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(71) Applicant: **THE FEINSTEIN INSTITUTE FOR MEDICAL RESEARCH** [US/US]; 350 Community Drive, Manhasset, New York 11030 (US).

(72) Inventors: **BOUTON, Chad E.**; 2 Leeds Lane, Darien, Connecticut 06820 (US). **ZANOS, Theodoros P.**; 2540 Shore Blvd.-Apt. 5M, Astoria, New York 11102 (US). **DATA-CHAUDHURI, Timir B.**; 10 Clen Road-Apt. 3F, Great Neck, New York 11021 (US). **MARTIN, Andrew**; P.O. Box 89, Bayport, New York 11705 (US). **MONTALBANO, Christopher**; 36 Artisan Avenue, Huntington, New York 11743 (US). **MONTALBANO, Gregory**; 8 Rodsfield Court, Huntington, New York 11743 (US). **BEAMER, Phillip**; 65 Eatons Neck Road, Northport, New York 11768 (US).

(74) Agent: **LIKOUREZOS, George**; Carter, DeLuca, Farrell & Schmidt, LLP, 445 Broad Hollow Rd.-Suite 420, Melville, New York 11747 (US).

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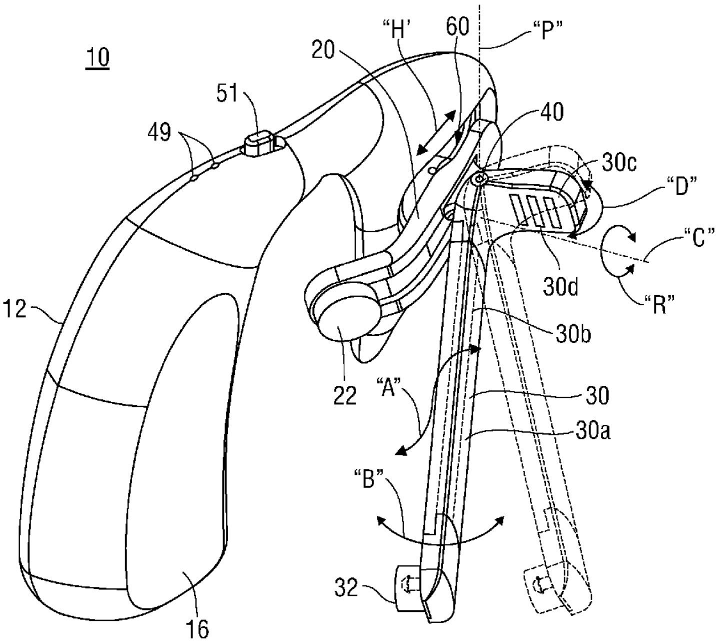

FIG. 1A

(57) Abstract: An auricular stimulation device having surface electrodes biased towards each other, and offset from one another, is provided. The stimulation device can be positioned about the ear of a patient with each of the electrodes overlaying auricular ear tissue containing innervation supplied by an auricular branch of the vagus nerve. The electrodes transcutaneously stimulate the auricular branch. Also provided is a method of treating a patient using the auricular stimulation device. The stimulation device can be used for treating patients with conditions such as high blood pressure, depression, high blood glucose level, and tinnitus. Also provided is a diagnostic and therapeutic system having the auricular stimulation device, a smart device and a monitoring device. The smart device controls the auricular stimulation device based on biomarker information received from the monitoring device; and on information related to the patient, such as age, musculoskeletal stability, etc.; and/or on user input.

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AURICULAR STIMULATION DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001[This application claims the benefit of U.S. Provisional Patent Application Serial No. 62/539,178, filed on July 31, 2017, the entire contents of which are incorporated by reference herein.

TECHNICAL FIELD

[0002[The present disclosure relates to treatment devices, and diagnostic and therapeutic systems and, more specifically, to auricular stimulation devices, diagnostic and therapeutic systems and methods of use thereof.

BACKGROUND

[0003[The auricular branch of the vagus nerve (also known as Alderman's nerve or Arnold's nerve) is located in the ear and supplies sensory innervation to the skin of the ear canal, tragus, and auricle. The auricular branch reaches the surface of the ear and divides into two branches. The first joins the posterior auricular nerve and the second is distributed to the skin on the back of the ear or auricle and to the posterior part of the ear canal.

[0004[Stimulation of the auricular branch of the vagus nerve has been shown to have diagnostic and therapeutic benefits. For example, various studies have shown that stimulation of the auricular branch of the vagus nerve can be used to treat seizures, atrial fibrillation, depression, diabetes, endotoxemia, myocardial infarction, and tinnitus (see references cited in the appendix).

[0005[In view of at least the foregoing benefits of stimulating the auricular branch of the vagus nerve, there is a continuing need for more effective auricular stimulation devices.

SUMMARY

[0006[The present disclosure provides an auricular stimulation device having at least two surface electrodes biased towards each other and offset from one other. In aspects described herein, the auricular stimulation device is configured for positioning about the ear of a patient with one or both of the electrodes in close proximity to and/or overlaying an auricular branch of the vagus nerve such that an electric field between the two electrodes passes through innervation that is connected to the auricular branch. The electrodes are configured to transcutaneously stimulate the auricular branch of the vagus nerve when activated by a stimulation circuit. The auricular stimulation device stimulates the auricular branch of the vagus nerve non-invasively.

[0007[The present disclosure further provides a method of treating a patient using the auricular stimulation device. The stimulation device can be used for treating patients with various conditions, including, but not limited to, high blood pressure, depression, high blood glucose level, and tinnitus.

[0008[The present disclosure further provides a diagnostic and therapeutic system having the auricular stimulation device, a smart device and a monitoring device. In aspects described herein, the auricular stimulation device of the system can be controlled by the smart device. Additionally, in aspects described herein, the smart device controls the auricular stimulation device based on biomarker information received from the monitoring device; information specific to the patient, such as age, musculoskeletal stability, etc.; and/or instructions received via a user input, such as instructions received via graphical user interface corresponding to an app. Further, in aspects described herein, the monitoring device can be an implantable sensor, such as the type configured to monitor and transmit a blood glucose level, cellular- and/or enzyme-related information, or any type of device external to the patient, such as a heart rate and respiratory rate monitor.

[0009[According to one aspect of the present disclosure, a stimulation device includes a first electrode disposed on a first arm, a second electrode disposed on a second arm, a biasing member configured to urge a portion of the first arm towards a portion of the second arm, and a stimulation circuit in operative communication with the first and second electrodes. The second electrode is in opposition to the first electrode and offset from the first electrode. One or both of the first and second electrodes is urged towards the other electrode to form a tissue clamping configuration. The stimulation circuit is configured for generating a stimulation signal for actuating one or both of the first and second electrodes for stimulating a nerve in close proximity to (and/or within) tissue clamped between the first and second electrodes. The first and second electrodes can be positioned such that the nerve does not have to be in the clamped tissue. In embodiments, the first and/or second electrodes are configured to generate electric field lines that may be straight and/or curved lines configured to pass through auricular tissue and electrically stimulate vagus nerve innervation within the auricle of the clamped ear.

[0010[In some embodiments, a controller may be in operative communication with the stimulation circuit for controlling operation of the stimulation circuit.

[0011[In certain embodiments, the stimulation device may further comprise a housing. The controller and the stimulation circuit may be disposed within the housing. The housing may be configured to be positioned about an ear of a patient.

[0012[In some embodiments, the stimulation device may further comprise an adjustment mechanism partially disposed within the housing and including the biasing member. The adjustment mechanism may enable the position of one or both of the arms to be changed for enabling the stimulation device to fit and conform to a variety of ears.

[0013[In certain embodiments, the stimulation device may further comprise a control interface for receiving one or more control signals from an external device for controlling the stimulation circuit. The external device may be a smart device.

[0014[In embodiments, the stimulation device may further comprise a power source in operative communicative with the stimulation circuit. The power source may be a rechargeable power source.

[0015[In some embodiments, the stimulation device may further comprise a memory in operative communication with the controller. The memory may be configured for storing usage data and operating parameters of the stimulation device.

[0016[In embodiments, the nerve may be the vagus nerve and the stimulation device may be configured to be positioned about an ear for stimulating an auricular branch of the vagus nerve.

[0017[In certain embodiments, one or both of the first and second arms is configured to move between one or more bent configurations and an unbent configuration.

[0018[According to yet another aspect of the present disclosure, a diagnostic and therapeutic system comprises a smart device and a stimulation device in operative communication with the smart device. The stimulation device is configured to receive one or more control signals from the smart device. The stimulation device includes a first electrode disposed on a first arm, a second electrode disposed on a second arm, a biasing member configured to urge a portion of the first arm towards a portion of the second arm, and a stimulation circuit in operative communication with the first and second electrodes. The second electrode is in opposition to the first electrode and offset from the first electrode. One or both of the first and second electrodes is urged towards the other electrode to form a tissue clamping configuration. The stimulation circuit is configured for generating a stimulation signal after receiving the one or more control signals for actuating one or both of the first and second electrodes for stimulating a nerve in within the auricle of the ear that is between the first and second electrodes.

[0019[In certain embodiments, the smart device may be in operative communication with one or both of a memory and a database storing a plurality of treatment regimens corresponding to a plurality of conditions.

[0020[In some embodiments, the system may further comprise a monitoring device in operative communication with one or both of the smart device and the stimulation device. The monitoring device may transmit biomarker information to one or both of the smart device and the stimulation device.

[0021[In embodiments, the smart device may determine one or more conditions of a patient using the biomarker information. The smart device may determine one or more treatment regimens from the plurality of treatment regimens for treating the one or more conditions of the patient.

[0022[In certain embodiments, the smart device may include one or more apps having a corresponding graphical user interface for receiving one or more user inputs for controlling one or more operating parameters of the stimulation device.

[0023[According to yet another aspect of the present disclosure, a method of treatment by stimulating a nerve is provided. The method includes clamping tissue between first and second electrodes of a stimulation device, the first electrode being disposed opposite from the second electrode, and offset from the second electrode; and actuating a stimulating circuit of the stimulation device to generate and deliver a stimulation signal to one or both of the first and second electrodes for stimulating a nerve within the auricle of the clamped ear.

[0024[In aspects, the tissue may be ear tissue and the nerve may be an auricular branch of the vagus nerve.

[0025[The method may further involve monitoring biomarker information and determining a treatment regimen in accordance with the biomarker information.

[0026[The method may further comprise changing one or more stimulation parameters of the stimulation device in accordance with biomarker information received by a monitoring device. The monitoring device may be external to a patient being treated. The monitoring device may be an implantable sensor.

[0027[The method may further involve controlling the stimulating circuit of the stimulation device by one or more controllers. The one or more controllers may be in a smart device in operative communication with the stimulation device.

