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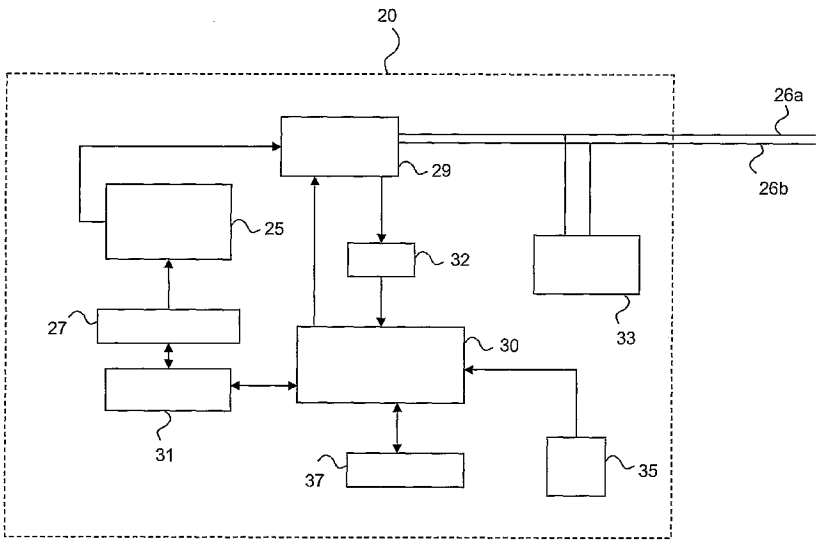
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(54) **Title:** METHOD AND IMPLANTABLE MEDICAL DEVICE FOR ASSESSING A DEGREE OF PULMONARY EDEMA OF A PATIENT.



(57) **Abstract:** The present invention relates to a method for assessing a degree of pulmonary edema of a patient using an implantable medical device. The method comprises the steps of detecting at least two specific body positions of the patient; initiating at least one impedance sensing session to sense trans-thoracic impedance signals when the patient is in one position of the at least two specific positions; obtaining impedance values from the impedance signals; determining a relation between respective impedance values at the at least two positions; storing the relation; and using the relation as a metric of pulmonary edema to assess the degree of pulmonary edema. The invention also relates to an implantable medical device, a computer program product, and a computer readable medium comprising instructions for bringing a computer to perform the method.

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Method and implantable medical device for assessing a degree of pulmonary edema of a patient.

TECHNICAL FIELD

The present invention generally relates to implantable medical devices, such as cardiac pacemakers and implantable cardioverter/defibrillators, and in particular to an improved method and an implantable medical device for assessing a degree of pulmonary edema of a patient.

BACKGROUND OF THE INVENTION

Today, in the modern society, heart diseases and/or conditions leading to an impaired heart function are a major problem entailing constantly increasing costs for medical services. For example, heart failure is a condition which affects thousands of people throughout the world. Congestive heart failure (CHF) is the inability of the heart to supply the body with an adequate amount of blood. Patients suffering from CHF are often afflicted by cardogenic pulmonary edema, which is caused by the accumulation of fluid in the lung interstitium and alveoli due to the fact the left ventricular venous return exceeds left ventricular cardiac output. That is, more fluids are transported to the lung region than from the lung region causing the accumulation of fluids in the lung region. Hence, pulmonary edema is a common effect of congestive heart failure (CHF) and CHF patients are often on diuretics to decrease the risk of this. However, diuretics can be difficult to titrate and the amount needed may differ from day to day. Accordingly, reliable and accurate information that can be used to assess a degree of pulmonary edema or amount of pulmonary fluid would be of great use. Such information should also be easy and convenient to obtain, should be sensitive to early changes of the pulmonary fluid, and should be obtained automatically. In this respect, the electrical bio-impedance and, in particular, the trans-thoracic impedance have been found to constitute an effective measure for identifying changes of different conditions of the body of a patient, such as incipient pulmonary edema and the progression of pulmonary edema due to CHF, i.e. the accumulation of fluids in the lung-region associated with pulmonary edema affects the thoracic impedance, or more specifically the DC impedance level, since the resistivity of the lung changes in accordance with a change of the ratio of fluid to air. The DC impedance level is negatively correlated with the amount of fluids in the lung. Studies have shown that hospitalization due to the development of acute CHF with the symptom pulmonary edema was preceded two or three weeks by a drop in the DC impedance by approximately 10-15 %.

In light of this, many approaches have been suggested for providing information that can be used to assess a degree of pulmonary edema or amount of pulmonary fluid by utilizing the

thoracic impedance. In U.S. 6,595,927 a method and system for diagnosing pulmonary congestion in a mammalian heart using trans-thoracic impedance is disclosed. The trans-thoracic impedance and a heart rate of a patient are measured and an activity sensor is used to sense a heart activity in order to determine an exercise level of the patient. The impedance change over time intervals between commencement and termination of exercise is used as a quantitative measure of the degree of pulmonary congestion. Another approach is shown in U.S. 6,104,949, where a method and system for diagnosing pulmonary congestion in a mammalian heart using trans-thoracic impedance is disclosed. The trans-thoracic impedance is measured and a body posture of the patient is sensed. Changes in posture is correlated with trans-thoracic impedance changes and the impedance change over a time interval after a posture change is used as a quantitative measure of the degree of congestive heart failure.

However, a problem associated with present methods for measuring the electrical bio-impedance and, in particular, the trans-thoracic impedance is the accurateness and reliability of the obtained signals since they are greatly affected by factors like the body position of the patient, patient activity levels, heart rate frequency, etc.. For example, it has been found that the body position of the patient is of major importance with regard to the thoracic impedance. In addition, it has recently been found that the posture or position dependence also is of a significant magnitude regarding different positions even when the patient is lying down, for example, whether the patient is lying on a side or is lying on the back. A major reason is that an impedance measurement depends on the measurement vector, i.e. the vector between the nodes that the current is applied between and the vector the voltage is measured between. When the body shifts position, these vectors will change since the gravity will influence, for example, tissue between the nodes and how it moves. Tests performed on animals have shown that the trans-thoracic impedance may vary up to 20 % depending on the position of the animal.

Accordingly, there is a need of an improved method and implantable medical device for assessing a degree of pulmonary edema of a patient or for obtaining reliable and accurate information for such an assessment in an automatic way.

BRIEF DESCRIPTION OF THE INVENTION

Thus, an object of the present invention is to provide an improved method and implantable medical device for assessing a degree of pulmonary edema of a patient.

