



(43) International Publication Date
16 September 2010 (16.09.2010)

PCT

(10) International Publication Number
WO 2010/104952 A2

(51) International Patent Classification:
A61B 5/0205 (2006.01) *A61B 5/02* (2006.01)

(21) International Application Number:
PCT/US2010/026828

(22) International Filing Date:
10 March 2010 (10.03.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/159,028 10 March 2009 (10.03.2009) US

(71) Applicant (for all designated States except US): **COR-VENTIS, INC.** [US/US]; 2226 N. First Street, San Jose, California 95131 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **MAZAR, Scott, T.** [US/US]; 10459 Glen Eagle Circle, Woodbury, Minnesota 55129 (US). **MANICKA, Yatheendhar** [US/US]; 10544 Hawthorn Trail, Woodbury, Minnesota 55129 (US). **AMURTHUR, Badri** [US/US]; 218 Mattson Avenue, Los Gatos, California 95032 (US). **BLY, Mark, J.** [US/US]; 1367 N. First Street, San Jose, California 95131 (US).

(74) Agents: **WILLINK, Christopher, L.** et al.; Townsend and Townsend and Crew LLP, Two Embarcadero Center, 8th Floor, San Francisco, California 94111 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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

Published:

— without international search report and to be republished upon receipt of that report (Rule 48.2(g))

(54) Title: DISPLAY SYSTEMS FOR BODY-WORN HEALTH MONITORING DEVICES

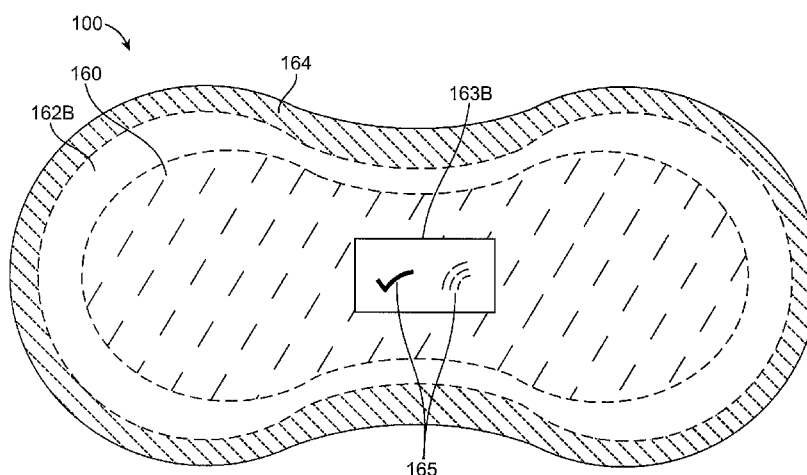


FIG. 1F2

(57) Abstract: Systems and methods for indicating an adverse, potentially adverse, or device related event has occurred. An adherent device to measure data from a patient having skin has a support configured to measure data from a patient and adhere to the skin of the patient, and a display coupled to the support. In many embodiments, the adherent device is flexible and includes a flexible display which flexes with movement of the adherent device. In many embodiments, adverse, potentially adverse, or adherent device related events are displayed on the flexible display.

DISPLAY SYSTEMS FOR BODY-WORN HEALTH MONITORING DEVICES

CROSS-REFERENCES TO RELATED APPLICATIONS

- 5 [0001] This application claims the benefit of U.S. Provisional Application No. 61/159,028, filed March 10, 2009, the content of which is incorporated herein by reference in its entirety and for all purposes.

BACKGROUND OF THE INVENTION

- 10 [0002] The present invention relates to patient monitoring. Although embodiments make specific reference to monitoring patients with an adherent patch device, the system methods and device described herein may be applicable to many applications in which physiological monitoring is used, for example wireless physiological monitoring with devices for extended periods.

- 15 [0003] Many devices have been developed to monitor patients. One example of a device that may be used to monitor a patient is the Holter monitor, or ambulatory electrocardiography device. Although such a device may be effective in measuring electrocardiography, it can be also bulky and uncomfortable for use. Other devices may use electrodes that are positioned across the midline of the patient, and may be somewhat uncomfortable and/or cumbersome for the patient to wear. In at least some instances, devices
20 that are worn by the patient may be somewhat uncomfortable, which may lead to patients not wearing the devices and not complying with direction from the health care provider, such that data collected may be less than ideal. Additionally, at least some devices may be relatively stiff, or may include stiff portions, which cause the device to un-adhere from a patient during normal patient movement, thus, preventing data collection in at least some instances.
- 25 Although implantable devices may be used, many of these devices can be invasive and/or costly, and may suffer at least some of the shortcomings of known wearable devices in at least some instances. As a result, at least some patients may not be adequately monitored due to discomfort and/or lack of patient compliance.

- 30 [0004] Although smaller devices have been proposed for patient monitoring, at least some of the current small devices may have less functionality that would be ideal. Work in relation to embodiments of the present invention suggest that many displays may not be well suited

for use devices adhered to the patient. At least some information displays may have a stiff portion that can be somewhat uncomfortable, so as to promote device removal in at least some instances. Information displays also add excessive weight and energy consumption in at least some instances. Thus, at least some patient measurement devices may not incorporate information displays, such that the device may be somewhat awkward to use in at least some instances.

[0005] Therefore, a need exists for improved patient monitoring that overcomes at least some of the above mentioned disadvantages of the current monitors. Ideally, such improved patient monitoring would provide the user of with a comfortable device that provides at least some output to the user.

BRIEF SUMMARY OF THE INVENTION

[0006] The present invention relates to patient monitoring. Although embodiments make specific reference to monitoring patients with an adherent patch device, the system methods and device described herein may be applicable to many applications in which physiological monitoring is used, for example wireless physiological monitoring with devices for extended periods.

[0007] Embodiments of the present invention provide systems, methods and devices to monitor or treat a patient for extended periods. In many embodiments, an adherent device is configured to adhere to a skin of the patient and to indicate at least one of physiological information or information related to the functionality of the device. The adherent device may comprise a flexible support which may flex, bends or stretches with movement of a patients skin and body movements, such that the patch can be comfortably worn continuously by the patient for an extended period, for example worn continuously for one week. In many embodiments the adherent device comprises a flexible device with a flexible display, which display may also flex with the movement of a patient's skin and body. In many embodiments the adherent device comprises a flexible and stretchable covering coupled to the support and at least one indicator, for example an LED, which indicator may be small enough to minimize, even avoid, separation of the support from the patient's skin from movement of the patient's skin and body. The covering may be coupled to the support and the display such that the covering and support stretch with the skin of the patient. In many embodiments, the covering can be configured to stretch more than the support to compensate for minimal stretching of the display. In many embodiments the adherent device comprises an audible indicator.

[0008] In a first aspect, embodiments of the present invention provide adherent device to measure data from a patient having skin. The device comprises a support configured to measure data from a patient and adhere to the skin of the patient, and a display coupled to the support.

5 [0009] In many embodiments the support comprises a flexible support, and the display comprises a flexible display. The flexible support is coupled to the flexible display to flex the flexible display in response to patient movement.

[0010] In many embodiments the flexible support is configured to stretch with the skin of the patient when the support is adhered to the skin of the patient. In many embodiments the
10 device further comprises a cover coupled to the display and the support to support the display with the cover and the support when the support is adhered to the skin of the patient and wherein the cover comprises a stretchable material such that cover is configured stretch with the support and the skin when the support is adhered to the skin of the patient. In many embodiments the cover is configured to stretch more than the flexible display to compensate
15 for minimal stretching of the flexible display when the support is stretched with the skin.

[0011] In many embodiments the flexible support comprises a breathable tape with an adhesive coating, at least one electrode affixed to the breathable tape and capable of electrically coupling to a skin of the patient, a printed circuit board connected to the
20 breathable tape to support the printed circuit board with the breathable tape when the tape is adhered to the patient; and electronic components electrically connected to the printed circuit board and coupled to the at least one electrode to measure physiologic signals of the patient, and coupled to the flexible display.

[0012] In many embodiments the flexible support further comprises at least one of a breathable cover or an electronics housing disposed over the circuit board and electronic
25 components and connected to at least one of the electronics components, the printed circuit board or the breathable tape. In many embodiments the display is affixed to the breathable cover or electronic housing.

[0013] In many embodiments the electronic components comprise a processor and a plurality of sensors coupled to the printed circuit board. The processor is configured to
30 process data received from the sensors and to display information regarding the data on the printed circuit board.

[0014] In many embodiments each of the plurality of sensors are chosen from a group consisting of: ECG, tissue resistance, bioimpedance, respiration, respiration rate variability, heart rate, heart rhythm, heart rate variability, heart rate turbulence, heart sounds, respiratory sounds, blood pressure, activity, posture, wake, sleep, orthopnea, temperature, heat flux, and weight.

[0015] In many embodiments the activity sensor is chosen from a group consisting of: ball switch, accelerometer, minute ventilation, bioimpedance noise, muscle noise, and posture.

[0016] In many embodiments the electronic components further comprise wireless communication circuitry coupled to the processor.

[0017] In many embodiments the display further comprises at least one visual indicator coupled to the processor and the flexible support.

[0018] In many embodiments the at least one visual indicator is an LED light.

[0019] In many embodiments the flexible display comprises a first flexible layer and a second flexible layer and a flexible material disposed between the first layer and the second flexible layer to convey information to the patient.

[0020] In many embodiments the first and second flexible layers include cutout portions for the flexible material to reside.

[0021] In many embodiments the flexible material comprises a flexible electrochromic display. In many embodiments the flexible electrochromic display is configured to display a plurality of symbols. In many embodiments each of the plurality of symbols are chosen from a group consisting of: a checkmark, a wireless symbol, a minus symbol, and combinations thereof.

[0022] In many embodiments the flexible material comprises a flexible LCD display. In many embodiments the flexible LCD display is configured to display a plurality of symbols. In many embodiments the plurality of symbols are chosen from a group consisting of: a checkmark, a wireless symbol, a minus symbol, and combinations thereof.

[0023] In another aspect the invention provides a method for measuring data from a patient having skin. The method comprises adhering a device to a skin of the patient, the device comprising a display and at least one sensor, measuring patient information from the sensor when the device adhered to the skin of the patient, and displaying information on the display in response to the patient information.

[0024] In many embodiments the adherent device comprises a support with an adhesive, and wherein the support stretches and bends with the skin of the patient when the support is adhered to the skin of the patient. In many embodiments the adherent device comprises a cover coupled to support and the display and wherein the cover stretches with the support
5 when the skin stretches.

[0025] In yet another aspect the invention provides a method for measuring data from a patient having skin. The method comprises detecting sensor information from the patient's skin using a support configured to measure the sensor information from a patient and adhere to the skin of the patient. The support having at least one visual indicator. The method also
10 comprises displaying at least one indication related to the sensor information on the at least one visual indicator.

[0026] In many embodiments the sensor information regards data from a plurality of sensors of the support, each sensor chosen from a group consisting of: ECG, tissue resistance, bioimpedance, respiration, respiration rate variability, heart rate, heart rhythm, heart rate
15 variability, heart rate turbulence, heart sounds, respiratory sounds, blood pressure, activity, posture, wake, sleep, orthopnea, temperature, heat flux, and weight. In many embodiments activity sensor is chosen from a group consisting of: ball switch, accelerometer, minute ventilation, bioimpedance noise, muscle noise, and posture.

[0027] In many embodiments the at least one visual indicator is a flexible display and the at
20 least one indication comprises a plurality of signals. In many embodiments the plurality of symbols are chosen from a group consisting of: a checkmark, a wireless symbol, a minus symbol, and combinations thereof.

[0028] In many embodiments the method also comprises determining that the at least one indication should be a warning displayed on the at least one visual indicator. In many
25 embodiments the warning regards a support malfunction and determining the at least one indication should be a warning comprises determining that a first sensor of the support has stopped providing sensor information. In many embodiments determining that a first sensor of the support has stopped providing sensor information comprises detecting that a first signal of the first sensor is not within a predetermined value and cross-checking the first signal of
30 the first sensor with a second signal of a second sensor. In many embodiments the second signal of the second sensor indicates that the patient is not undergoing an adverse event. In many embodiments the method further comprises sending a wireless signal from the support to a second device to indicate the support is not functioning properly. In many embodiments

the first and second signals are chosen from a group consisting of: ECG, tissue resistance, bioimpedance, bioimpedance noise, muscle noise, posture, respiration, respiration rate variability, heart rate, heart rhythm, heart rate variability, heart rate turbulence, heart sounds, respiratory sounds, blood pressure, activity, posture, wake, sleep, orthopnea, temperature, heat flux, and weight.

[0029] In many embodiments the warning regards an adverse patient event or potential adverse patient adverse event, and determining comprises determining that a first sensor of the support is functioning properly. In many embodiments determining that a first sensor of the support is functioning properly comprises detecting that a first signal of the first sensor is not within a predetermined value and cross-checking the first signal of the first sensor with a second signal of a second sensor. In many embodiments the second signal of the second sensor indicates that the patient is undergoing an adverse event or a potential adverse event. In many embodiments the method also comprises sending a wireless signal from the support to a second device to indicate that the patient is undergoing an adverse event or a potential adverse event. In many embodiments the first and second signals are chosen from a group consisting of: ECG, tissue resistance, bioimpedance, respiration, respiration rate variability, heart rate, heart rhythm, heart rate variability, heart rate turbulence, heart sounds, respiratory sounds, blood pressure, activity, posture, wake, sleep, orthopnea, temperature, heat flux, and weight.

[0030] In yet another aspect the invention provides an adherent device to measure data from a patient having skin. The device comprising a flexible support configured to measure data from a patient and adhere to the skin of the patient, and at least one visual indicator coupled to the support.

[0031] In many embodiments the support comprises a battery, a breathable tape with an adhesive coating, at least two electrodes affixed to the breathable tape and capable of electrically coupling to a skin of the patient, a printed circuit board connected to the breathable tape to support the printed circuit board with the breathable tape when the tape is adhered to the patient, electronic components electrically connected to the printed circuit board and coupled to the at least two electrodes to measure physiologic signals of the patient, and coupled to the visual indicator, and at least one switch coupled to the at least two electrodes, the battery and the electronic components, the at least one switch configured to detect tissue coupled to the at least two electrodes and connect the battery to electronic components in response to tissue coupling to the at least two electrodes.

[0032] In many embodiments the electronic components are configured to trigger the at least one visual indicator to indicate the coupling of the at least two electrodes. In many embodiments the electronic components are configured to trigger the at least one visual indicator to indicate a decoupling of the at least two electrodes. In many embodiments the electronic components are configured to send a wireless signal to an external device to indicate the decoupling of the at least two electrodes. In many embodiments the electronic components are configured to emit an audible signal to indicate the decoupling of the at least two electrodes. In many embodiments the at least one visual indicator is an LED and to indicate the coupling comprises flashing the LED at least once. In many embodiments the at least one visual indicator is a flexible display and to indicate the coupling comprises displaying at least one indicator on the screen. In many embodiments the indicator is a symbol.

[0033] In yet another aspect, the invention provides a method for indicating a support has coupled to a patient's skin. The method comprises detecting tissue coupled to at least two electrodes of a flexible support, which is coupled to a skin of the patient, connecting a battery of the support to electronic components of the support in response to detecting tissue, and triggering at least one visual indicator of the support in response to detecting tissue coupled to at least two electrodes of the support.

[0034] In many embodiments the method further comprises detecting a decoupling of the tissue and the at least two electrodes of the flexible support.

[0035] In many embodiments the method further comprises retriggering the at least one visual indicator of the support in response to detecting the tissue decoupling of the tissue and the at least two electrodes of the flexible support.

[0036] In many embodiments the method further comprises sending a wireless signal to an external device in response to detecting the tissue decoupling of the tissue and the at least two electrodes of the flexible support.

[0037] In many embodiments the method further comprises emitting an audible signal using the flexible support in response to detecting the tissue decoupling of the tissue and the at least two electrodes of the flexible support. In many embodiments triggering the at least one visual indicator of the support comprises activating at least one LED coupled to the support.

[0038] In many embodiments triggering the at least one visual indicator of the support comprises displaying at least one symbol on a flexible display coupled to the flexible support.

5 [0039] In yet another aspect, the invention provides an adherent device to measure data from a patient having skin. The device comprises a flexible support configured to adhere to the skin of the patient, at least one electrode affixed to the flexible support and capable of electrically coupling to a skin of the patient, at least one visual indicator coupled to the support, a printed circuit board connected to the flexible support to support the printed circuit board when the flexible support is adhered to the patient, and electronic components electrically connected to the printed circuit board and coupled to the at least one electrode to
10 measure physiologic signals of the patient, and coupled to the visual indicator, wherein the electrical components are configured to display an indicator on the at least one visual indicator when a predetermined event occurs.

[0040] In many embodiments the flexible support comprises a breathable tape with an adhesive coating.

15 [0041] In many embodiments the at least one electrode extends through at least one aperture in the breathable tape.

[0042] In many embodiments device further comprises at least one gel disposed over a contact surface of the at least one electrode to electrically connect the at least one electrode to the skin.

20 [0043] In many embodiments the at least one electrode extends through at least one aperture in the breathable tape.

[0044] In many embodiments the at least one visual indicator comprises an LED light. In many embodiments the LED light is configured to flash at least once when predetermined event occurs.

25 [0045] In many embodiments the at least one visual indicator comprises a flexible display. In many embodiments the flexible display comprises a first flexible layer and a second flexible layer and a flexible material disposed between the first layer and the second flexible layer to convey information to the patient. In many embodiments the first and second flexible layers include cutout portions for the flexible material to reside.

30 [0046] In many embodiments the flexible material comprises a flexible electrochromic display. In many embodiments the flexible electrochromic display is configured to display a plurality of symbols. In many embodiments each of the plurality of symbols are chosen from

a group consisting of: a checkmark, a wireless symbol, a minus symbol, and combinations thereof.

[0047] In many embodiments the flexible material comprises an flexible LCD display. In many embodiments the flexible LCD display is configured to display a plurality of symbols.

5 In many embodiments the plurality of symbols are chosen from a group consisting of: a checkmark, a wireless symbol, a minus symbol, and combinations thereof.

[0048] In many embodiments the electrical components comprise a memory for storing the physiologic signals. In many embodiments the predetermined event comprises determination of exceeding capacity of the memory for storing the physiologic signals.

10 [0049] In many embodiments the predetermined event comprises determination that a predetermined amount of time has elapsed. In many embodiments the predetermined amount of time is initiated when the at least one electrode begins to measure the physiologic signals of the patient. In many embodiments the predetermined amount of time is 7 days.

[0050] In many embodiments the electrical components are configured to stop measuring
15 physiologic signals of the patient when the predetermined event occurs.

[0051] In many embodiments the electronic components comprise a wireless transmitter. In many embodiments the wireless transmitter is configured to send a signal to an external device when the predetermined event occurs.

[0052] In yet another aspect, the invention provides a method for indicating a
20 predetermined event has occurred on a flexible device. The method comprises detecting sensor information from the patient's skin using a support configured to measure the sensor information from a patient and adhere to the skin of the patient, the support having at least one visual indicator, determining a predetermined event has occurred using the support, and displaying at least one indication related to the predetermined event on the at least one visual
25 indicator.

[0053] In many embodiments the sensor information regards data from a plurality of sensors of the support, each sensor chosen from a group consisting of: ECG, tissue resistance, bioimpedance, respiration, respiration rate variability, heart rate, heart rhythm, heart rate variability, heart rate turbulence, heart sounds, respiratory sounds, blood pressure, activity,
30 posture, wake, sleep, orthopnea, temperature, heat flux, and weight.

[0054] In many embodiments the at least one visual indicator is a flexible display.

[0055] In many embodiments the method further comprises storing the sensor information on a memory of the support. In many embodiments the predetermined event comprises determining that capacity of the memory for storing the physiologic signals has been exceeded.

5 [0056] In many embodiments the predetermined event comprises determining that a predetermined amount of time has elapsed. In many embodiments the predetermined amount of time is initiated when the at least one electrode begins to measure the physiologic signals of the patient. In many embodiments the predetermined amount of time is 7 days.

[0057] In many embodiments the at least one visual indicator comprises an LED and the at least one indication comprises at least one flash of the LED.

[0058] In many embodiments the at least one visual indicator comprises a flexible display and wherein the at least one indication comprises at least one symbol on the flexible display.

BRIEF DESCRIPTION OF THE DRAWINGS

15

[0059] Figure 1A shows a patient and a monitoring system comprising an adherent device, according to embodiments of the present invention;

[0060] Figure 1B shows a bottom view of the adherent device as in Figure 1A comprising an adherent patch;

20 [0061] Figure 1C shows a top view of the adherent patch, as in Figure 1B;

[0062] Figure 1D shows a printed circuit board and electronic components over the adherent patch, as in Figure 1C;

[0063] Figure 1D1 shows an equivalent circuit that can be used to determine optimal frequencies for determining patient hydration, according to embodiments of the present invention;

[0064] Figure 1E shows batteries positioned over the printed circuit board and electronic components as in Figure 1D;

[0065] Figure 1F1 shows a top view of an electronics housing and a breathable cover with visual indicators over the batteries, electronic components and printed circuit board as in Figure 1E;

[0066] Figure 1F2 shows a top view of an electronics housing and a breathable cover with a visual indicator over the batteries, electronic components and printed circuit board as in Figure 1E;

[0067] Figure 1G shows a side view of the adherent device as in Figures 1A to 1F;

5 [0068] Figure 1H shown a bottom isometric view of the adherent device as in Figures 1A to 1G;

[0069] Figures 1I1 and 1J1 show a side cross-sectional view and perspective exploded view, respectively, as in Figures 1A to 1F1, 1G, and 1H, according to embodiments of the present invention;

10 [0070] Figures 1I2 and 1J2 show a side cross-sectional view and perspective exploded view, respectively, as in Figures 1A to 1E and 1F2 to 1H, according to embodiments of the present invention;

[0071] Figure 1K shows at least one electrode configured to electrically couple to a skin of the patient through a breathable tape, according to embodiments of the present invention;

15 [0072] Figure 2A shows a simplified schematic illustration of a circuit for automatically turning on the device when tissue contacts with the electrodes, and in which the processor is able to turn off the device after tissue is removed from the electrodes, according to embodiments of the present invention;

[0073] Figure 2B shows additional detail of start-up circuitry of Figure 2A that
20 automatically turns on the device when tissue contacts the electrodes;

[0074] Figure 2B-1 shows the start-up circuitry of Figure 2B with a removable liner coupled to the electrodes;

[0075] Figure 2C shows additional detail of the sustain circuitry of Figure 2A that sustains power from the battery to the voltage regulator after the tissue is removed from the electrodes
25 and allows the processor to turn the device off after tissue is removed from the electrodes;

[0076] Figure 2D shows circuitry to decrease parasitic current flow through the electrodes coupled to the tissue detection circuitry when tissue is coupled to the electrodes;

[0077] Figure 2E shows a clock coupled to the battery to determine the current date and time when the circuit for automatically turning on the device is open;

[0078] Figure 3 shows a method of monitoring and/or treating a patient with a medical device that automatically turns on in response to patient tissue contact, according to embodiments of the present invention;

[0079] Figures 4A and 4B shows methods of predicting an impending cardiac decompensation, according to embodiments of the present invention;

[0080] Figure 5A shows an adherent device to measure an impedance signal and an electrocardiogram signal, according to embodiments of the present invention;

[0081] Figure 5B shows a method of measuring the impedance signal and the electrocardiogram signal, according to embodiments of the present invention;

[0082] Figure 5C shows a method for monitoring a patient and responding to a signal event, according to embodiments of the present invention;

[0083] Figures 5D, 5E and 5F show methods for monitoring body fluid of a patient, according to embodiments of the present invention; and

[0084] Figure 6 shows a method for triggering an indicator to indicate the occurrence of a predetermined event.

DETAILED DESCRIPTION OF THE INVENTION

[0085] The following is adapted from U.S. Application Ser. No.: 12/209,273, Docket No.: 026843-001320US, entitled "Adherent Device with Multiple Physiological Sensors":

[0086] Embodiments of the present invention relate to patient monitoring and/or therapy.

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

[0087] Embodiments of the invention provide information which can be displayed in proximity to a patient by a body-worn health monitoring device. The information provided may include one or a combination of the following: device status, health information, patient compliance, non-device and non-health information that is useful to the patient. The information may be of an immediate form such as component operation or patient health, or of a non-immediate form such as a long-term summary of status. Some specific examples of information types are power status, data transmission status, reminder to change device, patient health status, physiological information (such as HR), device functionality (e.g., not working), and battery status. The body-worn device may include a display module that is

flexibly integrated with the body-worn device, and which provides one or more following-indicators (e.g., instructive symbols). The body-worn device may include point light emitters in association with fixed labels on the body-worn device.

5 [0088] The adherent device comprises a support, for example a patch that may comprise breathable tape, and the support can be configured to adhere to the patient and support the electronics and sensors on the patient. The support can be porous and breathable so as to allow water vapor transmission. The support can also stretch with skin of the patient, so as to improve patient comfort and extend the time that the support can be adhered to the patient.

10 [0089] In many embodiments, the adherent devices described herein may be used for 90 day monitoring, or more, and may comprise completely disposable components and/or reusable components, and can provide reliable data acquisition and transfer. In many embodiments, the patch is configured for patient comfort, such that the patch can be worn and/or tolerated by the patient for extended periods, for example 90 days or more. The patch may be worn continuously for at least seven days, for example 14 days, and then replaced
15 with another patch. In many embodiments, the adherent patch comprises a tape, which comprises a material, preferably breathable, with an adhesive, such that trauma to the patient skin can be minimized while the patch is worn for the extended period. The printed circuit board may comprise a flex printed circuit board that can flex with the patient to provide improved patient comfort.

20 [0090] Figure 1A shows a patient P and a monitoring system 10. Patient P comprises a midline M, a first side S1, for example a right side, and a second side S2, for example a left side. Monitoring system 10 comprises an adherent device 100. Adherent device 100 can be adhered to a patient P at many locations, for example thorax T of patient P. In many embodiments, the adherent device may adhere to one side of the patient, from which side data
25 can be collected. Work in relation with embodiments of the present invention suggests that location on a side of the patient can provide comfort for the patient while the device is adhered to the patient.

[0091] Monitoring system 10 includes components to transmit data to a remote center 106. Remote center 106 can be located in a different building from the patient, for example in the
30 same town as the patient, and can be located as far from the patient as a separate continent from the patient, for example the patient located on a first continent and the remote center located on a second continent. Adherent device 100 can communicate wirelessly to an intermediate device 102, for example with a single wireless hop from the adherent device on

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

[0092] In many embodiments, the adherent device may continuously monitor physiological parameters, communicate wirelessly with a remote center, and provide alerts when necessary. The system may comprise an adherent patch, which attaches to the patient's thorax and contains sensing electrodes, battery, memory, logic, and wireless communication capabilities. In some embodiments, the patch can communicate with the remote center, via the intermediate device in the patient's home. In some embodiments, the remote center 106 receives the patient data and applies a patient evaluation and/or prediction algorithm. When a flag is raised, the center may communicate with the patient, hospital, nurse, and/or physician to allow for therapeutic intervention, for example to prevent decompensation.

[0093] The adherent device may be affixed and/or adhered to the body in many ways. For example, with at least one of the following an adhesive tape, a constant-force spring, suspenders around shoulders, a screw-in microneedle electrode, a pre-shaped electronics module to shape fabric to a thorax, a pinch onto roll of skin, or transcutaneous anchoring.

5 Patch and/or device replacement may occur with a keyed patch (e.g. two-part patch), an outline or anatomical mark, a low-adhesive guide (place guide | remove old patch | place new patch | remove guide), or a keyed attachment for chatter reduction. The patch and/or device may comprise an adhesiveless embodiment (e.g. chest strap), and/or a low-irritation adhesive for sensitive skin. The adherent patch and/or device can comprise many shapes, for example
10 at least one of a dog bone, an hourglass, an oblong, a circular or an oval shape.

[0094] In many embodiments, the adherent device may comprise a reusable electronics module with replaceable patches, and each of the replaceable patches may include a battery. The module may collect cumulative data for approximately 90 days and/or the entire adherent component (electronics + patch) may be disposable. In a completely disposable embodiment,
15 a "baton" mechanism may be used for data transfer and retention, for example baton transfer may include baseline information. In some embodiments, the device may have a rechargeable module, and may use dual battery and/or electronics modules, wherein one module 101A can be recharged using a charging station 103 while the other module 101B is placed on the adherent patch with connectors. In some embodiments, the intermediate device
20 102 may comprise the charging module, data transfer, storage and/or transmission, such that one of the electronics modules can be placed in the intermediate device for charging and/or data transfer while the other electronics module is worn by the patient.

[0095] System 10 can perform the following functions: initiation, programming, measuring, storing, analyzing, communicating, predicting, and displaying. The adherent
25 device may contain a subset of the following physiological sensors: bioimpedance, respiration, respiration rate variability, heart rate (avg, min, max), heart rhythm, heart rate variability (hereinafter "HRV"), heart rate turbulence (hereinafter "HRT"), heart sounds (e.g. S3), respiratory sounds, blood pressure, activity, posture, wake/sleep, orthopnea, temperature/heat flux, and weight. The activity sensor may comprise one or more of the
30 following: ball switch, accelerometer, minute ventilation, HR, bioimpedance noise, skin temperature/heat flux, BP, muscle noise, posture.

[0096] The adherent device can wirelessly communicate with remote center 106. The communication may occur directly (via a cellular or Wi-Fi network), or indirectly through

intermediate device 102. Intermediate device 102 may consist of multiple devices, which can communicate wired or wirelessly to relay data to remote center 106.

[0097] In many embodiments, instructions are transmitted from remote site 106 to a processor supported with the adherent patch on the patient, and the processor supported with the patient can receive updated instructions for the patient treatment and/or monitoring, for example while worn by the patient.

[0098] Figure 1B shows a bottom view of adherent device 100 as in Figure 1A comprising an adherent patch 110. Adherent patch 110 comprises a first side, or a lower side 110A, that is oriented toward the skin of the patient when placed on the patient. In many embodiments, adherent patch 110 comprises a tape 110T which is a material, preferably breathable, with an adhesive 116A. Patient side 110A comprises adhesive 116A to adhere the patch 110 and adherent device 100 to patient P. Electrodes 112A, 112B, 112C and 112D are affixed to adherent patch 110. In many embodiments, at least four electrodes are attached to the patch, for example six electrodes. In some embodiments the patch comprises two electrodes, for example two electrodes to measure the electrocardiogram (ECG) of the patient. Gel 114A, gel 114B, gel 114C and gel 114D can each be positioned over electrodes 112A, 112B, 112C and 112D, respectively, to provide electrical conductivity between the electrodes and the skin of the patient. In many embodiments, the electrodes can be affixed to the patch 110, for example with known methods and structures such as rivets, adhesive, stitches, etc. In many embodiments, patch 110 comprises a breathable material to permit air and/or vapor to flow to and from the surface of the skin.

