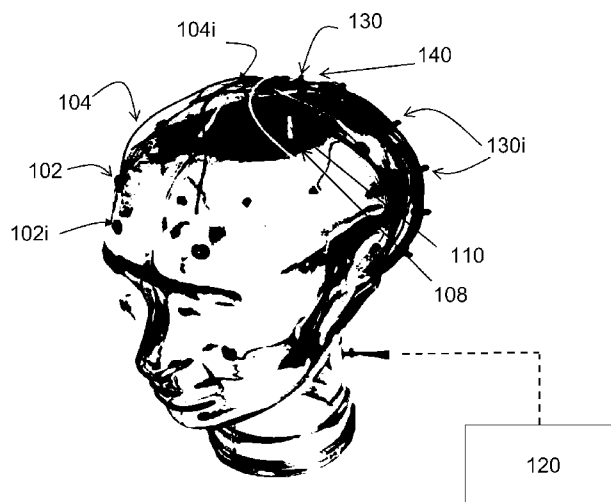




- (51) **International Patent Classification:**
A61B 5/0478 (2006.01) *A61N 1/04* (2006.01)
A61B 5/04 (2006.01)
- (21) **International Application Number:**
PCT/AU2018/000232
- (22) **International Filing Date:**
26 November 2018 (26.11.2018)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
2017904762 24 November 2017 (24.11.2017) AU
- (71) **Applicant: SEER MEDICAL PTY LTD [AU/AU];** PO Box 4017, South Fitzroy VIC 3065 (AU).
- (72) **Inventor: FREESTONE, Dean Robert;** 1 /23 Franklin Place, West Melbourne VIC 3003 (AU).
- (74) **Agent: ALLENS PATENT & TRADE MARK ATTORNEYS;** Deutsche Bank Place, Corner Hunter & Phillip Street, Sydney NSW 2000 (AU).
- (81) **Designated States** (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(54) **Title:** AN EEG MONITORING APPARATUS AND METHOD OF ITS PLACEMENT

Figure 1



(57) **Abstract:** An EEG monitoring apparatus comprises a plurality of electrode assemblies, each which include (i) an electrode element configured to be removably affixable to a user's scalp and (ii) an elongated flexible lead wire connected at one end to the electrode element. The apparatus also includes a strain relief (SR) electrode assembly which includes an anchor electrode element and an elongated flexible anchor wire. The apparatus further comprises EEG signal acquisition circuitry in communication with (i) the other end of the elongated flexible lead wire of the plurality of electrode assemblies and (ii) the other end of the elongated flexible anchor wire of the SR electrode assembly; and a strain relief coupling, where the EEG monitoring apparatus is configured such that each of the plurality of lead wires and the anchor wire defines a path from its associated electrode to the EEG signal acquisition circuitry via the strain relief coupling.



(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

- *with international search report (Art. 21(3))*
- *with information concerning incorporation by reference of missing parts and/or elements (Rule 20.6)*

AN EEG MONITORING APPARATUS AND METHOD OF ITS PLACEMENT

TECHNICAL FIELD

[001] The invention relates to an EEG monitoring apparatus and a method of placement of an EEG monitoring apparatus.

RELATED APPLICATION

[002] This application is based on and claims priority to Australian provisional patent application number 2017904762 filed by 24 November 2017, the content of which is incorporated by reference in its entirety.

BACKGROUND

[003] EEG is a tool for measuring the electrical activity generated in the brain. Typically a subject is fitted with several electrodes which are placed over the scalp. Each electrode measures the signal from the electrical field generated by the nerve cells in the region adjacent the electrode. EEG signals are used for a variety of applications, such as studying the brain's response to stimuli and events, and in the clinical diagnosis of patients with conditions such as epilepsy.

[004] For ease of convenience, EEG caps are commonly used which comprise a cap pre-populated with electrodes. The electrodes may be permanently fixed, or they may be snap fitted enabling removal and thus replacement of damaged electrodes or electrodes requiring sanitation. The use of a cap is seen as advantageous as the individual electrodes do not need to be positioned for each subject.

[005] For certain medical conditions, such as epilepsy, it is desirable to conduct prolonged monitoring of a subject. The gold standard for diagnosis of epileptic events is monitoring over a number of days. This typically requires that the subject spend several days in a hospital facility, which is not only inconvenient, but costly.

More recently, ambulatory EEG systems have been developed to enable the collection of data while the subject is in an out-patient setting, enabling the subject to go about his or her normal daily routines. However currently available mobile EEG systems have drawbacks including poor electrode contact with the scalp which impacts signal quality. This can be exacerbated when applications require greater channel numbers, as the quantity of electrode wiring will be increased as

well. With existing EEG systems, the quantity of electrode wires can significantly restrict a subject's mobility. Further, the electrode wires are prone to being pulled which dislodge the respective electrodes to which they are attached. This can further affect signal acquisition.

[006] In respect of EEG systems generally, it is desirable to increase the quality of the detected signal as this impacts the diagnosis directly. It is also desirable to minimize any obstruction or interference with a subject's motion whilst carrying out activities.

[007] Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present disclosure as it existed before the priority date of each claim of this application.

[008] Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

SUMMARY

[009] The present invention seeks to obviate, ameliorate or provide an alternative to prior art EEG monitoring apparatus.

[010] According to a first aspect of the present invention, an EEG monitoring apparatus is provided which comprises:

[011] a plurality of electrode assemblies, each electrode assembly including (i) an electrode element configured to be removably affixable to a user's scalp and (ii) an elongated flexible lead wire connected at one end to the electrode element;

[012] a strain relief (SR) electrode assembly, the SR electrode assembly including an anchor electrode element and an elongated flexible anchor wire connected at one end to the anchor electrode, a first portion of the elongated flexible anchor wire immediately adjacent to the anchor electrode being removably affixable along its length to the user's scalp;

[013] EEG signal acquisition circuitry in communication with (i) the other end of the elongated flexible lead wire of the plurality of electrode assemblies and (ii) the other end of the elongated flexible anchor wire of the SR electrode assembly; and

[014] a strain relief coupling; wherein the EEG monitoring apparatus is configured such that each of the plurality of lead wires and the anchor wire defines a path from its associated electrode to the EEG signal acquisition circuitry via the strain relief coupling.

[015] The following embodiments may apply to the first aspect of the invention.

[016] The plurality of electrode assemblies and the SR electrode assembly may be grouped into a predetermined number of groups. A portion of each of the lead wires in each group may be wrapped with a protective sheath. The protective sheath may be a shrinkable plastic tubing or other like insulating material. The strain relief coupling preferably couples all of the groups of electrode assemblies together in the immediate vicinity of the protective sheath.

[017] The EEG monitoring apparatus may further comprise a plurality of strain relief couplings, where the plurality of strain relief couplings are spaced along a length of the plurality of lead wires and the anchor wire. The plurality of strain relief couplings may be evenly spaced or they may be irregularly spaced.

[018] In one embodiment, the EEG monitoring apparatus further includes a wearable housing to accommodate the EEG signal acquisition circuitry. The wearable housing may be in the form of a pouch configured to be worn on the user's person, for instance around the user's waist or hips.

[019] The electrodes are preferably attached to the user's scalp skin with collodion or other like substance.

[020] The electrode elements are preferably surface/non-invasive, recording/monitoring electrodes which measure biopotentials as EEG. Preferably the electrode elements are metal electrodes, manufactured from a substantially inert metal or metal alloy such as gold, platinum, silver, titanium and stainless steel. Preferably the electrode elements are cup electrodes. Known electrode assemblies using cup electrodes may be used in some embodiments comprised of a dome surrounded by a wide edge in the shape of a disc which facilitates application of a layer of colloidal paste to enable the electrode to be fixed to the user's scalp skin. A hole may be provided in the top of the cap allows for easy filling of electrolytic gel after the electrode has been affixed to the scalp skin. The discs of the respective electrode elements may be fabricated with different external diameters and cable lengths to suit infant to adult utilization. Lead wires are preferably mounted to the disc of respective electrode elements.

