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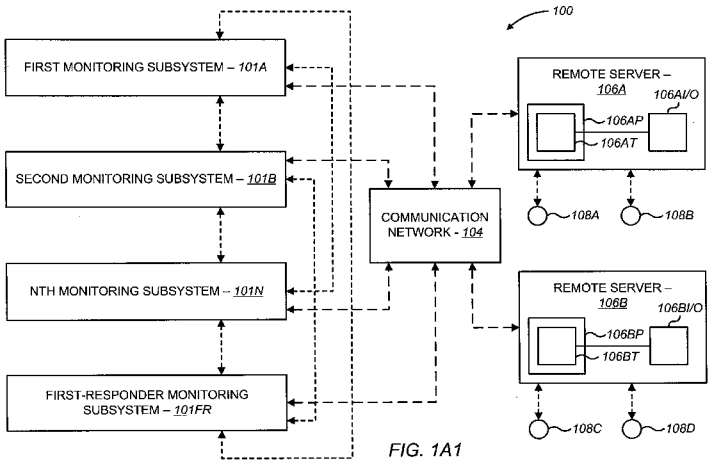

FIG. 1A1

(57) **Abstract**: Devices, system, and methods for monitoring the physiological status of one or more persons and/or for coordination of medical treatment of one or more persons are provided. A monitoring system can comprise an adherent support configured to adhere to the skin of a person, one or more physiological sensors coupled with the support and supported with the support, a processor coupled with the one or more physiological sensors, and an input/output device configured to display at least one of a condition for the monitored person and/or data for the monitored person. A monitoring system can further comprise a monitoring subsystem for use by a first responder in locating and/or treating a monitored person.

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ACUTE PATIENT MANAGEMENT FOR MILITARY AND EMERGENCY APPLICATIONS

BACKGROUND

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application claims priority to U.S. Application No. 61/160,245, filed on March 13, 2009 (Attorney Docket No. 026843-04600US), the full disclosures of which are incorporated herein by reference.

[0002] 1. Field of the Invention. The present invention relates to monitoring the physiological status of one or more persons in potentially urgent situations such as military combat. Although embodiments make specific reference to monitoring the physiological status of and coordination of medical treatment for one or more soldiers with wireless communication, the devices, systems, and methods described herein may be used in many other situations where physiological monitoring and wireless communication are used.

[0003] A person engaged in a strenuous activity may be at an increased risk of injury and unaware of the increased risk. For example, the person may experience a condition that can be treated so as to minimize harm. However, in at least some instances the person may be unaware of the condition due to engagement in the strenuous activity. Examples of conditions that may be treated with appropriate action include cardiac arrhythmia, dehydration and hypothermia. Work in relation to embodiments of the present invention suggests that known devices, systems, and methods for making a person aware of their present physiological status and for ensuring that such a person can receive prompt and appropriate medical attention when injured may be less than ideal. Persons engaged in strenuous activity may not want to be encumbered by additional equipment that can be used to monitor their condition as this monitoring equipment can be somewhat cumbersome and in at least some instances may interfere with performance of the strenuous activity. This may be especially true with respect to persons engaged in strenuous and/or dangerous activities such as military combat and fire fighting where performance of the strenuous and/or dangerous activities may be a matter of life and death.

[0004] Prompt medical attention to an injured person may avoid or lessen the severity of injury. However, people who are engaged in strenuous and/or dangerous activities may be located remote from treatment facilities. For example, a soldier or a firefighter who is wounded in the field, may be remote from a medical treatment facility that can provide prompt medical attention in at least some instances. Although a first responder may be able to provide at least some care, the first responder may have limited knowledge regarding how to diagnose and/or treat certain types of injuries. Work in relation to embodiments of the present invention suggests that current methods of assisting a first responder with limited knowledge are less than ideal.

[0005] Therefore, a need exists for improved devices, systems, and methods for monitoring and treatment of people engaged in strenuous and dangerous activities. Ideally, such improved monitoring and/or coordination of medical treatment would avoid at least some of the shortcomings of the present devices, systems, and methods.

[0006] 2. Description of the Background Art. The following U.S. Patents and Publications may describe relevant background art: 3,170,459; 3,370,459; 3,805,769; 3,845,757; 3,972,329; 4,121,573; 4,141,366; 4,838,273; 4,955,381; 4,981,139; 5,080,099; 5,335,664; 5,353,793; 5,511,553; 5,544,661; 5,558,638; 5,724,025; 5,772,586; 5,862,802; 6,047,203; 6,117,077; 6,129,744; 6,198,394; 6,225,901; 6,385,473; 6,416,471; 6,454,707; 6,527,711; 6,527,729; 6,551,252; 6,595,927; 6,595,929; 6,605,038; 6,645,153; 6,795,722; 6,821,249; 6,980,851; 7,020,508; 7,054,679; 7,153,262; 7,215,991; 7,294,105; 7,336,187; 7,382,247; 2003/0092975; 2004/0225203; 2005/0113703; 2005/0131288; 2005/0280531; 2006/0010090; 2006/0031102; 2006/0066449; 2006/0089679; 2006/122474; 2006/0155183; 2006/0224051; 2006/0264730; 2007/0021678; 2007/0038038; 2008/0224852; and 2008/0287752.

SUMMARY

[0007] Embodiments of the present invention relate to monitoring the physiological status of one or more persons. A system can be provided for monitoring one or more persons. The monitoring system can be used to monitor one or more persons engaged in an activity with a risk of injury with minimal interference from the monitoring system, which may comprise an adherent device configured to adhere to the skin of the person. The adherent device can be configured stretch with the skin of the person so as to minimize interference of the adherent device and allow the device to remain adhered to the skin, for example when the person engages in strenuous activity. The adherent device can measure data of the monitored person, for

example one or more of physiological data, location data, activity data or user orientation data. The adherent device can be configured to transmit the data wirelessly to a gateway device. The system can perform evaluation of the measured data so as to detect a event and/or condition of the monitored person. The monitoring system may also be used to monitor an injured person. The monitoring system can enable coordination of medical treatment of the injured person between a first responder and a remotely-located healthcare professional.

[0008] In many embodiments, the monitoring system comprises a network of monitoring subsystems. One or more monitoring subsystems can be used to monitor one or more persons. Each of the monitoring subsystems may comprise the adherent device coupled to the gateway and wireless communication circuitry configured to communicate with a secure wireless communication protocol, such as a military wireless communication protocol. The secure wireless communication protocol may comprise a robust protocol for use in a harsh environment such a frequency hopping protocol or a spread spectrum protocol, so as to minimize detection of the transmission and to ensure that the patient data can be transmitted reliably in a noisy environment, for example when frequencies are jammed. A first-responder subsystem can be used to monitor one or more of the monitoring subsystems with the secure wireless communication. Each of the monitoring subsystems and the first-responder subsystems may be configured to communicate with each other, for example with peer to peer communication.

[0009] In many embodiments, the monitoring system can further comprise one or more remote servers configured to communicate with one or more of the monitoring subsystems. The communication can occur via a communication network. The measured data can be communicated to the one or more remote servers for further evaluation and/or use by one or more healthcare professionals. The one or more healthcare professionals can provide instructions to the first responder via the communication network.

[0010] In many embodiments, a monitoring subsystem comprises an adherent device and an input/output device. The adherent device can be configured to adhere to a skin of a monitored person and comprise one or more physiological sensors for measuring data for the monitored person. The input/output device can be configured to be carried by the monitored person, or can be a separate unit that is configured to wirelessly communicate with the adherent device. The monitoring subsystem can comprise one or more processors comprising a tangible medium.

[0011] The devices, systems, and methods described herein provide a number of benefits. The active monitoring of at risk individuals provides the ability to identify, locate, and assess the condition of an at risk individual, for example, shortly after they suffer an injury, which may help to increase the chance that timely medical attention can be provided to the injured person. The active monitoring of at risk individuals may also help to avoid injuries by making the at risk person and/or a monitoring individual aware of a physiological status of the at risk person (*e.g.*, dehydration, blood loss, low body temperature, high body temperature, etc.), which may allow for appropriate action to be taken to avoid harm. The systems, devices and methods described herein can also be used to enable coordination between a first responder and a more experienced remotely-located healthcare professional, which may increase the quality of the medical attention provided to an injured person by a first responder. For example, vital signs of the injured person can be displayed to the first responder and the remotely-located healthcare professional for remote diagnosis and direction of treatment. In some embodiments, the first responder may have carry a subsystem comprising a processor having a tangible medium configured with instructions of a computer program embodied thereon to diagnosis a condition of the injured person and alert the first responder.

[0012] In a first aspect, a device for monitoring a person is provided. The device comprises an adherent device and a gateway. The adherent device comprises a support configured to adhere to a skin of the person. One or more physiological sensors is coupled with the support and supported with the support. The one or more physiological sensors is configured to measure physiological data of the person. Adherent device wireless communication circuitry is coupled to the one or more physiological sensors and configured to transmit the physiological data. A gateway comprising gateway wireless communication circuitry is configured to couple with the adherent device wireless communication circuitry and receive and transmit the physiological data. One or more of the adherent device wireless communication circuitry or the gateway wireless communication circuitry is configured to transmit the physiological data with a secure wireless communication protocol.

[0013] In many embodiments, the secure wireless communication protocol comprises a secure military wireless communication protocol and the secure military wireless communication protocol comprises one or more of a frequency hopping protocol or a spread spectrum protocol. In many embodiments the secure military wireless communication protocol comprises the spread spectrum protocol, and the spread spectrum protocol can comprise one or more of frequency-

hopping spread spectrum (FHSS), direct-sequence spread spectrum (DSSS), time-hopping spread spectrum (THSS), or chirp spread spectrum (CSS).

[0014] In many embodiments, the adherent device further comprises a processor comprising a tangible medium. The processor can be coupled with the one or more physiological sensors, the device wireless communication circuitry, and the support to support the processor and the device wireless communication with the skin of the person.

[0015] In many embodiments, the adherent device comprises a cover. The support can be configured to adhere to the skin when the skin is immersed in water. The support and the cover can be configured to stretch with the skin of the person when the support is adhered to the skin. The cover can comprise a breathable cover configured to dry when the skin is removed from the water. The support can comprise a breathable tape configured to dry when the support is removed from the water.

[0016] In many embodiments, the one or more physiological sensors can comprise at least one of a variety of sensors or be configured to measure at least one of a variety of data of the person. For example, the one or more physiological sensors can comprise at least one of an electrocardiogram sensor, an impedance sensor, or an accelerometer. The one or more physiological sensors can be configured to measure at least one of an electrocardiogram (ECG), a heart rate, a body fluid level, activity, respiration, a temperature, or a position of the person.

[0017] In many embodiments, the device for monitoring a person in an emergency situation further comprises a display coupled with the processor and configured to display physiological data of the person. The display can comprise the gateway. The processor comprising the tangible medium can be configured to determine a condition of the person in response to the measured data and display at least one of the condition or the measured data on the display in response to the condition of the person. The measured condition of the person can comprise at least one of a cardiac arrhythmia, dehydration, a fall, respiratory distress, stress, fever, or hypothermia. In many embodiments where measured data of the person is displayed on the display, the displayed measured data can comprise at least one of body temperature, heart rate, blood pressure, respiratory rate, or hydration level.

[0018] In many embodiments, the device for monitoring a person in an emergency situation is configured to provide for verbal communication between the person and a remotely-located

person. For example, the device can further comprises a microphone coupled with the device wireless communication circuitry or the gateway wireless communication circuitry and a speaker coupled with the device wireless communication circuitry or the gateway wireless communication circuitry, wherein the microphone and the speaker are configured to provide for verbal communication between the person and a remotely-located person.

[0019] In many embodiments, the device for monitoring a person in an emergency situation is configured to transmit and/or receive data for the person. For example, the gateway wireless communication circuitry can be configured to transmit physiological data of the person to a remote processor for remote processing to measure a condition of the person. At least one of the device wireless communication circuitry or the gateway wireless communication circuitry can be configured to receive remotely-processed data comprising a condition of the person. The remotely-processed data comprising a condition of the person can be displayed on the display in response to receiving the remotely-processed data comprising a condition of the person.

[0020] In another aspect, a system for monitoring a plurality of persons is provided. The system comprises a first subsystem configured to monitor a first person, a second subsystem configured to monitor a second person, and a first-responder subsystem for monitoring transmissions of each of the first and second monitoring subsystems.

[0021] In many embodiments, each of the first and second subsystems comprises an adherent support configured to adhere to a skin of the monitored person, one or more physiological sensors coupled with the support and supported with the support, a global positioning system receiver (GPS) for determining a location of the monitored person, wireless communication circuitry, and a processor comprising a tangible medium and coupled with the one or more sensors, the GPS receiver, and the wireless communication circuitry. The one or more physiological sensors can be configured to measure physiological data of the monitored person. The processor can be configured to measure a condition of the monitored person and transmit at least one of the location of the person, the condition of the person, or the measured data of the person in response to measuring the condition of the person.

[0022] In many embodiments, the first-responder subsystem comprises wireless communication circuitry and a display. The first-responder subsystem wireless communication circuitry can be configured to receive data comprising at least one of the location of the monitored person, the condition of the monitored person, or the data of the monitored person

transmitted by at least one of the first or second subsystems. The first-responder subsystem can be configured to display data comprising at least one of the location of a monitored person, the condition of a monitored person, or measured data of a monitored person on the display in response to reception of the data.

[0023] In many embodiments, the system is configured for secure communications. For example, the wireless communication circuitry of each subsystem can be configured to communicate using a secure military wireless communication protocol.

[0024] In many embodiments, each of the first and second subsystems further comprises a display. Each of the first and second subsystems can be configured to display at least one of the condition of the person or measured data of the person on the display in response to measuring the condition of the person. Each of the first and second subsystems can comprise a device configured to alert the monitored person of displayed information. The device configured to alert can comprise a non-aural device.

[0025] In many embodiments, each of the first and second subsystems is configured to receive and retransmit data comprising at least one of a location of a monitored person, a condition of the monitored person, or measured data of the monitored person. Each of the first and second subsystems can further comprise an input device coupled with the processor. Each of the first and second subsystems can be configured such that a command can be input via the input device to at least one of enable or inhibit retransmission of received data. Each of the first and second subsystems can be configured such that a command can be received via the wireless communication circuitry to at least one of enable or inhibit retransmission of received data.