[0099] Figure 1C shows a top view of the adherent patch 100, as in Figure 1B. Adherent patch 100 comprises a second side, or upper side 110B. In many embodiments, electrodes 112A, 112B, 112C and 112D extend from lower side 110A through adherent patch 110 to upper side 110B. An adhesive 116B can be applied to upper side 110B to adhere structures, for example a breathable cover, to the patch such that the patch can support the electronics and other structures when the patch is adhered to the patient. The printed circuit board (hereinafter "PCB") may comprise completely flex PCB, combined flex PCB and/or rigid PCB boards connected by cable.

[0100] Figure 1D shows a printed circuit boards and electronic components over adherent patch 110, as in Figures 1A to 1C. In some embodiments, a printed circuit board (PCB), for example flex printed circuit board 120, may be connected to electrodes 112A, 112B, 112C and 112D with connectors 122A, 122B, 122C and 122D. Flex printed circuit board 120 can

include traces 123A, 123B, 123C and 123D that extend to connectors 122A, 122B, 122C and 122D, respectively, on the flex printed circuit board. Connectors 122A, 122B, 122C and 122D can be positioned on flex printed circuit board 120 in alignment with electrodes 112A, 112B, 112C and 112D so as to electrically couple the flex PCB with the electrodes. In some
5 embodiments, connectors 122A, 122B, 122C and 122D may comprise insulated wires and/or a film with conductive ink that provide strain relief between the PCB and the electrodes. For example, connectors 122A, 122B, 122C and 122D may comprise a flexible film, such as at least one of known polyester film or known polyurethane film, coated with a conductive ink, for example a conductive silver ink. In some embodiments, additional PCB's, for example
10 rigid PCB's 120A, 120B, 120C and 120D, can be connected to flex PCB 120. Electronic components 130 can be connected to flex PCB 120 and/or mounted thereon. In some embodiments, electronic components 130 can be mounted on the additional PCB's.

[0101] Electronic components 130 comprise components to take physiologic measurements, transmit data to remote center 106 and receive commands from remote center
15 106. In many embodiments, electronics components 130 may comprise known low power circuitry, for example complementary metal oxide semiconductor (CMOS) circuitry components. Electronics components 130 comprise an activity sensor and activity circuitry 134, impedance circuitry 136 and electrocardiogram circuitry, for example ECG circuitry 136. In some embodiments, electronics circuitry 130 may comprise a microphone and
20 microphone circuitry 142 to detect an audio signal from within the patient, and the audio signal may comprise a heart sound and/or a respiratory sound, for example an S3 heart sound and a respiratory sound with rales and/or crackles.

[0102] Electronic components 130 may comprise a temperature sensor 177, for example a thermistor in contact with the skin of the patient, and temperature sensor circuitry 144 to
25 measure a temperature of the patient, for example a temperature of the skin of the patient. A temperature sensor 177 may be used to determine the sleep and wake state of the patient. The temperature of the patient can decrease as the patient goes to sleep and increase when the patient wakes up.

[0103] Work in relation to embodiments of the present invention suggests that skin
30 temperature may effect impedance and/or hydration measurements, and that skin temperature measurements may be used to correct impedance and/or hydration measurements. In some embodiments, increase in skin temperature or heat flux can be associated with increased vaso-dilation near the skin surface, such that measured impedance measurement decreased, even through the hydration of the patient in deeper tissues under the skin remains

substantially unchanged. Thus, use of the temperature sensor can allow for correction of the hydration signals to more accurately assess the hydration, for example extra cellular hydration, of deeper tissues of the patient, for example deeper tissues in the thorax.

[0104] Electronic components 130 may comprise a processor 146. Processor 146
5 comprises a tangible medium, for example read only memory (ROM), electrically erasable programmable read only memory (EEPROM) and/or random access memory (RAM). In some embodiments the tangible medium is configured to continuously store physiologic signals of a patient. In some embodiments the processor 146 is configured to stop storing and/or measuring physiologic signals when the storage capacity of the tangible medium has
10 been exceeded. Electronic circuitry 130 may comprise real time clock and frequency generator circuitry 148. In some embodiments, processor 136 may comprise the frequency generator and real time clock. The processor can be configured to control a collection and transmission of data from the impedance circuitry electrocardiogram circuitry and the accelerometer. In many embodiments, device 100 comprise a distributed processor system,
15 for example with multiple processors on device 100. In some embodiments the processor 146 may be configured to control a visual indicator, such as an LED or a display. In some embodiments the electronic components 130 include a dedicated graphics processor for controlling a visual indicator. In some embodiments the processor 146 includes a clock. In some embodiments the electronic components 130 include dedicated clock hardware.

20 [0105] In many embodiments, electronics components 130 comprise wireless communications circuitry 132 to communicate with remote center 106. Printed circuit board 120 may comprise an antenna to facilitate wireless communication. The antennae may be integral with printed circuit board 120 or may be separately coupled thereto. The wireless communication circuitry can be coupled to the impedance circuitry, the electrocardiogram
25 circuitry and the accelerometer to transmit to a remote center with a communication protocol at least one of the hydration signal, the electrocardiogram signal or the inclination signal. In specific embodiments, wireless communication circuitry is configured to transmit the hydration signal, the electrocardiogram signal and the inclination signal to the remote center with a single wireless hop, for example from wireless communication circuitry 132 to
30 intermediate device 102. The communication protocol comprises at least one of Bluetooth, Zigbee, WiFi, WiMax, IR, amplitude modulation or frequency modulation. In many embodiments, the communications protocol comprises a two way protocol such that the remote center is capable of issuing commands to control data collection.

[0106] Intermediate device 102 may comprise a data collection system to collect and store data from the wireless transmitter. The data collection system can be configured to communicate periodically with the remote center. The data collection system can transmit data in response to commands from remote center 106 and/or in response to commands from the adherent device.

[0107] Activity sensor and activity circuitry 134 can comprise many known activity sensors and circuitry. In many embodiments, the accelerometer comprises at least one of a piezoelectric accelerometer, capacitive accelerometer or electromechanical accelerometer. The accelerometer may comprises a 3-axis accelerometer to measure at least one of an inclination, a position, an orientation or acceleration of the patient in three dimensions. Work in relation to embodiments of the present invention suggests that three dimensional orientation of the patient and associated positions, for example sitting, standing, lying down, can be very useful when combined with data from other sensors, for example ECG data and/or hydration data.

[0108] Impedance circuitry 136 can generate both hydration data and respiration data. In many embodiments, impedance circuitry 136 is electrically connected to electrodes 112A, 112B, 112C and 112D such that electrodes 112A and 112D comprise outer electrodes that are driven with a current, or force electrodes. The current delivered between electrodes 112A and 112D generates a measurable voltage between electrodes 112B and 112C, such that electrodes 112B and 112C comprise inner sense electrodes that sense and/or measure the voltage in response to the current from the force electrodes. In some embodiments, electrodes 112B and 112C may comprise force electrodes and electrodes 112A and 112B may comprise sense electrodes. The voltage measured by the sense electrodes can be used to measure the impedance of the patient to determine respiration rate and/or the hydration of the patient.

[0109] Electronic components 130 may be configured to emit an audible signal, and also comprise an audible indicator to emit the audible signal. The audible indicator may be a microspeaker. The audible signal may be a single signal or a plurality of signals. The audible signal may be of a significant decibel rating within a short range, for example 100db at 300mm, to enable the patient to be immediately aware of the audible signal, even while asleep. Electronic components 130 may be configured to emit the audible signal when a predetermined or undesired patient event occurs, or is sensed to occur in the future. In some embodiments the predetermined event is the an expiration of a predetermined amount of time. The predetermined amount of time may be triggered when the adherent device 100 is first

used on a patient, for example seven days after the first physiologic measurement is taken. The predetermined amount of time may be related to the expected life of the adhesive 116A.

The predetermined event may be externally triggered by an external device in wireless communication with the electronic components. In some embodiments the predetermined

5 event is the processor detecting that the tangible medium of the processor 146, or a separate memory coupled to the electronic components 130, has exceeded capacity. In some embodiments the predetermined event is a determination by the electronic components that the adherent device is in or is not in wireless communication with an external device. In some embodiments the predetermined event is a determination by the electronic components
10 130 that an adverse patient event has occurred or is going to occur. In some embodiments the predetermined event is a determination by the electronic components 130 that one or more sensors has stopped functioning.

[0110] Figure 1D1 shows an equivalent circuit 152 that can be used to determine optimal frequencies for measuring patient hydration. Work in relation to embodiments of the present

15 invention indicates that the frequency of the current and/or voltage at the force electrodes can be selected so as to provide impedance signals related to the extracellular and/or intracellular hydration of the patient tissue. Equivalent circuit 152 comprises an intracellular resistance

156, or $R(ICW)$ in series with a capacitor 154, and an extracellular resistance 158, or $R(ECW)$. Extracellular resistance 158 is in parallel with intracellular resistance 156 and

20 capacitor 154 related to capacitance of cell membranes. In many embodiments, impedances can be measured and provide useful information over a wide range of frequencies, for example from about 0.5 kHz to about 200 KHz. Work in relation to embodiments of the

present invention suggests that extracellular resistance 158 can be significantly related to extracellular fluid and to cardiac decompensation, and that extracellular resistance 158 and

25 extracellular fluid can be effectively measured with frequencies in a range from about 0.5 kHz to about 20 kHz, for example from about 1 kHz to about 10 kHz. In some embodiments, a single frequency can be used to determine the extracellular resistance and/or fluid. As

sample frequencies increase from about 10 kHz to about 20 kHz, capacitance related to cell membranes decrease the impedance, such that the intracellular fluid contributes to the

30 impedance and/or hydration measurements. Thus, many embodiments of the present invention employ measure hydration with frequencies from about 0.5 kHz to about 20 kHz to determine patient hydration.

[0111] In many embodiments, impedance circuitry 136 can be configured to determine respiration of the patient. In specific embodiments, the impedance circuitry can measure the

hydration at 25 Hz intervals, for example at 25 Hz intervals using impedance measurements with a frequency from about 0.5 kHz to about 20 kHz.

[0112] ECG circuitry 138 can generate electrocardiogram signals and data from two or more of electrodes 112A, 112B, 112C and 112D in many ways. In some embodiments, ECG circuitry 138 is connected to inner electrodes 112B and 112C, which may comprise sense electrodes of the impedance circuitry as described above. In some embodiments, ECG circuitry 138 can be connected to electrodes 112A and 112D so as to increase spacing of the electrodes. The inner electrodes may be positioned near the outer electrodes to increase the voltage of the ECG signal measured by ECG circuitry 138. In many embodiments, the ECG circuitry may measure the ECG signal from electrodes 112A and 112D when current is not passed through electrodes 112A and 112D.

[0113] Figure 1E shows batteries 150 positioned over the flex printed circuit board and electronic components as in Figure 1D. Batteries 150 may comprise rechargeable batteries that can be removed and/or recharged. In some embodiments, batteries 150 can be removed from the adherent patch and recharged and/or replaced.

[0114] Figure 1F1 shows a top view of a cover 162A over the batteries, electronic components and flex printed circuit board as in Figures 1A to 1E. In many embodiments, an electronics housing 160 may be disposed under cover 162A to protect the electronic components, and in some embodiments electronics housing 160 may comprise an encapsulant over the electronic components and PCB. In some embodiments, cover 162A can be adhered to adherent patch 110 with an adhesive 164 on an underside of cover 162A. In many embodiments, electronics housing 160 may comprise a water proof material, for example a sealant adhesive such as epoxy or silicone coated over the electronics components and/or PCB. In some embodiments, electronics housing 160 may comprise metal and/or plastic. Metal or plastic may be potted with a material such as epoxy or silicone.

[0115] Cover 162A may comprise many known biocompatible cover, casing and/or housing materials, such as elastomers, for example silicone. The elastomer may be fenestrated to improve breathability. In some embodiments, cover 162A may comprise many known breathable materials, for example polyester, polyamide, nylon and/or elastane (SpandexTM). The breathable fabric may be coated to make it water resistant, waterproof, and/or to aid in wicking moisture away from the patch.

[0116] Cover 162A includes at least one visual indicator 163A, although more than one may be used. In some embodiments the visual indicator 163A is an LED light. The cover

162A may also include one or more symbols 165 adjacent to each visual indicator 163A. The symbols 165 may include minus symbols, checkmarks, wireless connectivity symbols, words, and combinations thereof. The symbols correspond to a particular status of the adherent device 100 or a warning symbol. In some embodiments the visual indicator 163A is small enough and spaced properly enough such it does not cause the adherent device 100 to lift off a patients skin under flexing or movement. In such embodiments the visual indicators 163A should be placed at proper distances from other visual indicators to avoid creating stiff sections of cover 162A which may promote the adherent device 100 to lift during flexing. The visual indicator 163A may be coupled to and controlled by the electronics components 130. The electronics components 130 may cause the visual indicator 163A to indicate by flashing the visual indicator 163A at least once. The visual indicator 163A may also be flashed multiple times in a pattern or left continuously on. Electronic components 130 may be configured to cause the visual indicator to indicate or warn when a predetermined or undesired patient event occurs, or is sensed to occur in the future. In some embodiments the electronic components 130 are configured to visually indicate or warn in conjunction with emitting an audible signal. In some embodiments the predetermined event is an expiration of a predetermined amount of time. The predetermined amount of time may be triggered when the adherent device 100 is first used on a patient, for example seven days after the first physiologic measurement is taken. The predetermined amount of time may be related to the expected life of the adhesive 116A. The predetermined event may be externally triggered by an external device in wireless communication with the electronic components. The predetermined event may be the processor 146 detecting that the tangible medium of the processor 146, or a separate memory coupled to the electronic components 130, has exceeded capacity. In some embodiments the predetermined event is a determination by the electronic components that the adherent device is in or is not in wireless communication with an external device. In some embodiments the predetermined event is a determination by the electronic components 130 that an adverse patient event has occurred or is going to occur. In some embodiments the predetermined event is a determination by the electronic components 130 that one or more sensors has stopped functioning.

[0117] Figure 1F2 shows a top view of a cover 162B over the batteries, electronic components and flex printed circuit board as in Figures 1A to 1E. Cover 162B may comprise a similar construction to cover 162A. Cover 162B includes at least one visual indicator 163B, although more than one may be used. In some embodiments the visual indicator 163B is a flexible display coupled to and controlled by the electronic components 130 to indicate

symbols in a manner similar to the visual indicator 163A shown in Figure 1F1. In some embodiments the flexible display is flexible enough to not cause the adherent device 100 from lifting off a patient's skin under flexing or movement. In some embodiments the flexible display may elastically stretch to not cause the adherent device 100 from lifting off a patient's skin under flexing or movement. In some embodiments the flexible display and cover 162B may together elastically stretch to not cause the adherent device 100 from lifting off a patient's skin under flexing or movement. In some embodiments the visual indicator 163B is a flexible electrochromic display. The flexible electrochromic display may use a reversible oxidation-reduction (redox) material is used to create a pH gradient and a separate pH sensitive dye which responds to the change in pH, resulting in the formation of a high contrast, reflective image. Traditional electrochromic materials rely on a "redox dye" that must serve as both the redox material and the color-changing agent. By requiring only one redox couple for producing the pH change, color selection flexibility and long life are achieved compared to systems that require a new redox couple for each color. The flexible electrochromic display may consume relatively little power. The flexible electrochromic display may be manufactured by Aveso Inc. of Fridley, MN, USA. In some embodiments the visual indicator 163B is a flexible LCD display. The flexible LCD display may be a monochrome display with total thickness of 0.45 mm and manufactured by EM Microelectronic-Marin SA of Marin, Switzerland. The flexible LCD display may consume relatively little power. Other flexible displays known in the art may also be used, such as organic thin film transistor based display or thin film organic LED display.

[0118] Figure 1G shows a side view of adherent device 100 as in Figures 1A to 1F.

Adherent device 100 comprises a maximum dimension, for example a length 170 from about 4 to 10 inches (from about 100 mm to about 250mm), for example from about 6 to 8 inches (from about 150 mm to about 200 mm). In some embodiments, length 170 may be no more than about 6 inches (no more than about 150 mm). Adherent device 100 comprises a thickness 172. Thickness 172 may comprise a maximum thickness along a profile of the device. Thickness 172 can be from about 0.2 inches to about 0.6 inches (from about 5 mm to about 15 mm), from about 0.2 inches to about 0.4 inches (from about 5 mm to about 10 mm), for example about 0.3 inches (about 7.5 mm) .

[0119] Figure 1H shown a bottom isometric view of adherent device 100 as in Figures 1A to 1G. Adherent device 100 comprises a width 174, for example a maximum width along a width profile of adherent device 100. Width 174 can be from about 2 to about 4 inches (from about 50 mm to 100 mm), for example about 3 inches (about 75 mm).

[0120] Figures 1I1 and 1J1 show a side cross-sectional view and an exploded view, respectively, of adherent device 100 as in Figures 1A to 1F1, 1G, and 1H. In many embodiments, device 100 comprises several layers.

[0121] In some embodiments, gel cover 180 extends over a wider area than shown. In some embodiments, a temperature sensor 177 is disposed over a peripheral portion of gel cover 180. The temperature sensor 177 can be affixed to gel cover 180 such that the temperature sensor can move when the gel cover stretches and tape stretch with the skin of the patient. The temperature sensor 177 may be coupled to temperature sensor circuitry 144 through a flex connection comprising at least one of wires, shielded wires, non-shielded wires, a flex circuit, or a flex PCB. This coupling of the temperature sensor allows the temperature near the skin to be measured through the breathable tape and the gel cover. The temperature sensor can be affixed to the breathable tape, for example through a cutout in the gel cover with the temperature sensor positioned away from the gel pads. A heat flux sensor can be positioned near the temperature sensor, for example to measure heat flux through to the gel cover, and the heat flux sensor coupled to heat flux circuitry similar to the temperature sensor.

[0122] In some embodiments, the adherent device can comprise electrodes configured to couple to tissue through apertures (not shown) in the breathable tape. The electrodes can be fabricated in many ways. For example, the electrodes can be printed on a flexible connector, such as silver ink on polyurethane. Breathable tape 110T may comprise apertures. The electrodes are exposed to the gel through apertures of breathable tape 110T. Gel 114A, gel 114B, gel 114C and gel 114D can be positioned over electrodes and the respective portions of breathable tape 110T proximate apertures so as to couple the electrodes to the skin of the patient. The flexible connector comprising the electrodes can extend from under the gel cover to the printed circuit board to connect to the printed circuit boards and/or components supported thereon. For example, flexible connector may comprise flexible connector 122A to provide strain relief, as described above.

[0123] In many embodiments, gel 114A, or gel layer, comprises a hydrogel that is positioned on electrode 112A to provide electrical conductivity between the electrode and the skin. In many embodiments, gel 114A comprises a hydrogel that provides a conductive interface between skin and electrode, so as to reduce impedance between electrode/skin interface. In many embodiments, gel may comprise water, glycerol, and electrolytes, pharmacological agents, such as beta blockers, ace inhibitors, diuretics, steroid for inflammation, antibiotic, antifungal agent. In specific embodiments the gel may comprise

cortisone steroid. The gel layer may comprise many shapes, for example, square, circular, oblong, star shaped, many any polygon shapes. In specific embodiments, the gel layer may comprise at least one of a square or circular geometry with a dimension in a range from about .005" to about .100", for example within a range from about .015" - .070", in some
5 embodiments within a range from about .015" - .040", and in specific embodiments within a range from about .020" - .040". In many embodiments, the gel layer of each electrode comprises an exposed surface area to contact the skin within a range from about 100 mm² to about 1500 mm², for example a range from about 250 mm² to about 750 mm², and in specific
10 embodiments within a range from about 350 mm² to about 650 mm². Work in relation with embodiments of the present invention suggests that such dimensions and/or exposed surface areas can provide enough gel area for robust skin interface without excessive skin coverage. In many embodiments, the gel may comprise an adhesion to skin, as may be tested with a 1800 degree peel test on stainless steel, of at least about 3 oz/in, for example an adhesion within a range from about 5-10 oz/in. In many embodiments, a spacing between gels is at
15 least about 5 mm, for example at least about 10mm. Work in relation to embodiments of the present invention suggests that this spacing may inhibit the gels from running together so as to avoid crosstalk between the electrodes. In many embodiments, the gels comprise a water content within a range from about 20% to about 30%, a volume resistivity within a range from about 500 to 2000 ohm-cm, and a pH within a range from about 3 to about 5.

20 **[0124]** In many embodiments, the electrodes, for example electrodes 112A to 112D, may comprise an electrode layer. A 0.001" - 0.005" polyester strip with silver ink for traces can extend to silver/silver chloride electrode pads. In many embodiments, the electrodes can provide electrical conduction through hydrogel to skin, and in some embodiments may be coupled directly to the skin. Although at least 4 electrodes are shown, some embodiments
25 comprise at least two electrodes, for example 2 electrodes. In some embodiments, the electrodes may comprise at least one of carbon-filled ABS plastic, silver, nickel, or electrically conductive acrylic tape. In specific embodiments, the electrodes may comprise at least one of carbon-filled ABS plastic, Ag/AgCl. The electrodes may comprise many geometric shapes to contact the skin, for example at least one of square, circular, oblong, star
30 shaped, polygon shaped, or round. In specific embodiments, a dimension across a width of each electrodes is within a range from about 0.002" to about .050", for example from about .010 to about .040". In many a surface area of the electrode toward the skin of the patient is within a range from about 25 mm² to about 1500 mm², for example from about 75 mm² to about 150 mm². In many embodiments, the electrode comprises a tape that may cover the gel

near the skin of the patient. In specific embodiments, the two inside electrodes may comprise force, or current electrodes, with a center to center spacing within a range from about 20 to about 50 mm. In specific embodiments, the two outside electrodes may comprise measurement electrodes, for example voltage electrodes, and a center-center spacing between adjacent voltage and current electrodes is within a range from about 15 mm to about 35 mm. Therefore, in many embodiments, a spacing between inner electrodes may be greater than a spacing between an inner electrode and an outer electrode.

[0125] In many embodiments, adherent patch 110 may comprise a layer of breathable tape 110T, for example a known breathable tape, such as tricot-knit polyester fabric. In many embodiments, breathable tape 110T comprises a backing material, or backing 111, with an adhesive. In many embodiments, the patch adheres to the skin of the patient's body, and comprises a breathable material to allow moisture vapor and air to circulate to and from the skin of the patient through the tape. In many embodiments, the backing is conformable and/or flexible, such that the device and/or patch does not become detached with body movement. In many embodiments, backing can sufficiently regulate gel moisture in absence of gel cover. In many embodiments, adhesive patch may comprise from 1 to 2 pieces, for example 1 piece. In many embodiments, adherent patch 110 comprises pharmacological agents, such as at least one of beta blockers, ace inhibitors, diuretics, steroid for inflammation, antibiotic, or antifungal agent. In specific embodiments, patch 110 comprises cortisone steroid. Patch 110 may comprise many geometric shapes, for example at least one of oblong, oval, butterfly, dog bone, dumbbell, round, square with rounded corners, rectangular with rounded corners, or a polygon with rounded corners. In specific embodiments, a geometric shape of patch 110 comprises at least one of an oblong, an oval or round. In many embodiments, the geometric shape of the patch comprises a radius on each corner that is no less than about one half a width and/or diameter of tape. Work in relation to embodiments of the present invention suggests that rounding the corner can improve adherence of the patch to the skin for an extended period of time because sharp corners, for example right angle corners, can be easy to peel. In specific embodiments, a thickness of adherent patch 110 is within a range from about 0.001" to about .020", for example within a range from about 0.005" to about 0.010". Work in relation to embodiments of the present invention indicates that these ranges of patch thickness can improve adhesion of the device to the skin of the patient for extended periods as a thicker adhesive patch, for example tape, may peel more readily. In many embodiments, length 170 of the patch is within a range from about 2" to about 10", width 174 of the patch is within a range from about 1" to about 5". In

specific embodiments, length 170 is within a range from about 4" to about 8" and width 174 is within a range from about 2" to about 4". In many embodiments, an adhesion to the skin, as measured with a 180 degree peel test on stainless steel, can be within a range from about 10 to about 100 oz/in width, for example within a range from about 30 to about 70 oz/in

5 width. Work in relation to embodiments of the present invention suggests that adhesion within these ranges may improve the measurement capabilities of the patch because if the adhesion is too low, patch will not adhere to the skin of the patient for a sufficient period of time and if the adhesion is too high, the patch may cause skin irritation upon removal. In many embodiments adherent patch 110 comprises a moisture vapor transmission rate

10 (MVTR, $\text{g/m}^2/24 \text{ hrs}$) per American Standard for Testing and Materials E-96 (ASTM E-96) is at least about 400, for example at least about 1000. Work in relation to embodiments of the present invention suggest that MVTR values as specified above can provide improved comfort, for example such that in many embodiments skin does not itch. In some embodiments, the breathable tape 110T of adherent patch 110 may comprise a porosity

15 (sec./100cc/in^2) within a wide range of values, for example within a range from about 0 to about 200. The porosity of breathable tape 110T may be within a range from about 0 to about 5. The above amounts of porosity can minimize itching of the patient's skin when the patch is positioned on the skin of the patient. In many embodiments, the MVTR values above may correspond to a MVTR through both the gel cover and the breathable tape. The

20 above MVTR values may also correspond to an MVTR through the breathable tape, the gel cover and the breathable cover. The MVTR can be selected to minimize patient discomfort, for example itching of the patient's skin.

[0126] In some embodiments, the breathable tape may contain and elute a pharmaceutical agent, such as an antibiotic, anti-inflammatory or antifungal agent, when the adherent device

25 is placed on the patient.

[0127] In many embodiments, tape 110T of adherent patch 110 may comprise backing material, or backing 111, such as a fabric configured to provide properties of patch 110 as described above. In many embodiments backing 111 provides structure to breathable tape 110T, and many functional properties of breathable tape 110T as described above. In many

30 embodiments, backing 111 comprises at least one of polyester, polyurethane, rayon, nylon, breathable plastic film; woven, nonwoven, spunlace, knit, film, or foam. In specific embodiments, backing 111 may comprise polyester tricot knit fabric. In many embodiments, backing 111 comprises a thickness within a range from about 0.0005" to about 0.020", for example within a range from about 0.005" to about 0.010".

[0128] In many embodiments, an adhesive 116A, for example breathable tape adhesive comprising a layer of acrylate pressure sensitive adhesive, can be disposed on underside 110A of patch 110. In many embodiments, adhesive 116A adheres adherent patch 110 comprising backing 111 to the skin of the patient, so as not to interfere with the functionality of breathable tape, for example water vapor transmission as described above. In many embodiments, adhesive 116A comprises at least one of acrylate, silicone, synthetic rubber, synthetic resin, hydrocolloid adhesive, pressure sensitive adhesive (PSA), or acrylate pressure sensitive adhesive. In many embodiments, adhesive 116A comprises a thickness from about 0.0005" to about 0.005", in specific embodiments no more than about 0.003". Work in relation to embodiments of the present invention suggests that these thicknesses can allow the tape to breathe and/or transmit moisture, so as to provide patient comfort.

[0129] A gel cover 180, or gel cover layer, for example a polyurethane non-woven tape, can be positioned over patch 110 comprising the breathable tape. A PCB layer, for example flex printed circuit board 120, or flex PCB layer, can be positioned over gel cover 180 with electronic components 130 connected and/or mounted to flex printed circuit board 120, for example mounted on flex PCB so as to comprise an electronics layer disposed on the flex PCB layer. In many embodiments, the adherent device may comprise a segmented inner component, for example the PCB may be segmented to provide at least some flexibility. In many embodiments, the electronics layer may be encapsulated in electronics housing 160 which may comprise a waterproof material, for example silicone or epoxy. In many embodiments, the electrodes are connected to the PCB with a flex connection, for example trace 123A of flex printed circuit board 120, so as to provide strain relive between the electrodes 112A, 112B, 112C and 112D and the PCB.

[0130] Gel cover 180 can inhibit flow of gel 114A and liquid. In many embodiments, gel cover 180 can inhibit gel 114A from seeping through breathable tape 110T to maintain gel integrity over time. Gel cover 180 can also keep external moisture from penetrating into gel 114A. For example gel cover 180 can keep liquid water from penetrating though the gel cover into gel 114A, while allowing moisture vapor from the gel, for example moisture vapor from the skin, to transmit through the gel cover. The gel cover may comprise a porosity at least 200 sec./100cc/in², and this porosity can ensure that there is a certain amount of protection from external moisture for the hydrogel.

[0131] In many embodiments, the gel cover can regulate moisture of the gel near the electrodes so as to keeps excessive moisture, for example from a patient shower, from penetrating gels near the electrodes. In many embodiments, the gel cover may avoid release

of excessive moisture form the gel, for example toward the electronics and/or PCB modules. Gel cover 180 may comprise at least one of a polyurethane, polyethylene, polyolefin, rayon, PVC, silicone, non-woven material, foam, or a film. In many embodiments gel cover 180 may comprise an adhesive, for example an acrylate pressure sensitive adhesive, to adhere the gel cover to adherent patch 110. In specific embodiments gel cover 180 may comprise a polyurethane film with acrylate pressure sensitive adhesive. In many embodiments, a geometric shape of gel cover 180 comprises at least one of oblong, oval, butterfly, dog bone, dumbbell, round, square, rectangular with rounded corners, or polygonal with rounded corners. In specific embodiments, a geometric shape of gel cover 180 comprises at least one of oblong, oval, or round. In many embodiments, a thickness of gel cover is within a range from about 0.0005" to about 0.020", for example within a range from about 0.0005 to about 0.010". In many embodiments, gel cover 180 can extend outward from about 0-20 mm from an edge of gels, for example from about 5-15 mm outward from an edge of the gels.

[0132] In many embodiments, the breathable tape of adherent patch 110 comprises a first mesh with a first porosity and gel cover 180 comprises a breathable tape with a second porosity, in which the second porosity is less than the first porosity to inhibit flow of the gel through the breathable tape.

