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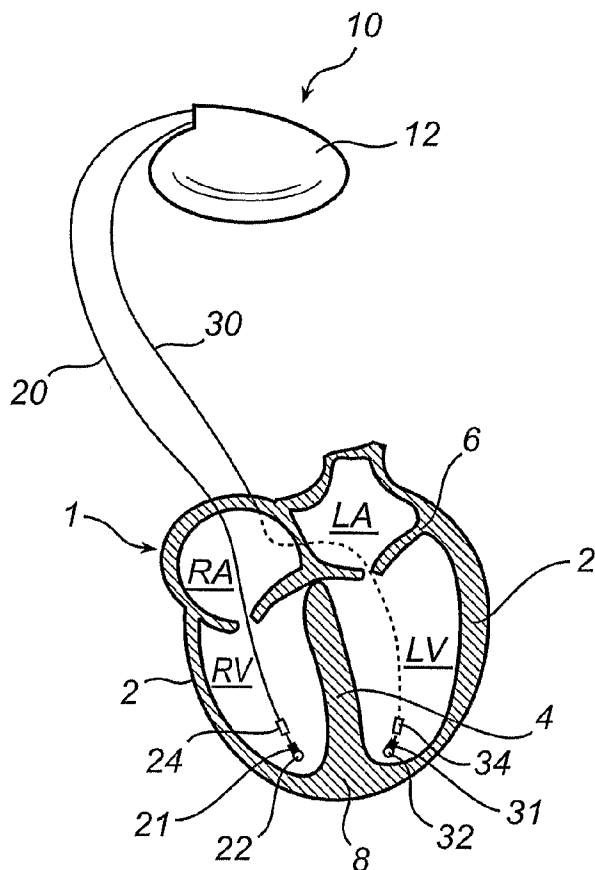
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(54) Title: IMPLANTABLE CARDIAC STIMULATOR, SYSTEM, DEVICE AND METHOD FOR MONITORING CARDIAC SYNCHRONY



(57) Abstract: A heart stimulator and a device for monitoring cardiac synchrony in a human heart. At least a first and a second sensor are adapted to be positioned at a first cardiac wall location and a second cardiac wall location subjected to movements related to longitudinal valve plane movements along the longitudinal axis of the heart, respectively. The sensors are arranged for measuring cardiac wall movements at the respective cardiac wall locations. Processing circuitry is arranged for receiving output signals from the sensors, the output signals being indicative of longitudinal valve plane movements at the respective cardiac wall location. The processing circuitry is further arranged for processing the signals and output a synchronization signal indicative of the synchrony in the valve plane movements at the cardiac wall locations .

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IMPLANTABLE CARDIAC STIMULATOR, SYSTEM, DEVICE  
AND METHOD FOR MONITORING CARDIAC SYNCHRONY

Technical field

The present invention generally relates to the field of implantable heart stimulation devices, such as pace-  
makers, implantable cardioverter-defibrillators (ICD),  
5 and similar cardiac stimulation devices that also are capable of monitoring and detecting electrical activities and events within the heart. More specifically, the present invention relates to a device for monitoring cardiac synchrony in a human heart, a system including  
10 such a device, an implantable cardiac stimulator comprising such a system, and a method of determining cardiac synchrony in a human heart.

Background art

15 Implantable heart stimulators that provide stimulation pulses to selected locations in the heart, e.g. selected chambers, have been developed for the treatment of cardiac diseases and dysfunctions. Heart stimulators have also been developed that affect the manner and  
20 degree to which the heart chambers contract during a cardiac cycle in order to promote the efficient pumping of blood. The heart will pump more effectively when a coordinated contraction of both atria and both ventricles can be provided.

25 In a healthy heart, the coordinated contraction is provided through conduction pathways in both the atria and the ventricles that enable a very rapid conduction of electrical signals to contractile tissue throughout the myocardium to effectuate the atrial and ventricular  
30 contractions. If these conduction pathways do not function properly, a slight or severe delay in the propagation of electrical pulses may arise, causing asynchronous contraction of the ventricles which would

greatly diminish the pumping efficiency of the heart. Patients who exhibit pathology of these conduction pathways, such as patients with bundle branch blocks, etc., can thus suffer compromised pumping performance.

5           Various prior art procedures have been developed for addressing these and other disorders. For instance, cardiac resynchronization therapy (CRT) can be used for effectuating synchronous atrial and/or ventricular  
10           contractions. Furthermore, cardiac stimulators may be provided that deliver stimulation pulses at several loca-  
15           tions in the heart simultaneously, such as biventricular stimulators. The stimulation pulses could also be delivered to different locations with a selected delay in  
          an attempt to optimize the hemodynamic performance, e.g. maximize cardiac output, in relation to the specific  
          cardiac dysfunction present at the time of implant.

          However, even though ventricular and atrial synchrony may be present at the time of implant, possibly supported by suitable cardiac stimulation therapy, this  
20           may not necessarily be the case at a later stage. For instance, during progression of cardiac therapy after implantation of a cardiac stimulator, the cardiac tissue  
          may adapt itself to the new conditions. Then, the function of hibernating myocardial tissue may be at least  
25           partially restored, and the overall cardiac function may become different from that at the time of implant.

          In other words, ventricular and atrial synchrony from the time of implant may turn into asynchrony at a  
          later stage, possibly supported or induced by stimulation  
30           therapy, as a result of a local improvement in the local function of myocardial tissue. For instance, the func-  
          tions of myocardial portions or regions that at the time of implant were affected by slow conduction or post-  
          systolic contractions (PSC), could at a later stage have  
35           improved their behavior such that there is no longer any slow conduction or PSC, or the PSC patterns have changed. Thus, even though there is an improvement in the behavior

of myocardial tissue through the remodulation or recovery of the heart during progression of cardiac therapy, there may be an impairment in the overall function of the heart since the pacing therapy is not adapted to the new  
5 situation. During follow-up, a physician may alter the delay settings in adaptation to altered cardiac status. However, a need still exists for monitoring changes in ventricular and/or atrial synchrony in the heart of a patient.

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#### Summary of the invention

An object of the present invention is to provide a new solution for monitoring cardiac synchrony of a human heart.

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This and other objects are achieved by a device and an implantable cardiac stimulator as defined in the independent claims. Further embodiments are defined in the dependent claims.

20

According to one aspect of the present invention, there is provided a device for monitoring cardiac synchrony in a human heart, the device being connectable to a first and a second sensor adapted to be positioned at a first cardiac wall location and a second cardiac wall location subjected to movements related to  
25 longitudinal valve plane movements along the longitudinal axis of the heart, respectively, wherein said first and second sensors are arranged for measuring cardiac wall movements at said first and said second cardiac wall location, respectively. The device comprises processing  
30 circuitry arranged for receiving output signals from said first and second sensors, said output signals being indicative of said longitudinal valve plane movements at said respective cardiac wall location, wherein said processing circuitry is arranged for processing said  
35 output signals and provide a synchronization signal indicative of the synchrony in the valve plane movements at said first and second cardiac wall locations.

According to another aspect of the present invention, there is provided a system for monitoring cardiac synchrony in a human heart. The system comprises a first sensor adapted to be positioned at a first cardiac wall location subjected to movements related to longitudinal valve plane movements along the longitudinal axis of the heart, wherein said first sensor is arranged for measuring cardiac wall movements at said first cardiac wall location, and a second sensor adapted to be positioned at a second cardiac wall location subjected to movements related to longitudinal valve plane movements along the longitudinal axis of the heart, wherein said second sensor is arranged for measuring cardiac wall movements at said second cardiac wall location. The system further comprises a device for monitoring cardiac synchrony in a human heart as described above.

According to yet another aspect of the present invention, there is provided an implantable cardiac stimulator for delivering stimulation pulses to a human heart. The cardiac stimulator comprises a housing, a pulse generator enclosed in said housing for generating said stimulation pulses, control circuitry for controlling the delivery of said stimulation pulses to the heart, and a device for determining cardiac synchrony in a human heart as mentioned above. The stimulator is connectable to a lead arrangement for conducting said stimulation pulses to the heart, and for conducting electrical signals from the heart to the control circuitry. It is to be noted that the term "implantable cardiac stimulator" is intended to encompass any implantable device arranged for providing electrical stimuli for controlling the operation of a human heart, such as an ICD or a pacemaker, e.g. of biventricular, dual-chamber, AV-sequential, or any other type known in the art.

According to a further aspect of the present invention, there is provided a method of determining cardiac

synchrony in a human heart. The method comprises the steps of sensing first cardiac wall movements at a first location subjected to movements related to longitudinal valve plane movements along the longitudinal axis of the heart, sensing second cardiac wall movements at a second location subjected to movements related to said longitudinal valve plane movements, and providing a synchronization signal based on said sensed first and second cardiac wall movements, the synchronization signal being indicative of the synchrony in the valve plane movements at said first and second locations.

According to a still further aspect of the present invention, there is provided a method of controlling the delivery of stimulation pulses to a human heart. The method comprises the steps of generating stimulation pulses, controlling parameters for the timing of stimulation pulse delivery to the heart, delivering said stimulation pulses to the heart, sensing first cardiac wall movements at a first location subjected to movements related to longitudinal valve plane movements along the longitudinal axis of the heart, sensing second cardiac wall movements at a second location subjected to movements related to said longitudinal valve plane movements, and providing a synchronization signal based on said sensed first and second cardiac wall movements, the synchronization signal being indicative of the synchrony in the valve plane movements at said first and second locations.

The present invention is based on the advantageous idea of monitoring the longitudinal movements of the valve-plane in order for determining cardiac synchrony in a human heart. A detected asynchrony in the longitudinal valve plane movement can be an indicator of an impaired cardiac function. Such an impairment can be related to ischemic heart disease, congestive heart failure, diastolic and/or systolic dysfunction, etc. Studies have shown that the valve plane of the heart in a healthy

individual moves longitudinally during the heart cycle. Simply put, ventricular contraction pulls the valve plane downwards, while ventricular relaxation moves the valve plane upwards. Furthermore, the movement of the valve  
5 plane in a healthy individual is essentially synchronous, while an asynchronous movement of the valve plane, e.g. a tilt in the valve plane movements, can be regarded as a strong indicator for an impaired cardiac function. Examples thereof can be found in "Left ventricular long  
10 axis function in diastolic heart failure is reduced in both diastole and systole: time for a redefinition", G Yip et al., Heart 2002; 87:121-125.

It should be noted that the cardiac synchrony in the longitudinal movements of the valve-plane could be  
15 related to synchrony during the systolic phase of the heart cycle, synchrony during the diastolic phase of the heart cycle, or synchrony of the overall heart cycle. The cardiac synchrony could also be determined for a shorter portion of the cardiac cycle, such as during the QRS-  
20 complex or the T-phase.

As stated above, a cardiac asynchrony result in a compromised pumping performance of the heart. Thus, one effect of maintaining or even improving the cardiac synchrony of the heart cycle, in particular during the  
25 systolic phase, is that the cardiac output may be maintained at a desired level, or even improved. Usually, an improvement in the cardiac output of a patient, i.e. the volume of blood ejected by the heart per minute, results in an improvement in the overall well-being of  
30 the patient.

