



(51) International Patent Classification:

A61N 1/362 (2006.01) A61N 1/37 (2006.01)
A61B 5/046 (2006.01) A61N 1/39 (2006.01)
A61B 5/0464 (2006.01)

(21) International Application Number:

PCT/SE2008/000312

(22) International Filing Date:

7 May 2008 (07.05.2008)

(25) Filing Language:

English

(26) Publication Language:

English

(71) Applicant (for all designated States except US): ST. JUDE MEDICAL AB [SE/SE]; SE-175 84 Järfälla (SE).

(72) Inventors; and

(75) Inventors/Applicants (for US only): BJÖRLING, Anders [SE/SE]; Näckrosvägen 35, SE-169 37 Solna (SE). BHARMI, Rupinder [IN/US]; 18126 Flynn Drive, 61606, 91387 Canyon Country (US). BROOME, Michael [SE/SE]; Mossvägen 24, SE-178 38 Ekerö (SE). JÄRVERUD, Karin [SE/SE]; Ballonggatan 17, 4 tr, SE-169 71 Solna (SE).

(74) Common Representative: ST. JUDE MEDICAL AB; Patent Department, SE-175 84 Järfälla (SE).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, 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, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— of inventorship (Rule 4.17(iv))

Published:

— with international search report (Art. 21(3))

(54) Title: AN IMPLANTABLE MEDICAL DEVICE AND METHOD FOR CLASSIFYING ARRHYTHMIA EVENTS

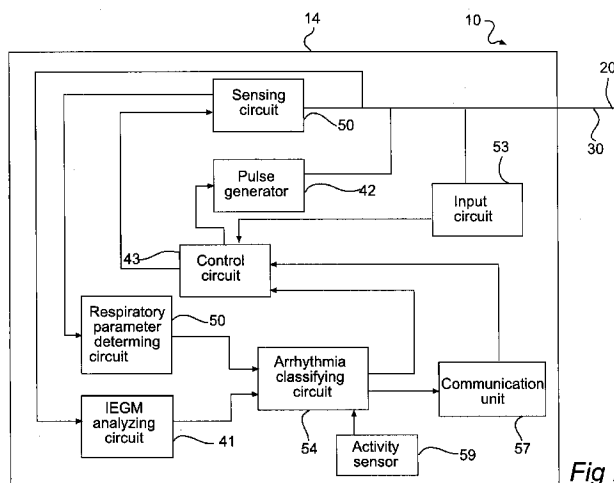


Fig 2

(57) Abstract: The present invention generally relates to the field of implantable devices. More specifically, the present invention relates to an implantable medical device, for example, an implantable cardiac defibrillator and a method for classifying arrhythmia events. IEGM signals are analysed to detect an arrhythmia event and a respiratory pattern of the patient is sensed. At least one respiratory parameter reflecting characteristics of the respiratory pattern of the patient is determined based on the sensed respiratory pattern and a respiratory measure corresponding to a change of a rate of change of the at least one respiratory parameter is calculated. The detected arrhythmic event is classified based on the respiratory measure and the IEGM signals, wherein arrhythmia events that satisfy at least a first criterion is classified as an arrhythmia event requiring therapy.

WO 2009/136817 A1

AN IMPLANTABLE MEDICAL DEVICE AND METHOD FOR CLASSIFYING
ARRHYTHMIA EVENTS

Technical field

The present invention generally relates to the field of implantable devices. More specifically, the present invention relates to an implantable
5 medical device, for example, an implantable cardiac defibrillator for the identification of arrhythmias and the discrimination between non-lethal arrhythmias and lethal arrhythmias that may or may not require therapy.

Background art

10 Identifying an arrhythmia based on its intracardiac electrogram is a commonly used technique in, for example, implantable cardiac defibrillators (ICD), which are designed to deliver therapy for life-threatening ventricular arrhythmias. The heart rate is measured by detecting R waves in the IEGM originating from the ventricle using a ventricular lead. If the rate is higher than
15 a specific limit, it is an indication that a tachycardia is present. A defibrillator is capable of delivering a high-energy electrical stimulus via medical leads to the heart that is sometimes referred to as defibrillation shocks. The shock interrupts a fibrillation, allowing the heart to re-establish a normal rhythm for efficient pumping of blood. The defibrillator is able to sense cardiac signals
20 deliver therapy to heart based on such signals. However, a problem often encountered in these implantable cardiac defibrillators is that shocks are delivered inappropriately for e.g. supraventricular tachycardias. In fact, studies do indicate that roughly 20-30 % of all delivered ICD shocks are inappropriate. About 16 % of patients receive inappropriate therapies (single
25 of multiple). It has further been found that patients experience 1.6 to 1.8 inappropriate shocks per year. One major reason for this delivery of inappropriate shock is the limited accuracy of the defibrillator in the discrimination between a truly life-threatening ventricular arrhythmia and a supraventricular tachycardia, which often causes similar electrical activity
30 patterns, i.e. similar intracardiac electrograms. These inappropriate delivered shocks constitute a significant source of physical and emotional stress and discomfort for the patient. Further, the shocks also cause unnecessary consumption of the device battery, which shorten the life of the device.

Therefore, ICDs of today often use different complementary discrimination techniques. For example, the interval stability is a parameter that may be used to improve the discrimination since VTs (ventricular tachycardia) tend to be more stable in rate than SVTs (supraventricular tachycardias). Another parameter is atrial-ventricular event association. During sinus tachycardias (i.e. benign tachycardias caused e.g. of high physical activity) shows atrial-ventricular event association, e.g. each P wave is followed by an R wave. In case of VTs, the atrial and ventricular events are disassociated. Morphology analysis may also be used since it has been shown that the IEGM during a VT is different from that of a normal heart beat. SVTs give in most cases a rise to the normal morphology.

A number of attempts have also been made within the prior art to overcome this problem.

For example, in US 7,206,633 a device and method for identification and detection of abnormal heart rhythm occurring in either the supraventricular or ventricular cardiac regions and in particular a device and method for discriminating between supraventricular tachycardia and ventricular arrhythmia. The technique according to US 7,206,633 is based on intracardiac electrograms recorded by atrial and ventricular sensing leads that distinguishes their temporal relationships following tachycardia recurrence subsequent to a train of simultaneous anti-tachycardia pacing (ATP) bursts in the atria and ventricles.

In US 2005/0154421 an implantable medical device for identifying suspected non-lethal or lethal arrhythmias is shown. The device takes actions to avoid or delay delivery of a defibrillation shock in case of a non-lethal arrhythmia and respiration rate, respiration depth, and/or activity level is used to discriminate between lethal and non-lethal arrhythmia. Impedance measured over the thoracic region of the patient can be used to calculate the respiration rate and respiration depth. Thus, in US 2005/0154421, the respiratory pattern and/or activity level are used as additional input to the analysis of the intracardiac electrograms in the discrimination between non-lethal and lethal arrhythmias.

Furthermore, in US 5,042,497 an implantable medical device capable of predicting and preventing cardiac arrhythmias is disclosed. The device monitors both ECG signals and autonomic neural tone signals. If both these signals indicate arrhythmia preventive or curative actions are taken by the device. Arrhythmias are characterized by increased sympathetic activity. This

sympathetic activity can be followed by monitoring, among other, the respiration rate variability of the patient. According to US 5,042,497, a decrease in variability of respiration rate indicate elevated sympathetic activity and thereby arrhythmia. The variability in respiration rate is determined on
5 basis on the interval between consecutive breaths of the patient.

In US 5,370,667 an implantable medical device that provides electrical therapy to a heart of a patient in order to treat pathological tachycardia is disclosed. The device has a first sensor that generates a signal indicative of the patient's ECG. A second sensor is an activity sensor that generates a
10 signal representative of the current status of physical activity by the patient. For example, the impedance over the chest is measured to indicate the activity of the patient. The readings of the first sensor (activity) sensor are employed for dynamically adjusting the arrhythmia threshold used, together with the ECG signal, for detecting the presence of arrhythmia. The device
15 utilizes different arrhythmia thresholds depending on the patient activity but the detection of the arrhythmia condition is performed solely based on ECG signals.

Consequently, a number of prior art solutions utilize breathing pattern as an additional parameter to the ECG signals to improve and increase the
20 accuracy in the discrimination between lethal and non-lethal arrhythmias in order to reduce the number of erroneously delivered defibrillation shocks. However, there is still a need within the art of improved devices and method that are capable of discriminating between lethal and non-lethal arrhythmias with a higher degree of accuracy in order to further reduce the number of
25 inappropriate delivered defibrillation shocks. As discussed above, such an improved device and method that is capable of reducing or even avoid inappropriate shock would have beneficial effect on the physical and emotional state of patients with defibrillators as well as reduce the cost of health care of the society.

30

Summary

Thus, an object of the present invention is to provide an improved implantable medical device and a method for such a device that are capable of discriminating between arrhythmias requiring therapy and arrhythmias that
35 do not require therapy with a high degree of accuracy.

