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(71) Applicant (for all designated States except US): **REMON  
MEDICAL TECHNOLOGIES LTD** [IL/IL]; 7 Halamish  
Street, Caesarea Industrial Park, 38900 Caesarea (IL).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **PENNER, Avi** [IL/IL];  
1/13 Boyer Street, 69127 Tel Aviv (IL).

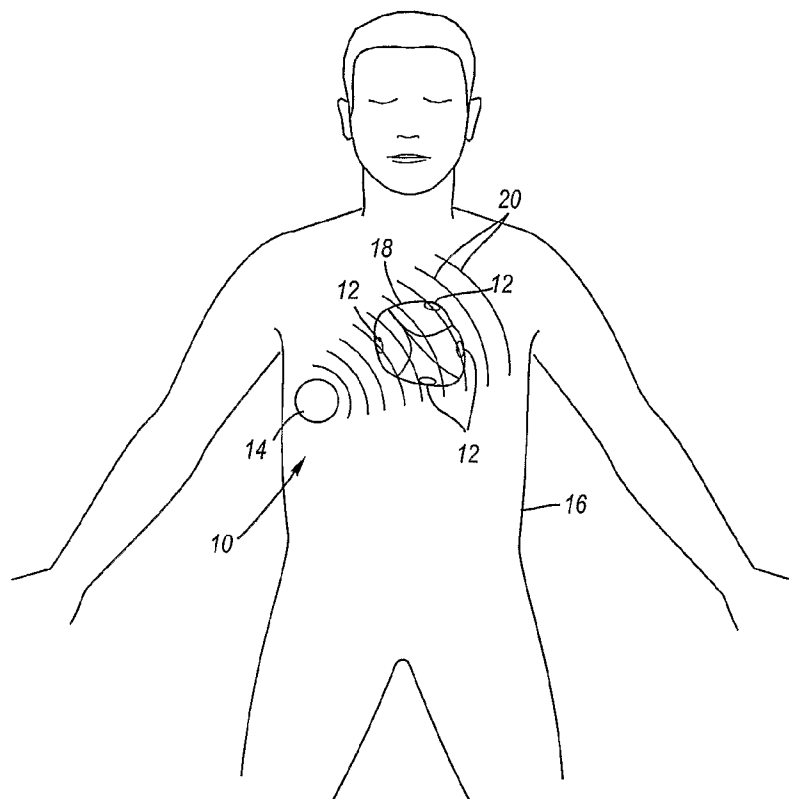
(74) Common Representative: **REMON MEDICAL  
TECHNOLOGIES LTD**; BURSE, David, T., Three Em-  
barcadero Center, Suite 1800, San Francisco, California  
94111-4067 (IL).

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(54) Title: ACOUSTICALLY POWERED IMPLANTABLE STIMULATING DEVICE



(57) Abstract: An implantable stimulation system comprises an implantable stimulator (12) and a control device (14). The control device (14) is configured to transmit acoustic waves to the implantable stimulator (12), and the implantable stimulator (12) is configured to transform the acoustic waves into electrical current, and generate stimulation energy based on the electrical current. For example, the electrical current can be transformed into electrical energy that can be used to generate the stimulation energy. Or the electrical current can contain signals used to directly or indirectly control the generation of the stimulation energy. The implantable stimulator may comprise a unique identification code enabling the control device to address the implantable stimulator. Further, the implantable stimulator may be configured to transmit acoustic waves containing diagnostic information (blood pressure information) to the control device.

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## ACOUSTICALLY POWERED IMPLANTABLE STIMULATING DEVICE

## FIELD OF THE INVENTION

The invention relates generally to medical devices for implantation within a  
5 patient's body.

## BACKGROUND OF THE INVENTION

Since the introduction of the heart rhythm control system--first as an  
implantable pacemaker in the 1960's, and then as an implantable defibrillator in 1980,  
implantable electrical stimulating devices have been developed to treat various  
10 medical diseases and physiological ailments, such as chronic pain disorders (e.g.,  
nerve injury, failed back syndrome, intractable facial pain, failed neck syndrome,  
reflex sympathetic dystrophy, thoracic outlet syndrome, and cancer), neurological  
disorders (e.g., intractable epilepsy and Parkinson's disease), motor disorders (e.g.,  
spasticity, dystonia, spasmodic torticollis, athetosis, head injury, spinal cord injury,  
15 stroke, multiple sclerosis, and cerebral palsy), cardiac rhythm disorders (e.g.,  
tachycardia and bradycardia), and psychosomatic disorders (e.g. depression and eating  
disorders).

Some of these implantable devices are currently being marketed. For  
example, implantable spinal cord stimulators are currently being used in patients to  
20 relieve pain in various parts of the body, e.g., chronic back and leg pain, cancer pain,  
postoperative spinal cord injury pain, and reflex sympathetic dystrophy pain. The  
implantation process involves placing leads in the epidural space of the spinal canal in  
a location that corresponds to the patient's zone of pain. A pulse generator is then  
implanted in the lower anterior abdominal wall and then connected to electrodes on

the leads via an extension that is percutaneously routed from the pulse generator to the leads. Once the system is fully implanted, the pulse generator can then be operated to provide low-voltage electrical stimulation of the spinal cord via the leads.

Another means for managing pain involves implanting micro-current electrical neuromuscular stimulators (MENS) within a patient in the area of the perceived pain. These devices use a very low current (typically 1-100 $\mu$ A) and operate on a cellular level to speed the healing process, thereby reducing pain. These devices have been specifically used to treat arthritic conditions, sports injuries, low back pain, carpal tunnel, tennis elbow, migraines and other disorders.

A stimulation system similar to the spinal cord stimulator described above is currently being used to treat Parkinson's Disease. In this application, a lead is surgically implanted into the patient's brain adjacent the subthalamic nucleus (STN) or globus pallidus internal (GPi), which control the involuntary movement symptomatic of Parkinson's Disease. A pulse generator is implanted in the patient's chest near the collarbone, and then connected to electrodes on the lead via an extension that percutaneously runs from the pulse generator to the lead. The pulse generator can then be operated to electrically stimulate the effected regions of the brain in order to block the signals that cause the disabling motor symptoms.

Pacemakers are used to alter the heart rate of a patient. A pacemaker, like the previously described devices, includes a pulse generator and leads. The pulse generator is implanted in a sub-dermal pocket in the patient chest, while the leads are inserted into a vein underneath the collar bone and threaded into the heart. Depending on the specific medical problem, a pacemaker can replace the S-A node signals that are delayed or get lost in the electrical pathway between the upper and lower heart. A pacemaker can also maintain a normal timing sequence between the upper and lower

heart, and make sure that the critical lower chambers of the heart contract at an adequate rate. A pacemaker can pace a single chamber or two chambers of the right side of the heart, or even synchronize the two ventricles for optimizing the heart pumping capability.

- 5           Other electrical stimulating devices might include peripheral nerve stimulators, medical delivery or activation systems, pumps for supporting a failing heart, controlling incontinence, or controlling the opening of a body passage, such as in a shunt for treating hydrocephalus.

- 10           All of the above-described devices provide power to the pulse generator in one of two ways: installing a battery within the pulse generator or transmitting wireless energy to the generator, e.g., by wirelessly transmitting power from an external transmitter via radio frequency (RF) telemetry to an internal sub-dermal receiver hard-wired to the pulse generator. In some cases, the pulse generators may be wirelessly controlled by an external command, for example, to obtain data, and/or to
- 15           activate or otherwise control the pulse generator. For those devices that use a battery, the size of the battery required to support the operational life of the device prevents the pulse generator from being located adjacent the stimulated region. As a result, the pulse generator is usually located in the body remote from electrodes, and a lead must be used to connect the generator and electrodes. For those devices that wirelessly
- 20           supply power or data to the generator, RF energy may only penetrate a few millimeters into a body, because of the body's dielectric nature. Thus, RF energy may not be able to provide power to, or otherwise communicate with, an implant that is located deep within the body.

- 25           Regardless of the means used to supply power to the pulse generator, it is sometimes possible to feel the pulse generator under the skin and visually notice a

slight deformity of the skin region that covers the generator. In addition, the requirement of a lead adds complexity to the medical procedure and increases the risk of infection, and in the case of pacemakers and spinal cord stimulators, increases the risk of damaging heart valves that are crossed by the lead or the spinal cord over which the lead is routed. In some cases, the electrodes may become destabilized due to the forces applied on them by the lead. In addition, the leads are typically composed of metal formed as a coil in which electrical current may be adversely induced in the presence of a strong magnetic field, such as that created during Magnetic Resonance Imaging (MRI). As a result, those patients in which these leads are implanted cannot undergo an MRI.

#### SUMMARY OF THE INVENTION

In one embodiment of the invention, an implantable stimulator is provided. The implantable stimulator comprises one or more acoustic transducers that are configured to transform acoustic waves into electrical current. The acoustic transducers can comprise any material capable of transforming acoustic energy into electrical energy, such as, e.g., a piezoelectric material. In selected embodiments, an array of acoustic transducers are used to maximize the received energy. The implantable stimulator further comprises a stimulating electrode configured to output stimulation energy to adjacent tissue. For example, the tissue can be heart tissue, in which case, the implantable stimulator may be a pacemaker or other cardiac therapeutic device, or the tissue can be nerve tissue, in which case, the implantable stimulator may be a neurostimulator. Other therapeutic devices are also contemplated by the invention. The stimulation energy is based on the electrical current resulting from the transformation in the acoustic transducers. For example, the energy of the electrical current can be used to generate the stimulation energy and/or signals within

the electrical current can be used to define the characteristics of the stimulation energy. The use of low-frequency acoustic energy (e.g., around 40 KHz) to energize and communication with the implantable stimulator allows the stimulator to be implanted deep within the tissue of a patient.

