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Cutaneous Electrode Positioning

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(54) Title: CUTANEOUS ELECTRODE POSITIONING

(57) Abstract: A device and method for positioning a cutaneous electrode for delivery of electrical stimulation to a subject's head. A harness is worn on a subject's head with a first band of the harness worn in a closed loop around the subject's head and around a desired contact location on the subject's head. A tensioning strap of the harness is worn across the desired contact location and connected at spaced-apart attachment locations of the strap to spaced-apart attachment locations of the harness such that an electrode disposed over the desired contact location on the subject's head is held in place by the tensioning strap.

CUTANEOUS ELECTRODE POSITIONING

CROSS-REFERENCES TO RELATED APPLICATIONS

This application claims priority in and is entitled to the benefit of the filing date of United States Provisional Patent Application Serial Number 61/786,848; which was filed March 15, 2013 and is incorporated herein by reference in its entirety.

BACKGROUND

FIELD

The present invention relates generally to noninvasive electrical stimulation of the head. More specifically, the present invention relates to apparatuses for configuring a cap to be worn on a head for purposes that include the placement of noninvasive electrodes used for providing electrical stimulation and making biophysical measurements.

DESCRIPTION OF RELATED ART INCLUDING INFORMATION DISCLOSED UNDER 37 CFR 1.97 AND 1.98 US7896517

Noninvasive stimulation of tissues inherent to a head can be accomplished using electrical interface electrodes, henceforth known as cutaneous electrodes or simply "electrodes" that are configured to rest on or adjacent the surface of the outer skin on or adjacent the head. A number of materials suitable for use as cutaneous electrodes are known in the art. A number of means for enhancing electrical conduction integrity between the electrode and the outer skin, such as the use of electrically conductive gels, are also known in the art.

Means of placing cutaneous electrodes used for making biophysical measures are also known in the at . For example, in measuring the biopotential voltage of an electroencephalogram, henceforth known as "EEG", it is known that electrode

placement can be assisted by the use of a cap-like apparatus or a net-like apparatus configured to be worn on a subject's head. Such apparatuses are particularly useful for assuring that cutaneous electrodes are placed in specific locations necessary to provide measurements from desired locations on a scalp.

When making biophysical measures, such as an EEC, very high electrical impedances inherent to measurement instraments known in the art provide means to make such measurements with minimal corresponding flow of electrical current. In other words, biopotential measures made by cutaneous electrodes are merely voltage measurements that can be made with very little current flow. In such measurement systems, the electrical impedance between a cutaneous electrode and the skin is relatively small in comparison to the very high impedance of measurement instruments. Accordingly, this impedance between a cutaneous electrode and the skin does not adversely inhibit the ability to make such biopotential measures.

Conversely, for purposes of electrically stimulating tissues, whether noninvasively or invasively, there is generally a need to provide for an amount of current to flow through the tissues. Unlike purposes of making biopotential measures, the intervening impedance between a cutaneous electrode and the skin presents a limitation of electrical conductivity for purposes of electrical stimulation. Namely, this impedance can significantly attenuate conductance and therefore attenuate the amount of current that can flow from an electrical stimulation signal source through the tissues.

When the tissues to be stimulated include tissues of a head, the presence of hair can further increase the intervening impedance between a cutaneous electrode and the skin. Accordingly, it is necessary to implement means to further enhance a stimulation system's ability to reduce such intervening impedance. Thus, means are needed to facilitate placement of cutaneous electrodes for electrical stimulation of tissues of a head that assist in correct placement of the electrodes and cause the electrodes to rest on or adjacent the skin in ways that enhance the system's ability to reduce intervening electrical impedance and therefore increase electrical conductivity.

SUMMARY

A device is provided for positioning a cutaneous electrode for deliver}' of electrical stimulation to a subject's head. The device comprises a harness comprising a first band configured to be worn in a closed loop around a subject's head and around a desired contact location on the subject's head. The device also comprises a tensioning strap configured to be worn across the desired contact location and to connect at spaced-apart attachment locations of the strap to spaced-apart attachment locations of the harness such that an electrode is disposed over the desired contact location on the subject's head, the strap having an elastic portion configured to provide and maintain contact pressure between the electrode and the desired contact location when the strap is stretched between the attachment locations.

DRAWING DESCRIPTIONS

Figure 1 is a top-view of a device for positioning a cutaneous electrode for deliver}' of electrical stimulation to a subject's head, with the device shown spread-out and resting on a surface and connected to a schematic representation of a biophysical measurement instrument;

Figure 2 is a back view of the device of Figure 1 shown as it appears when worn on a subject's head;

Figure 3 is a side view of the device and subject of Figure 2;

Figure 4 is a flow diagram illustrating a method for making a device such as the device of Figure 1;

Figure 5 is a front-left quarter view of a second embodiment of a device for positioning a cutaneous electrode for delivery of electrical stimulation to a subject's head, with the device shown as it appears when worn on a subject's head;

Figure 6 is a back view of the device and subject of Figure 5, with a second band portion of the device shown unfastened from a first band portion of the device;

Figure 7 is a back-left quarter view of the device and subject of Figure 5, with the second band portion of the device shown fastened to the first band portion of the device; and

Figure 8 is a flow diagram illustrating a method for making a device such as the device of Figure 5.

DETAILED DESCRIPTION

In the following description of the disclosed device and method, the terms "attach", "attachment", "attaching", "connect", "connection" and "connecting" are intended to mean any form of joining or causing to join, whether temporarily or permanently, elements of a device for positioning a cutaneous electrode.

The term "attachment location" is intended to mean any place on a device for positioning a cutaneous electrode where two or more elements are joined, whether temporarily or permanently.

The term "flexible member" is intended to mean any element of a device for positioning a cutaneous electrode where that element is at least not entirely mechanically rigid.

The terms "band" and "strap" are intended to mean any elongated member, to include but not limited to flexible members that may be either elastic or inelastic.

The term "interrelated", when used with "indicators" or "markings" is intended to mean any such two or more indicators or markings created in a way as to connote a relationship between the indicators or markings, wherein such relationship may indicate, for example, the location of a common connection or attachment point, or the location of a placement, such as placement of an electrode on a strap or a band, or at a marking on that strap or band that is related to a marking on another strap or a band.

The term "cutaneous electrode" is meant to refer to any electrode or sensor that rests on skin, in proximity to skin, or is implanted in the skin or in tissues adjacent the skin.

The term "adjacent" is meant to refer to a distance at which a referenced element is able to provide a desired effect of at least a minimum desired magnitude at a referenced location, but beyond which the element would be unable to provide the desired effect of at least the minimum desired magnitude at the referenced location.

A first embodiment of a device for positioning a cutaneous electrode 13 for the deliver}' of electrical stimulation to a subject's head 27 in shown at 10 in Figures 1-3. A second embodiment is shown at 10' in Figures 5-7. Reference numerals with the designation prime (') in Figures 5-7 indicate alternative configurations of elements that also appear in the first embodiment. Unless indicated otherwise, where a portion of the following description uses a reference numeral to refer to Figures 1-3, that portion of the description applies equally to elements designated by primed numerals in Figures 5-7.

As best shown in Figure 1, the device 10 may include a harness 11 comprising one or more bands 14, 15, 19. As shown in Figures 2 and 3, the bands 14, 15, 19 may be connected together in such a way as to be placed and worn on a subject's head 27. One or more portions of the bands 14, 15, 19 may be correctable together in such a way as to fasten the bands together permanently, or may be connectable together in such a way as to be releasable as desired by a user. The bands 14, 15, 19 of the harness 11 may be flexible or comprise flexible members or portions that may include elastic materials, inelastic materials, or any combination thereof. One or more of the bands 14, 15, 19 may also be configured to be selectively stretched when connected, so as to create tension between other elements of the device 10, or to cause other elements of the device 10 to apply pressure against tissues adjacent those elements.

As shown in Figures 1-3, a first band 14 of the one or more bands 14, 15, 19 of the harness 11 may be configured to be worn in a closed loop around a subject's head 27 as shown in Figures 2 and 3. The first band 14 may further be configured to fit around a circumference or perimeter of a subject's head 27 and to stretch while being worn, in a way that creates a snug fit when the first band 14 is engaged around the circumference of the subject's head 27.

The first band 14 may also comprise attachment locations 16 for fastening to other attachment locations on the first band 14 or to attachment locations 16

on the other bands 15, 19 of the one or more bands 14, 15, 19; such that one or more closed loops may be formed and/or the other bands 15, 19 may be shaped and/or interconnected in such a way that the harness 11 may be placed on, fitted to, and/or retained on a subject's head 27. At least one of the one or more bands 14, 15, 19 may be configured to rest on and/or wrap around a subject's head in respective positions extending across, around and/or surrounding a desired contact location 28 on the subject's head 27. The desired contact location 28 may include the location of tissues at or adjacent tissues where it is desired to provide electrical stimulation in either a noninvasive manner or an invasive manner.

