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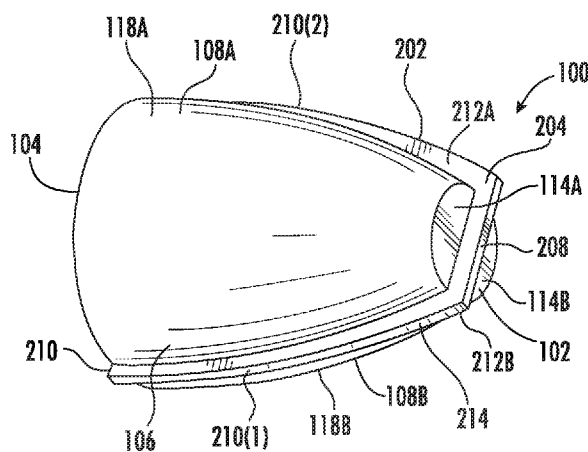


FIG. 2A

(57) Abstract: Disclosed herein are an electrode assembly, an in-ear headphone, an in-ear headphone pair, and an electrode pair assembly, each for non-invasive vagus nerve stimulation. Each of the foregoing items includes a first electrode and a second electrode. An electrode assembly configured for insertion into an ear of a user includes a first electrode, a second electrode, and a slim positioned therebetween. An in-ear headphone or headphone pair may include the electrode assembly with a housing and a waveform generator. An electrode pair assembly may include a first electrode configured for insertion into a first ear of a user, and a second electrode configured for insertion into a second ear of the user. Certain embodiments further include audio components positioned within a housing of at least one in-ear headphone to deliver audio stimulation through a central channel of a first electrode or second electrode, respectively.

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IN-EAR ELECTRODE ASSEMBLY FOR NON-INVASIVE VAGUS NERVE STIMULATION

RELATED APPLICATIONS

5 **[0001]** This application claims the benefit of priority under 35 U.S.C. § 119(e) of U.S. Provisional Application Serial No. 62/552,764 filed on August 31, 2017 and U.S. Provisional Application Serial No. 62/633,692 filed on February 22, 2018, the contents of which are relied upon and incorporated herein by reference in its entirety.

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TECHNICAL FIELD

[0002] The present disclosure relates to non-invasive vagus nerve stimulation. In particular, the present disclosure relates to an in-ear electrode assembly for non-invasive vagus nerve stimulation.

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BACKGROUND

[0003] Stress and anxiety are common emotional responses with differing levels of severity. In fact, over 40 million people in the U.S. are currently diagnosed with some form of anxiety disorder. There are many things that cause stress and anxiety, but the effects can seriously inhibit one's performance and drive, whether in the workplace, at school, at a public event, playing sports, social environments, etc. Some of the most significant effects include increased perspiration, elevated heart and breathing rate, high blood pressure, muscle tremors, and a list of others. It is not typically the stress itself that causes people to perform poorly, but rather these side effects of stress.

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[0004] There are various methods to help reduce the effects of stress, but each is limited. Meditation and mindfulness are very popular and natural stress relief methods, but they take large amounts of time and discipline to perform, and the concept is difficult for many people to understand. Recreational drugs and alcohol can immediately help reduce the effects of stress, but they are not

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considered viable long term treatments and they come with potentially harmful side effects. Other prescription drugs like beta blockers can lower heart rate without any euphoric sensations, but they are expensive, have various side effects, and take a large amount of time before the drug starts to work. People
5 who suffer from stress and anxiety need a solution that is inexpensive and drug-free with immediate relief and little or no side effects.

[0005] Vagus Nerve Stimulation (VNS) helps reduce the effects of stress and anxiety and provides treatment for a list of other ailments (e.g., epilepsy). The vagus nerve (cranial nerve X) is part of the autonomic nervous system. It travels
10 from the brain to the neck, chest, and heart where it regulates a list of automatic physiological functions (e.g., parasympathetic response of the heart, lungs, digestive tract, etc.). When it is depolarized (e.g., electrically stimulated), it simultaneously activates the parasympathetic response and deactivates the sympathetic response, resulting in a decreased heart rate and blood pressure.
15 The vagus nerve can be directly stimulated via a pacemaker-like device with electrodes implanted in the neck. However, due to high cost and high risk procedures, invasive methods to stimulate the vagus nerve are not ideal for general stress and anxiety relief.

[0006] Alternatively, the vagus nerve can be non-invasively stimulated with
20 electrodes placed in the ear canal or on the surface of the neck, but current methods of stimulating the vagus nerve through the neck or the ear both have limitations that prevent their widespread adoption. In particular, stimulation through the neck typically utilizes a sticky electrode, which requires a user's skin to be prepared with alcohol before each use and requires the user to remain still
25 to prevent the electrode from falling off. Another way to stimulate through the neck is with a handheld device, which can be more comfortable, but inhibits the user's freedom and mobility, since the handheld device must be held against the user's neck for the duration of treatment.

[0007] Stimulating the vagus nerve through the ear is generally more
30 appealing than through the neck, but it has its limitations as well. For example,

some devices for stimulating the vagus nerve through the ear include electrodes that need to be soaked in a saline solution to work, which may cause the electrodes to be uncomfortable, easily dislodged, and require resoaking after each use (since the saline solution dries quickly). Other ear electrodes can stimulate the vagus nerve without requiring saline solution, but they are neither comfortable nor designed for recreational use by people with active lifestyles. For example, some ear electrodes include spherical metal tips to deliver current to the vagus nerve, but the stimulation is painful due to the low resistance and high current density of the metal electrodes.

[0008] These and other technical challenges impede widespread adoption by the public of non-invasive vagus nerve stimulation.

SUMMARY

[0009] Disclosed herein are an electrode assembly, an in-ear headphone, an in-ear headphone pair, and an electrode pair assembly, each for non-invasive vagus nerve stimulation. Each of the foregoing items includes a first electrode and a second electrode, which may be fabricated of conductive silicone (e.g., entailing less pain than metal electrodes). An electrode assembly configured for insertion into an ear of a user includes a first electrode, a second electrode, and a shim positioned therebetween to separate and electrically insulate the first electrode and second electrode from one another. In such an electrode assembly, the first electrode and the second electrode may be complementary in shape such that the electrode assembly forms a frustoconical-shape to maximize surface area contact of the electrode assembly within the ear. An in-ear headphone or headphone pair may include an electrode assembly as previously described, in conjunction with a housing and a waveform generator positioned in the housing and configured to apply an electric signal to the electrode assembly. As an alternative to an electrode assembly, an electrode pair assembly may include a first electrode configured for insertion into a first ear of a user, and a second electrode configured for insertion into a second ear of the user, with the

electrode pair assembly being configured to form an electrical circuit when the first electrode is positioned in the first ear and the second electrode is positioned in the second ear of the user. Certain embodiments further include audio components positioned within a housing of at least one in-ear headphone to deliver audio stimulation through a central channel of a first electrode or second electrode, respectively.

[0010] In some embodiments, an electrode assembly includes an electrically conductive gel with separate portions positioned over the first electrode and/or second electrode (e.g., a first conductive gel portion on the first electrode and a second conductive gel portion on the second electrode) to increase distribution of current density for a more pleasant user experience without requiring reapplication between uses. For example, the conductive gel may include a hydrogel (e.g., dry and/or firm, etc.) deposited (e.g., pre-applied) on the first electrode and the second electrode, such as during a manufacturing process. In this way, the hydrogel stays in place on the first electrode and the second electrode and application by a consumer is not required. In some embodiments, the electrode assembly may be formed into an in-ear headphone tip, such as used in an in-ear headphone pair, to provide both electrical stimulation and audio stimulation to the ear. Accordingly, the dry and reusable electrode assembly maximizes or at least enhances skin contact for better non-invasive stimulation of the vagus nerve and increases current distribution for a more pleasant user experience.

[0011] In an aspect, the present disclosure relates to an electrode assembly for non-invasive nerve stimulation comprising a first electrode, a second electrode, and a shim. The first electrode forms a first body portion. The second electrode forms a second body portion complementary to the first body portion such that the first body portion of the first electrode and the second body portion of the second electrode in combination form a frustoconical-shape. The shim, optionally formed of a plastic material, is positioned between the first electrode and the second electrode to separate and electrically insulate the first electrode

and the second electrode from each other. The electrode assembly is configured for insertion into an ear of a user of the electrode assembly to form an electrical circuit including the first electrode, the second electrode, and a vagus nerve of the user to electrically stimulate the vagus nerve.

5 **[0012]** In certain embodiments, the first electrode and the second electrode comprise conductive silicone. In certain embodiments, the shim comprises a plastic material. In certain embodiments, the electrode assembly further comprises a conductive gel covering at least a portion of an outer surface of at least one of the first electrode or the second electrode. In certain embodiments,
10 the conductive gel comprises a hydrogel.

[0013] In certain embodiments, the shim comprises a ridge that extends beyond the outer surface of the first electrode and the second electrode. The conductive gel comprises a first gel portion covering at least a portion of the first electrode and a second gel portion covering at least a portion of the second
15 electrode. The first gel portion and the second gel portion are electrically insulated from each other by the ridge. In certain embodiments, the first electrode and the second electrode are substantially a same size and the shim is positioned in an approximate middle of the electrode assembly. In certain embodiments, the first electrode and the second electrode are differently sized
20 and the shim is positioned offset from a middle of the electrode assembly.

[0014] In another aspect, the present disclosure relates to an in-ear headphone comprising a housing, an electrode assembly, and a waveform generator. The electrode assembly forms an in-ear headphone tip attached to the housing. The electrode assembly comprises a first electrode, a second
25 electrode, and a shim. The first electrode forms a first body portion. The second electrode forms a second body portion complementary to the first body portion such that the first body portion of the first electrode and the second body portion of the second electrode in combination form a frustoconical-shape. The shim is positioned between the first electrode and the second electrode to separate and
30 electrically insulate the first electrode and the second electrode from each other.

The electrode assembly is configured for insertion into an ear of a user to form an electrical circuit including the first electrode, the second electrode, and a vagus nerve of the user to electrically stimulate the vagus nerve. The waveform generator is positioned within the housing and configured to apply an electric signal to the electrode assembly to stimulate the vagus nerve.

[0015] In certain embodiments, the first electrode and the second electrode comprise conductive silicone. In certain embodiments, the shim comprises a plastic material. In certain embodiments, the in-ear headphone further comprises a conductive gel covering at least a portion of an outer surface of at least one of the first electrode or the second electrode. In certain embodiments, the in-ear headphone comprises a signal transmitter and a signal receiver configured to permit wireless communication with an electronic device external to the in-ear headphone. In certain embodiments, the in-ear headphone is configured to allow a user to adjust an operating parameter of the waveform generator by an electronic device. The operating parameter comprises at least one of intensity, duration, or pulse pattern. In certain embodiments, the in-ear headphone comprises audio components within the housing. The audio components are configured to deliver audio stimulation through a central channel defined in the electrode assembly. The in-ear headphone is configured to provide the audio stimulation concurrently with electrical stimulation of the vagus nerve.

[0016] In another aspect, the present disclosure relates to an in-ear headphone pair comprising a right in-ear headphone and a left in-ear headphone. The right in-ear headphone is configured for insertion into a right ear, and comprises audio components configured to deliver audio stimulation to the right ear. The left in-ear headphone is configured for insertion into a left ear, and comprises a housing, an electrode assembly, a waveform generator, and audio components. The electrode assembly forms an in-ear headphone tip attached to the housing. The electrode assembly comprises a first electrode, a second electrode, and a shim. The first electrode forms a first body portion. The second electrode forms a second body portion complementary to the first body

portion such that the first body portion of the first electrode and the second body portion of the second electrode in combination form a frustoconical-shape. The shim is positioned between the first electrode and the second electrode to separate and electrically insulate the first electrode and the second electrode from each other. The electrode assembly is configured for insertion into an ear of a user to form an electrical circuit including the first electrode, the second electrode, and a vagus nerve of the user of the electrode assembly to electrically stimulate the vagus nerve. The waveform generator is positioned within the housing and configured to apply an electrical signal to the electrode assembly to stimulate the vagus nerve. The audio components are positioned within the housing and configured to deliver audio stimulation to the left ear through a central channel of the electrode assembly.

[0017] In certain embodiments, the first electrode and the second electrode comprise conductive silicone. In certain embodiments, the shim comprises a plastic material. In certain embodiments, the in-ear headphone pair further comprises a conductive gel covering at least a portion of an outer surface of at least one of the first electrode or the second electrode. In certain embodiments, the in-ear headphone comprises a signal transmitter and a signal receiver configured to permit wireless communication with an electronic device external to the in-ear headphone pair. In certain embodiments, the left in-ear headphone is configured to deliver the audio stimulation concurrently with electrical stimulation.

