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(54) **Heart monitoring system**

Herzüberwachungssystem

Système de surveillance cardiaque

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Description

[0001] The invention relates to a heart monitoring system comprising an implantable medical device, an external transceiver device and a service center.

[0002] The implantable medical device preferably is an implantable pacemaker or an implantable cardioverter/defibrillator (ICD) or a combination of both (CRT-D).

[0003] Some patients having an implantable pacemaker or an implantable cardioverter/defibrillator eventually suffer from decompensation. Decompensation needs to be detected and to be treated.

[0004] US patent application US 2006/0010090 A1 discloses a system where a plurality of implantable and external sensors, in combination with information from various databases are connected to an expert system to detect such decompensation.

[0005] The detection of decompensation of CRT patients with lung edema sensor (detection of offset of the DC-impedance versus baseline) lacks of specificity (personal reports from many physicians). Several patents exists which describes that combination of additional parameters (HRV, breathing, HR) with the DC impedance offset may increase specificity.

[0006] If decompensation in CRT patients are detected (e.g. with lung edema sensor (DC offset via impedance) or combination of additional parameters (HRV, breathing, HR), then the physician needs to react and change CRT therapy.

[0007] US 6,512,949 discloses a device that changes CRT therapy or activates drug pump automatically. This keeps the physician out of the loop for feedback and therapy control.

[0008] It is an object of the invention to provide a heart monitoring system that allows an improved detection of and response to decompensation.

[0009] It is proposed to use central service center as integral part of the problem solving. Instead of fixed threshold values/algorithms in the device the data of several indicators for CHF status are sent to the service center preferably once a day. The parameters that serve as indicators and that are to be transferred and monitored include:

- (1) DC thoracic impedance from lead combination 1 and its changes.
- (2) DC thoracic impedance from lead combination 2 and its changes.
- (3) heart rate variability and its changes
- (4) heart rate at rest
- (5) heart rate during exercise.
- (6) activity level
- (7) VES per h
- (8) breathing rate
- (9) tidal volume
- (10) weight
- (11) (12) parameters from at least another sensor (contractility of the heart, pressure, temperature)
- (13) diet

[0010] The service center stores the data. Furthermore, the service center provides trends of the data in one graph or more graphs to allow visual inspection of the trends, changes of trends, and the timely coincidence of changes in the trends. A user interface being connected to the service center or being part of the service center is adapted to allow the physician to set for each trend its own, patients customized trigger criteria. The trigger criteria may include offset versus baseline or slope (positive and negative) or others.

[0011] The user interface is adapted so that the physician can set trigger combination and its timely coincidence to receive alarm (via e-mail or otherwise); e.g. only by increase of both impedance vectors by x% and decrease of activity level by y% and increase of breathing rate by z% the service center triggers a decompensation alarm: "alarm - potential decompensation".

[0012] The service center and the user interface are adapted to interact such that

- the user receives a set of standard triggers/trigger combination by the service center that is stored in the service center
- the user can store its own trigger logic and apply it to other patients
- a supervisor can collect the data of trigger logic from all patients and all users (physicians) and generated there from an improved set standard trigger criteria

[0013] The following features may be provided:

- Additional data is collected from outside sensors
- Weight is determined via a scale which sends weight data to the service center

- blood pressure data is collected via manual or automatic measurements and the results are send to the service center
- Diet information data is determined via barcode in a refrigerator and is send to the service center
- Duration of daily exercise (treadmill reports duration/speed/activity level) are transmitted to the service center

5 **[0014]** Preferably the collected data is transmitted daily to the service center to allow trends with the same time basis.
[0015] The data evaluation module preferably is adapted to trend the data with one datapoint per day for each trend.
[0016] Regarding embodiments of the data evaluation module and the user interface and their interaction it is further preferred that they are adapted to allow

- 10 • a user to be able to activate / deactivate trigger for each trend (absolute value, positive/negative slope, duration of increase, 30 day line (to compensate for biological variations), 7 day line)
 • a user to be able to combine trigger to trigger logic comprising a combination of trigger criteria to be met
 • definition of a timely coincidence of triggers ("within 2 days")
 • a display of data wherein graph-lines changes colors for each trend separately if trigger is not reached ("green")
 15 versus trigger is reached ("red")
 • a display of data wherein a graph background changes colors for times for which the trigger logic was giving alarm ("alarm background")

[0017] the service center is adapted to indicate a decompensation via a user interface connected to the service center
 20 and to allow the physician to initiate therapy changes actively via several remote activities including:

- Change of CRT parameters (e.g. % LV pacing was seen to be insufficient, then AVD would be adapted) via remote programming via the user interface
- Change of diet via telephone call to the patients
- 25 • Change of medication (Lasix) via telephone call to the patients
- Change of medication (Lasix) via remote programming of a drug pump using the user interface of the service center.

[0018] Further, a feedback channel from an individual patient to the physician may be provided that allows for a feedback whether a therapy change was successful or not.

30 **[0019]** The invention is defined in claim 1.

[0020] The above and other aspects, features and advantages of the present invention will be more apparent from the following more particular description thereof, presented in conjunction with the following drawings wherein:

35 FIG. 1 is a schematic overview over a heart monitoring system comprising an implantable medical device, an external transceiver device and a service center.

FIG. 2 shows a three chamber bi-ventricular implantable cardioverter/defibrillator (ICD).

FIG. 3 is a schematic diagram of the device modules of the ICD of figure 3.

40 FIG. 4 is a schematic diagram of the service center.

[0021] The following description is of the best mode presently contemplated for carrying out the invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of describing the general principles of the invention. The scope of the invention should be determined with reference to the claims.

45 **[0022]** Figure 1 shows an implantable device system comprising an implantable medical device 10, an external transceiver device 80 and a central service center 90. The implantable medical device 10 is for example an implantable pacemaker or an implantable cardioverter/defibrillator or a combination of both. The implantable medical device 10 comprises an implant transceiver for wireless communication with the external transceiver device 80. The external
 50 transceiver device 80 comprises an external transceiver unit (not shown) for wireless communication with the implant transceiver unit and a data communication interface (also not shown) adapted to allow a data communication with the service center 90. The data communication interface preferably is adapted to use a public data communication line as a telephone landline connection or wireless connection via GPRS or SMS or bluetooth.

55 **[0023]** The central service center 90 comprises or is connected to a user interface allowing a physician or a team of physicians to interact with the central service center. The user interface may comprise a display for displaying data to the physician 100 and some input device allowing the physician 100 to enter instructions or data into the central service center 90. The central service center 90 further comprises a central data base that is connected to said data communication interface (see figure 4) and a data evaluation module that is connected to the data base that is adapted to evaluate

data stored and said data base.

[0024] In figure 2 the implantable medical device is a three chamber biventricular pacemaker and cardioverter/defibrillator 10 that is connected to pacing/sensing leads placed in a heart 12 is illustrated.

[0025] As shown in figure 2, the preferred embodiment is to couple the disclosed technology with an implantable bi-ventricular defibrillator.

[0026] The implantable medical device 10 is electrically coupled to heart 12 by way of leads 14, 16 and 30.

[0027] Lead 14 is a right atrial electrode lead that has a pair of right atrial electrodes 22 and 24 that are in contact with the right atria 26 of the heart 12.

[0028] Lead 16 is a right ventricular electrode lead that has a pair of ventricular stimulation and sensing electrodes 18 and 20 that are in contact with the right ventricle 28 of heart 12. Further, a ventricular defibrillation shock coil 38 and an atrial defibrillation shock coil 40 are arranged on lead 16.

