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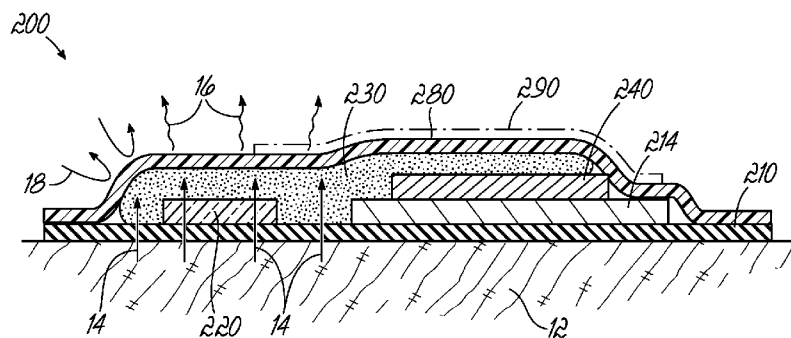
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(54) Title: ADVANCED SWEAT SENSOR ADHESION, SEALING, AND FLUIDIC STRATEGIES

**FIG. 2**

(57) **Abstract:** A sweat sensor device (200) includes one or more sweat sensors (220) and a seal (280) covering the one or more sweat sensors (220). The seal (280) is adapted to protect the sweat sensors (220) from outside contaminants when the device (200) is placed on the skin (12). The sweat sensor device (200) may include an absorbing medium (230) to absorb sweat from the skin (12) that is covered by the seal (280). The seal (280) can be permeable to gas, permeable to water and impermeable to at least one aqueous solute, or selectively permeable to at least one aqueous solute. The sweat sensor device (200) may include an artificial sweat stimulation mechanism (345) for stimulating sweat when the device (200) is placed on the skin (12).

**ADVANCED SWEAT SENSOR ADHESION, SEALING, AND FLUIDIC
STRATEGIES**

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Applications No. 62/003,675, filed on May 28, 2014, No. 62/114,835, filed on February 11, 2015, and No. 62/115,851, filed on February 13, 2015, the disclosures of which are hereby incorporated by reference herein in their entirety.

BACKGROUND OF THE INVENTION

[0002] Sweat sensing technologies have enormous potential for applications ranging from athletics, to neonates, to pharmacological monitoring, and to personal digital health, to name a few applications. Sweat contains many of the same biomarkers, chemicals, or solutes that are carried in blood and can provide significant information enabling one to diagnose ailments, health status, toxins, performance, and other physiological attributes even in advance of any physical sign. Furthermore, sweat itself, the action of sweating, and other parameters, attributes, solutes, or features on, near, or beneath the skin can be measured to further reveal physiological information.

[0003] If sweat has such significant potential as a sensing paradigm, then why has it not emerged beyond decades-old usage in infant chloride assays for Cystic Fibrosis or in illicit drug monitoring patches? In decades of sweat sensing literature, the majority of medical literature utilizes the crude, slow, and inconvenient process of sweat stimulation, collection of a sample, transport of the sample to a lab, and then analysis of the sample by a bench-top machine and a trained expert. This process is so labor intensive, complicated, and costly that in most cases, one would just as well implement a blood draw since it is the gold standard for most forms of high performance biomarker sensing. Hence, sweat sensing has not emerged into its fullest opportunity and capability for biosensing, especially for continuous or repeated biosensing or monitoring. Furthermore, attempts at using sweat to sense “holy grails” such as glucose have not yet succeeded to produce viable commercial products, reducing the publically perceived capability and opportunity space for sweat sensing.

[0004] Furthermore, existing approaches lack advanced adhesion, sealing, and fluidic strategies for sweat sensing materials, devices, and systems. For example, externally exposed devices have been demonstrated on skin but which could not be used by a swimmer, or used for high resolution chronological monitoring of biomarkers if placed in an area where ‘older sweat’ could contact the device. Sensors on skin have also been demonstrated in the lab, but only the sensors and not with the integrated and sealed electronics needed for real-world use. In summary, much of the prior art teaches interesting basic scientific demonstrations, but such devices severely lack the inventive steps and elements to enable high-performance, ergonomic, fail-proof, and compelling sweat sensing.

SUMMARY OF THE INVENTION

[0005] Many of the drawbacks stated above can be resolved by creating novel and advanced interplays of chemicals, materials, sensors, electronics, microfluidics, algorithms, computing, software, systems, and other features or designs, in a manner that affordably, effectively, conveniently, intelligently, or reliably brings sweat sensing technology into intimate proximity with sweat as it is generated. With such a new invention, sweat sensing could become a compelling new paradigm as a biosensing platform.

[0006] The present invention provides sweat sensor device with advanced sweat sensor adhesion, sealing, and fluidic strategies. In one embodiment, a sweat sensor device includes one or more sweat sensors and a seal covering said one or more sweat sensors, said seal for protecting said sweat sensors from outside contaminants when said device is placed on skin.

[0007] In one embodiment, a sweat sensor device includes one or more sweat sensors and a membrane between said sweat sensor and skin. Said membrane is effective to selectively transport one or more solutes from said sweat to said sweat sensor when the device is placed on the skin.

[0008] The objects and advantages of the present invention will be further appreciated in light of the following detailed descriptions and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Fig. 1A is a cross-sectional view of a sealed device according to one embodiment of the present invention.

[0010] Fig. 1B is a cross-sectional view of the sealed device of Fig. 1A after the device has begun sensing sweat.

[0011] Fig. 2 is a cross-sectional view of a sealed device according to one embodiment of the present invention.

[0012] Fig. 3 is a cross-sectional view of a sealed device according to one embodiment of the present invention where a portion of the device is sealed from contamination.

[0013] Fig. 3A is a cross-sectional view of a portion of the sealed device of Fig. 3.

[0014] Fig. 4 is a cross-sectional view of a sealed device according to one embodiment of the present invention where the sensors are in contact with the skin.