[0133] In many embodiments, device 100 includes a printed circuitry, for example a printed circuitry board (PCB) module that includes at least one PCB with the electronics components 130 mounted thereon on and the battery, as described above. In many embodiments, the PCB module comprises two rigid PCB modules with associated components mounted therein, and the two rigid PCB modules are connected by flex circuit, for example a flex PCB. In specific embodiments, the PCB module comprises a known rigid FR4 type PCB and a flex PCB comprising known polyimide type PCB. In specific embodiments, the PCB module comprises a rigid PCB with flex interconnects to allow the device to flex with patient movement. The geometry of flex PCB module may comprise many shapes, for example at least one of oblong, oval, butterfly, dog bone, dumbbell, round, square, rectangular with rounded corners, or polygon with rounded corners. In specific embodiments the geometric shape of the flex PCB module comprises at least one of a dog bone or dumbbell shape. The PCB module may comprise a PCB layer with flex PCB 120 can be positioned over gel cover 180 and electronic components 130 connected and/or mounted to flex PCB 120 so as to comprise an electronics layer disposed on the flex PCB. In many embodiments, the adherent device may comprise a segmented inner component, for example

the PCB, for limited flexibility. The printed circuit may comprise polyester film with silver traces printed thereon.

[0134] In many embodiments, the electronics layer may be encapsulated in electronics housing 160. Electronics housing 160 may comprise an encapsulant, such as a dip coating, which may comprise a waterproof material, for example silicone and/or epoxy. In many
5 embodiments, the PCB encapsulant protects the PCB and/or electronic components from moisture and/or mechanical forces. The encapsulant may comprise silicone, epoxy, other adhesives and/or sealants. In some embodiments, the electronics housing may comprising metal and/or plastic housing and potted with aforementioned sealants and/or adhesives.

[0135] In many embodiments, the electrodes are connected to the PCB with a flex connection, for example trace 123A of flex PCB 120, so as to provide strain relive between the electrodes 112A, 112B, 112C and 112D and the PCB. In such embodiments, motion of the electrodes relative to the electronics modules, for example rigid PCB's 120A, 120B, 120C and 120D with the electronic components mounted thereon, does not compromise integrity of
15 the electrode/hydrogel/skin contact. In some embodiments, the electrodes can be connected to the PCB and/or electronics module with a flex PCB 120, such that the electrodes and adherent patch can move independently from the PCB module. In many embodiments, the flex connection comprises at least one of wires, shielded wires, non-shielded wires, a flex circuit, or a flex PCB. In specific embodiments, the flex connection may comprise insulated,
20 non-shielded wires with loops to allow independent motion of the PCB module relative to the electrodes.

[0136] In many embodiments, cover 162A can encase the flex PCB and/or electronics and can be adhered to at least one of the electronics, the flex PCB or adherent patch 110, so as to protect at least the electronics components and the PCB. Cover 162A may include openings
25 162A-O for visual indicators 163A. The visual indicators 163A may be bonded to the cover 163A. In some embodiments the cover 162A is clear or opaque enough such that the visual indicators 163A may be used without openings. The visual indicators 163A are coupled to the electrical circuitry by wires (not shown) which pass through or under the electronics housing 160. Cover 162A can attach to adherent patch 110 with adhesive 116B. Cover 162A
30 can comprise many known biocompatible cover materials, for example silicone. Cover 162A can comprise an outer polymer cover to provide smooth contour without limiting flexibility. In many embodiments, cover 162A may comprise a breathable fabric. Cover 162A may comprise many known breathable fabrics, for example breathable fabrics as described above. In some embodiments, the breathable cover may comprise a breathable water resistant cover.

In some embodiments, the breathable fabric may comprise polyester, nylon, polyamide, and/or elastane (SpandexTM) to allow the breathable fabric to stretch with body movement. In some embodiments, the breathable tape may contain and elute a pharmaceutical agent, such as an antibiotic, anti-inflammatory or antifungal agent, when the adherent device is placed on the patient.

[0137] In specific embodiments, cover 162A comprises at least one of polyester, 5-25% elastane/spandex, polyamide fabric; silicone, a polyester knit, a polyester knit without elastane, or a thermoplastic elastomer. In many embodiments cover 162A comprises at least 400% elongation. In specific embodiments, cover 162A comprises at least one of a polyester knit with 10-20% spandex or a woven polyamide with 10-20% spandex. In many embodiments, cover 162A comprises a water repellent coating and/or layer on outside, for example a hydrophobic coating, and a hydrophilic coating on inside to wick moisture from body. In many embodiments the water repellent coating on the outside comprises a stain resistant coating. Work in relation to embodiments of the present invention suggests that these coatings can be important to keep excessive moisture from the gels near the electrodes and to remove moisture from body so as to provide patient comfort.

[0138] The breathable cover 162A and adherent patch 110 comprise breathable tape can be configured to couple continuously for at least one week the at least one electrode to the skin so as to measure breathing of the patient. The breathable tape may comprise the stretchable breathable material with the adhesive and the breathable cover may comprises a stretchable breathable material connected to the breathable tape, as described above, such that both the adherent patch and cover can stretch with the skin of the patient. The breathable cover may also comprise a water resistant material. Arrows 182 show stretching of adherent patch 110, and the stretching of adherent patch can be at least two dimensional along the surface of the skin of the patient. As noted above, connectors 122A, 122B, 122C and 122D between PCB 130 and electrodes 112A, 112B, 112C and 112D may comprise insulated wires that provide strain relief between the PCB and the electrodes, such that the electrodes can move with the adherent patch as the adherent patch comprising breathable tape stretches. Arrows 184 show stretching of cover 162A, and the stretching of the cover can be at least two dimensional along the surface of the skin of the patient.

[0139] Cover 162A can be attached to adherent patch 110 with adhesive 116B such that cover 162A stretches and/or retracts when adherent patch 110 stretches and/or retracts with the skin of the patient. For example, cover 162A and adherent patch 110 can stretch in two dimensions along length 170 and width 174 with the skin of the patient, and stretching along

length 170 can increase spacing between electrodes. Stretching of the cover and adherent patch 110, for example in two dimensions, can extend the time the patch is adhered to the skin as the patch can move with the skin such that the patch remains adhered to the skin.

Electronics housing 160 can be smooth and allow breathable cover 162A to slide over

- 5 electronics housing 160, such that motion and/or stretching of cover 162A is slidably coupled with housing 160. The printed circuit board can be slidably coupled with adherent patch 110 that comprises breathable tape 110T, such that the breathable tape can stretch with the skin of the patient when the breathable tape is adhered to the skin of the patient, for example along two dimensions comprising length 170 and width 174.

- 10 [0140] The stretching of the adherent device 100 along length 170 and width 174 can be characterized with a composite modulus of elasticity determined by stretching of cover 162A, adherent patch 110 comprising breathable tape 110T and gel cover 180. For the composite modulus of the composite fabric cover-breathable tape-gel cover structure that surrounds the electronics, the composite modulus may comprise no more than about 1MPa, for example no
15 more than about 0.3MPa at strain of no more than about 5%. These values apply to any transverse direction against the skin.

- [0141] The stretching of the adherent device 100 along length 170 and width 174, may also be described with a composite stretching elongation of cover 162A, adherent patch 110 comprising breathable tape 110T and gel cover 180. The composite
20 stretching elongation may comprise a percentage of at least about 10% when 3 kg load is applied, for example at least about 100% when the 3 kg load applied. These percentages apply to any transverse direction against the skin.

- [0142] The printed circuit board may be adhered to the adherent patch 110 comprising breathable tape 110T at a central portion, for example a single central location, such that
25 adherent patch 110 can stretch around this central region. The central portion can be sized such that the adherence of the printed circuit board to the breathable tape does not have a substantial effect of the modulus of the composite modulus for the fabric cover, breathable tape and gel cover, as described above. For example, the central portion adhered to the patch may be less than about 100 mm², for example with dimensions of approximately 10 mm by
30 10 mm (about 0.5" by 0.5"). Such a central region may comprise no more than about 10% of the area of patch 110, such that patch 110 can stretch with the skin of the patient along length 170 and width 174 when the patch is adhered to the patient.

[0143] The cover material may comprise a material with a low recovery, which can minimize retraction of the breathable tape from the pulling by the cover. Suitable cover materials with a low recovery include at least one of polyester or nylon, for example polyester or nylon with a loose knit. The recovery of the cover material may be within a
5 range from about 0% recovery to about 25% recovery. Recovery can refer to the percentage of retraction the cover material that occurs after the material has been stretched from a first length to a second length. For example, with 25% recovery, a cover that is stretched from a 4 inch length to a 5 inch length will retract by 25% to a final length of 4.75 inches.

[0144] Electronics components 130 can be affixed to printed circuit board 120, for example
10 with solder, and the electronics housing can be affixed over the PCB and electronics components, for example with dip coating, such that electronics components 130, printed circuit board 120 and electronics housing 160 are coupled together. Electronics components 130, printed circuit board 120, and electronics housing 160 are disposed between the stretchable breathable material of adherent patch 110 and the stretchable breathable material
15 of cover 160 so as to allow the adherent patch 110 and cover 160 to stretch together while electronics components 130, printed circuit board 120, and electronics housing 160 do not stretch substantially, if at all. This decoupling of electronics housing 160, printed circuit board 120 and electronic components 130 can allow the adherent patch 110 comprising
20 breathable tape to move with the skin of the patient, such that the adherent patch can remain adhered to the skin for an extended time of at least one week, for example two or more weeks.

[0145] An air gap 169 may extend from adherent patch 110 to the electronics module and/or PCB, so as to provide patient comfort. Air gap 169 allows adherent patch 110 and breathable tape 110T to remain supple and move, for example bend, with the skin of the
25 patient with minimal flexing and/or bending of printed circuit board 120 and electronic components 130, as indicated by arrows 186. Printed circuit board 120 and electronics components 130 that are separated from the breathable tape 110T with air gap 169 can allow the skin to release moisture as water vapor through the breathable tape, gel cover, and
30 breathable cover. This release of moisture from the skin through the air gap can minimize, and even avoid, excess moisture, for example when the patient sweats and/or showers.

[0146] The breathable tape of adherent patch 110 may comprise a first mesh with a first porosity and gel cover 180 may comprise a breathable tape with a second porosity, in which the second porosity is less than the first porosity to minimize, and even inhibit, flow of the

gel through the breathable tape. The gel cover may comprise a polyurethane film with the second porosity.

[0147] Cover 162A may comprise many shapes. In many embodiments, a geometry of cover 162A comprises at least one of oblong, oval, butterfly, dog bone, dumbbell, round, square, rectangular with rounded corners, or polygonal with rounded corners. In specific
5 embodiments, the geometric of cover 162A comprises at least one of an oblong, an oval or a round shape.

[0148] Cover 162A may comprise many thicknesses and/or weights. In many embodiments, cover 162A comprises a fabric weight: within a range from about 100 to about
10 200 g/m², for example a fabric weight within a range from about 130 to about 170 g/m².

[0149] In many embodiments, cover 162A can attach the PCB module to adherent patch 110 with cover 162A, so as to avoid interaction of adherent patch 110C with the PCB having the electronics mounted therein. Cover 162A can be attached to breathable tape 110T and/or electronics housing 160 comprising over the encapsulated PCB. In many embodiments,
15 adhesive 116B attaches cover 162A to adherent patch 110. In many embodiments, cover 162A attaches to adherent patch 110 with adhesive 116B, and cover 162A is adhered to the PCB module with an adhesive 161 on the upper surface of the electronics housing. Thus, the PCB module can be suspended above the adherent patch via connection to cover 162A, for example with a gap 169 between the PCB module and adherent patch. In many
20 embodiments, gap 169 permits air and/or water vapor to flow between the adherent patch and cover, for example through adherent patch 110 and cover 162A, so as to provide patient comfort.

[0150] In many embodiments, adhesive 116B is configured such that adherent patch 110 and cover 162A can be breathable from the skin to above cover 162A and so as to allow
25 moisture vapor and air to travel from the skin to outside cover 162A. In many embodiments, adhesive 116B is applied in a pattern on adherent patch 110 such that the patch and cover can be flexible so as to avoid detachment with body movement. Adhesive 116B can be applied to upper side 110B of patch 110 and comprise many shapes, for example a continuous ring, dots, dashes around the perimeter of adherent patch 110 and cover 162A. Adhesive 116B
30 may comprise at least one of acrylate, silicone, synthetic rubber, synthetic resin, pressure sensitive adhesive (PSA), or acrylate pressure sensitive adhesive. Adhesive 16B may comprise a thickness within a range from about 0.0005" to about 0.005", for example within a range from about .001 - .005". In many embodiments, adhesive 116B comprises a width near

the edge of patch 110 and/or cover 162A within a range from about 2 to about 15 mm , for example from about 3 to about 7 near the periphery. In many embodiments with such widths and/or thickness near the edge of the patch and/or cover, the tissue adhesion may be at least about 30 oz/in, for example at least about 40 oz/in, such that the cover remains attached to the adhesive patch when the patient moves.

[0151] In many embodiments, the cover is adhered to adherent patch 110 comprising breathable tape 110T at least about 1 mm away from an outer edge of adherent patch 110. This positioning protects the adherent patch comprising breathable tape 110T from peeling away from the skin and minimizes edge peeling, for example because the edge of the patch can be thinner. In some embodiments, the edge of the cover may be adhered at the edge of the adherent patch, such that the cover can be slightly thicker at the edge of the patch which may, in some instances, facilitate peeling of the breathable tape from the skin of the patient.

[0152] Gap 169 extend from adherent patch 110 to the electronics module and/or PCB a distance within a range from about 0.25 mm to about 4 mm, for example within a range from about 0.5 mm to about 2 mm.

[0153] In many embodiments, the adherent device comprises a patch component and at least one electronics module. The patch component may comprise adherent patch 110 comprising the breathable tape with adhesive coating 116A, at least one electrode, for example electrode 114A and gel 114. The at least one electronics module can be separable from the patch component. In many embodiments, the at least one electronics module comprises the flex printed circuit board 120, electronic components 130, electronics housing 160 and cover 162A, such that the flex printed circuit board, electronic components, electronics housing and cover are reusable and/or removable for recharging and data transfer, for example as described above. In many embodiments, adhesive 116B is coated on upper side 110A of adherent patch 110B, such that the electronics module can be adhered to and/or separated from the adhesive component. In specific embodiments, the electronic module can be adhered to the patch component with a releasable connection, for example with Velcro™, a known hook and loop connection, and/or snap directly to the electrodes. Two electronics modules can be provided, such that one electronics module can be worn by the patient while the other is charged, as described above. Many patch components can be provided for monitoring over the extended period. For example, about 12 patches can be used to monitor the patient for at least 90 days with at least one electronics module, for example with two reusable electronics modules.

[0154] At least one electrode 112A can extend through at least one aperture 180A in the breathable tape 110.

[0155] In some embodiments, the adhesive patch may comprise a medicated patch that releases a medicament, such as antibiotic, beta-blocker, ACE inhibitor, diuretic, or steroid to reduce skin irritation. The adhesive patch may comprise a thin, flexible, breathable patch with a polymer grid for stiffening. This grid may be anisotropic, may use electronic components to act as a stiffener, may use electronics-enhanced adhesive elution, and may use an alternating elution of adhesive and steroid.

[0156] The following is adapted from U.S. Application Ser. No.: 12/209,276, Docket No.: 026843-001410US, entitled "Medical Device Automatic Start-up Upon Contact to Patient Tissue":

[0157] In some embodiments, a removable liner (not shown) can cover the underside of the adhesive patch 110, the at least two electrodes and the gel pads, for example at least two gel pads comprising gel 114A and gel 114D. The liner may comprise a material having an impedance, for example a resistance, greater than human skin. The liner prevents the at least two electrodes from detecting an impedance or resistance similar to human tissue and activating the start-up circuitry, for example when the device is stored with the batteries positioned in the device for use prior to placement on the patient. The electrical impedance of the liner as measured from the electrodes can be greater than 50 M-Ohms, and may comprise a resistance greater than 50 M-Ohms, for example a resistance greater than about 1 G-Ohms. The threshold electrical resistance between the at least two electrodes that activates the start-up circuit can be within a range from about 2 k-Ohms to about 2 G-Ohms, for example from about 100 k-Ohms to about 1 G-Ohms. The liner may also cover the adhesive coating 116A on the underside of the adhesive patch 110 so as to keep the adhesive coating 116A clean so that the adhesive will adhere to the patient's skin when the gel pads and adhesive are placed against the skin of the patient. The liner comprises a non-stick surface in contact with the adhesive such that the liner can be peeled away from the adhesive on the underside of the adhesive patch 110, as indicated by arrow 113AP, so that the adhesive and gel pads can be applied to the skin of the patient.

[0158] In some embodiments, the liner can comprises a first piece and a second piece with overlap between the first piece and the second piece. The first piece and second piece may be sized and positioned so as to provide an overlap between the first piece and the second piece. The overlap can facilitate separation of the first and second pieces of the liner from the

adhesive. The first liner piece can be pulled from the second liner piece at overlap. The second liner piece can then be pulled from adhesive.

[0159] Figures 1I2 and 1J2 show the adherent device as in Figures 1A to 1E and 1F2 to 1H.

Cover 162B comprises many of structures and components of cover 162A. In some

5 embodiments cover 162B comprises two flexible layers 162B1 and 162B2 with a flexible visual indicator 163B bonded between openings 162B1-O and 162B2-O. The openings

162B1-O and 162B2-O may be sized to be slightly smaller than the visual indicator 163B.

The visual indicator may be bonded to the two layers 162B1 and 162B2, for example, by epoxy or laser welding. In some embodiments only one layer 162B2 is used. In some

10 embodiments the flexible visual indicator 163B comprises an elastically stretchable material.

In some embodiments the cover 162B and flexible visual indicator 163B may stretch and bend according to the movement and stretching of a patient's skin. The visual indicators

163B may be coupled to the electrical circuitry by wires which pass through or under the electronics housing 160.

15 [0160] Figure 1K shows at least one electrode 190 configured to electrically couple to a skin of the patient through a breathable tape 192. In many embodiments, at least one

electrode 190 and breathable tape 192 comprise electrodes and materials similar to those described above. Electrode 190 and breathable tape 192 can be incorporated into adherent devices as described above, so as to provide electrical coupling between the skin and an

20 electrode through the breathable tape, for example with the gel.

[0161] Figure 2A shows a simplified schematic illustration of a circuitry 200 for

automatically turning on the device when tissue contacts the electrodes, and in which the

processor is able to turn off the device after tissue is removed from the electrodes. Circuitry

200 can be used with many kinds of patient devices, for example an adherent device as

25 described above, an implantable device such as a pacemaker. Circuitry 200 can also be

adapted for use with injectable devices. Circuit 200 comprises a least four electrodes 240. At

least four electrodes 240 comprise a V+ electrode 242, an I+ electrode 244, an I- electrode

246 and a V- electrode 248. At least four electrodes 240 can be used to measure signals from

tissue, for example bioimpedance signals and ECG signals. Although at least four electrodes

30 240 are shown, in some embodiments the circuit can detect tissue contact with two

electrodes, for example I+ electrode 244 and I- electrode 244.

[0162] Circuit 200 comprises a battery 202 for power. Battery 202 may comprise at least one of a rechargeable battery or a disposable battery, and battery 202 may be connected to an inductive coil to charge the battery. Battery 202 comprises an output 204.

5 [0163] Circuit 200 comprises a voltage regulator 206. Voltage regulator 206 may comprise a known voltage regulator to provide a regulated voltage to the components of circuit 200. Voltage regulator 206 comprises an input that can be connected to battery output 204 to provide regulated voltage to the components of circuit 200.

10 [0164] Circuitry 200 comprises power management circuitry 210. Power management circuitry 210 can be connected in series between battery output 204 and voltage regulator 206, and can start-up and turn off components of circuitry 200. Power management circuitry 210 comprises a start-up circuitry 220 and sustain circuitry 230. Start-up circuitry 220 comprises at least one switch 212 and sustain circuitry 230 comprises at least one switch 214. At least one switch 212 of start-up circuitry 220 and at least one switch 214 of sustain circuitry 230 are in a parallel configuration, such that either switch is capable of connecting
15 battery 202 to voltage regulator 206. Power management circuitry 210 can start-up and turn off components of circuitry 200 with at least one switch 212 of start-up circuitry 220 and at least one switch 214 of sustain circuitry 230. At least one switch 212 can detect tissue contact to the electrodes and close to connect the battery to the circuitry and start-up components of circuitry 200. At least one switch 212 can open and may disconnect voltage
20 regulator 206 from battery output 204 when tissue disconnects from the electrodes. Components of circuitry 200 that can be turned on and off with output 209 of voltage regulator 206 include impedance circuitry 250, switches 252, a processor 262, ECG circuitry 270, accelerometer circuitry 280, and wireless circuitry 290. Circuitry 200 may comprise a processor system 260, for example with distributed processors, such that processor 262 of
25 processing system 260 can be turned on and off with output 209 from at least one switch 212, at least one switch 214 and/or voltage regulator 206.

30 [0165] Start-up circuitry 220 can detect tissue contact with electrodes and close at least one switch 212, for example a transistor, between battery output 204 and voltage regulator 206, so as to control power regulator 206. Prior to tissue contacting the electrodes, at least one switch 212 of start-up circuitry 220 comprises an open configuration, such that no power flows from battery 202 to regulator 206. When at least one switch 212 and at least one switch 214 are open, very little current flows from battery 202. Work in relation to embodiments of the present invention indicates that current from battery 202 may be no more than about 100 pA ($100 * 10^{-12}$ A), for example about 35 pA, such that the life of battery 202

is determined primarily by the storage life of the battery with no significant effect from start-up circuitry 202. When tissue contacts the electrodes, for example I+ electrode 244 and I- electrode 246, at least one switch 212 of start-up circuitry 220 closes and battery 202 is connected to voltage regulator 206, such that power is delivered to the components of circuitry 202 that depend on regulated voltage from regulator 206 for power. Thus, start-up circuitry 220 can start components of circuitry 200, for example those components that depend on regulated voltage and power regulator 206 as described above.

[0166] Although voltage regulator 206 is shown, the voltage regulator may not be present in some embodiments, such that at least one switch 212 can connect battery 202 to at least some components of circuitry 200 without a voltage regulator. For example at least one of impedance circuitry 250, switches 252, a processor 262, ECG circuitry 270, accelerometer circuitry 280, or wireless circuitry 290 may be powered without the voltage regulator when at least one switch 212 closes to connect battery 202 with these components.

[0167] Sustain circuitry 230 can sustain power to the regulator after tissue is removed from the electrodes. Sustain circuitry 230 allows battery 202 to remain connected to the power supply 206 and the associated circuitry, even after tissue is removed from the electrodes and at least one switch 212 opens, such that the connection between battery 202 and voltage regulator 206 can be sustained with at least one switch 214. At least one switch 214 of sustain circuitry 230 can connect battery 202 to regulator 206 when at least one switch 214 is closed and disconnect battery 202 from regulator 206 when at least one switch 214 is open. Processor 262 can be coupled to sustain circuitry 230 with a control line 264. When the start-up circuitry 220 powers up the regulator and processor 262, processor 262 asserts a digital on signal voltage on control line 264 so as to close at least one switch 214. Thereafter, processor 262 can continue to assert control line 264 with a digital on signal voltage such that sustain circuitry 230 remains closed, even after tissue is removed from the electrodes. When processor 262 asserts an off signal voltage on control line 264, sustain circuitry 230 opens at least one switch 214 between battery output 204 and voltage regulator 206 and may turn off the components connected to voltage regulator 206, including the processor.

[0168] Sustain circuitry 230 can be configured to shut down power to the voltage regulator and associated circuitry components after tissue is removed from contact with the electrodes. As noted above at least one switch 212 can open when tissue is disconnected from the electrodes. When at least one switch 212 is open, for example after the electrodes are disconnected from tissue, processor 262 can assert a digital off voltage signal on control line

264 so as to open at least one switch 214 such that processor 262 shuts itself down with a shutdown process.

[0169] Processor 262 can be configured to detect opening of at least one switch 212 in response to disconnection of tissue from the electrodes, such that the processor can respond to the disconnection of tissue in a controlled matter before the processor is shut down. In response to opening at least one switch 212, processor 262 may initiate processes, such as wireless transmission of data of data stored on processor 262 prior to the shutdown process. Processor 262 may also transmit a signal to a remote center, as described above, indicating that the patch has been removed from the patient. Once these processes are completed, processor 262 can execute the shutdown process by delivering an off signal voltage on control line 264 such that at least one switch 214 opens and processor 262 is turned off.

[0170] In specific embodiments, sustain circuitry 230 may comprise an additional switch that is in series with start-up circuitry 220 such that the additional switch can open to disconnect power from battery 202 to voltage regulator 206 while tissue remains in contact with the electrodes.

[0171] Circuitry 200 may comprise an accelerometer 280 to measure patient orientation, acceleration and/or activity of the patient. Accelerometer 280 may comprise many known accelerometers, for example three dimensional accelerometers. Accelerometer 280 may be connected to processor 262 to process signals from accelerometer 280.

[0172] Circuitry 200 may comprise wireless circuitry 290. Wireless circuitry 290 may comprise known wireless circuitry for wireless communication from the device. Wireless communications circuitry 290 can communicate with remote center as described above. The wireless communication circuitry can be coupled to the impedance circuitry, the electrocardiogram circuitry and the accelerometer to transmit to a remote center with a communication protocol at least one of the hydration signal, the electrocardiogram signal or the inclination signal from the accelerometer. In specific embodiments, wireless communication circuitry is configured to transmit the hydration signal, the electrocardiogram signal and the inclination signal to the remote center with a single wireless hop, for example from wireless communication circuitry 290 to the intermediate device as described above. As noted above, the communication methodology may comprise at least one of Bluetooth, Zigbee, WiFi, WiMax, and the communication signal may comprise IR, amplitude modulation or frequency modulation. In many embodiments, the communications protocol

comprises a two way protocol configured such that the remote center is capable of issuing commands to control data collection.

[0173] Processor system 260 may comprise processors in addition to processor 262, for example a remote processor as described above. Processor 262 comprises tangible medium
 5 266 that can be configured with instructions, and tangible medium 266 may comprise memory such as random access memory (RAM), read only memory (ROM), erasable read only memory (EPROM), and many additional types of known computer memory. Processor system 260 comprising processor 262 can be connected to impedance circuitry 250, switches 252, a processor 262, ECG circuitry 270, accelerometer circuitry 280, and wireless circuitry
 10 290 to transmit and/or process data.

[0174] Circuitry 200 comprises impedance circuitry 250 for measuring tissue impedance. Impedance circuitry 250 may comprise switches 252 to connect the impedance circuitry to at least four electrodes 240. In specific embodiments, V+ electrode 242 and V- electrode 248 are connected to drive circuitry of impedance circuitry 250 to drive a current through the
 15 tissue. An impedance signal comprising voltage drop can occur along the tissue as a result of the drive current, and I+ electrode 244 and I- electrode 246 can be connected to measurement circuitry of impedance circuitry 250 to measure the impedance signal from the tissue. Processor 262 can be coupled to switches 252 to connect the at least four electrodes 240 to impedance circuitry 250.

[0175] Figure 2B shows additional detail of the start-up circuitry 220 of Figure 2A that automatically turns on components of circuitry 200 when tissue contacts the electrodes. Start-up circuitry 220 can be connected to output 204 of battery 202. Start-up circuitry 220 comprises a transistor, for example a p-channel FET transistor 228. Transistor 228 comprises a switch that can be opened and closed in response to tissue contact to the electrodes.
 25 Transistor 228 comprises a gate G, such that current flow through transistor 228 is inhibited while voltage to gate G remains above a threshold voltage. When tissue does not contact electrodes 244 and 246, voltage to gate G is above the threshold voltage and current flow through transistor 228 is inhibited. Start-up circuitry 220 comprises resistor 222 and resistor 224. A capacitor 226 can be disposed in parallel to resistor 222.

[0176] When tissue T is coupled to, for example contacts, electrode 244 and electrode 246, current can flow through tissue T because gate G of transistor 228 is driven below the threshold voltage. In some embodiments, electrode 244 and electrode 246 may comprise know gels, for example hydrogels, to couple to the skin of a patient. Resistor 222 and resistor

224 are connected in series so as to form a voltage divider having an output 224D. Tissue T comprises a resistance that is much lower than resistor 222 and resistor 224. Resistor 222 comprises a resistance, for example 100 M Ω , that is much greater than a resistance of resistor 224, for example 1 M Ω . Resistor 222 comprises a resistance much greater than the resistance of tissue T. When tissue is connected across electrode 244 and electrode 246, current flows across the voltage divider from battery 202 to electrode 246 which is connected to ground. Thus, the voltage to gate G from the divider is driven substantially below the threshold value, such that the transistor switch closes and current can flow through transistor 228 to input 208 of voltage regulator 206. Capacitor 226 can delay switching for an amount of time after tissue contacts the electrodes, for example in response to an RC time constant of capacitor 226 and resistor 222. A high impedance resistor 229 can be provided to measure a signal voltage to input 208 to voltage regulator 206.

[0177] Start-up circuitry 220 can be configured such that the pre-determined threshold impedance of tissue corresponds to the voltage threshold of transistor 228 comprising the switch. For example, resistor 222 and resistor 224 of the voltage divider can be selected such that the voltage to gate G is driven to the threshold voltage, for example an FET switching voltage, so as to close the transistor switch when the impedance across the electrodes comprises a desired pre-determined tissue threshold impedance at which the switch is intended to close. Known circuit modeling methods can be used to determine the appropriate values of the gate threshold, resistors and capacitors so as to close the at least one switch when the impedance across the electrodes corresponds to the threshold tissue detection impedance.

[0178] Electrodes 244 and 246 can be separated by a distance 245. Distance 245 may be dimensioned so that electrodes 244 and 246 can detect tissue contact and make tissue measurements, as described above.

[0179] When circuitry 200 is configured for use with an implantable device, one of the at least two electrodes may comprise a housing of the device that contacts tissue.

[0180] Figure 2B-1 shows the start-up circuitry of Figure 2B with a liner, for example liner 113A coupled to the electrodes. Liner 113A comprises an impedance greater than tissue, such that the start-up circuitry is not activated and the at least one switch remains open when the liner is coupled to the at least two electrodes, for example electrode 244 and electrode 246. The liner can be coupled to the electrodes in many ways, for example with direct contact of liner 113 A to electrode 244 and electrode 246. The liner can also be coupled to

the electrodes with a gel, for example with a gel pad disposed on each electrode between the liner and the electrode such that the gel pads remain separated when the liner is placed over the electrodes, as described above. The gel pads may comprise a solid material, such that the gel pads do not contact each other when the device is adhered to the patient. The gel pads may comprise a solid gel, and may comprise internal structures such as a scrim, mesh, or scaffold, to retain the shape and separation of the gel pads.