5           In one embodiment, the implantable stimulator comprises an energy storage device configured for storing the electrical current as electrical energy. In this case, the stored electrical energy can be subsequently used to generate stimulation energy under control of the implantable stimulator or another control device. The implantable stimulator may also comprise a switch configured for selectively  
10   outputting the electrical energy from the energy storage device to alternately activate and deactivate the implantable stimulator. In this manner, the implantable stimulator can be placed in a “dormant mode” when not in operation in order to conserve energy, and placed in an “active mode” when operated.

          In one embodiment, the implantable stimulator comprises control circuitry  
15   configured to control the stimulation energy output from the stimulation electrode. For example, the control circuitry can generate and output the stimulation energy or alternately open and close a switch to generate the stimulation energy. Memory can be provided for storing stimulation parameters, which can be used by the control circuitry to control the stimulation energy output from the stimulation electrode.

20           In another embodiment, the implantable stimulator can be a “dumb device” in that it lacks control circuitry. In this case, the stimulation energy can be generated in response to the electrical current. For example, the electrical current can contain communication signals that alternately open and close a switch in order to generate the stimulation energy. Or the electrical current can be directly transformed into the  
25   stimulation energy.

In another embodiment of the invention, a self-contained implantable stimulator is provided. The implantable stimulator comprises a casing that integrates the previously described acoustic transducers, stimulator electrode, and control circuitry. In this manner, external leads are not required, since all components  
5 necessary to generate the stimulation energy are provided in the casing.

In yet another embodiment of the invention, a stimulation system is provided. The stimulation system comprises a control device configured for transmitting acoustic waves through tissue. The control device can be an external device that can be applied to the skin of the patient or worn by the patient. Or the control device can  
10 be an implantable device. In the latter, case the implantable control device may be advantageously charged by an external device using acoustic or radio frequency (RF) energy.

The stimulation system further comprises at least one implantable stimulator configured for transforming the acoustic waves into electrical current, and outputting  
15 stimulation energy to adjacent tissue, e.g., heart or nerve tissue. The implantable stimulator(s) can be configured to control the stimulation energy output from the implantable stimulator, in which case, stimulation parameters used to control the stimulation energy can be stored in the implantable stimulator. The controller can alternatively be configured to directly control the stimulation energy output from the  
20 implantable stimulator.

In one embodiment, the implantable stimulator(s) is configured for storing the electrical current as electrical energy. The control device may be configured for transmitting other acoustic waves through the tissue to alternately activate and deactivate the implantable stimulator(s). If a plurality of implantable stimulators is  
25 provided, each stimulator can be assigned a unique identification code, so that the



control device can specifically address the implantable stimulators. For example, the use of unique identification codes may be particularly useful when the timing of the stimulation amongst the implantable stimulators must be coordinated.

In another embodiment, the implantable stimulator(s) is configured for transmitting diagnostic information to the control device, and the control device is configured for controlling the stimulation energy output from the implantable stimulator(s) based on these acoustic waves. For example, if the implantable stimulator(s) is configured for stimulating heart tissue (e.g., in the case of a pacemaker or implantable cardioverter defibrillator (ICD)), the diagnostic information can be pressure information indicative of blood flow, in which case, the heart tissue can be stimulated based on this pressure information.

Other objects and features of the invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

The drawings illustrate the design and utility of embodiment(s) of the invention, in which similar elements are referred to by common reference numerals, and in which:

**Fig. 1** is a plan view of an acoustic stimulation system constructed in accordance with one embodiment of the invention, particularly showing its use within a patient;

**Fig. 2** is a partially cut-away side view of an implantable stimulator used in the acoustic stimulation system of **Fig. 1**;

**Fig. 3** is a top view of the implantable stimulator of **Fig. 2**;

**Fig. 4** is a block diagram of a power/communication unit that can be used in the implantable stimulator of **Fig. 2**;

**Fig. 5** is a block diagram of an alternative power/communication unit that can be used in the implantable stimulator of **Fig. 2**;

5        **Fig. 6** is a block diagram of another alternative power/communication unit that can be used in the implantable stimulator of **Fig. 2**;

**Fig. 7** is a block diagram of still another alternative power/communication unit that can be used in the implantable stimulator of **Fig. 2**;

**Fig. 8** is a block diagram of yet another alternative power/communication unit  
10 that can be used in the implantable stimulator of **Fig. 2**;

**Fig. 9** is a side view of an alternative implantable stimulator that can be used in the acoustic stimulation system of **Fig. 1**;

**Fig. 10** is a side view of an external control device used in the acoustic stimulation system of **Fig. 1**;

15        **Fig. 11** is a block diagram illustrating the components of the external control device of **Fig. 10**; and

**Fig. 12** is a side view showing the use of an alternative implantable control device used to control implantable stimulators within a patient.

#### DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

20        Referring to **Fig. 1**, an acoustic stimulating system 10 constructed in accordance with one embodiment of the invention is described. The stimulating system 10 generally comprises a plurality of implantable stimulators 12, which in this embodiment, take the form of pacemakers implanted within the heart 18 of a patient 16. The implantable stimulators 12 are implanted within the heart 18 using minimally  
25        invasive means, e.g., a catheter. The stimulating system 10 further comprises a

control device 14 configured for being placed on the skin of the patient 16 in order to acoustically transmit acoustic waves 20 through the tissue of the patient 16 to the implantable stimulators 12. In the illustrated embodiment, the acoustic waves 20 can either be acoustic energizing waves or acoustic communication waves, as will be  
5 discussed in further detail below. Although, in the illustrated embodiment, the control device 14 is disclosed as an external device, an implantable control device can also be used to transmit acoustic waves 20 to the implantable stimulators 12, as will be described in further detail below.

The acoustic waves 20 transmitted by the control device 14 have a low  
10 frequency (e.g., 40 KHz). As such, the implantable stimulators 12 can be implanted within the deep tissue (such as the heart in this case) of the patient 16 without the need to route and implant leads within the body, thereby avoiding, or at least minimizing, the previously described complications. That is, all of the components necessary to stimulate tissue over the lifetime of the implantable stimulators 12 are  
15 contained within the implantable stimulators 12.

The control device 14 is configured to energize the implantable stimulators 12, so that the implantable stimulators 12 may subsequently or immediately output stimulation energy into the heart tissue. Besides energizing the implantable stimulators 12, the control device 14 is also configured to control the operation and  
20 configuration of the implantable stimulators 12. For example, the control device 14 may activate and deactivate implantable stimulators 12 (i.e., alternately placing them in an "active mode" and "dormant mode"). The control device 14 may also control the parameters of the stimulation energy (e.g., stimulation intensity, pulse duration, and frequency) output from any of the implantable stimulators 12. Significantly, many  
25 cardiac applications require that different regions of the heart be stimulated in a

particular sequence and delay between stimulations. For example, the two ventricles of the heart may need to be synchronized to optimize the heart pumping capability. As such, the control device 14 may also control the stimulation sequence and timing of the implantable stimulators 12 to achieve this goal.

5           The control device 14 can selectively communicate with the implantable stimulators 12 by assigning a unique identification code to each implantable stimulator 12. Thus, the control device 14 can selectively energize or communicate with a specific implantable stimulator 12 by incorporating a corresponding unique identification code into the signal transmitted from the control device 14, or  
10   alternatively, by transmitting a predetermined pulse sequence representing the identification code prior to energizing or communicating with the specified implantable stimulator 12. By the same token, a specific implantable stimulator 12 can identify itself to the control device 14 by incorporating its unique identification code into the signal transmitting from the control device 14 or by transmitting a pulse  
15   sequence representing the unique identification code.

          The stimulating system 10 can be designed in a number of manners. For example, in the embodiment, the control device 14 transmits acoustic energizing waves to an implantable stimulator 14, which transforms the acoustic waves into electrical current that are then stored as electrical energy. The implantable stimulator  
20   12 is designed with control logic, in which case, the control device 14 need only transmit stimulation parameters in the form of acoustic communication waves to program the control logic within the implantable stimulator 12, or alternatively, the implantable stimulator 12 can be preprogrammed with the stimulation parameters. The control logic will then control the stimulation energy output from the implantable  
25   stimulator 12 in accordance with these programmed stimulation parameters. For

example, the control logic can, itself, generate and output the stimulation energy, or the control logic can alternately open and close a switch that selectively outputs the stored electrical energy as stimulation energy.

As another example, the control device 14 may transmit acoustic energizing waves to the implantable stimulator 12, which are then transformed into electrical energy that is immediately used to generate the stimulation energy. In this case, the control logic transforms the electrical energy into stimulation energy in accordance with stimulation parameters stored in the implantable stimulator 12. As still another example, the control device 14 may transmit acoustic energizing waves in accordance with stimulation parameters stored in the control device 14, in which case, the resulting electrical current in the implantable stimulator 12 are immediately output from the implantable stimulator 12 as stimulation energy. In the later case, the electrical current may be further processed in order to generate stimulation energy that is suitable for the intended therapy. The key here is that no energy storage device is required, since the stimulation energy is immediately output in response to the electrical current.

As still another example, the control device 14 may transmit a series of acoustic communication waves in accordance with stimulation parameters stored in the control device 14. The implantable stimulator 12 transforms the acoustic waves into electrical current that alternately open and close a switch that generates the stimulation energy.

Although the implantable stimulators 12 have been described as pacemakers, it should be appreciated that the implantable stimulators 12 may take the form of any device used to therapeutically stimulate body tissue using electrical energy, e.g., an implantable cardioverter defibrillator (ICD), deep brain stimulator (DBS), pain relief

nerve stimulator, vagus nerve stimulator, or bladder control stimulator. It should also be appreciated that, although four implantable stimulators 12 are shown, any suitable number of implantable stimulators 12 can be used, including a single implantable stimulator 12.

