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Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

[Continued on next page]

(54) **Title**: IMPLANTABLE CARDIAC DEVICE CONFIGURED TO DETECT REDUCED CARDIAC WALL MOTION AND TO ACTIVATE TRANSMITTERS UPON DETECTION

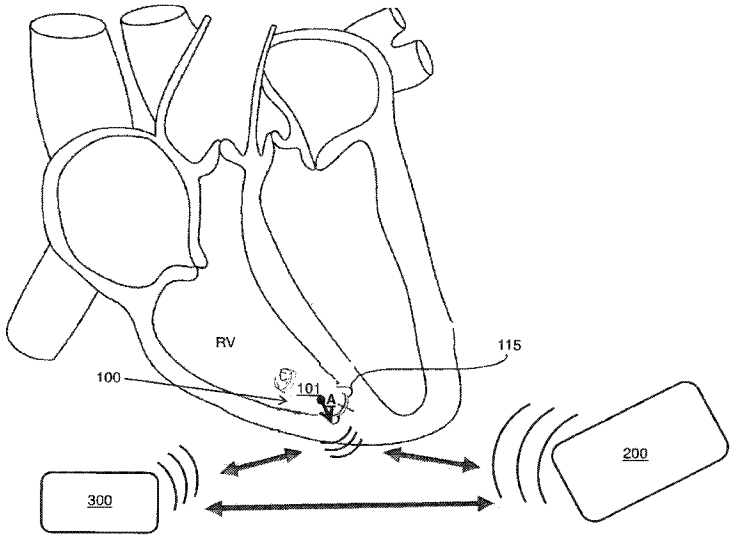

FIGURE 1

(57) **Abstract**: An anchorable implantable cardiac medical device (100) comprises a wall motion detector and a wireless communications module, which employs a directional antenna. Transmitter elements of the communications module are only activated for communication during a detected period of reduced ventricular wall motion. The period of reduced ventricular wall motion may comprise at least one time interval during which an axis of the directional antenna does not rotate out from a baseline orientation by more than 15 degrees. The communication may be conducted with an external programmer device (200) or with another implanted device (300), for example, located remote from the heart.

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— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

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IMPLANTABLE CARDIAC DEVICE CONFIGURED TO DETECT REDUCED CARDIAC WALL MOTION AND TO ACTIVATE TRANSMITTERS UPON DETECTION

TECHNICAL FIELD

The present invention pertains to implantable cardiac devices and more particularly to systems employing the devices and methods for controlling wireless communications thereof.

BACKGROUND

The traditional implantable cardiac monitoring and/or therapy delivery system includes a medical device to which one or more flexible elongate lead wires are coupled. The device is typically implanted in a subcutaneous pocket, remote from the heart, and each of the one or more lead wires extends therefrom to a corresponding cardiac site, either endocardial or epicardial, in order to deliver therapy to, and/or monitor the site. Mechanical complications and/or MRI compatibility issues, which are sometimes associated with elongate lead wires and are well known to those skilled in the art, have motivated the development of relatively compact cardiac medical devices that can be implanted in close proximity to the cardiac site, for example, within the right ventricle (RV) of the heart, so that elongate lead wires are not required. With reference to Figure 1, such a device 100 is illustrated, wherein a fixation member 115 anchors device 100 against the endocardial surface of the RV, for cardiac therapy delivery and/or monitoring, via medical components thereof, for example, a pair of electrodes, a mechanical transducer, and/or any other type of suitable sensor known in the art. Due to size constraints on device 100, limited space is available, within a hermetic enclosure/shell 101 thereof, for a power supply (i.e. battery) and circuitry (i.e. input/output circuit, a microcomputer circuit, memory, etc.) in support of the medical components. Device 100 is preferably accessible via wireless telemetry, for example, to update the programming of device 100 and/or to collect information from device 100, so a wireless communications module must also be contained within the limited space and supported by the contained power supply.

In order to increase the life of the power supply, the most efficient operation of every component of device 100, including the communications module, is highly desirable.

SUMMARY

According to embodiments of the present invention, a relatively compact cardiac medical device includes a wireless communications module that employs a directional antenna; the communications module is adapted to receive input concerning ventricular wall motion in order to stabilize telemetry signal strength from the antenna and thereby make communication more efficient. According to methods of the present invention, when such a device is anchored to a ventricular wall, transmitter elements of the communications module are only activated for communication during a detected period of reduced ventricular wall motion. The period of reduced ventricular wall motion may be defined as at least one time interval during which an axis of maximum signal strength for the directional antenna does not rotate significantly out from a baseline orientation, for example, by more than approximately 15 degrees. Wireless communication, according to some embodiments, is conducted with an external programmer-type device, while, according to some alternate embodiments, the communication is conducted with another implanted device, for example, located at a site remote from the heart.