[0026] In many embodiments, the first-responder subsystem further comprises additional components. For example, the first-responder subsystem can further comprise a processor comprising a tangible medium and configured to measure a condition of a monitored person in response to received measured data of the monitored person. The first-responder subsystem can further comprise a GPS receiver for determining a location of the first-responder subsystem.

[0027] In many embodiments, a system for monitoring a plurality of persons further comprises a communication network and a remote server coupled with the communication network. The remote server can comprise a server processor and a server display. The server processor can comprise a tangible medium. The remote server can be configured to receive data originating

from at least one of the first, second, or first-responder subsystems. The data received by the remote server can comprise at least one of a location of a monitored person, a condition of a monitored person, or measured data of a monitored person. The remote server can be configured to display the received data of the monitored person on the server display. Each of the first-responder subsystem and the remote server can further comprise one or more communication devices comprising at least one of a microphone, speaker, camera, video camera, video display, or keyboard. The system can be configured to provide for verbal communication between a first responder and a remotely-located person via the first-responder subsystem and the remote server, respectively.

[0028] In another aspect, a method of monitoring a person having a skin is provided. The method comprises adhering an adherent measuring device to the skin of the person, measuring physiological data of the person when the device is adhered to the skin, and transmitting the physiological data by using a secure military wireless protocol.

[0029] In another aspect, an adherent device for monitoring a person in an emergency situation is provided. The device comprises a support configured to adhere to a skin of the person, one or more physiological sensors coupled with the support and supported with the support, and wireless communication circuitry coupled with the one or more physiological sensors. The one or more sensors are configured to measure physiological data of the person. The wireless communication circuitry is configured to transmit the physiological data by using a secure military communication protocol.

BRIEF DESCRIPTION OF THE DRAWINGS

[0030] Fig. 1A shows people engaged in a strenuous activity coupled to a monitoring system, according to embodiments of the present invention;

[0031] Figure 1A1 shows a simplified block diagram of a system for monitoring a plurality of persons, according to embodiments of the present invention;

[0032] Figure 1A2 diagrammatically illustrates some of the communications and/or data transfers that can occur between components of a monitoring system as in Figure 1A1 when used to monitor soldiers in the field, according to embodiments of the present invention;

[0033] Figure 1A3 shows a simplified block diagram of a monitoring subsystem as in Figure 1A1, according to embodiments of the present invention;

[0034] Figure 1A4 shows a simplified block diagram of a first-responder subsystem as in Figure 1A1, according to embodiments of the present invention;

[0035] Figure 1A5 shows a monitoring subsystem as in Figure 1A1 as coupled with a monitored person, according to embodiments of the present invention;

[0036] Figure 1B shows a bottom view of the adherent device as in Figure 1A comprising an adherent patch;

[0037] Figure 1C shows a top view of the adherent patch, as in Figure 1B;

[0038] Figure 1D shows a printed circuit board and electronic components positioned over the adherent patch, as in Figure 1C;

[0039] Figure 1D1 shows an equivalent circuit that can be used to determine optimal frequencies for determining hydration of the monitored person, according to embodiments of the present invention;

[0040] Figure 1E shows batteries positioned over the printed circuit board and electronic components as in Figure 1D;

[0041] Figure 1F shows a top view of an electronics housing and a breathable cover over the batteries, electronic components and printed circuit board as in Figure 1E;

[0042] Figure 1G shows a side view of the adherent device as in Figures 1A to 1F;

[0043] Figure 1H shown a bottom isometric view of the adherent device as in Figures 1A to 1G;

[0044] Figures 1I and 1J show a side cross-sectional view and an exploded view, respectively, of the adherent device as in Figures 1A to 1H;

[0045] Figures 1I1 and 1J1 show a side cross-sectional view and an exploded view, respectively, of an adherent device with a temperature sensor affixed to the gel cover, according to embodiments of the present invention;

[0046] Figure 1K shows at least one electrode configured to electrically couple to a skin of the monitored person through a breathable tape, according to embodiments of the present invention; and

[0047] Figures 2A and 2B show components of an adherent device comprising an adhesive patch and connection structures to provide strain relief so as to decouple the adhesive patch from an electronics module, according to embodiments of the present invention.

DETAILED DESCRIPTION

[0048] Embodiments of the present invention relate to monitoring the physiological status of one or more persons and/or coordination of medical treatment of one or more persons. Although embodiments make specific reference to monitoring the physiological status of and/or coordination of medical treatment for one or more soldiers in the field, the devices, systems, and methods described herein may be used to in many other instances. For example, many embodiments may be used to monitor one or more persons engaging in any activity with a risk of injury, especially dangerous activities (*e.g.*, military operations, law enforcement, fire fighting, logging, etc.). Many embodiments may also be used to coordinate medical treatment of an injured person. For example, many embodiments can be used to measure data for the monitored person (*e.g.*, physiological data, location, physical orientation, activity level) for subsequent evaluation and/or use, for example by a first responder and/or by a remotely-located healthcare professional. Many embodiments provide a data and communication link between a first responder (*e.g.*, a military medic, a paramedic, a fire fighter, a police officer, a nurse, etc.) and a more experienced healthcare professional located remotely to the injured person, which can enable coordination between the first responder and the healthcare professional regarding medical treatment of the injured person.

[0049] In many embodiments, a network of body-borne monitoring subsystems are used to monitor one or more persons (*e.g.*, one or more uninjured persons that may be at risk of suffering an injury, one or more injured persons). Each monitoring subsystem can comprise an adherent monitoring device that comprises one or more sensors (*e.g.*, physiological sensor(s), microphone(s), accelerometer(s), global positioning system receiver(s) (GPS)) for monitoring the person (*e.g.*, electrocardiogram (ECG), heart rate, body fluid, activity, respiration, body temperature, location, body orientation, etc.). Each monitoring subsystem can comprise a unique identifier and location information, for example, via an identification code and a GPS receiver, respectively. Each adherent device can also be coupled with the one or more sensors, for example the above listed sensors. Separate components of a body-borne monitoring subsystem can be connected via wires and/or via wireless communication, for example, via a wireless personal area network (WPAN), for example Bluetooth or other known WPAN protocol. Each

body-borne monitoring subsystem comprises and is configured to communicate via a wireless body-borne gateway device. The wireless body-borne gateway device can be configured to communicate with other components of the network via a wireless local area network (WLAN) (*e.g.*, using an IEEE 802.11 series protocol or other known communication protocol), for example, to another monitoring subsystem, to a first-responder monitoring subsystem, and/or to a remote monitoring subsystem via a communication network. One or more persons (*e.g.*, medic(s), paramedic(s), monitored person(s), designated person(s), etc.) or a remote facility (*e.g.*, mobile army surgical hospital (MASH) unit, hospital, etc.) can act as a central hub for monitoring, diagnosis, and/or medical treatment coordination.

[0050] In many embodiments, the monitoring system and/or the monitoring subsystems can be configured for use in a specific environment in which they are intended to be used. For example, embodiments can be configured for military use, via ruggedized and/or hardened components and/or via the use of a secure military wireless communication protocol. The secure military wireless communication protocol can comprise one or more of a frequency hopping protocol or a spread spectrum protocol. Where the secure military wireless communication protocol used comprises a spread spectrum protocol, the spread spectrum protocol can comprise one or more of frequency-hopping spread spectrum (FHSS), direct-sequence spread spectrum (DSSS), time-hopping spread spectrum (THSS) or chirp spread spectrum (CSS). Sensor connections can be made to be durable, for example by soldering or through the use of other known robust connection methods. Electronic components can be made water resistant and/or waterproof (*e.g.*, via dip coating). The adherent monitoring devices can be made with water resistant and/or water proof materials and/or strong adhesives.

[0051] The information obtained from and/or generated for each monitored person can be used in a variety of ways. For example, one or more of the monitoring subsystems can comprise a body-borne display configured to display the information. For example, a wrist-mounted display can be used to provide basic information and/or alerts/alarms, for example heart rate, a dehydration alert/alarm, etc. The monitoring subsystem can comprise a device (*e.g.*, an aural device, a non-aural device) to apprise the person to displayed information (*e.g.*, data, alarm, alert) so that they may check the display. Alerts and/or alarms can be displayed on the display in a conspicuous manner (*e.g.*, flashing display, highlighted symbols, etc.).

[0052] The information can also be wirelessly communicated for remote viewing and/or further processing, for example to a computer monitored by a medic or to a computer at a hospital or a MASH unit. The unique identifier and/or the location information can be used by a first responder can get to the injured person and provide care appropriate for the specific person involved, as well as to locate the injured person for evacuation to a remote facility for additional medical treatment. Each monitored person can be paired with a first responder, for example one or more monitored soldiers can be paired with a medic.

[0053] Automated algorithms can be used for diagnosis, alerting, and/or alarming. The algorithms can reside at various locations within the monitoring system, for example within a monitoring subsystem (*e.g.*, within the adherent monitoring device, within the gateway, etc.) and/or within a remote location within the monitoring network (*e.g.*, within a remote computer monitored by a first responder or a healthcare professional, etc.).

[0054] Event detection can be coupled with the alerting and/or alarming features. The monitoring system can be configured to detect a variety of events, for example life-threatening cardiac arrhythmias, dehydration, falls, fainting, respiratory distress, stress, fever, and/or hypothermia.

[0055] The network of monitoring subsystems can be used in a variety of ways. For example, one or more persons (*e.g.*, soldiers, law enforcement officers, etc.) can be equipped with a body-borne monitoring subsystem for monitoring the one or more persons while engaged in a strenuous and/or dangerous activity. Similarly, a body-borne monitoring subsystem can be deployed on an injured person located remotely to a healthcare facility, for example an injured civilian located remote to a hospital, an injured soldier in the field, etc. The network can be configured to enable coordination between a first responder and a remotely-located healthcare professional, for example by communicating physiological data to the first responder and/or to the remotely-located healthcare profession and by providing a communication link between the first responder and the remotely-located healthcare professional. The remotely-located healthcare profession can then provide the first responder with informed guidance regarding treatment of the injured person. The first responder can request assistance, the assistance can be automatically provided, and/or the remotely-located healthcare facility/professional can use the network to intervene in the situation, for example by providing directions, ordering evacuation, etc..

[0056] Fig. 1A shows people engaged in a strenuous and dangerous activity coupled to a monitoring system 100. The system 100 comprises a first subsystem 101A coupled to a first person and a second system 101B coupled to a second person.

[0057] In many embodiments, a network of monitoring subsystems can be used to monitor a plurality of persons, for example, while they are engaged in an activity with a risk of injury. Figure 1A1 shows a simplified block diagram of system 100 for monitoring a plurality of persons, for example, soldiers engaged in military operations in the field. The system 100 comprises a plurality of body-borne monitoring subsystems 101A, 101B, 101N for monitoring a corresponding plurality of persons. The system 100 can also include one or more first-responder monitoring subsystems 101FR for use by one or more first responders in monitoring the persons monitored by the network. Each of the monitoring subsystems can be configured to communicate with any other monitoring subsystem in the network and to communicate with one or more remote servers 106A, 106B via a communication network 104, for example, an known military communication network when soldiers in the field are monitored. Each remote server 106A, 106B can comprise a remote-server processor 106AP, 106BP, which comprises a tangible medium 106AT, 106BT. The remote-server processor 106AP, 106BP can be coupled with a remote-server input/output device 106AI/O, 106BI/O. Healthcare professionals 108A, 108B, 108C, 108D can view information obtained and/or generated by the system 100, for example, via the remote-server input/output devices 106AI/O, 106BI/O.

[0058] In many embodiments, the monitoring subsystems 101A, 101B, 101N, 101FR are configured to provide for communication and/or data sharing within a sub-network comprising the monitoring subsystems. For example, each of the monitoring subsystems 101A, 101B, 101N, 101FR can be configured to monitor for and receive a communication and/or data transmitted from any of the other monitoring subsystems. Each of the monitoring subsystems can also be configured to retransmit a communication and/or data received from another monitoring subsystem so as to forward the communication and/or data received to another of the monitoring subsystems in the sub-network. Such communication and/or data sharing within the sub-network can be used so as to allow for communication between a specific monitoring subsystem and the first-responder monitoring subsystem 101FR and/or remote servers 106A, 106B, even where the originating monitoring subsystem is not within range of the first-responder monitoring subsystem and/or the communication network 104.

[0059] In many embodiments, the monitoring subsystems 101A, 101B, 101N, 101FR can be configured to remain normally passive (*i.e.*, monitoring for transmissions while refraining from transmitting) until the monitoring subsystem detects an event that justifies a transmission. During such passive periods, the monitoring subsystem can be monitoring the person via the one or more sensors. The data obtained can be processed using an event detection algorithm to monitor for events that may justify alerting the person, another monitoring subsystem, the first-responder monitoring subsystem, and/or a remotely-located healthcare professional. However, in many instances the monitored person may not be experiencing a physiological status that requires any attention from another person. For example, the monitored person may have a physiological status that is completely within acceptable bounds, or may have a physiological status that is compromised only to an extent that justifies alerting the monitored person of the status and/or directing the monitored person to take some appropriate action (*e.g.*, drink fluid to combat dehydration, take action to reduce or increase body temperature, etc.), but has not risen to a level of severity that justifies alerting another person in the network.

[0060] In many embodiments, a monitoring subsystem 101A, 101B, 101N, 101FR can be configured for automatic and/or manually initiated transmission of physiological data and/or monitored person condition upon detection of qualifying events (*e.g.*, physiological events, sound level, acceleration level, activity level). For example, a monitoring subsystem can be configured to automatically transmit physiological data and/or condition for the monitored person upon detection of certain physiological events, for example events for which the monitored person may not be able to initiate the transmission based on the nature of the physiological event. For other physiological events, for example less severe events where the monitored person is likely to be able to manually initiate the transmission, the monitoring subsystem can prompt the person to initiate the transmission. Such prompting may help to avoid a non-critical transmission, which may help to reduce power-consumption levels.

[0061] The use of prompting to avoid a non-critical transmission may also be beneficial when monitoring soldiers in the field. In some instances, transmissions may be used by opposing military forces to locate the transmitting soldier. The monitored soldier can assess the situation with respect to possibly providing location information to the opposing military forces and make a decision on whether to initiate the transmission.

