



(51) International Patent Classification:

A61B 5/0478 (2006.01) H01L 21/28 (2006.01)

A61B 5/16 (2006.01)

(21) International Application Number:

PCT/US2019/021379

(22) International Filing Date:

08 March 2019 (08.03.2019)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/641,242 09 March 2018 (09.03.2018) US

(71) Applicant: **THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA** [US/US]; 3160 Chestnut Street, Suite 200, Philadelphia, PA 19104 (US).

(72) Inventors: **RAMAKRISHNAN, Arjun**; 44 South Lansdowne Avenue, Lansdowne, PA 19050 (US). **PLATT, Michael, L.**; 2035 Spruce Street, Philadelphia, PA 19103 (US). **BELKAYA, Naz**; 1 Franklin Town Boulevard, Apt. 1405, Philadelphia, PA 19103 (US). **CHAUDHARY, Rimjhim**; 4415 Spruce St., Apt. 1F, Philadelphia, PA 19104 (US).

(74) Agent: **RABINOWITZ, Aaron, B.**; Baker & Hostetler LLP, 2929 Arch Street, Cira Centre, 12th Floor, Philadelphia, PA 19104-2891 (US).

(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.

(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).

(54) Title: MOBILE, WEARABLE EEG DEVICE WITH HIGH QUALITY SENSORS

(57) Abstract: Provided are sensor units that include conductive segments disposed in a flexible sensing layer material, which sensor units are useful in EEG and other diagnostic applications. The sensor units are capable of maintaining electrical contact with a subject's skin in the absence of electrolytic gel, and provide robust signal collection with minimal signal degradation over time.

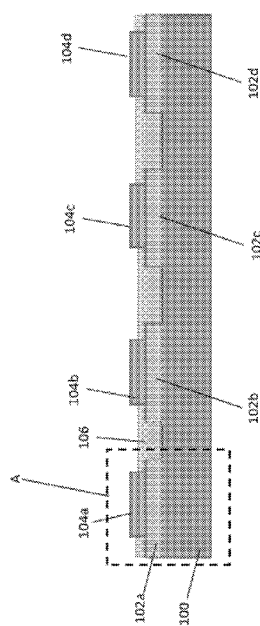


FIG. 7

Published:

- *with international search report (Art. 21(3))*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

MOBILE, WEARABLE EEG DEVICE WITH
HIGH QUALITY SENSORS

RELATED APPLICATION

[0001] This application claims priority to and the benefit of United States Application No. 62/641,242, “Mobile, Wearable, EEG Device With High Quality Nanowire Sensors” (filed March 9, 2018), the entirety of which application is incorporated here by reference for any and all purposes.

GOVERNMENT RIGHTS

[0002] This invention was made with government support under Grant Number 15-1519 awarded by the National Science Foundation. The government has certain rights in the invention.

TECHNICAL FIELD

[0003] The present disclosure relates to the field of electroencephalography monitors and to the field of nanowires.

BACKGROUND

[0004] Mobile, wearable, low-cost electro-encephalogram (EEG) devices that offer research grade signals can provide a wealth of information regarding the brain states of individuals. This knowledge can be effectively utilized to develop continuous healthcare monitoring applications, personalized treatment protocols in medicine, individual customer-based advertisements for marketing, and optimal training programs in sports.

[0005] Conventional EEG devices used in research and in the clinics for the last several decades are not conducive to mobile real world applications because these are wired devices that tether participants to a given location, limiting the activities that they can perform. Furthermore, these devices are not amenable for long-term use because electrodes in these devices typically require the use of an electrolytic gel to make contact with the scalp. Such a gel, however, dries out over time, thereby reducing signal quality and increasing

discomfort due to dried salt deposits. Accordingly, there is a long-felt need in the art for improved EEG devices.

SUMMARY

[0006] In meeting the long-felt needs described above, the present disclosure first provides a sensor unit, comprising a flexible sensing layer comprising a plurality of conductive segments disposed in a first matrix material, the flexible sensing layer having a first surface configured for placement against the skin of a subject and the flexible sensing layer having a second surface; a flexible support layer contacting the second surface of the flexible sensing layer, the flexible support layer comprising a second matrix material; and a current carrier in electronic communication with the conductive segments, the current carrier optionally extending through the flexible support layer, the current carrier being configured to carry a current to, from, or to and from the conductive segments.

[0007] Also provided are monitors, comprising: a headcovering comprising a plurality of devices according to the present disclosure, the head covering being configured to place the flexible sensing layers of at least some of the devices into contact with the skin of a subject.

[0008] Further provided are methods, comprising: with one or more sensor units according to the present disclosure, collecting one or more signals of neurological activity of a subject.

[0009] Additionally disclosed are methods of fabricating a sensor unit, comprising: atop a flexible support layer that comprises a second matrix, disposing a dispersion of conductive segments; placing a current carrier into electronic communication with at least some of the conductive segments; disposing a first matrix material atop the dispersion of conductive segments and at least some of the current carrier; and curing the first matrix material so as to form a flexible sensing layer that comprises at least some of the conductive segments, the current carrier being at least partially embedded within the flexible sensing layer, the flexible sensing layer being disposed atop the flexible support layer, and the current carrier extending through the flexible support layer.

[0010] Also provided are sensor units, comprising: a sensing portion that comprises a plurality of conductive segments; a conductive contact in electronic communication with the sensing portion; a substrate, the substrate supporting the conductive contact and the

sensing portion; and a sealing material disposed so as to mask at least a portion of the substrate and at least a portion of the conductive contact while a portion of the sensing portion is exposed through the sealing material.

[0011] Additionally disclosed are devices, the device comprising: a plurality of sensor units, a sensor unit, comprising: a sensing portion that comprises a plurality of conductive segments; a conductive contact in electronic communication with the sensing portion; a substrate, the substrate supporting the conductive contact and the sensing portion; and a sealing material disposed so as to mask at least a portion of the substrate and at least a portion of the conductive contact while a portion of the sensing portion is exposed through the sealing material, and at least two of the plurality of sensor units being individually electronically addressable.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] For the purpose of illustrating the invention, there is shown in the drawings a form that is presently preferred; it being understood, however, that this invention is not limited to the precise arrangements and instrumentalities shown.

[0013] FIGs. 1A-1C provide an exemplary device. FIG. 1A provides an exemplary device with two partially visible AgNW (i.e., silver nanowire)-PDMS sensors (located behind the band of the cap and the forehead of the model). FIG. 1B provides an interior view of the cap showing three sensors according to the present disclosure (sensors are located the front of the cap). FIG. 1C provides an exemplary arrangement of sensor units according to the present disclosure; sensors can be disposed at the forehead with ground electrodes disposed at other positions.

[0014] FIG. 2 provides a baseball cap having sensors according to the present disclosure placed around the headband of the baseball cap such that the sensors would contact the forehead of the cap's wearer.

[0015] FIGs. 3A-3C provide input-output characterizations of exemplary sensors. FIG. 3A illustrates the sensor output when a 50uV (peak-peak) signal was delivered, showing the near-zero lag of the sensor as the input and output traces essentially overlaid one another. FIG. 3B illustrates that signal loss increased only slightly (factor of 0.02) with a greater than 10-fold decrease in input voltage (3uV). FIG. 3C shows the ratio of the output to the input

for two frequencies. FIG. 4D shows that signal loss barely increased (factor of 0.002) even with a 50-fold increase in signal frequency.

[0016] FIGs. 4A and FIG. 4B provide comparisons between an exemplary silver nanowire sensor (AgNW) according to the present disclosure and an exemplary silver/silver chloride (Ag/AgCl) wet electrode, which is considered the “gold standard” for EEG measurements. FIG. 4A provides voltage fluctuations observed when eyes are open (spikes indicate blinks), the AgNW and Ag/AgCl traces are essentially identical to one another. FIG. 4B provides (top panel and lower left panel, showing magnified view of boxed region of top panel) the voltage fluctuations (for disclosed and standard electrodes) when the subject’s eyes were closed and also the power spectrum (lower right panel), with an increase in alpha power (8-12 Hz).

[0017] FIGs. 5A and 5B provide signal quality comparison over time. FIG. 5A shows that signals from standard Ag/AgCl sensors worsen over time as the contact gel dries up, whereas there is little to no signal degradation with use of the disclosed sensors (AgNW). FIG. 5B shows that the signals from two exemplary AgNW sensors remain highly correlated (>0.8), whereas the correlation between the AgNW and Ag/AgCl sensor reduces to zero over 70 min. FIG. 5C illustrates that a standard Ag/AgCl sensor picks up wire movement artifacts (noise, upper panel) and amplifier movement artifacts (noise, lower panel) when the gel dries up, whereas the disclosed AgNW sensors were robust to different noise artifacts.

[0018] FIG. 6 provides exemplary traces of signals with blink and eye movement artifact removal using Independent component analysis; as shown, artifact filtering was improved with three or more sensors than with two channels.

[0019] FIG. 7 provides a cross-sectional view of a device according to the present disclosure;

[0020] FIG. 8 provides a view of a device according to the present disclosure;

[0021] FIG. 9 provides engagement (theta/alpha EEG) during a user’s exploration of a conference, as gathered by a device according to the present disclosure; and

[0022] FIG. 10 provides a cross-sectional view of a device according to the present disclosure.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0023] The present disclosure may be understood more readily by reference to the following detailed description taken in connection with the accompanying figures and examples, which form a part of this disclosure. It is to be understood that this invention is not limited to the specific devices, methods, applications, conditions or parameters described and/or shown herein, and that the terminology used herein is for the purpose of describing particular embodiments by way of example only and is not intended to be limiting of the claimed invention.

[0024] Also, as used in the specification including the appended claims, the singular forms “a,” “an,” and “the” include the plural, and reference to a particular numerical value includes at least that particular value, unless the context clearly dictates otherwise. The term “plurality”, as used herein, means more than one.

[0025] When a range of values is expressed, another embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent “about,” it will be understood that the particular value forms another embodiment. All ranges are inclusive and combinable, and it should be understood that steps may be performed in any order. Any documents cited herein are incorporated by reference in their entireties for any and all purposes.

[0026] It is to be appreciated that certain features of the invention which are, for clarity, described herein in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention that are, for brevity, described in the context of a single embodiment, may also be provided separately or in any subcombination. Further, reference to values stated in ranges include each and every value within that range.

[0027] In addition, the term “comprising” should be understood as having its standard, open-ended meaning, but also as encompassing “consisting” as well. For example, a device that comprises Part A and Part B may include parts in addition to Part A and Part B, but may also be formed only from Part A and Part B.

[0028] To fill the long-felt needs described above, provided are improve EEG devices; these devices can utilize nanosensor electrodes that provide high-grade signals. Signals collected by the disclosed electrodes can be amplified by a wireless amplifier, which can be read out using, e.g., an open-source hardware and software.

[0029] The disclosed sensors make use of a variety of conductive materials, e.g., silver nanowires (AgNW). The conductive materials can (though this is not a requirement) be disposed within a soft polymeric material, e.g., polydimethylsiloxane (PDMS). PDMS is considered especially suitable for biosensors because of its hydrophobic nature, biocompatibility, and mechanical properties that are similar to human soft tissue. In addition, the pliability of PDMS can help the sensor adhere to the skin, which improves skin-sensor contact leading to better signals. This property also reduces relative skin-electrode movement thereby minimizing motion artifacts.

