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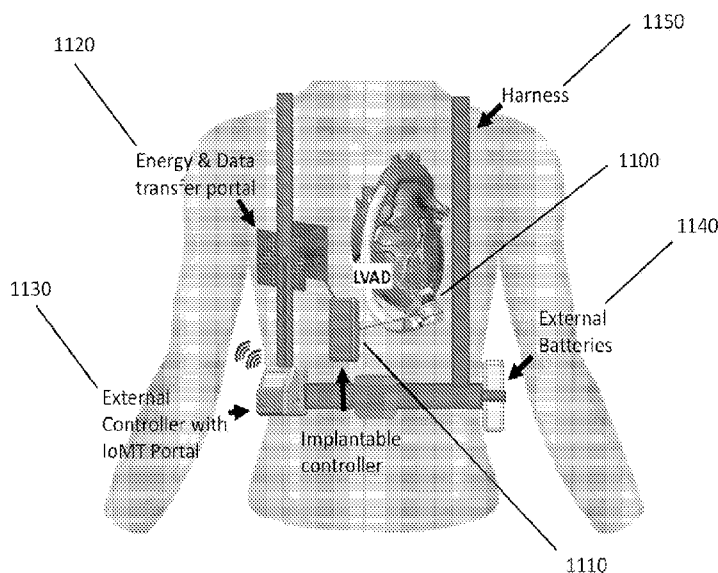


Fig. 11A

(57) Abstract: The present invention describes a system that uses ultrasonic waves to transfer energy and data, enabling for the control and recharging of a cardiac assist device. Data and energy transfer are accomplished using pulsed ultrasonic waves. The use of ultrasonic waves allows for wireless transcutaneous energy transfer to power the cardiac assist device pump in absence of a driveline, reducing complications associated with driveline infections and improving patient quality of life.



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**SYSTEMS AND METHODS FOR USING ULTRASONIC WAVES FOR  
WIRELESS POWERING AND COMMUNICATION OF A CARDIAC ASSIST  
DEVICE**

**CROSS REFERENCE TO RELATED APPLICATIONS**

- 5    **[0001]**       This application claims the priority benefit of U.S. Provisional Application  
Serial No. 62/905,648, filed September 25, 2019.

**TECHNICAL FIELD**

- [0002]**       This invention relates to networking protocols, software, hardware,  
accessories, and wearables that allow for wireless transcutaneous communications and  
10   energy transfer for the control and recharging of cardiac assist devices.

**BACKGROUND OF INVENTION**

- [0003]**       In the near future, wirelessly networked systems of implantable and non-  
implantable medical devices endowed with sensors and actuators will be the basis of many  
innovative, sometimes revolutionary therapies. However, radio-frequency (RF)  
15   electromagnetic waves, which are the physical basis of wireless technologies like Wi-Fi and  
Bluetooth, have limited penetration depth, low reliability, and high-energy consumption  
when propagating through biological tissues. Additionally, RF-based technologies are  
vulnerable to interference from other RF communication systems, and can be easily jammed  
or eavesdropped. The core technology on which this application is based uses ultrasonic  
20   waves for Ultrasound Wide Band (UsWB) communication, allowing for more reliable and  
energy efficient transmission of data and energy.

- [0004]**       The medical field increasingly relies on sophisticated medical implants,  
wearables or freestanding equipment. Medical implants are becoming smaller, smarter, and  
connected. A growing percentage of implants already have data processing and wireless  
25   connectivity (for diagnostics, real-time continuous monitoring, or device re-configuration).  
Wirelessly networked systems of implantable medical devices endowed with sensors and  
actuators will be the basis of many innovative, sometimes revolutionary therapies. Existing  
and future applications of wireless technology to medical implantable (as well as wearable)  
devices will grow into a new market refer to as “The Internet of Medical Things” (IoMT).  
30   To enable this, wireless networking devices will need to be based on: (i) miniaturized

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elements for less invasive deployment; (ii) energy-efficient and reliable data transmission within the body; (iii) minimal power consumption and capabilities to recharge; (iv) secure remote monitoring and control of the implantable device from outside the body; (v) capabilities to process data in real-time; and (vi) re-programmability and coordination of network devices.

**[0005]** Radio-frequency (RF) electromagnetic waves, and specifically microwaves, which are the physical basis of commercial wireless technologies like Wi-Fi, Bluetooth, and Medical Implant Communication Systems (MICS) are heavily absorbed by biological tissues. As a consequence, (i) RF based transmission heats up tissues, which limits applications in delicate parts of the body such as the brain; (ii) signal absorption limits efficiency, thus requiring larger energy storage/batteries; (iii) tissues also significantly distort and delay RF signals, which causes data transmission to become less reliable; and (iv) absorption limits depth of signal penetration for data or energy transmission.

**[0006]** In contrast, ultrasonic transmission of data and energy does not suffer from the drawbacks since mechanical waves are not absorbed to the same extent in biological tissues. Therefore, ultrasonic communication would better enable the creation of implantable Internet of Medical Things (IoMT) communicating devices with and within the human body. The specific communication techniques, hardware, software and protocols described here provide details on how to create an Ultrasonic Wide Band (UsWB) network of medical devices.

**[0007]** Some of the most advanced medical technologies rely on RF based technologies to communicate outside the human body from subcutaneous implants, but still rely on wired/cables connections to communicate to different areas of the body. Cardiac pacemakers and neurostimulation systems are good examples of such technologies where wires/leads are used to send data and energy to other locations in the body from subcutaneous devices. Several complications such as infections, lead failure, pain due to tethering of wires, heart valve malfunction, among others have been associated with the tunneling and chronic implant of such wires and/or leads. In more complex cases, such as in the use of ventricular assist devices wires are not only used for intra-corporeal connections but also to connect elements inside the body with elements outside the body through transcutaneous access sites, these access sites being specially prone to infection. Further, having transcutaneous access lines or drivelines, significantly reduces quality of

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life for such patients not only because of physical risk but also emotional constraints. Therefore, it would be beneficial to have a wireless system of implantable devices for both intra-corporeal and extracorporeal communication and/or energy transfer to minimize such complications. The UsWB platform allows for intelligent wireless communication and recharging networks for bi-ventricular pacing, deep brain stimulation, cardiac assist devices and several other applications that may also include remote monitoring capabilities. These networks will reduce mortality/complications in patients with different diseases while reducing healthcare costs associated with in-hospital visits.

[0008] Specifically, for cardiac assist devices which are standard surgical therapy for advanced heart failure (HF) patients refractory to medical management, the use of wireless transcutaneous communication and recharging would be of significant benefit. Commercially LVADs consist of an implanted pump with a driveline tunneled out through the skin, and connected to an external controller for power and communication. Patients are tethered to their external controller and/or battery pack, but normal wear and tear can lead to internal fatigue and external damage. The driveline exit site is a potential entry point for pathogens and requires vigilant care. Despite extensive training and daily care, LVAD recipients still experience driveline infections (14-28%) resulting in an annual cost of \$20,000 and represents a clinically-significant adverse event and one of the primary causes of death. Transcutaneous energy transmission systems (TETS) are being developed to eliminate the driveline with power inductively transmitted from an external coil to an implanted receiver. Currently, TETS technology is limited by (1) low energy transfer efficiency, (2) power loss due to coil misalignment, (3) reduced transmission efficiency with increasing depth of penetration, and (4) heating of tissue. Additionally, TETS lack capability for wireless communication and complementary radio frequency (RF) wireless technologies (Bluetooth, WiFi) are unreliable and inefficient. The ultrasonic recharging and energy transfer technology described herein will eliminate cardiac assist devices transcutaneous drivelines by solving the challenges associated with wireless power and data transfer to help improve patient outcomes and quality of life.

## SUMMARY OF THE INVENTION

[0009] Embodiments described herein provide devices, systems, communication protocols and wireless links, and methods for creating wireless networks of devices inside

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and outside the human body in order to treat patients without the complexity and complications associated with the use of implanted wired systems.

[0010] Many different networks of implantable devices to treat different etiologies may be designed using the UsWB technology to communicate and/or transmit energy. At the device level, the core building block unit, the “IoMT platform” is combined with functional units to define a functional network node. Typical functional nodes used as building blocks of medical devices (implants or wearables) are: (i) sensing node; (ii) actuation node; (iii) control node; and (iv) energy transfer/gateway node, or combinations thereof. In exemplary embodiments, a single medical device can be constructed with a single functional node, whereas in other exemplary embodiments a medical device may be defined by a plurality of functional nodes. Therefore, networked elements include both devices and/or functional nodes. A network under this definition can thus be described as a network of functional nodes or a network of medical devices, interchangeably, depending on the desired representation of the components.

[0011] A vast number of different networks of medical “things” may be created to treat or monitor patients with different pathologies. Most medical network applications can be grouped into two major categories: (i) intelligent monitoring and actuation networks; and (ii) monitoring and drug delivery control networks.

[0012] Several embodiments of implantable and non-implantable nodes have been designed for different applications such as: deep brain stimulation, cardiac pacing, cochlear/auditory device recharging and reprogramming, intra-ocular pressure monitoring for glaucoma, wireless neonatal monitoring, brain neuro-stimulation, peripheral nerve stimulation, spinal cord stimulation, gastric pacing, artificial limb control, cardiac assist device control and recharging, monitoring or orthopedic implants, monitoring or artificial heart valves, glucose monitoring and insulin pump control, and controlled drug delivery among others.

[0013] In an embodiment, specifically for cardiac assist devices, UsWB technology can be used to eliminate the transcutaneous tether between the extra-corporeal and implantable elements of the system. The external control and energy storage elements of the cardiac assist system are connected wirelessly with the implantable controller/energy storage and pump through an ultrasonic transcutaneous energy transfer portal which also

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allows for two way wireless communication. Wireless powering and control of implantable elements of the cardiac assist system will reduce clinical complications and improve quality of life for heart failure patients.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

5    **[0014]**       Having thus described various embodiments of the present invention in general terms, reference will now be made to the accompanying drawings, which are not necessarily drawn to scale, and wherein:

**[0015]**       Fig. 1 shows the different types of communication links used in the modular networks for both implantable and non-implantable components of the network.

10   **[0016]**       Fig. 2 Block diagram of the principal components of the IoMT platform. Three main block constitute the platform itself: i) Energy Storage unit, ii) Core Units, and iii) Ultrasonic interphase.

**[0017]**       Fig. 3 Block diagram of a functional node that can be recharged wirelessly using ultrasonic waves. The addition of a functional unit to the basic IoMT platform structure constitutes a functional node. The energy management unit includes energy harvesting components and energy storage elements. The embodiment described in this  
15   structure constitutes a functional node. The energy management unit includes energy harvesting components and energy storage elements. The embodiment described in this diagram also uses a capacitor bank as energy storage for improved safety.

**[0018]**       Fig. 4 Diagram of the different nodes/devices that constitute a wireless bi-ventricular pacing network enabled through ultrasonic communication and energy  
20   transmission.

**[0019]**       Fig. 5 Block diagram of the reprogrammable wireless pacing (RWP) nodes with vascular pressure monitoring. The components of the RWP nodes are similar to those of the generic IoMT platform with the addition of two functional units, a pressure sensor unit and an electric sensor/pacing unit. The RWP nodes are recharged using ultrasonic  
25   waves and therefore include the energy management unit with harvesting capabilities.

**[0020]**       Fig. 6 Diagram showing different types of treatments using neurostimulation referenced to a specific stimulation site.

**[0021]**       Fig. 7 Diagram of the different nodes/devices that constitute a wireless deep brain stimulation network enabled through ultrasonic communication and energy  
30   transmission.

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[0022] Fig. 8 Block diagram of a reprogrammable stimulation RSN node. The components of the RSN node are similar to those of the generic IoMT platform with the addition of two functional units, an electrical sensor unit and stimulation unit for multi-contact stimulation. The RSN node are recharged using ultrasonic waves and therefore  
5 include the energy management unit with harvesting capabilities.

[0023] Fig. 9 Diagram of the different nodes/devices that constitute a wireless neuromodulation/CRT network with vascular pressure monitoring capabilities for the treatment of heart failure patients.

[0024] Fig. 10 Block diagram of: A) Reprogrammable cardiac wireless pacing node  
10 and B) vascular pressure monitoring node, for a wireless neuromodulation/pacing network with vascular pressure monitoring capabilities.

[0025] Fig. 11A is a diagram of the primary elements of a wireless ultrasonically charged and controlled cardiac assist (UCCA) system.

[0026] FIG. 11B is a block diagram for components for the UCCA system.