Another object of the present invention is to provide an improved method and implantable medical device for obtaining reliable and accurate information for use in assessments of a degree of pulmonary edema of a patient.

A further object of the present invention is to provide an improved method and implantable medical device for automatically assessing a degree of pulmonary edema of a patient and for obtaining reliable and accurate information for such an assessment in an automatic way.

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

In the context of this application, the term "impedance" refers to both the DC component and the AC component of the impedance if not otherwise stated. The impedance is calculated as z=u/i, where u is the measured voltage between two electrodes and i is the applied excitation current between the two electrodes. As indicated above, the measured impedance consists of a DC component and an AC component, where the DC component is the baseline around which the AC component fluctuates. The DC component reflects the amount of tissue and fluids that are located between the measuring points that the impedance is measured in-between and the AC components reflects how, for example, respiration and cardiac activity influence the impedance signal.

For the sake of clarity, the term "trans-thoracic impedance" refers to an impedance measured over the thorax of the patient. For example the excitation current may be applied between an RV-tip (i.e. distal electrode in a bipolar lead located in right ventricle) and the case (or housing), and the voltage may be measured between the case and an RV-ring (i.e. the proximal electrode in a bipolar lead located in right ventricle).

According to an aspect of the present invention, there is provided a method for assessing a degree of pulmonary edema of a patient using an implantable medical device. The method comprises the steps of: detecting at least two specific body positions of the patient; initiating at least one impedance sensing session to sense trans-thoracic impedance signals when the patient is in one position of the at least two specific positions; obtaining impedance values from the impedance signals; determining a relation between respective impedance values at the at least

two positions; storing the relation; and using the relation as a metric of pulmonary edema to assess the degree of pulmonary edema.

According to a second aspect of the present invention, there is provided an implantable medical device for assessing a degree of pulmonary edema of a patient, the device being connectable to the patient in at least one electrode configuration. The device is characterized by an impedance sensor adapted to sense a trans-thoracic impedance of the patient via the at least one electrode configuration; position information obtaining circuit adapted to obtain information related to body positions of the patient; obtaining means adapted to obtain impedance values from the impedance signals; a processing unit adapted to: determine whether the patient is in one of at least two specific body positions using the position information; trigger the impedance sensor to initiate a sensing session in order to sense a trans-thoracic impedance when the patient is in one position of the at least two specific positions; and determine a relation between respective impedance values at the at least two positions; a storage adapted to store the relation; and wherein the relation is used as a metric of pulmonary edema to assess the degree of pulmonary edema.

According to a third aspect of the present invention, there is provided a computer program product, which when executed on a computer, performs steps in accordance with the first aspect of the present invention.

According to a further aspect of the present invention, there is provided a computer readable medium comprising instructions for bringing a computer to perform a method according to the first aspect of the present invention.

As discussed above, the body posture has been shown to heavily influence the impedance level, i.e. the DC level, since the fluid moves around in the body as the body posture is changed. The present invention does, however, in fact utilize this phenomenon, i.e. that the DC impedance level varies with posture, to obtain a measure of the amount fluid. To elaborate, a relation between impedance values obtained for at least two body positions is used as a metric of pulmonary edema to assess the degree of pulmonary edema. This is based on the assumption that if there is a high amount of fluid, the DC impedance level will behave in a different manner when the patient changes his or hers posture in comparison to the DC impedance level of patient having a smaller amount of fluid. This is due to the fact that the more fluid that is present in thorax, the more fluid will move around when the patient changes his or her posture.

In one embodiment of the present invention, the variability of the impedance values between different body positions is determined. In this embodiment, the assumption is that the more fluid that is present in thorax, the more fluid will move around when the patient changes his or hers posture and, hence the more variability will be found in the DC impedance signal.

In one embodiment the impedance values are transferred to an external unit, for example, a programming unit via a communication link, for example, a telemetry link. The relation between respective impedance values at the at least two positions is determined and used as a metric of pulmonary edema to assess the degree of pulmonary edema by the programming unit.

According to an embodiment of the present invention, an activity level signal of the patient is sensed and the sensed activity level signal is used to detect the body positions of the patient.

In another embodiment of the present invention, when one of the at least two specific body positions is sensed, the initiating of the impedance sensing session is delayed a predetermined period of time. Thereby, the performance and accuracy of the impedance measurements can be improved since the condition during which the measurements are performed has stabilized after a positions change. This is due to the fact that it takes some time for the interstitial and/or pulmonary fluid to redistribute in the body.

According to a further embodiment of the present invention, it is checked whether the sensed activity level signal is below a predetermined activity level signal limit; and it is detected that the patient is lying down when the sensed activity level signal has been below the signal limit during a predetermined period of time.

In a further embodiment of the present invention, an AC impedance morphology is created using the AC impedance values of the impedance signals; and it is detected whether the patient is lying on the back, the stomach, or on a side using the AC impedance morphology. Other measures such as heart rate, rate of breathing, size of breath can also be used to further improve the ability to accurately identify a specific body posture. Moreover, blood pressure and/or blood flow may also be used to improve the ability to accurately identify a specific body posture.

In alternative embodiments of the present invention, a morphology of the sensed activity level signal is determined; the sensed morphology is compared with a reference morphology; and it is

detected that the patient is walking if the sensed morphology and the reference morphology shows a correspondence within predetermined terms of reference. In an alternative embodiment, a frequency of the sensed activity level signal is determined; the sensed frequency is compared with a reference frequency; and it is detected that the patient is walking if a difference between the sensed frequency and the reference frequency is determined to be within a predetermined frequency range. The reference morphology and/or the reference frequency may be pre-stored in the medical device.

In one embodiment, the reference morphology and/or the reference frequency are obtained during a training session or initialization procedure, which may be performed at a follow-up visit after the implantation. The initialization protocol is initiated using an external programmer and the patient is asked to walk normally in the room for a while. The device stores the specific features of walking for that particular patient, including the frequency and signal morphology of the activity signal. Hence, the sensed morphology and/or frequency of the sensed activity level signal when the patient is walking is stored as a reference morphology and/or a reference frequency. The session comprises the steps of determining a morphology and/or frequency of a sensed activity level signal when the patient is walking; and storing the determined morphology and/or frequency of the sensed activity level signal when the patient is walking as a reference morphology and/or a reference frequency, respectively.