A further object of the present invention is to provide an improved implantable medical device and a method for such a device that are capable

of classifying arrhythmias depending on whether therapy is required or not with a high degree of accuracy.

Another object of the present invention is to provide an improved implantable medical device and a method for such a device that are capable
5 of substantially preventing misinterpretations of the cardiac electrical signals with regard to arrhythmias and to substantially avoid the delivery of inappropriate shocks.

These and other objects of the present invention are achieved by a device and method as claimed in the independent claims. Further
10 embodiments are defined in the dependent claims.

According to a first aspect of the present invention, there is provided an implantable medical device for classifying arrhythmia events being connectable to at least one medical lead adapted to be placed at or within a heart of a patient, which medical lead includes at least one electrode adapted
15 to sense electrical activity of the heart and to produce at least one signal representative of the electrical activity. The medical device comprises: an IEGM analyzing circuit adapted receive the signal representative of the electrical activity and to analyse IEGMs of the heart to detect an arrhythmia event, a sensing circuit adapted to sense a respiratory pattern of the patient
20 and to produce at least one signal representative of the respiratory pattern, a respiratory parameter determining circuit adapted to determine at least one respiratory parameter reflecting characteristics of the respiratory pattern of the patient based on the sensed respiratory pattern and to determine a respiratory measure corresponding to a change of a rate of change of the at
25 least one respiratory parameter; and an arrhythmia classifying circuit adapted to classify the detected arrhythmia event based on the respiratory measure and the analysis of the IEGM signals, wherein arrhythmia events that satisfy at least a first criterion is classified as an arrhythmia event requiring therapy.

According to second aspect of the present invention, there is provided
30 a method for classifying arrhythmia events in an implantable medical device being connectable to at least one medical lead adapted to be placed at or within a heart of a patient. The medical lead includes at least one electrode adapted to sense electrical activity of the heart and to produce at least one signal representative of the electrical activity, The method comprises the
35 steps:

- analysing IEGMs of the heart to detect an arrhythmia event;

- sensing a respiratory pattern of the patient producing at least one signal representative of the respiratory pattern;
- determining at least one respiratory parameter reflecting characteristics of the respiratory pattern of the patient based on the sensed respiratory pattern;
- determining a respiratory measure corresponding to a change of a rate of change of the at least one respiratory parameter; and
- classifying the detected arrhythmia event based on the respiratory measure and the analysis of the IEGM signals, wherein arrhythmia events that satisfy at least a first criterion is classified as an arrhythmia event requiring therapy.

The present invention is based on the finding that the time of onset of a change in the respiratory pattern or the changing rate of the respiratory pattern change is an early and accurate indication of a lethal arrhythmia and therefore is a better parameter to use in the discrimination between lethal and non-lethal arrhythmias, i.e. between arrhythmias requiring therapy and arrhythmias that do not require immediate therapy, than simply the actual change of the respiratory pattern. Thus, this information is used in combination with the IEGM data to determine whether a high rate is unstable (i.e. causes a low arterial pressure) and should be treated, for example, shocked, or a stable (i.e. the heart still manages to uphold a high arterial pressure) and should be treated with ATP or not at all. In connection with this, it has been found that the change of a rate of change of the respiratory frequency and/or the tidal volume are respiratory parameters containing valuable respiratory information for the discrimination. An unstable tachycardia causes lack of oxygen to the brain. This triggers a sympathetic activation which e.g. increases the respiratory drive. Since a stable tachycardia does not cause a lack of oxygen to the brain, the sympathetic response is not triggered and the respiratory pattern is not affected.

The respiratory components or parameters, e.g. the tidal volume and the respiratory frequency, can be determined by means of the cardiac impedance of the patient, which is indicative of the respiratory pattern of the patient. By measuring, for example, the impedance between the case of the implantable medical device and electrodes placed in the ventricle, for example, a tip electrode of a medical lead connectable to the device, an impedance signal that varies in connection with, inter alia, the respiration can be acquired.

According to another embodiment of the present invention, the IEGMs may be used to determine the respiratory pattern parameters.

In yet another embodiment, a left atrial pressure (LAP) sensor is arranged in left atrium LA, and the average LAP, which will vary with
5 inspiration and expiration, may be used by the the respiratory parameter to estimate the tidal volume and/or respiratory frequency.

During a hemodynamically compromising VT, the respiratory frequency may increase, the tidal volume may increase or both entities may increase. The respiratory measure in accordance with the present invention, may take
10 one of this parameters or both parameters into account. In one specific embodiment, a measure incorporating both parameter is utilized. Thus, to be able to detect the changes in respiratory drive using only a single measure, this measure must take both tidal volume and respiratory frequency into account. For example, the product of the two parameters can be calculated, a
15 measure that correlates to the minute ventilation (the minute ventilation represents the amount of oxygen delivered to the body per minute). In another alternative, the respiratory measure is set to a linear combination of the frequency and the tidal volume estimate. Assigning different weights to the frequency and the tidal volume estimate, the importance of them can be
20 different. Thus, if it is seen that the respiratory frequency changes more often as a cause of a VT requiring therapy than does the tidal volume, the respiratory frequency would have a higher weight than the tidal volume.

In a further alternative, the rate of change of the change of the respiratory parameter, e.g. the weighted combination of the tidal volume and
25 the respiratory frequency, is calculated to obtain the respiratory measure, for example, by calculating the second derivative of the respiratory parameter. However, as the skilled person realizes, another alternative may be to calculate the respiratory measure by determining the tidal volume and the respiratory frequency individually and determine a weighted combination of
30 the change of rate of changes.

According to an embodiment of the present invention, the arrhythmia classifying circuit is adapted to determine the at least first criterion to be satisfied if the respiratory measure, i.e. the change of the rate of change, is higher than a predetermined threshold value. Thereby, it is possible to
35 improve the discrimination since only arrhythmias being correlated with a sufficiently high rate of change (i.e. that exceeds the predetermined limit) of the respiratory measure are classified as arrhythmias requiring therapy.

In a further embodiment of the present invention, the arrhythmia classifying circuit is adapted to upon receiving information from the arrhythmia detection circuit that an arrhythmia event has been detected, monitor the respiratory measure, compare the time points for the respective onset of the detected arrhythmia event and of a respiratory measure being higher than the predetermined threshold; and determine the at least first criterion to be satisfied if the respiratory measure is higher than a predetermined threshold value and an onset of the change occur within a predetermined period of time from the onset of the detected arrhythmia event.

10 Thereby, it is possible to further improve the discrimination since only arrhythmias correlated with a sudden and sufficiently high rate of change (i.e. that exceeds the predetermined limit) of the respiratory measure is classified as arrhythmias requiring therapy.

15 According to an exemplary embodiment of the present invention, the implantable medical device includes an impedance measuring circuit adapted to, during impedance measuring sessions, measure at least one impedance signal between at least a first pair of electrodes being connectable to the implantable medical device, the electrodes being located such that measured impedance signals substantially reflects the respiratory pattern of the patient; and wherein the respiratory parameter determining circuit is adapted to determine the at least one respiratory parameter based on the measured impedance signals.

20 In a further embodiment of the present invention, the implantable medical device comprises an activity sensor adapted to sense a level of physiological activity the patient and to produce a signal representative of a current status of the physiological activity the patient; and wherein the arrhythmia classifying circuit is adapted to determine that the at least one first criterion is not satisfied if an activity level of the patient is above a predetermined level. Thereby, it is possible to further improve the discrimination since arrhythmias correlated with a increase of the respiratory frequency and/or tidal volume caused by physical activity are ruled out as arrhythmias requiring therapy.

25 The implantable medical device according to any one of preceding claims, wherein the arrhythmia classifying circuit is adapted to classify an arrhythmia event that satisfies at least the first criterion as an arrhythmia event requiring shock treatment and to classify an arrhythmia event that satisfies at least a second criterion as an arrhythmia event requiring anti-

arrhythmia pacing. Thus, the arrhythmias are classified in three groups. A first group including arrhythmias requiring therapy by means of a defibrillation shock (-s), a second group including arrhythmias requiring therapy by means of anti-arrhythmia pacing stimuli, and a third group including arrhythmias
5 determined not to require therapy. An arrhythmia event that satisfies at least a first criterion may be classified as an arrhythmia event requiring shock treatment, an arrhythmia event that satisfies at least a second criterion may be classified as an arrhythmia event requiring anti-arrhythmia pacing (ATP), and an arrhythmia event that satisfied at least a third criterion may be
10 classified as an arrhythmia event that do not require any therapy. For example, the first criterion may be the predetermined limit which in this embodiment corresponds to a significant impact on the respiration, i.e. a sudden increase of the rate of change of the respiratory frequency and/or tidal volume being above a predetermine limit, and an IEGM based determination
15 that indicates that the arrhythmia event is a ventricular tachycardia (VT) or ventricular fibrillation (VF). Further, the second criterion may include a small (or in certain cases no) impact on the respiration, i.e. an increase of the rate of change of the respiratory frequency and/or tidal volume being above a lower predetermine limit but below the predetermined limit indicating shock
20 therapy, and an IEGM based determination that indicates that the arrhythmia event is a ventricular tachycardia (VT). A third criterion may include no impact on the respiration, i.e. an increase of the rate of change of the respiratory frequency and/or tidal volume being below the lower predetermine limit indicating ATP, and, optionally, a determination that the activity level has
25 changed.

