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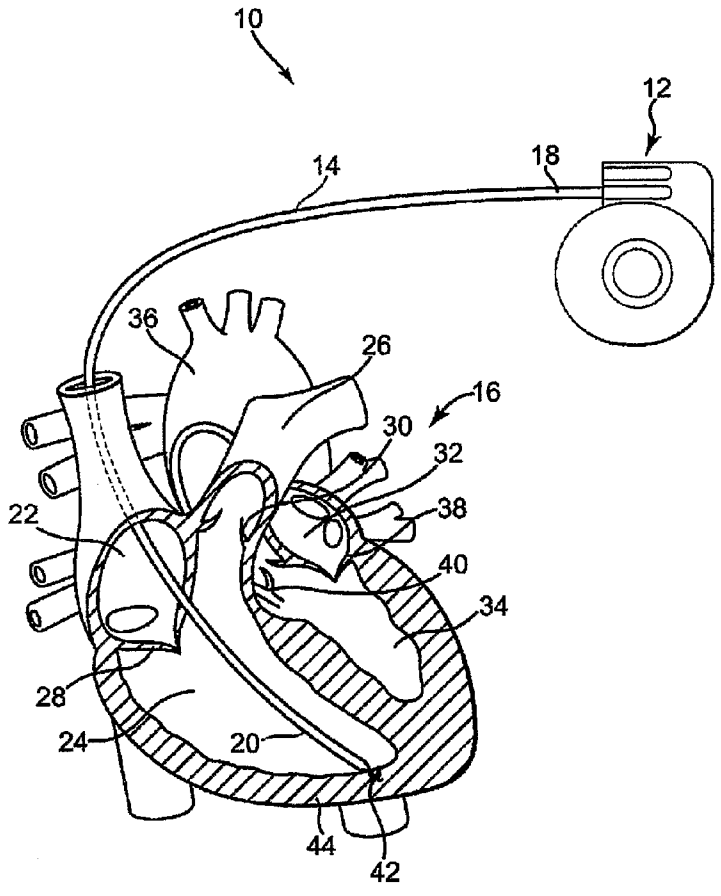
(54) Title: BROADBAND ACOUSTIC SENSOR FOR AN IMPLANTABLE MEDICAL DEVICE




(57) Abstract: An implantable medical device (IMD) is adapted for detecting acoustic chest sounds. The IMD includes a pulse generator having a compartment, the compartment defining an isolated cavity bounded by a back wall. A diaphragm is disposed over and encloses the cavity. An acoustic sensor adapted to sense chest sounds and generate a signal is disposed between the diaphragm and the back wall. The IMD also includes a control circuit disposed within the pulse generator. The circuit is operatively coupled to the acoustic sensor and is adapted to analyze the signal.

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# Broadband Acoustic Sensor for an Implantable Medical Device

## TECHNICAL FIELD

**[001]** The present invention relates to sensors used in combination with a cardiac function management device such as a heart pacemaker or defibrillator to monitor and control the rhythm of the heart. The present invention more particularly relates to sensors used to detect heart sounds and methods of modifying therapy based on these heart sounds.

## BACKGROUND

**[002]** Cardiac function management systems are used to treat heart arrhythmias. Pacemaker systems are commonly implanted in patients to treat bradycardia (i.e., abnormally slow heart rate). A pacemaker system includes an implantable pulse generator and leads, which form the electrical connection between the implantable pulse generator and the heart. An implantable cardioverter defibrillator ("ICD") is used to treat tachycardia (i.e., abnormally rapid heart rate). An ICD also includes a pulse generator and leads that deliver electrical energy to the heart. These systems are also useful in the treatment of heart failure, which is often caused by bundle branch block that can disrupt synchrony between the right and left ventricles. For example, cardiac resynchronization therapy ("CRT") (also commonly referred to as biventricular pacing) is an emerging treatment for heart failure, which involves stimulation of both the right and the left ventricles to increase hemodynamic efficiency and cardiac output.

**[003]** The beating heart produces a series of auditory vibrations (i.e., heart sounds) that can be characterized by intensity, frequency, quality, and timing with respect to the cardiac cycle. Two of the normal heart sounds, commonly known as the S1 and S2 sounds, relate to closing of various heart valves. Specifically, the S1 sound is generated by the closing of the mitral and tricuspid valves and thus generally correlates to the onset of ventricular systole, and the S2 sound is

generated by the closing of the pulmonary and aortic valves and thus generally correlates to the onset of ventricular diastole. These sounds may also indicate problems or abnormalities in the pumping process, such as for example a murmur or mitral regurgitation. There is thus a need for a cardiac rhythm management device that includes a sensor for sensing heart sounds.

## SUMMARY

**[004]** The present invention, according to one embodiment, is an implantable medical device (IMD) including a pulse generator having a compartment, which defines an isolated cavity bounded by a back wall. A compartment diaphragm is disposed over and encloses the cavity. An acoustic sensor adapted to sense chest sounds and generate a signal is disposed between the diaphragm and the back wall. A control circuit disposed within the pulse generator is operatively coupled to the acoustic sensor and is adapted to receive the signal.

