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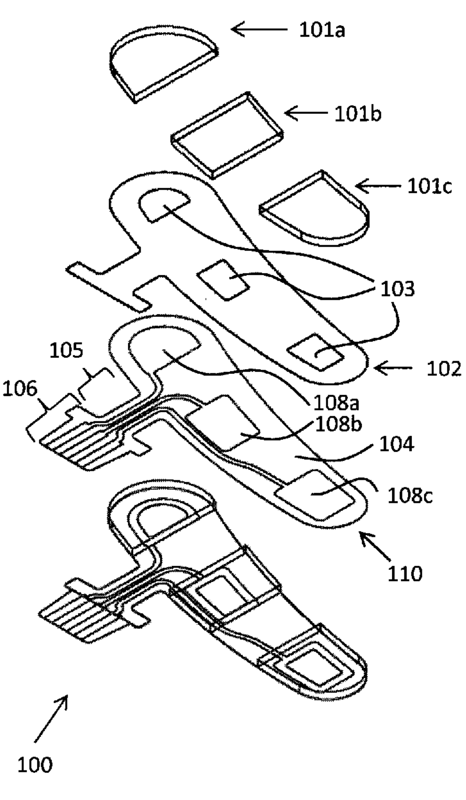

Fig 1a

(57) Abstract: Electrode arrays have a plurality of electrodes. These arrays may have any combination of the following improvements. The arrays may have features that enable easier electrical connections and reduced bending stiffness by having a stop region and a torsion relief region, respectively. The arrays may have a shielding feature that may reduce electrical interference. The arrays may come in pairs that are designed to simplify measurements of electric signals of bilateral organs and tissues, such as eyes and ears.

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TITLE

ELECTRODE ARRAYS

RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. provisional application 61/696,499, filed September 4, 2012, entitled "Electrode Arrays." The entirety of the aforementioned application is incorporated herein by reference.

GOVERNMENT RIGHTS

[0002] Inventions described herein were made with government support under grant 9R44EY021121 awarded by the National Institutes of Health, USA. Accordingly, per the terms and conditions of the grant, the U.S. government has certain license rights in the present application.

FIELD

[0003] Embodiments of the present invention relate to improved electrode arrays. These electrode arrays can be used to monitor physiological electric signals.

BACKGROUND

[0004] Electrodes can be used to monitor physiological electric signals on the skin of a patient. These signals may come from, for example, muscle, nerves, the heart, the brain, the ear, or the eye. Monitoring electric signals from a patient can be used, for example, to determine the health of various organs and organ systems. Applications include, but are not limited to electrocardiograms, electroretinograms, nerve conduction testing, electroencephalograms, electrogastrograms, and evoked potential measurements from optical, acoustic, tactile, thermal, olfactory, and taste stimulation.

[0005] One of the difficulties in monitoring physiological electric signals on the skin is the inconvenience and variability caused by have to place many electrodes separately. To overcome this difficulty, electrode arrays have been employed (*e.g.*, US patents 5,722,591; 6,032,064; and 6,564,079).

[0006] There still exists a need to make electrode arrays that are easier to use and/or have improved performance.

SUMMARY

[0007] In one embodiment, an electrode array is disclosed. The electrode array includes at least two hydrogel islands. At least two of the hydrogel islands have a corresponding electrode contacting said hydrogel island. The electrode array also has a flexible insulating substrate that includes an electrode region, a torsion relief region, and a connector region. The electrode array also comprises conductors located on said substrate that electrically connect the electrodes to the connector region. In these embodiments, all the electrodes are located in the electrode region. The connector region and the electrode region may be connected together through the torsion relief region. The torsion relief region may be narrower than the connector region and may be connected to a long side of the electrode region, the long side of the electrode region being defined as the long side of the smallest rectangle that encloses all the electrodes. The connector region may include a tip region and a stop region, the tip region arranged at an edge of the electrode array and the stop region arranged adjacent to the tip region, the stop region being wider than the tip region. The electrode array can be used, for example, for monitoring physiological electric signals

[0008] In accordance with another embodiment, an electrode array is disclosed. The electrode array includes a flexible insulating substrate having a first side and a second side. The substrate has an electrode region and a connector region. The electrode array has at least two of the hydrogel islands located on the first side of the substrate. At least two hydrogel islands have a corresponding electrode contacting said hydrogel island. Conductors located on the substrate electrically connect the electrodes to the connector region. A shield may be present. The shield may include a shield conductor adjacent to the second side of substrate, with the shield conductor covering at least half of the corresponding area on the second side of the substrate that the electrodes occupy of the first side the substrate. The electrode array can be used, for example, for monitoring physiological electric signals.

[0009] In accordance with another embodiment, a pair of electrode arrays is disclosed. The electrode array pair includes a first and a second electrode array. The first electrode array and the second electrode array both separately include a flexible insulating substrate that includes an electrode region and a connector region; at least two electrodes located in the electrode region; and conductors located on the substrate to electrically connect the electrodes to a set of contact locations in the connector region. In these embodiments, the contact locations in the first and second electrode array are in the same pattern so that one connector may alternatively make electrical connections to both electrode arrays; and the relation between contact locations and electrode locations on the second electrode array is a substantially mirror image to the relation between contact locations and electrode locations on the first electrode array. The pair can be used, for example, for monitoring physiological electric signals from the left and right sides of a human.

[0010] In accordance with another embodiment, a pair of electrode arrays is disclosed. The pair includes a first and a second electrode array. The first electrode array and the second electrode array both separately include a flexible insulating substrate that includes an electrode region and a connector region; at least two electrodes located in the electrode region; and conductors located on said substrate electrically connecting the electrodes to a set of contact locations in the connector region. The first electrode array has a first set of markings and the second electrode array has a second set of markings. The first set of markings is visually distinct from the second set of markings. The pair can be used, for example, for monitoring physiological electric signals from the left and right sides of a human.

[0011]Other embodiments include methods of using the electrode arrays described above to measure an electric signal from a patient, for example, a physiological electric signal. The method includes the steps of contacting the electrode array to the patient and measuring the electric signal from at least one electrode. The electric signal may be the potential difference between two electrodes in the electrode array.

[0012] Other embodiments include methods of using the pairs of electrode arrays described above to measure at least two electric signals from a patient, for example, two physiological electric signals. The method includes the steps of obtaining a pair of electrode arrays, contacting both electrode arrays to the patient, and measuring the electric signal from at least one electrode from each array. The electric signals may be the potential difference between two pairs of electrodes, where the members of each pair may or may not be on the same electrode array.

[0013] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention as claimed. The foregoing background and summary are not intended to provide any independent limitations on the claimed invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and together with the description, serve to explain the principles of the invention.

[0015] Fig. 1a is an exploded view of one embodiment of an electrode array, as seen from the patient side.

[0016] Fig. 1b is an exploded view of one embodiment of an electrode array, as seen from the operator side.

[0017] Fig. 1c is an enlarged view of one portion of Fig. 1a.

[0018] Fig. 2 is a view of one embodiment of an electrode array, as seen from the operator side.

[0019] Fig. 3 is a view of one embodiment of a pair of electrode arrays, as seen from the patient side.

[0020] Figs. 4a-4e are views of some embodiments showing sets of markings on pairs of electrode arrays, as seen from the operator side.

