MODULAR PHYSIOLOGIC MONITORING SYSTEMS, KITS, AND METHODS

CROSS REFERENCE TO RELATED APPLICATION

[0001] The present application is ~~an international~~ a national stage application of International Application PCT/US2014/041339 which claims benefit of and priority to U.S. Provisional Application Ser. No. 61/832,131, filed on June 6, 2013, and entitled "Modular Physiological Monitoring Systems, Kits, and Methods," by Landy Toth et al., the entire contents of which is incorporated by reference herein for all purposes.

BACKGROUND

Technical Field

[0002] The present disclosure relates to the field of physiologic monitoring. The disclosure relates to systems and methods for reliable measurement of one or more physiologic parameters of a subject. In particular, the disclosure relates to aspects of systems and methods for unobtrusively monitoring electrophysiological activity and/or related information from an ambulatory subject in an uncontrolled setting.

Background

[0003] As chronic diseases continue to proliferate throughout the world, there is a heightened need to treat such conditions in a cost effective manner. Remote monitoring of patients with cardiovascular diseases (heart failure, post stroke, etc.), diabetes, kidney failure, COPD, obesity, neurological disorders (depression, Alzheimer's disease, migraines, stress disorders, etc.), arthritis, among other ailments, for purposes of treatment or prevention of such diseases may substantially improve patient outcomes.

[0004] Although physiologic monitoring is performed today for a range of purposes, existing technologies are not without shortcomings.

[0005] There is a need to measure physiologic parameters of subjects, reliably, simply, and without cables. As the proliferation of mobile and remote medicine increases, simplified and unobtrusive means for monitoring the physiologic parameters of a patient become more important.

[0006] Patient compliance is critical to the success of such systems and is often directly correlated to the ease of use and unobtrusiveness of the monitoring solution used.

[0007] Existing monitoring systems are often prone to false alarms, usage related failures, unreliable user interfaces, cumbersome interfaces, artifact or electromagnetic interference (EMI) related interference, etc. Such problems decrease productivity of using these systems, can result in lost data, and lead to dissatisfaction on the part of both the subject being monitored and the practitioners monitoring the subject. In the case of a hospital setting, the continual drone of alarms can lead to alarm fatigue and decreased productivity.

[0008] Long term compliance of subjects may suffer due to uncomfortable interfaces with monitoring devices, involved maintenance or change-over of disposables, painful or itchy reactions to materials in the devices, and the like.

[0009] More reliable, redundant, and user friendly systems are needed that can provide valuable patient data even when operating with limited supervision, expert input, or user manipulation.

SUMMARY

[0010] One illustrative, non-limiting objective of this disclosure is to provide systems, devices, methods, and kits for monitoring physiologic and/or physical signals from a subject. Another illustrative, non-limiting objective is to provide simplified systems for monitoring subjects. Another illustrative, non-limiting objective is to provide comfortable long term wearable systems for monitoring subjects. Yet another illustrative, non-limiting objective is to provide systems for facilitating interaction between a user and a subject with regard to physiologic monitoring of the subject.

[0011] The above illustrative, non-limiting objectives are wholly or partially met by devices, systems, and methods according to the appended claims in accordance with the present disclosure. Features and aspects are set forth in the appended claims, in the following description, and in the annexed drawings in accordance with the present disclosure.

[0011A] Disclosed herein is a patch interface, comprising:

a substrate;

an adhesive coupled to the substrate formulated for attachment to the skin of a subject;

one or more interconnects embedded into the substrate for attachment of a patch to a microcircuit; and

at least one of: one or more sensors; and one or more electrodes attached to or embedded onto the surface of the substrate, and arranged, configured, and dimensioned to interface with the subject when the adhesive is attached thereto;

wherein the patch interface is configured to monitor one or more physiologic signals, physical signals, and electrophysiological signals from the subject.

[0011B] Disclosed herein is a module, comprising:

a housing;

a circuit board comprising one or more microcircuits; and

a module interconnect coupled to one or more of the microcircuits configured for placement and coupling of a device onto a patch interface, the patch interface comprising:

a substrate;

an adhesive coupled to the substrate formulated for attachment to the skin of a subject;

one or more interconnects embedded into the substrate for attachment of a patch to a microcircuit; and

at least one of: one or more sensors; and one or more electrodes attached to or embedded onto the surface of the substrate, and arranged, configured, and dimensioned to interface with the subject when the adhesive is attached thereto;

wherein the module is configured to monitor one or more physiologic signals, physical signals, and electrophysiological signals from the subject.

[0011C] Also disclosed herein is a device, comprising:

a patch interface; and

a module comprising:

a housing;

a circuit board comprising one or more microcircuits; and

a module interconnect coupled to one or more of the microcircuits configured for placement and coupling of the device onto the patch interface;

wherein the module interconnect is sized and dimensioned to interface with an interconnect within the patch interface, and the patch interface is coupled to a subject to form an operable interconnection between the patch interface and the module; and

wherein the device is configured to monitor one or more physiologic signals, physical signals, and electrophysiological signals from the subject.

[0012] According to a first aspect there is provided a system for monitoring one or more physiologic and/or physical signals from a subject including one or more patches each in accordance with the present disclosure configured for attachment to the subject, and one or more modules each in accordance with the present disclosure configured and

dimensioned to mate with a corresponding patch, and to interface with the subject there through. In aspects, one or more of the modules may be configured to convey and/or store one or more physiologic and/or physical signals, a signal derived therefrom, and/or a metric derived therefrom obtained via the interface with the subject.

[0013] In aspects, the system may include or interface with a host device in accordance with the present disclosure coupled in wireless communication with one or more of the modules configured to receive one or more of the signals and/or metrics therefrom. In aspects, the host device may include features for recharging and/or performing diagnostic tests on one or more of the modules.

[0014] According to aspects there is provided, use of a system in accordance with the present disclosure to monitor a subject, to monitor an electrocardiogram of a subject, to perform one or more tasks in accordance with the present disclosure, etc.

[0015] According to aspects there is provided an interface (i.e. a patch in accordance with the present disclosure) for monitoring a physiologic and/or physical signal from a subject, including a substrate, an adhesive coupled to the substrate formulated for attachment to the skin of a subject, and one or more sensors and/or electrodes each in accordance with the present disclosure coupled to the substrate, arranged, configured, and dimensioned to interface with the subject.

[0016] In aspects, the substrate may be formed from an elastic or polymeric material and the patch is configured to maintain operation when stretched to more than 25%, more than 50%, or more than 80%.

[0017] In aspects, the interface (i.e. the patch) may be configured with a moisture vapor transmission rate of between 200 grams/square meter (g/m^2)/24 hours (hrs) and 20,000g/m^2/24hrs, between 500g/m^2/24hrs and 12,000g/m^2/24hrs, or between 2,000g/m^2/24hrs and 8,000g/m^2/24hrs, etc.

[0018] In aspects, the interface may be used for a range of applications, some non-limiting examples of which include electrocardiography, sleep assessment, bruxism assessment, sleep apnea, traumatic brain injury, black box event based monitoring (e.g. for syncope, atrial fibrillation, etc.), biofeedback, stress management, relaxation,

physiotherapy, stroke or surgical recovery, or the like. Additional uses and details thereof are described throughout the present disclosure.

[0019] According to aspects there is provided a device (i.e. a module in accordance with the present disclosure) for monitoring a physiologic, physical, and/or electrophysiological signal from a subject including, a housing, a printed circuit board (PCB) including one or more microcircuits, and an interconnect configured for placement of the device onto a subject interface (i.e. a patch in accordance with the present disclosure).

[0020] In aspects, the printed circuit board may constitute at least a portion of the housing.

[0021] In aspects, the device may include a three dimensional antenna coupled to the microcircuits (i.e. coupled with a transceiver, transmitter, radio, etc. included within the microcircuits). In aspects, the antenna may be printed onto or embedded into the housing.

[0022] According to aspects there is provided a kit for monitoring a physiologic, physical, and/or electrophysiological signal from a subject, including one or more patches in accordance with the present disclosure, one or more modules in accordance with the present disclosure; a recharging bay in accordance with the present disclosure, and one or more accessories in accordance with the present disclosure.

[0023] In aspects, one or more of the accessories may include an adhesive removing agent configured to facilitate substantially pain free removal of one or more of the patches from a subject.

[0024] According to aspects there is provided, a service system for managing the collection of physiologic data from a customer, including a customer data management service, configure to generate and/or store the customer profile referencing customer preferences, data sets, and/or monitoring sessions, an automated product delivery service configured to provide the customer with one or more monitoring products or supplies in accordance with the present disclosure, and a datacenter configured to store, analyze,

and/or manage the data obtained from the customer during one or more monitoring sessions.

[0025] In aspects, the service system may include a report generating service configured to generate one or more monitoring reports based upon the data obtained during one or more monitoring sessions, a report generating service coupled to the datacenter configured to generate one or more monitoring reports based upon the data obtained during one or more monitoring sessions, and/or a recurrent billing system configured to bill the customer based upon the number or patches consumed, the data stored, and/or the reports generated throughout the course of one or more monitoring session.

[0026] According to aspects there is provided a method for monitoring a physiologic, physical, and/or electrophysiological signal from a subject, including one or more steps in accordance with the present disclosure.

[0027] In aspects, one or more of the steps may be performed at least in part by a system in accordance with the present disclosure.

[0028] According to aspects there is provided, an isolating patch for providing a barrier between a handheld monitoring device with a plurality of contact pads and a subject, including a flexible substrate with two surfaces, a patient facing surface and an opposing surface, and an electrically and/or ionically conducting adhesive coupled to at least a portion of the patient facing surface configured so as to electrically and mechanically couple with the subject when placed thereupon, wherein the conducting adhesive is exposed within one or more regions of the opposing surface of the substrate, the regions patterned so as to substantially match the dimensions and layout of the contact pads.

[0029] In aspects, the conducting adhesive may include an anisotropically conducting adhesive, with the direction of conduction oriented substantially normal to the surfaces of the substrate.

[0030] According to aspects there is provided, a patch interface (i.e. a patch in accordance with the present disclosure) for monitoring one or more physiologic and/or electrophysiological signals from a subject, including a substrate, an adhesive coupled to the substrate formulated for attachment to the skin of a subject, an interconnect embedded into the substrate for attachment of the patch to a microcircuit, and one or more sensors

include a temporary stiffening member attached to the substrate, the temporary stiffening member configured to provide retention of the shape of the patch interface prior to attachment to the subject, the stiffening member being removable from the substrate after attachment to the subject. In aspects, after removal of the stiffening member, the retention of the shape of the patch interface may be provided by the skin of the subject. Removal of the patch interface from the skin of the subject may result in a permanent loss in shape of the patch interface without tearing of the patch interface. In aspects, the interconnect may be sufficiently frail such that removal of the patch interface from the skin of the subject may result in a permanent loss of shape of the interconnect.

[0036] In aspects, an adhesive in accordance with the present disclosure may have a peel tack to mammalian skin of greater than 0.02 Newton/millimeter(N/mm), greater than 0.1N/mm, greater than 0.25N/mm, greater than 0.50N/mm, greater than 0.75N/mm, or the like. The patch interface may have a tear strength of greater than 0.5N/mm, greater than 1N/mm, greater than 2N/mm, greater than 8N/mm, or the like.

[0037] In aspects, a patch interface in accordance with the present disclosure may have a ratio between the tear strength of the patch and the peel tack of the adhesive to mammalian skin is greater than 8:1, greater than 4:1, greater than 2:1, or the like. In aspects, the substrate may be formed from a soft pseudo-elastic material and the patch interface may be configured to maintain operation when stretched to more than 25%, more than 50%, more than 80%, or the like. In aspects, the patch interface may be configured with a moisture vapor transmission rate of between 200g/m^2/24hrs and 20,000g/m^2/24hrs, between 500g/m^2/24hrs and 12,000g/m^2/24hrs, between 1,000g/m^2/24hrs and 8,000g/m^2/24hrs, or the like.

[0038] According to aspects, there is provided a module for monitoring one or more physiologic and/or electrophysiological signals from a subject, including a housing, a circuit board including one or more microcircuits, and a module interconnect coupled to one or more of the microcircuits configured for placement and coupling of the device onto a patch interface in accordance with the present disclosure.

[0039] In aspects, the module interconnect may be embedded into the circuit board, and/or the circuit board may constitute at least a portion of the housing. The module may

[0043] In aspects, the module interconnect may include an electrically conducting magnetic element, and the patch interface may include one or more ferromagnetic regions coupled to the substrate, the magnetic elements arranged so as to physically and/or electrically couple the module to the patch interface when the magnetic elements are aligned with the ferromagnetic regions. In aspects, the ferromagnetic regions may be formed from stretchable pseudo elastic material and/or may be printed onto the substrate. In aspects, the module and/or the patch interface may include one or more fiducial markings to visually assist with the alignment of the module to the patch during coupling thereof.

[0044] According to aspects there is provided, a system for monitoring one or more physiologic and/or electrophysiological signals from a subject including a patch interface in accordance with the present disclosure configured for attachment to the subject, and a module in accordance with the present disclosure configured and dimensioned to mate with the patch, and to interface with the subject there through, the module configured to convey and/or store one or more physiologic, electrophysiological, and/or physical signals, a signal derived therefrom, and/or a metric derived therefrom obtained via the interface with the subject.

[0045] In aspects, the system may include a host device coupled in wireless communication or physical communication with the module, configured to receive one or more of the signals and/or metrics therefrom. In aspects, the host device may include one or more features for recharging and/or performing diagnostic tests on one or more of the modules. In aspects, the system may include a plurality of modules, the modules being hot swappable with the patch interface, so as to maintain a nearly continuous or continuous operation thereof.

[0046] In aspects, the system may include a plurality of modules and associated patch interfaces for placement onto a signal subject, the host device, and/or one or more of the modules configured to coordinate synchronous monitoring of the signals amongst the modules on the subject. In aspects, a host device in accordance with the present disclosure may be integrated into a bedside alarm clock, housed in an accessory, within a purse, a backpack, a wallet, is or is included in a mobile computing device, a smartphone,

a tablet computer, a pager, a laptop, a local router, a data recorder, a network hub, a server, a secondary mobile computing device, a repeater, a combination thereof, or the like.