## 15 DETAILED DESCRIPTION OF THE INVENTION

[0027] Embodiments of the present invention now will be described more fully hereinafter with reference to the accompanying drawings, in which some, but not all, embodiments of the inventions are shown. Indeed, the invention may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein;  
20 rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. Like reference numbers refer to like elements throughout. The singular forms “a,” “an,” and “the” can refer to plural instances unless the context clearly dictates otherwise or unless explicitly stated.

25 [0028] The invention provides a wireless medical device network comprising: a plurality of networked elements, wherein at least two of these elements communicate with each other by sending or receiving data using ultrasonic waves. In embodiments, the ultrasonic wave is a pulsed wave. In embodiments, the ultrasonic wave is a continuous wave.

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**[0029]** The invention provides a wireless medical device network comprising: a plurality of networked elements, wherein data is encoded in the frequency domain of the ultrasonic wave. In embodiments, data is encoded in the phase domain of the ultrasonic wave. In embodiments, data is encoded in the amplitude domain of the ultrasonic wave.

5 **[0030]** The invention provides a wireless medical device network comprising: a plurality of networked elements, wherein data is encoded in the relative position of ultrasound pulses with respect to a reference. In embodiments, data is encoded using a time-hopping scheme in the ultrasonic pulses. In embodiments, a single bit of data is encoded in a single ultrasonic pulse. In embodiments, a single bit of data is encoded in multiple  
10 ultrasonic pulses.

**[0031]** The invention provides a wireless medical device network comprising: a plurality of networked elements, wherein the ultrasonic wave is generate by a unidirectional ultrasonic transducer. In embodiments, the ultrasonic wave is generate by a multidirectional ultrasonic transducer. In embodiments, at least one network element is implanted within  
15 the human body. In embodiments, at least one network element is wirelessly recharged using ultrasonic waves.

**[0032]** Embodiments include a cardiac medical device wireless network comprising: a plurality of networked elements, wherein at least one element is an implanted device; and wherein at least two of these elements communicate with each other by sending  
20 or receiving data using ultrasonic waves. In embodiments, at least one of the devices in the network is capable of pumping and/or aiding blood flow though the cardiac anatomy. In embodiments, at least one of the network elements can recharge another of the network elements using ultrasonic waves travelling at least a portion of their path through tissue.

**[0033]** The invention provides a cardiac medical device wireless network  
25 comprising: a plurality of networked elements, wherein at least one element is an implanted device; and, wherein at least two of these elements communicate with each other by sending or receiving data using ultrasonic waves. In embodiments, at least one implanted device is used for pacing of a heart chamber; wherein at least one implanted control element is used to control a pacing element. In embodiments, at least one implanted control element is used  
30 to wirelessly recharge a pacing element using ultrasonic waves.

**[0034]** The invention provides a wireless medical device network comprising: a plurality of networked elements, wherein at least one of the implanted elements has the capacity to measure blood pressure. In embodiments, at least one of the elements can communicate wirelessly to the internet.

5 **[0035]** The invention provides a cardiac medical device wireless network comprising: a plurality of networked elements. In embodiments, the ultrasonic wave is a pulsed wave. In embodiments, a single bit of data is encoded in multiple ultrasonic pulses.

**[0036]** The invention provides a neurostimulation medical device wireless network comprising: a plurality of networked elements, wherein at least one element stimulates or  
10 modulates the nervous system. In embodiments, at least two of these elements communicate with each other by sending or receiving data using ultrasonic waves. In embodiments, at least one element is an implanted device. In embodiments, at least one device is implanted within the brain. In embodiments, at least one element is used for deep brain stimulation therapy. In embodiments, the ultrasonic wave is a pulsed wave. In embodiments, at least  
15 one device is connected to the peripheral nervous system.

**[0037]** The invention provides a neurostimulation medical device wireless network comprising: a plurality of networked elements, wherein the ultrasonic wave is a pulsed wave. In embodiments, at least one network element can increase or decrease cardiac function.

20 **[0038]** Radio-frequency (RF) electromagnetic waves, and specifically microwaves, are heavily absorbed by biological tissues fluid and other solids. As a consequence, (i) RF based transmission heats up tissues, which limits applications in delicate parts of the body such as the brain; (ii) signal absorption limits efficiency, thus requiring larger energy storage/batteries; (iii) tissues also significantly distort and delay RF signals, which causes  
25 data transmission to become less reliable; and (iv) absorption limits depth of signal penetration for data or energy transmission. In contrast, ultrasonic transmission of data and energy does not suffer from the drawbacks, since mechanical waves are not absorbed to the same extent in biological tissues.

**[0039]** As shown in Fig. 1, in a preferred embodiment the nodes of the intra-body  
30 network 100 communicate/link and/or send energy using ultrasonic waves while the nodes external to the body 101 can use RF based communication links to communicate with other

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external elements. In exemplary embodiments, the extracorporeal nodes can still use ultrasonic waves to communicate through the air when such a link is desired. Using these external links the intra-corporeal network can communicate to the internet of things, the general internet, physical computers/servers/equipment, or the cloud. External communication links allow data to be stored or monitored remotely. In preferred embodiments, the intra-body network can also be controlled or re-programmed remotely using these data links. In exemplary embodiments, the data of one or more patients received from this networks can be processed using standard or artificial intelligence algorithms to improve patient treatment for the general patient population or provide patient centric tailored treatment.

**[0040]** Many different networks of implantable devices to treat different etiologies may be designed using the UsWB technology to communicate and/or transmit energy. There are several common types of implants that can be used in distinct networks to treat different forms of disease. Therefore, to reduce development timelines/cost and regulatory burden, proven modular hardware elements from one network are used in another to enable another applications. Therefore, a dual-level modular approach is the basis for the different networks. For the first level, implantable devices are designed and/or built following a modular approach (device level), by combining different functional units with the primary ultrasonic IoMT platform. Second, a networked medical application is built by combining the functionalities of different devices working in a coordinated fashion (network level).

**[0041]** At the device level, the core building block, "IoMT platform", is used to create implants (and wearables) with specific functions by adding one or several functional units. Devices configured in this way are defined as a functional node. Typical functional nodes to used as building blocks of medical devices (implants or wearables are (i) sensing nodes; (ii) actuation nodes; (iii) control nodes; and/or (iv) energy transfer/gateway nodes.

**[0042]** As shown in Fig. 2, in a preferred embodiment the basic IoMT platform is constructed from three primary units, although in some exemplary embodiments all these units may not be present. These primary units are: (i) power unit 200, (ii) core unit 201, and a (iii) ultrasonic interface 202. In exemplary embodiments, the different components that make up these units above can be implemented in several circuit boards or electronic components. In some preferred embodiments, the IoMT is implemented in a multi-layer board that may contain all the units named above. In a further embodiment System-on-Chip

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(SoC) solutions will be used to integrate different hardware components of the IoMT platform inside a single chip.

[0043] As shown in Fig. 3, in a preferred embodiment, the power unit will include both an energy harvester and/or energy storage/buffer when required, defining an energy management unit (EMU) 300. Storage/buffer 301 can take the form of a battery (standard  
5 or rechargeable), a capacitor, or an array of capacitors or any other voltage storing electronic element. The selection of the type of energy storage will depend on size requirements, life expectancy, and the risks associated with battery replacement.

[0044] In a preferred embodiment, the EMU 300 includes an ultrasonic energy  
10 harvester that is used to receive ultrasonic waves from other node/nodes of the network and transform these waves into energy that can be used to power the receiving node. In this embodiment, different network nodes can received and/or send energy using ultrasonic waves. When sending energy, the EMU in combination with other units of the node can take alternating current (AC) signal, or a square wave, generated at ultrasonic frequencies (> 20  
15 kHz) to drive an electro-acoustic transducer 302 that transmits power to another node. The transducer converts the electrical waveform to mechanical waves. When receiving ultrasonic energy, an acousto-electric transducer transforms the mechanical excitation back into an electrical AC signal. In an exemplary embodiment, the EMU can also contain a rectifier and/or a multiplier circuit, and a low dropout (LDO) regulator 303 to limit the  
20 voltage delivered. The storage components (battery, capacitors, etc) 301 need a direct current (DC) voltage to be recharged, which requires the presence of the rectifier 304 whose role is to generate a DC voltage from an oscillating input. The core unit 201 helps control part of the energy harvesting system as well as an ultrasonic transceiver for data communication. When utilizing the same transducer to send/receive data and energy, a  
25 switch 305 is used to change from an energy sending/receiving phase to a communication phase in the operation cycle of the transducer. During the first phase, the platform is remotely recharged via ultrasonic transcutaneous energy transfer (UTET). During the second phase, the harvested energy is used to power the circuitry to activate processing, sensing, actuation, and communication functions. In specific embodiments, the platform  
30 actually sends energy during the first phase and second phases, such as in the case of a IoMT platform as part of a control node. The phase switch can work using prescribed times from a timer, or can be controlled by the core unit elements 201. In exemplary embodiments of

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the energy harvesting system, different transducers are used to send/receive data and energy, thus not requiring the switch controlled 305 dual phase cycle described above. Additional elements as a secondary timer 306 to control switching between data processing in the core unit 201 and powering the functional unit 307 of the functional node, can be included, to  
5 improve energy efficiency. A multiplier circuit 308 can also be included to help with signal processing and/or amplification.

[0045] The core unit 201 may include a stand-alone microcontroller, or a combination of a microcontroller (MCU) 203 and reconfigurable hardware, such as a field-programmable gate array (FPGA) 204; or even a stand-alone FPGA. In exemplary  
10 embodiments, other type of reconfigurable hardware can be used like application-specific integrated circuits (ASICs). Depending on the processing requirements and desired size, any of these options may be used. In a preferred embodiment where the MCU and FPGA are combined, their combination results in hardware and software reconfigurability with very small packaging and low energy consumption. The miniaturized FPGA 204 hosts the  
15 physical PHY layer communication functionalities. The MCU 203 is in charge of data processing and of executing software-defined functionalities to implement flexible and reconfigurable upper-layer protocols. These upper-layer protocols may include in some embodiments non-time critical MAC functionalities, network, transport and application, among others. In the exemplary embodiment, the software is split between FPGA 204 and  
20 MCU 203. The FPGA 204 implements the PHY layer communication functionalities, as well as interfaces to connect the FPGA 204 chip with the MCU 203 and the peripherals. In the exemplary embodiment the MCU software design is based on the  $\mu$ Tasker real-time operating system (RTOS) that supports timers and interrupts for sensing and transmitting data and executes the upper layer networking protocols. The IoMT platform software  
25 framework also provides a set of primitive functions to be used as building blocks to develop specific data processing applications. To someone skilled in the art is it understandable that all software could be implement in any of the components that may be included in the core unit dependent on the algorithm design and processing requirements. In an embodiments the functionalities are implemented to minimize the system energy consumption by  
30 leveraging  $\mu$ Tasker primitives to access different power states. Specifically, an energy management module is able to (i) adjust at runtime the core clock frequency and low-power mode according to application requirements, and (ii) implement automatic wake-up

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functionalities. This implementation will allow the MCU current consumption to be reduced from its values in a RUN state down to lesser values in very-low-leakage-state, with intermediate states that trade current consumption for wake-up time.

[0046] The ultrasonic interface 202 in preferred embodiments will be common to  
5 different types of nodes in the same network, thus enabling internetworking; depending on the power unit type, it may also have an interface for energy harvesting. The ultrasonic interface enables wireless connectivity and consists of a receiver (Rx) and a transmitter (Tx) chain. Depending on the number of ultrasonic transducers, the Rx and Tx can work in parallel or may need to be switched 205 to work in series in controlled cycles over time.  
10 The Rx chain includes a low-noise amplifier (LNA) 206 and an analog-to-digital converter (ADC) 207 to amplify and digital-convert received signals, while the Tx chain embeds a digital-to-analog converter (DAC) and a power amplifier (PA) to analog-convert and amplify the digital waveform before transmission.

[0047] The ultrasonic interface can use a single or a plurality of transducers. When  
15 a single ultrasonic transducer is used to operate several send/receive cycles, these cycles will be gated in time. In some embodiments both energy and data could be send in the same acoustic signal, although with limitation in the data transmission rate. In exemplary embodiments, multiple transducers can to send and or receive different signals. In exemplary embodiments, different transducers can be used to separate the energy and data  
20 transmission functions or different transducers can be used to send signals in different directions. In exemplary embodiments, unidirectional transducers may suffice, but when directional tolerances are important so that the beam reaches efficiently another node, a multidirectional or omni-directional transducer should be used. Directionality of the transducers is achieved by an array design (array of unidirectional piezos pointed in different  
25 directions) or by the shape of the ultrasound emitting element or piezo (cylindrical, semi-spherical, spherical, etc). Both, piezoelectric ultrasonic transducers (crystal, ceramic, polymers, organics and composites) or capacitive ultrasonic transducers can be used in the ultrasonic interphase unit. In exemplary embodiments, capacitive transducers include those micro-machined using MEMs technologies and well as others which use more traditional  
30 manufacturing methods.