In another embodiment of the present invention, a sudden decrease of the respiratory frequency and/or the tidal volume to a very low value near zero is an indication of apnea. This in combination with a detected event similar to total circulatory collapse, for example, a detected ventricular
30 fibrillation is a clear indication that an arrhythmia requiring therapy by means of shock therapy has occurred.

As the skilled person realizes, steps of the methods according to the present invention, as well as preferred embodiments thereof, are suitable to realize as computer program or as a computer readable medium.

35 Further objects and advantages of the present invention will be discussed below by means of exemplifying embodiments.

Brief description of the drawings

Exemplifying embodiments of the invention will be described below with reference to the accompanying drawings, in which:

Fig. 1 is a schematic drawing of an exemplary human heart showing a configuration of one embodiment of an implantable medical device in accordance with the present invention;

Fig. 2 is an illustration in a block diagram form of an implantable stimulator according to the embodiment shown in Fig. 1;

Fig. 3 is a flow chart describing the general principles of the method of the present invention;

Fig. 4 is a flow chart describing another embodiment of the method according to the present invention; and

Fig. 5 is a flow chart describing a further embodiment of the method according to the present invention.

Description of exemplifying embodiments

The following is a description of exemplifying embodiments in accordance with the present invention. This description is not to be taken in limiting sense, but is made merely for the purposes of describing the general principles of the invention. Thus, even though particular types of implantable medical devices such as implantable cardioverter defibrillators (ICDs) will be described, the invention is also applicable to cardiac stimulators such as biventricular pacemakers, dual chamber stimulators, etc. Moreover, the invention is applicable to cardiac stimulators such as biventricular pacemakers, dual chamber stimulators, etc. including a defibrillator element.

With reference first to Fig. 1, there is shown a implantable medical device for classifying arrhythmias according to an embodiment of the present invention. According to this embodiment, the invention is implemented in an implantable cardiac defibrillator 10 even though, as indicated above, the invention can be implemented in a pacemaker, for example, a dual chamber stimulator.

The implantable medical device 10 is implanted in a surgically formed pocket in the flesh of the patient's chest (not shown), or other desired location within the body. A pace pulse generator (see Fig. 2), a control circuit (see Fig. 2) are included in the implantable medical device 10, which are housed in a case (can) 14 compatible with the tissue and fluids of the body (i.e. biocompatible). The control circuit (see Fig. 2) of the implantable medical

device 10 is micro-processor based and includes memory, logic and other components to provide processing, evaluation and other functions necessary to determine, select and deliver appropriate therapy including electrical defibrillation and pulses of different energy levels and timing for ventricular
5 defibrillation and pacing to the patient's heart 1 in response to an identified ventricular arrhythmia, which will be described in more detail below with reference to Fig. 2. The illustrated portions of the heart 1 include right atrium RA, the right ventricle RV, the left atrium LA, the left ventricle LV, cardiac walls 2, the ventricle septum 4, the valve plane 6, and the apex 8.

10 Implantable medical leads 20, 30 are connectable to the implantable medical device 10. The medical leads 20, 30 include distally located electrodes coupled at the proximal end to the signal generator 12 through an electrical connector in a header (not shown) of the case 14. The case 14 itself may be used as an electrode such as electrical ground, for sensing pacing, or
15 defibrillation.

Thus, the implantable medical device according to the present invention in electrical communication with a patient's heart 1 by way of medical leads 20, 30. The implantable right ventricular lead 20 may have an atrial electrode 26 (e.g. a ring electrode), a ventricular tip electrode 22 and a
20 ventricular annular or ring electrode 24. Thereby, right ventricular and atrial cardiac signals can be sensed and therapy can be delivered to the right ventricle RV. Furthermore, a "coronary sinus" lead 30 designed for placement via the coronary sinus in veins located distally thereof is connectable to the implantable medical device 10. For example, a distal tip electrode 32 and/or a
25 distal ring electrode 34 can be placed adjacent to the left ventricle. Further, an electrode (not shown) can be placed adjacent to the right atrium RA. Thereby, left atrium and ventricular cardiac signals can be obtained and pacing therapy for the left ventricle LV can be delivered. Active or passive fixation of the leads may be used to assure suitable excitation and/or measurements.

30 According to this illustrated embodiment of the present invention, the atrial electrode 26 and the ventricular electrode 24 are positioned for use as defibrillation electrodes as well as for sensing in the atrial and ventricle, respectively. For defibrillation, the electrodes 26, 24 may cooperate with the case 12. A pericardial lead (not shown) including electrodes may also be
35 connectable to the implantable medical device 10 and in such a case, the electrodes 26, 24 may cooperate with pericardially located electrodes. As the

skilled person realizes, there are a number of other conceivable defibrillator implementations that may be used.

Turning now to Fig. 2, the defibrillator 10 of Fig. 1 is shown in a block diagram form. For illustrative purposes, reference is made to Fig. 1 for the elements of the leads that are intended for positioning in or at the heart. 5 an embodiment of the implantable medical device according to the present invention will be shown. The implantable medical device 10 comprises a housing 14 being hermetically sealed and biologically inert, see Fig. 1. Normally, the housing is conductive and may, thus, serve as an electrode. 10 One or more pacemaker leads, where only two are shown in Fig. 1, 20 and 30, are electrically coupled to the implantable medical device 10 in a conventional manner. The leads 20, 30 extend into the heart (see Fig. 1) via a vein of the patient. It is understood that the line indicated by the reference numerals 20, 30 in this case represent the two medical leads 20, 30 of Fig. 1. 15 Further, more than two medical leads may be connected to the implantable medical device 10, in which case the line indicated by 20, 30 will represent more than two leads.

As discussed above with reference to Fig. 1, the leads 20, 30 comprise one or more electrodes, such a tip electrodes or a ring electrodes, arranged 20 to, inter alia, transmit defibrillation shocks, pacing pulses for causing depolarization of cardiac tissue adjacent to the electrode(-s) generated by a pace pulse generator 42 under influence of a control circuit 43 comprising a microprocessor. The control circuit 43 may control, inter alia, pace pulse parameters such as output voltage and pulse duration and memory, which 25 memory may include a random access memory (RAM) and/or a non-volatile memory such as a read-only memory (ROM). Detected signals from the patients heart are processed in an input circuit 45 and are forwarded to the microprocessor of the control circuit 43 for use in logic timing determination in known manner.

30 Furthermore, the implantable medical device 10 for classifying arrhythmia events comprises an IEGM analyzing circuit 41 adapted to receive signals representative of the electrical activity from electrodes arranged in the medical leads 20, 30, and to analyse IEGMs of the heart 1 to detect an arrhythmia event. The arrhythmia detection can be performed in accordance 35 with conventional manner. For example, the heart rate can be determined by detecting R waves in the IEGMs originating from the ventricle. If the rate is

higher than a predetermined limit, this is an indication that a tachycardia is present.

Moreover, the implantable medical device 10 includes a sensing circuit 50 adapted to sense a respiratory pattern of the patient and to produce at least one signal representative of the respiratory pattern and a respiratory parameter determining circuit 52 adapted to determine at least one respiratory parameter reflecting characteristics of the respiratory pattern of the patient based on the sensed respiratory pattern. The respiratory parameter determining circuit 52 is further adapted to determine a respiratory measure corresponding to a change of a rate of change of the at least one respiratory parameter. It has been found by the inventors that the respiratory frequency and the tidal volume (i.e. the size of a breath) and, in particular, the time of onset of a or the change of the change of the respiratory frequency or tidal volume are particularly good discrimination parameters in that they constitute an early and accurate indication of a lethal arrhythmia.

According to one embodiment of the present invention, the sensing circuit 50 is an impedance measuring unit adapted to carry out impedance measurements of the cardiac impedance of the patient indicative of the respiratory pattern of the patient. Now referring to Fig. 1, the respiratory pattern can be determined, by measuring, for example, the impedance between the case 12 and electrodes placed in the ventricle, for example, the tip electrode 22 or the ring electrode 24 whereby an impedance signal that varies in connection with, inter alia, the respiration can be obtained. Air has a high impedance compared to tissue and, hence, inspiration causes the impedance signal to rise. Similarly, expiration causes the impedance to drop. In this embodiment, the respiratory parameter determining circuit 52 may be adapted to calculate how often the impedance signal crosses a moving average of the impedance signal. Thereby, the respiratory frequency can be estimated. By counting how often a peak or trough occurs within a moving average window is also an alternative. Further alternatives for estimating respiratory frequency include FFT (fast fourier transform) or Hilbert transform.