Furthermore, it should in this context also be noted that the synchronization of myocardial relaxation during the diastolic phase of the heart cycle is beneficial for maintaining coronary flow at a desired level. All coro-  
35 nary blood supply, or cardiac perfusion, occurs during the diastolic phase of the heart cycle, i.e. when the myocardium relaxes between contractions. At the onset of

the systolic phase, the myocardial tissue is contracted, thereby also contracting the coronary arteries and arterioles such that coronary flow virtually comes to a stop during systole. When the myocardial tissue relaxes and dilates, the arteries and arterioles also become dilated and the pressure gradient built up during the systolic phase forces the flow of blood through the coronary arteries and veins. Thus, the diastolic phase should be sufficiently long and undisturbed for providing sufficient time for coronary flow to occur.

Moreover, the term "valve-plane" refers to the annulus fibrosis plane separating the ventricles from the atria and containing all four heart valves, i.e. the aortic, pulmonary, mitral, and tricuspid valves. The term "longitudinal axis of the heart" or "long-axis of the heart" refers to a direction of the heart which is substantially perpendicular to the valve plane.

Thus, according to the invention, longitudinal movements of the valve plane are measured at a plurality of locations in the heart, for the purpose of monitoring cardiac synchrony. At each location, a sensor is provided for sensing and measuring longitudinal cardiac wall movements at the location of the sensor. The sensor generates an output signal which is indicative of the sensed cardiac wall movements. Preferably, the output signals provide an indication of both the timing of the cardiac wall movements, and the magnitudes thereof. Furthermore, the sensors could be arranged to provide output signals indicative also of the directions of the cardiac wall movements. However, this is not a prerequisite for monitoring cardiac synchrony.

The output signals from the respective sensor are compared to one another, and a resulting comparison signal may be processed in order to arrive at a synchronization signal or index. Thereby, a level of synchrony in the longitudinal valve plane movements may be determined, which can be used as an indication of

whether the applied cardiac stimulation therapy needs adjustment.

According to the present invention, only longitudinal valve plane movements are measured for monitoring the synchrony in a human heart. Thus, the sensors may according to some embodiments be arranged to provide output signals which are substantially only indicative of movements related to the longitudinal movements of the valve plane. This can be achieved in a number of different ways. In one example, use can be made of sensors which are sensitive for one direction component of the movements only. The sensor could then be positioned and oriented such that the so called sensitive direction of the sensor is oriented in parallel to the longitudinal direction of the valve plane movements. In another example, the sensor could be positioned at a location in which the cardiac wall moves substantially only in the longitudinal direction of the valve plane. Such a location could be in the actual valve plane, for instance using an epicardial sensor attached to the epicardium of the human heart. Another location could be in the epicardium or the endocardium in the vicinity of the valve plane.

Furthermore, the processing circuitry could be arranged for discriminating longitudinal cardiac wall movements, i.e. parallel to the longitudinal valve plane movements, from lateral movements in an output signal from a sensor that is sensitive to movements in both the longitudinal and the lateral directions. The term "lateral movements" refers in this context to movements of the cardiac wall that is perpendicular to the longitudinal direction. Accordingly, a radial movement will herein be referred to as a lateral movement. It should in this context be noted that during the systolic and diastolic phases of a heart cycle, almost every cardiac wall portion of the heart will be moved due to the contractions and relaxations of the ventricles and

atria. Likewise, there will be a longitudinal direction component in the cardiac wall movements for almost all locations. Thus, the processing circuitry could be arranged for extracting the relevant longitudinal movement information from an aggregate signal. However, use is preferably made of sensors having directions of sensitivity which is weighted towards movements in the longitudinal axis of the heart such that the output signal thereof presents a significantly larger longitudinal than lateral direction component, or provided at a location subjected to significantly larger longitudinal than lateral movements during the heart cycle.

It should be noted that a number of different sensors could be used in the context of this invention for sensing cardiac wall movements, which are known per se to the person skilled in the art. For example, the sensors could be in the form of accelerometers, of any suitable type, or in the form of piezoelectric pressure transducers. Thus, the scope of the present invention is not restricted to the particular sensor alternatives disclosed herein.

Furthermore, according to exemplifying embodiments, different types of sensors for sensing or measuring cardiac wall movements may be used with the same cardiac stimulator. Thus, at least one sensor can be an accelerometer while at least one other sensor is a pressure sensor. Then, the output signals from the different types of sensors, respectively, are analyzed and compared to each other with regards to shape, timing and coherency.

According to embodiments of the present invention, two sensors may be used for determining cardiac synchrony. However, any number of sensors are contemplated within the scope of the present invention. Since the cardiac wall movements measured by the sensors are to a certain extent dependent on the actual location of the

sensor, the determined level of synchrony may be limited to a certain portion of the heart. Thus, if only two sensors are used, there may be a possibility of asynchronous behavior of the myocardium, or relevant portions thereof, not being detected by these two sensors. Thus, providing more than two sensors that are positioned at suitable spaced locations may increase the reliability of the synchronicity monitoring. However, this must of course be weighed against the possible trauma resulting from implantation of further sensors, as well as possible congestion in the veins in which possible implantable leads may be positioned. Consequently, the present invention is not restricted to the use of a specific number of cardiac wall movement sensors, even though specific examples and embodiments presented below may relate to the use of two or three sensors.

In exemplifying embodiments of the present invention, the synchronization monitoring is based on the output of two sensors, in which a first sensor is positioned at a location related to the right ventricle of the heart and arranged for sensing cardiac wall movements of the right ventricle, and the second sensor is positioned at a location related to the left ventricle of the heart and arranged for sensing cardiac wall movements of the left ventricle. Preferably, the right ventricle sensor is positioned within the right ventricle and attached to the ventricular wall, and the left ventricle sensor is positioned in the coronary sinus region outside the left ventricle and in contact with the left ventricular wall. In this example, interventricular or V-V synchronization may be monitored. As used herein, the phrase "coronary sinus region" refers to the vasculature of the left ventricle, including any portion of the coronary sinus, great cardiac vein, left marginal vein, left lateral vein, left posterior ventricular vein, middle cardiac vein, and/or small cardiac vein or any other cardiac vein accessible via the coronary sinus.

In further exemplifying embodiments of the present invention, the synchronization monitoring is based on the output of two sensors positioned in or at the same ventricle. Then, the sensors are suitably used for monitoring synchronization within the same ventricle, i.e. for the right or the left ventricle. However, if one sensor is positioned within the right ventricle and attached to the cardiac septum, or in the immediate vicinity thereof, the sensor could be arranged to sense cardiac wall movements related to myocardial wall movements related to contractions originating from the left ventricle.

Moreover, one or more additional sensors could in further examples of the invention be provided in or at the left or the right ventricle for providing additional output signal(s) on which the synchronization monitoring is based. Also, sensors could be provided in the atrium for delivering output signal(s) on which the synchronization is based.

In some embodiments of the invention, all sensors for measuring cardiac wall movements are positioned in the valve plane, or in a plane parallel thereto. Then, an asynchrony in the movements of the cardiac wall portions, related to the longitudinal movements of the valve plane, between the sensor locations can very easily be determined and interpreted as an asynchrony in the overall longitudinal movements of the valve plane.

In other embodiments of the invention, the sensors may be positioned at locations related to cardiac wall regions of interest. These locations can be positioned in a plane parallel to the valve plane, but it is more likely that they will not. The regions of interest can be determined by the physician and for instance refer to regions which are considered to be susceptible to post-systolic contractions (PSC), or have slow conduction pathways. A further example of a region of interest could be a region having hibernating tissue expected to recover

during progression of cardiac therapy, which could change cardiac function and require adjustment of pacing or stimulation therapy parameters.

According to the present invention, a  
5 synchronization signal can be derived, preferably using processing circuitry provided in a cardiac stimulator, on the basis of the output signals from the respective sensors using a number of different methods, as understood by the person skilled in the art. According to  
10 one example, the synchronization index could be the actual difference in time for the sensed onset of longitudinal valve plane movements related to ventricular contraction experienced by the different sensors.

Furthermore, in accordance with another exemplifying  
15 embodiment, the difference between sensor output signals could be calculated, for instance by simply subtracting one output signal from another. The resulting difference signal could then be used as said synchronization signal per se, or statistical calculations could be applied to  
20 the difference signal to arrive at a suitable value indicative of the synchronization. If more than two sensors are used, a plurality of difference signals could be provided, for selected sensor combinations or for all combinations. The plural difference signals could then  
25 simply be aggregated to obtain a synchronization signal that would take into account all sensors, or be subject to suitable statistical calculations to arrive at a synchronization index.

In yet further examples, the synchronization index  
30 or signal could be obtained through plotting of the sensor output signals in x-y plots and detecting patterns between the plots, for instance by cross-correlation, neural network signal processing, or loop discrimination. Such loop discrimination is disclosed in U.S. Patents  
35 Nos. 5,427,112 and 5,556,419, which are incorporated herein by reference.

However, the present invention is not intended to be restricted to the examples of methods for calculating a synchronization index or signal presented herein. On the contrary, any suitable method for calculating a  
5 synchronization signal or index from the output signals of the sensors measuring longitudinal valve plane movements is contemplated within the scope of the present invention.

According to some embodiments of the present  
10 invention, a comparison is made between the obtained synchronization index or signal and a threshold value or signal, preferably by processing circuitry provided in an implantable cardiac stimulator. Then, the threshold value would be an indicator whether the cardiac synchrony lies  
15 within an acceptable range or not. In other words, as long as the synchronization index is within a selected range, as defined by one or more threshold values, a desired level of cardiac synchrony is considered to be enabled. However, should the synchronization index fall  
20 outside the intended range, an indication of cardiac asynchrony, or insufficient cardiac synchrony, may be provided.

Such an indication could in exemplifying embodiments of the invention be used for triggering a change in the  
25 stimulation or pacing therapy. Such a change could for example refer to an adjustment in the VV-interval, e.g. for a biventricular heart stimulator; a change in the AV-interval, e.g. for a dual chamber heart stimulator; or combinations thereof. Thereby, the cardiac synchrony can  
30 be monitored during remodulation of the patient's heart, and the stimulation or pacing therapy can be adjusted in adaptation to the remodulation of the heart.

In further embodiments, the indication of cardiac asynchrony could be used for triggering an alarm signal  
35 to the patient. This alarm signal could be intended for prompting the patient to seek medical assistance for care or follow-up.

It should be understood that the indication of cardiac asynchrony does not have to be a binary value. On the contrary, the asynchrony indication preferably also provides information of the severity of asynchrony. Thus, 5 the threshold value as referred to above, may in fact be a number of threshold values. For instance, a first value could be an indication of slight asynchrony to be used for diagnostic purposes, a second value could trigger a change in the pacing therapy, and a third value could be 10 used for triggering an alarm to the patient that he needs to see his/her physician.

