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(54) Title: HEALTH PATCH

(57) Abstract: Adhesively attached wearable patches are described which include electronics and sensors for collecting an array of physiologic and health information. Also described are systems of computers and/or mobile devices which can receive health information from the adhesive patches, and which can be used in health and wellness programs.

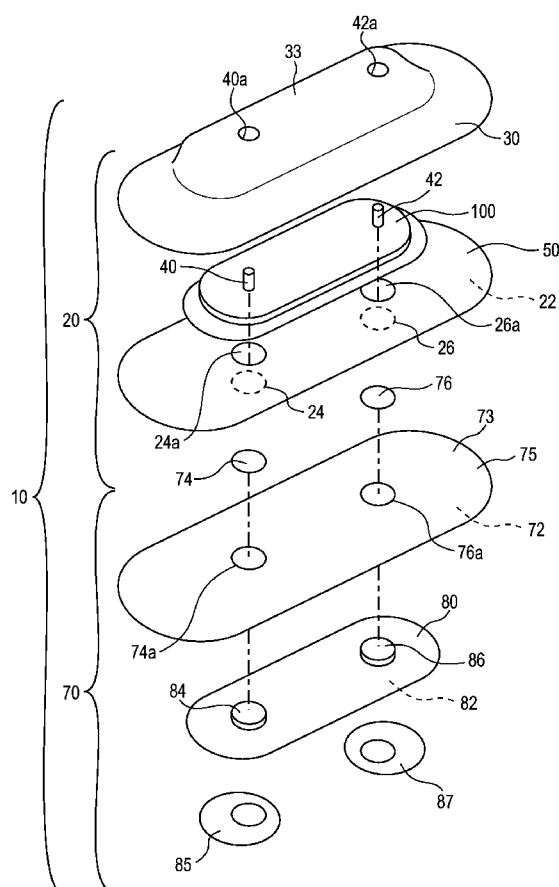


FIG. 1



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HEALTH PATCH

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application claims the benefit of U.S. Provisional Application No. 62/024,651, filed July 15, 2014, which is incorporated herein by reference in its entirety.

FIELD

[0002] The present subject matter relates to adhesively attached health patches for collecting physiologic information and data from a user. The health patches are attached to a user's skin and acquire information concerning the user and their lifestyle. The present subject matter also relates to systems using such patches and related methods of use. The health patches can be used in association with a variety of health, lifestyle, or wellness programs.

BACKGROUND

[0003] Products for monitoring a user's health or lifestyle have become increasingly popular. Many of these products are incorporated in athletic garments or shoes and can monitor movement or other motion of the user. Products in the form of bands are also known which can be worn about various regions of a user's body. The products typically include sophisticated electronics and are often used in association with a variety of software-based platforms to provide the user with information such as exertion or activity levels or certain health parameters.

[0004] Devices that are adhesively attached directly to a user's skin are also known. After use, the devices are usually discarded or otherwise disposed. For devices that include minimal electronics or which merely serve to collect a single type of data, such devices and their disposal are often satisfactory.

[0005] However, with the advent of wireless communications, cloud-based computing, continual miniaturization of electronics, and increasing sophistication of users and their concern for health; such health and lifestyle products now typically acquire multiple types of data and information, process such data, and retain and/or stream the processed data to other electronic devices. Accordingly, current and future health and lifestyle products will involve increasing complexity and sophistication of sensors and electronics.

[0006] Disposal of an adhesively attached device becomes undesirable with increasing device sophistication due to the corresponding cost of the device and its electronics. As will be appreciated, after purchasing a relatively costly device, many consumers would prefer to not discard the device after its first use. This is a significant factor discouraging adhesively attached devices and which factor promotes reusable devices. Moreover, as many devices now include batteries and electronic components with potentially hazardous or nonrecyclable agents, disposal of such devices is further discouraged.

[0007] In view of these and other factors, a need exists for an improved adhesively attached health and lifestyle device, which is not faced with the noted disposal concerns.

SUMMARY

[0008] The difficulties and drawbacks associated with previous approaches are addressed in the present subject matter as follows.

[0009] In one aspect, the present subject matter provides a health patch for application to biologic skin for obtaining physiologic information. The health patch comprises a primary patch component

including a housing that defines a hollow interior, and an underside with at least one electrical contact. The health patch also comprises a secondary patch component at least initially separate from the primary patch component. The secondary patch defines an outer face and an oppositely directed underside. The secondary patch component includes at least one electrical contact accessible along the outer face. The primary patch component and the secondary patch component are releasably securable to one another and are configured such that upon being secured to each other the at least one electrical contact of the primary patch is in electrical communication with the at least one electrical contact of the secondary patch.

[0010] In another aspect, the present subject matter provides a system for assessing a user's health or lifestyle. The system comprises at least one mobile device including communication provisions. The system also comprises a health patch including (i) a primary patch component having a housing that defines a hollow interior, and an underside with at least one electrical contact, (ii) a secondary patch component at least initially separate from the primary patch component, the secondary patch defining an outer face and an oppositely directed underside, the secondary patch component having at least one electrical contact accessible along the outer face, and (iii) communication provisions. The primary patch component and the secondary patch component are releasably securable to one another and are configured such that upon being secured to each other the at least one electrical contact of the primary patch is in electrical communication with the at least one electrical contact of the secondary patch. The communication provisions of the mobile device and the communication provisions of the health patch are capable of providing a communication link between the mobile device and the health patch.

[0011] In yet another aspect, the present subject matter provides a sensing system for acquiring physiologic information. The system comprises at least one ancillary electrode. The system also comprises a health patch including (i) a primary patch component including a housing that defines a hollow interior, and an underside with at least one electrical contact, and (ii) a secondary patch

component at least initially separate from the primary patch component. The secondary patch defines an outer face and an oppositely directed underside. The secondary patch component has at least one electrical contact accessible along the outer face. The primary patch component and the secondary patch component are releasably securable to one another and are configured such that upon being secured to each other the at least one electrical contact of the primary patch is in electrical communication with the at least one electrical contact of the secondary patch.

[0012] In yet another aspect, the present subject matter provides a method for acquiring health or lifestyle information from a user. The method comprises providing a health patch including (i) a primary patch component having a housing that defines a hollow interior, and an underside with at least one electrical contact, (ii) a secondary patch component at least initially separate from the primary patch component, the secondary patch defining an outer face and an oppositely directed underside, the secondary patch component having at least one electrical contact accessible along the outer face, (iii) at least one sensor, and (iv) data storage provisions. The method also comprises releasably securing the primary patch component with the secondary patch component such that upon being secured to each other the at least one electrical contact of the primary patch is in electrical communication with the at least one electrical contact of the secondary patch. The method also comprises adhesively attaching the health patch to a location on the body of the user. The method additionally comprises collecting information via the sensor over a period of time. And, the method comprises retaining the collected information in the data storage provisions, to thereby acquire health or lifestyle information from the user.

[0013] In still another aspect, the present subject matter provides a method of collecting physiologic information from a user. The method comprises providing a health patch including (i) a primary patch component having a housing that defines a hollow interior, and an underside with at least one electrical contact, (ii) a secondary patch component at least initially separate from the primary

patch component, the secondary patch defining an outer face and an oppositely directed underside, the secondary patch component having at least one electrical contact accessible along the outer face, (iii) at least one electrically conductive terminal, and (iv) data storage provisions. The method also comprises releasably securing the primary patch component with the secondary patch component such that upon being secured to each other the at least one electrical contact of the primary patch is in electrical communication with the at least one electrical contact of the secondary patch. The method additionally comprises adhesively attaching the health patch to a first location on the body of the user. The method also comprises providing at least one ancillary electrode. The method additionally comprises contacting the electrode to a second location on the body of the user. The method further comprises establishing electrical communication between the terminal of the health patch and the ancillary electrode. Physiologic information of the user is obtained by the ancillary electrode, transferred to the health patch, and retained in the data storage provisions of the health patch.

[0014] In yet another aspect, the subject matter provides a primary patch component adapted for use with a secondary patch component including at least one electrical contact. The primary patch component and the secondary patch component are at least initially separate from one another and releasably securable to one another to provide a health patch for obtaining physiologic information. The primary patch component comprises a housing that defines a hollow interior, and an underside with at least one electrical contact. The primary patch component also comprises an electronics assembly generally disposed within the hollow interior defined by the housing. Upon securing the primary patch component to the secondary patch component, the at least one electrical contact of the primary patch component is in electrical communication with the at least one electrical contact of the secondary patch component.

[0015] In still another aspect, the present subject matter also provides a secondary patch component adapted for use with a primary patch component including at least one electrical contact.

The secondary patch component and the primary patch component are at least initially separate from one another and releasably securable to one another to provide a health patch for obtaining physiologic information. The secondary patch component comprises a support layer including at least one electrical contact, and an electrode assembly. Upon securing the secondary patch component to the primary patch component, the at least one electrical contact of the secondary patch component is in electrical communication with the at least one electrical contact of the primary patch component.

[0016] As will be realized, the subject matter described herein is capable of other and different embodiments and its several details are capable of modifications in various respects, all without departing from the claimed subject matter. Accordingly, the drawings and description are to be regarded as illustrative and not restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Figure 1 is a schematic, partially exploded view illustrating a primary patch component and a secondary patch component of one embodiment of a health patch in accordance with the present subject matter.

[0018] Figure 2 is an exploded schematic side elevational view of the primary patch component depicted in Figure 1.

[0019] Figure 3 is a schematic view of an underside of the primary patch component depicted in Figure 1.

[0020] Figure 4 is a schematic view of the primary patch component of Figure 1 in a sealed package.

[0021] Figure 5 is an exploded schematic cross sectional view of the secondary patch component shown in Figure 1.

[0022] Figure 6 is a schematic view of an underside of the secondary patch component depicted in Figure 1.

[0023] Figure 7 is a schematic cross sectional view of an alternative embodiment of releasably adjoining the primary patch component and the secondary patch component.

[0024] Figure 8 is a schematic view of the secondary patch component of Figure 1 in a sealed package.

[0025] Figure 9 is a schematic illustration of an embodiment of an electronic assembly used in certain health patches of the present subject matter.

[0026] Figure 10 is a schematic illustration of a system of one or more health patches, one or more mobile devices, and one or more computers and/or servers, using cloud-based communication in accordance with the present subject matter.

[0027] Figure 11 schematically illustrates one embodiment of electrode locations for certain versions of health patches in accordance with the present subject matter.

[0028] Figure 12 schematically illustrates another embodiment of electrode locations for certain versions of health patches in accordance with the present subject matter.

[0029] Figure 13 is a schematic illustration of another embodiment illustrating a health patch and satellite electrodes in accordance with the present subject matter.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0030] In describing various embodiments and details of the present subject matter, a general description of the health patches is provided followed by a detailed description of the patches, their components, materials of constructions, packaging, systems using such patches, and representative methods of using the patches and systems.

[0031] Generally, the present subject matter relates to adhesive patches that can be attached to a user's skin and which collect physiologic health data and/or information pertaining to the user. In many embodiments, the health patches are modular and include a component that can be disposed after use,

and another component that can be reused. The components can initially be provided separate from one another, secured to one another to form the health patch, and after use of the patch separated from one another without damage to one of the components which can then be reused. Thus, as described herein the components are referred to as being "releasably secured" to one another. In certain embodiments, the present subject matter relates to disposable, peel-and-stick, biometric patches. In certain versions, the patch includes multiple sensors that collect physiologic data and provide information relating to one or more of calories burned, steps taken, activity levels, sleep patterns, and other parameters. The patches are attached to a user's skin and are worn continuously for a period of up to 7 days or longer.

[0032] Typically, the patches include multiple sensors and/or multiple sensor types that collect data which is stored in memory on the patch. The patches include provisions that enable wireless transfer of collected data to a computer or mobile device. In certain embodiments, the patch is adhesively attached to the back of a user's left tricep. In other embodiments, the patch is adhesively attached to a region of a user's chest. The patches can be used on other locations of a user's body.

[0033] In certain embodiments, the patches collect one or more of the following data: (i) skin surface temperature data of the user, (ii) core body temperature data of the user, (iii) motion or inactivity data of the user, (iv) body angle data of the user, and (v) heart rate and/or ECG data of the user. In particular versions, the patch may also acquire respiration information of the user. The patches utilize software algorithms to process the raw data and determine or provide indication of one or more of (i) sleep quality and quantity, (ii) activity level and step count, and (iii) caloric expenditures. In certain embodiments, the patches also utilize cloud-based infrastructure for the storage and presentation of the raw and/or processed data. In particular embodiments, the processed data that is generated or otherwise obtained includes one or more of (i) total number of steps taken per time period, (ii) total

number of calories expended per time period, (iii) an indication of activity level, e.g., non-active, moderate, vigorous, and sleep & lying, and (iv) total number of hours of sleep per time period.

[0034] In use, the health patches collect physiologic information and data. In many embodiments, the patches transfer the collected data using BLUETOOTH™ or BLUETOOTH SMART™ wireless communication to a PC/Mac computer and/or mobile device. The computer or device then uploads the data and/or desired parameters to a cloud-based infrastructure (generally referred to herein as the "cloud") for processing and reporting.

[0035] In certain embodiments, the patches include an electronic module which is positioned between an outer or top layer of a printed foam, and a bottom layer. The top layer may include or be formed from a wide assortment of cushioning materials. In particular embodiments, a layer of a skin adhesive is applied to an underside of the bottom layer or other substrate. And, a hydrophilic layer and more particularly a hydrocolloid layer is applied to the bottom face of the skin adhesive layer. A paper or film liner or assembly of liners cover the hydrocolloid layer and any exposed regions of the skin adhesive prior to use.

[0036] The health patches include an on-board battery and particularly a lithium battery that powers the electronics. Typically, the battery is not rechargeable however the present subject matter includes rechargeable batteries. The health patches can include a power button, one or more lights such as LED lights, and provisions for wireless communication. After activating the patch and removing the liner to expose the adhesive face of the patch, a user adheres the patch to a desired location on the user's body such as a rearward region of the user's arm or on the user's chest. In certain embodiments, the patch is activated upon attachment to a user. After wearing the patch for up to seven (7) days or longer, the patch is removed.

[0037] As noted, the health patches communicate wirelessly with a PC/Mac computer or mobile device and in certain embodiments employ bi-directional periodic "handshaking" communication. As

data is collected, data is stored in onboard memory on the patch and periodically transmitted wirelessly to the computer or device. As noted, the wireless protocol is typically BLUETOOTH SMART™. It is contemplated that a patch could be used with multiple devices. And, it is contemplated that multiple patches could be used with a single device, however, such use is generally not simultaneous. Instead, if multiple patches were used, their use would be sequential.

[0038] In certain embodiments, the health patches include several sets or types of sensors. In many embodiments, the health patches include a 3-axis accelerometer. The accelerometer acquires data regarding motion or inactivity. And, in many embodiments, the health patches include two temperature sensors in the form of thermistors. In particular embodiments, the health patches also sense ECG waveforms or data, and obtain heart rate information by measuring only the peaks of "R waves." In many embodiments, the health patches contain two "wet" Ag/AgCl electrodes that are used with a conductive gel to acquire heart rate information. It is contemplated that the patch and/or system may derive respiration information from ECG waveforms or data collected by the wet electrodes. In certain embodiments, the patches include components such as electrode(s) or sensor(s) that measure galvanic skin response (GSR). The health patches can include a wide variety of sensors and/or processing provisions to collect or obtain information relating to heart ECG waveforms, temperature, motion, body angle, and other parameters or aspects. It is also contemplated that the health patches can include provisions to obtain information relating to pulse oximetry or other physiologic monitors.

[0039] As a result of previous user registration with a database or other record retention system, a user's raw data which has been processed using algorithms is uploaded to the cloud. That raw data may be further processed using algorithms. The processed data is available via the cloud.

[0040] In many embodiments, the health patches are used for collecting physiologic data from their users. The patch collects data such as for example skin surface temperature, motion or inactivity, and heart rate. The patch may collect information used to derive respiration aspects. The patch

continuously, or substantially so, transmits wirelessly the heart rate data to the PC/Mac computer or mobile device so that such information can be viewed or displayed in real time at that computer or mobile device. The remaining data is stored in onboard memory on the patch and periodically transmitted wirelessly to the PC/Mac computer or mobile device. The computer or mobile device periodically uploads all of the collected data to the cloud for processing and derivation of sleep quality and quantity, activity level and step count, and caloric expenditures. The processed/derived information is then transferred to the computer or mobile device for viewing or use by the user. Thus, the user can, during use of the patch, view or use the information processed/derived at the cloud level.