According to some embodiments, the cardiac medical device includes electrodes to detect the period of reduced ventricular wall motion, while according to alternate embodiments, the device includes a mechanical transducer to detect the period. According to yet further embodiments the device includes a pulse generator, and, when the device is implanted at an apical location of the right ventricle, pacing pulses are applied, according to some methods, in order to create the period of reduced ventricular wall motion.

BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings are illustrative of particular embodiments of the present invention and therefore do not limit the scope of the invention. The drawings are not to scale (unless so stated) and are intended for use in conjunction with the explanations in the following detailed description. Embodiments will hereinafter be described in conjunction with the appended drawings wherein like numerals denote like elements, and

Figure 1 is a schematic showing an exemplary cardiac medical device implanted in a right ventricle of a heart;

Figure 2A is a block diagram showing main modules of an implantable cardiac medical device, according to some embodiments;

Figure 2B is a plan view of the exemplary device of Figure 1;

Figure 3 is a heart wall motion schematic diagram; and

Figure 4 is schematic diagram illustrating rotation of an antenna axis from a baseline orientation.

DETAILED DESCRIPTION

The following detailed description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention in any way. Rather, the following description provides practical examples, and those skilled in the art will recognize that some of the examples may have suitable alternatives.

Figure 1 illustrates device 100 with an axis A overlaid thereon to designate the direction of maximum signal strength from a directional antenna 103, which, with reference to Figures 2A-B is part of a wireless communications module 400 contained with shell 101 of device 100. At the time device 100 is implanted, radiopaque markers (not shown) included in device 100 may be viewed, via fluoroscopy, and/or telemetry signal strength, via antenna 103, may be monitored, in order to fix device 100 at the implant site in a particular orientation suitable to establish a favorable orientation of axis A. Figures 2A-B are a schematic block

diagram and a plan view, respectively, for device 100, according to some embodiments. Figure 1 further illustrates an external device 200, for example, an external programmer-type device, such as is known in the art, and another, optional, implanted device 300, either of which also includes a wireless communications module adapted for entering into wireless communications with device 100, according to any suitable configuration known in the art. According to preferred methods, a controller 405 of wireless communications module 400 of device 100 activates receiver elements 401 at predetermined/pre-programmed intervals to 'listen' for an activation signal from another device, such as device 200 or device 300, and once such a signal is detected, prepares for communication. If device 200 is a communication head of a programmer that requires positioning to align with axis A, for example, for inductive coupling telemetry, device 100 may transmit a beacon-type signal to help with the alignment of device 200. According to methods of the present invention, after controller 405 receives an activation signal from device 200, controller 405 activates transmitter elements 402 of communications module 400, but only according to input from a ventricular wall motion detector 440 of device 100.

With further reference to Figure 2B, according to embodiments and methods of the present invention, ventricular wall motion detector 440 provides input to controller 450 of communications module 400, which, after the aforementioned activation signal is received from device 200, activates transmitter elements 402 only during a detected period of reduced ventricular wall motion. Figure 3 is a schematic diagram showing orthogonal coordinate axes X,Y,Z overlaid on a heart in order to illustrate heart wall motion with each natural contraction of the heart. Those skilled in the art understand that the heart's intrinsic conduction system causes ventricular myocardium to contract with a twisting, or wringing (generally around axis Z), from the apex toward the base (generally along axis Z), per arrows C1 and C2, to squeeze blood out from the ventricles. With reference back to Figure 1, since device 100 is anchored to the right ventricular wall, each natural ventricular contraction causes axis A to shift and rotate, so that an alignment of axis A with a corresponding axis of device 200 (as well as with that of device 300) changes during each contraction and

causes a telemetry signal strength delivered via antenna 103 to sinusoidally alternate between approximately 0% and approximately 100%, thereby compromising wireless communication with device 100. According to some methods, the period of reduced ventricular wall motion includes one or more diastolic intervals between contractions (systolic intervals) of the heart. So, rather than powering up for transmission throughout the aforementioned sinusoidal variation caused by ventricular wall motion during systole, transmitter elements 402 are only powered during diastolic intervals, when the ventricular walls are relatively still for filling. During this period, a lower telemetry signal strength, which means less power consumption, is required from antenna 103, since the signal strength is relatively stable, thereby increasing the efficiency of outbound communication.

