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(54) **SYSTEMS AND METHOD FOR COMMUNICATING WITH IMPLANTABLE DEVICES**

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(73) Assignee: **Remon Medical Technologies, Ltd**, Caesarea (IL)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 437 days.

This patent is subject to a terminal disclaimer.

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Related U.S. Application Data

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(51) **Int. Cl.**
A61N 1/18 (2006.01)

(52) **U.S. Cl.** **607/60**; 607/30; 607/32

(58) **Field of Classification Search** 128/897–899, 128/903–904, 906; 607/29–34, 59–61
See application file for complete search history.

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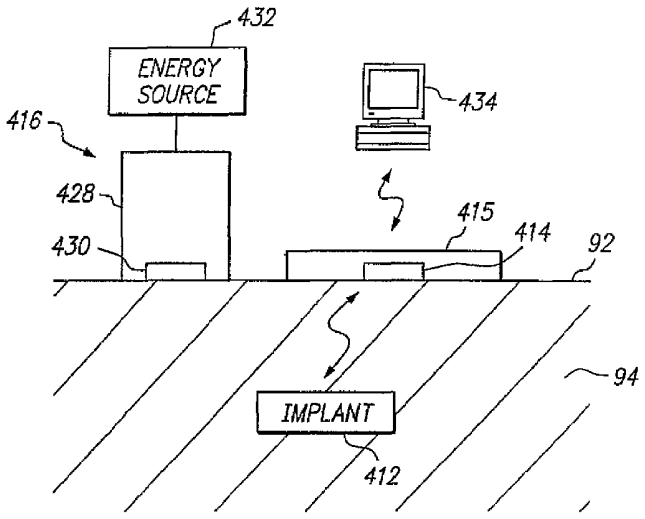
(57) **ABSTRACT**

Systems and methods for communicating with an implant within a patient's body using acoustic telemetry includes an external communications device attachable to the patient's skin. The device includes an acoustic transducer for transmitting acoustic signals into the patient's body and/or for receiving acoustic signals from the implant. The device includes a battery for providing electrical energy to operate the device, a processor for extracting data from acoustic signals received from the implant, and memory for storing the data. The device may include an interface for communicating with a recorder or computer, e.g., to transfer data from the implant and/or to receive instructions for controlling the implant. The device is secured to the patient's skin for controlling, monitoring, or otherwise communicating with the implant, while allowing the patient to remain mobile.

31 Claims, 4 Drawing Sheets



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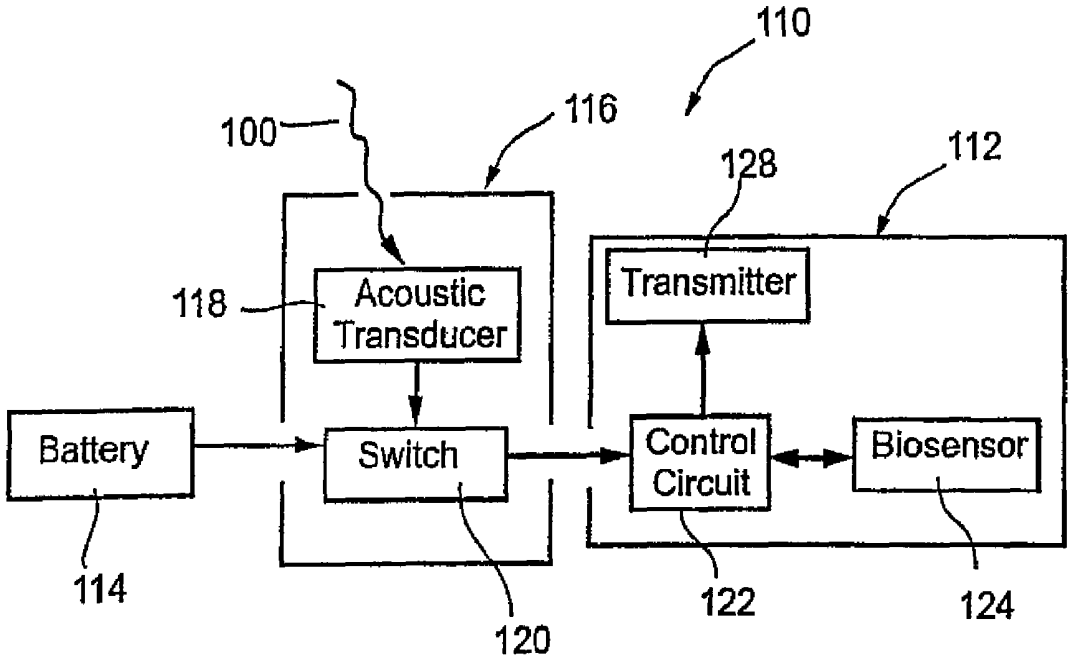
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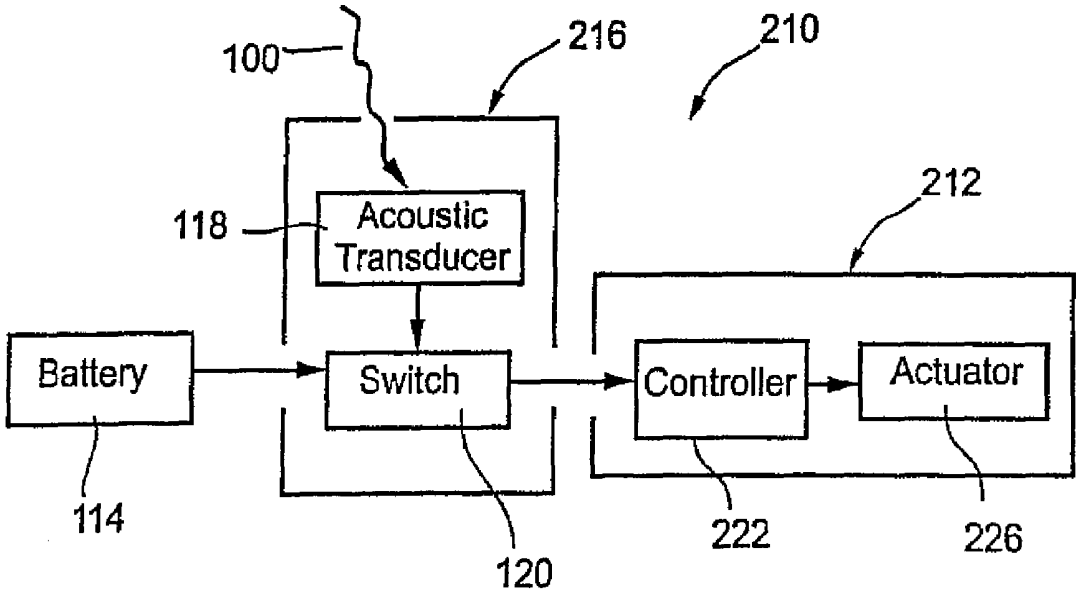
118
Acoustic Transducer
Transmitter
Battery
Switch
Control Circuit
Biosensor
114
120
122
124