[0048] There are several exemplary embodiments that describe the ultrasonic waveforms used to send or received energy and/or data using UsWB. In some embodiments

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continuous ultrasound waves can be used while in others pulsed ultrasound waves may be preferred. In preferred embodiments using pulsed ultrasonic waves, discrete digitally modulated pulses of ultrasound are emitted from the transducer (discrete ultrasound wave pulse packages). In embodiments where data is sent through continuous waves, data can be encoded in the frequency or phase (frequency shift keying or phase shift keying) or amplitude domain (amplitude shift keying) or in a combination (quadrature amplitude modulation). In other embodiments data can be encoded in the relative position of ultrasound pulses with respect to a reference (pulse position modulation). When using pulsed ultrasound waves, data can be encoded in the frequency or amplitude domain, or in the relative positions of pulses in the ultrasonic wave. In a preferred embodiments, a time-hopping scheme is used to encode the data in the ultrasonic pulses. In some exemplary embodiments each bit of data can be encoded in a single pulse, while in preferred embodiments a single bit can be encoded within the signal structure of multiple pulses. In certain embodiments each bit can be represented with multiple pulses whose polarity or position can be modulated following a binary spreading code. The spreading code can be obtained through a pseudo-random generator, or it can follow a known and pre-defined pattern.

**[0049]** The core building block, the IoMT platform, can be combined with a functional unit 307 to create a functional node as described above. Possible functional units may have the largest range of variability and will determine the nature of the node. For example, for control nodes, the specification in its processing (core unit) and communication elements (ultrasonic interface) can define its function completely. In contrast, for energy transfer/gateway node the specific data interface with the external environment (e.g., WiFi, Bluetooth) and the type of energy transfer interface will define its range and specific function. In some embodiments, sensing nodes or actuation nodes (e.g., pacers) may tend to have a simple microcontroller as core unit; whereas control nodes and energy transfer/gateway nodes may require a more reconfigurable hardware so the same unit can be used in several different types of networks with very limited changes to hardware. Therefore, a large variability of component architecture can be used in different functional nodes depending on specification.

**[0050]** For sensing nodes, the specific physical sensor (electrical, acoustic, EKG, pressure, temperature, voltage/current, flow, chemical, Gas, Ph+ sensor, photosensor,

accelerometer, etc) will define the functionality. Further, a specific sensing node can find many different medical applications in different parts of the body. For example, a pressure sensor can be used in cardiovascular (heart failure, Hypertension), ophthalmological (glaucoma), and spine (disk compression) applications, among others.

5    **[0051]**       In some applications sensors nodes may be used in wearables or outside the body to create wireless network links through the air in environments where sensing of the human body is required and RF based links are not possible or not preferable. In a particular embodiment of UsWB transmission through the air, in the nursery or neonatal intensive care unit wired connections to sensors on the child's body or surrounding environment may be  
10 exchanges for wireless UsWB links to diminish concerns of having a high density RF environment surrounding a neonate or young child. This link can interface with an external control gateway to send data to a computer or the internet.

**[0052]**       Actuation functional units also present a large range of variation, but in general for the human body the primary expected actuators are (i) mechanical/artificial  
15 limbs/prosthesis, (ii) electro stimulation/pacing, (iii) cameras, (iv) acoustic, blood pumps, and (v) drug delivery/pumps. Many applications may work in absence of a sensor node like when using a control or gateway node to recharge and/or reprogram and/or adjust a cochlear implant or auditory support device. In such an embodiment, the controller or gateway node may be located or embedded in an acoustic friendly environment like a gel pillow to  
20 recharge the auditory device when the patient is at rest, or as required.

**[0053]**       Although there is a large range of possibilities and scopes, it should also be understood that the nervous system and the heart work within a very similar electro-potential range. Therefore, reprogrammable-pacing/stimulation actuation functional units for pacing the myocardium, the brain or nerves, can have in many cases identical/similar electronics,  
25 with differences mostly associated to casing, software, and anchoring elements. Therefore, exemplary embodiments of pacing/stimulation actuation functional unit may generate many types of functional nodes for several parts of the body for heart, brain, and nerve stimulation. Exemplary embodiments of this functional nodes also includes pacing of the gastric system (stomach, intestine) that is accomplished using a similar electro-potential  
30 pacing actuation node. Increased energy capacity for pacing may also allow for skeletomuscular stimulation or prosthesis control.

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[0054] An embodiment of treatment specific modular networks is associated to cardiovascular disease and neurostimulation/neuromodulation. In these networks implantable pacing or stimulation nodes may be controlled and powered/recharged by an implantable control node, that itself can be controlled, recharged and linked to an external network using an energy transfer/gateway node. In some simpler embodiments the pacing or stimulation nodes can be recharged and controlled directly by the energy transfer/gateway node in absence of the implanted control node.

[0055] In a primary embodiment of UsWB enabled pacing networks, ultrasonic energy transfer and UsWB communication technologies can be used to reduce complications associated with wired pacing leads (infection, lead failure, pain, etc), reduce battery exchange rates, and hospital visits through remote monitoring in patients that need single chamber or multi-chamber cardiac pacing. A cardiac pacing network to pace a single chamber of the heart or multiple chambers can be constructed from pacing functional nodes, a control node and an energy transfer/gateway node. This network may also include cardiac pressure sensing within the pacing node or as an independent pressure-sensing node. The exemplary embodiments for this network include single ventricle pacing or bi-ventricular pacing, although other applications may include or be limited to atrial pacing of a single or both atria.

[0056] In a preferred embodiment for a bi-ventricular pacing UsWB network, three different types of functional nodes are defined as shown in Fig. 4: (1) reprogrammable wireless pacing (RWP) nodes with vascular pressure monitoring 400, (2) rechargeable system (RS) control 401 node, and (3) external recharging and communications (ERC) node 402. All the elements in this network communicate with each other through proprietary Ultrasonic Wide Band (UsWB) technology. The RWP nodes and the RS control node are wirelessly recharged using ultrasonic energy transmission. UsWB platform is capable of sending energy and data via ultrasonic waves through tissue, bone, and fluids at penetration depths significantly higher than RF waves (up to 30 cm depth) and with better reliability (bit error rates better than  $10^{-6}$ ). Since increasing energy efficiency results in reduced energy storage requirements, UsWB also enables miniaturization of medical devices. The RWP nodes 400 are implanted using minimally invasive (catheter based endovascular methods) in both ventricles, the RS controller 401 is implanted in a subcutaneous pocket in the chest of the patient, and the ERC node 402 is a wearable which is in contact with the skin. The

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ERC node 402 is removable and in preferred embodiments is attached to the skin using a glued patch. The contact area between the ERC node casing and the skin has ultrasonic coupling material.

[0057] As shown in Fig 5. The components of the RWP nodes are similar to those of the generic functional node described in Fig. 3 with the addition of two functional units, a pressure sensor 501 and an electric sensor and pacing unit 502. The RWP nodes are recharged using ultrasonic waves and therefore include the EMU 300 with harvesting capabilities. RWP nodes 400 have reprogrammable electronic hardware that can be easily adapted to pace cardiac muscle and/or other structures. RPWs are anchored to the myocardium with a conductive metallic coil (titanium, stainless steel, other conductive alloys) or any other conductive anchor (hooks, barbs, arms), and charged and controlled using ultrasonic communication and energy. The RPWs are able to communicate with each other to provide Cardiac Resynchronization Therapy (CRT) while in parallel storing energy for continued pacing for several hours or days using a capacitor bank. In this embodiment even in absence of the ultrasonic link to the control node a patient is given enough time to reach a hospital (safety feature) compared to current wired technology that immediately loses pacing capabilities after lead failure. In a preferred embodiment super-capacitor energy storing bank (2 or more capacitors) and rectifying circuit are used to have redundancy in a zero failure environment. One capacitor 503 will be dedicated to pacing and the other 504 will always be fully charged (safety). Although in some exemplary embodiments pressure sensors (MEMs or non-MEMs) may require separate implants, in an exemplary embodiment a MEMS pressure sensor 501 is integrated into the RPWs to actively monitor left and right ventricular pressures. The core unit can include a FPGA 204, a MCU 203 or an ASICs or any combination thereof. In a preferred embodiment a FPGA is used to drive the logic of the MEMs pressure sensor and control all functions within RPW lead in combination with the MCU 203. The electric sensor 502 is used to track real time the electrical behavior of the implant site in order to respond to changes in the rhythm of the heart. These responses from the RWP to changes in the rhythm of the heart can occur in a closed loop with its own core unit, or in a closed loop combination with data provide by the pressure sensor on any of the other of the implants. Pacing responses can also be re-programmed by a clinician on site or remotely using the ERC patch 402.

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[0058] In a preferred embodiment, the pacing electronics will be encased within a Polyether ether ketone (PEEK) casing and wrapped with medical-grade porous Dacron cloth to promote rapid tissue in-growth reducing thrombogenic risk. In exemplary embodiments the casing can be constructed of other polymers or metals, and may include a non-thrombogenic surface. In an exemplary embodiment the casing will have a single silicone (or other polymer) window above and in contact with the MEMS pressure sensor in order to transmit the external pressure to the sensor without or with reduced interference from the case itself.

[0059] Rechargeable system (RS) control node 401 consist of a reprogrammable controller that can coordinate and re-program other implantable elements of the network through the ultrasonic interface, the basic architecture is that shown in Fig.3 but doesn't include a functional unit 307 since this node doesn't require any sensory or actuator functionalities. The controller is also able to transmit energy from its position just below the skin to other elements implanted further away from the surface. The battery of the controller is recharged through the skin using ultrasonic power transmission, therefore requiring and EMU 300 with harvesting capabilities. The controller will also be reprogrammed/controlled from outside the body and serve as an interface for off-site remote monitoring. The basic architecture of the controller includes multidirectional ultrasonic transducers and a high-capacity rechargeable battery. In an exemplary embodiment a single omnidirectional ultrasonic transducer may be used. In a preferred embodiment two transducers may be used, one directed at the RWP nodes 400 and another toward the skin to communicate with the ERC patch 402.

[0060] External recharging and communication (ERC) 402 node/patch will recharge the RS control node through ultrasonic transcutaneous energy transfer when needed, and act as gateway to interconnect the intra-body network to the Internet. This energy transmission/gateway node is external element (wearable) to be used when needed to recharge or reprogram the network. The ERC node/patch has the same primary components as the IoMT platform shown in Fig. 2 with the addition of a functional unit to interphase with the internet or internet of things through WiFi and or Bluetooth BLE. In an Exemplary embodiment the ERC node can be recharged wirelessly, although in a preferred embodiment the ERC node will have a connector port to hookup a recharging cable that can be plugged to the wall. In some exemplary embodiments the ERC node may also have a USB port or

Ethernet cable connection slot so that it can be updated or directly connected to a wired modem.

[0061] In exemplary embodiments the bi-ventricular pacing network shown in Fig. 4 will be capable of demand pacing and/or rate-responsive pacing. When in demand mode  
5 the RWP nodes will monitor the patient's heart rhythm and send electrical pulses if heart rates drops below a predetermined threshold. When in rate-responsive mode the RWP nodes will speed up or slow down your heart rate by sending pacing pulses depending on how active the patient is. In exemplary embodiments of rate-responsive pacing, the elements of the network will monitor other variables of your activity level through sensors in the RWP  
10 nodes and RS controller. These additional sensor units will monitor breathing through motion detectors or accelerometer, blood temperature through sensors in the RWP nodes, and other factors independently or as a group, that drive pacing algorithms. Such algorithms will work in a closed loop within the intra-body network and should not require physician input during real time implementation.

15 [0062] In another preferred embodiment of UsWB enabled pacing/stimulation networks, ultrasonic energy transfer and communication technologies can be used to reduce complications associated with wired pacing leads (infection, lead failure, pain, etc), reduce battery exchange rates, and hospital visits through remote monitoring in patients who need Neuromodulation/neurostimulation therapies. As shown in Fig.6, many different  
20 pathologies may be treated using neurostimulation or neuromodulation both in the central and peripheral nervous systems. In a preferred embodiment a network of wireless leads nodes, controller node, and external network energy transfer/gateway node, can be used to treat tremors in the Parkinson's disease population through deep brain stimulation (DBS). Similar to the bi-ventricular pacing network the DBS wireless network shown in Fig 7.  
25 consists of three main types of components/nodes (1) reprogrammable stimulation nodes (RSN) 700, (2) rechargeable system (RS) control node 701, and (3) external recharging and communications (ERC) node 702. The ERC node/patch and the RS control node have the same architecture as that described above for the bi-ventricular pacing network, with basic differences in the energy storage/transfer capacity for these two nodes. For the DBS  
30 network, the RS control node is implanted in subcutaneous pockets in either the chest of the patient, the back near the neck between the shoulder-blades or subcutaneously in the head. ERC node for this DBS network is a wearable that is in contact with the skin as required.

