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(54) **Title:** AN ELECTROENCEPHALOGRAPH ELECTRODE SYSTEM

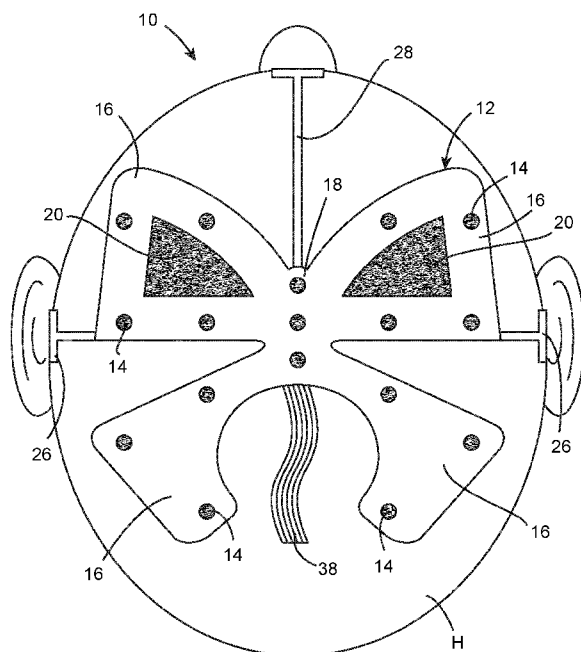


Fig. 1

(57) **Abstract:** The present invention provides an electroencephalogram electrode system for use in neonatal brain monitoring and comprising a deformable substrate shaped and dimensioned to conform to a head of an infant, the substrate preferably defining four lobes, the system further comprising an array of electrodes provided about the lobes of the substrate and capable of making electrical contact with the head when the substrate is positioned thereon.

An electroencephalogram electrode system5 **Field of the invention**

This invention relates to an electroencephalogram electrode system for use in neonatal brain monitoring.

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Background of the invention

When a premature or full term infant has seizures, they are admitted to the Neonatal Intensive Care Unit (NICU) and are generally required to undergo a test known as an EEG (electroencephalogram) brain monitoring scan which involves the use of up to 24 electrodes individually attached to the infant's scalp.

These electrodes record the brains' electricity levels, and assist in the diagnoses of any neurological impairment which may be present. The EEG is regarded as the "gold standard" of investigations into neonatal seizures. Typically a neuro-technician applies each electrode individually, by first preparing the scalp, to reduce electrode impedance and ensure a good quality electrical contact with the skin. The electrode is then applied using a combination of gels, pastes and adhesives. The electrodes are then individually connected to an EEG recording system to record the brain activity.

This process can take over an hour to complete. However, neuro-technicians usually work the standard hours of nine to five, Monday to Friday, and even with weekend on call arrangements, there is usually a significant lag between ordering the investigation on the Neonatal Intensive Care Unit (NICU) and getting the above mentioned test started. In addition, the electrodes are technically difficult to apply, especially given that access to the infant is often limited by being in an incubator, and many of these infants, especially the premature infants, are clinically unstable, and can have adverse reactions to being handled for too long.

Where EEG is not available, or would take too long to set up, a test called Cerebral Function Monitoring (CFM) may be performed. Here, the nurses or doctors on the NICU can attach 3, 4 or 5 electrodes and record limited amounts of brain activity. There is a significant error rate with relying on CFM data when dealing with neonatal seizures, due to the incomplete nature of the data. The treatment of neonatal seizures is generally a combination of brain cooling and medications, depending on the clinical presentation. Both treatment types carry significant risks, so the clinician

has to be absolutely sure that the infant is having seizures prior to treatment. The only recognised method of establishing this is EEG brain monitoring, and preferably full EEG using many electrodes.

5 An EEG performed by a technician is not always available, due to a worldwide lack of trained staff and the 24 hours a day, 365 days a year, working environment in the NICU. Furthermore, it can take over an hour for an experienced technician to set up the test correctly. The use of subdermal needles are effective, although there are issues with infection control, skin reactions and the procedure is invasive.

10 The present invention has therefore been developed with a view to solving the above mentioned problems of the prior art.

Summary of the invention

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According to a first aspect of the present invention there is provided an electroencephalogram electrode system comprising a deformable substrate shaped and dimensioned to conform to a head of an infant; and an array of electrodes provided about the substrate and capable of making electrical contact with the head when the substrate is positioned thereon.

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Preferably, the substrate comprises a plurality of lobes.

Preferably, the substrate is substantially quatrefoil in shape.

25 Preferably, the electrodes are arranged in a fixed pattern about the substrate which correspond with pre-determined locations on the scalp.

Preferably, the pattern of electrodes corresponds with the pattern of the 10-20 system or the modified combinatorial nomenclature.

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Preferably, each electrode is housed within the substrate and comprises an exposed skin contacting surface.

35 Preferably, the skin contacting surface is between substantially flush and slightly protruding of an underside of the substrate.

Preferably, one or more openings are provided in the substrate to permit, in use, temperature regulation of the head.

Preferably, one or more lobes are provided with a central aperture to permit, in use, temperature regulation of the head.

Preferably, the system comprises a template to facilitate the correct location of the substrate with
5 respect to one or more anatomical landmarks on the head.

Preferably, the template comprises at least one strap extending from the substrate for alignment and/or engagement with an anatomical landmark on the head.

10 Preferably, the template comprises a pair of lateral straps each extending from opposite sides of the substrate and shaped and/or dimensions to be aligned and/or engaged with a respective ear of the infant.

Preferably, the template comprises a third strap extending from an anterior of the substrate and
15 shaped and/or dimensioned to be aligned and/or engaged with a nose of the infant.

Preferably, the system comprises a transmission element adapted to transmit electrical signals from the electrodes to a receiver.

20 Preferably, the transmission element comprises a cable extending from the substrate.

Preferably, the cable comprises an electrically shielded multi-core cable.

Preferably, the cable exits a posterior or top of the substrate.
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Preferably, the system comprises one or more portions of adhesive carried on an underside or skin contacting side of the substrate.

Preferably, each electrode comprises a skin contacting surface and an array of micropins or sharp
30 protrusions projecting therefrom.

Preferably, each electrode comprises a skin contacting surface, an electrical terminal, and a layer of electrically conductive paste or gel disposed therebetween.

35 Preferably, the skin contacting surface comprises an array of skin contact elements defining an array of openings therebetween.

Preferably, the electrode comprises a corrosive compound on the skin contacting surface.