Fig. 1A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212
118
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Battery
Switch
Controller
Actuator
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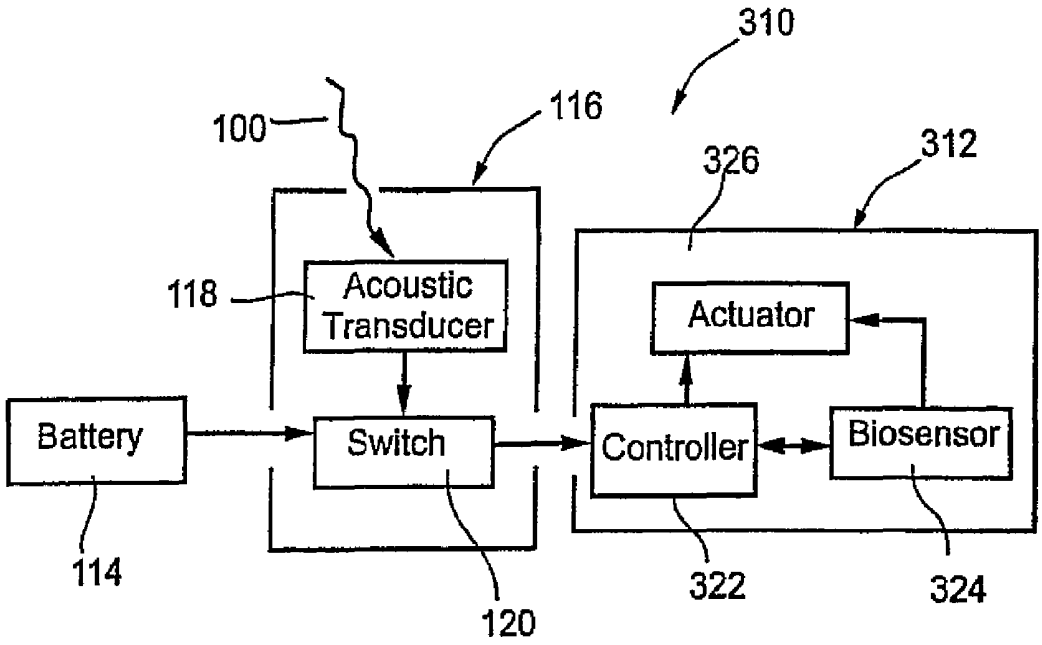
226

Fig. 1B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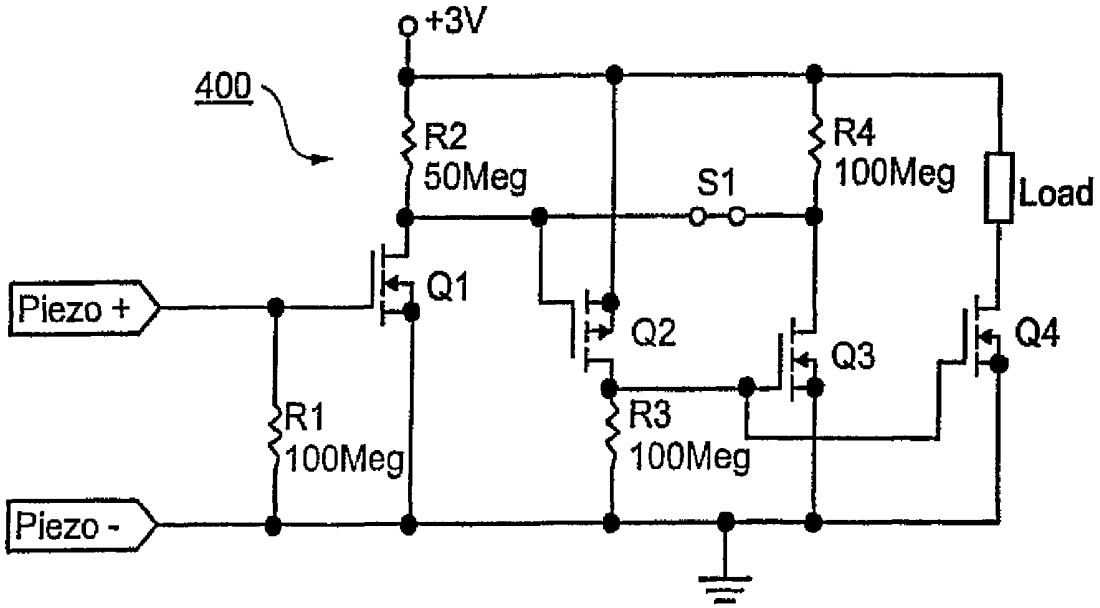
312
118
Acoustic Transducer
Actuator
Battery
Switch
Controller
Biosensor
114
120
322
324

Fig. 1C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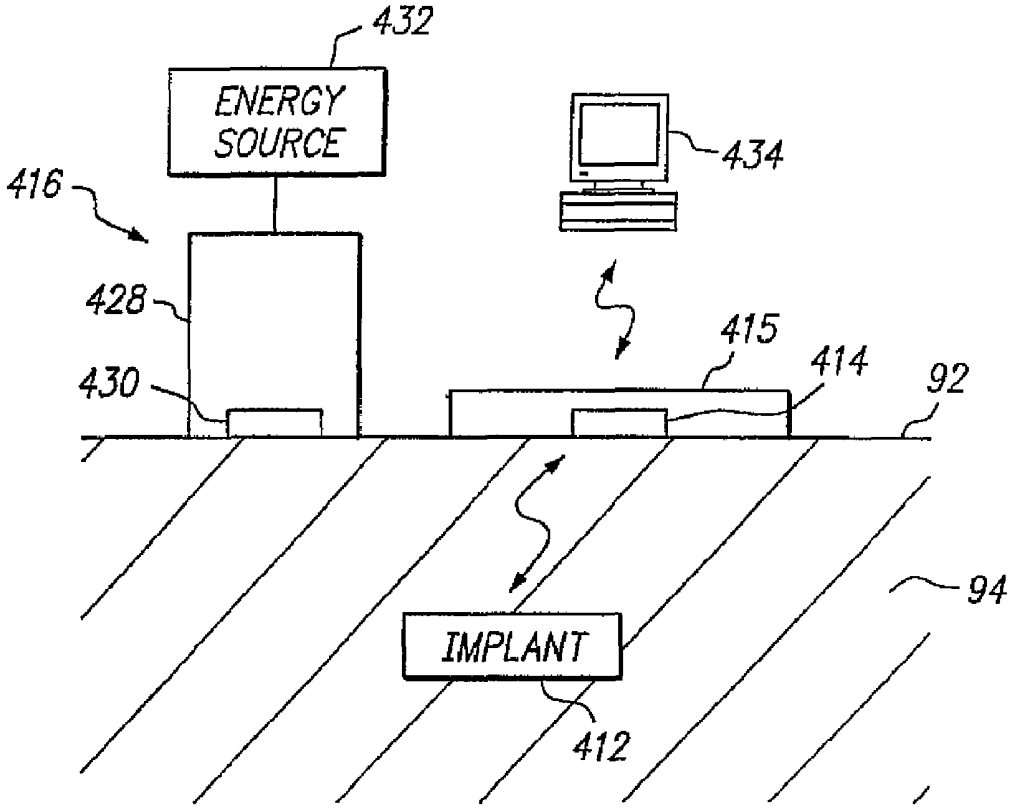
400
R2
50Meg
S1
R4
100Meg
Load
Piezo +
Q1
Q2
Q3
Q4
R1
100Meg
R3
100Meg
Piezo -

