

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
30 August 2007 (30.08.2007)

PCT

(10) International Publication Number
WO 2007/098202 A2

(51) International Patent Classification:
A61N 1/05 (2006.01)

(21) International Application Number:
PCT/US2007/004514

(22) International Filing Date:
16 February 2007 (16.02.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/774,040 16 February 2006 (16.02.2006) US
60/774,041 16 February 2006 (16.02.2006) US
60/774,039 16 February 2006 (16.02.2006) US

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(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS,
JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS,
LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY,
MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS,
RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT,
RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA,
GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished
upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: AN RFID BASED APPARATUS, SYSTEM, AND METHOD FOR THERAPEUTIC TREATMENT OF A PATIENT

(57) Abstract: Provided is an implantable RFID-enabled micro-electronic neurostimulator system comprising (a) an internal sub-
system having (i) an array of electrodes, where at least one electrode pair contacts a nerve; (ii) a multiplexer; (iii) digital to analog
signal converter; and (iv) a RFID based control and stimulation chip; and (b) an external subsystem having (i) a controller; and (ii)
an RP interface.



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**AN RFID-BASED APPARATUS, SYSTEM, AND METHOD FOR
THERAPEUTIC TREATMENT OF A PATIENT
RELATED APPLICATIONS**

This application claims priority to U.S. Provisional Applications 60/774,039,
5 60/774,040, and 60/774,041 filed on February 16, 2006, which are expressly
incorporated herein by reference in their entirety.

FIELD OF THE INVENTION

The present invention relates to an apparatus, system, and method for
implantable therapeutic treatment of a patient.

10 **BACKGROUND OF THE INVENTION**

Acute and chronic conditions such as pain, arthritis, sleep apnea, seizure,
incontinence, and migraine are physiological conditions affecting millions of people
worldwide. For example, sleep apnea is described as an iterated failure to respire
properly during sleep. Those affected by sleep apnea stop breathing during sleep
15 numerous times during the night. There are two types of sleep apnea, generally
described in medical literature as central and obstructive sleep apnea. Central sleep
apnea is a failure of the nervous system to produce proper signals for excitation of the
muscles involved with respiration. Obstructive sleep apnea (OSA) is cause by physical
obstruction of the upper airway channel (UAW).

20 Current treatment options range from drug intervention, non-invasive
approaches, to more invasive surgical procedures. In many of these instances, patient
acceptance and therapy compliance is well below desired levels, rendering the current
solutions ineffective as a long term solution.

Implants are a promising alternative to these forms of treatment. For example,
25 pharyngeal dilation via hypoglossal nerve (XII) stimulation has been shown to be an

effective treatment method for OSA. The nerves are stimulated using an implanted electrode. In particular, the medial XII nerve branch (i.e., in. genioglossus), has demonstrated significant reductions in UAW airflow resistance (i.e., increased pharyngeal caliber). Stimulation of the vagus nerve is thought to affect some of its
5 connections to areas in the brain prone to seizure activity. Sacral nerve stimulation is an FDA-approved electronic stimulation therapy for reducing urge incontinence. Stimulation of peripheral nerves may help treat arthritis pain.

While electrical stimulation of nerves has been experimentally shown to remove ameliorate certain conditions, e.g., obstructions in the UAW, current implementation
10 methods typically require accurate detection of an condition (e.g., a muscular obstruction of an airway), selective stimulation of a muscle or nerve, and a coupling of the detection and stimulation components. Additionally, attempts at selective stimulation have to date required multiple implants with multiple power sources, and the scope of therapeutic efficacy has been limited. A need therefore exists for an
15 apparatus and method for programmable and/or selective neural stimulation of multiple implants or contact excitation combinations using a single controller power source.

SUMMARY OF THE INVENTION

The present invention relates to an apparatus, system, and method for selective and programmable implants for the therapeutic treatment of obstructive sleep apnea.

20 In one embodiment, an implantable RFID-enabled micro-electronic neurostimulator includes an implantable RFID-enabled micro-electronic neurostimulator system having an implant subsystem including one or more of (a) an array of electrodes, where at least one electrode pair contacts a nerve, (b) a multiplexer digital to analog signal converter, and (c) a RFID based control and stimulation chip.

The system also includes an external subsystem having one or more of a controller, an RF interface and an optional power source.

In certain embodiments, the present invention is suitable for the stimulation of certain nerves to treat conditions which may be ameliorated by stimulation of a nerve.

5 Such nerves and conditions include, but are not limited to multiple small peripheral nerves for treatment of arthritis pain; deep brain/cortical stimulation for treatment of one or more of essential tremor, Parkinson's disease, dystonia, depression, tinnitus, epilepsy, stroke pain, and obsessive compulsive disorder; sacral nerve stimulation for the treatment of incontinence, pelvic pain and sexual dysfunction; vagus nerve
10 stimulation for treatment of epilepsy and/or depression; peripheral nerve stimulation for treatment of chronic pain; spinal cord stimulation for treatment of one or more of chronic pain, angina pain, and peripheral vascular disease pain; cochlear nerve stimulation for treatment of profound deafness; pulmonary nerve stimulation for treatment of respiratory support; gastric nerve stimulation for treatment of one or more
15 of obesity, gastroparesis, and irritable bowel syndrome; and occipital nerve stimulation for treatment of headaches/migraine and/or traumatic brain injury.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are included to provide a further understanding of the invention and are incorporated in and constitute a part of this
20 specification, illustrate embodiments of the invention, and together with the description serve to explain the principles of the invention. In the drawings:

Fig. 1 shows an embodiment of an internal subsystem.

Fig. 2 shows an embodiment of an internal subsystem with the core subsystem and internal RF interface in a silicon package.

25 Fig. 3 shows a hypoglossal nerve an implant.

Fig. 4 shows multiple embodiments of neural interface electrode arrays.

Fig. 5 shows an embodiment of an internal subsystem implant.

Fig. 5A is a breakout view of Fig. 1.

Fig. 6A shows an embodiment of an internal subsystem with the neural
5 interface electrodes on the bottom layer of the implant.

Fig. 6B shows an embodiment of an internal subsystem with the neural interface
electrodes on the top and bottom layers of the implant.

Fig. 7 shows an embodiment of an external subsystem with a controller.

Fig. 8 shows two embodiments of the external controller.

10 Fig. 9 shows an embodiment of a controller and implant used to treat
incontinence.

Fig. 10 shows an embodiment of a controller and implant used to treat seizures.

Fig. 11 shows a controller and network of implants used to treat arthritis pain.

15 **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

Reference will now be made in detail to the preferred embodiments of the
present invention, examples of which are illustrated in the accompanying drawings.

One embodiment the present invention includes an external subsystem and an
internal subsystem. In certain embodiments, the external subsystem can include one or
20 more of (1) a controller, (2) an external RF interface, and (3) an optional power source.
The internal subsystem may include an implant. In certain embodiments, the implant
can include one or more of (1) a neural interface which can include an array of
electrodes where at least one electrode contacts a nerve, is placed in close proximity to
a nerve, or wraps around a nerve, (2) a core subsystem, and (3) an internal RF interface.
25 In some embodiments, the neural interface may further include a digital to analog
signal converter and a multiplexer. In some embodiments the core subsystem may

include a microprocessor. The microprocessor may have a micrologic CPU and memory to store protocols selective to a patient. The microprocessor may be part of an integrated silicon package. In still further embodiments, the internal RF interface includes one or more of a transponder, internal antenna, modulator, demodulator, clock, and rectifier. The transponder can be passive or active. In some embodiments, one or more of a controller, external RF interface, and optional power source are positioned on the skin of a user / patient, typically directly over or in close proximity to, an implant.

In certain embodiments, the external subsystem controller is in the form of an earpiece or patch including any one or more of a controller, external RF interface, and optional power source, e.g., a battery, AC to DC converter, or other power source known to those skilled in the art. Still further embodiments include incorporation of the external subsystem 200 into a watch-like device for, e.g., the treatment of arthritic pain, or in a belt. In certain embodiments, the external subsystem sends and receives control logic and power using an external RF interface. In such embodiments, the external subsystem can further include one or more of a crypto block, data storage, memory, recording unit, microprocessor, and data port. In some embodiments the microprocessor may have a micrologic CPU and memory to store protocols selective to a patient. The microprocessor may be part of an integrated silicon package.

The system of the present invention can be used to treat a number of conditions by stimulating nerves which are associated with treating a condition. Stimulation can be such that the stimulus is transmitted by a nerve, or stimulation can be such that nerve transmission in a nerve is blocked by nerve depolarization. Some non-limiting examples of treatment by nerve stimulation include multiple small peripheral nerves for treatment of arthritis pain; deep brain/cortical stimulation for treatment of one or more of essential tremor, Parkinson's disease, dystonia, depression, tinnitus, epilepsy, stroke

pain, and obsessive compulsive disorder; sacral nerve stimulation for the treatment of incontinence, pelvic pain and sexual dysfunction; vagus nerve stimulation for treatment of epilepsy and/or depression; peripheral nerve stimulation for treatment of chronic pain; spinal cord stimulation for treatment of one or more of chronic pain, angina pain, and peripheral vascular disease pain; cochlear nerve stimulation for treatment of profound deafness; pulmonary nerve stimulation for treatment of respiratory support; gastric nerve stimulation for treatment of one or more of obesity, gastroparesis, and irritable bowel syndrome; and occipital nerve stimulation for treatment of headaches/migraine and/or traumatic brain injury.

Each of the components of various embodiments of the claimed invention is described hereafter. In certain embodiments, the present invention is an open loop system. In other embodiments the present invention is a closed loop system. The components of the embodiments can be rearranged or combined with other embodiments without departing from the scope of the present invention.

The Internal Subsystem

In certain embodiments, the internal subsystem includes an implant, which includes one or more of (1) a core subsystem, (2) a neural interface, and (3) an internal RF interface. Certain embodiments of the implant components and component arrangements are described below.

Implant Components

The following paragraphs describe embodiments of the implant of the present invention, which includes one or more of a core subsystem, neural interface, and internal RF interface components.