[0062] A monitoring subsystem can also be configured for automatic and/or manually initiated retransmission of physiological data and/or condition received from another monitoring subsystem within the network of monitoring subsystems. For example, in an example scenario, a first injured soldier's monitoring subsystem detects an event that justifies transmission. The transmission from the first injured soldier's monitoring subsystem is then received by a second soldiers monitoring subsystem. The transmission from the first soldier's monitoring subsystem does not include a confirmation that the transmission was received by the first responder's (*e.g.*, military medic's) monitoring subsystem. In such a circumstance, the second soldier's monitoring subsystem can be configured to automatically retransmit the data or can be configured to prompt the second soldier to manually initiate the retransmission. The choice between automatic retransmission and manually initiated retransmission may be influenced by operational security considerations, for example whether automatic retransmission would compromise the safety of the second soldier and/or the military mission. The medic's monitoring subsystem 101FR can be configured to transmit a confirmation that the injured soldier's transmission was received, which can be used by the monitoring subsystems of uninjured soldiers to avoid unnecessary retransmission.

[0063] Figure 1A2 illustrates some of the communication and/or data transfers that can occur between components of the monitoring system 100 in an example scenario. The example scenario involves three monitored soldiers (SOL1), (SOL2), (SOL3) and an associated medic (M) responsible for providing medical assistance to the three monitored soldiers. At the beginning of the scenario, each of the three soldiers and the medic have a physiological status that is within acceptable bounds or is not severe enough to warrant transmission by their monitoring subsystem so that each of the monitoring subsystems are monitoring both the physiological status of the soldier while monitoring for transmissions from another monitoring subsystem. Next, the first soldier (SOL1) suffers an injury that is detected by the first soldier's monitoring subsystem. The injury is severe enough to result in a transmission by the first soldier's monitoring subsystem. The first soldier's transmission has an associated effective range (WLAN1-R) and therefore is received by the second soldier's (SOL2) monitoring subsystem while not being received by the third soldier's (SOL3) or the medic's (M) monitoring subsystems.

[0064] Because the medic has not yet received (and confirmed receipt) of the first soldier's transmission, the first soldier's transmission does not contain an indication that the medic has

received the transmission, a fact that can be used to enable and/or encourage subsequent retransmission until the medic does receive and confirm receipt of the transmission. Accordingly, the second soldier's monitoring subsystem then retransmits first soldier's transmission (either automatically or manually initiated as discussed above). The second soldier's retransmission has an associated effective range (WLAN2-R) and therefore is received by the third soldier's monitoring subsystem but not by the medic's monitoring subsystem. The third soldier's monitoring subsystem then retransmits the second soldier's retransmission (once again, either automatically or manually initiated as discussed above). The third soldier's retransmission has an effective range (WLAN3-R) and therefore is received by a first military communication network component 104A, for example a military vehicle mounted network communication component. The transmission can then be routed to a second military communication network component 104B where it can be retransmitted in a manner that reaches the medic (M). For example, the retransmission can be accomplished via a wide area wireless transmission 104BT (*e.g.*, from a communication balloon, airplane, satellite, etc.). The retransmission can also be accomplished by other components of the military network, for example by a third military communication network component 104C (*e.g.*, a military vehicle mounted component). The information received by the medic (*e.g.*, the injured soldier's identification, location, physiological status and/or condition) can be used by the medic to travel to the injured soldier and provide medical assistance to the injured soldier.

[0065] The monitoring system enables coordination of medical care of the injured soldier between the medic (M) and one or more remote servers 106A, 106B. The medic can communicate with one or more remotely-located healthcare professionals 108A, 108B, 108C, 108D via the one or more remote servers 106A, 106B. In many instances, the medic will be within range of a military communication network component, for example, component 104C. Where the medic is out of range of a network component (*e.g.*, component 104A, 104B, 104C), the above described retransmission can also be employed to place the medic in communication with a remotely-located healthcare professional via the remote server 106A, 106B. The one or more remotely-located healthcare professionals can also intervene to direct the medical attention based upon their evaluation of the received physiological data for the injured soldier.

[0066] The communication between the monitoring subsystems (*e.g.*, medic, soldier, etc.) and/or the remote servers can comprise known communication methods. Such communication can include both audio and visual communications, for example, video, pictures, audio, text,

data, etc. A secure military wireless communication protocol can be used, for example, for monitoring soldiers in the field. The secure military wireless communication protocol used can comprise one or more know protocols, for example, one or more of a frequency hopping protocol or a spread spectrum protocol. When the secure military wireless communication protocol used comprises a spread spectrum protocol, the spread spectrum protocol can comprise one or more of frequency-hopping spread spectrum (FHSS), direct-sequence spread spectrum (DSSS), time-hopping spread spectrum (THSS) or chirp spread spectrum (CSS).

[0067] Figures 1A3, 1A4, and 1A5 show a simplified block diagram of a monitoring subsystem 101A, 101B, 101N; a simplified block diagram of a first-responder subsystem 101FR; and components of a monitoring subsystem 101A, 101B, 101N as coupled with a monitored person (P), respectively, according to embodiments. The monitoring subsystem 101A, 101B, 101N comprises an adherent device 102 configured to adhere to a skin of the monitored person (P), an input/output device 102I/O, and one or more processors 102P comprising a tangible medium 102T. The adherent device 102 can comprise one or more sensors and one or more components, as described in more detail below. The input/output device 102I/O can be configured in a variety of ways. For example, the input/output device 102I/O can be configured as a wrist-mounted device that comprises input/out features (*e.g.*, display, touch buttons, touch screen, cursor control device, microphone, speaker, etc.). The monitoring subsystem 101A, 101B, 101N comprises wireless communication circuitry for coupling the subsystem 101A, 101B, 101N with other components of the monitoring system 100 via a WLAN as discussed above. The WLAN communication circuitry can be incorporated as a separate body-borne component or can be integrated with other monitoring subsystem components (*e.g.*, with the input/output device 102I/O, with the adherent device 102).

[0068] The various components of the monitoring subsystem 101A, 101B, 101N can be coupled in a variety of ways. For example, the adherent device 102 and the input/output device 102I/O can be coupled via a WPAN (*e.g.*, Bluetooth). The components can also be coupled via hard wiring, which may reduce power consumption. Where soldiers in the field are monitored, hard wiring may also reduce the number of transmissions that may be subject to monitoring by opposing forces. The adherent device 102 and the input/output device 102I/O can be coupled using a secure military wireless communication protocol. The secure military wireless communication protocol used can comprise one or more of a frequency hopping protocol or a spread spectrum protocol. Where the secure military wireless communication protocol used

comprises a spread spectrum protocol, the spread spectrum protocol used can comprise one or more of frequency-hopping spread spectrum (FHSS), direct-sequence spread spectrum (DSSS), time-hopping spread spectrum (THSS) or chirp spread spectrum (CSS).

[0069] Although the first-responder monitoring subsystem 101FR can be configured similar to or identical to the above described monitoring subsystems 101A, 101B, 101N, it can also be configured without an adherent device 102 as shown in Figure 1A4. The first-responder subsystem 101FR shown comprises a display 102FRD and wireless communication circuitry 101FRWC. The first-responder subsystem 101FR optionally comprises a GPS receiver 101FRGPS, one or more processors 102FRP comprising a tangible medium 102FRT, and one or more known communication devices 102FRCD (*e.g.*, microphone, speaker, camera, video camera, display, video monitor, keyboard, etc.). The first-responder subsystem 101FR is configured to monitor for and received data transmitted from the monitoring subsystems 101A, 101B, 101N (*e.g.*, location of the monitored person, a condition of the monitored person, measured data for the monitored person, etc.) and display data for the monitored person on the display 102FRD. The optional processor 102FRP can be used to process further process the received data of the monitored person, for example, as discussed below.

[0070] 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 monitored person and support the electronics and sensors on the monitored person (*e.g.*, soldier, etc.). The support can be porous and breathable so as to allow water vapor transmission. The support can also stretch with skin of the monitored person, so as to improve comfort and extend the time that the support can be adhered to the monitored person.

[0071] 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 comfort of the monitored person, such that the patch can be worn and/or tolerated by the monitored person 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 with another patch. Adherent devices with comfortable patches that can be worn for extended periods and in which patches can be replaced and the electronics modules reused are described in U.S. Pat. App. Nos. 12/209,288, entitled "Adherent Device with Multiple Physiological Sensors"; and

12/209,273, entitled "Adherent Device with Multiple Physiological Sensors", both filed on September 12, 2008, the full disclosures of which have been previously incorporated herein by reference. In many embodiments, the adherent patch comprises a tape, which comprises a material, preferably breathable, with an adhesive, such that trauma to the monitored person's 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 monitored person to provide improved comfort.

[0072] In many embodiments, the devices and systems described herein may be configured for a specific use (*e.g.*, military use, law enforcement, fire fighting, logging, etc.). Many configurations are possible. For example, an adherent device can be configured with a stronger adhesive. The components of the adherent device can be configured to be water resistant or water proof. The adherent device can be configured to be impact resistant and/or shock resistant. For example, the adherent device can comprise a hardened circuit board and durable connections between components (*e.g.*, soldered connections). In some embodiments, an adherent device configured for a specific use (*e.g.*, military use, etc.) may sacrifice some level of comfort in exchange for increased durability.

[0073] Figure 1A4 shows a monitored person (P) configured to be monitored by the monitoring system 100 via a monitoring subsystem 101. The monitored person (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 subsystem 101 comprises an adherent device 102. Adherent device 102 can be adhered to a monitored person (P) at many locations, for example thorax (T) of the monitored person (P). In many embodiments, the adherent device may adhere to one side of the monitored person, from which side data can be collected. Work in relation with embodiments of the present invention suggests that location on a side of the monitored person can provide comfort for the monitored person while the device is adhered to the monitored person.

[0074] Monitoring system 100 includes components to transmit data to a remote server 106A, 106B. The remote server 106A, 106B can be located in a different location from the monitored person, and can be located as far from the monitored person as a separate continent from the monitored person, for example the monitored person located on a first continent and the remote server located on a second continent.

[0075] Adherent device 102 can communicate wirelessly to an intermediate device (*e.g.*, input/output device 102I/O), for example with a single wireless hop from the adherent device on the monitored person to the intermediate device. The wireless communication between the adherent device 102 and the intermediate device can comprise known wireless communication protocols, for example, a secure military wireless communication protocol can be used (*e.g.*, when monitoring soldiers in the field under conditions requiring operational security). The secure military wireless communication protocol used can comprise one or more of a frequency hopping protocol or a spread spectrum protocol. Where the secure military wireless communication protocol used comprises a spread spectrum protocol, the spread spectrum protocol used can comprise one or more of frequency-hopping spread spectrum (FHSS), direct-sequence spread spectrum (DSSS), time-hopping spread spectrum (THSS) or chirp spread spectrum (CSS).

[0076] The intermediate device can communicate with the remote server 106A, 106B in many ways, for example via communication network 104 as discussed above. The intermediate device can communicate with the remote server 106A, 106B by using a secure military wireless communication protocol, for example, the above discussed protocols.

[0077] In many embodiments, monitoring system 100 comprises a distributed processing system with at least one processor comprising a tangible medium on the adherent device 102, at least one processor on the intermediate device (*e.g.*, input/output device 102I/O), and at least one remote-server processor 106AP, 106BP, 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 106AP, 106BP comprises a tangible medium 106AT, 106BT. Remote processor 106AP, 106BP may comprise a backend server located at a remote center.

[0078] The remote server 106A, 106B can be in communication with a healthcare professional 108A, 108B, 108C, 108D via a remote-server input/output device 106AI/O, 106BI/O and/or via a communication system (not shown), such as the Internet, an intranet, phone lines, wireless and/or satellite phone. Healthcare professional 108A, 108B, 108C, 108D can be in communication with the monitored person (P) and/or the first responder via the communication network 104.

[0079] In many embodiments, the adherent device may continuously monitor physiological parameters, communicate wirelessly with other monitoring subsystems 101A, 101B, 101N, 101FR, with the remote server 106A, 106B, and provide alerts and/or alarms when necessary. The system may comprise an adherent patch, which attaches to the monitored person's thorax and contains sensing electrodes, battery, memory, logic, and wireless communication capabilities. In some embodiments, the other monitoring subsystems 101A, 101B, 101N, 101FR and/or the remote server 106A, 106B receives the monitored person's data and applies an evaluation and/or prediction algorithm. When a flag is raised, a first responder or a remotely-located healthcare professional can communicate with the monitored person (*e.g.*, soldier, law enforcement officer, injured person, etc.), and/or the remotely-located healthcare professional may can communicate with the first responder (*e.g.*, medic (M), paramedic, firefighter, etc.) to allow for therapeutic intervention, for example to prevent decompensation.

[0080] 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 micro needle electrode, a pre-shaped electronics module to shape fabric to a thorax, a pinch onto roll of skin, or transcutaneous anchoring. 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 at least one of a dog bone, an hourglass, an oblong, a circular or an oval shape.

[0081] In many embodiments, the adherent device may comprise a reusable electronics module with replaceable patches, and each of the replaceable patches may include a battery. The module may collect cumulative data for approximately 90 days and/or the entire adherent component (electronics + patch) may be disposable. In a completely disposable embodiment, a "baton" mechanism may be used for data transfer and retention, for example baton transfer may include baseline information. In some embodiments, the device may have a rechargeable module, and may use dual battery and/or electronics modules, wherein one module 102A can be recharged using a charging station 103 while the other module 102B is placed on the adherent patch with connectors.

[0082] System 100 can perform the following functions: initiation, programming, measuring, storing, analyzing, communicating, predicting, and displaying. The adherent device may contain a subset of the following physiological sensors: bioimpedance, respiration, respiration rate variability, heart rate (ave, min, max), heart rhythm, heart-rate variability (hereinafter "HRV"), heart-rate turbulence (hereinafter "HRT"), heart sounds (*e.g.*, S3), respiratory sounds, blood pressure, activity, posture, wake/sleep, orthopnea, temperature/heat flux, and weight. The activity sensor may comprise one or more of the following: ball switch, accelerometer, minute ventilation, HR, bioimpedance noise, skin temperature/heat flux, BP, muscle noise, posture.

[0083] In many embodiments, instructions are transmitted from remote server 106A, 106B to a processor supported with the adherent patch on the monitored person, and the processor supported with the monitored person can receive updated instructions for treatment of the monitored person and/or monitoring, for example while worn by the monitored person.

