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(54) **Method and system for ischemia detection**

Verfahren und System zur Ischämieerkennung

Procédé et système de détection d'ischémie

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Description

Field of the invention

[0001] The present invention relates generally to implantable medical devices and more particularly to systems and methods for automatically determining ST windows for ischemia detection.

Background of the invention

[0002] Many patients at risk of cardiac ischemia have pacemakers, ICDs or other medical devices implanted therein. Cardiac ischemia is a severe condition and great efforts has therefore been made within the medical community to find systems and methods for detecting and monitoring ischemia over time. Electrocardiograms (ECG) are useful for diagnosing ischemia and locate damaged areas within the heart. Cardiac ischemia is a condition whereby heart tissue does not receive adequate amounts of oxygen and is usually caused by a blockage of an artery leading to damage of heart tissue. ECGs are composed of various waves and segments that represent the heart depolarization and repolarization. The ST segment represent the portion of the cardiac signal between ventricular depolarization and ventricular repolarization.

[0003] In the prior art, there exist techniques for detecting cardiac ischemia using implanted medical devices. In some conventional IEGM-based ischemia detection techniques, changes in the elevation or depression of the ST segment from a IEGM baseline are used an indication of ischemia. Elevation or depression of the ST segment in an IEGM signal may be the result of abnormalities in the polarization of cardiac tissue during an acute myocardial infraction (MI). An ST segment shift arises because the differences in the electric potential between cells that have become ischemic and those cells are still receiving normal blood flow. Deviation of an ST segment from a baseline is a result of an injury to the cardiac muscle, changes in the synchronization of ventricular muscle depolarization, drug or electrolyte influences, or the like.

[0004] In some prior art methods for determining ST window for ischemia detection, the ST window is a fixed time interval relative the R-wave. This may lead to that the ST window may encompass parts of the T-wave or the R-wave. If changes occur to the amplitude of the T-wave or R-wave, this may result in a false indication of an ST episode. Accordingly, there is a need of improving the specificity of these prior art methods. Such improvement can be achieved by allowing manual adjustments of the default parameters defining e.g. the fixed time interval to adapt the parameters to a specific patient.

[0005] In US Pat. Appl. 7,865,232 to Krishnaswamy et al., a method and system for automatically determining ischemia detection parameters is disclosed. An ischemia detection window is based on physiological state indicators that define start and end of the ischemia detection window. The physiological state indicators can be located by identifying slope changes after the R-wave and before the T-wave, respectively. Slope changes are recognized by identifying when the derivative of the composite intrinsic baseline changes sign from positive to negative or vice versa following the R-wave marker. The slope changes are used to locate ischemia detection parameters (e.g. start and end of ST window). A first ischemia detection parameter (indicating the start of the ST window) can be identified as a point along the baseline following the first slope change but with a predetermined offset (e.g. about 25 msec). A second ischemia detection parameter (indicating the end of the ST window) can be identified as a point along the baseline preceding the third slope change with a negative offset (e.g. about 35 msec).

[0006] US 2011/0040200 A1 discloses a system for analyzing an ECG signal. One out of two isoelectric portions in the ECG signal is adaptively selected for a heart beat cycle as a baseline based on stability measures. A point of reference of an ST segments in the heart beat cycle is determined. A deviation of the point of reference on the ST segment from the selected baseline is evaluated.

[0007] US 2008/0058881 A1 discloses an implantable device for delivering phototherapy for treatment of post-MI patients.

[0008] US 2007/0150015 A1 discloses a cardiac device with the capability of detecting cardiac ischemia using multiple sensing modalities.

[0009] However, there is still a need within the art for a patient-specific determination of ST windows or segments for use in ischemia detection in order to inter alia improve the specificity of the ischemia detection.

Summary of the invention

[0010] An object of the present invention is to provide systems for improving the specificity of the ischemia detection.

[0011] Another object of the present invention is to provide systems for automatically determining ST windows for use in ischemia detection.

[0012] These and other objects of the present invention are achieved by means of an implantable medical device having the features defined in the independent claims. Embodiments of the invention are characterized by the dependent claims.

[0013] There is provided a method for ischemia detection not forming part of the current invention, comprising obtaining at least one IEGM signal representative of cardiac behavior of a patient over a period of time and calculating a derivative signal of the IEGM signal. The R-wave is identified in the derivative signal or in the original IEGM signal and data of the derivative signal following the identified R-wave is analyzed so as to find portions of the derivative signal comprising samples having lower

values than a predetermined threshold. Further, a portion of the derivative signal including samples having lower values than the threshold is determined to correspond to a ST window for that cardiac cycle if that portion fulfills predetermined requirements. A reference ST window based on a number of determined ST windows is determined. Using the reference ST window, ischemia can be detected by comparing IEGM data in the reference ST window with current IEGM data from a segment of the IEGM signal corresponding to the reference ST window. A shift in the ST segment, i.e. the portion of the signal in the ST window, from a baseline or reference level is an indication of cardiac ischemia. For example, a depression of the IEGM signal in the ST window may be an indication of cardiac ischemia. Deviation of the ST segment from a baseline may be a result of an injury to cardiac muscle arising from differences in electric potential between cells that have become ischemic and those cells still receiving normal blood flow.

[0014] According to an aspect of the present invention, there is provided a system for ischemia detection comprising a data collection module configured to obtain at least one IEGM signal indicating cardiac behavior of a cardiac cycle corresponding a heartbeat and a data processing module configured to calculate a derivative signal of the IEGM signal. Furthermore, the system comprises a morphology detector configured to identify an R-wave in the derivative signal or in the original IEGM signal and an ST window determining module. The ST window determining module is configured to analyze the derivative signal data following the identified R-wave so as to find portions of the derivative signal comprising samples having lower values than a predetermined threshold, determine a portion of the derivative signal including samples having lower values than the threshold to correspond to a ST window for that cardiac cycle if that portion fulfills predetermined requirements and create a reference ST window based on a number of determined ST windows. An ischemia detection module is configured to detect ischemia by comparing IEGM data in the reference ST window with current IEGM data from a segment of the IEGM signal corresponding to the reference ST window.

[0015] In preferred embodiments of the present invention, all or some modules of the system are implemented in an implantable medical device or cardiac stimulator such as a cardiac pacemaker (a dual or single chamber stimulation device), an implantable cardioverter defibrillator ("ICD"), a defibrillator, or an ICD coupled with a pacemaker.

[0016] In a further embodiment some modules are implemented in an extracorporal device such as a programmer. The collected IEGM signals may be stored in a memory. Examples of modules that may be located in a programmer that analyzes stored IEGM data that may be read out from a memory are the ST window determining module or the ischemia detection module. The division of modules for implementing the system may be made in several different ways.

[0017] According to embodiments of the present invention, the threshold is determined based on derivative signal data following the identified R-wave, such that the threshold is higher in a region following the R-wave. By making the threshold higher near the R-wave, the risk that a start point of an ST window is set to be too far away from the R-wave and/or too close to the T-wave can be significantly reduced. Preferably, the threshold is set to be linearly decreasing from the R-wave, for example, the peak value of the R-wave. Other shapes of the decreasing threshold can also be used, for example, quadratic, exponential, logarithmic, or step-wise. According to an embodiment of the present invention, the threshold has a value at a starting point of a search window being a multiple of the value of the threshold base sample and a value at an end point of the search window being lower than the value of the threshold base sample, wherein the threshold is linearly decreasing between the value of the starting point and the end point.

[0018] The predetermined requirements for determining a portion of the derivative signal to be a ST window comprises that:

- a predetermined number of samples in the portion has a value below the predetermined threshold;
- a predetermined number of samples having values below the threshold are consecutive; and
- the portion has a length exceeding a predetermined time interval.