[0181] The impedance of liner 113A, for example the resistance, is determined by the material properties of liner 113A, and also by the distance 245 between electrode 244 and electrode 246. An example of a relevant material property of the liner is the resistivity of the material, ρ . The resistivity is inversely proportional to the conductivity of the material, σ , which is given by $1/\rho$. In some embodiments, the resistivity of the material is substantially determined by the measured resistance, R , times the cross sectional area A , divided by the length L between electrodes. For example, an increase in distance 245 can increase the resistance of the liner between the electrodes. An increase in cross-sectional area of the liner between the electrodes can decrease the resistance of the liner between the electrodes. For example, an increase in thickness of the liner may increase the cross sectional area of the liner between the electrodes so as to decrease the resistance. Similarly, an increase in the width of the liner, for example width 174, as described above, may decrease the resistance of the liner between the electrodes. In many embodiments, the thickness of the liner may comprise no more than about 1 mm, such that the resistance of the liner minimizes current flow through the liner when the liner is placed over and/or coupled to the electrodes. In many embodiments, the electrodes are separated to provide a desired predetermined impedance, for example resistance, based on the thickness and material properties of the liner.

[0182] The liner thickness, material properties and electrode spacing can be configured to provide the desired liner resistance between electrode 244 and electrode 246 when the liner is coupled to the electrodes, for example coupled with a gel pad disposed between the liner and each electrode. For example the liner resistance comprises at least 1 M Ω , for example at least 10 M Ω , or even 100 M Ω . In many embodiments, at least one of the liner conductivity, the liner thickness, the liner width or the electrode spacing are configured to provide the resistance between the electrodes, for example a resistance of at least 100 M Ω , for example 1 G Ω (1000 M Ω). Therefore, the liner and electrode spacing can be configured to minimize current flow through the liner and degradation to the electrodes when the device is stored with power to the start-up circuitry 220 for an extended period of at least one month, for example at least 3 months. For example, with a liner configured for 3 G Ω impedance

between the electrodes and 3 volts to the start-up circuitry, the current flow through electrode 244 and electrode 246 is about 1 nA. In another example, the current flow through the electrode 244 and electrode 246 is about 15 nA, for a 3V battery, a liner having a resistance of about 100 M Ω between electrode 244 and electrode 246, resistor 222 having a resistance of about 100 M Ω , and resistor 224 having a resistance of about 1 M Ω .

[0183] The resistivity of the liner material may comprise at least about 5 k Ω -m. For example, PET has a resistivity of about 10^{20} Ω -m, hard rubber about 10^{13} Ω -m, and silicone about 240 M Ω -m. In a specific embodiment with a liner thickness of 1 mm, a width of 50 mm and a separation distance between electrodes of 100 mm, a liner material resistivity of about 5 k Ω -m can provide a resistance between electrodes about 10 M- Ω .

[0184] Figure 2E shows a load that is connected to the battery when the circuitry for automatically turning on the device is open. For example the load may comprise a clock coupled to the battery to determine the current date and time when the circuit for automatically turning on the device is open. The clock is coupled to the battery to draw power when the at least one switch is open, and the voltage regulator and processor are decoupled from the battery. Thus, the clock draws power to determine the date and time when the device is in the low power configuration, such that the clock can be set at the factory with the date and time when the battery is installed. The clock is coupled to the processor so that the data collected with the sensor circuitry can be date and time stamped when processor draws power and the data are measured. The amount of current used by the load, for example the clock, may comprise no more than about 1 μ A, for example no more than about 0.5 μ A. Therefore, the device is ready for use with the correct time upon activation of the sensor circuitry when the electrodes are coupled to the patient tissue.

[0185] Figure 2C shows additional detail of the sustain circuitry 230 of Figure 2A. Sustain circuitry 230 sustains power from the battery to the voltage regulator after tissue is removed from the electrodes, and allows the processor to turn the device off after the tissue is removed from the electrodes. Sustain circuitry 230 comprises a switch, for example a p-channel FET transistor 236, disposed in series between output 204 of battery 202 and input 208 of regulator 206.

[0186] Before tissue contacts the electrodes, gate G of transistor 236 is high so that the switch is open and battery 202 is disconnected from voltage regulator 206. One will appreciate that transistor 228 is parallel to transistor 236, such that no current can flow from battery 202 to regulator 206 when both switches are open. Thus, in the initial condition prior

to tissue contact to the electrodes, and battery 202 is disconnected from regulator 206. In this initial condition, no power is supplied to regulator 206, such that processor 262 receives no power and control line 264 comprises a low voltage signal. Control line 264 is connected to a gate of transistor switch, for example an n-channel FET transistor 232, such that the switch is open when gate G is below the threshold voltage of the gate. Before the processor is activated control line 264 comprises a low voltage signal that is below the threshold of transistor 232, the switch is open and no substantial current flows through transistor 232. Thus, in the initial condition prior to tissue contacting the electrodes, control line 264 comprises a low voltage signal and no substantial current flows through transistor 232, and gate G of transistor 236 comprises a high voltage such that the switch is open.

[0187] When tissue contacts the electrodes, at least one switch 212 of start-up circuitry 220 closes and processor 262 receives power from voltage regulator 206. Processor 262 comprises a tangible medium configured to close at least one switch 212 of sustain circuitry 230 when processor 262 is activated, such that battery 202 is connected to voltage regulator 206. Processor 262 can assert a high voltage signal on control line 264 when the processor boots up, such that gate G of transistor 232 receives a high voltage signal and the switch closes. Current through transistor 232 will also pass through resistor 234 and lower the voltage at gate G of transistor 236 below the threshold voltage, such that current passes through transistor 236 and at least one switch 214 is closed. Thus, output 204 of battery 202 remains connected to input 208 of voltage regulator 206 while processor 262 maintains a high voltage signal on control line 264 such that processor 262 sustains the connection of the battery to the voltage regulator with at least one switch 214.

[0188] Once tissue has been disconnected from the electrodes, at least one switch 212 of start-up circuitry 220 opens and the processor can execute the shut down process. After the tissue is disconnected from the electrodes, gate G of transistor 228 goes above the threshold voltage and current through the transistor is inhibited such the at least one switch 212 comprises open configuration, and battery 202 is not connected to voltage regulator 206 through the at least one switch 212 of start-up circuitry 220. In this configuration, voltage regulator 206 receives power from battery 202 through at least one switch 214 of sustain circuitry 230 that is in parallel to at least one switch 212 of start-up circuitry 220. When processor 262 asserts command line 264 to a low voltage signal in response to commands stored in processor memory, battery 202 is disconnected from voltage regulator 206 and the processor executes the shutdown process. In addition, the components of circuitry 200 that

receive power from voltage regulator 206 are also disconnected from battery 202 and turned off.

[0189] Figure 2D shows circuitry 220P to decrease parasitic current flow through the electrodes coupled to the tissue detection circuitry when tissue is coupled to the electrodes.

5 Circuitry 220P can also sustain voltage to the regulated power supply, microprocessor and other components that wake upon tissue contact, similar to the sustain circuitry described above. Resistor 222 and resistor 224 comprise a voltage divider 224D, as noted above. Resistor 224 may comprise a pair of resistors, for example a first resistor 224A and a second resistor 224B. A switch 224C is coupled to the voltage divider and to ground, such that when
10 switch 224C is closed the output 224D of the voltage divider is driven low, for example substantially to ground. Switch 224C is coupled to the processor, as above, such that the processor can open and close switch 224C in response to commands from the processor.

[0190] Switch 224C can be connected to resistor 224 between resistor 224A and resistor 224B to pull output 224D to a low state, for example substantially grounded. Resistor 224B
15 may comprise most of the resistance of resistor 224, for example at least 80%, or even 90%, such that when the processor closes switch 224C, output 224D is substantially grounded. As noted above, resistor 222 comprises a resistance, for example 100 M Ω , that is much greater than a resistance of resistor 224, for example 1 M Ω . Resistor 222 comprises a resistance much greater than the resistance of tissue T. Thus, when switch 224C closes, output 224D
20 comprises a low voltage state.

[0191] As switch 224C is coupled to the voltage divider comprises resistor 222 and resistor 224 so as to shunt the current passing through resistor 222 to ground. Resistor 222 comprises substantially more resistance than resistor 224, such that when output switch 224C is closed and output 222D is low most of the current through resistor 222 is shunted to ground instead
25 of through electrode 244 and electrode 246. Consequently parasitic current flow through electrode 244 and electrode is minimized. This minimization of the current flow through electrode 244 and electrode 246 may decrease degradation of the electrodes, for example from oxidation, and may increase the useful life of the electrodes when the electrodes contact the tissue.

30 [0192] To detect removal of tissue coupling from the electrodes, the processor can be configured to poll the tissue detection circuitry. For example the processor open switch 224C and measure the output voltage of the tissue detection circuit to determine if tissue has been removed from the electrodes. The processor can then close switch 224C to shunt the current

to ground. These polling steps can be repeated at regular intervals, for example once per minute, to determine if the adherent device has been removed from tissue so as to decouple the electrodes from the skin of the patient.

[0193] Figure 3 shows a method 300 of monitoring and/or treating a patient with a medical device, which automatically turns on in response to patient tissue contact. A step 305 manufactures the device. The device may comprise at least two electrodes and energy storage cells, for example batteries, that are used to power the device. A sub-step 305A installs batteries in the device. A step 312 places a gel over the electrodes and places a liner over the gel. The batteries can be installed at the factory as part of the manufacturing process. A step 315 ships the device from the factory to the health care provider and/or patient. A step 317 removes the liner from the gel. A step 320 places the gel covered electrodes against the patient tissue. The electrodes may comprise stimulation electrodes and/or measurement electrodes to measure biological signals from tissue. The contact of the tissue may comprise contact with the skin to the electrode and/or contact with an internal tissue, for example cardiac tissue that contacts a pacing lead. A step 322 senses current through the contact with the skin and/or tissue. A step 325 detects contact of the tissue to the electrodes. The tissue can be detected with at least one switch, as described above. A step 330 closes the tissue detection switch, for example the at least one switch that connects a battery to a voltage regulator as described above. The tissue detection switch closes when the current passed through the tissue exceeds a predetermined threshold current. A step 335 starts up the electronics circuitry, with power from the closed switch. A step 340 starts up, or boots up, a processor as described above. A step 342 shunts the tissue detection switch input. For example the processor may close a switch coupled to ground such that the output of a voltage divider is substantially 0, as described above. A step 344 minimizes parasitic current through the electrodes coupled to the tissue detection circuit, for example as described above. A step 345 closes a sustain power switch that sustains power to the processor, for example with at least one switch as described above. A step 350 monitors and/or treats the patient, for example with at least one of accelerometers, impedance measurements, ECG measurements, and/or wireless transmission of data, for example to a remote center. A step 353 polls the tissue detection circuitry to determine if the tissue has been removed from the electrodes, for example as described above. A step 355 removes tissue from the electrodes. A step 360 opens a tissue detection switch in response to removal of the tissue from the electrodes. For example, at least one tissue detection switch, as described above, can open in response to removal of the tissue from the electrodes. A step 365 detects tissue removal, for example

with a signal from a line connected to the processor, as described above. A step 370 initiates terminal processes in response to detection of removal of the tissue. For example, the processor can transmit patient measurement data to a remote center and/or a signal that the patient has removed the device in response to the tissue removal signal. A step 375 initiates a processor shutdown command. The processor shutdown command can be initiated after the terminal processes have been completed, such that the desired signals can be completely transmitted before the processor issues the shutdown command. A step 380 opens the sustain switch in response to the processor shutdown command. A step 385 powers down the processor in response to the sustain switch opening. A step 390 power down additional associated circuitry in response to the sustain switch opening. A step 395 can repeat the above steps. Repetition of at least some of the above steps can be desirable with a device in which the processor and measurement circuitry can be re-attached to the patient while the electrodes and adherent patch are disposed of after use. In some embodiments, a re-usable electronics module that can be coupled to disposable adherent patches. In some embodiments, the processor can execute the shutdown process to reduce power consumption when the device is removed from the patient, and subsequent re-attachment of the device to the patient can start-up the measurement and/or processor circuitry when the device is re-attached to the patient, thereby minimizing power consumption when the device is removed from the patient.

[0194] It should be appreciated that the specific steps illustrated in Figure 3 provide a particular method of monitoring and/or treating a patient, according to an embodiment of the present invention. Other sequences of steps may also be performed according to alternative embodiments. For example, alternative embodiments of the present invention may perform the steps outlined above in a different order. Moreover, the individual steps illustrated in Figure 3 may include multiple sub-steps that may be performed in various sequences as appropriate to the individual step. Furthermore, additional steps may be added or removed depending on the particular applications. One of ordinary skill in the art would recognize many variations, modifications, and alternatives.

[0195] The following is adapted from U.S. Application Ser. No.: 12/209,279, Docket No.: 026843-000110US, entitled "Multi-Sensor Patient Monitor to Detect Impending Cardiac Decompensation":

[0196] Figure 4 shows a method 400 of predicting an impending cardiac decompensation. A step 405 measures an ECG signal. The ECG signal may comprise a differential signal measured with at least two electrodes and may be measured in many known ways. A step

410 measures an hydration signal. The hydration signal may comprise an impedance signal, for example a four pole impedance signal, and may be measured in many known ways. A step 415 measures a respiration signal. The respiration signal may comprise an impedance signal, and may be measured in many known ways. A step 420 measures an activity signal.

- 5 The activity signal may be measured in many known ways and may comprise a three dimensional accelerometer signal to determine a position of the patient, for example from a three dimensional accelerometer signal. A step 425 measures a temperature signal. The temperature signal may be measured in many ways, for example with a thermistor, a thermocouple, and known temperature measurement devices. A step 430 records a time of day of the signals, for example a local time of day such as morning, afternoon, evening, and/or nighttime.

- [0197] A step 435 processes the signals. The signals may be processed in many known ways, for example to generate at least one of a derived signal, a time averaged signal, a filtered signal. In some embodiments, the signals may comprise raw signals. The ECG
15 signal may comprise at least one of a heart rate signal, a heart rate variability signal, an average heart rate signal, a maximum heart rate signal or a minimum heart rate signal. The hydration signal may comprise an impedance measurement signal. The activity signal may comprise at least one of an accelerometer signal, a position signal indicating the orientation of the patient, such as standing, lying, or sitting. The respiration signal may comprise a least
20 one of a respiration rate, a maximum respiration rate, a minimum respiration rate, an average respiration rate or respiration rate variability. The temperature may comprise an average temperature or a peak temperature.

- [0198] A step 440 compares the signals with baseline values. In many embodiments, the baseline values may comprise measurements from the same patient at an earlier time. In
25 some embodiments, the baseline values comprise values for a patient population. In some embodiments, the baseline values for a patient population may comprise empirical data from a suitable patient population size, for example at least about 144 patients, depending on the number of variables measured, statistical confidence and power used. The measured signals may comprise changes and/or deviations from the baseline values.

- 30 [0199] A step 445 transmits the signals. In many embodiments, the measurement signals, which may comprise derived and/or processed measurement signals, are transmitted to the remote site for comparison. In some embodiments, the signals may be transmitted to a processor supported with the patient for comparison.

[0200] A step 450 combines at least two of the ECG signal, the hydration signal, the respiration signal, the activity signal and the temperature signal to detect the impending decompensation. In many embodiments, at least three of the signals are combined. In some embodiments, at least four signals comprising ECG signal, the hydration signal, the respiration signal and the activity signal are combined to detect the impending decompensation. In specific embodiments, at least four signals comprising the ECG signal, the hydration signal, the respiration signal, the activity signal and the temperature signal are combined to detect the impending decompensation.

[0201] The signals can be combined in many ways. In some embodiments, the signals can be used simultaneously to determine the impending cardiac decompensation.

[0202] In some embodiments, the signals can be combined by using the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal to look up a value in a previously existing array.

[0203] Table 1. Lookup Table for ECG and Hydration Signals

<i>Heart Rate / Hydration</i>	<i>0-49 bpm</i>	<i>50-69 bpm</i>	<i>70-90 bpm</i>
>60 Ohms	N	N	Y
41-59 Ohms	N	Y	Y
0-40 Ohms	Y	Y	Y

[0204] Table 1 shows combination of the electrocardiogram signal with the hydration signal to look up a value in a pre-existing array. For example at a heart rate of 89 bpm and a hydration of 35 Ohms, the value in the table may comprise Y. In specific embodiments, the values of the look up table can be determined in response to empirical data measured for a patient population of at least about 100 patients, for example measurements on about 1000 to 10,000 patients.

[0205] In some embodiments, the table may comprise a three or more dimensional look up table.

[0206] In some embodiments, the signals may be combined with at least one of adding, subtracting, multiplying, scaling or dividing the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal. In specific embodiments, the measurement signals can be combined with positive and or negative coefficients determined in response to empirical data measured for a patient population of at least about 100 patients, for example data on about 1000 to 10,000 patients.

[0207] In some embodiments, a weighted combination may combine at least 3 measurement signals to generate an output value according to a formula of the general form

$$\text{OUTPUT} = aX + bY + cZ$$

where a, b and c comprise positive or negative coefficients determined from empirical data and X, Y and Z comprise measured signals for the patient, for example at least three of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal. While three coefficients and three variables are shown, the data may be combined with multiplication and/or division. One or more of the variables may be the inverse of a measured variable.

[0208] In some embodiments, the ECG signal comprises a heart rate signal that can be divided by the activity signal. Work in relation to embodiments of the present invention suggest that an increase in heart rate with a decrease in activity can indicate an impending decompensation. The signals can be combined to generate an output value with an equation of the general form

$$\text{OUTPUT} = aX/Y + bZ$$

where X comprise a heart rate signal, Y comprises a hydration rate signal and Z comprises a respiration signal, with each of the coefficients determined in response to empirical data as described above.

[0209] In some embodiments, the data may be combined with a tiered combination. While many tiered combinations can be used a tiered combination with three measurement signals can be expressed as

$$\text{OUTPUT} = (\Delta X) + (\Delta Y) + (\Delta Z)$$

where (ΔX) , (ΔY) , (ΔZ) may comprise change in heart rate signal from baseline, change in hydration signal from baseline and change in respiration signal from baseline, and each may have a value of zero or one, based on the values of the signals. For example if the heart rate increase by 10%, (ΔX) can be assigned a value of 1. If hydration increases by 5%, (ΔY) can be assigned a value of 1. If activity decreases below 10% of a baseline value (ΔZ) can be assigned a value of 1. When the output signal is three, a flag may be set to trigger an alarm.

[0210] In some embodiments, the data may be combined with a logic gated combination. While many logic gated combinations can be used a logic gated combination with three measurement signals can be expressed as

$$\text{OUTPUT} = (\Delta X) \text{ AND } (\Delta Y) \text{ AND } (\Delta Z)$$

where (ΔX) , (ΔY) , (ΔZ) may comprise change in heart rate signal from baseline, change in hydration signal from baseline and change in respiration signal from baseline, and each may have a value of zero or one, based on the values of the signals. For example if the heart rate

5 increase by 10%, (ΔX) can be assigned a value of 1. If hydration increases by 5%, (ΔY) can be assigned a value of 1. If activity decreases below 10% of a baseline value (ΔZ) can be assigned a value of 1. When each of (ΔX) , (ΔY) , (ΔZ) is one, the output signal is one, and a flag may be set to trigger an alarm. If any one of (ΔX) , (ΔY) or (ΔZ) is zero, the output signal is zero and a flag may be set so as not to trigger an alarm. While a specific example
10 with AND gates has been shown the data can be combined in many ways with known gates for example NAND, NOR, OR, NOT, XOR, XNOR gates. In some embodiments, the gated logic may be embodied in a truth table.

[0211] A step 455 sets a flag. The flag can be set in response to the output of the combined signals. In some embodiments, the flag may comprise a binary parameter in which a value of
15 zero does not trigger an alarm and a value of one triggers an alarm.

[0212] A step 460 communicates with the patient and/or a health care provider. In some embodiments, the remote site may contact the patient to determine if he or she is okay and communicate the impending decompensation such that the patient can receive needed medical care. In some embodiments, the remote site contacts the health care provider to warn
20 the provider of the impending decompensation and the need for the patient to receive medical care.

[0213] A step 465 collects additional measurements. Additional measurements may comprise additional measurements with the at least two signals, for example with greater sampling rates and or frequency of the measurements. Additional measurements may
25 comprise measurements with additional sensors, for example an onboard microphone to detect at least one of rales, S1 heart sounds, S2 heart sounds, S3 heart sounds, or arrhythmias. In some embodiments, the additional measurements, for example sounds, can be transmitted to the health care provider to diagnose the patient in real time.

[0214] The processor system, as described above, can be configured to perform the method
30 200, including many of the steps described above. It should be appreciated that the specific steps illustrated in Figure 4A provide a particular method of predicting an impending cardiac decompensation, according to an embodiment of the present invention. Other sequences of steps may also be performed according to alternative embodiments. For example, alternative

embodiments of the present invention may perform the steps outlined above in a different order. Moreover, the individual steps illustrated in Figure 4A may include multiple sub-steps that may be performed in various sequences as appropriate to the individual step.

Furthermore, additional steps may be added or removed depending on the particular
5 applications. One of ordinary skill in the art would recognize many variations, modifications, and alternatives.

[0215] The following is adapted from U.S. Provisional Application Ser. No.: 61/035,970, Docket No.: 026843-002100US, entitled "Heart Failure Decompensation Prediction Based on Cardiac Rhythm":

10 [0216] Figure 4B shows a method 400B of predicting an impending cardiac decompensation. Method 400B can be performed with at least one processor of a processor system, as described above. A step 405 measures an ECG signal. A step 410B determines an incidence of arrhythmias from the ECG signal. The incidence of arrhythmias can be determined using known methods and apparatus to detect arrhythmias. A step 415B
15 measures an impedance signal. The impedance signal can be used determine hydration and/or respiration of the patient. The impedance signal may comprise a four pole impedance signal, and may be measured in many known ways. Step 420 measures an activity signal. Step 425 measures a temperature signal. Step 430 records a time of day of the signals. Step 435 processes the signals.

20 [0217] A step 440B compares the incidence of arrhythmias and/or other patient data with baseline values. In many embodiments, the baseline values may comprise arrhythmia measurements and/or values from the same patient at an earlier time. In some embodiments, the baseline values comprise baseline arrhythmia values for a patient population. In some embodiments, the baseline values for a patient population may comprise empirical data from
25 a suitable patient population size, for example at least about 144 patients, depending on the number of variables measured, statistical confidence and power used. Additional measured signals, as described above, may be compared to baseline values to determine changes and/or deviations from the baseline values. A step 445 transmits the signals.

[0218] A step 450B combines the incidence of arrhythmias with additional patient
30 information, for example at least one of a heart rate, a heart rate variability, a bioimpedance signal, an activity, a hydration signal or a respiration of the patient to determine the risk of impending decompensation. As noted above, these signals may comprise signals derived from a common measurement, for example hydration signals and respiration signals derived from an impedance measurement. In many embodiments, at least two and sometime at least

three of the signals are combined. In some embodiments, at least four signals are combined to detect the impending decompensation.

[0219] The signals can be combined in many ways. In some embodiments, the signals can be used simultaneously to determine the impending cardiac decompensation.

- 5 [0220] In some embodiments, the signals can be combined by using a look up table, for example to look up a value in a previously existing array.

[0221] Table 2. Lookup Table for Incidence of Arrhythmias and Heart Rate Signals

<i>Heart Rate / Incidence of Arrhythmias</i>	<i>0-49 bpm</i>	<i>50-69 bpm</i>	<i>70-90 bpm</i>
Low	N	N	Y
Medium	N	Y	Y
High	Y	Y	Y

- [0222] Table 2 shows combination of the incidence of arrhythmias with heart rate signals to look up a value in a pre-existing array. For example, at a heart rate of 89 bpm and an incidence of arrhythmias of “High,” the value in the table may comprise Y. In specific embodiments, the values of the look up table can be determined in response to empirical data measured for a patient population of at least about 100 patients, for example measurements on about 1000 to 10,000 patients. The incidence of arrhythmias can be determined in many ways, for example based on the number of arrhythmias over time, for example number per day. The incidence of arrhythmias can also be determined with an index that is determined in response to the duration and/or severity of the arrhythmias, for example with calculations that include the duration of the arrhythmia and/or severity of the arrhythmias.

- [0223] In some embodiments, the table may comprise a three or more dimensional look up table.

- [0224] In some embodiments, the signals may be combined with at least one of adding, subtracting, multiplying, scaling or dividing. In specific embodiments, the measurement signals can be combined with positive and or negative coefficients determined in response to empirical data measured for a patient population of at least about 100 patients, for example data on about 1000 to 10,000 patients.

[0225] In some embodiments, a weighted combination may combine at least 3 measurement signals to generate an output value according to a formula of the general form

[0226] $OUTPUT = aX + bY + cZ$

[0227] where a, b and c comprise positive or negative coefficients determined from empirical data and X, Y and Z comprise measured signals for the patient, for example at least three of the incidence of arrhythmias, the heart rate, the heart rate variability, the
 5 bioimpedance and/or hydration signal, the respiration signal or the activity signal. While three coefficients and three variables are shown, the data may be combined with multiplication and/or division. One or more of the variables may be the inverse of a measured variable.

[0228] In some embodiments, the ECG signal comprises a heart rate signal that can be
 10 divided by the activity signal. Work in relation to embodiments of the present invention suggest that an increase in heart rate with a decrease in activity can indicate an impending decompensation. The signals can be combined to generate an output value with an equation of the general form

[0229] $OUTPUT = aX / Y + bZ$

15 [0230] where X comprise a heart rate signal, Y comprises a hydration rate signal and Z comprises a respiration signal, with each of the coefficients determined in response to empirical data as described above. The output value can be combined with other data, for example the lookup table and/or weighted combinations as described above.

[0231] In some embodiments, the data may be combined with a tiered combination. While
 20 many tiered combinations can be used a tiered combination with three measurement signals can be expressed as

[0232] $OUTPUT = (\Delta X) + (\Delta Y) + (\Delta Z)$

[0233] where (ΔX) , (ΔY) , (ΔZ) may comprise change in arrhythmias from baseline, change in heart rate from baseline and change in respiration signal from baseline, and each may have
 25 a value of zero or one, based on the values of the signals. For example if the incidence of arrhythmias increase by 50% or more, (ΔX) can be assigned a value of 1. If the heart rate increases by 100%, (ΔY) can be assigned a value of 1. If respiration decreases below 50% of a baseline value (ΔZ) can be assigned a value of 1. When the output signal is three, a flag may be set to trigger an alarm.

30 [0234] In some embodiments, the data may be combined with a logic gated combination. While many logic gated combinations can be used a logic gated combination with three measurement signals can be expressed as

[0235] $OUTPUT = (\Delta X) \text{ AND } (\Delta Y) \text{ AND } (\Delta Z)$

[0236] where (ΔX) , (ΔY) , (ΔZ) may comprise change in the incidence of arrhythmias from baseline, change in heart rate from baseline and change in respiration signal from baseline, and each may have a value of zero or one, based on the values of the signals. For example if the incidence of arrhythmias increase by 50%, (ΔX) can be assigned a value of 1. If heart rate increases by 100%, (ΔY) can be assigned a value of 1. If activity decreases below 50% of a baseline value (ΔZ) can be assigned a value of 1. When each of (ΔX) , (ΔY) , (ΔZ) is one, the output signal is one, and a flag may be set to trigger an alarm. If any one of (ΔX) , (ΔY) or (ΔZ) is zero, the output signal is zero and a flag may be set so as not to trigger an alarm.

While a specific example with AND gates has been shown the data can be combined in many ways with known gates for example NAND, NOR, OR, NOT, XOR, XNOR gates. In some embodiments, the gated logic may be embodied in a truth table.

[0237] One of ordinary skill in the art will recognize that the above ways of combining data can be used with known statistical techniques such as multiple regression, logistical regression and the like to fit data base on an empirical sampling of patient data. In addition, the above examples show specific combinations based on patient measurements, and other combinations and/or patient measurements can be used to determine the risk of impending decompensation.

[0238] Step 455 sets a flag. The flag can be set in response to the output of the combined signals. Step 265 communicates with the patient and/or a health care provider. Step 270 collects additional measurements.

[0239] The following is adapted from U.S. Application Ser. No.: 12/210,078, Docket No.: 026843-001900US, entitled "Systems and Methods for Wireless Body Fluid Monitoring":

[0240] Figure 5A shows a monitoring system 500 comprising an adherent device 4510 to measure an impedance signal and an electrocardiogram signal. Device 510 may comprise wireless communication circuitry, accelerometer sensors and/or circuitry and many sensors and electronics components and structures as described above. Adherent device 510 comprises at least four electrodes. In many embodiments, the at least four electrodes comprises four electrodes, for example a first electrode 512A, a second electrode 512B, a third electrode 512C and a fourth electrode 512D. Work in relation to embodiments of the present invention suggests that embodiments in which the at least four electrodes comprises four electrodes can decrease a footprint, or size, of the device on the patient and may provide improved patient comfort. In many embodiments, first electrode 512A and fourth electrode

512D comprise outer electrodes, and second electrode 512B and third electrode 512C comprise inner electrodes, for example in embodiments where the electrodes are arranged in an elongate pattern.

[0241] Adherent device 510 comprises impedance circuitry 520 that can be used to
5 measure hydration and respiration of the patient, and ECG circuitry 530 that is used to measure an electrocardiogram signal of the patient. Impedance circuitry 520 comprises force circuitry connected to the outer electrodes to drive a current between the electrodes. Impedance circuitry 520 comprises sense circuitry to measure a voltage between the inner electrodes resulting from the current passed between the outer force electrodes, such that the
10 impedance of the tissue can be determined. Impedance circuitry 520 may comprise known 4-pole, or quadrature, low power circuitry. ECG circuitry 530 can be connected to the outer electrodes, or force electrodes, to measure an ECG signal. Work in relation to embodiments of the present invention suggests that this use of the outer electrodes can increase the ECG signal as compared to the inner electrodes, in some embodiments, that may be due to the
15 increased distance between the outer electrodes. ECG circuitry 530 may comprise known ECG circuitry and components, for example low power instrumentation and/or operational amplifiers.

