



(19) **United States**

(12) **Patent Application Publication**

**Bae et al.**

(10) **Pub. No.: US 2020/0254283 A1**

(43) **Pub. Date: Aug. 13, 2020**

(54) **MEDICAL DEVICES FOR ULTRASONIC THERAPY**

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(21) Appl. No.: **16/785,255**

(22) Filed: **Feb. 7, 2020**

**Related U.S. Application Data**

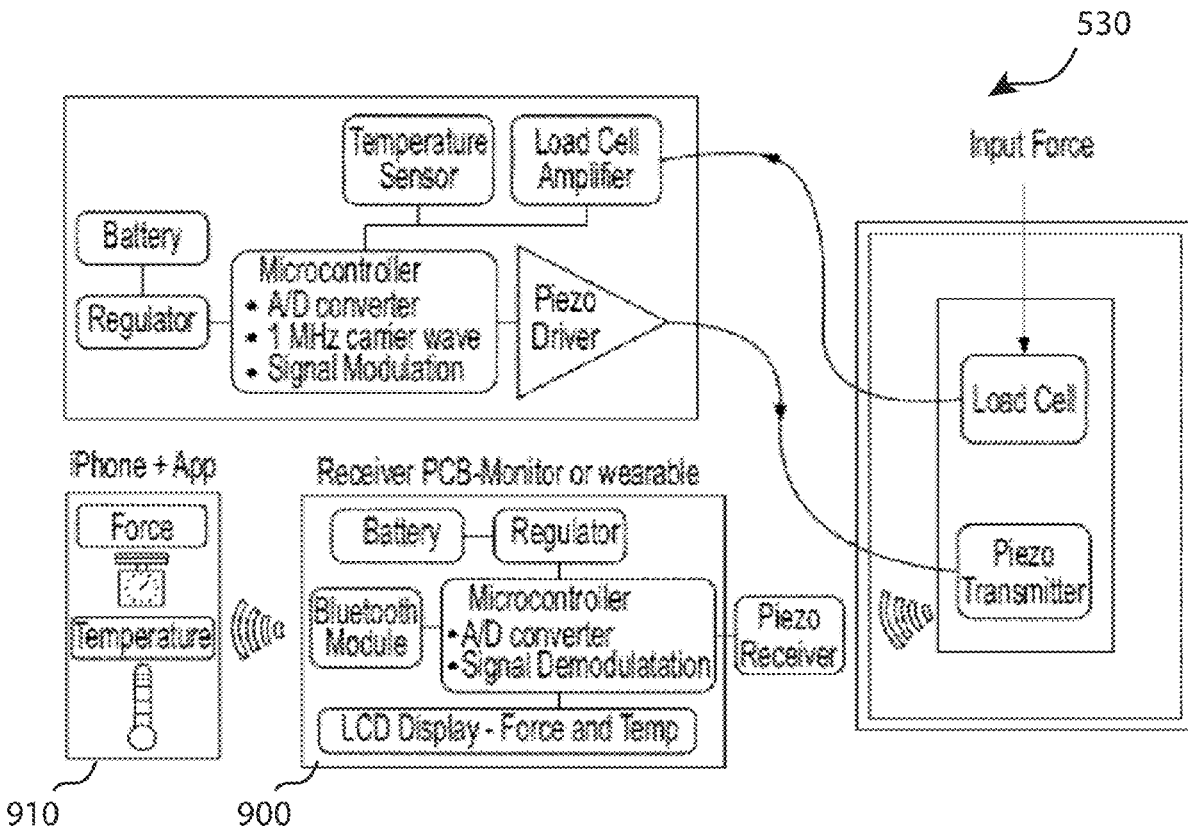
(60) Provisional application No. 62/959,357, filed on Jan. 10, 2020, provisional application No. 62/802,457, filed on Feb. 7, 2019.

**Publication Classification**

(51) **Int. Cl.**  
*A61N 7/00* (2006.01)  
(52) **U.S. Cl.**  
CPC ..... *A61N 7/00* (2013.01); *A61N 2007/0013* (2013.01); *A61B 8/0875* (2013.01); *A61N 2007/0052* (2013.01); *A61N 2007/0078* (2013.01)

(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.