In one embodiment, an excitation current pulse is applied between a first electrode, for example, arranged to positioned within the heart of the patient and a second electrode, for example, the case of the device and the voltage between the first and second electrode resulting from the excitation current pulse is sensed. As an example, the excitation current may be applied between the case (or housing) and an RV-tip (i.e. distal electrode in a bipolar lead located in right ventricle), and the voltage may be sensed between the case and an RV-ring (i.e. .e. the proximal electrode in a bipolar lead located in right ventricle). According to another example, the excitation current is be applied between the case and an RA-tip (i.e. the distal electrode in a bipolar lead located in right atrium) and the voltage is sensed between the case and RA-ring (i.e. the proximal electrode in a bipolar lead located in right atrium). Of course, as the skilled person realizes, there are other conceivable configurations that can be used. According to one embodiment, the first and second electrodes are arranged in a lead connectable to the device and arranged to be located in a right ventricle, in a right atrium, or in a left ventricle of the patient.

In yet another embodiment of the present invention, three specific body positions are detected, a derivative of the impedance values is calculated with respect to body position; and the derivative is used to assess the degree of pulmonary edema.

The assessed degree of pulmonary edema may be used to determine a suitable titration of a dose of diuretics to be delivered to the patient.

Furthermore, the assessed degree of pulmonary edema may be used to diagnose congestive heart failure.

In one embodiment, each impedance value is calculated as a mean value of impedance values obtained during a predetermined period of time; and a relation between respective impedance values at the at least two positions is determined using the calculated impedance values. Thereby, the accuracy and reliability of the impedance values can be increased and thus, in turn, the accuracy and reliability of relation between respective impedance values may be improved.

Alternatively, each relation between impedance values obtained in the at least two specific positions may be calculated as a mean value of relations obtained during a predetermined period of time.

As realized by the person skilled in the art, the methods of the present invention, as well as preferred embodiments thereof, are suitable to realize as a computer program or a computer readable medium.

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 a first embodiment of an implantable medical device in accordance with the present invention.

Fig. 2 is a schematic diagram showing the DC impedance variation with posture for two different subjects with a different degree of fluid in the thorax.

Fig. 3 is a high-level description of the method for assessing a degree of pulmonary edema of a patient using an implantable medical device according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

With reference first to Fig. 1, the configuration including the primary functional components of a first embodiment of an implantable medical device in accordance with the present invention will be described. In the following, the present invention will be described in the context of a pacemaker. However, as the person skilled within the art easily realizes, the present invention may also be implemented within the contents of, for example, an implantable cardioverter/defibrillator.

The illustrated embodiment comprises an implantable medical device 20, such as a pacemaker. 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, namely a ventricular lead 26a and an atrial lead 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 may be arranged near the distal ends of the leads 26a, 26b. As the skilled man in the art realizes, the leads 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. As an example, 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 25 under influence of a control circuit 27. The control circuit 27 controls pace pulse parameters such as output voltage and pulse duration.

Moreover, an impedance sensor circuit 29 is adapted to sense impedance signals. In one embodiment, the impedance circuit 29 is adapted to carry out impedance measurements for sensing a trans-thoracic impedance. The impedance circuit 29 is arranged to apply excitation current pulses between a first electrode and second electrode adapted to positioned, for example, within a heart of the patient in an embodiment where the cardiogenic impedance is measured. The impedance circuit 29 is also arranged to sense the impedance in the tissues between the first and second electrode to the excitation current pulse. Further, the impedance circuit 29 is coupled to a processing unit, for example, a microprocessor 30, where, inter alia, processing of the obtained impedance signals can be performed. In an embodiment where the trans-thoracic component of the electrical bio-impedance is sensed, the impedance circuit 29 is arranged to apply an excitation current pulse between a first electrode, for example, arranged to positioned within the heart of the patient and a second electrode, for example, the case of the device and to sense the voltage between the first and second electrode resulting from the excitation current pulse. As an example, the excitation current may be applied between the case (or housing) and an RV-tip (i.e. distal electrode in a bipolar lead located in right ventricle), and the voltage may be sensed between the case and an RV-ring (i.e. .e. the proximal electrode in a bipolar lead located in right ventricle). According to another example, the excitation current is be applied between the case and an RA-tip (i.e. the distal electrode in a bipolar lead located in right atrium) and the voltage is sensed between the case and the RA-ring (i.e. the proximal electrode in a bipolar lead located in right atrium). Of course, as the skilled man realizes, there are other conceivable configurations that can be used.

According to this embodiment, the impedance sensor 29 is connected to obtaining means 32 adapted to obtain the DC component of the impedance signals. According to one embodiment, the obtaining means is a low pass filter having a limiting frequency of 0.2 Hz. The impedance sensing circuit 29 is controlled by the microprocessor 30 and the control circuit 27. The control circuit 27 acts under influence of the microprocessor 30. A storage means 31 is connected to the control circuit 27 and the microprocessor 30, which storage means 31 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 30 for use in logic timing determination in known manner. For example, the input circuit 33 is connected to cardiogenic sensors located in the lead 26a and/or 26b adapted to

sense events of the heart cycles of the patient, such as a P-wave, a R-wave in the right or left ventricle or a pacing pulse in one of the heart chambers.

The implantable medical device 20 is powered by a battery 37, which supplies electrical power to all electrical active components of the medical device 20. Data contained in the storage means 31 can be transferred to a programmer (not shown) via a programmer interface (not shown). The implantable medical device 20 according to the present invention further comprises a position information obtaining circuit 35 adapted to obtain information related to body positions of the patient. The position information obtaining circuit 35 is connected to the microprocessor 30. The microprocessor 30 is adapted to determine which position the patient is in of at least two specific predetermined body positions or postures using the position information from the position information obtaining circuit 35. In one embodiment, the microprocessor 30 is adapted to send a triggering signal to the impedance sensor 29 to initiate a sensing session in order to sense a trans-thoracic impedance when the patient is in either one of the at least one position. In one embodiment, the initiating of the impedance sensing session is delayed a predetermined period of time thereby allowing the interstitial and/or pulmonary fluid to redistribute in the body after a change of body position. This predetermined period of time may be programmed into the device. In other embodiments, the implantable medical device may also include other sensors such as a heart rate sensor adapted to sense a heart rate of the patient, or a breath rate sensor adapted to sense a breath rate of the patient and/or a breath size of the patient. The information obtained by means of these sensors may be used to further increases the accuracy and reliability in the position determination.

