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(54) Title: BODY ADHERENT PATCH WITH ELECTRONICS FOR PHYSIOLOGIC MONITORING

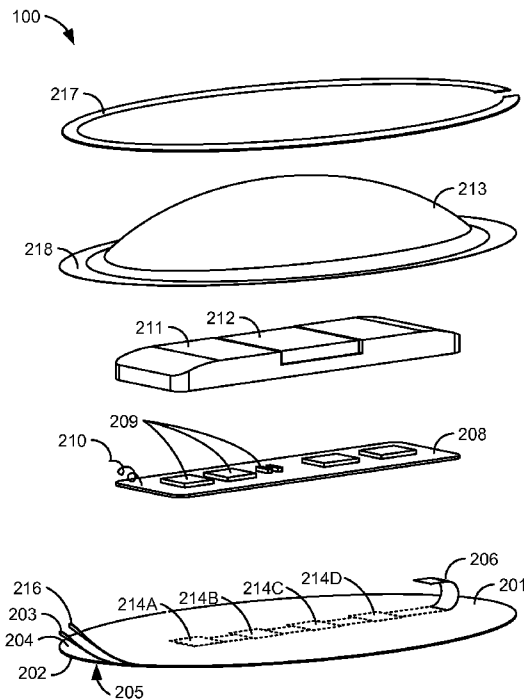


FIG. 2A

(57) Abstract: In one configuration, an adherent device to adhere to a skin of a subject includes a stretchable base layer having an upper side and a lower side and an adhesive coating on the lower side to adhere the base layer to the skin of the subject. The base layer has at least two openings extending therethrough, each of the at least two openings having a size. The adherent device also includes a stretchable covering layer positioned above and adhered to the base layer with an adhesive to define at least two pockets. The adherent device also includes at least two gels, each gel having a size larger than the size of openings to retain the gel substantially within the pocket, and a circuit carrier supported with the stretchable base layer to measure at least one physiologic signal of the subject. Other configurations and methods are also claimed.

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BODY ADHERENT PATCH WITH ELECTRONICS FOR PHYSIOLOGIC MONITORING

[0001] This application claims priority from provisional U.S. Patent Application No.

5 61/286,075, titled "Body Adherent Patch with Electronics for Physiologic Monitoring" and filed December 14, 2009, the entire disclosure of which is hereby incorporated by reference herein for all purposes.

BACKGROUND OF THE INVENTION

10 [0002] 1. Field of the Invention

[0003] The present invention relates to physiologic monitoring and/or therapy. Although embodiments make specific reference to monitoring impedance and electrocardiogram signals with an adherent device, the system methods and devices described herein may be applicable to many applications in which physiological monitoring and/or therapy is used for
15 extended periods, for example wireless physiological monitoring for extended periods.

[0004] Patients are often treated for diseases and/or conditions associated with a compromised status of the patient, for example a compromised physiologic status. In some instances, a patient may report symptoms that require diagnosis to determine the underlying cause. For example, a patient may report fainting or dizziness that requires diagnosis, in
20 which long term monitoring of the patient can provide useful information as to the physiologic status of the patient. In some instances a patient may have suffered a heart attack and require care and/or monitoring after release from the hospital. One example of a device to provide long term monitoring of a patient is the Holter monitor, or ambulatory electrocardiography device.

25 [0005] In addition to measuring heart signals with electrocardiograms, known physiologic measurements include impedance measurements. For example, transthoracic impedance measurements can be used to measure hydration and respiration. Although transthoracic measurements can be useful, such measurements may use electrodes that are positioned across the midline of the patient, and may be somewhat uncomfortable and/or cumbersome
30 for the patient to wear. In at least some instances, the electrodes that are held against the skin of the patient may become detached and/or dehydrated, such that the electrodes must be replaced, thereby making long term monitoring more difficult.

[0006] Work in relation to embodiments of the present invention suggests that known methods and apparatus for long term monitoring of patients may be less than ideal. In at least some instances, devices that are worn by the patient may be somewhat uncomfortable.

Although devices that adhere measurement electrodes and measurement circuitry to the skin with an adhesive can provide improved comfort, work in relation to embodiments of the present invention suggests that the adhesive of such devices can detach from the skin of the patient sooner than would be ideal. These limitations of current devices may lead to patients not wearing the devices as long as would be ideal and not complying with direction from the health care provider in at least some instances, such that data collected may be less than ideal.

[0007] Similar difficulties may arise in the monitoring of other subjects, such as persons in non-medical settings, or in the monitoring of animals such as veterinary, agricultural, or wild animal monitoring. Therefore, a need exists for improved subject monitoring. Ideally, such improved subject monitoring would avoid at least some of the short-comings of the present methods and devices. Ideally, such improved devices will allow an adherent device to be adhered to the skin of the subject with an adhesive so as to carry associated electronics comfortably with the skin of the subject for an extended period.

[0008] 2. Description of the Background Art

[0009] The following U.S. Patents and Publications may describe relevant background art: U.S. Pat. Nos. 3,170,459; 3,805,769; 3,845,757; 3,972,329; 4,141,366; 4,522,211; 4,669,480; 4,838,273; 5,133,355; 5,150,708; 5,450,845; 5,511,533; 5,607,454; 6,141,575; 6,198,955; 6,327,487; 6,795,722; 7,395,106; 2004/0006279; 2004/0015058; 2006/0264730; 2007/0106132; 2007/0208262; 2007/0249946; 2007/0255184; 2008/0171929; 2007/0276273; and 2009/0182204.

BRIEF SUMMARY OF THE INVENTION

[0010] In many embodiments, an adherent device to adhere to a skin of a subject comprises a stretchable base layer having an upper side and a lower side and an adhesive coating on the lower side to adhere the base layer to the skin of the subject. The base layer has at least two openings extending therethrough, each of the at least two openings having a size. The adherent device also comprises a stretchable covering layer positioned above and adhered to the base layer with an adhesive to define at least two pockets, and at least two gels, each gel having a size larger than the size of the at least two openings to retain said gel substantially within said pocket. The adherent device further comprises a circuit carrier supported with the stretchable base layer to measure at least one physiologic signal of the subject. The subject

may comprise a person, an athlete, a patient, or an animal such as a domesticated or a wild animal.

[0011] According to some embodiments, an adherent device to monitor a subject having a skin comprises a stretchable base layer having an upper side and a lower side and an adhesive coating disposed on the lower side to adhere the base layer to the skin of the subject. The base layer has at least two openings extending therethrough, each opening having a size. The adherent device further includes a flexible circuit support having at least two electrodes disposed thereon, each electrode positioned with a respective one of the at least two openings to couple to the skin of the subject. At least two gels are positioned with the at least two openings in the base layer, each gel having a size larger than the size of said each opening. The device also includes a stretchable covering layer positioned above the at least two gels and adhered to the base layer, such that each gel is constrained substantially within a corresponding pocket disposed between the base layer and the covering layer. The adherent device further includes a circuit carrier holding electronic components electrically connected to the at least one electrode with the flexible circuit support to measure at least one physiologic signal of the subject.

[0012] In some embodiments, each of the gels and each of the pockets is sized larger than a corresponding opening of the stretchable base layer to retain said gel in said pocket when the stretchable base layer is adhered to the skin of the subject. In some embodiments, the stretchable base layer comprises a thin, flexible, stretchable base layer to stretch with the skin of the subject and conform to folds of the skin of the subject. In some embodiments, the stretchable covering layer comprises a thin, flexible, stretchable covering layer to stretch with the skin of the subject and conform to folds of the skin of the subject. The adherent device may further include a thin, flexible, stretchable overlayer disposed above and adhered to the covering layer. The overlayer may be made of woven fabric.

[0013] In some embodiments, the adherent device further comprises a stiffening structure disposed over and coupled to a common perimeter of the base and covering layers and configured to stiffen the perimeter edges of the base and covering layers. The stiffening structure may be configured to be removable after the adherent device is adhered to the subject. In some embodiments, the adherent device further comprises a thin, flexible, stretchable overlayer disposed above and adhered to the covering layer, and the stiffening structure is disposed over and coupled to a common perimeter of the base and covering layers and the overlayer, and the stiffening structure is configured to stiffen the perimeter edges of the base and covering layers and the overlayer. The adherent device according to these

embodiments may further include a soft, flexible cover disposed over the circuit carrier and coupled at a common perimeter to the base and covering layers. The cover may comprise a material configured to inhibit liquids from reaching the electronic components. A perimeter of the cover may be disposed under the stiffening structure. In some embodiments, the
5 flexible circuit is configured to be stretchable.

[0014] In some embodiments, the flexible circuit is formed of a substantially non-stretchable material, and is geometrically configured to be stretchable. In some embodiments, the flexible circuit comprises a polyester base and traces formed of silver conductive ink. The flexible circuit may comprise a serpentine shape. The flexible circuit
10 may be disposed between the base layer and the covering layer.

[0015] In some embodiments, the adherent device further comprises a compliant connection between the circuit carrier and the base layer. In some embodiments, the combination of the base layer and the covering layer is breathable. The combination of the base layer and the covering layer may have a moisture vapor transmission rate of at least 100
15 g/m²/day.

[0016] According to some embodiments, an adherent device comprises a thin, flexible, stretchable base layer having an upper side and a lower side and an adhesive coating on the lower side. At least one electrode is affixed to the base layer and is capable of electrically coupling to the skin of a subject. A flexible circuit is connected to the at least one electrode,
20 and a circuit carrier holding electronic components is electrically connected to the at least one electrode via the flexible circuit and configured to measure at least one physiologic signal of the subject. The adherent device further includes a stiffening structure disposed over and coupled to a perimeter of the base layer and configured to stiffen the perimeter edge of the base layer. In some embodiments, the stiffening structure is configured to be removable
25 when the adherent device is adhered to the subject. The stiffening structure may be made from a vinyl sheet.