[0015] Fig. 5 is a cross-sectional view of a sealed device according to one embodiment of the present invention where a portion of the device is selectively sealed.

[0016] Fig. 6 is a cross-sectional view of a sealed device according to one embodiment of the present invention where the device includes a reusable portion and a disposable portion.

DETAILED DESCRIPTION OF THE INVENTION

[0017] With reference to Fig. 1A, in one embodiment of the present invention a sweat sensor device 100 is placed onto skin 12 by virtue of an adhesive 110. Adhesive 110 is porous or permeable to sweat or solutes in sweat. In other embodiments, adhesives can be electrically conductive, insulating, permeable, impermeable, or have other various properties. Exemplary adhesives useful in the present invention are manufactured by 3M Corp. Device 100 further includes a substrate 114 that carries electronics 140. In one embodiment, the substrate 114 is a Kapton film. Electronics 140 may include, for example, such components as an electronics controller, communication circuit, memory, microcontrollers, antennas, and other electronics useful in wearable sensors. Device 100 further includes one or more sensors 120 for sensing sweat, sweat solutes, skin impedance, biomarkers, or combinations thereof. Sensors 120 may be connected to electronics 140, as discussed further below. Embodiments of the present invention may include one or more sensors that may be of similar or different types. For instance, in one embodiment, a device may include a sensor for sensing sweat solutes and an impedance sensor. Device 100 includes an absorbent medium 130, which may absorb sweat when the device 100 is sensing sweat. In the illustrated embodiment, the absorbent medium 130 is in contact with the sensor 120 and electronics 140. By way of example, the absorbent medium 130 may be a textile, a desiccant, or a swelling hydrogel. The device 100 includes a seal 170 that covers the other components of device 100. By way of example, seal 170 could be a stretchable expandable film, such as one made of vinylidene chloride or plastic paraffin. The seal 170 is impervious to vapor or fluids and forms a seal between the device 100 and the skin. The seal 170 advantageously aids in protecting the

device 100 from outside contaminants. The seal between the device 100 and the skin 12 may be formed, for example, by both the seal 170 and a function of the adhesive 110, or through any other suitable mechanism such as applied pressure. In the illustrated embodiment, seal 170 and the adhesive 110 together seal the device 100 to the skin 12. Aspects of sweat sensing and sweat sensors are further discussed in PCT/US2013/035092, filed April 3, 2013, the disclosure of which is hereby incorporated herein by reference in its entirety.

[0018] With reference to Fig. 1B, a flow 14 of sweat from the skin 12 is measured by the sensor 120, and the sweat flows into the absorbent medium 130. As shown in Fig. 1B, the absorbent medium may swell, requiring the seal 170 to allow for expansion as swelling takes place. In this configuration, the device 100 may prevent old or contaminated sweat absorbed by medium 130 from mixing with the flow 14 of new sweat emerging from the skin 12 underneath the device 100. Furthermore, the device 100 may prevent sensing of sweat from areas of skin outside the device 100, which in many cases would be older sweat. For example, if the device 100 is placed on an individual's lower abdomen and the wearer is standing, the seal 170 may prevent the device 100 from sensing older sweat flowing down the torso from the chest and neck. In an exemplary application of device 100, the device is placed on the abdomen or forearm of a sweating individual; the device 100 could work properly to measure and report sweat biomarkers even if the user went swimming, took a shower, or other possible external contaminants were introduced. Although the seal 170 in Fig. 1B is described as being expandable or stretchable, alternate embodiments of the present invention could include a seal 170 that is not stretchable or that is rigid in mechanical form. In such an alternate embodiment, for example, a simple shape change of the seal 170 could accommodate swelling of the absorbing medium 130. In another embodiment, the absorbing medium 130 could be implemented with little or no swelling as it absorbs sweat 14. Similarly, other elements or materials used in embodiments of the present invention could be rigid in mechanical form.

[0019] With reference to Fig. 2, the device 200 is similar in construction to the device 100 shown in Figs. 1A and 1B, except as otherwise described below. In that regard, similar reference numerals refer to similar features shown and described in connection with Figs. 1A and 1B. Device 200 includes a gas-permeable seal 280. By way of example, the gas-permeable seal 280 may be a selectively sealing film, membrane, textile, or other covering. Because seal 280 is permeable to gas, water vapor from sensed sweat may escape the device 200. In one embodiment, seal 280 may be a textile that is hydrophobic, which therefore

repels water but which allows water vapor to escape the device 200 as indicated by arrows 16. Like seal 170, seal 280 protects the device 200 from outside contaminants, as indicated by arrows 18. This configuration allows the device 200 to be used in prolonged fashion while also sealing it from potential external fluid contamination. In this regard, device 200 may have an improved wearable duration and may be more practical to wear (e.g., by not swelling to as large a volume) as compared to device 100. Although the device 200 is shown including an absorbent medium 230, alternate embodiments may not include an absorbent medium. For example, in embodiments where the application of a device has a shorter term usage and where buildup of sweat solute concentrations around the sensor 220 would not be an issue, an absorbent medium may not be included.

[0020] With further reference to Fig. 2, in an alternate embodiment, seal 280 may also be water permeable but generally impermeable to one or more water soluble solutes (e.g. aqueous solutes), such as solutes in sweat. In one embodiment, seal 280 could be a reverse osmosis membrane. In this exemplary embodiment, water could traverse the seal 280 while external solute contaminants would be prevented from entering device 200. In an exemplary application of device 200, seal 280 could block a detergent used while a person wearing the device 200 takes a shower because a detergent could impair the function of some types of sensors or device configurations. Although water could enter the device 200 in this example, the water would not interfere with sensing of new sweat indicated by arrows 14 if the flow rate of the new sweat is adequate to provide only new sweat underneath the sensor 220.