[0030] A device according to the present disclosure can use one, two, or more such electrodes, which can be disposed on the subject's forehead. Signals from these sensors can be amplified and digitized using an amplifier.

[0031] Materials

[0032] To fabricate exemplary sensors according to the present disclosure, the following materials were used:

[0033] AgNW-L100™ in ethanol (www.acsmaterial.com/silvernanowire-500mg-3249.html)

[0034] PDMS – Sylgard™ 184 kit

[0035] 4-ch OpenBCI Cyton + OpenBCI software

[0036] EEG device designs

[0037] One exemplary design incorporated nanosensors in a baseball cap (FIG. 1A). This design included three AgNW sensors on the forehead (FIG. 1B) at Fp1, Fpz, and Fp2 based on a 10-20 EEG montage (FIG. 1C); the external ear (A2) was used as the ground. Three electrodes were used for removal of blink- and eye movement-related artifacts, the main source of noise at these locations. The signals from the AgNW sensors were amplified and digitized using an amplifier.

[0038] Nanosensor fabrication

[0039] For fabrication, PDMS, PDMS curing agent, AgNW-ethanol solution, 4-inch Si wafer, aluminum heating cup, weight, scalpel, light duty lead wire, heater, vacuum chamber were used. One set of exemplary fabrication steps is described below:

[0040] - Curing a desired thickness of PDMS on a Si surface.

[0041] - A rectangle in the dimensions of the electrode to be made is cut and peeled off, leaving the Si wafer below exposed.

[0042] - An AgNW-ethanol solution is drop-casted on the Si surface covering the exposed area with a thin layer. (Exemplary AgNWs were from ACS materials, e.g., <https://www.acsmaterial.com/silver-nanowire-500mg-3249.html>).

[0043] - After partial evaporation of the ethanol from the AgNW solution, the peeled wire tip of a light-duty lead wire was inserted on top of the solution and covered with another layer of AgNW which makes contact with the initial layer.

[0044] - After the ethanol evaporates from the solution, a 10:1 ratio PDMS solution without any bubbles was poured over the exposed area until it is at the same level of thickness as the cured part.

[0045] - The PDMS is cured, and then the relevant section of PDMS including the wire is cut and peeled off from the Si surface.

[0046] A schematic showing the different layers of an exemplary nanosensor is shown in FIG. 2B, along with a view of a prototype nanosensor.

[0047] Connecting the sensor with an amplifier and deriving EEG signals

[0048] Crimping pins were soldered onto the terminals of the light-duty lead wires and inserted into a 16-pole frame. The frame was attached to its male counterpart on the amplifier. Software was then used to read the raw EEG signals. EEG data was then exported in European Data format (EDF), opened and analyzed in Matlab using EEGLAB.

[0049] Results

[0050] Input-output characterization of the nanowire sensor: To test the conductivity of the sensors for EEG signals, currents were administered at various voltages and frequencies that encompass EEG voltage and frequency range (FIG. 3). The input and the output signals were closely matched for an example voltage and frequency (FIG. 3A) suggesting very low loss. Signal loss increased slightly at very low voltages (FIG. 3B) and at very high frequencies (FIG. 3D). Overall, the new nanosensor displayed very low signal loss at EEG-level voltages and frequencies.

[0051] Comparison of the silver nanowire sensor with the standard EEG Ag/AgCl electrodes: Following characterization, an exemplary sensor (AgNW) was compared against standard Ag/AgCl EEG wet electrodes in a traditional EEG set-up. To do this, the two sensors were both placed at the same location on the forehead (Fp2). EEG signals were then picked up, amplified and transmitted using an amplifier. The received EEG signals were then examined during epochs when the participant's eyes were open (FIG. 4A) and when the eyes

were closed (FIG. 4B). The signals from the new sensor were closely matched ($r > 0.9$) in terms of voltage fluctuations (inset, left panel, FIG. 4B) and power content (inset, right panel, FIG. 4B), thus validating the quality of the nanosensor.

[0052] Long-term recording and movement artifacts: Wet electrodes typically use gel, which will eventually dry out, affecting signal quality over time. Because the disclosed sensors do not use gel, one may expect the signal quality to remain unaffected over time.

[0053] To examine this aspect of the disclosed devices, signal quality from a wet electrode and a nanosensor was monitored over a period of 70 minutes. Initially, the signal quality of the Ag/AgCl electrode matched that of the AgNW electrodes (0-10 min, FIG. 5A). However, over time, as the gel started to dry, the Ag/AgCl signal quality deteriorated (30-40 min and 60-70 min, FIG. 5A).

[0054] To visualize signal loss, the signal correlation between two AgNW sensors was compared with that between an Ag/AgCl and AgNW sensor (FIG. 5B). The two AgNW sensors remained highly correlated ($r > 0.85$) over time. Reduction in Ag/AgCl signal quality decreased the latter correlation to zero within an hour (60-70 min, FIG. 5B).

[0055] In addition, when gel dries, Ag/AgCl wet electrodes are rendered vulnerable to noise artifacts. By contrast, AgNW sensors that do not use gel and that stick to the skin surface are robust against such movement noise.

[0056] To illustrate this, movement noise was induced by moving the wire connecting the sensor to the amplifier (upper panel, FIG. 5C), and then by moving the entire device including the amplifier (lower panel, FIG. 5C). When the wire moved (upper panel, FIG. 5C), and when the amplifier moved (lower panel, FIG. 5C), these movements contaminated the EEG signal from the Ag/AgCl sensor. However, as predicted the AgNW sensors were robust to these sources of noise (FIG. 5C).

[0057] Blink and eye-movement artifact removal: Blinks and eye movements induce artifacts in EEG signal. Typically, blinks are removed using independent component analysis (ICA). Since this is a comparative analysis, at least two channels of information are required. ICA was performed using data from two AgNW channels and then using three AgNW channels (FIG. 6). Clearly, higher channel count improved noise elimination. With three channels, blinks and eye movements were almost entirely removed. These results suggest that three or more channels are required for good quality filtering.

[0058] Sensor signal collection was assessed in a few ways. First, signal to noise ratio was measured at different voltages and frequencies. A known input signal was fed to the sensor and the corresponding out signal was measured to characterize signal to noise ratio. Voltages spanning 10-50 uV (peak to peak) and frequencies spanning (0.1-500 Hz) were tested. The signal to noise ratio was greater than 97% for the lowest voltages and the highest frequencies.

[0059] A sensor-skin interface impedance was measured over time; this is a passive measure of the contact quality which directly affects signal quality of the physiological signals. Impedance measured in this way was compared with industry standard Ag/AgCl wet electrodes. It was found that not only was the impedance of the disclosed devices low (< 15 kOhms), but the impedance also continued to remain low over long periods of time (120 minutes). By comparison, Ag/AgCl wet electrode impedance increased as the gel used with those wet electrodes dried up over time (> 30 kOhms after 90 minutes). Voltage fluctuations and frequency content of the signal from these sensors were also compared with those obtained using the industry standard Ag/AgCl wet electrode, and it was found that the signals were highly correlated ($r > 0.8$).

[0060] Additional device structure

[0061] An exemplary embodiment is shown in FIG. 7. As shown in that FIG., a device can be formed in a layered fashion. A substrate 100 can be used to support conductive contacts (e.g., gold, copper, silver, titanium, a carbonaceous material) 102a, 102b, 102c, and 102d. Sensing portions 104a, 104b, 104c, and 104d can be formed atop the conductive contacts. A sealing material 106 can be disposed so as to cover and protect portions of the substrate 100, the contacts 102a-102d, and the sensing portions 104a-104d. A single sensor unit is shown by the dashed-in box A.

[0062] An alternative embodiment is shown in FIG. 10. As shown in that FIG., a device can be formed in a layered fashion. A substrate 100 can be used to support a conductive contact 102f. The conductive contact 102f can be disposed such that it contacts the sensing portion (104f) and the substrate 100. Sealing material 106 can be disposed so as to cover and protect portions of the substrate 100, the contact 102f, and sensing portions 104f. As shown in FIG. 10, a sensing portion (104f) can contact the substrate (100) and also contact a conductive contact (102f), while also extending above the sealing material (106).

[0063] It should be understood that sensing portions can be formed directly on the substrate. As one example, silver nanowires can be deposited directly on a polyimide substrate. Conductive contacts can also be formed directly on the substrate, and can be in physical or electronic communication with the sensing portions. The sealing layer can, as described elsewhere herein, be deposited so as to cover the substrate and cover the conductive contacts, leaving exposed the sensing portions.

[0064] A sensing portion (e.g., 104a in FIG. 7, 104f in FIG. 10) can comprise conductive segments, such as nanowires, e.g., silver nanowires, but can also include, e.g., gold, copper, and/or platinum nanowires and/or nanoparticles. Carbon nanotubes, graphene portions, and the like are also suitable conductive segments. Conductive segments can be disposed in a matrix material (e.g., a polymeric material), but this is not a requirement, as conductive segments can be “bare” or otherwise free of being embedded in a matrix material.

[0065] The sealing material 106 can be a flexible material, and can be a material that is comfortable to touch to the skin. Polydimethylsiloxane (PDMS) (as well as other siloxanes), polymethyl methacrylate (PMMA), parylene, polyimide, flexible polyethylene terephthalate (PET), poly(3,4-ethylenedioxythiophene) (PEDOT), polyurethane (PU), and other such materials are all suitable sealing layer materials.

[0066] An exemplary process for fabricating a device such as that shown in FIG. 7 (and/or in FIG. 10) is as follows:

[0067] - A layer/film (e.g., Kapton™ or other polyimide; other materials are also suitable) is used as a substrate (100).

[0068] - A shadow mask (e.g., made of stainless steel), is prepared to facilitate deposition of conductive contacts (102a, 102b) of the desired size, shape, and spacing.

[0069] - In one exemplary deposition for gold, a 10nm thick layer of titanium is deposited followed by a 200 nm thick film of gold. Metal deposition can be done under a vacuum, and can be done by evaporating the metal using an electron beam evaporator.

[0070] - Another shadow mask can be used to deposit the conductive segments, which are then cast through the mask, e.g., via drop casting. A layer of the conductive segments can be, e.g., from 1000 to 2000 nm in thickness, although this is not a rule or requirement. The shadow mask can be used to pattern conductive segments in a periodic pattern, e.g., in evenly-spaced dots. A periodic pattern is not, however, a rule or a requirement.

[0071] - Following deposition of the conductive segments, the sealing layer (e.g., in a curable or harden-able liquid form) is applied. As one example, a PDMS solution is applied until the desired thickness (e.g., 1000 nm) is achieved. The sealing layer can be applied such that it covers the exposed substrate while also leaving the conductive segments exposed. In this way, a user is contacted by the sensing portion (e.g., 104a) and the sealing layer (106).

