ICD. Providing software, hardware, and/or firmware to accomplish the described functionality in the context of any modern ICD system, given the disclosure herein, is within the abilities of one of skill in the art.

Memory 82 may include any volatile, non-volatile, magnetic, or electrical non-transitory computer readable storage media, such as a random access memory (RAM), read-only memory (ROM), non-volatile RAM (NVRAM), electrically-erasable programmable ROM (EEPROM), flash memory, or any other memory device. Furthermore, memory 82 may include non-transitory computer readable media storing instructions that, when executed by one or more processing circuits, cause control circuit 80 or other ICD components to perform various functions attributed to ICD 14 or those ICD components. The non-transitory computer-readable media storing the instructions may include any of the media listed above.

The functions attributed to ICD 14 herein may be embodied as one or more integrated circuits. Depiction of different features as components is intended to highlight different functional aspects and does not necessarily imply that such components must be realized by separate hardware or software components. Rather, functionality associated with one or more components may be performed by separate hardware, firmware or software components, or integrated within common hardware, firmware or software components. For example, cardiac event sensing and tachyarrhythmia detection operations may be performed by sensing circuit 86 under the control of control circuit 80 and may include operations implemented in a processor or other signal processing circuitry included in control circuit 80 executing instructions stored in memory 82 and control signals such as blanking and timing intervals and sensing threshold amplitude signals sent from control circuit 80 to sensing circuit 86.

Control circuit 80 communicates, e.g., via a data bus, with therapy delivery circuit 84 and sensing circuit 86 for sensing cardiac electrical activity, detecting cardiac rhythms, and controlling delivery of cardiac electrical stimulation therapies in response to sensed cardiac signals. Therapy delivery circuit 84 and sensing circuit 86 are electrically coupled to electrodes 24, 26, 28, 30 and 31 (if present as shown in FIGS. 1A and 2A) carried by lead 16 (e.g., as shown in FIGS. 1A-3) and the housing 15, which may function as a common or ground electrode or as an active can electrode for delivering CV/DF shock pulses or cardiac pacing pulses.

Sensing circuit **86** may be selectively coupled to electrodes **28**, **30**, **31** and/or housing **15** in order to monitor electrical activity of the patient's heart. Sensing circuit **86** may additionally be selectively coupled to defibrillation electrodes **24** and/or **26** for use in a sensing electrode vector. Sensing circuit **86** is enabled to selectively receive cardiac electrical signals from at least two sensing electrode vectors from the available electrodes **24**, **26**, **28**, **30**, **31** and housing **15**. At least two cardiac electrical signals from two different sensing electrode vectors may be received simultaneously by sensing circuit **86**, and sensing circuit **86** may monitor one or both or the cardiac electrical signals at a time for sensing cardiac electrical signals. For example, sensing circuit **86** may include switching circuitry for selecting which of electrodes **24**, **26**, **28**, **30**, **31** and housing **15** are coupled to a sensing channel **83** or **85** including cardiac event detection circuitry, e.g., as described in conjunction with FIGS. **5** and **12**. Switching circuitry may include a switch array, switch matrix, multiplexer, or any other type of switching device suitable to selectively couple components of sensing circuit **86** to selected electrodes. The cardiac event detection circuitry within sensing circuit **86** may include one or more sense amplifiers, filters, rectifiers, threshold detectors, comparators, analog-to-digital converters (ADCs), or other analog or digital components as described further in conjunction with FIGS. **5** and **12**. A cardiac event sensing threshold may be automatically adjusted by sensing circuit **86** under the control of control circuit **80**, based on timing intervals and sensing threshold values determined by control circuit **80**, stored in memory **82**, and/or controlled by hardware of control circuit **80** and/or sensing circuit **86**.

In some examples, sensing circuit **86** includes multiple sensing channels **83** and **85** for acquiring cardiac electrical signals from multiple sensing vectors selected from electrodes **24**, **26**, **28**, **30**, **31** and housing **15**. Each sensing channel **83** and **85** may be configured to amplify, filter and digitize the cardiac electrical signal received from selected electrodes coupled to the respective sensing channel to improve the signal quality for detecting cardiac events, such as R-waves. For example, each sensing channel **83** and **85** may include a pre-filter and amplifier for filtering and amplifying a signal received from a selected pair of electrodes. The resulting raw cardiac electrical signal may be passed from the pre-filter and amplifier to cardiac event detection circuitry in at least one sensing channel **83** for sensing cardiac events from the received cardiac electrical signal in real time. As disclosed herein, sensing channel **83** may be configured to sense cardiac events such as R-waves based on a cardiac event sensing threshold, and second sensing channel **85** may be configured to pass a digitized cardiac electrical signal obtained from a different sensing electrode vector to control circuit **80** for use in confirming a cardiac event sensed by first sensing channel **83**.

Upon detecting a cardiac event based on a sensing threshold crossing, first sensing channel **83** may produce a sensed event signal, such as an R-wave sensed event signal, that is passed to control circuit **80**. The sensed event signal is used by control circuit **80** to trigger storage of a time segment of the second cardiac electrical signal for post-processing and analysis for confirming the R-wave sensed event signal as described below, e.g., in conjunction with FIGS. **7** through **9**. Memory **82** may be configured to store a predetermined number of cardiac electrical signal segments in circulating buffers under the control of control circuit **80**, e.g., at least one, two or other number of cardiac electrical signal segments. Each segment may be written to memory **82** over a time interval extending before and after the R-wave sensed event signal produced by the first sensing channel **83**. Control circuit **80** may access stored cardiac electrical signal segments when confirmation of R-waves sensed by the first sensing channel **83** is required based on the detection of a predetermined number of tachyarrhythmia intervals, which may precede tachyarrhythmia detection.

The R-wave sensed event signals are also used by control circuit **80** for determining RR intervals (RRIs) for detecting tachyarrhythmia and determining a need for therapy. An RRI is the time interval between consecutively sensed R-waves and may be determined between consecutive R-wave sensed event signals received from sensing circuit **86**. For example, control circuit **80** may include a timing circuit **90** for determining RRIs between consecutive R-wave sensed event signals received from sensing circuit **86** and for controlling various timers and/or counters used to control the timing of therapy delivery by therapy delivery circuit **84**. Timing circuit **90** may additionally set time windows such as morphology template windows, morphology analysis windows or perform other timing related functions of ICD **14** including synchronizing cardioversion shocks or other therapies delivered by therapy delivery circuit **84** with sensed cardiac events.

Control circuit **80** is also shown to include a tachyarrhythmia detector **92** configured to analyze signals received from sensing circuit **86** for detecting tachyarrhythmia episodes. Tachyarrhythmia detector **92** may be implemented in control circuit **80** as hardware and/or firmware that processes and analyzes signals received from sensing circuit **86** for detecting VT and/or VF. In some examples, the timing of R-wave sense event signals received from sensing circuit **86** is used by timing circuit **90** to determine RRIs between sensed event signals. Tachyarrhythmia detector **92** may include comparators and counters for counting RRIs determined by timing circuit **92** that fall into various rate detection zones for determining a ventricular rate or performing other rate- or interval-based assessment for detecting and discriminating VT and VF.

For example, tachyarrhythmia detector **92** may compare the RRIs determined by timing circuit **90** to one or more tachyarrhythmia detection interval zones, such as a tachycardia detection interval zone and a fibrillation detection interval zone. RRIs falling into a detection interval zone are counted by a respective VT interval counter or VF interval counter and in some cases in a combined VT/VF interval counter included in tachyarrhythmia detector **92**. When an interval counter reaches a detection threshold, a ventricular tachyarrhythmia may be detected by tachyarrhythmia detector **92**. Tachyarrhythmia detector **92** may be configured to perform other signal analysis for determining if other detection criteria are satisfied before detecting VT or VF, such as R-wave morphology criteria, onset criteria, and noise and oversensing rejection criteria. Examples of other parameters that may be determined from cardiac electrical signals received by sensing circuit **86** for determining the status of tachyarrhythmia detection rejection rules that may cause withholding to a VT or VF detection are described in conjunction with FIGS. **10**, **11** and **13**.

To support these additional analyses, sensing circuit **86** may pass a digitized electrocardiogram (ECG) signal to control circuit **80** for morphology analysis performed by tachyarrhythmia detector **92** for detecting and discriminating heart rhythms. A cardiac electrical signal from the selected sensing vector, e.g., from first sensing channel **83** and/or the second sensing channel **85**, may be passed through a filter and amplifier, provided to a multiplexer and thereafter converted to multi-bit digital signals by an analog-to-digital converter, all included in sensing circuit **86**, for storage in memory **82**. Memory **82** may include one or more circulating buffers to temporarily store digital cardiac electrical signal segments for analysis performed by control circuit **80** to confirm R-waves sensed by sensing channel **83**, determine morphology matching scores, detect T-wave oversensing, detect noise contamination, and more as further described below.

Control circuit **80** may be a microprocessor-based controller that employs digital signal analysis techniques to characterize the digitized signals stored in memory **82** to recognize and classify the patient's heart rhythm employing any of numerous signal processing methodologies for analyzing cardiac signals and cardiac event waveforms, e.g., R-waves. Examples of devices and algorithms that may be adapted to utilize techniques for R-wave sensing and confirmation and tachyarrhythmia detection described herein are generally disclosed in U.S. Pat. No. 5,354,316 (Keimel); U.S. Pat. No. 5,545,186 (Olson, et al.); U.S. Pat. No. 6,393,316 (Gillberg et al.); U.S. Pat. No. 7,031,771 (Brown, et al.); U.S. Pat. No. 8,160,684 (Ghanem, et al.), and U.S. Pat. No. 8,437,842 (Zhang, et al.), all of which patents are incorporated herein by reference in their entirety.

Therapy delivery circuit **84** includes charging circuitry; one or more charge storage devices, such as one or more high voltage capacitors and/or low voltage capacitors, and switching circuitry that controls when the capacitor(s) are discharged across a selected pacing electrode vector or CV/DF shock vector. Charging of capacitors to a programmed pulse amplitude and discharging of the capacitors for a programmed pulse width may be performed by therapy delivery circuit **84** according to control signals received from control circuit **80**. Timing circuit **90** of control circuit **80** may include various timers or counters that control when ATP or other cardiac pacing pulses are delivered. For example, timing circuit **90** may include programmable digital counters set by a microprocessor of the control circuit **80** for controlling the basic time intervals associated with various pacing modes or ATP sequences delivered by ICD **14**. The microprocessor of control circuit **80** may also set the amplitude, pulse width, polarity or other characteristics of the cardiac pacing pulses, which may be based on programmed values stored in memory **82**.

During pacing, escape interval counters within timing circuit **90** are reset upon sensing of R-waves as indicated by signals from sensing circuit **86**. In accordance with the selected mode of pacing, pacing pulses are generated by a pulse output circuit of therapy delivery circuit **84** when an escape interval counter expires. The pace output circuit is coupled to the desired pacing electrodes via a switch matrix for discharging one or more capacitors across the pacing load. The escape interval counters are reset upon generation of pacing pulses, and thereby control the basic timing of cardiac pacing functions, including ATP. The durations of the escape intervals are determined by control circuit **80** via a data/address bus. The value of the count present in the escape interval counters when reset by sensed R-waves can be used to measure RRIs by timing circuit **90** as described above for detecting the occurrence of a variety of arrhythmias by tachyarrhythmia detector **92**.

Memory **82** may include read-only memory (ROM) in which stored programs controlling the operation of the control circuit **80** reside. Memory **82** may further include random access memory (RAM) or other memory devices configured as a number of recirculating buffers capable of holding a series of measured RRIs, counts or other data for analysis by the tachyarrhythmia detector **92** for predicting or diagnosing an arrhythmia.

In response to the detection of ventricular tachycardia, ATP therapy can be delivered by loading a regimen from the microprocessor included in control circuit **80** into timing circuit **90** according to the type and rate of tachycardia detected. In the event that higher voltage cardioversion or defibrillation pulses are required, e.g., the tachyarrhythmia is VF or the VT is not terminated via the ATP therapy, the control circuit **80** activates cardioversion and defibrillation control circuitry included in control circuit **80** to initiate charging of the high voltage capacitors via a charging circuit, both included in therapy delivery circuit **84**, under the control of a high voltage charging control line. The voltage on the high voltage capacitors is monitored via a voltage capacitor line, which is passed to control circuit **80**. When the voltage reaches a predetermined value set by control circuit **80**, a logic signal is generated on a capacitor full line passed to therapy delivery circuit **84**, terminating charging. The defibrillation or cardioversion pulse is delivered to the heart under the control of the timing circuit **90** by an output circuit of therapy delivery circuit **84** via a control bus. The output circuit determines the electrodes used for delivering the cardioversion or defibrillation pulse and the pulse wave shape. Therapy delivery and control circuitry generally disclosed in any of the above-incorporated patents may be implemented in ICD **14**.

Control parameters utilized by control circuit **80** for detecting cardiac rhythms and controlling therapy delivery may be programmed into memory **82** via telemetry circuit **88**. Telemetry circuit **88** includes a transceiver and antenna for communicating with external device **40** (shown in FIG. 1A) using RF communication as described above. Under the control of control circuit **80**, telemetry circuit **88** may receive downlink telemetry from and send uplink telemetry to external device **40**. In some cases, telemetry circuit **88** may be used to transmit and receive communication signals to/from another medical device implanted in patient **12**.

FIG. **5** is diagram of circuitry included in first sensing channel **83** and second sensing channel **85** of sensing circuit **86** according to one example. First sensing channel **83** may be selectively coupled via switching circuitry (not shown) to a first sensing electrode vector including electrodes carried by extra-cardiovascular lead **16** as shown in FIGS. **1**A-**2**C for receiving a first cardiac electrical signal. First sensing channel **83** may be coupled to a sensing electrode vector that is a short bipole, having a relatively shorter inter-electrode distance or spacing than the second electrode vector coupled to second sensing channel **85**. In the example shown, the first sensing electrode vector may include pace/sense electrodes **28** and **30**. In other examples, the first sensing electrode vector coupled to sensing channel **83** may include pace/sense electrodes **30** and **31** and in some cases pace/sense electrodes **28** and **31** depending on the inter-electrode spacing and position of the distal portion **25** of lead **16**. In other examples, the first sensing channel **83** may be selectively coupled to a sensing electrode vector including a defibrillation electrode **24** and/or **26**, e.g., a sensing electrode vector between pace/sense electrode **28** and defibrillation electrode **24**, between pace/sense electrode **30** and either of defibrillation electrodes **24** or **26**, or between pace/sense electrode **26** and **31**, for example. In some examples, the first sensing electrode vector may be between defibrillation electrodes **24** and **26**.