[0047] According to aspects there is provided, use of a device, a module, a patch, and/or a system each in accordance with the present disclosure to monitor an electrocardiogram of a subject.

[0048] According to aspects there is provided, a method for monitoring one or more physiologic and/or electrophysiological signals from a subject, including attaching one or more soft breathable and hypoallergenic devices to one or more sites on the subject, obtaining one or more local physiologic and/or electrophysiological signals each of the devices, and analyzing the signals obtained from each of the devices to generate a metric, diagnostic, report, and/or additional signals therefrom.

[0049] In aspects, the method may include hot swapping one or more of the devices without interrupting the step of obtaining, and/or calibrating one or more of the devices while on the subject. In aspects, the step of calibrating may be performed with an additional medical device (e.g. a blood pressure cuff, a thermometer, a pulse oximeter, a cardiopulmonary assessment system, a clinical grade electrocardiogram (EKG) diagnostic system, etc.).

[0050] In aspects, the method may include determining the position and/or orientation of one or more of the devices on the subject, and/or determining the position and/or orientation from a photograph, a video, or a surveillance video.

[0051] In aspects, one or more steps of a method in accordance with the present disclosure may be performed at least in part by a device, patch interface, module, and/or system each in accordance with the present disclosure.

[0052] According to aspects there is provided, an isolating patch for providing a barrier between a handheld monitoring device with a plurality of contact pads and a subject, including a flexible substrate with two surfaces, a patient facing surface and an opposing surface, and an electrically and/or ionically conducting adhesive coupled to at

least a portion of the patient facing surface configured so as to electrically and mechanically couple with the subject when placed thereupon, wherein the conducting

include one or more of an altimeter, a barometer, a tilt sensor, a gyroscope, combinations thereof, or the like.

[0057] A system for measuring the effect of an impact on physiologic state of a subject including an electroencephalogram (EEG) device (i.e. a patch/module pair in accordance with the present disclosure configured to measure local electrophysiological signals associated with brain activity in adjacent tissues) in accordance with the present disclosure, configured for placement behind an ear, on the forehead, near a temple, onto the neck of the subject, or the like, the EEG device configured to measure an electroencephalographic signal from the head of the subject so as to produce an EEG signal, and configured to measure one or more kinetic and/or kinematic signals from the head of the subject so as to produce an impact signal, and a processor included in or coupled to the EEG device, the processor configured to receive the EEG signal, the impact signals, and/or signals generated therefrom, the processor including an algorithm, the algorithm configured to analyze the impact signals to determine if the subject has suffered an impact, to separate the signals into pre impact and post impact portions and to compare the pre and post impact portions of the EEG signal, to determine the effect of the impact on the subject.

[0058] In aspects, the EEG device may include additional sensors such as a temperature sensor configured to generate a temperature signal from the subject or a signal generated therefrom, the processor configured to receive the temperature signal and to assess a thermal state of the subject therefrom. In aspects, the EEG device may include a hydration sensor configured to generate a fluid level signal from the subject, the processor configured to receive the fluid level signal or a signal generated therefrom, and to assess the hydration state of the subject therefrom.

[0059] In aspects, the EEG device and/or the processor may include or be coupled to a memory element, the memory element including sufficiently large space to store the signals for a period of 3 minutes, 10 minutes, 30 minutes, or 1 hr.

[0060] In aspects, the system for measuring the effect of an impact on physiologic state of a subject may include an EKG device (i.e. a patch/module pair in accordance

with the present disclosure configured to measure local electrophysiological signals in adjacent tissues) in accordance with the present disclosure, the EKG device configured

for placement onto the torso or neck of the subject, the EKG device configured to measure an electrophysiological signal pertaining to cardiac function of the subject so as to produce an EKG signal, the processor configured to receive the EKG signal or a signal generated therefrom, the algorithm configured so as to incorporate the EKG signal into the assessment. In aspects, the processor may be configured to extract a heart rate variability (HRV) signal from the EKG signal, a pre impact and post impact portion of the HRV signal compared to determine at least a portion of the effect of the impact.

[0061] According to aspects there is provided, a system for assessing a sleep state of a subject including an electromyography (EMG)/ electrooculography (EOG) device (i.e. a patch/module pair in accordance with the present disclosure configured to measure local electromyographic and/or electrooculographic signals from adjacent tissues), in accordance with the present disclosure, configured for placement behind an ear, on a forehead, substantially around an eye, near a temple, or onto a neck of the subject, the EMG/EOG device configured to measure one or more electromyographic and/or electrooculographic signals from the head or neck of the subject so as to produce an EMG/EOG signal, and a processor included in or coupled to the EMG/EOG device, the processor configured to receive the EMG/EOG signal, and/or signals generated therefrom, the processor including an algorithm, the algorithm configured to analyze EMG/EOG signal, to determine the sleep state of the subject.

[0062] In aspects, the EMG/EOG device may include a microphone, the microphone configured to obtain an acoustic signal from the subject, the processor configured to receive the acoustic signal or a signal generated therefrom, the algorithm configured so as to incorporate the acoustic signal into the assessment.

[0063] In aspects, the system may include a sensor for evaluating oxygen saturation (sPO2) at one or more sites on the subject to obtain an oxygen saturation signal from the subject, the processor configured to receive the oxygen saturation signal or a signal generated therefrom, the algorithm configured so as to incorporate the oxygen saturation signal into the assessment.

[0064] In aspects, the processor may include a signal analysis function, the signal analysis function configured to analyze the EMG/EOG signals, the acoustic signal, and/or

the oxygen saturation signal to determine the sleep state of the subject, identify snoring, identify a sleep apnea event, identify a bruxism event, identify a rapid eye movement (REM) sleep state, identify a sleep walking state, a sleep talking state, a nightmare, or identify a waking event. In aspects, the system may include a feedback mechanism, configured to interact with the subject, a user, a doctor, a nurse, a partner, a combination thereof, or the like. The processor may be configured to provide a feedback signal to the feedback mechanism based upon the analysis of the sleep state of the subject. The feedback mechanism may include a transducer, a loudspeaker, tactile actuator, a visual feedback means, a light source, a buzzer, a combination thereof, or the like to interact with the subject, the user, the doctor, the nurse, the partner, or the like.

[0065] According to aspects there is provided, a system for assessing a gait and/or a muscle movement of a subject including an EMG device (i.e. a patch/module pair in accordance with the present disclosure configured to measure local electromyographic signals from adjacent tissues) in accordance with the present disclosure, configured for placement over a muscle group on the subject, the EMG device configured to measure one or more electromyographic signals from the muscle group of the subject so as to produce an EMG signal, and a processor included in or coupled to the EMG device, the processor configured to receive the EMG signal, and/or signals generated therefrom, the processor including an algorithm, the algorithm configured to analyze EMG signal to determine at least a portion of the gait and/or the muscle movement of the subject.

[0066] In aspects, the system may include a plurality of EMG devices, each EMG device configured to monitor a separate muscle group on the subject, the processor configured to synchronize and analyze the EMG signals received from each EMG device to determine at least a portion of the gait and/or the muscle movement of the subject.

[0067] In aspects, one or more of the EMG devices may include an orientation, kinetic, kinematic, and/or proprioception sensor each in accordance with the present disclosure, configured so as to generate a kinematic signal, the processor configured to incorporate the kinematic signal into the analysis. In aspects, the processor may be configured to analyze one or more of the EMG signals to generate a muscle exertion metric.

aspects, the physiologic monitoring system may include one or more modules, each module may include a power source (e.g. a battery, a rechargeable battery, an energy harvesting transducer, microcircuit, and an energy reservoir, a thermal gradient harvesting transducer, a kinetic energy harvesting transducer, a radio frequency energy harvesting transducer, a fuel cell, a biofuel cell, etc.), signal conditioning circuitry, communication circuitry, one or more sensors, or the like, configured to generate one or more signals (i.e. physiologic and/or physical signals).

[0090] One or more of the patches may include one or more interconnects, configured and dimensioned so as to couple with one or more of the modules, said modules including a complimentary interconnect configured and dimensioned to couple with the corresponding patch. The patch may include a bioadhesive interface for attachment to the subject, the module retainable against the subject via interconnection with the patch.

[0091] In aspects, the patch may be configured so as to be single use (i.e. disposable). The patch may include a thin, breathable, ~~streatchable~~stretchable laminate. In aspects, the laminate may include a substrate, a bioadhesive, one or more sensing elements in accordance with the present disclosure, and one or more interconnects for coupling one or more of the sensing elements with a corresponding module.

[0092] In aspects, to retain a high degree of comfort and long term wear-ability of the patch on a subject, to limit interference with normal body function, to limit interference with joint movement, or the like, the patch may be sufficiently thin and frail, such that it may not substantially retain a predetermined shape while free standing. Such a definition is described in further detail below. The patch may be provided with a temporary stiffening film to retain the shape thereof prior to placement of the patch onto the body of a subject. Once adhered to the subject, the temporary stiffening film may be removed from the patch. While the patch is adhered to the subject, the shape and functionality of the patch may be substantially retained. Upon removal of the patch from the subject, the, now freestanding patch is sufficiently frail such that the patch can no-longer substantially retain the predetermined shape (i.e. sufficiently frail such that the patch will not survive in a free standing state). In aspects, stretch applied to the patch while removing the patch

from the subject may result in snap back once the patch is in a freestanding state that renders such a patch to crumple into a ball and no longer function.

[0093] In aspects, the patch may include a film (e.g. a substrate), with sufficiently high tear strength, such that, as the patch is peeled from the skin of a subject, the patch does not tear. In aspects, the ratio between the tear strength of the patch and the peel adhesion strength of the patch to skin (i.e. tear strength: peel adhesion strength), is greater than 8:1, greater than 4:1, greater than 2:1, or the like. Such a configuration may be advantageous so as to ensure the patch may be easily and reliably removed from the subject after use without tearing.

[0094] In aspects, the patch may include a bioadhesive with peel tack to mammalian skin of greater than 0.02N/mm, greater than 0.1N/mm, greater than 0.25N/mm, greater than 0.50N/mm, greater than 0.75N/mm, or the like. Such peel tack may be approximately determined using an American Society for Testing and Materials (ASTM) standard test, ASTM D3330: Standard test method for peel adhesion of pressure-sensitive tape.

[0095] In aspects, the patch may exhibit a tear strength of greater than 0.5N/mm, greater than 1N/mm, greater than 2N/mm, greater than 8N/mm, or the like. Such tear strength may be approximately determined using an ASTM standard test, ASTM D624: Standard test method for tear strength of conventional vulcanized rubber and thermoplastic elastomers.

[0096] In aspects, the patch may be provided with a characteristic thickness, of less than 50 micrometer (um), less than 25um, less than 12um, less than 8um, less than 4um, or the like. Yet, in aspects, a balance between the thickness, stiffness, and tear strength may be obtained so as to maintain sufficiently high comfort levels for a subject, minimizing skin stresses during use (i.e. minimizing skin stretch related discomfort and extraneous signals as the body moves locally around the patch during use), minimizing impact on skin health, minimizing risk of rucking during use, and minimizing risk of maceration to the skin of a subject, while limiting risk of tearing of the patch during removal from a subject, etc.

[0097] In aspects, the properties of the patch may be further altered so as to balance the hydration levels of one or more hydrophilic or amphiphilic components of the patch

reports, recommendation signals, commands, combinations thereof, or the like for the subject , a user, a network, an electronic health record (EHR), a database (e.g. as part of a data management center, an EHR, a social network, etc.), a processor, combinations thereof, or the like.

[00102] In aspects, a system in accordance with the present disclosure may include a plurality of substantially similar modules (i.e. generally interchangeable modules, but with unique identifiers), for coupling with a plurality of patches, each patch, optionally different from the other patches in the system (e.g. potentially including alternative sensors, sensor types, sensor configurations, electrodes, electrode configurations, etc.). Each patch may include an interconnect suitable for attachment to an associated module. Upon attachment of a module to a corresponding patch, the module may validate the type and operation of the patch to which it has been mated. In aspects, the module may then initiate monitoring operations on the subject via the attached patch, communicate with one or more patches on the subject, a hub, etc. The data collection from each module may be coordinated through one or more modules and/or with a host device in accordance with the present disclosure. The modules may report a time stamp along with the data in order to synchronize data collection across multiple patch/module pairs on the subject, between subjects, etc. Thus, if a module is to be replaced, a hot swappable replacement (i.e. replacement during a monitoring procedure) can be carried out easily by the subject, a caregiver, practitioner, etc. during the monitoring process. Such a configuration may be advantageous for performing redundant, continuous monitoring of a subject, and/or to obtain spatially relevant information from a plurality of locations on the subject during use.

[00103] In aspects, the modules and/or patches may include corresponding interconnects for coupling with each other during use. The interconnects may include one or more connectors, configured such that the modules and patches may only couple in a single unique orientation with respect to each other. In aspects, the modules may be color coded by function. A temporary stiffening element attached to a patch may include instructions, corresponding color coding, etc. so as to assist a user or subject with simplifying the process of monitoring.

ST-segments, and T-wave configurations, calculating/showing/displaying/analyzing the standard electrocardiogram (ECG) lead configurations (Limb leads I,II,III,AVR, AVL, AVF) and precordial leads (V1-V6), combinations thereof, and the like.

[00112] In aspects, a system in accordance with the present disclosure may include a plurality of patches, each patch including one or more electrodes. In aspects, such electrode arrangements may be bipolar, tripolar, quadripolar, or otherwise multi-polar. In one non-limiting example, a single patch may contain one or more electrodes, the one or more electrodes arranged so as to establish a (virtual) reference for the system. During operation, the system may simultaneously monitor signals from the plurality of electrodes (i.e. via each patch/module pair), possibly in conjunction with the virtual reference. Within a patch/module pair a plurality of such electrodes may be coupled directly through a corresponding bioamplifier (i.e. such as may be located onboard the corresponding module). During a monitoring session, the patch/module pair, a hub, a coordinating module, or the like may be configured to extract multipolar signals, to detect, to amplify, and/or to algebraically combine such signals with one or more other multipolar signals monitored at sites located elsewhere on the body of the subject. In this manner, standard and/or higher level EKG lead configurations may be derived from multipolar signals obtained from a plurality of patch/module pairs on a subject.