[0019] According to embodiments of the present invention, the requirements for determining a portion of the derivative signal to be a ST window further comprises, if more than one portion fulfill the predetermined requirements to correspond to a ST window for that cardiac cycle, selecting the portion being closest to the R-wave to correspond to the ST window for that cardiac cycle.

[0020] An overall ST window is created by: identifying a predetermined number of ST windows, determining a starting point of the reference ST window based on starting points for the gathered ST windows, and determining an end point of the reference ST window based on end points for the gathered ST windows.

[0021] According to embodiments of the present invention, the sensitivity of the threshold is adjusted if a predetermined number of ST windows has not been identified during a predetermined period of time or from of a predetermined number of cardiac cycles. Thereafter, the derivative signal data following the identified R-wave is analyzed for each cardiac cycle so as to find portions of the derivative signal comprising samples having lower values than the adjusted threshold and a portion of the derivative signal including samples having lower values than the adjusted threshold is determined to correspond to an ST window for that cardiac cycle if that portion fulfills predetermined requirements.

[0022] Further objects and advantages of the present

invention will be discussed below by means of exemplifying embodiments.

[0023] These and other features, aspects and advantages of the invention will be more fully understood when considered with respect to the following detailed description, appended claims and accompanying drawings.

Brief description of the drawings

[0024] The drawings are not necessarily drawn to scale and illustrate generally, by way of example, but no way of limitation, various embodiments of the present invention. Thus, exemplifying embodiments of the invention are illustrated by way of example and not by way of limitation in the figures of the accompanying drawings in which like references indicate similar elements. It should be noted that references to "an" or "one" embodiment in this discussion are not necessarily to the same embodiment, and such references mean at least one.

Fig. 1 is a simplified and schematic diagram of one embodiment of a system configuration according to the present invention including an implantable stimulation device in electrical communication with several leads implanted in a patient's heart for detecting cardiac activity and for delivering multi-chamber stimulation;

Fig. 2 is a simplified functional block diagram of one embodiment of a system in accordance with the present invention, illustrating basic elements of the system;

Fig. 3a is a diagram showing original IEGM signal, the pre-processed signal, the rectified derivative IEGM signal, and ST threshold (coinciding with the ST search window). The period starting at 7 and ending at 16 samples is found to be the ST window for this heartbeat;

Fig. 3b is a diagram showing the rectified derivative IEGM signal and the threshold superimposed of Fig. 3a in more detail. The length of the threshold coincides with the ST search window. The period starting at 7 and ending at 16 samples is found to be the ST window for this heartbeat; and

Fig. 4 is a flow diagram of an ST window determining process, which may be performed by a cardiac stimulator configured in accordance with example embodiments of the invention.

Description of exemplifying embodiments

[0025] The following is a description of exemplifying embodiments in accordance with the present invention. Embodiments may be used with a pacemaker, a cardioverter, a defibrillator, and the like.

[0026] Referring to Fig. 1, one implementation of the present invention relating to a system including an implantable cardiac stimulator connectable to one or more medical leads will be discussed. Fig. 1 illustrates an implantable medical device (IMD), in the embodiments described below a cardiac stimulator 10, coupled to a heart 12. The implantable medical device may be a cardiac pacemaker, an implantable cardioverter defibrillator ("ICD"), a defibrillator, or an ICD coupled with a pacemaker implemented in accordance with embodiments of the present invention. The implantable medical device may be a dual-chamber stimulation device capable of treating both fast and slow arrhythmias with stimulation therapy, including cardioversion, defibrillation, and pacing stimulation, as well as capable of detecting heart failure, evaluating its severity, tracking the progression thereof, and controlling the delivery of therapy and warnings in response thereto. As explained below in more detail, the IMD may monitor cardiac signals and based thereof, identify potentially abnormal physiology (e.g. ischemia). The detected cardiac signals may include intrinsic heart beats that have no assistance from any type of manmade electrical stimulation. Alternatively, the detected cardiac signals may include heart beats that have been stimulated by an electrical source to produce a paced heartbeat. The electrical source that provides low energy electrical signals, such as provided by a pacemaker, a demand pacemaker, a single-chamber, a dual-chamber pacemaker, a biventricular pacemaker, and the like. Optionally, the paced heartbeat may be generated by an implantable device that provides high energy electrical signals such as those provided by an implantable cardioverter defibrillator.

[0027] The implantable cardiac stimulator 10 of the system 1 is in electrical communication with a patient's heart 12 by way of three leads 14, 16, and 18 suitable for delivering multichamber stimulation therapy.

[0028] To sense atrial signals and to provide right atrial chamber stimulation therapy, the stimulator 10 is coupled to an implantable right atrial lead 14 having, for example, an atrial tip electrode 20, which typically is implanted in the patient's right atrial appendage or septum. Fig. 1 shows the right atrial lead 14 as also having an atrial ring electrode 21.

[0029] To sense left atrial and ventricular cardiac signals and to provide left chamber pacing therapy the stimulator 10 is coupled to a coronary sinus lead 16 designed for placement in the coronary sinus region via the coronary sinus for positioning a distal electrode adjacent to the left ventricle and/or additional electrode(s) adjacent to the left atrium. As used herein, the phrase "coronary sinus region" refers to the vasculature of the left ventricle, including any portion of the coronary sinus, great cardiac vein, left marginal vein, left posterior ventricular vein, middle cardiac vein, and/or small cardiac vein or any other cardiac vein accessible via the coronary sinus.

[0030] The lead 16 is designed to receive atrial and ventricular cardiac signals and to deliver left ventricular pacing therapy using, for example, a left ventricular tip electrode 22, a left ventricular ring electrode 23, and left atrial pacing therapy using, for example, a left atrial ring electrode 24.

[0031] The cardiac stimulator 10 is also in electrical communication with the heart 12 by way of an implantable right ventricular lead 18 having, in this embodiment, a right ventricular tip electrode 28 and a right ventricular ring electrode 30. Typically, the right ventricular lead 18 is transvenously inserted into the heart 12 to place the right ventricular tip electrode 28 in the right ventricular apex. The right ventricular lead 18 is capable of sensing or receiving cardiac signals, and delivering stimulation in the form of pacing therapy.

[0032] The cardiac stimulator 10 may be used to collect cardiac signals (e.g. both intrinsic and paced heart beats). Initially, the cardiac stimulator 10 may collect baseline cardiac signals and programmable controller (e.g. processor) 41 (shown in Fig. 2) may determine ST segment variations for the baseline signals. The baseline cardiac signals and ST segment variations may be stored in memory 49 (shown in Fig. 2). The cardiac stimulator 10 may be reprogrammed by a programmer 54 (shown in Fig. 2) to adapt, for example, cardiac pacing settings. Further, the cardiac stimulator 10 may obtain cardiac signals (e.g. IEGM) on a beat-by-beat basis and store each heart in the memory 49. In addition, associated with each heart beat, the cardiac stimulator 10 may store the time the heart beat occurred and the heart rate of the heart beat. The processor 41 may determine the ST segment variation associated with the heart beat and store the ST segment variation associated with the heart beat the ST segment value in memory 49 as will be described below.

[0033] In Fig. 2, an exemplary, simplified block diagram depicting various components of the cardiac stimulator according to embodiments of the present invention is shown. The cardiac stimulator 10 is capable of delivering cardiac resynchronization therapy and is configured to integrate both monitoring and therapy features, as will be described below. Further, the cardiac stimulator 10 collects and processes data about the heart 12 from electrode pairs for sensing cardiac electrogram (EGM) signals. While a particular multi-chamber device is shown, it is to be appreciated and understood that this is done for illustration purposes only. Thus, the techniques and methods described below can be implemented in connection with any suitable configured or configurable stimulation device. Accordingly, one of skill in the art could readily duplicate, eliminate, or disable the appropriate circuitry in any desired combination to provide a device capable of treating the appropriate chamber with pacing stimulation including cardiac resynchronisation therapy.