The Core Subsystem

Fig. 1 shows an embodiment of the internal subsystem 100. In certain embodiments the internal subsystem 100 includes an implant 105 (non-limiting representative embodiments of implant 105 are shown in Figs. 3, 5, 5A, 6A, 6B, and 8-11) which may have a core subsystem 140. The middle portion of Fig. 1 shows a detailed view of an embodiment of the core subsystem 140. The core subsystem 140 may include one or more of a power module 144, microprocessor 141, crypto block 142, and input output buffer 143. In certain embodiments, the microprocessor 141 may have a micrologic CPU, and may have memory to store protocols selective to a patient. In the embodiment shown, the core subsystem includes a power module 144, a core subsystem microprocessor 141 for managing communication with an external RF interface 203, at least one I/O buffer 143 for storing inbound and outbound signal data, and a core subsystem crypto block 142. In some embodiments, the core subsystem microprocessor 141 communicates with the external RF interface 203 in full duplex. The core subsystem microprocessor 141 may generate signals for controlling stimulation delivered by the neural interface 160, and it may process signals received from the neural interface 160. In certain embodiments, the core subsystem microprocessor logic includes an anti-collision protocol for managing in-range multiple transponders and readers, a management protocol for reset, initialization, and tuning of the implant 105, and a protocol to facilitate the exchange of data with the neural interface 160. The core subsystem microprocessor 141 is programmable and may further include an attached non-volatile memory. The microprocessor 141 may be a single chip 145 or part of an integrated silicon package 170.

Fig. 2 shows an embodiment of an internal subsystem 100 with the core subsystem 140 and internal RF interface 150 in an integrated silicon package 170. For

size comparison, Fig. 2 shows the core subsystem 140, internal RF interface 150, and core subsystem microprocessor 141 next to the silicon package 170.

The Neural Interface

The right portion of Fig. 1 shows an embodiment of a neural interface 160. The neural interface 160 can include an array of electrodes 161 where at least one electrode 161 contacts a nerve. In one embodiment, the neural interface 160 includes an array of 10 to 16 electrodes 161. This arrangement is exemplary only however, and not limited to the quantity or arrangement shown. The core subsystem 140 connects to the neural interface 160, and controls neural interface stimulation. In the embodiment shown, the neural interface 160 is attached to the printed circuit board 130. In some embodiments, the neural interface 160 may further include a digital to analog signal converter 164 and a multiplexer 166. In certain embodiments the multiplexer 166 is included on the printed circuit board 130. In other embodiments, the multiplexer 166 is included on a thin layer film or flexible membrane around the surface of the chip.

In the embodiment shown, the neural interface 160 receives power from RF waves received by the implant 105. In one embodiment, the digital to analog signal converter 164 uses the RF waves to power one or more capacitors 165, which may be located in the converter 164. In certain embodiments, the capacitors 165 are arranged in an array on a microfilm. These capacitors 165 store charges, which are used to generate analog burst pulses for delivery by the neural interface 160. In embodiments including a multiplexer 166, the multiplexer 166 may be used to deliver power to multiple capacitors 165, and can be used to deliver power to multiple electrodes 161 in the neural interface 160. In still further embodiments, the multiplexer 166 is programmable.

In certain embodiments, the neural interface 160 is physically located on the opposite side of the printed circuit board 130 to which the core subsystem 140 is attached. In other embodiments, the one or more electrodes 161 are physically separated from the core subsystem 140 by the printed circuit board 130. Each electrode 5 161 connects to the core subsystem 140 through wires 133 (e.g., traced wires) on the printed circuit board 130. This layered approach to separating the core subsystem 140 from the electrodes 161 has significant benefits in the bio-compatible coating and manufacturing of the implant. By minimizing the area exposed to the HGN, the bio-compatible coating is only required in the area surrounding the exposed parts of the 10 electrodes 161.

In certain embodiments, the electrodes 161 may be manufactured with a biocompatible material coating. In other embodiments, the electrodes may include embedded platinum contacts spot-welded to a printed circuit board 130 on the implant 105. The electrodes 161 may be arrayed in a matrix, with the bottoms of the electrodes 15 161 exposed for contact to the HGN. Since the electrodes 161 attach to the top portion of the core subsystem 140 through leads on the printed circuit board, there is no need for wire-based leads attached to the contact points, allowing for miniaturization of the electrodes 161.

Fig. 3 shows a hypoglossal nerve implanted with a neural interface 160. In one 20 embodiment, exposed portions of the neural interface 160 deliver selective stimulation to fascicles of the HGN. Selective stimulation allows co-activation of both the lateral HGN branches, which innervate the hypoglossus (HG) and styloglossus (SG), and the medial branch. This selective stimulation of HG (tongue retraction and depression) and the SG (retraction and elevation of lateral aspect of tongue) results in an increased 25 maximum rate of airflow and mechanical stability of the upper airway (UAW).

Selective stimulation is a unique approach to nerve stimulation when implanted on the hypoglossal nerve (HGN). The neural interface 160 may also sense the neural activity of the nerve it interfaces with and may transmit that sensed activity to the core subsystem microprocessor 141.

5 Fig. 4 shows embodiments of neural interface electrode arrays. These embodiments are exemplary only, and the arrays are not limited to the quantity or arrangement of the electrodes shown in the figure. In one embodiment, at least one electrode 161 is in contact with a nerve. In certain embodiments, the electrodes 161 may be in the shape of a linear, regular, or irregular array. In certain embodiments, the electrode 161 array may be in a form suitable for wrapping around a nerve (e.g., a
10 helical shape or spring-like shape as shown in Fig. 3). The electrodes 161 may also be arranged in a planar form to help reshape the nerve and move the axons closer to the electrodes 161. This facilitates access to multiple nerve axons, which enables multiple modes of stimulation for enhanced UAW dilation and stability. With a planar form
15 factor, stimulation can also be delivered in two dimensions, enabling optimal excitation of the functional branches of the nerve. Excitation happens through bi-phasic electrical stimulation of individual electrodes 161.

The upper number of electrodes is determined by the space available for the implant, which varies by indication (e.g., arthritis). In one embodiment, the present
20 invention includes one or more electrodes in contact with a nerve. As shown in Fig. 3, in certain embodiments, the electrodes which may contact with a nerve (e.g., a hypoglossal nerve) or be placed in close proximity to a nerve, and may have any regular or irregular arrangement. In the embodiments shown in Figs. 4 and 6A/6B, the electrodes 161 are arranged in a matrix of pairs, with the pairs serving as anode and
25 cathode complementary elements 162/163. The matrix arrangement of electrodes 161

provides multiple nerve stimulating points, and has several advantages. The matrix arrangement allows a web of nerve fascicles of a nerve, e.g., the hypoglossal nerve to be accessed, enabling selective stimulation of particular areas of the nerve. Stimulation by the neural interface electrodes is controlled by the core subsystem microprocessor

5 141. This facilitates access to multiple nerve axons, which enables multiple modes of stimulation.

The Internal RF Interface

The left portion of Fig. 1 shows a detailed view of an embodiment of the internal RF interface. The internal RF interface may include one or more of a

10 transponder, internal antenna, modulator, demodulator, clock, and rectifier. The transponder can be passive or active. In certain embodiments, the internal RF interface can send and/or receive one or more of control logic and power. In still further

embodiments, the internal RF interface 150 delivers one or more of power, clock, and data to the implant core subsystem 140. In certain embodiments the data is delivered

15 via a full duplex data connection. In some embodiments, the internal RF interface 150 sends data (e.g., function status) of one or more electrodes 161 to a controller 205, described below, for review by a technician or physician.

The internal RF interface 150 operates according to the principle of inductive coupling. In an embodiment, the present invention exploits the near-field

20 characteristics of short wave carrier frequencies of approximately 13.56 MHz. This carrier frequency is further divided into at least one sub-carrier frequency. In certain embodiments, the present invention can use between 10 and 15 MHz. The internal RF interface 150 uses a sub carrier for communication with an external RF interface 203, which may be located in the controller 205. The sub-carrier frequency is obtained by

25 the binary division of the external RF interface 203 carrier frequency. In the

embodiment shown, the internal RF interface 150 is realized as part of a single silicon package 170. The package 170 may further include a chip 145 which is a programmable receive / transmit RF chip.

In certain embodiments, the internal RF interface 150 also includes a passive
5 RFID transponder 156 with a demodulator 158 and a modulator 157. The transponder 156 uses the sub carrier to modulate a signal back to the external RF interface 203. The transponder 156 may further have two channels, Channel A and Channel B. Channel A is for power delivery and Channel B is for data and control. In certain embodiments, the transponder 156 may employ a secure full-duplex data protocol.

10 The internal RF interface 150 further includes an inductive coupler 152, an RF to DC converter 155, and an internal antenna 151. In certain embodiments, the internal antenna 151 includes a magnetic component. In such embodiments, silicon traces may be used as magnetic antennas. In other embodiments, the antenna may be a high Q coil electroplated onto a silicon substrate, and can vary in size according to the amount of
15 power required in treating an indication and the required distance from the controller. A parallel resonant circuit 153 may be attached to the internal antenna 151 to improve the efficiency of the inductive coupling. The internal antenna 151 may be realized as a set of PCB traces 133 on the implant 105. Size of the antenna traces is chosen on the basis of power requirements, operating frequency, and distance to the controller 205.
20 Both the internal RF interface 150 and the core subsystem microprocessor 141 are powered from an RF signal received by the internal antenna 151. A shunt regulator 154 in the resonant circuit 153 keeps the derived voltage at a proper level.

Internal Subsystem Design

In the present invention it is important to note that the size of the internal
25 subsystem can vary, and can have any shape. For example, for the treatment of arthritic

pain, the internal subsystem 100 can be designed such that multiple implants 105 respond to the same secured RF signal from a single external subsystem 200. Similarly, the implant 105 can be small enough and properly shaped to facilitate placement at or near or on a nerve by injecting the implant 105.

5 **Implant Subsystem Arrangement**

The implant 105 may be located on any suitable substrate and may be a single layer or multi-layer form. Fig. 5 shows an implant 105 constructed as a single integrated unit, with a top layer 110 and a bottom layer 110 which may be implanted in proximity to, in contact with, or circumferentially around a nerve, e.g., the hypoglossal
10 nerve. Fig. 5A is a breakout view of Fig. 5.

In certain embodiments, implant components are layered on a nerve. This alleviates the need for complex wiring and leads. In Figs. 5 and 5A, the top layer 110 includes a core subsystem 140, an internal RF interface 150, and a neural interface 160. The top layer 110 serves as the attachment mechanism, with the implant components on
15 the bottom layer 110. The neural interface 160 may be surface bonded to contacts on a printed circuit board 130. The bottom layer 110 is the complementary portion to the top layer 110, and serves as an attachment mechanism so that the implant 105 encompasses the HGN. Although conductive parts in contact with the HGN may be located at any suitable position on the implant 105, in the embodiment shown in Figs. 5
20 and 5A, the bottom layer 110 has no conductive parts.