**[005]** According to another embodiment, the present invention is an implantable medical device (IMD) includinga pulse generator; a sensor module located remotely from the pulse generator, the sensor module defining a compartment having a compartment diaphragm, an acoustic sensor adapted to sense chest sounds and generate a signal, the acoustic sensor located in the compartment, and a control circuit disposed within the pulse generator, the circuit operatively coupled to the acoustic sensor and adapted to receive the signal.

**[006]** The present invention, according to yet another embodiment, is a cardiac function management (CFM) system for effecting operation of a human heart. The system includes a pulse generator having a compartment, the compartment defining an isolated cavity bounded by a back wall. A compartment diaphragm is disposed over and enclosing the cavity. An acoustic sensor adapted to sense chest sounds and generate a first signal is disposed between the compartment diaphragm and the back wall. A cardiac lead has an electrode and is adapted to sense electrical activity of the heart. A

control circuit is disposed within the pulse generator and is operatively coupled to the acoustic sensor and the cardiac lead.

[007] While multiple embodiments are disclosed, still other embodiments of the present invention will become apparent to those skilled in the art from the following detailed description, which shows and describes illustrative embodiments of the invention. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

## BRIEF DESCRIPTION OF THE DRAWINGS

[008] FIG. 1 shows a perspective view of a cardiac rhythm management device according to the present invention.

[009] FIGS. 2A-2C show various views of a cardiac rhythm management device having an acoustic sensor according to one embodiment of the present invention.

[010] FIGS. 3A-3B show various views of a cardiac rhythm management device having an acoustic sensor according to another embodiment of the present invention.

[011] FIGS. 4A-4B show various views of a cardiac rhythm management device having an acoustic sensor according to yet another embodiment of the present invention.

[012] FIG. 5 shows a perspective view of a cardiac rhythm management device having an acoustic sensor according to another embodiment of the present invention.

[013] FIG. 6 shows a circuit diagram, for receiving and processing a signal from an acoustic sensor, according to one embodiment of the present invention.

[014] While the invention is amenable to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and are described in detail below. The intention, however, is not to limit the invention to the particular embodiments described. On the contrary, the invention is intended to

cover all modifications, equivalents, and alternatives falling within the scope of the invention as defined by the appended claims.

## DETAILED DESCRIPTION

**[015]** FIG. 1 is a perspective view of an implantable medical device (IMD) or cardiac function management (CFM) system 10. The system 10 includes a pulse generator 12 and a cardiac lead 14. The lead 14 operates to convey electrical signals between the heart 16 and the pulse generator 12. A proximal end 18 of the lead 14 is coupled to the pulse generator 12 and a distal end 20 is coupled to the heart 16. The lead 14 includes a lead body extending from the lead proximal end 18 to the lead distal end 20.

**[016]** The heart 16 includes a right atrium 22, a right ventricle (RV) 24, and a pulmonary artery 26. A tricuspid valve 28 is located between and controls the flow of blood from the right atrium 22 and the right ventricle 24. A pulmonic valve 30 is located between and controls the flow of blood from the right ventricle 24 to the pulmonary artery 26. The heart 16 also includes a left atrium 32, a left ventricle (LV) 34, and an aorta 36. A mitral valve 38 is located between and controls the flow of blood from the left atrium 32 to the left ventricle 34. A aortic valve 40 is located between and controls the flow of blood from the left ventricle 34 to the aorta 36. In one embodiment, the CFM system 10 includes a plurality of leads 14. For example, it may include a first lead 14 in communication with the left ventricle 34 and a second lead in communication with the right ventricle 24.

**[017]** The heart sound S1 is generated when the mitral valve 38 and the tricuspid valve 28 close. The S1 sound is referred to as the "lub" part of the "lub-dub" rhythm of the heart. The heart sound S2 is generated when the pulmonic valve 30 and the aortic valve 40 close and is referred to as the "dub" sound. The S3 heart sound is known to be a ventricular diastolic filling sound often indicative of certain pathological conditions including heart failure, and the S4 heart sound is known to be a ventricular diastolic filling sound resulting from atrial

contraction and is also usually indicative of pathological conditions. The phrase "heart sound," as used herein refers to any sound made by the heart during operation, including any of S1, S2, S3, S4, or any components thereof. Other notable heart sounds include that of mitral regurgitation (MR). The phrase "chest sound," as used herein includes heart sounds as well as lung sounds and any other sounds that may be present in a patient's chest cavity. Common lung sounds of interest include coughs, rales and wheezes. Other chest sounds may include, for example, snoring and talking.

**[018]** In the embodiment shown in FIG. 1, a helical electrode 42 penetrates the endocardium of the RV 24 and is embedded in the myocardium 44 of the heart 16. When positioned as above, the electrode 42 can be used to sense the electrical activity of the heart 16 or to apply a stimulating pulse to the left ventricle 34. In other embodiments, the cardiac lead 14 of the present invention can also be implanted in any other portion of the heart 16 as known in the art of cardiac function management. For example, it may be implanted in the right atrium 22, the right ventricle 24, the pulmonary artery 26, the left ventricle 34, or in the coronary veins. In one embodiment, the system 10 includes multiple electrodes 42 disposed to sense electrical activity and/or deliver therapy to both the left and right sides of the heart 16.