[0034] The cardiac stimulator 10 has a housing 40, often referred to as the "can" or "case electrode". The housing 40 may function as a return electrode in "unipolar" modes. Further, the housing 40 includes connector (not shown) having a plurality of terminals (not shown) for connection with electrodes and/or sensors.

[0035] The cardiac stimulator 10 includes a programmable microcontroller or control module 41 that inter alia controls the various modes of stimulation therapy. As well known within the art, the microcontroller 41 typically includes a microprocessor, or equivalent control circuitry, designed specifically for controlling the delivery of stimulation therapy and may further include RAM or ROM memory, logic and timing circuitry, state machine circuitry, and I/O circuitry. Typically, the microcontroller 41 includes the ability to process or monitor input signals (data or information) as controlled by a program stored in a designated block of memory. The type of microcontroller is not critical to the described implementations. Rather, any suitable microcontroller 41 may be used that carries out the functions described herein. The use of microprocessor based control circuits for performing timing and data analysis are well known in the art.

[0036] Furthermore, the cardiac stimulator 10 includes pacing module 42 adapted to provide pacing signals for delivery to the patient. The pacing module 42 comprises an atrial pulse generator 43 and a ventricular pulse generator 44 that generate pacing stimulation pulses for delivery by the right atrial lead 14, the coronary sinus lead 16, and/or the right ventricular lead 18 via an electrode configuration switch 45. It is understood that in order to provide stimulation therapy in each of the four chambers, the atrial and ventricular pulse generators 43 and 44, may include dedicated, independent pulse generators, multiplexed pulse generators, or shared pulse generators. The pulse generators 43 and 44 are controlled by the microcontroller 41 via appropriate control signals to trigger or inhibit stimulation pulses.

[0037] A data collection module 62 is adapted to collect, for example, cardiac signals such as IEGM signals. More specifically, the data collection module 62 is configured to collect IEGM signals, convert raw analog data into digital IEGM signals and store the digital IEGM signals in a memory for later processing or provide the digital IEGM signals to a data processing module 65 for preprocessing. Control signals from the microcontroller 41 determine when the data collection module 62 collects signals, stores them in the memory or transmit them to the data processing module 65. The data collection module 62 is coupled to the right atrial lead 14, the coronary sinus lead 16, and the right ventricular lead 18 to sample cardiac signals across any combination of electrodes.

[0038] The data processing module 65 is configured to pre-process the received digital IEGM signals including a filtering process. In one embodiment of the present invention, a 2nd order Bessel filter with limiting frequencies 2 Hz and 20 Hz is used. Further, the signals may be filtered, reversed in the time domain, filtered again, and reversed in time again of the re-filtered signal. Thereby, the morphological changes induced by the filtering can be reduced and the time delays imposed by the filtering steps can be removed. A re-centering process may also be performed on the filtered signals including analyzing each heartbeat in a predetermined time window centered on an R-wave center, defined e.g. by the AnalyST™ algorithm provided by the applicant, where the greatest positive deflection is redefined as the heartbeat center. Moreover, the signals are differentiated with respect to

time thus providing a derivative IEGM signal. The derivative IEGM signal is thereafter provided to the microcontroller 41.

[0039] The microcontroller 41 includes timing control circuitry 46 to control timing of the stimulation pulses (e.g. pacing rate, AV delay, VV delay, etc.) as well as to keep track of timing of refractory periods, blanking intervals, etc. which is well known in the art. In addition, the microcontroller 41 may include components such as e.g. an arrhythmia detector (not shown).

[0040] The microcontroller 41 comprises a morphology detector 66 configured to detect and identify cardiac events in IEGM signals and/or derivative IEGM signals.

[0041] The morphology detector 66 detects and identifies the R-wave for each heartbeat or cardiac cycle in the derivative IEGM signal. The morphology detector can also operate on the original IEGM signal for identifying R-Waves.

[0042] In Fig. 3a, an original IEGM signal is shown together with the pre-processed signal (filtered) and the derivative signal. An ST search window is also shown. The R-wave is indicated in the diagram.

[0043] A threshold determining module 67 is configured to determine a threshold used for identifying the ST windows. According to an embodiment of the present invention, the threshold is determined as follows:

- All samples in the window to be analyzed following the R-wave are extracted.
- The 30th percentile value among these samples is identified. This is a preferred value and can be adapted to, for example, a specific patient.
- The 30th percentile value is set as the threshold value.

The length of the search window is about 150 - 300 ms and preferably about 200 - 300 ms, a more preferably about 250 - 285 and starts at the R-wave of each cardiac cycle. In one specific embodiment, the search window is about 275 ms.

[0044] To reduce the risk of having a ST window that starts too far away from the R-wave and/or too close to the T-wave, the threshold may be set to a higher value in an area close to the R-wave. Thus, the threshold is set to be higher at the start and lower at the end. In a preferred embodiment of the present invention, the threshold is linearly decreasing from the starting point to the end point. In a preferred embodiment of the present invention, the start value is a first multiplying factor (e.g. 1.5, 2, 2.2 or 2.5) times the 30th percentile value and the end value is a second multiplying factor (e.g. ¼, 1/3, ½ or ¾) of the 30th percentile value. In Fig. 3b, the rectified derivative IEGM signal is shown together with a linearly decreasing threshold. The length of the threshold coincides with ST search window in this case. The period starting at 7 and ending at 16 samples is found to be the ST window for this heartbeat. However, other shapes of the decreasing threshold can also be used, e.g. quadric, exponential, logarithmic, step-wise etc.

[0045] Furthermore, an ST window determining module 68 is configured to analyze the derivative signal data following the identified R-wave so as to find portions of the derivative signal comprising samples having lower values than the predetermined threshold. The ST window determining module 68 is configured to determine a portion of the derivative signal including samples having lower values than the threshold to correspond to a ST window for that cardiac cycle if that portion fulfills predetermined requirements. According to embodiments of the present invention, the following requirements have to be fulfilled:

i) The derivative of a sample is lower than the threshold.
ii) All samples matching i) are consecutive with the exception of a gap of a preset length (in a preferred embodiment a gap of 7.8 ms = 1 sample at 128 Hz is tolerated)
iii) The portion of the derivative signal having such consecutive samples below the threshold is longer than a minimum allowed ST window. In a preferred embodiment, the minimum length is about 20 - 30 ms, and in more preferred embodiment the minimum length is about 25 ms.

When a predetermined number of ST windows have been determined, i.e. the ST start and duration has been determined for respective cardiac cycles, an overall ST start and duration are determined based on these ST windows. This can be performed when ST start and duration has been established for a large enough portion of the analyzed heart beats, for example, more than 50%, 60% or 65%. The overall ST window can be determined by calculating the median of starting points and durations. It is however also possible to calculate the average, the average of a percentile, a weighted average etc.

[0046] The ST window determining module 68 may further be configured to perform a verification procedure to verify parameters of the overall ST window, i.e. starting point, duration and end point. The starting point, duration and end point are therefore analyzed to verify that they are within allowed ranges. If not, the parameters can be adjusted to fit into the ranges, or they can be recalculated. According to an embodiment of the present invention, the ranges are the following:

- The minimum allowed ST start value from the R-wave, for example, from the peak value of the R-wave is between 15 - 80 ms, and is preferably between 20 - 60 ms, and more preferably between 20 - 30 ms. An example of a minimum ST start value is 24 ms from the R-wave, for example, from the peak value of the R-wave. Another example minimum start value is 40 ms from the R-wave, for example, from the peak value of the R-wave.
- The maximum allowed ST start value from the R-

wave, for example, from the peak value of the R-wave is between 50 - 300 ms, and preferably between 100 - 280 ms, and more preferably between 200 - 270 ms. An example of a maximum ST start value is 250 ms from the R-wave, for example, from the peak value of the R-wave. Another example of the maximum start value is 110 ms from the R-wave, for example, from the peak value of the R-wave.