[0029] Electrodes 22 and 18 are tip electrodes at the very distal end of leads 14 and 16, respectively. Electrode 22 is a right atrial tip electrode RA Tip and electrode 18 is a right ventricular tip electrode. Electrodes 24 and 20 are ring electrodes in close proximity but electrically isolated from the respective tip electrodes 22 and 18. Electrode 24 forms a right atrial ring electrode RA Ring and electrode 20 forms a right ventricular ring electrode RV Ring. Atrial cardioversion shock coil 40 is a coil electrode providing a relatively large geometric area when compared to the stimulation electrodes 18, 20, 22 and 24.

[0030] Lead 30 is a left ventricular electrode lead passing through the coronary sinus of heart 12 and having a left ventricular ring electrode LV RING 32 a left ventricular tip electrode LV TIP 34. Further, a left ventricular defibrillation shock coil 36 is arranged on lead 30.

[0031] Implantable medical device 10 has a case 42 made from electrically conductive material such as titanium that can serve as a large surface electrode IMD CASE.

[0032] The plurality of electrodes 18, 20, 22, 24, 32, 34, 36, 38 and 40 connected to implantable medical device 10 together with case 42 allow for a number of different electrode configurations for measuring intrathoracic and intracardiac impedance.

[0033] The forcing function for intrathoracic impedance measurement preferably is sourced via the right ventricular or a left ventricular ring electrode and the current sink would be the implantable medical device's case. Measurement of the response function preferably is carried out between a right ventricular tip electrode and the implantable medical device's case or a left ventricular tip electrode and the implantable medical device's case.

[0034] For intracardiac impedance measurements, injecting a forcing function from a right ventricular ring electrode to a right ventricular tip electrode and measuring a response function between a left ventricular ring electrode and a left ventricular tip electrode is preferred.

[0035] Further possible electrode configurations for application of the forcing function and measurement of the response function become apparent from the following table:

Diagnostic Value	Polarity	Forcing contacts	Response contacts
Primary	Tripolar	RV Ring to Case	RV Tip to Case
Primary	Tripolar	LV Ring to Case	LV Tip to Case
Primary	Bipolar	RV Coil to Case	RV Coil to Case
Primary	Bipolar	LV Coil to Case	LV Coil to Case
Secondary	Quadrupolar #1	LV Ring to RV Ring	LV Tip to RV Tip
Secondary	Quadrupolar #2	RV Ring to RV Tip	LV Ring to LV Tip
Secondary	Tripolar	RV Ring to LV Ring	RV Tip to LV Ring
Secondary	Tripolar	RV Ring to LV Tip	RV Tip to LV Tip
Secondary	Tripolar	LV Ring to RV Ring	LV Tip to RV Ring
Secondary	Tripolar	LV Ring to RV Tip	LV Tip to RV Tip
Secondary	Bipolar	RV Ring to LV Ring	RV Ring to LV Ring
Secondary	Bipolar	RV Tip to LV Tip	RV Tip to LV Tip
Secondary	Bipolar	RV Ring to LV Tip	RV Ring to LV Tip
Secondary	Bipolar	RV Tip to LV Ring	RV Tip to LV Ring

[0036] Referring to figure 3 a simplified block diagram of an implantable medical device 10 is illustrated. During operation of the pacemaker leads 14 and 16 are connected to respective output/input terminals of pacemaker 10 as indicated in figure 2 and carry stimulating pulses to the tip electrodes 18 and 22 from an right atrial stimulation pulse generator RA-STIM in a right atrial sense / pace stage 56 and a right ventricular pulse generator RV-STIM in a right ventricular sense / pace stage 50, respectively. Further, electrical signals from the atrium are carried from the electrode pair 18 and 20, through the lead 14, to the input terminal of an right atrial channel sensing stage RA-SENS in 56; and electrical signals from the right ventricle are carried from the electrode pair 22 and 24, through the lead 16, to the input terminal of a right ventricular sensing stage RV-SENS in 50.

Left ventricular stimulating pulses are carried to the ring electrode 32 and the tip electrode 34 from a left ventricular pulse generator LV-STIM in the left ventricular sense / pace stage 52. Electrical signals from the left ventricle are carried from the electrode pair 32 and 34 to the input terminal of the left ventricular sensing stage RV-SENS in 52. Controlling the implantable medical device 10 is a control unit CTRL 54 that is connected to sensing stages A-SENS and V-SENS and to stimulation pulse generators A-STIM and V-STIM. Control unit CTRL 54 receives the output signals from the atrial sensing stage A-SENS and from the ventricular sensing stage V-SENS. The output signals of sensing stages A-SENS and V-SENS are generated each time that a P-wave representing an intrinsic atrial event or an R-wave representing an intrinsic ventricular event, respectively, is sensed within the heart 12. An As-signal is generated, when the atrial sensing stage A-SENS detects a P-wave and a Vs-signal is generated, when the ventricular sensing stage V-SENS detects an R-wave.

[0037] From a sequence of sensed R-waves control unit 54 can determine an intrinsic heart rate that is used for decompensation detection.

[0038] Control unit CTRL 54 also generates trigger signals that are sent to the atrial stimulation pulse generator A-STIM and the ventricular stimulation pulse generator V-STIM, respectively. These trigger signals are generated each time that a stimulation pulse is to be generated by the respective pulse generator A-STIM or V-STIM. The atrial trigger signal is referred to simply as the "A-pulse", and the ventricular trigger signal is referred to as the "V-pulse". During the time that either an atrial stimulation pulse or ventricular stimulation pulse is being delivered to the heart, the corresponding sensing stage, A-SENS and/or V-SENS, is typically disabled by way of a blanking signal presented to these amplifiers from the control unit CTRL 54, respectively. This blanking action prevents the sensing stages A-SENS and V-SENS from becoming saturated from the relatively large stimulation pulses that are present at their input terminals during this time. This blanking action also helps prevent residual electrical signals present in the muscle tissue as a result of the pacer stimulation from being interpreted as P-waves or R-waves.

[0039] Furthermore, atrial sense events As recorded shortly after delivery of a ventricular stimulation pulses during a preset time interval called post ventricular atrial refractory period (PVARP) are generally recorded as atrial refractory sense event Ars but ignored.

[0040] Control unit CTRL 54 comprises circuitry for timing ventricular and/or atrial stimulation pulses according to an adequate stimulation rate that can be adapted to a patient's hemodynamic need as pointed out below.

[0041] Still referring to figure 3, the implantable medical device 10 includes a memory circuit MEM 56 that is coupled to the control unit CTRL 54 over a suitable data/address bus ADR. This memory circuit MEM 56 allows certain control parameters, used by the control unit CTRL 54 in controlling the operation of the implantable medical device 10, to be programmable stored and modified, as required, in order to customize the implantable medical device's operation to suit the needs of a particular patient. Such data includes the basic timing intervals used during operation of the pacemaker 10 and AV delay values and hysteresis AV delay values in particular.

[0042] Further, data sensed during the operation of the implantable medical device 10 may be stored in the memory MEM 56 for later retrieval and analysis.

[0043] A telemetry circuit TEL 58 is further included in the implantable medical device 10. This telemetry circuit TEL 58 is connected to the control unit CTRL 54 by way of a suitable command/data bus. Telemetry circuit TEL 58 allows for wireless data exchange between the implantable medical device 10 and some remote programming or analyzing device which can be part of a centralized service center serving multiple pacemakers.

[0044] The implantable medical device 10 in figure 3 is referred to as a three chamber pacemaker/cardioverter/defibrillator because it interfaces with the right atrium 26, the right ventricle 28 and the left ventricle of the heart 12. Those portions of the pacemaker 10 that interface with the right atrium, e.g., the lead 14, the P-wave sensing stage A-SENSE, the atrial stimulation pulse generator A-STIM and corresponding portions of the control unit CTRL 54, are commonly referred to as the atrial channel. Similarly, those portions of the pacemaker 10 that interface with the right ventricle 28, e.g., the lead 16, the R-wave sensing stage V-SENSE, the ventricular stimulation pulse generator V-STIM, and corresponding portions of the control unit CTRL 54, are commonly referred to as the ventricular channel.