[0021] With further reference to Fig. 2, in an alternate embodiment, seal 280 may also be a membrane that selectively transports a species, such as a certain solute in sweat. This selective transport may advantageously remove a predetermined component of sweat that may build up to an undesirable concentration in device 200. For example, seal 280 could comprise one or more of several types of ion-selective or ion-permeable membranes that are not porous to free flow of fluid or are at least suitably restrictive to flow of fluid. In one embodiment, seal 280 allows Na^+ to be removed from the device 200 to prevent the solute from building up to too high of concentration over time. In an advantageous aspect, such a function provided by seal 280 could prolong usage of the device 200.

[0022] With further reference to Fig. 2, in an alternate embodiment, device 200 may include an additional material or layer(s) exterior to the seal 280. In the illustrated embodiment, device 200 includes an optional refreshable collection layer 290. The collection layer 290 is configured to collect sweat and/or sweat solutes and to be refreshed of the

collected sweat and/or sweat solutes where at least a portion of the collected sweat and/or sweat solutes is removed. In this regard, the collection layer 290 may be a textile, material, or surface that can be washed of some or all of the collected solutes or sweat and therefore be at least partially refreshed to collect more solutes or sweat. During the washing away of such sweat and/or sweat solutes, seal 280 also prevents substantial back-contamination of the washing fluid from reaching the contamination sensitive portions of the device 200.

Therefore, in one embodiment of the present invention, the seal 280 would seal only a portion of such a device 200 allowing limited fluidic contact between collection layer 290 and absorbent medium 230. In one embodiment, collection layer 290 is an externally evaporative textile. In an advantageous aspect, the presence of a refreshable collection layer could prolong the usable lifetime of a device such as device 200. For example, a refreshable collection layer 290 would extend the usable lifetime of a device 200 in applications where high sweat rates exist during use of the device 200.

[0023] With reference to Fig. 3, the device 300 includes similar features as the devices 100, 200, except as otherwise described below. In that regard, similar reference numerals refer to similar features shown and described in connection with Figs. 1A, 1B, and 2. The device 300 includes an artificial sweat stimulation and sensing mechanism 345. In this regard, the mechanism 345 includes an iontophoresis electrode 350, a sweat stimulant 360, such as a pilocarpine gel, and a sensor 320 as shown in Fig. 3A. The sensor 320 is porous such that the sweat stimulant 360 may be administered to the skin 12 through the sensor 320 by iontophoresis to artificially stimulate sweating. With further reference to Fig. 3, the device 300 includes a layer 330 and a sweat impermeable material 370. Layer 330 may be, for example, a gel or a textile covering at least a portion of sweat impermeable material 370. With the exception of pathway 370a, sweat impermeable membrane 370 seals possible contamination-sensitive features of device 300 from fluid from an external source. In this configuration, the opening in the membrane 370, which may also be viewed as a one-way flow component, is usually in a closed position. The pathway 370a allows fluid to escape as excess sweat pressure builds up between the skin 12 and the sweat impermeable material 370. In alternate embodiments, the open position of the pathway 370a may be the default position, but these embodiments would require a mechanism to actively close the pathway 370a when there is a chance of external contaminants coming back through the valve. For example, such a mechanism may be triggered by an external moisture sensor. By way of example, the sweat impermeable material 370 may be a membrane, textile, or film. In one embodiment, material

370 is a polymer film and pathway 370a is loose flap that will open with sweat pressure but close or remain suitably constrictive to fluid flow when external fluid pressure is provided, for example by swimming, washing, or from other sweat on the body. Material 370 could utilize any substantially one-way flow mechanisms including one-way valve mechanisms known by those skilled in the art. In this configuration, the sweat stimulation and sensing mechanism 345 is covered by the sweat impermeable material 370. Protecting the mechanism 345 from outside contaminants is important because, for example, a pilocarpine source could become diluted if exposed to water while the wearer of the device is bathing or swimming. Those skilled in the art will recognize that embodiments may use a combination of aspects of the present invention.

[0024] Embodiments of the present invention may include a variety of sweat stimulation techniques. By way of example, sweat stimulation may be applied by chemical, electrical, heat, or other mechanisms. In an aspect of the present invention, an artificial sweat stimulation component can be applied externally to any sealed sensing device. In one embodiment, a sweat sensing device is applied to the skin, and sweat stimulation is applied to regions near the sensing device. In this manner, sweat is therefore provided to the sensing device by sudo-motor axon reflex sweating. Accordingly, embodiments of the present invention may not include an integrated sweat stimulation technique, which may decrease the cost, increase ergonomics, or provide some other advantage. In one embodiment where a sweat sensing device is a patch, the patch may need to be held against the skin for device security and compliance reasons, and sweat sensing may only be tested as needed, initiated by an external sweat stimulation method. Some sweat stimulating chemicals can induce sweating even several hours after the chemical is dosed into the skin. Sweat stimulation could be performed by a re-usable device that also applies a sweat sensing patch. For example, an application device could apply a sweat sensing patch to the skin while using iontophoresis to provide a dose of pilocarpine around the external edge of the patch. Those skilled in the art will recognize that other stimulation techniques external or internal to a sealed device are possible.

[0025] With reference to Fig. 4, in one embodiment, a device 400 includes a plurality of sensors 422, 424, 426 in direct contact with the skin 12. Device 400 further includes an adhesive 410, an absorbent medium 430, and electronics 440 carried by a substrate 414. In this embodiment, adhesive 410 seals the sensors 422, 424, 426 against the skin 12. Depending on the application, having sensors in direct contact with the skin may be

advantageous. Although not shown, device 400 may include other aspects of the present invention. Those skilled in the art will recognize that methods other than using adhesives to hold devices according to embodiments of the present invention against skin may be used, such as mechanical pressure or a strap, among other methods.

