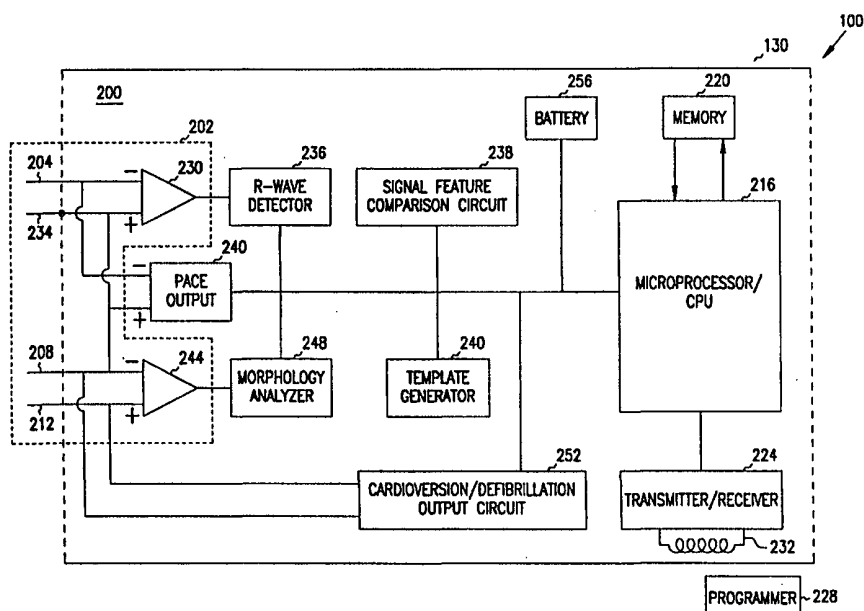




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61N 1/368	A1	(11) International Publication Number: WO 00/47275 (43) International Publication Date: 17 August 2000 (17.08.00)
(21) International Application Number: PCT/US00/03556 (22) International Filing Date: 11 February 2000 (11.02.00) (30) Priority Data: 09/248,800 12 February 1999 (12.02.99) US (71) Applicant: CARDIAC PACEMAKERS, INC. [US/US]; 4100 Hamline Avenue North, St. Paul, MN 55112 (US). (72) Inventors: HSU, William; 8631 Yalta Street N.E., Circle Pines, MN 55014 (US). SMITH, Joseph, Martin; 6343 Waterman Avenue, St. Louis, MO 63130 (US). (74) Agent: VIKSNINS, Ann, S.; Schwegman, Lundberg, Woessner & Kluth, P.O. Box 2938, Minneapolis, MN 55402 (US).		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>

(54) Title: SYSTEM AND METHOD FOR ARRHYTHMIA DISCRIMINATION



(57) Abstract

The present invention provides a system and a method for discriminating supraventricular tachyarrhythmias from ventricular arrhythmias during a tachycardia episode. First cardiac signals and second cardiac signals are sampled for cardiac complexes. A first feature on the first cardiac signal and a second feature on the second cardiac signal are utilized to determine an average time difference for a plurality of normal sinus rhythm complexes. A time difference between the first feature and the second feature is then determined for each cardiac complex of a tachycardiac rhythm. The cardiac complex is characterized as a ventricular tachycardia complex if the time difference exceeds the average time difference by a predetermined amount. Otherwise, it is classified as VT if its morphology after alignment is different from that during normal sinus rhythm.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

SYSTEM AND METHOD FOR ARRHYTHMIA DISCRIMINATION

Field of the Invention

The subject matter relates generally to implantable medical devices and more particularly to arrhythmia discrimination with an implantable medical device.

5

Background

Effective, efficient ventricular pumping action depends on proper cardiac function. Proper cardiac function, in turn, relies on the synchronized contractions of the heart at regular intervals. When normal cardiac rhythm is initiated at the sinoatrial node, the heart is said to be in sinus rhythm. However, 10 when the heart experiences irregularities in its coordinated contraction, due to electrophysiologic disturbances caused by a disease process or from an electrical disturbance, the heart is denoted to be arrhythmic. The resulting cardiac arrhythmia impairs cardiac efficiency and can be a potential life threatening event.

15

Cardiac arrhythmias occurring in the atrial of the heart are called supraventricular tachyarrhythmias (SVTs). Cardiac arrhythmias occurring in the ventricular region of the heart are called ventricular tachyarrhythmias (VTs). SVTs and VTs are morphologically and physiologically distinct events. VTs take many forms, including ventricular fibrillation and ventricular tachycardia.

20

Ventricular fibrillation is a condition denoted by extremely rapid, nonsynchronous contractions of the ventricles. This condition is fatal unless the heart is returned to sinus rhythm within a few minutes. Ventricular tachycardia are conditions denoted by a rapid heart beat, 150 to 250 beats per minute, that has its origin in some abnormal location within the ventricular myocardium. The 25 abnormal location is typically results from damage to the ventricular myocardium from a myocardial infarction. Ventricular tachycardia can quickly degenerate into ventricular fibrillation.

25

SVTs also take many forms, including atrial fibrillation and atrial flutter. Both conditions are characterized by rapid uncoordinated contractions of 30 the atria. Besides being hemodynamically inefficient, the rapid contractions of the atria can also adversely effect the ventricular rate. This occurs when the

aberrant contractile impulse in the atria are transmitted to the ventricles. It is then possible for the aberrant atrial signals to induce VTs, such as a ventricular tachycardia.

Implantable cardioverter/defibrillators (ICDs) have been
5 established as an effective treatment for patients with serious ventricular tachyarrhythmias. ICDs are able to recognize and treat tachyarrhythmias with a variety of tiered therapies. These tiered therapies range from providing antitachycardia pacing or cardioversion energy for treating ventricular tachycardia to defibrillation energy for treating ventricular fibrillation. To
10 effectively deliver these treatments, the ICD must first identify the type of tachyrrhythmia that is occurring, after which appropriate therapy is provided to the heart. A problem arises, however, when the ICD delivers therapy to treat a ventricular tachycardia that is caused and sustained by an SVT.

Delivered therapy is typically ineffective in treating the
15 ventricular tachycardia in these instances, as the pacing and/or cardioverting electrical energy has little or no effect on the true source of the ventricular tachycardia. As a result, the ICD delivers inappropriate treatment to the patient, which besides being painful is also very disconcerting to the patient. Accurate discrimination of an SVT versus a malignant ventricular tachycardia is,
20 therefore, an important factor in ensuring the appropriate therapy is delivered to an arrhythmic heart.

For the reasons stated above, and for other reasons stated below which will become apparent to those skilled in the art upon reading and understanding the present specification, there is a need in the art for providing a
25 reliable system of discriminating SVT induced ventricular tachycardia from malignant ventricular tachycardia which can provide effective and reliable therapy to patients experiencing malignant ventricular tachycardia.

Summary of the Invention

As explained in detail below, the present invention is directed to a
30 system for distinguishing between the occurrence of a ventricular tachycardia (VT) and a supraventricular tachycardia (SVT) during a tachycardia episode. Upon detecting a tachycardia episode, the system determines features and/or metric values from the sensed cardiac complexes and compares them to the same

general features sensed during normal sinus rhythm. Using this comparison, the system is able to distinguish the underlying cause of a tachycardia episode as either being an SVT or as a VT. Once the determination has been made, the system then provides therapy to treat the underlying cause of the tachycardia episode. In turn, this provides more effective and efficient treatment to the patient.

The present system uses information sensed from normal sinus rhythm complexes to create a template against which cardiac complexes sensed during a tachycardia episode are compared in order to classify them as either VT or SVT complexes. In one embodiment, the system uses information contained in cardiac rate signals (near-field signals) and cardiac morphology signals (far-field signals) of a transvenous lead system in distinguishing VT from SVT during a tachycardia episode. To make this distinction, the system first uses cardiac complexes sensed during normal sinus rhythm to create a normal sinus rhythm template. In one embodiment, the normal sinus rhythm template is derived from the timing differences between at a first feature point on a first signal of a cardiac complex and a second feature point on a second signal of the cardiac complex. In one embodiment, the first signal is a near-field signal and the second signal is a far-field signal.

In one embodiment, the first feature point along the first cardiac signal and the second feature point along the second cardiac signal are determined from morphological features along the cardiac signals. In one embodiment, the morphological features along the cardiac signals can be any combination of maximum deflection points of the cardiac signals, the beginning or ending of cardiac signals, and/or fiducial points along the cardiac signals. Timing differences between the first and second feature points are then determined and median or average values of the timing differences are calculated.

In addition, other metric values can be derived from the feature points, such as median or average signal amplitude values, standard deviation values from the median or average signal amplitude values, slopes and/or slew rates from the cardiac complex signals can also be used in creating the normal sinus rhythm template. Feature values from the normal sinus rhythm cardiac

signals can also be recorded and stored for future comparison to cardiac signal sensed during a tachycardia episode. The stored feature values can then be used alone or in conjunction with the timing difference values and/or metric values in distinguishing VT from SVT.

5 In one embodiment, the system determines the timing differences and/or the other metric values from a first feature point and a second feature point taken from cardiac complexes sensed during a tachycardia episode. The system then compares the timing differences and/or cardiac metric values from the cardiac complexes and the values stored for the normal sinus rhythm
10 template. In one embodiment, if the timing differences exceed a template time difference of the normal sinus rhythm template by a predetermined amount, the cardiac complex is characterized as a VT complex. In an additional embodiment, changes in the metric values can also be used in determining whether a cardiac complex sensed during a tachycardia episode is a VT complex
15 or an SVT complex. When a predetermined number, or percentage, of the cardiac complexes sensed during a tachycardia episode are classified as either VT or SVT complexes, the system then responds to treat the heart.

 In an additional embodiment, if the timing differences are less than the template time difference of the normal sinus rhythm template by the
20 predetermined amount, the cardiac complex is characterized by comparing the morphology of the first signal and/or the second signal of the sensed cardiac complex to the first signal and/or the second signal of a representative normal sinus rhythm complex to classify the cardiac complex. Before a morphology comparison is made, however, a common feature in either the first signal or the
25 second signal of both the cardiac complex and the representative normal sinus rhythm complex are aligned. The morphology of the unaligned cardiac complexes is then compared to classify the cardiac complex as either a VT complex or an SVT complex.

 These and other features and advantages of the invention will become
30 apparent from the following description of the embodiments of the invention.

Brief Description of the Drawings

Figure 1 is a schematic view of one embodiment of an implantable medical device with an endocardial lead implanted in a heart from which segments have been removed to show details;

5 Figure 2 is a block diagram of an implantable medical device according to one embodiment of the present system;

Figure 3 is a flow diagram illustrating one embodiment of the present system;

10 Figure 4 is a flow diagram illustrating one embodiment of the present system;

Figure 5 is an example of a far-field signal and a near-field signal from a normal rhythm complex;

Figure 6 is an example of a far-field signal and a near-field signal from an arrhythmic complex;

15 Figure 7 is an example of a far-field signal and a near-field signal from an arrhythmic complex;

Figure 8 is a flow diagram illustrating one embodiment of the present system;

20 Figure 9 is a flow diagram illustrating one embodiment of the present system;

Figure 10 is one embodiment of a first signal and a second signal of a cardiac complex and a first signal and a second signal of a normal sinus rhythm complex, where the first signal of the cardiac complex and the first signal of the normal sinus rhythm complex are aligned;

25 Figure 11 is one embodiment of a first signal and a second signal of a cardiac complex and a first signal and a second signal of a normal sinus rhythm complex, where the second signal of the cardiac complex and the second signal of the normal sinus rhythm complex are aligned; and

30 Figure 12 is an example of a plurality of sensing channels useful in one embodiment of the present system.

Detailed Description

In the following detailed description, reference is made to the accompanying drawings which form a part hereof and in which is shown by way

of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice and use the invention, and it is to be understood that other embodiments may be utilized and that electrical, logical, and structural changes
5 may be made without departing from the spirit and scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense and the scope of the present invention is defined by the appended claims and their equivalents.

The embodiments of the present system illustrated herein are
10 described as being included in an implantable cardiac defibrillator, which may include numerous pacing modes known in the art, and an external medical device programmer. In one embodiment, the implantable cardiac defibrillator is a single chamber defibrillator. In an alternative embodiment, the implantable cardiac defibrillator is a dual chamber defibrillator. Examples of both single and
15 dual chamber implantable cardiac defibrillators are known in the art. However, the present medical system can also be implemented in an external cardioverter/monitor system as are known in the art. Also, the present medical system can also be implemented in an implantable atrial cardioverter-defibrillator, which may include numerous pacing modes known in the art.
20 Furthermore, although the present system is described in conjunction with an implantable cardiac defibrillator having a microprocessor based architecture, it will be understood that the implantable cardiac defibrillator (or other implanted device) may be implemented in any logic based, custom integrated circuit architecture, if desired.

25 Referring now to Figure 1 of the drawings, there is shown one embodiment of a medical device system which includes an implantable cardiac defibrillator 100 electrically and physically coupled to at least one intracardiac catheter 102. In one embodiment, the intracardiac catheter 102 includes one or more pacing electrodes and one or more intracardiac defibrillation electrodes.

30 The intracardiac catheter 102 is implanted in a human body 104 with portions of the intracardiac catheter 102 inserted into a heart 106 to detect and analyze electric cardiac signals produced by the heart 106 and to provide

electrical energy to the heart 106 under certain predetermined conditions to treat cardia arrhythmias, including ventricular fibrillation, of the heart 106.

In one embodiment, the intracardiac catheter 102 is an endocardial lead adapted to be releasably attached to the cardiac defibrillator 100. The
5 intracardiac catheter 102 has an elongate body with a proximal end 108 and a distal end 110, and has at least one pacing electrode. In one embodiment, the intracardiac catheter 102 has a pacing electrode 112 located at, or adjacent, the distal end 110 of the intracardiac catheter 102. Additional pacing electrodes can also be included on the intracardiac catheter 102 to allow for bipolar sensing and
10 pacing with the pacing electrode 112. In addition, other pacing and sensing electrode configurations are also possible.

In one embodiment, the intracardiac catheter 102 includes one or more defibrillation electrodes. In one embodiment, the intracardiac catheter 102 has a first defibrillation electrode 114 and a second defibrillation electrode 116,
15 where the first defibrillation electrode 114 and the second defibrillation electrode 116 are defibrillation coil electrodes. The first defibrillation electrode 114 is spaced apart and proximal from the pacing electrode 112, and the second defibrillation electrode 116 is spaced apart and proximal from the first defibrillation electrode 114 such that when the intracardiac catheter 102 is
20 positioned within the heart 106 the pacing electrode 112 and the first defibrillation electrode 114 reside within a right ventricle 118 of the heart 106, with the pacing electrode 112 in an apex location within the right ventricle 118, and the second defibrillation electrode 116 is positioned within the right atrium chamber 120 of the heart 106 or a major vein leading to the right atrium chamber
25 120 of the heart 106.

Referring now to Figure 2, there is shown an embodiment of a block diagram of a cardiac defibrillator 100. The cardiac defibrillator 100 includes control system circuitry 200 for receiving cardiac signals from a heart 106 and delivering electrical energy to the heart 106. The control system
30 circuitry 200 includes and is attached to a sensing system 202. The sensing system 202 includes terminals labeled with reference numbers 204, 208, and 212 for connection to electrodes attached to the surface of the intracardiac catheter 102. The pacing electrode 112 is electrically connected to terminal 204 and to

the control system circuitry 200 through an electrically insulated conductor provided within the elongate body of the intracardiac catheter 102. The first defibrillation electrode 114 and the second defibrillation electrode 116 are connected to terminals 208 and 212, respectively, and to the control system
5 circuitry 200 through electrically insulated conductors provided within the elongate body of the intracardiac catheter 102.

In one embodiment, the control system circuitry 200 of the cardiac defibrillator 100 is encased and hermetically sealed in a housing 130 suitable for implanting in a human body as are known in the art. A connector block 132
10 (Figure 1) is additionally attached to the housing 130 of the cardiac defibrillator 100 to allow for the physical and the electrical attachment of the intracardiac catheter 102 and the electrodes to the cardiac defibrillator 100 and the encased control system circuitry 200.

