(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
13 April 2006 (13.04.2006)

PCT

(10) International Publication Number
WO 2006/039694 A2

(51) International Patent Classification:
A61N 1/362 (2006.01) *A61B 5/0452* (2006.01)

(21) International Application Number:
PCT/US2005/035641

(22) International Filing Date:
30 September 2005 (30.09.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

10/955,831	30 September 2004 (30.09.2004)	US
10/995,655	23 November 2004 (23.11.2004)	US
10/995,704	23 November 2004 (23.11.2004)	US
10/996,340	23 November 2004 (23.11.2004)	US

(71) Applicant *(for all designated States except US)*: **CARDIAC PACEMAKERS, INC.** [US/US]; 4100 Hamline Avenue North, Saint Paul, MN 55112 (US).

(72) Inventors: **KIM, Jaeho**; 13323 Northeast 69th Way, Redmond, WA 98052 (US). **BOCEK, Joseph**; 857 E. Gwinn Place, Seattle, WA 98102 (US). **LOVETT, Eric, G.**; 1080 Lovell Avenue, Roseville, MN 55113 (US). **CAZARES, Shelley, Marie**; 110 West Grand Avenue, Apt.20D, Minneapolis, MN 55403 (US). **LIN, Yayun**; 1866 Huron Avenue, St. Paul, MN 55113 (US). **SATHAYE, Alok**; 110 West Grant Street, Apt.25A, Minneapolis, MN 55403 (US).

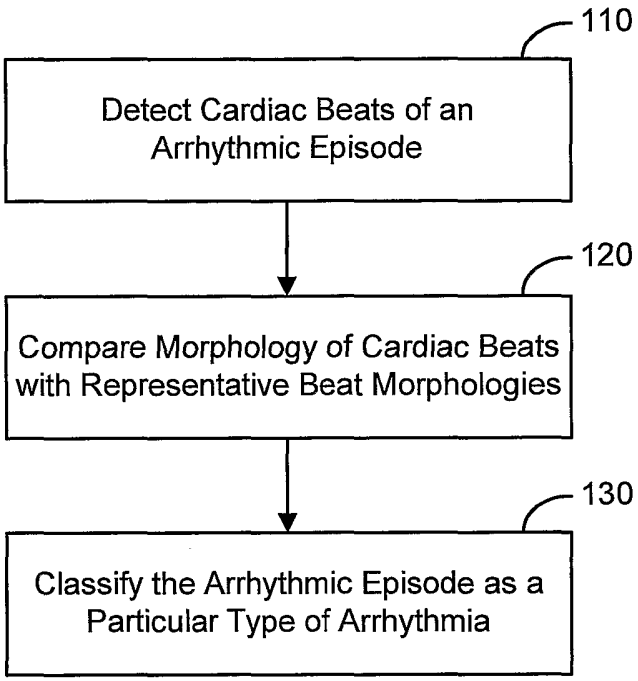
(74) Agent: **DAVIS, Clara**; Hollingsworth & Funk, LLC, 8009 34th Avenue South, Suite 125, Minneapolis, MN 55425 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT,

[Continued on next page]

(54) Title: ARRHYTHMIA CLASSIFICATION AND THERAPY SELECTION



(57) Abstract: Different types of cardiac arrhythmia are classified based on the morphology of the arrhythmic beats. Cardiac beats associated with an arrhythmic episode are compared to a plurality of representative beat morphologies, each representative beat morphology characterizing a type of arrhythmia. An arrhythmic episode may be classified as a particular type of arrhythmia if the morphology of the arrhythmic cardiac beats matches a representative beat morphology characterizing the particular type of arrhythmia. A particular type of arrhythmia may be associated with one or more therapies used to treat the arrhythmia. The therapy used to treat the arrhythmia may comprise a therapy identified as a previously successful therapy, for example.

WO 2006/039694 A2

RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

ARRHYTHMIA CLASSIFICATION AND THERAPY SELECTION

FIELD OF THE INVENTION

The present invention relates generally to implantable medical devices, and more particularly, to classifying cardiac rhythms and providing arrhythmia therapy.

BACKGROUND OF THE INVENTION

Rhythmic contractions of a healthy heart are normally initiated by the sinoatrial (SA) node, specialized cells located in the upper right atrium. The SA node is the normal pacemaker of the heart. When functioning normally, the heart produces rhythmic contractions and is capable of pumping blood throughout the body. However, due to disease or injury, the heart rhythm may become irregular resulting in diminished blood circulation. Arrhythmia is a general term used to describe heart rhythm irregularities arising from a variety of physical conditions and disease processes.

A cardiac tachyarrhythmia that originates in a non-ventricular region of the heart is denoted a supra-ventricular tachyarrhythmia (SVT). Atrial fibrillation and atrial flutter are examples of SVT. Both conditions are characterized by rapid contractions of the atria resulting in hemodynamically inefficient pumping action.

Cardiac arrhythmias originating in a ventricular region of the heart are denoted ventricular tachyarrhythmias (VT). Some types of ventricular tachyarrhythmia are characterized by rapid ventricular contractions that are fairly regular and coordinated. Such rhythms can degenerate into ventricular fibrillation (VF). Ventricular fibrillation produces extremely rapid, non-coordinated contractions of the ventricles and is fatal unless the heart is returned to sinus rhythm within a few minutes.

Implantable cardiac rhythm management (CRM) devices, including pacemakers and implantable cardioverter/defibrillators (ICDs), have been used to deliver effective treatment to patients with serious cardiac arrhythmias. Leads extending into the patient's heart are connected to electrodes electrically coupled to the myocardium for sensing the heart's electrical signals and for delivering stimulation pulses to the heart in accordance with various therapies for treating the arrhythmias.

A number of CRM devices having various modes for sensing and pacing one or more heart chambers and can treat cardiac arrhythmias using a variety of tiered therapies. These tiered therapies range from the delivery of low energy pacing pulses timed to assist the heart in maintaining pumping efficiency to high energy shocks to terminate fibrillation. To effectively deliver these treatments the CRM device must first identify the type of arrhythmia that is occurring.

For the reasons stated above, and for other reasons stated below which will become apparent to those skilled in the art upon reading the present specification, there is a need in the art for methods and systems that accurately identify and treat cardiac arrhythmias. There exists a further need to deliver proper cardiac therapy. The present invention fulfills these and other needs.

SUMMARY OF THE INVENTION

Various embodiments of present invention are directed to systems for classifying types of cardiac arrhythmia and/or for delivering cardiac therapies. In one embodiment of the invention, a cardiac arrhythmia classification system is implemented to classify arrhythmic episodes. The cardiac arrhythmia classification system includes a sensor system comprising electrodes for electrically coupling to a heart. The sensor system is configured to detect cardiac beats associated with an arrhythmic episode of the heart. An arrhythmia classification processor is coupled to the sensor system. The arrhythmia classification processor is configured to compare the morphology of each cardiac beat to a plurality of representative beat morphologies respectively associated with a plurality of types of arrhythmia. The arrhythmia classification processor classifies the arrhythmic episode as a particular type of arrhythmia if the morphologies of the cardiac beats are consistent with a representative beat morphology of a particular type of arrhythmia.

According to one aspect of this embodiment, the arrhythmia classification processor is configured to classify the arrhythmic episode as an unknown type of arrhythmia if the morphologies of the cardiac beats are not consistent with any of the plurality of representative beat morphologies.

According to another aspect of this embodiment the arrhythmia classification processor is configured to compare the morphology of each cardiac beat to the plurality of representative beat morphology templates and classify the arrhythmic episode as the particular type of arrhythmia if the morphologies of the cardiac beats are consistent with a representative beat morphology template associated with the particular type of arrhythmia.

According to a further aspect of this embodiment, the arrhythmia classification processor is configured to compare the morphology of each cardiac beat to the plurality of representative beat morphologies in a selected order. The selected order may be based on history of success of the representative beat morphologies at identifying an arrhythmia.

According to another aspect of this embodiment the arrhythmia classification processor is configured to classify the arrhythmic episode as an unknown type of arrhythmia if the morphologies of the cardiac beats are not consistent with the plurality of representative beat morphologies and to determine that the arrhythmic episode is characterizable as a new type of arrhythmia if the cardiac beats are classified as the unknown type of arrhythmia and to determine a representative beat morphology associated with the new type of arrhythmia.

According to another aspect of this embodiment the arrhythmia classification processor is configured to classify the arrhythmic episode as an unknown type of arrhythmia if the morphologies of the cardiac beats are not consistent with the plurality of representative beat morphologies and determine that the cardiac beats are morphologically uncharacterizable if a representative beat morphology cannot be acquired for the cardiac beats.

In another aspect of this embodiment, the arrhythmia classification processor is configured to associate a set of arrhythmia discrimination parameters with the particular type of arrhythmia and to compare the morphology of each cardiac beat to the representative beat morphology using the set of arrhythmia discrimination parameters associated with the particular type of arrhythmia.

The arrhythmia classification processor is configured to modify the one or more of the arrhythmia discrimination parameters to enhance characterization of the particular type of arrhythmia. For example, the arrhythmia classification processor may be configured to modify one or more arrhythmia discrimination parameters before comparing each cardiac beat signal to the plurality of representative beat morphologies. The one or more

arrhythmia discrimination parameters may include one or more of an onset, rate, stability or duration parameter.

According to another aspect of this embodiment, a therapy processor is coupled to the arrhythmia classification processor, the therapy processor configured to associate one or more cardiac therapies respectively with the one or more types of arrhythmia and to deliver one or more particular therapies associated with the particular type of arrhythmia if the cardiac beats are characterized as the particular type of arrhythmia.

According to another aspect of this embodiment the cardiac beat signals are ventricular beat signals, the plurality of representative beat morphologies are a plurality of ventricular tachyarrhythmia templates and the one or more cardiac therapies are ventricular therapies.

According to another aspect of this embodiment, the cardiac beat signals are atrial beat signals, the plurality of representative beat morphologies are a plurality of atrial tachyarrhythmia templates, and the one or more cardiac therapies are atrial therapies.

According to another aspect of this embodiment, the arrhythmia classification processor is configured to classify the arrhythmic episode as an unknown type of cardiac arrhythmia if the morphology of the cardiac beats is not consistent with any of the plurality of representative beat morphologies and the therapy processor is configured to deliver one or more selected therapies to treat the unknown arrhythmia if the arrhythmic episode is classified as the unknown type of cardiac arrhythmia.

According to another aspect of this embodiment, the therapy processor is configured to associate at least one cardiac therapy with an arrhythmia that was successfully treated using the at least one cardiac therapy.

According to another aspect of this embodiment the therapy processor is configured to deliver the one or more particular therapies in a selected order based on a history of success of the one or more particular therapies.

According to another aspect of this embodiment the arrhythmia classification processor is configure to classify the arrhythmic episode as an unknown type of cardiac arrhythmia if the morphologies of the cardiac beats are not consistent with any of the plurality of representative beat morphologies, attempting to acquire a new representative beat morphology associated with the unknown type of cardiac arrhythmia and associate

the new representative beat morphology with a new type of cardiac arrhythmia if the new representative beat morphology is acquired.

According to another aspect of this embodiment the therapy processor is configured to deliver one or more selected therapies to terminate the new type of cardiac arrhythmia, determine if a particular one or more of the selected therapies is successful and associate the successful therapy with the new type of cardiac arrhythmia.

According to another aspect of this embodiment the arrhythmia classification processor is configured to determine that the cardiac beats are an uncharacterizable cardiac arrhythmia if the representative beat morphology is not acquired.

According to another aspect of this embodiment the arrhythmia classification processor is configured to determine that the arrhythmic episode is uncharacterizable if morphologies of cardiac beat signals are unstable from beat to beat.

According to another aspect of this embodiment the therapy processor is configured to deliver one or more selected therapies to terminate the uncharacterizable cardiac arrhythmia, determine if a particular one of the one or more selected therapies is successful and associate the successful therapy with the uncharacterizable cardiac arrhythmia.

According to another aspect of this embodiment one or more of the plurality of representative beat morphologies determined based at least in part on user input.

According to another aspect of this embodiment one or more of the plurality of representative beat morphologies are deleted based at least in part on user input.

According to another aspect of this embodiment one or more of the plurality of representative beat morphologies are automatically determined.

According to another aspect of this embodiment the arrhythmia classification processor is further configured to determine if the particular type of arrhythmia is a sustained or unsustained arrhythmia and a therapy processor is configured to deliver the one or more particular therapies associated with the particular type of arrhythmia if the particular type of arrhythmia was determined to be a sustained arrhythmia during one or more previous arrhythmic episodes.

According to another aspect of this embodiment the arrhythmia classification processor is configured to determine a duration of the particular arrhythmia if the particular arrhythmia is unsustained and the therapy processor is configured to delay

therapy for a period of time associated with the duration of the particular unsustained arrhythmia determined during one or more previous arrhythmic episodes.

According to another aspect of this embodiment the arrhythmia classification processor is configured to reclassify the arrhythmic episode after delivery of a therapy.

According to another aspect of this embodiment the plurality of cardiac therapies comprises one or more antitachyarrhythmia pacing therapies or one or more cardioversion therapies or one or more defibrillation therapies or any combination of antitachyarrhythmia pacing therapies, cardioversion therapies and defibrillation therapies.

According to another aspect of this embodiment the therapy processor delivers the one or more particular therapies associated with the particular type of arrhythmia based at least in part on additional patient information. The additional patient information may include, for example, drug regimen information, medical information, neural activity information, patient activity information, hemodynamic status information, cardiac tissue impedance information, transthoracic impedance information, respiratory information, or any combination thereof.

According to another aspect of this embodiment the therapy processor delivers the one or more particular therapies associated with the particular type of arrhythmia based at least in part on rate of the arrhythmic episode.

According to another aspect of this embodiment the therapy processor is configured to associate the one or more cardiac therapies respectively with the one or more types of arrhythmia based on satisfaction with the one or more cardiac therapies. Satisfaction may be determined based on one or more of the prior effectiveness of one or more cardiac therapies, the length of time the one or more cardiac therapies were applied before mitigating previous arrhythmic episodes, pain caused by the one or more cardiac therapies during previous arrhythmic episodes, and energy requirements of the one or more cardiac therapies.

According to another aspect of this embodiment the therapy processor eliminates a previous therapy as an option for treating a subsequent arrhythmic episode if the previous therapy was unsuccessful.

According to another aspect of this embodiment the arrhythmia classification processor arbitrates between two or more representative beat morphologies if the cardiac

beats of the arrhythmic episode are consistent with the two or more representative beat morphologies.

Another embodiment of the invention involves a cardiac arrhythmia classification system. The system includes a sensor system comprising electrodes for electrically coupling to a heart. The sensor system is configured to detect cardiac beat signals associated with an arrhythmic episode of the heart. An arrhythmia classification processor is coupled to the sensor system. The arrhythmia classification processor is configured to compare each cardiac beat signal to a plurality of templates respectively associated with a plurality of types of arrhythmia and classify the arrhythmic episode as a particular type of arrhythmia if the cardiac beat signals correspond to a particular template associated with a particular type of arrhythmia. The processor is further configured to determine if the arrhythmic episode is characterizable as a new type of arrhythmia if the cardiac beat signals do not correspond to any template of the plurality of templates. The arrhythmia classification processor may be configured to acquire a template representing the new type of arrhythmia.

For example, each template of the plurality of templates may include at least one morphological feature of the cardiac beat signals. One or more templates of the plurality of templates may be determined based at least in part on user input. One or more templates of the plurality of templates may be deleted based at least in part on user input. One or more templates of the plurality of templates may be automatically determined or deleted.

In some implementations, the arrhythmia classification processor may be configured to determine whether the arrhythmic episode is characterizable as the new type of arrhythmia if a template can be acquired that characterizes the cardiac beat signals. The arrhythmia classification processor may be configured to determine that the arrhythmic episode is uncharacterizable if a template cannot be acquired for the cardiac beat signals. The arrhythmia classification processor may be configured to determine that the arrhythmic episode is uncharacterizable if morphologies of cardiac beat signals are unstable from beat to beat.

According to one scenario, the cardiac beat signals are ventricular beat signals and the plurality of templates comprises a plurality of ventricular tachyarrhythmia templates.

According to another scenario the cardiac beat signals are atrial beat signals and the plurality of templates comprises a plurality of atrial tachyarrhythmia templates.

In some implementations, the arrhythmia classification processor may be configured to alter one or more arrhythmia discrimination parameters before comparing each cardiac beat signal to the plurality of templates respectively associated with a plurality of types of arrhythmia to facilitate characterizing the arrhythmia. For example, the one or more arrhythmia discrimination parameters may comprise an onset, rate, stability or duration parameter.

Another embodiment of the invention is directed to a cardiac arrhythmia classification system. The system includes a sensor system comprising electrodes for electrically coupling to a heart. The sensor system is configured to detect cardiac beat signals associated with an arrhythmic episode of the heart. The system also includes an arrhythmia classification processor coupled to the sensor system. The arrhythmia classification processor is configured to compare each cardiac beat signal to a plurality of templates according to a selected order of templates. The plurality of templates are respectively associated with a plurality of types of arrhythmia. The arrhythmia classification processor is configured to classify the arrhythmic episode as a particular type of arrhythmia if the cardiac beat signals correspond to a particular template associated with a particular type of arrhythmia. The selected order of the templates may be based on success of the templates at identifying previously detected arrhythmic episodes.

The system may further include a therapy unit configured to deliver therapy to treat the arrhythmic episode. The therapy unit is configured to associate one or more therapies respectively with each of the plurality of arrhythmia types and to deliver a particular one or more therapies associated with the particular arrhythmia. The therapy unit may be configured to associate the one or more therapies respectively with each of the plurality of arrhythmia types based on success of the one or more therapies.

Yet another embodiment of the invention is directed to an apparatus including at least one electrical sensor configured to sense an intrinsic electrical heart signal and a memory circuit configured to store candidate supraventricular tachyarrhythmia (SVT) templates respectively associated with heart rates. The apparatus further includes a processor configured to determine a heart rate from the intrinsic heart signal. The processor selects an SVT template associated with the heart rate of the intrinsic heart

signal from the candidate supraventricular tachyarrhythmia templates and determines whether antitachyarrhythmia therapy should be delivered in response to a tachyarrhythmia episode based on the degree of similarity between the heart signal and the selected SVT template.

According to one aspect of the embodiment, the processor is further configured to discard the oldest candidate SVT template from the memory circuit to make room for a new SVT template. According to another aspect, the processor is configured to discard from the processing system the least frequently selected SVT template.

A further embodiment of the invention is directed to a template selection system. The system includes sensor circuitry configured to sense an intrinsic electrical heart signal of a patient, a memory configured to store a plurality of supraventricular tachyarrhythmia (SVT) templates, and circuitry configured to monitor patient information. A processor is coupled the sensor circuitry, memory, and monitoring circuitry. The processor is configured to select at least one supraventricular tachyarrhythmia (SVT) template from the plurality of SVT templates using the patient information and to determine if the heart signal represents an SVT episode based on the selected SVT template. For example, the processor may be configured to withhold treatment based on a similarity between the heart signal detected during a tachyarrhythmia episode and the selected SVT template. The patient information may comprise one or more of drug treatment, neural activity, sleep state, hemodynamic status, transthoracic impedance, and blood pressure. The processor may be configured to select the SVT template based on data from patients having characteristics similar to characteristics of the patient.

One embodiment of the invention is related to a template generation apparatus. The apparatus includes implantable sensor circuitry configured to sense an intrinsic electrical heart signal. An arrhythmia detector is configured to identify an arrhythmic episode of the intrinsic electrical heart signal. User interface circuitry is configured to present the arrhythmic episode to a user and to receive user input declaring the arrhythmic episode to be indicative of supraventricular tachyarrhythmia (SVT). A processor is configured to generate an SVT template from the arrhythmic episode based on the user input.

For example, the user interface circuitry may be configured to present a plurality of arrhythmic episodes of the heart signal to the user and to receive user input indicating which of the arrhythmic episodes are to be used to generate one or more SVT templates.

Another embodiment of the invention is directed to a cardiac therapy system. The system includes a sensor system comprising electrodes for electrically coupling to a heart of a patient. The sensor system is configured to detect cardiac beat signals of an arrhythmic episode of the heart. The system also includes an arrhythmia detector coupled to the sensor system. The arrhythmia detector is configured determine if the arrhythmic episode is characterizable, to compare a morphology of each cardiac beat signal to plurality of templates respectively associated with a plurality of types of arrhythmia, and to classify the arrhythmic episode as a particular type of arrhythmia if the morphologies of the cardiac beat signals are consistent with a template of a particular type of arrhythmia. A therapy processor is coupled to the arrhythmia classification processor. The therapy processor is configured to associate one or more cardiac therapies respectively with the one or more types of arrhythmia and to deliver one or more particular therapies associated with the particular type of arrhythmia if the cardiac beats are characterized as the particular type of arrhythmia.

In accordance with one aspect, the one or more particular therapies are associated with the particular type of arrhythmia based on a history of success of the one or more particular therapies. In accordance with another aspect of the arrhythmia detector is configured to classify the arrhythmic episode as an unknown type of arrhythmia if the morphology of the cardiac beats is not consistent with any of the plurality of representative beat morphologies. Another aspect of the invention involves a template generator configured to acquire a template associated with the unknown type of arrhythmia if the unknown type of arrhythmia is a new type of arrhythmia that is characterizable.

In one implementation, the therapy processor is configured to deliver one or more selected therapies to terminate the new type of arrhythmia, determine if a particular one of the selected therapies is successful, and associate the successful therapy with the new type of arrhythmia. The therapy processor may be configured to deliver one or more selected therapies if the arrhythmia is uncharacterizable. For example, the therapy processor may

be configured to determine if a particular one of the one or more selected therapies is successful, and to associate the successful therapy with the uncharacterizable arrhythmia.

In some implementations, the therapy processor is configured to associate the one or more cardiac therapies respectively with the one or more types of arrhythmia based at least in part on user input. The therapy processor may be configured to associate the one or more cardiac therapies respectively with the one or more types of arrhythmia based at least in part on data from a previous device of the patient.

According to one scenario, the cardiac beat signals are associated with ventricular beats, the templates are ventricular tachyarrhythmia templates, the one or more arrhythmias are ventricular tachyarrhythmias, and the one or more therapies are ventricular therapies. According to another scenario, the cardiac beat signals are associated with atrial beats, the templates are atrial tachyarrhythmia templates, the one or more arrhythmias are atrial tachyarrhythmias, and the one or more therapies are atrial therapies.

A further embodiment involves a cardiac therapy system. The system includes a sensor system comprising electrodes for electrically coupling to a heart of a patient. The sensor system configured to detect cardiac beat signals of an arrhythmic episode of the heart. The therapy system also includes an arrhythmia detector coupled to the sensor system and configured to compare a morphology of each cardiac beat signal to a plurality of templates respectively associated with a plurality of types of arrhythmia and to classify the arrhythmic episode as a particular type of arrhythmia if the morphologies of the cardiac beat signals are consistent with a template of a particular type of arrhythmia. The arrhythmia detector is further configured to determine if the particular type of arrhythmia is a sustained or unsustained arrhythmia. The therapy system also includes a therapy processor coupled to the arrhythmia classification processor. The therapy processor is configured to associate one or more cardiac therapies respectively with the one or more types of arrhythmia and to deliver one or more particular therapies associated with the particular type of arrhythmia if the cardiac beats are characterized as the particular type of arrhythmia and if the particular type of arrhythmia was determined to be a sustained arrhythmia during one or more previous arrhythmic episodes. In one implementation, the therapy processor is configured to associate the one or more cardiac therapies respectively

with the one or more types of arrhythmia based on a historical success of the one or more cardiac therapies.

According to some implementations, the arrhythmia detector is configured to determine a duration of the particular arrhythmia if the particular arrhythmia is unsustained. The therapy processor is configured to delay therapy for a period of time associated with the duration of the particular arrhythmia determined during one or more previous arrhythmic episodes. The arrhythmia detector may be configured to reclassify the arrhythmic episode after delivery of a therapy.

The plurality of cardiac therapies may comprise one or more antitachyarrhythmia pacing therapies and/or one or more cardioversion therapies and/or one or more defibrillation therapies.

Another embodiment of the invention relates to a medical system. The medical system includes a cardiac therapy system configured to deliver a cardiac therapy to a patient. The medical system includes a detector system configured to detect a cardiac waveform associated with a tachyarrhythmia. The medical system includes a processor coupled to the detector system and the cardiac therapy system. The processor is configured to provide one or more templates representative of cardiac signals of one or more of a patient's past tachyarrhythmia events and additional patient information associated with tachyarrhythmia episodes. Each of the templates is associated with a therapy to treat the tachyarrhythmia episodes. If the cardiac waveform corresponds to a particular template of the one or more templates and the additional patient information associated with the tachyarrhythmia events, the processor is configured to determine if a previous therapy associated with the particular template was satisfactory in terminating a past tachyarrhythmia event corresponding to the particular template, If the previous therapy is determined satisfactory the processor is configured to prompt the cardiac therapy system to deliver the previous therapy.

For example, the cardiac therapy system may be configured to deliver an anti-tachycardia pacing therapy to the patient to treat the tachyarrhythmia and determine one or both of the effectiveness and satisfaction of the anti-tachycardia pacing therapy.

The medical system may also include one or more of a patient activity sensor configured to provide patient activity information associated with tachyarrhythmia episodes to the template processor, a neural activity sensor configured to provide patient

neural activity information associated with tachyarrhythmia episodes to the template processor, a transthoracic impedance sensor configured to provide patient transthoracic impedance information associated with tachyarrhythmia episodes to the template processor, an accelerometer configured to provide acceleration information associated with tachyarrhythmia episodes to the template processor, a cardiac tissue impedance sensing system configured to provide patient cardiac tissue impedance information associated with tachyarrhythmia episodes to the template processor, a hemodynamic status sensor configured to provide patient hemodynamic status information associated with tachyarrhythmia episodes.

Another embodiment is directed to a medical system including a cardiac therapy system, detector system, and template processor. The cardiac therapy system is configured to deliver a cardiac therapy to a patient. The detector system is configured to detect a cardiac waveform associated with an arrhythmic event. The template processor coupled to the detector system and the cardiac therapy system. The template processor configured to provide, patient-externally, the cardiac waveform, identify, patient-externally, a portion of the cardiac waveform indicative of the arrhythmic event, generate a cardiac template corresponding to the cardiac waveform portion, and associate a therapy with the cardiac template useful for treating a subsequent arrhythmic event corresponding to the cardiac template.

According to one aspect, the cardiac therapy system is configured to provide an anti-tachycardia pacing therapy to the patient to treat the arrhythmic event and determine the effectiveness of the anti-tachycardia therapy. According to another aspect, the cardiac therapy system is configured to provide an anti-tachycardia pacing therapy to the patient to treat the arrhythmic event and determine if the treatment was satisfactory.

In one implementation, the medical system may include a communication system configured to communicate with a patient-external device housing the template processor. In another implementation, the medical system may include a communication system configured to communicate with a patient-external device accessible by a clinician, wherein the clinician may initiate or override addition of a new template if the cardiac waveform does not match with any existing templates.

The above summary of the present invention is not intended to describe each embodiment or every implementation of the present invention. Advantages and

attainments, together with a more complete understanding of the invention, will become apparent and appreciated by referring to the following detailed description and claims taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figures 1A and 1B are flowcharts of methods for classifying cardiac rhythms in accordance with embodiments of the invention;

Figures 2A and 2B are flowcharts illustrating a process in which a degree of similarity is determined between a SVT template and a heart signal in accordance with embodiments of the invention;

Figure 2C is a flowchart that illustrates a process in which a template is generated for an arrhythmia morphology that does not require antitachyarrhythmia therapy in accordance with embodiments of the invention;

Figure 3 is a flow chart that illustrates a method in which a degree of similarity is determined between a monitored heart signal and a SVT template selected from a group of candidate SVT templates in accordance with embodiments of the invention;

Figure 4 is a flowchart that illustrates a method in which a heart signal is compared to a normal sinus rhythm and a SVT template in accordance with embodiments of the invention;

Figure 5 is a flow chart that illustrates methods by which a SVT template is discarded from a storage medium and a new SVT template is added in accordance with embodiments of the invention;

Figure 6 is a flow chart that illustrates an embodiment of a process in which a heart signal from a tachyarrhythmia episode is compared to a normal sinus rhythm (NSR) template and then compared to a supraventricular tachyarrhythmia (SVT) template in accordance with embodiments of the invention;.

Figure 7 is a block diagram of an implantable device configured to determine similarity between a heart signal and at least one SVT template and to suppress ventricular antitachyarrhythmia therapy based on the similarity in accordance with embodiments of the invention;

Figure 8 shows an example of a normal sinus rhythm morphology;

Figure 9 shows an example of a SVT morphology;

Figures 10 and 11 are flowcharts of methods for classifying cardiac rhythms and delivering therapy to a patient in accordance with embodiments of the invention;

Figure 12 is a partial view of an implantable medical device suitable for implementing arrhythmia classification and therapy delivery methods in accordance with embodiments of the invention;

Figures 13A and 13B are a block diagram of a cardiac rhythm management system in accordance with embodiments of the invention;

Figure 14 is a flowchart illustrating a method for classifying arrhythmia and delivering cardiac therapy to a patient in accordance with embodiments of the invention;

Figure 15 is a graph illustrating a cardiac signal having cardiac waveform features useful for template creation in accordance with embodiments of the invention;

Figures 16A and 16B are graphs illustrating the use of rate and shock channel signals for arrhythmia classification in accordance with embodiments of the invention;

Figure 17 is a flowchart illustrating a method of forming a template that may be used for arrhythmia classification in accordance with embodiments of the invention;

Figure 18 is a flowchart of a method of therapy selection using patient response information in accordance with embodiments of the present invention;

Figure 19 is a flowchart illustrating a method of template selection and generation for therapy selection using patient response information in accordance with embodiments of the invention;

Figure 20 is a flow chart illustrating a method of determining patient therapy response information in accordance with embodiments of the invention;

Figure 21 is a block diagram illustrating determination of patient therapy response information in accordance with embodiments of the invention;

Figures 22A and 22B are flowcharts illustrating a method of providing therapy for characterizable and uncharacterizable arrhythmic episodes in accordance with embodiments of the invention;

Figure 22C is a flowchart illustrating a method of modifying arrhythmia discrimination parameters in accordance with embodiments of the invention;

Figures 23A and 23B are flowcharts illustrating a method of associating a successful therapy with a type of arrhythmia in accordance with embodiments of the invention;

Figure 24 illustrates a method of determining if a cardiac beat is correlated to a template in accordance with embodiments of the invention; and

Figure 25 provides graphs illustrating alignment of rate and shock channel signals of a cardiac beat and an arrhythmia template in accordance with embodiments of the invention.

Figure 26 is a flow chart illustrating a method of initializing templates in accordance with embodiments of the invention; and

Figure 27 is a block diagram of a medical system that may be used to implement arrhythmia therapy selection using patient therapy response information and other patient information in accordance with embodiments of the present invention.

While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail below. It is to be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the invention is intended to cover all modifications, equivalents, and alternatives falling within the scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF VARIOUS EMBODIMENTS

In the following description of the illustrated embodiments, references are made to the accompanying drawings which form a part hereof, and in which is shown by way of illustration, various embodiments in which the invention may be practiced. It is to be understood that other embodiments may be utilized, and structural and functional changes may be made without departing from the scope of the present invention.

Ventricular tachyarrhythmias are fast heart rhythms that arise within one or more ventricles. Atrial tachyarrhythmias, e.g., atrial flutter or atrial fibrillation, are fast heart rhythms that arise within one or more atria. Cardiac signals representative of ventricular or atrial tachyarrhythmic beats may involve a number of different morphologies. Some

types of tachyarrhythmia may be monomorphic. Cardiac signals representing a monomorphic tachyarrhythmia may exhibit a fairly regular rhythm and a similar shape or morphology.

Other types of tachyarrhythmia may comprise multi-morphology or polymorphic ventricular tachyarrhythmia. Each beat of a multi-morphology or polymorphic tachyarrhythmia may be different, making the polymorphic tachyarrhythmia difficult to characterize based on morphology. Ventricular fibrillation is an example of a polymorphic ventricular tachyarrhythmia that presents a disorganized, inconsistent morphology.

Episodes of monomorphic tachyarrhythmia may last only a few beats and may produce minimal symptoms. If the cardiac rate is relatively low, the tachyarrhythmia may be tolerated even if sustained for a number of minutes. Tachyarrhythmia may be treated using a variety of therapies. For example, in some cases, ventricular tachycardia (VT) may be effectively treated by pacing at relatively high energy output when compared to bradycardia pacing. Pacing to mitigate VT may involve one or more pacing bursts and is typically denoted anti-tachycardia pacing (ATP). Other types of VT may require a more aggressive therapy, including high energy cardioversion and/or defibrillation shocks. Still other types of VT may terminate spontaneously without therapy.

The most dangerous form of polymorphic ventricular tachyarrhythmia is ventricular fibrillation, which involves very rapid, small-scale, and uncoordinated contractions. The rapid contractions cause a precipitous drop in blood pressure and low cardiac output. Ventricular fibrillation involving heart rates in excess of about 220 beats per minute rarely terminate spontaneously and may be fatal without rapid therapeutic intervention. Typically therapy for ventricular fibrillation involves a series of high energy defibrillation shocks.

Various embodiments of the invention are directed to an automated process for classifying different types of arrhythmia, e.g., atrial or ventricular tachyarrhythmia. For example, each type of arrhythmia may be associated with a representative beat morphology. A detected arrhythmic episode may be classified as a particular type of arrhythmia by comparing a sample of tachyarrhythmic cardiac beats of the arrhythmic episode with a number of representative beat morphologies associated with the various types of arrhythmia. The arrhythmia may be classified as a particular type of arrhythmia if

the sample of the arrhythmic cardiac beats is consistent with the representative beat morphology associated with the particular arrhythmia type.

Various embodiments of the invention are directed to delivering a therapy based on the historical success of the therapy. One or more therapies that were previously successful at treating a particular type of arrhythmia may be associated with the representative beat morphology of the particular type of arrhythmia. Future occurrences of the particular type of arrhythmia may be first treated with a previously successful therapy.

A particular therapy may be selected to treat a particular type of VT. For example, if a therapy is determined to have successfully mitigated or terminated a particular type of VT, information identifying and associating the previously successful therapy with the particular type of VT may be stored in the CRM device memory and utilized by the therapy control unit. If a subsequent episode of the particular type of VT is detected, the previously successful therapy may be selected to treat the particular type of VT. Identification of a therapy that will be used for treatment of a particular type of VT may be performed automatically, e.g., by the CRM device, or manually, e.g., by a physician based on electrogram (EGM) or other data.

Methods, devices, and systems implementing arrhythmia classification and therapy selection in accordance with the present invention may incorporate one or more of the features, structures, methods, or combinations thereof described herein below. For example, a medical system may be implemented to include one or more of the features and/or processes described below. It is intended that such a method, device, or system need not include all of the features and functions described herein, but may be implemented to include one or more selected features and functions that provide useful structures and/or functionality.

While some of examples provided herein have generally been described in terms of an implanted or implantable device, the examples can also be implemented in non-implantable devices and systems, or some functionality may be implemented in an implantable device and other functionality may be implemented in a patient-external device where there is communication between the implantable and the patient-external devices.

The flowchart of Figure 1A illustrates a method of classifying arrhythmia in accordance with embodiments of the invention. As discussed above, various types of arrhythmia, for example, types of monomorphic atrial tachyarrhythmia or monomorphic ventricular tachyarrhythmia, exhibit characteristic beat morphologies that are relatively consistent from beat to beat for a given patient. The representative beat morphologies of various types of monomorphic tachyarrhythmia experienced by the patient may be identified and used to classify subsequent arrhythmic episodes.

An arrhythmic episode may initially be detected using rate criteria. For example, if a heart rate beyond a predetermined threshold is sensed, the episode may be determined to be a tachyarrhythmic episode. The tachyarrhythmic episode may be further classified using morphology criteria. For example, the tachyarrhythmic episode may exhibit a morphology indicative of a particular type of monomorphic tachyarrhythmia. Cardiac beats of the arrhythmic episode may be detected 110 and compared 120 to representative beat morphologies associated with the various types of arrhythmia of the heart. Atrial beats are used to identify types of atrial arrhythmia, ventricular beats are used to identify types of ventricular arrhythmia. If the morphology of the detected cardiac beats is consistent with (i.e., corresponds with or is sufficiently similar to) a particular type of arrhythmia, then the arrhythmic episode is classified 130 as the particular type of arrhythmia.

In some scenarios, the cardiac beat signals may correspond to two or more representative morphologies. In this scenario, the system may arbitrate between the two or more representative morphologies. For example, arbitration may involve consideration of other factors related to the arrhythmia episode, including, for example, rate of the cardiac beats, drug regimen of the patient, medical information about the patient, neural activity, patient activity, hemodynamic status, cardiac tissue impedance, transthoracic impedance, respiration and/or other factors.