[00113] In another non-limiting example, patch/module pairs including bipolar or multipolar electrode configurations may be placed on a body at standard EKG locations (limb or precordial sites), but not physically connected to one another. One or more electrode sites within the arrangement may be automatically designated as 'references' for the purposes of intra patch signal comparison. In aspects, the system may be configured to designate creation of a 'virtual' reference, and 'virtual' (i.e. calculated) standard leads (limb and precordial) equivalent recordings, performed using mathematics/signal processing techniques (e.g. algebraic transformations based upon one or more of the monitored signals, an image of the patch arrangement on the subject, a network topology of the patches, etc.).

[00114] Such a configuration may be advantageous for partially or completely eliminating the necessity of physical interconnection of electrodes via direct wire leads.

upon the subject. In aspects, such feedback may be used to enhance the sleep state of a subject, interrupt a sleep event to return a subject to a safe or comfortable sleeping state (e.g. interrupt a sleep walking event, a snoring event, a sleep apnea event, night terrors, nightmares, etc.). In aspects, such feedback may be analyzed in combination with the electrophysiological and/or physiologic signals to alter the state of the subject (e.g. the mood, the sleep pattern, the state of sleep, to prevent wake-up, to initiate wake-up, etc.).

[00122] In aspects, a feedback component in accordance with the present disclosure may include or be included in a wristwatch (e.g. a biometric watch, a smart watch, etc.). Such a wristwatch may include a display, a touch screen, or user input device, a tactile (i.e. vibrating) aspect, an audible feedback aspect or the like. Such feedback components may be used to convey signals, or metrics relating to the physiologic and/or physical signals to the wearer (e.g. the subject, a coach, a physician, a caregiver, a partner, etc.).

[00123] In aspects, a feedback component in accordance with the present disclosure may include a heads-up-display (HUD), such as may be provided by a pair of HUD ready glasses, Google Glass™, or the like. In aspects, the HUD may include visual representation of the physiologic and/or physical signals for a wearer (e.g. the subject, a coach, a caregiver, etc.), and/or signals or metrics related thereto or derived therefrom. In aspects, a plurality of such feedback mechanisms may be used to enhance the user experience, such as a combination of audible feedback (i.e. via a loudspeaker), and visual feedback (e.g. on a HUD, via a~~n~~ light emitting diode (LED), etc.).

[00124] In aspects, an augmented reality application may be envisaged using a pair of HUD ready glasses, or via a handheld device with both display and camera functionality (e.g. a tablet, etc.). In aspects, aspects associated with muscle exertion, electrocardiographic data, etc. may be superimposed onto movements associated with the monitoring site so as to highlight such activities to an observer. In one non-limiting example, heart-rate data may be translated into an amplitude parameter for pixel movements and overlaid onto the display or HUD over top of the torso of the subject as displayed in the image. In such an example, a physiotherapist may be able to visualize "exertion" of a muscle group of a subject as it is overlaid onto that particular muscle group during a monitoring session. The exertion may be compared against previous

[00132] In aspects, component operation on and data communication over the network may be coordinated through addition of a time stamp. The time stamp may be used by an associated processor to temporally compare data collected by a plurality of patches on a subject, between a patch on a subject and another recording device located in the environment, etc. One or more patch/module pairs may include a clock, an ultra-low power clock, for generation of the time stamp.

[00133] In aspects, each patch/module may be allocated a temporal window (i.e. temporally multiplexed) within which to broadcast a signal to the host and/or a commanding patch/module in the network. Such a configuration may be advantageous to coordinate significant amounts of data on a network within a limited number of channels.

[00134] In aspects, a system in accordance with the present disclosure may be applied to a stress monitoring application. Such a system may include one or more patches or patch/modules each in accordance with the present disclosure, attached to a subject. The system may be configured to measure one or more physiologic parameters from the subject (e.g. heart rate variability, sympathetic tone, muscular sympathetic nerve activity, galvanic skin response, skin sympathetic tone, electromyographic activity, respiration rate, etc.). Such information may be combined to form a metric relating to the stress state of the subject. Such a stress state may be represented by a feedback component in accordance with the present disclosure, as part of a biofeedback loop (e.g. a centering algorithm, a calming algorithm, etc.), provided in conjunction with a light and sound show, provided as an "emotional" input to a light and sound show, etc.

[00135] In aspects, the stress state may be used in conjunction with a biofeedback algorithm to help a subject lower the stress state during a monitoring session. Such a system may be advantageous for helping subjects reduce anxiety, reach a meditative state, realize when their stress state is elevated, help adjust respiratory rate, enter into a meditative state, etc.

[00136] In aspects, one or more patches and/or patch/module pairs may include one or more sensors configured to monitor one or more physiologic, environmental, and/or physical parameter locally on the subject. Some non-limiting examples of such sensors

include electrophysiologic sensors (e.g. EKG, EMG, EEG, electroretinogram (ERG), EOG, respiration,

bioimpedance, activity, etc.), temperature sensor (e.g. near to the skin, within a module, ambient [environmental], etc.), thermal gradient sensor (i.e. so as to calculate a heat transfer vector locally on the body of the subject, to estimate a core temperature), barometer, altimeter, accelerometer, gyroscope, humidity sensor, magnetometer, inclinometer, oximeter, colorimetric monitor (e.g. color change analysis of underlying tissue, for respiration, blood flow, pulse, etc.), sweat analyte sensor (e.g. so as to measure sweat constituents, salt content, etc.), galvanic skin response, neural activity (e.g. skin ~~sympathethic~~sympathetic activity), interfacial pressure sensors (e.g. for contact assessment, compliance measurement, blood pressure, etc.), flow sensor (e.g. airflow over a module, or the like), surface strain sensor (e.g. via integration of stretch sensors into the patch, evaluation of stretch along one or more electrical interconnect within the patch, integrated capacitive stretch sensors, etc.), a microphone, combinations thereof, and the like.

[00137] One or more patches and/or patch/module pairs may be configured so as to harvest power from a nearby power source (e.g. via inductive coupling, optical radiation, radio frequency waves, thermal gradients, kinetic energy, or the like). In aspects, one or more patches and/or patch/module pairs may include an antenna configured to communicate inductively with a nearby radio frequency power source. Such a configuration may be advantageous to work towards minimization of size and weight of the patch or patch/module pair, to reduce costs, recharge the modules without the need for physical connections, etc.

[00138] In aspects, an application for providing a physiologic input tool is envisaged. A system in accordance with the present disclosure may include one or more patches and/or patch/module pairs configured and arranged upon a subject so as to monitor one or more proprioceptive and/or electromyographic signals therefrom (e.g. such as from a muscle group, a bicep, a forearm, a finger, etc.). Such information may be coupled to a software program, such as a music generation program, a toy, a training program, etc. In aspects, the effort with which a muscle group, and/or appendage is moved may be used as an input to the software. In aspects, such input may be attributed to a musical note, an instrument, an avatar of the subject, etc. In aspects, such notes, instruments, etc. may be attributed to a particular patch and/or module, thus an orchestrated score may be

deadlift, leg press, feet in squats, and good mornings (bend over with a bar on the shoulders with a light amount of weight). Such monitored information may be used to assist with exertion feedback, limiting movement, and the like, so as to provide a subject or trainer with information during the exercise, limit the risk of damage, optimize training, maximize performance gains, or the like.

[00149] In aspects, such monitoring may be applied to virtually any muscle group or groups on the subject. Such approaches as described herein may be adapted to serve a range of exercises and sports, so as to assist subjects, trainers, physiotherapists, and the like with improving performance, adjusting gait, monitoring progression of an injury, comparing capabilities to previous efforts, assess or assist with sexual dysfunction, etc.

[00150] In aspects, a system in accordance with the present disclosure may be configured for long-term wear by a subject. The system may include one or more patches and/or patch/modules in accordance with the present disclosure, configured to comfortably attach to the subject and remain attached for a prolonged period of time (e.g. days, weeks, greater than 3 weeks, etc.). In aspects, the patch may include a bioadhesive with suitable breathability for long term wear (i.e. with moisture vapor transmission rate (MVTR) in a range such that tissues underlying the patch do not undergo maceration but also do not sufficiently dry out so as to impede electrophysiological measurement thereupon). In aspects, the module may include a gasket arranged so as to bias towards a mating patch when the two are assembled (i.e. so as to form a substantially water tight structure).

[00151] In aspects, the module may include a moisture sensor and/or humidity sensor positioned so as to monitor the environment between the module and the patch during use. Such information may be advantageous for determining if the patch needs to be swapped out during use.

[00152] In aspects, such a system may be suitable for use as a heart-rate variability (HRV) monitor. In aspects, such a module may include circuitry or be programmed with a function to calculate HRV from an EKG or extracted heart-rate metric. Thus, physiologic signals pertaining to HRV, heart rate (HR), etc. may be conveyed from the

module to the host during a monitoring session (i.e. as a means for reducing the amount of raw data to

be sent from the module to the host during a session). HRV monitoring may be advantageous for gauging training recovery, for evaluating a subject who has experienced a traumatic brain injury (e.g. via a sudden impact, repeated impacts, etc.), to grossly interpret activity of the sympathetic nervous system, to evaluate an emotional state or response of a subject, or the like.

[00153] In aspects, a system in accordance with the present disclosure may be adapted to monitor impact to a subject during a monitoring session. In aspects, the system may include a patch and/or patch/module pair including an accelerometer, a gyroscope, an altimeter, a barometer, stretch sensor, and/or a magnetometer configured so as to measure a sudden impact on the patch during a monitoring session. In aspects, the module may include circuitry or be programmed to monitor data derived from the sensors so as to determine if an impact has occurred (e.g. a rapid change one or more of the sensor data streams, a change of sufficient magnitude, etc.). Such information may be directed to a trainer, a doctor, a coach, a parent, or the like to alert them to the impact. In aspects, such information may be useful to determine if an impact requires further investigation, etc.

[00154] A system in accordance with the present disclosure may be configured for analyzing traumatic brain injury of a subject. The system may include one or more patch/module pairs in accordance with the present disclosure sized, dimensioned, and configured for placement at one or more sites on the head (e.g. sites 50, 131, 137, 140 as indicated in Fig. 1a, along a neck, along a forehead, along a temple, behind an ear, etc.) forming a head mounted patch/module pair, and optionally elsewhere on the body (e.g. on the chest, over a muscle group, etc.) forming a second patch/module pair.

[00155] In aspects, the head mounted patch/module pair may include one or more electrodes for monitoring local physiologic activity (e.g. EEG, EOG, EMG, etc.), near the brain of the subject, one or more kinetic or kinematic sensors (e.g. accelerometer, gyroscope, barometer), one or more additional sensors (e.g. local bioimpedance, hydration, temperature), and one or more acoustic sensors (e.g. a down facing microphone). The head mounted patch/module pair, or a processor coupled thereto may be configured to capture signals related to the above sensors in a black box, virtual black

box, rolling first in first out (FIFO) buffer, or the like. In addition a processor on or coupled with the head

present disclosure, the patch including at least one temperature sensor (e.g. a microcircuit based temperature sensor, a thermocouple, a bimetal strip, etc.), the patch configured so as to mate with a corresponding module, the module including one or more additional temperature sensors. The combination patch/module pair thus includes a plurality of temperature sensors (e.g. included in the patch, included in the module, etc.). Heat transfer from the adjacent tissues past the plurality of temperature sensors and into the surrounding environment will follow different pathways. The patch and/or module may include a plurality of controlled pathways with known heat transfer coefficients (e.g. such that the ratio of heat transfer coefficients between the pathways can be reasonably predicted). In aspects, the heat transfer coefficient along the pathway between the skin and each sensor may be known, and the heat transfer coefficient between each sensor and the surrounding environment may be known (e.g. to within a ratio). In aspects, the patch/module pair may include an additional temperature sensor, positioned so as to monitor a temperature near that of the surrounding environment (e.g. such as exposed on the surface of the module, on the surface of the patch pointing way from the body, collected from a local hub, from a smartphone, from a local weather report, or the like).

[00159] The temperature at a site remote from the patch (e.g. deeper into the tissue), may be estimated from the plurality of temperature readings in combination with thermal pathway coefficients. In aspects, temperature measurement may be improved by single point calibration with a traditional core temperature sensor. After calibration, the temperature measurements may be sufficient to estimate changes in core temperature over time while the subject wears the patch/module pair. In aspects, a plurality of patches worn by a subject may be used to improve an estimate of core temperature thereof.

[00160] In aspects, one approach for forming an embedded hydration sensor into a patch/module pair may include, embedding a plurality of electrodes into a patch in accordance with the present disclosure (e.g. 2 or more electrodes, 4 electrodes, etc.). The corresponding module may include a signal generator and one or more bioamps (or multiplexing circuits in combination with a reduced number of bioamps, etc.), the signal generator configured so as to provide a signal between two or more of the electrodes (e.g.

in a frequency range of generally between 1 hertz (Hz) and 10GHz, 1kHz and 10MHz, 5kHz and

1MHz, or the like, at multiple frequencies, swept over a range of frequencies, etc.), while the bioamps are configured to capture one or more signals from two or more of the electrodes. The processor, gate array, digital signal processor, or an associated microcircuit, configured to analyze the captured signals to determine a bioimpedance of the nearby tissues. Such a bioimpedance may be advantageous for monitoring a change in fluid level in the adjacent tissues. Such a configuration may be advantageous for assessing the fluid level of a subject. In aspects, two or more of the electrodes may be coupled to a second bioamp (an additional amplifier, the same amplifier, etc.), the second bioamp configured to capture a biosignal (e.g. EKG, HR, EMG, EOG, EEG, ERG, or the like) from the electrodes. Assessment of the signals at a plurality of frequencies may provide sufficient data to extract electrode impedance, from the reading, to estimate tissue impedance at different frequencies, and to extract the extracellular (ECW), intracellular (ICW), and total body water (TBW) content from the tissues under analysis by the patch/module pair.

[00161] In aspects, the patch/module pair includes an antenna, the antenna coupled to convey one or more signals to an external hub, additional patch/module pair, etc. The antenna may be coupled to the adjacent body, such that during signal transfer, the impedance of the antenna varies with water concentration of the adjacent tissues. During operation, changes in the S11 parameter for the antenna may be monitored, so as to determine local fluid levels in the adjacent tissues, while also transferring data back and forth for completing other functions.