In one embodiment, the control system circuitry 200 of the cardiac
15 defibrillator 100 is a programmable microprocessor-based system, with a microprocessor 216 and a memory circuit 220, which contains parameters for various pacing, defibrillation, and sensing modes and stores data indicative of cardiac signals received by the control system circuitry 200. A transmitter circuit 224 is additionally coupled to the control system circuitry 200 and the
20 memory circuit 220 to allow the cardiac defibrillator 100 to communicate with an programmer unit 228. In one embodiment, the transmitter circuit 224 and the programmer unit 228 use a wire loop antenna 232 and a radio frequency telemetric link, as is known in the art, to receive and transmit signals and data to and from the programmer unit 228 and the control system circuitry 200. In this
25 manner, programming commands or instructions are transferred to the microprocessor 216 of the cardiac defibrillator 100 after implant, and stored cardiac data pertaining to sensed arrhythmic episodes within the heart 106 and subsequent therapy, or therapies, applied to correct the sensed arrhythmic event are transferred to the programmer unit 228 from the cardiac defibrillator 100.

30 The cardiac signals sensed through the pacing electrode 112 are near-field signals or rate signals as are known in the art. The embodiment of the cardiac defibrillator block diagram (Figure 2) shows the pacing electrode 112 coupled to a sense amplifier 230 within the sensing system 202. In one

embodiment, the housing 130 of the cardiac defibrillator 100 is coupled to the sense amplified 230 at 234 to allow for unipolar cardiac rate sensing between the pacing electrode 112 and the housing 130 of the cardiac defibrillator 100. In an alternative embodiment, the cardiac rate signal is sensed using pacing electrode
5 112 and the first defibrillation electrode 114.

The output of the sense amplifier 230 is shown connected to an R-wave detector 236. In one embodiment, the input to the R-wave detector 236 are the rate signals. The R-wave detector 236 serves to sense and amplify the electrical activity of the heart (R-waves), and apply signals indicative thereof to a
10 signal feature comparison circuit 238. The signal feature comparison circuit 238 is coupled to the microprocessor 216. Among other things, microprocessor 216 responds to signals from the R-wave detector 236 by providing pacing signals to a pace output circuit 240, as needed according to the programmed pacing mode. Pace output circuit 240 provides output pacing signals to terminals 204 and 234,
15 which connect to the pacing electrode 112 and the housing 130 of the cardiac defibrillator 100, for cardiac pacing.

Cardiac signals sensed through the first defibrillation electrode 114 and the second defibrillation electrode 116 are far-field signals or morphology signals as are known in the art. The first defibrillation electrode 114 and the
20 second defibrillation electrode 116 are coupled to a sense amplifier 244, which is used to sense far-field signals from the heart. In an alternative embodiment, far-field signals are sensed between the first defibrillation electrode 114, the second defibrillation electrode 116 and the housing 130. The output of the sense amplifier 244 is coupled to a morphology analyzer circuit 248. In one
25 embodiment, the morphology analyzer circuit locates features along cardiac signals sensed by the control system circuitry 200.

In one embodiment, the sense amplifier 244 amplifies cardiac electrical activation sequences (such as the QRS-waves of the cardiac cycle) sensed in the ventricular region of the heart 106. After the signals have passed through the
30 morphology analyzer circuit 248, the signals are received by a signal feature comparison circuit 238 which is coupled to the morphology analyzer circuit 248. In one embodiment, the signal feature comparison circuit 238 determines a time difference between the features tachycardia complexes sensed by the sensing

system 202 and compares the time differences to a template time difference determined from the time difference between features for a plurality of cardiac complexes sensed during normal sinus rhythm.

In one embodiment, the morphology analyzer circuit 248 includes an
5 analog filter for filtering cardiac signal noise sensed by the electrodes. The cardiac signals are then bandlimited before arriving at an analog-to-digital filter. The cardiac signals are then A/D converted into a digital signal and subsequently received by the signal feature comparison circuit 238 and then by the microprocessor 216. In an alternative embodiment, the cardiac signals are
10 filtered through an analog peak detector to extract the maximum and minimum cardiac signal values for each sensed cardiac interval before being received by the signal feature comparison circuit 238 and then by the microprocessor 216.

The signal feature comparison circuit 238 uses information contained in the far-field and the near-field sensing channels of a transvenous
15 lead system in discriminating ventricular tachycardias (VT) from non-malignant supraventricular tachycardias (SVT) during a tachycardia episode. In one embodiment, the signal feature comparison circuit 238 discriminates VT from SVT by comparing cardiac complexes sensed during a tachycardia episode to a normal sinus rhythm template. In another embodiment, the normal sinus rhythm
20 template is generated on a patient-by-patient basis with a template generator 240 from sensed normal sinus rhythm complexes. The normal sinus rhythm template contains information related to specific characteristics of a patient's cardiac complexes sensed with their implantable medical device during normal sinus rhythm. By sensing cardiac complexes using at least two different types of
25 sensing configurations (*e.g.* sensing near-field and far field signals for each sensed cardiac complex) the differences observed between the sensed cardiac complexes and the normal sinus template acquired during normal sinus rhythm can be used to determine the origin of the tachycardia episode.

Upon determining the origin of the sensed tachycardia episode, the
30 microprocessor 216 responds by providing signals to cardioversion/defibrillation output circuitry 252 to deliver either cardioversion or defibrillation electrical energy to the heart 106 depending upon whether the tachycardia episode was determined to be a VT or an SVT. Power to the cardiac defibrillator 100 is

supplied by an electrochemical battery 256 that is housed within the cardiac defibrillator 100.

In addition to the intracardiac catheter 102, it is possible to add additional electrodes, catheters and the accompanying required circuitry to the medical device system. For example, the cardiac defibrillator 100 can be equipped with electrodes on the surface of the housing 130 to sense surface like cardiac signals. In addition, the medical device system can further include an additional intracardiac catheter implanted in the supraventricular region of the heart. The additional intracardiac catheter includes at least one pacing electrode from which rate signals, or near field signals, from the atria are sensed and pacing pulses are delivered to pace the atrial chamber of the patient's heart. In an additional embodiment, the additional intracardiac catheter is implanted through the coronary sinus vein and down the great cardiac vein to position an electrode, such as a pacing electrode, adjacent to the left ventricular chamber of the heart. In an alternative embodiment, the intracardiac catheter 102 is implanted the supraventricular region of the heart for sensing cardiac signals from the patient's atrial regions. In one embodiment, a pacing electrode at or adjacent the distal end of the intracardiac catheter is implanted in the coronary sinus vein to allow for rate signals to be sensed from the left atrium. In addition, far-field signals, or morphology signals, are sensed from the supraventricular region of the heart through the first defibrillation electrode and the second defibrillation electrode. In addition to implanting the intracardiac catheter 102 in the supraventricular region of the heart, an additional atrial catheter can be implanted into the supraventricular region of the heart to allow for additional rate signals, or near-field signals, to be sensed along with the rate signals and morphology signals sensed with the intracardiac catheter 102. Other intracardiac catheter arrangements and configurations known in the art are also possible and considered to be within the scope of the present system.

With respect to the present system, prompt diagnosis and treatment of a tachycardia episode is important to a patient's health, as an untreated tachycardia episode has the potential, if the episode is a ventricular tachycardia, to degenerate into a ventricular fibrillation. Therefore, accurately discriminating VT from SVT during a tachycardia episode in a quick and effective manner is

critical in delivering the most appropriate and effective treatment to the patient. As was previously mentioned, determining the origin of a detected tachycardia episode is an important aspect of diagnosing and treating the patient's condition. Implantable cardioverter defibrillators frequently deliver inappropriate

5 ventricular therapy to patients afflicted with an SVT. These inappropriate therapies are usually delivered due to the device's inability to reliably discriminate SVT from malignant ventricular tachycardias (VT). Therefore, when the tachycardia episode is a VT, anti-tachycardia therapy delivered to the ventricles of the heart can be effectively directed at the source or origin of the

10 problem. In contrast, if the detected tachycardia episode is an SVT, delivering anti-tachycardia therapy to the ventricles of the heart will be ineffective in treating the underlying cause of the tachycardia episode.

One aspect of the present system is to address the problem of differentiating, or discriminating, whether a detected tachycardia episode is the

15 result of an SVT or an a VT episode in the heart. In one embodiment, the present system utilizes the medical device system to differentiate, or distinguish, between SVT and VT episodes when a tachycardia episode is detected.

Referring to Figure 3, there is shown one embodiment of the present system for distinguishing between SVT and VT episodes. In one

20 embodiment, the present system differentiates between VT and SVT during a tachycardia episode by performing a cross channel analysis of the sensed cardiac complexes. The cross channel analysis exploits the difference in activation sequence between normally conducted activation sequences and those resulting from a ventricular tachycardia. In one embodiment, the cross channel analysis

25 determines timing differences between predetermined features on cardiac complexes sensed by at least a near-field channel and a far-field channel. The timing differences are then used in determining the origin of the tachycardia episode.

At 300, a plurality of cardiac complexes are sensed during normal

30 sinus rhythm. In one embodiment, a near-field channel and a far-field channel are used to sense the cardiac complexes during the normal sinus rhythm. In one embodiment, the near-field signal (rate signal) is sensed from the pacing electrode 112 to the first defibrillation electrode 114, both of which are located

in the right ventricle. The far-field signal (the morphology channel) is sensed between the first defibrillation electrode 114, the second defibrillation electrode 116 and the housing 130 of the implantable pulse generator. As a result, each cardiac complex sensed during the normal sinus rhythm has associated with
5 signals sensed from two different cardiac channels (*i.e.*, a near-field and a far-field signal). This necessarily means that the differentiation, or determination, of the tachycardia episode as being either a VT or SVT is based on characteristics of cardiac complexes sensed in, or across, at least two different areas of the heart. In addition to using near-field and far-field signals sensed from the right
10 ventricles and/or atria of the heart, it is also possible to use any combination of these types of signals with cardiac signals sensed from the left side of the heart.

As the cardiac complexes are sensed, predetermined features are located along each of the near-field and a far-field signals for the cardiac complexes. In one embodiment, the template time difference is calculated from
15 timing differences for a plurality of cardiac electrical activation sequences (e.g., QRS-cardiac complexes) sensed during normal sinus rhythm. In one embodiment, the template time difference is the median time difference between the relative timing of features on the cardiac signal sensed in each of a plurality of sensing channels during a patient's normal sinus rhythm. In an alternative
20 embodiment, the template time difference is the average time difference between the relative timing of features on the cardiac signal sensed in each of a plurality of sensing channels during a patient's normal sinus rhythm. Therefore, in one embodiment, a timing difference is determined between the predetermined feature, or features, on the near-field signal and the predetermined feature, or
25 features, on the far-field signal for each sensed cardiac complex. In one embodiment, from the plurality of cardiac complexes, a template time difference is determined from the patient's cardiac complexes sensed during normal sinus rhythm. In addition to sensing cardiac signals during a patient's normal sinus rhythm, a pre-processing step can be added to the system to exclude premature
30 ventricular contraction signals from being included in the determination of the template time difference value. Once the template time difference is calculated it is stored in the medical device system.

At 310, the template time difference is compared to a time difference calculated from the corresponding features on a cardiac complex sensed during a tachycardia episode. In one embodiment, the time difference is calculated using the same method used to acquire and compute the time differences during normal sinus rhythm. Based on the comparison, a decision is made at 320 whether the time difference value exceeds the template time difference value by a predetermined margin. In one embodiment, the system proceeds to 330 when the time difference exceeds the template time difference by the predetermined margin. The cardiac complex is then classified as a VT complex. However, if the time difference does not exceed the template time difference by the predetermined margin, the system proceeds to 340. At 340, the system utilizes additional procedures to classify the cardiac complex as either VT complex or non-VT complex. If the additional classification procedures determine the cardiac complex to be a non-VT complex and/or an SVT complex, the system passes the information to 350 and then returns to 310 to continue to sense and analyze cardiac complexes. Alternatively, if the additional classification procedure classifies the cardiac complex as a VT complex the information is passed to 350 where the percentage of cardiac complexes classified as ventricular tachycardias is determined.

As each sensed cardiac complex is classified, percentage values for cardiac complexes classified as VT complexes and SVT complexes are calculated at 350. At 360, a decision is made whether the percentage of cardiac complexes classified as either VT or SVT has reached a predetermined percentage threshold. If the percentage of cardiac complexes has not reached the threshold value, the system returns to 310 to analyze the next cardiac complex. If the percentage of cardiac complexes has reached the threshold value, the system proceeds to 370, where the tachycardia episode is declared as either VT or SVT and the appropriate therapy is delivered to the patient to terminate the convert the heart to normal sinus rhythm.

As mentioned, values derived from characteristics of cardiac complexes signals sensed during a tachycardia episode are compared to values derived from cardiac complex characteristics sensed during normal sinus rhythm. In one embodiment, the values compared are timing differences between

morphological characteristics, or characteristic values, on at least two different cardiac sensing channels (*e.g.*, far-field signals and near-field signals) for cardiac complexes sensed during normal sinus rhythm and for cardiac complexes sensed during a tachycardia episode where the origin of the tachycardia is unknown.

- 5 In one embodiment, the values for timing differences between the morphological characteristics from the different cardiac sensing channels are calculated, stored and subsequently used by comparing them to the timing differences calculated from the corresponding morphological characteristics, or characteristic values, of cardiac complexes sensed during a tachycardia episode.
- 10 Based on the comparison between the normal sinus rhythm characteristic value (*e.g.*, the timing differences between the morphological characteristics) and the characteristic value for the cardiac complex sensed during the tachycardia episode, the cardiac complex is classified as either being a VT complex or an SVT complex. Finally, it is possible to use a combination of timing differences
- 15 between the morphological features on cardiac complex signals and morphological characteristics of cardiac complexes sensed using at least two different types of cardiac sensing channels, such as far-field and near-field sensing.

- Referring now to Figure 4, there is shown an alternative
- 20 embodiment of the present system. At step 400, a medical device system, such as the cardiac defibrillator 100, senses cardiac signals during normal sinus rhythm using two or more simultaneous sensing channels. In one embodiment, the two or more simultaneous sensing channels include both a far-field channel and a near field channel. In providing two or more simultaneous sensing
- 25 channels, cardiac complexes of the heart are being sensed from at least two different cardiac locations. So, sensed cardiac complexes include at least a first signal representative of electrical activity of the heart sensed at a first cardiac region, and a second signal representative of electrical activity of the heart is sensed at a second cardiac region. In the present embodiment, the sensed cardiac
- 30 signals include cardiac electrical activation sequences (*e.g.*, QRS-cardiac complexes) representative of a cardiac cycle.

In one embodiment, the first cardiac region and the second cardiac region are in or adjacent ventricular regions of the heart. This allows for

ventricular activity to be sensed in a plurality of locations by the medical device system. In an alternative embodiment, the first cardiac region and the second cardiac region are both in a supraventricular region of the heart. In this embodiment, the medical device system senses cardiac complexes indicative of atrial activity. In an alternative embodiment, both an atrial region of the heart and a ventricular region of the heart are used as the first cardiac region and the second cardiac region. For example, one of the first cardiac region or the second cardiac region is a ventricular region of the heart, such as the right ventricle, while the remaining cardiac region is an area of the patient's heart sensed across, or in, both the ventricular and atrial regions of the heart.

The medical device system can also be configured to sense any combination of cardiac near-field signals (rate signal) and/or far-field signals (morphology signal). This will depend upon the electrode system employed to sense each cardiac region in the heart. In one embodiment, two or more cardiac near-field signals are sensed from two or more cardiac regions in the heart. In an alternative embodiment, two or more cardiac far-field signals are sensed from two or more cardiac regions in the heart. In an additional embodiment, at least one of a cardiac far-field signal and at least one of a cardiac near-field signal are sensed from two or more cardiac regions in the heart. Additionally, cardiac signals can be sensed by electrodes positioned on the housing of an implantable system.

At 404, a normal sinus rhythm template, or model, is computed from cardiac complexes sensed during normal sinus rhythm at 400. In one embodiment, the purpose of the normal sinus rhythm template is to record the feature values corresponding to a normal sinus rhythm. After the normal sinus rhythm template is calculated, it is stored and subsequently used during a tachycardia episode to determine the origin of the tachycardia episode. In one embodiment, the template is determined from timing differences between features on the cardiac complexes sensed during normal sinus rhythm. In an alternative embodiment, the template is determined from characteristics of the sensed cardiac signals sensed during normal sinus rhythm.

In addition, the template can be updated, either manually or automatically, to reflect changes in a patient's implantable medical device. For

example, timing differences for the template could change due to the type of drug or dosage of drugs being delivered to the patient and the cardiac disease state of the patient. Therefore, the system is able to recompute the normal sinus rhythm timing template at regular intervals based either on the physician's
5 judgement or on the implantable medical devices assessment of the template. Additionally, a safe-check algorithm is used in conjunction with any automatic updating procedure to ensure that only normal sinus rhythm complexes are used in updating the template.