[0017] In some embodiments, the adherent device further comprises a thin, flexible, stretchable overlayer disposed above and adhered to the base layer, and the stiffening structure is disposed over and coupled to a common perimeter of the base layer and overlayer
30 and is configured to stiffen the perimeter edge of the base layer and overlayer. According to some embodiments, the adherent device further includes a gel patch under each electrode, and each gel patch enhances electrical conductivity between its respective electrode and the skin of the subject. The flexible circuit is configured to be stretchable.

[0018] In some embodiments, the adherent device further comprises a soft, flexible cover disposed over the circuit carrier and coupled at a perimeter to the base layer. The cover may comprise a material configured to inhibit liquids from reaching the electronic components. The lower side of the base layer is configured to adhere to the skin of a subject.

5 [0019] In some embodiments, the adherent device further comprises a thin, flexible, stretchable underlayer adhered to the lower side of the base layer, the underlayer configured to adhere to the skin of the subject. The combination of the base layer and underlayer may be breathable. The combination of the base layer and underlayer may have a moisture vapor transmission rate of at least 100 g/m²/day.

10 [0020] In some embodiments, the adherent device further comprises a gel patch under each electrode, and each gel patch enhances electrical conductivity between its respective electrode and the skin of the subject, and a perimeter of each gel patch is sandwiched between the base layer and the underlayer. In some embodiments, the underlayer comprises at least one opening through which electrical contact is made between the at least one
15 electrode and the skin of the subject. The adherent device may further include a compliant connection between the circuit carrier and the base layer.

[0021] According to some embodiments, an adherent device comprises a thin, flexible, stretchable base layer having an upper side and a lower side and an adhesive coating on the lower side. At least one electrode is affixed to the base layer and capable of electrically
20 coupling to the skin of a subject. A flexible circuit is connected to the at least one electrode, and is configured to stretch. The adherent device further includes a circuit carrier holding electronic components electrically connected to the at least one electrode via the flexible circuit and configured to measure at least one physiologic signal of the subject.

[0022] In some embodiments, the flexible circuit is formed of a substantially non-
25 stretchable material, and is geometrically configured to be stretchable. In some embodiments, the flexible circuit comprises a polyester base and traces formed of silver conductive ink. The flexible circuit may comprise a serpentine shape. The flexible circuit may comprise a sawtooth shape.

[0023] In some embodiments, the adherent device further comprises gel patch under each
30 electrode, and each gel patch enhances electrical conductivity between its respective electrode and the skin of the subject. In some embodiments, the base layer is configured to adhere to the skin of the subject, and the adherent device further comprises a thin, flexible, stretchable overlayer disposed above and adhered to the base layer. In some embodiments,

the adherent device further comprises a thin, flexible, stretchable underlayer disposed below and adhered to the base layer, and the underlayer is configured to adhere to the skin of the subject. In some embodiments the adherent device further comprises a stiffening structure disposed over and coupled to a perimeter of the base layer and configured to stiffen the perimeter edge of the base layer. The adherent device may comprise a compliant connection
5 between the circuit carrier and the base layer.

[0024] According to some embodiments, an adherent device to monitor a subject having a skin comprises a stretchable base layer having an upper side and a lower side and an adhesive coating on the lower side to adhere the base layer to the skin of a subject. The base layer has
10 at least two openings extending therethrough, each of the at least two openings having a size. A stretchable covering layer is positioned above and adhered to the base layer with an adhesive to define at least two pockets. The adherent device further comprises a flexible circuit support that includes a first portion and a second portion, the first portion of the support adhered between the stretchable base layer and the stretchable covering layer, the
15 second portion extending from the first portion. At least two electrodes are disposed on the first portion of the flex circuit support. The adherent device further includes at least two gels, and each gel and each electrode are positioned within a corresponding pocket, each gel having a size larger than the size of the respective opening to retain said gel substantially within said pocket between the base layer and the covering layer. The adherent device
20 further includes a circuit carrier supported with the stretchable base layer, the circuit carrier holding electronic components electrically connected to the at least two electrodes with the second portion of the flexible circuit support to relieve strain when the stretchable base layer stretches with the skin of the subject, the electronic components configured to measure at least one physiologic signal of the subject.

[0025] According to some embodiments, a method of manufacturing an adherent device to adhere to a skin of a subject comprises providing a stretchable base layer having an upper side and a lower side and an adhesive coating on the lower side to adhere the base layer to the skin of a subject. The base layer has at least two openings extending therethrough, each of the at least two openings having a size. The method further comprises providing a flexible
30 circuit support having at least two electrodes and traces of electrically conductive material disposed thereon, providing at least two gels, and providing a stretchable covering layer. The method further comprises positioning the flexible circuit support and at least two gels between the stretchable base layer and the stretchable covering layer, and adhering the stretchable base layer to the stretchable covering layer to form at least two pockets, wherein

each pocket has one of the at least two gels and one of the electrodes disposed therein. The method also includes coupling a circuit carrier to the at least two electrodes with the flexible circuit support.

5 [0026] According to some embodiments, a method of monitoring a patient having a skin comprises adhering a stretchable base layer affixed to a stretchable covering layer to the skin of the patient. The stretchable base layer and the stretchable covering layer define a plurality of pockets with gels and electrodes disposed therein and the electrodes are coupled to the skin with the gels disposed in the pockets. The method further comprises measuring signals from the electrodes to monitor the patient.

10 [0027] According to some embodiments, an adherent device to adhere to a skin of a subject comprises means for adhering to a skin of a subject, and a circuit carrier means coupled to the means for adhering to measure at least one physiologic signal of the subject.

[0028] Other embodiments are also described and claimed.

15 BRIEF DESCRIPTION OF THE DRAWINGS

[0029] Figure 1 shows a patient and a monitoring system comprising an adherent device, in accordance with embodiments of the present invention.

[0030] Figure 2A shows a partial exploded perspective view of an adherent device as in Figure 1, in accordance with embodiments of the invention.

20 [0031] Figure 2B illustrates an exploded view of a support patch, according to embodiments of the invention.

[0032] Figure 2C shows a bottom view of the support patch of Figure 2B.

[0033] Figure 3 shows a flexible circuit that is configured to be stretchable, in accordance with embodiments of the invention.

25 [0034] Figure 4 illustrates a compliant connection between a circuit carrier and a base layer, in accordance with embodiments of the invention.

[0035] Figure 5 illustrates an exploded view of an adherent device in accordance with additional embodiments of the invention.

30 [0036] Figure 6 illustrates an exploded oblique view of an adherent device in accordance with additional embodiments of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0037] Embodiments of the present invention relate to subject monitoring and/or therapy.

Although embodiments make specific reference to monitoring impedance and

5 electrocardiogram signals with an adherent device, the system methods and device described herein may be applicable to any application in which physiological monitoring and/or therapy is used for extended periods, for example wireless physiological monitoring for extended periods.

[0038] Embodiments of the present invention can be particularly well suited for use with an

10 adherent device that comprises a support, for example a patch that may comprise stretchable tape, such that the support can be configured to adhere to the subject and support the

electronics and sensors on the subject. The support may also be porous and breathable so as to allow water vapor transmission, for example as described U.S. Pat. Pub. No.

2009/0076363, the full disclosure of which is incorporated herein by reference and suitable

15 for combination in accordance with some embodiments of the present invention described herein. The adherent device may comprise a cover and electronic components disposed on a carrier coupled to the support so as to provide strain relief, such that the support can stretch and flex with the skin of the subject. The embodiments described herein can be particularly useful to inhibit motion of the electronics circuitry carrier when the support stretches and

20 flexes, so as to decrease localized loading of the support that may contribute to peeling.

When forces are localized near an edge of the adherent device, for example when the carrier moves against a cover, the localized forces may cause peeling near the edge, and the embodiments described herein can inhibit such localized forces with a compliant structure that inhibits motion of the carrier relative to the support and also allows the support to stretch.

25 [0039] **Figure 1** shows an example subject, patient **P**, and a monitoring system **10**. Patient **P** comprises a midline **M**, a first side **S1**, for example a right side, and a second side **S2**, for example a left side. Monitoring system **10** comprises an adherent device **100**. Adherent device **100** can be adhered to a patient **P** at many locations, for example thorax **T** or arm **A** of patient **P**. In many embodiments, the adherent device may adhere to one side of the patient,

30 from which side data can be collected. Work in relation with embodiments of the present invention suggests that location on a side of the patient can provide comfort for the patient while the device is adhered to the patient.

[0040] Monitoring system **10** includes components to transmit data to a remote center **106**.

Remote center **106** can be located in a different building from a subject such as patient **P**, for

example in the same town as the subject, and can be located as far from the subject as a separate continent from the subject, for example the subject located on a first continent and the remote center located on a second continent. Adherent device **100** can communicate wirelessly to an intermediate device **102**, for example with a single wireless hop from the adherent device on the subject to the intermediate device. Intermediate device **102** can communicate with remote center **106** in many ways, for example with an internet connection and/or with a cellular connection. In many embodiments, monitoring system **10** comprises a distributed processing system with at least one processor comprising a tangible medium on device **100**, at least one processor on intermediate device **102**, and at least one processor **106P** at remote center **106**, each of which processors can be in electronic communication with the other processors. At least one processor **102P** comprises a tangible medium **102T**, and at least one processor **106P** comprises a tangible medium **106T**. Remote processor **106P** may comprise a backend server located at the remote center. Remote center **106** can be in communication with a health care provider **108A** with a communication system **107A**, such as the Internet, an intranet, phone lines, wireless and/or satellite phone. Health care provider **108A**, for example a family member, can be in communication with patient **P** with a communication, for example with a two way communication system, as indicated by arrow **109A**, for example by cell phone, email, landline. Remote center **106** can be in communication with a health care professional, for example a physician **108B**, with a communication system **107B**, such as the Internet, an intranet, phone lines, wireless and/or satellite phone. Physician **108B** can be in communication with patient **P** with a communication, for example with a two way communication system, as indicated by arrow **109B**, for example by cell phone, email, landline. Remote center **106** can be in communication with an emergency responder **108C**, for example a 911 operator and/or paramedic, with a communication system **107C**, such as the Internet, an intranet, phone lines, wireless and/or satellite phone. Emergency responder **108C** can travel to the patient as indicated by arrow **109C**. Thus, in many embodiments, monitoring system **10** comprises a closed loop system in which patient care can be monitored and implemented from the remote center in response to signals from the adherent device.