Fig. 2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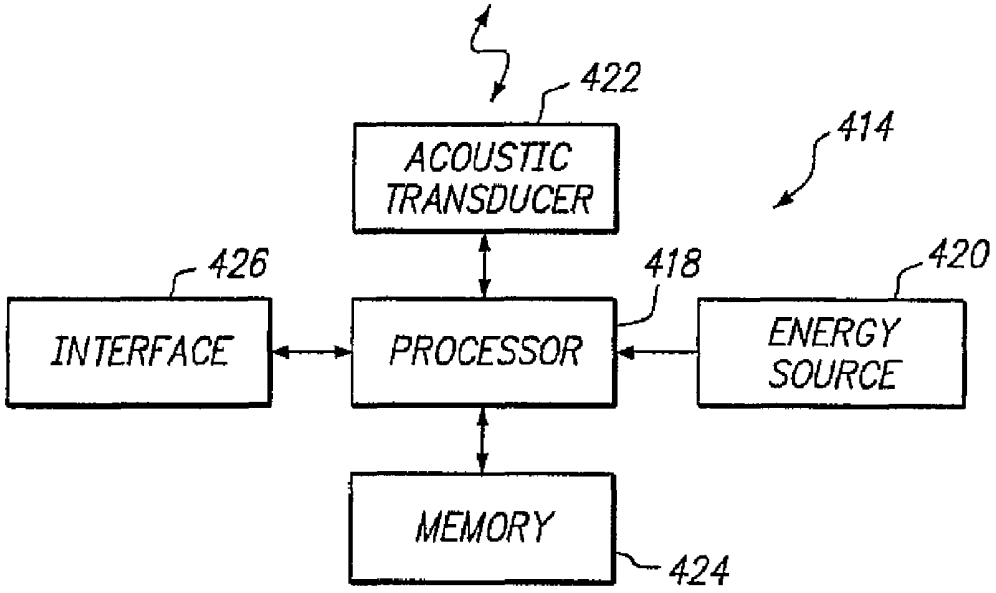
ENERGY SOURCE
434
416
428
415
414
430
92
94
IMPLANT
412

FIG. 3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414
ACOUSTIC TRANSDUCER
426
418
420
INTERFACE
PROCESSOR
ENERGY SOURCE
MEMORY
424

FIG. 4

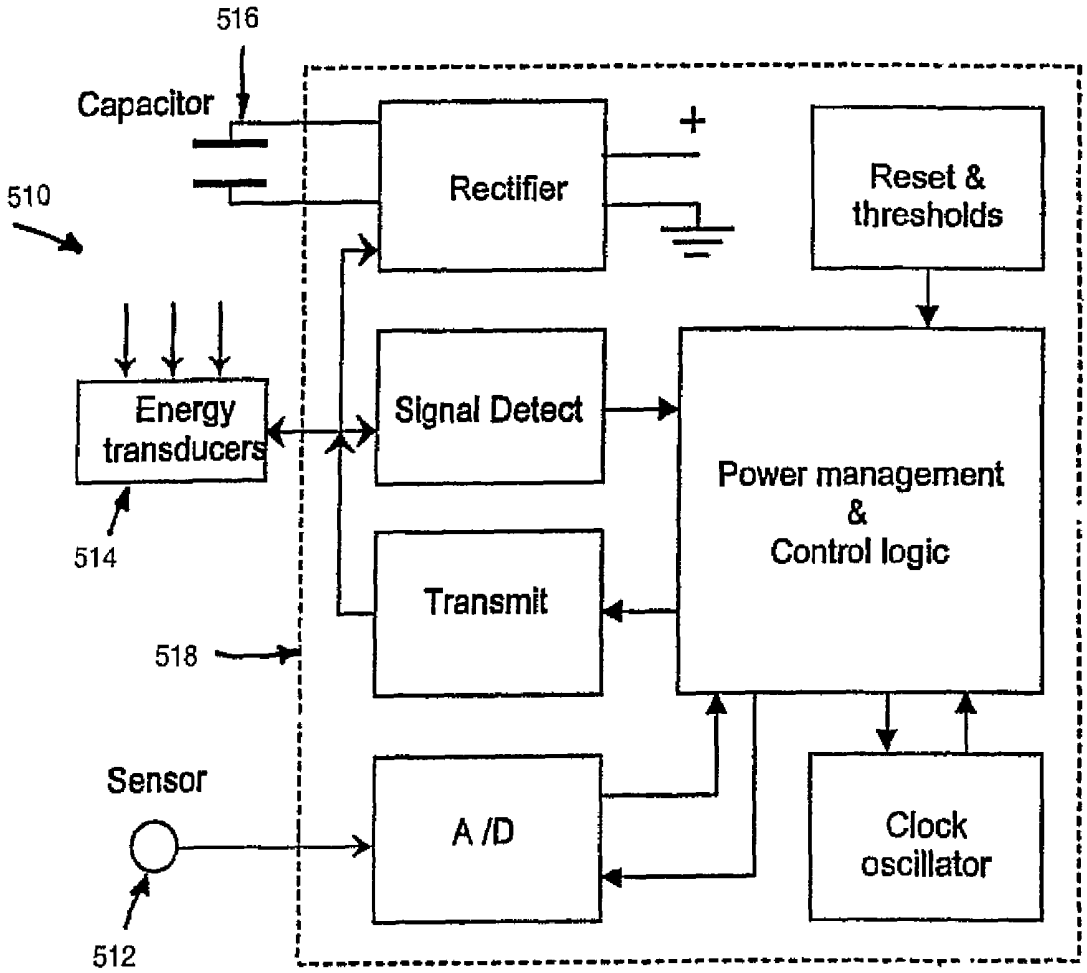

516
Capacitor
510
Rectifier
+
Reset &
thresholds
Energy
transducers
514
Signal Detect
Power management
&
Control logic
Transmit
518
Sensor
512
A /D
Clock
oscillator

Fig. 5

SYSTEMS AND METHOD FOR COMMUNICATING WITH IMPLANTABLE DEVICES

CROSS-REFERENCE TO RELATED APPLICATIONS

This Application is a continuation of application Ser. No. 09/989,912, filed Nov. 19, 2001, now U.S. Pat. No. 7,024,248, issued on Apr. 4, 2006, which is a continuation-in-part of application Ser. No. 09/690,015, filed Oct. 16, 2000, now U.S. Pat. No. 6,628,989, issued on Sep. 30, 2003, the disclosures of which are expressly incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to systems and methods for measuring physiological conditions and/or performing therapeutic functions within a patient's body, particularly to systems and methods for controlling and/or energizing devices that may be implanted within a body, and more particularly to implants that may be energized, activated, controlled, and/or otherwise communicate via acoustic energy.

BACKGROUND OF THE INVENTION

Devices are known that may be implanted within a patient's body for monitoring one or more physiological conditions and/or to provide therapeutic functions. For example, sensors or transducers may be located deep within the body for monitoring a variety of properties, such as temperature, pressure, strain, fluid flow, chemical properties, electrical properties, magnetic properties, and the like. In addition, devices may be implanted that perform one or more therapeutic functions, such as drug delivery, defibrillation, electrical stimulation, and the like.

Often it is desirable to communicate with such devices once they are implanted within a patient by external command, for example, to obtain data, and/or to activate or otherwise control the implant. An implant may include wire leads from the implant to an exterior surface of the patient, thereby allowing an external controller or other device to be directly coupled to the implant. Alternatively, the implant may be remotely controlled, e.g., using an external induction device. For example, an external radio frequency (RF) transmitter may be used to communicate with the implant. RF energy, however, may only penetrate a few millimeters into a body, because of the body's dielectric nature, and therefore may not be able to communicate effectively with an implant that is located deep within the body. In addition, although an RF transmitter may be able to induce a current within an implant, the implant's receiving antenna, generally a low impedance coil, may generate a voltage that is too low to provide a reliable switching mechanism.