[0018] In another aspect, the present disclosure relates to an electrode pair assembly for non-invasive nerve stimulation comprising a first electrode and a second electrode. The first electrode forms a first frustoconical-shape configured for insertion into a first ear of a user, and the second electrode forms a second frustoconical-shape configured for insertion into a second ear of the user. The electrode pair assembly is configured to form an electrical circuit when the first electrode is positioned within the first ear of the user and the second electrode is positioned within the second ear of the user. The electrical circuit includes the

first electrode, the second electrode, and a vagus nerve of the user to electrically stimulate the vagus nerve.

[0019] In certain embodiments, the first electrode and the second electrode are in conductive electrical communication via electrical wiring. In certain
5 embodiments, at least one of the first electrode or the second electrode comprises conductive silicone. In certain embodiments, at least one of the first electrode or the second electrode comprises a conductive gel. In certain embodiments, the electrode pair assembly further comprises a conductive gel covering at least a portion of an outer surface of at least one of the first electrode
10 or the second electrode. In certain embodiments, the conductive gel comprises a hydrogel. In certain embodiments, the first electrode comprises a first conductive gel forming the first frustoconical-shape, and the second electrode comprises a second conductive gel forming the second frustoconical-shape. In certain embodiments, the first conductive gel comprises a first hydrogel and the second
15 conductive gel comprises a second hydrogel.

[0020] In another aspect, the present disclosure relates to an in-ear headphone pair comprising a first in-ear headphone and a second in-ear headphone. The first in-ear headphone is configured for insertion into a first ear of a user. The first in-ear headphone comprises a first housing, a first electrode,
20 and first audio components. The first electrode forms a first in-ear headphone tip attached to the first housing. The first electrode defines a first central channel. The first audio components are positioned within the first housing and are configured to deliver audio stimulation to the first ear through the first central channel of the first electrode. The second in-ear headphone is configured for
25 insertion into a second ear of the user. The second in-ear headphone comprises a second housing, a second electrode, and second audio components. The second electrode forms a second in-ear headphone tip attached to the second housing. The second electrode defines a second central channel. The second audio components are positioned within the second housing and are configured
30 to deliver audio stimulation to the second ear through the second central channel

of the second electrode. The in-ear headphone pair is configured to form an electrical circuit when the first electrode is positioned within the first ear of the user and the second electrode is positioned within the second ear of the user. The electrical circuit includes the first electrode, the second electrode, and a
5 vagus nerve of the user to electrically stimulate the vagus nerve.

[0021] In certain embodiments, the in-ear headphone pair further comprises electrical wiring electrically connecting the first electrode to the second electrode. In certain embodiments, at least one of the first electrode or the second electrode comprises conductive silicone. In certain embodiments, at least one of the first
10 electrode or the second electrode comprises an electrically conductive gel. In certain embodiments, the in-ear headphone pair further comprises a conductive gel covering at least a portion of an outer surface of at least one of the first electrode or the second electrode. In certain embodiments, the conductive gel comprises a hydrogel. In certain embodiments, the first electrode forms a first
15 frustoconical-shape and the second electrode forms a second frustoconical-shape. In certain embodiments, the first electrode comprises a first conductive gel forming the first frustoconical-shape, and the second electrode comprises a second conductive gel forming the second frustoconical-shape. In certain embodiments, the first conductive gel comprises a first hydrogel and the second
20 conductive gel comprises a second hydrogel. In certain embodiments, at least one of the first in-ear headphone or the second in-ear headphone comprises a signal transmitter and a signal receiver configured to permit wireless communication with an electronic device external to the first in-ear headphone and the second in-ear headphone. In certain embodiments, at least one of the
25 first in-ear headphone or the second in-ear headphone is configured to deliver the audio stimulation concurrently with electrical stimulation. In certain embodiments, at least one of the first in-ear headphone or the second in-ear headphone includes a waveform generator configured to apply an electrical signal to at least one of the first electrode or the second electrode. In certain
30 embodiments, the at least one of the first in-ear headphone and the second in-

ear headphone is configured to allow the user to adjust an operating parameter of the waveform generator by an electronic device. The operating parameter comprises at least one of intensity, duration, or pulse pattern. In certain embodiments, the waveform generator is configured to deliver a biphasic waveform.

[0022] In certain embodiments, one of the first electrode or the second electrode comprises an anode, and the other of the first electrode or the second electrode comprises a cathode.

[0023] In another aspect, any one or more aspects or features described herein may be combined with any one or more other aspects or features for additional advantage.

[0024] Other aspects and embodiments will be apparent from the detailed description and accompanying drawings.

[0025] Those skilled in the art will appreciate the scope of the present disclosure and realize additional aspects thereof after reading the following detailed description of the preferred embodiments in association with the accompanying drawing figures.

BRIEF DESCRIPTION OF DRAWINGS

[0026] FIG. 1A is a top front perspective view of an electrode assembly for non-invasive vagus nerve stimulation with wires attached thereto;

[0027] FIG. 1B is another top front perspective view of the electrode assembly of FIG. 1A;

[0028] FIG. 1C is a top back perspective view of the electrode assembly of FIG. 1A;

[0029] FIG. 2A is a top front perspective view of the electrode assembly of FIGS. 1A-1C with a shim with ridges for separating a first electrode and a second electrode, and separating portions of conductive gel on each of the first electrode and the second electrode;

[0030] FIG. 2B is a bottom perspective view of the electrode assembly of FIG. 2A;

[0031] FIG. 2C is a top elevation view of the electrode assembly of FIG. 2A;

[0032] FIG. 2D is a cross-sectional side view of the electrode assembly of FIG. 2A;

[0033] FIG. 2E is a front elevation view of the electrode assembly of FIG. 2A;

[0034] FIG. 2F is a back elevation view of the electrode assembly of FIG. 2A;

[0035] FIG. 3 is a perspective view of another embodiment of the electrode assembly of FIGS. 1A-2F with an offset shim separating an asymmetric first electrode and second electrode;

[0036] FIG. 4A is a top front perspective view of another embodiment of the electrode assembly of FIGS. 1A-2F forming an in-ear headphone tip;

[0037] FIG. 4B is a bottom perspective view of the electrode assembly of FIG. 4A;

[0038] FIG. 4C is a top elevation view of the electrode assembly of FIG. 4A;

[0039] FIG. 4D is a cross-sectional side view of the electrode assembly of FIG. 4A;

[0040] FIG. 4E is a front elevation view of the electrode assembly of FIG. 4A;

[0041] FIG. 4F is a back elevation view of the electrode assembly of FIG. 4A;

[0042] FIG. 5 is a general diagram illustrating an in-ear headphone pair including the in-ear headphone tip of FIGS. 4A-4F;

[0043] FIG. 6 is a perspective view of another embodiment of a stimulation electrode assembly with the in-ear headphone tip of FIG. 5 and with a return path electrode assembly;

[0044] FIG. 7 is a perspective view of another embodiment of an in-ear headphone pair for non-invasive vagus nerve stimulation; and

[0045] FIG. 8 is a general diagram illustrating the in-ear headphone pair of FIG. 7.

DETAILED DESCRIPTION

[0046] The embodiments set forth below represent the necessary information to enable those skilled in the art to practice the embodiments and illustrate the best mode of practicing the embodiments. Upon reading the following description in light of the accompanying drawing figures, those skilled in the art will understand the concepts of the disclosure and will recognize applications of these concepts not particularly addressed herein. It should be understood that these concepts and applications fall within the scope of the disclosure and the accompanying claims.

[0047] It will be understood that, although the terms first, second, etc. may be used herein to describe various elements, these elements should not be limited by these terms. These terms are only used to distinguish one element from another. For example, a first element could be termed a second element, and, similarly, a second element could be termed a first element, without departing from the scope of the present disclosure. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items.

[0048] It will be understood that when an element such as a layer, region, or substrate is referred to as being "on" or extending "onto" another element, it can be directly on or extend directly onto the other element or intervening elements may also be present. In contrast, when an element is referred to as being "directly on" or extending "directly onto" another element, there are no intervening elements present. Likewise, it will be understood that when an element such as a layer, region, or substrate is referred to as being "over" or extending "over" another element, it can be directly over or extend directly over the other element or intervening elements may also be present. In contrast, when an element is referred to as being "directly over" or extending "directly over" another element, there are no intervening elements present. It will also be understood that when an element is referred to as being "connected" or "coupled" to another element, it can be directly connected or coupled to the other element or intervening elements may be present. In contrast, when an element

is referred to as being "directly connected" or "directly coupled" to another element, there are no intervening elements present.

[0049] Relative terms such as "below" or "above" or "upper" or "lower" or "horizontal" or "vertical" may be used herein to describe a relationship of one element, layer, or region to another element, layer, or region as illustrated in the drawing figures. It will be understood that these terms and those discussed above are intended to encompass different orientations of the device in addition to the orientation depicted in the drawing figures.

[0050] The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the disclosure. As used herein, the singular forms "a," "an," and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises," "comprising," "includes," and/or "including" when used herein specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof.

[0051] Unless otherwise defined, all terms (including technical and scientific terms) used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure belongs. It will be further understood that terms used herein should be interpreted as having a meaning that is consistent with their meaning in the context of this specification and the relevant art and will not be interpreted in an idealized or overly formal sense unless expressly so defined herein.

[0052] Disclosed herein is an electrode assembly for non-invasive vagus nerve stimulation. In particular, the electrode assembly is configured for insertion into an ear of a user and includes a first electrode, a second electrode, and a shim positioned therebetween. The first electrode and second electrode may be made of conductive silicone which provides for improved stimulation (e.g., less painful than metal electrodes). The shim separates and electrically insulates the

first electrode from the second electrode from each other. The first electrode and the second electrode are complementary in shape such that the electrode assembly forms a frustoconical-shape to maximize surface area contact of the electrode assembly within the ear. In some embodiments, the electrode assembly includes a conductive gel with separate portions positioned over the first electrode and/or second electrode (e.g., a first conductive gel portion on the first electrode and a second conductive gel portion on the second electrode) to increase distribution of current density for a more pleasant user experience and which does not need to be reapplied between uses. For example, the conductive gel may include a hydrogel (e.g., dry and/or firm, etc.) deposited (e.g., pre-applied) on the first electrode and the second electrode, such as during a manufacturing process. In this way, the hydrogel stays in place on the first electrode and the second electrode and post-sale application by a consumer is not required. In some embodiments, the electrode assembly may be formed into an in-ear headphone tip, such as used in an in-ear headphone pair, to provide both electrical stimulation and audio stimulation to the ear. Accordingly, the dry and reusable electrode assembly maximizes skin contact for better non-invasive stimulation of the vagus nerve and increases current distribution for a more pleasant user experience.

[0053] FIGS. 1A-1C are views of an electrode assembly **100** for non-invasive vagus nerve stimulation. In particular, the electrode assembly **100** is configured for non-invasively stimulating (e.g., modulating) the activity of one or more nerve parts of the auricular branch of the vagus nerve. Stimulating (e.g., depolarizing) the vagus nerve can have significant relaxing effects on the body, such as by lowering heart rate and blood pressure, reducing breathing rate and adrenaline, etc. Accordingly, devices disclosed herein may be used for medical or therapeutic purposes, mitigating deleterious side effects of high stress jobs or situations, etc.

[0054] The electrode assembly **100** is configured for insertion into an ear canal of an ear of a user. The electrode assembly **100** is of a generally

frustoconical-shape, which as used herein, includes shapes generally similar to a cone, parabolic cone, elliptical cone, etc. In other words, the frustoconical-shape, as used herein, refers to a truncated bell-shape, flat-nose bullet-shape, truncated ellipsoidal cone, truncated parabolic cone, etc. In particular, the electrode assembly **100** includes a proximal end **102** (e.g., planar proximal end), a distal end **104** (e.g., planar distal end) opposite the planar proximal end **102**, and a curved outer surface **106**. However, other shapes could be used, such as a semi-spherical shape, etc.