[0045] In order to be able to detect periods of physical activity of a patient indicating that the patient is awake and in order to allow rate adaptive pacing in a DDDR or a DDIR mode, the pacemaker 10 further includes a physiological sensor ACT 60 that is connected to the control unit CTRL 54 of the pacemaker 10. While this sensor ACT 60 is illustrated in figure 2 as being included within the pacemaker 10, it is to be understood that the sensor may also be external to the

implantable medical device 10, yet still be implanted within or carried by the patient. A common type of sensor is an accelerometer, such as a piezoelectric crystal, mounted to the case of the pacemaker. Other types of physiologic sensors are also known, such as sensors that sense the oxygen content of blood, respiration rate, blood pH, intra-cardiac impedance changes, and the like. The type of sensor used is not critical to the present invention. Any sensor capable of sensing some physiological parameter relatable to physical activity of a patient can be used. Such sensors are commonly used with "rate-responsive" pacemakers in order to adjust the rate of the pacemaker in a manner that tracks the physiological needs of the patient. The output of sensor 48 represents an activity level.

[0046] By means of the output signal of activity sensor 60 the control unit 54 is able to assign each intrinsic heart rate to an activity thus enabling collection of intrinsic heart rate value for a patient's state of rest and a patient's state of exercise separately.

[0047] The control unit CTRL 54 is adapted to determine an adequate heart rate or stimulation rate in any manner known as such.

[0048] For impedance measurement, an impedance determination unit 70 is provided. Impedance determination unit 70 comprises a constant current source 72 that is connected or can be connected to electrodes for intracorporeal placement as shown in figure 2. In order to allow for a plurality of impedance measurement electrode configurations, preferably some means of switching is provided between the constant current source 72 and the electrode terminals of the implantable medical device 10. The switch is not shown in figure 3. Rather, particular impedance measurement configurations are shown as examples.

[0049] Similarly, a impedance measuring unit 74 for measuring a voltage corresponding to a current fed through a body by said constant current source is provided and can be connected to a number of electrodes although a switch for switching between these configurations is not shown in figure 3.

[0050] As an alternative to constant current source 72 a constant voltage source can be provided to generate the forcing function. Then, the measuring unit will be adapted to measure a current strength of a current fed through a body by said constant voltage source.

[0051] Both, constant current source 72 and impedance measurement unit 74, are connected to an impedance value determination unit 76 that is adapted to determine an impedance value for each measuring current pulse delivered by the constant current source 72.

[0052] Further, an impedance measuring control and evaluation unit 78 is provided, that is connected to said impedance measurement unit and that is adapted to evaluate a sequence of consecutive impedance values determined by said impedance measurement unit. Impedance measuring control and evaluation unit 78 comprises a signal generator module (not shown) to construct the intra-cardiac impedance or conductance signal reflecting the time course of the impedance measurement unit's output signal and its derivative,

[0053] Impedance measuring control and evaluation unit 78 further comprises a filter module (not shown) to filter the intra-cardiac impedance signal. Impedance measuring control and evaluation unit 78 comprises is connected to memory 56 and to telemetry unit 58 to allow for storing of impedance data and further evaluation by an external service center.

[0054] Via intracardiac impedance measurement, control unit 54 is able to determine a stroke volume. From the stroke volume and the intrinsic heart rate the control unit calculates the cardiac output by multiplying the stroke volume and the heart rate.

[0055] Via intrathoracic impedance measurement control unit 54 is able to determine a tidal volume and a ventilation rate (breathing rate) in a manner generally known to the skilled person.

[0056] Thus, the control unit 54 collects data representing:

- DC thoracic impedance from said first electrode combination
- DC thoracic impedance from said second electrode combination
- cardiac output
- heart rate variability
- heart rate at a resting state of a patient
- heart rate during exercise of a patient
- activity level of a patient
- ventricular extra systoles (VES) per time unit
- breathing rate
- tidal volume

once a day and initiates transmission of these data via the external transceiver to the central service center 90.

[0057] Figure 4 shows the central service center 90 comprising a data communication interface 92 for communicating with the external transceiver device 80. Connected to the data communication interface 92 is a central data base 94 for storing data representing measurements performed by the implantable medical device 10 and the external transceiver device 80. The central data base 94 is connected to a data evaluation module 96 that is adapted to evaluate data stored

in said data base. The evaluation includes data trending of stored data.

[0058] Connected to the data analysis module is a user interface 98 for displaying data generated by the data analysis module 96 to a user allowing a user to enter instructions or data for controlling the data analysis module 96.

[0059] In addition to the data collected by the implantable medical device 10, the central service center receives data relating to

- weight
- blood pressure
- parameter from at least another sensor (contractility, pressure, temperature) and
- diet

of a patient wearing the implantable medical device 10.

[0060] By the service center, the data is trended in one graph or more graphs to visually inspect trends and the timely coincidence of trends. The user interface 98 is adapted to allow the physician to set for each trend its own, patients customized trigger criteria. The trigger criteria may include offset versus baseline or slope (positive and negative) or others.

[0061] Preferably, the user interface 98 is adapted so that the physician can set trigger combination and its timely coincidence to receive an alarm triggered by the data evaluation module 96 when the trigger criteria are met and the data evaluation module generates a decompensation indicator signal. Then the service center 90 generates a decompensation alarm message that is transmitted to a physician via e-mail or otherwise. E.g. only by increase of both impedance vectors by x% and decrease of activity level by y% and increase of breathing rate by z% the service center triggers a decompensation alarm: "alarm - potential decompensation".

[0062] The service center and the user interface are adapted to interact such that

- the user receives a set of standard triggers/trigger combination by the service center that is stored in the service center
- the user can store its own trigger logic and apply it to other patients
- a supervisor can collect the data of trigger logic from all patients and all users (physicians) and generated there from an improved set standard trigger criteria

[0063] Additional features of the system are:

- Additional data is collected from outside sensors
- Weight is determined via a scale which sends weight data to the service center
- blood pressure data is send to the service center
- Diet information data is determined via barcode in a refrigerator and is send to the service center
- Duration of daily exercise (treadmill reports duration/speed/activity level) are transmitted to the service center

[0064] The data evaluation module trends the data with one datapoint per day for each trend.

[0065] The data evaluation module and the user interface and their interaction are adapted to allow

- a user to be able to activate / deactivate trigger for each trend (absolute value, positive/negative slope, duration of increase, 30 day line (to compensate for biological variations), 7 day line)
- a user to be able to combine trigger to trigger logic comprising a combination of trigger criteria to be met
- a definition of a timely coincidence of triggers ("within 2 days")

[0066] The data evaluation module and the user interface are further adapted to generate

- a display of data wherein graph-lines changes colors for each trend separately if trigger is not reached ("green") versus trigger is reached ("red")
- a display of data wherein a graph background changes colors for times for which the trigger logic was giving alarm ("alarm background")

[0067] Once a potential decompensation is detected the service center 90 indicates a decompensation via the user interface 98 and allows the physician to initiate therapy changes actively via several remote activities including:

- Change of CRT parameters (e.g. % LV pacing was seen to be insufficient, then AVD would be adapted) via remote programming via the user interface
- Change of diet via telephone call to the patients
- Change of medication (e.g. Lasix) via telephone call to the patients

- Change of medication (e.g. Lasix) via remote programming of a drug pump using the user interface of the service center.

[0068] Further, a feedback channel (not shown) from an individual patient to the physician is provided that allows for a feedback whether a therapy change was successful or not.

[0069] Although an exemplary embodiment of the present invention has been shown and described, it should be apparent to those of ordinary skill that a number of changes and modifications to the invention may be made without departing from the scope of the invention. This invention can readily be adapted to a number of different kinds of heart monitoring systems by following the present teachings. All such changes, modifications and alterations should therefore be recognized as falling within the scope of the present invention.

