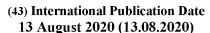
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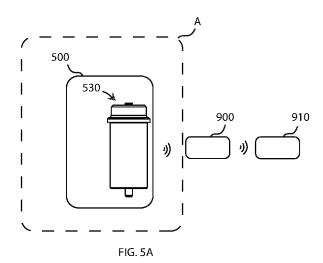
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(57) **Abstract:** The present disclosure provides implants, sensor modules, networks, and methods configured to establish transcutaneous power and transcutaneous bidirectional data communication using ultrasound signals between two or more medical devices located on and within a body of a patient.



ULTRASONIC COMMUNICATION IN MEDICAL DEVICES

FIELD OF DISCLOSURE

[0001] The present disclosure generally relates to the field of ultrasound communication. More specifically, the present disclosure includes medical devices configured for bidirectional communication using ultrasound signals.

BACKGROUND

[0002] Medical implants have various forces exerted on them in vivo, especially medical implants that are adjustable in situ. Such adjustable medical implants for example, are used in limb lengthening and spinal adjustable surgical procedures to treat conditions such as limb deformities and scoliosis. Typically, these adjustable medical implants are secured to one or more bones and gradually adjusted over time until some patient outcome is achieved.

[0003] These surgical implants and procedures do not include an accurate and non-invasive means of measurement of in vivo conditions, such as forces and pressures, present at the implant site. Particularly, during the course of treatment. A need exists for a device and method to facilitate the ability of care providers to non-invasively ascertain conditions present at the implant.

SUMMARY OF THE INVENTION

[0004] The present disclosure provides transcutaneous ultrasonic power transmission and bidirectional data communication between medical devices located on and/or within a body of a patient.

[0005] In some aspects, the present disclosure provides a system including: an implant and an external transceiver, the implant having at least one ultrasonic transducer configured to receive an ultrasound signal sent by the external transceiver and convert that ultrasound signal to electrical energy to power the implant.

[0006] In some aspects, the present disclosure provides an implant including a sensor and an ultrasonic transducer, wherein the sensor is configured to measure a physical property of the implant, and wherein the implant is configured to transmit data corresponding the measurement via an ultrasound signal produced by the ultrasonic transducer.

In some aspects, the present disclosure provides an adjustable implant, the adjustable implant including an actuator and at least one ultrasonic transducer, wherein the ultrasonic transducer is configured to receive an ultrasound signal sent by an external transceiver, and convert that ultrasound signal to electrical energy to power the actuator, and wherein the implant is configured for the bidirectional ultrasonic data communication using the ultrasonic transducer to send and receive adjustment instructions between the adjustable implant and the external transceiver.

[0008] In some aspects, the present disclosure provides a sensor module configured to be integrated with an implant, the sensor module including: a sensor, an ultrasonic transducer, and a controller, wherein the sensor, ultrasonic transducer, and controller are operably connected, and wherein the sensor module is configured for bidirectional data communication using ultrasound signals.

[0009] In some aspects, the present disclosure provides an external transceiver configured to be placed adjacent to a patient's skin having at least one ultrasonic transducer, wherein the at least one ultrasonic transducer is configured for bidirectional data communication using ultrasound signals.

[0010] In some aspects, the present disclosure provides a method of transcutaneous transmission of power to an implant positioned within a subject via an ultrasound signal.

[0011] In some aspects, the present disclosure provides a method of transcutaneous transmission of power to an implant using an ultrasound signal including: transmitting an ultrasound signal from an external transceiver to the implant, receiving the ultrasound signal at the implant with an ultrasonic transducer; converting the signal to electrical energy using the ultrasonic transducer; and using the electrical energy to power the implant.

[0012] In some aspects, the present disclosure provides a method of transcutaneous bidirectional data communication using an ultrasound signal, the method including: placing an implant within a body of a patient, placing a transceiver on or within the body of the patient, and transcutaneously transmitting ultrasound signals between the implant and the transceiver.

[0013] In some aspects, the present disclosure provides a method of transcutaneous bidirectional data communication using an ultrasound signal, the method including: implanting a device within a body of a patient, transmitting at least one of power or data to the device using an ultrasound signal, and transmitting data from the device using an ultrasound signal.

[0014] In some aspects, the present disclosure provides a method of c using an ultrasound signal, the method comprising the steps of: implanting a sensor module within a body of a patient, transmitting at least one of wireless power or data to the sensor module using an ultrasound signal; and transmitting data from the sensor module using an ultrasound signal.

[0015] In some aspects, the present disclosure provides a local body area network (BAN), the local body area network includes one or more implants configured for transcutaneous bidirectional data communication, allowing the one or more implants to communicate data across the local body area network transcutaneously.

[0016] In some aspects, the present disclosure provides a local body area network (BAN), the local body area network includes an external transceiver configured for transcutaneous ultrasonic communication, and one or more implants configured for transcutaneous ultrasonic communication, wherein the external transceiver and the one or more implants are configured to communicate data across the local body area network (BAN).

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] These and other features will be further understood by those with skill in the art upon a review of the appended drawings, wherein:

[0018] FIG. 1 shows an implant in accordance with a first embodiment disposed within a patient, the implant configured to receive power transcutaneously via an ultrasound signal;

[0019] FIG. 2 shows an implant in accordance with a second embodiment, the implant configured for transcutaneous bidirectional ultrasonic data communication with an external transceiver;

[0020] FIG.3A shows a side view of an implant in accordance with a third embodiment, the implant configured for transcutaneous bidirectional data communication using an ultrasound signal, the implant including a sensor module disposed therein;

[0021] FIG.3B shows a cross-sectional side view of the implant in accordance with the third embodiment, the implant shown having a sensor module disposed therein, the sensor module configured for transcutaneous bidirectional data communication using an ultrasound signal.

[0022] FIG.4A shows a perspective view of a sensor module in accordance with a first embodiment;

[0023] FIG.4B shows a side view of the sensor module in accordance with the first embodiment;

[0024] FIG.4C shows a side view of the sensor module in accordance with the first embodiment, the sensor module shown with a portion of an external encapsulation removed;

[0025] FIG.4D shows a cross-sectional side view of the sensor module in accordance with the first embodiment, the sensor module shown including a three-dimensional stacked circuitry design;

- [0026] FIG.4E shows a printed circuit board, configured for three-dimensional stacked circuit integration;
- [0027] FIG.4F shows a chassis, the chassis configured for three-dimensional stacked circuit integration;
- [0028] FIG.5A shows a sensor module in accordance with a second embodiment, the sensor module integrated with an implant disposed within the body of a patient, the sensor module configured to enable the implant transcutaneous bidirectional data communication using an ultrasound signal;
- [0029] FIG.5B shows a schematic of implant transcutaneous bidirectional data communication using an ultrasound signal between the sensor module and an external transceiver;
- [0030] FIG.5C shows an external transceiver configured for transcutaneous bidirectional data communication using an ultrasound signal, communicating with the sensor module;
- [0031] FIG.5D shows an external transceiver configured for transcutaneous bidirectional data communication using an ultrasound signal, including a standoff;
- [0032] FIG.6A shows an embodiment of an external transceiver configured for transcutaneous bidirectional data communication using an ultrasound signal, the external transceiver including a knee brace;
- [0033] FIG.6B shows a cross-sectional view of the external transceiver being worn by a patient having an intramedullary implant disposed within a bone;
- [0034] FIG.7 shows a diagram of the external transceiver determining a location of low bone density and transmitting ultrasound waves modulated at a healing frequency to the location;

[0035] FIG.8 shows an exemplary Body Area Network established between two implants and an external transceiver, with the Body Area Network established using ultrasound waves;

[0036] FIG.9A shows an exemplary Body Area Network established between three implants located inside a body of a patient and an external transceiver; and

[0037] FIG.9B shows an exemplary Body Area Network established between three implants located inside a body of a patient wherein one of the implants has been designated host status.

[0038] FIG.10 shows an exemplary method of powering an implant using ultrasound waves;

[0039] FIG.11 shows an exemplary method of transcutaneous data transmission using ultrasound waves;

[0040] FIG.12 shows an exemplary method of transcutaneous power and/or data transmission using ultrasound waves;

[0041] FIG.13 shows an exemplary method of using a sensor module;

[0042] FIG.14 shows an exemplary method for a plotting bone density;

[0043] FIG.15 shows an exemplary method for three-dimensional bone density imaging; and

[0044] FIG. 16 shows an exemplary method for measuring an increase in length of a bone.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0045] For purposes of explanation and not limitation, details and descriptions of certain embodiments are hereinafter provided such that one having ordinary skill in the art may be enabled to make and use the invention. These details and descriptions are representative only of certain embodiments, however, and a myriad of other embodiments which will not be expressly described will be readily understood by those having skill in the art upon a thorough review hereof. Accordingly, any reviewer of the instant disclosure should interpret the scope of the invention by the claims, and such scope shall not be limited by the embodiments described and illustrated herein.

[0046] Ultrasonic communication in medical implants can provide one or more of: power, enhanced control, and feedback between medical implants and/or external transceivers.

In Radio Frequency (RF) signals, which utilize electromagnetic waves, information may be conveyed within the body. But RF signals experience large amounts of attenuation in aqueous tissues, bone tissues, and largely reflect off metallic surfaces. Ultrasound waves experience much less attenuation within aqueous tissues, bone tissues, and can even penetrate through metallic surfaces. Ultrasound signals are ultrasound waves that convey information via known amplitude and phase shifting techniques, similar to common techniques used in RF telecommunication. Phase-Shift Keying is a digital modulation process which conveys data by changing the phase of a constant frequency carrier wave. The modulation is accomplished by varying the sine and cosine inputs at a precise time. It is widely used for wireless LANs, RFID and Bluetooth (BT). Binary phase-shift keying (BPSK) or any known modulation technique may be used in ultrasound communication including: On-Off Keying (OOK), Amplitude-Shift Keying (ASK) and Frequency-Shift Keying (FSK).

[0048] The frequency of ultrasound sound waves chosen to establish the bidirectional ultrasonic communication may include any frequency of ultrasound, but are generally greater

than about 20 kilohertz. In some embodiments, the frequency of ultrasound sound waves may be between 200 and 400 kilohertz, for example about 300 kilohertz. The benefits of utilizing ultrasound sound waves for power and data transmission include: (1) that ultrasound sound waves have favorable propagation and minimal attenuation characteristics through metal or solid mediums (e.g., metallic medical implants), and (2) that ultrasound sound waves transmit data transcutaneously through various aqueous tissues in animals (e.g. human skin, muscle and bone).

Once a transcutaneous bidirectional ultrasound communication link is established, the implant may have a power consumption of between 0.5 mW and 80 mW, 1 mW and 60 mW, and 2.0 mW and 40 mW, 10 mW, 5 mW, and any subrange thereof. The ultrasonic transducer may consume about 20 mW of power when in operation. The ultrasonic transducer may be configured to transmit data through at least four inches of water or aqueous tissues at a rate of 5 values per second (1kb/s) with a data reliability of over 95%. Data reliability transmitted from the ultrasonic transducer at these power levels may be at least 95%, at least 99%, at least 99.9%, or 100%. "Data reliability" means reliability over 10 minutes as calculated from a bit error rate (BER).