Sensing circuit **86** includes a second sensing channel **85** that receives a second cardiac electrical signal from a second sensing vector, for example from a vector that includes electrode **30** and housing **15**, as shown, or a vector that includes electrode **28** and housing **15**. Second sensing channel **85** may be selectively coupled to other sensing electrode vectors, which may form a long bipole having an inter-electrode distance or spacing that is greater than the sensing electrode vector coupled to first sensing channel **83**. As described below, the second cardiac electrical signal received by second sensing channel **85** via a long bipole may be used by control circuit **80** for morphology analysis (including beat morphology analysis, noise rejection and other analyses, for example as described in conjunction with FIG. **10**). In other examples, any vector selected from the available electrodes, e.g., electrodes **24**, **26**, **28**, **30** and/or **31** and/or housing **15** may be included in a sensing electrode vector coupled to second sensing channel **85**.

The electrical signals developed across input electrodes **28** and **30** of sensing channel **83** and across input electrodes **30** and **15** of sensing channel **85** are provided as differential input signals to the pre-filter and pre-amplifiers **62** and **72**, respectively. Non-physiological high frequency and DC signals may be filtered by a low pass or bandpass filter included in each of pre-filter and pre-amplifiers **62** and **72**, and high voltage signals may be removed by protection diodes included in pre-filter and pre-amplifiers **62** and **72**. Pre-filter and pre-amplifiers **62** and **72** may amplify the pre-filtered signal by a gain of between 10 and 100, and in one example a gain of 17.5, and may convert the differential signal to a single-ended output signal passed to analog-to-digital converter (ADC) **63** in first sensing channel **83** and to ADC **73** in second sensing channel **85**. Pre-filters and amplifiers **62** and **72** may provide anti-alias filtering and noise reduction prior to digitization.

ADC **63** and ADC **73**, respectively, convert the first cardiac electrical signal from an analog signal to a first digital bit stream and the second cardiac electrical signal to a second digital bit stream. In one example, ADC **63** and ADC **73** may be sigma-delta converters (SDC), but other types of ADCs may be used. In some examples, the outputs of ADC **63** and ADC **73** may be provided to decimators (not shown), which function as digital low-pass filters that increase the resolution and reduce the sampling rate of the respective first and second cardiac electrical signals.

In sensing channel **83**, the digital output of ADC **63** is passed to filter **64** which may be a digital bandpass filter have a bandpass of approximately 10 Hz to 30 Hz for passing cardiac electrical signals such as R-waves typically occurring in this frequency range. The bandpass filtered signal is passed from filter **64** to rectifier **65** then to R-wave detector **66**. R-wave detector **66** may include an auto-adjusting sense amplifier, comparator and/or other detection circuitry that compares the filtered and rectified first cardiac electrical signal to an R-wave sensing threshold in real time and produces an R-wave sensed event signal **68** when the cardiac electrical signal crosses the R-wave sensing threshold.

The R-wave sensing threshold may be controlled by sensing circuit **86** and/or control circuit **80** to be a multi-level sensing threshold as disclosed in U.S. patent application Ser. No. 15/142,171 (Cao, et al., filed on Apr. 29, 2016), incorporated herein by reference in its entirety. Briefly, the multi-level sensing threshold may have a starting sensing threshold value held for a time interval equal to a tachycardia detection interval, then drops to a second sensing threshold value held until a drop time interval expires, which may be 1 to 2 seconds long. The sensing threshold drops to a minimum sensing threshold after the drop time interval. The starting sensing threshold value may be the lower of a predetermined percentage of the most recent, preceding sensed R-wave peak amplitude and a maximum sensing threshold limit determined using a sensitivity-dependent gain and the programmed sensitivity setting. In other examples, the R-wave sensing threshold used by R-wave detector **66** may be set to a starting value based on a preceding R-wave peak amplitude and decay linearly or exponentially over time until reaching a minimum sensing threshold. However, the techniques of this application are not limited to a specific behavior of the sensing threshold. Instead, other automatically adjusted sensing thresholds may be utilized.

In some examples, the filtered, digitized cardiac electrical signal from sensing channel **83** (output of filter **64**) may be stored in memory **82** for signal processing by control circuit **80** for use in detecting tachyarrhythmia episodes. In one example, the output of rectifier **64** is passed to differentiator **67** which determines an Nth order differential signal **69** that is passed to memory **82**. The differential signal **69** is also sometimes referred to as a “difference signal” because each sample point of the differential signal **69** may be determined as the difference between the ith input sample point and a corresponding i-N input sample point. Control circuit **80** may retrieve the stored signal from memory **82** for performing signal analysis by tachyarrhythmia detector **92** according to implemented tachyarrhythmia detection algorithms. For example, a T-wave oversensing algorithm implemented in tachyarrhythmia detector **92** may detect evidence of T-wave oversensing from a first order differential signal **69** produced by differentiator **67** as described in U.S. Pat. Application No. 62/367,221, incorporated herein by reference in its entirety. Other examples of methods for detecting T-wave oversensing using a differential signal may be performed by tachyarrhythmia detector **92** as generally disclosed in U.S. Pat. No. 7,831,304 (Cao, et al.), incorporated herein by reference in its entirety.

The second cardiac electrical signal, digitized by ADC **73**, may be passed to filter **74** for bandpass filtering, e.g., from 10 Hz to 30 Hz. In some examples, sensing channel **85** includes notch filter **76**. Notch filter **76** may be implemented in firmware or hardware and is provided to attenuate 50-60 Hz electrical noise, muscle noise and other electromagnetic interference (EMI) or electrical noise/artifacts in the second cardiac electrical signal. Cardiac electrical signals acquired using extra-cardiovascular electrodes as shown, for example in FIGS. **1A-3**, may be more likely to be contaminated by 50-60 Hz electrical noise, muscle noise and other EMI, electrical noise/artifacts than intra-cardiac electrodes. As such, notch filter **76** may be provided to significantly attenuate the magnitude of signals in the range of 50-60 Hz with minimum attenuation of signals in the range of approximately 1-30 Hz, corresponding to typical cardiac electrical signal frequencies. One example of a notch filter, designed with minimal computational requirements, and its filtering characteristics are described in conjunction with FIG. **6**.

The output signal **78** of notch filter **76** may be passed from sensing circuit **86** to memory **82** under the control of control circuit **80** for storing segments of the second cardiac electrical signal **78** in temporary buffers of memory **82**. For example, timing circuit **90** of control circuit **80** may set a time interval or number of sample points relative to an R-wave sensed event signal **68** received from first sensing channel **83**, over which the second cardiac electrical signal **78** is stored in memory **82**. The buffered, second cardiac electrical signal segment is analyzed by control circuit **80** on a triggered, as needed basis, as described in conjunction with FIGS. **7-13** to confirm R-waves sensed by the first sensing channel **83**.

Notch filter **76** may be implemented as a digital filter for real-time filtering performed by firmware as part of sensing channel **85** or by control circuit **80** for filtering the buffered digital output of filter **74**. In some examples, the output of filter **74** of sensing channel **85** may be stored in memory **82** in time segments defined relative to an R-wave sense event signal **68** prior to filtering by notch filter **76**. When control circuit **80** is triggered to analyze the stored, second cardiac electrical signal for confirming an R-wave sensed event signal, for example as described in conjunction with FIGS. **7**, **10**, **11** and **13**, the notch filter **76** may be applied to the stored segment of the second cardiac electrical signal before further processing and analysis of the stored segment. In this way, if analysis of the stored signal segment is not required for confirming an R-wave sensed by first sensing channel **83**, firmware implemented to perform the operation of notch filter **76** need not be executed.

The configuration of sensing channels **83** and **85** is illustrative in nature and should not be considered limiting of the techniques described herein. The sensing channels **83** and **85** of sensing circuit **86** may include more or fewer components than illustrated and described in FIG. **5**. First sensing channel **83**, however, is configured to detect R-waves in real time, e.g., in hardware implemented components, from a first cardiac electrical signal based on crossings of an R-wave sensing threshold by the first cardiac electrical signal, and second sensing channel **85** is configured to provide a second cardiac electrical signal for storage in memory **82** for post-processing and analysis by control circuit **80** for confirming R-wave sensed event signals produced by the first sensing channel **83**.

FIG. **6** is a plot **50** of the attenuation characteristics of notch filter **76** of the second sensing channel **85**. In one example, notch filter **76** is implemented in firmware as a digital filter. The output of the digital notch filter may be determined by firmware implemented in the second sensing channel **85** according to the equation:

$$Y(n)=(x(n)+2x(n-2)+x(n-4))/4$$

where x(n) is the amplitude of the nth sample point of the digital signal received by the notch filter **76**, x(n−2) is the amplitude of the n−2 sample point, and x(n−4) is the amplitude of the n−4 sample point for a sampling rate of 256 Hz. Y(n) is the amplitude of the nth sample point of the notch-filtered, digital second cardiac electrical signal. The plot **50** of FIG. **6** represents the resulting attenuation of the amplitude Y(n) as a function of frequency. At a frequency of 60 Hz, the attenuation of the magnitude of Y(n) is −40 decibels (dB). At a frequency of 50 Hz, the attenuation is −20 dB, and at 23 Hz, which may be typical of an R-wave of the cardiac electrical signal, the attenuation is limited to −3 dB. Notch filter **76** may therefore provide highly attenuated 50 and 60 Hz noise, muscle noise, other EMI, and other electrical noise/artifacts while passing lower frequency cardiac signals in the second cardiac electrical signal output of sensing channel **85**. Although the notch filter **76** may not attenuate frequencies approaching the maximum frequency of 128 Hz, filter **74** of second sensing channel **85**, which may be a bandpass filter, may adequately reduce the higher frequency range signal content above 60 Hz.

The sample point numbers indicated in the equation above for determining a notch-filtered signal may be modified as needed when a different sampling rate other than 256 Hz is used, however, the resulting frequency response may or may not be the same as that shown in FIG. **6**. The notch filter **76** uses minimal computations with only two adds and three shifts required. In other examples, other digital filters may be used for attenuation of 50 and 60 Hz. For example, for a sampling rate of 256 Hz, a filtered signal Y(n) may be determined as $Y(n)=(x(n)+x(n-1)+x(n-2)+x(n-3))/4$ which has less attenuation at 50 and 60 Hz than the frequency response shown in FIG. **6** but acts as a low-pass, notch filter with greater attenuation at higher frequencies (greater than 60 Hz) than the frequency response shown FIG. **6**.

FIG. **7** is a flow chart **100** of a method performed by ICD **14** for sensing and confirming R-waves for use in tachyarrhythmia detection according to one example. At blocks **102** and **104**, two different sensing electrode vectors are selected by sensing circuit **86** for receiving a first cardiac electrical signal by a first sensing channel **83** and a second cardiac electrical signal by a second sensing channel **85**. The two sensing electrode vectors may be selected by switching circuitry included in sensing circuit **86** under the control of control circuit **80**. In some examples, the two sensing electrode vectors are programmed by a user and retrieved from memory **82** by control circuit **80** and passed to sensing circuit **86** as vector selection control signals.

The first sensing vector selected at block **102** for obtaining a first cardiac electrical signal may be a relatively short bipole, e.g., between electrodes **28** and **30** or between electrodes **28** and **24** of lead **16** or other electrode combinations as described above. The relatively short bipole may include electrodes that are in relative close proximity to each other and to the ventricular heart chambers compared to other available sensing electrode pairs. The first sensing vector may be a vertical sensing vector (with respect to an upright or standing position of the patient) or approximately aligned with the cardiac axis for maximizing the amplitude of R-waves in the first cardiac electrical signal for reliable R-wave sensing.

The second sensing electrode vector used to obtain a second cardiac electrical signal at block **104** may be a relatively long bipole having an inter-electrode distance that is greater than the first sensing electrode vector. For example, the second sensing electrode vector may be selected as the vector between one of the pace sense electrodes **28** or **30** and ICD housing **15**, one of defibrillation electrodes **24** or **26** and housing **15** or other combinations of one electrode along the distal portion of the lead **16** and the housing **15**. This sensing vector may be orthogonal or almost orthogonal to the first sensing vector in some examples, but the first and second sensing vectors are not required to be orthogonal vectors. The second sensing electrode vector may provide a relatively more global or far-field cardiac electrical signal compared to the first sensing electrode vector. The second cardiac electrical signal obtained at block **104** may be used for waveform morphology analysis by the tachyarrhythmia detector **92** of control circuit **80** and is used for cardiac signal analysis for confirming an R-wave sensed event signal produced by first sensing channel **83** of sensing circuit **86**.

Sensing circuit **86** may produce an R-wave sensed event signal at block **106** in response to the first sensing channel **83** detecting an R-wave sensing threshold crossing by the first cardiac electrical signal. The R-wave sensed event signal may be passed to control circuit **80**. In response to the R-wave sensed event signal, down-going "yes" branch of block **106**, control circuit **80** is triggered at block **108** to store a segment of the second cardiac electrical signal received from the second sensing channel **85** (sensing vector **2**, block **104**) in a circulating buffer of memory **82**. A digitized segment of the second cardiac electrical signal may be 100 to 500 ms long, for example, including sample points before and after the time of the R-wave sensed event signal, which may or may not be centered in time on the R-wave sensed event signal received from sensing circuit **86**. For instance, the segment may extend 100 ms after the R-wave sensed event signal and be 200 to 500 ms in duration such that the segment extends from about 100 to 400 ms before the R-wave sensed event signal to 100 ms after. In other examples, the segment may be centered on the R-wave sensed event signal or extend a greater number of sample points after the R-wave sensed event signal than before. In one example, the buffered segment of the cardiac electrical signal is at least 50 sample points obtained at a sampling rate of 256 Hz, or about 200 ms. In another example, the buffered segment is at least 92 sample points, or approximately 360 ms, sampled at 256 Hz and is available for morphology analysis, noise analysis, T-wave oversensing, and/or other analysis performed by tachyarrhythmia detector **92** for detecting VT or VF. Other analyses of the buffered second cardiac electrical signal that may be performed by tachyarrhythmia detector **92** for detecting VT or VF, or withholding detection of VT or VF, are described in conjunction with FIG. **10**. Memory **82** may be configured to store a predetermined number of second cardiac electrical segments, e.g., at least 1 and in some cases two or more cardiac electrical signal segments, in circulating buffers such that the oldest segment is overwritten by the newest segment. However, previously stored segments may never be analyzed for R-wave confirmation before being overwritten if an R-wave confirmation threshold is not reached as described below. In some examples, a single segment of the second cardiac electrical signal may be stored and if not needed for confirming an R-wave sensed by the first channel, the segment is overwritten by the next segment corresponding to the next R-wave sensed event signal.