**[019]** FIGS. 2A and 2B show side views of the pulse generator 12 according to embodiments of the present invention. As shown in FIG. 2A, the pulse generator 12 includes a header 46 and a housing 48. The header 46 includes connectors 50 for connecting to the lead 14. The housing 48 encloses circuitry 52 and includes an outer wall or substantially planar face 54.

**[020]** As shown in FIG. 2B, a coin or compartment 56 is located on the planar face 54. The compartment 56 may protrude from the planar face 54 (in which case the back wall of the compartment 56 is the substantially planar face 54 of the housing 48) or may be inset into the housing 48. The compartment 56 includes a compartment diaphragm 58 and a cavity 60 located behind the compartment

diaphragm 58 (shown in the enlarged section of FIG. 2A). An acoustic sensor 62 is located in the cavity 60 between the compartment diaphragm 58 and back wall of the compartment 56. In the embodiment where the compartment 56 is inset into the housing, the compartment diaphragm 58 is generally flush with the face of the surrounding wall of the housing 48. In one embodiment, the cavity 60 contains a fluid or gel having an acoustic impedance that is generally an acoustic match to that of the body in which it is implanted. This fluid or gel may be any substance generally known in the art having an impedance that generally matches that of the human body, such as for example water or an ultrasound gel.

**[021]** In the embodiment shown in FIGS. 2A-2C, the cavity 60 is hermetically sealed. The housing 48 is comprised of titanium and may for example have a thickness of about 0.010 inch. The compartment diaphragm 58 is also comprised of titanium and has a thickness less than the thickness of the housing. Reducing the thickness of the compartment diaphragm 58 allows acoustic energy to vibrate the compartment diaphragm 58 more easily. In one embodiment, the compartment diaphragm 58 has a thickness of between about 0.002 inch and about 0.010 inch. In one embodiment, the resonant frequency of the compartment diaphragm 58 is much higher than the acoustic frequencies of interest in order to ensure a reasonably flat acoustic response over frequency. In one embodiment, for example, the resonant frequency of the compartment diaphragm 58 is greater than about 20,000 Hz.

**[022]** The acoustic sensor 62 is adapted to sense broadband chest sounds, which may include for example heart and lung sounds such as S2 splitting, mitral regurgitation, coughs, rales, and wheezes. Other chest sounds, which may be detected by the acoustic sensor 62 include Gallop sounds, snoring and a patient's voice. The acoustic sensor 62 is electrically connected to the circuitry 52 by one or more feedthroughs 64. The sensor 62 may have, for example, a broadband acoustic range of from about 10 to about 20,000 Hz. In one

embodiment, the range of the sensor 62 is from about 100 to about 5,000 Hz, and, in yet another embodiment, the range is from about 100 to about 3,000 Hz.

**[023]** The acoustic sensor 62 can be comprised of any of a variety of microphones known in the art. Exemplary microphones include piezoelectric, piezoresistive, and capacitive-type microphones. The piezoelectric microphone may be made from any piezoelectric material, including piezocomposites, piezoceramics, piezoplastics and the like. The sensor 62 may, for example, be comprised of a piezoelectric film, such as polyvinylidine fluoride (PVDF), which takes the form of a thin plastic polymer sheet and may have a thin electrically conductive nickel copper alloy deposited on each side. The sensor 62 acts as a strain gage that generates an electrical signal when the compartment diaphragm 58 vibrates in response to a heart or lung sound.

**[024]** In one embodiment, the acoustic sensor 62 is a micro-electrical mechanical system (MEMS) device. One such exemplary device is the SiSonic MEMS microphone available from Knowles Acoustics, Inc. (www.knowlesacoustics.com) of Itasca, Illinois. A MEMS microphone is fabricated from a silicon chip using standard semiconductor processing techniques. Such a microphone may include a diaphragm and a backplate fabricated from a silicon wafer. In one embodiment, the thickness of the sensor 62 is from about 0.01 to about 2 mm. In another embodiment, the thickness of the sensor 62 is less than about 0.5 mm. The acoustic sensor 62 may have a width dimension and a length dimension each between about 1 and about 2 mm.

**[025]** FIGS. 2A and 2B illustrative two exemplary locations for the sensor 62 in the cavity 60. As shown in FIG. 2A, the sensor 62 is coupled to the compartment diaphragm 58. In this embodiment, the diaphragm of the sensor 62 may be mechanically coupled to the compartment diaphragm 58. In one exemplary embodiment, a piezoelectric or piezoresistive material is attached to an inner surface

of the compartment diaphragm 58 using an epoxy or a medical adhesive as is known in the art.

**[026]** As shown in FIG. 2B, the sensor 62 is located on the back wall of the compartment 56, which is defined by the planar face 54 of the housing 48. In this embodiment, the sensor 62 may include an opening to allow the portion of the sensor 62 located between the diaphragm and the planar face 54 to communicate with the remainder of the cavity 60, which minimizes acoustic dampening in the sensor 62. In the embodiment of FIG. 2B, the diaphragm of the acoustic sensor 62 is separated from the compartment diaphragm 58 by a small distance. As noted above, this separation space in the cavity 60 may be filled with a fluid having an appropriate acoustic impedance.