[0041] In many embodiments, the health patch and its associated system and method of use will provide information to one or more users who are typically wearers of the patch.

[0042] Particular details of the present subject matter are as follows.

Patches

[0043] In certain embodiments of the present subject matter, a modular health patch 10 having two or more replaceable or removable components is provided as shown in Figures 1-8. The health patch 10 comprises a primary patch component 20 and a secondary patch component 70 which can be positioned and secured to one another to provide a unitary device for assessment of a user's health and lifestyle. Initially or at least prior to use of the health patch 10, the secondary patch 70 is separate from the primary patch 20. Typically, in many embodiments of the present subject matter, the primary patch component 20 includes most or all of the electronics used in the health patch. And typically, in many embodiments, the secondary patch component 70 is free or substantially free of electronics or like components. This configuration of primary and secondary components enables the primary patch component 20 to be reused or used with different secondary patch components 70. Thus the primary patch can be used multiple times by reusing that component with a new secondary patch component

prior to each use. Thus, the secondary patch is typically disposable. However, it will be appreciated that the present subject matter includes configuring the secondary patch component 70 to be reusable rather than a disposable or single use component. But, most embodiments of the present subject matter feature a reusable primary patch 20 and a disposable secondary patch 70.

[0044] The primary patch component 20 and the secondary patch component 70 are sized and shaped to matingly contact and be releasably secured to one another. In many embodiments and as described in greater detail herein, one or more regions of adhesive are provided along an interface between the primary and secondary patches. Once adhered to each other, the primary patch 20 is adhesively secured to the secondary patch 70 to thereby form a unitary health patch as described herein. Although many of the embodiments utilize adhesive securement between the primary and the secondary patch components, the present subject matter includes other provisions and techniques for releasably securing and/or attaching the primary and secondary patch components together. For example, mechanical affixment such as by use of releasably engaging fasteners, threaded fasteners, spring clips, tensioned fasteners, wire retainers, velcro components, and like means could be used to releasably secure the primary and secondary patch components together. In certain versions of the health patches, one or more magnets can be used to releasably secure the primary and secondary patch components to one another.

[0045] In many embodiments of the health patch 10, the primary and secondary patch components 20 and 70 respectively, are releasably coupled or secured together by adhesively contacting an underside of the primary patch component 20 with an outer face of the secondary patch component 70. Upon adhesive application to a user's skin, the secondary patch component is disposed between the user's skin and the primary patch component.

[0046] The health patch 10 and its components, i.e., the primary patch component 20 and the secondary patch component 70, can be shaped to exhibit a wide array of "footprints." The term

"footprint" as used herein refers to the area along the underside of the patch 10 which contacts and/or is disposed immediately adjacent to the user upon application of the patch. Nonlimiting examples of shapes of the health patch footprint include circular, oval, square, rectangular, triangular, hexagonal, and polygonal. Irregular or nonsymmetrical shapes are also contemplated. The size or maximum span of the health patch footprint can range from 10 mm or smaller, up to about 150 mm or larger. For many embodiments, a size of from 75 mm to 100 mm is convenient. However, it will be appreciated that the present subject matter includes adhesive patches having footprints larger and smaller than these representative dimensions. In one embodiment, the health patch has an oval footprint with dimensions of about 90 mm for a major axis of the oval, and about 50 mm for a minor axis of the oval.

[0047] In many embodiments, the primary and secondary patch components 20 and 70 respectively, each include provisions for establishing electrical contact and/or communication between the components. In certain versions, each of the primary and secondary patch components includes electrical contacts as described in greater detail herein.

[0048] Additional details and aspects of the various health patches of the present subject matter are as follows.

Primary Patch

[0049] Referring to Figures 1-4, the primary patch component 20 includes a housing 30 and defines an outer surface 33. The primary patch component 20 also includes a base layer 50 that defines an underside 22 of the primary patch. Disposed between, and in many embodiments sealingly enclosed between, the housing 30 and the base layer 50 is an electronics module 100, described in greater detail herein. The underside 22 of the primary patch is typically provided by one or more layer(s) of an adhesive, and particularly a pressure sensitive adhesive described in greater detail herein.

[0050] The primary patch component 20 also includes one or more outwardly projecting terminals accessible along the housing outer surface 33, such as for example terminals or studs 40 and 42. The terminals are formed from an electrically conductive material. In certain embodiments, the terminals 40, 42 can be used to provide electrical connection to the electronics module 100 via leads or wires to one or more electrodes and particularly to satellite electrodes. Satellite electrodes and representative electrode configurations using satellite electrodes are described in greater detail herein.

[0051] The primary patch component 20 further includes one or more electrical contacts accessible along the underside 22, such as for example electrical contacts 24 and 26. The electrical contacts are formed from an electrically conductive material and are described in greater detail herein. In many embodiments, the base layer 50 defines apertures 24a and 26a sized and shaped to fittingly receive the electrical contacts 24 and 26, respectively.

[0052] In the illustrated embodiment of the health patch 10, the primary patch component 20 comprises various electronics, components, and sensors generally enclosed within an interior hollow region of the housing 30. Typically, the terminals 40, 42 and the contacts 24, 26 provide electrical communication to one or more electronics, components, and/or sensors within the primary patch 20 and in many embodiments associated with the electronics module 100. These aspects are all described in greater detail herein.

[0053] Figure 2 is an exploded schematic cross sectional view of the primary patch 20 depicted in Figure 1. The housing 30 generally encloses the electronics, components, and sensors collectively shown as an electronics assembly 100, disposed on a base or substrate layer 50. The terminals 40, 42 extend through the outer face 33 of the housing 30, and particularly through apertures 40a and 42a, respectively, defined in the housing 30. The contacts 24, 26 are disposed in the apertures 24a, 26a, and are accessible along the underside 22. An underside 101 of the electronics module 100 can be provided with electrical traces or pathways for providing electrical communication between the contacts 24, 26 and the electronics module 100. One or more layers of an adhesive such as a pressure sensitive adhesive are disposed along the underside 22 of the base layer 50. In many embodiments, the housing 30 is sealed with the base layer 50 to provide a sealed interior for enclosing and retaining the electronics module 100.

[0054] Figure 3 is a schematic view of the underside 22 of the primary patch component 20 and more particularly of the base layer 50. The electrical contacts 24 and 26 are exposed along the underside 22.

[0055] Figure 4 is a schematic view of the primary patch component 20 packaged in a container 3. If a layer of an adhesive is provided along the underside 22 of the primary patch component, a release liner 2 can be used to cover the noted adhesive layer. The container 3 is typically sealed and may be in the form of a flexible wall pouch or a rigid or semi-rigid wall container. Additional details of packaging and release liners are provided herein.

[0056] Typically, the total thickness of the primary patch component 20 is within a range of from about 1 mm to about 20 mm, more particularly from about 1 mm to about 10 mm, and in certain embodiments from about 2 mm to about 6.5 mm. These representative total thickness ranges typically include one or more layers of a pressure sensitive adhesive, which is from about 0.1 mm to about 0.5 mm. It will be understood however that the present subject matter is not limited to any of these

thicknesses and instead includes layers and/or materials having thicknesses less than and/or greater than these representative values.

Secondary Patch

[0057] Referring to Figures 1 and 5-8, the secondary patch component 70 includes a support layer 75 and an electrode assembly 80. The support layer 75 defines an underside 72 and an oppositely directed outer face 73. The outer face 73 may include one or more layer(s) of an adhesive, and particularly a pressure sensitive adhesive. The underside of the secondary patch, i.e., the underside 72, is typically provided by one or more layer(s) of an adhesive, and particularly a pressure sensitive adhesive described herein. One or more hydrophilic agents and/or hydrocolloid agents can be incorporated in the adhesive layer(s) and/or provided in a layer or region of their own. These aspects are described in greater detail herein.

[0058] The secondary patch component 70 also includes one or more electrical contacts, such as electrical contacts 74 and 76, accessible along the outer face 73. The electrical contacts are formed from an electrically conductive material. In many embodiments, the support layer 75 defines apertures 74a and 76a sized and shaped to fittingly receive the electrical contacts 74 and 76, respectively. The electrical contacts such as contacts 74, 76 are arranged and/or positioned on the outer face 73 such that upon securing the primary patch component 20 and the secondary patch component 70 together, the contacts 74, 76 of the secondary patch component 70 are in electrical contact and/or communication with the contacts 24, 26 of the primary patch component 20.

[0059] Figure 1 schematically depicts positioning of the primary and secondary patch components 20, 70 relative to one another prior to contact between their respective faces. As evident in Figure 1 the contacts 24 and 26 of the primary patch component 20 are aligned with the contacts 74 and 76 respectively, of the secondary patch component 70 such that upon contact and/or securement between

the primary and secondary patch components, electrical contact and/or communication is established between the contacts 24 and 74, and between the contacts 26 and 76.

[0060] Figure 5 is an exploded schematic cross sectional view of the secondary patch 70 depicted in Figure 1. Generally, the support layer 75 covers and/or overlies the electrode assembly 80. One or more regions of adhesive along the underside 72 of the support layer 75 can be used to adjoin the support layer 75 with the electrode assembly 80. The electrode assembly 80 includes electrodes 84 and 86 exposed along the underside 82 of the electrode assembly 80. In many embodiments, the electrodes 84, 86 are in the form of Ag/AgCl electrodes. Additional details of such electrodes are described herein. The secondary patch 70 and its components are configured such that the contacts 74, 76 are in electrical communication with electrodes 84, 86, respectively. One or more electrical traces and/or pathways 81 can be provided to establish such electrical communication.

[0061] Figure 6 is a schematic view of the underside of the secondary patch component 70 illustrating electrodes 84 and 86 exposed along the underside. Specifically, in the particular embodiment illustrated, an outer peripheral region of the underside 72 of the support layer 75 is exposed, and a portion of the underside 82 of the electrode assembly 80 is exposed. Adhesive, and particularly pressure sensitive adhesive, may be disposed on the underside 82 of the electrode assembly 80. Adhesive, and particularly pressure sensitive adhesive, may be disposed on the outer peripheral region of the underside 72 of the support layer 75. One or more regions 85, 87 of hydrophilic agents such as for example hydrocolloids are also provided along the underside of the secondary patch component. The region(s) 85, 87 of hydrophilic agents may be disposed on a portion or an entirety of the underside 82 of the electrode assembly 80; and/or on a portion or an entirety of any exposed areas of the underside 72 of the support layer 75.

[0062] Figure 7 is a schematic illustration showing use of a double-sided adhesive tape 90 or like component, positioned between the base layer 50 of the primary patch component and the support

layer 75 of the secondary patch component. In many embodiments, a double-sided adhesive tape 90 can be used to releasably adhere and secure the primary patch component with the secondary patch component. Such tape 90 can be used in addition to, or instead of, the use of adhesives along the underside 22 of the base layer 50 and/or the outer face 73 of the support layer 75. Although an array of various types and configurations of double-sided adhesive tape could potentially be used for the tape 90, it is contemplated that double-sided adhesive tapes commercially available from Avery Dennison and/or Vancive Medical Technologies could be used.

[0063] In particular embodiments of the present subject matter in which the primary and secondary components are adhesively adjoined to one another, adhesives having certain levels of bond strength are used in association with the primary patch component and adhesives with other certain levels of bond strength are used in association with the secondary patch component. For example, adhesives having a relatively high bond strength can be used in conjunction with the secondary component and may be disposed on, or constitute, one or more regions of the outer face 73 of the support layer 75. And for example, adhesives having a relatively low bond strength can be used in conjunction with the primary component and may be disposed on, or constitute, one or more regions of the underside 22 of the base layer 50.

[0064] For embodiments using a double-sided adhesive tape 90, a tape 90 including a backing 94 with a layer 92 of a low bond strength adhesive and an oppositely directed layer 96 of a high bond strength adhesive can be used. As depicted in Figure 7, the layer 92 of the low bond strength adhesive is directed toward and contacting the underside 22 of the base layer 50; and the layer 96 of the high bond strength adhesive is directed toward and contacting the outer face 73 of the support layer 75. The term "low bond strength adhesive" and the term "high bond strength adhesive" refer to adhesives having differing bond peel strengths. Typically, the high bond strength adhesive exhibits an adhesive peel bond strength that is greater than the adhesive peel bond strength of the low bond strength

adhesive by a factor of from 2 times to 10 times, and more particularly from 2 times to 5 times. In certain embodiments, the low bond strength adhesive exhibits an adhesive peel bond strength typically less than 5 Newtons, and in many embodiments from 2 to 5 Newtons, and particularly from 2 to 3 Newtons. And, in certain embodiments, the high bond strength adhesive exhibits an adhesive peel bond strength typically greater than 10 Newtons, and in many embodiments from 10 to 20 Newtons, and particularly from 10 to 15 Newtons. It will be understood that these representative adhesive peel bond strengths (expressed in Newtons) are for adhesive samples adhered to stainless steel and/or hard plastic substrates. Adhesive peel bond strengths for adhesion to other surfaces can vary and depend upon a host of factors.

[0065] Typically, the total thickness of the secondary patch component 70 is within a range of from about 1 mm to about 10 mm, and in certain embodiments from about 2 mm to about 6.5 mm. These representative total thickness ranges typically include one or more layers of a pressure sensitive adhesive which is from about 0.1 mm to about 0.5 mm thick. However, it will be appreciated that the present subject matter is not limited to any of these thicknesses, and instead includes layers and/or materials having thicknesses less than and/or greater than these representative values.

[0066] Figure 8 is a schematic view of the secondary patch component 70 packaged in a container 5. If a layer of an adhesive is provided along the outer face 73 (Figure 5) of the support layer 75, a release liner 4 can be used to cover the noted adhesive layer. As previously described, in many embodiments, a layer or region of adhesive is typically provided along the underside, i.e., regions 82 and 72 (Figure 5); and regions of hydrocolloid 85, 87 (Figure 5) are typically provided. A release liner 6 can be applied to cover and protect those areas until use and application of the patch. The container 5 is typically sealed and may be in the form of a flexible wall pouch or a rigid or semi-rigid wall container. Additional details of packaging and release liners are provided herein.

Electronics, Components, and Sensors

[0067] The health patch 10 comprises the electronics assembly 100 that includes various electronics, components, and sensors. In many embodiments, except for electrodes 84 and 86, these are incorporated in the primary patch component 20 and particularly, generally enclosed between the housing 30 and the base layer 50. Figures 1, 2, 4, and 9 schematically illustrate the electronics assembly 100 used in the health patch 10. Generally as shown in Figure 9, the electronics assembly 100 comprises one or more microprocessors 110, a communications transmitter 120, a communications receiver 130, one or more batteries 140 or other power source(s), data storage provisions 150, and one or more sensors and/or sensor provisions depicted as 160, 162, and 164 and the like.

[0068] The communications transmitter and receiver, i.e., 120 and 130 respectively, are typically in the form of radio transmitters and receivers. The communications transmitter and receiver include or utilize electronics and processors to enable the desired communication protocol, which as previously noted is typically BLUETOOTH™ or BLUETOOTH SMART™. Additional or different communication protocols can be used, as described herein. In many embodiments, the health patches include communication provisions, and particularly wireless communication provisions such as for example the noted radio transmitters and/or receivers.

[0069] As previously noted, a wide variety of sensors can be used. Typically, the sensors include one or more accelerometers and particularly a 3-axis accelerometer. Details of a typical 3-axis accelerometer and its use are set forth in US 4,817,628. Additional details as to accelerometers and their use and assessing body position and/or activity levels are provided in US 6,307,481; 6,501,386; 6,661,437; 7,020,508; 7,145,461; 7,313,440; 7,382,247; 7,407,484; 7,668,588, for example. The sensors can also include one or more temperature sensors which for example can be in the form of thermistors. Details of sensing skin temperature and/or thermistors are set forth in US 3,872,455; 3,949,388; 3,646,606; 4,321,933; 4,471,354; 4,509,531; 4,686,998; 4,957,109; 5,307,263; and 5,634,468. The

sensors can also include one or more heart rate sensors and particularly those known in the art as "ECG" or "EKG" sensors which can be in the form of "wet" Ag/AgCl electrodes. In many versions of the present subject matter health patch, the electrodes 84 and 86 are wet Ag/AgCl electrodes. Details of wet Ag/AgCl electrodes and related sensors are provided in US 3,872,455; 4,121,573; 3,646,606; 4,681,118; 4,686,998; 4,957,109; 4,981,141; 5,153,584; 5,125,405; 5,228,449; 5,168,874; 5,307,263; 5,307,818; 5,400,794; and 5,634,468. Sensors may also be included and/or utilized to sense respiration or aspects thereof such as described in US 4,957,109. Galvanic skin response (GSR) sensors can also be included. Details of GSR sensors and their use are provided in US 6,605,038; 7,020,508; 7,769,464; 7,822,481; 7,952,475; 8,032,229; and 8,016,776. It will be understood that the health patches of the present subject matter can include different and/or other types of sensors.