In a further alternative, electromagnetic energy may be used to control an implant, since a body generally does not attenuate magnetic fields. The presence of external magnetic fields encountered by the patient during normal activity, however, may expose the patient to the risk of false positives, i.e., accidental activation or deactivation of the implant. Furthermore, external electromagnetic systems may be cumbersome and may not be able to effectively transfer coded information to an implant.

Accordingly, systems and methods for communicating with an implant that may be implanted within a patient's body, such as a pressure sensor, a drug delivery device, a pacemaker, or a nerve stimulator, would be considered useful.

SUMMARY OF THE INVENTION

The present invention is generally directed to systems and methods for communicating with implants or other devices that are placed, e.g., using open surgical or minimally invasive techniques, within a mammalian body. The implant may include one or more sensors for monitoring pressure or other physiological parameters and/or may perform one or more therapeutic functions. More particularly, the present invention is directed to external systems for controlling, activating, energizing, and/or otherwise communicating with such implants using acoustic telemetry, and to methods for using such systems.

In accordance with one aspect of the present invention, a system is provided for communicating with an implant within a body that includes an external communications device, e.g., a controller, securable to an exterior surface of a patient's body. Preferably, the controller is sufficiently small and portable that it may remain secured to the patient, possibly for extended time periods. For example, the device may be attached to or within a patch that may be secured to a patient's skin.

In one embodiment, the device is an external controller that generally includes one or more acoustic transducers, including a first acoustic transducer, for transmitting one or more acoustic signals into the patient's body. The controller may also include an energy source for powering the one or more acoustic transducers, and/or a processor or other electrical circuit for controlling operation of the controller. In addition, one or more of the acoustic transducers, such as the first acoustic transducer, may be configured for receiving acoustic signals from an implant within the patient's body. The controller may include memory for storing data, and the processor may extract sensor data and/or other data from acoustic signals received from an implant, e.g., for storage in the memory. In addition, the controller may include a connector, lead, transmitter, receiver, or other interface for communicating with a recorder or other electronic device, such as a computer, personal digital assistant, or a wireless device, such as a cellular phone. The controller may be coupled to such an electronic device for transferring sensor data or other data stored in the memory of the controller and/or for receiving instructions or commands from the electronic device.

In addition, the system may include an implant for placement within the patient's body. The implant may include an electrical circuit for performing one or more commands when the implant is activated, an energy storage device, and/or one or more acoustic transducers, e.g., a second acoustic transducer, coupled to the electrical circuit and/or the energy storage device. Optionally, the electrical circuit may include a switch coupled to the energy storage device and/or the second acoustic transducer. The second acoustic transducer may receive one or more acoustic signals from the first acoustic transducer of the external device. For example, the switch may be closed and/or opened in response to a first acoustic signal to begin or discontinue current flow from the energy storage device to the electrical circuit or other components of the implant.

In a preferred embodiment, the external controller's processor controls the first acoustic transducer to transmit a first acoustic signal and/or and a second acoustic signal. The switch of the implant may be closed when the first acoustic signal is received by the second acoustic transducer, while the switch may be opened when the second acoustic signal is

received by the second acoustic transducer. In addition or alternatively, the first acoustic transducer may transmit first and second acoustic signals separated by a delay. The switch may be closed and/or opened only when the second acoustic transducer receives the first and second acoustic signals separated by a predetermined delay, thereby minimizing the risk of accidental activation or deactivation of the implant.

In yet another alternative, the first acoustic transducer may transmit a first acoustic signal, e.g., an activation signal, followed by a second acoustic signal, e.g., including a set of commands. The second acoustic transducer may receive the first and second acoustic signals, and the electrical circuit of the implant may extract the set of commands from the second acoustic signal, and control operation of the implant as instructed by the set of commands. In a further alternative, the implant may run continuously or intermittently, and the external controller may control monitor, energize, and/or program the implant using acoustic telemetry during operation of the implant.

In an exemplary embodiment, the implant may include a sensor coupled to the electrical circuit, and the one or more commands may include measuring a physiological parameter within the body using the sensor. The second acoustic transmitter may transmit one or more acoustic signals including sensor data indicating the physiological parameter to the controller. In an alternative embodiment, the implant may be coupled to a therapeutic device or may include an internal therapeutic device coupled to the electrical circuit. The electrical circuit may control the therapeutic device in response to a physiological parameter measured by the sensor or in response to acoustic signals received from the external controller. For example, the implant may include a pacemaker that may be implanted via a minimally invasive catheter-based procedure. Any programming and/or interrogation of the pacemaker may be accomplished using acoustic telemetry from the external controller. In yet another alternative embodiment, the implant may include an actuator coupled to the electrical circuit, and the one or more commands may include activating the actuator to control a therapeutic device coupled to the actuator, such as a nerve stimulator or a controlled delivery drug release system.

In addition, the energy storage device of the implant may include a rechargeable device, such as a capacitor or a battery. For this embodiment, the system may include an external charger that may include a probe configured for placement against an exterior of the patient's body. The charger may include a source of electrical energy, such as a radio frequency (RF) generator, that is coupled to the probe. The probe may include another acoustic transducer, e.g., a third acoustic transducer, for converting electrical energy from the source of electrical energy into acoustic energy. The third acoustic transducer may transmit acoustic signals including acoustic energy into the patient's body. One or more acoustic transducers of the implant, e.g., the second acoustic transducer, may be configured for converting these acoustic signals into electrical energy for recharging the energy storage device and/or powering the implant.

Thus, a system in accordance with the present invention may include an external controller that has sufficient power to control its own operation and to communicate with the implant. Because of its limited energy requirements, however, the controller may be relatively small and portable, e.g., may be attached to the patient, while still allowing the patient to engage in normal physical activity. The controller may be used to communicate with an implant, e.g., periodically activating or deactivating the implant, and/or recording data generated and transmitted by the implant. Because it is located outside the patient's body, the controller may be more easily programmed or reprogrammed than the implant, and/or may be repaired or replaced if necessary without requiring an interventional procedure.

In addition, the system may include a separate external charger that includes a substantially more powerful energy source, enabling it to recharge the energy storage device of the implant. For this reason, unlike the external controller, the charger may be a relatively bulky device that may include a portable probe for contacting the patient's skin, and a large energy generator or converter that is stationary or of limited mobility. In an alternative embodiment, the external controller and charger may be provided as a single device, e.g., including one or more acoustic transducers and/or one or more processors for performing the functions of both devices, as described above. In this embodiment, however, portability of the system and convenience to the patient may be compromised.

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

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

FIGS. **1A-1C** are schematic drawings, showing exemplary embodiments of an implant, in accordance with the present invention.

FIG. **2** is a schematic of an exemplary circuit for use as an acoustic switch, in accordance with the present invention.

FIG. **3** is a cross-sectional view of a patient's body, showing a system for communicating with an implant, in accordance with the present invention.

FIG. **4** is a schematic of an external controller for communicating with an implant, such as that shown in FIG. **3**, in accordance with the present invention.

FIG. **5** is a schematic of another exemplary embodiment of an implant, in accordance with the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning to the drawings, FIGS. **1A-1C** schematically show several exemplary embodiments of an implant **110**, **210**, **310**, in accordance with the present invention. Generally, the implant **110**, **210**, **310** includes an electrical circuit **112**, **212**, **312** configured for performing one or more functions or commands when the implant **110**, **210** **310** is activated, as described further below. In addition, the implant **110**, **210**, **310** includes an energy storage device **114** and optionally may include a switch **116** coupled to the electrical circuit **112**, **212**, **312** and the energy storage device **114**. The switch **116** may be activated upon acoustic excitation **100** from an external acoustic energy source (not shown) to allow current flow from the energy storage device **114** to the electrical circuit **112**, **212**, **312**.

