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(54) **ADHERENT DEVICE FOR RESPIRATORY MONITORING**

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(57)   **ABSTRACT**

A respiratory monitoring system is provided. A measuring
system is provided that includes, (i) an adherent device con-
figured to be coupled to a patient, the adherent device includ-
ing a plurality of sensors that monitor respiratory status, at
least one of the sensors configured to monitor the patient's
respiration, and (ii) a wireless communication device coupled
to the plurality of sensors and configured to transfer patient
data directly or indirectly from the plurality of sensors to a
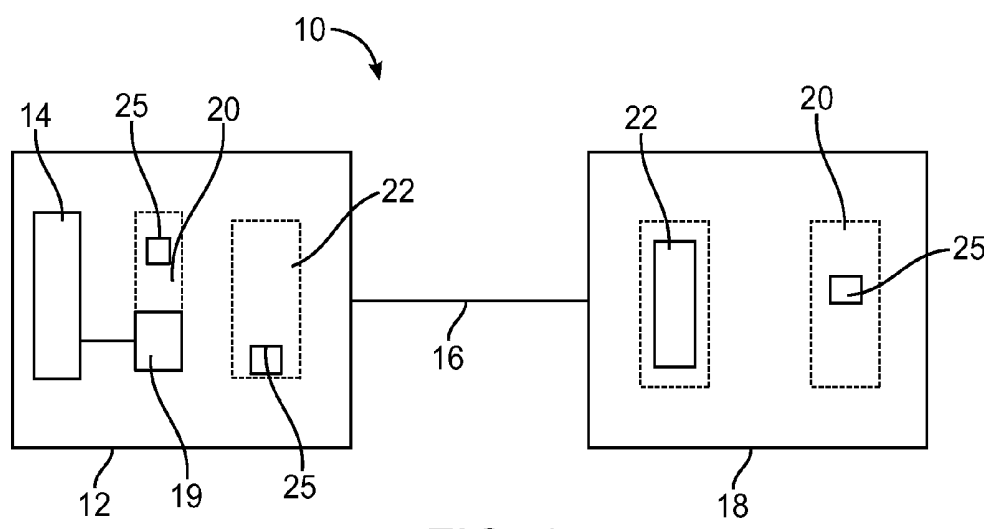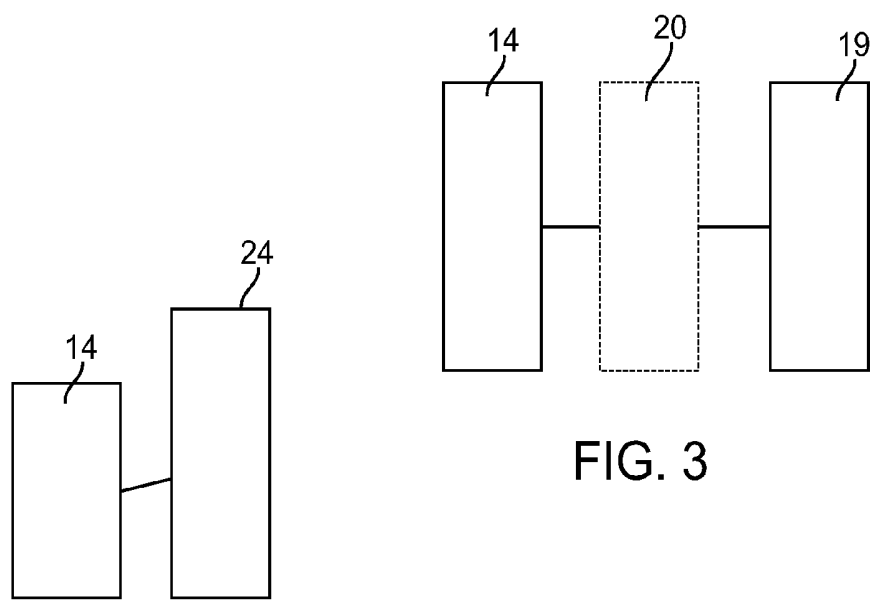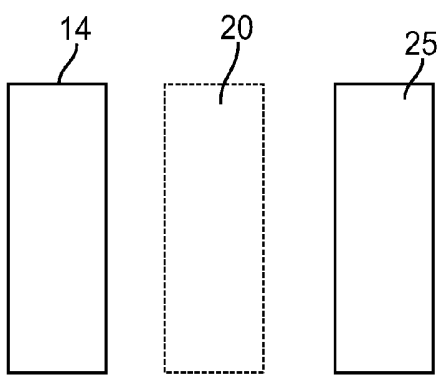remote monitoring system. A remote monitoring system is
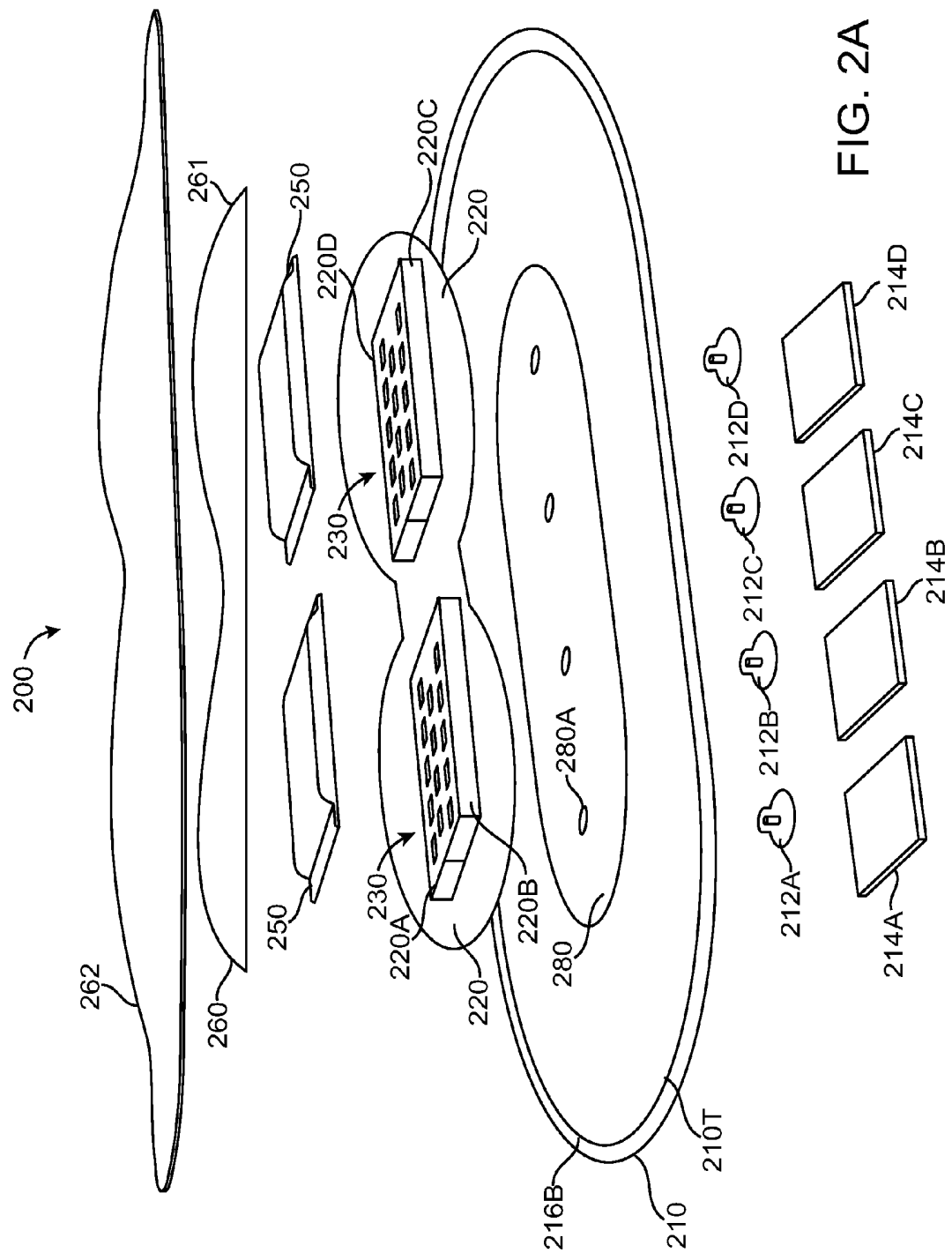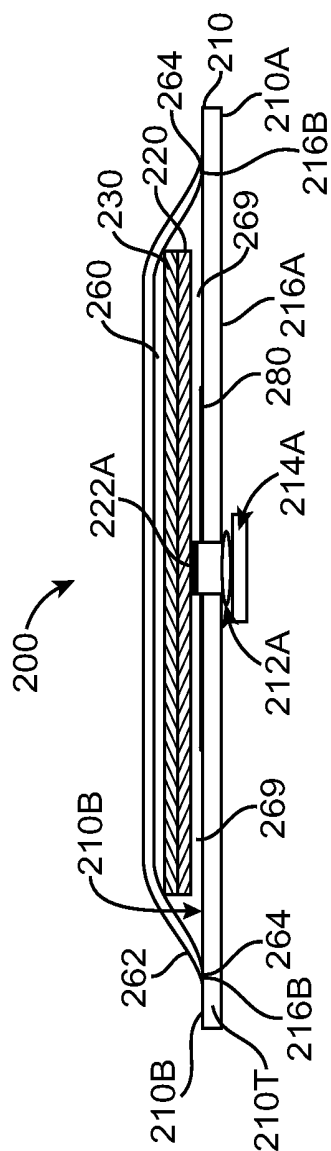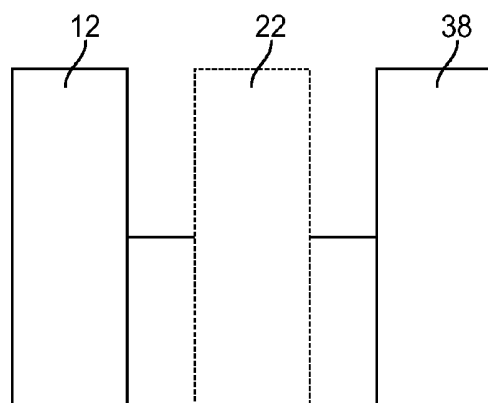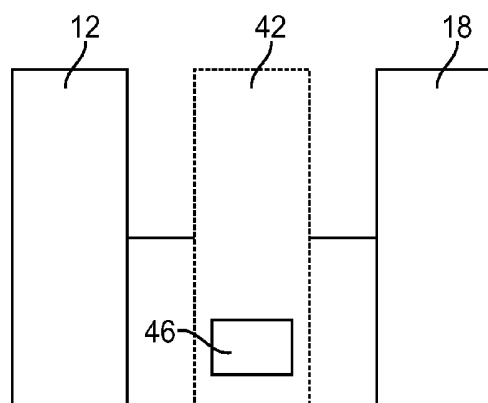coupled to the wireless communication device.
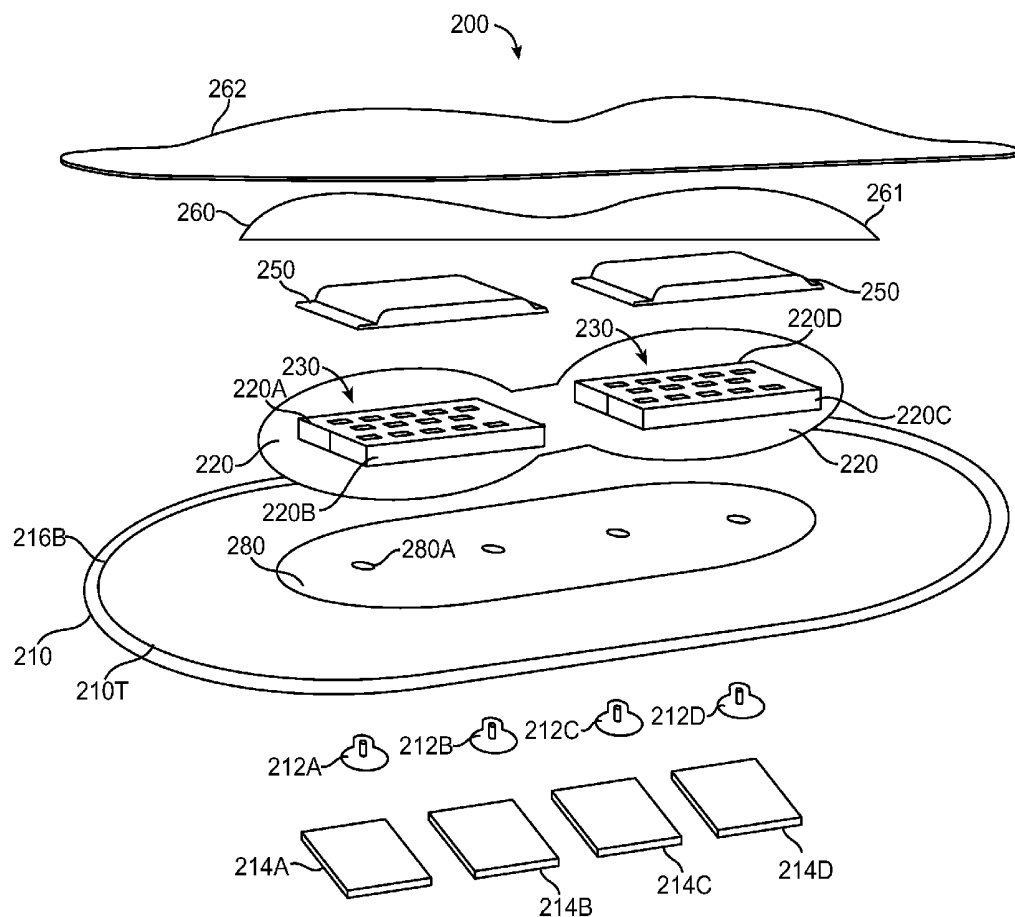
FIG. 1