[0055] The electrode assembly **100** includes a first electrode **108A** (e.g., anode), a second electrode **108B** (e.g., cathode), and a shim **110** positioned therebetween. In other words, the electrode assembly **100** includes an electrode pair including the first electrode **108A** and the second electrode **108B**. One or both of the first electrode **108A** and the second electrode **108B** include a conductive material, such as conductive silver and/or conductive silicone (e.g., carbon filled silicone, silver filled silicone, etc.). The first electrode **108A** and the second electrode **108B** are complementary in shape to form the overall frustoconical-shape of the electrode assembly **100**. In particular, the first electrode **108A** includes a first body portion **112A** having a proximal end **114A**, a distal end **116A** opposite the proximal end **114A**, a curved outer surface **118A** extending between the proximal end **114A** and distal ends **116A**, and a planar internal surface **120A** extending between the proximal end **114A** and the distal end **116A**. Similarly, the second electrode **108B** includes a second body portion **112B** having a proximal end **114B**, a distal end **116B** opposite the proximal end **114B**, a curved outer surface **118B** extending between the proximal end **114B** and the distal end **116B**, and a planar internal surface **120B** extending between the proximal end **114B** and the distal end **116B**. Accordingly, when assembled, the internal surfaces **120A**, **120B** of the first electrode **108A** and the second electrode **108B** are proximate to one another, such that the proximal ends **114A**, **114B**, distal ends **116A**, **116B**, and curved outer surfaces **118A**, **118B** of the first electrode **108A** and the second electrode **108B** form the overall frustoconical-

shape of the electrode assembly **100**. In other words, the first body portion **112A** of the first electrode **108A** and the second body portion **112B** of the second electrode **108B** in combination form the frustoconical-shape of the electrode assembly **100**. Further, the electrode assembly **100** includes a first wire **122A** connected to the distal end **116A** of the first electrode **108A** and a second wire **122B** connected to the distal end **116B** of the second electrode **108B**. The first and the second wires **122A**, **122B** may be inserted into the first electrode **108A** and the second electrode **108B** (e.g., pressed into during or after the curing phase of the anode **108A** and second electrode **108B**) or otherwise touching the first electrode **108A** and the second electrode **108B**. For example, rather than inserting the wires **122A**, **122B** into the first electrode **108A** and the second electrode **108B**, the electrode assembly **100** (e.g., first electrode **108A** and the second electrode **108B**) may be configured with one or more holes (as similarly shown in **FIGS. 4A-4F**) to slide over and contact at least a portion of a first wire **122A** and the second wire **122B**, such as where the first wire **122A** and the second wire **122B** are exposed metal contacts of an in-ear housing. Such a configuration may make the manufacturing process less complex and allow for an improved user experience.

[0056] The frustoconical-shape of the electrode assembly **100** facilitates insertion into user ears of various sizes and increases the surface area of contact between the electrode assembly **100** and skin (e.g., skin tissue) within the ear canal of the ear of the user. Further, it is noted that the electrode assembly **100** is configured to be inserted such that the shim **110** is oriented horizontally to a head of the user. In other words, the electrode assembly **100** is configured for insertion such that the shim **110** extends from front to back of the head of the user (not vertically from top to bottom). Such an orientation provides electrical stimulation within the ear canal from top to bottom (not front to back). In particular, in certain embodiments, the first electrode **108A** includes the anode and the second electrode **108B** includes the cathode such that electrical stimulation within the ear canal is from top to bottom. This increases the

effectiveness of stimulating the vagus nerve, since nerve endings of the vagus nerve are more concentrated in the bottom of the ear canal.

[0057] The shim **110** is positioned between the first electrode **108A** and the second electrode **108B** to separate and electrically insulate the first electrode **108A** and the second electrode **108B** from each other. In this way, when the electrode assembly **100** is positioned within the ear, the skin (e.g., skin tissue) within the ear canal of the user completes the circuit. The shim **110** may be made of plastic or other electrically insulative material and may be of any thickness (e.g., 0.5 mm, 1 mm, 2 mm, etc.). The shim **110** is shown as planar, but in other embodiments may be angled in a non-planar configuration, as explained below in more detail. The shim **110** is positioned in the general middle of the electrode assembly **100** to bisect the first electrode **108A** and the second electrode **108B**. In other words, the shim **110** intersects and is oriented along a center axis of the electrode assembly **100**. In particular, the shim **110** is positioned proximate the planar surfaces **120A**, **120B** of the first electrode **108A** and the second electrode **108B** and extends from the proximal end **102** and distal end **104** of the electrode assembly **100** and from one side of the curved outer surface through a center of the electrode assembly to another side of the curved outer surface. In this way, the first electrode **108A** and the second electrode **108B** are about the same size (e.g., same volume, same dimensions, etc.).

[0058] When the electrode assembly **100** is inserted into an ear of a user and an electrical signal is generated, an electrical circuit is formed which includes the first electrode **108A**, second electrode **108B**, skin tissue within the ear canal of the user, and vagus nerve of the user to electrically stimulate the vagus nerve. The electrical signal could be alternating current (AC) or direct current (DC). In certain embodiments, the electrical signal comprises a pulsed DC signal.

[0059] As explained in more detail below, an electrically conductive gel **124** (e.g., a hydrogel) may be applied to the curved outer surface **106** of the electrode assembly **100** to maximize contact with the skin in the ear canal and to increase

current distribution for increased comfort. For illustrative purposes, the conductive gel **124** is shown in dashed lines. In other words, it reduces a sensation of electric shock experienced by the user. When applied, the conductive gel **124** (also referred to herein as a conductive gel coating, etc.) includes a first portion **126A** in contact with and/or covering the first electrode **108A**, and a second portion **126B** in contact with and/or covering the second electrode **108B**. The conductive gel **124** increases distribution of current density within the ear canal for increased comfort during stimulation for a better user experience. Further, the conductive gel **124** does not need to be reapplied between uses, since it does not wear off easily and does not dry out quickly, especially compared with saline. Additionally, the friction and feel of the conductive gel **124** is improved, and is also less likely to fall out since it is more viscous than saline. Accordingly, the electrode assembly **100** provides reusable, comfortable, and drier stimulation of the vagus nerve.

[0060] **FIGS. 2A-2F** are views of another embodiment of the electrode assembly **200** of **FIGS. 1A-1C** with a shim **110** with ridges **204**. The shim **110** includes an internal planar surface **206** (see **FIG. 2D**) positioned between the first electrode **108A** and the second electrode **108B** and a ridge **204** extending from an outer surface **106** of the electrode assembly **100**. The ridge **204** includes a proximal end **208** extending past the proximal ends **114A**, **114B** of the first electrode **108A** and the second electrode **108B**, and first and second curves **210(1)**, **210(2)** extending past the curved outer surfaces **118A**, **118B** of the first electrode **108A** and the second electrode **108B**. These ridges **204** further ensure electrical insulation between the first electrode **108A** and the second electrode **108B**. Further, the ridges **204** provide an attachment point and divide for the first and second portions **126A**, **126B** of the conductive gel **124** (see **FIGS. 1A-1C**). In particular, the first portion **126A** of the conductive gel **124** may be attached to the first electrode **108A** by an adhesive (e.g., glue). The adhesive may be positioned on the curved outer surface **118A** of the first electrode **108A**, the proximal end **114A** of the first electrode **108A**, and/or a portion of a first

surface **212A** of the ridge **204** of the shim **110**. Similarly, the second portion **126B** of the conductive gel **124** may be attached to the second electrode **108B** by an adhesive (e.g., glue). The adhesive may be positioned on the curved outer surface **118B** of the second electrode **108B**, the proximal end **114B** of the second electrode **108B**, and/or a portion of a second surface **212B** of the ridge **204** of the shim **110**. Alternatively, in other embodiments, the conductive gel **124** is a hydrogel and may be placed on the first electrode **108A** and/or the second electrode **108B** by hydrogel deposition techniques without the use of an adhesive. In this way, the ridges **204** of the shim **110** electrically insulate the first and second hydrogel portions **126A**, **126B** from each other (see **FIGS. 1A-1C**). The height of each ridge **204** may be configured to be the same thickness as, or to have a greater thickness than, the thickness of the conductive gel **124**. In this way, after the conductive gel **124** is applied to the electrode assembly **100**, the conductive gel **124** may be approximately flush with the edge surface **214** of the ridge **204**. It is noted that the shim **110** may instead be flush with the proximal end **102**, distal end **104**, and/or curved outer surface **106** of the electrode assembly **200**, as discussed in more detail below.

[0061] In other embodiments, the conductive gel **124** may be attached to the first electrode **108A** and second electrode **108B** by dipping the assembled first electrode **108A** and second electrode **108B** in uncured hydrogel, and then cutting the hydrogel along the shim **110** to separate the first and second portions **126A**, **126B** of the conductive gel **124**.

[0062] **FIG. 3** is a perspective view of another embodiment of the electrode assembly **100** of **FIGS. 1A-2F** with an offset shim **110**. The shim **110'** of **FIG. 3** is offset from a center of the electrode assembly **100'** such that the first electrode **108A'** is smaller than the second electrode **108B'**. In other words, the shim **110'** extends parallel and offset to a central axis of the electrode assembly. In such a configuration, the volume and surface area of the first electrode **108A'** are smaller than the volume and surface area, respectively, of the second electrode **108B'**. Accordingly, in such a configuration, the electrode assembly **100'** is

configured to be oriented within the ear canal such that the second electrode **108B'** (e.g., the cathode) is toward a bottom of the ear canal. Increasing the surface area of contact of the second electrode **108B'** (e.g., cathode) increases the contact area of the second electrode **108B'** with the bottom of the ear canal and thereby improves electrical stimulation of the vagus nerve. Accordingly, decreasing the size of the first electrode **108A'** (e.g., anode) and respective contact area thereof relative to the second electrode **108B'** improves performance, however, decreasing the size of the first electrode **108A'** too much limits the magnitude of the electrical connection, and correspondingly limits electrical stimulation of the vagus nerve. Thus, the size of the first electrode **108A'** should be decreased but not to a degree that would unduly limit the electrical connection.

[0063] It is noted that the shim **110'** may be offset such that the second electrode **108B'** (e.g., cathode) is smaller than the first electrode **108A'** (e.g., anode), but that in such a configuration the electrode assembly **100'** is configured to be oriented within the ear canal such that the first electrode **108A'** (e.g., anode) is toward a bottom of the ear canal. It is also noted that the relative sizes of the first electrode **108A'** and the second electrode **108B'** may be varied in other ways, such as by using a shim **110'** that forms an angle along (i.e., is non-parallel to) the central axis of the electrode assembly **100**.

[0064] **FIGS. 4A-4F** are views of another embodiment of the electrode assembly of **FIGS. 1A-2F** forming an in-ear headphone tip **100''**. The in-ear headphone tip **100''** (may also be referred to herein as an electrode assembly) defines a central channel **402** extending along the central axis of the in-ear headphone tip **100''**. In particular, the internal surfaces **120A**, **120B** of the first electrode **108A''** and the second electrode **108B''** each include a channel portion **404A**, **404B** extending from the proximal end **114A** to the distal end **116B** of the first electrode **108A''** and the second electrode **108B''**. As a result, the shim **110''** includes first and second segments **406(1)**, **406(2)** separated by the channel **402** therebetween. The channel **402** is configured to attach to or receive

a portion of a housing and/or audio speaker of a conventional in-ear headphone, thereby allowing for audio stimulation through the channel simultaneously or concurrently with electrical stimulation.

5 **[0065]** The shim **110''** includes an edge surface **408** flush with the ends **114A**, **114B** and/or curved outer surface **106** of the in-ear headphone tip **100''**. It is noted that the shim **110''** may include a ridge as discussed above. As with the electrode assembly **100**, **100'** of **FIGS. 1A-3** discussed above, a conductive gel **124** (see **FIGS. 1A-1C**) may be applied to the outer surface **106** of the first electrode **108A''** and the second electrode **108B''**. Where the edge surface **408** of the shim **110''** is flush, the conductive gel **124** may be applied, and then cut to
10 form a gap between the first and second portions **126A**, **126B** of the conductive gel **124**, thereby electrically insulating the first and second portions **126A**, **126B** of the conductive gel **124**.

15 **[0066]** The in-ear headphone tip **100''** has the same form as a conventional in-ear headphone tip seen on a consumer pair of in-ear headphones. In some embodiments, the in-ear headphone **100''** is fabricated by pouring the wet silver/silicone rubber into a custom-made mold. As the silver/silicone rubber dries (e.g., over a 24 hours period), the plastic shim **110''** is placed down the middle of the silver/silicone rubber. After the shim **110''** is placed in the mold,
20 thin wires are inserted into the conductive silicone near the edges. When the in-ear headphone dries (e.g., after 24 hours), it is removed from the mold and dipped into the conductive gel **124**.

25 **[0067]** Another fabrication process includes pouring the conductive silicone into a mold and then curing the conductive silicone (e.g., letting the molded silicone dry). Then the conductive silicone can be cut (e.g., cut in half) to form the first electrode **108''** and the second electrode **108B''**. Conductive gel **124** (e.g., hydrogel) can be applied (e.g., adhered) to each of the first electrode **108''** and the second electrode **108B''**. The first electrode **108''** and the second electrode **108B''** can then be adhered to opposite sides of the shim **110''**.

[0068] It is noted that the wires can be inserted into the conductive silicone during the curing phase. In another embodiment, the wires protrude outward (or are otherwise exposed) relative to the in-ear housing, and the in-ear headphone can be pressed over the wires (rather than into the wires). In this way, as long as the wires are in insulated contact with each half of the electrode assembly, current is delivered through the whole electrode assembly.