[00162] In aspects, a second approach for forming an embedded hydration sensor into a patch/module pair may include, embedding a visible, near infrared, or infrared emitter into the module such that, upon coupling of the module with a corresponding patch, the emitter is arranged such that radiation emitted therefrom is directed into the tissues of the subject, the module including a photodetector (e.g. a narrow band detector, centered generally about 510 nanometer (nm), 578nm, 630nm, 750nm, 1000nm, 1180nm, 1040nm, 1210nm, 1300nm, 1500nm, a multi-band detector <combinations thereof>, a broad band detector, multiple detectors, etc.) to capture reflected or back scattered radiation from the skin from the emitter. In aspects, the corresponding patch may be

configured with a window transparent to, or polarized so as to exclude light, such that when the module is coupled

inclusion of one or more patch/module pairs equipped with an interfacial pressure sensor, local pulse assessment sensor, a compliance sensor, or the like), a modular EKG monitor (i.e. via inclusion of one or more patches or patch/module pairs configured to monitor local electrophysiological information from the torso of a subject), a modular EMG monitor (i.e. via inclusion of one or more patches or patch/module pairs configured to monitor electrophysiological information in the vicinity of functional muscle groups on the subject), an edema assessment system (i.e. via inclusion of a patch or patch/module pair configured to measure water content of tissues in the vicinity of the patch as placed onto the subject), a blood clot detection system (i.e. via inclusion of two or more patches to monitor changes in blood flow dynamics between the patches as placed along one or more appendages of a subject, e.g. flow dynamics as measured along the leg), a peripheral vasculature diagnostic system (e.g. via inclusion of one or more patches to monitor arterial flow, arterial brachial index, etc.), or utility in the monitoring of heart failure patients, patients that are short of breath, chronic obstructive pulmonary disease (COPD) patients, patients suffering or suspected of suffering from sleep apnea, valvular disease, metabolic syndrome, etc. to track cardiopulmonary parameters as indicators of disease state/progression, diagnostics, and/or therapeutic progress with the disease.

[00171] According to aspects a system for monitoring blood pressure of a subject is provided, the system including a plurality of patch/module pairs, at least one patch module pair configured to measure an electrophysiological signal in accordance with the present disclosure (i.e. an EKG patch), and at least one or more patch module pairs configured to measure a local signal relating to blood oxygen level and/or pulse in a tissue volume in the vicinity thereof (e.g. via optical methods, bioimpedance, spectroscopic, local counter pressure assessment, or the like in accordance with the present disclosure) (i.e. a local pulse patch). The EKG patch configured for placement on the torso of the subject, and one or more of the local pulse patches configured for placement at least on an extremity of the subject (e.g. on the torso and on an extremity, near a wrist, on an arm, on a leg, etc.). The system may include a time stamp in accordance with the present disclosure such that the timing of the electrophysiological signal obtained by the EKG patch may be compared to the pulse response signal(s) obtained by the local pulse patch(es). A time delay(s) between a reference wave on the

[00174] In aspects, a system in accordance with the present disclosure may be adapted for follow-up of a joint replacement surgery. In aspects, the system may include one or more patches and/or patch/module pairs configured for placement in the vicinity of the joint, or arranged so as to monitor muscle movement or exertion associated with the joint. In addition the to the physiotherapy related aspects discussed throughout the present disclosure, the patch and or module may be configured to monitor one or more aspects of the joint (e.g. joint acoustic signature, thermal changes in the joint during use, joint impacts, etc.). The system may be configured so as to analyze such data to predict a lifetime of the joint, predict patient outcome, detect early signs of grinding, or the like.

[00175] In aspects, one or more patches and/or modules in accordance with the present disclosure may include a micro compliance sensor and/or an interfacial pressure sensing element so as to assess local changes in blood pressure, pulse, arterial pressure, or the like. The microcompliance sensor can be used to assess local tissue stiffness, or placed in close proximity to vascular structures in order to measure vessel stiffness and/or pulse pressure. Arrangements of such sensors along the extremities of a subject may be advantageous for assessing blood flow (i.e. via pulse time of flight measurements), blood pressure, pulse, or the like. A microcompliance sensor may include a deformable part, and a Micro-Electro-Mechanical system (MEMs), or optoelectronic sensing element to determine the state of deformation of the deformable part. In one non-limiting example, a microcompliance sensor may include an elastomeric deformable part, configured so as to move when a pressure is applied thereto, and an optical source and detector, configured to deliver a light source into the deformable part and monitor a return signal therefrom. Changes in the return signal may be correlated to the deformation state of the deformable part, thus providing the necessary feedback. Such a patch may be advantageously applied to a blood pressure monitoring system as a local pulse patch in accordance with the present disclosure.

[00176] In aspects, a system in accordance with the present disclosure may be configured for simplified use by a subject. One or more patches or modules may include an interfacial monitor to determine if the system is attached to the subject. Upon attachment, the module may be configured to determine the quality of the attachment,

and connect to the BAN to start a monitoring session. In aspects, one or more patches or modules may include a battery monitor, interface monitor, etc. to determine if the patch

[00186] In aspects, the patch may be configured such that it is sufficiently breathable to water vapor and/or oxygen that it can be worn comfortably by a subject for a prolonged period of time. In aspects, one or more regions of the patch may be configured with a moisture vapor transmission rate of greater than 200g/m^2/24hrs, greater than 500g/m^2/24hrs, greater than 2,000g/m^2/24hrs, etc. In aspects, one or more regions of the patch may be configured with a moisture vapor transmission rate of less than 20,000g/m^2/24hrs, less than 12,000g/m^2/24hrs, less than 8,000g/m^2/24hrs, or the like. Such moisture vapor transmission rate (MVTR) may be approximately determined using ASTM standard ASTM E96: Standard test methods for water vapor transmission of materials.

[00187] In aspects, the substrate or the patch in accordance with the present disclosure on the whole may be stretchable, so as to maintain operation while stretching in conjunction with the surface of the subject where it is attached (e.g. on the torso, across a joint, along a muscle, etc.). In aspects, the substrate or the patch on the whole may be highly elastic so as to easily stretch with the skin without rucking, curling, lifting from the skin surface, etc. Such a soft and thin patch may be advantageous for substantially maximizing comfort of the subject, reducing skin irritation, etc. thus improving subject compliance for long term monitoring.

[00188] In aspects, an adhesive layer in accordance with the present disclosure may include a dielectric or an electrically conducting adhesive, a biocompatible pressure sensitive adhesive, a gel layer, a hydrogel layer, or the like. In aspects, the adhesive layer may include one or more patterned features, configured so as to provide regional variation in adhesion, to isolate regions of the skin surface in one region from adhesive located in other regions, and the like. In aspects, the adhesive layer may include a biodegradable polymer.

[00189] In aspects, one or more regions of an adhesive layer in accordance with the present disclosure may be electrically and/or ionically conducting and patterned onto the substrate so as to provide adhesion thereof to a skin surface. The substrate may be patterned with one or more electrical traces configured to connect one or more electrodes

with one or more connectors in an interconnect each in accordance with the present disclosure. In aspects, the electrical traces may be isolated from one or more regions of

medicated tips (e.g. tips formed from a medication filled biodegradable polymer, sugar, etc.) in the form of an arrow structure, a barb, etc. so as to maintain the electrode feature in place after an initial engagement with an adjacent tissue (i.e. so as to form an indwelling electrode – tissue arrangement). Such a configuration may improve retention of the tips within the tissues. Biodegradable or soluble tips may be advantageous to provide a slowly disengaging interconnection between the electrode features and the tissues over a desired time frame.

[00207] In aspects, a patch in accordance with the present disclosure may include one or more electrically conducting and/or one or more electrically insulating features (e.g. microfibers, barbs, microneedles, spikes, or the like) arranged so as to intimately interconnect the patch to the patient during a monitoring session. Such a configuration may be advantageous for reducing and/or eliminating the need for an adhesive layer in such a patch configuration.

[00208] In aspects, an electrode including one or more features in accordance with the present disclosure may be dimensioned with an area of less than 4 centimeter (cm)$^{\wedge 2}$, less than 1cm$^{\wedge 2}$, less than 0.5cm$^{\wedge 2}$, less than 0.25cm$^{\wedge 2}$, or the like for monitoring a macro signal such as is related to an EKG, an EEG, a surface EMG, etc. One or more of the electrodes (or one or more microneedle electrode features) may be dimensioned with an exposed electrode area of less than 1000um$^{\wedge 2}$, less than 200um$^{\wedge 2}$, less than 100um$^{\wedge 2}$, less than 50um$^{\wedge 2}$, less than 5um$^{\wedge 2}$, or the like, in the case of the microneedle electrode features optionally exposed at the tip thereof, so as to measure one or more micro-electrophysiological signals, a multi-unit nerve study, or the like. In aspects, a plurality of microneedle electrode elements may be electrically isolated from the others such that a plurality of micro electrophysiological measurements may be made therefrom. In aspects, the array may be coupled with a plurality of preamplifiers, multiplexers, analog to digital converters, comparators, or the like, so as to collectively capture micro-electrophysiological signals therefrom. In aspects, such a configuration may be advantageous for monitoring neural traffic at the surface of the skin, measuring skin sympathetic neural activity, ocular nerve activity, touch analysis, etc.

[00209] In aspects, the microneedles may be configured for providing a stimulating current into the adjacent tissues, the patch and/or module including one or more pulse generators configured to provide the stimulating current. Such a configuration may be advantageous for providing an easy to apply acupuncture system for treating a subject.

[00210] In aspects, a system in accordance with the present disclosure may include one or more patches for attachment to a subject at alternative, seemingly arbitrary locations. The patches may be attached over the body of the subject to investigate physiologic parameters related to specific regions of the body, to determine blood flow propagation, electric field propagation, local muscle response, etc. as discussed throughout the present disclosure.

[00211] In aspects, one or more sensors may be formed from one or more organic electronic elements, patterned versions thereof, semiconducting versions thereof, etc.

[00212] In aspects, other methods for rendering the skin conductive and/or for generating conductive portals on the body include subdermally implantable studs, infusions of conducting materials, ~~influsion~~ infusion of hyaluronic acid and optional in situ gelation thereof in the tissues, in situ polymerization of an intrinsically conducting polymer, application of electroporation (e.g. optionally via a patch/module pair, a handheld device, etc.), abrasion, or the like.

[00213] In aspects, a wide range of functions for microcircuits in accordance with the present disclosure are envisaged, including storing identification information, configuring an inductive interface (i.e. with an antenna embedded into a patch) to provide inductive coupling of one or more patch elements to a corresponding module, etc. In aspects, one or more microcircuit may be embedded into a patch in accordance with the present disclosure, embedded into the housing of a module, etc.

[00214] In aspects, a microstud in accordance with the present disclosure may be configured to form an interconnect between a patch and a mating structure on a module as well as to provide a medium for conducting electricity between the patch and the module during use.

[00215] In aspects, a patch and/or module in accordance with the present disclosure may include means for biasing a sensor included therein towards the subject so as to maintain more intimate contact between the sensor and the subject during a monitoring session.

[00216] In aspects, a system in accordance with the present disclosure may include an isolating patch for interfacing a handheld unit monitoring device with a subject. In aspects, the isolating patch may include one or more subject side electrodes and one or more device side electrodes. Each subject side electrode coupled to one or more of the device side electrodes so as to provide a means for communicating between the skin of the subject and the handheld unit (i.e. without the handheld unit coming into direct contact with the subject). Such an isolating patch may be advantageous for interfacing a handheld EKG monitoring apparatus (e.g. a hand held unit with contact electrodes, an AliveCor™ module, etc.).

[00217] In aspects, such an isolating patch may include a z-axis conducting adhesive, formed so as to provide a conductive medium through the thickness of the isolating patch without allowing for transfer of biological species there between.

[00218] In aspects, the z-axis conductive adhesive may be patterned such that an operator of the handheld unit may observe one or more visual cues when aligning the handheld unit with the isolating patch in order to interface with the subject.

[00219] In aspects, a patch in accordance with the present disclosure may be configured and dimensioned for attachment to the bridge of a subject's nose (i.e., a nasal patch configuration). Such a nasal patch may include an optical sensor and optionally a light source each in accordance with the present disclosure. The optical sensor may be configured to capture light from an adjacent skin surface (i.e. nasal tissues) for purposes of measuring local blood flow, a heart-rate, etc. therefrom. In aspects, the nasal patch may include a flexing member (e.g. a stiffened polymer element, etc.) optionally integrated into, or representing the substrate, the flexing member configured so as to pull upon the sides of the nose after placement, so as to improve airflow there through. Such a configuration may be advantageous for monitoring a subject during exercise while improving performance of the subject (i.e. via improving breathe exchange).

electrically conducting interconnect, each patch and module interconnect may include complimentary electrically conducting connectors, configured and dimensioned so as to conduct current there between upon attachment.

[00224] In aspects, the module may include a housing, the housing including one or more aspects of the interconnect, optionally providing a sealed cavity in which other components of the module may reside. One or more of the circuits may be integrated into the housing. In aspects, the interconnect may be integrated into one or more circuits included in the housing. The antenna may be integrated into the housing (e.g. printed onto the housing, embedded into the housing, sealed within the housing, etc.).

[00225] In aspects, an interconnect in accordance with the present disclosure may be embedded into one or more of the circuits. The interconnect may be at least partially formed from a through-hole within the circuit (i.e. formed in conjunction with a through hole interconnect on a circuit board of the module). The interconnect may include a cap configured as a surface mount component to form a hermetic seal around the interconnect itself (i.e. so as to isolate the interior of the module from the interconnect).

[00226] In aspects, an interconnect, circuit, circuit board, high density interconnect (HDI) board, or the like may include a magnetic. In aspects, the magnet may be embedded into a circuit of the module (e.g. embedded into a region, attached to, or embedded into a through-hole of the circuit). Such a configuration may be advantageous to simplify assembly of the module and reduce the form factor taken up by the interconnects within the module.

[00227] In aspects, an interconnect and/or circuit board including a magnet may be configured such that the magnet forms the electrical connection to the patch as well as maintains a bias force between the module and the patch during the attachment period.