The monitoring of cardiac synchrony and/or detection of cardiac asynchrony is preferably performed at predetermined time intervals. As an example, the 15 monitoring could be performed by receiving the output signals from the sensors, and providing a synchronization signal once a week, every three days, once a day, every 8 hours, etc. Preferably, the time interval is set such that monitoring is performed often enough for a cardiac 20 asynchrony to be detected at such an early stage that corrective action may be immediately taken and possible detrimental effects avoided, and seldom enough such that an unduly large energy consumption resulting from the monitoring procedure may be avoided.

25 In some embodiments, the time interval may be varied in adaptation to expected possible changes in the function of the heart. For instance, it may be expected that variations and changes in the myocardial function is most likely to occur, and to occur most frequently, in 30 the time immediately following implantation. Thus, the monitoring interval can be set at a short interval for the period immediately following implant, and then be automatically extended as the time from implantation increases.

35 Furthermore, the time interval may be shortened as a result of detected changes in the cardiac synchrony. Thus, following a change in cardiac synchrony, possibly

into asynchrony with ensuing corrective actions taking place, the time interval is suitably decreased in order to frequently monitor for possible further deterioration, or for an improvement as a result of the corrective actions taken.

Moreover, immediately following a change in the pacing therapy, determinations of possible asynchrony should take place. Also, if the synchronization signal or index is a quantitative value directly indicating the level of synchrony, the change in synchronization based on any pacing therapy variations can be monitored and the pacing therapy further adjusted accordingly.

In further examples, if the monitoring should indicate that cardiac asynchrony has arisen, then one or more further measurements and determinations of cardiac synchronization may be performed before an indication of asynchrony is provided and possible ensuing actions are initiated. Thereby, a sudden, isolated asynchronous event will not have an undue impact on the overall stimulation pacing therapy.

In the examples that will be presented in the following, the sensors are provided at the distal end of cardiac leads that are arranged for providing stimulation pulses to the atria and/or ventricles of the heart, or for conducting sensed intrinsic cardiac signals from the heart to the heart stimulator. However, it should be noted that sensors provided on separate implantable leads, or other implantable devices, are also contemplated in the context of this application. Thus, the scope of the present invention is not restricted to sensors arranged on such implantable leads for stimulation and sensing as will be discussed below.

Further objects and advantages of the present invention will be discussed below by means of exemplifying embodiments.

Brief description of the drawings

Exemplifying embodiments of the invention will be described below with reference to the accompanying drawings, in which:

5 Fig. 1 is a simplified, partly cutaway view illustrating an implantable stimulator according to one exemplifying embodiment of the present invention;

Figs. 2 and 3 are partly cut-away views of a human heart provided with leads and sensors according to  
10 further exemplifying embodiments;

Fig. 4 is an illustration in a block diagram form of an implantable stimulator according to the embodiment shown in Fig. 1;

Fig. 5 is an illustration in a block diagram of  
15 an enhanced analysis device arranged to receive signals from three cardiac wall motion sensors;

Figs. 6a-6c are schematic illustrations of the determination of synchrony according to embodiments of the present invention,

20 Figs. 7a-7c are schematic illustrations corresponding to those of Figs. 6a-6c, but in which an asynchrony is determined;

Figs. 8a-8c illustrate the determination of an asynchrony resulting from a local post-systolic  
25 contraction in the diastolic phase;

Figs. 9a-9d illustrate examples of sensor positions where all sensors are positioned at the left ventricle;

30 Figs. 10a-10d illustrate examples of sensor positions where sensors are positioned at both the right and the left ventricle, respectively;

Figs. 11a and 11b illustrate in diagram form a first example of how a synchronization index may be obtained; and

16A

Figs. 12a and 12b illustrate in diagram form a second example of how a synchronization index may be obtained.

5

Description of exemplifying embodiments

The following is a description of exemplifying embodiments in accordance with the present invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of describing the general principles of the invention. Thus, even though particular types of heart stimulators will be described, such as biventricular pacemakers with or without atrial sensing and/or stimulation, the invention is also applicable to other types of cardiac stimulators, such as univentricular or dual chamber pacemakers, implantable cardioverter defibrillators (ICD's), etc.

With reference first to fig. 1, there is shown a stimulation device 10 in electrical communication with a patient's heart 1 by way of two leads 20 and 30 suitable for delivering multi-chamber stimulation (and possible shock therapy). The heart illustrated portions of the heart 1 include the right atrium RA, the right ventricle RV, the left atrium LA, the left ventricle LV, cardiac walls 2, the ventricular septum 4, the valve plane 6, and the apex 8. The valve plane 6 refers to the annulus fibrosis plane separating the ventricles from the atria and containing all four heart valves, i.e. the aortic, pulmonary, mitral, and tricuspid valves.

In order to sense right ventricular cardiac signals and to provide stimulation therapy to the right ventricle RV, the stimulation device 10 is coupled to an implantable right ventricular lead 20 having a ventricular tip electrode 22, a ventricular annular or ring electrode 24, and a cardiac wall movement sensor 21. The ring electrode 24 is arranged for sensing electrical activity, intrinsic or evoked, in the right ventricle RV. The right ventricular tip electrode 22 is arranged to be implanted in the endocardium of the right ventricle, e.g. near the apex 8 of the heart. Thereby, the tip electrode 22 becomes attached to the cardiac wall and follows the cardiac wall movements, which movements can be sensed by the sensor 21

arranged near the tip electrode. In this example, the sensor is fixedly mounted in a distal header portion of the lead 20, in which the tip electrode 22 is also fixedly mounted. Furthermore in this example, the sensor is in the form of an accelerometer. However, other arrangements sensor types are contemplated for the cardiac wall motion sensor 21.

In order to sense left ventricular cardiac signals and to provide pacing therapy for the left ventricle LV, the stimulation device 10 is coupled to a "coronary sinus" lead 30 designed for placement via the coronary sinus in veins located distally thereof, so as to place a distal electrode adjacent to the left ventricle. Also, additional electrode(s) (not shown) could thereby be positioned adjacent to the left atrium. The coronary sinus lead 30 is designed to receive ventricular cardiac signals from the cardiac stimulator 10 and to deliver left ventricular LV pacing therapy using at least a left ventricular tip electrode 32 to the heart 1. In the illustrated example the LV lead 30 comprises an annular ring electrode 34 for sensing electrical activity related to the left ventricle LV of the heart. Furthermore, a cardiac wall movement sensor 31 is arranged at the tip electrode 32 for sensing left ventricular LV cardiac wall movements.

Turning briefly to Figs. 2 and 3, two alternative embodiments for placement of cardiac leads, cardiac electrodes and sensors for sensing cardiac wall movements related to longitudinal valve plane movements are illustrated. In Fig. 2, the RV and LV leads 20, 30 have been supplemented with a right atrial RA lead 80. The lead comprises an RA tip electrode 82 positioned in the patient's right atrial appendage for delivering electrical stimuli to the right atrium, and an RA ring electrode 84 for sensing and conducting cardiac signals from the right atrium to the cardiac stimulator. A cardiac wall motion sensor is provided at the RA tip

electrode 82 for sensing cardiac wall movements of the RA wall. Furthermore, the LV lead 30 is provided with an additional cardiac wall movement sensor 33 arranged at the valve plane 6, as well as an additional stimulating electrode, of the ring type, arranged distally of the movement sensor 33. Thereby, cardiac wall movements related to longitudinal valve plane movements at a plurality of locations, i.e. three or four, may be sensed and conducted via the cardiac leads 20, 30, 80 to the cardiac stimulator.

Furthermore, Fig. 3 illustrates yet another example of lead, electrode and sensor placements. Here, the RV, RA and LV leads 20, 30 and 80 have been supplemented by an external epicardial lead 90 connected to the implantable stimulator 10. The epicardial lead 90 may be arranged for delivering stimulation pulses to the left ventricle LV of the heart, but is in this example only arranged for sensing cardiac wall movements related to longitudinal valve plane movements and comprises a cardiac wall motion sensor 91. Thus, even though the LV lead 30 terminates and the stimulation electrode 32 for stimulation of the left ventricle arranged at a position near the valve plane 6 of the heart, local wall movements occurring in the LV cardiac wall further down towards the apex 8 may still be sensed.

Even though three examples have been illustrated in Figs. 1-3, the invention is not restricted to the illustrated examples of lead, electrode and sensor placement. For example, several epicardial electrodes and/or wall motion sensors could be used, wall motion sensors could be arranged at plural positions in the ventricles only, all wall motion sensors could be arranged in the same ventricle, plural atrial wall sensors could be used, etc. Also, in the illustrated examples, the wall motion sensors are of accelerometer type. However, other types of sensors for sensing and measuring wall movements related to longitudinal valve

plane movements are to be comprised in the scope of the present application. Further examples of sensor placements will be presented in relation to the further embodiments that will be described below.

5           Turning now to Fig. 4, the heart stimulator 10 of Fig. 1 is shown in a block diagram form. For illustrative purposes, reference is made to Fig. 1 for the elements of the leads that are intended for positioning in or at the heart. The heart stimulator 10 is connected to a heart 1  
10 in order to sense heart signals and emit stimulation pulses to the heart 1. A first tip electrode 22 is anchored in the right ventricle RV of the heart 1 and connected, via a first electrode conductor in the lead  
20, to a first pulse generator 26 in the heart stimulator 2. A first ring electrode 24 is connected near the first  
15 tip electrode 22 and, via a second electrode conductor in the first lead 20, to the first pulse generator 26. A stimulation pulse to the right ventricle can be delivered to heart tissue by the first pulse generator via the  
20 first lead 20 and the first tip electrode 22. The stimulation pulse is then returned, via the first ring electrode 24 and the first lead 20, to the first pulse generator 26. Alternately, the stimulation pulse can be delivered via the first tip electrode 22 and an  
25 indifferent electrode 12 which, in this instance, consists of the enclosure of the heart stimulator 10 but can also consist of a separate electrode located somewhere in the body. The indifferent electrode 12 is connected to the first pulse generator 26 via an  
30 electrode conductor 14 in order to return stimulation pulses from the right ventricle. A first detector 28 is connected in parallel across the output terminal of the first pulse generator 26 in order to sense right  
ventricular activity in the heart.

35           In corresponding manner, a second tip electrode 32 is positioned in a vein distally of the coronary sinus and, thus, connected to the left ventricle LV of the

heart 1, and, via a conductor in the second lead 30, to a second pulse generator 36. A second ring electrode 34 is located near the second tip electrode 32 and connected, via a further conductor in the second electrode lead 30, to the second pulse generator 36. Delivery of a stimulation pulse to the ventricle can be bipolar via the second tip electrode 32 and the second ring electrode 34, or unipolar via the second tip electrode 32 and the indifferent electrode 12. A second detector 38 is connected in parallel across the output terminal of the second pulse generator 36 in order to sense left ventricular activity in the heart. The pulse generators 26 and 36 and the detectors 28 and 38 are controlled by a control unit 40 which regulates the stimulation pulses with respect to amplitude, duration and stimulation interval, the sensitivity of the detectors 28 and 38 etc.