Materials of Housing and Substrate(s)

[0070] The housing of the health patch, e.g., the housing 30, is typically formed from a rigid or semi-rigid polymer. The housing can include a laminate or multilayer construction. Foamed materials are also contemplated for the housing. The base layer, e.g., the base layer 50 of the primary patch component and/or the support layer 75 of the secondary patch component, is typically formed from a breathable nonwoven material and/or a polymer film. The base layer and/or the support layer 75 generally has a thickness of about 2.5 microns to about 500 microns, or from about 10 microns to about 375 microns, or even from about 20 microns to about 250 microns.

[0071] A wide array of nonwoven materials could be used in either or both of the primary patch component and/or the secondary patch component. Typically, in many applications the nonwoven material is breathable. Medical grade nonwoven materials are commercially available from numerous suppliers.

[0072] If a polymeric film material is used, the film for the base layer and/or the support layer may be oriented or non-oriented. In another embodiment, the polymer film from which the base layer and/or the support layer is formed is optionally subjected to orientation. The base layer film and/or the support layer film may be either uniaxially or biaxially oriented. If the film is uniaxially oriented, such orientation can be in either the machine direction or the transverse direction.

[0073] Suitable polymers for the housing and/or the base layer and/or the support layer include, but are not limited to, polycarbonate, polyacryl polymer, polymethacryl polymer, styrenic polymer, polyolefin polymer or polyester polymer or co-polymer(s) formed from one or more of the above-mentioned polymers.

[0074] In one embodiment, the housing and/or the base layer and/or the support layer is formed from a polyolefin polymer. The polyolefins which can be utilized as the material from which the housing and/or the base layer and/or the support layer is formed include, but are not limited to, polymers and copolymers of ethylene, propylene, 1-butene, hexene, octene, or blends or mixtures of such polymers and copolymers. In one embodiment, the polyolefins comprise polymers and copolymers of ethylene and propylene. In another embodiment, the polyolefins comprise propylene homopolymers, and copolymers, such as propylene-ethylene and propylene-1-butene copolymers. Blends of polypropylene and polyethylene with each other, or blends of either or both of them with polypropylene-polyethylene copolymer also are useful. In another embodiment, the polyolefin film materials are those with a very high propylenic content, either polypropylene homopolymer or propylene-ethylene copolymers or blends of polypropylene and polyethylene with low ethylene content, or propylene-1-butene copolymers or blends of polypropylene and poly-1-butene with low butene content.

[0075] Various polyethylenes can be utilized as the first polymer material including low, medium, and high density polyethylenes. An example of a useful low density polyethylene (LDPE) is Rexene 1017, available from Huntsman.

[0076] In another embodiment, useful polyolefins include very low density polyethylene (ULDPE), which has been referred to as ultra low density polyethylene, linear low density polyethylene (LLDPE), linear low density polyethylene (LLPE), etc. Very low density polyethylene (VLDPE) has a density of about 0.885–0.912 g/cc. Such VLDPE resins are commercially available from Union Polymer Co.

[0077] In still another embodiment, the polymer utilized to form the housing and/or the base layer and/or the support layer is a polyolefin or a thermoplastic polymer of ethylene or propylene, or a mixture containing these polymers. In another embodiment, the polymer is polyethylene, polypropylene, thermoplastic polymers of ethylene or propylene.

[0078] In still another embodiment, the polymer from which the housing and/or the base layer and/or the support layer is formed is an ethylene/alpha-olefin copolymer. These polymers generally designate copolymers of ethylene with one or more co-monomers, such as 1-butene, 1-pentene, 1-hexene, 1-octene, methyl pentene and the like, in which the polymer molecules comprise long chains with relatively few side chain branches. These polymers are obtained by low pressure polymerization processes and the side branching, which if present, will be short compared to non-linear polyethylenes (e.g., LDPE, a low density polyethylene homopolymer).

[0079] Ethylene/alpha-olefin copolymers generally have a density in the range of from about 0.86 g/cc to about 0.94 g/cc. The term linear low density polyethylene (LLDPE) is generally understood to include that group of ethylene/alpha-olefin copolymers which fall into the density range of about 0.915 g/cc to about 0.94 g/cc. Linear polyethylene in the density range from about 0.926 g/cc to about 0.94 g/cc is often referred to as linear medium density polyethylene (LMDPE). Lower density ethylene/alpha-olefin copolymers may be referred to as very low density polyethylene (VLDPE, typically used to refer to the ethylene/butene copolymers available from Union Carbide with a density ranging from about 0.88 g/cc to about 0.91 g/cc) and ultra-low density polyethylene (ULDPE, typically used to refer to the ethylene/octene copolymers supplied by Dow). Specific examples of useful, commercially available low

density ethylene-1-octene copolymers include: Dowlex 2036A with a density in the range of 0.9330 g/cc to 0.9370 g/cc; Dowlex 2032PER with a density of 0.9240 g/cc to 9280 g/cc; Affinity PF1140 with a density of 0.895 g/cc to 0.898 g/cc; Affinity VP8770 with a density of 0.885 g/cc; Attane 4402 with a density of 0.912 g/cc; and Attane 4401 with a density of 0.912 g/cc. All of these copolymers are available from the Dow Chemical Co.

[0080] A variety of propylene copolymers are useful as the housing and/or the base layer and/or the support layer. The propylene copolymers generally comprise copolymers of propylene and up to 10%, or even 20%, by weight of at least one other alpha olefin, such as ethylene, 1-butene, 1-pentene, etc. In one embodiment, the propylene copolymers are propylene-ethylene copolymers with ethylenic content from about 0.2% to about 10% by weight. Such copolymers are prepared by techniques well known to those skilled in the art, and these copolymers are available commercially from, for example, Union Carbide. A propylene-ethylene copolymer containing about 3.2% by weight of ethylene is available from Union Carbide under the designation D56D20. Another Union Carbide propylene-ethylene copolymer is D56D8, which contains 5.5% by weight of ethylene.

[0081] In another embodiment, the housing and/or the base layer and/or the support layer comprises at least one thermoplastic copolymer or terpolymer derived from ethylene or propylene, and a functional monomer selected from the group consisting of alkyl acrylate, acrylic acid, alkyl acrylic acid, and combinations of two or more thereof. In one embodiment, the functional monomer is selected from alkyl acrylate, acrylic acid, alkyl acrylic acid, and combinations of two or more thereof. In one embodiment, the first polymer is characterized by the absence of ethylene vinyl acetate resins, and acid or acid/acrylate-modified ethylene vinyl acetate resins. The alkyl groups in the alkyl acrylates and the alkyl acrylic acids typically contain 1 to about 8 carbon atoms, and, in one embodiment, 1 to about 2 carbon atoms. The functional monomer(s) component of the copolymer or terpolymer ranges from about 1 to about 15 mole percent, and, in one embodiment, about 1 to about 10 mole percent of the

copolymer or terpolymer molecule. Examples include: ethylene/methyl acrylate copolymers; ethylene/ethylacrylate copolymers; ethylene/butyl acrylate copolymers; ethylene/methacrylic acid copolymers; ethylene/acrylic acid copolymers; anhydride-modified low density polyethylenes; anhydride-modified linear low density polyethylene, and mixtures of two or more thereof.

[0082] Ethylene acid copolymers can also be used and are available from DuPont under the tradename Nucrel. These include Nucrel 0407, which has a methacrylic acid content of 4% by weight and a melting point of 109° C., and Nucrel 0910, which has a methacrylic acid content of 8.7% by weight and a melting point of 100° C. The ethylene/acrylic acid copolymers available from Dow Chemical, under the tradename Primacor, are also useful. These include Primacor 1430, which has an acrylic acid monomer content of 9.5% by weight, a melting point of about 97° C. and a Tg of about -7.7° C. The ethylene/methyl acrylate copolymers available from Chevron, under the tradename EMAC, can be used. These include EMAC 2205, which has a methyl acrylate content of 20% by weight and a melting point of 83° C., and EMAC 2268, which has a methyl acrylate content of 24% by weight, a melting point of about 74° C. and a Tg of about -40.6° C.

[0083] In one embodiment, the housing and/or the base layer and/or the support layer comprises at least one polyester. Polyesters are prepared from various glycols (including ethylene glycol, propylene glycol, neopentyl glycol, etc.) or polyols (including glycerol, trimethylolpropane, pentaerythritol, etc.) and one or more aliphatic or aromatic carboxylic acids. Polyethylene terephthalate (PET), PETG (PET modified with cyclohexanedimethanol), and polybutylene terephthalate (PBT) are useful and are available from a variety of commercial sources, including Eastman. For example, Kodar 6763 is a PETG, available from Eastman Chemical. Another useful polyester from DuPont is Sclar PT-8307, which is polyethylene terephthalate. Another useful polyester is polyethylene naphthenate.

[0084] In another embodiment, the housing and/or the base layer and/or the support layer comprises at least one polystyrene (or styrenic polymer). Polystyrenes include homopolymers, as well

as, copolymers of styrene and substituted styrene, such as alpha-methyl styrene. Examples of styrene copolymers and terpolymers include: acrylonitrile-butene-styrene (ABS); styrene-acrylonitrile copolymers (SAN); styrene butadiene (SB); styrene-maleic anhydride (SMA); styrene-methyl methacrylate (SMMA); etc. An example of a useful styrene copolymer is KR-10 from Phillip Petroleum Co. KR-10 is believed to be a copolymer of styrene with 1,3-butadiene.

[0085] In another embodiment, the housing and/or the base layer and/or the support layer is composed of a polyacryl or polymethacryl resin. As used herein, a "polyacryl" includes polyacrylates, polyacrylics or polyacrylamides, and "polymethacryl" includes polymethacrylates, polymethacrylics or polymethacrylamides. These resins include those derived from acrylic acid, acrylate esters, acrylamide, methacrylic acid, methacrylate esters, and methacrylamide. The acrylate and methacrylate ester generally contain from 1 to about 30 carbon atoms in the pendant group, or from 1 to about 18 carbon atoms in the pendant group, or from 2 to about 12 carbon atoms in the pendant group.

[0086] Examples of commercial polyacryls and polymethacryls include Gelva® 2497 (commercially available from Monsanto Co., St. Louis, Mo.), Duraplus® 2 (commercially available from Rohm & Haas Co., Philadelphia, Pa.), Joncryl® 95 (commercially available from S. C. Johnson Polymer, Sturtevant, Wis.), SCX-1537 (S. C. Johnson Polymer), SCX-1959 (S. C. Johnson Polymer), SCX-1965 (S. C. Johnson Polymer), Joncryl® 530 (S. C. Johnson Polymer), Joncryl® 537 (S. C. Johnson Polymer), Glascol LS20 (commercially available from Allied Colloids, Suffolk, Va.), Glascol C37 (Allied Colloids), Glascol LS26 (Allied Colloids), Glascol LS24 (Allied Colloids), Glascol LE45 (Allied Colloids), Carboset® CR760 (commercially available from BFGoodrich, Cleveland, Ohio), Carboset® CR761 (BFGoodrich), Carboset® CR763 (BFGoodrich), Carboset® 765 (BFGoodrich), Carboset® 19X2 (BFGoodrich), Carbosete XL28 (BFGoodrich), Hycar 26084 (BFGoodrich), Hycar 26091 (BFGoodrich), Carbobond 26373 (BFGoodrich), Neocryl® A-601 (commercially available from Avecia Resins, Wilmington, Mass.), Neocryl® A-612 (Avecia Resins), Neocryl® A-6044

(Avecia Resins), Neocryl® A-622 (Avecia Resins), Neocryl® A-623 (Avecia Resins), Neocryl® A-634 (Avecia Resins), and Neocryl® A-640 (Avecia Resins).

[0087] Polycarbonates also are useful as the housing and/or the base layer and/or the support layer of the health patches of the present subject matter. Suitable polycarbonates are available from the Dow Chemical Co. (Calibre), G.E. Plastics (Lexan) and Bayer (Makrolon). Most commercial polycarbonates are obtained by the reaction of bisphenol A and carbonyl chloride in an interfacial process. Molecular weights of the typical commercial polycarbonates vary from about 22,000 to about 35,000, and the melt flow rates generally are in the range of from 4 to 22 g/10 min.

[0088] In certain embodiments, the primary patch component includes an upper or outer layer of a foamed material which generally encloses the electronics assembly. Although a variety of foams and materials can be used, in certain versions, the foam layer exhibits the following physical characteristics. The foam layered material exhibits a minimal tensile strength in a machine direction (MD) of at least 350 psi (2413 kPa); a minimum elongation in the machine direction of at least 310%; and a minimum tear strength in the machine direction of at least 43 lbs/inch (7530 N/m).

Adhesives

[0089] Any pressure sensitive adhesive that is capable of adhering to mammalian skin for the desired period of use, is free of ingredients known to cause undue irritation or toxicity to mammals, and which can be removed from the skin without damage thereto can be utilized in the health patches of the present subject matter. For example, the pressure sensitive adhesive may include one or more of a silicone pressure sensitive adhesive, rubber pressure sensitive adhesive, acrylic pressure sensitive adhesive, a hydrogel pressure sensitive adhesive or other known pressure sensitive adhesives. A description of useful pressure sensitive adhesives may be found in *Encyclopedia of Polymer Science and Engineering*, Vol. 13. Wiley-Interscience Publishers (New York, 1988). Additional description of useful

pressure sensitive adhesives may be found in *Encyclopedia of Polymer Science and Technology*, Vol. 1, Interscience Publishers (New York, 1964).

[0090] In many embodiments of the present subject matter, the health patches utilize one or more medical adhesives or skin-friendly adhesives which are available from Avery Dennison Corporation and/or its medical business group, Vancive Medical Technologies. Nonlimiting examples of such adhesives include MED5750A. In certain embodiments, the health patches can comprise a hydrocolloid adhesive although other skin-friendly adhesives may be provided such as integrated hydrocolloid or other adhesives capable of absorbing moisture. Hydrocolloids are described in greater detail herein. For example, the health patches can comprise a hydrocolloid such as the hydrocolloid material disclosed in any one of U.S. Patent No. 7,335,416 that issued on February 6, 2008, U.S. Patent No. 6,710,100 that issued on March 23, 2004, U.S. Patent No. 6,583,220 that issued on June 24, 2003, U.S. Patent No. 6,326,421 that issued on December 4, 2001, U.S. Patent Application No. 12/866,750 filed August 9, 2010, and U.S. Provisional Patent 61/467,553 filed March 25, 2011. The subject matter of these references is incorporated herein by reference.

[0091] In general, the pressure sensitive adhesives used herein may be any of the pressure sensitive adhesives described in the above citations. In one embodiment of the health patches of the present subject matter, pressure sensitive adhesives comprise natural or synthetic elastomers, or acrylic-based adhesives. Two or more pressure sensitive adhesive layers may be used in the health patch and may be of the same composition or they may be different so long as the adhesive layers have sufficient tack to adhere to each other, to the backing, and optionally to a release liner.

[0092] The pressure sensitive adhesives in each adhesive layer of the health patches can be acrylic based such as those taught in U.S. Pat. No. 5,164,444 (Bernard, acrylic emulsion), U.S. Pat. No. 5,623,011 (Bernard, tackified acrylic emulsion) and U.S. Pat. No. 6,306,982 (Lee et al., general purpose inherently tacky acrylic pressure sensitive adhesives). The adhesive can also be rubber-based such as those taught

in U.S. Pat. No. 5,705,551 (Sasaki et al, rubber hot melt). The adhesive can also be radiation curable mixture of monomers with initiators and other ingredients such as those taught in U.S. Pat. No. 5,232,958 (Ang, UV cured acrylic) and U.S. Pat. No. 5,232,958 (Mallya et al, EB cured). The disclosures of these patents as they relate to acrylic adhesives are hereby incorporated by reference.

[0093] Commercially available pressure sensitive adhesives may also be useful in the health patches. Examples of other potentially useful adhesives besides those noted from Avery Dennison and/or Vancive Medical Technologies include the hot melt pressure sensitive adhesives available from H.B. Fuller Company, St. Paul, Minn. as HM-1597, HL-2207-X, HL-2115-X, HL-2193-X. Other potentially useful commercially available pressure sensitive adhesives include those available from Century Adhesives Corporation, Columbus, Ohio. Another potentially useful acrylic pressure sensitive adhesive comprises a blend of emulsion polymer particles with dispersion tackifier particles as generally described in Example 2 of U.S. Pat. No. 6,306,982, to Lee et al. The polymer is made by emulsion polymerization of 2-ethylhexyl acrylate, vinyl acetate, dioctyl maleate, acrylic and methacrylic comonomers as described in U.S. Pat. No. 5,164,444 by M. Bernard, resulting in the latex particle size of about 0.2 microns in weight average diameters and a gel content of about 60%.

