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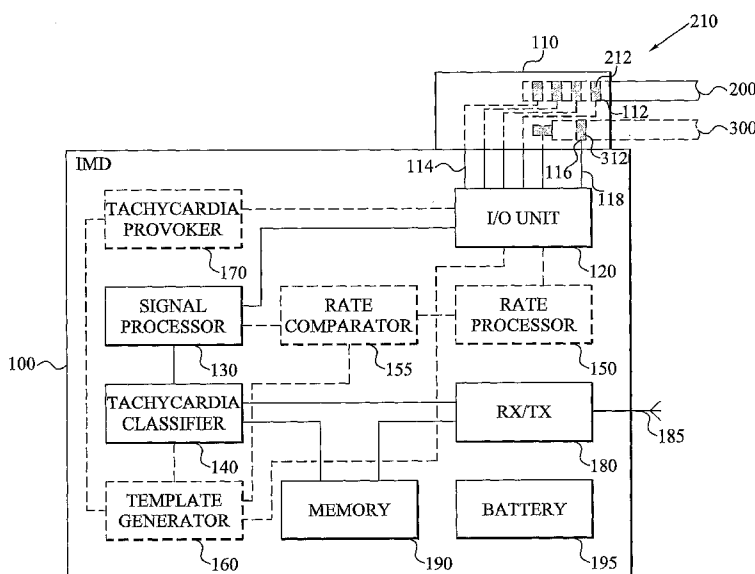


Fig. 3

(57) Abstract: An implantable medical device (100) is connectable to an epicardial multi-electrode lead (200) employed for registering a depolarization wave propagation pattern across a ventricle (12) of a heart (10). A signal processor (130) generates, based on the electrical activity sensed by the lead (200), a representation of the depolarization wave propagation pattern. A tachycardia classifier (140) of the medical device (100) classifies a tachycardia event of the heart (10) based on a comparison of the generated representation and a template representation of a template depolarization wave propagation pattern across the ventricle (12).

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TACHYCARDIA CLASSIFICATION

TECHNICAL FIELD

The present invention generally relates to heart diagnosis using implantable medical devices, and in particular to such devices capable of discriminating between different forms of tachycardia.

BACKGROUND

Implantable medical devices (IMDs), including implantable cardiac defibrillators, cardioverters and pacemakers, can today be used for detecting and combating tachycardia in IMD patients. Such tachycardias need to be detected as early as possible as they may otherwise lead to the death of the patient if not quickly terminated. As a consequence, once tachycardia is detected, the IMD will combat it by delivering one or more defibrillation or cardioversion shocks.

There are different forms of tachycardia that may have more or less severe consequences to the patient and his/her heart. For instance, the mechanical activation of the ventricles during a ventricular tachycardia may in some cases have no essential negative influence on the cardiac output. However, in other cases, the activation patterns are more detrimental leading to inefficient blood pumping.

Today, tachycardia is mainly detected and diagnosed through an increased ventricular rate. However, such diagnosing techniques may run into problems when trying to discriminate between ventricular tachycardia and normal physiological responses to physical activity or stress and more so when trying to discriminate between ventricular tachycardias with and without hemodynamic impairments.

US 5,366,487 discloses a tachycardia detection system for a cardioverter or defibrillator. The system senses a local electrical signal representing cardiac activity in one of a plurality of local areas of the patient's heart. A

corresponding global electrical signal representing cardiac activity in a global area of the patient's heart is also sensed. The signals are processed to form pulses. The amount of delay between the corresponding pulses in two pulse trains is used for distinguishing between monomorphic ventricular tachycardia and more benign conditions.

EP 1 314 450 discloses usage of unipolar signals obtained from a cardiac lead having a tip at which a number of separate electrodes are disposed for detecting cardiac rhythm abnormalities. A time relationship is calculated relative the respective unipolar signals and is used to determine whether a cardiac rhythm abnormality is present. Alternatively, one or more unipolar signals are compared to a template which is known to represent a cardiac abnormality.

SUMMARY

The present invention overcomes these and other drawbacks of the prior art arrangements.

It is a general object of the present invention to provide a heart diagnosis based on epicardial electrical signals.

It is another object of the invention to provide a tachycardia classification using epicardial multi-electrode registrations.

These and other objects are met by the invention as defined by the accompanying patent claims.

Briefly, the present invention involves an implantable medical device (IMD) connectable to an epicardial multi-electrode lead, preferably an intrapericardial lead attachable to the outside surface of a heart ventricle, preferably the left ventricle. The multi-electrode lead senses the electrical activity of the ventricle(s) during heart cycles. A signal processor of the IMD processes the sensed electrical signals and generates, based thereon, a

representation of the depolarization wave propagation pattern across the ventricle. The generated pattern representation is compared by a tachycardia classifier to at least one pre-defined template representation of a template depolarization wave propagation pattern. A tachycardia condition of the heart can then be classified as hemodynamically stable or hemodynamically stable based on the pattern comparison.

In a preferred embodiment, the IMD has access to multiple pre-defined templates representing the depolarization wave propagation across the ventricle at different conditions of the heart, such as a SVT template generated from sensed electrical signal collected during a SVT event of the heart, a VT template, and templates generated during different levels of physical activity (rest vs. high activity) of the patient.

The tachycardia classification of the present invention is preferably initiated based on a triggering event, such as an increase in ventricular and/or atrial rate.

The IMD preferably also comprises a template generator that is adapted for generating, based on electrical activity signals sensed by the epicardial multi-electrode lead, the template representations during spontaneous or provoked tachycardia periods.

The epicardial multi-electrode lead preferably comprises a branch point at which the distal lead end is branched into multiple parallel lead branches, each comprising multiple spatially and electrically separated electrodes. Such a lead branching creates an extensive electrode network, allowing the lead to capture and follow the depolarization wave propagation across a substantive part of the ventricle.

SHORT DESCRIPTION OF THE DRAWINGS

The invention together with further objects and advantages thereof, may best be understood by making reference to the following description taken together with the accompanying drawings, in which:

Fig. 1 is a schematic overview of a patient having an implantable medical device according to the present invention and an external unit capable of conducting communication with the implantable medical device;

Fig. 2 is an illustration of a heart having an epicardial multi-electrode lead according to the present invention;

Fig. 3 is a schematic block diagram of an implantable medical device according to an embodiment of the present invention;

Fig. 4 is a schematic block diagram of an embodiment of a signal processor in the implantable medical device;

Fig. 5 is a schematic block diagram of an embodiment of a tachycardia classifier in the implantable medical device;

Fig. 6 is a schematic block diagram of an embodiment of a template generator in the implantable medical device;

Fig. 7 is a flow diagram illustrating a heart diagnosis method according to an embodiment of the present invention;

Fig. 8 is a flow diagram illustrating additional steps of the heart diagnosing method of Fig. 7;

Fig. 9 is a flow diagram illustrating an embodiment of the generating and comparing steps of the heart diagnosing method of Fig. 7;

Fig. 10 is flow diagram illustrating a method of generating template representations according to an embodiment of the present invention; and

Fig. 11 is flow diagram illustrating a method of generating template representations according to another embodiment of the present invention.

DETAILED DESCRIPTION

Throughout the drawings, the same reference characters will be used for corresponding or similar elements.

The present invention relates to heart diagnosis using an implantable medical device, IMD, having at least one connected epicardial multi-electrode lead for sensing electrical activity of the heart, preferably of at least one ventricle, more preferably at least the left ventricle of the heart in an animal, preferably mammalian animal and more preferably in a human being.

The invention is based on the finding that the mechanical activation of the ventricles can be monitored by generating an electrical activity pattern over at least one ventricle. However, the distribution of electrical signal across the ventricle during its mechanical activity is by far better followed using epicardial leads being able to cover electrical sensing of a significant portion of the ventricle.

It is traditional practice to use endocardial right ventricular leads for both pacing and electrical sensing. However, today leads connectable to the left ventricle have been limited to implanting the lead in the coronary vein. This strongly restricts the actual position of the lead electrodes and in particular their spatial distribution of sensing electrodes across the left ventricle.

The present invention, in clear contrast, uses an epicardial multi-electrode lead having a network of electrically and spatially separated electrodes for monitoring electrical activity over a substantial portion of the surface of a heart ventricle, preferably the left ventricle, or both ventricles.

As is well-known in the art, "epicardial" means relating to the outside of the cardiac muscle. An epicardial lead can therefore be attached to the myocardium or be attached to the pericardium. A preferred example of an epicardial lead is an intrapericardial lead. "Intrapericardial" is defined as inside the pericardium, i.e. inside the fibroserous sac that surrounds the heart. A multi-electrode lead of the present invention is, thus, adapted for positioning the lead header outside of the cardiac muscle. In a preferred embodiment, the lead is positioned between the pericardium and the outside of the myocardium.

Fig. 1 is a schematic overview of a subject 1 equipped with an IMD 100 connected to the subject's heart 10. The IMD 100 is illustrated as a device that monitors and/or provides therapy to the heart 10 of the patient 1, such as a pacemaker, defibrillator or cardioverter. The IMD 100 is connectable to at least one, preferably one, epicardial multi-electrode lead 200 according to the present invention. In the figure, the multi-electrode header of the lead 200 is attached to the left ventricle of the heart 10 and is arranged for sensing electrical activity over the heart ventricle.

The IMD 100 is preferably also connectable to at least one endocardial lead 300 employed for applying pacing pulses and/or shocking pulses to the heart 10, in addition to cardiogenic sensing. The endocardial lead 300 could be a right ventricular lead as in the figure or an atrial lead. The IMD 100 can alternatively be connectable to both an atrial lead and an intraventricular lead 300 in addition to the epicardial multi-electrode lead 200 according to the present invention.