A physician using an extracorporeal programmer 56 can, via a telemetry unit 54, communicate with the heart stimulator 10 and thereby obtain information on identified conditions and also reprogram the different functions of the heart stimulator 10.

Fig. 4 further shows a first embodiment of an analysis device. The analysis device 50 is connected via the first electrode lead 20 to a first cardiac wall motion sensor 21 for sensing cardiac wall movements related to longitudinal valve plane movements, and via the second electrode lead 30 to a second cardiac wall motion sensor 31 for sensing cardiac wall movements related to longitudinal valve plane movements. The analysis device 50 includes a measurement unit 52 which is capable of selectively receiving signals from any of the sensors, and which filters and amplifies the incoming signals in an appropriate manner.

The output signal from the measurement unit 52, which is proportional to the measurement signal, is then sent to a buffer 54 and to a differentiating circuit 56. Buffering is performed so that the differentiated signal

is in phase with the proportional signal when they are sent to a calculator unit 58. The calculator unit 58 calculates a synchronization or synchrony value or signal based on the output signals from the respective sensors.

5 The calculated synchronization signal 58 is sent to a comparator 60 for comparison with a threshold value, for instance indicative of when insufficient cardiac synchrony is present.

The output signal from the comparator comprises  
10 information of whether the synchronization signal passes the threshold value, or one of the threshold values for embodiments where a plurality of threshold values are utilized, and is forwarded to a microprocessor 62 which communicates with the control unit 40. If, e.g., an  
15 arisen asynchrony is identified, the control device 40 can institute therapeutic treatment with stimulation pulses in order to restore cardiac synchrony. The microprocessor 62 further controls the measurement unit 52 with respect to the measurement signal to be sent to the  
20 analysis device 50 and can also control the comparator 60, for example for varying threshold values in response to altered pacing therapy or due to altered settings by the physician.

With reference now to Fig. 5, there is shown an  
25 alternative analysis device 51. This alternative analysis device 51 basically comprises the same or similar elements as described in relation to the measurement unit analysis device 50 of Fig. 4. However, the alternative analysis device 51 is arranged for receiving output  
30 signals from three cardiac wall motion sensors via conductors 70, 72 and 74, the analysis device thus being arranged to provide a synchronization signal indicative of cardiac synchrony between three different locations of the heart.

35 Furthermore, a fourth conductor 76 provides an IEGM signal for the measurement unit. The IEGM signal may provide an indication related to when the output signals

of the sensors may be used for determining cardiac synchrony for a particular portion of the heart cycle. Thus, the IEGM signal may for instance be used by the analysis device 50, or rather by the differentiating circuit 54 and the calculator unit 58, as an aid in discriminating between the systolic and the diastolic phases of the heart cycle. Thereby, the analysis device can for instance be arranged to only process sensor output signals provided during the diastolic phase. Then, there will be no risk of misinterpreting an asynchrony that may be present in the systolic phase as an asynchrony in the diastolic phase.

Turning now to Figs. 6-6c and 7a-7c, there will be shown in schematic form the presence and determination of cardiac synchrony and asynchrony, respectively. In Figs. 6a, 6b, 7a, and 7b, a heart is schematically illustrated with three cardiac wall motion sensors a, b and c positioned in the left ventricle LV of the heart.

In Fig. 6a, the position of the sensors, i.e. the cardiac wall portions in which the sensors are arranged, are illustrated at an instant when the myocardium is fully dilated, in particular during the diastolic phase of the heart cycle. Thus, the sensors and the wall portions thereof are in a respective position obtained from the longitudinal or long-axis valve plane movements as a result of myocardial relaxation. In Fig. 6b, an instant when the myocardium is at a state of myocardial contraction is illustrated, in particular during the systolic phase of the heart cycle. Thus, the movement of the sensors and the wall portions into the contracted positions have ceased and they are in a respective position obtained from the longitudinal valve plane movements as a result of myocardial contraction.

The output signals of the sensors are illustrated in Fig. 6c, and it can be seen that the movements sensed by the three sensors are substantially simultaneous throughout the heart cycle. Therefore, the processing circuitry,

or analysis device, of the cardiac stimulator determines that there is cardiac synchrony. As a consequence, no further actions related to change in pacing therapy is performed. It should be noted that the determination of cardiac synchrony can be determined for the entire heart cycle, for the systolic phase, the diastolic phase, the transitions between diastolic and systolic phase, and vice versa, or any other time interval of the heart cycle that may be of particular interest for the determination of cardiac synchrony.

In Fig. 7a., the position of the sensors and the respective cardiac wall portions thereof correspond to that of Fig. 6a at an instant when the myocardium is fully dilated. Thus, the sensor positions are derived from the longitudinal valve plane movements resulting from myocardial relaxation. However, at the particular instant illustrated in Fig. 7b, only sensor b, and the cardiac wall portion to which sensor b is attached, has reached the position derived from the longitudinal valve plane movements obtained in the fully contracted state of the myocardium. Hence, there is lack in synchrony between the longitudinal valve plane movements for the cardiac wall portions at which the sensor a, b and c are attached, respectively. This lack in synchrony also appears in the output signals a, b and c of the cardiac wall motion sensors a, b and c, respectively. Thus, upon performing a synchronicity analysis for the output signals, for instance in the systolic phase of the heart cycle, it can be determined that cardiac asynchrony is present and that suitable measures should be taken. Such measures could include restoring the cardiac synchrony or to derive an alarm signal indicative of the cardiac asynchrony.

Turning now to Figs. 8a-8c, there is shown a further example of the occurrence and detection of cardiac asynchrony related to longitudinal valve plane movements. In Fig. 8a, the positions of the cardiac wall motion sensors

a, b and c at an instant where the myocardium has assumed a contracted state is shown. In Fig. 8b, a post-systolic contraction PSC occurs in the cardiac wall portion where sensor a is arranged for sensing cardiac wall movements derived from longitudinal valve plane movements. Consequently, sensor a is subjected to a longitudinal movement at an instant when sensors b and c remain substantially stationary during diastole. This appears in the combined sensor signal outputs a, b and c, and can be detected and determined as an asynchrony in the diastolic phase by the analysis device 50 of the stimulator 10. In the signal diagram of Fig. 8c, the portion comprising the signal output during the PSC is encircled. Thus, as a result of the determined asynchrony, appropriate adjustment of the pacing therapy may be executed in order to restore the cardiac synchrony.

In Figs. 6a through 8b, substantially only one example of the positioning of cardiac wall motion sensors for sensing movements related to the longitudinal movements of the valve plane is provided. However, there are a vast number of sensor positioning alternatives that are contemplated within the scope of the present application. In fact, any placement of sensors for measuring cardiac wall motions occurring during the heart cycle may be used, as long as there is in fact movements of the particular portion to which the sensor is located and attached in relation to the longitudinal movements of the valve plane during the heart cycle, or any portion thereof. Thus, the present application is not limited to a particular number of wall motion sensors, or to particular positioning thereof.

Turning to Figs. 9a-9d, further examples of wall motion sensors are provided. In these examples, the sensors a, b and c are arranged at the same ventricle, i.e. for measuring cardiac wall movements at several locations in the left ventricle LV of the heart. Fig. 9a is intended to illustrate the orientation of the valve

plane, which is indicated by numeral 6 in Fig. 1. In the example illustrated in Fig. 9b, the sensors are positioned in the actual valve plane, which of course is suitable for detecting valve plane movements. Then, the sensors could in one alternative be positioned in the actual annulus fibrosis tissue, or epicardially outside the annulus fibrosis plane.

In Fig. 9c and 9d, two alternative examples of sensor positionings are presented. In Fig. 9c, the sensors a, b and c have been positioned at equal distances from the valve plane, thus forming a sensor plane parallel to the valve plane. Thereby, the sensors are assumed to be subjected to movements related to the longitudinal valve plane movements of substantially the same distance during the heart cycle, which may be beneficial when calculating and determining synchrony and possible sudden or expected appearance of asynchrony in the valve plane movements.

In the example shown in Fig. 9d, the sensors are positioned at different levels at one ventricle along the longitudinal axis, or long-axis, of the heart. In this example, the physician has positioned the sensors at selected regions of interest, for instance regions suffering from a conductive disorder or having hibernating tissue which is expected or suspected to become active during remodulation of the heart due to progressing stimulation therapy.

Turning now to Figs. 10a to 10d, further examples of sensor positioning are illustrated. In the examples, the sensors are arranged in or at both ventricles of the heart. First, Fig. 10a illustrates the valve plane and the longitudinal direction of the heart. Then, Fig. 10b illustrates the example where the cardiac wall motion sensors are positioned and arranged to sense longitudinal cardiac wall movements of the valve plane. The benefits thereof would of course be similar to the placement in the same ventricle as illustrated in Fig. 9b.

Furthermore, in the same manner as mentioned above in relation to Fig. 9b, the sensors could in one alternative be positioned in the actual annulus fibrosis tissue, or epicardially outside the annulus fibrosis plane.

5 Suitably, the right ventricular sensor a is arranged endocardially in the valve plane, and the left ventricular sensor c is arranged epicardially. The sensor b arranged at the septum 4 could be arranged epicardially either directly or via a coronary vein, or endocardially,  
10 via the right atrium and ventricle. Possibly, the RV sensor a arranged at the valve plane could be replaced for an RA sensor arranged in or at the valve plane, e.g. in the annulus fibrosis tissue.

In fig. 10c, the sensors a, b and c have been  
15 positioned in or at the right and the left ventricle, respectively, at equal distances from the valve plane, thus forming a sensor plane parallel to the valve plane. Thereby, similar to the example shown in Fig. 9c, the sensors are assumed to be subjected to movements of  
20 substantially the same distance during the heart cycle, which may be beneficial when calculating and determining synchrony and possible sudden or expected appearance of asynchrony in the longitudinal valve plane movements.

Finally, in the example illustrated in Fig. 10d, the  
25 sensors are positioned at different levels, in or at the right and the left ventricle, along the longitudinal axis of the heart. In this example, similar to the example shown in Fig. 9d, the physician has positioned the sensors at selected regions of interest, for instance  
30 regions suffering from a conductive disorder or having hibernating tissue which is expected or suspected to become active during remodulation of the heart due to progressing stimulation therapy.

When the signal output from the sensors a, b and c  
35 is received by the analysis device 50, a calculation of a synchronization index or signal is performed, which can be used for determining synchrony of the heart. In Fig.

11a, the output signals a, b and c, stemming from the sensors a, b and c, respectively, indicative of cardiac wall movements are illustrated in a diagram. In the portion of the diagram illustrating sensor output signal a, the sensor output signal b has been added as shown by the dotted line. Similarly, the sensor output signal c has been added to the portion of the diagram illustrating sensor output signal b. In this example, the difference between the sensor output signals a and b and the difference between the sensor output signals is calculated. This is performed by simply subtracting sensor output signal b from a and sensor output signal c from b.