[0069] FIG. 5 is a general diagram illustrating an in-ear headphone pair 500 including the in-ear headphone tip 100” of FIGS. 4A-4F. An in-ear headphone pair 500 includes an electronic device 502, a left in-ear headphone 504(1), and a right in-ear headphone 504(2).

[0070] The left in-ear headphone 504(1) includes a housing 506(1) and a left in-ear headphone tip 508(1), as discussed with respect to FIGS. 4A-4F. The left and right in-ear headphones 504(1), 504(2) have the same form as a conventional in-ear headphone seen on a consumer pair of in-ear headphones. The left in-ear headphone housing 506(1) includes electrical stimulation components 510 and audio stimulation components 512(1). The electrical stimulation components 510 include a waveform generator to provide the electrical stimulation parameters. The waveform generator may be configured to deliver a biphasic waveform (e.g., periodically altering the direction of current between the first electrode and the second electrode by periodically flipping polarity). The stimulation waveform parameters can produce an output of 0-20mA at a frequency of 0-1MHz and pulse width of 0-1000us. The audio stimulation components 512(1), 512(2) include a speaker. In particular, it is anticipated that at least a portion of the housing 506(1) may be inserted into the central channel 402 (see FIGS. 4A-4F) of the left in-ear headphone tip 508(1) to attach the housing 506(1) and the left in-ear headphone tip 508(1) to one other.

[0071] The right in-ear headphone 504(2) includes a housing 506(2) and a right in-ear headphone tip 508(2) with audio stimulation components 512(2) positioned within the housing 506(2). Only the left in-ear headphone 504(1) includes the electrical stimulation components 510 as the left ear canal contains

a higher density of vagal nerve afferents than the right ear canal. However, in certain embodiments, the right in-ear headphone **504(2)** may also include electrical stimulation components similar to those of the left in-ear headphone **504(1)** and as discussed with respect to **FIGS. 4A-4F**.

5 **[0072]** The housings **506(1)**, **506(2)** of the left and right in-ear headphones **504(1)**, **504(2)** may be in the shape of a standard pair of wireless in-ear headphones and may be made of plastic, rubber, and/or metal materials, etc. The wires coming from the left and right in-ear headphone tip **508(1)**, **508(2)** may be soldered onto or otherwise electrically connected with printed circuit boards or
10 other electrical components in the left and right housings.

[0073] The electronic device **502** of the in-ear headphone pair **500** is in electronic communication with the left in-ear headphone **504(1)**, where the electronic communication could be wired or wireless (e.g., Bluetooth). It is anticipated that when the left and right in-ear headphones **504(1)**, **504(2)** are
15 wired, the wired connection can assist users in orienting the left in-ear headphone **504(1)** for top-bottom stimulation, as discussed above. The left in-ear housing **506(1)** may include a portion that extends over the ear of a user and may include batteries therein, such as for a wireless configuration. Similarly, the right in-ear housing **506(2)** may include a portion that extends over the ear of the
20 user and may include batteries therein, such as for a wireless configuration. In this way, the in-ear headphone pair **500** may be used as a traditional wireless pair of headphones controlled by a wireless application (e.g., mobile application, smartphone application, etc.) of an electronic device (e.g., laptop, smartphone, etc.) external to the in-ear headphone pair **500**, but with the additional ability to
25 stimulate the vagus nerve. In particular, the left and right in-ear headphones **504(1)**, **504(2)** may include wireless communication components, such as a signal transmitter and/or a signal receiver for wireless communication with the electronic device **502**.

[0074] The electronic device **502** of the in-ear headphone pair **500** controls
30 operation of the electrical stimulation components **510** and/or the audio

stimulation components **512(1)**, **512(2)**. In this way, a user can receive simultaneous or concurrent electrical stimulation (of the vagus nerve) and audio stimulation (e.g., music). In other words, for example, the left in-ear headphone **504(1)** provides electric stimulation of the vagus nerve while simultaneously
5 allowing audio to be transmitted through the in-ear headphone tip **508(1)**. The electronic device **502** (e.g., smartphone, laptop, etc.) can control or modify the electrical stimulation components **510** including stimulation intensity, duration, pulsing pattern, length of session, and/or audio controls, among other operating parameters. Each of the left and right in-ear headphones **504(1)**, **504(2)** may
10 include a power button to turn on and off the left and right in-ear headphones **504(1)**, **504(2)**.

[0075] **FIG. 6** is a perspective view of another embodiment of a stimulation electrode assembly **600** with an in-ear headphone tip **602** (may also be referred to as a stimulation electrode, contact electrode, etc.) and with a return path
15 electrode assembly **604**. In this embodiment, the stimulation electrode **602** is generally frustoconical (as discussed above) for insertion into the ear canal of the ear. The stimulation electrode **602** can include a conductive gel coated on an outer surface thereof. The return path contact electrode **604** may also include a conductive gel coated on an outer surface thereof. When the stimulation
20 electrode **602** is inserted into the ear, the return path contact electrode **604** is positioned at some other point on the body (e.g., ear, neck, chest, etc.) to form an electrical circuit, thereby allowing the stimulation electrode **602** to stimulate the vagus nerve of a user. The more surface area in contact with the stimulation electrode **602** and the more pressure applied, the more current flows out of the
25 stimulation electrode **602**.

[0076] **FIG. 7** is a perspective view of another embodiment of an in-ear headphone pair **700** for non-invasive vagus nerve stimulation. The in-ear headphone pair **700** includes an electronic device (see e.g., **FIG. 8** below), a left in-ear headphone **702(1)** (e.g., first in-ear headphone), and a right in-ear
30 headphone **702(2)** (e.g., second in-ear headphone).

[0077] The left in-ear headphone **702(1)** includes a left housing **704(1)** and a left in-ear headphone tip **706(1)** including a first electrode **708(1)** (e.g., anode or cathode) of a generally frustoconical-shape. The left in-ear headphone tip **706(1)** defines a left central channel (see **FIGS. 4A-4F**). The right in-ear headphone

5 **702(2)** includes a right housing **704(2)** and a right in-ear headphone tip **706(2)** including a second electrode **708(2)** (e.g., cathode or anode) of a generally frustoconical-shape. The right in-ear headphone tip **706(2)** defines a right central channel (see **FIGS. 4A-4F**). When the left in-ear headphone tip **706(1)** is positioned in the left ear of a user and the right in-ear headphone tip **706(2)** is

10 positioned in the right ear of the user, an electrical circuit is created from the first electrode **708(1)** of the left in-ear headphone **702(1)** through skin tissue of the left ear, through the vagus nerve, across the user's skin, through skin tissue of the right ear, and to the second electrode **708(2)** of the right in-ear headphone **702(2)**. In this way, the in-ear headphone pair **700** non-invasively stimulates the

15 vagus nerve of the user, and may be produced by a simplified the manufacturing process. It is noted that the vagus nerve will be stimulated regardless of whether the left in-ear headphone is placed in the left ear or the right ear.

[0078] In certain embodiments, one or both of the first electrode **708(1)** and the second electrode **708(2)** include a conductive material, such as conductive

20 silver and/or conductive silicone (e.g., carbon-filled silicone, silver-filled silicone, etc.). In certain embodiments, the first electrode **708(1)** and/or the second electrode **708(2)** (either one or both) include a conductive gel (e.g., hydrogel) applied to the outer surface of the first electrode **708(1)** and the second electrode **708(2)** to maximize contact with the skin in the ear canal and to increase current

25 distribution for increased comfort of the user. In other embodiments, the first electrode **708(1)** and the second electrode **708(2)** are made (e.g., exclusively) of the conductive gel such that the conductive gel forms the frustoconical-shape of the first electrode **708(1)** and the second electrode **708(2)**. Forming the first electrode **708(1)** and/or the second electrode **708(2)** from the conductive gel

(e.g., devoid of silver and/or silicon) simplifies the manufacturing process without sacrificing performance or comfort.

[0079] In certain embodiments, the first electrode **708(1)** and/or the second electrode **708(2)** do not include a central channel, and the in-ear headphone pair **700** is configured to deliver electrical stimulation only (not audio stimulation).

[0080] **FIG. 8** is a general diagram illustrating the in-ear headphone pair **700** of **FIG. 7**. The in-ear headphone pair **800** includes an electronic device **802**, a left in-ear headphone **804(1)**, and a right in-ear headphone **804(2)**.

[0081] As discussed above, the left in-ear headphone **804(1)** includes a housing **806(1)** and a left in-ear headphone tip **808(1)** with electrical stimulation components **810(1)** and audio stimulation components **812(1)** positioned within the left in-ear headphone housing **806(1)**. The right in-ear headphone **804(2)** includes a housing **806(2)** and a right in-ear headphone tip **808(2)** with electrical stimulation components **810(2)** and audio stimulation components **812(2)** positioned within the housing **806(2)**.

[0082] The left and/or right in-ear headphones **804(1)**, **804(2)** have the same form as a conventional in-ear headphone seen on a consumer pair of in-ear headphones. The left and/or right in-ear headphone housings **806(1)**, **806(2)** of the left and right in-ear headphones **804(1)**, **804(2)** each include electrical stimulation components **810(1)**, **810(2)** and audio stimulation components **812(1)**, **812(2)**. The electrical stimulation components **810(1)**, **810(2)** include a waveform generator (e.g., left waveform generator and/or right waveform generator) to provide the electrical stimulation parameters. The waveform generator may be configured to deliver a biphasic waveform (e.g., periodically altering the direction of current between the first electrode and the second electrode by periodically flipping polarity). The stimulation waveform parameters can produce an output of 0-20mA at a frequency of 0-1MHz and pulse width of 0-1000us. The audio stimulation components **812(1)**, **812(2)** include a speaker. In particular, it is anticipated that at least a portion of the left housing **806(1)** may be inserted into the left central channel (see **FIGS. 4A-4F**) of the left in-ear

headphone tip **808(1)** to attach the left housing **806(1)** and the left in-ear
headphone tip **808(1)** to each other, such that the audio components **812(1)**
positioned within the left housing **806(1)** can deliver audio stimulation to the left
ear through the left central channel of the first electrode of the left in-ear
5 headphone tip **808(1)**. Similarly, at least a portion of the right housing **806(2)**
may be inserted into the right central channel (see **FIGS. 4A-4F**) to attach the
right housing **806(2)** and the right in-ear headphone tip **808(2)** to each other,
such that the audio components **812(2)** positioned within the right housing **806(2)**
can deliver audio stimulation to the right ear through the right central channel of
10 the second electrode of the right in-ear headphone tip **808(2)**.

[0083] The housings **806(1)**, **806(2)** of the left and/or right in-ear headphones
804(1), **804(2)** may be in the shape of a standard pair of wireless in-ear
headphones and may be made of plastic, rubber, and/or metal materials, etc.
The wires coming from the left and right in-ear headphone tips **808(1)**, **808(2)**
15 may be soldered onto or otherwise electrically connected to a printed circuit
board or other electrical components in the left and right housings **806(1)**, **806(2)**.

[0084] The electronic device **802** is in electronic communication with the left
and/or right in-ear headphone **804(1)**, **804(2)**, where the electronic
communication could be wired or wireless (e.g., Bluetooth). It is anticipated that
20 when the left and right in-ear headphones **804(1)**, **804(2)** are wired, the wired
connection can assist users in orienting the left in-ear headphone tip **808(1)** for
top-bottom stimulation, as discussed above. The left and/or right in-ear housing
806(1), **806(2)** may include a portion that extends over the ear and may include
batteries therein, such as for a wireless configuration. In this way, the in-ear
25 headphone pair **800** may be used as a traditional wireless pair of headphones
controlled by a wireless application (e.g., mobile application, smartphone
application, etc.) of an electronic device **802** (e.g., laptop, smartphone, etc.)
external to the in-ear headphone pair **800**, but with the additional ability to
stimulate the vagus nerve of a user. In particular, the left and right in-ear
30 headphones **804(1)**, **804(2)** may include wireless communication components,

such as a signal transmitter and/or a signal receiver for wireless communication with the electronic device **802**.

[0085] The electronic device **802** controls operation of the electrical stimulation components **810(1)**, **810(2)** and/or the audio stimulation components **812(1)**, **812(2)** of the left and/or right in-ear headphone **804(1)**, **804(2)**. In this way, a user can receive simultaneous or concurrent electrical stimulation (of the vagus nerve) and audio stimulation (e.g., music) in the left and/or right ears. In other words, the left and right in-ear headphone tips **808(1)**, **808(2)** provide electric stimulation of the vagus nerve while simultaneously allowing audio to be transmitted through the left and/or right in-ear headphone tip **808(1)**, **808(2)**. The electronic device **802** (e.g., smartphone, laptop, etc.) can control or modify the electrical stimulation components **810(1)**, **810(2)** including stimulation intensity, duration, pulsing pattern, length of session, and/or audio controls, among other operating parameters. Each of the left and right in-ear headphones **804(1)**, **804(2)** may include a power button to turn on and off the left and right in-ear headphones **804(1)**, **804(2)**.

