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(71) Applicant *(for all designated States except US):* **ST. JUDE MEDICAL AB** [SE/SE], S-175 84 Jarfalla (SE)

(72) Inventors; and

(75) Inventors/Applicants *(for US only):* **JÄRVERUD, Karin** [SE/SE], Ballonggatan 17, S-169 71 Solna (SE) **NOREN, Kjell** [SE/SE], Karolinagatan 10 C, S-171 58 Solna (SE)

(74) Common Representative: **ST. JUDE MEDICAL AB,** Patent Department, S-175 84 Jarfalla (SE)

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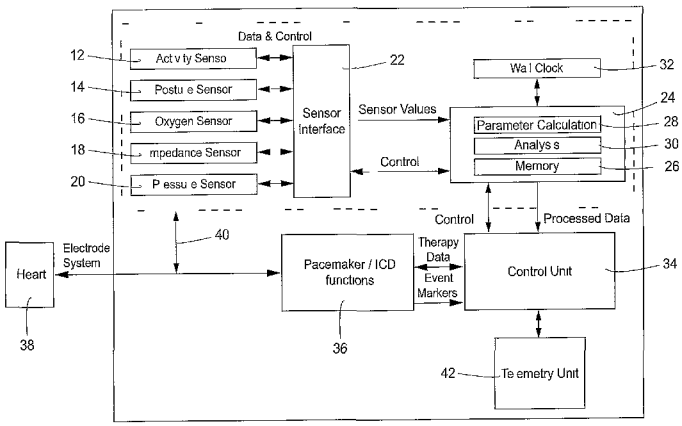
(54) **Title:** DETERMINING THE VARIATION OVER THE TIME OF A MEDICAL PARAMETER OF A HUMAN BEING



(57) **Abstract:** An apparatus for determining variation over time of a medical parameter of a human being obtained from a sensed signal comprises a sensor (12, 14, 16, 18, 20) implantable in the human being for sensing the signal A comparing means (8, 30) compares at least one characteristic property, deπved from the sensed signal obtained for at least one predetermined first level of activity of the human being, with corresponding reference property of a sensed reference signal, obtained for a predetermined reference level of activity of the human being, for determining a relation between the characteristic property of the sensed signal and the reference property Trend determining means (10, 30) determine trends in the medical parameter by analysing the relation between the characteristic property of the sensed signal obtained at different times and the reference property A corresponding method is also disclosed, as well as an implant for heart failure diagnostics comprising an apparatus as described A sensor (12, 14, 16, 18, 20) is then arranged to pick up dynamic mechanical information from the heart of the human being and generate a corresponding signal A heart stimulator compπses such an implant and a control means (34) arranged to control stimulation of the heart depending on determined trends in the medical parameter

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DETERMINING THE VARIATION OVER TIME OF A MEDICAL PARAMETER OF A HUMAN BEING

Technical Field

The present invention relates to an apparatus and a method for determining variation over time of a medical parameter of a human being. The invention also relates to an implant for heart failure diagnostics comprising such an apparatus as well as a heart stimulator including such an implant to be used for controlling the stimulation.

Background

The progress of medical parameters over time needs to be closely monitored to minimize patient pain, discomfort and hospitalization. Thus, as an example, for this purpose the progress of the cardiac function must be closely monitored over time as the cardiac failure condition changes.

An example of long term monitoring of a medical parameter is disclosed in US 5 792 197. An implantable rate responsive pacemaker uses a physiological demand parameter to classify the patient's degree of congestive heart failure. The parameter is monitored for extended time periods to determine the levels for this parameter for different levels of physical activity of the patient.

Implantable sensors are most often incapable of sensing static information. The signal can be described as being dynamic. Due to this, it is of particular interest to be able to retrieve information for long term monitoring from dynamic sensor signals obtained from implanted sensors.

The purpose of the present invention therefore is to propose a technique for determining variations over time - trending - of a medical, diagnostic parameter obtained from the sensed dynamic signal of an implanted sensor.

Disclosure of the Invention

This purpose is obtained by a apparatus according to claim 1 and a method according to claim 22.

Since some implanted dynamic sensors do not pick up any absolute signal magnitudes, i.e. no DC signal, but only variations in the signal, i.e. AC

signals, some sort of pseudo-zero-level or pseudo-reference must be created for the comparisons from time to time needed for the trend analysis as specified in the above mentioned claims. The relations determined between characteristic properties of the sensor signal at the first level of activity and the reference level of activity of the patient can be stored and displayed at follow-up or distributed continuously to a central diagnostic unit of a hospital for evaluation.

According to advantageous embodiments of the invention the implantable sensor is a piezoelectric pressure sensor. In his sensor, which is primarily intended for cardiac use, the indifferent electrode lead is coated by piezoelectric material, such that the output signal of the sensor contains both electric and pressure information. The dynamic pressure information includes several components and information of interest can be retrieved by suitable filtering.