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During its function it will be located externally on the skin just above the RS control pocket. The ERC node is removable and in preferred embodiments will be attached to the skin using a glued patch. The contact area between the ERC node casing and the skin has ultrasonic coupling material.

5     **[0063]**         As shown in Fig 8. the components of the RSN nodes are similar to those of the generic functional node described in Fig. 3 with the addition of two functional units, an electrical sensor unit 800 and stimulation unit 801 for multi-contact stimulation. The RSN nodes have reprogrammable electronic hardware that can be easily adapted to unilaterally or bilaterally stimulate the subthalamic nucleus (STN) and/or other structures. The nodes  
10     are anchored in the brain and use one or more conductive (metallic) electrode ring contact points. In a preferred embodiment 4 to 8 contact electrode rings are used per RSN node. In a preferred embodiment these ring are made of a platinum Iridium alloy. The RNS node is recharged using ultrasonic waves and therefore include the EMU 802 with harvesting capabilities. RNS nodes 700 have reprogrammable electronic hardware that can be easily  
15     adapted to deep brain stimulation or other types of neurostimulation. The RNS nodes are able to communicate with each other to provide bilateral DBS while in parallel storing energy for continued stimulation for several hours using a capacitor 803. In some exemplary embodiments the RNS node will not need long term energy storage (capacitor or battery) as it may use directly the energy being transmitted to it with just transient energy buffering. In  
20     a preferred embodiment, energy long-term storage or transient energy buffering need a rectifying circuit 804 to convert AC voltage from the transducer to circuit usable DC voltage. The core unit 805 will include a FPGA , a MCU or an ASICs or any combination thereof. In a preferred embodiment a FPGA is used to control all functions within RNS node in combination with the MCU. The electric sensor 800 is used to track real time the electrical  
25     behavior of the implant site in order to respond to abnormal firing of neurons directly associated to tremors. The stimulation ring array 801 will emit electrical signals (square wave, sinusoidal wave, or other wave geometries) with frequencies between 3-250Hz (mode dependent) to mitigate tremors in the patient. The processing, communication, and rapid response capabilities of the RNS nodes also allow the system to sense from the electrode  
30     rings and then alter the stimulation output based upon that input – a so-called “closed-loop” system, which is the basis for a new technology paradigm in DBS. Although unidirectional ultrasonic transducers may be used; in preferred embodiments Semi-spherical piezo electric

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transducers and/or omni-directional piezoelectric transducers are used by the RNS nodes to reduce directional sensitivity when emitting or receiving the ultrasonic waves. The casing is constructed of electric insulating materials, in a preferred embodiment the casing will be constructed of polyurethane. Use of a single RNS node in the network allow for uni-lateral stimulation while two RNS nodes are used for bilateral stimulation. DBS sites in which the RNS transducers can be used include the subthalamic nucleus, globus pallidus internus, pedunculo pontine nucleus, and ventral intermediate nucleus of the thalamus among others.

**[0064]** In an exemplary embodiment of wireless UsWB treatment networks, elements from the bi-ventricular cardiac pacing network and the DBS network can be combined to help patients with heart failure (HF). Recent declines in mortality of HF patients have been attributed to the use of cardiac resynchronization therapy (CRT). Studies have also shown that remote monitoring of cardiac implantable electronic devices improves HF patient survival and is also associated with reductions in hospitalization and health care costs. CRT combined with inotropes has been shown to improve heart function leading to reduced mortality. Neurostimulation of the sympathetic and parasympathetic nerves can control stroke volume (sympathetic to increase, parasympathetic to decrease contraction), thus provide similar mechanistic results as the use of inotropes. Therefore, clinical evidence suggests that an intelligent CRT device that can be monitored and reprogramed remotely, and that can be combined with neuromodulation to improve heart function would have a profound impact on treatment of HF patients.

**[0065]** A modular neuromodulation/CRT network with pressure monitoring capabilities will not only improve patient outcomes but also reduce hospitalization rates and healthcare economics. The primary elements of the network for treatment of HF in patients through pacing/neuromodulation, as illustrated in Fig. 9, are: (i) Reprogrammable cardiac wireless pacing (RCWP) node 900; (ii) reprogrammable neuro wireless pacing (RNWP) node 901; (iii) vascular pressure monitoring (VPM) node; (iv) rechargeable system (RS) control node; and (v) external recharging and communication (ERC) node. All the elements in this network communicate through the Ultrasonic WideBand (UsWB) technology; and are recharged using ultrasonic energy transmission (excluding recharging of the ERC node).

**[0066]** The ERC node and the RS control node have the same architecture as that described above for the bi-ventricular pacing network and DBS network, with basic differences in the energy storage and transfer capacity of these two nodes. For the

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neuromodulation/CRT network, the RS controller is implanted in subcutaneous pockets in either the chest of the patient. In an exemplary embodiment, a second RS controller may be required in the network if the distance between the RCWP and RNWP is too long and requires a network bridge. Since the RS control node in this network is required to communicate with the RCWP nodes, the RNWP nodes, and the ERC patch, several ultrasonic transducers are required. These transducers may be unidirectional, multidirectional or omnidirectional as required by implant location geometry. ERC node/patch for this DBS network is a wearable which is in contact with the skin that during its function will be located externally on the skin just above the RS control pocket. The ERC patch is removable and in preferred embodiments is attached to the skin using a glued patch. The contact area between the ERC node casing and the skin has ultrasonic coupling material.

**[0067]** As shown in Fig. 10A. Reprogrammable wireless pacing (RCWP) nodes architecture is similar to those of the generic functional node described in Fig. 3 with and additional electric sensing and pacing functional units 1000. The RCWP nodes are recharged using ultrasonic waves and therefore include the EMU 1001 with harvesting capabilities. Reprogrammable wireless pacing RCWP nodes 900 have reprogrammable electronic hardware and are anchored to the myocardium with a conductive metallic coil 905 (titanium, Stainless Steel, Other conductive alloys) or any other conductive anchor (hooks, barbs, arms), and are controlled using UsWB. The RCPWs are able to communicate with each other to provide CRT while in parallel storing energy for continued pacing for several hours or days using a single capacitor or capacitor bank. In a preferred embodiment, even in absence of the ultrasonic link to the RS control node, a patient is given enough time to reach a hospital (safety feature). In a preferred embodiment, a capacitor energy storing bank (2 or more capacitors) and rectifying circuit are used to have redundancy in a zero failure environment. The core unit can include a FPGA 1002, a MCU 1003 or an ASICs or any combination thereof. In a preferred embodiment a FPGA is used to control all functions within RCPW node in combination with the MCU. The electric sensor 1000 is used to track real time the electrical behavior (EKG) of the implant site in order to respond to changes in the rhythm of the heart. These responses from the RWP to changes in the rhythm of the heart can occur in a closed loop with its own core unit, or in a closed loop combination with data provide by the VPM node or any of the other network elements. Pacing responses can

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also be re-programmed by a clinician on site or remotely using the ERC node 903. In a preferred embodiment the pacing electronics will be encased within a Polyether ether ketone (PEEK) casing and wrapped with medical-grade porous Dacron cloth to promote rapid tissue in-growth reducing thrombogenic risk. In exemplary embodiments the casing can be constructed of other polymers or metals, and may include a non-thrombogenic surface.

**[0068]** As shown in Fig. 10b, the vascular pressure monitor (VPM) node is a discrete implant in the neuromodulation/CRT network. The core unit for the VPM node may include a FPGA 1002, and/or MCU and/or ASICs. In a preferred embodiment the core unit only includes a FPGA 1002 in order to reduce implant size. The VPM node is recharged using ultrasonic waves and therefore include the EMU 1001. The ultrasonic interface of the IoMT platform, together with the energy management unit (Energy harvesting unit and capacitor-based energy storage) allows for wireless node function. In a preferred embodiment only transient energy storage (small capacitor or energy buffer) is required. Ultrasonic powering and communication capabilities are connected to a pressure sensor, in a preferred embodiment a MEMs pressure sensor is used. The VPN node uses a polymeric or resin casing to isolate the electronics from contacting blood. In a preferred embodiment, non-thrombogenic surfaces are used on the external faces of the casing. In an exemplary embodiment a window of elastomeric, linear elastic and or thinned out polymer is used to transfer the pressure load from the fluid to the MEMs sensor. Many exemplary embodiments can use, hooks, rods, suture, coils, arms, cylindrical stents among other as anchoring elements. In a preferred embodiment, a self-expanding Nitinol anchor wire is used to attach the VPN node to the pulmonary artery 906. The VPN node will be deliver to its implant site using catheter based endovascular methods.

**[0069]** The components of the RNWP nodes are similar to those of the generic functional node described in Fig. 3 with the addition of two functional units, an electrical sensor unit and stimulation unit for single contact and/or multi-contact stimulation. The RNWP nodes have reprogrammable electronic hardware that can be easily adapted for unilateral or bilateral (multipoint) stimulation of sympathetic and parasympathetic nerves at the carotid level. The nodes are anchored to the carotid nerves and use one or more conductive (metallic) electrode ring contact points located on the inner surface of the anchoring collar 907. In a preferred embodiment these rings are made of a platinum Iridium alloy. The RNWP nodes are recharged using ultrasonic waves and therefore include the

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energy management unit with harvesting capabilities. The RNWP nodes are able to communicate with each other to provide bilateral carotid nerve stimulation while in parallel storing energy for continued stimulation for several hours/days using a capacitor or capacitor bank. In a preferred embodiment energy storage elements need a rectifying circuit

5 804 to convert AC voltage from the transducer to circuit usable DC voltage. The core unit will include a FPGA a MCU or an ASICs or any combination thereof. In a preferred embodiment a FPGA is used to control all functions within RNWP nodes in combination with the MCU. The electric sensor is used to track real time the electrical behavior of the implant site in order to stimulate at different frequencies and times the parasympathetic and

10 sympathetic nerves to increase or decrease heart contractility/stroke volume. The stimulation ring array will emit electrical signals (square wave, sinusoidal wave, or other wave geometries) to change contractility of the heart/stroke volume. The processing, communication, and rapid response capabilities of the RNWP nodes also allow the system to sense from the electrode rings and then alter the stimulation output based upon that input

15 – a so-called “closed-loop” system. Although unidirectional transducers may be used, in preferred embodiments multidirectional transducers, semi-spherical piezo electric transducers and/or omni-directional piezoelectric transducers are used by the RNWP nodes to reduce directional sensitivity. The casing is constructed of electric insulating materials, in a preferred embodiment the casing will be constructed of a polymer or resin.

20 **[0070]** The RS control node will coordinate CRT with neuromodulation to ensure synchronized changes in heart rate and contraction. Interaction with the VPM node will allow to improve therapy according to changes in hemodynamics. Use of the ERC node to send pacing, neuromodulation, and vascular pressure data remotely will allow clinicians to closely monitor patients reducing the need on in-hospital visits.

25 **[0071]** Figs. 11A-B show a system that uses ultrasonic energy and data transfer to control and recharge a cardiac assist device 1100. In such a system, an external wearable control node (External controller 1130) is wired and connected to an external energy storage and or energy source node (external batteries 1140) and to recharging and communication node (data and energy transfer portal 1120). Such elements are used to transfer data and

30 energy into the body wirelessly using ultrasonic waves travelling transcutaneous through the portal 1120. The energy and data in the body can be used to control, recharge, and drive a cardiac assist device 1100 which is normally used by heart failure patients. An implantable

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controller node 1110 with energy storage can be used to autonomously drive and control the cardiac assist device 1100 in the absence of a link to the extracorporeal elements. To achieve the prescribed function of the system described in Figs. 11A-B, the system converts Direct Current (DC) electric energy from the external batteries to Alternating Current (AC) electric energy which drives the ultrasonic transducers, which is then converted to ultrasonic energy (sound waves) that travels through the tissue and then is converted again to AC electric energy by the implanted ultrasonic transducers. This AC electric energy is then converted to DC energy to power the implantable controller 1110 and to be stored in implantable batteries, and this energy is also converted to multiphasic AC (also known as multi-phase AC) electric energy to drive the motor of the cardiac assist device 1100 pump. In some embodiments the cardiac assist device 1100 pump is driven by DC energy, thus, eliminating the need to convert the energy to multiphasic AC energy. Energy converter elements may include but are not limited to: ultrasonic transducers, piezo electric transducers, capacitive transducers, digital to analogue converters, analogue to digital converters, Rectifiers, multipliers, mixers, inverters, oscillators, MCUs, FPGAs, smart MCUs, and Complex Programmable Logic Devices (CPLD) among others.