[0041] In many embodiments, the adherent device may continuously monitor physiological parameters, communicate wirelessly with a remote center, and provide alerts when necessary. The system may comprise an adherent patch, which attaches to the subject's thorax and contains sensing electrodes, battery, memory, logic, and wireless communication capabilities. In some embodiments, the device can communicate with the remote center, via the intermediate device in the subject's home. In some embodiments, the remote center **106**

receives the patient data and applies a patient evaluation and/or prediction algorithm. When a flag is raised, the center may communicate with the patient, hospital, nurse, and/or physician to allow for therapeutic intervention, for example to prevent decompensation.

[0042] In many embodiments, the adherent device may comprise a reusable electronics module with replaceable patches, and each of the replaceable patches may include a battery. The module may collect cumulative data for approximately 90 days and/or the entire adherent component (electronics+patch) may be disposable. In a completely disposable embodiment, a "baton" mechanism may be used for data transfer and retention, for example baton transfer may include baseline information. In some embodiments, the device may have a rechargeable module, and may use dual battery and/or electronics modules, wherein one module **101A** can be recharged using a charging station **103** while the other module **101B** is placed on the adherent patch with connectors. In some embodiments, the intermediate device **102** may comprise the charging module, data transfer, storage and/or transmission, such that one of the electronics modules can be placed in the intermediate device for charging and/or data transfer while the other electronics module is worn by the subject.

[0043] System **10** can perform the following functions: initiation, programming, measuring, storing, analyzing, communicating, predicting, and displaying. The adherent device may contain a subset of the following physiological sensors: bioimpedance, respiration, respiration rate variability, heart rate (ave, min, max), heart rhythm, heart rate variability (hereinafter "HRV"), heart rate turbulence (hereinafter "HRT"), heart sounds (e.g. S3), respiratory sounds, blood pressure, activity, posture, wake/sleep, orthopnea, temperature/heat flux, and weight. The activity sensor may comprise one or more of the following: ball switch, accelerometer, minute ventilation, HR, bioimpedance noise, skin temperature/heat flux, BP, muscle noise, posture. Additional details about the use of an adherent patch to measure particular physiologic signals may be found in co-pending U.S. patent applications 12/209,273 (publication 2009/0076363) and 12/209,288 (publication 2009/0076345), both filed on September 12, 2008 and titled "Adherent Device with Multiple Physiologic Sensors"

[0044] The adherent device can wirelessly communicate with remote center **106**. The communication may occur directly (via a cellular or Wi-Fi network), or indirectly through intermediate device **102**. Intermediate device **102** may consist of multiple devices, which can communicate wired **104** or wirelessly to relay data to remote center **106**.

[0045] In many embodiments, instructions are transmitted from remote site **106** to a processor supported with the adherent patch on the subject, and the processor supported with the subject can receive updated instructions for the subject treatment and/or monitoring, for example while worn by the subject.

5 [0046] In order for complete and reliable data to be gathered by system **10**, and for optimal subject comfort, it is desirable that adherent device **100** remain securely attached to subject for a predetermined period of time, for example one week, or two weeks or more. If adherent device **100** becomes dislodged prematurely, such that one or more of the sensing electrodes no longer makes secure contact with the subject's skin, valuable medical or other data may be
10 lost. For example, a dislodged adherent device **100** may also need to be replaced, causing discomfort for a patient, inconvenience for medical personnel, and unwanted expense.

[0047] Various adhesion failure mechanisms have been noted. Normal subject activity may result in adherent device **100** being stretched, bumped, jostled, or otherwise moved in a way that tends to stress the adhesive joint with the subject's skin. This may be especially true
15 for an adherent device that is worn for a long period of time, during which the subject may wish to carry on normal activities, including exercise, bathing, and the like. The edges of the support patch may be especially prone to separation from the skin, and may form pathways for ingress of moisture, which can accelerate the deterioration of the adhesive bond between the adherent device and the skin. The difficulty of maintaining a secure bond to the subject's
20 skin may be further exacerbated as it becomes desirable to add new features and capabilities to a device such as adherent device **100**. For example, in order to extend the working life of adherent device **100** or to provide sophisticated features, it may be desirable to include a battery having considerable weight, and additional electronics or packaging as compared with previous designs. The combined weight of the battery and electronics may be as much as 60
25 grams or more, such that jostling of the unit may impart significant inertial loads on the bond with the subject's skin. In addition, the position of the adherent device may affect the durability of the adhesive bond with the subject's skin. For example, especially useful electrocardiogram readings may be obtained by a device placed between a patient's left clavicle and left nipple. However, this area is also prone to stretching, and may present a
30 difficult site for long-term adhesion. Even if an alternative site is used, for example along the patient's rib line, enhanced adhesion durability is desirable.

[0048] In addition to the medical setting described above, embodiments of the present invention may also be used in non-medical settings, and on subjects other than human medical patients. For example, an adherent device according to embodiments of the

invention may be used to monitor the heart rate or other data of an athlete during exercise. In another setting, an adherent device according to embodiments of the invention may be used to monitor an animal for agricultural research, veterinary medical testing or treatment, or other purposes. For the purposes of this disclosure, a subject is any human or animal to which an adherent device according to embodiments of the invention may be adhered, for any purpose. While certain example uses of adherent devices are described herein in relation to monitoring or treatment of a medical patient, the appended claims are not so limited.

Whatever the setting or subject, embodiments of the present invention provide improved durability of the adhesive bond between the adherent device and the subject's skin, as compared with prior adherent devices.

[0049] **Figure 2A** shows a partial exploded perspective view of adherent device **100** as in Figure 1, in accordance with embodiments of the invention. Adherent device **100** comprises a support patch **201**, which may further comprise a base layer **202** and a covering layer **203**. Base layer **202** is stretchable, and has an upper side **204** and a lower side **205**, and an adhesive coating on lower side **205** to adhere base layer **202** to the skin of a subject.

Covering layer **203** is also stretchable, and is positioned above and adhered to base layer **202**.

Figure 2B illustrates an exploded view of support patch **201**, according to embodiments of the invention. As is best seen in Figure 2B, a flexible circuit **206** includes at least two electrodes, for example electrodes **207A**, **207B**, **207C**, and **207D** that during use are in electrical contact with the skin of the subject. Flexible circuit **206** may also sometimes be called a flexible circuit support. Flexible circuit **206** electrically connects electrodes **207A**, **207B**, **207C**, and **207D** to a circuit carrier **208**, which holds electronic components **209** configured to measure at least one physiologic signal of the subject. Electronic components **209** may include an antenna **210** so that adherent device **100** can communicate its readings for remote monitoring. Circuit carrier **208** may be mechanically connected to and supported by base layer **202** by any suitable means, including those discussed in more detail below.

[0050] Adherent device **100** may further comprise a housing **211** that fits over electronic components **209**, providing protection, insulation, and cushioning for electronic components **209**. Housing **211** may further include features for holding a battery **212**. Housing **211** may be made, for example of a soft silicone rubber. In other embodiments, housing **211** may comprise an encapsulant over electronic components **209** and circuit carrier **208**. Housing **211** may provide protection of electronic components **209** from moisture.

[0051] Adherent device **100** may also comprise a cover **213** adhered to support patch **201**. Cover **213** may comprise any known biocompatible cover, casing and/or housing materials,

such as elastomers, for example silicone. The elastomer may be fenestrated to improve breathability. In some embodiments, cover **213** may comprise other breathable materials, for example a cloth including polyester, polyamide, nylon and/or elastane (Spandex™). The breathable fabric may be coated or otherwise configured to make it water resistant, waterproof, for example to aid in wicking moisture away from the patch, or to inhibit liquids from reaching electronic components **209**.

[0052] While adherent device **100** is shown as generally oblong and having a length of about two to three times its width, this is not a requirement. One of skill in the art will recognize that other shapes are possible for an adherent device according to embodiments of the invention. For example, support patch **201** could be round, elliptical or oblong with a length only slightly larger than its width, square, rectangular, or some other shape. And while electrodes **207A**, **207B**, **207C**, and **207D** are illustrated as being arranged linearly, this is also not a requirement. One of skill in the art will recognize that electrodes **207A**, **207B**, **207C**, and **207D** could be arranged in any pattern suitable for the intended use of adherent device **100**, including in a circular, oblong, square, rectangular, or other pattern.

[0053] Referring again to Figure 2B, base layer **202** includes at least two openings, in this case four openings **215A**, **215B**, **215C**, and **215D**, each corresponding to one of electrodes **207A**, **207B**, **207C**, and **207D**. Each opening is of a certain size. Gels **214A**, **214B**, **214C**, and **214D** are placed at the openings, between base layer **202** and covering layer **203**. Each of gels **214A**, **214B**, **214C**, and **214D** comprises a hydrogel patch of electrically conductive gel material that enhances electrical conductivity between its respective electrode and the skin of the subject. For example, the gels **214A**, **214B**, **214C**, and **214D** may be made of hydrogel adhesive 9880 available from the 3M Company of St. Paul, Minnesota, USA, or another suitable material.

[0054] Each of gels **214A**, **214B**, **214C**, and **214D** is larger than its respective opening **215A**, **215B**, **215C**, or **215D**, such that when covering layer **203** and base layer **202** are adhered together, a pocket is formed over each of openings **215A**, **215B**, **215C**, and **215D**, with one of gels **214A**, **214B**, **214C**, and **214D** retained in each respective pocket.

[0055] Preferably, base layer **202**, covering layer **203**, or both are thin, flexible, and stretchable to stretch with the skin of the subject and conform to folds of the skin of the subject. For example, either or both of these layers may be made of MED 5021 polyurethane film available from Avery Dennison Corporation of Pasadena, California, USA, or

Tegaderm™ film available from the 3M Company of St. Paul, Minnesota, USA. Other suitable materials may be used.