In addition to buffering a segment of the second cardiac electrical signal, control circuit **80** responds to the R-wave sensed event signal produced at block **106** by determining an RRI at block **110** ending with the current R-wave sensed event signal and beginning with the most recent preceding R-wave sensed event signal. The timing circuit **90** of control circuit **80** may pass the RRI timing information to the tachyarrhythmia detection circuit **92** which adjusts tachyarrhythmia interval counters at block **112**. If the RRI is longer than a tachycardia detection interval (TDI), the tachyarrhythmia interval counters remain unchanged. If the RRI is shorter than the TDI but longer than a fibrillation detection interval (FDI), i.e., if the RRI is in a tachycardia detection interval zone, a VT interval counter is increased at block **112**. If the RRI is shorter than or equal to the FDI, a VF interval counter is increased at block **112**. In some examples, a combined VT/VF interval counter is increased if the RRI is less than the TDI.

After updating the tachyarrhythmia interval counters at block **112**, tachyarrhythmia detector **92** compares the counter values to an R-sense confirmation threshold at block **114** and to VT and VF detection thresholds at block **132**. If a VT or VF detection interval counter has reached an R-sense confirmation threshold, "yes" branch of block **114**, the second cardiac electrical signal from sensing channel **85** is analyzed to confirm the R-wave sensed at block **106** by the first sensing channel **83**. The R-sense confirmation threshold may be a VT or VF interval count that is greater than or equal to a count of one or another higher count value. Different R-sense confirmation thresholds may be applied to the VT interval counter and the VF interval counter. For example, the R-sense confirmation threshold may be a count of two on the VT interval counter and a count of three on the VF interval counter. In other examples, the R-sense confirmation threshold is a higher number, for example five or higher, but may be less than the number of intervals required to detect VT or VF. In addition or alternatively to applying an R-sense confirmation threshold to the individual VT and VF counters, an R-sense confirmation threshold may be applied to a combined VT/VF interval counter.

If the R-sense confirmation threshold is not reached by any of the tachyarrhythmia interval counters at block **114**, the control circuit **80** waits for the next R-wave sensed event signal at block **108** to buffer the next segment of the second cardiac electrical signal. If the R-sense confirmation threshold is reached at block **114**, the control circuit **80** determines a maximum amplitude at block **116** of the buffered signal segment stored for the most recent R-wave sensed event signal. The maximum amplitude may be determined from a differential signal determined from the buffered signal segment. For example, an nth-order differential signal may be determined from the buffered signal segment by determining a difference between the ith and the ith-n signal sample points of the buffered signal segment. In one example a 4th order differential signal is determined.

The maximum absolute value of the differential signal is estimated as the amplitude of the event in the second cardiac electrical signal that was sensed as an R-wave from the first cardiac electrical signal. The time of the maximum absolute value of the signal is identified as the time of the event in the second cardiac electrical signal. When the R-wave is not the first R-wave to be confirmed since the R-sense confirmation threshold was reached, the control circuit **80** determines an amplitude ratio at block **118** as the ratio of the maximum absolute value determined at block **116** to the event amplitude determined from the second cardiac electrical signal for the most recently confirmed R-wave sensed event. At block **120**, the control circuit **80** determines a time interval from the most recent event of the second cardiac electrical signal confirmed as an R-wave sensed event to the time of the event determined at block **116**.

When the R-wave is the first R-wave to be confirmed after the R-sense confirmation threshold is reached, the first confirmed event on the second cardiac electrical signal may be assumed to occur at the same time as the R-wave sensed event signal with a default maximum amplitude. The default maximum amplitude may be set equal to the amplitude of the R-wave sensed by the first sensing channel **83**, a nominal value, e.g., 1 millivolt, or a previously determined R-wave amplitude or average R-wave amplitude determined from the second cardiac electrical signal. Alternatively, the maximum absolute amplitude of the differential signal and its time may be identified and stored as initial values used for determining an amplitude ratio and time at blocks **118** and **120** for the next R-wave to be confirmed. In other examples, an amplitude ratio may be determined for the first R-wave to be confirmed after the R-sense confirmation threshold is reached using a previously determined R-wave amplitude, e.g., from a prior time that the R-sense confirmation threshold was reached or a default R-wave amplitude. The first R-wave may be confirmed based on this amplitude ratio and/or time since the preceding R-wave sensed event signal.

At block **122**, the control circuit **80** determines a ratio threshold to be applied to the amplitude ratio based on the time interval determined at block **120**. In one example, the ratio threshold is retrieved from a look-up table stored in memory. In other examples, the ratio threshold may be computed as a function of the time interval determined at block **120**. The ratio threshold may be a variable threshold that decreases as the time interval since the most recent confirmed R-wave increases. As such, the time interval determined at block **120** is used to determine what ratio threshold should be applied to the amplitude ratio determined at block **118** for confirming the R-wave sensed by first sensing channel **83**. The ratio threshold may decrease in a linear, exponential or stepwise manner, or a combination thereof. For instance, the ratio threshold may decrease with a continuous slope or decay rate over some portions of time since the most recent confirmed R-wave and may be held constant over other portions of time since the most recent confirmed R-wave. An example of a time-varying ratio threshold and method for determining the ratio threshold at block **122** is described in conjunction with FIGS. **8** and **9**.

At block **124**, control circuit **80** compares the ratio threshold determined at block **122** to the amplitude ratio determined at block **118**. If the amplitude ratio is equal to or greater than the ratio threshold, the R-wave sensed event is confirmed at block **126**. If the amplitude ratio is less than the ratio threshold, the R-wave sensed event is not confirmed at block **128**. The event may be an oversensed T-wave, P-wave, muscle noise, electromagnetic interference or other or non-cardiac electrical noise that has been oversensed by the first sensing channel **83**.

At block **130** the control circuit **80** adjusts an unconfirmed beat counter. If the R-wave sensed event is not confirmed, the unconfirmed beat counter is increased by one count. If the R-wave sensed event is confirmed at block **126**, the unconfirmed beat counter may be kept at its current value or decreased. In some examples, the unconfirmed beat counter tracks how many out of the most recent predetermined number of consecutive R-wave sensed event signals produced by first sensing channel **83** are not confirmed in an x out of y manner. For example, the unconfirmed beat counter may track how many out of the most recent 12 R-wave sensed event signals are not confirmed to be R-waves based on the amplitude ratio comparison made at block **124**.

In addition to counting how many beats are unconfirmed at block **130**, data relating to the most recent n events analyzed by control circuit **80** may be stored in a rolling buffer. For example, data may be stored for the most recent twelve events analyzed for confirming an R-wave sensed event signal. The stored data may include the event amplitude, the amplitude ratio, the event timing, the time interval since the most recent confirmed event, and whether the event was confirmed or not confirmed.

While the R-wave sensed event signal is either confirmed or not confirmed based on an amplitude ratio determined from the second cardiac electrical signal according to the example of FIG. **7**, it is recognized that other features of the second cardiac signal may be compared to R-wave confirmation criteria in addition to or instead of the event amplitude as described above. For example, a peak slew rate, an event area, an event signal width, or other features of the buffered cardiac electrical signal segment may be compared to respective thresholds for confirming the event as being an R-wave. The thresholds may be defined as a minimum ratio of the feature relative to an analogous feature of the most recent preceding event confirmed to be an R-wave or may be thresholds compared directly to features determined from the buffered cardiac electrical signal segment independent of preceding events.

If any of the tachyarrhythmia interval counters adjusted at block **112** reach a number of intervals to detect (NID) tachyarrhythmia, as determined at block **132**, tachyarrhythmia detector **92** of control circuit **80** determines whether a rejection rule is satisfied at block **134** before detecting the tachyarrhythmia. In one example, the NID required to detect VT may be a count of 16 VT intervals, which are RRIs that fall into a predetermined VT interval range or zone. The NID to detect VF may be a count of 30 VF intervals out of the last 40 RRIs where the VF intervals are RRIs that fall into a predetermined VF interval range or zone. If an NID is reached, one or more rejection rules may be applied for rejecting a VT or VF detection based on RRI counts satisfying the NID. Various rejection rules are described below, e.g., in conjunction with FIGS. **10**, **11** and **13**. At least one rejection rule may relate to the number of R-waves sensed by the first sensing channel **83** that were not confirmed by the analysis of the second cardiac electrical signal. Another rejection rule may relate to the detection of noisy signal segments based on gross morphology analysis as described in conjunction with FIGS. **14** through **19**.

For instance, the unconfirmed beat counter updated at block **130** may be compared to a rejection rule criterion at block **134**. The rejection rule criterion may be a rejection threshold requiring that at least x of y events are not confirmed R-waves. For example, if at least 3, at least 4, at least 6 or other predetermined number of the most recent 12 events (or other predetermined number of events) analyzed for confirming an R-wave sensed event signal are not confirmed R-waves, the rejection rule is satisfied, "yes" branch of block **134**. The pending VT or VF detection based on the NID being reached at block **132** is withheld at block **140**, and no anti-tachyarrhythmia therapy is delivered.

If all rejection rules are not satisfied, "no" branch of block **134**, the pending detection of the VT or VF episode is not withheld. VT or VF is detected at block **136** based on the respective VT or VF interval counter reaching a corresponding NID. Control circuit **80** controls therapy delivery circuit **84** to deliver an appropriate anti-tachyarrhythmia therapy, e.g., ATP or a cardioversion/defibrillation shock, according to programmed therapy control parameters.

FIG. **8** is a diagram of a filtered, second cardiac electrical signal **200** and an amplitude ratio threshold **210** that may be applied to the amplitude ratio determined from the second cardiac electrical signal at block **118** of FIG. **7** for confirming an R-wave sensed event signal from the first sensing channel **83**. The amplitude ratio is not a sensing threshold that is compared to the second cardiac electrical signal **200** in real time. The first sensing channel **83** may operate by sensing an R-wave when the first cardiac electrical signal crosses an R-wave amplitude sensing threshold defined in mV. The second cardiac electrical signal provided to control circuit **80** by the second sensing channel **85**, however, is not compared to an amplitude sensing threshold in real time as it is acquired. Rather, as described in conjunction with FIG. **7**, if the first sensing channel **83** produces an R-wave sensed event signal, the second cardiac electrical signal is buffered in memory **82** and if a tachyarrhythmia interval counter reaches an R-wave confirmation threshold, the buffered signal is post-processed to determine if the ratio of a maximum amplitude determined from the buffered signal segment to the maximum amplitude determined from a preceding confirmed R-wave of the second cardiac electrical signal reaches or exceeds the ratio threshold **210**.

The ratio threshold **210** is shown relative to the second cardiac electrical signal **200** because the ratio threshold **210** is not a fixed value but varies over time. Ratio threshold **210** decreases as the time since the confirmed R-wave **202** increases. This time-variant ratio threshold is why the control circuit **80** determines the time since the preceding confirmed R-wave sensed event at block **120** of FIG. **7** in order to determine the value of the ratio threshold at block **122** that is applied to the amplitude ratio for confirming or not confirming the R-wave sensed event signal.

Cardiac electrical signal **200** may be produced by the second sensing channel **85** by filtering, amplifying and digitizing the cardiac electrical signal received by the second sensing electrode vector. While signal **200** is shown conceptually as having only positive-going waveforms it is to be understood that signal **200** may have positive- and negative-going portions and need not be a rectified signal. The absolute value of the maximum peak amplitude, positive or negative, may be determined from the stored second cardiac electrical signal segment at block **116** of FIG. **7**. Cardiac electrical signal **200** includes an R-wave **202**, a T-wave **204**, a P-wave **206**, and a subsequent R-wave **240**. R-wave **202** represents a confirmed event occurring at time point **205**. Time point **205** is the sample point of the maximum absolute value of the differential signal determined in response to an R-wave sense event signal **250** as described above in conjunction with FIG. **7**.

If an R-wave sensed event signal occurs during a blanking interval **214** following time point **205** of a preceding confirmed R-wave **202**, the new R-wave sensed event is not confirmed. Sensing channel **83** may have sensed the same R-wave **202** twice or sensed non-cardiac electrical noise as an R-wave.

After the blanking interval, the ratio threshold **210**, at a time point corresponding to the expiration of blanking interval **214**, is equal to a starting value **220** which may be set to 0.6 in one example, but may range between 0.4 and 0.7 in other examples. In one implementation, the ratio threshold **210** is stored in a look-up table and retrieved from memory **82** by control circuit **80** for comparison to an amplitude ratio determined in response to an R-wave sensed event signal from the first sensing channel.

FIG. **9** is an example of a look-up table **300** of ratio threshold values **304** that may be stored in memory **82** for respective event time intervals, which may be stored as corresponding sample point numbers **302**. If the blanking interval **214** is approximately 150 ms, the first sample point at which a maximum amplitude may be determined as an event time point is at sample point **38** when the sampling rate is 256 Hz. In other examples, blanking interval **214** may be longer or shorter than 150 ms and the first sample point number stored in look-up table **300** will correspond to the sample point number at which the blanking interval **214** expires after the confirmed event time point **205**, considered to "zero" sample point.

The ratio threshold is stored for the first sample point number entry as being the starting ratio threshold value **220**, which is 0.6 in this example. If the control circuit **80** receives an R-wave sensed event signal from the first sensing channel **83**, and a detection interval counter is equal to or greater than the R-wave confirmation threshold, a maximum event amplitude and event time is determined from the buffered, second cardiac electrical signal. The event time may be determined as the sample point number since the event time **205** of the most recent confirmed R-wave **202**. If the event time is determined to be sample point number **38**, control circuit **80** retrieves the ratio threshold, 0.6 in this example, stored in the look-up table **300** for the sample point number **38**. This ratio threshold value is applied to the amplitude ratio determined from the maximum amplitude of the buffered, second cardiac electrical signal to the maximum amplitude determined from the most recent confirmed R-wave **202**.

