(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 December 2007 (27.12.2007)

PCT

(10) International Publication Number
WO 2007/149018 A1

(51) International Patent Classification:
A61N 1/365 (2006.01) *A61B 5/053* (2006.01)

(21) International Application Number:
PCT/SE2006/000756

(22) International Filing Date: 21 June 2006 (21.06.2006)

(25) Filing Language: English

(26) Publication Language: English

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

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **BLOMQVIST, Andreas** [SE/SE]; Emundskroken 57, S-163 43 Spånga (SE). **SVAHN, Johan** [SE/SE]; Galonvägen 25, S-168 73 Bromma (SE).

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

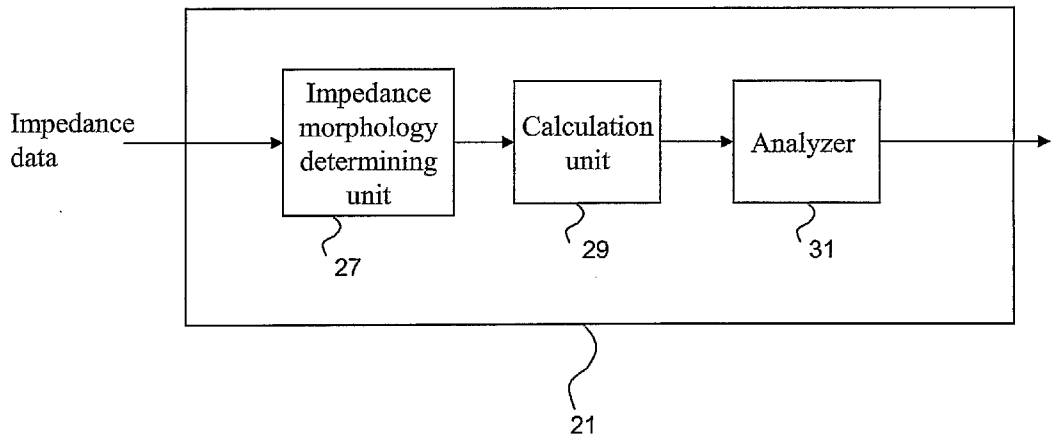
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) **Title:** MEDICAL DEVICE AND SYSTEM FOR DETERMINING A HEMODYNAMIC PARAMETER USING INTRACARDIAC IMPEDANCE



(57) **Abstract:** The present invention relates to implantable medical devices such a pacemaker or cardioverter/defibrillators (ICDs) and systems including such a device and an external programmer for determining a measure of a hemodynamic parameter such as the cardiac output, the stroke volume, or the contractility of a patient for use, for example, in trending heart failure or in an AV/VV optimization scheme. The implantable medical device is adapted to measure the cardiac impedance and the cardiac impedance data is used to determine impedance morphology curves, which, in turn, are used to compute a measure of the hemodynamic parameter.

WO 2007/149018 A1

MEDICAL DEVICE AND SYSTEM FOR DETERMINING A HEMODYNAMIC PARAMETER USING INTRACARDIAC IMPEDANCE

TECHNICAL FIELD

The present invention generally relates to medical devices for determining a measure of hemodynamic parameters such as the cardiac output, the stroke volume, or the contractility of a patient and in particular to implantable medical devices such a pacemaker or cardioverter/defibrillators (ICDs) and systems including such a device and an external programmer for determining a measure of a hemodynamic parameter such as the cardiac output, the stroke volume, or the contractility of a patient for use, for example, in trending heart failure or in an AV/VV optimization scheme.

BACKGROUND OF THE INVENTION

Intracardiac impedance variations has been found to reflect the cardiac function and may hence be utilized for heart therapy in an implantable medical device such as a heart stimulator. In particular, the cardiac impedance has been found to be of great therapeutic value since the cardiac impedance correlates well with hemodynamic parameters such as, for example, cardiac output and stroke volume.

Implantable medical devices of this above-mentioned general type is known. For example, according to U.S. 2005/0215914 the ventricular impedance is used as a measure of end-diastolic volume in order to detect heart failure. The measured impedance, which is in inverse proportion to the ventricular end-diastolic value, is compared with threshold values representative of the onset and severity of heart failure and for comparison against previously detected ventricular end-diastolic values of the patient for use in tracking the progression of heart failure over time.

U.S. 2004/0078058 describes a heart stimulator including an analyzer that analyzes at least one predetermined parameter of an average impedance morphology curve for use for the control of the stimulation. A parameter having a value that is primarily dependent on the left ventricular ejection is used. The parameter may, for example, be the integrated area below the averaged impedance morphology curve versus time, maximum or minimum value of the average impedance morphology curve, or the difference between the maximum and minimum value of the average impedance morphology curve.

U.S. 5,843,137 discloses a method and apparatus for automatic determination of a pacing stimulations threshold. Values such as maximum, minimum and direction values that characterize the morphology of the impedance waveform is used to discriminate between capture and loss of capture.

U.S. 6,134,472 describes an implantable heart stimulation device that measures electrical impedance to obtain a measure of the ventricular filling. The impedance is measured at the time when the impedance reaches a peak value, which occurs at an approximately fixed time about 250 to 300 ms after the stimulation pulse, and immediately prior to emission of a stimulation pulse. The difference between these two measurement values provides a measure of the stroke volume. This procedure requires a precise synchronization between the impedance measurements and the stimulation pulses in order to provide a measure of the stroke volume and accordingly it may be sensitive to disturbances and/or time delays.

Thus, there is a need of an improved implantable medical device and method for such a device that are capable of providing a reliable and accurate measure of hemodynamic parameters such as stroke volume, cardiac output, or contractility.

BRIEF DESCRIPTION OF THE INVENTION

An object of the present invention is to provide an improved implantable medical device and method for such a device that are capable of providing a reliable and accurate measure of hemodynamic parameters such as stroke volume, cardiac output, or contractility.

Another object of the present invention is to provide a system including an implantable medical device and an external programmer apparatus that is capable of providing a reliable and accurate measure of hemodynamic parameters such as stroke volume, cardiac output, or contractility.

A further object of the present invention is to provide an implantable medical device and a system including an implantable medical device and an external programmer apparatus that are capable of providing a reliable and accurate measure of hemodynamic parameters such as stroke volume, cardiac output, or contractility for use in optimizing settings of the implantable device, for example, pacing parameters or for deriving a condition or change of a condition of a patient.

These and other objects are achieved according to the present invention by providing a method, a medical device, and a computer readable medium having the features defined in the independent claim. Preferable embodiments of the invention are characterised by the dependent claims.

According to an aspect of the present invention, there is provided an implantable medical device including a pulse generator adapted to produce cardiac stimulating pacing pulses, the device being connectable to at least one lead comprising electrodes for delivering the pulses to cardiac tissue of a heart of a patient. The implantable medical device

comprises an impedance measuring unit connectable to at least two electrodes adapted to measure cardiac impedance of the heart, the impedance measuring unit being adapted to provide impedance information corresponding to the measured impedance; an impedance morphology determining unit adapted to receive the impedance information and to determine an impedance morphology curve from the impedance information; and a calculation unit adapted to detect an extreme point section of the impedance morphology curve and to calculate a measure of a hemodynamic parameter of the heart utilizing the extreme point section.

According to a second aspect of the present invention, there is provided a medical system including an external programmer apparatus comprising a communication unit and an implantable medical device including a pulse generator adapted to produce cardiac stimulating pacing pulses, the implantable device being connectable to at least one lead comprising electrodes for delivering the pulses to cardiac tissue of a heart of a patient, and a communication unit, wherein the external apparatus and the implantable device are adapted for two-way communication of data using the communication units. The implantable medical device further comprises an impedance measuring unit connectable to at least two electrodes adapted to measure cardiac impedance of the heart, the impedance measuring unit being adapted to provide impedance information corresponding to the measured impedance. The external apparatus is adapted to obtain the impedance information via the communication unit and further comprises an impedance morphology determining unit adapted to receive the impedance information and to determine an impedance morphology curve from the impedance information; and a calculation unit adapted to detect an extreme point section of the impedance morphology curve and to calculate a measure of a hemodynamic parameter of the heart utilizing the extreme point section.

According to a third aspect of the present invention, there is provided a medical system including an external programmer apparatus comprising a communication unit and an implantable medical device including a pulse generator adapted to produce cardiac stimulating pacing pulses, the implantable device being connectable to at least one lead comprising electrodes for delivering the pulses to cardiac tissue of a heart of a patient, and a communication unit, wherein the external apparatus and the implantable device are adapted for two-way communication of data using the communication units. The implantable medical device further comprises an impedance measuring unit connectable to at least two electrodes adapted to measure cardiac impedance of the heart, the impedance measuring unit being adapted to provide impedance information corresponding to the measured impedance; and an impedance morphology determining unit adapted to receive the impedance information and to determine an impedance morphology curve from the impedance information. The external apparatus is adapted to obtain the impedance morphology curve via the communication unit and further comprises a calculation unit adapted to detect an extreme point section of the impedance morphology curve and to calculate a measure of a hemodynamic parameter of the heart utilizing the extreme point section.

Thus, the present invention is based on the insight that the intracardiac impedance variations reflect the cardiac function and hence can be utilized for heart therapy in an implantable medical device such as a heart stimulator and that the cardiac impedance has been found to be of great therapeutic value since the cardiac impedance correlates very well with hemodynamic parameters such as, for example, cardiac output and stroke volume. In particular, the actual shape of the cardiac impedance signal and the morphology of the peak section and its immediate surroundings has been found to contain valuable information regarding the hemodynamic performance of a patient. This information is, according to

the present invention, used to determine or calculate a measure of a hemodynamic parameter of the patient, for example, cardiac output, stroke volume, or contractility. This measure may, in turn, be used to control heart stimulation to optimize hemodynamics or to trend, for example, the development of heart failure.

According to the second aspect of the present invention, the programmer obtains impedance data from the implantable device and performs the impedance morphology determination and the calculation of the hemodynamic measure. That is, the impedance data processing is mainly performed in the programmer and thus the data processing executed in the implantable device can be minimized. The impedance data transfer to the programmer may be performed continuously or at regular intervals.

According to the third aspect of the present invention, the programmer obtains impedance curves from the implantable device and performs the calculation of the hemodynamic measure. That is, the calculation of the hemodynamic measure is performed in the programmer and thus the data processing executed in the implantable device can be reduced. The transfer of impedance curves to the programmer may be performed continuously or at regular intervals.

In one embodiment of the present invention, the implantable medical device includes an analyzer adapted to analyze the measure to optimize at least one pacing parameter of the pulse generator or to derive a change of a condition of the patient. Thereby, the heart stimulation pulses may be controlled such that the patient hemodynamics is optimized. For example, an AV/VV interval may be optimized. The obtained measure can also be used to trend conditions such as, for example, heart failure. In an alternative embodiment, the analyzer is arranged in the external programmer apparatus.

According another embodiment of the present invention, the calculation unit is adapted to calculate the measure by means of the shape of the impedance morphology curve in a time window surrounding the peak section of the impedance morphology curve.

In a further embodiment of the present invention, the impedance morphology determining unit is adapted to determine an averaged impedance morphology curve from the impedance information during a time interval of a plurality of cardiac cycles of the heart. For example, a predetermined number of consecutive heart beats may be used to create the averaged impedance curve. In an alternative embodiment, the impedance morphology determining unit is adapted to perform a filtering procedure of the received impedance information and to determine an impedance morphology curve from the filtered impedance information.