[0056] In some embodiments, support patch **201** may further include an overlayer **216** disposed above and adhered to covering layer **203**. Overlayer **216** is also preferably thin, flexible, and stretchable. For example, overlayer **216** may be made of a woven fabric.

[0057] Referring again to Figure 2A, gels **214A**, **214B**, **214C**, and **214D** are preferably placed under covering layer **203** (and overlayer **216**, if present). Flexible circuit **206** may also be positioned under covering layer **203**, as indicated by the broken line depiction of part of flexible circuit **206** in Figure 2B. Gels **214A**, **214B**, **214C**, and **214D** may thus be retained in pockets between base layer **202** and covering layer **203**.

[0058] Adherent device **100** may further comprise a stiffening structure such as stiffening structure **217** shown in Figure 2A. In this example embodiment, stiffening structure **217** is configured to adhere to the top of cover **213**, at an outer area **218** of cover **213**. As assembled, stiffening structure **217** is then coupled to a common perimeter of the base and covering layers, so that the perimeter edges of the base and covering layers are stiffened, for example to prevent curling or unintentional adhesion of the lower side **205** of base layer **202** to itself. Stiffening structure **217** may be made of a material that is stiffer than the materials used in base patch **201**, but still compliant enough to allow base patch **201** to conform to the subject's skin as the patch is adhered to the skin. For example, stiffening structure **217** may be made from a vinyl sheet. Stiffening structure **217** may also be configured to be removable after adherent device **100** is adhered to the subject's skin. For example, stiffening structure **217** may include an adhesive configured to hold stiffening structure **217** in place during application of adherent device **100** to the subject, but to release easily without dislodging adherent device **100** from the subject's skin. In this way, stiffening structure **217** may aid in achieving a secure adhesion of adherent device **100** to the subject, but not interfere with the ability of support patch **201** to conform to wrinkles, folds, and other movements of the subject's skin while adherent device **100** is worn.

[0059] Figure 2C shows a bottom view of support patch **201**, with bottom lower side **205** of base layer **202** visible. Also visible are openings **215A**, **215B**, **215C**, and **215D**, exposing portions of gels **214A**, **214B**, **214C**, and **214D**. Other portions of gels **214A**, **214B**, **214C**, and **214D** are behind base layer **202**, in pockets formed between base layer **202** and covering layer **203**.

[0060] In some embodiments, flexible circuit **206** may be made of a flexible material such as polyimide, polyester, or another base material, having circuit traces formed in or on the base material. The circuit traces may be, for example, made of copper, a copper alloy, silver ink, or another conductive material. In one preferred embodiment, flexible circuit **206**

5 comprises a polyester base and traces formed of silver conductive ink. In some embodiments, flexible circuit **206** may be configured to be stretchable, as well as flexible. Even if the material of the flexible circuit **206** is not inherently stretchable, the flexible circuit may be made effectively stretchable by properly configuring its geometric shape. For example, at least the portion of flexible circuit **206** in contact with support patch **201** may have a
10 serpentine shape that allows support patch **201** to stretch and conform itself to the skin of the subject to which adherent device **100** is adhered, without being unduly constrained by flexible circuit **206**. A flexible circuit **206A** having this characteristic is shown in **Figure 3**. Other configurations may be used as well. For example, flexible circuit **206A** may have a sawtooth shape, or another shape that enables stretching of the flexible circuit **206A**.

15 [0061] As was mentioned previously, circuit carrier **208** may have a compliant connection to base layer **202**. One exemplary kind of compliant connection is illustrated in **Figure 4**. In this connection, bridging loops **401A**, **401B**, **401C**, and **401D** connect from support patch **201** (which includes base layer **202**) to circuit carrier **208**. Loops **401A**, **401B**, **401C**, and **401D** may be made, for example, of a plastic reinforced paper, a plastic film, a fabric, metal,
20 or any other suitable material. Preferably, loops **401A**, **401B**, **401C**, and **401D** permit relatively free rotation of circuit carrier **208** about the X and Y axes illustrated in **Figure 4**, but constrain the rotation of circuit carrier **208** about the Z axis. Because each of loops **401A**, **401B**, **401C**, and **401D** connects to support patch **201** at an inner portion **402** rather than at an outer portion **403** of support patch **201**, loads imparted to support patch **201** tend not to
25 disturb the vulnerable perimeter of support patch **201**, where detachment from the subject's skin is especially likely to start. More detail about compliant connections between circuit carrier **208** and base layer **202** may be found in copending provisional U.S. patent application 61/241,713, filed September 11, 2009 and titled "Electronics Integration in Adherent Patch for Physiologic Monitoring", the entire disclosure of which is hereby incorporated by
30 reference for all purposes.

[0062] In some embodiments, base layer **202**, covering layer **203**, or their combination may be breathable. For example, the combination of base layer **202** and covering layer **203** may have a moisture vapor transmission rate of at least 100 g/m²/day.

[0063] **Figure 5** illustrates an exploded view of an adherent device **500** in accordance with additional embodiments of the invention. Adherent device **500** includes several components similar to those in adherent device **100**, and similar components are given the same reference numbers in Figure 5. Adherent device **500** may include different combinations of layers than adherent device **100**.

[0064] Adherent device **500** comprises a support patch **501** that includes a base layer **502**. Base layer **502** has an upper side **504** and a lower side **505**. Lower side **505** includes an adhesive coating. At least one electrode, in this example four electrodes **207A**, **207B**, **207C**, and **207D** are affixed to base layer **502** and connected to flexible circuit **206**. Besides being flexible, flexible circuit **206** may also be configured to be stretchable, for example due to its geometric configuration. In some embodiments, a portion of flexible circuit **206** may have a serpentine or sawtooth shape. Circuit carrier **208** holds electronic components **209**, which may include an antenna **210**. Electronic components **209** are electrically connected to electrodes **207A**, **207B**, **207C**, and **207D** and are configured to measure at least one physiologic signal of a subject to which adherent device **500** is adhered.

[0065] A stiffening structure **217** may be disposed over and coupled, directly or indirectly, to a perimeter area of base layer **502**, to stiffen the perimeter edge of base layer **502**. In some embodiments, a cover **213** is disposed over circuit carrier **208** and coupled at a perimeter **218** to base layer **502**. In that case, stiffening structure **217** is disposed over and coupled to cover **213**, and is therefore indirectly coupled to base layer **502**. Cover **213** is preferably soft and flexible, and may be made of a material configured to inhibit liquids from reaching electronic components **209**.

[0066] Similarly, in some embodiments, an overlayer **503** may be disposed above and adhered to base layer **502**. Overlayer **503** is preferably thin, flexible, and stretchable, and may be made of a woven cloth or another suitable material. When overlayer **503** is present, stiffening structure **217** is also disposed over and coupled to the perimeter of overlayer **503**, and stiffens at least the perimeter edges of the base layer and overlayer. All of the layers of a support patch such as support patch **501** or support patch **201** may be coextensive, having their edges aligned as was shown in Figure 2C. Alternatively, one or more layers in a support patch may not be coextensive with the others. For example, overlayer **503** is slightly smaller than base layer **502**, so that the edges of base layer **502** extend beyond the edges of overlayer **503**. This arrangement may further reduce the stresses on the edge of base layer **502**, thus promoting long adhesion to the subject to which adherent device **500** is adhered. This arrangement may be used in any of the embodiments described herein.

[0067] Adherent device **500** may comprise one or more gel patches **214A**, **214B**, **214C**, and **214D**, one gel disposed under each of electrodes **207A**, **207B**, **207C**, and **207D**. Gel patches **214A**, **214B**, **214C**, and **214D** enhance electrical conductivity between electrodes **207A**, **207B**, **207C**, and **207D** and the skin of a subject to which adherent device **500** is adhered.

5 [0068] In some embodiments, lower side **505** of base layer **502** is configured to adhere to the skin of a subject. In that configuration, gel patches **214A**, **214B**, **214C**, and **214D** are captured between base layer **502** and the subject's skin. Optionally, an underlayer **506** may be provided, adhered to lower side **505** of base layer **504**, and configured to adhere to the skin of a subject. Preferably, underlayer **506** is also thin, flexible, and stretchable. For example,
10 base layer **202**, underlayer **506**, or both may be made of MED 5021 polyurethane film available from Avery Dennison Corporation of Pasadena, California, USA, or Tegaderm™ film available from the 3M Company of St. Paul, Minnesota, USA. Other suitable materials may be used. Underlayer **506** may comprise openings **215A**, **215B**, **215C**, and **215D**, and may capture gels **214A**, **214B**, **214C**, and **214D** in pockets formed between base layer **502**
15 and underlayer **506**.

[0069] As in adherent device **100**, adherent device **500** may include a compliant connection between circuit carrier **208** and base layer **502**, for example a compliant connection as shown in Figure 4 and described previously.

[0070] **Figure 6** illustrates an exploded oblique view of an adherent device **600** in
20 accordance with additional embodiments of the present invention. In this embodiment, a support patch **601** may be configured to adhere to a subject's skin, and may be a support patch as in any of the embodiments described above. Support patch **601** may include a base layer, a covering layer, an overlayer, an underlayer, or any workable combination of these. Support patch **601** may include one or more electrodes (not visible in Figure 6) electrically
25 connected to a flexible circuit **206**. A label **610** may be affixed to support patch **601**. A circuit carrier **208** holds various electronic components **209**, which may include a processor, memory, wireless communication circuitry, an antenna **210**, and other electronic components. Adherent device **600** may also include a temperature or heat flux sensor **602**. Bridging loops **603A**, **603B**, **603C** (and a fourth bridging loop not visible in Figure 3B) are affixed to support
30 patch **201** and to circuit carrier **208**, and form a compliant structure that compliantly restrains motion of circuit carrier **208** with respect to support patch **601** in some degrees of freedom more stiffly than in other degrees of freedom. A housing **604** and protector **605** may insulate, cushion, or otherwise protect circuit carrier **208**. The adherent device may further comprise a battery **606** or other energy source, a battery cover **607**, a cover **608**, and a display **609**.