Claims

1. A heart monitoring system comprising an implantable medical device (10) and a service center (90), wherein the implantable medical device comprises
 - a stimulation pulse generator adapted to generate electric stimulation pulses and being connected or being connectable to at least a ventricular stimulation electrode for delivering electric stimulation pulses to at least said ventricle of the heart,
 - a ventricular sensing stage connected or being connectable to an electrode for picking up electric potentials inside at least a ventricle of a heart, said sensing stage being adapted to sense an excitation or a contraction of ventricular myocardium,
 - an activity sensor,
 - an impedance determination unit comprising
 - a constant current source or a constant voltage source having current feed terminals that are connected or can be connected to electrodes for intracorporeal placement and that is adapted to generate sub-threshold measuring current pulses having a constant current strength or a constant voltage, respectively, for causing a current to be fed through a body via intracorporeally placed electrodes,
 - a measuring unit for measuring a voltage corresponding to a current fed through a body by said constant current source or a current strength of a current fed through a body by said constant voltage source, respectively,
 - an impedance value determination unit that is connected to said constant current source or said constant voltage source and the measuring unit that is adapted to determine an impedance value for each measuring current pulse, and,
 - said impedance determination unit being adapted to perform an intrathoracic impedance measurement via a first and a second electrode combination wherein said second electrode configuration is different from said first electrode configuration,
 - a control unit that is connected to said battery, said stimulation pulse generator, said sensing stage, said activity sensor and said impedance determination unit and that is adapted to collect data representing values of:
 - DC thoracic impedance from said first electrode combination
 - DC thoracic impedance from said second electrode combination
 - cardiac output
 - heart rate at a resting state of a patient
 - heart rate during exercise of a patient
 - activity level of a patient
 - ventricular extra systoles (VES) per time unit
 - breathing rate
 - tidal volume
- and
 - an implant transceiver unit communication with the service center and
 - the service center comprises another data communication interface adapted to allow at least an indirect data communication with said implantable medical device and is connected to a central data base and to a user interface, wherein said control unit that is adapted to initiate transmission of said collected data to said data center, said service center further comprises a data evaluation module connected to said data base and adapted to evaluate data stored in said data base wherein said evaluation includes data trending of stored data and

said user interface and said data evaluation module are adapted to allow the physician to set for each data trend trigger criteria for the detection of decompensation and said data evaluation module is further adapted to generate a decompensation indicator signal whenever the trigger criteria are met by the trended data wherein said data evaluation module is further adapted to generate a decompensation indicator signal whenever a combination of trigger criteria are met by the trended data and/or whenever a plurality of trigger criteria are met in a preset timely coincidence, wherein

said data evaluation module is further adapted to generate a decompensation indicator signal if said DC thoracic impedance from said first electrode combination and said DC thoracic impedance from said second electrode combination show a preset increase and activity level shows a preset decrease and said breathing rate shows a preset increase.

2. The heart monitoring system according to claim 1, wherein the heart monitoring system further comprises an external transceiver device said external transceiver device comprises an external transceiver unit for wireless communication with the implant transceiver unit and a data communication interface adapted to allow a data communication with the service center.
3. The heart monitoring system according to claim 1 or 2, wherein said trigger criteria include an offset versus baseline or slope of the trended data as to trigger generation of said decompensation indicator signal whenever said offset is exceeded.
4. The heart monitoring system according to claim 1, wherein user interface is adapted so that a user can set trigger combination and/or its timely coincidence.
5. The heart monitoring system according to one of the preceding claims, wherein said service center is to transmit a decompensation alarm message adapted whenever the data evaluation module generates a decompensation indicator signal.
6. The heart monitoring system according to one of the preceding claims, wherein said implantable medical device is adapted to transmit the collected raw data daily to the service center.
7. The heart monitoring system according to one of the preceding claims, wherein said data evaluation module is adapted to trend the data with one datapoint per day for each trend.
8. The heart monitoring system according to one of the preceding claims, wherein said data evaluation module and said user interface and their interaction are designed to allow a user to be able to activate or deactivate trigger for each trend.
9. The heart monitoring system according to one of the preceding claims, wherein said data evaluation module and said user interface and their interaction are designed to allow a user to be able to combine trigger to trigger logic comprising a combination of trigger criteria to be met.
10. The heart monitoring system according to one of the preceding claims, wherein said data evaluation module and said user interface and their interaction are adapted to generate a display of data wherein graph-lines changes colors for each trend separately if trigger is not reached green versus trigger is reached red
11. The heart monitoring system according to one of the preceding claims, wherein said data evaluation module and said user interface and their interaction are adapted to generate a display of data wherein a graph background changes colors for times for which the trigger logic was giving alarm.
12. The heart monitoring system according to one of the preceding claims, wherein said service center is adapted to indicate a decompensation alarm via said user interface connected to the service center and to allow the physician to initiate therapy changes actively via several remote activities including:
 - Change of pacing parameters via remote programming via the user interface
 - Change of diet via telephone call to a patient
 - Change of medication via telephone call to a patient
 - Change of medication via remote programming of a drug pump using the user interface of the service center.

13. The heart monitoring system according to one of the proceeding claims, further including a feedback channel from an individual patient to the user interface that allows for a feedback whether a therapy change was successful or not.

5 Patentansprüche

1. Herzüberwachungssystem, umfassend eine implantierbare medizinische Vorrichtung (10) und ein Service-Center (90), wobei
 - die implantierbare medizinische Vorrichtung umfasst
 - einen Stimulationsimpulsgenerator, der dazu ausgebildet ist, elektrische Stimulationsimpulse zu erzeugen und an mindestens eine ventrikuläre Stimulationselektrode angeschlossen oder anschließbar ist, um elektrische Stimulationsimpulse an mindestens den Ventrikel des Herzens abzugeben,
 - eine ventrikuläre Erfassungsstufe, die an eine Elektrode zur Aufnahme elektrischer Potenziale im Inneren mindestens eines Ventrikels eines Herzens angeschlossen oder anschließbar ist, wobei die Erfassungsstufe dazu ausgebildet ist, eine Erregung oder Kontraktion des ventrikulären Myokards zu erfassen,
 - einen Aktivitätssensor,
 - eine Impedanzbestimmungseinheit, umfassend
 - eine Konstantstromquelle oder eine Konstantspannungsquelle mit Stromzufuhranschlusssklemmen, die an Elektroden zur intrakorporalen Anordnung angeschlossen oder anschließbar sind und die dazu ausgebildet ist, Messstromimpulse unter einem Schwellenwert mit konstanter Stromstärke beziehungsweise konstanter Spannung zu erzeugen, so dass ein Strom durch einen Körper über intrakorporal angeordnete Elektroden geleitet wird,
 - eine Messeinheit zum Messen einer Spannung, die einem Strom entspricht, der durch einen Körper durch die Konstantstromquelle geleitet wird, beziehungsweise einer Stromstärke eines Stroms, der durch einen Körper durch die Konstantspannungsquelle geleitet wird,
 - eine Impedanzwertbestimmungseinheit, die an die Konstantstromquelle oder Konstantspannungsquelle und die Messeinheit angeschlossen ist, die dazu ausgebildet ist, einen Impedanzwert für jeden Messstromimpuls zu bestimmen, und
 - wobei die Impedanzbestimmungseinheit dazu ausgebildet ist, eine intrathorakale Impedanzmessung über eine erste und eine zweite Elektrodenkombination auszuführen, wobei sich die zweite Elektrodenkonfiguration von der ersten Elektrodenkonfiguration unterscheidet,
 - eine Steuereinheit, die an die Batterie, den Stimulationsimpulsgenerator, die Erfassungsstufe, den Aktivitätssensor und die Impedanzbestimmungseinheit angeschlossen ist und dazu ausgebildet ist, Daten zu sammeln, die folgende Werte darstellen:
 - thorakale Gleichstromimpedanz von der ersten Elektrodenkombination
 - thorakale Gleichstromimpedanz von der zweiten Elektrodenkombination
 - Herzleistung
 - Herzfrequenz im Ruhezustand eines Patienten
 - Herzfrequenz während des Trainings eines Patienten
 - Aktivitätsniveau eines Patienten
 - ventrikuläre Extrasystolen (VES) pro Zeiteinheit
 - Atmungsfrequenz
 - Atemhubvolumen
 - und
 - eine Implantant-Sender/Empfängereinheit in Kommunikation mit dem Service-Center, und
 - wobei das Service-Center eine andere Datenkommunikationsschnittstelle umfasst, die dazu ausgebildet ist, mindestens eine indirekte Datenkommunikation mit der implantierbaren medizinischen Vorrichtung zu ermöglichen, und die an eine zentrale Datenbank und an eine Benutzerschnittstelle angeschlossen ist,
 - wobei die Steuereinheit dazu ausgebildet ist, eine Übertragung der gesammelten Daten zu dem Daten-Center einzuleiten,
 - wobei das Service-Center des Weiteren ein Datenauswertungsmodul umfasst, das an die Datenbank angeschlossen und dazu ausgebildet ist, Daten, die in der Datenbank gespeichert sind, auszuwerten, wobei die Auswertung eine Daten-Trenddarstellung gespeicherter Daten enthält, und
 - die Benutzerschnittstelle und das Datenauswertungsmodul dazu ausgebildet sind, dem Arzt die Einstellung von Auslösekriterien für die Erfassung einer Dekompensierung für jeden Daten-Trend zu ermöglichen, und das Datenauswertungsmodul des Weiteren dazu ausgebildet ist, ein Dekompensierungsanzeigesignal zu erzeugen, sobald die Auslösekriterien von den als Trend dargestellten Daten erfüllt sind, wobei das Datenauswertungsmodul des