Further, and as is also shown in Figures 1-3, the device 10 may include one or more straps, such as a tensioning straps 12, 17, that may be configured and positioned to be worn across the desired contact location 28 or across any other desired location. One or more of the tensioning straps 12, 17 may include or cany connectors 22 at one or more connecting locations 16, for connecting one or more of the straps 12, 17 to another one or more of the straps 12, 17 or to one or more of the bands 14, 15, 19 of the harness 11 as shown in Figures 2 and 3. The connectors 22 may include, but are not limited to including, materials such as adhesive materials, tape, mechanical connectors such as snaps, hooks, clips, D-rings or buckles, fabric connectors, or common hook and loop connectors such as Velcro®. As shown in Figure 7, one or more of the connectors 22' may also include at least one hole or similar feature in a strap 12' configured to articulate or interface with a mechanical connector 22' such as a hook on a band 14' of a harness *IV*, Alternatively, the hole (or similar feature) may be in a band of a harness and the hook (or other mechanical connector) may be in a strap of the harness. The connectors 22 may be sufficiently spaced-apart so as to be able to connect to various locations on other straps 12, 17 or on one or more bands 14, 15, 19 of the harness 11. The straps 12, 17 may also be configured to selectively stretch when connected, so as to create tension between other members, or to create means to cause elements of the device 10 to produce pressure against tissues adjacent the elements.

Attachment locations 16 of the straps 12, 17 may be sufficiently spaced apart and configured to attach to any number of spaced-apart attachment locations 16 of the harness 11 such that an electrode 13 configured to provide electrical stimulation carried by either a band 14, 15, 19 or a strap 12, 17 is disposed over or adjacent a desired

contact location 28 on the subject's head 27 as shown in Figures 2 and 3. Further, the electrode 13 may be configured to be positioned at or adjacent a location on a subject's head 27, which is consistent with the standard international 10-20 electrode positioning system commonly used for electroencephalogram (EEG) electrode placement.

At least one of the straps 12, 17 may have one or more elastic portions 18 that may be configured to provide and maintain or assist in providing and maintaining contact pressure between the electrode 13 and the desired contact location 28 when the strap 12, 17 is stretched and subsequently attached between attachment locations 16 on any element of the harness 11 while it is being worn on a subject's head 27.

Inelastic materials of a strap 12, 17 or a band 14, 15, 19 may include, but are not limited to, inelastic fabric, cloth, paper, polymers or composites thereof. Elastic materials of a strap 12, 17 or a band 14, 15, 19 may include, but are not limited to, elastic fabric, cloth, polymers or composites thereof.

The harness 11 may include a second band 15 of the bands 14, 15, 19 carried by the first band 14 such that the second band 15 rests in a position to extend along the median plane of a subject's head 27 when the harness 11 is worn. Further, the second band 15 may be configured to extend over tissues adjacent the inion 29 and nasioii 30 locations of a subject's head 27, and may include means of attaching or connecting to the first band 14 at locations on the first band 14 that are at or adjacent tissues further adjacent the inion 29 or the nasion 30 of a subject's head 27.

The harness 11 may also include a third band 19 that may also be carried by the first band 14, and may be configured so that the third band 19 rests in a position that extends under a chin of a subject, as shown in Figure 3, when the harness 11 is worn. The third band 19 may have an elastic portion 18, an inelastic portion or any combination thereof.

Further, the harness 11 may comprise two or more bands 14, 15, 19 such that attachment locations 16 of the harness 11 are disposed on one or more of the bands 14, 15, 19. One or more of the straps 12, 17 may be configured to attach at attachment locations 16 to any one or more of the attachment locations 16 of the harness 11, and may be configured such that one of the straps 12, 17 is stretched between two attachment

locations 16 when attached and while the harness 11 is being worn on a subject's head 97.

At least one strap 17 of the straps 12, 17 may be further configured such that the strap 17, when stretched between selected attachment locations 16 and while the harness 11 is being worn on a subject's head 27, creates mechanical force that is configured to hold at least one element of the device 10 closer to skin covering a subject's head 27. The strap 17 may further be configured to cooperate with other elements of the device 10 in locating at least one electrode 13 in a desired location on or adjacent a subject's head 27 for electrical stimulation.

At least one strap 17 of the straps 12, 17 may further be configured such that the strap 17, when stretched between the selected attachment locations 16 and while a harness 11 is being worn on a subject's head 27, creates mechanical force configured to hold at least one electrode 13 for electrical stimulation closer to skin covering a subject's head 12, 27 so that electrical conductivity between the electrode 13 and the skin is improved. The mechanical force may be configured to hold at least one electrode 13 for electrical stimulation at one or more standard international 10-20 electrode positioning system sites.

As best shown in Figure 1, the harness 11 may comprise indicators 20 positioned on any one or more of its bands 14, 15, 19, which are configured to identify a location for desired placement of another band 14, 15, 19 or a strap 12, 17. The indicators 20 may include, but are not limited to letters, numbers, symbols, or colors. The indicators 20 may further be configured to correspond to at least one landmark or physical dimension on a subject's head 27, with the indicators 20 being positioned to assist in placing the harness 11 so that it may be properly worn on a subject's head 27 and to accommodate heads of varying sizes.

As is also best shown in Figure 1, a band 14, 15, 19 or strap 12, 17 of the device 10 may comprise or carry an embossment 21 at a location where the band 14, 15, 19 or strap 12, 17 carries an electrode 13, and the embossment 21 may be configured so that the embossment 21 aids in positioning the electrode 13 closer to the skin of a subject's head 27.

Further, the device 10 may be coupled to and configured to transmit biophysical data to an instrument 31 configured to provide electrical stimulation and/or to make biophysical measurements, as shown in Figure 1. The ability to measure such data may be useful for assessing or characterizing a physical status or condition of a subject at or near the time of receiving electrical stimulation. The instrument 31 may be configured to measure biopotential voltage such as being configured to measure electroencephalography, or an EEG. Such measurement of biopotential voltage may be accomplished using at least one cutaneous electrode 13, and thai cutaneous electrode 13 may also be usable for electrical stimulation.

Further, the first band 14 may be configured to be worn in a closed loop around a subject's head 27 and around, over, and/or surrounding a desired contact location 28 on the subject's head 27, and may further be configured such that the harness 11 can be adjusted in size to fit different subjects' heads. Further still, an electrode 13 may be carried by the device 10 in a position such thai the electrode 13 may be disposed over the desired contact location 28 on the subject's head 27 when the subject wears the harness 11. Further still, the device 10 may feature at least one indicator 20 in a position configured to guide size adjustment of the harness 11 for a given subject's head 27.

At one or more attachment locations 16 of at least one of the bands 14, 15, 19 of the harness 11, a connector 22 may be carried by the harness. The connector 22 may comprise connecting material, such as Velcro©, that is configured to engage connecting material of at least one other connector 22 of the bands 14, 15, 19 in such a way as to allow sufficient overlap upon connection to accommodate different head sizes.

The harness 11 may include a plurality of indicators 20 that correspond to a plurality of measurements associated with different head sizes. Such indicators 20 may include, but are not limited to letters, numbers, or symbols, as shown at 20 in Figure 1; or colors as shown at 20' in Figures 6 and 7. Such indicators 20 may also feature interrelated markings so that matching indicators 20 can be used to identify locations for connecting two or more of the bands 14, 15, 19 or straps 12, 17 of the device 10.

As shown in Figures 2 and 3, at least one strap 17 of the tensioning straps 12, 17 may be configured to be worn across a desired contact location 28 and to connect

at spaced-apart attachment locations 16 of the harness 11. Alternately, the tensioning strap 12, 17 may feature a series of spaced-apart attachment locations, at which a series of spaced-apart connectors 22 may be disposed, and may be configured to be worn across a desired contact location 28 and to connect in at least one attachment location 16 of the harness 11 to a connector 22 disposed at the at least one attachment location 16. The tensioning strap 17 may further comprise an elastic portion 18 configured to provide and maintain contact pressure between the electrode 13 and the desired contact location 28 when the strap 17 is stretched between the attachment locations 16.

Further, at least one of the straps 12, 17 may comprise a connector 22 having sufficient connecting material to engage connecting material of another connector 22 on the harness 11 while allowing for adjustment to accommodate different head sizes. Further still, and as best shown in Figure 1, at least one of the straps 12, 17 may comprise a plurality of indicators 20 that correspond to a plurality of measurements associated with different head sizes. Such indicators 20 may include, but are not limited to letters, numbers, or symbols, as shown in Figure 1; or colors as shown in Figures 6 and 7. Further still, the device 10 may include at least one embossment 21 carried by at least one of the straps 12, 17, with such embossment 21 configured to displace the electrode 13 toward the skin when the harness 11 is worn on a subject's head 27.

Further, as indicated above, the device 10 may be coupled and configured to transmit biophysical data to the instrument 31. Such data may be useful for measuring or characterizing a physical status or condition of a subject at or near the time of receiving electrical stimulation. The instrument 31 may be configured to measure biopotential voltage such as being configured to measure electroencephalography, or an EEC Such measurement of biopotential voltage may be accomplished using at least one cutaneous electrode 13, and that cutaneous electrode 13 may also be usable for electrical stimulation.

Further still, the device 10 may feature at least one indicator 20 in a position configured to guide electrode positioning for a given subject's head 27 such that the electrode 13 will be disposed at the desired contact location 28 when the subject wears the harness 11, and may further comprise a mount 23 configured to carry an electrode 13 on the harness 11 at the location of an indicator 20.