In the embodiment shown in Figs. 5 and 5A, and as described above, the core subsystem 140 is included in a silicon package 170 (Fig. 2) attached to a printed circuit board (PCB) 130 on the top layer 110. The PCB 130 has a first side 131 and a second side 132. The silicon package 170 is placed on a first side 131 of the printed circuit
25 board 130. In certain embodiments the PCB 130 may be replaced with a flexible

membrane substrate. In the embodiment shown, the silicon package 170 further includes the internal RF interface 150. The neural interface 160 attaches to the second side 132 of the PCB 130. In this embodiment, the neural interface 160 (Fig. 6B) further includes a plurality of neural interface electrodes 161 (Fig. 4) arranged into anode and cathode pairs 162/163, shown in this embodiment as an array of 10 to 16 elements. The number and arrangement of anode and cathode pairs 162/163 is exemplary only, and not limited to the embodiment shown. The silicon package 170 (Fig. 2) connects to the anode and cathode pairs 162/163 via traced wires 133 printed on the PCB 130.

In other embodiments, such as the one shown in Fig. 6A, the neural interface electrode anode and cathode pairs 162/163 are located on the bottom layer 110 of the implant 105. In still other embodiments, such as the one shown in Fig. 6B, the neural interface electrode anode and cathode pairs 162/163 are located on both the top and the bottom layers 110/120. The matrix arrangement of electrodes 161 provides multiple nerve stimulating points, and has several advantages. The matrix arrangement allows a web of nerve fascicles of the hypoglossal nerve to be accessed, enabling selective stimulation of particular areas of the nerve. In some embodiments, power is delivered to the matrix of electrodes 161 from the D/A converter 164 to capacitors 165 via a multiplexer 166.

The implant 105 may further include an isolation layer 112 (Fig. 6A). In certain embodiments a protective coating 114 (Figs. 6A and 6B) may be applied to the top and bottom layers 110/120 of the implant 105. The implant 105 may further be coated with a protective coating 114 for biological implantation. Further, in certain embodiments all or a portion of the device may be encased in a biocompatible casing. In such embodiments, the casing may be a material selected from the group consisting of one or more titanium alloys, ceramic, and polyetheretherketone (PEEK).

External Subsystem

In certain embodiments, the external subsystem 200 may include one or more of (1) a controller, (2) an external RF interface and (3) an optional power source. An embodiment of an external subsystem 200 including these elements is shown in Fig. 7.

5 Typically the external subsystem 200 is located externally on or near the skin of a patient.

The Controller

Fig. 7 shows an embodiment of an external subsystem 200 with a controller 205. The controller 205 controls and initiates implant functions. In other
10 embodiments, the controller 205 may be part of the internal subsystem 100 instead of external subsystem 200, and in still further embodiments, portions of the controller 205 may be in both the external and internal subsystems 200/100. In certain embodiments, the controller 205 may further have one or more of a controller crypto block 201, data storage 206, a recording unit 207, and a controller microprocessor 204. In some
15 embodiments the controller microprocessor 204 may have a micrologic CPU and memory to store protocols selective to a patient. The controller microprocessor 204 is programmable and may further include an attached non-volatile memory. The microprocessor 204 may be a single chip or part of an integrated silicon package.

In certain embodiments, the controller may further include one or more of an
20 external RF interface 203 having RF transmit and receive logic, a data storage 206 that may be used to store patient protocols, an interface 202 (e.g., a USB port), a microprocessor 203, an external antenna (not shown), a functionality to permit the controller 205 to interface with a particular implant 105, and an optional power source 215. In certain embodiments, the controller electronics can be either physically or
25 electromagnetically coupled to an antenna. The distance between the external RF

interface antenna and the implant 105 may vary with indication. In certain embodiments, distance is minimized to reduce the possibility of interference from other RF waves or frequencies. Minimizing the distance between the external antenna and the implant 105 provides a better RF coupling between the external and internal subsystems 200/100, further reducing the possibility of implant activation by a foreign RF source. An encrypted link between the external and internal subsystems 200/100 further reduces the possibility of implant activation by foreign RF. In other embodiments, one or more of the internal antenna 151 and external antenna are maintained in a fixed position. Potential design complexity associated with internal RF interface antenna 151 orientation is minimized through the ability to position the external RF interface antenna in a specific location (e.g., near the patient's ear). Even if the patient moves, the internal RF interface antenna 151 and controller 205 remain coupled.

In certain other embodiments, the controller 205 also serves as (1) a data gathering and/or (2) programming interface to the implant 105. The controller 205 has full control over the operation of the implant 105. It can turn the implant 105 on/off, and may be paired to the implant 105 via a device specific ID, as described herein below with respect to use of the implant 105 and controller 205 of the present invention. In still further embodiments, the controller microprocessor 204 calculates stimulus information. The stimulus information is then communicated to the implant 105. The implant 105 then provides a calculated stimulus to a nerve. In another embodiment, the controller 205 preloads the implant 105 with an algorithmic protocol for neural stimulation and then provides power to the implant 105.

External RF Interface

In the embodiment shown in Fig. 7, the external subsystem 200 includes an external RF interface 203 that provides an RF signal for powering and controlling the implant 105. The external RF interface 203 can be realized as a single chip, a plurality of chips, a printed circuit board, or even a plurality of printed circuit boards. In other
5 embodiments, the printed circuit board can be replaced with a flexible membrane. The external RF interface 203 may include one or more of a transponder 208 (not shown), external antenna (not shown), modulator 210 (not shown), and demodulator 211, clock 212 (not shown), and rectifier 213 (not shown). The external RF interface transponder 208 can be passive or active. In certain embodiments, the external RF interface 203
10 can send and/or receive one or more of control logic and power. In still further embodiments, the external RF interface 203 delivers one or more of power, clock, and data to one or more of the external subsystem controller 205 and the internal subsystem 100 via the internal RF interface 150. In certain embodiments the data is delivered via a full duplex data connection.

15 In an embodiment, the external RF interface 203 operates at a carrier frequency of about 13.56 MHz. In certain embodiments, the external RF interface 203 can operate between 10 and 15 MHz. This carrier frequency is further divided into at least one sub-carrier frequency. The sub-carrier frequency is obtained by the binary division of the external RF interface 203 carrier frequency. The external RF interface 203 uses
20 the sub carrier for communication with the internal RF interface 150. The external RF interface transponder 208 (not shown) uses the sub carrier to modulate a signal to the internal RF interface 150. The transponder 208 (not shown) may further have two channels, Channel A and Channel B. Channel A is for power delivery and Channel B is for data and control. The transponder 208 (not shown) may employ a secure full-
25 duplex data protocol.

In certain embodiments, the external RF interface 203 may further include a demodulator 211 (not shown) and a modulator 210 (not shown). In still further embodiments, the external RF interface 203 further includes an external antenna. In certain embodiments, the external antenna includes a magnetic component. In such
5 embodiments, silicon traces may be used as magnetic antennas. The external antenna may be realized as a set of PCB traces. In other embodiments, the antenna may be a high Q coil electroplated onto a silicon substrate. Size of the antenna traces is chosen on the basis of power requirements, operating frequency, and distance to the internal subsystem 100. Antenna size may also be chosen according to the indication to be
10 treated. In certain embodiments, the external antenna may transmit the power received by internal subsystem 100. In certain other embodiments, the external antenna may be larger, and have a higher power handling capacity than the internal antenna 151, and can be realized using other antenna embodiments known by those skilled in the art.

In certain embodiments, the external subsystem 200 is loosely coupled to an
15 optional power source 215. In one embodiment, the controller power source 215 is not co-located with the external RF interface antenna. The external power source 215 may be in one location, and the external RF interface 203 and optionally the controller 205 are in a second location and/or third location. For example, each of the power source 215, controller 205 and external RF interface 203 can be located in difference areas. In
20 one embodiment, the power source 215 and the controller 205 and the external RF interface 203 are each connected by one or more conductive members, e.g. a flexible cable or wire. Additionally, in certain embodiments, the controller 205 and optional power source 215 may be co-located, and the external RF interface 203 may be located elsewhere (i.e., loosely coupled to the controller 205). In such embodiments, the
25 external RF interface 203 is connected to the controller 205 by a flexible cable or wire.

Since the power source 215 may be separately located from the controller 205 and/or external RF interface antenna, a larger power source 215 can be externally located but positioned away from the nerve that requires stimulation. Further, to reduce wasted power, a larger external RF interface antenna can be used. This provides the advantage of less discomfort to a user and therefore enhances patient compliance.

Such embodiments can also provide power to 2, 3, 4, 5 or more loosely coupled external RF interfaces 203. Thus, each external RF interface 203 can be positioned at or near the site of an implant 105 without the need for a co-located power source 215. In certain embodiments, each external RF interface 203 draws power from a single power source 215, and thus a single power source 215 powers a plurality of implants 105. Of course, the amount of power provided to each implant 105 will vary by indication and distance between the external RF interface 203 and the implant 105. The greater the distance between the external RF interface 203 and the implant 105, the greater the power level required. For example, a lower power is generally required to stimulate peripheral nerves, which are closer to the surface of the skin. As apparent to one of skill in the art, the power received at the implant 105 must be high enough to produce the desired nerve stimulus, but low enough to avoid damaging the nerve or surrounding tissue.

The external RF interface 203 may further include a programmable receive / transmit RF chip, and may interface with the controller crypto unit 201 for secure and one-to-one communication with its associated implant 105. The external RF interface 203 includes a parameterized control algorithm, wherein the parameterized control algorithm compares the sensed information to a reference data set in real time. The algorithm may be included in the controller microprocessor 204. Depending upon the patient's size and severity of disease state, the algorithm will vary a number of

parameters which include frequency, amplitude of the signal, number of electrodes involved, etc.

Interaction With Outside Information Sources

The external subsystem controller 205 may also interface with a computer. In some embodiments, the controller interface 202 is a built-in data port (e.g., a USB port). The built-in micro USB port serves as the interface to a physician's PC. The purpose of the PC interface is to tune (and re-tune) the implant system and transfer recorded data. Via the controller interface 202 a computer also transfer historical data recorded by the implant 105. The controller 205 may obtain and update its software from the computer, and may upload and download neural interface data to and from the computer. The software may be included in the controller microprocessor 204 and associated memory. The software allows a user to interface with the controller 205, and stores the patient's protocol program.