In addition to, or as an alternative to diastolic intervals, the period of reduced ventricular wall motion may be created by pacing stimulation, for example, delivered from a pulse generator 420 of device 100, when device 100 is implanted at an apical location, as illustrated in Figure 1, at a rate that is greater (i.e. 10 to 20 beats per minute) than an intrinsic heart rate of the patient. Those skilled in the art understand that the ventricular wall motion, which corresponds to ventricular contractions that are externally stimulated from the apex of the heart, as opposed to those generated, from base to apex, by the heart's intrinsic conduction system, is reduced in the directions indicated by arrows C1 and C2 of Figure 3. Thus pacing stimulation may extend the period of reduced ventricular wall motion into systolic intervals of each cardiac cycle. With reference back to Figures 2A-B, device 100 includes a pair of electrodes 111, 112, by which such pacing stimulation may be applied, wherein electrode 111 is coupled to internal pulse generator circuitry 420 via a hermetic feedthrough, known in the art, and electrode 112 is formed by an exposed conductive portion of shell 101, according to some embodiments. According to some methods, once an inbound activation signal is received, for example, from device 200 or device 300 (Figure 1), by controller 405 of wireless communications module 400, via receiver elements 401, controller 405 sends a signal to activate pulse generator 420, in order to create the period of reduced ventricular wall motion via pacing stimulation. It should be noted

that electrodes 111, 112 may also be employed by ventricular wall motion detector 440 for detection of the period of reduced ventricular wall motion that results from the applied pacing stimulation, as described below. The activation signal to create the period of reduced ventricular wall motion by the applied pacing stimulation is preferably sent by device 200 when the patient is in a clinical setting for a checkup, so that a clinician can monitor the patient's intrinsic heart rate, for example, to assure that the heart rate is a resting heart rate and stable before the higher rate pacing stimulation is applied. Furthermore, controller 406 of device 100 may have a programmable setting to limit the rate of applied pacing stimulation from the activated pulse generator 420, according to the patient's condition, for example, to prevent the stimulation from inadvertently triggering a cardiac arrhythmia.

According to some embodiments, ventricular wall motion detector 440 includes a mechanical transducer adapted to sense mechanical changes indicative of ventricular wall motion, for example, a pressure sensor for indirect detection of the period of reduced ventricular wall motion (i.e. intraventricular pressure changes over each cardiac cycle), an accelerometer for direct detection of reduced ventricular wall motion, a Doppler sensor to detect blood flow, or an auditory/acoustic sensor to detect heart valve, lung and/or blood flow sounds. According to alternate embodiments, ventricular wall motion detector 440 includes a pair of electrodes, for example, electrodes 111, 112 of Figure 2B, which are adapted to sense electrical cardiac signals indicative of ventricular wall motion, for example, timing of the QRS complex to find diastolic intervals and/or QRS morphology to identify retrograde conduction resulting from applied pacing stimulation, for example, when the pulse generator is employed to create a period of reduced ventricular wall motion, as described above. According to yet further embodiments a chemical sensor may be employed in device 100, to provide additional input to controller 406, for example, of blood pH or blood oxygen saturation that may be indicative of a patient's physiological condition.

Figure 4 is a schematic diagram illustrating a baseline orientation of axis A, designated AB, which corresponds to a best alignment of axis A with the maximum

signal strength axis of the communications module antenna of another device, such as device 200 (Figure 1). Figure 4 further illustrates limits of rotation RX and RZ out from AB, about axes X and Z, respectively, within which the period of reduced ventricular wall motion is defined. According to some preferred embodiments, the limits of rotation RX and RZ are no greater than approximately 15 degrees, and rotation within these limits may be correlated to diastolic intervals and/or to extended intervals during pacing stimulation, as detected by ventricular wall motion detector 440. By means of in vivo experimentation that employed biplane fluoroscopic tracking of radiopaque markers attached to a device similar to device 100, which was implanted at an apical location (similar to Figure 1), we have found that, when pacing stimulation was applied, device rotation during ventricular contractions, from a baseline orientation such as AB, is significantly reduced from that which was typical during intrinsic ventricular contractions.

