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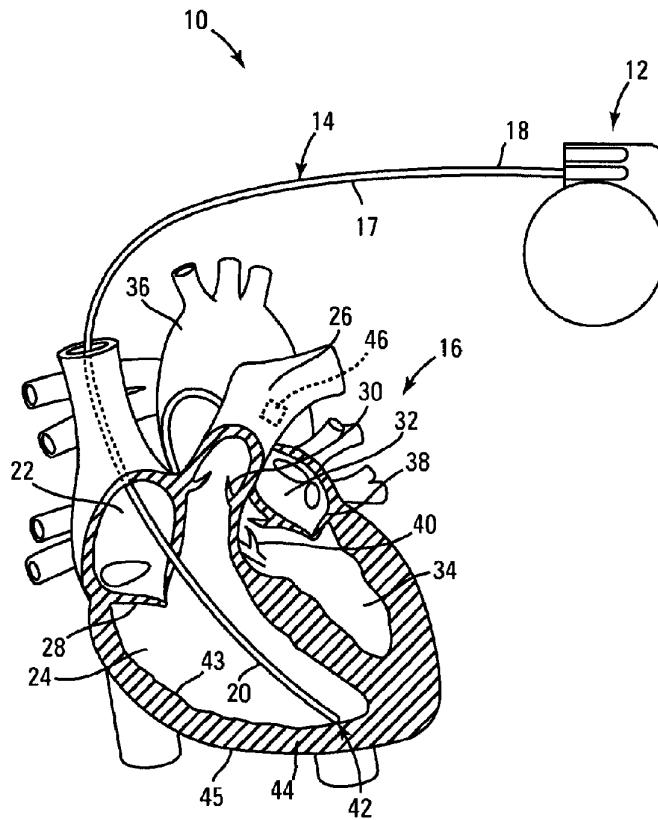
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(54) Title: ACOUSTIC COMMUNICATION TRANSDUCER IN IMPLANTABLE MEDICAL DEVICE HEADER



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(57) Abstract: An implantable medical device is adapted for implantation into body tissue. The implantable medical device comprises a housing and a header coupled to the housing. A cavity is located in the header. An ultrasonic transducer adapted to transmit acoustic waves at a communication frequency is located in the cavity, and a coupling surface is interposed between the ultrasonic transducer and the body tissue and is acoustically coupled with the body tissue.



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ACOUSTIC COMMUNICATION TRANSDUCER IN IMPLANTABLE MEDICAL DEVICE HEADER

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to Provisional Application No. 60/820,062, 5 filed July 21, 2006, and is a continuation-in-part application of Application No. 11/212,176, filed August 26, 2005, both of which are herein incorporated by reference in their entirety.

TECHNICAL FIELD

10 The present invention relates to transducers used in combination with an implantable medical device to wirelessly communicate between the implantable medical device and remote sensors implanted in the body or other implantable medical devices. The present invention more particularly relates to transducers located in the header of the implantable medical device.

BACKGROUND

15 Implantable medical devices are often used to treat a variety of medical conditions. Examples of implantable medical devices include drug delivery devices, pain management devices, and devices that treat heart arrhythmias. One example of an implantable medical device used to treat heart arrhythmias is a cardiac pacemaker, which is commonly implanted in a patient to treat 20 bradycardia (i.e., abnormally slow heart rate). A pacemaker includes a pulse generator and leads, which form the electrical connection between the 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. Pulse 25 generators typically include a housing for a battery and electrical circuitry and a header for connecting the leads to the pulse generator.

Implantable medical devices are also useful in the treatment of heart failure. For example, cardiac resynchronization therapy ("CRT") (also commonly referred to as biventricular pacing) is an emerging treatment for heart failure, 30 which involves stimulation of both the right and the left ventricles to increase

hemodynamic efficiency and cardiac output. The treatment of heart failure and heart arrhythmias can be enhanced through the use of chronically implanted sensors. For example, it can be useful to place a pressure sensor in the vasculature because the diastolic pressure can be a good predictor of decompensation in heart failure patients.

5 Pressure sensors can also be used as part of pacing or defibrillation therapy. Communication between the implantable medical device and the chronically implanted sensor can allow the sensor data to be downloaded by a clinician or used to modify the therapy delivered by the implantable medical device. There is therefore a need for an implantable medical device that includes a transducer for communication with a

10 chronically implanted sensor.

SUMMARY

The present invention, according to one embodiment, is an implantable medical device for implantation into body tissue. The implantable medical device comprises a housing and a header coupled to the housing; a cavity located in the header; a casing disposed within the cavity, the casing having a wall defining a coupling surface; an ultrasonic transducer disposed inside the casing, the transducer adapted to transmit acoustic waves at a communication frequency; and control circuitry disposed in the housing, the control circuitry adapted to communicate with a remote device by driving the transducer at the communication frequency and processing electrical signals received from the transducer. The coupling surface is configured to be interposed between the ultrasonic transducer and the body tissue, the coupling surface having a resonance frequency greater than about 20kHz and the coupling surface configured to be acoustically coupled with the body tissue.