5 Referring to **Figs. 2 and 3**, the implantable stimulator 10 will now be described in greater detail. The implantable stimulator 10 generally includes a casing 22 that is composed of a biocompatible material, e.g., titanium, gold, platinum, tantalum, stainless steel, or other metal. Other biocompatible materials may be used, e.g., a polymer, such as a fluorocarbon, polyamide, or poly ether ether ketone  
10 (PEEK), preferably covered with a metallization layer to improve the polymer's performance and/or to enhance its moisture resistance. The casing 22 is shaped such that the implantable stimulator 10 can be embedded within the tissue to be stimulated. In the illustrated embodiment, the casing 22 is bullet-shaped, with a flat end 24 that tapers down to a pointed region 26, that can penetrate into tissue. In order to secure  
15 and stabilize the implantable stimulator 10 within the tissue, several fixation hooks 28 are mounted to the exterior of the casing 22 near the pointed region 26.

The casing 22 is substantially sealed, and preferably hermetically sealed, to isolate the components of the implantable stimulator 12 from the environment in which the implantable stimulator 10 is to be placed. The casing 22 may include one  
20 or more regions that facilitate the passage of acoustic energy through the casing 22. For example, an acoustically transparent panel 30 is suitably mounted over the exposed flat side 24 of the casing 22. Preferably, the panel 30 is a relatively thin wall of titanium or other material, e.g., having a thickness of about one half millimeter (0.5 mm) or less, that may allow the acoustic waves 20 to pass substantially therethrough.

The implantable stimulator 10 further includes an acoustic transducer array 32, a stimulation electrode 34, a reference electrode 36, and a power/communication unit 38. The stimulation electrode 34 is mounted on the pointed region 26 of the casing 22, and the reference electrode 36 is mounted on the flat side 24 of the casing 22. The stimulation electrode 34 is used to electrically stimulate adjacent tissue, and the reference electrode 36 is used as a reference. In the illustrated embodiment, the transducer array 32 comprises four acoustic transducer cells 40 (shown in phantom in **Fig. 3**). It should be appreciated, however, that the number of transducer cells 40 will ultimately depend on the amount of power needed to energize the implantable stimulator 10, as will be described in further detail below.

The power/communication unit 38 is coupled to the acoustic transducer array 32 and reference electrode 36 via lead 42 and coupled to the stimulation electrode 34 via lead 44 (shown partially in phantom). The power/communication unit 38 is configured for providing electrical stimulation energy to the stimulation electrode 34 in accordance with stimulation parameters stored within the implantable stimulator 12. The implantable stimulator 12 may optionally include additional secondary stimulation electrodes (not shown), which may be coupled to the power/communication unit 38 via either separate leads, so that the power/communication unit 38 can independently transmit stimulation energy to the electrodes, or using lead 44, so that the power/communication unit 38 can transmit stimulation energy to the electrodes as a group. The implantable stimulator 12 may optionally include one or more sensors (not shown) capable of measuring physiological parameters, such as temperature, electrical impedance, pressure, position, strain, pH, fluid flow, and the like. As will be described in further detail below, this diagnostic information can be used to control the transmission of

stimulation energy. Further details regarding the use of sensors and corresponding componentry is disclosed in U.S. Patent Application Serial No. 09/989,912.

Referring still to **Fig. 2**, the acoustic transducer array 32 comprises a substrate 46, four cavities 48 formed completely or partially through the substrate 46, and a flexible piezoelectric layer 50 disposed over the substrate 46 across the cavities 48. The four cavities 48 are filled with a gas, such as air, and thus, the piezoelectric layer 50 will vibrate over the cavities 48, preferably at a frequency equal to the natural frequency of the piezoelectric layer 50. In the illustrated embodiment, each cavity 48 is circular, but can also have other shapes, such as elliptical or rectangular.

The previously described reference electrode 36 is mounted to the outer surface of the piezoelectric layer 50 between the cavities 48. Thus, it can be appreciated that the reference transducer 36 serves as both a common electrode that couples the transducer cells 40 together to provide energizing electrical energy, and a reference point during electrical stimulation of the stimulation electrode 34.

Alternatively, a separate common electrode or multiple electrodes (one for each transducer cell 40) can be used to provide the energizing electrical energy to the power/communication unit 38. The acoustic transducer array 32 further comprises four counter electrodes 52 (only two shown in **Fig. 2**) that are mounted to the inner surface of the piezoelectric layer 50 within the respective cavities 48. In the illustrated embodiment, the transducer cells 40 are connected in parallel by the common electrode 36 in order to increase the generated current. Alternatively, the transducer cells 40 can be connected in series in order to increase the generated voltage.

Thus, it can be appreciated that acoustic waves transmitted to the acoustic transducer array 32 from an external source will cause the piezoelectric layer 50 to



vibrate above the cavities 48. As a result, the periodic mechanical strain exerted on the piezoelectric layer 50 generates electrical current at the common electrode 36. Similarly, as electrical current are transmitted to the acoustic transducer array 32 from the power/communication unit 38, an electrical charge will be induced in the  
5 piezoelectric layer 50, thereby causing the piezoelectric layer 50 above the cavities 48 to periodically vibrate, resulting in the transmission of acoustic waves.

As best illustrated in **Fig. 2**, a plurality of depressions are formed in the piezoelectric layer 50, thereby enhancing the efficiency and/or sensitivity of the acoustic transducer array 32. The depressions may also be used to tune the natural  
10 resonant frequency of the piezoelectric layer 50. The depressions can be formed by providing the cavities 48 with an internal pressure that is less than the atmospheric pressure, such that the piezoelectric layer 50 partially enters the cavities 48.

In the illustrated embodiment, the diameter of each cavity 48 is approximately 1.2 mm, which results in a maximum acoustic to electrical energy exchange at a  
15 frequency of about 40 KHz—translating to a wavelength of 4 cm in water. Since each transducer cell 40 is much smaller than this wavelength, the performance of the implantable stimulator 12 is not affected by the orientation of the transducer array 32 with respect to the acoustic waves 20 transmitted by the control device 14. Further details regarding the structure and manufacture of acoustic transducer arrays are  
20 described in U.S. Patent No. 6,140,740.

Referring now to **Fig. 4**, the power/communication unit 38 comprises a rectifier 54 and an energy storage device 56. The rectifier 54 is coupled to the transducer array 32 for converting the electrical current generated by the transducer array 32 into a form suitable for powering components of the implantable stimulator  
25 12. Specifically, the rectifier 54 is configured for converting incoming alternating

current (AC) voltage from the transducer array 32 into direct current (DC) voltage for storage by the energy storage device 56. The rectification may be performed by diodes arranged in a configuration suitable for the requirements of the mode of operation, preferably resulting in a passive circuit that draws substantially no current.

5 For example, a half-bridge and full-bridge configuration can be used. Alternatively, other rectification circuits (not shown) may be used, including Schottky diodes, voltage triplers or other multiplier circuits, and the like. In addition, the rectifier 54 may include an overvoltage protector (not shown), which may prevent the energy storage device 56 from overcharging to unsafe levels. For example, the overvoltage  
10 protector may include a Zener diode, or a transistor that opens at a predetermined threshold voltage.

The energy storage device 56 is capable of being charged from an external source (such as the control device 14) using acoustic energy received by the acoustic transducer array 32. The energy storage device 56 may include any of a variety of  
15 devices, such as an energy exchanger, a battery, and/or a capacitor. Preferably, the energy storage device 56 is a battery capable of storing electrical energy substantially indefinitely unless actively discharged. In another embodiment, the energy storage device 56 may include both a capacitor and a primary, non-rechargeable battery, although, alternatively, the energy storage device 56 may include a secondary,  
20 rechargeable battery and/or capacitor that may be energized before activation or use of the implantable stimulator 12. For example, the energy storage device 56 may include a Lithium thin film battery, such as those available from Oak Ridge Micro-energy Inc. of Salt Lake City, Utah, Infinite Power Supply of Denver, Colorado, or Cymber Corporation of Elk River, Minnesota. Alternatively, the energy storage  
25 device 56 may include a standard coin type manganese lithium rechargeable battery,

such as those available from Matsushita Battery Industrial Co., Ltd. (MBI) of Osaka, Japan.

The power/communication unit 38 further comprises a controller 58 coupled between the electrodes 34 and 36 for providing electrical stimulation energy to the electrode 34. The controller 58 may include one or more controllers for controlling components of the implantable stimulator 12, timer circuitry (e.g., a clock or counter), reset and threshold circuitry, and/or a processor for generating electrical signals being transmitted by and/or analyzing electrical signals received by the transducer array 32. The controller 58 can be configured using digital signal processors (DSPs), Field Programmable Gate Arrays (FPGAs), Application Specific Integrated Circuit (ASIC)-compatible microprocessors, such as a CoolRISC processor available from Xemics, or other programmable devices, and/or any other hardware components or software modules that may be required for processing, analyzing, storing data, and controlling operation of the implantable stimulator 12.

The power/communication unit 38 further comprises signal detect circuitry 60 coupled to the transducer array 32 for providing a communication channel into the implantable stimulator 12, and specifically, to pass commands and/or information in the acoustic communication waves received by the transducer array 32 for use by the controller 58. For example, the signal detect circuitry 60 may pass commands or other signals to the controller 58, e.g., that acoustic energizing waves have been discontinued, that the implantable stimulator 12 should become operative and/or stimulation parameters. The signal detect circuitry 60 may be a passive FET circuit, thereby drawing substantially no current. The signal detect circuitry 60 may also include a smoothing capacitor (not shown) and/or logic for reducing the sensitivity of the signal detect circuitry 60 to spurious transient signals.

The power/communication unit 38 comprises optional transmission circuitry 62 coupled to the transducer array 32 for providing a communication channel from the implantable stimulator 12, e.g., to pass status information or optional sensor data to the control device 14 as acoustic communication waves. The signals are preferably digital electrical signals, which may be generated, for example, by grounding the counter electrodes 52 (shown in **Fig. 2**) of the transducer array 32 and alternately connecting the common electrode 36 (shown in **Fig. 2**) between ground and a predetermined voltage. Alternatively, the signals may be generated by alternately grounding the common electrode 36 and connecting the counter electrodes 52 to the predetermined voltage, and then grounding the counter electrodes 52 and connecting the common electrode 36 to the predetermined voltage. In a further alternative, the signal may be processed or modulated, e.g., using spread spectrum, direct sequence mixing, code division multiple access (CDMA), or other technologies, as will be appreciated by those skilled in the art.

