(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 March 2009 (19.03.2009)

PCT

(10) International Publication Number
WO 2009/036327 A1

(51) International Patent Classification:
A61B 5/08 (2006.01)

(21) International Application Number:
PCT/US2008/076241

(22) International Filing Date:
12 September 2008 (12.09.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/972,363	14 September 2007 (14.09.2007)	US
60/972,537	14 September 2007 (14.09.2007)	US
60/972,336	14 September 2007 (14.09.2007)	US
61/055,666	23 May 2008 (23.05.2008)	US
61/055,656	23 May 2008 (23.05.2008)	US

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

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

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(54) Title: ADHERENT DEVICE FOR RESPIRATORY MONITORING AND SLEEP DISORDERED BREATHING

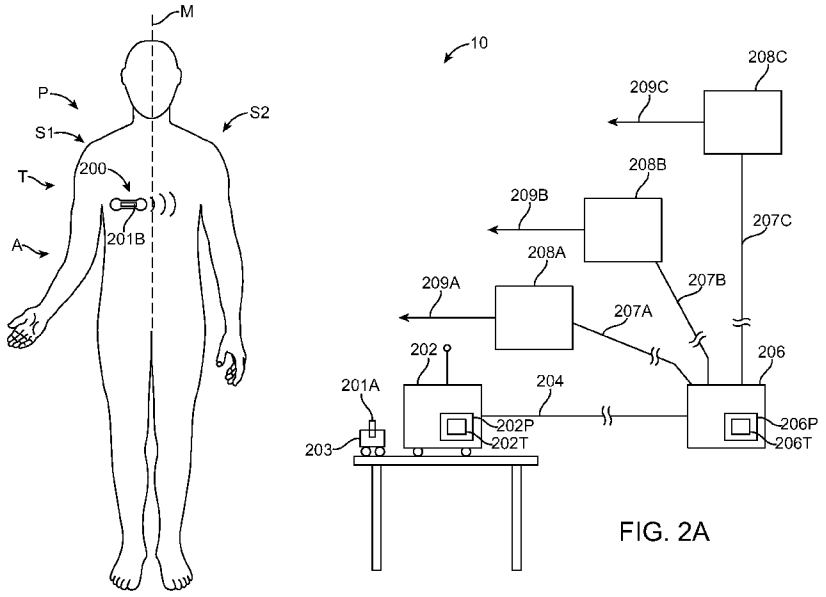


FIG. 2A

(57) Abstract: A respiratory monitoring system is provided. A measuring 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.

WO 2009/036327 A1

Declaration under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

— *with international search report*

ADHERENT DEVICE FOR RESPIRATORY MONITORING AND SLEEP DISORDERED BREATHING

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application claims the benefit under 35 USC 119(e) of US Provisional Application No. 60/972,363, 60/972,537, 60/972,336 all filed September 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.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention. This invention relates generally to systems and methods that use wireless physiological monitoring and more particularly to respiratory monitoring.

[0003] 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.

[0004] 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.

[0005] 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.

[0006] 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 treatment efficacy and patient compliance over extended periods of time, such as days, weeks, or months.

[0007] 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.

[0008] 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.

[0009] 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.

[0010] 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.

[0011] 2. Description of the Background Art. The following U.S. Patents and Publications may describe relevant background art: 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

[0012] 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.

[0013] The plurality of sensors may be configured to monitor respiration of the patient with a bioimpedance sensor, and the plurality of sensors may comprise a combination of sensors. For example, the combination of sensors may comprise at 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.

[0014] 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.

[0015] 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.

[0016] 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.

[0017] 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.

[0018] 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.

[0019] 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.

[0020] 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.

[0021] 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.

[0022] 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.

[0023] 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.

[0024] In many embodiments, the plurality of sensors may comprise at least a first sensor, a second sensor and a third sensor.

[0025] In another aspect, embodiments of the present invention provide an adherent device to monitor a sleep apnea and/or hypopnea of a patient. The device comprises an adhesive patch to adhere to a skin of the patient. At least four electrodes are connected to the patch and capable of electrically coupling to the patient. Impedance circuitry is coupled to the at least four electrodes to measure an impedance signal of the patient. A processor system comprises a tangible medium configured to determine a respiration rate and detect the apnea and/or hypopnea in response to the impedance signal. This use of the impedance signal to detect the apnea and/or hypopnea of the patient provides accurate detection of apnea and/or hypopnea and allows the device to be compact and comfortably worn when adhered to the patient.

[0026] In many embodiments, the processor system is configured to determine an apnea hypopnea index of the patient in response to the impedance signal. The impedance circuitry may be configured to measure extra cellular fluid of the patient with at least one frequency within a range from about 0.5 kHz to about 200 kHz, and the impedance circuitry can be configured to determine a respiration of the patient.

[0027] In many embodiments, the processor system is configured to control a collection and transmission of data from the impedance circuitry.

[0028] In many embodiments, an accelerometer is mechanically coupled to a second adhesive patch to generate an accelerometer signal when the second adhesive patch is adhered to the skin of the patient. The second adhesive patch can be configured to adhere to at least one of an ankle, a leg a foot, or a jaw of the patient. The processor system can be configured to detect at least one of a restless leg or a bruxation of the patient in response to the accelerometer signal. The accelerometer may be coupled to wireless communication circuitry supported with the second patch to transmit the accelerometer signal to the processor system.

[0029] In many embodiments, electromyogram circuitry can be mechanically coupled to a second adhesive patch to generate an electromyogram signal when the second adhesive patch

is adhered to the skin of the patient. The second adhesive patch can be configured to adhere to at least one of an ankle, a leg a foot, or a jaw of the patient. The processor system can be configured to detect at least one of a restless leg or a bruxation of the patient in response to the electromyogram signal. The second electromyogram circuitry can be coupled to wireless communication circuitry supported with the second patch to transmit the electromyogram signal to the processor system.

[0030] In many embodiments, an accelerometer is mechanically coupled to the adherent patch to generate an accelerometer signal when the adhesive patch is adhered to the skin of the patient, and can result in very reliable measurement of the patient as the accelerometer is mechanically coupled to the patch adhered to the patient. The processor system can be configured to determine that the patient is asleep in response to the accelerometer signal. The accelerometer may comprise at least one of a piezoelectric accelerometer, capacitive accelerometer or electromechanical accelerometer and wherein the accelerometer comprises a 3-axis accelerometer to measure at least one of an inclination, a position, an orientation or acceleration of the patient in three dimensions.

[0031] In many embodiments, electrocardiogram circuitry is coupled to at least two of the at least four electrodes to measure an electrocardiogram signal of the patient. The electrocardiogram signal may be used to detect the sleep apnea and/or hypopnea, for example in response to a heart rate variability from the electrocardiogram signal. This use of the at least two of the at least four electrodes, which are used for the impedance signal, may allow for the collection of additional patient data without increasing the footprint size of the patch adhered to the patient. The processor system can be configured to determine that the patient is asleep in response to the electrocardiogram signal and the accelerometer signal.

[0032] In many embodiments, the adhesive patch is mechanically coupled to the at least four electrodes, the impedance circuitry, the electrocardiogram circuitry, the accelerometer and at least one processor of the processor system, such that the patch is capable of supporting the at least four electrodes, the impedance circuitry, the electrocardiogram circuitry, the accelerometer and the at least one processor when the adherent patch is adhered to the skin of the patient.

[0033] In many embodiments, the adherent device comprising wireless communication circuitry coupled to the impedance circuitry to transmit the impedance signal to a remote center with a communication protocol.

[0034] In many embodiments, at least one processor of the processor system is supported with the adherent patch, and the at least one processor is configured to determine a respiration rate from the impedance signal and a heart rate from the electrocardiogram signal. This processing of the impedance signal to determine the respiration rate and processing of the electrocardiogram signal to determine heart rate can decrease data transmission requirements, for example so as to decrease bandwidth requirements of the communication system, while also allowing faster communication of relevant patient information to the remote center. The wireless communication circuitry can be configured to transmit at least one of the heart rate or the respiration rate to the remote center to determine the apnea hypopnea index.

[0035] In many embodiments, the adherent device comprises wireless communication circuitry coupled to the impedance circuitry to transmit the respiration rate to a remote center with a communication protocol. The wireless communication circuitry can be configured to transmit the respiration rate to the remote center with an intermediate device. The communication protocol may comprise at least one of Bluetooth, Zigbee, WiFi, WiMax, IR, a cellular protocol, amplitude modulation or frequency modulation. The intermediate device may comprise a data collection system to collect and/or store data from the wireless transmitter and wherein the data collection system is configured to communicate periodically with the remote center with wireless connection and/or wired communication. The communications protocol may comprise a two way protocol such that the remote center is capable of issuing commands to control data collection.

[0036] In many embodiments, the adhesive patch comprises a breathable tape, in which the breathable tape comprises a breathable material with an adhesive.

[0037] In another aspect, embodiments of the present invention provide a method of monitoring a sleep apnea of a patient. An adhesive patch is adhered to a skin of the patient to couple at least four electrodes to the skin of the patient. An impedance signal of the patient is measured with impedance circuitry coupled to the at least four electrodes. A respiration rate is determined from the impedance signal to detect an apnea and/or hypopnea of the patient.

[0038] In many embodiments, an apnea hypopnea index of the patient is determined in response to the impedance signal.

[0039] In many embodiments, an accelerometer signal is measured with an accelerometer in response to at least one of an activity, a restless leg, a bruxation or an orientation of the patient. The patient is determined to be asleep in response to the accelerometer signal.

[0040] In many embodiments, an electrocardiogram signal of the patient is measured with electrocardiogram circuitry coupled to at least two of the at least four electrodes. The adhesive patch may support the at least four electrodes, the impedance circuitry, the electrocardiogram circuitry and the accelerometer when the adherent patch is adhered to the skin of the patient.

[0041] In another aspect, embodiments of the present invention provide an adherent device to monitor an apnea and/or hypopnea of a patient for an extended period. The device comprises a breathable tape. The breathable tape comprises a porous material with an adhesive coating to adhere the breathable tape to a skin of the patient. At least one electrode is affixed to the breathable tape and capable of electrically coupling to a skin of the patient. At least one gel is disposed over a contact surface of the at least one electrode to electrically connect the electrode to the skin. A printed circuit board is supported with the breathable tape when the tape is adhered to the patient, the circuit board is connected to the at least one electrode with a flexible intermediate connector to provide strain relief between the printed circuit board and the at least one electrode. Electronic components are electrically connected to the printed circuit board and the at least one electrode to measure breathing of the patient and determine the apnea and/or hypopnea of the patient. A breathable cover is disposed over the circuit board and the electronic components, the breathable cover connected to at least one of the electronics components, the printed circuit board or the breathable tape.

[0042] In some embodiments, the breathable cover comprises a water resistant cover.

[0043] In many embodiments, the electronic components comprise a processor and wireless transmission circuitry. The processor comprises a tangible medium and may be configured to determine an apnea hypopnea index from the breathing of the patient. The wireless transmission circuitry can be configured to transmit the apnea hypopnea index from the processor to a remote center.