DETAILED DESCRIPTION

[0021] The following detailed description is presented to enable any person skilled in the art to make and use the invention. For purposes of explanation, specific nomenclature is set forth to provide a thorough understanding of the present invention. However, it will be apparent to one skilled in the art that these specific details are not required to practice the invention. Descriptions of specific applications are provided only as representative examples. The present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest possible scope consistent with the principles and features disclosed herein.

[0022] Unless otherwise defined, scientific and technical terms used in connection with the present invention shall have the meanings that are commonly understood by those of ordinary skill in the art. Although any methods, devices, and materials similar or equivalent to those described herein can be used in the practice of the presently disclosed subject matter, representative methods, devices, and materials are now described. Further, unless otherwise required by context, singular terms shall include pluralities and plural terms shall include the singular.

[0023] As used herein, the term "hydrogel" refers to a nonfluid colloidal network or polymer network that is expanded throughout its volume by water. Hydrogel also refers to any electrically-conductive, water-comprising gel known in the medicinal, biofeedback, or biological testing arts. A hydrogel may comprise, for example, silicone, polyacrylamides, polyethylene oxide, polyAMPS, polyvinylpyrrolidone, polyvinyl alcohol, acrylate polymers, sodium polyacrylate, agarose, methylcellulose, or hyaluronan. A hydrogel optionally may contain mechanical strengthening members as well as the water-expanded colloidal network or polymer network. Further, a hydrogel is a "hydrogel island" if the hydrogel does not contact a second hydrogel. For example, one hydrogel is always a hydrogel island. As another example, three hydrogels, if mutually non-contacting, form three hydrogel islands.

[0024] As used herein, the term "patient" refers a human or other mammal from which electric signals are to be measured. It is contemplated that the electrode arrays of the invention will contact the patient to enable measurement of electric signals.

[0025] As used herein, the term "substrate" refers to a supporting material on which electrodes and conductors can be placed. A substrate may be, for example, a single sheet of plastic or a laminate of materials. The plastic used may be chosen from one or more (*i.e.*, a combination) of the following: polycarbonate, cellulose, poly vinyl chloride (PVC), polypropylene, ABS, polyethylene, low density polyethylene, high density polyethylene, ultra-high molecular weight polyethylene, PTFE, acetal, polyester, PVDF, FEP, PFA, Ultem, PEEK, polyimide, garolite, polyethylene terephthalate (PET), and biaxially-oriented polyethylene terephthalate (boPET).

[0026]The improved electrode arrays, as well as additional objects, features, and advantages thereof, will be understood more fully from the following detailed description of certain preferred embodiments. These electrode arrays can be used to monitor physiological electric signals from the skin, for example, physiological electric signals. These signals may come from, for example, muscle, nerves, the heart, the brain, one or both ears, or one or both eyes. For bilaterally symmetric organs and tissues, a pair of electrode arrays may be advantageously used.

[0027] Fig. 1a and Fig. 1b are exploded views of one embodiment of an electrode array 100. Fig. 1c has an enlargement of a conductive layer 110 from Fig. 1a. In this example, the electrode array 100 includes a layer of hydrogel islands (101a, 101b, 101c), an optional insulating layer 102, and a conductive layer 110. Collectively, all the hydrogel islands may be referred to by the reference number 101. An insulating layer 102 has apertures 103 so that hydrogel islands 101a, 101b, 101c contact electrodes 108a, 108b, 108c, respectively. Collectively, all the electrodes may be referred to by the reference number 108. Electrodes 108 are located on the conductive layer 110. A conductive layer 110 has a flexible insulating substrate 104. The substrate 104 can be logically split into a connector region 106, a torsion relief region 105, and an electrode region 111, which is in this example the remainder of substrate 104. In Fig. 1c, the conductive layer 110 has conductors 107a, 107b, and 107c (collectively, 107) that electrically connect the corresponding electrodes 108a, 108b, and 108c through the torsion relief region 105 to the connector region 106. As an example, electrode 108a is connected to conductor 107a to contact location 109a in connector region 106. Contact locations 109b and 109c are analogously connected through conductors 107b and 107c to electrodes 108b and 108c, respectively.

[0028] Although three hydrogel islands (101a, 101b, 101c) and three electrodes (108a, 108b, 108c) are shown in Fig 1a and Fig 1b, other quantities are contemplated. For example, electrode 108b may be omitted. In this case, the corresponding hydrogel island 101b may or may not be omitted; hydrogel island 101b may still be useful to help adhere the electrode array 100 to a human subject. In other embodiments, four or more hydrogel islands may be used, at least two of which having corresponding electrodes. For example, an electrode array 100 may have 5, 10, 20, 50, or more electrodes.

[0029] An insulating layer 102 prevents hydrogel islands from contacting conductors that connect to electrodes other than those intended. When an insulating layer 102 is not used, vias may be used or smaller hydrogel islands may be used to route distant conductors to a connector region 106 (*e.g.*, routing conductor 107c past hydrogel 101b).

[0030] When present, an aperture 103 may be larger than, smaller than, or equal to the size of an electrode 108. If an aperture 103 is smaller than its corresponding electrode 108, the aperture 103 defines the effective size that electrode. An aperture 103 may differ from the size of an electrode 108 in order to reduce the variability in electrode size due to manufacturing tolerances in the fabrication of the insulating layer 102 or the registration of the insulating layer 102 and the conductive layer 110.

[0031] In some embodiments, the hydrogel islands 101 contact a patient's skin during use to carry electric signals between the electrodes and the patient. Hydrogel islands 101 may also help an electrode array 100 adhere or otherwise stick to a patient's skin. Additionally, an electrode array 100 may include foam-backed adhesives, pressure-sensitive adhesives, or other materials that help the electrode array adhere or otherwise stick to a patient's skin, although no such substance is required or shown in Fig 1.

[0032] In some embodiments, a torsion relief region 105 provides improved operation, as described hereafter. In operation, the electrode array 100 contacts a patient's skin. An electrode array 100 can be flexible so as to conform to the shape of the relevant portion of the patient's body. On the other hand, the connector region 106 will likely conform to the shape of an electrical connector that carries electric signals between electrode array 100 and attached instrumentation. In use, the shape in connector region 106 is unlikely to be the same shape as electrode region 111 when it is conforming to the shape of the contact region of the patient's body; accordingly, the electrode array 100 may bend. This bending may cause forces on the hydrogel islands 101 that reduces adherence to the patient's body and, therefore, affects the ability of the electrode array 100 to measure electric signals from the patient. The torsion relief region 105 is narrower than connector region 106 so as to reduce the bending stiffness and ameliorate this adherence issue. In various embodiments, torsion relief region 105 may have a width falling in a variety of ranges relative to the maximum width of the connector region 106. For example, the torsion relief region 105 may have a width less than 0.9, 0.8, 0.7, 0.5, 0.3, 0.2, or 0.1 times less than the maximum width of the connector region 106. Other ranges of width may be chosen as well. To reduce the effect of the weight of the electrical connector as the electrical connector possibly pulls away from the patient's skin, potentially peeling off a single hydrogel island, the torsion relief region is connected to a long side of the electrode region, the long side of the electrode region being defined as the long side of the smallest rectangle that encloses all the electrodes. Consequently, the weight of the connector is distributed more evenly across the hydrogels, assuming in operation the short side of the electrode region is more closely aligned to the gravitational direction than the long side of the electrode region.