[0086] It is contemplated that any or more features or characteristics of any one or more embodiments disclosed herein may be combined with those of other embodiments, unless specifically indicated to the contrary herein.

[0087] Those skilled in the art will recognize improvements and modifications to the preferred embodiments of the present disclosure. All such improvements and modifications are considered within the scope of the concepts disclosed herein and the claims that follow.

Claims

What is claimed is:

- 5 1. An electrode assembly for non-invasive nerve stimulation, comprising:
a first electrode forming a first body portion;
a second electrode forming a second body portion complementary to the
first body portion such that the first body portion of the first electrode and the
second body portion of the second electrode in combination form a frustoconical-
10 shape; and
a shim positioned between the first electrode and the second electrode to
separate and electrically insulate the first electrode and the second electrode
from each other;
wherein the electrode assembly is configured for insertion into an ear of a
15 user to form an electrical circuit including the first electrode, the second
electrode, and a vagus nerve of the user to electrically stimulate the vagus nerve.
2. The electrode assembly of claim 1, wherein the first electrode and the
second electrode comprise conductive silicone.
- 20 3. The electrode assembly of claim 1, wherein the shim comprises a plastic
material.
4. The electrode assembly of claim 1, further comprising a conductive gel
25 covering at least a portion of an outer surface of at least one of the first electrode
or the second electrode.
5. The electrode assembly of claim 4, wherein the conductive gel comprises
a hydrogel.

6. The electrode assembly of claim 4, wherein:

the shim comprises a ridge that extends beyond the outer surface of the first electrode and the second electrode;

the conductive gel comprises a first gel portion covering at least a portion
5 of the first electrode and a second gel portion covering at least a portion of the second electrode; and

the first gel portion and the second gel portion are electrically insulated from each other by the ridge.

10 7. The electrode assembly of claim 1, wherein the first electrode and the second electrode are substantially a same size and the shim is positioned in an approximate middle of the electrode assembly.

8. The electrode assembly of claim 1, wherein the first electrode and the
15 second electrode are differently sized and the shim is positioned offset from a middle of the electrode assembly.

9. An in-ear headphone, comprising:

a housing;

20 an electrode assembly forming an in-ear headphone tip attached to the housing, the electrode assembly comprising:

a first electrode forming a first body portion;

a second electrode forming a second body portion complementary
to the first body portion such that the first body portion of the first electrode
25 and the second body portion of the second electrode in combination form a frustoconical-shape; and

a shim positioned between the first electrode and the second electrode to separate and electrically insulate the first electrode and the second electrode from each other;

wherein the electrode assembly is configured for insertion into an ear of a user to form an electrical circuit including the first electrode, the second electrode, and a vagus nerve of the user to electrically stimulate the vagus nerve; and

5 a waveform generator positioned within the housing and configured to apply an electric signal to the electrode assembly to stimulate the vagus nerve.

10. The in-ear headphone of claim 9, wherein the first electrode and the second electrode comprise conductive silicone.

10 11. The in-ear headphone of claim 9, wherein the shim comprises a plastic material.

12. The in-ear headphone of claim 9, further comprising a conductive gel
15 covering at least a portion of an outer surface of at least one of the first electrode or the second electrode.

13. The in-ear headphone of claim 9, wherein the in-ear headphone
20 comprises a signal transmitter and a signal receiver configured to permit wireless communication with an electronic device external to the in-ear headphone.

14. The in-ear headphone of claim 9, wherein the in-ear headphone is
configured to allow a user to adjust an operating parameter of the waveform
generator by an electronic device, the operating parameter comprising at least
25 one of intensity, duration, or pulse pattern.

15. The in-ear headphone of claim 9, wherein the in-ear headphone
comprises audio components within the housing, the audio components
configured to deliver audio stimulation through a central channel defined in the

electrode assembly, the in-ear headphone configured to provide the audio stimulation concurrently with electrical stimulation of the vagus nerve.

16. An in-ear headphone pair, comprising:

5 a right in-ear headphone configured for insertion into a right ear, the right in-ear headphone comprising audio components configured to deliver audio stimulation to the right ear; and

a left in-ear headphone configured for insertion into a left ear, the left in-ear headphone comprising:

10 a housing;

an electrode assembly forming an in-ear headphone tip attached to the housing, the electrode assembly comprising:

a first electrode forming a first body portion;

15 a second electrode forming a second body portion complementary to the first body portion such that the first body portion of the first electrode and the second body portion of the second electrode in combination form a frustoconical-shape; and

20 a shim positioned between the first electrode and the second electrode to separate and electrically insulate the first electrode and the second electrode from each other;

wherein the electrode assembly is configured for insertion into an ear of a user to form an electrical circuit including the first electrode, the second electrode, and a vagus nerve of the user to electrically stimulate the vagus nerve;

25 a waveform generator positioned within the housing and configured to apply an electrical signal to the electrode assembly to stimulate the vagus nerve; and

audio components positioned within the housing and configured to deliver audio stimulation to the left ear through a central channel of the electrode assembly.

5 17. The in-ear headphone pair of claim 16, wherein the first electrode and the second electrode comprise conductive silicone.

18. The in-ear headphone pair of claim 16, wherein the shim comprises a plastic material.

10

19. The in-ear headphone pair of claim 16, further comprising a conductive gel covering at least a portion of an outer surface of at least one of the first electrode or the second electrode.

15 20. The in-ear headphone pair of claim 16, wherein the in-ear headphone pair comprises a signal transmitter and a signal receiver configured to permit wireless communication with an electronic device external to the in-ear headphone pair.

21. The in-ear headphone pair of claim 16, wherein the left in-ear headphone
20 is configured to deliver the audio stimulation concurrently with electrical stimulation.

22. An electrode pair assembly for non-invasive nerve stimulation, comprising:
a first electrode forming a first frustoconical-shape configured for insertion
25 into a first ear of a user; and

a second electrode forming a second frustoconical-shape configured for insertion into a second ear of the user;

wherein the electrode pair assembly is configured to form an electrical circuit when the first electrode is positioned within the first ear of the user and the

second electrode is positioned within the second ear of the user, the electrical circuit including the first electrode, the second electrode, and a vagus nerve of the user to electrically stimulate the vagus nerve.

5 23. The electrode pair assembly of claim 22, wherein the first electrode and the second electrode are in conductive electrical communication via electrical wiring.

24. The electrode pair assembly of claim 22, wherein at least one of the first
10 electrode or the second electrode comprises conductive silicone.

25. The electrode pair assembly of claim 22, wherein at least one of the first electrode or the second electrode comprises a conductive gel.

15 26. The electrode pair assembly of claim 22, further comprising a conductive gel covering at least a portion of an outer surface of at least one of the first electrode or the second electrode.

27. The electrode pair assembly of claim 26, wherein the conductive gel
20 comprises a hydrogel.

28. The electrode pair assembly of claim 22, wherein the first electrode
comprises a first conductive gel forming the first frustoconical-shape, and the
second electrode comprises a second conductive gel forming the second
25 frustoconical-shape.

29. The electrode pair assembly of claim 28, wherein the first conductive gel
comprises a first hydrogel and the second conductive gel comprises a second
hydrogel.

30. An in-ear headphone pair, comprising:

a first in-ear headphone configured for insertion into a first ear of a user,
the first in-ear headphone comprising:

5 a first housing;

a first electrode forming a first in-ear headphone tip attached to the
first housing, the first electrode defining a first central channel; and

first audio components positioned within the first housing and
configured to deliver audio stimulation to the first ear through the first
10 central channel of the first electrode; and

a second in-ear headphone configured for insertion into a second ear of
the user, the second in-ear headphone comprising:

a second housing;

a second electrode forming a second in-ear headphone tip attached
15 to the second housing, the second electrode defining a second central
channel; and

second audio components positioned within the second housing
and configured to deliver audio stimulation to the second ear through the
second central channel of the second electrode;

20 wherein the in-ear headphone pair is configured to form an electrical
circuit when the first electrode is positioned within the first ear of the user and the
second electrode is positioned within the second ear of the user, the electrical
circuit including the first electrode, the second electrode, and a vagus nerve of
the user to electrically stimulate the vagus nerve.

25

31. The in-ear headphone pair of claim 30, further comprising electrical wiring
electrically connecting the first electrode to the second electrode.

32. The in-ear headphone pair of claim 30, wherein at least one of the first electrode or the second electrode comprises conductive silicone.

5 33. The in-ear headphone pair of claim 30, wherein at least one of the first electrode or the second electrode comprises a conductive gel.

34. The in-ear headphone pair of claim 30, further comprising a conductive gel covering at least a portion of an outer surface of at least one of the first electrode or the second electrode.

10

35. The in-ear headphone pair of claim 34, wherein the conductive gel comprises a hydrogel.

15 36. The in-ear headphone pair of claim 30, wherein the first electrode forms a first frustoconical-shape and the second electrode forms a second frustoconical-shape.

37. The in-ear headphone pair of claim 36, wherein the first electrode comprises a first conductive gel forming the first frustoconical-shape, and the
20 second electrode comprises a second conductive gel forming the second frustoconical-shape.

38. The in-ear headphone pair of claim 37, wherein the first conductive gel comprises a first hydrogel and the second conductive gel comprises a second
25 hydrogel.

39. The in-ear headphone pair of claim 30, wherein at least one of the first in-ear headphone or the second in-ear headphone comprises a signal transmitter and a signal receiver configured to permit wireless communication with an

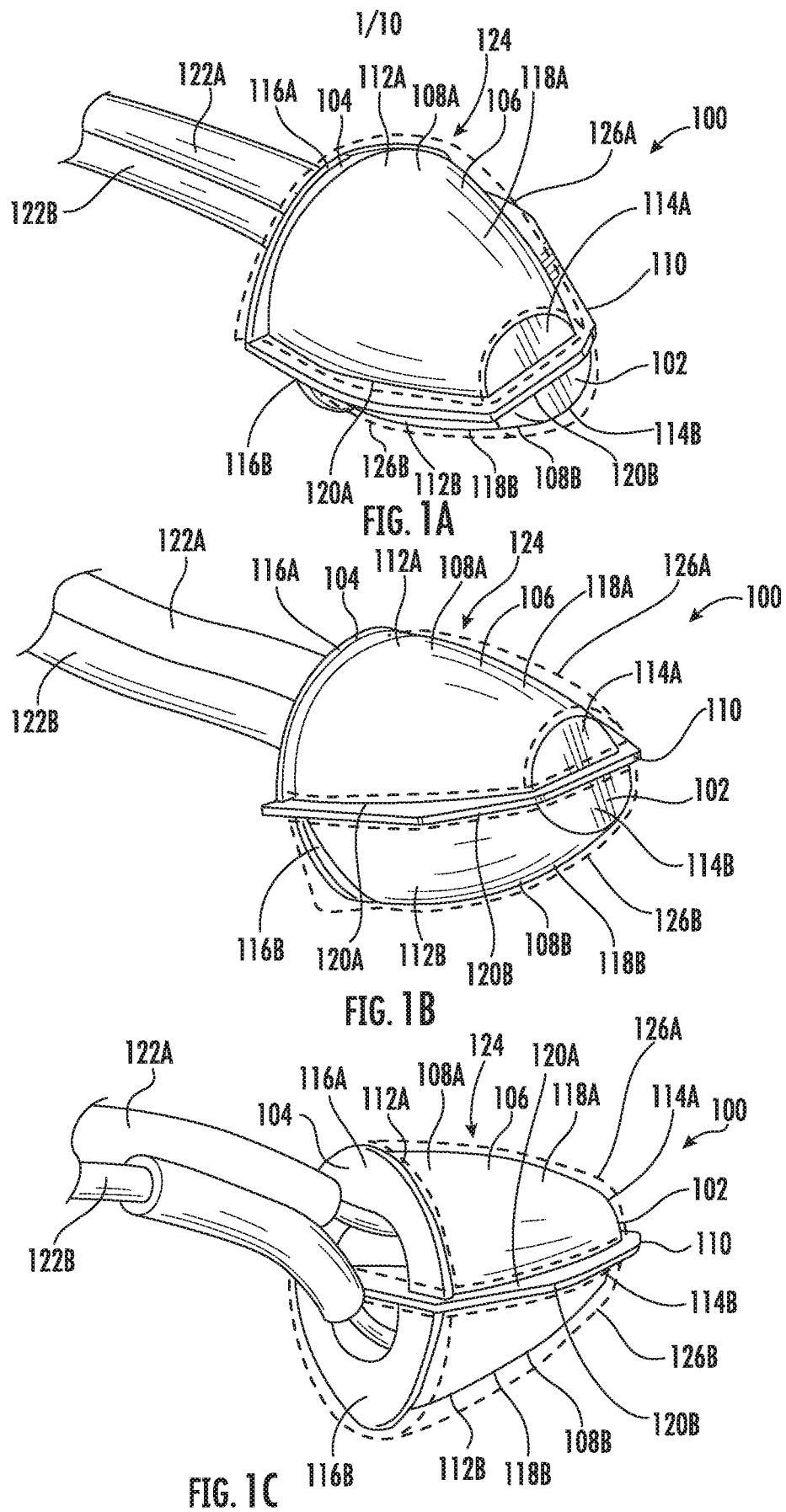
electronic device external to the first in-ear headphone and the second in-ear headphone.