The IMD 100 can wirelessly communicate with an external device 400, non-limitedly illustrated as a programmer 400 in the figure. The external device 400 could alternatively be a physician's workstation, a home monitoring device, base station or actually any data processing unit having capability of receiving data collected by the IMD 100 and preferably sending instructions

and commands to the IMD 100. The external device 400 is preferably connected to a display screen 410 allowing display of the collected diagnostic parameters and data.

The IMD 100 is in particular adapted for transmitting diagnostic heart data generated according to the present invention, i.e. tachycardia classification data. Furthermore, the programmer 400 can download different parameters and templates used by the IMD 100 in the heart diagnosis of the present invention, which is described further herein.

Fig. 2 is an illustration of a human heart 10 and the distal header portion 220 of an implantable epicardial lead 200 according to the present invention. The lead 200 of the invention is a multi-electrode lead, implying that it comprises a plurality of electrically and spatially separated electrodes 232 at its distal lead end 220. The electrical separation can be achieved using different embodiments.

Firstly, a separate lead conductor is provided for each electrode 232 or at least for a majority of the electrodes 232. The lead conductors end at respective electrode terminals of the proximal lead ends. These terminals are connectable to mating terminals in the IMD to thereby provide an electrical contact between the IMD and the plurality of electrodes 232 at the distal lead end 220.

Alternatively, the multi-electrode lead comprises a multiplexor, such as provided in the branch point 223. Conductors from the different electrodes 232 in the branches 230 end at the multiplexor. The multiplexor is then connected to at least one conductor that runs along the lead body up to the proximal end. At this end, a demultiplexor is provided for dividing the signals transmitted on the conductor and originating from the different electrodes 232 into separate electrode terminals in the proximal end.

A third alternative is to use the above-described multiplexor arrangement in connection with the distal lead end 220 and at least one conductor in the lead body. However, in this embodiment the demultiplexor is omitted in the proximal end. As a consequence, the lead connecting arrangement of the IMD need only have a single terminal that is connectable to the electrode terminal of the lead (in the case of a single conductor). The electrical signals sensed by the different electrodes 232 are then transmitted on the conductor from the multiplexor in a pre-defined time order. Due to this time-separation of signals, the IMD can determine from which electrode 232 a given received electrical signals originates. There is therefore no need of having different electrode terminals for the different electrodes 232.

In an alternative approach, each branch 230 has its own multiplexor handling the electrical signals from the electrodes 232 of that branch. The lead body then comprises one separate conductor for each multiplexor-branch pair. The proximal lead end can then have a demultiplexor per conductor or no demultiplexors as all according to the above-described principles.

The lead 200 is designed for being connected or attached to the surface of the myocardium, so the electrodes 232, or at least a major portion thereof, can register electrical activity of a ventricle 12, preferably left ventricle. Thus, the electrodes 232 will sense and register the propagation of a depolarization wave (action potential) across the ventricle 12.

A preferred lead 200 of the invention has a distal lead end 200 with at least one branch point 223. At this branch point 223, the lead 200 is branched into at least three distal lead branches 230. Each of these distal lead branches 230 comprises at least two spatially and electrically separated electrodes 232. Due to this branching with multiple electrodes per branch, the electrode header 220 may cover a major portion of the myocardium surface of one ventricle 12 or indeed partly over both ventricles. As a consequence, the depolarization propagation across the ventricle 12 can be

detected at different times by the electrodes 232 as the depolarization wave is spreading across the ventricle 12. This timing of electrode sensing is employed for generating a detection pattern by the IMD, which is employed in the heart diagnosis of the present invention.

The electrodes 232 of the lead branches 230 are preferably spatially separated along the respective branches 230 with at least 5 mm, preferably at least 7 mm, such as at least 10 mm or more. The electrodes 232 can therefore be regarded as pearls on a string and spaced apart with these preferred distances to thereby cover at least a substantial part of the myocardium across the ventricle 12.

In order to simplify implantation of the lead 200 and attaching the lead 200 to the myocardium, the most distal ends of the lead branches 230 are preferably mechanically interconnected at a distal focus point 225. The branching point 223 and the focus point 225 defines the end-point of the three dimensional electrode network that is expanded between the end points 223, 225.

The electrodes 230 of the multi-electrode lead 200 can be in the form of ring electrodes, thereby having electrical sensing ability all around its circumference. In another embodiment, the portion of the electrodes 230 facing away from the myocardium is electrically insulated. Alternatively, the electrodes 230 only have dedicated electrical sensing surfaces facing the same side of the lead 200, i.e. towards the myocardium. This electrode configuration is in particular advantageous when employing the epicardial multi-electrode lead 200 for signal delivery, such as delivery of pacing pulses or applying current/voltage signals for the purpose of impedance measurements. In such a case, the screening of the electrodes from the other parts of the body will have positive effects.

Fig. 3 is a schematic block diagram of an IMD 100 according to the present invention. The IMD 100 comprises a lead connecting arrangement 110 that

is connectable to cardiogenic leads 200, 300, including the epicardial multi-electrode lead 200 of the present invention. The arrangement 110 therefore comprises at least one electrical terminal 112 adapted for providing an electric contact to a mating terminal 212 at the proximal end 210 of the multi-electrode lead 200. Through this terminal-to-terminal connection, electric connection can be established between the IMD 100 and the different individual electrodes at the distal lead end. Corresponding electric terminal(s) 116 for providing electric contact with terminal(s) 312 at the proximal end of an endocardial lead 300 are preferably provided in the lead connecting arrangement 110.

In the figure, multiple electric terminals 112 are provided for connection with separate mating terminals 212 in the multi-electrode lead 200. In such a case, a separate terminal pair 112, 212 can be provided for each electrode at the distal lead end. Alternatively, the connecting arrangement 110 can contain fewer terminals than there are electrodes at the distal lead end. In this case, one or more demultiplexors (not illustrated) may be included in the arrangement 110 or in the IMD 100 for separating the incoming electric signals from the epicardial multi-electrode lead 200 as previously described.

In the case of fewer terminals 112 than electrodes and no demultiplexor, a general input/output (I/O) unit 120 of the IMD 100 can be used for determining the particular electrode the different electric signals originate from. The I/O unit 120 is in electric contact with one or more wires or conductors 114, 118 to the terminals 112, 116 in the connecting arrangement 110. The I/O unit 120 constitutes the interface between the internal IMD functionalites and units and the external electrodes of the leads 200, 300.

The IMD 100 also comprises a signal processor 130 connected to the plurality of electrode terminals 112 of the lead connecting arrangement 110 through the I/O unit 120. The processor 130 is implemented for generating a representation of a depolarization wave propagation pattern across a

ventricle, preferably left ventricle, of a heart. This pattern representation generation is performed by the processor 130 based on the electrical activity of the ventricle sensed by the multiple electrodes of the epicardial multi-electrode lead 200. The pattern representation comprises information relating to the timings of detections at the different electrodes caused by the propagating depolarization wave.

The invention is based on the finding that these epicardially sensed depolarization wave patterns are closely linked to the condition of the heart. As a consequence, according to the invention, the generated depolarization wave pattern representations can be used for classifying a sensed tachycardia event of the heart and discriminate between different types of tachycardia. The IMD 100 therefore comprises a tachycardia classifier 140 adapted to classify a tachycardia based on a comparison of the pattern representation generated by the signal processor 130 and a template representation. This template representation is indicative of a corresponding template depolarization wave propagation pattern.

In a preferred embodiment, the tachycardia classifier 140 has access to multiple pre-defined template representations, for instance stored in an accessible memory 190. The different template representations can then be indicative of the depolarization wave propagation pattern of the ventricle at different tachycardia conditions, in addition to the propagation pattern for a healthy non-tachycardia heart. The classification is then performed by comparing the generated pattern representation with each pre-defined template pattern to thereby identify the template pattern that is most closely correlated with the currently generated pattern. The tachycardia condition of the heart is classified as the particular tachycardia type associated with the identified template pattern.

In either case, the result from the tachycardia classification can be stored in an associated memory 190 for a later retrieval in connection with a patient follow-up. Alternatively, or in addition, the classifier 140 compiles a

diagnosis message comprising information of the performed tachycardia classification and preferably the result therefrom, i.e. the classified type of tachycardia. The message is provided to a transmitter 180 having a connected antenna 185 for wireless transmission of the diagnosis message to an external, possibly remote, receiver, such as a receiver of a programmer (see Fig. 1). The transmitter 180 can be a dedicated transmitter or a transmitter unit of a transceiver 180 that then also comprises a receiver unit.

The IMD 100 preferably comprises a rate processor 150 connected to the lead connecting arrangement 110 through the I/O unit 120. The rate processor 150 receives measurement results from the electrical terminals 112, 116 connected to the endocardial lead 300 and/or the multi-electrode epicardial lead 200. The measurement results are employed by the rate processor 150 for determining a ventricular rate of the heart, i.e. the heart rate. The processor 150 preferably determines the ventricular rate as an average heart rate taken over multiple consecutive heart cycles. A rate comparator 155 is adapted to process the (average) ventricular rate determined by the rate processor 150. This rate processing involves comparing the determined rate with a pre-defined rate threshold accessible at the comparator 155, e.g. from the memory 190. The rate comparator 155 also generates an activation signal if the determined rate exceeds the rate threshold.

The signal processor 130 is responsive to the activation signal from the rate comparator 155. This means that the processor 130 starts generating a pattern representation based on the electrode readings from the epicardial multi-electrode 200 upon reception of the activation signal from the comparator 155.

As a consequence, the IMD 100 of the present invention preferably first detects a condition which could indicate an emerging tachycardia through an increase in ventricular rate. Thereafter, a tachycardia classification is

performed based on the depolarization wave propagation pattern across the ventricle to determine whether the rate increase was indeed due to a tachycardia or was due to increased activity, stress or some other non-tachycardia classifier. In the former case, the IMD 100 also performs an actual classification of the tachycardia as is described further herein.