Representative cardiac beat morphologies may be determined based on user input, may be determined automatically, or may be determined using a combination of user input and automatic processing. Representative beat morphologies may be developed using data from a previous device that gathered information from the patient, including cardiac beat signals. Representative beat morphologies may be developed using information gathered from other patients, for example, patients similarly situated and having similar

characteristics to the patient. Representative beat morphologies may be developed using externally detected parameters, internally detected parameters, or a combination of externally and internally detected parameters.

Figure 1B is a flowchart illustrating another method of classifying arrhythmia in accordance with embodiments of the invention. A sample of cardiac beats of an arrhythmic episode is detected 122. The sample of cardiac beats may comprise sequential or non-sequential beats. The morphology of the detected cardiac beats is compared 124 to a first representative beat morphology associated with a type of arrhythmia. If the morphology of the cardiac beats is consistent 126 with the representative beat morphology, then the arrhythmic episode is classified 128 as the particular type of arrhythmia.

If the cardiac beat morphology is not consistent 126 with the representative beat morphology, and there is another representative beat morphology to compare 130, then the next representative beat morphology is compared 124 to the detected cardiac beats.

If the morphology of the detected cardiac beats does not match any of the representative beat morphologies 130, then the arrhythmic episode comprises an arrhythmia of unknown type. The arrhythmic episode is classified 132 as an unknown or unclassified type of arrhythmia. In one example, the unclassified arrhythmic episode may involve a monomorphic arrhythmia that is characterizable by acquiring a representative beat morphology for the monomorphic arrhythmia. In another example, the unclassified arrhythmic episode may involve a polymorphic arrhythmia, such as ventricular fibrillation, for which characterization using a representative beat morphology may not be achievable.

Some current medical devices discriminate between supraventricular tachyarrhythmia (SVT) and ventricular tachyarrhythmia (VT) using cardiac waveform templates. Such devices typically detect a cardiac episode, and compare the episode in question to a normal sinus rhythm (NSR) template using an algorithm that determines a correspondence between episode information and template information. If the episode corresponds with the NSR template, the episode is diagnosed as SVT tachycardia, and therapy is withheld. In contrast, if the episode does not correspond with the NSR template, processes are typically performed to diagnose and verify the episode as ventricular tachycardia, after which therapy may be delivered. In current devices, the particular type of therapy delivered must be decided upon and programmed into the device

in advance by the physician. Furthermore, if it is found that a particular type of therapy is not suitable for a patient, the physician must re-program the device during a follow-up visit such that a different type of therapy is delivered for treating the patient's subsequent ventricular tachyarrhythmias.

In varying examples, a morphological template can be generated from a tachyarrhythmia episode and used to identify a later episode. For example, a tachyarrhythmia episode can be detected by an implantable medical device and analyzed to determine whether the episode is a type that necessitates antitachyarrhythmia therapy. In one example, a morphological graph of a tachyarrhythmia episode is presented to a human analyst, such as a physician, and an assessment of the tachyarrhythmia episode is received from the human analyst. The assessment can, for example, include an input that indicates whether the human analyst deems the tachyarrhythmia episode is a ventricular tachyarrhythmia (VT) episode or a supraventricular tachyarrhythmia (SVT) episode. In another example, the tachyarrhythmia episode can be analyzed by a computer to determine whether it is a VT or SVT episode. The computer can be in an implanted medical device, or external to the patient. A morphological template can be generated from the tachyarrhythmia episode and later used to identify a similar episode as it is occurring. For example, if a tachyarrhythmia episode correlates with an SVT template, an SVT can be declared, i.e. the episode can be identified as an SVT and treated accordingly. Templates can be selected or discarded based a variety of factors including conditions in the patient or characteristics of arrhythmias.

In an example, a template comprises one or more points of a sampled data representation of a heart depolarization. In another example, a template is a set of selected features from a sampled data representation of a heart depolarization. In another example a template is generated from multiple SVT beats, for example by taking an average of several beats.

Figure 2A is a flow chart that illustrates a process in which a SVT episode is identified and declared. At 210, an implantable medical device senses an intrinsic heart signal. At 220, the medical device stores a portion of the intrinsic electrical heart signal that was sensed during a tachyarrhythmia episode. At 230, a user indicates whether the portion of the intrinsic electrical heart signal is considered to be indicative of a SVT. In an alternative embodiment, a processor analyzes the portion of the signal to determine

whether it is indicative of a SVT. If the portion of the intrinsic electrical heart signal is determined to be indicative of a SVT, a SVT template is generated at 240. In an example, a processor in the implanted medical device generates the template. In another example, the template is generated on an external computer system and downloaded to the implanted medical device. Various techniques can be used to generate the template. In an example, the template consists of one heart beat from the SVT episode. Alternatively, the template includes more than one heart beat. In an example, the template consists of the actual data from the intrinsic electrical heart signal as the template. Alternatively, a processor converts the intrinsic electrical heart signal data into a file that requires less storage space than the original data.

Returning to Figure 2A, at 250, a processor determines at least one degree of similarity between a second portion of the heart signal from a later tachyarrhythmia episode and at least one SVT template. The degree of similarity is a quantity that is computed through an algorithm that uses the sensed intrinsic electrical heart signal (or a derivative thereof) as an input. In varying examples, determining the degree of similarity includes computing a feature correlation coefficient, a wavelet coefficient, or areas or integrals of a heart signal waveform or an approximation thereof. In varying examples, determining the degree of similarity involves computation of data in the time domain, wavelet domain, frequency domain, or other domains.

At 260, the device declares the second portion of the heart signal to represent a SVT episode if the degree of similarity exceeds a threshold valued. In one example, a processor in the medical device declares a SVT episode if a feature correlation coefficient for a heart beat exceeds a threshold. In another example, a processor declares a SVT if multiple feature correlation coefficients for respective multiple beats exceed a threshold value. In one scenario, a SVT is declared if a specified fraction of heart beats in a sequence of beats (e.g. 3 out of 10 beats) exhibit a feature correlation coefficient that exceeds a threshold. In another example, a SVT is declared if an average feature correlation coefficient for a number of beats exceeds a threshold (e.g. the average for 10 beats ≥ 0.94).

In an example, the processor determines a degree of similarity between the second portion and multiple SVT templates. In one example, the processor begins determining degrees of similarity for the second portion for a sequence of templates and stops

determining the degree of similarity if the degree of similarity for one of the templates exceeds a threshold. In other words, the processor compares the heart signal to a sequence of templates until a template match is found or all the templates are used. In another example, the portion of the heart signal is compared to all of the templates regardless of whether a match is found, and an SVT is declared if the degree of similarity for any one of the templates exceeds a threshold.

In addition to supraventricular tachyarrhythmia (SVT) episodes, a heart can exhibit other types of tachyarrhythmia that do not warrant antitachyarrhythmia therapy, including some instances ventricular tachyarrhythmia (VT). Such other non-lethal VT episodes can also be identified and used to generate templates.

Figure 2B is another flow chart that illustrates a process in which a degree of similarity is determined between a SVT template and a heart signal. At 212, an implantable medical device senses an intrinsic heart signal. At 222, the medical device stores a tachyarrhythmia portion of the intrinsic electrical heart signal that was sensed during a tachyarrhythmia episode. At 232, a processor determines at least one degree of similarity between the tachyarrhythmia portion of the heart signal and at least one SVT template. At 242, the processor determines whether the at least one degree of similarity exceeds at least one threshold value. In an example, the processor determines degrees of similarity for multiple beats and determines whether the degree of similarity exceeds a threshold for at least a predetermined fraction of the beats (e.g. 3 out of 8 beats). If the at least one degree of similarity exceeds at least one threshold value, the portion of the heart signal is declared to represent a SVT episode and antitachyarrhythmia therapy is suppressed, at 252. If the at least one degree of similarity does not exceed at least one threshold value (e.g. fewer than 3 out of 10 beats exhibit a degree of similarity in excess of a threshold), the portion of the heart signal is declared to represent a VT episode and antitachyarrhythmia therapy is delivered, at 262. The portion of the heart signal is stored and later presented to a user. If, at 272, an input from the user indicates that the portion is indicative of SVT, an SVT template is generated at 282. If another tachyarrhythmia event occurs, the process returns to box 232 and determines at least one degree of similarity between the tachyarrhythmia portion of the heart signal from the next tachyarrhythmia event and at least one SVT template, which can be the template generated at 282. If the

user input does not indicate that the portion is indicative of SVT, a template is not generated, at 292.

Figure 2C is a flow chart that illustrates a process in which a template is generated for an arrhythmia morphology that does not require antitachyarrhythmia therapy. At 205, an implantable medical device senses an intrinsic heart signal. At 215, the medical device stores one or more portions of the intrinsic electrical heart signal that were sensed during a tachyarrhythmia episode. At 225, a graphical representation of one or more stored portions of the intrinsic electrical heart signal is presented to a user. At 235, the user provides input that identifies at least one tachyarrhythmic portion of the intrinsic electrical heart signal that did not require antitachyarrhythmia therapy. The portion of the intrinsic electrical heart signal that did not require antitachyarrhythmia therapy can be, but is not necessarily, indicative of SVT. At 245, input is received from a user designating at least one portion of the intrinsic electrical heart signal that should be used to generate a template. At 255, a template is generated from a portion of the heart signal designated by the user. In an embodiment, an external computer system receives the input from the user to generate the template, which is downloaded to the implantable medical device. In another example, the user communicates directly with the implantable medical device, which generates the template. In an example, the user designates multiple portions of the heart signal, and multiple templates are generated.

Referring again to Figure 2C, at 265, a processor in the medical device determines one or more degrees of similarity between a second portion of the intrinsic electrical heart signal from a later tachyarrhythmia episode and the template. At 275, the processor determines whether the one or more degrees of similarity exceed a threshold value. If the one or more degrees of similarity exceed a threshold value, the processor suppresses an antitachyarrhythmia therapy at 285.

In an alternative embodiment, in lieu of presenting a graphical representation to a user and receiving an input, a portion of the heart signal is analyzed automatically by a processor to determine whether antitachyarrhythmia therapy is appropriate.

Figure 3 is a flow chart that illustrates a method in which a degree of similarity is determined between a monitored heart signal and a SVT template selected from a group of candidate SVT templates. At 305, a medical device monitors a heart signal. At 310, portions of the heart signal that are indicative of SVT are identified. In varying examples,

the portions that are indicative of SVT can be identified by a physician, for example, or identified by an automated computerized analysis. At 315, portions of the heart signal that are indicative of SVT are stored as candidate SVT templates. The candidate template can be stored with a corresponding heart rate at which the template was observed. One or more selection protocols can be used to select a SVT template from a group of candidate SVT templates when analyzing a later tachyarrhythmia episode. For example, at 320, a SVT template is selected from a group of candidate templates based upon the heart rate associated with the candidate templates. The processor selects a template having a heart rate that is closest to the heart rate of the later tachyarrhythmia episode.

Alternatively, at 325, a candidate SVT template is selected based other information about the patient. In an example, the drug treatment regimen of a patient is considered in the selection of a SVT template. The morphology of SVT episodes in a patient can vary depending upon the drug treatment regimen of the patient. In one example, the medical device stores information about drug treatment regimens associated with the tachyarrhythmia episodes used to generate the candidate templates. The current drug regimen is also stored in the device. The processor selects a SVT template based upon a similarity between the drug treatment associated with the selected template and the current drug treatment. In another example, the medical device detects one or more of neural activity, patient activity, sleep state, hemodynamic status, transthoracic impedance, or cardiac impedance. In further examples, the device detects REM (random eye movement) status, sympathetic/parasympathetic tone, intercardiac blood pressure including right ventricular pressure, left atrial pressure, or pulmonary artery pressure, oxygen saturation, heart size and contractability, blood flow, or edema. In varying examples, the medical device considers one or more of these parameters in selecting an SVT template. In another example, the processor identifies one or more characteristics of the patient, and selects a SVT template using statistics from other patients having similar characteristics. In varying examples, the characteristics include (but are not limited to) as height, weight, age, disease history, medication, and patient status (such as neural activity, blood pressure, etc.)

In another alternative, at 330, a candidate SVT template is selected based upon multiple factors. In an example, both the heart rate and the drug treatment regimen are taken into consideration.

At 335, the processor determines a degree of similarity between the heart signal from the later tachyarrhythmia episode and the selected SVT template. The processor compares the degree of similarity to at least one threshold, at 340. If the degree of similarity falls below a threshold, a SVT episode is not declared. In an example, if a SVT episode is not declared, the medical device declares a VT episode at 341 and delivers a ventricular antitachyarrhythmia therapy at 342. Alternatively, other determinations can be made before the medical device administers ventricular antitachyarrhythmia therapy. If the degree of similarity does exceed a threshold, the medical device declares the heart signal from the later tachyarrhythmia episode to represent a SVT episode at 345. The medical device then suppresses ventricular antitachyarrhythmia therapy at 350.

Figure 4 is a flow chart that illustrates a method in which a heart signal from a tachyarrhythmia episode is compared to a normal sinus rhythm and to a SVT template. At 405, a medical device senses an intrinsic electrical heart signal. The medical device monitors the heart rate at 410. At 415, the medical device compares the heart rate to a threshold. If the heart rate does not exceed the threshold, the medical device continues sensing the heart signal but does not perform a tachyarrhythmia discrimination algorithm. If the heart rate does exceed a threshold, the medical device declares a tachyarrhythmia episode at 420. At 425, the medical device compares the tachyarrhythmia portion of the heart signal to the normal sinus rhythm (NSR) template for the patient. In an example, the medical device computes a feature correlation coefficient between the tachyarrhythmia portion of the heart signal and the NSR template. If the tachyarrhythmia portion of the heart signal sufficiently correlates with the NSR template (e.g. the feature correlation coefficient exceeds a threshold), the medical device declares the tachyarrhythmia portion of the heart signal to represent a SVT episode at 430 and suppresses a ventricular antitachyarrhythmia therapy during the episode, at 435.

If the tachyarrhythmia portion of the heart signal is not similar to the NSR template, at 440 the medical device determines a degree of similarity between a portion of the heart signal and a SVT template. At 445, the medical device determines whether the degree of similarity exceeds a threshold. If the degree of similarity exceeds a threshold, the medical device declares the portion of the heart signal to represent a SVT episode at 450. In an example, declaring the portion of the heart signal to represent a SVT episode

merely means making a determination to executing a response that is consistent with a SVT, such as suppressing a ventricular antitachyarrhythmia episode at 455.

If, at 445, the degree of similarity does not exceed a threshold, the medical device stores the tachyarrhythmia portion of the heart signal at 460. The stored portion is displayed to a user at 465 and an input is received from the user at 470. At 475, if the user indicates that the heart signal is indicative of SVT, a template is generated from the tachyarrhythmia portion of the heart signal, at 480.

Figure 5 is a flow chart that illustrates examples of methods by which a SVT template is added and an old SVT template is discarded. A medical device monitors a heart signal at 510. Portions of the heart signal that are indicative of SVT are identified at 520 through computer analysis or input from a user. The medical device stores the portions of the heart signal that are indicative of SVT as SVT candidate templates at 530. At 540, the medical device discards the oldest SVT template. Alternatively, the medical device tracks the frequency of similarity of a portion of the heart signal from a tachyarrhythmia episode to one of a plurality of SVT templates at 550 and discards the SVT template exhibiting the least frequent similarity with the heart signal and saves a new template at 560. In another alternative example, the medical device discards a SVT template with a heart rate similar to heart rates of other SVT templates at 570. In the example at 580, the medical device discards a SVT template that is associated with a discontinued drug therapy regimen. In the example at 590, the medical device discards a SVT template that is most correlated to other SVT templates. In varying examples, a decision of which template to discard is made by a computer system, the medical device, or a user who inputs a direction to discard a template.

Figure 6 is a flow chart that illustrates an example of a process in which a heart signal from a tachyarrhythmia episode is compared against a normal sinus rhythm (NSR) template 630 and then a supraventricular tachyarrhythmia (SVT) template 660. At 610, a tachyarrhythmia episode is detected. A NSR correlation module 620 computes a NSR feature correlation coefficient (FCC) for 10 heart beats. If the NSR feature correlation coefficient is equal to or greater than 0.94 for 3 out of 10 beats, the correlation module 620 declares a SVT and a SVT protocol 640 is followed. If the fewer than 3 out of 10 beats have a NSR feature correlation coefficient greater than or equal to 0.94, a SVT correlation module 650 computes a SVT feature correlation coefficient for the 10 heart beats. If the

SVT feature correlation coefficient is equal to or greater than 0.95 for 3 out of 10 beats, the SVT correlation module 650 declares a SVT. If fewer than 3 out of 10 beats have a SVT feature correlation coefficient equal or greater than 0.95, the episode is treated as a ventricular tachyarrhythmia (VT) and a VT protocol is followed. For example, VT protocol 670 can include administration of antitachyarrhythmia therapy.

Figure 7 is a block diagram of an exemplary implantable device 700 incorporating a processor 710 and that runs software modules to analyze a signal from a heart 720 through a lead 770. A sensor 720 detects an intrinsic electrical heart signal. The processor 710 receives the signal from the sensor 720 and interprets the signal to determine whether an antitachyarrhythmia therapy should be delivered. A similarity module 740 determines a degree of similarity between portion of the heart signal from a tachyarrhythmia episode and a SVT template representative of a previous SVT episode. A suppress therapy module 750 suppresses a ventricular antitachyarrhythmia therapy if the degree of similarity exceeds a threshold value. SVT templates are stored in a memory circuit 760. A lead 770 delivers ventricular antitachyarrhythmia therapy as directed by the processor.

Figure 8 shows an example of a normal sinus rhythm morphology. Figure 9 shows an example of a SVT morphology. In an example, a template includes a morphology for a single beat, as shown in Figure 8. In another example, a template includes multiple beats, as shown if Figure 9. In another example, a template for an atrial tachyarrhythmia can be created. The atrial tachyarrhythmia template can be used to declare a future episode of atrial tachyarrhythmia and suppress antitachyarrhythmia therapy as appropriate.

Varying algorithms can be used to generate a template and determine the degree of similarity between a heart signal and a template. In one example, a set of pre-determined rules are used to locate a number of points on a waveform, and those points are used as the template for comparison against a heart signal. In an example, eight pre-determined points can be located. In one example, the maxima, minima, and inflection points are located. The located points are stored as the template. Features are extracted from a portion of the heart signal by aligning the portion of the heart signal with the template. In an example, a peak on the template is aligned with a peak on the portion of the heart signal from one beat of a tachyarrhythmia episode. The amplitude of the points on the portion of the heart signal is measured at times corresponding to the points in the template. To determine the

degree of similarity, a feature correlation coefficient (FCC) is computed using the amplitudes measured from the signal and the amplitude in the template.

In an example, a cardiac rate channel signal and a shock channel signal are sensed. The rate channel signal is measured from a sensing tip to a distal coil on a lead. The shock channel is measured from a distal coil to a proximal coil of the RV lead. A fiducial point is determined from the cardiac rate channel signals. A shock channel signal is aligned using the fiducial point. A template is generated using the aligned shock channel signal. In other examples, a signal is sensed and then aligned using the same channel from which it was sensed.

In another example, a processor computes a wavelet transform or Fourier transform of the signal from which a template is to be generated. A predetermined number of largest wavelet coefficients are saved as a template. Features are extracted from a heart signal by aligning the peak of the signal with the peak of the template and computing the wavelet transform of the aligned tachy beat waveform. A predetermined number of largest wavelet coefficients are saved. The sum of the absolute value of the differences between the saved wavelet coefficients and the wavelet coefficients in the template is determined and divided by the sum of absolute value of the wavelet coefficients in the template. The resulting value is subtracted from 1 and multiplied by 100 to provide a "percent match score", which is compared to a threshold. In an example, the threshold is 70%, and beats having a percent match score greater than or equal to 70% are considered SVT in origin. In an example, if 3 out of 8 beats are SVT, an SVT episode is declared.

In another example, a heart signal waveform is approximated as three consecutive triangles. The areas of each of the triangles is calculated and saved in a template. To extract features from a portion of a heart signal, peaks in the heart signal are aligned with the template, and the heart signal is approximated as three triangles. The area of each of the three triangles is calculated. To determine the degree of similarity to the template, a "similarity score" is determined based on the sum of the differences in the areas of the signal triangles and the template triangle. The similarity score is inversely proportional to this sum. If the similarity score is greater than a threshold, the beat is considered SVT in origin. If a predetermined number of beats exceed a threshold, an SVT episode is declared.

Various embodiments of the invention are directed to delivering an appropriate therapy for a particular of type of arrhythmia experienced by the patient. In accordance with embodiments of the invention, types of arrhythmia are respectively associated with various therapies used to treat the types of arrhythmia. In some embodiments, a therapy is associated with a particular type of arrhythmia if the therapy is determined to be successful at treating the particular type of arrhythmia.

In one implementation, if a particular type of arrhythmia occurs, then a first therapy assigned to treat the particular type of arrhythmia is delivered to the patient. Additional therapies may be applied in the event that the first therapy does not successfully mitigate the arrhythmia. If a therapy other than the first therapy is successful at terminating or mitigating the arrhythmia, the successful therapy may be used as the first therapy to treat subsequent episodes of the particular type of arrhythmia.

Figure 10 illustrates a method of delivering cardiac therapy to a patient in accordance with embodiments of the invention. Various cardiac therapies are respectively associated 1040 with types of arrhythmia. A representative set of cardiac therapies may involve, for example, antitachycardia pacing (ATP) including burst pacing, (e.g., pacing at 25 Hz or 50 Hz sequences), ramp pacing (e.g., burst pacing with each pace-to-pace interval shortened), scan pacing (e.g., burst pacing with the burst cycle length of each burst shortened between successive bursts, cardioversion shocks (e.g., cardioversion shocks delivered at about 0.5 Joules to about 2 Joules), and titration of defibrillation shocks.

The cardiac beats of an arrhythmic episode are detected 1042. The morphology of the detected cardiac beats is compared 1044 to representative beat morphologies associated with various types of arrhythmia. The arrhythmic episode is classified 1046 as a particular type of arrhythmia based on the comparison. A therapy associated with the particular type of arrhythmia is delivered 1048 to the patient.

Figure 11 illustrates another method of delivering cardiac therapy to a patient in accordance with embodiments of the invention. Various cardiac therapies are respectively associated 1162 with types of arrhythmia. The cardiac beats of an arrhythmic episode are detected 1164. The morphology of the detected cardiac beats is compared 1166 to a representative beat morphology associated with a type of VT. If the morphologies of the cardiac beats are consistent 1168 with the representative beat morphology, then the

arrhythmic episode is classified 1170 as the particular type. A therapy associated with the particular type of arrhythmia is delivered 1172 to the patient.

If the morphologies of the detected cardiac beats do not match any of the representative beat morphologies 1174, then the arrhythmic episode may be classified 1176 as an arrhythmia of unknown type and is an unclassified tachyarrhythmia. In one example, the unclassified arrhythmic episode may involve a monomorphic arrhythmia that is characterizable if a representative beat morphology for the monomorphic arrhythmia were acquired. In another example, the unclassified arrhythmic episode may involve a polymorphic arrhythmia, such as ventricular fibrillation, that is not characterizable using a representative beat morphology. A therapy is delivered 1178 to treat the unclassified tachyarrhythmia.

According to one scenario, illustrated in Figures 1A and 10, arrhythmia classification may be performed by comparing the morphology of the cardiac beats associated with the arrhythmia episode to representative beat morphologies of various types of arrhythmia. The representative beat morphologies may be characterized by stored morphology templates. The morphology templates comprise one or more features, samples, and/or morphological characteristics of cardiac beat signals representative of particular types of arrhythmia. An arrhythmic episode may be characterized as a particular type of arrhythmia, for example, a monomorphic VT (MVT), by determining that samples of the cardiac beats of the arrhythmic episode are correlated to the samples of a particular template. If the arrhythmic episode can be classified as the particular type of arrhythmia, then an appropriate therapy is delivered. For example, a therapy that was previously successful at terminating or mitigating the particular type of arrhythmia may be delivered to the patient.

In another scenario, illustrated by the flowcharts of Figures 1B and 11, the type of arrhythmia experienced by the patient may not match with any previously stored representative beat morphology and the type of arrhythmic episode is thus unknown. If the tachyarrhythmia is a monomorphic arrhythmia, the type of arrhythmia may be characterizable by acquiring a morphology template representing the beat morphology of the type of arrhythmia. However, if the arrhythmia is polymorphic, a template representing a characteristic beat cannot be acquired.

A therapy may be delivered to treat the unclassified arrhythmia. If the arrhythmia is characterizable, then a first therapy may be delivered. If the arrhythmia is not characterizable, a different therapy may be delivered. Information related to the success of a therapy at treating an unclassified VT may be stored to enhance future treatment of an arrhythmia having similar characteristics.

In one example, a morphology template may be acquired for an unknown but characterizable arrhythmia. A therapy is delivered to treat the arrhythmia. The success of the therapy is determined. A therapy that is successful at treating the arrhythmia may be associated with the type of arrhythmia characterized by the acquired morphology template. If a subsequent episode of arrhythmia comprising cardiac beats that match the morphology template is detected, the episode may be treated using the successful therapy.

In various implementations, success of a therapy may be based on effectiveness of the therapy at mitigating arrhythmia, the length of time the therapy had to by applied to mitigate the arrhythmia, the unnecessary pain caused by the therapy, if any, the power requirements of the therapy, and/or other objective or subjective factors.

Therapies associated with types of arrhythmia and/or used to treat known, unknown, new, characterizable, and/or uncharacterizable arrhythmias may be associated or used based on various factors. For example, therapies may be associated or used based on success of the therapy, the most recent use of the therapy, and/or the frequency of use of the therapy.

Therapies associated with types of arrhythmia and/or used to treat known, unknown, new, characterizable, and/or uncharacterizable arrhythmias may be associated and/or used based on various patient information. For example, such therapies may be associated and/or used based on consideration of various factors, for example, rate of the cardiac beats, drug regimen of the patient, medical information about the patient, neural activity, patient activity, hemodynamic status, cardiac tissue impedance, transthoracic impedance, respiration and/or other factors.

Embodiments of the present system illustrated herein are generally described as being implemented in a cardiac rhythm management (CRM) device which may operate in numerous cardioversion/defibrillation and pacing modes known in the art. Various types of single and multiple chamber CRM devices may be used to implement a number of pacing therapies as are known in the art, in addition to cardioversion/defibrillation

therapies. A CRM device may implement various anti-tachyarrhythmia therapies, such as tiered anti-tachyarrhythmia therapies, which may involve performing rate-based and/or morphological tachyarrhythmia discrimination analyses.

It is understood that configurations, features, and combination of features described in the present disclosure can be implemented in a wide range of implantable or external medical devices, and that such embodiments and features are not limited to the particular devices described herein. The systems and methods described herein may be implemented in a wide variety of implantable or external diagnostic and/or therapeutic cardiac devices such as defibrillators, cardioverters, pacemakers, cardiac monitors, and resynchronizers, for example.

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 device) may be implemented in any logic-based integrated circuit architecture, if desired.

In one embodiment, the CRM device is an implantable cardioverter/defibrillator configured as a single chamber device that operates to process cardiac waveforms according to a template methodology in accordance with the principles of the present invention. In another embodiment, the CRM device is an implantable cardioverter/defibrillator that is configured as a dual chamber device. In yet another embodiment, the CRM device is an implantable cardioverter/defibrillator configured to sense and/or provide electrical stimulation to multiple heart chambers, for example, both ventricles of the heart, as in a resynchronizer used to treat congestive heart failure (CHF).

Figure 12 is a partial view of a CRM device that may be used to implement arrhythmia classification and therapy methods in accordance with embodiments of the invention. The CRM device illustrated in Figure 12 includes a pulse generator 1200 electrically and physically coupled to lead system 1202. The lead system 1202 is implanted in a human body with portions of the lead system 1202 inserted into a heart 1201. The lead system 1202 is used to detect electric cardiac signals produced by the heart 1201 and to provide electrical energy to the heart 1201 under predetermined conditions to treat cardiac arrhythmias.

The lead system 1202 includes one or more electrodes used for pacing, sensing, and/or defibrillation. In the particular embodiment shown in Figure 12, the lead system

1202 includes a right ventricular lead system 1204, a right atrial lead system 1205, and a left ventricular lead system 1206. In one embodiment, the right ventricular lead system 1204 is configured as an integrated bipolar pace/shock lead.

The right ventricular lead system 1204 includes an SVC-coil 1216, an RV-coil 1214, and an RV-tip electrode 1212. The RV-coil 1214, which may alternatively be configured as an RV-ring electrode, is spaced apart from the RV-tip electrode 1212, which is a pacing electrode for the right ventricle.

The right atrial lead system 1205 includes a RA-tip electrode 1256 and an RA-ring electrode 1254. The RA-tip 1256 and RA-ring 1254 electrodes may provide pacing pulses to the right atrium of the heart and may also be used to detect cardiac signals from the right atrium. In one configuration, the right atrial lead system 1205 is configured as a J-lead. The lead system 1202 may also include a left atrial lead (not shown) which may be disposed in, on or about the heart to detect electrical signals of the left atrium. In some implementations, for example, the left atrial lead may comprise one or more electrodes attached to the external surface of the heart.

In the configuration of Figure 12, the lead system 1202 is shown positioned within the heart 1201, with the right ventricular lead system 1204 extending through the right atrium 1220 and into the right ventricle 1218. Typical locations for placement of the RV tip electrode are at the RV apex or the RV outflow tract.

In particular, the RV-tip electrode 1212 and RV-coil electrode 1214 are positioned at appropriate locations within the right ventricle 1218. The SVC-coil 1216 is positioned at an appropriate location within the right atrium chamber 1220 of the heart 1201 or a major vein leading to the right atrium chamber 1220 of the heart 1201. The RV-coil 1214 and SVC-coil 1216 depicted in Figure 12 are defibrillation electrodes.

An LV distal electrode 1213, and an LV proximal electrode 1217 may be inserted through the coronary venous system and positioned adjacent to the left ventricle 1224 of the heart 1201. The LV proximal electrode 1217 is spaced apart from the LV distal electrode, 1213 which is a pacing electrode for the left ventricle. The LV distal 1213 and LV proximal 1217 electrodes may also be used for sensing the left ventricle.

The left ventricular lead system 1206 includes endocardial pacing leads that are advanced through the superior vena cava (SVC), the right atrium 1220, the ostium of the coronary sinus, and the coronary sinus 1250 to locate the LV distal 1213 and LV proximal

1217 electrodes at appropriate locations adjacent to the left atrium and ventricle 1222, 1224, respectively.

The left ventricular lead 1206 is guided into the right atrium 1220 of the heart via the superior vena cava. From the right atrium 1220, the left ventricular lead system 1206 is deployed into the coronary sinus ostium, the opening of the coronary sinus 1250. The lead system 1206 is guided through the coronary sinus 1250 to a coronary vein of the left ventricle 1224. This vein is used as an access pathway for leads to reach the surfaces of the left atrium 1222 and the left ventricle 1224 which are not directly accessible from the right side of the heart. Lead placement for the left ventricular lead system 1206 may be achieved via subclavian vein access and a preformed guiding catheter for insertion of the LV electrodes 1213 and 1217 adjacent the left ventricle 1224. In one configuration, the left ventricular lead system 1206 is implemented as a single-pass lead.

Referring now to Figure 13A, there is shown a block diagram of a cardiac rhythm management (CRM) device 1300 suitable for implementing arrhythmia classification and therapy delivery in accordance with embodiments of the invention. Figure 13A shows a CRM device 1300 divided into functional blocks. It is understood by those skilled in the art that there exist many possible configurations in which these functional blocks can be arranged. The example depicted in Figure 13A is one possible functional arrangement. Various functions of the CRM device 1300 may be accomplished by hardware, software, or a combination of hardware and software.

The CRM device 1300 includes components for sensing cardiac signals from a heart and delivering therapy, e.g., pacing pulses or defibrillation shocks, to the heart. The pulse generator (PG) 1303 of the CRM device 1300 may be encased and hermetically sealed in a housing 1301 suitable for implanting in a human body. Power to the PG 1303 is supplied by an electrochemical battery 1333 that is enclosed within the housing 1301. A connector block with lead terminals (not shown) is additionally attached to housing 1301 to allow for the physical and electrical attachment of the intracardiac lead system conductors to the encased PG 1303.

In one embodiment, the PG 1303 is a programmable microprocessor-based system, including a control system 1320, memory circuit 1336, sensing circuitry 1321, 1323, 1325, 1329, pacemaker 1322, and a cardioverter/defibrillator therapy circuit 1330. Components of the PG 1303 cooperatively perform operations involving arrhythmia classification and

therapy delivery according to the approaches of the present invention. The control system 1320 is responsible for arrhythmia detection, classification, and therapy control. The control system 1320 may encompass various functional components, for example, an arrhythmia classification processor 1341 and a therapy control unit 1342.

A memory circuit 1336 may be used to store historical records of sensed cardiac signals, including arrhythmic episodes, and/or information about therapy delivered to the patient. The memory circuit 1336 may be used, for example, to store representative beat morphologies of various types of cardiac signals. Further associations between types of arrhythmia and therapies to treat the arrhythmia types may be stored in the memory 1336.

The historical data stored in memory 1336 may be used for various purposes, including diagnosis of patient diseases or disorders. Analysis of the historical data may be used and/or to adjust the operations of the CRM device 1300. Data stored in the memory 1336 may be transmitted to an external programmer unit 1334 or other computing device, such as an advanced patient management system as needed or desired.

Telemetry circuitry 1331 may be coupled to the PG 1303 to allow the CRM device 1300 to communicate with an external programmer unit 1334 or other remote devices. In one embodiment, the telemetry circuitry 1331 and the programmer unit 1334 use a wire loop antenna and a radio frequency telemetric link to receive and transmit signals and data between the programmer unit 1334 telemetry circuitry 1331. In this manner, programming commands may be transferred to the control system 1320 of the PG 1303 from the programmer unit 1334 during and after implant. The remote device may include a display device 1370 capable of displaying various information related to template creation and/or maintenance, and/or cardiac rhythm analysis, such as morphological analysis, rate analysis, wavelet analysis, or other types of rhythm analysis. For example, the display device 1370 may depict a graphical display of one or more detected cardiac waveforms along with the templates used to analyze or classify the detected cardiac waveforms. The display may show various data regarding the number of templates used by the CRM device, including, for example, statistics relating to the frequency particular templates were used to analyze or classify cardiac waveforms. Other uses for the display in connection with the template creation and therapy selection methods of the invention are also possible.

The pacemaker 1322 may be used to deliver a series of electrical stimulations to the heart to regulate heart rhythm. In various embodiments, the pacemaker 1322 may deliver pacing pulses to one or more of the right atrium, left atrium, right ventricle and the left ventricle. The heart may be paced to treat bradycardia, or to synchronize and/or coordinate contractions of the right and left ventricles. The pacemaker 1322 may also provide tachyarrhythmia therapy in the form of anti-tachycardia pacing (ATP) pulses delivered to the heart. The ATP pulses may involve a series of timed paces of programmable width and amplitude that are implemented to interrupt a tachyarrhythmia episode. The ATP therapy may involve, for example, burst pacing at about 25 Hz to about 50 Hz. In various implementations, the pace-to-pace interval may have a variable or constant length.

In the embodiment depicted in Figure 13A, electrodes RA-tip 1256, RA-ring 1254, RV-tip 1212, RV-coil 1214, SVC coil 1216, LV distal electrode 1213, LV proximal electrode 1217, and can 1309 are coupled through a switching matrix 1326 to various sensing circuits 1321, 1323, 1325, 1329. A right atrial sensing channel circuit 1321 serves to detect and amplify electrical signals from the right atrium of the heart. For example, bipolar sensing in the right atrium may be implemented by sensing signals developed between the RA-tip 1256 and RA-ring 1254 electrodes. The switch matrix 1326 is operated to couple the RA-tip 1256 and RA-ring 1254 electrodes to the RA sensing channel circuit 1321 to effect bipolar sensing of right atrial signals. Alternatively, unipolar right atrial sensing may be accomplished by operating the switch matrix 1326 to couple the RA-tip 1256 and can 1309 electrodes to the RA sensing channel circuit 1321.

Cardiac signals sensed through the use of the RV-tip electrode 1212 are right ventricular (RV) near-field signals and are referred to as RV rate channel signals herein. In the system shown in Figure 12, the right ventricular lead is illustrated as an integrated pace/shock lead. In this configuration, bipolar rate channel sensing may be accomplished by operating the switch matrix 1326 to couple the RV-tip 1212 and the RV-coil electrodes 1214 through the RV rate channel sensing circuitry 1323. The rate channel signal may be detected, for example, as a voltage developed between the RV-tip 1212 and the RV-coil 1214 electrodes. The RV rate channel sensing circuitry 1323 serves to sense and amplify the RV rate channel signal.

Unipolar RV sensing may be implemented, for example, by coupling the RV-tip 1212 and can 1309 electrodes to the RV rate channel sensing circuitry 1323. In this configuration, the rate channel signal is detected as a voltage developed between the RV-tip 1212 to can 1309 sensing vector.