[0084] Figure 1B shows a bottom view of adherent device 102 as in Figure 1A4 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 monitored person when placed on the monitored person. In many embodiments, adherent patch 110 comprises a tape 110T which is a material, preferably breathable, with an adhesive 116A. Monitored person side 110A comprises adhesive 116A to adhere the patch 110 and adherent device 102 to the monitored person. 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 monitored person. 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 monitored person. 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.

[0085] Figure 1C shows a top view of the adherent patch 102, as in Figure 1B. Adherent patch 102 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 monitored person. The printed circuit board (hereinafter "PCB") may comprise completely flex PCB, combined flex PCB and/or rigid PCB boards connected by cable.

[0086] 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 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 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.

[0087] Electronic components 130 comprise components to take physiologic measurements, transmit data (*e.g.*, to an intermediate device 102I/O, to another monitoring subsystem 101A, 101B, 101N, 101FR, to a remote server 106A, 106B), and receive commands from the remote servers 106A, 106B (*e.g.*, via communication network 104). 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 microphone circuitry 142 to detect an audio signal from within the monitored person, 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.

[0088] Electronics circuitry 130 may comprise a temperature sensor 177, for example a thermistor in contact with the skin of the monitored person, and temperature sensor circuitry 144 to measure a temperature of the monitored person, for example a temperature of the skin of the monitored person. A temperature sensor 177 may be used to determine the sleep and wake state of the monitored person. The temperature of the monitored person can decrease as the monitored person goes to sleep and increase when the monitored person wakes up.

[0089] Work in relation to embodiments of the present invention suggests that skin 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 monitored person 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 monitored person, for example deeper tissues in the thorax.

[0090] Electronics circuitry 130 may comprise a processor 146. Processor 146 comprises a tangible medium, for example read only memory (ROM), electrically erasable programmable read only memory (EEPROM) and/or random access memory (RAM). 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 102 comprises a distributed processor system, for example with multiple processors on device 102.

[0091] In many embodiments, electronics components 130 comprise wireless communications circuitry 132 to communicate with an intermediate device (*e.g.*, input/output device 102I/O), another monitoring subsystem 101A, 101B, 101N, 101FR, and/or remote server 106A, 106B (*e.g.*, via communication network 104). 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 circuitry and the accelerometer to transmit to a remote server 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 server 106A, 106B with a single wireless hop. 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 server is capable of issuing commands to control data collection.

[0092] An intermediate device (*e.g.*, input/output device 102I/O) 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 one or more of the other monitoring subsystems 101A, 101B, 101N, 101FR (*e.g.*, the first-responder monitoring subsystem 101FR) and/or a remote server 106A, 106B. The data collection system can transmit data in response to commands from one or more of the other monitoring subsystems and/or the remote server 106A, 106B and/or in response to commands from the adherent device.

[0093] 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 comprise a 3-axis accelerometer to measure at least one of an inclination, a position, an orientation or acceleration of the monitored person in three dimensions. Work in relation to embodiments of the present invention suggests that three dimensional orientation of the monitored person 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.

[0094] 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 measure the impedance of the monitored person to determine respiration rate and/or the hydration of the monitored person.

[0095] Figure 1D1 shows an equivalent circuit 152 that can be used to determine optimal frequencies for measuring hydration of the monitored person. Work in relation to embodiments of the present 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 monitored person's 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 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 extracellular fluid and to cardiac decompensation, and that extracellular resistance 158 and 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 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 hydration of the monitored person.

[0096] In many embodiments, impedance circuitry 136 can be configured to determine respiration of the monitored person. 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.

[0097] 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 122C, 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, for example with switches as described in U.S. App. No. 12/209,288, the full disclosure of which has been previously incorporated herein by reference.

[0098] 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.

[0099] Figure 1F shows a top view of a cover 162 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 162 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 162 can be adhered to adherent patch 110 with an adhesive 164 on an underside of cover 162. 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.

[0100] Cover 162 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 162 may comprise many known breathable materials, for example polyester, polyamide, nylon and/or elastane (Spandex™). The breathable fabric may be coated to make it water resistant, waterproof, and/or to aid in wicking moisture away from the patch.

[0101] Figure 1G shows a side view of adherent device 102 as in Figures 1A to 1F. Adherent device 102 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 102 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) .

[0102] Figure 1H shown a bottom isometric view of adherent device 102 as in Figures 1A to 1G. Adherent device 102 comprises a width 174, for example a maximum width along a width profile of adherent device 102. 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).

[0103] Figures 1I and 1J show a side cross-sectional view and an exploded view, respectively, of adherent device 102 as in Figures 1A to 1H. In many embodiments, device 102 comprises several layers.

[0104] Figures 1I1 and 1J1 show a side cross-sectional view and an exploded view, respectively, of embodiments of the adherent device with a temperature sensor affixed to the gel cover. In these embodiments, gel cover 180 extends over a wider area than in the embodiments shown in Figures 1I and 1J. Temperature sensor 177 is disposed over a peripheral portion of gel cover 180. 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 monitored person. 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 though 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.

[0105] The adherent device comprises electrodes 112A1, 112B1, 112C1 and 112D1 configured to couple to tissue through apertures in the breathable tape 110T. Electrodes 112A1, 112B1, 112C1 and 112D1 can be fabricated in many ways. For example, electrodes 112A1, 112B1, 112C1 and 112D1 can be printed on a flexible connector 112F, such as silver ink on polyurethane. Breathable tape 110T comprise apertures 180A1, 180B1, 180C1 and 180D1. Electrodes 112A1, 112B1, 112C1 and 112D1 are exposed to the gel through apertures 180A1, 180B1, 180C1 and 180D1 of breathable tape 110T. Gel 114A, gel 114B, gel 114C and gel 114D

can be positioned over electrodes 112A1, 112B1, 112C1 and 112D1 and the respective portions of breathable tape 110T proximate apertures 180A1, 180B1, 180C1 and 180D1, so as to couple electrodes 112A1, 112B1, 112C1 and 112D1 to the skin of the monitored person. The flexible connector 112F 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 112F may comprise flexible connector 122A to provide strain relief, as described above.

[0106] 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 inhibiters, 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 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 mm^2 to about 1500mm^2, for example a range from about 250 mm^2 to about 750 mm^2, and in specific embodiments within a range from about 350 mm^2 to about 650 mm^2. 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 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.

[0107] 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 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 shaped, polygon shaped, or round. In specific embodiments, a dimension across a width of each electrodes is within a range from about 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 monitored person is within a range from about 25mm^2 to about 1500 mm^2 , for example from about 75 mm^2 to about 150 mm^2. In many embodiments, the electrode comprises a tape that may cover the gel near the skin of the monitored person. 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.

[0108] 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 monitored person's body, and comprises a breathable material to allow moisture vapor and air to circulate to and from the skin of the monitored person 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 inhibiters, 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 monitored person 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 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 monitored person 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 (MVTR, g/m^2/24 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 (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 monitored person's skin when the patch is positioned on the skin of the monitored person. In many embodiments, the MVTR values above may correspond to a MVTR through both the gel cover and the breathable tape. The 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 discomfort of the monitored person, for example itching of the monitored person's skin.

[0109] 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 monitored person.

[0110] 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 embodiments, backing 111 comprises at least one of polyester, polyurethane, rayon, nylon, breathable plastic film; woven, nonwoven, spun lace, 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".

[0111] 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 monitored person, 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 comfort for the monitored person.

[0112] 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.

[0113] 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/in^2, and this porosity can ensure that there is a certain amount of protection from external moisture for the hydrogel.

[0114] 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 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 a 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.

[0115] 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.

[0116] In many embodiments, device 102 includes a printed circuitry, for example a printed circuitry board (PCB) module that includes at least one PCB with electronics component 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 movement of the monitored person. 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 dog bone or dumbbell. 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.

[0117] 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 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.

[0118] 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 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, non-shielded wires with loops to allow independent motion of the PCB module relative to the electrodes.

[0119] In many embodiments, cover 162 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 162 can attach to adherent patch 110 with adhesive 116B. Cover 162 can comprise many known biocompatible cover materials, for example silicone. Cover 162 can comprise an outer polymer cover to provide smooth contour without limiting flexibility. In many embodiments, cover 162 may comprise a breathable fabric. Cover 162 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 (Spandex™) 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 monitored person.

[0120] In specific embodiments, cover 162 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 162 comprises at least 400% elongation. In specific embodiments, cover 162 comprises at least one of a polyester knit with 10-20% spandex or a woven polyamide with 10-20% spandex. In many embodiments, cover 162 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 comfort for the monitored person.

[0121] The breathable cover 162 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 monitored person. 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 monitored person. 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 162, and the stretching of the cover can be at least two dimensional along the surface of the skin of the monitored person.

[0122] Cover 162 can be attached to adherent patch 110 with adhesive 116B such that cover 162 stretches and/or retracts when adherent patch 110 stretches and/or retracts with the skin of the monitored person. For example, cover 162 and adherent patch 110 can stretch in two dimensions along length 170 and width 174 with the skin of the monitored person, 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 162 to slide over electronics housing 160, such that motion and/or stretching of cover 162 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 monitored person when the breathable tape is adhered to the skin of the monitored person, for example along two dimensions comprising length 170 and width 174.

[0123] The stretching of the adherent device 102 along length 170 and width 174 can be characterized with a composite modulus of elasticity determined by stretching of cover 162, 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 more than about 0.3MPa at strain of no more than about 5%. These values apply to any transverse direction against the skin.

[0124] The stretching of the adherent device 102 along length 170 and width 174, may also be described with a composite stretching elongation of cover 162, adherent patch 110 comprising breathable tape breathable tape 110T and gel cover 180. The composite stretching elongation may comprise a percentage of at least about 10% when 3 kg load is a applied, for example at least about 100% when the 3 kg load applied. These percentages apply to any transverse direction against the skin.

[0125] 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 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 mm^2, for example with dimensions of approximately 10 mm by 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 monitored person along length 170 and width 174 when the patch is adhered to the monitored person.

[0126] 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 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.

[0127] Electronics components 130 can be affixed to printed circuit board 120, for example 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 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 breathable tape to move with the skin of the monitored person, 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.

[0128] An air gap 169 may extend from adherent patch 110 to the electronics module and/or PCB, so as to provide comfort for the monitored person. Air gap 169 allows adherent patch 110 and breathable tape 110T to remain supple and move, for example bend, with the skin of the monitored person 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 breathable cover. This release of moisture from the skin through the air gap can minimize, and even avoid, excess moisture, for example when the monitored person sweats and/or showers.

[0129] 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.

[0130] Cover 162 may comprise many shapes. In many embodiments, a geometry of cover 162 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, the geometric of cover 162 comprises at least one of an oblong, an oval or a round shape.

[0131] Cover 162 may comprise many thicknesses and/or weights. In many embodiments, cover 162 comprises a fabric weight: within a range from about 100 to about 200 g/m^2, for example a fabric weight within a range from about 130 to about 170 g/m^2.

[0132] In many embodiments, cover162 can attach the PCB module to adherent patch 110 with cover 162, so as to avoid interaction of adherent patch 110C with the PCB having the electronics mounted therein. Cover 162 can be attached to breathable tape 110T and/or electronics housing 160 comprising over the encapsulated PCB. In many embodiments, adhesive 116B attaches cover 162 to adherent patch 110. In many embodiments, cover 162 attaches to adherent patch 110 with adhesive 116B, and cover 162 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 162, for example with a gap 169 between the PCB module and adherent patch. In many 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 162, so as to provide comfort for the monitored person.

[0133] In many embodiments, adhesive 116B is configured such that adherent patch 110 and cover 162 can be breathable from the skin to above cover 162 and so as to allow moisture vapor and air to travel from the skin to outside cover 162. 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 162. Adhesive 116B 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 162 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 monitored person moves.

[0134] 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 monitored person.

[0135] 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.

[0136] 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 162, 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 monitored person 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 person for at least 90 days with at least one electronics module, for example with two reusable electronics modules.

[0137] At least one electrode 112A can extend through at least one aperture 180A in the breathable tape 110.

[0138] 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.

[0139] Figure 1K shows at least one electrode 190 configured to electrically couple to a skin of the monitored person 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 electrode through the breathable tape, for example with the gel.

[0140] Figures 2A and 2B show components of an adherent device 200 comprising an adhesive patch 210 and connection structures to provide strain relief so as to decouple the patch from an electronics module 220. Adherent device 200 comprises many structures similar to those shown above. Adherent device 200 comprises electrodes 212A, 212B, 212C and 212D affixed to adherent patch 210. Adherent device 200 may comprise a gel, for example gel 214A over the electrodes, for example over electrode 212A. Electrodes 212A, 212B, 212C and 212D are connected to electronics module 220 with structures 223A, 223B, 223C and 223D. Electronics module 220 may comprise PCB with components mounted thereon, as described above. In many embodiments, structures 223A, 223B, 223C and 223D connect adhesive patch 210 to electronics module 220 with a flexible connection. In many embodiments, structures 223A, 223B, 223C and 223D comprise curved flexible wires, for example spirals and/or loops of wire that connect electrodes 212A, 212B, 212C and 212D to an electronics module 220. Structures 223A, 223B, 223C and 223D may comprise polyester film with silver traces coupled to silver/silver chloride electrodes to provide strain relief. Adhesive patch 210 comprises a lower side 210A toward the skin of the monitored person and an upper side 210B away from the skin of the monitored person. Adhesive 216B is disposed on upper side 210B of patch 210 to connect the adhesive patch to a cover, as described above. Electronics module 220 can be connected to the cover, as described above, such that module 220 is suspended above adhesive patch 210 with a gap 269. Gap 269 can decouple movement between patch 210 and electronic module 220. In many embodiments, gap 260 allows adhesive patch 210 and/or device 200 to breathe, for example from the skin through the patch and cover to the outside of the cover, as described above.

[0141] In many embodiments, gap 269 can extend from adherent patch 210 to the electronics module 220 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.

[0142] 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 present invention should be limited solely by the appended claims.

WHAT IS CLAIMED IS:

1. A device for monitoring a person, the device comprising:

an adherent device comprising,

a support configured to adhere to a skin of the person,

one or more physiological sensors coupled with the support and supported with the support, the one or more sensors configured to measure physiological data of the person, and

adherent device wireless communication circuitry coupled to the one or more physiological sensors and configured to transmit the physiological data; and

a gateway comprising gateway wireless communication circuitry configured to couple with the adherent device wireless communication circuitry and receive and transmit the physiological data;

wherein one or more of the device wireless communication circuitry or the gateway wireless communication circuitry is configured to transmit the physiological data with a secure wireless communication protocol.