[0028[The method may further include controlling the one or more controllers by user input via a graphical user interface.

[0029[Further, to the extent consistent, any of the aspects or features described in the present disclosure may be used in conjunction with any or all of the other aspects or features described herein.

[0030[Other aspects, features, and advantages will be apparent from the description, the drawings, and the claims that follow.

BRIEF DESCRIPTION OF THE DRAWINGS

[0031[Various aspects of the present disclosure are described hereinbelow with reference to the drawings, which are incorporated in and constitute a part of this specification, wherein:

[0032[FIG. 1A is a perspective view of one embodiment of a stimulation device configured to stimulate the auricular branch of the vagus nerve in accordance with the present disclosure, the stimulation device including an outer probe, the outer probe illustrated in an unbent configuration;

[0033[FIG. 1B is a perspective view of the stimulation device of FIG. 1A with the outer probe thereof illustrated in a bent configuration;

[0034[FIG. 2 is a perspective view, with parts separated, of the stimulation device of FIGS. 1A and 1B;

[0035[FIG. 3 is a cross-sectional view taken along section line 3-3 of FIG. 1B;

[0036[FIG. 4 is a cross-sectional view taken along section line 4-4 of FIG. 1B;

[0037[FIG. 5 is a schematic view of a system configured to stimulate the auricular branch of the vagus nerve in accordance with the present disclosure;

[0038[FIG. 6 is a flowchart of an exemplary method of diagnosing and treating a condition with a stimulation device configured to stimulate the auricular branch of the vagus nerve in accordance with the present disclosure;

[0039[FIG. 7 is a flowchart of an exemplary treatment method of stimulating an auricular branch of the vagus nerve, such as with the stimulation device of FIGS. 1A and 1B, in accordance with the present disclosure; and

[0040[FIG. 8 is a perspective view of another embodiment of a stimulation device configured to stimulate the auricular branch of the vagus nerve in accordance with the present disclosure.

DETAILED DESCRIPTION

[0041[Embodiments of the present disclosure are now described in detail with reference to the drawings in which like reference numerals designate identical or corresponding elements in each of the several views. As used herein, the term "clinician" refers to a doctor, a nurse, or any other care provider and may include support personnel. As used herein, the term "electrode" is defined herein as a single electrode or an array of electrodes.

[0042[Referring now to FIGS. 1A and 1B, one embodiment of a StimClip™ or auricular stimulation device 10 is shown in accordance with the present disclosure. The stimulation device 10 includes a housing 12, a first or inner arm 20 (e.g., a probe), and a second or outer arm 30 (e.g., a probe). The housing 12 is shaped and configured for being secured over the ear of a patient (see FIG. 5). As seen in FIG. 2, the housing 12 of stimulation device 10 includes an outer flat portion 14, a middle flat portion 15, and an outer shell-shaped portion 16. Two triangular spacers 14A and 15A are provided in proximity to outer flat portion 14 and middle flat portion 15 to prevent housing portions 14 and 15 from abutting against each other.

[0043[With continued reference to FIGS. 1A-3, the housing 12 of stimulation device 10 supports an adjustment mechanism 60 for horizontally and rotationally adjusting the position of the probes 20, 30 for fitting or conforming the stimulation device 10 to ears having a variety of sizes and shapes. In particular, as indicated by arrows "H," adjustment mechanism 60 is slidably movable relative to housing 12 through mounting slot 64 of housing 12 to selectively axially move probes 20, 30 relative to housing 12. Further, adjustment mechanism 60 defines a central axis "C" therethrough about which probes 20, 30 selectively rotate relative to housing 12 and adjustment mechanism 60, as indicated by arrows "R." The stimulation device 10 is configured to be disposed on the left ear of a patient; however, in embodiments, a stimulation device 10 may be configured (e.g., as a mirror image of the left ear configuration) to be disposed on the right ear of the patient either separately or in conjunction with a stimulation device 10 disposed on the left ear of a patient. In addition, the stimulation device 10 may come in a variety of sizes to be disposed on the ear of an infant, a child, and/or an adult. The adjustment mechanism 60 also secures the inner and outer probes 20, 30 to the housing 12 and in a fixed position relative to housing 12 upon tightening of a mounting nut 65 of adjustment mechanism 60.

[0044[In particular, the adjustment mechanism 60 of the stimulation device 10 includes a mounting shaft 62 that is selectively slidably secured, as indicated by arrows “H,” and selectively rotatably secured, as indicated by arrows “R,” in a mounting slot 64 defined by the outer shell-shaped portion 16 of the housing 12. Allowing the mounting shaft 62 to selectively slide along and/or selectively rotate within the mounting slot 64 enables the housing 12 and the probes 20, 30 of the stimulation device 10 to be fitted or conformed to ears having a variety of sizes and shapes. As detailed herein, rotation of the probes 20, 30 relative to housing 12 is limited by movement of pin 68 through a predetermined arc length defined by opposite ends of pin slot 67. Once a suitable size and/or comfort is established mounting nut 65 can be threadably rotated or tightened on mounting shaft 62 of adjustment mechanism 60 to fix the adjustment mechanism 60 and the probes 20, 30 relative to the housing 12.

[0045[The mounting shaft 62 of adjustment mechanism 60 includes an inner segment 63 that extends inward and receives a mounting nut 65 thereabout to secure the mounting shaft 62 of adjustment mechanism 60 within the mounting slot 64 of the housing 12. The mounting shaft 62 also includes outer segment 66 that extends outward and defines a pin slot 67 that receives a pin 68 to secure the inner probe 20 to the outer segment 66 of the mounting shaft 62. Pin slot 67 is configured to limit rotational movement of the inner and outer probes 20, 30 relative to housing 12 such that pin 68 is configured to abut opposite ends of pin slot 67 to prevent further rotational movement of the probes 20, 30 in a given direction.

[0046[With continued reference to FIGS. 2 and 3, the inner and outer probes 20, 30 of the stimulation device 10 are pivotally mounted to one another by a pivot 40 of the stimulation device 10 that defines pivot axis "P." The pivot 40 includes a pivot pin 41 and a biasing member 42 that urges the inner and outer probes 20, 30 towards one another and into a tissue clamping position as shown in FIG. 3. The biasing member 42 may be any suitable spring (e.g., a torsion spring) disposed about the pivot pin 41.

[0047[The inner probe 20 of the stimulation device 10 includes a first or inner electrode 22. The outer probe 30 of stimulation device 10 includes a second or outer electrode 32 that opposes the inner electrode 22 and is offset from the inner electrode 22.

[0048[The outer probe 30 of the stimulation device 10 includes an elongate body 30a that is formed of a flexible material and supports one or more flexible wires 30b that extend through elongate body 30a to facilitate flexing and/or bending of elongate body 30a, as indicated by arrows "A," between an unbent configuration (FIG. 1A) and one or more bent configurations (FIG. 1B). The elongate body 30a and/or flexible wires 30b of outer probe 30 may be formed of any suitable polymeric and/or metallic material. While outer probe 30 may be bent in any number of configurations to accommodate different user comforts, ear sizes, ear shapes, etc., flexible wires 30b are configured to maintain outer probe 30 fixed in a respective configuration until subsequently bent to a different configuration. The outer probe 30 further includes a rigid foot 30c that extends transverse to the elongate body 30a of the outer probe 30. The foot 30c may include a finger grip 30d that may include any suitable surface texturing such as ridges, knurling, etc. The foot 30c is actuatable a user's finger, as indicated by arrows "D," to facilitate pivotal movement of outer probe 30 relative to inner probe 20 about pivot axis "P."

[0049[The biasing member 42 of pivot 40 urges the inner and outer probes 20, 30 towards one another, such that the inner and outer electrodes 22, 32 of the inner and outer probes 20, 30, respectively, are urged towards one another into the tissue clamping configuration to secure the stimulation device 10 to tissue supported between the inner and outer electrodes 22, 32. Specifically, a force is created by the biasing member 42 of the pivot 40 that urges the electrodes 22, 32 towards each other to clamp or clasp tissue between the electrodes 22, 32, and also secure the stimulation device 10 on the ear of a patient. The electrodes 22, 32 are positioned to overlay outer ear tissue (e.g., the auricle) innervated by the auricular branch of the vagus nerve when the stimulation device 10 is clamped to the ear.

[0050[With continued reference to FIG. 3, the outer electrode 32 of the outer probe 30 is offset from the inner electrode 22 of the inner probe 20. Offsetting the inner and outer electrodes 22, 32 provides improved stimulation of the auricular branch of the vagus nerve when both electrodes 22, 32 are activated and when one of the two electrodes 22, 32 is activated, as compared to having the electrodes 22, 32 directly oppose one another.

[0051[With continued reference to FIGS. 2-4, one or both of the inner and outer probes 20, 30 and/or the housing 12 of the stimulation device 10 may house a circuit board 50 of the stimulation device 10 with associated electronics for coordinating the activation of the electrodes 22, 32 of the inner and outer probes 20, 30, either separately or together. The circuit board 50 may have several elements including, but not limited to, a rechargeable power source 52, a stimulation circuit 54, electrode outputs 56 (FIG. 2) in operative communication with the stimulation circuit 54, a control interface 58, and a memory 59. The circuit board 50 may also include a power switch 51 and a corresponding status indicator 49 (FIG. 1) that extends from the housing 12 for being accessible by a patient or clinician. The circuit board 50 may also include an over-current protection circuit (not shown) and/or an over-heating protection circuit (not shown). The status indicator 49 of the circuit board 50 indicates whether the power switch 51 is in the "on" or "off" position. For example, the status indicator 49 can be an LED that is illuminated when the power switch 51 is in the "on" position and not illuminated when the power switch 51 is in the 'off' position.

[0052[The circuit board 50 of the stimulation device 10 also includes a controller 55, such as a microcontroller, for controlling the operation of the stimulation device 10. The controller 55 can be programmed with a variety of operating protocols and parameters. The operating protocols and parameters can be stored in the memory 59 or in a memory of controller 55. The memory 59 and/or the controller's memory store data, such as data logged during usage of the stimulation device 10 including, but not limited to, duration of use, time of day of use, and operating parameters of the stimulation circuit 54.

[0053[One or more elements of the circuit board 50 of the stimulation device 10 may be integrated into an application-specific integrated circuit (ASIC) or controller 55. By integrating and packaging elements of the circuit board 50 into and ASIC or controller 55, the wiring and/or size of one or both of the inner and outer probes 20, 30 may be reduced. In addition, the integration of elements into an ASIC or controller 55 may increase the battery life of the stimulation device 10. Alternatively, elements of the circuit board 50 and the controller 55 can be housed in a separate unit other than the stimulation device 10, and wirelessly or by wired connection communicate with the stimulation circuit 54 of the stimulation device 10. For example, the stimulation circuit 54 can be powered and controlled inductively via inductive coupling by control circuitry positioned in proximity to the stimulation device 10.