Referring again to FIG. **8**, the ratio threshold **210** is shown to decrease at a constant decay rate **222** until the expiration of a first time interval **216**. Time interval **216** may be defined to start at the time point **205** of the confirmed event **202** or start upon expiration of blanking interval **205**. Time interval **216** may extend for up to 1 second from the time point **205** of the most recent confirmed R-wave **202**. The decay rate **222** may, in one example, be approximately 0.3/second so that if time interval **216** is approximately 1 second, ratio threshold value **224** is 0.3 when the starting ratio threshold value **220** is 0.6.

Beginning at the expiration of time interval **216**, ratio threshold **210** is held at a constant value **224** until a second time interval **218** expires. The constant value **224** is a ratio of approximately ⅓ (0.3) in one example but may be between ⅕ (0.2) and ½ (0.5) in other examples. Value **224** may be held for up to 500 ms after time interval **216** expires (for a total time interval **218** of up to 1.5 seconds). This change from the decay rate **222** to the constant value **224** is reflected in look-up table **300** as the ratio threshold 0.3 starting at sample point number **256** extending through sample point number **383**.

At the expiration of time interval **218**, the ratio threshold **210** drops stepwise to an intermediate ratio threshold value **226** then decays at a constant rate **228** until it reaches a minimum ratio threshold **230**. The step drop from constant value **224** may be a drop to a ratio threshold of approximately ⅙ to ¼. In one example, the ratio threshold drops from approximately ⅓ (0.3) to an intermediate ratio threshold of ⅕ (0.2) at 0.5 seconds after the expiration of time interval **216**. This change is reflected in look-up table **300** as the ratio threshold of 0.2 at sample point **384** (0.5 seconds after sample point **256**).

The second decay rate **228** may be the same as decay rate **222** or a slower decay rate such that ratio threshold **210** reaches the minimum ratio threshold **230**, e.g., 1/32 (0.03), 1/64 (0.015) or other predetermined minimum ratio, approximately 2.5 seconds (sample point number **640**) after the time point **205** of the preceding confirmed R-wave **202**. The behavior of ratio threshold **210** moving forward in time from confirmed R-wave **202** is captured in look-up table **300** (FIG. **9**). For example, at the example decay rate **222** of 0.3/second, the ratio threshold is 0.587 at sample point number **48**, and so on.

The values recited here and reflected in look-up table **300** for ratio threshold values **220**, **224**, and **226** and **230** and time intervals **216** and **218** are illustrative in nature; other values less than or greater than the recited values may be used to implement a time-varying ratio amplitude for use in confirming an R-wave sensed event. The values for the ratio thresholds and time intervals used to control changes from one ratio threshold value to another or a decay rate and total decay interval will depend in part on the sampling rate, which is 256 Hz in the examples provided but may be greater than or less than 256 Hz in other examples.

Referring again to FIG. **8**, if an R-wave sensed event signal **252** is produced by first sensing channel **83**, control circuit **80** is triggered to store a time segment **254** of the second cardiac electrical signal **200** in memory **80**. Time segment **254** may be 360 ms in one example, and may be between 300 ms and 500 ms in other examples. If a VT or VF or combined VT/VF interval counter has reached an R-wave confirmation threshold, control circuit **80** determines a maximum amplitude from the buffered cardiac signal time segment. As described above, the maximum amplitude may be the maximum absolute value of an x-order differential signal determined from the second cardiac electrical signal **200**. The maximum amplitude may be determined from a portion of the stored cardiac signal time segment. For example, the maximum amplitude may be determined from a segment **255** that is a sub-segment or portion of the stored time segment **254**. Segment **255** may be approximately 50 to 300 ms long, e.g., 200 ms long, when the total time segment **254** is 360 ms to 500 ms long. The segment **255** may be defined relative to the time the R-wave sensed event signal **252** is received.

The sample point number **197** at which the maximum amplitude within the time segment **255** occurs represents the number of sample points since the event time **205** (sample point number zero) of the most recent confirmed R-wave **202**. The sample point number **197** is determined as the event time of the maximum amplitude of cardiac signal time segment **255**. Control circuit **80** uses this sample point number to look up the corresponding ratio threshold **304** in look-up table **300**. For the sake of example, the maximum amplitude during time segment **255** obtained in response to R-wave sensed event signal **252** may occur at sample point number **197** approximately 0.77 seconds after event time point **205**. The stored ratio threshold for sample point number **197** may be approximately 0.4 for a decay rate **222** of approximately 0.3/second (or 0.0012 per sample point) from the starting value **220**, which is 0.6 beginning at sample point number **38** in this example. If the amplitude ratio of the maximum amplitude determined at sample point number **197** during time segment **255** to the maximum amplitude determined for confirmed R-wave **202** is greater than or equal to 0.4, R-wave sensed event **252** is confirmed. In this example, the cardiac electrical signal has a low, baseline amplitude during interval **255**, and as such the R-wave sensed event signal **252** is not confirmed. Control circuit **80** increases the unconfirmed event counter as described in conjunction with FIG. **7**.

Similarly, control circuit **80** may receive R-wave sensed event signal **256** and determine a maximum amplitude during time segment **259**, defined relative to R-wave sensed event signal **256**, of the buffered cardiac electrical signal segment **258**. The event time sample point number **403** at which the maximum amplitude occurs since event time **205** is used to look up the ratio threshold from look up table **300**. In this case, the amplitude ratio determined from the buffered, second cardiac electrical signal during time segment **259** exceeds the ratio threshold **210** at the event time sample point number **403** of the maximum amplitude during time segment **259**, which corresponds to R-wave **240**. R-wave sensed event signal **256** is confirmed by control circuit **80**. In this way, the second cardiac electrical signal from sensing channel **85** is analyzed only when an R-wave sensed event confirmation condition is met, e.g., a tachyarrhythmia interval counter is active and has reached a threshold count, which may be less than a required number of intervals to detect a VT or VF episode. The R-wave sensed event of the first sensing channel is confirmed based on post-processing of the buffered, second cardiac electrical signal.

FIG. **10** is a flow chart **400** of a method for detecting tachyarrhythmia by ICD **14** according to another example. Operations performed at blocks **102-114**, **132**, **136**, **138** and **140** in flow chart **400** may generally correspond to identically-numbered blocks shown in FIG. **7** and described above. At blocks **102** and **104**, two different sensing electrode vectors are selected by sensing circuit **86** for receiving a first cardiac electrical signal by first sensing channel **83** and a second cardiac electrical signal by second sensing channel **85** as described above in conjunction with FIGS. **5** and **7**.

Sensing circuit **86** may produce an R-wave sensed event signal at block **106** in response to the first sensing channel **83** detecting an R-wave sensing threshold crossing by the first cardiac electrical signal. The R-wave sensed event signal may be passed to control circuit **80**. In response to the R-wave sensed event signal, control circuit **80** is triggered at block **108** to store a segment of the second cardiac electrical signal received from the second sensing channel **85** in a circulating buffer of memory **82**. A digitized segment of the second cardiac electrical signal, which may be defined in time relative to the time of the R-wave sensed event signal received from sensing circuit **86**, and may be 100 to 500 ms long, for example. In one example, the buffered segment of the cardiac electrical signal is at least 92 sample points obtained at a sampling rate of 256 Hz, or approximately 360 ms, of which 68 sample points may precede and include the sample point at which the R-wave sensed event signal was received and 24 sample points may extend after the sample point at which the R-wave sensed event signal was received.

In addition to buffering a segment of the second cardiac electrical signal, control circuit **80** responds to the R-wave sensed event signal produced at block **106** by determining an RRI at block **110** ending with the current R-wave sensed event signal and beginning with the most recent preceding R-wave sensed event signal. The timing circuit **90** of control circuit **80** may pass the RRI timing information to the tachyarrhythmia detection circuit **92** which adjusts tachyarrhythmia detection counters at block **112** as described above in conjunction with FIG. **7**.

After updating the VT and VF interval counters at block **112**, tachyarrhythmia detector **92** compares the interval counter values to an R-sense confirmation threshold at block **114** and to VT and VF NID detection thresholds at block **132**. If a VT or VF interval counter has reached an R-sense confirmation threshold, "yes" branch of block **114**, the second cardiac electrical signal from sensing channel **85** is analyzed to confirm the R-wave sensed at block **106** by the first sensing channel **83**. The R-sense confirmation threshold is a count of two on the VT interval counter and a count of 3 on the VF interval counter in one example. Other examples are given above in conjunction with FIG. **7**.

If the R-sense confirmation threshold is not reached by any of the interval counters at block **114**, the control circuit **80** waits for the next R-wave sensed event signal at block **108** to buffer the next segment of the second cardiac electrical signal. In some cases, the oldest buffered cardiac signal segment may be overwritten by the next cardiac signal segment without ever being analyzed for confirming an R-wave, or analyzed for any other purpose, since analysis of the buffered cardiac signal segment is not required if the VT and VF interval counters are inactive (at a count of zero) or remain below the R-sense confirmation threshold.

If an R-sense confirmation threshold is reached at block **114**, the control circuit **80** applies a notch filter to the stored, second cardiac electrical signal segment at block **416**. The notch filter applied at block **416** may correspond to the filter described in conjunction with FIG. **6**. The notch filter significantly attenuates 50-60 Hz electrical noise, muscle noise, other EMI, and other noise/artifacts in the stored, second cardiac electrical signal segment. Using the notch filtered segment, control circuit **80** performs multiple analyses on the segment to determine if any rejection rules are satisfied. As described below, if a rejection rule is satisfied, a pending VT or VF episode detection made based on an NID threshold being reached at block **132** may be withheld.

As described in conjunction with FIG. **7**, an amplitude ratio may be determined at block **418** for confirming the

R-wave sensed event signal that triggered the buffering of the currently stored, second cardiac electrical signal segment. Determinations made at block **418** may include the operations performed at blocks **116**, **118** and **120** of FIG. **7**. The amplitude ratio is used to update an R-wave confirmation rejection rule at block **428**.

The maximum peak amplitude used to determine the amplitude ratio may be determined from a portion of the stored cardiac signal segment at block **418**. For example, if a 360 ms or 500 ms segment is stored at block **108**, only a 200 ms segment, e.g., approximately 52 sample points sampled at 256 Hz, which may be centered in time on the R-wave sensed event signal may be analyzed for determining the amplitude ratio at block **418**. A longer signal segment may be stored at block **108** than required for determining the amplitude ratio at block **418** so that a longer segment is available for other signal analysis procedures performed by tachyarrhythmia detector **92** as described below, e.g., for determining a baseline noise parameter and other gross morphology parameters for detecting noisy signal segments as described in conjunction with FIGS. **14** through **19**.

Control circuit **80** may determine an event interval at block **418** as the time interval or number of sample points from the maximum peak amplitude to the preceding confirmed R-wave sensed event, when the current R-wave sensed event signal is not the first one being confirmed since the R-sense confirmation threshold was reached at block **114**. At block **428**, control circuit **80** may compare the amplitude ratio to a ratio threshold, which may be retrieved from a look-up table stored in memory **82** using the determined event interval as described in conjunction with FIGS. **8** and **9**. If the amplitude ratio is greater than the ratio threshold, the sensed R-wave is confirmed. If the amplitude ratio is less than the ratio threshold, the sensed R-wave is not confirmed.

An X of Y unconfirmed beat counter may be updated by tachyarrhythmia detector **92** at block **428** to reflect the number of R-wave sensed event signals that are not confirmed out of the most recent Y R-wave sensed event signals. For example, the X of Y counter may count how many R-waves are not confirmed to be R-waves out of the most recent 12 R-wave sensed event signals. If the X of Y count reaches a rejection threshold, e.g., if at least 3, 4, 5 or another predetermined number out of 12 R-wave sensed event signals are not confirmed to be R-waves, the R-wave rejection rule for withholding tachyarrhythmia detection is satisfied. A flag or logic value may set by control circuit **80** to indicate the R-wave rejection rule is satisfied. Updating the R-wave rejection rule at block **428** may include operations described in conjunction with FIG. **7** for blocks **122**, **124**, **126**, **128**, **130** and **134**.

At blocks **420**, **422**, **424** and **426**, other cardiac signal parameters may be determined from the notch-filtered, cardiac signal segment for updating the status of other tachyarrhythmia detection rejection rules at respective blocks **430**, **432**, **434** and **436**. In some examples, a digitized cardiac electrical signal from first sensing channel **83** may be analyzed and used in updating the status of a tachyarrhythmia detection withhold rule. For example, the notch filtered, cardiac electrical signal from the second sensing channel **85** may be analyzed at blocks **420**, **422** and **426** for updating a gross morphology rejection rule, a beat morphology rejection rule and a noise rejection rule at blocks **430**, **432**, and **436**, respectively. The differential signal **69** (see FIG. **5**) from the first sensing channel **83** may be analyzed at block **424** for updating the T-wave oversensing (TWOS) rule at block **434**.

At block **420** one or more gross morphology parameters are determined from the notch-filtered, second cardiac signal segment. Gross morphology parameters may include, but are not limited to, a low slope content, a noise pulse count, a normalized rectified amplitude, a maximum signal width, or other noise metrics. Examples of gross morphology parameters that may be determined at block **420** are described below in conjunction with FIGS. **15**, **16** and **17**. Other examples of gross morphology parameters that may be determined are generally disclosed in the above-incorporated U.S. Pat. No. 7,761,150 (Ghanem, et al.) and U.S. Pat. No. 8,437,842 (Zhang, et al.). The gross morphology parameters may be determined using the entire second cardiac signal segment stored at block **108** or a portion of the stored segment. In one example, at least 92 sample points, approximately 360 ms, are analyzed for determining the gross morphology parameters, which may be a portion of or the entire stored segment. The portion of the signal segment analyzed for determining gross morphology metrics extends beyond an expected QRS signal width so that at least a portion of the segment being analyzed corresponds to an expected baseline portion. In this way, at least one gross morphology parameter determined, such as the noise pulse count described in conjunction with FIG. **15**, is correlated to non-cardiac signal noise that may be occurring during the baseline portion, such as non-cardiac myoelectric noise or electromagnetic interference (EMI).

The gross morphology parameters are used at block **430** to update the status of a gross morphology rejection rule. Gross morphology parameters are determined from the signal segment for determining whether the signal segment, and therefore the second cardiac electrical signal, is noisy. A noisy segment may include multiple noise signal pulses that are evidence of non-cardiac muscle (myoelectric) noise, EMI, or other non-cardiac noise signals. A noisy signal segment may be an indication that an R-wave sensed event signal during the noisy signal segment is not reliable for contributing to a VT or VF detection. The gross morphology analysis may therefore analyze signal segment sample points that are not limited to the R-wave but may extend along an expected baseline portion of the segment prior to the R-wave sensed event signal that triggers the storage of the signal segment. By performing signal morphology analysis that includes expected baseline portions, which may be referred to as "gross morphology analysis" since it involves analysis of an entire signal segment or an extended portion of the signal segment that extends beyond just an expected R-wave or QRS waveform, noise pulses may be identified and detected to enable detection of noisy signal segments.