[0072] - FIG. 8 provides a top view of a device according to the present disclosure. As shown, a sensor unit (again shown by the dashed-in box A, as in FIG. 7) can be connected via conductor 202 to a contact 204. A sensor unit can be connected directly to an amplifier 210, without any intervening signal processing. In some embodiments, signal collected by a sensor unit can undergo processing at processing train 208 (optional) before being communicated to amplifier 210.

[0073] - FIG. 9 provides provides engagement (theta/alpha EEG, shown by solid trace) during a user's exploration of a SAP TECHED conference, as gathered by a device according to the present disclosure. The bouts of activities (texting, talking, etc.) that participants engaged in as they moved around the conference show floor are overlaid in grey. Unmarked periods indicate the participant is walking. Entry to the conference hall is indicated by a dashed line. As shown, various activities resulted in various levels of engagement by the subject.

[0074] Exemplary Embodiments

[0075] The following embodiments are exemplary only and do not limit the scope of the present disclosure or the appended claims.

[0076] Embodiment 1. A sensor unit, comprising: a flexible sensing layer comprising a plurality of conductive segments disposed in a first matrix material, the flexible sensing layer having a first surface configured for placement against the skin of a subject and the flexible sensing layer having a second surface; a flexible support layer contacting the second surface of the flexible sensing layer, the flexible support layer comprising a second matrix material; and a current carrier in electronic communication with the conductive segments, the current carrier optionally extending through the flexible support layer, the current carrier being configured to carry a current to, from, or to and from the conductive segments.

[0077] The flexible sensing layer can have a thickness in the range of from about 0.2 to about 2 mm, in some embodiments.

[0078] Embodiment 2. The sensor unit of Embodiment 1, wherein the current carrier is at least partially embedded in the flexible sensing layer.

[0079] Embodiment 3. The sensor unit of any of Embodiments 1-2, wherein the current carrier is characterized as being a wire.

[0080] Embodiment 4. The sensor unit of any of Embodiments 1-3, wherein the conductive segments comprise one or more metals, graphene, carbon nanotubes, or any combination thereof. Single- and multi-wall carbon nanotubes can be used, as can be other carbonaceous materials.

[0081] Conductive segments can be in the form of, e.g., nanowires. A nanowire can have a cross-sectional dimension (e.g., a diameter) in the range of from, e.g., about 1 to about 1000 nm, or even from about 5 to about 500 nm.

[0082] Nanowires having an average diameter in the range of from about 50 to about 300 nm are considered suitable. As described elsewhere herein, a nanowire can be metallic; gold and silver nanowires are considered especially suitable. A nanowire can have a length in the range of, e.g., from about 1 to about 1000 micrometer, or even from about 100 to about 200 micrometers.

[0083] A conductive segment can be a nanowire, but can also be of another nanostructure, including carbonaceous and metallic nanostructures such as nanofoams, nanofibers, nanoflakes, nanoparticles, nanoshells, quantum dots, and the like, as well as combinations of nanostructures. A device according to the present disclosure can include as conductive segments one, two, or more types of materials, e.g., nanowires and graphene platelets.

[0084] Without being bound to any particular theory, at least some the conductive segments disposed in the flexible sensing layer can be in contact with one another; such contact gives rise to a network (continuous or semi-continuous) of such segments. The network can be termed a nanomesh or even a “mat” of the conductive segments.

[0085] The conductive segments can be disposed uniformly/homogeneously (or nearly so) within the first matrix material. Put another way, the density of the conductive segments can be uniform through the thickness of the first matrix material, although this is not a rule or a requirement.

[0086] Embodiment 5. The sensor unit of Embodiment 4, wherein the conductive segments comprise one or more metals, e.g., silver or gold. Conductive segments can

comprise, e.g., metallic nanostructures or a combination of metallic nanostructures. Silver nanowires are considered especially suitable, but are not the only suitable conductive segments.

[0087] Embodiment 6. The sensor unit of Embodiment 5, wherein the conductive segments comprise one or more metallic nanowires.

[0088] Embodiment 7. The sensor unit of Embodiment 6, wherein the conductive segments comprise gold nanowires, silver nanowires, or any combination thereof.

[0089] Conductive segments (whether metallic nanowires or other materials) can be bare or coating-free, but can also include a coating or functionalization. Salts (e.g., AgCl, NaCl, and the like) can be used as coatings, as one example. A conductive segment can also undergo a surface treatment, e.g., treatment by an oxidative plasma.

[0090] Before, during, or after incorporation of conductive segments into the first matrix material, the first matrix material can be stretched, bent, folded, wrinkled, or otherwise physically manipulated. Without being bound to any particular theory, such manipulation can improve the incorporation of the conductive segments into the first matrix material, e.g., increasing the physical density of the conductive segments in the first matrix material.

[0091] With respect to the conductive segments, the conductive segments can define from 0.1 to 99 % of the overall volume of the volume of the first matrix material and the conductive segments.

[0092] It should be understood that any embodiment of the disclosed sensor units can include one or more surface features that engage with a user. Such surface features can include, e.g., a ridge, a bump, a cone, a pyramid, a “soft needle” (e.g., a soft bristle, fiber, or other protrusion extending from the sensor unit), and the like. Such features can facilitate suitable contact between the device and the user.

[0093] Embodiment 8. The sensor unit of any of Embodiments 6-7, wherein the metallic nanowires have a diameter in the range of from about 1 to about 1000 nm, e.g., from about 1 to about 1000 nm, from about 5 to about 750 nm, from about 10 to about 500 nm, or even from about 20 to about 200 nm.

[0094] Embodiment 9. The sensor unit of any of Embodiments 6-8, wherein the metallic nanowires have a length in the range of from about 1 to about 1000 micrometers, e.g., from about 1 to about 1000 nm, from about 5 to about 750 nm, from about 10 to about 500 nm, or even from about 20 to about 200 nm.

[0095] Embodiment 10. The sensor unit of any of Embodiments 1-9, wherein one or both of the first matrix material and the second matrix material is characterized as polymeric.

[0096] The first matrix material is suitably a material that is high-friction or “tacky” to the touch, as such materials are particularly well-suited to maintaining their position on a subject’s skin without excessive sliding.

[0097] Embodiment 11. The sensor unit of Embodiment 10, wherein one or both of the first matrix material and the second matrix material is characterized as a polysiloxane and/or a silicon(e) elastomer.

[0098] Embodiment 12. The sensor unit of Embodiment 7, wherein one or both of the first matrix material and the second matrix material comprises polydimethylsiloxane (PDMS).

[0099] Embodiment 13. The sensor unit of any of Embodiments 1-8, wherein the first matrix material is characterized as being hydrophobic. Without being bound to any particular theory, a material that does not react with a subject’s skin is considered especially suitable.

[00100] Embodiment 14. The sensor unit of any of Embodiments 1-9, wherein the sensor unit is capable of maintaining electrical contact with a subject’s skin in the absence of an electrolytic material disposed between the flexible sensing layer of the sensor unit and the subject’s skin.

[00101] Again without being bound to any particular theory, this can be accomplished by direct contact between the conductive segments in the flexible sensing layer and the subject’s skin. The matrix material of the flexible material (e.g., PDMS) can be “tacky” or high-friction, which qualities can help the material maintain contact with the subject’s skin.

[00102] Embodiment 15. The sensor unit of any of Embodiments 1-14, wherein the sensor unit’s collection of an electrical signal from a subject is substantially unaffected by movement artifacts (e.g., current carrier movement, amplifier movement, or even subject movement), in the absence of an electrolytic material disposed between the flexible sensing layer of the sensor unit and the subject’s skin.

[00103] As shown in FIG. 5C, sensors according to the present disclosure are able to collect signals from a subject with little to no change in the signal as a result of wire or amplifier movement.

[00104] It should also be understood that the disclosed sensors are capable of collecting consistent signals from a subject over an extended period of time (e.g., 30, 60, or even more minutes) in the absence of an electrolytic material between the sensor and the user's skin, i.e., without degradation of the signal during that period of time.

[00105] This stands in contrast to existing Ag/AgCl electrodes, which electrodes require the use of an electrolytic gel that, over time, dries out and results in signal degradation. This is shown by, e.g., FIG. 5, which shows the degradation of the signal collected by an Ag/AgCl electrode arrangement (with an electrolyte gel between the electrode and the subject) over 60 minutes.

[00106] Embodiment 16. The sensor unit of any of Embodiments 1-15, wherein noise in the sensor unit's collection of an electrical signal from a subject is substantially unaffected by movement artifacts, in the absence of an electrolytic material disposed between the flexible sensing layer of the sensor unit and the subject's skin.

[00107] Embodiment 17. The sensor unit of any of Embodiments 1-16, wherein the sensor is capable of maintaining electrical contact with a subject's skin at a hairy region of the scalp, in the absence of an electrolytic material disposed between the flexible sensing layer of the sensor unit and the subject's skin. Without being bound to any particular theory, the flexibility and/or tackiness of the disclosed sensors allows for this improved performance.

[00108] Embodiment 18. A monitor, comprising: a headcovering comprising a plurality of devices according to any of Embodiments 1-17, the head covering being configured to place the flexible sensing layers of at least some of the devices into contact with the skin of a subject.

[00109] Embodiment 19. The monitor of Embodiment 18, further comprising an amplifier in electronic communication with one or more of the plurality of devices. It should be understood that an amplifier can be separate from the device and/or the head covering. In some embodiments, however, the amplifier can be incorporated into the device or into the head covering.

[00110] Embodiment 20. The monitor of Embodiment 19, further comprising a filtration train configured to filter one or more signals collected by one or more of the plurality of devices.

[00111] Embodiment 21. The monitor of Embodiment 20, wherein one or more signals are of neurological activity of the subject.

[00112] Embodiment 22. The monitor of any of Embodiments 18-21, further comprising a portable power source in electronic communication with the amplifier. Such portable power sources include, e.g., batteries, solar cells, and the like.

[00113] Embodiment 23. The monitor of any of Embodiments 18-22, further comprising a display configured to display a signal of neurological activity of a subject that is collected by one or more of the plurality of devices.

[00114] Embodiment 24. The monitor of any of Embodiments 18-23, wherein the head covering is characterized as a hat.

[00115] Embodiment 25. The monitor of any of Embodiments 18-24, wherein the monitor is characterized as being portable.

[00116] Embodiment 26. A method, comprising: with one or more sensor units according to any of Embodiments 1-17, collecting one or more signals of neurological activity of a subject. The disclosed sensor units can be used in, e.g., EEG measurements and other medical diagnostic applications, in sports and daily routine.

[00117] Embodiment 27. The method of Embodiment 26, wherein the flexible sensing layers of the one or more sensor units contact the skin of the subject.

[00118] Embodiment 28. The method of any of Embodiments 26-27, further comprising removing one or more artifacts from one or more of the signals.

[00119] Embodiment 29. The method of any of Embodiments 26-28, further comprising filtering one or more of the signals.

[00120] Embodiment 30. The method of any of Embodiments 26-29, further comprising correlating one or more of the signals to an activity of the subject, to a stimulus received by the subject, or any combination thereof.