[021] The electrode element and lead wire of each electrode assembly may be those which are commercially available. With respect to the electrode element

which are generally cup-shaped, they may be supplied with either a solid or a liquid conductive gel pre-applied to sit within the cup. The electrode element may be provided with a removable protective member to prevent the gel from drying out prior to use.

[022] According to a second aspect of the present invention, a method of placement of an EEG monitoring apparatus is provided, the apparatus including a plurality of electrode assemblies and a strain relief (SR) electrode assembly, the SR electrode assembly including an anchor electrode element and an elongated flexible anchor wire connected at one end to the anchor electrode, the method comprising:

[023] grouping the plurality of electrode assemblies into a predetermined number of groups;

[024] within each group, (i) determining a bind point in respect of each elongated flexible lead wire and (ii) binding the group of elongated flexible lead wires together at the bind point;

[025] sequentially attaching the electrodes within each group of electrode assemblies to a scalp of a user, one group at a time;

[026] affixing the anchor electrode and a portion of the elongated flexible anchor wire on the scalp of the user at a first location; and

[027] coupling the groups and the elongated flexible anchor wire together using a strain relief coupling.

[028] In a preferred embodiment of the second aspect of the invention, a plurality of electrodes are provided, wherein each electrode is removeably anchored to the patient's head in a predetermined pattern. The step of sequentially affixing the electrodes within each group of electrode assemblies preferably comprises layering subsequent groups on top of one another.

[029] The positioning of the wires may be determined by the subject's preferred sleeping side. For example, if the patient prefers to sleep on their left side then the bundle of electrodes are preferably directed towards the back-right hand side of the head and vice –versa.

BRIEF DESCRIPTION OF THE DRAWINGS

[030] An example of the invention will now be described with reference to the accompanying drawings, in which:

[031] **Figure 1** illustrates a schematic diagram of an EEG monitoring apparatus 100;

[032] **Figure 2** illustrates the International 10-20 System for electrode placement on the scalp;

[033] **Figure 3a** illustrates the grouping of the plurality of electrode assemblies and the SR electrode assembly in accordance with an embodiment of the invention;

[034] **Figure 3b** illustrates the percentage-distance conversion used to determine the wrap region length for respective lead wires within each group;

[035] **Figure 4** illustrates a schematic showing sequential placement of the electrodes within each group;

[036] **Figure 5** illustrates respective lengths of lead wires for each of the electrodes in the electrode groups; and

[037] **Figure 6** is a graph showing longitudinal impedance data recorded from EEG electrodes during ambulatory recordings.

DETAILED DESCRIPTION OF THE DRAWINGS

[038] Embodiments of the invention are generally directed to an ambulatory EEG monitoring apparatus and a method of placement of an ambulatory EEG monitoring apparatus.

[039] Figure 1 illustrates a schematic diagram of an ambulatory EEG monitoring apparatus 100. The ambulatory EEG monitoring apparatus 100 includes a plurality of electrode assemblies, each of which includes an electrode element 102 configured to be removably affixable to a user's scalp and an elongated flexible lead wire 104 connected at one end to the electrode element 102. Each of the electrode elements 102 are surface monitoring cup electrodes which each measure biopotentials as EEG. Each electrode element 102 is coupled to a pre-amplifier circuit (not shown) configured to sense an intrinsic brain signal and to output a resulting sensed brain signal that is indicative of the intrinsic brain signal. Each elongated flexible lead wire 104_i is secured at one end to its electrode element 102_i. An approximately 2cm length section of heat shrink is then applied to the lead wire in the immediate vicinity of the electrode.

[040] Monitoring apparatus 100 further includes a strain relief (SR) electrode assembly which includes an anchor electrode element 108 and an elongated flexible anchor wire 110 connected at one end to the anchor electrode.

[041] As with the electrode assemblies, a section of heat shrink of approximately 2cm length is then applied to the anchor wire 110 in the immediate vicinity of the anchor electrode element 108.

[042] Monitoring apparatus 100 further includes EEG signal acquisition circuitry 120 in communication with the other end of the elongated flexible lead wire 104 of the plurality of electrode assemblies and the other end of the elongated flexible anchor wire of the SR electrode assembly. In this embodiment, the EEG signal acquisition circuitry 120 includes a filter and amplifier circuit to bring the received signals into a range where they are able to be reliably digitalized. The amplifiers need to be able to provide amplification selective to the physiological signal, as well as rejecting interference signals. Further, the amplifiers need to be offer protection to the wearer of the device. An A/D converter changes the signal to a digital form which is then stored to memory. The EEG signal acquisition circuitry 120 is housed in a bag designed to be worn around the waist of the subject.

[043] A non-limiting example of electronics that can be included in the EEG signal acquisition circuitry 120, is described in U.S. patent application Ser. No. 11/694,816, entitled Brain signal telemetry and seizure prediction, which is hereby incorporated herein by reference in its entirety. Briefly, US 11/694,816 describes an ambulatory intrinsic brain signal processor circuit is coupled to a plurality of electrodes. The signal processor circuit can include a digital multiplexer circuit coupled to the electrodes to multiplex brain signal data from different electrodes together into a multiplexed data stream. An ambulatory transceiver circuit wirelessly communicates information to and from a remote transceiver. A controller circuit permits a user to control which of the electrodes contribute data, a data resolution, and whether the data includes one or both of neural action or local field potential data. While U.S. 11/694,816 emphasizes seizure prediction, its systems and methods can also be used to diagnose a seizure that is already present.

[044] The EEG signal acquisition circuitry can wirelessly transfer recorded EEG information to a local user interface (not shown) via a wireless modality such as Bluetooth. The local user interface can also be coupled to a wireless computer or communications network (not shown), such as the internet, such as to transfer the EEG information to one or more remote user interfaces. Either way, the local user interface may include signal processing circuitry configured to process the EEG

information such as to automatically determine whether a seizure or other neurological condition is present.

[045] Monitoring apparatus 100 further includes a first strain relief coupling 130 wherein the EEG monitoring apparatus 100 is configured such that each of the plurality of lead wires 104 and the anchor wire 110 defines a path from its associated electrode to the EEG signal acquisition circuitry 120 via the strain relief coupling 130. Additional strain relief couplings 130i and provided which are substantially evenly spaced along a length of the plurality of lead wires and the anchor wire.

[046] In this embodiment, the plurality of electrode assemblies and the SR electrode assembly are grouped into five groups. The lead wires in each group are wrapped with a protective sheath 140 in the form of heat shrink at a specific region along the respective lengths of wire. The strain relief coupling couples all of the groups of electrode assemblies together in the immediate vicinity of the protective sheath 140.

Layout of the Electrode configuration

[047] The International 10-20 System is the standardized system for electrode placement on the scalp, based on four identifiable landmarks. As illustrated in Figure 2, this system divides the scalp into proportional distances from prominent landmarks: the nasion, inion, and left and right pre-auricular points. The 10-20 terminology is because the measurements are spaced either 10% or 20% of the distance between a given pair of landmarks. The longitudinal fiducial line passes through nasion and inion, and the overall distance is divided into six lengths: 10%, 20%, 20%, 20%, 20% and 10% with five points: Fpz, Fz, Cz, Pz and Oz from front to back. The transversal fiducial line passes through both pre-auricular points, and the overall distance is divided into six lengths: 10%, 20%, 20%, 20%, 20% and 10% with five points: T3, C3, Cz, C4 and T4 from left to right. The head circumference is the horizontal line passing through Fpz, T3, Oz and T4, wherein the left half distance is divided into six lengths: 10%, 20%, 20%, 20%, 20% and 10% with five points: Fp1, F7, T3, T5 and O1 from front to back, and the right half distance is divided into six lengths: 10%, 20%, 20%, 20%, 20% and 10% with five points: Fp2, F8, T4, T6 and O2 from front to back. The ground electrode (GN) is necessary for getting the differential voltage by subtracting the same voltages showing at active and reference points (REF).