[0050] As discussed above, ultrasonic communication in medical implants can provide one or more of: power, enhanced control, and biofeedback between medical implants and external transceivers. Ultrasonic communication in medical implants includes of one or more of power transmission and data transmission using ultrasound signals. The ultrasound signal may be one or more of filtered, demodulated, amplified, and analyzed using one or more of physical components and software techniques.

[0051] Communication may be established in one direction. In some embodiments, the external transceiver may transmit an ultrasound signal to the implant to transfer power from

the external transceiver to the implant. As discussed above, the ultrasound signal may be modulated. The implant is configured to harvest electrical energy from the ultrasound signal and may include one or more of a filter, a mixer, and a modulator to configure the implant for power reception. In some embodiments, the circuitry of the implant may include one or more of a filter, a mixer, and a modulator with and any known electrical components and circuitry to configure the implant for data communication. In some embodiments, one or more of a discrete demodulator and mixer implemented on the implants controller.

[0052] For bidirectional communication, and communication across a network, the implant may communicate back to the external transceiver during one or more of a pause and a release the line time period, during which the external transceiver may cease signal transmission allowing the implant to send modulated ultrasound signals back to the transceiver. For example, the transceiver may act as a master and command or query the implant acting as a slave, then pause ultrasound signal transmission for a period and allow the slave implant to send an ultrasound signal and for example: confirm or reply to the query.

In some embodiments, bidirectional communication may include continuous power transmission. For example, the external transceiver sending a constant power signal to the implant. This power signal from external transceiver to implant may be modulated using the techniques above to transmit data from external transceiver to implant. The implant, may communicate data back to the external transceiver via backscatter/load modulation. For example, the incident energy from the external transceiver may be reflected back by the implant towards the external transceiver to communicate.

[0054] In some embodiments the ultrasound transducer may be shorted by a switching device, for example a BJT or MOSFET on an integrated circuit. In some embodiments, the ultrasound transducer may be shorted by a switch, relay, solid state relay, vacuum tube, and

any other known device configured to short the ultrasound transducer for backscattering/load modulation.

[0055] In some embodiments, power transmission may be sequential. For example, the external transceiver sending a pulsed power signal to the implant. This power signal from external transceiver to implant may be modulated using the techniques above to transmit data from external transceiver to implant. The implant, may communicate data back to the external transceiver when during pauses in data transmission.

[0056] In the near field region (with the implant and the external transceiver in close proximity), adjusting the impedance of the load is known as load modulation. Due to the coupling of the relatively closely spaced transducers, a change in the impedance of the ultrasound transducer of the implant, will be observable by the external transceiver. The external transceiver's ultrasound transducer will appear to its driving circuit to change in impedance, and draw different amounts of current.

[0057] In the far field region (implant and external transceiver at a greater distance), adjusting the impedance of the load is known as backscatter communications. Changing the impedance of the implant's ultrasound transducer changes the magnitude of the reflected energy. Shorting out the implant's ultrasound transducer will result in increased reflection of energy. This reflected energy pattern may be visible at the external transceiver.

These and other data communication protocols may be readily understood by those having skill in the art. As one with skill in the art may appreciate, the above communication protocols are described with an implant communicating with an external transceiver. In some embodiments, each of the implant and the external transceiver can be replaced by one or more of: a second implant, a sensor module, and a tertiary device.

[0059] In FIG. 1, a schematic diagram is provided showing an implant **100** adapted to receive wireless power from an external transceiver **900** via an ultrasound signal. The

ultrasound signal may include modulated ultrasound waves produced by an ultrasonic transducer. The implant 100 is shown disposed within a body of a patient A. The patient A may include any animal, and may be a human. The implant 100 may include at least one ultrasonic transducer 101 configured to receive an ultrasound signal sent by an external transceiver 900, and convert that ultrasound signal to electrical energy. The implant 100 may include for example a patch configured to be attached to one or more of a bone and a tissue within the patient. The ultrasonic transducer 101 may include for example a piezoelectric polyvinylidene fluoride (PVDF) flexible thin film piezoelectric transducer, which may be operably connected to other circuitry of the implant 100. The electrical energy harvested by the ultrasonic transducer 101 may be used to activate or power any circuitry of the implant 100.

[0060] In some aspects, the implant **100** may be, by way of example, a distraction rod, an intramedullary rod, or any other adjustable implant or medical device intended for placement on and within the body of a patient. Wireless activation and or powering of the implant **100** using ultrasound waves, may eliminate a need for the internal power storage devices required by some known adjustable implants.

[0061] The implant **100**, may be made of Polyether ether ketone (PEEK), Polyetherketone (PEK), Titanium (Ti), and any other material known and used in the art of manufacture of medical implants. The material may be chosen depending on the application of the implant **100**. The implant **100**, may be fabricated using known fabrication, including known electronic fabrication techniques.

[0062] In some embodiments, the ultrasonic transducer **101** may include any device that induces sound waves or mechanical vibration, and converts soundwaves to electronic signals, including for example: a piezoelectric transducer, a single crystal ultrasonic transducer, a lead zirconate titanate (PZT) ultrasonic transducer, piezoelectric polyvinylidene fluoride

(PVDF) ultrasonic transducer, capacitive micromachined ultrasonic transducers (CMUT), piezoelectric micromachined ultrasonic transducers (CMUT), or any ultrasonic transducer known and used in the art. In some embodiments, the ultrasonic transducer 101 may include one or more of: a thin film ultrasonic transducer, a flat ultrasonic transducer, a tubular ultrasonic transducer. A benefit for example of a thin film ultrasonic transducer is the reduced thickness of the ultrasonic transducer. A benefit for example of a flat ultrasonic transducer is improved transmission and reception characteristics. A benefit for example of a tubular ultrasonic transducer is multi-directional transmission and reception. The type of ultrasonic transducer may be chosen to complement the application of the implant 100.

In some embodiments, the external device 900 may retrieve an ID tag of an implant 100 using ultrasound waves. For example, the implant 100 may include an integrated circuit and an ultrasonic transceiver 101, which are used to transmit data corresponding to an ID tag of the mplant 100 to the external device 900 using ultrasound waves. The external device 900 may transmit an ultrasound signal modulated at a particular temperance to the implant 100. Upon receipt, the modulated ultrasound signal will be converted to electrical power by the ultrasonic transducer and may activate a digital switch of the implant 100. Upon activation, the implant may transmit a modulated ultrasound signal corresponding to the ID tag, back to the external device 900. Allowing a user to determine the ID tag and corresponding implant 100 without for example taking unnecessary radiological images which may expose the patient to radiation.

[0064] In some embodiments, a phased array containing multiple ultrasonic transducers may be provided to one or more of the external device and the implant to provide enhanced reception capabilities to the implant or external device.

Turning to FIG. 2, a schematic diagram is provided showing implant 200 in accordance with a second embodiment, the implant 200 is configured for transcutaneous ultrasonic data communication with at least an external transceiver 900. The implant 200 is shown having operatively connected circuitry including at least one ultrasonic transducer 201, a controller 202, a sensor 205, and a power storage device 204. In some embodiments, one or more of these components may be duplicated, substituted, or withheld.

The controller **202** may be any type of controller **202** known and used in the art including: high performance microcontrollers (MCUs), Programmable System on Chip (PSoC), Application Specific Integrated Circuit (ASIC) or any other type of controller or microcomputer. The controller **202** may be disposed on a printed circuit board which may also contain other electronic circuitry and connect other electrical components including: Analog to Digital Converter (ADC), Digital to Analog Converter (DAC), op-amps, memory or any other electrical component. The controller may further include a frequency synthesizer (i.e., creates carrier waves for ultrasonic transducer **201**), power amplifiers, noise filters (i.e., conditions carrier wave), power and read strain gauges (i.e., force sensor controls), and may be configured to adjust carrier waves, power, etc. such as by computer executable instructions that interface with a user via a graphical user interface, as discussed below.

A power storage device **204** may be provided. The power storage device **204** may include a battery, a capacitor, and any other power storage device. The power storage device **204** may include a rechargeable battery, for example a Lithium ion rechargeable battery. The power storage device may include a solid state battery and any battery including any known battery chemistry.

[0068] The implant **200** may include a charging circuit operably connected to one or more of the power storage device **204** and the piezoelectric transducer **201**. The charging

circuit may be at least partially integrated into for example the controller **202**. The power storage device **204** may be operably connected to the controller **202** via any electronic conductor including wires, boards, and interconnects. The charging circuit may include any charging circuit known and used in the art.

[0069] The implant **200** may be configured to receive an ultrasound signal sent by an external transceiver **900**, and convert that ultrasound signal to electrical energy using the ultrasonic transducer **201**. The recharging circuit may use the generated electrical energy to charge the power storage device **204**.

[0070] The external transceiver **900** may recharge a battery of the implant **200**, by transmitting an ultrasound signal to the implant **100**, with the piezo electric transducer configured to convert the ultrasound signal to electrical power to recharge the battery. In some embodiments, the external transceiver **900** may activate the implant **100** by sending pulses of ultrasound signal for "stop and go" charging of the capacitor. For example, the capacitor may be charged by a pulse or a series of pulses, with just enough energy to one or more of: make an incremental adjustment and send a signal back to the external transceiver. In some embodiments, real time charging of the power storage device can enable continuous drive of an actuator of the implant.

[0071] In some embodiments, other known wireless charging circuits and techniques including for example, inductive coupling and magnetic coupling may be used to wirelessly transfer power to the implant **200**.

[0072] In some embodiments, an external transceiver **900** may activate the circuitry of the implant **200** by transmitting an ultrasound signal to the ultrasonic transducer **201**. The ultrasound waves of the ultrasound signal may be received by the ultrasonic transducer **201** and converted into electrical energy. The controller **202** may be programmed such that upon

receipt of ultrasound waves corresponding to a modulated signal, for example a particular step function of a particular temperance, the controller **202** will close an electrical switch and activate the implant **200**. Similarly, in other embodiments a particular step function may be used to open an electrical switch and deactivate the implant **200** to conserve power stored in the power storage device **204**.

In some embodiments, the controller **202** may be programmed to time the implant **200** out after a certain period of time, for example if the ultrasound transducer **201** has not sent or received an ultrasound signal for a test period of time, the controller **202** may deactivate the implant **200**.

In some embodiments, the controller **202** may be programmed to turn off the power storage device **204** and to put the implant **200** to sleep for a certain period of time to conserve power. For example, the controller may activate the implant **200** for ¼ of 1 second to one or more of: transmit ultrasound signals using the ultrasound transducer **201**, obtain measurements using the sensor **205**, control an actuator, communicate with other electronics of the implant **200**, etc. During this ¼ of the second the implant **200** is said to be "awake". The controller **202** may deactivate the implant **200** for ¾ of the second. During this ¾ of the second the device is said to be asleep.

In some embodiments the implant **200** may include one or more sensor **205** operably connected to the controller **202**. The one or more sensor **205** may be designed to measure temperature, position, force, pressure, capacitance, resistance, and any other physical property or characteristic of the implant **200** or surrounding anatomical structures of the patient **A**. In some embodiments, the sensor may include for example a position sensor (e.g. optical sensor). In the illustrated embodiment, the sensor **205** may be configured to sense force or temperature for example.