[0242] In many embodiments, electronic switch 532A and electronic switch 532D are connected in series between impedance circuitry 520 and electrode 512A and 512D,
20 respectively. In many embodiments, electronic switch 532A and electronic switch 532D open such that the outer electrodes can be isolated from the impedance circuitry when the ECG circuitry measures ECG signals. When electronic switch 532A and electronic switch 532D are closed, impedance circuitry 520 can force electrical current through the outer electrodes to measure impedance. In many embodiments, electronic switch 532A and
25 electronic switch 532D can be located in the same packaging, and may comprise CMOS, precision, analog switches with low power consumption, low leakage currents, and fast switching speeds.

[0243] A processor 540 can be connected to electronic switch 523A, electronic switch 532D, impedance circuitry 520 and ECG circuitry 530 to control measurement of the ECG
30 and impedance signals. Processor 530 comprises a tangible medium, for example read only memory (ROM), electrically erasable programmable read only memory (EEPROM) and/or random access memory (RAM). In many embodiments, processor 540 controls the measurements such that the measurements from impedance circuitry 520 and ECG circuitry 530 are time division multiplexed in response to control signals from processor 540.

[0244] Figure 5B shows a method 550 of measuring the impedance signal and the electrocardiogram signal with processor 540. A step 552 closes the switches. A step 554 drives the force electrodes. A step 556 measures the impedance signal with the inner electrodes. A step 558 determines the impedance, hydration and/or respiration from the impedance signal. A step 560 opens the switches. A step 562 measures the ECG signal with the outer electrodes. A step 564 stores data from the impedance signals and ECG signals. A step 566 processes the data. A step 568 transmits the data, for example, wirelessly to the remote center. A step 570 repeats the above steps.

[0245] It should be appreciated that the specific steps illustrated in Figure 5B provide a particular method of measuring signals, according to an embodiment of the present invention. Other sequences of steps may also be performed according to alternative embodiments. For example, alternative embodiments of the present invention may perform the steps outlined above in a different order. Moreover, the individual steps illustrated in Figure 5B may include multiple sub-steps that may be performed in various sequences as appropriate to the individual step. Furthermore, additional steps may be added or removed depending on the particular applications. One of ordinary skill in the art would recognize many variations, modifications, and alternatives.

[0246] Figure 5C shows a method 600 for monitoring a patient and responding to a signal event. A step 601 activates a processor system. A step 603 calculates a risk of sudden cardiac death. A step 606 reports to a remote center and/or physician. A step 609 combines at least two of the electrocardiogram signal, respiration signal, and/or activity signals. A step 612 detects an adverse cardiac event. An adverse cardiac event may comprise an atrial fibrillation in response to the electrocardiogram signal and/or an acute myocardial infarction in response to an ST segment elevation of the electrocardiogram signal. A step 615 triggers an alarm. A step 618 continuously monitors and stores in tangible media at least two of the electrocardiogram signal, the respiration signal, or the activity signal. In some embodiments, a step may also comprise monitoring a high risk patient post myocardial infarction with the at least two of the electrocardiogram signal, the respiration signal or the activity signal, and/or a bradycardia of the patient at risk for sudden death. The electrocardiogram signal may comprise at least one of a Brugada Syndrome with an ST elevation and a short QT interval or long-QT interval. A step 621 loop records the aforementioned data. A step 624 determines a tiered response. In many embodiments, the tiered response may comprise tiers, or levels, appropriate to the detected status of the patient. A step 627 comprises a first tier response which alerts an emergency responder. A step 630 comprises a second tier response which

alerts a physician. A step 633 comprises a third tier response which alerts a patient, family, or caregiver. A step 637 comprises a fourth tier response which alerts a remote center. A tiered response may also comprise of wirelessly transmitting the at least two of the electrocardiogram signal, the respiration signal, or the activity signal with a single wireless hop from
 5 a wireless communication circuitry to an intermediate device.

[0247] The signals can be combined in many ways. In some embodiments, the signals can be used simultaneously to determine the impending cardiac decompensation.

[0248] In some embodiments, the signals can be combined by using the at least two of the electrocardiogram signal, the respiration signal or the activity signal to look up a value in a
 10 previously existing array.

[0249] Table 3. Lookup Table for ECG and Respiration Signals.

<i>Heart Rate / Respiration</i>	<i>A-B bpm</i>	<i>C-D bpm</i>	<i>E-F bpm</i>
U-V per min	N	N	Y
W-X per min	N	Y	Y
Y-Z per min	Y	Y	Y

[0250] Table 3 shows combination of the electrocardiogram signal with the respiration signal to look up a value in a pre-existing array. For example, at a heart rate in the range
 15 from A to B bpm and a respiration rate in the range from U to V per minute triggers a response of N. In some embodiments, the values in the table may comprise a tier or level of the response, for example four tiers. In specific embodiments, the values of the look up table can be determined in response to empirical data measured for a patient population of at least about 100 patients, for example measurements on about 1000 to 10,000 patients. The look up
 20 table shown in Table 1 illustrates the use of a look up table according to one embodiment, and one will recognize that many variables can be combined with a look up table.

[0251] In some embodiments, the table may comprise a three or more dimensional look up table, and the look up table may comprises a tier, or level, of the response, for example an alarm.

25 [0252] In some embodiments, the signals may be combined with at least one of adding, subtracting, multiplying, scaling or dividing the at least two of the electrocardiogram signal, the respiration signal or the activity signal. In specific embodiments, the measurement signals can be combined with positive and or negative coefficients determined in response to

empirical data measured for a patient population of at least about 100 patients, for example data on about 1000 to 10,000 patients.

[0253] In some embodiments, a weighted combination may combine at least two measurement signals to generate an output value according to a formula of the general form

5 [0254] $OUTPUT = aX + bY$

[0255] where a and b comprise positive or negative coefficients determined from empirical data and X, and Z comprise measured signals for the patient, for example at least two of the electrocardiogram signal, the respiration signal or the activity signal. While two coefficients and two variables are shown, the data may be combined with multiplication and/or division.

10 One or more of the variables may be the inverse of a measured variable.

[0256] In some embodiments, the ECG signal comprises a heart rate signal that can be divided by the activity signal. Work in relation to embodiments of the present invention suggests that an increase in heart rate with a decrease in activity can indicate an impending decompensation. The signals can be combined to generate an output value with an equation

15 of the general form

[0257] $OUTPUT = aX / Y + bZ$

[0258] where X comprise a heart rate signal, Y comprises an activity signal and Z comprises a respiration signal, with each of the coefficients determined in response to empirical data as described above.

20 [0259] In some embodiments, the data may be combined with a tiered combination. While many tiered combinations can be used a tiered combination with three measurement signals can be expressed as

[0260] $OUTPUT = (\Delta X) + (\Delta Y) + (\Delta Z)$

[0261] where (ΔX) , (ΔY) , (ΔZ) may comprise change in heart rate signal from baseline, change in respiration signal from baseline and change in activity signal from baseline, and each may have a value of zero or one, based on the values of the signals. For example if the heart rate increase by 10%, (ΔX) can be assigned a value of 1. If respiration increases by 5%, (ΔY) can be assigned a value of 1. If activity decreases below 10% of a baseline value (ΔZ) can be assigned a value of 1. When the output signal is three, a flag may be set to trigger an alarm.

25

30

[0262] In some embodiments, the data may be combined with a logic gated combination. While many logic gated combinations can be used, a logic gated combination with three measurement signals can be expressed as

[0263] $OUTPUT = (\Delta X) \text{ AND } (\Delta Y) \text{ AND } (\Delta Z)$

5 [0264] where (ΔX) , (ΔY) , (ΔZ) may comprise change in heart rate signal from baseline, change in respiration signal from baseline and change in activity signal from baseline, and each may have a value of zero or one, based on the values of the signals. For example if the heart rate increase by 10%, (ΔX) can be assigned a value of 1. If respiration increases by 5%, (ΔY) can be assigned a value of 1. If activity decreases below 10% of a baseline value (ΔZ) can be assigned a value of 1. When each of (ΔX) , (ΔY) , (ΔZ) is one, the output signal is one, and a flag may be set to trigger an alarm. If any one of (ΔX) , (ΔY) or (ΔZ) is zero, the output signal is zero and a flag may be set so as not to trigger an alarm. While a specific example with AND gates has been shown the data can be combined in many ways with known gates for example NAND, NOR, OR, NOT, XOR, XNOR gates. In some embodiments, the gated logic may be embodied in a truth table.

[0265] The processor system, as described above, performs the methods 600, including many of the steps described above. It should be appreciated that the specific steps illustrated in Figure 5C provide a particular method of monitoring a patient and responding to a signal event, according to an embodiment of the present invention. Other sequences of steps may also be performed according to alternative embodiments. For example, alternative embodiments of the present invention may perform the steps outlined above in a different order. Moreover, the individual steps illustrated in Figure 5C may include multiple sub-steps that may be performed in various sequences as appropriate to the individual step. Furthermore, additional steps may be added or removed depending on the particular applications. One of ordinary skill in the art would recognize many variations, modifications, and alternatives.

[0266] Fig. 5D shows a method of using bioimpedance measurements to determine changes in the body fluid of a patient for heart failure monitoring. In step 650, an adhesive patch with at least four electrodes is placed on the skin of the patient, as described above with respect to other embodiments of the invention. In step 652, the electrodes are coupled to the skin to form an interface. A single frequency is used to measure the tissue resistance via the impedance circuitry in step 654. A low frequency is preferably chosen as the single measurement frequency. There are two capacitances that must be considered when taking

these measurements: the capacitance of the skin-electrode interface and the intracellular capacitance. A low frequency for the measurement frequency isolates the skin-electrode interface measurement, because at low frequencies, the effect of the intracellular capacitance is negligible. The low frequency is preferably less than 200 kHz and more preferably less than 100 kHz. In a particularly preferred embodiment, the frequency is about 10 kHz. The tissue resistance measurements are transmitted to a processor in step 656.

[0267] In step 658, the processor determines whether the tissue resistance measurements exhibit a "low frequency droop." A threshold decline in the measured resistance may be selected in order to identify a low frequency droop. For example, a decline of over 10 % from the nominal value of the measurements, or over 15 or 20 %, may indicate an irregular or anomalous skin-electrode coupling. Wetting of the skin, such as while showering or from sweating during physical exercise, can cause a low frequency droop. To verify that an abnormal reading is caused by a wetting of the skin, a second measurement can be taken at an additional low frequency, as in step 668. The additional frequency is preferably lower than the frequency of the regular measurements. In a particularly preferred embodiment, the additional frequency is about 2 kHz. If the low frequency droop is determined to be caused by wetting of the skin, measurements can be temporarily suspended, or affected data points can be disregarded, if necessary. In step 670, the quality of the skin-electrode interface is determined, and in step 672, the adhesive patch and electrodes are replaced when necessary.

[0268] When the tissue resistance measurements do not show a low frequency droop, the processor efficiently calculates a change in the patient body fluid in step 660. As described above, the change in body fluid is related to the amount of extracellular edema, which is determined in step 662. In step 664, the amount of edema is used to calculate the patient's risk of an adverse cardiac event. An alert is transmitted in step 666 when the patient's risk exceeds a preset level.

[0269] Fig. 5E shows a method of using bioimpedance measurements to determine changes in the body fluid of a patient for heart failure monitoring, where the bioimpedance measurements include tissue resistance and tissue reactance. In step 750, an adhesive patch with at least four electrodes is placed on the skin of the patient, as described above with respect to other embodiments of the invention. The electrodes are coupled to the skin to form an interface in step 752. In step 754, tissue resistance and tissue reactance are measured at successive time intervals via the impedance circuitry. The measurements are then transmitted to a processor in step 756. From the tissue resistance measurements, in step 758, the processor calculates a change in the patient body fluid. In steps 760 and 762, respectively,

the amount of extracellular edema is determined and the patient's risk of an adverse cardiac event is calculated. When the risk is above a preset level, an alert signal is transmitted in step 764.

5 [0270] In step 766, the processor uses the tissue reactance measurements to determine the quality of the skin-electrode interface. A threshold value for the reactance may be selected such that a reactance value in excess of the threshold indicates that the quality of the skin-electrode interface is poor. For example, the reactance threshold may be set at between approximately 8 and 15 ohms, such as 10 ohms. As described above, the quality of the interface can be affected by wetting of the skin or by degradation of the adhesive strength of
10 the adhesive patch. If the processor determines that the adhesive patch requires replacement in step 768, then it is replaced in step 770. If the adhesive patch does not require replacement, then further measurements of the tissue resistance and tissue reactance are taken.

15 [0271] Fig. 5F shows a method of using bioimpedance measurements to determine changes in the body fluid of a patient for heart failure monitoring. The method is related to the method shown in Fig. 5E, but uses the tissue impedance measured between any two electrodes to determine the quality of the skin-electrode coupling. Steps 850 through 864 correspond to steps 750 through 764 of Fig. 5E.

20 [0272] In step 866, an impedance measurement is taken between any two of the electrodes coupled to the skin. The processor uses the impedance measurements to determine the quality of the skin-electrode coupling in step 868. A poor connection at the skin-electrode interface, such as when the adhesive patch begins to lose its adhesive strength, will cause the impedance measured between any two electrodes to increase. A threshold for the impedance increase may be selected, such that when the impedance measured between two electrodes
25 exceeds the threshold, a poor skin-electrode coupling is indicated. For example, a threshold may be selected between 4 and 6 k Ω , such as 5 k Ω . If the impedance measurements indicate that the coupling is poor, then the patch and electrodes will be replaced, as in steps 870 and 872. If the patch does not require replacement, then measurements will continue to be taken.

30 [0273] The processor system, as described above, can perform many of the above described methods, including many of the steps described above. It should be appreciated that the specific steps illustrated above provide a particular methods of monitoring a patient, according to some embodiments of the present invention. Other sequences of steps may also be performed according to alternative embodiments. For example, alternative embodiments

of the present invention may perform the steps outlined above in a different order. Moreover, the individual steps illustrated may include multiple sub-steps that may be performed in various sequences as appropriate to the individual step. Furthermore, additional steps may be added or removed depending on the particular applications. One of ordinary skill in the art
5 would recognize many variations, modifications, and alternatives.

[0274] Figure 6 shows a method 600 of using a support for triggering an indication on a support or adherent device. The method 600 may be used on any of the devices described herein. A step 902 measures sensor information from an adherent device. The sensor
10 information may include sensor measurements from at least one electrode as described in many embodiments described herein, for example a sensor measurement regarding ECG, tissue resistance, bioimpedance, respiration, respiration rate variability, heart rate, heart rhythm, heart rate variability, heart rate turbulence, heart sounds, respiratory sounds, blood pressure, activity, posture, wake, sleep, orthopnea, temperature, heat flux, weight, and any combination thereof. In step 904 a predetermined event has been determined to have
15 occurred. A predetermined event may include the expected or unexpected occurrence of an event which is predetermined to trigger a determination.

[0275] In some embodiments the predetermined event is an undesired patient event, or a calculation of the likelihood that undesired patient event will occur in the future, for example as shown in figures 3, 4A-4B, and 5B-5F. In some embodiments the predetermined event is
20 the adherent device detecting tissue contact or tissue non-contact such as shown in figure 3. In some embodiments the predetermined event is the occurrence or impending occurrence of cardiac compensation such as shown in figures 4A, 4B, and 5B-5F. In some embodiments the predetermined event is a failure, detachment, or misplacement of the adherent device. In some embodiments the predetermined event is a calculation that the patient has fallen down,
25 for example using activity sensors.

[0276] In some embodiments the predetermined event is the an expiration of a predetermined amount of time. In some embodiments the predetermined amount of time may be triggered when the adherent device is first used on a patient, for example seven days after a first physiologic measurement is taken. The predetermined amount of time may be
30 associated with the expected life of the adherent device. In some embodiments the predetermined event may be externally triggered by an external device in wireless communication with electronic components of the adherent device. In some embodiments the predetermined event is a determination that a memory of the adherent device has exceeded capacity to store physiologic data. In some embodiments the predetermined event

is a determination by the electronic components that the adherent device is in or is not in wireless communication with an external device.

[0277] In some embodiments the predetermined event is a determination by the adherent device that one or more sensors has stopped functioning or stopped gathering data. In some
5 embodiments the determination of sensor failure may be cross-checked with one or more other sensors, to differentiate the sensor failure from an adverse event. For example, a failing blood pressure sensor may be cross checked with a functioning heart rate sensor to determine that the blood pressure sensor has failed and that an adverse cardiac event has not occurred. For example, a failing accelerometer sensor may be cross checked with a functioning posture
10 sensor to determine that the accelerometer sensor has failed and that an adverse falling event has not occurred. Many more combinations are possible. In some embodiments the predetermined event is a determination that a battery of the adherent device needs replacing or recharging. In some embodiments the predetermined event is a combination of other predetermined events and methods described above.

[0278] In step 906 the adherent device triggers an indicator which indicates the predetermined event has occurred. The indicator triggered may be different for different predetermined events, thus, a first predetermined event may trigger a first indicator and a second predetermined event may trigger a second indicator. In some embodiments the indicator is a visual indicator, for example as shown in figures 1F1 and 1F2. In some
20 embodiments indicator is an audible signal. In some embodiments the indicator is a combination of a visual and audible signal. The indicator may use symbols, words, or audible signals to indicate to a patient, or patient caregiver, that the patient is in need of immediate medical care or that the adherent device is broken, needs maintenance, is out of wireless transmitting range, is not wirelessly synchronized with an external device, needs
25 replacing on the patients skin, is partially failing, is running low on battery power, has run out of memory, is functioning properly, or has expired.

[0279] In step 908 the adherent device optionally transmits a wireless signal to an external device, for example, as shown in Figure 1A. The wireless signal may cause the external device to alert a caregiver that the patient needs immediate care or that the adherent device
30 needs replacing or maintenance.

[0280] Figure 6 also shows a sub-method 904A for determining that a predetermined event has occurred. The sub-method 904A may be used for step 904 in method 900 of Figure 6. In step 910 a first sensor measurement may be detected. In some embodiments the first sensor

measurement may be the very first sensor measurement that the adherent device detects upon placement onto a patient's skin. In some embodiments the first sensor measurement may be triggered by a switch on the adherent device, for example, by detection of tissue, or external triggering. In step 912 a timer of the adherent device may be triggered to begin counting to a predetermined number. In some embodiments the timer is a clock which counts time based units, for example seconds, until a predetermined time is reached, for example seven days. In step 914 the adherent device may determine that the timer has counted to a predetermined number. In some embodiments the timer is triggered when a liner covering an adhesive portion of the adherent device is removed from the adherent device.

[0281] Figure 6 also shows a sub-method 904B for determining that a predetermined event has occurred. The sub-method 904B may be used for step 904 in method 900 of Figure 6. In step 918 it may be determined if the sensor information indicates an adverse patient event, for example a cardiac related event. If no adverse patient event occurs then the method 904B may cycle back to step 916. If an adverse patient event has been determined to occur, the sub-method 904B may proceed to step 918. Alternatively, if no adverse patient event occurs in step 918, the method may also proceed to step 918 to check the functionality of the first sensor. In step 920 the first sensor 920 may be crosschecked with at least a second sensor to verify the first sensor is operational and that the first sensor measurement is reliable. For example, a respiration sensor may be crosschecked with an ECG sensor to determine that the respiration sensor is functioning correctly. The respiration sensor may be further crosschecked with a third sensor, for example, a heart sound sensor. Crosschecking for each sensor may include a calculation of an output and a comparison of that output with tabulated data, for example as shown above in tables 1-3. If the first sensor is determined to be functioning correctly then the sub-method may proceed to 906 for triggering a first indicator of the occurrence of a first predetermined event, for example, a health warning indicator. If the first sensor is determined to not be functioning correctly, then the sub-method may proceed to 906 for triggering a second indicator of the occurrence of a second predetermined event, for example, a device malfunction indicator.

[0282] Figure 6A also shows a sub-method 904C for determining that a predetermined event has occurred. The sub-method 904C may be used for step 904 in method 900 of Figure 6A. In step 924 it may be determined that tissue has coupled to at least two electrodes of an adherent device, for example, as shown in Figure 3. The sub-method 904C may then proceed to step 906 for triggering a first indicator of the occurrence of a second predetermined event, for example, a device "on" indicator. In step 926 it may be determined that tissue has

decoupled from the at least two electrodes of the adherent device, for example, as shown in Figure 3. The sub-method 904C may then proceed to step 906 for triggering a second indicator of the occurrence of a second predetermined event, for example, triggering a device “off” indicator, or turning off the “on” indicator.

5 [0283] It should be noted that many other predetermined events are within the scope of the present invention, and that many combinations of triggered sensors and switches may be used in determining a predetermined event. In some embodiments an oximetry sensor may be used to determine if a patient's oxygenation is stable or unstable. In some embodiments the adherent device may include a strain gauge coupled to a flexible portion of the adherent
10 device to measure chest expansion upon breathing and further determine breathing rate or exertion. Many other sensors and sensor schemes can be used.

[0284] While the exemplary embodiments have been described in some detail, by way of example and for clarity of understanding, those of skill in the art will recognize that a variety of modifications, adaptations, and changes may be employed. Hence, the scope of the
15 present invention should be limited solely by the appended claims.

WHAT IS CLAIMED IS:

- 1 1. An adherent device to measure data from a patient having skin, the .
2 device comprising:
3 a support configured to measure data from a patient and adhere to the skin of
4 the patient; and
5 a display coupled to the support.
- 1 2. The device of claim 1 wherein the support comprises a flexible .
2 support, and the display comprises a flexible display, the flexible support coupled to
3 the flexible display to flex the flexible display in response to patient movement.
- 1 3. The device of claim 2 wherein the flexible support is configured to
2 stretch with the skin of the patient when the support is adhered to the skin of the patient.
- 1 4. The device of claim 3 further comprising a cover coupled to the
2 display and the support to support the display with the cover and the support when the
3 support is adhered to the skin of the patient and wherein the cover comprises a stretchable
4 material such that cover is configured stretch with the support and the skin when the support
5 is adhered to the skin of the patient.
- 1 5. The device of claim 4 wherein the cover is configured to stretch more
2 than the flexible display to compensate for minimal stretching of the flexible display when
3 the support is stretched with the skin.
- 1 6. The device of claim 2 wherein the flexible support comprises:
2 a breathable tape with an adhesive coating;
3 at least one electrode affixed to the breathable tape and capable of electrically
4 coupling to a skin of the patient;
5 a printed circuit board connected to the breathable tape to support the printed
6 circuit board with the breathable tape when the tape is adhered to the patient; and
7 electronic components electrically connected to the printed circuit board and
8 coupled to the at least one electrode to measure physiologic signals of the patient, and
9 coupled to the flexible display.
- 1 7. The device of claim 6 wherein the flexible support further comprises at
2 least one of a breathable cover or an electronics housing disposed over the circuit board and

3 electronic components and connected to at least one of the electronics components, the
4 printed circuit board or the breathable tape.

1 8. The device of claim 7 wherein the display is affixed to the breathable
2 cover or electronic housing.

1 9. The device of claim 6 wherein electronic components comprise a
2 processor and a plurality of sensors coupled to the printed circuit board, the processor
3 configured to process data received from the sensors and to display information regarding the
4 data on the printed circuit board.

1 10. The device of claim 9 wherein each of the plurality of sensors are
2 chosen from a group consisting of: ECG, tissue resistance, bioimpedance, respiration,
3 respiration rate variability, heart rate, heart rhythm, heart rate variability, heart rate
4 turbulence, heart sounds, respiratory sounds, blood pressure, activity, posture, wake, sleep,
5 orthopnea, temperature, heat flux, and weight.

1 11. The device of claim 10 wherein the activity sensor is chosen from a
2 group consisting of: ball switch, accelerometer, minute ventilation, bioimpedance noise,
3 muscle noise, and posture.

1 12. The device of claim 9 wherein the electronic components further
2 comprises wireless communication circuitry coupled to the processor.

1 13. The device of claim 9 wherein the display further comprises at least
2 one visual indicator coupled to the processor and the flexible support.

1 14. The device of claim 13 wherein the at least one visual indicator is an
2 LED light.

1 15. The device of claim 2 wherein the flexible display comprises a first
2 flexible layer and a second flexible layer and a flexible material disposed between the first
3 layer and the second flexible layer to convey information to the patient.

1 16. The device of claim 15 wherein the first and second flexible layers
2 include cutout portions for the flexible material to reside.

1 17. The device of claim 15 wherein the flexible material comprises a
2 flexible electrochromic display.

1 18. The device of claim 17 wherein the flexible electrochromic display is
2 configured to display a plurality of symbols.

1 19. The device of claim 18 wherein each of the plurality of symbols are
2 chosen from a group consisting of: a checkmark, a wireless symbol, a minus symbol, and
3 combinations thereof.

1 20. The device of claim 15 wherein the flexible material comprises a
2 flexible LCD display.

1 21. The device of claim 20 wherein the flexible LCD display is configured
2 to display a plurality of symbols.

1 22. The device of claim 21 wherein the plurality of symbols are chosen
2 from a group consisting of: a checkmark, a wireless symbol, a minus symbol, and
3 combinations thereof.

1 23. A method for measuring data from a patient having skin, the method
2 comprising :
3 adhering a device to a skin of the patient, the device comprising a display and
4 at least one sensor;
5 measuring patient information from the sensor when the device adhered to the
6 skin of the patient; and
7 displaying information on the display in response to the patient information.

1 24. The device of claim 23 wherein the adherent device comprises a
2 support with an adhesive, and wherein the support stretches and bends with the skin of the
3 patient when the support is adhered to the skin of the patient.

1 25. The device of claim 23 wherein the adherent device comprises a cover
2 coupled to support and the display and wherein the cover stretches with the support when the
3 skin stretches.

1 26. A method for measuring data from a patient having skin, the method
2 comprising:
3 detecting sensor information from the patient's skin using a support
4 configured to measure the sensor information from a patient and adhere to the skin of the
5 patient, the support having at least one visual indicator;

6 displaying at least one indication related to the sensor information on the at
7 least one visual indicator.

1 27. The method of claim 26 wherein the sensor information regards data
2 from a plurality of sensors of the support, each sensor chosen from a group consisting of:
3 ECG, tissue resistance, bioimpedance, respiration, respiration rate variability, heart rate, heart
4 rhythm, heart rate variability, heart rate turbulence, heart sounds, respiratory sounds, blood
5 pressure, activity, posture, wake, sleep, orthopnea, temperature, heat flux, and weight.

1 28. The method of claim 27 wherein the activity sensor is chosen from a
2 group consisting of: ball switch, accelerometer, minute ventilation, bioimpedance noise,
3 muscle noise, and posture.

1 29. The method of claim 26 wherein the at least one visual indicator is a
2 flexible display and the at least one indication comprises a plurality of signals.

1 30. The method of claim 29 wherein each of the plurality of symbols are
2 chosen from a group consisting of: a checkmark, a wireless symbol, a minus symbol, and
3 combinations thereof.

1 31. The method of claim 26 further comprising determining the at least
2 one indication should be a warning displayed on the at least one visual indicator.

1 32. The method of claim 31 wherein the warning regards a support
2 malfunction and determining the at least one indication should be a warning comprises
3 determining that a first sensor of the support has stopped providing sensor information.

1 33. The method of claim 32 wherein determining that a first sensor of the
2 support has stopped providing sensor information comprises detecting that a first signal of the
3 first sensor is not within a predetermined value and cross-checking the first signal of the first
4 sensor with a second signal of a second sensor.

1 34. The method of claim 33 wherein the second signal of the second sensor
2 indicates that the patient is not undergoing an adverse event.

1 35. The method of claim 33 further comprising sending a wireless signal
2 from the support to a second device to indicate the support is not functioning properly.

1 36. The method of claim 33 wherein the first and second signals are chosen
2 from a group consisting of: ECG, tissue resistance, bioimpedance, bioimpedance noise,
3 muscle noise, posture, respiration, respiration rate variability, heart rate, heart rhythm, heart
4 rate variability, heart rate turbulence, heart sounds, respiratory sounds, blood pressure,
5 activity, posture, wake, sleep, orthopnea, temperature, heat flux, and weight.

1 37. The method of claim 31 wherein the warning regards an adverse
2 patient event or potential adverse patient adverse event, and determining comprises
3 determining that a first sensor of the support is functioning properly.

1 38. The method of claim 37 wherein determining that a first sensor of the
2 support is functioning properly comprises detecting that a first signal of the first sensor is not
3 within a predetermined value and cross-checking the first signal of the first sensor with a
4 second signal of a second sensor.

1 39. The method of claim 38 wherein the second signal of the second sensor
2 indicates that the patient is undergoing an adverse event or a potential adverse event.

1 40. The method of claim 38 further comprising sending a wireless signal
2 from the support to a second device to indicate that the patient is undergoing an adverse event
3 or a potential adverse event.

1 41. The method of claim 38 wherein the first and second signals are
2 chosen from a group consisting of: ECG, tissue resistance, bioimpedance, respiration,
3 respiration rate variability, heart rate, heart rhythm, heart rate variability, heart rate
4 turbulence, heart sounds, respiratory sounds, blood pressure, activity, posture, wake, sleep,
5 orthopnea, temperature, heat flux, and weight.

1 42. An adherent device to measure data from a patient having skin, the
2 device comprising:
3 a flexible support configured to measure data from a patient and adhere to the
4 skin of the patient; and
5 at least one visual indicator coupled to the support.

1 43. The device of claim 42 wherein the support comprises:
2 a battery;
3 a breathable tape with an adhesive coating;

4 at least two electrodes affixed to the breathable tape and capable of electrically
5 coupling to a skin of the patient;

6 a printed circuit board connected to the breathable tape to support the printed
7 circuit board with the breathable tape when the tape is adhered to the patient;

8 electronic components electrically connected to the printed circuit board and
9 coupled to the at least two electrodes to measure physiologic signals of the patient, and
10 coupled to the visual indicator; and

11 at least one switch coupled to the at least two electrodes, the battery and the
12 electronic components, the at least one switch configured to detect tissue coupled to the at
13 least two electrodes and connect the battery to electronic components in response to tissue
14 coupling to the at least two electrodes.

1 44. The device of claim 43 wherein the electronic components are
2 configured to trigger the at least one visual indicator to indicate the coupling of the at least
3 two electrodes.

1 45. The device of claim 44 wherein the electronic components are
2 configured to trigger the at least one visual indicator to indicate a decoupling of the at least
3 two electrodes.

1 46. The device of claim 45 wherein electronic components are configured
2 to send a wireless signal to an external device to indicate the decoupling of the at least two
3 electrodes.

1 47. The device of claim 45 wherein the electronic components are
2 configured to emit an audible signal to indicate the decoupling of the at least two electrodes.

1 48. The device of claim 44 wherein the at least one visual indicator is an
2 LED and to indicate the coupling comprises flashing the LED at least once.