**[027]** In one embodiment, the acoustic sensor 62 is an accelerometer, including, for example, a piezoelectric crystal accelerometer sensor of the type used by pacemakers to sense the level of activity of the patient. Use of such an accelerometer for detecting heart sounds is described in more detail, for example, in U.S. Publication 2005/0137490 and U.S. Publication 2005/0102001, both of which are hereby incorporated by reference. In another exemplary embodiment, the IMD 10 includes both an accelerometer and a piezoelectric sensor. In this embodiment, the accelerometer is typically located inside the hermetic housing and is generally most effective at sensing lower frequencies, whereas the sensor is in a cavity located behind a diaphragm and is optimized for detecting frequencies above that detected by the accelerometer.

**[028]** The compartment diaphragm 58 and the compartment 56 can be any shape, including circular, oval, rectangular, or square. In the embodiment shown in FIG. 2C, the compartment diaphragm 58 and the compartment 56 both have a circular shape. The compartment 46 may include a chamfer 66 to avoid irritation of the body tissue adjacent to the compartment 56. In one embodiment, the compartment 56 extends outwardly from the planar face 54, while in other

embodiments, the compartment 56 is disposed within or behind the planar face 54.

**[029]** FIGS. 3A-3B show another embodiment of the present invention. As shown, the acoustic sensor 62 is located in a cavity 60 behind an outer surface 68 of the header 46. The header 46 can be comprised of Tecothane or any other suitable material as is known in the art. Sealed hermetic feedthroughs 64 electrically connect the acoustic sensor 62 to the circuitry 52. The acoustic sensor 62 shown in FIGS. 3A-3B is a substantially flat piezoelectric, piezoresistive, or capacitive device (e.g., a MEMS microphone), but in an alternative embodiment, the acoustic sensor 62 could comprise a piezoelectric cylindrical transducer, as is known in the art. In this embodiment, the acoustic sensor 62 may be disposed within a cavity 60 behind the outer surface 68, as described with respect to FIGS. 2A-2B above. Alternatively, the diaphragm of the sensor 62 may be positioned such that it is not covered over by the material that forms the header body (e.g., Tecothane). In both of these embodiment, the sensor 62 is directly exposed to bodily fluids, as the header material is not hermetically sealed and thus is penetrable by bodily fluids.

**[030]** In one embodiment, the acoustic sensor 62 of FIGS. 3A-3B is contained in a hermetically sealed, titanium tab or housing (e.g., such as is described below with reference to FIGS. 4A and 4B). In this exemplary embodiment, the tab or housing includes a relatively thin diaphragm to allow sound to penetrate the tab and reach the acoustic sensor 62.

**[031]** FIGS. 4A-4B show yet another embodiment of the present invention. The acoustic sensor 62 shown in FIGS. 4A-4B is located in a sensor module or tab 70, which is located outside of the pulse generator 12. In one embodiment, as shown in FIG. 4A, the tab 70 is structurally separate from the pulse generator 12. As shown in FIG. 4A, the acoustic sensor 62 is electrically connected to the circuitry 52 via a conductive member 72. In another embodiment, the acoustic sensor 62 is coupled using any wireless communication technique

known in the art. The tab 70 can be comprised of titanium and includes a compartment diaphragm 58 and a cavity 60. The tab 70 may be implanted near the patient's heart in a location adapted to detect key heart sounds, such as S1 and S2. As described above with respect to FIGS. 2A and 2B, the sensor 62 may be coupled either to the back wall of the tab 70 or directly to the diaphragm 58. Also as described above, in one embodiment the cavity 60 is filled with a fluid or gel that has an acoustic impedance generally matching that of the body.

**[032]** FIG. 5 shows yet another embodiment of the present invention. In this embodiment, the acoustic sensor 62 may comprise a cylindrical transducer as is known in the art, such as for example a piezoelectric cylindrical transducer. In this embodiment, the sensor 62 may also comprise a generally flat MEMS transducer, as described above. This MEMS transducer may have a variety of shapes, including for example round, oval, rectangular or square. The acoustic sensor 62 is located on the lead 14 near the distal end 20 and is electrically connected to the circuitry 52 via a conductive member 72. In yet another embodiment, the IMD 10 includes more than one acoustic sensor 62. For example, it may include a first acoustic sensor 62 located in the housing 48 (see for example FIG. 2A) and a second acoustic sensor 62 located on a lead (see for example FIG. 5).

**[033]** FIG. 6 shows at least a portion of the circuitry 52, for processing the signals received from the acoustic sensor 62, according to one embodiment of the present invention. As shown, the signal (e.g., a voltage) from the acoustic sensor 62 is processed by an analog pre-processing circuit 74, which may include, for example, a filter and/or an amplifier. The analog signal is then converted to a digital signal by an analog-to-digital converter 76. This digital signal is then directed into a microprocessor or controller 78 for analysis. The signals may also be stored in a memory 80 coupled to the controller 78. As further shown in FIG. 6, the circuitry 52 may also include a sensing/stimulating circuit 82 for processing the electrical signals

received from or delivered to the lead 14. The circuit 82, in one embodiment, generates an electrocardiogram (ECG), which is provided to the controller 78.