The RV lead system may also include an RV-ring electrode (not shown in Figure 13A) used for bipolar pacing and sensing. If an RV-ring electrode is included in the lead system, bipolar sensing may be accomplished by sensing a voltage developed between the RV-tip 1212 and RV-ring (not shown) electrodes.

Far-field signals, such as cardiac signals sensed through use of one of the defibrillation coils or electrodes 1214, 1216 and the can 1309, or using both of the defibrillation coils or electrodes 1214, 1216, are referred to as morphology or shock channel signals herein. The shock channel signal may be detected as a voltage developed between the RV-coil 1214 to the can electrode 1309, the RV-coil 1214 to the SVC-coil 1216, or the RV-coil 1214 to the can electrode 1309 shorted to the SVC-coil 1216. The switch matrix 1326 is operated to couple the desired shock channel sensing vector, e.g., RV-coil to can, to the RV shock channel sensing circuitry 1325. The RV shock channel circuitry 1325 serves to sense and amplify the shock channel signal.

The outputs of the switching matrix 1326 may also be operated to couple selected combinations of the electrodes to LV sensing channel circuitry 1329 for capture detection. For example, the LV proximal electrode 1217 and the LV distal electrode 1213 may be coupled though the switch matrix 1326 to the LV sensing channel circuitry 1329 to sense electrical signals from the left ventricle of the heart. The control system 1320 receives signals from other components of the CRM device 1300 and controls the operation of various CRM functions. The control system 1320 serves as the control for a pacemaker 1322 that delivers pacing pulses to one or more heart chambers. For example, pacing signals may be delivered to selected electrodes according to a preestablished pacing regimen under appropriate conditions.

Unipolar pacing of the right atrium may be accomplished, for example, by delivering pacing pulses between the RA-tip 1256 and can 1309 electrodes. Bipolar pacing of the right atrium may be accomplished by delivering pacing pulses between the RA-tip 1256 and RA-ring 1254 electrodes.

Right ventricular pacing may similarly be implemented using unipolar or bipolar configurations. Unipolar RV pacing involves, for example, pacing pulses delivered between the RV-tip 12 12 to can 1309 electrodes. Bipolar pacing involves, for example, delivery of pacing pulses between the RV-tip 1212 to RV-coil 1214 electrodes. If an RV-ring electrode is present, bipolar pacing may be accomplished by delivering the pacing pulses to the RV-tip 1212 and RV-ring (not shown) electrodes.

Left ventricular pacing may be implemented using unipolar or bipolar configurations. Unipolar LV pacing may include, for example, pacing pulses delivered between the LV distal electrode 1213 and the can 1309. Alternatively, bipolar LV pacing may be accomplished by delivering the pacing pulses using the LV distal electrode 1213 and the LV proximal electrode 1217.

The CRM device 1300 includes an arrhythmia classification processor 1341 configured to classify a variety of arrhythmias, including types of monomorphic tachyarrhythmia. The arrhythmia classification processor 1341 may detect and/or classify arrhythmia based on morphological analysis of cardiac signals. The morphological analysis may be performed, for example, by comparing detected atrial or ventricular cardiac beats to stored templates characterizing arrhythmic beats and/or normally conducted beats.

In one implementation, discrimination between supraventricular tachyarrhythmia (SVT) and ventricular tachyarrhythmia (VT) may be accomplished by comparing cardiac beats to a template characterizing the patient's normal supraventricular tachyarrhythmia (SVT). If the cardiac beats are consistent with the SVT template, then the tachyarrhythmia is determined to be supraventricular in origin. In another example, the arrhythmia classification processor 1341 may classify an arrhythmia by comparing the morphology of cardiac beats to templates characterizing ventricular tachycardia, atrial fibrillation and/or atrial flutter. Other arrhythmia detection and/or classification methodologies, e.g., rate based and pattern based arrhythmia detection, are known in the art and may also be implemented by the arrhythmia classification processor 1341.

If an arrhythmia is classified by the arrhythmia classification processor 1341, the control system 1320 may communicate with the cardioverter/defibrillator pulse generator 1330 or the pacemaker 1322 to initiate an appropriate therapy, such as ATP, cardioversion and/or defibrillation shocks, to mitigate or terminate the arrhythmia. The therapy control

unit 1342 may associate one or more therapies with types of arrhythmias. For example, if a therapy proves to be successful at treating a particular type of arrhythmia, the therapy control unit associates the therapy with the type of arrhythmia. If the particular type of arrhythmia is subsequently detected, the therapy control unit selects the previously successful therapy to be delivered to the patient.

The therapies delivered to treat the arrhythmia may be delivered in a selected order. The order of therapy delivery may involve delivering a more successful therapy first, followed by other therapies.

Figure 13B illustrates another configuration of a CRM device 1350 employing a circuitry suitable for implementing therapy selection methodologies of the present invention. Figure 13B shows the CRM device 1350 divided into functional blocks. There exist many possible configurations in which these functional blocks can be arranged. The example depicted in Figure 13B is one possible functional arrangement. The CRM device 1350 includes circuitry for receiving cardiac signals from a heart and delivering electrical energy in the form of pace pulses or cardioversion/defibrillation pulses to the heart.

A cardiac lead system 1360 may be implanted so that cardiac electrodes contact heart tissue as described above in connection with Figure 12. The cardiac electrodes of the lead system 1360 sense cardiac signals associated with electrical activity of the heart. The sensed cardiac signals may be transmitted to a CRM circuitry 1351 through the lead system 1360. The cardiac electrodes and lead system 1360 may be used to deliver electrical stimulation generated by the CRM circuitry 1351 to the heart to mitigate various cardiac arrhythmias. The CRM circuitry 1351, in combination with the cardiac electrodes and lead system 1360, may detect cardiac signals and deliver therapeutic electrical stimulation to any of the left and right ventricles and left and right atria, for example. A can electrode 1355 coupled to a housing of the CRM circuitry 1351 may additionally be used to sense cardiac signals and deliver electrical stimulation to the heart.

In one embodiment, CRM circuitry 1351 is encased in a hermetically sealed housing suitable for implanting in a human body. Power is supplied by an electrochemical battery 1380 disposed within the housing. In one embodiment, the CRM circuitry 1351 is a programmable microprocessor-based system, including a control system 1390, sensing circuit 1370, pacing therapy circuit 1 365, shock therapy circuit 13755, and memory 1386. The memory 1386 may be used, for example, to store template information, parameters for

various pacing, defibrillation, and sensing modes, and data associated with sensed cardiac signals or other information. The parameters and data stored in the memory 240 may be used on-board for various purposes and/or transmitted via telemetry to an external programmer unit 1392 or other patient-external device, as desired.

The control system 1390 may used to control various subsystems of the CRM device 1350, including the pacing therapy circuit 1365, the shock therapy circuitry 1375, and the sensing circuitry1370. The control system 139O may also include a template processor 1395 for implementing a template initiation, template generation, template updating, and methodologies for therapy selection according to embodiments of the invention.

Communications circuitry 1385 allows the CRM device 1350 to communicate with an external programmer unit 1392 and/or other patient-external system(s). In one embodiment, the communications circuitry 1385 and the programmer unit 1392 use a wire loop antenna and a radio frequency telemetric link to receive and transmit signals and data between the programmer 1392 and communications circuitry 1385. In this manner, programming commands may be transferred to the CRM circuitry 1351 from the programmer 1392 during and after implant. In addition, stored cardiac data may be transferred to the programmer unit 1392 from the CRM circuitry 1351, for example.

Sensing circuitry 1370 detects cardiac signals sensed at the cardiac electrodes 1360. The sensing circuitry 1370 may include, for example, amplifiers, filters, A/D converters and other signal processing circuitry. Cardiac signals processed by the sensing circuitry 1370 may be communicated the control system 1390 and to the template processor 1395.

The control system 1390 is coupled to the template processor 1395 and uses templates created and maintained by the template processor 1395 to perform various functions, including, for example, arrhythmia analysis and therapy selection. An arrhythmia analysis section of the control system 1390 may compare cardiac signals detected through the sensing circuitry 1370 to the templates created and maintained by the template processor 1395 to detect or predict various cardiac arrhythmias, and to assist selection of appropriate therapies for the patient.

The pacing therapy circuit 1365 is controlled by a pacemaker in the control system 1390 and may be used to deliver pacing stimulation pulses to the heart through one or

more of the cardiac electrodes, according to a pre-established pacing regimen under appropriate conditions. Also, the pacing therapy circuit 1365 may deliver ATP therapy in response to VTs that correspond to templates associated with ATP.

The shock therapy circuit 1375 and pacing therapy circuit 1365 are coupled to an arrhythmia analysis section of the control system 1390. The shock therapy circuit 1375 may be used to deliver high-energy electrical stimulation to the heart to terminate or mitigate cardiac arrhythmias such as atrial or ventricular tachycardia or fibrillation detected or predicted by the control system 1390 when patient history suggests that ATP is not effective and/or satisfactory, and/or when a template does not correspond to a cardiac episode.

The CRM 1350 may optionally be coupled to a display device 1 394 capable of displaying various information related to template creation and maintenance, and/or cardiac rhythm analysis using morphological templates, as well as other information. For example, the display device 1394 may depict a graphical display of one or more detected cardiac waveforms along with the templates used to analyze or classify the detected cardiac waveforms. The display may show various data regarding the number of templates used by the CRM device 1350, including, for example, statistics relating to the frequency particular templates were used to analyze or classify cardiac waveforms. Other uses for the display in connection with the template creation and adjustment methods of the invention are also possible.

Figure 14 is a flowchart illustrating a method for delivering cardiac therapy to a patient in accordance with embodiments of the invention. An arrhythmia is detected 1410 based on heart rate. For example, tachyarrhythmia may initially be detected based on ventricular rate by evaluating the patient's R—R intervals. If the system detects a ventricular rate above a threshold, then the system flags the episode as a tachyarrhythmic episode. The tachyarrhythmic rate may be categorized as a relatively fast, medium, or slow tachyarrhythmia based on a number or percentage of intervals, e.g., R—R intervals, that fall within specified ranges for relatively fast, medium, or slow tachyarrhythmia.

After the tachyarrhythmia is initially detected 1410 based on rate, a morphological analysis process may be implemented to further classify the type of tachyarrhythmia. In one implementation, the morphology of one or more cardiac beats of the tachyarrhythmic

episode is compared to an SVT morphology template characterizing the patient's supraventricular rhythm.

If the one or more cardiac beats are consistent with 1420 the SVT template, then the tachyarrhythmia is classified 1425 as a supraventricular tachyarrhythmia (SVT). In one embodiment, the tachyarrhythmia is classified as an SVT if x out of y beats are consistent with the SVT template. For example, the tachyarrhythmia may be classified as an SVT if at least about 3 out of about 10 beats are consistent with the SVT template. If the tachyarrhythmia is classified as SVT, therapy may not be indicated.

If the morphology of the cardiac beats is not consistent 1420 with the SVT template, then the morphology of the cardiac beats may be compared to previously stored VT templates. If the cardiac beat morphology is consistent with 1440 a VT morphology template, then a therapy that was previously successful at treating the VT is delivered 1450. If the cardiac beat morphology is not consistent with 1440 a VT template, or if there are no previously stored 1430 VT templates, then the system delivers 1435 a programmed therapy.

According to embodiments of present invention, VT templates may be acquired and/or updated and made available for classification of detected arrhythmic episodes. Templates characterizing VT rhythms can only be updated when additional similar VT episodes occur. Templates associated with types of arrhythmia can be acquired or updated automatically or manually. For example, a CRM device may automatically attempt to acquire a VT template upon detection of a rapid ventricular rate that is determined to be ventricular in origin and for which no stored template exists. Alternatively, the physician may identify a VT stored in memory as a past episode and request the implantable system to form a VT template from episode records. In one scenario, the physician may identify a new type of VT and may request that a new VT template be formed. In another scenario, the physician may identify a misclassified VT and request the implantable system to form a VT template for the misclassified VT.

Accurate template formation for a particular type of VT is dependent on the presentation of a consistent beat-to-beat morphology. However, if the cardiac rhythm is disorganized, such as in a polymorphic VT, determination of a representative beat morphology that characterizes the rhythm may not be possible.

A particular therapy may be selected to treat a particular type of VT. For example, if a therapy is determined to have successfully mitigated or terminated a particular type of VT, information identifying and associating the previously successful therapy with the particular type of VT may be stored in the CRM device memory and utilized by the therapy control unit. If a subsequent episode of the particular type of VT is detected, the previously successful therapy may be selected to treat the particular type of VT. Identification of a therapy that will be used for treatment of a particular type of VT may be performed automatically by the CRM device or manually based on electrogram (EGM) data.

Some current medical devices can treat a VT by delivering a high-energy, painful shock or a low-energy, pain-free burst of anti-tachycardia pacing (ATP). Many physicians program these devices to deliver shocks for high-rate VT and reserve ATP for low-rate VT and fast atrial rhythms, such as atrial flutter. However, ATP may be safe and effective for treating high-rate VT, as well.

Furthermore, studies have shown that, for those patients for whom ATP successfully converts their first VT, there is a 99% probability that ATP will successfully convert their subsequent VTs. In contrast, studies have shown that, for those patients for whom ATP does not convert their first VT, the probability of ATP efficacy for subsequent VTs drops to only 38%.

Embodiments of methods and devices in accordance with the present invention may be implemented to adapt to changing patient conditions, medications, and/or cardiac pathology over time. Adaptation over time may possibly decrease the time to effective therapy, and increases the ratio of pain-free to painful therapy, by automatically incorporating information about that patient's prior therapy efficacy when deciding what type of therapy, if any, should be delivered to the current tachyarrhythmia episode.

In various embodiments, cardiac beats may be analyzed by examining the morphology of the electrical cardiac signal waveform. For example, a cardiac beat may be classified as a normal beat, e.g., a normally conducted SVT rhythm, by comparing the cardiac signal waveform to a template characterizing a normal beat. If the cardiac signal waveform is consistent with the template, the cardiac beat may be classified as normal. Similarly, a sensed abnormal or arrhythmic cardiac beat may be classified by comparing the abnormal cardiac signal waveform to one or more templates characterizing an

abnormal beat experienced by the patient in the past. The beat may be classified as abnormal if the beat waveform does not match or correspond to a normal beat template and/or if the beat waveform matches or corresponds to an abnormal beat template. Such comparisons may be used to determine that the sensed cardiac beat is abnormal as well as to assess the type of abnormality.

A cardiac waveform template may be created and used to analyze or otherwise process a sensed cardiac signal for a variety of purposes, including, for example, arrhythmia prediction or detection. Cardiac templates may include representative waveforms and/or information derived from waveforms, such as various attributes and/or ranges of attributes of the sensed cardiac signal, including, but not limited to: timing and/or rate information, changes in QRS width, T-wave amplitude, Q-wave amplitude, QT interval, R-R intervals, interval statistics, or other intervals or attributes useful for determining a correspondence between a cardiac waveform and a template. A cardiac waveform template may be formed, for example, by identifying one or more cardiac waveform features representative of a particular cardiac beat morphology. The particular waveform features may include morphological features such as critical points, significant points, curvature, local extrema, inflection points, rise or fall times, slopes, areas above and/or below baselines, and frequency and/or wavelet coefficients, or the like.

In addition to cardiac waveform features, such as waveform morphology, templates in accordance with the present invention may include other information. Patient history to previous therapy, indicating the efficacy of previous therapy attempts for arrhythmias corresponding to a given template, may also be included. Further, other patient information, such as patient activity levels, accelerometer information, hemodynamic status (e.g., blood pressure and blood oxygen level), cardiac tissue impedance, neural activity information, transthoracic impedance, pharmacological agent type and/or level information, respiratory information (e.g., patient disordered breathing information), or other patient information may be associated with a cardiac waveform template in accordance with the present invention. Pharmacological agent type and/or level information may include a change in medications prescribed by a physician, which may alter a patient's heart rhythms, and may require adapting one or more templates to the patient's altered rhythms.

Providing this additional information as a part of the cardiac waveform template enables automated re-programming of implantable medical devices on an episode-by-episode basis, and/or in response to patient-related changes, such as a change in a patient's medication or follow-up from a physician. Information such as medication change information may be provided to an implantable medical device using an advanced patient management system, as will be further described below.

It is understood that the devices and methodologies in accordance with the present invention described with reference to ventricular tachycardia and VT templates are similarly applicable to atrial tachycardia and atrial tachycardia templates, as well as SVT/NSR and SVT/NSR templates. For SVT templates and NSR templates, the therapy associated with the template may be "none" or "withhold therapy" for example. For simplicity of explanation, and not of limitation, the description of devices and methodologies provided herein will generally be made in the context of ventricular tachycardia and VT templates.

Consider, for example, a device configured to treat VT. Once it has been confirmed that a patient has experienced at least one true VT, one or more VT templates may be generated from the prior VT episodes. A VT template may include timing and morphology information, as well as information regarding the type and efficacy of therapy used to treat the prior VT from which the template was generated. The device may use the VT template(s) to automate selection of a therapy for subsequent VTs corresponding to the template(s).

Embodiments of methods and devices in accordance with the present invention may automate this re-programming on an episode-by-episode basis. An episode in question is first compared to one or more templates indicative of a normal supra-ventricular conducted beat, such as an NSR template and/or a template indicative of fast ventricular rhythms originating in the patient's atria. If the episode corresponds to the NSR template and/or the fast atrial-originated template, it is diagnosed as SVT tachycardia (SVT) and therapy is withheld.

However, if the episode does not correspond with the one or more templates indicative of the patient's normal rhythms, the episode is then compared to the VT template(s) created from the patient's prior VT episode(s). If the current episode corresponds with any one of the VT templates, the device then checks the VT template to

see if the therapy delivered to the prior VT was satisfactory. If the prior therapy was satisfactory, that same type of therapy is delivered to the current episode, regardless of the rate of the current episode.

In this way, ATP can be delivered to high-rate VTs if ATP was effective at treating similar low-rate VTs in the past. If, however, the therapy delivered to the prior VT was not effective and/or satisfactory, then a different or more aggressive therapy is delivered to the current episode. In this way, the time to effective and/or satisfactory treatment is shortened, as the device does not attempt to use a particular ATP therapy to treat a VT if that ATP therapy was not effective and/or satisfactory at treating similar VTs in the past. The time to effective treatment may be significantly shortened in accordance with an approach that does not attempt to use any type of ATP therapy to treat a VT if a prior ATP therapy was not effective and/or satisfactory at treating similar VTs in the past. In this approach, the device may immediately deliver a cardioversion or defibrillation therapy. In an alternate approach, a particular ATP therapy may be eliminated as an option for treatment if it was not satisfactory, and other ATP therapies may be attempted for subsequent events.

Cardiac beat morphology that may be used to identify SVT and different types of VT may include one of more sample points of the cardiac waveform and/or may include one or more attributes characterizing the cardiac waveform representative of the particular beat morphology, for example. As illustrated in Figure 15, a cardiac waveform 1510 representing a particular beat morphology is sensed and occurrences of one or more cardiac waveform sample points or features 1520 are detected. A waveform feature 1520 may include a particular point of a cardiac signal waveform 1510. The waveform features 1520 may be identified based on various morphological aspects of the cardiac waveform, such as critical points, local extrema, inflection points, rise or fall times, slopes, areas above and/or below a baseline, and frequency and/or wavelet coefficients, or by other aspects, as is known in the art.

The representative beat morphologies of a number of types of VT may be characterized using morphology templates. In one implementation, template acquisition may be accomplished using a two channel approach. Cardiac beats are sensed on a rate channel and a shock channel. In this example, a feature of the rate channel signal, e.g., the rate channel R-wave peak, may be used to align the shock channels of multiple cardiac

beats. Samples or features of the aligned shock channel signals are used to form the template. Figures 16A and 16B illustrate the process of rate and shock channel alignment. Figure 16A illustrates aligned rate channel signals of a normal sinus rhythm (NSR) beat 1610 and a VT beat 1620, respectively. Figure 16B illustrates the aligned shock channel signals of the NSR beat 1630 and the VT beat 1640.

Template formation may involve applying one or more initial criteria to a cardiac beat or a series of cardiac beats before a cardiac beat is used for template formation. For example, the initial criteria may involve meeting various duration, stability, rate, onset, and/or other arrhythmia discrimination criteria prior to using a cardiac beat as a template beat. For example, prior to using a beat as a template beat, the duration of the cardiac rhythm, the rate of the cardiac rhythm, the stability of the cardiac rhythm and/or the onset of the cardiac rhythm may be respectively compared to duration, rate, stability, and onset criteria.

For example, the cardiac rhythm stability may be evaluated by evaluating R—R intervals. A stability analysis algorithm calculates R—R interval differences. The rhythm stability is evaluated by comparing the current average difference to a programmed stability threshold. If the rhythm does not meet stability criteria, then acquisition of a template may not be desirable because unstable rhythms are presumed to be less morphologically consistent than stable rhythms. In this scenario, the unstable rhythm is classified as an unknown rhythm.

Onset criteria may involve, for example, evaluation of how quickly a particular rhythm occurs. An onset algorithm measures the rate of transition in a rhythm from a first rate to a second rate. If the onset of a cardiac rhythm occurs at a rate that is inconsistent with a threshold rate, then the rhythm may not be suitable for template generation. For example, if the rhythm onset is gradual, the rhythm is likely to be sinus tachycardia and a VT template is not needed. Figure 17 provides a more detailed illustration of the processes associated with forming a template in accordance with embodiments of the invention.

A template may be formed by combining one or more beats, wherein the combination of beats represents one beat of a particular rhythm, such as a monomorphic VT rhythm. Rate channel signals and shock channel signals of one or more cardiac beats representative of the cardiac rhythm being characterized are sensed 1702, 1704. The

peaks of the rate channel signals are identified 1706 as fiducial points. The rate channel fiducial points are used to align 1708 the corresponding shock channel signals of each template beat. The aligned shock channel signals may be combined, for example, by averaging the aligned signals sample by sample, or by other methods.

In one implementation, the template may comprise all samples of the average shock channel waveform. In another implementation, a selected set of samples of the average shock channel waveform may be extracted and used to form the template. In yet another implementation, morphological characteristics of the cardiac beats used to form the template may be used as the template. For example, the template may comprise one or more features such as a QRS width, an amplitude, peak timing, and/or other morphological features of the rate channel, shock channel, or combinations thereof.

As previously discussed, the representative beat morphology of various types of VT may be acquired manually. Manual identification of representative beat morphology may be accomplished by a physician or other person. For example, the patient's physician may examine stored electrogram (EGM) data acquired by the CRM device or another device to determine morphological features characterizing the representative beat morphology of monomorphic VT episodes. The morphological features may be input to the CRM device for use in identifying subsequent episodes of the type of VT.

Therapies may also be selected and associated with VT types through a manual process. A physician or other person may identify therapies that are likely to be, or have been, most successful at treating various types of VT. Identification of the therapies may be accomplished by examining EGM data corresponding to previous VT episodes and the result of treatment of the VT episodes. A therapy that was previously successful at treating a particular type of VT may be identified by the physician. Knowledge of an effective therapy or therapies may be acquired from a patient's previous device and/or during experience gained during an electrophysiological (EP) study. An association between the particular type of VT and the successful therapy may be input to the CRM device and stored in memory. When the CRM device detects a subsequent episode of the particular type of VT, the previously successful therapy is delivered.

Figure 18 is a flowchart of a method of therapy selection in accordance with embodiments of the present invention. The method begins with an episode 1810 being detected. The episode 1810 may be, for example, a rate-based or other anomaly for which

discrimination is desired. Information from the episode corresponds to templates 1820. The information may be a cardiac waveform encompassing a series of beats sensed from one or more electrodes, a portion of a cardiac waveform, a portion of a beat, or attributes from a cardiac waveform, as well as other information such as patient information. As an example, useful for illustrative purposes but not limiting, consider that morphological features correspond 1830 to at least one of the templates 1820, indicating that the episode 1810 is an arrhythmia. The template 1820 that corresponds to the episode 1810 is then used to determine if a previous therapy was satisfactory in treating the arrhythmia. Correspondence to a template may be determined by, for example, correlation, convolution, and/or statistical analysis of cardiac waveform information.

If a previous therapy was satisfactory, for example if the template indicates that ATP was satisfactory in treating the last arrhythmia that corresponded to the template 1820, then the previous therapy is delivered 1860 again. If the previous therapy attempt 1850 was not satisfactory, for example if the template indicates that ATP was not satisfactory in treating the last arrhythmia that corresponded to the template 1820 or if the previous therapy accelerated the cardiac rhythm, then a different and/or more aggressive therapy 1870 is delivered. If no templates 1820 are found to correspond to 1830 the current episode, then a new template may be created 1840, as will be described in more detail below. Whether or not a particular therapy was satisfactory may be based upon one or more of a variety of factors, including: if the therapy was effective, if the therapy didn't take too long, if the therapy didn't cause unnecessary pain, if the therapy didn't require unnecessary energy, and/or other subjective and/or objective factors.

Figure 19 is a flow chart illustrating a method of template selection and generation for therapy selection in accordance with embodiments of the invention. According to this embodiment, an initial template list comprising a list of templates representative of various cardiac beat morphologies and/or characteristics may optionally be established 1910. Alternatively, new templates may be formed without an initial template list using the processes described below.

A ventricular tachycardia is sensed 1920 using a cardiac waveform signal. The waveform features of the cardiac signal are detected 1930 and compared 1940 to each template in the template list, if any. In one example, if a predetermined number of the detected features of the cardiac waveform fall within the target ranges of the template,

e.g., six of seven cardiac waveform features fall within target ranges of the template, the cardiac waveform may be classified as matching or corresponding 1950 to the template. The template may then be used for therapy selection 1960, based on patient therapy history information associated with the template, as described above.

If the detected waveform features do not correspond 1950 to a template, the waveform features are compared to the next template until all templates have been compared 1955 to the cardiac waveform features. If none of the templates correspond to the cardiac waveform features, a new template may be created 1970 by, for example, extracting features of the cardiac waveform for correspondence purposes with future sensed episodes, and then associating therapy effectiveness and/or satisfaction information as therapy is delivered to the current episode. Other information may also be associated with the template, such as patient medication levels, patient activity information, and other sensor information measured at or near the time the arrhythmia occurred that may provide improved discrimination for therapy delivery selection.

Figure 20 is a flow chart illustrating a method of determining patient therapy response information, such as therapy effectiveness and/or whether or not the therapy was satisfactory, in accordance with embodiments of the invention. The method 600 begins with an episode being detected 2010. The detected episode may be, for example, a rate-based or other anomaly for which discrimination and/or characterization is desired. Information from the detected episode 2010 is compared or matched 2020 to one or more NSR/SVT templates to determine correspondence with the template. One method of determining that a cardiac signal may match, or correspond, to a template utilizes a correlation algorithm or other form of comparison. For example, morphological features of a signal may be measured with respect to amplitudes, inflection points, curvatures, timing of features, or other attributes. Characteristics such as timing onset, stability, variability of intervals between features of successive heartbeats, rates, and other characteristics may be included as part of a template. A template may include acceptable ranges and/or acceptable statistics of measurable features.

As an example, useful for illustrative purposes but not limiting, consider that morphological features are used to match 2020 a set of templates. If the episode 2010 matches or corresponds 2020 to one or more NSR/SVT templates, then the episode is determined to not require therapy 2025.

If the episode 2010 does not match 2020 to one or more NSR/SVT templates, then the morphological features of the episode 2010 are compared 2030 to a set of VT templates. If the morphological features do not match any NSR/SVT templates 620 or any VT templates 2030, then a default therapy 2040 is attempted, and a new VT template may be established 2050. If a maximum number of templates have been reached, the method may erase a template by overwriting it with new information from the latest episode 2010.

In accordance with embodiments of devices that provide communications with a patient-external device, a clinician may be queried to determine if a new template is desired, or if an existing template needs to be updated or erased. This may be accomplished in coordination with an arrhythmia logbook of an implantable medical device, such as a CRM, during patient follow-up. Patient information acquired by such logbook systems may be incorporated or associated with VT (or atrial) templates.

In other embodiments, a template is selected for replacement using a criterion such as: templates older than a predetermined age; the oldest out of all current templates; templates that have not corresponded to an arrhythmia for a pre-determined time period; templates selected for replacement by an advanced patient management (APM) system via manual selection or via algorithmic selection; templates that have corresponded least frequently to an arrhythmia relative to other templates; templates having a pre-determined association (e.g., a drug regimen association); templates having an associated heart-rate or other identified features similar to other templates; or other template selection criteria.

After the new template 2050 is established, patient history information may be acquired to fill in the necessary information of the template for future episodes. If an existing template is matched 2030, or a new template 2050 has been established, a check 2070 determines if the previous therapy was successful and/or satisfactory. The previous therapy may be, for example, a therapy delivered in response to a prior episode, or a therapy previously attempted for the current episode. If the check 2070 determines that the therapy was unsatisfactory, such as by not successfully terminating an arrhythmia, or by accelerating the heart rhythm, then an alternate ATP therapy 2080 may be attempted.

If all alternative ATP therapies 2080 have been attempted, then a cardioversion or defibrillation shock 2095 is delivered to treat the episode 2010, and the template is updated with information 2060 such that the next time a cardiac signal matches that template, ATP will not be attempted, and shock therapy will be chosen. If alternative ATP

therapies 2080 have not been tried, then an attempt 2090 is made to determine if a therapy less extreme (e.g., less painful) than cardioversion/defibrillation may correct the episode 610, and another check 2070 is performed. An update 2060 will occur to retain the most recent satisfactory treatment selection determined by the check 2070, such that for any future episode 2010 that corresponds to the template, treatment selection information will be provided for the treatment selection process.

If multiple templates are matched to the episode, then an arbitration process may be initiated to determine which of the multiple templates is to be selected. For example, the most recently used matched template with a successful therapy may be selected as the "best" template. Other criteria may be used to select between multiple matched templates, such as using the template most frequently matched to arrhythmia episodes in the past, the template having the closest rate to the current episode, the template having the highest treatment satisfaction with respect to past arrhythmia episodes, the template having the least aggressive successful treatment, or other useful criterion. The method 600 provides that a CRM incorporating the method may automatically incorporate information about that patient's prior treatment efficacy, and may automatically re-program the CRM on an episode-by-episode basis.

Figure 21 is a block diagram illustrating a methodology for determining patient therapy response information in accordance with embodiments of the invention. An arrhythmia treatment methodology 2100 may be used to associate a therapy with a template in accordance with embodiments of the present invention. The template 2120 may be associated with an arrhythmia event 2110, such as by corresponding to or matching the template 2120, or as having been used to generate the template 2120. A therapy 2130 is associated with the template 2120.

The therapy 2130 may have been associated with the template 2120 after successfully treating the arrhythmia event 2110. The therapy 2130 may have been delivered to a prior episode, may have been algorithmically selected via an APM system, may have been selected by a physician using a programmer or APM system, or may have been delivered to the current arrhythmia event 2110. For example, an APM system may maintain a database of templates from patients other than the patient experiencing the arrhythmia event 2110. The APM system may find a corresponding template, and determine what was the most satisfactory therapy for treating arrhythmias in other

patients. The APM system may then select that most successful therapy as the therapy to associate with the template 2120.

The therapy 2130 associated with the template 2120 may be a single therapy or include a number of therapies, as is shown in Figure 21 as therapies 2140. Therapies 2140 include one or more shock therapies 2142, which may be, for example, a maximum energy shock available from a PIMD, such as a 31 Joule shock (e.g., mono-phasic, bi-phasic, or tri-phasic shocks). Therapies 2140 may also include one or more cardioversion therapies 2144, which may be, for example, a lower energy shock, such as a 14 Joule shock, or other value. Therapies 2140 may also include several ATP therapies, such as ATP1 therapy 2148, ATP2 therapy 2147, ATP3 therapy 2146, and ATP4 therapy 2145. The ATP therapies 2145-2148 may be all different therapies having the same energy level, for example. An aggressiveness level 2150 indicates that ATP therapies 2145-2148 are considered less aggressive than the cardioversion therapy 2144, which is less aggressive than shock therapy 2142.

When a template is originated, an initial arrhythmia may be treated with a lower aggression therapy first, and different therapies, increasing in aggressiveness, may be attempted until a therapy is successful at treating the arrhythmia. The lowest aggressiveness therapy that successfully treats the arrhythmia may then be associated with the template for future reference. This corresponds to a hierarchical approach, where therapies are attempted in an ordered fashion according to an aggressiveness hierarchy.

In other embodiments, a more aggressive therapy may be used when a cardiac waveform is sensed that does not match or correspond to any template, and the waveform may be saved or transmitted for assessment by a clinician to determine if a template should be made, or if another therapy should be associated with that type of cardiac waveform. For example, upon initial determination of a new arrhythmia, a high-energy shock, an initial ATP therapy, or other default therapy, may be used and the cardiac waveform may be designated for review to determine which therapy, if any, should be associated with subsequent corresponding arrhythmias.

In other embodiments, a heuristic approach is used where no hierarchy is established. For example, the last therapy delivered may be repeated, or a therapy may be randomly selected from available therapies until a satisfactory therapy is determined. Satisfaction with a therapy may include parameters other than just effectiveness such as,

for example, time to effectiveness, patient pain, patient loss of consciousness, or other satisfaction criteria.

Figures 22A and 22B illustrate a flowchart of a method for delivering therapy to a patient based on recognition of particular types of arrhythmia according to embodiments of the invention. Representative beat morphologies associated with types of arrhythmia may be acquired and stored for use in classification of subsequent arrhythmic episodes. One or more particular therapies may be associated with one or more types of arrhythmia and may be the first therapy used to treat the VT types with which it is associated. In one implementation, additional therapies may be delivered following delivery of the first therapy.

Turning to the flowchart of Figure 22A, cardiac beats of an arrhythmic episode are detected 2205. The morphologies of the cardiac beats are compared 2210 to a representative beat morphology associated with a type of arrhythmia. In one example, the representative beat morphologies are compared to the cardiac beats in a specified order. For example, a representative beat morphology of a more frequently detected type of arrhythmia may be compared to the cardiac beats before other representative beat morphologies are compared. If the morphologies of the cardiac beats are consistent with 2215 a representative beat morphology, then the arrhythmic episode is classified 2220 as the particular type of arrhythmia associated with the representative beat morphology. A therapy associated with the particular type of arrhythmia is delivered 2225.

If the morphologies of the cardiac beats are not consistent 2215 with the particular type of VT, and there are more representative beat morphologies to compare 2230, then the cardiac beat morphologies are compared 2210 to the representative beat morphology of the next type of arrhythmia. If all the stored representative beat morphologies are checked 2230 and the morphologies of the cardiac beats are not consistent with any of the stored representative beat morphologies, then the arrhythmic episode is classified 2235 as an unknown or unclassified type of arrhythmia.

The process of characterizing an unknown type of arrhythmia and identifying a successful therapy continues in Figure 22B. The morphologies of the cardiac beats of the arrhythmic episode may be characterizable 2240 if the arrhythmia comprises a monomorphic tachyarrhythmia having a consistent morphology. However, if the morphologies of the cardiac beats of the arrhythmic episode are uncharacterizable, then

the arrhythmic episode is classified as an uncharacterizable arrhythmia, e.g., a polymorphic or multi-morphology VT episode, then a therapy selected for uncharacterizable ventricular tachyarrhythmia may be delivered 2247. If the therapy successfully treats 2265 the uncharacterizable arrhythmia, then the successful therapy may be associated 2270 with uncharacterizable arrhythmia.

If the therapy is not successful 2265 at treating the uncharacterizable arrhythmia, then additional therapies may be tried 2247. The successful therapy, if any, may be associated 2270 with uncharacterizable arrhythmia. The successful therapy may then be selected and used to treat subsequently detected episodes of uncharacterizable arrhythmia. A representative set of cardiac therapies for uncharacterizable arrhythmia such as polymorphic VT or VF may include, for example, burst, ramp, or scan ATP pacing, cardioversion shocks, and defibrillation shocks.

Association of a particular therapy with an uncharacterizable arrhythmia may not always be desirable. For example, ATP may terminate a polymorphic VT, but would be inappropriate for torsade de pointes. Thus, this feature may be disabled on a case by case basis depending on the types of arrhythmias the patient is expected to experience.

The ATP therapy schemes and redetection time should be brief before advancing to therapeutic shock due to minimize duration of any hemodynamic instability associated with the polymorphic rhythm.

If the cardiac beat morphology of the arrhythmia is characterizable 2240, then a representative beat morphology is acquired 2250 and stored for the new type of arrhythmia. A therapy is delivered 2252 to treat the new type of VT. If the first delivered therapy is successful 2255 then the successful therapy is associated 2260 with the new type of arrhythmia, e.g., an arrhythmia for which a representative morphology had not been previously acquired. If the first delivered therapy is not successful 2255, then a next available therapy is delivered 2252. The successful therapy, if any, is associated 2260 with new type of arrhythmia. The successful therapy may then be selected and used to treat subsequently detected episodes of the new type of arrhythmia.