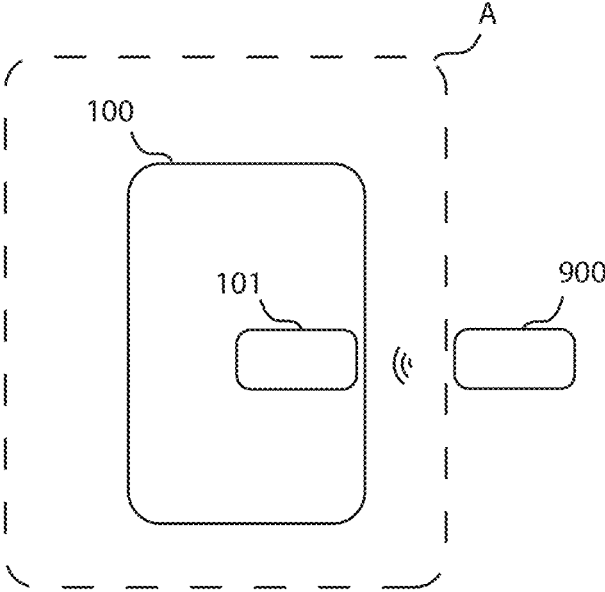


FIG. 1

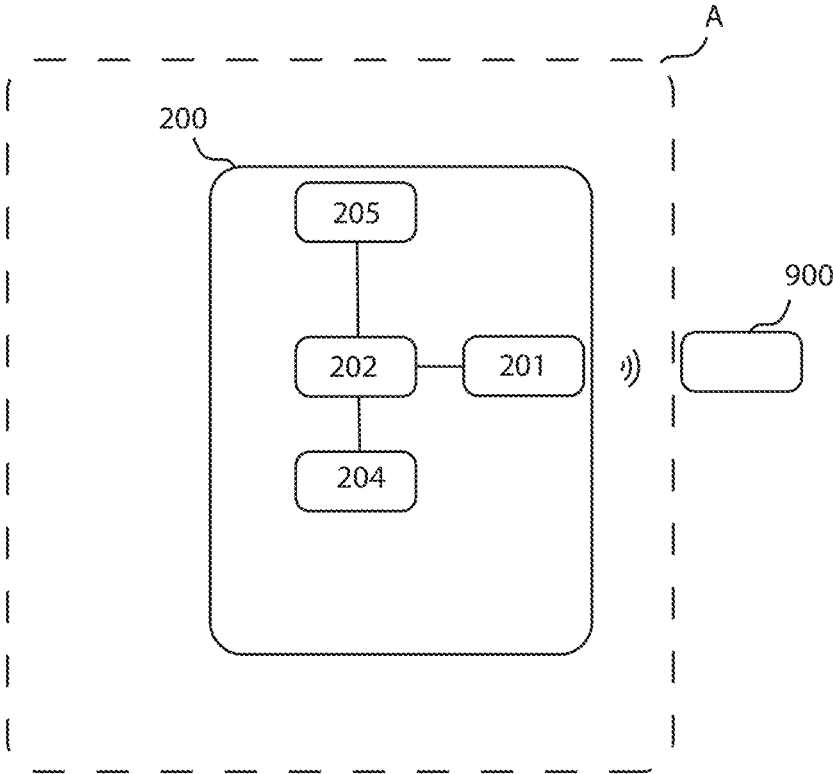


FIG. 2

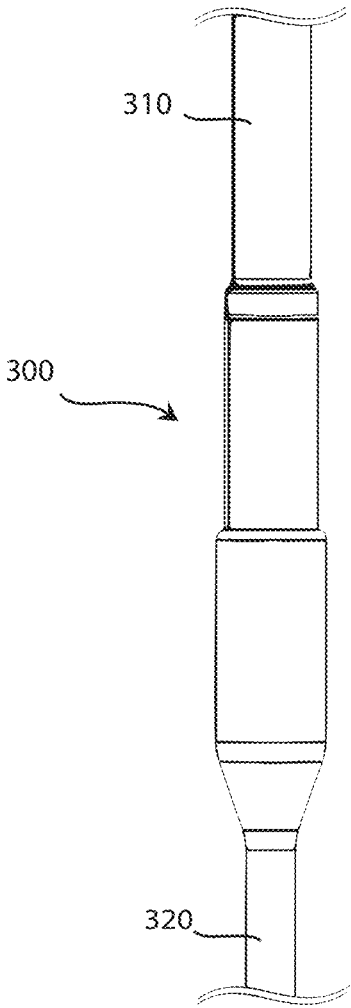


FIG. 3A

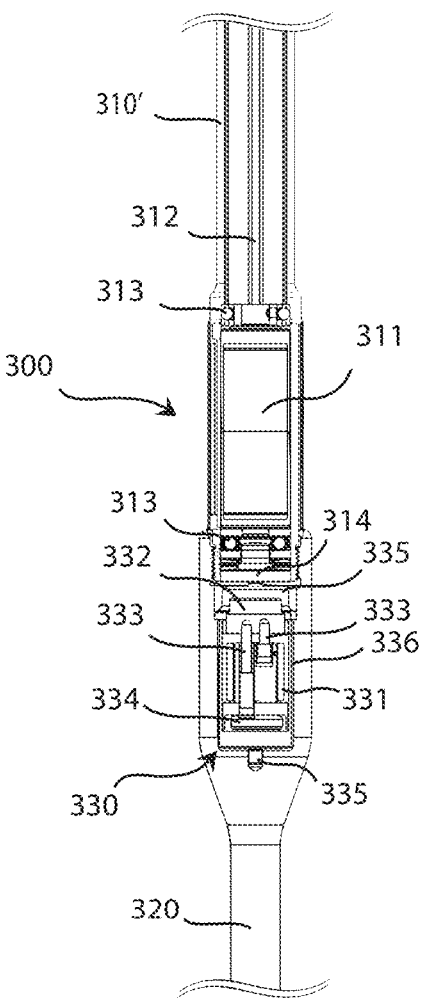


FIG. 3B

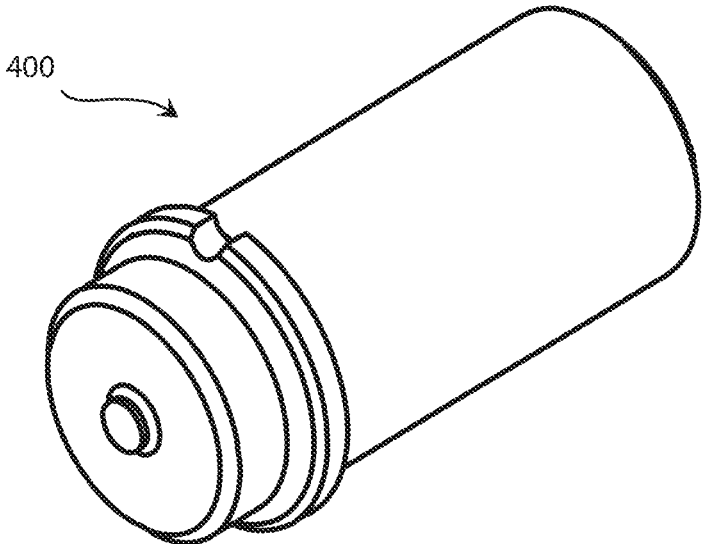