In one embodiment, the template is derived from timing differences
10 between features on the cardiac signals. In deriving the timing difference, the medical device system first determines the occurrence of a first feature on the first cardiac signal and a second feature on the second cardiac signal. In one embodiment, the morphology analyzer circuit 248 is used to locate features along the cardiac signals received by the cardiac defibrillator 100. In one
15 embodiment, the first feature and the second feature are based on a selection criteria. The selection criteria is used to identify a first portion and a second portion of the cardiac complex which is repeatably identifiable in subsequent cardiac complexes. In one embodiment, the selection criterion includes a point at the beginning of the sensed cardiac signal. In one embodiment, the beginning
20 of the QRS-cardiac complex is determined by sensing a predetermined deviation of the first signal from a baseline signal of the first signal and of the second signal from a baseline signal of the second signal.

Alternatively, the selection criterion is a maximum deflection point of the cardiac signal, such as a maximum absolute value (*i.e.*, largest maximum or
25 minimum value) point along either the first cardiac signal or the second cardiac signal. In an additional embodiment, the selection criterion is a point at the end of the sensed cardiac signal. In one embodiment, the end of a QRS-cardiac complex is determined by sensing the point at which the first signal returns to a baseline signal of the first signal within a predetermined time window and the
30 point at which the second signal returns to a baseline signal of the second signal for the predetermined time window. The selection criterion can also be the fiducial point along the sensed cardiac signal, where the fiducial point is the point along the cardiac signal with the largest first derivative of the electrogram

signal (*i.e.*, the point of largest slope along the sensed QRS-cardiac complex signal) Alternatively, the selection criterion is any repeatably identifiable feature along sensed cardiac signals.

In an alternative embodiment, the template is determined from
5 characteristics of the sensed cardiac signals sensed during normal sinus rhythm. In one embodiment, the characteristic of the sensed cardiac signal is the slope of a predetermined portion of the cardiac signal. In an additional embodiment, the characteristic used to create the template is the amplitude of a maximum deflection point (point along the sensed signal having the maximum absolute
10 value) of the cardiac signal, such as a maximum or minimum point along either the first cardiac signal or the second cardiac signal. In an alternative embodiment, the characteristic is the slew rate of the cardiac signals sensed during normal sinus rhythm.

Figure 5 shows examples of the possible selection criteria useful
15 with the present system. Figure 5 shows examples of a first cardiac signal 500 and a second cardiac signal 502 of a cardiac electrical activation sequence (*e.g.*, a QRS-cardiac complex). In the present embodiment, the first cardiac signal 500 and the second cardiac signal 502 were recorded during normal sinus rhythm. The first cardiac signal 500 is an example of a far-field cardiac signal, and the
20 second cardiac signal 502 is an example of a near-field cardiac signal. As previously mentioned, a variety of selection criterion can be selected and use to identify features along the cardiac signals that are repeatably identifiable. For example, the selection criterion used is determining a point at the beginning of the QRS-cardiac complex. In one embodiment, this point is shown
25 approximately at 504 for the first cardiac signal 500 and at 506 for the second cardiac signal 502. In one embodiment, the beginning of the QRS-cardiac complex is denoted by the deflection in the first signal and the second signal which is caused by an intrinsic contraction of the heart.

In an alternative embodiment, the selection criterion is a maximum
30 absolute value (*i.e.*, largest maximum or minimum value) point of the QRS-cardiac complex. Figure 5 shows the maximum deflection point (largest absolute peak) of the cardiac signal at approximately 508 for the first cardiac signal 500 and 510 for the second cardiac signal 502. In one embodiment, the

maximum point of the QRS-cardiac complex is indicated by a point in the first signal and the second signal having approximately the largest deflection from a baseline signal. In one embodiment, the baseline signal is the approximate value of the signal between the occurrence of QRS-cardiac complexes. The location and size of the maximum point of the QRS-cardiac complex will depend upon the location and type electrodes used to sense the heart. In one embodiment, when the medical device system is the cardiac defibrillator 100 of Figure 1, the maximum point in the first signal and the second signal is caused by the occurrence of the ventricular R-wave.

10 In an additional embodiment, the selection criterion is determining a point at the end of the cardiac electrical activation sequence (the QRS-cardiac complex). In one embodiment, the end of the QRS-cardiac complex is denoted by the first signal and the second signal returning to a baseline value after the occurrence of an intrinsic contraction of the heart. Figure 5 shows the point at the end of the sensed cardiac signal approximately at 512 for the first cardiac signal 500 and at 514 for the second cardiac signal 502. In a further embodiment, the selection criterion is a fiducial point, which is shown at approximately 516 on the second cardiac signal 502.

In an alternative embodiment, characteristics of the cardiac signal are used in creating the template. In one embodiment, the slope of the cardiac signal is used as the selection criteria, where the slope is taken along the first major inflection of the cardiac signal which is shown approximately at 518 for the first cardiac signal 500 and at 520 for the second cardiac signal 502. In an additional embodiment, the amplitude of the maximum deflection point is used to create the template. One embodiment of the amplitude of a maximum deflection point is shown at 522 for the first cardiac signal 500 and at 526 for the second cardiac signal 502. In an alternative embodiment, the characteristic used to determine the template is the slew rate of the cardiac signals sensed during normal sinus rhythm.

30 In an additional embodiment, when two or more peaks along a cardiac signal have approximately the same maximum absolute value, the system is programmed to make a choice between the two portions of the signal to use as the maximum deflection point. In one embodiment, the system is programmed

to select the maximum deflection point that is encountered first. In an alternative embodiment, the system is programmed to select the maximum deflection point that is encountered second. Subsequent maximum deflection points on signals sensed during either normal sinus rhythm or during a tachycardia episode are
5 then determined from the same relative signal programmed into the system.

Referring again to Figure 4, at step 408 the time difference between features on the cardiac complexes are determined for the cardiac complexes sensed during normal sinus rhythm. Because the cardiac complexes are being sensed at different cardiac locations (*e.g.*, the first cardiac location and the
10 second cardiac location), there is an inherent difference in the time that the cardiac complexes will be sensed. As a result, the timing difference can be taken between corresponding features on cardiac complexes. For example, in Figure 5 there is a time difference 528 between 508 and 510 when the selection criterion is a maximum deflection point of the cardiac complex. In an additional example,
15 there is a time difference 524 between the largest absolute peak 508 in the first cardiac signal 500 and the fiducial point 516 in the second cardiac signal 502.

In addition to determining time differences between corresponding features on cardiac complex, it is also possible to determine timing differences between different combination of features on the cardiac complexes. When more
20 than two cardiac complexes are sensed, time differences between the selected features for any or all of the combinations of cardiac complexes may be use in creating the template for the normal sinus rhythm.

At step 412, the timing template for the normal sinus rhythm cardiac complexes is determined. In one embodiment, the timing template is a
25 median value of the timing differences between the features on a plurality of cardiac complexes sensed during normal sinus rhythm. In an alternative embodiment, the timing template is an average value of the timing differences between the features on a plurality of cardiac complexes sensed during normal sinus rhythm. In one embodiment, the medical device system senses complexes
30 during normal sinus rhythm and determines a template time difference between a first feature on the first signal and a second feature on the second signal for a plurality of QRS-cardiac complexes. In one embodiment, the timing template is computed from five (5) or more cardiac complexes sensed during normal sinus

rhythm. In one embodiment, the five (5) or more cardiac complexes are cardiac complexes signals consecutively, or sequentially, sensed during normal sinus rhythm. In one embodiment, if the variability in the template time difference calculated during normal sinus rhythm is greater than or equal to approximately
5 10 milliseconds, the template time difference value is redetermined.

Alternatively, the variability in the template time difference at which the template time difference will be redetermined is a predetermined value in the range of 0 to 40 milliseconds, where 10 milliseconds is an acceptable value.

In addition to calculating the timing template, a feature template is
10 also computed at 416. The feature template is derived from the characteristics of the sensed cardiac complexes. In one embodiment, the feature template is a median signal amplitude of one or more features on the cardiac complexes sensed during normal sinus rhythm. In one embodiment, the medical device system senses complexes during normal sinus rhythm and determines a median
15 signal amplitude for the first feature and the second feature from a plurality of normal sinus rhythm complexes. In one embodiment, the median signal amplitude for the first feature is determined relative a baseline signal of the first signal and the median signal amplitude for the second feature is determined relative a baseline signal of the second signal. In one embodiment, median
20 signal amplitudes are computed from five (5) or more cardiac complexes sensed during normal sinus rhythm. In one embodiment, the five (5) or more cardiac complexes are cardiac complexes signals sequentially sensed during normal sinus rhythm. In one embodiment, if the variability in the median signal amplitude calculated during normal sinus rhythm is greater than or equal to
25 approximately 20 percent, the median signal amplitude is redetermined.

When the medical device system encounters a tachycardia episode, a signal amplitude of the first feature point and the second feature point for a sensed cardiac complex is determined. In one embodiment, the signal amplitude for the first feature and the second feature are calculated relative the baseline
30 signal of the first signal and the second signal respectively. The signal amplitude of the first feature point and the second feature point are then compared to the corresponding median signal amplitude of the first feature point and the second feature point, and if the signal amplitude of at least one of the first feature and

the second feature exceeds the corresponding median signal amplitude of the first feature and the second feature by a predetermined amount, the cardiac complex is characterized as a VT complex.

Other features of the first signal and the second signal are also
5 useful in determining whether a cardiac complex is a VT complex. In one embodiment, the medical device system senses the first signal representative of electrical activity at a first cardiac region, where the first signal includes a QRS-complex representative of a cardiac cycle. The medical device system also senses the second signal representative of electrical activity at a second cardiac
10 region, where the second signal including the QRS-complex as sensed in the second cardiac region. Initially, a representative slope value for both the first signal and the second signal is determined from a plurality of normal sinus rhythm complexes. In one embodiment, the representative slope value is a median slope value derived from the plurality of normal sinus rhythm
15 complexes.

During a tachycardia episode, the medical device system senses cardiac complexes (*e.g.*, QRS-cardiac complexes) and determines a first slope for the first signal and a second slope for the second signal. In one embodiment, both the first signal and the second signal are maximum slopes (the fiducial
20 point) for both the first signal and the second signal. The medical device system then compares the maximum slope of the first signal and the second signal of the QRS-cardiac complex to the corresponding representative slope for the first signal and the second signal. Based on this comparison, if the slope of at least one of the first signal and/or the second signal deviates from the corresponding
25 representative slope for the first signal and the second signal by a predetermined amount, the cardiac complex is characterized as a ventricular tachycardia complex. In one embodiment, the predetermined amount is based on the percent deviation of the first signal and/or the second signal from the corresponding representative slope, where the predetermined amount is greater than or equal to
30 20% deviation.

Referring again to Figure 4, at 420 cardiac complexes are sensed to determine the onset of a tachycardia episode. If no tachycardia episode is sensed, the system continues to sense cardiac signals and analyzes them for the

occurrence of a tachycardia episode. In one embodiment, the occurrence of a tachycardia episode is based on the cardiac rate, where a tachycardia episode is declared when the cardiac rate exceeds a predetermined threshold. In one embodiment, the predetermined threshold is a cardiac rate of between 150 and 180 beats per minute. Other systems of determining the occurrence of a tachycardia episode are known and are considered to be within the scope of the present system.

When a tachycardia episode is detected the system then proceeds to 428. At 428, cardiac complexes from the tachycardia episode are sensed and features from the sensed cardiac complexes are determined. The features determined on the cardiac complexes of the tachycardia episode are the corresponding features that were detected in the cardiac complexes during normal sinus rhythm. In other words, the features and characteristics that were used in determining the timing template and the feature template during normal sinus rhythm are the features and characteristics that are extracted from the cardiac signals sensed during the ventricular tachycardia episode.

In one embodiment, the determination of whether a QRS-cardiac complex of a tachycardia episode is a VT complex or a SVT complex is based on a comparison of time differences between features on the sensed normal sinus rhythm and tachycardia episode complexes. When the medical device encounters a tachycardia episode, a time difference for each cardiac electrical activation sequence sensed during the tachycardia episode is determined. In one embodiment, the medical device system determines the time difference between the occurrence of the first feature on the first signal and the second feature on the second signal of the QRS-cardiac complex at 432. The time difference of the QRS-cardiac complex is then compared to the template time difference calculated for normal sinus rhythm at 436. Based on the comparison, if the time difference of the cardiac complex exceeds the template time difference by a predetermined margin, the cardiac complex is characterized as a ventricular tachycardia complex at 440.

In one embodiment, a ventricular tachycardiac complex is a cardiac complex that is characteristic of the occurrence of the ventricular tachycardia episode. In other words, the ventricular tachycardiac complex is a cardiac

complex that makes up the occurrence of the ventricular tachycardiac episode. In one embodiment, the predetermined margin is a value which is programmable in the range of 0 to 40 milliseconds, where 10 milliseconds is an appropriate value. The time programmed for the predetermined margin will depend upon the
5 resolution of the measuring device used within the implantable medical device.

In one embodiment, the predetermined margin programmed into the implantable medical device will depend on the cardiac signal features used in determining the timing differences. For example, when timing differences being used are between the largest peak in the morphology channel signal (far-field
10 channel) and the fiducial point along the rate channel signal, the predetermined margin is approximately plus or minus 10 milliseconds. In other words, if the timing difference for the tachycardia complex and the template complex differs by more than 10 milliseconds, the complex is classified as a VT complex. In this embodiment, the predetermined margin, or threshold, of 10 milliseconds is
15 sufficient for most patients, however, the value may need to be customized for some patients.

Referring now to Figure 6 there is shown an embodiment a cardiac complex sensed during a tachycardia episode. Figure 6 shows one embodiment of a first cardiac signal 600 and a second cardiac signal 604 of a QRS-cardiac
20 complex sensed during a ventricular tachycardia. The first cardiac signal 600 is an example of a far-field cardiac signal, and the second cardiac signal 604 is an example of a near-field cardiac signal sensed using the same electrodes used to sense the far-field cardiac signal of the first cardiac signal 500 and the near-field signal of the second cardiac signal 502.

25 In addition to using the same electrodes to sense the cardiac signals, the same selection criterion that were used in determining the timing template and the feature template for the normal sinus rhythm complexes are also used on the cardiac complexes sensed during the tachycardia episode. In one embodiment, the selection criterion is the maximum point of the QRS-cardiac complex. Figure 6 shows the maximum deflection point of the cardiac
30 signal at approximately 608 for the first cardiac signal 600 and 616 for the second cardiac signal 604. In one embodiment, a time difference 624 is determined between the maximum deflection point 608 for the first cardiac

signal and the maximum deflection point 616 for the second cardiac signal. In an additional embodiment, a fiducial point 612 is shown on the second cardiac signal 604, where the timing difference 620 between the first cardiac signal 600 and the second cardiac signal 604 is taken between the fiducial point 612 and the maximum deflection point 616 along the first cardiac signal 600.

Referring now to Figure 7 there is shown an embodiment of a sensed cardiac complex. Figure 7 shows one embodiment of a first cardiac signal 700 and a second cardiac signal 704 of a QRS-cardiac complex sensed during a ventricular tachycardia. The first cardiac signal 700 is an example of a far-field cardiac signal, and the second cardiac signal 704 is an example of a near-field cardiac signal sensed using the same electrodes used to sense the far-field cardiac signal of the first cardiac signal 500 and the near-field signal of the second cardiac signal 502.

In addition to using the same electrodes to sense the cardiac signals, the same selection criterion that were used in determining the timing template and the feature template for the normal sinus rhythm complexes are also used on the cardiac complexes sensed during the tachycardia episode. In one embodiment, the selection criterion is the maximum point of the QRS-cardiac complex. Figure 7 shows the maximum deflection point of the cardiac signal at approximately 708 for the first cardiac signal 700 and 716 for the second cardiac signal 704. In one embodiment, a time difference 724 is determined between the maximum deflection point 708 for the first cardiac signal and the maximum deflection point 716 for the second cardiac signal. In an additional embodiment, a fiducial point 712 is shown on the second cardiac signal 704, where the timing difference 720 between the first cardiac signal 700 and the second cardiac signal 704 is taken between the fiducial point 712 and the maximum deflection point 708 along the first cardiac signal 700.