Electrode configuration

[048] As stated above, the plurality of electrode assemblies and the SR electrode assembly are grouped into five groups. Figure 3a illustrates the division of electrode assemblies into groups. The determination of the wrap region at which the lead wires within a group are wrapped in a protective sheath 140 is based on a percentage of the hemi-circumference of a user, whereby a user is classified as having either a small (35cm), medium (37cm) or large (40cm) sized head-circumference. Figure 3b shows the percentage-distance conversion used to determine the wrap region length for respective lead wires within each group. Table 1 and the schematic illustration shown in Figure 5, shows the actual lengths, depending on whether the subject's hemi-circumference is small, medium or large. Note that the Ground (GND), Reference (REF), Cz and anchor lead wires are collectively referred to as the 'S' Group. The wire length for each of the GND, REF and Cz lead wires is approximately 20% (+/- 3%) of the hemi-circumference value. The wire length for the anchor electrode is approximately 40% of the hemi-circumference value.

Small	Medium	Large
20% = 7 cm	20% = 7.4 cm	20% = 8 cm
40% = 14 cm	40% = 14.8 cm	40% = 16 cm
47.5% = 16.6 cm	47.5% = 17.5 cm	47.5% = 19 cm

[049] The wire leads within each group are measured to determine the wrap region and the wire leads are bound in heat shrink at the wrap region. As should be evident, pre-grouping of electrode assemblies into small, medium and large sizes is able to be performed in advance of a clinical setting, thereby enabling rapid fitting of a subject, once the subject is determined to have either a small, medium or large head circumference.

Application of the electrodes to the subject's scalp

[050] Initially, the subject is made to feel comfortable which involves setting an appropriate chair height for the patient/subject. Then the distance between the subject's nasion and inion is measured, as is the distance between the subject's pre-auricular points. Depending on the average of these two measurements, an appropriate electrode size is selected. If the average measurement is less than

35cm then small electrodes are selected. If the average measurement is between 35cm and 37cm, then medium sized electrodes are selected and if the average measurement is greater than 37cm then large sized electrodes are selected.

[051] The subject/patient is asked to specify their preferred sleeping side, this assists to determine the direction of the lead wires 104. For instance if the patient sleeps on their left side, direct the 'S' group towards the right dorsolateral (back-right) side of the head. The wire bundle also follows this direction.

[052] Next, electrode positions are marked on the subject's scalp. The subject's skin in the vicinity of where the electrodes are to be located is then cleaned and abraded to reduce spurious electrical impedances and then the electrodes are attached to the scalp surface with collodion.

[053] With reference to Figure 4, electrodes within each electrode group are attached in a symmetrical manner. Initially, from the 'S' group, the GND, REF and Cz lead wires are attached to the scalp. The anchor electrode 108 remains temporarily unattached. Then, when attaching group 1: if Fz (1) is attached first, Pz (2) should be attached second. This ensures that the heat shrink region remains above the GND/Cz positions. For group 3, T3 and T4 are attached before A1 and A2 to ensure wires do not get in the way. For each electrode, a small amount of collodion is added at the end of the ~2cm section of heat shrink, to ensure that the entire electrode is attached to the scalp. A strain relief coupling in the form of a cable tie is then used to group wires above GND/Cz position. Groups 1-5 and 'S' are tied directly above GND/Cz. The very last electrode to be glued down is the anchor electrode 108. In addition to the gluing down of the anchor electrode, a portion of the elongated flexible anchor wire immediately adjacent to the anchor electrode 108 is affixed along its length to the user's scalp with collodion.

[054] Further cable ties are then used to bundle together the groups of lead wires down to the patient's neck. Next, Fixomull® stretch tape is used to hold the wire bundle to the patient's neck. It is preferable to ensure that there is sufficient 'slack' on the wires to minimize pull on the electrodes in all head positions. Finally the wire bundle is placed into a fabric sleeve.

[055] As is particularly evident from figure 4, the grouped wiring is anchored to the central upper apex point of the patient's head, with the electrodes fanning out from the apex point to the recording locations. Having the electrodes fanning out from a central location means that the forces applied due to gravity together with the weight and movement of the wiring will have a minimal impact on the electrode

stability. This configuration enables a small amount of slack on the wiring to respective electrode elements.

[056] With reference to figure 6, the stability of the electrode elements was determined using a group of 59 ambulatory pediatric and adult patients. Each patient wore an EEG apparatus configured and positioned in accordance with the invention, and recordings (depicted by 202) were measured at daily intervals over a 7 day period. The solid line 204, depicts the median filtered signal at 6 hourly intervals. The median starting impedance is 3.7k Ohms, and the median impedance of recording electrodes after 7 days is 50 kOhms. The dashed line 206, depicts the trend line which has a R value of 0.78 and a R^2 value of 0.60. The graph clearly depicts the stability of the electrodes over the 7 day period.

[057] As should be evident from the foregoing, the EEG monitoring apparatus is configurable to minimise unwanted forces and movements from the plurality of electrode assemblies when the electrodes are positioned on a subject. The unwanted forces are translated to wiring that is positioned specifically for the strain or stress relief purpose.

[058] It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the above-described embodiments, without departing from the broad general scope of the present disclosure. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Claims

-
1. A method for a polyolefin film with capability of being directly coated, comprising following steps:
- 5 (1) cleaning a surface of the polyolefin film to be treated, and drying the polyolefin film in the air for later use;
- (2) placing the polyolefin film in step (1) into a low-temperature plasma reaction chamber, and vacuuming the low-temperature plasma reaction chamber;
- 10 (3) after step (2) ends up, introducing polar molecules into the reaction chamber, adjusting temperature and pressure, and performing a gas-phase graft reaction on the surface of the polyolefin by a low-temperature plasma treatment.
2. The method according to claim 1, wherein, the polyolefin film comprises low-density polyethylene, high-density polyethylene, linear low-density polyethylene, or polypropylene.
- 15 3. The method according to claim 1, wherein, the low-temperature plasma treatment in step (3) comprises a radio-frequency low-temperature plasma discharge process, treatment power of a power supply selected is 100-600W, preferably 200-600W, and more preferably 300-400W.
- 20 4. The method according to claim 1, wherein, the gas-phase graft reaction in step (3) is carried out for 2-10min at a temperature of 0-75° C under a pressure of 15-50Pa, preferably, for 2-5min at a temperature of 20-50° C under a pressure of 35-50Pa.
- 25 5. The method according to claim 1, wherein, a vacuum degree in step (2) is 10-30Pa, preferably 15-30Pa, and more preferably 15-20Pa.
6. The method according to claim 1, wherein, the polar molecules in step (3) is gaseous polar molecules and/or vaporable polar molecules,
- 30 preferably one or more than one selected from a group consisting of chlorine gas, hydrogen sulfide, ammonia gas, hydrogen chloride, acrylic acid, 3-aminopropyltriethoxysilane, 3-aminopropyltrimethoxysilane, 3-aminopropyl-diethoxysilane, cyclohexylaminopropyltrimethoxysilane, 3-ureidopropyltrimethoxysilane, 3-mercaptopropyltriethoxysilane,

3-mercaptopropyltripropoxysilane,
3-chloropropyltriethoxysilane,
3-chloropropylmethyldiethoxysilane.