The harness 11 may include a plurality of indicators 20 that correspond to a plurality of measurements associated with different head sizes. Such indicators 20 may include, but are not limited to letters, numbers, symbols, or colors. Such indicators 20 may also feature interrelated markings so that matching indicators 20 can be used to position a cutaneous electrode 13 for delivery of electrical stimulation to a subject's head 27, or to identify locations for connecting one or more elements of the device 10.

The device 10 may also comprise a number of characteristics that provide practical benefit or advantage to a user. For example, an electrode 13 for providing stimulation may comprise a pre-gelled electrode. As another example, an electrode 13 for providing stimulation may also comprise a disposable electrode 13. As another example, an electrode 13 for providing stimulation may also comprise a means of connecting to a strap 12, 17 or band 14, 15, 19 of a harness 11. Such means of connecting may include, but are not limited to, adhesives and mechanical connectors. As yet another example, the entire device 10 may be disposable.

The device 10 may also include a plurality of electrodes 13 carried in a multiplicity of positions such that the plurality of electrodes 13 may be disposed over a multiplicity of desired contact locations 28 on a subject's head 27 when the subject wears the harness 11. Such plurality of electrodes 13 may further be configured to transmit biophysical data to the instrument 31. Such data may be useful for measuring or characterizing a physical status or condition of a subject. The instrument 31 may be configured to measure biopotential voltage such as being configured to measure electroencephalography, or an EEG. Such measurement of biopotential voltage may be accomplished using the plurality of electrodes 13, including at least one cutaneous electrode 13 that may also be usable for electrical stimulation.

With reference to Figure 4, a method is provided for making and using the device 10 for providing electrical stimulation to a subject's head 27. As shown in action step 40, the method may include first making at least one spatial measurement of a head 27 to determine the size of the subject's head 27, then, using this measurement, selecting a first strap 12, 17 or a band 14, 15, 19 of the device 10 and modifying the length of the strap 12, 17 or band 14, 15, 19 in relationship to the at least one spatial measurement taken of the subject's head 27.

As is also shown in action step 40, the method may further include connecting the selected strap 12, 17 or band 14, 15, 19 at spaced-apart locations to create a continuous band 25 configured so that it may be placed on the subject's head 27.

Further, and as shown in action step 42, the method may include selecting a second strap 12, 17 or band 14, 15, 19 for traversing the head 27, modifying the second strap 12, 17 or band 14, 15, 19 in length in relationship to the at least one spatial measurement of a head 27, and connecting the second strap 12, 17 or band 14, 15, 19 to the continuous band 25 to form a cap subassembly.

Further, and as shown in action step 44, the method may include connecting at least one electrode 13 to the cap subassembly, and configuring and positioning the electrode 13 in a way so that it rests in proximity to a tissue to be electrically stimulated 26.

Further to the method, the steps of modifying the length of a strap 12, 17 or a band 14, 15, 19 may include methods such as cutting the strap 12, 17 or band 14, 15, 19, folding the strap 12, 17 or band 14, 15, 19 or attaching at least two straps 12, 17 or bands 14, 15, 19 in a way that causes the at least two straps 12, 17 or bands 14, 15, 19 to variably overlap. Further still, the step of modifying the length of a strap 12, 17 or band 14, 15, 19 may include the use of indicators 20 on a strap 12, 17 or band 14, 15, 19 that correspond to a spatial measurement of a head 27, whereas such indicators 20 may include, but are not limited to, letters, numbers, symbols, or colors.

Further, the method of making and using a cap device for providing electrical stimulation may include creating a continuous band 25 that is configured to be placed on a head 27 and further configured so that the length of the continuous band 25 is sufficiently small so that the continuous band 25 is sufficiently taut when placed on a subject's head 27 so as to inhibit movement of the continuous band 25 when worn on a head 27.

Further to the method, the step of selecting a strap 12, 17 or band 14, 15, 19 may include selecting a strap 12, 17 or band 14, 15, 19 comprising an elastic material, or an inelastic material, or any combination thereof.

Further to the method, the steps of fastening and/or attaching may include, but are not limited to, using fastening means consisting of adhesive materials, tape, mechanical connectors such as snaps, hooks, clips, D-rings or buckles, fabric connectors, or common hook and loop connectors such as Velcro®.

Further to the method, the step of connecting an electrode 13 may include the use of indicators 20 corresponding to a spatial measurement of a head 27 on a cap subassembly. Further still, the step of connecting may include the use of at least one indicator 20 on at least one strap 12, 17 or band 14, 15, 19 corresponding to the spatial measurement of a head 27, and further may include the step of connecting at least one additional strap 12, 17 or band 14, 15, 19 to a location corresponding to the indicator 20.

Further to the method, the step of connecting may include the use of at least one indicator 20 on or carried by at least one strap 12, 17 or band 14, 15, 19 corresponding to the spatial measurement of a head 27, and may further include the step of connecting at least one electrode 3 to a location corresponding to the indicator 20.

According to the second embodiment, and as shown in figures 5-7, the device 10' may include a harness 11' comprising a first band 14', which, as best shown in Figure 5, comprises an elastic portion 18' and an inelastic portion 33, and is configured to be worn in a closed loop around a subject's head 27'. The first band 14' may be configured such that it can be adjusted in size to fit different subjects' heads in a way that creates a snug fit when the first band 14' is engaged around the circumference or perimeter of the subject's head 27' and provides tension adequate to inhibit movement to maintain the first band's position on the head 27' once it is applied. Such adjustment may be accomplished in the embodiment using a connector such as a pair of D-rings 34, which permits the first band 14' to be tightened and held in a sufficiently stretched position. Other connectors may be utilized, such as but not limited to adhesive materials, tape, mechanical connectors such as snaps, hooks, clips, or buckles, fabric connectors, and common hook and loop connectors such as Velco ©.

Further according to the second embodiment, the harness 11' may further comprise a second band 15' configured to attach to the first band 14' and further configured to rest on a subject's head in a position extending across, around or

surrounding a desired contact location 28' on the subject's head 27' as best shown in Figure 7. The second band 15' may be configured to rest in a position to extend along the median plane of a subject's head 27' when the harness 11' is worn. The second band 15' may be configured to extend over tissues adjacent the inion 29' and nasion 30' locations of a subject's head 27'. The harness 1 *V* may include means to attach the second band 15' to the first band 14' at variable locations to fit different subjects' heads. Such means may include the use of a connector 22' such as a mechanical clip 35, as shown in Figure 7. Any other suitable types of connectors 22' may be utilized, such as but not limited to adhesive materials, tape, mechanical connectors such as snaps, hooks or buckles, fabric connectors, and common hook and loop connectors such as Velcro®.

The first band 14' or second band 15' may feature a series of interrelated indicators 20' that can be used to position a cutaneous electrode 13' for delivery of electrical stimulation to a subject's head 27' relative to the location of at least one landmark on a head 27', whereas the landmark may include, but is not limited to the nose, inion 29', nasion 30', central zenith, or at least one eye, eyebrow, ear or mastoid process. A first series of indicators 36 may be located on the second band 15' and configured to identify an intersection point when the second band 15' is attached to the first band 14', as shown in Figure 7. Further to the embodiment, a second series of indicators 37 is also provided on the second band 15 and configured so that each indicator of the first series of indicators 36 has a corresponding indicator of the second series of indicators 37.

The indicators of the first series of indicators 36 and the indicators of the second series of indicators 37 may comprise shapes of differing colors, and the two series of indicators 36, 37 may be configured and positioned in such a way as to guide electrode positioning on a given subject's head 27' such that the electrode 13' will be disposed at the desired contact location 28' when the subject wears the harness 11'. The two series of indicators 36, 37 may be further configured to provide a location for attaching an electrode 13' on the harness 11'. This may be accomplished by attaching the electrode 13' to the second band 15' in a location where there is disposed an indicator of the second series of indicators 37, which corresponds to, for example, a like-colored or like-shaped indicator of the first series of indicators 36, and coinciding with a landmark point on the harness 11. Such landmark point may be the intersection of the first band 14'

and the second band 15' at the inion 29' of the subject's head 27'. Electrode placement may alternatively be accomplished using any other suitable means to include any suitable configuration of interrelated or interrelatable indicators, such as but not limited to letters, numbers, or symbols. In addition, any point or location on the harness 11, including points or locations coinciding with or adjacent indicators of the second series of indicators 37, may comprise means of attaching an electrode 13, such means including but not limited to adhesive materials, tape, mechanical connectors such as snaps, hooks or clips, fabric connectors, or common hook and loop connectors such as Veicro®. Alternately, the electrode 13' may include any other suitable means of attaching to any point on the harness 11'. Such means may include but are not limited to adhesive materials, tape, mechanical connectors such as snaps, hooks or clips, fabric connectors, or common hook and loop connectors such as Veicro©.