FIG. 3

FIG. 4

FIG. 5

FIG. 2A

FIG. 2B

FIG. 6

FIG. 7
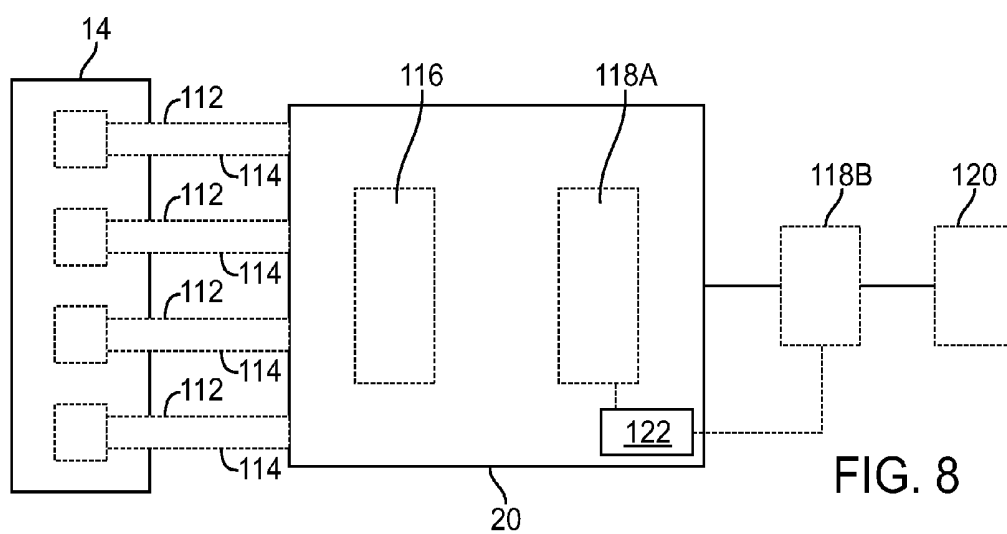
FIG. 8

FIG. 9

FIG. 10

FIG. 11

FIG. 12
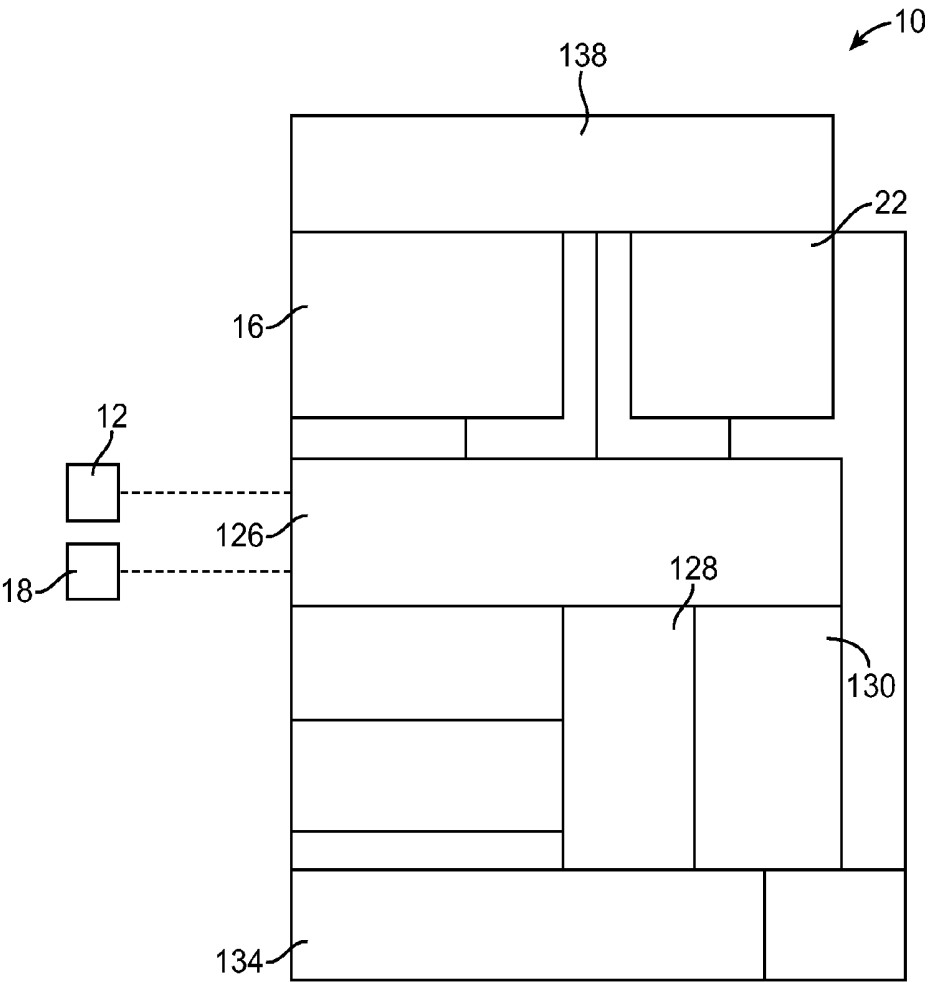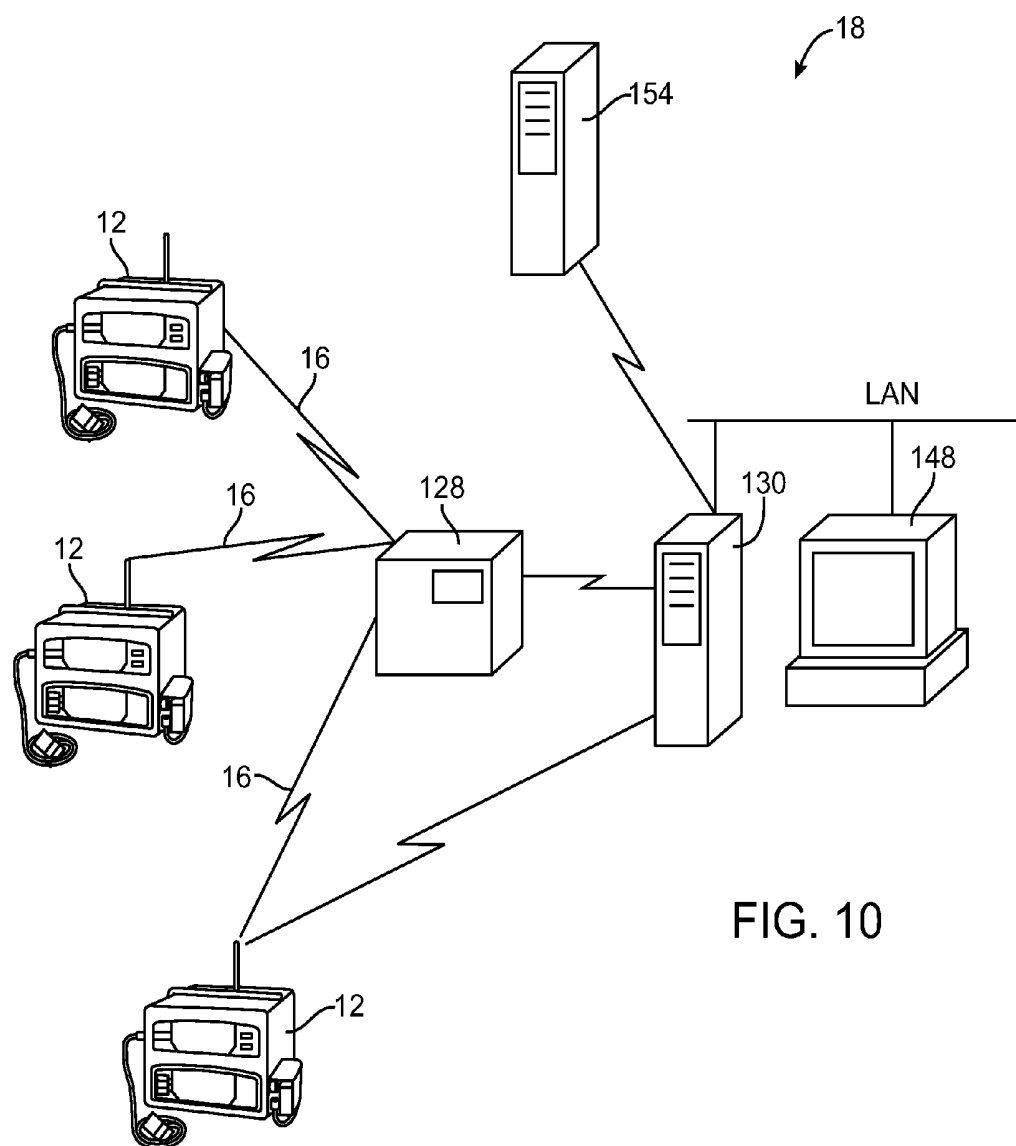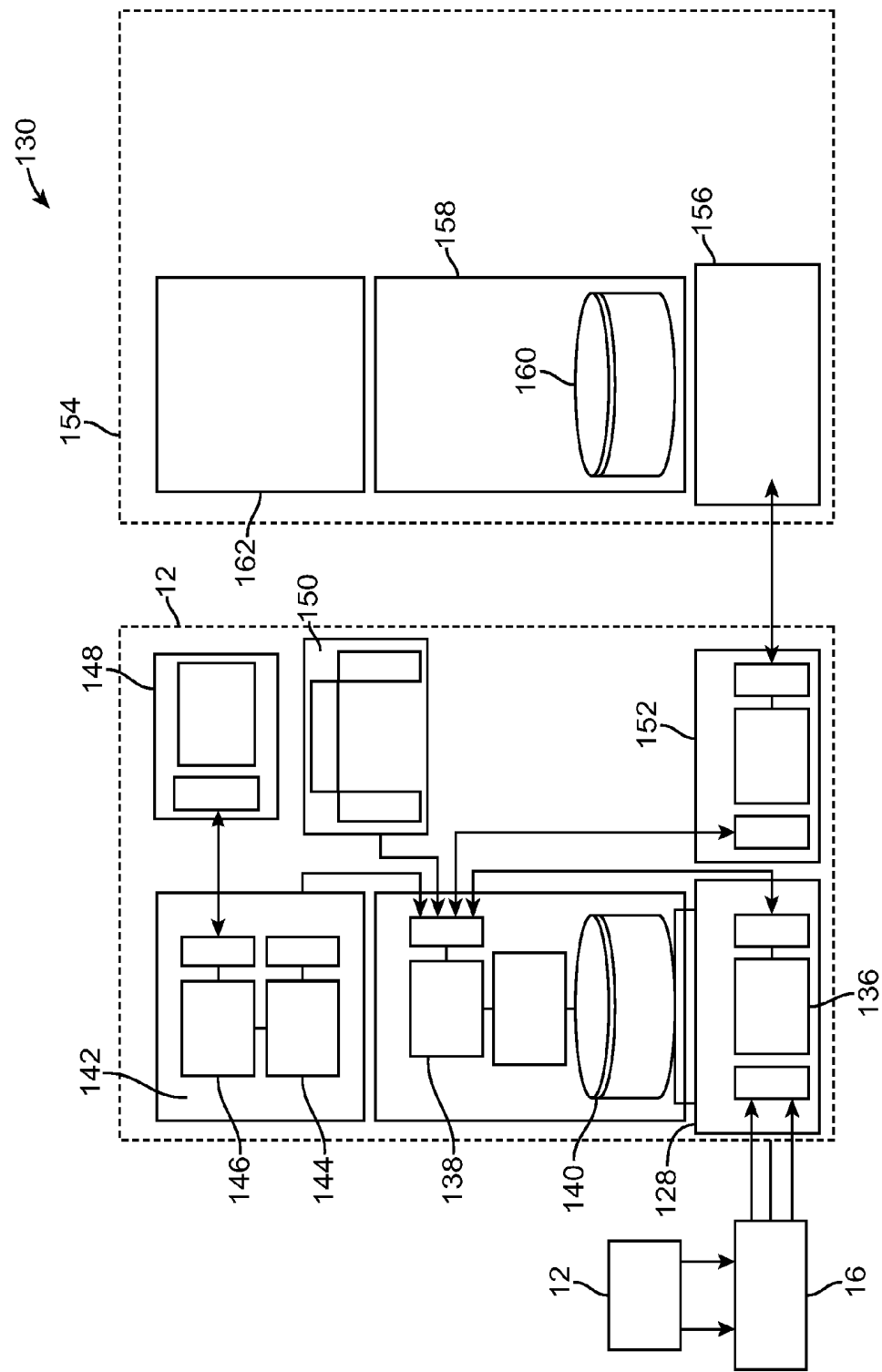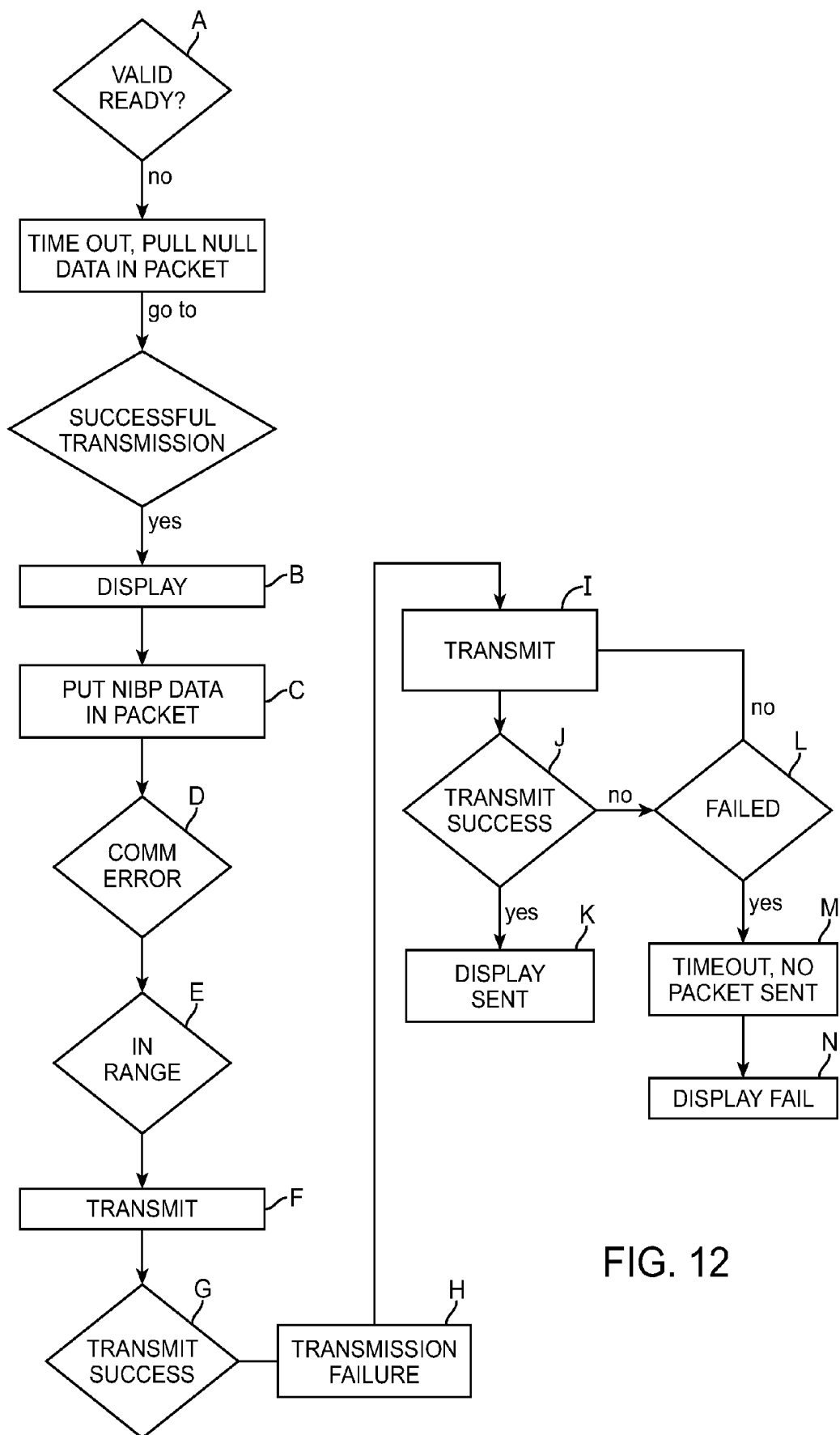
ADHERENT DEVICE FOR RESPIRATORY MONITORING