In attempting to acquire templates and/or classify the types of arrhythmia, the CRM device may alter one or more of the arrhythmia discrimination parameters, such as the duration interval or number of cardiac beats used for identifying the rhythm. In one example, the CRM device may learn that certain types of monomorphic arrhythmia or other

rhythms may be non-sustained. If a particular type of rhythm is identified as a previously non-sustained arrhythmia type, the device may respond by increasing the duration that an episode is evaluated to allow the arrhythmia episode to self-terminate. For example, a non-sustained VT may last less than about 5 to about 20 seconds, for example. A flowchart illustrating this process is provided in Figure 22C.

Cardiac beats of an arrhythmic episode are detected 2275. The morphologies of the cardiac beats are compared 2277 to a representative beat morphology associated with a particular type of arrhythmia. If the morphologies of the cardiac beats are consistent with 2279 the representative beat morphology, then the arrhythmic episode is classified 2280 as the particular type of arrhythmia.

If the cardiac beats are not consistent with the representative beat morphology 2279 and there are no more representative beats morphologies to compare 2281, the cardiac beats are classified 2283 as an unknown arrhythmia and the process continues as in Figure 22B.

If the particular type of arrhythmia was previously a sustained arrhythmia 2282, then the therapy associated with the particular type of arrhythmia is delivered 2287. However, if the particular type of arrhythmia was previously a non-sustained arrhythmia 2282, then the length of time that the arrhythmia is evaluated may be increased 2284. After the increased evaluation time, the rhythm is rechecked. If the arrhythmia self-terminated 2285, then no therapy is required 2289. If the arrhythmia continues 2285, then the therapy associated with the particular type of arrhythmia is delivered 2287. The type of arrhythmia may be reclassified during or following the increased evaluation interval. In this situation, a therapy associated with the reclassified VT is delivered. The system may update information stored about the arrhythmia, for example whether the arrhythmia was sustained or non-sustained, the duration of the non-sustained rhythms, and/or whether the arrhythmia was reclassified during the increased evaluation period.

Figures 23A and 23B are flowcharts illustrating a process of using morphology templates to identify types of arrhythmia and to select an appropriate therapy. Morphology templates characterizing one or more types of identified arrhythmia are provided 2310, e.g., stored in memory. In one implementation, each morphology template may be associated 2320 with a particular type of arrhythmia. Each particular type of arrhythmia may be associated with a therapy that is used to treat the particular type of arrhythmia. A therapy may be associated with multiple types of arrhythmia.

Cardiac beats of an arrhythmic episode are detected and compared 2330 to templates characterizing the various types of identified arrhythmias. The order in which the stored templates are compared to the cardiac beats may vary. In one implementation, the order in which the arrhythmia templates are compared to the cardiac beats is determined based on the frequency of occurrence of the types of arrhythmia. For example, the cardiac beats of an arrhythmic episode may be compared to a template characterizing a more frequently occurring type of arrhythmia before the cardiac beats are compared to a template characterizing a less frequently occurring type of arrhythmia. The number of templates compared to the cardiac beat morphology may be limited to a predetermined number of templates.

If the morphology of the detected cardiac beats is correlated 2340 to a stored arrhythmia template, a therapy associated with the type of arrhythmia is delivered 2345. In a preferred implementation, the therapy associated with the type of arrhythmia comprises a previously successful therapy.

If the previously successful therapy is attempted and again successfully terminates 2346 the arrhythmia, the association between the type of arrhythmia and the therapy is maintained 2347. If the previously successful therapy does not terminate 2346 the arrhythmia, then the therapy may be retried 2348 for a predetermined number of times, for example, about 2 times. If the previously successful therapy does not successfully terminate 2346 the arrhythmia after being retried 2348 the predetermined number of times, then the next programmed therapy is delivered 2375.

A number of therapies may be associated with a type of arrhythmia. The therapies delivered to treat the type of arrhythmia may be delivered in a particular order, for example, in the order of a therapy success rating. For example, a therapy determined to be more successful at treating the type of arrhythmia may be delivered first, followed by delivery of the next most successful therapy if the more successful therapy does not mitigate the arrhythmia, and so forth. The therapy success rating for a particular therapy may be determined, for example, based on a percentage of successful treatments using the particular therapy. Thus, if a therapy was previously successful, but becomes less successful at treating the type of arrhythmia, then the previously successful therapy may be replaced by other, more successful therapies. Another example of determining the order of therapies delivered to treat a type of arrhythmia may involve first delivering the one or more therapies

that were most recently successful at treating the particular arrhythmia or other arrhythmias, or first delivering the one or more therapies that are most frequently used to treat the particular arrhythmia or other arrhythmias.

If the morphology of the detected cardiac beats is not correlated 2340 to a stored arrhythmia template, an arrhythmia template characterizing the type of arrhythmia may be acquired 2370, if possible 2360. In one implementation, a morphology template may be acquired 2370 by a quick template formation method using about 23 to about 10 cardiac beats.

In some embodiments, illustrated by Figure 23A, a template is acquired 2370, if possible 2360, and a therapy is delivered 2375 to treat the arrhythmia. In other embodiments, a template may be acquired for previously unknown arrhythmias without the delivery of therapy. If the arrhythmia is uncharacterizable 2360, then no template is acquired 2350 (Figure 23B) and therapy to treat the uncharacterizable arrhythmia may be delivered 2365. If the therapy to treat the uncharacterizable arrhythmia is successful 2385, then the therapy may be associated with uncharacterizable arrhythmia 2386 as a successful therapy. Otherwise, the next programmed therapy may be delivered 2365. The system may attempt 2388 a predetermined number of therapies before therapy attempts are exhausted 2389. Information linking a successful therapy with uncharacterizable arrhythmia may be stored in the device memory. The successful therapy may be used to treat subsequent episodes of uncharacterizable arrhythmia as a first selected therapy.

If a template representing the type of arrhythmia was acquired 2370 (Figure 23A) and the therapy delivered 2375 was successful 2380, then information linking the successful therapy to the arrhythmia is stored 2390. Otherwise, the next programmed therapy may be delivered 2375. The system may attempt 2392 a predetermined number of therapies before therapy attempts are exhausted 2389.

Memory available to store templates associated with the arrhythmias may be limited. Thus, templates may be deleted from memory if the arrhythmias they represent have not been detected for a period of time, thus freeing up memory space for more recently detected arrhythmia templates. In one scenario, a newly acquired template may replace a template representing a rhythm that has not been detected for the longest period of time. Further, a manual process for deleting old and/or spurious templates may be used, wherein a physician deletes templates from memory.

Figure 24 provides a more detailed illustration of various steps associated with determining if a cardiac beat is correlated to a template in accordance with embodiments of the invention. The processes described with reference to Figure 9 may be utilized, for example, in connection with block 2340 of Figure 23. According to one method, template features or samples are identified relative to the fiducial point of the template. The fiducial point, e.g., the R-wave peak, is determined from the rate channel signal of the cardiac beat 2405. The cardiac beat is aligned with the template using the fiducial points of the template and the cardiac beat 2410. A number of features or samples of the cardiac beat are identified at the locations relative to the fiducial point corresponding to previously determined features of samples of the template 2415. The template features or samples and the cardiac beat features or samples may be compared by calculating a feature correlation coefficient (FCC) 2420. In one particular embodiment, Equation 1, provided below, is used to compute the FCC between the template features and the beat features.

$$FCC = \frac{(N\sum_{i=1}^{N} X_i Y_i - (\sum_{i=1}^{N} X_i)(\sum_{i=1}^{N} Y_i))^2}{(N\sum_{i=1}^{N} X_i^2 - (\sum_{i=1}^{N} X_i)^2)(N\sum_{i=1}^{N} Y_i^2 - (\sum_{i=1}^{N} Y_i)^2)} \quad [1]$$

where, Xi represents template N features and Yi represents beat N features, and N=8 in this illustrative example. The sign of the numerator term is checked before squaring. If the numerator is negative, the beat is uncorrelated, and the remainder of the computation need not be performed.

If the FCC is greater than a predetermined value, as tested at block 2425, for example, about 0.8 to about 0.9, then the cardiac beat is correlated 2435 to the template. If the FCC is less than or equal to the predetermined value, then the cardiac beat is uncorrelated 2430 to the template. The FCC threshold may be configured to be modified by the physician to tailor the sensitivity and specificity of VT recognition to the needs of a particular patient. Increasing the FCC threshold will require a tighter morphological match and will help discriminate between differing VT morphologies. Lowering the FCC threshold will increase the range of related morphologies that will be associated and treated with a particular therapy.

Alternatively, a generalized equation may be used for computation of a correlation coefficient in accordance with a correlation waveform analysis (CWA) technique. An equation for calculation of the correlation coefficient (CC) using this technique may be determined according to Equation 2.

$$CC = \frac{N\sum_{i=1}^{N} X_i Y_i - (\sum_{i=1}^{N} X_i)(\sum_{i=1}^{N} Y_i)}{\sqrt{(N\sum_{i=1}^{N} X_i^2 - (\sum_{i=1}^{N} X_i)^2)(N\sum_{i=1}^{N} Y_i^2 - (\sum_{i=1}^{N} Y_i)^2)}} \quad [2]$$

where, Xi represents template N samples and Yi represents signal N samples in this illustrative example.

Figure 25 provides graphs illustrating rate and shock channel signals corresponding to a VT template and a cardiac beat. To determine correlation between the cardiac beat and the VT template, the shock channel signals of the template 2510 and the cardiac beat 2520 are aligned based on the R-wave peak of the rate channel signals 2530, 2540. Sample points 2550 of the cardiac beat shock channel signal are compared to template sample points 2560. In one implementation, the feature correlation coefficient between the template and the cardiac beat may be calculated as described above using the selected sample points 2550, 2560. If the feature correlation coefficient is greater than a predetermined value, then the cardiac beat is determined to be correlated to the template. If the feature correlation coefficient is less than or equal to the predetermined value, then the cardiac beat is determined to be uncorrelated to the template.

In some situations, modification of one or more arrhythmia discrimination parameters may facilitate classification of types of cardiac rhythms, such as atrial arrhythmia, ventricular arrhythmia, monomorphic VT, and polymorphic VT rhythms. Retrospective analysis of the classification of cardiac rhythms may reveal that some rhythms were misclassified. Misclassification may occur, for example, if an SVT is misclassified as a VT or if a VT is misclassified as an SVT. Misclassification may also occur, for example, if a characterizable arrhythmia is classified as an uncharacterizable arrhythmia or if an uncharacterizable, polymorphic arrhythmia is classified as a characterizable monomorphic arrhythmia.

In some situations, classification may be enhanced by adjusting one or more arrhythmia discrimination parameters. For example, arrhythmia discrimination parameters may involve the number of cardiac beats used to classify the cardiac rhythm, the beat-to-beat stability of the cardiac beats used to classify the rhythm, the rate of the arrhythmia and/or other parameters used in connection with rhythm classification. Rhythm classification may be enhanced by modifying any or all of the arrhythmia discrimination parameters. The rhythm discrimination parameters that improve the identification of various rhythms represent rhythm characteristics that could also be used to further subclassify arrhythmias, and, as a result, fine-tune therapeutic regimens associated with the arrhythmias.

It is believed that the processes described herein may be utilized in connection with many cardiac beat morphology characterization methodologies.

Figure 26 is a flow chart illustrating a method of template selection and generation for therapy selection using patient response information in accordance with embodiments of the invention. According to this embodiment, templates are established by a physician selecting a cardiac waveform for template creation after reviewing a logbook of arrhythmia episodes and treatments. An arrhythmia is detected 2620 using a cardiac waveform signal. The waveform is compared 2630 to each template in the template list, if any. If the cardiac waveform corresponds to a template 2640, the template may then be used for therapy selection 2650, based on patient therapy history information associated with the template, as described above.

If the detected waveform does not correspond to the template 2640, the waveform is compared to the next template until all templates have been compared 2660 to the cardiac waveform. If none of the templates 2640 correspond to the cardiac waveform, the arrhythmia is treated 2662. Treatment 2662 may be performed using one or more of the ATP methods previously described, for example, using a cardioversion and/or defibrillation methodology, or other predetermined default treatment. The cardiac waveform, and any associated information, such as treatment history, and/or other sensor information is recorded 2664, such as by using a memory or logbook feature.

The cardiac waveform and associated information is then reviewed by a clinician, such as a physician 2666. The physician 2666 may select particular recorded waveforms for template generation 2670. The selected waveforms then have templates formed 2670,

and a therapy is associated with the template. When reviewing the recording 2664, the physician may select or eliminate from consideration one or more therapies 2672 for association with the template. For example, the physician may determine that a defibrillation was performed on a cardiac waveform that may be treated by ATP. The physician may select ATP therapy as the associated therapy for the template 2670, such that the next arrhythmia associated with a morphology that matches or corresponds to the template 2670 is treated with ATP therapy. The physician may also select an order of multiple therapies to try, for example.

The physician may select an ATP therapy of similar aggression, but different coupling interval. The coupling interval is the point in time during the cardiac cycle at which the pacing pulse should be delivered. A typical coupling interval is 80%, with the pacing pulse delivered at a time predicted to be 80% between the last R wave and the next R wave. ATP with a coupling interval of 70% may deliver the same energy to the patient as ATP with a coupling interval of 80%. However, shorter coupling intervals are considered to be more aggressive, as there is more risk that the pacing pulse could accelerate the rhythm instead of terminating the rhythm.

Other information may also be associated with the template, such as patient medication levels, patient activity information, and other information provided by the physician that may provide improved discrimination for therapy delivery selection. The physician may provide the information during a follow-up office visit, using a programmer, for example. The physician or a clinician may also perform the method of Figure 8 remotely, such as by using an advanced patient management (APM) system 2668 as will be described below. In other embodiments, the APM system may incorporate an artificial intelligence system or other programming to remotely perform methods of template generation, initialization, updating, therapy association, and/or selection in accordance with the present invention.

Referring now to Figure 27, a CRM of the present invention may be used within the structure of an APM system 2700. The APM system 2700 allows physicians and/or other clinicians to remotely and automatically monitor cardiac and respiratory functions, as well as other patient conditions. The APM system 2700 may also be used to provide information to the CRM for incorporation into templates, such as medication information or other patient information useful in accordance with the present invention. The APM

system 2700 may also be used to select portions of cardiac waveforms for which templates are desired. The APM system 2700 may also be used to select or eliminate therapies associate with templates. In one example, a CRM implemented as a cardiac pacemaker, defibrillator, or resynchronization device may be equipped with various telecommunications and information technologies that enable real-time data collection, diagnosis, and treatment of the patient.

As is illustrated in Figure 27, the medical system 2700 may be used to implement template generation, template updating, template initialization, template selection, patient measuring, patient monitoring, patient diagnosis, patient therapy, therapy selection, and/or therapy elimination in accordance with embodiments of the invention. The medical system 2700 may include, for example, one or more patient-internal medical devices 2710, such as a CRM, and one or more patient-external medical devices 2720, such as a monitor or signal display device. Each of the patient-internal 2710 and patient-external 2720 medical devices may include one or more of a patient monitoring unit 2712, 2722, a diagnostics unit 2714, 2724, and/or a therapy unit 2716, 2726.

The patient-external medical device 2720 performs monitoring, and/or diagnosis and/or therapy functions external to the patient (i.e., not invasively implanted within the patient's body). The patient-external medical device 2720 may be positioned on the patient, near the patient, or in any location external to the patient.

The patient-internal and patient-external medical devices 2710, 2720 may be coupled to one or more sensors 2741, 2742, 2745, 2746, patient input / trigger devices 2743, 2747 and/or other information acquisition devices 2744, 2748. The sensors 2741, 2742, 2745, 2746, patient input/trigger devices 2743, 2747, and/or other information acquisition devices 2744, 2748 may be employed to detect conditions relevant to the monitoring, diagnostic, and/or therapeutic functions of the patient-internal and patient-external medical devices 2710, 2720.

The medical devices 2710, 2720 may each be coupled to one or more patient-internal sensors 2741, 2745 that are fully or partially implantable within the patient. The medical devices 2710, 2720 may also be coupled to patient-external sensors positioned on, near, or in a remote location with respect to the patient. The patient-internal and patient-external sensors are used to sense conditions, such as physiological or environmental conditions, that affect the patient.

The patient-internal sensors 2741 may be coupled to the patient-internal medical device 2710 through one or more internal leads 2753. Still referring to Figure 27, one or more patient-internal sensors 2741 may be equipped with transceiver circuitry to support wireless communications between the one or more patient-internal sensors 2741 and the patient-internal medical device 2710 and/or the patient-external medical device 2720. The patient-internal sensors 2745 may be coupled to the patient-external medical device 2720 through a wireless connection 2759, and/or using communications between the patient-internal medical device 2710 and the patient-external medical device 2720, or may be coupled using a wire or other communications channel.

The patient-external sensors 2742 may be coupled to the patient-internal medical device 2710 through one or more internal leads 2755. Patient-external sensors 2742 may communicate with the patient-internal medical device 2710 wirelessly. Patient-external sensors 2742 may be coupled to the patient-external medical device 2720 through one or more leads 2757 or through a wireless link.

In an embodiment of the present invention, the patient-external medical device 2720 includes a visual display configured to concurrently display non-electrophysiological signals and electrogram signals. For example, the display may present the information visually. The patient-external medical device 2720 may also, or alternately, provide signals to other components of the medical system 2700 for presentation to a clinician, whether local to the patient or remote to the patient.

Referring still to Figure 27, the medical devices 2710, 2720 may be connected to one or more information acquisition devices 2744, 2748, such as a database that stores information useful in connection with the monitoring, diagnostic, or therapy functions of the medical devices 2710, 2720. For example, one or more of the medical devices 2710, 2720 may be coupled through a network to a patient information server 2730.

The input/trigger devices 2743, 2747 are used to allow the physician, clinician, and/or patient to manually trigger and/or transfer information to the medical devices 2710, 2720 and/or from the APM system 2740 and/or patient-external medical device 2720 back to the patient-internal device 2710. The input/trigger devices 2743, 2747 may be particularly useful for inputting information concerning patient perceptions, such as a perceived cardiac event, how well the patient feels, and other information not automatically sensed or detected by the medical devices 2710, 2720. For example, the

patient may trigger the input/trigger device 2743 upon perceiving a cardiac event. The trigger may then initiate the recording of cardiac signals and/or other sensor signals in the patient-internal device 2710. Later, a clinician may trigger the input/trigger device 2747, initiating the transfer of the recorded cardiac and/or other signals from the patient-internal device 2710 to the patient-external device 2720 for display and diagnosis.

In one embodiment, the patient-internal medical device 2710 and the patient-external medical device 2720 may communicate through a wireless link between the medical devices 2710, 2720. For example, the patient-internal and patient-external devices 2710, 2720 may be coupled through a short-range radio link, such as Bluetooth, IEEE 802.11, and/or a proprietary wireless protocol. The communications link may facilitate uni-directional or bi-directional communication between the patient-internal 2710 and patient-external 2720 medical devices. Data and/or control signals may be transmitted between the patient-internal 2710 and patient-external 2720 medical devices to coordinate the functions of the medical devices 2710, 2720.

In another embodiment, patient data may be downloaded from one or more of the medical devices periodically or on command, and stored at the patient information server 2730. The physician and/or the patient may communicate with the medical devices and the patient information server 2730, for example, to acquire patient data or to initiate, terminate or modify recording and/or therapy.

The data stored on the patient information server 2730 may be accessible by the patient and the patient's physician through one or more terminals 2750, e.g., remote computers located in the patient's home or the physician's office. The patient information server 2730 may be used to communicate to one or more of the patient-internal and patient-external medical devices 2710, 2720 to provide remote control of the monitoring, diagnosis, and/or therapy functions of the medical devices 2710, 2720.

In one embodiment, the patient's physician may access patient data transmitted from the medical devices 2710, 2720 to the patient information server 2730. After evaluation of the patient data, the patient's physician may communicate with one or more of the patient-internal or patient-external devices 2710, 2720 through an APM system 2740 to initiate, terminate, or modify the monitoring, diagnostic, and/or therapy functions of the patient-internal and/or patient-external medical systems 2710, 2720.

In another embodiment, the patient-internal and patient-external medical devices 2710, 2720 may not communicate directly, but may communicate indirectly through the APM system 2740. In this embodiment, the APM system 2740 may operate as an intermediary between two or more of the medical devices 2710, 2720. For example, data and/or control information may be transferred from one of the medical devices 2710, 2720 to the APM system 2740. The APM system 2740 may transfer the data and/or control information to another of the medical devices 2710, 2720.

In one embodiment, the APM system 2740 may communicate directly with the patient-internal and/or patient-external medical devices 2710, 2720. In another embodiment, the APM system 2740 may communicate with the patient-internal and/or patient-external medical devices 2710, 2720 through medical device programmers 2760, 2770 respectively associated with each medical device 2710, 2720. As was stated previously, the patient-internal medical device 2710 may take the form of an implantable PIMD.

Various modifications and additions can be made to the preferred embodiments discussed hereinabove without departing from the scope of the present invention. Accordingly, the scope of the present invention should not be limited by the particular embodiments described above, but should be defined only by the claims set forth below and equivalents thereof.

CLAIMS

What is claimed is:

1. A cardiac arrhythmia classification system, comprising:

a sensor system comprising electrodes for electrically coupling to a heart, the sensor system configured to detect cardiac beat signals associated with an arrhythmic episode of the heart;

an arrhythmia classification processor coupled to the sensor system, the arrhythmia classification processor configured to compare a morphology of each cardiac beat signal to a plurality of representative beat morphologies respectively associated with a plurality of types of arrhythmia and classify the arrhythmic episode as a particular type of arrhythmia if the morphologies of the cardiac beat signals are consistent with a representative beat morphology of a particular type of arrhythmia.

2. The system of claim 1, wherein the arrhythmia classification processor is configured to classify the arrhythmic episode as an unknown type of arrhythmia if the morphologies of the cardiac beat signals are not consistent with any of the plurality of representative beat morphologies.

3. The system of claim 1, wherein the arrhythmia classification processor is configured to compare the morphology of each cardiac beat signal to the plurality of representative beat morphology templates and classify the arrhythmic episode as the particular type of arrhythmia if the morphologies of the cardiac beat signals are consistent with a representative beat morphology template associated with the particular type of arrhythmia.

4. The system of claim 1, wherein the arrhythmia classification processor is configured to compare the morphology of each cardiac beat signal to the plurality of representative beat morphologies in a selected order.

5. The system of claim 4, wherein the selected order is based on history of success of the representative beat morphologies at identifying an arrhythmia.

6. The system of claim 1, wherein the arrhythmia classification processor is configured to classify the arrhythmic episode as an unknown type of arrhythmia if the morphologies of the cardiac beat signals are not consistent with the plurality of representative beat morphologies and to determine that the arrhythmic episode is characterizable as a new type of arrhythmia if the cardiac beat signals are classified as the unknown type of arrhythmia and to determine a representative beat morphology associated with the new type of arrhythmia.

7. The system of claim 1, wherein the arrhythmia classification processor is configured to classify the arrhythmic episode as an unknown type of arrhythmia if the morphologies of the cardiac beat signals are not consistent with the plurality of representative beat morphologies and determine that the cardiac beat signals are morphologically uncharacterizable if a representative beat morphology cannot be acquired for the cardiac beat signals.

8. The system of claim 1, wherein the arrhythmia classification processor is configured to associate a set of arrhythmia discrimination parameters with the particular type of arrhythmia and to compare the morphology of each cardiac beat signal to the representative beat morphology using the set of arrhythmia discrimination parameters associated with the particular type of arrhythmia.

9. The system of claim 8, wherein the arrhythmia classification processor is configured to modify the one or more of the arrhythmia discrimination parameters to enhance characterization of the particular type of arrhythmia.

10. The system of claim 1, wherein the arrhythmia classification processor is configured to modify one or more arrhythmia discrimination parameters before comparing each cardiac beat signal to the plurality of representative beat morphologies.

11. The system of claim 10, wherein the one or more arrhythmia discrimination parameters comprises an onset, rate, stability or duration parameter.

12. The system of claim 1, further comprising a therapy processor coupled to the arrhythmia classification processor, the therapy processor configured to associate one or more cardiac therapies respectively with the one or more types of arrhythmia and to deliver one or more particular therapies associated with the particular type of arrhythmia if the cardiac beat signals are characterized as the particular type of arrhythmia.

13. The system of claim 12, wherein the cardiac beat signals are ventricular beat signals, the plurality of representative beat morphologies are a plurality of ventricular tachyarrhythmia templates and the one or more cardiac therapies are ventricular therapies.

14. The system of claim 12, wherein the cardiac beat signals are atrial beat signals, the plurality of representative beat morphologies are a plurality of atrial tachyarrhythmia templates, and the one or more cardiac therapies are atrial therapies.

15. The system of claim 12, wherein:

the arrhythmia classification processor is configured to classify the arrhythmic episode as an unknown type of cardiac arrhythmia if the morphology of the cardiac beat signals is not consistent with any of the plurality of representative beat morphologies; and

the therapy processor is configured to deliver one or more selected therapies to treat the unknown arrhythmia if the arrhythmic episode is classified as the unknown type of cardiac arrhythmia.

16. The system of claim 12, the therapy processor is configured to associate at least one cardiac therapy with an arrhythmia that was successfully treated using the at least one cardiac therapy.

17. The system of claim 12, wherein the therapy processor is configured to deliver the one or more particular therapies in a selected order based on a history of success of the one or more particular therapies.

18. The system of claim 12, wherein the arrhythmia classification processor is configure to classify the arrhythmic episode as an unknown type of cardiac arrhythmia if the morphologies of the cardiac beat signals are not consistent with any of the plurality of representative beat morphologies, attempting to acquire a new representative beat morphology associated with the unknown type of cardiac arrhythmia and associate the new representative beat morphology with a new type of cardiac arrhythmia if the new representative beat morphology is acquired.

19. The system of claim 18, wherein the therapy processor is configured to deliver one or more selected therapies to terminate the new type of cardiac arrhythmia, determining if a particular one or more of the selected therapies is successful and associate the successful therapy with the new type of cardiac arrhythmia.

20. The system of claim 12, wherein the arrhythmia classification processor is configured to determine that the cardiac beat signals are uncharacterizable and represent an uncharacterizable cardiac arrhythmia if the representative beat morphology is not acquired.

21. The system of claim 12, wherein the arrhythmia classification processor is configured to determine that the arrhythmic episode is uncharacterizable if morphologies of cardiac beat signals are unstable from beat to beat.

22. The system of claim 21, wherein the therapy processor is configured to deliver one or more selected therapies to terminate the uncharacterizable cardiac arrhythmia, determine if a particular one of the one or more selected therapies is successful and associate the successful therapy with the uncharacterizable cardiac arrhythmia.

23. The system of claim 1, wherein one or more of the plurality of representative beat morphologies is determined based at least in part on user input.

24. The system of claim 1, wherein one or more of the plurality of representative beat morphologies are deleted based at least in part on user input.

25. The system of claim 1, wherein one or more of the plurality of representative beat morphologies are automatically determined or deleted.

26. The system of claim 12, wherein:

the arrhythmia classification processor is further configured to determine if the particular type of arrhythmia is a sustained or unsustained arrhythmia; and

a therapy processor is configured to deliver the one or more particular therapies associated with the particular type of arrhythmia if the particular type of arrhythmia was determined to be a sustained arrhythmia during one or more previous arrhythmic episodes.

27. The system of claim 26, wherein:

the arrhythmia classification processor is configured to determine a duration of the particular arrhythmia if the particular arrhythmia is unsustained; and

the therapy processor is configured to delay therapy for a period of time associated with the duration of the particular unsustained arrhythmia determined during one or more previous arrhythmic episodes.

28. The system of claim 12, wherein the arrhythmia classification processor is configured to reclassify the arrhythmic episode after delivery of a therapy.

29. The system of claim 12, wherein the plurality of cardiac therapies comprises one or more antitachyarrhythmia pacing therapies or one or more cardioversion therapies or one or more defibrillation therapies or any combination of antitachyarrhythmia pacing therapies, cardioversion therapies and defibrillation therapies.

30. The system of claim 12, wherein the therapy processor delivers the one or more particular therapies associated with the particular type of arrhythmia based at least in part on additional patient information.

31. The system of claim 30, wherein the additional patient information comprises cardiac rate, drug regimen information, medical information, neural activity information, patient activity information, hemodynamic status information, cardiac tissue impedance information, transthoracic impedance information, respiratory information, or any combination thereof.

32. The system of claim 12, wherein the therapy processor is configured to associate the one or more cardiac therapies respectively with the one or more types of arrhythmia based on satisfaction with the one or more cardiac therapies.

33. The system of claim 32, wherein the satisfaction is determined based on one or more of the prior effectiveness of one or more cardiac therapies, the length of time the one or more cardiac therapies were applied before mitigating previous arrhythmic episodes, pain caused by the one or more cardiac therapies during previous arrhythmic episodes, and energy requirements of the one or more cardiac therapies.

34. The system of claim 33, wherein the therapy processor eliminates a previously delivered therapy associated with a particular arrhythmia as an option for treating a subsequently detected arrhythmic episode of the particular arrhythmia if the previously delivered therapy was unsuccessful.

35. The system of claim 1, wherein the arrhythmia classification processor arbitrates between two or more representative beat morphologies if the cardiac beat signals of the arrhythmic episode are consistent with the two or more representative beat morphologies.

36. A cardiac arrhythmia classification system, comprising:

a sensor system comprising electrodes for electrically coupling to a heart, the sensor system configured to detect cardiac beat signals associated with an arrhythmic episode of the heart;

an arrhythmia classification processor coupled to the sensor system, the arrhythmia classification processor configured to compare each cardiac beat signal to a plurality of templates respectively associated with a plurality of types of arrhythmia and classify the

arrhythmic episode as a particular type of arrhythmia if the cardiac beat signals correspond to a particular template associated with a particular type of arrhythmia, the processor further configured to determine if the arrhythmic episode is characterizable as a new type of arrhythmia if the cardiac beat signals do not correspond to any template of the plurality of templates .

37. The system of claim 36, wherein each template of the plurality of templates includes at least one morphological feature of the cardiac beat signals.

38. The system of claim 36, wherein one or more templates of the plurality of templates are determined based at least in part on user input.

39. The system of claim 36, wherein one or more templates of the plurality of templates are deleted based at least in part on user input.

40. The system of claim 36, wherein one or more templates of the plurality of templates are automatically determined.

41. The system of claim 36, wherein the arrhythmia classification processor is configured to determine that the arrhythmic episode is characterizable as the new type of arrhythmia if a template can be acquired that characterizes the cardiac beat signals.

42. The system of claim 36, wherein the arrhythmia classification processor is configured to determine that the arrhythmic episode is uncharacterizable if a template cannot be acquired for the cardiac beat signals.

43. The system of claim 36, wherein the arrhythmia classification processor is configured to determine that the arrhythmic episode is uncharacterizable if morphologies of cardiac beat signals are unstable from beat to beat.

44. The system of claim 36, wherein the arrhythmia classification processor is configured to acquire a template representing the new type of arrhythmia.

45. The system of claim 36, wherein the cardiac beat signals are ventricular beat signals and the plurality of templates comprises a plurality of ventricular tachyarrhythmia templates.

46. The system of claim 36, wherein the cardiac beat signals are atrial beat signals and the plurality of templates comprises a plurality of atrial tachyarrhythmia templates.

47. The system of claim 36, wherein the arrhythmia classification processor is configured to alter one or more arrhythmia discrimination parameters before comparing each cardiac beat signal to a plurality of templates respectively associated with a plurality of types of arrhythmia to facilitate characterizing the arrhythmia.

48. The system of claim 47, wherein the one or more arrhythmia discrimination parameters comprises an onset, rate, stability or duration parameter.

49. A cardiac arrhythmia classification system, comprising:

a sensor system comprising electrodes for electrically coupling to a heart, the sensor system configured to detect cardiac beat signals associated with an arrhythmic episode of the heart;

an arrhythmia classification processor coupled to the sensor system, the arrhythmia classification processor configured to compare each cardiac beat signal to a plurality of templates according to a selected order of templates, the plurality of templates respectively associated with a plurality of types of arrhythmia and classify the arrhythmic episode as a particular type of arrhythmia if the cardiac beat signals correspond to a particular template associated with a particular type of arrhythmia.

50. The system of claim 49, wherein the selected order of the templates is based on success of the templates at identifying previous arrhythmic episodes.

51. The system of claim 49, further comprising a therapy unit configured to deliver therapy to treat the arrhythmic episode, the therapy unit configured to associate one or

more therapies respectively with each of the plurality of arrhythmia types and to deliver a particular one or more therapies associated with the particular arrhythmia of arrhythmia.

52. The system of claim 49, wherein the therapy unit is configured to associate the one or more therapies respectively with each of the plurality of arrhythmia types based on success of the one or more therapies.

53. An apparatus comprising:

at least one electrical sensor configured to sense an intrinsic electrical heart signal;

a memory circuit configured to store candidate supraventricular tachyarrhythmia (SVT) templates respectively associated with heart rates;

a processor configured to determine a heart rate from the intrinsic heart signal, to select an SVT template associated with the heart rate of the intrinsic heart signal from the candidate supraventricular tachyarrhythmia templates, and to determine whether antitachyarrhythmia therapy should be delivered in response to a tachyarrhythmia episode based on the degree of similarity between the heart signal and the selected SVT template.

54. The apparatus of claim 53, wherein the processor is further configured to discard the oldest candidate SVT template from the memory circuit to make room for a new SVT template.

55. The apparatus of claim 53, wherein the processor is further configured to discard from the processing system the least frequently selected SVT template.

56. An apparatus, comprising:

sensor circuitry configured to sense an intrinsic electrical heart signal of a patient;

a memory configured to store a plurality of supraventricular tachyarrhythmia (SVT) templates;

circuitry configured to monitor patient information; and

a processor coupled to the sensor circuitry, memory, and monitoring circuitry, the processor configured to select at least one supraventricular tachyarrhythmia (SVT) template from the plurality of SVT templates using the patient information and to

determine if the heart signal represents an SVT episode based on the selected SVT template.

57. The apparatus of claim 56, wherein the processor is configured to withhold treatment based on a similarity between the heart signal detected during a tachyarrhythmia episode and the selected SVT template.

58. The apparatus of claim 56, wherein the patient information comprises one or more of drug treatment, neural activity, sleep state, hemodynamic status, transthoracic impedance, and blood pressure.

59. The apparatus of claim 56, the processor is configured to select the SVT template based on data from patients having characteristics similar to characteristics of the patient.

60. An apparatus, comprising:

implantable sensor circuitry configured to sense an intrinsic electrical heart signal;

an arrhythmia detector configured to identify an arrhythmic episode of the intrinsic electrical heart signal;

user interface circuitry configured to present the arrhythmic episode to a user and to receive user input declaring the arrhythmic episode to be indicative of supraventricular tachyarrhythmia (SVT); and

a processor configured to generate an SVT template from the arrhythmic episode based on the user input.

61. The apparatus of claim 60, wherein the user interface circuitry is configured to present a plurality of arrhythmic episodes of the heart signal to the user and to receive user input indicating which of the arrhythmic episodes are to be used to generate one or more SVT templates.

62. A cardiac therapy system, comprising:

a sensor system comprising electrodes for electrically coupling to a heart of a patient, the sensor system configured to detect cardiac beat signals of an arrhythmic episode of the heart;

an arrhythmia detector coupled to the sensor system, the arrhythmia detector configured determine if the arrhythmic episode is characterizable, to compare a morphology of each cardiac beat signal to plurality of templates respectively associated with a plurality of types of arrhythmia and to classify the arrhythmic episode as a particular type of arrhythmia if the morphologies of the cardiac beat signals are consistent with a template of a particular type of arrhythmia; and

a therapy processor coupled to the arrhythmia classification processor, the therapy processor configured to associate one or more cardiac therapies respectively with the one or more types of arrhythmia and to deliver one or more particular therapies associated with the particular type of arrhythmia if the cardiac beats are characterized as the particular type of arrhythmia.

63. The system of claim 62, wherein the one or more particular therapies are associated with the particular type of arrhythmia based on a history of success of the one or more particular therapies.

64. The system of claim 62, wherein the arrhythmia detector is configured to classify the arrhythmic episode as an unknown type of arrhythmia if the morphology of the cardiac beats is not consistent with any of the plurality of representative beat morphologies.

65. The system of claim 62, further comprising a template generator configured to acquire a template associated with the unknown type of arrhythmia if the unknown type of arrhythmia is a new type of arrhythmia that is characterizable.

66. The system of claim 65, wherein the therapy processor is configured to deliver one or more selected therapies to terminate the new type of arrhythmia, determine if a particular one of the selected therapies is successful, and associate the successful therapy with the new type of arrhythmia.

67. The system of claim 62, wherein the therapy processor is configured to deliver one or more selected therapies if the arrhythmia is uncharacterizable.

68. The system of claim 67, wherein the therapy processor is configured to determine if a particular one of the one or more selected therapies is successful, and to associate the successful therapy with the uncharacterizable arrhythmia.

69. The system of claim 62, wherein the therapy processor is configured to associate the one or more cardiac therapies respectively with the one or more types of arrhythmia based at least in part on user input.