[00228] In aspects, the module may include one or more sensors each in accordance with the present disclosure. A system in accordance with the present disclosure may include a plurality of module types (i.e. modules with differing sensing aspects). In one non-limiting example, the system includes a kinetic module including an accelerometer, a gyroscope, and/or a magnetometer, a thermal module including one or more temperature

sensors, an airflow sensor, and/or a moisture sensor, and an optical module including an optical sensor configured to monitor one or more optical parameter in an associated patch

or skin surface. Such module functionality may be included in addition to the communication and power aspects provided to interface with a corresponding patch (which may include one or more sensors, electrodes, etc.).

[00229] In aspects, the interconnect may include one or more snap connectors (i.e. so as to interface with a corresponding microstud based patch, etc.).

[00230] In aspects, one or more modules in accordance with the present disclosure may include one or more sensors and/or microcircuitry configured to interface with the sensor(s), the sensors configured to monitor one or more physiologic, environmental, and/or physical parameters locally on the subject. Some non-limiting examples of such sensors include electrophysiologic sensors (e.g. EKG, EMG, EEG, ERG, EOG, respiration, bioimpedance, activity, etc.), temperature sensor (e.g. near to the skin, within a module, ambient [environmental], etc.), thermal gradient sensor (e.g. so as to calculate a heat transfer vector locally on the body of the subject, to estimate a core temperature, etc.), barometer, altimeter, accelerometer, gyroscope, humidity sensor, magnetometer, inclinometer, oximeter, colorimetric monitor (e.g. color change analysis of underlying tissue, for respiration, blood flow, pulse, etc.), sweat analyte sensor (e.g. so as to measure sweat constituents, salt content, etc.), galvanic skin response, neural activity (e.g. skin ~~sympathethic~~sympathetic activity), interfacial pressure sensors (e.g. for contact assessment, compliance measurement, blood pressure, etc.), flow sensor (e.g. airflow over a module, etc.), surface strain sensor (e.g. via integration of stretch sensors into the patch, evaluation of stretch along one or more electrical interconnect within the patch, integrated capacitive stretch sensors, etc.), a microphone, combinations thereof, and the like.

[00231] In aspects, a module in accordance with the present disclosure may include a three dimensional antenna. The antenna may be arranged along, or embedded within a wall of the module housing (e.g. printed along the wall of the housing, embedded within the outer wall of the housing, particularly in a dome shaped, or pseudo hemi-spherically shaped module, etc.). In aspects, the antenna may be formed from a freestanding conducting structure, suspended above a ground plane situated within the module (e.g. incorporated into a circuit thereof), etc. Such a configuration may be advantageous for

ALGORITHM ASPECTS:

[00252] A method for monitoring one or more physiologic and/or physical signals from the body of a subject in accordance with the present disclosure includes applying one or more patches each in accordance with the present disclosure to the body of the subject, and attaching a corresponding number of modules each in accordance with the present disclosure to the patches (i.e. so as to form one or more patch/module pairs in accordance with the present disclosure), establishing a body area network among the modules, and collecting physiologic and/or physical signals from the subject using the patches and modules during a monitoring session (i.e. for a period of time suitable for the desired purpose of the method, e.g. 10seconds, 1 minute (min), 1hr, 8hrs, 24hrs, 1week, 1month, 3 months, chronically, etc.).

[00253] In aspects, the method may include storing the collected signals on a memory device (e.g. a memory location on the patches, the modules, a host device, a user device, a datacenter, etc.). In aspects, the body area network may be extended to include a host device in accordance with the present disclosure. The method may include transferring the signals and/or one or more signals and/or metrics derived therefrom from the patches and/or modules to the host device, in real-time, intermittently, in a time synchronous fashion, or the like, during and/or after the monitoring session. In a range of applications, the system may be configured to monitor for an event (e.g. a change in heart function, a change in EMG, a change in posture, an impact, a change in breathing rate, etc.).

[00254] In aspects, there may be applications where real-time or even pseudo real-time data collection is not necessary (i.e. during aspects of a home sleep study, etc.). In such scenarios, a module in accordance with the present disclosure may be configured to store the collected data locally on a memory device. The module may be configured to download the data to a recharging bay in accordance with the present disclosure at the conclusion of the monitoring session, periodically throughout the monitoring session, or the like in order to transfer the data to a processor for analysis, review, etc.

[00255] In aspects, a method for interacting with a subject with one or more patch/module pairs in accordance with the present disclosure may include measuring one or more physiologic signals therefrom. The method may include deriving a feedback

signal, a command, an alert, a metric, a diagnostic value, a schedule, an augmented reality overlay, etc. from one or more of the signals. The method may include identifying when one of the modules requires attention (e.g. the battery is low, a poor interconnection has been made with a corresponding patch, or between a corresponding patch and the subject, a malfunction has occurred, a poor signal quality is being obtained therefrom, etc.). Attention may include swapping the module with a new module, swapping the module out without interrupting the monitoring procedure, removing the module and corresponding patch from the subject, etc.

[00256] In aspects, the method may include providing feedback to a user (e.g. the subject, a physician, a therapist, an officer, a soldier, a group leader, a teacher, a student, an emergency medical technician (EMT), a coach, a trainer, a partner, etc.) relating to the physiologic and/or physical signals. The method may include representing a signal, value, metric, graphic, etc. related to the signals on a feedback component in accordance with the present disclosure (e.g. on a display, a HUD, a wristwatch, an earpiece, a loudspeaker, a tactile display, etc.).

[00257] In aspects, the method may include coordinating the monitoring session across multiple subjects, and optionally synchronizing data collection across the subjects for purposes of calibration, comparative analysis, etc.

[00258] In aspects, a method for identifying a patch/module pair participating in a body area network (BAN) on a subject in accordance with the present disclosure includes placing an object (e.g. a hand, a phone, etc.), over a patch/module pair on the subject while listening to the wireless signal strength of all patches within range, and identifying the patch/module pair by a change in the wireless signal strength measured at a receiving hub (e.g. the phone, a hub, one or more modules, etc.), witnessed during the placing process. Such a configuration may be advantageous for establishing a communication link (i.e. pairing) one or more patch/module pairs on a subject with a host device within an environment with a large number of wireless devices or significant wireless signal clutter (e.g. a gym, a spin class, a conference, an airport, etc.).

[00259] In aspects, one or more steps in the method may be included as part of a BAN initiation routine, to identify placement of one or more modules on a subject, etc. The

method may include prompting a user to place a hand over each module in order to identify it on the subject. The method may include prompting the subject with an image, showing where to place the patch/module pairs. In aspects, the method may include assessing the accuracy of the placement of a patch on the subject (e.g. by assessing the physiologic signal obtained therefrom, comparing such readings against a reference, prompting the subject to perform a test routine such as moving an arm, transitioning the subject from a sitting to a standing position, etc.).

[00260] In aspects, a method for identifying a patch/module pair on a subject in accordance with the present disclosure irrespective of the number of patches placed in the vicinity thereof may include, applying one or more patches to the subject (e.g. in a predetermined pattern, substantially random pattern, etc.). Once the system is in communication with and optionally sending data to a host device (e.g. via a wireless link), the host device or a feedback component may prompt the user (e.g. the subject, the care giver, the nurse, the physician, etc.) to place a hand over a patch, a preselected patch, the patch generally nearest to the heart. Upon placement of the hand over the patch, the RF signal power strengths from the patch in question may change appreciably compared with other RF signal power strengths within communication range and thus a positive identification (ID) can be attained without additional hardware requirements.

[00261] Such a method may be adapted for simplifying the pairing process between a host device (e.g. a smartphone, a wireless local area network (WLAN), etc.), and one or more patches arranged on the subject. In one non-limiting example, such a method may be used to determine which module a user's hand is placed over during a pairing procedure (e.g. perhaps within range of 100s of other wireless devices, modules, etc.). Such a method may be advantageous for use within a gym setting, a fitness class setting, etc.

[00262] In aspects, a system may, at least roughly, determine the general location of one or more patch/module pairs with respect to a host device, by assessing the RF signal strength as received by the host device from one or more of the patch/module pairs in comparison with those received from the other patches in the system.

[00263] In aspects, a modular physiologic monitoring system in accordance with the present disclosure may include a plurality of patches (e.g. patches, patch/module pairs,

[00282] The recharging bay may be configured to interface with a host device, a user device, etc. for purposes of monitoring the subject, and/or providing alerts, assisting with configuration of a system in accordance with the present disclosure, etc.

[00283] In aspects, the kit may include a patch set configured for providing specific functionality on a subject, or sized to fit the subject (e.g. small, medium, large, custom, etc.). In aspects, the patch set may be configured to perform a 3 lead EKG, a redundant 12 lead EKG, a biomechanic assessment (e.g. for a leg, a hand, an arm, a foot, etc.), a sleep lab assessment, an impact study, a sport specific application, a heart-rate monitoring session, a thermal overload monitoring session (e.g. for monitoring for heat exhaustion, etc.), a weight lifting workout, etc.

[00284] In aspects, there is provided, an adhesive test kit for determining preferences of a user prior to performing a monitoring session in accordance with the present disclosure. The adhesive test kit may include a series of patches, each patch with identification markings and an associated adhesive (i.e. each with an alternative type of adhesive). The adhesive test kit may be provided to a perspective customer, so as to choose the adhesive type that best suits their needs (e.g. the adhesive with the best long-term wear ability for their skin type, for their diet, adhesive with the lowest irritation for that person, etc.).

[00285] In aspects, the adhesive test kit may include a plurality of test patches with a range of adhesive options for potential customers to test during a workout, in a shower, during rest, etc. in order to determine which best suits their needs, best limit skin irritation, best adhere to their skin, etc. In aspects, a customer to a service plan in accordance with the present disclosure may receive periodic adhesive test kits to determine if alternative adhesives would better serve their changing needs, etc.

[00286] In aspects, one or more adhesive samples in the kit may include polyacrylate, polyisobutylene, polysiloxane, polyurethane, pressure sensitive adhesive, amphiphilic adhesive, polyvinylpyrrolidone (PVP), polyvinyl Alcohol (PVA), polyethylene glycol (PEG), or poly (2-acrylamido-2-methyl propyl sulfonic acid (PAMPS) based hydrogel adhesives, combinations thereof, or the like.

[00287] As part of a service plan, an adhesive test kit may be provided to a customer. The customer may wear the samples provided in the kit for a suitable period of time

depending on the intended application, to determine which adhesive is best for them (e.g. most compatible with their skin, wearable, reliable, etc.).

[00288] The test patches may be configured with additional weight, etc. to simulate the attachment of a module thereto. One or more test patches may include an impedance monitoring circuit to assess the reliability of a monitoring process provided therewith.

[00289] The recharging bay may be integrated into a display (e.g. into the chassis of a signal display system, etc.). Such a display may provide a means for a user to interact with the recharging bay, provide data, metrics, or visualization of the signals, etc. Such a display may be advantageous for use within a hospital setting, as a monitor and/or analyzer in an intensive care unit (ICU), an operating room (OR), etc. with a cluster of modules, patient interfaces and hand-held coordination devices.

BUSINESS METHOD ASPECTS:

[00290] According to aspects, there is provided a service (i.e. optionally embodied in the form of a service system) for managing the collection of physiologic data from a customer, including a subscription service in which a customer is assigned a profile including usage related information (e.g. purposes for monitoring, billing, etc.), an automated patch delivery system configured to provide a customer with a timely series of patches for use in one or more associated monitoring sessions, a datacenter configured to store, analyze, etc. the data obtained from the customer during one or more monitoring sessions, a report generating service configured to generate one or more monitoring reports based upon the data obtained during one or more monitoring sessions, and a recurrent billing system configured to bill the customer based upon the number or patches consumed, the data stored, the reports generated, or the like.

[00291] The service may include a module replacement system configured to identify from the data when a customer may require additional modules and to include such modules along with a replacement patch set delivery, for immediate delivery, etc. depending on the particular needs of the customer.

[00292] The service may include one or more application programming interfaces (APIs) whereby one or more 3rd parties (e.g. a data repositories, government agencies,

In aspects, the host device may be configured to generate one or more physiologic signals, alerts, etc. therefrom.

[00298] In aspects, one or more patches, modules, a host device, user device, and/or an analysis device may fuse sensory information from one or more patches during a monitoring session. If sensory information is missing from a particular patch, module, etc. or if it is in some way compromised, etc. the one or more patches, modules, the host device and/or the analysis device may ignore, remove, de-emphasize, etc. the information. As such, the system may be advantageous for providing a robust, fault tolerance means for monitoring one or more physiologic parameters of a subject.

[00299] In aspects, one or more patches, modules, a host device, a user device, and/or an analysis device may generate various levels of alerts for maintaining the monitoring session during a long-term monitoring session on a subject. Such alerts may be related to a subject emergency (e.g. a fall, a heart arrhythmia, a neurological arrhythmia [e.g. due to a seizure], an elevated heart-rate, syncope, an accident, an impact, a sleep apnea event, respiratory arrhythmia, choking, a drop in arterial carbon dioxide (CO_2), hypercapnia, a missing heart-rate, etc.), a moderate priority maintenance need (e.g. a high number of compromised signals, a high number of low or depleted power sources, etc.), a low priority maintenance need (e.g. a limited number of compromised signals, one or more low battery indications, etc.).

[00300] In aspects, one or more patches, modules, a host device and/or an analysis device may generate an "information quality" signal related to the overall quality of one or more signals (e.g. individual information signals, a collective signal, a physiologic parameter, etc.) related to one or more patches on the subject, and/or the overall system. Such an "information quality" signal may be used to determine and/or convey the degree of confidence that the system has in the physiologic parameters of a subject being measured during a monitoring session. The signal may be good, average, compromised, poor, unacceptable and/or the like. An alert may be advantageously constructed from the information quality signal so as to optimally compromise between functionality (e.g. basic quality of the monitoring session) and productivity (e.g. number of alerts requiring attention) during a monitoring session.

patches and/or patch module pairs 5 – 137, and/or the feedback devices 135, 140 may be configured for wireless communication 146, 149 during a monitoring session.