2. The device of claim 1, wherein the secure wireless communication protocol comprises a secure military wireless communication protocol comprising one or more of a frequency hopping protocol or a spread spectrum protocol.

3. The device of claim 2 wherein the secure military wireless communication protocol comprises the spread spectrum protocol and wherein the spread spectrum protocol comprises one or more of frequency-hopping spread spectrum (FHSS), direct-sequence spread spectrum (DSSS), time-hopping spread spectrum (THSS) or chirp spread spectrum (CSS).

4. The device of claim 1, wherein the adherent device further comprises a processor comprising a tangible medium coupled with the one or more physiological sensors, and the device wireless communication circuitry, the support coupled with the processor and the device wireless communication circuitry to support the processor and the device wireless communication circuitry with the skin of the person.

5. The device of claim 4, wherein the adherent device comprises a cover and wherein the support is configured to adhere to the skin when the skin is immersed in water and

wherein the support and the cover are configured to stretch with the skin of the person when the support is adhered to the skin.

6. The device of claim 5, wherein the cover comprises a breathable cover configured to dry when the skin is removed from the water and wherein the support comprises a breathable tape configured to dry when the support is removed from the water.

7. The device of claim 4, wherein the one or more physiological sensors comprise at least one of an electrocardiogram sensor, an impedance sensor, or an accelerometer.

8. The device of claim 4, wherein the one or more physiological sensors is configured to measure at least one of an electrocardiogram (ECG), a heart rate, a body fluid level, activity, respiration, a temperature, or a position of the person.

9. The device of claim 4, further comprising a display coupled with the processor and configured to display physiological data of the person.

10. The device of claim 9, wherein the display comprises the gateway.

11. The device of claim 9, wherein the processor comprising a tangible medium is configured to determine a condition of the person in response to the measured data and display at least one of the condition or the measured data on the display in response to the condition of the person.

12. The device of claim 11, wherein the measured condition of the person comprises at least one of a cardiac arrhythmia, dehydration, a fall, respiratory distress, stress, fever, or hypothermia.

13. The device of claim 11, wherein measured data of the person is displayed on the display, and wherein the displayed measured data comprises at least one of body temperature, heart rate, blood pressure, respiratory rate, or hydration level.

14. The device of claim 4, further comprising:

a microphone coupled with the device wireless communication circuitry or the gateway wireless communication circuitry; and

a speaker coupled with the device wireless communication circuitry or the gateway wireless communication circuitry,

wherein the microphone and the speaker are configured to provide for verbal communication between the person and a remotely-located person.

15. The device of claim 4, wherein the gateway wireless communication circuitry is configured to transmit physiological data of the person to a remote processor for remote processing to measure a condition of the person.

16. The device of claim 15, wherein at least one of the device wireless communication circuitry or the gateway wireless communication circuitry is configured to receive remotely-processed data comprising a condition of the person.

17. The device of claim 16, wherein the remotely-processed data comprising a condition of the person is displayed on the display in response to receiving the remotely-processed data comprising a condition of the person.

18. A system for monitoring a plurality of persons, the system comprising:

a first subsystem configured to monitor a first person;

a second subsystem configured to monitor a second person; and

a first-responder subsystem for monitoring transmissions of each of the first and second monitoring subsystems.

19. The system of claim 18 wherein each of the first and second subsystems comprises

an adherent support configured to adhere to a skin of the monitored person,

one or more physiological sensors coupled with the support and supported with the support, the one or more sensors configured to measure physiological data of the monitored person,

a global positioning system receiver (GPS) for determining a location of the monitored person,

wireless communication circuitry, and

a processor comprising a tangible medium and coupled with the one or more sensors, the GPS receiver, and the wireless communication circuitry, the processor configured to measure a condition of the monitored person and transmit at least one of the location of the person, the condition of the person, or the measured data of the person in response to measuring the condition of the person,

wherein the first-responder subsystem comprises

wireless communication circuitry configured to receive data comprising at least one of the location of a monitored person, the condition of a monitored person, or the data of a monitored person transmitted by at least one of the first or second subsystems, and

a display,

wherein the first-responder subsystem is configured to display data comprising at least one of the location of a monitored person, the condition of a monitored person, or measured data of a monitored person on the display in response to reception of said data.

20. The system of claim 19, wherein the wireless communication circuitry of each subsystem is configured to communicate using a secure military wireless communication protocol.

21. The system of claim 19, wherein each of the first and second subsystems further comprises a display, and wherein each of the first and second subsystems is configured to display at least one of the condition of the person or measured data of the person on the display in response to measuring the condition of the person.

22. The system of claim 19, wherein each of the first and second subsystems comprises a device configured to alert the monitored person of displayed information.

23. The system of claim 22, wherein the device configured to alert comprises a non-aural device.

24. The system of claim 19, wherein each of the first and second subsystems is configured to receive and retransmit data comprising at least one of a location of a monitored person, a condition of the monitored person, or measured data of the monitored person.

25. The system of claim 24, wherein each of the first and second subsystems further comprises an input device coupled with the processor.

26. The system of claim 25, wherein each of the first and second subsystems are configured such that a command can be input via the input device to at least one of enable or inhibit retransmission of received data.

27. The system of claim 24, wherein each of the first and second subsystems are configured such that a command can be received via the wireless communication circuitry to at least one of enable or inhibit retransmission of received data.

28. The system of claim 19, wherein the first-responder subsystem further comprises a processor comprising a tangible medium and configured to measure a condition of a monitored person in response to received measured data of the monitored person.

29. The system of claim 19, wherein the first-responder subsystem further comprises a GPS receiver for determining a location of the first-responder subsystem.

30. The system of claim 19, further comprising:

a communication network; and

a remote server coupled with the communication network, the remote server comprising a server processor and a server display, the server processor comprising a tangible medium, the remote server configured to receive data originating from at least one of the first, second, or first-responder subsystems, the data comprising at least one of a location of a monitored person, a condition of a monitored person, or measured data of a monitored person, the remote server configured to display the received data of the monitored person on the server display.

31. The system of claim 30, wherein the each of the first-responder subsystem and the remote server further comprises one or more communication devices comprising at least one of a microphone, speaker, camera, video camera, video display, or keyboard.

32. The system of claim 31, and wherein the system is configured to provide for verbal communication between a first responder and a remotely-located person via the first-responder subsystem and the remote server, respectively.

33. A method of monitoring a person having a skin, the method comprising:

adhering an adherent measurement device to the skin of the person;

measuring physiological data when the device is adhered to the skin; and

transmitting the physiological data by using a secure military wireless communication protocol.

34. An adherent device for monitoring a person in an emergency situation, the device comprising:

a support configured to adhere to a skin of the person;

one or more physiological sensors coupled with the support and supported with the support, the one or more sensors configured to measure physiological data of the person; and

wireless communication circuitry coupled to the one or more physiological sensors,

wherein the wireless communication circuitry is configured to transmit the physiological data by using a secure military wireless communication protocol.

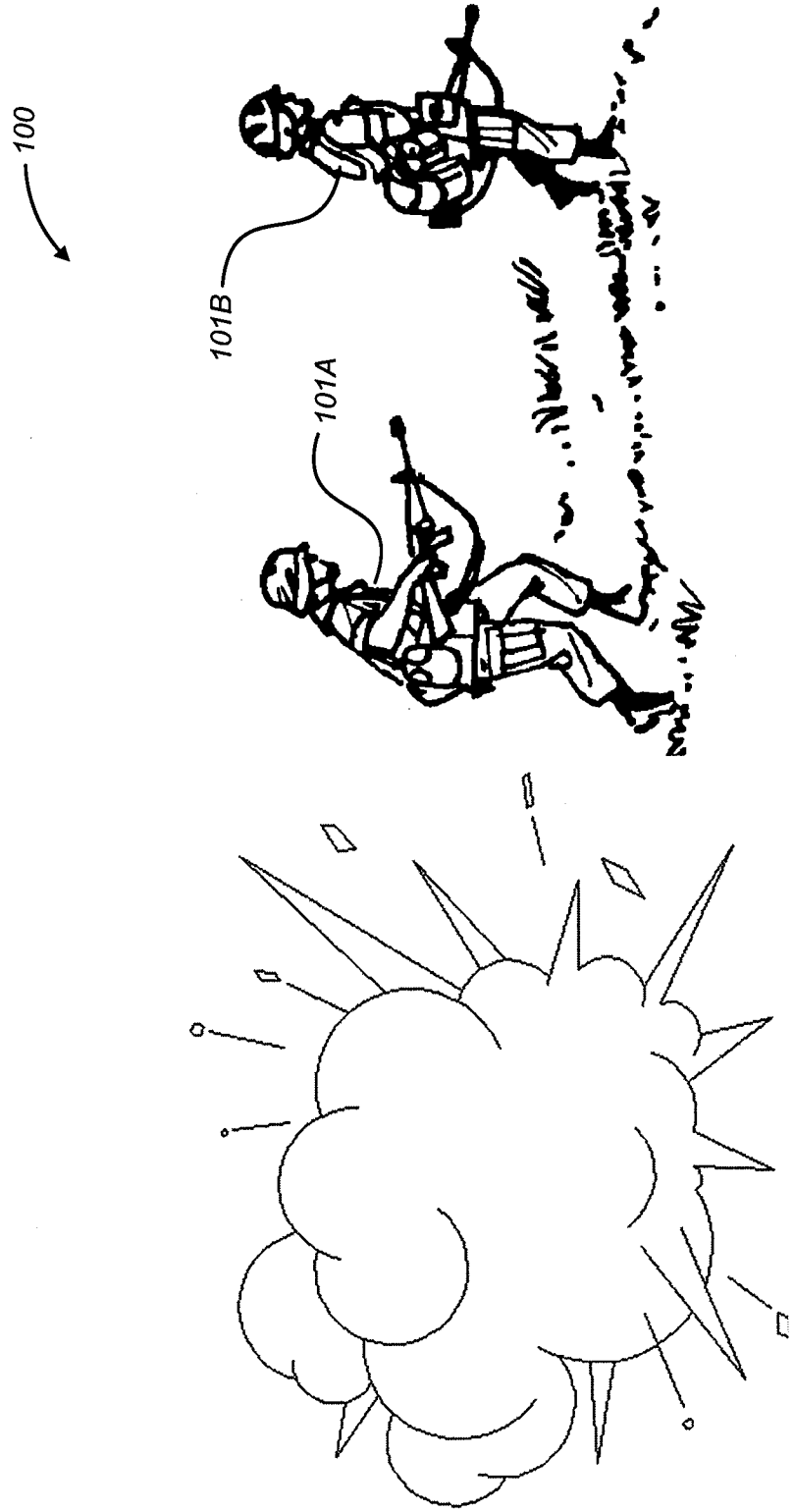
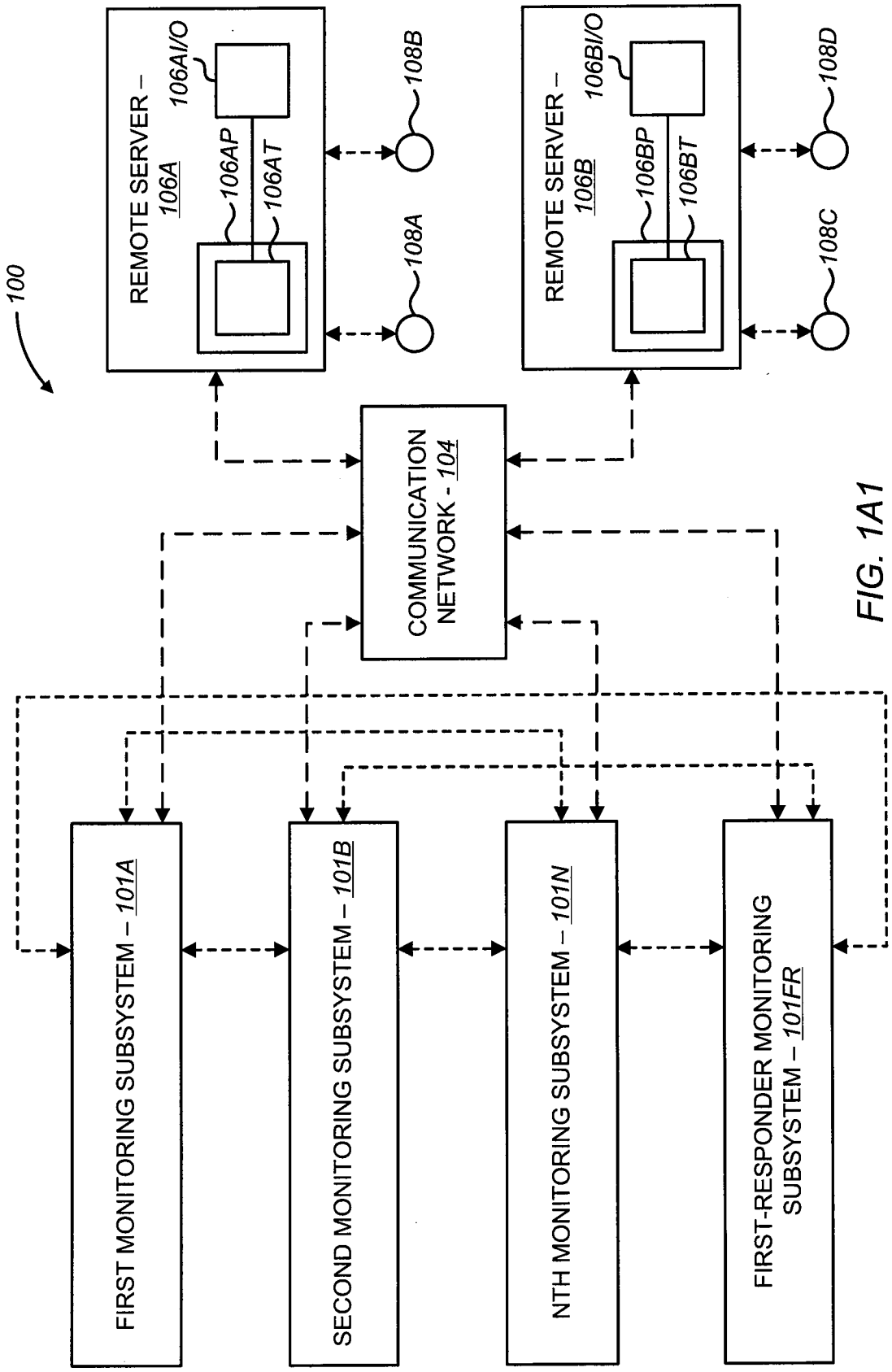