[0071] An adherent device of the present disclosure is to adhere to a skin of a subject and can include a stretchable base means having an upper side and a lower side and an adhesive coating means on the lower side to adhere the base means to the skin of the subject, the base means having at least two openings extending therethrough, each of the at least two openings
5 having a size; a stretchable covering means positioned above and adhered to the base means with an adhesive to define at least two pocket means; at least two gel means, each gel means having a size larger than the size of the at least two openings to retain the gel substantially within the pocket means; and a circuit carrier means supported with the stretchable base means to measure at least one physiologic signal of the subject.

10 [0072] An adherent device of the present disclosure is to monitor a subject having a skin and can include a stretchable base means having an upper side and a lower side and an adhesive means disposed on the lower side to adhere the base means to the skin of the subject, the base means having at least two openings extending therethrough, each opening
15 having a size; a flexible circuit means having at least two electrodes disposed thereon, each electrode positioned with a respective one of the at least two openings to couple to the skin of the subject; at least two gel means positioned with the at least two openings in the base means, each gel means having a size larger than the size of each opening; a stretchable covering means positioned above the at least two gel means and adhered to the base means, such that each gel means is constrained substantially within a corresponding pocket disposed
20 between the base means and the covering means; and a circuit carrier means holding electronic means electrically connected to the at least one electrode means with the flexible circuit means to measure at least one physiologic signal of the subject.

[0073] While exemplary embodiments have been described in some detail, by way of example and for clarity of understanding, those of skill in the art will recognize that a variety
25 of modifications, adaptations, and changes may be employed. Hence, the scope of the present invention should be limited solely by the appended claims.

WHAT IS CLAIMED IS:

1 1. An adherent device to adhere to a skin of a subject, comprising:
2 a stretchable base layer having an upper side and a lower side and an adhesive
3 coating on the lower side to adhere the base layer to the skin of the subject, the base layer
4 having at least two openings extending therethrough, each of the at least two openings having
5 a size;
6 a stretchable covering layer positioned above and adhered to the base layer
7 with an adhesive to define at least two pockets;
8 at least two gels, each gel having a size larger than the size of the at least two
9 openings to retain said gel substantially within said pocket; and
10 a circuit carrier supported with the stretchable base layer to measure at least
11 one physiologic signal of the subject.

1 2. An adherent device to monitor a subject having a skin, comprising:
2 a stretchable base layer having an upper side and a lower side and an adhesive
3 coating disposed on the lower side to adhere the base layer to the skin of the subject, the base
4 layer having at least two openings extending therethrough, each opening having a size;
5 a flexible circuit support having at least two electrodes disposed thereon, each
6 electrode positioned with a respective one of the at least two openings to couple to the skin of
7 the subject;
8 at least two gels positioned with the at least two openings in the base layer,
9 each gel having a size larger than the size of said each opening;
10 a stretchable covering layer positioned above the at least two gels and adhered
11 to the base layer, such that each gel is constrained substantially within a corresponding
12 pocket disposed between the base layer and the covering layer; and
13 a circuit carrier holding electronic components electrically connected to the at
14 least one electrode with the flexible circuit support to measure at least one physiologic signal
15 of the subject.

1 3. The adherent device of claim 2 wherein each of the gels and each of the pockets is
2 sized larger than a corresponding opening of the stretchable base layer to retain said gel in
3 said pocket when the stretchable base layer is adhered to the skin of the subject.

1 4. The adherent device of any preceding claim, wherein the stretchable base layer
2 comprises a thin, flexible, stretchable base layer to stretch with the skin of the subject and
3 conform to folds of the skin of the subject.

1 5. The adherent device of any preceding claim, wherein the stretchable covering layer
2 comprises a thin, flexible, stretchable covering layer to stretch with the skin of the subject
3 and conform to folds of the skin of the subject.

1 6. The adherent device of any preceding claim, further comprising a thin, flexible,
2 stretchable overlayer disposed above and adhered to the covering layer.

1 7. The adherent device of claim 6, wherein the overlayer is made of woven fabric.

1 8. The adherent device of any preceding claim, further comprising a stiffening structure
2 disposed over and coupled to a common perimeter of the base and covering layers and
3 configured to stiffen the perimeter edges of the base and covering layers.

1 9. The adherent device of claim 8, wherein the stiffening structure is configured to be
2 removable after the adherent device is adhered to the subject.

1 10. The adherent device of any of claims 8-9, further comprising a thin, flexible,
2 stretchable overlayer disposed above and adhered to the covering layer, the stiffening
3 structure disposed over and coupled to a common perimeter of the base and covering layers
4 and the overlayer, the stiffening structure configured to stiffen the perimeter edges of the base
5 and covering layers and the overlayer.

1 11. The adherent device of any preceding claim, further comprising a soft, flexible cover
2 disposed over the circuit carrier and coupled at a common perimeter to the base and covering
3 layers.

1 12. The adherent device of claim 11, wherein the cover comprises a material configured
2 to inhibit liquids from reaching the electronic components.

1 13. The adherent device of any of claims 11-12, wherein a perimeter of the cover is
2 disposed under the stiffening structure.

1 14. The adherent device of any of claims 2-13, wherein the flexible circuit is configured
2 to be stretchable.

- 1 15. The adherent device of any of claims 2-14, wherein the flexible circuit is formed of a
2 substantially non-stretchable material, and is geometrically configured to be stretchable.
- 1 16. The adherent device of claim 15, wherein the flexible circuit comprises:
2 a polyester base; and
3 traces formed of silver conductive ink.
- 1 17. The adherent device of claim 15, wherein the flexible circuit comprises a serpentine
2 shape.
- 1 18. The adherent device of any of claims 2-14, wherein the flexible circuit is disposed
2 between the base layer and the covering layer.
- 1 19. The adherent device of any preceding claim, further comprising a compliant
2 connection between the circuit carrier and the base layer.
- 1 20. The adherent device of any preceding claim, wherein the combination of the base
2 layer and the covering layer is breathable.
- 1 21. The adherent device of claim 20, wherein the combination of the base layer and the
2 covering layer has a moisture vapor transmission rate of at least $100 \text{ g/m}^2/\text{day}$.
- 1 22. An adherent device, comprising:
2 a thin, flexible, stretchable base layer having an upper side and a lower side
3 and an adhesive coating on the lower side;
4 at least one electrode affixed to the base layer and capable of electrically
5 coupling to the skin of a subject;
6 a flexible circuit connected to the at least one electrode;
7 a circuit carrier holding electronic components electrically connected to the at
8 least one electrode via the flexible circuit and configured to measure at least one physiologic
9 signal of the subject; and
10 a stiffening structure disposed over and coupled to a perimeter of the base
11 layer and configured to stiffen the perimeter edge of the base layer.
- 1 23. The adherent device of claim 22, wherein the stiffening structure is configured to be
2 removable when the adherent device is adhered to the subject.

- 1 24. The adherent device of any of claims 22-23, wherein the stiffening structure is made
2 from a vinyl sheet.
- 1 25. The adherent device of any of claims 22-24, further comprising a thin, flexible,
2 stretchable overlayer disposed above and adhered to the base layer, the stiffening structure
3 disposed over and coupled to a common perimeter of the base layer and overlayer and
4 configured to stiffen the perimeter edge of the base layer and overlayer.
- 1 26. The adherent device of any of claims 22-25, further comprising gel patch under each
2 electrode, wherein each gel patch enhances electrical conductivity between its respective
3 electrode and the skin of the subject.
- 1 27. The adherent device of any of claims 22-26, wherein the flexible circuit is configured
2 to be stretchable.
- 1 28. The adherent device of any of claims 22-27, further comprising a soft, flexible cover
2 disposed over the circuit carrier and coupled at a perimeter to the base layer.
- 1 29. The adherent device of claim 28, wherein the cover comprises a material configured
2 to inhibit liquids from reaching the electronic components.
- 1 30. The adherent device of any of claims 22-29, wherein the lower side of the base layer
2 is configured to adhere to the skin of a subject.
- 1 31. The adherent device of any of claims 22-30, further comprising a thin, flexible,
2 stretchable underlayer adhered to the lower side of the base layer, the underlayer configured
3 to adhere to the skin of the subject.
- 1 32. The adherent device of claim 31, wherein the combination of the base layer and
2 underlayer is breathable.
- 1 33. The adherent device of claim 32, wherein the combination of the base layer and
2 underlayer has a moisture vapor transmission rate of at least 100 g/m²/day.
- 1 34. The adherent device of any of claims 31-33, further comprising gel patch under each
2 electrode, wherein each gel patch enhances electrical conductivity between its respective
3 electrode and the skin of the subject, and wherein a perimeter of each gel patch is sandwiched
4 between the base layer and the underlayer.

1 35. The adherent device of any of claims 31-34, wherein the underlayer comprises at least
2 one opening through which electrical contact is made between the at least one electrode and
3 the skin of the subject.

1 36. The adherent device of any of claims 22-35, further comprising a compliant
2 connection between the circuit carrier and the base layer.

1 37. An adherent device, comprising:

2 a thin, flexible, stretchable base layer having an upper side and a lower side
3 and an adhesive coating on the lower side;

4 at least one electrode affixed to the base layer and capable of electrically
5 coupling to the skin of a subject;

6 a flexible circuit connected to the at least one electrode, the flexible circuit
7 configured to stretch; and

8 a circuit carrier holding electronic components electrically connected to the at
9 least one electrode via the flexible circuit and configured to measure at least one physiologic
10 signal of the subject.

1 38. The adherent device of claim 37, wherein the flexible circuit is formed of a
2 substantially non-stretchable material, and is geometrically configured to be stretchable.

1 39. The adherent device of claim 38, wherein the flexible circuit comprises

2 a polyester base; and

3 traces formed of silver conductive ink.

1 40. The adherent device of any of claims 37-39, wherein the flexible circuit comprises a
2 serpentine shape.

1 41. The adherent device of any of claims 37-39, wherein the flexible circuit comprises a
2 sawtooth shape.