[00306] In aspects, a patch/module pair may be adapted for placement almost anywhere on the body of a subject 1. As shown in Fig. 1a, some sites may include attachment to the cranium or forehead 131, the temple, the ear or behind the ear 50, the neck, the front, side, or back of the neck 137, a shoulder 105, a chest region with minimal muscle mass 100, integrated into a piece of ornamental jewelry 55 (may be a host, a hub, a feedback device, etc.), arrangement on the torso 110a-c, arrangement on the abdomen 80 for monitoring movement or breathing, below the rib cage 90 for monitoring respiration (generally on the right side of the body to substantially reduce EKG influences on the measurements), on a muscle such as a bicep 85, on a wrist 135 or in combination with a wearable computing device 60 on the wrist (e.g. a smart watch, a fitness band, etc.), on a buttocks 25, on a thigh 75, on a calf muscle 70, on a knee 35 particularly for proprioception based studies and impact studies, on a shin 30 primarily for impact studies, on an ankle 65, over an Achilles tendon 20, on the front or top of the foot 15, on a heel 5, or around the bottom of a foot or toes 10. Other sites for placement of such devices are envisioned. Selection of the monitoring sites is generally determined based upon the intended application of the patch/module pairs described herein.

[00307] Fig. 1b shows a series of patch/module pairs 150a-e each in accordance with the present disclosure placed upon a subject 2 as part of a monitoring session in accordance with the present disclosure, in this case an EKG monitoring session. An image 152 of the subject 2 has been taken and may be analyzed in accordance with the present disclosure to calculate one or more standard lead configurations from the arrangement of patch/modules 150a-e shown.

[00308] Fig. 1c shows aspects of communication between ~~a~~ subjects 155, 160 and ~~a~~ non-subject users 156, 161 partaking in a monitoring session in accordance with the present disclosure. In a first aspect, the subject 155 is wearing a series of patches and modules each in accordance with the present disclosure configured to communicate with one or more of a host device 158, a display 157b, a HUD, a pair of virtual reality goggles, a Google Glasses™ based feedback device 157a (i.e. potentially via a smartphone hub),

and/or a wristwatch ~~147c~~ 157c to ~~communication~~ communicate one or more feedback signals in accordance with the present disclosure to the user 156.

[00309] In a second aspect, the subject 160 is wearing a series of patches and modules each in accordance with the present disclosure configured to communicate with one or more of a host device 163, a display 162b, a virtual reality headset, a HUD, a Google Glasses™ based feedback device 162a (i.e. via a smartphone hub), a wristwatch 162c, and/or one or more patches and/or modules configured upon the body of the user 161 to ~~communication~~ communicate one or more feedback signals in accordance with the present disclosure to the user 161 or to convey one or more sensations to the body of the user 161 (i.e. via the attached patches).

[00310] In aspects, the communication between the subjects 155, 160 and the users 156, 161 may be bidirectional (i.e. the subject 155, 160 may also receive information corresponding to physiologic and/or physical information obtained from the user 156, 161).

[00311] Fig. 1d shows a time series example of an identification process for a patch/module pair in accordance with the present disclosure. In the non-limiting example shown, the modules are equipped with radios, each radio capable of sending a signal with a predetermined signal strength (left vertical axis) and equipped with a barometer or altimeter calibrated to give a relative height signal (right vertical axis). In aspects, a user, a program on a feedback device, on a host device, on a user device, etc. may prompt a subject or user to cover a particular patch on the body of the subject (e.g. communicated to the subject or user via an instruction pamphlet, via a screen prompt, etc.). When the prompted module is covered (period between timestamps 180, 185) the signal strength of the module is changed by a substantially identifiable amount 175. Thus a simple procedure may be used to identify a module in the BAN, correlate a module on a particular site on the subject with a corresponding ID received by the host device, etc. Other aspects and variants of a localization and/or orientation procedure are discussed throughout this disclosure.

may be advantageous to assist a user with alignment and attachment of a module 292 to a patch 290 as well as may be useful for a vision algorithm to extract orientation, functional (e.g. by color or pattern of the markings 294, 296, 298), and/or identification information from an image of the patch 290 and module 292 as placed onto a subject as part of a monitoring session.

[00322] Figs. 3a-f show aspects of patches in accordance with the present disclosure.

[00323] Fig. 3a shows a patch 301 coupled to a module 305 each in accordance with the present disclosure. The patch 301 includes a plurality of electrodes 303a-~~d~~ e for interfacing with a subject. The electrodes 303a-~~d~~ e are arranged in a somewhat linear fashion along the patch 301, perhaps for assessing electrocardiographic signals at sites in the vicinity of the heart of a subject.

[00324] Fig. 3b shows a patch 306 coupled to a module 310 each in accordance with the present disclosure. The patch 306 includes a bipolar electrode arrangement 307a,b for interfacing with a subject. Such an arrangement may be advantageous for monitoring heart-rate, a signal channel EKG, EMG, respiration rate, acoustic monitoring coupled with EMG of one or more neck or facial muscles, EEG monitoring coupled with kinematic sensors behind the ear, etc. of a subject as part of a monitoring session.

[00325] Fig. 3c shows a patch 311 coupled to a module 315 each in accordance with the present disclosure. The patch 311 includes multiple electrodes 313a-~~e~~ f for interfacing with a subject. The electrodes 313a-~~e~~ f may be arranged so as to interface with one or more muscle groups along an appendage of a subject, as part of an EMG study in accordance with the present disclosure. The patch 311 may be formed so as to maintain an electrical interface between the electrodes and the module 315 while undergoing stretch during the monitoring session (e.g. in aspects where the length between the electrodes may change substantially during the monitoring session, etc.). In aspects, such a configuration may be advantageous for spanning the length of a muscle, crossing a joint, wrapping around the curvature of a limb, a foot, etc. of a subject as part of a monitoring session.

[00326] Fig. 3d shows a patch 316 coupled to a module 320 each in accordance with the present disclosure. The patch 316 includes three electrodes 318a-c for interfacing

with a subject. The electrodes 318a-c may be arranged so as to provide multi-site capture of electrophysiological activity on the subject. Such an arrangement may be advantageous for generating a field vector in the vicinity of the patch 316. In aspects, the module 320 may include an algorithm configured to analyze incoming data from the electrodes 318a-c (i.e. perhaps with a signal electrode in the set selected as a reference etc.) and to calculate field vector with orientation and magnitude in relationship to the orientation of the electrodes on the patch 316. In aspects, such a configuration may be advantageous for calculating a vector electrocardiogram on a subject, calculating muscle action potential vectors, muscle signal orientation, calculating electric field propagation directions along the surface of the subject, or the like.

[00327] Fig. 3e shows a patch 322 in accordance with the present disclosure. The patch 322 includes a window 324 through which a sensor (e.g. an optical sensor, etc.) included in an associated module (not explicitly shown) may interface with the subject during a monitoring procedure. The patch 322 may include further electrodes, sensors, etc. (not explicitly shown) to enable additional monitoring functionality from the same module. Such a configuration may be advantageous for monitoring local blood flow optically, perform colorimetric assessment of underlying tissues, provide seamless entry of radiation into the tissues, etc. during a monitoring session in accordance with the present disclosure.

[00328] Fig. 3f shows a patch 328 in accordance with the present disclosure. The patch 328 includes multiple sensors 333a,b, coupled with a plurality of conducting members (e.g. electrical traces, printed conductors, spun nanotube fibers, stretchable conducting traces, etc.) 336a-c, and a plurality of interconnects 331a-c each in accordance with the present disclose. The sensors 333a,b may be arranged, configured, and dimensioned so as to interface with and/or monitor an underlying tissue structure, property, and/or tissue or fluid analyte (such as tissue composition, fat content, water content, blood oxygen saturation levels, etc.), of a subject during a monitoring procedure.

[00329] Figs. 4a-f show top, side, and isometric views of a mated patch 401, 405 and module 403, 407 each in accordance with the present disclosure. Such a configuration

subject with a very small profile. In aspects, one or more of the electrodes 805a,b may include an electrode feature in accordance with the present disclosure for enhancing the electrical coupling between the module 803 and the underlying tissues of a subject. In aspects, pressure applied to the top of an attached module 803 may be suitable for engaging an electrode feature with the underlying tissue of the subject. Such an arrangement may be advantageous for providing an ultra-miniature heart-rate monitor, a pediatric heart-rate monitor, an EMG sensor for placement near a sexual organ, an electrophysiological monitor behind an ear, on a neck, etc.

[00335] Fig. 8b shows a patch 807 coupled to a module 809 each in accordance with the present disclosure. The patch 807 includes a bipolar electrode arrangement 811a,b for interfacing with a subject. Such an arrangement may be advantageous for monitoring heart-rate, a signal channel EKG, respiration rate, etc. of a subject as part of a monitoring session. A plurality of such patches 807 may be applied to a subject to simultaneously extract a higher level or spatially distributed electrical field over the body of the subject.

[00336] Fig. 8c shows a patch 813 coupled to a module 815 each in accordance with the present disclosure. The patch 813 includes three electrodes 817a-c for interfacing with a subject. The electrodes 817a-c may be arranged so as to allow for multi-site capture of electrophysiological activity on the subject. Such an arrangement may be advantageous for generating a field vector in the vicinity of the patch 813.

[00337] Fig. 8d shows a patch 819 coupled to a module 821 each in accordance with the present disclosure. The patch 819 includes a quadripolar electrode arrangement 823a-d for interfacing with a subject. The quadripolar electrodes 823a-d may be arranged so as to allow for multi-site capture of electrophysiological activity on the subject. Such an arrangement may be advantageous for generating a field vector in the vicinity of the patch 819, for mapping electric field propagation across the surface of the subject, etc.

[00338] Fig. 8e shows a patch 825 coupled to a module 827 each in accordance with the present disclosure. The patch 825 includes a plurality of electrodes 829a-b for interfacing with a subject. The electrodes 829a-b are shown in a bipolar arrangement connected to stretchable conducting elements 831a,b. In aspects, such a configuration may be advantageous to freely flex and stretch 833 along with the nearby tissues of the

module 1215 upon assembly, alternatively an inductive interface, or a capacitive interface in accordance with the present disclosure.

[00352] Also shown, the patch 1201 includes a plurality of electrodes 1208a,b each in accordance with the present disclosure. The electrodes 1208a,b are coupled to the patch interconnect 1211a,b with one or more stretchy electrically conducting traces each in accordance with the present disclosure (e.g. in this case provided by a stretchable electrically conducting ink, printed onto a surface 1212 of the substrate 1203 so as to be sandwiched between the substrate 1203 and the adhesive 1205). The electrodes 1208a,b may include one or more electrically conducting and/or ionically conducting substances each in accordance with the present disclosure for interfacing with an adjacent subject during use.

[00353] Fig. 12b shows aspects of a patch 1227 coupled to a module 1225 in accordance with the present disclosure. The patch 1227 includes a substrate 1230 and adhesive 1235 for interfacing with a subject, each of which are substantially transparent to energy transferred to and/or from 1245 the module 1225 into the subject during use. Such energy transfer 1245 may be completed by a transducer 1240 and may be monitored by the same or an equivalent sensitive transducer 1240.

[00354] Fig. 12c shows aspects of a patch 1251 and a corresponding module 1265 each in accordance with the present disclosure. The patch 1251 includes a substrate 1253 and electrodes 1255a-c for interfacing with a subject. The patch 1251 includes multiple microstuds 1271a-c in accordance with the present disclosure. The studs 1271a-c may be electrically coupled with the electrodes 1255a-c via traces included in the substrate 1253 (e.g. patterned on, coated on, printed onto, embedded into the substrate 1253, etc.). The studs 1271a-c may coated with an insulating layer 1260, in this case configured so as to both insulate the studs 1271a-c from the subject but also to add local rigidity to the region of the patch 1251 in the vicinity of the interconnect (i.e. the collection of microstuds 1271a-c).

[00355] The module 1265 may include a plurality of corresponding connectors 1275a-c for interfacing with the microstuds 1271a-c. The connectors 1275a-c may be integrated into a printed circuit board 1270, which duals as a portion of the housing of the module

1265. In aspects, the connectors 1275a-c may include solderable components for securement to the

PCB 1270. In aspects, the connectors 1275a-c may be substantially formed from through hole interconnects in the PCB 1270 (i.e. so as to simplify the assembly process thereof). In aspects, the PCB 1270 may include an undercoating, gasket, etc. in order to substantially isolate the interconnects 1271a-c, 1275a-c from the surroundings during use.

[00356] Fig. 13 shows a schematic of a patch/module pair 1300 configured to apply energy 1325 (in this case vibrational energy) to the surface 7 a subject 1301 in accordance with the present disclosure. The patch/module pair 1300 includes an adhesive layer 1310 (i.e. potentially formed from a patch coupled to the module ~~1300~~) for securement to the subject 7. The module 1315 includes a transducer 1305 configured to for generate vibrational energy 1325 for transfer 1330 into the subject 1301. The transducer 1305 may be controlled and/or powered by an electronics unit 1320 included in the module 1315. In the non-limiting example shown, the transducer 1305 may be piezoelectric material (e.g. polymer, ceramic, etc.).

[00357] Fig. 14 shows a patch/module pair 1400 for applying thermal energy 1430 to a subject 1402 in accordance with the present disclosure. The patch/module pair 1400 includes an adhesive layer 1410 for attachment to a skin surface 1402 of the subject 1401. The module 1415 includes one or more heater bands 1405 or RF heating circuits, and thermocouples ~~1506~~ 1406 coupled to an electronics unit 1420 including a power source, a microcircuit, etc. via one or more electronic interconnects 1408.

[00358] Fig. 15 shows a vibrating patch/module pair 1500 configured to apply a tactile input 1525 to the surface 1502 of a subject 1501 in accordance with the present disclosure. The patch/module pair 1500 includes an adhesive layer 1510 (i.e. potentially formed from a patch coupled to the module ~~1500~~) for securement to the subject 1501. The module 1515 includes a transducer 1505 configured to for generate the torsional energy 1525 for transfer 1530, 1535, ~~1545~~ 1540 into the subject 1501. The transducer 1505 may be controlled and/or powered by an electronics unit 1520 included in the module 1515. In the non-limiting example shown, the transducer 1505 may be an electric motor with an eccentricity on the output shaft thereof. The transfer 1530, 1535, ~~1545~~ 1540 of energy into the surface 1502 of the subject 1501 may induce a range of

sensations, from poking, to rubbing, dependent upon the amplitude, frequency, duration, duty cycle of the

compression thereof). In aspects, the gel adhesive 1743 may be patterned onto the substrate 1741 and conducting trace 1745 so as to embed the electrode features 1747 within the gel adhesive 1743 (i.e. so as to just cover the electrode features 1747 such that upon placement of a skin surface 14, the electrode features 1747 do not engage with the skin surface 14).