[0094] Conventional pressure sensitive adhesives, including silicone-based pressure sensitive adhesives, rubber-based pressure sensitive adhesives, and acrylic-based pressure sensitive adhesives may in certain applications be useful. A commercial example of a hot melt adhesive is H2187-01, sold by Ato Findley, Inc., of Wauwatusa, Wis. In addition, rubber-based block copolymer pressure sensitive adhesives described in U.S. Pat. No. 3,239,478 (Harlan) also can be utilized in the adhesive constructions of the present subject matter, and this patent is hereby incorporated by a reference for its disclosure of such hot melt adhesives.

[0095] In one embodiment, the skin-contacting pressure sensitive adhesive layer may be formed from an acrylic based polymer. It is contemplated that any acrylic based polymer capable of forming an

adhesive layer with sufficient tack to adhere to the base or substrate layer, the release liner and to mammalian skin may function in the health patches. In certain embodiments, the acrylic polymers for the pressure sensitive adhesive layers include those formed from polymerization of at least one alkyl acrylate monomer containing from about 4 to about 12 carbon atoms in the alkyl group, and present in an amount from about 35-95% by weight of the polymer or copolymer, as disclosed in U.S. Pat. No. 5,264,532 issued to Barnard. Optionally, the acrylic based pressure sensitive adhesive might be formed from a single polymeric species.

[0096] Advantageously, the glass transition temperature of a pressure sensitive adhesive layer comprising acrylic polymers can be varied by adjusting the amount of polar, or "hard monomers", in the copolymer, as taught by U.S. Pat. No. 5,264,532, incorporated herein by reference. The greater the percentage by weight of hard monomers in an acrylic copolymer, the higher the glass transition temperature. Hard monomers contemplated useful for the present subject matter include vinyl esters, carboxylic acids, and methacrylates, in concentrations by weight ranging from about zero to about thirty-five percent by weight of the polymer.

[0097] In another embodiment, the pressure sensitive adhesive utilized in the health patches may comprise rubber based elastomer materials containing useful rubber based elastomer materials include linear, branched, grafted, or radial block copolymers represented by the diblock structure A-B, the triblock A-B-A, the radial or coupled structures (A-B)_n, and combinations of these where A represents a hard thermoplastic phase or block which is non-rubbery or glassy or crystalline at room temperature but fluid at higher temperatures, and B represents a soft block which is rubbery or elastomeric at service or room temperature. These thermoplastic elastomers may comprise from about 75% to about 95% by weight of rubbery segments and from about 5% to about 25% by weight of non-rubbery segments.

[0098] The non-rubbery segments or hard blocks comprise polymers of mono- and polycyclic aromatic hydrocarbons, and more particularly vinyl-substituted aromatic hydrocarbons which may be

monocyclic or bicyclic in nature. The preferred rubbery blocks or segments are polymer blocks of homopolymers or copolymers of aliphatic conjugated dienes. Rubbery materials such as polyisoprene, polybutadiene, and styrene butadiene rubbers may be used to form the rubbery block or segment. Particularly preferred rubbery segments include polydienes and saturated olefin rubbers of ethylene/butylene or ethylene/propylene copolymers. The latter rubbers may be obtained from the corresponding unsaturated polyalkylene moieties such as polybutadiene and polyisoprene by hydrogenation thereof.

[0099] The block copolymers of vinyl aromatic hydrocarbons and conjugated dienes which may be utilized include any of those which exhibit elastomeric properties. The block copolymers may be diblock, triblock, multiblock, starblock, polyblock or graftblock copolymers. Throughout this specification and claims, the terms diblock, triblock, multiblock, polyblock, and graft or grafted-block with respect to the structural features of block copolymers are to be given their normal meaning as defined in the literature such as in the *Encyclopedia of Polymer Science and Engineering*, Vol. 2, (1985) John Wiley & Sons, Inc., New York, pp. 325-326, and by J. E. McGrath in *Block Copolymers, Science Technology*, Dale J. Meier, Ed., Harwood Academic Publishers, 1979, at pages 1-5.

[00100] Such block copolymers may contain various ratios of conjugated dienes to vinyl aromatic hydrocarbons including those containing up to about 40% by weight of vinyl aromatic hydrocarbon. Accordingly, multi-block copolymers may be utilized which are linear or radial symmetric or asymmetric and which have structures represented by the formulae A-B, A-B-A, A-B-A-B, B-A-B, (AB)_{0,1,2} . . . BA, etc., wherein A is a polymer block of a vinyl aromatic hydrocarbon or a conjugated diene/vinyl aromatic hydrocarbon tapered copolymer block, and B is a rubbery polymer block of a conjugated diene.

[00101] The block copolymers may be prepared by any of the well known block polymerization or copolymerization procedures including sequential addition of monomer, incremental addition of monomer, or coupling techniques as illustrated in, for example, U.S. Pat. Nos. 3,251,905; 3,390,207;

3,598,887; and 4,219,627. As well known, tapered copolymer blocks can be incorporated in the multi-block copolymers by copolymerizing a mixture of conjugated diene and vinyl aromatic hydrocarbon monomers utilizing the difference in their copolymerization reactivity rates. Various patents describe the preparation of multi-block copolymers containing tapered copolymer blocks including U.S. Pat. Nos. 3,251,905; 3,639,521; and 4,208,356, the disclosures of which are hereby incorporated by reference.

[00102] Conjugated dienes which may be utilized to prepare the polymers and copolymers are those containing from 4 to about 10 carbon atoms and more generally, from 4 to 6 carbon atoms. Examples include from 1,3-butadiene, 2-methyl-1,3-butadiene (isoprene), 2,3-dimethyl-1,3-butadiene, chloroprene, 1,3-pentadiene, 1,3-hexadiene, etc. Mixtures of these conjugated dienes also may be used. In many embodiments, the conjugated dienes are isoprene and 1,3-butadiene.

[00103] Examples of vinyl aromatic hydrocarbons which may be utilized to prepare the copolymers include styrene and the various substituted styrenes such as o-methylstyrene, p-methylstyrene, p-tert-butylstyrene, 1,3-dimethylstyrene, alpha-methylstyrene, beta-methylstyrene, p-isopropylstyrene, 2,3-dimethylstyrene, o-chlorostyrene, p-chlorostyrene, o-bromostyrene, 2-chloro-4-methylstyrene, etc. In certain embodiments, the vinyl aromatic hydrocarbon is styrene.

[00104] Many of the previously noted copolymers of conjugated dienes and vinyl aromatic compounds are commercially available. The number average molecular weight of the block copolymers, prior to hydrogenation, is from about 20,000 to about 500,000, and in certain embodiments from about 40,000 to about 300,000.

[00105] The average molecular weights of the individual blocks within the copolymers may vary within certain limits. In most instances, the vinyl aromatic block will have a number average molecular weight in the order of about 2000 to about 125,000, and particularly between about 4000 and 60,000. The conjugated diene blocks either before or after hydrogenation will have number average molecular

weights in the order of about 10,000 to about 450,000 and more particularly from about 35,000 to 150,000.

[00106] Also, prior to hydrogenation, the vinyl content of the conjugated diene portion generally is from about 10% to about 80%, and the vinyl content is particularly from about 25% to about 65%, and more particularly 35% to 55% when it is desired that the modified block copolymer exhibit rubbery elasticity. The vinyl content of the block copolymer can be measured by means of nuclear magnetic resonance.

[00107] Specific examples of diblock copolymers include styrene-butadiene (SB), styrene-isoprene (SI), and the hydrogenated derivatives thereof. Examples of triblock polymers include styrene-butadiene-styrene (SBS), styrene-isoprene-styrene (SIS), alpha-methylstyrene-butadiene-alpha-methylstyrene, and alpha-methylstyrene-isoprene alpha-methylstyrene. Examples of commercially available block copolymers which may be useful as the adhesives in the health patches of the present subject matter include those available from Shell Chemical Company. Normally liquid low molecular weight diblock copolymers, such as liquid SI copolymers, may be advantageously employed as components of the adhesives of the health patches.

[00108] Additional examples of potentially useful block copolymers also are available from Nippon Zeon Co., 2-1, Marunochi, Chiyoda-ku, Tokyo, Japan. For example, Quintac 3530 is available from Nippon Zeon and is believed to be a linear styrene-isoprene-styrene block copolymer.

[00109] Unsaturated elastomeric polymers and other polymers and copolymers which are not inherently tacky can be rendered tacky when compounded with an external tackifier. Tackifiers, are generally hydrocarbon resins, wood resins, rosins, rosin derivatives, and the like, which when present in concentrations ranging from about 40% to about 90% by weight of the total adhesive composition, more particularly from about 45% to about 85% by weight, impart pressure sensitive adhesive characteristics to the elastomeric polymer adhesive formulation. Compositions containing less than about 40% by

weight of tackifier additive do not generally show sufficient "quickstick," or initial adhesion, to function as a pressure sensitive adhesive, and therefore are not inherently tacky. Compositions with too high a concentration of tackifying additive, on the other hand, generally show too little cohesive strength to work properly in most intended use applications of constructions made in accordance with the present subject matter.

[00110] It is contemplated that any tackifier known by those of skill in the art to be compatible with elastomeric polymer compositions may be used with the health patches of the subject matter. One such tackifier, found useful is Wingtak 10, a synthetic polyterpene resin which is liquid at room temperature, and sold by the Goodyear Tire and Rubber Company of Akron, Ohio. Wingtak 95 is a synthetic tackifier resin also available from Goodyear which comprises predominantly a polymer derived from piperylene and isoprene. Other suitable tackifying additives may include Escorez 1310, an aliphatic hydrocarbon resin, and Escorez 2596, a C5-C9 (aromatic modified aliphatic) resin, both manufactured by Exxon of Irving, Tex. Of course, as can be appreciated by those of skill in the art, a variety of different tackifying additives may be used.

[00111] In addition to the tackifiers, other additives may be included in the pressure sensitive adhesives to impart desired properties. For example, plasticizers may be included, and they are known to decrease the glass transition temperature of an adhesive composition containing elastomeric polymers. An example of a useful plasticizer is Shellflex 371, a naphthenic processing oil available from Shell Oil Company of Houston, Tex. Antioxidants also may be included on the adhesive compositions. Suitable antioxidants include Irgafos 168 and Irganox 565 available from Ciba-Geigy, Hawthorne, N.Y. Cutting agents such as waxes and surfactants also may be included in the adhesives.

[00112] In many embodiments, an acrylic adhesive commercially available under the designation DURO-TAK 380-2819 has been found useful, particularly at a coat weight of about 60 g/m².

Hydrophilics and Hydrocolloids

[00113] As previously described, the health patches of the present subject matter can include one or more layer(s) or region(s) of hydrophilic agents and particularly hydrocolloid agents along the underside of the primary patch and/or the secondary patch. It is also contemplated to incorporate the hydrophilic and/or hydrocolloid agent(s) within the adhesive layer(s). Typically, the hydrophilic agents include hydrophilic absorbent polymers. In one embodiment, the hydrophilic absorbent polymers include one or more of alginic acid, sodium alginate, calcium alginate, cellulose-derived material, starch or a modified starch, a copolymer of a starch or a cellulosic material, a water soluble hydrocolloid, a synthetic resin, a mannan, seaweeds, and a plant mucilage. One or more such hydrophilic absorbent polymers may be present and a mixture of soluble and insoluble hydrophilic absorbent polymers can be used. Suitable swellable hydrophilic absorbent polymers include, e.g., cross-linked sodium carboxymethyl cellulose, crystalline sodium carboxymethyl cellulose, cross-linked dextran and starch-acrylonitrile graft copolymer. Others are discussed below. The swellable polymer may also be a so-called "super absorbent" material such as starch sodium polyacrylate. In one embodiment, the swellable polymer is other than a "super absorbent" material. Other hydrophilic absorbent polymers such as gluten and polymers of methyl vinyl ether and maleic acid and derivatives thereof may also be included with the water-soluble and/or water-swellable polymer.

[00114] In one embodiment, the water-soluble and/or water-swellable polymer comprises one or more hydrophilic absorbent polymers. In one embodiment, the hydrophilic absorbent polymer includes one or more of alginic acid, sodium or calcium alginate, a carboxymethyl cellulose salt (e.g., sodium, calcium, or other alkali or alkaline earth ions), a water soluble hydrocolloid, a cross-linked carboxymethyl cellulose salt, a crystalline carboxymethyl cellulose salt, a cross-linked dextrin, a starch-acrylonitrile graft copolymer, a starch polyacrylate salt, a water soluble gum, for example, pectin, guar gum or xanthene gum, gelatin, polysaccharides and the like.

[00115] In one embodiment, the water-soluble and/or water-swellaable polymer may comprise one or more water-soluble hydrocolloids, alone or blended with one or more swellaable polymers. Such soluble hydrocolloids include naturally derived products such as pectin, gelatin, starches, guar gum, locust bean gum, gum arabic, gum karaya, collagen, karaya gum, alginic acid and its sodium and/or calcium salts. Also useful are the synthetic hydrocolloids such as sodium carboxymethyl cellulose, crosslinked sodium carboxymethyl cellulose, polyvinyl alcohol, polyvinyl pyrrolidone, high molecular weight polyethylene glycols and polypropylene glycols.

[00116] In one embodiment, the water-soluble and/or water-swellaable polymer may comprise one or more of, e.g., starches such as flour starch, corn starch, potato starch, etc. In another embodiment, mannan such as yeast gum, manna or konjak may be included. In another embodiment, the water-soluble and/or water-swellaable polymer may comprise one or more of various seaweeds such as agar-agar, sodium alginate, etc. In another embodiment, the water-soluble and/or water-swellaable polymer may comprise one or more plant mucilages such as tragacanth gum, gum arabic, karaya gum, guar gum, psyllium seed gum, dammar gum, pectin etc., various proteins such as gelatin, collagen, casein, etc. In another embodiment, the water-soluble and/or water-swellaable polymer may comprise one or more cellulose-derived materials such as carboxymethyl cellulose, hydroxyethyl cellulose, methyl cellulose, etc., modified starches such as soluble starch, carboxymethyl starch, dialdehyde starch, a cross-linked dextrin, etc. In another embodiment, the water-soluble and/or water-swellaable polymer may comprise one or more copolymers of starch or cellulose, such as starch-acrylonitrile graft copolymer, a starch polyacrylate salt. In another embodiment, the water-soluble and/or water-swellaable polymer may comprise one or more synthetic resins such as polyvinyl alcohol, sodium polyacrylate, polyethylene oxide, etc., and copolymers of starches or celluloses and acrylonitrile, acrylic acid, methacrylic acid, vinyl alcohol, vinyl chloride, etc. In some embodiment, the water-soluble and/or water-swellaable polymer may comprise one or more of plant mucilages such as tragacanth gum, gum arabic, karaya gum, guar

gum, psyllium seed gum, dammar gum, pectin, etc., the celluloses such as CMC (carboxymethyl cellulose), HEC (hydroxyethyl cellulose), etc., and the copolymers of starches or celluloses and acrylonitrile, acrylic acid, sulfuric acid, vinyl sulfonate, etc. The foregoing embodiments may be combined with one another, and may be combined with water swellable polymers and/or super-absorbent materials.

[00117] In one embodiment, the water swellable polymers include, for example, hydroxypropylcellulose (HPC) and polyethylene oxide (PEO). HPC is available from commercial suppliers including, for example, Aqualon, Inc., (Wilmington, Del.). The useful HPC generally has an average molecular weight in the range of about 60,000 to 1,200,000. In another embodiment, the water swellable polymer includes homopolymers and copolymers of carboxymethyl cellulose, hydroxyethyl cellulose, hydroxymethyl cellulose). In another embodiment, the water swellable polymer includes a water-soluble or water-swallowable polymer derived from acrylic acid or a pharmaceutically acceptable salt thereof, such as the polyacrylic acid polymers as follows: Polycarbophil (Noveon AA-1), carbomer (Carbopol 974P or 971P or 907), or a water-soluble salt of a co-polymer of methyl vinyl ether and maleic acid or anhydride (Gantrez MS-955).

[00118] The amount of hydrophilic absorbent polymer, the water-soluble and/or water-swallowable polymer, may be from about 10% to about 70% of the total weight of the fluid-absorbing hydrogel pressure sensitive adhesive material, in one embodiment from about 20% to about 55% of the total weight of the fluid-absorbing pressure sensitive adhesive material.