In some embodiments, the sensor **205** may include a Micro-Electro-Mechanical-System (MEMS) sensor. These sensors provide a reduced profile (e.g. 1 μm-100 μm size). The MEMS sensor may include an accelerometer, pressure sensor, gas sensors, humidity sensor, a gyrosensor, ambient light sensor, optical sensor, gesture sensor, proximity sensor, position sensor, touch sensor, and may include any other known sensory functionality.

[0077] The sensor **205** may communicate a sensor reading to the controller **202**, which may convert the reading to a modulated electrical signal. The modulated electrical signal may then be used to drive the ultrasonic transducer **201**, which then transmits ultrasound waves at a frequency corresponding to the modulated electrical signal.

[0078] The controller **202** may change analogue information from the sensor to digital values and may drive modulation of the ultrasonic transducer **201**, to transmit data using ultrasound waves. Any known signal modification technique for data transmission may be used for ultrasound waves that may be used for example with RF data transmission. Including any type of pass band modulation.

The implant **200** may include an adjustable implant. The adjustable implant may include any actuator known and used in the art. As one with skill in the art may appreciate, the actuator may include for example an electric motor, a rotatable magnet, an impact driver, and any known actuator used in medical implants. The implant **200** may be configured to harvest ultrasound waves transmitted by another implant or an external transceiver, and convert the ultrasound waves to electrical energy to power the actuator.

[0080] In FIG. 3A-3B, an adjustable implant **300** is shown. The adjustable implant **300** includes a first portion **310** configured to be attached to a bone of a patient at a first location and a second portion **320** configured to be attached to a bone of a patient at a second location.

The adjustable implant **300** may be any type of adjustable implant. By way of example, an adjustable implant may include magnetically adjustable systems, such as the PRECICE® or MAGEC® magnetically adjustable implant systems for spinal and limb lengthening procedures sold by NuVasive, Inc. of San Diego, California. Such adjustable systems are disclosed in, for example, US Patent Nos. 9,398,925 and 9,393,117, which are incorporated by reference herein in their entireties.

[0081] FIG. 3B shows a cross-sectional view of the adjustable implant 300, the first portion 310 includes a distraction rod. The distraction rod comprises a magnet 311, and the magnet 311 is connected to a lead screw 312. Upon an axial rotation of the magnet 311 due to an externally applied rotating magnetic field, the lead screw 312 will rotate. Rotation of the lead screw 312 will cause an axial distraction of the distraction rod.

[0082] Now, adjustable implants experience numerous forces in vivo. For example, as the length of the illustrated distraction rod is increased, the distraction rod will experience axial forces pushing down through the lead screw on the magnet 311. Thrust bearings 313 are provided to mitigate the effect of these forces on the rotation of the magnet 311. However, when using an External Controller to noninvasively apply the magnetic field and adjust the distraction rod, biofeedback is often limited.

The implant **300** in FIG.3B includes a sensor module **330** disposed within the second portion **320**. The sensor module **330** includes a tubular piezoelectric transducer **331** operably connected to a controller **332**. The tubular piezoelectric transducer **331** is configured to transmit and receive ultrasound signals. The tubular piezoelectric transducer **331** is operably connected to the controller **332** via an interconnect **333**. As discussed above, the controller **332** may be any type of controller **332** known and used in the art including high performance microcontrollers (MCUs), Programmable System on Chip (PSoC), or any other type of

controller. The controller **332** may be disposed on a printed circuit board which may also contain other electronic circuitry and components therein including: Analog to Digital Converter (ADC), Digital to Analog Converter (DAC), op-amps, memory and any other known electronic component.

[0084] A power storage device **334** is provided. The power storage device **334** may include a battery, a capacitor, and any other rechargeable power storage device.

[0085] The sensor module **330** may include a recharging circuit operably connected to the power storage device **334** and the tubular piezoelectric transducer **331**. The recharging circuit may be for example: integrated into the controller **332** or disposed on another printed circuit board. The power storage device **334** may be operably connected to the controller **332** via an interconnect **333**.

[0086] The sensor module **330** is configured to receive an ultrasound signal sent by an external transceiver **900**, and convert that ultrasound signal to electrical energy using the tubular piezoelectric transducer **331**. The recharging circuit may use the harvested electrical energy to charge the power storage device **334**.

In some embodiments, an external transceiver 900 may activate the circuitry of the sensor module 330 by transmitting ultrasound waves to the sensor module 330. The ultrasound waves are received by the tubular piezoelectric transducer 331 and converted into electrical energy. The controller 332 may be programmed such that upon receipt of ultrasound waves corresponding to a particular modulated signal, for example a particular step function of particular temperance, the controller may close an electrical switch and activate the device. Similarly, in other embodiments a particular step function may open the electrical switch and deactivate the device to conserve power.

[0088] In some embodiments, the controller **332** may be programmed to time out after a certain period of time, wherein if for example the piezoelectric transducer **331** has not sent or received ultrasound waves, thereby conserving charged power levels of the power storage device **334**, extending a battery life thereof.

In some embodiments the sensor module **330** may be configured to have a power consumption of between 0.5 mW and 80 mW, 1 mW and 60 mW, and 2.0 mW and 40 mW, 10 mW, 5 mW, or any subrange thereof. The transmitter 30 may consume about 20 mW of power when in operation. The transmitter 30 may be configured to transmit data at least four inches through water at a rate of 5 values per second (1kb/s) with a data reliability of 95%. Data reliability transmitted from the transmitter at these power levels may be at least 95%, at least 98%, at least 99%, at least 99.9%, or 100%. "Data reliability" means reliability over 10 minutes as calculated from a bit error rate (BER).

[0090] The sensor module 330 may include one or more sensors 335 operably connected to the controller 332. The sensors 335 may be designed to measure force, temperature, pressure, capacitance, resistance, and any other type of sensor known and used in the art. In the instant embodiment the sensor module 330 is configured to sense axial force from the distraction device using a force sensor 335. The force sensor 335 of the sensor module 330 is operably coupled to the distraction rod using an adapter plate 314.

The force sensor 335 communicates a sensor reading to the controller 332, which may convert the reading to a modulated electrical signal. The modulated electrical signal may then be used to drive the piezoelectric transducer 331, which then transmits ultrasound waves transcutaneously to an external transceiver 900. In some embodiments, forms of modulation may include: on-off keying, amplitude shift keying (ASK), frequency shift keying (FSK), phase shift keying (PSK), analogue frequency modulation, or any other form of

modulation commonly known and used for data transmission. Advantageously, signals that are modulated use less power than non-modulated signals and may be transmitted and received at greater distance from the sensor module **330** than non-modulated signals. Modulated signals may also have a greater accuracy than non-modulated signals.

In some embodiments, the sensor module **330** includes an encapsulation **336** providing a hermetic seal to the sensor module **330**. In order to prevent air gaps which include pockets of unnecessary ultrasonic impedance, in some embodiments the piezoelectric transducer **331** is coupled to at least a portion of the encapsulation **336** using a conductive epoxy (see FIG. 4D, **408**). In this embodiment the sensor module **330** is disposed adjacent to a surface of the implant **300** to minimize airgaps and impedance.

[0093] The conductive epoxy may include any ultrasound conductive material to reduce air gaps, including aluminum epoxy, copper epoxy, copper tape, Ti-epoxy, industry acoustic couplant, and any other material providing favorable electrical and acoustic conductive properties. When selecting a conductive epoxy one may consider: i.) impedance matching to improve the ultrasonic transmission efficiency between the implant and the piezoelectric transducer, and ii.) the circuit grounding the electronics.

The sensor module **330** may include a memory and may log data corresponding to one or more of a reading of the sensor **335**, data received from the external transceiver **900** via ultrasound signals, and other data corresponding to the implant **300** and a biological condition of the patient. For example, the sensor module **330** may record sensor **335** data at various time intervals. In some embodiments data logging includes overwriting the data where needed to maintain files similar to for example a car dash camera.

[0095] Upon establishing a bidirectional communication link with an external transceiver **900** using ultrasound signals, the external transceiver **900** may download the data

from the sensor module **330**. A user may later retrieve the data from the external transceiver **900** and be able to plot the data, giving the user invaluable insights into the in-situ forces being placed on the implant **100**.

In some embodiments, the external transceiver **900** may include a wired or RF communication capability and may additionally be accessible to a remote user through one or more of the internet, WiFi, Bluetooth, and cellular networks. In some embodiments, the user can remotely update a firmware of the controller **332**, for example across the internet by remotely accessing the external transceiver **900**. In some embodiments, the user can transmit adjustment instructions to the implant **100**, for example across the internet by remotely accessing the external transceiver **900**. In some embodiments, the user can access data from the implant **100**, for example across the internet by remotely accessing the external transceiver **900**.

[0097] As one with skill in the art may appreciate, in the instant embodiment the implant **300** includes a sensor module **330** having various capabilities and features. In some other embodiments, these various components and features may be incorporated directly into the implant **300** similar to those discussed supra.

[0098] FIG.4A shows a perspective view of a sensor module **400**. The sensor module **400** is configured to interface with any implant to provide at least one of remote activation, transcutaneous power, transcutaneous bidirectional ultrasonic data communication, or remote measurements of properties of the implant. FIG.4B shows a side view of the sensor module **400**, the sensor module **400** shown including an encapsulation **406** hermetically sealing the internal components of the sensor module **400** therein.

[0099] In the illustrated embodiment, the sensor module **400** has a cylindrical profile. As one with skill in the art may appreciate the sensor module **400** may conform to any profile

including: a rectangular profile, a block profile, a disc profile, a patch, a membrane, and any known profile of an implant and a surface of an implant. Wherein the implant is a distraction rod, the cylindrical profile may provide some advantageous. For example, the cylindrical profile of the sensor module **400** is intended to allow a maximum amount of contact surface of the sensor module **400** across an internal surface of the distraction rod. Matching the curvature of the sensor module to the intended implant provides improved transmission and reception characteristics of the sensor module **400**, across greater surface area of the implant, and provides up to 360 degrees of reception.

[0100] In FIG.4C, the sensor module **400** is shown with part of the encapsulation **406** removed for convenience, revealing some of the internal components of the sensor module **400**. The sensor module **400** is shown having a tubular ultrasound transducer **401**, a controller **402**, at least one interconnect **403**, a power storage device **404**, and a sensor **405**.

In FIG.4D a cross-sectional side view of the sensor module **400** is provided, revealing the internal circuitry and structure of the sensor module **400**. In this embodiment the circuitry is arranged in a three dimensional stacked configuration. In this configuration the tubular ultrasonic transducer **401**, power storage device **404**, and controller **402** are stacked on top of one another and connected via interconnects **403**. This stacked arrangement provides reduced dimensions to the sensor module **400**. This stacked arrangement is achieved using the tubular piezoelectric transducer **401** and a specially designed chassis **407**.

[0102] In some embodiments the ultrasonic transducer **401** is tubular, for example having a channel extending axially therethrough. In such embodiments, the ultrasonic transducer **401** may be coupled to a chassis **407** having interconnects extending therethrough. One interconnect **433** may be configured to operably connect the ultrasonic transducer **401** to a first terminal of the controller **402**. The other interconnect **403** may be configured to operably

connect the power storage device **404** to a second terminal of the controller **402**. The controller **402** may interface with, be integrated with, or otherwise operably connected to a sensor **405**.