The resulting difference signals are shown in Fig. 11b. These signals could be further added to each other in order to arrive at the synchronization index or signal. Alternatively, the difference signals could be used separately in order to provide dual synchronization indices or signals. Furthermore, statistical calculations could be applied to the difference signal(s) to arrive at a suitable value indicative of the level of synchronization.

Fig. 12a and 12b illustrate a further example of deriving one or more synchronization indices or signals. Here, the upper and lower portions of the diagram in Fig. 12a illustrates two signals obtained from two sensor output signals, respectively. One signal is indicated with a solid line, and the other one with a dotted line, respectively. These pairs of sensor output signals are cross-correlated in order to arrive at a cross-correlation result which is used as said synchronization indices or signals. In the illustrated example, two cross-correlation results in the form of synchronization index A and synchronization index B are obtained. The synchronization signals can then be compared with a threshold value, which is illustrated in Fig. 12b with the dotted straight line, and appropriate measures be

taken when the synchronization signal exceeds the threshold level.

When the monitoring of cardiac synchronization has revealed that a cardiac asynchrony has arisen, or that a  
5 reduction of cardiac synchrony has occurred, the parameters for timing of stimulation pulse delivery may be changed in order to restore or improve the cardiac synchrony. Such an indication could in exemplifying  
10 embodiments of the invention be used for triggering a change in the stimulation therapy. Such a change could for example refer to an adjustment in the VV-interval, e.g. for a biventricular heart stimulator; a change in the AV-interval, e.g. for a dual chamber or an AV-sequential heart stimulator; or combinations thereof.  
15 Thereby, the cardiac synchrony can be monitored during remodulation of the patient's heart, and the pacing therapy can be adjusted in adaptation to the remodulation of the heart.

For heart stimulators in which the pacing therapy  
20 may be automatically adjusted by the heart stimulator in order to optimize or maximize cardiac output, a synchronized and elongated diastolic phase may be given priority over the optimization of cardiac output. For instance, in patients suffering from ischemic heart  
25 disease, it may be more important to ensure synchronized diastole and, thereby, adequate coronary flow at all times rather than maximized cardiac output.

In further embodiments, the indication of cardiac asynchrony could be used for triggering an alarm signal  
30 to the patient. This alarm signal could be intended for prompting the patient to seek medical assistance for care or follow-up.

It should be noted that the sensors may be subjected to pressures, movements and/or accelerations that are not  
35 derived from or related to the intrinsic movements of the myocardium and the cardiac walls thereof. For instance, accelerations derived from extra-cardiac movements of the

patient, such as from running, vibrations in the patient environment, thoracic movements etc. However, output signal contributions deriving from intrinsic movements of the myocardial tissue can easily be discriminated from  
5 signal contributions from such extra-cardiac movements since the latter have a substantially identical impact on the respective sensor. Furthermore, by designing the sensors to be sensitive for certain frequency ranges, the majority of the extra-cardiac signal contributions may be  
10 omitted. Furthermore, band-pass filtering of the sensor outputs may also be used for discriminating or filter out the signal contribution from extra-cardiac movements.

While the invention disclosed herein has been described by means of specific embodiments and applica-  
15 tions thereof, numerous modifications and variations could be made therein by those skilled in the art without departing from the scope of the invention, which is defined by the appended claims.

CLAIMS

1. A device for monitoring cardiac synchrony in a human heart, the device being connectable to a first and  
5 a second sensor adapted to be positioned at a first cardiac wall location and a second cardiac wall location subjected to movements related to longitudinal valve plane movements along the longitudinal axis of the heart, respectively, wherein said first and second sensors are  
10 arranged for measuring cardiac wall movements at said first and said second cardiac wall location, respectively, comprising:

processing circuitry arranged for receiving output signals from said first and second sensors, said output  
15 signals being indicative of said longitudinal valve plane movements at said respective cardiac wall location, wherein said processing circuitry is arranged for processing said output signals and provide a synchronization signal indicative of the synchrony in the valve plane  
20 movements at said first and second cardiac wall locations.

2. The device as claimed in claim 1, wherein the first cardiac wall and the second cardiac wall are  
25 ventricular walls.

3. The device as claimed in claim 2, wherein the first cardiac wall is a wall of the right ventricle of the heart and the second cardiac wall is a wall of the  
30 left ventricle of the heart, and wherein the cardiac synchrony is interventricular synchrony.

4. The device as claimed in claim 2, wherein the first and the second cardiac walls are walls of the right  
35 or the left ventricle of the heart, respectively.

5. The device as claimed in claim 1, wherein at least one of the first and the second cardiac wall is an atrial wall.

5           6. The device as claimed in any one of the preceding claims, wherein said cardiac wall locations are in the vicinity of said valve plane, at which locations the movements of said cardiac wall locations are substantially longitudinal in correspondence with the movements  
10 of the valve plane.

7. The device as claimed in any one of the preceding claims, wherein the device is further connectable to a third sensor adapted to be positioned at a third cardiac  
15 wall location subjected to movements related to longitudinal valve plane movements along the longitudinal axis of the heart, wherein said third sensor is arranged for measuring cardiac wall movements at said third cardiac wall location, and

20           wherein said processing is further arranged for receiving and processing output signals from said third sensor, whereby said synchronization signal is indicative of the synchrony in the valve plane movements at said first, second and third cardiac wall locations.

25           8. The device as claimed in claim 7, wherein the device is connectable to at least one further sensor to be positioned at least one further cardiac wall location subjected to movements related to said longitudinal valve plane movements, and  
30

          wherein said processing circuitry is arranged for receiving and processing output signals indicative of longitudinal valve plane movements from all sensors, and for providing a corresponding synchronization signal.

35           9. The device as claimed in any one of the preceding claims, wherein the processing circuitry is arranged for

discriminating between the signal contributions from longitudinal and lateral movements in said output signals from the sensors.

5           10. The device as claimed in any one of the preceding claims, wherein the processing circuitry is further arranged for comparing said synchronization signal with a threshold signal and providing an output indicative of whether cardiac synchrony is present.

10

          11. The device as claimed in any one of the preceding claims, wherein the processing circuitry is arranged for processing said output signals by calculating the difference between the signals and providing the calculated difference signal as said synchronization signal.

15

          12. The device as claimed in any one of claims 1-10, wherein the processing circuitry is arranged for processing said output signals by cross-correlating the signal patterns of the output signals, and providing the cross-correlation result as said synchronization signal.

20

          13. The device as claimed in any one of claims 1-10, wherein the processing circuitry is arranged for processing said output signals using neural network signal processing.

25

          14. A system for monitoring cardiac synchrony in a human heart, comprising:

30

          a first sensor adapted to be positioned at a first cardiac wall location subjected to movements related to longitudinal valve plane movements along the longitudinal axis of the heart, wherein said first sensor is arranged for measuring cardiac wall movements at said first cardiac wall location,

35

a second sensor adapted to be positioned at a second cardiac wall location subjected to movements related to longitudinal valve plane movements along the longitudinal axis of the heart, wherein said second sensor is arranged  
5 for measuring cardiac wall movements at said second cardiac wall location, and

a device for monitoring cardiac synchrony in a human heart as claimed in any one of the preceding claims.

10 15. The system as claimed in claim 14, further comprising:

a third sensor adapted to be positioned at a third cardiac wall location subjected to movements related to longitudinal valve plane movements along the longitudinal  
15 axis of the heart, wherein said third sensor is arranged for measuring cardiac wall movements at said third cardiac wall location.

20 16. The system as claimed in claim 15, further comprising:

at least one further sensor adapted to be positioned at least one further cardiac wall location(s) subjected to movements related to said longitudinal valve plane movements.

25

17. The device as claimed in any one of the preceding claims, wherein said sensors are accelerometers.

30 18. The device as claimed in any one of claims 14-16, wherein said sensors are piezoelectric pressure sensors.

35 19. The device as claimed in any one of the preceding claims, wherein said sensors are arranged for providing measurement signals substantially indicative of longitudinal movements only.

20. An implantable cardiac stimulator for delivering stimulation pulses to a human heart, comprising:

a housing;

5 a pulse generator enclosed in said housing for generating said stimulation pulses;

control circuitry for controlling the delivery of said stimulation pulses to the heart; and

a system for determining cardiac synchrony in a human heart as claimed in any one of claims 14-19;

10 wherein the stimulator is connectable to a lead arrangement for conducting said stimulation pulses to the heart, and for conducting sensed electrical signals from the heart to the control circuitry.

15 21. The cardiac stimulator as claimed in claim 20, wherein the lead arrangement comprises said sensors for measuring cardiac wall movements.

20 22. The cardiac stimulator as claimed in claim 21, wherein the lead arrangement comprises a plurality of leads for conducting said stimulation pulses to the heart and/or said sensed electrical signals from the heart, and wherein each of said sensors is comprised in one of said plurality of leads.

25 23. The cardiac stimulator as claimed in claim 21, wherein the lead arrangement comprises a plurality of leads for conducting said stimulation pulses to the heart and/or said sensed electrical signals from the heart, and  
30 at least one further lead for conducting said output signals from at least one of said sensors to the processing circuitry.

35 24. The cardiac stimulator as claimed in any one of claims 20-23, wherein the control circuitry is arranged for changing timing parameters for the delivery of said

stimulation pulses in adaptation to said synchronization signal.

25. The cardiac stimulator as claimed in claim 24,  
5 wherein the control circuitry is arranged for changing the timing parameters when said synchronization signal indicates an absence or reduction of cardiac synchrony.

26. The cardiac stimulator as claimed in claim 25,  
10 wherein the control circuitry is arranged for changing the timing parameters such that cardiac synchrony is restored.

27. The cardiac stimulator as claimed in any one of  
15 claims 24-26, wherein the stimulator is a biventricular stimulator, wherein the lead arrangement is arranged for conducting stimulation pulses to the right and left ventricle, respectively, wherein the sensors are arranged for positioning at right and left ventricular wall  
20 locations, respectively, and wherein said timing parameters include a VV-interval.

28. The cardiac stimulator as claimed in any one of  
25 claims 24-27, wherein the lead arrangement is arranged for conducting stimulation pulses to at least one ventricle and conducting stimulation pulses to and/or sensed electrical signals from at least one atrium, and wherein said timing parameters include an AV-interval.

30 29. A method of determining cardiac synchrony in a human heart, comprising the steps of:

sensing first cardiac wall movements at a first  
location subjected to movements related to longitudinal  
valve plane movements along the longitudinal axis of the  
35 heart;

sensing second cardiac wall movements at a second location subjected to movements related to said longitudinal valve plane movements; and

5 providing a synchronization signal based on said sensed first and second cardiac wall movements, the synchronization signal being indicative of the synchrony in the valve plane movements at said first and second locations.

10 30. The method as claimed in claim 29, wherein said first location and said second location are locations for sensing cardiac wall movements of a ventricle, respectively, of the heart.