In another embodiment of the present invention, the calculation unit is adapted to detect the maximum value of the impedance morphology curve and to centre the time window about the value. The maximum value or peak section of the curve may be located by using the first and second time derivatives of the curve section.

In yet another embodiment of the present invention, the calculation unit is adapted to fit a polynomial of degree two to the section of the impedance morphology curve in the time window.

According to further embodiment of the present invention, a curvature component of the polynomial is used as the measure. The second degree constant has been found to contain information of the magnitude of the curvature of the cardiac impedance waveform and may thus be used as the measure of the shape of the cardiac impedance signal, and, in turn, as a

measure of the hemodynamic parameter, for example, the stroke volume or the cardiac output.

In another embodiment of the procedure for calculating the measure according to the present invention, the sample corresponding to the maximum value is identified, a window centred about the maximum value containing a predetermined number of samples is defined, the values of the start and end samples of the window, respectively, are identified, an average value of the start and end values is calculated, and a ratio of the average value and the maximum value is calculated as the measure. According to an alternative, a window centred about the maximum value having a predetermined length of time is defined and the samples corresponding to the start and end of the time window are identified and used to calculate the ratio.

Alternatively, to calculate the measure of the hemodynamic parameter, the sample corresponding to the maximum value is identified, a window centred about the maximum value containing a predetermined number of samples is defined, and an area of the window by adding the values of the predetermined number of samples is calculated as the measure. According to an alternative, a window centred about the maximum value having a predetermined length of time is defined and the values of the samples included in the time window are added up to calculate the area.

In a further embodiment of the procedure for calculating the measure in accordance with the present invention, the sample corresponding to the maximum value is identified, a time window centred about the maximum value containing a predetermined number of samples is defined, the values of the start and end values of the window, respectively, are identified, a first average slope from the sample corresponding to the start value to the sample corresponding

to the maximum value is calculated, a second average slope from the sample corresponding to the maximum value to the sample corresponding to the end value is calculated, and the first slope and the second slope is used to calculate the measure. For example, a ratio between the slopes or a product of the slopes can be calculated.

In yet another embodiment of the present invention, a time window is defined at a predetermined amplitude in relation to the maximum value and a width of the time window as the measure is calculated.

In one embodiment, the resistive part of the cardiac impedance is used. Furthermore, the impedance information may also or alternatively, for example, include the magnitude of the complex impedance, the real and/or imaginary part (i.e. the inductive or capacitive part) of the complex impedance.

According to further embodiments, the hemodynamic parameter is stroke volume, cardiac output, or contractility.

In an embodiment, the implantable medical device may a posture sensor adapted to sense at least one predetermined posture of the patient and to provide at least one posture indicating signal. A cardiac impedance measuring session may be initiated upon an indication that the patient is in at least one predetermined posture. Alternatively, the implantable medical may comprise a breathing rate sensor adapted to sense a breathing rate of the patient and to provide at least one breathing rate indicating signal. A cardiac impedance measuring session may be initiated upon an indication of a breating rate within at least one predetermined interval. In a further example, the implantable medical device may include an activity level sensor adapted to sense an activity level of the patient and to provide at least one activity level indicating signal. In this case, a cardiac impedance measuring

session may be initiated upon indication of an activity level within at least one predetermined interval. As the skilled person realizes, one or several of the above-mentioned criterias may be combined. Moreover, other criteria´s may also be conceivable, for example, the heart rate of the patient. By only performing the cardiac impedance measurements under certain conditions, e.g. at a specific body posture, the reliability and accuracy of the impedance data, and thereby of the measure of the hemodynamic, can be improved since the measurements are performed under reproducable conditions.

The features that characterize the invention, both as to organization and to method of operation, together with further objects and advantages thereof, will be better understood from the following description used in conjunction with the accompanying drawings. It is to be expressly understood that the drawings is for the purpose of illustration and description and is not intended as a definition of the limits of the invention. These and other objects attained, and advantages offered, by the present invention will become more fully apparent as the description that now follows is read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

In the following detailed description, reference will be made to the accompanying drawings, of which:

Fig. 1 is block diagram of the primary functional components of an embodiment of the implantable medical device according to the present invention.

Fig. 2 is a block diagram of a part of the embodiment of the implantable medical device shown in Fig. 1.

Fig. 3 is a general block diagram of an embodiment of the system according to the present invention.

Fig. 4 is block diagram of the primary functional components of an embodiment of the implantable medical device of the system shown in Fig. 4 according to the present invention.

Fig. 5 is a general block diagram of another embodiment of the system according to the present invention.

Fig. 6 is block diagram of the primary functional components of an embodiment of the implantable medical device of the system shown in Fig. 5 according to the present invention.

Fig. 7 is a flow chart illustrating the steps in accordance with one embodiment of the present invention for determining a measure of a hemodynamic parameter.

Fig. 8 is a flow chart of an embodiment of the calculation procedure according to the present invention.

Fig. 9 is a flow chart of another embodiment of the calculation procedure according to the present invention.

Fig. 10 is a flow chart of yet another embodiment of the calculation procedure according to the present invention.

Fig. 11 is a flow chart of a further embodiment of the calculation procedure according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

With reference first to Fig. 1, an embodiment of the implantable medical device according to the present invention will be shown. This embodiment of the present invention is implemented in the context of a pacemaker 20 implanted in a patient (not shown). The pacemaker 20 comprises a housing being hermetically sealed and biologically inert. Normally, the housing is conductive and may, thus, serve as an

electrode. One or more pacemaker leads, where only two are shown in Fig. 1, 26a and 26b, are electrically coupled to the pacemaker 20 in a conventional manner. The leads 26a, 26b extend into the heart (not shown) via a vein of the patient. One or more conductive electrodes for receiving electrical cardiac signals and/or for delivering electrical pacing to the heart are arranged near the distal ends of the leads 26a, 26b. As the skilled man in the art realizes, the leads 26a, 26b may be implanted with its distal end located in either the atrium or ventricle of the heart.

The leads 26a, 26b may be unipolar or bipolar, and may include any of the passive or active fixation means known in the art for fixation of the lead to the cardiac tissue. For example, a good fixation of electrodes can be obtained by means of a screw-in electrodes. Alternatively, the lead distal tip (not shown) may include a tined tip or a fixation helix.

The leads 26a, 26b comprises one or more electrodes, such a tip electrode or a ring electrode, arranged to, inter alia, transmit pacing pulses for causing depolarization of cardiac tissue adjacent to the electrode(-s) generated by a pace pulse generator 22 under influence of a control circuit 23 comprising a microprocessor. The control circuit 23 controls, inter alia, pace pulse parameters such as output voltage and pulse duration. A memory circuit 31 is connected to the control circuit 27, which memory circuit 35 may include a random access memory (RAM) and/or a non-volatile memory such as a read-only memory (ROM). Detected signals from the patients heart are processed in an input circuit 33 and are forwarded to the microprocessor of the control circuit 27 for use in logic timing determination in known manner.

Furthermore, an impedance measuring unit 25 is adapted to carry out impedance measurements of the cardiac impedance of the patient. The impedance vector used should preferably

capture the filling and emptying of the ventricle (right or left). The impedance measuring unit 25 is thus arranged to apply excitation current pulses between a first electrode and a second electrode arranged to positioned, for example, within a heart of the patient. In one embodiment, the current is emitted between a right ventricular tip electrode and a left ventricular tip electrode. The first and second electrode may also be positioned outside the heart. The impedance measuring unit 25 is also arranged to measure the voltage between a third and fourth electrode arranged, for example, at a lead 26a, or 26b. The third and fourth electrode are arranged such that they can be located within the heart of the patient, for example, in a vein/artery of the heart. In one embodiment, the voltage is sensed between a right ventricular ring electrode and a left ventricular ring electrode.

According to another embodiment, tri-polar measurements are used to perform the impedance measurements where the current is sent out between an RV-tip (i.e. the distal electrode in a bipolar lead located in right ventricle) and an RV-coil (i.e. the conductor in a bipolar lead having a helical configuration located in the right ventricle) and the voltage is measured between an RV-ring (i.e. the proximal electrode in a bipolar lead located in right ventricle) and the RV-coil.

The impedance measuring unit 25 may comprise an amplifier (not shown) that amplifies the evoked voltage response, i.e. the measured voltage, and may be synchronized in a multiplier with the excitation current. Thus, the impedance measuring unit 25 obtains the cardiac impedance given by the delivered current and the evoked voltage response. Then, the impedance information corresponding to the measured impedance is sent to an impedance processing unit 21.

The impedance information used may include the resistive part of the cardiac impedance. Furthermore, the impedance

information may also or alternatively, for example, include the magnitude of the complex impedance, the real and/or imaginary part (i.e. the inductive or capacitive part) of the complex impedance.

The impedance processing unit 21 may be adapted to determine an averaged impedance morphology curve from the received impedance information during a time interval of a plurality of cardiac cycles. In another embodiment, the received impedance information is filtered and a morphology curve based on the impedance information obtained during one heart beat is determined. The signals may be bandpass filtered to remove the DC-component. Furthermore, an extreme point section of the impedance morphology curve is detected and a measure of a hemodynamic parameter of the heart, for example, stroke volume, cardiac output, or contractility, utilizing the extreme point section is calculated. In one embodiment, the extreme point section is a peak section. Different approaches for calculating the measure will be discussed below. Thereafter, the obtained measure is analyzed to optimize at least one pacing parameter of the pulse generator or to derive a change of a condition of the patient. The control circuit 23 may be connected to the impedance processing unit 21 to control the heart stimulation pulse generator 22 in response to the output from the impedance processing unit 21 such that the patient hemodynamics can be optimized. For example, an AV/VV interval may be optimized. The obtained measure can also be used to trend, for example, heart failure.

With reference to Fig. 2, an embodiment of the impedance processing unit 21 will be described. An impedance morphology determining unit 27 is adapted to receive the impedance information corresponding to the measured impedance from the impedance measuring unit 25. The impedance morphology determining unit 27 may be adapted to determine an averaged impedance morphology curve from the received impedance

information during a time interval of a plurality of cardiac cycles. In another embodiment, the received impedance information is median filtered and a morphology curve based on the impedance signal obtained during one heart beat is determined.

In a calculation unit 29, an extreme point section of the impedance morphology curve is detected and a measure of a hemodynamic parameter of the heart, for example, stroke volume, cardiac output, or contractility, utilizing the extreme point section is calculated. In one embodiment, the extreme point section is a peak section. The measure obtained from the calculation unit 29 is analyzed in an analyzer 31 to optimize at least one pacing parameter of the pulse generator or to derive a change of a condition of the patient. The control circuit 23 may be connected to the analyzer 31 for the optimization discussed above.

The implantable medical device 20 is powered by a battery (not shown), which supplies electrical power to all electrical active components of the medical device 20. Data contained in, for example, the memory circuit 35 can be transferred to a programmer (not shown in Fig. 1) via a communication unit 37, e.g. a telemetry unit, including a programmer interface for use in analyzing system conditions, patient information, etc. The analyzer 31 may also transfer data to the programmer via the communication unit 37.