[00370] After placement onto the skin 14 of a subject, referring to frame 2, a bias force 1749 may be applied to patch 1740 in the general vicinity of the electrode features 1747 causing the electrode features 1747 to engage with the skin 14 (e.g. to embed into the skin 14, penetrating 1753 into the stratum corneum thereof). During application of the bias force 1749, the gel adhesive 1743 may deform 1751 allowing for the electrode features 1747 to penetrate into the skin 14.

[00371] Referring to frame 3, upon release of the bias force 1749, the gel adhesive 1743 may (may be slowly) return 1757 to a somewhat undeformed state and thus the electrode features 1747 embedded therein may disengage from the skin 14 leaving behind a series of micropunctures 1759, thus lowering the impedance of the electrical connection between the patch and the subject (i.e. via the skin 14). In aspects, the gel adhesive 1743 may be configured to maintain a relatively humid and biofriendly environment in the vicinity of the micropunctures 1759, thus maintaining the micropunctures for a prolonged monitoring period without irritating the skin 14.

[00372] Fig. 18 illustrates an isolation patch 1801 in accordance with the present disclosure. The isolation patch 1801 may be configured to allow a user to electrically interface a handheld monitoring device 1805 (e.g. a handheld EKG monitor, an Alivecor™ device, etc.) with a plurality of electrodes 1807a,b with a subject 15 without bringing the device 1805 into physical contact therewith. In aspects, the isolation patch 1801 may include a substrate ~~1801~~ in accordance with the present disclosure and include one or more patterned regions 1803 thereupon through which a conduction adhesive layer patterned on the substrate of patch 1801 may be accessed from the surface of the substrate 1801 facing away from the subject 15 upon placement. To monitor the patient, the user may position the handheld monitoring device 1805 against the isolation patch 1801 such that electrodes 1807a,b touch the patch 1801 on the regions 1803.

WHAT IS CLAIMED IS:

1. A patch interface for monitoring one or more physiologic, physical, and/or electrophysiological signals from a subject, comprising:

- a substrate;
- an adhesive coupled to the substrate formulated for attachment to the skin of a subject;
- an interconnect embedded into the substrate for attachment of the patch to a microcircuit; and
- one or more sensors and/or electrodes attached to or embedded onto the surface of the substrate, the sensors and/or electrodes arranged, configured, and dimensioned to interface with the subject when the adhesive is attached thereto.

2. The patch interface in accordance with claim 1 wherein the adhesive is patterned onto the substrate so as to form one or more exposed regions of the substrate, one or more of the sensors and/or electrodes arranged within the exposed regions.

3. The patch interface in accordance with claim 1 or 2 wherein one or more of the electrodes comprises an inherently or ionically conducting gel adhesive.

4. The patch interface in accordance with any one of claims 1 – 3, wherein the electrode comprises an electrode feature arranged so as to improve the electrical connection between the electrode and the skin upon placement on a subject.

5. The patch interface in accordance with claim 4, wherein the improved electrical connection is achieved after pressure is applied to the electrode.

6. The patch interface in accordance with claim 4 or claim 5, wherein the electrode feature comprises one or more microfibers, barbs, microneedles, or spikes to penetrate into a stratum corneum of the skin.

7. The patch electrode in accordance with any one of claim 6, wherein the electrode feature is configured to penetrate less than 2mm into the skin, less than 1mm, less than 0.5mm, less than 0.2mm, or the like during engagement therewith.

8. The patch interface in accordance with any one of claims 4 – 7, further in accordance with claim 3, wherein the gel adhesive is configured to maintain the improved electrical connection to the skin for more than 1hr, more than 1day, or more than 3days after the electrode contacts the skin or pressure is applied to the electrode.

9. The patch interface in accordance with any one of claims 1 – 8, comprising one or more stretchable electrically conducting traces attached to the substrate, arranged so as to coupled one or more of the sensors and/or electrodes with one or more of the interconnects.

10. The patch interface in accordance with any one of claims 1 – 9, wherein the interconnect comprises a plurality of connectors, the connectors physically connected to each other through the substrate.

11. The patch interface in accordance with claim 10, wherein the patch comprises an isolating region arranged so as to isolate one or more of the connectors from the skin while the patch is engaged therewith.

12. The patch interface in accordance with any preceding claim, wherein the patch interface is sufficiently physically frail such that it cannot retain a predetermined shape in a free standing state.

13. The patch interface in accordance with claim 12, comprising a temporary stiffening member attached to the substrate, the temporary stiffening member configured to provide retention of the shape of the patch interface prior to attachment to the subject, the stiffening member being removable from the substrate after attachment to the subject.

14. The patch interface in accordance with claim 13, wherein after removal of the stiffening member, the retention of the shape of the patch interface is provided by the skin of the subject.

15. The patch interface in accordance with any one of claims 12 – 14, wherein removal of the patch interface from the skin of the subject results in a permanent loss in shape of the patch interface without tearing of the patch interface.

16. The patch interface in accordance with any one of claims 12 – 15, wherein the interconnect is sufficiently frail such that removal of the patch interface from the skin of the subject results in a permanent loss of shape of the interconnect.

17. The patch interface in accordance with any preceding claim, wherein the adhesive has a peel tack to mammalian skin of greater than 0.02N/mm, greater than 0.1N/mm, greater than 0.25N/mm, greater than 0.50N/mm, or greater than 0.75N/mm.

18. The patch interface in accordance with any preceding claim, wherein the patch has a tear strength of greater than 0.5N/mm, greater than 1N/mm, greater than 2N/mm, or greater than 8N/mm.

19. The patch interface in accordance with any one of claims 12 – 18, wherein the ratio between the tear strength of the patch and the peel tack of the adhesive to mammalian skin is greater than 8:1, greater than 4:1, or greater than 2:1.

20. The patch interface in accordance with any preceding claim wherein the substrate is formed from a soft pseudo-elastic material and the patch interface is configured to maintain operation when stretched to more than 25%, more than 50%, or more than 80%.

21. The patch interface in accordance with any preceding claim, wherein the patch interface is configured with a moisture vapor transmission rate of between 200g/m^2/24hrs and 20,000g/m^2/24hrs, between 500g/m^2/24hrs and 12,000g/m^2/24hrs, or between 1,000g/m^2/24hrs and 8,000g/m^2/24hrs.

22. A module for monitoring one or more physiologic, physical, and/or electrophysiological signals from a subject, comprising:

- a housing;
- a circuit board comprising one or more microcircuits; and
- a module interconnect coupled to one or more of the microcircuits configured for placement and coupling of the device onto a patch interface in accordance with any one of claims 1 – 21.

23. The module in accordance with claim 22, wherein the module interconnect is embedded into the circuit board.

24. The module in accordance with claim 22 or 23, wherein the circuit board constitutes at least a portion of the housing.

25. The module in accordance with any one of claims 22 – 24, comprising a three dimensional antenna coupled to one or more of the microcircuits, the microcircuits comprising a transceiver or transmitter coupled to the antenna.

26. The module in accordance with claim 25, wherein the antenna is printed on an interior wall of or embedded into the housing, the circuit board providing a ground plane for the antenna.

27. The module in accordance with claim 25 or 26, wherein the housing is shaped like a dome and the antenna is patterned into a spiraling helix centered within the dome.

28. The module in accordance with any one of claims 22 – 27 comprising a sensor coupled with one or more of the microcircuits, the sensor configured to interface with the subject upon attachment of the module to the patch interface.

29. The module in accordance with claim 28 wherein the module comprises a sensor and/or microelectronics configured to interface with a sensor included on the patch interface, one or more of the sensors comprising an electrophysiologic sensor, a temperature sensor, a thermal gradient sensor, a barometer, an altimeter, an accelerometer, a gyroscope, a humidity sensor, a magnetometer, an inclinometer, an oximeter, a colorimetric monitor, a sweat analyte sensor, a galvanic skin response sensor, an interfacial pressure sensor, a flow sensor, a stretch sensor, or a microphone.

30. The module in accordance with any one of claims 22 – 29, wherein the module is hermetically sealed.

31. The module in accordance with any one of claims 22 – 30, wherein the module comprises a gasket coupled to the circuit board, the gasket formed so as to isolate the region formed by the module interconnect and the patch from a surrounding environment, when the module is coupled with the patch.

32. A device for monitoring one or more physiologic, physical, and/or electrophysiologic signals from a subject comprising:

- a patch interface in accordance with any one of claims 1 – 21; and
- a module in accordance with any one of claims 22 – 31, the module interconnect comprised within the module sized and dimensioned to interface with the interconnect comprised within the patch interface, wherein to form an operable interconnection between the patch interface and the module, the patch interface must first be coupled to the subject.

33. The device in accordance with claim 32, wherein the module interconnect comprises an electrically conducting magnetic element, and the patch interface comprises one or more ferromagnetic regions coupled to the substrate, the magnetic elements arranged so as to physically and electrically couple the module to the patch interface when the magnetic elements are aligned with the ferromagnetic regions.

34. The device in accordance with claim 33, wherein the ferromagnetic regions are formed from stretchable pseudo elastic material and are printed onto the substrate.

35. The device in accordance with any one of claims 32 – 34, wherein the module and/or the patch interface comprise one or more fiducial markings to visually assist with the alignment of the module to the patch during coupling thereof.

36. A system for monitoring one or more physiologic, physical, and/or electrophysiological signals from a subject comprising:

- a patch interface in accordance with any one of claims 1 - 21 configured for attachment to the subject; and

- a module in accordance with any one of claims 22 - 31 configured and dimensioned to mate with the patch, and to interface with the subject there through, the module configured to convey and/or store one or more physiologic and/or physical signals, a signal derived therefrom, and/or a metric derived therefrom obtained via the interface with the subject.

37. The system in accordance with claim 36, comprising a host device coupled in wireless communication or physical communication with the module, configured to receive one or more of the signals and/or metrics therefrom.

38. The system in accordance with claim 37, wherein the host device comprises features for recharging and/or performing diagnostic tests on one or more of the modules.

39. The system in accordance with any one of claims 36 – 38, wherein the system comprises a plurality of modules, the modules being hot swappable with the patch interface, so as to maintain a nearly continuous operation thereof.

40. The system in accordance with any one of claims 36 – 39, wherein the system comprises a plurality of modules and associated patch interfaces for placement onto a signal subject, the host device, and/or one or more of the modules configured to coordinate synchronous monitoring of the signals amongst the modules on the subject.

41. The system in accordance with any one of claims 37 – 40, wherein the host device is integrated into a bedside alarm clock, housed in an accessory, within a purse, a backpack, a wallet, is or is included in a mobile computing device, a smartphone, a tablet computer, a pager, a laptop, a local router, a data recorder, a

network hub, a server, a secondary mobile computing device, a repeater, or a combination thereof.

42. Use of a device in accordance with any one of claims 32 – 35, or a system in accordance with any one of claims 36 – 41, to monitor an electrocardiogram of a subject.

43. A kit for monitoring one or more physiologic, physical, and/or an electrophysiological signals from a subject, comprising:

- one or more patch interfaces in accordance with any one of claims 1 - 21;
- one or more modules in accordance with any one of claims 22 – 31;
- a recharging bay configured to recharge one or more of the modules; and
- one or more accessories, each accessory configured to assess with the usage of the patch interfaces and/or modules.

44. The kit in accordance with claim 43, wherein one or more of the accessories comprises an adhesive removing agent configured to facilitate substantially pain free removal of one or more of the patches from a subject.

45. A service system for managing the collection of physiologic data from a customer, comprising:

- a customer data management service, configure to generate and store the customer profile referencing customer preferences, data sets, and/or monitoring sessions;
- an automated product delivery service configured to provide the customer with one or more monitoring products or supplies in accordance with the present disclosure; and

- a datacenter configured to store, analyze, and/or manage the data obtained from the customer during one or more monitoring sessions.

46. The service system in accordance with claim 45 comprising a report generating service configured to generate one or more monitoring reports based upon the data obtained during one or more monitoring sessions.

47. The service system in accordance with claim 45 or 46 comprising a report generating service coupled to the datacenter configured to generate one or more monitoring reports based upon the data obtained during one or more monitoring sessions.

48. The service system in accordance with any one of claims 45 – 47, comprising a recurrent billing system configured to bill the customer based upon the number or patches consumed, the data stored, and/or the reports generated throughout the course of one or more monitoring session

49. A method for monitoring one or more physiologic, physical, and/or electrophysiological signals from a subject, comprising:

- attaching one or more soft breathable and hypoallergenic devices to one or more sites on the subject;
- obtaining one or more local physiologic and/or electrophysiological signals each of the devices; and
- analyzing the signals obtained from each of the devices to generate a metric, diagnostic, report, and/or additional signals therefrom.

50. The method in accordance with claim 49, comprising hot swapping one or more of the devices without interrupting the step of obtaining.

51. The method in accordance with one of claims 49 or 50, comprising calibrating one or more of the devices while on the subject.

52. The method in accordance with claim 51, wherein the step of calibrating is performed with an additional medical device.

53. The method in accordance with claim 52, wherein the medical device is a blood pressure cuff, a thermometer, a pulse oximeter, a cardiopulmonary assessment system, or a clinical grade EKG diagnostic system.

54. The method in accordance with any one of claims 49 – 53, comprising determining the position and/or orientation of one or more of the devices on the subject.

55. The method in accordance with claim 54, comprising determining the position and/or orientation from a photograph, a video, or a surveillance video.

56. The method in accordance with any one of claims 49 – 55, wherein one or more of the steps is performed at least in part by a device in accordance with one of claims 32 – 35, a system in accordance with any one of 36 – 42, a module in accordance with 22 – 31, and/or a patch interface in accordance with any one of claims 1 - 21.

57. An isolating patch for providing a barrier between a handheld monitoring device with a plurality of contact pads and a subject, comprising:

- a flexible substrate with two surfaces, a patient facing surface and an opposing surface; and
- an electrically and/or ionically conducting adhesive coupled to at least a portion of the patient facing surface configured so as to electrically and mechanically couple with the subject when placed thereupon, wherein the conducting adhesive is exposed within one or more regions of the

opposing surface of the substrate, the regions patterned so as to substantially match the dimensions and layout of the contact pads.