**[034]** Such a configuration as is shown in FIG. 6 allows the controller 78 to receive and store signals from the acoustic sensor 62 and/or from the lead 14. The controller 78 then analyzes these signals to identify heart sounds (e.g., S1, S2, S3, S4, MR and S2 splitting) and lung sounds (e.g., coughs, rales, and wheezes) and modifies therapy, as appropriate, based on the information these signals provide about the functioning of a patient's heart. In one embodiment, the controller 78 stores and averages several cycles (e.g., 10 cycles) of heart sound data, to help attenuate signal noise. In another embodiment, the controller 78 is programmed to subject the signal to a Fourier transform algorithm, such as a fast Fourier transform (FFT), which may provide for a more efficient technique for identifying certain chest sounds. In one embodiment, the controller 78 initiates this process of receiving signals from the acoustic sensor 62 at a predetermined time interval (e.g., hourly). In other embodiments, the controller 78 continuously receives and evaluates signals from the acoustic sensor 62. In another embodiment, the process is initiated upon detection of some pre-specified condition, such as for example the detection by the controller 78 of a cardiac arrhythmia.

**[035]** Several techniques for identifying a specified chest sounds may be employed, including, for example, analyzing the signal from the acoustic sensor 62 to identify the presence of a signal exceeding a certain amplitude within a certain frequency range and within a specified portion of the cardiac cycle. In one embodiment, a specified chest sound is identified by comparing the signal to an acoustic template representing a "normal" condition or to sounds previously recorded for that particular patient. These previously recorded sounds could, for example, be stored during an examination by a physician, after the physician confirms acceptable heart function. In one embodiment, the ECG information is used to further assist in

detecting a specified heart sound. The ECG information, for example, may be used to "window" a certain portion of the acoustic data, based on knowledge of a skilled artisan relating to the location in the cardiac cycle during which a specified sound is likely to occur. Exemplary techniques for identifying a specified heart sound and for correlating the acoustic data to a certain location in the cardiac cycle is disclosed in commonly-assigned U.S. Publication 2004/0106961, which is hereby incorporated by reference.

**[036]** In one embodiment, the circuitry 52 further includes a logbook feature. In this embodiment, for example, the controller 78 may operate to store a predetermined time period of data in a specified area of the memory 80 periodically, or it may operate to store a specified time period of data only upon detection of an abnormal condition. This feature then allows a user to access this stored data at a later time for additional analysis.

**[037]** In one embodiment, the system further includes an external device 84, which is operatively coupled to the circuitry 52 by, for example, a wireless RF communication link. The external device 84 may, for example, be an external programmer adapted for use with the implanted medical device 10. This external device 84 is, in turn, coupled to a remote system 86. The external device 84 and remote system 86 may, for example, be coupled by a telephone line, electrical or optical cable, RF interface, satellite link, local area network or wide area network. The remote system 86 allows a user (e.g., a physician) located at a remote location to obtain data relating to the heart sounds and to conduct or aid in the diagnosis of a patient based on such data. In one embodiment, the remote system 86 includes an advanced patient management system, such as is disclosed in U.S. Publication 2004/0122484, which is hereby incorporated by reference in its entirety.

**[038]** Various modifications and additions can be made to the exemplary embodiments discussed without departing from the scope of the present invention. Accordingly, the scope of the present invention

is intended to embrace all such alternatives, modifications, and variations as fall within the scope of the claims, together with all equivalents thereof.

# CLAIMS

We claim:

1. An implantable medical device (IMD) comprising:

a pulse generator having a compartment, the compartment defining an isolated cavity bounded by a back wall;

a compartment diaphragm disposed over and enclosing the cavity;

an acoustic sensor adapted to sense chest sounds and generate a signal, the sensor disposed between the diaphragm and the back wall; and

a control circuit disposed within the pulse generator, the circuit operatively coupled to the acoustic sensor and adapted to receive the signal.

2. The IMD of any of the preceding claims wherein an acoustic range of the acoustic sensor is from about 100 to about 5,000 Hz.

3. The IMD of any of the preceding claims further comprising an accelerometer operatively coupled to the control circuit.

4. The IMD of any of the preceding claims wherein the acoustic sensor includes an amplifier for amplifying the signal detected by the acoustic sensor.

5. The IMD of any of the preceding claims wherein the acoustic sensor is a piezoresistive sensor or a capacitive sensor.

6. The IMD of any of the preceding claims wherein the acoustic sensor is a MEMS microphone, and further wherein the MEMS microphone is attached to the back wall.

7. The IMD of any of the preceding claims wherein a sensor diaphragm of the acoustic sensor is made from a piezoelectric material.

8. The IMD of any of the preceding claims wherein the piezoelectric material comprises a piezoceramic material.

9. The IMD of any of the preceding claims wherein the sensor diaphragm is attached to the compartment diaphragm using an epoxy or medical adhesive.

10. The IMD of any of the preceding claims wherein the sensor diaphragm is separated from the compartment diaphragm by a gel having an acoustic impedance generally matching a second acoustic impedance of a body location in which the IMD is implanted.