3-chloropropyltrimethoxysilane,
3-chloropropylmethyldimethoxysilane,

5 7. A polyolefin film with capability of being directly coated prepared by the method according to any one of claims 1-6, comprising, a graft layer of a surface of the polyolefin film being a thinness of 5-80nm.

10 8. The polyolefin film with capability of being directly coated according to claim 7, wherein, polar elements contained in the graft layer of the surface of the polyolefin film comprise one or more than one selected from a group consisting of nitrogen element, oxygen element, chlorine element, silicon element and sulfur element.

15 9. The polyolefin film with capability of being directly coated according to claim 8, wherein, the polar elements contained in the graft layer account for 20-35wt% of total elements of the graft layer.

20 10. The polyolefin film with capability of being directly coated according to claim 7, wherein, the polyolefin film has a critical surface tension of 45-55dyne/cm, and a water contact angle of 30-60°.

CLAIMS

1. An EEG monitoring apparatus comprising:

a plurality of electrode assemblies, each electrode assembly including (i) an electrode element configured to be removably affixable to a user's scalp and (ii) an elongated flexible lead wire connected at one end to the electrode element;

a strain relief (SR) electrode assembly, the SR electrode assembly including an anchor electrode element and an elongated flexible anchor wire connected at one end to the anchor electrode, a first portion of the elongated flexible anchor wire immediately adjacent to the anchor electrode being removably affixable along its length to the user's scalp;

EEG signal acquisition circuitry in communication with (i) the other end of the elongated flexible lead wire of the plurality of electrode assemblies and (ii) the other end of the elongated flexible anchor wire of the SR electrode assembly; and

a strain relief coupling; wherein the EEG monitoring apparatus is configured such that each of the plurality of lead wires and the anchor wire defines a path from its associated electrode to the EEG signal acquisition circuitry via the strain relief coupling.

2. An EEG monitoring apparatus according to claim 1, where the plurality of electrode assemblies and the SR electrode assembly are grouped into a predetermined number of groups.

3. An EEG monitoring apparatus according to claim 2, where a portion of each of the lead wires in each group are wrapped with a protective sheath.

4. An EEG monitoring apparatus according to claim 3, where the strain relief coupling couples all of the groups of electrode assemblies together in the immediate vicinity of the protective sheath.

5. An EEG monitoring apparatus according to claim 2, further comprising a plurality of strain relief couplings, the plurality of strain relief couplings spaced along a length of the plurality of lead wires and the anchor wire.

6. An EEG monitoring apparatus according to claim 5, wherein the plurality of strain relief couplings are substantially evenly spaced.
7. An EEG monitoring apparatus according to any one of the preceding claims, where the plurality of electrode assemblies include a ground electrode element and at least one reference element, and where the SR electrode assembly is grouped with the lead wires connected to the ground electrode element and the at least one reference element.
8. An EEG monitoring apparatus according to any one of the preceding claims, further comprising a wearable housing to accommodate the EEG signal acquisition circuitry.
9. An EEG monitoring apparatus according to claim 7, where the wearable housing is in the form of a pouch configured to be worn on the user's person.
10. A method of placement of an EEG monitoring apparatus, the apparatus including a plurality of electrode assemblies and a strain relief (SR) electrode assembly, the SR electrode assembly including an anchor electrode element and an elongated flexible anchor wire connected at one end to the anchor electrode, the method comprising:
 - grouping the plurality of electrode assemblies into a predetermined number of groups;
 - within each group, (i) determining a bind point in respect of each elongated flexible lead wire and (ii) binding the group of elongated flexible lead wires together at the bind point;
 - sequentially attaching the electrodes within each group of electrode assemblies to a scalp of a user, one group at a time;
 - affixing the anchor electrode and a portion of the elongated flexible anchor wire on the scalp of the user at a first location; and
 - coupling the groups and the elongated flexible anchor wire together using a strain relief coupling.

11. A method of placement of an EEG monitoring apparatus according to claim 10, wherein the step of sequentially affixing the electrodes within each group of electrode assemblies, one group at a time comprises layering subsequent groups onto top of one another.