Further, a tensioning strap 17' may be configured to be worn across a point that coincides with at least one of a desired contact location 28', an electrode 13' or the second band 15'. As shown in Figure 7, the tensioning strap 17' may also or alternatively be configured to connect to the harness 11' at spaced-apart connection locations 38' so as to accommodate different head sizes. A hole may be disposed at each of the spaced-apart connection locations 38', and each such hole may be configured to interface with a suitable connector 22' carried in at least one attachment location 16' by the first band 14'. As shown in Figure 7, such attachment location 16' may comprise a mechanical hook 22' configured to articulate with and/or be received by at least one hole in the tensioning strap 17'. The tensioning strap 17' may be configured to provide and maintain contact pressure between the electrode 13' and the desired contact location 28' when the tensioning strap 17' is stretched between the attachment locations 16'.

The harness 11 may further comprise indicators 40 positioned to identify a location for desired placement of at least one of the first band 14', the second band 15 or the tensioning band 17'. The indicators 40 may include, but are not limited to numbers, symbols, colors, or, as shown in Figure 5, letters.

With reference to Figure 8, a method is provided for making and using a device 10' constnicted according to the second embodiment. The method may include

placing a first band 14' around a subject's head 27 and connecting the first band 14' so as to create a continuous loop, as shown in action step 50.

Further, the method may include tightening the first band 14' around the subject's head 27' so as to inhibit movement of the first band 14', as shown in action step 52.

Further, the method may include pulling a second band 15' securely along the median plane of a subject's head 27' and identifying a first indicator 36 on the second band 15' positioned at the intersection of the first band 14' and the second band 15' at or adjacent the subject's inion 29', as shown in action step 54.

Further, the method may include identifying a corresponding second indicator 37 on the second band 15', and attaching an electrode 13' at or adjacent the corresponding second indicator 37, as shown in action step 56.

Further, the method may include pulling the second band 15' securely back along the median plane of a subject's head 27 so as to position an electrode 13' in a way so that it rests in proximity to a desired contact location 28 comprising a tissue to be electrically stimulated 26, and attaching the second band 15' to the first band 14' at or adjacent the subject's inion 29', as shown in action step 58.

The method may further include selecting a tensioning strap 17 configured to be worn across a point that coincides with at least one of a desired contact location 28, an electrode 13', or a second band 15', as shown in action step 60.

The method may further include attaching the tensioning strap 17 to a first band 14' in a way to provide and maintain contact pressure between the electrode 13' and the desired contact location 28 when the tensioning strap 17' is stretched between the attachment locations 39 of the first band 14', as shown in action step 62.

The invention is not limited in any way to the embodiment or variations described herein. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the method of the invention. The description is intended only to make apparent to those skilled in the art how the several forms of the invention may be embodied in practice.

What is claimed:

1. A device for positioning a cutaneous electrode for delivery of electrical stimulation to a subject's head, the device comprising:

a harness comprising a first band configured to be worn in a closed loop around a subject's head and around a desired contact location on the subject's head; and

a tensioning strap configured to be worn across the desired contact location and to connect at spaced-apart attachment locations of the strap to spaced-apart attachment locations of the harness such that an electrode disposed over the desired contact location on the subject's head is held in place by the tensioning strap, the tensioning strap having an elastic portion configured to provide and maintain contact pressure between the electrode and the desired contact location when the strap is stretched between the attachment locations.

2. The device of claim 1, in which the harness comprises an elastic material, or an inelastic material, or any combination thereof

3. The device of claim 1, in which the electrode is configured to apply electrical stimulation in a noninvasive manner.

4. The device of claim 1, in which the electrode is configured to apply electrical stimulation in an invasive manner.

5. The harness of claim 2, in which the inelastic material includes one or more materials chosen from the group of materials consisting of inelastic fabric, cloth, paper, polymers or composites thereof.

6. The harness of claim 2, in which the elastic material includes one or more materials chosen from the group of materials consisting of elastic fabric, cloth, polymers or composites thereof.

7. The device of claim 1, in which at least one of the strap or the band is configured to cany at least one electrode for electrical stimulation.

8. The device of claim 1, in which the strap comprises an elastic material, or an inelastic material, or any combination thereof.

9. The device of claim 1 fuxther including at least two strap connectors configured to releasably connect the respective spaced-apart attachment locations of the strap to the respective spaced-apart attachment locations of the harness, the connectors each comprising one or more items chosen from the group of items consisting of adhesive materials, tape, mechanical connectors such as snaps, hooks, clips, D-rings or buckles, fabric connectors, or hook and loop connectors such as Velcro®.

10. The device of claim 1, in which the first band is further configured to fit around a circumference of a subject's head and to stretch sufficiently to create a snug fit when the first band is engaged around the circumference of the subject's head.

11. The device of claim 1 in which the strap is further configured to position at least one electrode in a location on a subject's head consistent with the standard international 10-20 electrode positioning system.

12. The device of claim 1 in which the harness includes a second band carried by the first band in a position to extend along the median plane of a head.

13. The device of claim 1 in which the harness includes a third band carried by the first band in a position to extend under a chin of a subject and having an elastic portion.

14. The device of claim 1 in which the harness comprises two or more bands, the attachment locations of the harness are disposed on two or more of the bands, and the strap is further configured to connect at its attachment locations to any two selected respective attachment locations of the harness such that the strap is stretched between the selected attachment locations when connected.

15. The device of claim 14 in which the strap is further configured such that the strap, when stretched between the selected attachment locations, creates mechanical force holding at least one element of a device for positioning a cutaneous electrode, closer to skin covering a subject's head.

16. The device of claim 14 in which the strap is further configured to cooperate with other elements of the device in locating at least one electrode in a desired location on or adjacent a subject's head for electrical stimulation.

17. The device of claim 14 in which the strap is further configured such that the strap, when stretched between the selected attachment locations, creates mechanical force holding at least one electrode for electrical stimulation closer to skin covering a subject's head, thereby improving electrical conductivity between the at least one electrode and the skin.

18. The device of claim 14 in which the strap is further configured such that the strap, when stretched between the selected attachment locations, creates mechanical force holding at least one electrode for electrical stimulation at one or more standard international 10-20 electrode positioning system sites.

19. The device of claim 1 in which the harness further comprises indicators positioned and configured to identify a location for desired placement of at least one of the strap or the band.

20. The device of claim 19 in which the indicators on the harness are chosen from the group of indicators consisting of letters, numbers, symbols, or colors.

21. The device of claim 1 in which the harness further comprises indicators corresponding to at least one landmark on a subject's head, the indicators being positioned to assist in proper placement of the harness.

22. The device of claim 21, in which the harness indicators are chosen from the group of indicators consisting of letters, numbers, symbols, or colors.

23. The device of claim 1 further comprising an embossment at the location of an electrode for providing electrical stimulation, and the embossment being configured so that the embossment aids in positioning the electrode closer to the skin of a subject's head.

24. The device of claim 1 further comprising at least one pre-gelled electrode for providing stimulation.

25. The device of claim 1 configured to transmit biophysical data to an instrument.

26. The device of claim 25, in which the instrument is configured to measure biopotential voltage.

27. The device of claim 26, in which the instrument is configured to measure biopotential voltage using at least one cutaneous electrode.

28. The device of claim 27, in which the at least one cutaneous electrode is a cutaneous electrode that is also usable for electrical stimulation.

29. The device of claim 26, in which the instrument is configured for electroencephalography.

30. A device for positioning a cutaneous electrode for delivery of electrical stimulation to a subject's head, the device comprising:

a harness comprising a first band configured to be worn in a closed loop around a subject's head and around a desired contact location on the subject's head, the harness being configured for adjustment in size to fit different subjects' heads;

an electrode carried by the harness in a position to be disposed over the desired contact location on the subject's head when the subject wears the harness; and

at least one indicator borne by the harness in a position to guide size adjustment of the harness for a given subject's head.

31. The device of claim 30, in which the harness includes a second band configured to engage and connect to the first band, and further configured to allow sufficient overlap upon connection to accommodate different head sizes.

32. The device of claim 30, in which the first band comprises a plurality of indicators that correspond to a plurality of measurements associated with different head sizes.

33. The device of claim 32, in which indicators on the first band are chosen from the group of indicators consisting of letters, numbers, symbols, or colors.

34. The device of claim 32 in which the indicators are interrelated so that matching indicators identify locations for connecting two or more bands and/or straps of the device for positioning a cutaneous electrode for delivery of electrical stimulation to a subject's head.

35. The device of claim 30, further comprising a tensioning strap configured to be worn across the desired contact location and to connect spaced-apart attachment locations of the strap to spaced-apart attachment locations of the harness.

36. The tensioning strap of claim 35, further comprising an elastic portion configured to provide and maintain contact pressure between the electrode and the desired contact location when the strap is stretched between the attachment locations.

37. The device of claim 35, in which the strap comprises sufficient connecting material to engage connecting material on the harness while allowing for adjustment to accommodate different head sizes.

38. The device of claim 35, in which the strap comprises a plurality of indicators that correspond to a plurality of measurements associated with different head sizes.

39. The device of claim 38, in which the plurality of indicators of the strap are chosen from the group of indicators consisting of letters, numbers, symbols, or colors.

40. The device of claim 30 in which the electrode is carried by an embossment carried by the harness and configured to displace the electrode toward the skin of a subject's head from the harness.