[0033] The connector region 106 may include a tip region 112 and a stop region 113. An electrical connector used in operation may slide onto tip region 112. In some embodiments, the stop region 113 physically stops the connector from sliding further onto electrode array 100. In some embodiments, the stop region 113 provides visual feedback to the user that the connector is fully seated on electrode array 100. In some embodiments, the tip region 112 has tapered sides, as shown in Fig. 1, so as to make it easier for a connector to slide onto connector region 106. The tip region 112 may also have straight sides. The tip region 112 may have one or more holes or notches to aid in the alignment of a connector.

[0034] Electrodes 108 may be fabricated from metal or a semiconductor. Electrodes 108 in operation are able to convert a flow of electrons/holes into a flow of ions in hydrogel islands 101. Electrodes 108 may be fabricated from at least one of gold, silver, platinum, palladium, rhodium, nickel, carbon, indium, tin, or copper. Electrodes 108 may comprise at least one of gold, silver, or carbon. Electrodes 108 may comprise silver/sliver chloride. Electrodes 108 may be deposited on substrate 104 by any means known to the art, for example, by printing, silk screening, ink jet printing, sputtering, or printed circuit board fabrication methods. Electrodes 108 may be silkscreened silver, silver/silver chloride, carbon black, or carbon nanotubes. Having a large electrochemical surface area reduces the impedance and improves operation.

[0035] Conductors 107 may be fabricated from metal or a semiconductor. Conductors 107 may be fabricated from material that is the same or different than electrodes 108. Conductors 107 can be fabricated using the same types of methods used to fabricate electrodes 108. In some embodiments, conductors 107 are made from the same material and deposited on substrate 104 at the same time as electrodes 108. In some embodiments, conductors 107 are deposited first, and electrodes 108 are deposited on top of a portion of conductors 107. For example, conductors 107 may be silkscreened carbon black that is applied before a silver/silver chloride layer is applied to form electrodes 108. Alternatively, conductors 107 may be silkscreened silver that is applied before a carbon or silver/silver chloride layer is applied to form electrodes 108. In some embodiments, conductors 107 and electrodes 108 are silver/silver chloride fabricated using a silk screen process.

[0036] Conductors 107a, 107b, 107c may have corresponding contact locations 109a, 109b, 109c (collectively 109) in the connector region 106. Contact locations 109 may be wider than the conductors 107 so as to make a larger target for an electrical connector that connects to electrode array 100. Some of the edges of connector region 106 may form guides that help in positioning a connector to make electrical connection to contact locations 109. Contact locations 109 may be fabricated from metal or a semiconductor. Contact locations 109 may be fabricated a material that is the same or different than conductors 107. Contact locations 109 may be fabricated using the same types of methods used to fabricate conductors 109. In some embodiments, conductors 107 are deposited first, and contact locations 109 are deposited on top of a portion of conductors 107. For example, conductors 107 may be silkscreened carbon black that is applied before a silver or a gold layer is applied to form contact locations 109. In some embodiments, conductors 107 and contact locations 109 are silver/silver chloride fabricated using a silk screen process.

[0037] In some embodiments, electrodes 108 are substantially evenly spaced. In some embodiments, a ratio of the largest distance between adjacent electrodes to the smallest distance between adjacent electrodes is less than 3. In some embodiments, the ratio is less than 2. In some embodiments, the ratio is less than 1.5. The distance between adjacent electrodes is defined as the shortest line or curve traveling along the substrate where one of the endpoints of the line or curve is in one electrode and the other endpoint is in the other electrode.

[0038] Hydrogels 101 may include water and ions in a polymer matrix. Having a large surface area reduces the impedance to the skin and also increases the adherence of the hydrogels to the skin. Excessively large surface areas of hydrogels reduce the spatial resolution in electric signals. Hydrogels that are too sticky are uncomfortable upon removal from the skin, which is particularly important in cases where the electrode array is used on sensitive skin, such as below the eye. Hydrogels that are not sticky enough may lead to poor electrode array contact in embodiments where no other means of ensuring contact is provided. In some embodiments, the hydrogel islands have a peel strength to stainless steel of no more than 1500 grams per inch and no less than 100 grams per inch. In some embodiments, the hydrogel islands have a peel strength to stainless steel of no more than 1000 grams per inch and no less than 400 grams per inch.

[0039] In some embodiments, including the embodiment shown in Fig. 1, the electrodes are all located on one side of the substrate. Other embodiments may have electrodes on both sides.

[0040] Turning now to Fig. 2, electrode array 200 is another embodiment of the invention. Electrode array 200 has similar hydrogel islands 201a, 201b, 202c, as well as many of the other features of electrode array 100, including a flexible insulating substrate 204 having a connector region 206 and an electrode region 211. Electrode array 200 optionally has a torsion relief region 205, a connector region 206, including tip and stop regions, as well as other features in the above described electrode array 100. In some embodiments, only two hydrogel islands are required. Conductors on electrode array 200 are similar to those of electrode array 100. Electrode array 200 has a new feature: a shield comprising a shield conductor 214. The shield conductor 214 covers at least half of the corresponding area on the second side of substrate 204 that the electrodes occupy of the first side the substrate 204. The shield conductor 214 may be solid or it may include regions that have a mesh, comb, or hatch pattern. A mesh, comb, or hatch pattern may reduce the material cost of shield conductor 204 and may reduce the stiffness of electrode array 200 so that it will more easily conform to the patient during use. The area of the shield conductor 214 is defined to include the interior of any meshes or hatch patterns as well at the interdigitated space of any comb structures on in the shield conductor. As shown in Fig. 2, the shield conductor 214 may cover all the electrode area and most of the conductor area. Optionally, the shield conductor 214 may extend to the connector region and/or cover the entire second side of substrate 204. In some embodiments, the shield is simply the shield conductor 214.

[0041] As described for electrode array 100, electrode array 200 has conductors that connect electrodes in the electrode region 211 to the connector region 206. These conductors may be located on the same side as the electrodes, the opposite side, or on a combination.

[0042] Electrodes in electrode array 200 may be susceptible to interference capacitively-coupled in from the surroundings. A shield conductor 214 may reduce the capacitance of some or all the electrodes to the surroundings, making measurements with electrode array 200 cleaner by reducing outside interference. To perform this function, a shield conductor 214 may cover at least part of the electrodes. Conveniently, the shield conductor 214 may be deposited to the side of substrate 204 opposite that of the electrodes. Alternatively, the shield conductor 214 can form at least part of an additional layer that gets attached to the substrate 204. For example, the shield can be an adhesive-backed conducting layer or a conductive layer that is laminated to substrate 204.

[0043] The shield conductor 214 can optionally be connected to an electrode or can be disconnected from all the electrodes. For example, a shield conductor 214 may be connected to an electrode corresponding to hydrogel island 201b. As another example, the shield conductor 214 may have a contact location in the connector region to enable an electrical connection between the shield conductor 214 and an electrical connector. In operation, the shield conductor 214 may be driven to an instrument's ground, an instrument's reference voltage, or a right-leg drive output that measures and attempts to cancel common-mode signals on at least two electrodes. If a shield conductor 214 is connected to an electrode, the connection may be made with a via on electrode array 200 or through a connection made using an electrical connector and wiring external to electrode array 200.