- The maximum ST end time from the R-wave, for example, from the peak value of the R-wave is between 200 - 300 ms, and preferably between 220 - 290 ms, and more preferably between 250 - 280 ms. An example of a maximum ST end time is 274 ms from the R-wave, for example, from the peak value of the R-wave.
- A maximum duration value may also be applied, for example, between 30 - 90 ms, or preferably between 40 - 80 ms, or more preferably between 50 - 70 ms. In one specific embodiment, the maximum duration value is about 60 ms.

[0047] An ischemia detection module 69 is configured to use the overall ST window as a reference ST window in detecting ischemia by comparing IEGM data in the reference ST window with current IEGM data from a segment of the IEGM signal corresponding to the reference ST window. By comparing the reference ST window with current IEGM data in the corresponding window, shifts in the ST segment can be monitored, which are an indicator of a potential abnormal physiology, such as, ischemia.

[0048] The aforementioned components may be implemented as part of the microcontroller 41, or as softwarelfirmware instructions programmed into the device and executed on the microcontroller 41 during certain modes of operation. Several of the components discussed above such as the threshold determining module 67, the ST determining module 68 and the ischemia detection module may be implemented in an extracorporal device such as a programmer. In fact there are several different possibilities to split components between the cardiac stimulator and the external instrument.

[0049] Moreover, the cardiac stimulator 10 additionally includes a battery 58 that provides operating power to all of the circuits shown in Fig. 2. Preferably, the stimulator 10 employs lithium or similar battery technology.

[0050] With reference now to Fig. 4, an embodiment of the method for generating a patient specific ST window not forming part of the current invention, will be discussed. Fig. 4 is a flow diagram of a ST window generation process 100, which may be performed by a cardiac stimulator configured in accordance with an example embodiment of the inventions, for example, as illustrated in Fig. 2. The various tasks performed in connection with the process 100 may be performed by software, hardware, firmware, or any combination thereof. For illustrative purposes, the following description of the process 100 refers to elements mentioned above in connection with Figs. 1 - 2. In practical embodiments, portions of the process 100 may be performed by different elements of the described cardiac stimulator. It should be appreciated that the process 100 may include any number of additional or alternative tasks, the tasks shown in Fig. 4 need not be performed in the illustrated order, and the process 100 may be incorporated into a more comprehensive procedure or process having additional functionality not described in detail herein.

[0051] The process 100 obtains at least one IEGM signal indicating cardiac behavior of a cardiac cycle corresponding a heartbeat, in task 110, using the data collection module 62 which is configured to obtain data about the patient.

[0052] The IEGM signals are pre-processed in task 120 by the data processing module 65. For example, the signals may be re-centered and filtered, e.g. by using a 2^{nd} order Bessel filter with limiting frequencies 2 Hz and 20 Hz as have been described above.

[0053] In task 130, the IEGM signals are differentiated with respect to time in the data processing module 65.

[0054] Thereafter, in task 140, the R-wave is identified in the derivative signal for respective heart beat in the morphology detector 66. The R-wave can also be identified by analyzing the original IEGM-signal, for example through amplitude comparison with a predetermined value.

[0055] The threshold determining module 67 determines a threshold used for identifying the ST windows in task 150 as has been described above. To reduce the risk of having an ST window that starts too far away from the R-wave and/or too close to the T-wave, the threshold may be set to a higher value in an area close to the R-wave. Thus, the threshold is set to be higher at the start and lower at the end as has been described above.

[0056] In task 160, the differentiated IEGM signal for respective heart beat is analyzed by the ST window determining module 68. Preferably, a signal portion following the identified R-wave is analyzed so as to find portions of the signal that comprises samples having lower values than a predetermined threshold. A portion of the differentiated signal for a cardiac cycle including samples having lower values than the threshold is determined to correspond to an ST window for that cardiac cycle if that portion fulfills predetermined requirements, which according to an embodiment of the present invention are:

(i) The derivative of a sample is lower than the threshold,

(ii) All samples matching i) are consecutive with the exception of a gap of a predetermined length (in a preferred embodiment a gap of 7.8 ms = 1 sample at 128 Hz is tolerated), and

(iii) The portion of the derivative signal having such consecutive samples below the threshold is longer than a minimum allowed ST window. In a preferred embodiment, the minimum length is about 20 - 30 ms, and in more preferred embodiment the minimum

length is about 25 ms.

[0057] In query task 170, it is checked whether enough ST windows have been found in the analysis, for example, more than 50%, 60% or 65% of the heart beats. Hence, it is checked that the number of ST windows found in relation to the total number of heart beats is not too low. If the number of identified ST windows is too low, the process 100 proceeds to task 180 where the threshold is adjusted to a higher value, i.e. the threshold is increased. Then, task 160 is repeated but with the adjusted threshold. Preferably, the present threshold is multiplied with 2, which entails that the inclination of the threshold is preserved. Another alternative is to change the percentile value or any other parameter that controls the threshold, in such a case the process 100 is repeated from task 150 instead. However, if enough ST windows have been found, the process 100 continues to task 190 where an overall ST window start point and ST window duration are determined based on all identified ST windows. In a preferred embodiment, the median of all start points and durations are calculated while ignoring the heart beats for which a ST window could not be determined. It is however also possible to calculate, for example, the average of one or more percentiles, a weighted average.

[0058] When the overall ST window start point and ST window duration have been determined, a verification of the determined start point and duration is performed in task 200. The ST window start point, the ST window duration and ST window end point are analyzed to check whether they fall within allowed ranges. If the start point, duration and/or end point fall outside predetermined ranges (discussed above), an adjustment is performed in task 210. For example, if the ST window start value is smaller than the lowest allowed value, it is changed to this lowest allowed value. In an alternative embodiment, the process 100 returns to task 150 for a new calculation of ST windows before the adjustment in task 210 is performed. If the overall ST window is approved, i.e. the start value, duration and end value are within the predetermined ranges, the process is finished and the overall ST window is ready for use as a reference ST window in, for example, ischemia detection in an ischemia detection process 300.

Claims

1. A system (1) for ischemia detection comprising:

a data collection module (62) configured to obtain at least one IEGM signal indicating cardiac behavior of a cardiac cycle corresponding to a heartbeat;
a data processing module (65) configured to calculate a derivative signal of the IEGM signal;
a detector (66) configured to identify a R-wave in the derivative signal or in the IEGM signal, **characterized by**:

an ST window determining module (68) configured to:

analyze said derivative signal data following said identified R-wave so as to find portions of said derivative signal comprising samples having lower values than a predetermined threshold;
determine a portion of said derivative signal including samples having lower values than said threshold to correspond to a ST window for that cardiac cycle if that portion fulfills predetermined requirements comprising:

a predetermined number of samples in said portion has a value below said predetermined threshold;
a predetermined number of samples having values below said threshold are consecutive; and
the portion has a length exceeding a predetermined time interval; and

create a reference ST window based on a number of determined ST windows; and

an ischemia detection module (69) configured to detect ischemia by comparing IEGM data in said reference ST window with current IEGM data from a segment of a current IEGM signal corresponding to the reference ST window.

2. The system according to claim 1, further comprising a threshold determining module (67) configured to determine said threshold based on derivative signal data following said identified R-wave, said threshold having a higher value in a region following said R-wave.

3. The system according to claim 2, wherein said threshold determining module (67) is further configured to find a threshold base sample having a value that is equal to a 30^{th} percentile value among samples in said derivative signal in a search window following said R-wave.