Furthermore, the implantable medical device according to the present invention may comprise a posture detecting sensor (not shown) arranged to detect, for example, a predetermined, specific body posture of the patient. The posture detecting sensor may be connected to the control circuit and adapted to provide at least one posture indicating signal. In one embodiment, the impedance measuring unit is adapted to initiate an impedance measuring session upon receiving a

posture indicating signal that indicates that the patient is in at least one predetermined posture. For example, the impedance measuring session may be initiated when the patient is lying on the back.

In another embodiment, the implantable medical device may comprise a breathing rate sensor (not shown) adapted to sense a breathing rate of the patient. The breathing rate sensor may be connected to the control circuit and is adapted to provide at least one breathing rate indicating signal. The impedance measuring unit may be adapted to initiate a cardiac impedance measuring session upon receiving a breathing rate indicating signal that indicates a breathing rate within at least one predetermined interval. For example, the impedance measuring session may be initiated when the breating rate is below a certain level.

In yet another embodiment, the implantable medical device may comprise an activity level sensor (not shown) adapted to sense an activity level of the patient. The activity level sensor may be connected to the control circuit and is adapted to provide at least one activity level indicating signal. The impedance measuring unit may be adapted to initiate a cardiac impedance measuring session upon receiving an activity level signal indicating signal that indicates an activity level within at least one predetermined interval.

As the skilled person realizes, one or several of the above-mentioned criterias may be combined. Moreover, other criteria´s may also be conceivable, for example, the heart rate of the patient. By only performing the cardiac impedance measurements under certain conditions, e.g. at a specific body posture, the reliability and accuracy of the impedance data, and thereby of the measure of the hemodynamic, can be improved since the measurements are performed under reproducable conditions.

With reference now to Figs. 3-6, embodiments of the system according to the present invention will be discussed. Like or similar parts in Fig. 1, 2, 4 and 6 are denoted with the same reference numerals and therefore the description of such parts will omitted since they were discussed above with respect to Figs. 1 and 2. Likewise, like or similar parts in Fig. 3 and 5 are denoted with the same reference numerals and therefore the description of such parts will omitted since they were discussed above with respect to Fig. 3.

With reference first to Fig. 3 and 4, one embodiment of the system according to the present invention will be described. In Fig. 3, it can be seen that the system 50 includes an implantable medical device 40, which is shown in more detail in Fig. 4, and an external programmer apparatus 51. The implantable device 40 and the external programmer 51 are adapted for two-way communication of data between each other via communication units 37 and 53, respectively. In this embodiment, the implantable medical device 40 comprises the impedance morphology determining unit 27 adapted to receive the impedance information from the impedance measuring unit 25 and to determine an impedance morphology curve from the impedance information. The impedance morphology curves can be stored in the memory circuit 37 or they may be buffered locally in the impedance morphology determining unit 27 before being transferred to the external programmer apparatus 51 via the communication units 37 and 53, respectively. This data transfer can be performed either continuously or at predetermined intervals of time. In the external programmer apparatus 51, the received impedance morphology data is processed in a calculation unit 55 to detect an extreme point section of the impedance morphology curve (or extreme points sections of respective curves) and a measure of a hemodynamic parameter of the heart, for example, stroke volume, cardiac output, or contractility, utilizing the extreme point section

is calculated using the extreme point section. In one embodiment, the extreme point section is a peak section. The measure obtained from the calculation unit 55 may be analyzed in an analyzer 57 to optimize at least one pacing parameter of the pulse generator of the implantable medical device 40 or to derive a change of a condition of the patient. The updated pacing parameters may be communicated to the implantable medical device 40 via the communication units 53 and 37, respectively, to control the heart stimulation pulse generator 22 in response to the output from the impedance processing unit 57 such that the patient hemodynamics can be optimized. For example, an AV/VV interval may be optimized. The obtained measure can also be used to trend, for example, heart failure.

With reference first to Fig. 5 and 6, another embodiment of the system according to the present invention will be described. In Fig. 5, it can be seen that the system 70 includes an implantable medical device 60, which is shown in more detail in Fig. 6, and an external programmer apparatus 71. The implantable device 60 and the external programmer 71 are adapted for two-way communication of data between each other via communication units 37 and 53, respectively. In this embodiment, the impedance information data from the impedance measuring unit 25 is streamed to the external programmer apparatus 71. Alternatively, the impedance information data can be stored in the memory circuit 37 or buffered locally in the impedance measuring unit 25 before being transferred to the external programmer apparatus 71 via the communication units 37 and 53, respectively. This data transfer can be performed at predetermined intervals of time. In the external programmer apparatus 71, the received impedance data is processed in a impedance morphology determination unit 54 to determine an averaged impedance morphology curve from the received impedance information during a time interval of a plurality of cardiac cycles. In another embodiment, the received impedance information filtered and a morphology curve

based on the impedance signal obtained during one heart beat is determined. In the calculation unit 55 an extreme point section of the impedance morphology curve (or extreme points sections of respective curves) and a measure of a hemodynamic parameter of the heart, for example, stroke volume, cardiac output, or contractility, utilizing the extreme point section is calculated using the extreme point section. In one embodiment, the extreme point section is a peak section. The measure obtained from the calculation unit 55 may be analyzed in an analyzer 57 to optimize at least one pacing parameter of the pulse generator of the implantable medical device 60 or to derive a change of a condition of the patient. The updated pacing parameters may be communicated to the implantable medical device 60 via the communication units 53 and 37, respectively, to control the heart stimulation pulse generator 22 in response to the output from the impedance processing unit 57 such that the patient hemodynamics can be optimized. For example, an AV/VV interval may be optimized. The obtained measure can also be used to trend, for example, heart failure.

Turning now to Fig. 7, a general description of the method for calculating the measure of a hemodynamic parameter according to the present invention will be given. First, at step 100, it may be checked whether at least one predetermined measurement criteria is fulfilled, for example, whether the patient is in a predetermined body posture or whether an breathing rate is within a predetermined interval. However, this step is optional. At step 102, impedance measurements of the cardiac impedance of the patient is performed. If the criteria check step is performed, the measurement step 102 is performed if the predetermined criteria is fulfilled. Thereafter, at step 104, an averaged impedance morphology curve from the received impedance information during a time interval of a plurality of cardiac cycles is determined. In another embodiment, the received impedance information is filtered and a morphology curve based on the impedance signal obtain during one heart

beat is determined. As discussed above, this step may be performed either in the implantable medical device or in the external programmer apparatus. If the morphology curves are calculated in the programmer, the impedance data may streamed over to the prgrammer from the implantable device or is may be transferred at regular intervals. If the curves are calculated in the implantable device, the curves may be transferred on a continuos basis or at regular intervals. Then, at step 106, an extreme point section of the impedance morphology curve is detected. In one embodiment, the extreme point section is a peak section. A measure of a hemodynamic parameter of the heart, for example, stroke volume, cardiac output, or contractility, utilizing the extreme point section is calculated. Different approaches for calculating the measure will be discussed below. The calculation step may be executed in the programmer or in the implantable device.

Thereafter, at step 108, the obtained measure may be analyzed to optimize at least one pacing parameter of the pulse generator or to derive a change of a condition of the patient. The control circuit 23 may receive the updated pacing parameters to control the heart stimulation pulse generator 22 in response to the output from the such that the patient hemodynamics can be optimized. For example, an AV/VV interval may be optimized. The obtained measure can also be used to trend, for example, heart failure.

Referring now to Figs. 8-12, different calculations procedures for calculating the measure of a hemodynamic parameter of the heart, for example, stroke volume, cardiac output, or contractility according to the present invention will be described. As discussed above, the actual shape of the cardiac impedance signal and especially the morphology of the extreme points sections, e.g. the peak point section, and the immediate surroundings contain information of the hemodynamic

status of the patient that can be used to obtain the above-mentioned relative measure of the hemodynamic parameter.

With reference first to Fig. 8, a first embodiment of the calculation procedure according to the present invention will be disscussed. First, at step 120, an extreme point of the impedance morphology curve is detected. In this embodiment, a top part or peak value of the impedance morhology curve is detected and time window having a predetermined length is centered about this peak value. To locate the peak section of the curve, minima and maxima in the first and second time derivative of the curve can be used. Thereafter, at step 122, a polynomial of a predetermined degree, e.g. a 2^{nd} degree polynomial, is adapted to the curve section of the predetermined time window. If the 2^{nd} degree polynomial is used, it will hence be the following form: $a \cdot x^2 + b \cdot x + c$. Then, at step 124, the constant a is stored as a measure of the curvature of the waveform peak and is used as a measure of the hemodynamic parameter.

Turning instead to Fig. 9, another embodiment of the calculation procedure according to the present invention will be disscussed. First, at step 130, an extreme point of the impedance morphology curve is detected. In this embodiment, a top part or peak value of the impedance morhology curve is detected and time window having a predetermined length is centered about this peak value. Then, at step 132, the sample, S_n, corresponding to the maximum value or peak value is identified. Subsequently, at step 134, a window consiting of samples S_{n-m} to S_{n+m} centred about the maximum value containing a predetermined number 2m+1 of samples, wherein m may be a number between 5 and 35 with $f_s = 128\,\mathrm{Hz}$ (corresponding to 40-280 mS). Thereafter, at step 136, the values of the start and end points or samples of the window, respectively, are identified

and an average value of the start and end values are calculated in accordance with:

$$\frac{Value\_S_{n+m} + Value\_S_{n-m}}{2} = \alpha$$

Then, at step 138, a measure of the hemodynamic parameter is calculated as a ratio of the average value and the maximum value β in accordance with:

Measure of hemodynamic parameter = $\frac{\alpha}{\beta}$

With reference now to Fig. 10, a further embodiment of the calculation procedure according to the present invention will be disscussed. First, at step 140, an extreme point of the impedance morphology curve is detected. In this embodiment, a top part or peak value of the impedance morhology curve is detected and a time window having a predetermined length is centered about this peak value. Then, at step 142, the sample, S_n, corresponding to the maximum value or peak value is identified. Subsequently, at step 144, a window consiting of samples S_{n-m} to S_{n+m} centred about the maximum value containing a predetermined number 2m+1 of samples, wherein m may be a number between 5 and 35 with $f_s = 128$ Hz (corresponding to 40-280 mS). Thereafter, at step 146, the area of the defined curve section is estimated by adding up sample values for the samples S_{n-m} to S_{n+m}. This can be performed with or without time- or amplitude normalization. Finally, at step 148, the calculated area is used a the measure of the hemodynamic parameter, for example, cardiac output or stroke volume.

Turning to Fig. 11, yet another embodiment of the calculation procedure according to the present invention will be disscussed. First, at step 150, an extreme point of the

impedance morphology curve is detected. In this embodiment, a top part or peak value of the impedance morhology curve is detected and time window having a predetermined length is centered about this peak value. Then, at step 152, the sample, S_n, corresponding to the maximum value or peak value is identified. Subsequently, at step 154, a window consiting of samples S_{n-m} to S_{n+m} centred about the maximum value containing a predetermined number 2m+1 of samples, wherein m may be a number between 5 and 35 with $f_s = 128\,\mathrm{Hz}$ (corresponding to 40-280 mS). Thereafter, at step 156, the average slopes from sample S_{n-m} to the maximum point, A, and from the maximum point to the sample S_{n+m}, B, are calculated, respectively. Finally, at step 158, the measure is calculated as the ratio between the slopes in accordance with the following:

Measure of hemodynamic parameter = $\frac{A}{-B}$.