To estimate the tidal volume, for example, the peak-to-peak value of the impedance signal in a moving window (e.g. a few seconds wide) can be studied. This estimation will provide a relative measure.

Due to the influence of the cardiac activity, the measure impedance signal is preferably filtered using a low pass filter, for example, a filter having

a limiting frequency of about 2.5 Hz before the actual analysis of the signal is performed.

According to another embodiment of the present invention, the IEGMs may be used to determine the respiratory pattern and in this case. For
5 example, there is a baseline drift in the IEGM caused by the respiratory. This baseline drift is unwanted in cardiac event detection and is usually blocked out or attenuated by filtering. However, the respiratory parameter determining circuit 52 may be adapted to utilize this drift in that the IEGM signal is processed such that a more pronounced respiratory artefact is obtained. This
10 artefact can then be processed in similar way as the impedance signal to acquire estimates of the tidal volume and/or the respiratory frequency. In case of ventricular IEGMs, the amplitude of the R waves (which varies with the respiratory cycle) can be assessed to estimate the tidal volume and the respiratory frequency.

15 In yet another embodiment, a left atrial pressure (LAP) sensor is arranged in left atrium LA, for example, by entering from right atrium, puncturing septum and attaching the sensor to wall in the left atrium. The average LAP will vary with inspiration and expiration and this signal may be used by the respiratory parameter determining circuit 52 to estimate the tidal
20 volume and/or respiratory frequency.

During a hemodynamically compromising VT, the respiratory frequency may increase, the tidal volume may increase or both entities may increase. The respiratory measure in accordance with the present invention, may take one of this parameters or both parameters into account. In one specific
25 embodiment, a measure incorporating both parameter is utilized. Thus, to be able to detect the changes in respiratory drive using only a single measure, this measure must take both tidal volume and respiratory frequency into account. According to embodiments of the present invention, the respiratory parameter determining circuit 52 calculates the product of the two
30 parameters. This correlates to the minute ventilation, which represents the amount of oxygen delivered to the body per minute. In another alternative, the respiratory parameter determining circuit 52 sets the respiratory measure to a linear combination of the frequency and the tidal volume estimate. Assigning different weights to the frequency and the tidal volume estimate, the
35 importance of them can be different. Thus, if it is seen that the respiratory frequency changes more often as a cause of a VT requiring therapy than

does the tidal volume, the respiratory frequency would have a higher weight than the tidal volume.

Further, the respiratory parameter determining circuit 52 calculates the change of the rate of change of the respiratory parameter, e.g. the weighted
5 combination of the tidal volume and the respiratory frequency, to obtain the respiratory measure by calculating the second derivative of the respiratory parameter. However, as the skilled person realizes, the respiratory parameter determining circuit 52 may in another alternative calculate the change of the rate of the change of the tidal volume and the respiratory frequency
10 individually and calculate a weighted combination of the change of the rate of changes.

The implantable medical device 10 further comprises an arrhythmia classifying circuit 54 adapted to classify a detected arrhythmia event based on the calculated respiratory measure, wherein arrhythmia events that satisfy
15 at least a first criterion is classified as an arrhythmia event requiring therapy.

Additionally, the implantable medical device 10 comprises a communication circuit 57, for example, an RF telemetry circuitry for providing RF communications including a transmitter and a receiver connected to an antenna. Thereby, for example, data contained in the memory of the control
20 circuit 43 can be transferred to, for example, an external programmer device. Moreover, arrhythmia information can be transferred, via the communication circuit 57 and a wireless communication network, to a physician of the patient, for example, to a work station located at a hospital or care institution. Thus, the physician may be informed of the status of the patient and can be updated
25 of the status at regular intervals or when an arrhythmia requiring therapy has occurred. The patient may also be provided with arrhythmia information. For example, an information message may be sent, via the communication circuit 57, to a work station located at the patients home or a cellular phone of the patient, or a PDA (personal digital assistant), or a laptop computer, or a home
30 monitoring device. The information message may inform the user, e.g. the patient, of the device receiving the message of the present status of the patient, for example, that an arrhythmias has been detected but that no therapy was required. A physician using an extracorporeal programmer can also communicate with the implantable medical device 10 and thereby obtain
35 information on identified conditions and also reprogram the different functions of the implantable medical device 10.

In one embodiment, the implantable medical device includes an activity sensor 59 adapted to sense a level of physiological activity the patient and to produce a signal representative of a current status of the physiological activity patient. The activity sensor may be an accelerometer of conventional type.

5 The arrhythmia classifying circuit 54 may be adapted to determine that the at least one first criterion is not satisfied if an activity level of the patient is above a predetermined level. Physical activity increases both the respiratory frequency and the tidal volume but the respiratory drive do not come as fast as in case of an arrhythmia. Using also the physical activity as a
10 discrimination parameter, the specificity of the arrhythmia classification can be increased.

Turning now to Fig. 3, the principles of the method for classifying a ventricular arrhythmia according to the present invention will be described. First, at step S100, IEGMs of the heart, i.e. electrical activity of the heart, are
15 analyzed to detect a ventricular arrhythmia event, which may a continuous procedure. The acquired IEGMs are monitored and analysed in order to detect arrhythmias, for example, the heart rate may be measured by detecting R waves in the IEGMs originating from the ventricle. If the measured rate is higher than a specific predetermined limit, it is an indication that a tachycardia
20 is present. Hence, in step S110, it is determined whether a ventricular arrhythmia event has been detected on not. If no, the procedure returns to step S100. On the other hand, if yes, the procedure proceeds to step S120 where additional discrimination factors are investigated. According to one embodiment, the respiratory pattern is investigated and respiratory measure
25 corresponding to a change of a rate of change of at least one respiratory parameter reflecting characteristics of the respiratory pattern of the patient is determined. As discussed above, the respiratory frequency and/or the tidal volume (i.e. the size of a breath) and, in particular, the time of onset or a change of a change of the respiratory frequency and/or tidal volume have
30 been found to be particularly good discrimination parameters in that they constitute an early and accurate indication of a ventricular arrhythmia requiring therapy.

Thereafter, at step S130, it is checked whether the respiratory measure corresponding to a change of rate of change of the at least one respiratory
35 parameter satisfies predetermined at least one respiratory parameter criterion. According to this embodiment, the respiratory parameter determining circuit 52 sets the respiratory measure to a linear combination of

the frequency and the tidal volume estimate. Assigning different weights to the frequency and the tidal volume estimate, the importance of them can be different. Thus, if it is seen that the respiratory frequency changes more often as a cause of a VT requiring therapy than does the tidal volume, the
5 respiratory frequency would have a higher weight than the tidal volume. In this embodiment, the at least one respiratory parameter criterion is found to be satisfied if the respiratory measure exceeds a predetermined limit. If the respiratory parameter criterion is not satisfied, the procedure proceeds to step S140 where the detected arrhythmia is classified as an arrhythmia that do not
10 require therapy. Optionally, the patient may be informed of this event and/or a physician of the patient. For example, an information message may be sent from the arrhythmia classifying circuit 54 via the communication circuit 57. Thereafter, the procedure returns to step S100. On the other hand, if the predetermined limit is exceeded, the procedure proceeds to step S150 where
15 the detected arrhythmias is classified as an arrhythmias requiring therapy. Optionally, the patient may be informed of this event and/or a physician of the patient. For example, an information message may be sent from the arrhythmia classifying circuit 54 via the communication circuit 57.

In one embodiment, the arrhythmia classifying circuit 54 is adapted to
20 classify an arrhythmia event that satisfies at least a first criterion as an arrhythmia event requiring shock treatment, to classify an arrhythmia event that satisfies at least a second criterion as an arrhythmia event requiring anti-arrhythmia pacing (ATP), and to classify an arrhythmia event that satisfied at least a third criterion as an arrhythmia event that do not require any therapy.
25 For example, the first criterion is the predetermined limit which in this embodiment corresponds to a significant impact on the respiration, i.e. a sudden increase of the rate of change of the respiratory frequency and/or tidal volume being above a predetermine limit, and an IEGM based determination that indicates that the arrhythmia event is a ventricular tachycardia (VT) or
30 ventricular fibrillation (VF). Further, the second criterion may include a small (or in certain cases no) impact on the respiration, i.e. an increase of the rate of change of the respiratory frequency and/or tidal volume being above a lower predetermine limit but below the predetermined limit indicating shock therapy, and an IEGM based determination that indicates that the arrhythmia
35 event is a ventricular tachycardia (VT). A third criterion may include no impact on the respiration, i.e. an increase of the rate of change of the respiratory frequency and/or tidal volume being below the lower predetermine limit

indicating ATP, and, optionally, a determination that the activity level has changed.