4. The system according to claim 2 or 3, wherein said threshold determining module (67) is further configured to determine a value of a starting point of a search window to be a multiple of said value of said threshold base sample and a value at an end point of said search window to be lower than said value

of said threshold base sample, wherein said threshold is linearly decreasing between the value of the starting point and said end point.

5. The system according to any one of the preceding claims , wherein said requirements for determining a portion of the derivative signal to be a ST window further comprises, if more than one portion fulfill said predetermined requirements to correspond to a ST window for that cardiac cycle, selecting the portion being closest to the R-wave to correspond to the ST window for that cardiac cycle.

6. The system according to any one of preceding claims, wherein said ST window determining module (68) is further configured to:

identify a predetermined number of ST windows;
determine a starting point of the reference ST window based on starting points for said determined ST windows; and
determine an end point of the reference ST window based on end points for said determined ST windows.

7. The system according to claim 6, wherein said threshold determining module (68) is further configured to, if a predetermined number of ST windows has not been identified during a predetermined period of time or from of a predetermined number of cardiac cycles, adjust said threshold to a higher value; and wherein said ST window determining module (68) is further configured to:

analyze said derivative signal data following said identified R-wave for each cardiac cycle so as to find portions of said derivative signal comprising samples having lower values than said adjusted threshold; and
determine a portion of said derivative signal including samples having lower values than said threshold to correspond to a ST window for that cardiac cycle if that portion fulfills predetermined requirements.

Patentansprüche

1. System (1) zur Ischämieerkennung, umfassend:

ein Datenerfassungsmodul (62), das zum Erhalt wenigstens eines IEGM-Signals, konfiguriert ist, welches das Verhalten eines Herzens während eines Herzzyklus anzeigt, der mit einem Herzschlag übereinstimmt;
ein Datenverarbeitungsmodul (65), das zur Berechnung eines aus dem IEGM-Signal abgeleiteten Signals konfiguriert ist;
einen Detektor (66), der zur Identifizierung einer R-Welle in dem abgeleiteten Signal oder in dem IEGM-Signal konfiguriert ist, **gekennzeichnet durch**:

ein Modul (68) zur Bestimmung eines ST-Fensters, konfiguriert zur:
Analyse von Daten des abgeleiteten Signals, die der identifizierten R-Welle folgen, zum Auffinden von Abschnitten des abgeleiteten Signals, die Proben umfassen, welche niedrigere Werte als eine vorbestimmte Schwelle aufweisen;
Bestimmung eines Abschnitts des abgeleiteten Signals, der Proben beinhaltet, die niedrigere Werte als die Schwelle aufweisen, um mit einem ST-Fenster für diesen Herzzyklus übereinzustimmen, falls der Abschnitt vorbestimmte Erfordernisse erfüllt, umfassend:

eine vorbestimmte Anzahl von Proben in dem Abschnitt weist einen Wert unterhalb der vorbestimmten Schwelle auf;
eine vorbestimmte Anzahl von Proben mit Werten unterhalb der Schwelle folgt aufeinander; und
der Abschnitt weist eine Länge auf, die ein vorbestimmtes Zeitintervall überschreitet; und

Erzeugung eines Referenz-ST-Fensters, basierend auf einer Anzahl von vorbestimmten ST-Fenstern; und
ein Ischämieerkennungsmodul (69), das zur Erkennung von Ischämie durch Vergleich von IEGM-Daten in dem Referenz-ST-Fenster mit aktuellen IEGM-Daten eines Segments eines aktuellen IEGM-Signals, welches mit dem Referenz- ST-Fenster übereinstimmt, konfiguriert ist.

2. System nach Anspruch 1, weiter umfassend ein Schwellenbestimmungsmodul (67), das zur Bestimmung der Schwelle konfiguriert ist, basierend auf Daten des abgeleiteten Signals, die der identifizierten R-Welle folgen, wobei die Schwelle einen höheren Wert in einer Region aufweist, die der R-Welle folgt.

3. System nach Anspruch 2, bei dem das Schwellenbestimmungsmodul (67) weiter zur Ermittlung einer Schwellenbasisprobe konfiguriert ist, die einen Wert aufweist, der einem 30-ten Perzentilwert aus Proben in dem abgeleiteten Signal in einem Suchfenster entspricht, welche der R-Welle folgen.

4. System nach Anspruch 2 oder 3, bei dem das

Schwellenbestimmungsmodul (67) weiter zur Bestimmung eines Werts eines Ausgangspunktes eines Suchfensters konfiguriert ist, ein Vielfaches des Werts der Schwellenbasisprobe zu sein, und eines Werts an einem Endpunkt des Suchfensters, niedriger zu sein als der Wert der Schwellenbasisprobe, wobei die Schwelle zwischen dem Wert des Ausgangspunkts und des Endpunkts linear abfällt.

5. System nach einem der vorhergehenden Ansprüche, bei dem die Erfordernisse zur Bestimmung, dass ein Abschnitt des abgeleiteten Signals ein ST-Fenster ist, weiter umfasst, falls mehr als ein Abschnitt die vorgenannten Erfordernisse erfüllt, mit einem ST-Fenster für diesen Herzzyklus übereinzustimmen, Auswählen des Bereichs, der der R-Welle am nächsten liegt, mit dem ST-Fenster für diesen Herzzyklus übereinzustimmen.

6. System nach einem der vorhergehenden Ansprüche, bei dem das Modul (68) zur Bestimmung des ST-Fensters weiter konfiguriert ist, um:

eine vorbestimmte Anzahl von ST-Fenstern zu identifizieren;
einen Ausgangspunkt des Referenz-ST-Fensters zu bestimmen, basierend auf Ausgangspunkten für die vorbestimmten ST-Fenster; und
einen Endpunkt des Referenz-ST-Fensters basierend auf Endpunkten für die vorbestimmten ST-Fenster zu bestimmen.

7. System nach Anspruch 6, bei dem das Schwellenbestimmungsmodul (68) weiter konfiguriert ist, falls eine vorbestimmte Anzahl von ST-Fenstern während einer vorbestimmten Zeitperiode oder aus einer vorbestimmten Anzahl von Herzzyklen nicht identifiziert worden ist, die Schwelle auf einen höheren Wert anzupassen; und bei dem das Modul (68) zur Bestimmung des ST-Fensters weiter konfiguriert ist:

zur Analyse der auf die identifizierte R-Welle folgenden Daten des abgeleiteten Signals für jeden Herzzyklus, um Abschnitte des abgeleiteten Signals zu ermitteln, die Proben umfassen, die niedrigere Werte aufweisen als die angepasste Schwelle; und
zur Bestimmung eines Abschnitts des abgeleiteten Signals, der Proben beinhaltet, die geringere Werte aufweisen als die Schwelle, um mit einem ST-Fenster für diesen Herzzyklus übereinzustimmen, falls dieser Abschnitt die vorbestimmten Erfordernisse erfüllt.

Revendications

1. Système (1) pour détecter l'ischémie comprenant :

un module de collecte de données (62) configuré pour obtenir au moins un signal IEGM indiquant le comportement cardiaque d'un cycle cardiaque correspondant à un battement de coeur ;
un module de traitement de données (65) configuré pour calculer un signal dérivé du signal IEGM ;
un détecteur (66) configuré pour identifier une onde R dans le signal dérivé ou dans le signal IEGM, **caractérisé par** :

un module de détermination de fenêtre ST (68) configuré pour :

analyser les données dudit signal dérivé à la suite de ladite onde R identifiée afin de trouver des parties dudit signal dérivé comprenant des échantillons ayant des valeurs inférieures à un seuil prédéterminé ;
déterminer une partie dudit signal dérivé comprenant des échantillons ayant des valeurs inférieures audit seuil pour correspondre à une fenêtre ST pour ce cycle cardiaque si cette partie est conforme à des exigences prédéterminées comprenant :

un nombre prédéterminé d'échantillons dans ladite partie a une valeur inférieure audit seuil prédéterminé ;
un nombre prédéterminé d'échantillons ayant des valeurs inférieures audit seuil sont consécutifs ; et
la partie a une longueur dépassant un intervalle temporel prédéterminé ; et

créer une fenêtre ST de référence fondée sur un nombre déterminé de fenêtres ST ; et

un module de détection d'ischémie (69) configuré pour détecter l'ischémie en comparant les données IEGM dans ladite fenêtre ST de référence avec les données IEGM courantes d'un segment d'un signal IEGM courant correspondant à la fenêtre ST de référence.