25 According to another embodiment, the present invention is an implantable medical device for implantation into body tissue. The implantable medical device comprises a housing and a header coupled to the housing; a cavity located in the header; a casing disposed within the cavity, the casing having a surface defining a coupling surface; a means for communicating ultrasonic signals, the means for communication located in the casing; and control circuitry disposed in the housing, the control circuitry adapted to communicate with a remote device by driving the means for communication at the communication frequency and processing electrical signals received from the means for communication. The coupling surface is configured to be interposed between the means for communicating ultrasonic signals and the body tissue,

the coupling surface having a resonance frequency greater than about 20 kHz and the coupling surface is configured to be acoustically coupled with the body tissue.

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

10 FIG. 1 is a combined cutaway and perspective view of an implantable medical device in accordance with one embodiment of the present invention.

FIG. 2 shows a front view of an implantable medical device having an acoustic transducer located in the header according to one embodiment of the present invention.

15 FIG. 3 shows a cross-sectional view of one embodiment of the implantable medical device of FIG. 2.

FIG. 4 shows a cross-sectional view of another embodiment of the implantable medical device of FIG. 2.

FIG. 5 shows a perspective view of one embodiment of the ultrasonic transducer of FIG. 2.

20 FIG. 6 shows a front view of yet another embodiment of an implantable medical device according to the present invention.

FIG. 7 shows a front view of yet another embodiment of an implantable medical device according to the present invention. FIG. 8 depicts a block diagram of an implantable medical device according to the present invention.

25 FIG. 9 is a flowchart depicting an exemplary method of using the implantable medical device of FIG. 2 to transmit acoustic signals.

FIG. 10 is a flowchart depicting an exemplary method of using the implantable medical device of FIG. 2 to receive acoustic signals.

30 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

5 FIG. 1 is a perspective view of an implantable medical device (IMD) 10. The IMD 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 17 extending from the lead proximal end 18 to the lead distal end 20.

10 The heart 16 includes a right atrium 22, a right ventricle 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 15 pulmonary artery 26. The heart 16 also includes a left atrium 32, a left ventricle 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. An aortic valve 40 is located between and controls the flow of blood from the left ventricle 34 to the aorta 36. In the embodiment shown, the IMD 10 includes one lead 14, but in other 20 embodiments, the IMD 10 includes a plurality of leads 14. For example, it may include a first lead 14 adapted to convey electrical signals between the pulse generator 12 and the left ventricle 34 and a second lead 14 adapted to convey electrical signals between the pulse generator 12 and the right ventricle 24.

25 In the embodiment shown in FIG. 1, a helical electrode 42 penetrates the endocardium 43 of the right ventricle 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 right ventricle 24. 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 30 the art. 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 IMD 10 includes multiple electrodes 42 disposed to sense

electrical activity and/or deliver therapy to the left and right sides of the heart 16 or to both sides of the heart 16. In one embodiment, the lead 14 can be an epicardial lead where the electrode 42 penetrates the epicardium 45. While the IMD 10 shown in FIG. 1 is a cardiac pacemaker, in other embodiments, the IMD 5 10 could comprise any other medical device suitable for implantation in the body.

As shown in FIG. 1, a remote device 46 is located in the pulmonary artery 26. Alternatively, the device 46 could be located in the right ventricle 24, the aorta 36, or any other location in or near the heart 16 or vasculature. The device 46 could sense pressure or could alternatively comprise a volume sensor or sense 10 any other cardiac parameter, such as maximum or minimum pressure, or calculate a cardiac parameter derivative, such as the slope of the pressure. In other embodiments, the device 46 can be located anywhere in the body adapted for sensing a desired biological parameter. For example the device 46 could be used to sense or monitor other biological functions, such as glucose level. The 15 device 46 shown in FIG. 1 can be a remote pressure sensor used to sense pressure in the pulmonary artery 26. The sensed pressure can be used to predict decompensation of a heart failure patient or to optimize pacing or defibrillation therapy. One example of a remote pressure sensor 46 adapted to measure pressure is disclosed in U.S. Patent No. 6,764,446 to Wolinsky et al.