This ratio thus describes a warpedness of the section of the curve of the window.

Alternatively, the measure can be calculated as:

Measure of hemodynamic parameter = $A \cdot (-B)$.

According to a further alternative, the measure is calculated as:

Measure of hemodynamic parameter = $\frac{1}{A+(-B)}$.

According to still another embodiment, a time window at a predetermined amplitude in relation to the maximum value is

defined and a width of the time window is calculated as the measure.

Although an exemplary embodiment of the present invention has been shown and described, it will be apparent to those having ordinary skill in the art that a number of changes, modifications, or alterations to the inventions as described herein may be made. Thus, it is to be understood that the above description of the invention and the accompanying drawings is to be regarded as a non-limiting example thereof and that the scope of protection is defined by the appended patent claims.

CLAIMS

1. An implantable medical device including a pulse generator adapted to produce cardiac stimulating pacing pulses, said device being connectable to at least one lead comprising electrodes for delivering said pulses to cardiac tissue of a heart of a patient, comprising:

an impedance measuring unit connectable to at least two electrodes adapted to measure cardiac impedance of said heart, said impedance measuring unit being adapted to provide impedance information corresponding to said measured impedance;

an impedance morphology determining unit adapted to receive said impedance information and to determine an impedance morphology curve from said impedance information; and

a calculation unit adapted to detect an extreme point section of said impedance morphology curve and to calculate a measure of a hemodynamic parameter of said heart utilizing said an extreme point section.

2. The implantable medical device according to claim 1, wherein said extreme point section is a peak section.

3. The implantable medical device according to claim 1 or 2, further comprising an analyzer adapted to analyze said measure to optimize at least one pacing parameter of said pulse generator or to derive a change of a condition of said patient.

4. The implantable medical device according to claim 2 or 3, wherein said calculation unit is adapted to calculate said measure by means of the shape of the impedance morphology curve in a time window surrounding said peak section of said impedance morphology curve.

5. The implantable medical device according to any one of preceding claims, wherein said impedance morphology determining unit is adapted to determine an averaged impedance morphology curve from said impedance information during a time interval of a plurality of cardiac cycles of said heart.

6. The implantable medical device according to any one of claims 1-4, wherein said impedance morphology determining unit is adapted to perform a filtering procedure of said received impedance information and to determine an impedance morphology curve from said filtered impedance information.

7. The implantable medical device according to any one of preceding claims, wherein said calculation unit is adapted to detect the maximum value of said impedance morphology curve and to centre said time window about said value.

8. The implantable medical device according to any one of preceding claims, wherein said calculation unit is adapted to fit a polynomial of degree two to the section of the impedance morphology curve in said time window.

9. The implantable medical device according to claim 8, wherein said calculation unit is adapted to calculate a curvature component of said polynomial as said measure.

10. The implantable medical device according to claim 7, wherein said calculation unit is adapted to:

identify the sample corresponding to the maximum value;

define a window centred about the maximum value containing a predetermined number of samples;

identify the values of the start and end samples of said window, respectively;

calculate an average value of said start and end values; and

calculate a ratio of said average value and said maximum value as said measure.

11. The implantable medical device according to claim 7, wherein said calculation unit is adapted to

identify the sample corresponding to the maximum value;

define a window centred about the maximum value containing a predetermined number of samples; and

calculating an area of said window by adding the values of said predetermined number of samples as said measure.

12. The implantable medical device according to claim 7, wherein said calculation unit is adapted to

identify the sample corresponding to the maximum value;

define a time window centred about the maximum value containing a predetermined number of samples;

identify the values of the start and end values of said window, respectively;

calculate a first average slope from the sample corresponding to said start value to said sample corresponding to said maximum value;

calculate a second average slope from the sample corresponding to the maximum value to the sample corresponding to the end value; and

calculate a ratio between said first slope and said second slope as said measure.

13. The implantable medica device according to claim 7, wherein said calculation unit is adapted to

define a time window at a predetermined amplitude in relation to the maximum value; and

calculating a width of said time window as said measure.

14. The implantable medical device according to any one of preceding claims, wherein said hemodynamic parameter is stroke volume, cardiac output, or contractility.

15. The implantable medical device according to any one of preceding claims, further comprising

a posture sensor adapted to sense at least one predetermined posture of said patient and to provide at least one posture indicating signal; and wherein

said impedance measuring unit is adapted to initiate a cardiac impedance measuring session upon receiving a posture indicating signal that indicates that said patient is in at least one predetermined posture.

16. The implantable medical device according to any one of preceding claims, further comprising

a breathing rate sensor adapted to sense a breathing rate of said patient and to provide at least one breathing rate indicating signal; and wherein

said impedance measuring unit is adapted to initiate a cardiac impedance measuring session upon receiving a breathing rate indicating signal that indicates a breating rate within at least one predetermined interval.

17. The implantable medical device according to any one of preceding claims, further comprising

an activity level sensor adapted to sense an activity level of said patient and to provide at least one activity level indicating signal; and wherein

said impedance measuring unit is adapted to

initiate a cardiac impedance measuring session upon receiving an activity level indicating signal that indicates an activity level within at least one predetermined interval.

18. A medical system including an external programmer apparatus comprising a communication unit and an implantable medical device including a pulse generator adapted to produce cardiac stimulating pacing pulses, said implantable device being connectable to at least one lead comprising electrodes for delivering said pulses to cardiac tissue of a heart of a patient, and a communication unit, said external apparatus and said implantable device being adapted for two-way communication of data using said communication units,

wherein said implantable medical device further comprises an impedance measuring unit connectable to at least two electrodes adapted to measure cardiac impedance of said heart, said impedance measuring unit being adapted to provide impedance information corresponding to said measured impedance; and

wherein said external apparatus is adapted to obtain said impedance information via said communication unit and further comprises

an impedance morphology determining unit adapted to receive said impedance information and to determine an impedance morphology curve from said impedance information; and

a calculation unit adapted to detect an extreme point section of said impedance morphology curve and to calculate a measure of a hemodynamic parameter of said heart utilizing said an extreme point section.

19. The system according to claim 18, wherein said extreme point section is a peak section.

20. The system according to claim 18 or 19, wherein said external programmer apparatus further comprises an analyzer adapted to analyze said measure to optimize at least one pacing parameter of said pulse generator or to derive a change of a condition of said patient, said external apparatus being adapted to communicate said at least one pacing parameter to said implantable device.

21. The system according to claim 18 or 19, wherein said external programmer apparatus is adapted to communicate said measure to said implantable device and wherein said implantable medical device further comprises an analyzer adapted to analyze said measure to optimize at least one pacing parameter of said pulse generator or to derive a change of a condition of said patient.

22. The system according to claim 20 or 21, wherein said calculation unit is adapted to calculate said measure by means of the shape of the impedance morphology curve in a time window surrounding said peak section of said impedance morphology curve.

23. The system according to any one of preceding claims 18-22, wherein said impedance morphology determining unit is adapted to determine an averaged impedance morphology curve from said impedance information during a time interval of a plurality of cardiac cycles of said heart.

24. The system according to any one of claims 18-23, wherein said impedance morphology determining unit is adapted to perform a filtering procedure of said received impedance information and to determine an impedance morphology curve from said filtered impedance information.

25. The system according to any one of preceding claims 18-24, wherein said calculation unit is adapted to detect the maximum value of said impedance morphology curve and to centre said time window about said value.

26. The system according to any one of preceding claims 18-25, wherein said calculation unit is adapted to fit a polynomial of degree two to the section of the impedance morphology curve in said time window.

27. The system according to claim 26, wherein said calculation unit is adapted to calculate a curvature component of said polynomial as said measure.

28. The system according to claim 25, wherein said calculation unit is adapted to:

identify the sample corresponding to the maximum value;

define a window centred about the maximum value containing a predetermined number of samples;

identify the values of the start and end values of said window, respectively;

calculate an average value of said start and end values; and

calculate a ratio of said average value and said maximum value as said measure.

29. The system according to claim 25, wherein said calculation unit is adapted to

identify the sample corresponding to the maximum value;

define a window centred about the maximum value containing a predetermined number of samples; and

calculating an area of said window by adding the values of said predetermined number of samples as said measure.

30. The system according to claim 25, wherein said calculation unit is adapted to

identify the sample corresponding to the maximum value;

define a time window centred about the maximum value containing a predetermined number of samples;

identify the values of the start and end values of said window, respectively

calculate a first average slope from the sample corresponding to said start value to said sample corresponding to said maximum value;

calculate a second average slope from the sample corresponding to the maximum value to the sample corresponding to the end value; and

calculate said measure using said first slope and said second slope.

31. The system according to claim 25, wherein said calculation unit is adapted to

define a time window at a predetermined amplitude in relation to the maximum value; and

calculating a width of said time window as said measure.

32. The system according to any one of preceding claims 18-31, wherein said hemodynamic parameter is stroke volume, cardiac output, or contractility.

33. The system according to any one of preceding claims 18-32, further comprising

a posture sensor adapted to sense at least one predetermined posture of said patient and to provide at least one posture indicating signal; and wherein

said impedance measuring unit is adapted to initiate a cardiac impedance measuring session upon

receiving a posture indicating signal that indicates that said patient is in at least one predetermined posture.

34. The system according to any one of preceding claims 18-33, further comprising

a breathing rate sensor adapted to sense a breathing rate of said patient and to provide at least one breathing rate indicating signal; and wherein

said impedance measuring unit is adapted to initiate a cardiac impedance measuring session upon receiving a breathing rate indicating signal that indicates a breating rate within at least one predetermined interval.

35. The system according to any one of preceding claims 18-34, further comprising

an activity level sensor adapted to sense an activity level of said patient and to provide at least one activity level indicating signal; and wherein

said impedance measuring unit is adapted to initiate a cardiac impedance measuring session upon receiving an activity level indicating signal that indicates an activity level within at least one predetermined interval.

36. A medical system including an external programmer apparatus comprising a communication unit and an implantable medical device including a pulse generator adapted to produce cardiac stimulating pacing pulses, said implantable device being connectable to at least one lead comprising electrodes for delivering said pulses to cardiac tissue of a heart of a patient, and a communication unit, said external apparatus and said implantable device being adapted for two-way communication of data using said communication units,

wherein said implantable medical device further

comprises an impedance measuring unit connectable to at least two electrodes adapted to measure cardiac impedance of said heart, said impedance measuring unit being adapted to provide impedance information corresponding to said measured impedance; and

an impedance morphology determining unit adapted to receive said impedance information and to determine an impedance morphology curve from said impedance information; and

wherein said external apparatus is adapted to obtain said impedance morphology curve via said communication unit and further comprising

a calculation unit adapted to detect an extreme point section of said impedance morphology curve and to calculate a measure of a hemodynamic parameter of said heart utilizing said an extreme point section.

37. The system according to claim 36, wherein said extreme point section is a peak section.

38. The system according to claim 36 or 37, wherein said external programmer apparatus further comprises an analyzer adapted to analyze said measure to optimize at least one pacing parameter of said pulse generator or to derive a change of a condition of said patient, said external apparatus being adapted to communicate said at least one pacing parameter to said implantable device.