The reference signal is sensed for a predetermined reference level of activity of the patient in question. The term activity in this context includes both actual physical activity of the patient and his or her body position or posture. In principle any well-defined level of activity of the patient can be used as reference level of activity, e.g. the human being lying down resting or being at maximum activity. However, according to an advantageous embodiment of the apparatus according to the invention the predetermined reference level of activity of the patient is a situation of minimum activity. It is particularly suitable to use the signal sensed during night- time when the patient is at sleep as reference signal, because posture changes during night-time do not cause problems as the reference signal can be averaged over some time with the patient at sleep. In its simplest form this can be realized by a clock-triggered analysis, for instance between 00.00 and 02.00 am. In a more advanced solution combined informations from a clock, activity and posture sensors can be used for reference signal determination.

According to still another advantageous embodiment of the apparatus according to the invention the comparing means is arranged to determine relations between the characteristic property of the sensed signal and the reference property for more than one different level of activity of the human being, and the trend determining means is arranged to determine trends in the medical parameter

by analysing the relations obtained for more than one different level of activity. In this way the quality of the trending analysis is improved.

According to yet another advantageous embodiment of the apparatus according to the invention an averaging means is provided to form an average reference signal measured during a certain time period for the reference level of activity of the human being for determining the reference property from the average reference signal. The reference signal can be averaged over long time periods, e.g. months or even years. In this way the influence from temporary disturbances in the reference signal is reduced.

According to another advantageous embodiment of the apparatus according to the invention activity and posture sensors are provided to determine the levels of activity of the patient. As mentioned above the term "activity" includes in this context both true physical activity of the patient as well as his or her posture.

According to still another advantageous embodiment of the apparatus according to the invention calculating means is provided to form the root-mean-square of the sensed signal, viz. the effect in the signal, as the characteristic property.

According to yet another advantageous embodiment of the apparatus according to the invention a frequency analyzer is provided to determine major and/or secondary frequencies of the sensed signal as characteristic properties. Frequencies of the fundamental tone and one or more harmonics are then determined, and/or the amplitudes of these tones or harmonics. Also the quotient between e.g. frequencies of the fundamental tone and the first harmonics or the quotient between corresponding amplitudes can be used as characteristic property of the signal.

According to other advantageous embodiments of the apparatus according to the invention a loop creator is connected to two units arranged to determine two different quantities of the sensed signal for plotting related values of the quantities against each other to form a loop for each signal period, and a comparator is connected to the loop creator for comparing the loop with a loop template calculated from the reference signal. One of these quantities can be the signal itself, received from the sensor, and the other one the time derivative of the sensed signal formed by a differentiating means. As characteristic property of the

signal can then be chosen e.g. area within the loop, number of turn-arounds in the loop per signal period, the length of the radius to a point on the loop contour corresponding to a specific point in the signal time period, or the angle which this radius forms to an axis of a loop coordinate system.

According to still another advantageous embodiment of the apparatus according to the invention an alerting means is arranged to be triggered in response to a change in the reference property exceeding a predetermined limit within a predetermine time. Thus if a sufficiently large change is detected in the reference property from e.g. one data collection point to another, this is reported for checking or evaluation, especially if this phenomenon is repeated the patient should be called in for a check.

The invention also relates to an implant for heart failure diagnostics comprising an apparatus as discussed above in which the sensor is arranged to pick up dynamic mechanical information from the heart of the patient and generate a corresponding signal, as well as a heart stimulator comprising such an implant and a control means to control stimulation of the heart depending on the determined trends in the medical parameter. Thus by implanting e. g. a piezoelectric sensor or another pressure sensor in the heart of a patient these sensors will pick up dynamic mechanical information which can be used for heart failure diagnostics and heart stimulation control to obtain e. g. true mechanical synchronization, AV- and W-interval optimization in the operation of the heart.

Brief Description of the Drawings

To explain the invention in greater details embodiments of the invention, chosen as examples, will now be described with reference to the drawings, on which figure 1 shows an example of typical qualitative variation of a physiologic parameter of a human being, figure 2 a corresponding sensed signal, figure 3 is a flow chart schematically illustrating the procedure of an embodiment of the invention, figures 4 - 6 illustrate examples of the analysis of sensed signals according to different embodiments of the invention, and figure 7 is a block diagram of an embodiment of the invention implemented in a pacemaker or implantable cardio-defibrillator, ICD.

Description of Preferred Embodiments

Dynamic sensing is of particular interest in the field of medical implants, since the sensor most often needs to be designed according to coarse demands inside the body, thus disabling measurements of static parameters. Figure 1 shows qualitatively the typical variation of a physiologic parameter as a function of time. As appears from the figure the parameter is varying around a certain DC level. A corresponding sensed signal is not available. P-P denotes peak-to-peak.

Figure 2 shows a corresponding sensed dynamic signal. As appears the variation as a function of time is the same as in figure 1, but the used sensor does not pick up the DC component but only the AC component, i.e. the variation information. The sensed signal in figure 2 is consequently varying around the zero line of the diagram.

Trending analysis requires, however, some sort of zero or reference level for the necessary comparison analysis. A pseudo-zero or reference level must therefore be determined.

According to the present invention this pseudo-reference level is obtained from a signal sensed by the implanted sensor for a predetermined situation of the patient. This predetermined situation of the patient includes both a predetermined physical activity and a predetermined body position or posture of the patient. In the following the term "activity" of the patient will include the patient's physical activity as well as his or her posture.