20 FIG. 2 depicts a front view of one embodiment of the pulse generator 12 of FIG. 1. As shown in FIG. 2, the pulse generator 12 includes a housing 48 and a header 50. The housing 48 includes control circuitry 52. The header 50 includes connectors 51 for connection to the lead 14 or leads 14. An acoustic transducer 54 is located in the header 50, which is connected to the control circuitry 52 via 25 the electrical feedthroughs 55. In one embodiment, the acoustic transducer 54 sends and receives acoustic signals at a frequency above about 20 kiloHertz. In another embodiment, the acoustic transducer 54 sends and receives acoustic signals at a frequency of about 40 kiloHertz. The acoustic transducer 54 shown in FIG. 2 has a circular shape, but alternatively could have any other shape, including square, rectangular, triangular, or irregular. The acoustic transducer 54 can comprise any piezoelectric material. In one embodiment, the acoustic transducer 54 can comprise a polyvinylidene diflouride (PVDF) material. One acoustic transducer comprised of PVDF material is disclosed in U.S. Patent 30

Application Publication No. 2002/0036446 to Toda et al., herein incorporated by reference in its entirety. In another embodiment, the acoustic transducer 54 can comprise a lead zirconate titanate (PZT) material. One acoustic transducer comprised of PZT material is disclosed in U.S. Patent Application Publication No. 5 2002/0027400 to Toda, herein incorporated by reference in its entirety. Alternatively, the acoustic transducer 54 can comprise a capacitor micromachined ultrasonic transducer (cMUT) or any other transducer as is known in the art.

10 A cross-sectional view of one embodiment of the implantable medical device 10 is shown in FIG. 3. In the embodiment shown in FIG. 3, the acoustic transducer 54 comprises a PVDF transducer. A cavity 56 is located in the header 50. A ceramic or silicon substrate 58 is located against a back wall 60 of the cavity 56. The substrate 58 includes an aperture 62, and a PVDF material 64 is disposed over and covers the aperture 62. The PVDF material 64 can be coupled to the substrate 58 using epoxy or medical adhesive. In one embodiment, the 15 PVDF material 64 can comprise a bimorph structure having two layers of PVDF material. The cavity 56 can be filled with water, oil, an acoustic gel, or any other medium or material adapted for transmitting acoustic waves. In one embodiment, the cavity 56 can be filled with any biocompatible material adapted for transmitting acoustic waves.

20 A coupling surface 66 is disposed over and covers the cavity 56. In one embodiment, the coupling surface 66 comprises any surface capable of propagating acoustic pressure between the medium of cavity 56 and body tissue. In one embodiment, the coupling surface 66 can comprise a thin titanium diaphragm. In other embodiments, the coupling surface 66 comprises any 25 biocompatible material having dimensions capable of propagating acoustic pressure between the medium of cavity 56 and body tissue. One example of PVDF material adapted for use in the acoustic transducer can be obtained from Measurement Specialties, Inc., located at 950 Forge Avenue, Norristown, PA 19403.

30 FIG. 4 depicts an alternative embodiment of the implantable medical device of FIG. 2. In this embodiment, the acoustic transducer 54 comprises a PZT material 68. A cavity 56 is located in the header 50 and is covered by a coupling surface 66. The PZT material 68 is coupled to the coupling surface 66. The PZT

material 68 can be coupled to the coupling surface 66 using epoxy or any medical adhesive. The cavity 56 can be filled with air, nitrogen, or any other gas. Alternatively, the cavity 56 can comprise a vacuum. In the embodiment shown in FIG. 4, the coupling surface 66 comprises a resonant surface that resonates at 5 the acoustic communication frequency. In one embodiment, this frequency is above 20 kiloHertz. In another embodiment, this frequency is about 40 kiloHertz.

An alternative structure for the acoustic transducer 54 is shown in FIG. 5. In this embodiment, the acoustic transducer 54 is located inside a casing 70. The casing 70 can be inserted into the cavity 56 located in the header 50. The casing 10 70 can comprise titanium or any other suitable material. The coupling surface 66 is disposed over the casing 70. The acoustic transducer 54 structure inside the casing 70 can comprise the structures discussed with respect to FIGS. 3 and 4, or could comprise any other acoustic transducer structure as is known in the art. The casing 70 has a cylindrical shape in FIG. 5, but can have any shape adapted 15 to fit the shape of the acoustic transducer 54.

FIG. 6 depicts another embodiment of the implantable medical device 10 of the present invention. In this embodiment, a plurality of acoustic transducers 54 are located in the header 50. The acoustic transducers 54 may comprise the acoustic transducers discussed with respect to FIG. 3, FIG. 4, or any combination 20 of FIGS. 3 and 4. The plurality of acoustic transducers 54 could also include cMUT transducers or other types of acoustic transducers as is known in the art. Acoustic transducers 54 could be located on multiple surfaces of the header 50. Six circular acoustic transducers 54 are shown in FIG. 4, but any number of any 25 shape of transducers could be used. If desired, the acoustic transducers 54 can include casings 70. Such an arrangement allows the acoustic transducer 54 to act in parallel, which results in better resonance and amplification characteristics.