The microprocessor 30 is adapted to determine a relation between respective impedance values obtained at the at least two positions, which may be stored in the storage 31. The relations may be used as a metric of pulmonary edema to assess the degree of pulmonary edema. In one embodiment, the variability of the impedance values between different body positions is determined. The assumption is accordingly that the more fluid that is present in thorax, the more fluid will move around when the patient changes his or hers posture and, hence the more variability will be found in the DC impedance signal is utilized. This is shown schematically in Fig. 2 where the DC impedance variation with posture for two different subjects with a different degree of fluid in the thorax is shown. The DC impedance at different postures, i.e. supine and upright, for a subject having high amount of fluid is indicated by the unbroken line and the DC impedance at the same postures for a subject having low amount of fluid is indicated by the broken line.

In an alternative embodiment, the impedance values at the different positions and/or the relations can be transferred to an external programmer (not shown). In this case, the signals and/or relations are transferred to the external programmer from the implantable medical device via a telemetry link (not shown)

According to one embodiment, the position information obtaining circuit 35 is an activity level sensor connected to the microprocessor 30 adapted to sense an activity level of the patient supply the microprocessor 30 with an activity level signal. The microprocessor 30 may be adapted to determine whether the sensed activity level signal is below a predetermined activity level signal limit and determine that the patient is lying down if the sensed activity level signal is found to be below the signal limit during a predetermined period of time. Thus, a low activity level during a long period of time, i.e. the patient is inactive, is a significant indication of that the patient is sleeping and, moreover, that he or she is lying down. However, in order to improve the accuracy and reliability of the method it may also be advantageous to identify whether the patient is lying, for example, on the back, on the stomach, or on a side. As discussed above, it has been found that the posture or position dependence also is of a significant magnitude regarding different positions when the patient is lying down, for example, whether the patient is lying on the back, on the stomach, or on a side. A major reason is that an impedance measurement depends on the measurement vector, i.e. the vector between the nodes that the current is applied between and the vector the voltage is measured between. When the body shifts position, these vectors will change since the gravity will influence, for example, tissue between the nodes and how it moves. Tests performed on animals have shown that the trans-thoracic impedance may vary up to 20 % depending on which position the animal was lying in. In order to identify whether the patient is lying on the back, on the stomach, or on a side, the AC impedance components of the impedance signals are taken care of in the low pass filter 32, i.e. the signal components above the limit frequency of 0.2 Hz. The AC components of the signals is analysed in the microprocessor 30 and the fact that the impedance morphology is very posture dependent is utilized to determine whether the patient is lying on the back, on the stomach, or on a side.

Furthermore, the microprocessor 30 is adapted to determine a morphology of the sensed activity level signal and the sensed morphology with a reference morphology is compared with a reference morphology, which may be pre-stored in the storage 31. It is determined that the patient is walking if the sensed morphology and the reference morphology show a

correspondence within predetermined terms of reference. Alternatively, a frequency of the sensed activity level signal may be determined and compared with a reference frequency. In this case, it is detected that the patient is walking if a difference between the sensed frequency and the reference frequency is determined to be within a predetermined frequency range. According to another embodiment, both the morphology and the frequency of the sensed activity level signal are used to identify if the patient is walking. The reference morphology and/or the reference frequency may be pre-stored in hardware (e.g. in the storage) or software (e.g. implemented in the processing unit) of the implantable medical device.

According to another embodiment, the reference morphology and/or the reference frequency are obtained during a training session or initialization procedure, which may be performed at a follow-up visit after the implantation. The initialization protocol is initiated using an external programmer and the patient is asked to walk normally in the room for a while. The device stores the specific features of walking for that particular patient, including the frequency and signal morphology of the activity signal. Hence, the sensed morphology and/or frequency of the sensed activity level signal when the patient is walking is stored as a reference morphology and/or a reference frequency.

In one embodiment of the present invention, the position information obtaining circuit 35 is a position sensor adapted to detect the position or posture of the patient. The position sensor may be, for example, a 3 axis accelerometer. The position sensor can be incorporated in the device in accordance with conventional practice within the art.

Referring now to Fig. 3, a high-level description of the method for assessing a degree of pulmonary edema of a patient using an implantable medical device according to the present invention will be given. First, in step 100, the body position or posture of the patient is sensed or, in other words, position information is obtained. This may be performed by means of the activity level sensor 35. Then, in step 102, the microprocessor 30 identifies or determines whether the patient is in one of at least two predetermined postures using the position information. In one embodiment, these predetermined postures are when the patient is lying and when the patient is walking, which can be identified in accordance with the description above. In one embodiment, if it has been determined that the patient is lying down, a further determination may be executed in order to identify whether the patient is lying on the back, on the stomach, or on a side. In this case, the AC impedance components of the impedance signals are obtained from filter 32, i.e. the signal components above the limit frequency of 0.2 Hz, and

analysed in the microprocessor 30 and the fact that the impedance morphology is very posture dependent is utilized to determine whether the patient is lying on the back, on the stomach, or on a side. In accordance to other embodiments, other information such as heart rate, rate of breathing, and/or size of breath can be obtained and used in the determination of the position to further improve the ability to accurately identify a specific body posture.

If it is determined that the patient is not in any one of the predetermined positions, the procedure returns to step 100. However, if it is determined the patient is in one of the predetermined positions, the procedure proceeds to step 104 where an impedance sensing session to obtain impedance signals is initiated. According to an embodiment, the initiating of the impedance sensing session is delayed a predetermined period of time. Thereby, accuracy and reliability of the sensed signals may be improved due to the fact that it takes some time for the interstitial and/or pulmonary fluid to redistribute in the body after a change of body position. In yet another embodiment, information regarding heart rate, rate of breathing, a blood flow, a blood pressure, or size of breath is obtained and used to further improve the accuracy in the impedance measurements. For example, it may be determined that the impedance sensing session only is initiated if the heart rate of the patient is within a predetermined interval or if the rate of breathing is in a predetermined interval.

Thereafter, at step 106, impedance values are obtained from the sensed impedance signals. In one embodiment, the AC impedance component of the signal is filtered off in the low pass filter 32 (i.e. the signal components above the limit frequency of 0.2 Hz is filtered off). The remaining DC component (i.e. the signal components below the limit frequency of 0.2 Hz) is the supplied to the microprocessor 30. Then, at step 108, the obtained DC component is stored, for example, in the storage 31. At step 110, a relation between respective impedance values for the two positions is determined and stored. In one embodiment, the variability of the impedance values between different body positions is determined. In Fig. 2 the DC impedance variation with posture for two different subjects with a different degree of fluid in the thorax is shown. The DC impedance at different postures, i.e. supine and upright, for a subject having high amount of fluid is indicated by the unbroken line and the DC impedance at the same postures for a subject having low amount of fluid is indicated by the broken line. In one embodiment, it is checked whether a predetermined number of DC impedance values has been obtained for each position and a means value for each position is calculated. Alternatively, a weighted average value may be calculated for each position using the predetermined number of values. Subsequently, at step 112, the relation(-s) is (are) used as a metric or measure of pulmonary

edema to assess the degree of pulmonary edema. A measure based on the derivative of the DC component with respect to body posture may be the difference between the average DC impedance between two positions. If one value per day and per position are created, the variability measure would be the difference between the two values. Thus, one single value in Ohms per day would be trended.