Figure 1

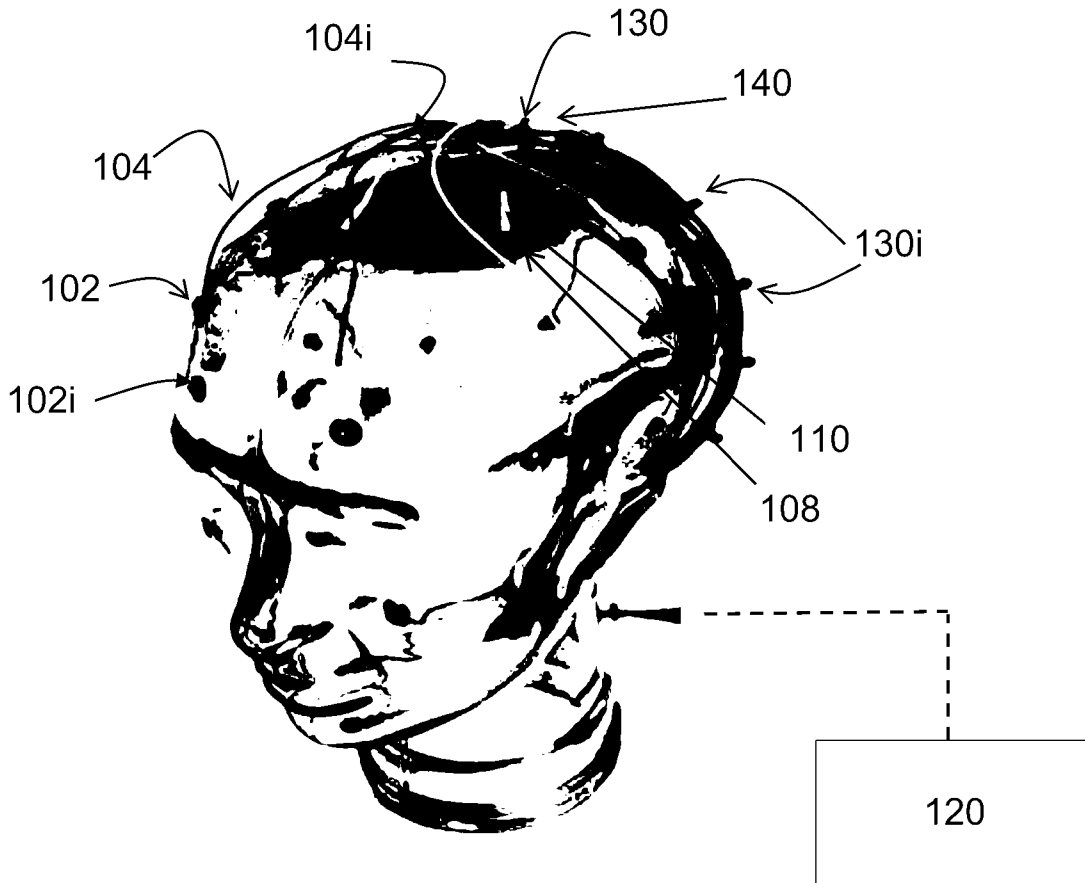


Figure 2

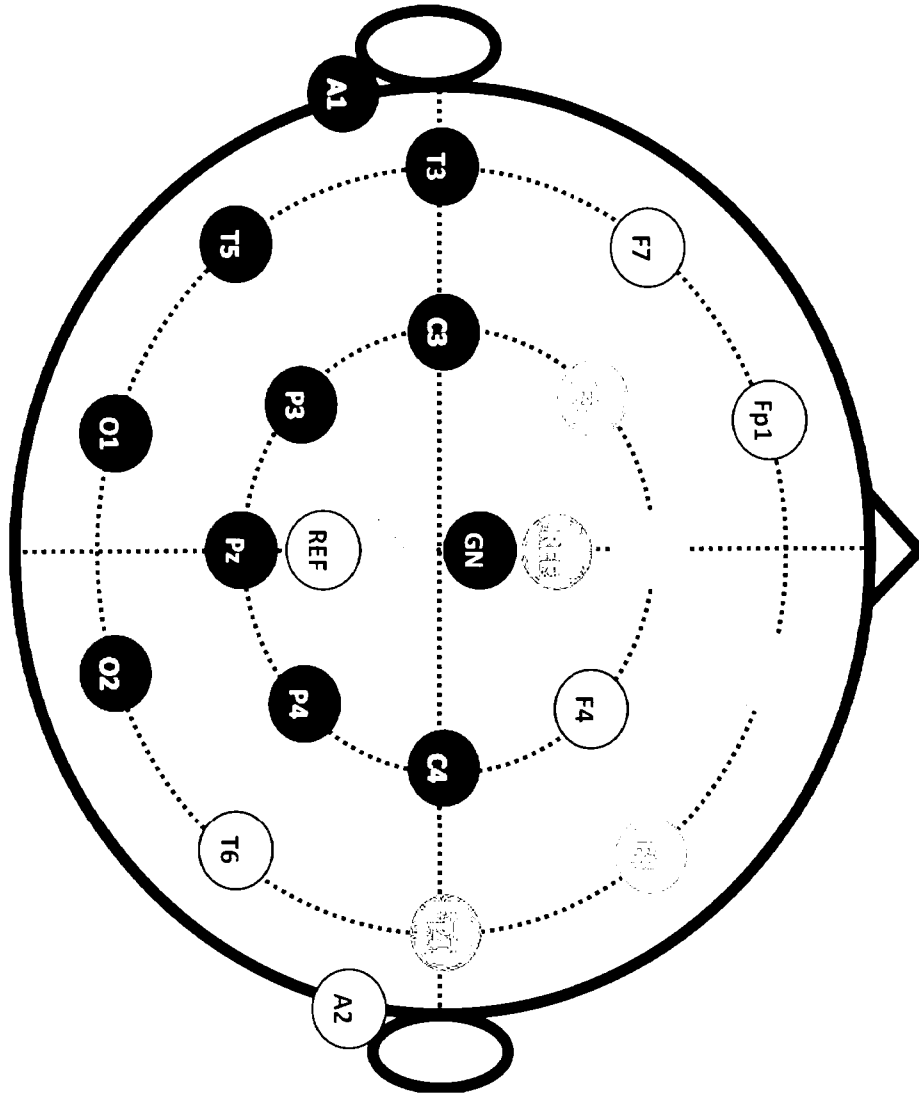


Figure 3a

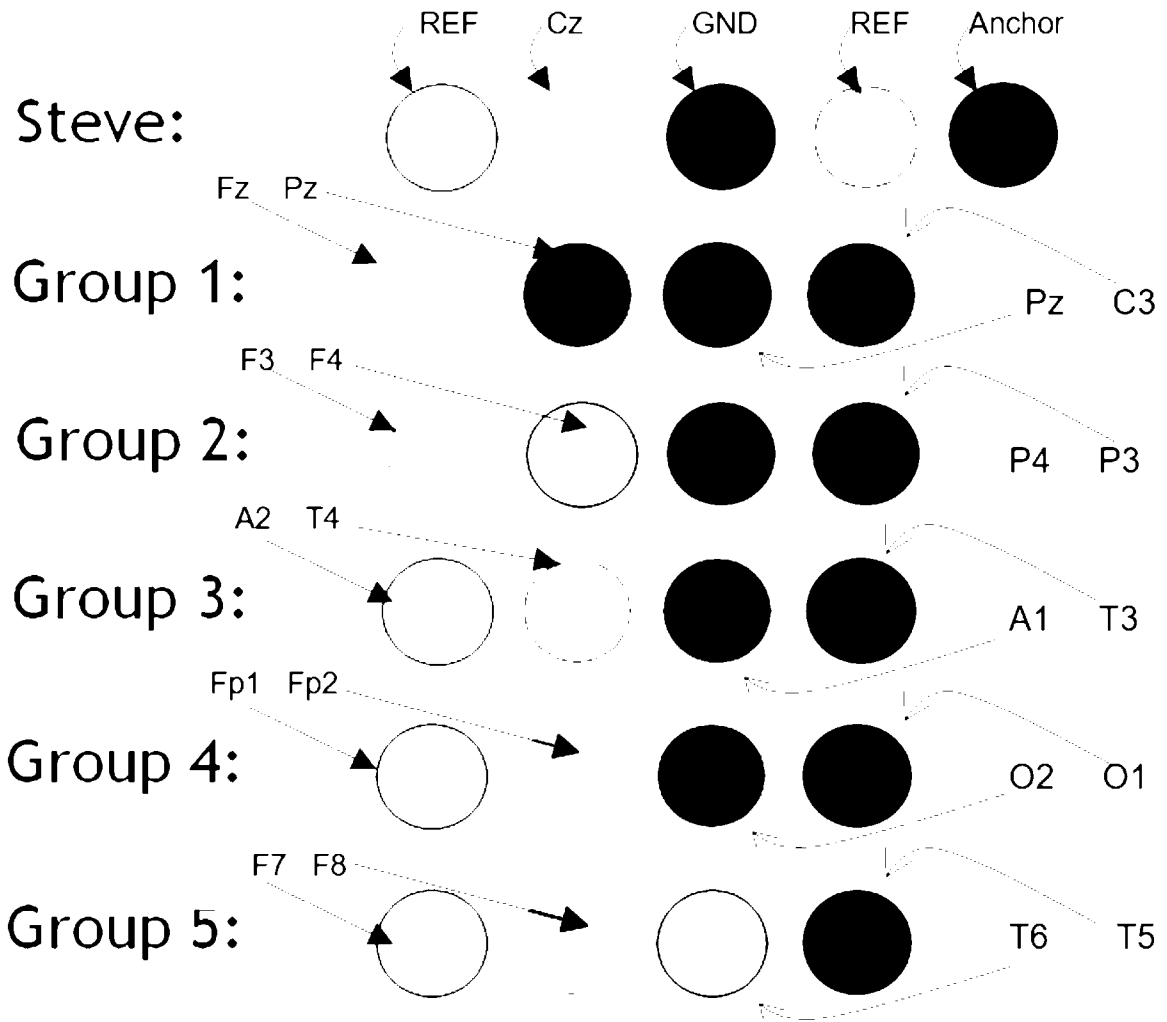