FIG. 4A

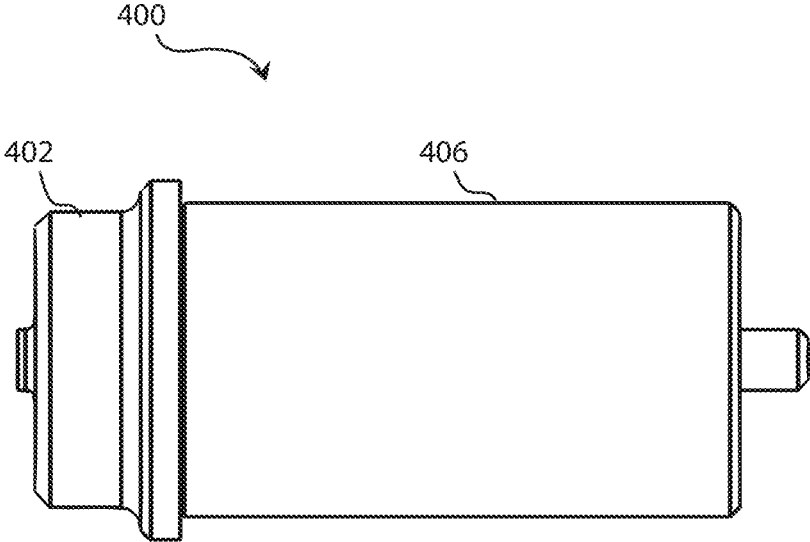


FIG. 4B

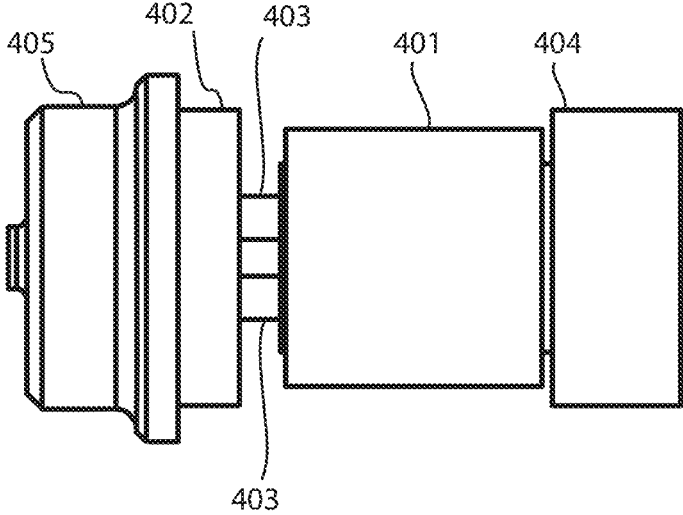


FIG. 4C

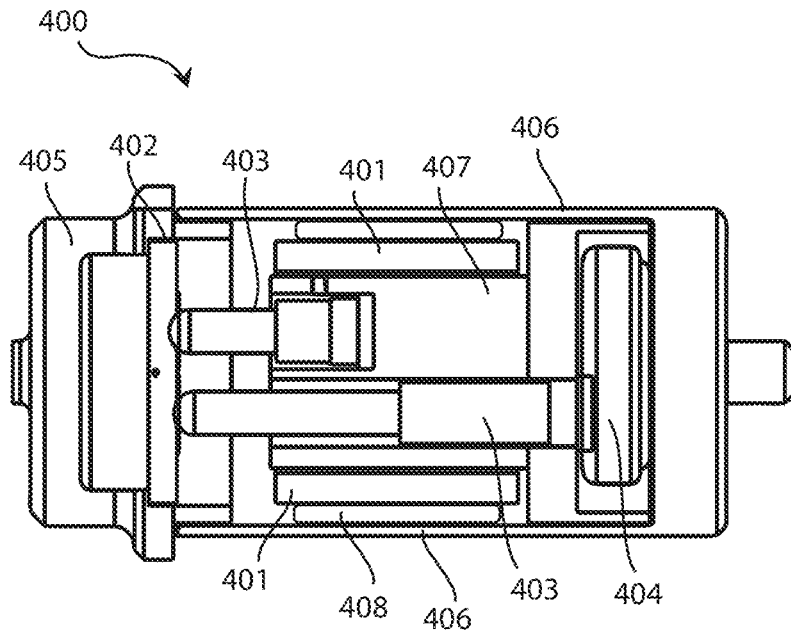


FIG. 4D

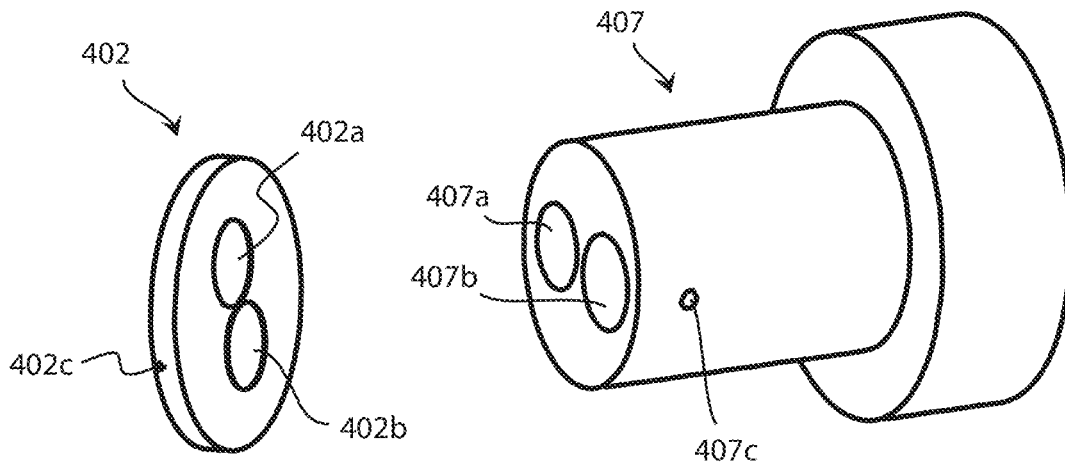


FIG. 4E

FIG. 4F

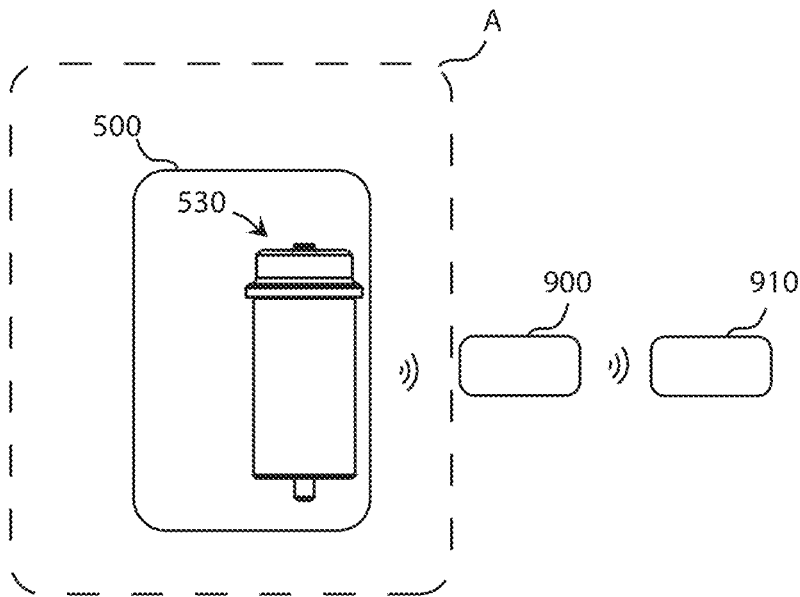