[0026] With reference to Fig. 5, in one embodiment, a device 500 includes a sensor 520 in electric communication with electronics 540. Device 500 is adhered to the skin 12 by an adhesive 510 and includes an absorbent medium 530. With the exception of regions 570a, 570b, the sensor 520 and electronics 540 are sealed by sweat impermeable materials 570, 572, respectively. The sweat impermeable materials 570, 572 may be, for example, a membrane, textile, coating, or film. In region 570a, the sensor 520 electrically contacts the electronics 540 through an interconnecting component 590. The component 590 provides a vertical electronic connection between the sensor 520 and the electronics 540, provides horizontal electrical insulation for the electronic connection, and provides a seal such that sweat does not come into contact with electronics 540 or any interconnection between electronics 540 and sensor 520. In this embodiment, component 590 could be a double-sided tape, or elastomeric interconnect, where the edges of the component 590 may contact sweat but do not conduct electricity in the horizontal direction therefore providing adequate electrical insulation and sealing of said electrical connection. In one embodiment of the present invention, the component 590 is a double-sided z-axis electrical tape (i.e., anisotropically conductive tape), such as a tape manufactured by 3M Corp. For example, the 3M Anisotropic Conductive Film can, along with impermeable materials 570, 572, seal the device 500 from sweat except where it is desirable for sweat to touch the device 500, such as the side of sensor 520 facing the skin 12 as indicated by 570b. In an alternate embodiment of the present invention, the component 590 could be an elastomeric interconnect, such as a ZEBRA connector sold by Fuji Polymer Industries Co. Such a component 590 or similar components can be referred to as a hermetically sealing and electrically interconnecting component. Seal 570 allows sweat to reach the sensor 520 surface at the region 570b without electrically shorting the sensor 520 or the electric connection through the component 590. In one embodiment, material 570 is a parylene coating applied to the exposed surfaces of the sensor 520 to electrically insulate the sensor 520, except for regions 570a, 570b. In this regard, the sensor 520 may be masked during parylene deposition by using, for example, a removable piece of adhesive tape such as Kapton tape. After removal of the tape, regions 570a, 570b of the sensor 520 are not coated by the material 570. Other sealants are possible

that can be selectively placed by area, as commonly used in electronics and printed circuit boards.

[0027] With reference to Fig. 6, in one embodiment, the device 600 includes similar features as the device 500, except as otherwise described below. In that regard, similar reference numerals refer to similar features shown and described in connection with Fig. 5. Device 600 includes a sensor 620 electrically connected to electronics 640 by a component 690. The sensor 620 and electronics 640 are sealed by sweat impermeable materials 670, 672, respectively. Device 600 is adhered to the skin 12 by an adhesive 610 and includes an absorbent medium 630. Seal 680 seals the device 600 against the adhesive 610 and, thus, the skin 12. Because electronics 640, which may include a battery, may be expensive, it is advantageous to configure the device 600 such that the electronics 640 may be reusable. In the illustrated embodiment, excepting electronics 640 and impermeable material 672, the remainder of the device 600 is disposable. Thus, in one aspect, one or more components of devices according to embodiments of the present invention may be disposable, refreshable, or reusable in any electrical, fluidic, chemical, or other useful manner. In one embodiment, the component 690 is a pressure sensitive adhesive that allows attachment of reusable electronics 640 and provides sealing as well. Device 600 further includes an optional adhesive 612, which aids in mechanically coupling the electronics 640 to the other components of the device 600. In one embodiment, electronics 640 could additionally include microfluidics or other lab-on-chip type features for sensing sweat or its solutes.

[0028] With further reference to Fig. 6, in alternate embodiments, the component 640 could contain both electronics and sensors or could contain no electronics at all and could be a reusable device for collecting sweat samples (e.g., contains fluidics) or a reusable device that provides other sensing methods (e.g., optical, colorimetric, or other suitable techniques) for sensing sweat or its solutes. In such embodiments, component 620 could therefore be a microfluidic sampling component, for example. Therefore, component 690 could provide a seal while also acting as an interconnecting component by providing a fluidic or microfluidic interconnection between elements 620 and 640. In this configuration, sweat could pass through component 620, through component 690 and into component 640. This again illustrates that more portions of the present invention may be disposable, refreshable, or reusable in any electrical, fluidic, chemical, or other useful manner, therefore element 690 can be more broadly referred to as a sealed and adhesive interconnect component.

[0029] In one aspect of the present invention, because many sensors and antennas (especially for RFID applications) or other electrical components are sensitive to impedance and sweat contact can change the electrical capacitance seen by such electrical components, impedance sensitive electrical components may be insulated. In one embodiment of the present invention, the impedance sensitive electrical components of a device are coated with an electrical insulator, the coating being at least 5 μm in thickness. In another embodiment, the impedance sensitive electrical components have an electrically insulating coating with a thickness of at least 50 μm . By way of example, the electrical insulator may be acrylic, silicone, or parylene. The electrical insulator minimizes any undesirable change in electrical capacitance as the device is placed adjacent to or wetted nearby by sweat.

[0030] Embodiments of the present invention may include sweat or sweat solute absorptive mediums that are reusable or refreshable. Such absorptive mediums useful in the present invention may include, for example, gels, charcoals, filters, textiles, and pouches. Using reusable or refreshable absorptive mediums may prolong usage of the device. In one embodiment, a device includes an absorbing medium that may be attached, detached, and reattached to the device. Such absorbing medium could be for example element 290 shown for device 200 in Fig. 2. Such an absorbing medium may be attached to a device using a variety of methods, such as using adhesives. Absorbing mediums may also be attached to a device using more rigid fixation methods, such as with a latch or a screw.

[0031] In one aspect of the present invention, components of a device, such as a sensor, are protected from possible contamination from the skin. Contaminants from the surface can also be thought of being ‘outside contaminants’ because the skin surface is outside the body and external to the sweat ducts which are the targeted source of analytes to be measured. In this regard, one or more solutes in sweat could foul the surface of, or degrade a sensor or other component. For example, oil from the skin could foul or degrade a sensor. Embodiments of the present invention may include a membrane or material that provides a seal and protects the components of the device that are susceptible to contamination. By way of example, a device may include, for example, a dialysis membrane or microfiltration membrane between newly generated sweat and the sensors. The membrane material may allow for selective solute transport between the skin and, for example, a sensor, which would narrow the range of solutes that reach the sensor. Such a sealing material with solute selective transport between the sensors and the skin could also be adhesive or be coated with

an adhesive. In one embodiment, this sealing material capable of solute selective transport may be represented as element 210 as shown in Fig. 2.