In another embodiment, the DC impedance value for each body posture is an average of a number of measurements and the difference in impedance is divided with the standard deviation of these values.

If more than two body postures are used, the difference between all pairs of body postures may be added. Thus, the value to trend would be

$$|v1 - v2| + |v2 - v3| + |v1 - v3| \qquad (1)$$

, where vX is the DC impedance at body posture X. If the differences are divided with the standard deviation, the value to trend would be

$$(|v1 - v2|)/s12 + (|v2 - v3|)/s23 + (|v1 - v3|)/s13 \qquad (2)$$

, where sXY is the composite standard deviation for values at postures X and Y.

The values obtained in accordance with (1) or (2) may hence be used to trend the pulmonary edema. For example, a current relation may be compared with at least one preceding relation to determine a difference between the current relation and the at least one preceding relation. Thereby, it is possible to identify trends in the impedance such as long-term changes in the impedance, which can be used to assess the degree of pulmonary edema. This, can, in turn, be used to detect, for example, CHF. The relation or trend values can also be compared with at least one reference relation value to determine a difference between the current relation and the at least one reference relation, which also may be used to identify trends in the impedance such as long-term changes in the impedance in order to assess the degree of pulmonary edema.

These calculations may be performed in the medical device or, in an alternative embodiment, the impedance values at the different positions and/or the relations can be transferred to an external programmer for executing of the calculations. In this case, the signals and/or relations

are transferred to the external programmer from the implantable medical device via a telemetry link.

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. A method for assessing a degree of pulmonary edema of a patient using an implantable medical device, comprising the steps of:

detecting at least two specific body positions of said patient;

initiating at least one impedance sensing session to sense trans-thoracic impedance signals when said patient is in one position of said at least two specific positions;

obtaining impedance values from said impedance signals;

determining a relation between respective impedance values at said at least two positions;

storing said relation; and

using said relation as a metric of pulmonary edema to assess the degree of pulmonary edema.

2. The method according to claim 1, wherein the step of determining a relation comprises the step of

determining the variability of the impedance values between different body positions.

3. The method according to claim 1 or 2, further comprising the steps of:

comparing a current relation with at least one preceding relation to determine a difference between said current relation and said at least one preceding relation; and

using said difference to assess the degree of pulmonary edema.

4. The method according to claim 1 or 2, wherein the step of using said relation comprises the steps of:

comparing a current relation with at least one reference relation value to determine a difference between said current relation and said at least one reference relation; and

using said difference to assess the degree of pulmonary edema.

5. The method according to any one pf preceding claims, wherein the step of obtaining comprises the step of:

filtering said impedance signals in order to obtain DC impedance values.

6. The method according to any one of preceding claims 1-5, wherein the step of detecting comprises the steps of

sensing an activity level signal of said patient; and

using said sensed activity level signal to detect said body positions of said patient.

7. The method according to any one of preceding claims 1-6, wherein the step of detecting at least two specific positions further comprises the step of:

when one of said at least two specific body positions is sensed, delaying the initiating of the impedance sensing session a predetermined period of time.

8. The method according to claim 6 or 7, further comprising the steps of:

determining whether said sensed activity level signal is below a predetermined activity level signal limit; and

detecting that the patient is lying down when said sensed activity level signal has been below said signal limit during a predetermined period of time.

9. The method according to claim 8, wherein the step of detecting that the patient is lying down when said sensed activity level signal has been below said signal limit during a predetermined period of time comprises the steps of:

obtaining AC impedance values from said impedance signals;

creating an AC impedance morphology using said AC impedance values; and

detecting whether the patient is lying on the back, on the stomach, or on a side using a AC impedance morphology.

10. The method according to any one of preceding claims, further comprising the steps of

sensing a heart rate, a rate of breathing, a blood pressure, a blood flow, or a size of breath of said patient; and

using said information in said detecting of at least two specific body positions of said patient.

11. The method according to claim 6-10, further comprising the steps of:

determining a morphology of said sensed activity level signal;

comparing the sensed morphology with a reference morphology; and

detecting that said patient is walking if said sensed morphology and said reference morphology shows a correspondence within predetermined terms of reference.

12. The method according to any one of preceding claims 6-11, further comprising the steps of:

determining a frequency of said sensed activity level signal;

comparing the sensed frequency with a reference frequency; and

detecting that said patient is walking if a difference between said sensed frequency and said reference frequency is determined to be within a predetermined frequency range.

13. The method according to claim 11 or 12, wherein the reference morphology and/or the reference frequency are pre-stored in said medical device.

14. The method according to claim 11 or 12, wherein the reference morphology and/or the reference frequency are obtained during a training session including the steps of:

determining a morphology and/or frequency of a sensed activity level signal when said patient is walking; and

storing said determined morphology and/or frequency of the sensed activity level signal when said patient is walking as a reference morphology and/or a reference frequency, respectively.

15. The method according to any one of preceding claims, wherein the step of sensing a trans-thoracic impedance comprises the steps of:

applying an excitation current pulse between a first electrode arranged to positioned within a heart of the patient and a case of said device; and

sensing a voltage between a second electrode arranged to positioned within a heart of the patient and said case.

16. The method according to claim 15, wherein said first and second electrode are arranged in a lead connectable to said device arranged to be located in a right ventricle, in a right atrium, or in a left ventricle of said patient.

17. The method according to any one of preceding claims, further comprising the steps of:

detecting three specific body positions;

calculating a derivative of the impedance values with respect to body position; and

using said derivative to assess the degree of pulmonary edema.

18. The method according to any one of preceding claims, further comprising the step of:

calculating each impedance value as a mean value of impedance values obtained during a predetermined period of time; and

determining said relation between respective impedance values at said at least two positions using said calculated impedance values.

19. The method according to any one of preceding claims, further comprising the steps of:

calculating each relation between impedance values obtained in said at least two specific positions as a mean value of relations obtained during a predetermined period of time.

20. The method according to any one of preceding claims, further comprising the step of:

communicating said relation and/or said assessed degree of pulmonary edema to an external device on a continuous basis or at regular intervals.