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 12/209,268 filed Sep. 12, 2008 and titled "Adherent Device for Respiratory Monitoring", which claims the benefit under 35 USC 119(e) of U.S. Provisional Application No. 60/972,363, 60/972,537, 60/972,336 all filed Sep. 14, 2007; and 61/055,656 and 61/055,666 both filed May 23, 2008; the full disclosures of which are incorporated herein by reference in their entirety.

[0002] The subject matter of the present application is related to the following applications: 60/972,512; 60/972,329; 60/972,354; 60/972,616; 60/972,343; 60/972,581; 60/972,629; 60/972,316; 60/972,333; 60/972,359; 60/972,340 all of which were filed on Sep. 14, 2007; 61/046,196 filed Apr. 18, 2008; 61/047,875 filed Apr. 25, 2008; 61/055,645 and 61/055,662 both filed May 23, 2008; and 61/079,746 filed Jul. 10, 2008.

[0003] The subject matter of the present application is related to the following applications: Ser. Nos. 12/209,279; 12/209,288; 12/209,430; 12/209,479; 12/209,262; 12/209,269; 12/209,259; 12/209,273; 12/209,276; 12/210,078; 12/209,265; 12/209,292; 12/209,278; 12/209,508; 12/209,528; 12/209,271; 12/209,274; and 12/209,294 all of which were filed on Sep. 12, 2008.

BACKGROUND OF THE INVENTION

[0004] 1. Field of the Invention

[0005] This invention relates generally to systems and methods that use wireless physiological monitoring and more particularly to respiratory monitoring.

[0006] People need to breathe to stay alive. The medical term "apnea" refers to temporary cessation of respiration or breathing or an irregular breathing pattern. Some people do not have normal breathing, for example when they sleep, and monitoring breathing can be helpful to diagnose patients.

[0007] One conventional approach to diagnosis of sleep disorders has been to require the patient to participate in a "sleep study." The patient is outfitted with an array of sensors attached to the surface of the body to monitor the patient's respiration, pulse, and blood oxygen saturation. A strip chart recorder can trace the sensor signals on paper for later analysis by a health care professional.

[0008] Conventional sleep studies may have several shortcomings in at least some instances. The complexity and expense of the required equipment can dictate that sleep studies be conducted in a clinic setting, i.e., a hospital or sleep laboratory. This can significantly increase the costs involved. In at least some instances, the patient may find it difficult to sleep in a strange setting, particularly while wearing sensors tethered by wires to a recorder, such as a strip chart recorder. In some instances, respiration may be measured by requiring the patient to wear sensor devices applied to the face and body, which can especially uncomfortable to wear while trying to sleep.

[0009] With newer technology, sleep studies can be done in the home, but this may still involve attaching various sensor devices and wires to the body surface. These tests may be single night events, and in at least some instances may be too complex and expensive to be practical in monitoring treat-

ment efficacy and patient compliance over extended periods of time, such as days, weeks, or months.

[0010] One common treatment of sleep apnea may involve blowing air under pressure into the upper airway via a mask strapped to the face, which may be uncomfortable in at least some instances. Continuous positive airway pressure (CPAP) and bi-level positive airway pressure (BiPAP) are the treatment modalities that have been delivered by masks. Even though sleep apnea can be corrected with CPAP and BiPAP, both may have excessively high non-compliance rates due patient discomfort in at least some instances.

[0011] The apnea condition has become associated in recent years with the sudden infant death syndrome, or SIDS, in which an apparently healthy infant dies of an unexplained cause. Although much research has been done, many infants still die of this disease.

[0012] Cough can be a complaint of COPD (chronic obstructive pulmonary disease) patients (and other patients) that may impact sleep and can significantly impact quality of life at a functional, in at least some instances.

[0013] Therefore, a need exists for improved sleep monitoring and management of sleep disordered breathing, such as a respiration monitoring system for diagnosis of sleep disorders that is suitable for use outside of clinical settings, and which minimizes patient discomfort and can be used on patients of all ages from infant to adult. Ideally such systems would be less obtrusive to the patient than current, systems, and provide monitoring that can be used to improve patient therapy.

[0014] 2. Description of the Background Art

[0015] The following U.S. patents and Publications may describe relevant background art: U.S. Pat. Nos. 4,121,573; 4,955,381; 4,981,139; 5,080,099; 5,353,793; 5,511,553; 5,544,661; 5,558,638; 5,724,025; 5,772,586; 5,862,802; 6,047,203; 6,117,077; 6,129,744; 6,225,901; 6,385,473; 6,416,471; 6,454,707; 6,494,829; 6,527,711; 6,527,729; 6,551,252; 6,595,927; 6,595,929; 6,605,038; 6,641,542; 6,645,153; 6,821,249; 6,980,851; 7,020,508; 7,041,062; 7,054,679; 7,153,262; 7,206,630; 7,297,119; 2003/0092975; 2005/0113703; 2005/0131288; 2005/0137464; 2005/0277841; 2005/0277842; 2006/0010090; 2006/0031102; 2006/0089679; 2006/122474; 2006/0155183; 2006/0161205; 2006/0173257; 2006/0173269; 2006/0195144; 2006/0224051; 2006/0224072; 2006/0264730; 2007/0021678; 2007/0038038; 2007/0073132; 2007/0123756; 2007/0129643; 2007/0150008; and 2007/0255531.

BRIEF SUMMARY OF THE INVENTION

[0016] Accordingly, an object of the present invention is to provide an improved a respiratory monitoring system.