[0044] Shield conductor 214 may be fabricated from metal or a semiconductor. The shield conductor 214 may be fabricated from at least one of gold, silver, platinum, palladium, rhodium, nickel, carbon, indium, tin, or copper. In another embodiment, the shield conductor 214 may be fabricated from at least one of gold, silver, or carbon. In a further embodiment, the shield conductor 214 may comprise silver/silver chloride. The shield conductor 214 may be deposited on a shield or on substrate 104 by any means know to the art, for example, by printing, silk screening, ink jet printing, sputtering, or printed circuit board fabrication methods. The shield conductor 214 may be silkscreened silver, silver/silver chloride, carbon black, or carbon nanotubes.

[0045] In some embodiments where a plurality of electrode arrays are used, the shield conductor 214 may be made of different colors of materials to visually differentiate the electrode arrays. For example, if a pair of electrode arrays was used, the first in the pair may have a carbon shield conductor and the second a silver or a silver/silver chloride shield conductor.

[0046] Turning now to Fig. 3, an exemplary embodiment of a pair of electrode arrays for monitoring physiological electric signals from the left and right sides of a human is shown. Pair 300 includes an electrode array 301a and an electrode array 301b. To better show the relation between elements, all features on electrode array 301a are designated with the letter "a" after the number, while all features on electrode array 301b are designated with the letter "b" after the number.

[0047] Both electrode arrays have a connector region (306a and 306b) as part of a flexible insulating substrate (304a and 304b). Electrodes 308aa, 308ab, 308ac are located on electrode array 301a, while electrodes 308ba, 308bb, and 308bc are located on electrode array 301b. Conductors 307aa, 307ab, 307ac provide an electrical connection between electrodes 308aa, 308ab, 308ac and contact locations 309aa, 309ab, and 309ac, respectively. Similarly, conductors 307ba, 307bb, 307bc provide an electrical connection between electrodes 308ba, 308bb, 308bc and contact locations 309ba, 309bb, and 309bc, respectively. Contact locations on electrode array 301a are found in connector region 306a while contact locations on electrode array 301b are found in connector region 306b. Both electrode arrays have optional torsion relief regions 305a and 305b, respectively and may optionally have other features described in electrode array 100 and/or electrode array 200.

[0048] The electrode arrays in pair 300 have their contact locations 309ba, 309bb, and 309bc in the same pattern so that one connector can alternatively make electrical connections to both electrode arrays. For example, the contact location 309aa may be located in the same position (left-most) as contact location 309ba. Further, it is possible to design a connector so that each connection that is made on electrode array 301a has an analogous connection in electrode array 301b. This property is ensured in the embodiment in Fig. 3 by making the connector region 306a the same shape as connector region 306b as well as having the same size and location of the contact regions on both electrode arrays. In alternative embodiments, the connector region shapes may differ between the electrode arrays as long as one connector can be used for both. Alternatively, the contact locations may differ in size or location between the electrode arrays as long as one connector can be used for both.

[0049] Pair 300 may be used, for example, to monitor physiological electric signals from the left and right sides of a patient. For example, electrode array 301a can be placed on the patient's left side and electrode 301b can be placed on the patient's right side. As a more specific example, electrode array 301a can be placed so that electrode 308ac is placed under the left eye and electrode 308aa is placed near the left temple. Similarly, electrode array 301b can be placed so that electrode 308bc is placed under the right eye and electrode 308ba is placed near the right temple. In these examples, the electrode placements map to the same contact location: for example, the electrode under the eye is electrically connected to the right-most contact region 309ac or 309bc for both electrode arrays.

[0050] Advantageously, instrumentation connected to either electrode array in pair 300 can interpret the electric signals in the same fashion. As a concrete example, suppose

(1) electrode 308ac/308bc is placed on the skin under the left/right eye, respectively, and electrode 308aa/308ba is placed near the left/ right temple, respectively;

(2) a voltage difference is measured between contact location 309ac/309bc and contact location 309aa/309ba, respectively, and

(3) both eyes generate a positive electrical potential,

then the voltage difference measured with electrode array 301a and electrode array 301b will both be positive, because of the mirror symmetry in pair 300.

[0051] Generally in pair 300, the relation between contact locations and electrode locations on the second electrode array is a mirror image to the relation between contact locations and electrode locations on the first electrode array. While not required, the substrate of the second electrode array may be a substantially mirror-image of the substrate of the first electrode array.

[0052] Analogous elements in pair 300 may be constructed in the same or a similar fashion to the corresponding elements found in electrode array 100 or electrode array 200, and may be fabricated from the same or similar materials. For example, electrodes in pair 300 can be constructed in the same manner as electrodes 108. Conductors in pair 300 can be constructed in the same manner as conductors 107.

[0053] The electrode arrays in pair 300 may optionally include hydrogels constructed in the same or similar fashion as those described in electrode array 100, and fabricated from the same or similar materials. The hydrogel islands of the second electrode array can be substantially mirror-images of the hydrogel islands of the first electrode array.

[0054] The electrode arrays in pair 300 may optionally include a shield constructed in the same or similar fashion as those described in electrode array 200, and fabricated from the same or similar materials.

[0055] The electrode arrays in pair 300 may be connected to each other or may not be connected to each other. Connecting has the potential advantage of having fewer ways in which an operator applying the electrodes to a patient can do so incorrectly, but has the potential disadvantage of being more restricted in accommodating differences in anatomy.

[0056] Turning now to Fig. 4, exemplary embodiments for marking a pair of electrode arrays are shown. In Fig 4, pair 401, pair 402, pair 403, pair 404, and pair 405 are shown from the side opposite that of an electrode. Pairs 401, 402, 403, 404, and 405 have markings that differ on each electrode array in the respective pair. These marking can be used, for example, to indicate the desired placement orientation of the electrode arrays, the testing order of the electrode arrays, or other information. Fig. 4a shows markings that are representative of the anatomical part of the body that the electrode array should be placed near or on. For example, symbol 422a and symbol 422b show eyes that may indicate the portion of the electrode array that should be placed near the eye. Some embodiments may have additional symbols 421a and 421b to indicate more precisely the desired location of the electrode array. Fig. 4b shows markings where 423a has a distinctive pattern or coloring that differentiates it clearly from markings 423b. Color differences may result from shield conductors 214 of different materials; for example, marking 423a may comprise silver while marking 423b may comprise carbon. Fig. 4c shows markings where words are used to signify an electrode array 403 indented for the right side (424a) or for the left side (424b). Fig. 4d shows markings where numbers are used. Numbers may also indicate the test order: Number 425a may indicate the electrode array that should be tested first while number 425b may indicate the electrode array that should be tested second. Fig. 4e shows markings that are representative of the anatomical part of the body that the electrode array should be placed near or on. For example, symbol 426a and symbol 426b show eyes that may indicate the portion of the electrode array that should be placed near the eye. Some embodiments may have additional symbols 427a and 427b, which is the outline of the electrode array, to indicate more precisely the desired location of the electrode array relative to the anatomical part. Combinations of colors, words, symbols, and pictures are also contemplated.

[0057] These marked pairs of electrodes may have features of pair 300, or of electrode array 100, or of electrode array 200.

[0058] The size of the electrode arrays according to the embodiments described herein may be scaled to match the size of the intended patient. For example, an electrode array for a human infant may be smaller than an electrode array for a human adult.