1 42. The adherent device of any of claims 37-41, further comprising gel patch under each
2 electrode, wherein each gel patch enhances electrical conductivity between its respective
3 electrode and the skin of the subject.

1 43. The adherent device of any of claims 37-42, wherein the base layer is configured to
2 adhere to the skin of the subject, the adherent device further comprising a thin, flexible,
3 stretchable overlayer disposed above and adhered to the base layer.

1 44. The adherent device of any of claims 37-42, further comprising a thin, flexible,
2 stretchable underlayer disposed below and adhered to the base layer, the underlayer
3 configured to adhere to the skin of the subject.

1 45. The adherent device of any of claims 37-42, further comprising a stiffening
2 structure disposed over and coupled to a perimeter of the base layer and configured to stiffen
3 the perimeter edge of the base layer.

1 46. The adherent device of any of claim 37-42, further comprising a compliant connection
2 between the circuit carrier and the base layer.

3 47. An adherent device to monitor a subject having a skin, comprising:

4 a stretchable base layer having an upper side and a lower side and an adhesive
5 coating on the lower side to adhere the base layer to the skin of a subject, the base layer
6 having at least two openings extending therethrough, each of the at least two openings having
7 a size;

8 a stretchable covering layer positioned above and adhered to the base layer
9 with an adhesive to define at least two pockets;

10 a flexible circuit support comprising a first portion and a second portion, the
11 first portion of the support adhered between the stretchable base layer and the stretchable
12 covering layer, the second portion extending from the first portion;

13 at least two electrodes disposed on the first portion of the flex circuit support;

14 at least two gels, wherein each gel and each electrode are positioned within a
15 corresponding pocket, each gel having a size larger than the size of the respective opening to
16 retain said gel substantially within said pocket between the base layer and the covering layer;
17 and

18 a circuit carrier supported with the stretchable base layer, the circuit carrier
19 holding electronic components electrically connected to the at least two electrodes with the
20 second portion of the flexible circuit support to relieve strain when the stretchable base layer
21 stretches with the skin of the subject, the electronic components configured to measure at
22 least one physiologic signal of the subject.

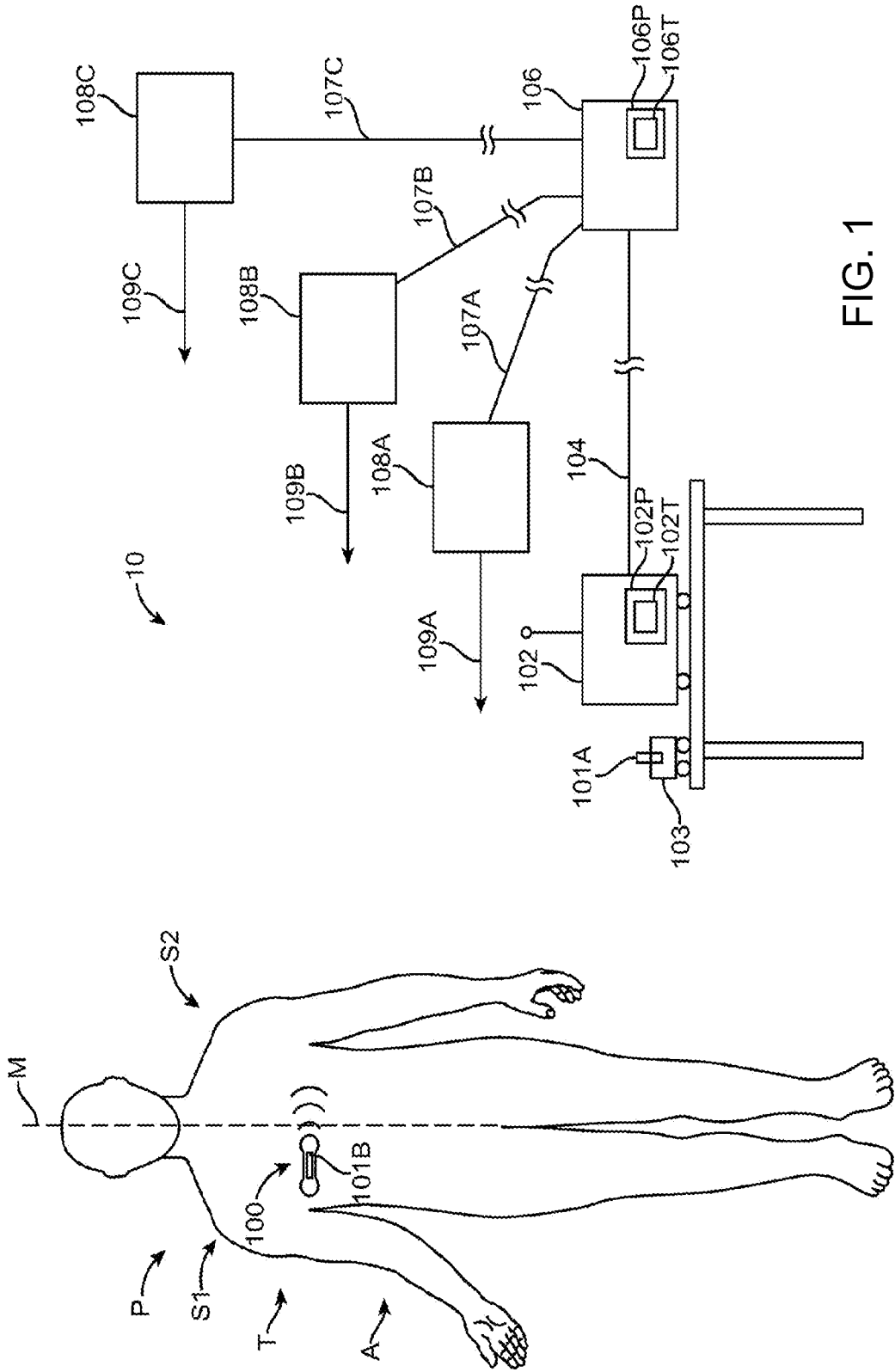
1 48. A method of manufacturing an adherent device to adhere to a skin of a subject,
2 comprising:

3 providing a stretchable base layer having an upper side and a lower side and
4 an adhesive coating on the lower side to adhere the base layer to the skin of a subject, the

5 base layer having at least two openings extending therethrough, each of the at least two
6 openings having a size;
7 providing a flexible circuit support, the flexible circuit support having at least
8 two electrodes and traces of electrically conductive material disposed thereon;
9 providing at least two gels; and
10 providing a stretchable covering layer;
11 positioning the flexible circuit support and at least two gels between the
12 stretchable base layer and the stretchable covering layer;
13 adhering the stretchable base layer to the stretchable covering layer to form at
14 least two pockets, wherein each pocket has one of the at least two gels and one of the
15 electrodes disposed therein;
16 coupling a circuit carrier to the at least two electrodes with the flexible circuit
17 support.

1 49. A method of monitoring a patient having a skin, the method comprising:
2 adhering a stretchable base layer affixed to a stretchable covering layer to the
3 skin of the patient, wherein the stretchable base layer and the stretchable covering layer
4 define a plurality of pockets with gels and electrodes disposed therein and wherein the
5 electrodes are coupled to the skin with the gels disposed in the pockets; and
6 measuring signals from the electrodes to monitor the patient.

1 50. An adherent device to adhere to a skin of a subject, comprising:
2 means for adhering to a skin of a subject; and
3 a circuit carrier means coupled to the means for adhering to measure at least
4 one physiologic signal of the subject.



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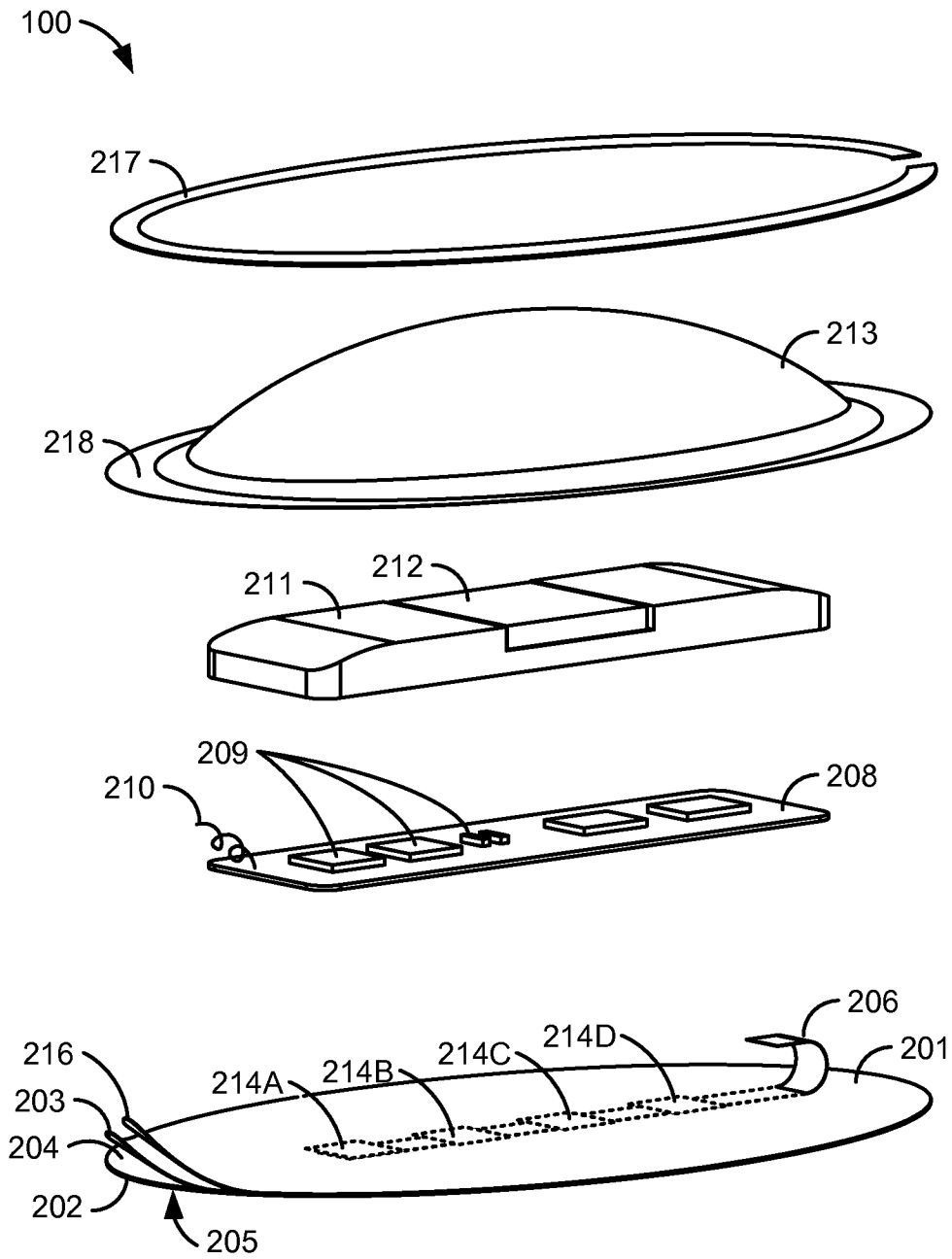