The power/communication unit 38 comprises memory 64, e.g., volatile or non-volatile memory, including flash memory or ferroelectric memory. The memory 64 may store information, e.g., data received from the optional sensors of the implantable stimulator 12, commands and stimulation parameters for use by the controller 58 to provide stimulation energy to the electrode 34.

The power/communication unit 38 comprises a switch 66 coupled between the energy storage device 56 and the controller 58, such that all or part of the controller 58 may be selectively activated and deactivated under control of the control device 14. Optionally, use of the switch 66 may be foregone, in which case, the controller 58 can be directly connected to the energy storage device 56, such that at least some component(s) of the controller 58 may remain active at all times.

The switch 66 can be operated to alternately place the implantable stimulator 12 in an “active mode” or a “dormant mode.” Specifically, to place the implantable stimulator 12 in the active mode, the switch 66 may be closed upon acoustic excitation by an external acoustic energy source, e.g., from the control device 14, to allow current flow from the energy storage device 56 to the controller 58, thereby activating the implantable stimulator 12. To place the implantable stimulator 12 in a “dormant mode,” the switch 66 can may be opened upon acoustic excitation by the control device 14, to prevent current from flowing from the energy storage device 56 to the controller 58. Basically, an acoustic transmission from the control device 14 may vibrate the transducer array 32, forming a voltage pulse that is conveyed to the switch 66. When the voltage exceeds a predetermined threshold, e.g., about a half volt (0.5 V), the switch 66 may close if previously in an open state, or open if previously in an a closed state. Further details regarding the structure and function of the power/communication unit 38 are disclosed in U.S. Patent Application Serial No. 09/989,912.

Referring to **Fig. 5**, an alternative embodiment of a power/communication unit 138 that can be used in the acoustic stimulator 12 is described. The power/communication unit 138 is similar to the power/communication unit 38 described above, with the exception that the controller 58 immediately uses the electrical current to generate the stimulation energy. Specifically, the controller 58 receives the electrical energy directly from the rectifier 54 and generates the stimulation energy in response thereto. Any excess electrical energy not used by the controller 58 to generate the stimulation energy is output to the energy storage device 56 for subsequent use by the controller 58 or other components.

The following description illustrates exemplary energy consumption parameters needed for the power/communication unit 138 to generate the proper amount of stimulation energy, and, consequently, exemplary power requirements for the acoustic transducer array 32. A single acoustic transducer cell 40 will typically

5 generate 15 Pq/KPa at a frequency of approximately 40 KHz and a voltage of 10 V. The theoretical induced current at an acoustic pressure of 50 KPa will be 15 Pq/KPa X 50 KPa X 40 KHz = 30  $\mu$ A. Assuming a 50% AC to DC rectification efficiency, the practical induced current will be 15  $\mu$ A. The resulting power will be 15  $\mu$ A X 10 V = .15 mW. Assuming that twenty acoustic transducer cells 40 are connected in

10 parallel, the total power generated by the transducer array 32 will be 20 X .15 mW = 3 mW. A typical pacemaker has the following operational characteristics: amplitude of 2.5 V, frequency of 80 Hz, pulse width of 0.4 msec, and impedance of 1000 ohms. Thus, the power required by the acoustic stimulator 12 will be  $(2.5 \text{ V})^2 \times 1/1000$  ohms X 80 Hz X  $4 \times 10^{-4}$  sec = 0.2 mW. As such, the implantable stimulator 12

15 (assuming 20 transducer cells 40) will generate 15 times the energy required for pacing the heart 18. The excess energy can be used to charge the energy storage device 56 to allow operation of the implantable stimulator 12 without acoustic excitation from the control device 14.

Referring to **Fig. 6**, another alternative embodiment of a

20 power/communication unit 238 that can be used in the acoustic stimulator 12 will now be described. The power/communication unit 238 is similar to the previously described power/communication unit 38, with the exception that the controller 58 does not output the stimulation energy. Rather, the controller 58 alternately opens and closes the switch 66 in order to discharge the energy storage device 56 through the switch 66

25 to produce the stimulation energy. In this case, the frequency that the switch 66 is

opened and closed defines the frequency of the stimulation energy, and the duration that the switch 66 is opened in each cycle defines the pulse width of the stimulation energy.

Referring to **Fig. 7**, still another alternative embodiment of a power/communication unit 338 that can be used in the acoustic stimulator 12 will now be described. The power/communication unit 338 is similar to the previously described power/communication unit 238, with the exception that a controller 58 is not used to alternately open and close the switch 66. Instead, the control device 14 alternately opens and closes the switch 66 by transmitting acoustic communication waves 20 to the implantable stimulator 12. Because output of the stimulation energy is completely controlled by the control device 14, the power/communication unit 338 need not include a controller 58, thereby rendering the implantable stimulator 12 a “dumb device.” Of course, the power/communication unit 338 can alternatively use a controller 58 if control of other functions within the implantable stimulator 12, such as sensing, is needed.

Referring to **Fig. 8**, yet another alternative embodiment of a power/communication unit 438 that can be used in the acoustic stimulator 12 will now be described. Like the power/communication unit 338, the power/communication unit 438 is a “dumb device.” Unlike the power/communication unit 338, the output of the stimulation energy is not controlled by alternately opening and closing a switch 66. Rather, the control device 14 transmits acoustic energizing waves 20 in accordance with stimulation parameters stored in the control device 14. For example, the control device 14 can generate pulsed acoustic energizing waves 20 that is transformed into pulsed electrical energizing waves in the implantable stimulator 12. The power/communication unit 338 comprises a rectifier 54 that then transforms the AC

components of the pulsed electrical current into DC components, thereby resulting in a digital electrical signal, which is then output from the implantable stimulator 12 as stimulation energy.

Although the previously described implantable stimulator 12 is self-contained,  
5 thereby eliminating the need to implant and route external leads, other types of implantable stimulators can be used in the stimulation system 10 instead of the implantable stimulator 12. For example, **Fig. 9** illustrates an alternative embodiment of an implantable stimulator 72 that uses an external lead. Specifically, the implantable stimulator 72 comprises a stimulating electrode 74 and a control unit 76  
10 that are coupled together through an external lead 78. Alternatively, several stimulating electrodes can be provided. For example, the stimulating electrodes may be independent of each other, in which case, the electrodes can be connected to the control unit 76 via parallel external leads. Or the stimulating electrodes may be integrated together on a single unit, in which case, the electrode unit can be connected  
15 to the control unit 76 via a single external lead with one or more wires.

The control unit 76 comprises a casing 80 that is similar to the previously described casing 22, with the exception that the casing 80 is cylindrically shaped. The control unit 76 further comprises an acoustic transducer array 82 that is similar to the previously described transducer array 32, with the exception the transducer array 82 is  
20 circumferentially distributed around the cylindrical casing 80. The control unit 76 further comprises the previously described power/communication unit 84, which is suitably mounted within the casing 80. Since almost all of the componentry is located within the control unit 76, the stimulation electrode 74 can be made smaller, thereby facilitating delivery and implantation of the stimulation electrode 74 in the target



region of the heart 18. The control unit 76 may be implanted in the chest region of the patient 16.

With particular reference to **Figs. 10 and 11**, the control device 14 will now be described in detail. The control device 14 comprises a controller 86 for controlling its operation, and an energy storage device 88, e.g., a nonrechargeable or a rechargeable battery, coupled to the controller 86 and/or other components of the control device 14, such as a power amplifier or an oscillator (not shown). In addition, the control device 14 comprises an acoustic transducer 90 configured for converting between electrical current and acoustic waves in a similar manner described above with respect to the transducer array 32. Alternatively, separate and/or multiple acoustic transducers may be provided for transmitting and receiving acoustic waves.

The control device 14 further comprises memory 92 coupled to the controller 86, e.g., for storing commands, stimulation parameters, and/or data provided to the control device 14, as explained further below. The memory 92 may be a temporary buffer that holds data before transfer to another device, or non-volatile memory capable of storing the data substantially indefinitely, e.g., until extracted by the controller 86. For example, the memory 92 may be a memory card or an EPROM (not shown) built into the control device 14 or otherwise coupled to the controller 86. In the illustrated embodiment, the implantable stimulator 12 may be operated in a “half-duplex” mode. In this mode, the implantable stimulator 12 can only either transmit or receive during any given time. To this end, the control device 14 comprises a transmitting/receiving (T/R) switch 94, which toggles the transducer 90 to alternately transmit and receive acoustic energy. Lastly, the control device 14 comprises a casing 96 for housing the previously described components.

As best illustrated in **Fig. 10**, the control device 14 is preferably carried by a patch 15 that may be secured to a patient, e.g., to the patient's skin. For example, the patch 15 may include one or more layers of substantially flexible material to which the control device 14 and/or its individual components are attached. The patch 15 may include a single flexible membrane (not shown) to which the control device 14 is bonded or otherwise attached, e.g., using a substantially permanent adhesive, which may facilitate conformance of the patch 15 to the patient's anatomy. Alternatively, the control device 14 may be secured between layers of material, e.g., within a pouch or other compartment (not shown) within the patch 15. For example, the patch 15 may include a pair of membranes (not shown) defining the pouch or compartment. The space within which the control device 14 is disposed may be filled with material to acoustically couple the acoustic transducer 90 of the control device 14 to an outer surface of the patch 15. Alternatively, the acoustic transducer 90 may be exposed, e.g., in a window formed in a wall of the patch 15.