70. The system of claim 62, wherein the therapy processor is configured to associate the one or more cardiac therapies respectively with the one or more types of arrhythmia based at least in part on data from a previous device of the patient.

71. The system of claim 62, wherein:
the cardiac beat signals are associated with ventricular beats;
the templates are ventricular tachyarrhythmia templates;
the one or more arrhythmias are ventricular tachyarrhythmias; and
the one or more therapies are ventricular therapies.

72. The system of claim 62, wherein:
the cardiac beat signals are associated with atrial beats;
the templates are atrial tachyarrhythmia templates;
the one or more arrhythmias are atrial tachyarrhythmias; and
the one or more therapies are atrial therapies.

73. A cardiac therapy system, comprising:
a sensor system comprising electrodes for electrically coupling to a heart of a patient, the sensor system configured to detect cardiac beat signals of an arrhythmic episode of the heart;

an arrhythmia detector coupled to the sensor system and configured to compare a morphology of each cardiac beat signal to a plurality of templates respectively associated with a plurality of types of arrhythmia and to classify the arrhythmic episode as a particular type of arrhythmia if the morphologies of the cardiac beat signals are consistent with a template of a particular type of arrhythmia, the arrhythmia detector further configured to determine if the particular type of arrhythmia is a sustained or unsustained arrhythmia; and

a therapy processor coupled to the arrhythmia classification processor, the therapy processor configured to associate one or more cardiac therapies respectively with the one or more types of arrhythmia and to deliver one or more particular therapies associated with the particular type of arrhythmia if the cardiac beats are characterized as the particular type of arrhythmia and if the particular type of arrhythmia was determined to be a sustained arrhythmia during one or more previous arrhythmic episodes.

74. The cardiac therapy system of claim 73, wherein the therapy processor is configured to associate the one or more cardiac therapies respectively with the one or more types of arrhythmia based on a historical success of the one or more cardiac therapies.

75. The cardiac therapy system of claim 73, wherein:

the arrhythmia detector is configured to determine a duration of the particular arrhythmia if the particular arrhythmia is unsustained; and

the therapy processor is configured to delay therapy for a period of time associated with the duration of the particular arrhythmia determined during one or more previous arrhythmic episodes.

76. The cardiac therapy system of claim 73, wherein the arrhythmia detector is configured to reclassify the arrhythmic episode after delivery of a therapy.

77. The cardiac therapy system of claim 73, wherein the plurality of cardiac therapies comprises one or more antitachyarrhythmia pacing therapies.

78. The cardiac therapy system of claim 73, wherein the plurality of cardiac therapies comprises one or more cardioversion therapies.

79. The cardiac therapy system of claim 73, wherein the plurality of cardiac therapies comprises one or more defibrillation therapies.

80. A medical system, comprising:

a cardiac therapy system configured to deliver a cardiac therapy to a patient;

a detector system configured to detect a cardiac waveform associated with a tachyarrhythmia; and

a processor coupled to the detector system and the cardiac therapy system, the processor configured to provide one or more templates representative of cardiac signals of one or more of a patient's past tachyarrhythmia events and additional patient information associated with tachyarrhythmia episodes, each of the one or more templates associated with a therapy to treat the tachyarrhythmia episodes, and, if the cardiac waveform corresponds to a particular template of the one or more templates and the additional patient information associated with the tachyarrhythmia episodes, the processor is configured to determine if a previous therapy associated with the particular template was satisfactory in terminating a past tachyarrhythmia event corresponding to the particular template, and if determined satisfactory, prompt the cardiac therapy system to deliver the previous therapy.

81. The system of claim 80, wherein the cardiac therapy system is configured to deliver an anti-tachycardia pacing therapy to the patient to treat the tachyarrhythmia and determine one or both of the effectiveness and satisfaction of the anti-tachycardia pacing therapy.

82. The system of claim 80, comprising a patient activity sensor configured to provide patient activity information associated with tachyarrhythmia episodes to the template processor.

83. The system of claim 80, comprising a neural activity sensor configured to provide patient neural activity information associated with tachyarrhythmia episodes to the template processor.

84. The system of claim 80, comprising a transthoracic impedance sensor configured to provide patient transthoracic impedance information associated with tachyarrhythmia episodes to the template processor.

85. The system of claim 80, comprising an accelerometer configured to provide acceleration information associated with tachyarrhythmia episodes to the template processor.

86. The system of claim 80, comprising a cardiac tissue impedance sensing system configured to provide patient cardiac tissue impedance information associated with tachyarrhythmia episodes to the template processor.

87. The system of claim 80, comprising a hemodynamic status sensor configured to provide patient hemodynamic status information associated with tachyarrhythmia episodes.

88. A medical system, comprising:

a cardiac therapy system configured to deliver a cardiac therapy to a patient;

a detector system configured to detect a cardiac waveform associated with an arrhythmic event; and

a template processor coupled to the detector system and the cardiac therapy system, the template processor configured to provide, patient-externally, the cardiac waveform, identify, patient-externally, a portion of the cardiac waveform indicative of the arrhythmic event, generate a cardiac template corresponding to the cardiac waveform portion, and associate a therapy with the cardiac template useful for treating a subsequent arrhythmic event corresponding to the cardiac template.

89. The system of claim 88, wherein the cardiac therapy system is configured to provide an anti-tachycardia pacing therapy to the patient to treat the arrhythmic event and determine the effectiveness of the anti-tachycardia therapy.

90. The system of claim 88, wherein the cardiac therapy system is configured to provide an anti-tachycardia pacing therapy to the patient to treat the arrhythmic event and determine if the treatment was satisfactory.

91. The system of claim 88, comprising a communication system configured to communicate with a patient-external device housing the template processor.

92. The system of claim 88, comprising a communication system configured to communicate with a patient-external device accessible by a clinician, wherein the clinician may initiate or override addition of a new template if the cardiac waveform does not match with any existing templates.

93. A system for discriminating between types of arrhythmia affecting one or more heart chambers, comprising:

means for detecting cardiac beats associated with an arrhythmic episode;

means for comparing a morphology of each cardiac beat to a plurality of representative beat morphologies respectively associated with a plurality of types of arrhythmia; and

means for classifying the arrhythmic episode as a particular type of arrhythmia if the morphologies of the cardiac beats are consistent with a representative beat morphology of the particular type of arrhythmia.

94. The system of claim 93, further comprising:

means for associating a set of arrhythmia discrimination parameters with the particular type of arrhythmia; and

means for comparing the morphology of each cardiac beat to the representative beat morphology using the set of arrhythmia discrimination parameters associated with the particular type of arrhythmia.

95. The system of claim 93, further comprising means for modifying the one or more of the arrhythmia discrimination parameters to enhance characterization of the particular type of arrhythmia.

96. The system of claim 93, further comprising means for classifying the arrhythmic episode as an unknown type of arrhythmia if the morphologies of the cardiac beats are not consistent with the plurality of representative beat morphologies.

97. The system of claim 96, further comprising:

means for attempting to acquire a new representative beat morphology associated with the unknown type of arrhythmia; and

means for classifying the arrhythmic episode as a new type of arrhythmia associated with the new representative beat morphology if the new representative beat morphology associated with the unknown type of arrhythmia is acquired.

98. The system of claim 97, further comprising means for classifying the arrhythmic episode as an uncharacterizable arrhythmia if the new representative beat morphology is not acquired.

99. The system of claim 93, further comprising means for delivering one or more particular therapies associated with the particular type of cardiac arrhythmia if the arrhythmic episode is classified as the particular type of cardiac arrhythmia.

100. The system of claim 99, further comprising:

means for classifying the arrhythmic episode as an unknown type of cardiac arrhythmia if the morphology of the cardiac beats is not consistent with any of the plurality of representative beat morphologies; and

means for delivering one or more selected therapies to treat the unknown arrhythmia if the arrhythmic episode is classified as the unknown type of cardiac arrhythmia.

101. The system of claim 99, further comprising means for associating at least one cardiac therapy with an arrhythmia that was successfully treated using the at least one cardiac therapy.

102. The system of claim 99, further comprising means for delivering the one or more particular therapies in a selected order.

103. The system of claim 102, further comprising means for delivering the one or more particular therapies based on a history of effectiveness of the one or more particular therapies.

104. The system of claim 99, further comprising:

means for classifying the arrhythmic episode as an unknown type of cardiac arrhythmia if the morphologies of the cardiac beats are not consistent with any of the plurality of representative beat morphologies;

means for attempting to acquire a new representative beat morphology associated with the unknown type of cardiac arrhythmia;

means for associating the new representative beat morphology with a new type of cardiac arrhythmia if the new representative beat morphology is acquired.

means for delivering one or more selected therapies to terminate the new type of cardiac arrhythmia;

means for determining if a particular one of the selected therapies is successful; and

means for associating the successful therapy with the new type of cardiac arrhythmia.

105. The system of claim 104, further comprising means for determining that the cardiac beats are an uncharacterizable cardiac arrhythmia if the representative beat morphology is not acquired.

106. The system of claim 105, further comprising:

means for delivering one or more selected therapies to terminate the uncharacterizable cardiac arrhythmia;

means for determining if a particular one of the one or more selected therapies is successful; and

means for associating the successful therapy with the uncharacterizable cardiac arrhythmia.

107. The system of claim 99, further comprising:

means for associating one or more previously successful cardiac therapies with each of the one or more types of cardiac arrhythmia; and

means for delivering the one or more particular therapies comprises delivering the one or more previously successful cardiac therapies.

108. A system, comprising:

means for providing one or more templates representative of one or more of a patient's past tachyarrhythmia events, each of the templates associated with a therapy to treat tachyarrhythmia events;

means for detecting a cardiac waveform; and

means for, if the cardiac waveform corresponds to a particular template of the one or more templates, determining if a previous therapy associated with the particular template was satisfactory in terminating a past tachyarrhythmia event associated with the particular template, and if determined satisfactory, delivering the previous therapy, and if determined unsatisfactory, eliminating the previous therapy as an option for treating a subsequent tachyarrhythmia event associated with the particular template.

109. The system of claim 108, wherein if the previous therapy was an antitachycardia pacing therapy determined to be unsatisfactory in terminating the past tachyarrhythmia event, means for eliminating delivery of the antitachycardia pacing therapy as an option for treating a subsequent tachyarrhythmia event and means for associating one or more of a cardioversion, a defibrillation therapy, or an alternate anti-tachycardia pacing therapy with the particular template.

110. The system of claim 108, wherein the correspondence between the cardiac waveform and the particular template is a correspondence in terms of morphology.

111. The system of claim 108, wherein the correspondence between the cardiac waveform and the particular template is a correspondence in terms of timing.

112. The system of claim 108, wherein the correspondence between the cardiac waveform and the particular template is a correspondence in terms of a) drug regimen and morphology or b) drug regimen and timing.

113. The system of claim 108, comprising means for adding a new template to the one or more templates by replacing an oldest template of the one or more templates with the new template.

114. The system of claim 108, comprising means for associating one or more of medication information, neural activity information, patient activity information, hemodynamic status information, cardiac tissue impedance information, and transthoracic impedance information with the one or more templates.

115. The system of claim 108, comprising means for deleting a particular template of the one or more templates if the particular template is older than a predetermined age, or has not corresponded to a cardiac waveform for a predetermined time, or has corresponded to past arrhythmias least frequently relative to other templates, or represents a heart-rate similar to other existing templates.

116. The system of claim 108, comprising means for deleting a particular template of the one or more templates if the particular template is associated with a drug regimen that no longer matches the patient's current drug regimen.

117. The system of claim 108, wherein the detected cardiac waveform is indicative of an arrhythmia in the ventricles, of ventricular or supra-ventricular origin.

118. The system of claim 108, wherein the detected cardiac waveform is indicative of an arrhythmia in the atria.

119. The system of claim 108, further comprising means for arbitrating between two or more templates if the cardiac waveform corresponds to two or more templates.

120. The system of claim 108, further comprising, means for, if the cardiac waveform corresponds to two or more templates, selecting a template of the two or more templates associated with a treatment satisfactory in terminating the past tachyarrhythmia event, and delivering its associated tachyarrhythmia therapy.

121. The system of claim 108, further comprising, means for, if the cardiac waveform corresponds to two or more templates, selecting a most recently used or generated template associated with a treatment satisfactory in terminating the past tachyarrhythmia event, and delivering its associated tachyarrhythmia therapy.

122. The system of claim 108, further comprising, means for, if the cardiac waveform corresponds to two or more templates, selecting the most frequently matched template associated with a treatment satisfactory in terminating the past tachyarrhythmia event, and delivering its associated tachyarrhythmia therapy.

123. The system of claim 108, further comprising, means for if the cardiac waveform corresponds to two or more templates, selecting the template associated with a treatment satisfactory in terminating the past tachyarrhythmia event whose rate information most closely corresponds to the detected cardiac waveform, and delivering its associated tachyarrhythmia therapy.

124. The system of claim 108, further comprising, means for if the cardiac waveform corresponds to two or more templates, selecting the template associated with one or more of a patient's drug regimen, neural activity, patient activity, hemodynamic state, transthoracic impedance, and cardiac tissue impedance similar to the patient's current status.

125. The system of claim 108, further comprising means for associating the particular template with a new therapy if the previous therapy was unsatisfactory.

126. The system of claim 125, wherein the new therapy comprises an anti-tachycardia pacing therapy of substantially equivalent aggression in terms of energy or coupling interval.

127. The system of claim 125, wherein the new therapy comprises an anti-tachycardia pacing therapy of greater aggression in terms of energy or coupling interval.

128. The system of claim 125, wherein the new therapy comprises a cardioversion or defibrillation therapy.

129. A system, comprising:

means for providing one or more templates representative of one or more of a patient's past tachyarrhythmia events, each of the templates associated with a therapy delivered to treat a past tachyarrhythmia event, the one or more templates comprising a low-rate template;

means for detecting a cardiac waveform;

means for determining that the cardiac waveform is indicative of a high-rate tachyarrhythmia event having one or both of a morphology and timing corresponding to the low-rate template; and

means for determining if the delivered therapy associated with the low-rate template was satisfactory in terminating the past tachyarrhythmia event associated with the low-rate template, and if determined satisfactory, delivering the therapy associated with the low-rate template to treat the high-rate tachyarrhythmia event.

130. The system of claim 129, further comprising means for delivering a therapy different from the therapy associated with the low-rate template if the delivered therapy associated with the low-rate template was unsatisfactory in terminating the past ventricular tachyarrhythmia event associated with the low-rate template.

131. A cardiac template generation system, comprising:

means for providing, patient-externally, a cardiac waveform representative of a patient's cardiac activity comprising an arrhythmic event;

means for identifying, patient-externally, a portion of the cardiac waveform indicative of the arrhythmic event;

means for generating a cardiac template corresponding to the cardiac waveform portion; and

means for associating a therapy with the cardiac template useful for treating a subsequent arrhythmic event corresponding to the cardiac template.

132. The system of claim 131, wherein the portion of the cardiac waveform indicative of the arrhythmic event is identified by a physician using a patient-external device configured to display the cardiac waveform.

133. The system of claim 131, wherein the template is generated in response to a physician selecting the portion of the cardiac waveform indicative of the arrhythmic event.

134. The system of claim 131, comprising means for determining if the therapy associated with the cardiac template was satisfactory in treating the arrhythmic event.

135. The system of claim 131, comprising means for determining if the therapy associated with the cardiac template was effective in terminating the arrhythmic event.

136. The system of claim 131, further comprising means for matching the arrhythmic event to one of a plurality of templates generated using cardiac waveforms other than the patient's cardiac waveforms.

137. The system of claim 131, wherein the template is generated in a patient-internal medical device.

138. The system of claim 131, wherein the template is generated in a patient-external medical device.

139. The system of claim 131, wherein the template is generated in an advanced patient management system.

140. The system of claim 131, further comprising means for determining if the therapy associated with the template is an antitachycardia pacing therapy determined to be unsatisfactory in treating the arrhythmic event and means for eliminating delivery of the antitachycardia pacing therapy as an option for treating a subsequent tachyarrhythmia event and associating one or more of a cardioversion, a defibrillation therapy, or an alternate ATP therapy with the template.

141. The system of claim 131, comprising means for enabling use of a previously eliminated therapy option in response to one or more of a physician and an advanced patient management system selecting the previously eliminated therapy option to be re-associated with the particular template.

142. The system of claim 131, further comprising means for associating the template with a new therapy if a previous therapy was unsatisfactory.

143. The system of claim 142, wherein the new therapy is selected by one or more of a physician and an advanced patient management system or is randomly selected from two or more therapies.

144. A system comprising:

means for sensing an intrinsic electrical heart signal using an implantable medical device;

means for identifying a tachyarrhythmia portion of the intrinsic electrical heart signal and storing at least part of the tachyarrhythmia portion of the intrinsic electrical heart signal;

means for receiving user input declaring the tachyarrhythmia portion of the intrinsic electrical heart signal to be indicative of SVT;

means for generating a SVT template from the tachyarrhythmia portion of the heart signal;

means for determining at least one degree of similarity between a second portion of the heart signal from a later tachyarrhythmia episode and the SVT template; and

means for declaring the second portion of the heart signal to represent an SVT episode if the at least one degree of similarity exceeds at least one threshold value.

145. The system of claim 144, further comprising means for presenting the tachyarrhythmia portion of the intrinsic electrical heart signal to a user and receiving input indicating a segment of the tachyarrhythmia portion of the intrinsic electrical heart signal to be used to generated the SVT template.

146. The system of claim 145, further comprising means for presenting a plurality of portions of the intrinsic electrical heart signal corresponding to a plurality of tachyarrhythmia episodes to a user and receiving input indicating which of the plurality of portions of the intrinsic electrical signal are to be used to generate one or more SVT templates.

147. The system of claim 144, further comprising means for suppressing a ventricular tachyarrhythmia therapy during the declared SVT episode.

148. The system of claim 144, further comprising means for selecting the SVT template from a group of two or more candidate SVT templates.

149. The system of claim 144, further comprising:

means for monitoring a heart rate;

means for determining if the heart rate exceeds a rate threshold; and

declaring a tachyarrhythmia if the heart rate exceeds the rate threshold.

150. The system of claim 149, further comprising:

means for comparing the second portion of the electrical signal with a normal sinus rhythm (NSR) template; and

means for, if the second portion of the electrical signal sufficiently correlates to the NSR template, declaring the second portion of the electrical signal to be a SVT episode and suppressing a ventricular tachyarrhythmia therapy during the declared SVT episode.

151. A system comprising:

means for sensing an intrinsic electrical heart signal using an implantable medical device;

means for identifying a tachyarrhythmia portion of the heart signal that is indicative of a tachyarrhythmia episode;

means for receiving user input declaring the tachyarrhythmia portion of the heart signal to be indicative of the tachyarrhythmia episode that does not require ventricular antitachyarrhythmia therapy;

means for generating from the tachyarrhythmia portion of the heart signal at least one template representative of the tachyarrhythmia episode that does not require therapy;

means for detecting a heart rate using the heart signal; and

means for, if the heart rate exceeds a rate threshold value at a later time, then declaring a later tachyarrhythmia, and if a later tachyarrhythmia is declared, then:

determining at least one degree of similarity between a second portion of the heart signal from the later tachyarrhythmia and at least one template representative of a tachyarrhythmia episode that does not require therapy; and

if the at least one degree of similarity exceeds at least one threshold value, suppressing a ventricular tachyarrhythmia therapy, otherwise delivering a ventricular antitachyarrhythmia therapy.

152. A system comprising:

means for sensing an intrinsic electrical heart signal;

means for monitoring information about a patient;

means for using the information about the patient to select at least one supraventricular tachyarrhythmia (SVT) template from a group of two or more candidate SVT templates;

means for determining at least one degree of similarity between a portion of the heart signal from a tachyarrhythmia episode and the at least one SVT template; and

means for declaring the portion of the heart signal from the tachyarrhythmia episode to represent a SVT episode if the at least one degree of similarity exceeds at least one threshold value.

153. The system of claim 152, wherein each candidate SVT template is associated with a heart rate at which the prior tachyarrhythmia episode used to generate the SVT template was observed.

154. The system of claim 152, further comprising means for monitoring a patient's heart rate from the intrinsic electrical heart signal from a tachyarrhythmia episode; and

means for selecting the candidate SVT template having the associated heart rate that is closest to the monitored heart rate.

155. The system of claim 154, further comprising means for selecting the candidate SVT template having the associated heart rate that is second closest to the heart rate of the tachyarrhythmia episode.

156. The system of claim 152, further comprising means for determining degrees of similarity between the portion of the heart signal from the tachyarrhythmia episode and multiple SVT templates.

157. The system of claim 152, further comprising:

means for identifying portions of the heart signal that are indicative of SVT; and

means for storing the portions of the heart signal that are indicative of SVT as candidate SVT templates.

158. The system of claim 157, further comprising:

means for storing SVT templates in a medium; and

means for discarding an oldest one of the SVT templates.

159. The system of claim 157, further comprising:

means for storing SVT templates in a medium; and

means for discarding a SVT template associated with a discontinued drug therapy regimen.

160. The system of claim 157, wherein further comprising:

means for storing SVT templates in a medium; and

means for further comprising receiving an input from a user designating a SVT template to be discarded, and discarding the designated SVT template.

161. The system of claim 157, further comprising:

means for tracking the degree of similarity of the heart signal from a tachyarrhythmia episode to the candidate SVT templates; and

means for discarding a candidate SVT template exhibiting the least frequent similarity with the heart signal.

162. The system of claim 157, further comprising:

means for storing SVT templates in a medium; and

means for discarding an SVT template with a heart rate similar to heart rates at which other SVT templates were identified.

163. The system of claim 157, further comprising:

means for storing SVT templates in a medium; and

means for discarding an SVT template that is most similar to other SVT templates.

164. The system of claim 152, further comprising:

means for determining at least one degree of similarity between a portion of the heart signal from a tachyarrhythmia episode and a first SVT template; and

means for, if the degree of similarity between the portion of the heart signal and the first template does not exceed a threshold, determining at least one degree of similarity between the portion of the heart signal from the tachyarrhythmia episode and a second template.

165. The system of claim 152, further comprising:

means for computing a feature correlation coefficient for each of a plurality of portions of the intrinsic electrical heart signal detected during a tachyarrhythmia episode; and

means for withholding treatment if at least a predetermined fraction of the feature correlation coefficients exceed a predetermined threshold.

166. The system of claim 165, further comprising means for computing a feature correlation coefficient for each of a plurality of sequential heart beats.

167. The system of claim 166, wherein the predetermined fraction and the predetermined threshold are programmably selectable.

168. The system of claim 167, wherein the threshold is selected using statistics from patients having similar characteristics.

169. The system of claim 168, wherein the threshold is selected based upon the patient's age, disease history, and medication.

170. The system of claim 152, wherein monitoring information about the patient includes monitoring the patient's neural activity, sleep state, hemodynamic status, transthoracic impedance and cardiac impedance.

171. The system of claim 152, further comprising:

means for comparing the portion of the electrical signal from a tachyarrhythmia episode with a normal sinus rhythm (NSR) template; and

means for determining if the portion of the electrical signal sufficiently correlates to the NSR template;

means for declaring the portion of the electrical signal to be an SVT episode if the portion of the electrical signal sufficiently correlates to the NSR template.

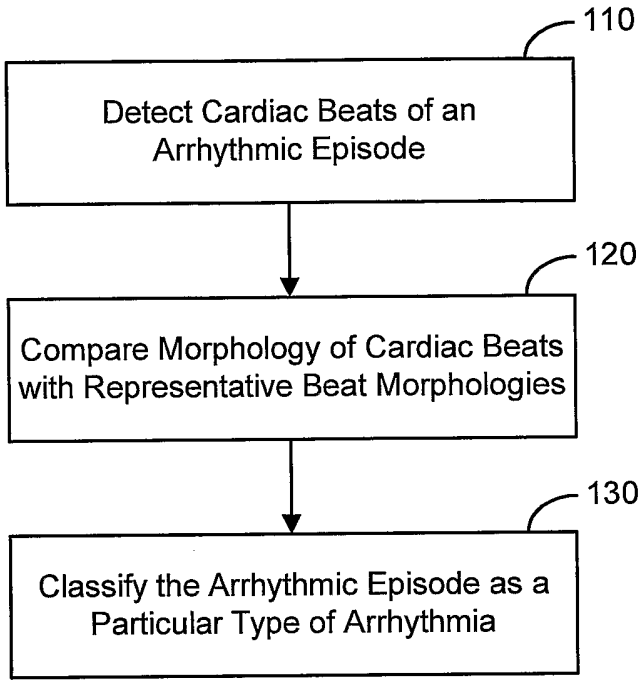

110
Detect Cardiac Beats of an Arrhythmic Episode
120
Compare Morphology of Cardiac Beats with Representative Beat Morphologies
130
Classify the Arrhythmic Episode as a Particular Type of Arrhythmia

Figure 1A

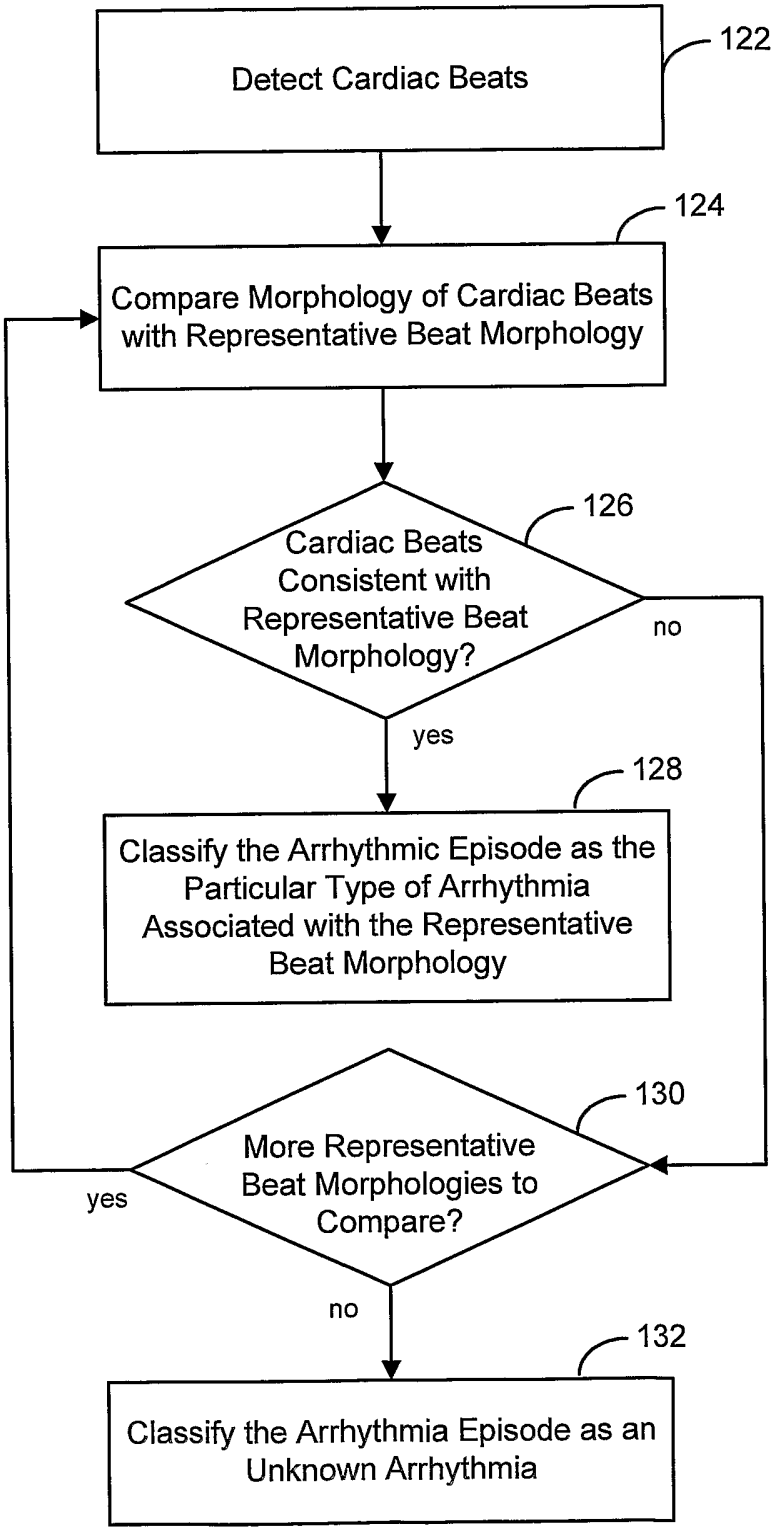

Detect Cardiac Beats
122
Compare Morphology of Cardiac Beats with Representative Beat Morphology
124
Cardiac Beats Consistent with Representative Beat Morphology?
126
no
yes
Classify the Arrhythmic Episode as the Particular Type of Arrhythmia Associated with the Representative Beat Morphology
128
More Representative Beat Morphologies to Compare?
130
yes
no
Classify the Arrhythmia Episode as an Unknown Arrhythmia
132

Figure 1B

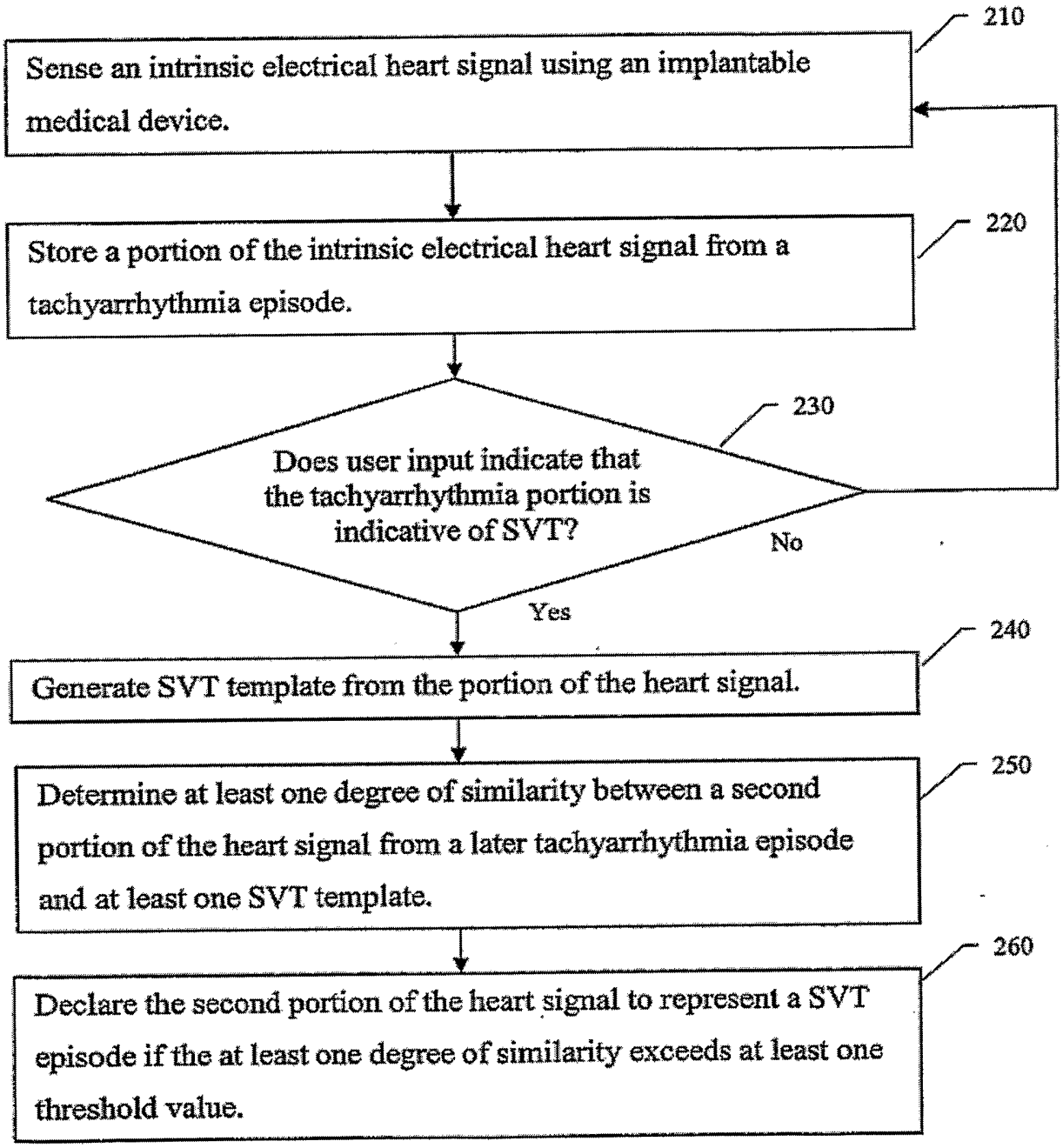

210
Sense an intrinsic electrical heart signal using an implantable medical device.
220
Store a portion of the intrinsic electrical heart signal from a tachyarrhythmia episode.
230
Does user input indicate that the tachyarrhythmia portion is indicative of SVT?
No
Yes
240
Generate SVT template from the portion of the heart signal.
250
Determine at least one degree of similarity between a second portion of the heart signal from a later tachyarrhythmia episode and at least one SVT template.
260
Declare the second portion of the heart signal to represent a SVT episode if the at least one degree of similarity exceeds at least one threshold value.

Figure 2A

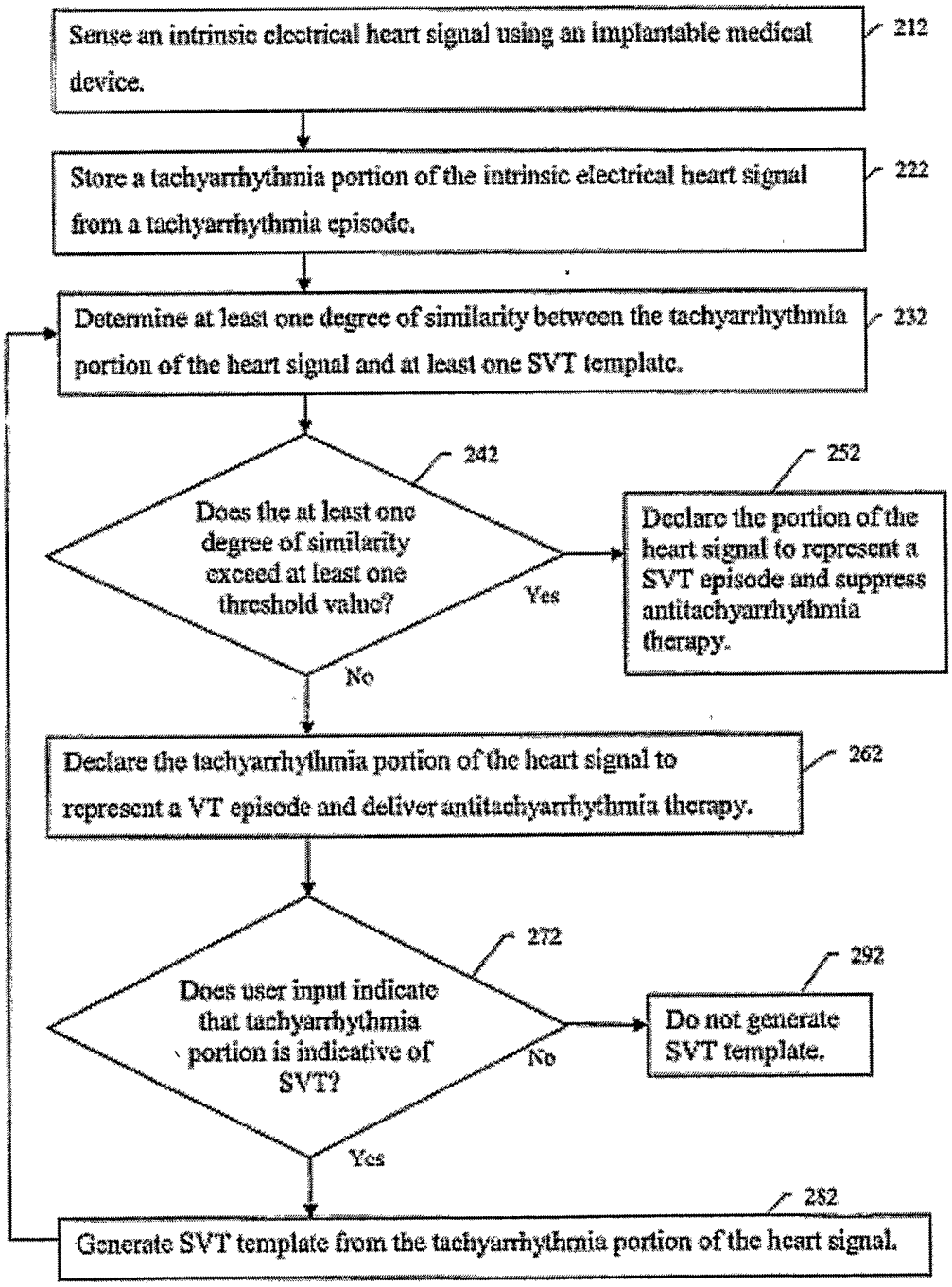

Sense an intrinsic electrical heart signal using an implantable medical device.
212
Store a tachyarrhythmia portion of the intrinsic electrical heart signal from a tachyarrhythmia episode.
222
Determine at least one degree of similarity between the tachyarrhythmia portion of the heart signal and at least one SVT template.
232
242
Does the at least one degree of similarity exceed at least one threshold value?
Yes
252
Declare the portion of the heart signal to represent a SVT episode and suppress antitachyarrhythmia therapy.
No
Declare the tachyarrhythmia portion of the heart signal to represent a VT episode and deliver antitachyarrhythmia therapy.
262
272
Does user input indicate that tachyarrhythmia portion is indicative of SVT?
No
292
Do not generate SVT template.
Yes
282
Generate SVT template from the tachyarrhythmia portion of the heart signal.