External Subsystem Design

The external subsystem 200 can be of regular or irregular shape. Fig. 8 shows two embodiments of an external subsystem controller 205, one with the controller 205 included with an earpiece much like a Bluetooth earpiece, and one with the controller 205 included with a patch. In the embodiments shown, potential design complexity associated with internal RF antenna 151 orientation is minimized through the single and fixed position of the controller 205. The patient may move and turn without disrupting the coupling between the controller 205 and the internal antenna 151. In the embodiment with the controller 205 in an earpiece, a flexible receive/transmit tip in the earpiece aligns the controller external RF interface antenna with the implant 105. In the embodiment with the controller 205 in a patch, the patch is aligned with the implant 105 and placed skin. The patch may include one or more of the controller 205, a

replaceable adhesive layer, power and RFID coupling indication LED, and a thin layer rechargeable battery. Still further embodiments include incorporation of the external subsystem 200 into a watch-like device for, e.g., the treatment of arthritic pain, or in a belt. Yet another range of variations are flexible antennas and the controller RF chip
5 woven into clothing or an elastic cuff, attached to controller electronics and remotely powered. Controller 205 designs may be indication specific, and can vary widely. The controller 205 embodiments in Fig. 8 are exemplary only, and not limited to those shown.

Communication With the Implant as a Function of Design

10 The distance between the external RF interface antenna and the implant 105 may vary with indication. In certain embodiments, e.g., in an embodiment for treating sleep apnea, the distance between this contact area and the actual implant 105 on a nerve is 1 to 10 cm, typically 3 cm, through human flesh. This distance, along with the controller crypto unit 201 and the core subsystem crypto unit 142 in the implant 105,
15 reduces potential interference from other RF signals. Minimizing the distance between the external antenna and the implant 105 provides a better RF coupling between the external and internal subsystems 200/100, further reducing the possibility of implant activation by a foreign RF source. An encrypted link between the external and internal subsystems 200/100 further reduces the possibility of implant activation by foreign RF.
20 In other embodiments, one or more of the internal antenna 151 and external antenna are maintained in a fixed position. Potential design complexity associated with internal RF interface antenna 151 orientation is minimized through the ability to position the external RF interface antenna in a specific location (e.g., near the patient's ear). Even if the patient moves, the internal RF interface antenna 151 and controller 205 remain
25 coupled.

Implant Power

In certain embodiments, the implant 105 is externally powered by near field RF waves, the RF waves are inductively converted to DC power, which powers the implant 105 and delivers electrical signals to selected elements of the neural interface 160. In one embodiment, the implant 100 uses between 0.1 to about 1 milliamps, preferably averaging about 0.5 milliamps of current and about 10 to 30 microwatts of power. In some embodiments, the near field RF waves are emitted from the controller 205. In certain embodiments, controller 205 can be powered by an optional power source 215, e.g., a battery. In certain embodiments, the battery can be rechargeable battery. In other embodiments, the optional power source 215 is AC to DC converter, or other power sources known to those skilled in the art.

Implant and Controller Security

In certain embodiments, the controller 205 identifies the patient's unique ID tag, communicates with and sends signals to the implant 105. In certain embodiments, a controller crypto unit 201 may be installed to ensure that communication between the controller 205 and the implant 105 is secure and one-to-one. The controller crypto unit 201 may include the implant's unique ID tag.

In particular, the implant 105 may have a unique ID tag, which the controller 205 can be programmed to recognize. A controller microprocessor 204 confirms the identity of the implant 105 associated with the controller 205, thereby allowing setting of the patient's specific protocol. The setting may be accomplished using a computer interfaced with the controller 205 through an interface 202 on the controller 205.

More particularly, once the controller crypto unit 201 establishes a link with the core subsystem crypto unit 142, the controller 205 communicates a stimulation scenario to the core subsystem microprocessor 141. The controller 205 initiates a stimulation

cycle by making a request to the core subsystem 140 by sending an encoded RF waveform including control data via the external RF interface 203. The core subsystem 140 selects a trained waveform from memory and transmits the stimulation waveform to the core subsystem microprocessor 141. Once the core subsystem microprocessor 141 receives the waveform, the core subsystem 140 generates a stimulating signal for distribution to the neural interface 160.

In certain embodiments, the controller 205 prevents self-activation or autonomous operation by the implant 105 by handshaking. Handshaking occurs during each communications cycle and ensures that security is maintained. This prevents other devices operating in the same frequency range from compromising operation of the implant 105. Implant stimulus will not commence unless an encrypted connection is established between the external RF interface 203 and the implant 105. This serves as an anti-tampering mechanism by providing the implant 105 with a unique ID tag. The external controller 205 is matched, either at the point manufacture or by a physician, to a particular ID tag of the implant 105, typically located in an EPROM of the implant 105. In certain embodiments, the EPROM may be included in the core subsystem microprocessor 141. In other embodiments, the EPROM may be included in the controller microprocessor 204. This prevents alien RF interference from 'triggering' activation of the implant 105. While arbitrary RF sources may provide power to the implant 105, the uniquely matched controller 205 establishes an encrypted connection before directing the implant 105 to commence stimulus, thereby serving as a security mechanism.

Implant and Controller Positioning

Prior to implantation of the present invention for the treatment of a condition, the patient is first diagnosed as being a suitable candidate for such treatment. For

example, with respect to sleep apnea, patients are diagnosed in a sleep lab and an implant 105 is prescribed for their specifically diagnosed condition. Once diagnosis is complete, the implant 105 is implanted in the patient's body, typically on or in the vicinity of a nerve. In certain embodiments, the implant 105 is implanted on the HGN.

5 In such embodiments, the implant 105 may be implanted below the ear unilaterally at the sub-mandibular triangle, encasing the hypoglossal nerve. In treatment of incontinence the implant 105 is placed on or near the sacral nerve, and in treatment of arthritis, implants 105 are placed near the peripheral nerves transmitting pain.

Once implanted, the implant 105 is used to stimulate the nerve. Stimulation of a
10 fascicle or axon can act to maintain nerve activity. Hence in certain embodiments, the present invention can maintain muscular tone (e.g., in the tongue, thereby preventing apnea). Therefore, in certain embodiments, controller 205, described in more detail above, activates implant 105 to stimulate neural activity to ameliorate the negative physiological impact associated an indication.

15 In embodiments where the device is implanted in a manner to stimulate the HGN, the implant 105 delivers tone to the tongue. Maintaining tongue muscle tone stops the tongue from falling back and obstructing the upper airway. In embodiments where the device is implanted to stimulate the sacral nerve, the controller 205 sends small electrical impulses to the sacral nerve, acting as a bladder toner, reducing or
20 eliminating the patient's urge incontinence. In other embodiments, the implant subsystem is implanted in a manner so as to provide analgesia to a patient by using stimulation to suppress transmission of nerve impulses from a nerve by depolarizing the nerve using bi-phasic stimulation. The stimulation may be provided continuously during sleep hours, or upon preprogrammed customer-specific intervals. The implant
25 105 may also sense and record neural activity.

Implant and Controller Treatments

The desired treatment is determined by assessing a patient's needs and measuring a patient's needs against predetermined stimulation protocols. The neural interface 160 stimulation protocols are measured until a desired response is achieved.

5 Once a desired stimulation level is achieved, those protocols may be programmed into a controller 205. Stimulation may be programmed for delivery in an open loop or closed loop. After the controller 205 is programmed, the patient activates the controller 205 at bed time or at desired intervals. In the case of arthritic pain or other pain, the patient can activate the controller on an "as needed" basis. This electrical stimulation provides
10 a signal to the targeted nerve and starts the treatment. Upon completion of one treatment cycle, the duration of which is determined in the tuning phase of the implantation procedure, described above, the core subsystem 140 can report completion back to the controller 205 via RF communication, and optionally goes to an idle state until receiving another set of instructions.

15 Typically, the controller is programmed post-implantation at the time of customization. The patient's muscle activity or sensed pain level is measured against the stimulation parameters. Multi-contact design of the electrodes 161 (Fig. 4) allows a technician to measure effectiveness of stimulating each of the electrode points individually and in combination. This is accomplished by a PC software application
20 that takes into account patient history and response, thus eliminating redundant combinations as the calibration proceeds. Once a desired stimulation level is achieved, those parameters are programmed in the controller.

In certain embodiments, controller 205 can also determine when treatment is required, and stimulate a targeted nerve based on that determination. In order to make
25 such a determination, controller 205 can include one or more sensors that generate

signals as a function of the activity and/or posture of the patient. In other embodiments the patient may enter an input into the controller 205 telling it to commence treatment. However, as noted above, controller 205 can be activated by a user and then function in a manner such that the implant is continuously active until the patient manually
5 deactivates the controller by pressing a button on the controller 205, or by moving the controller 205 out of range of the implant. In other embodiments, the controller 205 can be programmed to activate and deactivate an implant 105 at programmed intervals.

This electrical stimulation provides a signal to the nerve or nerves of interest and starts the treatment of the patient's condition. Upon completion of one cycle, the
10 duration of which is determined in the tuning phase of the implantation procedure, described above, the core subsystem 140 can report completion back to the controller 205 via RF communication, and optionally goes to an idle state until receiving another set of instructions. Non-limiting examples of treatment programs are provided below.

Sleep Apnea

15 Fig. 3 shows an embodiment of an implant 105 and controller 205 that may be used to treat obstructive sleep apnea. In certain embodiments, such as the one shown in Fig. 3, the implant 105 is implanted on or in the vicinity of the HGN. In such
embodiments, the implant 105 may be implanted below the ear unilaterally at the sub-
mandibular triangle, encasing the hypoglossal nerve. In certain embodiments, a
20 stimulation frequency of about 10-40 Hz can be used. Stimulation may also be delivered in pulses, with pulse widths about 100 to 300 microseconds, more typically 200 microseconds. Although any suitable pulse width can be used, preferred pulses are at a width that simultaneously prevent nerve damage and reduce or eliminate corrosion of neural interface electrodes. The embodiment in Fig. 3 is exemplary only, and not
25 limited to what is shown.

Incontinence

Fig. 9 shows an embodiment of a controller 205 and implant 105 used to treat incontinence. The system treats incontinence by stimulating the sacral nerve, which controls voiding function. Sacral nerve stimulation is an FDA-approved electronic stimulation therapy for reducing urge incontinence. The implant is surgically placed on the sacral nerve in the lower spine. An external subsystem controller 205 then sends small electrical impulses continuously to the sacral nerve, acting as a bladder toner, reducing or eliminating the patient's urge incontinence.

Stimulation may be programmed for delivery in an open loop or closed loop at a suitable frequency. In certain embodiments, a stimulation frequency of about 5 to 25 Hz is used, preferably 15 Hz. Stimulation may also be delivered in pulses of 0.5 to 3 mA, with pulse widths of about 100 to 300 microseconds, more typically 210 microseconds. Although any suitable pulse width can be used, preferred pulses are at a width that simultaneously prevent nerve damage and reduce or eliminate corrosion of neural interface electrodes. After the controller 205 is programmed, the patient activates the controller 205 when the urge to void is felt, at bed time, or at desired intervals. The embodiment in Fig. 9 is exemplary only, and not limited to what is shown.