**[0072]** In embodiments of the system with wireless ultrasonic energy and data transmission to control and recharge a cardiac assist device, data is transmitted wirelessly using a pulsed ultrasonic wave, while energy is transmitted using a continuous ultrasonic wave. In some embodiments, both data and energy may be transmitted wirelessly using continuous ultrasonic waves. In further embodiments both wireless data and energy may be transmitted using pulsed ultrasonic waves. Both continuous or pulsed waves may have any shape of a sound wave including but not limited to sinusoidal, triangular, trapezoidal, square, longitudinal, transverse, non-uniform in frequency and or amplitude, and polynomial.

**[0073]** In the embodiment shown in Fig. 11A, ultrasonic energy and data transmission are used to control and recharge a cardiac assist device 1100 through a wireless ultrasonic link. In the illustrated example, the assist device is a left ventricular assist device, although other embodiments may include systems for right ventricular assist devices, intracardiac assist devices, intra-vascular assist devices, counter-pulsation devices and/or a combination thereof. An implantable controller 1110 is used to control the function of the pump. The implantable controller 1110 can be held within its own casing, although in some

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modifications the controller may be held in the same casing of the cardiac assist pump. In some embodiments, implantable batteries 1240, capacitors or other energy storage elements are held within the implantable controller unit while in other embodiments the energy storage elements may be held within their own unit casing. For implantable energy storage units, multiple batteries or battery cells are used so that some units are used actively while others are used as backup in case of failure or discharge. In the depicted example, the implantable controller 1110 is connected to the transcutaneous energy and data transfer port 1120, specifically to the implantable transducer array patch 1210. The implantable transducer array patch 1210 is connected through a wireless ultrasonic link for data and energy transfer to the external transducer array patch 1205. In some embodiments the data transcutaneous link may be achieved through non-ultrasonic waves, such as radio frequency waves. The transcutaneous portal, specifically the external transducer array patch 1205 is connected to an external controller 1130. In some embodiments the external controller can connect to the internet through wired (LAN) or wireless (WIFI, Bluetooth, other RF waves) means. The external controller may be connected to an external energy storage. In such embodiments, the external energy storage is a rechargeable battery pack 1140. In some instances, the non-implantable elements of the system may be carried by the patient using a harness 1150 or other wearable support structure.

**[0074]** In embodiments, the Energy and Data Transfer Portal 1120 uses two ultrasonic transducer patches (external 1205, implanted 1210) to transfer transcutaneous energy and data. The implanted patch 1210 is placed in a subcutaneous pocket in the chest. The external patch 1205 is placed in front of the internal patch, being separated by skin and other tissue layers. To maximize energy efficiency during external patch attachment 1205, the patient can use feedback information from the implanted patch 1210, including level of power received, and adjust positioning of the external patch to maximize energy transfer. In an embodiment the internal controller senses the amount of energy being transferred in real time and sends the information to the external elements of the system while the user tries to align the external patch 1205 to the internal patch 1210. In the example embodiment the external controller receives this information from the internal controller and provides this information to the user through visual, auditory, or tactile means so that the user can improve alignment. Although in the example embodiment a single pair of ultrasonic transducer patches (external 1205, implanted 1210) is used, in other embodiments multiple ultrasonic

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transducer patch pairs, external 1205 and implanted, may be used at different locations in the body to reduce the size of each implant site, and reduce the energy being transferred per site, to prevent heating of tissue and add redundancy.

[0075] In some embodiments the Energy and Data Transfer Portal 1120, the  
5 ultrasonic transducer patches includes a plurality of piezo electric ultrasonic transducers to transfer and receive energy and data via ultrasonic waves. The individual transducers 1220 resonate at frequencies designed for energy efficient transmission (0-1000 kHz). In some embodiments, transducers resonate at 700KHz. In some embodiments, piezoelectric transducers are used while in other embodiments capacitive transducers may be used in the  
10 energy and data transfer ports patches. Piezo electric transducer geometries used in the data and energy transfer portal can include 1120, spherical transducers, linear transducers, disc transducers, cylindrical transducers, and semi-spherical transducers, among others. Materials for the piezo-electric transducers may include both piezoelectric ceramics and single crystal materials.

15 [0076] In some embodiments all ultrasonic transducers are used to send/receive data and energy using time gated energy transfer and data transfer cycles. In an embodiment specific ultrasonic transducers from each patch are used to send/receive data while others are used to send/receive energy avoiding the need for time gating such operations. In some embodiments the internal and/or external controllers can select what transducers should be  
20 used for each transfer operation (energy, data), while in other embodiments the type of transfer operation for each individual transducer is fixed in the system. In such embodiments where the controllers can select the type of transfer operation each transducers does at a specific moment, this feature may be used to optimize function and energy consumption as required, or may be used to create redundancy for a specific operation in the event of discrete  
25 transducer failure. The transducers are connected to a rectifying circuit. Matching circuits and/or electronic switches are used to switch between receiving and transmitting phases of the data transfer cycles.

[0077] In an embodiment of the system for ultrasonic wireless control and recharging of a cardiac assist device shown in Fig. 11A are encased within biocompatible  
30 casings. Such casings may be designed to isolate physically and electrically their internal components from surrounding tissue. Materials for encasement of implantable elements

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include biocompatible polymers and metals, including but not limited to: PEEK, Polyurethane, silicone, PTFE, Titanium, Stainless Steel among, others.

[0078] In some embodiments, the Energy and Data Transfer (EDT) Portal 1120 patches (external 1205, implanted 1210) use ultrasonic transducers which are insulated  
5 electrically and disposed within a biocompatible matrix. In some embodiments the ultrasonic transducers are coated or encased by a material which provide electrical insulation. The encased or coated transducers are then disposed within a matrix which provides structural support and a defined geometry. In an embodiment, the material of the matrix can provide both electrical insulation and biocompatibility to the ultrasonic  
10 transducers by covering all their surfaces. In such preferred embodiments, no further insulation beyond that provided by the matrix may be required. In a further preferred embodiment, the material of the matrix is a polymer with preference to flexible or elastomeric polymers that can conform to the human body. Such embodiments may include matrixes made from biocompatible silicones or polyurethanes. In an embodiment for such  
15 matrix, the thickness of the layer covering the ultrasonic transducer surface is designed to minimize acoustic energy losses ( $1/4$  of ultrasonic wavelength used).

[0079] In some embodiments, the Implantable Controller (IC) 1110 will be encased within sealed implantable PEEK shell, and have an energy harvesting unit, processing and communication unit, and battery storage as shown in Fig 11B. The IC 1110 will be wired  
20 to the cardiac assist pump 1100 and EDT portal 1120. Charge harvesters (passive bridge rectifier, four diodes) attain/transform energy from the EDT portal 1120 and send it to a buffer capacitor to allow for a stable energy supply independent of spikes or valleys in the power transmission. Voltage switches controlled by the FPGA will coordinate energy transfer between the harvesters, pump, an/or rechargeable batteries. The cardiac assist  
25 device pump is directly powered by the buffer capacitor with energy from the harvesters when wirelessly tethered through the EDT portal 1120 to extracorporeal element of the system, or energy from the rechargeable multi-cell battery when untethered from the extracorporeal elements of the system. During tethered operation the harvesters will power the cardiac assist device pump 1100, as well as recharge the battery. The multi-cell battery  
30 can operate the pump 1100 (full support, 5L/min) for several hours in absence of the ultrasonic link. A multi cell battery, dual battery, or multiple batteries design will be used for redundancy. This setup allows to externally recharge the implants using a wearable

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harness or while tethered to external AC (rapid recharge). Data transmission transducers will be controlled by an IoMT chip using the FPGA and microcontroller to allow data from the pump (system status and function) to be relayed externally every few milliseconds, or immediately in an abnormal load or other condition detected by the IC 1110. High data rate communications from the external controller 1130 will also allow for better system management, remote monitoring, and link to electronic health records (EHR).

**[0080]** In an embodiment the External controller (EC) will have similar components as the IC, and will also include Bluetooth and WiFi connectivity. Similar to the IC controller, the EC will contain the algorithms and motor control board for pump function and also a IoMT chip to connect and control the energy transfer portal during tethered operation. The EC will also have a direct connection to external AC energy to enable both the internal and/or external batteries (EB) 1140 to be recharged while the patient is resting. The EB will be wired to the EC casing and both the EC and EB may be supported by a harness 1150. In an embodiment, the EC case will have basic controls, a simple display and LED and auditory signals for alarms.

**[0081]** In some embodiments of the system that use ultrasonic energy and data transfer to control and recharge a cardiac assist device 1100 shown in Figs. 11A-B, additional sensing nodes as previously described may be added to the systems network. Sensor nodes that may be added include: electrical, acoustic, EKG, pressure, temperature, voltage/current, flow, chemical, Gas, Ph+ sensor, photosensor, accelerometer, among others. In these embodiments a single or multiple sensor nodes may be added to the system. In an embodiment a pressure sensor can be added to the system to help with the control and or synchronization of cardiac assist device pump 1100 function; or to prevent abnormal function, damage or thrombosis with changes in cardiac pressure. In some embodiments an electric or EKG sensor may be added to help synchronize pump function to cardiac rhythm. Further, a chemical sensor may be added to assess blood damage due to pump 1100 function. Temperature sensors and accelerometer sensing nodes may also be added to assess cardiac pump function and/or mechanical integrity.

**[0082]** In some embodiments of the system that use ultrasonic energy and data transfer to control and recharge a cardiac assist device 1100 shown in Fig. 11, additional actuation functional units may be added (mechanical/artificial limbs/prosthesis, electro

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stimulation/pacing, drug delivery/pumps). The additional functional units will help enhance patient treatment.

[0083] It is to be understood that the above-described devices and methods for treatment of patients using ultrasonic wireless networks of implantable and non-implantable devices may include additional or alternative steps and aspects, based on the foregoing description relating to the various nodes/devices and tools described herein. Accordingly, as a result of the structure and functionality of the above-described networks, devices/nodes and tools, one skilled in the art would appreciate the different methods in which they may be utilized.

10 [0084] Many modifications and other embodiments of the present invention will come to mind to one skilled in the art to which the invention pertains upon having the benefit of the teachings presented herein through the foregoing descriptions and the associated drawings. Therefore, it is to be understood that the present invention is not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation.

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What is claimed is:

1. A system configured to wirelessly control and wirelessly provide power to a cardiac assist device, the system comprising:
  - an implantable cardiac assist pump; and
  - an extracorporeal energy source;wherein energy is transferred from the extracorporeal energy source to the implantable cardiac assist pump using ultrasonic waves for at least a portion of the energy transfer path.
2. The system of claim 1, wherein the at least the portion of the energy transfer path is configured to enable wireless transcutaneous energy transfer between the extracorporeal energy source and the implantable cardiac assist pump.
3. The system of claim 2, wherein the ultrasonic waves are emitted by piezoelectric transducers.
4. The system of claim 3, wherein data is transferred using pulsed ultrasonic waves.
5. The system of claim 4, wherein a single bit of data is encoded in multiple ultrasonic pulses.
6. The system of claim 1, wherein the ultrasonic waves are also used for data transfer between the implantable cardiac assist pump and the extracorporeal energy source.
7. The system of claim 6, wherein data is encoded in a frequency domain.
8. The system of claim 1, wherein the cardiac assist device comprises at least one of the following:
  - a. A left ventricular assist device;
  - b. A right ventricular assist device;
  - c. A intra-cardiac assist device;
  - d. A intravascular assist device; or
  - e. A counter-pulsation device.

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9. The system of claim 1, further comprising an implantable controller and implantable energy storage allowing for function of the cardiac assist pump untethered from extracorporeal system elements.
10. The system of claim 1, further comprising a pump controller configured to use data from at least one of the following wireless implantable sensors:
  - a. Pressure sensor;
  - b. EKG sensor;
  - c. Temperature sensor; or
  - d. Chemical sensor.
11. A system to power a medical device, the system comprising:
  - an extracorporeal element; and
  - a converter;wherein direct current electric energy from the extracorporeal element is converted to alternating current electric energy, acoustic energy, and multiphasic alternating energy by the converter, so as to wirelessly and transcutaneous power an implanted device.
12. The system of claim 11, wherein the implanted device is a cardiac assist device.
13. The system of claim 11, wherein the extracorporeal element is a battery pack.
14. The system of claim 11, wherein the converter comprises one or more ultrasonic transducers that are used to convert alternating current energy to acoustic energy.
15. The system of claim 14, wherein the ultrasonic transducers are linear transducers.
16. The system of claim 14, wherein the ultrasonic transducers are made from ceramic piezoelectric elements.
17. The system of claim 14, wherein the ultrasonic transducers are embedded in a flexible polymeric matrix.
18. The system of claim 11, wherein the ultrasonic waves are also used to wirelessly transfer data from the extracorporeal element to the implanted device.