Figure 2B

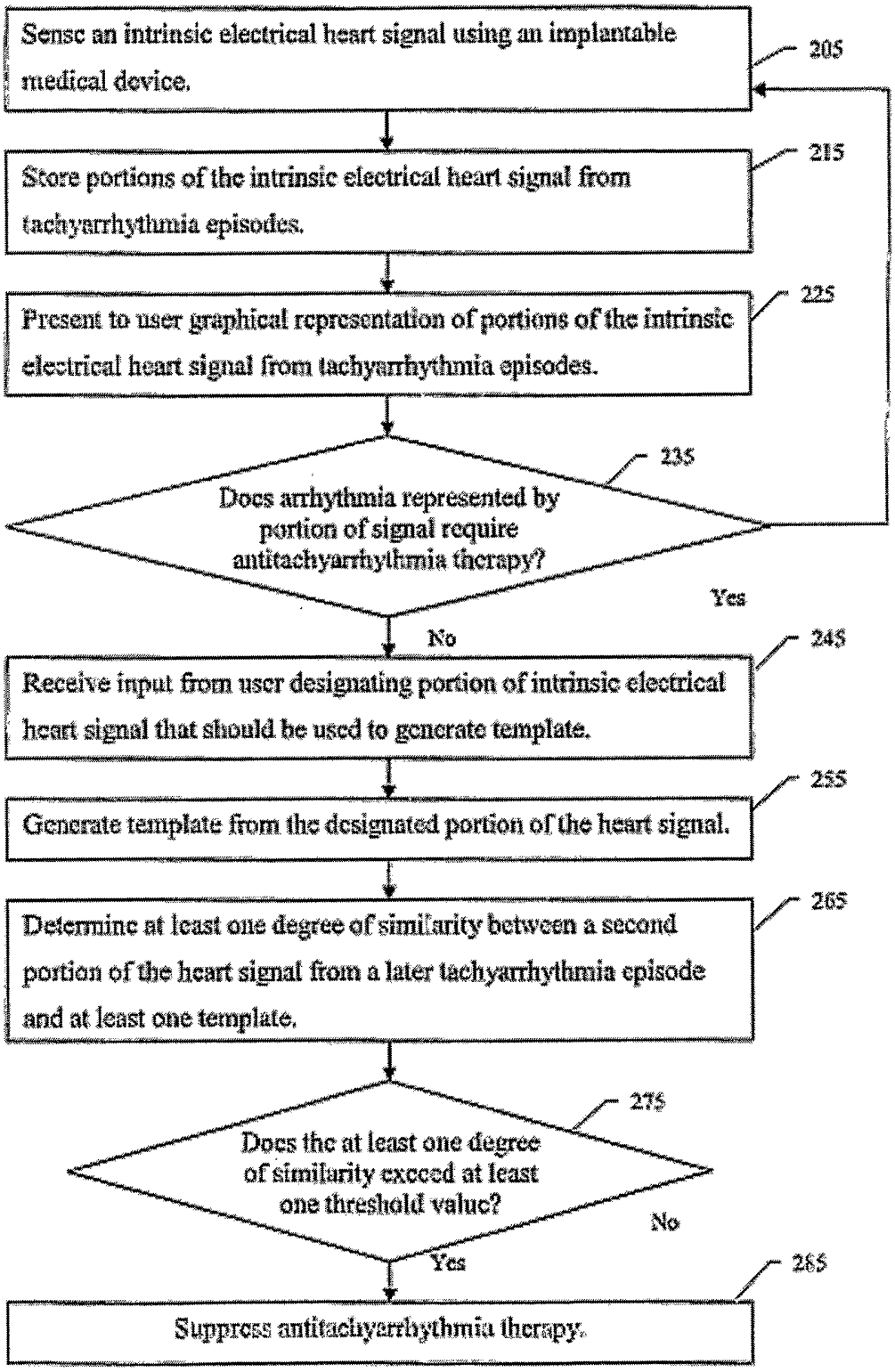

Sense an intrinsic electrical heart signal using an implantable medical device.
205
Store portions of the intrinsic electrical heart signal from tachyarrhythmia episodes.
215
Present to user graphical representation of portions of the intrinsic electrical heart signal from tachyarrhythmia episodes.
225
Does arrhythmia represented by portion of signal require antitachyarrhythmia therapy?
235
Yes
No
Receive input from user designating portion of intrinsic electrical heart signal that should be used to generate template.
245
Generate template from the designated portion of the heart signal.
255
Determine at least one degree of similarity between a second portion of the heart signal from a later tachyarrhythmia episode and at least one template.
265
Does the at least one degree of similarity exceed at least one threshold value?
275
No
Yes
Suppress antitachyarrhythmia therapy.
285

Figure 2C

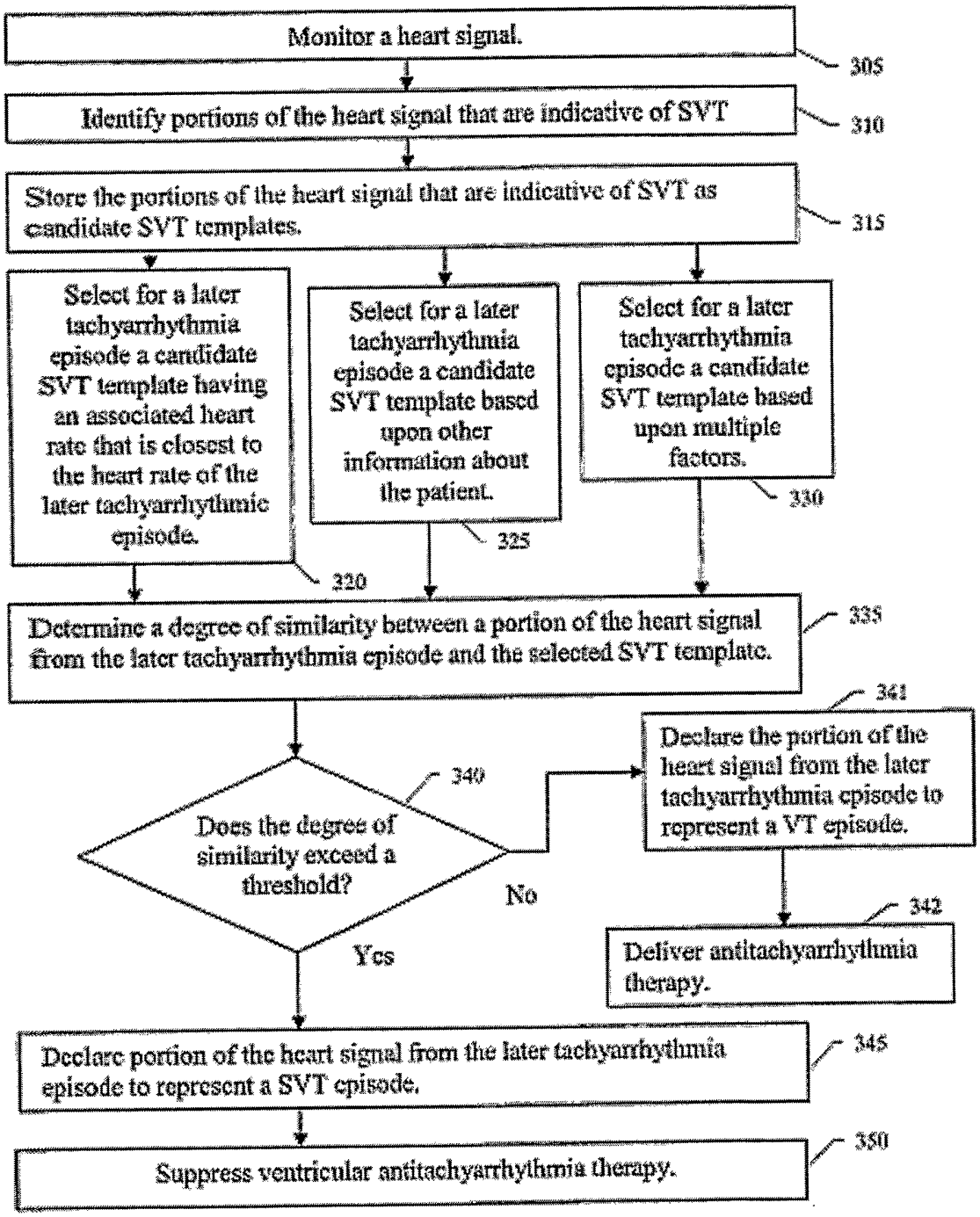

Monitor a heart signal.
305
Identify portions of the heart signal that are indicative of SVT
310
Store the portions of the heart signal that are indicative of SVT as candidate SVT templates.
315
Select for a later tachyarrhythmia episode a candidate SVT template having an associated heart rate that is closest to the heart rate of the later tachyarrhythmic episode.
320
Select for a later tachyarrhythmia episode a candidate SVT template based upon other information about the patient.
325
Select for a later tachyarrhythmia episode a candidate SVT template based upon multiple factors.
330
Determine a degree of similarity between a portion of the heart signal from the later tachyarrhythmia episode and the selected SVT template.
335
Does the degree of similarity exceed a threshold?
340
No
Yes
Declare the portion of the heart signal from the later tachyarrhythmia episode to represent a VT episode.
341
Deliver antitachyarrhythmia therapy.
342
Declare portion of the heart signal from the later tachyarrhythmia episode to represent a SVT episode.
345
Suppress ventricular antitachyarrhythmia therapy.
350

Figure 3

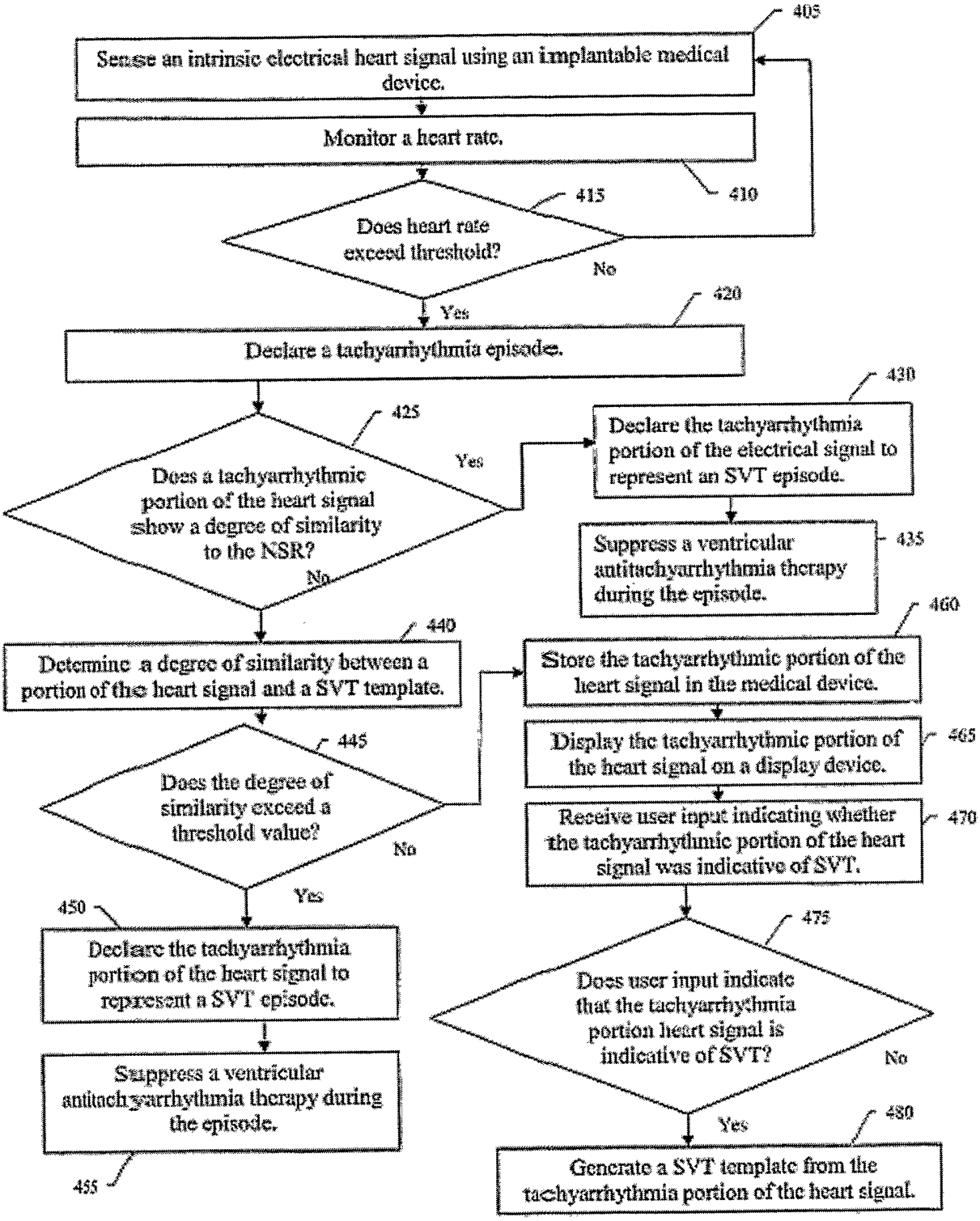

405
Sense an intrinsic electrical heart signal using an implantable medical device.
Monitor a heart rate.
410
415
Does heart rate exceed threshold?
No
Yes
420
Declare a tachyarrhythmia episode.
425
Does a tachyarrhythmic portion of the heart signal show a degree of similarity to the NSR?
Yes
No
430
Declare the tachyarrhythmia portion of the electrical signal to represent an SVT episode.
435
Suppress a ventricular antitachyarrhythmia therapy during the episode.
440
Determine a degree of similarity between a portion of the heart signal and a SVT template.
445
Does the degree of similarity exceed a threshold value?
No
Yes
450
Declare the tachyarrhythmia portion of the heart signal to represent a SVT episode.
Suppress a ventricular antitachyarrhythmia therapy during the episode.
455
460
Store the tachyarrhythmic portion of the heart signal in the medical device.
465
Display the tachyarrhythmic portion of the heart signal on a display device.
470
Receive user input indicating whether the tachyarrhythmic portion of the heart signal was indicative of SVT.
475
Does user input indicate that the tachyarrhythmia portion heart signal is indicative of SVT?
No
Yes
480
Generate a SVT template from the tachyarrhythmia portion of the heart signal.

Figure 4

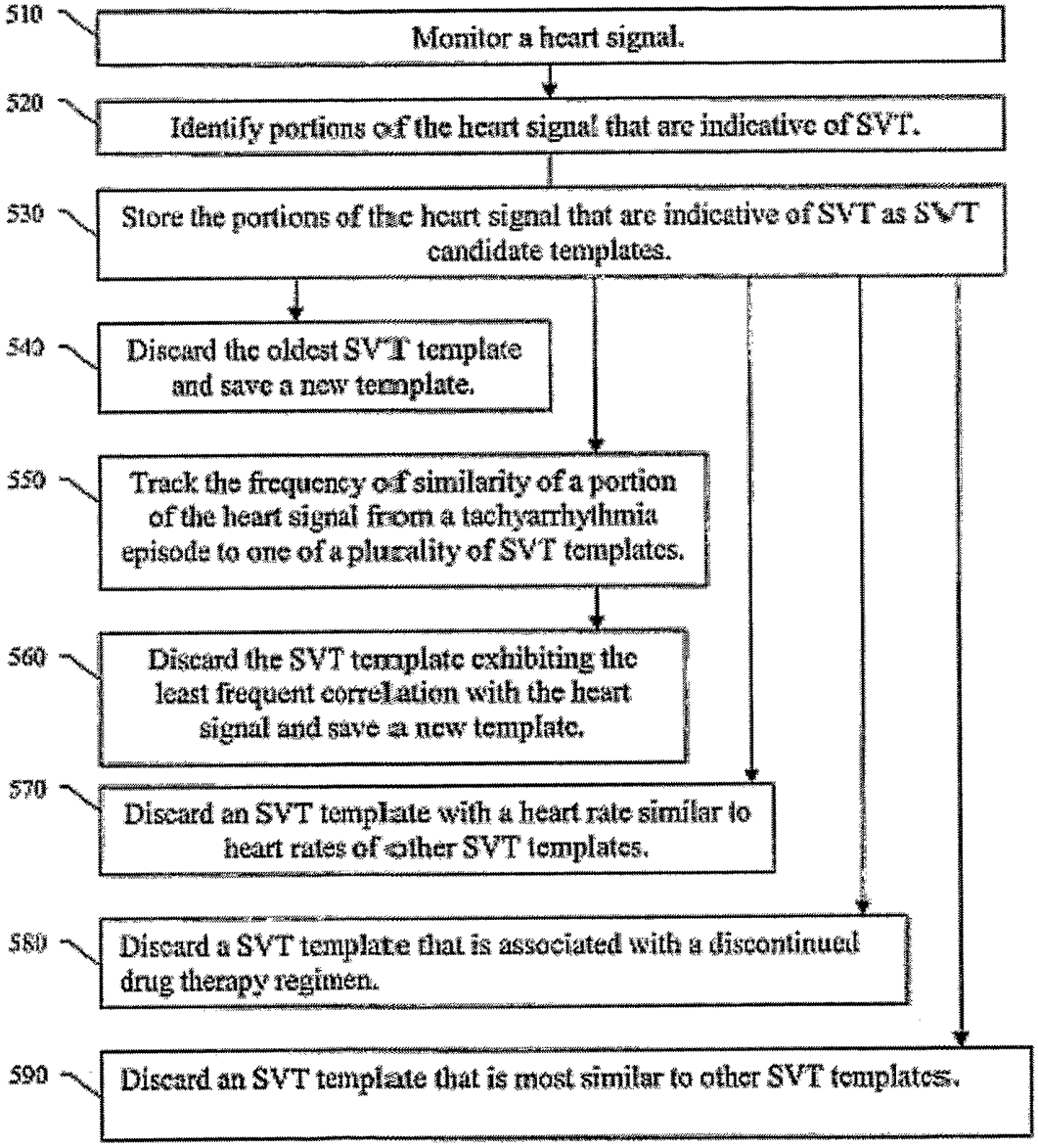

510
Monitor a heart signal.
520
Identify portions of the heart signal that are indicative of SVT.
530
Store the portions of the heart signal that are indicative of SVT as SVT candidate templates.
540
Discard the oldest SVT template and save a new template.
550
Track the frequency of similarity of a portion of the heart signal from a tachyarrhythmia episode to one of a plurality of SVT templates.
560
Discard the SVT template exhibiting the least frequent correlation with the heart signal and save a new template.
570
Discard an SVT template with a heart rate similar to heart rates of other SVT templates.
580
Discard a SVT template that is associated with a discontinued drug therapy regimen.
590
Discard an SVT template that is most similar to other SVT templates.

Figure 5

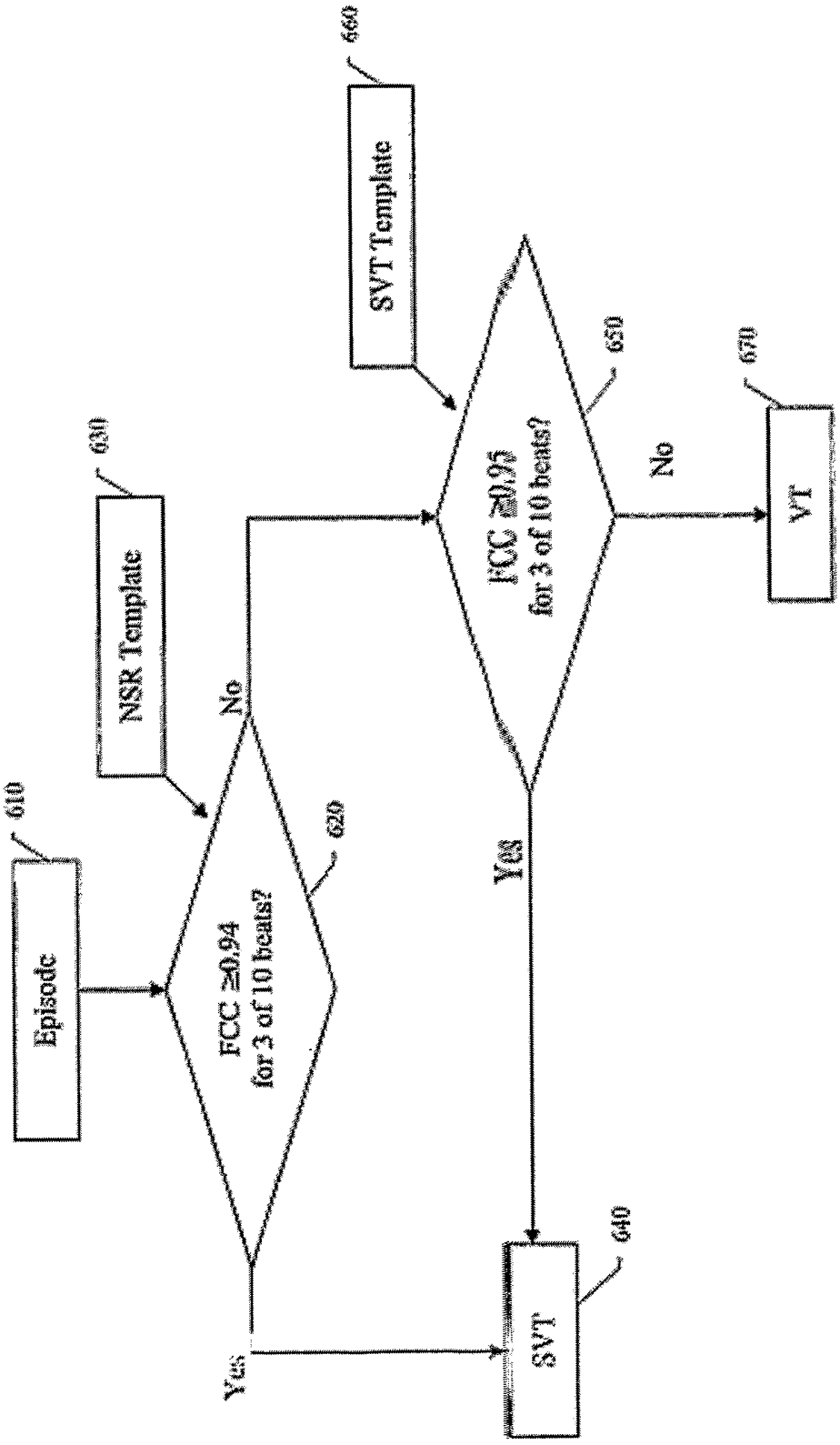

660
SVT Template
650
FCC ≥0.95
for 3 of 10 beats?
No
670
VT
Yes
630
NSR Template
No
610
Episode
620
FCC ≥0.94
for 3 of 10 beats?
Yes
640
SVT

Figure 6

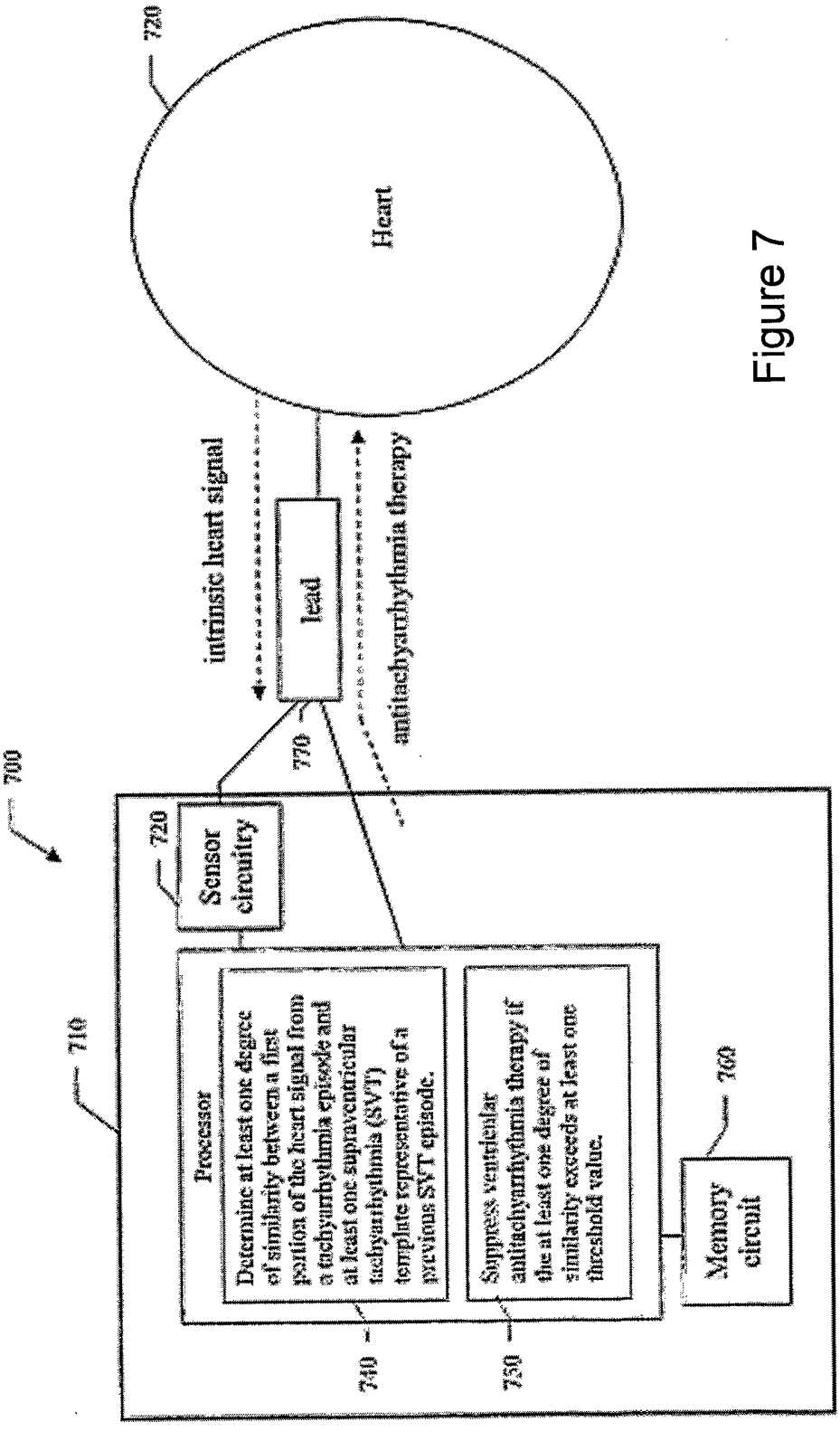

700
710
720
Sensor circuitry
Processor
Determine at least one degree of similarity between a first portion of the heart signal from a tachyarrhythmia episode and at least one supraventricular tachyarrhythmia (SVT) template representative of a previous SVT episode.
740
Suppress ventricular antitachyarrhythmia therapy if the at least one degree of similarity exceeds at least one threshold value.
750
Memory circuit
760
770
lead
intrinsic heart signal
antitachyarrhythmia therapy
720
Heart

Figure 7

NSR Template

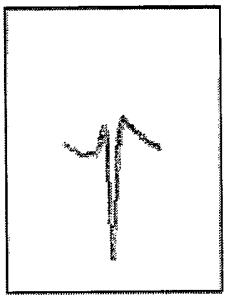


Figure 8

SVT

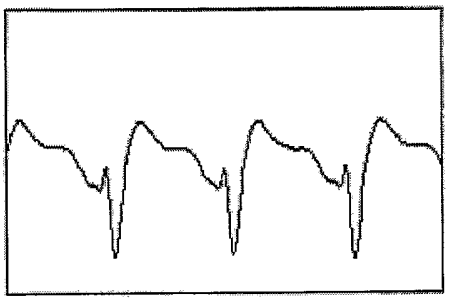


Figure 9

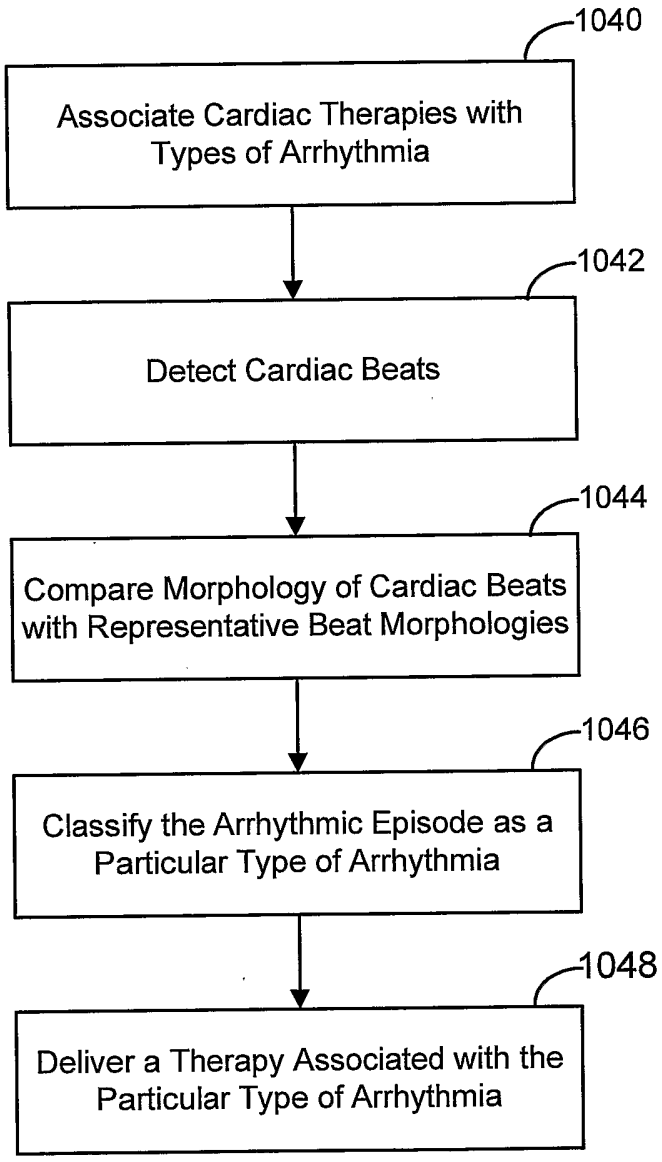

1040
Associate Cardiac Therapies with Types of Arrhythmia
1042
Detect Cardiac Beats
1044
Compare Morphology of Cardiac Beats with Representative Beat Morphologies
1046
Classify the Arrhythmic Episode as a Particular Type of Arrhythmia
1048
Deliver a Therapy Associated with the Particular Type of Arrhythmia

Figure 10

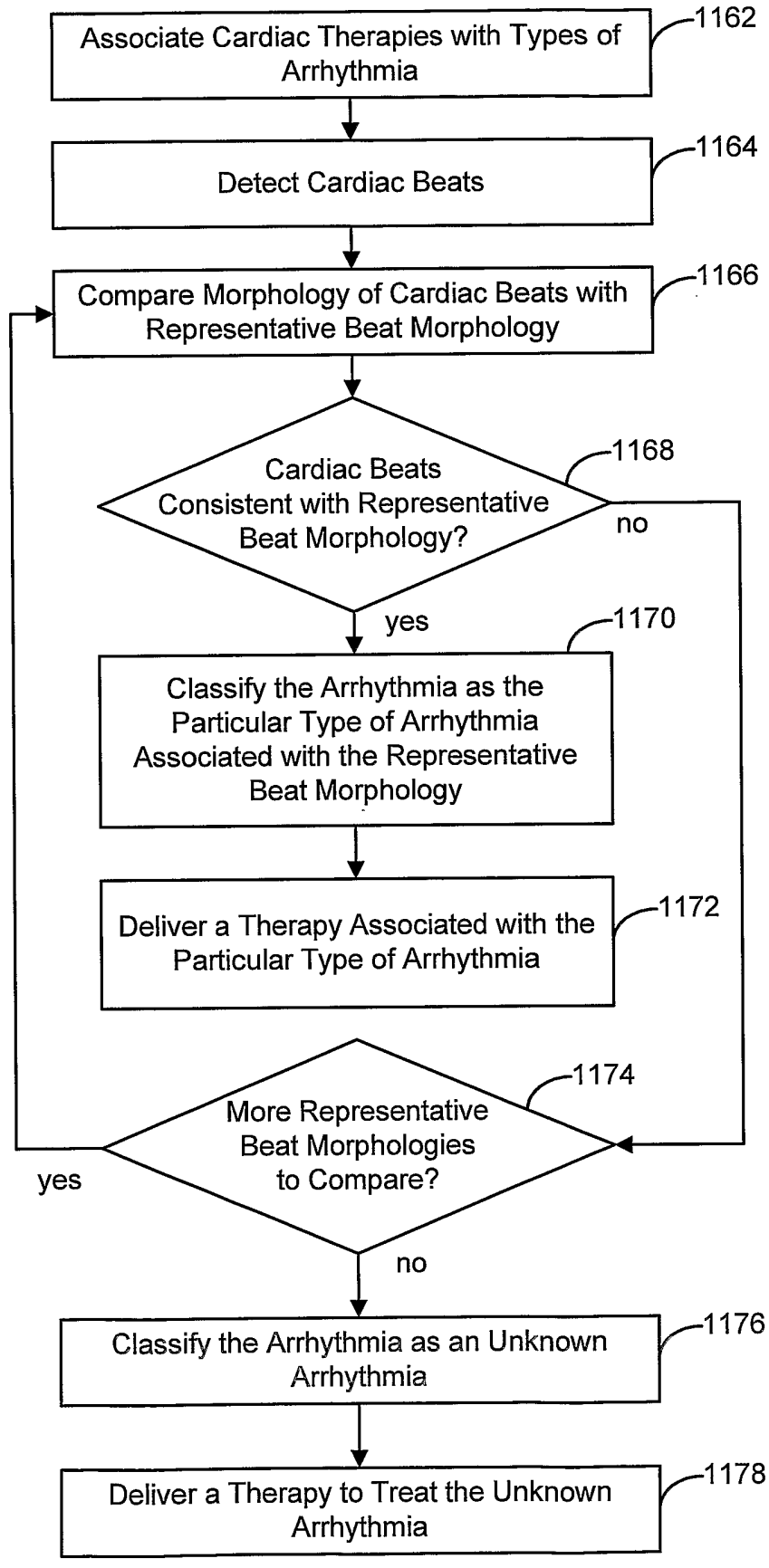

Associate Cardiac Therapies with Types of Arrhythmia
1162
Detect Cardiac Beats
1164
Compare Morphology of Cardiac Beats with Representative Beat Morphology
1166
Cardiac Beats Consistent with Representative Beat Morphology?
1168
no
yes
Classify the Arrhythmia as the Particular Type of Arrhythmia Associated with the Representative Beat Morphology
1170
Deliver a Therapy Associated with the Particular Type of Arrhythmia
1172
More Representative Beat Morphologies to Compare?
1174
yes
no
Classify the Arrhythmia as an Unknown Arrhythmia
1176
Deliver a Therapy to Treat the Unknown Arrhythmia
1178