Fig. 4 illustrates a preferred embodiment of the signal processor 130 in Fig. 3. The processor 130 comprises a matrix generator 132. In a first embodiment, this matrix generator 132 generates a one-dimensional matrix, i.e. vector, comprising identifiers of electrodes of the epicardial multi-electrode lead and in which order the propagating depolarization wave front passed the electrodes. For example, the generated matrix could look like:

$$M = [e_1^1 \quad e_3^1 \quad e_2^2 \quad \dots \quad e_n^k]$$

wherein e_i^j denotes electrode number i of lead branch j . Thus, the matrix lists the order of the wave sensing at the spatially separated electrodes on the ventricle myocardium. This matrix constitutes a representation of the depolarization wave propagation pattern across the ventricle registered by the epicardial multi-electrode lead. The pattern representation merely comprises relative sensing timings but does not take any time delays into account.

Another embodiment of the matrix generator 132 generates a matrix having one row (or column) for each electrode and then the columns (or rows) represent contiguous time slots. An associated time slot marker 134 puts a marker in a time slot at which a particular electrode detected the propagating depolarization wave. The marker could be a one, while the remaining matrix elements, corresponding to time slots for which no detection was made with an electrode, are filled with zeros. An example of such a matrix could then be:

$$M = \begin{bmatrix} 1 & 0 & 0 & \dots & 0 \\ 1 & 1 & 0 & \dots & 0 \\ 0 & 0 & 0 & \dots & 1 \\ \vdots & \vdots & \vdots & \ddots & \vdots \\ 0 & 0 & 0 & \dots & 1 \end{bmatrix}$$

wherein each electrode has a dedicated row and the columns represent contiguous time slots TS_0 to TS_m . As is seen in the second row, it is actually possible to have detection markers (1) in neighboring time slots (columns) for the purpose of widening the time slot. The reason for performing such time slot widening could be to increase the tolerance for pattern recognition.

Instead of putting a simple detection marker, the time slot marker 134 can use qualitative markers to thereby provide a grading in detection/recognition quality. In such a case, zero could represent no detection at a particular electrode, one could mean weak signal detection, two is medium signal detection, while three could then represent strong signal detection. This provides an even more detailed pattern representation as compared to only defining electrode detection timings and relative time delays.

The matrix generator 132 and the time slot marker 134 of the signal processor 130 may be provided as hardware, software or a combination of hardware and software. The generator 132 and the marker 134 may all be implemented in the processor 130. In an alternative distributed implementation, at least one of the generator 132 and the marker 134 is provided elsewhere in the IMD.

Returning to Fig. 3, the tachycardia classifier 140 is arranged for classifying a detected tachycardia based on a comparison of the generated pattern representation with at least one pre-defined template pattern representation. In this classification, the classifier 140 is preferably able, based on the detected depolarization wave propagation across the ventricle, to discriminate between tachycardias with and without hemodynamic impairments. In the latter case, even though the mechanical activation of the

ventricles differs from the normal activation pattern of a healthy heart, it does not have any essential negative influence on the cardiac output. A hemodynamically stable tachycardia is a tachycardia that is generally tolerable by the patient. A supra-ventricular tachycardia may sometimes be hemodynamically stable, while in other cases it can be unstable. Another example of hemodynamically stable tachycardia is flutter. A ventricular tachycardia except flutter is generally hemodynamically unstable, such as ventricular fibrillation.

The depolarization wave propagation across the ventricle follows different parts for different tachycardia types and also for healthy hearts. Therefore, the tachycardia classifier 140 preferably has access to one template pattern representation for each classifiable tachycardia condition in addition to a healthy template representation.

Fig. 5 is a schematic block diagram of an embodiment of the tachycardia classifier 140 of Fig. 3 in more detail. The classifier 140 comprises a correlation calculator 142 adapted to calculate, for each available template representation, a correlation factor indicative of a correlation between the generated pattern representation and a given template representation. The calculator 142 could fetch the template representations from an IMD-implemented memory or a dedicated template memory 146 in or accessible to the classifier 140.

In the case the pattern representations are in the form of a matrix having time slot markers, the calculator 142 generates the correlation factors as indicative of a correlation between the rows (or columns) in the matrix with corresponding rows (or columns) in the template matrices.

A correlation comparator 144 is implemented in the classifier 140 for comparing the correlation factors calculated by the correlation calculator 142. The comparator 144 furthermore identifies the template representation (matrix) having the highest correlation with the determined pattern

representation. The classifier 140 classifies the tachycardia based on the tachycardia type being associated with the identified template.

The correlation calculator 142 and the correlation comparator 144 of the tachycardia classifier 140 may be provided as hardware, software or a combination of hardware and software. The calculator 142, the comparator 144 and the template memory 146 may all be implemented in the classifier 140. In an alternative distributed implementation, at least one of the calculator 142, the comparator 144 and the memory 146 is provided elsewhere in the IMD.

The pre-defined tachycardia template patterns used by the tachycardia classifier 140 in Fig. 3 can be wirelessly provided to the IMD 100 from an external source, such as the programmer. In such a case, the templates are transmitted to the IMD antenna 185 and the receiver 180 and can then be provided to an associated memory 190 for storage. It is anticipated that depolarization wave propagations will differ from patient heart to heart and will also be highly dependent on the particular lead attachment to the outside of the ventricle myocardium. Furthermore, the wave propagations may also change, at least slightly, over time as the patient ages. As a consequence, usage of standard template patterns downloaded to the IMD 100 may be of little usage unless they are generated as average patterns taken from multiple different patients suffering from the same tachycardia type. Such statistics gathering will therefore significantly improve the usability of the standard templates.

In a preferred implementation, the IMD 100 comprises a template generator 160 provided for generating patient-specific template pattern representations. In such a case, there may be no need for receiving any standard templates or such standard templates can be used together with patient-specific templates to form an IMD database of different tachycardia-associated wave propagation templates.

The template generator 160 is connected to the electrode terminals 112 in the lead connecting arrangement 110 connectable to mating terminals 212 of the epicardial multi-electrode lead 200. The generator 160 collects electrode readings and generates template pattern representations, preferably in the same way as the previously described signal processor 130. Thus, the template representations are preferably in the form of one-dimensional or two-dimensional matrices indicating the electrode detection timings and preferably relative time delays and possible detection quality markers.

The template generator 160 can be operated during spontaneous elapses of different tachycardias. In such a case, the rate processor 150 preferably determines the ventricular rate of the heart based on readings from the endocardial lead 300 and/or the epicardial lead 200. If the determined ventricular rate, preferably ventricular rate averaged over multiple heart beats, exceeds a pre-defined threshold rate, a spontaneous tachycardia event can be present. An example of such a threshold rate could be 100 beats per minute in an adult human patient. If the IMD 100 comprises or is connectable to an activity sensor, the readings thereof can be used to confirm that the increased ventricular rate is originating from a tachycardia event and not simply due to physical activity of the patient. The rate threshold can be pre-configured in the IMD 100, determined during operation of the IMD 100 or be received by the receiver 180 from an external source.

The rate processor 150 preferably also determines an (average) atrial rate from lead measurements. In such a case, the rate comparator 155 can compare the determined ventricular and atrial rates for determining whether the spontaneously occurring tachycardia is a ventricular tachycardia (VT), having a ventricular rate that exceeds the pre-defined threshold and exceeds an atrial rate, or a supra-ventricular rate (SVT), having a ventricular rate that exceeds the pre-defined threshold and an atrial rate that exceeds the ventricular rate. In the former case, the comparator 155 generates a VT activation signal and in the latter case a SVT activation signal. The signal is

provided to the template generator 160 and triggers the generation of a template pattern representation based on electrode readings of the interpericardial lead 300. The generated pattern is further assigned a tachycardia class based on the activation signal, i.e. either VT or SVT.

Alternatively, the IMD 100 comprises a tachycardia provoker 170 implemented for inducing a tachycardia to the heart. The provoker 170 is connected to the lead connecting arrangement 110 via the I/O unit 120 and more precisely to the electrode terminals 116 electrically connected to the endocardial lead 300. The provoker then generates and forwards stimulating signals that are applied to different portions of the heart using the electrodes of the endocardial lead 300 and/or the epicardial lead 200. For instance, a first stimulating signal causes a provocation of ventricular tachycardia (VT), while a second stimulating signal causes a supra-ventricular tachycardia (SVT).

The rate processor 150 preferably confirms whether a provoked tachycardia event is actually taking place by comparing a measured ventricular rate and/or a measured atrial rate with each other and/or different threshold rates. Once a provoked tachycardia event has been confirmed, the template generator 160 generates a template pattern representation based on the electrode detections of the epicardial multi-electrode lead 200 performed during the provoked tachycardia event. The generator 160 also assigns a given tachycardia classification, such as VT or SVT, to the generated template pattern.

Fig. 6 is a schematic block diagram of an embodiment of the template generator 160 of Fig. 3. The generator 160 comprises a VT template generator 162 for determining a VT template pattern representation following a provoked VT event or following detection of a spontaneous tentative VT event. A corresponding SVT template generator 164 is adapted to determine a SVT template pattern representation following a SVT event.

The generated templates are forwarded to the IMD memory (see Fig. 3) for storage and later use of the tachycardia classifier.

The VT template generator 162 and the SVT template generator 164 of the template generator 160 may be provided as hardware, software or a combination of hardware and software. The generators 162, 164 may all be implemented in the template generator 160. In an alternative distributed implementation, at least one of the generators 162, 164 is provided elsewhere in the IMD.