Figure 3b

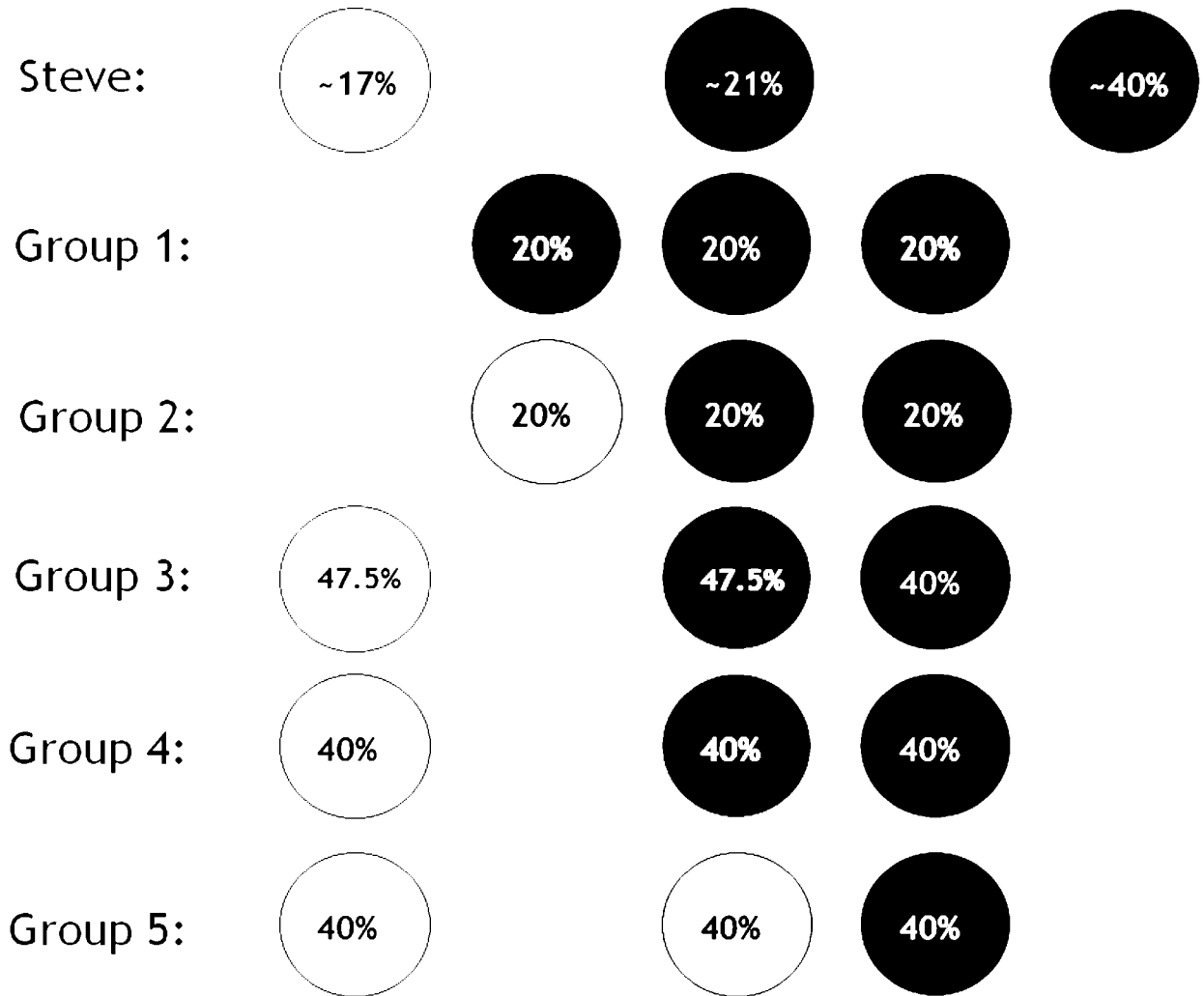


Figure 4

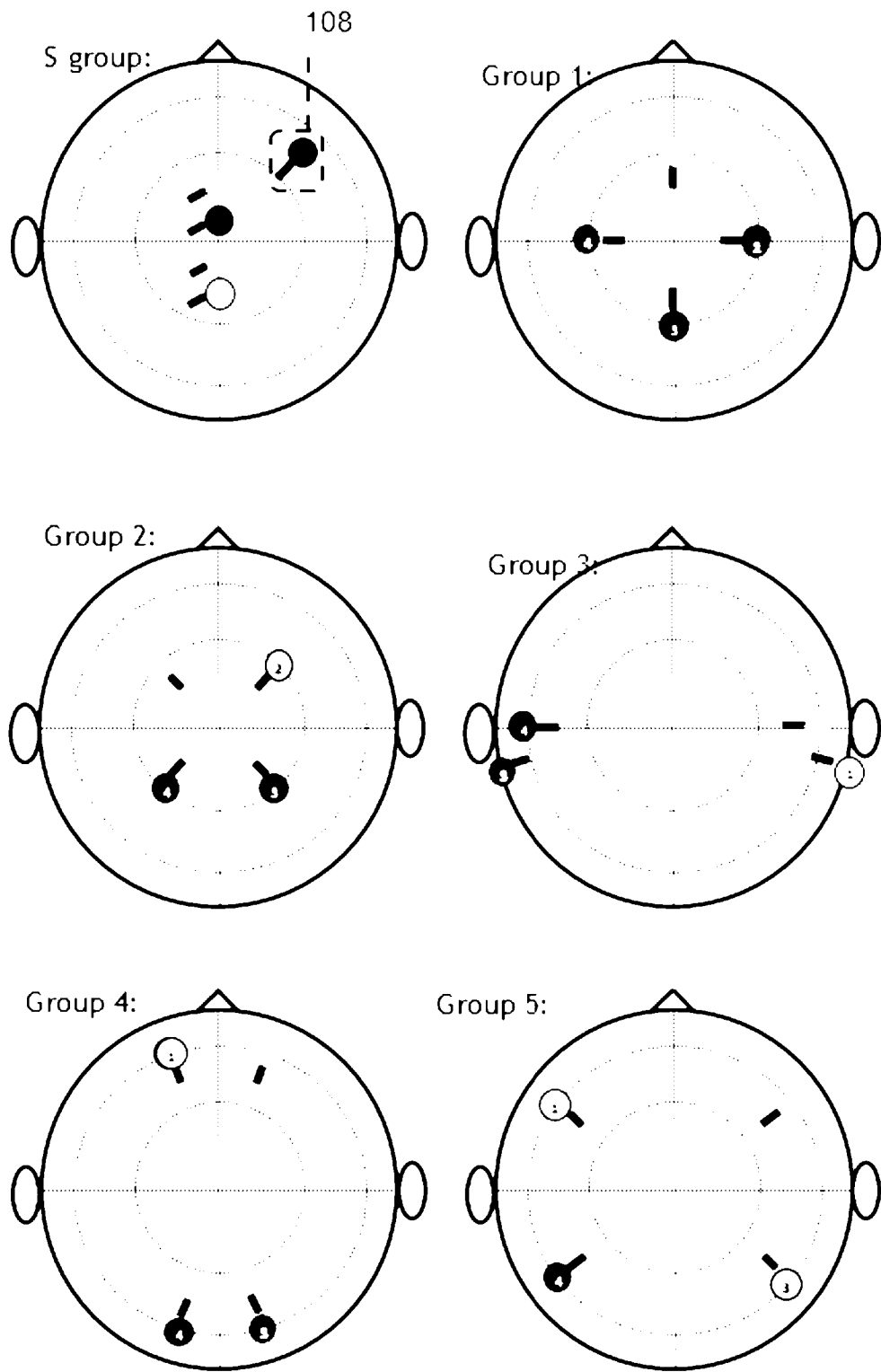


Figure 5

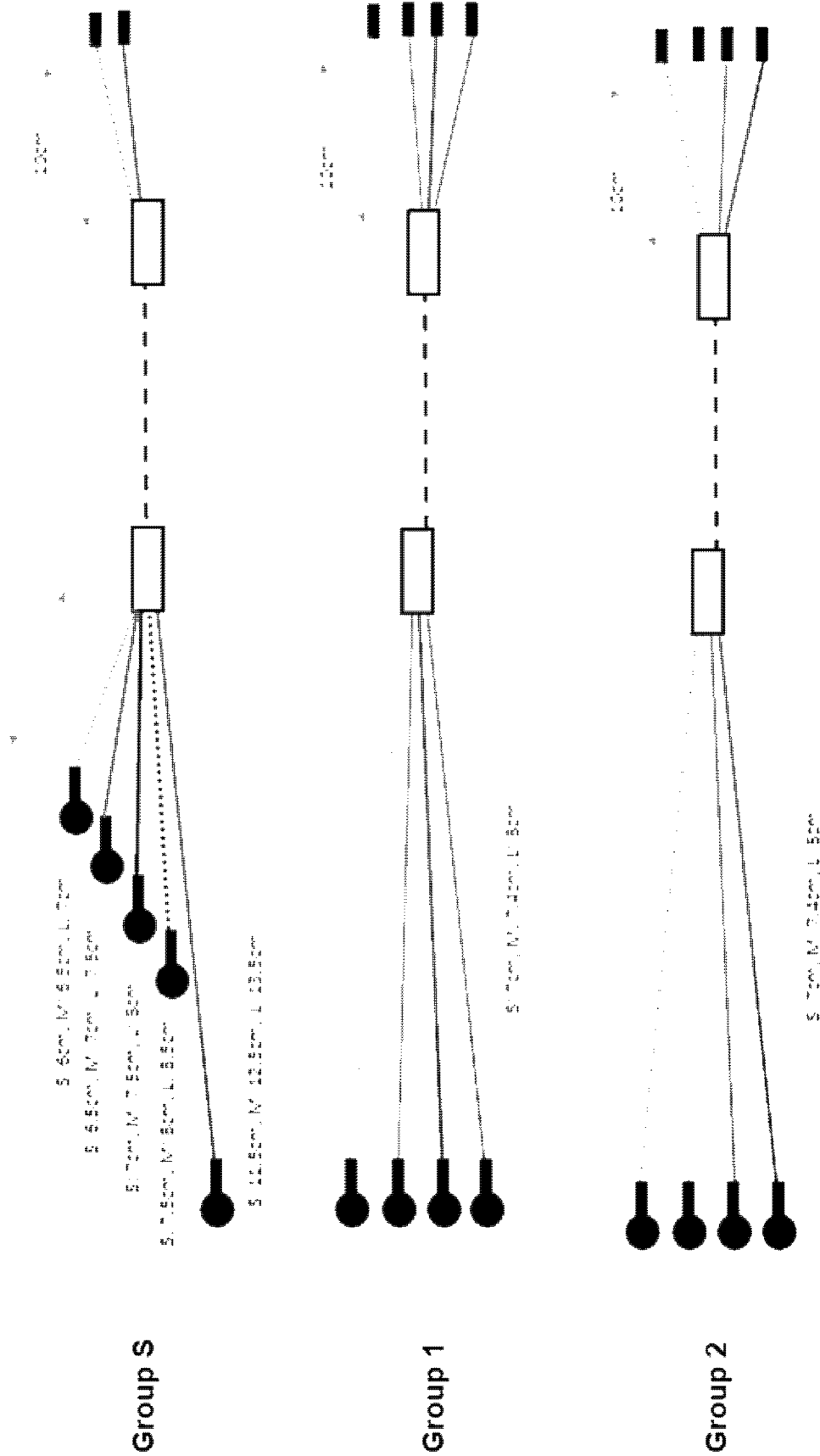