In a preferred embodiment, the switch **116** includes an acoustic transducer **118**, such as that disclosed in PCT Publication No. WO 99/34,453, published Jul. 8, 1999, or in U.S. application Ser. No. 09/888,272, filed Jun. 21, 2001, the disclosures of which are expressly incorporated herein by reference. In addition, the switch **116** also includes a switch circuit **120**, such as switch circuit **400** shown in FIG. **2**, although alternatively other switches, such as a miniature electromechanical switch and the like (not shown) may be provided. In

a further alternative, the acoustic transducer **118** may be coupled to the electrical circuit **112**, **212**, **312** and/or the energy storage device **114**, and the switch circuit **120** may be eliminated.

The energy storage device **114** may be any of a variety of known devices, such as an energy exchanger, a battery and/or a capacitor (not shown). Preferably, the energy storage device **114** is capable of storing electrical energy substantially indefinitely for as long as the acoustic switch **116** remains open, i.e., when the implant **110**, **210**, **310** is in a "sleep" mode. In addition, the energy storage device **114** may be capable of being charged from an external source, e.g., inductively using acoustic telemetry, as will be appreciated by those skilled in the art. In a preferred embodiment, the energy storage device **114** includes both a capacitor and a primary, non-rechargeable battery. Alternatively, the energy storage device **114** may include a secondary, rechargeable battery and/or capacitor that may be energized before activation or use of the implant **110**, **210**, **310**.

The implant **110**, **210**, **310** may be surgically or minimally invasively inserted within a human body in order to carry out a variety of monitoring and/or therapeutic functions. For example, the electrical circuit **112**, **212**, **312** may include a control circuit **122**, **222**, **322**, a biosensor **124**, **324**, an actuator **226**, **326**, and/or a transmitter **128**, as explained in application Ser. No. 09/690,015, incorporated by reference above. The implant **210**, **310** may be configured for providing one or more therapeutic functions, for example, to activate and/or control a therapeutic device implanted within a patient's body, such as an atrial defibrillator or pacemaker, a pain relief stimulator, a neuro-stimulator, a drug delivery device, and/or a light source used for photodynamic therapy. Alternatively, the implant may be used to monitor a radiation dose including ionizing, magnetic and/or acoustic radiation, to monitor flow in a bypass graft, to produce cell oxygenation and membrane electroporation, and the like. In addition or alternatively, the implant **110** may be used to measure one or more physiological parameters within the patient's body, such as pressure, temperature, electrical impedance, position, strain, pH, and the like.

The implant may operate in one of two modes, a "sleep" or "passive" mode when the implant remains dormant and not in use, i.e., when the acoustic switch **116** is open, and an "active" mode, when the acoustic switch **116** is closed, and electrical energy is delivered from the energy storage device **114** to the electrical circuit **112**, **212**, **312**. Alternatively, the implant may operate continuously or intermittently. Because the acoustic switch **116** is open in the sleep mode, there is substantially no energy consumption from the energy storage device **114**, and consequently, the implant may remain in the sleep mode virtually indefinitely, i.e., until activated. Thus, an implant in accordance with the-present invention may be more energy efficient and, therefore, may require a relatively small energy storage device than implants that continuously draw at least a small amount of current in their "passive" mode.

Turning to FIG. **1**A, a first preferred embodiment of an implant **110** is shown in which the electrical circuit **112** includes a control circuit **122**, a biosensor **124** coupled to the controller **122**, and a transmitter **128** coupled to the control circuit **122**. The controller **122** may include circuitry for activating or controlling the biosensor **124**, for receiving signals from the biosensor **124**, and/or for processing the signals into data, for example, to be transmitted by the transmitter **128**. Optionally, the electrical circuit **112** may include memory (not shown) for storing the data. The transmitter **128** may be any device capable of transmitting data from the control circuit **122** to a remote location outside the body, such as an acoustic transmitter, a radio frequency transmitter, and the like. Preferably, the control circuit **122** is coupled to the acoustic transducer **118** such that the acoustic transducer **118** may be used as a transmitter **128**, as well as a receiver, instead of providing a separate transmitter.

The biosensor **124** may include one or more sensors capable of measuring physiological parameters, such as pressure, temperature, electrical impedance, position, strain, pH, fluid flow, electrochemical sensor, and the like. Thus, the biosensor **124** may generate a signal proportional to a physiological parameter that may be processed and/or relayed by the control circuit **122** to the transmitter **128**, which, in turn, may generate a transmission signal to be received by a device outside the patient's body. Data regarding the physiological parameter(s) may be transmitted continuously or periodically until the acoustic switch **116** is deactivated, or for a fixed predetermined time, as will be appreciated by those skilled in the art.

Turning to FIG. **1**B, a second preferred embodiment of an implant **210** is shown in which the electrical circuit **212** includes a control circuit **222** and an actuator **226**. The actuator **226** may be coupled to a therapeutic device (not shown) provided in or otherwise coupled to the implant **210**, such as a light source, a nerve stimulator, a defibrillator, an electrochemical oxidation/reduction electrode, or a valve communicating with an implanted drug reservoir (in the implant or otherwise implanted within the body in association with the implant).

When the switch **120** is closed, the control circuit **222** may activate the actuator **226** using a pre-programmed protocol, e.g., to complete a predetermined therapeutic procedure, whereupon the switch **120** may automatically open, or the controller **222** may follow a continuous or looped protocol until the switch **120** is deactivated. Alternatively, the acoustic transducer **118** may be coupled to the control circuit **222** for communicating a new or unique set of commands to the control circuit **222**. For example, a particular course of treatment for a patient having the implant **210** may be determined, such as a flow rate and duration of drug delivery, drug activation, drug production, or an energy level and duration of electrical stimulation. Acoustic signals including commands specifying this course of treatment may be transmitted from an external controller (not shown), as described below, to the acoustic switch **116**, e.g., along with or subsequent to the activation signal **100**. The control circuit **222** may interpret these commands and control the actuator **226** accordingly to complete the course of treatment.

Turning to FIG. **1**C, yet another preferred embodiment of an implant **310** is shown in which the electrical circuit **312** includes a control circuit **322**, a biosensor **324**, and an actuator **326**, all of which may be coupled to one another. This embodiment may operate similarly to the embodiments described above, e.g., to obtain data regarding one or more physiological parameters and/or to control a therapeutic device. In addition, once activated, the control circuit **322** may control the actuator **326** in response to data obtained from the biosensor **324** to control or adjust automatically a course of treatment being provided by a device connected to the actuator **326**. For example, the actuator **326** may be coupled to an insulin pump (not shown), and the biosensor **324** may measure glucose levels within the patient's body. The control circuit **322** may control the actuator to open or close a valve on the insulin pump to adjust a rate of insulin delivery based upon glucose levels measured by the biosensor **324** in order to maintain the patient's glucose within a desired range.