FIG. 1A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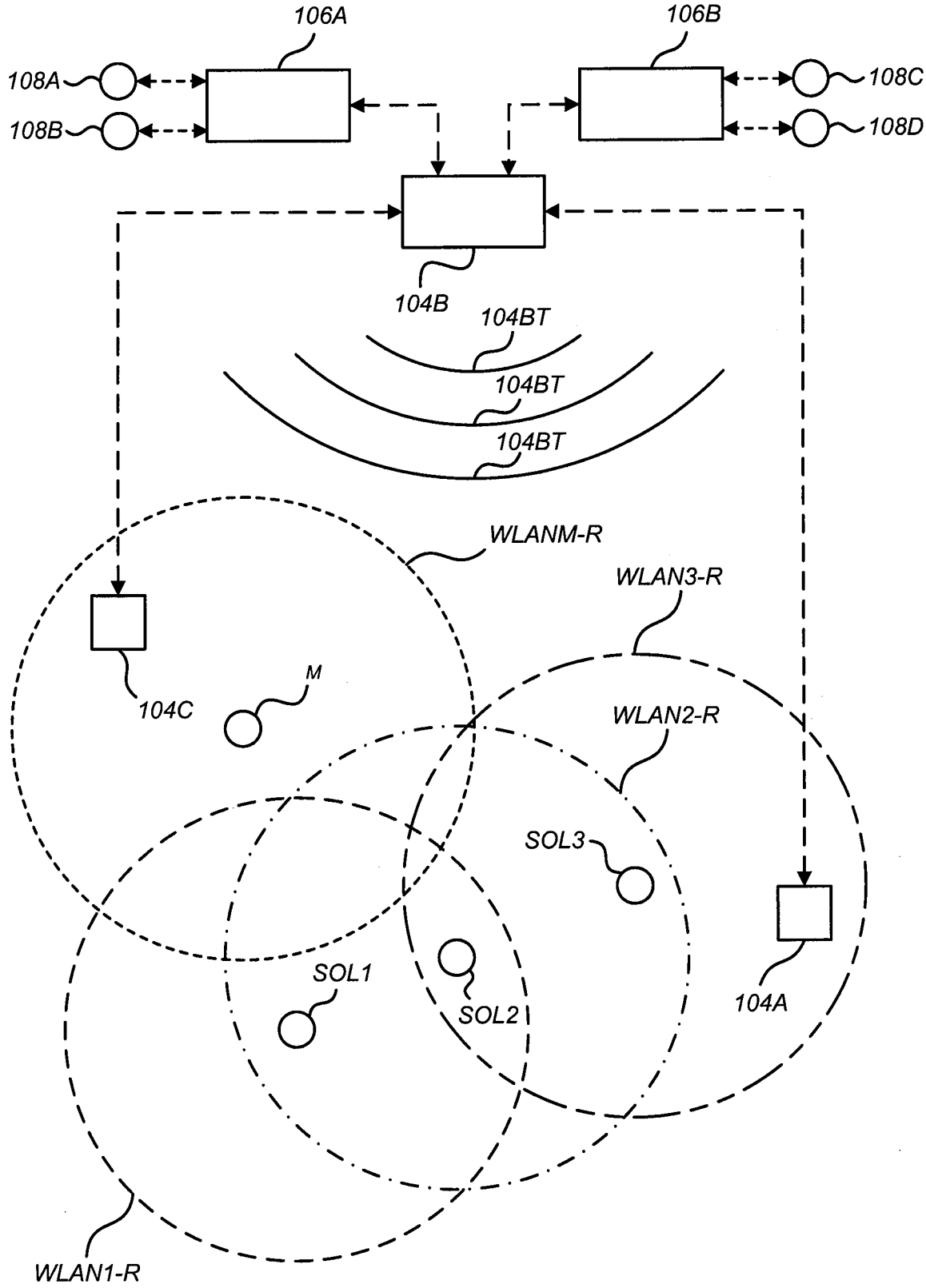
REMOTE SERVER – 106A
106AI/O
106AP
106AT
108A
108B
REMOTE SERVER – 106B
106BI/O
106BP
106BT
108C
108D
COMMUNICATION NETWORK - 104
FIRST MONITORING SUBSYSTEM – 101A
SECOND MONITORING SUBSYSTEM – 101B
NTH MONITORING SUBSYSTEM – 101N
FIRST-RESPONDER MONITORING SUBSYSTEM – 101FR

FIG. 1A1


106A
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108B
108C
108D
104B
104BT
104BT
104BT
WLANM-R
WLAN3-R
104C
M
WLAN2-R
SOL3
SOL1
SOL2
104A
WLAN1-R

FIG. 1A2

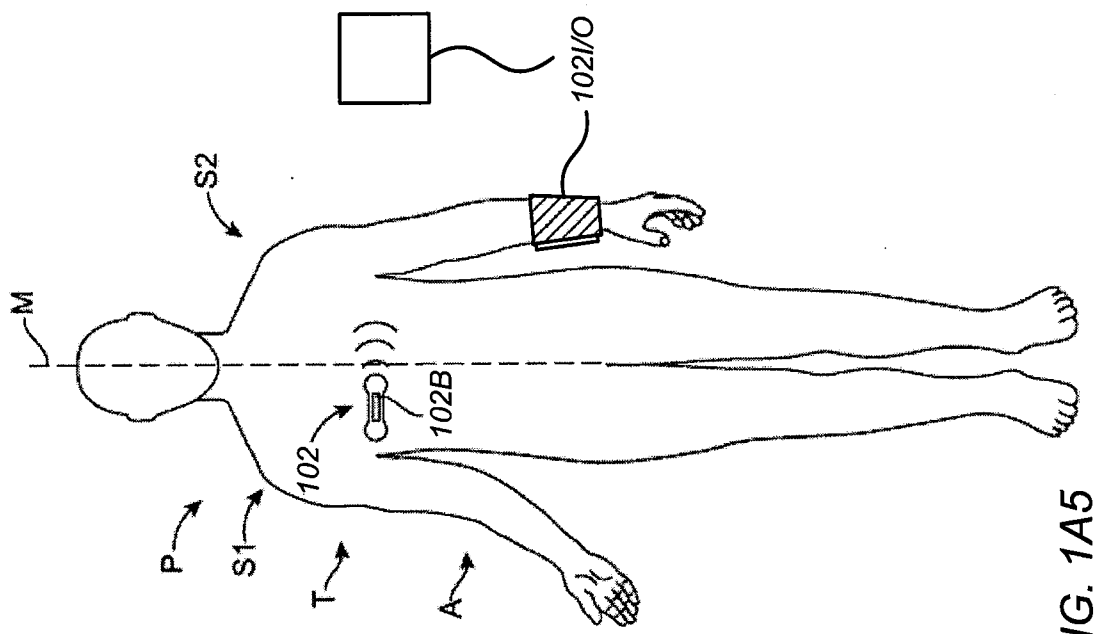


FIG. 1A5

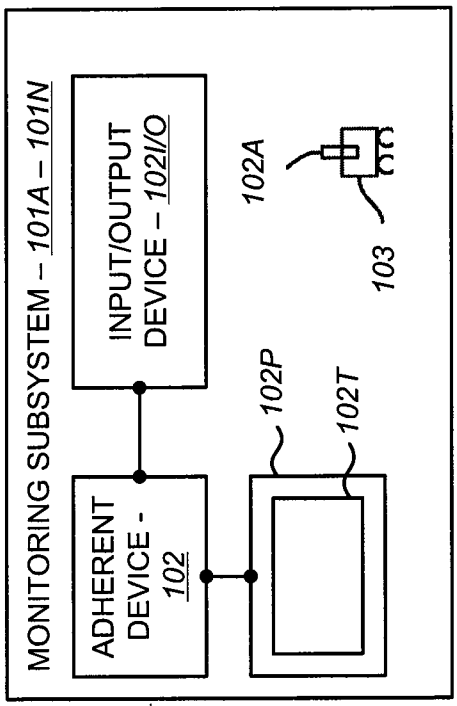


FIG. 1A3

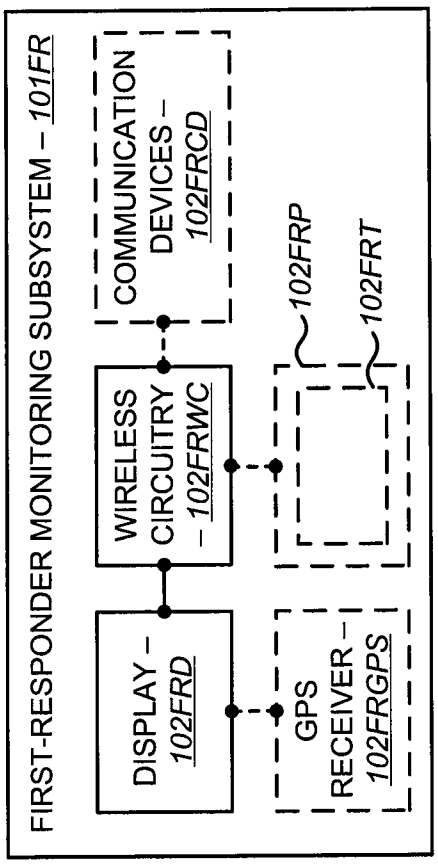
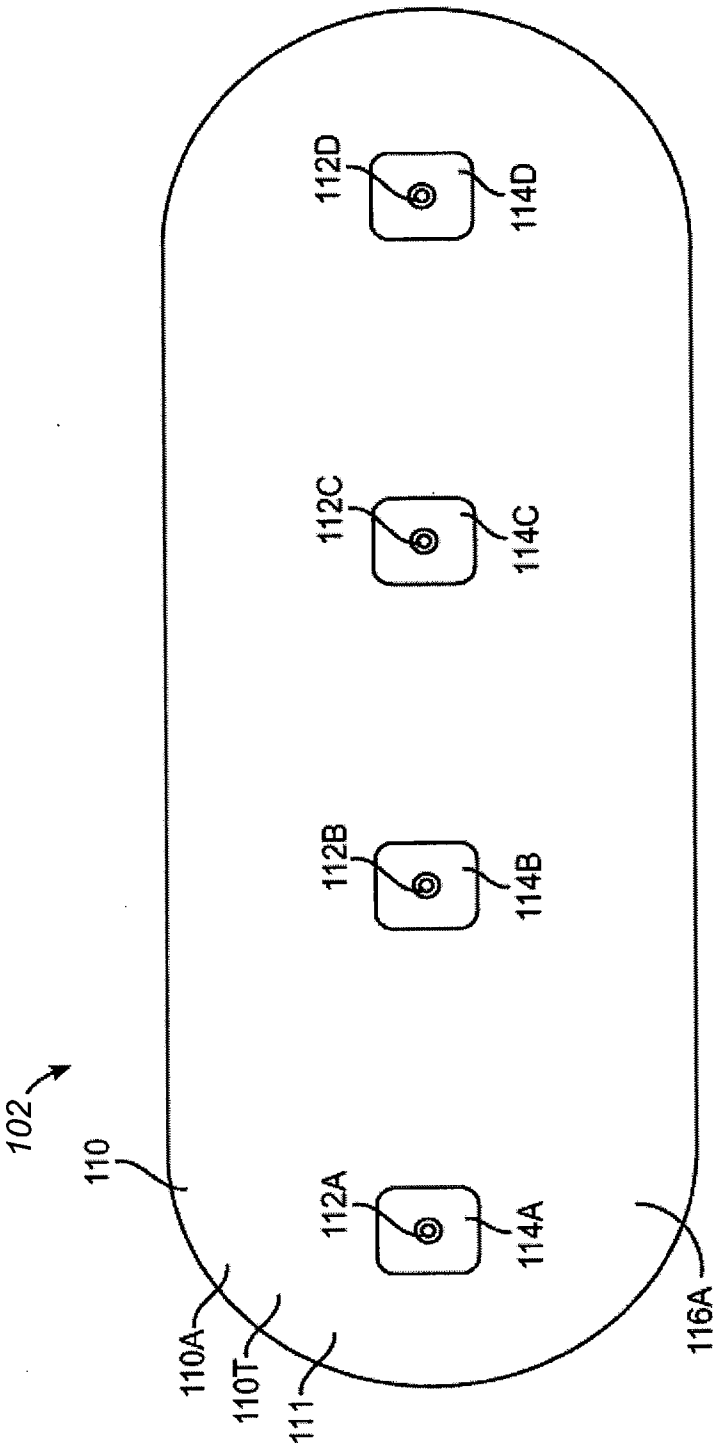


FIG. 1A4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110
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114A
112B
114B
112C
114C
112D
114D
110A
110T
111
116A