41. The device of claim 30 further comprising at least one pre-gelled electrode.

42. The device of claim 30 coupled to an instrument and configured to transmit biophysical data to the instrument.

43. The device of claim 42, in which the instrument is configured to measure a biopotential voltage.

44. The device of claim 43, in which the instrument is coupled to at least one cutaneous electrode of the device and is configured to measure biopotential voltage received from a subject via the at least one cutaneous electrode.

45. The device of claim 44, in which the at least one cutaneous electrode is configured for delivery of electrical stimulation.

46. The device of claim 43, in which the instrument is configured for electroencephalography.

47. A device for positioning a cutaneous electrode for delivery of electrical stimulation to a subject's head, the device comprising:

a harness comprising a first band configured to be worn in a closed loop around a subject's head and around a desired contact location on the subject's head, the harness being configured for adjustment in size to fit different subjects' heads;

an electrode carried by the harness in a position to be disposed over the desired contact location on the subject's head when the subject wears the harness; and

at least one indicator borne by the harness in a position to guide electrode positioning for a given subject's head such that the electrode will be disposed at the desired contact location when the subject wears the harness.

48. The device of claim 47, further comprising at least one indicator borne by the harness in a position to guide size adjustment of the harness for a given subject's head.

49. The device of claim 47 in which the harness bears interrelated indicators configured to identify the location for desired placement of at least one electrode used for electrical stimulation.

50. The device of claim 47, in which the harness bears indicators interrelated such that corresponding indicators identify locations for connecting one or more elements of a device for positioning a cutaneous electrode for delivery of electrical stimulation to a subject's head.

51. The device of claim 47 in which the indicator is further configured to identify the location of at least one standard international 10-20 electrode positioning system site.

52. The device of claim 47 in which the indicator is further configured to identify the location of standard international 10-20 electrode positioning system site PZ.

53. The device of claim 49 further configured so that interrelated indicators are configured to locate at least one electrode relative to the location of at least one landmark on a head.

54. The device of claim 53, in which the landmark is chosen from the group of landmarks consisting of the nose, inion, nasion, central zenith or at least one eye, eyebrow, ear or mastoid process.

55. The device of claim 47 further comprising a connector configured to mount at least one electrode on the harness at or adjacent the location of an indicator.

56. The device of claim 47, in which the indicator is chosen from the group of indicators consisting of letters, numbers, symbols, or colors.

57. The device of claim 47 further comprising an electrode carried by an embossment carried by the harness, and the embossment being configured to position the electrode on or adjacent the skin of a head.

58. The device of claim 47 further comprising at least one pre-gelled electrode carried by the harness.

59. The device of claim 47 configured to transmit biophysical data to an instalment.

60. The device of claim 59, in which the instrument is configured to measure a biopotential voltage.

61. The device of claim 60, in which the instrument is configured to measure biopotential voltage using at least one cutaneous electrode.

62. The device of claim 61, in which the cutaneous electrode is configured to deliver electrical stimulation to the subject's head.

63. The device of claim 60, in which the instrument is configured for electroencephalography.

64. The device of claim 47, further comprising a tensioning strap configured to be worn across the desired contact location and to connect at spaced-apart attachment locations of the strap to spaced-apart attachment locations of the harness.

65. The tensioning strap of claim 64, further comprising an elastic portion configured to provide and maintain contact pressure between the electrode and the desired contact location when the strap is stretched between the attachment locations.

66. A method for positioning and securing an electrode for providing electrical stimulation to a subject's head, the method including the steps of:

making at least one spatial measurement of a head;

selecting at least one band and/or strap of a device for positioning a cutaneous electrode for delivery of electrical stimulation to a subject's head;

modifying the length of the at least one band and/or strap in relationship to the at least one spatial measurement of a head;

connecting the at least one band and/or strap at spaced-apart locations creating at least one continuous band configured to be placed on a head;

selecting at least one additional band and/or strap for traversing the head, and connecting the second band to the continuous band to form a cap subassembly;

modifying the length of the at least one additional band and/or strap in relationship to the at least one spatial measurement of a head; and

connecting at least one electrode to the cap subassembly, positioning the electrode to rest in proximity to a tissue to be electrically stimulated.

67. The method of claim 66, in which the step of modifying the length of the at least one band and'or strap includes cutting the at least one band and/or strap; and/or the step of modifying the length of the at least one additional band and'or strap includes cutting the at least one additional band and or strap.

68. The method of claim 66, in which the step of creating at least one continuous band includes making the length of the continuous band sufficiently small so that the continuous band is sufficiently taut to inhibit movement of the continuous band when worn on a head.

69. The method of claim 66, in which the step of modifying the length of the at least one band includes the use of indicators on the at least one band that correspond to a spatial measurement of a head; and/or the step of modifying the length of the at least one additional band and'or strap includes the use of indicators on the at least one band that correspond to a spatial measurement of a head.

70. The method of claim 69, in which the indicators are chosen from the group of indicators consisting of letters, numbers, symbols, or colors.

71. The method of claim 66, in which the steps of fastening comprise using items chosen from the group of items consisting of adhesive materials, tape, mechanical connectors, fabric connectors, or common hook and loop connectors such as Velcro®.

72. The method of claim 66, in which the step of selecting at least one band or strap includes selecting a band or strap comprising an elastic material, or an inelastic material, or any combination thereof; and/or the step of selecting at least one additional band or strap includes selecting a band or strap comprising an elastic material, or an inelastic material, or any combination thereof.

73. The method of claim 66, in which the step of connecting an electrode includes the use of indicators corresponding to a spatial measurement of a head on a cap subassembly.

74. The method of claim 66, in which the steps of connecting include the use of at least one indicator on at least one band or strap corresponding to the spatial measurement of a head, and further including the step of connecting at least one additional band to a location corresponding to the indicator.

75. The method of claim 66, in which the steps of connecting include the use of at least one indicator on at least one band or strap corresponding to the spatial measurement of a head, and further including the step of connecting at least one electrode to a location corresponding to the indicator.

76. The method of claim 66, in which the step of modifying includes cutting a band or strap in accordance with indicators corresponding to at least one spatial measurement of a head.

77. The method of claim 66, in which the step of modifying includes folding a band or strap in accordance with indicators corresponding to at least one spatial measurement of a head.

78. The method of claim 66, in which the step of modifying includes attaching at least two bands and/or straps in a way that causes the at least two bands and/or straps to variably overlap.

79. The device of claim 1, in which the electrode includes at least one material for connecting to a harness, band or strap; such material for connecting being chosen from the group consisting of adhesives or mechanical connectors.

80. The device of claim 30, in which the electrode includes at least one material for connecting to a harness, band or strap; such material for connecting being chosen from the group consisting of adhesives or mechanical connectors.

81. The device of claim 47, in which the electrode includes at least one material for connecting to a harness, band or strap; such material for connecting being chosen from the group consisting of adhesives or mechanical connectors.

82. A method for positioning and securing an electrode for providing electrical stimulation to a subject's head, the method including the steps of:

placing a first band around a subject's head;

connecting the first band so as to create a continuous loop;

tightening the first band around the subject's head so as to inhibit movement of the first band;

pulling a second band securely along a subject's head;

identifying a first indicator of the second band;

identifying a corresponding second indicator on the second band;

attaching an electrode at or adjacent the corresponding second indicator;

pulling the second band securely back along a subject's head so as to position the electrode to rest in proximity to a desired contact location;

attaching the second band to the first band;

selecting a tensioning strap; and

attaching the tensioning strap to the first and/or second band in a position biasing the electrode into contact with the subject at the desired location.

83. The method of claim 82, in which the step of pulling includes placing a second band along the median plane of a subject's head.

84. The method of claim 82, in which the step of identifying a first indicator includes locating an indicator positioned at the intersection of the first band and the second band.