The cardiac complex sensed in Figure 6 is a ventricular tachycardia complex. The cardiac complex sensed in Figure 7 is a supraventricular tachycardiac complex. As Figures 6 and 7 show, there is a notable difference in the time difference for ventricular tachycardia complexes and supraventricular tachycardia complexes. In comparing time differences 624 and 724 to 526, the value of time difference 724 is closer to the value of time difference 528 than the

value or time difference 624. Alternatively, the time differences between 620 and 720 as compared to 524 show that the value of time difference 720 is closer to the value of time difference 524 than the value or time difference 620. In one embodiment, the differences in timing difference values are used to differentiate
5 VT from SVT.

In addition, comparisons of characteristics of cardiac signals are also used to differentiate VT from SVT. Referring again to Figure 5, the slope 518 of the first cardiac signal 500 and the slope 520 of the second cardiac signal 502 are used to differentiate VT complexes from non-VT complexes. In Figures
10 6 and 7, the corresponding characteristics are also found on the cardiac signals. In Figure 6, the slope of the first cardiac signal 600 is shown generally along 628 and the slope of the second cardiac signal 604 is shown generally along 632. In Figure 7, the slope of the first cardiac signal 700 is shown generally along 728 and the slope of the second cardiac signal 704 is shown generally along 732.
15 Comparing the characteristics of the sensed cardiac signal in Figures 5, 6 and 7 shows that there are once again discernable differences in the signal characteristics. In one embodiment, the slopes shown in Figures 5 and 7 are considerably more similar than the slopes shown in Figures 5 and 6. These differences allow for a determination of the origin of the ventricular tachycardia.

20 Referring again to Figure 4, if the cardiac complex of the tachycardia episode is not categorized as a ventricular tachycardiac complex at 440 based on a comparison of time difference or a signal characteristic, the cardiac complex is analyzed using at least one additional classification procedure. This is necessary to rule out VT that may appear similar to NSR
25 based on a small number of features. In one embodiment, the additional classification procedure is used to classify cardiac signals sensed during the tachycardia episode as either VT complex or non-VT complex.

After making a determination as to whether a cardiac complex is a VT or a non-VT complex, a percentage of ventricular tachycardia complexes is
30 determined at 448. At 452, the calculated percentage of the ventricular tachycardia is compared to a predetermined percentage threshold. In one embodiment, therapy for treating a ventricular tachycardia is applied to the patient's heart at 456 when the percentage of ventricular tachycardia complexes

exceeds the predetermined percentage threshold. If the percentage of ventricular tachycardia does not exceed the predetermined percentage threshold, the system returns to 420. In one embodiment, a plurality of cardiac complexes are sampled and categorized for a ventricular tachycardia. In one embodiment, the
5 predetermined percentage threshold is a programmable value in the range of 40 to 60 percent, where a value of approximately 50 percent is an acceptable value.

Referring now to Figure 8, there is shown an alternative embodiment of the present system for distinguishing VT from SVT during a tachycardia episode. In one embodiment, cardiac complexes are sensed at 400 as
10 previously discussed. At 800, the sensed cardiac complexes are used to determine or calculate a normal sinus rhythm template, or a model, against which cardiac signals sensed during a tachycardia episode are compared. At 800, the template is determined from characteristics of the sensed cardiac signals sensed during normal sinus rhythm.

15 In one embodiment, the characteristic of the sensed cardiac signal is the slope of a predetermined portion of the cardiac signal. In an additional embodiment, the characteristic used to create the template is the amplitude of a maximum deflection point (point along the sensed signal having the maximum absolute value) of the cardiac signal, such as a maximum or minimum point along either
20 the first cardiac signal or the second cardiac signal. In an alternative embodiment, the characteristic is the slew rate of the cardiac signals sensed during normal sinus rhythm.

At step 804 the characteristic values for the normal sinus rhythm cardiac complexes are determined by the system. The feature template is derived
25 from the characteristics of the sensed cardiac complexes. In one embodiment, the feature template is a median signal amplitude of one or more features on the cardiac complexes sensed during normal sinus rhythm. In one embodiment, the medical device system senses complexes during normal sinus rhythm and determines a median signal amplitude for the first feature and the second feature
30 from a plurality of normal sinus rhythm complexes. In one embodiment, the median signal amplitude for the first feature is determined relative a baseline signal of the first signal and the median signal amplitude for the second feature is determined relative a baseline signal of the second signal. In one embodiment,

median signal amplitudes are computed from five (5) or more cardiac complexes sensed during normal sinus rhythm. In one embodiment, the five (5) or more cardiac complexes are cardiac complexes signals sequentially sensed during normal sinus rhythm. In one embodiment, if the variability in the median signal
5 amplitude calculated during normal sinus rhythm is greater than or equal to approximately 20 percent, the median signal amplitude is redetermined.

When the medical device system encounters a tachycardia episode, a signal amplitude of the first feature point and the second feature point for each cardiac complex is determined. In one embodiment, the signal amplitude for the
10 first feature and the second feature are calculated relative the baseline signal of the first signal and the second signal respectively. The signal amplitude of the first feature point and the second feature point are then compared to the corresponding median signal amplitude of the first feature point and the second feature point, and if the signal amplitude of at least one of the first feature and
15 the second feature exceeds the corresponding median signal amplitude of the first feature and the second feature by a predetermined amount, the cardiac complex is characterized as a ventricular tachycardia complex.

Other features of the first signal and the second signal are also useful in determining whether a cardiac complex is a ventricular tachycardiac
20 complex. In one embodiment, the medical device system senses the first signal representative of electrical activity at a first cardiac region, where the first signal includes a QRS-complex representative of a cardiac cycle. The medical device system also senses the second signal representative of electrical activity at a second cardiac region, where the second signal including the QRS-complex as
25 sensed in the second cardiac region. Initially, a representative slope value for both the first signal and the second signal is determined from a plurality of normal sinus rhythm complexes. In one embodiment, the representative slope value is a median slope value determined from the plurality of normal sinus rhythm complexes.

30 During a tachycardia episode, the medical device system senses cardiac signals (e.g., QRS-cardiac complexes) and determines a first slope for the first signal and a second slope for the second signal. In one embodiment, the both the first signal and the second signal are maximum slopes for both the first

signal and the second signal. The medical device system then compares the maximum slope of the first signal and the second signal of the QRS-cardiac complex to the corresponding representative slope for the first signal and the second signal. Based on this comparison, if the slope of at least one of the first
5 signal and/or the second signal deviates from the corresponding representative slope for the first signal and the second signal by a predetermined amount, the cardiac complex is characterized as a ventricular tachycardia complex.

At 420 cardiac complexes are sensed to determine the onset of a tachycardia episode. If no tachycardia episode is sensed, the system continues to
10 sense cardiac signals and analyzes them for the occurrence of a tachycardia episode. In one embodiment, the occurrence of a tachycardia episode is based on the cardiac rate, where a tachycardia episode is declared when the cardiac rate exceeds a predetermined threshold. In one embodiment, the predetermined threshold is a cardiac rate of between 150 and 180 beats per minute. Other
15 systems of determining the occurrence of a tachycardia episode are known and are considered to be within the scope of the present system.

When a tachycardia episode is detected the system then proceeds to 812. At 812, cardiac complexes from the tachycardia episode are sensed and characteristics from the sensed cardiac complexes are determined. The
20 characteristics determined on the cardiac complexes of the tachycardia episode are the corresponding characteristics that were detected in the cardiac complexes during normal sinus rhythm. In other words, the characteristics that were used in determining the feature template during normal sinus rhythm are the characteristics that are extracted from the cardiac signals sensed during the
25 ventricular tachycardia episode.

In one embodiment, the determination of whether a QRS-cardiac complex of a tachycardia episode is a VT complex or a SVT complex is based on a comparison of characteristic values and the feature template. When the medical device encounters a tachycardia episode, characteristic values for each
30 QRS-cardiac complex sensed during the tachycardia episode is determined. In one embodiment, the medical device system determines the characteristic value for the first feature on the first signal and the second feature on the second signal of the QRS-cardiac complex at 816. The characteristic values of the QRS-

cardiac complex is then compared to the feature template calculated for normal sinus rhythm at 808. Based on the comparison, if the characteristic values of the cardiac complex exceeds the feature template by a predetermined margin, the cardiac complex is characterized as a ventricular tachycardia complex at 440. In one embodiment, a ventricular tachycardiac complex is a cardiac complex that is characteristic of the occurrence of the ventricular tachycardia episode. In other words, the ventricular tachycardiac complex is a cardiac complex that makes up the occurrence of the ventricular tachycardiac episode.

When the cardiac complex of the tachycardia episode is not categorized as a ventricular tachycardiac complex at 816, the cardiac complex is analyzed using at least one additional classification procedure at 444. In one embodiment, the additional classification procedure is used to classify cardiac signals sensed during the tachycardia episode as either VT complex or non-VT complex.

After making a determination as to whether a cardiac complex is a VT or a SVT complex, a percentage of ventricular tachycardia complexes is determined at 448. At 452, the calculated percentage of the ventricular tachycardia is compared to a predetermined percentage threshold. In one embodiment, therapy for treating a ventricular tachycardia is applied to the patient's heart at 456 when the percentage of ventricular tachycardia complexes exceeds the predetermined percentage threshold. If the percentage of ventricular tachycardia does not exceed the predetermined percentage threshold, the system returns to 420. In one embodiment, a plurality of cardiac complexes are sampled and categorized for a ventricular tachycardia. In one embodiment, the predetermined percentage threshold is a programmable value in the range of 40 to 60 percent, where a value of approximately 50 percent is an acceptable value.

Referring now to Figure 9, there is shown an alternative embodiment of the present system. At step 900 a timing template is determined for normal sinus rhythm signals. The timing template can be determined as previously discussed. In the present embodiment, the timing template is determined using the time difference between the absolute maximum deflection point along a far-field signal and the fiducial point along a near-field signal. At

904, a feature template is also determined. The feature template can be computed as previously discussed.

Cardiac complexes are then sensed at 908 to determine when the heart has entered a tachycardia episode. If the heart enters into a tachycardia episode, the system proceeds to 912. At 912, the timing difference between the absolute maximum deflection point along a far-field signal and the fiducial point along a near-field signal is taken for the sensed cardiac complex. At 916, feature values are derived from the far-field signal and the near-field signal for the sensed cardiac complex. The system then proceeds to 920 where the timing difference of the cardiac complex sensed during the tachycardia episode is compared to the timing template. If the timing difference is greater than about a predetermined threshold (*e.g.*, 10 milliseconds), the cardiac complex is classified as VT complex at 924. If the timing difference is not greater than about +/- 10 milliseconds, the system then proceeds to 928 where the morphology of the far-field signal and the near-field signal are used to determine whether the cardiac complex is a VT complex or a SVT complex. Some methods useful for comparing morphologies of cardiac complexes in two or more cardiac signals are presented in U.S. Patent Application Serial No. 09/249,128, entitled "System and Method for Classifying Cardiac Complexes" which is filed on the same day as the instant U.S. Patent application and that is hereby incorporated by reference in its entirety.

In one embodiment, at 928 morphology of the far-field signals and/or the near-field signals of the unknown cardiac complex are compared to a representative normal sinus rhythm complex in a comparison window to determine whether the unknown cardiac complex is a VT complex or a SVT complex. In one embodiment, the representative normal sinus rhythm complex includes a first normal sinus rhythm (NSR) representative complex and a second NSR representative complex determined from the plurality QRS-cardiac complexes sensed during normal sinus rhythm. In one embodiment, the template generator 240 determines the first and second NSR representative complexes. In one embodiment, the morphologies of the first signal (the far-field signal) and the second signal (the near-field signal) for the unknown cardiac complex are compared to the morphologies of the first NSR representative complex (a far-

field signal in this example) and the second NSR representative complex (a near-field signal in this example) of the representative normal sinus rhythm complex in the comparison window. From the morphology comparison of the cardiac complex sensed in the first signal to the morphology of the first NSR

- 5 representative complex and the morphology of the cardiac complex sensed in the second signal to the morphology of the second NSR representative complex the cardiac complex can be classified as either a VT complex or a SVT complex.

- In an alternative embodiment, before a morphology comparison is made between the cardiac complex sensed in the first signal or the second signal
- 10 (*e.g.*, the near-field or far-field signals) of the unknown cardiac complexes and the first NSR representative complex and a second NSR representative complex, the cardiac complex sensed in the first signal and the second signal and the first and second NSR representative complexes are positioned in a comparison window. In one embodiment, the comparison window isolates an individual
- 15 cardiac complex as sensed in the first signal and the second signal, where the first signal and the second signal of the cardiac complex are positioned relative to each other based on their time of occurrence (*i.e.*, the x-axis of the cardiac complex plot has the units of time on which the relative occurrence of the cardiac complex sensed in the first signal and the second signal are plotted).
- 20 Within the comparison window, the cardiac complex sensed in the first signal and the first NSR representative complex are aligned around a predetermined feature that is common to both cardiac complexes. In one embodiment, the signal feature comparison circuit 238 aligns the unknown cardiac complex and the representative NSR complex around the predetermined feature. After the
- 25 representative NSR complex and the unknown cardiac complex have been aligned around the predetermined feature the morphology of the cardiac complex sensed in the second signal is then compared to the second NSE representative complex to allow the unknown cardiac complex to be classified as either a VT complex or an SVT complex. In one embodiment, the morphology analyzer
- 30 circuit 248 compares the morphology of the unknown cardiac complex to determine whether the tachycardia complex is a ventricular tachycardia complex.

Figure 10 shows one embodiment of aligning an unknown cardiac complex with a NSR representative complex in a comparison window. In one

embodiment, the NSR representative complex is an average or a median NSR complex generated from NSR complexes sensed with the implantable medical device. A NSR representative complex is shown at 1000, where 1010 represents a first NSR representative complex (a far-field signal in this example) and 1020
5 represents a second NSR representative complex (a near field signal in this example). An unknown cardiac complex is shown in 1030, where 1040 represents the first signal (a far-field signal) and 1050 represents the second signal (a near field signal) of the unknown cardiac complex.

The second features of both the unknown cardiac complex and the
10 NSR representative complex are first aligned along a predetermined feature that is common in both the cardiac complex sensed in the second signal and the second NSR representative complex. In one embodiment, the maximum deflection point ($dV/dt=0$) in the near-field signals is used as the predetermined feature (or reference point) around which to align the unknown cardiac complex
15 and the representative normal sinus rhythm complex. Other feature points on the near-field signals can also be used to align the unknown cardiac complex and the representative normal sinus rhythm complex. Once the second signals (near-field signals) have been aligned (*i.e.*, located at the same point in the comparison window), the morphology of the first signal (far-field signal) and the
20 morphology of the first representative NSR signal (far-field signal) can then be compared to determine whether the unknown cardiac complex is similar (SVT) or dissimilar (VT) with respect to a predetermined threshold. By first aligning the cardiac complexes, the relative time of occurrence of the far-field signals is used to further accentuate any morphological differences in the two signals being
25 compared.

Figure 11 shows an additional embodiment of aligning an unknown cardiac complex with a representative normal sinus rhythm complex. A NSR representative complex is shown at 1100, where 1110 represents the first NSR representative complex (a far-field signal) and 1120 represents the second NSR
30 representative complex (a near field signal). An unknown cardiac complex is shown in 1130, where 1140 represents the first signal (a far-field signal) and 1150 represents the second signal (a near field signal).

In the present embodiment, the first features of both the unknown cardiac complex and the NSR representative complex are taken as the predetermined feature around which to align the cardiac complex in the first signal and the first NSR representative complex. In one embodiment, the maximum deflection point ($dV/dt=0$) in the far-field signals is used as the first feature (or reference point) around which to align the unknown cardiac complex and the NSR representative complex. Other feature points on the far-field signals can also be used to align the unknown cardiac complex and the representative normal sinus rhythm complex. Once the first signals (far-field signals) have been aligned, the morphology of the second signal (near-field signal) and the morphology of the second representative NSR signal (near-field signal) can then be compared to determine whether the unknown cardiac complex is a VT complex or an SVT complex. By first aligning the cardiac complexes, the relative time of occurrence of the far-field signals is used to further accentuate any morphological differences in the two signals being compared.

In one embodiment, the morphology of the far-field and/or near-field signals is compared using a correlation waveform analysis, as is known in the art. The correlation waveform analysis is a method of comparing two waveforms to determine how similar they are to one another, where being similar indicates SVT and being dissimilar indicates VT. Correlation waveform analysis uses a correlation coefficient between a template of sinus rhythm and the unknown complex under analysis. The correlation coefficient for each unknown complex falls between -1 and 1, where 1 indicates a perfect match between the unknown complex and the template. In addition to correlation waveform analysis, other morphology comparison methods or methods of classifying unknown cardiac complexes can be used to distinguish VT complex from SVT complex once the unknown cardiac complex is aligned around a common feature with a representative normal sinus rhythm complex.