40. The in-ear headphone pair of claim 30, wherein at least one of the first in-ear headphone or the second in-ear headphone is configured to deliver the audio stimulation concurrently with electrical stimulation.

41. The in-ear headphone pair of claim 30, wherein at least one of the first in-ear headphone or the second in-ear headphone includes a waveform generator configured to apply an electrical signal to at least one of the first electrode or the second electrode.

42. The in-ear headphone pair of claim 41, wherein the at least one of the first in-ear headphone or the second in-ear headphone is configured to allow the user to adjust an operating parameter of the waveform generator by an electronic device, the operating parameter comprising at least one of intensity, duration, or pulse pattern.

43. The in-ear headphone pair of claim 41, wherein the waveform generator is configured to deliver a biphasic waveform.



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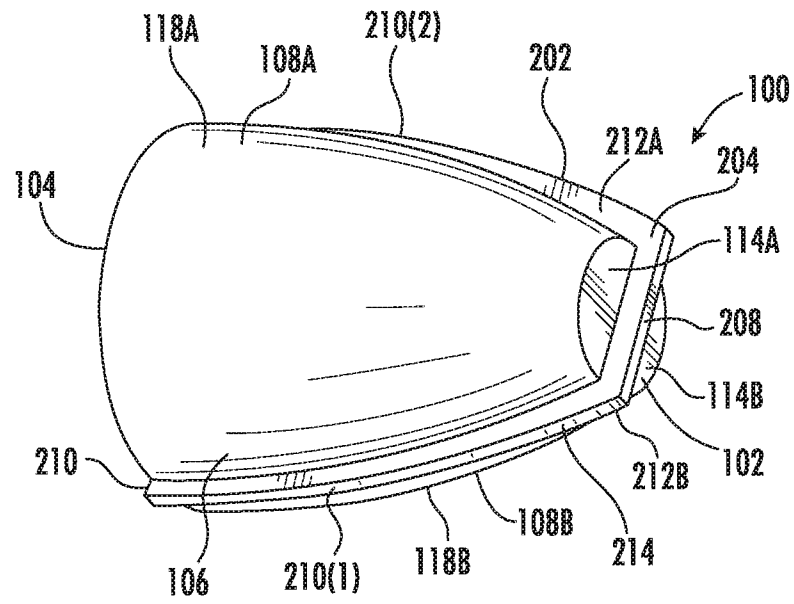