[0054[The rechargeable power source 52 of the circuit board 50 may be a battery or other device suitable for providing power to elements of the circuit board 50 and/or controller 55. The rechargeable power source 52 may be recharged through direct contact with an external power source (e.g., via a selectively removable power chord that may couple to a port such as a USB (not shown) supported by housing 12) or may be inductively charged by positioning a suitable power source adjacent the respective inner or outer probe 20, 30. The rechargeable power source 52 may be in communication with an induction coil 53 that receives power by inductive coupling from an external power supply (not shown) for recharging the power source 52. In some embodiments, the rechargeable power source 52 may include one or more photovoltaics to enable recharging by light energy.

[0055[The stimulation circuit 54 of the circuit board 50 is configured to generate stimulation signals, such as pulses, oscillations, sinusoidal waveforms, square waveforms, triangular waveforms, etc., when activated, and to transmit the stimulation signals via the electrode outputs 56 to one or both of the electrodes 22, 32 of the inner and outer probes 20, 30, respectively. The stimulation circuit 54 can be an oscillator or other electronic element configured to produce a signal or pulses which can stimulate the auricular branch of the vagus nerve to treat a predetermined condition. In some embodiments, the circuit board 50 may have a circuit configured to sense when the electrodes 22, 32 are clamped to tissue, such as by an impedance measurement, and to prevent actuation of the stimulation circuit 54 when tissue is not clamped between the electrodes 22, 32.

[0056[Each of the electrode outputs 56 of the circuit board 50 connected to the stimulation circuit 54 is in communication with a respective one of the electrodes 22, 32 of the inner and outer probes 20, 30 to deliver a stimulation signal, such as, for example, a waveform or a series of pulse bursts, generated by the stimulation circuit 54 to the electrodes 22, 32. The stimulation signal causes one or both of the electrodes 22, 32 to transcutaneously stimulate the auricular branch of the vagus nerve within the tissue. In certain embodiments, the electrodes 22, 32 may sense when they are in contact with tissue, for instance, an ear of a patient, and provide a tissue sensing signal via the electrode outputs 56 to the stimulation circuit 54 or the controller 50. If the stimulation circuit 54 or the controller 55 does not receive the tissue sensing signal from one or both electrodes 22, 32, the stimulation circuit 54 will not be actuated.

[0057[Besides the controller 55 of the circuit board 50, the stimulation circuit 54 of the circuit board 50 can also be controlled by an external device via the control interface 58 as detailed below. The controller 55 or external device can enable fine control of the operating parameters of the stimulation circuit 54, including, but not limited to, the duration, the amplitude, the frequency, the type of stimulation or oscillation waveform, or burst rate of the pulses, etc. Additionally or alternatively, the stimulation device 10 may be provided without the controller 55 such that one or more elements of the circuit board 50 are controlled by an external controller or an external control mechanism, such as by the controller 122 (FIG. 5) of the smart device 120.

[0058[The stimulation circuit 54 and other elements of the circuit board 50, including the controller 55, can be controlled or programmed using an app running on a smart device 120 (FIG. 5) or other electronic device (e.g., external controller). The app through the control interface 58, for example, can receive and transmit control signals wirelessly (e.g., WIFI signals) and program and/or control the stimulation circuit 54 and/or the controller 55 in order for the stimulation device 10 to generate a stimulation signal for treating the predetermined condition by stimulating the auricular branch of the vagus nerve. The stimulation device 10 can be connected via the control interface 58 or other communication circuitry to the internet or other network for receiving the control signals. In this case, the stimulation device 10 can be an internet of things (IoT) device configured to be remotely controlled via a network connection.

[0059[The control interface 58 of the circuit board 50 may be a wireless transmitter/receiver in wireless communication with the smart device 120 or external controller. The wireless communication may be radio frequency, optical, WIFI, BLUETOOTH® (an open wireless protocol for exchanging data over short distances (using short length radio waves) from fixed and mobile devices, ZigBee® (a specification for a suite of high level communication protocols using small, low-power digital radios based on the IEEE 802.15.4-2003 standard for wireless personal area networks (WPANs)), etc.

[0060[As stated above, the control interface 58 of the circuit board 50 may link to a smart device 120. Through the link, the control interface 58 may transfer data from the memory 59 and/or real-time data from the stimulation circuit 54 to the smart device 120. The controller 55 of the circuit board 50 may also receive control signals from the smart device 120 via the communication link for controlling the stimulation circuit 54 of the circuit board 50. The smart device 120 through the app may visually or audibly present data from the stimulation device10 to a clinician in real-time or other individual, including the patient. For example, a GUI of the app can provide visual information, such as the type of condition being treated and the operating parameters of the stimulation circuit 54 of the circuit board 50, such as the frequency and amplitude of the stimulation signal generated by the stimulation circuit 54.

[0061[With reference to FIG. 5, a system 100 is provided which can include the features described herein above and other features, and configured for stimulating the auricular branch of the vagus nerve and treating a condition in accordance with the present disclosure. The system 100 includes an auricular stimulation device 10 (see FIGS. 1A and 1B), a monitoring device 110, and a smart device 120. The auricular stimulation device 10 can be the device described above with reference to FIGS. 1A-4, or it can be any stimulation device for stimulating the auricular branch of the vagus nerve, e.g., auricular stimulation. The monitoring device 110 is any monitoring device suitable for measuring, monitoring, and/or determining biomarker information of a patient, such as heart rate, respiration rate, electro-dermal activity, neural activity, EEG, EKG, glucose level, cholesterol, blood pressure, levels of cytokines present, and/or other physiological measurements or molecular or enzyme-related information corresponding to the patient. For example, the monitoring device 110 may be an implanted sensor within the patient for measuring the patient's blood glucose level. The monitoring device 110 may also be a wearable device, such as a smart watch, or a finger pulse oximeter which monitors and determines the heart rate and respiration rate of a patient.

[0062[The smart device 120 of the system 100 may be, but not limited to, a smartphone, a portable computer, a tablet, a fixed computer, or a wearable device connected to a network, such as the internet, and/or operating under a communications protocol, such as BLUETOOTH™. In some embodiment, the smart device 120 may be an external controller configured to communicate wirelessly or via a wired connection and control the stimulation device 10.

[0063[With continued reference to FIG. 5, the communications links between the smart device 120 and the stimulation device 10 and monitoring device 110 of the system 100 can be wireless or non-wireless. A processor 124 of the smart device 120 receives biomarker information from the monitoring device 110. The biomarker information can be used by the smart device 120 to determine the type of stimulation signal configured to treat the patient's condition. The processor 124 then communicates with a controller 122 of the smart device 122 to transmit control signals to the stimulation device 10, either wirelessly or non-wirelessly. The control signals are received by the controller interface

58 and are used to control the stimulation circuit 54 for generating the processor-determined stimulation signal.

[0064[As stated above, the smart device 120 of the system 100 may also receive data from the memory 59 of the stimulation device 10, such as previous usage data, operating parameters of the stimulation device 10 during a previous treatment session or cycle, etc. which can aid the processor 124 to determine the most effective stimulation signal and associated operating parameters of the stimulation circuit 54 for treating the patient. Alternatively or additionally, user input 126 can be received by the smart device 120 via a GUI of an app to operate the stimulation circuit 54 based on user-selected operating parameters.

[0065[With reference to FIG. 6, an exemplary method 200 of treating a condition is described in accordance with the present disclosure with reference to the system 100 detailed above. Other methods of treatment are contemplated and envisioned using the stimulation device 10 and system 100 described herein. For example, as shown the stimulation device 10 is configured for attachment to the left ear of a patient; however, the stimulation device 10 may be configured as the "mirror image" of the device shown, and attached to the right ear of the patient. Alternatively, two stimulation devices 10 may be configured as "mirror images" of each other, and each attached to a respective ear of a patient and simultaneously or sequentially used to stimulate the auricular vagus innervation bilaterally, as detailed below.

[0066[Initially, with continued reference to FIG. 6, the stimulation device 10 and the monitoring device 110 of the system 100 are attached to the patient such that the stimulation device 10 is positioned to stimulate the vagus nerve, for example, the auricular branch of the vagus nerve in the ear of the patient (step 202), and the monitoring device 110 is positioned to monitor and determine biomarker information of the patient, for example, the heart rate and/or the respiration rate of the patient (step 204). Where the monitoring device 110 is an implantable device, such as a glucose monitoring implantable device, the monitoring device 110 includes transmission circuitry for transmitting the biomarker information, such as blood glucose level to the processor 124 of the smart device 120.

[0067[With the stimulation device 10 and the monitoring device 110 in position, the smart device 120 can be linked to the stimulation device 10 and the monitoring device 110 (step 206). The smart device 120 can be in wireless communication with the stimulation device 10 and the monitoring device 110; however, in embodiments, the smart device 120 may be physically linked or hardwired to the stimulation device 10 and the monitoring device 110. In certain embodiments, the smart device 120 is linked to the stimulation device 10 and the monitoring device 110 prior to the stimulation device 10 and the monitoring device 110 being in position.

[0068[When the stimulation device 10 of the system 100 is positioned about the ear, the stimulation device 10 may sense tissue properties via the inner and/or outer electrode 22, 32 of the inner and outer probes 20, 30 and internally calibrate one or more operating parameters in response to the sensed tissue properties. The operating parameters can also be calibrated or initially determined using the initial biomarker information received from the monitoring device 110, and/or user input 126 (step 208). The initial biomarker information refers to information received prior to stimulating the auricular branch of the vagus nerve. The initial biomarker information received by the smart device 120 from the monitoring device 110 can be used to establish a pre-stimulated state of the patient (step 210). That is, the state of the patient prior to stimulation of the auricular branch of the vagus nerve. This state corresponds to the patient having a condition which necessitates the patient be treated by stimulating the auricular branch of the vagus nerve. Therefore, it is the objective of the treatment method to stimulate the vagus nerve to treat the patient and adjust the patient's pre-stimulated state to a post-stimulated state which is healthier than the pre-stimulated state.

[0069[Based on at least the initial biomarker information, the smart device 120 of the system 100 can access one or more databases or a memory which correlates the initial biomarker information to a plurality of conditions, and determine one or more conditions of the patient, such as high blood pressure, high blood glucose level, high temperature, etc., based on the initial biomarker information. Therefore, the smart device 120 is configured to diagnose or determine one or more conditions of the patient using the initial biomarker information.