39. The system according to claim 36 or 37, wherein said external programmer apparatus is adapted to communicate said measure to said implantable device and wherein said implantable medical device further comprises an analyzer adapted to analyze said measure to optimize at least one pacing parameter of said pulse generator or to derive a change of a condition of said patient.

40. The system according to claim 38 or 39, wherein said calculation unit is adapted to calculate said measure by means of the shape of the impedance morphology curve in a time window surrounding said peak section of said impedance morphology curve.

41. The system according to any one of preceding claims 36-40, wherein said impedance morphology determining unit is adapted to determine an averaged impedance morphology curve from said impedance information during a time interval of a plurality of cardiac cycles of said heart.

42. The system according to any one of claims 36-41, wherein said impedance morphology determining unit is adapted to perform a filtering procedure of said received impedance information and to determine an impedance morphology curve from said filtered impedance information.

43. The system according to any one of preceding claims 36-42, wherein said calculation unit is adapted to detect the maximum value of said impedance morphology curve and to centre said time window about said value.

44. The system according to any one of preceding claims 36-43, wherein said calculation unit is adapted to fit a polynomial of degree two to the section of the impedance morphology curve in said time window.

45. The system according to claim 43, wherein said calculation unit is adapted to calculate a curvature component of said polynomial as said measure.

46. The system according to claim 43, wherein said calculation unit is adapted to:

identify the sample corresponding to the maximum value;

define a window centred about the maximum value containing a predetermined number of samples;

identify the values of the start and end values of said window, respectively;

calculate an average value of said start and end values; and

calculate a ratio of said average value and said maximum value as said measure.

47. The system according to claim 43, wherein said calculation unit is adapted to

identify the sample corresponding to the maximum value;

define a window centred about the maximum value containing a predetermined number of samples; and

calculating an area of said window by adding the values of said predetermined number of samples as said measure.

48. The system according to claim 43, wherein said calculation unit is adapted to

identify the sample corresponding to the maximum value;

define a time window centred about the maximum value containing a predetermined number of samples;

identify the values of the start and end values of said window, respectively

calculate a first average slope from the sample corresponding to said start value to said sample corresponding to said maximum value;

calculate a second average slope from the sample corresponding to the maximum value to the sample corresponding to the end value; and

calculate said measure using said first slope and said second slope.

49. The system according to claim 43, wherein said calculation unit is adapted to

define a time window at a predetermined amplitude in relation to the maximum value; and

calculating a width of said time window as said measure.

50. The system according to any one of preceding claims 36-49, wherein said hemodynamic parameter is stroke volume, cardiac output, or contractility.

51. The system according to any one of preceding claims 36-50, further comprising

a posture sensor adapted to sense at least one predetermined posture of said patient and to provide at least one posture indicating signal; and wherein

said impedance measuring unit is adapted to initiate a cardiac impedance measuring session upon receiving a posture indicating signal that indicates that said patient is in at least one predetermined posture.

52. The system according to any one of preceding claims 36-51, further comprising

a breathing rate sensor adapted to sense a breathing rate of said patient and to provide at least one breathing rate indicating signal; and wherein

said impedance measuring unit is adapted to initiate a cardiac impedance measuring session upon receiving a breathing rate indicating signal that indicates a breating rate within at least one predetermined interval.

53. The system according to any one of preceding claims 36-52, further comprising

an activity level sensor adapted to sense an activity level of said patient and to provide at least one activity level indicating signal; and wherein

said impedance measuring unit is adapted to initiate a cardiac impedance measuring session upon receiving an activity level indicating signal that indicates an activity level within at least one predetermined interval.

54. A method for calculating a measure of a hemodynamic parameter of a heart of a patient, comprising the steps of:

measuring a cardiac impedance of said heart;

determining an impedance morphology curve from said impedance information;

calculating an extreme point section of said impedance morphology curve; and

calculating a measure of a hemodynamic parameter of said heart utilizing said an extreme point section.

55. The method according to claim 54, wherein said extreme point section is a peak section.

56. The method according to claim 54 or 55, further comprising the step of analyzing said measure to optimize at least one pacing parameter of said pulse generator or to derive a change of a condition of said patient.

57. The method according to claim 55 or 56, further comprising the step of calculating said measure by means of the shape of the impedance morphology curve in a time window surrounding said peak section of said impedance morphology curve.

58. The method according to any one of preceding claims 54-57, further comprising the step of determining an averaged impedance morphology curve from said impedance information during a time interval of a plurality of cardiac cycles of said heart.

59. The method according to any one of claims 54-57, further comprising the step of performing a filtering procedure of said impedance information and to determine an impedance morphology curve from said filtered impedance information.

60. The method according to any one of preceding claims 54-59, further comprising the step of detecting the maximum value of said impedance morphology curve and to centre said time window about said value.

61. The method according to any one of preceding claims 54-60, further comprising the step of fitting a polynomial of degree two to the section of the impedance morphology curve in said time window.

62. The method according to claim 61, further comprising the step of calculating a curvature component of said polynomial as said measure.

63. The method according to claim 60, further comprising the steps of:

identifying the sample corresponding to the maximum value;

defining a window centred about the maximum value containing a predetermined number of samples;

identifying the values of the start and end samples of said window, respectively;

calculating an average value of said start and end values; and

calculating a ratio of said average value and said maximum value as said measure.

64. The method according to claim 60, further comprising the steps of:

identifying the sample corresponding to the maximum value;

defining a window centred about the maximum value containing a predetermined number of samples; and

calculating an area of said window by adding the values of said predetermined number of samples as said measure.

65. The method according to claim 60, further comprising the steps of:

identifying the sample corresponding to the maximum value;

defining a time window centred about the maximum value containing a predetermined number of samples;

identifying the values of the start and end values of said window, respectively;

calculating a first average slope from the sample corresponding to said start value to said sample corresponding to said maximum value;

calculating a second average slope from the sample corresponding to the maximum value to the sample corresponding to the end value; and

calculating said measure using said first slope and said second slope.

66. The implantable medica device according to claim 60, further comprising the steps of:

defining a time window at a predetermined amplitude in relation to the maximum value; and

calculating a width of said time window as said measure.

67. The method according to any one of preceding claims 54-66, wherein said hemodynamic parameter is stroke volume, cardiac output, or contractility.

68. The method according to any one of preceding claims 54-67, further comprising the steps of:

sensing at least one predetermined posture of said patient; and

initiating a cardiac impedance measuring session upon an indication that said patient is in at least one predetermined posture.

69. The method according to any one of preceding claims 54-68, further comprising the steps of:

sensing a breathing rate of said patient; and

initiating a cardiac impedance measuring session upon an indication of a breating rate within at least one predetermined interval.

70. The method according to any one of preceding claims 54-69, further comprising the steps of:

sensing an activity level of said patient; and

initiating a cardiac impedance measuring session upon an indication that an activity level is within at least one predetermined interval.

71. A computer program product, which when executed on a computer, performs steps in accordance with any one of claims 54-70.

72. Computer readable medium comprising instructions for bringing a computer to perform steps in accordance with a method according to any one of the preceding claims 54-70.

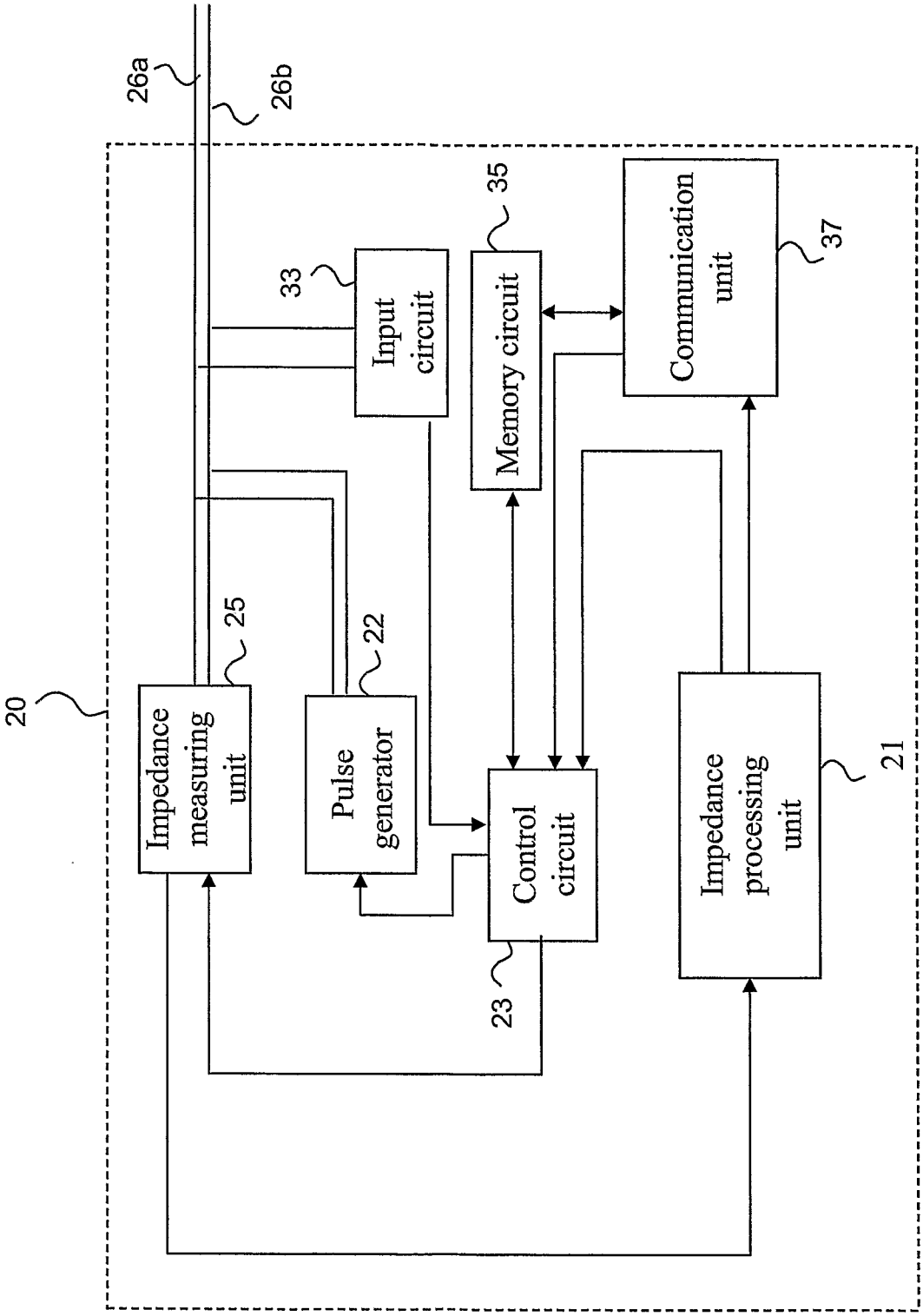
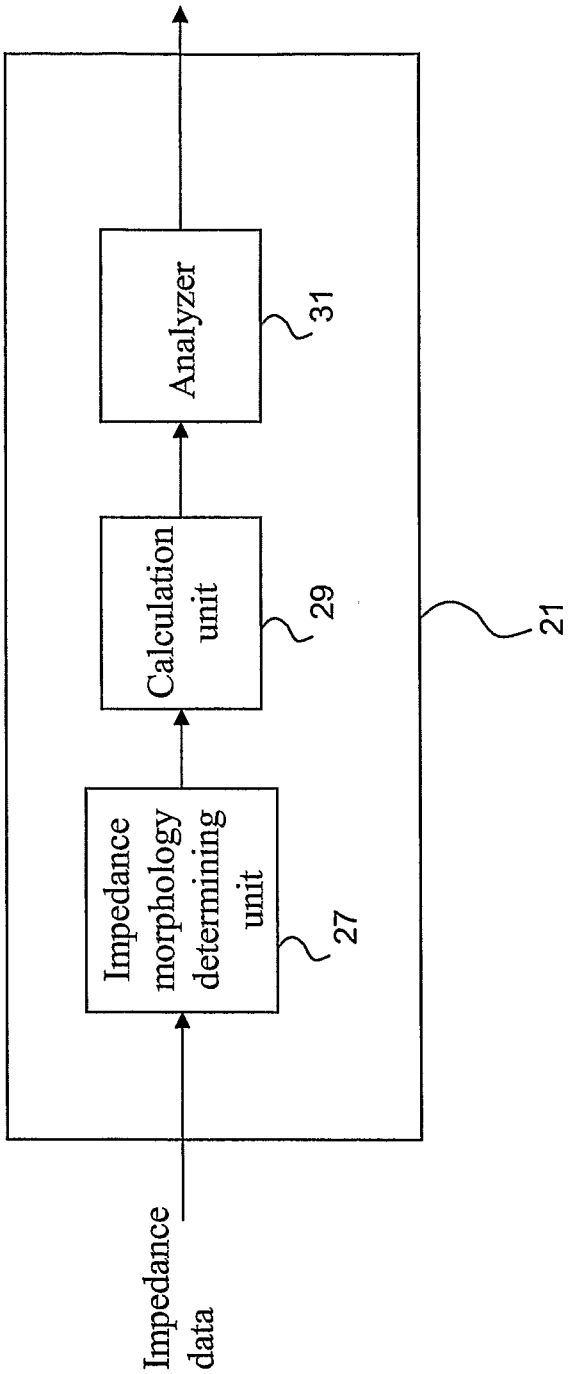