FIG. 2A

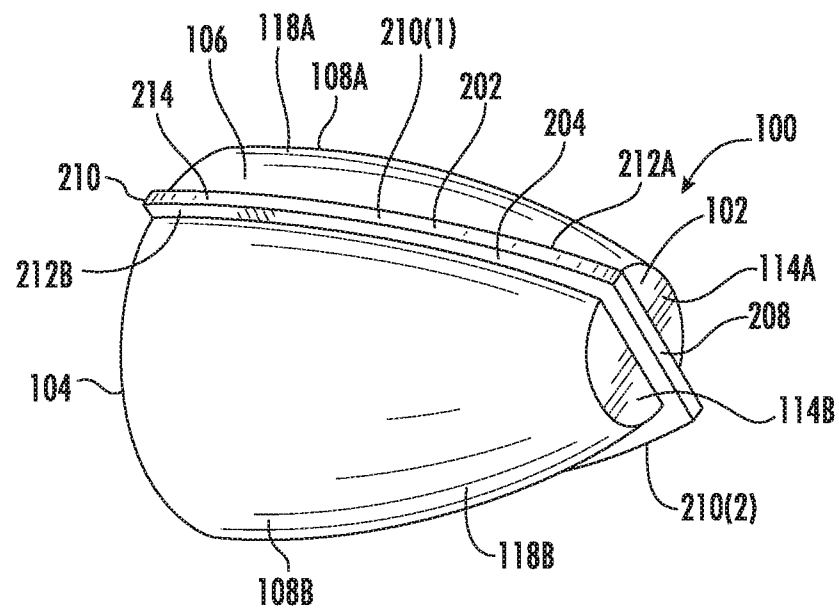


FIG. 2B

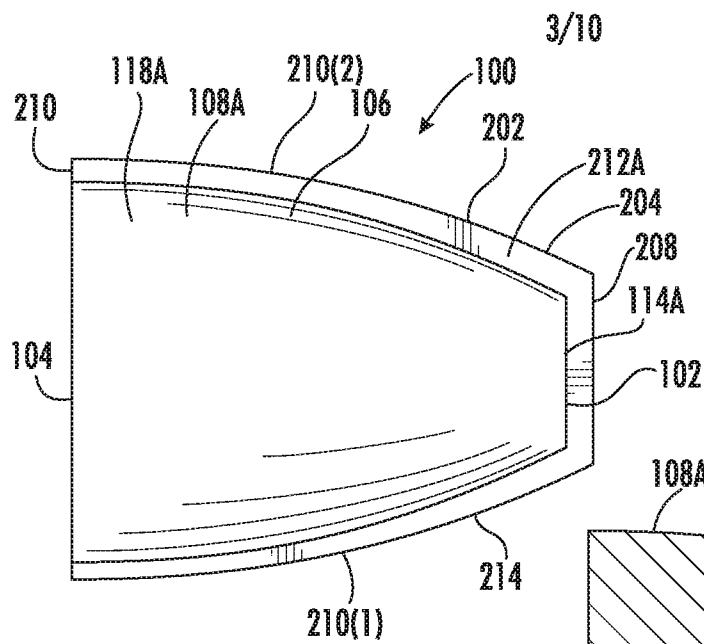


FIG. 2C

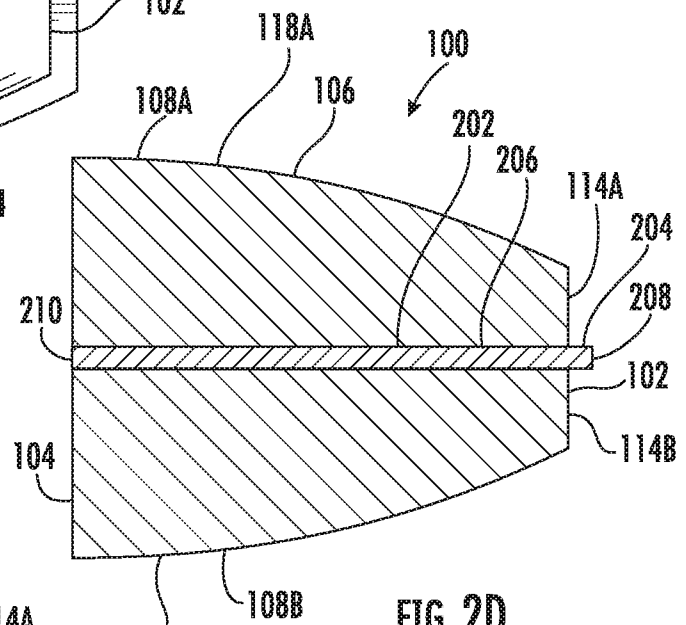


FIG. 2D

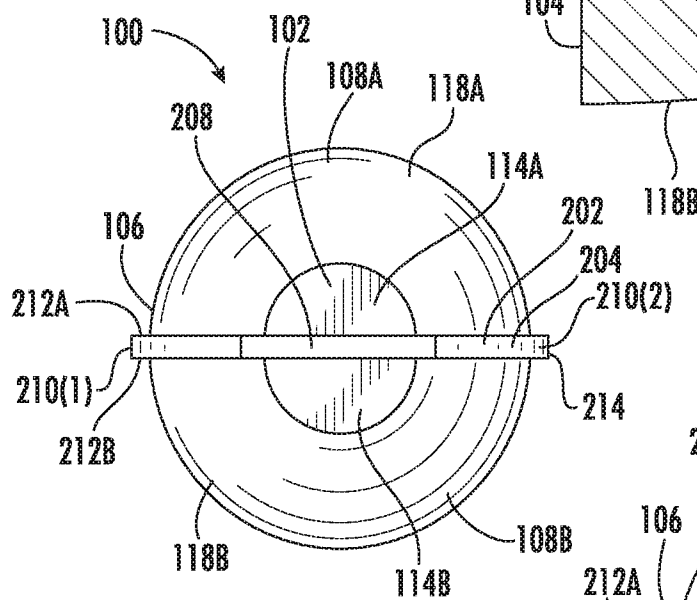


FIG. 2E

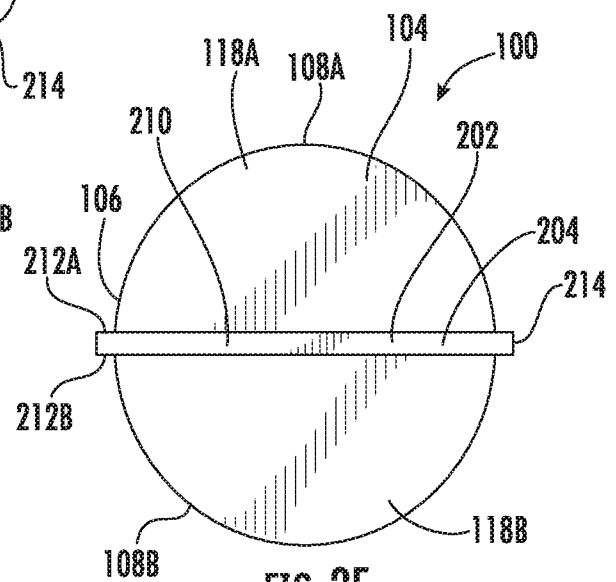


FIG. 2F

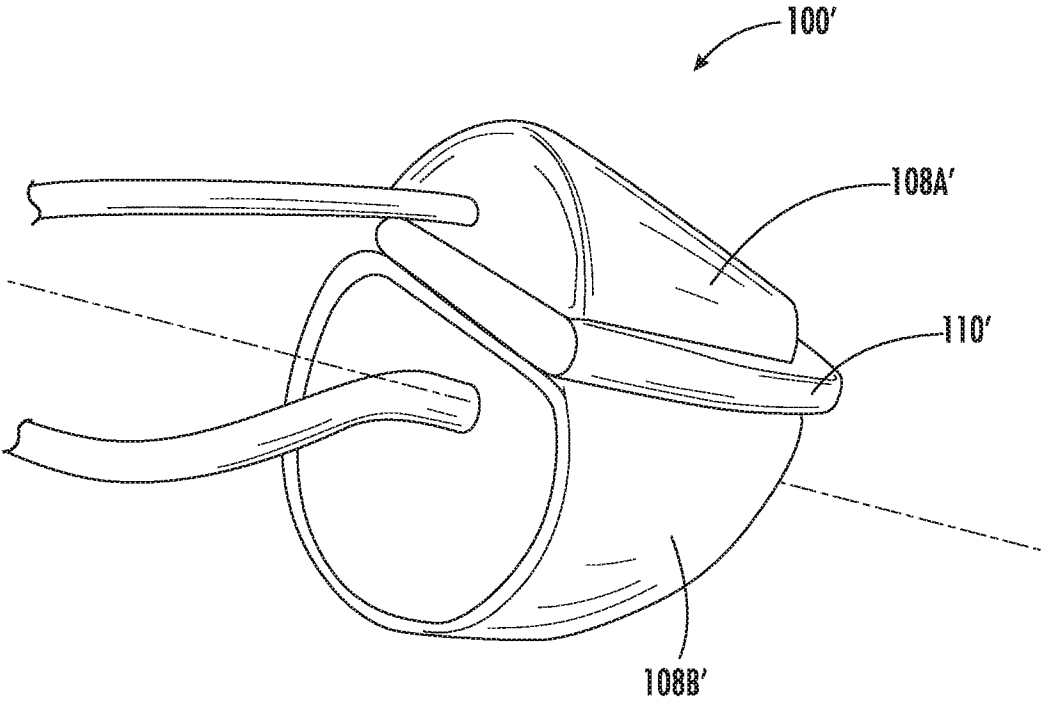


FIG. 3

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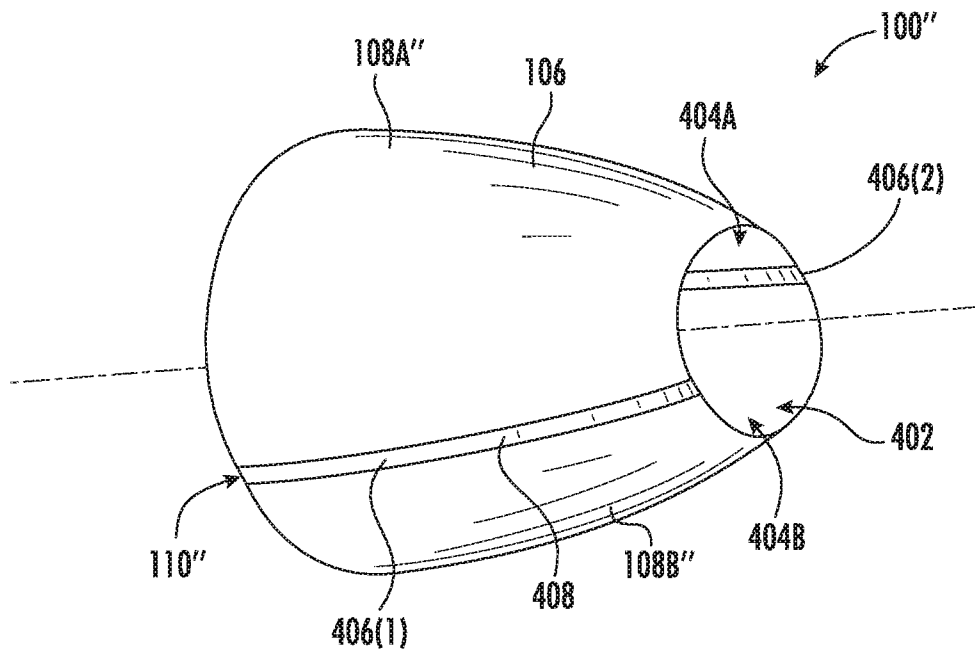


FIG. 4A

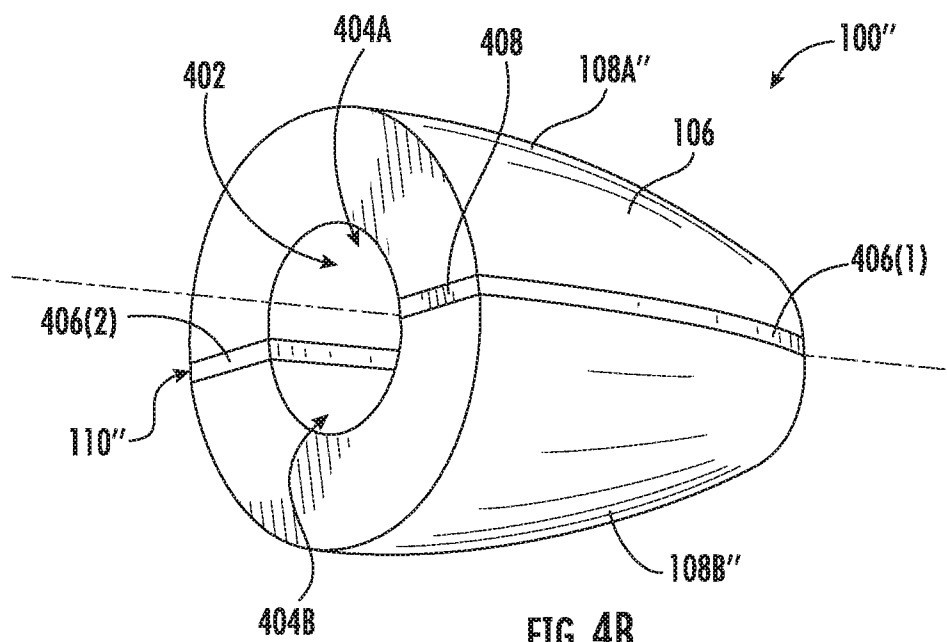


FIG. 4B

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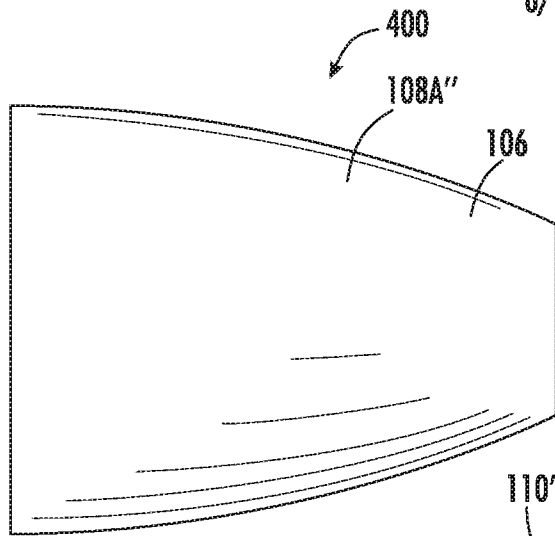