FIG. 5A

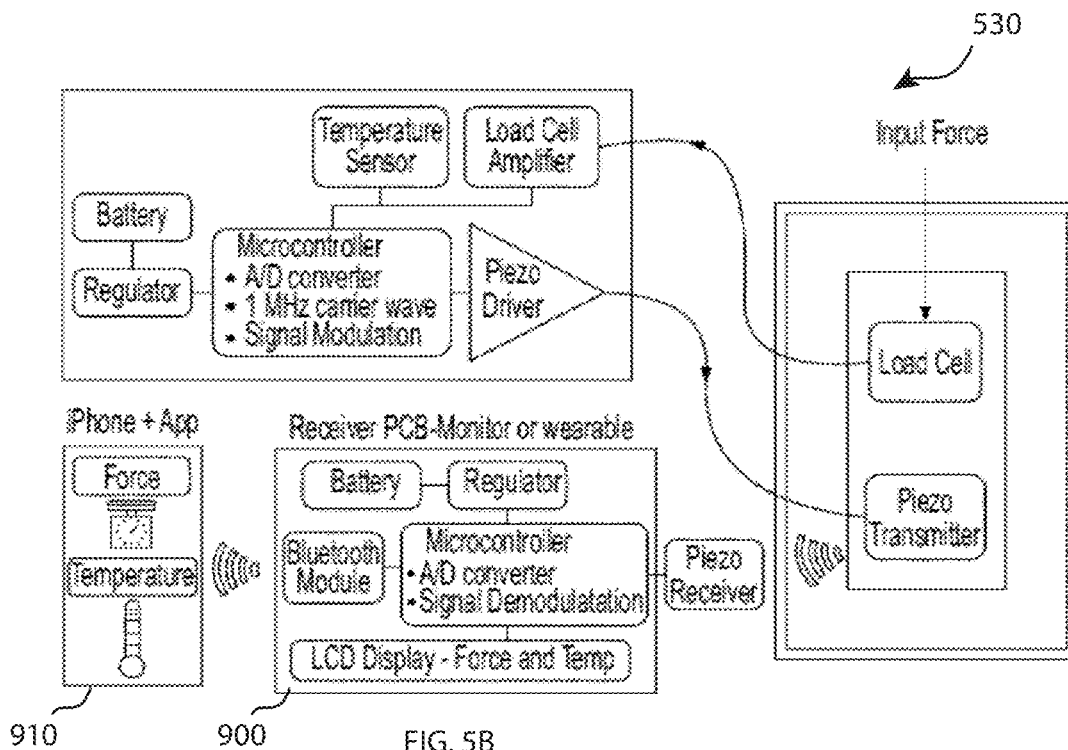


FIG. 5B



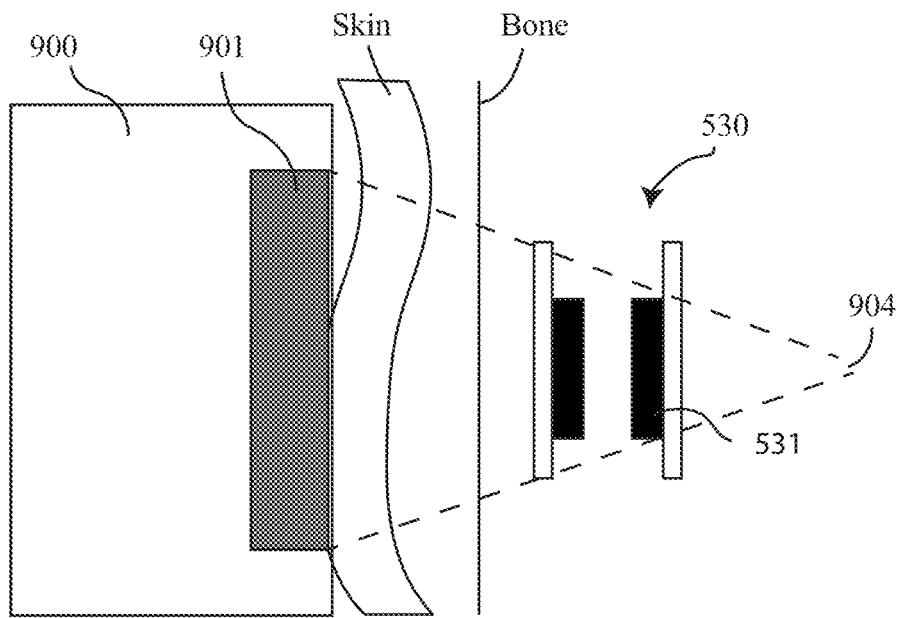


FIG. 5C

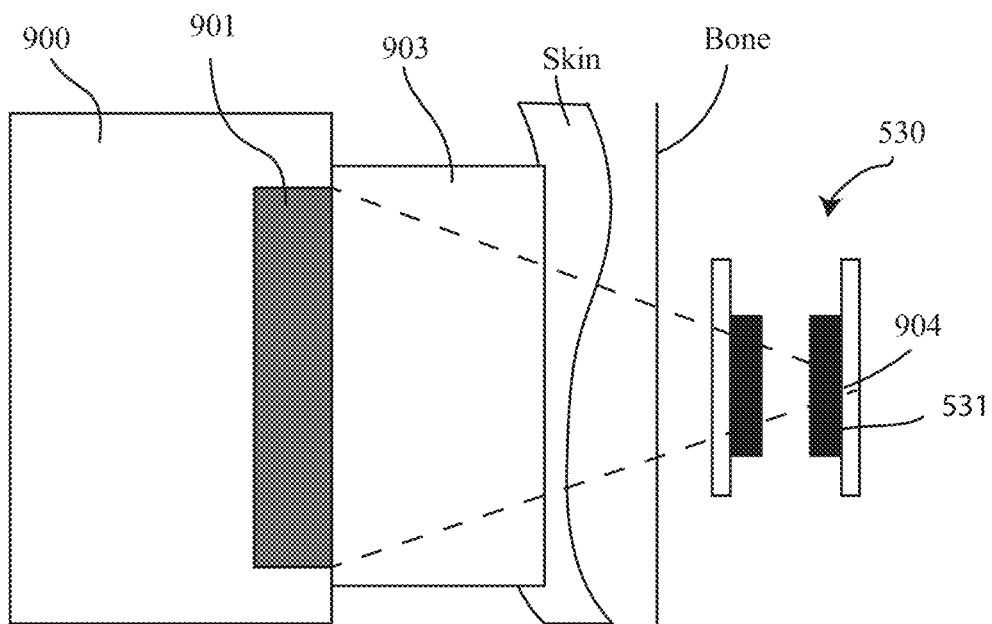
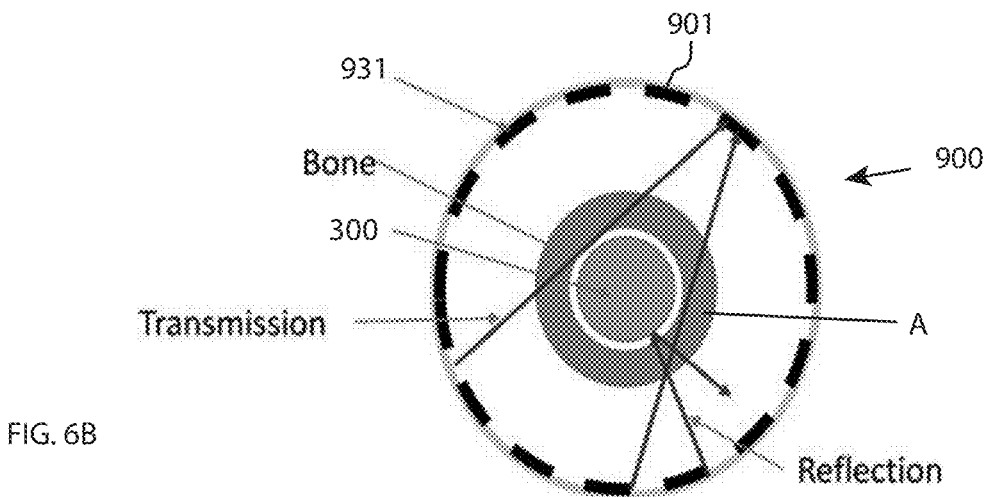
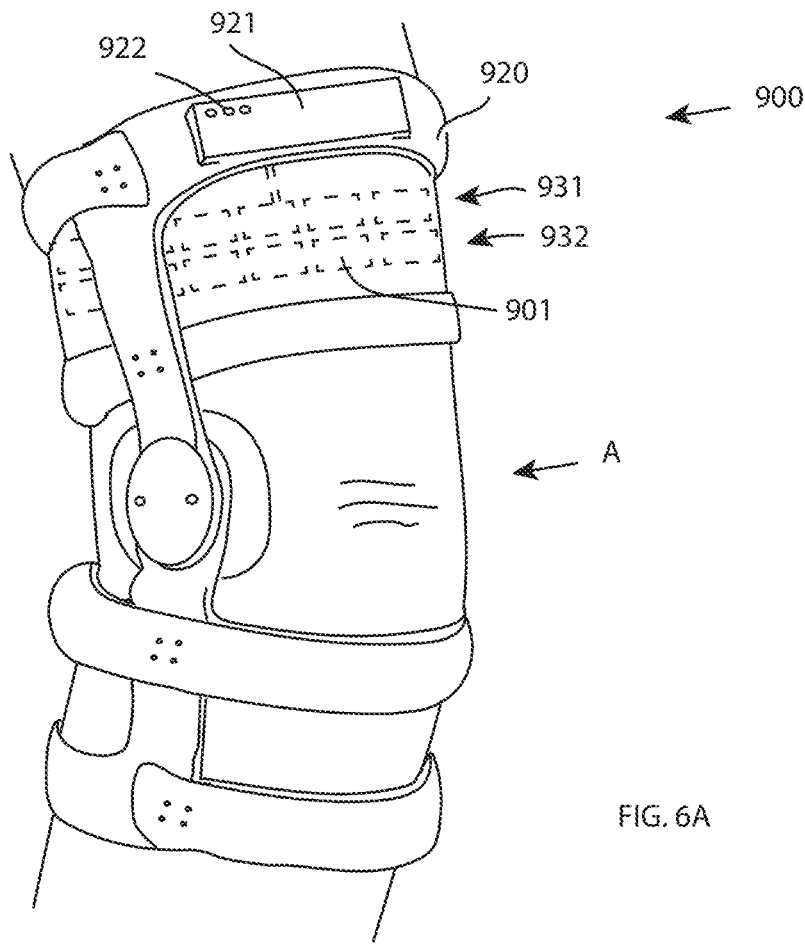