In an alternative embodiment, see Fig. 4 (where similar functions are indicated with the same reference numerals), a first check is made in step
5 S132 whether the respiratory frequency exceeds a predetermined limit, i.e. whether the frequency has increased. If no, the procedure proceeds to step S140 where the detected arrhythmia is classified as an arrhythmia that do not require therapy. Thereafter the procedure returns to step S100. However, if
10 the respiratory frequency exceeds the predetermined limit, the procedure proceeds to step S134 where it is checked whether the tidal volume exceeds a predetermined limit, i.e. whether the volume has increased. If no, the procedure proceeds to step S140 where the detected arrhythmia is classified as an arrhythmia that do not require therapy. Thereafter the procedure returns to step S100. If the tidal volume also has increased, the procedure proceeds
15 to step S136 where it is checked whether the increase of the tidal volume and respiratory frequency is sudden, i.e. whether the change of a rate of changes exceed predetermined limits. Alternative, the product of the two parameters can be calculated, which gives a value that correlates to the minute ventilation which represents the amount of oxygen delivered to the body per minute, and
20 the rate of change of the product may be compared to the predetermined limit. If no, the procedure proceeds to step S140 where the detected arrhythmia is classified as an arrhythmia that do not require therapy. Thereafter the procedure returns to step S100. On the other hand, if the predetermined limit is exceeded, the procedure proceeds to step S150 where
25 the detected arrhythmias is classified as an arrhythmias requiring therapy. In one embodiment, the arrhythmia classifying circuit 54 is adapted to classify an arrhythmia event that satisfies at least a first criterion as an arrhythmia event requiring shock treatment, and to classify an arrhythmia event that satisfies at least a second criterion as an arrhythmia event requiring anti-
30 arrhythmia pacing (ATP). For example, the criteria may be the same as discussed above.

In a further embodiment, see Fig. 5 (where similar functions are indicated with the same reference numerals), a first check is made in step
35 S131 whether an activity signal is above a first predetermined activity limit. If yes, the procedure proceeds to step S140 where the detected arrhythmia is classified as an arrhythmia that do not require therapy. Thereafter the procedure returns to step S100. However, if the activity level of the patient is

below the predetermined limit, the procedure proceeds to step S132, where it is checked whether the respiratory frequency exceeds a predetermined limit, i.e. whether the frequency has increased. If no, the procedure proceeds to step S140 where the detected arrhythmia is classified as an arrhythmia that do not require therapy. Thereafter the procedure returns to step S100. However, if the respiratory frequency exceeds the predetermined limit, the procedure proceeds to step S134, where it is checked whether the tidal volume exceeds a predetermined limit, i.e. whether the volume has increased. If no, the procedure proceeds to step S140 where the detected arrhythmia is classified as an arrhythmia that do not require therapy.

Thereafter the procedure returns to step S100. If the tidal volume also has increased, the procedure proceeds to step S136 where it is checked whether the increase of the tidal volume and respiratory frequency is sudden, i.e. whether the change of a rate of changes exceed predetermined limits. Alternative, the product of the two parameters can be calculated, which gives a value that correlates to the minute ventilation which represents the amount of oxygen delivered to the body per minute, and the rate of change of the product may be compared to the predetermined limit. If no, the procedure proceeds to step S140 where the detected arrhythmia is classified as an arrhythmia that do not require therapy. Thereafter the procedure returns to step S100. On the other hand, if the predetermined limit is exceeded, the procedure proceeds to step S150 where the detected arrhythmias is classified as an arrhythmias requiring therapy. In one embodiment, the arrhythmia classifying circuit 54 is adapted to classify an arrhythmia event that satisfies at least a first criterion as an arrhythmia event requiring shock treatment, and to classify an arrhythmia event that satisfies at least a second criterion as an arrhythmia event requiring anti-arrhythmia pacing (ATP). For example, the first criterion is the predetermined limit which in this embodiment corresponds to a significant impact on the respiration, i.e. a sudden increase of the rate of change of the respiratory frequency and/or tidal volume being above a predetermine limit, and an IEGM based determination that indicates that the arrhythmia event is a ventricular tachycardia (VT) or ventricular fibrillation (VF). Further, the second criterion may include a small (or in certain cases no) impact on the respiration, i.e. an increase of the rate of change of the respiratory frequency and/or tidal volume being above a lower predetermine limit but below the predetermined limit indicating shock therapy, and an IEGM

based determination that indicates that the arrhythmia event is a ventricular tachycardia (VT).

While the invention disclosed herein has been described by means of specific embodiments and applications thereof, numerous modifications and variations could be made therein by those skilled in the art without departing
5 from the scope of the inventions, which is defined by the appended claims.

10

15

20

25

30

35

Claims

1. An implantable medical device for classifying arrhythmia events being connectable to at least one medical lead adapted to be placed at or within a heart of a patient, said medical lead including at least one electrode adapted to sense electrical activity of said heart and to produce at least one signal representative of said electrical activity, wherein said medical device comprises:
- 5
- an IEGM analyzing circuit adapted receive said signal representative of said electrical activity and to analyse IEGMs of said heart to detect an arrhythmia event;
- 10
- a sensing circuit adapted to sense a respiratory pattern of said patient and to produce at least one signal representative of said respiratory pattern;
- 15
- a respiratory parameter determining circuit adapted to determine at least one respiratory parameter reflecting characteristics of the respiratory pattern of said patient based on said sensed respiratory pattern and to determine a respiratory measure corresponding to a change of a rate of change of said at least one respiratory parameter;
- 20
- and
- an arrhythmia classifying circuit adapted to classify the detected arrhythmia event based on said respiratory measure, wherein arrhythmia events that satisfy at least a first criterion is classified as an arrhythmia event requiring therapy.
- 25
2. The implantable medical device according to claim 1, wherein said respiratory parameter determining circuit is adapted to determine a respiratory frequency and/or a tidal volume using said sensed respiratory pattern and to determine a change of a rate of change of said respiratory frequency and/or said tidal volume and/or a weighted combination of said respiratory frequency and said tidal volume.
- 30
3. The implantable medical device according to claim 1 or 2, wherein said arrhythmia classifying circuit is adapted to determine said at least first criterion to be satisfied if said respiratory measure is higher than a predetermined threshold value.
- 35

4. The implantable medical device according to claim 3, wherein said arrhythmia classifying circuit is adapted to
upon receiving information from said arrhythmia detection circuit that an arrhythmia event has been detected, monitor said respiratory measure;
5 compare the time points for the respective onset of said detected arrhythmia event and of a respiratory measure being higher than said predetermined threshold; and
determine said at least first criterion to be satisfied if said
10 respiratory measure is higher than a predetermined threshold value and an onset of said change occur within a predetermined period of time from the onset of said detected arrhythmia event.
5. The implantable medical device according to any one of preceding
15 claims, further comprising:
an impedance measuring circuit adapted to, during impedance measuring sessions, measure at least one impedance signal between at least a first pair of electrodes being connectable to said implantable medical device, said electrodes being located such that measured
20 impedance signals substantially reflects the respiratory pattern of said patient; and wherein
said respiratory parameter determining circuit is adapted to determine said at least one respiratory parameter based on said measured impedance signals.
25
6. The implantable medical device according to any one of preceding claims further comprising:
an activity sensor adapted to sense a level of physiological activity said patient and to produce a signal representative of
30 a current status of said physiological activity said patient; and wherein
said arrhythmia classifying circuit is adapted to determine that said at least one first criterion is not satisfied if an activity level of said patient is above a predetermined level.
7. The implantable medical device according to any one of preceding
35 claims, wherein said arrhythmia classifying circuit is adapted to classify an arrhythmia event that satisfies at least said first criterion as

an arrhythmia event requiring shock treatment and to classify an arrhythmia event that satisfies at least a second criterion as an arrhythmia event requiring anti-arrhythmia pacing.

- 5 8. A method for classifying arrhythmia events in an implantable medical device being connectable to at least one medical lead adapted to be placed at or within a heart of a patient, said medical lead including at least one electrode adapted to sense electrical activity of said heart and to produce at least one signal representative of said electrical activity, wherein said method comprises the steps of:
- 10 analysing IEGMs of said heart to detect an arrhythmia event;
sensing a respiratory pattern of said patient producing at least one signal representative of said respiratory pattern;
determining at least one respiratory parameter reflecting characteristics of the respiratory pattern of said patient based on said sensed respiratory pattern;
- 15 determining a respiratory measure corresponding to a change of a rate of change of said at least one respiratory parameter; and
classifying the detected arrhythmia event based on said respiratory measure, wherein arrhythmia events that satisfy at least a first criterion is classified as an arrhythmia event requiring therapy.
- 20
9. The method according to claim 8, wherein said step of determining at least one respiratory parameter reflecting comprises the step of determining a respiratory frequency and/or a tidal volume using said sensed respiratory pattern and wherein said step of determining a respiratory measure comprises the step of determining a change of a rate of change of said respiratory frequency and/or said tidal volume and/or a weighted combination of said respiratory frequency and said tidal volume.
- 25
- 30
10. The method according to claim 8 or 9, wherein said step of classifying comprises the step of: determining said at least first criterion to be satisfied if said respiratory measure is higher than a predetermined threshold value.
- 35