The patch 15 may be formed from a flexible piezoelectric material, such as Polyvinylidene Fluoride (PVDF) or a PVDF copolymer. Such polymers may allow the patch 15 to produce ultrasonic waves, as well as allowing the control device 14 to be secured to the patient's skin. Thus, the wall of the patch 15 itself may provide an acoustic transducer for the control device 14, i.e., for transmitting acoustic energy to and/or receiving acoustic energy from the implantable stimulator 12.

The patch 15 may then be secured to the patient's skin using a material, such as a layer of adhesive (not shown), substantially permanently affixed or otherwise provided on a surface of the patch 15. The adhesive may be hydrogel, silicon, polyurethane, polyethylene, polypropylene, fluorocarbon polymer, and the like. Alternatively, a separate adhesive may be applied to the patch 15 and/or to the

patient's skin before applying the patch 15 in order to secure the control device 14 to the patient's skin. Such an adhesive may enhance acoustic coupling of the acoustic transducer(s) of the control device 14 to the patient's skin, and consequently to the implantable stimulator 12. Optionally, additional wetting material, including water, 5 silicone oil, silicone gel, hydrogel, and the like, and/or other acoustically conductive material may be provided between the patch 15 or the acoustic transducer 90, and the patient's skin, e.g., to provide substantial continuity and minimize reflection or other losses and/or to secure the patch 15 to the patient 16.

The patch 15 may be relatively light and compact, for example, having a 10 maximum surface dimension (e.g., width or height) not more than about ten to two hundred millimeters (10-200 mm), a thickness not more than about five to one hundred millimeters (5100 mm), and a weight not more than about twenty to four hundred grams (20-400 g), such that the control device 14 may be inconspicuously attached to the patient. Thus, the patient 16 may be able to resume normal physical 15 activity, without substantial impairment from the control device 14. Yet, the energy storage device 88 may be sufficiently large to communicate with the implantable stimulator 12 for an extended period of time, e.g., for hours or days, without requiring recharging or continuous coupling to a separate energy source.

Alternatively, the control device 14 may be carried by a belt (not shown) that 20 may be secured around the patient, e.g., such that the acoustic transducer 90 is secured against the patient's skin. The belt may carry other components, e.g., an external power supply for the control device 14. For example, a battery pack (not shown) may be carried by the belt that may be coupled to the control device 14 for providing electrical energy for its operation. Alternatively, the control device 14 may take the

form of a probe that is not worn by the patient 16, but rather can be selectively placed on the chest in order to communicate with the implantable stimulator 16.

Alternatively, a control device, similar to the previously described control device 14, may be implanted within the patient 16, e.g., the chest near the heart region. For example, **Fig. 12** illustrates an implantable control device 114 that can be used to communicate with an implantable stimulators 16 within the heart 18 of the patient 16. In this case, the implantable control device 114 communicate in the same manner as the control device 14. The main difference is that the implantable control device 114 is preferably capable of being recharged by an external energizing device 116 via RF or acoustic energy. In addition, the implantable control device 114 will typically not have the required stored energy for energizing the implantable stimulators 16. Instead, the implantable stimulators 16 may be energized by the external energizing device 116. In this case, the implantable control device 114 will be used to control the operation of the implantable stimulators 16, e.g., by alternately activating and deactivating selected implantable stimulators 16, or otherwise controlling the stimulation energy output from the implantable stimulators 16. Further details on this particular arrangement are disclosed in U.S. Patent Application Serial No. 10/413,428.

When used in conjunction with the implantable stimulator 12 having the power/communication unit 36 or power/communication unit 236 illustrated in respective **Figs. 4 and 6**, the control device 14 can be operated in an “energizing mode” or “activation mode.” When operated in either of these modes, the control device 14 transmits acoustic waves 20 from the acoustic transducer 90 through the body of the patient 16, with at least a portion of the acoustic waves 20 striking the transducer array 32 of the implantable stimulator 12. The transducer array 32

converts the acoustic waves into electrical current, which are used to either charge the energy storage device 56 or communicate with the controller 86 in the implantable stimulator 12 depending on the operational mode.

At the beginning of the energizing mode, the control device 14 determines the optimum frequency at which the implantable stimulator 12 should be energized. For example, the control device 14 may transmit a broadband acoustic waves or scanning waves, i.e., scanning through a range of frequencies, and wait for the implantable stimulator 12 to respond. The implantable stimulator 12 may transmit acoustic waves at different frequencies in response to the diagnostic signal, and the control device 14 may determine the optimal frequency for communicating with the implantable stimulator 12 based upon the responses. For example, the control device 14 may repeatedly charge the implantable stimulator 12 using different frequency signals and measure the length of time that the implantable stimulator 12 is capable of transmitting data signals at each frequency to determine the optimal frequency. Alternatively, when the implantable stimulator 12 detects the signal, it may transmit a response at an optimal frequency that should be used to communicate with the implantable stimulator 12.

Once the control device 14 has determined the optimal frequency for communicating with the implantable stimulator 12 (or the control device 14 may already know the proper frequency to use), the control device 14 then transmits acoustic energizing waves 20 to the implantable stimulator 12, which are transformed and stored in the energy storage device 56 as electrical energy. The energy storage device 56 continues to store electrical energy until a predetermined voltage is achieved, e.g., about eight Volts (8 V), and then the controller 58 automatically disconnects the energy storage device 56 from the transducer array 32. After a

predetermined time, e.g., between about five and sixty seconds (5-60 sec.), the control device 14 automatically ceases the energizing transmission. Alternatively, the control device 14 may cease energizing the implantable stimulator 12 by transmitting a stop command.

5           During the activation mode, the control device 14 transmits a command to the implantable stimulator 12 to close the switch 66, thereby placing the implantable stimulator 12 in the active mode. Once activated, the implantable stimulator 12 draws electrical energy from the energy storage device 56, and begins to transmit electrical energy to the stimulation electrode 34 in accordance with stimulation parameters,  
10   which may be previously stored in the memory 92 or may be transmitted from the control device 14 immediately after activation of the implantable stimulator 12. Alternatively, if no switch 66 is used, the control device 14 may transmit a start command to the implantable stimulator 12, which responds by transmitting electrical energy to the stimulation electrode 34.

15           The implantable stimulator 12 continues to stimulate the tissue until the control device 14 transmits a command to the implantable stimulator 12 to open the switch 66, thereby deactivating the implantable stimulator 12 and placing it in the dormant mode. Alternatively, if no switch 66 is used, the control device 14 may transmit a stop command to the implantable stimulator 12, which responds by ceasing  
20   transmission of the electrical energy to the stimulation electrode 34. Stimulation may also cease if the voltage of the energy storage device 56 falls below a predetermined threshold, e.g., below a level at which the stimulation electrode 34 may not continue to operate effectively, such as 1.5 volts. After the voltage falls below the predetermined threshold, the controller 58 may automatically discontinue operation of

the implantable stimulator 12 by opening the switch 66 and returning to a dormant state until energized and activated by the control device 14.

Prior to, during, or subsequent to the activation mode, the control device 14 and implantable stimulator 12 may communicate additional information to each other.

5 For example, the implantable stimulator 12 may transmit diagnostic information, which has been sensed by the optional sensor (not shown), to the control device 14. The control device 14 can then use this information to control the operation of the implantable stimulator 12. For example, the optional sensor can be a pressure sensor that can sense the blood flow through the heart chamber in which the implantable  
10 stimulator 12 is located. In this case, the implantable stimulator 12 can transmit pressure information to the control device 14. Alternatively, the pressure sensor may be even associated with another implantable device that is located in another region of the body, e.g., a pulmonary vein. The control device 14 may then respond to this pressure information by either activating or deactivating the implantable stimulator  
15 12.

For example, if the pressure information indicates that the blood flow is below normal, the control device 14 may activate the implantable stimulator 12 by transmitting commands to close the switch 66, thereby initiating stimulation of the heart tissue. Once the diagnostic information indicates that the blood flow has been  
20 normal for a predetermined period of time, the control device 14 can then deactivate the implantable stimulator 12 by transmitting commands to open the switch 66, thereby ceasing stimulation of the heart tissue. This technique lends itself well to implantable cardioverter defibrillators (ICDs), which are designed to shock the heart when the blood pressure within the heart falls to a dangerous level. The control  
25 device 14 may alternatively or optionally use the diagnostic information to control the

implantable stimulator 12 by controlling the parameters of the stimulation energy output by the implantable stimulator 12.

As another example for communicating information to each other, the control device 14 may transmit an identification code when transmitting commands to open or close the switch 66 in the implantable stimulator 12. In this manner, timing and sequence of the stimulation energy output from all of the implantable stimulators 12 can be controlled. Prior to placing the implantable stimulator 12 in the dormant mode, the controller 58 may transmit status information to the control device 14, e.g., an initial confirmation of instructions received from the control device 14, an identification code identifying the implantable stimulator 12, and/or a stop notice when stimulation is being discontinued by the controller 58.

As a safety measure against false positives (e.g., erroneous activation or deactivation), the control device 14 may acoustically transmit an initiation signal followed by a confirmation signal. When the implantable stimulator 12 receives these signals, the controller 58 may monitor the signals for a proper sequence, thereby ensuring that the switch 66 only closes upon receiving the proper initiation and confirmation signals. For example, the controller 58 may only acknowledge an activation signal that includes a first pulse followed by a second pulse separated by a predetermined delay. Use of a confirmation signal may be particularly important for certain applications, for example, to prevent unintentional stimulation of the heart 18.

In the case where the power/communication unit 138 illustrated in Fig. 5 is used in the implantable stimulator 12, the electrical current transformed by the implantable stimulator 12 is not used to charge the energy storage device 56, but rather to immediately generate stimulation energy. As such, the control device 14 is operated in the energizing mode in order to energize the implantable stimulator 12,



resulting in immediate output of the stimulation energy to the tissue. Communication between the implantable stimulator 12 and control device 14 can be accomplished in the same manner previously discussed above.