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19. The system of claim 18, wherein the data transfer is bi-directional.
20. The system of claim 18, wherein pulsed ultrasonic waves are used for communication.

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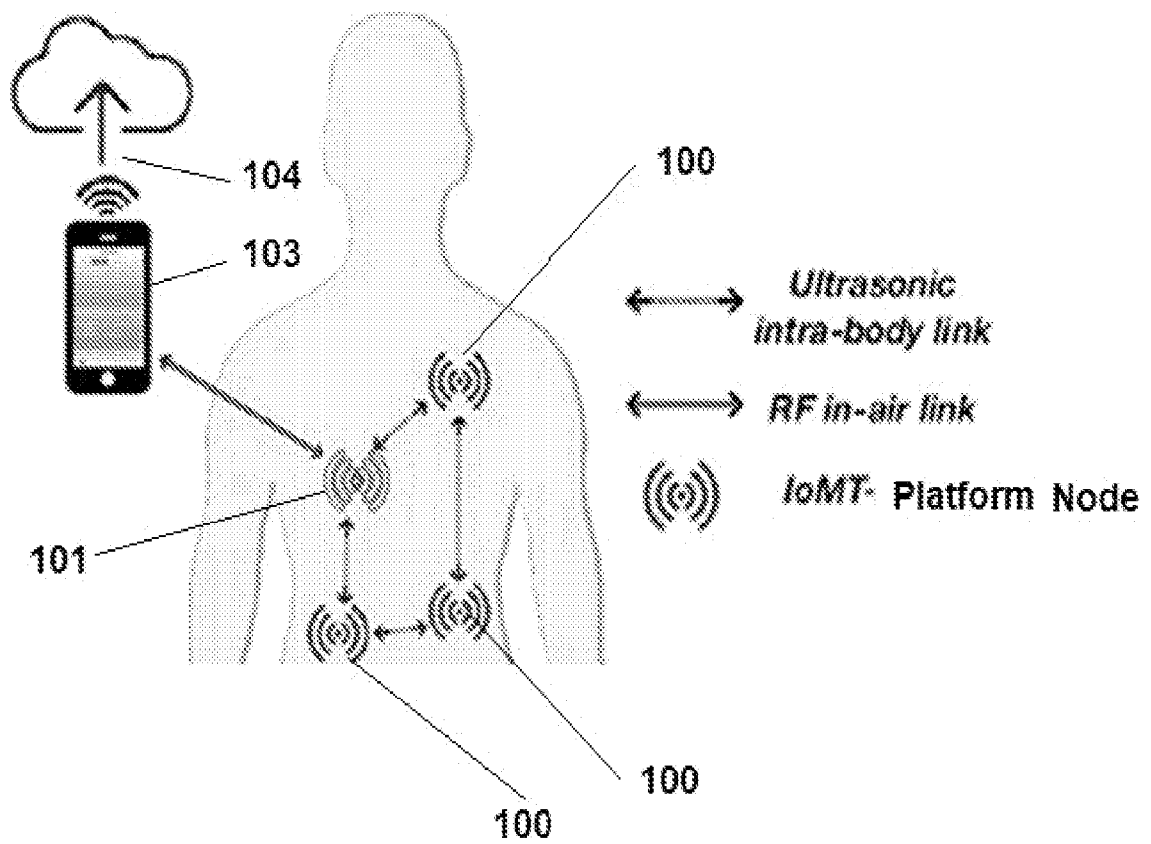


FIG. 1

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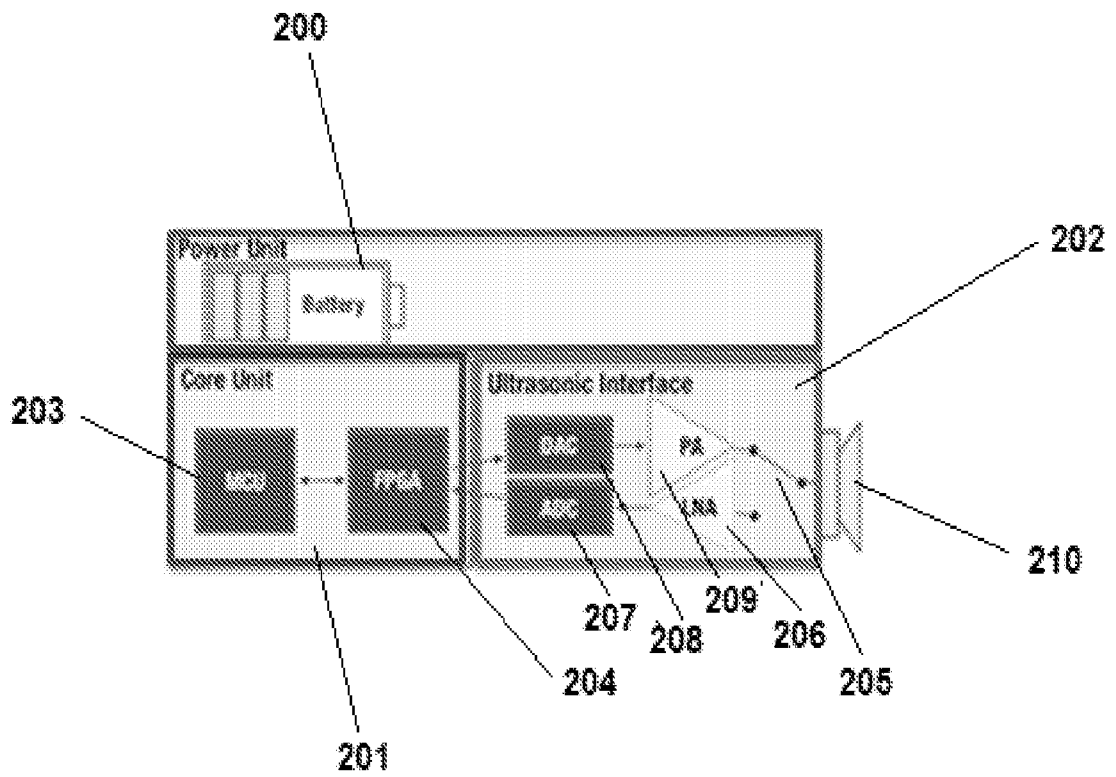


FIG. 2

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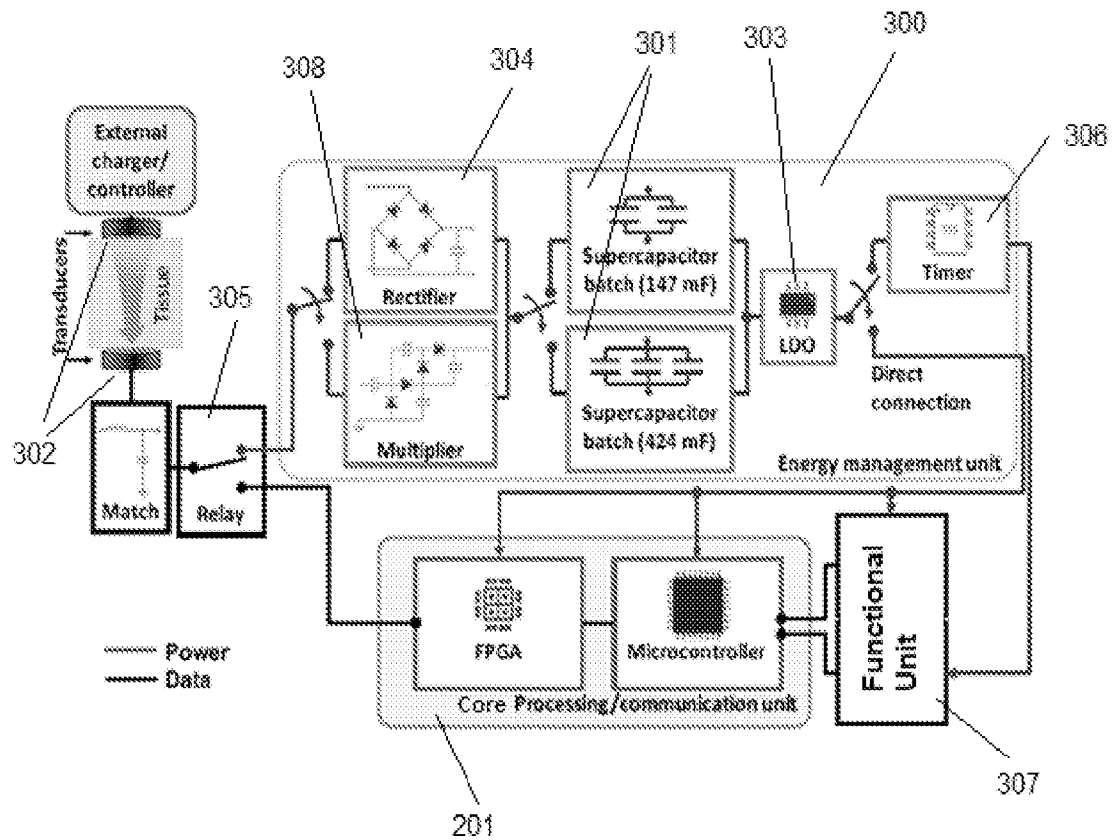
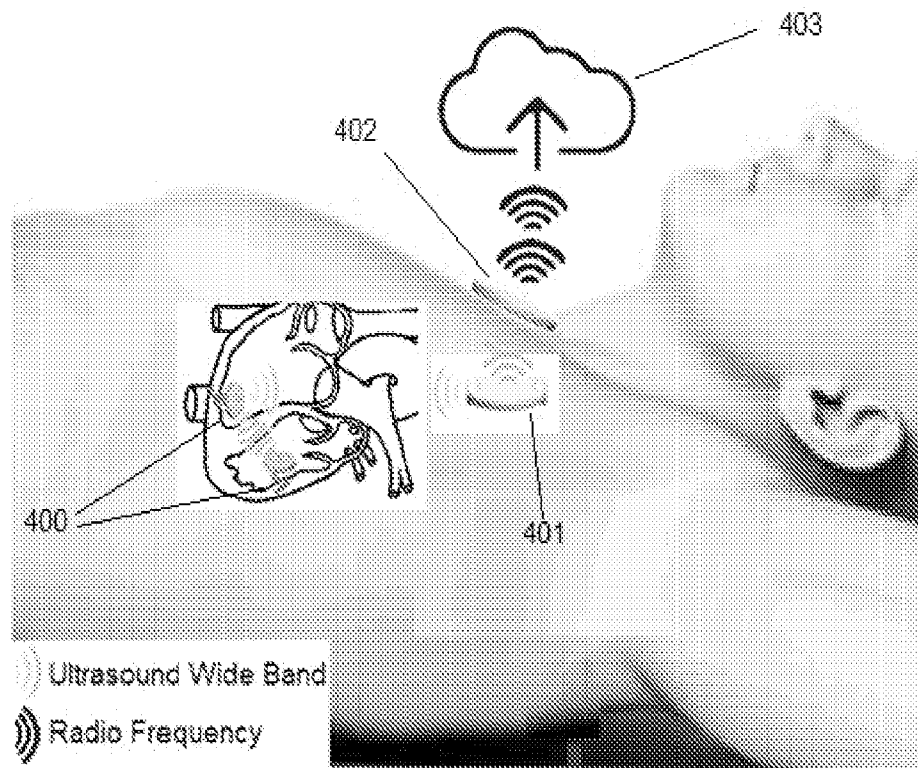


Fig 3.