[00119] The hydrophilic polymer functions as the absorbent, and to help provide the "wet tack" that ensures the adhesive adheres to the skin and to mucous membranes when they are moist.

[00120] In one embodiment, the hydrophilic polymer is capable of swelling in water and transporting water.

Release Liners

[00121] In one embodiment, the pressure sensitive adhesive includes a release-coated liner on the skin-contacting side, e.g., release liner 6 shown in Figure 8, which is retained in place prior to use and is removed just prior to application to the skin of a user. In addition and as previously noted, the primary patch component may include a release liner, e.g., release liner 2 shown in Figure 4. The secondary patch component may also include another release liner such as release liner 4 shown in Figure 8. The release-coated liner(s) may be any release-coated liner known in the art which is compatible with the particular pressure sensitive adhesive selected for use the dressing.

[00122] The release-coated liner may comprise a substrate sheet of paper, polymer film or combinations thereof coated with a release composition. The typical release coating used in the industry is a silicone-based molecule which can be cured either thermally or with irradiation energy such as ultraviolet light or electron beam. Paper substrates are useful because of the wide variety of applications in which they can be employed. Paper is also relatively inexpensive and has desirable properties such as antiblocking, antistatic, dimensional stability, and can potentially be recycled. Any type of paper having sufficient tensile strength to be handled in conventional paper coating and treating apparatus can be employed as the substrate layer. Thus, any type of paper can be used depending upon the end use and particular personal preferences. Included among the types of paper which can be used is paper, clay coated paper, glassine, polymer coated paper, paperboard from straw, bark, wood, cotton, flax, cornstalks, sugarcane, bagasse, bamboo, hemp, and similar cellulose materials prepared by such processes as the soda, sulfite or sulfate processes, the neutral sulfide cooking process, alkali-chlorine processes, nitric acid processes, semi-chemical processes, etc. Although paper of any weight can be employed as a substrate material, paper having weights in the range of from about 30 to about 120 pounds per ream (48.9 to 195.6 g/m²) are useful, and papers having weights in the range of from about 60 to about 100 pounds per ream (97.8 to 163 g/m²) are presently preferred. The term "ream" as used

herein equals 3000 square feet (approximately 279 m²). Examples of specific papers which can be utilized as substrates in preparing the deposit laminates of the present invention include 41 pound (18.6 kg) offset grade bleached Kraft; 78 pound (35.5 kg) bleached Kraft paper, etc.

[00123] Alternatively, the substrate of the release-coated liner may be a polymer film, and examples of polymer films include polyolefin, polyester, polyvinyl chloride, polyvinyl fluoride (PVF), polyvinylidene difluoride (PVDF), etc., and combinations thereof. The polyolefin films may comprise polymer and copolymers of monoolefins having from 2 to 12 carbon atoms or from 2 to about 4 or 8 carbon atoms per molecule. Examples of such homopolymers include polyethylene, polypropylene, poly-1-butene, etc. The examples of copolymers within the above definition include copolymers of ethylene with from about 1% to about 10% by weight of propylene, copolymers of propylene with about 1% to about 10% by weight of ethylene or 1-butene, etc. Films prepared from blends of copolymers or blends of copolymers with homopolymers also are useful. In addition films may be extruded in mono or multilayers.

[00124] A third type of material used as a substrate for the release liner is a polycoated kraft liner which is basically comprised of a kraft liner that is coated on either one or both sides with a polymer coating. The polymer coating, which can be comprised of high, medium, or low density polyethylene, propylene, polyester, and other similar polymer films, is coated onto the substrate surface to add strength and/or dimensional stability to the liner. The weight of these types of liners ranges from 30 to 100 pounds per ream (48.9 to 163 g/m²), with 40 to 94 pounds per ream (65.2 to 153 g/m²) representing a typical range. In total, the final liner is comprised of between 10% and 40% polymer and from 60% to 90% paper. For two sided coatings, the quantity of polymer is approximately evenly divided between the top and bottom surface of the paper.

[00125] The release coating which is contained on the substrate to form the release-coated liner may be any release coating known in the art. Silicone release coatings are particularly useful, and any of

the silicone release coating compositions which are known in the art can be used. In one embodiment, it is desired to have a release coating having a smooth surface.

[00126] In many embodiments, a double siliconized polyethylene protected paper release liner is useful. A polyethylene protected paper, white, and having a thickness of about 125 microns can be used. One side or face of the paper coated with a silicone release system at a coating weight of 1.4 g/m², and the other side is coated with a silicone release system at a coating weight of 1.6 g/m². In particular embodiments, a paper release liner having a thickness of about 67 microns has also been found to be useful.

[00127] The one or more release liners, or release liner assemblies can be provided on the underside 22 of primary patch component 20; the undersides 72 and/or 82 of the secondary patch component 70; and/or on the outer face 73 of the secondary patch component 70.

Packaging

[00128] The health patch and/or its components for example the primary and secondary patch components can be packaged in one or more containers using known packaging techniques. The containers may be in the form of rigid wall containers and/or flexible wall containers such as pouches. The containers can include the use of heat sealable materials for heat sealing the packages closed to thereby contain and seal the interior of the package and the health patch and/or its components from adverse environmental factors. The packaging may also include one or more ports to facilitate gas sterilization and/or be receptive for UV sterilization. The packaging particularly if in the form of a pouch, can include one or more thin metallic layers such as foils. As previously described, the health patch components can for example be packaged in sealed containers 3 and 5 as shown in Figures 4 and 8, respectively.

[00129] In certain embodiments of the present subject matter, each of the primary and secondary patch components are individually packaged, such as for example as depicted in Figures 4 and 8. Packaging each component separately promotes ease in subsequent re-use of the primary patch component with new or different secondary patch components and avoids the purchase of another primary patch component if only a secondary patch component is needed or desired.

[00130] In other embodiments of the present subject matter, the primary and secondary patch components can be packaged together and within a single or common container.

[00131] Regardless of the packaging configuration, the containers can include decorative printing, indicia, text, identifiers, dates, trademarks and/or source identifiers, and any other information as desired. Bar codes and/or other machine identifiers or symbols can be provided on the containers.

[00132] In certain instances, it may be desirable to provide two or more package configurations as follows. A "first use" configuration may utilize a single container that encloses both of the primary and secondary patch containers, typically disengaged or unattached from one another, along with one or more optional items such as (i) instruction booklet(s) or pamphlets, (ii) alcohol wipe(s) for cleaning skin prior to application of the patch, (iii) wipe(s) or solvent to assist in removal of the patch after use, (iv) one or more batteries if not already included with the primary patch component, and (v) adhesive tape(s) such as a double-side adhesive tape. A "subsequent use" configuration may utilize separate containers for the primary and secondary components. Items (i), (iv), and/or (v) from above can optionally be provided in, or with, the package of the primary patch component. And, items (ii), (iii), and/or (v) from above can optionally be provided in, or with, the package of the secondary patch component.

Systems

[00133] Figure 10 schematically illustrates an embodiment of a system 200 in accordance with the present subject matter. The system 200 comprises one or more health patches such as 210 and 212, one or more mobile devices such as 220 and 222, one or more computers such as 230 and 232, and optionally a registration and control component such as a computer server 240. In many embodiments of the present subject matter, the system 200 also comprises a cloud-based infrastructure 250 for providing communication between the registration and control component 240, the computers 230, 232, and/or the one or more mobile devices 220 and 222. In certain embodiments of the present subject matter, the systems include one or more health patches and one or more mobile devices. In other embodiments, the present subject matter includes the health patch(es), the mobile device(s), and one or more computers and optionally in further combination with one or more servers or registration and control components.

[00134] The system 200 comprises one or more communication links between the health patches 210, 212 and the mobile device(s) 220, 222 collectively shown in Figure 10 as link(s) A and A'. The system 200 also comprises one or more communication links between the mobile device(s) 220, 222 and the cloud-based infrastructure 250 collectively shown in Figure 10 as link(s) B and B'. The system 200 also comprises one or more communication links between the registration and control component 240 and the cloud-based infrastructure 250 collectively shown in Figure 10 as link(s) C. In addition, the system 200 can comprise one or more personal computers (PCs) or laptop computers 232 which can communicate via link(s) D with the registration and control component 240. And, the system 200 can also comprise one or more personal computers (PCs) or laptop computers 230 which can communicate with the cloud 250 via link(s) E. Communication link(s) can also be provided directly between the registration and control component 240 and the mobile device(s) 220, 222. The communication links enable information, data, instructions, and/or other parameters to be exchanged or transferred between the component(s).

Mobile Device(s)

[00135] The present subject matter system comprises one or more mobile electronic devices. The mobile devices can be in a variety of forms such as smartphones, tablet computers, or laptop computers for example. More particularly, the mobile device includes a computing device that may be a small-form factor portable (or mobile) electronic device such as a mobile phone or smartphone, or, alternatively, a personal data assistant (PDA), a personal media player device, an application specific device such as a tablet or slate computing device, or a hybrid device that may include any of the above functions. Nonlimiting examples of smartphones include devices running on ANDROID or IPHONE platforms. Nonlimiting examples of tablet computing devices include IPAD available from Apple Corporation. Nonlimiting examples of a personal media player device is an IPOD or more particularly an IPOD TOUCH available from Apple. The mobile device may also be in the form of a personal computer including both laptop computer and non-laptop computer configurations.

[00136] The mobile devices include electronic data storage provisions, control provisions, communication provisions, and user interface provisions. The data storage provisions of the mobile devices enable information relating to health patch use, user information, and data and/or permissions from the registration and control component to be stored and/or accessed at the mobile device. The data storage provisions can be in the form of known data storage formats such as flash memory components. The data storage provisions may also include or be in the form of memory cards, disk or drive components, data cartridges or components such as ROM or RAM memory, and peripheral data storage components.

[00137] The control provisions of the mobile devices typically include electronic circuitry and generally in the form of one or more processors. In many embodiments, the mobile devices control

data and/or information exchange or transmission with one or more health patches registered with the system.

[00138] The mobile devices also include communication provisions between the mobile device and one or more health patches; and between the mobile device and the PCs and/or the registration and control component. Communication between the mobile device and the health patch(es) can be established or provided using one or more communication formats such as radio frequency (RF), infrared (IR), and/or BLUETOOTH as known in the art. In particular embodiments, communication is by a wireless local area network (WLAN), i.e., Wi-Fi. The present subject matter also includes the use of other types of communication such as near-field communications (NFC). A nonlimiting list of other potentially suitable wireless protocols for communication between the mobile device and patch(es) of interest include ZIGBEE, GLOWPAN, Wireless HART, ISA 100, WiMi, SimpliciTI, KNX, EnOcean, Dash7, WISA, ANT, ANT+, WiMax, ONE-NET, Z-Wave, Insteon, and RuBee. It is also contemplated that other protocols could be used such as 2.4 MED from Steute Meditech, Inc. In certain embodiments, communication between the mobile device and patch(es) can also be established by cables or other hardwired connections.

[00139] Mobile devices may be communicatively coupled to cloud-based service and data centers and/or a third party entity via, e.g., at least a wireless local area network technology (WLAN), i.e., Wi-Fi. However, embodiments of local access to cloud-based storage are not limited to wireless communications, and therefore hard-wired communications may also apply to the embodiments described herein.

[00140] The mobile devices also include communication provisions between the mobile device and the PCs and/or the registration and control component. Typically, such communications are via the internet, and utilize a cloud-based infrastructure. However, the present subject matter also includes the

use of other communications between the mobile devices and the PCs and/or the registration and control component.

[00141] The mobile devices also include one or more user interface provisions. In a particular embodiment of the present subject matter, the mobile device is in the form of a smartphone or portable electronic computer for example an IPAD. The mobile device may also include a keyboard which can be virtual or provided as a physical input device incorporated in the mobile device or separate therefrom but connectable thereto. Other input components can be used such as mice, track balls, and joysticks for example. The mobile device typically also includes a display or other information output so that information can be displayed for viewing by a user. Again, the display is typically incorporated within the mobile device, but the present subject matter includes the use of separate but connectable displays.

[00142] As previously noted, the mobile devices also include electronic data storage provisions and control provisions. In many embodiments of the present subject matter, the mobile device is configured to run or execute an algorithm or "app" as known in the art which facilitates communication with the PCs and/or the registration and control component and/or the health patch(es). Apps, their transfer or download, and running and maintenance thereof are described in the prior art such as for example in US 8,549,656; US 2013/0122861; WO 2013/163249; and WO 2012/155937. The algorithm or app may also facilitate administration of permissions from the PCs and/or registration and control component, transmission of data or information between the PCs and/or registration and control component and the mobile device, and/or the mobile device and the health patch(es) of interest.

Computers and Servers

[00143] The PCs and/or registration and control component receives information and data, retains information and data, administers access and use permissions, and governs user access to, and use of,

health patches registered with the system. The registration and control component in many embodiments of the present subject matter is provided by one or more computer servers or units which may be remotely located. As described herein, typically the PCs and/or one or more registration and control component(s) are accessed via the internet and can include cloud-based storage, processing, and/or communication.

[00144] The PCs and/or registration and control component includes a database and/or data storage provisions in which user information is retained. Nonlimiting examples of such information include user name; registrant name if different than the user name; date of birth; gender; height; weight; right or left handed; smoker or nonsmoker; time zone; step target daily; step target weekly; calorie expenditure target daily; calorie expenditure target weekly; activity level target daily; activity level target weekly; sleep target daily; sleep target weekly; company or organization name if applicable; contact information of user, registrant, and/or company; date of initial registration of user and/or health patch(es) and optionally dates of subsequent registrations or logins; password(s) and other confidential information relating to the user, registrant, and/or company; designation or status of the user, registrant, and/or company; location of registered user and/or health patch; other preset or predesignated health patch parameters; other actual use-based health patch parameters; warnings or indicators associated with registered health patches and/or users; status of warnings or indicators; and a wide array of other information and data.

[00145] The PCs and/or registration and control component may include communication provisions so that the component can exchange, transmit, and/or receive information or data from the one or more mobile electronic devices. In many embodiments of the present subject matter, the registration and control component includes internet communication provisions.

Cloud

[00146] In many versions of the present subject matter, the systems and particularly the PCs and/or registration and control component use cloud-based storage and/or cloud-based processing and thus can be accessed and implemented in a distributed fashion using remotely located servers or other computers. Typically such servers, computers or other devices are accessed via the internet.

[00147] Cloud-based storage and/or processing refers to online storage and/or processing by which data is virtually stored and/or processed across one or multiple servers, which are typically hosted by service providers. The term "cloud-based computing" refers to one or more of cloud-based data storage, cloud-based data processing, and/or cloud-based data communication. The service providers may include data center operators, which virtualize resources based on customer requirements. The storage services may be accessed via web service application programming interfaces (API) or via web-based user interfaces (UI). Cloud-based computing is described in the prior art such as for example in WO 2013/141868; US 2012/0060165; WO 2013/119247; and US 2011/0153868.

Ancillary Electrodes and Electrode Configurations

[00148] The present subject matter also provides an array of uses and configurations of the health patches in conjunction with one or more ancillary electrodes or other components such as external sensors. The present subject matter provides a variety of sensing systems using the health patches in combination with one or more ancillary electrodes. The term "ancillary electrode" as used herein refers to an electrode or like sensor which is not incorporated in the health patch. Instead, ancillary electrodes can be in the form of satellite electrodes which are external to the health patch (in contrast to electrodes 84 and 86 of the secondary patch 70 for example) and which can be selectively positioned and/or located at one or more remote locations from the health patch.

[00149] In one embodiment, the present subject matter health patches are used in a two lead, three electrode system such as illustrated in Figure 11. There, a health patch 310 having two electrodes 320

and 322 along its underside and in contact with skin of user 300 is shown. A third electrode in the form of a satellite electrode 330 is appropriately positioned along a region of the user's body and electrical connections provided between the satellite electrode 330 and the health patch 310.

[00150] In another embodiment, the present subject matter health patches are used in a three lead, four electrode system such as shown in Figure 12. There, a health patch 410 having two electrodes 420 and 422 along its underside and in contact with skin of a user 400 is depicted. A third electrode 430 and a fourth electrode 432, both in the form of satellite electrodes, are appropriately positioned along a region of the user's body and electrical connections provided between the satellite electrodes 430, 432 and the health patch 410.