FIG. 7 depicts a front view of yet another embodiment of the implantable medical device 10. In this embodiment, the acoustic transducer 54 is located in a tab 72, which is attached to the housing 48 and is connected to the control 30 circuitry via feedthroughs 74. The tab 72 may comprise the same material as is used in the header 50. In one embodiment, the tab 72 comprises Tecothane. Alternatively, the tab 72 can comprise any biocompatible material, such as titanium, and can be welded or otherwise attached to the housing 48. The tab 72

could include a plurality of acoustic transducers 54. The IMD 10 could include a plurality of tabs 72. Acoustic transducers 54 could be located in the header 50, in the tab or tabs 72, or both in the header 50 and tab or tabs 72. The acoustic transducers 54 can include any combination of PZT, PVDF, cMUT, or any other 5 transducers as known in the art.

FIG. 8 is a schematic of the implantable medical device 10. As described, the pulse generator 12 includes a housing 48 and a header 50. The housing 48 includes control circuitry 52, a memory 80, a battery 82, a receiver 84, and a transmitter 86. The acoustic transducer 54 is located in the header 50 and is 10 electrically connected to the transmitter 86 and the receiver 84. The transmitter 86, receiver 84, and memory 80 are connected to the control circuitry 52. The control circuitry 52 is powered by the battery 82.

FIG. 9 is a flowchart depicting an exemplary method 200 of using the implantable medical device 10 of FIG. 1 to transmit acoustic signals. The control 15 circuitry 52 instructs the transmitter 86 to apply an AC voltage at the communication frequency to the acoustic transducer 54 (block 210). This voltage results in the periodic deformation of the acoustic transducer 54 (block 220) at the communication frequency. This periodic deformation results in vibration of the coupling surface 66 at the communication frequency, causing acoustic signals to 20 travel through the tissue at the communication frequency (block 230). In one embodiment, the acoustic transducer 54 comprises a PVDF material 64 and the coupling surface 66 comprises a diaphragm that propagates the acoustic waves from the PVDF material 64 to the external tissue. In another embodiment, the acoustic transducer 54 comprises a PZT material 58 and the coupling surface 66 25 comprises a resonant surface that resonates at the communication frequency.

FIG. 10 is a flowchart depicting an exemplary method 300 of using the implantable medical device of FIG. 1 to receive ultrasonic signals. The impingement of acoustic signals on the coupling surface 66 causes it to vibrate at the communication frequency (block 310). In one embodiment, the acoustic 30 transducer 54 comprises a PVDF material 64 and the coupling surface 66 comprises a diaphragm that propagates the acoustic waves from the external tissue to the PVDF material 64. In another embodiment, the acoustic transducer 54 comprises a PZT material 58 and the coupling surface 66 comprises a

resonant surface that resonates at the communication frequency. The vibration of the coupling surface 66 results in periodic deformation of the acoustic transducer 54 (block 320). This periodic deformation causes a voltage or current change in the acoustic transducer 54 at the communication frequency, which is detected by 5 the receiver 84 and processed by the control circuitry 52 (block 330). In the manner shown in FIGS. 9 and 10, the acoustic transducer 54 can be used to transmit signals from an implantable medical device 10 to a remote sensor 46 and receive signals from a remote sensor 46.

The invention has been described with respect to implantable medical 10 devices such as pacemakers and defibrillators, but could be adapted for use in any other implantable medical device, such as an insulin pump, neurostimulator, drug delivery system, pain management system, heart or lung sound sensor, or any other implantable medical device. The remote device 46 can comprise any 15 type of chronically implanted device or remote sensor adapted to deliver therapy or monitor biological functions, such as pressure sensor, glucose level monitor, a pulmonary sound sensor, volume sensor, satellite pacing device, or any other remote sensing or therapy-delivering device, and can be located anywhere in the body adapted for sensing a desired biological parameter or delivering therapy. A plurality of remote devices 46 could be implanted throughout the body and in 20 wireless communication with each other and with an IMD 10.

Various modifications and additions can be made to the exemplary 25 embodiments discussed without departing from the scope of the present invention. For example, while the embodiments described above refer to particular features, the scope of this invention also includes embodiments having different combinations of features and embodiments that do not include all of the described features. 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.

The claims defining the invention are as follows:

1. An implantable medical device for implantation into body tissue comprising:
 - a housing and a header coupled to the housing;
 - a cavity located in the header;
 - 5 a casing disposed within the cavity, the casing having a wall defining a coupling surface;
 - an ultrasonic transducer disposed inside the casing, the transducer adapted to transmit acoustic waves at a communication frequency; and
 - control circuitry disposed in the housing, the control circuitry adapted to
- 10 communicate with a remote device by driving the transducer at the communication frequency and processing electrical signals received from the transducer;
- 15 wherein the coupling surface is configured to be interposed between the ultrasonic transducer and the body tissue, the coupling surface having a resonance frequency greater than about 20kHz and the coupling surface configured to be acoustically coupled with the body tissue.
2. The implantable medical device of claim 1 wherein the ultrasonic transducer comprises a polyvinylidene diflouride (PVDF) material.
- 20 3. The implantable medical device of claim 2 wherein the ultrasonic transducer further comprises a substrate located adjacent to a back wall of the casing, the substrate includes an aperture, and the PVDF material is disposed over the aperture.
- 25 4. The implantable medical device of claim 1 wherein the ultrasonic transducer comprises a lead zirconate titanate (PZT) material and the coupling surface comprises a surface that resonates at the communication frequency.
- 30 5. The implantable medical device of claim 4 wherein the PZT material is coupled to the coupling surface.
- 35 6. The implantable medical device of claim 1 wherein a plurality of cavities are located in the header, each cavity having a casing disposed therein and each casing having an ultrasonic transducer disposed therein, each casing having a coupling surface that is interposed between each ultrasonic transducer and the body tissue and is acoustically coupled with the body tissue.

7. The implantable medical device of claim 6 wherein the header includes a plurality of surfaces, and at least two of the surfaces include a cavity.
8. The implantable medical device of claim 1 wherein the approximate shape of the ultrasonic transducer is circular.
9. The implantable medical device of claim 1 wherein the communication frequency is approximately 40 kiloHertz.
10. The implantable medical device of claim 1 wherein the ultrasonic transducer is adapted to receive acoustic waves at the communication frequency.
11. The implantable medical device of claim 1 wherein the implantable medical device includes a pulse generator.
12. An implantable medical device for implantation into body tissue comprising:
 - a housing and a header coupled to the housing;
 - a cavity located in the header;
 - a casing disposed within the cavity, the casing having a surface defining a coupling surface;
 - a means for communicating ultrasonic signals, the means for communicating located in the casing; and
 - control circuitry disposed in the housing, the control circuitry adapted to communicate with a remote device by driving the means for communication at the communication frequency and processing electrical signals received from the means for communication;
 - wherein the coupling surface is configured to be interposed between the means for communicating ultrasonic signals and the body tissue, the coupling surface having a resonance frequency greater than about 20 kHz and the coupling surface is configured to be acoustically coupled with the body tissue.
13. The implantable medical device of claim 12 wherein the means for communicating an ultrasonic signal comprises a piezoelectric transducer.

14. The implantable medical device of claim 12 wherein the means for communicating an ultrasonic signal comprises a cMUT transducer.

15. The implantable medical device of claim 12 wherein the means for communicating an ultrasonic signal comprises a plurality of cavities located in the header, each cavity having a casing disposed therein and each casing having an ultrasonic transducer disposed therein, each casing having a coupling surface that is interposed between each ultrasonic transducer and the body tissue and is acoustically coupled with the body tissue.

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16. The implantable medical device of claim 1 wherein the transducer is disposed within the casing such that a space is maintained between the transducer and an inner surface of the casing, the space being filled with a medium having an impedance that generally matches the impedance of the human body.

15

17. The implantable medical device of claim 1 wherein the transducer is disposed within the casing on the coupling surface.

20

18. The implantable medical device of claim 12 wherein the means for communicating is located within the casing such that a space is maintained between the means for communicating and the inner surface of the casing, the space being filled with a medium having an impedance that generally matches the impedance of the human body.

25

19. The implantable medical device of claim 12, wherein the transducer is located within the casing on the coupling surface.

Dated 23 June, 2009

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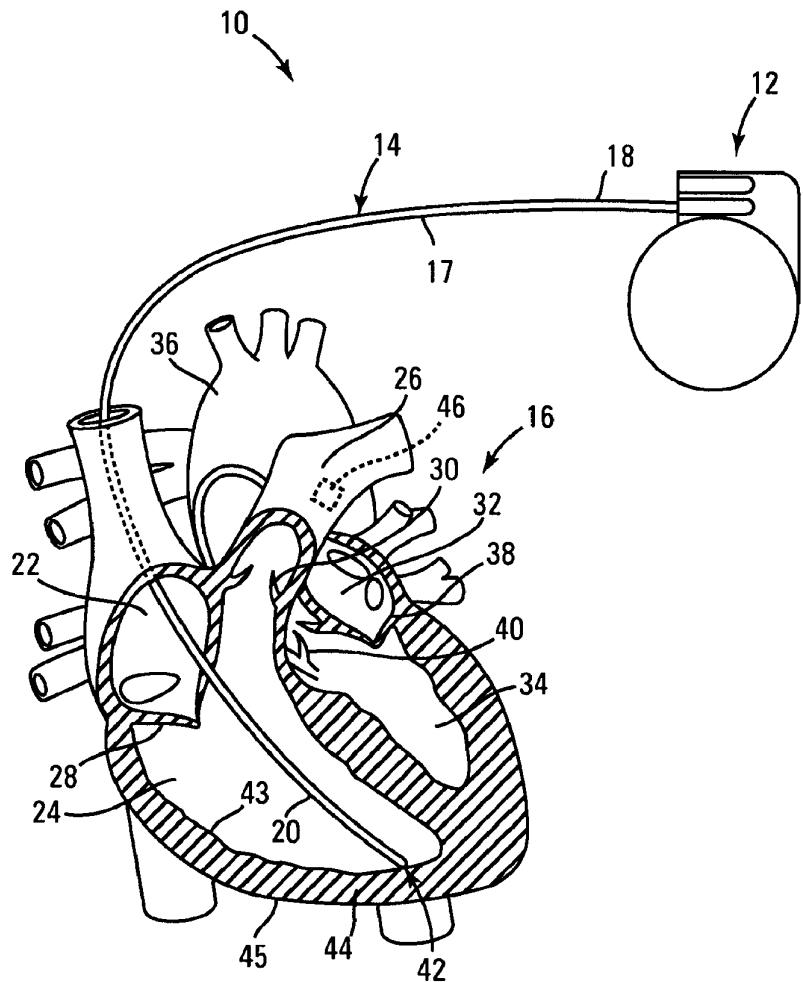