[00121] Embodiment 31. A method of fabricating a sensor unit, comprising: atop a flexible support layer that comprises a second matrix, disposing a dispersion of conductive segments; placing a current carrier into electronic communication with at least some of the conductive segments; disposing a first matrix material atop the dispersion of conductive

segments and at least some of the current carrier; and curing the first matrix material so as to form a flexible sensing layer that comprises at least some of the conductive segments, the current carrier being at least partially embedded within the flexible sensing layer, the flexible sensing layer being disposed atop the flexible support layer, and the current carrier extending through the flexible support layer.

[00122] Suitable first and second matrix materials are provided elsewhere herein, and can include, e.g., PDMS. Similarly, suitable current carriers include, e.g., wires. Suitable conductive segments are also described elsewhere herein. The disclosed methods can be used, e.g., to fabricate a sensor unit according to any of Embodiments 1-17.

[00123] Curing of a matrix material can be effected by heat, UV illumination, or other methods known in the art.

[00124] Embodiment 32. The method of Embodiment 31, the method being performed so as to give rise to one or more sensor units according to any of Embodiments 1-14.

[00125] Embodiment 33. The method of any of Embodiments 31-32, wherein the flexible support layer is disposed atop a template substrate. Suitable template substrates include, e.g., Si, SiO₂, and the like.

[00126] Embodiment 34. The method of Embodiment 33, further comprising freeing the flexible support layer from the template substrate. This can be accomplished by, e.g., peeling.

[00127] Embodiment 35. The method of any of Embodiments 31-34, further comprising placing the sensor unit in a head covering.

[00128] Embodiment 36. A sensor unit, comprising: a sensing portion that comprises a plurality of conductive segments; a conductive contact in electronic communication with the sensing portion; a substrate, the substrate supporting the conductive contact and the sensing portion; and a sealing material disposed so as to mask at least a portion of the substrate and at least a portion of the conductive contact while a portion of the sensing portion is exposed through the sealing material.

[00129] Embodiment 37. The sensor unit of Embodiment 36, wherein the sensing portion contacts the substrate. In some embodiments, e.g., FIG. 7, the sensing portion does not contact the substrate.

[00130] A sensing portion can present a flat surface, e.g., a flat-topped cylinder or other formation. A sensing portion can also present a non-flat surface, e.g., a rippled, wrinkled, or otherwise uneven surface. In this way, a sensing portion can conform to the user.

[00131] Embodiment 38. The sensor unit of any one of Embodiments 36-37, wherein the conductive contact is in physical contact with the sensing portion and the substrate. As an example, a conductive contact can be formed on the substrate such that the conductive contact touches the substrate and also touches the sensing portion. Such an embodiment is provided in FIG. 10, in which the conductive contact 102f contacts the substrate 100 and also the sensing portion 104f. As shown in FIG. 10, the sealing material 106 can be such that the sensing portion 104f is exposed above the sealing material, which the sealing material covers the substrate 100 and conductive contact 102f.

[00132] The sensing portion can be “taller” than the conductive contact in order that the sensing portion extends through and above the sealing layer, while the conductive contact remains covered by the sealing layer. One example of this is shown in FIG. 7, which depicts a sensing portion (104a) being “taller” than the conductive contact (102a) that is associated with that sensing portion.

[00133] Embodiment 39. The sensor unit of any one of Embodiments 36-38, wherein the conductive contact is disposed between the sensing portion and the substrate. One such example is shown in FIG. 7.

[00134] Embodiment 40. The sensor unit of any one of Embodiments 36-39, wherein a conductive segment comprises a metal nanowire, a carbon nanotube, a graphene portion, of any combination thereof. Silver nanowires are considered especially suitable as conductive segments.

[00135] Embodiment 41. The sensor unit of any one of Embodiments 36-40, wherein the substrate comprises a polyimide. Other materials, including flexible materials, are also considered suitable.

[00136] Embodiment 42. The sensor unit of any one of Embodiments 36-41, wherein the sealing material comprises PDMS, PMMA, parylene, polyimide, PET, poly(3,4-ethylenedioxythiophene); polyurethane, or any combination thereof.

[00137] Embodiment 43. The sensor unit of any one of Embodiments 36-43, wherein the plurality of conductive segments are disposed in a matrix material.

[00138] Embodiment 44. The sensor unit of Embodiment 43, wherein the matrix material comprises a polymeric material. PDMS is one suitable polymeric material, although others are also suitable.

[00139] Embodiment 45. The sensor unit of any one of Embodiments 36-43, wherein the sensor unit is in electronic communication with an amplifier.

[00140] Embodiment 46. A device, the device comprising: a plurality of sensor units, with a sensor unit comprising: a sensing portion that comprises a plurality of conductive segments; a conductive contact in electronic communication with the sensing portion; a substrate, the substrate supporting the conductive contact and the sensing portion; and a sealing material disposed so as to mask at least a portion of the substrate and at least a portion of the conductive contact while a portion of the sensing portion is exposed through the sealing material, and at least two of the plurality of sensor units being individually electronically addressable. As described elsewhere herein, a user can thus utilize individual sensing portions to collect signals from different regions of a user.

[00141] The present disclosure also contemplates methods of utilizing the disclosed devices. As one example, one can, based on a signal or signals collected by a device according to the present disclosure, alter (and/or initiate and/or cease) a stimulus that is administered to a subject being monitored by the device. As an example, one can alter and/or initiate and/or cease content (music, advertising, educational materials) that is delivered to a user based on a signal collected from the user during (or before or after) exposure to the content.

[00142] A subject can also utilize a device according to the present disclosure to modify their own activity. For example, a subject can monitor a figure of merit (e.g., engagement) while engaged in an activity, and alter their own activity (physical and/or mental) to affect that figure of merit while engaged in the activity. As another example, the disclosed technology can be used for fatigue monitoring, including real-time fatigue monitoring. The disclosed technology can further be used for stress monitoring, including real-time stress monitoring.

[00143] For any of the foregoing applications, a user can alter, remove, or add a task or other obligation depending on results collected using the disclosed technology. As one example, a user who is seen to experience a fatigue at or above a certain threshold level might be relieved of one or more tasks, e.g., a train dispatcher who is seen to experience

fatigue may be replaced by a “fresh” dispatcher. In this way, a user can adjust work conditions and tasks, in real-time, based on the engagement, stress, and/or fatigue of workers.

[00144] References

[00145] Bertrand, A., Mihajlović, V., Grundlehner, B., Van Hoof, C. & Moonen, M. Motion artifact reduction in EEG recordings using multi-channel contact impedance measurements. In 2013 IEEE Biomedical Circuits and Systems Conference, BioCAS 2013 (2013). doi:10.1109/BioCAS.2013.6679688

[00146] Ratti, E., Waninger, S., Berka, C., Ruffini, G. & Verma, A. Comparison of Medical and Consumer Wireless EEG Systems for Use in Clinical Trials. Front. Hum. Neurosci. 11,(2017).

[00147] Hecht, D. S., Hu, L. & Irvin, G. Emerging transparent electrodes based on thin films of carbon nanotubes, graphene, and metallic nanostructures. Advanced Materials 23, 1482–1513 (2011).

[00148] Xu, F. & Zhu, Y. Highly conductive and stretchable silver nanowire conductors. Adv. Mater. 24, 5117–5122 (2012).

[00149] McClain, M. A. et al. Highly-compliant, microcable neuroelectrodes fabricated from thinfilm gold and PDMS. Biomed. Microdevices 13, 361–373 (2011).

[00150] Myers, A. C., Huang, H. & Zhu, Y. Wearable silver nanowire dry electrodes for electrophysiological sensing. RSC Adv. 5, 11627–11632 (2015).

[00151] www.cognionics.com/index.php/products/hd-eeeg-systems/quick-20-dry-headset

[00152] www.choosemuse.com/

[00153] www.emotiv.com/epoc/

[00154] www.openbci.com/

[00155] www.sccn.ucsd.edu/eeglab/index.php

What is Claimed:

1. A sensor unit, comprising:

a flexible sensing layer comprising a plurality of conductive segments disposed in a first matrix material,

the flexible sensing layer having a first surface configured for placement against the skin of a subject and the flexible sensing layer having a second surface;

a flexible support layer contacting the second surface of the flexible sensing layer, the flexible support layer comprising a second matrix material; and

a current carrier in electronic communication with the conductive segments, the current carrier optionally extending through the flexible support layer,

the current carrier being configured to carry a current to, from, or to and from the conductive segments.

2. The sensor unit of claim 1, wherein the current carrier is at least partially embedded in the flexible sensing layer.
3. The sensor unit of claim 1, wherein the current carrier is characterized as being a wire.
4. The sensor unit of claim 1, wherein the conductive segments comprise one or more metals, graphene, carbon nanotubes, or any combination thereof.
5. The sensor unit of claim 4, wherein the conductive segments comprise one or more metals.
6. The sensor unit of claim 5, wherein the conductive segments comprise one or more metallic nanowires.
7. The sensor unit of claim 6, wherein the conductive segments comprise gold nanowires, silver nanowires, or any combination thereof.

8. The sensor unit of any one of claims 6-7, wherein the metallic nanowires have a diameter in the range of from about 1 to about 1000 nm.
9. The sensor unit of any one of claims 6-7, wherein the metallic nanowires have a length in the range of from about 1 to about 1000 micrometers.
10. The sensor unit of any one of claims 1-7, wherein one or both of the first matrix material and the second matrix material is characterized as polymeric.
11. The sensor unit of claim 10, wherein one or both of the first matrix material and the second matrix material is characterized as a polysiloxane, a silicon(e) elastomer, or any combination thereof.
12. The sensor unit of claim 11, wherein one or both of the first matrix material and the second matrix material comprises polydimethylsiloxane.
13. The sensor unit of any one of claims 1-7, wherein the first matrix material is characterized as being hydrophobic.
14. The sensor unit of any one of claims 1-7, wherein the sensor unit is capable of maintaining electrical contact with a subject's skin in the absence of an electrolytic material disposed between the flexible sensing layer of the sensor unit and the subject's skin.
15. The sensor unit of any one of claims 1-7, wherein the sensor unit's collection of an electrical signal from a subject is substantially unaffected by movement artifacts, in the absence of an electrolytic material disposed between the flexible sensing layer of the sensor unit and the subject's skin.
16. The sensor unit of any one of claims 1-7, wherein noise in the sensor unit's collection of an electrical signal from a subject is substantially unaffected by movement artifacts, in the absence of an electrolytic material disposed between the flexible sensing layer of the sensor unit and the subject's skin.
17. The sensor unit of any one of claims 1-7, wherein the sensor is capable of maintaining electrical contact with a subject's skin at a hairy region of the scalp, in the absence of

an electrolytic material disposed between the flexible sensing layer of the sensor unit and the subject's skin.

18. A monitor, comprising:

a headcovering comprising a plurality of devices according to any of claims 1-7,

the head covering being configured to place the flexible sensing layers of at least some of the devices into contact with the skin of a subject.

19. The monitor of claim 18, further comprising an amplifier in electronic communication with one or more of the plurality of devices.

20. The monitor of claim 19, further comprising a filtration train configured to filter one or more signals collected by one or more of the plurality of devices.