Turning to FIG. **2**, a preferred embodiment of a switch **400** is shown that may be incorporated into an implant in accordance with the present invention. The switch **400** includes a piezoelectric transducer, or other acoustic transducer (not shown, but generally connected to the switch **400** at locations piezo+ and piezo−), a plurality of MOSFET transistors (Q1-Q4) and resistors (R1-R4), and switch S1. A "load" may be coupled to the switch **400**, such as one of the electrical circuits described above. In the switch's "sleep" mode, all of the MOSFET transistors (Q1-Q4) are in an off state. To maintain the off state, the gates of the transistors are biased by pull-up and pull-down resistors. The gates of N-channel transistors (Q1, Q3 & Q4) are biased to ground and the gate of P-channel transistor Q2 is biased to +3V. During this quiescent stage, switch S1 is closed and no current flows through the circuit. Therefore, although an energy storage device (not shown, but coupled between the hot post, labeled with an exemplary voltage of +3V, and ground) is connected to the switch **400**, no current is being drawn therefrom since all of the transistors are quiescent.

When the acoustic transducer of the implant detects an external acoustic signal, e.g., having a particular frequency, such as the transducer's resonant frequency, the voltage on the transistor Q1 will exceed the transistor threshold voltage of about one half of a volt. Transistor Q1 is thereby switched on and current flows through transistor Q1 and pull-up resistor R2. As a result of the current flow through transistor Q1, the voltage on the drain of transistor Q1 and the gate of transistor Q2 drops from +3V substantially to zero (ground). This drop in voltage switches on the P-channel transistor Q2, which begins to conduct current through transistor Q2 and pull-down resistor R3.

As a result of the current flowing through transistor Q2, the voltage on the drain of transistor Q2 and the gates of transistors Q3 and Q4 increases from substantially zero to +3V. The increase in voltage switches on transistors Q3 and Q4. As a result, transistor Q3 begins to conduct current through resistor R4 and main switching transistor Q4 begins to conduct current through the "load," thereby switching on the electrical circuit.

As a result of the current flowing through transistor Q3, the gate of transistor Q2 is connected to ground through transistor Q3, irrespective of whether or not transistor Q1 is conducting. At this stage, the transistors (Q2, Q3, & Q4) are latched to the conducting state, even if the piezoelectric voltage on transistor Q1 is subsequently reduced to zero and transistor Q1 ceases to conduct. Thus, main switching transistor Q4 will remain on until switch S1 is opened.

In order to deactivate or open the switch **400**, switch S1 must be opened, for example, while there is no acoustic excitation of the piezoelectric transducer. If this occurs, the gate of transistor Q2 increases to +3V due to pull-up resistor R2. Transistor Q2 then switches off, thereby, in turn, switching off transistors Q3 and Q4. At this stage, the switch **400** returns to its sleep mode, even if switch S1 is again closed. The switch **400** will only return to its active mode upon receiving a new acoustic activation signal from the piezoelectric transducer.

It should be apparent to one of ordinary skill in the art that the above-mentioned electrical circuit is not the only possible implementation of a switch for use with the present invention. For example, the switching operation may be performed using a CMOS circuit, which may draw less current when switched on, an electromechanical switch, and the like.

Turning to FIGS. **3** and **4**, a system **410** is shown for communicating with an implant **412**, such as one of those described above. Generally, the system **410** includes an external communications device or controller **414**, and may include a charger **416**, one or more implants **412** (only one shown for simplicity), and an external recorder, computer, or other electronic device **434**.

With particular reference to FIG. **4**, the external controller **414** may include a processor or other electrical circuit **418** for controlling its operation, and an energy source **420**, e.g., a nonrechargeable or a rechargeable battery, coupled to the processor **418** and/or other components of the controller **414**, such as a power amplifier or an oscillator (not shown). In addition, the controller **414** may include one or more acoustic transducers **422** that are configured for converting between electrical energy and acoustic energy, similar to those described above. As shown, a single acoustic transducer **422** is provided that may communicate using acoustic telemetry, i.e., capable both of converting electrical energy to acoustic energy to transmit acoustic signals, and converting acoustic energy to electrical energy to receive acoustic signals, as explained further below. Alternatively, separate and/or multiple acoustic transducers may be provided for transmitting and receiving acoustic signals.

In a preferred embodiment, the controller **414** also includes memory **424** coupled to the processor **418**, e.g., for storing data provided to the controller **414**, as explained further below. The memory **424** 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 processor **418** or other electronic device. For example, the memory **424** may be a memory card or an eprom (not shown) built into the controller **414** or otherwise coupled to the processor **418**. The controller **414** may also include an interface **426**, such as a lead or connector, or a transmitter and/or receiver, that may communicate with the external electronic device, as explained further below.

Preferably, the controller **414** is carried by a patch **415** that may be secured to a patient, e.g., o the patient's skin **92**. For example, the patch **415** may include one or more layers of substantially flexible material to which the controller **414** and/or its individual components are attached. The patch **415** may include a single flexible membrane (not shown) to which the controller **414** is bonded or otherwise attached, e.g., using a substantially permanent adhesive, which may facilitate the patch **415** conforming to a patient's anatomy. Alternatively, the controller **414** may be secured between layers of material, e.g., within a pouch or other compartment (not shown) within the patch **415**. For example, the patch **415** may include a pair of membranes (not shown) defining the pouch or compartment. The space within which the controller **414** is disposed may be filled with material to acoustically couple the acoustic transducer(s) (formed, for example, from PZT, composite PZT, Quartz, PVDF, and/or other piezoelectric material) of the controller **414** to an outer surface of the patch **415**. Alternatively, the acoustic transducer(s) may be exposed, e.g., in a window formed in a wall of the patch **415**.

The patch **415** may be formed from a flexible piezoelectric material, such as PVDF or a PVDF copolymer. Such polymers may allow the patch **415** to produce ultrasonic waves, as well as allowing the controller **414** to be secured to the patient's skin **92**. Thus, the wall of the patch **415** itself may provide an acoustic transducer for the controller **414**, i.e., for transmitting acoustic energy-to and/or receiving acoustic energy from the implant **412**.

The patch **415** may then be secured to the patient's skin **92** using a material, such as a layer of adhesive (not shown), substantially permanently affixed or otherwise provided on a surface of the patch. The adhesive may be hydrogel, silicon, polyurethane, polyethylene, polypropylene, fluorocarbon

polymer, and the like. Alternatively, a separate adhesive may be applied to the patch **415** and/or to the patient's skin **92** before applying the patch **415** in order to secure the controller **414** to the patient's skin **92**. Such an adhesive may enhance acoustically coupling of the acoustic transducer(s) of the controller **414** to the patient's skin **92**, and consequently to the implant **412** within the patient's body **94**. Optionally, additional wetting material, including water, silicone oil, silicone gel, hydrogel, and the like, and/or other acoustically conductive material may be provided between the patch **415** or the acoustic transducer **422**, and the patient's skin **92**, e.g., to provide substantial continuity and minimize reflection or other losses and/or to secure the patch **415** to the patient.

Alternatively, the controller **414** may be carried by a belt (not shown) that may be secured around the patient, e.g., such that the acoustic transducer **422** is secured against the patient's skin. The belt may carry other components of the system **410**, e.g., an external power supply for the controller **414**. For example, a battery pack (not shown) may be carried by the belt that may be coupled to the controller **414** for providing electrical energy for its operation.

The patch **415** may be relatively light and compact, for example, having a 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 (5-100 mm), and a weight not more than about twenty to four hundred grams (20-400 g), such that the controller **414** may be inconspicuously attached to the patient. Thus, the patient may be able to resume normal physical activity, without substantial impairment from the controller. Yet, the internal energy source of the controller **414** may be sufficiently large to communicate with the implant **412** for an extended period of time, e.g., for hours or days, without requiring recharging or continuous coupling to a separate energy source.