FIG. 1B

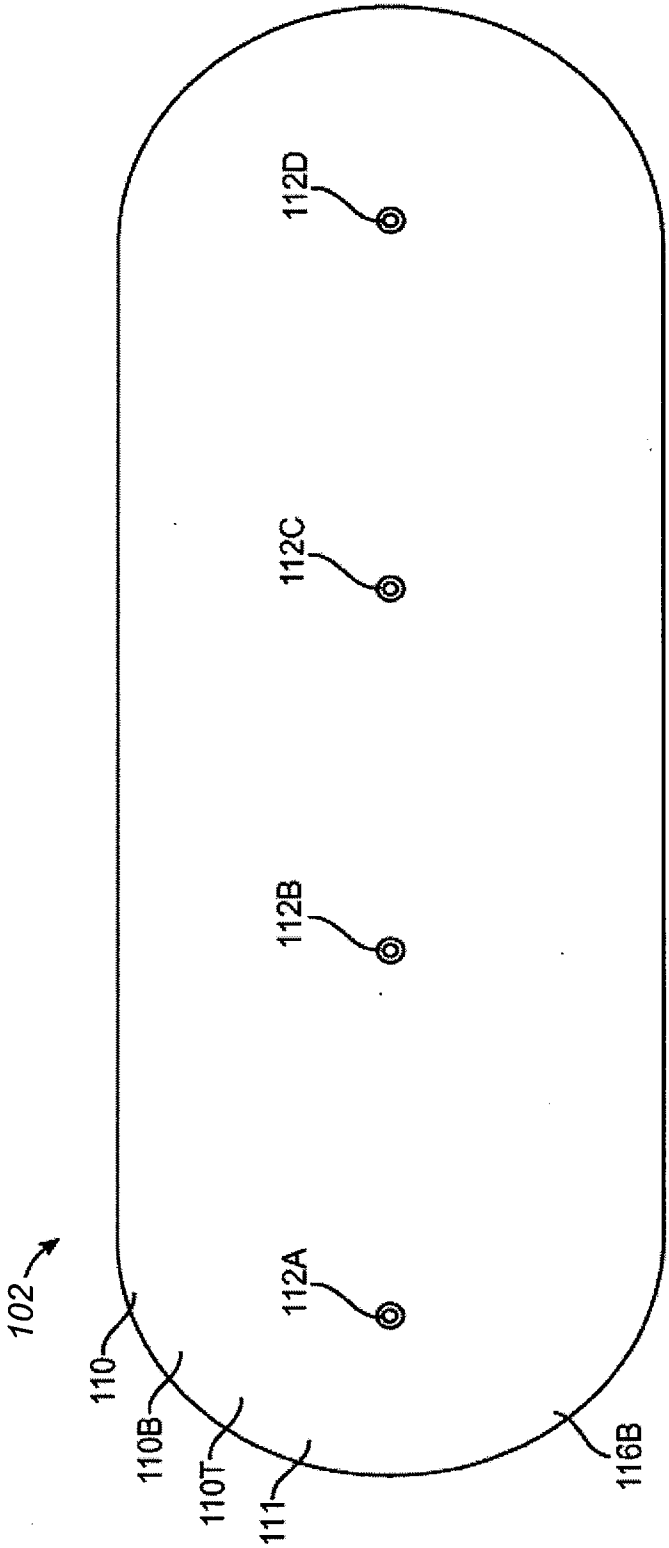


FIG. 1C

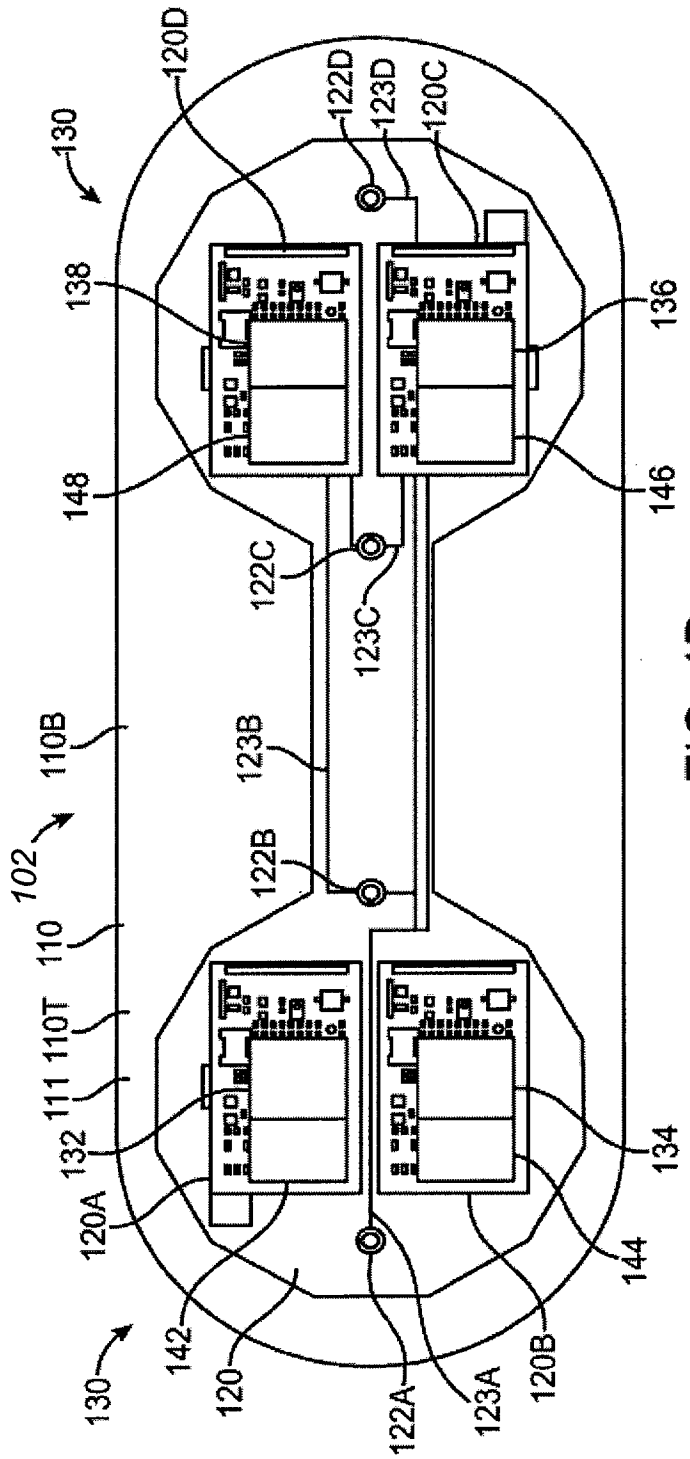


FIG. 1D

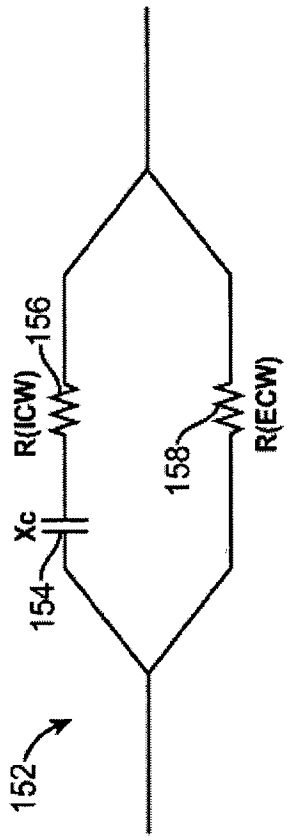


FIG. 1D1

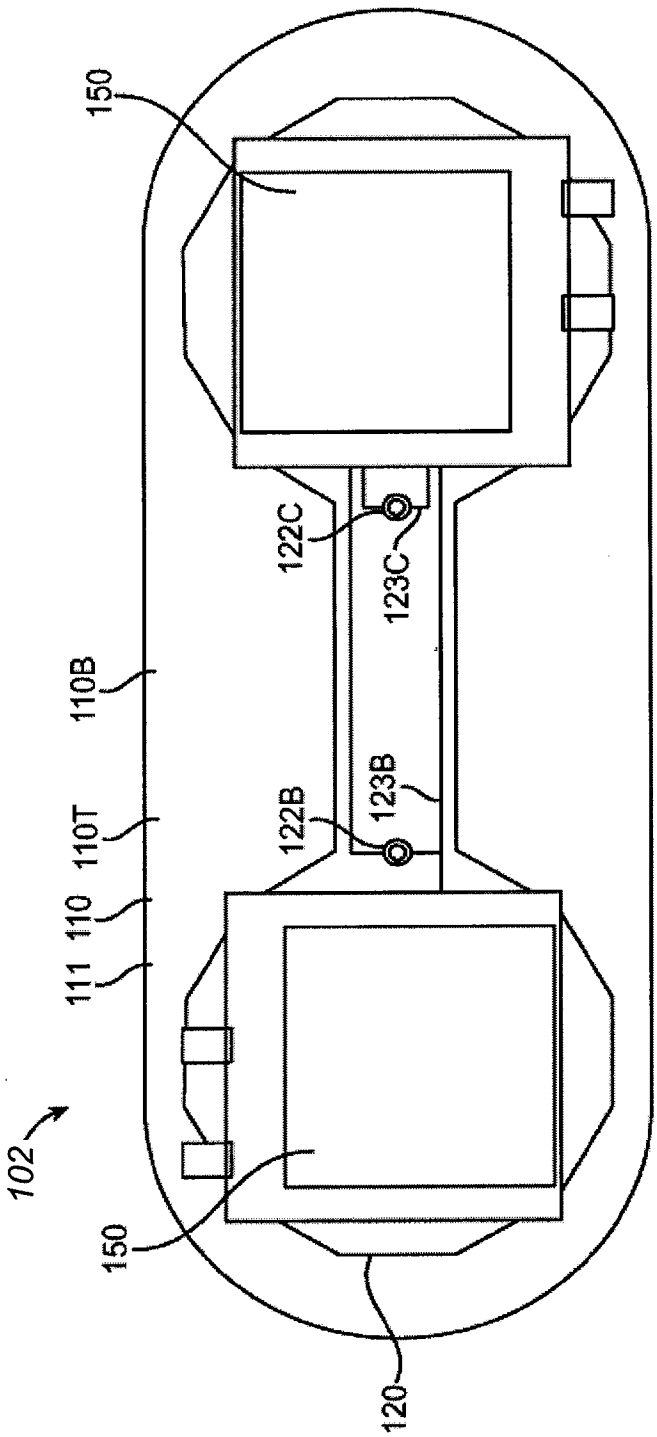


FIG. 1E

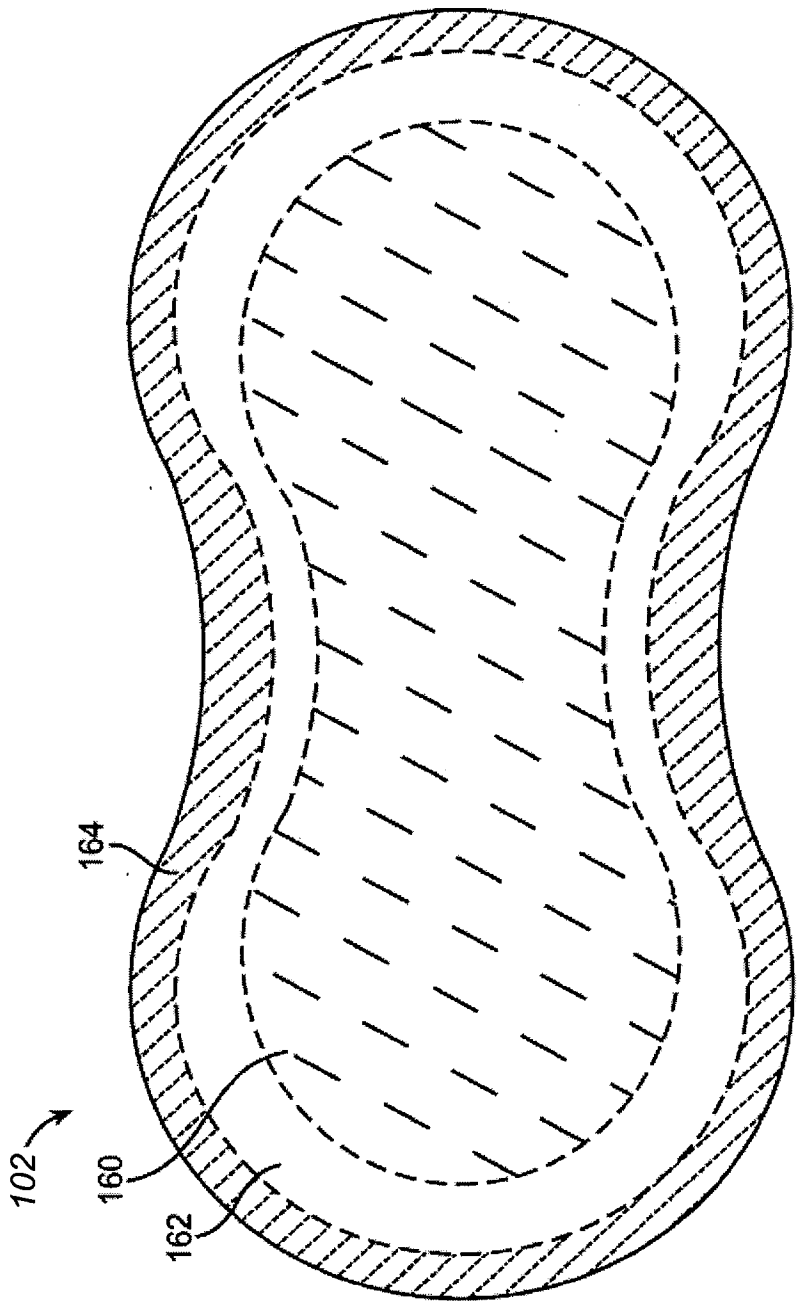
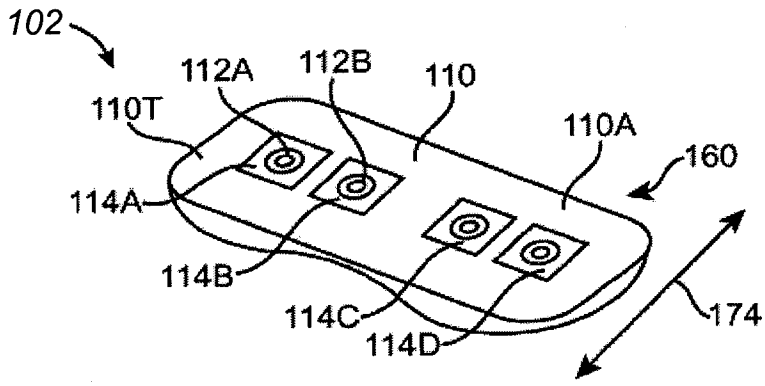


FIG. 1F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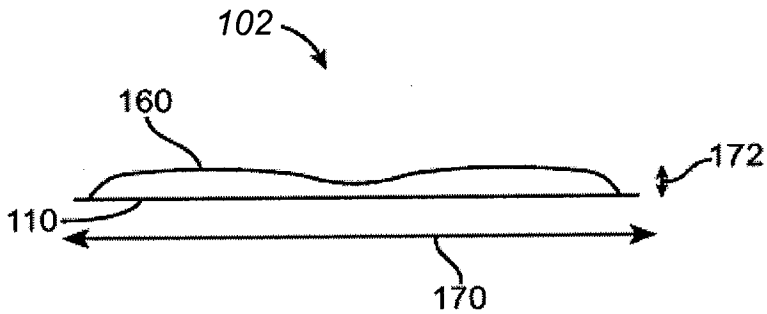
110T
110A
160
114A
114B
114C
114D
174