Preferably, the system comprises a protective barrier along an edge of at least a portion of the substrate.

Preferably, the protective barrier comprises a lip adapted to prevent the migration of liquid or gel
5 beneath the substrate.

Preferably, the substrate is shaped to define an access zone positioned to be aligned with or overlie, in use, the anterior fontanel.

10 Preferably, the system comprises one or more cushioning pads positioned and adapted to reduce or prevent pressure effects on the head.

According to a second aspect of the present invention there is provided an electrode for use with an electroencephalogram system according to the first aspect of the invention comprising a skin
15 contacting surface and an array of micropins or sharp protrusions projecting from the skin contacting surface.

Preferably, the electrode comprises an electrical terminal, and a layer of electrically conductive paste or gel disposed between the skin contacting surface and the electrical terminal.
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Preferably, the skin contacting surface comprises an array of skin contact elements defining an array of openings therebetween.

Preferably, the electrode comprises a corrosive compound on the skin contacting surface.
25

Brief description of the drawings

The present invention will now be described with reference to the accompanying drawings, in which:
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Figure 1 illustrates a schematic plan view of an infant's head having an electroencephalogram electrode system according to the present invention located thereon, including a removable location template for the accurate and expedited positioning of the system;

35 Figure 2 illustrates a plan view of the electroencephalogram electrode system illustrated in Figure 1, in isolation;

Figure 3 illustrates a schematic plan view of an infant's head having an alternative embodiment of an electroencephalogram electrode system according to the present invention located thereon, which is intended for use in cerebral function monitoring;

- 5 Figure 4 illustrates a sectioned side elevation of the system illustrated in Figures 1 – 3;

Figure 5 illustrates a sectioned side elevation of an electrode forming part of the system of the present invention;

- 10 Figure 6 illustrates a plan view of the electrode illustrated in Figure 5;

Figure 7 illustrates a perspective view of an alternative configuration of an electrode for use with the system of the present invention; and

- 15 Figure 8 illustrates a schematic plan view of a further alternative embodiment of an electroencephalogram electrode system according to the present invention.

Detailed description of the drawings

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Referring now to Figures 1, 2, 4 and 5, there is illustrated an electroencephalogram (EEG) electrode system according to the present invention, generally indicated as 10, for use in conducting EEG brain monitoring of an infant (not shown) in the known manner.

- 25 Referring in particular to Figures 1 and 2, it can be seen that the electrode system 10 comprises a substrate 12 that is substantially planar or laminar in form, and may be formed from any suitable material having the desired characteristics. In particular it is desirable that the substrate 12 is sufficiently flexible to allow it to conform to the head H or more particularly the scalp of an infant, while being sufficiently rigid to ensure that it remains in the correct position throughout the operation
- 30 of the system 10, as will be described in detail hereinafter. For example, the substrate 12 may be formed from a plastics material, or a combination of materials which together provide the desired physical characteristics. The substrate 12 may be a matrix of various material, a laminate, or any other desired constituency which provides the desired functionality and characteristics. The substrate 12 may be provided pre-formed to the shape of the head H of an infant, or may be
- 35 provided flat to be lightly pressed into shape against the head of the infant as the substrate 12 is being applied. The substrate may for example comprise one or more lines of weakness or fold lines (not shown), one or more regions of increased flexibility or deformability, in order to allow the substrate to be displaced from a substantially flat or planar form into the desired profile or shape to conform to the head H of an infant. The substrate could also be formed from, or comprise regions of,

a thermally activated material which for example softens in response to the application of heat, for example from the head H of the infant, in order to allow the substrate to then conform to the contours of the head of the infant.

- 5 The electrode system 10 further comprises an array of electrodes 14 carried by the substrate 12, and exposed at an underside or skin contacting side of the substrate 12. In this way, with the substrate 12 located against the head of the infant, an exposed skin contacting surface 30 of each electrode 14 will contact the infant's scalp in order to achieve an electrical contact therewith in order to permit the EEG testing to be performed.

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- The electrodes 14 are located about the substrate 12 in a predetermined array or pattern which ensures that when the substrate 12 is located in position on the head H of the infant, each of the electrodes 14 is located at a predetermined site on the scalp at which the brain's electrical levels/activity are to be measured. In a particularly preferred embodiment, the electrodes 14 are
- 15 located about the substrate 12 in a pattern that approximately corresponds with the pattern of the International Standard positions of the so called "10-20 system", and optionally the "modified combinatorial nomenclature". The semi-rigid nature of the substrate 12 then ensures that each of the electrodes 14 is maintained in this precise position throughout the EEG testing. This approach significantly reduces the preparation time and complexity of locating each of the electrodes 14 in
- 20 position, allowing the EEG test to be performed in a fraction of the time, at a significantly reduced cost, and optionally without the presence of an expert to locate the electrodes.

- Referring to Figures 1 and 2, it can be seen that in a preferred embodiment of the electrode system 10, the substrate 12 comprises a plurality of lobes 16, and preferably four such lobes 16 such as to
- 25 define a quatrefoil shape, each of the lobes 16 carrying an array of the electrodes 14 in a particular pattern. A number of the electrodes 14 are also located along the centreline of the substrate 12 which in use will run along an imaginary line from an anterior to a posterior of head H.

- The provision of the lobes 16 provides a number of benefits over a more conventional hemispherical
- 30 cap configuration. Each of the lobes 16 is connected to a central node 18, with the relatively narrow path of contact between the respective lobe 16 and node 18 providing the lobe 16 with a degree of flexibility relative to the node 18 and thus the remaining three lobes 16. This allows each of lobes 16 to flex relative to the node 18 in order to more closely conform to the shape of the head of the infant, which will vary from infant to infant, providing the system with a greater tolerance for variation in
- 35 head shape/size.

In addition, the use of lobes 16 reduces the surface area in contact with the head of the infant, thus reducing both discomfort and overheating of the infant, which is a significant issue, in particular during the treatment of neonatal seizures. As a result, the system 10 can be worn throughout brain

cooling treatments that may be employed. In order to further reduce any heating effects which the system 10 may generate, where possible the lobes 16, depending on the pattern of electrodes 14 carried thereon, are provided with one or more apertures or openings 20, to again allow the head of the infant to breath and thus minimise heating effects of the system 10.