The system **410** may be used to control, energize, and/or otherwise communicate with the implant **412**. For example, the controller **414** may be used to activate the implant **412**. One or more external acoustic energy waves or signals **430** may be transmitted from the controller **414** into the patient's body **94**, e.g., generally towards the location of the implant **412** until the signal is received by the acoustic transducer (not shown in FIGS. **3** and **4**) of the implant **412**. Upon excitation by the acoustic wave(s) **430**, the acoustic transducer produces an electrical output that is used to close, open, or otherwise activate the switch (also not shown in FIGS. **3** and **4**) of the implant **412**. Preferably, in order to achieve reliable switching, the acoustic transducer of the implant **412** is configured to generate a voltage of at least several tenths of a volt upon excitation that may be used as an activation signal to close the switch, as described above.

As a safety measure against false positives (e.g., erroneous activation or deactivation), the controller **414** may be configured to direct its acoustic transducer **422** to transmit an initiation signal followed by a confirmation signal. When the acoustic transducer of the implant **412** receives these signals, the electrical circuit may monitor the signals for a proper sequence of signals, thereby ensuring that the acoustic switch of the implant **412** only closes upon receiving the proper initiation and confirmation signals. For example, the acoustic switch 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 release of drugs by a drug delivery implant.

In addition to an activation signal, the controller **414** may transmit a second acoustic signal that may be the same as or different than the acoustic wave(s) used to activate the acoustic switch of the implant **412**. Thus, the switch may be opened when the acoustic transducer of the implant **412** receives this second acoustic signal, e.g., by the acoustic transducer generating a termination signal in response to the second acoustic signal, in order to return the implant **412** to its sleep mode.

For example, once activated, the switch may remain closed indefinitely, e.g., until the energy storage device (not shown in FIGS. **3** and **4**) of the implant **412** is completely depleted, falls below a predetermined threshold, or until a termination signal is received by the acoustic transducer of the implant **412** from the controller **414**. Alternatively, the acoustic switch of the implant **412** may include a timer (not shown), such that the switch remains closed only for a predetermined time, whereupon the switch may automatically open, returning the implant **412** to its sleep mode.

FIG. **5** shows an alternative embodiment of an implant **510** that does not include an acoustic switch. Generally, the implant includes a sensor **512**, one or more energy transducers **514**, one or more energy storage devices **516**, and a control circuit **518**, similar to the embodiments described above. The sensor **512** is preferably a pressure sensor for measuring intra-body pressure, such as an absolute variable capacitance type pressure sensor. In alternative embodiments, one or more other sensors may be provided instead of or in addition to a pressure sensor **512**. For example, the sensor **512** may include one or more biosensors capable of measuring physiological parameters, such as temperature, electrical impedance, position, strain, pH, fluid flow, and the like. An external controller (not shown), such as that described above, may also be used to communicate with this implant.

Returning to FIG. **3**, an external controller **414** in accordance with the present invention preferably has only sufficient power to control its own operation and to communicate with the implant **412**. Because of its limited energy requirements, the controller **414** may be relatively small and portable, e.g., may be attached to the patient, while still allowing the patient to engage in normal physical activity. The controller **414** may be used to communicate with the implant **412**, e.g., periodically activating or deactivating the implant **412**, and/or recording data generated and transmitted by the implant **412**. Because it is located outside the patient's body, the controller **414** may be more easily programmed or reprogrammed than the implant **412** itself, and/or may be repaired or replaced if necessary or desired.

In addition to the external controller **414**, the system **410** may include one or more electronic devices **434** that may be coupled to the controller **414** via the interface **426**, such as a recorder, a computer, a personal digital assistant, and/or a wireless device, such as a cellular telephone. The electronic device **434** may be directly coupled to the controller **414**, by a connector or lead (not shown) extending from the patch **415** within which the controller **414** is provided. Alternatively, the controller **414** and/or patch **415** may include a wireless transmitter and/or receiver (not shown), e.g., a short-range RF transceiver, for communicating with the electronic device **434**.

The electronic device **434** may be used to extract data from the memory **424** of the controller **414**, e.g., sensor data and the like, received from the implant **412**. This data may be included in a patient database maintained by health care professionals monitoring the patient receiving the implant **412**. In addition, the electronic device **434** may be used to program the controller **414**, e.g., to program commands, timing sequences, and the like.

The system **410** may also include an external charger **416**. For example, the implant **412** may include a rechargeable energy storage device (not shown in FIG. **3**), preferably one or more capacitors, that are coupled to the acoustic transducer (also not shown in FIG. **3**). The charger **416** may include a probe **428**, including an acoustic transducer **430** for contacting a patient's skin **92**. The charger **416** also includes a source of electrical energy **432**, such as a radio frequency (RF) generator, that is coupled to the acoustic transducer **430**. The charger **418** may also include electrical circuits for controlling its operation and buttons or other controls (not shown) for activating and/or deactivating the acoustic transducer **430**.

The charger **416** may be used to charge or recharge the implant, e.g., periodically or before each activation. Because the charger **416** includes a substantially more powerful energy source than the controller **414**, the charger **416** is generally a relatively bulky device compared to the controller **414**, in particular due to the energy generator, which may be stationary or of limited mobility. In addition, the charger **416** may be used to recharge the controller **414** periodically, e.g., by a direct or wireless coupling. Alternatively, the controller **414** and patch **415** may be disposable, e.g., after its energy has been depleted, and replaced with another.

For purposes of comparison, an exemplary charger **416** may need to generate about ten kiloPascals (10 kPa) of acoustic energy for about twenty seconds (20 sec.) in order to fully charge the implant **412**. In contrast, an exemplary controller **414** may be limited to outputting relatively smaller bursts of acoustic energy for communicating with, but not charging, the implant **412**. Such acoustic signals may have a duration of as little as about one millisecond (1 ms), as opposed to the significantly longer charging signals generated by the charger **416**.

The transducer **422** of the controller **414** may consume about one Watt (1 W) of power to produce a 1 kPa acoustic signal for about one millisecond. If the controller **414** communicates with the implant **412** on an hourly basis, the energy source **420** of the controller **414** may only need sufficient capacity to provide 0.024 Watt seconds per day (0.024 W.sec./day). Because of this low energy requirement, the energy source **420**, and, consequently, the controller **414**, may be relatively compact and portable, as compared to the charger **416**. Thus, the energy source **420** may be self-contained within the controller **414**, i.e., carried by the patch **415**. Alternatively, a portable energy source, e.g., an external battery pack (not shown) may be provided for supplying electrical energy to the controller **414** that may be carried by the patient, e.g., on a belt (not shown).

In an alternative embodiment the controller and charger may be provided as a single device (not shown), e.g., including one or more acoustic transducers and/or one or more processors for performing the functions of both devices, as described above. In this embodiment, the implant **412** may operate in a "half-duplex" mode, a quasi-continuous mode, or in a "full-duplex" mode, as described in the applications incorporated above.

It will be appreciated that the above descriptions are intended only to serve as examples, and that many other embodiments are possible within the spirit and the scope of the present invention.

What is claimed is:

1. A system for activating an implant within a body, comprising:

an external controller for placement adjacent to an exterior surface of a patient's body, the controller comprising a controller transducer for transmitting an acoustic control signal including one or more commands into the patient's body and an energy storage device for providing electrical energy to operate the external controller; and

one or more implants for placement within the patient's body, at least one implant comprising an electrical circuit configured for performing the one or more commands when the implant is activated, an energy storage device, a switch coupled between the electrical circuit and the energy storage device, and an acoustic implant transducer coupled to the switch, the implant transducer configured for receiving the acoustic control signal from the controller transducer to activate the switch between a first state, in which current is limited from flowing from the energy storage device of the at least one implant to the electrical circuit, and a second state, in which current flows from the energy storage device of the at least one implant to the electrical circuit.