In some embodiments, the ground terminal of the power storage device **404** may be shorted to the encapsulation **406**. In such embodiments, the outer diameter of the tubular ultrasonic transducer **401** may also be shorted to ground at the encapsulation **406**, through a conductive epoxy **408**. At least one of the controller **402** or a sensor **405** may also be shorted to ground at the encapsulation **406**. In such embodiments, the chassis **407** may provide insulation of the positive terminal of the power storage device **404**, and interconnects **403** from ground.

[0104] In some embodiments, wherein the implant is made of a metallic material, the encapsulation **406** may be shorted to the implant grounding the internal circuitry of the sensor module.

[0105] FIG.4E shows a controller **402** including small circular printed circuit board having two interconnect terminals **402a**, **402b** to connect the controller **402** to the power storage device **404** and ultrasonic transducer **401**. The controller may include a ground terminal **402c**, to ground connect the controller **402** to the encapsulation. In some embodiments, the ground terminal **402c** is disposed on the side of the circuit board.

As discussed above, the circuit board may further include other electronic circuitry and components therein including: Analog to Digital Converter (ADC), Digital to Analog Converter (DAC), op-amps, memory and other known electronic components. The controller 402 may be integrated to include a frequency synthesizer (i.e., creates carrier waves for ultrasonic transducer 401), power amplifier and noise filters (i.e., conditions carrier wave), power and read strain gauge (i.e., force sensor controls), and may be configured to adjust carrier

waves, power, etc. (such as by computer executable instructions that interface with a user via a graphical user interface, as discussed below).

[0107] FIG.4F shows a chassis **407** configured to receive a tubular ultrasonic transducer **401**. The chassis **407** is shown having a first shelf configured to receive and at least partially extend through a tubular ultrasonic transducer **401**. The chassis **407** is also shown having two channels **407a**, **407b** extending axially therethrough. The channels configured to receive at least a portion of an interconnect therein. The chassis **407** is also shown having a connection cavity **407c** for connecting one of the interconnects to the ultrasonic transducer **401**.

Turning to FIG.5A, a sensor module **530** is shown integrated with an implant **500** disposed within a body of a patient **A**, the sensor module **530** enabling the implant **500** with ultrasonic data communication. The sensor module **530** may enable any implant **500** to transcutaneouly transmit and receive data from an external transceiver **900**. The data may correspond to one or more of measurements obtained by the sensor module **530**, some physical property of the implant **500** and to some physical property of an anatomical item, tissue or structure of the body of the patient **A**. Additionally, the external transceiver **900** may transmit information to the sensor module **530** and the sensor module **530** may be operably connected to internal circuitry of the implant **500**. For example, in some embodiments the external transceiver **900** may transmit adjustment instructions to the sensor module **530** and the sensor module **530** may communicate the adjustment instructions to one or more of a controller and an actuator of an adjustable implant **500**.

[0109] In some embodiments, the sensor module **530** may be integrated with a processor circuit of an implant using any type of interconnection, cable, or communication protocol including RF, Bluetooth, and ultrasound as described above. The sensor module **530**

may receive data from the processor circuit of the implant, and communicate the data transcutaneously to the external transceiver 900.

In some embodiments, the external transceiver **900** may obtain data from the implant **500**, for example in the instant embodiment data is obtained via the sensor module **530**. The external transceiver **900** may then report the data to a tertiary device **910** via an ultrasonic connection, an RF connection, a cable connection, an internet connection, a cell phone connection, a Wi-Fi connection, a Bluetooth connection, and any known data communication protocol. The tertiary device **910** may be for example: a computer, a cell phone, a server, and any other device capable of data communication. The tertiary device **910** may be enabled to drive the external transceiver **900** to communicate with the sensor module **530**, including for example having the capability to actively control an actuator of the implant **500**.

[0111] FIG.5B shows an exemplary schematic of communication between the sensor module **530**, the external transceiver **900**, and the tertiary device **910**. In the instant embodiment the transceiver **900** may be for example a piece of wearable technology, and the tertiary device **910** may be for example a cell phone.

[0112] The external transceiver **900** may include an external adjustment device configured to for adjusting an adjustable implant. The external adjustment device may include one or more ultrasonic transducer disposed on a surface of the external adjustment device. Upon placing the external adjustment device in close proximity to a patient's skin, a bidirectional ultrasound communication link or network may be established between the external adjustment device and one or more implants configured for ultrasound communication. The bidirectional ultrasound communication link established to pass distraction and or bioinformation between the external transceiver **900** and the one or more implants.

[0113] In some embodiments, the external transceiver **900** may be a wearable device. The wearable device may be for example: a bracelet, a watch, an arm band, arm sleeve, arm brace, a leg band, a leg sleeve, a leg brace, a back brace, a body sleeve, a neck brace, a head brace, and any type of other wearable device known and used in the art. The wearable device may be made using additive manufacturing techniques including 3D printing.

- [0114] The external transceiver may include a ultrasonic transducer, or multiple ultrasonic transducers forming one or more array. A one dimensional array has multiple ultrasonic transducers disposed in a column. The ultrasonic transducer of a one dimensional array can be assigned a position relative to their position on the array. A two dimensional array has multiple ultrasonic transducers disposed in a matrix or pattern. The ultrasonic transducer can be assigned a location relative to two dimensions of the matrix.
- [0115] Now, the external transceiver **900** communicates with the sensor module **530** using transcutaneous bidirectional ultrasound signals transmitted from an ultrasound transducer **501** to the external transceiver **900**, and from the external transceiver **900** to the ultrasound transducer **501**. In this embodiment, the ultrasound transducer **501** includes a piezoelectric transducer.
- [0116] The external transceiver **900** may communicate with the tertiary device **910**. In some embodiments the tertiary device **910** may communicate with one or more of the external transceiver **900** and the sensor module **530** using ultrasound signals. In some embodiments, the tertiary device **910** may communicate with the external transceiver **900** using for example RF communication protocols. The tertiary device **910** may be in further communication with one or more of the internet and other telecommunication networks, allowing a user to remotely access the sensor module **530**, and even control an implant **500** from anywhere.

[0117] In some embodiments, a High-intensity focused ultrasound (HIFU) ultrasonic transducer having a fixed focal depth may be provided to one or more of the external transceiver and the sensor module to provide enhanced reception capabilities to the sensor module or the external transceiver. An offset, including an adjustable offset, may be provided to the external transceiver to move the external transceiver to and hold the external transceiver at a distance from the sensor module corresponding to the fixed focal depth of the HIFU ultrasonic transducer. This allows a user to find a maximum amount of transmission to or from the sensor module and improves power transmission and data communication between the sensor module and the external transceiver.

- [0118] FIG.5C shows an external transceiver **900** including a High-intensity focused ultrasound (HIFU) ultrasonic transducer **901** having a fixed focal depth **904**, the ultrasonic transducer configured to communicate with the sensor module **530**. The ultrasound signals transmitted by the external transceiver **900** are focused to the focal depth **904** which may provide improved transcutaneous transmission of ultrasound signal as compared with a non-focused ultrasound signal.
- [0119] However, as one with skill in the art may appreciate, improper alignment of focal depth **904** of the HIFU ultrasonic transducer **901** to the skin may induce air-gaps between the skin of the patient and the HIFU ultrasonic transducer **901**. These air gaps can result in high impedance to the ultrasound signal, reducing transmission to the sensor module **530** disposed within the body of the patient. Further because the focal depth **904** is fixed, some of the ultrasound signal will miss the ultrasonic transducer **531** of the sensor module **530**. This may result in for example less power being communicated to the sensor module **530**.
- [0120] FIG.5D shows the external transceiver **901** configured for transcutaneous bidirectional data communication using an ultrasound signal, including a standoff **903**. The

standoff 903 may be made out of and include a gel material having favorable ultrasound transmission characteristics. At least a portion of the standoff 903, may be malleable and configured to conform to curvature of a patient's skin. The standoff 903 is configured to form to the skin of the patient, provide an air tight connection to the skin, and minimize the air-gaps between the HIFU ultrasound transducer 901 and the skin of the patient. Further, the standoff 903 may be adjustable in depth, allowing a user change an amount of displacement between the external transceiver 900 and the skin of the patient, and thereby allowing a user change an amount of displacement between the ultrasonic transducer 901 and the sensor module 530. Allowing the user to change the amount of displacement allows the user to move the external transceiver 900 relative to the sensor module 530, such that the user can actively adjust and optimize an amount of signal transmitted to the sensor module 530.

- [0121] As one with skill in the art may appreciate, the amount of transmission observed at the sensor module **530** in FIG.5D will be greater than the amount of transmission observed at the sensor module in FIG.5C. This is because the standoff **903** allows the user to align the focal depth **904** to the sensor module **530**. The bidirectional ultrasonic data communication link between the sensor module **530** and the external transceiver **900** may be used to give live-feedback and enable the user to search for a maximum amount of transmission.
- [0122] FIG.6A shows an embodiment of an external transceiver **900** configured for ultrasonic communication including a knee brace **920**. In this embodiment, the external transceiver **900** includes a controller **902** and one or more led display indicators **922**. The one or more led display indicators **922** may indicate to a user a status of the device.
- [0123] The external transceiver **900** may include any number of ultrasonic transducers **901** or ultrasonic transducer arrays **931**.

[0124] In some embodiments the external transceiver **900** may include a display. The display may be a programmable touch screen display. For example, LED, LCD, or plasma display.

Or a controller **902** of the external transceiver **900** with a first set of operational instructions. The external transceiver **900** may be programmed such that these operational instructions may be password protected. In some embodiments, the first user may be able to access the device remotely through for example the internet. The first user may send operational instructions to the external transceiver **900** over a remote connection. The first user may also download from the external transceiver **900**, data regarding measurements obtained by the external transceiver **900**.

[0126] A second user may be able to operate the external transceiver **900** through their cell phone, a computer, any other tertiary device **910**, or the display. The second user may be able to program the device with a second set of operational instructions. The second user may be able to pair a tertiary device **910** to the external transceiver **900**.

The external transceiver **900** of FIG.6A includes two arrays of ultrasonic transducers **931**, **932** extending around at least a portion of the patient **A**. The array includes a plurality of ultrasonic transducers **901**. The ultrasonic transducers **901** are disposed on an inner surface of the knee brace such that they are in close proximity to the patient's **A** skin when the patient **A** wears the knee brace. In FIG.6A the array of ultrasonic transducers **931**, **932** extends around the patient's **A** leg, encircling at least a portion the patient's **A** leg, and a Femur therein. As one with skill in the art can appreciate the external transceiver **900** may include any wearable medium including a leg brace **920**, an arm brace, a neck brace, a head brace, an arm sleeve, a leg sleeve, and any other wearable article as discussed above.

[0128] FIG.6B shows a cross-sectional view of the external transceiver **900**, the external transceiver worn by a patient having an implant **300** disposed inside their body. In this example, the external transceiver **900** may be the same external transceiver **900** as FIG.6A. The implant **300** may be disposed in the patient's **A** body. In this example, the implant **300** may be in the patient's Femur.