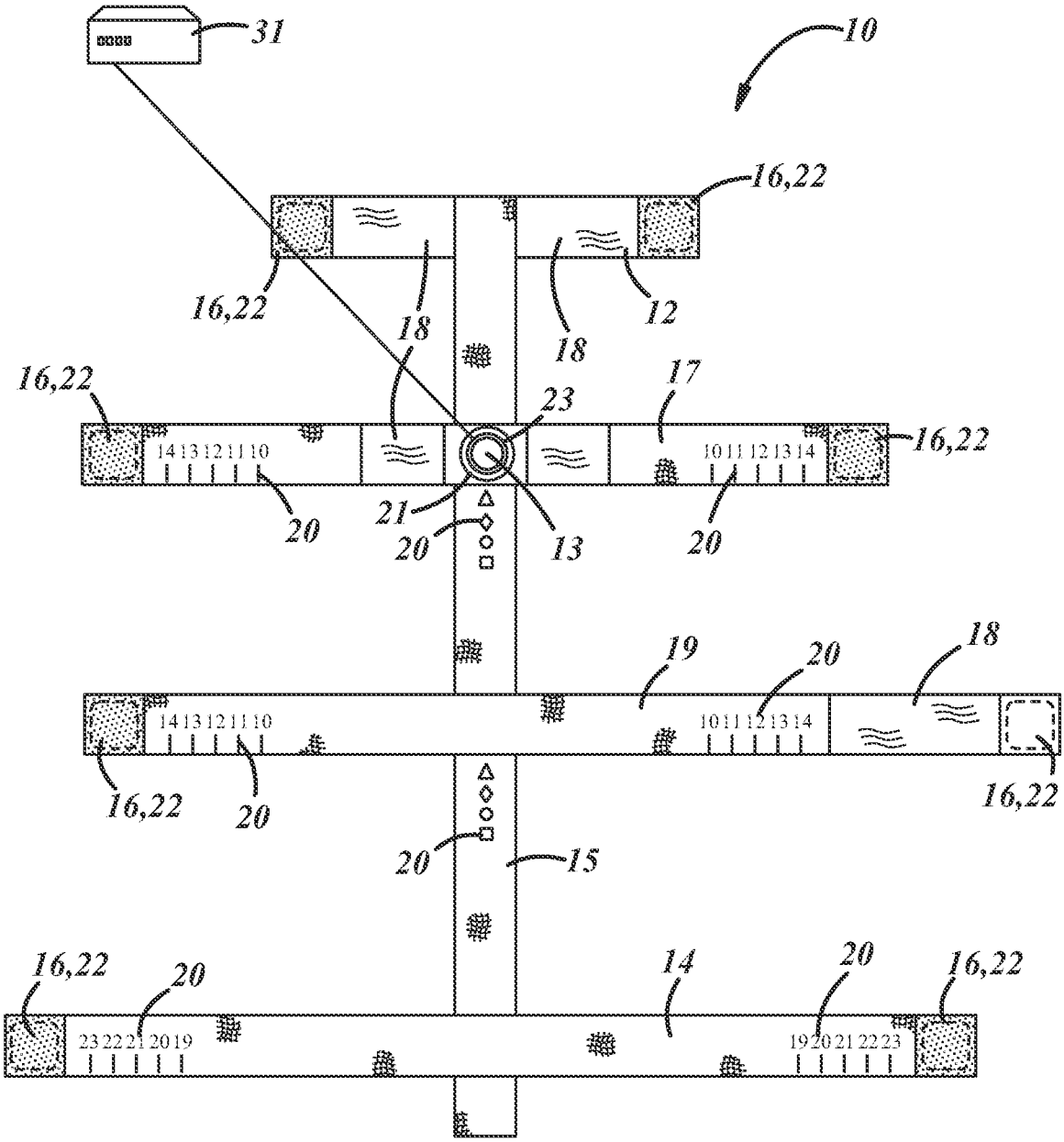
85. The method of claim 84, in which the first indicator is located at or adjacent the subject's inion.

86. The method of claim 82, in which the step of attaching the second band includes connecting a first band and a second band at or adjacent the subject's inion.

87. The method of claim 82, in which the step of selecting includes a tensioning strap configured to be worn across a point that coincides with at least one of a desired contact location, an electrode, or a second band.

88. The method of claim 82, in which the step of attaching the tensioning strap provides and maintains contact pressure between the electrode and the desired contact.

89. The method of claim 82, in which the tensioning strap is stretched between attachment locations of the first band.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23 22 21 20 19
19 20 21 22 23

FIG. 1

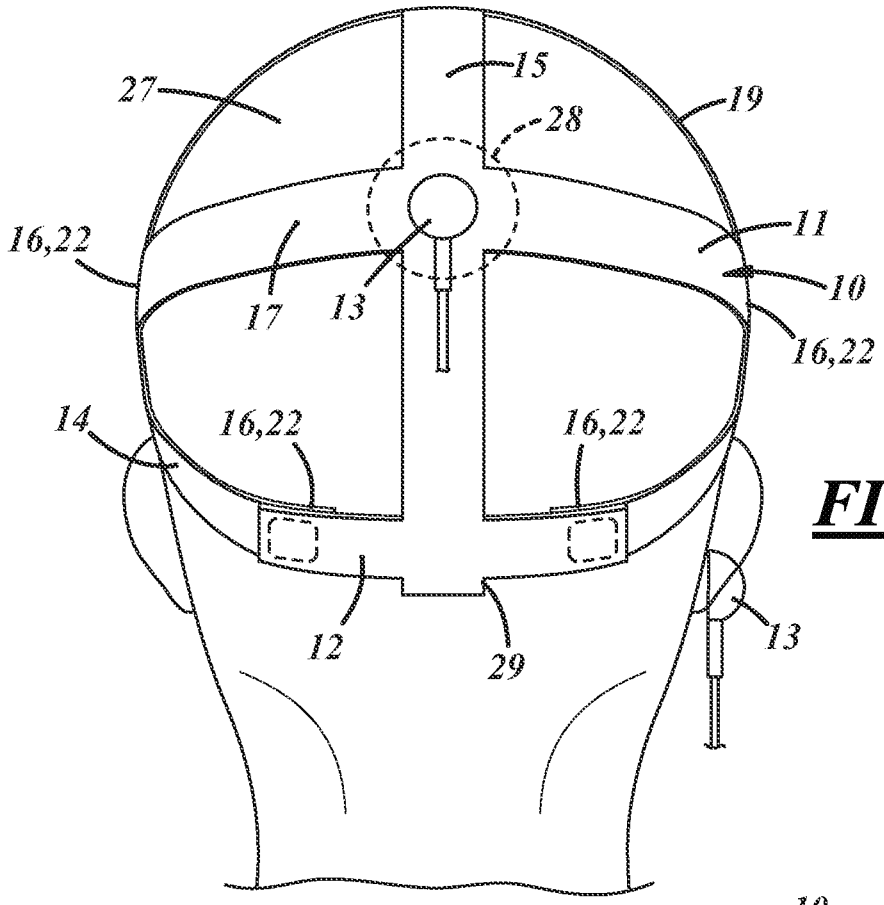
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FIG. 2

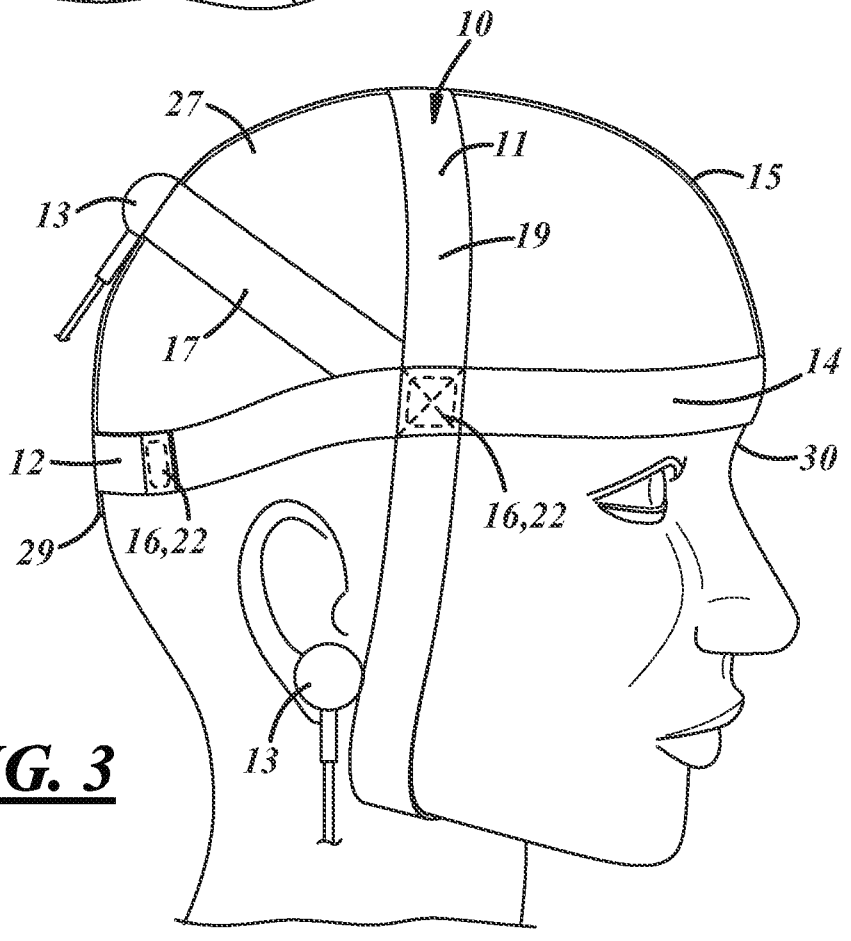
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FIG. 3