Fig. 1

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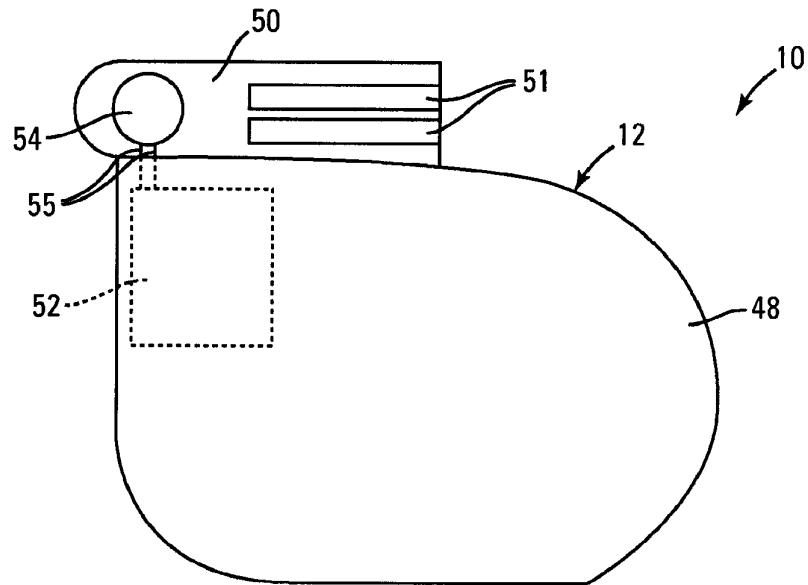


Fig. 2

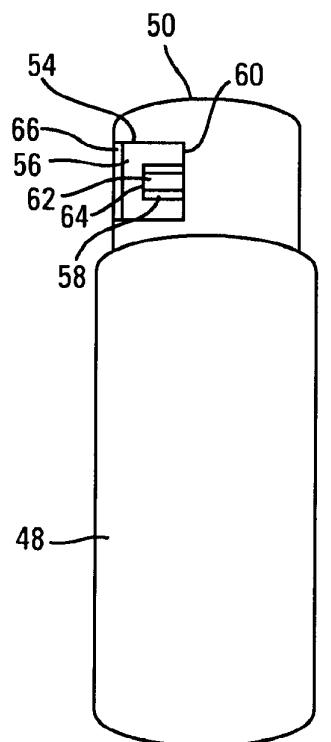


Fig. 3

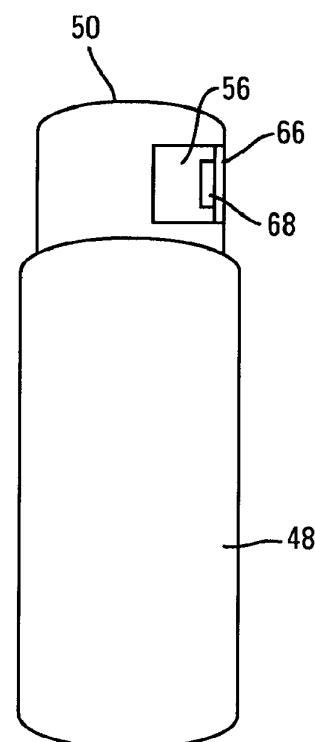


Fig. 4

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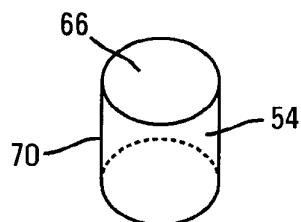