[0017] A further object of the present invention is to provide a respiratory monitoring system that can be used for sleep studies, improved detection of apnea, monitoring of apnea, monitoring of COPD, monitoring and treatment of asthma, monitoring and treatment or orthopnea and other respiratory conditions.

[0018] A further object of the present invention is to provide a respiratory monitoring system that uses outputs of a plurality of sensors with multiple features to enhance physiological sensing performance.

[0019] Still a further object of the present invention is to provide a respiratory monitoring system where respiration status is determined by a weighted combination change in sensor outputs.

[0020] Yet another object of the present invention is to provide a respiratory monitoring system where respiration status is determined when a rate of change of at least two sensor outputs is an abrupt change in the sensor outputs as compared to a change in the sensor outputs over a longer period of time.

[0021] A further object of the present invention is to provide a respiratory monitoring system where respiration status is determined by a tiered combination of at least a first and a second sensor output, with the first sensor output indicating a problem that is then verified by at least a second sensor output.

[0022] Another object of the present invention is to provide a respiratory monitoring system where respiration status is determined by a variance from a baseline value of sensor outputs.

[0023] Yet another object of the present invention is to provide a respiratory monitoring system where baseline values are defined by a look up table.

[0024] Still a further object of the present invention is to provide a respiratory monitoring system where respiration status is determined when a first sensor output is at a high value that is greater than a baseline value, and at least one of a second a third sensor outputs is at a high value also sufficiently greater than a baseline value to indicate respiration status.

[0025] Another object of the present invention is to provide a respiratory monitoring system where respiration status is determined by time weighting the outputs of at least first, second and third sensors, and the time weighting indicates a recent event that is indicative of the respiration status.

[0026] These and other objects of the present invention are achieved in many embodiments that comprise a respiratory monitoring system. A detecting system is provided that includes, (i) an adherent device configured to be coupled to a patient, the adherent device including a plurality of sensors that monitor respiratory status, at least one of the sensors configured to monitor the patient's respiration, and (ii) a wireless communication device coupled to the plurality of sensors and configured to transfer patient data directly or indirectly from the plurality of sensors to a remote monitoring system. A remote monitoring system is coupled to the wireless communication device.

[0027] In a first aspect, embodiments of the present invention provide a respiratory monitoring system for monitoring a patient. The respiratory monitoring system comprises a patient detecting system, the patient detecting system comprising an adherent device configured to couple to a patient. The adherent device comprises a plurality of sensors configured to monitor physiological parameters of the patient to determine respiratory status. At least one of the plurality of sensors is configured to monitor the patient's respiration. The adherent device further comprises a wireless communication device coupled to the plurality of sensors. The respirator monitoring system further comprises a remote monitoring system coupled to the wireless communication device. The wireless communication device is configured to transfer patient data from the plurality of sensors to the remote monitoring system.

[0028] The plurality of sensors may be configured to monitor respiration of the patient with a bioimpedance sensor. The plurality of sensors may comprise a combination of sensors. The combination of sensors comprises as least one of a bioimpedance sensor, a heart rate sensor or a pulse oximeter

sensor. The wireless communication device may be configured to receive instructional data from the remote monitoring system.

[0029] In many embodiments, the respiratory monitoring system further comprises a processor coupled to the plurality of sensors and to the wireless communication device. The processor is configured to receive data from the plurality of sensors and process the patient data to generate processed patient data. The processor may be located at the remote monitoring system. The patient detecting system may comprise a monitoring unit.

[0030] The remote monitoring system may comprise logic resources located at the remote monitoring system. The logic resources are configured to determine a physiological event of the patient and determine the respiratory status of the patient. The monitoring unit may comprise logic resources configured to determine the respiratory status of the patient and to determine a physiological event of a patient. The physiological event may comprise apnea.

[0031] The plurality of sensors may be configured to monitor respiration of the patient with at least one of heart rate or pulse oximetry monitoring. The plurality of sensors may be configured to monitor respiration of the patient with a bioimpedance sensor and at least one of heart rate monitoring or pulse oximetry monitoring.

[0032] The adherent device may be configured to monitor the patient's respiration continuously. The adherent device may be configured to monitor a pulmonary disorder comprising at least one of chronic obstructive pulmonary disease, asthma or sleep disordered breathing.

[0033] The plurality of sensors may comprise a posture sensor for orthopnea monitoring. The posture sensor may comprise at least one of a piezoelectric accelerometer, capacitive accelerometer or electromechanical accelerometer. The posture sensor may comprise a 3-axis accelerometer.

[0034] The patient detecting system and the remote monitoring system may be configured to monitor the patient for a patient sleep study. The plurality of sensors may comprise a patient movement sensor. The patient movement sensor may comprise at least one of a piezoelectric accelerometer, a capacitive accelerometer or an electromechanical accelerometer. The adherent device may comprise a plurality of patches. At least a first patch of the plurality is configured for placement a thorax of the patient, and at least a second patch of the plurality is configured for placement at another patient site away from the thorax to measure patient movement.

[0035] In many embodiments, the respiratory monitoring system further comprises a processor configured to determine the respiratory status in response to a weighted combination of change in sensor outputs.

[0036] In many embodiments, the respiratory monitoring system further comprises a processor configured to determine the respiratory status of the patient when a rate of change of at least two sensor outputs comprises an abrupt change in the sensor outputs as compared to a change in the sensor outputs over a longer period of time. The abrupt change may comprise no more than about 10 seconds and the longer period of time may comprise at least about one hour.

[0037] In many embodiments, the respiratory monitoring system further comprises a processor configured to determine the respiratory status of the patient in response to a tiered combination of at least a first sensor output and a second sensor output. The first sensor output indicates a problem that is then verified by at least a second sensor output.

[0038] In many embodiments, the respiratory monitoring system further comprises a processor configured to determine a physiological event of the patient in response to a variance from baseline values of sensor outputs. The baseline values may be defined by a look up table.

[0039] In many embodiments, the plurality of sensors may comprise at least a first sensor, a second sensor and a third sensor.

BRIEF DESCRIPTION OF THE DRAWINGS

[0040] FIG. 1 is a block diagram illustrating one embodiment of a patient monitoring system of the present invention;

[0041] FIGS. 2A and 2B illustrate an exploded view and side view of embodiments of an adherent device with sensors configured to be coupled to the skin of a patient for monitoring purposes;

[0042] FIG. 3 illustrates one embodiment of an energy management device that is coupled to the plurality of sensors of FIG. 1;

[0043] FIG. 4 illustrates one embodiment of present invention illustrating logic resources configured to receive data from the sensors and/or the processed patient for monitoring purposes, analysis and/or prediction purposes;

[0044] FIG. 5 illustrates an embodiment of the patient monitoring system of the present invention with a memory management device;

[0045] FIG. 6 illustrates an embodiment of the patient monitoring system of the present invention with an external device coupled to the sensors;

[0046] FIG. 7 illustrates an embodiment of the patient monitoring system of the present invention with a notification device;

[0047] FIG. 8 is a block diagram illustrating an embodiment of the present invention with sensor leads that convey signals from the sensors to a monitoring unit at the detecting system, or through a wireless communication device to a remote monitoring system;

[0048] FIG. 9 is a block diagram illustrating an embodiment of the present invention with a control unit at the detecting system and/or the remote monitoring system;

[0049] FIG. 10 is a block diagram illustrating an embodiment of the present invention where a control unit encodes patient data and transmits it to a wireless network storage unit at the remote monitoring system;

[0050] FIG. 11 is a block diagram illustrating one embodiment of an internal structure of a main data collection station at the remote monitoring system of the present invention; and

[0051] FIG. 12 is a flow chart illustrating an embodiment of the present invention with operation steps performed by the system of the present invention in transmitting information to the main data collection station.

DETAILED DESCRIPTION OF THE INVENTION

[0052] Embodiments of the present invention comprise an adherent multi-sensor patient monitor capable of tracking a patient's physiological status with a suite of sensors and wirelessly communicating with a remote site. The device may comprise specific sensors and algorithms for the monitoring and detection of pulmonary and breathing disorders.

[0053] An external, adherent patch device can be configured to be affixed to the patient's thorax and may contain multiple physiological sensors. The patch can wirelessly communicate with a remote center, either directly or indi-

rectly via an intermediate device. The system can continuously monitor physiologic variables and issue patient and/or physician alerts when appropriate.

[0054] The adherent patch device may directly and/or indirectly monitor respiration with physiological sensors. Direct monitoring may comprise bioimpedance sensor measurements, for example. Indirect monitoring may comprise at least one of heart rate measurements or pulse oximetry monitoring measurements, for example.

[0055] Examples of target pulmonary disorders that can be monitored and/or treated include chronic obstructive pulmonary disease, asthma, sleep disordered breathing, such as apnea, dyspnea and orthopnea. Continuous physiological monitoring of the patient with breathing disorders can be used.

[0056] Embodiments of the present invention may also be used for inpatient sleep studies, allowing for patient-friendly wireless monitoring. This embodiment may also include an activity sensor (either on the primary patch or on a secondary, limb patch) to monitor the quality of the patient's sleep.

[0057] In one embodiment, illustrated in FIG. 1, the present invention is a patient management system, generally denoted as 10, that tracks the patient's physiological status, detects and predicts negative physiological events. In one embodiment, a plurality of sensors are used in combination to enhance detection and prediction capabilities as more fully explained below.

[0058] In one specific embodiment, the system 10 is a respiratory monitoring system. A detecting system including, denoted as 12, is provided. The detecting system includes, an adherent device configured to be coupled to a patient. The adherent device includes a plurality of sensors 14 that monitor a patient's respiration. At least one of the sensors monitors the patient's respiration. In one embodiment, the adherent device includes a plurality of patches, with at least one patch at a patient's thorax, and at least one patch at another patient site to measure patient movement.

[0059] The detecting system 12 also includes a wireless communication device 16, coupled to the plurality of sensors 14. The wireless communication device transfers patient data directly or indirectly from the plurality of sensors 14 to a remote monitoring system 18. The remote monitoring system 18 uses data from the sensors to determine respiratory status and predict impending decompensation of the patient. The detecting system 12 can continuously, or non-continuously, monitor the patient, alerts are provided as necessary and medical intervention is provided when required. In one embodiment, the wireless communication device 16 is a wireless local area network for receiving data from the plurality of sensors 12.

[0060] FIGS. 2A and 2B show embodiments of the plurality of sensors 14 with supported with an adherent device 200 configured to adhere to the skin. The plurality of sensors 14 with an adherent device to the skin is provided. As illustrated, a cover, batteries, electronics, including but not limited to flex circuits and the like, an adherent tape, the actual sensors (electrodes) and hydrogels which interface the sensors 14 with the skin, are provided. Adherent device 200 is described in U.S. App. No. 60/972,537, the full disclosure of which has been previously incorporated herein by reference. As illustrated in an exploded view of the adherent device, a cover 262, batteries 250, electronics 230, including but not limited to flex circuits and the like, an adherent tape 210T, the plurality of

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sensors may comprise electrodes and sensor circuitry, and hydrogels which interface the plurality of sensors **14** with the skin, are provided.