FIG. 5D



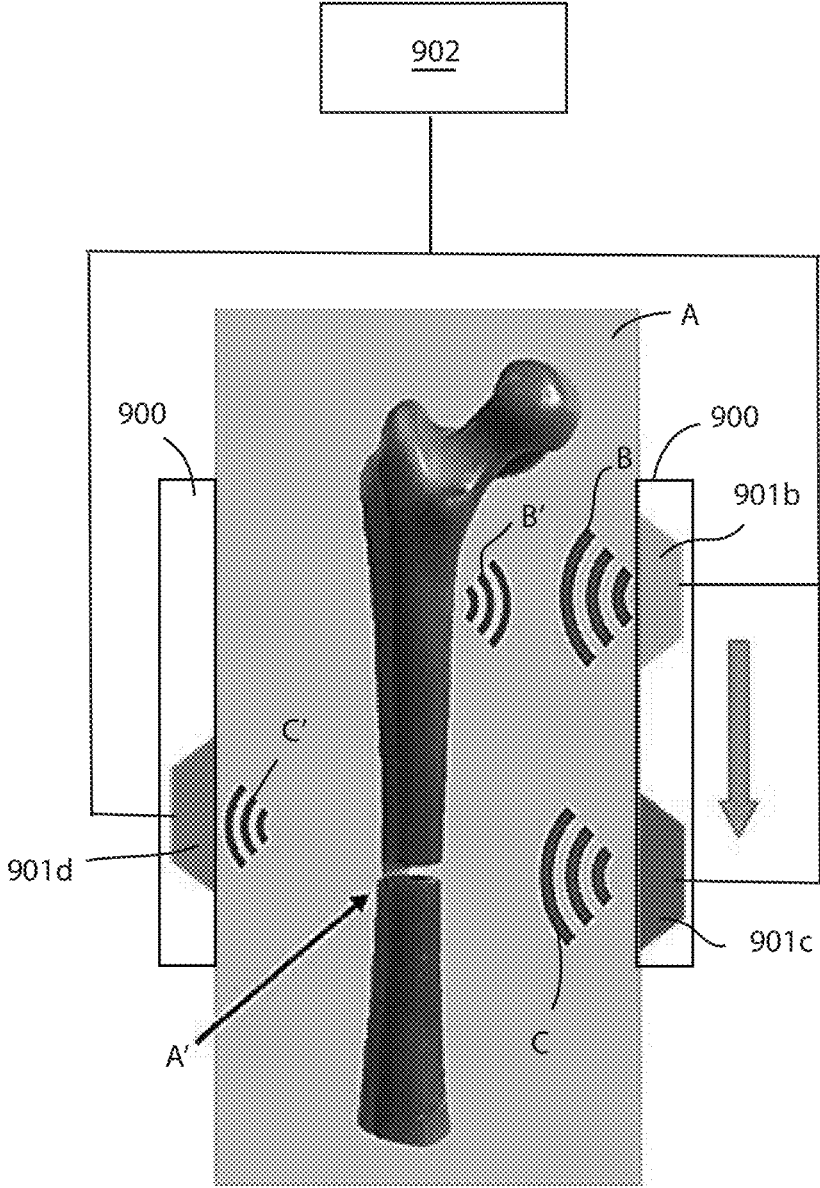


FIG. 7

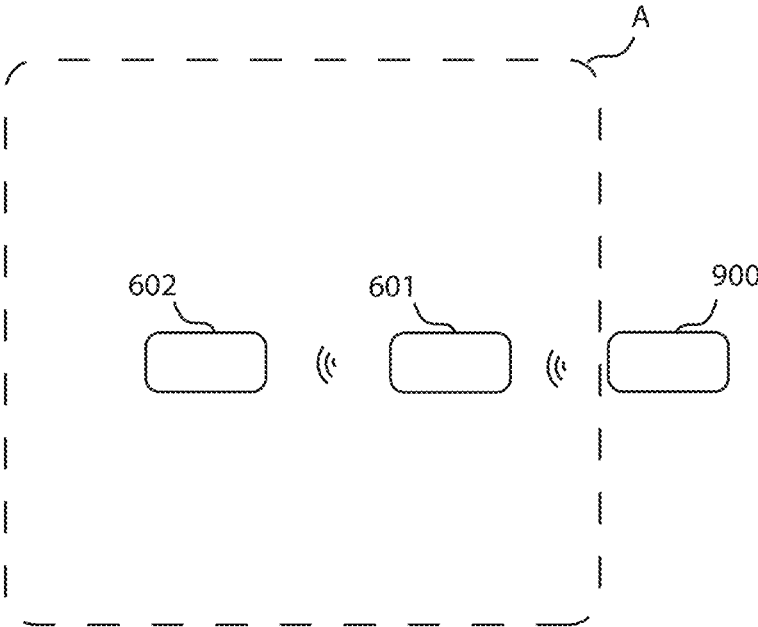


FIG. 8

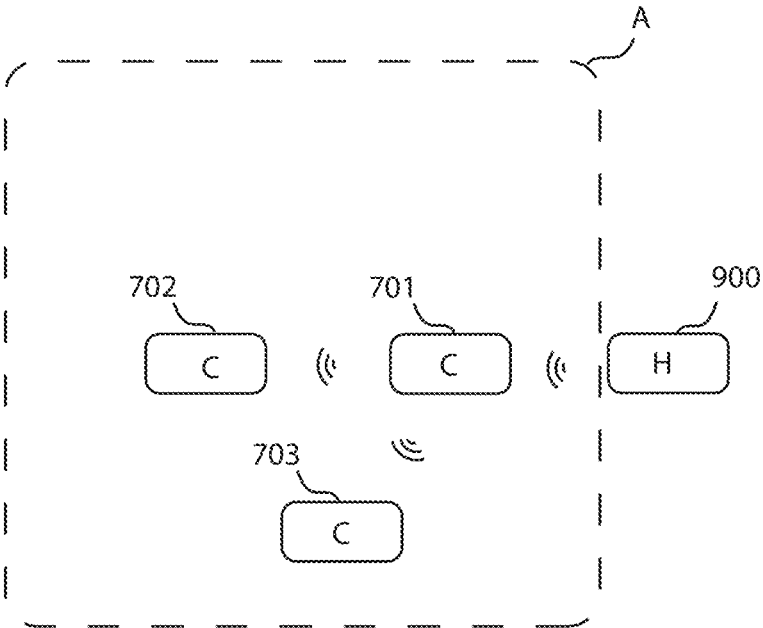


FIG. 9A

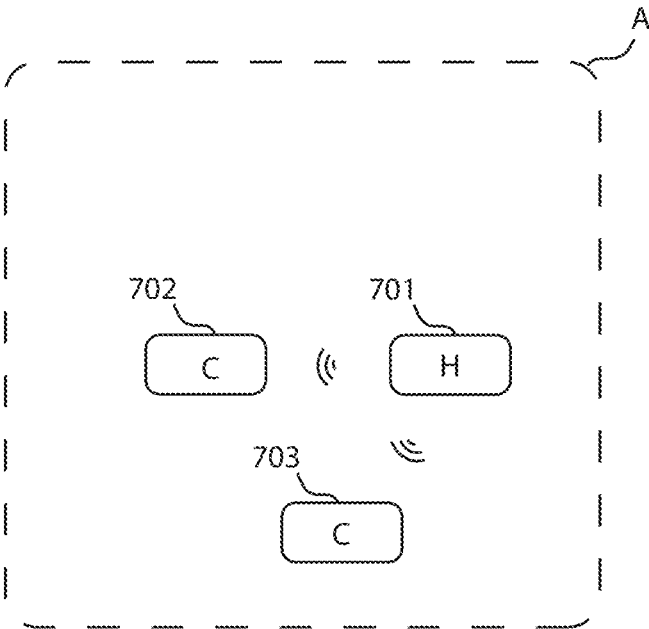


FIG. 9B

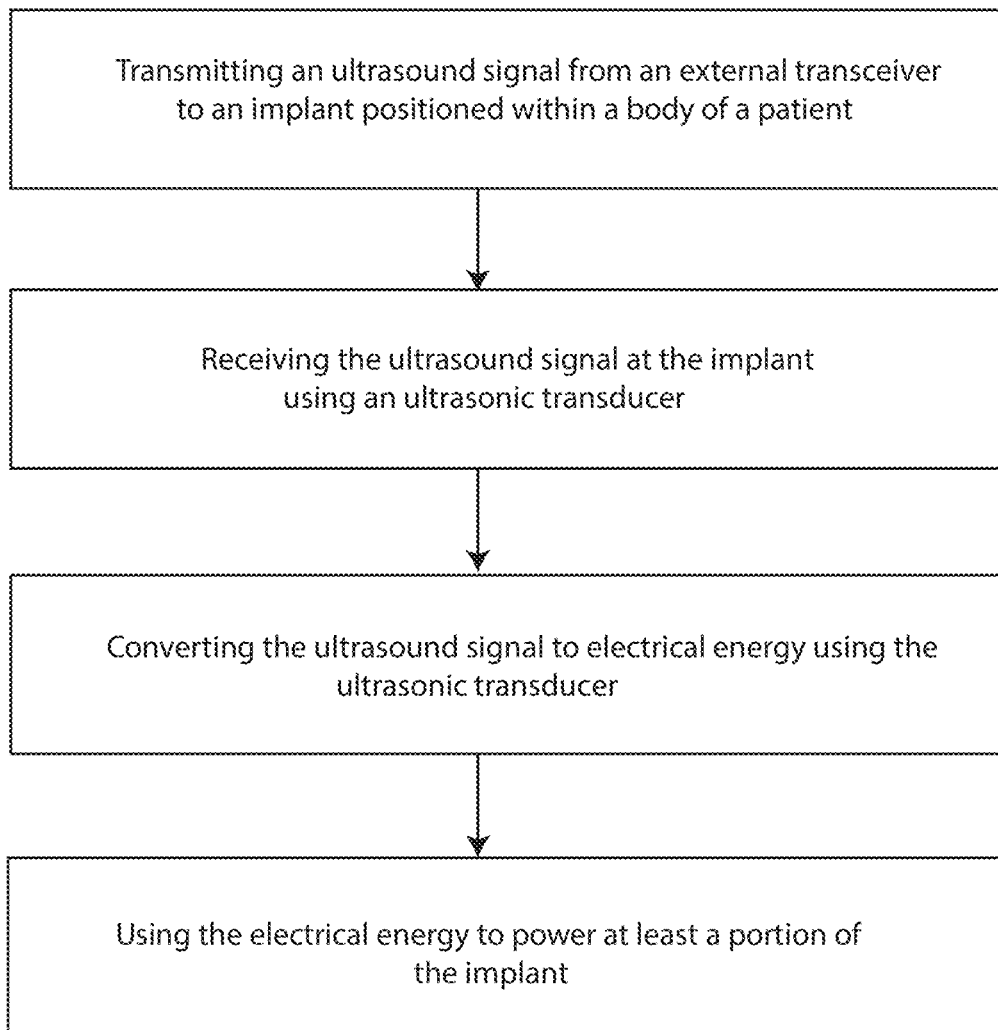


FIG. 10

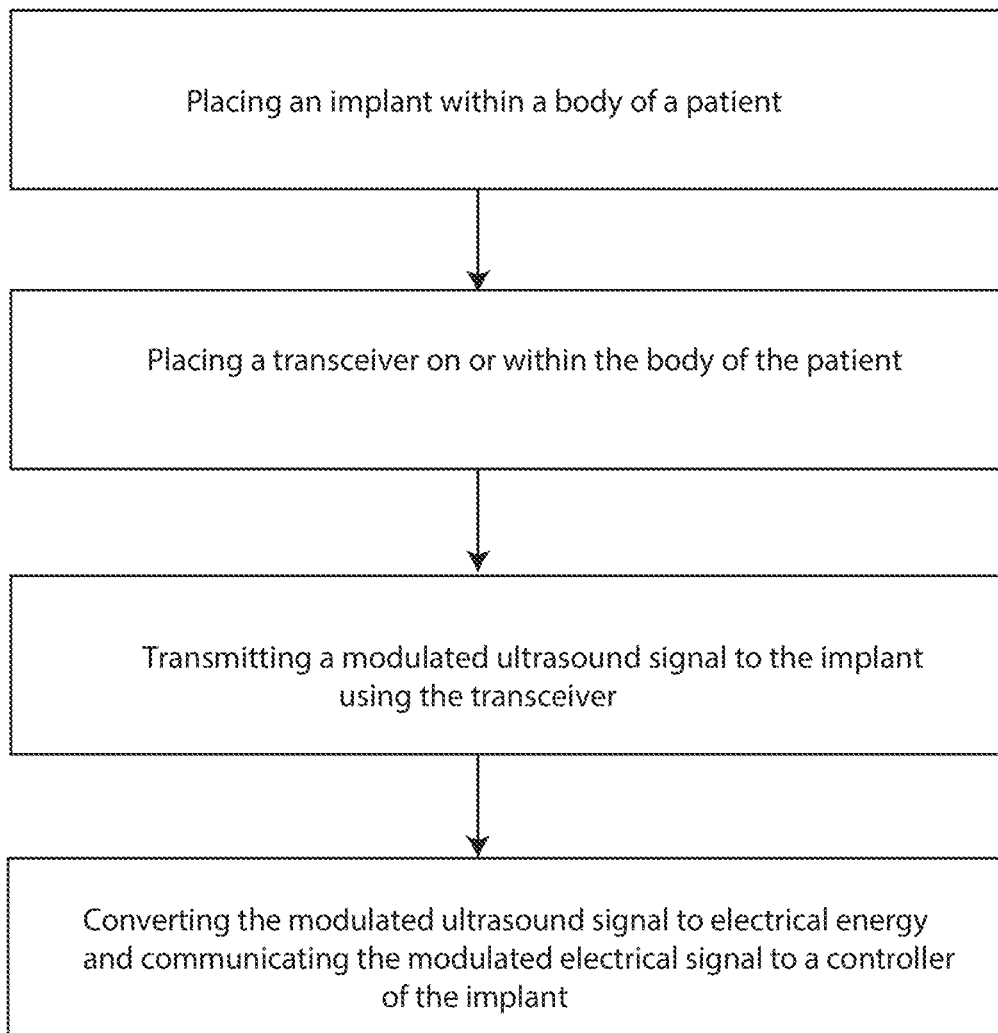