After making a determination as to whether a cardiac complex is a VT or a non-VT complex, a percentage of ventricular tachycardia complexes is determined at 936. At 936, the calculated percentage of the ventricular tachycardia is compared to a predetermined percentage threshold. In one

embodiment, therapy for treating a ventricular tachycardia is applied to the patient's heart at 936 when the percentage of ventricular tachycardia complexes exceeds the predetermined percentage threshold. If the percentage of ventricular tachycardia does not exceed the predetermined percentage threshold, the system
5 returns to 908. In one embodiment, the predetermined percentage threshold is a programmable value in the range of 40 to 60 percent, where a value of approximately 50 percent is an acceptable value. Once the percentage of VT complexes exceeds the predetermined percentage threshold the system then delivers appropriate therapy at 940 to treat the ventricular tachycardia.

10 In an additional embodiment, it is possible to use three or more cardiac sensing channels to classify a tachycardiac complex as either a VT complex or an SVT complex. For example, cardiac sensing channels can include a far-field channel and a near-field channel sensed in and around the right atrial and ventricular chambers of the heart as previously described. In addition, a far-
15 field or a near-field channel sensed at a location adjacent to the left ventricular chamber can also be used in classifying a tachycardiac complex as either a VT complex or an SVT complex.

Figure 12 shows one embodiment of three sensing channels being used to detect a cardiac complex. In one embodiment, a third signal
20 representative of electrical activity at a third cardiac region is sensed, where the third signal includes a QRS-cardiac complex representative of a cardiac cycle sensed in the third cardiac region. A cardiac complex sensed with three sensing channels is shown at 1200. In one embodiment, the first sensing channel 1210 is detecting right ventricular far-field signals; the second sensing channel 1220 is
25 detecting right ventricular near-field signals; and the third sensing channel 1230 is detecting a left ventricular near-field signal. In one embodiment, the third sensing channel is sensed from a position that is adjacent the left ventricular chamber of the heart.

A comparison template is created from feature values and/or timing
30 differences between features from sensed normal sinus rhythm complexes. In one embodiment, the comparison template has a plurality of values derived from one or more features on the first signal, the second signal and the third signal of the normal sinus rhythm complexes. In one embodiment, the plurality of values

includes a series of timing differences and/or feature values derived from any combination of the sensed cardiac signals. In one embodiment, the template generator 240 generates the comparison template from cardiac complexes sensed during normal sinus rhythm.

5 The timing differences and/or features used in developing a comparison template are programmable parameters in the implantable medical device. To create the comparison template, one or more features are selected on the first signal, the second signal and the third signal. The features are selected based on the selection criterion previously discussed. Once the features have
10 been selected and the way in which the features are to be used in the comparison template defined (*e.g.*, used to generate timing differences or used to generate feature values), the comparison template is generated from a plurality of sensed normal sinus rhythm complexes. In one embodiment, the values calculated for the comparison template are average values of the sensed normal sinus rhythm
15 complexes. Alternatively, the values calculated for the comparison template are median values of the sensed normal sinus rhythm complexes.

 As unknown cardiac complexes are sensed, the corresponding plurality of values determined from the normal sinus rhythm complexes to create the comparison template are determined from the one or more features on the
20 first signal, the second signal and the third signal of the cardiac complex. The plurality of values derived from the cardiac complex is then compared to the comparison template. When one or more of the plurality of values of the cardiac complex exceed the corresponding value in the comparison template by a predetermined margin, the control system characterizes the cardiac complex as a
25 VT complex.

 In one embodiment, the plurality of values are derived from timing differences between the one or more features on the first signal, the second signal and the third signal. For example, an not by way of limitation, a six value comparison template can be generated by taking the timing differences between
30 a series of features along any combination of the right ventricular far-field signal 1210, the right ventricular near-field signal 1220 and/or the left ventricular near-field signal 1230. In one embodiment, the comparison template is created by (1) taking the timing differences between the start of the right ventricular far-field

signal 1210, shown at 1234, and the maximum deflection point along the right ventricular far-field signal 1210, shown at 1238; (2) taking the timing differences between the maximum deflection point 1238 and the end of the right ventricular far-field signal 1210, shown at 1242; (3) taking the timing differences between
5 the start of the right ventricular far-field signal 1234 and the start of the right ventricular near-field signal 1220, shown at 1246; (4) taking the timing differences between the start of the right ventricular near-field signal 1246 and the maximum deflection point of the right ventricular near-field signal 1220, shown at 1250; (5) taking the timing differences between the maximum
10 deflection point of the right ventricular near-field signal 1250 and the start of the left ventricular near-field signal 1230, shown at 1254; and (6) taking the timing differences between the start of the left ventricular near-field signal 1254 and the end of the left ventricular near-field signal 1230, shown at 1256.

In this embodiment, the comparison template has six values, which
15 are derived from timing differences between features along a plurality of cardiac sensing channel. Once the comparison template has been generated from sensed normal sinus rhythm complexes, the same timing differences are taken along the same three sensing channels for unknown cardiac complexes and the resulting six values are compared to the comparison template. Based on the timing
20 differences between the six values, cardiac complexes are classified as either VT complexes or SVT complexes.

Alternatively, comparison templates can be generated from a first signal and a second signal. In this embodiment, one or more features, based on the selection criterion, are selected for the first signal and the second signal. The
25 comparison template is then created from normal sinus rhythm complexes, where the comparison template has a plurality of values derived from the one or more features on the first signal and the second signal of the normal sinus rhythm complexes. In one embodiment, the plurality of values can include timing differences between features on either the first signal and/or the second
30 signal. Alternatively, the plurality of values can include feature values on either the first signal and/or the second signal. Combinations of feature values and timing differences are also possible.

As unknown cardiac complexes are sensed, the corresponding plurality of values determined from the normal sinus rhythm complexes to create the comparison template are determined from the one or more features on the first signal and the second signal. The plurality of values derived from the cardiac complex is then compared to the comparison template. When one or more of the plurality of values of the cardiac complex exceed the corresponding value in the comparison template by a predetermined margin, the cardiac complex is characterized as a VT complex.

In addition, one or more of the positions in a comparison template can also have a weighting factor associated with it. The weighting factor, or factors, allow one or more of the individual values within the comparison template to have more, or less, influence on the decision to classify a cardiac complex as either a VT complex or an SVT complex. For example, when a particular timing difference or feature value in a patient's sensed cardiac signal is known to be indicative of a particular cardiac condition (*e.g.*, VT or SVT), more weight can be given to that position in the comparison template as compared to any other position in the comparison template. So, when the more heavily weighted timing difference or feature value in the comparison template exceeds the predetermined minimum value, the system can classify the cardiac complex regardless of what the other timing differences or feature values in the template indicate. In addition, the weightings can be predetermined from patient population studies and research on individual patients.

In addition to using three cardiac channels in developing the comparison template, it is also possible to use four or more cardiac channels in developing the comparison template. Other channels that are useful include those sensing cardiac complexes from the housing of the implantable medical device or atrial near-field or far-field channels, just as examples. Other combinations of sensing channels are possible and considered within the present subject matter.

WHAT IS CLAIMED IS:

1. A system, comprising:
 - at least one lead;
 - a sensing system attached to the at least one lead; and
 - 5 a control system attached to the sensing system, where the control system monitors a first signal and a second signal for complexes;
 - a morphology analyzer circuit coupled to the control system, where the morphology analyzer circuit locates a first feature on the first signal and a second feature on the second signal;
 - 10 a signal feature comparison circuit coupled to the morphology analyzer circuit, where the signal feature comparison circuit determines a time difference between the first feature and the second feature on a complex and compares the time difference to a template time difference determined from the time difference between the first feature and the
 - 15 second feature for a plurality of complexes sensed during normal rhythm; and
 - where the control system designates the complex as a rapid complex when the time difference exceeds the template time difference by a predetermined margin.
 - 20
2. The system of claim 1, where the morphology analyzer circuit locates the first feature at a maximum deflection of the first signal and locates the second feature at a maximum deflection of the second signal.
- 25 3. The system of claim 2, where the control system determines a first median signal amplitude of the first feature relative a baseline signal for the first signal for the plurality of complexes sensed during normal rhythm and a second median signal amplitude of the second feature relative a baseline signal for the second signal for the plurality of complexes sensed
- 30 during normal rhythm;
- the morphology analyzer circuit determines for the complex a first signal amplitude for the first feature and a second signal amplitude for the second feature; and

the control system designates the complex as a rapid complex when the signal feature comparison circuit determines either the first signal amplitude exceeds the first median signal amplitude by a predetermined amount or the second signal amplitude exceeds the second median signal amplitude by the predetermined amount.

4. The system of claim 1, where the morphology analyzer circuit locates the first feature at a beginning of the complex as indicated by a predetermined deviation of the first signal from a baseline signal of the first signal and locates the second feature at the beginning of the complex as indicated by the predetermined deviation of the second signal from a baseline signal of the second signal.
5. The system of claim 1, where the morphology analyzer circuit locates the first feature at an ending of the complex as indicated by a return of the first signal to a baseline signal of the first signal within a predetermined time window and by a return of the second signal to a baseline signal of the second signal for the predetermined time period.
6. The system of claim 1, where the morphology analyzer circuit locates the first feature at a region having the largest slope along first signal and the second feature at the region having the largest slope along the second signal.
7. The system of claim 1, where the sensing system includes a far-field sensing channel through which the first signal is received and a near-field sensing channel through which the second signal is received.
8. The system of claim 7, where the morphology analyzer circuit locates the first feature at a maximum deflection of the first signal and locates the second feature at the region having the largest slope along the second signal; and

the signal feature comparison circuit determines a time difference between the first feature and the second feature on the complex and compares the time difference to the template time difference determined from the time difference between the first feature and the second feature
5 for the plurality of complexes sensed during normal rhythm.

9. The system of claim 1, where the control system monitors the first signal and the second signal for complexes sensed during an episode, and the control system determines a percentage of complexes designated as
10 rapid complexes.

10. The system of claim 1, where the template time difference is approximately 10 milliseconds.

15 11. The system of claim 1, including a template generator attached to the control system, where the template generator determines a first representative signal and a second representative signal from the plurality complexes sensed during normal rhythm; and

when the signal feature comparison circuit determines the time
20 difference is lower than the template time difference value, the template generator compares the morphology of the first signal to the morphology of the first representative signal and the morphology of the second signal to the morphology of the second representative signal to determine whether the complex is a rapid complex.

25

12. The system of claim 11, where the template generator aligns the first feature on the first signal with the first feature on the first representative signal, and compares the morphology of the second signal to the morphology of the second representative signal to determine whether
30 the complex is a rapid complex.

13. The system of claim 11, where the template generator aligns the second feature on the second signal with the second feature on the second

representative signal, and compares the morphology of the first signal to the morphology of the first representative signal to determine whether the complex is a rapid complex.

- 5 14. The system of claim 11, where
 the morphology analyzer circuit locates one or more features of the
 first signal, which include a first portion of the complex which is
 repeatably identifiable in subsequent complexes, and locates one or more
 features of the second signal, which include a second portion of the
10 complex which is repeatably identifiable in subsequent complexes;
 the template generator generates a comparison template from
 complexes sensed during normal rhythm, where the comparison template
 has a plurality of values derived from the one or more features on the first
 signal and the second signal, and for the complex the template generator
15 determines the plurality of values derived from the one or more features of
 the first signal and the one or more features of the second signal and
 compares each of the plurality of values of the complex to each
 corresponding value in the comparison template; and
 the control system designates the complex as a rapid complex when
20 one or more of the plurality of values of the complex exceed the
 corresponding value in the comparison template by a predetermined
 margin.

15. The system of claim 14, where the template generator generates the
25 comparison template from time differences between the one or more
 features on the first signal and the second signal.

16. The system of claim 14, where
 the morphology analyzer circuit locates one or more features of a
30 third signal, where each of the one or more features include a third portion
 of the complex which is repeatably identifiable in subsequent complexes;
 the template generator generates a comparison template from
 complexes sensed during normal rhythm, where the comparison template

has the plurality of values derived from the one or more features on the first signal, the second signal, and the third signal, and for the complex the template generator determines the plurality of values derived from the one or more features of the first signal, the one or more features of the second
5 signal and the one or more features of the third signal, and compares each of the plurality of values of the complex to each corresponding value in the comparison template; and

the control system designates the complex as a rapid complex when one or more of the plurality of values of the complex exceed the
10 corresponding value in the comparison template by a predetermined margin.

17. The system of claim 16, where the template generator generates the comparison template from time differences between the one or more
15 features on the first signal, the second signal and the third signal.

18. A method, comprising:
sensing a first signal representative of electrical activity at a first region, the first signal including a complex representative of a cycle sensed
20 in the first region;

sensing a second signal representative of electrical activity at a second region, the second signal including the complex as sensed in the second region;

selecting a first feature of the first signal, where the first feature
25 includes a first portion of the complex which is repeatably identifiable in subsequent complexes;

selecting a second feature of the second signal, where the second feature includes a second portion of the complex which is repeatably identifiable in subsequent complexes;

30 during an episode, determining a time difference between the first feature and the second feature;

comparing the time difference to a template time difference, where the template time difference is determined from the time difference

between the first feature and the second feature for a plurality of normal complexes; and

if the time difference exceeds the template time difference value by a predetermined margin, characterizing the complex as a rapid complex.

5

19. The method of claim 18, where the first portion and the second portion of the complex which are repeatably identifiable in subsequent complexes is a maximum deflection of the complex.

10 20. The method of claim 19, including:

for the plurality of normal complexes, determining a first median signal amplitude for the first feature relative a baseline signal of the first signal, and a second median signal amplitude for the second feature relative a baseline signal of the second signal;

15 for the complex, determining a first signal amplitude for the first feature relative the baseline signal of the first signal and a second signal amplitude for the second feature relative the baseline signal of the second signal; and

20 when either the first signal amplitude exceed the first median signal amplitude by a predetermined amount or the second signal amplitude exceed the second median signal amplitude by the predetermined amount, characterizing the complex as a rapid complex.

21. The method of claim 18, where the first portion and the second
25 portion of the complex which are repeatably identifiable is a predetermined deviation of the first signal from a baseline signal of the first signal and of the second signal from a baseline signal of the second signal indicating a beginning of the complex.

30 22. The method of claim 18, where the first portion and the second portion of the complex which are repeatably identifiable is a return of the first signal to a baseline signal of the first signal within a predetermined time window and of the second signal to a baseline signal of the second

signal for the predetermined time window, indicating an ending of the complex.

23. The method of claim 18, where the first portion and the second
5 portion of the complex which are repeatably identifiable in subsequent
complexes is a region having the largest slope along the complex.
24. The method of claim 18, where sensing the first signal includes
sensing the electrical activity with a far-field sensing channel, and sensing
10 the second signal includes sensing the electrical activity with a near-field
sensing channel.
25. The method of claim 24, determining the time difference includes
determining the time difference between a maximum deflection along the
15 first signal and a region having the largest slope along the second signal.
26. The method of claim 18, including recalculating the template time
difference when the template time difference has a variability of greater
than 20 percent.
20
27. The method of claim 18, including:
during an episode, sensing the first signal and the second signal for
a plurality of complexes;
determining a percentage of rapid complexes in the plurality of
25 complexes; and
designating therapy for treating a rapid condition when the
percentage of rapid complexes exceeds a predetermined percentage
threshold.
- 30 28. The method of claim 27, where the predetermined percentage
threshold is 50 percent.

29. The method of claim 18, including characterizing the complex as a rapid complex when the time difference exceeds the template time difference value by approximately 10 milliseconds.
- 5 30. The method of claim 18, including:
determining a first representative complex and a second representative complex from the plurality normal complexes; and
if the time difference is less than the template time difference value, comparing the morphology of the complex sensed in the second
10 signal to the morphology of the second representative complex to determine whether the complex is a rapid complex.
31. The method of claim 30, including:
if the time difference is less than the template time difference
15 value, comparing the morphology of the complex sensed in the first signal to the morphology of the first representative complex to determine whether the complex is a rapid complex.
- 20 32. The method of claim 30, including:
positioning the complex, as sensed in the first signal and the second signal, and the first representative complex and the second representative complex in a comparison window;
aligning the first portion of the complex sensed in the first signal with the first portion of the first representative complex in the comparison
25 window; and
comparing the morphology of the complex as sensed in the second signal to the morphology of the second representative complex to determine whether the complex is a rapid complex.
- 30 33. The method of claim 18, including:
determining a first representative complex and a second representative complex from the plurality normal complexes; and

if the time difference is less than the template time difference value, comparing the morphology of the complex sensed in the first signal to the morphology of the first representative complex to determine whether the complex is a rapid complex.