Weiteren dazu ausgebildet ist, ein Dekompensierungsanzeigesignal zu erzeugen, sobald eine Kombination von Auslösekriterien von den als Trend dargestellten Daten erfüllt ist und/oder sobald mehrere Auslösekriterien in einer im Voraus eingestellten zeitlichen Übereinstimmung erfüllt sind, wobei das Datenauswertungsmodul des Weiteren dazu ausgebildet ist, ein Dekompensierungsanzeigesignal zu erzeugen, wenn die thorakale Gleichstromimpedanz von der ersten Elektrodenkombination und die thorakale Gleichstromimpedanz von der zweiten Elektrodenkombination einen im Voraus eingestellten Anstieg zeigen und das Aktivitätsniveau eine im Voraus eingestellte Abnahme zeigt und die Atmungsrate einen im Voraus eingestellten Anstieg zeigt.

2. Herzüberwachungssystem nach Anspruch 1, wobei das Herzüberwachungssystem des Weiteren eine externe Sender/Empfängervorrichtung umfasst, wobei die externe Sender/Empfängervorrichtung eine externe Sender/Empfängereinheit für eine drahtlose Kommunikation mit der Implantant-Sender/Empfängereinheit und eine Datenkommunikationsschnittstelle umfasst, die dazu ausgebildet ist, eine Datenkommunikation mit dem Service-Center zu ermöglichen.

3. Herzüberwachungssystem nach Anspruch 1 oder 2, wobei die Auslösekriterien einen Versatz gegenüber der Grundlinie oder eine Neigung der als Trend dargestellten Daten enthalten, um die Erzeugung des Dekompensierungsanzeigesignals auszulösen, sobald der Versatz überschritten wird.

4. Herzüberwachungssystem nach Anspruch 1, wobei die Benutzerschnittstelle so ausgebildet ist, dass ein Benutzer eine Auslösekombination und/oder deren zeitliche Übereinstimmung einstellen kann.

5. Herzüberwachungssystem nach einem der vorangehenden Ansprüche, wobei das Service-Center zum Übertragen einer Dekompensierungsalarmnachricht dient, sobald das Datenauswertungsmodul ein Dekompensierungsanzeigesignal erzeugt.

6. Herzüberwachungssystem nach einem der vorangehenden Ansprüche, wobei die implantierbare medizinische Vorrichtung dazu ausgebildet ist, die gesammelten Rohdaten täglich zu dem Service-Center zu senden.

7. Herzüberwachungssystem nach einem der vorangehenden Ansprüche, wobei das Datenauswertungsmodul dazu ausgebildet ist, die Daten mit einem Datenpunkt pro Tag für jeden Trend als Trend darzustellen.

8. Herzüberwachungssystem nach einem der vorangehenden Ansprüche, wobei das Datenauswertungsmodul und die Benutzerschnittstelle und deren Wechselwirkung so gestaltet sind, dass ein Benutzer imstande ist, das Auslösen für jeden Trend zu aktivieren oder zu deaktivieren.

9. Herzüberwachungssystem nach einem der vorangehenden Ansprüche, wobei das Datenauswertungsmodul und die Benutzerschnittstelle und deren Wechselwirkung so gestaltet sind, dass ein Benutzer imstande ist, ein Auslösen mit einer Auslöselogik zu kombinieren, die eine Kombination zu erfüllender Auslösekriterien umfasst.

10. Herzüberwachungssystem nach einem der vorangehenden Ansprüche, wobei das Datenauswertungsmodul und die Benutzerschnittstelle und deren Wechselwirkung dazu ausgebildet sind, eine Anzeige von Daten zu erzeugen, wobei Grafiklinien für jeden Trend separat die Farbe ändern, grün, wenn kein Auslösen erreicht wird, rot, wenn ein Auslösen erreicht wird.

11. Herzüberwachungssystem nach einem der vorangehenden Ansprüche, wobei das Datenauswertungsmodul und die Benutzerschnittstelle und deren Wechselwirkung dazu ausgebildet sind, eine Anzeige von Daten zu erzeugen, wobei ein grafischer Hintergrund die Farbe für Zeiten ändert, in welchen die Auslöselogik einen Alarm ausgegeben hat.

12. Herzüberwachungssystem nach einem der vorangehenden Ansprüche, wobei das Service-Center dazu ausgebildet ist, einen Dekompensierungsalarm über die Benutzerschnittstelle anzuzeigen, die an das Service-Center angeschlossen ist, und dem Arzt zu ermöglichen, Therapieänderungen aktiv über mehrere Fernaktivitäten einzuleiten, enthaltend:

- Änderung von Schrittsteuerungsparametern mittels Fernprogrammierung über die Benutzerschnittstelle
- Änderung einer Ernährung mittels Telefonanruf eines Patienten
- Änderung der Medikation mittels Telefonanruf eines Patienten
- Änderung einer Medikation mittels Fernprogrammierung einer Arzneimittelpumpe unter Verwendung der Be-

nutzerschnittstelle des Service-Centers.

13. Herzüberwachungssystem nach einem der vorangehenden Ansprüche, des Weiteren umfassend einen Rückkopplungskanal von einem einzelnen Patienten zu der Benutzerschnittstelle, der eine Rückkopplung ermöglicht, ob eine Therapieänderung erfolgreich war oder nicht.