[0044] In many embodiments, the breathable tape, the at least one electrode, the at least one gel and the breathable cover are configured to couple the at least one electrode to the skin to measure breathing of the patient for at least one week and the extended period comprises at least one week. The breathable tape may comprise a stretchable breathable material with an adhesive, and the breathable cover may comprises a stretchable material connected to the breathable tape. Advantageously, the breathable tape and the breathable cover can stretch with the skin of the patient, for example when the patient moves. This stretching of the

materials can minimize, and in some instances avoid, the formation of creases that may decrease the useful life of the patch and/or coupling of the at least one electrode to the patient. The printed circuit board may be slidably coupled with the breathable tape and the breathable cover such that the breathable tape and breathable cover are configured to stretch with the skin of the patient when the breathable tape is adhered to the skin of the patient. In specific embodiments, the electronics components are affixed to the printed circuit board, and the electronics components and the printed circuit board are disposed between the stretchable breathable material with the adhesive and the stretchable cover. The printed circuit board can be separated from the breathable tape with an air gap to allow the skin to release moisture and receive oxygen through the breathable tape and the breathable cover.

[0045] In many embodiments, an electronics housing is adhered to at least one of the electronics components or the printed circuit board, such that the electronics housing is disposed between the cover and electronics components. The electronics housing can be configured to keep water away from the at least one of the printed circuit board or the electronic components. This can be advantageous with an extended wear device as the patient may live a more normal life and can take a shower, for example, without destroying the electronic components and/or the printed circuit board.

[0046] In many embodiments, the electronics housing comprises at least one of a cover or a sealant configured to protect the at least one of the printed circuit board or the electronic components from water. The electronics housing may comprise a water resistant coating disposed over the at least one the electronic components or the printed circuit board so as to seal the at least one of electronic components or the printed circuitry board and inhibit water penetration. The water resistant coating may comprise a dip coating disposed over the at least one of the electronics components or the printed circuit board.

[0047] In many embodiments, a gel cover is positioned over the breathable tape. The gel cover may comprise a breathable material, for example a water resistant material, to inhibit moisture penetration from outside the patch into the at least one gel.

[0048] The gel cover many comprise a breathable material to inhibit a flow of the gel through the breathable tape and wherein the printed circuit board is located over the gel cover such that the gel cover is disposed between the breathable tape and the printed circuit board. In specific embodiments, he breathable tape comprises a tricot-knit polyester fabric backing and the gel cover comprises a polyurethane, non-woven backing. The breathable tape may

comprise a first porosity and the gel cover may comprise a breathable tape with a second porosity, in which the second porosity is less than the first porosity to minimize, or even inhibit, flow of the gel through the breathable tape having the first porosity.

[0049] In many embodiments, the breathable tape, the adhesive coating, the at least one electrode and gel are separable from the printed circuit board, electronic components and cover, such that the printed circuit board, electronic components, housing and cover are reusable.

[0050] In many embodiments, the at least one electrode extends through at least one aperture in the breathable tape.

BRIEF DESCRIPTION OF THE DRAWINGS

[0051] Fig. 1A is a block diagram illustrating one embodiment of a patient monitoring system of the present invention;

[0052] Fig. 1B illustrates one embodiment of an energy management device that is coupled to the plurality of sensors of Fig. 1A;

[0053] Fig. 1C illustrates one embodiment of present invention illustrating logic resources configured to receive data from the sensors and/or the processed patient data for monitoring purposes, analysis and/or prediction purposes;

[0054] Fig. 1D illustrates an embodiment of the patient monitoring system of the present invention with a memory management device;

[0055] Fig. 1E illustrates an embodiment of the patient monitoring system of the present invention with an external device coupled to the sensors;

[0056] Fig. 1F illustrates an embodiment of the patient monitoring system of the present invention with a notification device;

[0057] Fig. 2A shows a patient and a monitoring system comprising an adherent device, according to embodiments of the present invention;

[0058] Fig. 2A1 shows an adherent device system 200S comprising a plurality of adherent devices simultaneously adhered to the patient, according to embodiments of the present invention;

[0059] Fig. 2B shows a bottom view of the adherent device as in Fig. 2A comprising an adherent patch;

[0060] Fig. 2C shows a top view of the adherent patch, as in Fig. 2B;

[0061] Fig. 2D shows a printed circuit boards and electronic components over the adherent patch, as in Fig. 2C;

[0062] Fig. 2D1 shows an equivalent circuit that can be used to determine optimal frequencies for determining patient hydration, according to embodiments of the present invention;

[0063] Fig. 2E shows batteries positioned over the printed circuit board and electronic components as in Fig. 2D;

[0064] Fig. 2F shows a top view of an electronics housing and a breathable cover over the batteries, electronic components and printed circuit board as in Fig. 2E;

[0065] Fig. 2G shows a side view of the adherent device as in Fig. 2A to 2F;

[0066] Fig. 2H shown a bottom isometric view of the adherent device as in Fig. 2A to 2G;

[0067] Fig. 2I and 2J show a side cross-sectional view and an exploded view, respectively, of the adherent device as in Fig. 2A to 2H;

[0068] Fig. 2K shows at least one electrode configured to electrically couple to a skin of the patient through a breathable tape, according to embodiments of the present invention;

[0069] Fig. 3A shows a method of detecting apnea and/or hypopnea of a patient, according to embodiments of the present invention;

[0070] Fig. 4 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;

[0071] Fig. 5 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;

[0072] Fig. 6 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;

[0073] Fig. 7 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

[0074] Fig. 8 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

[0075] 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.

[0076] Embodiments of the present invention relate to patient monitoring. Although embodiments make specific reference to monitoring impedance, accelerometer and electrocardiogram signals with an adherent device, the system methods and device described herein may be applicable to any application in which physiological monitoring is used, for example wireless physiological monitoring for extended periods.

[0077] 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 indirectly via an intermediate device. The system can continuously monitor physiologic variables and issue patient and/or physician alerts when appropriate.

[0078] 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.

[0079] 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.

[0080] 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.

[0081] An adherent device is configured to adhere to the skin of the patient with an adherent patch, for example breathable tape, coupled to at least four electrodes. The device comprises impedance circuitry coupled to the at least four electrodes and configured to measure respiration of the patient to detect sleep apnea and/or hypopnea. Apnea can be an important hare failure comorbidity. The impedance circuitry may be used to measure hydration of the patient, which can be useful evaluating the physiologic status of the patient, for example in combination with the detected sleep apnea and/or hypopnea. An accelerometer can be mechanically coupled to the adherent patch such that the accelerometer can be coupled to and move with the skin of the patient, thereby providing an accurate and reliable measurement of the orientation and/or activity of the patient, which can be helpful in determining that the patient is asleep. The accelerometer can be mechanically coupled to the adherent patch such that the accelerometer can detect motion of the jaw and/or legs. Electrocardiogram circuitry to generate an electrocardiogram signal may be coupled to at least two of the at least four electrodes, such that the sleep apnea and/or hypopnea can be detected in response to a heart rate variability from the electrocardiogram signal.

[0082] Decompensation is failure of the heart to maintain adequate blood circulation. Although the heart can maintain at least some pumping of blood, the quantity is inadequate to maintain healthy tissues. Several symptoms can result from decompensation including pulmonary congestion, breathlessness, faintness, cardiac palpitation, edema of the extremities, and enlargement of the liver. Cardiac decompensation can result in slow or sudden death. Sudden Cardiac Arrest (hereinafter "SCA"), also referred to as sudden cardiac death, is an abrupt loss of cardiac pumping function that can be caused by a ventricular arrhythmia, for example ventricular tachycardia and/or ventricular fibrillation. Although decompensation and SCA can be related in that patients with decompensation are also at an increased risk for SCA, decompensation is primarily a mechanical dysfunction caused by inadequate blood flow, and SCA is primarily an electrical dysfunction caused by inadequate and/or inappropriate electrical signals of the heart.

[0083] In many embodiments, the adherent devices described herein may be used for 90 day monitoring, or more, and may comprise completely disposable components and/or reusable components, and can provide reliable data acquisition and transfer. In many

embodiments, the patch is configured for patient comfort, such that the adherent patch can be worn and/or tolerated by the patient for extended periods, for example 90 days or more. The patch may be worn continuously for at least seven days, for example 14 days, and then replaced with another patch. Adherent devices with comfortable patches that can be worn for extended periods and in which patches can be replaced and the electronics modules reused are described in U.S. Pat. App. Nos. 60/972,537, entitled "Adherent Device with Multiple Physiological Sensors"; and 60/972,629, entitled "Adherent Device with Multiple Physiological Sensors", both filed on September 14, 2007, the full disclosures of which have been previously incorporated herein by reference. In many embodiments, the adherent patch comprises a tape, which comprises a material, preferably breathable, with an adhesive, such that trauma to the patient skin can be minimized while the patch is worn for the extended period. The printed circuit board may comprise a flex printed circuit board that can flex with the patient to provide improved patient comfort.

[0084] In one embodiment, illustrated in Fig. 1A, 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.

[0085] 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.

[0086] 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.

[0087] Referring to Figs. 1A and 1B, 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.

[0088] 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.

[0089] 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.

[0090] The system can use an intelligent combination of sensors to enhance detection and prediction capabilities, as more fully discloses in U.S. patent application, Serial No 60/972,537 identified as Attorney Docket No. 026843-000200US, previously incorporated herein by reference, and as more fully explained below.

[0091] 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.

[0092] 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.

[0093] 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.

[0094] 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.

[0095] 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.

[0096] Referring to Fig. 1C, logic resources 24, for example a processor system, 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.

[0097] In one embodiment, a memory management device 25 is provided as shown in Fig. 1D. 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.

[0098] 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, Sp02, 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.

[0099] 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.

[0100] 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.

[0101] 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.

[0102] 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.

[0103] 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.

[0104] Referring to Fig. 1E, 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.

[0105] 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.

[0106] 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 communication 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.

[0107] 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.

[0108] 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.

[0109] Referring to Fig. 1F, 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.

[0110] 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.

[0111] 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.

[0112] 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.

[0113] 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.

[0114] 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.

[0115] 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.

[0116] 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.

[0117] Fig. 2A shows a patient P and a monitoring system 10. Patient P comprises a midline M, a first side S1, for example a right side, and a second side S2, for example a left side. Monitoring system 10 comprises an adherent device 200. Adherent device 200 can be adhered to a patient P at many locations, for example thorax T of patient P. In many embodiments, the adherent device may adhere to one side of the patient, from which side data can be collected. Work in relation with embodiments of the present invention suggests that

location on a side of the patient can provide comfort for the patient while the device is adhered to the patient.

[0118] Monitoring system 10 includes components to transmit data to a remote center 206. Remote center 206 can be located in a different building from the patient, for example in the same town as the patient, and can be located as far from the patient as a separate continent from the patient, for example the patient located on a first continent and the remote center located on a second continent. Adherent device 200 can communicate wirelessly to an intermediate device 202, for example with a single wireless hop from the adherent device on the patient to the intermediate device. Intermediate device 202 can communicate with remote center 206 in many ways, for example with an internet connection and/or with a cellular connection. In many embodiments, monitoring system 10 comprises a distributed processing system with at least one processor comprising a tangible medium of device 200, at least one processor 202P of intermediate device 202, and at least one processor 206P at remote center 206, each of which processors can be in electronic communication with the other processors. At least one processor 202P comprises a tangible medium 202T, and at least one processor 206P comprises a tangible medium 206T. Remote processor 206P may comprise a backend server located at the remote center. Remote center 206 can be in communication with a health care provider 208A with a communication system 207A, such as the Internet, an intranet, phone lines, wireless and/or satellite phone. Health care provider 208A, for example a family member, can be in communication with patient P with a communication, for example with a two way communication system, as indicated by arrow 209A, for example by cell phone, email, landline. Remote center 206 can be in communication with a health care professional, for example a physician 208B, with a communication system 207B, such as the Internet, an intranet, phone lines, wireless and/or satellite phone. Physician 208B can be in communication with patient P with a communication, for example with a two way communication system, as indicated by arrow 209B, for example by cell phone, email, landline. Remote center 206 can be in communication with an emergency responder 208C, for example a 911 operator and/or paramedic, with a communication system 207C, such as the Internet, an intranet, phone lines, wireless and/or satellite phone. Emergency responder 208C can travel to the patient as indicated by arrow 209C. Thus, in many embodiments, monitoring system 10 comprises a closed loop system in which patient care can be monitored and implemented from the remote center in response to signals from the adherent device.