[0129] As discussed above the external transceiver 900 may be configured to communicate with the implant using ultrasound waves. For example, the array of ultrasonic transducers 931 may transmit a particular step function of ultrasound waves to the implant 300. The implant 300 may include an ultrasonic transducer 301 configured to receive the ultrasound waves and convert them to electrical energy. The implant 300 may use the electrical energy to power the implant 300. The implant 300 may be an adjustable implant and may use the electrical energy to activate an actuator of the implant 300, for example an electric motor to change a dimension of the implant 300. The implant 300 may use the electrical energy to activate a controller 302 of the implant 300. The controller 302 of the implant 300 may communicate with the controller of the external device 900. The controller 302 may establish a connection to the internet, or to a tertiary device 910 through the external transceiver 900. The implant 300 may include a sensor 305 configured to sense a measurement of the implant **300** or surrounding tissues or fluids. The implant **300** may communicate sensor measurements to the external transceiver 900 using ultrasound waves. One or more of the external transceiver and the implant may include some of the various components and functionalities as discussed throughout this disclosure.

[0130] In some embodiments the external transceiver **900** may image or detect a location of the implant **300** by detecting an amount of transmission or an amount of reflection

of ultrasound waves. In some embodiments the external transceiver **900** may form one or more ultrasound images of the bone and or implant **300** using ultrasound waves.

In some embodiments to form a three dimensional image, the external transceiver 900 may yield bone densities in four or more quadrants of a bone. In some embodiments: ultrasound waves may be generated by one ultrasonic transducer 901 of the array of ultrasonic transducers 931, the ultrasound waves emitted by the one ultrasonic transducer 901 may act analogously to a light source in a camera. The rest of the ultrasonic transducers 901 will detect the reflection and/or transmission of the ultrasound waves, the array 931 acting analogously to the focal plane array of a camera. This sequence may repeat one element at a time around the array. The controller 902 or some tertiary device 910 may process the data obtained by the ultrasonic transducers to form a stereoscopic three dimensional image looking at the subject from multiple perspectives.

[0132] FIG.7 shows a diagram of an external transceiver **900** having at least three ultrasonic transducers **901b**, **901c**, **901d** configured to transmit ultrasound waves. The first ultrasonic transducer **901b** may be part of a first array **931**, the second and third ultrasonic transducers **901c**, **901d** may be part of a second array **932**, the array extending around at least a portion of the patient's **A** leg.

[0133] The external transceiver **900** is shown including a controller **902**, operably connected to the ultrasonic transducers **901b**, **901c**, **901d**. In some embodiments the external transceiver **900** may include one or more of a memory module for storing data obtained by the ultrasonic transducers **901b**, **901c**, **901d**, a networking device for transferring the data to a tertiary device, and a power storage device operably coupled to the controller.

[0134] The external transceiver **900** is configured to noninvasively detect a location corresponding to a position of low bone density **A'** on a bone of the patient **A**. The external

transceiver **900** may also be configured to generate a three dimensional plot of bone density. For example, the controller may assign known locations along a length of the external transceiver **900**, to the ultrasonic transducer **901b**, **901c**, **901d** or to the array of ultrasonic transducers disposed on the external transceiver **900**.

[0135] The controller will instruct a first ultrasonic transducer **901b**, or a first array of ultrasonic transducers, to emit ultrasound waves at a chosen frequency **B**. One or more of the ultrasonic transducers **901b**, **901c**, **901d** may then be instructed to sense the ultrasound waves **B** of the first ultrasonic transducer **901b**.

[0136] In areas of relatively high bone density, there will be a relatively strong reflection of the ultrasound waves by the bone. In areas of relatively low bone density, elevated transmission rates of ultrasound waves across the bone will be observed.

In the illustrated embodiment, relatively high amounts of reflection will be observed by the first ultrasonic transducer 901b and the controller will assign high bone density to the position correlated with the position of the first ultrasonic transducer 901b or to the region associated with the array assigned to the first ultrasonic transducer 901b. The controller may instruct a second ultrasonic transducer 901c to transmit ultrasound waves at a chosen frequency C. The ultrasound waves C' will pass through the area of low bone density A' and will be observed by a third ultrasonic transducer 901d for example on the other side of the bone. The controller will assign a low bone density to the position correlated with the position of the second ultrasonic transducer 901c or to a region associated with an array assigned to the second ultrasonic transducer 901c. The controller can then construct a plot of bone density along the length of the external transceiver 900.

[0138] In some embodiments, the external transceiver **900** is configured to locate a position of low bone density **A'** on a bone of the patient **A**, and wherein upon determining the

location, the controller is configured to instruct one or more of the ultrasonic transducers **901b**, **901c**, **901d** to transmit ultrasound waves at a therapeutic ultrasonic frequency to promote bone healing or bone growth. Studies have correlated certain ultrasound frequencies to improved bone healing and therapy.

The position of low bone density **A'** may be determined by the external transceiver **900** as described above. However, in some embodiments the position of low bone density may be acquired by inputting the location into the external transceiver **900** using for example a touch screen LCD display operably coupled to the controller. In some embodiments, the position of low bone density may be acquired by inputting the location into the external transceiver **900** remotely from a tertiary device **910** using an established radiofrequency connection, for example a Wi-Fi or a Bluetooth connection. In some embodiments, the external transceiver **900** may be in communication with one or more implants within the patient via ultrasound waves and the one or more implants may determine the location of bone density and communicate that position to the external transceiver **900**.

[0140] Knowing the position of low bone density **A'**, the controller **902** may be preprogrammed or remotely programmed with treatment instructions. The controller **902** may then instruct one or more of the ultrasonic transducers to transmit ultrasound waves at a bone healing frequency to the position.

[0141] For example, in FIG.7 the controller **902** of the external transceiver **900** may drive the second ultrasonic transducer **901c** and the third ultrasonic transducer **901d** to transmit ultrasound waves at a specific healing frequency. The healing frequency may be the same or different than the frequency chosen to determine the location of low bone density. Also, the second ultrasonic transducer **901c** and the third ultrasonic transducer **901d** may be part of an array, in which case the controller **902** may instruct the ultrasonic transducers of that array to

transmit ultrasound waves at the bone healing frequency to the location of low bone density A'.

- [0142] FIG.8 shows a first implant **601** in communication with a second implant **602** within the body of a patient **A**, the communication established using ultrasound waves. Communication between two or more of the implants or the external transceiver **900** may establish a Body Area Network (BAN). In some embodiments, an ad hoc mesh network may be established across the implants using ultrasound signals.
- [0143] As discussed above, the implant may include a sensor module, or have an ultrasonic data communication circuit integrated into the implant.
- [0144] Turning to FIG. 9A, in some embodiments, a Body Area Network may be established having an external transceiver **900** assigned a host status, and one or more implants **701**, **702**, **703** assigned a client status.
- [0145] As seen in FIG. 9B, in some embodiments, the network may be programmed such that upon a disconnection of the host from the network, a new host will be chosen between the remaining clients. The host status may be transferred around the network as the implants activate and deactivate.
- [0146] The Body Area Network connection may provide the host access to drive the client implants. This includes one or more of: powering the client implant, activating the client implant, activating the client implant, and adjusting the client implant in any way as discussed supra or commonly known in the art.
- [0147] The Body Area Network may establish through the host a connection to any external network. For example, in FIG.9A if the host external transceiver **900** is configured to connect to an external network, the host will provide access to the clients across said network.

Similarly, in FIG.9B if the host implant **701** is configured to connect to an external network, the host will provide access to the clients across said network. This allows the hosts and clients alike to be controlled, observed, and accessed remotely. In some embodiments the firmware of the host and clients may be updated remotely using this connection.

As one with skill in the art may appreciate, these exemplary embodiments are not intended to be exhaustive. The structure and features of the individual embodiments may be interchangeable between the other various embodiments. Wherein a specific feature of one embodiment is not explicitly stated as part of another, this disclosure is intended to include variations, with features of the embodiment intended to be communicable to other embodiments to arrive at the full and reasonable scope of the claims.

[0149] FIG.10-16 represent flow diagrams of exemplary methods of transcutaneous transmission of power and/or data between one or more implant using an ultrasound signal, in accordance with at least some of the embodiment as described herein. Although the blocks in the figure are illustrated in a sequential order, the blocks may in some instances be performed in parallel, and/or in a different order than those described therein. Also, the various blocks may be combined into fewer blocks, divided into additional blocks, and/or removed based upon the desired implementation.

[0150] In addition, the blocks in the figure may show functionality and operation of one possible implementation of the present embodiment. In this regard, the block may represent a module, a segment, or a portion of program code, which includes one or more instructions executable by a processor for implementing specific logical functions or steps in the process. The program code may be stored on any type of computer readable medium, for example, such as a storage device including a disk or hard drive. The computer readable medium may include non-transitory computer-readable media that stores data for short periods

of time, such as register memory, processor cache, or Random Access Memory (RAM), and/or persistent long term storage, such as read only memory (ROM), optical or magnetic disks, or compact-disc read only memory (CD-ROM), for example. The computer readable media may be able, or include, any other volatile or non-volatile storage systems. The computer readable medium may be considered a computer readable storage medium, a tangible storage device, or other article of manufacture, for example.

Alternatively, the blocks in the figure may represent circuitry that is wired to perform the specific logical functions in the process. Illustrative methods, such as those shown in the blocks in the figure, may be carried out in part by a component or components on the internet, in the cloud and/or on a computer system. However, it should be understood that the example methods may instead be carried out by other entities or combinations of entities (i.e., by other computing devices and/or combination of computer devices), without departing from the scope of this disclosure. For example, functions of the method of the blocks in the figure may be fully performed by a computing device (or components of a computing device such as one or more processors), or may be distributed across multiple components of the computing device, across multiple computing devices (e.g., control unit and image processing device), and/or across a server.

[0152] Now, the exemplary method shown in FIG.10 provides an exemplary method of transcutaneous power transmission using ultrasound waves, the method including the steps: transmitting an ultrasound signal from an external transceiver to an implant positioned within a body of a patient, receiving the ultrasound signal at the implant using an ultrasonic transducer; converting the ultrasound signal to electrical energy using the ultrasonic transducer; and using the electrical energy to power at least a portion of the implant.

[0153] As discussed above, powering the implant may include activating the implant, actuating the implant, charging the implant, or any other form of supplying power to internal circuitry of the implant. The electrical energy may be immediately or subsequently used. Further, the implant may have an ultrasonic transducer, and as described above may include a sensor module.

[0154] FIG.11 provides an exemplary method of transcutaneous signal transmission using ultrasound waves, the method including: placing an implant within a body of a patient, placing a transceiver on or within the body of the patient, transmitting a modulated ultrasound signal to the implant using the transceiver, and converting the modulated ultrasound signal to electrical energy and communicating the modulated electrical signal to a controller of the implant.

[0155] FIG.12 provides an exemplary method of transcutaneous bidirectional data transmission using an ultrasound signal, the method including: placing an implant within a body of a patient, transmitting at least one of wireless power or data to the implant from the transceiver using an ultrasound signal, and transmitting at least one of wireless power or data to the transceiver from the implant using an ultrasound signal.

[0156] FIG.13 provides an exemplary method of transcutaneous bidirectional data transmission using ultrasound waves, the method comprising the steps of: providing a sensor module to an implant, placing the implant within a body of a patient, transcutaneously transmitting at least one of wireless power or data to the sensor module from the transceiver using an ultrasound signal, and transmitting at least one of wireless power or data to the transceiver from the sensor module using an ultrasound signal.

[0157] In some embodiments the method may further include the step of communicating information received by the sensor module to a controller of the implant. In

some embodiments this step may be performed through a direct connection, for example a wired connection. In some embodiments this step may be performed through an indirect connection, for example a wireless connection including one or more of RF communication and ultrasound communication.