Seizures

Fig. 10 shows an embodiment of an controller 205 and implant 105 used to treat seizures. The embodiment in Fig. 10 is exemplary only, and not limited to what is shown. In the embodiment shown, the implant is attached to, or in the vicinity of, the vagus nerve. Stimulation of the vagus nerve is thought to affect some of its connections to areas in the brain prone to seizure activity. Patients who suffer from complex partial seizures or generalized seizures where consciousness is lost, and who

do not respond to anticonvulsant medication, and patients who cannot undergo brain surgery are candidates for vagus nerve stimulation therapy. Vagus nerve stimulation may also be used to treat photosensitive epilepsy and epilepsy resulting from head injury.

5 Vagus nerve stimulation may be programmed for delivery in an open or closed loop. In certain embodiments, a stimulation frequency of about 100 to 300 Hz is used, preferably 200 Hz. Stimulation is delivered in pulses of 3 to 10 mA, typically 7 mA. In certain embodiments, pulses are applied in bursts of 10 to 30, preferably 20 pulse bursts, with burst durations of 150 to 350 microseconds, typically 95 microseconds.

10 Although any suitable pulse width can be used, preferred pulses are at a width that simultaneously prevents nerve damage and reduces or eliminates corrosion of neural interface electrodes. The controller 205 may be programmed to provide stimulation constantly, or at predetermined intervals. In other embodiments, the patient activates the controller 205 to provide stimulation prior to the onset of a seizure.

15 **Arthritis**

Fig. 11 shows a controller 205 and network of implants 105 for treating arthritis pain. In the embodiment shown, the implants 105 reduce or eliminate arthritis pain by bi-phasic stimulation and depolarization of nerve pain signals. In certain embodiments the implant 105 is surgically implanted on or in the vicinity of a nerve that transmits
20 arthritis pain. In other embodiments, the implant 105 is injected. In certain embodiments, an implant 105 is less than 1 square centimeter in size, and includes only a single pair of electrodes 161 (not shown).

The controller 205 is multiplexed and/or networked to the internal RF interface antennas 151 of multiple implants 105. In the embodiment shown, a network of
25 multiple implants 105 is controlled and powered by a single external controller 205. In

other embodiments, multiple controllers 205 power and control multiple implants 105. The number and location of controllers 205 and implants 105 is exemplary only, and not limited to what is shown in the figure.

In certain embodiments the controller 205 is in a patch (Fig. 8). In other
5 embodiments, the controller is in a wrist band (not shown), and in still further
embodiments, the controller may be in a belt (not shown), or an earpiece (Fig. 8). In
still further embodiments, a single controller 205 may control and power a single
implant 105. The shape of the controller 205 and number of implants 105 shown in Fig.
11 is exemplary only, and not limited to what is shown.

10 Other embodiments of the apparatus and methods described can be used in the
present invention. Various alternatives, substitutions and modifications for each of the
embodiments and methods of the invention may be made without departing from the
scope thereof, which is defined by the following claims. All references, patents, patent
applications cited in this application are herein incorporated by reference in their
15 entirety.

What is claimed is:

1. An implantable RFID-enabled micro-electronic neurostimulator system comprising:

(a) an internal subsystem implant having

5 (i) an array of electrodes, where at least one electrode pair contacts a nerve;

(ii) a multiplexer;

(iii) digital to analog signal converter; and

(iv) a RFID based control and stimulation chip; and

10 (b) an external subsystem having

(i) a controller; and

(ii) an RF interface.

2. The RFID-enabled micro-electronic neurostimulator system of claim 1,
15 wherein the controller is configured to be programmable and to supply power to the internal subsystem.

3. The RFID-enabled micro-electronic neurostimulator system of claim 2,
20 wherein the supplied power includes RF energy emitted by the controller.

4. The RFID-enabled micro-electronic neurostimulator system of claim 1,
wherein the internal subsystem is encased in a casing, the casing being a material
selected from the group consisting of one or more titanium alloys, ceramic, and
polyetheretherketone (PEEK).

25

5. The RFID-enabled micro-electronic neurostimulator system of claim 1,
wherein the controller includes an interface for interfacing with a computer.

6. The RFID-enabled micro-electronic neurostimulator system of claim 1,
30 wherein the controller is configured to stimulate patient specific nerve physiology and stimulation parameters.

7. The RFID-enabled micro-electronic neurostimulator system of claim 1, wherein the controller is shaped for placement around a patient's ear.

8. The RFID-enabled micro-electronic neurostimulator system of claim 1,
5 wherein the controller is shaped in the form of a patch.

9. The RFID-enabled micro-electronic neurostimulator system of claim 1, wherein the controller is included in a watch-like device.

10. The RFID-enabled micro-electronic neurostimulator system of claim 1,
10 wherein the external subsystem is flexible.

11. The RFID-enabled micro-electronic neurostimulator system of claim 7c, wherein the controller and RF interface are woven into clothing and remotely powered.

15

12. The RFID-enabled micro-electronic neurostimulator system of claim 1, further comprising a transponder located in the internal subsystem, wherein the external subsystem controller is configured to:

20

identify a unique ID tag corresponding to the implant;
communicate with the implant having the unique ID tag; and
send a signal to the internal subsystem transponder.

13. The RFID-enabled micro-electronic neurostimulator system of claim 12, wherein the transponder is a passive RFID transponder.

25

14. The RFID-enabled micro-electronic neurostimulator system of claim 1, wherein the controller further includes a programming device and wherein the controller is configured to:

30

provide an RF signal to the implant;
sense and record data; and
interface with the programming device.

15. The RFID-enabled micro-electronic neurostimulator system of claim 1, wherein the controller is configured to communicate with the implant at preprogrammed intervals.

5 16. The RFID-enabled micro-electronic neurostimulator system of claim 1, further comprising a core subsystem within the internal subsystem, wherein the controller is configured to initiate a stimulation cycle by making a request to the core subsystem, the request being in the form of an encoded RF waveform including control data.

10

17. The RFID-enabled micro-electronic neurostimulator system of claim 16, wherein the request is encrypted.

15 18. The RFID-enabled micro-electronic neurostimulator system of claim 1, wherein the implant is hermetically sealed.

19. The RFID-enabled micro-electronic neurostimulator system of claim 1, wherein the implant is configured to provide continuous open loop electrical stimulation to a nerve during sleep hours.

20

20. The RFID-enabled micro-electronic neurostimulator system of claim 1, wherein the implant is configured to provide constant stimulation to a nerve during sleep hours.

25 21. The RFID-enabled micro-electronic neurostimulator system of claim 20, wherein the implant is configured to provide bi-phasic stimulation to a nerve.

22. The RFID-enabled micro-electronic neurostimulator system of claim 20, wherein the stimulation pulse width is about 200 microseconds at a stimulation
30 frequency of about 10-40 hertz.

23. The RFID-enabled micro-electronic neurostimulator system of claim 1, wherein the implant is configured to provide stimulation to a nerve at preprogrammed conditions.

5 24. The RFID-enabled micro-electronic neurostimulator system of claim 23, wherein the implant is configured to provide bi-phasic stimulation to a nerve.

25. The RFID-enabled micro-electronic neurostimulator system of claim 23, wherein the implant stimulation pulse width is about 200 microseconds at a stimulation
10 frequency of about 10-40 hertz.

26. The implantable RFID-enabled micro-electronic neurostimulator system of claim 1, further comprising an antenna, a micrologic CPU, and a memory configured to store protocols which are selective to a patient in need of neurostimulation.
15

27. The implantable RFID-enabled micro-electronic neurostimulator system of claim 1, wherein the nerve is selected from the group consisting of one or more peripheral nerves, deep brain/cortical nerves, sacral nerve, vagus nerve, spinal cord, cochlear nerve, pulmonary nerve, gastric nerve and occipital nerve.
20