For the determination of the reference level in principal any predetermined activity of the patient, e.g. a minimum or a maximum activity, can be used. In the following preferred embodiment the reference level will be determined for a minimum activity of the patient. The reference level is thus preferably determined in night time, when the patient is asleep. The reference level is then preferably obtained from a sensed reference signal which is averaged over some time with the patient asleep. In this way possible influences from posture changes of the patient in sleep state are minimized.

The easiest way of getting a reference level from an averaged sensed signal is to use a clock-triggered function for this purpose, e.g. for using an averaged sensor signal recorded between 00.00 and 02.00 a.m. The reference

level can, however, be determined by a more advanced analysis, for instance by using information from a clock, activity and posture sensors.

A mean value of reference levels obtained from this averaged detector signal during a plurality of nights, e.g. for total time periods of months or even years, can also be formed. In this way the reference level, which is needed for the relation analysis, will not be lost in a situation of rapidly worsening conditions of the patient.

Figure 3 is a flow-chart illustrating an example of the procedure in the present invention.

In block 2 the reference level is determined from the sensed signal at a minimum activity (rest or sleep), or another predetermined reference activity, of the patient 4.

In block 6 the signal is sensed by the implanted sensor at every-day-activities or predefined activities of the patient. The sensed signal is stored and/or processed at different times during the day. The signal can be acquired from the sensor continuously or on-demand, controlled by the patient 4, physician, or automatically by a device. In the on-demand mode the implant can be awakened by e.g. a communication device.

Patient hand-held communication devices for patient-interactive therapy with an implanted device is previously known, cf. e.g. the system HeartPod, marketed by the company Savacor, for measuring left atrial pressure interactively with the patient. This system also alerts the patient when it is time to measure. A similar system can be used in connection with the present invention too.

An activity sensor can be provided to sense the patient's activity and for a predetermined activity automatically trigger storage or processing of the sensed signal. Alternatively, the predetermined activity can by defined for instance by 5 steps in a staircase for the patient, or the like.

In block 8 characteristic properties derived from sensed signals are compared with corresponding reference properties of sensed reference signals for determining a relation between the characteristic properties of the sensed signals and the reference properties. These relations can be established for presently sensed signals as well as for previously stored signals.

In block 10, finally, trends are determined in a medical parameter related to the sensed signal by analysing the above-mentioned relations between the characteristic properties of the sensed signal and corresponding reference properties over time. The trend is presented to a physician at e.g. follow-up or is transferred to a remote database for diagnostic purposes.

The horisontal axis of the schematically shown coordinate system in block 10 can represent time, and the vertical axis the magnitude of quantity suitable for representing the trend. The arrows in block 10 indicate examples of determined trends.

The characteristic properties of the sensed signals for the subsequent comparison can be derived in different ways.

- The reference signal can be stored as a template to form the reference property with which the sensed signal itself is compared.
- The root-mean-square, viz. the effect of the signal, can be calculated as the characteristic property.
- Two different quantities of the sensed signal can be determined, and a loop creator is provided to plot related quantity values against each other to form a loop for each signal period. An example of such a loop is shown in figure 4. In this example a differentiating means is provided to form the time derivative, d(SS)/dt, of the sensed signal, SS, and the shown loop is formed of related values of d(SS)/dt and SS. Characteristic properties of the signal can then be determined from e.g. the area within the loop, the length of the radius to a specific point A on the loop contour corresponding to a specific time in the signal period, the angle α of the radius to point A, the number of tum-arounds in the loop - two turn-arounds are shown in figure 4 - and the general morphology of the loop. This kind of signal processing has been previously used for other purposes, see e.g. WO 2002/043587.
- The variability of the signal period can be used as characteristic property.
- The major and/or the secondary frequency components of the sensed signal can be used as characteristic properties. Thus the frequencies of the fundamental tone of the signal as well as of its

first harmonics can be determined, or the amplitudes, of these tones.

Relation between characteristic properties of the sensed signal and corresponding reference properties are stored and displayed at follow-up or distributed to a central diagnostic unit at a hospital for evaluation, as explained above. Figures 5 and 6 illustrate two examples of the comparison analysis over time of sensed signal and reference level. The vertical axis represent a quantity corresponding to the signal level.

In figure 5 signals DS are sensed for one defined activity level of the patient. The reference level, which is an average value of DS during a certain time period of substantially constant level of activity of the patient, is denoted by PZDS, represented by the first bar to the left in the figure. Signals situated within an acceptance interval around PZDS are considered as normal according to preset criteria. For a couple of days, Day 1, Day 2, etc. the sensed signal DS is within the acceptance interval. Then a sensed signal DS appears, the sectioned bar, which significantly exceeds the upper limit of the acceptance interval. This event is highlightened for subsequent observations. Thereafter sensed signals follow which fall within the acceptance interval.

Figure 6 illustrates an example of the comparison analysis in a situation where signals are sensed for two different predefined levels of activity, Activity level 1 and Activity level 2, of the patient. In this case the inter-relation levels (DS-X_{n+}i) - (DS-X_n) is trended, DS-X_n denoting the signal at period X and activity level number n. Thus DS-Ai denotes the signal for activity level 1 in period A, DS-A_2 the signal for activity level 2 in period A, DS-Bi the signal for activity level 1 in period B, etc. In this example the situation is considered as "normal", provided the criterion (DS-Xi)<(DS-X_2) is fulfilled. From the figure it appears that this criterion is satisfied for Period A and Period B but not for Period C which event is consequently highlighted for evaluation.