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Referring now in particular to Figure 4, it can be seen that an underside or skin contacting side of the substrate 12, along which the electrodes 14 are exposed, may be provided with one or more sections of adhesive 22, for example in the form of an adhesive paste or the like in order to adhere the substrate 12 in position on the head of the infant. The adhesive 22 is preferably water soluble so as to be easily removed from the head H once the system 10 has been removed, and non-electrically conducting. The use of the adhesive 22 further ensures that the electrodes 14 remain in the correct position throughout the EEG testing procedure.

In order to ensure that the substrate 12 is initially positioned at the correct location on the head of the infant, the system 10 preferably comprises a template 24 to facilitate the correct location of the substrate 12, in particular with respect to one or more anatomical landmarks, preferably bony landmarks, on the head, for example the nasion, inion, mastoid and vertex of the skull. In the embodiment illustrated, the template 24 comprises a pair of lateral strips 26, one extending from either side of the substrate 12, and a third or anterior strip 28 extending from a front of the substrate 12, preferably the node 18, and shaped and dimensioned to be aligned and/or engaged with the nose of the infant. By positioning the strips 26, 28 in alignment with the ears and nose, the substrate 12 will then be positioned such that each of the electrodes 14 is accurately aligned with the correct region of the scalp. Once the substrate 12 has been adhered into place, the strips 26, 28 are then preferably removed, in order to avoid discomfort. The strips 26, 28 are therefore preferably releasably secured to the substrate 12, for example via a perforated line of weakness (not shown) or the like. By removing the strips 26, 28 the aesthetics of the system 10 are also improved, which is an important consideration, in particular for the parents of the infant, who are likely to be under considerable stress given the circumstances. The more aesthetically pleasing or less visually intrusive the system 10 the less intimidating the system 10 will appear. The template 24 is thus used exclusively to position the substrate 12 on the head H, and is thus not intended to be a fastening or attachment mechanism.

Referring now to Figure 3 there is illustrated an alternative embodiment of an electroencephalogram (EEG) electrode system according to the present invention, generally indicated as 110, for use in conducting Cerebral Function Monitoring (CFM) of an infant (not shown). In this alternative embodiment like components have been accorded a like reference numeral, and unless otherwise stated perform a like function.

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The electrode system 110 comprises a substrate 112 which is again substantially planar or laminar in form, and may be formed from any suitable material having the desired characteristics to allow it to conform to the head H, or more particularly the scalp, of an infant, while being sufficiently rigid to ensure that it remains in the correct position throughout the operation of the system 110. The
5 electrode system 110 further comprises an array of the electrodes 14 carried by the substrate 112, and exposed at an underside or skin contacting side of the substrate 112. In this way, with the substrate 112 located against the head of the infant, an exposed skin contacting surface (not shown) of each electrode 14 will contact the infant's scalp in order to achieve an electrical contact therewith in order to permit the CFM testing to be performed.

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As the system 110 is designed for performing CFM testing, the substrate 112 is required to carry fewer of the electrodes 14 than the system 10 of the first embodiment, and thus the substrate 112 itself may be of smaller dimensions, as can be seen from Figure 3. The substrate 112 carries ten of the electrodes 14 in a predetermined array or pattern which ensures that when the substrate 112 is
15 located in position on the head H of the infant, each of the electrodes 14 is located at a predetermined site on the scalp which allows CFM to be performed. The semi-rigid nature of the substrate 112 then ensures that each of the electrodes 14 is maintained in this precise position throughout the CFM testing. This approach significantly reduces the preparation time and complexity of locating each of the electrodes 14 in position, allowing the CFM test to be performed in
20 a fraction of the time, at a significantly reduced cost, and optionally without the presence of an expert to locate the electrodes.

The substrate 112 comprises a plurality of lobes 116, and preferably four such lobes 16 such as to define a quatrefoil shape, each of the lobes 116 carrying an array of the electrodes 14 in the
25 requisite CFM testing pattern. A pair of the electrodes 14 are also located along the centreline of the substrate 112 which in use will run along an imaginary line from an anterior to a posterior of head H. The lobes 116 are each connected to a central node 118, with the relatively narrow path of contact between the respective lobe 116 and node 118 providing the lobe 116 with a degree of flexibility relative to the node 118 and thus the remaining three lobes 116. This allows each of lobes 116 to
30 flex relative to the node 118 in order to more closely conform to the shape of the head of the infant, which will vary from infant to infant, providing the system with a greater tolerance for variation in head shape/size.

As with the first embodiment, the use of lobes 116 reduces the surface area in contact with the head
35 H of the infant, thus reducing both discomfort and overheating of the infant. In order to further reduce any heating effects, where possible the lobes 116, depending on the pattern of electrodes 14 carried thereon and the overall dimensions of the lobe 116, are provided with one or more apertures or openings 120, to again allow the head of the infant to breath and thus minimise heating effects of the system 110.

Again as provided as part of the first embodiment, the system 110 preferably comprises a template 124 to facilitate the correct location of the substrate 112, in particular with respect to one or more anatomical and preferably bony landmarks on the head, for example the for example the nasion,
5 inion, mastoid and vertex of the skull. The template 124 comprises a pair of lateral strips 126, one extending from either side of the substrate 112, and a third or anterior strip 128 extending from a front of the substrate 112, preferably the node 118, and shaped and dimensioned to be aligned and/or engaged with the nose of the infant. By positioning the strips 126, 128 in alignment with the ears and nose, the substrate 112 will then be correctly and accurately positioned. The strips 126, 128 are
10 then preferably removed.

Once in position on the head of the infant, the array of electrodes 14 will be in direct contact with the skin in order to accurately measure the brain's electrical activity. The electrodes 14 may use either mechanical or biochemical means in order to reduce the skin contact impedance, in order to improve
15 the operation of the electrodes 14. Referring in particular to Figures 4, 5 and 6, there is illustrated an embodiment of the electrode 14 in isolation from the electrode system 10, 110. This electrode 14 may be used with either the system 10 of the first embodiment or the system 110 of the second embodiment of the invention.

20 The electrode 14 comprises the skin contacting surface 30 from which preferably projects an array of sharp protrusions or micropins 32 which will permeate the stratum corneum of the skin, preferably without breaking the skin or drawing blood. As a result of the above features the electrode 14 is self impedance reducing on contact with the skin, thus eliminating the need for skin preparation by hospital staff. Circumscribing the skin contacting surface 30 is a ring of adhesive 34 in order to
25 ensure satisfactory and persistent contact with the skin. Extending from a rear of the electrode 14 is a wire 36 which, referring in particular to Figure 4, is routed through the substrate 12, 112, along with a corresponding wire 36 from each of the additional electrodes 14, which then preferably exit the substrate 12, 112 at a single location to form a cable 38, 138. The cable 38, 138 preferably interfaces with the substrate 12, 112 at the posterior or top of the substrate 12, 112, in order to
30 ensure that the cable 38, 138 is as unobtrusive as possible, both to the infant and to medical staff. The cable 38, 138 is preferably in the form of an electrically shielded multi-core cable such as a ribbon cable. The cable 38, 138 also comprises electrically shielding insulation. The cable 38, 138 may be terminated with any suitable coupling (not shown) allowing the system 10, 110 to be connected to any desired EEG recording device (not shown).