[0119] In many embodiments, the adherent device may continuously monitor physiological parameters, communicate wirelessly with a remote center, and provide alerts when necessary. The system may comprise an adherent patch, which attaches to the patient's thorax and contains sensing electrodes, battery, memory, logic, and wireless communication capabilities. In some embodiments, the patch can communicate with the remote center, via the intermediate device in the patient's home. In some embodiments, remote center 206 receives the patient data and applies a patient evaluation algorithm, for example an algorithm to calculate the apnea hypopnea index. When a flag is raised, the center may communicate with the patient, hospital, nurse, and/or physician to allow for therapeutic intervention.

[0120] The adherent device may be affixed and/or adhered to the body in many ways. For example, with at least one of the following: an adhesive tape, a constant-force spring, suspenders around shoulders, a screw-in microneedle electrode, a pre-shaped electronics module to shape fabric to a thorax, a pinch onto roll of skin, or transcutaneous anchoring. Patch and/or device replacement may occur with a keyed patch (e.g. two-part patch), an outline or anatomical mark, a low-adhesive guide (place guide | remove old patch | place new patch | remove guide), or a keyed attachment for chatter reduction. The patch and/or device may comprise an adhesiveless embodiment (e.g. chest strap), and/or a low-irritation adhesive for sensitive skin. The adherent patch and/or device can comprise many shapes, for example at least one of a dogbone, an hourglass, an oblong, a circular or an oval shape.

[0121] In many embodiments, the adherent device may comprise a reusable electronics module with replaceable patches, and each of the replaceable patches may include a battery. The module may collect cumulative data for approximately 90 days and/or the entire adherent component (electronics + patch) may be disposable. In a completely disposable embodiment, a "baton" mechanism may be used for data transfer and retention, for example baton transfer may include baseline information. In some embodiments, the device may have a rechargeable module, and may use dual battery and/or electronics modules, wherein one module 201A can be recharged using a charging station 203 while the other module 201B is placed on the adherent patch with connectors. In some embodiments, the intermediate device 202 may comprise the charging module, data transfer, storage and/or transmission, such that one of the electronics modules can be placed in the intermediate device for charging and/or data transfer while the other electronics module is worn by the patient.

[0122] System 10 can perform the following functions: initiation, programming, measuring, storing, analyzing, communicating, predicting, and displaying. The adherent device may contain a subset of the following physiological sensors: bioimpedance, respiration, respiration rate variability, heart rate (ave, min, max), heart rhythm, hear rate variability (HRV), heart rate turbulence (HRT), heart sounds (e.g. S3), respiratory sounds, blood pressure, activity, posture, wake/sleep, orthopnea, temperature/heat flux, and weight. The activity sensor may comprise one or more of the following: ball switch, accelerometer, minute ventilation, HR, bioimpedance noise, skin temperature/heat flux, BP, muscle noise, posture.

[0123] The adherent device can wirelessly communicate with remote center 206. The communication may occur directly (via a cellular or Wi-Fi network), or indirectly through intermediate device 202. Intermediate device 202 may consist of multiple devices, which can communicate wired or wirelessly to relay data to remote center 206.

[0124] In many embodiments, instructions are transmitted from remote site 206 to a processor supported with the adherent patch on the patient, and the processor supported with the patient can receive updated instructions for the patient treatment and/or monitoring, for example while worn by the patient.

[0125] Fig. 2A1 shows an adherent device system 200S comprising a plurality of adherent devices simultaneously adhered to the patient, for example adherent device 200, second adherent device 200J and third adherent device 200A. Adherent device system 200S may comprise wireless communication between and/or among devices adhered to the patient. Adherent device system 200S may comprise a component of system 10 described above. Second adherent device 200J can be disposed on the jaw of the patient to detect jaw movement and/or orientation, for example bruxation. Second adherent device 200J may comprise an accelerometer and/or electromyogram (EMG) circuitry comprising electrodes to detect patient jaw movement such as bruxation to determine the patient sleep status. Third adherent device 200A can be disposed on the patient to detect leg movement and/or orientation, for example on the leg, ankle and/or foot of the patient to detect restless leg syndrome. Third adherent device 200A may comprise an accelerometer and/or electromyogram (EMG) circuitry comprising electrodes to detect patient leg movement to determine the patient sleep status. Adherent device 200 may comprise an accelerometer

and/or electromyogram circuitry comprising electrodes to detect patient motion, for example motion and/or orientation of the thorax.

[0126] Fig. 2B shows a bottom view of adherent device 200 as in Fig. 2A comprising an adherent patch 210. 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. 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.

[0127] Fig. 2C shows a top view of the adherent patch 200, as in Fig. 2B. Adherent patch 200 comprises a second side, or upper side 210B. In many embodiments, electrodes 212A, 212B, 212C and 212D extend from lower side 210A through adherent patch 210 to upper side 210B. An adhesive 216B can be applied to upper side 210B to adhere structures, for example a breathable cover, to the patch such that the patch can support the electronics and other structures when the patch is adhered to the patient. The PCB may comprise completely flex PCB, rigid PCB, rigid PCB combined flex PCB and/or rigid PCB boards connected by cable.

[0128] Fig. 2D shows a printed circuit boards and electronic components over adherent patch 210, as in Fig. 2A to 2C. In some embodiments, a printed circuit board (PCB), for example flex printed circuit board 220, may be connected to electrodes 212A, 212B, 212C and 212D with connectors 222A, 222B, 222C and 222D. Flex printed circuit board 220 can include traces 223A, 223B, 223C and 223D that extend to connectors 222A, 222B, 222C and 222D, respectively, on the flex PCB. Connectors 222A, 222B, 222C and 222D can be positioned on flex printed circuit board 220 in alignment with electrodes 212A, 212B, 212C and 212D so as to electrically couple the flex PCB with the electrodes. In some

embodiments, connectors 222A, 222B, 222C and 222D may comprise insulated wires and/or a film with conductive ink that provide strain relief between the PCB and the electrodes. For example, connectors 222A, 222B, 222C and 222D may comprise a flexible polyester film coated with conductive silver ink. In some embodiments, additional PCB's, for example rigid PCB's 220A, 220B, 220C and 220D, can be connected to flex printed circuit board 220. Electronic components 230 can be connected to flex printed circuit board 220 and/or mounted thereon. In some embodiments, electronic components 230 can be mounted on the additional PCB's.

[0129] Electronic components 230 comprise components to take physiologic measurements, transmit data to remote center 206 and receive commands from remote center 206. 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 234, impedance circuitry 236 and electrocardiogram circuitry, for example ECG circuitry 236. In some embodiments, electronics circuitry 230 may comprise a microphone and microphone circuitry 242 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.

[0130] Electronics circuitry 230 may comprise a temperature sensor, for example a thermistor in contact with the skin of the patient, and temperature sensor circuitry 244 to measure a temperature of the patient, for example a temperature of the skin of the patient. A temperature sensor may be used to determine the sleep and wake state of the patient. The temperature of the patient can decrease as the patient goes to sleep and increase when the patient wakes up.

[0131] Work in relation to embodiments of the present invention suggests that skin temperature may effect impedance and/or hydration measurements, and that skin temperature measurements may be used to correct impedance and/or hydration measurements. In some embodiments, increase in skin temperature or heat flux can be associated with increased vaso-dilation near the skin surface, such that measured impedance measurement decreased, even through the hydration of the patient in deeper tissues under the skin remains substantially unchanged. Thus, use of the temperature sensor can allow for correction of the

hydration signals to more accurately assess the hydration, for example extra cellular hydration, of deeper tissues of the patient, for example deeper tissues in the thorax.

[0132] Electronics circuitry 230 may comprise a processor 246. Processor 246 comprises a tangible medium, for example read only memory (ROM), electrically erasable programmable read only memory (EEPROM) and/or random access memory (RAM). Processor 246 may comprise many known processors with real time clock and frequency generator circuitry, for example the PIC series of processors available from Microchip, of Chandler AZ.. In some embodiments, processor 236 may comprise the frequency generator and real time clock. The processor can be configured to control a collection and transmission of data from the impedance circuitry electrocardiogram circuitry and the accelerometer. In many embodiments, device 200 comprise a distributed processor system, for example with multiple processors on device 200.

[0133] Electronics circuitry 230 may comprise electromyogram (hereinafter "EMG") circuitry 248 to measure muscle activity. EMG circuitry 248 can measure signals from muscles and may be connected to and/or comprise at least two of electrode 212A, electrode 212B, electrode 212C or electrode 212D. EMG circuitry 248 comprises an amplifier to amplify signals from contracting muscles so as to generate an EMG signal. EMG circuitry 248 can be connected to processor to send the EMG signal to the processor for storage and/or analysis.

[0134] In many embodiments, electronics components 230 comprise wireless communications circuitry 232 to communicate with remote center 206. The wireless communication circuitry can be coupled to the impedance circuitry, the electrocardiogram circuitry and the accelerometer to transmit to a remote center with a communication protocol at least one of the hydration signal, the electrocardiogram signal or the inclination signal. In specific embodiments, wireless communication circuitry is configured to transmit the hydration signal, the electrocardiogram signal and the inclination signal to the remote center with a single wireless hop, for example from wireless communication circuitry 232 to intermediate device 202. The communication protocol comprises at least one of Bluetooth, Zigbee, WiFi, WiMax, IR, amplitude modulation or frequency modulation. In many embodiments, the communications protocol comprises a two way protocol such that the remote center is capable of issuing commands to control data collection.

[0135] Intermediate device 202 may comprise a data collection system to collect and store data from the wireless transmitter. The data collection system can be configured to communicate periodically with the remote center. The data collection system can transmit data in response to commands from remote center 206 and/or in response to commands from the adherent device.

[0136] Activity sensor and activity circuitry 234 can comprise many known activity sensors and circuitry. In many embodiments, the accelerometer comprises at least one of a piezoelectric accelerometer, capacitive accelerometer or electromechanical accelerometer. The accelerometer may comprises a 3-axis accelerometer to measure at least one of an inclination, a position, an orientation or acceleration of the patient in three dimensions. Work in relation to embodiments of the present invention suggests that three dimensional orientation of the patient and associated positions, for example sitting, standing, lying down, can be very useful when combined with data from other sensors, for example ECG data and/or bioimpedance data, for example a respiration rate of the patient.

[0137] Impedance circuitry 236 can generate both hydration data and respiration data. In many embodiments, impedance circuitry 236 is electrically connected to electrodes 212A, 212B, 212C and 212D in a four pole configuration, such that electrodes 212A and 212D comprise outer electrodes that are driven with a current and comprise force electrodes that force the current through the tissue. The current delivered between electrodes 212A and 212D generates a measurable voltage between electrodes 212B and 212C, such that electrodes 212B and 212C comprise inner, sense, electrodes that sense and/or measure the voltage in response to the current from the force electrodes. In some embodiments, electrodes 212B and 212C may comprise force electrodes and electrodes 212A and 212B may comprise sense electrodes. The voltage measured by the sense electrodes can be used to measure the impedance of the patient and determine the respiration rate and/or hydration of the patient.