11. The IMD of any of the preceding claims wherein the pulse generator includes a housing and a header.

12. The IMD of any of the preceding claims wherein the compartment is disposed in the housing, such that the compartment diaphragm is generally flush with a housing outer wall.

13. The IMD of any of the preceding claims wherein the compartment extends outwardly from a housing outer wall and further wherein the back wall is formed by the housing outer wall.

14. The IMD of any of the preceding claims wherein the electrical connection between the acoustic sensor and the controller includes a hermetically sealed feedthrough.

15. The IMD of any of the preceding claims wherein the compartment is disposed in the header.

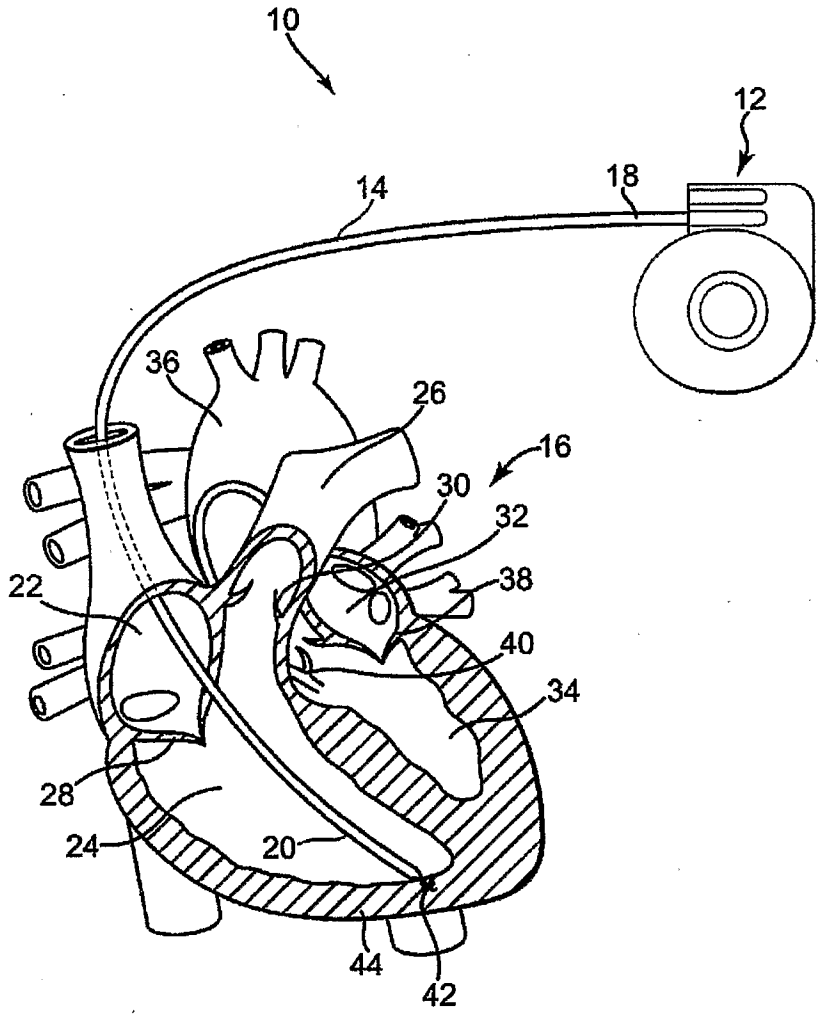


Fig. 1

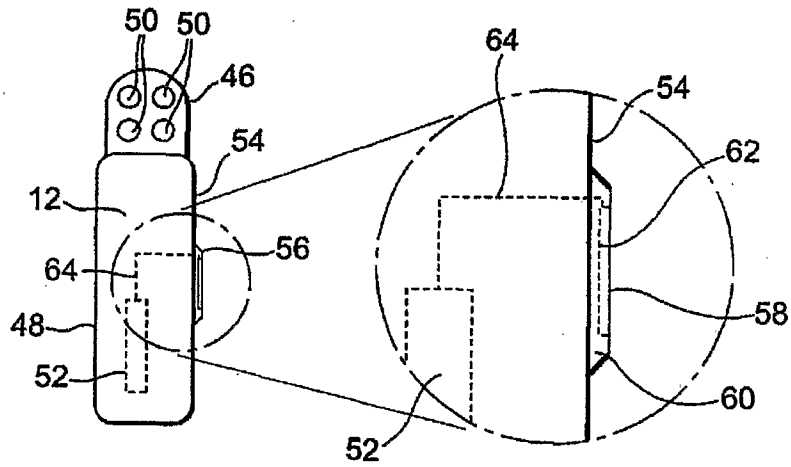


Fig. 2A

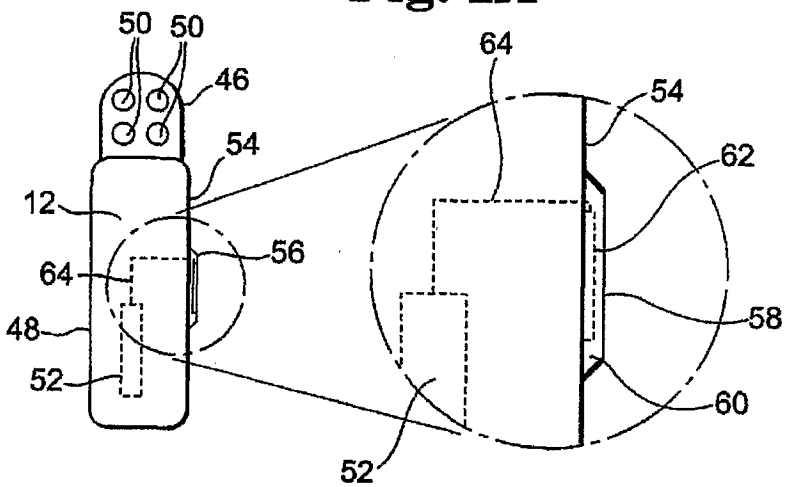


Fig. 2B

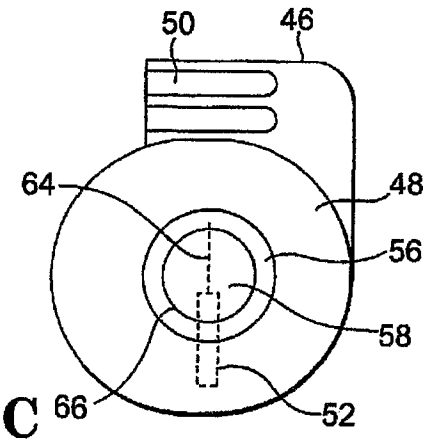