15 31. The method as claimed in claim 30, wherein at the first location, cardiac wall movements of the right ventricle of the heart is sensed, and at the second location, cardiac wall movements of the left ventricle of the heart is sensed, and wherein the cardiac synchrony is  
20 interventricular synchrony.

25 32. The method as claimed in claim 30, wherein at the first and second locations, cardiac wall movements of the right or the left ventricle is sensed, respectively.

30 33. The method as claimed in claim 29, wherein at least one of said first location and said second location is a location for sensing cardiac wall movements of an atrium.

35 34. The method as claimed in any one of claims 29-33, wherein said first and second locations are in the vicinity of said valve plane, at which locations the movements of said cardiac wall locations are substantially longitudinal in correspondence with the movements of the valve plane.

35. The method as claimed in any one of claims 29-34, further comprising the steps of:

sensing third cardiac wall movements at a third location subjected to movements related to said longitudinal valve plane movements;

providing a synchronization signal based on said sensed first, second and third cardiac wall movements, the synchronization signal being indicative of the synchrony in the valve plane movements at said first, second and third locations.

36. The method as claimed in any one of claims 29-35, further comprising the step of:

comparing said synchronization signal with a threshold signal and providing an output indicative of whether cardiac synchrony is present.

37. A method of controlling the delivery of stimulation pulses to a human heart, comprising the steps of:

generating stimulation pulses;  
controlling parameters for the timing of stimulation pulse delivery to the heart;

delivering said stimulation pulses to the heart;  
sensing first cardiac wall movements at a first location subjected to movements related to longitudinal valve plane movements along the longitudinal axis of the heart;

sensing second cardiac wall movements at a second location subjected to movements related to said longitudinal valve plane movements; and

providing a synchronization signal based on said sensed first and second cardiac wall movements, the synchronization signal being indicative of the synchrony in the valve plane movements at said first and second locations.

38. The method as claimed in claim 37, further comprising the steps of:

receiving parameters for timing of stimulation pulse delivery for providing cardiac synchrony at implantation;

5 monitoring cardiac synchrony for determining the synchrony in the valve plane movements at said first and second locations; and

adapting said parameters on the basis of said monitoring for maintaining cardiac synchrony.

10

39. The method as claimed in claim 37 or 38, further comprising the steps of:

comparing said synchronization signal with a threshold signal;

15 providing an output indicative of whether sufficient cardiac synchrony is present; and

adjusting the timing of stimulation pulse delivery when sufficient cardiac synchrony is no longer present.

20

40. The method as claimed in any one of claims 37-39, further comprising the step of:

adjusting the timing of stimulation pulse delivery in adaptation to said synchronization signal.