[0059] While the figures in this disclosure have a similar shape to the electrode arrays depicted, other shapes are contemplated. For example, the pair of electrode arrays in Fig. 3 may be connected so as to reduce the likelihood of incorrect placement on a patient.

[0060] Methods of using the electrode arrays and pairs of electrode arrays of the invention are contemplated to measure electric signals from patients, for example, physiological electric signals. These signals may come from, for example, muscle, nerves, the heart, the brain, one or both ears, or one or both eyes. The methods can include obtaining electrodes arrays or pairs of electrode arrays, contacting the patient with the electrode arrays or pairs of electrode arrays, and measuring electric signals from at least one electrode. The reference potential for the voltage measurements can be another electrode or conductor that is capacitively coupled to the patient. The patient can be a human. Many devices are available that can be used to measure the electric signals, including for example generic data acquisition systems such as voltmeters and oscilloscopes, as well as data acquisition systems that have been designed for particular applications such as electroretinography (*e.g.*, the LKC RETeval^{TM} device or the LKC UTAS device, Gaithersburg, MD, USA).

[0061] The present invention is not to be limited in scope by the specific embodiments described herein. Indeed, various modification of the invention in addition to those described herein will become apparent to those skilled in the art from the foregoing description and accompanying figures. Such modifications are intended to fall within the scope of the claims.

WHAT IS CLAIMED IS:

1. An electrode array comprising:

(a) at least two hydrogel islands, wherein at least two of the hydrogel islands have a corresponding electrode contacting said hydrogel island;

(b) a flexible insulating substrate comprising an electrode region, a torsion relief region, and a connector region; and

(c) conductors located on said substrate electrically connecting the electrodes to the connector region,

wherein all the electrodes are located in the electrode region;

wherein the connector region and the electrode region are connected together through the torsion relief region;

wherein the torsion relief region is narrower than the connector region;

wherein the torsion relief region is connected to a long side of the electrode region, the long side of the electrode region being defined as the long side of the smallest rectangle that encloses all the electrodes; and

wherein the connector region comprises a tip region and a stop region, the tip region arranged at an edge of the electrode array and the stop region arranged adjacent to the tip region, the stop region being wider than the tip region.

2. The electrode array of claim 1, wherein the edges of the substrate in the connector region form guides that help in the positioning of a connector to make electrical contact with said conductors.

3. The electrode array of claim 1 or 2, wherein a ratio of the largest distance between adjacent electrodes to the smallest distance between adjacent electrodes is less than 3.

4. The electrode array of claim 3, wherein the ratio is less than 2.

5. The electrode array of any of the above claims, wherein the conductors and the electrodes are all located on one side of the substrate.

6. An electrode array comprising:

(a) a flexible insulating substrate having a first side and a second side, said substrate comprising an electrode region and a connector region;

(b) at least two hydrogel islands located on the first side of the substrate, wherein at least two of the hydrogel islands have a corresponding electrode contacting said hydrogel island;

(c) conductors located on said substrate electrically connecting the electrodes to the connector region; and

(d) a shield comprising a shield conductor adjacent to the second side of substrate, said shield conductor covering at least half of the corresponding area on the second side of the substrate that the electrodes occupy of the first side the substrate.

7. The electrode array of claim 6, wherein the conductors electrically connecting the electrodes to the connector region are located on the first side of said substrate.

8. The electrode array of claim 6 or 7, wherein the shield conductor is located on the second side of the substrate.

9. The electrode array of any of claims 6 to 8, wherein the shield conductor is held adjacent to the second side of the substrate with at least one of an adhesive or a layer that is connected to the substrate.

10. The electrode array of any of claims 6 to 9, wherein the shield is electrically connected to one of the electrodes.

11. The electrode array of any of claims 6 to 10, wherein the edges of the substrate in the connector region form guides that help in the positioning of a connector to make electrical contact with said conductors.

12. The electrode array of any of claims 6 to 11, wherein the substrate further comprises a torsion relief region,

wherein the connector region and the electrode region are connected together through the torsion relief region; and

wherein the torsion relief region is narrower than the connector region.

13. The electrode array of claim 12, wherein the torsion relief region is connected to a long side of the electrode region, the long side of the electrode region being defined as the long side of the smallest rectangle that encloses all the electrodes.

14. The electrode array of any of claims 6 to 13, wherein the connector region comprises a tip region and a stop region, the tip region arranged at an edge of the electrode array and the

stop region arranged adjacent to the tip region, the stop region being wider than the tip region.

15. The electrode array of any of claims 6 to 14, wherein a ratio of the largest distance between adjacent electrodes to the smallest distance between adjacent electrodes is less than 3.

16. The electrode array of claim 15, wherein the ratio is less than 2.

17. The electrode array of any of the above claims, wherein the hydrogel islands have a peel strength to stainless steel of no more than 1500 grams per inch and no less than 100 grams per inch.

18. The electrode array of any of the above claims, wherein the electrode array has exactly 3 electrodes.

19. The electrode array of any of the above claims, wherein the electrodes comprise at least one of gold, silver, platinum, palladium, rhodium, nickel, carbon, indium, tin, or copper.

20. The electrode array of claim 19, wherein the electrodes comprise at least one of gold, silver, or carbon.

21. The electrode array of claim 19, wherein the electrodes comprise silver / sliver chloride.

22. A pair of electrode arrays comprising a first and a second electrode array, the first electrode array and the second electrode array both separately comprising:

(a) a flexible insulating substrate comprising an electrode region and a connector region;

(b) at least two electrodes located in the electrode region; and

(c) conductors located on said substrate electrically connecting the electrodes to a set of contact locations in the connector region;

wherein the contact locations in the first and second electrode array are in the same pattern so that one connector can alternatively make electrical connections to both electrode arrays; and

wherein the relation between contact locations and electrode locations on the second electrode array is a substantially mirror image to the relation between contact locations and electrode locations on the first electrode array.

23. The pair of electrode arrays of claim 22, wherein at least two of the electrodes have a corresponding hydrogel island contacting said electrode.

24. The pair of electrode arrays of claim 23, wherein the hydrogel islands of the second electrode array are substantially mirror-images of the hydrogel islands of the first electrode array.

25. The pair of electrode arrays claim 23 or 24, wherein the hydrogel islands on both electrode arrays have a peel strength to stainless steel of no more than 1500 grams per inch and no less than 100 grams per inch.

26. The pair of electrode arrays of any of claims 22 to 25, wherein the substrate of the second electrode array is a substantially mirror-image of the substrate of the first electrode array.

27. The pair of electrode arrays of any of claims 22 to 26, wherein the substrate of both electrode arrays further comprise a torsion relief region,

wherein the connector region and the electrode region are connected together through the torsion relief region; and

wherein the torsion relief region is narrower than the connector region.

28. The pair of electrode arrays of claim 27, wherein the torsion relief region is connected to a long side of the electrode region, the long side of the electrode region being defined as the long side of the smallest rectangle that encloses all the electrodes.

29. The pair of electrode arrays of any of claims 22 to 28, wherein the connector region of the first electrode array comprises a tip region and a stop region, the tip region arranged at an edge of the electrode array and the stop region arranged adjacent to the tip region, the stop region being wider than the tip region.

30. The pair of electrode arrays of any of claims 22 to 29, wherein the first electrode array is not connected to the second electrode array.

31. The pair of electrode arrays of any of claims 22 to 30, wherein a ratio of the largest distance between adjacent electrodes in the first electrode array to the smallest distance between adjacent electrodes in the first electrode array is less than 3.