FIG. 2A

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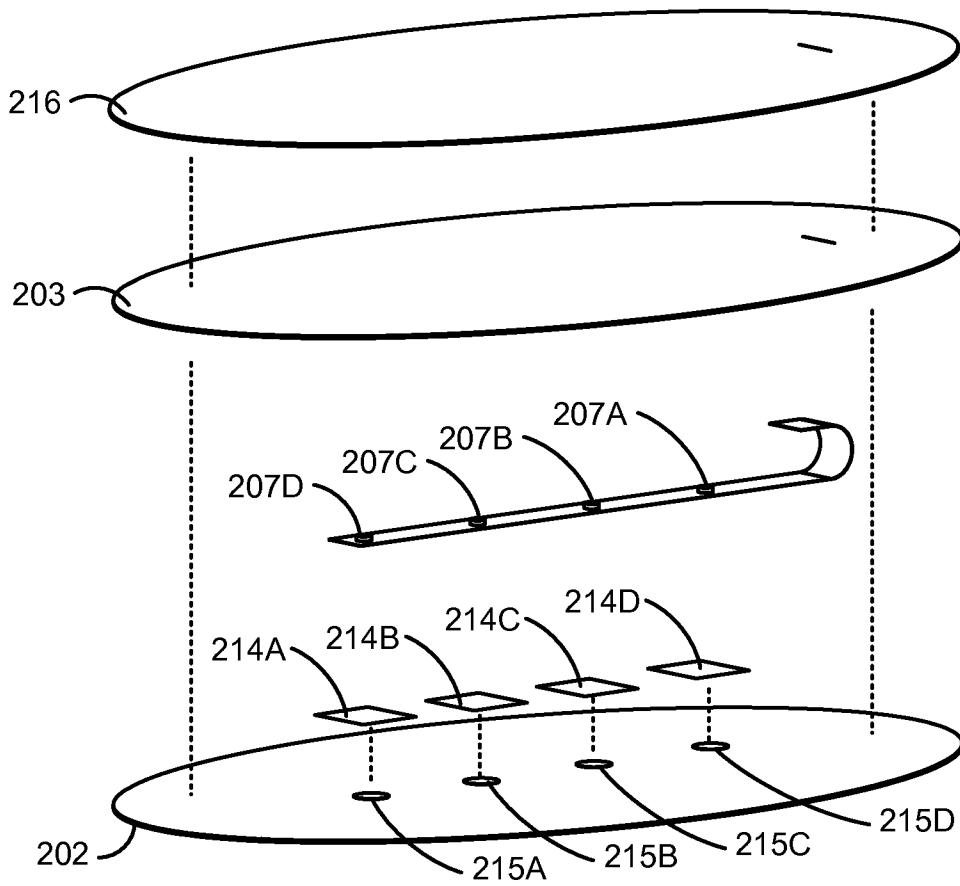


FIG. 2B

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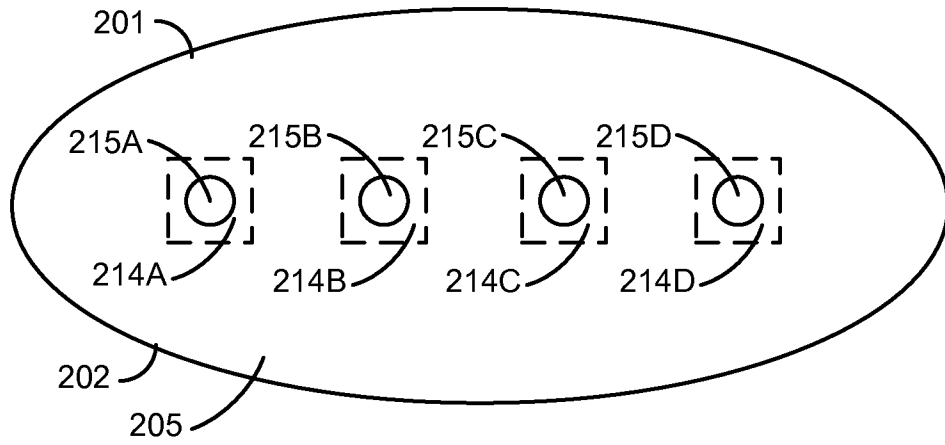


FIG. 2C

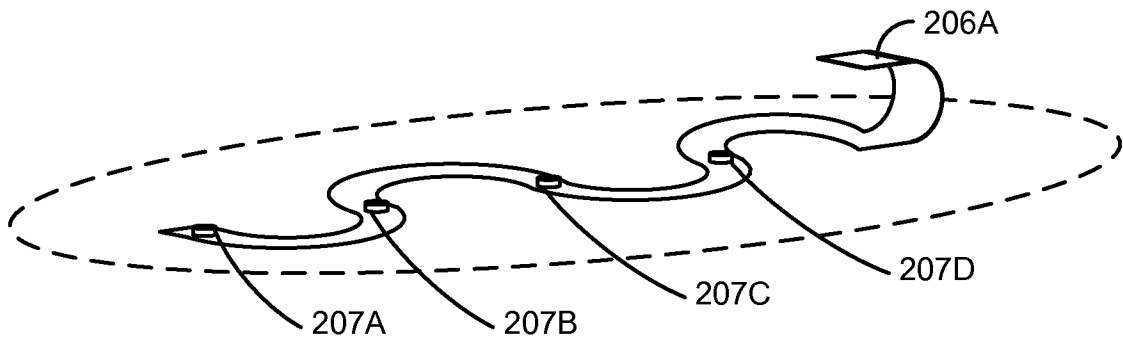


FIG. 3

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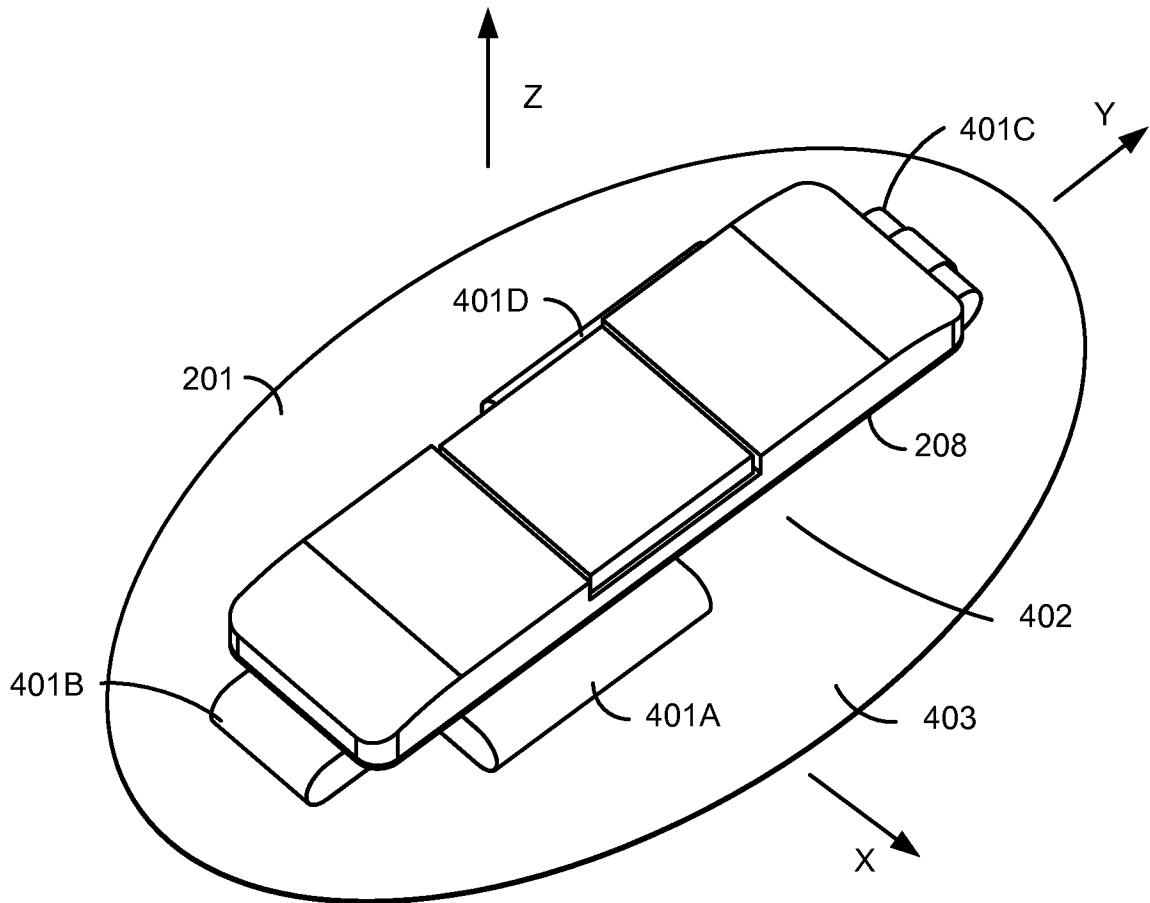