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It will be appreciated that the electrodes 14 may be of any other suitable design. For example, instead of the sharp protrusions or micropins 32, the skin-contacting surface 30 of the electrode 14 may be provided with a mildly corrosive hydrogel or the like in order to minimise the skin contact impedance.

Referring to Figure 7, there is illustrated an alternative embodiment of an electrode for use with the system 10 of the present invention, generally indicated as 114. In this alternative embodiment, like components have been accorded like reference numerals, and unless otherwise stated, perform a like function. The electrode 114 comprises a skin contacting surface 130 which, in the embodiment illustrated, is a circular disc shaped mesh. The mesh may be formed from any suitable material, for example silver chloride alloy or gold, or a suitable equivalent. The skin contacting surface 130 is again preferably provided with sharp protrusions or micropins (not shown) projecting downwardly from the underside thereof. The electrode 114 further comprises a terminal 50, again of disc-shaped form, secured to which is a wire 136 which will pass through the substrate 12 to form part of the cable 38. Located between the terminal 50 and the skin-contacting surface 130 is a disc of electrically conductive paste 52, for example 4-5mm in thickness. The paste 52 provides an electrical path between the skin-contacting surface 130 and the terminal 50. In addition, as the substrate 12 is pressed into position on the head of the infant, the electrodes 114 will be compressed, causing compression of the disc of conductive paste 52. The paste 52 will therefore be compressed and partially forced through the reticulations in the meshed skin contacting surface 130, thus improving the electrical contact. In order to prevent excessive outward dispersion of the conductive paste 52 during compression of the electrode 114, the skin-contacting surface 130, terminal 50 and paste 52 may be housed within a short length of cylindrical tubing (not shown) which will thus only permit axial or longitudinal displacement of the paste 52 through the reticulated mesh of the skin contacting surface 130, as opposed to the lateral dispersion of the paste 52. The skin-contacting surface 130 may also be varied in shape from the disc form shown, and could for example be star-shaped or any other suitable alternative.

Referring to Figure 8 there is illustrated a further alternative embodiment of an electroencephalogram (EEG) electrode system according to the present invention, generally indicated as 210, for use in conducting EEG brain monitoring of an infant (not shown). In this further alternative embodiment like components have been accorded a like reference numeral, and unless otherwise stated perform a like function.

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The electrode system 210 comprises a substrate 212 which is again substantially planar or laminar in form and adapted to allow it to conform to the head H, or more particularly the scalp, of an infant, while being sufficiently rigid to ensure that it remains in the correct position throughout the operation of the system 210. The electrode system 210 comprises an array of electrodes 214 carried by the substrate 212, and exposed at an underside or skin contacting side of the substrate 212. In this way, with the substrate 212 located against the head of the infant, each electrode 214 will contact the infant's scalp in order to achieve an electrical contact therewith in order to permit the EEG testing to be performed. The electrodes 214 may be of any suitable design or configuration, and for example may comprise the electrode 14 or electrode 114 hereinbefore described.

The substrate carries the array of the electrodes 214 in a predetermined array or pattern that ensures that when the substrate 212 is located in position on the head H of the infant, each of the electrodes 214 is located at a predetermined site on the scalp which allows EEG monitoring to be performed. The electrodes 214 are most preferably located about the substrate 212 in a pattern that approximately corresponds with the pattern of the International Standard positions of the so called "10-20 system", and optionally the "modified combinatorial nomenclature". The semi-rigid nature of the substrate 12 then ensures that each of the electrodes 214 is maintained in this precise position throughout the EEG testing.

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The substrate 212 comprises a plurality of lobes 216, and preferably four lobes 216 such as to define a quatrefoil shape, each of the lobes 116 carrying an array of the electrodes 214 as hereinbefore described with reference to the first and second embodiments of the invention. The lobes 216 are capable of flexing relative to one another in order to more closely conform to the shape of the head of the infant, which will vary from infant to infant, providing the system with a greater tolerance for variation in head shape/size. The use of lobes 216 again reduces the surface area in contact with the head H of the infant, thus reducing both discomfort and overheating of the infant. Where possible the lobes 216 are provided with one or more apertures or openings 220, to again allow the head of the infant to breath and thus minimise heating effects of the system 210. In this particular embodiment the pair of frontal lobes 216 are each provided with an aperture 220 therein. In order to further reduce the heating effects of the system 210 the surface area of the substrate 212 has been significantly reduced relative to the first and second embodiments.

The system 210 is also preferably provided with cushioning pads 65 provided at least at the rear of the substrate 212, about the rearmost electrodes 214 (labelled as O1 and O2) in order to prevent or reduce pressure effects when the head of the infant is resting on these electrodes 214 for prolonged periods. The pads 65 may be of any suitable size and shaped, and may be formed from any suitable material, for example expanded foam or gel.

The substrate 212 is shaped, in the region between the frontal lobes 216, to define an enlarged space or access zone 60 which, when the substrate 212 is secured in position on the head of an infant, overlies the anterior fontanel region. The access zone 60 preferably extends from the midline of the substrate 212, originating anteriorly to the midpoint electrode 214 (labelled as Cz) and stretching anteriorly toward the adjacent electrodes 214 (labelled as F3 and F4). The access zone 60 thus defines a space for an ultrasound probe (not shown) to be positioned, allowing an ultrasound to be performed while the system 210 is in position.

The outer edge of the substrate 212, in the region bordering or defining the access zone 60, is preferably provided with a protective barrier or skirt (not shown) adapted to prevent the migration of

ultrasound conductive gel beneath the substrate 212, which might otherwise adversely effect the operation of the electrodes 214. The barrier may be of any suitable form, and for example may comprise a silicone lip along the edge of the substrate 212 which, when positioned against the scalp, forms a fluid tight seal between the skin and the edge of the substrate 212.