[0138] Fig. 2D1 shows an equivalent circuit 252 that can be used to determine optimal frequencies for measuring patient hydration. Work in relation to embodiments of the present invention indicates that the frequency of the current and/or voltage at the force electrodes can be selected so as to provide impedance signals related to the extracellular and/or intracellular hydration of the patient tissue. Equivalent circuit 252 comprises an intracellular resistance 256, or R(ICW) in series with a capacitor 254, and an extracellular resistance 258, or

R(ECW). Extracellular resistance 258 is in parallel with intracellular resistance 256 and capacitor 254 related to capacitance of cell membranes. In many embodiments, impedances can be measured and provide useful information over a wide range of frequencies, for example from about 0.5 kHz to about 200 KHz. Work in relation to embodiments of the present invention suggests that extracellular resistance 258 can be significantly related extracellular fluid and to cardiac decompensation, and that extracellular resistance 258 and extracellular fluid can be effectively measured with frequencies in a range from about 0.5 kHz to about 20 kHz, for example from about 1 kHz to about 10 kHz. In some embodiments, a single frequency can be used to determine the extracellular resistance and/or fluid. As sample frequencies increase from about 10 kHz to about 20 kHz, capacitance related to cell membranes decrease the impedance, such that the intracellular fluid contributes to the impedance and/or hydration measurements. Thus, many embodiments of the present invention measure hydration with frequencies from about 0.5 kHz to about 20 kHz to determine patient hydration.

[0139] In many embodiments, impedance circuitry 236 can be configured to determine respiration of the patient. In specific embodiments, the impedance circuitry can measure the hydration at 25 Hz intervals, for example at 25 Hz intervals using impedance measurements with a frequency from about 0.5 kHz to about 20 kHz.

[0140] ECG circuitry 238 can generate electrocardiogram signals and data from two or more of electrodes 212A, 212B, 212C and 212D in many ways. In some embodiments, ECG circuitry 238 is connected to inner electrodes 212B and 222C, which may comprise sense electrodes of the impedance circuitry as described above. In some embodiments, ECG circuitry 238 can be connected to electrodes 212A and 212D so as to increase spacing of the electrodes. The inner electrodes may be positioned near the outer electrodes to increase the voltage of the ECG signal measured by ECG circuitry 238. In many embodiments, the ECG circuitry may measure the ECG signal from electrodes 212A and 212D when current is not passed through electrodes 212A and 212D, for example with switches as described in U.S. App. No. 60/972,527, the full disclosure of which has been previously incorporated herein by reference.

[0141] Fig. 2E shows batteries 250 positioned over the flex printed circuit board and electronic components as in Fig. 2D. Batteries 250 may comprise rechargeable batteries that

can be removed and/or recharged. In some embodiments, batteries 250 can be removed from the adherent patch and recharged and/or replaced.

[0142] Fig. 2F shows a top view of a cover 262 over the batteries, electronic components and flex printed circuit board as in Fig. 2A to 2E. 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 adherent patch 210 with an adhesive 264 on an underside of cover 262. 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.

[0143] 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.

[0144] Fig. 2G shows a side view of adherent device 200 as in Fig. 2A to 2F. Adherent device 200 comprises a maximum dimension, for example a length 270 from about 2 to 10 inches (from about 50 mm to about 250 mm), for example from about 4 to 6 inches (from about 100 mm to about 150 mm). In some embodiments, length 270 may be no more than about 6 inches (no more than about 150 mm). Adherent device 200 comprises a thickness 272. Thickness 272 may comprise a maximum thickness along a profile of the device. Thickness 272 can be from about 0.1 inches to about 0.4 inches (from about 5 mm to about 10 mm), for example about 0.3 inches (about 7.5 mm) .

[0145] Fig. 2H shown a bottom isometric view of adherent device 200 as in Fig. 2A to 2G. Adherent device 200 comprises a width 274, for example a maximum width along a width profile of adherent device 200. Width 274 can be from about 1 to about 4 inches (from about 25 mm to 100 mm), for example about 2 inches (about 50 mm).

[0146] Fig. 2I and 2J show a side cross-sectional view and an exploded view, respectively, of adherent device 100 as in Fig. 2A to 2H. 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. Adherent patch 210 may comprise a layer of breathable tape 210T, for example a known breathable tape, such as tricot-knit polyester fabric. An adhesive 216A, for example a layer of acrylate pressure sensitive adhesive, can be disposed on underside 210A of adherent patch 210.

[0147] 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 printed circuit board 220, or flex PCB layer, can be positioned over gel cover 280 with electronic components 230 connected and/or mounted to flex printed circuit board 220, for example mounted on flex PCB so as to comprise an electronics layer disposed on the flex PCB layer. In many embodiments, the adherent device may comprise a segmented inner component, for example the PCB may be segmented to provide at least some flexibility. In many embodiments, the electronics layer may be encapsulated in electronics housing 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 trace 223A of flex printed circuit board 220, so as to provide strain relive between the electrodes 212A, 212B, 212C and 212D and the PCB.

[0148] 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, for example liquid water, from penetrating though the gel cover into gel 214A while allowing moisture vapor from the gel, for example moisture vapor from the skin, to transmit through the gel cover.

[0149] 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 adherent patch 210, so as to protect at least the electronics components and the PCB. Cover 262 can attach to adherent patch 210 with adhesive 216B. Cover 262 can comprise many known biocompatible cover materials, for example silicone. Cover 262 can comprise an outer polymer cover to provide smooth contour without limiting flexibility. In many 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 cover may comprise a breathable water resistant cover. In some embodiments, the breathable fabric may comprise polyester, nylon, polyamide, and/or elastane (Spandex) to allow the breathable

fabric to stretch with body movement. In some embodiments, the breathable tape may contain and elute a pharmaceutical agent, such as an antibiotic, anti-inflammatory or antifungal agent, when the adherent device is placed on the patient.

[0150] The breathable cover 262 and adherent patch 210 comprise breathable tape can be configured to couple continuously for at least one week the at least one electrode to the skin so as to measure breathing of the patient. The breathable tape may comprise the stretchable breathable material with the adhesive and the breathable cover may comprises a stretchable water resistant material connected to the breathable tape, as described above, such that both the adherent patch and cover can stretch with the skin of the patient. Arrows 282 show stretching of adherent patch 210, and the stretching of adherent patch can be at least two dimensional along the surface of the skin of the patient. As noted above, connectors 222A, 222B, 222C and 222D between PCB 230 and electrodes 212A, 212B, 212C and 212D may comprise insulated wires that provide strain relief between the PCB and the electrodes, such that the electrodes can move with the adherent patch as the adherent patch comprising breathable tape stretches. Arrows 284 show stretching of cover 262, and the stretching of the cover can be at least two dimensional along the surface of the skin of the patient. Cover 262 can be attached to adherent patch 210 with adhesive 216B such that cover 262 stretches and/or retracts when adherent patch 210 stretches and/or retracts with the skin of the patient. For example, cover 262 and adherent patch 210 can stretch in two dimensions along length 270 and width 274 with the skin of the patient, and stretching along length 270 can increase spacing between electrodes. Stretching of the cover and adherent patch 210, for example in two dimensions, can extend the time the patch is adhered to the skin as the patch can move with the skin such that the patch remains adhered to the skin Electronics housing 260 can be smooth and allow breathable cover 262 to slide over electronics housing 260, such that motion and/or stretching of cover 262 is slidably coupled with housing 260. The printed circuit board can be slidably coupled with adherent patch 210 that comprises breathable tape 210T, such that the breathable tape can stretch with the skin of the patient when the breathable tape is adhered to the skin of the patient, for example along two dimensions comprising length 270 and width 274. Electronics components 230 can be affixed to printed circuit board 220, for example with solder, and the electronics housing can be affixed over the PCB and electronics components, for example with dip coating, such that electronics components 230, printed circuit board 220 and electronics housing 260 are coupled together. Electronics components 230, printed circuit board 220, and electronics housing 260 are

disposed between the stretchable breathable material of adherent patch 210 and the stretchable water resistant material of cover 260 so as to allow the adherent patch 210 and cover 260 to stretch together while electronics components 230, printed circuit board 220, and electronics housing 260 do not stretch substantially, if at all. This decoupling of electronics housing 260, printed circuit board 220 and electronic components 230 can allow the adherent patch 210 comprising breathable tape to move with the skin of the patient, such that the adherent patch can remain adhered to the skin for an extended time of at least one week, for example two or more weeks.

[0151] An air gap 269 may extend from adherent patch 210 to the electronics module and/or PCB, so as to provide patient comfort. Air gap 269 allows adherent patch 210 and breathable tape 210T to remain supple and move, for example bend, with the skin of the patient with minimal flexing and/or bending of printed circuit board 220 and electronic components 230, as indicated by arrows 286. Printed circuit board 220 and electronics components 230 that are separated from the breathable tape 210T with air gap 269 can allow the skin to release moisture as water vapor through the breathable tape, gel cover, and breathable cover. This release of moisture from the skin through the air gap can minimize, and even avoid, excess moisture, for example when the patient sweats and/or showers.

[0152] The breathable tape of adherent patch 210 may comprise a first mesh with a first porosity and gel cover 280 may comprise a breathable tape with a second porosity, in which the second porosity is less than the first porosity to minimize, and even inhibit, flow of the gel through the breathable tape. The gel cover may comprise a polyurethane film with the second porosity.

[0153] In many embodiments, the adherent device comprises a patch component and at least one electronics module. The patch component may comprise adherent patch 210 comprising the breathable tape with adhesive coating 216A, at least one electrode, for example electrode 214A and gel 214. The at least one electronics module can be separable from the patch component. In many embodiments, the at least one electronics module comprises the flex printed circuit board 220, electronic components 230, electronics housing 260 and cover 262, such that the flex printed circuit board, electronic components, electronics housing and cover are reusable and/or removable for recharging and data transfer, for example as described above. In many embodiments, adhesive 216B is coated on upper side 210A of adherent patch 210B, such that the electronics module can be adhered to and/or

separated from the adhesive component. In specific embodiments, the electronic module can be adhered to the patch component with a releasable connection, for example with Velcro™, a known hook and loop connection, and/or snap directly to the electrodes. Two electronics modules can be provided, such that one electronics module can be worn by the patient while the other is charged, as described above. Monitoring with multiple adherent patches for an extended period is described in U.S. Pat. App. No. 60/972,537, the full disclosure of which has been previously incorporated herein by reference. Many patch components can be provided for monitoring over the extended period. For example, about 12 patches can be used to monitor the patient for at least 90 days with at least one electronics module, for example with two reusable electronics modules.

[0154] At least one electrode 212A can extend through at least one aperture 280A in the breathable tape 210 and gel cover 280.

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

[0156] Fig. 2K shows at least one electrode 290 configured to electrically couple to a skin of the patient through a breathable tape 292. In many embodiments, at least one electrode 290 and breathable tape 292 comprise electrodes and materials similar to those described above. Electrode 290 and breathable tape 292 can be incorporated into adherent devices as described above, so as to provide electrical coupling between the skin and electrode through the breathable tape, for example with the gel.

[0157] Second adherent device 200J and third adherent device 200A may comprise components similar to adherent device 200, described above. The processor of adherent device 200, described above may comprise a system controller to control communication and/or actions of first adherent device 200J and second device 200A, for example data collection and transmission. In many embodiments, data collected from second adherent device 200J and third adherent device 200A is sent wirelessly to device 200, which device 200 transmits the data to the intermediate device. In some embodiments, adherent device 200, second adherent device 200J and third adherent device 200A can each communicate data

wirelessly with the intermediate device and may each receive instructions from the intermediate device.