Criteria or thresholds may be applied to each gross morphology parameter determined, and the gross morphology rejection rule may be satisfied when a required number of the gross morphology parameters meet the criteria or threshold applied to the respective parameter. For example, if at least two out of three gross morphology parameters satisfy noise detection criteria, the gross morphology rejection rule is satisfied. Control circuit **80** may set a flag or logic signal indicating so at block **430**. Methods for determining gross morphology parameters and whether or not the gross morphology rejection rule is satisfied are described below in conjunction with FIGS. **14** through **19**.

At block **422** a morphology matching score is determined from the stored, second cardiac electrical signal segment. The morphology matching score may be determined by performing wavelet transform or other morphology matching analysis on a portion of the stored segment, e.g., on at least 48 signal sample points or about 190 ms, and may be performed using the notch filtered signal produced at block **416**. The morphology matching analysis may include aligning a selected portion of the stored segment with a previously-determined known R-wave template and determining a morphology matching score. The morphology matching score may have a possible range of values from 0 to 100 and indicates how well the morphology of the second cardiac signal segment matches the known R-wave template. A wavelet transform method as generally disclosed in U.S. Pat. No. 6,393,316 (Gillberg et al.) is one example of a morphology matching method that may be performed at block **422** for determining a matching score.

Other morphology matching methods that may be implemented by tachyarrhythmia detector **92** may compare the wave shape, amplitudes, slopes, inflection time points, number of peaks, or other features of the stored second cardiac electrical signal to a known R-wave template. More specifically, waveform duration or width, waveform polarity, waveform positive-going slope, waveform negative-going slope, and/or other waveform features may be used alone or in combination to characterize the similarity between the unknown waveform and a known R-wave template. Morphology matching methods may use one or a combination of two or more morphology features of the stored second cardiac electrical signal for determining a match to a known R-wave template. A posture-independent method for determining a morphology match score may be performed that includes generating posture-independent R-wave templates for use in template matching as generally disclosed in pre-grant U.S. Pat. Publication No. 2016/0022166 (Stadler, et al.), incorporated herein by reference in its entirety. Other beat morphology matching techniques that may be used at block **422** are generally disclosed in U.S. Pat. No. 8,825,145 (Zhang, et al.) and U.S. Pat. No. 8,983,586 (Zhang et al.), both incorporated herein by reference in their entirety.

The morphology matching score is used at block **432** by tachyarrhythmia detector **92** to update a beat morphology rejection rule. The beat morphology rejection rule may be satisfied when a minimum number of morphology match scores out of a predetermined number of most recent morphology match scores exceed a match score threshold in one example. For example, if at least three out of 8 of the most recent morphology match scores exceed a match score threshold of 50, 60, 70 or other score threshold, the beat morphology rejection rule is satisfied. A relatively high match score, exceeding a selected match score threshold, indicates the unknown beat matches the known R-wave template and is therefore a normal R-wave rather than a VT or VF beat. As such, when a threshold number of the most recent morphology match scores are determined to be normal R-waves, the beat morphology rejection rule is satisfied, and control circuit **80** may set a flag or logic signal indicating so.

The beat morphology rejection rule differs from the gross morphology rejection rule in that the beat morphology rejection rule is based on an analysis of the suspected R-wave signal to determine how likely it is to be normal R-wave. In other words the beat morphology rejection rule is applied to withhold a VT or VF detection based on verifying normal ventricular beats (or at least identifying beats that are not likely VT or VF beats). The gross morphology rejection rule is based on an analysis of a longer time interval of the signal segment than the beat morphology rejection rule so that a signal morphology parameter correlated to non-cardiac noise pulses, e.g., during the baseline portion of the second cardiac electrical signal may be detected. The gross morphology rejection rule is applied to withhold a VT or VF detection based on detecting noisy signal segments that may be interfering with reliable VT or VF detection or leading to a false VT or VF detection.

At block **424**, TWOS parameters are determined from a stored, digitized cardiac electrical signal. In some cases, the TWOS parameters are determined from a first order differential signal **69** received from first sensing channel **83** as described in conjunction with FIG. **5** above. The first order differential signal is determined by subtracting the amplitude of the n−1 sample point from the nth sample point. Alternatively or additionally, the second cardiac electrical signal from sensing channel **85**, before or after notch filtering, may be used for determining TWOS parameters for detecting TWOS based on morphology analysis of the stored cardiac signal, e.g., as generally disclosed in the above-incorporated U.S. Pat. Application No. 62/367,221. Tachyarrhythmia detector **92** may be configured to execute T-wave oversensing rejection algorithms by determining a differential filtered cardiac electrical signal and TWOS parameters as generally disclosed in the above-incorporated U.S. Pat. No. 7,831,304 (Cao, et al). Other aspects of detecting TWOS that may be used for determining TWOS parameters from the either the first and/or second cardiac electrical signal are generally disclosed in U.S. Pat. No. 8,886,296 (Patel, et al.) and U.S. Pat. No. 8,914,106 (Charlton, et al.), both incorporated herein by reference in their entirety.

At block **434**, the TWOS parameter(s) determined for the currently stored cardiac signal segment are used by the tachyarrhythmia detector **92** to update the status of a TWOS rejection rule as being either satisfied or unsatisfied. For example, if one or more TWOS parameters indicate the R-wave sensed event signal produced by the first sensing channel **83** is likely to be an oversensed T-wave, a TWOS event counter may be updated at block **434**. If the TWOS event counter reaches a threshold, the TWOS rejection rule is satisfied. Control circuit **80** may set a flag or logic signal indicating when the TWOS rejection rule is satisfied.

Other noise parameters may be determined at block **426** to identify oversensing due to noise artifacts. The noise parameters determined at block **426** may include determining peak amplitudes from the notch-filtered second cardiac electrical signal segment. All or a portion of the stored signal segment may be used for determining one or more amplitude peaks. In other examples, the first cardiac electrical signal segment may undergo notch filtering and be used for determining noise parameters at bock **426**. The peak amplitudes determined at block **426** may include the maximum peak amplitude determined at block **418** for use in determining the amplitude ratio. The maximum peak amplitudes for one or more stored cardiac signal segments are compared to noise detection criteria for determining whether the noise rejection rule is satisfied at block **436**. Control circuit **80** sets a flag or logic signal to indicate the status of the noise rejection rule at block **436**. Methods for determining noise parameters at block **426** and updating a noise rejection rule at block **436** are generally disclosed in U.S. Pat. Application No. 62/367,170, incorporated herein by reference in its entirety.

After adjusting the VT and VF interval counters at block **112**, the tachyarrhythmia detector **92** compares the interval counters to VT and VF NID detection thresholds at block **132**. If the NID has been reached by either the VT or VF interval counter, tachyarrhythmia detector **92** checks the status of the rejection rules at block **440**. If rejection criteria are satisfied at block **440**, "yes" branch of block **440**, based on the status of one or more rejection rules, the VT or VF detection based on RRI analysis at blocks **110**, **112**, and **132** is withheld at block **140**. No VT or VF therapy is delivered. The process returns to block **110** to determine the next RRI upon receiving the next R-wave sensed event signal from sensing channel **83**.

If the rejection criteria are not satisfied, "no" branch of block **440**, the VT or VF episode is detected at block **136** according to which VT or VF interval counter reached its respective NID threshold. Control circuit **80** controls therapy delivery circuit **84** to deliver a therapy at block **138** according to the type of episode detected and programmed therapy delivery control parameters.

In some examples, the rejection criteria applied at block **440** require only a single rejection rule be satisfied in order to cause the tachyarrhythmia detector **92** to withhold a VT or VF detection. In other examples, two or more rejection rules may be required to be satisfied before an RRI-based VT or VF detection is withheld. In still other examples, one rejection rule may be linked with another rejection rule in order to have rejection criteria satisfied at block **440**. For instance, the R-wave confirmation rejection rule may only be used to satisfy the rejection criteria when the gross morphology rejection rule is also satisfied. In this case, the R-wave confirmation rejection rule alone may not be used to satisfy the rejection criteria at block **440**. The gross morphology rejection rule may be used only with the R-wave confirmation rejection rule, alone or in combination with another rule to satisfy the rejection criteria.

The rejection rules updated at blocks **428** through **436** may be programmably enabled or disabled by a user using external device **40**. Control circuit **80** may determine which parameters are determined at blocks **418** through **426** as required for updating the status of only the rejection rules that are enabled or programmed "ON."

FIG. **11** is a flow chart **500** of a method for detecting tachyarrhythmia by ICD **14** according to another example. In the examples of FIG. **7** and FIG. **10**, the number of RRIs determined from the first sensing electrode vector **102** that fall into a respective VT or VF interval range or zone are tracked by respective VT and VF interval counters. The counts of the VT and VF interval counters are compared to respective VT and VF NID thresholds at block **132**. Identically-numbered blocks in FIG. **11** correspond to like-numbered blocks shown in FIGS. **7** and **10** as described above.

In other examples, the second cardiac electrical signal received by the second sensing channel **85** from the second electrode vector at block **104** may also be used for determining RRIs and determining whether an NID threshold is reached at decision block **438**. Tachyarrhythmia detector **92** may include second VT and VF interval counters for counting RRIs determined from the second cardiac electrical signal received by the second sensing channel **85**. The second VT and VF interval counters may be updated at block **415** based on RRIs determined from the second cardiac electrical signal received via the second sensing electrode vector **104**.

In one instance, the tachyarrhythmia detector **92** may begin updating second VT and VF interval counters at block **415** after the R-sense confirmation threshold is reached at block **114**. The process of updating the second VT and VF interval counters from an initialized zero count may include confirming an R-wave at block **428** based on comparing an amplitude ratio to a ratio threshold as described in conjunction with blocks **122**, **124**, **126**, and **128** of FIG. **7**. If the R-wave sense is confirmed at block **126**, the R-wave confirmation rejection rule is updated at block **428** based on the confirmed R-wave sensed event, and tachyarrhythmia detector **92** compares the event interval determined at block **418** to VT and VF interval zones at block **415**. The event interval determined at block **418** is the time interval from the most recently confirmed R-wave event time to the event time of the maximum absolute amplitude of the time segment stored for the most recent R-wave sensed event signal.

If the most recent R-wave sensed event signal is confirmed at block **428**, the event interval may be compared at block **415** to VT and VF interval zones defined to be the same as the interval zones applied at block **112** to RRIs determined from R-wave sensed event signals produced by the first sensing channel **83**. If the event interval determined at block **418** for a confirmed R-wave falls into the VT interval zone, the second VT interval counter is increased at block **415**. If the event interval falls into the VF interval zone, the second VF interval counter is increased at block **415**. In some examples, a combined VT/VF interval counter is increased if the event interval falls into either a VT or VF interval zone.

If one of the first VT or VF interval counters (or a combined VT/VF interval counter) applied to RRIs determined from the first sensing channel **83** reaches an NID at block **132**, tachyarrhythmia detector **92** may compare the second VT and VF interval counters to second NID requirements at block **438**. The second VT NID and the second VF NID used by tachyarrhythmia detector **92** may be less than the VT NID and VF NID applied to the first VT and VF interval counters at block **132**. The second VT and VF interval counters begin to be updated after the R-sense confirmation threshold is reached at block **114** in some examples. As such, the second VT and VF interval counters may have counts that are less than the first VT and VF interval counters (that are adjusted at block **112**). The counts of the second VT and VF interval counters may fall behind the first VT and VF interval counts by the number of intervals required to reach the R-sense confirmation threshold. For example, if a first VT interval counter is required to have a count of at least 2 or the first VF interval counter is required to have a count of at least 3 in order for the R-sense confirmation threshold to be reached at block **114**, the second VT or VF interval counter may have a count that is at least 2 or 3, respectively, less than the first respective VT or VF interval counter.

If a second NID is reached by one of the second VT or VF interval counters, "yes" branch of block **438**, tachyarrhythmia detector **92** determines if rejection criteria are met at block **440** based on the status of the rejection rules updated at block **428** through **436** as described above in conjunction with FIG. **10**. If the second NID is not reached at block **438** by neither of the second VT or VF interval counters, "no" branch of block **438**, tachyarrhythmia detector **92** does not advance to checking the rejection criteria at block **440**. Rather, tachyarrhythmia detector **92** may wait for the first VT or VF NID to be reached at block **132** by the respective first VT or VF interval counter and for the respective second NID to be reached at block **438** by the respective second VT or VF interval counter. For instance, in order to advance to block **440** to determine if rejection criteria are satisfied and subsequently either detect VT at block **136** or withhold a VT detection at block **140**, the first VT interval counter is required to reach the first VT NID at block **132** and the second VT interval counter is required to reach the second VT NID at block **438**. Similarly, in order to advance to block **440** to determine if rejection criteria are satisfied and subsequently either detect VF at block **136** or withhold a VF detection at block **140**, the first VF interval counter is required to reach the first VF NID at block **132** and the second VF interval counter is required to reach the second VF NID at block **438**.

FIG. **12** is a diagram of circuitry included in the sensing circuit of FIG. **4** according to another example. In FIG. **12**, identically-numbered components of sensing channels **83** and **85** correspond to like-numbered components described in conjunction with and shown in FIG. **5**. In the example of FIG. **5**, first sensing channel **83** is configured to sense R-waves by R-wave detector **66** in real time and produce R-wave sensed event signals **68** that are passed to timing circuit **90** as the R-waves are sensed. Second sensing channel **85** is configured to pass the filtered, digitized output signal **78** to memory **82** for storage of second cardiac electrical signal segments as triggered by R-wave sensed event signals **68** from first sensing channel **83** without performing real-time R-wave sensing from the second cardiac electrical signal.

In the example of FIG. **12**, second sensing channel **85** is configured to pass the digitized filtered output signal **78** to memory **82** for storage of second cardiac electrical signal segments as described above. Sensing channel **85** is additionally configured to perform real-time R-wave sensing from the second cardiac electrical signal. In this case, second sensing channel **85** includes rectifier **75** for rectifying the digitized and bandpass filtered signal output of filter **74**. The rectified signal is passed from rectifier **75** to R-wave detector **77**. R-wave detector may include a sense amplifier, comparator or other R-wave detection circuitry configured to apply an auto-adjusting R-wave sensing threshold to the rectified signal for sensing an R-wave in response to a positive-going R-wave sensing threshold crossing.