Revendications

1. Système de surveillance cardiaque comprenant un dispositif médical implantable (10) et un centre de service (90), le dispositif médical implantable comportant un générateur d'impulsions de stimulation apte à générer des impulsions de stimulation électrique et connecté ou pouvant être connecté à au moins une électrode de stimulation ventriculaire pour délivrer des impulsions de stimulation électrique au moins audit ventricule du coeur, un niveau de détection ventriculaire connecté ou pouvant être connecté à une électrode pour enregistrer des potentiels électriques à l'intérieur d'au moins un ventricule d'un coeur, ledit niveau de détection étant apte à détecter une excitation ou une contraction du myocarde ventriculaire, un capteur d'activité, une unité de détermination d'impédance comportant une source de courant constant ou une source de tension constante ayant des bornes d'alimentation en courant qui sont connectées ou peuvent être connectées à des électrodes à placer dans le corps et qui est apte à générer des impulsions de courant de mesure de sous-seuil ayant une intensité de courant constante ou une tension constante respectivement pour occasionner l'apport d'un courant dans un corps via des électrodes placées dans le corps, une unité de mesure pour mesurer une tension correspondant à un courant apporté dans un corps par ladite source de courant constant ou une intensité de courant d'un courant apporté dans un corps par ladite source de tension constante respectivement, une unité de détermination de valeur d'impédance qui est connectée à ladite source de courant constant ou à ladite source de tension constante et à l'unité de mesure et qui est apte à déterminer une valeur d'impédance pour chaque impulsion de mesure de courant, et ladite unité de détermination d'impédance étant apte à réaliser une mesure d'impédance intra-thoracique via une première une seconde combinaison d'électrodes, ladite seconde configuration d'électrodes étant différente de ladite première configuration d'électrodes, une unité de commande qui est connectée à ladite batterie, audit générateur d'impulsions de stimulation, audit niveau de détection, audit capteur d'activité et à ladite unité de détermination d'impédance et qui est apte à collecter des données représentant les valeurs suivantes :

- impédance thoracique CC depuis ladite première combinaison d'électrodes,
- impédance thoracique CC depuis ladite seconde combinaison d'électrodes,
- débit cardiaque,
- rythme cardiaque en position de repos d'un patient,
- rythme cardiaque en cours d'exercice d'un patient,
- niveau d'activité d'un patient,
- extrasystoles ventriculaires (VES) par unité de temps,
- rythme respiratoire,
- volume respiratoire de levée,

et

une unité de communication émettrice-réceptrice avec le centre de service et le centre de service comprenant une autre interface de communication de données apte à permettre au moins une communication indirecte de données avec ledit dispositif médical implantable et étant connecté à une base de données centrale et à une interface utilisateur, ladite unité de commande étant apte à initier la transmission desdites données collectées audit centre de données, ledit centre de service comprenant en outre un module d'évaluation de données connecté à ladite base de données et apte à évaluer les données enregistrées dans ladite base de données, ladite évaluation incluant l'établissement de tendances de données des données enregistrées et ladite interface utilisateur et ledit module d'évaluation de données étant aptes à permettre au médecin d'établir pour chaque tendance de données des critères de déclenchement pour la détection de la décompensation et ledit module d'évaluation de données étant en outre apte à générer un signal indicateur de décompensation chaque fois que les

critères de déclenchement sont remplis par les tendances de données, ledit module d'évaluation de données étant en outre apte à générer un signal indicateur de décompensation chaque fois qu'une combinaison de critères de déclenchement est remplie par les tendances de données et/ou chaque fois qu'une pluralité de critères de déclenchement sont remplis dans une coïncidence temporelle préétablie, ledit module d'évaluation de données étant en outre apte à générer un signal indicateur de décompensation si ladite impédance thoracique CC issue de ladite première combinaison d'électrodes et ladite impédance thoracique CC issue de ladite seconde combinaison d'électrodes présentent une augmentation préétablie et si le niveau d'activité présente une diminution préétablie et si ledit rythme respiratoire présente une augmentation préétablie.

2. Système de surveillance cardiaque selon la revendication 1, ce système de surveillance cardiaque comprenant en outre un dispositif émetteur-récepteur externe, ledit dispositif émetteur-récepteur externe comprenant une unité émettrice-réceptrice externe pour la communication sans fil avec l'unité émettrice-réceptrice d'implant et une interface de communication de données apte à permettre une communication de données avec le centre de service.

3. Système de surveillance cardiaque selon la revendication 1 ou 2, lesdits critères de déclenchement incluant un décalage par rapport à la ligne de base ou à la pente des tendances de données de nature à déclencher la génération dudit signal indicateur de décompensation chaque fois que ledit décalage est dépassé.

4. Système de surveillance cardiaque selon la revendication 1, l'interface utilisateur étant adaptée pour qu'un utilisateur puisse établir la combinaison de déclenchement et/ou sa coïncidence temporelle.

5. Système de surveillance cardiaque selon une des revendications précédentes, ledit centre de service servant à transmettre un message d'alarme de décompensation adapté chaque fois que le module d'évaluation de données génère un signal indicateur de décompensation.

6. Système de surveillance cardiaque selon une des revendications précédentes, ledit dispositif médical implantable étant apte à transmettre les données brutes collectées quotidiennement au centre de service.

7. Système de surveillance cardiaque selon une des revendications précédentes, ledit module d'évaluation de données étant apte à établir une tendance de données avec un point sur les données par jour pour chaque tendance.

8. Système de surveillance cardiaque selon une des revendications précédentes, ledit module d'évaluation de données et ladite interface utilisateur et leur interaction étant conçus pour permettre à un utilisateur d'être capable d'activer ou désactiver le déclenchement pour chaque tendance.

9. Système de surveillance cardiaque selon une des revendications précédentes, ledit module d'évaluation de données et ladite interface utilisateur et leur interaction étant conçus pour permettre à un utilisateur de combiner une logique déclenchement à déclenchement comprenant une combinaison de critères de déclenchement à remplir.

10. Système de surveillance cardiaque selon une des revendications précédentes, ledit module d'évaluation de données et ladite interface utilisateur et leur interaction étant aptes à générer un affichage de données dans lequel des lignes graphiques changent séparément de couleur pour chaque tendance, à savoir sont en vert si le déclenchement n'est pas atteint et en rouge si le déclenchement est atteint.

11. Système de surveillance cardiaque selon une des revendications précédentes, ledit module d'évaluation de données et ladite interface utilisateur et leur interaction étant aptes à générer un affichage de données dans lequel un arrière-plan graphique change de couleur pour les périodes pour lesquelles la logique de déclenchement émettait une alarme.

12. Système de surveillance cardiaque selon une des revendications précédentes, ledit centre de service étant apte à indiquer une alarme de décompensation via ladite interface utilisateur connectée au centre de service et à permettre au médecin d'initier activement des changements de thérapie via plusieurs activités distantes incluant :

- le changement de paramètres de stimulation via une programmation à distance via l'interface utilisateur,
- le changement de régime en appelant un patient au téléphone,
- le changement de médication en appelant un patient au téléphone,
- le changement de médication via une programmation à distance d'une pompe à médicaments en utilisant l'interface utilisateur du centre de service.

- 13.** Système de surveillance cardiaque selon une des revendications précédentes, comprenant en outre un canal de retour d'information depuis un patient individuel jusqu'à l'interface utilisateur et qui permet un retour d'information indiquant si un changement de thérapie a été ou non une réussite.