With reference back to Figure 1, according to some embodiments, third device 300 may be implanted at a site remote from the heart, for example, to monitor and/or deliver therapy. Communication between device 300 and device 100 may be necessary to coordinate therapy delivery, from one or both devices, and/or to transfer data/information from device 100 to device 300, for example, for storage in a data storage module of a memory of device 300 until predetermined time periods when an external device, such as device 200, is employed to retrieve the stored data/information. For example, device 300 may be a cardiac defibrillation generator that is implanted in an abdomen of the patient, a neuromodulation generator implanted in the abdomen or pectoral region, or a cardiac monitor implanted in the pectoral region, any of which, in addition to having a more stable axis of maximum wireless communication strength, by virtue of their implant location, may also have a size sufficient to include greater battery capacity and more sophisticated telemetry hardware (relative to device 100), for example, capable of long range and/or automated telemetry with an external device, which is known in the art.

In the foregoing detailed description, the invention has been described with reference to specific embodiments. However, it may be appreciated that various modifications and changes can be made without departing from the scope of the invention as set forth in the appended claims.

5

We claim:

1. An implantable cardiac medical device configured to be wholly implanted at a cardiac site via anchoring to a heart chamber wall, the device comprising a wall motion detector and a wireless communications module compatible for communication with another medical device; the communications module comprising receiver elements, transmitter elements and a controller, the controller adapted to receive input from the wall motion detector and being programmed to execute a method comprising the following steps:

activating the receiver elements at predetermined intervals to receive an inbound activation signal from the other medical device; and

activating the transmitter elements for outbound communication, once the inbound activation signal is received, but only if a signal from the wall motion detector indicates a present period of reduced wall motion.

2. An implantable cardiac medical device according to claim 1 wherein the period of reduced wall motion comprises one or more time intervals during which an axis of a directional antenna of the communications module does not rotate out from a baseline orientation by more than a predetermined number of degrees.

3. An implantable cardiac medical device according to claim 2 wherein the predetermined number of degrees is approximately 15 degrees.

4. The device of any of claims 1 - 3, further comprising a pacing pulse generator, the pacing pulse generator being adapted to receive input from the controller of the wireless communications module; and wherein the method further comprises sending a signal to activate the pacing pulse generator, once the inbound activation signal is received and before activating the transmitter elements.

5. The device of any of claims 1 - 3 wherein the wall motion detector comprises electrodes adapted to sense electrical cardiac signals; and the signal from the detector that indicates a present period of reduced wall motion results from sensing electrical cardiac signals.

6. The device of any of claims 1 - 3 wherein the wall motion detector comprises a mechanical transducer, the transducer being adapted to sense mechanical changes, either pressure or motion; and the signal from the detector that indicates a present period of reduced wall motion results from sensing mechanical changes.

7. A cardiac medical system comprising at least two devices, a first of the devices comprising a wireless communications module, and a second of the devices being configured to be wholly implanted at a cardiac site, via anchoring to a heart chamber wall, and comprising a wall motion detector and a wireless communications module compatible for communication with the wireless communications module of the first device; the communications module of the second device comprising receiver elements, transmitter elements and a controller, the controller adapted to receive input from the wall motion detector and being programmed to execute a method comprising the following steps:

activating the receiver elements at predetermined intervals to receive an inbound activation signal; and

activating the transmitter elements for outbound communication, once the inbound activation signal is received, but only if a signal from the wall motion detector indicates a present period of reduced wall motion.

8. A system according to claim 7 wherein the period of reduced wall motion comprises one or more time intervals during which an axis of a directional antenna of the communications module does not rotate out from a baseline orientation by more than a predetermined number of degrees.

9. A system according to claim 8 wherein the predetermined number of degrees is approximately 15 degrees.

10. The system of any of claims 7 – 9 wherein the first device comprises an external programmer type device.

11. The system of any of claims 7 – 9 further comprising a third device configured to be implanted at a site remote from the heart; the third device being adapted for therapy delivery and/or data storage and including a wireless communications module compatible for communication with the communications modules of both the first and second devices; wherein the outbound communication from the second device is directed to the third device.

12. The system of any of claims 7 – 9 wherein the first device is configured to be implanted at a site remote from the heart; the first device being adapted for therapy delivery and/or data storage.

13. The system of any of claims 7 – 9 wherein the second device further comprises a pacing pulse generator, the pacing pulse generator being adapted to receive input from the controller of the wireless communications module of the second device; and wherein the method executed by the controller of the communications module of the second device further comprises sending a signal to activate the pacing pulse generator, once the inbound activation signal is received and before activating the transmitter elements.