Second sensing channel **85** may produce R-wave sensed event signals **79** that are passed to timing circuit **90** in real time for use in determining RRIs based on the second cardiac electrical signal. RRIs may be determined as the time interval or sample point count between consecutively received R-wave sensed event signals **79**. Timing circuit **90** may pass RRIs determined from R-wave sensed event signals **79** from second sensing channel **85** to tachyarrhythmia detector **92** for use in updating second VT and VF interval counters based on RRIs determined from real-time sensing of R-waves by the second sensing channel **85**.

In the flow chart **500** of FIG. **11**, second VT and VF interval counters are updated at block **415** by tachyarrhythmia detector **92** based on R-waves confirmed at block **428** as a result of post-processing of the stored second cardiac electrical signal segments. R-waves are not sensed by the second sensing channel **85** in real time in the example of FIG. **11** (the signal segments may be recorded but R-wave sense event signals are not produced in real time as R-waves are sensed based on an R-wave sensing threshold). In FIG. **12**, the second sensing channel **85** is configured to sense R-waves in real time from the second cardiac electrical signal received by the second sensing vector **104**, and, as such, tachyarrhythmia detector **92** may update second VT and VF interval counters based on real-time sensing of R-waves by the second sensing channel **85**.

FIG. **13** is a flow chart **550** of a method for detecting tachyarrhythmia by ICD **14** according to another example in which the second sensing channel **85** is configured for real-time sensing of R-waves from the second cardiac electrical signal in addition to the control circuit **80** being configured to confirm R-waves sensed by the first sensing channel **83** by post-processing of the second cardiac electrical signal. Identically-numbered blocks in FIG. **13** correspond to like-numbered blocks shown in FIGS. **7** and/or **11** and described in conjunction therewith.

In the example of FIG. **13**, at block **105**, R-wave detector **77** of sensing channel **85** produces R-wave sensed event signals **79** (shown in FIG. **12**), e.g., in response to crossings of a second R-wave sensing threshold by the second cardiac electrical signal. The second R-wave sensing threshold may be an auto-adjusting threshold and may be different than the R-wave sensing threshold used by R-wave detector **66** of the first sensing channel **83**. Timing circuit **90** determines RRIs between consecutive R-wave sensed event signals **79** received from second sensing channel **85** at block **105** and passes the determined RRIs to tachyarrhythmia detector **92**. At block **419**, tachyarrhythmia detector **92** adjusts the second VT interval counter or the second VF interval counter, which may both be X of Y type counters, in response to each RRI determined at block **105**. In this example, the second VT and VF interval counters of tachyarrhythmia detector **92** may be updated in real time, similar to the first VT and VF interval counters used to count RRIs determined from the first cardiac electrical signal. The second VT and VF interval counters may be updated on a beat-by-beat basis without requiring the R-sense confirmation threshold to be reached first (block **114**).

If the tachyarrhythmia detector **92** determines that a first VT NID or first VF NID is reached at block **132**, the tachyarrhythmia detector **92** compares the second VT and VF interval counters to a second VT NID and second VF NID, respectively, at block **439**. In this case, the second VT NID and second VF NID may be the same as the first VT NID and the first VF NID since all of the first and second VT interval counters and the first and second VF interval counters are being updated in response to R-waves that are sensed in real time. If the second VT or VF NID has not been reached ("no" branch of block **430**), the tachyarrhythmia detector **92** may return to block **132** to wait for the VT or VF NID thresholds to be reached based on R-waves sensed in real time by both the respective first and second sensing channels **83** and **85**.

If a second VT or VF NID is reached at block **439** when a corresponding first VT or VF NID is reached at block **132**, the tachyarrhythmia detector **92** determines if rejection criteria are satisfied at block **440** as described previously in conjunction with FIG. **10**. A pending VT of VF detection based on tachyarrhythmia intervals being detected in real time from both the first and second cardiac electrical signals is either withheld at block **140** in response to rejection criteria being met or the VT or VF detection is confirmed at block **135** if the rejection criteria are not satisfied. Control circuit **80** controls the therapy delivery circuit to deliver an anti-tachyarrhythmia therapy at block **138** in response to the VT or VF detection.

FIG. **14** is a flow chart **600** of a method performed by ICD **14** for withholding a VT or VF detection in response to the gross morphology rejection rule (block **430**, FIGS. **10**, **11** and **13**) being satisfied. Blocks **102** through **114**, **132**, **136**, **138**, and **140** of FIG. **14** correspond to identically-numbered blocks described above in conjunction with FIGS. **10**, **11** and **13**.

As described above, if the R-sense confirmation threshold is reached at block **114**, the control circuit **80** applies a notch filter to the stored, second cardiac electrical signal segment at block **416**. The notch filter applied at block **416** may correspond to the filter described in conjunction with FIG. **6**. The notch-filtered, second cardiac electrical signal segments are used at blocks **602**, **604** and **606** to determine morphology parameters relating to baseline noise (block **602**), maximum signal amplitude (block **604**) and maximum signal width (block **606**). Examples of methods that may be performed by control circuit **80** for determining a baseline noise parameter, determining a signal amplitude parameter, and determining a signal width parameter are described below in conjunction with FIGS. **15**, **16** and **17**, respectively. The methods performed at blocks **602**, **604** and **608** may correspond to the determination of gross morphology parameters at block **420** of FIGS. **10**, **11** and **13**.

These parameters are compared to noise detection criteria at block **608**. If the noise detection criteria are satisfied at block **608**, the second cardiac signal segment being analyzed is determined to be a noisy segment at block **610**. The noise contamination of the signal segment may be caused by muscle (myoelectric) noise, EMI or other non-cardiac electrical noise sources.

In response to detecting a noisy segment at block **610** ("yes" branch), control circuit **80** increases a noisy segment count at block **614** to track the number of segments identified as being noisy based on the morphology parameters after the R-wave confirmation threshold is reached at block **114**. The status of the gross morphology rejection rule is updated at block **430** based on the value of the noisy segment count. When the segment is not detected as being noisy, "no" branch of block **610**, the gross morphology rejection rule may be updated at block **430** to track the number of noisy segments that are detected out of a predetermined number of segments analyzed or out of the most recent R-wave sensed event signals. The gross morphology rejection rule may be satisfied based on the noisy segment count value. If a threshold number of noisy segments are detected, the rejection rule is satisfied at block **430**. For example, if at least two out of the most recent eight (or other predetermined number) analyzed cardiac electrical signal segments are classified as noisy, the rejection rule is updated as being satisfied at block **430**. If less than two out of the most recent eight analyzed cardiac electrical signal segments are classified as noisy, the rejection rules are updated as being unsatisfied.

The next signal segment is fetched at block **612** and undergoes the same analysis at blocks **602** through **610** to determine whether the segment is noisy or not based on the noise detection criteria applied at block **608**. As described below in conjunction with FIG. **19**, the next signal segment to undergo analysis for detecting a noisy signal segment may not correspond to the next consecutive R-wave sensed event signal. In some cases, the next signal segment that is fetched at block **612** corresponds to an R-wave sensed event signal that occurs at least 300 ms or another predetermined time limit after the R-wave sensed event signal that triggered storage of the signal segment currently being analyzed. In this way, signal segments analyzed for being identified as noisy signal segments may sometimes be consecutive and at other times be non-consecutive. R-wave sensed event signals that occur at an RRI less than the predetermined time limit may be skipped for the purposes of determining gross morphology parameters. In other examples, each R-wave sensed event signal that occurs outside of the post-sense blanking interval is analyzed for determining gross morphology parameters.

In response to the NID being reached at block **132**, based on RRIs determined from the cardiac electrical signal received via the first sensing vector **102** by the first sensing channel **83**, control circuit **80** determines if rejection criteria are satisfied at block **440**. In the example of FIG. **14**, control circuit **80** checks the status of the gross morphology rejection rule updated at block **430**. If the gross morphology rejection rule is satisfied when the NID is reached at block **132**, e.g., if at least two out of the most recent eight signal segments analyzed, as given in the example above, are detected as noisy segments, a VT or VF detection based on the NID being reached at block **132** is withheld at block **140**; no therapy is delivered.

This process of analyzing signal segments for detecting noisy segments may be repeated as long as the R-sense confirmation threshold is still being met or until a VT or VF is detected. VT or VF is detected at block **136** when the NID is reached and the gross morphology rejection rule (and any other rejection rules applied at block **440** as described previously herein) is not satisfied ("no" branch of block **440**). Control circuit **80** controls therapy delivery circuit **84** to deliver a therapy, e.g., ATP or a shock therapy, according to programmed therapies. It is to be understood that in some examples, the VT or VF detection made at block **136** may require a second NID to be reached based on RRIs determined from the second cardiac electrical signal as described in conjunction with FIGS. **11** and **13**.

FIG. **15** is a flow chart **700** of a method performed by ICD **14** for determining a morphology parameter correlated to baseline noise at block **602** of FIG. **14** according to one example. The morphology parameter correlated to baseline noise is referred to herein as a baseline noise parameter and in the example of FIG. **15** the morphology parameter correlated to baseline noise is a count of signal pulses during the signal segment.

At block **702** a first order differential signal may be determined from the notch-filtered second cardiac electrical signal segment. In one example, the stored segment is at least 360 ms long so that a first order differential signal is determined using sample points over a 360 ms segment of the second cardiac electrical signal, e.g., after notch-filtering. The 360 ms segment may include sample points preceding and following an R-wave sensed event signal. For instance, the 360 ms segment may include 92 sample points when the sampling rate is 256 Hz with 24 of the sample points occurring after the R-wave sensed event signal that triggered the storage of the signal segment and 68 sample points extending from the R-wave sensed event signal earlier in time from the R-wave sensed event signal. By processing relatively fewer sample points occurring after the R-wave sensed event signal, control circuit **80** does not need to wait long after the R-wave sensed event signal for acquiring all sample points needed to determine the baseline noise parameter (and other gross morphology parameters), thereby minimizing the signal processing delay in detecting noise and updating the gross morphology rejection rule. The first order differential signal is computed by computing successive differences, $A(n)-A(n-1)$, between sample points, where n is the sample point number, ranging from 1 to 92 in the example given above, $A(n)$ is the amplitude of the nth sample point and $A(n-1)$ is the amplitude of the immediately preceding $n-1$ sample point.

At block **704**, zero crossings are set by identifying consecutive sample points of the differential signal having opposite polarity. For example, a positive sample point followed by a negative sample point is identified as a zero crossing, or a negative sample point followed by a positive sample point is identified as a zero crossing. Control circuit **80** compares the absolute values of the two signal sample points identified as a zero crossing. The sample point of the differential signal having the smaller absolute value amplitude is set to zero amplitude to clearly demark each zero crossing with two consecutive zero crossings defining a baseline noise pulse.

The differential signal with zero crossings set is rectified at block **706**. At block **708**, a noise pulse amplitude threshold is determined. The noise pulse amplitude threshold may be determined based on the maximum amplitude of the rectified differential signal over the entire segment being analyzed, over 360 ms in the example given above. The noise pulse amplitude threshold may be set to a portion or percentage of the maximum amplitude of the rectified differential signal. For instance, the noise pulse amplitude threshold may be set to be one-eighth of the maximum amplitude of the rectified differential signal.

At block **710**, signal pulses within the segment being analyzed are identified and counted. Signal pulses are identified by comparing the sample point amplitudes of the rectified differential signal occurring between two consecutive zero crossings to the noise pulse amplitude threshold. If the rectified differential signal amplitude crosses the noise pulse amplitude threshold, a signal pulse is identified and counted at block **710**. The control circuit **80** may advance through the entire stored signal segment, or selected portion thereof that extends earlier in time than the QRS complex to include a baseline signal portion, to identify and count all pulses exceeding the noise pulse amplitude threshold in the segment under analysis. The baseline noise parameter determined at block **602** of FIG. **14** is the count of identified signal pulses determined at block **710**. Other techniques that may be implemented for determining a baseline noise parameter at block **602**, such as a muscle noise pulse count, are generally disclosed in U.S. Pat. No. 8,435,185 (Ghanem, et al.), incorporated herein by reference in its entirety.

FIG. **16** is a flow chart **800** of a method for determining an amplitude parameter at block **605** of FIG. **14** according to one example. At block **802**, the notch-filtered signal segment is rectified, e.g., a 360 ms segment as described above in conjunction with FIG. **15** is rectified. Control circuit **80** determines the maximum absolute amplitude of the rectified, notch-filtered segment at block **804**. The amplitudes of all sample points of the rectified signal segment under analysis are summed at block **806**. At block **808**, the normalized rectified amplitude (NRA) is determined based on the maximum absolute amplitude determined at block **804** and the summed sample point amplitudes determined at block **806**. In one example, the NRA is determined as the ratio of a predetermined multiple of the summation of all sample point amplitudes of the notch-filtered and rectified signal segment to the maximum absolute amplitude. For instance, the NRA may be determined as four times the summed amplitudes divided by the maximum absolute amplitude, which may be truncated to an integer value. This NRA may be determined as the amplitude parameter at block **604** of FIG. **14**. The higher this amplitude parameter value is, the more likely that the signal segment contains a valid R-wave of a VT or VF episode. The signal segment may be identified as a "shockable beat" when the amplitude parameter is greater than a shockable beat amplitude threshold as described below in conjunction with FIG. **18**.

FIG. **17** is a flow chart **810** of a method that may be performed by control circuit **80** for determining a signal width parameter at block **606** of FIG. **14**. Blocks **802** and **804** correspond to identically-numbered blocks described above in conjunction with FIG. **16**. The notch-filtered, rectified signal segment determined at block **802** and the maximum absolute amplitude of the rectified signal segment determined at block **804** are used for determining the signal amplitude parameter at block **604** of FIG. **14** and the signal width parameter at block **606** of FIG. **14**. In other examples, however, the differential signal with set zero crossings used to determine the pulse count as described in conjunction with FIG. **15** may also be used to determine the signal amplitude and signal width parameters instead of the notch-filtered, rectified signal segment.