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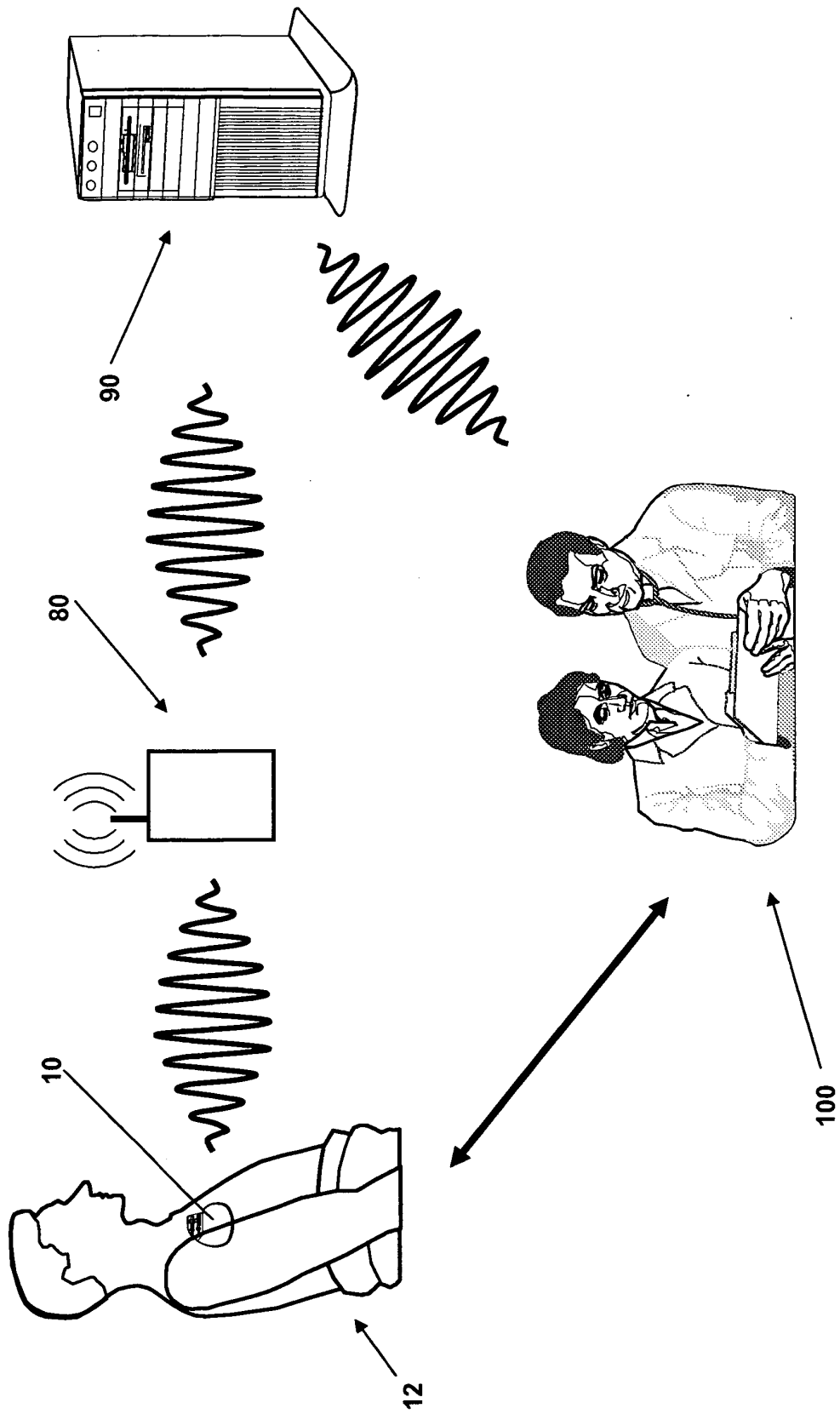