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It will therefore be understood that the system 10, 110, 210 of the present invention allows a clinician (nurse or doctor) on the NICU to apply a full set of EEG electrodes 14, 114, 214 in minutes, with no preparation of the scalp required. The system 10, 110, 210 can interface with any brand of EEG recording equipment. The system 10, 110, 210 may be provided in a range of sizes, and preferably
10 in sterile pre-packed bags (not shown) for application when needed. The system 10, 110, 210 is preferably disposable (single use) for up to 24 hours recording (possibly longer depending on ambient conditions such as humidity, temperature etc). The system 10, 110, 210 can remain in place during brain cooling treatment and ultrasound procedures.

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Claims

1. An electroencephalogram electrode system comprising a deformable substrate shaped and dimensioned to conform to a head of an infant; and an array of electrodes provided about the
5 substrate and capable of making electrical contact with the head when the substrate is positioned thereon.
2. A system according to claim 1 in which the substrate comprises a plurality of lobes.
- 10 3. A system according to claim 1 or 2 in which the substrate is substantially quatrefoil in shape.
4. A system according to any preceding claim in which the electrodes are arranged in a fixed pattern about the substrate which correspond with pre-determined locations on the scalp.
- 15 5. A system according to claim 4 in which the pattern of electrodes corresponds with the pattern of the 10-20 system or the modified combinatorial nomenclature.
6. A system according to any preceding claim in which each electrode is housed within the substrate and comprises an exposed skin contacting surface.
- 20 7. A system according to claim 6 in which the skin contacting surface is substantially flush or slightly protruding of an underside of the substrate.
8. A system according to any preceding claim in which one or more openings are provided in
25 the substrate to permit, in use, temperature regulation of the head.
9. A system according to any of claims 2 to 8 in which one or more lobes are provided with a central aperture to permit, in use, temperature regulation of the head.
- 30 10. A system according to any preceding claim comprising a template to facilitate the correct location of the substrate with respect to one ore more anatomical landmarks on the head.
11. A system according to claim 10 in which the template comprises at least one strap extending from the substrate for alignment and/or engagement with an anatomical landmark on the head.
- 35 12. A system according to claim 11 in which the template comprises a pair of lateral straps each extending from opposite sides of the substrate and shaped and/or dimensions to be aligned and/or engaged with a respective ear of the infant.

13. A system according to claim 12 in which the template comprises a third strap extending from an anterior of the substrate and shaped and/or dimensioned to be aligned and/or engaged with a nose of the infant.
- 5 14. A system according to any preceding claim comprising a transmission element adapted to transmit electrical signals from the electrodes to a receiver.
15. A system according to claim 14 in which the transmission element comprises a cable extending from the substrate.
- 10 16. A system according to claim 15 in which the cable comprises an electrically shielded multi-core cable.
- 15 17. A system according to claim 15 or 16 in which the cable exits a posterior or top of the substrate.
18. A system according to any preceding claim comprising one or more portions of adhesive carried on an underside or skin contacting side of the substrate.
- 20 19. A system according to any preceding claim in which each electrode comprises a skin contacting surface and an array of micropins or sharp protrusions projecting therefrom.
20. A system according to any preceding claim in which each electrode comprises a skin contacting surface, an electrical terminal, and a layer of electrically conductive paste or gel disposed therebetween.
- 25 21. A system according to claim 19 or 20 in which the skin contacting surface comprises an array of skin contact elements defining an array of openings therebetween.
- 30 22. A system according to any of claims 19 to 21 in which the electrode comprises a corrosive compound on the skin contacting surface.
23. A system according to any preceding claim comprising a protective barrier along an edge of at least a portion of the substrate.
- 35 24. A system according to claim 23 in which the protective barrier comprises a lip adapted to prevent the migration of liquid or gel beneath the substrate.

25. A system according to any preceding claim in which the substrate is shaped to define an access zone positioned to be aligned with or overlie, in use, the anterior fontanel.
26. A system according to any preceding claim comprising one or more cushioning pads
5 positioned and adapted to reduce or prevent pressure effects on the head.
27. An electrode for use with an electroencephalogram system according to any of claims 1 to 26 comprising a skin contacting surface and an array of micropins or sharp protrusions projecting from the skin contacting surface.
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28. An electrode according to claim 27 comprising an electrical terminal, and a layer of electrically conductive paste or gel disposed between the skin contacting surface and the electrical terminal.
- 15 29. An electrode according to claim 27 or 28 in which the skin contacting surface comprises an array of skin contact elements defining an array of openings therebetween.
30. An electrode according to any of claims 27 to 29 in which the electrode comprises a corrosive compound on the skin contacting surface.
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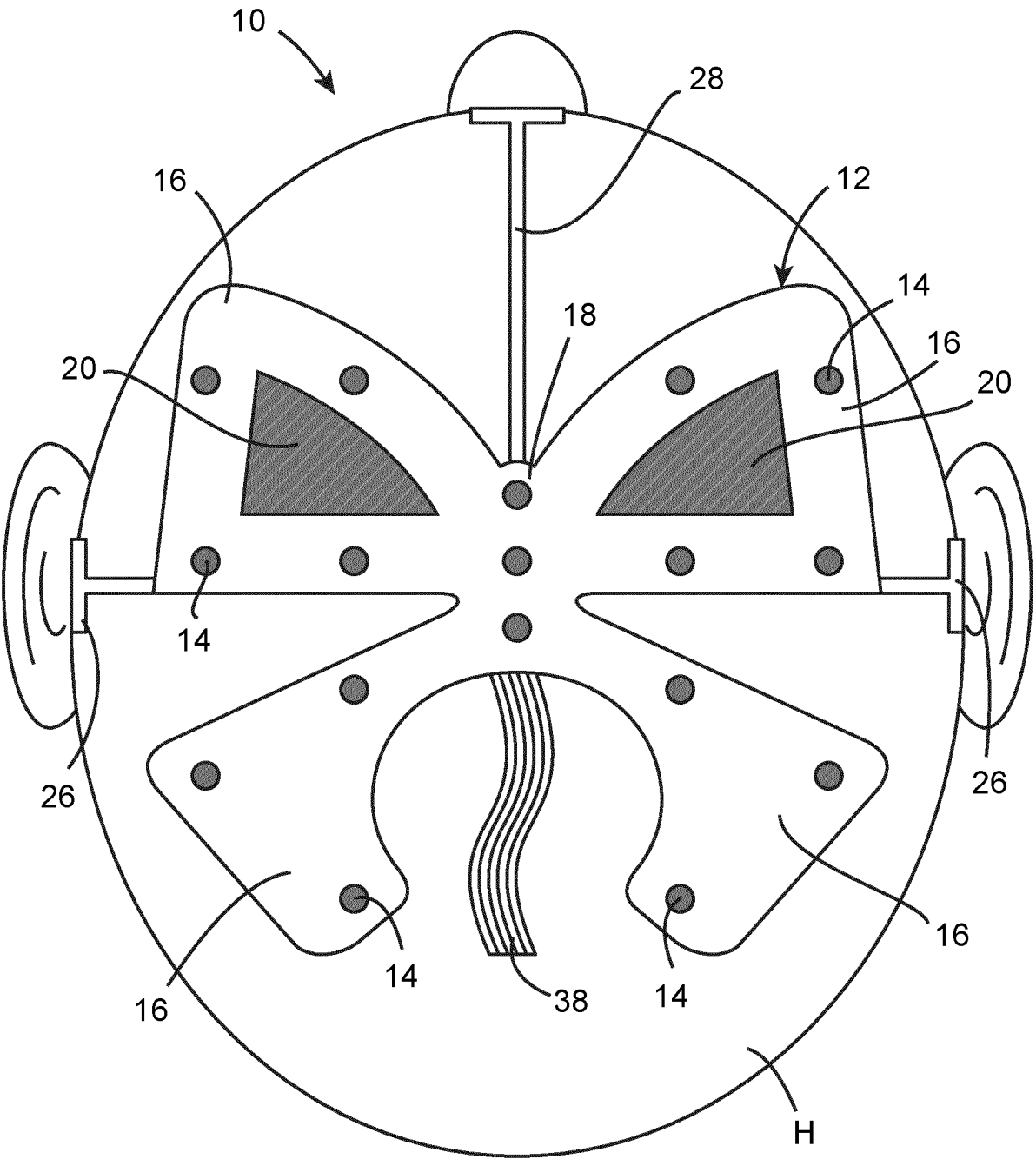