5

34. The method of claim 33, including:

positioning the complex, as sensed in the first signal and the second signal, and the first representative complex and the second representative complex in a comparison window;

10

aligning the first portion of the complex sensed in the second signal with the first portion of the second representative complex in the comparison window; and

comparing the morphology of the complex as sensed in the first signal to the morphology of the first representative complex to determine whether the complex is a rapid complex.

15

35. The method of claim 18, including:

selecting one or more features of the first signal where each of the one or more features include a first portion of the complex which is repeatably

20

identifiable in subsequent complexes;

selecting one or more features of the second signal, where each of the one or more features include a second portion of the complex which is repeatably identifiable in subsequent complexes;

25

creating a comparison template from normal complexes, where the comparison template has a plurality of values derived from the one or more features on the first signal and the second signal of the normal complexes;

determining the plurality of values derived from the one or more features of the first signal and the one or more features of the second signal of the complex;

30

comparing each of the plurality of values of the complex to each corresponding value in the comparison template; and

if one or more of the plurality of values of the complex exceed the corresponding value in the comparison template by a predetermined margin, characterizing the complex as a rapid complex.

5 36. The method of claim 18, including

sensing a third signal representative of electrical activity at a third region, the third signal including the complex representative of the cycle sensed in the third region;

10 selecting one or more features of the first signal where each of the one or more features include a first portion of the complex which is repeatably identifiable in subsequent complexes;

selecting one or more features of the second signal where each of the one or more features include a second portion of the complex which is repeatably identifiable in subsequent complexes;

15 selecting one or more features of the third signal, where each of the one or more features include a third portion of the complex which is repeatably identifiable in subsequent complexes;

creating a comparison template from normal complexes, where the comparison template has a plurality of values derived from the one or more features on the first signal, the second signal and the third signal of the normal complexes;

determining the plurality of values derived from the one or more features of the first signal, the one or more features of the second signal and the one or more features of the third signal of the complex;

25 comparing each of the plurality of values of the complex to each corresponding value in the comparison template; and

if one or more of the plurality of values of the complex exceed the corresponding value in the comparison template by a predetermined margin, characterizing the complex as a rapid complex.

30

37. The method of claim 36, including deriving the plurality of values from time differences between the one or more features on the first signal, the second signal and the third signal.

38. A method, comprising:
sensing a first signal representative of electrical activity at a first region, the first signal including a complex representative of a cycle sensed in the first region;
5 sensing a second signal representative of electrical activity at a second region, the second signal including the complex as sensed in the second region;
determining a first slope of the first signal;
determining a second slope of the second signal;
10 determining a representative slope for the first signal for a plurality of normal complexes;
determining a representative slope for the second signal for the plurality of normal complexes;
during an episode, comparing the first slope for a complex to the
15 representative slope for the first signal and comparing the second slope for the complex to the representative slope for the second signal; and
when the first slope is less than the representative slope for the first signal by a predetermined amount or the second slope is less than the representative slope for the second signal by the predetermined amount,
20 characterizing the complex as a rapid complex.
39. The method of claim 38, where the first slope is a maximum slope along the first signal, and the second slope is the maximum slope along the second signal.
- 25
40. The method of claim 38, where the predetermined amount is greater than or equal to 20 percent.
41. A method, comprising:
30 sampling a first signal representative of electrical activity at a first region;

sampling a second signal representative of electrical activity at a second region, where the first signal and the second signal are sensed using different sensing channels;

5 selecting a first feature of the first signal, where a selection criterion is used to identify the first feature;

selecting a second feature of the second signal, where the selection criterion is used to identify the second feature;

10 for a plurality of normal complexes, determining a median signal amplitude for the first feature relative a baseline signal of the first signal, and a median signal amplitude for the second feature relative a baseline signal of the second signal;

during an episode, determining a signal amplitude for the first feature relative the baseline signal of the first signal and the second feature relative the baseline signal of the second signal for a complex; and

15 when the signal amplitude for the first feature exceeds the median signal amplitude for the first feature by a predetermined amount or the signal amplitude of the second feature exceeds the median signal amplitude for the second feature by the predetermined amount, characterizing the complex as a rapid complex.

20

42. The method of claim 41, where the selection criterion is determining a maximum deflection of the first signal and the second signal.

25 43. The method of claim 41, including redetermining the median signal amplitude for the first feature and the median signal amplitude for the second feature when either the median signal amplitude for the first feature or the median signal amplitude for the second feature have a variability of greater than 20 percent.

30

44. The method of claim 41, including:
sampling a plurality of complexes;

determining a percentage of rapid complexes in the plurality of complexes; and

determining therapy for treating a rapid event when the percentage exceeds a predetermined percentage threshold.

5

45. The method of claim 44, where the predetermined percentage threshold is 50 percent.

46. A method, comprising:

10 sensing a first signal, the first signal including a complex;
sensing a second signal, the second signal including the complex;
determining a time difference between at least one feature on the complex in the first signal and the second signal during an episode;
comparing the time difference to a template time difference; and
15 characterizing the complex as a rapid complex when the time difference exceeds the template time difference value by a predetermined margin.

47. A method, comprising:

sensing a first signal, the first signal including a complex;
20 sensing a second signal, the second signal including the complex;
determining a metric from the complex in the first signal and the second signal during an episode;
comparing the metric from the complex in the first and second signal to a template metric; and
25 characterizing the complex based on the comparison of the metric.

48. A system, comprising:

at least one lead;
a sensing system attached to the at least one lead; and
30 a control system attached to the sensing system, where the control system monitors a first signal and a second signal for complexes;

a morphology analyzer circuit coupled to the control system, where the morphology analyzer circuit locates in the complexes at least one feature in the first signal and the second signal;

5 a signal feature comparison circuit coupled to the morphology analyzer circuit, where the signal feature comparison circuit measures a metric of the at least one feature in the first and second signal and compares the metric to a template, where the control system characterizes the complex based on the comparison of the metric.

- 10 49. The system or method of any of the forgoing claims, wherein:
- the first region is a first cardiac region;
 - the second region is a second cardiac region;
 - the third region is a third cardiac region;
 - the complex is a QRS-cardiac complex;
 - 15 the cycle is a cardiac cycle;
 - the episodes is a tachycardia episode;
 - the plurality of complexes is a plurality QRS-cardiac complexes;
 - the normal rhythm is a normal sinus rhythm;
 - the rapid complex is a ventricular tachycardia complex;
 - 20 the first representative complex is a first normal sinus rhythm (NSR) representative complex;
 - the second representative complex is a second normal sinus rhythm (NSR) representative complex; and
 - the sensing channels are cardiac sensing channels.