FIG. 1

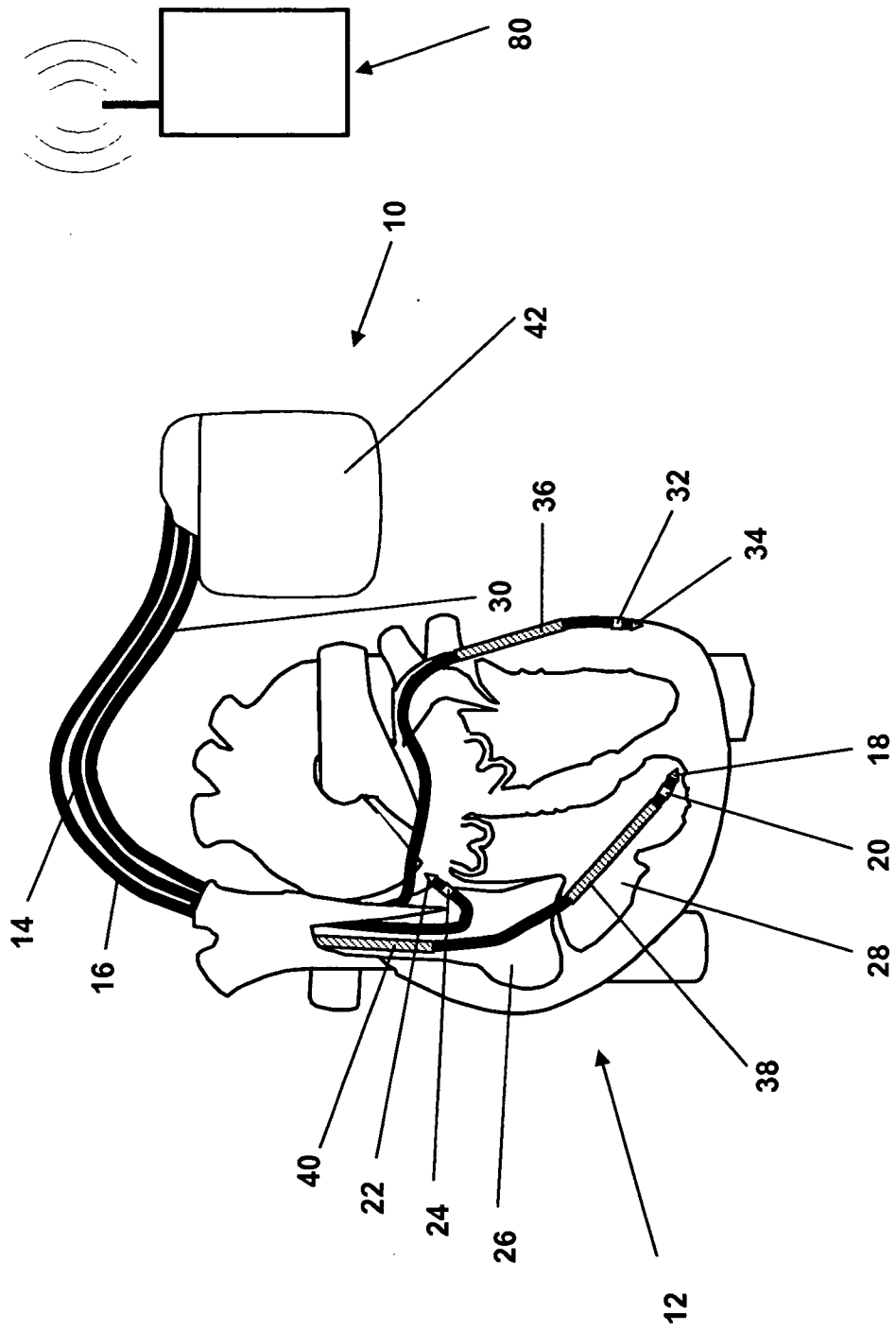


FIG. 2

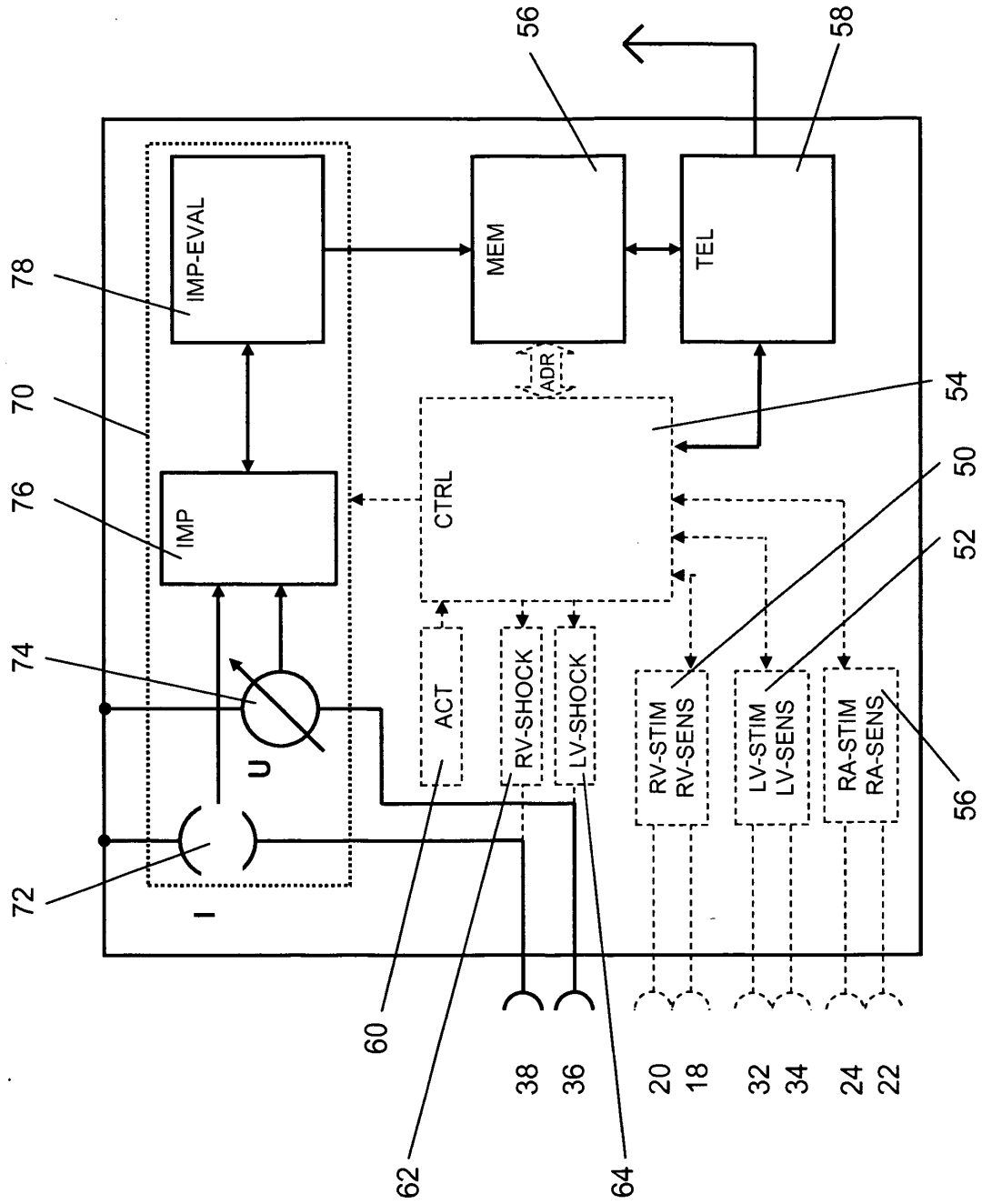


FIG. 3

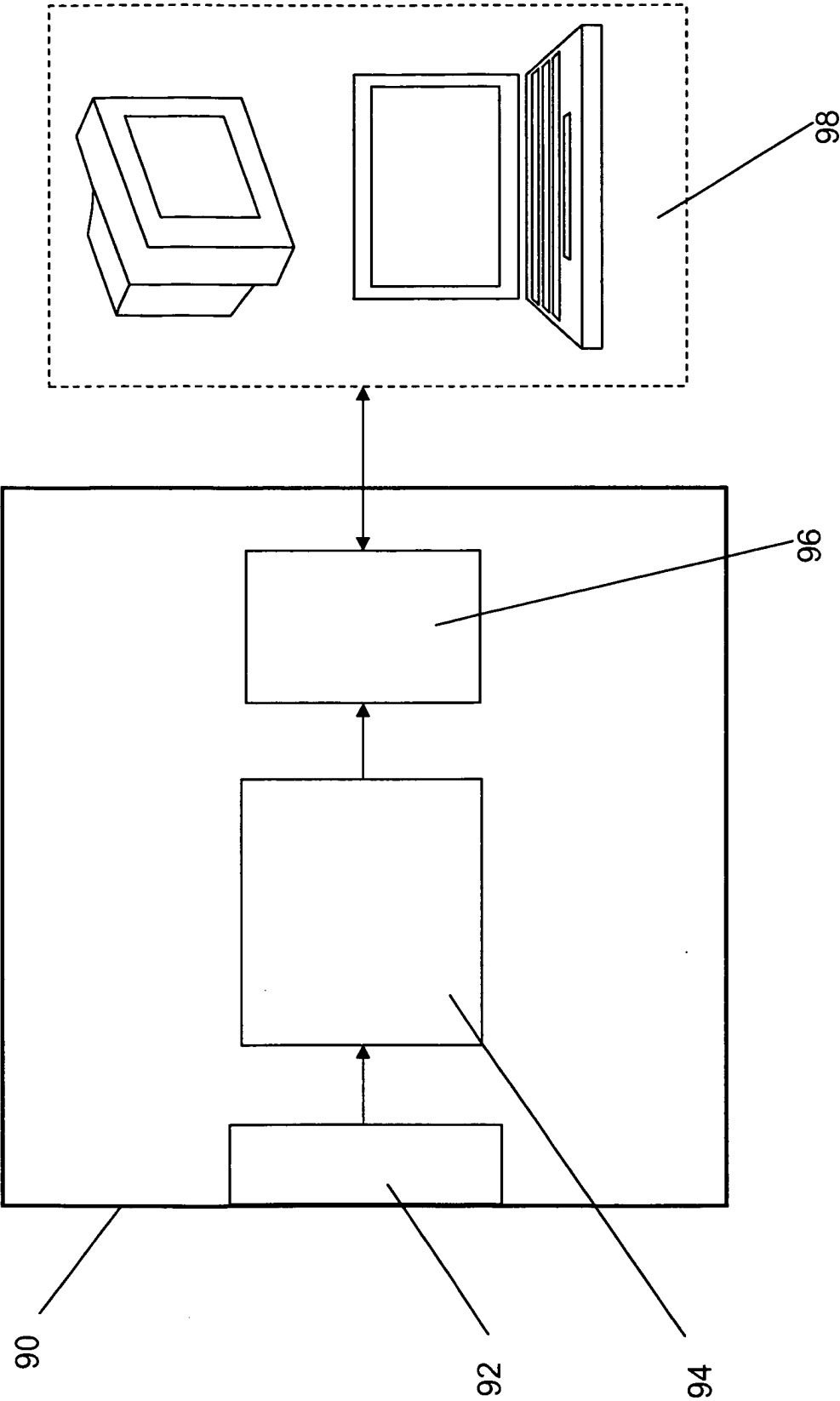


FIG. 4

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

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专利名称(译)	心脏监测系统		
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[标]申请(专利权)人(译)	百多力CRM专利公司		
申请(专利权)人(译)	BIOTRONIK CRM专利AG		
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CPC分类号	A61N1/3627 A61B5/0031 A61B5/0537 A61N1/36521 A61N1/3702 A61N1/37258 A61N1/37264 A61N1/37282		
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外部链接	Espacenet		

摘要(译)

心脏监测系统包括可植入医疗设备和服务中心。可植入医疗装置包括刺激脉冲发生器，心室感测级，活动传感器，阻抗确定单元，其包括恒定电流或电压源，适于分别产生具有恒定电流强度或恒定电压的亚阈值测量电流脉冲。，测量单元，用于测量与通过主体馈送的电流相对应的电压；阻抗值确定单元，连接到所述恒定电流或电压源；以及测量单元，适于确定每个测量电流脉冲的阻抗值，并适于执行经由第一和第二电极组合的胸内阻抗测量，控制单元适于收集表示例如变化值的数据来自所述第一电极组合的DC胸阻抗，每时间单位的心输出变化或心室额外心脏收缩（VES）并且启动所述数据的传输，以及与服务中心通信的植入收发器单元包括适于至少允许的另一数据通信接口与所述可植入医疗设备的间接数据通信，所述服务中心还包括数据评估模块，其包括存储数据的数据趋势，并且所述用户界面和所述数据评估模块适于允许医师为每个数据趋势设置触发标准。检测失代偿并产生失代偿指示信号。