Control circuit **80** determines a pulse amplitude threshold at block **812** based on the maximum absolute amplitude. This pulse amplitude threshold is used for identifying a signal pulse having the maximum signal width in the second cardiac electrical signal segment. The pulse amplitude threshold determined at block **812** may be a different threshold than the noise pulse amplitude threshold determined at block **708** of FIG. **15**. For example, the pulse amplitude threshold used for determining the signal width parameter may be set to half the maximum absolute amplitude of the rectified, notch-filtered signal segment whereas the noise pulse amplitude threshold used in FIG. **15** to determine a count of signal pulses may be set to one-eighth the maximum amplitude of rectified, differential signal segment.

The signal amplitude parameter determined by the method of FIG. **16** and the signal width parameter determined by the method of FIG. **17** are used to identify signal pulses that are more likely to be an R-wave of a potential VT or VF rhythm than a baseline noise pulse. A signal segment that has a relatively large signal amplitude parameter and/or relatively large signal width parameter is potentially a heartbeat of a VT or VF rhythm rather than noise, and is referred to herein as a "potential shockable beat." When a potential shockable beat is detected based on a large signal amplitude and/or signal width parameter, more stringent criteria may be applied for detecting the signal segment as a noisy segment to avoid withholding a VT or VF detection based on a potential shockable beat. The signal segment including a potential shockable beat is required to meet higher noise detection criteria in order to justify counting the signal segment as a noisy segment at block **614** (FIG. **14**), which may lead toward satisfying the gross morphology rejection rule and withholding a VT or VF detection. Otherwise a potential shockable beat that is counted as a noisy segment based on less stringent noise detection criteria may lead to withholding or delay of a VT or VF detection during a true tachyarrhythmia episode.

At block **814**, control circuit **80** determines the signal width for all pulses of the segment as the number of sample points (or corresponding time interval) between a pair of consecutive zero crossings of the rectified signal. The maximum peak of each pulse is determined at block **816**. All pulses having a maximum peak that is greater than or equal to the pulse amplitude threshold determined at block **812**, e.g., greater than half the maximum absolute amplitude, are identified. Of the pulses having a maximum peak amplitude that is at least the pulse amplitude threshold, the pulse having the greatest pulse width is identified at block **820**. This maximum pulse width is determined as the signal width parameter at block **606** of FIG. **14**.

FIG. **18** is a flow chart **900** of a method for comparing the gross morphology parameters to noise detection criteria and detecting the segment as a noisy segment. The process of flow chart **900** may be performed at blocks **608** and **610** of FIG. **14**. At block **902**, control circuit **80** fetches the gross morphology parameters determined at blocks **602**, **604** and **606** for comparison to noise detection criteria. The NRA is compared to a potential shockable beat amplitude threshold at block **904**. When the NRA is determined as described above in conjunction with FIG. **16**, the potential shockable beat amplitude threshold may be set between 100 and 150, and to 140 in some examples. If the NRA is greater than the threshold, the signal segment may likely include a true

R-wave of a VT or VF episode and is therefore a potential shockable beat (if it is occurring at a VT or VF interval).

At block **906**, the maximum pulse width is compared to a potential shockable beat width threshold. If the NRA and the maximum pulse width for the signal segment are both greater than the respective amplitude and width thresholds at blocks **904** and **906**, the segment is identified as a potential shockable beat at block **908**. In one example, the potential shockable beat width threshold is set to 20 sample points when the sampling rate is 256 Hz. The signal pulse count determined as the baseline noise parameter (as described in conjunction with FIG. **15**) is compared to a first noisy segment threshold at block **910**. If the signal pulse count is greater than the noisy segment threshold, e.g., greater than 12, the segment is detected as a noisy segment at block **916**. The noisy segment count is increased by one at block **614** of FIG. **14** in response to detecting the noisy segment.

If the pulse count is less than the first noisy segment threshold, "no" branch of block **910**, the segment is not detected as a noisy segment, and the process returns to block **902** to fetch the gross morphology parameters for the next signal segment, as long as the R-sense confirmation threshold is still being reached at block **114** and VT or VF has not been detected.

If the segment is not identified as a potential shockable beat, "no" branch of block **904** or "no" branch of block **906**, the count of identified signal pulses is compared to a second noisy segment threshold at block **914**. The second noisy segment threshold may be lower than the first noisy segment threshold. If the segment is not identified as a potential shockable beat based on the amplitude parameter and the signal width parameter, less stringent criteria, e.g., a lower noisy segment threshold, may be applied for classifying the segment as a noisy segment. In one example, the second noisy segment threshold is six. If the pulse count exceeds the second noisy segment threshold, the segment is detected as a noisy segment at block **916** and will be counted by the control circuit **80** at block **614** of FIG. **14**. Otherwise, the segment is not detected as a noisy segment ("no" branch of block **914**), and the gross morphology parameters for the next segment are fetched at block **902**.

The gross morphology rejection rule is satisfied when the value of the noisy segment count reaches or exceeds a rejection threshold, e.g., two noisy segments counted out of the eight most recent analyzed segments as described above in conjunction with FIG. **14**. The segment is classified as noisy based on a count of signal pulses, positive- or negative-going in the originally stored segment, that have a differential signal absolute amplitude greater than a noise pulse amplitude threshold. In the example of FIG. **18**, the number of signal pulses required to detect a noisy segment is smaller when the segment is identified as a potential shockable beat based on a relatively large amplitude parameter and/or a relatively large signal width parameter than the number of signal pulses required to detect a noisy segment when the segment is not identified as a potential shockable beat. In the example of FIG. **18**, both the amplitude parameter and the signal width parameter are required to exceed a respective amplitude threshold and width threshold in order to identify the segment as a potential shockable beat. In other examples, only one of the amplitude parameter or the signal width parameter may be required to exceed its respective threshold in order to identify the segment as a potential shockable beat.

FIG. **19** is a timing diagram **950** depicting time segments over which the morphology parameter correlated to baseline noise, amplitude parameter and signal width parameter may be determined. An R-wave sensed event signal **952** occurring at time **962** may cause the R-wave confirmation threshold to be reached. The next R-wave sensed event signal **953** at time **963** triggers storage of a time segment **970** of the second cardiac electrical signal segment. A portion **972** of the time segment **970** extends earlier than the R-wave sensed event signal **953** and a portion **974** extends after the R-wave sensed event signal **953**. The gross morphology parameters may be determined for the time segment **970** and analyzed for determining if noise detection criteria are satisfied for detecting segment **970** as a noisy segment according to the methods of FIGS. **15** through **18**.

The next R-wave sensed event signal **954** occurs within a predetermined time limit **980** from time **963**. As such, analysis of a time segment corresponding to R-wave sensed event signal **954** is skipped in some examples. A second cardiac electrical signal segment may be stored for R-wave sensed event signal **954** and used in other signal analysis for use in confirming a sensed R-wave and/or determining the status of other rejection rules, but is not used in the gross morphology rejection rule analysis in some examples. Time limit **980** may be 300 ms in one example but may be longer or shorter than this value. The time limit **980** may be set to enable processing time of the analysis of a time segment **970** to be performed prior to starting analysis of the next time segment. The next R-wave sensed event signal **955** occurs at time **965**, after time limit **980** expires. A time segment **975** buffered in memory **82** in response to R-wave sensed event signal **955** is analyzed for determining if it is a noisy segment.

R-wave sensed event **956** at time **966** occurs after time limit **980** expires, so time segment **976** of the second cardiac electrical signal is analyzed according to the methods of FIGS. **15-18**. R-wave sensed event signal **957** occurs within the time limit **980** after R-wave sensed event signal **956** so analysis of a corresponding time segment is skipped according to the example of FIG. **19**. The next time segment **978** corresponding to R-wave sensed event **958** at time **968** is the earliest occurring R-wave sensed event after time limit **980** expires and is therefore analyzed for determining if the segment **978** is a noisy segment. As such, time segments of the second cardiac electrical signal may sometimes correspond to consecutive R-wave sensed event signals and sometimes correspond to non-consecutive R-wave sensed event signals when one or more time segments corresponding to R-wave sensed events that occur within the predetermined time limit **980** are skipped.

FIG. **20** is a flow chart **920** of a method for comparing the gross morphology parameters to noise detection criteria and detecting the segment as a noisy segment according to another example. In some examples, each second cardiac electrical signal time segment corresponding to each R-wave sensed event signal received after the R-sense confirmation threshold is reached is analyzed without requiring that the R-wave sensed event signal occurs after a predetermined time limit as shown in FIG. **19**. A post-sense blanking interval, e.g., blanking interval **214** of FIG. **8**, may be applied after each R-wave sensed event signal, precluding an R-wave sensed event signal earlier than the post-sense blanking interval expiration. The post-sense blanking interval may be 150 ms for example. The second cardiac electrical signal segment buffered for each consecutive R-wave sensed event signal that occurs outside the post-sense blanking interval may be analyzed. In examples including a predetermined time limit **980** as shown in FIG. **19**, the time limit **980** may be set to zero such that every R-wave sensed event signal after the post-sense blanking interval expires results in gross morphology analysis of the corresponding second cardiac electrical signal segment (after the R-sense confirmation threshold is reached).

Blocks **902** through **908** correspond to identically-numbered blocks of FIG. **18**. The segment parameters are fetched at block **902**, and the NRA and max pulse width are compared to respective shockable beat amplitude and width thresholds at blocks **904** and **906**. If both the NRA and max pulse width are greater than their respective amplitude and width thresholds ("yes" branches of both blocks **904** and **906**), the segment is classified as a potential shockable beat at block **908**. In this example, no comparison is made to a noisy segment threshold when the segment is classified as a potential shockable beat. The segment does not cause the gross morphology rejection rule to be satisfied so that if the NID is reached (block **132** of FIG. **14**), detection and therapy are not withheld. The process returns to block **902** to fetch the segment parameters for the next stored, second cardiac electrical signal segment if the R-sense confirmation threshold is still met and a VT or VF episode is not detected.

If one or both of the NRA and max pulse width are less than their respective thresholds ("no" branch of block **904** and/or block **906**), the signal pulse count determined for the segment is compared to a noisy segment threshold at block **922**. The noise segment threshold may be a pulse count of 8, 10, 12 or other predetermined threshold, which will depend in part on the duration of the signal segment being analyzed. If the pulse count is not greater than the noisy segment threshold, "no" branch, the segment is not classified as noisy and does not cause the noisy segment count to be increased at block **614** of FIG. **14**. If the pulse count is greater than the noisy segment threshold, e.g., a pulse count of 12 or more, the segment is classified as a noisy segment at block **924**. The noisy segment count is increased at block **614** of FIG. **14** and the gross morphology rejection rule status is updated at block **430**. If the gross morphology rejection rule is satisfied, as determined at block **440**, e.g., based on the noisy segment count reaching a threshold value such as at least two segments classified as noisy out of the most recent eight analyzed segments, the gross morphology rejection rule is satisfied. If the NID is reached based on the first cardiac electrical signal, the VT/VF detection is withheld, and therapy is withheld at block **140** of FIG. **14**.

In the example of FIG. **18**, a segment classified as a potential shockable beat could still be classified as a noisy segment based on a higher, more stringent pulse count threshold (block **910** of FIG. **18**). In the example of FIG. **20**, all second cardiac electrical signal segments that are identified as potential shockable beats based on the signal amplitude parameter and/or signal width parameter are not classified as noisy segments and do not lead to withholding of VT/VF detection and therapy. At least one or both of the amplitude and width parameters are required to be less than their respective potential shockable beat amplitude and width thresholds in order to make the comparison of the signal pulse count to the noisy segment threshold at block **922** and detect a noisy segment at block **924**.

Thus, a method and apparatus for withholding a ventricular tachyarrhythmia detection in response to detecting noise contamination of cardiac electrical signal segments in an extra-cardiovascular ICD system have been presented in the foregoing description with reference to specific embodiments. In other examples, various methods described herein may include steps performed in a different order or combination than the illustrative examples shown and described herein. It is appreciated that various modifications to the referenced embodiments may be made without departing from the scope of the disclosure and the following claims.

The invention claimed is:

1. A medical device system comprising:

a sensing circuit comprising:

a first sensing channel configured to receive a first cardiac electrical signal via a first sensing electrode vector coupled to the medical device system, the first sensing channel configured to sense R-waves in response to crossings of a sensing amplitude threshold by the first cardiac electrical signal, and

a second sensing channel configured to receive a second cardiac electrical signal via a second sensing electrode vector coupled to the medical device system, the second sensing electrode vector being different than the first sensing electrode vector;

a memory; and

a control circuit coupled to the sensing circuit and the memory, the control circuit configured to:

store a time segment of the second cardiac electrical signal in the memory in response to each one of a plurality of R-waves sensed by the first sensing channel from the first cardiac electrical signal;

for each of the stored time segments,

determine a morphology parameter correlated to signal noise from the stored time segment; and

detect the stored time segment as being one of a noisy signal segment or a not noisy signal segment based on the morphology parameter determined for the respective stored time segment;

detect a threshold number of the stored time segments as noisy signal segments; and

withhold detection of a tachyarrhythmia episode in response to detecting at least the threshold number of the stored time segments as noisy signal segments.

2. The system of claim **1**, further comprising a notch filter, wherein the time segments of the second cardiac electrical signal are filtered by the notch filter prior to determining the morphology parameter.

3. The system of claim **1**, wherein the control circuit is further configured to:

determine a plurality of intervals between successive ones of the R-waves sensed by the first sensing channel; and

determine the morphology parameter from each of the stored time segments in response to at least a predetermined number of the plurality of intervals being less than a tachyarrhythmia detection interval.

4. The system of claim **1**, wherein the control circuit is configured to determine the morphology parameter for each of the stored time segments by:

identifying signal pulses occurring during the stored time segment of the second cardiac electrical signal; and

determining a count of the identified signal pulses.

5. The system of claim **4**, wherein the control circuit is configured to identify the signal pulses by:

identifying zero crossings of the second cardiac electrical signal during the stored time segment;

determining that the second cardiac electrical signal crosses a noise pulse amplitude threshold between two consecutive zero crossings; and

identifying a signal pulse in response to the second cardiac electrical signal crossing the noise pulse amplitude threshold between two consecutive zero crossings.

6. The system of claim **1**, wherein the control circuit is further configured to, for each of the stored time segments:

determine from the stored time segment at least one of a signal width parameter or a signal amplitude parameter;

detect a potential shockable beat based on at least one of the signal width parameter or the signal amplitude parameter;

compare the morphology parameter to a first noisy segment threshold in response to detecting the potential shockable beat;

determine that the morphology parameter determined for the stored time segment is greater than or equal to the first noisy segment threshold;

determine that the stored time segment is a noisy signal segment in response to the morphology parameter determined for the stored time segment being greater than or equal to the first noisy segment threshold.