[00151] Figure 13 schematically illustrates additional aspects of using a health patch with one or more satellite electrodes. Figure 13 depicts a system 500 comprising a health patch 510 in electrical communication with two satellite electrodes 590 and 592. Specifically, in this embodiment, the health patch 510 includes two terminals 540 and 542 that extend from the interior of the patch through a housing 530 to thereby expose the terminals. Electrical leads or wires such as 584 and 586 can be used to provide electrical communication between the patch 510 and the satellite electrodes 590, 592. Additional satellite electrodes, sensors, or other components can be electrically connected to one or both leads 584, 586.

[00152] Details of electrodes, their construction, and uses are described in US 6,494,829; 6,577,893; 6,881,191; 7,161,484; 7,502,643; and 8,032,206, for example.

Methods

[00153] The present subject matter also provides various methods of using the health patches, the systems utilizing the health patches with one or more mobile devices, and the sensing systems using the health patches with one or more ancillary electrodes as described herein.

[00154] In many embodiments, the health patches are provided to a user or consumer in one or more sealed package(s). Both the primary patch component and the secondary patch component can be included together in the sealed package, or each component may be enclosed within separate packaging. The use of separate packaging may be useful for instances in which a user wishes to reuse a primary patch component with a new secondary patch component.

[00155] After removing any release liners from one or both of the primary and secondary patch components to expose adhesive, the user mates or otherwise secures the primary and secondary patch components together and then adhesively attaches the resulting health patch to a desired location on the user's body. Adhesive attachment may be facilitated by removing any hair from the user's skin in the desired region, and/or wiping the region with an alcohol wipe. As previously noted, typical locations include a region of the user's arm such as a rear triceps portion, or along a region of the user's chest. Alternatively, a user can first adhesively attach the secondary patch component to the user's skin, and then attach the primary patch component to the secondary patch component.

[00156] The health patch is activated, typically by actuation of a power switch or "on" switch. As previously noted in certain versions, the health patches are activated upon adhering to a user's body. Once activated, and in appropriate contact with the user's skin, the health patch collects and acquires information and/or data via its sensors. Various sensors can be sampled at designated sampling rates. Information and data is stored or retained in onboard data storage provisions in the health patch.

[00157] If the health patch is used in conjunction with one or more mobile devices and/or other information processing components such as computers or servers such as the noted registration and

control components, then the health patch and the devices/components are appropriately configured such that information and data can be transferred between them. In many embodiments of the present subject matter, previously collected data such as from sensors of the health patches, which is retained in data storage provisions onboard the health patches, is transferred from the health patches to the mobile device(s) and/or other information processing components. In certain embodiments of the present subject matter, data acquired by sensors of the health patches is transferred from the health patch to a mobile device or other information processing component, immediately after acquisition by the sensor(s), or substantially so. This enables real-time display and/or processing of physiologic data.

[00158] Typically, the health patch is worn continuously by a user for a time period of from about several hours up to about 7 days, or longer. Upon removal, the health patch can be removed from the skin of its user. Removal may be assisted by exposing the adhesive interface to water, and particularly warm flowing water.

[00159] After removal of the health patch, previously acquired data and information can be transferred to one or more mobile devices, computers, servers, and/or other information processing components as described herein. Typically, the health patch and receiving device are synced to one another, and then data and information in the data storage provisions onboard the health patch are transferred to the device of interest.

[00160] The present subject matter may involve configuring one or more of (i) the health patches and particularly the electronic assemblies thereof, (ii) mobile devices, (iii) computers, servers, and/or other information processing components, to process information or data acquired by the health patch to provide indication of caloric expenditures, steps taken, activity levels, sleep patterns, and other parameters.

[00161] Many other benefits will no doubt become apparent from future application and development of this technology.

[00162] All patents, applications, standards, and articles noted herein are hereby incorporated by reference in their entirety.

[00163] The present subject matter includes all operable combinations of features and aspects described herein. Thus, for example if one feature is described in association with an embodiment and another feature is described in association with another embodiment, it will be understood that the present subject matter includes embodiments having a combination of these features.

[00164] As described hereinabove, the present subject matter solves many problems associated with previous strategies, systems and/or devices. However, it will be appreciated that various changes in the details, materials and arrangements of components, which have been herein described and illustrated in order to explain the nature of the present subject matter, may be made by those skilled in the art without departing from the principle and scope of the claimed subject matter, as expressed in the appended claims.

Claims

WHAT IS CLAIMED IS:

1. A health patch for application to biologic skin for obtaining physiologic information, the health patch comprising:

a primary patch component including a housing that defines a hollow interior, and an underside with at least one electrical contact;

a secondary patch component at least initially separate from the primary patch component, the secondary patch defining an outer face and an oppositely directed underside, the secondary patch component including at least one electrical contact accessible along the outer face;

wherein the primary patch component and the secondary patch component are releasably securable to one another and are configured such that upon being secured to each other the at least one electrical contact of the primary patch is in electrical communication with the at least one electrical contact of the secondary patch.

2. The health patch of claim 1 wherein the primary patch component further includes an electronics assembly generally disposed within the hollow interior defined by the housing.

3. The health patch of claim 2 wherein the electronics assembly comprises (i) at least one microprocessor, (ii) a communications transmitter, (iii) a communications receiver, (iv) data storage provisions, and (v) at least one sensor or sensor provisions.

4. The health patch of claim 3 wherein the communications transmitter and the communications receiver are wireless.

5. The health patch of claim 4 wherein the wireless communications transmitter is a radio transmitter.

6. The health patch of claim 4 wherein the wireless communications receiver is a radio receiver.

7. The health patch of any one of claims 3-6 wherein the at least one sensor includes an accelerometer.

8. The health patch of claim 7 wherein the accelerometer is a 3-axis accelerometer.

9. The health patch of any one of claims 3-8 wherein the at least one sensor includes a temperature sensor.

10. The health patch of claim 9 wherein the temperature sensor is a thermistor.

11. The health patch of any one of claims 3-10 wherein the at least one sensor includes a heart rate sensor.

12. The health patch of any one of claims 1-11 further comprising a layer or region of adhesive disposed on one of (i) at least a portion of the underside of the primary patch, (ii) at least a portion of the outer face of the secondary patch, and (iii) a combination of (i) and (ii).

13. The health patch of claim 12 wherein the layer or region of adhesive disposed on at least a portion of the underside of the primary patch is a low bond strength adhesive.

14. The health patch of any one of claims 12-13 wherein the layer or region of adhesive disposed on at least a portion of the outer face of the secondary patch is a high bond strength adhesive.

15. The health patch of any one of claims 1-14 further comprising a layer or region of a pressure sensitive adhesive disposed on at least a portion of the underside of the secondary patch component.

16. The health patch of claims 15 further comprising at least one hydrophilic agent incorporated in the pressure sensitive adhesive.

17. The health patch of any one of claims 15-16 further comprising a layer or region of a hydrophilic agent disposed on the layer of the pressure sensitive adhesive.

18. The health patch of any one of claims 16-17 wherein the hydrophilic agent includes at least one hydrocolloid agent.

19. The health patch of any one of claims 12-18 further comprising at least one release liner contacting one or more of adhesive, hydrophilic agent, and hydrocolloid agent.

20. The health patch of any one of claims 1-18 wherein the primary patch component includes two electrical contacts, the secondary patch component includes two electrical contacts, and the electrical contacts of the primary patch component are aligned with the electrical contacts of the secondary patch component to provide two pairs of electrical contacts that provide electrical communication between the primary and secondary patch components.

21. The health patch of any one of claims 1-20 wherein the primary patch further includes at least one electrically conductive terminal extending through the housing of the primary patch component.

22. The health patch of any one of claims 1-21 further comprising:
a container enclosing at least one of the primary patch component and the secondary patch component.

23. The health patch of claim 22 wherein the container encloses both of the primary patch component and the secondary patch component.

24. The health patch of claim 23 wherein prior to use of the health patch, the primary patch component and the secondary patch component are not attached to one another.

25. The health patch of claim 22 wherein the container is a first container and encloses the primary patch component and the health patch further comprises:

a second container enclosing the secondary patch component.

26. A system for assessing a user's health or lifestyle, the system comprising:

at least one mobile device including communication provisions; and

a health patch including (i) a primary patch component having a housing that defines a hollow interior, and an underside with at least one electrical contact, (ii) a secondary patch component at least initially separate from the primary patch component, the secondary patch defining an outer face and an oppositely directed underside, the secondary patch component having at least one electrical contact accessible along the outer face, and (iii) communication provisions, wherein the primary patch component and the secondary patch component are releasably securable to one another and are configured such that upon being secured to each other the at least one electrical contact of the primary patch is in electrical communication with the at least one electrical contact of the secondary patch;

wherein the communication provisions of the mobile device and the communication provisions of the health patch are capable of providing a communication link between the mobile device and the health patch.

27. The system of claim 26 further comprising:

at least one computer including communication provisions capable of providing a communication link with at least one of the mobile device and the health patch.

28. The system of any one of claims 26-27 wherein the primary patch component further has an electronics assembly generally disposed within the hollow interior defined by the housing.

29. The system of claim 28 wherein the electronics assembly includes (i) at least one microprocessor, (ii) data storage provisions, and (iii) at least one sensor or sensor provisions.

30. The system of any one of claims 26-29 wherein the communications provisions are wireless.

31. The system of claim 30 wherein the wireless communications provisions include a radio transmitter.

32. The system of claim 30 wherein the wireless communications provisions include a radio receiver.

33. The system of any one of claims 29-32 wherein the at least one sensor includes an accelerometer.

34. The system of claim 33 wherein the accelerometer is a 3-axis accelerometer.

35. The system of any one of claims 29-34 wherein the at least one sensor includes a temperature sensor.

36. The system of claim 35 wherein the temperature sensor is a thermistor.

37. The system of any one of claims 29-36 wherein the at least one sensor includes a heart rate sensor.

38. The system of any one of claims 26-37 wherein the health patch further includes a layer or region of adhesive disposed on one of (i) at least a portion of the underside of the primary patch, (ii) at least a portion of the outer face of the secondary patch, and (iii) a combination of (i) and (ii).

39. The system of claim 38 wherein the layer or region of adhesive disposed on at least a portion of the underside of the primary patch is a low bond strength adhesive.

40. The system of any one of claims 38-39 wherein the layer or region of adhesive disposed on at least a portion of the outer face of the secondary patch is a high bond strength adhesive.

41. The system of any one of claims 26-40 wherein the health patch further includes a layer or region of a pressure sensitive adhesive disposed on at least a portion of the underside of the secondary patch component.

42. The system of claim 41 wherein the health patch further includes at least one hydrophilic agent incorporated in the pressure sensitive adhesive.

43. The system of any one of claims 41-42 wherein the health patch further includes a layer or region of a hydrophilic agent disposed on the layer of the pressure sensitive adhesive.

44. The system of claim 43 wherein the hydrophilic agent includes at least one hydrocolloid agent.

45. The system of any one of claims 26-44 wherein the primary patch component includes two electrical contacts, the secondary patch component includes two electrical contacts, and the electrical contacts of the primary patch component are aligned with the electrical contacts of the secondary patch component to provide two pairs of electrical contacts that provide electrical communication between the primary and secondary patch components.

46. The system of any one of claims 26-45 wherein the primary patch further includes at least one electrically conductive terminal extending through the housing of the primary patch component.

47. A sensing system for acquiring physiologic information, the system comprising:
at least one ancillary electrode;
a health patch including (i) a primary patch component including a housing that defines a hollow interior, and an underside with at least one electrical contact, and (ii) a secondary patch component at least initially separate from the primary patch component, the secondary patch defining an outer face and an oppositely directed underside, the secondary patch component having at least one electrical contact accessible along the outer face, wherein the primary patch component and the secondary patch component are releasably securable to one another and are configured such that upon being secured to each other the at least one electrical contact of the primary patch is in electrical communication with the at least one electrical contact of the secondary patch; and

a lead extending between and providing electrical communication between the ancillary electrode and the health patch.

48. The system of claim 47 wherein the primary patch component further includes an electronics assembly generally disposed within the hollow interior defined by the housing.

49. The system of claim 48 wherein the electronics assembly comprises (i) at least one microprocessor, (ii) a communications transmitter, (iii) a communications receiver, (iv) data storage provisions, and (v) at least one sensor or sensor provisions.

50. The system of claim 49 wherein the communications transmitter and the communications receiver are wireless.

51. The system of claim 50 wherein the wireless communications transmitter is a radio transmitter.

52. The system of claim 50 wherein the wireless communications receiver is a radio receiver.

53. The system of any one of claims 49-52 wherein the at least one sensor includes an accelerometer.

54. The system of claim 53 wherein the accelerometer is a 3-axis accelerometer.

55. The system of any one of claims 49-54 wherein the at least one sensor includes a temperature sensor.

56. The system of claim 55 wherein the temperature sensor is a thermistor.

57. The system of any one of claims 49-56 wherein the at least one sensor includes a heart rate sensor.

58. The system of any one of claims 47-54 wherein the health patch further includes a layer or region of adhesive disposed on one of (i) at least a portion of the underside of the primary patch, (ii) at least a portion of the outer face of the secondary patch, and (iii) a combination of (i) and (ii).

59. The system of claim 58 wherein the layer or region of adhesive disposed on at least a portion of the underside of the primary patch is a low bond strength adhesive.

60. The system of any one of claims 58-59 wherein the layer or region of adhesive disposed on at least a portion of the outer face of the secondary patch is a high bond strength adhesive.

61. The system of any one of claims 47-60 wherein the health patch further includes a layer or region of a pressure sensitive adhesive disposed on at least a portion of the underside of the secondary patch component.

62. The system of claim 61 wherein the health patch further includes at least one hydrophilic agent incorporated in the pressure sensitive adhesive.

63. The system of any one of claims 61-62 wherein the health patch further includes a layer or region of a hydrophilic agent disposed on the layer of the pressure sensitive adhesive.

64. The system of claim 63 wherein the hydrophilic agent includes at least one hydrocolloid agent.

65. The system of any one of claims 47-64 wherein the primary patch component includes two electrical contacts, the secondary patch component includes two electrical contacts, and the electrical contacts of the primary patch component are aligned with the electrical contacts of the secondary patch component to provide two pairs of electrical contacts that provide electrical communication between the primary and secondary patch components.

66. The system of any one of claims 47-65 wherein the primary patch further includes at least one electrically conductive terminal extending through the housing of the primary patch component.

67. The system of any one of claims 47-66 wherein the primary patch component includes two electrodes.

68. The system of claim 67 wherein the at least one ancillary electrode is a single electrode and the system is a three electrode system.

69. The system of claim 67 wherein the at least one ancillary electrode includes two electrodes and the system is a four electrode system.

70. A method for acquiring health or lifestyle information from a user, the method comprising:

providing a health patch including (i) a primary patch component having a housing that defines a hollow interior, and an underside with at least one electrical contact, (ii) a secondary patch component at least initially separate from the primary patch component, the secondary patch defining an outer face and an oppositely directed underside, the secondary patch component having at least one electrical contact accessible along the outer face, (iii) at least one sensor, and (iv) data storage provisions;

releasably securing the primary patch component with the secondary patch component such that upon being secured to each other the at least one electrical contact of the primary patch is in electrical communication with the at least one electrical contact of the secondary patch;

adhesively attaching the health patch to a location on the body of the user;

collecting information via the sensor over a period of time; and

retaining the collected information in the data storage provisions, to thereby acquire health or lifestyle information from the user.

71. The method of claim 70 wherein the at least one sensor includes an accelerometer and the collecting information includes collecting acceleration data.

72. The method of claim 71 wherein the accelerometer is a 3-axis accelerometer.

73. The method of any one of claims 70-71 wherein the at least one sensor includes a temperature sensor and the collecting information includes collecting temperature data.

74. The method of claim 73 wherein the temperature sensor is a thermistor.

75. The method of any one of claims 70-74 wherein the at least one sensor includes a heart rate sensor and the collecting information includes collecting heart rate data.

76. The method of any one of claims 70-75 wherein the health patch further includes (v) at least one microprocessor, (vi) a communications transmitter, (vii) a communications receiver, and the method further comprises:

providing at least one mobile device including communications provisions;

establishing a communication link between the at least one mobile device and the health patch;

and

transferring collected information from the health patch to the at least one mobile device.