[0070[Once one or more conditions are determined by the smart device 120, the smart device can access one or more additional databases or the same databases, or a memory, which correlate a plurality of conditions with a plurality of treatment regimens or protocols. All of the databases referred to herein can be accessed by the smart device 120 or other computing device via a network connection, such as the internet.

[0071[For example, the smart device 120 of the system 100 can access a variety of treatment regimens stored within one or more databases stored in a remote location (i.e., cloud-based network architecture). The databases can be stand-alone databases or data structures stored in a remote server or other computing device. After accessing the plurality of treatment regimens stored within the one or more databases, the smart device 120 or other computing device selects the treatment regimen that is most suitable for treating a patient having the determined condition(s) of the patient. For example, if the initial biomarker information indicates the patient has a high glucose level, the smart device 120 or other computing device selects the treatment regimen which has been previously determined to be effective in treating patients with a high glucose level. The treatment regimen selected can be tailored or adjusted based on other information gleaned from the patient's biomarker information or other information related to the patient, including, but not limited to, blood pressure and heart rate of the patient, musculoskeletal stability, age of the patient, medical history, prescription medication(s) administered to the patient, etc. The treatment regimen can also be manually selected or tailored by a clinician, and communicated to the smart device 120 via the user input 126 (e.g., via a graphical user interface) or other controller in operative communication with the stimulation device 10.

[0072[Each treatment regimen can include, but not limited to, the operating parameters of the stimulation circuit 54, such as, the type of waveform and corresponding characteristics (e.g., frequency and amplitude), the duration of the treatment session, and the number of treatment sessions.

[0073[After the treatment regimen is selected or determined, and/or adjusted or tailored to the patient being treated, either by a clinician, the smart device 120 or other computing device, the controller 122 of the smart device 120 or other controller in operative communication with the stimulation device 10 transmits a control signal to the controller interface 58 of the stimulation device 10 to begin the treatment session and treat the patient in accordance with the treatment regimen (step 220).

[0074[The control signal may include parameters for the desired stimulation in accordance with the treatment regimen. In response to receiving the control signal via the controller interface 58, the controller 55 controls the stimulation circuit 54 to generate and deliver a waveform, a series of pulses or other stimulating signals to the inner and/or outer electrodes 22, 32 via the electrode outputs 56 to transcutaneously stimulate the vagus nerve, i.e., the auricular branch of the vagus nerve.

[0075[As the stimulation device 10 non-invasively stimulates the vagus nerve, the smart device 120 receives and monitors biomarker information, e.g., heart rate and/or respiration rate of the patient, via the monitoring device 110, continuously in real-time or at pre-set intervals (step 230). In some embodiments, the controller interface 58 of the stimulation device 10 can also receive the biomarker information from the monitoring device 10.

[0076[In response to the stimulation, the smart device 120 may detect a change (or detect no change, or detect no significant therapeutic change) in the biomarker information received from the monitoring device 110 (step 240). If no change or no significant therapeutic change is determined in the biomarker information, the smart device 120 sends a control signal to the auricular stimulation device 10 to change or adjust the stimulation parameters (step 242). The method then proceeds to step 220 where the patient is stimulated with the stimulation device 10 using the new stimulation parameters.

[0077[For example, when no change or no significant therapeutic change is detected in the biomarker information in step 240, the smart device 120 may increase the duration, amplitude, frequency, and/or burst rate of the pulses or other signal parameters, change the type of waveform, etc. until a desired or noticeable therapeutic change is detected in the biomarker information (step 244). These stimulation parameters are then maintained (step 250) and stimulation continues in step 220.

[0078[However, before continuing with stimulation using the new stimulation parameters in step 220, the system may check to determine if the temperature and current of the stimulation device 10 are within acceptable ranges (step 256). The stimulation device 10 is turned off if the temperature and/or current are outside acceptable ranges (step 258).

[0079[If in step 244, a change is detected in the biomarker information of the patient and the biomarker information is within an acceptable range, for instance, heart rate and/or the respiration rate of the patient is in the normal range, the smart device 120 may control the stimulation device 10 to cease the operation of the stimulation circuit 54 (step 250) and conclude the treatment session. That is, if it is determined by the smart device 120 that the stimulation treatment was effective in bringing the initial biomarker information of the pre-stimulated state of the patient within an acceptable range, the stimulation treatment session is finished.

[0080[The data acquired during the treatment session, including the stimulation parameters which were effective in treating the patient's condition can be stored in memory 59, smart device 120 or other computing device (steps 252, 254). The stimulation device 10 or smart device 120 may also be programmed to operate the stimulation circuit 54 in a future treatment session using the stimulation parameters that brought the initial biomarker information within the normal or accepted range.

[0081[The stimulation parameters can also be transmitted to a remote server and stored in a data structure or in the one or more databases for being accessed by clinicians as a set of treatment parameters for a given condition. Hence, over time, a "smart" database or artificial intelligence (AI) system is built having a plurality of sets of treatment parameters corresponding to the treatment of a plurality of conditions and patient characteristics (e.g., age, musculoskeletal stability, etc.); that is, the database or AI system can eliminate or shorten the treatment sessions for many patients since the most optimum treatment and stimulation parameters for a plurality of conditions will be known in advance.

[0082[In some embodiments, the smart device 120 of the system 100 may provide visual and/or audible feedback to the patient and/or a clinician before, during, and/or after a treatment session.

[0083[With reference to FIG. 7, an exemplary treatment method 300 of stimulating a vagus nerve is disclosed using pulses as the stimulation signal in accordance with the present disclosure and with reference to the stimulation device 10 of FIGS. 1A-4. Initially, the stimulation device 10 is attached to the ear of a patient such that the inner and outer electrodes 22, 32 of the inner and outer probes 20, 30, respectively, are positioned in opposition and offset from one another (step 310). The patient or a third party, such as a clinician, may position the stimulation device 10 on the ear of a patient. When the stimulation device 10 is positioned on the ear of the patient, the inner and outer electrodes 22, 32 are positioned about the auricular branch of the vagus nerve.

[0084[With the stimulation device 10 positioned and the power switch 51 has been set to the “on” position to allow operation of the stimulation device 10, the stimulation circuit 54 is activated to deliver pulses to the electrode outputs 56 which are transmitted from the inner and/or outer electrode 22, 32 of the inner and outer probes 20, 30, respectively. The stimulation circuit 54 may detect when the stimulation device 10 is attached to the tissue, e.g., an ear, and self-activate or by control of the smart device 120 to deliver therapeutic pulses to the auricular branch of the vagus nerve (step 320). For example, a circuit may be completed between the inner and outer electrodes 22, 32 as tissue is clamped therebetween.

[0085[The offset between the inner and outer electrodes 22, 32 of the inner and outer probes 20, 30, respectively, may prevent the circuit from being completed when the stimulation device 10 is in a clamped configuration with no tissue disposed between the inner and outer electrodes 22, 32. After interposed tissue is detected and before the therapeutic pulses are delivered, the stimulation circuit 54 may calibrate to tissue between the inner and outer electrodes 22, 32 by sending calibrating pulses from one of the inner or outer electrodes 22, 32 to the other and determining a resistance of tissue between the inner and outer electrodes 22, 32 (step 330). The resistance between the inner and outer electrodes 22, 32 may be used to determine one of the parameters of the therapeutic pulses to be delivered.

[0086[After activation of the stimulation circuit 54, the stimulation circuit 54 generates and delivers pulses to the inner and/or outer electrodes 22, 32 for a predetermined amount of time or until tissue is not detected between the two electrodes (e.g., the user removed the stimulation device 10 from the ear) (step 340). As the stimulation circuit 54 delivers pulses to the inner and/or outer electrodes 22, 32, the memory 58 may record data of the delivered pulses including, but not limited to, calibration data, time tissue detected, duration of tissue detection, and parameters of the pulses delivered (step 350).

[0087[As the stimulation circuit 54 delivers pulses, the stimulation device 10, e.g., the controller 50 may conduct safety checks (step 370). For example, the controller 50 or circuitry may verify whether the current being drawn from the power source 52 is below a maximum allowed current level. If the current being drawn from the power source 52 exceeds the maximum allowed current, the controller 50 may cease the operation of the stimulation circuit 54. Additionally or alternatively, the controller 50 or circuitry may monitor the temperature of the stimulation device 10, such that if the temperature of the stimulation device 10 exceeds a maximum allowed temperature, the controller 50 may cease operation of the stimulation circuit 54. This treatment method may be repeated multiple times over an extended period of time allowing for out-patient procedures to be completed between visits to a clinician's office.

[0088[During or after the delivery of pulses to the auricular branch of the vagus nerve by the stimulation device 10, the stimulation device 10 may link with a smart device 120 which receives data from the memory 59 including information related to one or more treatment sessions, such as, for example, operating parameters of the stimulation circuit 54 (step 360). The smart device 120 may be the patient's smart device and transmit the data to a clinician. Additionally or alternatively, the smart device 120 may be a clinician's such that at periodic visits, the clinician links to the stimulation device 10 to receive data from the memory 59 of the stimulation device 10. The clinician may analyze the data and update or change one or more operating parameters of the stimulation circuit 54 to update or change one or more characteristics of the pulses generated and delivered by the stimulation circuit 54. The clinician may use the smart device 120, e.g., in the clinician's office and/or remotely via a network connection, to connect with the stimulation device 10 and update or change the operating parameters of the stimulation circuit 54 to update or change one or more characteristics of the pulses.

[0089[Turning now to FIG. 8, another embodiment of a StimClip™ or auricular stimulation device 410 is illustrated that is substantially similar to stimulation device 10 and is only described herein to the extent necessary to describe the differences in operation and construction of stimulation device 410. In general, stimulation device 410 includes a housing 412, a first or inner arm 420 (e.g. probe), a second or outer arm 430 (e.g., probe), and an adjustment mechanism 460 that couples inner and outer probes 420, 430 to housing 412 and enables horizontal and rotational adjustment of probes 420, 430 relative to housing 412, as indicated by arrows "H" and "R," respectively. The inner and outer probes 420, 430 are pivotally coupled together about pivot axis "P" to selectively clamp electrodes 422, 432 of respective inner and outer probes 420, 430 to an ear while the housing 412 is supported on the ear. More specifically, the outer probe 430 pivots relative to first probe 420 about pivot axis "P" to move probes 420, 430 between a clamped position and an unclamped position, as indicated by arrows "B."

[0090[The outer probe 430 of the stimulation device 410 includes a foot 430a that facilitates pivotal movement of outer probe 430 about pivot axis "P," as detailed above with respect to outer probe 30 of the stimulation device 410. The outer probe 430 further includes an arched or pre-bent body 430b and a head 430c that supports the electrode 432 of the outer probe 430. The foot 430a, pre-bent body 430b, and the head 430c of the outer probe 430 are formed of rigid material to prevent flexing of outer probe 430.