1 49. The device of claim 44 wherein the at least one visual indicator is a
2 flexible display and to indicate the coupling comprises displaying at least one indicator on the
3 screen.

1 50. The device of claim 48 wherein the indicator is a symbol.

1 51. A method for indicating a support has coupled to a patient's skin, the
2 method comprising:

3 detecting tissue coupled to at least two electrodes of a flexible support, which
4 is coupled to a skin of the patient;
5 connecting a battery of the support to electronic components of the support in
6 response to detecting tissue; and
7 triggering at least one visual indicator of the support in response to detecting
8 tissue coupled to at least two electrodes of the support.

1 52. The method of claim 51 further comprising detecting a decoupling of
2 the tissue and the at least two electrodes of the flexible support.

1 53. The method of claim 52 further comprising retriggering the at least one
2 visual indicator of the support in response to detecting the tissue decoupling of the tissue and
3 the at least two electrodes of the flexible support.

1 54. The method of claim 53 further comprising sending a wireless signal to
2 an external device in response to detecting the tissue decoupling of the tissue and the at least
3 two electrodes of the flexible support.

1 55. The method of claim 53 further comprising emitting an audible signal
2 using the flexible support in response to detecting the tissue decoupling of the tissue and the
3 at least two electrodes of the flexible support.

1 56. The method of claim 51 wherein triggering the at least one visual
2 indicator of the support comprises activating at least one LED coupled to the support.

1 57. The method of claim 51 wherein triggering the at least one visual
2 indicator of the support comprises displaying at least one symbol on a flexible display
3 coupled to the flexible support.

1 58. An adherent device to measure data from a patient having skin, the
2 device comprising:
3 a flexible support configured to adhere to the skin of the patient;
4 at least one electrode affixed to the flexible support and capable of electrically
5 coupling to a skin of the patient;
6 at least one visual indicator coupled to the support;
7 a printed circuit board connected to the flexible support to support the printed
8 circuit board when the flexible support is adhered to the patient; and

9 electronic components electrically connected to the printed circuit board and
10 coupled to the at least one electrode to measure physiologic signals of the patient, and
11 coupled to the visual indicator, wherein the electrical components are configured to display
12 an indicator on the at least one visual indicator when a predetermined event occurs.

1 59. The device of claim 58 wherein the flexible support comprises a
2 breathable tape with an adhesive coating.

1 60. The device of claim 58 wherein the at least one electrode extends
2 through at least one aperture in the breathable tape.

1 61. The device of claim 58 further comprising at least one gel disposed
2 over a contact surface of the at least one electrode to electrically connect the at least one
3 electrode to the skin.

1 62. The device of claim 58 wherein the at least one electrode extends
2 through at least one aperture in the breathable tape.

1 63. The device of claim 58 wherein the at least one visual indicator
2 comprises an LED light.

1 64. The device of claim 63 wherein the LED light is configured to flash at
2 least once when a predetermined event occurs.

1 65. The device of claim 58 wherein the at least one visual indicator
2 comprises a flexible display.

1 66. The device of claim 65 wherein the flexible display comprises a first
2 flexible layer and a second flexible layer and a flexible material disposed between the first
3 layer and the second flexible layer to convey information to the patient.

1 67. The device of claim 66 wherein the first and second flexible layers
2 include cutout portions for the flexible material to reside.

1 68. The device of claim 66 wherein the flexible material comprises a
2 flexible electrochromic display.

1 69. The device of claim 68 wherein the flexible electrochromic display is
2 configured to display a plurality of symbols.

1 70. The device of claim 18 wherein each of the plurality of symbols are
2 chosen from a group consisting of: a checkmark, a wireless symbol, a minus symbol, and
3 combinations thereof.

1 71. The device of claim 68 wherein the flexible material comprises an
2 flexible LCD display.

1 72. The device of claim 71 wherein the flexible LCD display is configured
2 . to display a plurality of symbols.

1 73. The device of claim 72 wherein the plurality of symbols are chosen
2 from a group consisting of: a checkmark, a wireless symbol, a minus symbol, and
3 combinations thereof.

1 74. The device of claim 58 wherein the electrical components comprise a
2 memory for storing the physiologic signals.

1 75. The device of claim 74 wherein the predetermined event comprises
2 determination of exceeding capacity of the memory for storing the physiologic signals.

1 76. The device of claim 58 wherein the predetermined event comprises a
2 determination that a predetermined amount of time has elapsed.

1 77. The device of claim 75 wherein the predetermined about of time is
2 initiated when the at least one electrode begins to measure the physiologic signals of the
3 patient.

1 78. The device of claim 77 wherein the predetermined about of time is 7
2 days.

1 79. The device of claim 58 wherein the electrical components are
2 configured to stop measuring physiologic signals of the patient when the predetermined event
3 occurs.

1 80. The device of claim 58 wherein the electronic components comprise a
2 wireless transmitter.

1 81. The device of claim 80 wherein the wireless transmitter is configured
2 to send a signal to an external device when the predetermined event occurs.

1 82. A method for indicating a predetermined event has occurred on a
2 flexible device, the method comprising:
3 detecting sensor information from the patient's skin using a support
4 configured to measure the sensor information from a patient and adhere to the skin of the
5 patient, the support having at least one visual indicator;
6 determining a predetermined event has occurred using the support; and
7 displaying at least one indication related to the predetermined event on the at
8 least one visual indicator.

1 83. The method of claim 82 wherein the sensor information regards data
2 from a plurality of sensors of the support, each sensor chosen from a group consisting of:
3 ECG, tissue resistance, bioimpedance, respiration, respiration rate variability, heart rate, heart
4 rhythm, heart rate variability, heart rate turbulence, heart sounds, respiratory sounds, blood
5 pressure, activity, posture, wake, sleep, orthopnea, temperature, heat flux, and weight.

1 84. The method of claim 82 wherein the at least one visual indicator is a
2 flexible display.

1 85. The method of claim 82 further comprising storing the sensor
2 information on a memory of the support.

1 86. The method of claim 85 wherein the predetermined event comprises
2 determining that a capacity of the memory for storing the physiologic signals has been
3 exceeded

1 87. The method of claim 82 wherein the predetermined event comprises
2 determining that a predetermined amount of time has elapsed

1 88. The method of claim 87 wherein the predetermined amount of time is
2 initiated when the at least one electrode begins to measure the physiologic signals of the
3 patient.

1 89. The method of claim 88 wherein the predetermined amount of time is 7
2 days.

1 90. The method of claim 82 wherein the at least one visual indicator
2 comprises an LED and wherein the at least one indication comprises at least one flash of the
3 LED.

- 1 91. The method of claim 82 wherein the at least one visual indicator
2 comprises a flexible display and wherein the at least one indication comprises at least one
3 symbol on the flexible display.