25

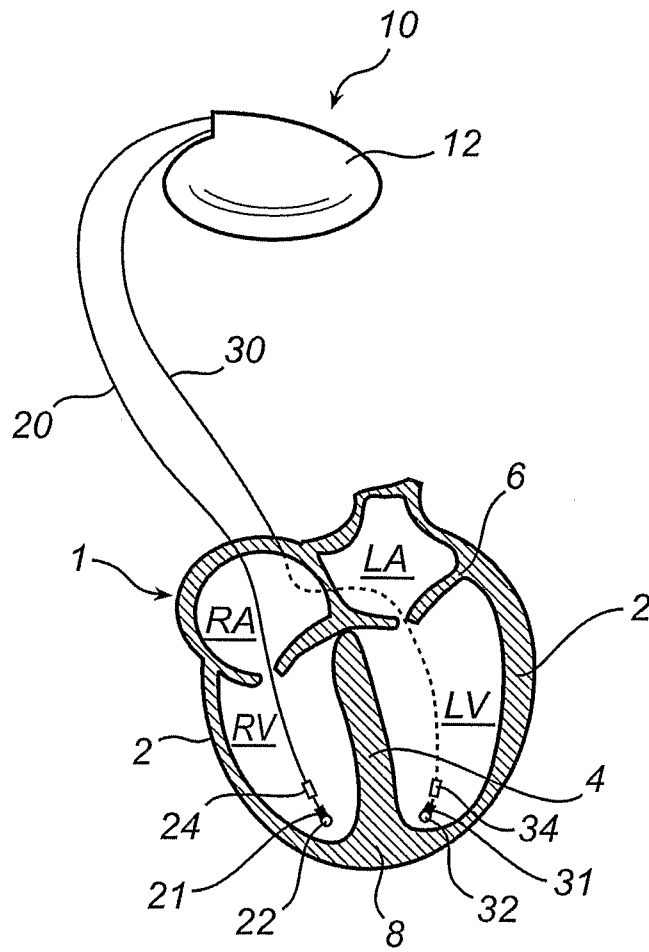


Fig. 1

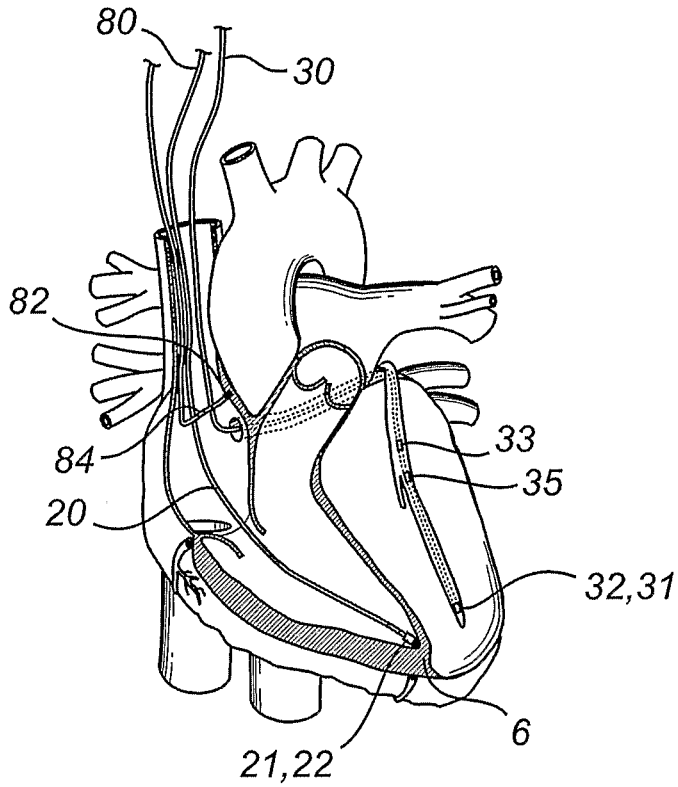


Fig. 2

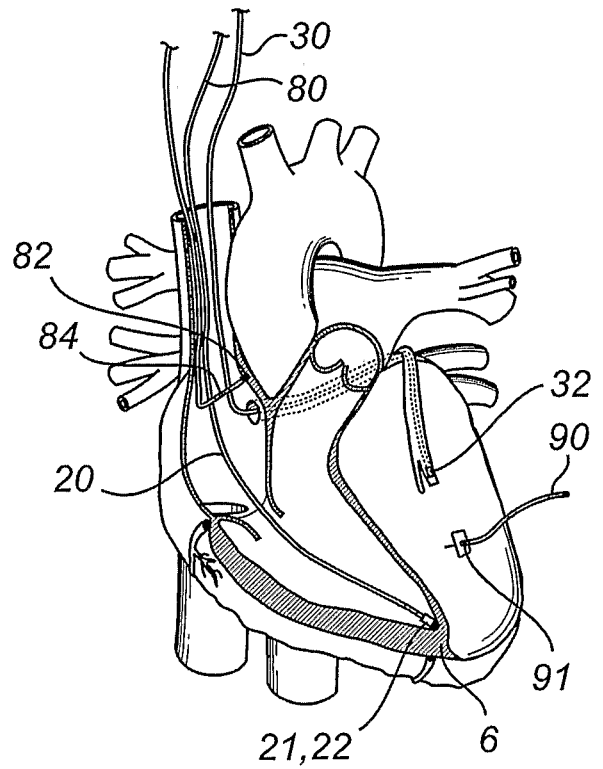


Fig. 3

3/8

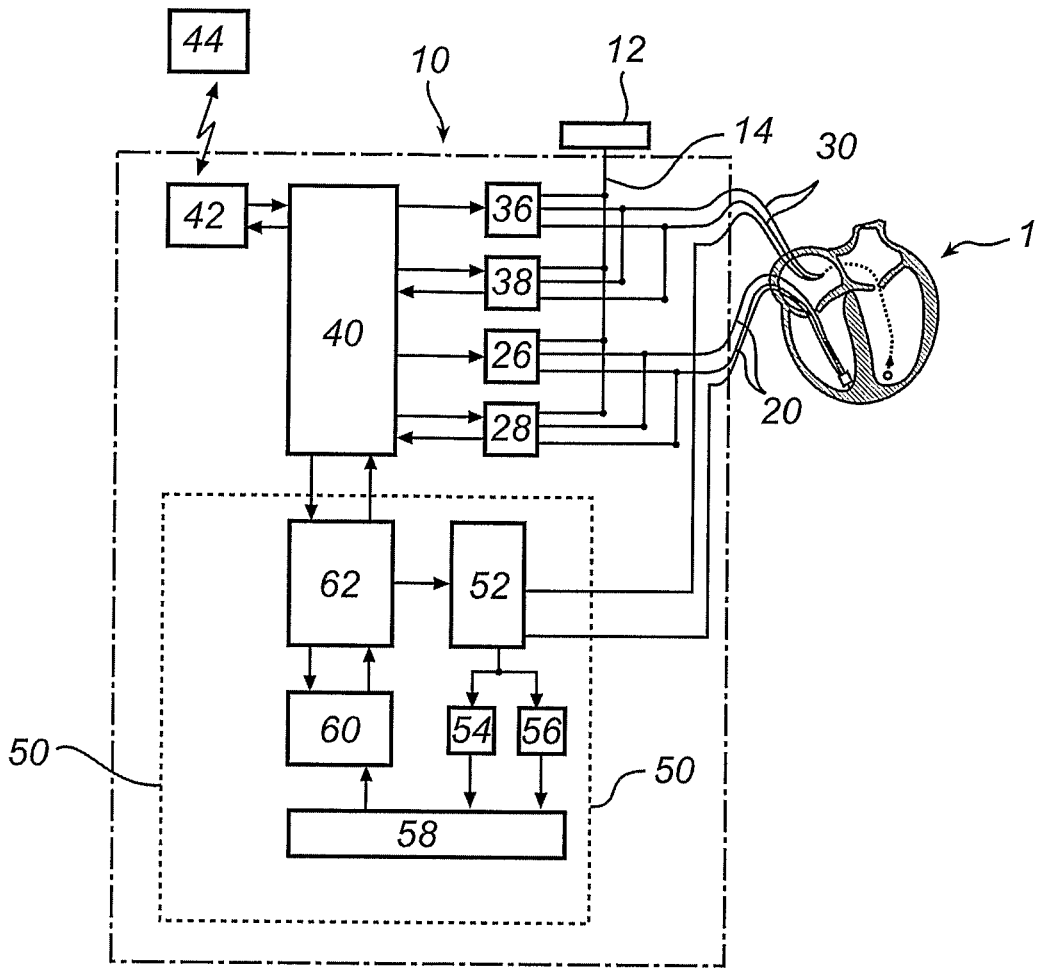


Fig. 4

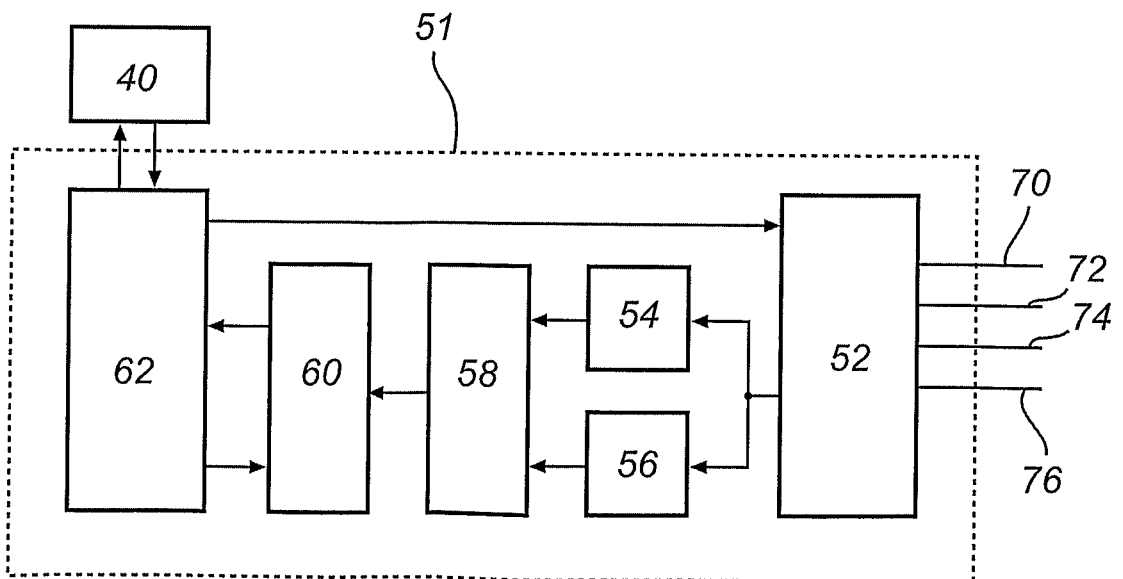


Fig. 5

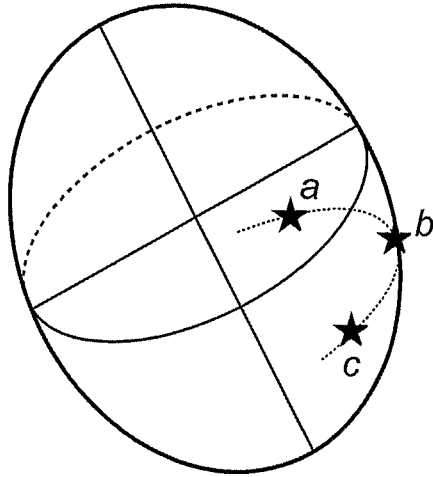


Fig. 6a

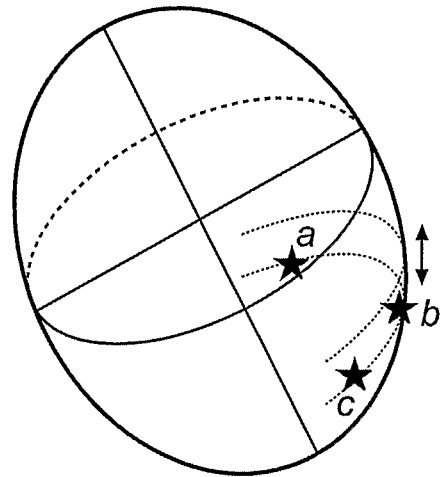


Fig. 6b

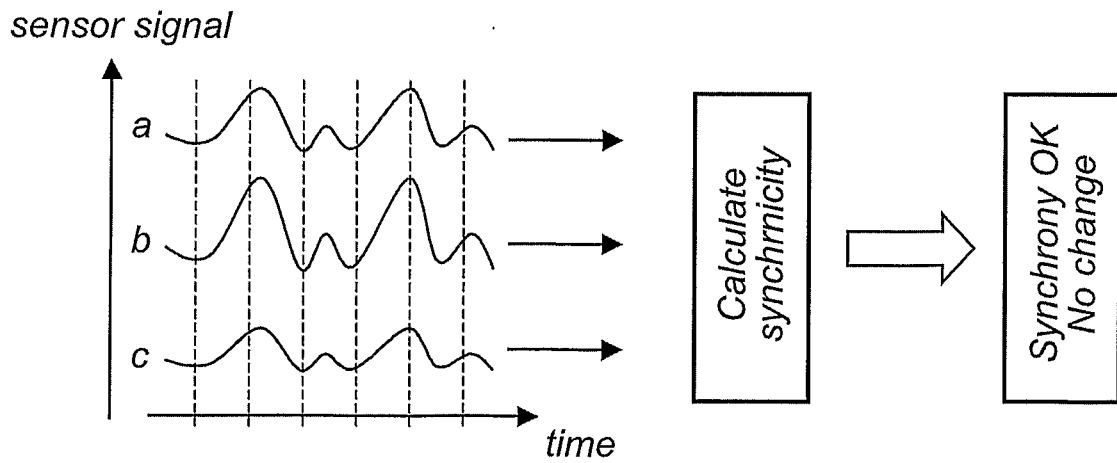


Fig. 6c

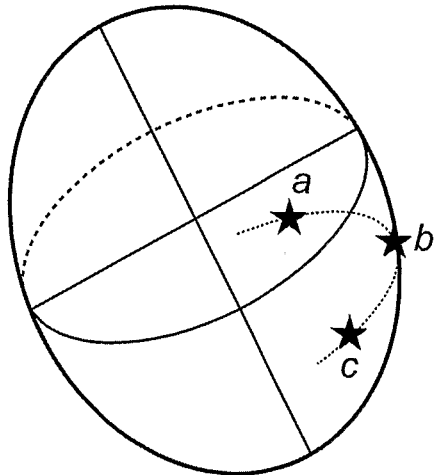


Fig. 7a

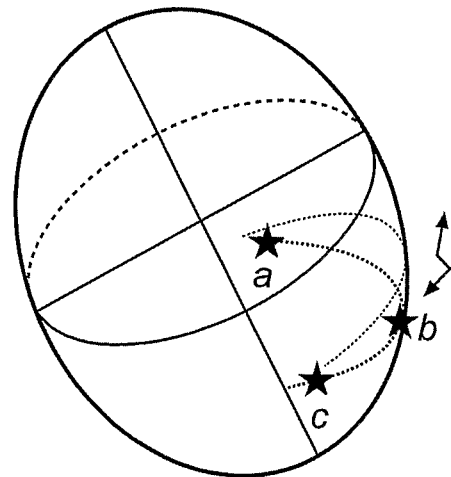


Fig. 7b

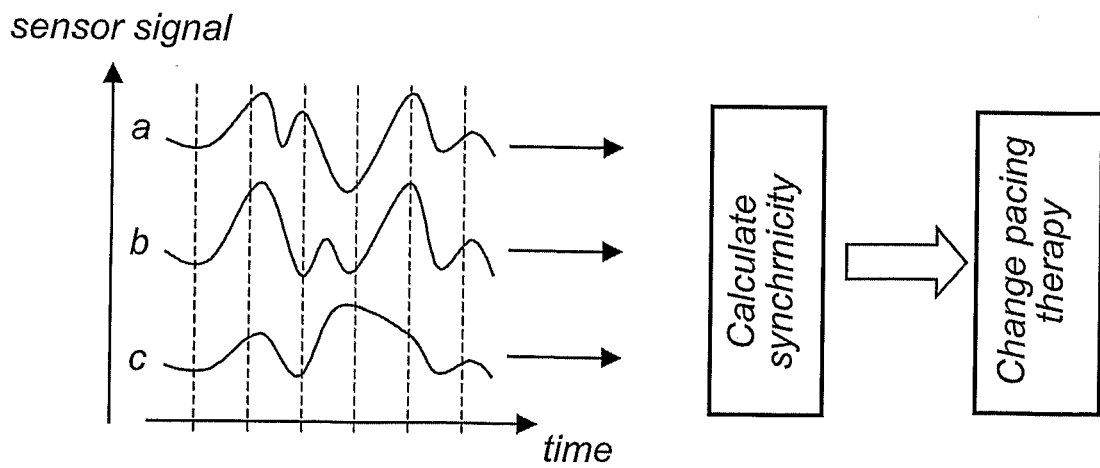


Fig. 7c

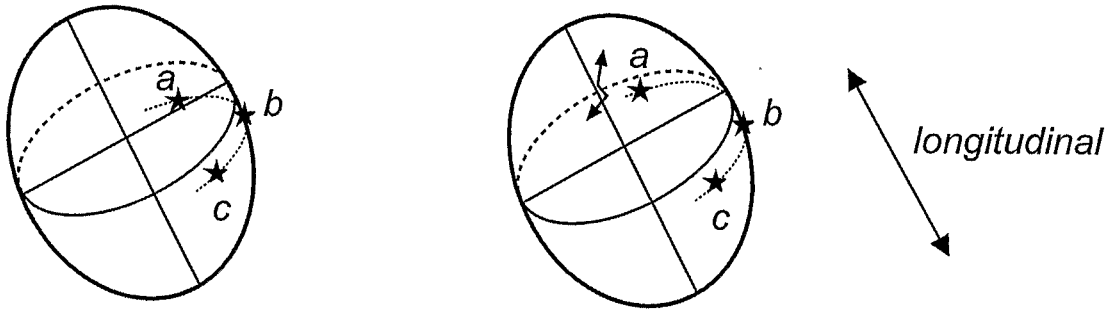


Fig. 8a

Fig. 8b

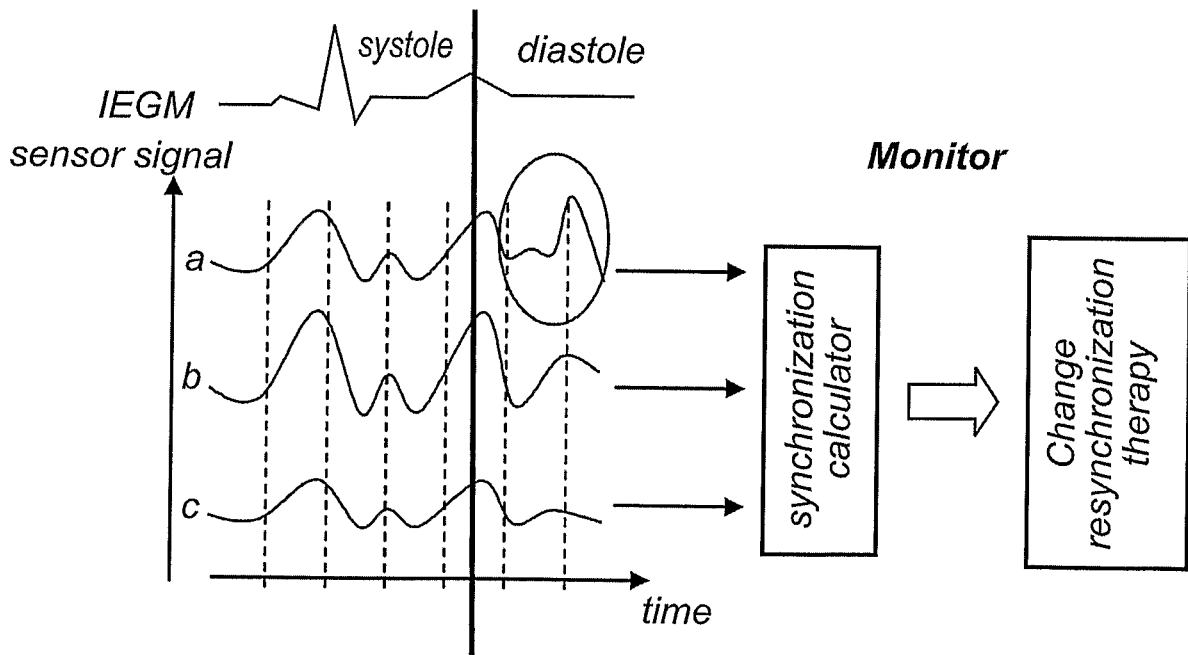


Fig. 8c

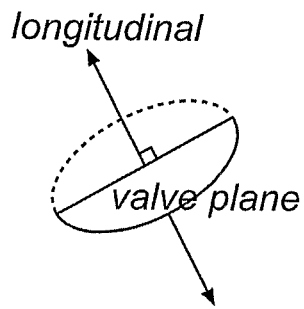


Fig. 9a

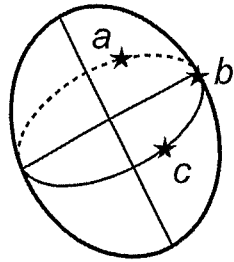


Fig. 9b

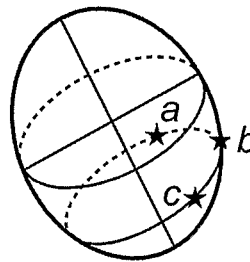


Fig. 9c

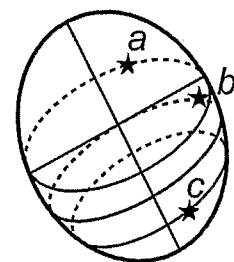


Fig. 9d

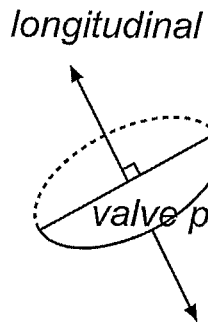


Fig. 10a

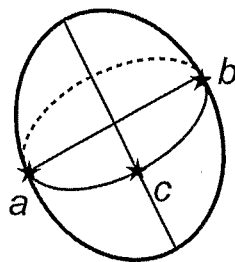


Fig. 10b

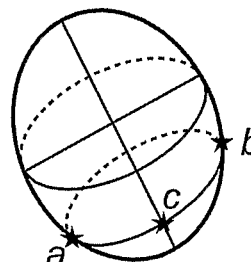


Fig. 10c

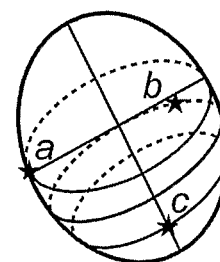


Fig. 10d

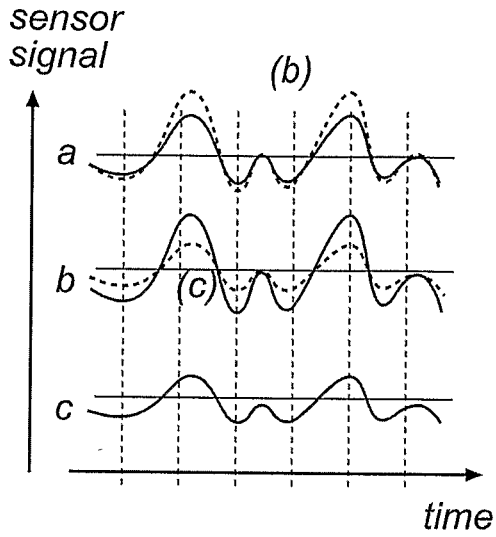


Fig. 11a

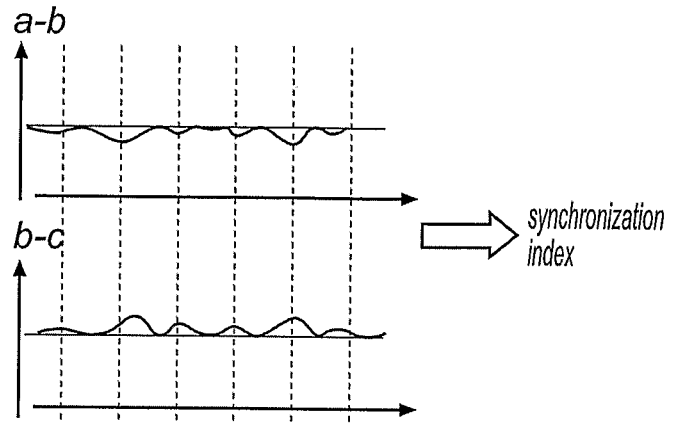


Fig. 11b

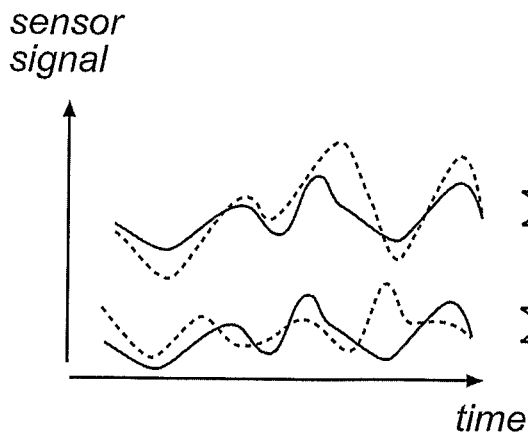


Fig. 12a

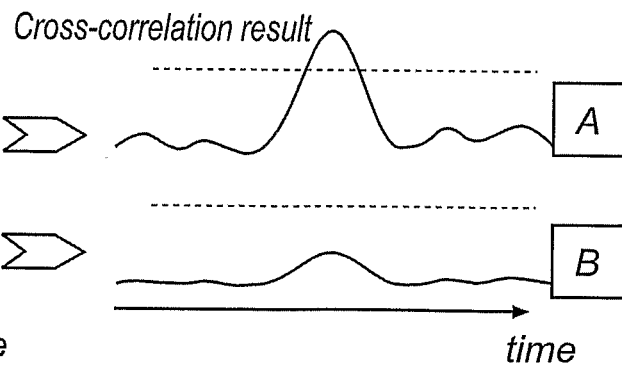


Fig. 12b

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/SE2005/001806

## 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.: 29-40  
because they relate to subject matter not required to be searched by this Authority, namely:  
  
See extra sheet.
2.  Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. 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/SE2005/001806

Box II.1

Claims 29-40 relate to a method of treatment of the human or animal body by surgery or by therapy, as well as diagnostic methods /Rule 39.1(iv). Nevertheless, a search has been executed for these claims. The search has been based on the alleged effects of the device.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE2005/001806

## 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: 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.
Y	US 20030105496 A1 (YU ET AL), 5 June 2003 (05.06.2003), the whole document --	1-40
Y	US 20040172079 A1 (CHINCHOY), 2 Sept 2004 (02.09.2004), paragraph [0034],[0040],[0041], [0049], fig 1-10 --	1-40