[0158] Fig. 3A shows a method 300 of monitoring a sleep apnea and/or hypopnea in a patient. Method 300 can be performed with the processor system, as described above. A step 305 measures an impedance signal of the patient. The impedance signal can be measured with a four pole impedance system as described above. A step 310 determines the respiration rate of the patient, for example from the impedance signal. Step 310 can be performed with at least one processor supported with the adhesive patch as descried above, so as to decrease data storage requirements of the electronic components supported with the adhesive patch. A step 315 measures extracellular fluid of the patient. The extracellular fluid can be used to monitor the hydration status of the patient and detect edema. A step 320 measures an accelerometer signal. The accelerometer signal can be generated with many accelerometers as described above, for example a three axis accelerometer. The accelerometer may correspond to patient activity, for example patient activity and orientation may be determined from the accelerometer signal. A step 325 determines orientation and/or activity of the patient, for example in response to the accelerometer signal. A step 330 measures an electrocardiogram signal of the patient. A step 335 determines a heart rate of the patient in response to the electrocardiogram signal. The heart rate of the patient can be determined with at least one processor supported with the adhesive patch, so as to decrease data storage requirements of the electronic components supported with the adhesive patch. A step 340 determines that the patient is asleep, for example in response to the respiration rate from the impedance signal, the activity and orientation of the patient from the accelerometer signal, and the heart rate from electrocardiogram signal. For example, a combination of low heart rate, low respiration rate, low activity amount and/or horizontal position can be used to determine the patient sleep state of the patient, for example that the patient is asleep A step 345 determines the apnea hypopnea index. In some embodiments, the apnea hypopnea index is determined at the remote center and/or the intermediate device in response to the heart rate and respiration rate determined with at least one processor supported with the adhesive patch. Known methods of calculating the apnea hypopnea index can be used, and at least some of the following U.S. patent publications and patents describe calculation of the apnea hypopnea index (AHI): 2007/0129643 (Kwok et al.); 2007/0123756 (Kitajima et al.); 2006/0173257 (Nagai et al.); and 6,641,542 (Cho et al.).. A step 350 transmits patient information to the remote center, for example the patient apnea hypopnea index. A step 355 transmits data

collection commands from the remote center to a processor supported with the adhesive patch. A step 360 provides the apnea hypopnea index to a decompensation prediction algorithm, for example as described in U.S. App. Nos. 60/972,512, entitled " Multi-Sensor Patient Monitor to Detect Impending Cardiac Decompensation"; and 61/035,970, entitled " Heart Failure Decompensation Prediction Based on Cardiac Rhythm", filed on March 12, 2008; the full disclosures of which are incorporated by reference. A step 365 can alter a health care provider in response to one or more of the measured signals, for example the heart rate signal and/or the respiration rate signal, and provide the apnea hypopnea index to the treating physician and/or health care provider as a report.

[0159] The processor system, as described above, can be configured to perform the method 300, including many of the steps described above. It should be appreciated that the specific steps illustrated in Fig. 3A provide a particular method of monitoring a patient for sleep disordered breathing, according to an embodiment of the present invention. Other sequences of steps may also be performed according to alternative embodiments. For example, alternative embodiments of the present invention may perform the steps outlined above in a different order. Moreover, the individual steps illustrated in Fig. 3A may include multiple sub-steps that may be performed in various sequences as appropriate to the individual step. Furthermore, additional steps may be added or removed depending on the particular applications. One of ordinary skill in the art would recognize many variations, modifications, and alternatives.

EXAMPLE 1

Sleep Apnea

[0160] 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.

[0161] 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.

[0162] 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.

[0163] 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.

[0164] 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.

[0165] 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.

[0166] 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.

[0167] 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.

[0168] 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

[0169] 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.

[0170] Generally, there are four types of Polysomnographic Studies. They are:

[0171] Diagnostic Overnight PSG - General monitoring and evaluation.

[0172] 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.

[0173] 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.

[0174] 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.

[0175] 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.

[0176] 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.

[0177] 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.

[0178] 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.

[0179] 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.

[0180] 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.

[0181] 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.

[0182] 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.

[0183] 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.

[0184] 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.

[0185] 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

[0186] 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.

[0187] 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.

[0188] 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

[0189] 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.

[0190] 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.

[0191] 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.

[0192] Referring now to Fig. 4, 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.

[0193] 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.

[0194] As can be seen in Fig. 5, a control unit 126 is included at the detecting system 12, the remote monitoring system 18 or at both locations.

[0195] In one embodiment, the control unit 126 can be a 486 microprocessor, available from Intel, Inc. of Santa Clara, CA. 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.

[0196] 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. 6. 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.

[0197] 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.

[0198] Referring now to Fig. 7, 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.

[0199] 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 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.

[0200] 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.

[0201] 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.

[0202] 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.

[0203] 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.

[0204] 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.

[0205] 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.

[0206] 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.

[0207] 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.

[0208] 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.

[0209] Referring now to the flow chart of Fig. 8, 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.

[0210] 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.

[0211] 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.

[0212] 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.

[0213] 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.

[0214] 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.

[0215] 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.

[0216] 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.

[0217] 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:

[0218] 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.

[0219] 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.

[0220] 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.

[0221] 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.

[0222] 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.

[0223] 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.

[0224] While the exemplary embodiments have been described in some detail, by way of example and for clarity of understanding, those of skill in the art will recognize that a variety of modifications, adaptations, and changes may be employed. Hence, the scope of the present invention should be limited solely by the appended claims.

WHAT IS CLAIMED IS:

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

a patient detecting system comprising,

an adherent device configured to couple to a patient, the adherent device comprising a plurality of sensors configured to monitor physiological parameters of the patient to determine respiratory status, at least one of the plurality of sensors configured to monitor the patient's respiration, and

a wireless communication device coupled to the plurality of sensors; 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.

2. The system of claim 1, wherein the plurality of sensors are configured to monitor respiration of the patient with a bioimpedance sensor.

3. The system of claim 1, wherein the plurality of sensors comprises a combination of sensors and the combination of sensors comprises as least one of a bioimpedance sensor, a heart rate sensor or a pulse oximeter sensor.

4. The system of claim 1, wherein the wireless communication device is configured to receive instructional data from the remote monitoring system.

5. The system of claim 1, 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, the patient detecting system comprises a monitoring unit.

8. The system of claim 1, wherein the remote monitoring system comprises logic resources located at the remote monitoring system, the logic resources

configured to determine a physiological event of the patient and determine the respiratory status of the patient.

9. The system of claim 7, wherein the monitoring unit comprises logic resources configured to determine the respiratory status of the patient and to determine a physiological event of a patient, the physiological event comprising apnea.

10. The system of claim 1, wherein the plurality of sensors are configured to monitor respiration of the patient with at least one of heart rate or pulse oximetry monitoring.

11. The system of claim 1, wherein the plurality of sensors are configured to monitor respiration of the patient with a bioimpedance sensor and at least one of heart rate monitoring or pulse oximetry monitoring.

12. The system of claim 1, wherein the adherent device is configured to monitor the patient's respiration continuously.

13. The system of claim 1, 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.

14. The system of claim 1, wherein the plurality of sensors comprises a posture sensor for orthopnea monitoring.

15. The system of claim 14, wherein the posture sensor comprises at least one of a piezoelectric accelerometer, capacitive accelerometer or electromechanical accelerometer.

16. The system of claim 14, wherein the posture sensor comprises a 3-axis accelerometer.

17. The system of claim 1, wherein the patient detecting system and the remote monitoring system are configured to monitor the patient for a patient sleep study.

18. The system of claim 17, wherein the plurality of sensors comprises a patient movement sensor.

19. The system of claim 18, wherein the patient movement sensor comprises at least one of a piezoelectric accelerometer, a capacitive accelerometer or an electromechanical accelerometer.

20. The system of claim 18, 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.

21. The system of claim 1, further comprising a processor configured to determine the respiratory status in response to a weighted combination of change in sensor outputs.

22. The system of claim 1, further comprising 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.

23. The system of claim 22 wherein the abrupt change comprises no more than about 10 seconds and the longer period of time comprises at least about one hour.

24. The system of claim 1, further comprising 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, with the first sensor output indicating a problem that is then verified by at least a second sensor output.

25. The system of claim 1, further comprising a processor configured to determine a physiological event of the patient in response to a variance from baseline values of sensor outputs.

26. The system of claim 25, wherein the baseline values are defined by a look up table.

27. The system of claim 1, wherein the plurality of sensors comprises at least a first sensor, a second sensor and a third sensor.

28. An adherent device to monitor a sleep apnea and/or hypopnea of a patient, the device comprising:

an adhesive patch to adhere to a skin of the patient;

at least four electrodes connected to the patch and capable of electrically coupling to the patient;

impedance circuitry coupled to the at least four electrodes to measure an impedance signal of the patient; and

a processor system comprising a tangible medium configured to determine a respiration rate and detect the apnea and/or hypopnea in response to the impedance signal.

29. The adherent device of claim 28, wherein the processor system is configured to determine an apnea hypopnea index of the patient in response to the impedance signal.

30. The adherent device of claim 28 wherein the impedance circuitry is configured to measure extra cellular fluid of the patient with at least one frequency within a range from about 0.5 kHz to about 200 kHz. and wherein the impedance circuitry is configured to determine a respiration of the patient.

31. The adherent device of claim 28 comprising wherein the processor system is configured to control a collection and transmission of data from the impedance circuitry.

32. The adherent device of claim 28, further comprising at least one of electromyogram circuitry or an accelerometer mechanically coupled to a second adhesive patch to generate at least one of an electromyogram signal or an accelerometer signal when the second adhesive patch is adhered to the skin of the patient.

33. The adherent device of claim 32 and wherein the second adhesive patch is configured to adhere to at least one of an ankle, a leg a foot, or a jaw of the patient and wherein the processor system is configured to detect at least one of a restless leg or a bruxation of the patient in response to the accelerometer signal.

34. The adherent device of claim 31 wherein the accelerometer is coupled to wireless communication circuitry supported with the second patch to transmit the accelerometer signal to the processor system.

35. The adherent device of claim 28, further comprising at least one of electromyogram circuitry or an accelerometer mechanically coupled to at least one of an adhesive patch or a strap to generate at least one of an electromyogram signal or an accelerometer signal when the at least one of the adhesive patch or the strap is position on the patient.

36. The adherent device of claim 35, wherein the at least one of the electromyogram circuitry of the accelerometer is coupled to wireless communication circuitry supported with the second patch to transmit the accelerometer signal to the processor system.

37. The adherent device of claim 28, further comprising an accelerometer mechanically coupled to the adherent patch to generate an accelerometer signal in response to at least one of an activity or a position of the patient when the adhesive patch is adhered to the skin of the patient and wherein the processor system is configured to determine that the patient is asleep in response to the accelerometer signal.

38. The adherent device of claim 37 wherein the accelerometer comprises at least one of a piezoelectric accelerometer, capacitive accelerometer or electromechanical accelerometer and wherein the accelerometer comprises a 3-axis accelerometer to measure at least one of an inclination, a position, an orientation or acceleration of the patient in three dimensions.

39. The adherent device of claim 37, further comprising:

electrocardiogram circuitry coupled to at least two of the at least four electrodes to measure an electrocardiogram signal of the patient.