21. The monitor of claim 20, wherein the one or more signals are of neurological activity of the subject.

22. The monitor of claim 19, further comprising a portable power source in electronic communication with the amplifier.

23. The monitor of claim 18, further comprising a display configured to display a signal of neurological activity of a subject that is collected by one or more of the plurality of devices.

24. The monitor of claim 18, wherein the headcovering is characterized as a hat or cap.

25. The monitor of claim 18, wherein the monitor is characterized as being portable.

26. A method, comprising:

with one or more sensor units according to any of claims 1-7,

collecting one or more signals of neurological activity of a subject.

27. The method of claim 27, wherein the flexible sensing layers of the one or more sensor units contact the skin of the subject.

28. The method of claim 26, further comprising removing one or more artifacts from one or more of the signals.
29. The method of claim 26, further comprising filtering one or more of the signals.
30. The method of claim 26, further comprising correlating one or more of the signals to an activity of the subject, to a stimulus received by the subject, or any combination thereof.
31. A method of fabricating a sensor unit, comprising;
- atop a flexible support layer that comprises a second matrix,
- disposing a dispersion of conductive segments;
- placing a current carrier into electronic communication with at least some of the conductive segments;
- disposing a first matrix material atop the dispersion of conductive segments and at least some of the current carrier; and
- curing the first matrix material so as to form a flexible sensing layer that comprises at least some of the conductive segments,
- the current carrier being at least partially embedded within the flexible sensing layer,
- the flexible sensing layer being disposed atop the flexible support layer, and
- the current carrier extending through the flexible support layer.
32. The method of claim 33, the method being performed so as to give rise to one or more sensor units according to any of claims 1-7.
33. The method of claim 31, wherein the flexible support layer is disposed atop a template substrate.
34. The method of claim 33, further comprising freeing the flexible support layer from the template substrate.

35. The method of any one of claim 31, further comprising placing the sensor unit in a head covering.
36. A sensor unit, comprising:
- a sensing portion that comprises a plurality of conductive segments;
 - a conductive contact in electronic communication with the sensing portion;
 - a substrate, the substrate supporting the conductive contact and the sensing portion;
 - and
 - a sealing material disposed so as to mask at least a portion of the substrate and at least a portion of the conductive contact while a portion of the sensing portion is exposed through the sealing material.
37. The sensor unit of claim 36, wherein the sensing portion contacts the substrate.
38. The sensor unit of any one of claims 36-37, wherein the conductive contact is in physical contact with the sensing portion and the substrate.
39. The sensor unit of any one of claims 36-37, wherein the conductive contact is disposed between the sensing portion and the substrate.
40. The sensor unit of any one of claims 36-37, wherein a conductive segment comprises a metal nanowire, a carbon nanotube, a graphene portion, of any combination thereof.
41. The sensor unit of any one of claims 36-37, wherein the substrate comprises a polyimide.
42. The sensor unit of any one of claims 36-37, wherein the sealing material comprises PDMS, PMMA, parylene, polyimide, PET, poly(3,4-ethylenedioxythiophene); polyurethane, or any combination thereof.
43. The sensor unit of any one of claims 36-37, wherein the plurality of conductive segments are disposed in a matrix material.

44. The sensor unit of claim 43, wherein the matrix material comprises a polymeric material.
45. The sensor unit of any one of claims 36-37, wherein the sensor unit is in electronic communication with an amplifier.
46. A device, the device comprising:
- a plurality of sensor units, a sensor unit comprising:
 - a sensing portion that comprises a plurality of conductive segments;
 - a conductive contact in electronic communication with the sensing portion;
 - a substrate, the substrate supporting the conductive contact and the sensing portion;
 - and
 - a sealing material disposed so as to mask at least a portion of the substrate and at least a portion of the conductive contact while a portion of the sensing portion is exposed through the sealing material, and
 - at least two of the plurality of sensor units being individually electronically addressable.

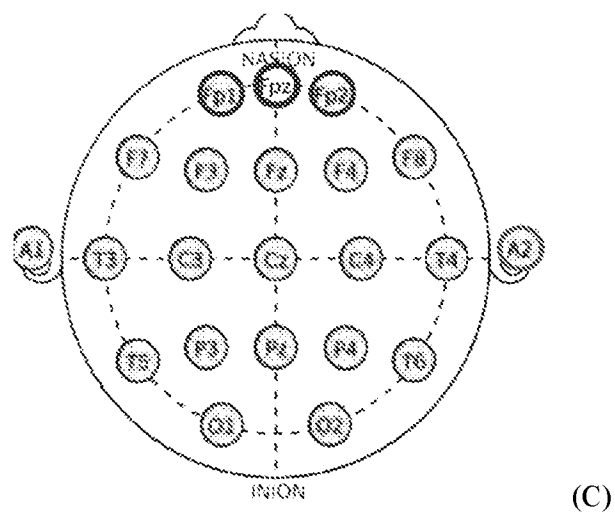
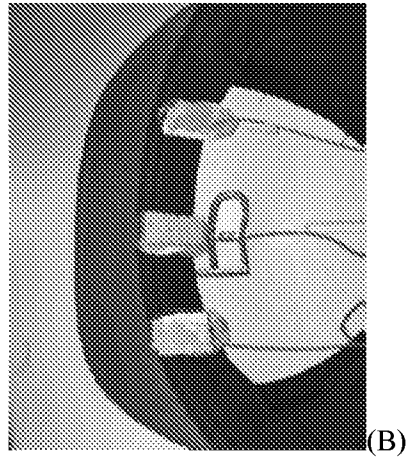