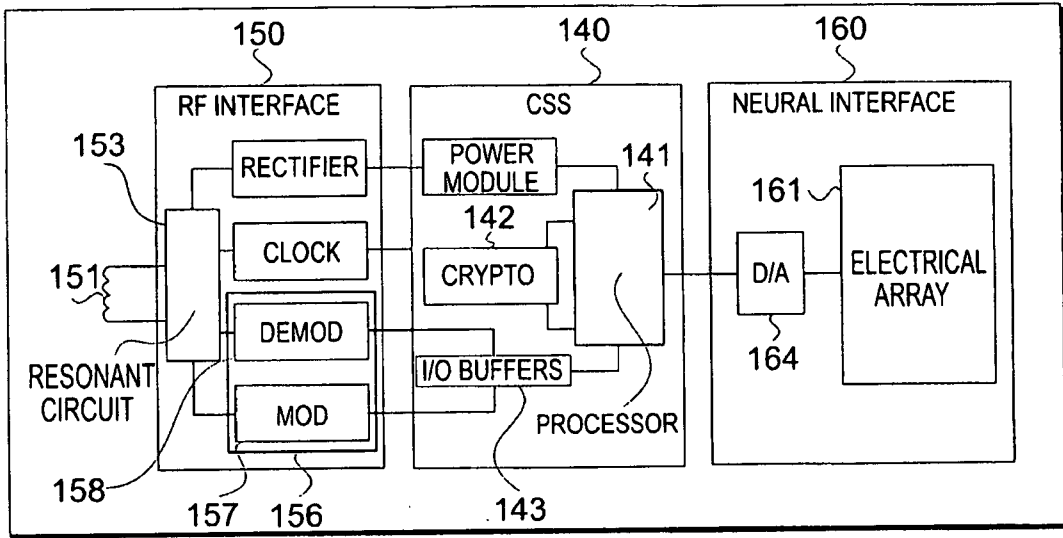


FIG. 1

100

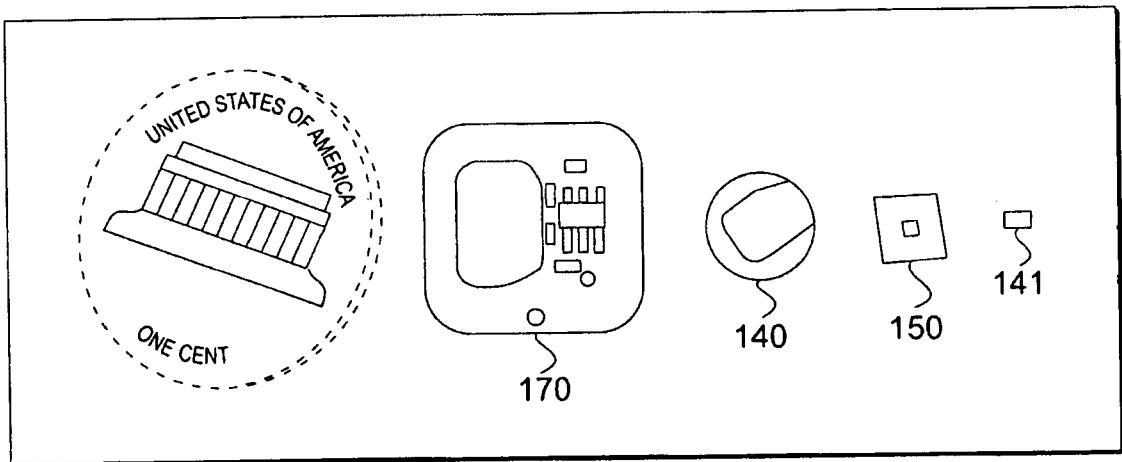


FIG. 2

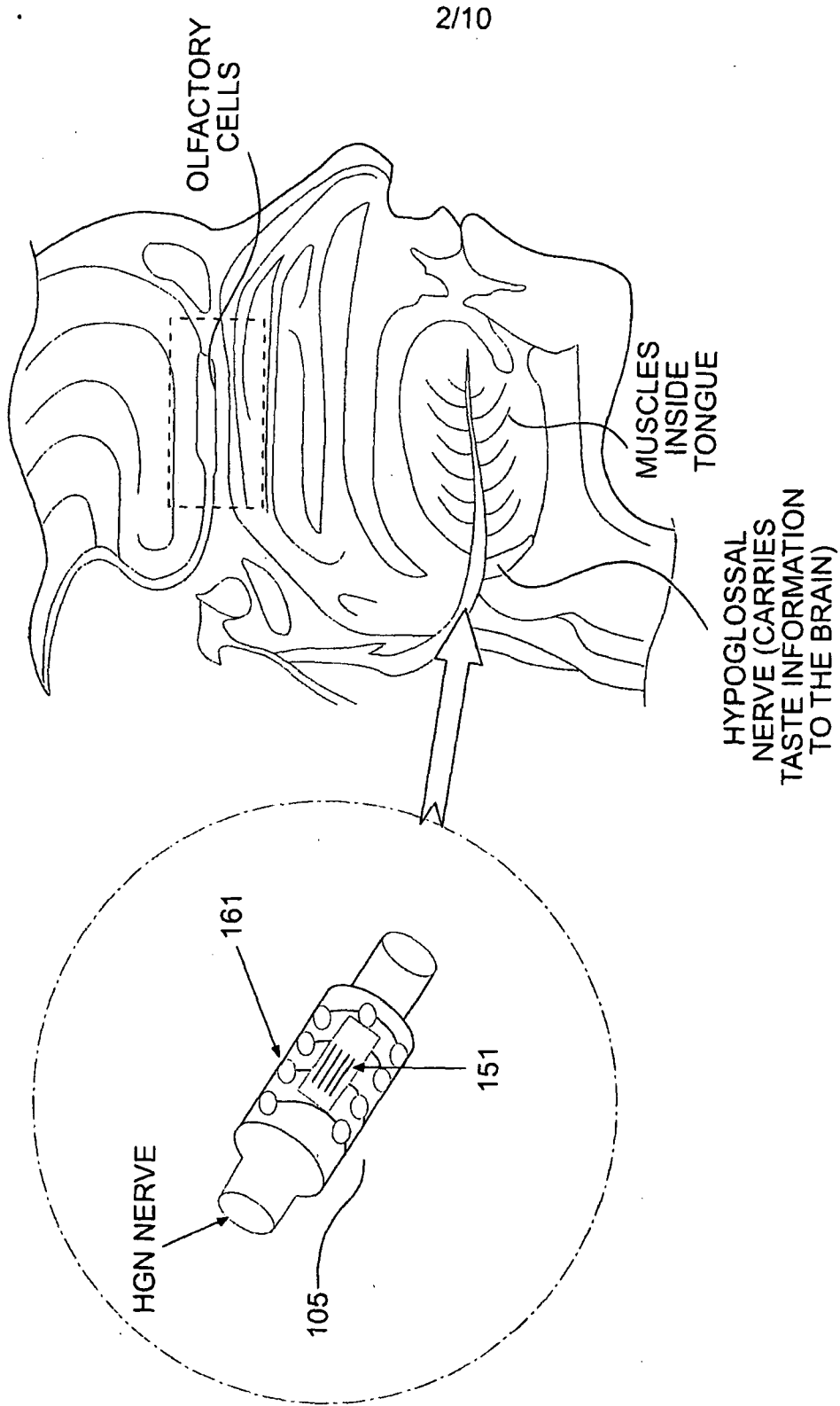


FIG. 3

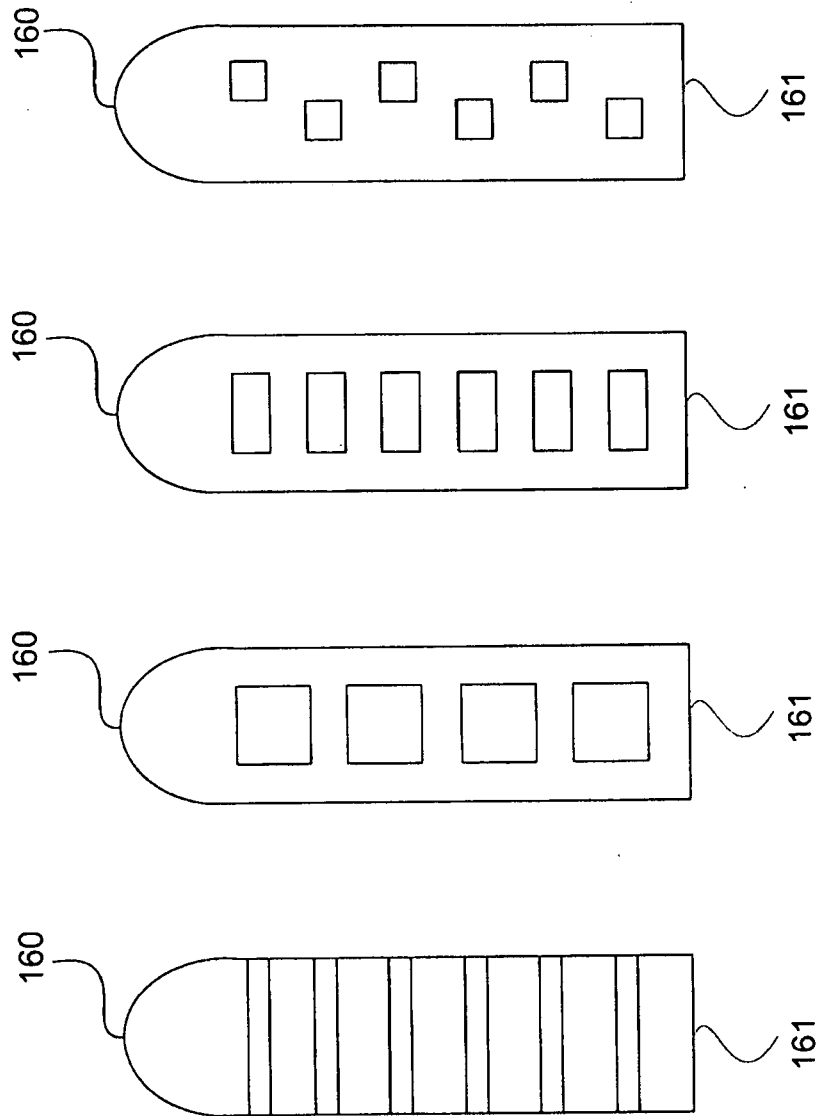