Figure 7 is a block diagram of an implantable pacemaker or ICD provided with an apparatus according to the invention, located within the dashed line in the figure.

A plurality of different, implantable sensors can be used in the present invention, viz. an activity sensor 12, a posture sensor 14, an oxygen sensor 16, an impedance sensor 18 and a pressure sensor 20. One or more of the sensors are

connected through a sensor interface 22 to a signal processing, calculating and analysing device 24. Signals or sensor values from the sensor 12, 14, 16, 18, 20 are supplied to the device 24 for storing in a memory 26 for subsequent use or processed and supplied to a calculation unit 28 for calculation of one or more characteristic properties. The calculated characteristic properties can be supplied to the analysis unit 30 for establishing a relation to a stored reference property and comparing this relation with stored relations, obtained from previous measurements for determining trends in a medical parameter related to the sensed signal. Alternatively, the calculated characteristic properties can be stored in the memory 26 for later trending analysis.

A clock 32 is connected to the device 24 for setting the time for e. g. reading, through the sensor interface 22, sensed values to the device 24 for processing and analysis. The clock can also control the time for the trending analysis based on stored data. In case of time averaging of the sensed signal the clock 32 controls the period for the averaging, and the clock 32 also controls the transfer of trend data to the control unit 34 for the pacemaker or ICD 36.

The control unit 34 controls the therapy, i. e. the cardiac stimulation delivered by the pacemaker 36 via electrodes implanted in a patient's heart 38 by exchange of theraphy data between control unit 34 and pacemaker 36.

The arrow 40 indicates that the sensors are preferably connected to the patient's heart 38 through the pacemaker electrode system

Detected cardiac event markers are transferred to the control unit 34 and there is a feedback from the control unit 34 to the processing and analyzing device 24.

A telemetry unit 42 is provided for reading out data from the trending analysis at follow-up or for transfer to a central diagnostic station for evaluation. Also theraphy data and other information can be communicated by this unit between the implant and external equipments.

CLAIMS

1. An apparatus for determining variation over time of a medical parameter of a human being obtained from a sensed signal, comprising a sensor (12, 14, 16, 18, 20) implantable in the human being for sensing said signal, a comparing means (8, 30) for comparing at least one characteristic property derived from said sensed signal, obtained for at least one predetermined first level of activity of the human being, with corresponding reference property of a sensed reference signal, obtained for a predetermined reference level of activity of the human being, for determining a relation between said characteristic property of said sensed signal and said reference property, and trend determining means (10, 30) for determining trends in said medical parameter by analysing said relation between the characteristic property of said sensed signal obtained at different times and said reference property.

2. The apparatus according to claim 1, **characterized in** that said sensor is a pressure sensor (20).

3. The apparatus according to claim 1, **characterized in** that said sensor is a piezoelectric sensor sensing mechanical activity.

4. The apparatus according to any one of the preceding claims, **characterized in** that said predetermined reference level of activity of the human being is a situation of a minimum activity.

5. The apparatus according to any one of the preceding claims, **characterized in** that a data storing means (26) is provided for storing signal values sensed at different times for said at least one predetermined level of activity of the human being.

6. The apparatus according to any one of the preceding claims, **characterized in** that said comparing means (8, 30) is arranged to determine relations between said characteristic property of said sensed signal and said reference property for more than one different level of activity of the human being, and in that said trend determining means is arranged to determine trends in said medical parameter by analysing said relations obtained for more than one different level of activity.

7. The apparatus according to any one of the preceding claims, **characterized in** that an averaging means is provided to form an average reference signal measured during a certain time period for said reference level of activity of the human being for determining said reference property from said average reference signal.

8. The apparatus according to any one of the preceding claims, **characterized in** that activity and posture sensors (12, 14) are provided to determine said levels of activity of the human being.

9. The apparatus according to any one of the preceding claims, **characterized in** that said reference property comprises the sensed reference signal itself stored as a reference template.

10. The apparatus according to any one of the claims 1 - 8, **characterized in** that a calculating means is provided to form the root-mean-square of the sensed signal as said characteristic property.

11. The apparatus according to any one of the claims 1 - 8, **characterized in** that a signal analyzor is provided to determine peak-to-peak values of the sensed signal as said characteristic properties.

12. The apparatus according to any one of the claims 1 - 8, **characterized in** that a frequency analyzor is provided to determine major and/or secondary frequencies of the sensed signal as said characteristic properties.

13. The apparatus according to any one of the claims 1 - 8, **characterized in** that a differentiating means is provided to form the time derivative of the sensed signal as said characteristic property.

14. The apparatus according to any one of the claims 1 - 8, said sensed signal being periodic, **characterized in** that a loop creator is connected to two units arranged to determine two different quantities of the sensed signal for plotting related values of said quantities against each other to form a loop for each signal period, and in that a comparator is connected to said loop creator for comparing said loop with a loop template calculated from said reference signal.