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**Fig 4.**

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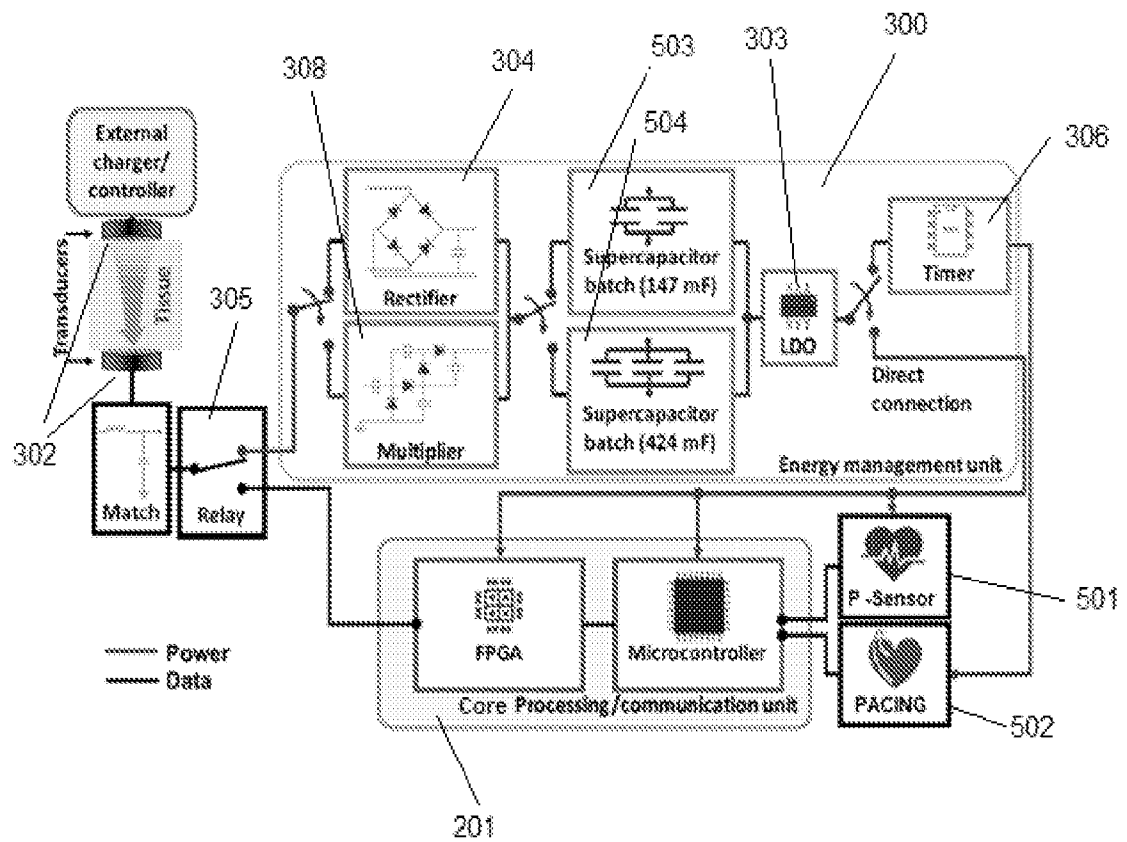
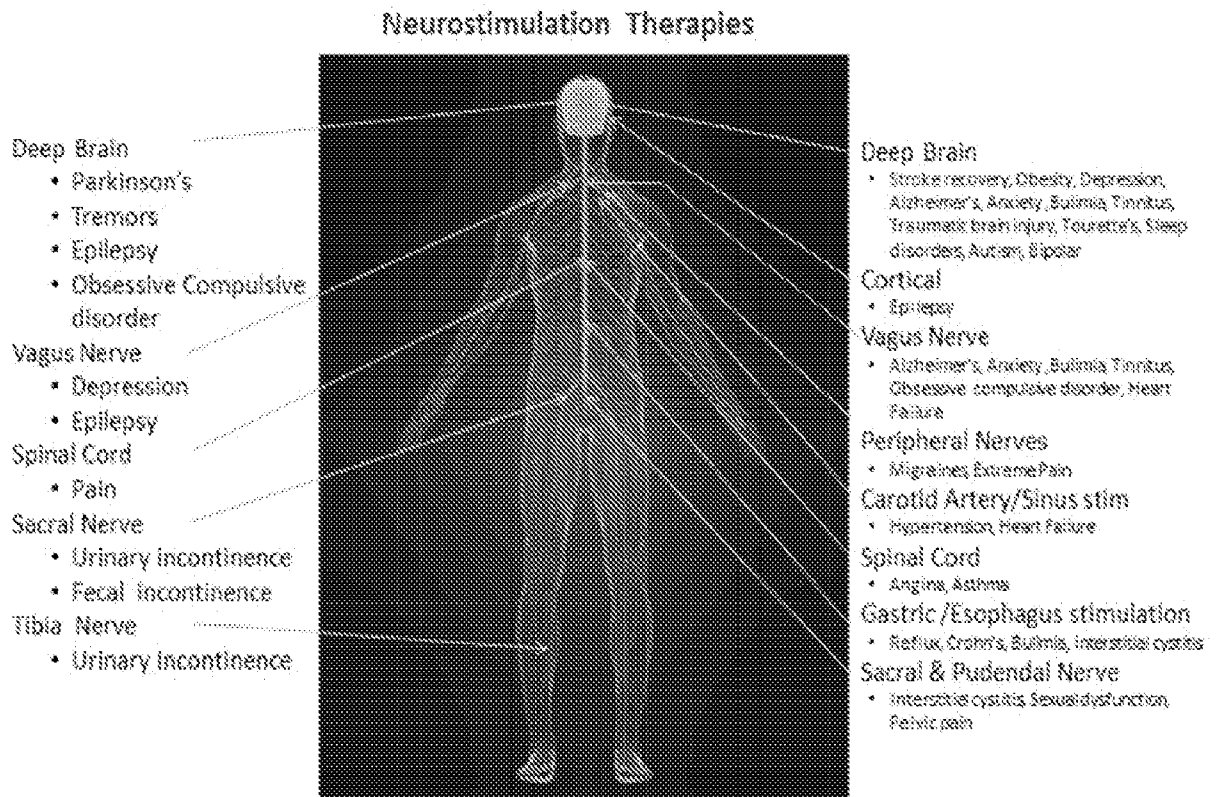
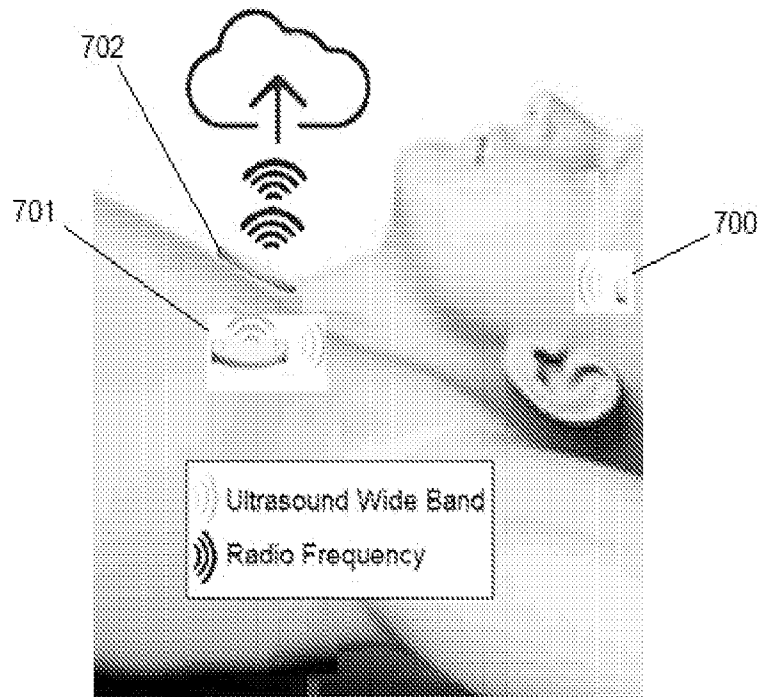


Fig 5.

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**Fig. 6**

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**Fig 7.**

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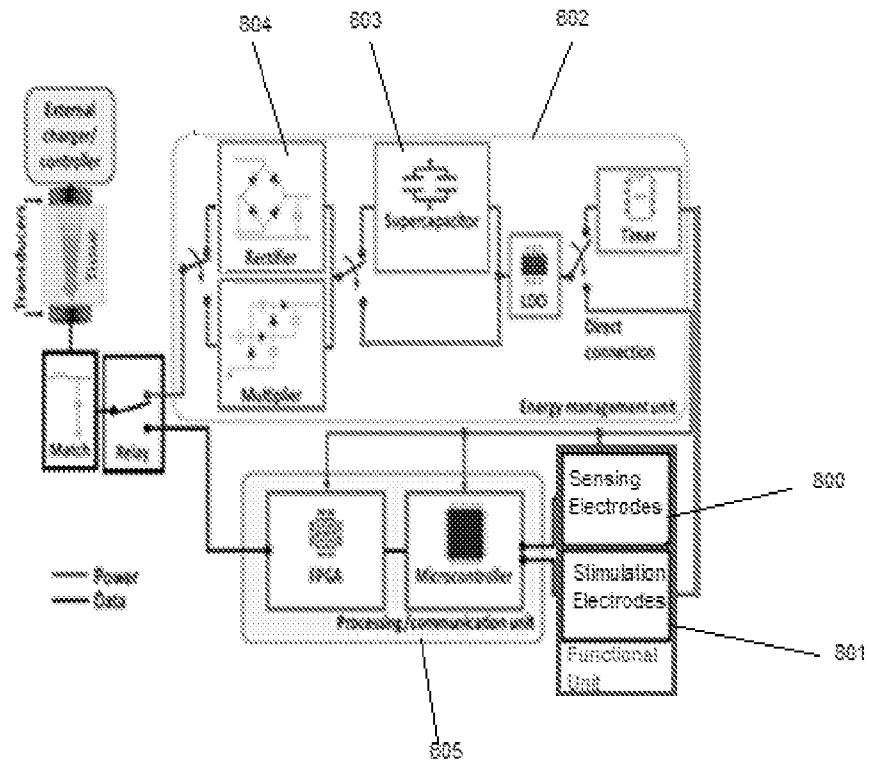


Fig. 8

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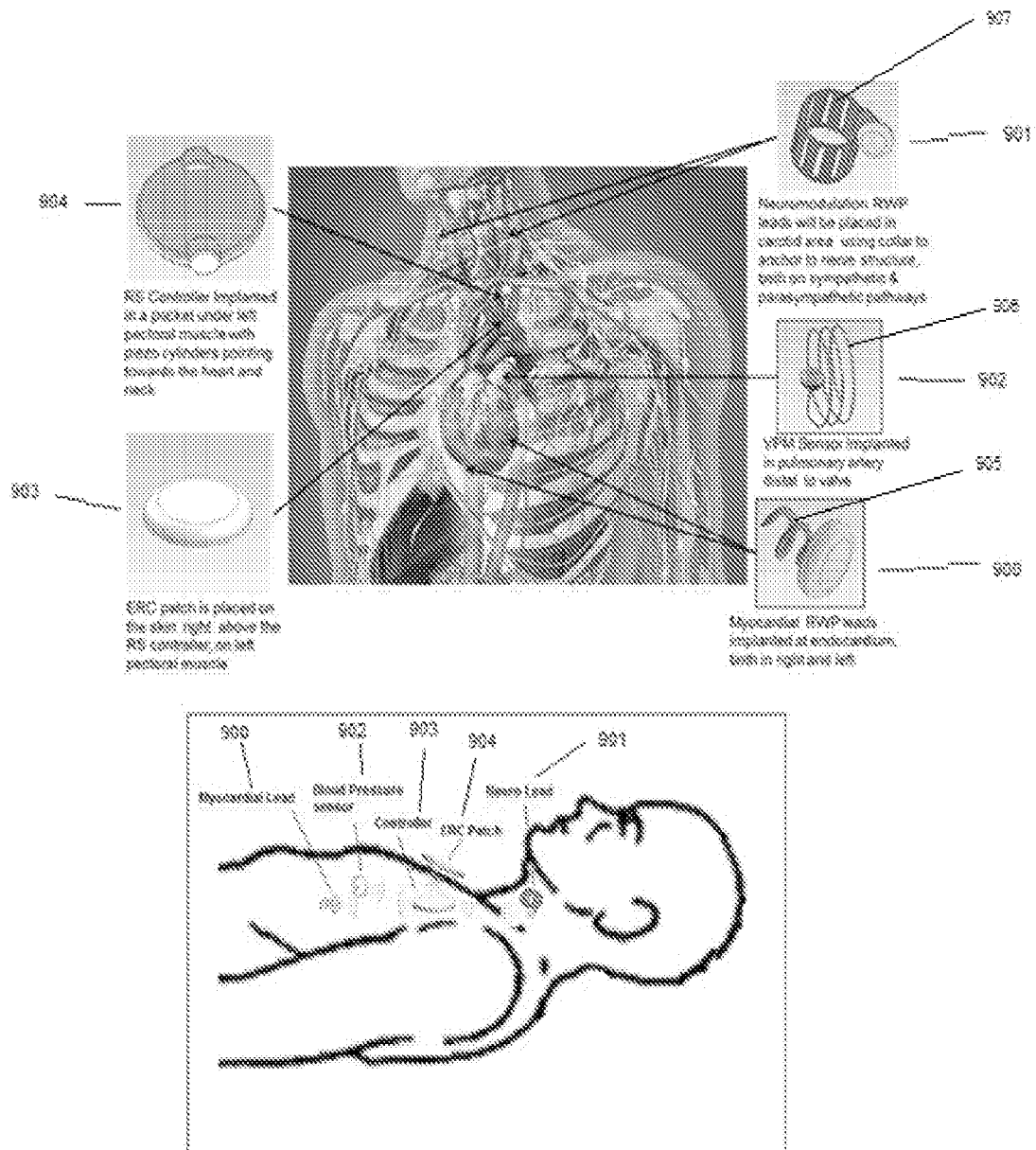