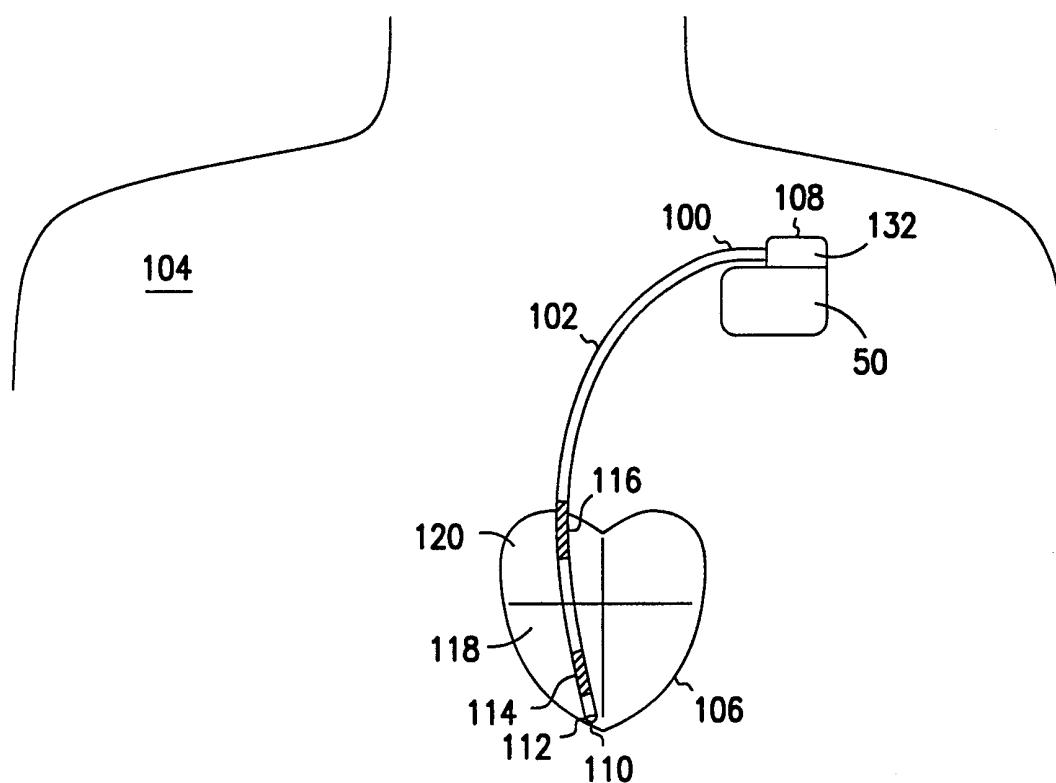


FIG. 1

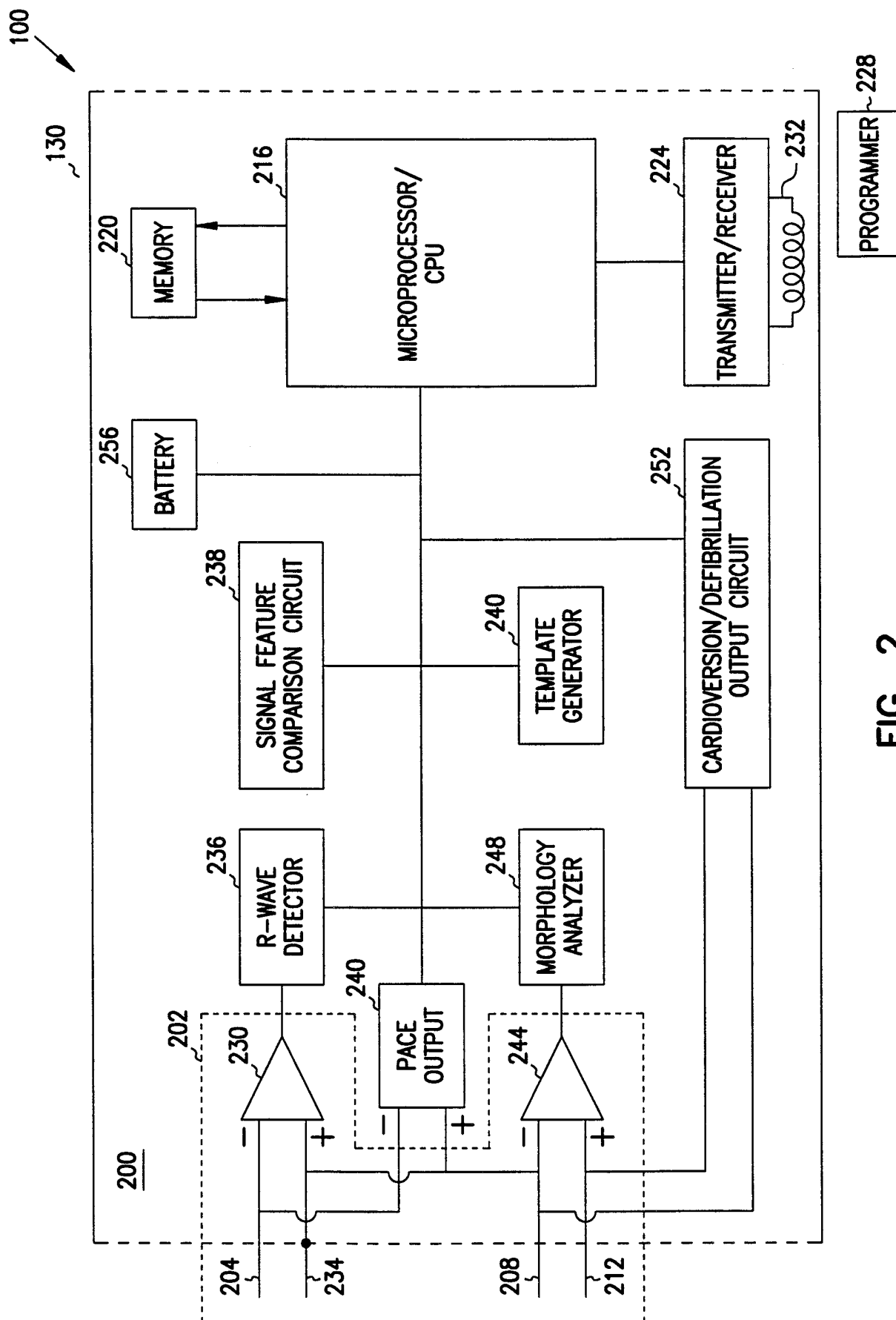


FIG. 2

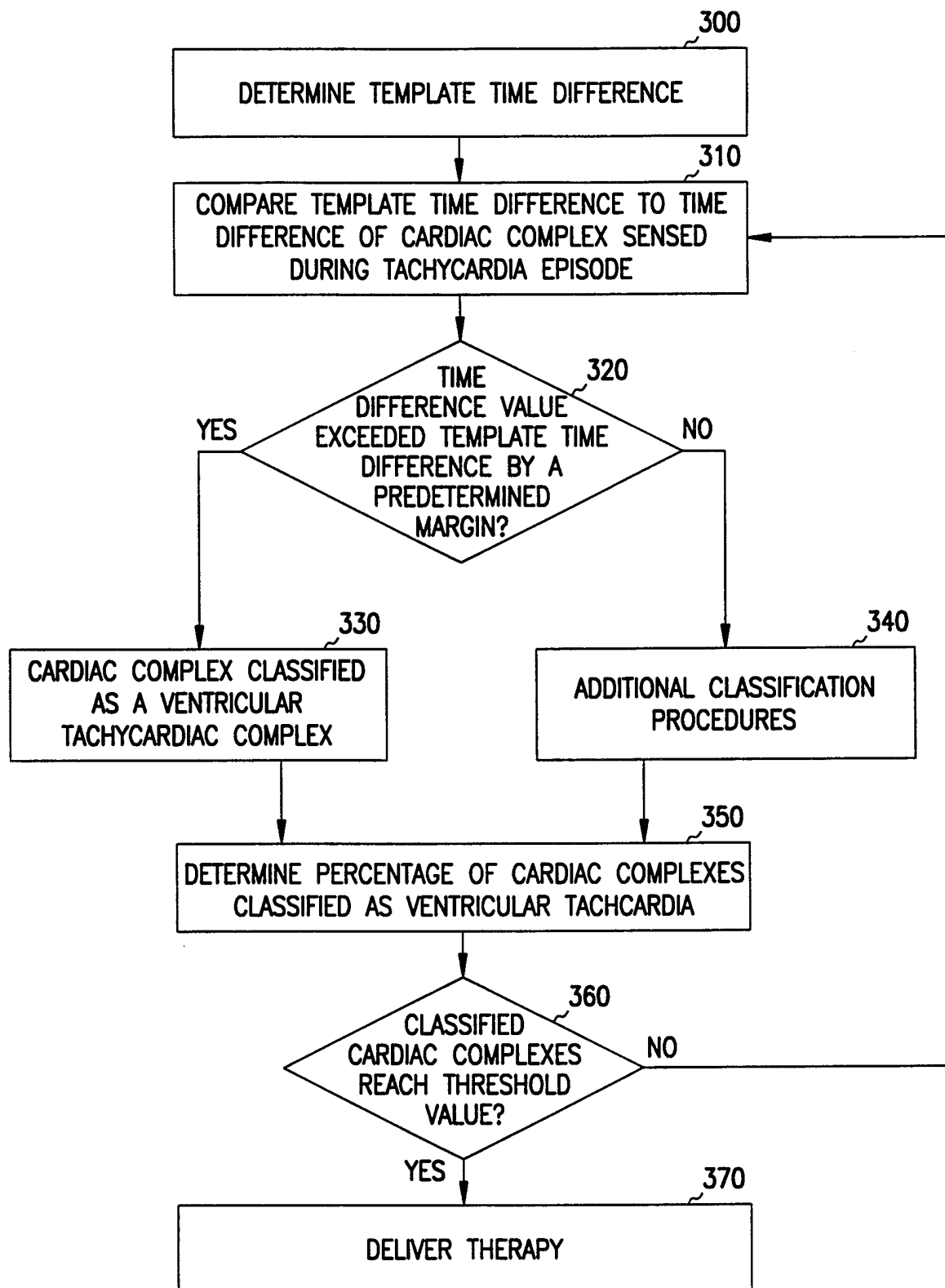


FIG. 3

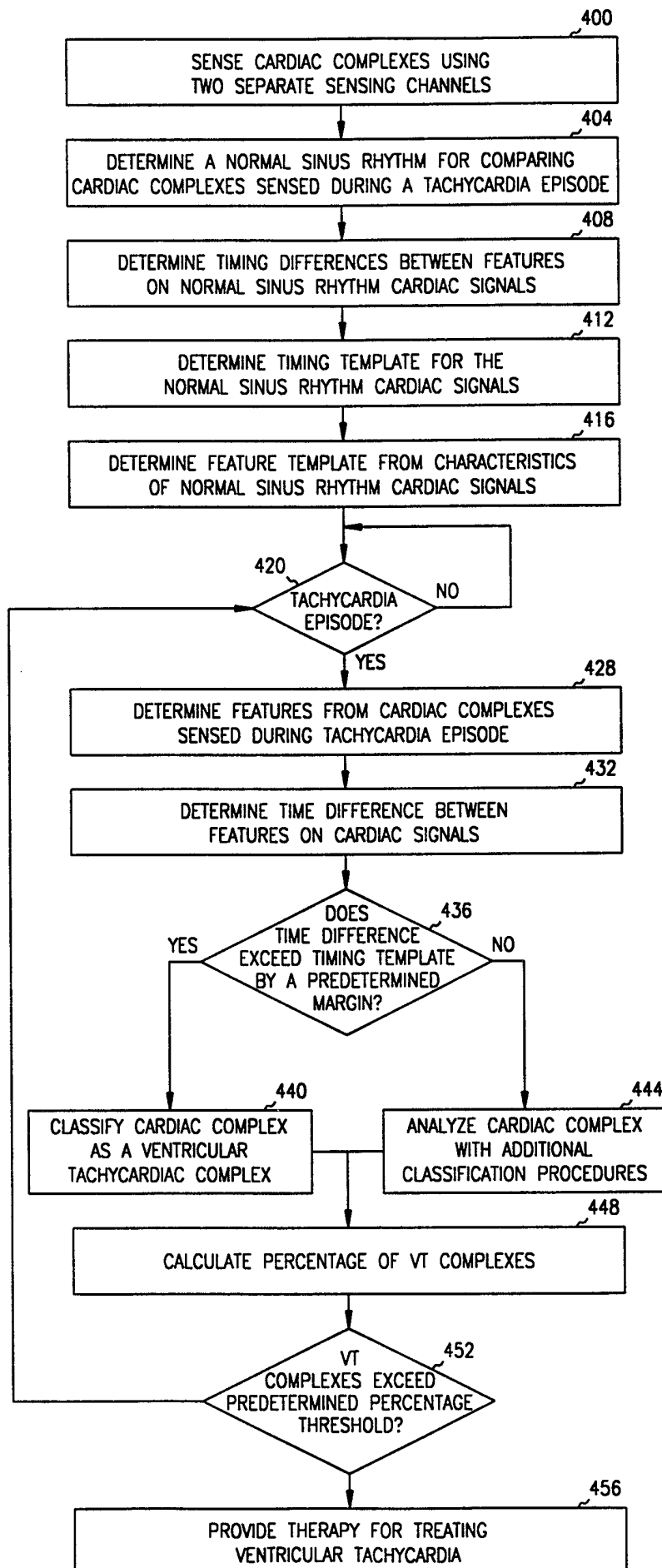


FIG. 4

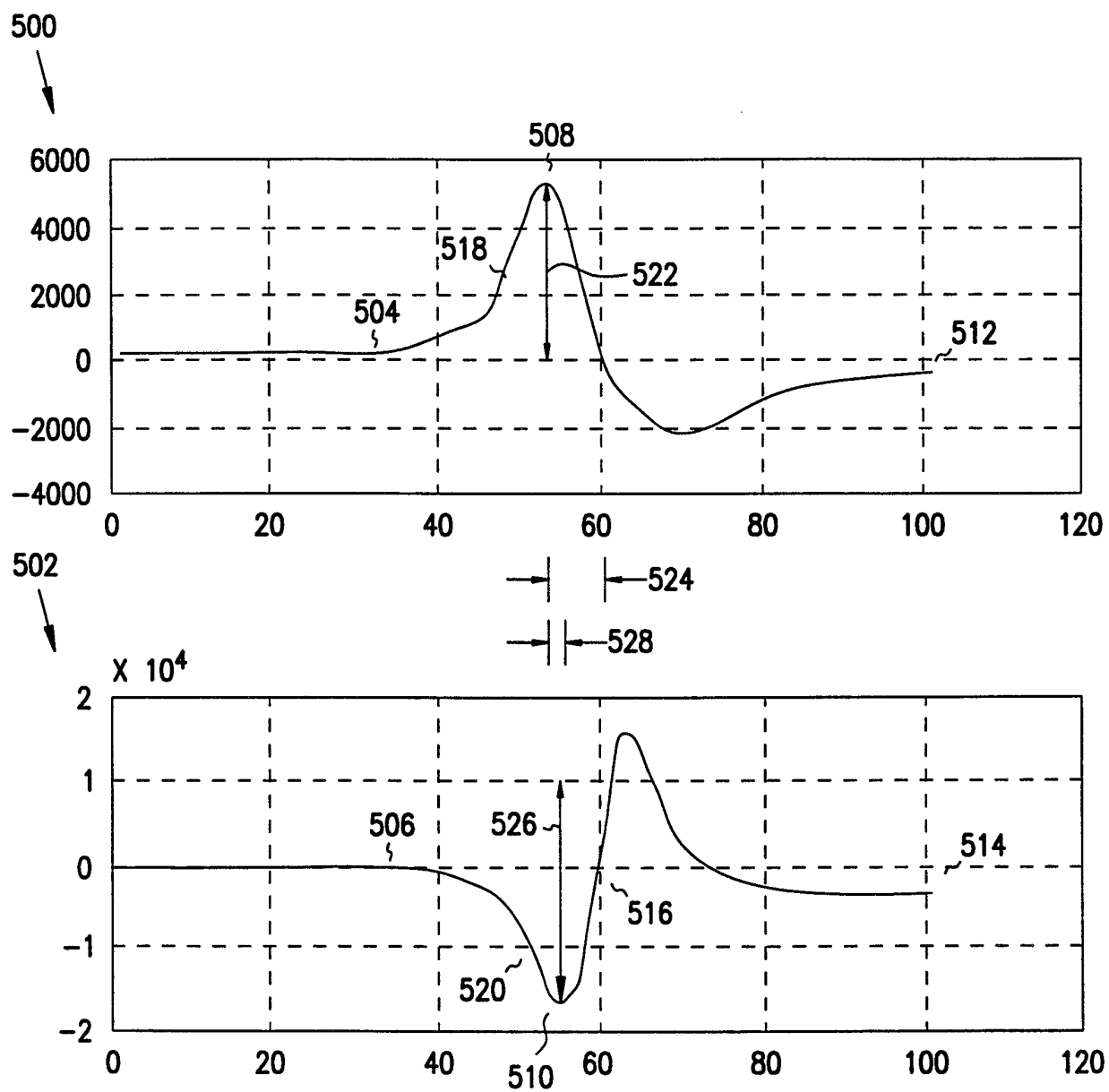


FIG. 5

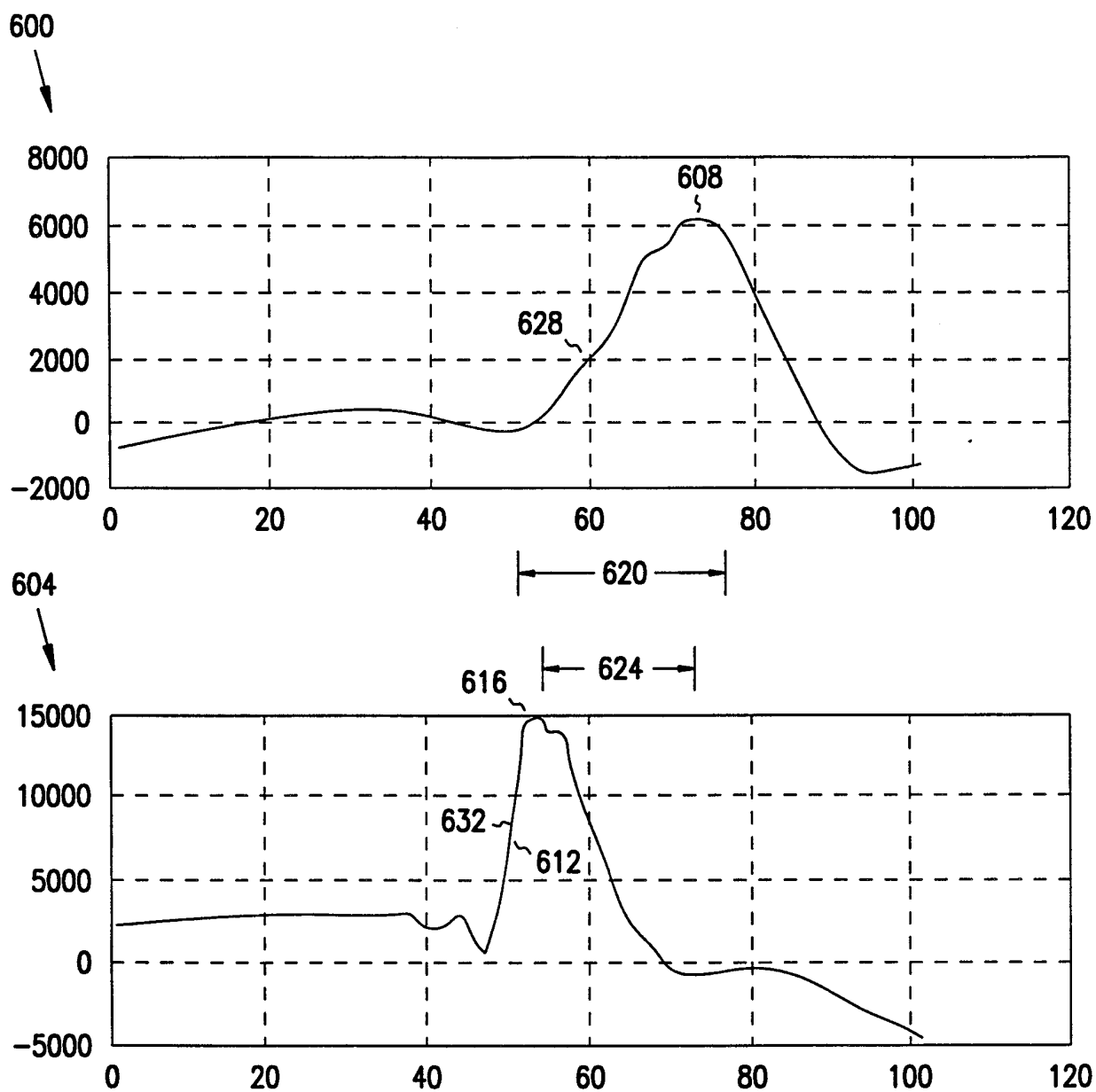


FIG. 6

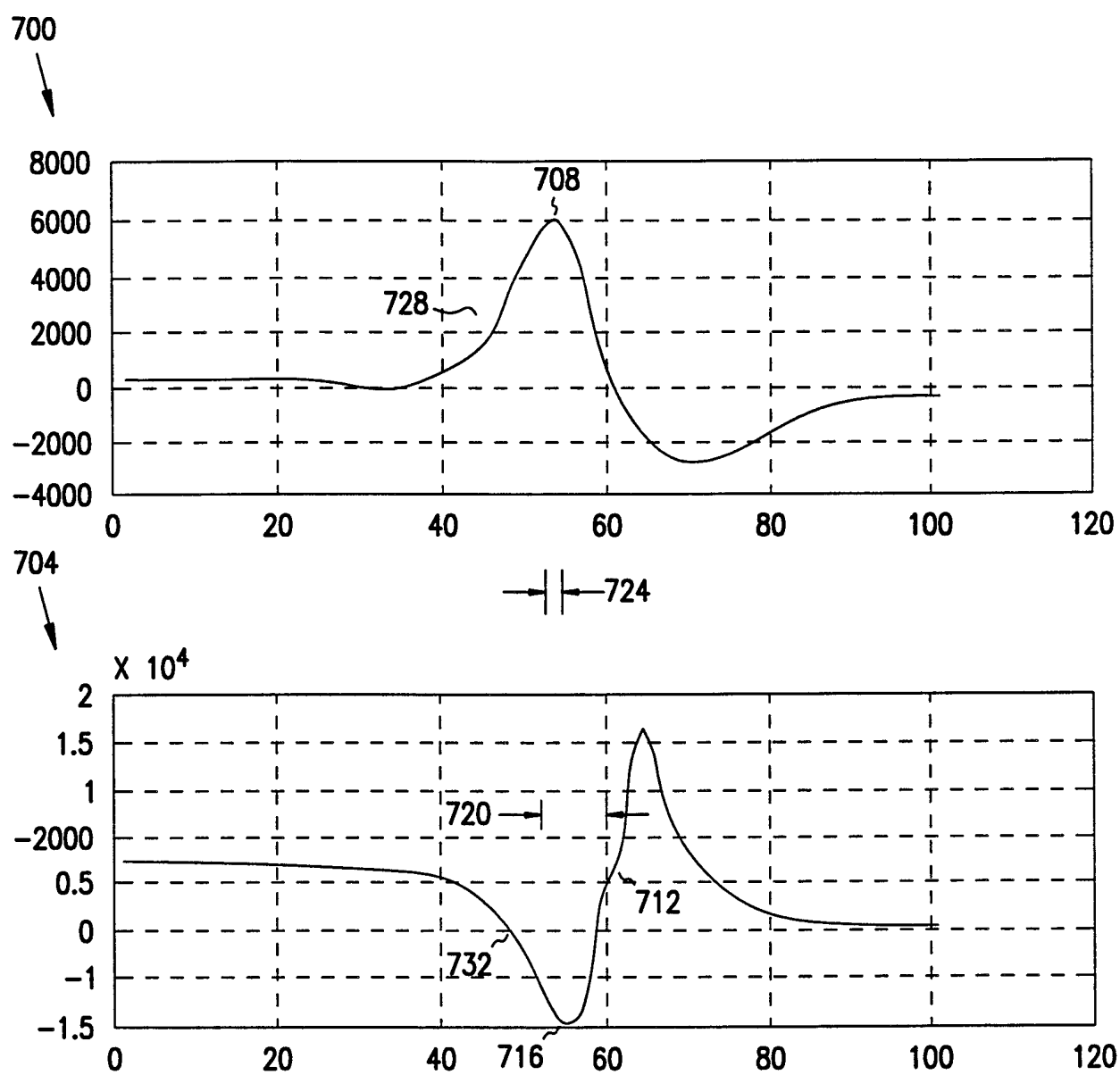


FIG. 7

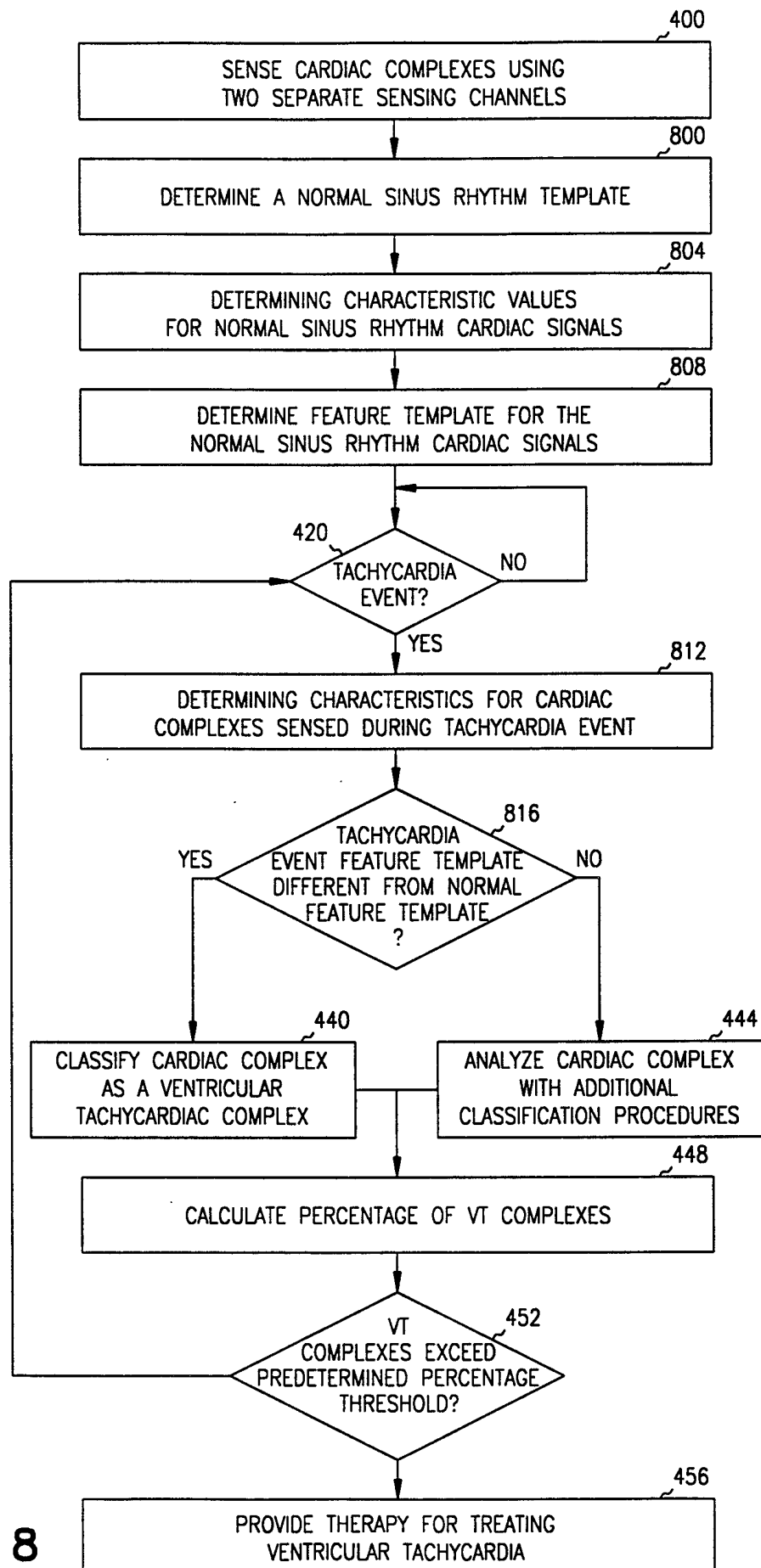


FIG. 8

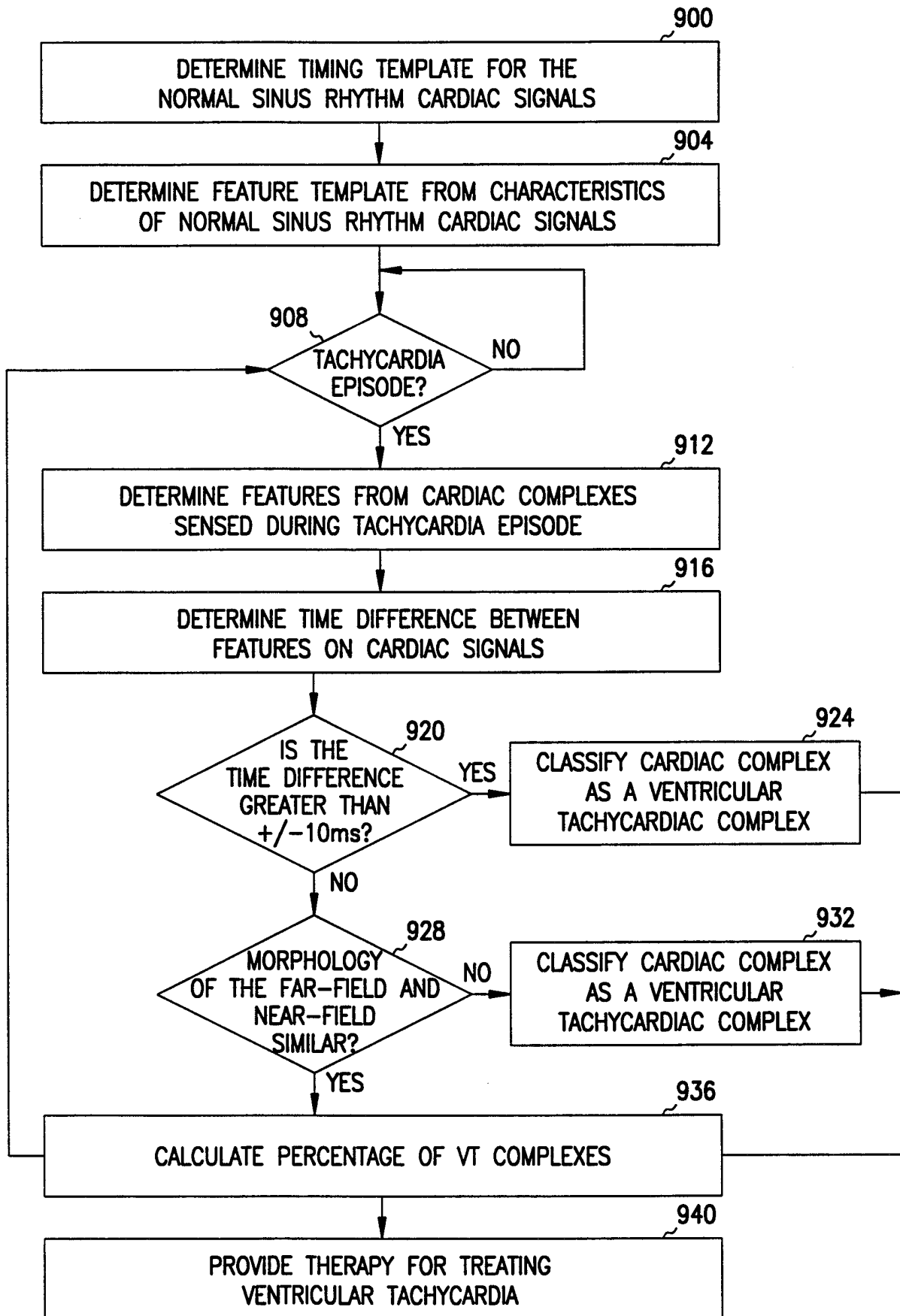


FIG. 9

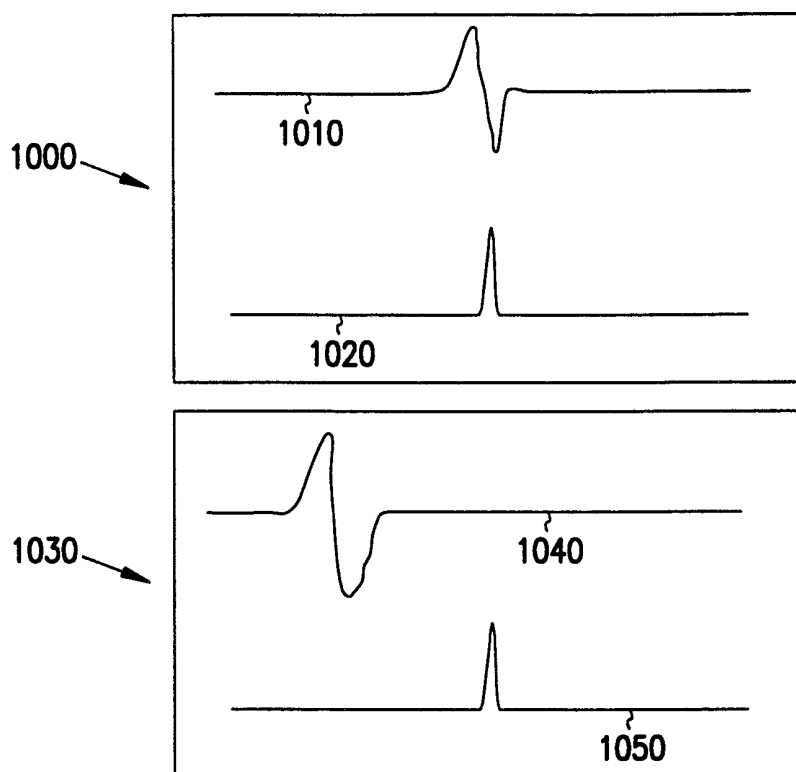


FIG. 10

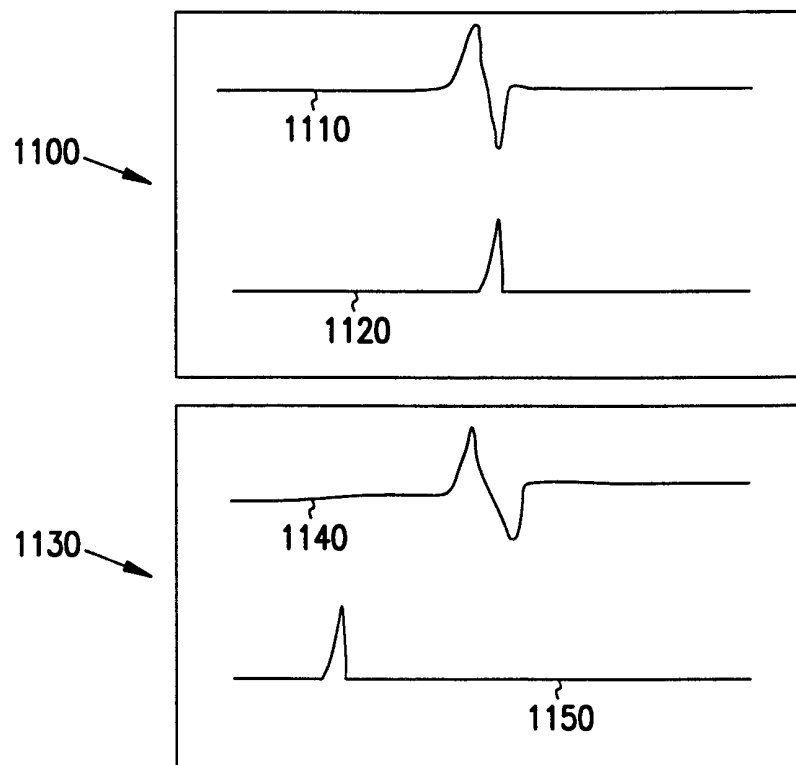


FIG. 11

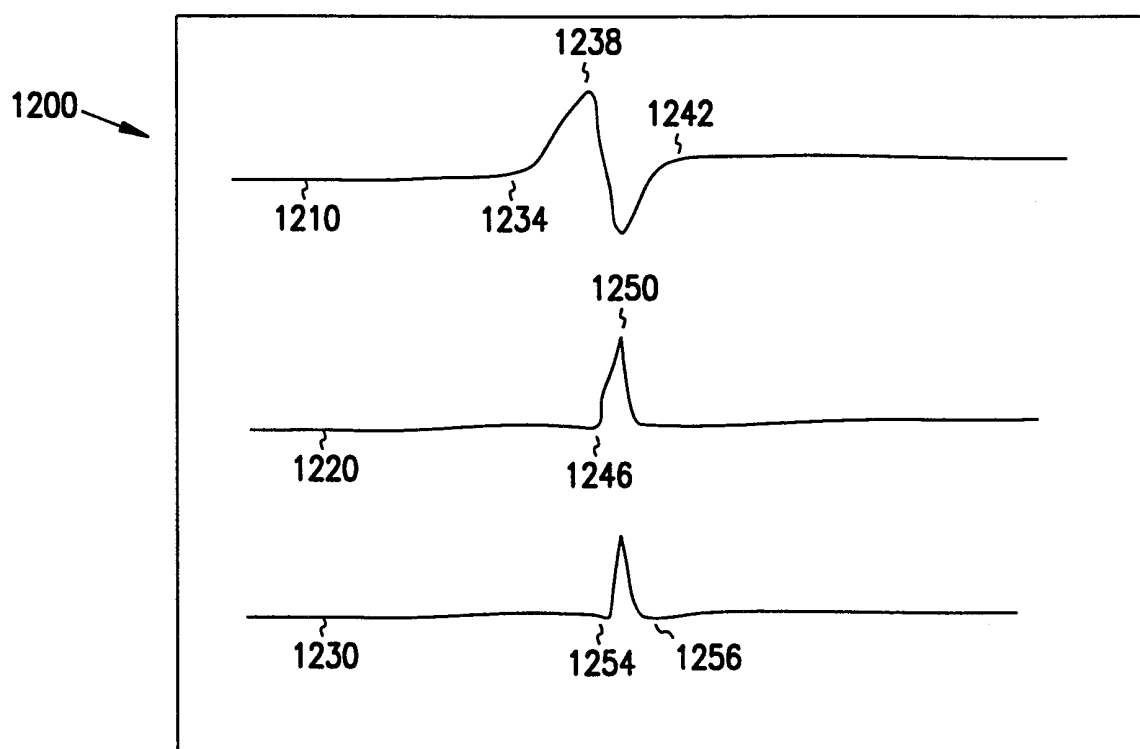


FIG. 12

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 00/03556

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/368

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61N A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 400 795 A (BASSIN DAVID ET AL) 28 March 1995 (1995-03-28) the whole document ---	1,48
A	US 5 275 621 A (MEHRA RAHUL) 4 January 1994 (1994-01-04) column 1, line 61 -column 2, line 64; figures ---	1,48
A	US 5 755 739 A (PANKEN ERIC J ET AL) 26 May 1998 (1998-05-26) abstract column 1, line 26 - line 35 column 8, line 66 -column 9, line 5 column 10, line 21 -column 13, line 19 figure 4 --- -/--	1,48

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

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

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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

"&" document member of the same patent family

Date of the actual completion of the international search

18 May 2000

Date of mailing of the international search report

24/05/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Ferrigno, A

INTERNATIONAL SEARCH REPORT

Inte. .onal Application No

PCT/US 00/03556