2. Système selon la revendication 1, comprenant également un module de détermination de seuil (67) configuré pour déterminer ledit seuil sur la base des données de signal dérivé à la suite de ladite onde R identifiée, ledit seuil ayant une valeur supérieure dans une région à la suite de ladite onde R.

3. Système selon la revendication 2, dans lequel ledit module de détermination de seuil (67) est également configuré pour trouver un échantillon de seuil de base ayant une valeur égale à une valeur de 30 pour cent parmi les échantillons dans ledit signal dérivé dans une fenêtre de recherche à la suite de ladite onde R.

4. Système selon la revendication 2 ou 3, dans lequel ledit module de détermination de seuil (67) est également configuré pour déterminer une valeur d'un point de départ d'une fenêtre de recherche pour qu'elle soit un multiple de ladite valeur dudit échantillon de seuil de base et une valeur à un point de fin de ladite fenêtre de recherche pour qu'elle soit inférieure à ladite valeur dudit échantillon de seuil de base, dans lequel ledit seuil diminue linéairement entre la valeur du point de départ et dudit point de fin.

5. Système selon l'une quelconque des revendications précédentes, dans lequel lesdites exigences pour déterminer une partie du signal dérivé comme une fenêtre ST comprennent également, si plus d'une partie remplit lesdites exigences prédéterminées pour correspondre à une fenêtre ST pour ce cycle cardiaque, la sélection de la partie la plus proche de l'onde R pour correspondre à la fenêtre ST pour ce cycle cardiaque.

6. Système selon l'une quelconque des revendications précédentes, dans lequel ledit module de détermination de fenêtre ST (68) est également configuré pour :

identifier un nombre prédéterminé de fenêtres ST ;
déterminer un point de départ de la fenêtre ST de référence fondé sur les points de départ pour lesdites fenêtres ST déterminées ; et
déterminer un point de fin de la fenêtre ST de référence fondé sur les points de fin pour lesdites fenêtres ST déterminées.

7. Système selon la revendication 6, dans lequel ledit module de détermination de seuil (68) est également configuré, si un nombre prédéterminé de fenêtres ST n'a pas été identifié pendant une durée prédéterminée ou à partir d'un nombre prédéterminé de cycles cardiaques, pour ajuster ledit seuil à une valeur supérieure ; et dans lequel ledit module de détermination de fenêtre ST (68) est également configuré pour :

analyser les données dudit signal dérivé à la suite de ladite onde R identifiée pour chaque cycle cardiaque afin de trouver des parties dudit signal dérivé comprenant des échantillons ayant des valeurs inférieures audit seuil ajusté ; et
déterminer une partie dudit signal dérivé comprenant des échantillons ayant des valeurs inférieures audit seuil pour correspondre à une fenêtre ST pour ce cycle cardiaque si cette partie répond aux exigences prédéterminées.