Fig. 9

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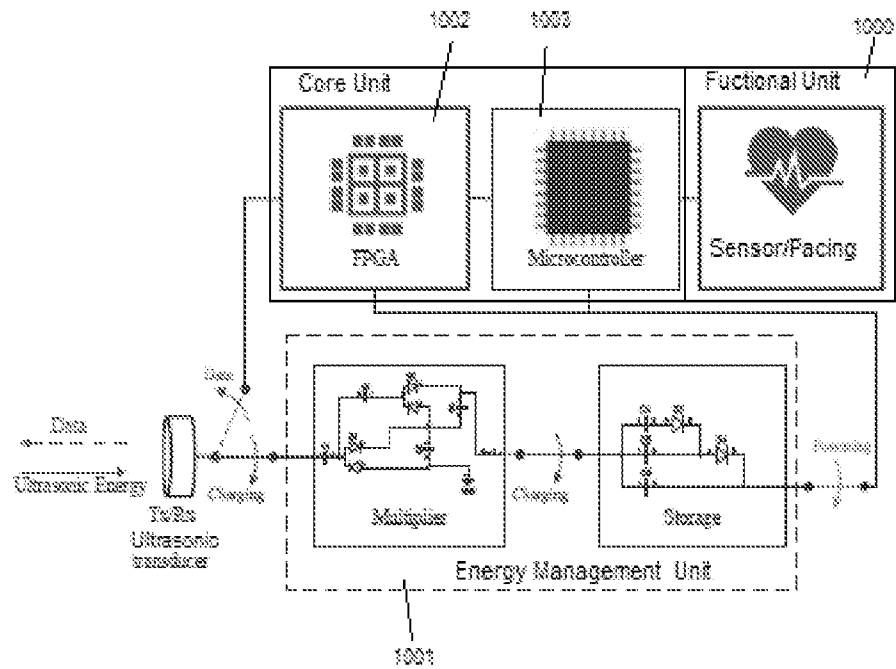


Fig. 10a

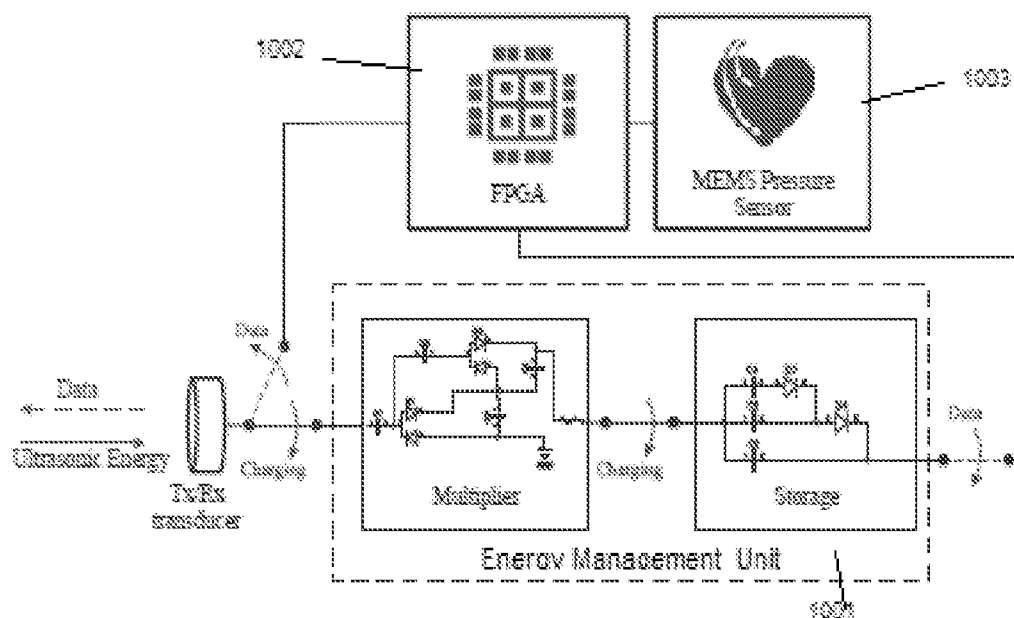


Fig. 10b

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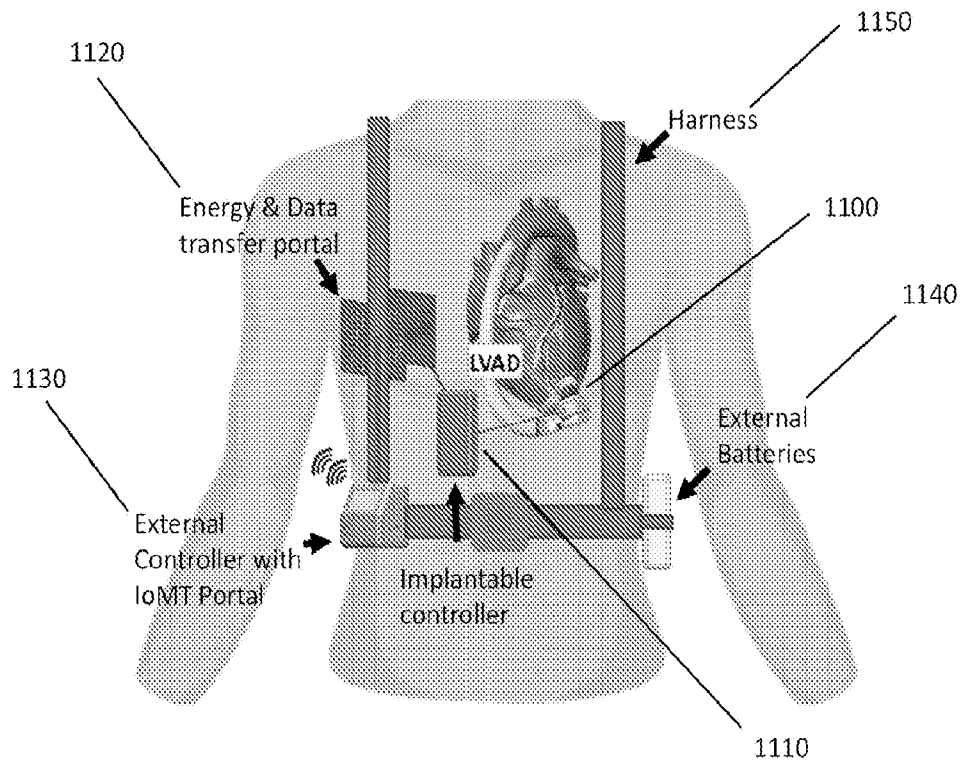


Fig. 11A

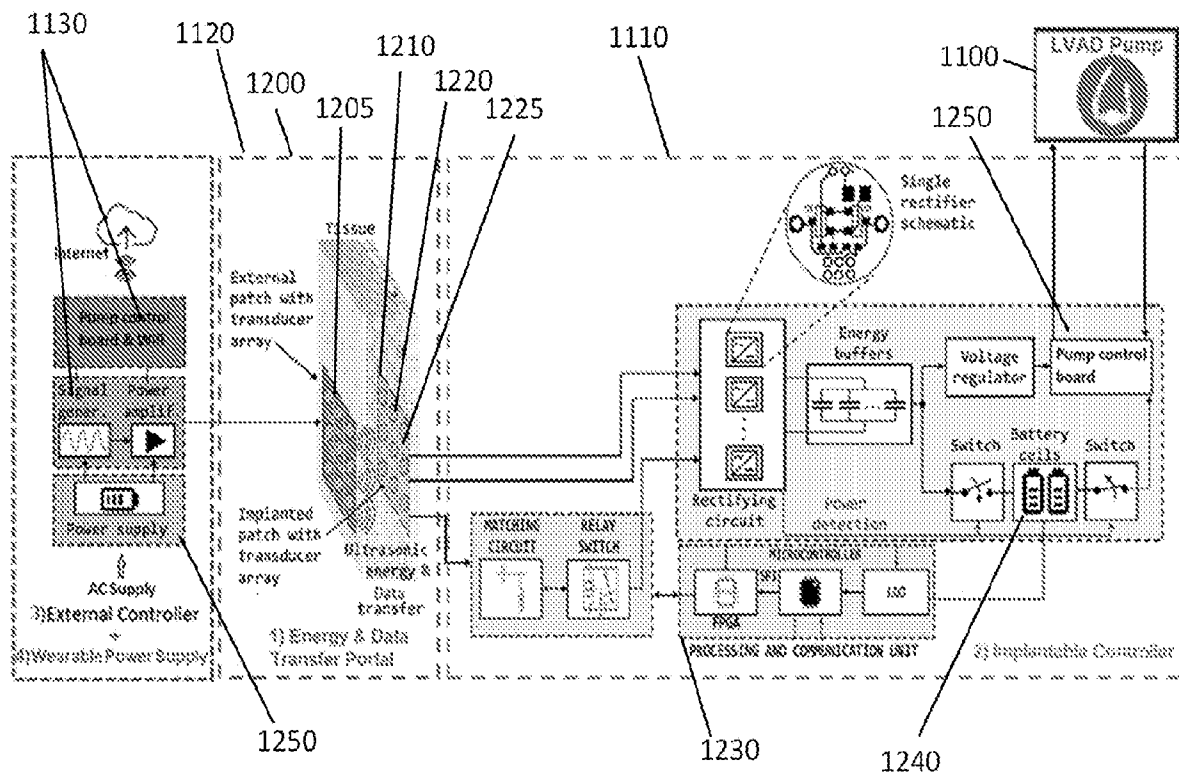


Fig. 11B

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 20/52620

## A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61M 1/10, A61M 1/12, H04L 29/04, H04R 1/22 (2021.01)

CPC - A61M 60/40, H02J 50/15, G01S 15/104, A61M 60/422, A61M 2205/8237, A61M 60/00, A61M 60/50, A61M 60/122, A61M 60/205, A61M 60/857, A61M 60/871, A61N 1/3787

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category*   | Citation of document, with indication, where appropriate, of the relevant passages                                                   | Relevant to claim No. |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| X<br>—<br>Y | US 2011/0201870 A1 (FORSELL) 18 August 2011 (18.08.2011), para [0069], [0081], [0121]-[0130], [0150]                                 | 1, 2, 8-10<br>3-7     |
| Y           | US 2013/0178915 A1 (PIEZO ENERGY TECHNOLOGIES, LLC) 11 July 2013 (11.07.2013), abstract; para [0010], [0011], [0028], [0029], [0070] | 3-7                   |
| Y           | US 2015/0063072 A1 (DENG et al.) 05 March 2015 (05.03.2015), para [0005], [0018], [0054], [0072]                                     | 4, 5                  |

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

## \* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"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

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;" document member of the same patent family

Date of the actual completion of the international search

11 January 2021

Date of mailing of the international search report

04 FEB 2021

Name and mailing address of the ISA/US

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P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Lee Young

Telephone No. PCT Helpdesk: 571-272-4300

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 20/52620

## 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:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-10 drawn to a system configured to wirelessly control and wirelessly provide power to a cardiac assist device.

Group II: Claims 11-20, drawn to a system to power a medical device.

—see extra sheet

1. ☐ 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 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.:  
1-10

### 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.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 20/52620

Continuation of Box No. III – Observations where unity of invention is lacking

The inventions listed in the above-mentioned groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

### Special Technical Features

Group I includes the special technical feature of energy is transferred from the extracorporeal energy source to the implantable cardiac assist pump using ultrasonic waves, not included in the other groups.

Group II includes the special technical feature of direct current electric energy from the extracorporeal element is converted to alternating current electric energy, acoustic energy, and multiphasic alternating energy, not included in the other groups.

### Common Technical Features:

The only technical features shared by Groups I and II that would otherwise unify the groups, are a medical device, an extracorporeal element and energy is transferred from the extracorporeal element to the medical device and ultrasonic/acoustic energy. However, these shared technical features do not represent a contribution over prior art, because the shared technical features are disclosed by US 8,974,366 B1 to Piezo Energy Technologies, LLC (hereinafter Piezo).

Piezo discloses a medical device, an extracorporeal element and energy is transferred from the extracorporeal element to the medical device and ultrasonic/acoustic energy (abstract; col 4, ln 24-29: present invention provides a new method and apparatus for powering an implanted device. Such as a heart-assist device, and more particularly to an ultrasound wireless Transcutaneous Energy Transfer (US-TET) source generating 40, 50 or 60 or more Watts of acoustic power to operate an implanted device 24/7).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13.