The template generator 160 also preferably generates a normal template pattern representation associated with a normal heart non-tachycardia heart condition. Such a condition is preferably detected based on ventricular and/or atrial rates determined by the rate processor 150. Furthermore, especially if the IMD 100 has access to an activity sensor, the template generator 160 preferably generates an increased activity template pattern during a period of increased ventricular rate, as determined by the rate processor, but where the increased rate is due to an increased physical activity of the patient, as determined by the activity sensor. In such a case, the tachycardia classifier 140 will have access to template patterns representing normal heart condition and increased physical activity, in addition to the different tachycardia template patterns.

Furthermore, at least a portion of the template patterns can be standard patterns received from an external source, at least a portion of the templates can be patient-specific generated during different tachycardia provocations and at least a portion of the templates can be patient-specific generated during different spontaneous tachycardia events.

The template generator 160 preferably updates its template pattern representations over time to reflect changes in the depolarization wave propagation due to aging and changes to the detection sensitivity of the plurality of electrodes in the epicardial lead. For instance, each time the

tachycardia classifier 140 performs a tachycardia classification, the generated depolarization propagation pattern can be forwarded from the processor 130 not only to the classifier 140 but also to the template generator 160. The generator 160 can therefore update its corresponding template representation associated with the classified tachycardia type. The update can be realized as an averaging of the two patterns or by using a weighted averaging.

The IMD 100 also comprises a battery 195 that constitutes the power source for the other functionalities in the IMD 100.

The units of the IMD 100 can be provided as hardware, software or a combination thereof.

Fig. 7 is a flow diagram illustrating a heart diagnosing method according to the present invention. The method starts in step S1, where the electrical activity of a ventricle of a heart is sensed by multiple spatially and electrically separated electrodes of an epicardial multi-electrode lead. A next step S2 generates a representation of a depolarization wave propagation pattern across the ventricle based on the sensed electrical activity. The generated pattern representation is compared in step S3 with at least one pre-defined template representation of a template depolarization wave propagation pattern. Step S4 classifies a tachycardia of the heart based on the representation comparison performed in step S4.

The heart diagnosing method of the present invention is preferably performed multiple times based on different triggering events, which is schematically illustrated by the line L1.

Fig. 8 is a flow diagram illustrating such a trigger condition according to the invention. The method starts in step S10, where a ventricular rate of the heart is determined based on electrical activity sensing using the epicardial lead or an endocardial lead connected to the IMD. The ventricular rate is

compared to a pre-defined rate threshold, such as about 100 beats per minute, in step S11. If the rate does not exceed the threshold, no triggering has occurred and the method returns to step S10. In such case, the rate monitoring and determination of step S10 can be performed continuously during the operation of the IMD, such as investigating each heart beat. However, in order to save battery, the rate sensing can be performed periodically or intermittently, such as once every half second, once every minute, once every 10 minutes, once every hour or some other suitable time period. However, if the determined rate exceeds the threshold a tentative tachycardia is present and the method continues to step S1 of Fig. 7.

If the IMD also has access to activity sensors, such a sensor reading can be investigated if the ventricular rate exceeds the threshold in step S11. If the activity sensor indicates high physical activity, the increased ventricular rate is not due to a tachycardia and the method can return to step S10. However, if the sensor indicates no or only moderate physical activity, the method instead continues to step S1 of Fig. 7.

Fig. 9 is a flow diagram illustrating an embodiment of the pattern representation generating step and the comparing step of Fig. 7 in more detail. The method continues from step S1 of Fig. 7. A next step S20 generates the pattern representation as a matrix specifying a time order at which the multiple electrodes of the epicardial lead sensed the depolarization wave propagation across the ventricle. The generating step S20 is performed based on the sensed electrical activity of the ventricle. An optional, but preferred, next step S21 marks time slots for the different electrodes and representative of the time at which electrical activity were sensed by the electrodes. This time slot marking also provides relative time delays of the wave propagation across the ventricle. The time slot marking can also have qualitative character associated with the detected signal strength.

The next step S22 and S23 calculates correlation factors for each template pattern representation available at the IMD. For instance, in step S22 a VT

correlation factor indicative of a correlation between the determined pattern representation and a VT template representation is calculated. A corresponding SVT correlation factor is calculated in step S23 and is indicative of a correlation between the determined pattern representation and a SVT template representation.

The correlation calculation is preferably based on calculating a correlation between the rows (or columns) in the matrix determined in steps S21 and S22 with corresponding VT and SVT template matrices.

A next optional step S24 checks whether the calculated correlation factors exceeds a minimum correlation threshold. If none of the factors is larger than the threshold, a hitherto non-characterized heart condition giving rise to a new depolarization wave propagation pattern has been detected. The method then continues to step S1 of Fig. 7 or step S10 of Fig. 8 for thereby performing a new electrode reading. Alternatively, the generated pattern representation (matrix) can be stored as a new template representation. In such a case, the template is preferably associated with other hemodynamic parameters provided from other sensors in or attachable to the IMD.

If at least one correlation factor exceeds the threshold, the method continues to step S25 where the largest correlation factor is identified. The method then continues to step S4 of Fig. 7 where the tachycardia classification is performed based on the largest correlation factor. In other words, the tachycardia is classified as the tachycardia class being associated with the largest correlation factor.

Fig. 10 is a flow diagram illustrating an embodiment of generating template pattern representations. The method starts in step S30, where ventricular tachycardia is provoked in the patient. This provocation is preferably conducted by applying stimulating or shocking electrical signals by the IMD to the heart. Alternatively, the provocation can be induced by administration of tachycardia-triggering drugs or using externally applied tachycardia-

triggering devices to the patient body. In either case, once a tentative ventricular tachycardia has been confirmed, preferably through analysis of heart rate (ventricular rate > threshold, ventricular rate \geq atrial rate), the method continues to step S31. This step S31 involves sensing electrical activity of the ventricle using the epicardial multi-electrode lead of the invention to thereby register the propagation pattern of the depolarization wave across the ventricle during ventricle tachycardia. A next step S31 generates a VT template representation based on the sensed electrical activity. The generated template representation is preferably a similar matrix as can be used as representation of the depolarization wave propagation pattern in the heart diagnosis.

The following steps S33 to S35 provoke supra-ventricular tachycardia and generate a SVT template representation of the depolarization wave propagation across the ventricle during the supra-ventricular tachycardia. These steps S33 to S35 are performed in a similar manner to the steps S30 to S32 with the exception that SVT is detected in the case the ventricular rate > threshold and the atrial rate > ventricular rate.

The generated VT and SVT template representations are then stored in step S36 for later used in the heart diagnosis of the present invention.

Fig. 11 is a flow diagram illustrating another embodiment of generating template representations for use in the heart diagnosis of the present invention. This embodiment in particular utilizes spontaneously triggered tachycardia events for the purpose of generating the template representations. The method starts in step S40, where the ventricular and atrial rates of the heart are determined. This rate determination can be performed continuously, periodically or intermittently. A next step S41 compares the determined ventricular rate with a threshold rate. If the rate exceeds the threshold, a tentative tachycardia event is present. The method therefore continues to step S42, where the determined ventricular rate is compared to the atrial rate. If the atrial rate is indeed larger than the

ventricular rate, the heart may suffer from supra-ventricular tachycardia. A next step S45 senses electrical activity of the ventricle using the epicardial multi-electrode lead to capture the depolarization wave propagation pattern over the ventricle during SVT. Step S46 generates a SVT template representation based on the sensed electrical activity. If the IMD already has access to a previously generated SVT template representation that representation can be updated in step S46 based on the newly acquired electrical activity data from step S45.

If, however, the atrial rate does not exceed the ventricular rate in step S42, the heart may suffer from ventricular tachycardia. The method continues to step S47, which sensing the electrical activity of the ventricular during the ventricular tachycardia event. This step S47 is performed in a similar manner to step S45. A next step S48 generates a VT template representation or updates an existing VT template based on the sensed electrical activity.

If the ventricular rate does not exceed the threshold in step S41, the method continues to step S43, where the electrical activity of the ventricle is sensed by the epicardial multi-electrode lead during a normal, non-tachycardia period. A normal template representation is generated in step S44 based on the sensed electrical activity.

If the IMD has access to activity data from one or more physical activity sensors, the activity data can be compared to an activity threshold in the case the ventricular rate exceeds the rate threshold in step S41. This can be performed to elucidate whether the rate increase is due to a tachycardia event or regular physical activity. In the latter case, the electrical activity of the ventricle can be sensed in similarity to the operations in steps S45, S47 and S49. The sensed electrical activity is then used for generating a template representation indicative of a period with increased physical activity.

In either case, the generated template representations are stored in step S49 for later use and comparison with determined pattern representations for

heart diagnosis. The template representations are preferably periodically or intermittently updated as described above. This is schematically illustrated by the line L2 in the figure.

The detection and classification of tachycardia events according to the present invention using an intrapericardial multi-electrode lead and depolarization wave propagation patterns provide a much more reliable classification than the simple rate-based techniques used in the art. As a consequence, the invention can be used for providing a more reliable discrimination between hemodynamically unstable tachycardias, which should be treated through application of defibrillation shocks, and hemodynamically stable tachycardias, which generally do not need to be treated by shocking but will instead spontaneously revert to normal heart activity.

Once the tachycardia event has been classified according to the present invention, the IMD can trigger different tachycardia combating actions, which are well known in the art. The refined classification of the invention provides valuable information in determining the particular treatment response to adopt. This means that the IMD can select, among different known anti-tachycardia treatment operations, the particular treatment that is most suitable to the current situation as determined based on the tachycardia classification.