FIG. 1H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160
172
110
170

FIG. 1G

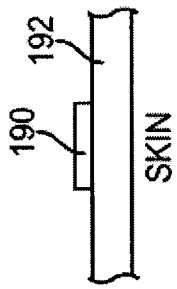
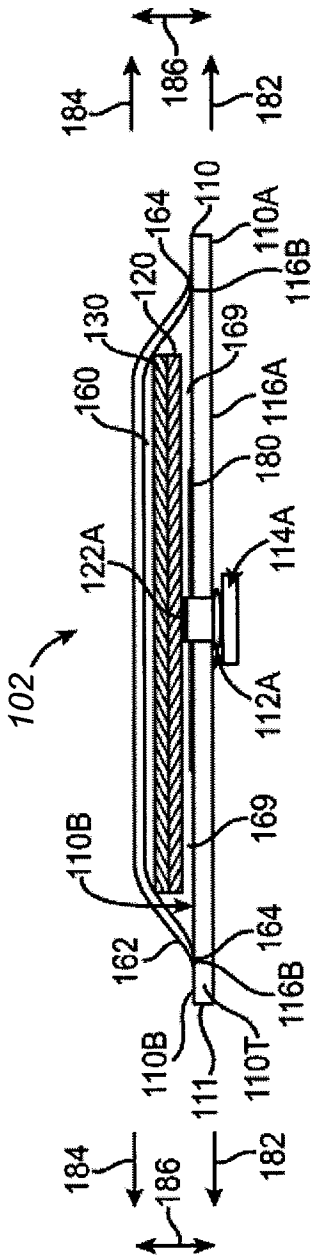

192
190
SKIN

FIG. 1K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116A
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162
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116B
110B
110T
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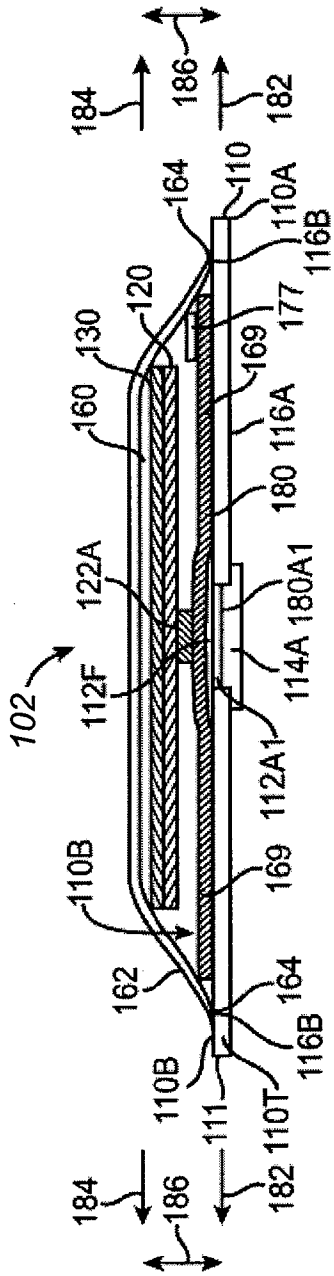
184
186
182

FIG. 1I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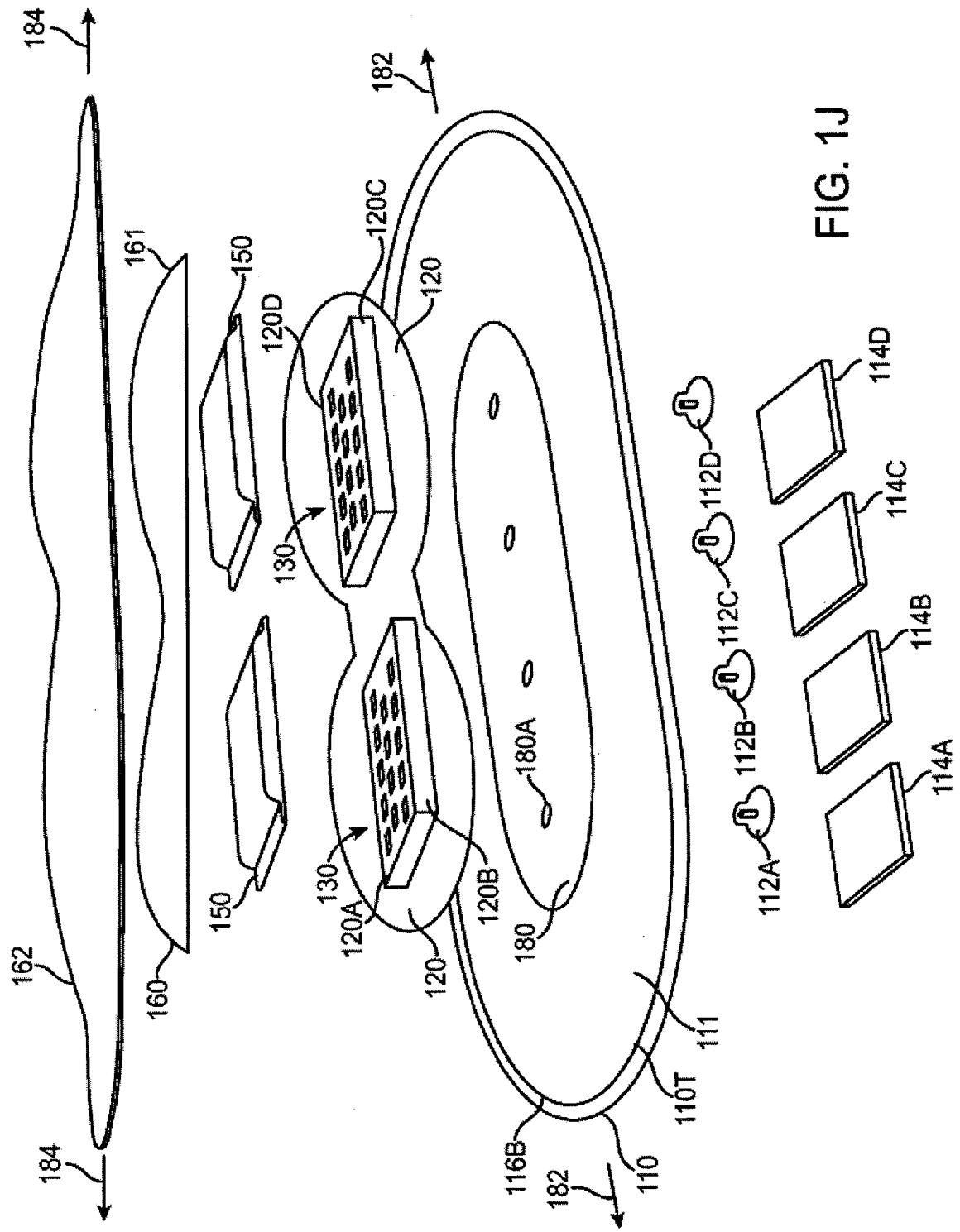
110T

FIG. 1I1


184
182
161
150
120C
120D
120
130
112D
114D
114C
112C
114B
112B
114A
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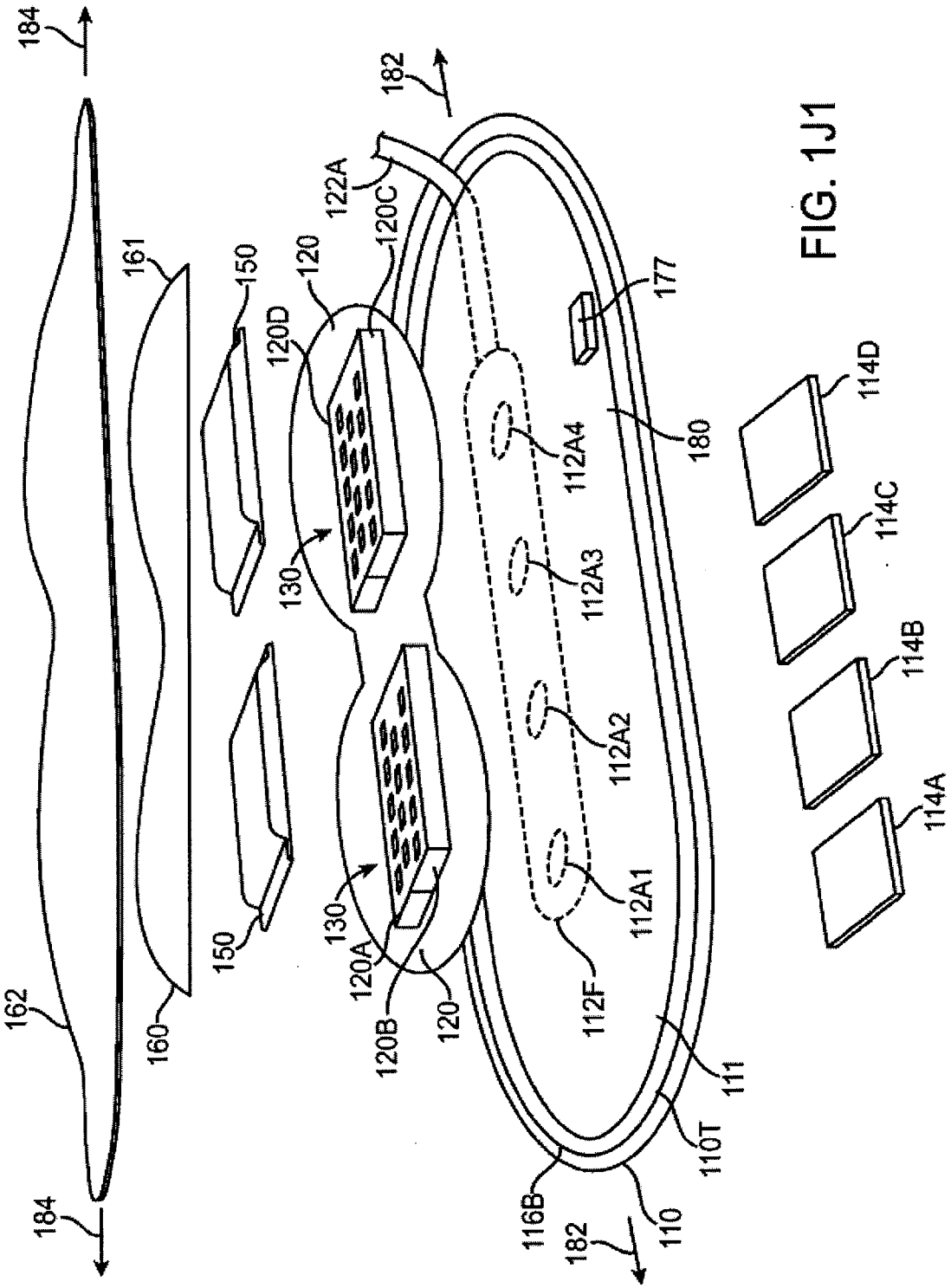
120B
120
180
111
110T
116B
182
110
184

FIG. 1J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182
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120C
120
150
161
120D
177
112A4
180
114D
114C
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114A
130
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112A2
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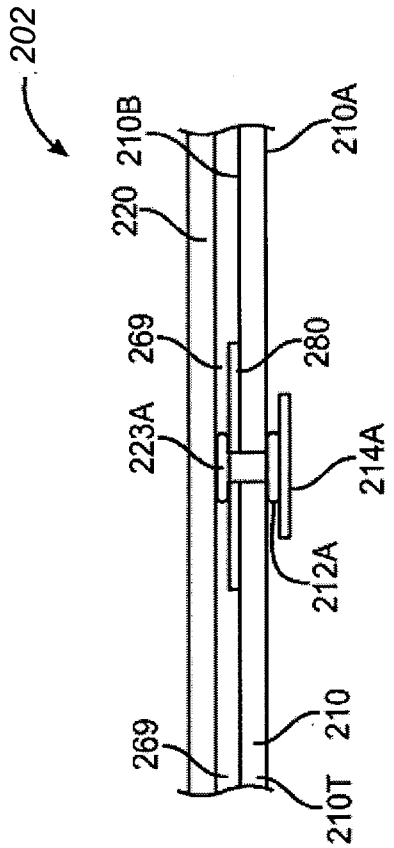
120A
120B
120

FIG. 1J1


202
210B
210A
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269
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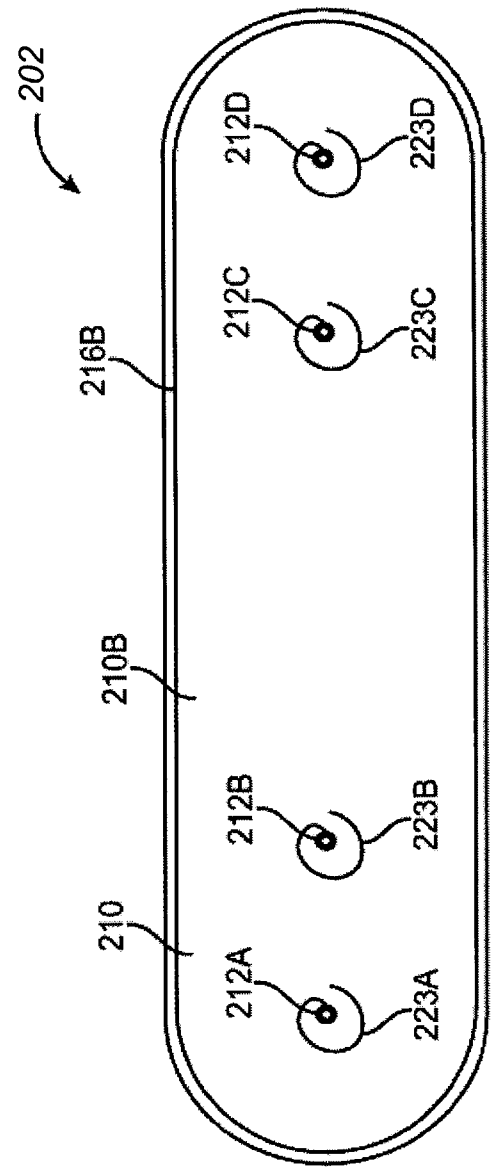
223A
214A
212A
269
210
210T

FIG. 2B


202
212D
223D
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223C
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210B
212B
223B
210
212A
223A

FIG. 2A