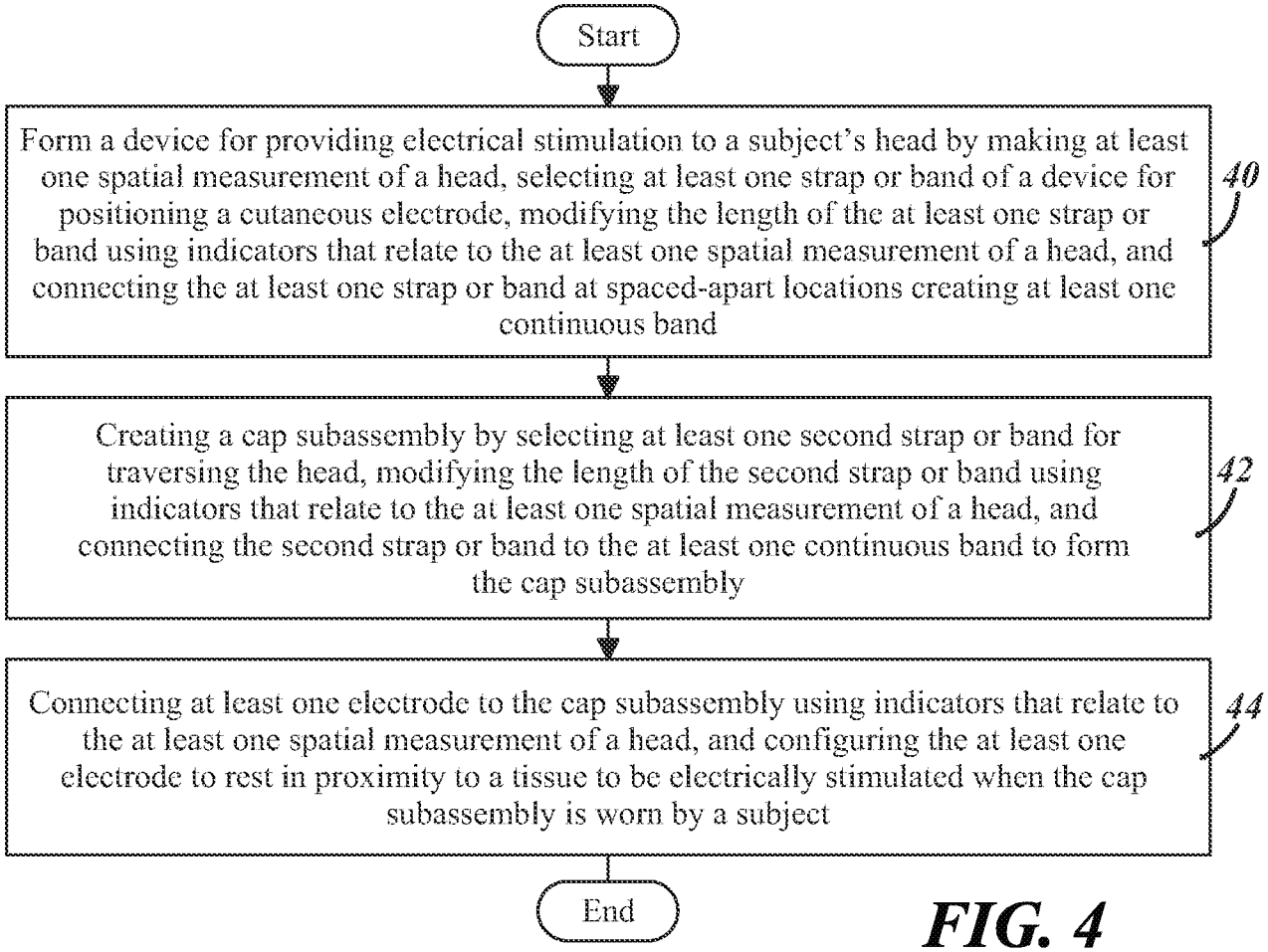

Start
Form a device for providing electrical stimulation to a subject's head by making at least one spatial measurement of a head, selecting at least one strap or band of a device for positioning a cutaneous electrode, modifying the length of the at least one strap or band using indicators that relate to the at least one spatial measurement of a head, and connecting the at least one strap or band at spaced-apart locations creating at least one continuous band
40
Creating a cap subassembly by selecting at least one second strap or band for traversing the head, modifying the length of the second strap or band using indicators that relate to the at least one spatial measurement of a head, and connecting the second strap or band to the at least one continuous band to form the cap subassembly
42
Connecting at least one electrode to the cap subassembly using indicators that relate to the at least one spatial measurement of a head, and configuring the at least one electrode to rest in proximity to a tissue to be electrically stimulated when the cap subassembly is worn by a subject
44
End

FIG. 4

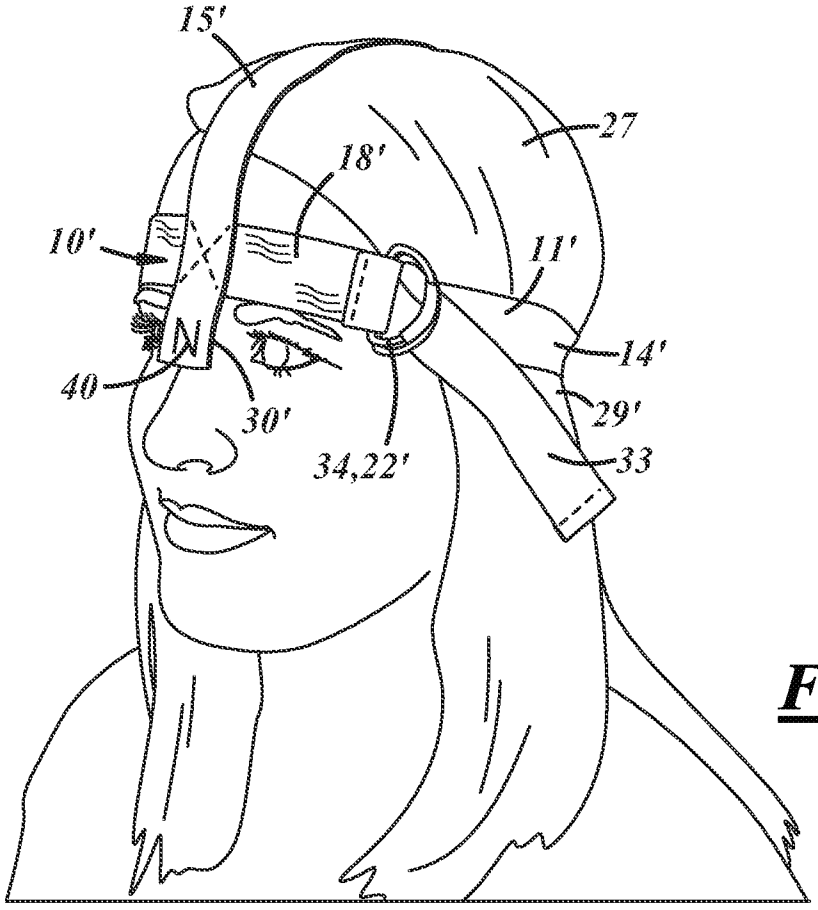
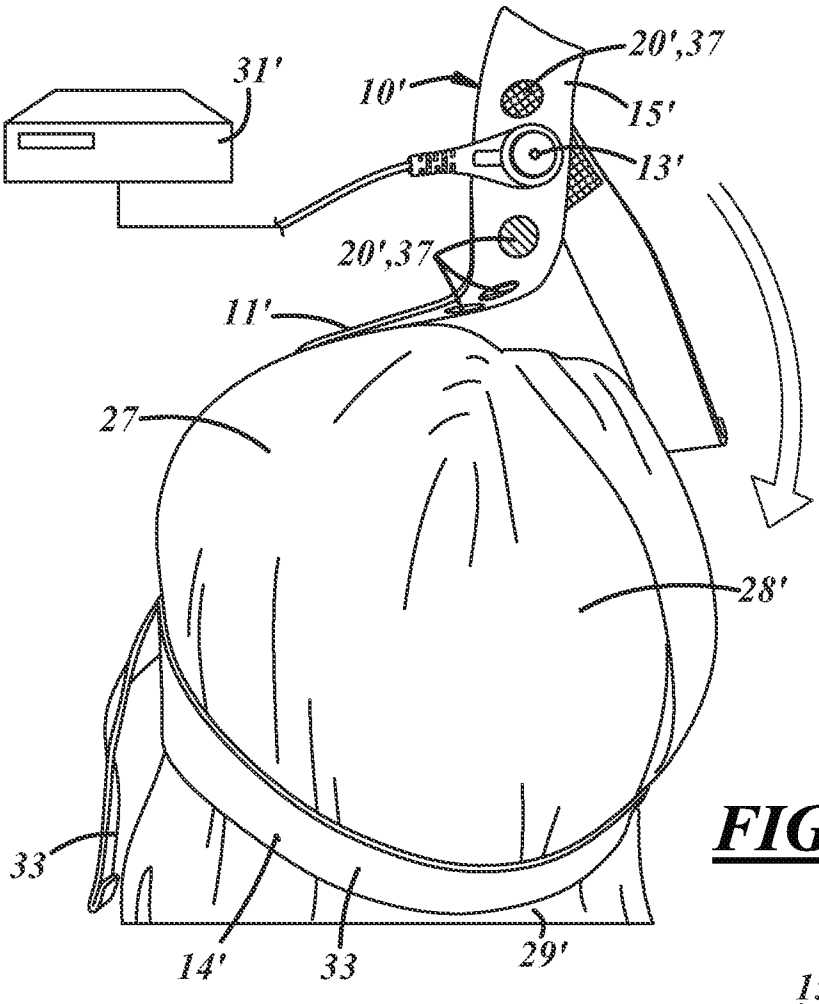

15'
27
18'
10'
11'
14'
40
29'
30'
33
34,22'