[0061] Adherent device **200** comprises a support, for example adherent patch **210**, configured to adhere the device to the patient. Adherent patch **210** comprises a first side, or a lower side **210A**, that is oriented toward the skin of the patient when placed on the patient and a second side, or upper side **210B**, opposite of the first side. In many embodiments, adherent patch **210** comprises a tape **210T** which is a material, preferably breathable, with an adhesive **216A**. Patient side **210A** comprises adhesive **216A** to adhere the patch **210** and adherent device **200** to patient P. Electrodes **212A**, **212B**, **212C** and **212D** are affixed to adherent patch **210**. In many embodiments, at least four electrodes are attached to the patch, for example six electrodes. In some embodiments the patch comprises two electrodes, for example two electrodes to measure the electrocardiogram (ECG) of the patient. Gel **214A**, gel **214B**, gel **214C** and gel **214D** can each be positioned over electrodes **212A**, **212B**, **212C** and **212D**, respectively, to provide electrical conductivity between the electrodes and the skin of the patient. In many embodiments, the electrodes can be affixed to the patch **210**, for example with known methods and structures such as rivets, adhesive, stitches, etc. In many embodiments, patch **210** comprises a breathable material to permit air and/or vapor to flow to and from the surface of the skin. In some embodiments, a printed circuit board (PCB), for example flex PCB **220**, may be connected to upper side **210B** of patch **210** with connectors. In some embodiments, additional PCB's, for example rigid PCB's **220A**, **220B**, **220C** and **220D**, can be connected to flex PCB **220**. Electronic components **230** can be connected to flex PCB **220** and/or mounted thereon. In some embodiments, electronic components **230** can be mounted on the additional PCB's.

[0062] Electronic circuitry and components **230** comprise circuitry and components to take physiologic measurements, transmit data to remote center and receive commands from remote center. In many embodiments, electronics components **230** may comprise known low power circuitry, for example complementary metal oxide semiconductor (CMOS) circuitry components. Electronics components **230** comprise an activity sensor and activity circuitry, impedance circuitry and electrocardiogram circuitry, for example ECG circuitry. In some embodiments, electronics circuitry may comprise a microphone and microphone circuitry to detect an audio signal from within the patient, and the audio signal may comprise a heart sound and/or a respiratory sound, for example an S3 heart sound and a respiratory sound with rales and/or crackles. Electronics circuitry and components **230** may comprise a temperature sensor, for example a thermistor, and temperature sensor circuitry to measure a temperature of the patient, for example a temperature of a skin of the patient.

[0063] A cover **262** can extend over the batteries, electronic components and flex printed circuit board. In many embodiments, an electronics housing **260** may be disposed under cover **262** to protect the electronic components, and in some embodiments electronics housing **260** may comprise an encapsulant over the electronic components and PCB. In some embodiments, cover **262** can be adhered to adhesive patch with an adhesive. In many embodiments, electronics housing **260** may comprise a water proof material, for example a sealant adhesive such as epoxy or silicone coated over the electronics components and/or PCB. In some

embodiments, electronics housing **260** may comprise metal and/or plastic. Metal or plastic may be potted with a material such as epoxy or silicone.

[0064] Cover **262** may comprise many known biocompatible cover, casing and/or housing materials, such as elastomers, for example silicone. The elastomer may be fenestrated to improve breathability. In some embodiments, cover **262** may comprise many known breathable materials, for example polyester, polyamide, and/or elastane (Spandex). The breathable fabric may be coated to make it water resistant, waterproof, and/or to aid in wicking moisture away from the patch.

[0065] Adherent device **200** comprises several layers. Gel **214A**, or gel layer, is positioned on electrode **212A** to provide electrical conductivity between the electrode and the skin. Electrode **212A** may comprise an electrode layer. Adhesive patch **210** may comprise a layer of breathable tape **210T**, for example a known breathable tape, such as tricot-knit polyester fabric. In many embodiments, a gap **269** extends from adhesive patch **210** to the electronics circuitry and components **230**, such that breathable tape **210T** can breathe to provide patient comfort. An adhesive **216A**, for example a layer of acrylate pressure sensitive adhesive, can be disposed on underside **210A** of patch **210**. A gel cover **280**, or gel cover layer, for example a polyurethane non-woven tape, can be positioned over patch **210** comprising the breathable tape. A PCB layer, for example flex PCB **220**, or flex PCB layer, can be positioned over gel cover **280** with electronic components **230** connected and/or mounted to flex PCB **220**, for example mounted on flex PCB so as to comprise an electronics layer disposed on the flex PCB. In many embodiments, the adherent device may comprise a segmented inner component, for example the PCB, for limited flexibility. In many embodiments, the electronics layer may be encapsulated in electronics housing **260** which may comprise a waterproof material, for example silicone or epoxy. In many embodiments, the electrodes are connected to the PCB with a flex connection, for example a trace **222A** of flex PCB **220**, so as to provide strain relief between the electrodes **212A**, **212B**, **212C** and **212D** and the PCB. Gel cover **280** can inhibit flow of gel **214A** and liquid. In many embodiments, gel cover **280** can inhibit gel **214A** from seeping through breathable tape **210T** to maintain gel integrity over time. Gel cover **280** can also keep external moisture from penetrating into gel **214A**. Gel cover **280** may comprise at least one aperture **280A** sized to receive one of the electrodes. In many embodiments, cover **262** can encase the flex PCB and/or electronics and can be adhered to at least one of the electronics, the flex PCB or the adherent patch, so as to protect the device. In some embodiments, cover **262** attaches to adhesive patch **210** with adhesive **216B** or adhesive **264**. Cover **262** can comprise many known biocompatible cover, housing and/or casing materials, for example silicone. In many embodiments, cover **262** comprises an outer polymer cover to provide smooth contour without limiting flexibility. In some embodiments, cover **262** may comprise a breathable fabric. Cover **262** may comprise many known breathable fabrics, for example breathable fabrics as described above. In some embodiments, the breathable fabric may comprise polyester, polyamide, and/or elastane (Spandex™) to allow the breathable fabric to stretch with body movement. In some embodiments, the breathable tape may contain and elute a pharmaceutical agent, such as an antibiotic, anti-inflammatory or antifungal agent, when the adherent device is placed on the patient.

[0066] The patient's respiration can be measured by a variety of means including but not limited to, a bioimpedance sensor, heart rate, pulse oximetry monitoring and the like. In one embodiment, the patient's respiration is continuously monitored. The respiration can be monitored to monitor a number of disorders including but not limited to, chronic obstructive pulmonary disease, asthma, sleep disordered breathing and the like. In one specific embodiment, the patient's respiration is monitored for a patient's sleep study. One of the sensors 14 can be a patient movement sensor. Respiration sensing can be used in conjunction with a posture sensor, including but not limited to a 3-axis accelerometer, to detect orthopnea. Respiration sensing can be in conjunction with HR sensing. The system can be used for, sleep studies, improved detection of apnea, monitoring of apnea, monitoring of COPD, monitoring and treatment of asthma, monitoring and treatment of orthopnea and other respiratory conditions.

[0067] Referring to FIG. 3, an energy management device 19 can be coupled to the plurality of sensors. In one embodiment, the energy management device 19 is part of the detecting system. In various embodiments, the energy management device 19 performs one or more of modulate drive levels per sensed signal of a sensor 14, modulate a clock speed to optimize energy, watch cell voltage drop—unload cell, coulomb-meter or other battery monitor, sensor dropoff at an end of life of a battery coupled to a sensor, battery end of life dropoff to transfer data, elective replacement indicator, call center notification, sensing windows by the sensors 14 based on a monitored physiological parameter and sensing rate control.

[0068] In one embodiment, the energy management device 19 is configured to manage energy by at least one of, a thermo-electric unit, kinetics, fuel cell, through solar power, a zinc air interface, Faraday generator, internal combustion, nuclear power, a micro-battery and with a rechargeable device.

[0069] The system 10 is configured to automatically detect events. The system 10 automatically detects events by at least one of, high noise states, physiological quietness, sensor continuity and compliance. In response to a detected physiological event, patient states are identified when data collection is inappropriate. In response to a detected physiological event, patient states are identified when data collection is desirable. Patient states include, physiological quietness, rest, relaxation, agitation, movement, lack of movement and a patient's higher level of patient activity.

[0070] The system can use an intelligent combination of sensors to enhance detection and prediction capabilities, as more fully discloses in U.S. patent application Ser. No. 60/972,537 identified as Attorney Docket No. 026843-000200US, previously incorporated herein by reference, and as more fully explained below.

[0071] In one embodiment, the detecting system 12 communicates with the remote monitoring system 18 periodically or in response to a trigger event. The trigger event can include but is not limited to at least one of, time of day, if a memory is full, if an action is patient initiated, if an action is initiated from the remote monitoring system, a diagnostic event of the monitoring system, an alarm trigger, a mechanical trigger, and the like.

[0072] The adherent device be activated by a variety of different means including but not limited to, a physiological trigger, automatic impedance, a tab pull, battery insertion, a

hall or reed switch, a breakable glass capsule, a dome switch, by light activation, pressure activation, body temperature activation, a connection between electronics associated with the sensors and the adherent device, exposure to air, by a capacitive skin sensor and the like.

[0073] The detecting system 12 can continuously, or non-continuously, monitor the patient, alerts are provided as necessary and medical intervention is provided when required. In one embodiment, the wireless communication device 16 is a wireless local area network for receiving data from the plurality of sensors.

[0074] A processor 20 is coupled to the plurality of sensors 14 and can also be a part of the wireless communication device 16. The processor 20 receives data from the plurality of sensors 14 and creates processed patient data. In one embodiment, the processor 20 is at the remote monitoring system. In another embodiment, the processor 20 is at the detecting system 12. The processor 20 can be integral with a monitoring unit 22 that is part of the detecting system 12 or part of the remote monitoring system.

[0075] The processor 20 has program instructions for evaluating values received from the sensors 14 with respect to acceptable physiological ranges for each value received by the processor 20 and determine variances. The processor 20 can receive and store a sensed measured parameter from the sensors 14, compare the sensed measured value with a predetermined target value, determine a variance, accept and store a new predetermined target value and also store a series of questions from the remote monitoring system 18.

[0076] Referring to FIG. 4, logic resources 24 are provided that take the data from the sensors 14, and/or the processed patient data from the processor 20, to predict an impending decompensation. The logic resources 24 can be at the remote monitoring system 18 or at the detecting system 12, such as in the monitoring unit 22.

[0077] In one embodiment, a memory management device 25 is provided as shown in FIG. 5. In various embodiments, the memory management device 25 performs one or more of data compression, prioritizing of sensing by a sensor 14, monitoring all or some of sensor data by all or a portion of the sensors 14, sensing by the sensors 14 in real time, noise blanking to provide that sensor data is not stored if a selected noise level is determined, low-power of battery caching and decimation of old sensor data.

[0078] The sensors 14 can provide a variety of different functions, including but not limited to, initiation, programming, measuring, storing, analyzing, communicating, predicting, and displaying of a physiological event of the patient. A wide variety of different sensors 14 can be utilized, including but not limited to, bioimpedance, heart rate, heart rhythm, HRV, HRT, heart sounds, respiration rate, respiration rate variability, respiratory sounds, SpO2, blood pressure, activity, posture, wake/sleep, orthopnea, temperature, heat flux and an accelerometer. A variety activity sensors can be utilized, including but not limited to a, ball switch, accelerometer, minute ventilation, HR, bioimpedance noise, skin temperature/heat flux, BP, muscle noise, posture and the like.

[0079] The outputs of the sensors 14 can have multiple features to enhance physiological sensing performance. These multiple features have multiple sensing vectors that can include redundant vectors. The sensors can include current delivery electrodes and sensing electrodes. Size and shape of current delivery electrodes, and the sensing electrodes, can be optimized to maximize sensing performance.

The system 10 can be configured to determine an optimal sensing configuration and electronically reposition at least a portion of a sensing vector of a sensing electrode. The multiple features enhance the system's 10 ability to determine an optimal sensing configuration and electronically reposition sensing vectors. In one embodiment, the sensors 14 can be partially masked to minimize contamination of parameters sensed by the sensors 14.

[0080] The size and shape of current delivery electrodes, for bioimpedance, and sensing electrodes can be optimized to maximize sensing performance. Additionally, the outputs of the sensors 14 can be used to calculate and monitor blended indices. Examples of the blended indices include but are not limited to, heart rate (HR) or respiratory rate (RR) response to activity, HR/RR response to posture change, HR+RR, HR/RR+bioimpedance, and/or minute ventilation/accelerometer and the like.

[0081] The sensors 14 can be cycled in order to manage energy, and different sensors 14 can sample at different times. By way of illustration, and without limitation, instead of each sensor 14 being sampled at a physiologically relevant interval, e.g. every 30 seconds, one sensor 14 can be sampled at each interval, and sampling cycles between available sensors.