FIG. 4

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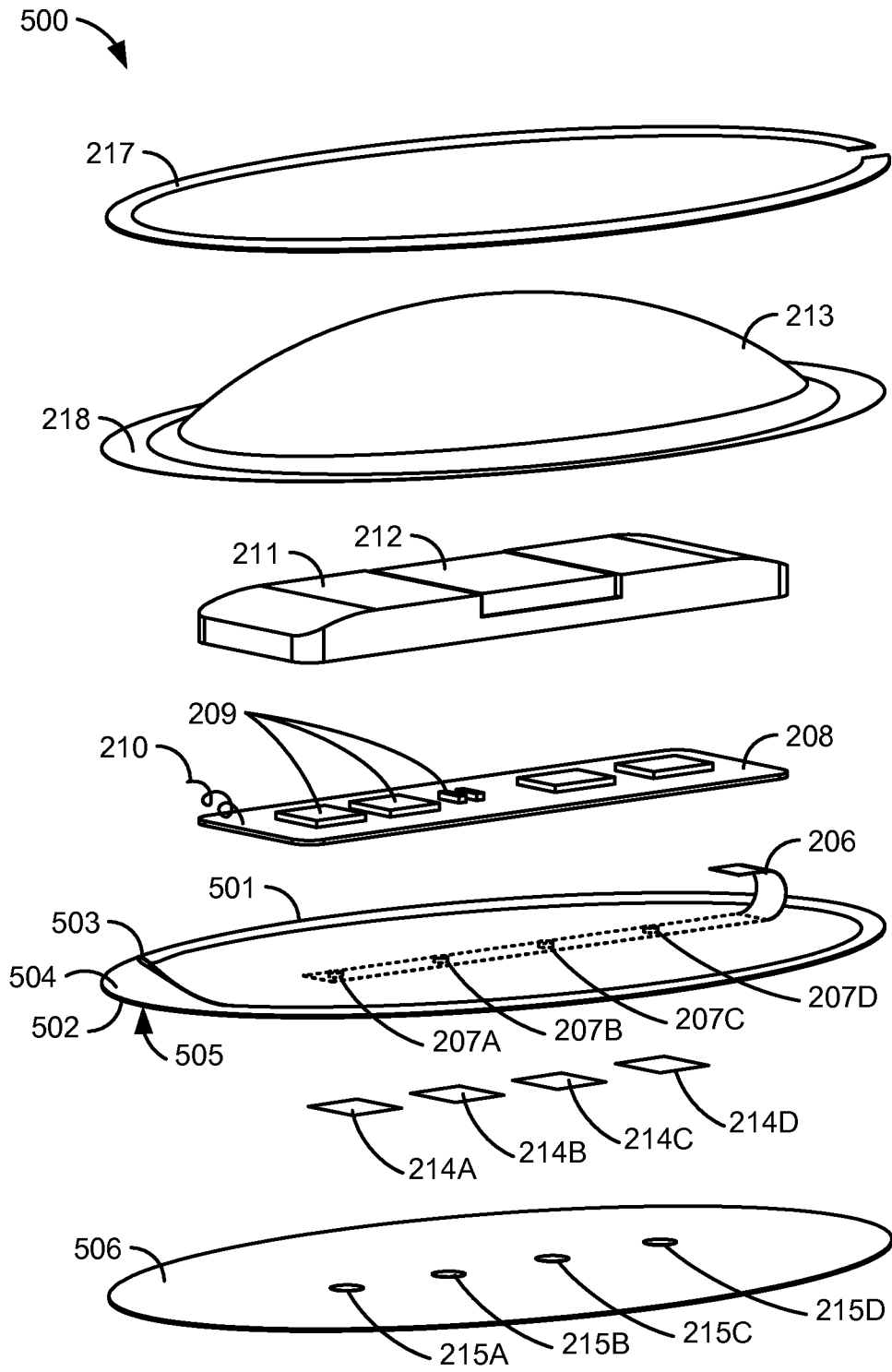


FIG. 5

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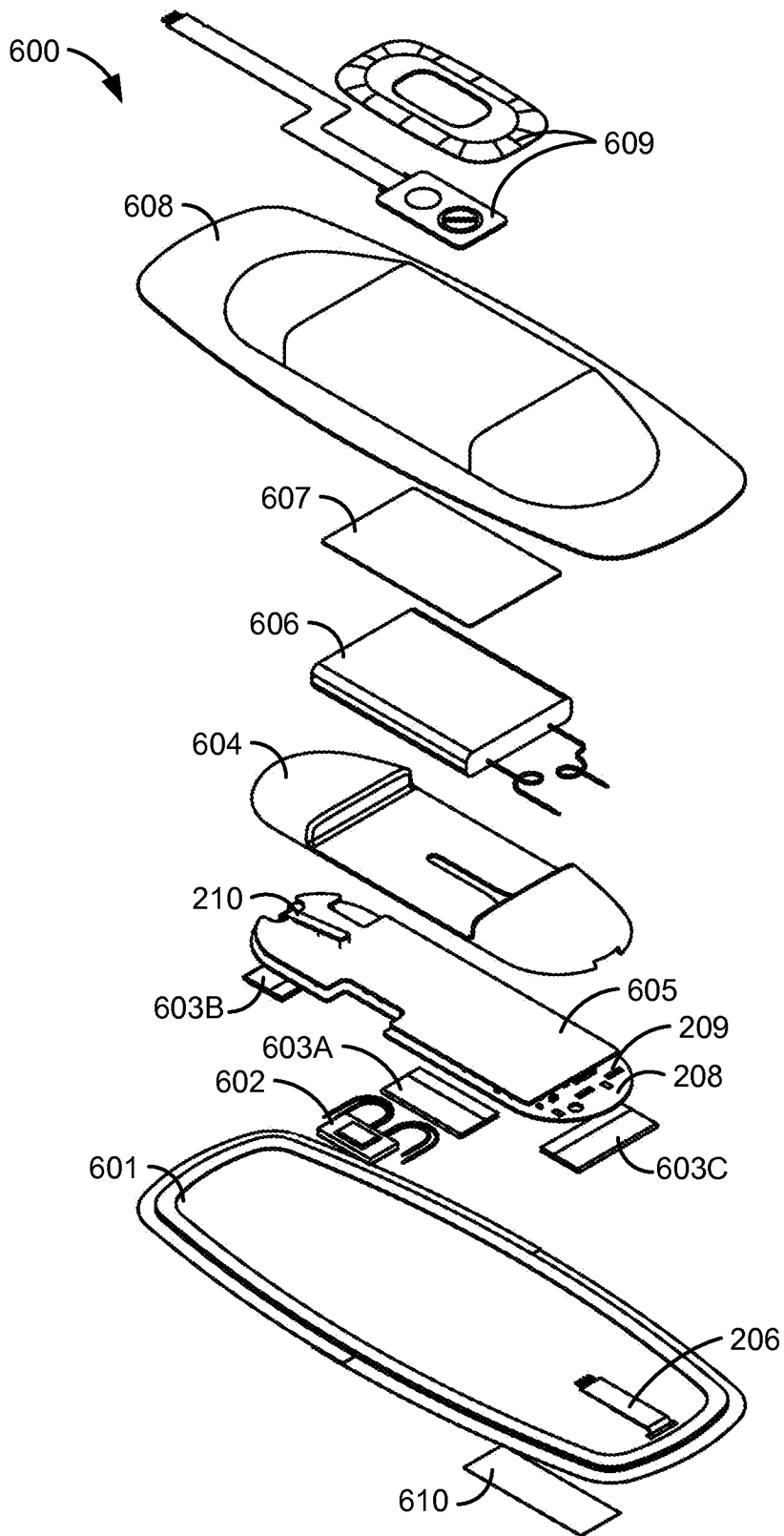


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2010/060121

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61B5/0408 A61B5/0432
 ADD. A61B5/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 A61B

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|---|---|
| X A | US 2008/259577 A1 (HU YING-CHIANG [TW] ET AL) 23 October 2008 (2008-10-23) figures 3A, 3B ----- | 49,50 1-21 |
| X | US 2008/139953 A1 (BAKER STEVEN D [US] ET AL) 12 June 2008 (2008-06-12) ----- | 1,2,4-8, 11,12, 14-16, 18-21, 48-50 |
| Y | paragraphs [0043], [0 46], [0 55] figures 2, 4A ----- | 17 |
| X | US 2008/288026 A1 (CROSS BRETT [US] ET AL) 20 November 2008 (2008-11-20) paragraphs [0003], [0 49], [0 56], [0 88] figures 1, 2, 5, 8, ----- | 1,2,4-6, 8-21, 48-50 |
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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 document 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

3 March 2011

Date of mailing of the international search report

17/05/2011

Name and mailing address of the ISA/

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 Fax: (+31-70) 340-3016

Authorized officer

Worms, Georg

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2010/060121

| C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT | | |
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| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| X | WO 2008/068695 A1 (KONINKL PHILIPS ELECTRONICS NV [NL]; CROSS BRETT [US]; LYSTER THOMAS []) 12 June 2008 (2008-06-12) page 6, lines 26-29, 32-33 figures 2a, 2b ----- | 1-4, 48-50 |
| Y | US 2007/270678 A1 (FADEM KALFORD C [US] ET AL) 22 November 2007 (2007-11-22) figure 2 ----- | 17 |
| A | US 2009/076336 A1 (MAZAR SCOTT T [US] ET AL) 19 March 2009 (2009-03-19) figure 1 ----- | 1-21 |

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/060121

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:

see additional 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 an 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.:

1-21, 48-50

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-21, 48-50

directed towards preventing the gels from moving during use of the adherent device

2. claims: 22-36

directed towards giving the adherent device a specific shape

3. claims: 37-46

directed towards allowing measurements independent of the site the adherent device is attached to

4. claim: 47

directed towards relieving stress applied upon the circuit carrier

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2010/060121

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
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