The epicardial multi-electrode lead of the present invention may also be used for other purposes besides tachycardia classification. For instance, by registering the depolarization wave propagation pattern across the ventricle, the IMD can differentiate between flutter and fibrillation using the generated pattern representation. A flutter typically has a non-varying propagation pattern, while the pattern during fibrillation is constantly varying.

Furthermore, the epicardial multi-electrode lead can be used as a pacing lead of the IMD. In such a case, at least a sub-set of the plurality of electrodes can deliver an electric pacing pulse to the ventricle. There is a

major advantage in having access to multiple electrodes at the lead in that the lead can switch between active pacing electrodes if for instance the capture threshold of an electrode is high. Thus, optimal pacing electrodes can be selected, preferably dynamically selected, during operation of the IMD to thereby only use such electrodes having associated low capture thresholds.

Correspondingly, the electrodes of the epicardial multi-electrode lead can be used for individual electrogram (EGM) sensing. In such a case, electrograms can be generated from only those electrodes that result in a large EGM amplitude. If the EGM would be too low for a particular electrode, the IMD can instead activate another electrode of the multi-electrode lead to thereby obtain a better EGM signal.

The epicardial multi-electrode lead is also highly suitable for ischemia detection, such as based on impedance measurements. As the distal lead end and the electrode network cover a substantive portion of at least one ventricle, local ischemia can be detected at a high level of precision using a current/voltage signal applied over two electrodes and the resulting voltage/current signal sensed of two electrodes, which can be the same or different from the signal applying electrodes. Local ischemia can also or instead be detected by the epicardial multi-electrode lead from electric signals collected by the electrodes, e.g. from the different local EGMs.

It will be understood by a person skilled in the art that various modifications and changes may be made to the present invention without departure from the scope thereof, which is defined by the appended claims.

CLAIMS

1. An implantable medical device (100) comprising:
 - a lead connecting arrangement (110) connectable to an epicardial multi-electrode lead (200) and having at least one electrode terminal (112) connectable to corresponding electrode terminal (212) of a proximal end (210) of said lead (200) to provide electrical connection between said at least one electrode terminal (112) and the multiple electrodes (232) of said lead (200);
 - a signal processor (130) connected to said plurality of electrode terminals (112) and adapted to generate, based on electrical activity of a ventricle (12) of a heart (10) sensed by said multiple electrodes (232), a representation of a depolarization wave propagation pattern across said ventricle (12); and
 - a tachycardia classifier (140) adapted to classify a tachycardia of said heart (10) based on a comparison of said representation and a template representation of a template depolarization wave propagation pattern.
2. The device according to claim 1, further comprising:
 - a rate processor (150) connected to said lead connecting arrangement (110) and adapted to determine a ventricular rate of said heart (10); and
 - a rate comparator (155) adapted to generate an activation signal if said ventricular rate exceeds a rate threshold, wherein said signal processor (130) is responsive to said activation signal and generates said representation upon reception of said activation signal.
3. The device according to claim 1 or 2, wherein said signal processor (130) is adapted to generate, based on said electrical activity of said ventricle (12) sensed by said multiple electrodes (232), said representation as a matrix specifying a time order at which said multiple electrodes (232) sensed said depolarization wave propagation across said ventricle (12).
4. The device according to claim 3, wherein said signal processor (130) comprises:

- a matrix generator (132) adapted to generate said matrix having a respective row/column associated with each electrode of said multiple electrodes (232) and where said columns/rows represent contiguous time slots; and

- a time slot marker (134) connected to said matrix generator (132) and adapted to mark, for each row/column, a time slot corresponding to a point in time at which an electrode associated with said row/column sensed said electrical activity of said ventricle (12).

5. The device according to any of the claims 1 to 4, wherein said tachycardia classifier (140) having access to at least a ventricular tachycardia, VT, template representation of a VT template depolarization wave propagation pattern across said ventricle (12) during a VT state of said heart (10) and a supra-ventricular tachycardia, SVT, template representation of a SVT template depolarization wave propagation pattern across said ventricle (12) during a SVT state of said heart (10) and comprising a correlation generator (142) adapted to calculate a first correlation factor indicative of a correlation between said representation and said VT template representation and a second correlation factor indicative of a correlation between said representation and said SVT template representation, said tachycardia classifier (140) is adapted to classify said heart (10) as suffering from VT or SVT based on at least one said first correlation factor and said second correlation factor.

6. The device according to claim 4 and 5, wherein said correlation generator (142) is adapted to generate said first correlation factor as indicative of a correlation between rows/columns in said matrix with corresponding rows/columns in a VT matrix and generate said second correlation factor as indicative of a correlation between rows/columns in said matrix with corresponding rows/columns in a SVT matrix, said tachycardia classifier (140) is adapted to classify said heart (10) as suffering from VT or SVT based on a highest factor of said first and second correlation factor.

7. The device according to any of the claims 1 to 6, further comprising a template generator (160) connected to said plurality of electrode terminals (112) and adapted to generate, based on electrical activity of said ventricle (12) sensed by said multiple electrodes (232), said template representation of a template depolarization wave propagation pattern across said ventricle (12).

8. The device according to any of the claims 1 to 7, further comprising a tachycardia provoker (170) connected to said lead connecting arrangement (110) and adapted to apply, through at least one endocardial lead (300) connectable to said lead connecting arrangement (110), a first stimulating signal causing a provocation of ventricular tachycardia, VT, of said heart (10) or a second stimulating signal causing a provocation of supra-ventricular tachycardia, SVT, of said heart (10).

9. The device according to claim 7 and 8, wherein said template generator (160) comprises:

- a VT template generator (162) adapted to generate, based on electrical activity of said ventricle (12) sensed by said multiple electrodes (232), a VT template representation of a VT template depolarization wave propagation pattern across said ventricle (12) following a provoked VT of said heart (10) through application of said first stimulating signal; and

- a SVT template generator (164) adapted to generate, based on electrical activity of said ventricle (12) sensed by said multiple electrodes (232), a SVT template representation of a SVT template depolarization wave propagation pattern across said ventricle (12) following a provoked SVT of said heart (10) through application of said second stimulating signal.

10. The device according to any of the claims 1 to 9, further comprising:

- a rate processor (150) connected to said lead connecting arrangement (110) and adapted to determine a ventricular rate of said heart (10); and

- a rate comparator (155) connected to said rate processor (150) and adapted to generate an activation signal if said ventricular rate exceeds a rate threshold, wherein said template generator (180) is responsive to said activation signal and generates said template representation upon reception of said activation signal.

11. The device according to claim 10, wherein said rate processor (150) is adapted to determine an atrial rate and a ventricular rate, said rate comparator (155) is adapted to generate a SVT activation signal if said ventricular rate exceeds said rate threshold and if said atrial rate exceeds said ventricular rate, said template generator (160) comprises a SVT template generator (164) responsive to said SVT activation signal and generates a SVT template representation upon reception of said SVT activation signal.

12. The device according to claim 10 or 11, wherein said rate processor (150) is adapted to determine an atrial rate and a ventricular rate, said rate comparator (155) is adapted to generate a VT activation signal if said ventricular rate exceeds said rate threshold and if said atrial rate does not exceed said ventricular rate, said template generator (160) comprises a VT template generator (162) responsive to said VT activation signal and generates a VT template representation upon reception of said VT activation signal.

13. A heart diagnosing method comprising the steps of:

- sensing electrical activity of a ventricle (12) of a heart (10) by multiple spatially and electrically separated electrodes (232) of an epicardial multi-electrode lead (200);

- generating, based on said sensed electrical activity of said ventricle (12), a representation of a depolarization wave propagation pattern across said ventricle (12);

- comparing said representation with a template representation of a template depolarization wave propagation pattern; and

- classifying a tachycardia of said heart (10) based on said comparison.

14. The method according to claim 13, further comprising the steps of:

- determining a ventricular rate of said heart (10); and
- comparing said ventricular rate with a rate threshold, wherein said

sensing step and said generating step are performed if said ventricular rate exceeds said rate threshold.

15. The method according to claim 13 or 14, wherein said generating step comprises generating, based on said sensed electrical activity of said ventricle (12), said representation as a matrix specifying a time order at which said multiple electrodes (232) sensed said depolarization wave propagation across said ventricle (12).

16. The method according to claim 15, wherein said generating step comprises the steps of:

- generating said matrix having a respective row/column associated with each electrode of said multiple electrodes (232) and where said columns/rows represent contiguous time slots; and
- marking, for each row/column, a time slot corresponding to a point in time at which an electrode associated with said row/column sensed said electrical activity of said ventricle (12).

17. The method according to any of the claims 13 to 16, wherein said comparing step comprises the steps of:

- calculating a first correlation factor indicative of a correlation between said representation and a ventricular tachycardia, VT, template representation of a VT template depolarization wave propagation pattern across said ventricle (12) during a VT state of said heart (10);
- calculating a second correlation factor indicative of a correlation between said representation and a supra-ventricular tachycardia, SVT, template representation of a SVT template depolarization wave propagation pattern across said ventricle (12) during a SVT state of said heart (10).

18. The method according to claim 16 and 17, wherein said step of calculating said first correlation factor comprises calculating said first correlation factor as indicative of a correlation between rows/columns in said matrix with corresponding rows/columns in a VT matrix and said step of calculating said second correlation factor comprises calculating said second correlation factor as indicative of a correlation between rows/columns in said matrix with corresponding rows/columns in a SVT matrix.

19. The method according to claim 17 or 18, wherein said classifying step comprises classifying said heart (10) as suffering from VT or SVT based on a highest factor of said first and second correlation factor.

20. The method according to any of the claims 13 to 19, further comprising generating, based on electrical activity of said ventricle (12) sensed by said multiple electrodes (232), said template representation of a template depolarization wave propagation pattern across said ventricle (12).