FIG. 4C

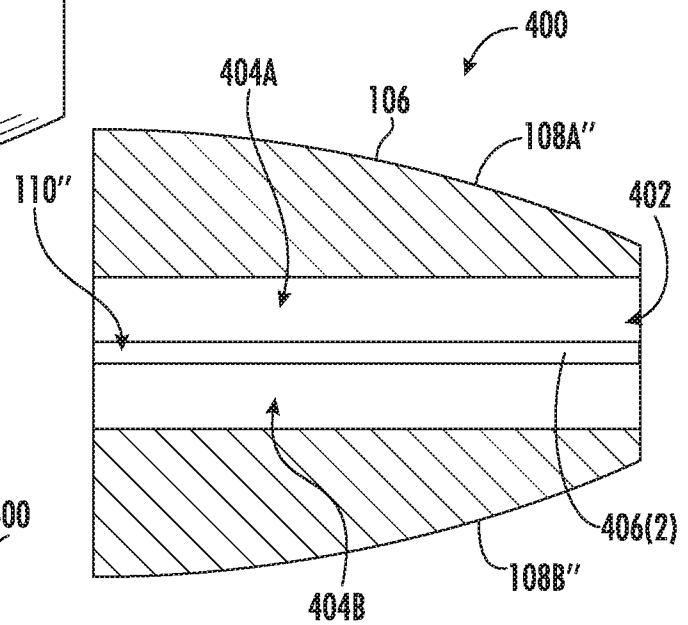


FIG. 4D

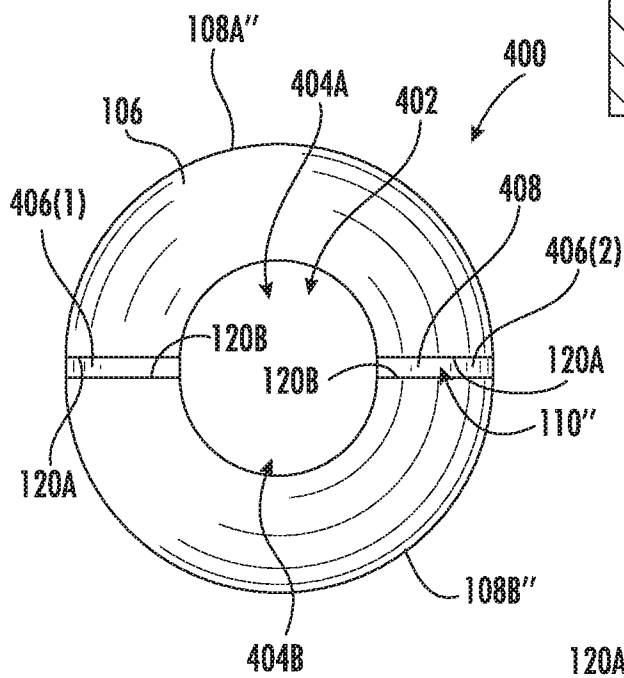


FIG. 4E

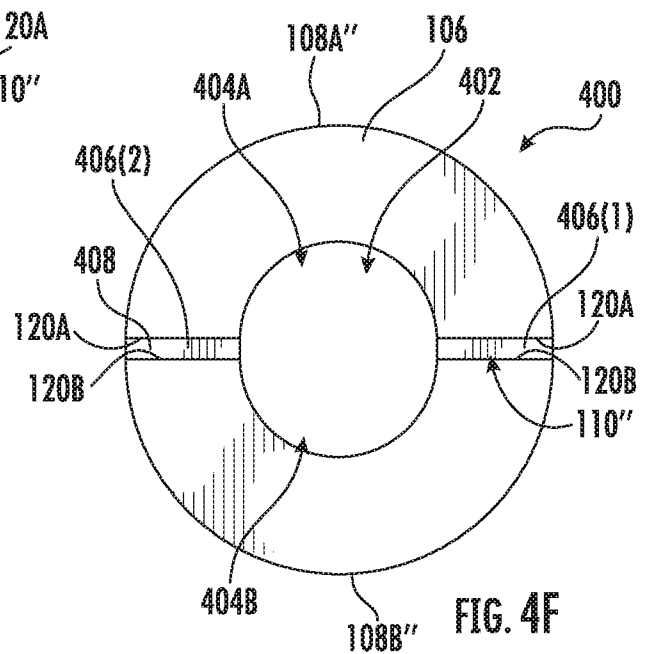


FIG. 4F

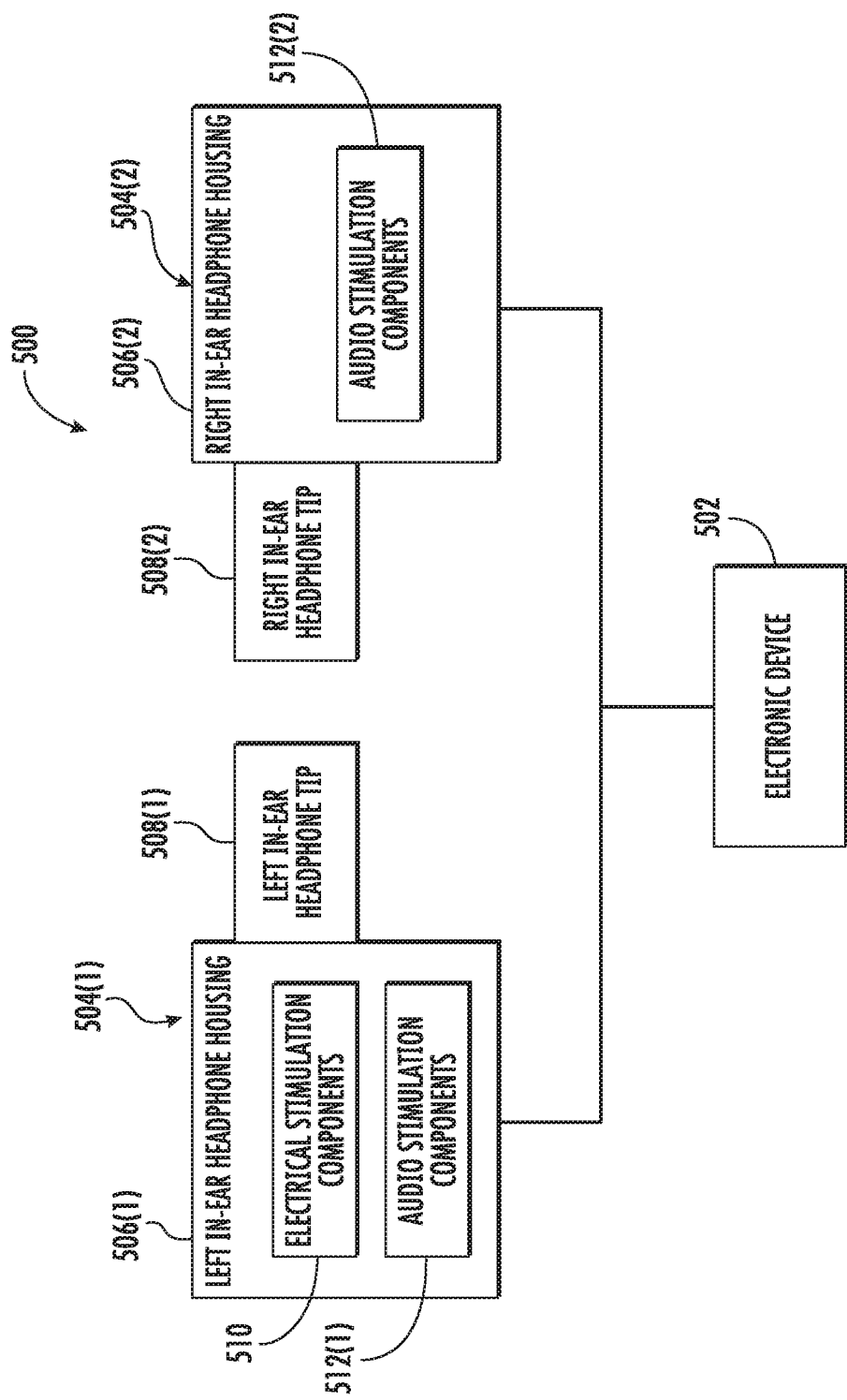


FIG. 5

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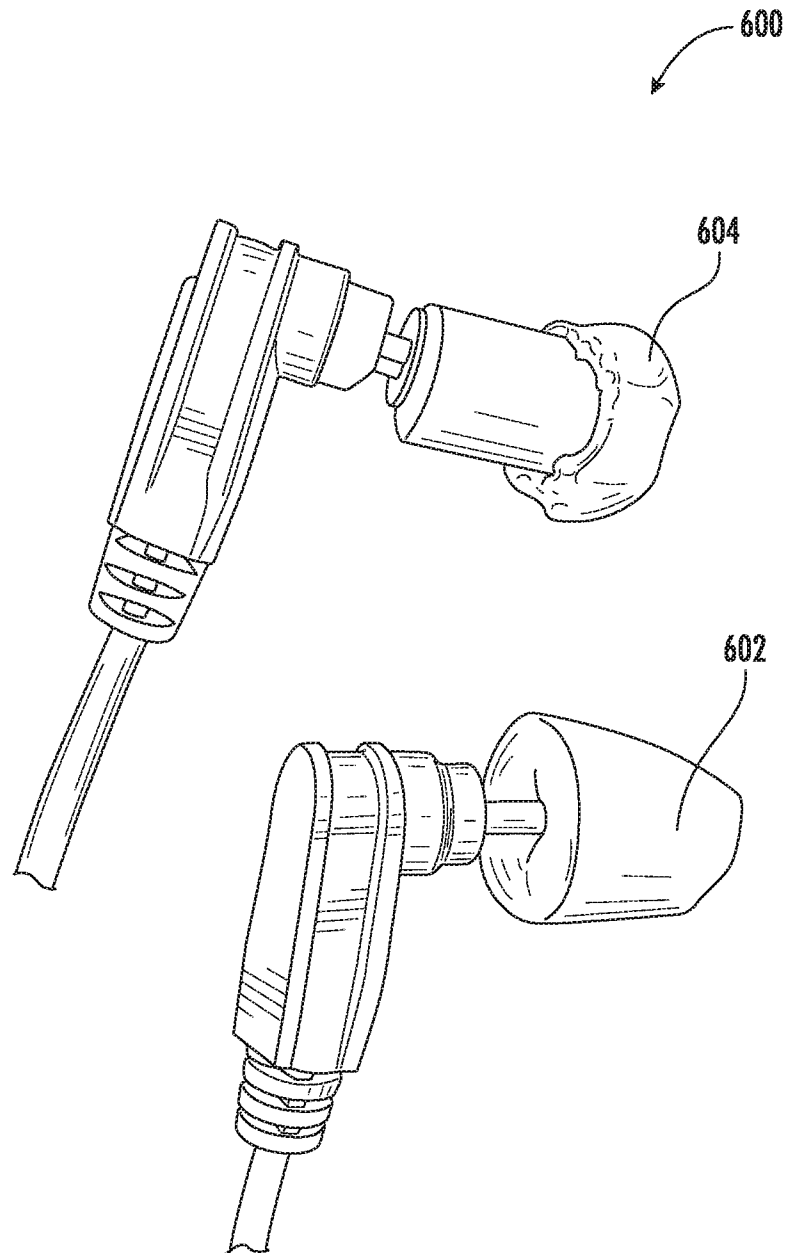
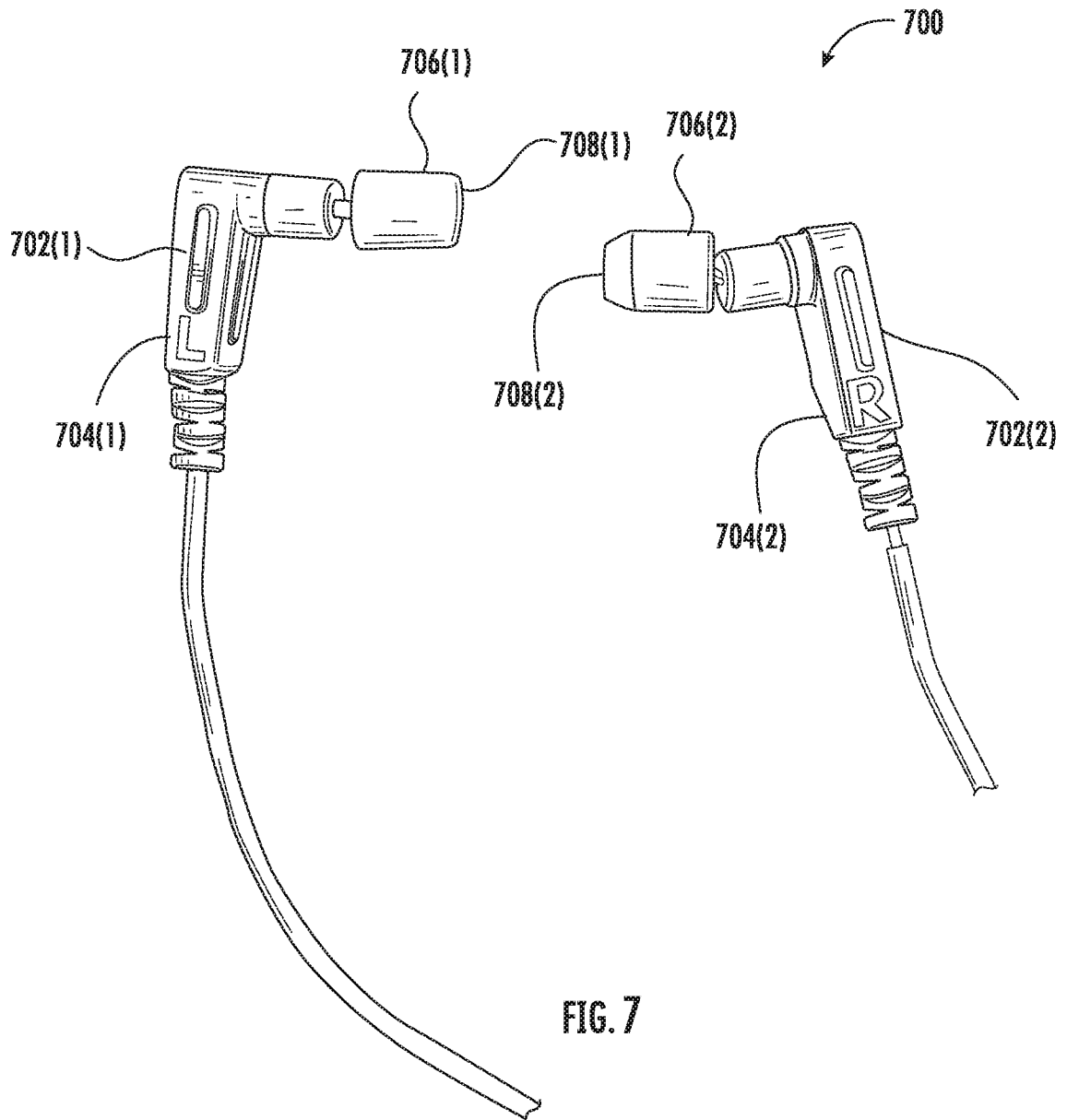


FIG. 6

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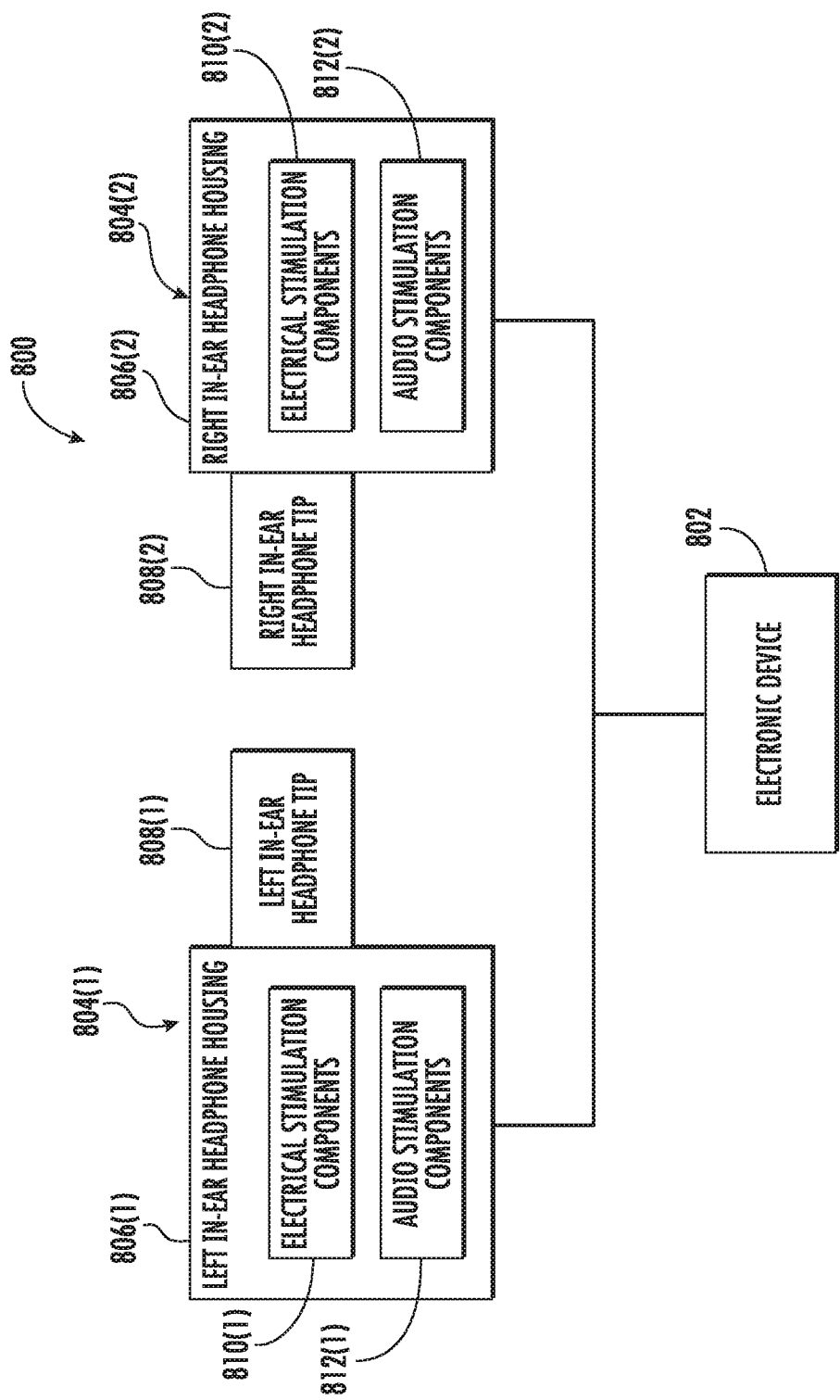


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2018/049157

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61N 1/04; A61N 1/00; A61N 1/02; A61N 1/05; A61N 1/06; A61N 1/18; A61N 1/32 (2018.01)

CPC - A61N 1/0472; A61N 1/00; A61N 1/02; A61N 1/04; A61N 1/0404; A61N 1/0476; A61N 1/05; A61N 1/06; A61N 1/18; A61N 1/32; A61N 1/36; A61N 1/3601; A61N 1/36014; A61N 1/36017; H04R 1/10 (2018.08)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

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

USPC - 381/151; 381/328; 607/115; 607/136 (keyword delimited)

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2016/0346117 A1 (SCION NEUROSTIM LLC) 01 December 2016 (01.12.2016) entire document	22-29
X	US 2017/0087364 A1 (NERVANA, LLC) 30 March 2017 (30.03.2017) entire document	30-42
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Y		43
Y	US 8,249,711 B2 (LIBBUS et al) 21 August 2012 (21.08.2012) entire document	43
A	US 2013/0150653 A1 (BORSODY) 13 June 2013 (13.06.2013) entire document	1-43
A	US 4,966,164 A (COLSEN et al) 30 October 1990 (30.10.1990) entire document	1-43
A	WO 2017/091705 A1 (THE GENERAL HOSPITAL CORPORATION) 01 June 2017 (01.06.2017) entire document	1-43

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

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"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

06 October 2018

Date of mailing of the international search report

19 OCT 2018

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
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