40. The adherent device of claim 39 wherein the processor system is configured to determine that the patient is asleep in response to the accelerometer signal and the electrocardiogram signal.

41. The adherent device of claim 39 wherein the processor system is configured to detect the sleep apnea and/or hypopnea in response to a heart rate variability from the electrocardiogram signal.

42. The adherent device of claim 39 wherein the adhesive patch is mechanically coupled to the at least four electrodes, the impedance circuitry, the electrocardiogram circuitry, the accelerometer and at least one processor of the processor system, such that the patch is capable of supporting the at least four electrodes, the impedance circuitry, the electrocardiogram circuitry the accelerometer and the at least one processor when the adherent patch is adhered to the skin of the patient.

43. The adherent device of claim 28 further comprising wireless communication circuitry coupled to the impedance circuitry to transmit the impedance signal to a remote center with a communication protocol.

44. The adherent device of claim 39 wherein at least one processor of the processor system is supported with the adherent patch and wherein the at least one processor is configured to determine a respiration rate from the impedance signal and a heart rate from the electrocardiogram signal.

45. The adherent device of claim 44 wherein the wireless communication circuitry is configured to transmit at least one of the heart rate or the respiration rate to the remote center to determine the apnea hypopnea index.

46. The adherent device of claim 28 further comprising wireless communication circuitry coupled to the impedance circuitry to transmit the respiration rate to a remote center with a communication protocol.

47. The adherent device of claim 46 wherein wireless communication circuitry is configured to transmit the respiration rate to the remote center with an intermediate device.

48. The adherent device of claim 47 wherein the communication protocol comprises at least one of Bluetooth, Zigbee, WiFi, WiMax, IR, a cellular protocol, amplitude modulation or frequency modulation.

49. The adherent device of claim 47 wherein the intermediate device comprises a data collection system to collect and/or store data from the wireless transmitter and wherein the data collection system is configured to communicate periodically with the remote center with wireless connection and/or wired communication.

50. The adherent device of claim 47 wherein the communications protocol comprises a two way protocol such that the remote center is capable of issuing commands to control data collection.

51. The adherent device of claim 28 wherein the adhesive patch comprises a breathable tape, in which the breathable tape comprises a breathable material with an adhesive.

52. The adherent device of claim 28 further comprising a temperature sensor to generate a temperature signal, the temperature sensor coupled to the processor system to determine when the patient is asleep.

53. A method of monitoring a sleep apnea of a patient, the method comprising:

adhering an adhesive patch to a skin of the patient to couple at least four electrodes to the skin of the patient;

measuring an impedance signal of the patient with impedance circuitry coupled to the at least four electrodes; and

determining a respiration rate from the impedance signal to detect an apnea and/or hypopnea of the patient in response to the impedance signal.

54. The method of claim 53, further comprising determining an apnea hypopnea index of the patient in response to the impedance signal.

55. The method of claim 53, further comprising:

generating an accelerometer signal with an accelerometer; and

determining that the patient is asleep in response to the accelerometer signal.

56. The method of claim 53, further comprising:

measuring an electrocardiogram signal of the patient with electrocardiogram circuitry coupled to at least two of the at least four electrodes; and

measuring a signal from an accelerometer in response to at least one of an activity, a restless leg, a bruxation or a position of the patient.

57. The method of claim 56 wherein the adhesive patch supports the at least four electrodes, the impedance circuitry, the electrocardiogram circuitry and the accelerometer when the adherent patch is adhered to the skin of the patient.

58. An adherent device to monitor an apnea and/or hypopnea of a patient for an extended period, the device comprising:

a breathable tape comprising a porous material with an adhesive coating to adhere the breathable tape to a skin of the patient;

at least one electrode affixed to the breathable tape and capable of electrically coupling to a skin of the patient;

at least one gel disposed over a contact surface of the at least one electrode to electrically connect the electrode to the skin;

a printed circuit board supported with the breathable tape when the tape is adhered to the patient, the circuit board connected to the at one electrode with a flexible intermediate connector to provide strain relief between the printed circuit board and the at least one electrode;

electronic components electrically connected to the printed circuit board and the at least one electrode to measure breathing of the patient and determine the apnea and/or hypopnea of the patient; and

a breathable cover disposed over the circuit board and the electronic components, the breathable cover connected to at least one of the electronics components, the printed circuit board or the breathable tape.

59. The adherent device of claim 58 wherein the breathable cover comprises a water resistant cover.

60. The adherent device of claim 58 wherein the electronic components comprise a processor and wireless transmission circuitry, the processor comprising a tangible medium configured to determine an apnea hypopnea index from the breathing of the patient and wherein the wireless transmission circuitry is configured to transmit the apnea hypopnea index from the processor to a remote center.

61. The adherent device of claim 58 wherein the breathable tape, the at least one electrode, the at least one gel and the breathable cover are configured to couple the at least one electrode to the skin to measure breathing of the patient for at least one week and the extended period comprises at least one week.

62. The adherent device of claim 61 wherein the breathable tape comprises a stretchable breathable material with an adhesive and the breathable cover comprises a stretchable material connected to the breathable tape, and wherein the printed circuit board is slidably coupled with the breathable tape and the breathable cover such that the breathable tape and breathable cover are configured to stretch with the skin of the patient when the breathable tape is adhered to the skin of the patient.

63. The adherent device of claim 62 wherein the electronics components are affixed to the printed circuit board and wherein the electronics components and the printed circuit board are disposed between the stretchable breathable material with the adhesive and the stretchable material.

64. The adherent device of claim 63 wherein the printed circuit board is separated from the breathable tape with an air gap to allow the skin to release moisture and receive oxygen through the breathable tape and breathable cover.

65. The adherent device of claim 58 further comprising an electronics housing adhered to at least one of the electronics components or the printed circuit board, such that the electronics housing is disposed between the cover and electronics components.

66. The adherent device of claim 65 wherein the electronics housing is configured to keep water away from the at least one of the printed circuit board or the electronic components.

67. The adherent device of claim 65 wherein the electronics housing comprises at least one of a cover or a sealant configured to protect the at least one of the printed circuit board or the electronic components from water.

68. The adherent device of claim 65 the electronics housing comprises a water resistant coating disposed over the at least one the electronic components or the printed

circuit board so as to seal the at least one of electronic components or the printed circuitry board and inhibit water penetration.

69. The adherent device of claim 59 wherein the water resistant coating comprises a dip coating disposed over the at least one of the electronics components or the printed circuit board.

70. The adherent device of claim 58 further comprising a gel cover positioned over the breathable tape.

71. The adherent device of claim 70 wherein the gel cover comprises a material to inhibit moisture penetration from outside the patch into the at least one gel.

72. The adherent device of claim 70 wherein the gel cover comprises a breathable water resistant cover to inhibit moisture penetration from outside the patch into the at least one gel.

73. The adherent device of claim 70 wherein the gel cover comprises a material to inhibit a flow of the gel through the breathable tape and wherein the printed circuit board is located over the gel cover such that the gel cover is disposed between the breathable tape and the printed circuit board.

74. The adherent device of claim 70 wherein the breathable tape comprises a tricot-knit polyester fabric backing and the gel cover comprises a polyurethane film backing.

75. The adherent device of claim 70 wherein the breathable tape comprises a first porosity and wherein the gel cover comprises a breathable tape with a second porosity, the second porosity less than the first porosity to minimize flow of the gel through the breathable tape having the first porosity.

76. The adherent device of claim 58 wherein breathable tape, the adhesive coating, the at least one electrode and gel are separable from the printed circuit board, electronic components and cover, such that the printed circuit board, electronic components, housing and cover are reusable.

77. The adherent device of claim 58 wherein the at least one electrode extends through at least one aperture in the breathable tape.