77. The method of claim 76 wherein the communications transmitter and the communications receiver are wireless.

78. The method of claim 77 wherein the wireless communications transmitter is a radio transmitter.

79. The health patch of claim 77 wherein the wireless communications receiver is a radio receiver.

80. A method of collecting physiologic information from a user, the method comprising:

- providing a health patch including (i) a primary patch component having a housing that defines a hollow interior, and an underside with at least one electrical contact, (ii) a secondary patch component at least initially separate from the primary patch component, the secondary patch defining an outer face and an oppositely directed underside, the secondary patch component having at least one electrical contact accessible along the outer face, (iii) at least one electrically conductive terminal, and (iv) data storage provisions;
- releasably securing the primary patch component with the secondary patch component such that upon being secured to each other the at least one electrical contact of the primary patch is in electrical communication with the at least one electrical contact of the secondary patch;
- adhesively attaching the health patch to a first location on the body of the user;
- providing at least one ancillary electrode;
- contacting the electrode to a second location on the body of the user;
- establishing electrical communication between the terminal of the health patch and the ancillary electrode;
- whereby physiologic information of the user is obtained by the ancillary electrode, transferred to the health patch, and retained in the data storage provisions of the health patch.

81. The method of claim 80 wherein the health patch further includes two electrodes, and the providing at least one ancillary electrode provides a single ancillary electrode.

82. The method of claim 80 wherein the health patch further includes two electrodes, and the providing at least one ancillary electrode provides two ancillary electrodes.

83. A primary patch component adapted for use with a secondary patch component including at least one electrical contact, wherein the primary patch component and the secondary patch component are at least initially separate from one another and releasably securable to one another to provide a health patch for obtaining physiologic information, the primary patch component comprising:

a housing that defines a hollow interior, and an underside with at least one electrical contact;

an electronics assembly generally disposed within the hollow interior defined by the housing;

wherein upon securing the primary patch component to the secondary patch component, the at least one electrical contact of the primary patch component is in electrical communication with the at least one electrical contact of the secondary patch component.

84. The primary patch component of claim 83 wherein the electronics assembly comprises (i) at least one microprocessor, (ii) a communications transmitter, (iii) a communications receiver, (iv) data storage provisions, and (v) at least one sensor or sensor provisions.

85. The primary patch component of claim 84 wherein the communications transmitter and the communications receiver are wireless.

86. The primary patch component of claim 85 wherein the wireless communications transmitter is a radio transmitter.

87. The primary patch component of claim 85 wherein the wireless communications receiver is a radio receiver.

88. The primary patch component of any one of claims 84-87 wherein the at least one sensor includes an accelerometer.

89. The primary patch component of claim 88 wherein the accelerometer is a 3-axis accelerometer.

90. The primary patch component of any one of claims 84-89 wherein the at least one sensor includes a temperature sensor.

91. The primary patch component of claim 90 wherein the temperature sensor is a thermistor.

92. The primary patch component of any one of claims 83-91 further comprising a layer or region of adhesive disposed on at least a portion of the underside of the primary patch.

93. The primary patch component of claim 92 further comprising a release liner disposed on the layer or region of adhesive.

94. The primary patch component of any one of claims 83-93 further comprising a container enclosing the primary patch component.

95. A secondary patch component adapted for use with a primary patch component including at least one electrical contact, wherein the secondary patch component and the primary patch component are at least initially separate from one another and releasably securable to one another to provide a health patch for obtaining physiologic information, the secondary patch component comprising:

a support layer including at least one electrical contact;

an electrode assembly;

wherein upon securing the secondary patch component to the primary patch component, the at least one electrical contact of the secondary patch component is in electrical communication with the at least one electrical contact of the primary patch component.

96. The secondary patch component of claim 95 further comprising a layer or region of adhesive disposed on at least a portion of an underside of the secondary patch.

97. The secondary patch component of claim 96 further comprising a release liner disposed on the layer or region of adhesive.

98. The secondary patch component of claim 96 wherein the layer of adhesive is a first layer of adhesive, the secondary patch component further comprising a second layer of adhesive disposed on an outer face of the support layer oppositely directed from the underside.

99. The secondary patch component of claim 98 further comprising a release liner disposed on the second layer of adhesive.

100. The secondary patch component of any one of claims 95-99 further comprising a container enclosing the secondary patch component.

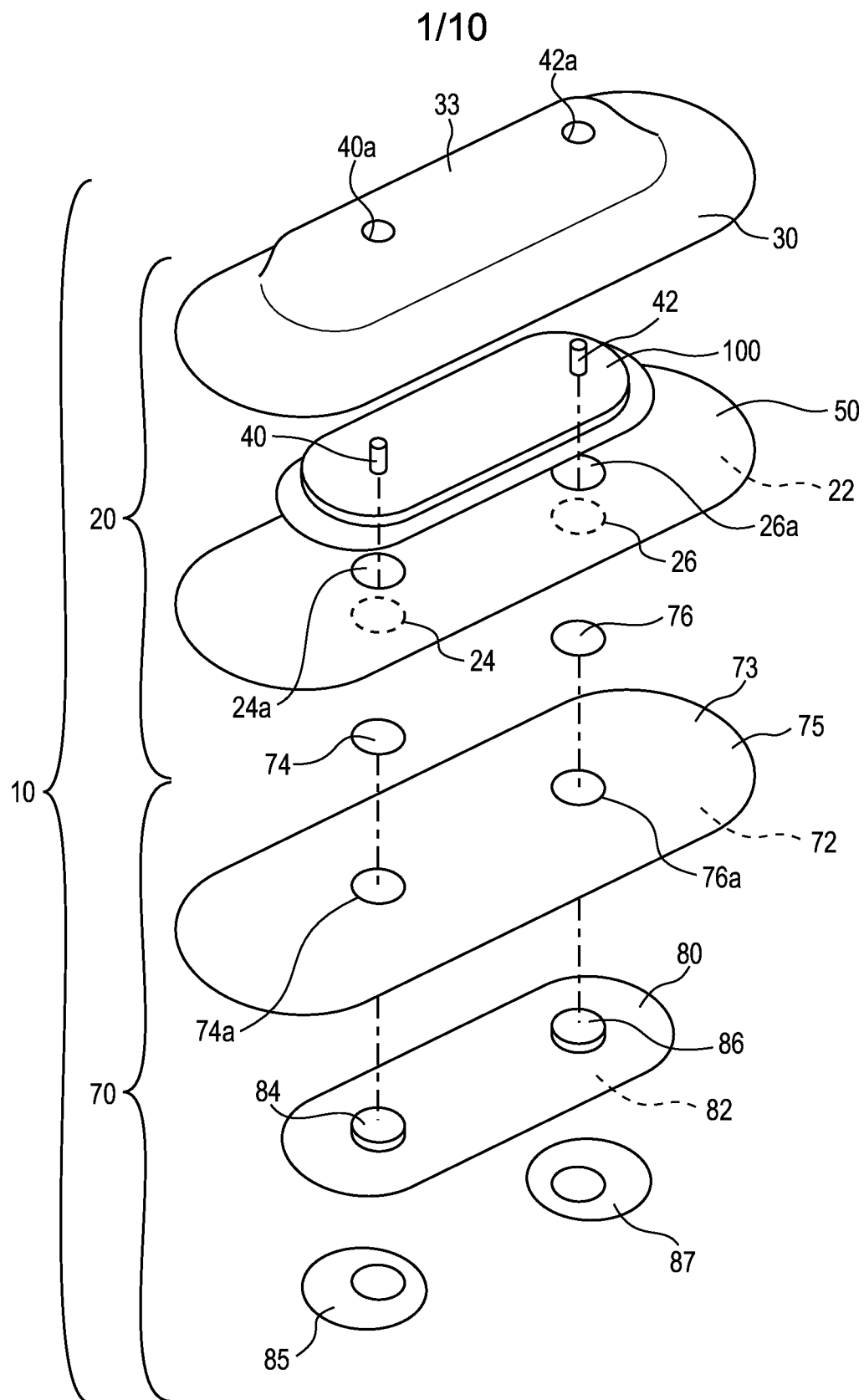


FIG. 1

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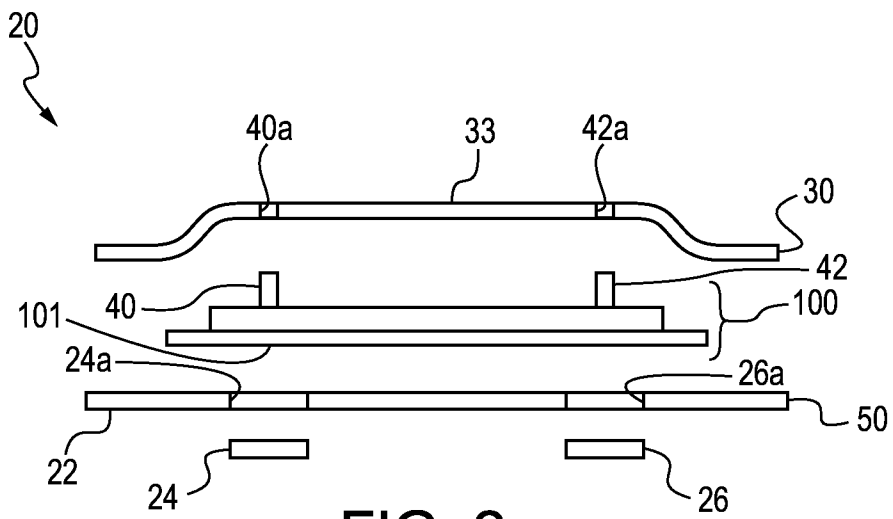


FIG. 2

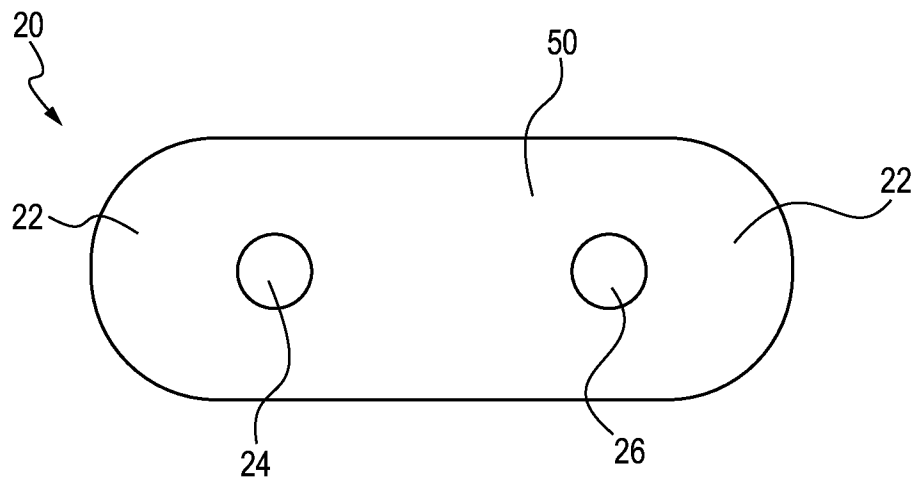


FIG. 3

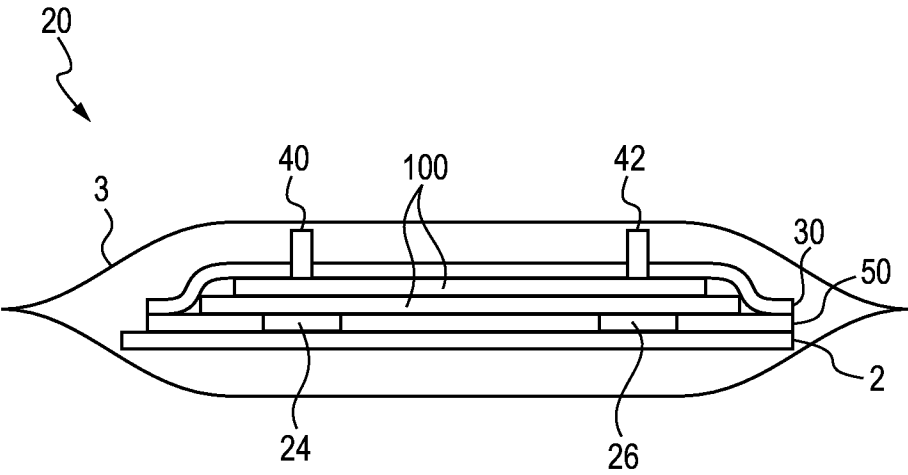


FIG. 4

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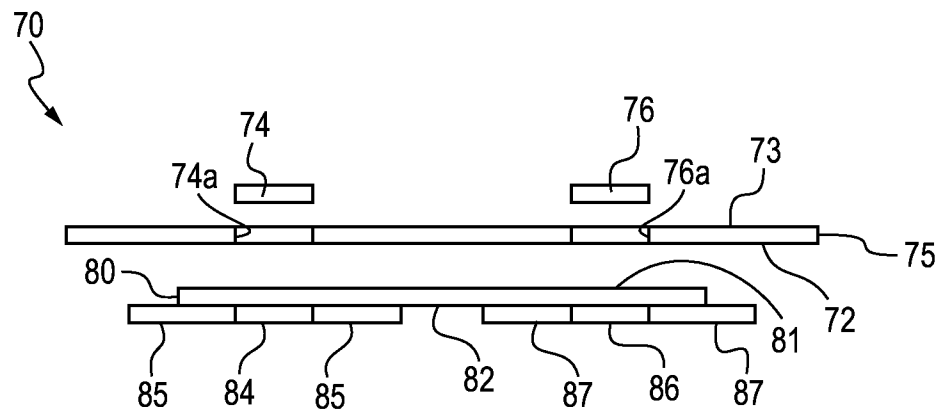