In the case where the power/communication unit 238 illustrated in **Fig. 7** is used in the implantable stimulator 12, the control device 14 can be designed to operate in the previously described “energizing mode” and a “stimulation mode.” In the energizing mode, the control device 14 energizes the implantable stimulator 12 in the same manner described above. In the stimulation mode, the control device 14 transmits acoustic communication waves to the implantable stimulator 12 in order to alternately open and close the switch 66, so that energy storage device 56 is periodically discharged to generate and output the stimulation energy.

In the case where the power/communication unit 338 illustrated in **Fig. 8** is used in the implantable stimulator 12, the control device 14 can be designed to operate in the energizing mode. In this case, the control device 14 transmits pulsed acoustic energizing waves in accordance with stimulation parameters stored in the control device 14. The implantable stimulator 12 responds by transforming the AC components of the resulting electrical current into DC components. That is, the pulsed AC electrical current are transformed into pulses DC electrical current, which are then output as the stimulation energy.

## CLAIMS

1. An implantable stimulator, comprising:  
one or more acoustic transducers configured to transform acoustic waves into electrical current; and  
5 a stimulating electrode configured to output stimulation energy to adjacent tissue, the stimulation energy based on the electrical current.
2. The implantable stimulator of claim 1, wherein the one or more acoustic transducers comprises an array of acoustic transducers.
3. The implantable stimulator of claims 1 - 2, further comprising an  
10 energy storage device configured for storing the electrical current as electrical energy.
4. The implantable stimulator of claim 3, further comprising a switch configured to selectively output the electrical energy from the energy storage device to alternately activate and deactivate the implantable stimulator.
5. The implantable stimulator of claim 1, further comprising control  
15 circuitry configured to control the stimulation energy output from the stimulation electrode.
6. The implantable stimulator of claim 5, further comprising memory for storing stimulation parameters, the control circuitry using the stored stimulation parameters to control the stimulation energy output from the stimulation electrode.
- 20 7. The implantable stimulator of claim 5, wherein the control circuitry outputs the stimulation energy.
8. The implantable stimulator of claim 5, further comprising a switch that is alternately opened and closed by the control circuitry to generate the stimulation energy.

9. The implantable stimulator of claim 1, wherein the stimulation energy is generated in response to the electrical current.
10. The implantable stimulator of claim 9, further comprising a switch that is alternately opened and closed in response to the electrical current to generate the stimulation energy.
11. The implantable stimulator of claim 9, wherein the stimulation energy is directly transformed from the electrical current.
12. The implantable stimulator of any of claims 1 - 11, wherein the stimulation energy output from the stimulating electrode is configured to therapeutically stimulate heart tissue.
13. The implantable stimulator of any of claims 1 - 11, wherein the stimulation energy output from the stimulating electrode is configured to therapeutically stimulate nerve tissue.
14. An implantable stimulator, comprising:  
one or more acoustic transducers configured to transform acoustic waves into electrical current;  
a stimulating electrode configured to output stimulation energy to tissue adjacent the electrode, the stimulation energy based on the electrical current;  
control circuitry configured to control the stimulation energy output from the stimulation electrode; and  
a casing that integrates the one or more acoustic transducers, stimulating electrode, and control circuitry.
15. The implantable stimulator of claim 14, further comprising an energy storage device configured for storing the electrical current as electrical energy,

wherein the casing integrates the energy storage device with the one or more acoustic transducers, stimulating electrode, and control circuitry.

16. The implantable stimulator of claim 15, further comprising a switch configured to selectively output the electrical energy from the energy storage device to alternately activate and deactivate the implantable stimulator, wherein the casing integrates the switch with the one or more acoustic transducers, stimulating electrode, and control circuitry.

17. The implantable stimulator of claim 14, further comprising memory for storing stimulation parameters, the control circuitry using the stored stimulation parameters to control the stimulation energy output from the stimulation electrode, wherein the casing integrates the memory with the one or more acoustic transducers, stimulating electrode, and control circuitry.

18. The implantable stimulator of claim 14, further comprising a switch that is alternately opened and closed by the control circuitry to generate the stimulation energy.

19. The implantable stimulator of claim 14, wherein the stimulation energy output from the stimulating electrode is configured to therapeutically stimulate heart tissue or nerve tissue.

20. A stimulation system, comprising:  
a control device configured for transmitting acoustic waves through tissue;  
at least one implantable stimulator configured for transforming the acoustic waves into electrical current, and outputting stimulation energy to adjacent tissue, the stimulation energy based on the electrical current.

21. The stimulation system of claim 20, wherein the control device is configured for transmitting other acoustic waves through the tissue to alternately activate and deactivate the at least one implantable stimulator.

22. The stimulation system of claim 20, wherein the at least one  
5 implantable stimulator is configured to control the stimulation energy output from the implantable stimulator.

23. The stimulation system of claim 20, wherein the at least one  
implantable stimulator is configured for storing stimulation parameters, and using the  
stored stimulation parameters to control the stimulation energy output from the  
10 implantable stimulator.

24. The stimulation system of claim 20, wherein the at least one  
implantable stimulator is configured to therapeutically stimulate heart tissue or nerve  
tissue.

25. The stimulation system of claim 20, wherein the at least one  
15 implantable stimulator comprises a plurality of implantable stimulators.

26. The stimulation system of claim 25, wherein the plurality of  
implantable stimulators comprises a respective plurality of unique identification  
codes, and wherein the control device is configured to specifically address the  
implantable stimulators based on the unique identification codes.

20 27. The stimulation system of claim 25, wherein the control device is  
configured for controlling the stimulation energy output from the respective  
implantable stimulators in accordance with a timing pattern.

28. The stimulation system of claim 20, wherein the control device is an  
external device.

29. The stimulation system of claim 20, wherein the control device is an implantable stimulator.

30. The stimulation system of claim 20, wherein the at least implantable stimulator is configured for transmitting acoustic waves to the control device, and the control device is configured for controlling the stimulation energy output from the at least one implantable stimulator based on the acoustic waves transmitted by the at least one implantable stimulator.

31. The stimulation system of claim 20, wherein the acoustic waves transmitted by the at least one implantable stimulator contains diagnostic information.

32. The stimulation system of claim 31, wherein the at least one implantable stimulator is configured to therapeutically stimulate heart tissue, and the diagnostic information is blood pressure information.