Fig. 5

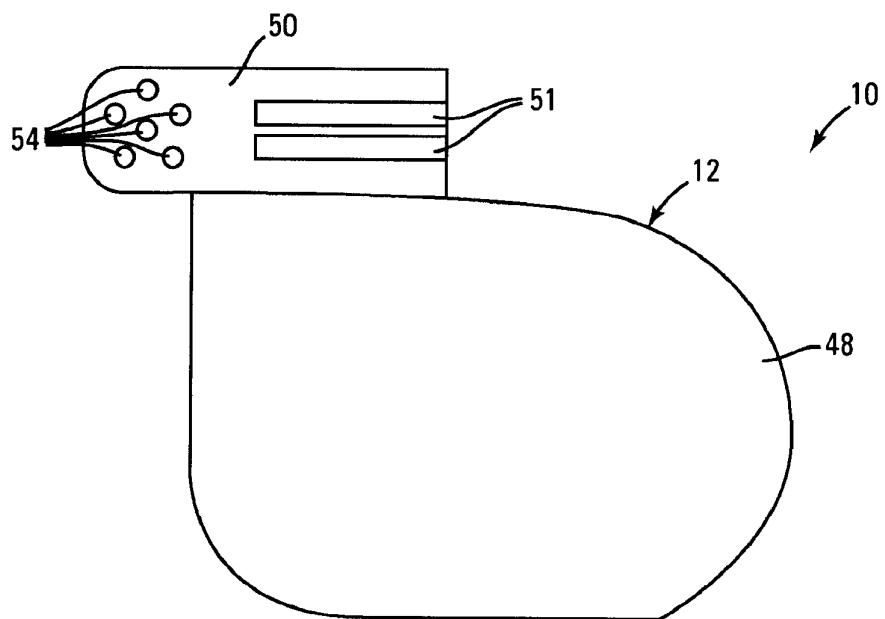
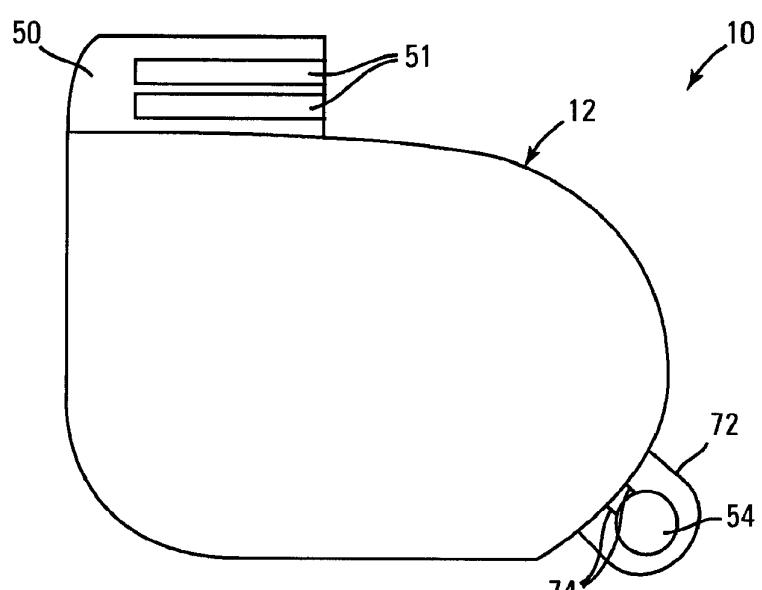