26a
26b
20
Impedance measuring unit
25
Pulse generator
22
Input circuit
33
Memory circuit
35
Communication unit
37
Control circuit
23
Impedance processing unit
21

Fig. 1


Impedance data
Impedance morphology determining unit
27
Calculation unit
29
Analyzer
31
21

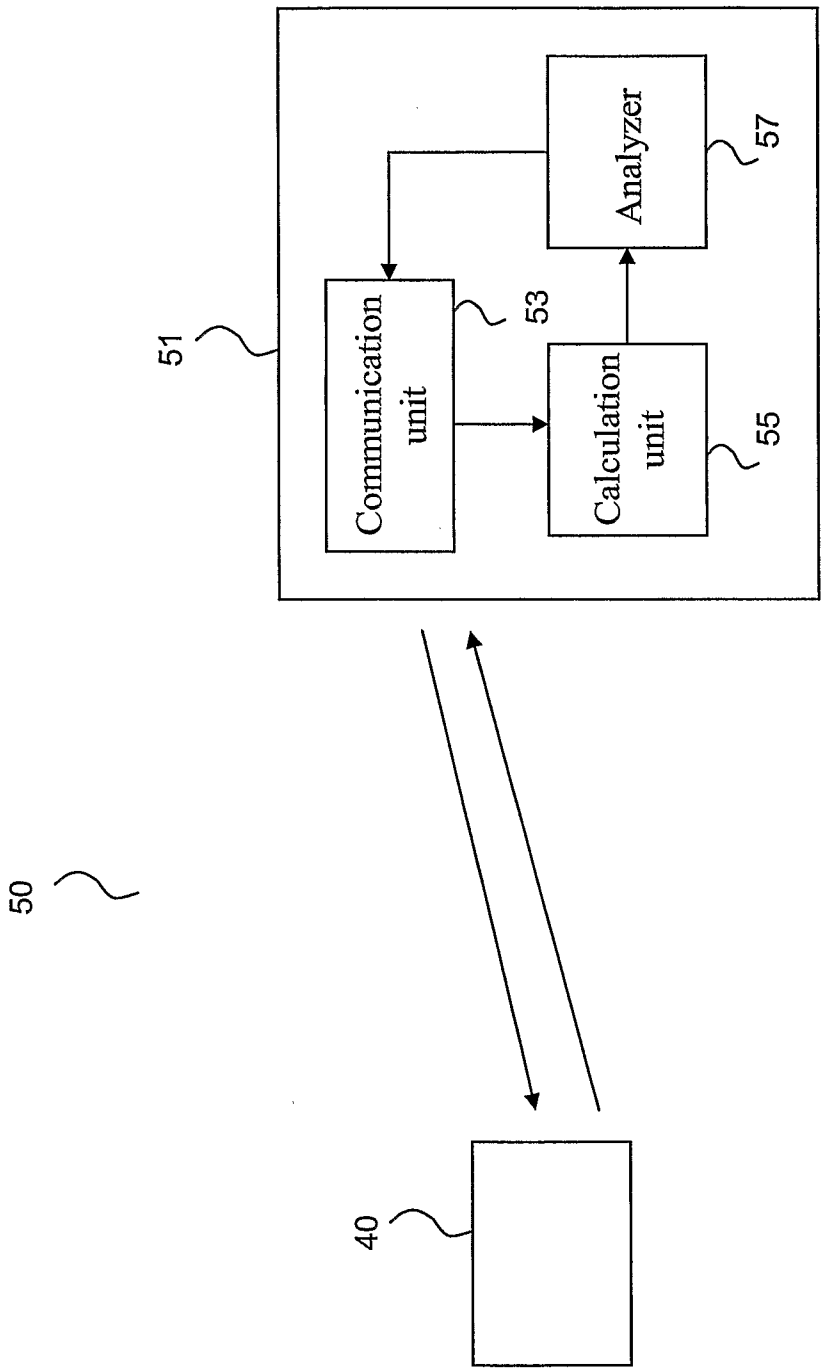

50
51
Communication unit
53
Calculation unit
55
Analyzer
57
40

Fig. 3

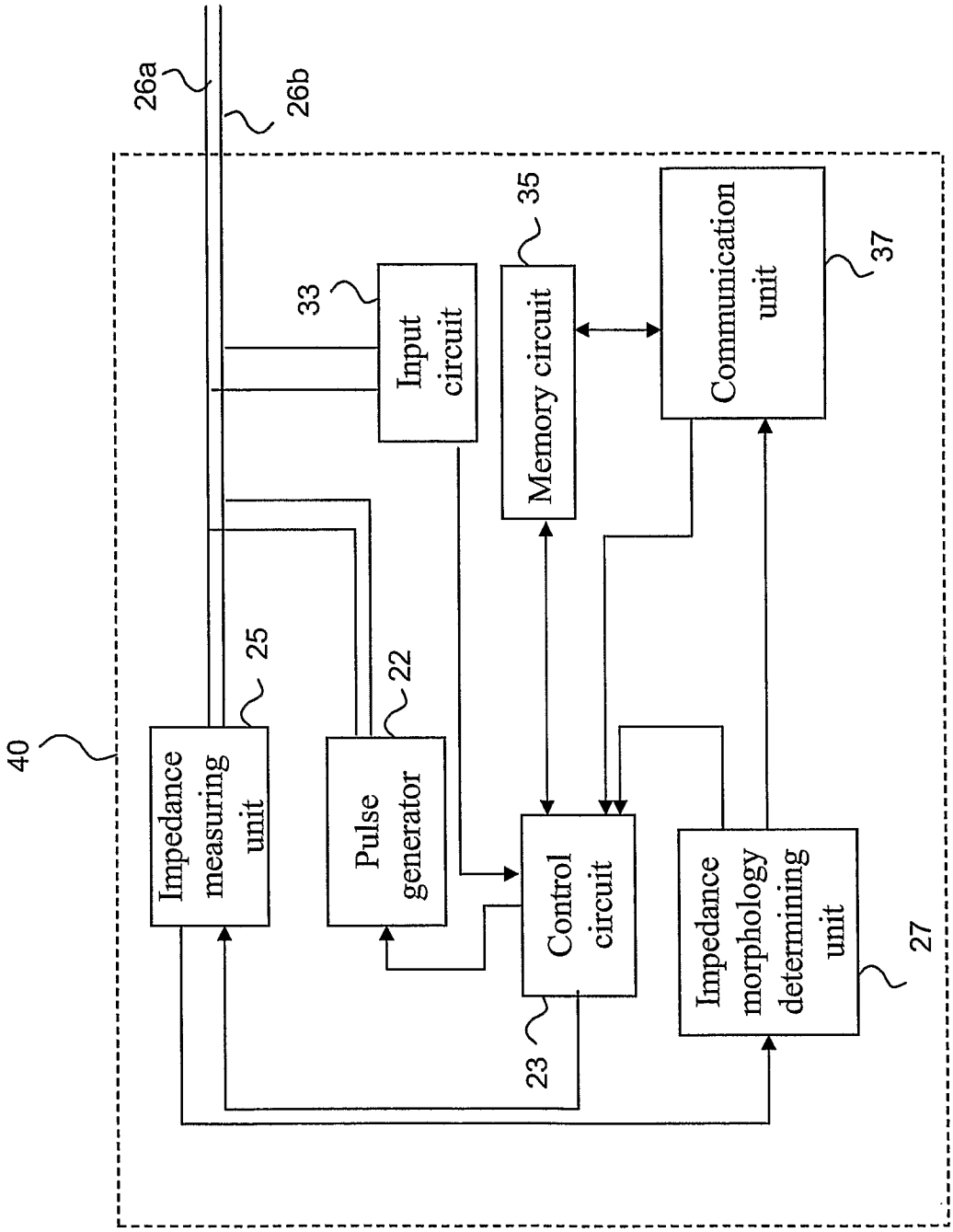

26a
26b
35
33
Input circuit
Memory circuit
Communication unit
37
40
25
22
Impedance measuring unit
Pulse generator
Control circuit
Impedance morphology determining unit
27
23