14. The device of any of claims 7 – 9 wherein the wall motion detector of the second device comprises electrodes adapted to sense electrical cardiac signals; and the signal from the detector that indicates a present period of reduced ventricular wall motion results from sensing electrical cardiac signals.

15. The device of any of claims 7 – 9 wherein the wall motion detector of the second device comprises a mechanical transducer, the transducer being adapted to sense mechanical changes, either pressure or motion; and the signal from the detector that indicates a present period of reduced wall motion results from sensing mechanical changes.

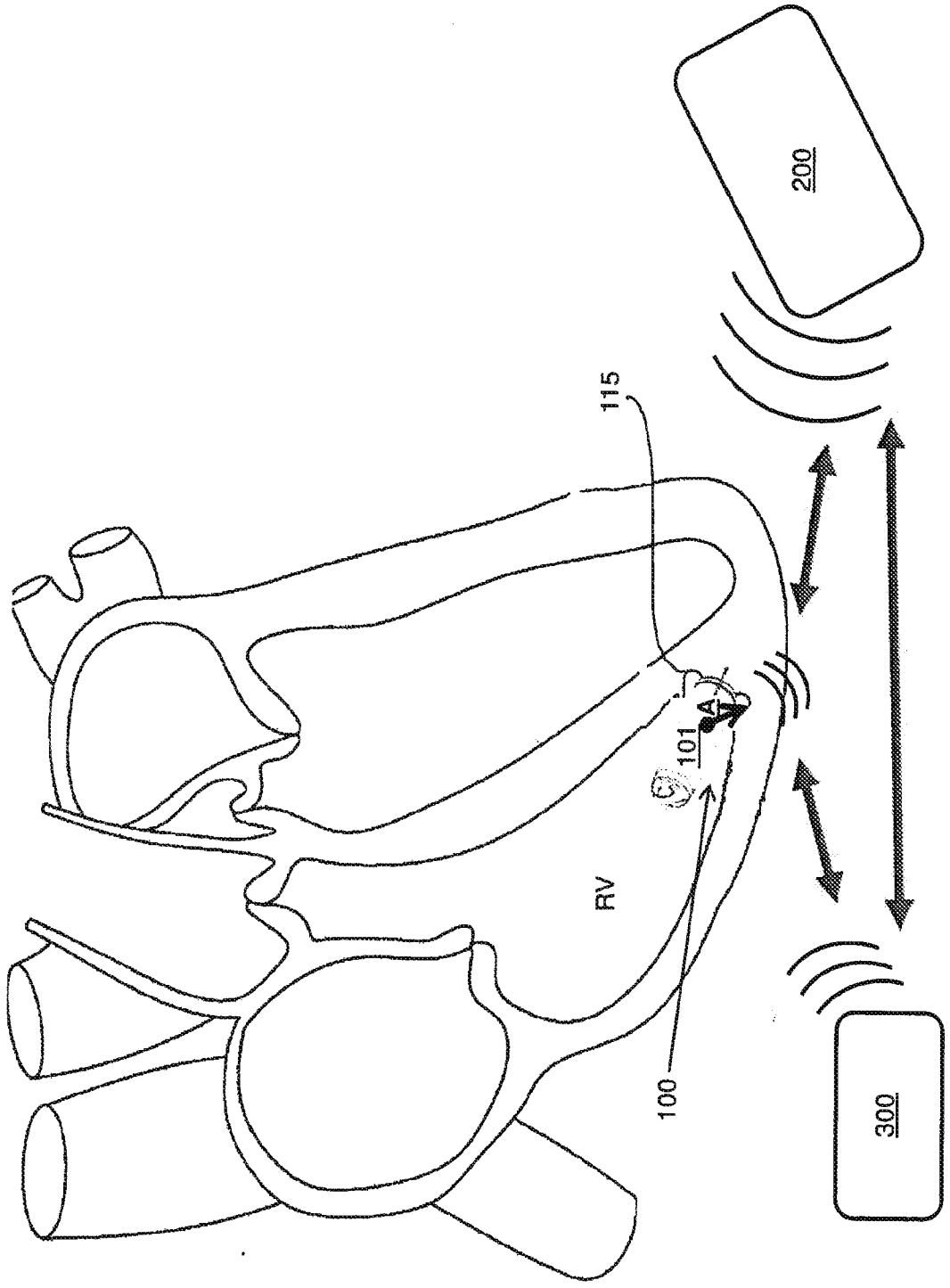

FIGURE 1

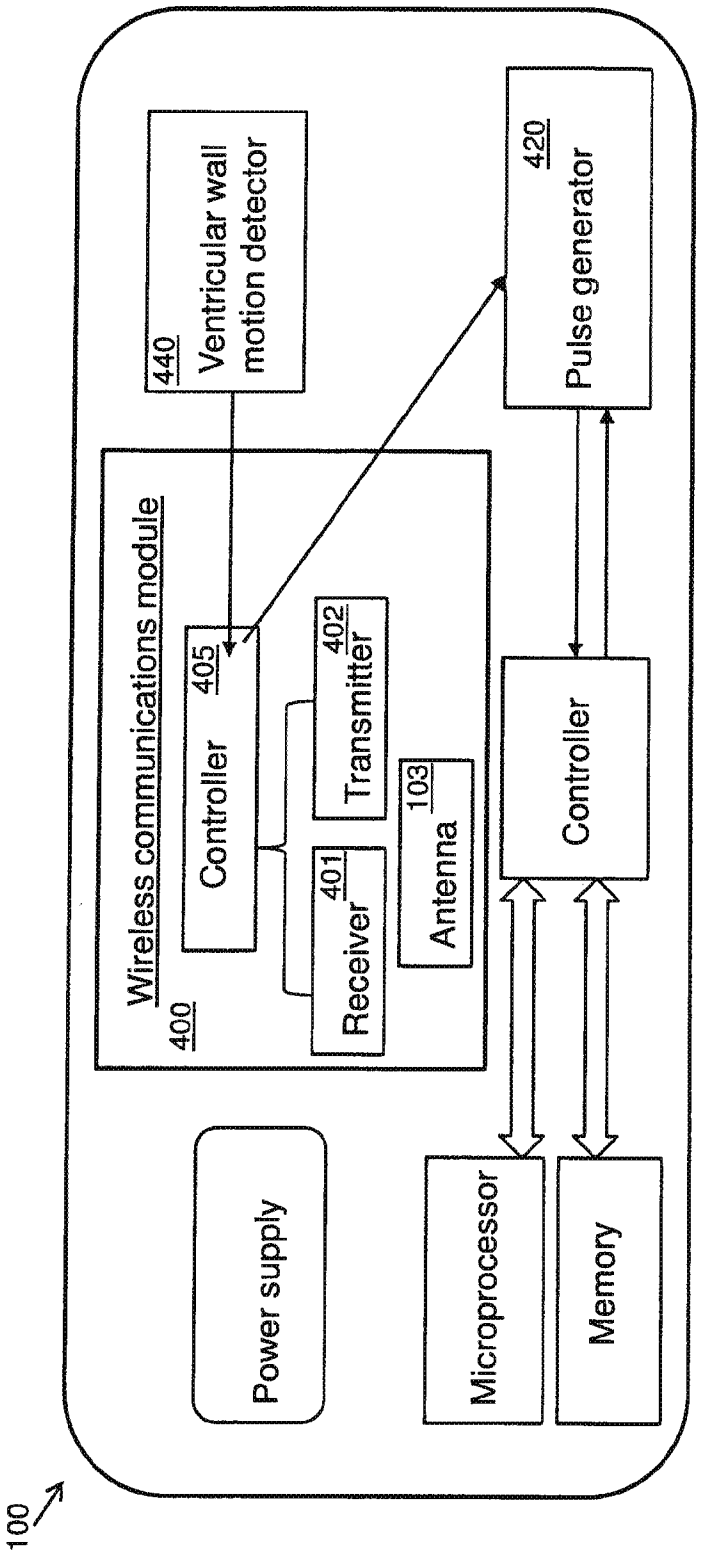

FIGURE 2A

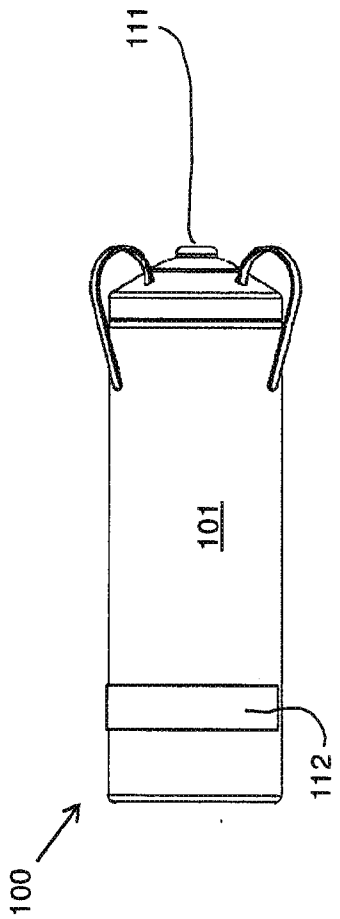

FIGURE 2B

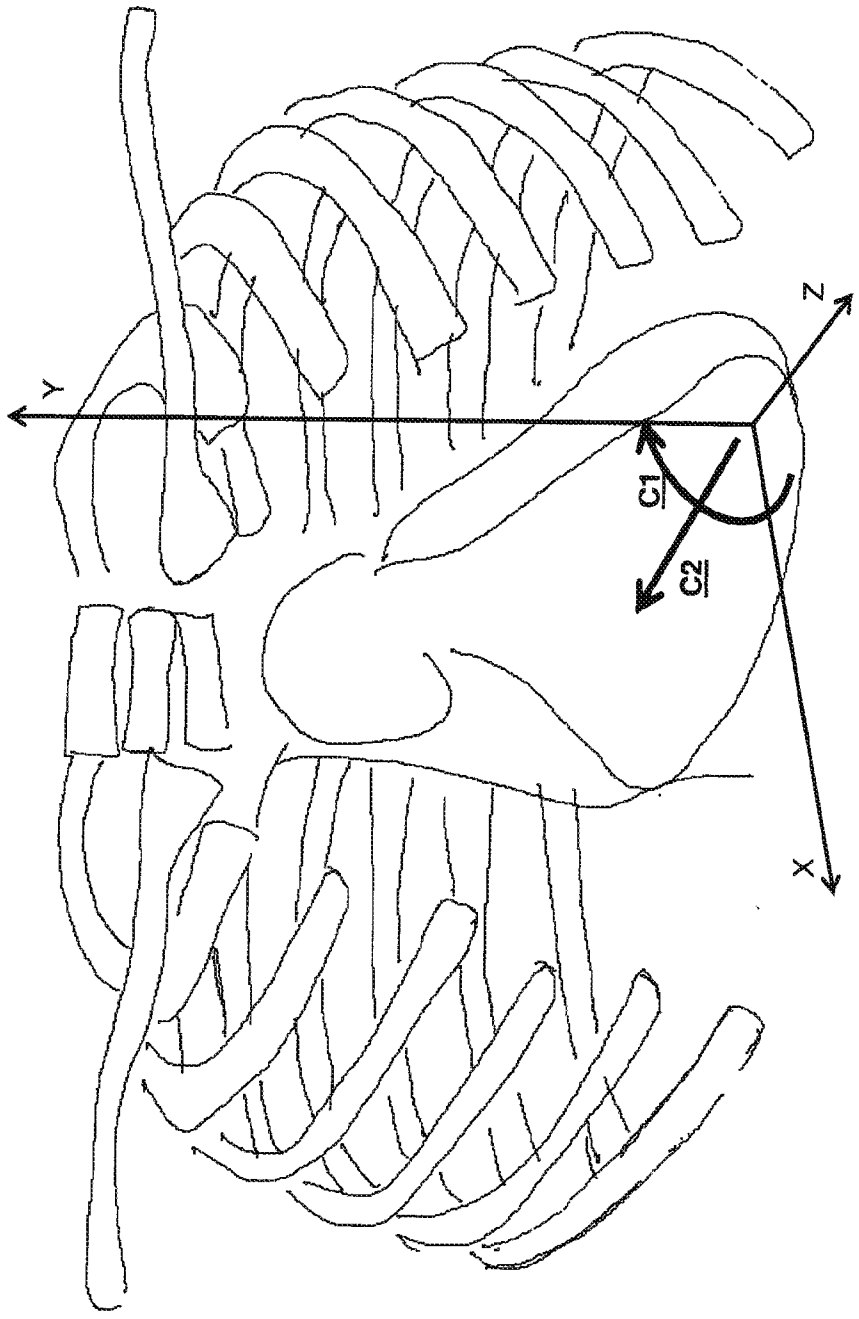

FIGURE 3