[0032] In another aspect of the present invention, a device includes an oil absorbing or oleoscopic material to seal or protect the sensors, or other oil-sensitive features of the device, from oil emerging from skin. For example, commercially available Imbiber Beads or the materials used in Imbiber Beads for oil cleanup applications can be incorporated between the skin and the sensors in several ways. In one embodiment, such beads may be embedded in the adhesive material 210 of Fig. 2. In this embodiment, the beads effectively form a seal against oil, while allowing sweat to flow through the material 210. In this regard, the seal provided by adhesive 210 is selectively permeable. Any such implementation of a method of protecting devices or sensors of the present invention from skin oil can be referred to as a device having a protecting material for oil from skin.

[0033] This has been a description of the present invention along with a preferred method of practicing the present invention, however the invention itself should only be defined by the appended claims.

WHAT IS CLAIMED IS:

1. A sweat sensor device comprising:
one or more sweat sensors; and
a seal covering said one or more sweat sensors, said seal adapted to protect said sweat sensors from outside contaminants when said device is placed on skin.
2. The device of claim 1, further comprising:
an absorbing medium to absorb sweat from the skin, said absorbing medium being covered by said seal.
3. The device of claim 2, wherein said seal is expandable.
4. The device of claim 2, wherein the absorbing medium is selectively attachable to the device and selectively detachable from the device.
5. The device of claim 1, wherein said seal is permeable to gas.
6. The device of claim 1, wherein said seal is permeable to liquid water and impermeable to at least one solute.
7. The device of claim 1, wherein said seal is selectively permeable to at least one aqueous solute.
8. The device of claim 1, wherein said seal is an adhesive.
9. The device of claim 1, further comprising:
a refreshable collection layer for collecting sweat and/or sweat solutes and configured to be refreshed where at least a portion of the collected sweat and/or sweat solutes is removed.
10. The device of claim 1, further comprising:
an artificial sweat stimulation mechanism for stimulating sweat when the device is placed on the skin.
11. The device of claim 10, wherein said artificial sweat stimulation mechanism is covered by said seal.
12. The device of claim 10, wherein said artificial sweat stimulation mechanism is external to said seal.

13. The device of claim 1, wherein said seal includes at least one one-way flow component for permitting a flow of sweat from the skin to pass through and for restricting a flow provided by an external source.
14. The device of claim 1, further comprising:
electronics in electronic communication with said one or more sweat sensors.
15. The device of claim 14, further comprising:
an interconnecting component for providing an electrical connection between said one or more sensors and said electronics and for sealing said electronics and said electrical connection from sweat.
16. The device of claim 15, wherein said sensors are generally coplanar and said interconnecting component conducting electricity perpendicular to said sensors.
17. The device of claim 14, wherein said electronics are selectively attachable to and selectively detachable from said device.
18. The device of claim 1, wherein at least one component of said device is sensitive to impedance and said impedance sensitive component includes an electrical insulator coating having a thickness of at least 5 μm .
19. A sweat sensor device comprising:
one or more sweat sensors; and
a membrane between said sweat sensor and skin, said membrane is effective to selectively transport one or more solutes from said sweat to said sweat sensor when the device is placed on the skin.
20. The device of claim 19, wherein said membrane protects said sweat sensor from oil on the skin.

21. A sweat sensor device comprising:
- a microfluidic sampling component; and
 - an interconnecting component providing a fluidic connection between said microfluidic sampling component and said one or more sensors,
 - said interconnecting component sealing said fluidic connection from external contaminants.