Y	US 5628777 A (MOBERG ET AL), 13 May 1997 (13.05.1997), column 21, line 14 - line 33, figure 20 --	1-40
A	US 20020143368 A1 (BAKELS ET AL), 3 October 2002 (03.10.2002), paragraph [0021]-[0022] --	1-40

 Further documents are listed in the continuation of Box C. 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

"&amp;" document member of the same patent family

Date of the actual completion of the international search

7 July 2006

Date of mailing of the international search report

10-07-2006

Name and mailing address of the ISA/

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**International patent classification (IPC)****A61N 1/362** (2006.01)**A61B 5/00** (2006.01)**A61N 1/365** (2006.01)**Download your patent documents at [www.prv.se](http://www.prv.se)**

The cited patent documents can be downloaded at [www.prv.se](http://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 **QMWNEWBBRJ**.

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  
Information on patent family members

International application No.  
PCT/SE2005/001806

US	20030105496	A1	05/06/2003	NONE		
US	20040172079	A1	02/09/2004	AU	2004218488 A	16/09/2004
				CA	2517173 A	16/09/2004
				EP	1599257 A	30/11/2005
				US	6885889 B	26/04/2005
				WO	2004078257 A,B	16/09/2004
US	5628777	A	13/05/1997	AU	7331694 A	20/02/1995
				US	5496361 A	05/03/1996
				WO	9503086 A	02/02/1995
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				AU	1714499 A	05/07/1999
				DE	69829207 D,T	12/01/2006
				EP	1039951 A,B	04/10/2000
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				US	6223079 B	24/04/2001
				US	6223082 B	24/04/2001
				US	6238420 B	29/05/2001
				WO	9930777 A	24/06/1999

专利名称(译)	用于监测心脏同步的可植入心脏刺激器，系统，装置和方法		
公开(公告)号	<a href="#">EP1957158A1</a>	公开(公告)日	2008-08-20
申请号	EP2005810065	申请日	2005-11-30
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	JARVERUD KARIN NILSSON KENTH HEDBERG SVEN ERIK		
发明人	JÄRVERUD, KARIN NILSSON, KENTH HEDBERG, SVEN-ERIK		
IPC分类号	A61N1/362 A61B5/00 A61N1/365 A61B5/11		
CPC分类号	A61N1/3627 A61B5/1107 A61B5/6869 A61B2562/0219 A61N1/36514 A61N1/36578		
其他公开文献	EP1957158A4 EP1957158B1		
外部链接	<a href="#">Espacenet</a>		

#### 摘要(译)

心脏刺激器和用于监测人类心脏中的心脏同步的装置。至少第一和第二传感器适于分别定位在第一心脏壁位置和第二心脏壁位置，所述第二心脏壁位置经受与沿着心脏的纵向轴线的纵向瓣膜平面运动相关的运动。传感器布置成用于测量相应心壁位置处的心脏壁运动。处理电路布置成接收来自传感器的输出信号，输出信号指示相应心壁位置处的纵向瓣膜平面运动。处理电路还被布置用于处理信号并输出指示心脏壁位置处的瓣膜平面运动的同步的信号。