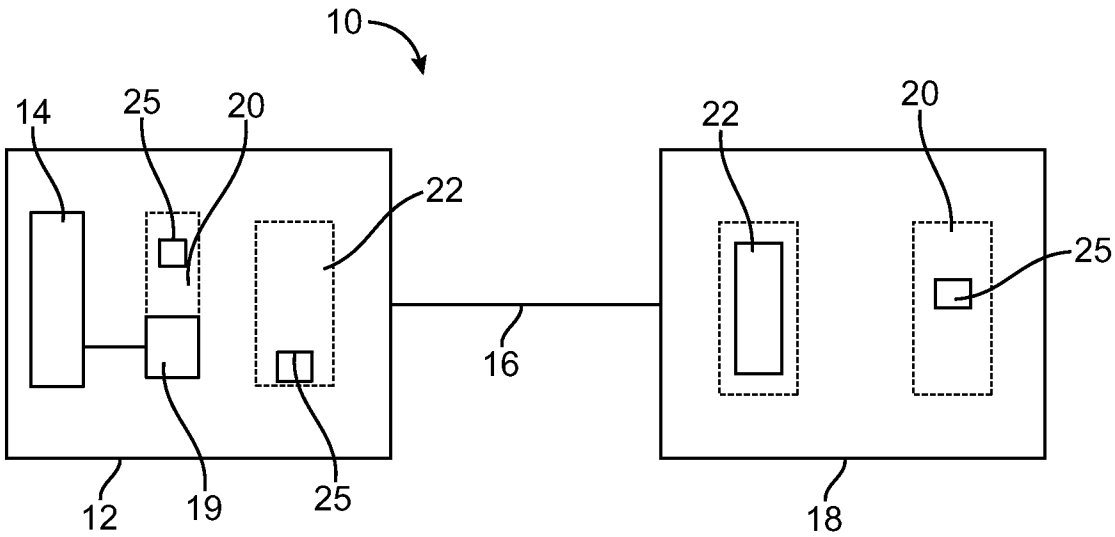


FIG. 1A

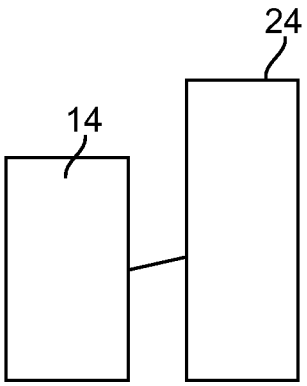


FIG. 1C

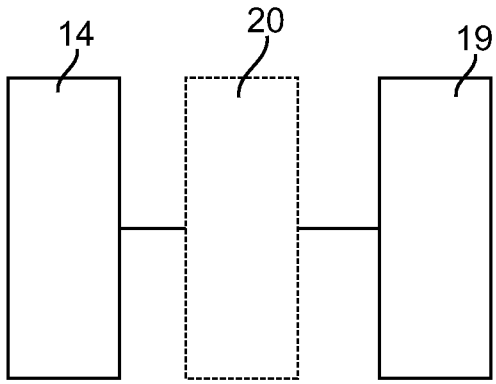


FIG. 1B

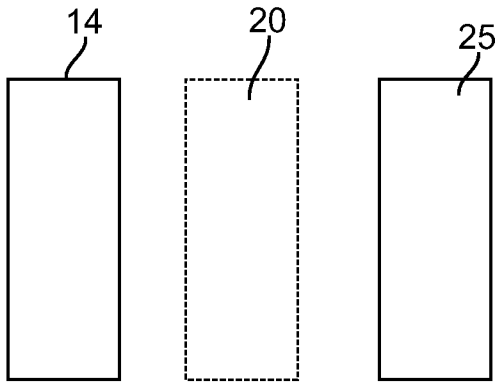


FIG. 1D

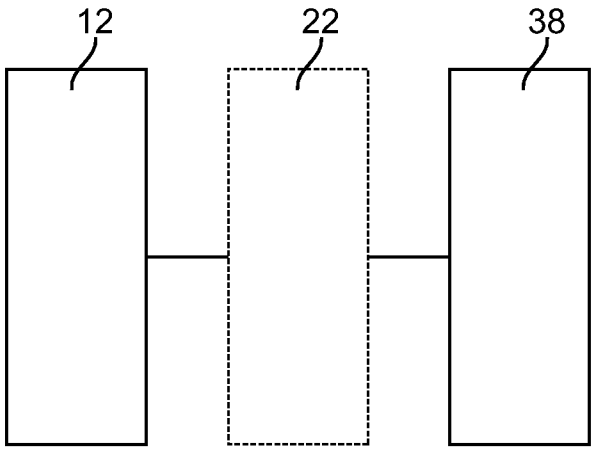


FIG. 1E

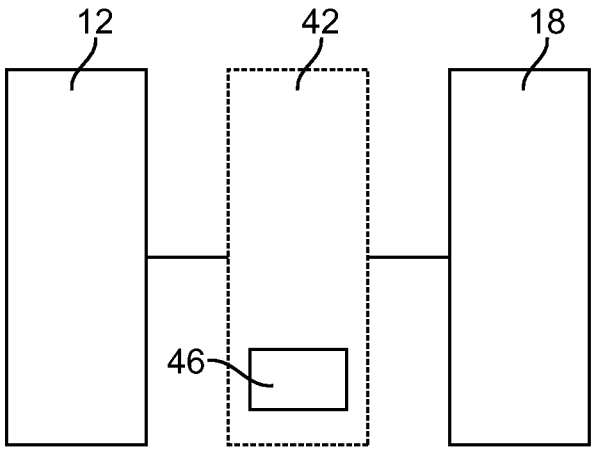


FIG. 1F

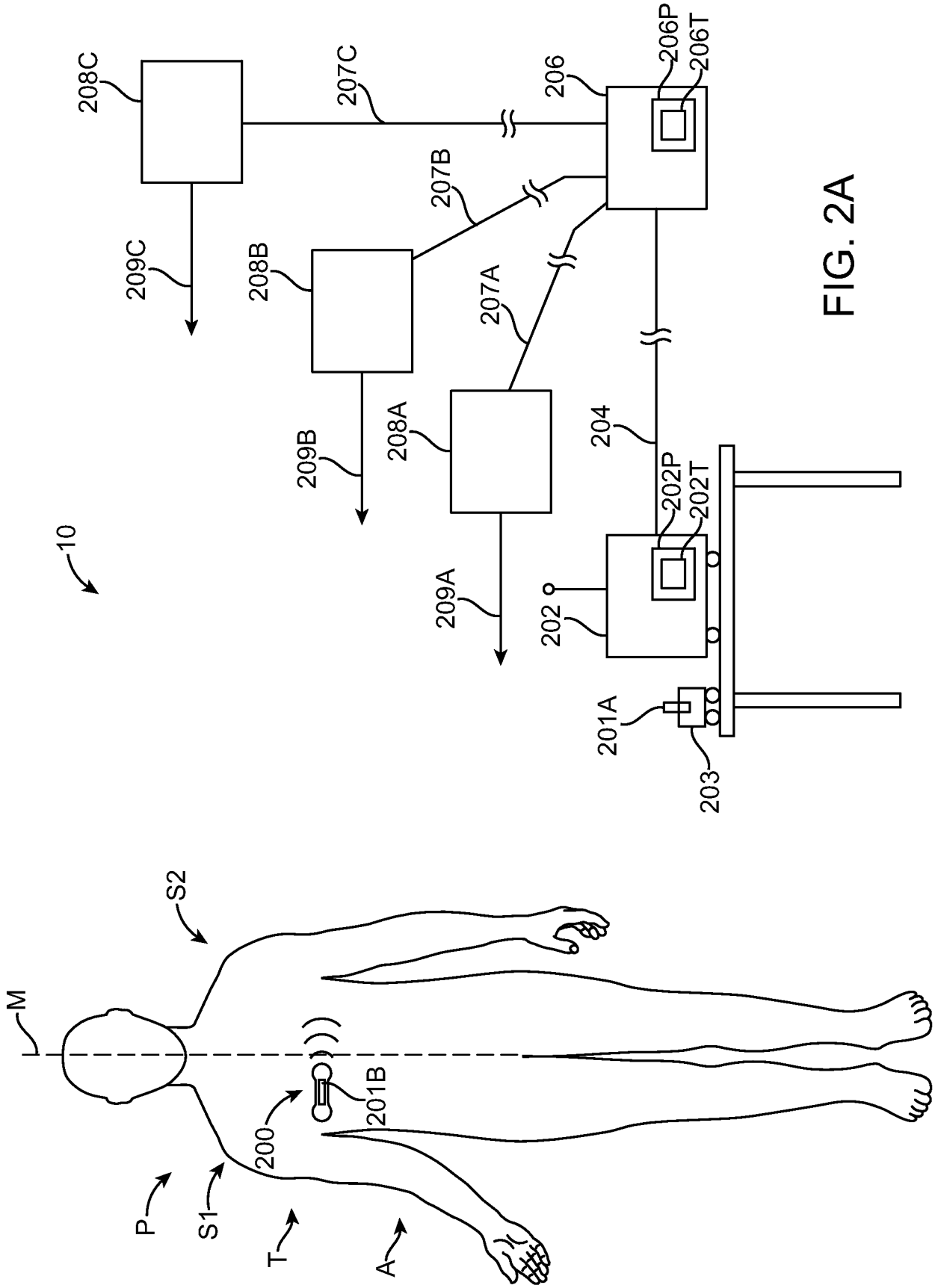

10
208C
207C
206
206P
206T
207B
209C
208B
207A
209B
208A
204
202P
202T
209A