FIG. 4

FIG. 5

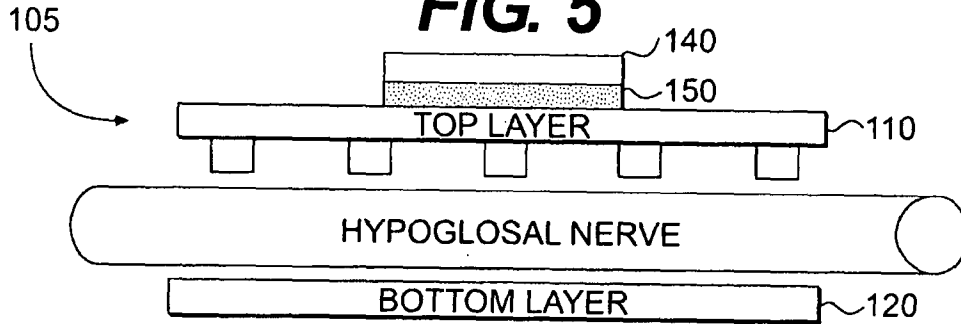


FIG. 5A

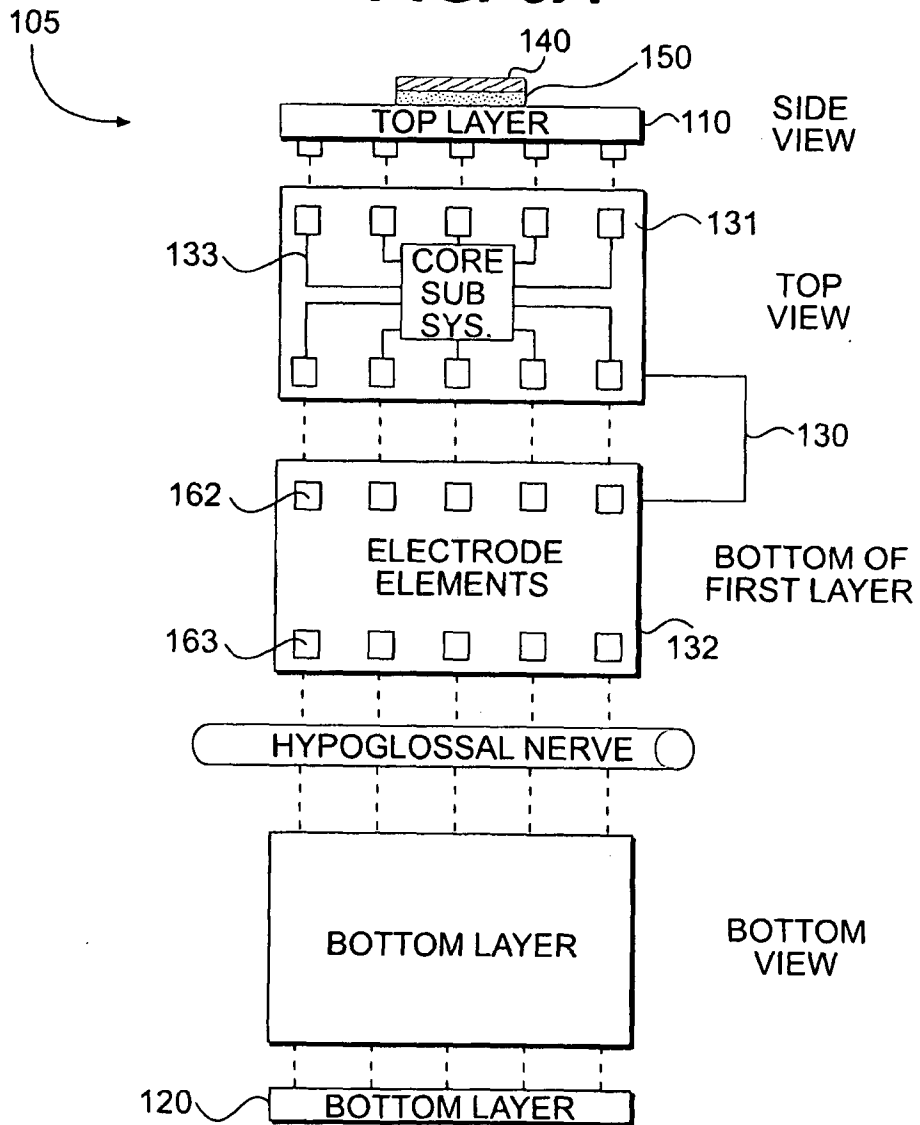


FIG. 6A

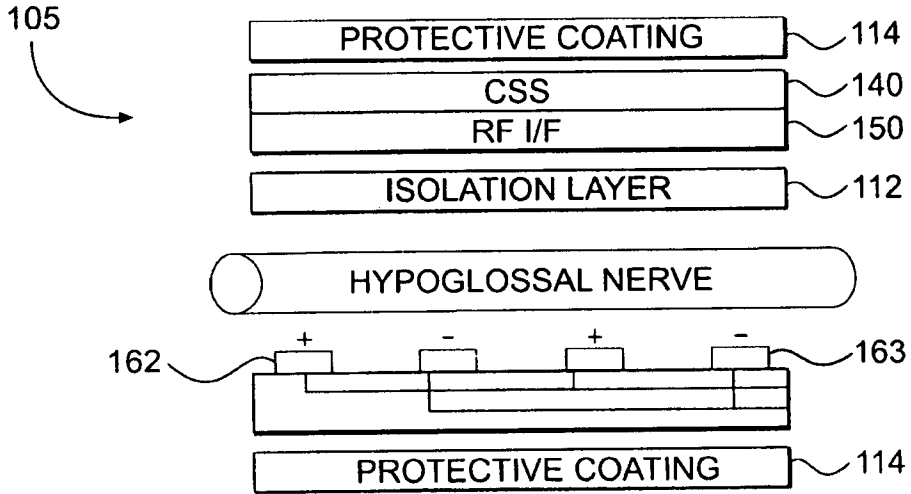
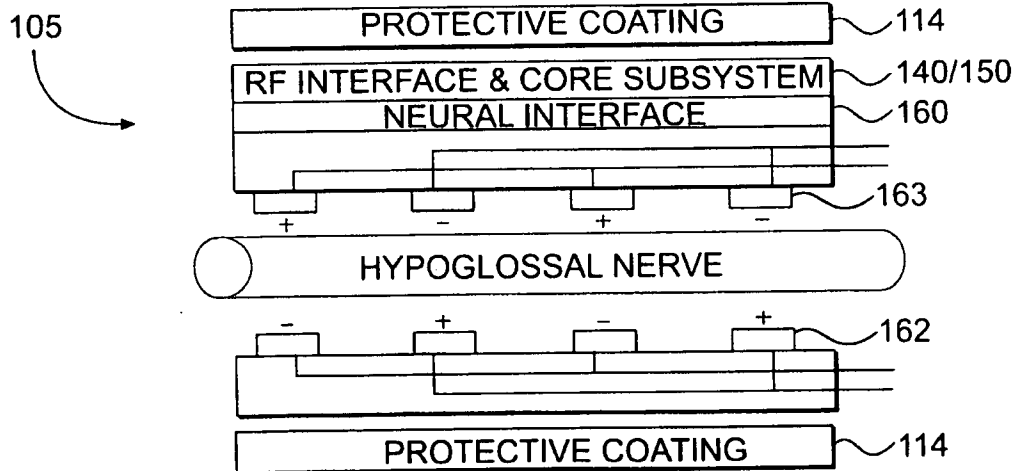