FIG. 1

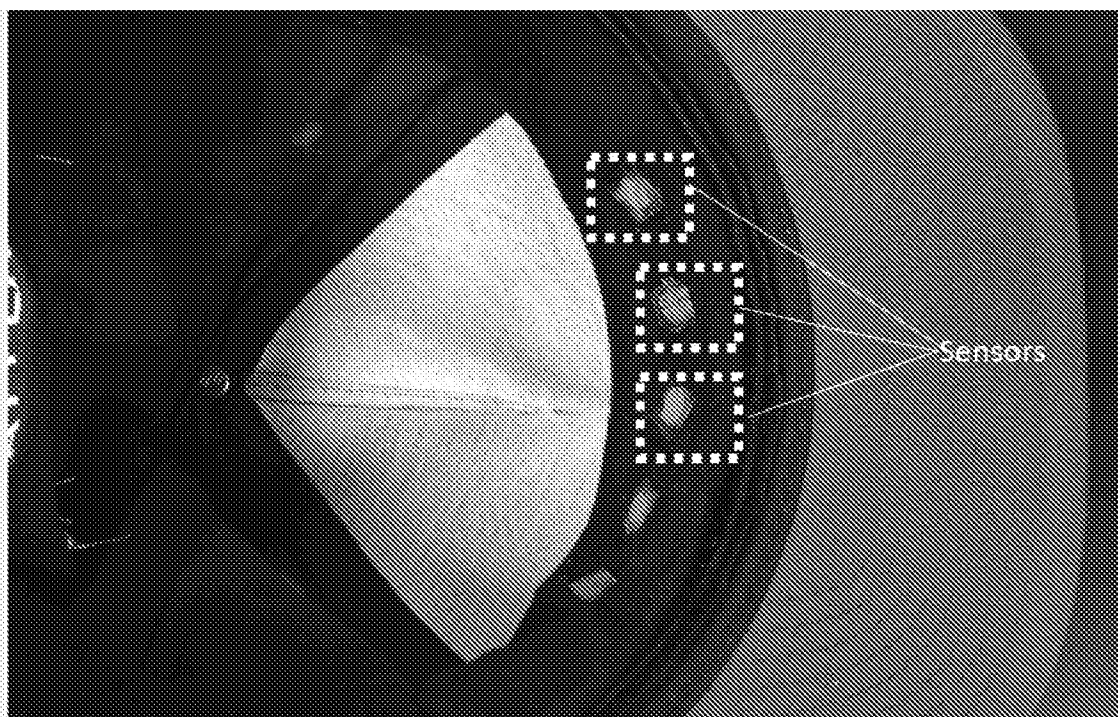


FIG. 2

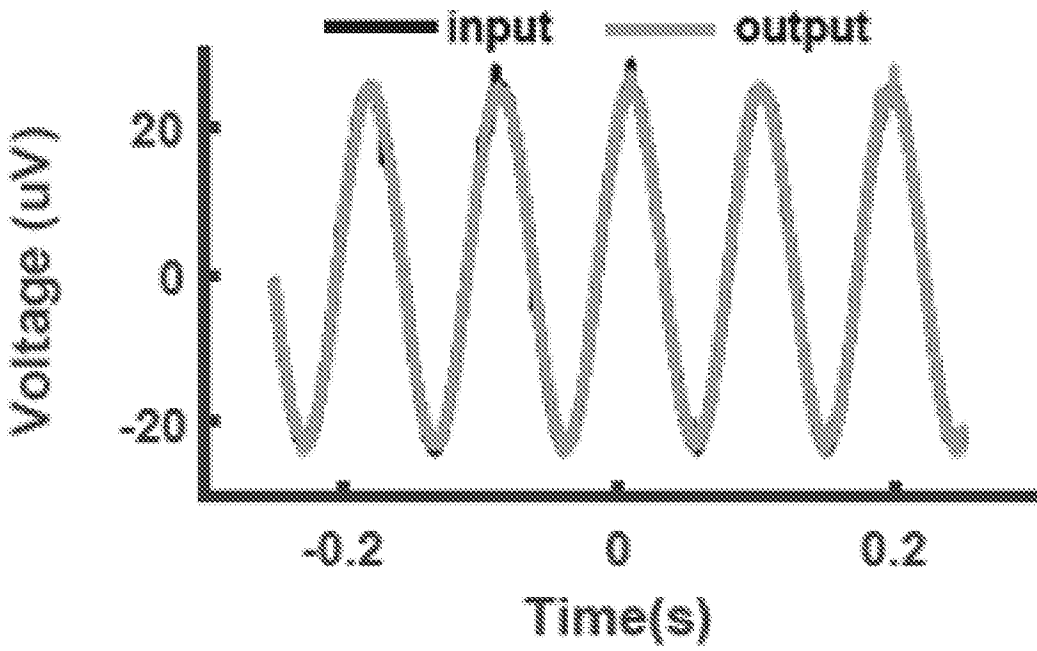


FIG. 3A

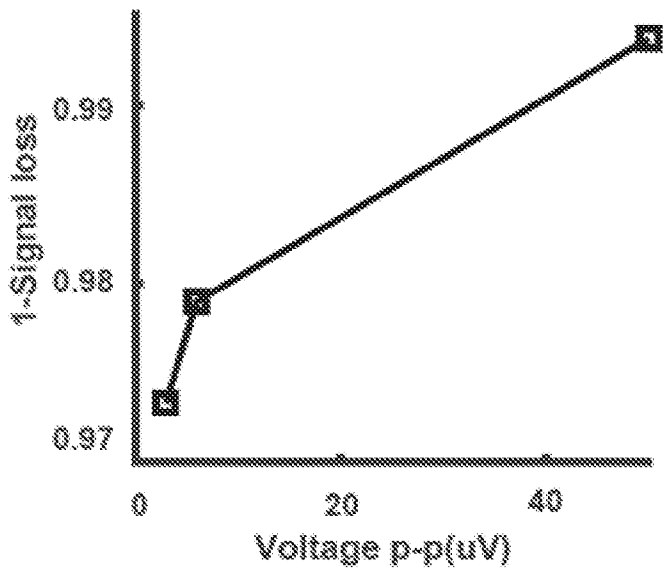


FIG. 3B

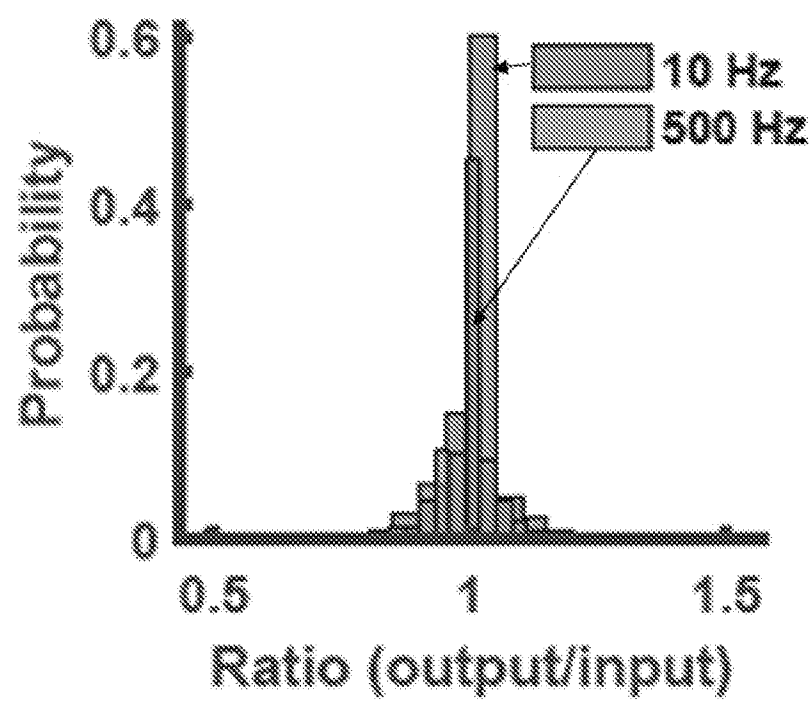


FIG. 3C

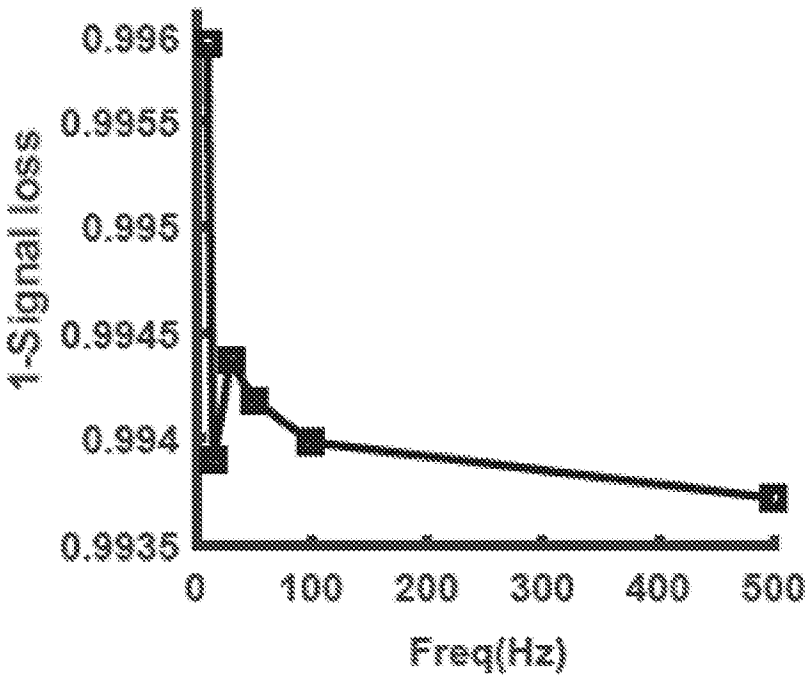


FIG. 3D

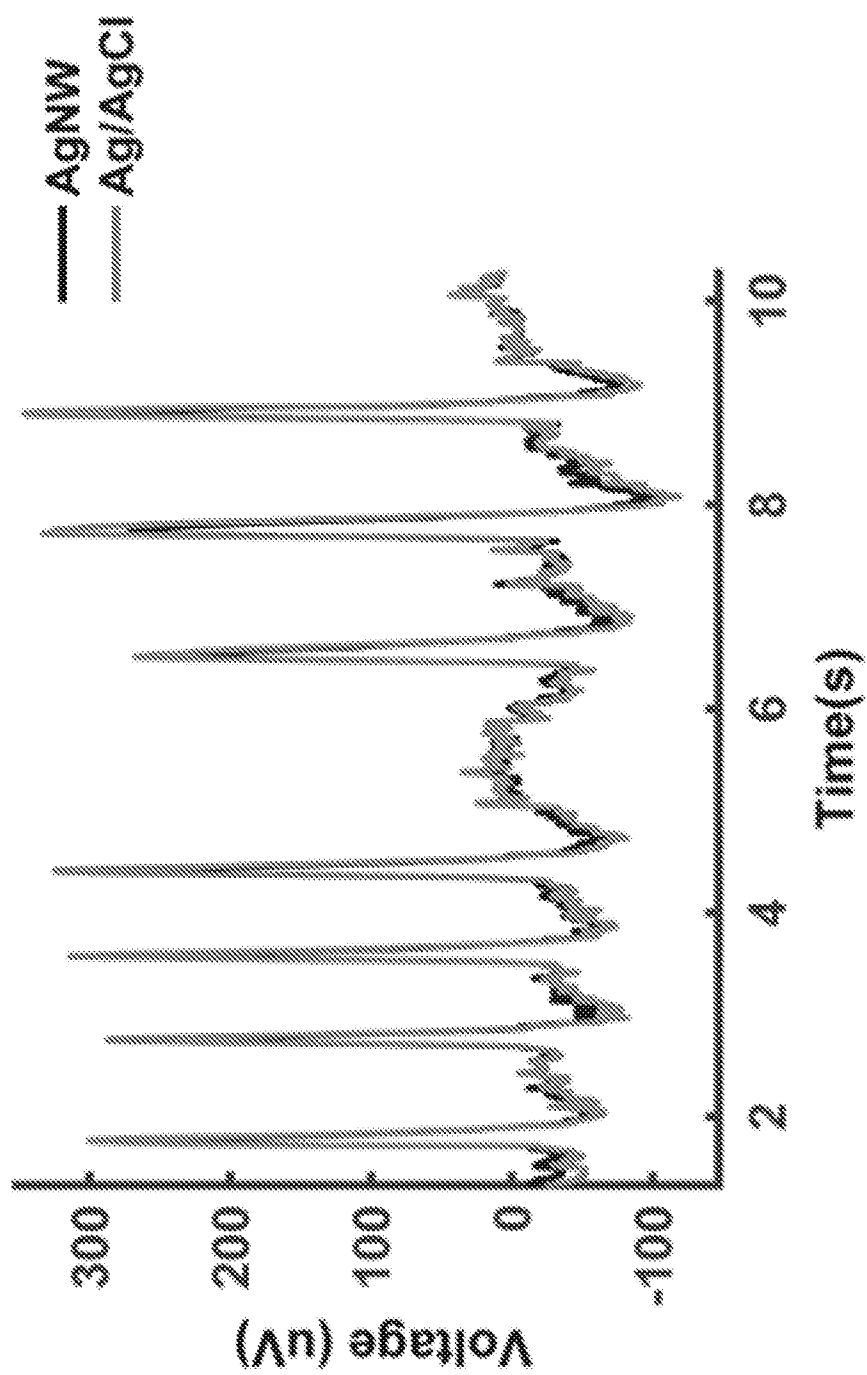


FIG. 4A

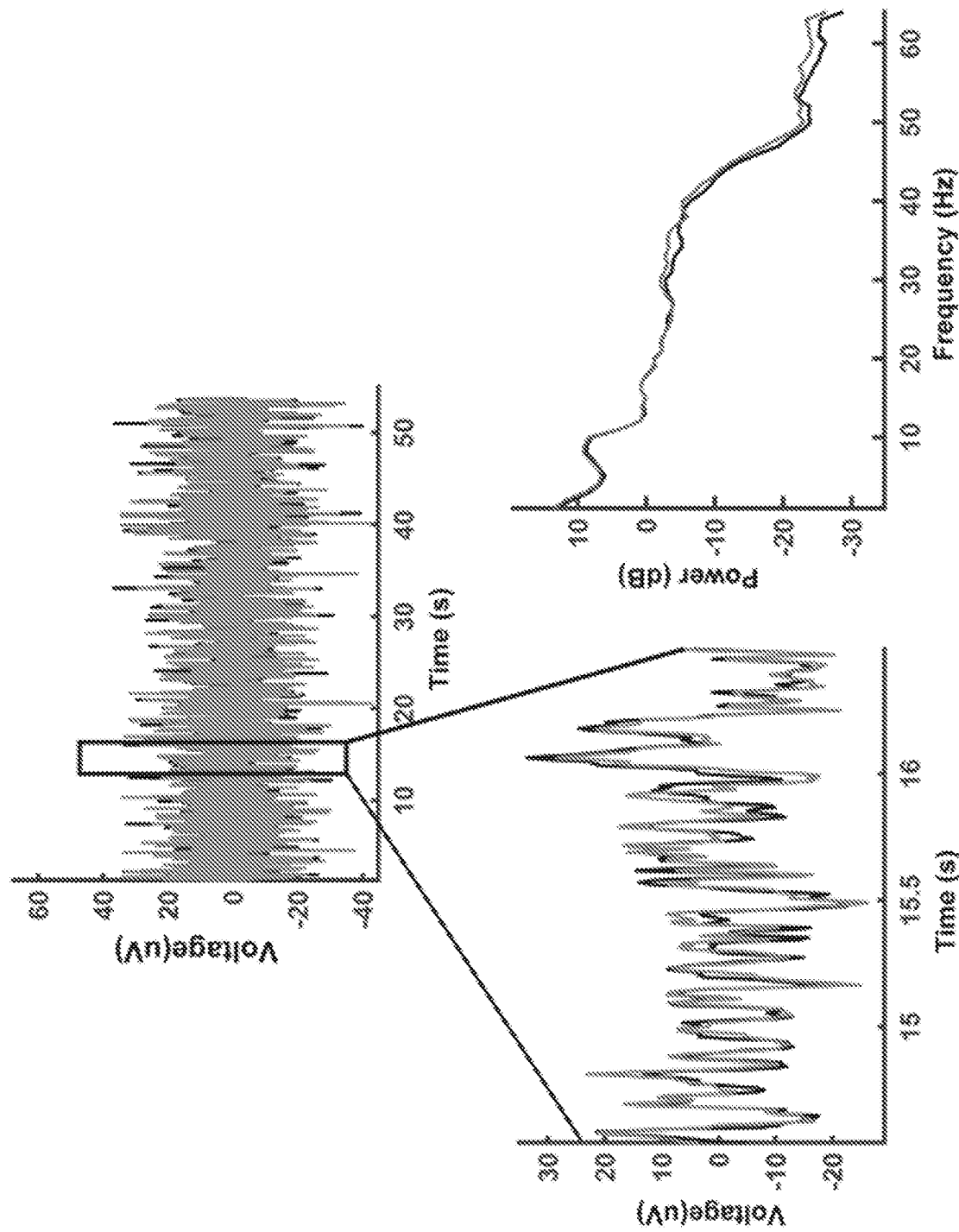


FIG. 4B

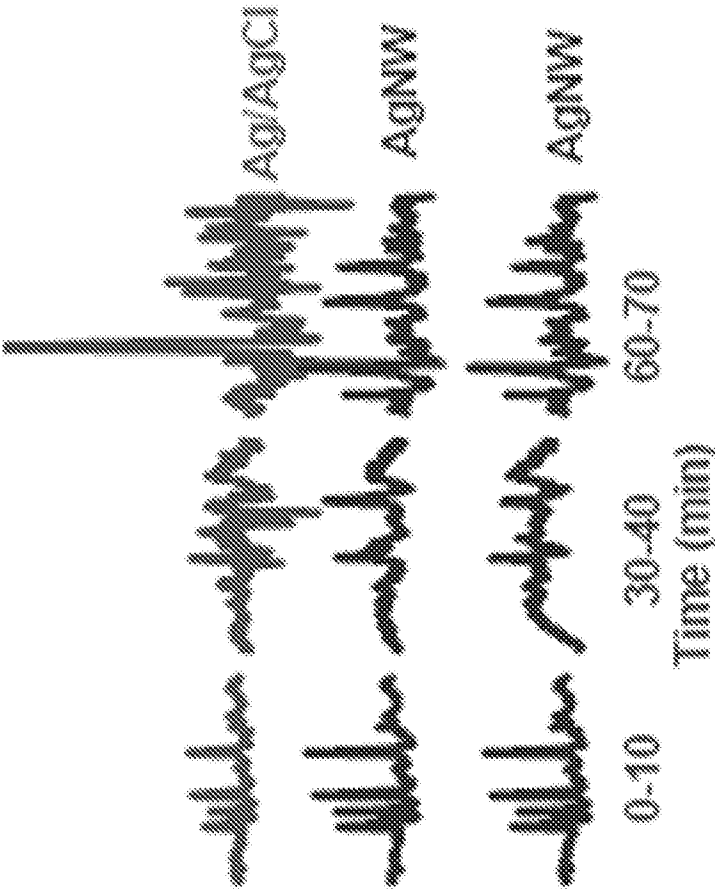


FIG. 5A

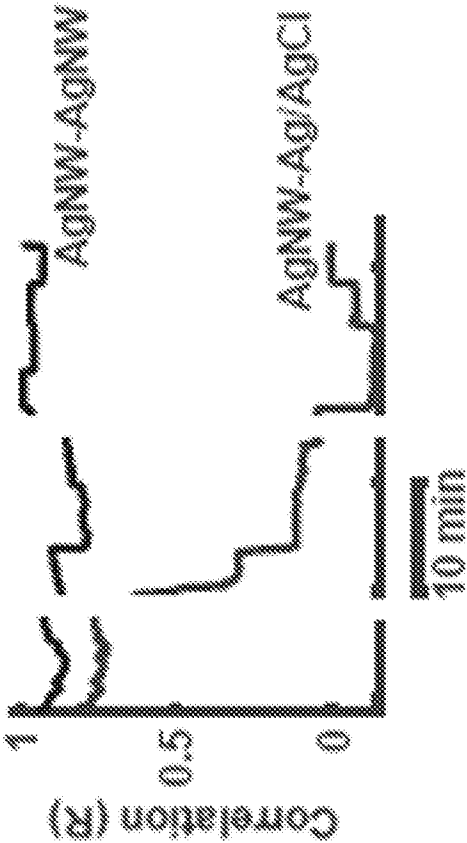


FIG. 5B

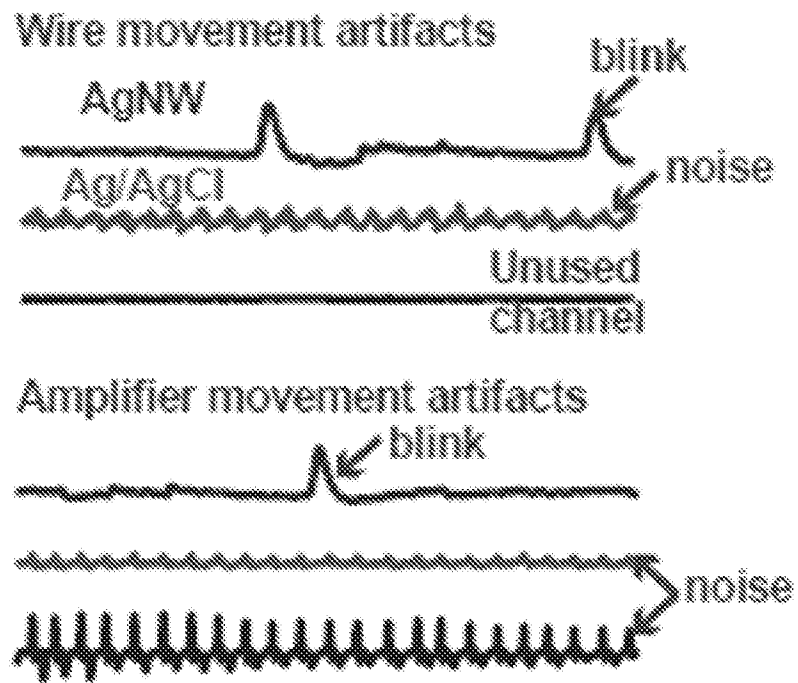


FIG. 5C

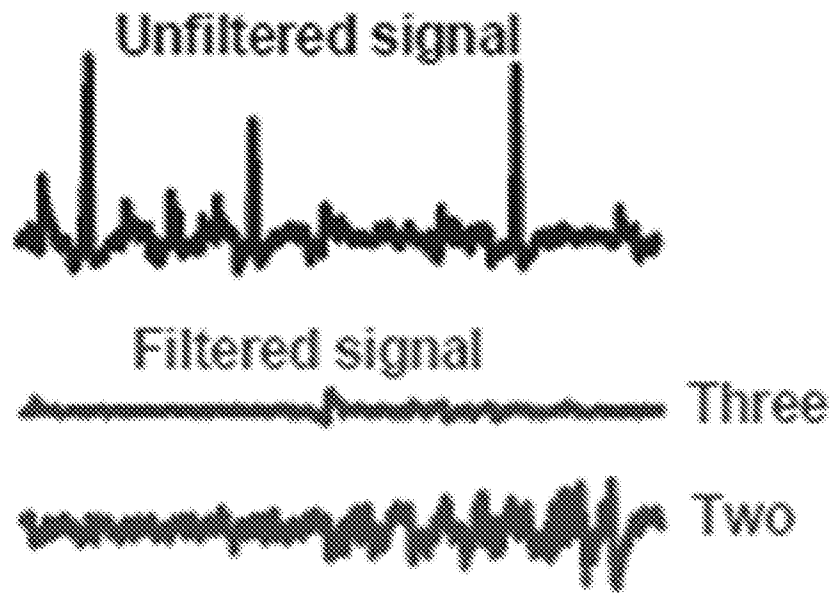


FIG. 6

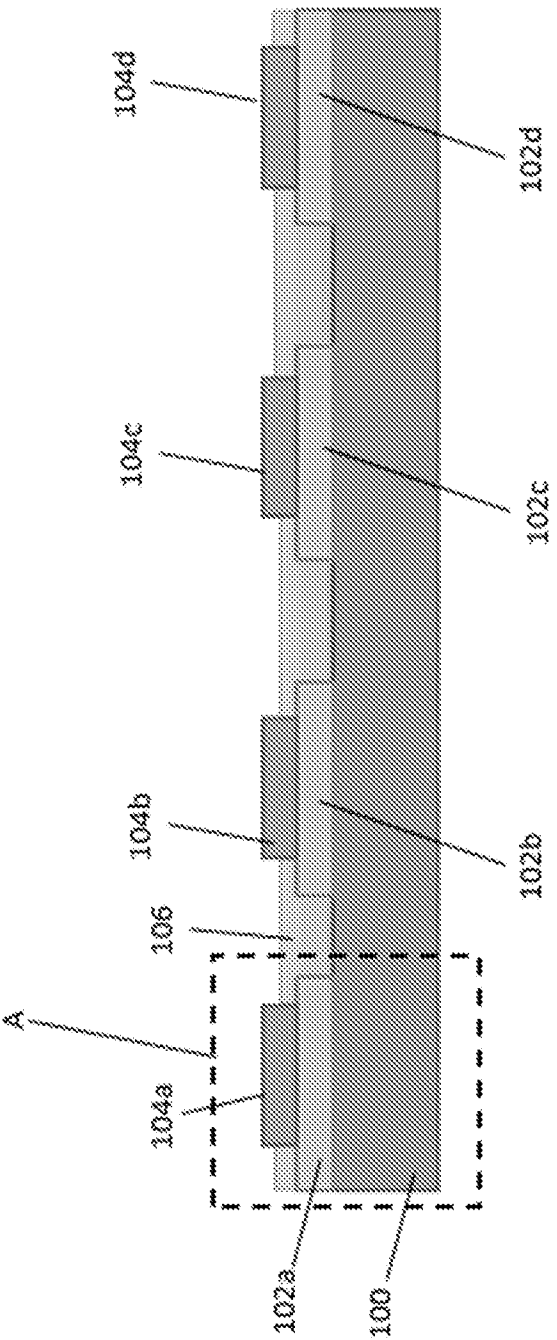


FIG. 7

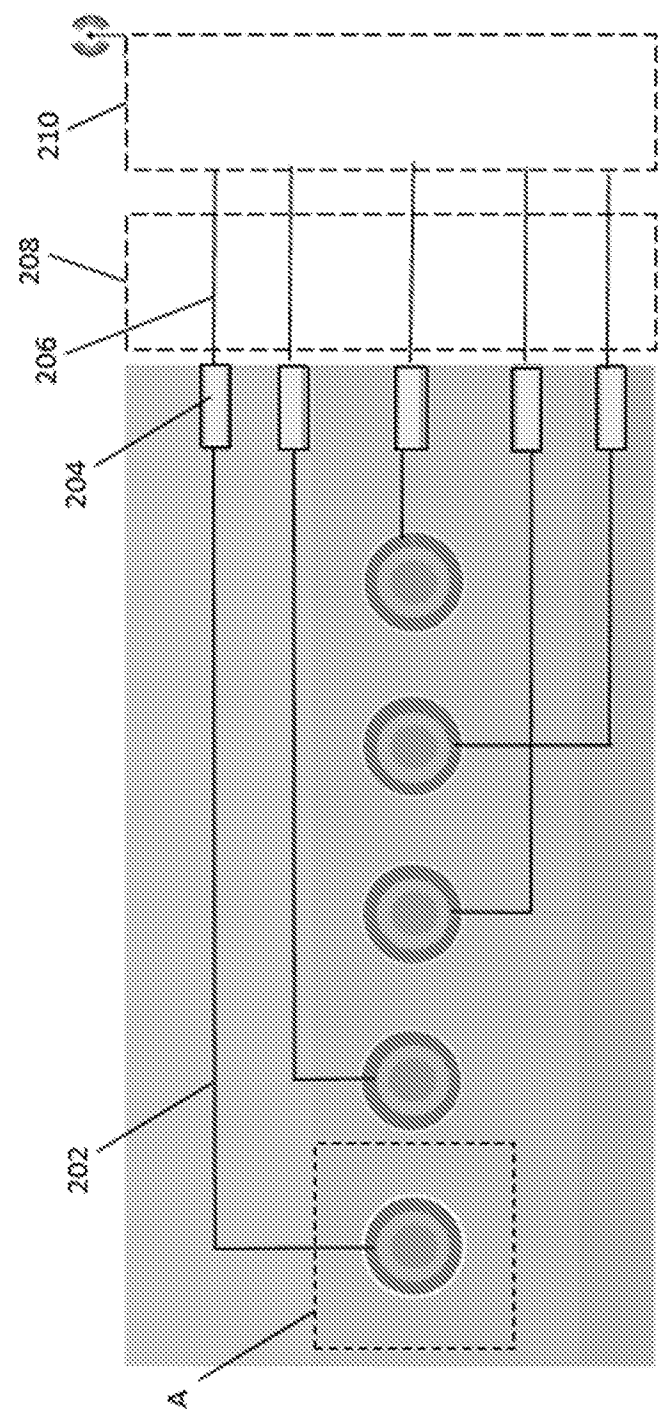


FIG. 8

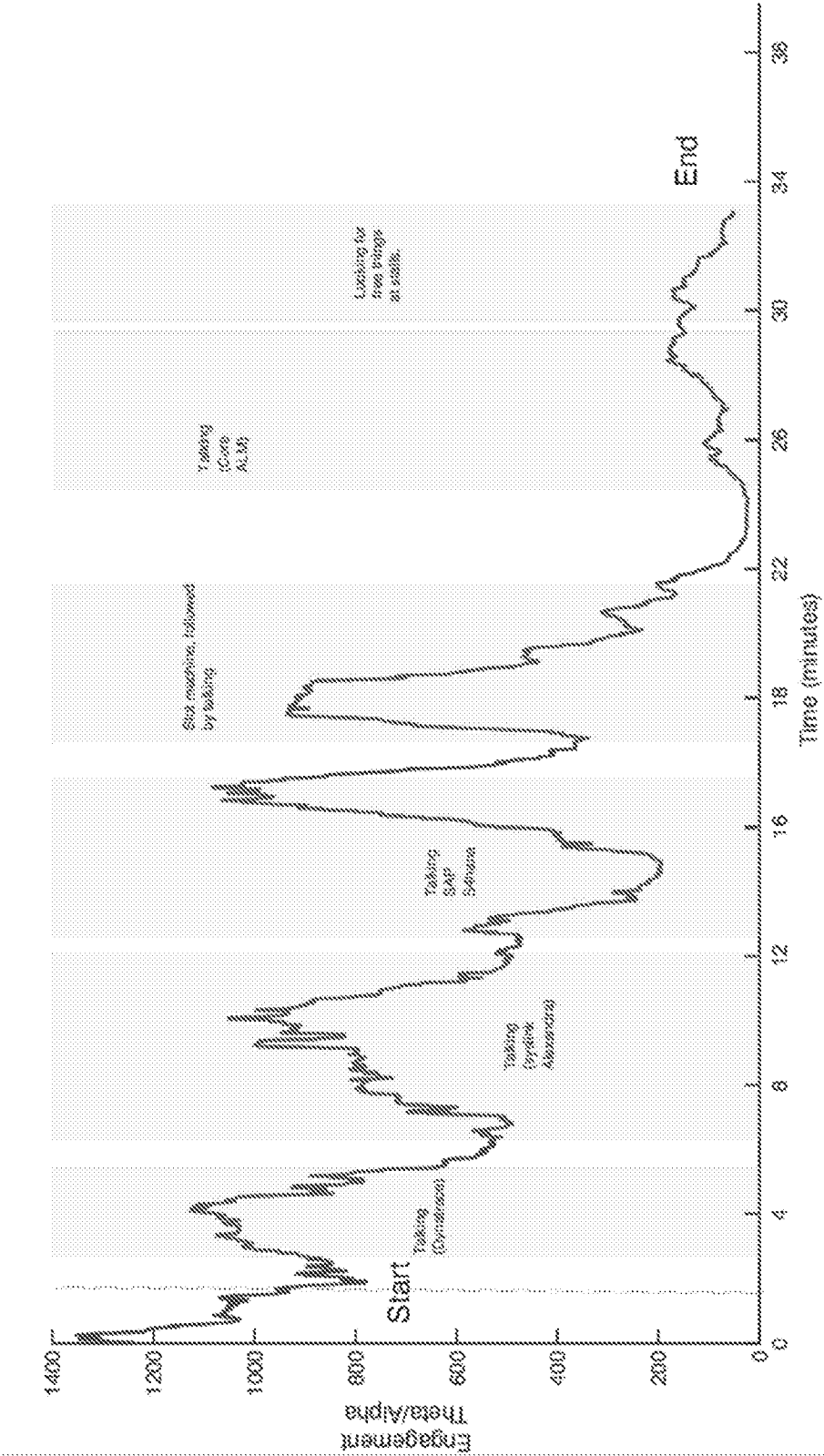


FIG. 9

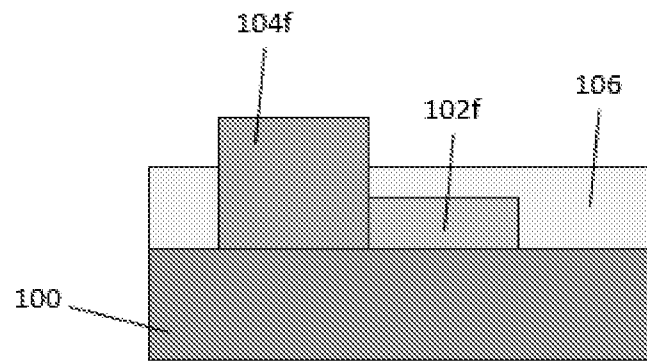


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US19/21379

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 5/0478, 5/16; H01L 21/28 (2019.01)

CPC - A61B 5/6803, 5/683, 5/0478, 5/04001, 5/04004; H01L 21/28

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

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

See Search History document

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	↖ CN 104224167 A (UNIVERSITY BEIJING NORMAL) 24 December 2014; see machine translation entire document	1-7, 10/1-10/7, 13/1-13/7, 26/1-26/7, 27/26/1-27/26/7, 30/26/1-30/26/7, 31 -- 8/6-8/7, 9/6-9/7, 11/10/1-11/10/7, 12/11/10/1-12/11/10/7, 14/1-14/7, 15/1-15/7, 16/1-16/7, 17/1-17/7, 18/1-18/7, 19/18/1-19/18/7, 20/19/18/1-20/19/18/7, 21/20/19/18/1-21/20/19/1 8/7, 22/19/18/1-22/19/18/7, 23/18/1-23/18/7, 24/18/1-24/18/7, 25/18/1-25/18/7, 28/26/1-28/26/7, 29/26/1-29/26/7, 33-35

☒ 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

20 June 2019 (20.06.2019)

Date of mailing of the international search report

10 JUL 2019

Name and mailing address of the ISA/