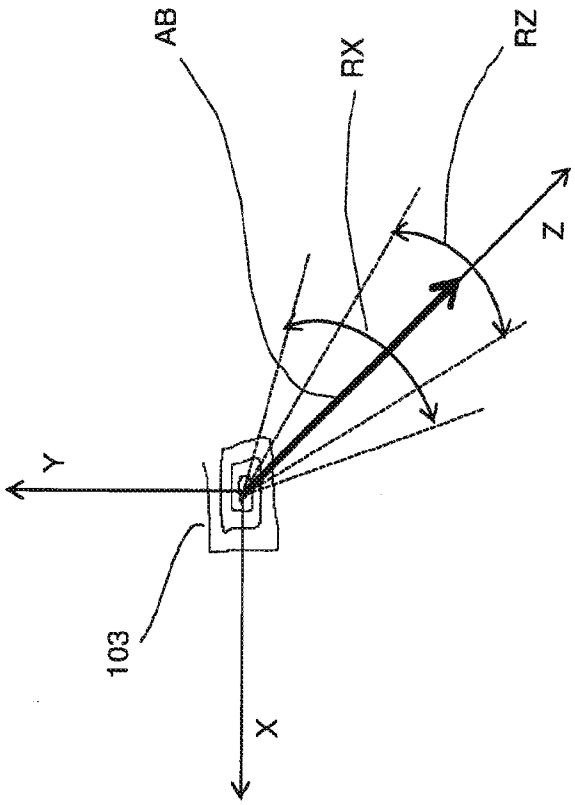

FIGURE 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/053948

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/02 A61B5/11 A61N1/372 H01Q1/27
ADD.

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)
A61B A61N A61F H01Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 7 338 436 B1 (SNELL JEFFERY D [US] ET AL) 4 March 2008 (2008-03-04) column 2, line 47 - column 3, line 25 column 3, line 49 - column 4, line 34 column 5, line 4 - line 50 column 7, line 57 - column 8, line 52; figures 1, 5-7	1-15
A	US 2009/082645 A1 (HAFEZI HOOMAN [US] ET AL) 26 March 2009 (2009-03-26) paragraph [0015] - paragraph [0021] paragraph [0047] - paragraph [0048] paragraph [0116] - paragraph [0122]; figures 4A-4C	1-15

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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