Fig. 2C

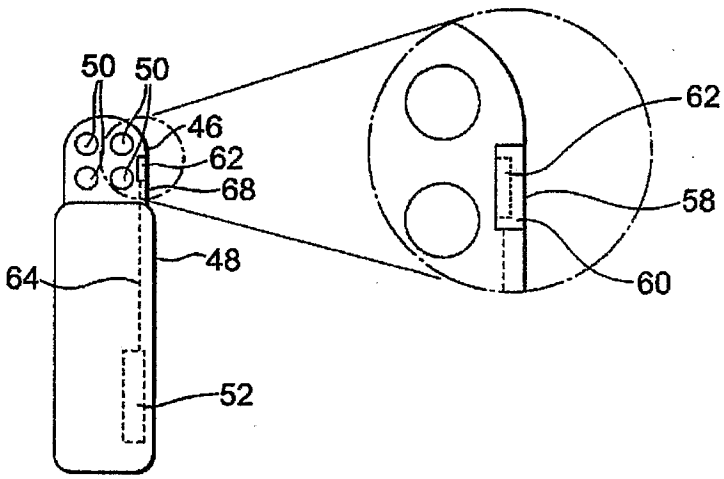


Fig. 3A

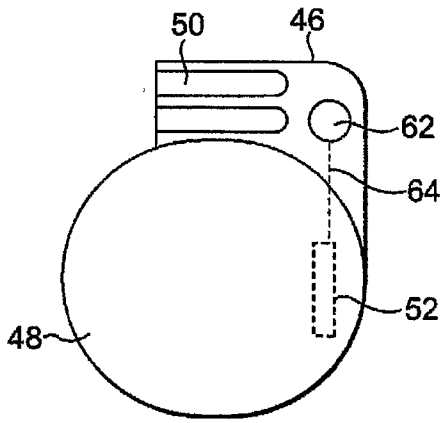


Fig. 3B

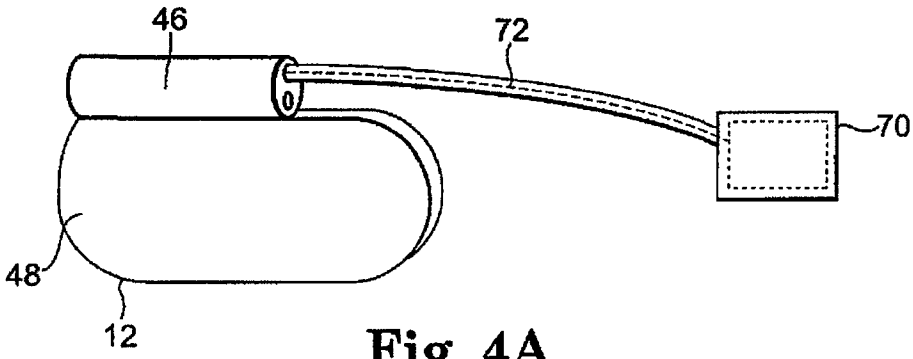


Fig. 4A

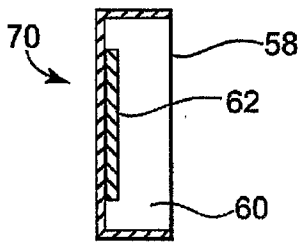


Fig. 4B

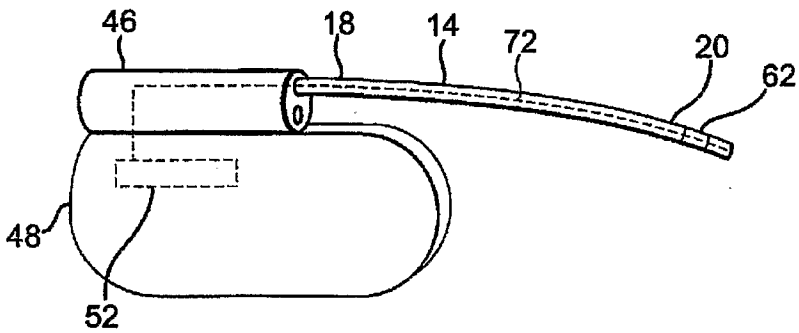


Fig. 5

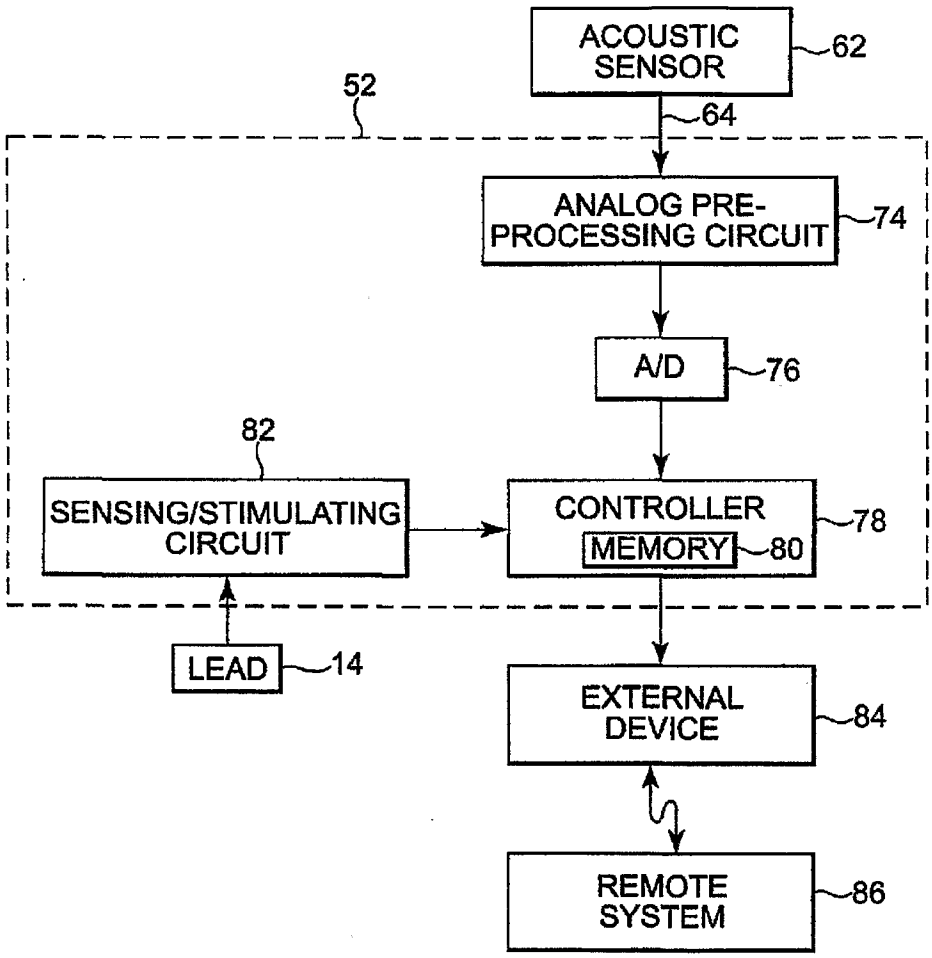
ACOUSTIC SENSOR
62
52
64
ANALOG PRE-PROCESSING CIRCUIT
74
A/D
76
82
SENSING/STIMULATING CIRCUIT
CONTROLLER
MEMORY
80
78
LEAD
14
EXTERNAL DEVICE
84
REMOTE SYSTEM
86

**Fig. 6**

# INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/033273

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B7/02

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

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | EP 1 151 719 A2 (PACESETTER INC [US])<br>7 November 2001 (2001-11-07)<br>paragraphs [0032] - [0037], [0063] - [0067] | 1-8,11, 12,14,15 |
| Y | EP 0 798 016 A2 (VITATRON MEDICAL BV [NL])<br>1 October 1997 (1997-10-01)<br>the whole document | 1-8,11, 12,14,15 |
| A | WO 97/35636 A (MEDTRONIC INC [US])<br>2 October 1997 (1997-10-02)<br>the whole document | 1-8,11, 14,15 |

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 11 January 2007 | 19/01/2007 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31–70) 340–2040, Tx. 31 651 epo nl,<br>Fax: (+31–70) 340–3016 | Ferrigno, Antonio |

# INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/033273

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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|---|---|---|
| A | WO 2004/091719 A2 (CARDIAC PACEMAKERS [US]) 28 October 2004 (2004-10-28)<br>page 20, lines 16-27<br>page 23, lines 18-21<br>page 26, lines 5-15<br>page 27, line 11 - page 28, line 11 | 1-8,11 |
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International application No
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