[0158] FIG.14 provides an exemplary method for a plotting bone density including: placing at least one ultrasonic transducer adjacent to a patient's skin, transmitting ultrasound waves using the at least one ultrasonic transducer; measuring at least one of an amount of transmission or an amount of reflection of the ultrasound waves, plotting the measurements vs the known location of the ultrasonic transducers to form a plot of bone density.

FIG.15 provides an exemplary method for three-dimensional bone density imaging including: placing at least one array including at least one ultrasonic transducer adjacent to a patient's skin, transmitting ultrasound waves from at least one ultrasonic transducer in a direction of a bone of a patient, measuring at least one of an amount of transmission or an amount of reflection of the ultrasound waves, transmitting ultrasound waves from at least one ultrasonic transducer at locations across the transducer array; stitching together the measurements to form a three dimensional plot of bone density.

[0160] FIG. 16 provides an exemplary method for measuring an increase in length of a bone including: placing a first ultrasonic marker on a first location on the bone, placing a second ultrasonic marker on a second location on the bone, placing a transducer array around at least a portion of the bone, the transducer array comprising at least one ultrasonic transducer; transmitting ultrasound waves from the at least one ultrasonic transducer; measuring at least one of an amount of transmission or an amount of reflection observed by the ultrasonic transducer at the location on the transducer array; stitching together the measurements obtained

by the transducer array to form an ultrasound image; measuring the distance on the ultrasound image between the first ultrasonic marker and the second ultrasonic marker.

[0161] As one with skill in the art can appreciate, these exemplary embodiments of methods are not intended to be exhaustive. The blocks of the individual methods may be substituted and interchangeable between the various embodiments. Additional blocks may be added and substituted to the various embodiments corresponding to additional steps and features disclosed throughout these papers.

[0162] Now, although particular features and embodiments have been described in an effort to enable those with skill in the art to make and use the claimed invention, it should be understood that several variations, alterations or substitutions can be achieved to arrive at the subject matter disclosed. Nothing in this description shall be construed as limiting the spirit and scope of the invention as set forth in the appended claims, below.

What is claimed is:

 A system for ultrasonic communication, comprising: an implant having at least one ultrasonic transducer; and an external transceiver;

wherein the ultrasonic transducer is adapted to receive power from an ultrasonic signal sent by the external transceiver.

- 2. The system of claim 1, wherein the at least one ultrasonic transducer comprises a piezoelectric transducer.
- 3. The system of claim 2, the implant comprising an adjustable implant.
- 4. The system of claim 3, wherein an actuator of the adjustable implant is powered by electrical energy received from the ultrasonic signal by the ultrasonic transducer.
- 5. The system of claim 4, the adjustable implant further comprising a power storage device, and a charging circuit, and wherein the charging circuit is configured to charge the power storage device using the electrical energy received from the ultrasonic transducer.
- 6. The system of claim 5, the implant further comprising a controller.
- 7. A system for ultrasonic communication, comprising: an implant including a sensor and an ultrasonic transducer; and an external transceiver;

wherein the implant is adapted to transmit data obtained by the sensor to the external transceiver using an ultrasonic signal produced by the ultrasonic transducer.

- 8. They system of claim 7, wherein the ultrasonic transducer comprises a piezoelectric transducer.
- 9. The system of claim 8, the implant further comprising a controller;

wherein the controller is configured to convert data sensed by the sensor to a modulated signal.

- 10. The system of claim 9, the implant further comprising an actuator powered by electrical energy received from the ultrasonic signal produced by the ultrasonic transducer.
- 11. The system of claim 10, the implant further comprising a power storage device, and a charging circuit, and wherein the charging circuit is configured to charge the power storage device using the electrical energy received from the ultrasonic signal by the ultrasonic transducer.
- 12. A system for ultrasonic communication, comprising:
 an implant having an actuator operatively coupled to an ultrasonic transducer; and
 an external transceiver;
 wherein the ultrasonic transducer is configured to receive power from an ultrasonic signal
 sent by the external transceiver to power the actuator; and
 wherein the implant is configured to transmit data to and receive data from the external
 transceiver via the ultrasonic transducer.
 - 13. They system of claim 12, wherein the ultrasonic transducer comprises a piezoelectric transducer.
 - 14. The system of claim 13, wherein the implant receives power from the ultrasonic signal received by the piezoelectric transducer.
- 15. The system of claim 14, the implant further comprising a sensor and a controller; wherein the controller is configured to convert the data obtained by the sensor to a modulated signal.
- 16. The system of claim 15, the implant further comprising:
 a power storage device and a corresponding charging circuit;
 wherein the charging circuit is configured to charge the power storage device using electrical energy received from the ultrasonic signal by the ultrasonic transducer.

17. A sensor module for ultrasonic communication, comprising:

an ultrasonic transducer; and

a controller operatively coupled to the ultrasonic transducer;

wherein the sensor module is configured for at least one of transcutaneous ultrasonic power or data transfer using an ultrasound signal.

- 18. The sensor module of claim 17, wherein the sensor module is adapted to be integrated with an implant.
- 19. The sensor module of claim 18, wherein at least a portion of the sensor module is disposed within an interior portion of the implant.
- 20. The sensor module of claim 18, wherein at least a portion of the sensor module is disposed on an exterior portion of the implant.
- 21. The sensor module of claim 17, wherein the ultrasonic transducer is configured to receive an ultrasound signal from an external transceiver and convert the ultrasound signal to electrical energy.
- 22. The sensor module of claim 17, wherein the ultrasonic transducer is configured to receive an ultrasound signal from a second implant and convert the ultrasound signal to electrical energy.
- 23. The sensor module of claim 17, wherein the ultrasonic transducer comprises a piezoelectric transducer.
- 24. The sensor module of claim 17, wherein the controller is configured to modulate the ultrasound signal using binary phase shift keying.
- 25. The sensor module of claim 17, further comprising an encapsulation, wherein the encapsulation provides a hermetic seal.
- 26. The sensor module of claim 17, further comprising a power storage device.

27. The sensor module of claim 26, further comprising a recharging circuit configured to charge the power storage device using electrical energy harvested by the ultrasonic transducer.

- 28. The sensor module of claim 27, further comprising a sensor.
- 29. The sensor module of claim 28, further comprising at least one interconnect operably connecting the sensor, the ultrasonic transducer, the controller and the power storage device.
- 30. The sensor module of claim 29, wherein the ultrasonic transducer comprises a hollow cylindrical piezoelectric transducer.
- 31. The sensor module of claim 30, the sensor module further comprising a chassis; wherein at least a portion of the chassis is configured to extend through the hollow cylindrical piezoelectric transducer; and wherein at least a portion of the at least one interconnect extends through the chassis operably connecting the power storage device to a printed circuit board.
- 32. A method of ultrasound communication, comprising the steps of: placing an implant within a body of a patient; placing an external transceiver adjacent to the body of the patient; transmitting at least one of wireless power or data to the implant using an ultrasound signal.
- 33. The method of claim 32, further comprising the step of: transmitting at least one of wireless power or data to the external transceiver from the implant using an ultrasound signal.
- 34. A method of ultrasound communication, comprising the steps of: integrating a sensor module with an implant; placing the implant within a body of a patient; placing an external transceiver adjacent to the body of the patient;

transmitting at least one of wireless power or data to the sensor module using an ultrasound signal; and

transmitting at least one of wireless power or data to the external transceiver from the sensor module using an ultrasound signal.

35. A method of transmitting power using ultrasound waves, the method comprising the steps of:

transmitting an ultrasonic signal from an external transceiver to an implant having an ultrasonic transducer;

receiving the ultrasonic signal at the implant with the ultrasonic transducer; converting the ultrasonic signal to electrical energy using the ultrasonic transducer; and using the electrical energy to power the implant.

36. A method of achieving transcutaneous data communication using ultrasound waves, the method comprising:

providing an implant having at least one ultrasonic transducer within a body of a patient; placing a transceiver on the body of the patient;

transmitting data from the implant to the transceiver using an ultrasonic signal.

37. A method of achieving transcutaneous data transmission using ultrasound waves, the method comprising:

providing an implant having at least one ultrasonic transducer within a body of a patient; placing a transceiver on the body of the patient;

transmitting data from the implant to the transceiver using ultrasound waves.

38. A method of achieving transcutaneous bidirectional data transmission using ultrasound waves, the method comprising the steps of:

providing an implant having at least one ultrasonic transducer within a body of a patient; transmitting at least one of wireless power or data to the implant using an external transceiver; and

transmitting data from the implant to the external transceiver using a modulated ultrasound signal.

39. A method of achieving transcutaneous bidirectional data transmission using ultrasound waves, the method comprising the steps of:

providing an implant having a sensor module within a body of a patient; transmitting at least one of wireless power or data to the sensor module; and transmitting data from the sensor module using a modulated ultrasound signal.

- 40. The method of claim 39, wherein the sensor module is configured to be removably coupled to an implant.
- 41. The method of claim 39, wherein the sensor module further comprises a sensor configured to sense data from the implant, the data corresponding to a physical property of the implant.
- 42. The method of claim 39, wherein the sensor module further comprises a controller.
- 43. The method of claim 42, wherein the sensor module further comprises an ultrasonic transducer operatively coupled to the controller, the ultrasonic transducer configured to transmit a modulated ultrasound signal.
- 44. The method of claim 43, further comprising a conductive epoxy, wherein the conductive epoxy is disposed between the ultrasonic transducer and the implant, reducing an amount of impedance observed by ultrasound waves.
- 45. A body area network comprising:
- a plurality of medical implants adapted for ultrasound communication and configured to be placed within a body of a patient;
- at least one of the plurality of medical implants designated a host status and a remainder of the plurality of medical implants designated a client status;
- wherein data is transmitted across the body area network via an ultrasound signal.
 - 46. The body area network of claim 45, further comprising an external transceiver, the external transceiver configured for ultrasound communication and placed adjacent to or within the body of the patient.

47. The body area network of claim 46, wherein the external transceiver has a master host status such that when the external transceiver is available, the external transceiver is given host status.

- 48. A method for bone density imaging comprising:
 placing at least one ultrasonic transducer adjacent to a patient's skin;
 transmitting ultrasonic waves using the at least one ultrasonic transducer;
 measuring at least one of an amount of transmission or an amount of reflection observed by the
 at least one ultrasonic transducer; and
 stitching together the measurements to form a plot of bone density.
 - 49. The method of claim 48, wherein the at least one ultrasonic transducer comprises a one dimensional array.
 - 50. The method of claim 48, wherein the at least one ultrasonic transducer comprises a two dimensional array.
 - 51. The method of claim 48, wherein the at least one ultrasonic transducer is disposed on an interior surface of a wearable device configured to be worn by a patient.
 - 52. The method of claim 51, wherein the wearable device is manufactured using an additive manufacturing technique.
 - 53. The method of claim 51, wherein the at least one ultrasonic transducer is operably connected to a controller configured to receive measurement data from the at least one ultrasonic transducer, and wherein the controller is configured to process the measurement data to form the plot of bone density.
- 54. The method of claim 52, further comprising the step of: determining a location of low bone density and transmitting ultrasound waves at a treatment frequency to the location of low bone density.
 - 55. The method of claim 48, the at least one ultrasonic transducer comprising a piezoelectric polyvinylidene fluoride (PVDF) material.