32. The pair of electrode arrays of claim 31, wherein the ratio is less than 2.

33. The pair of electrode arrays of any of claims 22 to 32, wherein both the electrode arrays have exactly 3 electrodes.

34. The pair of electrode arrays of any of claims 22 to 33, wherein the electrodes in both electrode arrays comprise at least one of gold, silver, platinum, palladium, rhodium, nickel, carbon, indium, tin, or copper.

35. The pair of electrode arrays of claim 34, wherein the electrodes in both electrode arrays comprise at least one of gold, silver, or carbon.

36. The pair of electrode arrays of claim 35, wherein the electrodes in both electrode arrays comprise silver/silver chloride.

37. The pair of electrode arrays of any of claims 22 to 36,

wherein the first electrode array comprises a first set of markings and the second electrode array comprises a second set of markings; and

wherein the first set of markings is visually distinct from the second set of markings.

38. The pair of electrode arrays of claim 37, wherein the first set of markings differ from the second set of markings in at least one of color, pictures, symbols, and words.

39. A pair of electrode arrays comprising a first and a second electrode array, the first electrode array and the second electrode array both separately comprising:

(a) a flexible insulating substrate comprising an electrode region and a connector region;

(b) at least two electrodes located in the electrode region; and

(c) conductors located on said substrate electrically connecting the electrodes to a set of contact locations in the connector region;

wherein the first electrode array comprises a first set of markings and the second electrode array comprises a second set of markings; and

wherein the first set of markings is visually distinct from the second set of markings.

40. The pair of electrode arrays of claim 39, wherein the first set of markings differ from the second set of markings in at least one of color, pictures, symbols, and words.

41. The pair of electrode arrays of claim 39 or 40, wherein the first set of markings comprises features that indicate the desired placement orientation of the first electrode array; and wherein the second set of markings comprises features that indicate the desired placement orientation of the second electrode array.

42. The pair of electrode arrays of any of claims 39 to 41, wherein at least two of the electrodes have a corresponding hydrogel island contacting said electrode.

43. The pair of electrode arrays of claim 42, wherein the hydrogel islands of the second electrode array are substantially mirror-images of the hydrogel islands of the first electrode array.

44. The pair of electrode arrays of claim 42 or 43, wherein the hydrogel islands on both electrode arrays have a peel strength to stainless steel of no more than 1500 grams per inch and no less than 100 grams per inch.

45. The pair of electrode arrays of any of claims 39 to 44, wherein the substrate of the second electrode array is a substantially mirror-image of the substrate of the first electrode array.

46. The pair of electrode arrays of any of claims 39 to 45, wherein the substrate of both electrode arrays further comprise a torsion relief region,

wherein the connector region and the electrode region are connected together through the torsion relief region; and

wherein the torsion relief region is narrower than the connector region.

47. The pair of electrode arrays of claim 46, wherein the torsion relief region is connected to a long side of the electrode region, the long side of the electrode region being defined as the long side of the smallest rectangle that encloses all the electrodes.

48. The pair of electrode arrays of any of claims 39 to 47, wherein the connector region of the first electrode array comprises a tip region and a stop region, the tip region arranged at an edge of the electrode array and the stop region arranged adjacent to the tip region, the stop region being wider than the tip region.

49. The pair of electrode arrays of any of claims 39 to 48, wherein the first electrode array is not connected to the second electrode array.

50. The pair of electrode arrays of any of claims 39 – 49, wherein a ratio of the largest distance between adjacent electrodes in the first electrode array to the smallest distance between adjacent electrodes in the first electrode array is less than 3.

51. The pair of electrode arrays of claim 50, wherein the ratio is less than 2.

52. The pair of electrode arrays of any of claims 39 to 51, wherein both the electrode arrays have exactly 3 electrodes.

53. The pair of electrode arrays of any of claims 39 to 52, wherein the electrodes in both electrode arrays comprise at least one of gold, silver, platinum, palladium, rhodium, nickel, carbon, indium, tin, or copper.

54. The pair of electrode arrays of claim 53, wherein the electrodes in both electrode arrays comprise at least one of gold, silver, or carbon.

55. The pair of electrode arrays of claim 54, wherein the electrodes in both electrode arrays comprise silver/silver chloride.

56. A method of measuring an electric signal from a patient comprising:

contacting an electrode array of any of claims 1 to 21 to the patient; and

measuring the electric signal from at least one electrode.

57. The method of claim 56, wherein the electric signal is a potential difference between two electrodes in the electrode array.

58. A method of measuring from a patient a first electric signal from a first location and a second electric signal from a second location, the method comprising:

obtaining a pair of electrodes according to any of claims 22 to 55;

contacting the first electrode array to the first location on the patient;

contacting the second electrode array to the second location on the patient;

measuring the first electric signal from at least one electrode in the first electrode array; and

measuring the second electric signal from at least one electrode in the second electrode array.

59. The method of claim 58, wherein the first electric signal is a potential difference between two electrodes in the pair of electrodes; and wherein the second electric signal is a potential difference between two electrodes in the pair of electrodes.