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"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
23 November 2012	05/12/2012

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Sigurd, Karin

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/053948

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2005/065445 A1 (ARZBAECHER ROBERT C [US] ET AL) 24 March 2005 (2005-03-24) paragraph [0029] - paragraph [0033] paragraph [0057] - paragraph [0060] paragraph [0073]; figure 2 -----	1-15
A	WO 2011/063848 A1 (ST JUDE MEDICAL [SE]; SKOELDENGEN NIKLAS [SE]; ABRAHAMSON HANS [SE]; D) 3 June 2011 (2011-06-03) page 3, line 18 - page 4, line 2 page 8, line 25 - page 9, line 14; figures 1, 3 -----	1-15

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2012/053948

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 7338436 B1	04-03-2008	NONE	
US 2009082645 A1	26-03-2009	EP 2192946 A1	09-06-2010
		US 2009082645 A1	26-03-2009
		WO 2009042812 A1	02-04-2009
US 2005065445 A1	24-03-2005	NONE	
WO 2011063848 A1	03-06-2011	US 2012229299 A1	13-09-2012
		WO 2011063848 A1	03-06-2011

专利名称(译)	可植入心脏装置，其被配置为检测减少的心壁运动并在检测时激活发射器		
公开(公告)号	EP2753234A1	公开(公告)日	2014-07-16
申请号	EP2012758971	申请日	2012-09-06
[标]申请(专利权)人(译)	美敦力公司		
申请(专利权)人(译)	美敦力公司.		
当前申请(专利权)人(译)	美敦力公司.		
[标]发明人	RYS KENNETH D REINERT MICHAEL ANDREW		
发明人	RYS, KENNETH D. REINERT, MICHAEL ANDREW		
IPC分类号	A61B5/02 A61B5/11 A61N1/372 H01Q1/27 A61B5/00 A61B5/024 A61B5/07 H01Q1/44 H01Q9/27		
CPC分类号	A61N1/37276 A61B5/02438 A61B5/076 A61B5/1107 A61B5/6869 H01Q1/44 H01Q9/27		
优先权	13/228607 2011-09-09 US		
其他公开文献	EP2753234B1		
外部链接	Espacenet		

摘要(译)

可锚定的可植入心脏医疗设备（100）包括壁运动检测器和无线通信模块，其采用定向天线。通信模块的发射器元件仅在检测到的心室壁运动减少期间被激活用于通信。心室壁运动减少的时段可以包括至少一个时间间隔，在该时间间隔期间定向天线的轴线不会从基线方向旋转超过15度。可以与外部编程器设备（200）或与远离心脏的另一个植入设备（300）进行通信。