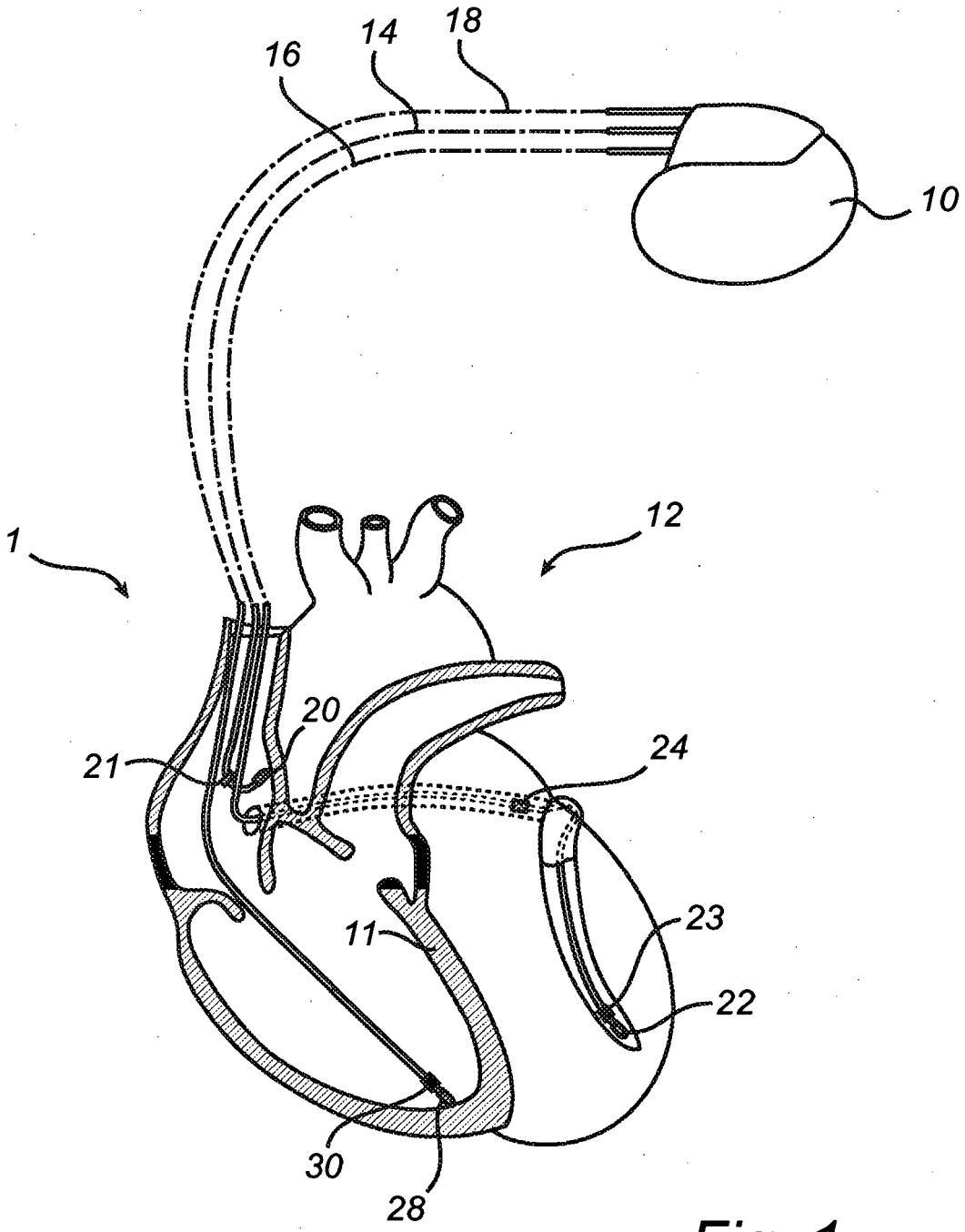

Fig. 1

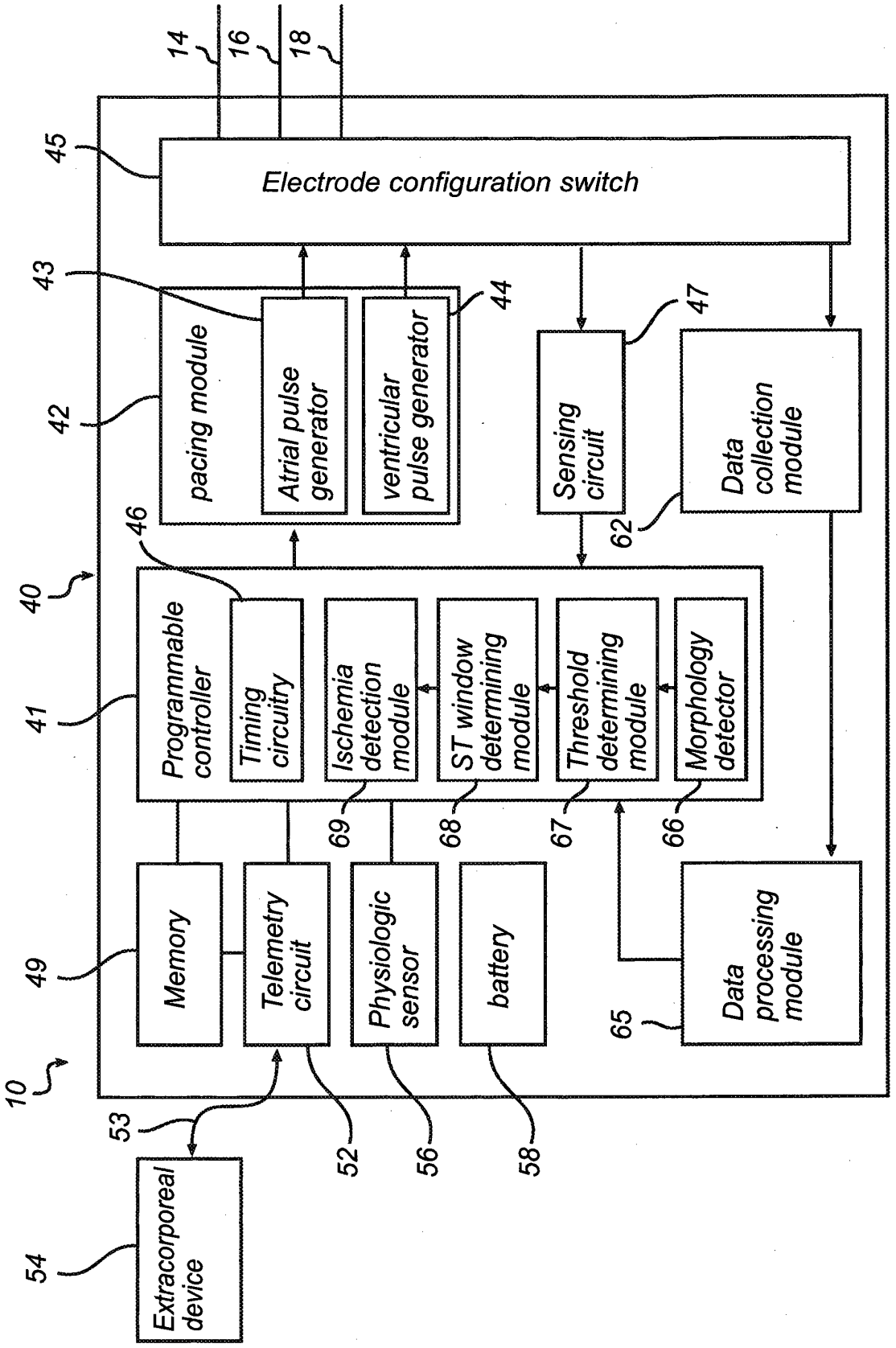
14
16
18
45
Electrode configuration switch
43
44
47
pacing module
Atrial pulse generator
ventricular pulse generator
Sensing circuit
Data collection module
42
62
46
40
Programmable controller
Timing circuitry
Ischemia detection module
ST window determining module
Threshold determining module
Morphology detector
41
69
68
67
66
Memory
Telemetry circuit
Physiologic sensor
battery
Data processing module
49
65
10
53
52
56
58
Extracorporeal device
54

Fig. 2

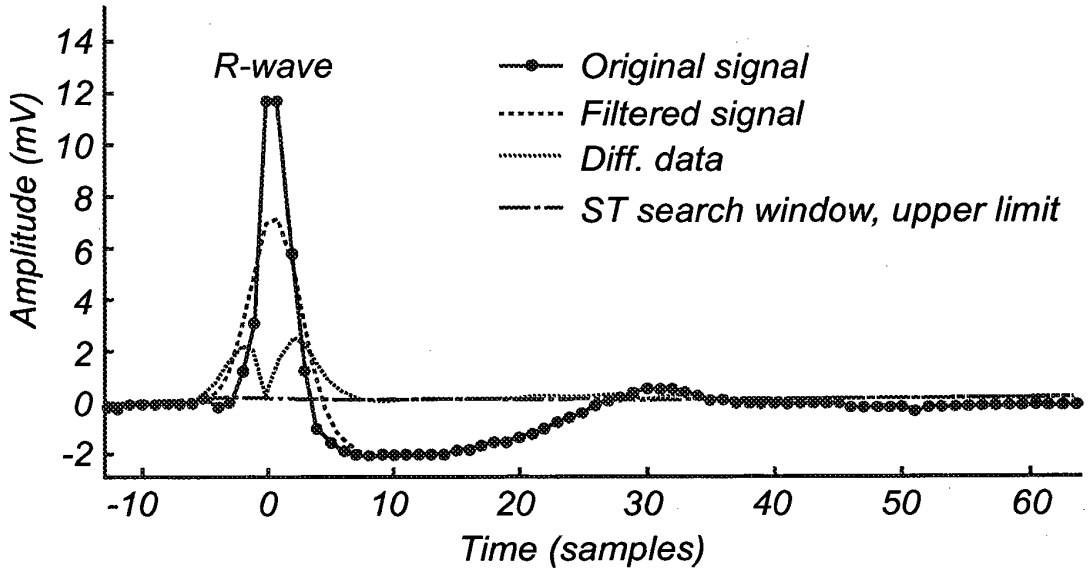
R-wave
Original signal
Filtered signal
Diff. data
ST search window, upper limit
Amplitude (mV)
14
12
10
8
6
4
2
0
-2
-10
0
10
20
30
40
50
60
Time (samples)

Fig. 3a

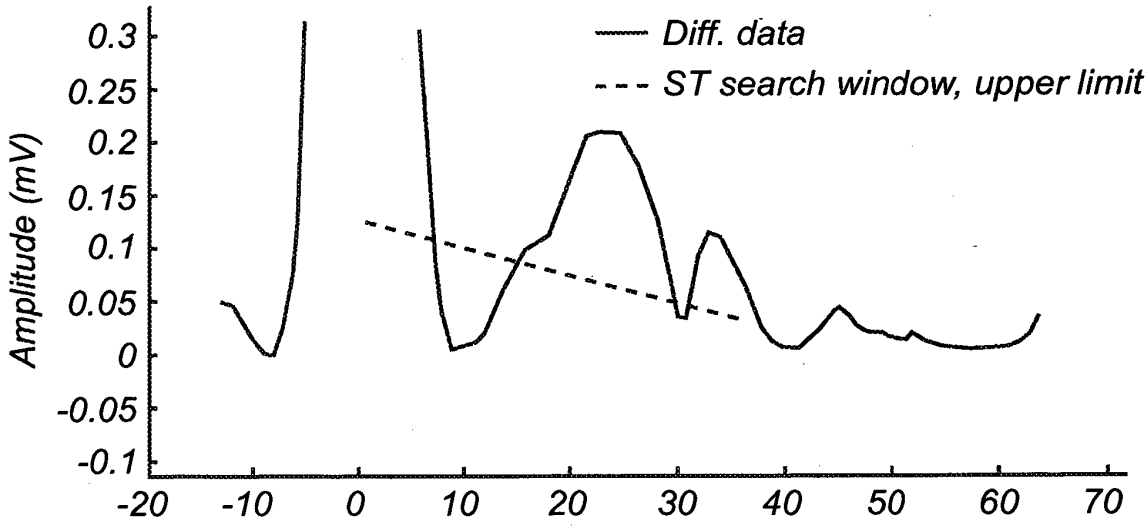
Diff. data
ST search window, upper limit
Amplitude (mV)
0.3
0.25
0.2
0.15
0.1
0.05
0
-0.05
-0.1
-20
-10
0
10
20
30
40
50
60
70