7. The system of claim 6, wherein the control circuit is further configured to, for each of the stored time segments:

compare the morphology parameter to a second noisy segment threshold in response to not detecting a potential shockable beat based on the at least one of the signal width parameter or the signal amplitude parameter; and

determine that the stored time segment is a noisy signal segment in response to the morphology parameter determined for the stored time segment being greater than or equal to the second noisy segment threshold, the second noisy segment threshold less than the first noisy segment threshold.

8. The system of claim 1, wherein the control circuit is further configured to, for each of the stored time segments:

determine from the stored time segment at least one of a signal width parameter or a signal amplitude parameter;

determine that the stored time segment is not a potential shockable beat based on at least one of the signal width parameter or the signal amplitude parameter;

compare the morphology parameter to a noisy segment threshold in response to determining the stored time segment is not a potential shockable beat; and

determine that the stored time segment is a noisy signal segment in response to the morphology parameter determined for the stored time segment being greater than or equal to the noisy segment threshold.

9. The system of claim 8, wherein the control circuit is configured to determine the signal width parameter by:

identifying zero crossings of the second cardiac electrical signal during the stored time segment;

identifying a signal pulse in response to the second cardiac electrical signal crossing a pulse amplitude threshold between two consecutive zero crossings;

determining a pulse width of each identified signal pulse as a time interval between the two consecutive zero crossings of each respective identified signal pulse;

determining the signal width parameter as a maximum one of the determined pulse widths.

10. The system of claim 8, wherein the control circuit is further configured to:

determine the signal amplitude parameter by:

determining a summation of absolute amplitudes of all sample points of the stored time segment; and

normalizing the summation by a maximum sample point amplitude of the stored time segment;

compare the signal amplitude parameter to a shockable beat amplitude threshold;

determine that the signal amplitude parameter is greater than the shockable beat amplitude threshold;

compare the signal width parameter to a shockable beat width threshold;

determine that the signal width parameter is greater than the shockable beat width threshold; and

detect the potential shockable beat when the signal amplitude parameter is greater than the shockable beat amplitude threshold and the signal width parameter is greater than the shockable beat width threshold.

11. The system of claim 1, wherein the control circuit is further configured to:

increase a count of noisy signal segments in response to each one of the stored time segments being detected as a noisy signal segment;

determine a plurality of intervals between successive ones of the R-waves sensed by the first sensing channel;

determine that a predetermined number of the plurality of intervals are less than a tachyarrhythmia detection interval;

compare a value of the count of noisy signal segments to a rejection threshold in response to detecting the predetermined number of the plurality of intervals being less than the tachyarrhythmia detection interval;

determine that the value of the count of noisy signal segments is equal to or greater than the rejection threshold; and

withhold the detection of the tachyarrhythmia episode in response to the value of the count of noisy signal segments being equal to or greater than the rejection threshold.

12. The system of claim 1, wherein the control circuit is configured to:

determine the morphology parameter for a first stored time segment of the stored time segments of the second cardiac electrical signal corresponding to a first sensed R-wave of the plurality of R-waves;

determine that a next sensed R-wave of the plurality of R-waves occurs within a pre-determined time limit from the first sensed R-wave; and

skip determining the morphology parameter from a second stored time segment of the stored time segments of the second cardiac electrical signal corresponding to the next sensed R-wave in response to the next sensed R-wave occurring within the pre-determined time limit.

13. The system of claim 1, further comprising an extra-cardiovascular lead, wherein at least one electrode of the first sensing electrode vector is carried by the extra-cardiovascular lead.

14. The system of claim 1, wherein the first sensing electrode vector has a first inter-electrode spacing and the second electrode vector has a second inter-electrode spacing, the second inter-electrode spacing being greater than the first inter-electrode spacing.

15. The system of claim 1, further comprising a therapy delivery circuit configured to deliver an anti-tachyarrhythmia therapy to a patient's heart via electrodes coupled to the medical device system, wherein the control circuit is further configured to:

increase a count of noisy segments in response to each one of the stored time segments being detected as a noisy signal segment;

determine a plurality of intervals between successive ones of the of R-waves sensed by the first sensing channel;

detecting a predetermined number of the plurality of intervals being less than a tachyarrhythmia detection interval;

compare a value of the count of noisy signal segments to a rejection threshold in response to detecting the predetermined number of the plurality of intervals being less than the tachyarrhythmia detection interval;

determining that the value of the count of noisy signal segments is less than the rejection threshold;

detect the tachyarrhythmia episode in response to the value of the count being less than the rejection threshold; and

control the therapy delivery circuit to deliver the anti-tachyarrhythmia therapy in response to detecting the tachyarrhythmia episode.

16. A method comprising:

sensing R waves by a first sensing channel of a sensing circuit of a medical device system in response to crossings of a sensing amplitude threshold by a first cardiac electrical signal, the first cardiac electrical signal received by the first sensing channel via a first sensing electrode vector coupled to the medical device system;

storing a time segment of a second cardiac electrical signal in a memory in response to each one of a plurality of R-waves sensed by the first sensing channel from the first cardiac electrical signal, the second cardiac electrical signal received via a second sensing electrode vector coupled to the medical device system, the second sensing electrode vector being different than the first sensing electrode vector;

for each of the stored time segments,

determining a morphology parameter correlated to signal noise from the stored time segment; and

detecting the stored time segment as being one of a noisy signal segment or not a noisy signal segment based on the morphology parameter determined for the respective stored time segment;

detecting a threshold number of the stored time segments as noisy signal segments; and

withholding detection of a tachyarrhythmia episode in response to detecting at least the threshold number of the stored time segments as noisy signal segments.

17. The method of claim **16**, further comprising filtering the time segments of the second cardiac electrical signal by a notch filter prior to determining the morphology parameter.

18. The system of claim **16**, further comprising:

determining a plurality of intervals between successive ones of the R-waves sensed by the first sensing channel;

determining that at least a predetermined number of the plurality of intervals are less than a tachyarrhythmia detection interval; and

determining the morphology parameter from each of the stored time segments in response to the predetermined number of the plurality of intervals being less than the tachyarrhythmia detection interval.

19. The method of claim **16**, wherein determining the morphology parameter for each of the stored time segments comprises:

identifying signal pulses occurring during the stored time segment of the second cardiac electrical signal; and

determining a count of the identified signal pulses.

20. The method of claim **19**, wherein identifying the signal pulses comprises:

identifying zero crossings of the second cardiac electrical signal during the stored time segment; and

determining that the second cardiac electrical signal crosses a noise pulse amplitude threshold between two consecutive zero crossings; and

identifying a signal pulse in response to the second cardiac electrical signal crossing the noise pulse amplitude threshold between two consecutive zero crossings.

21. The method of claim **16**, further comprising, for each of the stored time segments:

determining at least one of a signal width parameter or a signal amplitude parameter for the stored time segment;

detecting a potential shockable beat based on at least one of the signal width parameter or the signal amplitude parameter;

comparing the morphology parameter to a first noisy segment threshold in response to detecting the potential shockable beat;

determining that the morphology parameter determined for the stored time segment is greater than or equal to the first noisy segment threshold; and

detecting the stored time segment as a noisy signal segment in response to the morphology parameter determined for the stored time segment being greater than or equal to the first noisy segment threshold.

22. The method of claim **21**, further comprising, for each of the stored time segments:

comparing the morphology parameter to a second noisy segment threshold in response to not detecting a potential shockable beat based on the at least one of the signal width parameter or the signal amplitude parameter;

determining that the morphology parameter is greater than or equal to the second noisy segment threshold, the second noisy segment threshold less than the first noisy segment threshold; and

detecting the stored time segment as a noisy signal segment in response to the morphology parameter being greater than or equal to the second noisy segment threshold, the second noisy segment threshold less than the first noisy segment threshold.

23. The method of claim **16**, further comprising, for each of the stored time segments:

determining from the stored time segment at least one of a signal width parameter and/or a signal amplitude parameter;

determining that the stored time segment is not a potential shockable beat based on at least one of the signal width parameter and/or the signal amplitude parameter;

comparing the morphology parameter to a noisy segment threshold in response to determining the stored time segment is not a potential shockable beat; and

determining that the stored time segment is a noisy signal segment in response to the morphology parameter determined for the respective stored time segment being greater than or equal to the noisy segment threshold.

24. The method of claim **23**, wherein determining the signal width parameter comprises:

identifying zero crossings of the second cardiac electrical signal during the stored time segment;

determining that the second cardiac electrical signal crosses a pulse amplitude threshold between two consecutive zero crossings;

identifying a signal pulse in response to the second cardiac electrical signal crossing the pulse amplitude threshold between two consecutive zero crossings;

determining a pulse width of each identified signal pulse as a time interval between the two consecutive zero crossings of each respective identified signal pulse;

determining the signal width parameter as a maximum one of the determined pulse widths.

25. The method of claim **23**, further comprising:

determining the signal amplitude parameter by:

determining a summation of absolute amplitudes of all sample points of the time segment; and

normalizing the summation by a maximum sample point amplitude of the time segment;

comparing the signal amplitude parameter to a shockable beat amplitude threshold;

determining that the signal amplitude parameter is greater than the shockable beat amplitude threshold;

comparing the signal width parameter to a shockable beat width threshold;

determining that the signal width parameter is greater than the shockable beat width threshold; and

detecting the potential shockable beat when the signal amplitude parameter is greater than the shockable beat amplitude threshold and the signal width parameter is greater than the shockable beat width threshold.

26. The method of claim **16**, further comprising:

increasing a count of noisy signal segments in response to each one of the stored time segments being detected as a noisy signal segment;

determining a plurality of intervals between successive ones of the R-waves sensed by the first sensing channel;

determining that a predetermined number of the plurality of intervals are less than a tachyarrhythmia detection interval;

comparing a value of the count of noisy signal segments to a rejection threshold in response to detecting the predetermined number of the plurality of intervals being less than the tachyarrhythmia detection interval;

determining that the value of the count of noisy signal segments is equal to or greater than the rejection threshold; and

withholding the detection of the tachyarrhythmia episode in response to the value of the count of noisy signal segments being equal to or greater than the rejection threshold.

27. The method of claim **16**, further comprising:

determining the morphology parameter for a first stored time segment of the stored time segments of the second cardiac electrical signal corresponding to a first sensed R-wave of the plurality of R-waves;

determining that a next sensed R-wave of the plurality of R-waves occurs within a pre-determined time limit from the first sensed R-wave;

and

skipping determining the morphology parameter from a second stored time segment of the stored time segments of the second cardiac electrical signal corresponding to the next sensed R-wave in response to the next sensed R-wave occurring within the pre-determined time limit.

28. The method of claim **16**, further comprising sensing the first cardiac electrical signal via at least one electrode carried by an extra-cardiovascular lead.

29. The method of claim **16**, further comprising:

sensing the first cardiac electrical signal by the first sensing electrode vector having a first inter-electrode spacing; and

sensing the second cardiac electrical signal by the second sensing electrode vector having a second inter-electrode spacing, the second inter-electrode spacing being greater than the first inter-electrode spacing.

30. The method of claim **16**, further comprising:

increasing a count of noisy segments in response to each one of the stored time segments being detected as a noisy signal segment;

determining a plurality of intervals between successive ones of the of R-waves sensed by the first sensing channel;

detecting a predetermined number of the plurality of intervals being less than a tachyarrhythmia detection interval;

comparing a value of the count of noisy signal segments to a rejection threshold in response to detecting the predetermined number of the plurality of intervals being less than the tachyarrhythmia detection interval;

determining that the value of the count of noisy signal segments is less than the rejection threshold;

detecting the tachyarrhythmia episode in response to the value of the count being less than the rejection threshold; and

controlling a therapy delivery circuit of the medical device system to deliver an anti-tachyarrhythmia therapy in response to detecting the tachyarrhythmia episode.

31. A non-transitory, computer-readable storage medium comprising a set of instructions which, when executed by a control circuit of an extra-cardiovascular implantable cardioverter defibrillator (ICD), cause the extra-cardiovascular ICD to:

sense a plurality of R-waves by a first sensing channel of a sensing circuit of the extra-cardiovascular ICD in response to crossings of a sensing amplitude threshold by a first cardiac electrical signal, the first cardiac electrical signal received by the first sensing channel via a first extra-cardiovascular sensing electrode vector coupled to the extra-cardiovascular ICD;

store a time segment of a second cardiac electrical signal in ICD memory in response to each one of the plurality of R-waves sensed by the first sensing channel, the second cardiac electrical signal received via a second extra-cardiovascular sensing electrode vector by a second sensing channel of the extra-cardiovascular ICD, the second extra-cardiovascular sensing electrode vector different than the first extra-cardiovascular sensing electrode vector;

for each one of the stored time segments:

determine a morphology parameter correlated to signal noise from the stored time segment; and

detect the stored time segment as being one of a noisy signal segment or not a noisy signal segment based on the morphology parameter determined for the respective stored time segment;

detect a threshold number of the stored time segments as noisy signal segments; and

withhold detection of a tachyarrhythmia episode in response to detecting at least the threshold number of the stored time segments as noisy signal segments.

* * * * *

专利名称(译)	基于心脏电信号总体形态学的噪声检测，用于排除室速性心律失常		
公开(公告)号	US10561332	公开(公告)日	2020-02-18
申请号	US15/653969	申请日	2017-07-19
[标]申请(专利权)人(译)	美敦力公司		
申请(专利权)人(译)	美敦力公司，INC.		
当前申请(专利权)人(译)	美敦力公司，INC.		
[标]发明人	ZHANG XUSHENG CAO JIAN GREENHUT SAUL E		
发明人	ZHANG, XUSHENG CAO, JIAN GREENHUT, SAUL E.		
IPC分类号	A61B5/0464 A61B5/0452 A61B5/00 A61N1/39 A61B5/04 A61B5/021 A61B5/0245 A61N1/37 H03H21/00		
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优先权	62/367166 2016-07-27 US		
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外部链接	Espacenet		

摘要(译)

一种医疗设备系统，例如心血管植入式心脏复律除颤器ICD，通过第一感应通道感应来自第一心脏电信号的R波，并响应于每个感应到的R波存储第二心脏电信号的时间段。 医疗设备系统从第二心脏电信号的时间段中确定与信号噪声相关的形态学参数，基于信号形态学参数检测噪声信号段； 并根据检测到阈值数量的嘈杂信号段而停止检测快速性心律失常发作。