11. The method according to claim 10, wherein the step of classifying further comprises the steps of:
upon receiving information from said arrhythmia detection circuit that an arrhythmia event has been detected, monitoring said
5 respiratory measure;
comparing the time points for the respective onset of said detected arrhythmia event and of a respiratory measure being higher than said predetermined threshold; and
determining said at least first criterion to be satisfied if said
10 respiratory measure is higher than a predetermined threshold value and an onset of said change occur within a predetermined period of time from the onset of said detected arrhythmia event.
12. The method according to any one of preceding claims, further
15 comprising the step of, during impedance measuring sessions, measuring at least one impedance signal between at least a first pair of electrodes being connectable to said implantable medical device, said electrodes being located such that measured impedance signals substantially reflects the respiratory pattern of said patient; and
20 wherein the step of determining said respiratory parameter includes the step of determining said at least one respiratory parameter based on said measured impedance signals.
13. The method according to any one of preceding claims, further
25 comprising the steps of:
sensing a level of physiological activity said patient; and
wherein said step of classifying comprises the step of
determining that said at least one first criterion is not satisfied if an
activity level of said patient is above a predetermined level.
30
14. The method according to any one of preceding claims, wherein said
step of classifying further comprises the step of:
classifying an arrhythmia event that satisfies at least said first
criterion as an arrhythmia event requiring shock treatment; and
35 classifying an arrhythmia event that satisfies at least a second criterion as an arrhythmia event requiring anti-arrhythmia pacing.