21. The method according to any of the claims 13 to 20, further comprising applying, through at least one endocardial lead (300) and to said heart (10), a first stimulating signal causing a provocation of ventricular tachycardia, VT, of said heart (10) or a second stimulating signal causing a provocation of supra-ventricular tachycardia, SVT, of said heart (10).

22. The method according to claim 20 and 21, wherein said step of generating said template representation comprises:

- generating, based on electrical activity of said ventricle (12) sensed by said multiple electrodes (232), a VT template representation of a VT template depolarization wave propagation pattern across said ventricle (12) following a provoked VT of said heart (10) through application of said first stimulating signal; and

- generating, based on electrical activity of said ventricle (12) sensed by said multiple electrodes (232), a SVT template representation of a SVT

template depolarization wave propagation pattern across said ventricle (12) following a provoked SVT of said heart (10) through application of said second stimulating signal.

23. The method according to any of the claims 13 to 22, further comprising:

- determining a ventricular rate of said heart (10); and
- comparing said ventricular rate with a rate threshold, wherein said step of generating said template representation is performed if said ventricular rate exceeds said rate threshold.

24. The method according to claim 23, wherein said ventricular rate determining step comprises the steps of:

- determining an atrial rate of said heart (10); and
- determining a ventricular rate of said heart (10), wherein said step of generating said template representation comprises the steps of:
 - generating a supra-ventricular tachycardia, SVT, template representation if said ventricular rate exceeds said rate threshold and if said atrial rate exceeds said ventricular rate; and
 - generating a ventricular tachycardia, VT, template representation if said ventricular rate exceeds said rate threshold and if said atrial rate does not exceed said ventricular rate.

25. An implantable epicardial lead (200) comprising:

- a distal lead end (220) having a branch point (223) at which said lead (200) is branched into at least three distal lead branches (230), each of said distal lead branches (230) comprises at least two spatially and electrically separated electrodes (232);
- a proximal lead end (210) connectable to an implantable medical device (100) and having at least one electrode terminal (212); and
- a lead body connecting said distal lead end (220) and said proximal lead end (210) and housing at least one conductor connecting said electrodes (232) with said at least one electrode terminal (212).

26. The lead according to claim 25, wherein said lead is an intrapericardial multi-electrode lead (200) adapted for attachment to at least one ventricle (12) of a heart (10).

27. The lead according to claim 25 or 26, wherein said at least two electrodes (232) of a distal lead branch (230) are spatially separated with at least a minimum distance of 1 cm along said distal lead branch (230).

28. The lead according to any of the claims 25 to 27, wherein the most distal ends of said distal lead branches (230) are mechanically interconnected.

29. The lead according to any of the claims 25 to 28, wherein said electrodes (232) are all facing a same side of said distal lead end (220).

30. The lead according to any of the claims 25 to 29, wherein said distal lead end (220) comprises at least one multiplexor connected to at least a portion of said electrodes (232) and to said at least one conductor and adapted to separate electric signals sensed by said at least a portion of said electrodes (232) for transmission to said proximal lead end using said at least one conductor.

31. An implantable system comprising:

- an implantable medical device (100) according to any of the claims 1 to 12 and having a lead connecting arrangement (110); and
- an epicardial multi-electrode lead (200) having a proximal end (210) connectable to said lead connecting arrangement (110).

32. The implantable system according to claim 31, wherein said epicardial multi-electrode lead (200) is the epicardial multi-electrode lead according to any of the claims 25 to 30.