15. The apparatus according to claim 14, **characterized in** that one of said quantities is the sensed signal itself and the other one the time derivative of the sensed signal.

16. The apparatus according to claim 14 or 15, **characterized in** that said characteristic property corresponds to an area within the loop.

17. The apparatus according to claim 14 or 15, **characterized in** that said characteristic property corresponds to the length of the radius to a specific point on the loop contour corresponding to a specific time in the signal period.

18. The apparatus according to claim 14 or 15, **characterized in** that said characteristic property corresponds to the angle which the radius to a specific point on the loop contour corresponding to a specific time in the signal period forms to an axis of a loop coordinate system.

19. The apparatus according to claim 14 or 15, **characterized in** that said characteristic property corresponds to the number of turn-arounds of the loop during a signal period.

20. The apparatus according to claim 14 or 15, **characterized in** that said characteristic property corresponds to the general morphology of the loop.

21. The apparatus according to any one of the preceding claims, **characterized in** that an alerting means is arranged to be triggered in response to a change in said reference property exceeding a predetermined limit within a predetermined time.

22. A method for determining variation over time of a medical parameter of a human being obtained from a sensed signal, comprising the steps of sensing said signal by a sensor implantable in the human being, comparing at least one characteristic property, derived from said sensed signal for at least one predetermined first level of activity of the human being, with a corresponding reference property of a sensed reference signal, obtained for a predetermined reference level of activity of the human being, for determining a relation between said characteristic property of said sensed signal and said reference property, and determining trends in said medical parameter by analysing said relation between said characteristic property of said sensed signal obtained at different times and said reference property.

23. The method according to claim 22, **characterized in** that said reference level of activity of the human being is a situation of a minimum activity.

24. The method according to claims 22 or 23, **characterized in** that signal values sensed at different times for said at least one predetermined activity of the human being are stored.

25. The method according to any one of the claims 22 - 24, **characterized in** that relations between said characteristic property of said sensed signal and said reference property are determined for more than one different level of activity of the human being, and in that trends in said medical parameter are determined by analysing said relations obtained for more than one different level of activity.

26. The method according to any one of the preceding claims, **characterized in** that an average value is formed of the reference signal measured during a certain time period for said reference level of activity of the human being, and in that said reference property is determined from the average reference signal.

27. The method according to any one of the claims 22 - 26, **characterized in** that activity and posture of the human being are sensed to determine said levels of activity of the human being.

28. The method according to any one of the claims 22 - 27, **characterized in** that the sensed reference signal itself is stored as a reference template.

29. The method according to any one of the claims 22 - 27, **characterized in** that root-mean-square of the sensed signal is formed as said characteristic property.

30. The method according to any one of the claims 22 - 27, **characterized in** that peak-to-peak values of the sensed signal are determined as said characteristic properties.

31. The method according to any one of the claims 22 - 27, **characterized in** that major and/or secondary frequencies of the sensed signal are determined as said characteristic properties.

32. The method according to any one of the claims 22 - 27, **characterized in** that the time derivative of the sensed signal is formed as said characteristic property.

33. The method according to any one of the claims 22 - 27, said sensed signal being periodic, **characterized in** that two different quantities of the

sensed signal are formed for plotting related values of said quantities against each other to form a loop for each signal period, and in that said loop is compared with a loop template calculated from said reference signal.

34. The apparatus according to claim 33, **characterized in** that one of said quantities is the sensed signal itself and the other one the time derivative of the sensed signal.

35. The method according to claims 33 or 34, **characterized in** that said characteristic property corresponds to an area within the loop.

36. The method according to claims 33 or 34, **characterized in** that said characteristic property corresponds to the length of the radius to a specific point on the loop contour corresponding to a specific time in the signal period.

37. The method according to claims 33 or 34, **characterized in** that said characteristic property corresponds to the angle which the radius to a specific point on the loop contour, corresponding to a specific time in the signal period, forms to an axis of a loop coordinate system.

38. The method according to claims 33 or 34, **characterized in** that said characteristic property corresponds to the number of tum-arounds of the loop during a signal period.

39. The method according to claims 14 or 15, **characterized in** that said characteristic property corresponds to the general morphology of the loop.

40. The method according to any one of the claims 22 - 39, **characterized in** that an alarm is triggered in response to a change in said reference property exceeding a predetermined limit within a predetermined time.

41. An implant for heart failure diagnostics, **characterized in** that it comprises an apparatus according to any one of the claims 1 - 21, said sensor (12, 14, 16, 18, 20) being arranged to pick up dynamic mechanical information from the heart of the human being and generate a corresponding signal.

42. The implant according to claim 41, **characterized in** that communication means (42) are provided for triggering, from outside the human being, storage of data obtained from said sensed signal.

43. A heart stimulator, **characterized in** that in that it comprises an implant according to claims 41 or 42, and in that a control means (34) is arranged to control stimulation of the heart depending on determined trends in said medical parameter.