FIG. 5

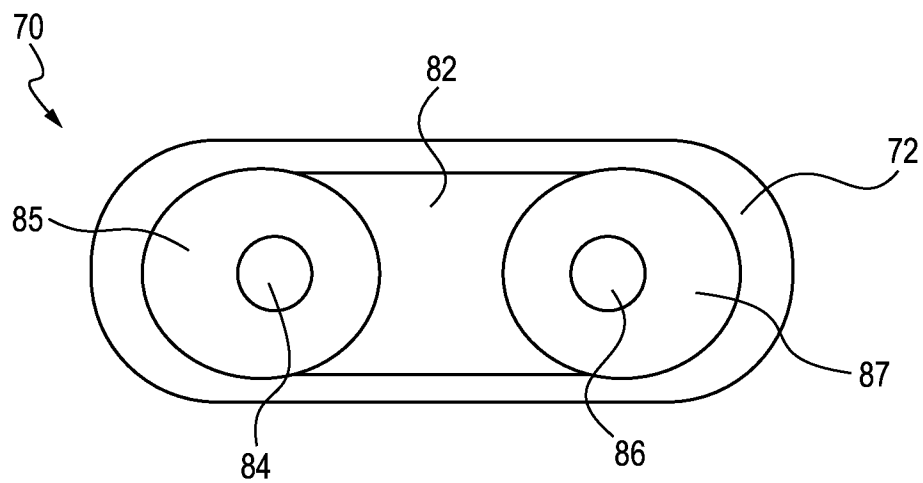


FIG. 6

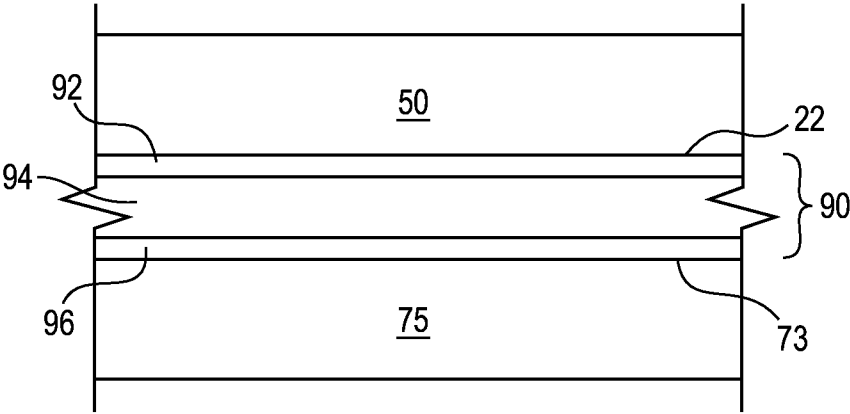


FIG. 7

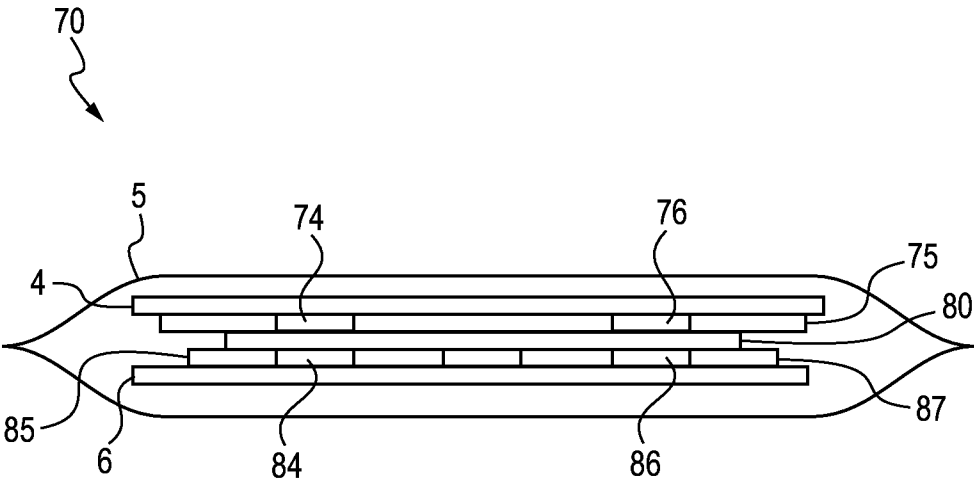


FIG. 8

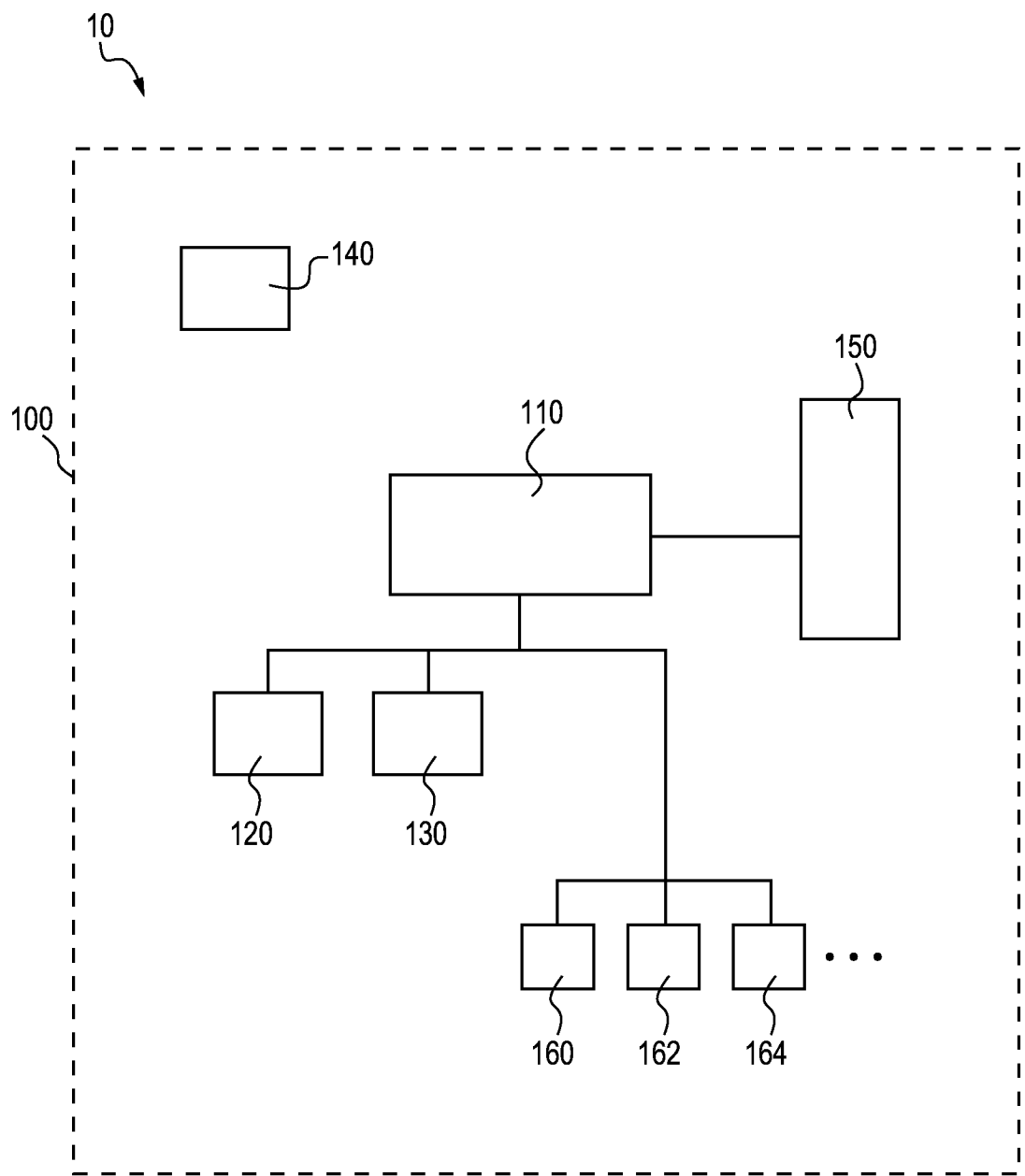


FIG. 9

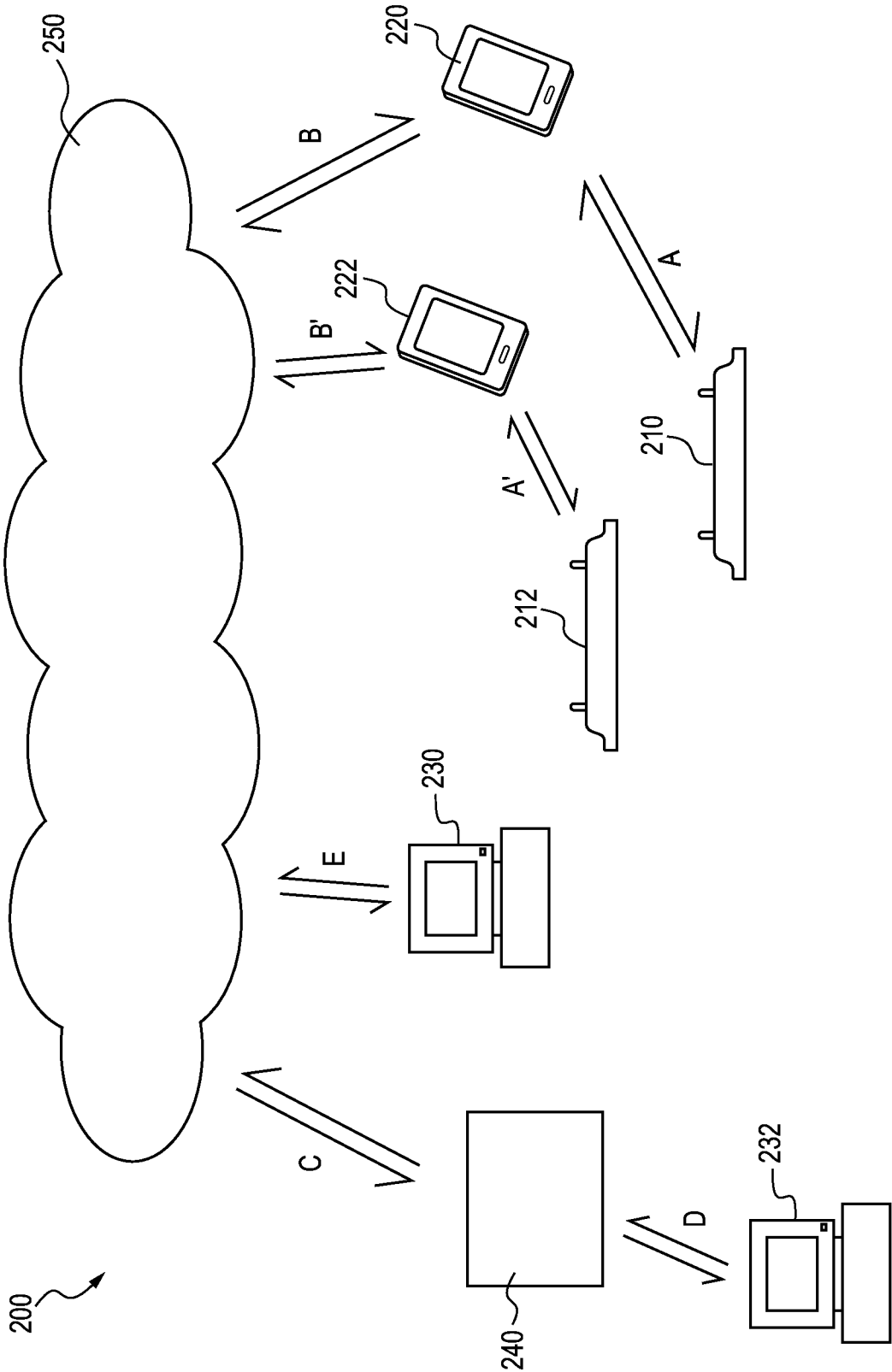


FIG. 10

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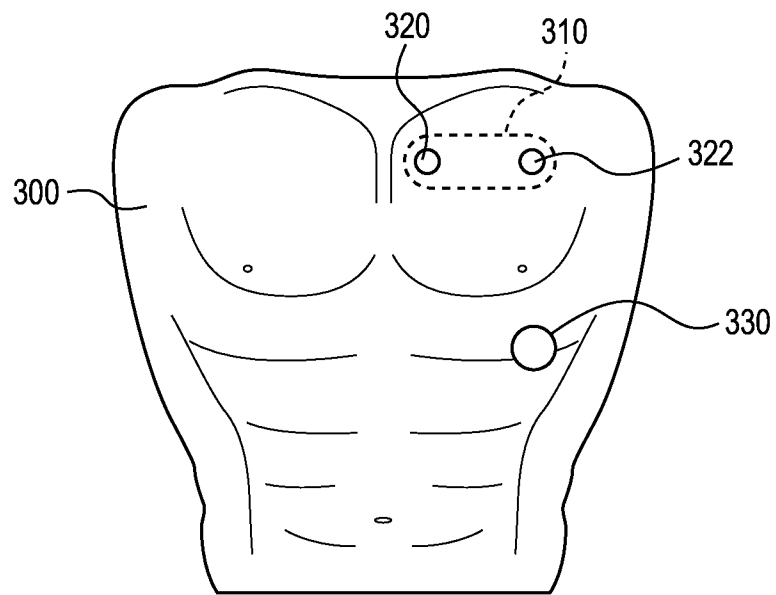


FIG. 11

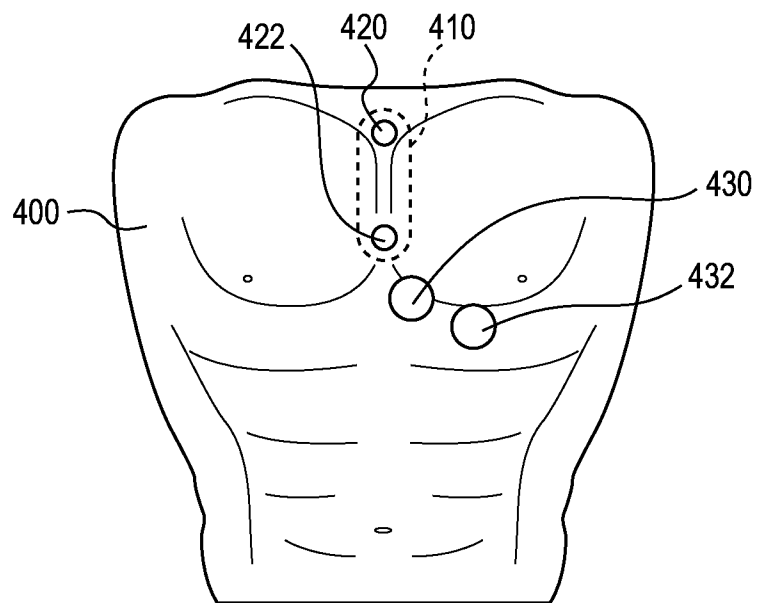


FIG. 12

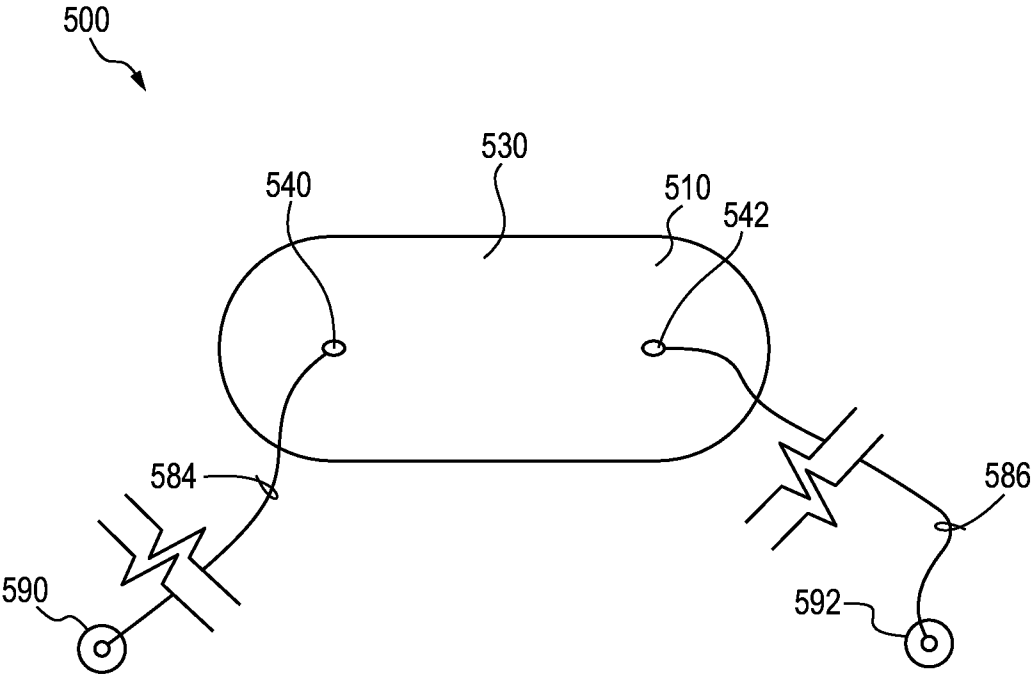


FIG. 13

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2015/040313

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/00
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B A61N

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2013/116534 A1 (WOO SUNG HUN [KR]) 9 May 2013 (2013-05-09) paragraph [0003] paragraph [0023] paragraph [0024] - paragraph [0025] paragraph [0026] - paragraph [0027] figure 2	1-11, 70-79
X	US 2010/160762 A1 (MCLAUGHLIN JAMES ANDREW [GB] ET AL) 24 June 2010 (2010-06-24) paragraph [0001] paragraph [0003] paragraph [0011] paragraph [0023] - paragraph [0026] ----- -/-	1-11, 70-79



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

24 September 2015

Date of mailing of the international search report

14/12/2015

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
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Fax: (+31-70) 340-3016

Authorized officer

Faymann, Juan

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2015/040313

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 4 915 656 A (ALFERNESS CLIFTON A [US]) 10 April 1990 (1990-04-10) column 3, lines 30-34 column 3, line 53 - column 4, line 29 figures 1A, 1B -----	1,70 2-11, 71-79

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/040313

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.:
1-11, 70-79

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: 1-11, 70-79

A health patch and method of attaching and using said health patch on a patient, the patch comprising primary and secondary patches configured to be releasably securable to one another and to make electrical contact when secured, wherein the primary patch includes an electronics assembly disposed in a hollow interior.

2. claims: 1, 12-19, 95-100

A health patch comprising primary and/or secondary patches configured to be releasably securable to one another and to make electrical contact when secured, wherein the outer face of the secondary patch or underside of the primary patch, or both, comprises an adhesive layer or region.

3. claims: 1, 20, 21

A health patch comprising primary and secondary patches configured to be releasably securable to one another and to make electrical contact when secured, wherein each patch includes two electrical contacts aligned with those of the other patch, said contacts extending through a housing of the primary patch component.

4. claims: 1, 22-25

A health patch comprising primary and secondary patches configured to be releasably securable to one another and to make electrical contact when secured, wherein a container encloses the primary patch.

5. claims: 26-69

System for assessing user's health or lifestyle comprising a health patch, the patch including primary and secondary patches configured to be releasably securable to one another and to make electrical contact when secured, wherein the system further comprises a mobile device including communication provisions.

6. claims: 47-69, 80-94

System and method for acquiring physiological information comprising a health patch, the patch including primary and secondary patches configured to be releasably securable to

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

one another and to make electrical contact when secured,
wherein the system further comprises an ancillary electrode
and a lead connecting it to the health patch.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2015/040313

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2013116534 A1	09-05-2013	CN 103025233 A	03-04-2013
		US 2013116534 A1	09-05-2013
		US 2015150506 A1	04-06-2015
		WO 2012011780 A2	26-01-2012

US 2010160762 A1	24-06-2010	EP 2155053 A1	24-02-2010
		US 2010160762 A1	24-06-2010
		WO 2008142365 A1	27-11-2008

US 4915656 A	10-04-1990	NONE	