Fig. 4

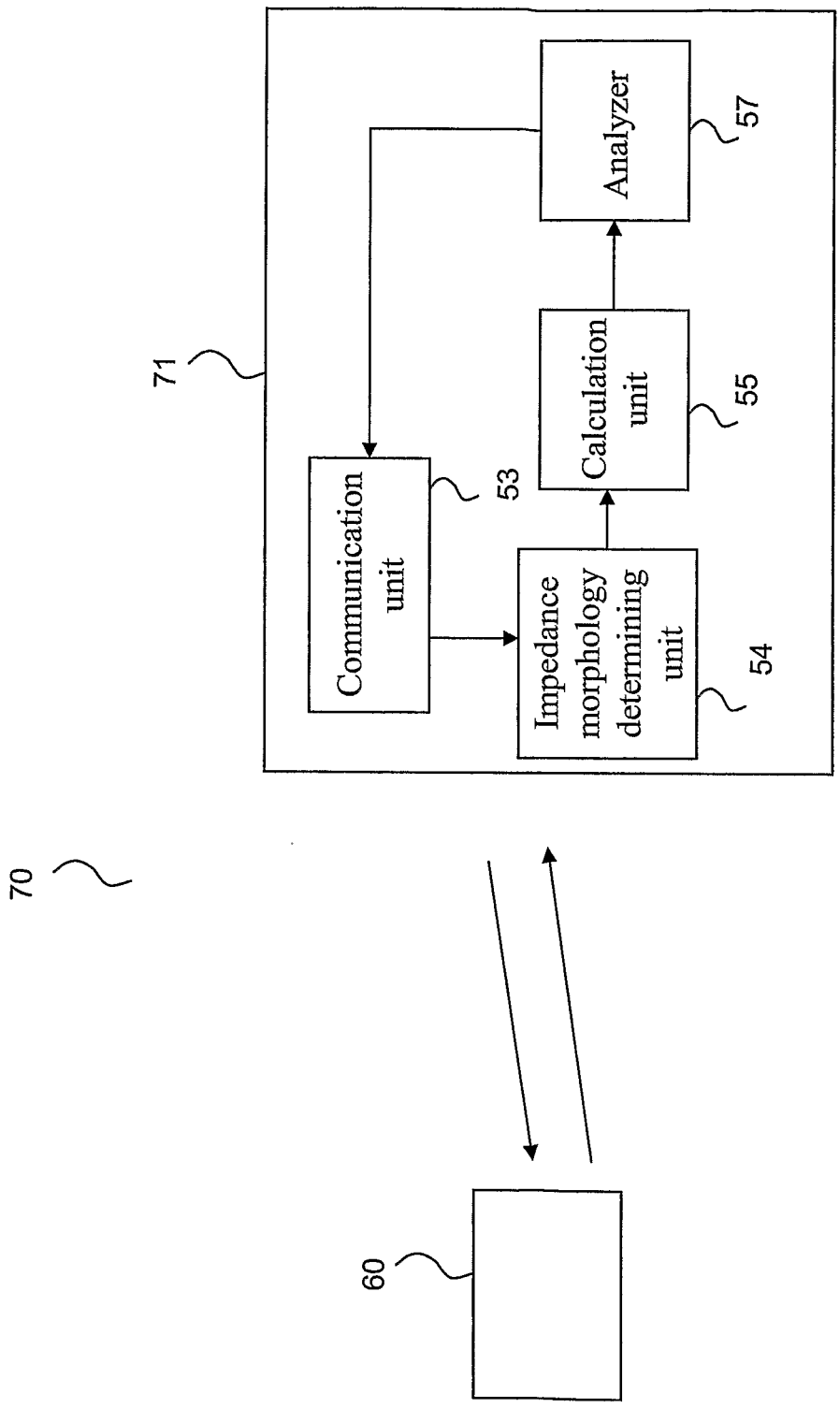

70
71
Communication unit
53
Impedance morphology determining unit
54
Calculation unit
55
Analyzer
57
60

Fig. 5

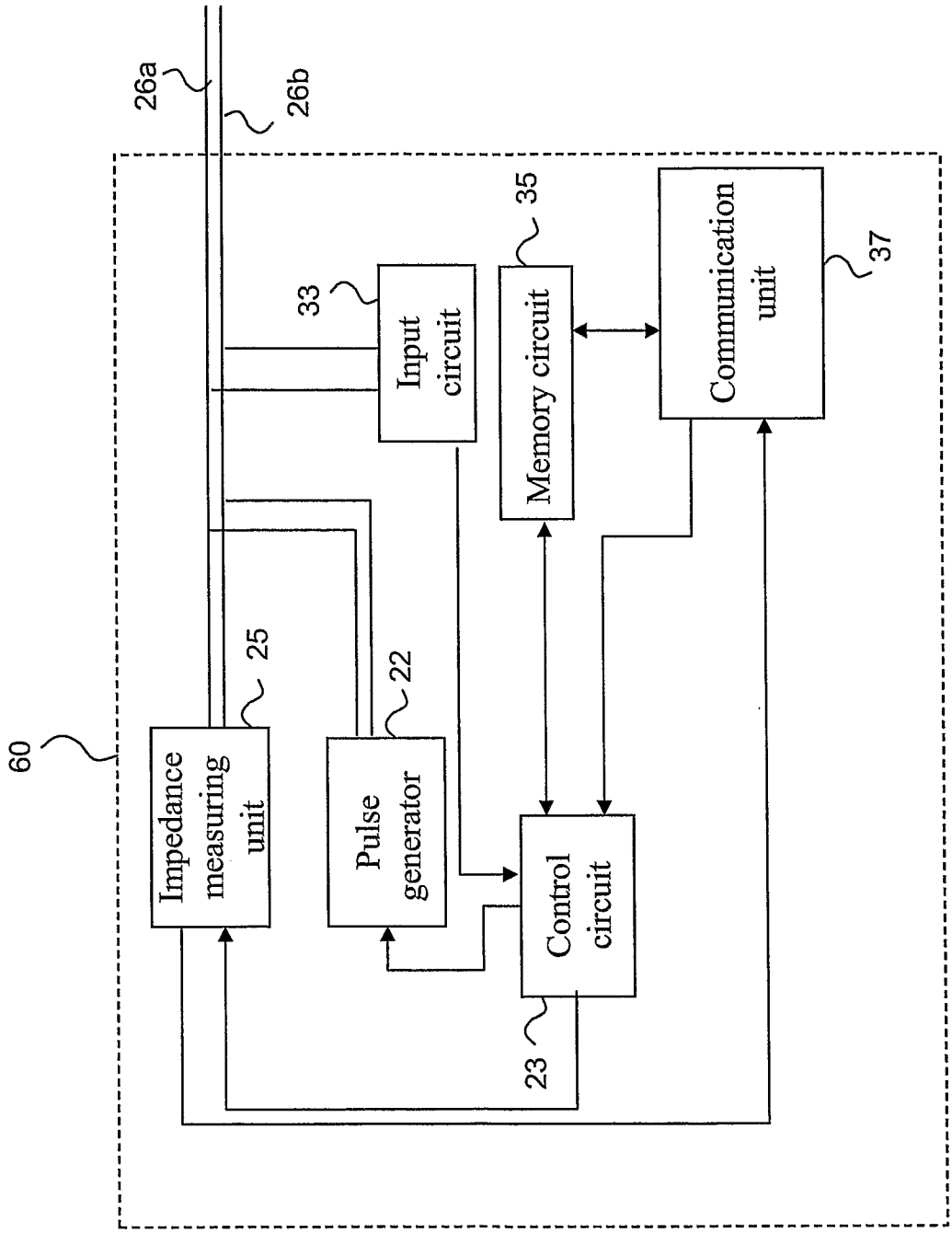

26a
26b
60
Impedance measuring unit
25
Pulse generator
22
Control circuit
23
Input circuit
33
Memory circuit
35
Communication unit
37

Fig. 6

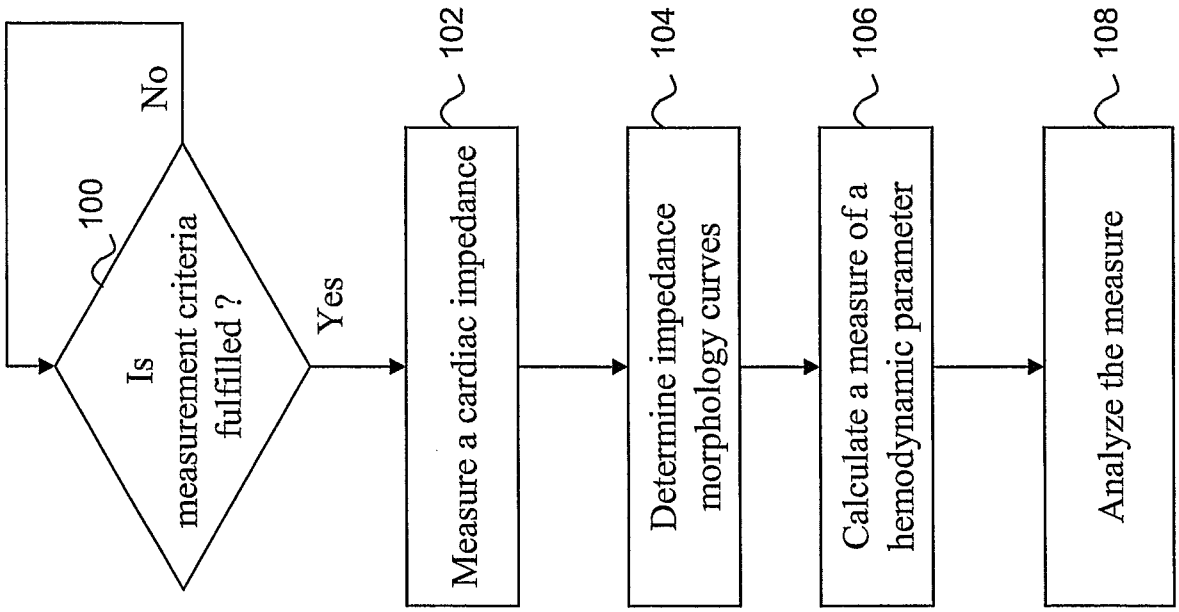

Is measurement criteria fulfilled ?
100
No
Yes
Measure a cardiac impedance
102
Determine impedance morphology curves
104
Calculate a measure of a hemodynamic parameter
106
Analyze the measure
108

Fig. 7

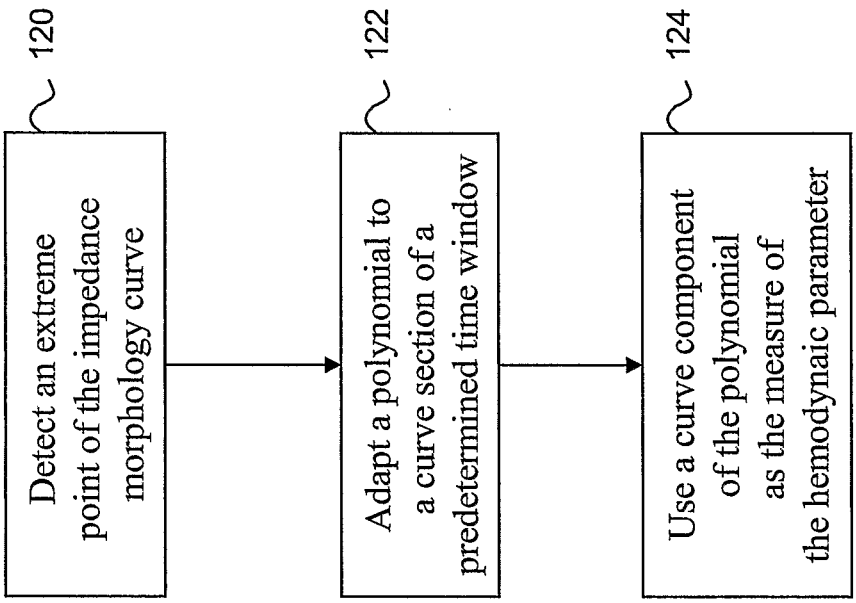

120
Detect an extreme point of the impedance morphology curve
122
Adapt a polynomial to a curve section of a predetermined time window
124
Use a curve component of the polynomial as the measure of the hemodynaic parameter