21. The method according to claim 20, wherein said relation and/or said assessed degree of pulmonary edema is communicated via telemetry or transtelephonically.

22. An implantable medical device for assessing a degree of pulmonary edema of a patient, said device being connectable to the patient in at least one electrode configuration, **c h a r a c t e r i z e d** by

an impedance sensor adapted to sense a trans-thoracic impedance of said patient via said at least one electrode configuration;

position information obtaining circuit adapted to obtain information related to body positions of said patient;

obtaining means adapted to obtain impedance values from said impedance signals;

a processing unit adapted to:

determine whether said patient is in one of at least two specific body positions using said position information;

trigger said impedance sensor to initiate a sensing session in order to sense a trans-thoracic impedance when said patient is in one position of said at least two specific positions; and

determine a relation between respective impedance values at said at least two positions;

a storage adapted to store said relation; and

wherein said relation is used as a metric of pulmonary edema to assess the degree of pulmonary edema.

23. The device according to claim 22, wherein said processing unit is adapted to determine the variability of the impedance values between different body positions.

24. The device according to claim 22 or 23, wherein said processing unit is adapted to compare a current relation with at least one preceding relation to determine a difference between said current relation and said at least one preceding relation; and wherein said difference is used to assess the degree of pulmonary edema.

25. The device according to claim 22 or 23, wherein the processing unit is adapted to:

compare a current relation with at least one reference relation value to determine a difference between said current relation and said at least one reference relation; and

use said difference to assess the degree of pulmonary edema.

26. The device according to any one of preceding claims 22-25, wherein said obtaining means comprises a low pass filter adapted to filter off the AC component of said impedance to obtain impedance values containing substantially only a DC component.

27. The device according to any one of preceding claims 22-26, wherein said position information obtaining circuit comprises an activity level sensor adapted to sense an activity level signal of said patient; and

wherein said processing unit is adapted to use said sensed activity level signal to detect said body positions of said patient.

28. The device according to any one of preceding claims 22-27, wherein said processing unit is adapted to, when one of said at least two specific body positions is sensed, delay the initiating of the impedance sensing session a predetermined period of time.

29. The device according to claim 27 or 28, wherein said processing unit is adapted to:

determine whether said sensed activity level signal is below a predetermined activity level signal limit; and

detect that the patient is lying down when said sensed activity level signal has been below said signal limit during a predetermined period of time.

30. The device according to claim 29, wherein said obtaining means is adapted to obtain AC impedance values from said impedance signals; and wherein said processing unit is adapted to create an AC impedance morphology using said AC impedance values; and to detect whether the patient is lying on the back, on the stomach, or on a side using a AC impedance morphology.

31. The device according to any one of preceding claims 22-30, further comprising:

a heart rate sensor, a breath rate sensor, a blood pressure sensor, a blood flow sensor, or a sensor for sensing a size of breath of said patient; and

wherein said processing unit is adapted to use said information in said detecting one of at least two specific body positions of said patient.

32. The device according to claim 27-31, wherein said processing unit is adapted to:

determine a morphology of said sensed activity level signal;

compare the sensed morphology with a reference morphology; and

detect that said patient is walking if said sensed morphology and said reference morphology shows a correspondence within predetermined terms of reference.

33. The device according to any one of preceding claims 27-32, wherein said processing unit is adapted to:

determine a frequency of said sensed activity level signal;

compare the sensed frequency with a reference frequency; and

detect that said patient is walking if a difference between said sensed frequency and said reference frequency is determined to be within a predetermined frequency range.

34. The device according to claim 32 or 33, wherein the reference morphology and/or the reference frequency are pre-stored in said medical device.

35. The device according to claim 32 or 33, wherein the reference morphology and/or the reference frequency are obtained during a training session, wherein said processing unit is adapted to:

determine a morphology and/or frequency of a sensed activity level signal when said patient is walking; and

wherein said determined morphology and/or frequency of the sensed activity level signal when said patient is walking is stored as a reference morphology and/or a reference frequency, respectively, in said storage.

36. The device according to any one of preceding claims 22-35, further comprising:

means for applying an excitation current pulse between a first electrode arranged to positioned within a heart of the patient and a case of said device; and

means for sensing a voltage between a second electrode arranged to positioned within a heart of the patient and said case.

37. The device according to claim 36, wherein said first and second electrode are arranged in a lead connectable to said device arranged to be located in a right ventricle, in a right atrium, or in a left ventricle of said patient.

38. The device according to any one of preceding claims 22-37, wherein said processing unit is adapted to:

detect three specific body positions;

calculate a derivative of the impedance values with respect to body position; and

use said derivative to assess the degree of pulmonary edema.

39. The device according to any one of preceding claims 22-40, wherein said processing unit is adapted to:

calculate each impedance value as a mean value of impedance values obtained during a predetermined period of time; and

determine said relation between respective impedance values at said at least two positions using said calculated impedance values.

40. The device according to any one of preceding claims 22-40, wherein said processing unit is adapted to:

calculate each relation between impedance values obtained in said at least two specific positions as a mean value of relations obtained during a predetermined period of time.

41. The device according to any one of preceding claims 22-42, further comprising means for communicating said relation and/or said assessed degree of pulmonary edema to an external device on a continuous basis or at regular intervals.

42. The device according to claim 43, wherein said relation and/or said assessed degree of pulmonary edema is communicated via telemetry or transtelephonically.

43. A computer program product, which when executed on a computer, performs steps in accordance with any one of claim 1-21.

44. A computer readable medium comprising instructions for bringing a computer to perform a method according to any one of the preceding claims 1-21.