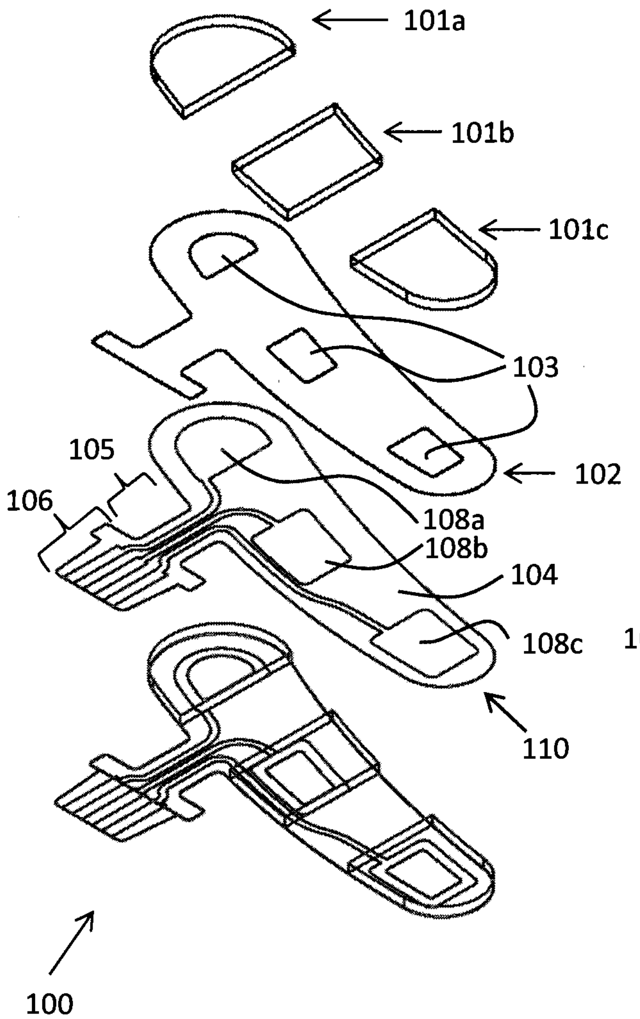

Fig 1a

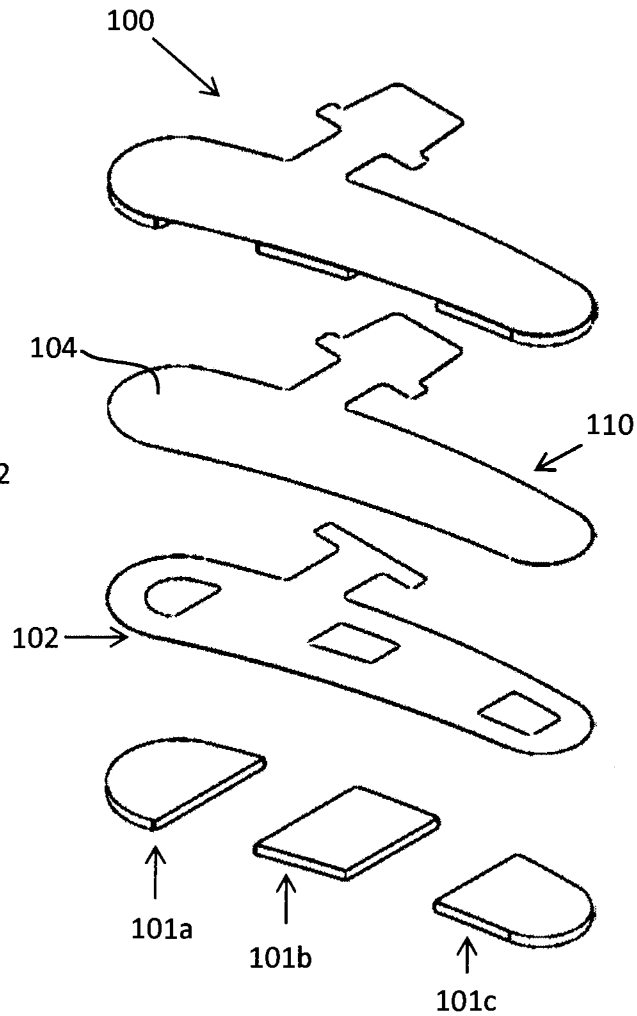

Fig 1b

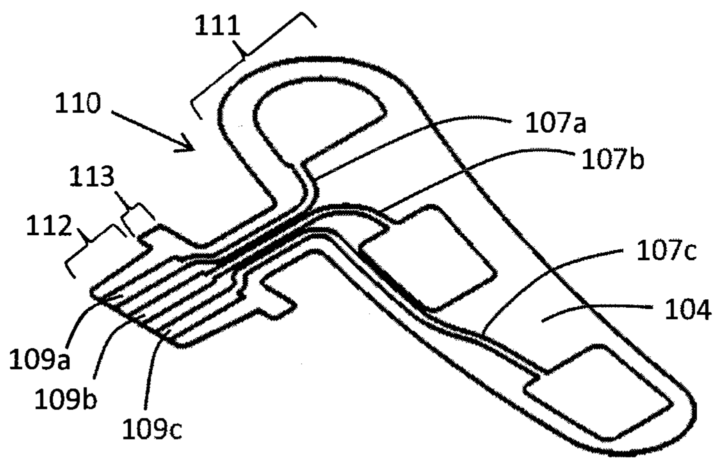

Fig 1c

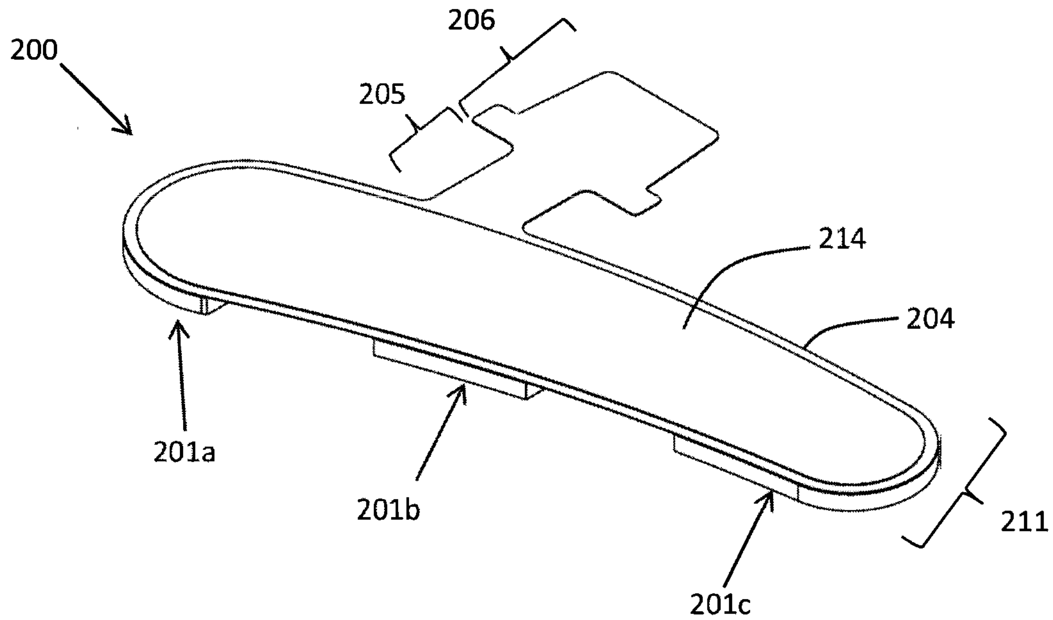

Fig 2

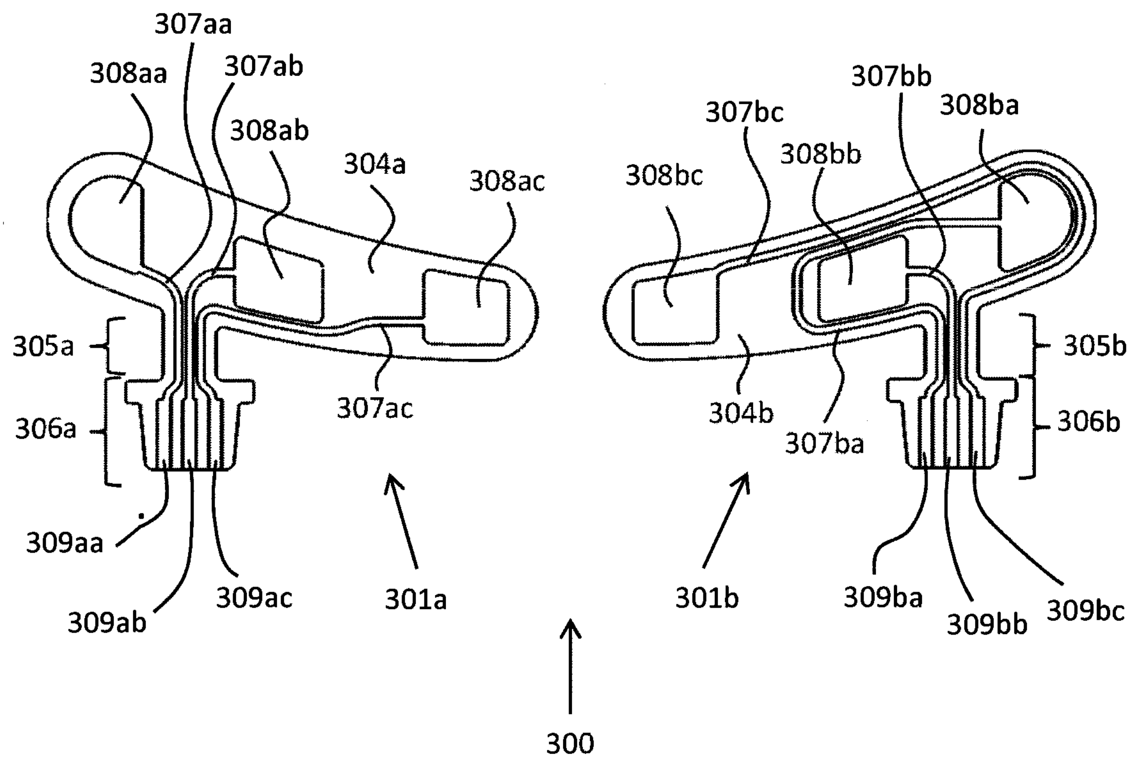
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Fig 3