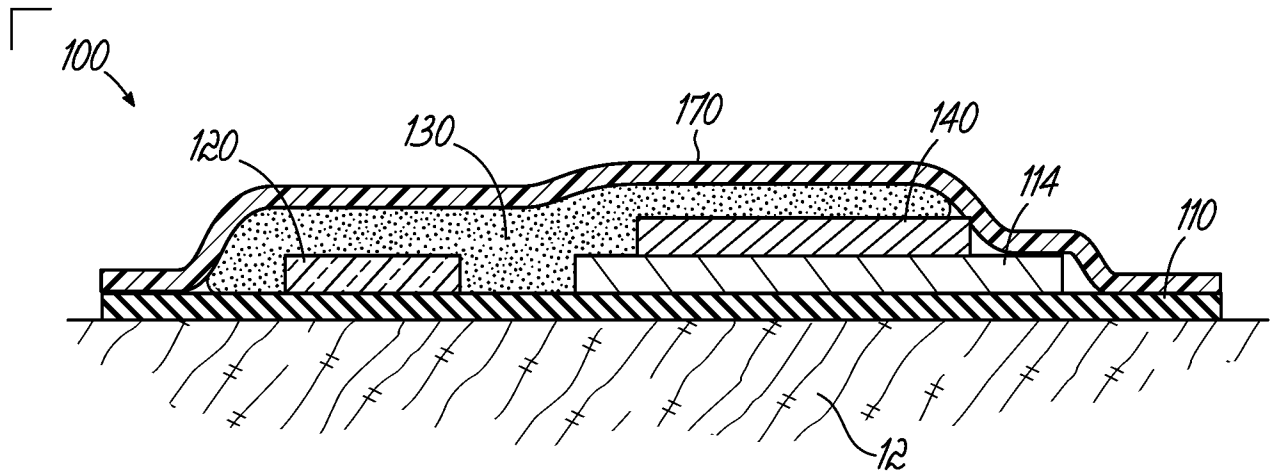


FIG. 1A

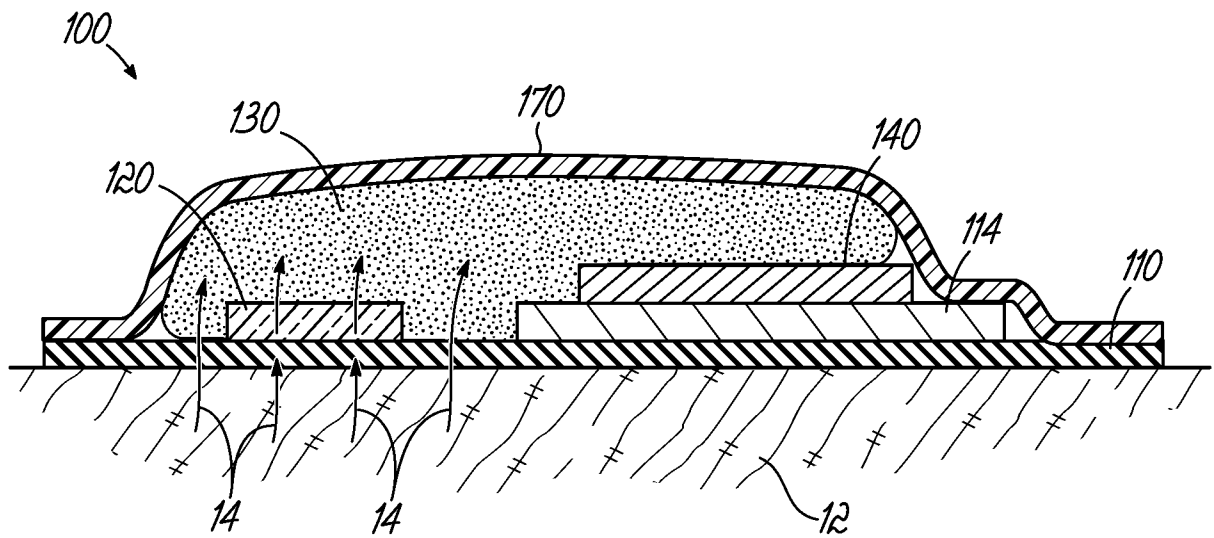


FIG. 1B

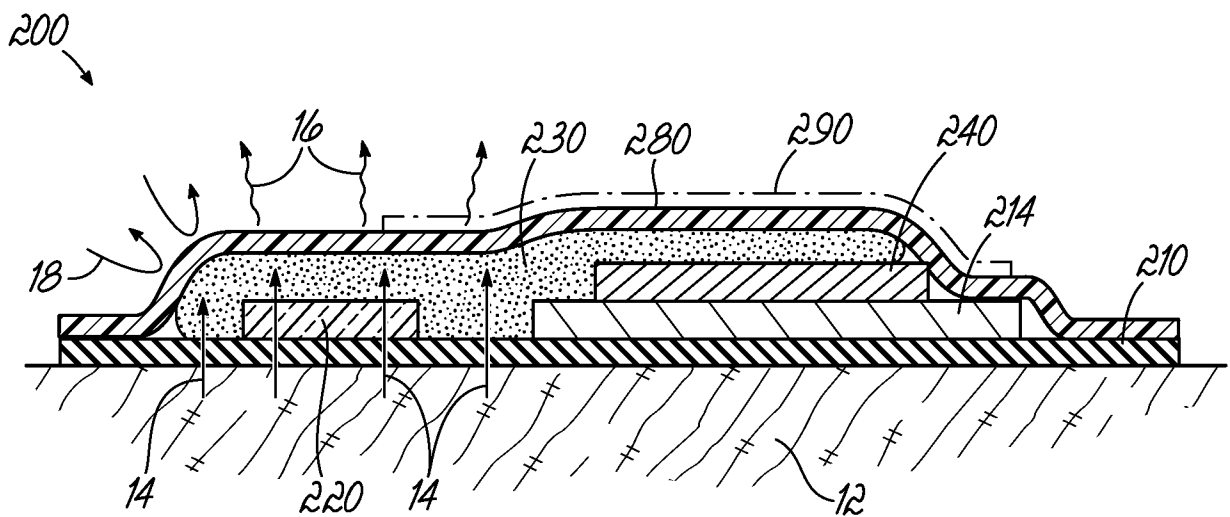


FIG. 2

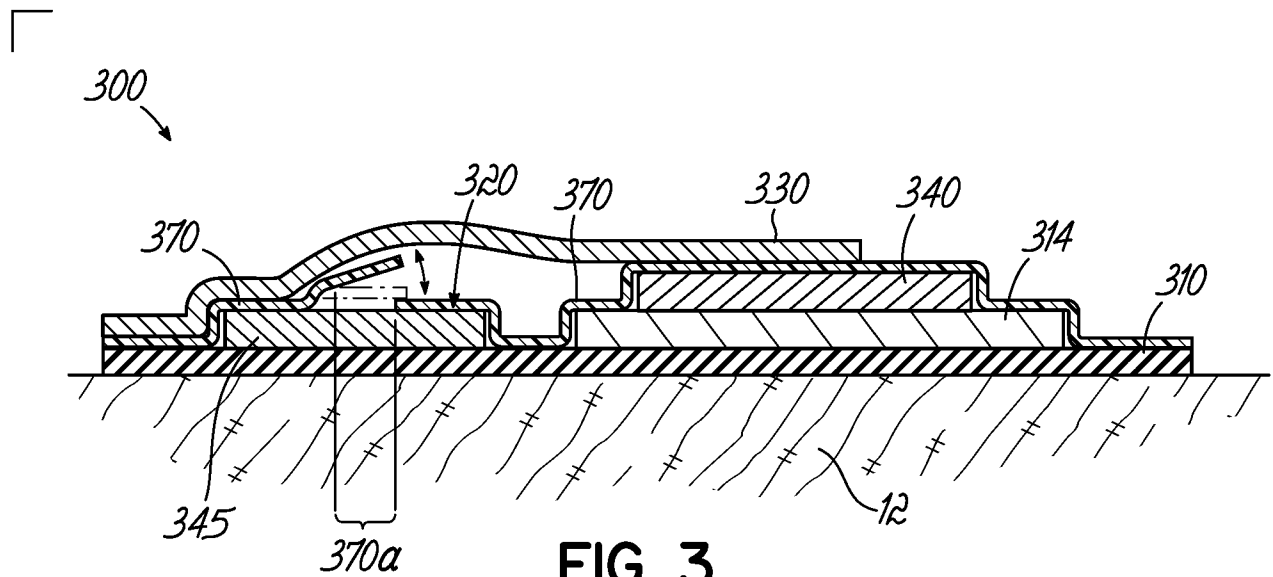


FIG. 3

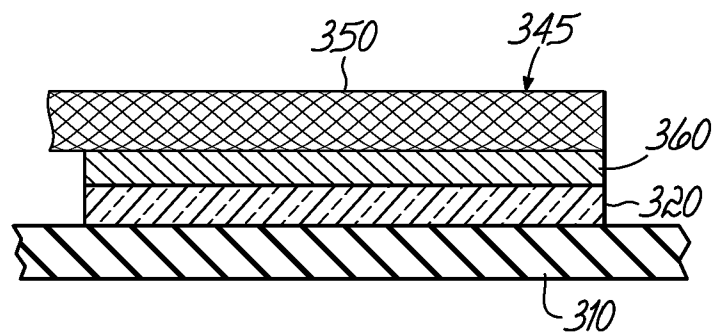


FIG. 3A

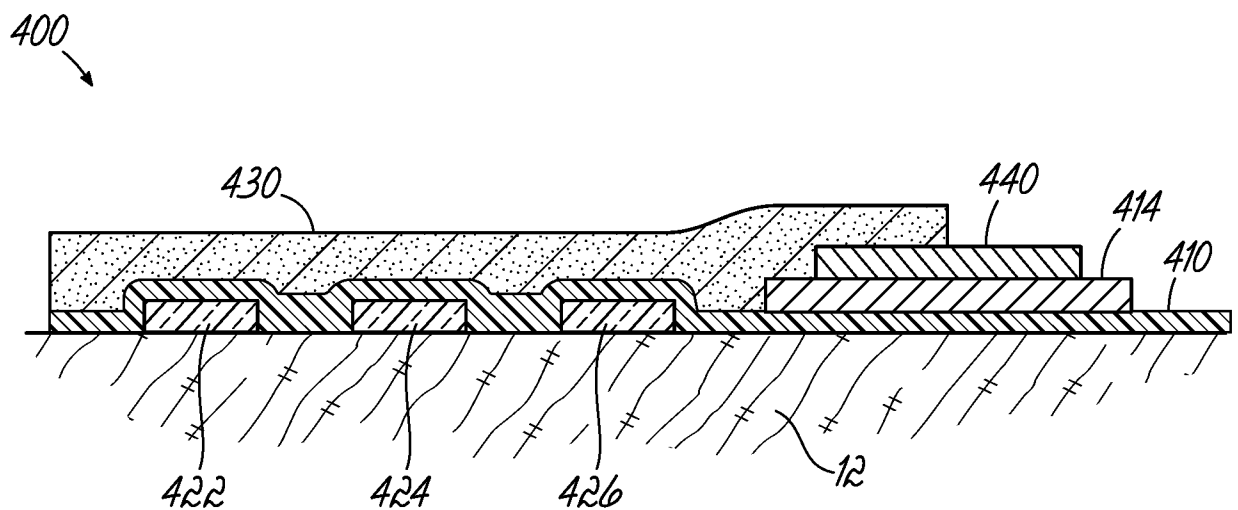


FIG. 4

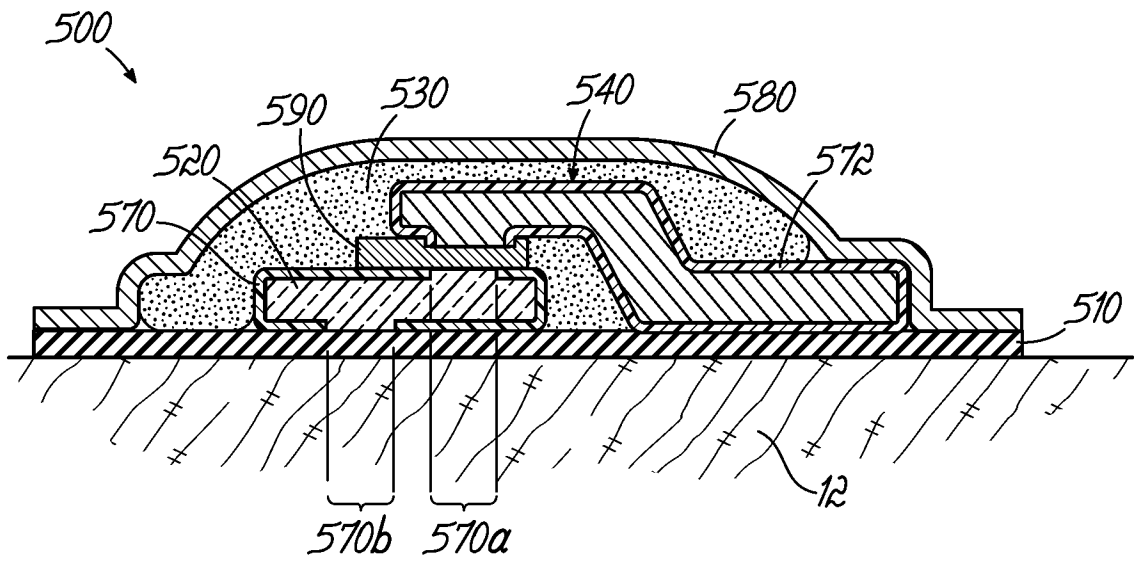


FIG. 5

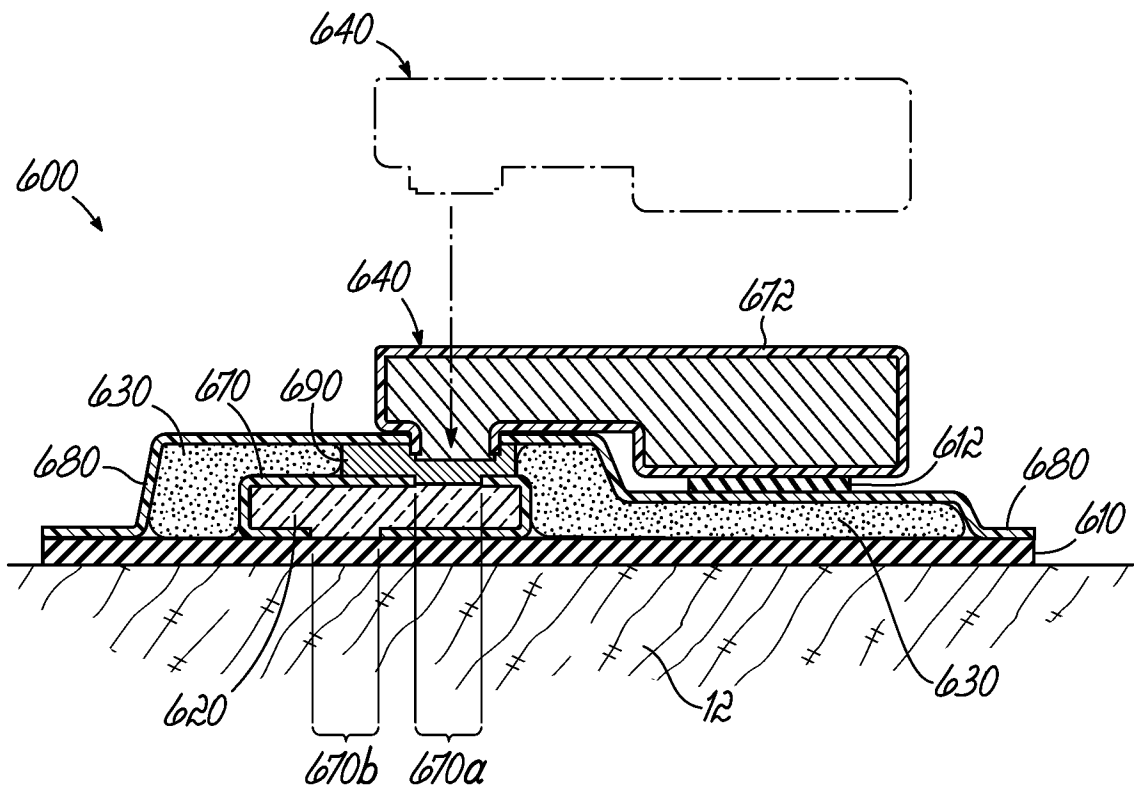


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 15/32843

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 5/05 (2015.01)

CPC - A61B 5/4266

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)
CPC: A61B 5/4266 IPC(8): A61B 5/05 (2015.01)Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 600/346, 307, 345, 348, 362
CPC: A61B 5/14521, 5/6832, 5/6833 (keyword limited; terms below)Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase; Google Patents; Google

Search Terms Used: sweat, perspiration, sens*, analy*, select*, transfer*, pass*, solute%, biomarker%, permea*, microfluidic, capillary, water, impedance, sensor, insulating coating, removable, replaceable, chip, sensor, electronics

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2013/152087 A2 (HAGEN et al) 10 October 2013 (10.10.2013) fig 6-9, para [0015], [0033]-[0038]	1-5, 7-16, 19-20
Y		6, 17-18
X	US 2007/0027383 A1 (PEYSER et al) 01 February 2007 (01.02.2007) fig 2B; para [0082], [0086]-[0087]	21