Figure 11

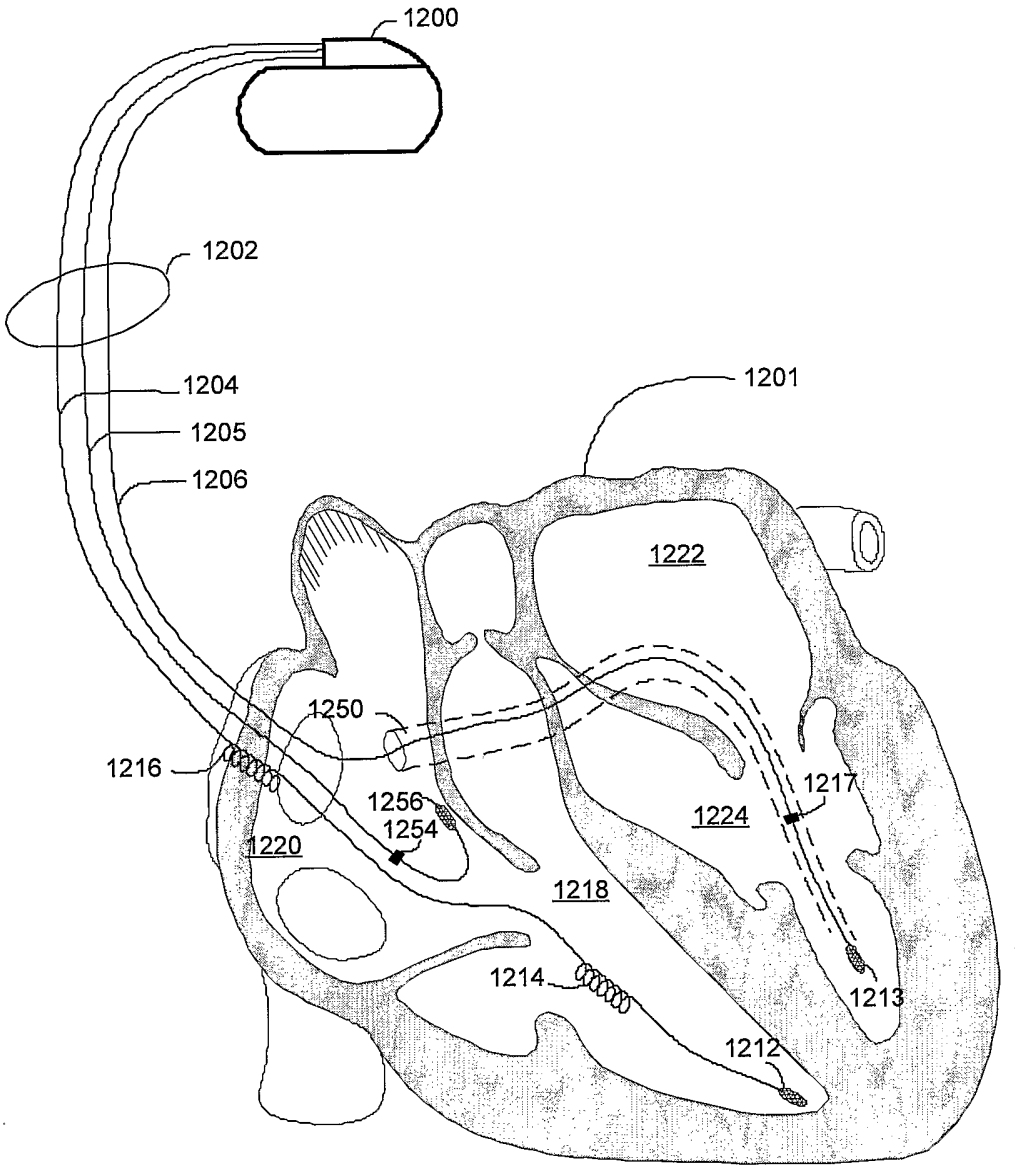

1200
1202
1204
1205
1206
1201
1222
1250
1216
1256
1254
1220
1224
1217
1218
1214
1213
1212

Figure 12

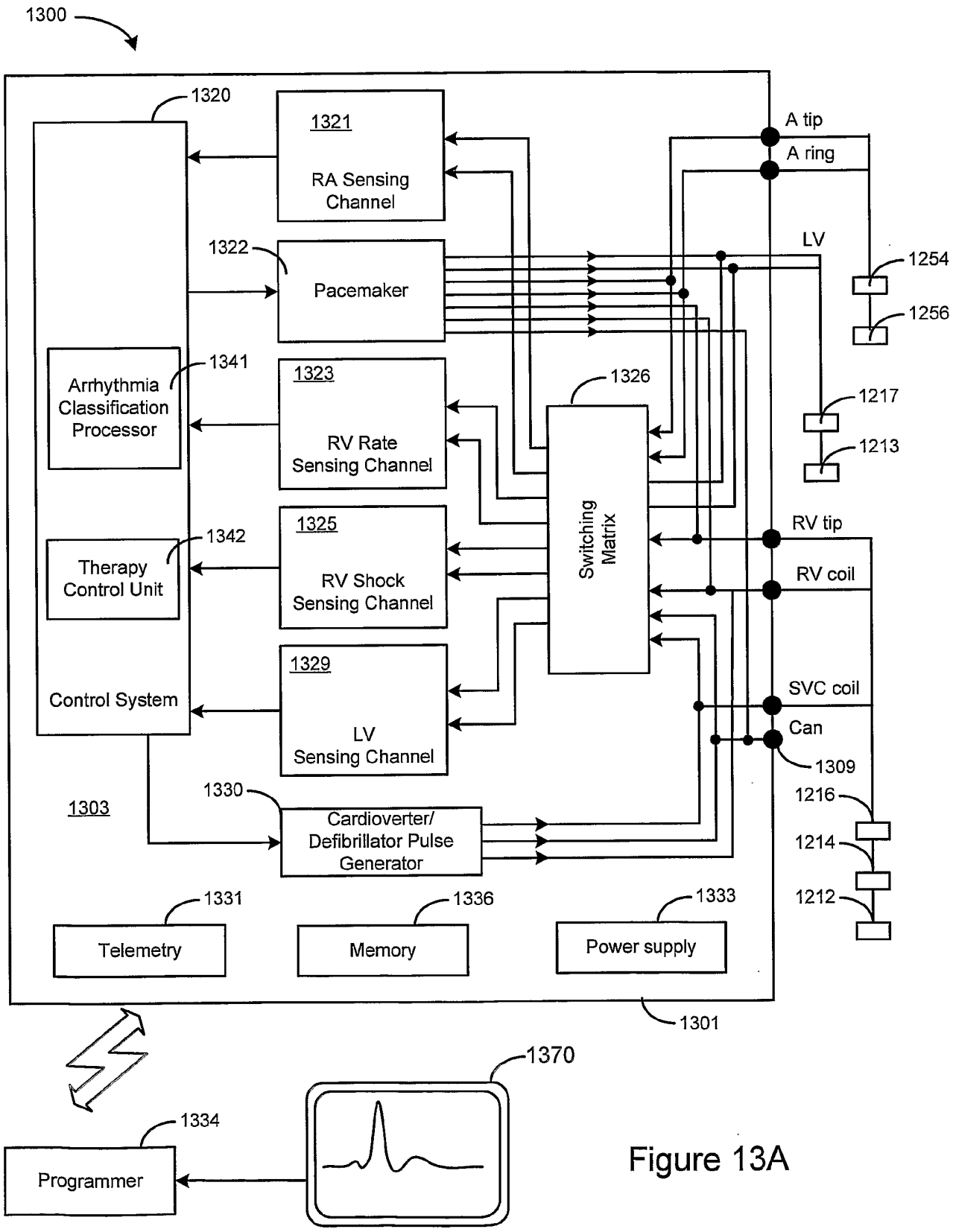

1300
1320
1321
RA Sensing Channel
1322
Pacemaker
1341
Arrhythmia Classification Processor
1323
RV Rate Sensing Channel
1326
1342
Therapy Control Unit
1325
RV Shock Sensing Channel
1329
LV Sensing Channel
Control System
1303
1330
Cardioverter/ Defibrillator Pulse Generator
Switching Matrix
A tip
A ring
LV
1254
1256
1217
1213
RV tip
RV coil
SVC coil
Can
1309
1216
1214
1212
1331
Telemetry
1336
Memory
1333
Power supply
1301
1370
1334
Programmer

Figure 13A

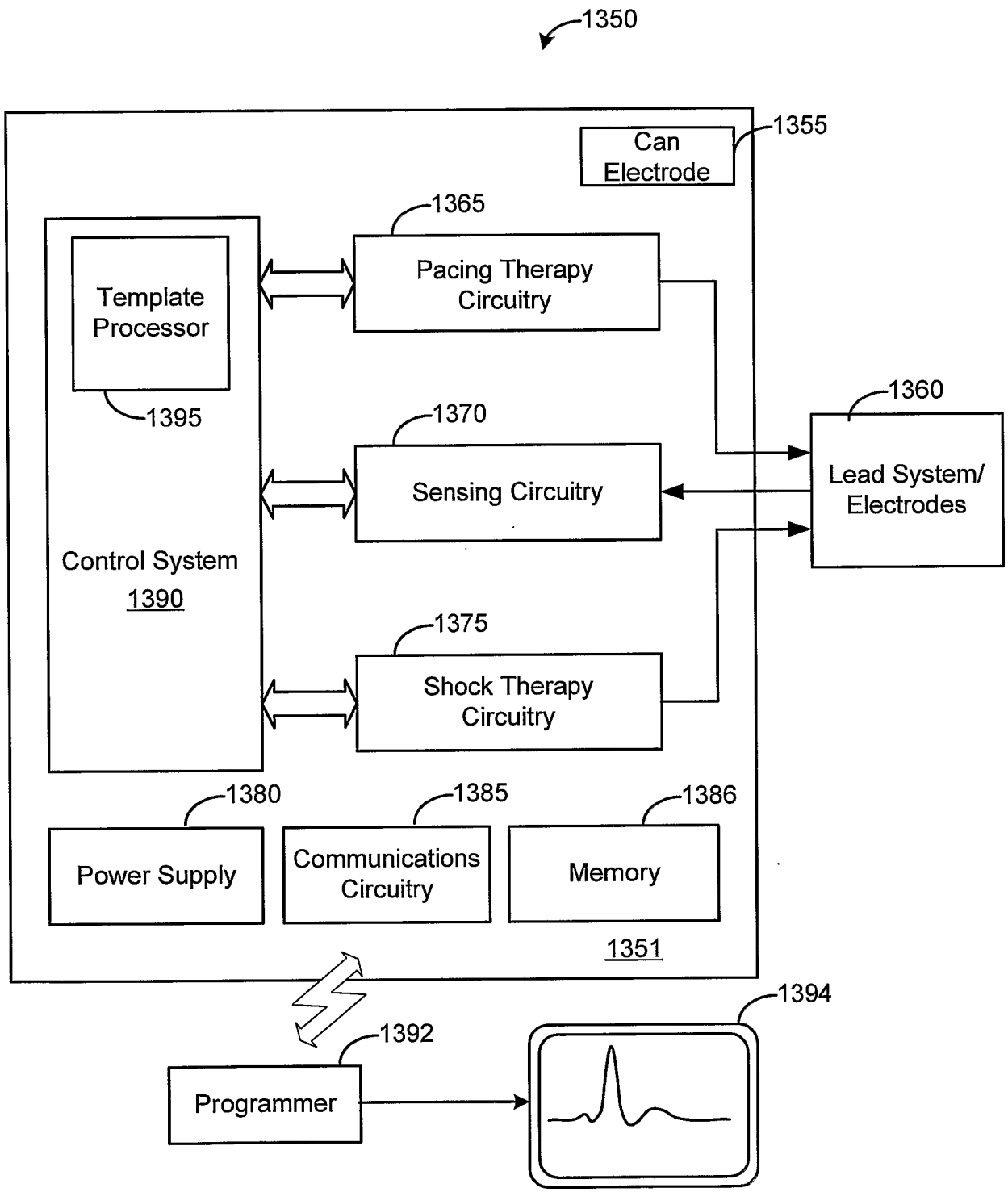

1350
1355
Can Electrode
1365
Pacing Therapy Circuitry
Template Processor
1395
1360
Lead System/ Electrodes
1370
Sensing Circuitry
Control System
1390
1375
Shock Therapy Circuitry
1380
1385
1386
Power Supply
Communications Circuitry
Memory
1351
1394
1392
Programmer

Figure 13B

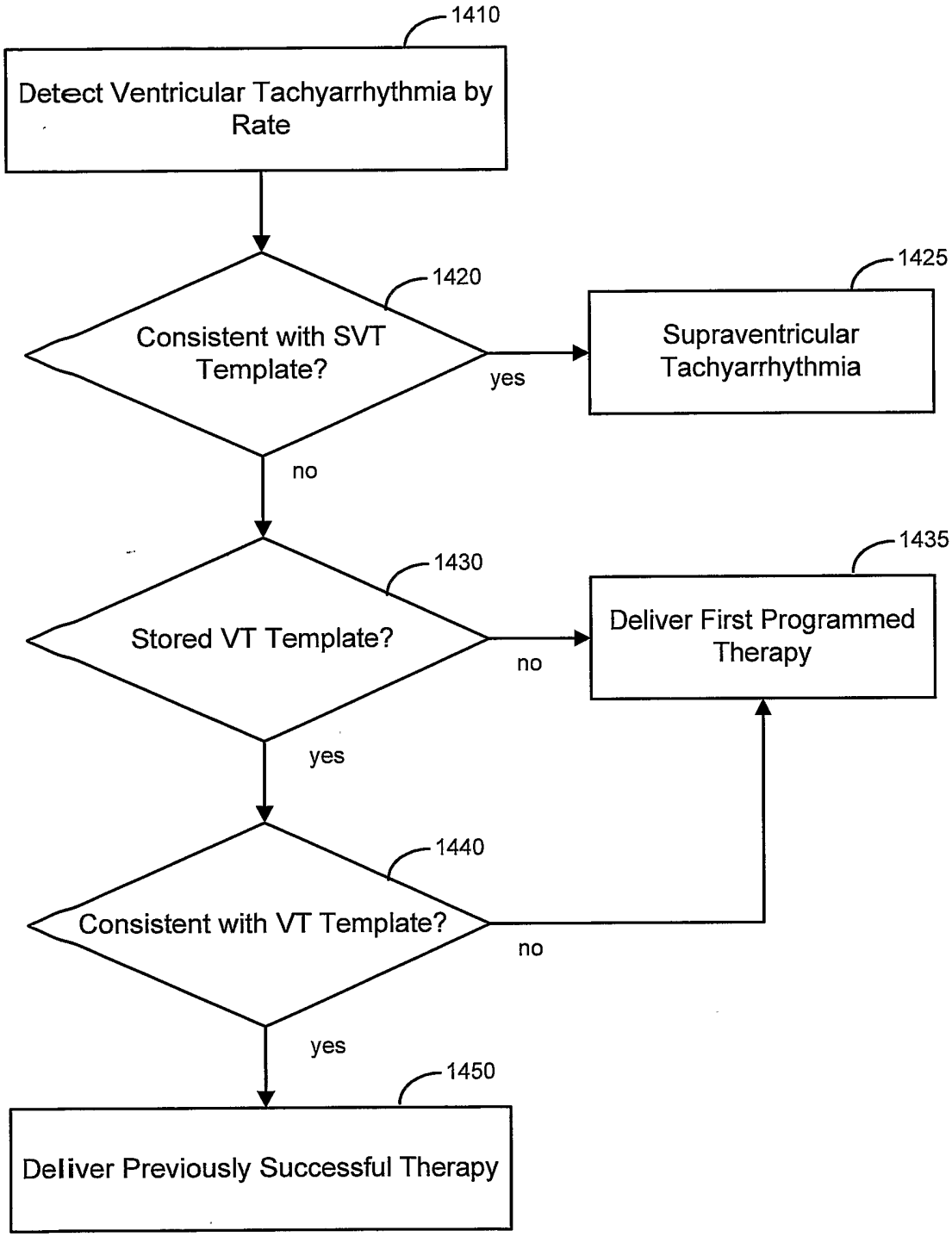

1410
Detect Ventricular Tachyarrhythmia by Rate
1420
Consistent with SVT Template?
yes
1425
Supraventricular Tachyarrhythmia
no
1430
Stored VT Template?
no
1435
Deliver First Programmed Therapy
yes
1440
Consistent with VT Template?
no
yes
1450
Deliver Previously Successful Therapy

Figure 14

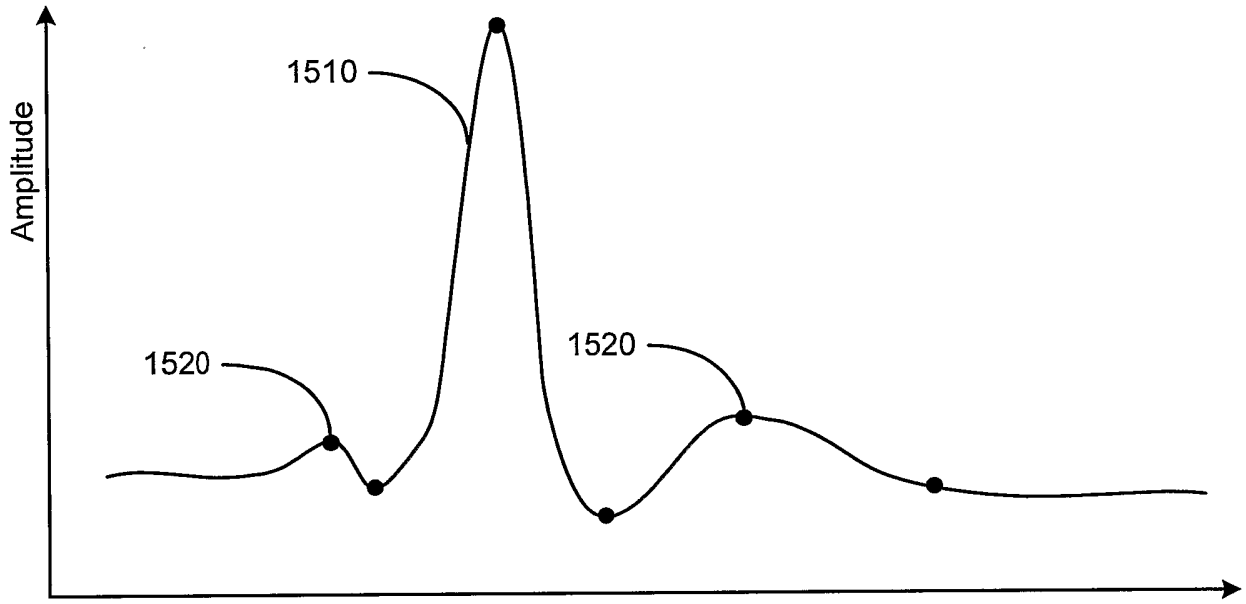


Figure 15

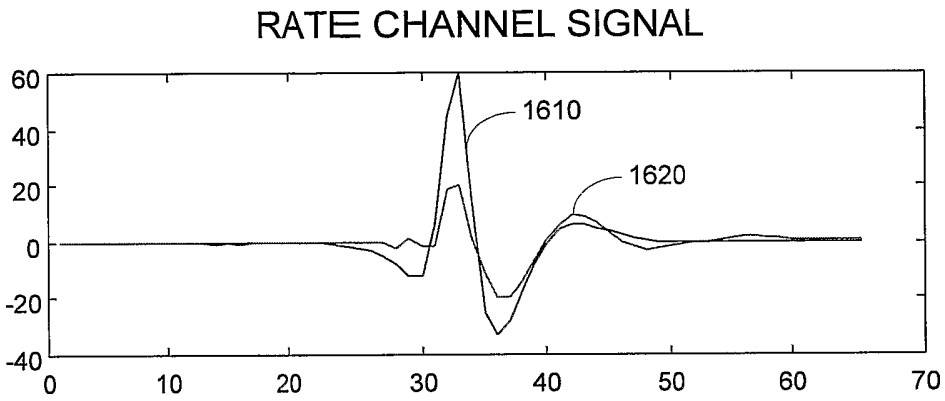


Figure 16A

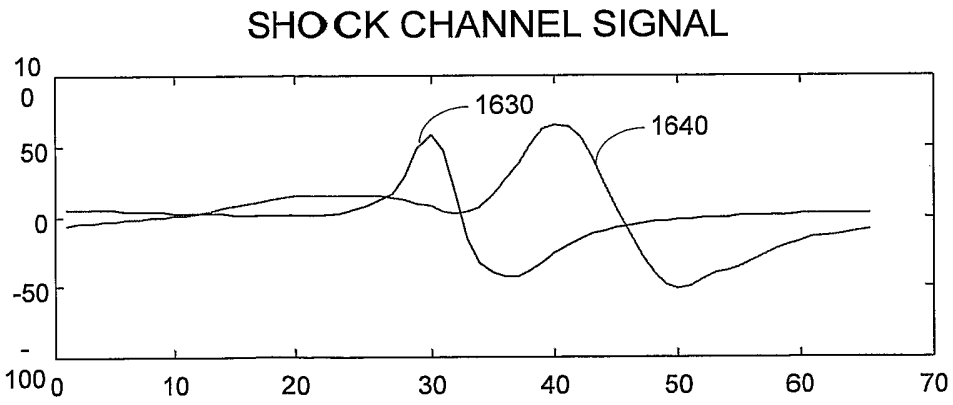


Figure 16B

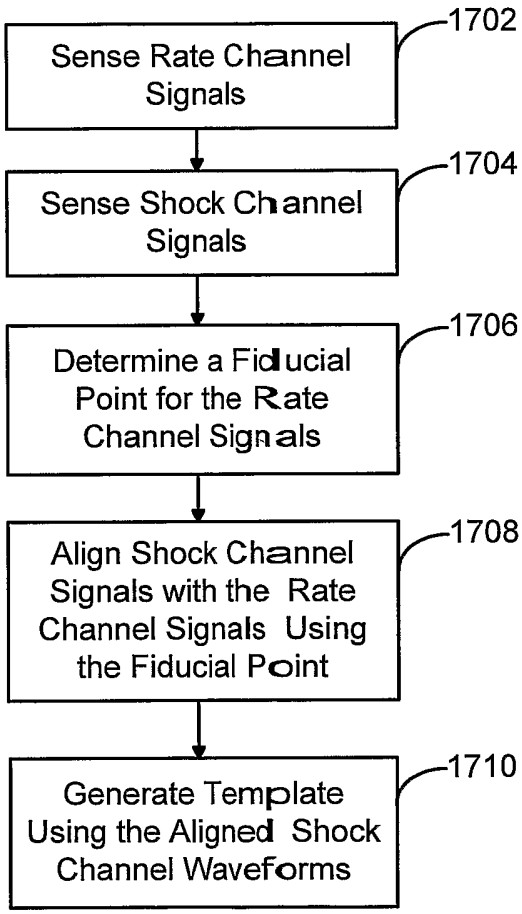

Sense Rate Channel Signals
1702
Sense Shock Channel Signals
1704
Determine a Fiducial Point for the Rate Channel Signals
1706
Align Shock Channel Signals with the Rate Channel Signals Using the Fiducial Point
1708
Generate Template Using the Aligned Shock Channel Waveforms
1710

Figure 17

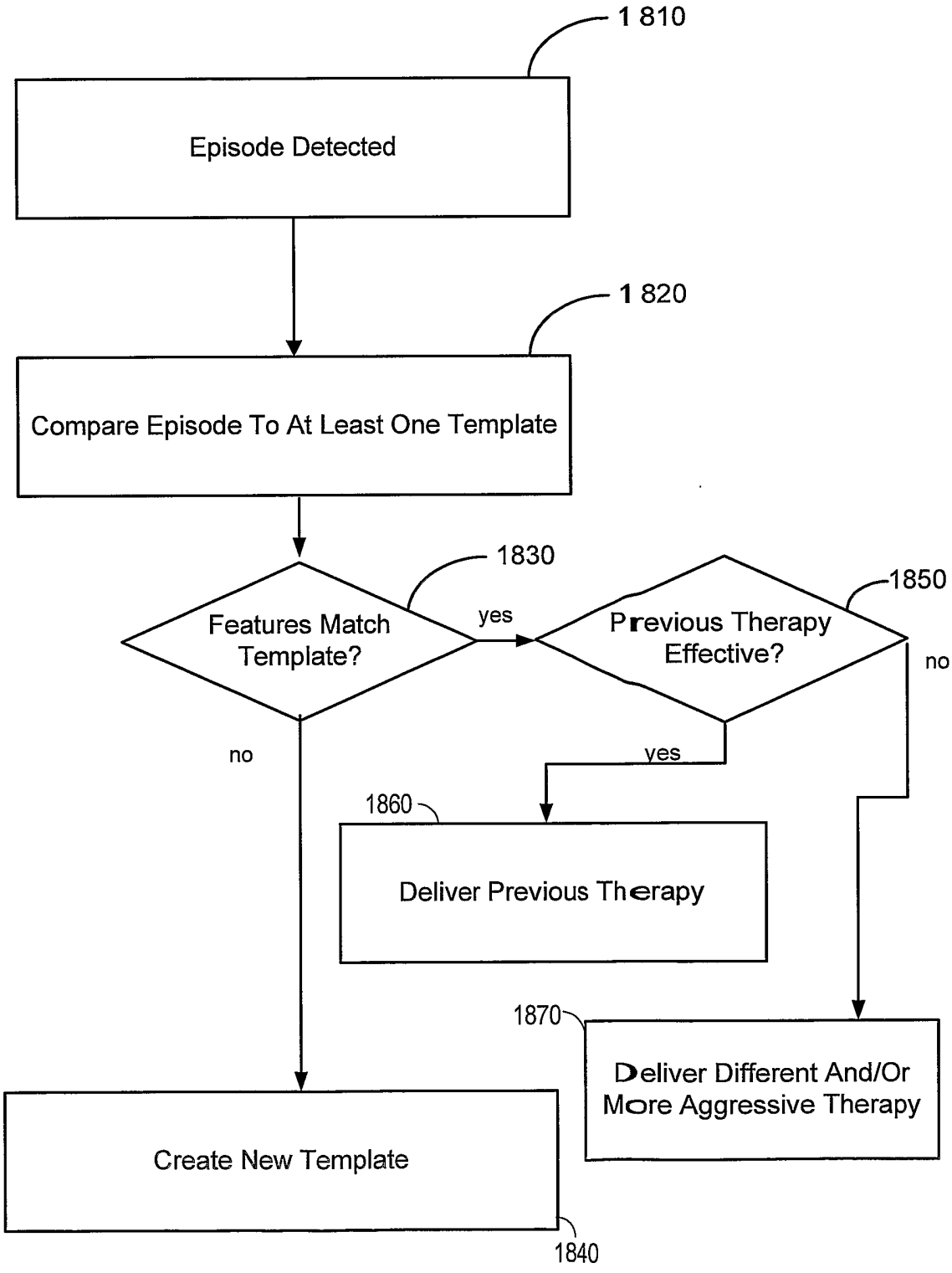

1 810
Episode Detected
1 820
Compare Episode To At Least One Template
1830
Features Match Template?
yes
no
1850
Previous Therapy Effective?
no
yes
1860
Deliver Previous Therapy
1870
Deliver Different And/Or More Aggressive Therapy
Create New Template
1840

Figure 18

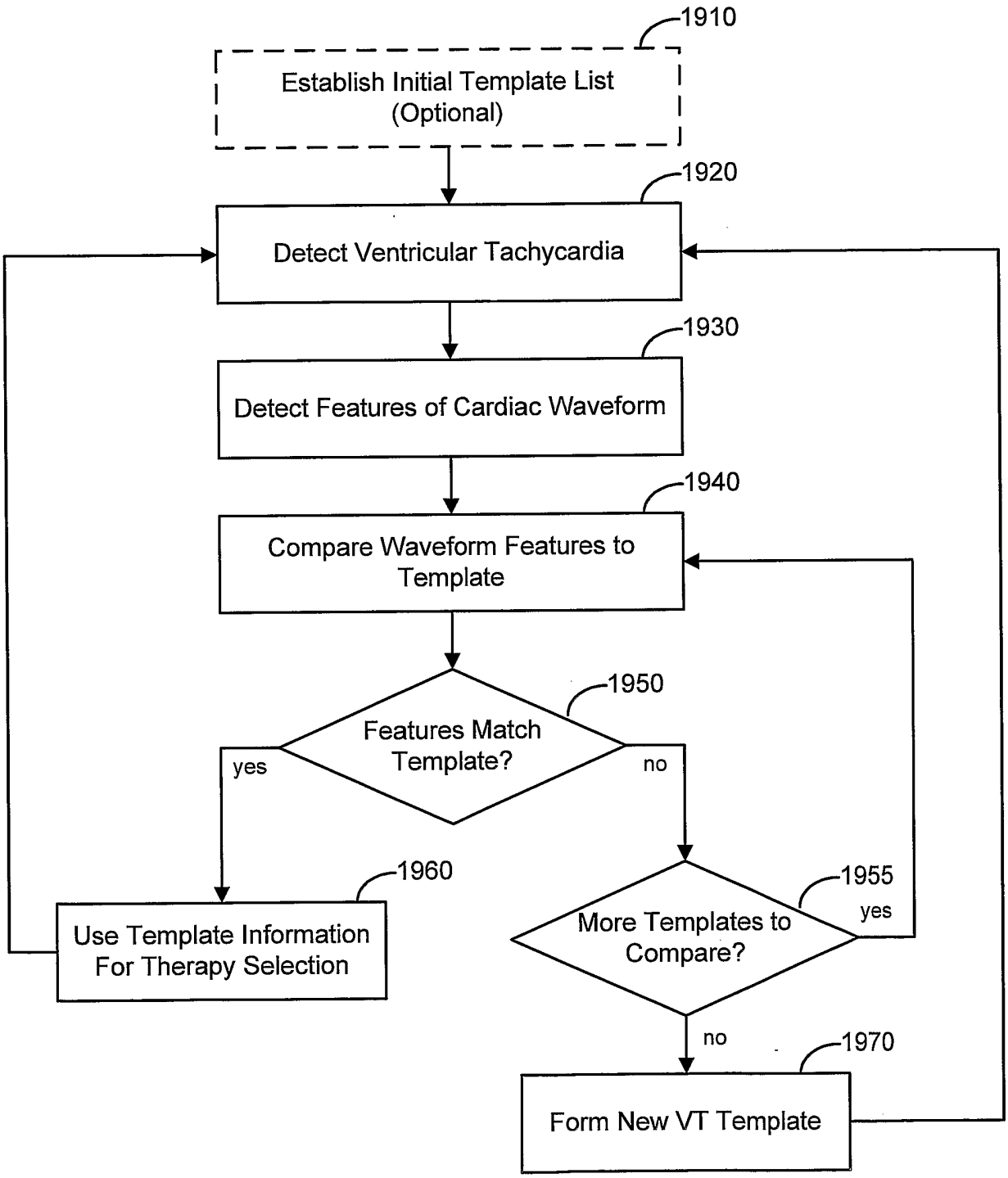

1910
Establish Initial Template List (Optional)
1920
Detect Ventricular Tachycardia
1930
Detect Features of Cardiac Waveform
1940
Compare Waveform Features to Template
1950
Features Match Template?
yes
no
1960
Use Template Information For Therapy Selection
1955
More Templates to Compare?
yes
no
1970
Form New VT Template

Figure 19

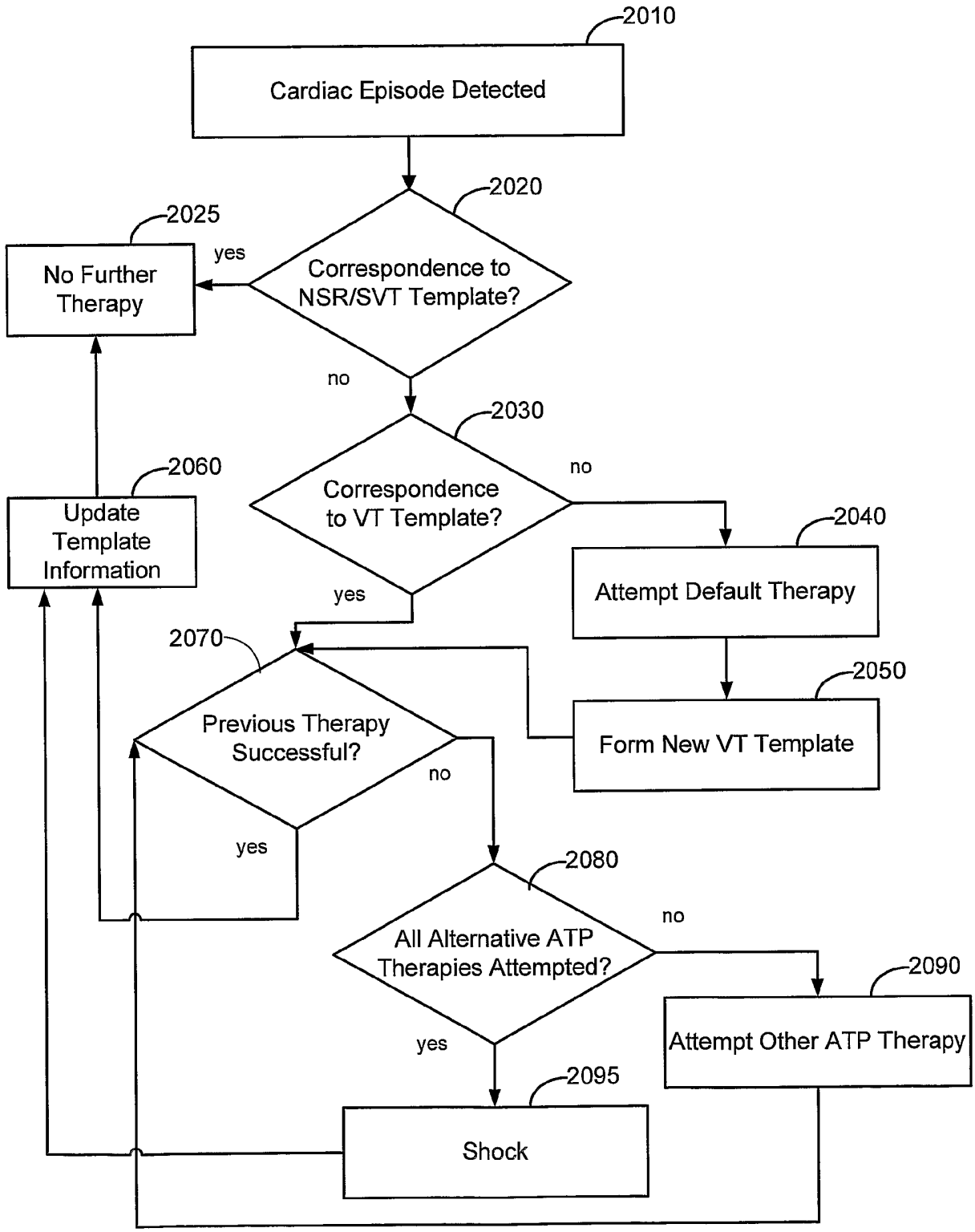
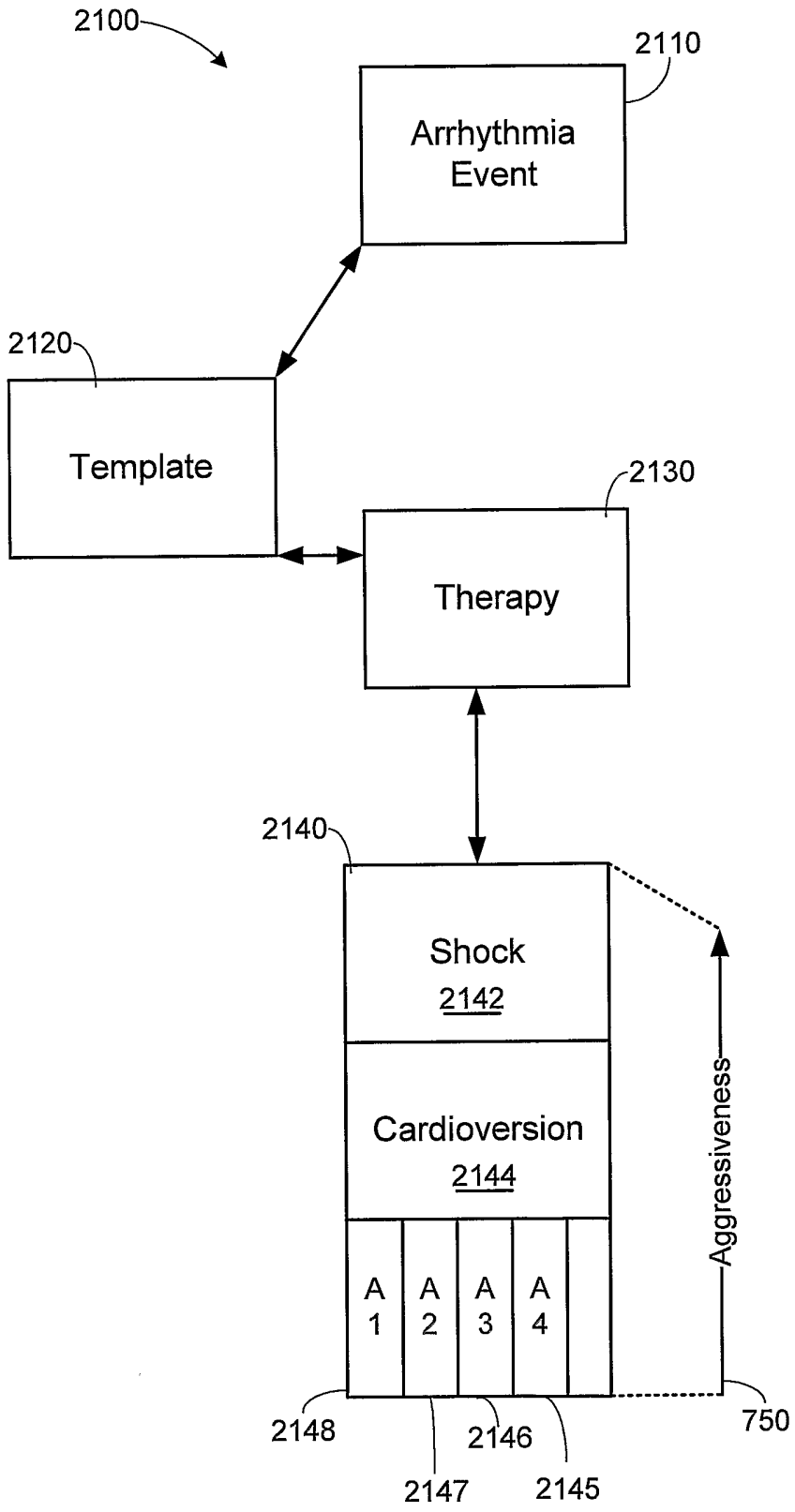