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Shane Thomas

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US19/21379

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.:
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:

3. ☒ Claims Nos.: 32
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:

-*Continued within Extra Sheet*-

1. ☐ As all required additional 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 additional fees, this Authority did not invite payment of 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.:
1-31, 33-35

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.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US19/21379

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2017/0172439 A1 (NORTH CAROLINA STATE UNIVERSITY) 22 June 2017; figure 1B, paragraphs [0057-0058, 0067, 0094]	8/6-8/7, 9/6-9/7, 11/10/1-11/10/7, 12/11/10/1-12/11/10/7, 14/1-14/7, 15/1-15/7, 16/1-16/7, 33-34
Y	US 4,967,038 A (GEVINS, A et al.) 30 October 1990; figures 1, 3-4; abstract; column 4, lines 20-60; column 5, lines 52-54; column 6, lines 3-9, 24-48; column 7, lines 44-47; claims 1, 16	17/1-17/7, 18/1-18/7, 19/18/1-19/18/7, 20/19/18/1-20/19/18/7, 21/20/19/18/1-21/20/19/1 8/7, 22/19/18/1-22/19/18/7, 24/18/1-24/18/7, 25/18/1-25/18/7, 28/26/1-28/26/7, 29/26/1-29/26/7, 35
Y	US 2017/0095176 A1 (UNIVERSITY OF PITTSBURGH - OF THE COMMONWEALTH SYSTEM OF HIGHER EDUCATION) 06 April 2017; figure 1, paragraph [0042]	23/18/1-23/18/7
A	US 8,326,396 B2 (PICHT, B et al.) 04 December 2012; entire document	1-31, 33-35
A	US 8,626,258 B2 (CHANDRASEKARAN, S et al.) 07 January 2014; entire document	1-31, 33-35

---Continued from Box III ---

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fee must be paid.

Group I: Claims 1-31 and 33-35 are directed towards a sensor unit comprising matrix materials, a monitor, and a method of fabricating.