Y	US 2005/0197554 A1 (POLCHA) 08 September 2005 (08.09.2005) para [0043]	6
Y	US 2005/0069925 A1 (FORD et al) 31 March 2003 (31.03.2003) fig 1, para [0324]	17
Y	WO 2014/001577 A1 (BARBER et al) 03 January 2014 (03.01.2014) para [062], [090]	18

☐ Further documents are listed in the continuation of Box C.

* 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

28 September 2015 (28.09.2015)

Date of mailing of the international search report

23 OCT 2015

Name and mailing address of the ISA/US

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Lee W. Young

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PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 15/32843

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.:
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:
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 fees must be paid.

Group I: Claims 1-18, directed to a sweat sensor device having a seal covering one or more sensors.

Group II: Claims 19-20, directed to a sweat sensor device having a membrane between said sweat sensor and skin.

Group III: Claim 21, directed to a sweat sensor device having a microfluidic sampling component.

The inventions listed as Groups I-III 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:

---Continued on Supplemental Page---

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.:

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

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Continuation of Box III: Observations where unity of invention is lacking

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a seal covering said one or more sweat sensors, said seal adapted to protect said sweat sensors from outside contaminants when said device is placed on skin, not required by the claims of Groups II-III.

The invention of Group II includes the special technical feature of a membrane between said sweat sensor and skin, said membrane is effective to selectively transport one or more solutes from said sweat to said sweat sensor when the device is placed on the skin, not required by Groups I or III.

The invention of Group III includes the special technical feature of a microfluidic sampling component; and an interconnecting component, not required by the claims of Groups I-II.

COMMON TECHNICAL FEATURES

Groups I-III share the common technical features of a sweat sensor device having a sensor. However, these shared technical features fail to make a contribution over the prior art of WO 2013/152087 A2 to Hagen, et al. (hereinafter 'Hagen'), which teaches a sweat sensor device (abstract) having a sensor (98, fig 6-9, para [0037]-[0038]).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.