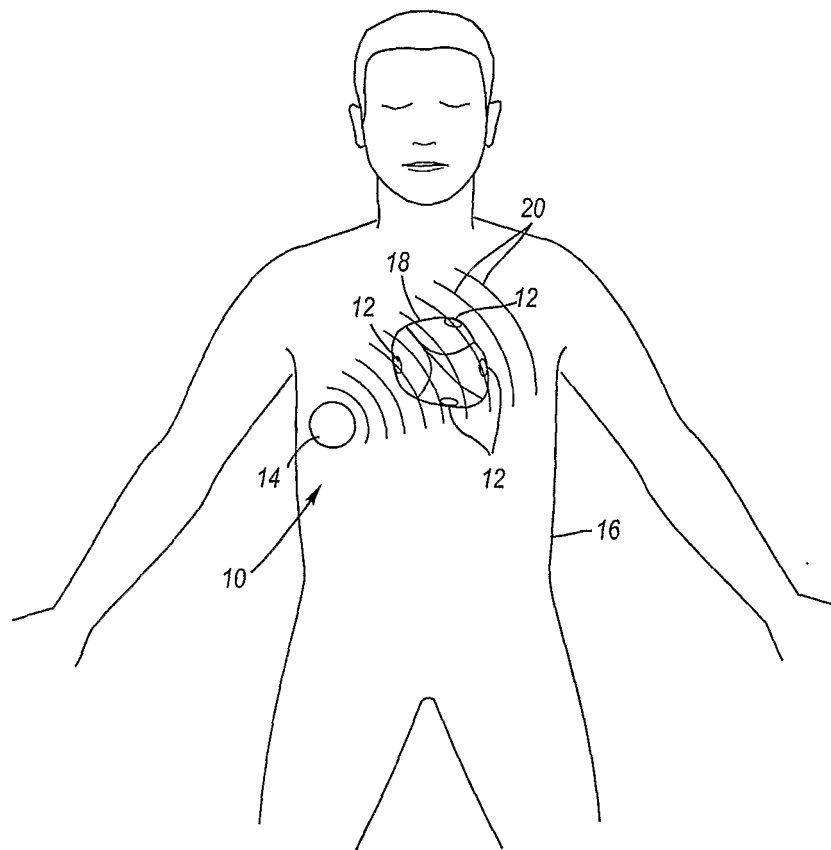


FIG. 1

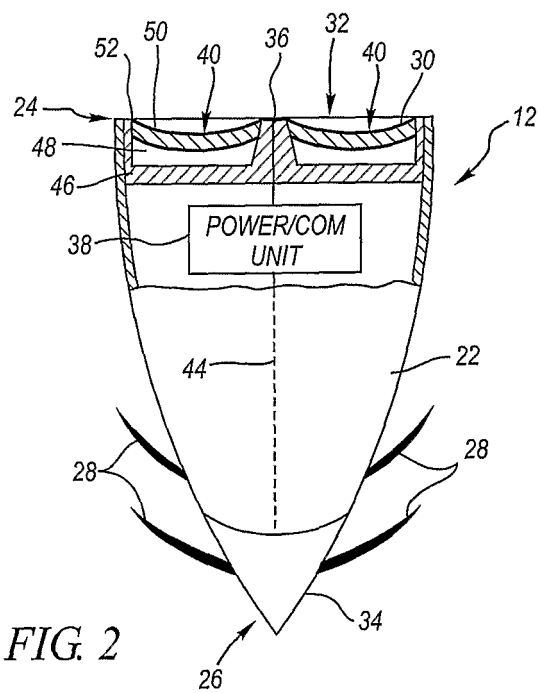


FIG. 2

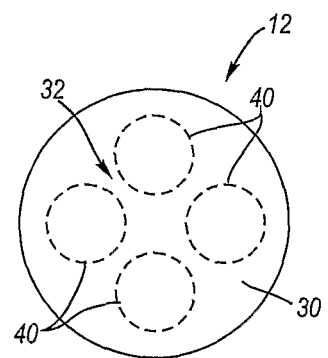


FIG. 3

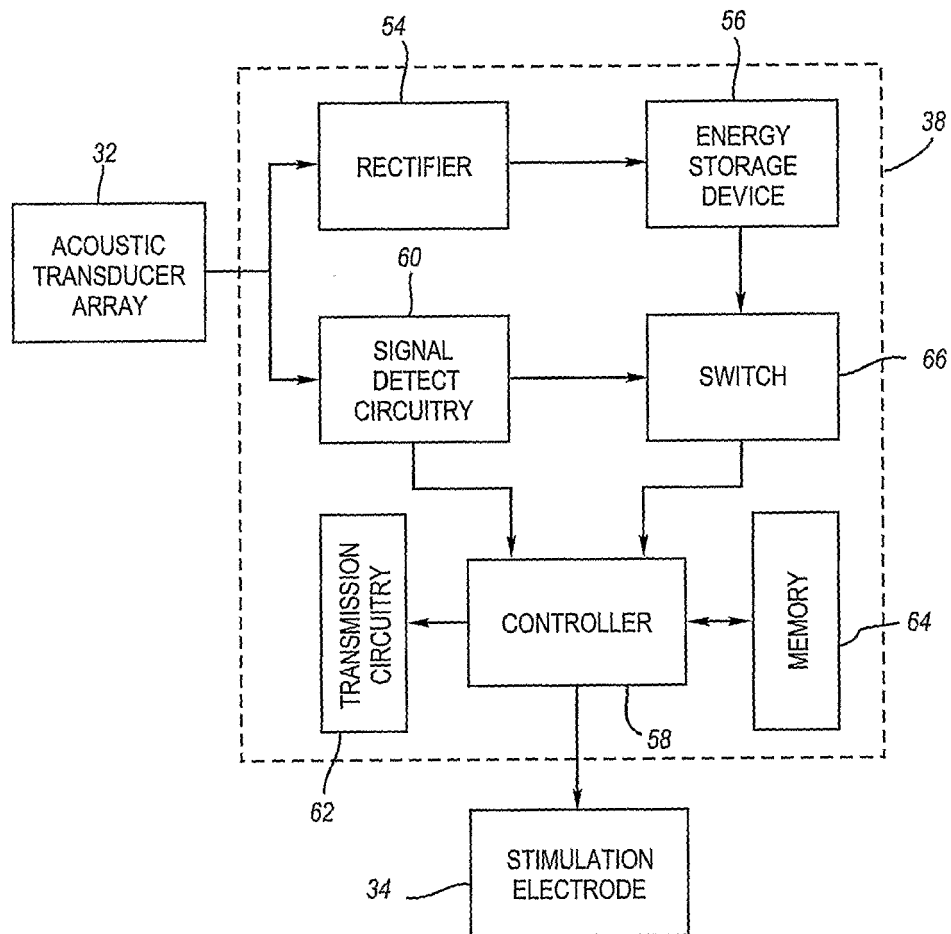


FIG. 4



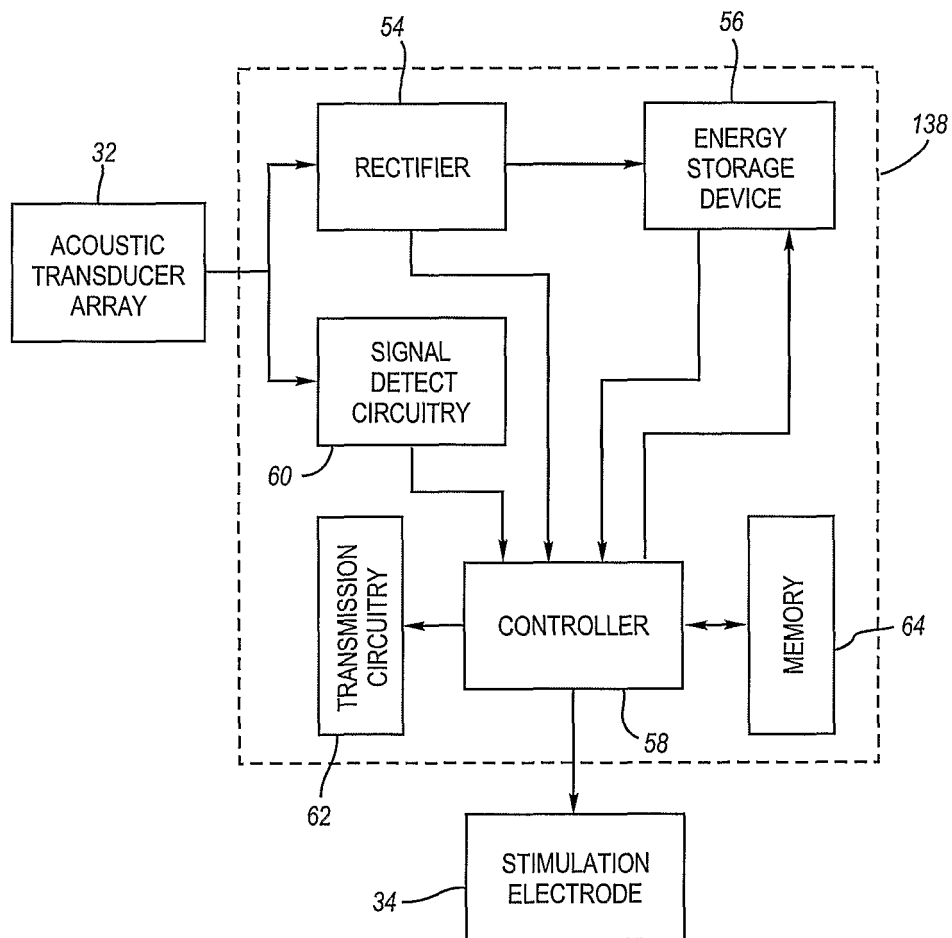


FIG. 5

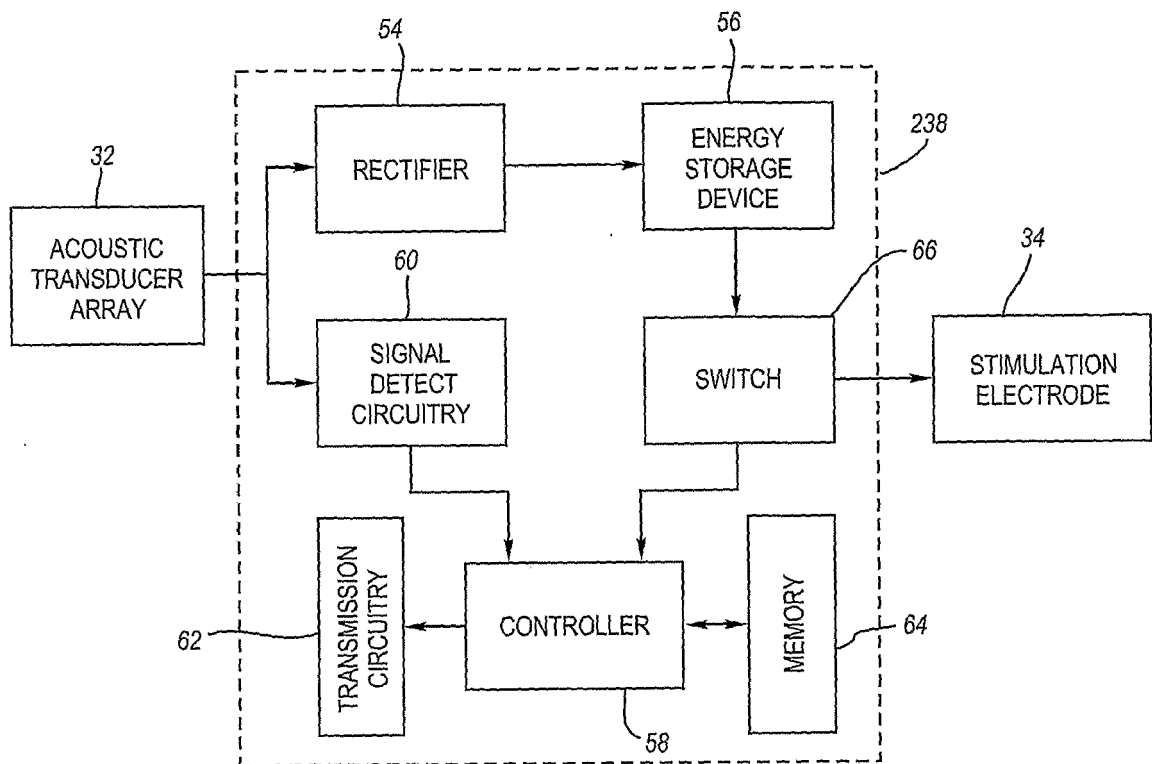


FIG. 6

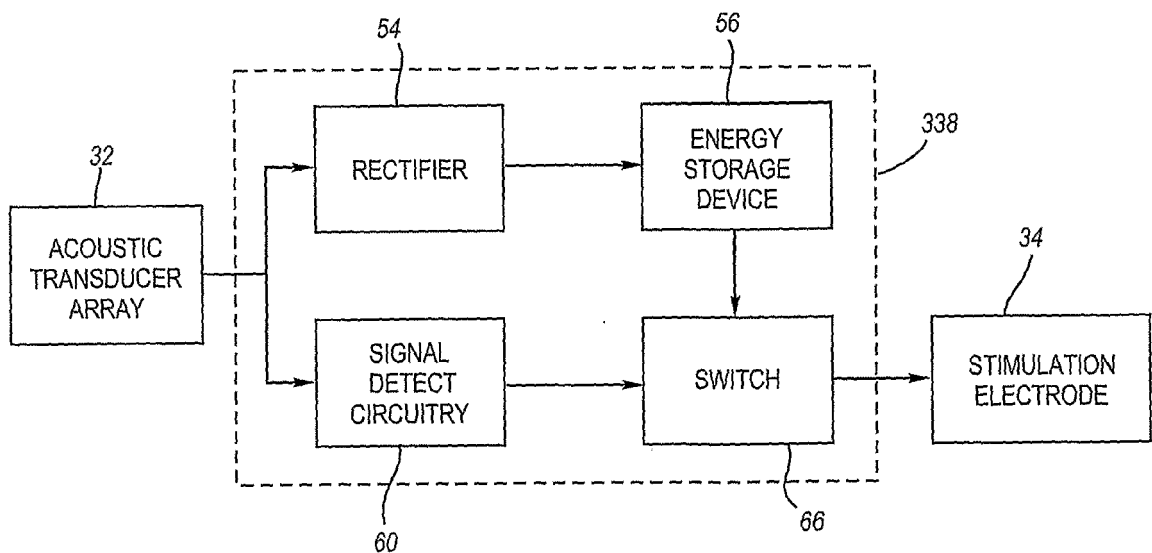


FIG. 7

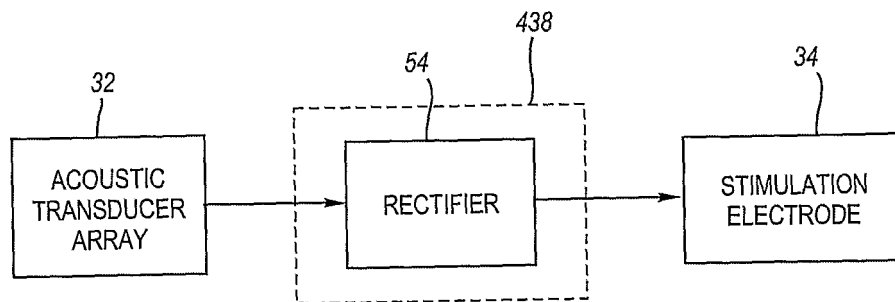


FIG. 8

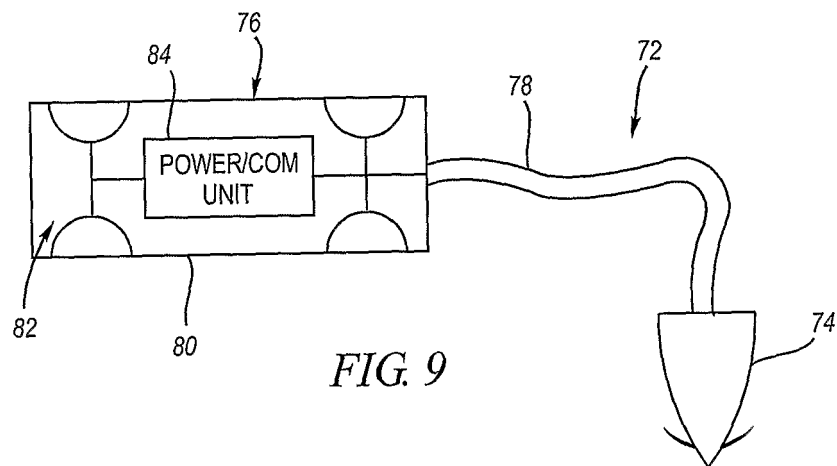


FIG. 9

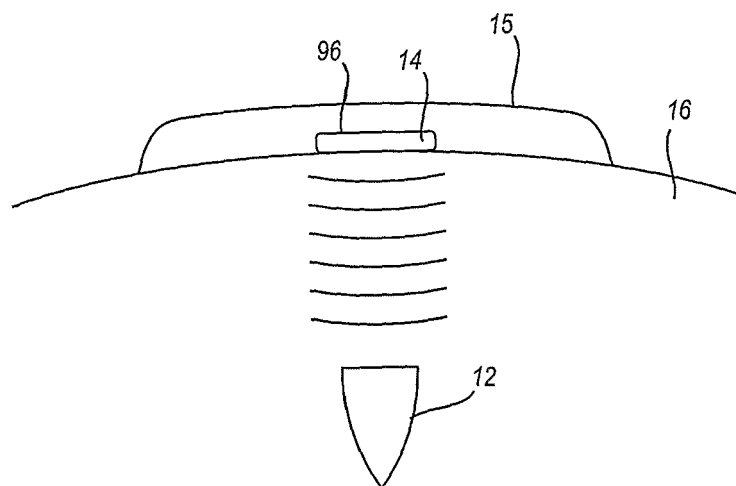


FIG. 10

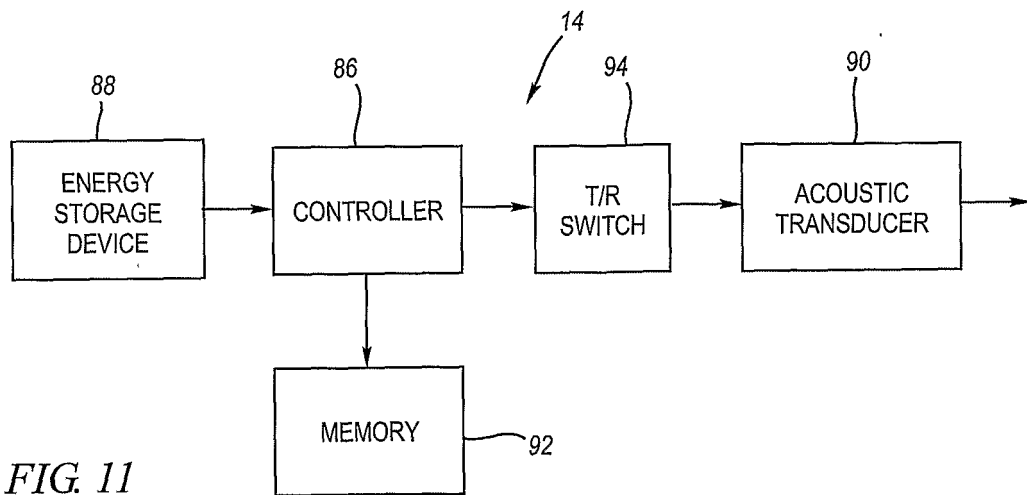


FIG. 11

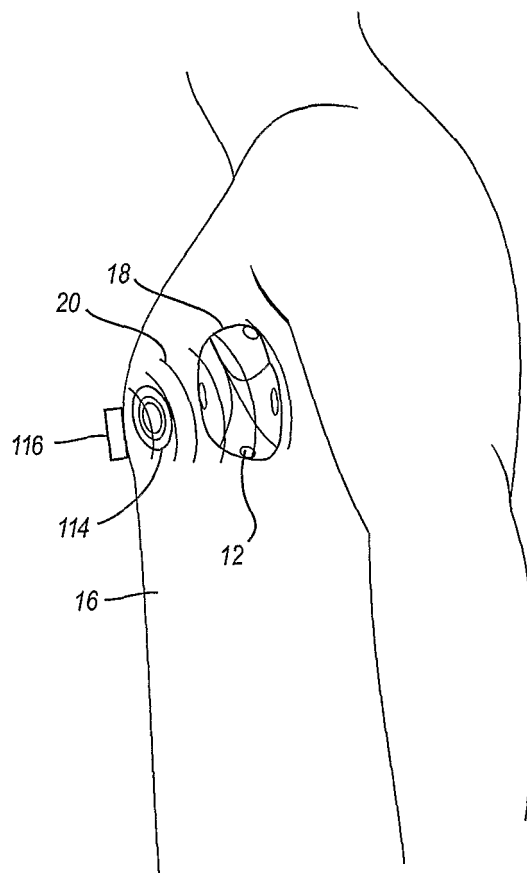


FIG. 12

## INTERNATIONAL SEARCH REPORT

IB2004/001167

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC 7 A61N1/378 A61N1/372 A61B5/00 A61N1/36				
According to International Patent Classification (IPC) or to both national classification and IPC				
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61N A61B H04B				
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, WPI Data				
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>				
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
X  A	US 2002/077673 A1 (DORON EYAL ET AL) 20 June 2002 (2002-06-20) cited in the application  the whole document -----  -/--	1-9, 12-25, 28, 30-32 10, 11, 26, 27, 29		
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.				
° Special categories of cited documents : <table border="0"> <tr> <td>           *A* document defining the general state of the art which is not considered to be of particular relevance            *E* earlier document but published on or after the international filing date            *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)            *O* document referring to an oral disclosure, use, exhibition or other means            *P* document published prior to the international filing date but later than the priority date claimed         </td> <td>           *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention            *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone            *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.            *&amp;* document member of the same patent family         </td> </tr> </table>			*A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *&* document member of the same patent family
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Date of the actual completion of the international search		Date of mailing of the international search report		
20 September 2004		27/09/2004		
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer  Fischer, O		

## INTERNATIONAL SEARCH REPORT

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专利名称(译)	声学驱动的植入式刺激装置		
公开(公告)号	<a href="#">EP1648559A1</a>	公开(公告)日	2006-04-26
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[标]申请(专利权)人(译)	REMON医疗TECH		
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当前申请(专利权)人(译)	REMON MEDICAL TECHNOLOGIES LTD.		
[标]发明人	PENNER AVI		
发明人	PENNER, AVI		
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#### 摘要(译)

可植入刺激系统包括可植入刺激器 ( 12 ) 和控制装置 ( 14 )。控制装置 ( 14 ) 配置成将声波传输到可植入刺激器 ( 12 )，并且可植入刺激器 ( 12 ) 配置成将声波转换成电流，并基于电流产生刺激能量。例如，电流可以转换成可以用于产生刺激能量的电能。或者，电流可以包含用于直接或间接控制刺激能量的产生的信号。可植入刺激器可以包括使控制装置能够对可植入刺激器进行加密的唯一识别码。此外，可植入刺激器可以被配置为传输声学。包含诊断信息 ( 血压信息 ) 的波到控制装置。