[0091[As can be appreciated, securement of any of the components of the presently disclosed apparatus can be effectuated using known securement techniques such welding, crimping, adhesion, fastening, etc.

[0092[Persons skilled in the art will understand that the structures and methods specifically described herein and shown in the accompanying figures are non-limiting exemplary embodiments, and that the description, disclosure, and figures should be construed merely as exemplary of particular embodiments. It is to be understood, therefore, that the present disclosure is not limited to the precise embodiments described, and that various other changes and modifications may be effected by one skilled in the art without departing from the scope or spirit of the disclosure. Additionally, the elements and features shown or described in connection with certain embodiments may be combined with the elements and features of certain other embodiments without departing from the scope of the present disclosure, and that such modifications and variations are also included within the scope of the present disclosure. Accordingly, the subject matter of the present disclosure is not limited by what has been particularly shown and described.

APPENDIX

The following references are incorporated herein by reference:

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What is Claimed:

1. A stimulation device comprising:

a first electrode disposed on a first arm;

a second electrode disposed on a second arm, wherein the second electrode is in opposition to the first electrode and offset from the first electrode;

a biasing member configured to urge a portion of the first arm towards a portion of the second arm, wherein at least one of the first and second electrodes is urged towards the other electrode to form a tissue clamping configuration; and

a stimulation circuit in operative communication with the first and second electrodes, wherein the stimulation circuit is configured for generating a stimulation signal for actuating at least one of the first and second electrodes for stimulating a nerve within tissue clamped between the first and second electrodes.

2. The stimulation device according to claim 1, further comprising a controller in operative communication with the stimulation circuit for controlling operation of the stimulation circuit.

3. The stimulation device according to claim 2, further comprising a housing, wherein the controller and the stimulation circuit are disposed within the housing.

4. The stimulation device according to claim 3, wherein the housing is configured to be positioned about an ear of a patient.

5. The stimulation device according to claim 1, further comprising an adjustment mechanism partially disposed within the housing and including the biasing member, wherein the adjustment mechanism enables the position of at least one of the arms to be changed for enabling the stimulation device to fit and conform to a variety of ears.

6. The stimulation device according to claim 1, further comprising a control interface for receiving at least one control signal from an external device for controlling the stimulation circuit.

7. The stimulation device according to claim 6, wherein the external device is a smart device.

8. The stimulation device according to claim 1, further comprising a power source in operative communicative with the stimulation circuit.

9. The stimulation device according to claim 8, wherein the power source is a rechargeable power source.

10. The stimulation device according to claim 2, further comprising a memory in operative communication with the controller, wherein the memory is configured for storing usage data and operating parameters of the stimulation device.

11. The stimulation device according to claim 1, wherein the nerve is the vagus nerve, and wherein the stimulation device is configured to be positioned about an ear for stimulating an auricular branch of the vagus nerve.

12. A diagnostic and therapeutic system comprising:

a smart device; and

a stimulation device in operative communication with the smart device and configured to receive at least one control signal from the smart device, the stimulation device comprising:

a first electrode disposed on a first arm;

a second electrode disposed on a second arm, wherein the second electrode is in opposition to the first electrode and offset from the first electrode;

a biasing member configured to urge a portion of the first arm towards a portion of the second arm, wherein at least one of the first and second electrodes is urged towards the other electrode to form a tissue clamping configuration; and

a stimulation circuit in operative communication with the first and second electrodes, wherein the stimulation circuit is configured for generating a stimulation signal after receiving the at least one control signal for actuating at least one of the first and second electrodes for stimulating a nerve within tissue clamped between the first and second electrodes.

13. The system according to claim 12, wherein the smart device is in operative communication with at least one of a memory and a database storing a plurality of treatment regimens corresponding to a plurality of conditions.

14. The system according to claim 12, further comprising a monitoring device in operative communication with at least one of the smart device and the stimulation device, wherein the monitoring device transmits biomarker information to the at least one of the smart device and the stimulation device.

15. The system according to claim 14, wherein the smart device determines at least one condition of a patient using the biomarker information, and wherein the smart device determines at least one treatment regimen from the plurality of treatment regimens for treating the at least one condition of the patient.

16. The system according to claim 12, wherein the smart device includes at least one app having a corresponding graphical user interface for receiving at least one user input for controlling at least one operating parameter of the stimulation device.

17. A method of treatment by stimulating a nerve, the method comprising:

clamping tissue between first and second electrodes of a stimulation device, the first electrode being disposed opposite from the second electrode, and offset from the second electrode; and actuating a stimulating circuit of the stimulation device to generate and deliver a stimulation signal to at least one of the first and second electrodes for stimulating a nerve within the clamped tissue.

18. The method according to claim 17, wherein the tissue is ear tissue and the nerve is an auricular branch of the vagus nerve.

19. The method according to claim 17, further comprising monitoring biomarker information and determining a treatment regimen in accordance with the biomarker information.

20. The method according to claim 17, further comprising changing at least one stimulation parameter of the stimulation device in accordance with biomarker information received by a monitoring device.

21. The method according to claim 20, wherein the monitoring device is external to a patient being treated.

22. The method according to claim 20, wherein the monitoring device is an implantable sensor.

23. The method according to claim 17, further comprising controlling the stimulating circuit of the stimulation device by at least one controller.

24. The method according to claim 23, wherein the at least one controller is in a smart device in operative communication with the stimulation device.

25. The method according to claim 23, further comprising controlling the at least one controller by user input via a graphical user interface.

26. The stimulation device of claim 1, wherein at least one of the first and second arms is configured to move between at least one bent configuration and an unbent configuration.