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>WO 98 53879 A (CARDIAC PACEMAKERS) 3 December 1998 (1998-12-03) page 8, line 26 -page 9, line 24 page 12, line 5 - line 18 figures</p> <p style="text-align: center;">---</p>	1,48
A	<p>US 5 447 519 A (PETERSON DAVID K) 5 September 1995 (1995-09-05) the whole document</p> <p style="text-align: center;">---</p>	1,48
A	<p>US 5 193 550 A (DUFFIN EDWIN G) 16 March 1993 (1993-03-16) the whole document</p> <p style="text-align: center;">---</p>	1,48
A	<p>US 5 366 487 A (ADAMS THEODORE P ET AL) 22 November 1994 (1994-11-22) the whole document</p> <p style="text-align: center;">---</p>	1,48

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 00/03556

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 18-47
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Diagnostic method practised on the human or animal body: the claimed method relates to a diagnosis of a cardiac arrhythmia (cf. page 1 of the description) and involves the selection of a therapy (cf. claim 27) for treating the arrhythmia.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. .onal Application No

PCT/US 00/03556

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5400795 A	28-03-1995	EP 0653224 A	17-05-1995
US 5275621 A	04-01-1994	AU 3471093 A	18-11-1993
		CA 2102492 A,C	14-10-1993
		DE 69314747 D	27-11-1997
		DE 69314747 T	20-05-1998
		EP 0592617 A	20-04-1994
		JP 2601762 B	16-04-1997
		JP 6503505 T	21-04-1994
		WO 9320891 A	28-10-1993
US 5755739 A	26-05-1998	NONE	
WO 9853879 A	03-12-1998	EP 0988088 A	29-03-2000
US 5447519 A	05-09-1995	NONE	
US 5193550 A	16-03-1993	AU 651649 B	28-07-1994
		AU 9112191 A	25-06-1992
		CA 2095014 A	31-05-1992
		DE 69106531 D	16-02-1995
		DE 69106531 T	11-05-1995
		EP 0559780 A	15-09-1993
		WO 9209331 A	11-06-1992
US 5366487 A	22-11-1994	DE 69319641 D	20-08-1998
		DE 69319641 T	18-02-1999
		EP 0560569 A	15-09-1993