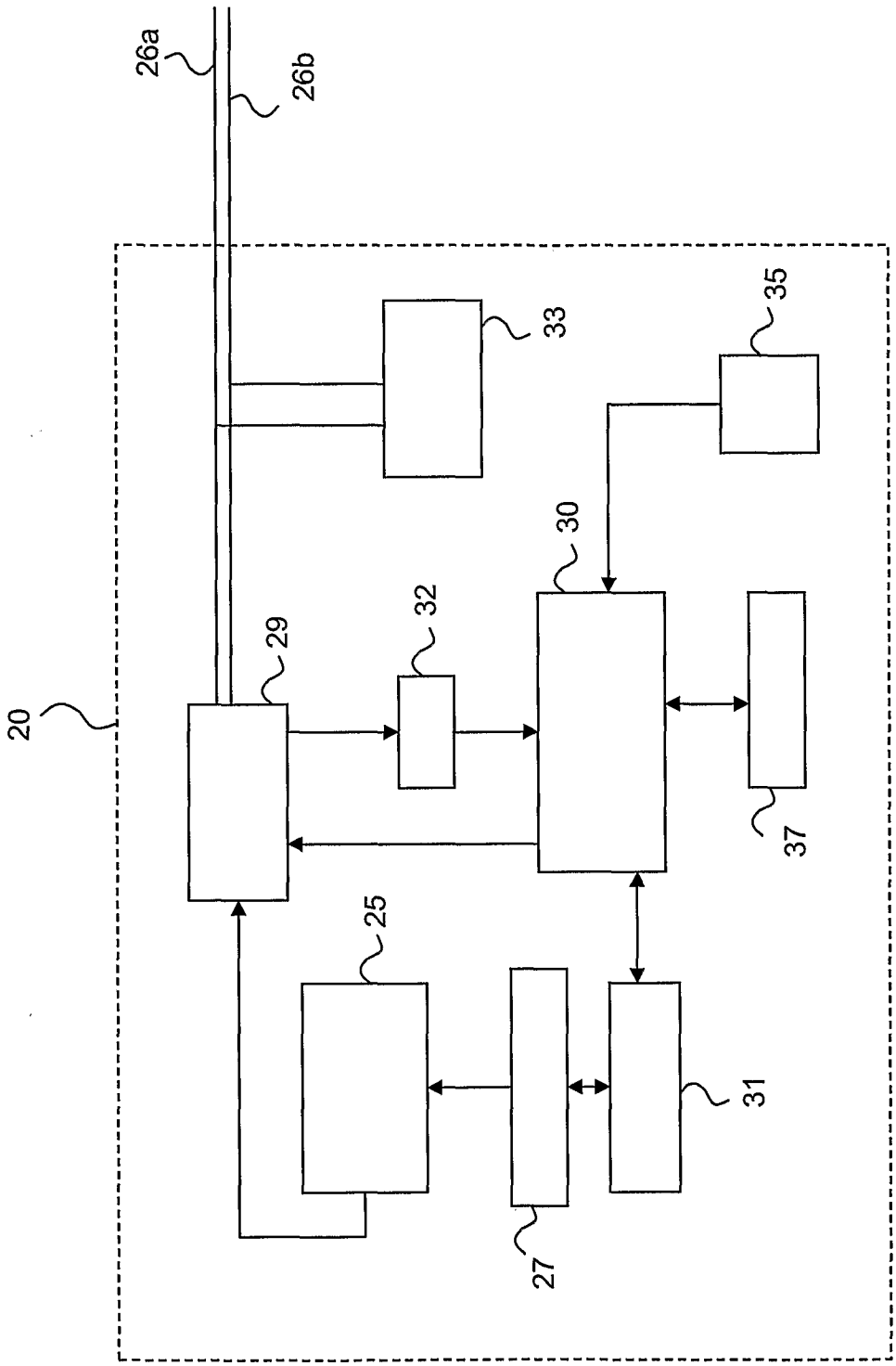


Fig. 1

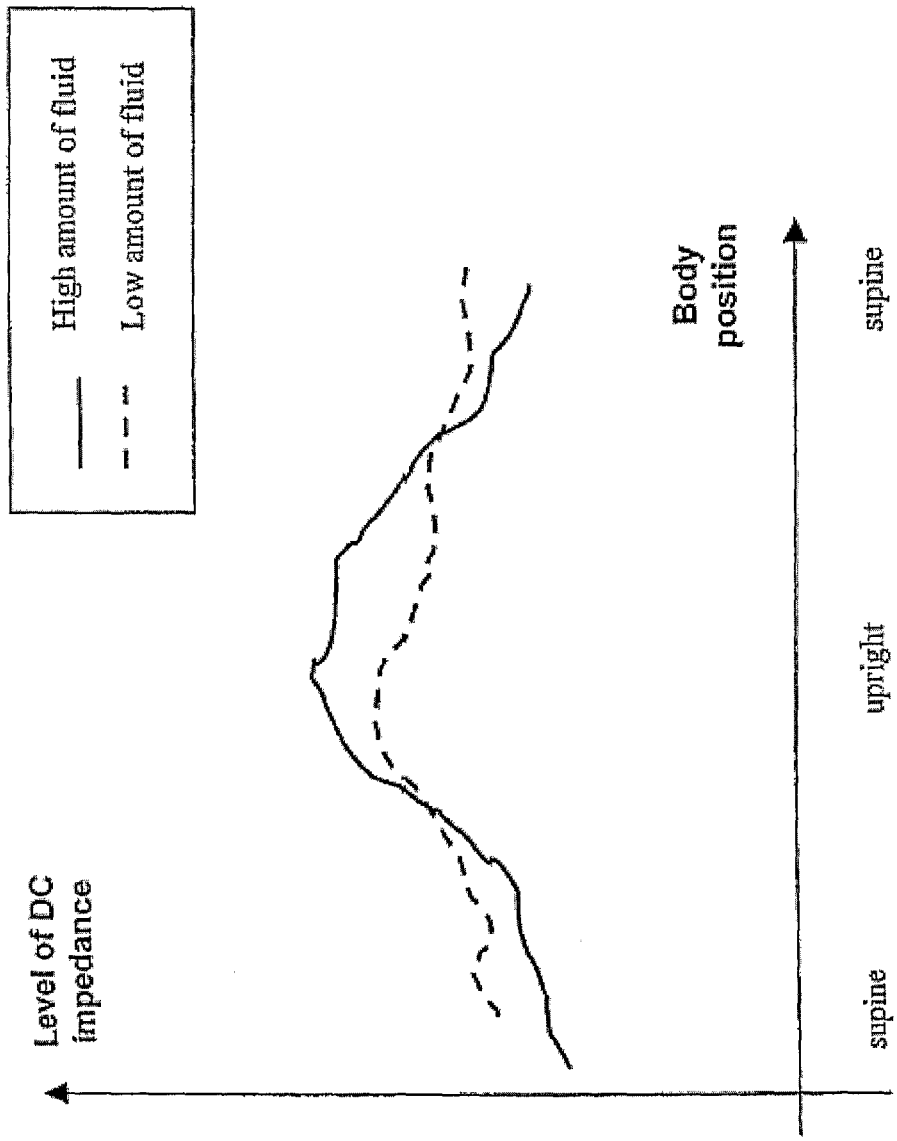

High amount of fluid
Low amount of fluid
Level of DC impedance
Body position
supine
upright
supine