2010
Cardiac Episode Detected
2020
Correspondence to NSR/SVT Template?
yes
2025
No Further Therapy
no
2030
Correspondence to VT Template?
no
2040
Attempt Default Therapy
yes
2060
Update Template Information
2070
Previous Therapy Successful?
no
yes
2050
Form New VT Template
2080
All Alternative ATP Therapies Attempted?
no
yes
2090
Attempt Other ATP Therapy
2095
Shock

Figure 20

Figure 21


2100
2110
Arrhythmia Event
2120
Template
2130
Therapy
2140
Shock
2142
Cardioversion
2144
A 1
A 2
A 3
A 4
Aggressiveness
2148
2147
2146
2145
750

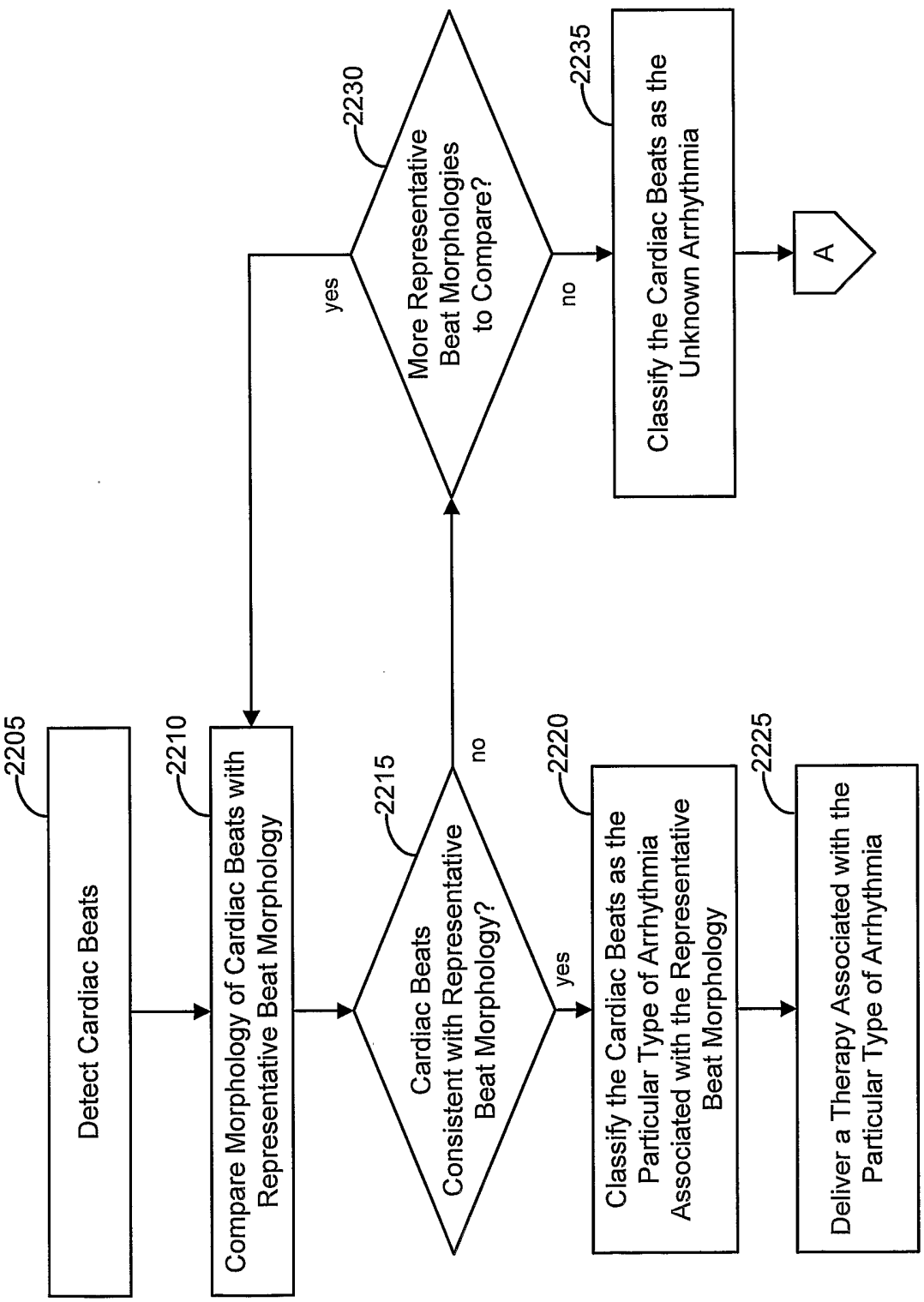

2205
Detect Cardiac Beats
2210
Compare Morphology of Cardiac Beats with Representative Beat Morphology
2215
Cardiac Beats Consistent with Representative Beat Morphology?
yes
no
2220
Classify the Cardiac Beats as the Particular Type of Arrhythmia Associated with the Representative Beat Morphology
2225
Deliver a Therapy Associated with the Particular Type of Arrhythmia
2230
More Representative Beat Morphologies to Compare?
yes
no
2235
Classify the Cardiac Beats as the Unknown Arrhythmia
A

Figure 22A

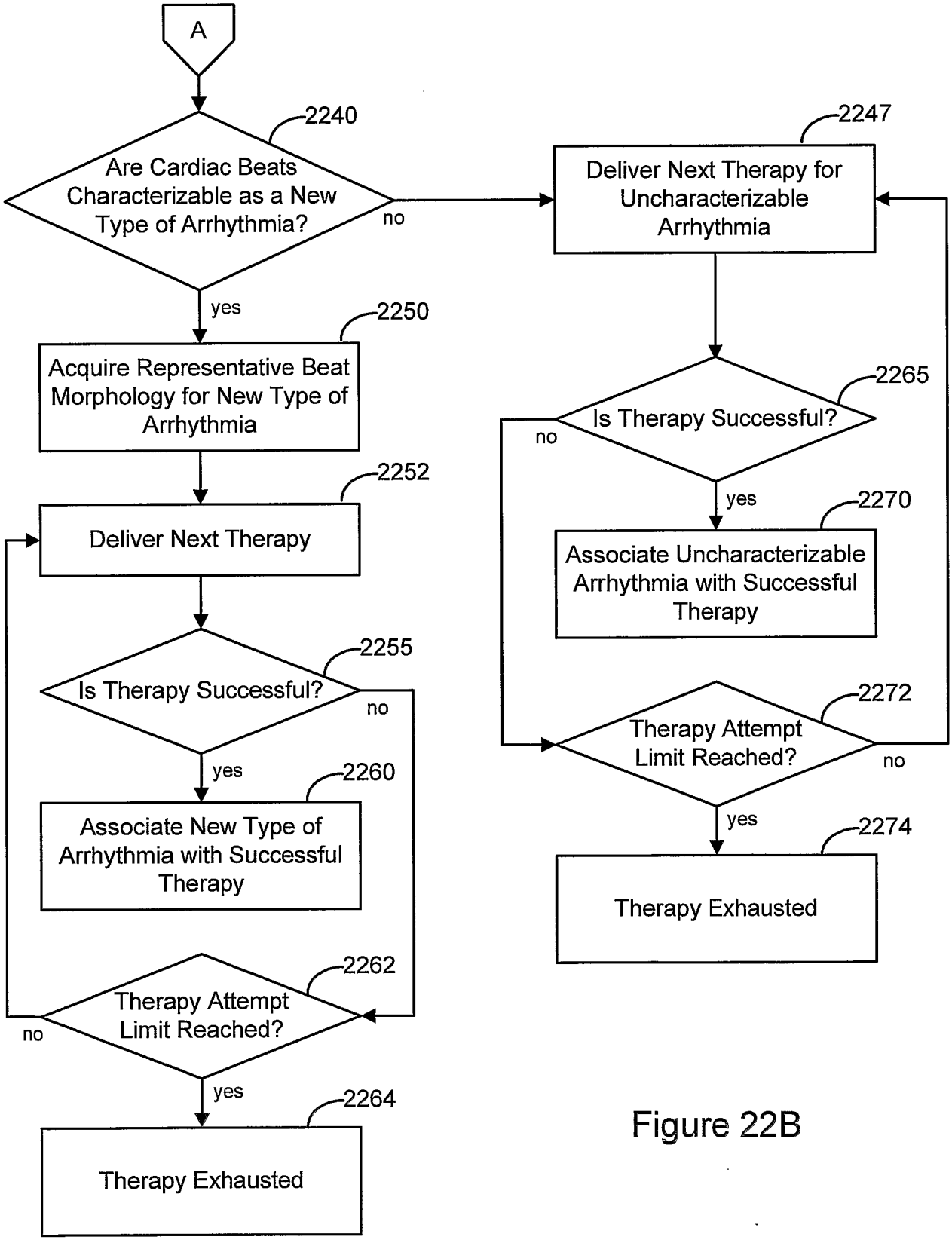

A
2240
Are Cardiac Beats Characterizable as a New Type of Arrhythmia?
no
yes
2247
Deliver Next Therapy for Uncharacterizable Arrhythmia
2250
Acquire Representative Beat Morphology for New Type of Arrhythmia
2252
Deliver Next Therapy
2255
Is Therapy Successful?
no
yes
2260
Associate New Type of Arrhythmia with Successful Therapy
2262
Therapy Attempt Limit Reached?
no
yes
2264
Therapy Exhausted
2265
Is Therapy Successful?
no
yes
2270
Associate Uncharacterizable Arrhythmia with Successful Therapy
2272
Therapy Attempt Limit Reached?
no
yes
2274
Therapy Exhausted

Figure 22B

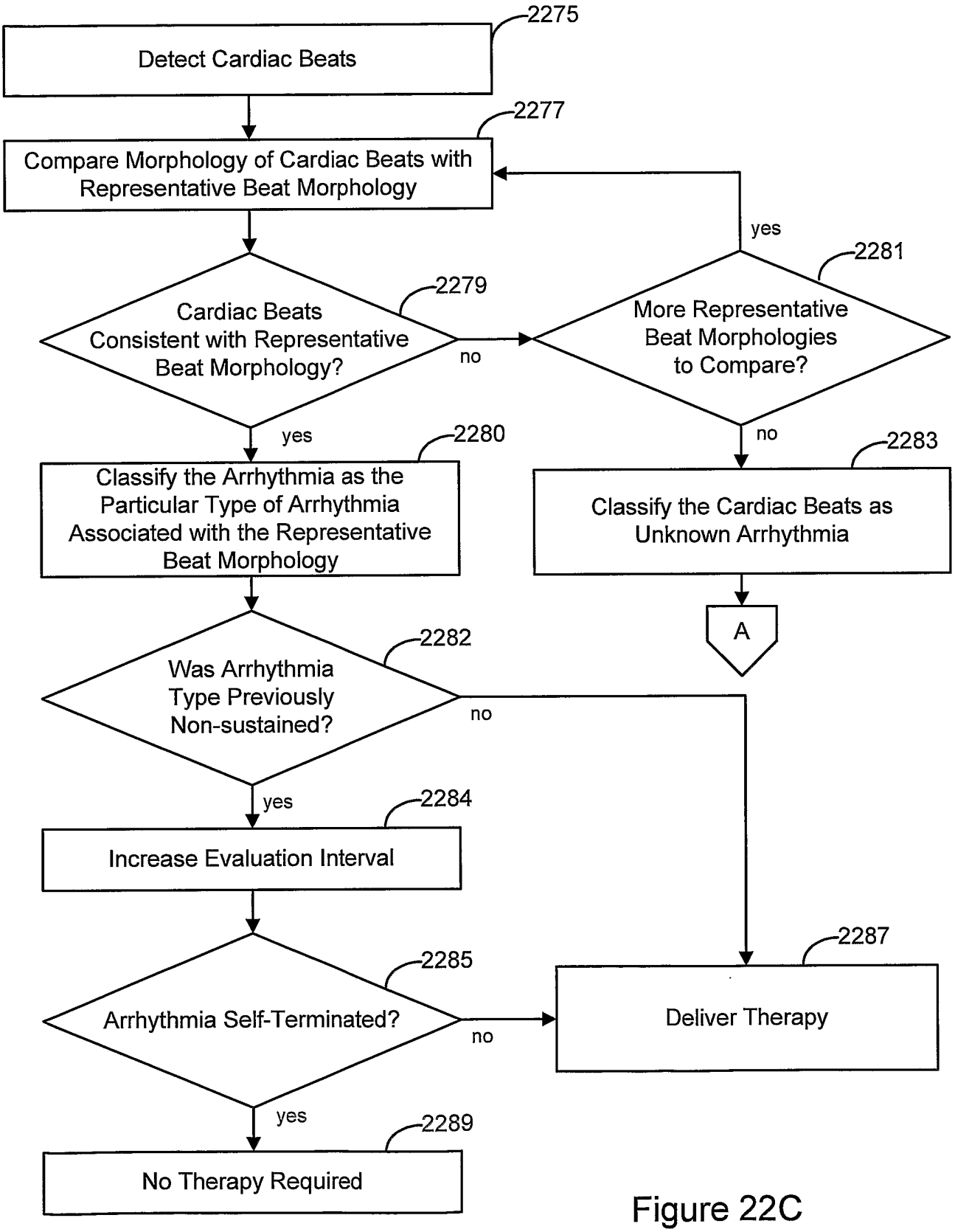

2275
Detect Cardiac Beats
2277
Compare Morphology of Cardiac Beats with Representative Beat Morphology
2279
Cardiac Beats Consistent with Representative Beat Morphology?
yes
no
2281
More Representative Beat Morphologies to Compare?
yes
no
2280
Classify the Arrhythmia as the Particular Type of Arrhythmia Associated with the Representative Beat Morphology
2283
Classify the Cardiac Beats as Unknown Arrhythmia
A
2282
Was Arrhythmia Type Previously Non-sustained?
yes
no
2284
Increase Evaluation Interval
2285
Arrhythmia Self-Terminated?
yes
no
2287
Deliver Therapy
2289
No Therapy Required

Figure 22C

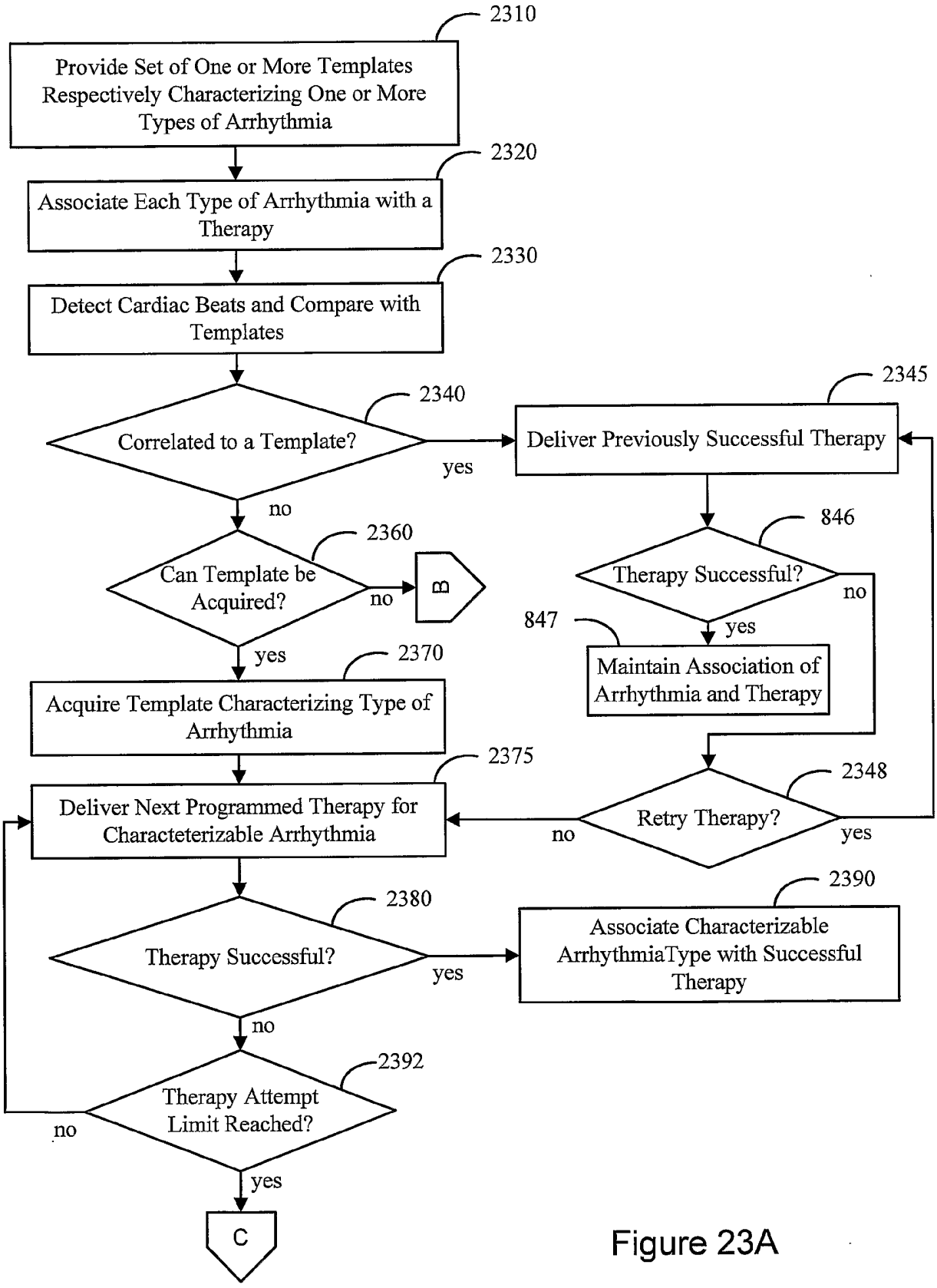

2310
Provide Set of One or More Templates Respectively Characterizing One or More Types of Arrhythmia
2320
Associate Each Type of Arrhythmia with a Therapy
2330
Detect Cardiac Beats and Compare with Templates
2340
Correlated to a Template?
yes
no
2345
Deliver Previously Successful Therapy
846
Therapy Successful?
no
yes
847
Maintain Association of Arrhythmia and Therapy
2360
Can Template be Acquired?
no
B
yes
2370
Acquire Template Characterizing Type of Arrhythmia
2375
Deliver Next Programmed Therapy for Characteterizable Arrhythmia
2348
Retry Therapy?
no
yes
2380
Therapy Successful?
yes
2390
Associate Characterizable ArrhythmiaType with Successful Therapy
no
2392
Therapy Attempt Limit Reached?
no
yes
C

Figure 23A

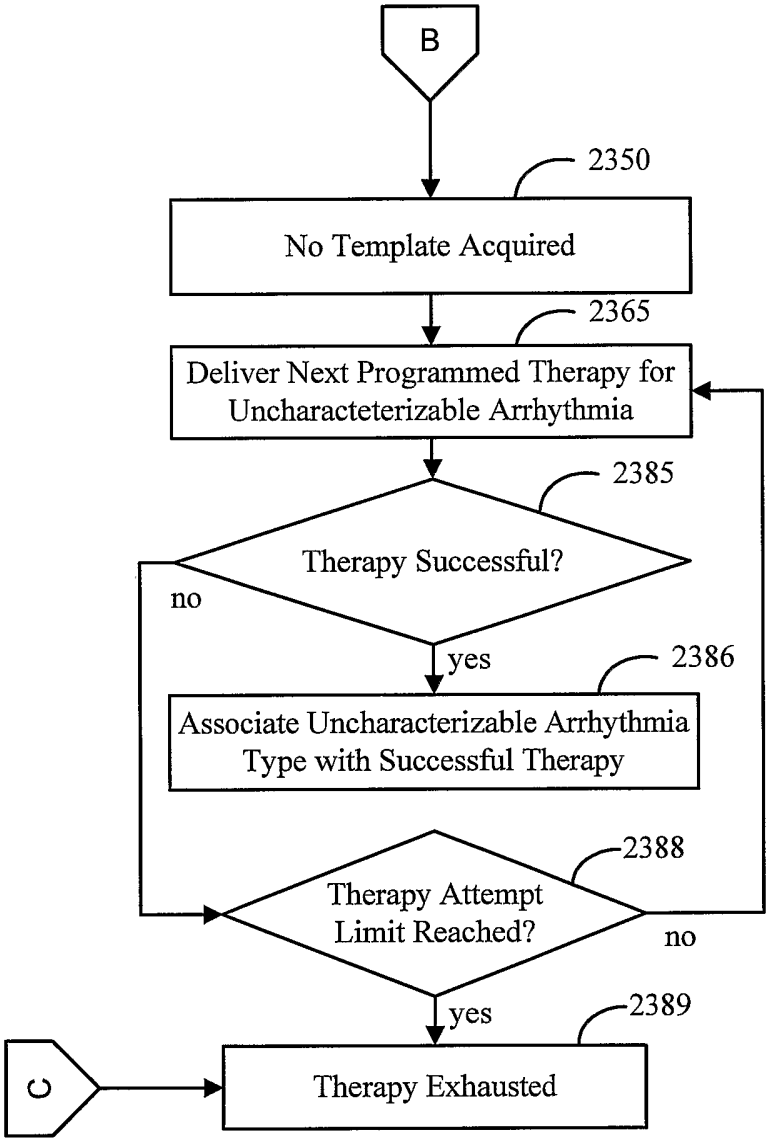

B
2350
No Template Acquired
2365
Deliver Next Programmed Therapy for Uncharacteterizable Arrhythmia
2385
Therapy Successful?
no
yes
2386
Associate Uncharacterizable Arrhythmia Type with Successful Therapy
2388
Therapy Attempt Limit Reached?
no
yes
2389
Therapy Exhausted
C

Figure 23B

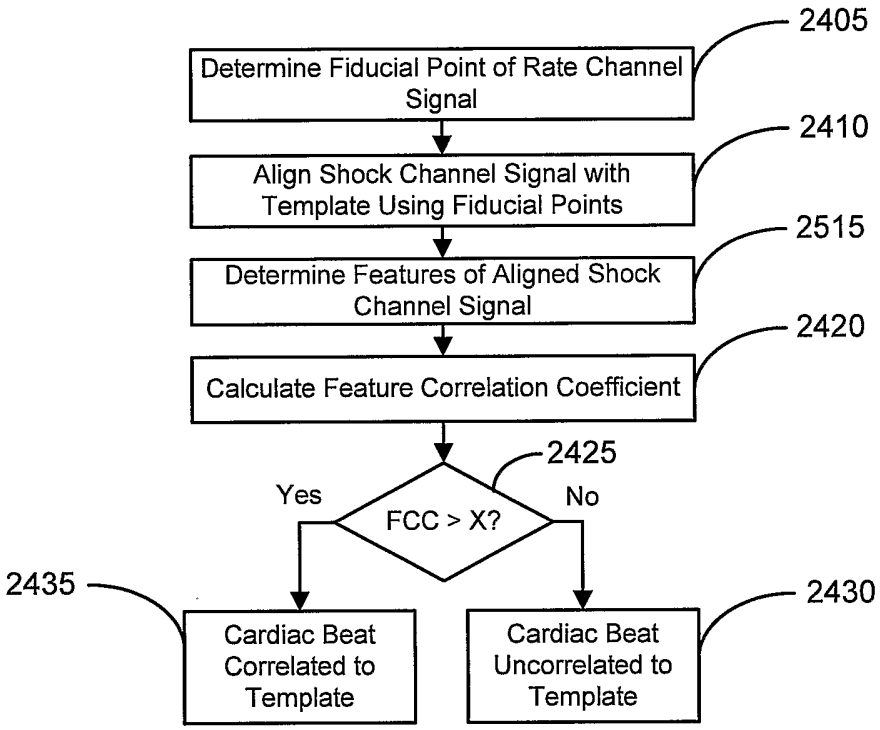

2405
Determine Fiducial Point of Rate Channel Signal
2410
Align Shock Channel Signal with Template Using Fiducial Points
2515
Determine Features of Aligned Shock Channel Signal
2420
Calculate Feature Correlation Coefficient
2425
Yes
FCC > X?
No
2435
Cardiac Beat Correlated to Template
Cardiac Beat Uncorrelated to Template
2430

Figure 24

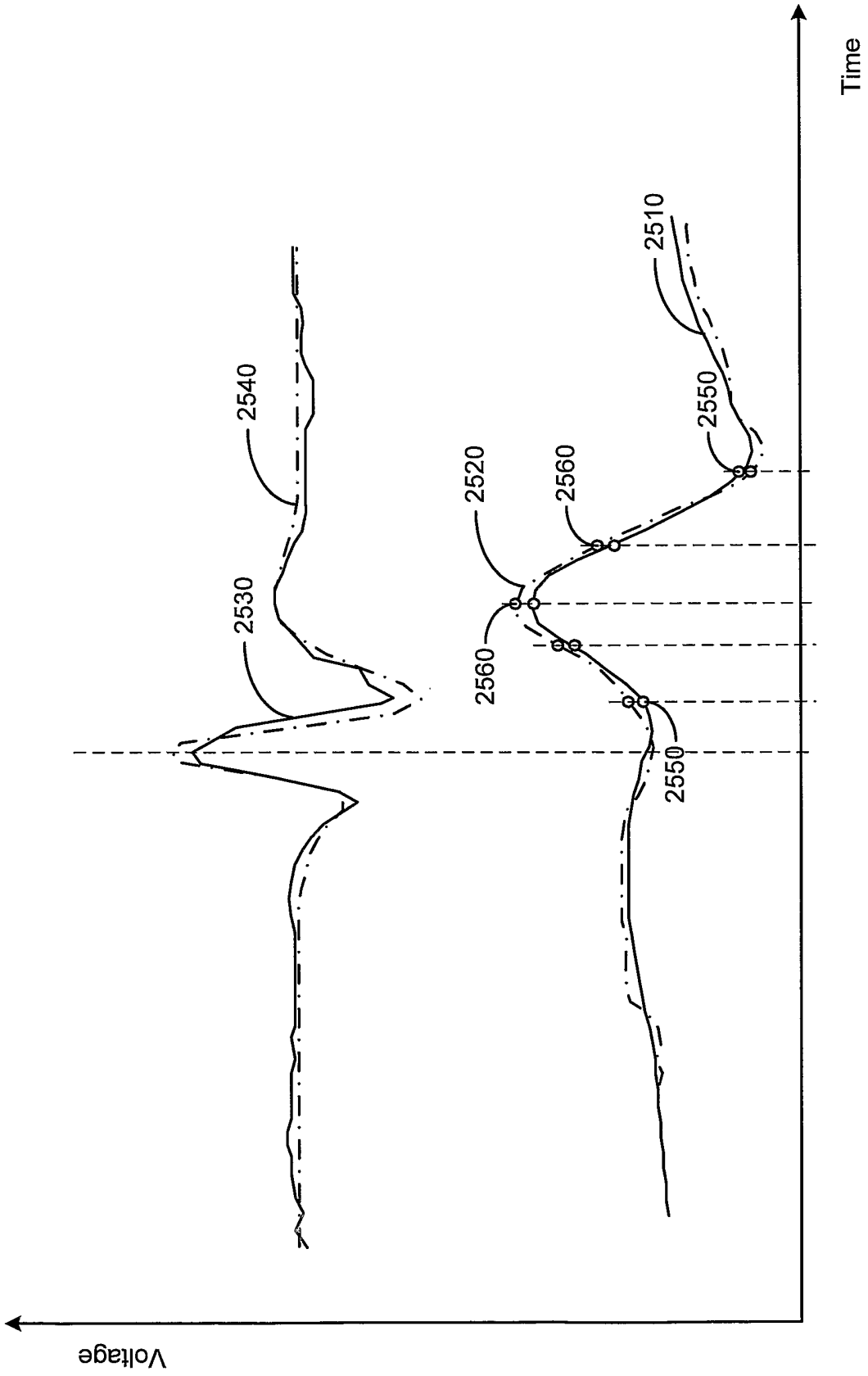


Figure 25

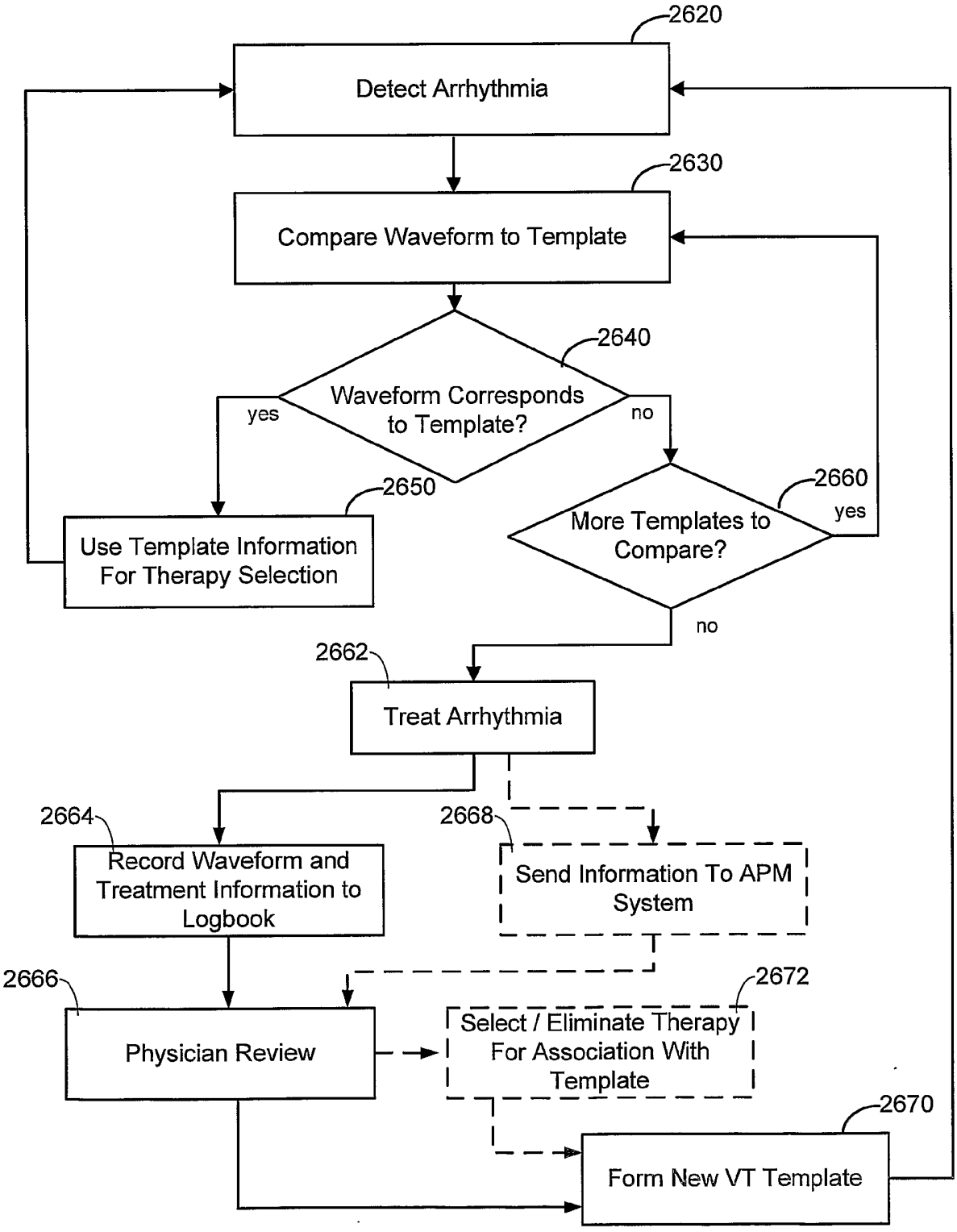

2620
Detect Arrhythmia
2630
Compare Waveform to Template
2640
Waveform Corresponds to Template?
yes
no
2650
Use Template Information For Therapy Selection
2660
More Templates to Compare?
yes
no
2662
Treat Arrhythmia
2664
Record Waveform and Treatment Information to Logbook
2668
Send Information To APM System
2666
Physician Review
2672
Select / Eliminate Therapy For Association With Template
2670
Form New VT Template

Figure 26

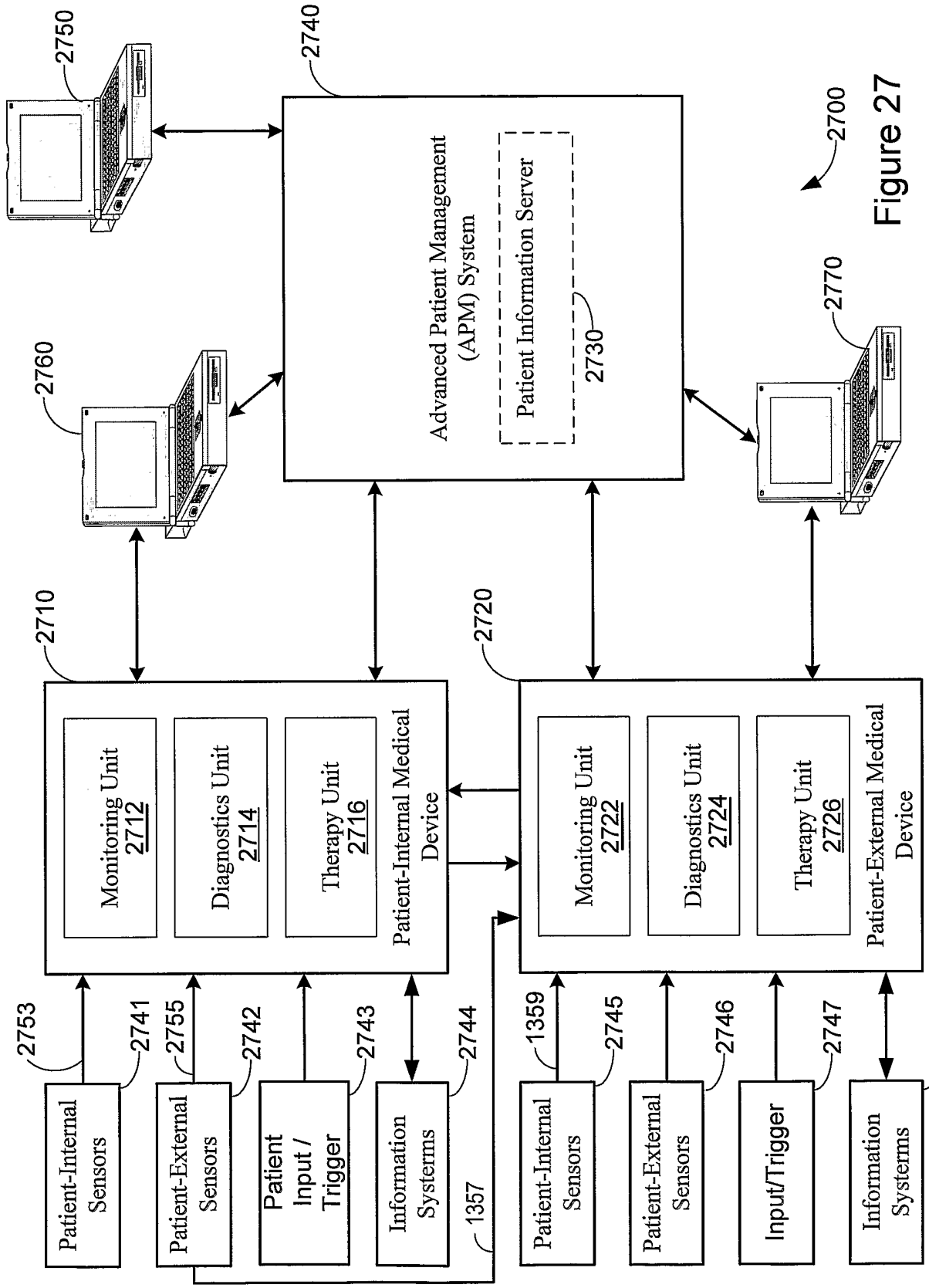

2750
2740
2700
Advanced Patient Management (APM) System
Patient Information Server
2730
2760
2770
2710
2720
Monitoring Unit 2712
Diagnostics Unit 2714
Therapy Unit 2716
Patient-Internal Medical Device
Monitoring Unit 2722
Diagnostics Unit 2724
Therapy Unit 2726
Patient-External Medical Device
2753
2741
2755
2742
2743
2744
1359
2745
2746
2747
2748
1357
Patient-Internal Sensors
Patient-External Sensors
Patient Input / Trigger
Information Systems
Patient-Internal Sensors
Patient-External Sensors
Input/Trigger
Information Systems

Figure 27