[0082] By way of illustration, and without limitation, the sensors 14 can sample 5 seconds for every minute for ECG, once a second for an accelerometer sensor, and 10 seconds for every 5 minutes for impedance.

[0083] In one embodiment, a first sensor 14 is a core sensor 14 that continuously monitors and detects, and a second sensor 14 verifies a physiological status in response to the core sensor 14 raising a flag. Additionally, some sensors 14 can be used for short term tracking, and other sensors 14 used for long term tracking.

[0084] Referring to FIG. 6, in one embodiment, an external device 38, including a medical treatment device, is coupled to the sensors 14. The external device 38 can be coupled to a monitoring unit 22 that is part of the detecting system 12, or in direct communication with the sensors 14. A variety of different external devices 38 can be used, including but not limited to, a weight scale, blood pressure cuff, cardiac rhythm management device, a medical treatment device, medicament dispenser and the like). Suitable cardiac rhythm management devices include but are not limited to, Boston Scientific's Latitude system, Medtronic's CareLink system, St. Jude Medical's HouseCall system and the like. Such communication may occur directly, or via an external translator unit.

[0085] The external device 38 can be coupled to an auxiliary input of the monitoring unit 22 at the detecting system 12 or to the monitoring system 22 at the remote monitoring system 18. Additionally, an automated reader can be coupled to an auxiliary input in order to allow a single monitoring unit 22 to be used by multiple patients. As previously mentioned above, the monitoring unit 22 can be at the remote monitoring system 18 and each patient can have a patient identifier (ID) including a distinct patient identifier. In addition, the ID identifier can also contain patient specific configuration parameters. The automated reader can scan the patient identifier ID and transmit the patient ID number with a patient data packet such that the main data collection station can identify the patient.

[0086] It will be appreciated that other medical treatment devices can also be used. The sensors 14 can communicate wirelessly with the external devices 38 in a variety of ways including but not limited to, a public or proprietary commu-

nication standard and the like. The sensors 14 can be configured to serve as a communication hub for multiple medical devices, coordinating sensor data and therapy delivery while transmitting and receiving data from the remote monitoring system 18.

[0087] In one embodiment, the sensors 14 coordinate data sharing between the external systems 38 allowing for sensor integration across devices. The coordination of the sensors 14 provides for new pacing, sensing, defibrillation vectors and the like.

[0088] In one embodiment, the processor 20 is included in the monitoring unit 22 and the external device 38 is in direct communication with the monitoring unit 22.

[0089] Referring to FIG. 7, in another embodiment, a notification device 42 is coupled to the detecting system 12 and the remote monitoring system 18. The notification device 42 is configured to provide notification when values received from the sensors 14 are not within acceptable physiological ranges. The notification device 42 can be at the remote monitoring system 18 or at the monitoring unit 22 that is part of the detecting system 12. A variety of notification devices 42 can be utilized, including but not limited to, a visible patient indicator, an audible alarm, an emergency medical service notification, a call center alert, direct medical provider notification and the like. The notification device 42 provides notification to a variety of different entities, including but not limited to, the patient, a caregiver, the remote monitoring system, a spouse, a family member, a medical provider, from one device to another device such as the external device 38, and the like.

[0090] Notification can be according to a preset hierarchy. By way of illustration, and without limitation, the preset hierarchy can be, patient notification first and medical provider second, patient notification second and medical provider first, and the like. Upon receipt of a notification, a medical provider, the remote monitoring system 18, or a medical treatment device can trigger a high-rate sampling of physiological parameters for alert verification.

[0091] The system 10 can also include an alarm 46, that can be coupled to the notification device 42, for generating a human perceptible signal when values received from the sensors 14 are not within acceptable physiological ranges. The alarm 46 can trigger an event to render medical assistance to the patient, provide notification as set forth above, continue to monitor, wait and see, and the like.

[0092] When the values received from the sensors 14 are not within acceptable physiological ranges the notification is with the at least one of, the patient, a spouse, a family member, a caregiver, a medical provider and from one device to another device, to allow for therapeutic intervention to prevent decompensation, and the like.

[0093] In another embodiment, the sensors 14 can switch between different modes, wherein the modes are selected from at least one of, a stand alone mode with communication directly with the remote monitoring system 18, communication with an implanted device, communication with a single implanted device, coordination between different devices (external systems) coupled to the plurality of sensors and different device communication protocols.

[0094] Respiratory status can be determined by a weighted combination change in sensor outputs and be determined by a number of different means, including but not limited to, (i) when a rate of change of at least two sensor outputs is an abrupt change in the sensor outputs as compared to a change

in the sensor outputs over a longer period of time, (ii) by a tiered combination of at least a first and a second sensor output, with the first sensor output indicating a problem that is then verified by at least a second sensor output, (iii) by a variance from a baseline value of sensor outputs, and the like. The baseline values can be defined in a look up table.

[0095] In another embodiment, respiratory status is determined using three or more sensors by at least one of, (i) when the first sensor output is at a value that is sufficiently different from a baseline value, and at least one of the second and third sensor outputs is at a value also sufficiently different from a baseline value to indicate respiratory status, (ii) by time weighting the outputs of the first, second and third sensors, and the time weighting indicates a recent event that is indicative of the respiratory status and the like.

[0096] In one embodiment, the wireless communication device **16** can include a, modem, a controller to control data supplied by the sensors **14**, serial interface, LAN or equivalent network connection and a wireless transmitter. Additionally, the wireless communication device **16** can include a receiver and a transmitter for receiving data indicating the values of the physiological event detected by the plurality of sensors, and for communicating the data to the remote monitoring system **18**. Further, the wireless communication device **16** can have data storage for recording the data received from the sensors **14** and an access device for enabling access to information recording in the data storage from the remote monitoring system **18**.

Example 1

Sleep Apnea

[0097] Sleep apnea is a disorder characterized by a reduction or cessation (pause of breathing, airflow) during sleep. It is common among adults but rare among children. There are two types of sleep apnea, the more common obstructive sleep apnea and the less common central sleep apnea, both of which will be described later in this article. Although a diagnosis of sleep apnea often will be suspected on the basis of a person's history, there are several tests that can be used to confirm the diagnosis. The treatment of sleep apnea may be either surgical or nonsurgical.

[0098] An apnea is a period of time during which breathing stops or is markedly reduced. In simplified terms, an apnea occurs when a person stops breathing for 10 seconds or more. So, if normal breath airflow is 70% to 100%, an apnea is if you stop breathing completely, or take less than 25% of a normal breath (for a period that lasts 10 seconds or more). This definition includes complete stoppage of airflow. Other definitions of apnea that may be used include at least a 4% drop in the saturation of oxygen in the blood, a direct result of the reduction in the transfer of oxygen into the blood when breathing stops.

[0099] Apneas usually occur during sleep. When an apnea occurs, sleep is disrupted. Sometimes this means the person wakes up completely, but sometimes this can mean the person comes out of a deep level of sleep and into a more shallow level of sleep. Apneas are usually measured during sleep (preferably in all stages of sleep) over a two-hour period. An estimate of the severity of apnea is calculated by dividing the number of apneas by the number of hours of sleep, giving an apnea index (AI). The greater the AI, the more severe the apnea.

[0100] A hypopnea is a decrease in breathing that is not as severe as an apnea. So, if normal breath airflow is 100% to 70%, a hypopnea is 69% to 26% of a normal breath. Like apneas, hypopneas are associated with a 4% or greater drop in the saturation of oxygen in the blood and usually occur during sleep. Also like apneas, hypopneas usually disrupt the level of sleep. A hypopnea index (HI) can be calculated by dividing the number of hypopneas by the number of hours of sleep.

[0101] The apnea-hypopnea index (AHI) is an index of severity that combines apneas and hypopneas. Combining them both gives an overall severity of sleep apnea including sleep disruptions and desaturations (a low level of oxygen in the blood). The apnea-hypopnea index, like the apnea index and hypopnea index, is calculated by dividing the number of apneas and hypopneas by the number of hours of sleep. Another index that is used to measure sleep apnea is the respiratory disturbance index (RDI). The respiratory disturbance index is similar to the apnea-hypopnea index, however, it also includes respiratory events that do not technically meet the definitions of apneas or hypopneas, but do disrupt sleep.

[0102] Sleep apnea is formally defined as an apnea-hypopnea index of at least 15 episodes/hour in a patient without medical problems that may be related to the sleep apnea. That is the equivalent of one episode every 4 minutes. In a patient with high blood pressure, stroke, daytime sleepiness, ischemic heart disease (low flow of blood to the heart), insomnia, or mood disorders—all of which can be caused or worsened by sleep apnea—sleep apnea is defined as an apnea-hypopnea index of at least 5 episodes/hour. This definition is stricter because the patient may be already experiencing the negative medical effects of sleep apnea, and it may be important to begin treatment at a lower apnea-hypopnea index.

[0103] The system **10** of the present invention is used for detecting apnea and respiratory arrest. An alarm can be provided to wake the individual or to summon help to restore a normal breathing cycle. The system senses the cyclical rhythm of an individual's breathing.

[0104] The system **10** includes logic resources that incorporates a first preselected or predetermined time, which for purpose of illustration can be about twenty minutes. Then, when the system **10** detects an individual's cyclical rhythm of breathing for that period of time, the system can arm the alarm.

[0105] The system **10** detects an interruption in the breathing cycle and times the interruption in the cyclical rhythm of breathing. If the interruption of the breathing cycle continues for a period of time, any number of different actions can be taken to jar the patient into an awakened state.

Example 2

Sleep Study and Multiple Sleep Latency Test or MSLT

[0106] A Sleep Study or Polysomnogram (PSG) is a multiple-component test, which electronically transmits and records specific physical activities while you sleep. The recordings become data, which are read or analyzed by a qualified physician to determine is a patient has a sleep disorder.

[0107] Generally, there are four types of Polysomnographic Studies. They are:

[0108] Diagnostic Overnight PSG—General monitoring and evaluation.

[0109] Diagnostic Daytime Multiple Sleep Latency Test (MSLT)—Used to diagnose Narcolepsy and measure the degree of daytime sleepiness. To ensure accurate results, it is performed on the morning following a Diagnostic Overnight PSG.

[0110] Two Night PSG with CPAP Titration—General monitoring and diagnostic evaluation is conducted on the first night. If Sleep Apnea is discovered, the patient returns for a second night to determine the necessary CPAP pressure required to alleviate apnea.

[0111] Split Night PSG with CPAP Titration—Split Night PSG is conducted when moderate or severe Sleep Apnea has been discovered or strongly suspected during the first part of the nights study. The second half of the night is used for CPAP Titration.

[0112] The system 10 is used in a sleep study for a patient to determine if the patient has sleep apnea. The patient is coupled to sensors, monitoring devices, from the system 10, and the like, during a setup can take 30-45 minutes or more in order to get everything connected properly. Belts are placed around the patient's chest and abdomen to measure respiratory efforts, and a band-aid like oximeter probe is placed on the patient's finger to measure the amount of oxygen. The sensors or electrodes from system 10 are adhered to the patient's skin and scalp.

[0113] Recorded electrical signals generated by the patient's brain and muscle activity are sent to the system 10 and are recorded digitally and on continuous strips of paper. The pattern of this activity is recognized by a sleep specialist who reads or interprets the study.

[0114] An EEG, or electroencephalogram, is a major part of the sleep study. It measures and records four forms of brain wave activity—alpha, beta, delta and theta waves. Alpha waves are usually found during relaxed wakefulness, particularly when the patient's eyes are closed. Theta waves are seen during the lighter sleep stages 1 and 2, while delta waves occur chiefly in deep sleep, the so-called "slow wave sleep" found in sleep stages 3 and 4.