56. A method for measuring an increase in length of a bone comprising:

placing a first ultrasonic marker on a first location on the bone;

placing a second ultrasonic marker on a second section on the bone;

placing a transducer array around at least a portion of the bone, the transducer array comprising at least one ultrasonic transducer;

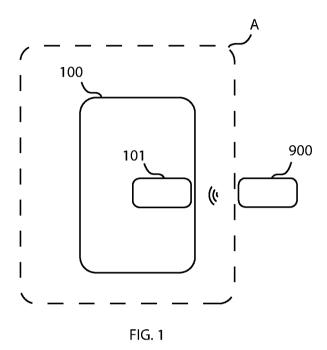
transmitting ultrasonic waves from the at least one ultrasonic transducer;

measuring at least one of an amount of transmission or an amount of reflection observed by the ultrasonic transducer at each location on the transducer array;

stitching together measurements obtained by the transducer array to form an ultrasound image; measuring a distance on the ultrasound image between the first ultrasonic marker and the second ultrasonic marker.

- 57. The method of claim 56, wherein the transducer array comprises a one dimensional array.
- 58. The method of claim 56, wherein the transducer array comprises a two dimensional array.
- 59. The method of claim 56, wherein the transducer array is disposed on an interior surface of a wearable device configured to be worn by a patient.
- 60. The method of claim 59, wherein the wearable device is manufactured using an additive manufacturing technique.
- 61. The method of claim 60, wherein the transducer array is operably connected to a controller configured to receive measurements from the at least one ultrasonic transducer and wherein the controller is configured to process the measurements to determine a change in length of the bone.
- 62. The method of claim 61, further comprising an ultrasonic conductive material disposed on the transducer array, the ultrasonic conductive material configured to minimize an impedance between the at least one ultrasonic transducer and the patient's skin.

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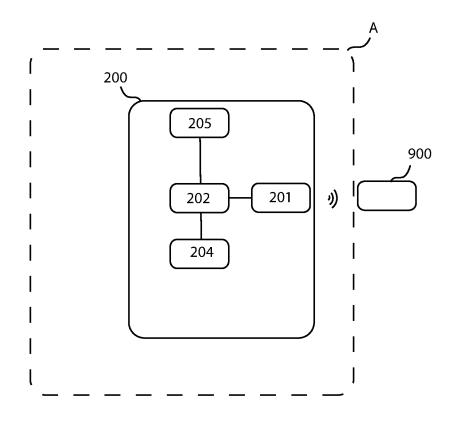
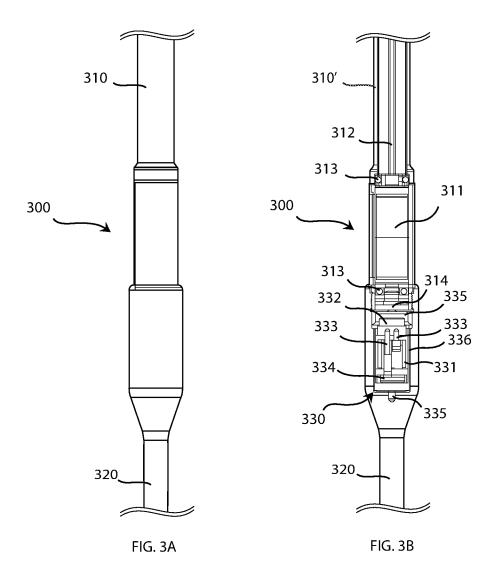


FIG. 2



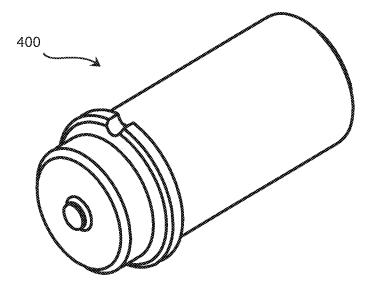
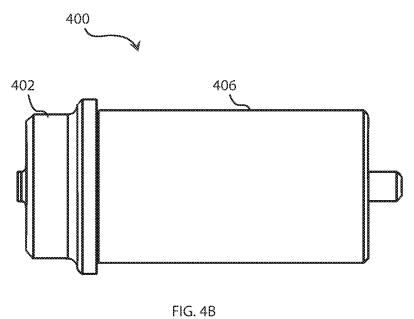
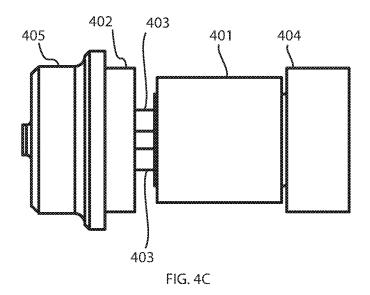
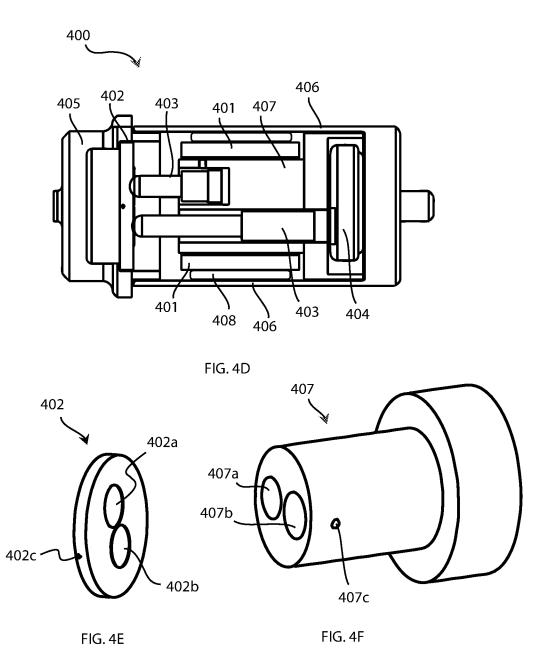
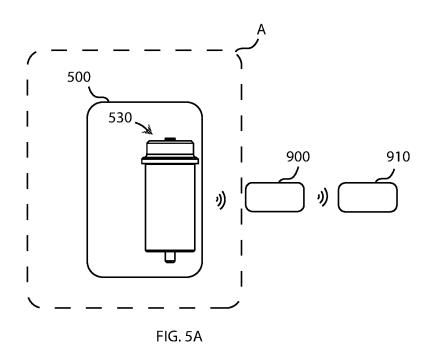


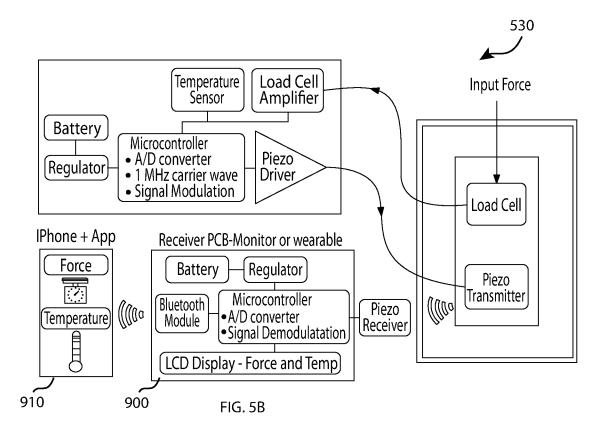
FIG. 4A











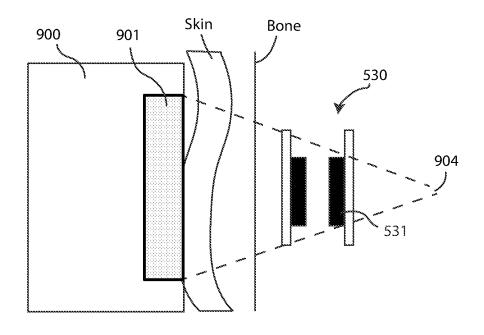


FIG. 5C

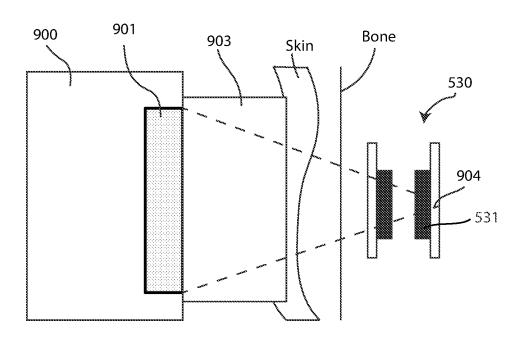
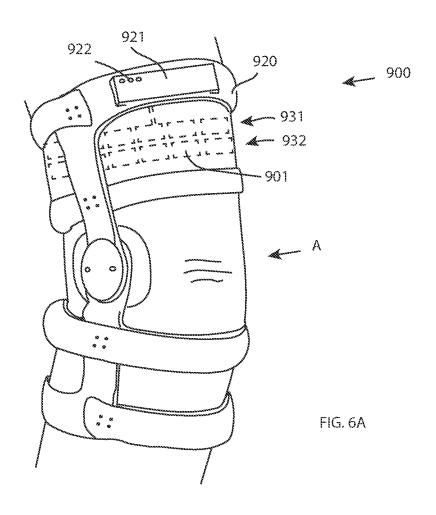
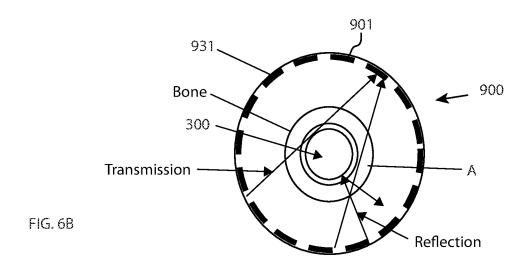


FIG. 5D





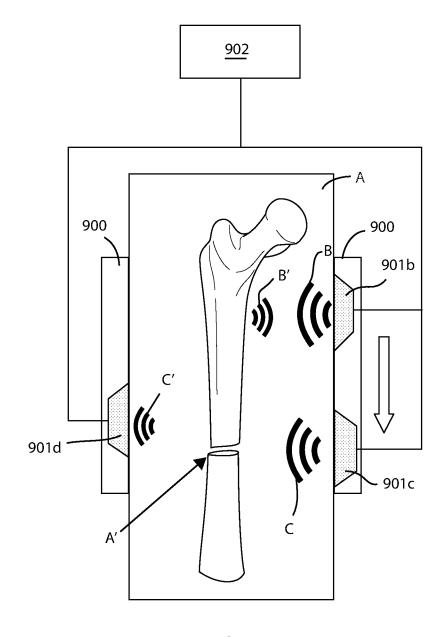
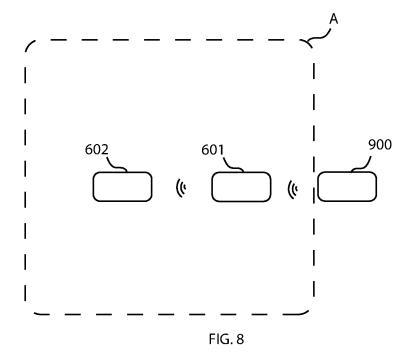
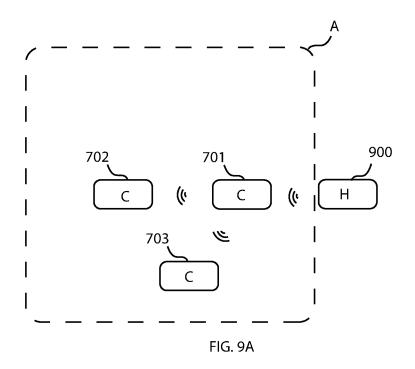
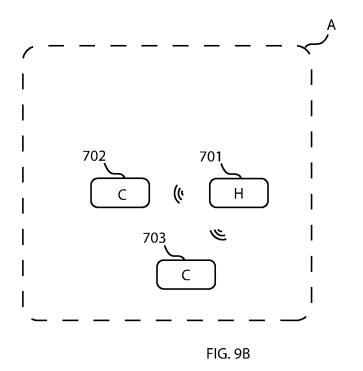