Fig. 2

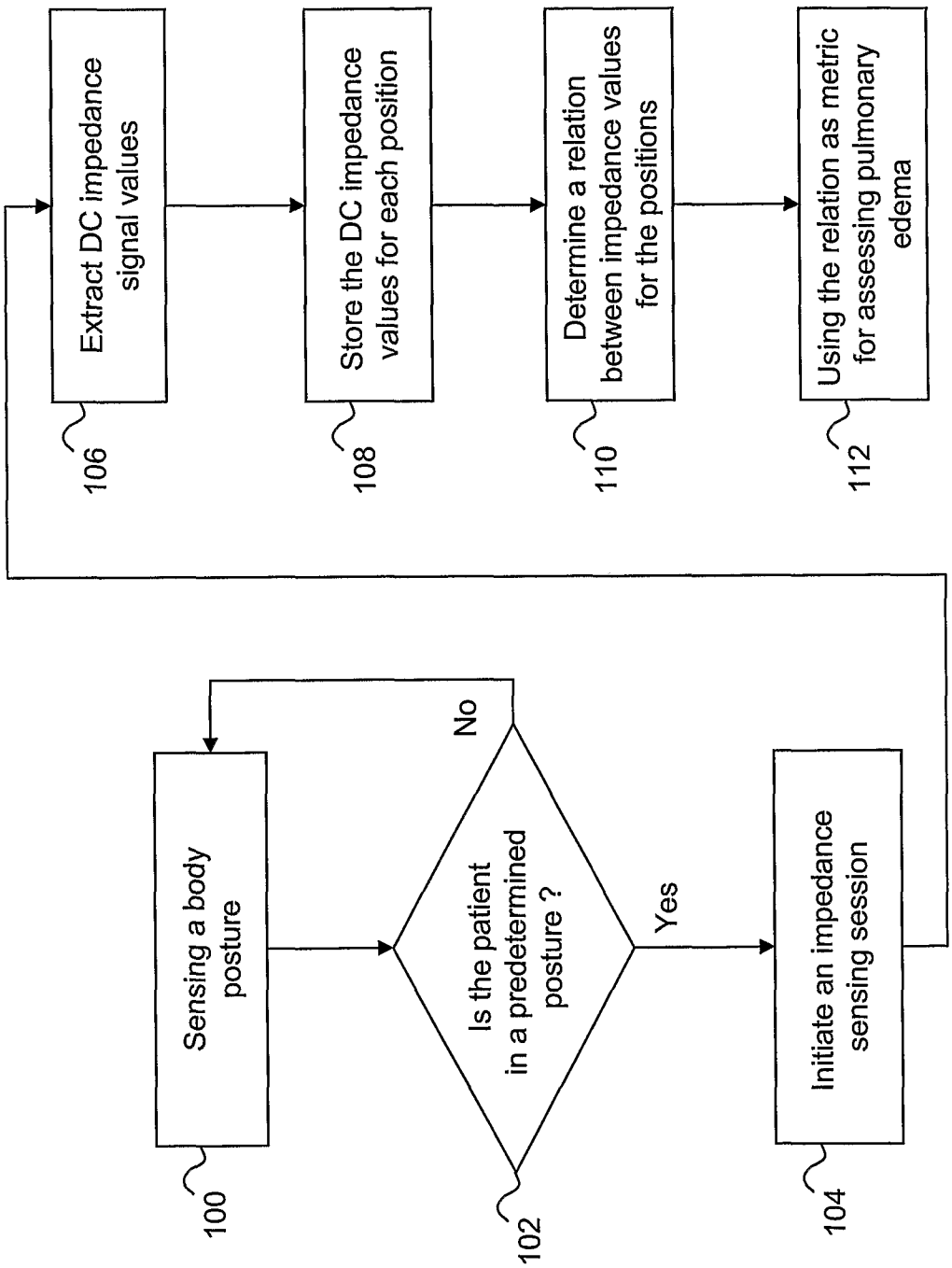

Sensing a body posture
100
Is the patient in a predetermined posture ?
102
No
Yes
Initiate an impedance sensing session
104
Extract DC impedance signal values
106
Store the DC impedance values for each position
108
Determine a relation between impedance values for the positions
110
Using the relation as metric for assessing pulmonary edema
112

Fig. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2006/000338

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.: 1-21
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 1-21 relate to a method of treatment of the human or animal body by surgery or by therapy, as well as diagnostic methods /Rule 39.1(iv). Nevertheless, a search has been executed for these claims. The search has been based on the alleged effects of the device.

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.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2006/000338

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.
X	EP 0985429 A2 (VITATRON MEDICAL BV), 15 March 2000 (15.03.2000), paragraphs 0008-0009; 0012-0016; 0020	1-44
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X	US 20040102712 A1 (BELALCAZAR, A. ET AL), 27 May 2004 (27.05.2004), paragraphs 0004-0013, claims 12, 28	1-44
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X	EP 1598093 A2 (PACESETTER, INC.), 23 November 2005 (23.11.2005), claims 0011-0013; 0070	1-44
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[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
16 October 2006	17 -10- 2006
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 Nincovic /OGU Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2006/000338

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6473640 B1 (ERLEBACHER, J.), 29 October 2002 (29.10.2002), column 5, line 15 - line 35; column 9, line 46 - column 10, line 18	1-44
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A	US 20050216067 A1 (MIN, X. ET AL), 29 Sept 2005 (29.09.2005), abstract	1-44
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A	WO 9833554 A1 (MEDTRONIC, INC.), 6 August 1998 (06.08.1998), abstract	1-44
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A	US 5562711 A (YERICH, C.G. ET AL), 8 October 1996 (08.10.1996), abstract	1-44
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A	US 6512949 B1 (COMBS, W.J. ET AL), 28 January 2003 (28.01.2003), abstract	1-44
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A	FEIN, A. ET AL "Evaluation of trans thoracic electrical impedance in the diagnosis of pulmonary edema". CIRCULATION, 1979, Vol.60, No.5, pages 1156-1160, see abstract	1-44
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E	WO 2006068566 A1 (ST. JUDE MEDICAL AB), 29 June 2006 (29.06.2006), abstract	1-44
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International patent classification (IPC)
A61B 5/053 (2006.01)
A61N 1/372 (2006.01)

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

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.

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				CA	2204499	A	06/06/1996
				EP	0794812	A	17/09/1997
				JP	3816101	B	30/08/2006
				JP	10509897	T	29/09/1998
				WO	9616695	A	06/06/1996
US	6512949	B1	28/01/2003	NONE			
WO	2006068566	A1	29/06/2006	NONE			