1 / 27

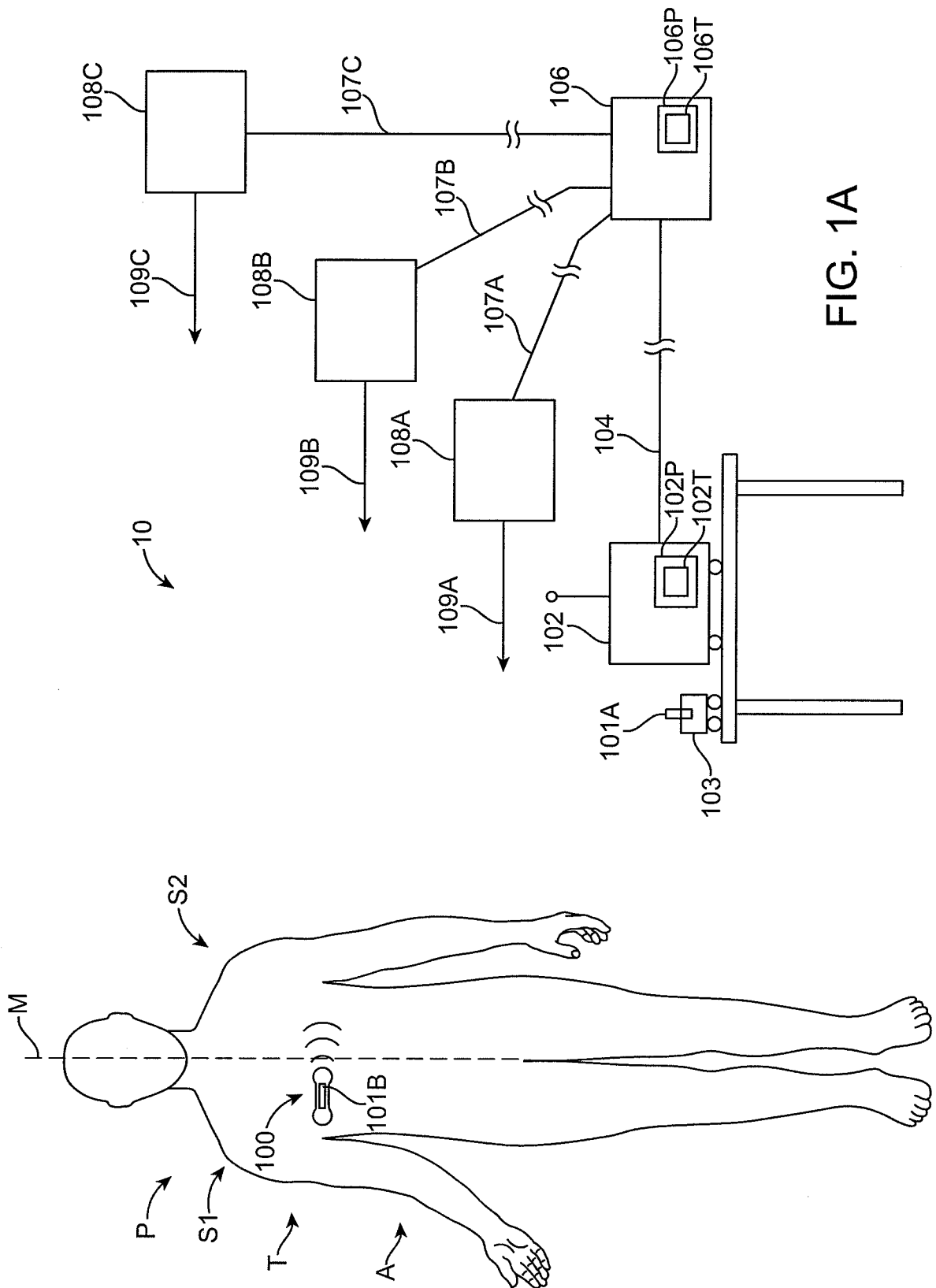


FIG. 1A

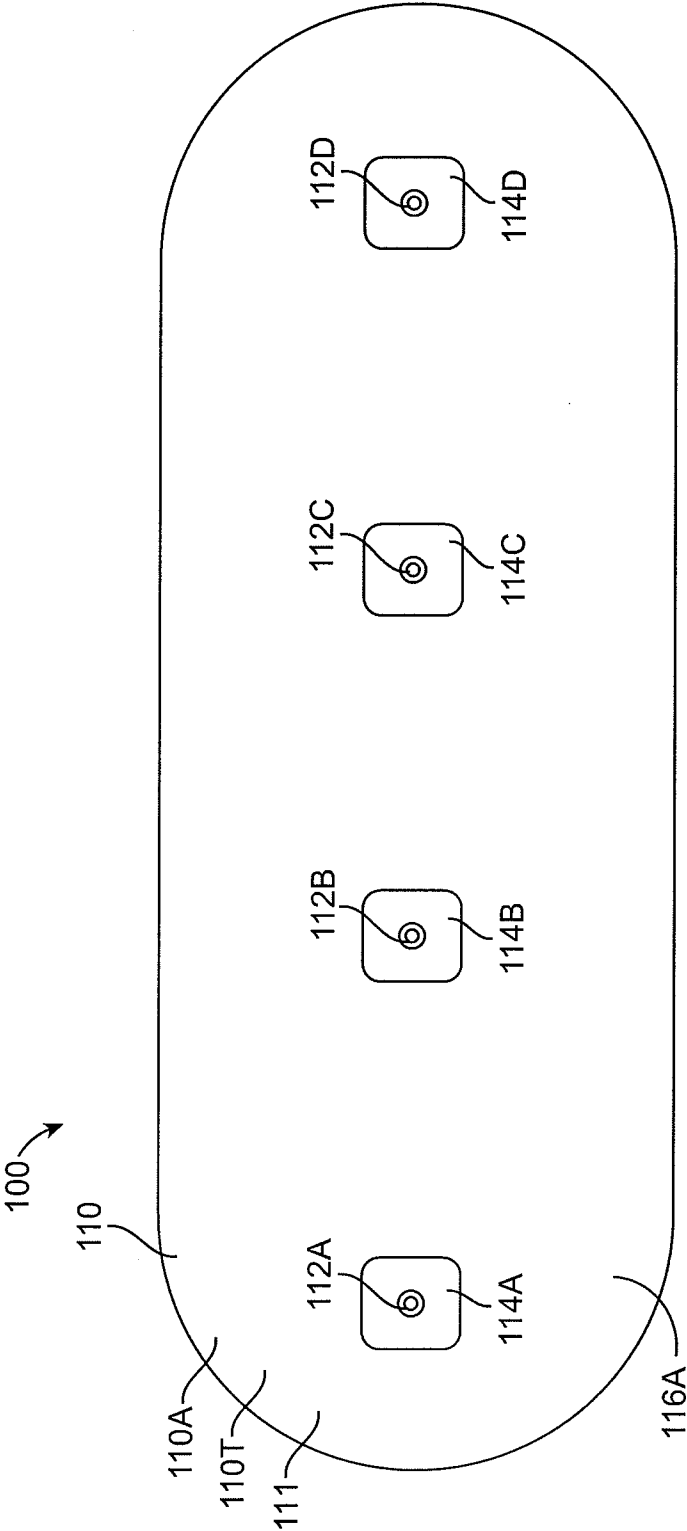


FIG. 1B

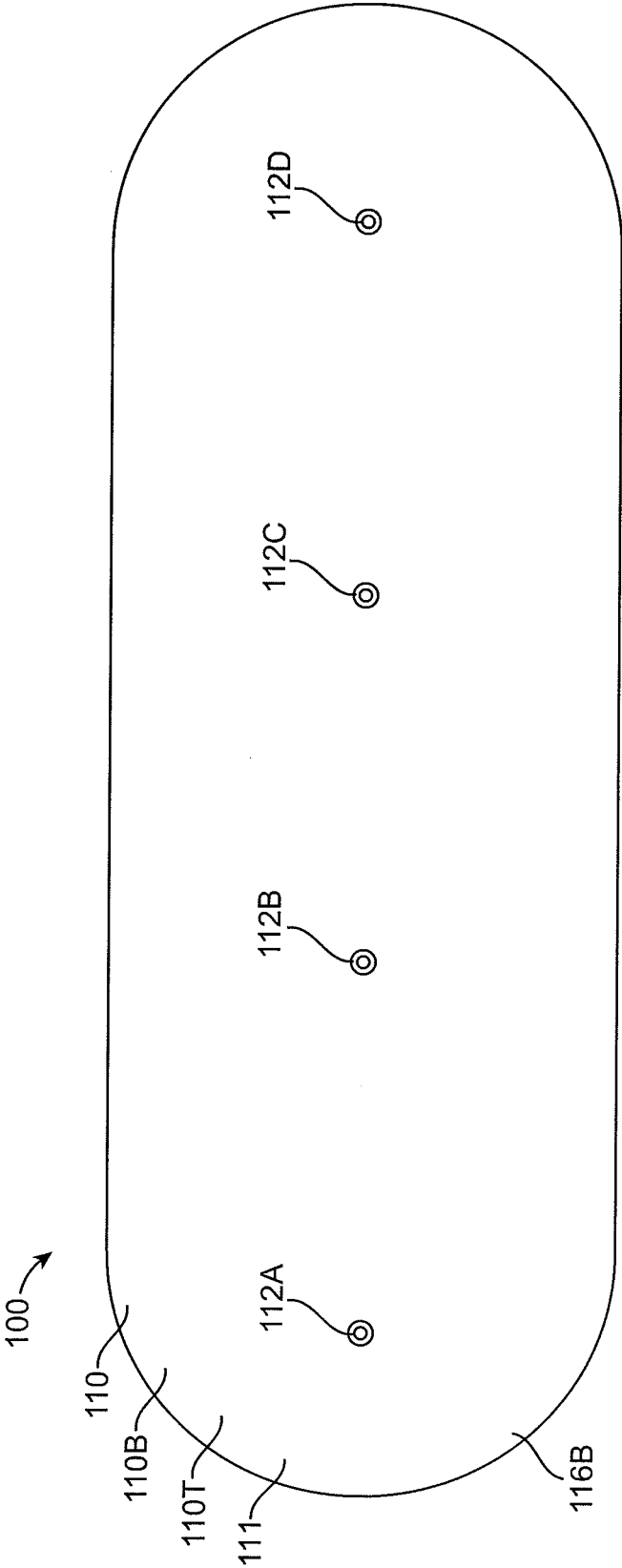


FIG. 1C

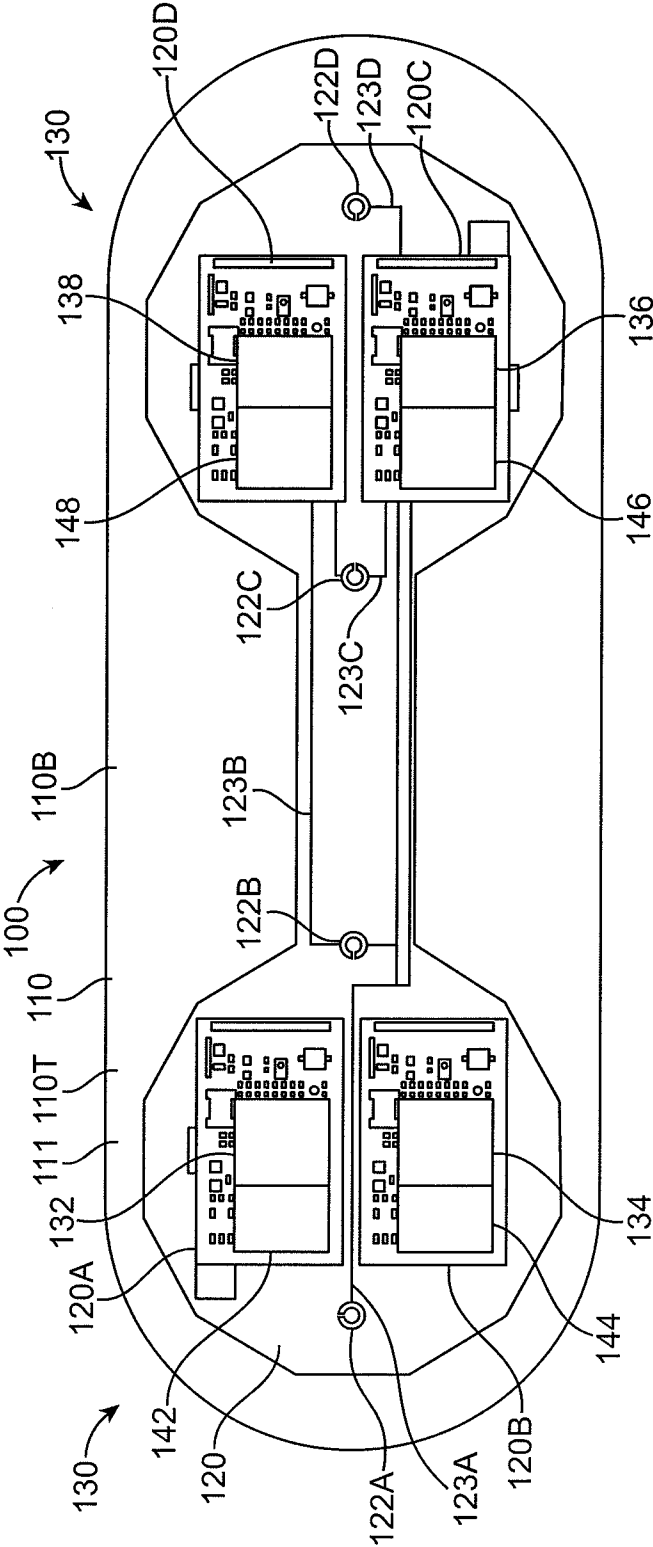


FIG. 1D

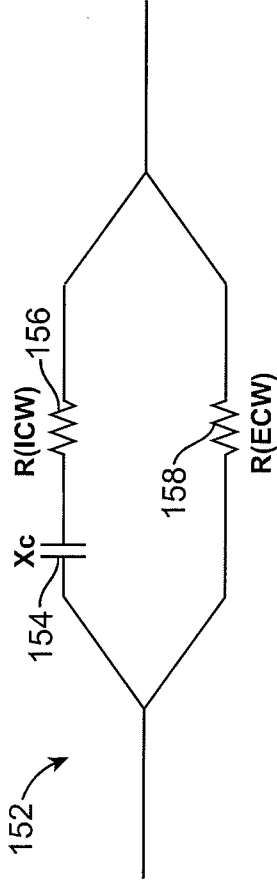


FIG. 1D1

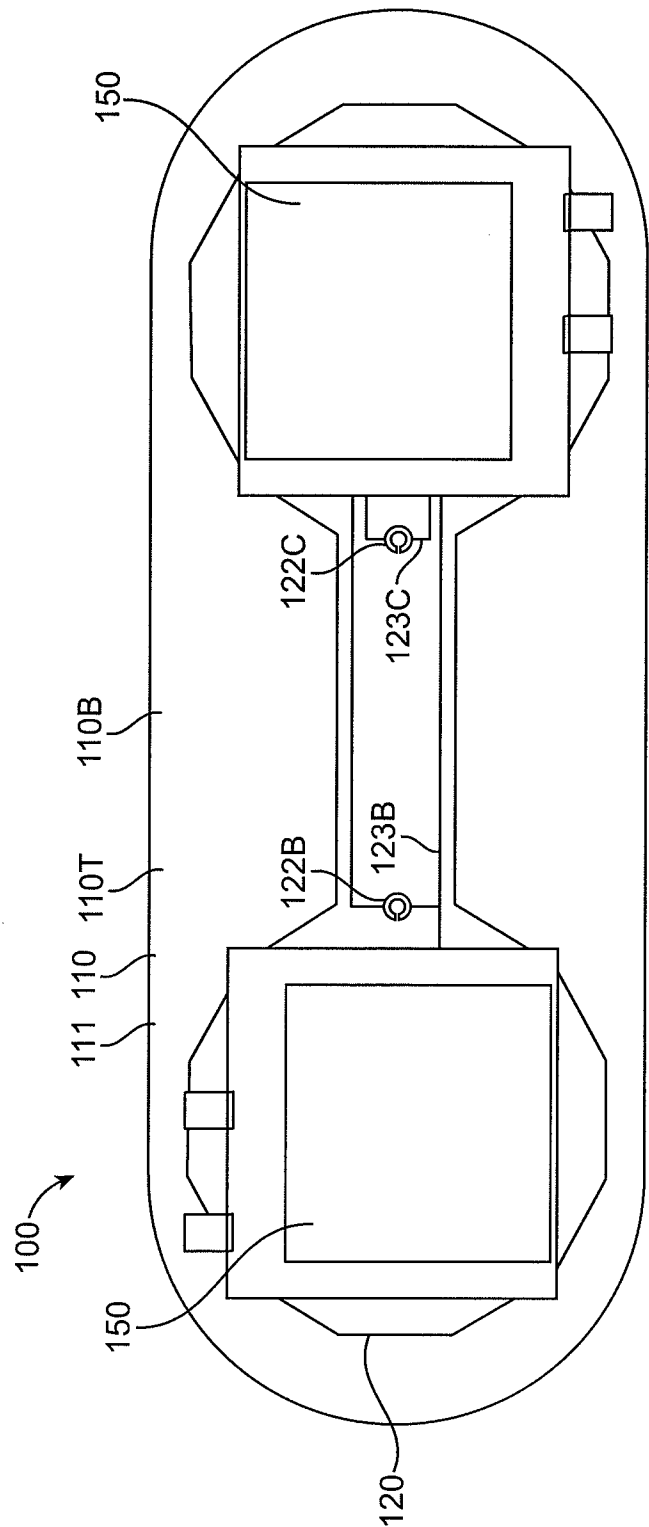


FIG. 1E

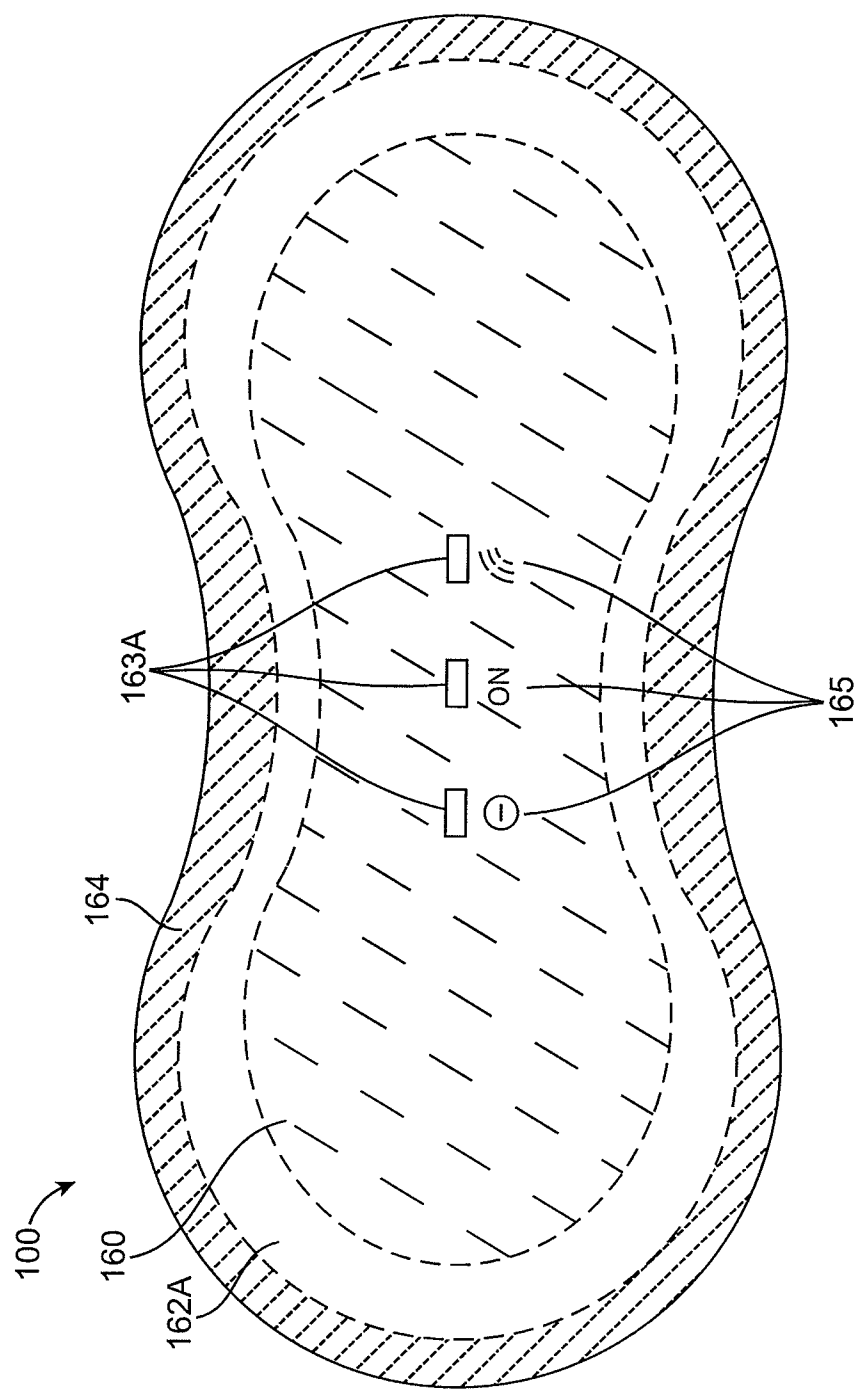


FIG. 1F1

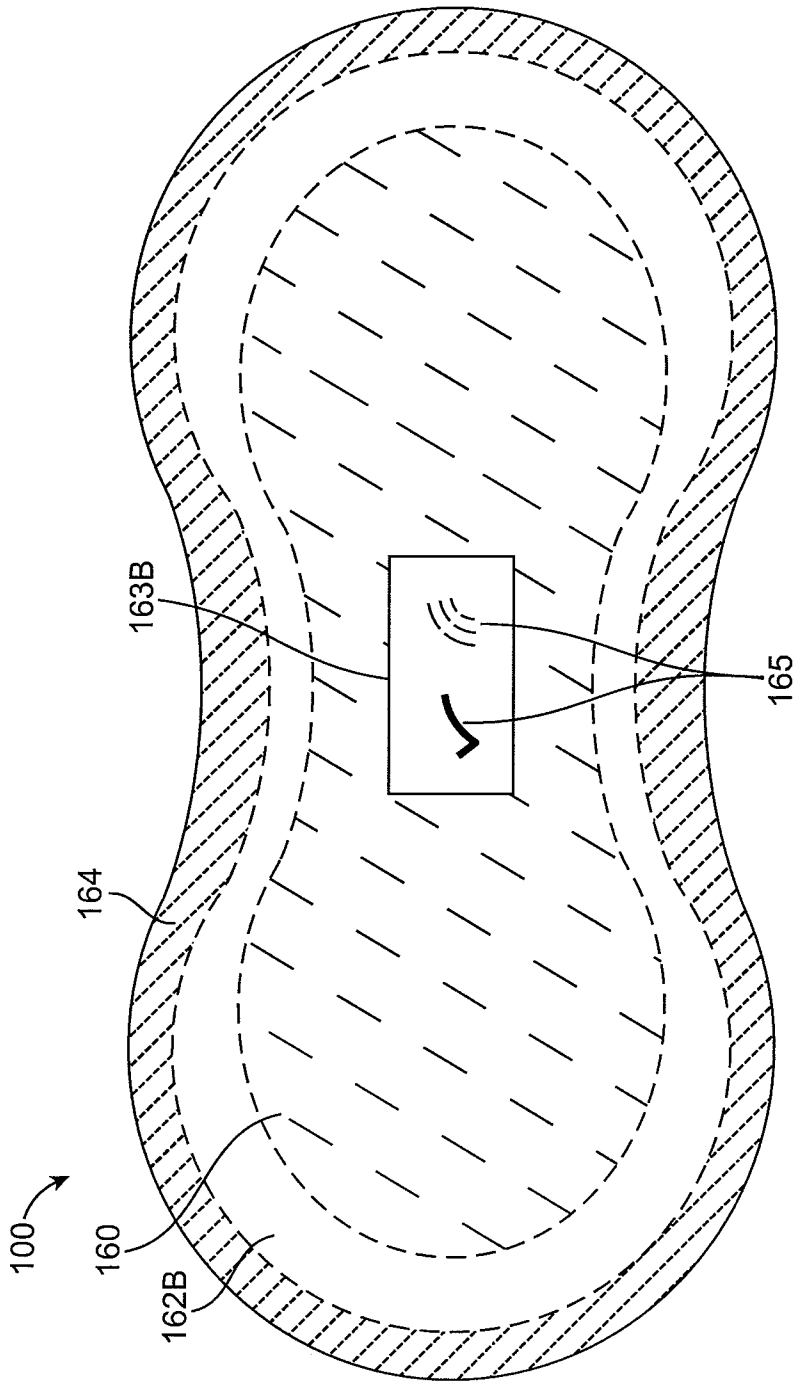


FIG. 1F2

8 / 27

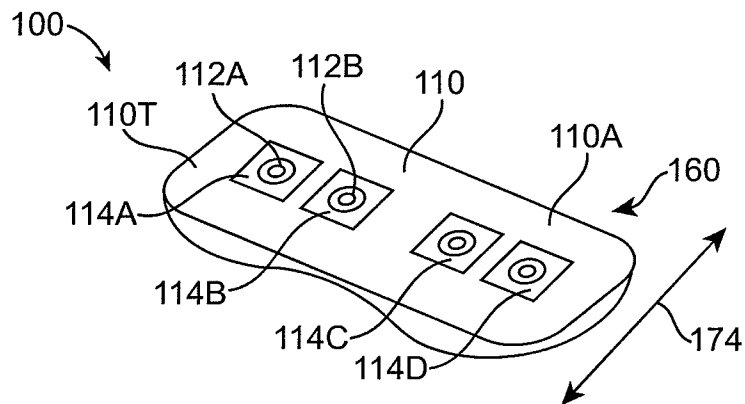


FIG. 1H

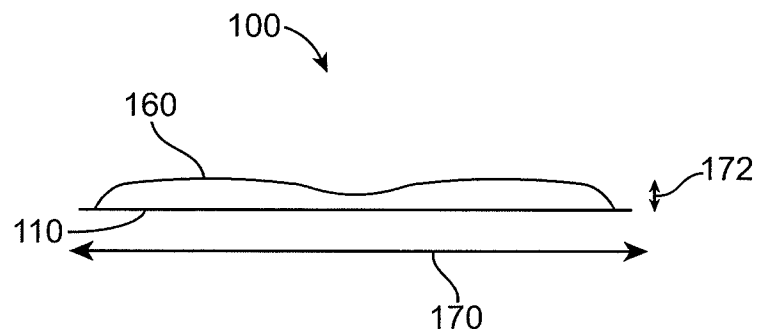


FIG. 1G

9 / 27

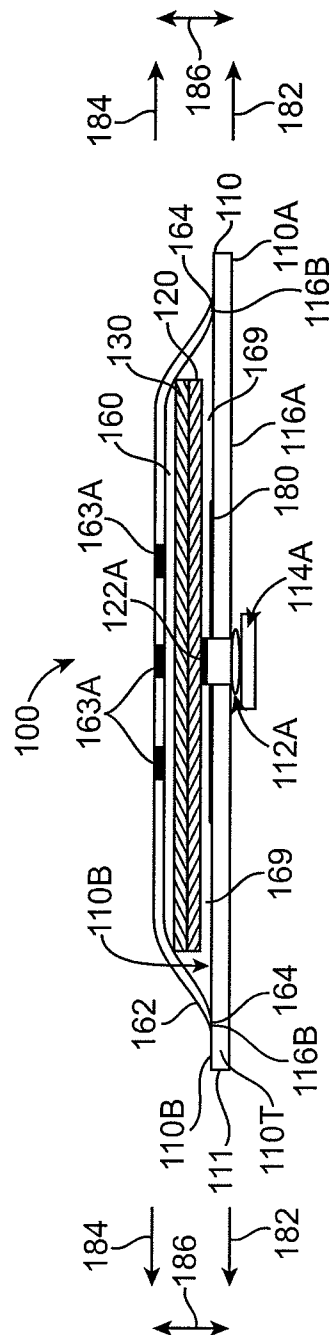


FIG. 111

10 / 27

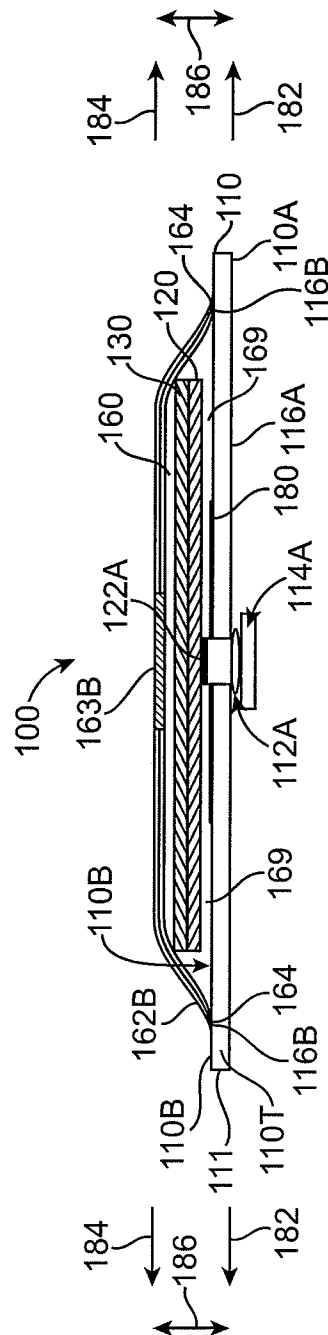
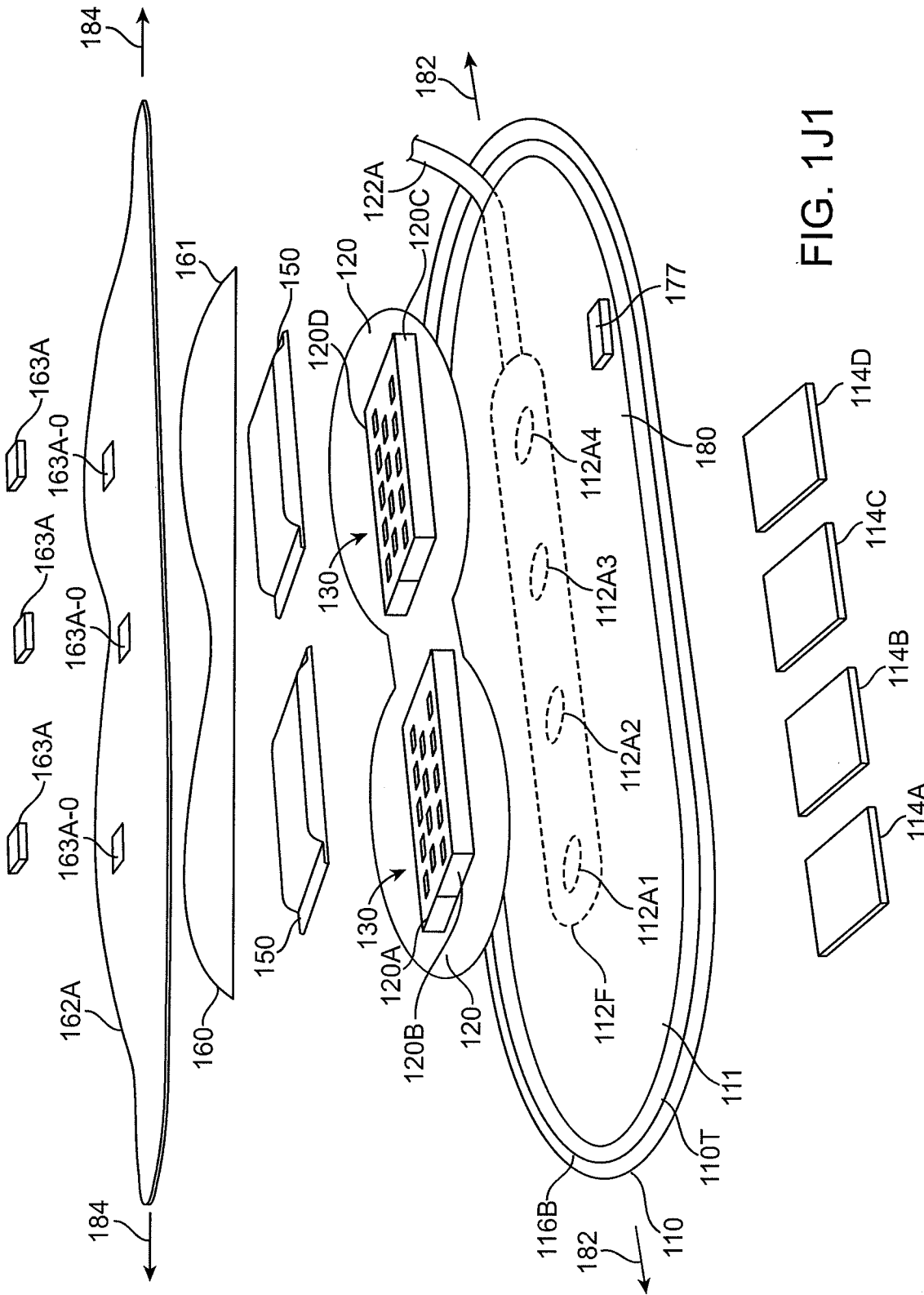


FIG. 112



12 / 27

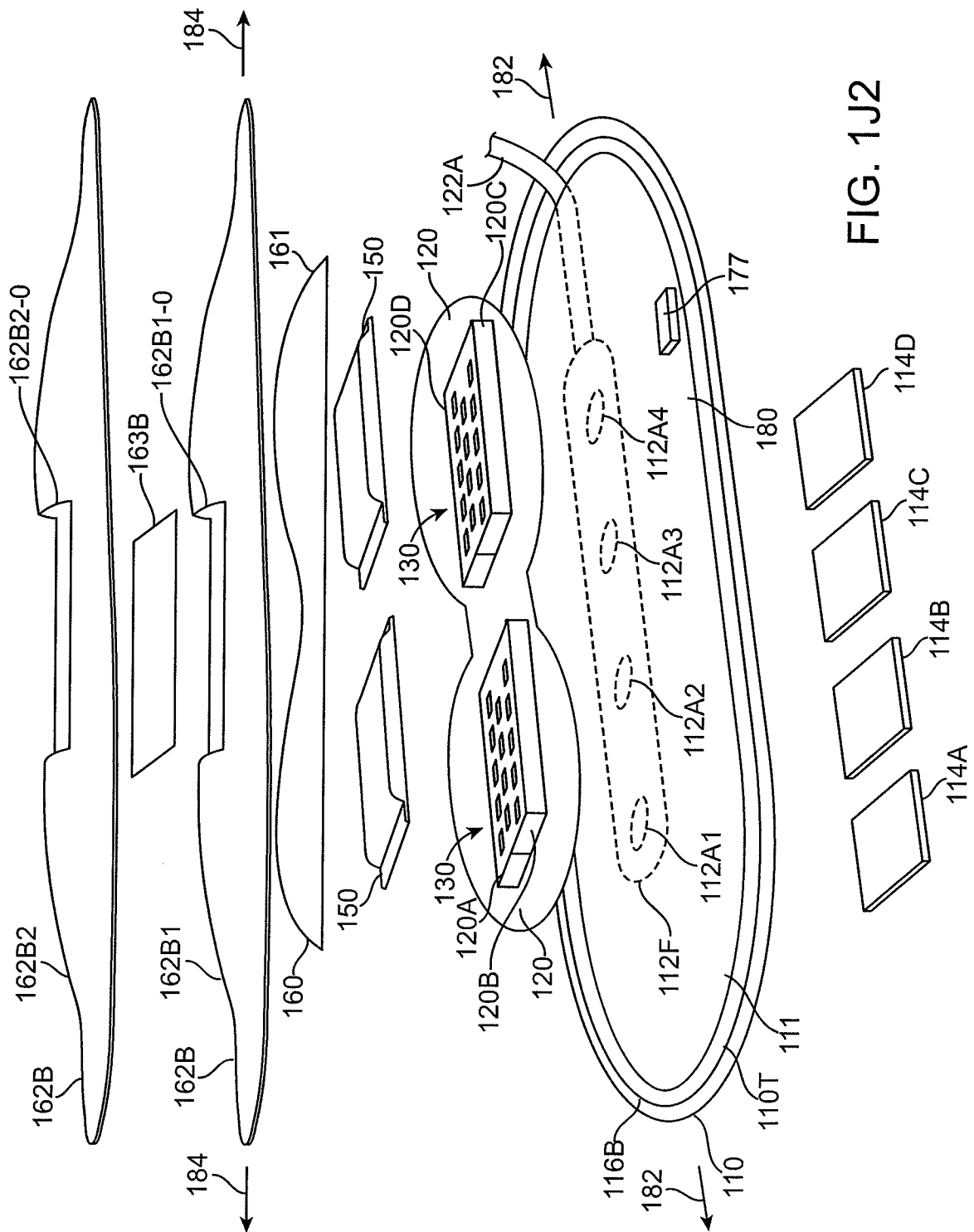


FIG. 1J2

13 / 27

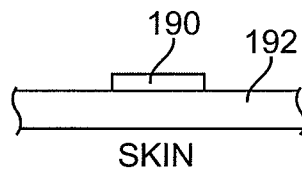
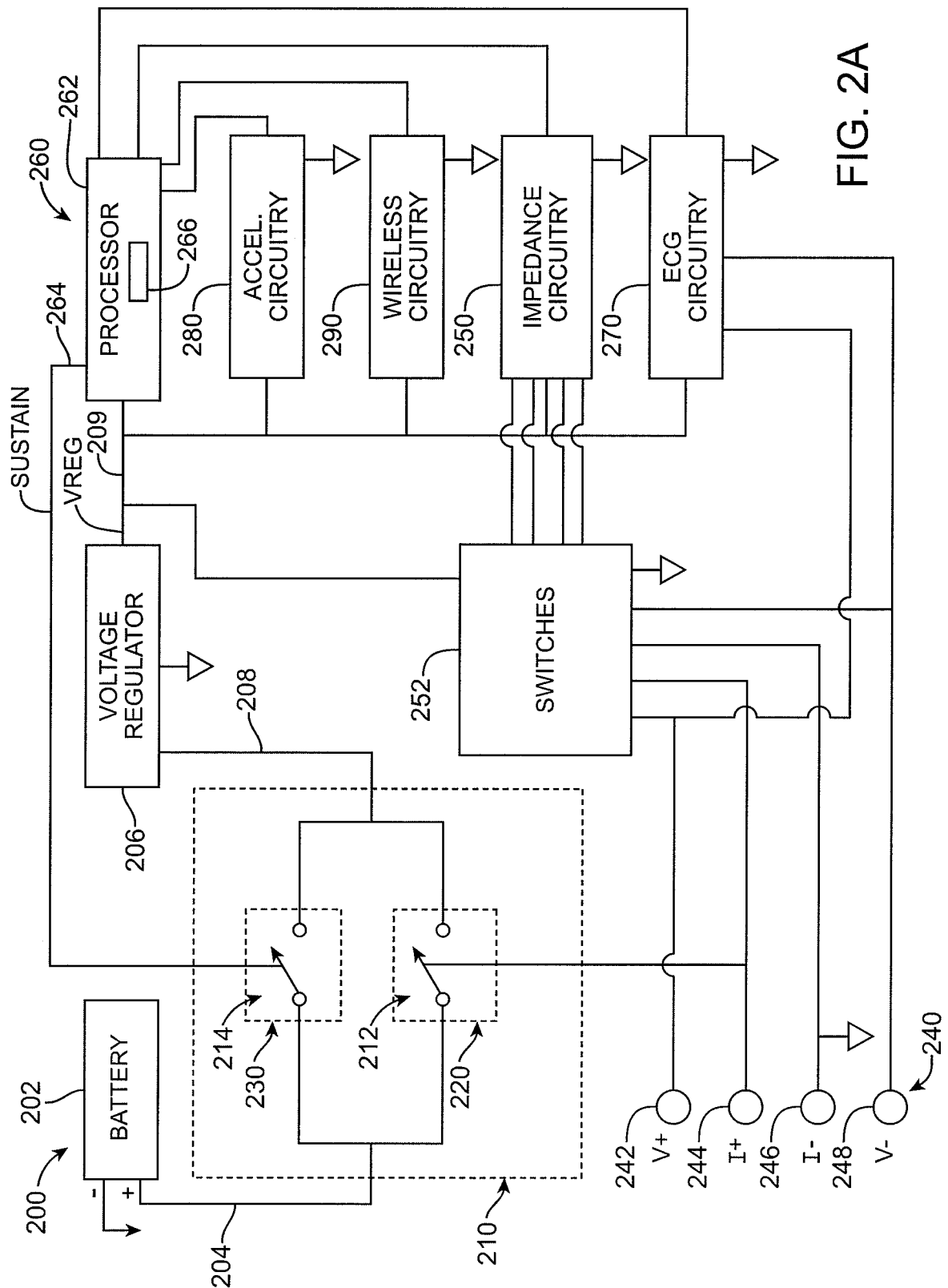