FIG. 5


31'
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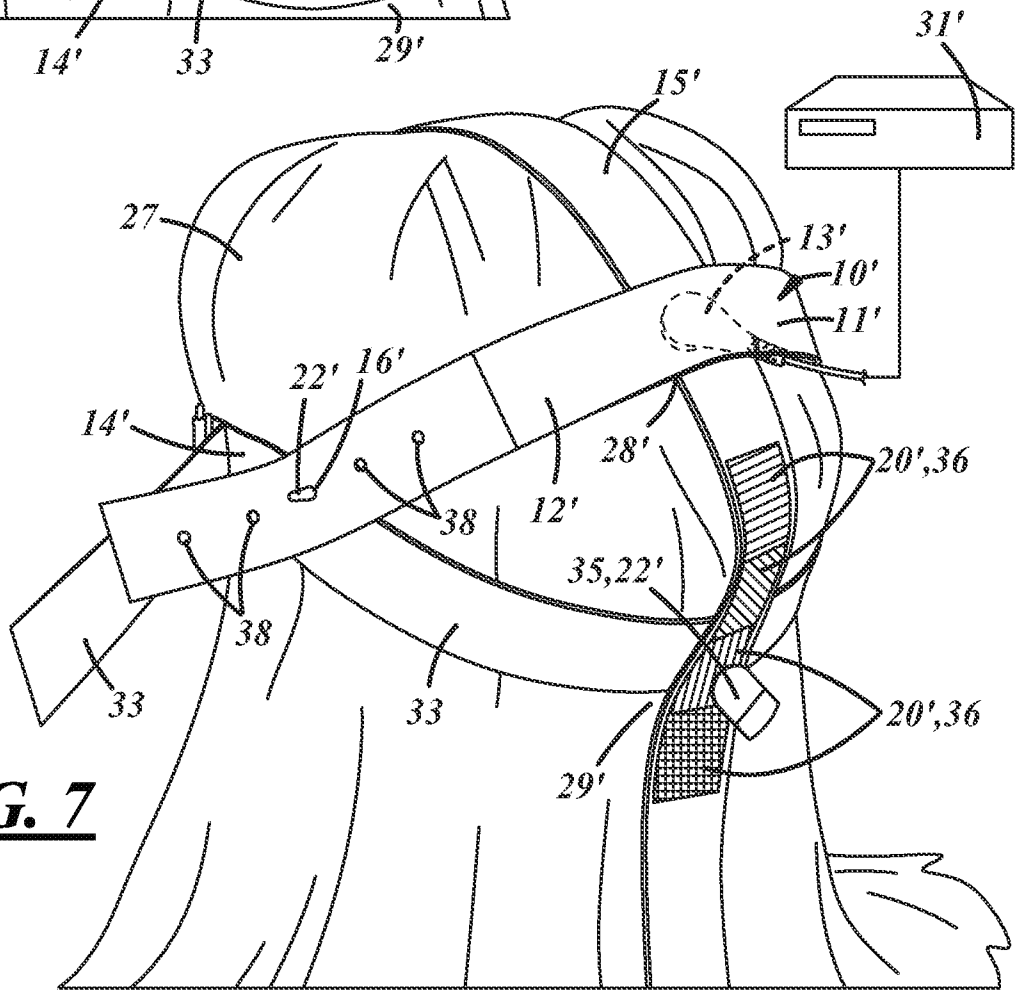
14'
33
29'

FIG. 6


31'
15'
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13'
10'
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29'

FIG. 7

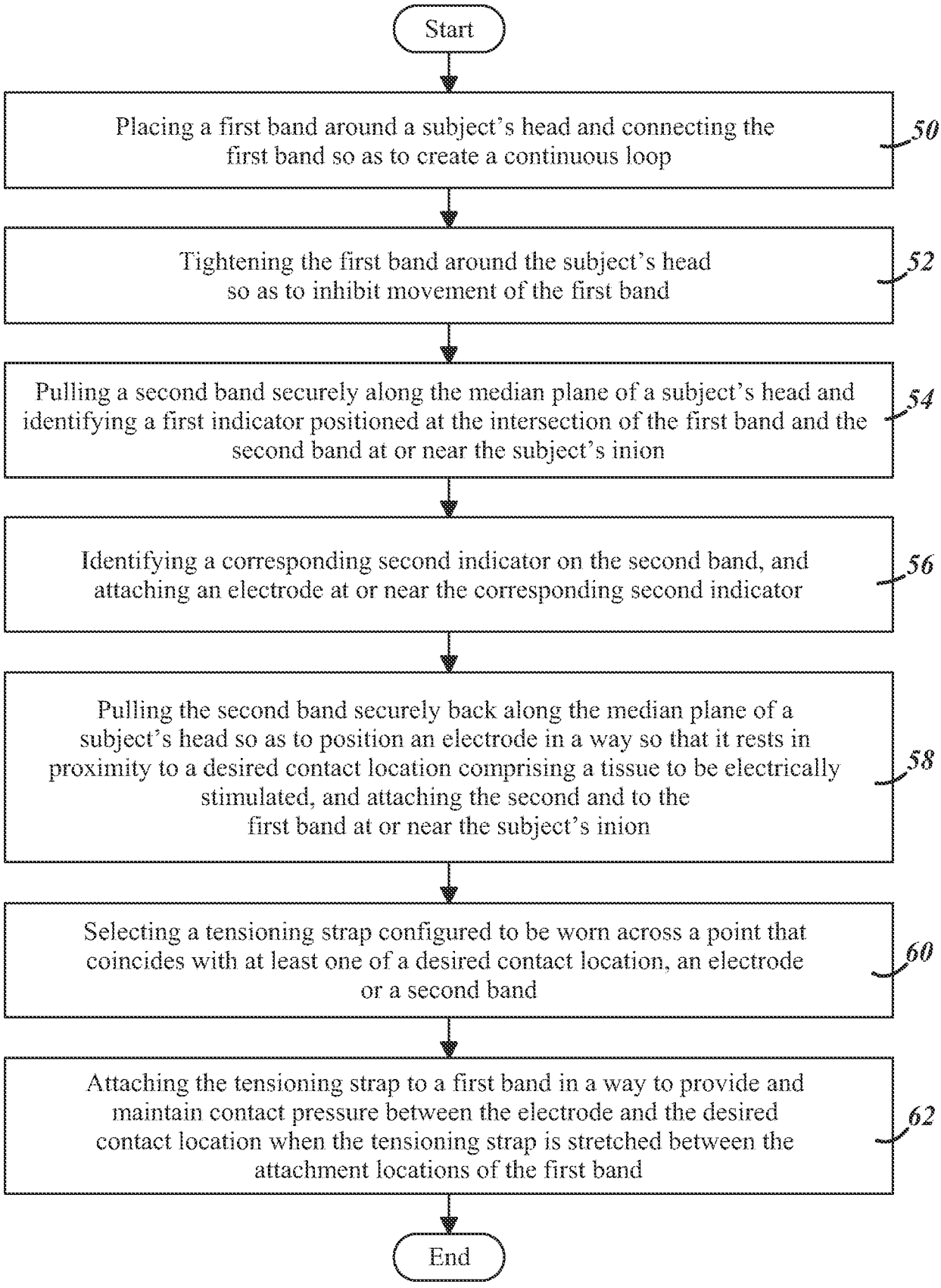
Start
Placing a first band around a subject's head and connecting the first band so as to create a continuous loop
50
Tightening the first band around the subject's head so as to inhibit movement of the first band
52
Pulling a second band securely along the median plane of a subject's head and identifying a first indicator positioned at the intersection of the first band and the second band at or near the subject's inion
54
Identifying a corresponding second indicator on the second band, and attaching an electrode at or near the corresponding second indicator
56
Pulling the second band securely back along the median plane of a subject's head so as to position an electrode in a way so that it rests in proximity to a desired contact location comprising a tissue to be electrically stimulated, and attaching the second and to the first band at or near the subject's inion
58
Selecting a tensioning strap configured to be worn across a point that coincides with at least one of a desired contact location, an electrode or a second band
60
Attaching the tensioning strap to a first band in a way to provide and maintain contact pressure between the electrode and the desired contact location when the tensioning strap is stretched between the attachment locations of the first band
62
End

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/030263

A. CLASSIFICATION OF SUBJECT MATTER

A61N l/36(2006.01)i, A61N l/04(2006.01)i, A61B 5/0476(2006.01)i

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 1/36; A61B 5/04; A61N 5/067; A61B 5/0408; A61N 1/04; A61B 5/0476

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: head harness, electrode, stimulation, strap, band, electroencephalograph

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2012-0330125 Al (WILSON, S. B. et al.) 27 December 2012 See abstract; claims 1-11.	1-89
Y	US 2005-0197556 Al (STOLER, D. R.) 8 September 2005 See abstract; paragraphs [0029], [0031], [0041], [0045], [0052]; claims 1-17.	1-89
A	US 2003-0018278 Al (JORDAN, K. G.) 23 January 2003 See abstract; claims 1-6.	1-89
A	US 2003-0032888 Al (DEWAN, E. M.) 13 February 2003 See abstract; claims 1 and 2.	1-89
A	US 2010-0131025 Al (HENRY, S.) 27 May 2010 See abstract; claims 1-5.	1-89

☐ 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
08 August 2014 (08.08.2014)	**08 August 2014 (08.08.2014)**

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