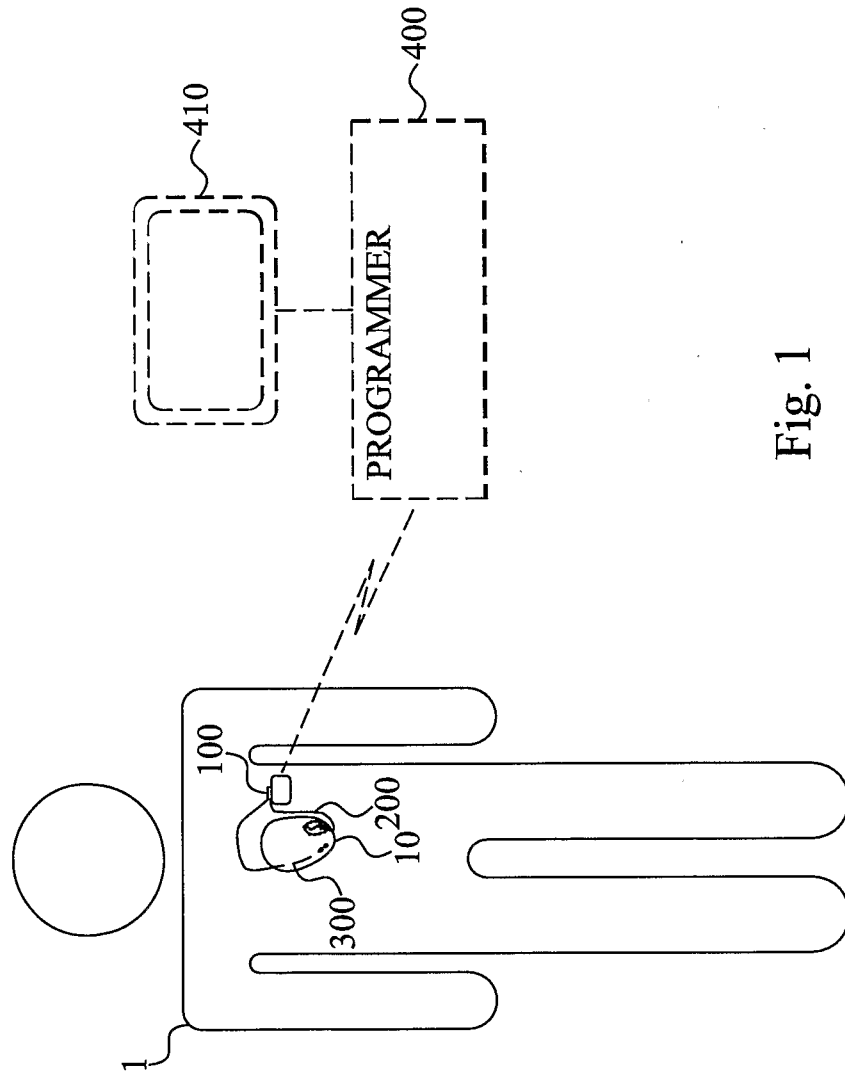


Fig. 1

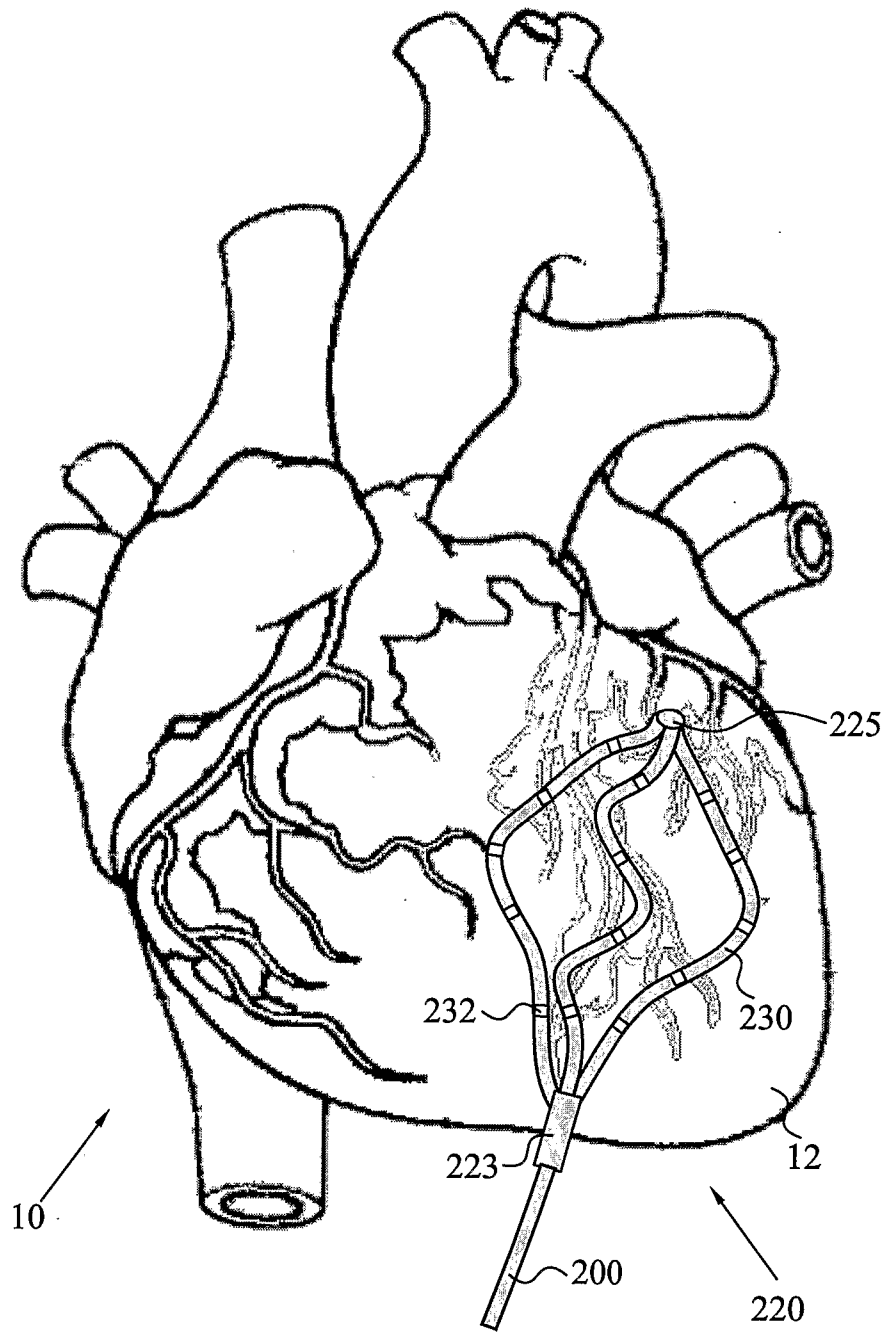


Fig. 2

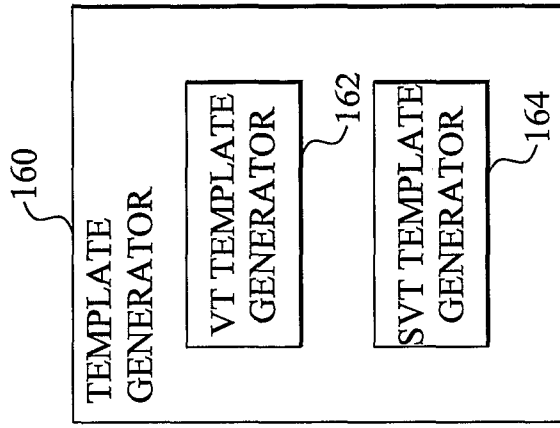


Fig. 6

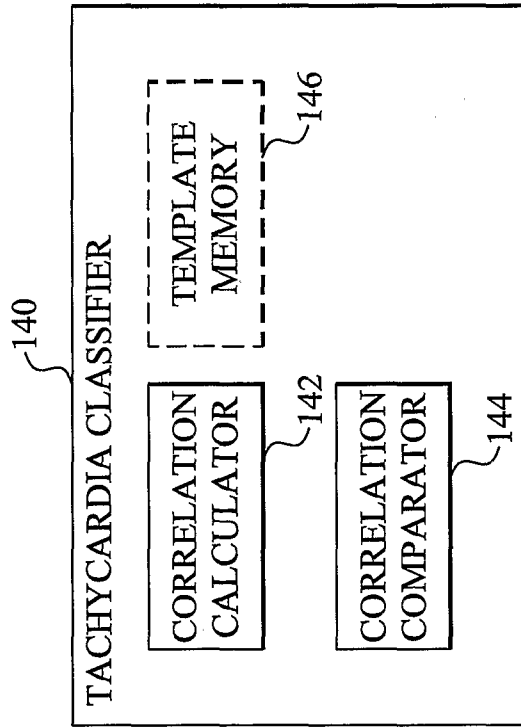


Fig. 5

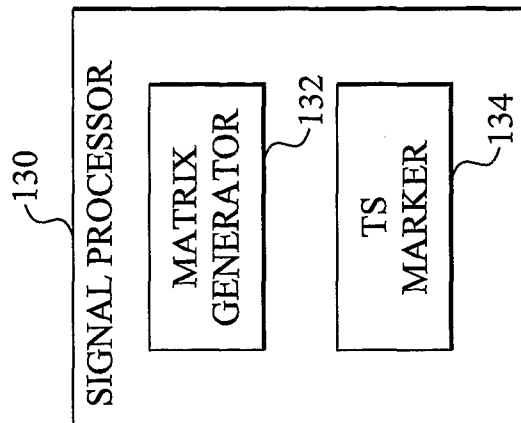


Fig. 4

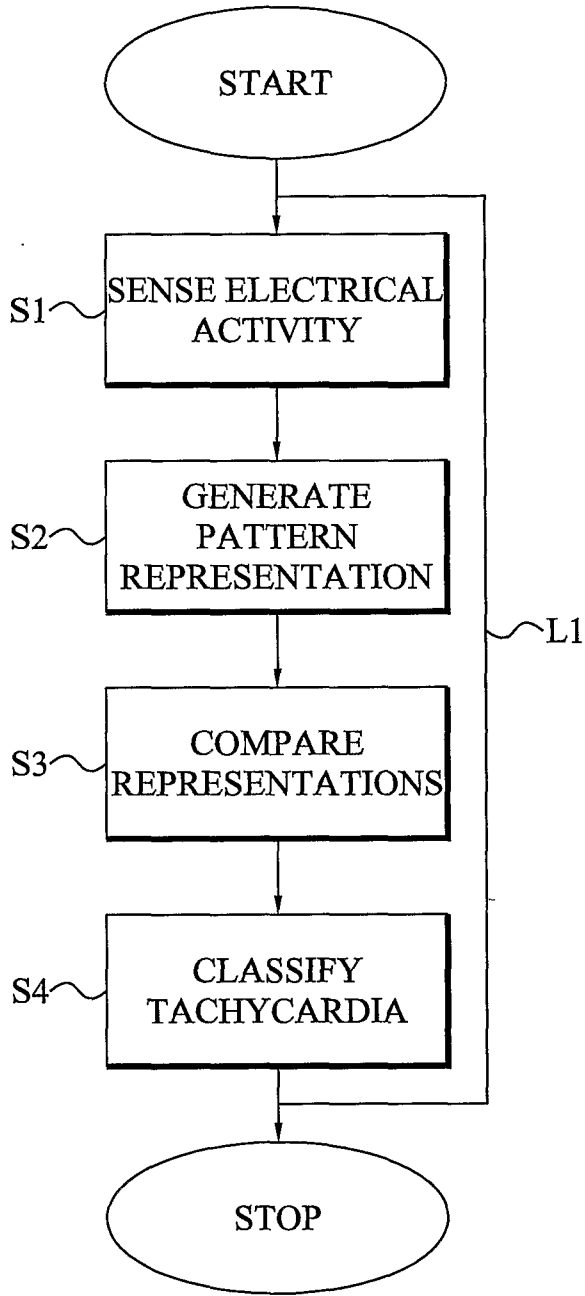


Fig. 7

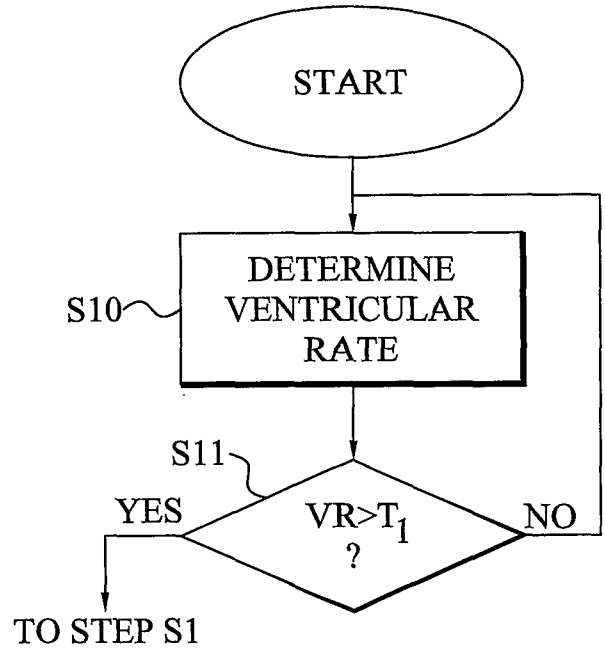


Fig. 8

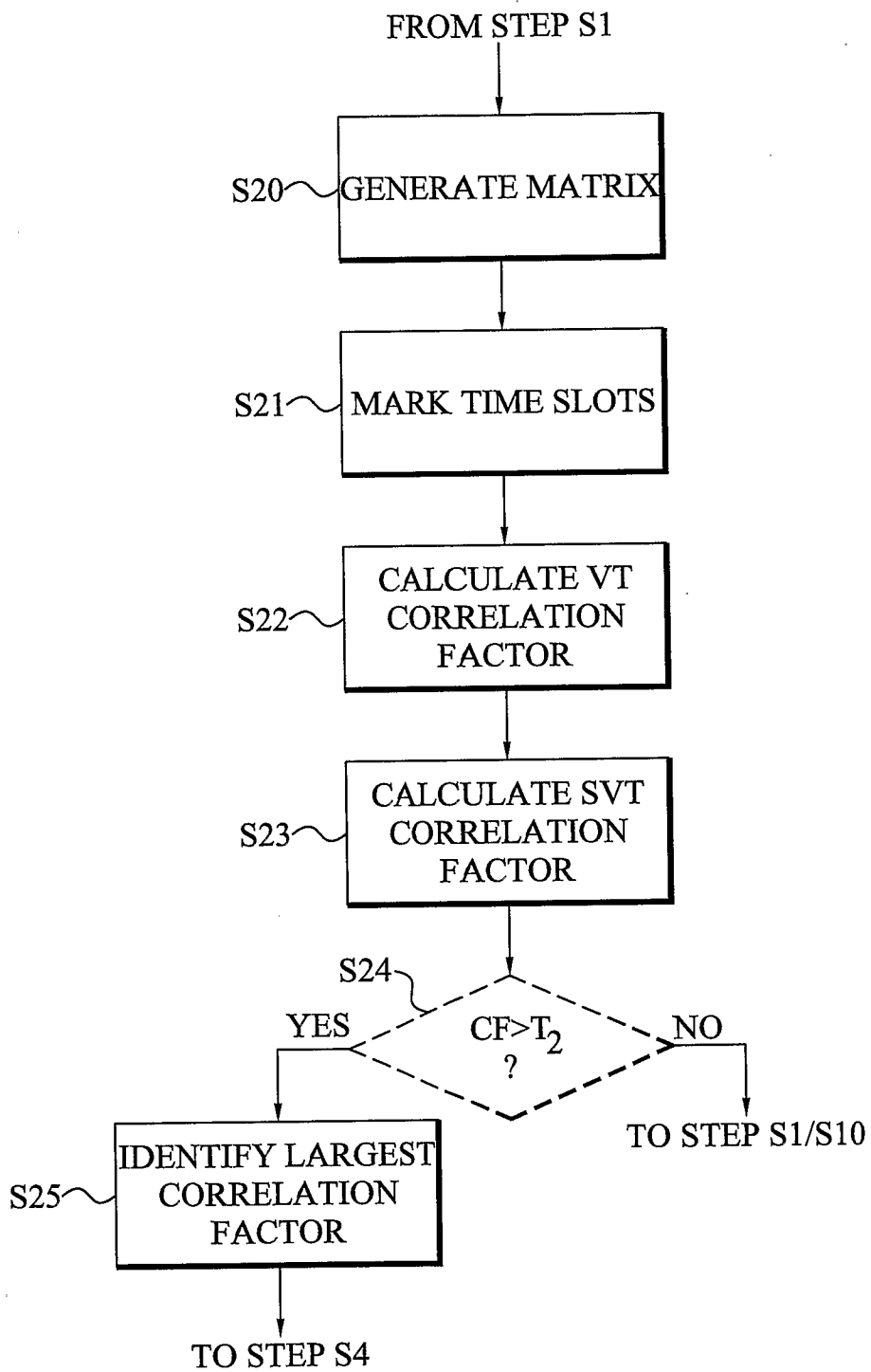


Fig. 9

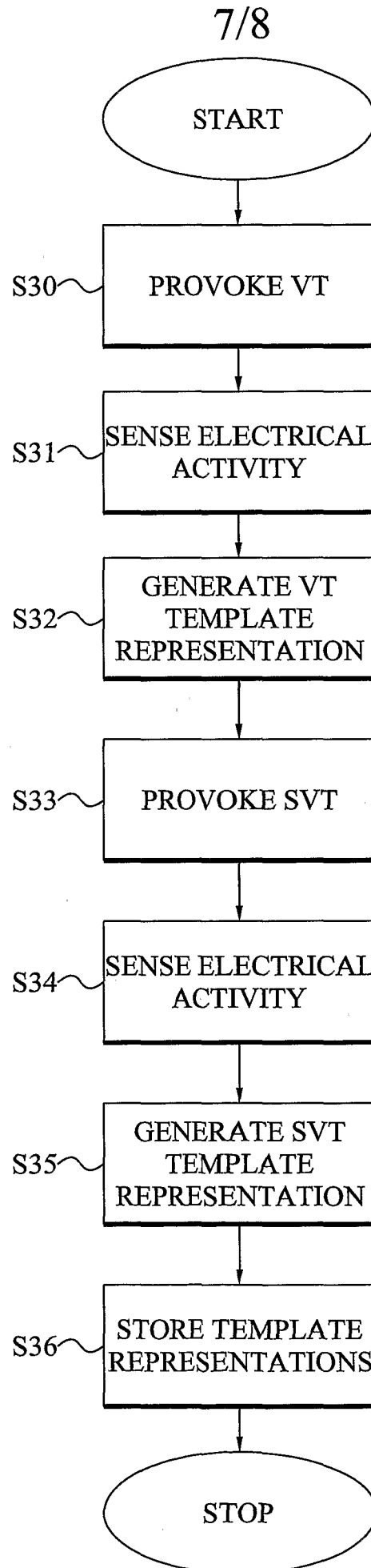


Fig. 10

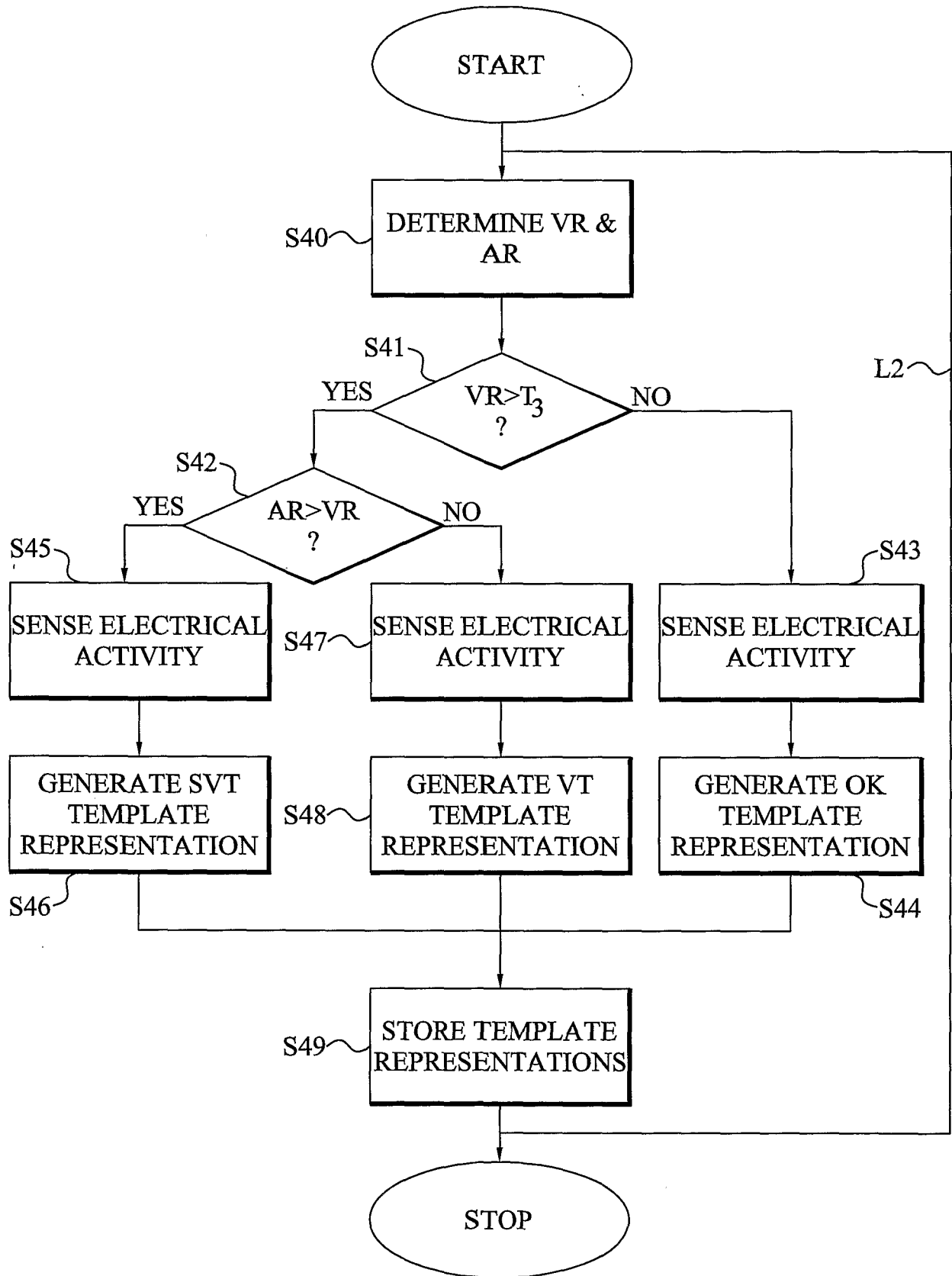


Fig. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2007/001006

A. CLASSIFICATION OF SUBJECT MATTER		
IPC: see extra sheet According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
IPC: A61N, A61B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
SE,DK,FI,NO classes as above		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
EPO-INTERNAL, WPI DATA, PAJ, BIOSIS, MEDLINE		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5476503 A (YANG, M-Y), 19 December 1995 (19.12.1995), column 1, line 7 - column 3, line 26; column 5, line 40 - column 6, line 58, claims 11-17	1-24,31
Y	--	32
X	US 20030083586 A1 (FEREK-PETRIC, B), 1 May 2003 (01.05.2003), paragraphs [0003]-[0010],[0090], [0136]-[0137]	1-24,31
Y	--	32
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
<p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>		
Date of the actual completion of the international search		Date of mailing of the international search report
15 July 2008		17 -07- 2008
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86		Authorized officer Gordana Ninkovic/PR Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2007/001006

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	--	32
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2007/001006

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	--	32
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2007/001006

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9717892 A1 (CARDIAC PATHWAYS CORPORATION), 22 May 1997 (22.05.1997), abstract -- -----	25-30,32

International patent classification (IPC)**A61N 1/362** (2006.01)**A61B 5/0464** (2006.01)**A61N 1/05** (2006.01)**Download your patent documents at www.prv.se**