Fig. 8

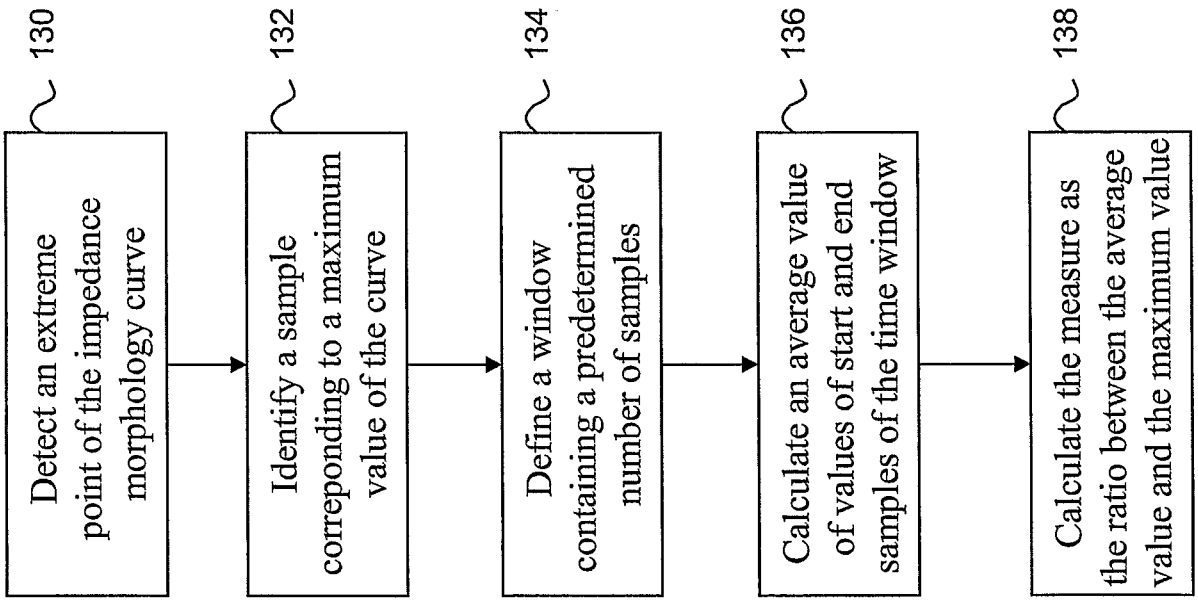

130
Detect an extreme point of the impedance morphology curve
132
Identify a sample correponding to a maximum value of the curve
134
Define a window containing a predetermined number of samples
136
Calculate an average value of values of start and end samples of the time window
138
Calculate the measure as the ratio between the average value and the maximum value

Fig. 9

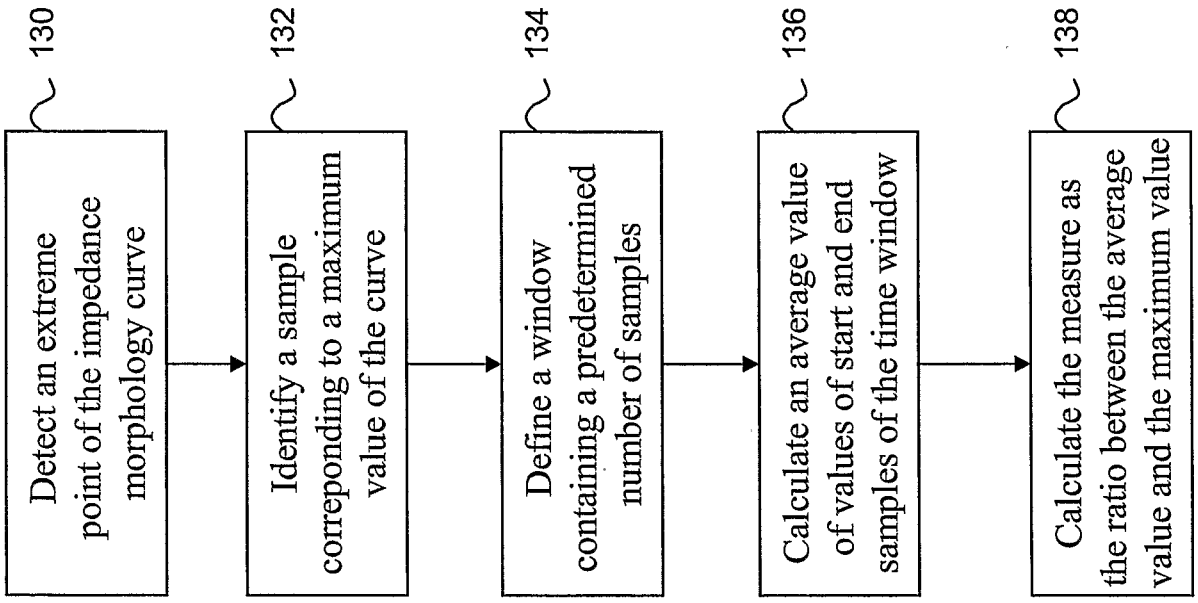

130
Detect an extreme point of the impedance morphology curve
132
Identify a sample correponding to a maximum value of the curve
134
Define a window containing a predetermined number of samples
136
Calculate an average value of values of start and end samples of the time window
138
Calculate the measure as the ratio between the average value and the maximum value

Fig. 10

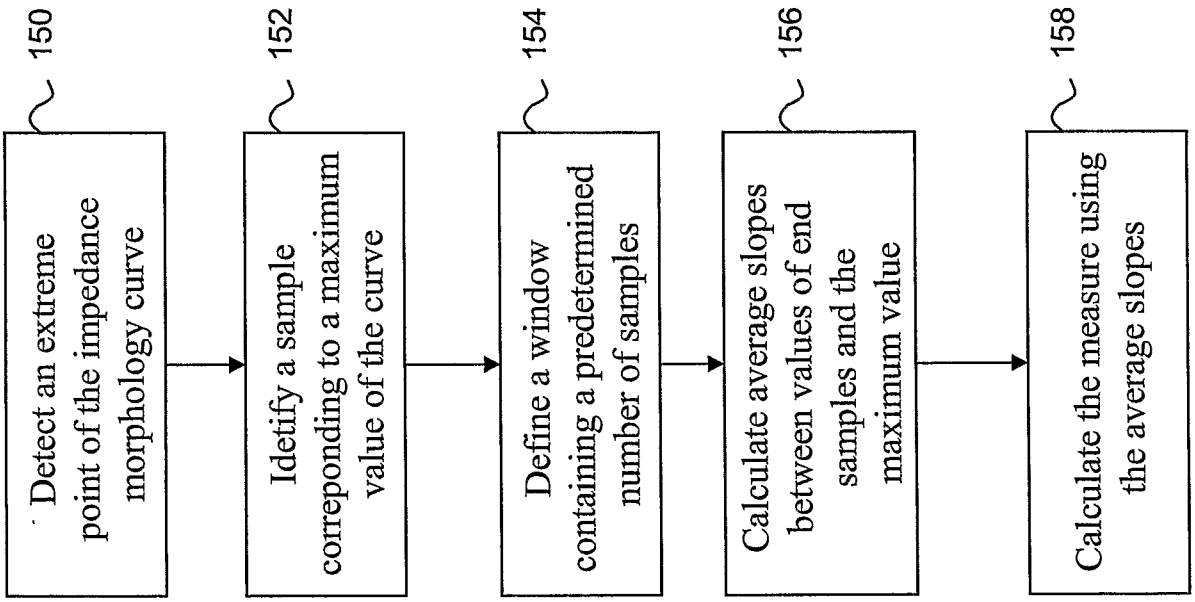

150
Detect an extreme point of the impedance morphology curve
152
Idetify a sample correponding to a maximum value of the curve
154
Define a window containing a predetermined number of samples
156
Calculate average slopes between values of end samples and the maximum value
158
Calculate the measure using the average slopes

Fig. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2006/000756

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: A61B, A61N

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.
A	EP 1384492 A1 (ST. JUDE MEDICAL AB), 28 January 2004 (28.01.2004), figure 10, abstract, [0007] --	1-72
A	US 5824019 A (JOHN C. RUETER ET AL), 20 October 1998 (20.10.1998), abstract --	1-72
A	US 6522914 B1 (ETIENNE HUVELLE ET AL), 18 February 2003 (18.02.2003), column 4, line 20 - line 45, abstract --	1-72

[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 on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 January 2007	02 -02- 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 Gordana Ninkovic/MN Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2006/000756

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 20020138014 A1 (GAIL D. BAURA ET AL), 26 Sept 2002 (26.09.2002), figure 6, abstract ---	1-72
A	US 30101 E (WILLIAM G. KUBICEK ET AL), 25 Sept 1979 (25.09.1979), abstract, Reissue of US A 3340867 ---	1-72
A	JOHNSTON P.W. ET AL "The transthoracic impedance cardiogram is a potential haemodynamic sensor for an automated external defibrillator", European Heart Journal, 1998, vol. 19, p. 18791888, ISSN 0195-668X see figure 3; abstract ---	1-72

International patent classification (IPC)

A61N 1/365 (2006.01)
A61B 5/053 (2006.01)

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

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

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

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/SE2006/000756

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

1. ☒ Claims Nos.: 54-72
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 54-72 relate to a method of treatment of the human or animal body by surgery or by therapy, as well as diagnostic

.../...

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional 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.

☐ 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.

Box II.1

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 device.

EP	1384492	A1	28/01/2004	AU	2002359115 A	00/00/0000
				EP	1465566 A	13/10/2004
				JP	2005514162 T	19/05/2005
				MX	PA04005481 A	06/12/2004
				SE	0202288 D	00/00/0000
				US	20040078058 A	22/04/2004
US	5824019	A	20/10/1998	NONE		
US	6522914	B1	18/02/2003	AU	8049801 A	30/01/2002
				US	7062326 B	13/06/2006
				US	20030114889 A	19/06/2003
				WO	0205893 A	24/01/2002
US	20020138014	A1	26/09/2002	US	6561986 B	13/05/2003
US	30101	E	25/09/1979	NONE		

专利名称(译)	使用心内阻抗确定血液动力学参数的医疗装置和系统		
公开(公告)号	EP2035083A1	公开(公告)日	2009-03-18
申请号	EP2006747945	申请日	2006-06-21
申请(专利权)人(译)	ST.犹达医疗用品AB		
当前申请(专利权)人(译)	ST.犹达医疗用品AB		
[标]发明人	BLOMQVIST ANDREAS SVAHN JOHAN		
发明人	BLOMQVIST, ANDREAS SVAHN, JOHAN		
IPC分类号	A61N1/365 A61B5/053 A61B5/00 A61B5/0402		
CPC分类号	A61N1/36521 A61B5/0031 A61B5/02028 A61B5/053		
其他公开文献	EP2035083B1 EP2035083A4		
外部链接	Espacenet		

摘要(译)

本发明涉及可植入医疗设备，例如起搏器或心律转变器/除颤器（ICD），以及包括这种设备和外部编程器的系统，用于确定血液动力学参数的测量，例如心输出量，每搏输出量或收缩性。患者，例如，用于趋势性心力衰竭或AV / VV优化方案。可植入医疗设备适于测量心脏阻抗，心脏阻抗数据用于确定阻抗形态曲线，其又用于计算血液动力学参数的测量值。