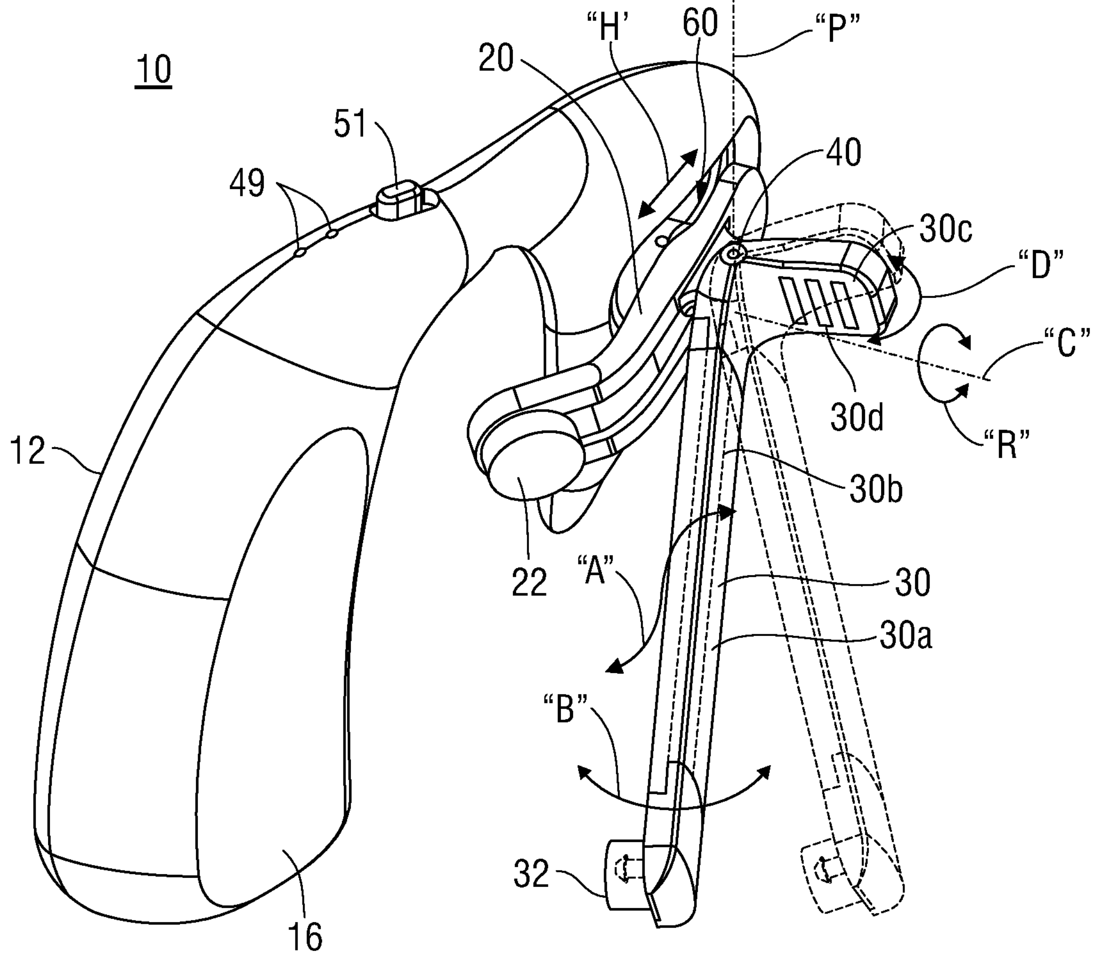

FIG. 1A

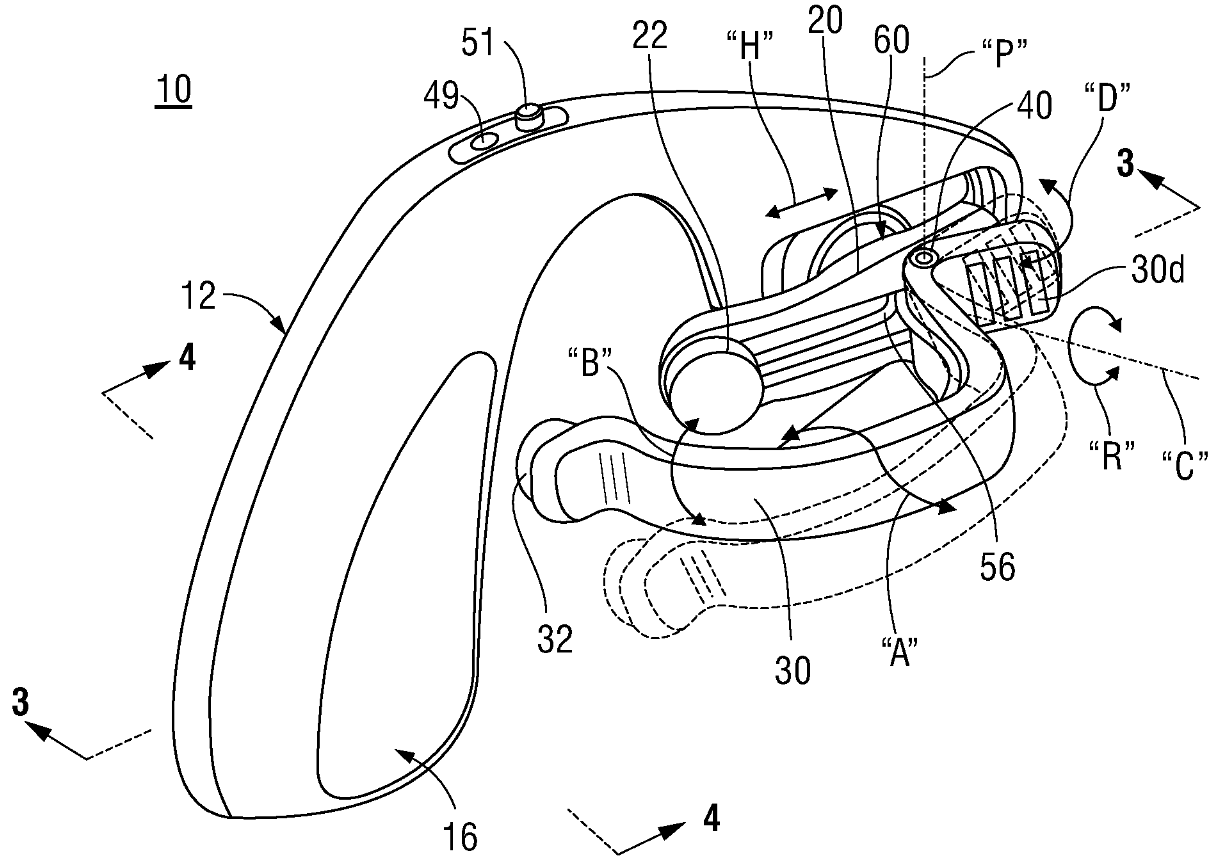

FIG. 1B

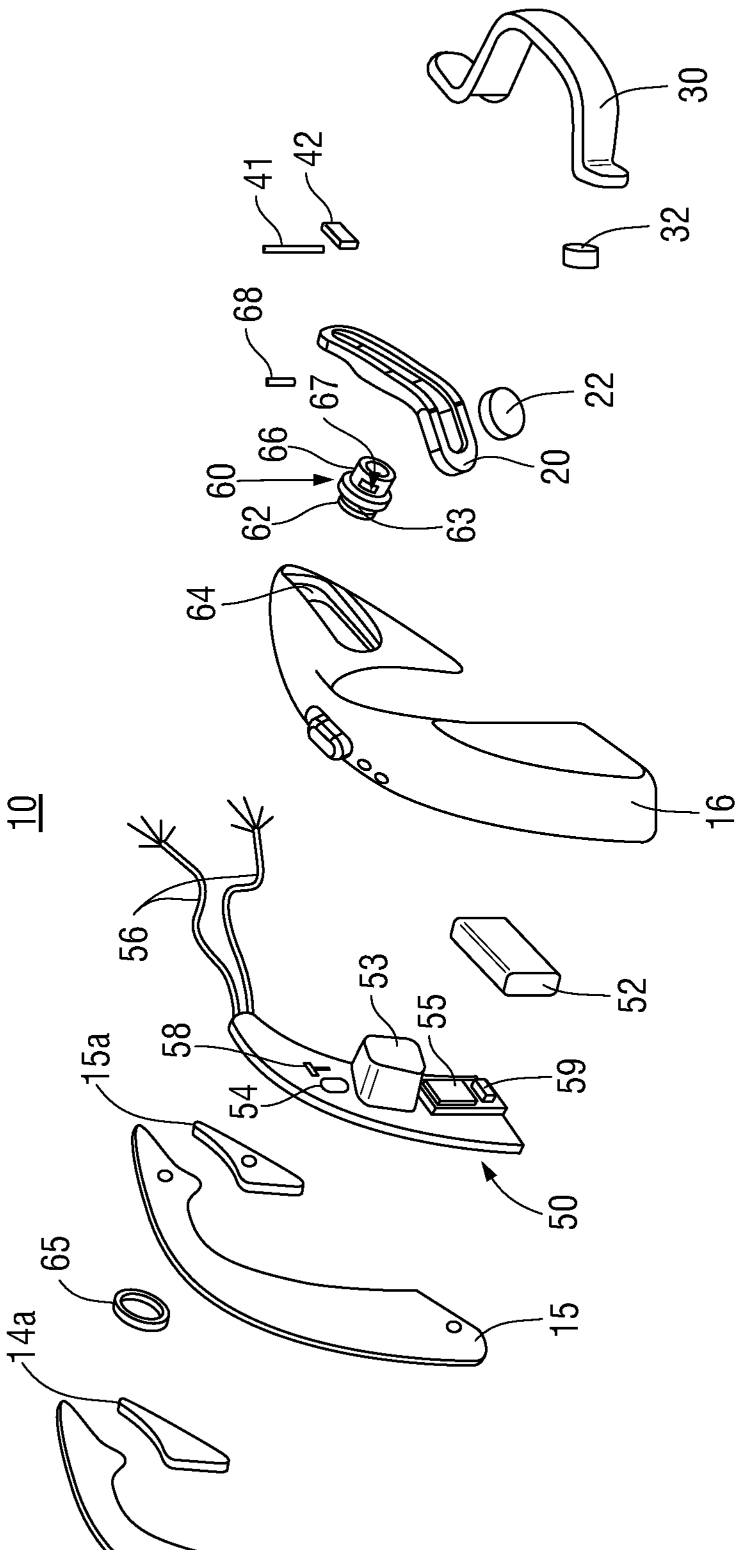
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FIG. 2