FIG. 1K



15 / 27

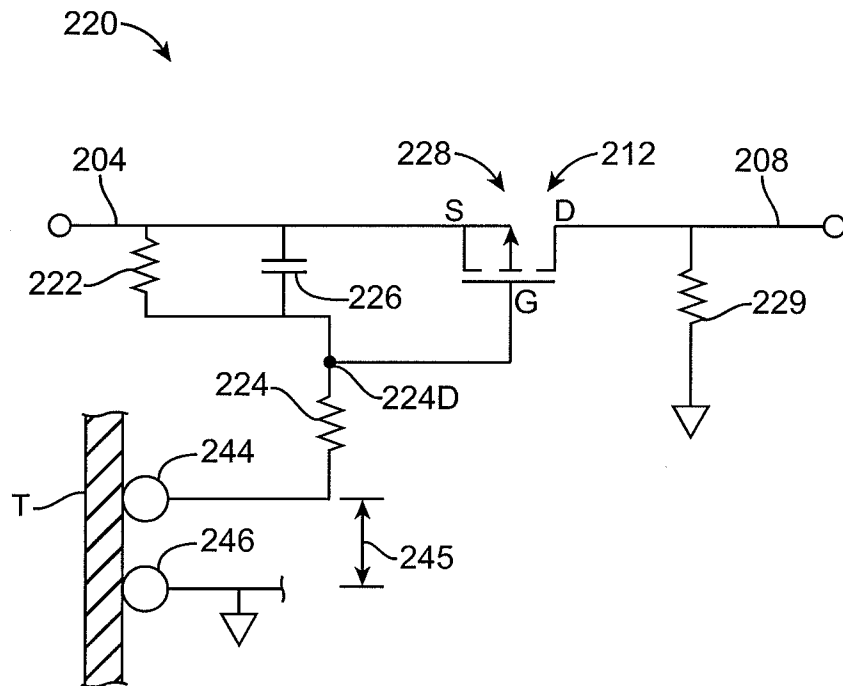


FIG. 2B

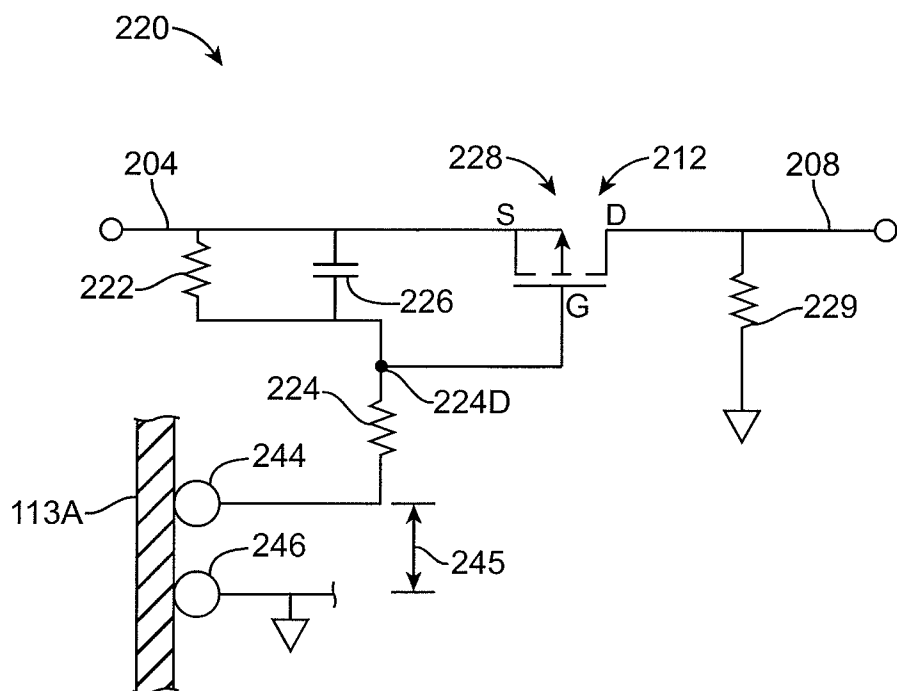


FIG. 2B-1

16 / 27

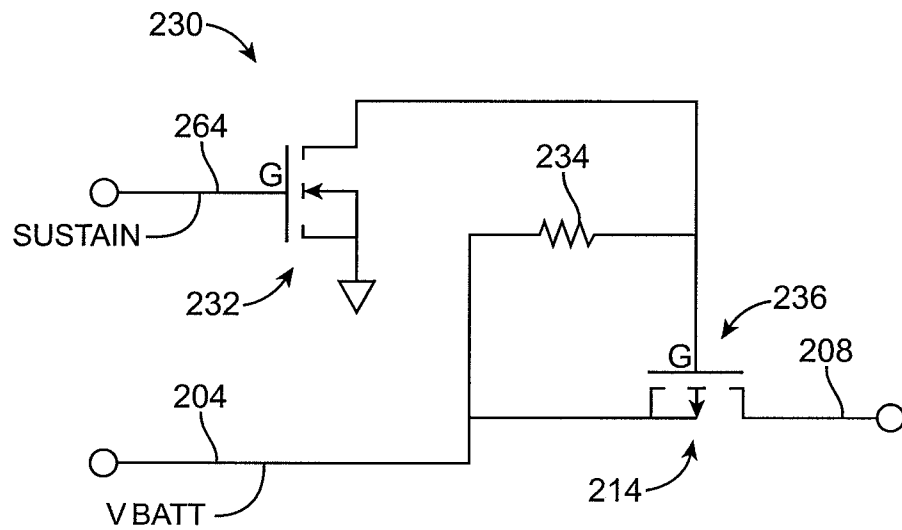


FIG. 2C

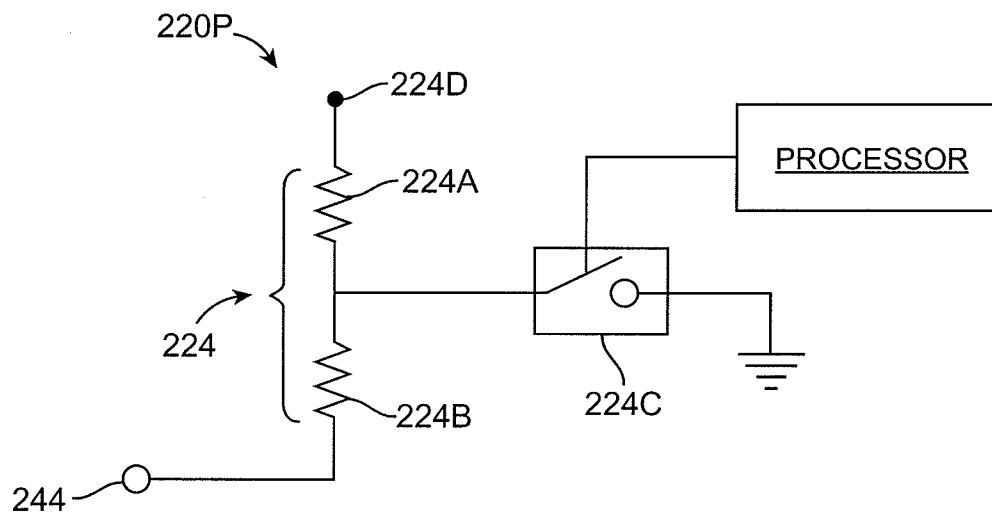


FIG. 2D

17 / 27

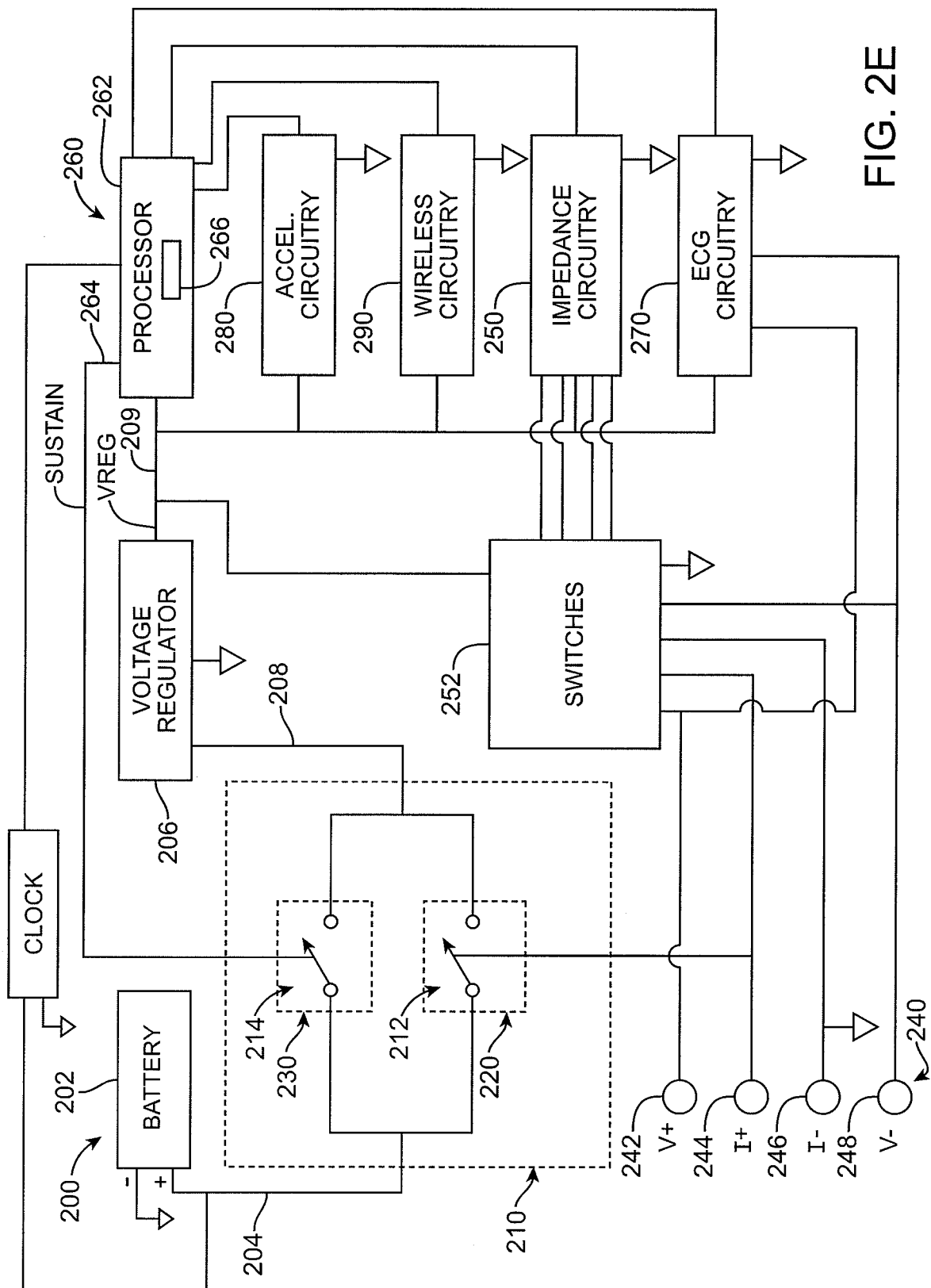


FIG. 2E

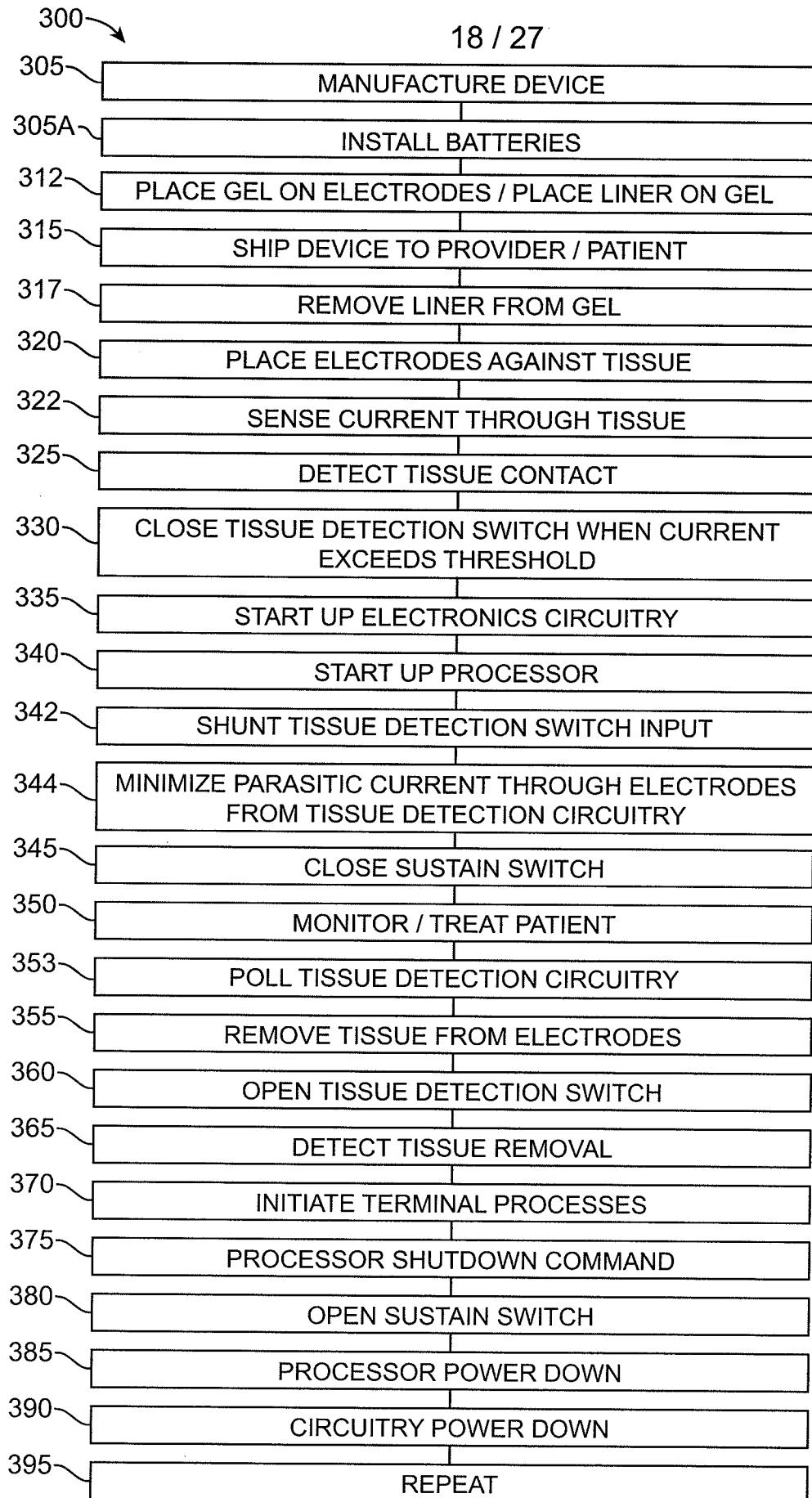


FIG. 3

19 / 27

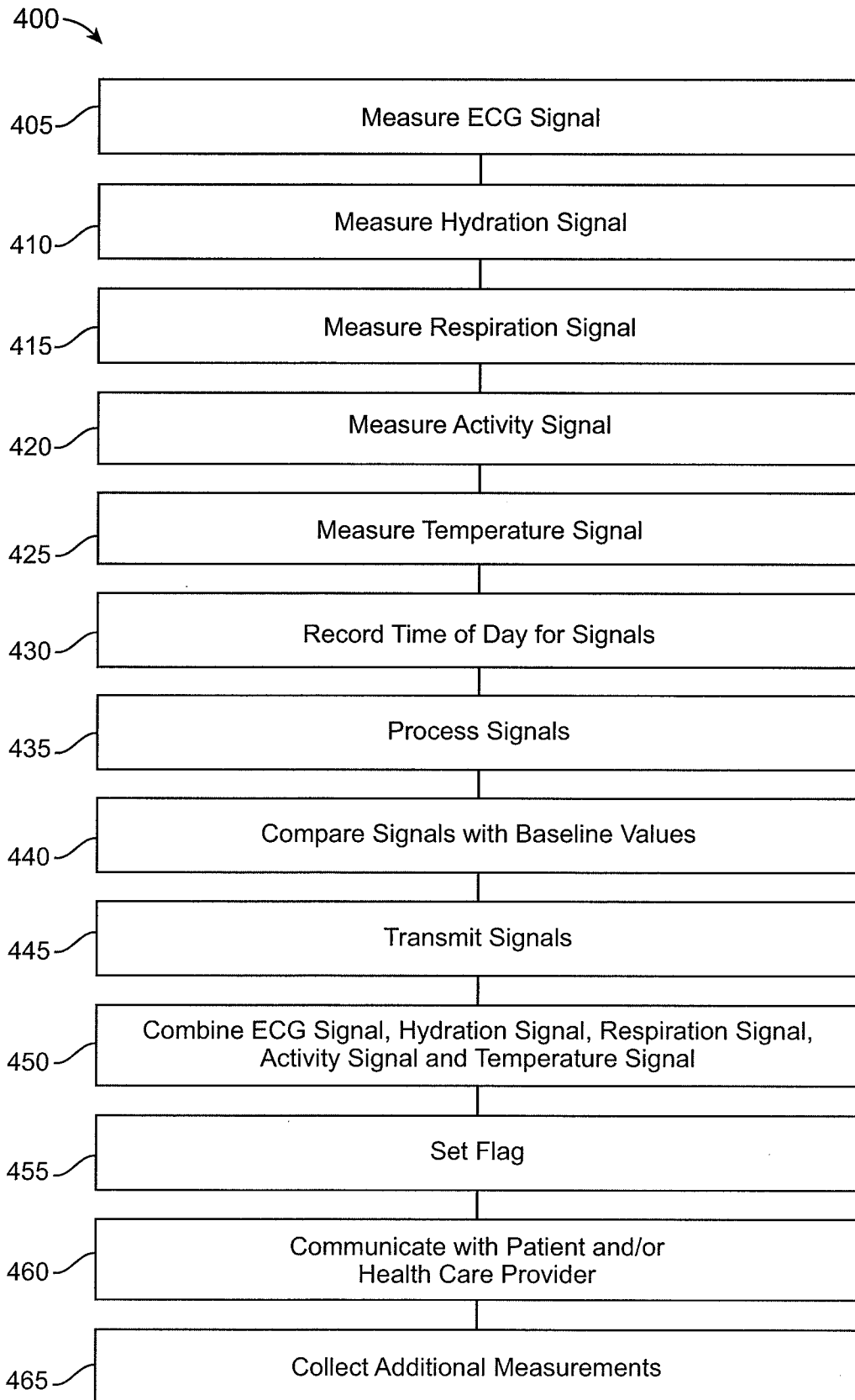


FIG. 4A

20 / 27

400B →

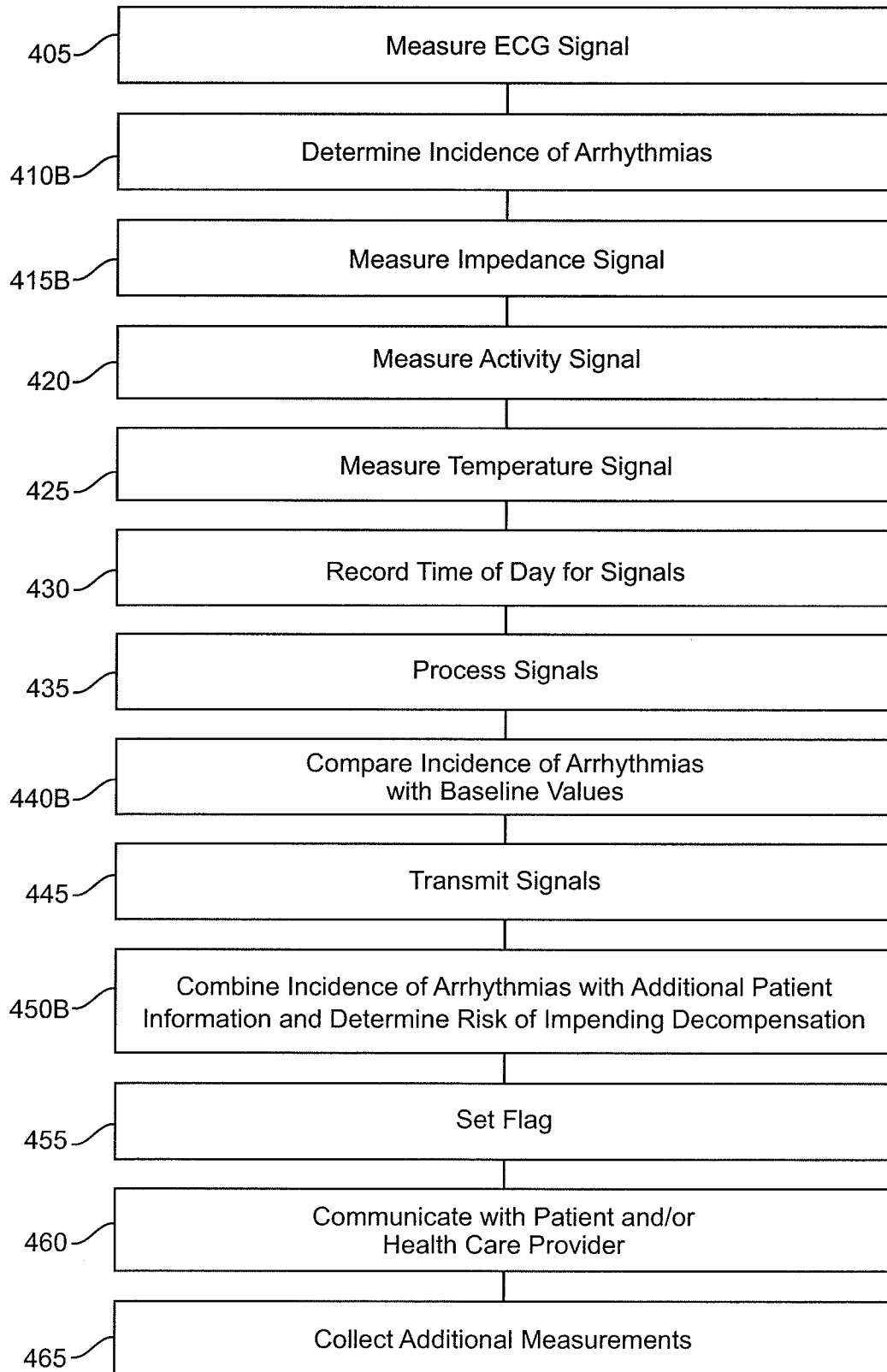


FIG. 4B

21 / 27

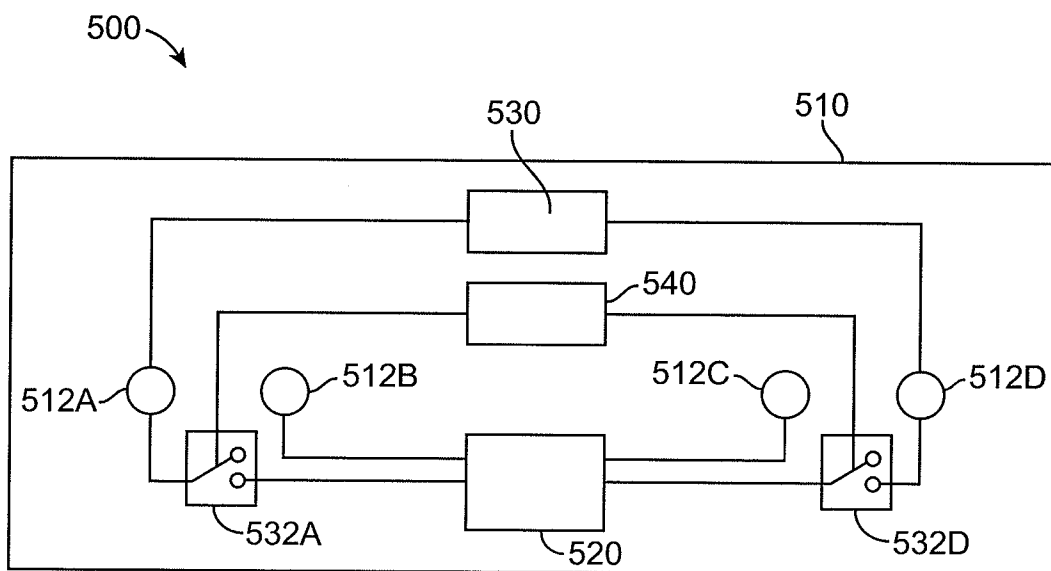


FIG. 5A

22 / 27

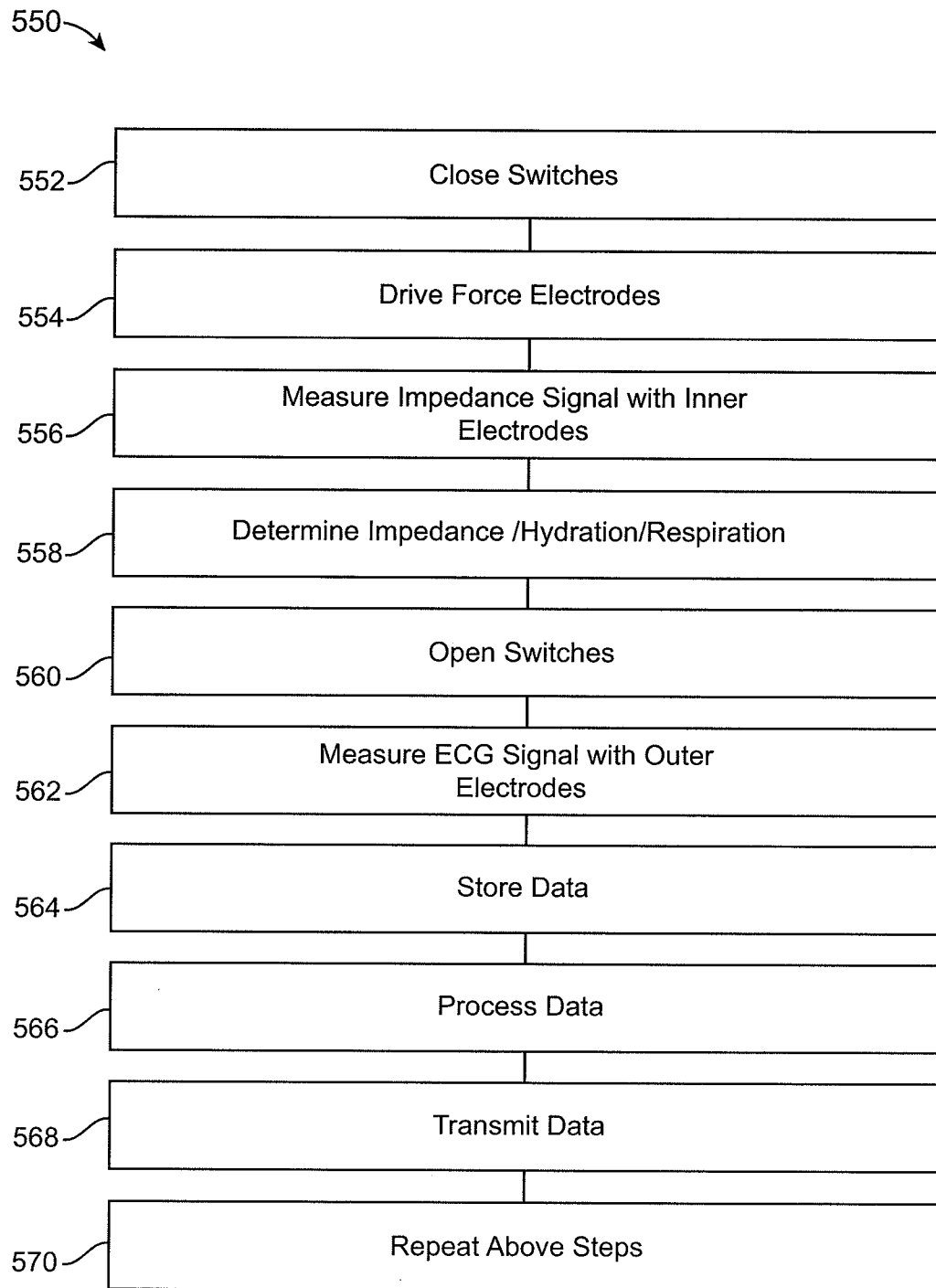


FIG. 5B

23 / 27

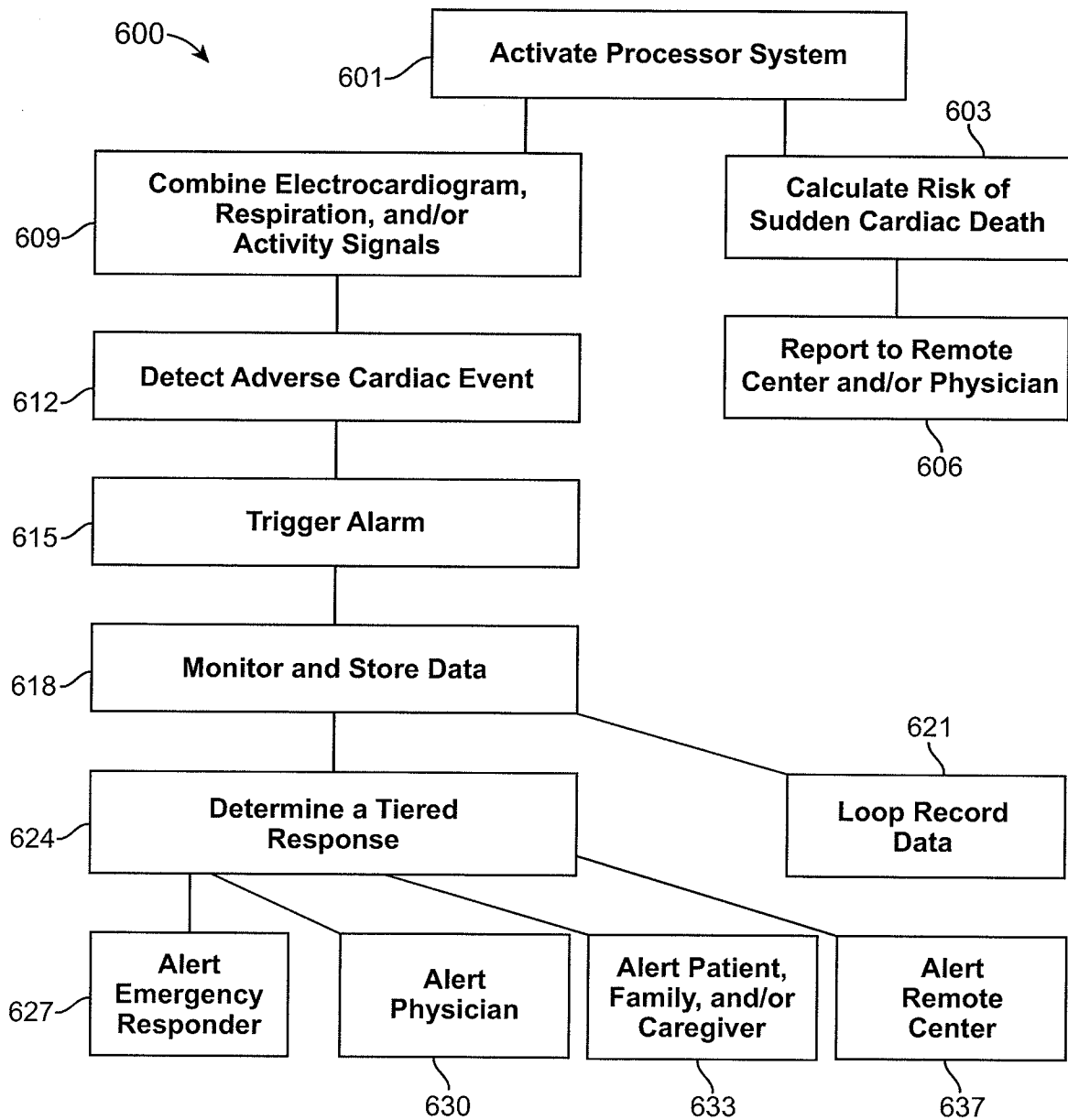


FIG. 5C

24 / 27

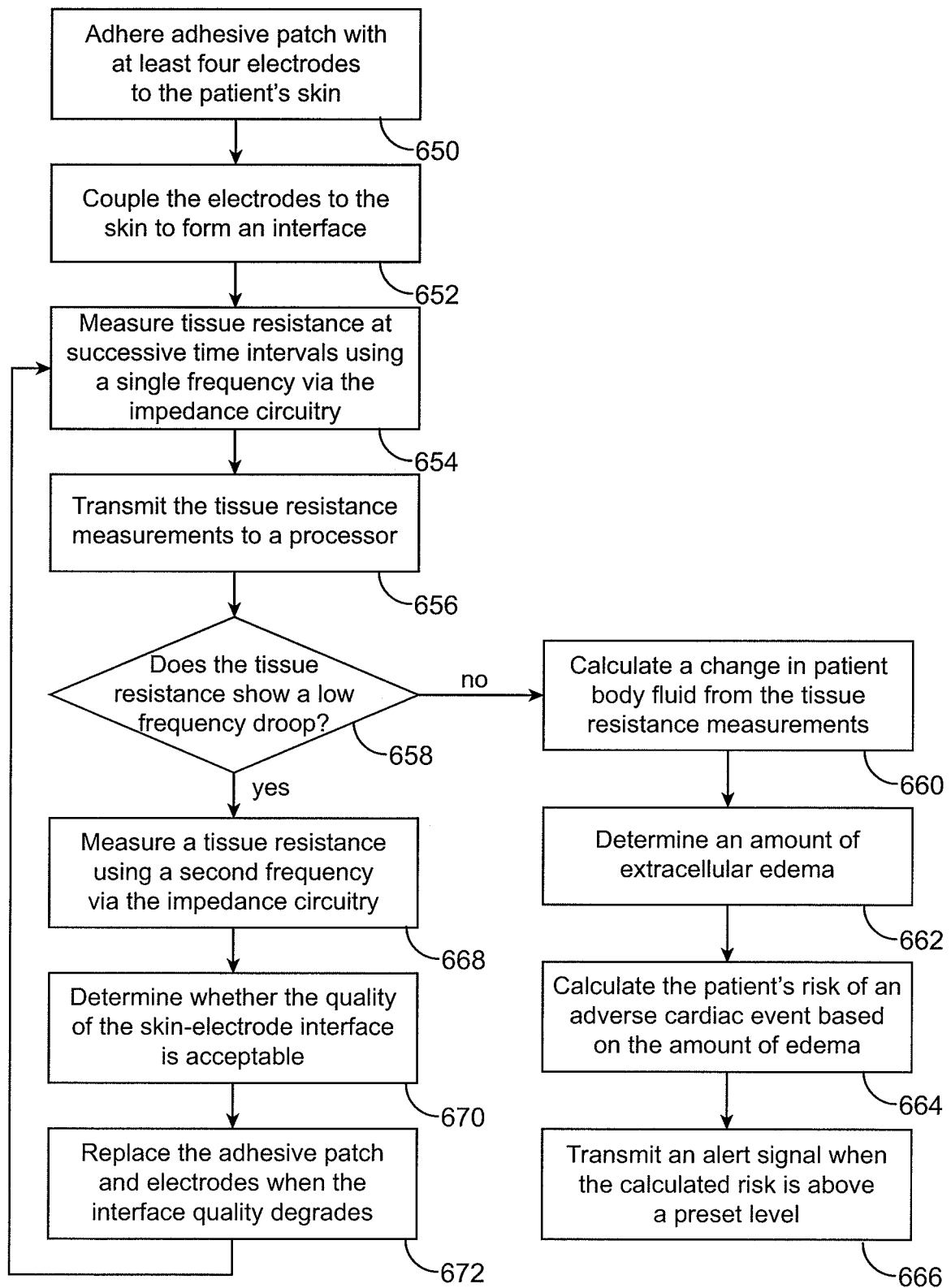


FIG. 5D

25 / 27

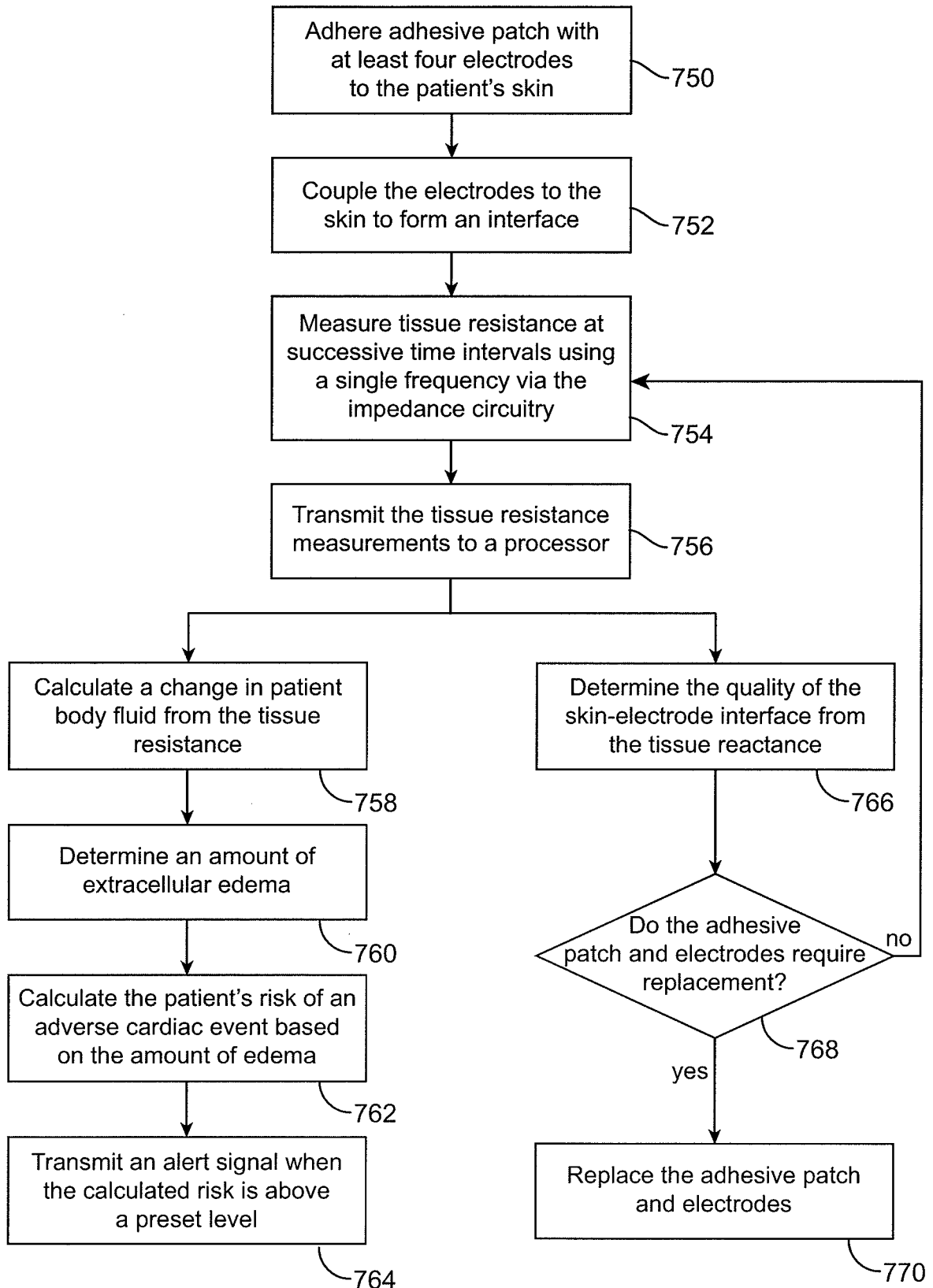


FIG. 5E

26 / 27

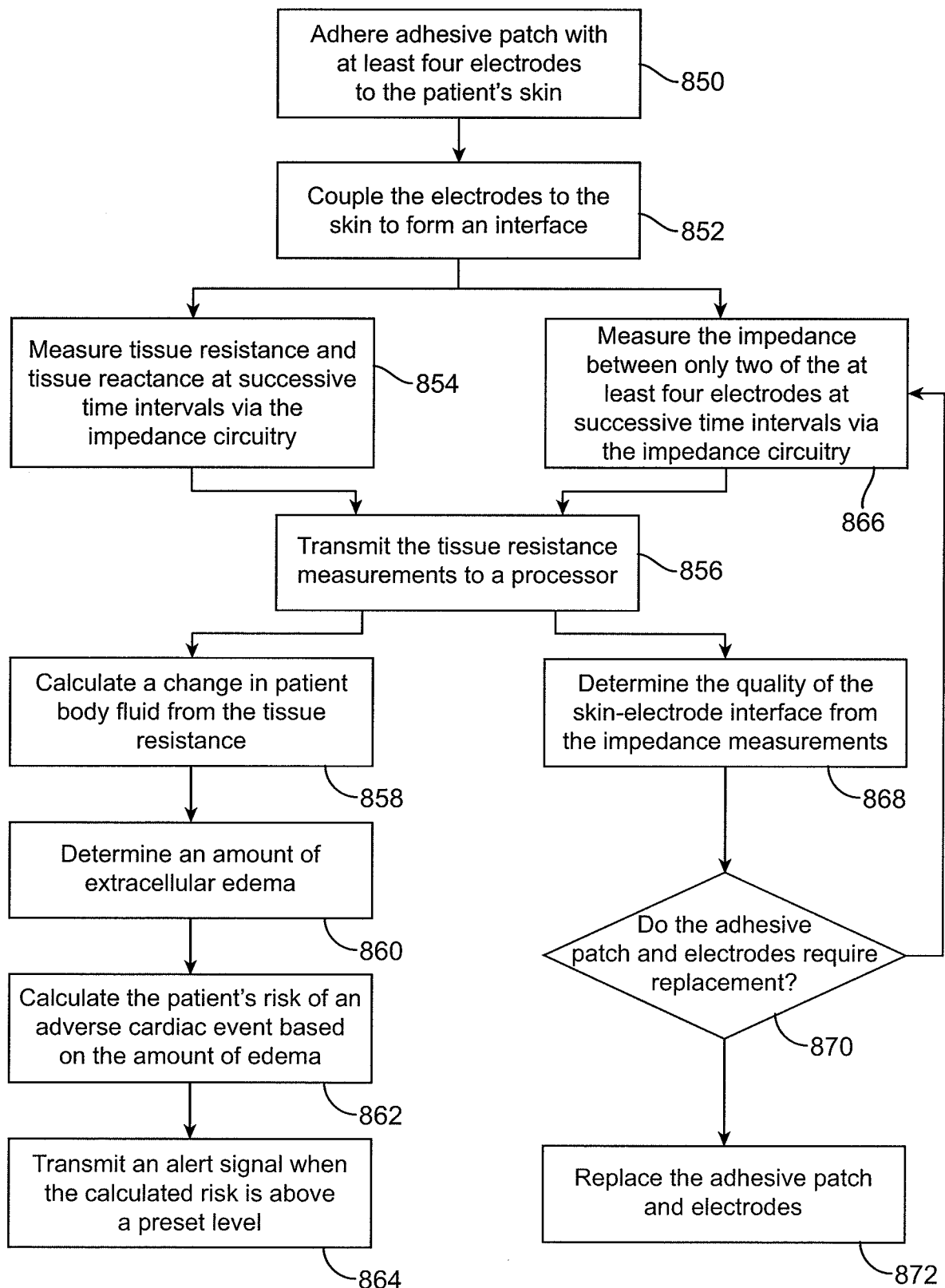


FIG. 5F

27 / 27