Group II: Claims 36-46 are directed towards a sensor unit and device comprising a sealing material.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical features of Group I include at least a flexible sensing layer; a first matrix material; a flexible support layer; and a second matrix, which are not present in Group II.

The special technical features of Group II include at least a sealing material disposed so as to mask at least a portion of the substrate and at least a portion of the conductive contact while a portion of the sensing portion is exposed through the sealing material, which are not present in Group I.

The common technical features shared by Groups I-II are a sensor unit, comprising: a sensing portion that comprises a plurality of conductive segments; a conductive contact in electronic communication with the sensing portion.

However, these common features are previously disclosed by US 20170095176 A1 to University of Pittsburgh – Of Commonwealth System of Higher Education (hereinafter "University of Pittsburgh"). University of Pittsburgh discloses a sensor unit (electroencephalographic EEG sensor 400; figure 4, paragraph [0047]), comprising: a sensing portion that comprises a plurality of conductive segments (EEG sensor 400 comprising distal electrode surfaces 410, 412 for detecting EEG signals include fasteners 414, 416 providing electrical coupling; figure 4, paragraph [0047]); a conductive contact in electronic communication with the sensing portion (electrode 404 is a conductive contact in electrical communication with electrode surfaces 410; figure 4, paragraph [0047]).

Since the common technical features are previously disclosed by the University of Pittsburgh reference, these common features are not special and so Groups I-II lack unity.