2. The system of claim **1**, wherein at least one of the one or more implants comprises a transmitter for transmitting data from the implant.

3. The system of claim **1**, wherein at least one of the one or more implants comprises a biosensor.

4. The system of claim **3**, wherein the biosensor comprises one or more sensors capable of measuring a physiological parameter.

5. The system of claim **1**, wherein the at least one implant comprises an actuator coupled to the switch and a therapeutic device coupled to the actuator such that a therapeutic procedure is completed when the at least one implant is activated.

6. The system of claim **1**, wherein the controller transducer is configured for transmitting first and second acoustic control signals separated by a predetermined delay, and wherein the switch of the at least one implant is configured to actuate to the second state only when the implant transducer receives the first and second control signals separated by the predetermined delay.

7. The system of claim **1**, the controller further comprising a processor for controlling the controller transducer to transmit one of a first acoustic control signal and a second acoustic control signal, wherein the switch of the at least one implant is in the first state when the first control signal is received by the implant transducer, and in the second state when the second control signal is received by the implant transducer.

8. The system of claim **1**, wherein the at least one implant further comprises a sensor coupled to the electrical circuit, the one or more commands comprising measuring a physiological parameter within the body using the sensor.

9. The system of claim **8**, wherein the implant transducer is configured for transmitting an acoustic data signal to the controller, the data signal comprising sensor data indicative of the physiological parameter, and wherein the controller transducer is configured for receiving the data signal from the implant.

10. The system of claim **9**, wherein the controller further comprises memory for storing the sensor data.

11. The system of claim **10**, wherein the controller further comprises a processor for extracting the sensor data from the data signal.

12. The system of claim **1**, further comprising an external charger configured for placement adjacent to an exterior surface of the patient's body, the charger comprising a source of electrical energy and an energy exchange transducer, the energy exchange transducer configured for converting electrical energy from the source of electrical energy into acoustic energy and transmitting an acoustic energy signal comprising the acoustic energy into the patient's body.

13. The system of claim 12, wherein the implant transducer of the at least one implant is further configured for converting the acoustic energy signal into electrical energy for recharging the energy storage device.

14. The system of claim 1, further comprising an adhesive for securing the controller to the exterior surface of the patient's body.

15. The system of claim 1, wherein the controller is carried by a patch attachable to the exterior surface of the patient's body.

16. The system of claim 1, wherein the external controller is adapted to be coupled to the exterior surface of the patient's body.

17. The system of claim 1, wherein the external controller is adapted to be secured to the exterior surface of the patient's body.

18. An apparatus for communicating with an implant located within a patient's body, the implant including one or more acoustic transducers configured for communicating using acoustic telemetry, comprising:

one or more acoustic transducers for placement in contact with an exterior surface of the patient's body;

a controller coupled to the one or more acoustic transducers such that the one or more acoustic transducers are configured for at least one of transmitting acoustic signals to and receiving acoustic signals from within the patient's body to communicate with the implant;

an interface configured for wirelessly communicating data between the controller and a device separate from the controller;

an energy storage device for providing electrical energy to at least one of the controller and the one or more acoustic transducers; and

an external charger configured for placement against an exterior surface of the patient's body, the charger comprising a source of electrical energy, and an acoustic transducer for converting electrical energy from the source of electrical energy into acoustic energy and transmitting the acoustic energy into the patient's body for energizing an energy storage device in the implant.

19. The apparatus of claim 18, wherein the one or more acoustic transducers of the controller are configured for transmitting first and second acoustic control signals separated by a predetermined delay.

20. The apparatus of claim 18, wherein the controller includes a processor for controlling the one or more acoustic transducers of the controller to transmit one of a first acoustic control signal and a second acoustic control signal.

21. The apparatus of claim 18, wherein the controller is carried by a patch attachable to the exterior surface of the patient's body.

22. The apparatus of claim 21, wherein the patch comprises a flexible piezoelectric material.

23. A method for communicating with one or more implants located within a patient's body, at least one implant comprising an acoustic implant transducer configured for communicating using acoustic telemetry, the method comprising:

placing a portable communications device adjacent to an exterior surface of the patient's body, the communications device comprising one or more acoustic transducers, and an energy storage device for providing electrical energy to operate the communications device;

transmitting an acoustic control signal into the patient's body and communicating with the at least one implant using the one or more acoustic transducers, the acoustic control signal adapted to activate a switch, said switch being coupled to the acoustic implant transducer and an energy storage device of the at least one implant, wherein the switch is configured to actuate the at least one implant between a sleep mode, in which current is limited from flowing from the energy storage device of the at least one implant to the electrical circuit, and an active mode, in which current flows from the energy storage device of the at least one implant to the electrical circuit; and

wherein communicating with the at least one implant includes transmitting one or more acoustic signals from the communications device into the patient's body, the one or more acoustic signals including a command for controlling an operation of the at least one implant.

24. The method of claim 23, wherein the command comprises measuring a physiological parameter within the body.

25. The method of claim 23, wherein the command comprises controlling a therapeutic device coupled to the at least one implant.

26. The method of claim 23, wherein upon receiving an acoustic control signal from the communications device, the acoustic implant transducer closes the switch to allow electrical energy to flow from the energy storage device of the at least one implant to power the at least one implant.

27. The method of claim 23, wherein communicating with the at least one implant comprises the portable communications device receiving one or more acoustic signals from the at least one implant, the one or more acoustic signals comprising data indicative of a physiological parameter measured by the at least one implant.

28. The method of claim 27, further comprising the portable communications device extracting data from the one or more acoustic signals received from the at least one implant.

29. The method of claim 28, further comprising storing the extracted data in a memory of the communications device.

30. The method of claim 28, further comprising transferring the extracted data to an electronic device external to the patient's body.

31. The method of claim 28, wherein the communications device comprises a patch carrying the one or more acoustic transducers, and where placing the device adjacent to the patient's body comprises securing the patch to the exterior surface of the patient's body.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,617,001 B2
APPLICATION NO. : 11/276576
DATED : November 10, 2009
INVENTOR(S) : Penner et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

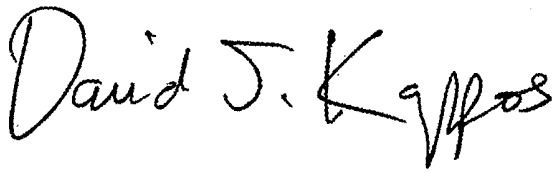
On the Title Page:

The first or sole Notice should read --

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 686 days.

Signed and Sealed this

Fourteenth Day of December, 2010



David J. Kappos
Director of the United States Patent and Trademark Office

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摘要(译)

使用声学遥测技术与患者体内的植入物通信的系统和方法包括可附接到患者皮肤的外部通信设备。该装置包括声换能器，用于将声信号传输到患者体内和/或用于从植入物接收声信号。该装置包括用于提供电能以操作该装置的电池，用于从植入物接收的声信号中提取数据的处理器，以及用于存储数据的存储器。该设备可以包括用于与记录器或计算机通信的接口，例如，从植入物传输数据和/或接收用于控制植入物的指令。该装置固定到患者的皮肤上，用于控制，监测或以其他方式与植入物通信，同时允许患者保持活动。