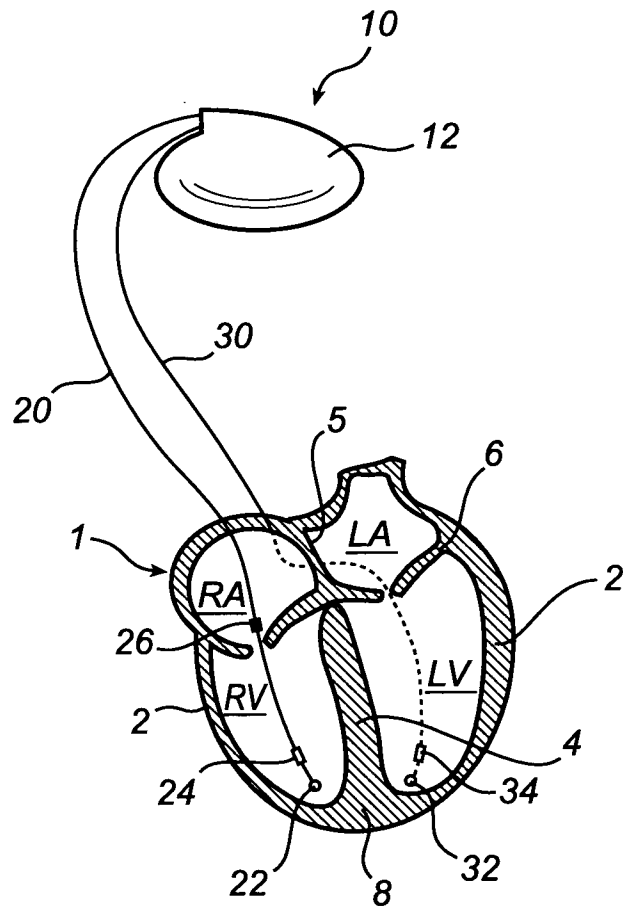


Fig. 1

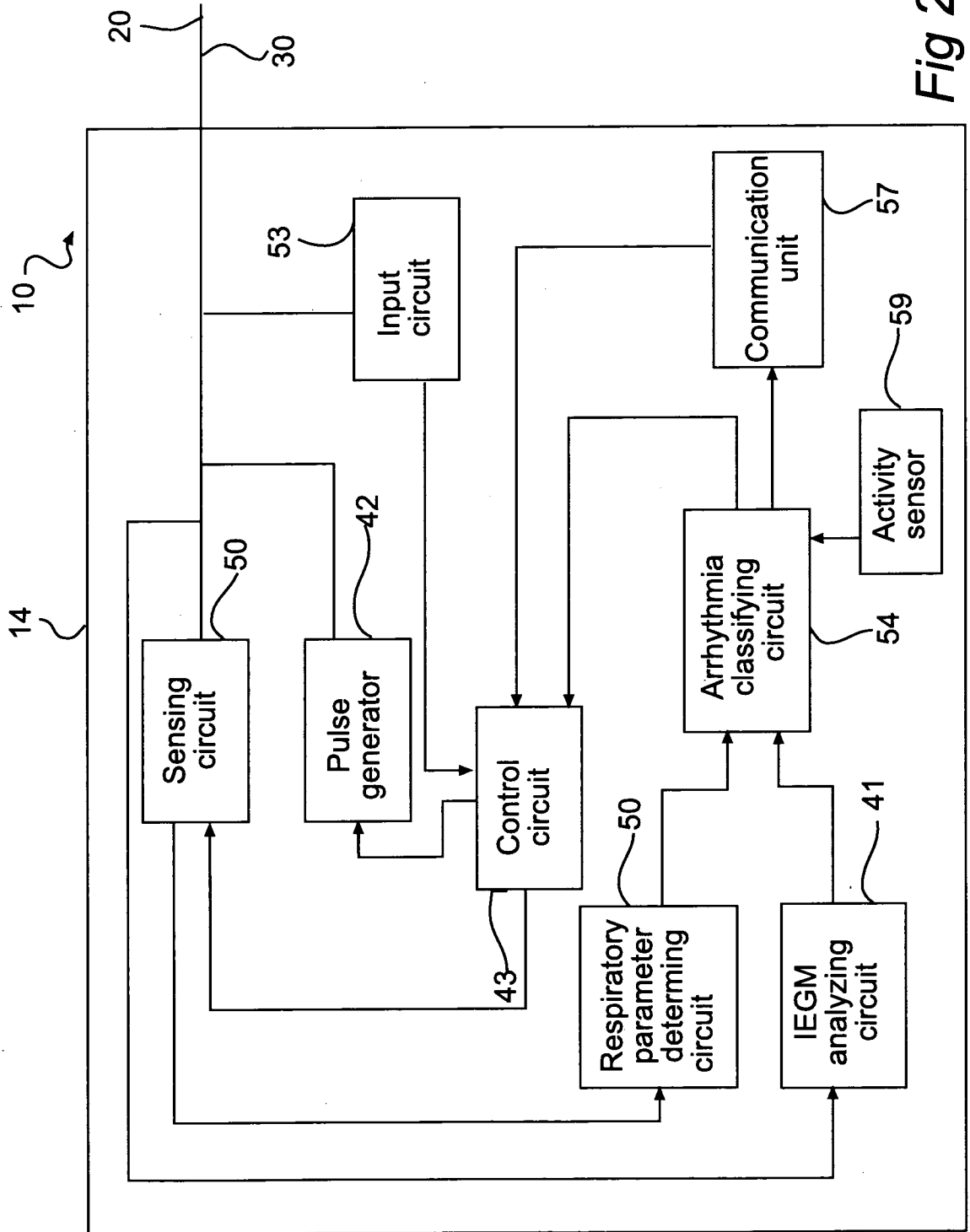


Fig 2

3/5

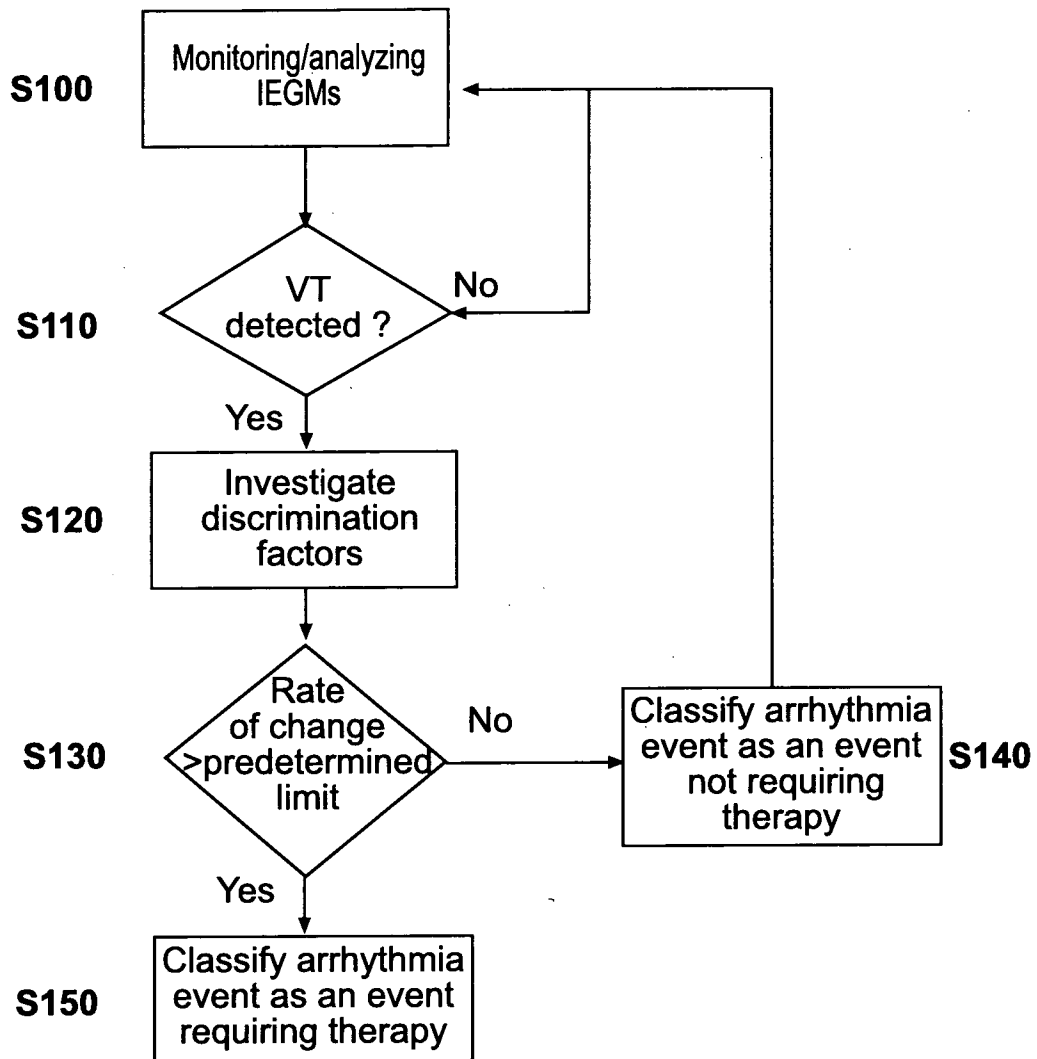


Fig. 3

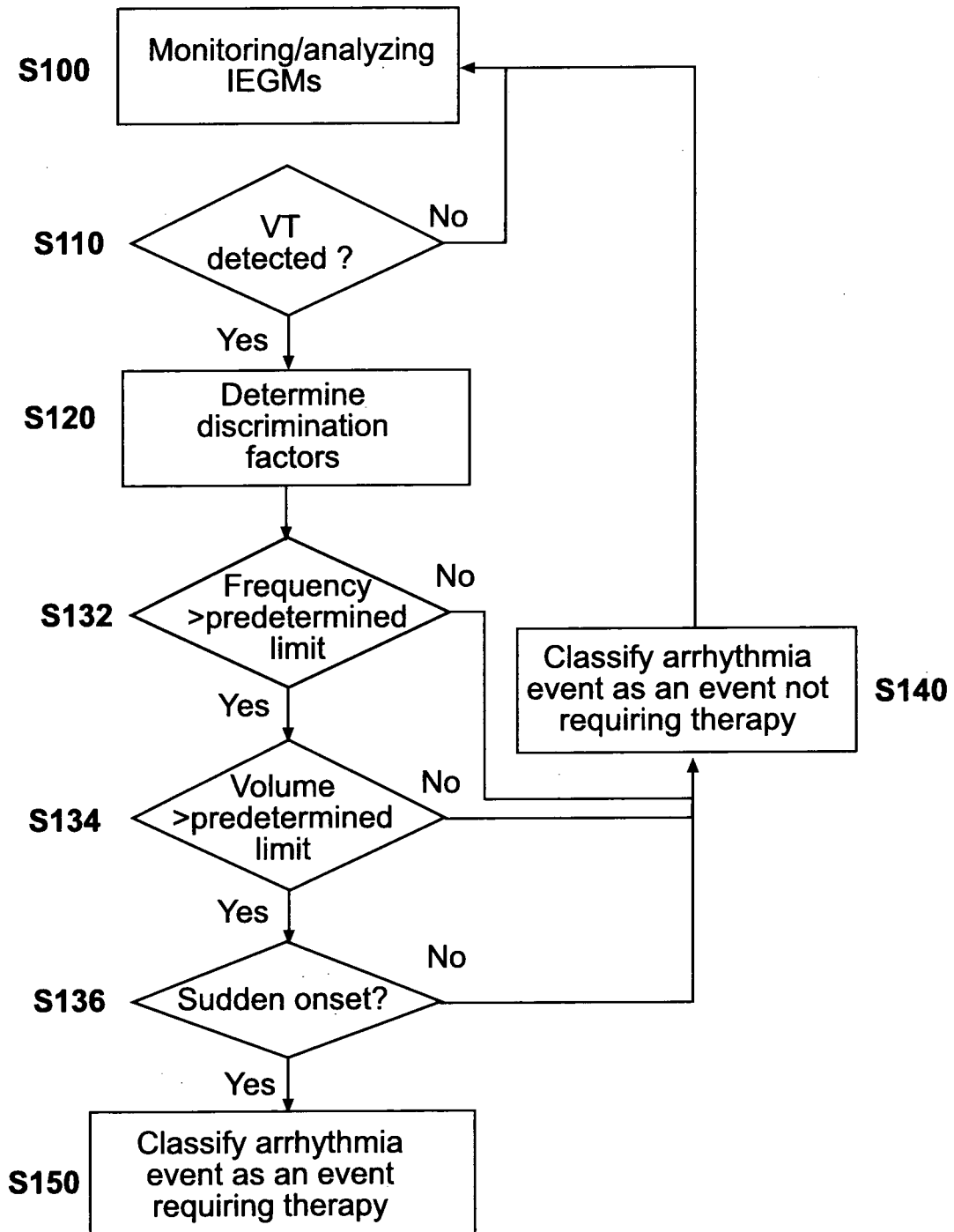


Fig. 4

5/5

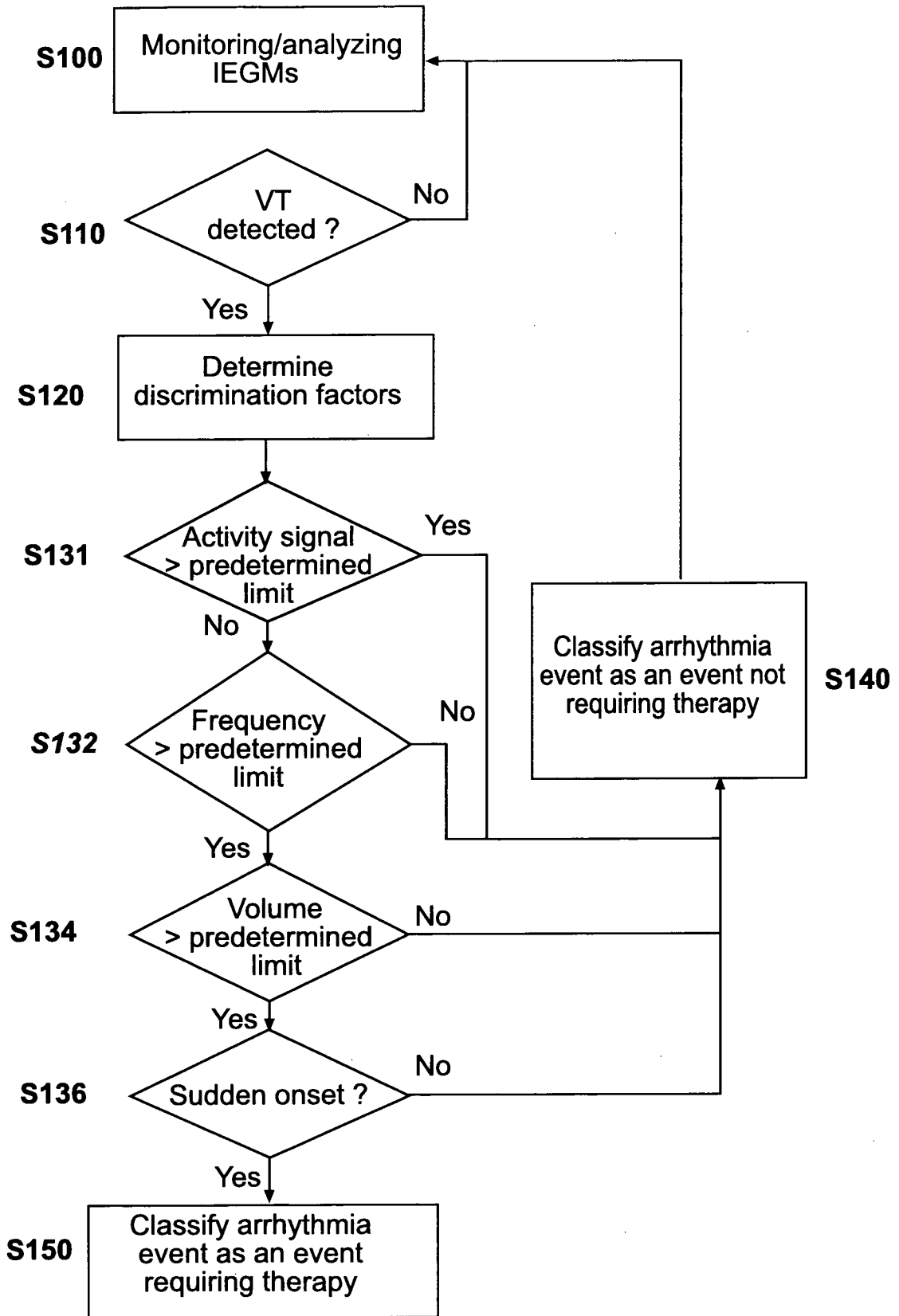


Fig. 5

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE2008/000312

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 7308309 B1 (S.KOH), 11 December 2007 (11.12.2007), column 1, line 59 - line 67; column 4, line 38 - line 53; column 6, line 3 - line 12, col.7, li.15-col.8, li.21 --	1-14
X	US 20070239053 A1 (S.BHUNIA), 11 October 2007 (11.10.2007), paragraphs [0037]-[0039], claims 1-4, 9 --	1-14
A	US 5042497 A (C.SHAPLAND), 27 August 1991 (27.08.1991), claims 1-4, 13-15, abstract --	1-14