[0115] An EMG, or electromyogram, records muscle activity such as face twitches, teeth grinding, and leg movements. It also helps in determining the presence of REM stage sleep. The amount and duration of these activities provides the doctor important information about the patient's sleep. An EOG or electro-oculogram, records eye movements. These movements are important in determining the different sleep stages, particularly REM stage sleep. The electrodes are usually placed on the outer aspect of your right eyebrow and along the outer aspect below or beneath the left eye.

[0116] An EKG, or electrocardiogram records heart activities, such as rate and rhythm. Electrodes are placed on the patient's chest. A nasal airflow sensor records breath temperature, airflow, apnea and hypopnea events. A sensor is placed near the patient's nose and mouth. Chest/abdomen belts are used to record breathing depth, apnea and hypopnea events. Elastic belts are placed around the patient's chest and abdomen. An oximeter records blood oxygen saturation. A band-aid like clip is placed on a finger. Video is used to records body positioning and movements. A snore microphone is used to record snoring. An electrode is placed over the patient's trachea, on the lower neck.

[0117] Sleeping is a complex activity that must occur for a successful polysomnographic study. During sleep, our brain and body cycle between NREM and REM sleep approximately every 90 minutes.

[0118] During these transitions, major changes occur in EEG, EOG, EMG, heartrate and respiration that are necessary for healthy sleep. If abnormal changes are observed during a particular sleep stage, then the system 10 defines this problem as it occurs during the night.

[0119] Elastic belts are placed around the patient's and abdomen to record breathing rate and effort from the diaphragm, as well as apnea and hypopnea events.

[0120] A Multiple Sleep Latency Test, or MSLT, is designed to measure the degree of sleep tendency or sleepiness in a given patient. This test is conducted during the day, with the system 10, following a routine PSG and features a series of up to 5 naps, each lasting usually less than 30 minutes that are timed to start every two hours during the day. For example, 10 am, 12 (noon), 2 pm, 4 pm and 6 pm represent a possible nap schedule.

[0121] The purpose of the MSLT is two fold: first, to average the number of minutes that it takes to fall asleep (sleep onset latency) during all the naps and second, to record if REM stage sleep occurs during any of these scheduled napping periods. The testing procedure includes essentially the same PSG leads as for a diagnostic overnight study. During the periods between naps, the patient stays awake and does not fall asleep.

[0122] This test is particularly useful in determining if a patient with narcolepsy is adjusting to its medication, diagnose Narcolepsy, objectively quantify the degree of sleepiness in a particular patient, such as an OSA (obstructive sleep apnea) patient who is still sleepy despite CPAP treatment and in diagnosing Idiopathic Hypersomnolence.

Example 3

COPD

[0123] Patients with mild to severe COPD are monitored in their homes performing their normal daily activities (including sleep) using the system 10. RC and an AB RIP band sensors, a modified limb II ECG sensor, an accelerometer sensor, filtered for posture and movement, are used to identify cough sounds. During sleep, data from associated EEG and EOG sensors is also recorded. This physiological monitoring data was processed by the remote monitoring system 18.

[0124] Results of these measurements indicated that cough frequency followed circadian patterns. Nocturnal cough occurred at a significant frequency throughout most of the night except the early morning. A number of these nocturnal coughs occurred during an EEG arousal or within a permissible time window associated with an arousal. The number of coughs during each sleep stage is determined COPD patients experienced cough evenly distributed throughout both stages 3 and 4 of NREM sleep and also REM sleep. However, during NREM stage 1, coughs are somewhat increased; and during NREM stage 2, an exceptional number of coughs occurred. Thus, nocturnal cough occurred most frequently during the lighter sleep stages, and hence these COPD patients spent a greater than normal percentage of time in stage 1 sleep.

[0125] Thus, nocturnal cough is preventing these COPD patients from progressing naturally to deeper sleep stages, leading a disruption of sleep architecture in which an unusual percentage of time is spent in stage 1 and 2 sleep.

Example 4

Orthopnea

[0126] By way of illustration, orthopnea, or paroxysmal nocturnal dyspnea ("PND") of a patient is monitored. The processor **20** compares at least two respiration patterns. The non-recumbent respiration pattern shows that the patient is taking relatively slow and deep breaths as can be seen by the relatively low frequency and high amplitude of the pattern. However, the recumbent respiration pattern shows that the patient is taking relatively rapid and shallow breaths as indicated by the relatively high frequency and low amplitude of the pattern. The rapid and shallow breathing of the recumbent respiration pattern indicates a patient suffering from orthopnea that eventually occurs upon lying down.

[0127] The presence of orthopnea is known to be a sign of congestion. However, other recumbent respiration pattern changes resulting from lying down may also be indicative of congestion. Therefore, the processor **20** may perform various comparisons in addition to or as an alternative to looking for both rapid and shallow breaths. For example, the processor **20** may search for only rapid recumbent respiration relative to upright respiration. Similarly, the processor **20** may search for only shallow, or low tidal volume, recumbent respiration relative to upright respiration. As another example, the processor **20** may search for a difference in the combination of respiratory rate to tidal volume between tile recumbent and non-recumbent respiration patterns. Such a combination may be a ratio of respiratory rate to tidal volume. Additionally, the processor **20** may search for a difference in inspiration times and expiratory times, inspiration time of a recumbent pattern versus inspiratory for a non-recumbent pattern, and/or expiratory time of a recumbent pattern versus expiratory time of a non-recumbent pattern.

[0128] In various embodiments, the remote monitoring system **18** can include a receiver, a transmitter and a display for displaying data representative of values of the one physiological event detected by the sensors **14**. The remote monitoring system can also include a, data storage mechanism that has acceptable ranges for physiological values stored therein, a comparator for comparing the data received from the monitoring system **12** with the acceptable ranges stored in the data storage device and a portable computer. The remote monitoring system **18** can be a portable unit with a display screen and a data entry device for communicating with the wireless communication device **16**.

[0129] Referring now to FIG. **8**, for each sensor **14**, a sensor lead **112** and **114** conveys signals from the sensor **14** to the monitoring unit **22** at the detecting system **12**, or through the wireless communication device **16** to the remote monitoring system **18**. In one embodiment, each signal from a sensor **14** is first passed through a low-pass filter **116**, at the detecting system **12** or at the remote monitoring system **18**, to smooth the signal and reduce noise. The signal is then transmitted to an analog-to-digital converter **118A**, which transforms the signals into a stream of digital data values that can be stored in a digital memory **118B**. From the digital memory **118B**, data values are transmitted to a data bus **120**, along which they are transmitted to other components of the circuitry to be processed and archived. From the data bus **120**, the digital data can be stored in a non-volatile data archive memory. The digital data can be transferred via the data bus **120** to the

processor **20**, which processes the data based in part on algorithms and other data stored in a non-volatile program memory.

[0130] The detecting system **12** can also include a power management module **122** configured to power down certain components of the system, including but not limited to, the analog-to-digital converters **118A**, digital memories **118B** and the non-volatile data archive memory and the like, between times when these components are in use. This helps to conserve battery power and thereby extend the useful life. Other circuitry and signaling modes may be devised by one skilled in the art.

[0131] As can be seen in FIG. **9**, a control unit **126** is included at the detecting system **12**, the remote monitoring system **18** or at both locations.

[0132] In one embodiment, the control unit **126** can be a 486 microprocessor, available from Intel, Inc. of Santa Clara, Calif. The control unit **126** can be coupled to the sensors **14** directly at the detecting system **12**, indirectly at the detecting system **12** or indirectly at the remote monitoring system **18**. Additionally the control unit **126** can be coupled to a blood pressure monitor, a cardiac rhythm management device, a scale or a device that dispenses medication that can indicate the medication has been dispensed.

[0133] The control unit **126** can be powered by AC inputs which are coupled to internal AC/DC converters **134** that generate multiple DC voltage levels. After the control unit **126** has collected the patient data from the sensors **14**, the control unit **126** encodes the recorded patient data and transmits the patient data through the wireless communication device **16** to transmit the encoded patient data to a wireless network storage unit **128** at the remote monitoring system **18** as shown in FIG. **10**. In another embodiment, wireless communication device **16** transmits the patient data from the sensors **14** to the control unit **126** when it is at the remote monitoring system **18**.

[0134] Every time the control unit **126** plans to transmit patient data to a main data collection station **130**, located at the remote monitoring system **18**, the control unit **126** attempts to establish a communication link. The communication link can be wireless, wired, or a combination of wireless and wired for redundancy, e.g., the wired link checks to see if a wireless communication can be established. If the wireless communication link **16** is available, the control unit **126** transmits the encoded patient data through the wireless communication device **16**. However, if the wireless communication device **16** is not available for any reason, the control unit **126** waits and tries again until a link is established.

[0135] Referring now to FIG. **11**, one embodiment of an internal structure of a main data collection station **130**, at the remote monitoring system **18**, is illustrated. The patient data can be transmitted by the remote monitoring system **18** by either the wireless communication device **16** or conventional modem to the wireless network storage unit **128**. After receiving the patient data, the wireless network storage unit **128** can be accessed by the main data collection station **130**. The main data collection station **130** allows the remote monitoring system **18** to monitor the patient data of numerous patients from a centralized location without requiring the patient or a medical provider to physically interact with each other.

[0136] The main data collection station **130** can include a communications server **136** that communicates with the wireless network storage unit **128**. The wireless network storage unit **128** can be a centralized computer server that includes a

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unique, password protected mailbox assigned to and accessible by the main data collection station 130. The main data collection station 130 contacts the wireless network storage unit 128 and downloads the patient data stored in a mailbox assigned to the main data collection station 130.

[0137] Once the communications server 136 has formed a link with the wireless network storage unit 128, and has downloaded the patient data, the patient data can be transferred to a database server 138. The database server 138 includes a patient database 140 that records and stores the patient data of the patients based upon identification included in the data packets sent by each of the monitoring units 22. For example, each data packet can include an identifier.

[0138] Each data packet transferred from the remote monitoring system 18 to the main data collection station 130 does not have to include any patient identifiable information. Instead, the data packet can include the serial number assigned to the specific detecting system 12. The serial number associated with the detecting system 12 can then be correlated to a specific patient by using information stored on the patient database 138. In this manner, the data packets transferred through the wireless network storage unit 128 do not include any patient-specific identification. Therefore, if the data packets are intercepted or improperly routed, patient confidentiality can not be breached.

[0139] The database server 138 can be accessible by an application server 142. The application server 142 can include a data adapter 144 that formats the patient data information into a form that can be viewed over a conventional web-based connection. The transformed data from the data adapter 144 can be accessible by propriety application software through a web server-146 such that the data can be viewed by a workstation 148. The workstation 148 can be a conventional personal computer that can access the patient data using proprietary software applications through, for example, HTTP protocol, and the like.

[0140] The main data collection station further can include an escalation server 150 that communicates with the database server 138. The escalation server 150 monitors the patient data packets that are received by the database server 138 from the monitoring unit 22. Specifically, the escalation server 150 can periodically poll the database server 138 for unacknowledged patient data packets. The patient data packets are sent to the remote monitoring system 18 where the processing of patient data occurs. The remote monitoring system 18 communicates with a medical provider if the event that an alert is required. If data packets are not acknowledged by the remote monitoring system 18, the escalation server 150 can be programmed to automatically deliver alerts to a specific medical provider if an alarm message has not been acknowledged within a selected time period after receipt of the data packet.

[0141] The escalation server 150 can be configured to generate the notification message to different people by different modes of communication after different delay periods and during different time periods.

[0142] The main data collection station 130 can include a batch server 152 connected to the database server 138. The batch server 152 allows an administration server 154 to have access to the patient data stored in the patient database 140. The administration server allows for centralized management of patient information and patient classifications.

[0143] The administration server 154 can include a batch server 156 that communicates with the batch server 152 and provides the downloaded data to a data warehouse server 158.

The data warehouse server 158 can include a large database 160 that records and stores the patient data.

[0144] The administration server 154 can further include an application server 162 and a maintenance workstation 164 that allow personnel from an administrator to access and monitor the data stored in the database 160.