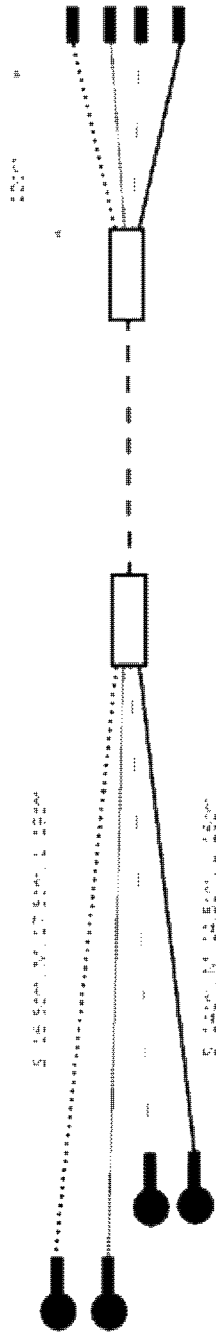
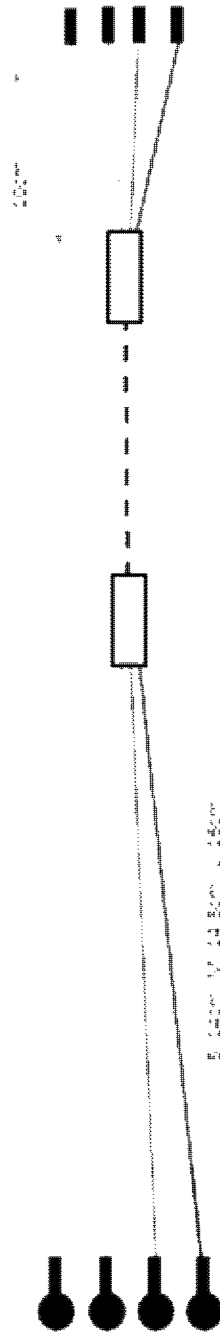


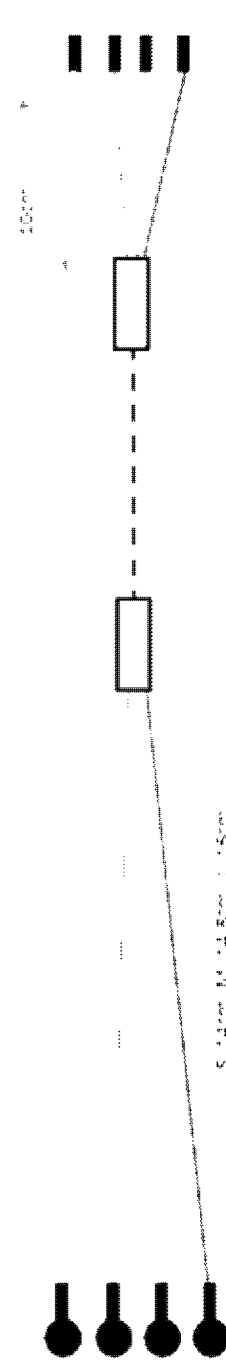
Figure 5 (cont)