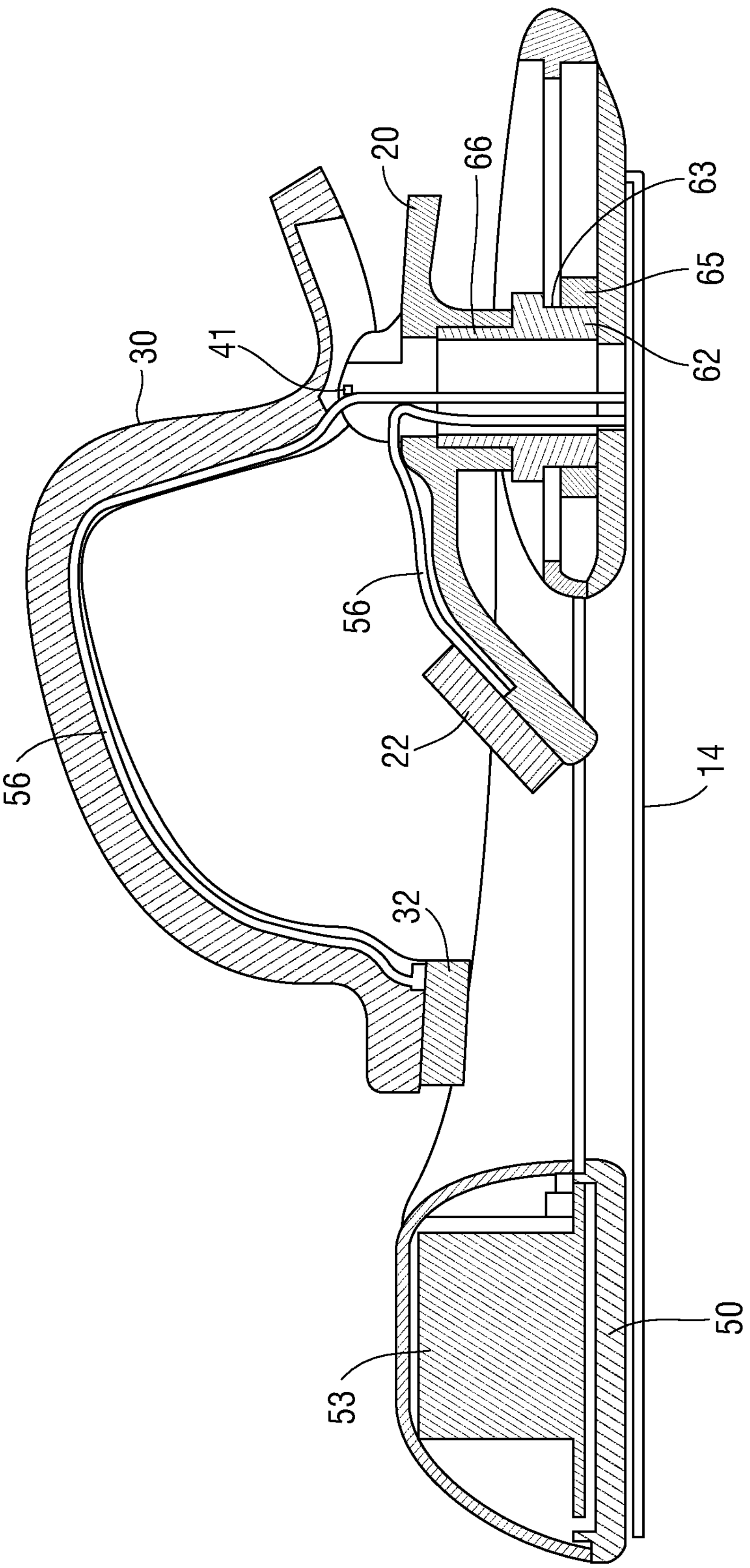


FIG. 3

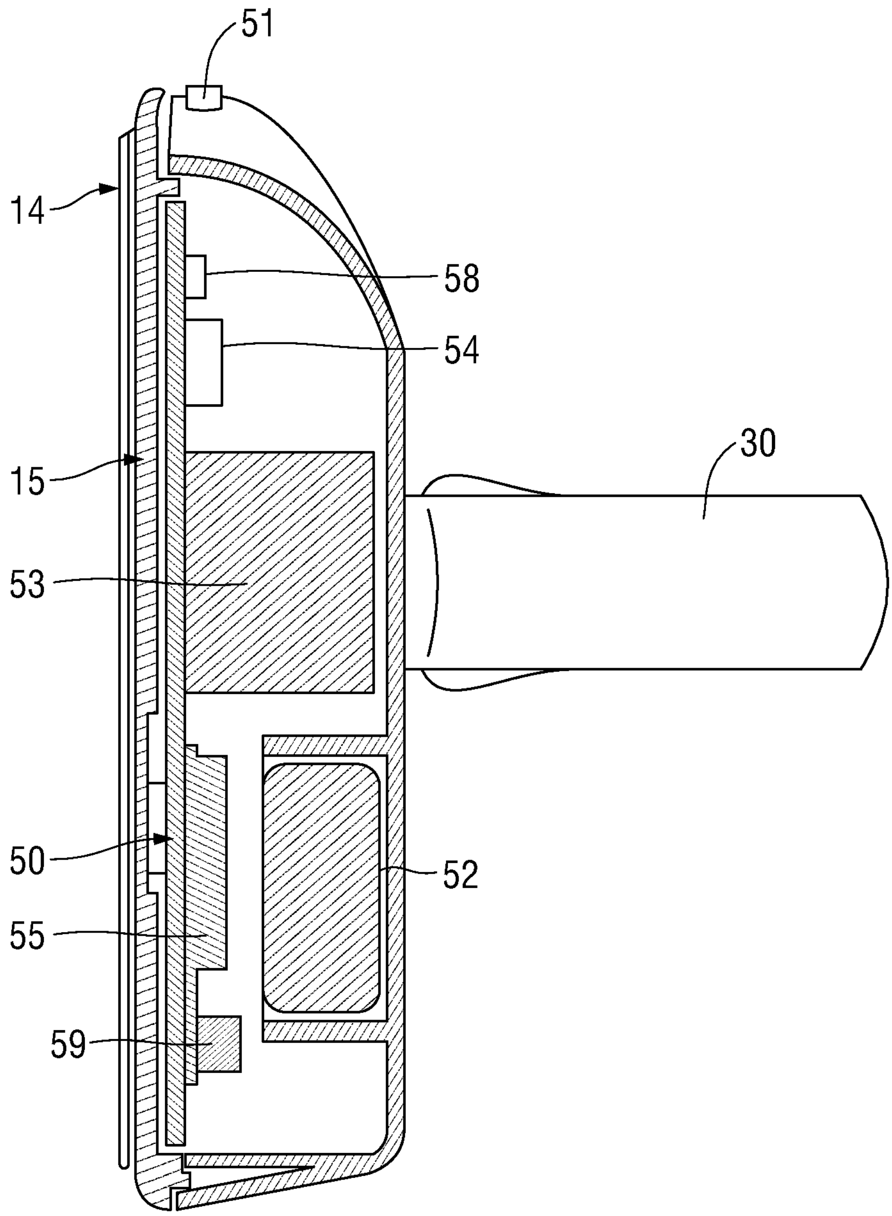


FIG. 4

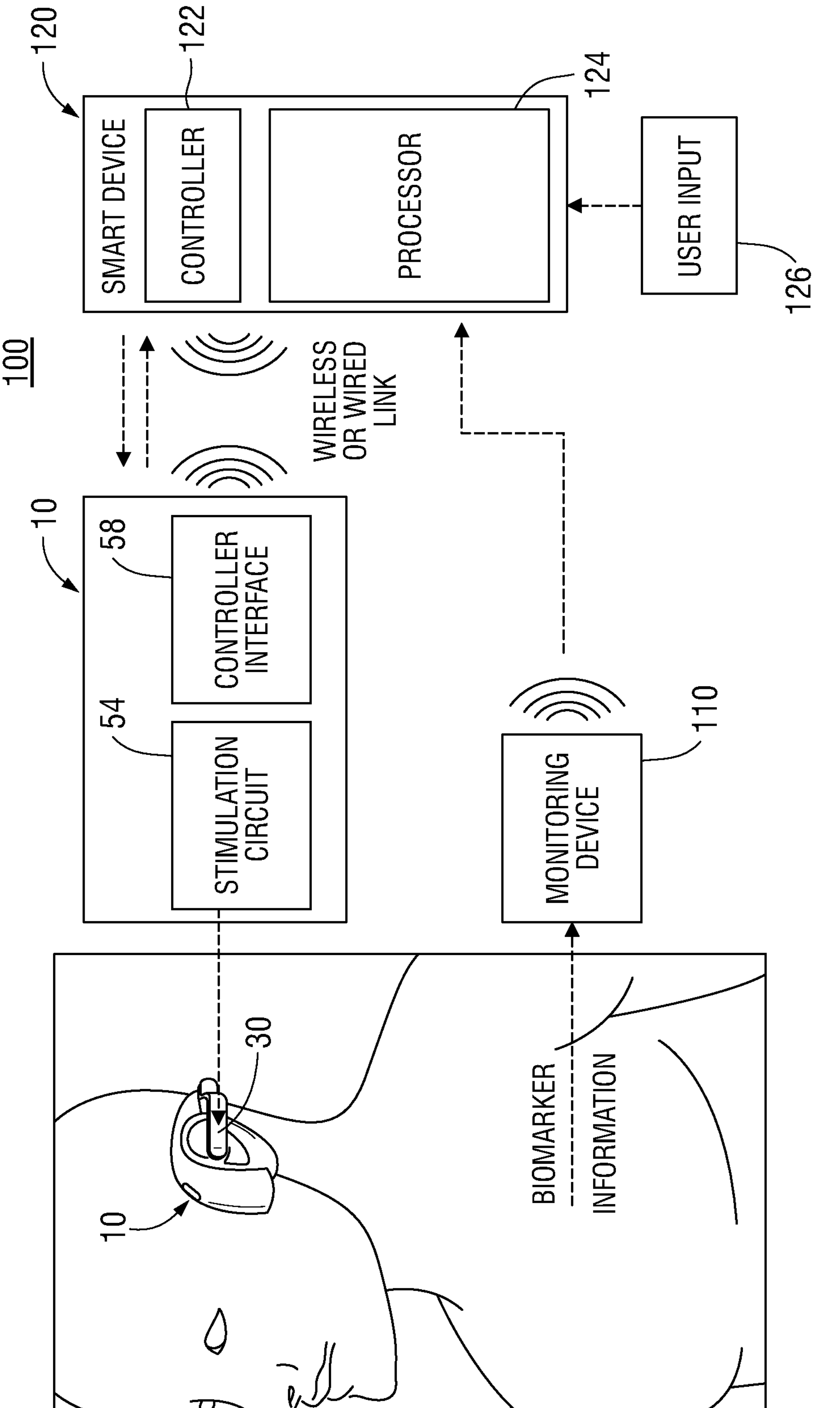

100
120
SMART DEVICE
122
CONTROLLER
124
PROCESSOR
USER INPUT
126
WIRELESS OR WIRED LINK
10
58
CONTROLLER INTERFACE
54
STIMULATION CIRCUIT
MONITORING DEVICE
110
30
BIOMARKER INFORMATION

FIG. 5

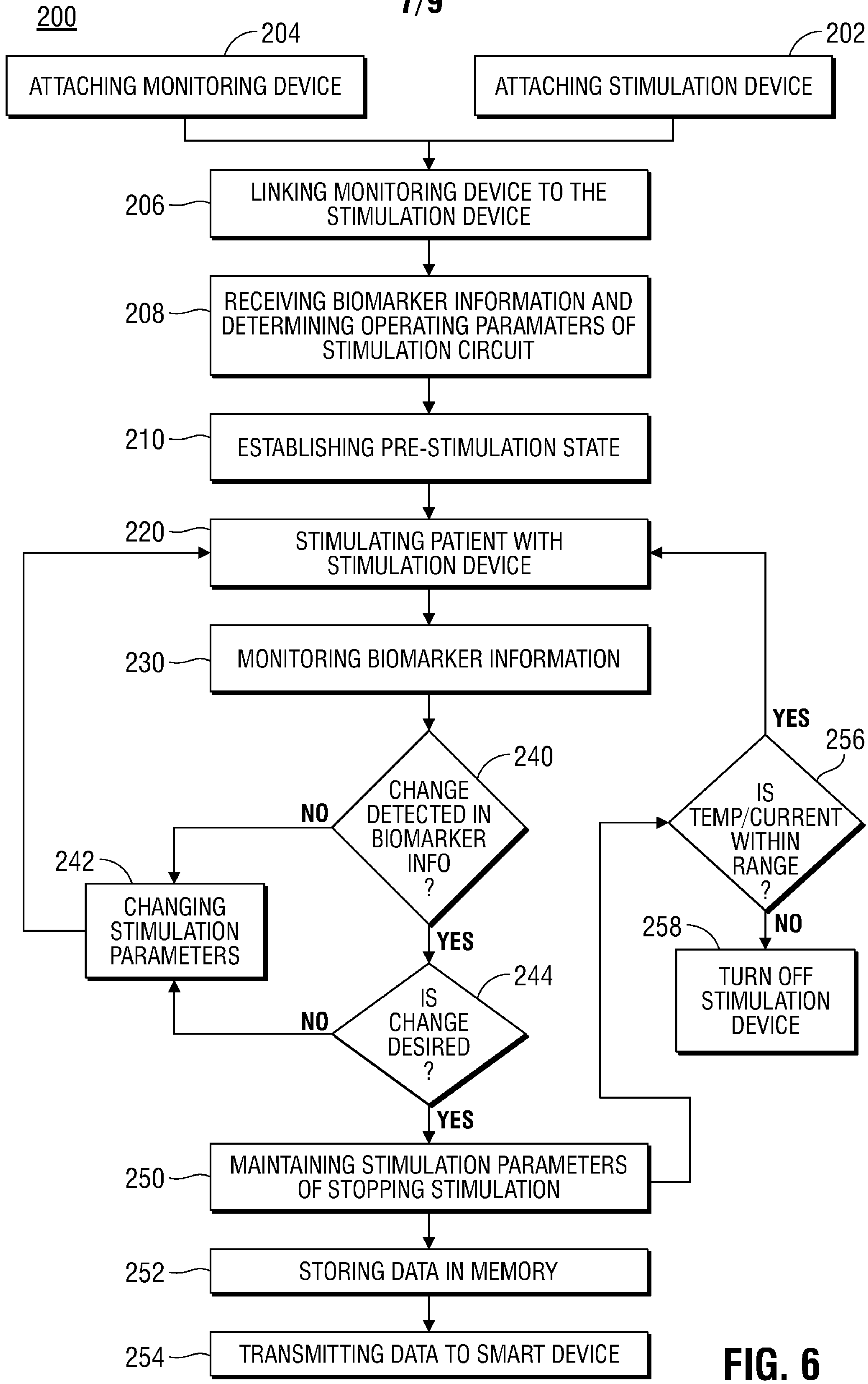
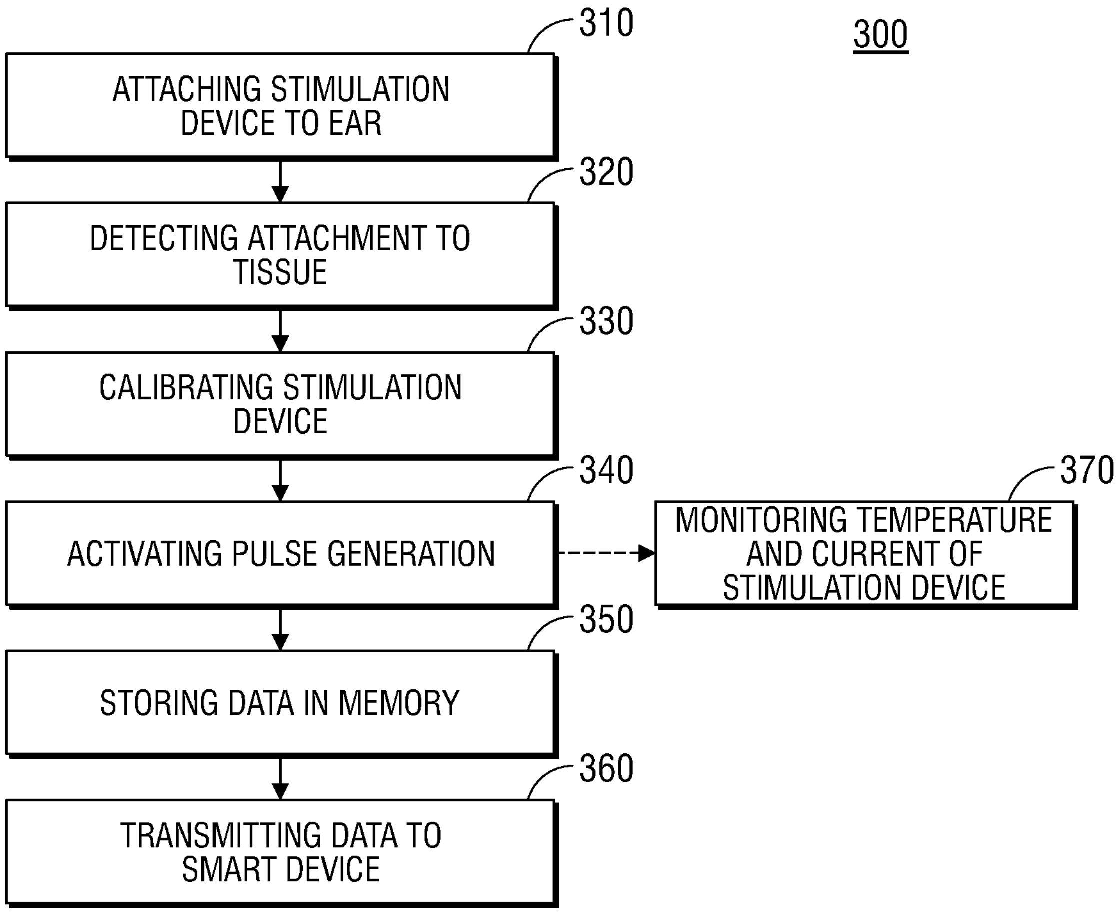