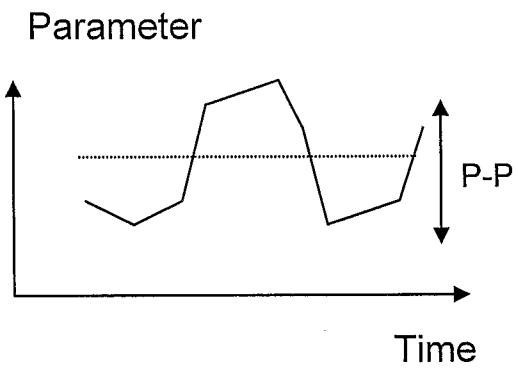


Fig. 1

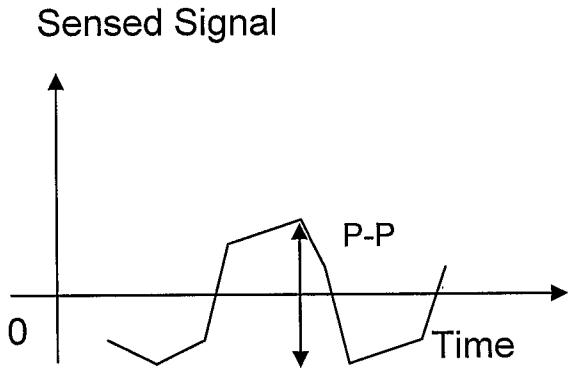


Fig. 2

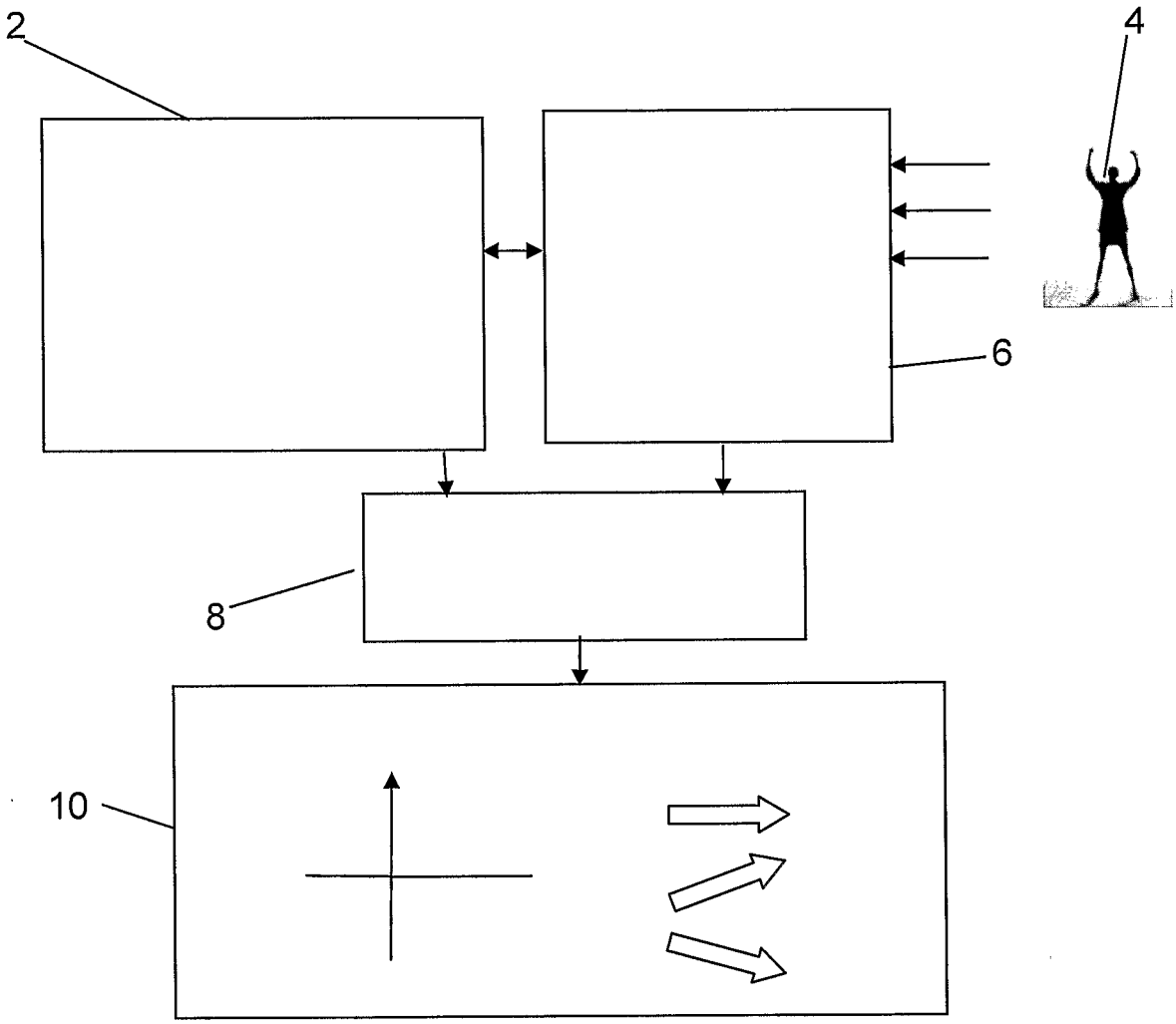


Fig. 3