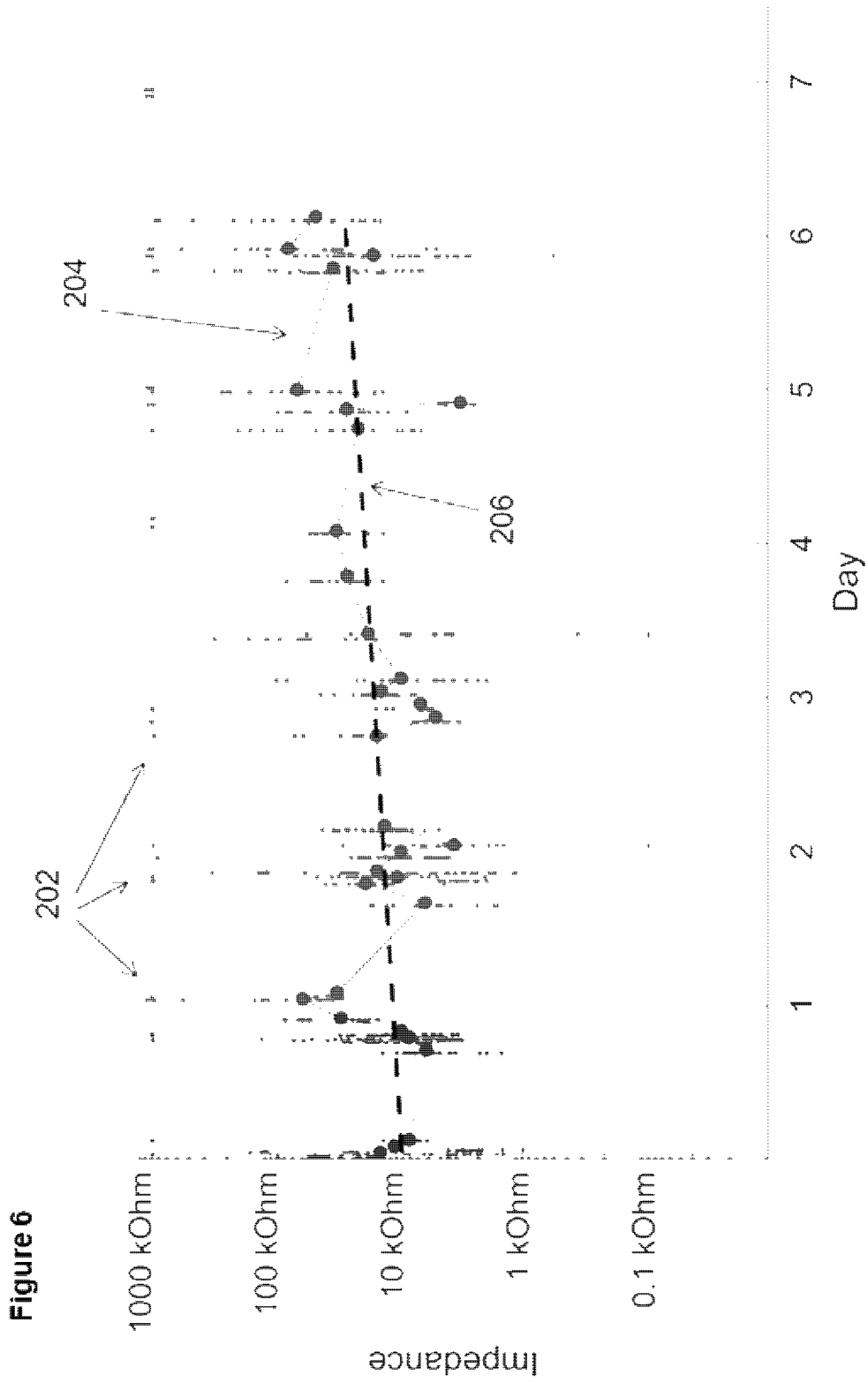
Group 3



Group 4



Group 5



INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2018/000232

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/0478 (2006.01) A61B 5/04 (2006.01) A61N 1/04 (2006.01)

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)

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)

PATENW (EPODOC, WPIAP, TXPEA, TXPEB, TXPEC, TXPEE, TXPEF, TXPEH, TXPEI, TXPEP, TXPES, TXPEPEA, TXPUSE0A, TXPUSE1A, TXPUSEA, TXPUSEB, TXPW0EA): IPC/CPC includes A61B5/0478, A61B5/6814, A61B5/04004, A61B5/0006, A61B2562/04, A61B2562/222, A61N1/0404 and available lower marks; keywords include strain, stress, bend, relief, reduce, minimise, couple, arrange, group, bundle, wire, lead, and like terms. Cited and citing documents of relevant documents were also viewed.

Espacenet (Worldwide): searched for applicant/inventor names.

Applicant(s)/Inventor(s) name searched in internal databases provided by IP Australia.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	

 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	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"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
"O" document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search
16 January 2019Date of mailing of the international search report
16 January 2019

Name and mailing address of the ISA/AU

AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
Email address: pct@ipaustralia.gov.au

Authorised officer

Aisha Qi
AUSTRALIAN PATENT OFFICE
(ISO 9001 Quality Certified Service)
Telephone No. +61262832028

INTERNATIONAL SEARCH REPORT		International application No.
C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		PCT/AU2018/000232
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2013/0204122 A1 (HENDLER et al.) 08 August 2013 Figures 1, 4-7 and accompany description including paragraphs [0012], [0103]-[0107], [0118], [0128]-[0131]	1-7, 10-11
Y	Figure 7	8-9
X	US 2009/0099473 A1 (DUNSEATH et al.) 16 April 2009 Figures 1A-D, 3, 9 and accompany description including paragraphs [0103], [0121]-[0126], [0133]	1-7, 10-11
Y	Figure 9	8-9
X	US 2015/0265177 A1 (COVIDIEN LP) 24 September 2015 Figures 1, 3A-F, 4A-B and accompany description including paragraph [0033]	1-7, 10-11
Y	Figures 4A-B	8-9
X	US 4503860 A (SAMS et al.) 12 March 1985 Figures 1-2, column 3 line 49 to column 4 line 60	1-11
Y	US 2017/0027466 A1 (KERTH et al.) 02 February 2017 Figures 1-4 and accompany description including paragraphs [0020]-[0021], [0031]	8-9
Y	WO 2011/038103 A1 (NEURONETRIX SOLUTIONS, LLC) 31 March 2011 Figures 1-3 and paragraph [00025]	8-9
A	US 5978693 A (HAMILTON et al.) 02 November 1999	
A	US 2010/0075527 A1 (MCINTIRE et al.) 25 March 2010	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2018/000232

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	Publication Date	Publication Number	Publication Date
US 2013/0204122 A1	08 August 2013	US 2013204122 A1	08 Aug 2013
		US 9636019 B2	02 May 2017
		EP 2624748 A2	14 Aug 2013
		IL 225215 A	28 Sep 2017
		WO 2012046237 A2	12 Apr 2012
US 2009/0099473 A1	16 April 2009	US 2009099473 A1	16 Apr 2009
		US 7715894 B2	11 May 2010
		EP 1945097 A1	23 Jul 2008
		JP 2009514629 A	09 Apr 2009
		US 2007106170 A1	10 May 2007
		WO 2007054273 A1	18 May 2007
US 2015/0265177 A1	24 September 2015	US 2015265177 A1	24 Sep 2015
		AU 2007237339 A1	19 Jun 2008
		AU 2007237339 B2	15 Aug 2013
		CA 2612783 A1	05 Jun 2008
		CN 101234019 A	06 Aug 2008
		CN 101234019 B	30 May 2012
		EP 1932470 A1	18 Jun 2008
		EP 3001948 A1	06 Apr 2016
		JP 2013090964 A	16 May 2013
		JP 5639206 B2	10 Dec 2014
		JP 2008142544 A	26 Jun 2008
		MX 2007015295 A	20 Feb 2009
		US 2008132106 A1	05 Jun 2008
		US 8668651 B2	11 Mar 2014
		US 2013303927 A1	14 Nov 2013
US 9072444 B2	07 Jul 2015		
US 4503860 A	12 March 1985	US 4503860 A	12 Mar 1985
US 2017/0027466 A1	02 February 2017	US 2017027466 A1	02 Feb 2017
		WO 2015153744 A1	08 Oct 2015
WO 2011/038103 A1	31 March 2011	WO 2011038103 A1	31 Mar 2011
		AU 2010298299 A1	19 Apr 2012
		AU 2010298299 B2	20 Nov 2014
		EP 2480131 A1	01 Aug 2012

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

Form PCT/ISA/210 (Family Annex)(January 2015)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2018/000232

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	Publication Date	Publication Number	Publication Date
		JP 2013505783 A	21 Feb 2013
		JP 5677440 B2	25 Feb 2015
		JP 2015083212 A	30 Apr 2015
		JP 6017530 B2	02 Nov 2016
		US 2012179019 A1	12 Jul 2012
		US 8463354 B2	11 Jun 2013
		US 2013253300 A1	26 Sep 2013
		US 9072448 B2	07 Jul 2015
US 5978693 A	02 November 1999	US 5978693 A	02 Nov 1999
US 2010/0075527 A1	25 March 2010	US 2010075527 A1	25 Mar 2010
		US 8251736 B2	28 Aug 2012
		AU 2009297071 A1	01 Apr 2010
		CA 2737621 A1	01 Apr 2010
		CN 102164538 A	24 Aug 2011
		EP 2346397 A1	27 Jul 2011
		JP 2012503497 A	09 Feb 2012
		KR 20110066953 A	17 Jun 2011
		WO 2010036315 A1	01 Apr 2010
End of Annex			