FIG. 7







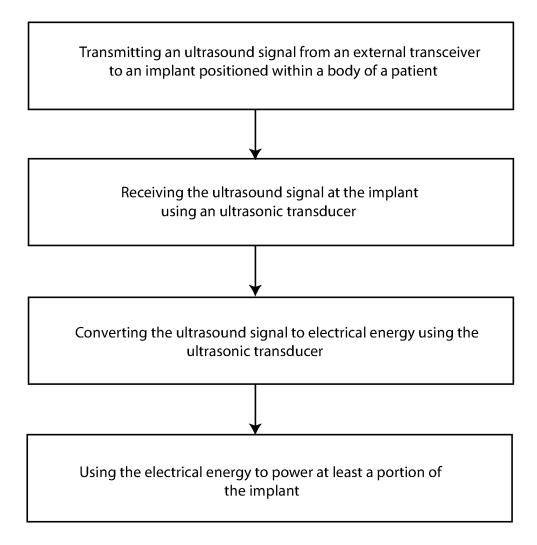


FIG. 10

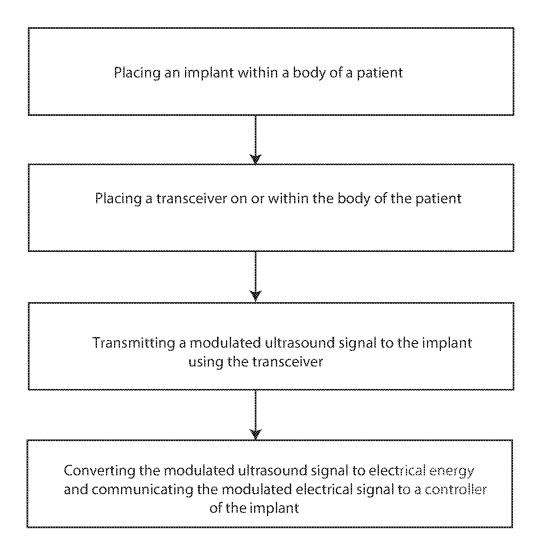


FIG. 11

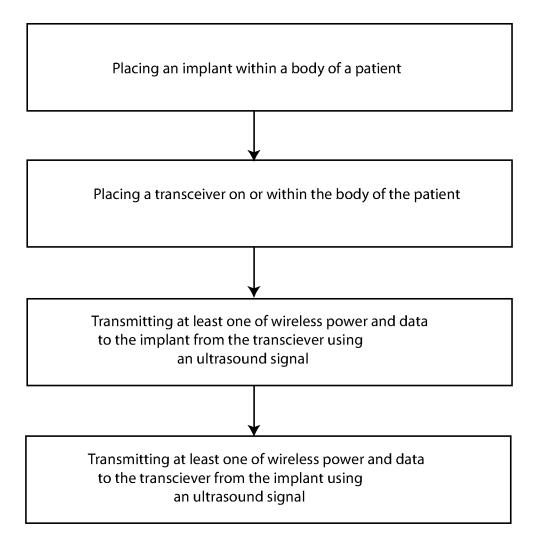


FIG. 12

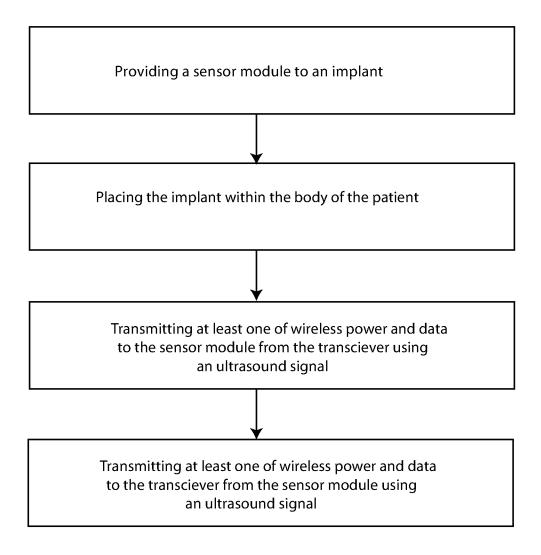


FIG. 13

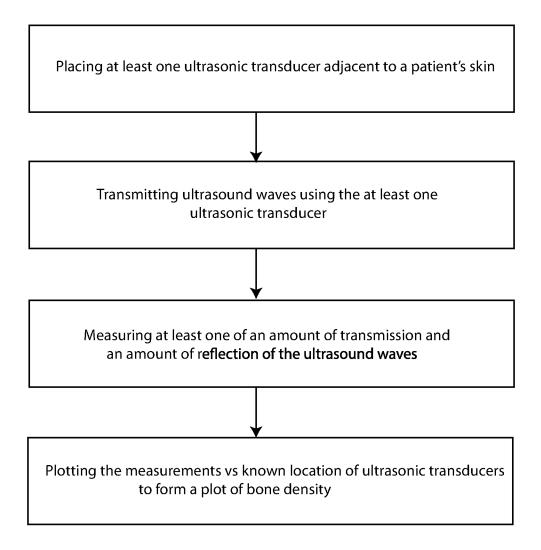


FIG. 14

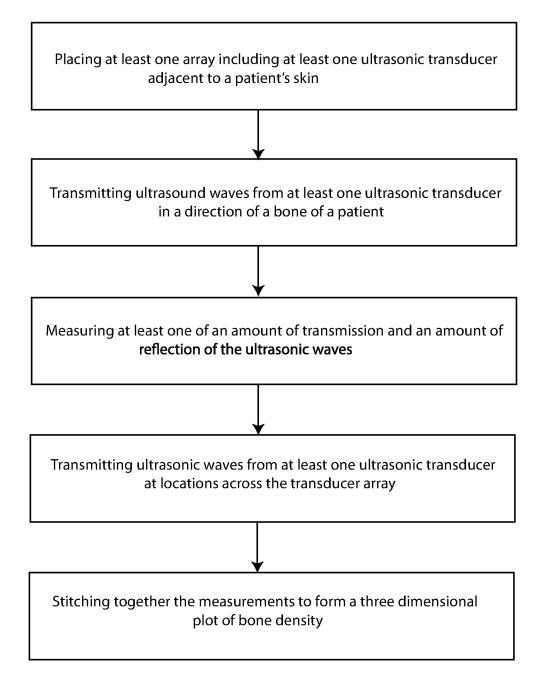


FIG. 15

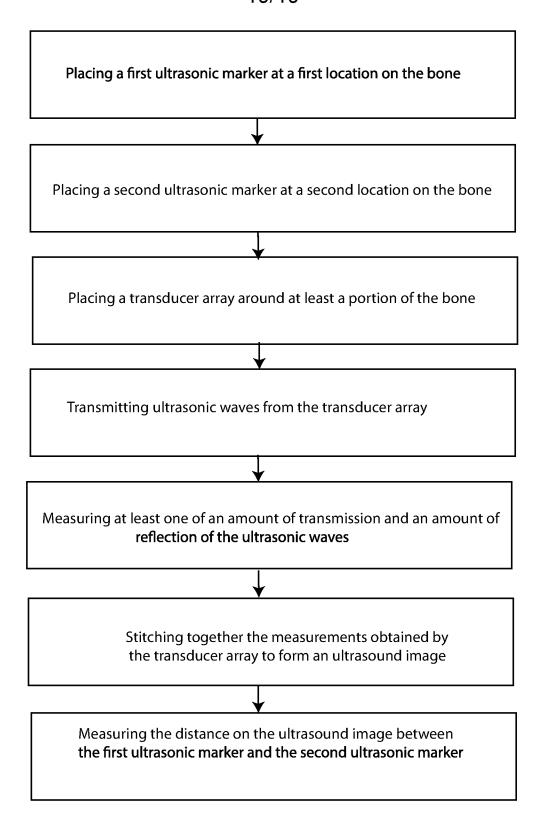


FIG. 16

INTERNATIONAL SEARCH REPORT

International application No PCT/US2020/017330

	FICATION OF SUBJECT MATTER H04Q9/00			
According to	o International Patent Classification (IPC) or to both national classifica	ation and IPC		
	SEARCHED			
Minimum do H04Q	cumentation searched (classification system followed by classification	on symbols)		
Documentat	tion searched other than minimum documentation to the extent that s	uch documents are included in the fields sea	arched	
Electronic d	ata base consulted during the international search (name of data bas	se and, where practicable, search terms use	d)	
EPO-In	ternal			
C. DOCUME	ENTS CONSIDERED TO BE RELEVANT			
Category*	Citation of document, with indication, where appropriate, of the rele	Relevant to claim No.		
X	W0 2018/017591 A1 (NUVASIVE INC 25 January 2018 (2018-01-25) page 1, line 12 - line 21 page 3, line 12 - page 4, line 12 page 6, line 5 - page 7, line 20 page 8, line 19 - line 24 page 9, line 13 - line 19 page 11, line 11 - page 12, line figures 3,4	7	1-44	
Furth	ner documents are listed in the continuation of Box C.	X See patent family annex.		
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "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 "6"		"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 4 May 2020		Date of mailing of the international search report $21/07/2020$		
	nailing address of the ISA/	Authorized officer		
	European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fay: (+31-70) 340-3016	Lamadie, Sylvain		

International application No. PCT/US2020/017330

INTERNATIONAL SEARCH REPORT

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)
This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
2. Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)
This International Searching Authority found multiple inventions in this international application, as follows:
see additional sheet
As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-44
Remark on Protest The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-44

System and method for ultrasonic communication using an implant having an ultrasonic transducer and an external transceiver, the ultrasonic transducer receiving power from the ultrasonic signal sent by the external transceiver.

2. claims: 45-47

Body area network comprising a plurality of medical implants, at least one of the plurality of medical implants being designated as a host status and the remainder of the plurality of implants being designated as a client status.

3. claims: 48-55

Method for bone density imaging by placing an ultrasonic transducer adjacent to a patient's skin measuring an amount of reflection of transmitted ultrasonic waves.

4. claims: 56-62

Method for measuring an increase in length of a bone using first and second ultrasonic markers and a transducer array.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2020/017330

Patent document cited in search report Publication date Patent family member(s) Publication date				,	,
CN 109688902 A 26-04-2019 EP 3484352 A1 22-05-2019 JP 2019522548 A 15-08-2019 US 2019150835 A1 23-05-2019				,	
	WO 2018017591 A1	25-01-2018	CN 10968896 EP 348435 JP 201952254 US 201915083	02 A 52 A1 18 A 35 A1	26-04-2019 22-05-2019 15-08-2019 23-05-2019