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

20 January 2009

Date of mailing of the international search report

23-01-2009

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/ itw
Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE2008/000312

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 20070179386 A1 (F.MICHARD ET AL), 2 August 2007 (02.08.2007), paragraphs [0021]-[0026] --	1-14
A	US 20040230129 A1 (P.HAEFNER), 18 November 2004 (18.11.2004), paragraphs [0011]-[0016], [0071]-[0072] --	1-14
A	US 20060178704 A1 (B.ELAHI ET AL), 10 August 2006 (10.08.2006), paragraphs [0005]-[0007],[0059] --	1-14
A	EP 1151719 A2 (PACESETTER NC.), 7 November 2001 (07.11.2001), paragraphs [0023]-[0024],[0062], [0084] --	1-14
A	US 6813514 B1 (M.W.KROLL ET AL), 2 November 2004 (02.11.2004), paragraphs [0052]-[0056] --	1-14
A	US 20070238939 A1 (J.E.GIFTAKIS ET AL), 11 October 2007 (11.10.2007), paragraphs [0209]-[0214] --	1-14
A	US 20070112276 A1 (H.D.SIMMS, JR.), 17 May 2007 (17.05.2007), paragraphs [0007]-[0010] --	1-14
E	US 7435221 B1 (R.BHARMI ET AL), 14 October 2008 (14.10.2008), column 20, line 54 - column 26, line 39 -- -----	1-14

International patent classification (IPC)

A61N 1/362 (2006.01)
A61B 5/046 (2006.01)
A61B 5/0464 (2006.01)
A61N 1/37 (2006.01)
A61N 1/39 (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:

- In English/Searches and advisory services/Cited documents (service in English) or
- e-tjänster/anförda dokument (service in Swedish).

Use the application number as username.

The password is **XJJXBTIFRW**.

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 REPORT

Information on patent family members

01/11/2008

International application No.

PCT/SE2008/000312

US	7308309	B1	11/12/2007	NONE		
US	20070239053	A1	11/10/2007	EP	2001357 A	17/12/2008
				US	20070239052 A	11/10/2007
				US	20070255148 A	01/11/2007
				WO	2007117843 A	18/10/2007
US	5042497	A	27/08/1991	NONE		
US	20070179386	A1	02/08/2007	AT	412367 T	15/11/2008
				BR	PI0700149 A	06/11/2007
				DE	602007000195 D	00/00/0000
				EP	1813187 A,B	01/08/2007
				JP	2007203041 A	16/08/2007

INTERNATIONAL SEARCH REPORT
Information on patent family members

01/11/2008

International application No.

PCT/SE2008/000312

US	20040230129	A1	18/11/2004	EP	1615692	A	18/01/2006
				JP	2006524106	T	26/10/2006
				US	7218966	B	15/05/2007
				US	20070293896	A	20/12/2007
				WO	2004091719	A	28/10/2004
				EP	1613395	A	11/01/2006
				EP	1617894	A	25/01/2006
				EP	1620165	A	01/02/2006
				JP	2006522650	T	05/10/2006
				JP	2006522659	T	05/10/2006
				JP	2006522661	T	05/10/2006
				US	6887860	B	03/05/2005
				US	7047071	B	16/05/2006
				US	7117035	B	03/10/2006
				US	7236819	B	26/06/2007
				US	7302294	B	27/11/2007
				US	7389138	B	17/06/2008
				US	20040033998	A	19/02/2004
				US	20040204728	A	14/10/2004
				US	20040204734	A	14/10/2004
				US	20040204735	A	14/10/2004
				US	20040215239	A	28/10/2004
				US	20040215240	A	28/10/2004
				US	20040215258	A	28/10/2004
				US	20040220626	A	04/11/2004
				US	20040220628	A	04/11/2004
				US	20040220629	A	04/11/2004
				US	20040220633	A	04/11/2004
				US	20040220641	A	04/11/2004
				US	20040225329	A	11/11/2004
				US	20040230128	A	18/11/2004
				US	20040230229	A	18/11/2004
				US	20040230230	A	18/11/2004
				US	20040230243	A	18/11/2004
				US	20040230249	A	18/11/2004
				US	20040230272	A	18/11/2004
				US	20040230273	A	18/11/2004
				US	20040230274	A	18/11/2004
				US	20040230279	A	18/11/2004
				US	20040230280	A	18/11/2004
				US	20040230281	A	18/11/2004
				US	20040230282	A	18/11/2004
				US	20050004615	A	06/01/2005
				US	20050038350	A	17/02/2005
				US	20050096300	A	05/05/2005
				US	20050119708	A	02/06/2005
				US	20080096851	A	24/04/2008
				WO	2004091715	A	28/10/2004
				WO	2004091717	A	28/10/2004
				WO	2004091720	A	28/10/2004

US	20060178704	A1	10/08/2006	US	20080147132	A	19/06/2008
----	-------------	----	------------	----	-------------	---	------------

EP	1151719	A2	07/11/2001	DE	60130395	D,T	05/06/2008
				US	6600949	B	29/07/2003

INTERNATIONAL SEARCH REPORT
Information on patent family members

01/11/2008

International application No.

PCT/SE2008/000312

US 6813514 B1 02/11/2004 NONE

US 20070238939 A1 11/10/2007

US 20060195144 A 31/08/2006
US 20060224067 A 05/10/2006
US 20070260147 A 08/11/2007
US 20070260286 A 08/11/2007
US 20070260289 A 08/11/2007
US 20070265536 A 15/11/2007
US 20070265677 A 15/11/2007
US 20080033490 A 07/02/2008
US 20060136006 A 22/06/2006
US 20070239060 A 11/10/2007
US 20070239230 A 11/10/2007
US 20060135877 A 22/06/2006
US 20070239054 A 11/10/2007
US 20060135881 A 22/06/2006
EP 1833557 A 19/09/2007
EP 1833558 A 19/09/2007
WO 2006066098 A 22/06/2006
WO 2006066099 A 22/06/2006
WO 2006066280 A 22/06/2006
WO 2006086075 A 17/08/2006

US 20070112276 A1 17/05/2007 NONE

US 7435221 B1 14/10/2008

US 7361146 B 22/04/2008

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2008/000312**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.: 8-14
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 8-14 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:

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.

专利名称(译)	一种用于分类心律失常事件的可植入医疗装置和方法		
公开(公告)号	EP2282811A1	公开(公告)日	2011-02-16
申请号	EP2008767036	申请日	2008-05-07
申请(专利权)人(译)	ST.犹达医疗用品AB		
当前申请(专利权)人(译)	ST.犹达医疗用品AB		
[标]发明人	BJORLING ANDERS BHARMI RUPINDER BROOME MICHAEL JARVERUD KARIN		
发明人	BJÖRLING, ANDERS BHARMI, RUPINDER BROOME, MICHAEL JÄRVERUD, KARIN		
IPC分类号	A61N1/362 A61B5/046 A61B5/0464 A61N1/37 A61N1/39 A61B5/00 A61B5/08 A61N1/365		
CPC分类号	A61B5/0464 A61B5/0809 A61B5/7264 A61N1/3622 A61N1/36585 A61N1/395 A61N1/3987 G16H50/20		
其他公开文献	EP2282811B1 EP2282811A4		
外部链接	Espacenet		

摘要(译)

本发明一般涉及可植入装置领域。更具体地，本发明涉及可植入医疗设备，例如，可植入心脏除颤器和用于对心律失常事件进行分类的方法。分析IEGM信号以检测心律失常事件并且感测患者的呼吸模式。基于感测到的呼吸模式确定反映患者呼吸模式特征的至少一个呼吸参数，并计算对应于至少一个呼吸参数的变化率变化的呼吸测量。基于呼吸测量和IEGM信号对检测到的心律失常事件进行分类，其中满足至少第一标准的心律失常事件被分类为需要治疗的心律失常事件。