Fig. 3b

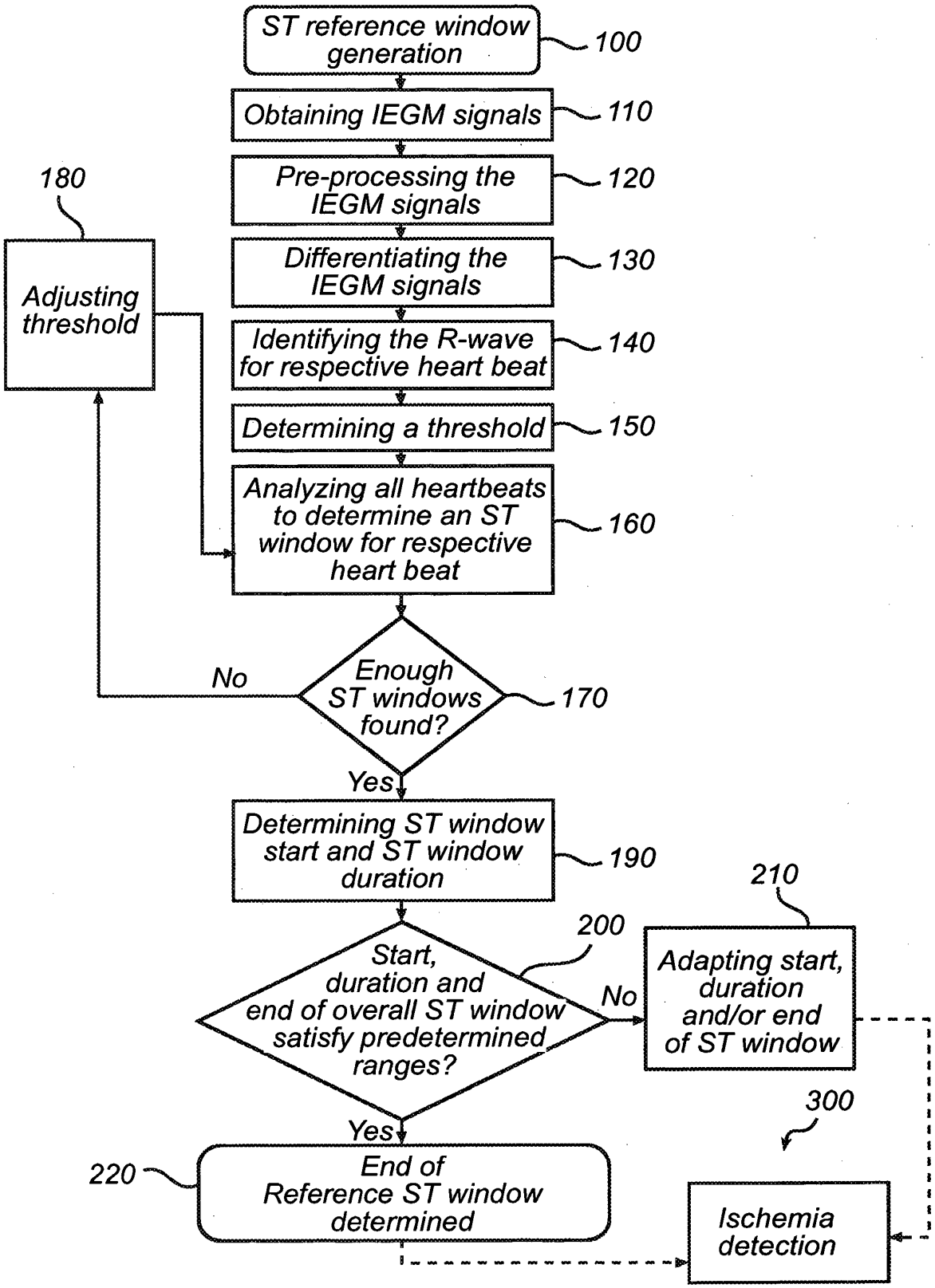
ST reference window generation
100
Obtaining IEGM signals
110
Pre-processing the IEGM signals
120
Differentiating the IEGM signals
130
Identifying the R-wave for respective heart beat
140
Determining a threshold
150
Analyzing all heartbeats to determine an ST window for respective heart beat
160
180
Adjusting threshold
Enough ST windows found?
170
No
Yes
Determining ST window start and ST window duration
190
Start, duration and end of overall ST window satisfy predetermined ranges?
200
No
Yes
210
Adapting start, duration and/or end of ST window
300
220
End of Reference ST window determined
Ischemia detection

Fig. 4

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 7865232 B **[0005]**
- US 20110040200 A1 **[0006]**
- US 20080058881 A1 **[0007]**
- US 20070150015 A1 **[0008]**

专利名称(译)	用于缺血检测的方法和系统		
公开(公告)号	EP2537460B1	公开(公告)日	2015-01-07
申请号	EP2011170536	申请日	2011-06-20
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		
发明人	BJÖRLING, ANDERS		
IPC分类号	A61B5/00 A61B5/0452 A61B5/0456 A61B5/0468 A61N1/39 G06F19/00		
CPC分类号	A61B5/0472 A61B5/0456 A61B5/14542 A61B5/7239 A61N1/36557 A61N1/3702		
其他公开文献	EP2537460A1		
外部链接	Espacenet		

摘要(译)

本发明一般涉及可植入医疗装置，更具体地涉及用于自动确定用于缺血检测的ST窗口的系统和方法。获得至少一个IEGM信号，其代表患者在一段时间内的心脏行为，然后计算IEGM信号的导数信号。在导数信号中识别R波，并且分析在识别的R波之后的导数信号数据，以便找到包括具有比预定阈值低的值的样本的导数信号的部分。此外，如果该部分满足预定要求，则确定包括具有比阈值低的值的样本的导数信号的一部分对应于该心动周期的ST窗口。确定基于多个确定的ST窗口的参考ST窗口。使用参考ST窗口，可以通过将参考ST窗口中的IEGM数据与来自对应于参考ST窗口的IEGM信号的片段的当前IEGM数据进行比较来检测缺血。

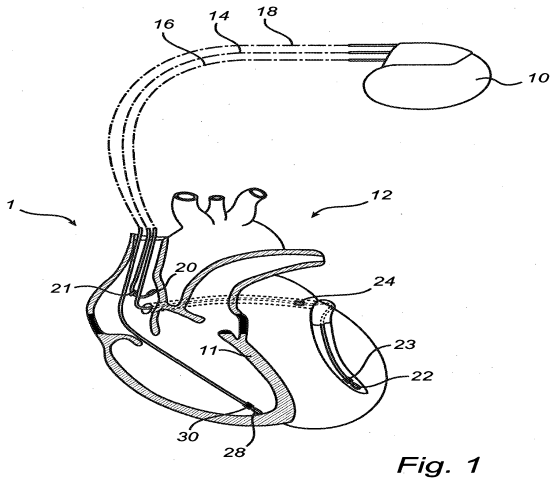

Fig. 1