The cited patent documents can be downloaded at www.prv.se by following the links:

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Use the application number as username.

The password is **RZZUZHVAW**.

Paper copies can be ordered at a cost of 50 SEK per copy from PRV InterPat (telephone number 08-782 28 85).

Cited literature, if any, will be enclosed in paper form.

INTERNATIONAL SEARCH REPORTInternational application No.
PCT/SE2007/001006**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 13 - 24
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 13-24 relate to a method for treatment of the human or animal body by surgery or by therapy, as well as diagnostic methods, see PCT rule 39.1(iv). Nevertheless, a search has been made for these claims. The search has been directed to the technical content of the claims.
2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

See extra sheet

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

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

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Box III

The following separate inventions were identified:

1: Claims 1-24,31-32 directed to a medical implantable device and an implantable heart diagnosing system and a method involving epicardial multi-electrode registrations, whereby a depolarization wave propagation pattern across a ventricle is used for obtaining tachycardia classification.

2: Claims 25-30 directed to an implantable epicardial lead comprising several distal end branches provided with several separated electrodes.

The present application has been considered to contain 2 inventions which are not linked such that they form a single general inventive concept, as required by Rule 13 PCT. As both the problems and solutions are technically different, no single general concept can be formulated based on the technical features of the inventions.

However, all claims could be searched without efforts justifying additional fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

26/01/2008

International application No.

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