58. The isolating patch in accordance with clam 57 wherein the conducting adhesive is an anisotropically conducting adhesive, with the direction of conduction oriented substantially normal to the surfaces of the substrate.

59. A system for measuring blood pressure of a subject in an ambulatory setting comprising:

- an EKG device in accordance with any one of claims 32 – 35, configured for placement onto a torso of the subject, the EKG device configured to measure an electrocardiographic signal from the torso of the subject so as to produce an EKG signal;
- one or more pulse devices each in accordance with any one of claims 32 – 35, configured for placement onto one or more sites on one or more extremities of the subject, each of the pulse devices configured to measure a local pulse at the placement site so as to produce one or more pulse signals; and
- a processor comprised in or coupled to one or more of the EKG device and the pulse devices, the processor configured to receive the EKG signal, the pulse signals, and/or signals generated therefrom, the processor comprising an algorithm, the algorithm configured to analyze one or more temporal metrics from the signals in combination with one or more calibration parameters, to determine the blood pressure of the subject.

60. The system for monitoring blood pressure of a subject in accordance with claim 59, comprising a blood pressure cuff configured to produce a calibration signal, the processor configured to generate one or more of the calibration parameters, from the calibration signal in combination with the EKG signal, and pulse signals.

61. The system in accordance with any one of claims 59 – 60, wherein one or more of the devices comprises an orientation sensor, the orientation sensor configured to obtain an orientation signal, the processor configured to receive the orientation signal or a signal generated therefrom, and to incorporate the orientation signal into the analysis.

62. The system in accordance with claim 61, wherein the orientation sensor comprises one or more of an altimeter, a barometer, a tilt sensor, or a gyroscope.

63. A system for measuring the effect of an impact on physiologic state of a subject comprising:

- an EEG device in accordance with any one of claims 32 – 35, configured for placement behind an ear, on the forehead, near a temple, or onto the neck of the subject, the EEG device configured to measure an electroencephalographic signal from the head of the subject so as to produce an EEG signal, and configured to measure one or more kinetic and/or kinematic signals from the head of the subject so as to produce an impact signal; and
- a processor comprised in or coupled to the EEG device, the processor configured to receive the EEG signal, the impact signals, and/or signals generated therefrom, the processor comprising an algorithm, the algorithm configured to analyze the impact signals to determine if the subject has

suffered an impact, to separate the signals into pre impact and post impact portions and to compare the pre and post impact portions of the EEG signal, to determine the effect of the impact on the subject.

64. The system for measuring the effect of an impact on physiologic state of a subject in accordance with claim 63, the EEG device comprising a temperature sensor configured to generate a temperature signal from the subject or a signal generated therefrom, the processor configured to receive the temperature signal and to assess a thermal state of the subject therefrom.

65. The system for measuring the effect of an impact on a physiological state of a subject in accordance with claim 63 or 64, the EEG device comprising a hydration sensor configured to generate a fluid level signal from the subject, the processor configured to receive the fluid level signal or a signal generated therefrom and to assess the hydration state of the subject therefrom.

66. The system for measuring the effect of an impact on a physiological state of a subject in accordance with any one of claims 63 – 65, the EEG device comprising a memory element, the memory element comprising sufficiently large space to store the signals for a period of 3 minutes, 10 minutes, 30 minutes, or 1 hr.

67. The system for measuring the effect of an impact on a physiological state of a subject in accordance with any one of claims 63 – 66, comprising an EKG device in accordance with any one of claims 32 – 35, the EKG device configured for placement onto the torso or neck of the subject, the EKG device configured to measure an electrophysiological signal pertaining to cardiac function of the subject so as to produce an EKG signal, the processor configured to receive the EKG signal or a signal generated

therefrom, the algorithm configured so as to incorporate the EKG signal into the assessment.

68. The system for measuring the effect of an impact on a physiological state of a subject in accordance with any one of claims 63 – 67, wherein the processor is configured to extract a heart rate variability (HRV) signal from the EKG signal, a pre impact and post impact portion of the HRV signal compared to determine at least a portion of the effect of the impact.

69. A system for assessing a sleep state of a subject comprising:

- an EMG/EOG device in accordance with any one of claims 32 – 35, configured for placement behind an ear, on a forehead, substantially around an eye, near a temple, or onto a neck of the subject, the EMG/EOG device configured to measure one or more electromyographic and/or electrooculographic signals from the head or neck of the subject so as to produce an EMG/EOG signal; and
- a processor comprised in or coupled to the EMG/EOG device, the processor configured to receive the EMG/EOG signal, and/or signals generated therefrom, the processor comprising an algorithm, the algorithm configured to analyze EMG/EOG signal, to determine the sleep state of the subject.

70. The system for assessing a sleep state of a subject in accordance with claim 69, the EMG/EOG device comprising a microphone, the microphone configured to obtain an acoustic signal from the subject, the processor configured to receive the

acoustic signal or a signal generated therefrom, the algorithm configured so as to incorporate the acoustic signal into the assessment.

71. The system for assessing a sleep state of a subject in accordance with claim 69 or 70, comprising a sensor for evaluating sPO2 at one or more sites on the subject to obtain an oxygen saturation signal from the subject, the processor configured to receive the oxygen saturation signal or a signal generated therefrom, the algorithm configured so as to incorporate the oxygen saturation signal into the assessment.

72. The system for assessing a sleep state of a subject in accordance with any one of claims 69 – 71, wherein the processor comprises a signal analysis function, the signal analysis function configured to analyze the EMG/EOG signals, the acoustic signal, and/or the oxygen saturation signal to determine the sleep state of the subject, identify snoring, identify a sleep apnea event, identify a bruxism event, identify a REM sleep state, identify a sleep walking state, a sleep talking state, a nightmare, or identify a waking event.

73. The system for assessing a sleep state of a subject in accordance with any one of claims 69 – 72, comprising a feedback mechanism, configured to interact with the subject, a user, a doctor, a nurse, or a partner, the processor configured to provide a feedback signal to the feedback mechanism based upon the analysis of the sleep state of the subject.

74. The system for assessing a sleep state of a subject in accordance with claim 73, wherein the feedback mechanism comprises a transducer, a loudspeaker, tactile actuator, a visual feedback means, a light source, a buzzer, or a combination thereof to interact with the subject, the user, the doctor, the nurse, or the partner.

75. A system for assessing a gait and/or a muscle movement of a subject comprising:

- an EMG device in accordance with any one of claims 32 – 35, configured for placement over a muscle group on the subject, the EMG device configured to measure one or more electromyographic signals from the muscle group of the subject so as to produce an EMG signal; and
- a processor comprised in or coupled to the EMG device, the processor configured to receive the EMG signal, and/or signals generated therefrom, the processor comprising an algorithm, the algorithm configured to analyze EMG signal to determine at least a portion of the gait and/or the muscle movement of the subject.

76. The system for assessing a gait and/or a muscle movement of a subject in accordance with claim 75, comprising a plurality of EMG devices, each EMG device configured to monitor a separate muscle group on the subject, the processor configured to synchronize and analyze the EMG signals received from each EMG device to determine at least a portion of the gait and/or the muscle movement of the subject.

77. The system for assessing gait and/or muscle movement of a subject in accordance with claim 75 or 76, wherein one or more of the EMG devices comprises an orientation, kinetic, kinematic, and/or proprioception sensor, configured so as to generate a kinematic signal, the processor configured to incorporate the kinematic signal into the analysis.

78. The system for assessing gait and/or muscle movement of a subject in accordance with any one of claims 75 – 77, wherein the processor is configured to analyze one or more of the EMG signals to generate a muscle exertion metric.

WHAT IS CLAIMED IS:

1. A patch interface, comprising:

a substrate;

an adhesive coupled to the substrate formulated for attachment to the skin of a subject;

one or more interconnects embedded into the substrate for attachment of a patch to a microcircuit; and

at least one of: one or more sensors; and one or more electrodes attached to or embedded onto the surface of the substrate, and arranged, configured, and dimensioned to interface with the subject when the adhesive is attached thereto;

wherein the patch interface is configured to monitor one or more physiologic signals, physical signals, and electrophysiological signals from the subject.

2. The patch interface in accordance with claim 1, wherein the adhesive is patterned onto the substrate so as to form one or more exposed regions of the substrate, at least one of the one or more of the sensors and one or more electrodes arranged within the exposed regions; and wherein at least one of the one or more electrodes comprise one of an inherently conducting and an ionically conducting gel adhesive.

3. The patch interface in accordance with claim 1, wherein at least one of the one or more electrodes comprises an electrode feature comprising one or more microfibers, barbs, microneedles, and spikes to penetrate into a stratum corneum of the skin.

4. The patch interface in accordance with claim 3, wherein the electrode feature is configured to penetrate into the skin during engagement therewith one of less than 2mm, less than 1mm, less than 0.5mm, and less than 0.2mm.

5. The patch interface in accordance with claim 2, wherein the gel adhesive is configured to maintain an improved electrical connection to the skin for one of more than one hour, more than one day, and more than three days after one of: the electrode contacts the skin; and pressure is applied to the electrode.

6. The patch interface in accordance with claim 1, further comprising one or more stretchable electrically conducting traces attached to the substrate, arranged so as to couple one or more of the sensors and electrodes with one or more of the interconnects.

7. The patch interface in accordance with claim 6, wherein the one or more interconnects comprise a plurality of connectors, the connectors physically connected to each other through the substrate; and wherein the patch comprises an isolating region arranged so as to isolate one or more of the connectors from the skin while the patch interface is engaged therewith.

8. The patch interface in accordance with claim 1, wherein the patch interface is sufficiently physically frail such that it cannot retain a predetermined shape in a free standing state.

9. The patch interface in accordance with claim 8, further comprising a temporary stiffening member attached to the substrate, the temporary stiffening member configured to provide retention of the shape of the patch interface prior to attachment to the subject, the stiffening member being removable from the substrate after attachment to the subject.

10. The patch interface in accordance with claim 8, wherein removal of the patch interface from the skin of the subject results in a permanent loss in shape of the patch interface without tearing of the patch interface.

11. The patch interface in accordance with claim 1, wherein the adhesive has a peel tack to mammalian skin of one of greater than 0.02 N/mm, greater than 0.1N/mm, greater than 0.25N/mm, greater than 0.50N/mm, and greater than 0.75N/mm.

12. The patch interface in accordance with claim 1, wherein the substrate is formed from a soft pseudo-elastic material and the patch interface is configured to maintain operation when stretched to one of more than 25%, more than 50%, and more than 80%.

13. The patch interface in accordance with a claim 1, wherein the patch interface is configured with a moisture vapor transmission rate of one of between 200g/m2/24hrs and 20,000g/m2/24hrs, between 500g/m2/24hrs and 12,000g/m2/24hrs, and between 1,000g/m2/24hrs and 8,000g/m2/24hrs.

14. A module, comprising:

a housing;

a circuit board comprising one or more microcircuits; and

a module interconnect coupled to one or more of the microcircuits configured for placement and coupling of a device onto a patch interface, the patch interface comprising:

a substrate;

an adhesive coupled to the substrate formulated for attachment to the skin of a subject;

one or more interconnects embedded into the substrate for attachment of a patch to a microcircuit; and

at least one of: one or more sensors; and one or more electrodes attached to or embedded onto the surface of the substrate, and arranged, configured, and dimensioned to interface with the subject when the adhesive is attached thereto;

wherein the module is configured to monitor one or more physiologic signals, physical signals, and electrophysiological signals from the subject.

15. The module in accordance with claim 14, wherein the module interconnect is embedded into the circuit board and the circuit board constitutes at least a portion of the housing.

16. The module in accordance with claim 14, further comprising a three dimensional antenna coupled to at least one of the one or more microcircuits, the one or more microcircuits comprising a transceiver or transmitter coupled to the antenna.

17. The module in accordance with claim 14, further comprising a sensor coupled with at least one of the one or more microcircuits, the sensor configured to interface with the subject upon attachment of the module to the patch interface.

18. The module in accordance with claim 17, wherein the module comprises at least one of: one or more sensors; and one or more microelectronics, configured to interface with a sensor included on the patch interface, at least one of the one or more sensors comprising: an electrophysiologic sensor, a temperature sensor, a thermal gradient sensor, a barometer, an altimeter, an accelerometer, a gyroscope, a humidity sensor, a magnetometer, an inclinometer, an oximeter, a colorimetric monitor, a sweat analyte sensor, a galvanic skin response sensor, an interfacial pressure sensor, a flow sensor, a stretch sensor, and a microphone.

19. The module in accordance with claims 14, wherein the module is hermetically sealed.

20. The module in accordance with claim 14, further comprising a gasket coupled to the circuit board, the gasket formed so as to isolate the region formed by the module interconnect and the patch from a surrounding environment when the module is coupled with the patch.

21. A device, comprising:

a patch interface; and

a module comprising:

a housing;

a circuit board comprising one or more microcircuits; and

a module interconnect coupled to one or more of the microcircuits configured for placement and coupling of the device onto the patch interface;

wherein the module interconnect is sized and dimensioned to interface with an interconnect within the patch interface, and the patch interface is coupled to a subject to form an operable interconnection between the patch interface and the module; and

wherein the device is configured to monitor one or more physiologic signals, physical signals, and electrophysiological signals from the subject.

22. The device in accordance with claim 21, wherein the module interconnect comprises one or more electrically conducting magnetic elements, and the patch interface comprises one or

more ferromagnetic regions coupled to a substrate, the one or more magnetic elements arranged so as to physically and electrically couple the module to the patch interface when the one or more magnetic elements are aligned with the ferromagnetic regions.

23. The device in accordance with claim 22, wherein the ferromagnetic regions are formed from stretchable pseudo elastic material and are printed onto the substrate.

24. The device in accordance with claim 21, wherein at least one of the module and the patch interface comprises one or more fiducial markings to visually assist with alignment of the module to the patch during coupling thereof.

25. The device in accordance with claim 24, wherein both the module and the patch interface comprise one or more fiducial markers to visually assist with alignment of the module to the path during coupling thereof.