Fig. 1

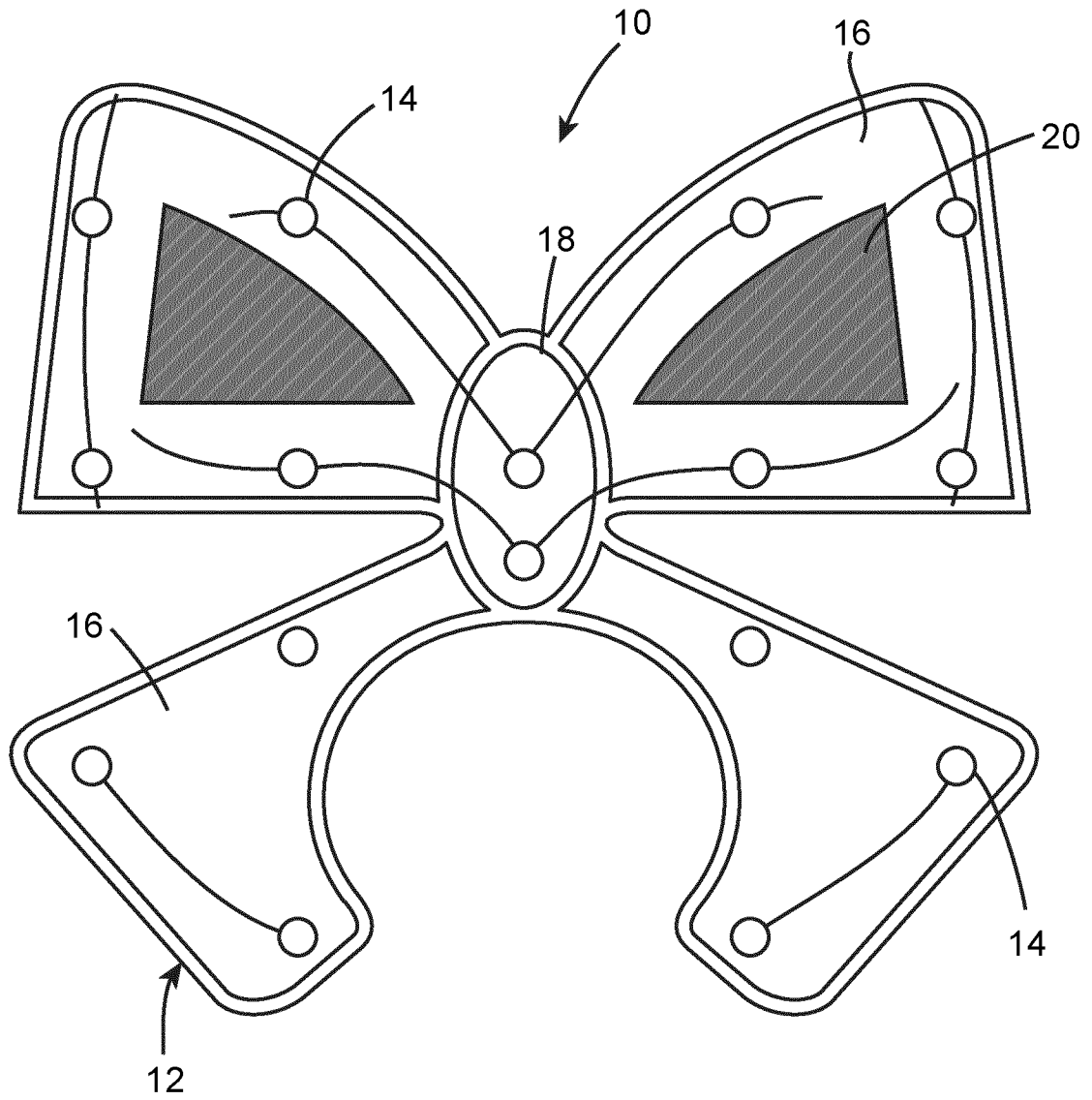


Fig. 2

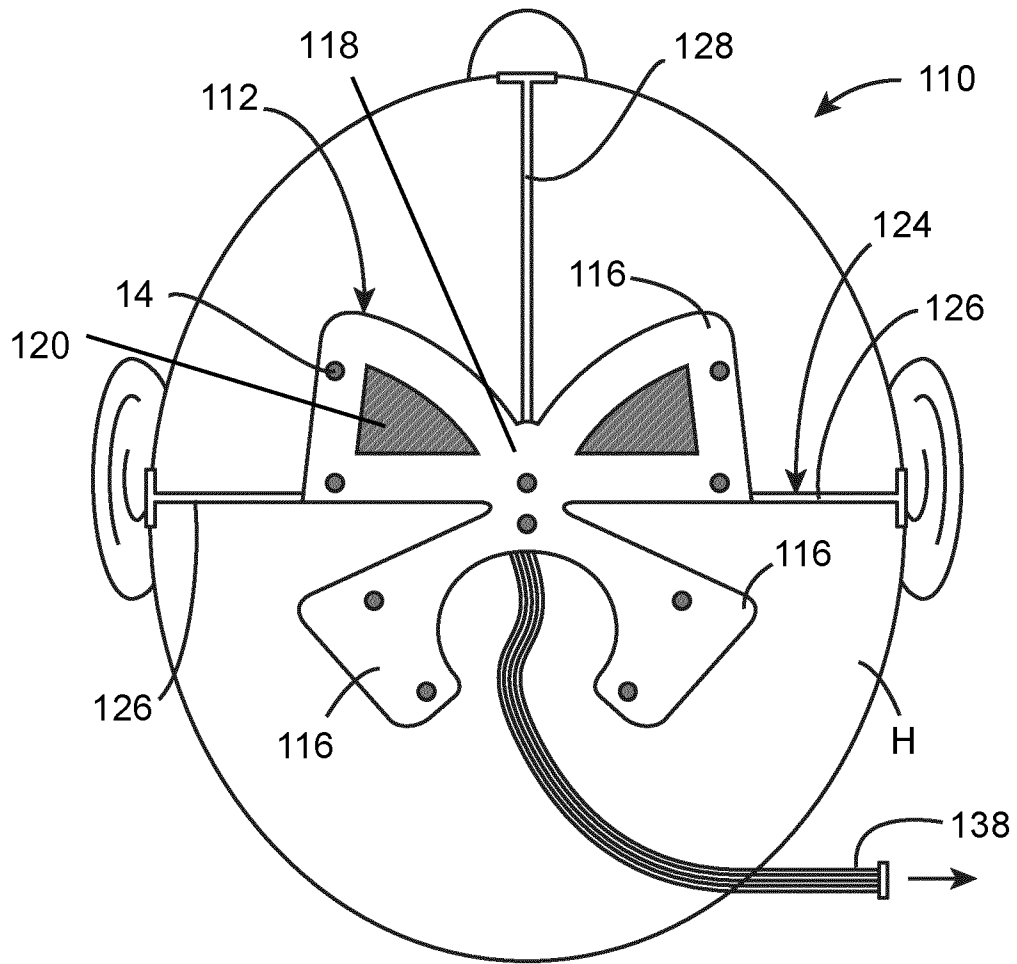


Fig. 3

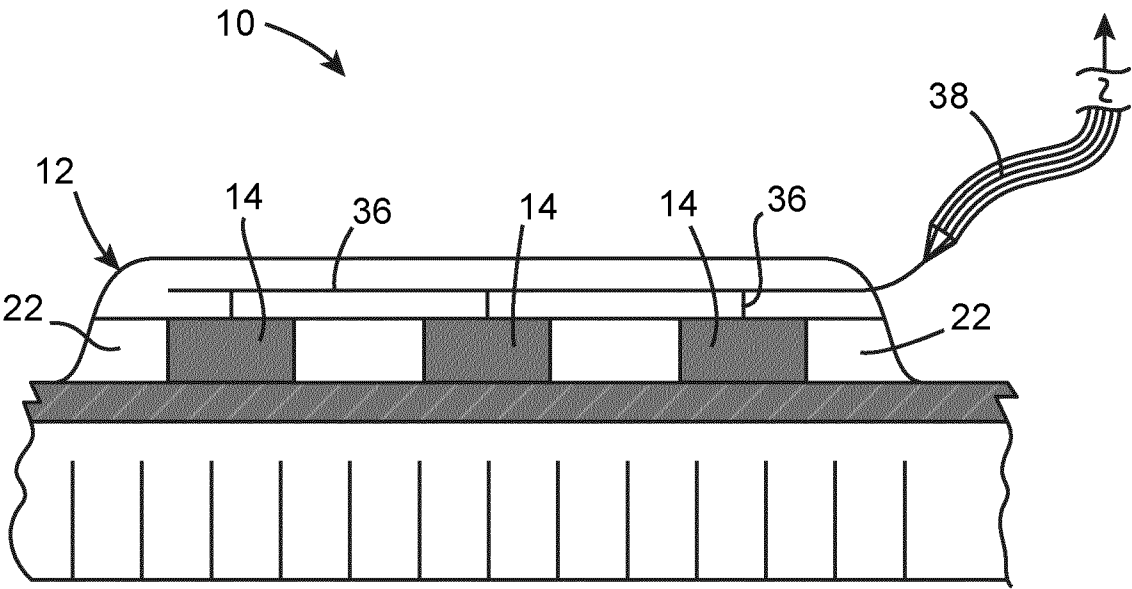


Fig. 4

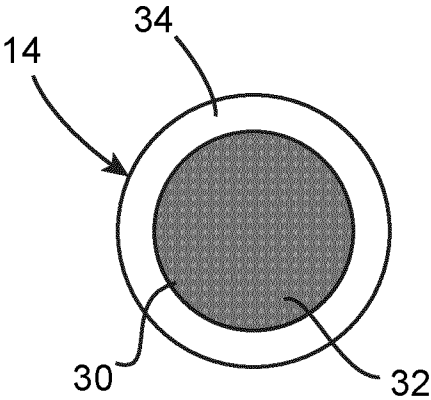


Fig. 6

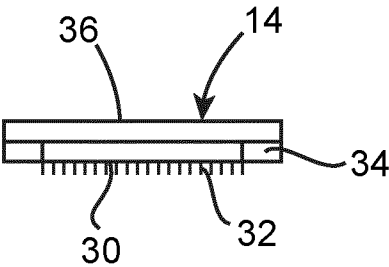


Fig. 5

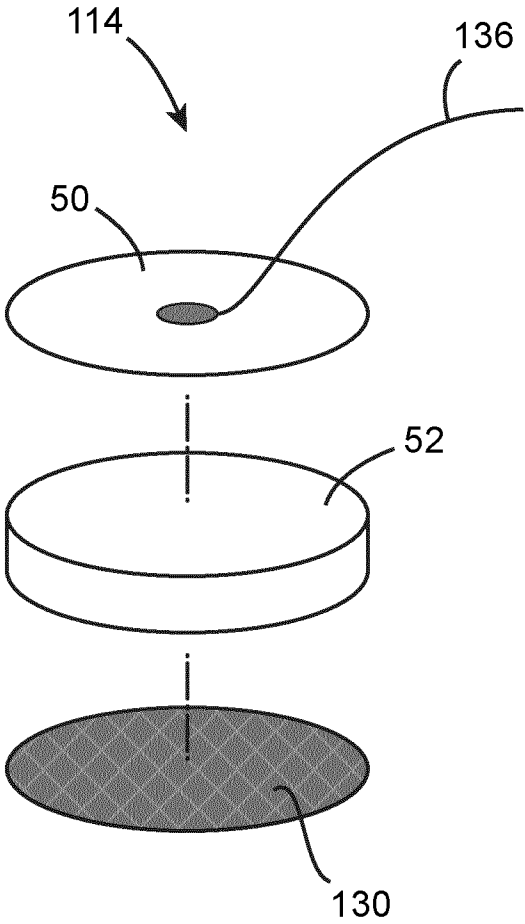


Fig. 7

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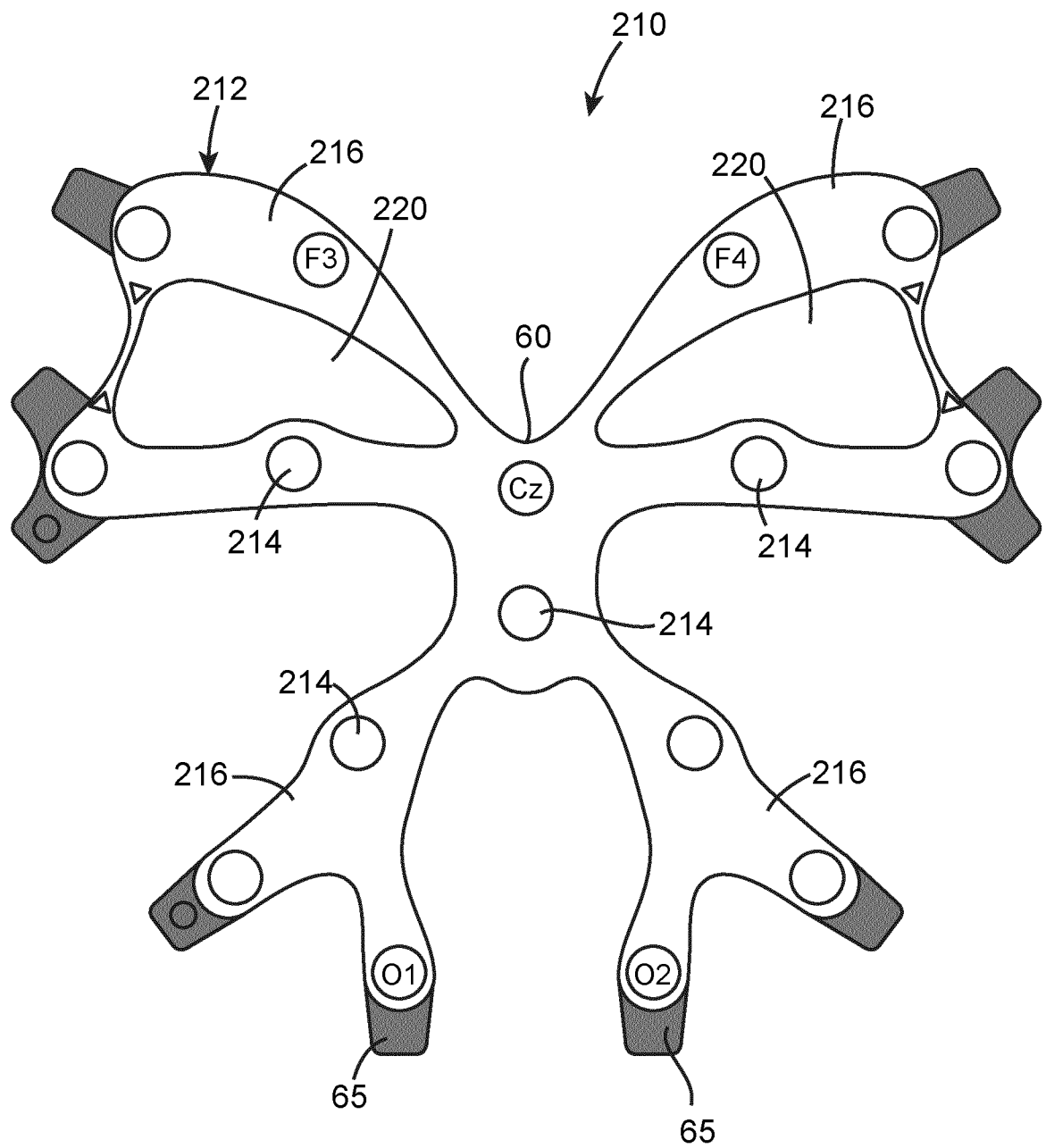


Fig. 8

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2013/053477

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/00 A61B5/0478
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2009/061920 A1 (HYDRODOT INC [US]; MCPECK JOHN P [US]; PRINCIPE KATHLEEN M [US]) 14 May 2009 (2009-05-14)	1-26
A	figures 2,3,6,7 paragraphs [0025], [0031], [0034] - [0040], [0041] - [0042], [0046] -----	27-30
X	WO 2004/000115 A1 (BRAINZ INSTR LTD [NZ]; WILLIAMS CHRISTOPHER EDWARD [NZ]; EMMANUEL SUDE) 31 December 2003 (2003-12-31)	1-27
A	page 5, lines 155-159 page 10, lines 307-328 -----	28-30
X	WO 2006/009771 A1 (NEURONETRIX INC [US]; FADEM KALFORD C [US])	1-26
A	26 January 2006 (2006-01-26) paragraphs [0105], [0149] -----	27-30
	-/-	



Further documents are listed in the continuation of Box C.



See patent family annex.

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"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

24 April 2013

Date of mailing of the international search report

07/05/2013

Name and mailing address of the ISA/

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Authorized officer

Albrecht, Ronald

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2013/053477

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2009/135200 A2 (ASPECT MEDICAL SYSTEMS INC [US]; CORDERO RAFAEL M [US]; HARHEN ROBERT) 5 November 2009 (2009-11-05) figures 1A-6 paragraphs [0011], [0035] - [0042] -----	1-30

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2013/053477

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