200
204
202
ATTACHING MONITORING DEVICE
ATTACHING STIMULATION DEVICE
206
LINKING MONITORING DEVICE TO THE STIMULATION DEVICE
208
RECEIVING BIOMARKER INFORMATION AND DETERMINING OPERATING PARAMATERS OF STIMULATION CIRCUIT
210
ESTABLISHING PRE-STIMULATION STATE
220
STIMULATING PATIENT WITH STIMULATION DEVICE
230
MONITORING BIOMARKER INFORMATION
240
CHANGE DETECTED IN BIOMARKER INFO ?
NO
YES
242
CHANGING STIMULATION PARAMETERS
244
IS CHANGE DESIRED ?
NO
YES
256
IS TEMP/CURRENT WITHIN RANGE ?
YES
NO
258
TURN OFF STIMULATION DEVICE
250
MAINTAINING STIMULATION PARAMETERS OF STOPPING STIMULATION
252
STORING DATA IN MEMORY
254
TRANSMITTING DATA TO SMART DEVICE

FIG. 6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ATTACHING STIMULATION DEVICE TO EAR
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DETECTING ATTACHMENT TO TISSUE
330
CALIBRATING STIMULATION DEVICE
340
ACTIVATING PULSE GENERATION
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MONITORING TEMPERATURE AND CURRENT OF STIMULATION DEVICE
350
STORING DATA IN MEMORY
360
TRANSMITTING DATA TO SMART DEVICE

FIG. 7

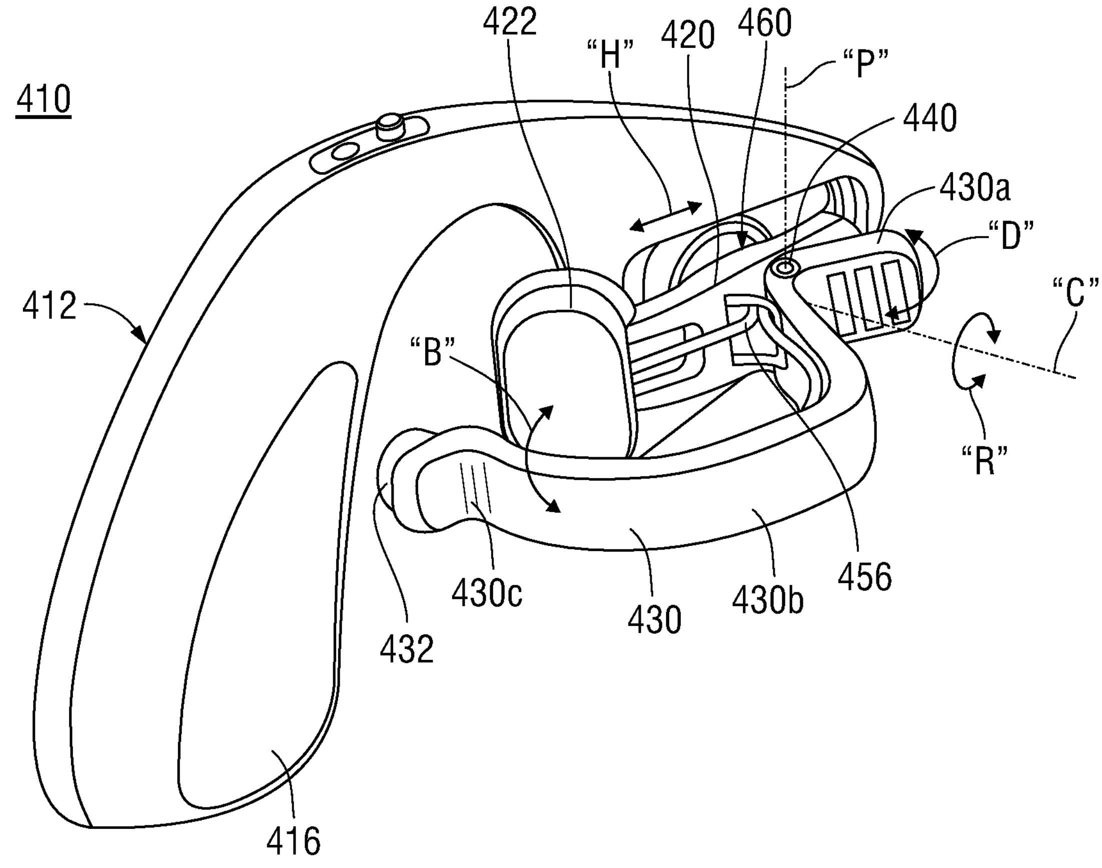

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/044568

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/05 A61B5/00 A61N1/36
ADD.

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)
A61N A61B

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2017/120023 A1 (NERVANA LLC [US]) 13 July 2017 (2017-07-13) abstract; claim *; figure * pages 42-49	1-16,26
A	US 9 415 220 B1 (SPINELLI JULIO CÉSAR [US] ET AL) 16 August 2016 (2016-08-16) the whole document	1-16,26
A	US 2017/043160 A1 (GOODALL ELEANOR V [US] ET AL) 16 February 2017 (2017-02-16) the whole document	1-16,26
A	WO 2015/192114 A1 (NERVANA LLC [US]) 17 December 2015 (2015-12-17) the whole document	1-16,26

☐ 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

"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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 October 2018	19/10/2018

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European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer
Scheffler, Arnaud

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/044568

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. [X] Claims Nos.: 17-25
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210

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:

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 an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 17-25

The method of treatment by stimulation as defined in claims 17-25 is regarded to be a method for treatment of the human or animal body by therapy. Therefore, the subject-matter of claims 17-25 has not been searched (Art.17(2)(a)(i) and Rule 39.1). Moreover, according to Article 34(4)(a)(i) PCT and Rule 67.1(iv) PCT, no international preliminary examination is required to be carried out on the subject-matter of these claims.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2017120023 A1	13-07-2017	AU 2016385453 A1	05-07-2018
		CA 3010057 A1	13-07-2017
		US 2017087364 A1	30-03-2017
		WO 2017120023 A1	13-07-2017
US 9415220 B1	16-08-2016	NONE	
US 2017043160 A1	16-02-2017	NONE	
WO 2015192114 A1	17-12-2015	CA 2951699 A1	17-12-2015
		EP 3154626 A1	19-04-2017
		SG 11201701091Q A	30-05-2017
		US 2015360030 A1	17-12-2015
		US 2017361094 A1	21-12-2017
		WO 2015192114 A1	17-12-2015

patsnap

专利名称(译)	耳刺激仪		
公开(公告)号	EP3661590A1	公开(公告)日	2020-06-10
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[标]申请(专利权)人(译)	范因斯坦医学研究院		
申请(专利权)人(译)	范士丹的医学研究所		
当前申请(专利权)人(译)	范士丹的医学研究所		
[标]发明人	BOUTON CHAD E ZANOS THEODOROS P DATA CHAUDHURI TIMIR B MARTIN ANDREW MONTALBANO CHRISTOPHER MONTALBANO GREGORY BEAMER PHILLIP		
发明人	BOUTON, CHAD E. ZANOS, THEODOROS P. DATA-CHAUDHURI, TIMIR B. MARTIN, ANDREW MONTALBANO, CHRISTOPHER MONTALBANO, GREGORY BEAMER, PHILLIP		
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优先权	62/539178 2017-07-31 US		
外部链接	Espacenet		

摘要(译)

提供一种耳科刺激装置，其表面电极彼此偏置并且彼此偏置。 刺激装置可以定位在患者的耳朵周围，每个电极覆盖包含由迷走神经的耳廓分支提供的神经支配的耳廓耳组织。 电极经皮刺激耳分支。 还提供了一种使用耳廓刺激装置治疗患者的方法。 该刺激装置可以用于治疗患有诸如高血压，抑郁，高血糖水平和耳鸣的病症的患者。 还提供了一种具有耳刺激装置，智能装置和监视装置的诊断和治疗系统。 智能设备基于从监测设备接收的生物标记信息来控制耳廓刺激设备。 以及与患者有关的信息，例如年龄，肌肉骨骼稳定性等； 和/或根据用户输入。