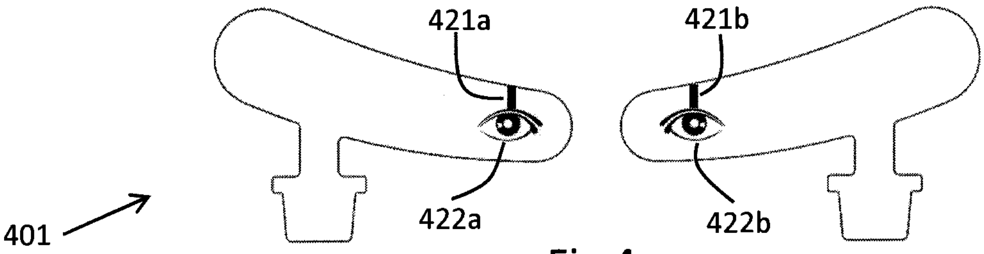

Fig 4a

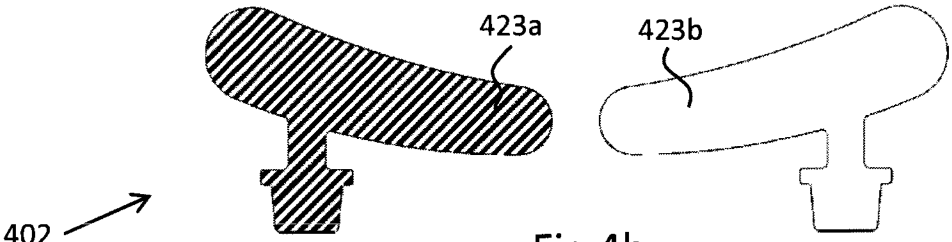

Fig 4b

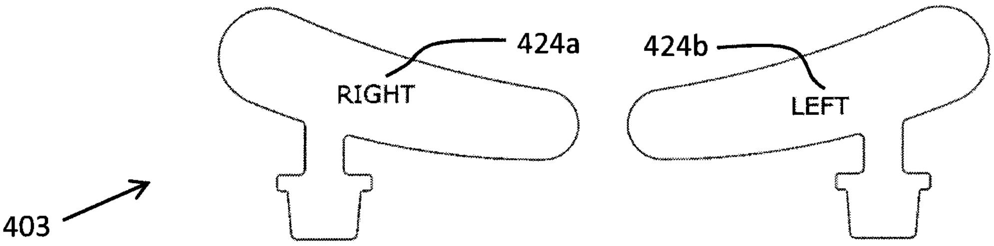

Fig 4c

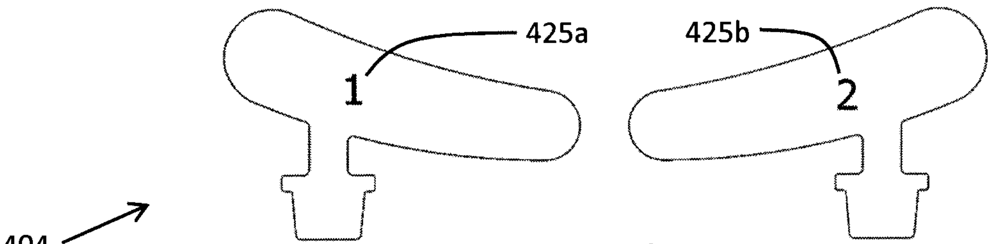

Fig 4d

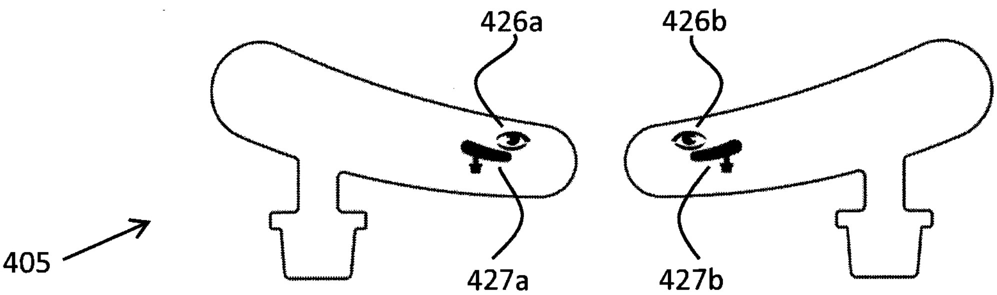

Fig 4e

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/058007

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/04(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)
A61B 5/04; A61N 1/34; A61B 5/0492; A61B 005/0476; A61B 5/0402

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: electrode, hydrogel islands, torsion relief, connector, conductor

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004-0030258 A1 (CHRISTOPHER EDWARD WILLIAMS et al.) 12 February 2004 See abstract, paragraphs [0012]-[0019],[0057]-[0068] and figures 1-11.	1-4,6-8,39-41
Y		22-25
Y	US 2001-0031916 A1 (HENRY L. BENNETT et al.) 18 October 2001 See abstract, paragraphs [0076]-[0083] and figures 1,9-11.	22-25
A		1-4,6-8,39-41
A	US 2003-0130585 A1 (WILLIAM K. WENGER) 10 July 2003 See abstract, paragraphs [0044]-[0058] and figures 1,2.	1-4,6-8,22-25,39-41
A	US 2007-0060975 A1 (JEFFREY S. MANNHEIMER et al.) 15 March 2007 See abstract, paragraphs [0060]-[0065] and figure 1.	1-4,6-8,22-25,39-41
A	US 2002-0177767 A1 (STEVE BURTON et al.) 28 November 2002 See abstract, paragraphs [0053]-[0064] and figures 8-12.	1-4,6-8,22-25,39-41

☐ 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
23 December 2013 (23.12.2013)

Date of mailing of the international search report
24 December 2013 (24.12.2013)

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/058007

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 13, 16, 20, 21, 28, 32, 35, 36, 38, 43, 47, 51, 54, 55, 57, 59
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Claims 13, 16, 20, 21, 28, 32, 35, 36, 38, 43, 47, 51, 54, 55, 57, 59 are unclear since they are referring to the multiple dependent claims 12, 15, 19, 27, 31, 34, 37, 42, 46, 50, 53, 56, 58 which do not comply with PCT Rule 6.4(a).

3. ☒ Claims Nos.: 5,9-12,14,15,17-19,26,27,29-31,33,34,37,42,44-46,48-50,52,53,56,58
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.

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

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

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

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