FIG. 6B



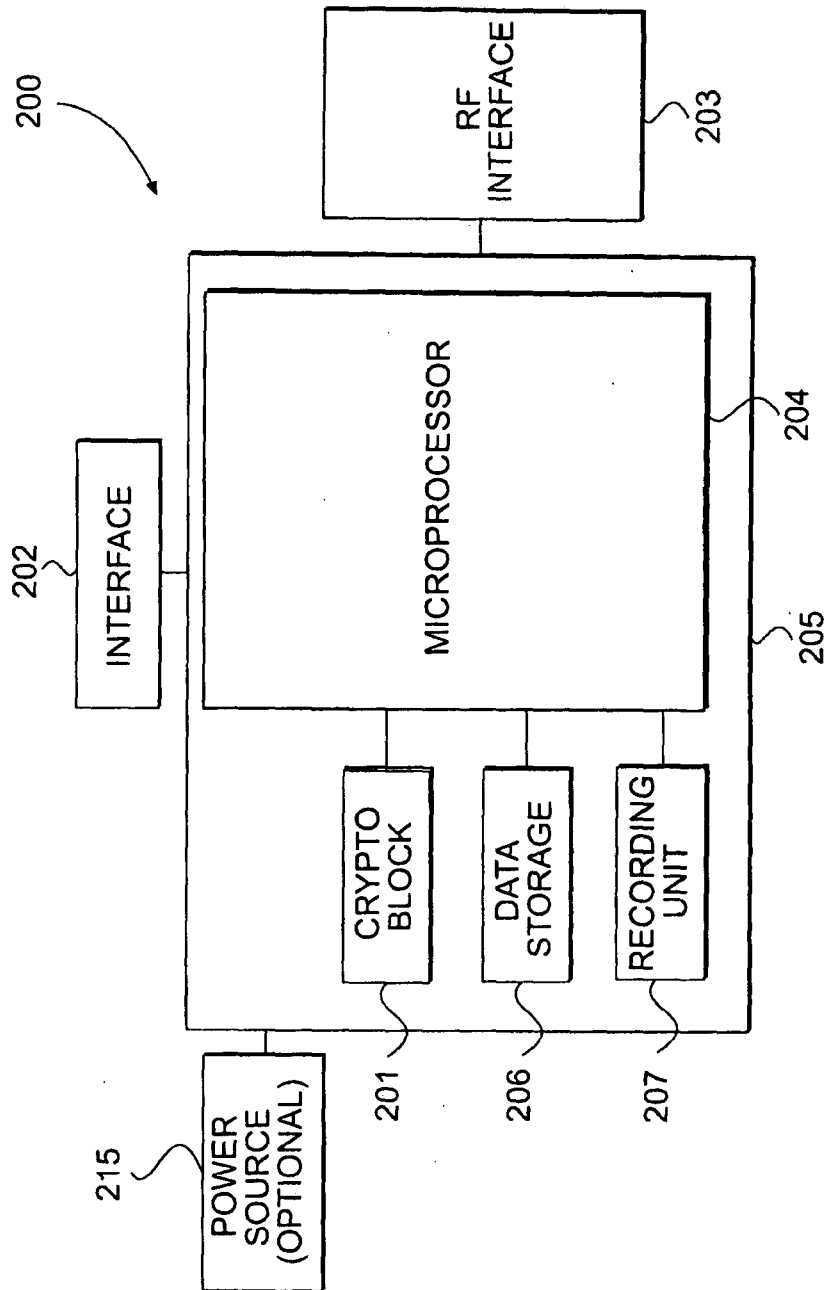


FIG. 7

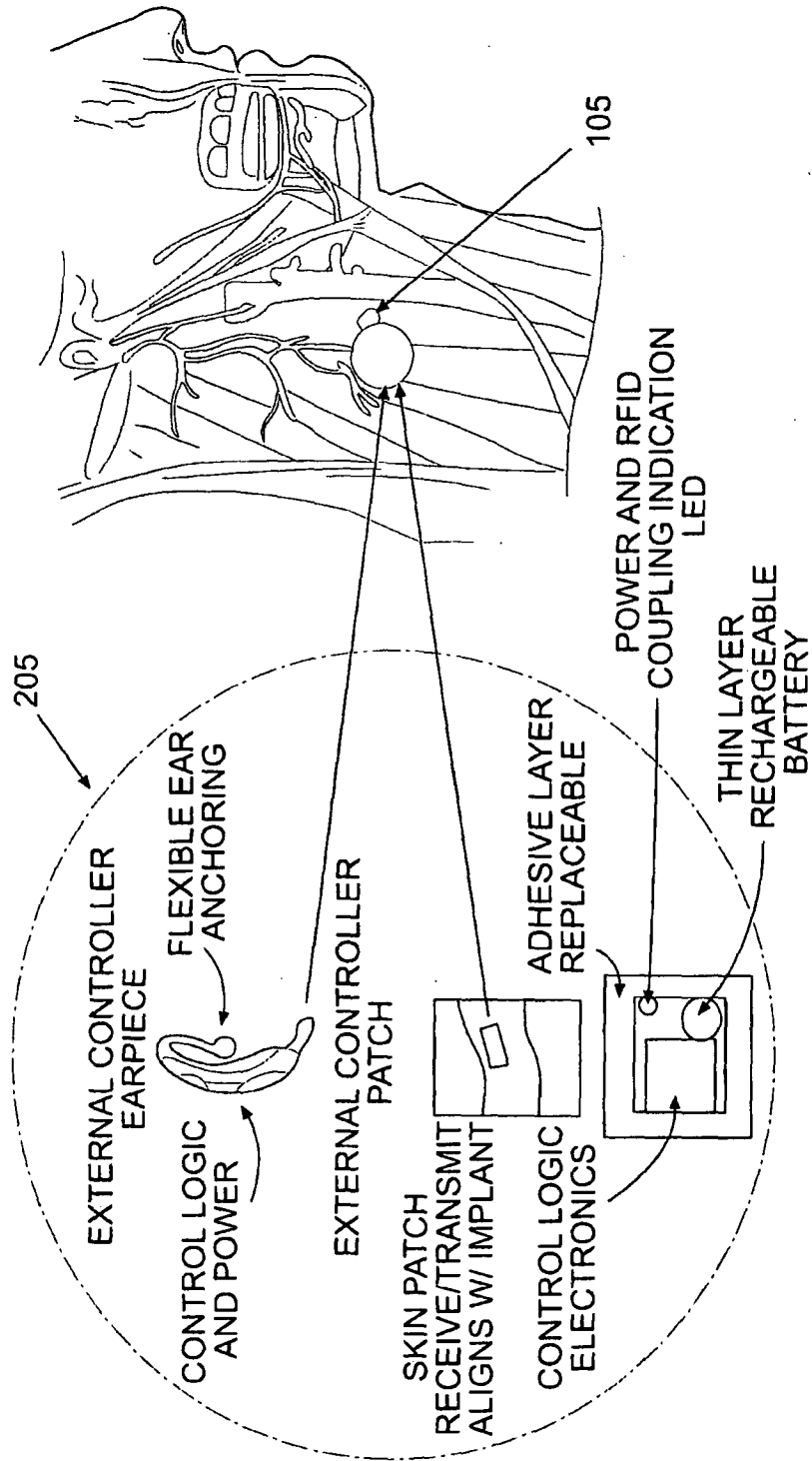


FIG. 8

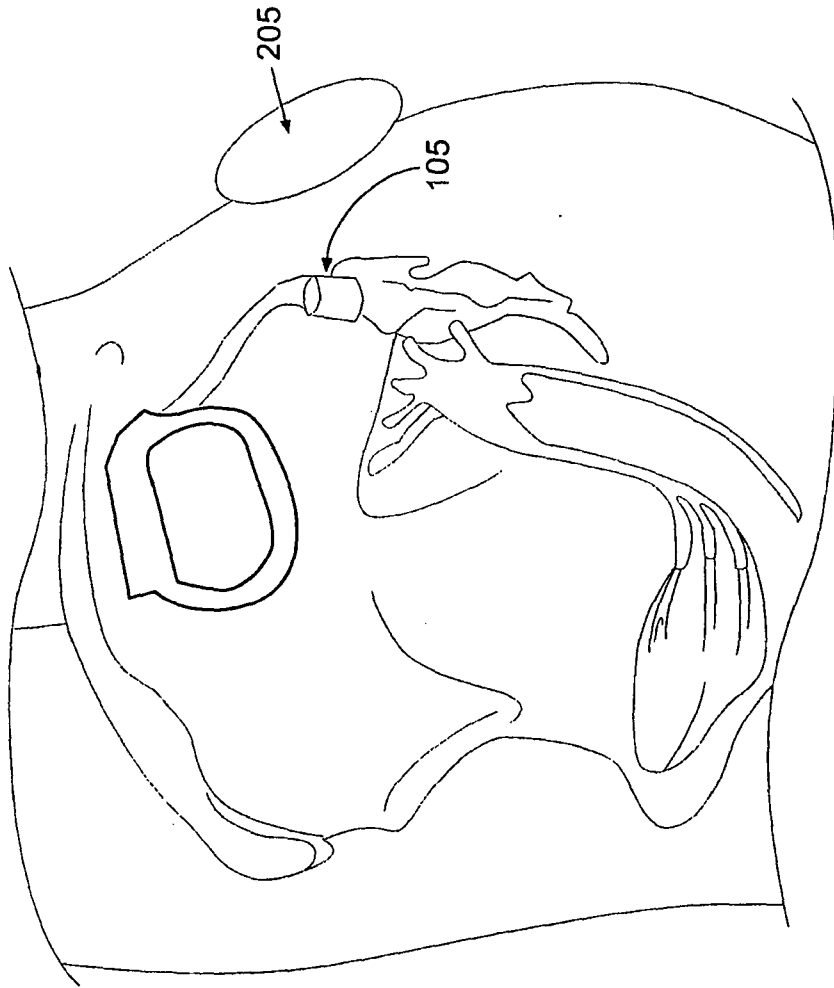


FIG. 9

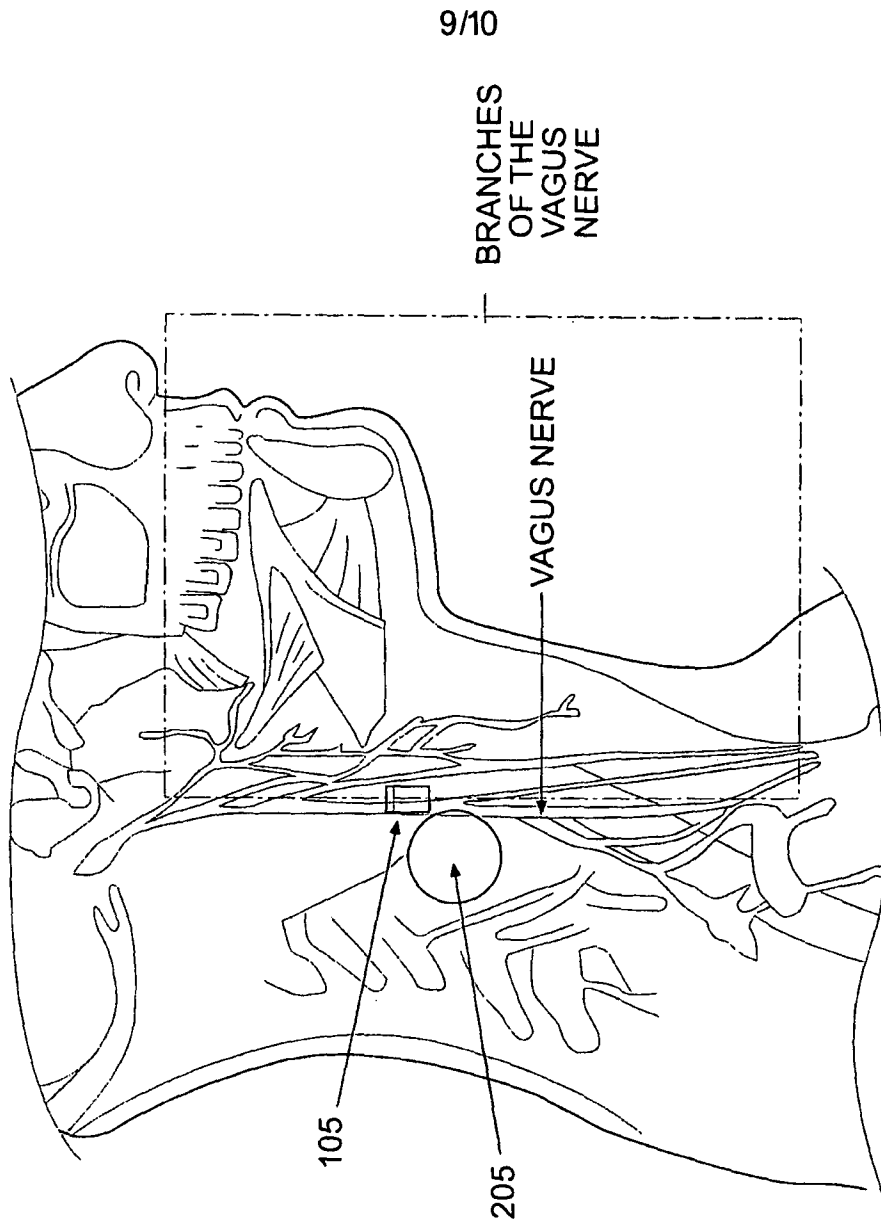


FIG. 10

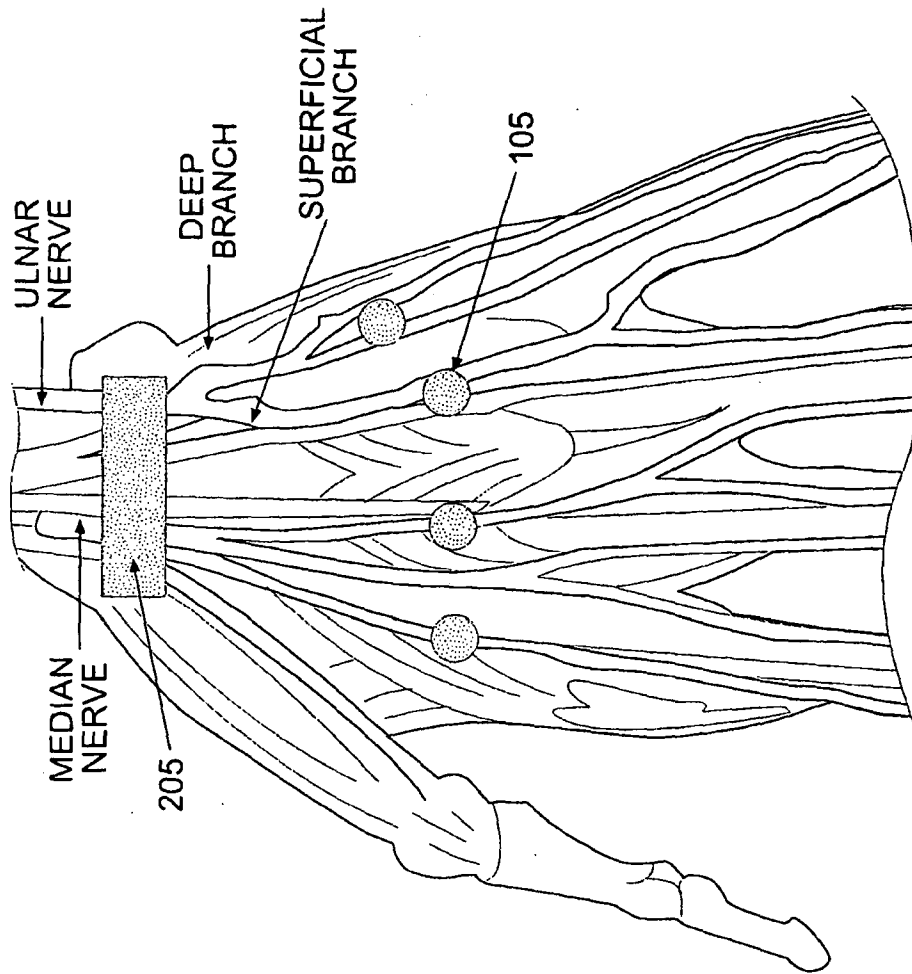


FIG. 11