FIG. 11

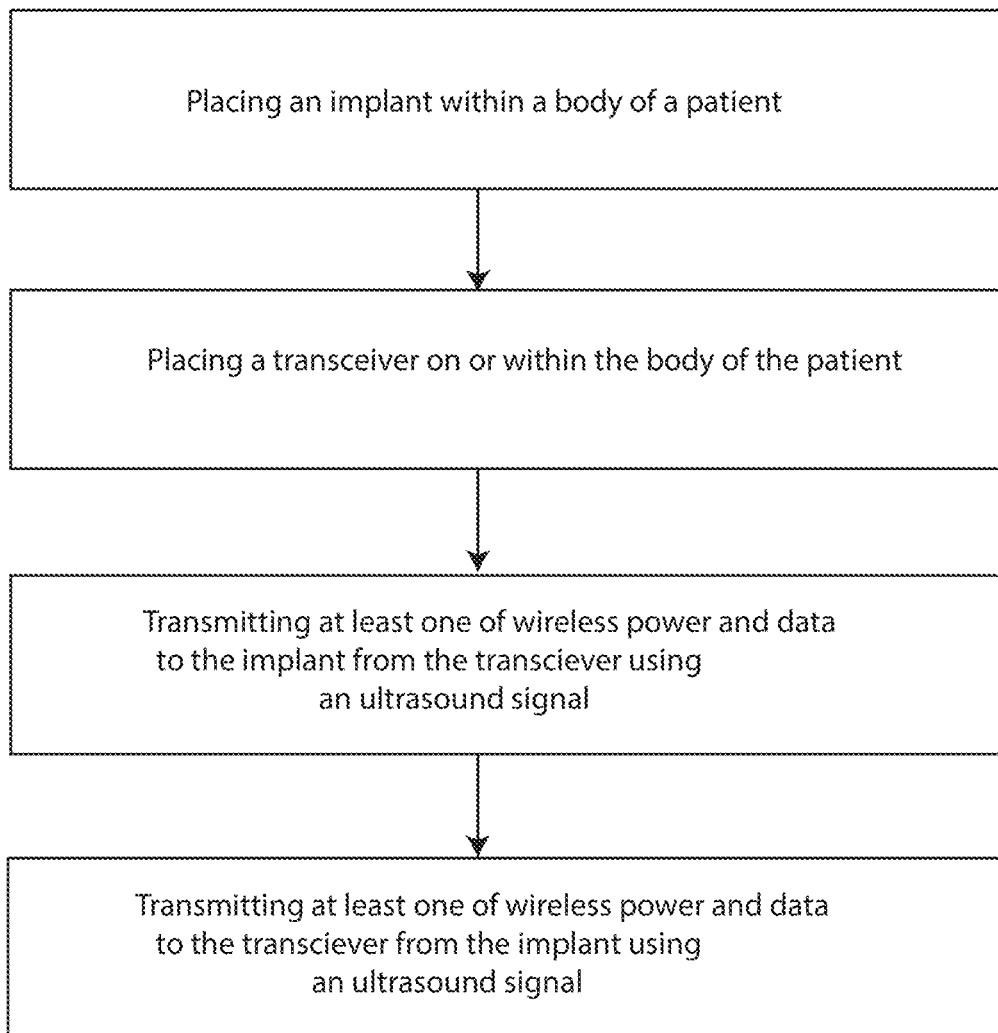


FIG. 12



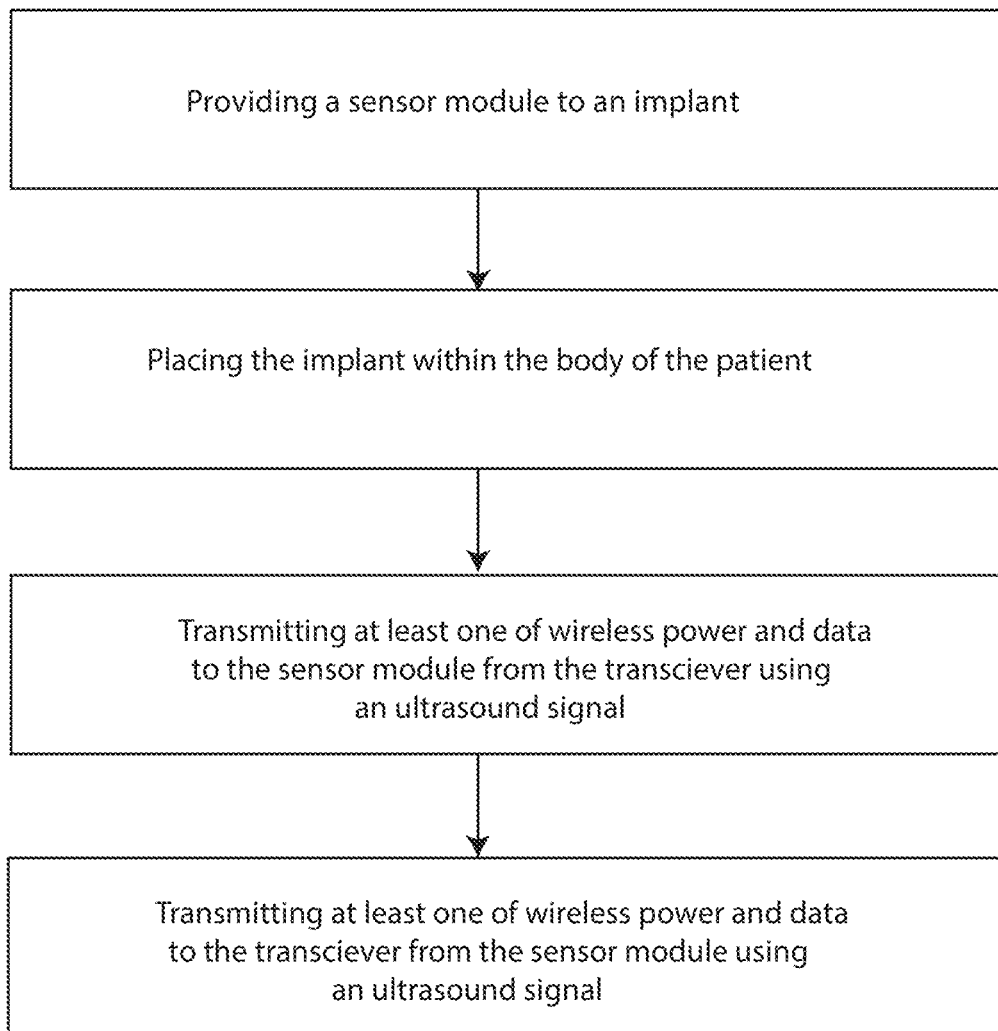


FIG. 13

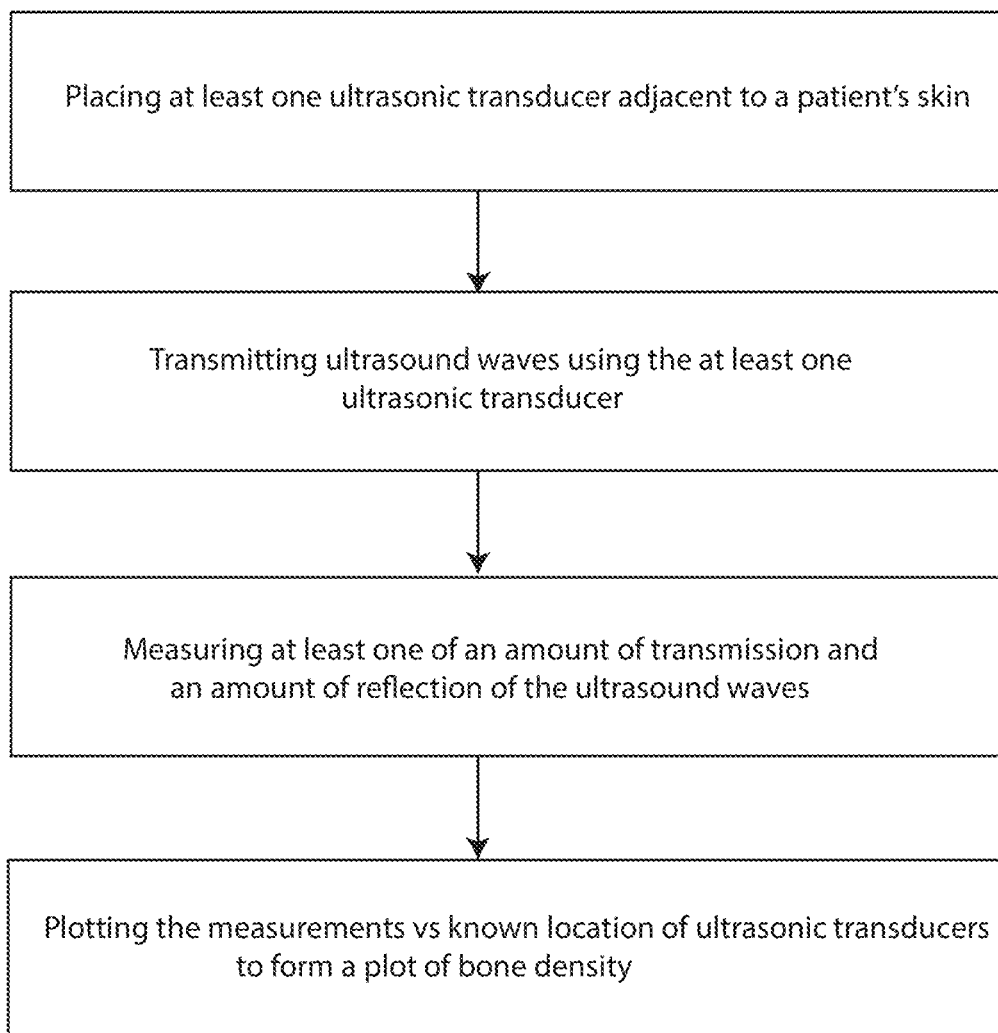


FIG. 14

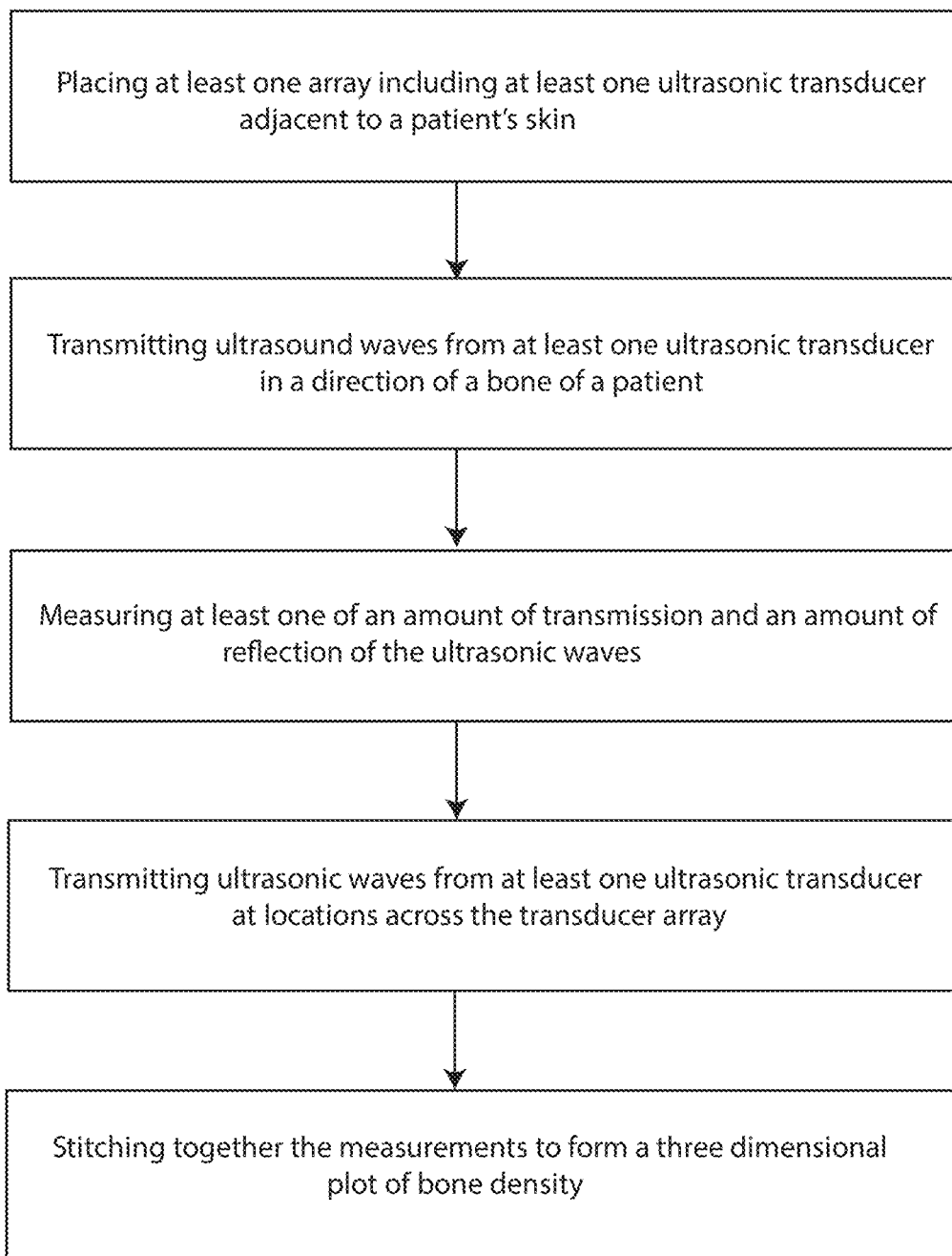


FIG. 15

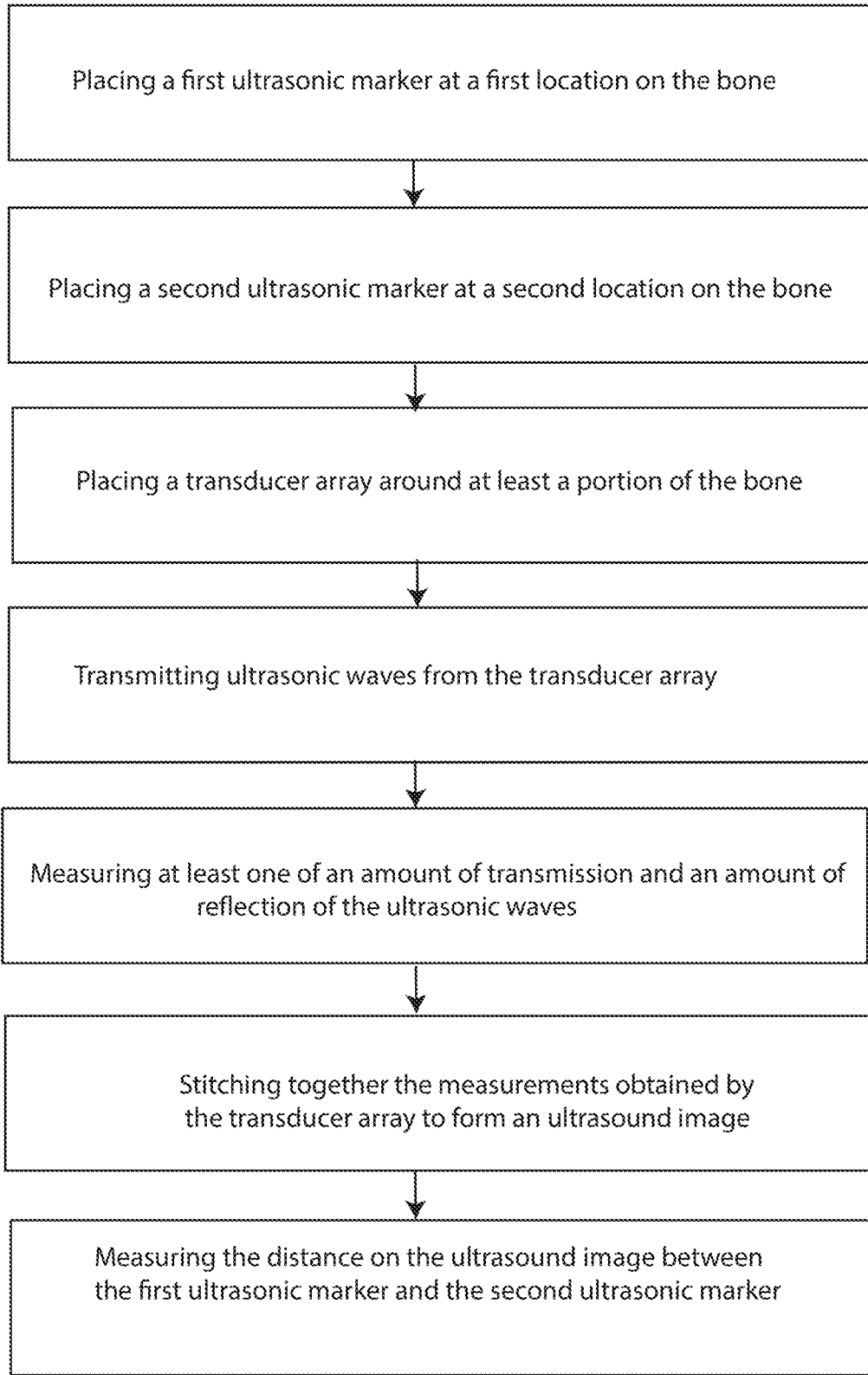


FIG. 16

## MEDICAL DEVICES FOR ULTRASONIC THERAPY

### CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of and priority to U.S. Provisional Application No. 62/802,457, filed on Feb. 7, 2019, and U.S. Provisional Application No. 62/959,357, filed on Jan. 10, 2020, the entire disclosures of which is incorporated herein by reference.