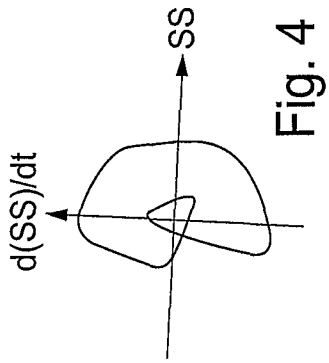


Fig. 4

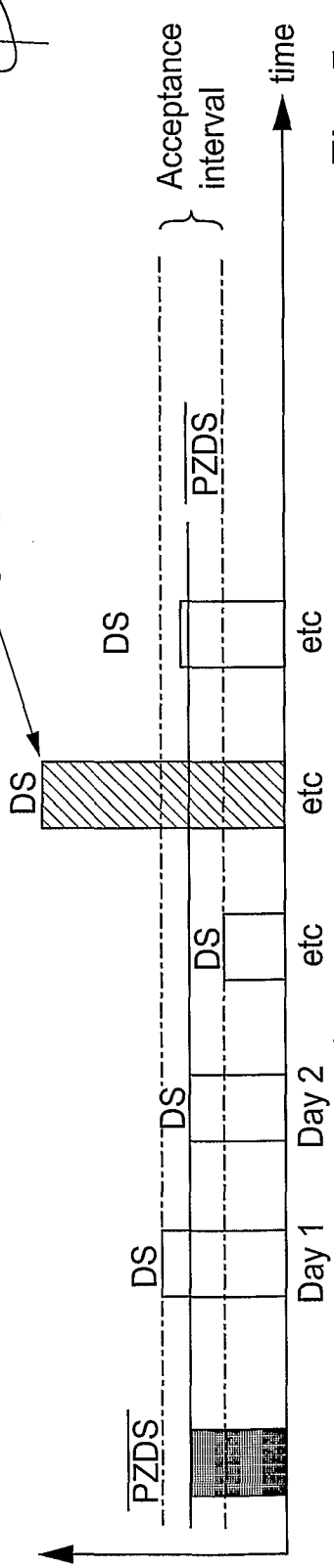


Fig. 5

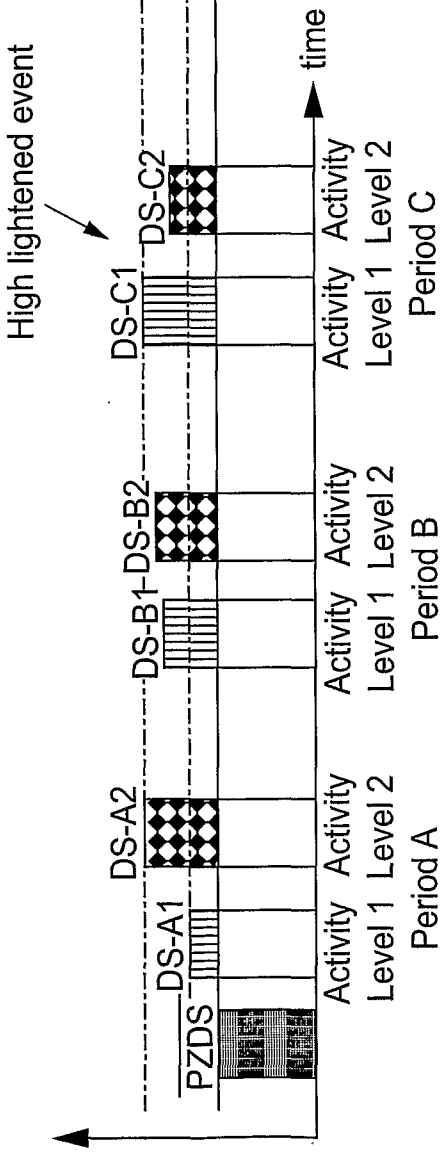
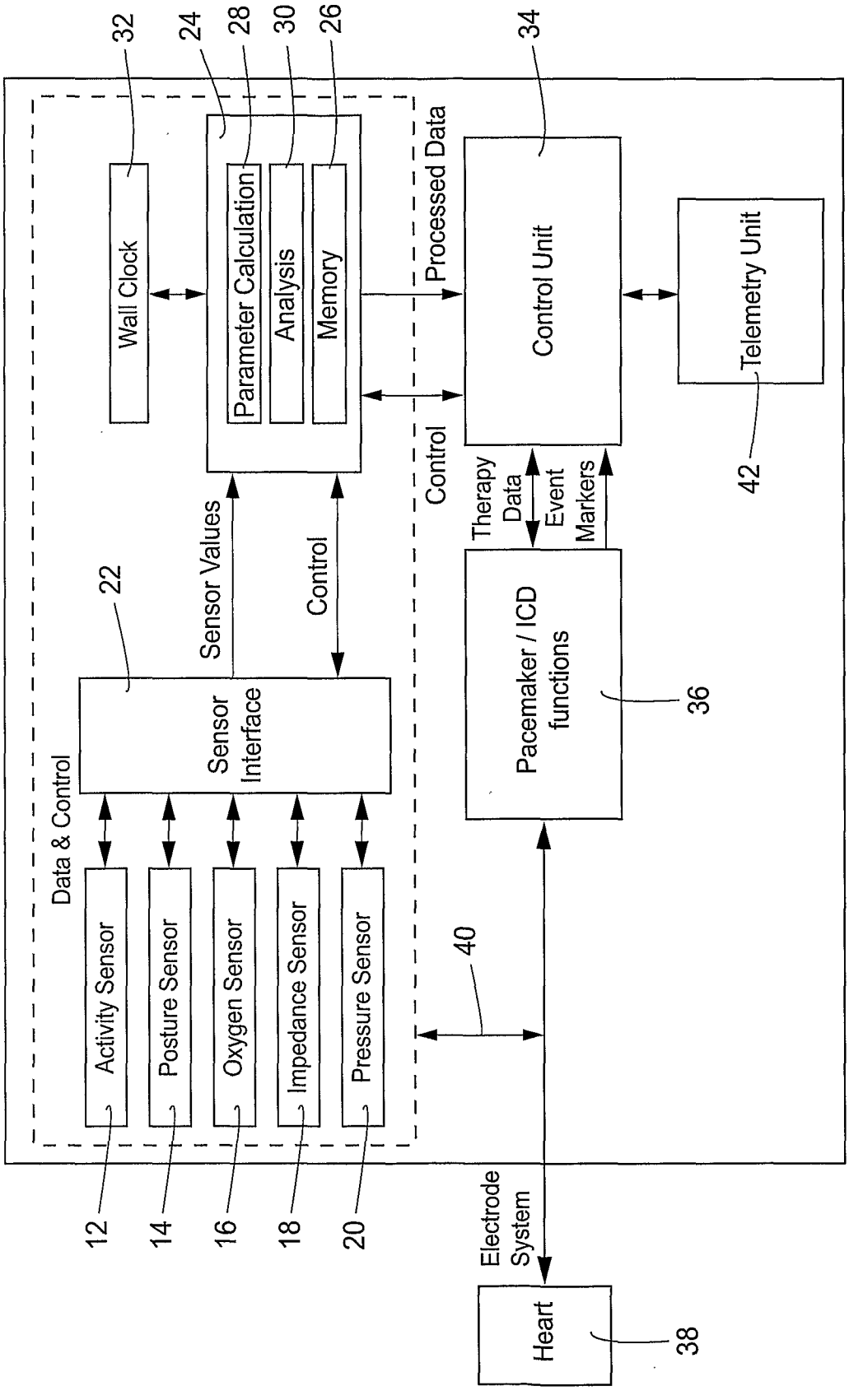