Fig. 6

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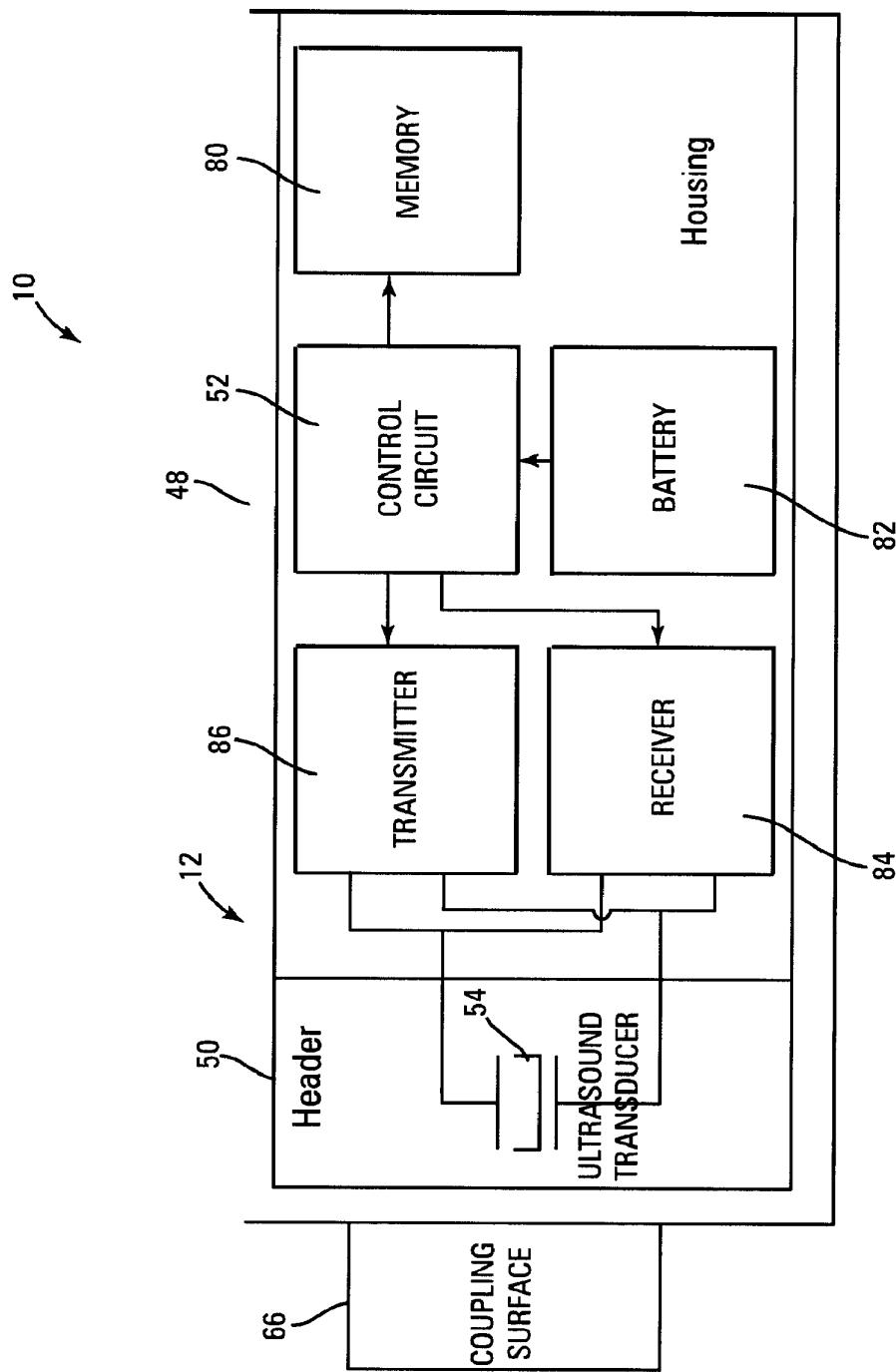


Fig. 8

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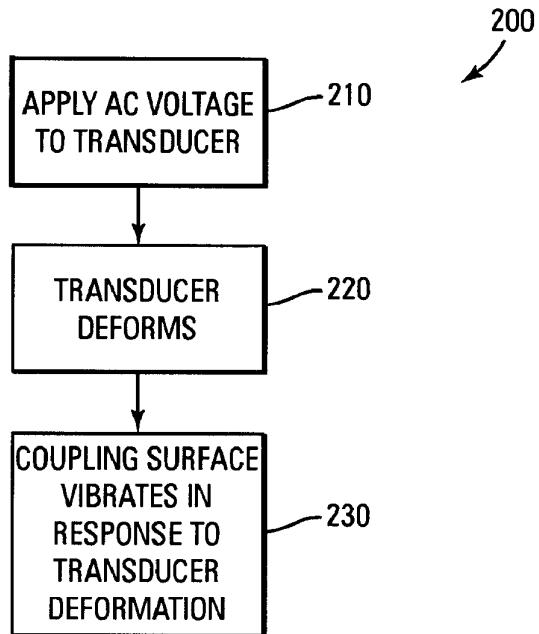


Fig. 9

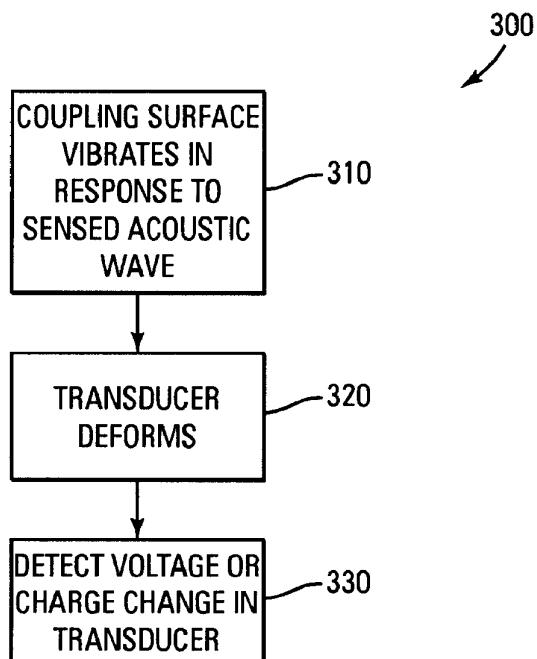


Fig. 10