### FIELD OF DISCLOSURE

[0002] 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

[0003] 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.

[0004] 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

[0005] 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.

[0006] 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.

[0007] 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.

[0008] 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.

[0009] 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.

[0010] 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.

[0011] 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.

[0012] 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.

[0013] 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.

[0014] 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.

[0015] 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.

[0016] 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.

[0017] 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

[0018] These and other features will be further understood by those with skill in the art upon a review of the appended drawings, wherein:

[0019] 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;

[0020] FIG. 2 shows an implant in accordance with a second embodiment, the implant configured for transcutaneous bidirectional ultrasonic data communication with an external transceiver;

[0021] 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;

[0022] 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.

[0023] FIG. 4A shows a perspective view of a sensor module in accordance with a first embodiment;

[0024] FIG. 4B shows a side view of the sensor module in accordance with the first embodiment;

[0025] 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;

[0026] 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;

[0027] FIG. 4E shows a printed circuit board, configured for three-dimensional stacked circuit integration;

[0028] FIG. 4F shows a chassis, the chassis configured for three-dimensional stacked circuit integration;

[0029] 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;

[0030] FIG. 5B shows a schematic of implant transcutaneous bidirectional data communication using an ultrasound signal between the sensor module and an external transceiver;

[0031] FIG. 5C shows an external transceiver configured for transcutaneous bidirectional data communication using an ultrasound signal, communicating with the sensor module;

[0032] FIG. 5D shows an external transceiver configured for transcutaneous bidirectional data communication using an ultrasound signal, including a standoff;

[0033] 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;

[0034] FIG. 6B shows a cross-sectional view of the external transceiver being worn by a patient having an intramedullary implant disposed within a bone;

[0035] 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;

[0036] 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;

[0037] FIG. 9A shows an exemplary Body Area Network established between three implants located inside a body of a patient and an external transceiver; and

[0038] 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.

[0039] FIG. 10 shows an exemplary method of powering an implant using ultrasound waves;

[0040] FIG. 11 shows an exemplary method of transcutaneous data transmission using ultrasound waves;

[0041] FIG. 12 shows an exemplary method of transcutaneous power and/or data transmission using ultrasound waves;

[0042] FIG. 13 shows an exemplary method of using a sensor module;

[0043] FIG. 14 shows an exemplary method for a plotting bone density;

[0044] FIG. 15 shows an exemplary method for three-dimensional bone density imaging; and

[0045] FIG. 16 shows an exemplary method for measuring an increase in length of a bone.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0046] For purposes of explanation and not limitation, details and descriptions of certain embodiments are herein-after 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.

[0047] Ultrasonic communication in medical implants can provide one or more of: power, enhanced control, and feedback between medical implants and/or external transceivers.

[0048] 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).

**[0049]** 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).

**[0050]** 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 (1 kb/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 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).

**[0051]** 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.

**[0052]** 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.

**[0053]** 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.

**[0054]** 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.

**[0055]** 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.

**[0056]** 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.

**[0057]** 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.

**[0058]** 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.

**[0059]** 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.

**[0060]** 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**.

**[0061]** 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.

**[0062]** 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.

**[0063]** 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**.

**[0064]** 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 implant **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.

**[0065]** 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.

**[0066]** 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.

**[0067]** 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.

**[0068]** 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.

**[0069]** 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.

**[0070]** 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**.

**[0071]** 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.

**[0072]** 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**.

**[0073]** 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**.

**[0074]** 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**.

**[0075]** 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  $\frac{1}{4}$  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  $\frac{1}{4}$  of the second the implant **200** is said to be “awake”. The controller **202** may deactivate the implant **200** for  $\frac{3}{4}$  of the second. During this  $\frac{3}{4}$  of the second the device is said to be asleep.

**[0076]** 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.

**[0077]** In some embodiments, the sensor **205** may include a Micro-Electro-Mechanical-System (MEMS) sensor. These sensors provide a reduced profile (e.g. 1  $\mu\text{m}$ -100  $\mu\text{m}$  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.

**[0078]** 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.

**[0079]** 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.

**[0080]** 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.

**[0081]** 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, Calif. Such adjustable systems are disclosed in, for example, U.S. Pat. Nos. 9,398,925 and 9,393,117, which are incorporated by reference herein in their entireties.

**[0082]** 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.

**[0083]** 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.

**[0084]** 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.

**[0085]** 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.

**[0086]** 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**.

**[0087]** 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**.

**[0088]** 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.

**[0089]** 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.

**[0090]** 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 (1 kb/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).

**[0091]** 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**.

**[0092]** 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.

**[0093]** 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.

**[0094]** 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.

**[0095]** 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.

**[0096]** 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**.

**[0097]** 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**.

**[0098]** 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.

**[0099]** 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.

**[0100]** 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.

[0101] 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.

[0102] 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.

[0103] 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.

[0104] 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.

[0105] 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.

[0106] 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.

[0107] 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).

[0108] 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.

[0109] 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 transcutaneously 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.

[0110] 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.

[0111] 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.

[0112] 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.

[0113] The external transceiver 900 may include an external adjustment device configured to for adjusting an adjust-

able 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.

[0114] 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.

[0115] 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.

[0116] 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.

[0117] 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.

[0118] 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.

[0119] 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.

[0120] 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.

[0121] 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.

[0122] 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.

[0123] 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.

[0124] The external transceiver 900 may include any number of ultrasonic transducers 901 or ultrasonic transducer arrays 931.

[0125] 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.

[0126] A first user, for example a physician, may program the external transceiver 900 or a controller 902 of the external transceiver 900 with a first set of operational instructions. The external transceiver 900 may be pro-

grammed 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.

[0127] 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.

[0128] 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.

[0129] 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.

[0130] 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.

[0131] 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.

[0132] 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.

[0133] 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.

[0134] 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.

[0135] The external transceiver 900 is configured to non-invasively 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.

[0136] 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.

[0137] 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.

[0138] 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**.

**[0139]** 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.

**[0140]** 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**.

**[0141]** 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.

**[0142]** 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'.

**[0143]** 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.

**[0144]** As discussed above, the implant may include a sensor module, or have an ultrasonic data communication circuit integrated into the implant.

**[0145]** 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.

**[0146]** 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.

**[0147]** 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, actuating the client implant, receiving data from the client implant, and adjusting the client implant in any way as discussed supra or commonly known in the art.

**[0148]** 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.

**[0149]** 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.

**[0150]** 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.

**[0151]** 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.

**[0152]** 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.

**[0153]** 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.

**[0154]** 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.

**[0155]** 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.

**[0156]** 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.

**[0157]** 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.

**[0158]** 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.

**[0159]** 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.

**[0160]** 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.

**[0161]** 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.

**[0162]** 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.

**[0163]** 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:

1. A system comprising:

a wearable device having an interior surface and an exterior surface;

at least one ultrasonic transducer disposed on at least a portion of the interior surface of the wearable device; wherein the at least one ultrasonic transducer is configured to detect a location corresponding to a low density bone site of a patient.

2. The system of claim 1, further comprising a controller operatively connected to the at least one ultrasonic transducer, wherein the at least one ultrasonic transducer is configured to communicate information to the controller.

3. The system of claim 1, wherein a location value is assigned to each of the at least one ultrasonic transducer.

4. The system of claim 1, wherein the at least one ultrasonic transducer forms a one dimensional array.

5. The system of claim 1, wherein the at least one ultrasonic transducer forms a two dimensional array.

6. The system of claim 5, wherein the controller forms an image by stitching together the data from the at least one ultrasonic transducer.

7. The system of claim 6, the controller is configured to determine a location of low bone density, and wherein the controller is configured to use the at least one ultrasonic transducer to transmit ultrasonic waves at a therapeutic frequency to the location of low bone density.

8. The system of claim 7, wherein the controller instructs the at least one ultrasonic transducer to transmit ultrasonic waves at the therapeutic frequency to the location of low bone density for a set interval of time.

9. The system of claim 1, further comprising a power storage device.

10. The system of claim 9, wherein the power storage device comprises a rechargeable battery.

11. The system of claim 1, further comprising a conductive material disposed on the at least one ultrasonic transducer, the conductive material configured to minimize an impedance between the at least one ultrasonic transducer and the patient's skin.

12. The system of claim 1, wherein the low bone density site comprises a bone fracture.

13. The system of claim 1, wherein low bone density site comprises an osteotomy site.

14. The system of claim 1, further comprising a conductive material disposed on the at least one ultrasonic transducer, the conductive material configured to minimize an impedance between the at least one ultrasonic transducer and the patient's skin.

15. The system of claim 1, wherein the wearable device is manufactured using an additive manufacturing technique.

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