Fig. 6


Data & Control
Activity Sensor
Posture Sensor
Oxygen Sensor
Impedance Sensor
Pressure Sensor
Sensor Interface
Sensor Values
Control
Wall Clock
Parameter Calculation
Analysis
Memory
Processed Data
Control
Control Unit
Telemetry Unit
Therapy Data
Event Markers
Pacemaker / ICD functions
Electrode System
Heart
12
14
16
18
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22
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Fig. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2006/000985

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: G01N, G06F

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1595574 A1 (PACESETTER, INC.), 16 November 2005 (16.11.2005), paragraphs (0001),(0025), (0028)-(0030),(0038),(0055),(0060)-(0066) --	1-43
X	WO 2005102451 A1 (ST JUDE MEDICAL AB), 3 November 2005 (03.11.2005), page 2, line 9 - page 4, line 12 --	1-43
X	US 20050137489 A1 (JACKSON ET AL), 23 June 2005 (23.06.2005), paragraphs (0011),(0012),(0025), (0026),(0033)-(0037) --	1-43

[X] Further documents are listed in the continuation of Box C. [X] 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 oft prionty claun(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 pnority 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 invenUve 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	Date of mailing of the international search report
24 April 2007	26 -04- 2007
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 Henrïk Eriksson / JA A Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (April 2007)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2006/000985

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 20050124900 Al (STADLER ET AL), 9 June 2005 (09.06.2005), abstract	1-43

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International patent classification (IPC)

A δlN 1/365 (2006.01)

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- e-tjanster/anf δrda dokument (service in Swedish).

Use the application number as username.
The password is **LPNUVXBPFY.**

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

International application No.
PCT/SE2 0 0 6 / 0 0 0 9 8 5

Box No. π Observations where certain claims were found onsearcbable (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.: 2 2 - 4 0
because they relate to subject matter not required to be searched by this Authority, namely:

See extra sheet .

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. Ill 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. r~j 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 effortjustifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] AS only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

r] 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.

International application No.
PCT/SE2006/000985

Box II.1

Claims 22-40 relate to a method of treatment of the human or animal body by surgery or by therapy, as well as diagnostic methods /Rule 39.1(iv). Nevertheless, a search has been executed for these claims. The search has been based on the alleged effects of the compound(s) /product/device.

EP	1595574	A1	16/11/2005	US	7171271	B	30/01/2007
				US	20050256545	A	17/11/2005
WO	2005102451	A1	03/11/2005	EP	1740266	A	10/01/2007
				US	20060149327	A	06/07/2006
US	20050137489	A1	23/06/2005	EP	1703945	A	27/09/2006
				WO	2005056107	A	23/06/2005
US	20050124900	A1	09/06/2005	EP	1694201	A	30/08/2006
				WO	2005055823	A	23/06/2005