[0145] The data packet utilized in the transmission of the patient data can be a variable length ASCII character packet, or any generic data formats, in which the various patient data measurements are placed in a specific sequence with the specific readings separated by commas. The control unit 126 can convert the readings from each sensor 14 into a standardized sequence that forms part of the patient data packet. In this manner, the control unit 126 can be programmed to convert the patient data readings from the sensors 14 into a standardized data packet that can be interpreted and displayed by the main data collection station 130 at the remote monitoring system 18.

[0146] Referring now to the flow chart of FIG. 12, if an external device 38 fails to generate a valid reading, as illustrated in step A, the control unit 126 fills the portion of the patient data packet associated with the external device 38 with a null indicator. The null indicator can be the lack of any characters between commas in the patient data packet. The lack of characters in the patient data packet can indicate that the patient was not available for the patient data recording. The null indicator in the patient data packet can be interpreted by the main data collection station 130 at the remote monitoring system 18 as a failed attempt to record the patient data due to the unavailability of the patient, a malfunction in one or more of the sensors 14, or a malfunction in one of the external devices 38. The null indicator received by the main data collection station 130 can indicate that the transmission from the detecting system 12 to the remote monitoring system 18 was successful. In one embodiment, the integrity of the data packet received by the main data collection station 130 can be determined using a cyclic redundancy code, CRC-16, check sum algorithm. The check sum algorithm can be applied to the data when the message can be sent and then again to the received message.

[0147] After the patient data measurements are complete, the control unit 126 displays the sensor data, including but not limited to blood pressure cuff data and the like, as illustrated by step B. In addition to displaying this data, the patient data can be placed in the patient data packet, as illustrated in step C.

[0148] As previously described, the system 10 can take additional measurements utilizing one or more auxiliary or external devices 38 such as those mentioned previously. Since the patient data packet has a variable length, the auxiliary device patient information can be added to the patient data packet being compiled by the remote monitoring unit 22 during patient data acquisition period being described. Data from the external devices 38 is transmitted by the wireless communication device 16 to the remote monitoring system 18 and can be included in the patient data packet.

[0149] If the remote monitoring system 18 can be set in either the auto mode or the wireless only mode, the remote monitoring unit 22 can first determine if there can be an internal communication error, as illustrated in step D.

[0150] A no communication error can be noted as illustrated in step E. If a communication error is noted the control unit 126 can proceed to wireless communication device 16 or to a conventional modem transmission sequence, as will be

described below. However, if the communication device is working the control unit **126** can transmit the patient data information over the wireless network **16**, as illustrated in step F. After the communication device has transmitted the data packet, the control unit **126** determines whether the transmission was successful, as illustrated in step G. If the transmission has been unsuccessful only once, the control unit **126** retries the transmission. However, if the communication device has failed twice, as illustrated in step H, the control unit **126** proceeds to the conventional modem process if the remote monitoring unit **22** was configured in an auto mode.

[0151] When the control unit **126** is at the detecting system **12**, and the control unit **126** transmits the patient data over the wireless communication device **16**, as illustrated in step I, if the transmission has been successful, the display of the remote monitoring unit **22** can display a successful message, as illustrated in step J. However, if the control unit **126** determines in step K that the communication of patient data has failed, the control unit **126** repeats the transmission until the control unit **126** either successfully completes the transmission or determines that the transmission has failed a selected number of times, as illustrated in step L. The control unit **126** can time out the and a failure message can be displayed, as illustrated in steps M and N. Once the transmission sequence has either failed or successfully transmitted the data to the main data collection station, the control unit **126** returns to a start program step 0.

[0152] As discussed previously, the patient data packets are first sent and stored in the wireless network storage unit **128**. From there, the patient data packets are downloaded into the main data collection station **130**. The main data collection station **130** decodes the encoded patient data packets and records the patient data in the patient database **140**. The patient database **140** can be divided into individual storage locations for each patient such that the main data collection station **130** can store and compile patient data information from a plurality of individual patients.

[0153] A report on the patient's status can be accessed by a medical provider through a medical provider workstation that is coupled to the remote monitoring system **18**. Unauthorized access to the patient database can be prevented by individual medical provider usernames and passwords to provide additional security for the patient's recorded patient data.

[0154] The main data collection station **130** and the series of work stations **148** allow the remote monitoring system **18** to monitor the daily patient data measurements taken by a plurality of patients reporting patient data to the single main data collection station **130**. The main data collection station **130** can be configured to display multiple patients on the display of the workstations **148**. The internal programming for the main data collection station **130** can operate such that the patients are placed in a sequential top-to-bottom order based upon whether or not the patient can be generating an alarm signal for one of the patient data being monitored. For example, if one of the patients monitored by monitoring system **130** has a blood pressure exceeding a predetermined maximum amount, this patient can be moved toward the top of the list of patients and the patient's name and/or patient data can be highlighted such that the medical personnel can quickly identify those patients who may be in need of medical assistance. By way of illustration, and without limitation, the

following paragraphs is a representative order ranking method for determining the order which the monitored patients are displayed:

[0155] Alarm Display Order Patient Status Patients are then sorted 1 Medical Alarm Most alarms violated to least alarms violated, then oldest to newest 2 Missing Data Alarm Oldest to newest 3 Late Oldest to newest 4 Reviewed Medical Alarms Oldest to newest 5 Reviewed Missing Data Oldest to newest Alarms 6 Reviewed Null Oldest to newest 7 NDR Oldest to newest 8 Reviewed NDR Oldest to newest.

[0156] Alarm Display Order Patient Status Patients can then sorted 1 Medical Alarm Most alarms violated to least alarms violated, then oldest to newest 2 Missing Data Alarm Oldest to newest 3 Late Oldest to newest 4 Reviewed Medical Alarms Oldest to newest 5 Reviewed Missing Data Oldest to newest Alarms 6 Reviewed Null Oldest to newest 7 NDR Oldest to newest 8 Reviewed NDR Oldest to newest.

[0157] As listed in the above, the order of patients listed on the display can be ranked based upon the seriousness and number of alarms that are registered based upon the latest patient data information. For example, if the blood pressure of a single patient exceeds the tolerance level and the patient's heart rate also exceeds the maximum level, this patient will be placed above a patient who only has one alarm condition. In this manner, the medical provider can quickly determine which patient most urgently needs medical attention by simply identifying the patient's name at the top of the patient list. The order which the patients are displayed can be configurable by the remote monitoring system **18** depending on various preferences.

[0158] As discussed previously, the escalation server **150** automatically generates a notification message to a specified medical provider for unacknowledged data packets based on user specified parameters.

[0159] In addition to displaying the current patient data for the numerous patients being monitored, the software of the main data collection station **130** allows the medical provider to trend the patient data over a number of prior measurements in order to monitor the progress of a particular patient. In addition, the software allows the medical provider to determine whether or not a patient has been successful in recording their patient data as well as monitor the questions being asked by the remote monitoring unit **22**.

[0160] As previously mentioned, the system **10** uses an intelligent combination of sensors to enhance detection and prediction capabilities. Electrocardiogram circuitry can be coupled to the sensors **14**, or electrodes, to measure an electrocardiogram signal of the patient. An accelerometer can be mechanically coupled, for example adhered or affixed, to the sensors **14**, adherent patch and the like, to generate an accelerometer signal in response to at least one of an activity or a position of the patient. The accelerometer signals improve patient diagnosis, and can be especially useful when used with other signals, such as electrocardiogram signals and impedance signals, including but not limited to, hydration respiration, and the like. Mechanically coupling the accelerometer to the sensors **14**, electrodes, for measuring impedance, hydration and the like can improve the quality and/or usefulness of the impedance and/or electrocardiogram signals. By way of illustration, and without limitation, mechanical coupling of the accelerometer to the sensors **14**, electrodes, and to the skin of the patient can improve the reliability, quality and/or accuracy of the accelerometer measurements, as the sensor **14**, electrode, signals can indicate the

quality of mechanical coupling of the patch to the patient so as to indicate that the device is connected to the patient and that the accelerometer signals are valid. Other examples of sensor interaction include but are not limited to, (i) orthopnea measurement where the breathing rate is correlated with posture during sleep, and detection of orthopnea, (ii) a blended activity sensor using the respiratory rate to exclude high activity levels caused by vibration (e.g. driving on a bumpy road) rather than exercise or extreme physical activity, (iii) sharing common power, logic and memory for sensors, electrodes, and the like.

[0161] While the exemplary embodiments have been described in some detail, by way of example and for clarity of understanding, those of skill in the art will recognize that a variety of modifications, adaptations, and changes may be employed. Hence, the scope of the present invention should be limited solely by the appended claims.

1. (canceled)

2. A respiratory monitoring system for monitoring a patient, comprising:

an adherent device comprising:

an adhesive layer to hold the adherent device in contact with the skin of the patient;

four electrodes that couple to the skin of the patient when the adherent device is adhered to the skin of the patient;

a plurality of sensors configured to monitor physiological parameters of the patient to determine respiratory status, wherein one of the sensors measures a localized tissue impedance of the patient using the four electrodes; and

electronic circuitry coupled to the plurality of sensors, the electronic circuitry comprising a wireless communication device; and

a remote monitoring system coupled to the wireless communication device, the wireless communication device configured to transfer patient data from the plurality of sensors to the remote monitoring system.

3. The system of claim 2, further wherein the four electrodes comprise current delivery electrodes and sensing electrodes, and wherein the system supplies current through the current delivery electrodes and monitors the respiration of the patient at least in part using signals from the sensing electrodes.

4. The system of claim 2, wherein the plurality of sensors comprises a combination of sensors and the combination of sensors comprises at least one sensor selected from the group consisting of a heart rate sensor and a pulse oximeter sensor.

5. The system of claim 2, further comprising:

a processor coupled to the plurality of sensors and to the wireless communication device, the processor configured to receive data from the plurality of sensors and process the patient data to generate processed patient data.

6. The system of claim 5, wherein the processor is located at the remote monitoring system.

7. The system of claim 5, wherein the processor processes the patient data to detect an apnea of the patient.

8. The system of claim 5, wherein the adherent device is configured to monitor the patient's respiration continuously.

9. The system of claim 5, wherein the adherent device is configured to monitor a pulmonary disorder comprising at least one of chronic obstructive pulmonary disease, asthma, or sleep disordered breathing.

10. The system of claim 5, wherein the plurality of sensors comprises a posture sensor for orthopnea monitoring.

11. The system of claim 5, wherein the system is configured to monitor the patient for a patient sleep study.

12. The system of claim 2, wherein the plurality of sensors comprises a patient movement sensor.

13. The system of claim 2, wherein the adherent device comprises a plurality of patches, wherein at least a first patch of the plurality is configured for placement a thorax of the patient, and at least a second patch of the plurality is configured for placement at another patient site away from the thorax to measure patient movement.

14. The system of claim 2, further comprising a processor configured to determine the respiratory status in response to a weighted combination of change in sensor outputs.

15. The system of claim 2, further comprising a processor configured to:

detect when a first rate of change of at least two sensor outputs measured over a first period of time is greater than a second rate of change in the sensor outputs measured over a second period of time that is longer than the first period of time; and

upon such detection, determine the respiratory status of the patient.

16. The system of claim 15 wherein the first period of time comprises no more than about 10 seconds and the second period of time comprises at least about one hour.

17. The system of claim 2, further comprising a processor configured to determine a physiological event of the patient in response to a variance from baseline values of sensor outputs.

18. The system of claim 2, further comprising a flexible, breathable cover disposed over the electronic circuitry.

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摘要(译)

提供呼吸监测系统。提供一种测量系统,其包括:(ⅰ)被配置为耦合到患者的粘附装置,所述粘附装置包括监测呼吸状态的多个传感器,所述传感器中的至少一个被配置为监测患者的呼吸,以及(ⅱ)无线通信设备,其耦合到多个传感器并且被配置为将患者数据直接或间接地从多个传感器传输到远程监控系统。远程监控系统耦合到无线通信设备。