202
201A
203
S2
M
200
201B
P
S1
T
A

FIG. 2A

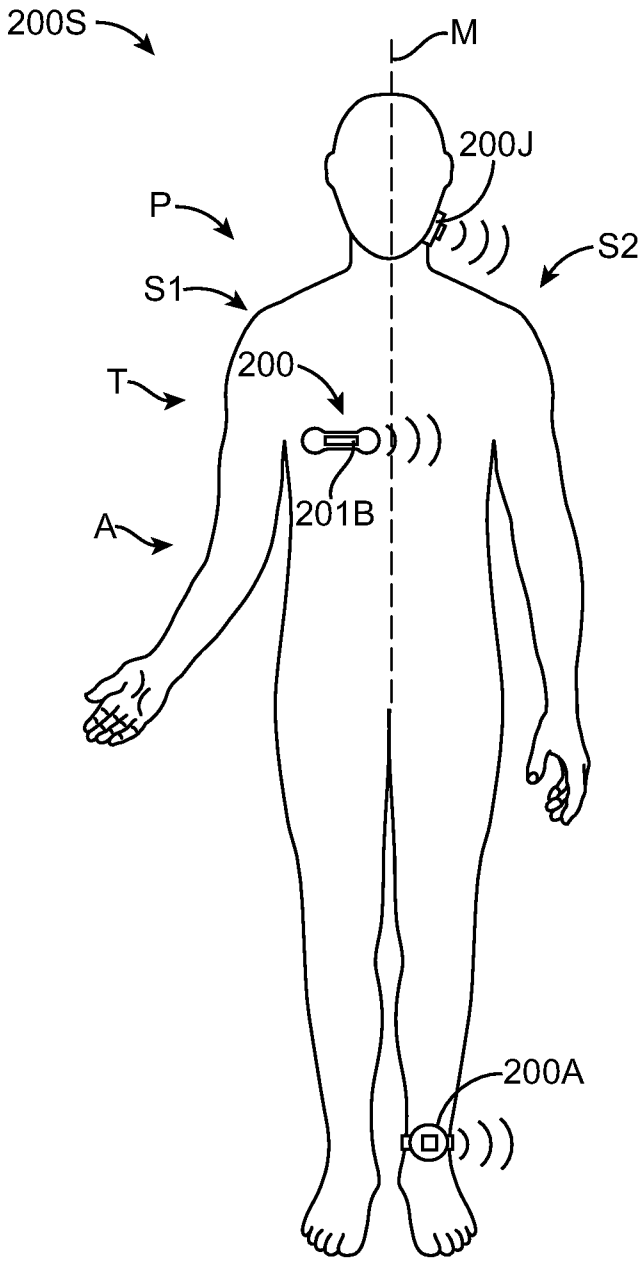


FIG. 2A1

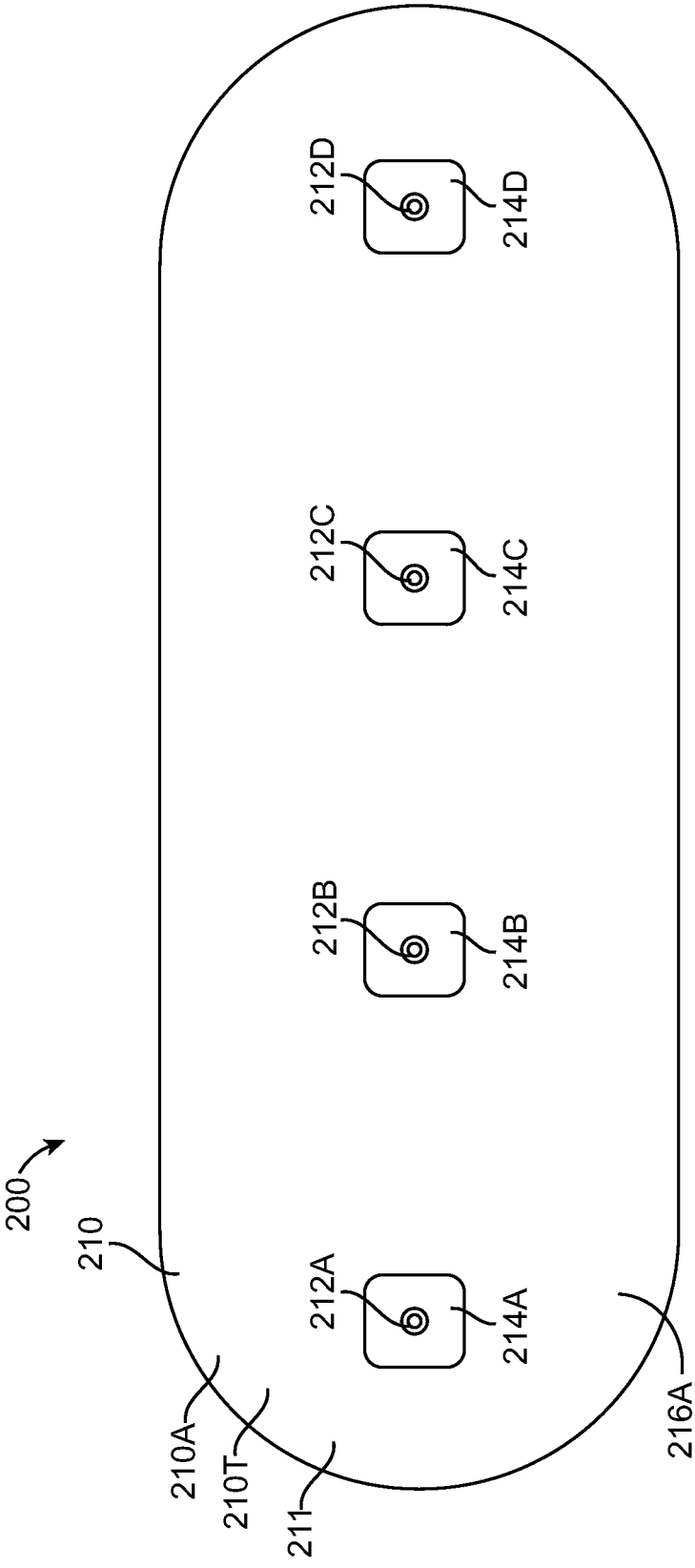

200
210
212A
214A
212B
214B
212C
214C
212D
214D
210A
210T
211
216A

FIG. 2B

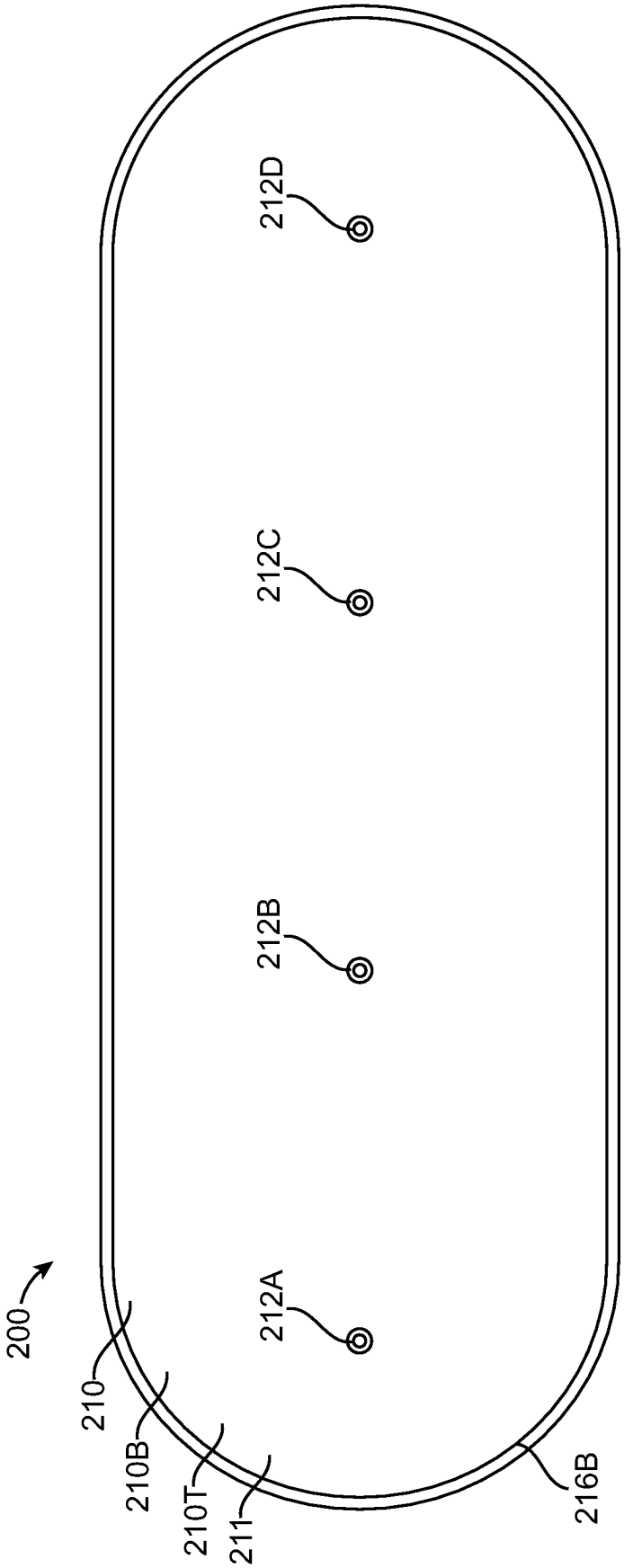


FIG. 2C

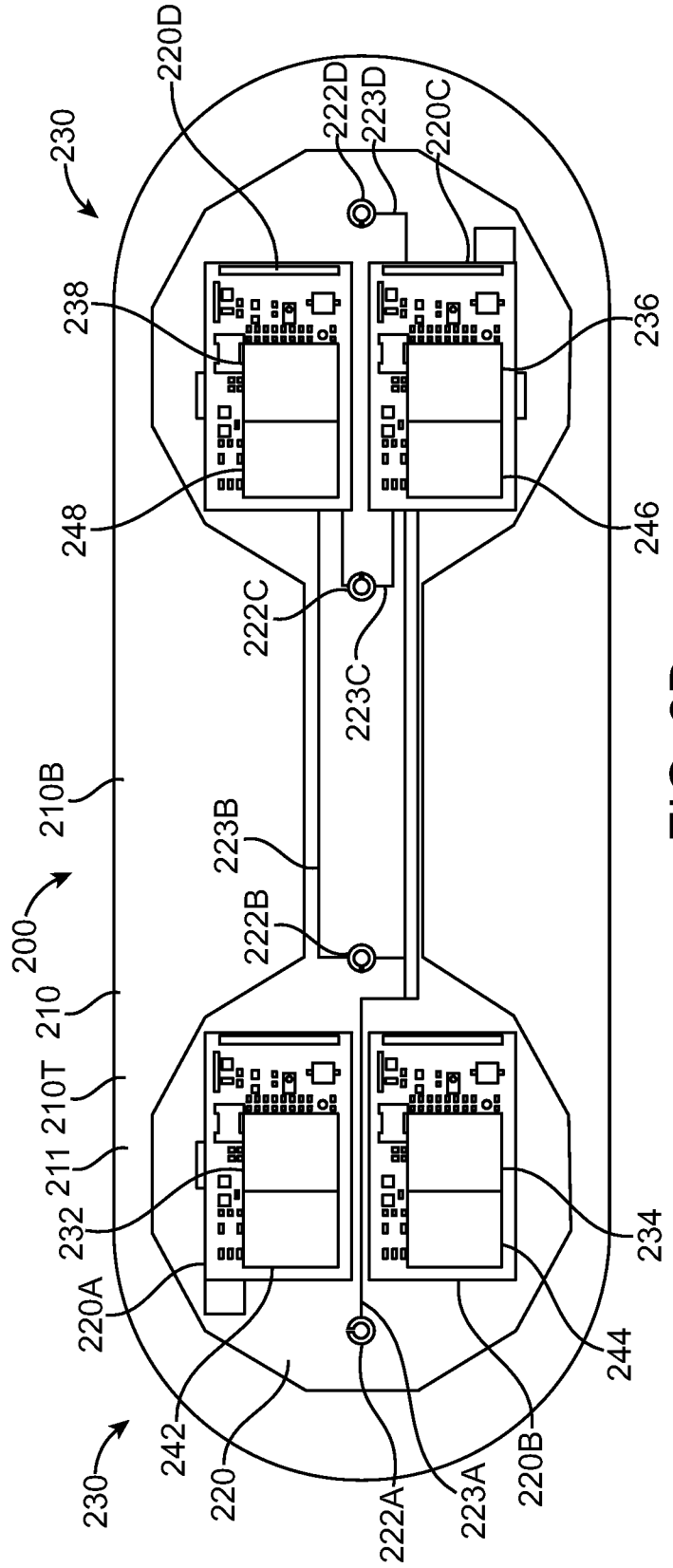


FIG. 2D

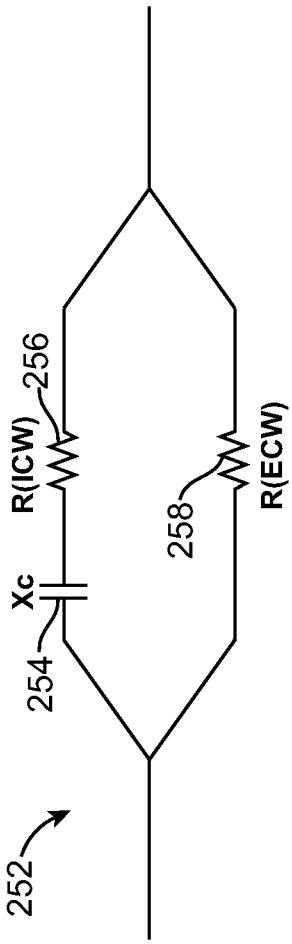


FIG. 2D1

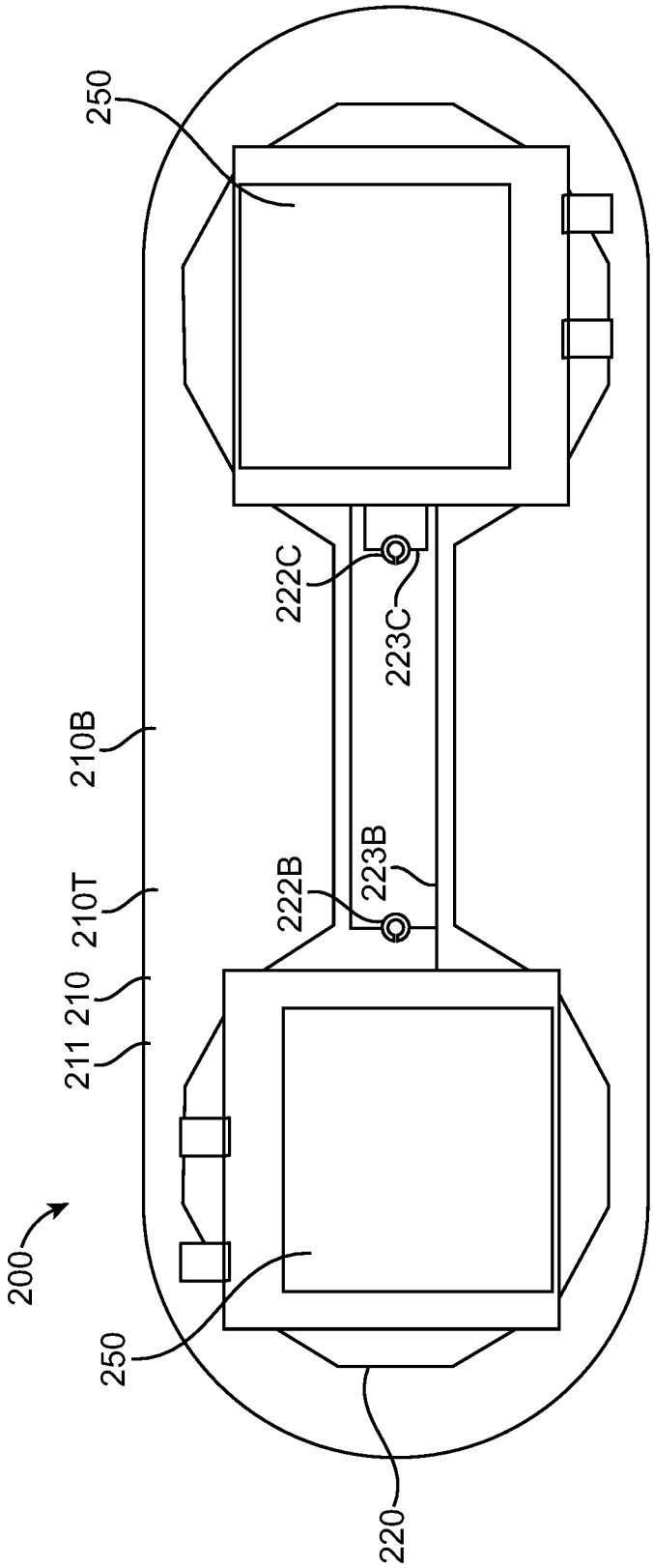


FIG. 2E

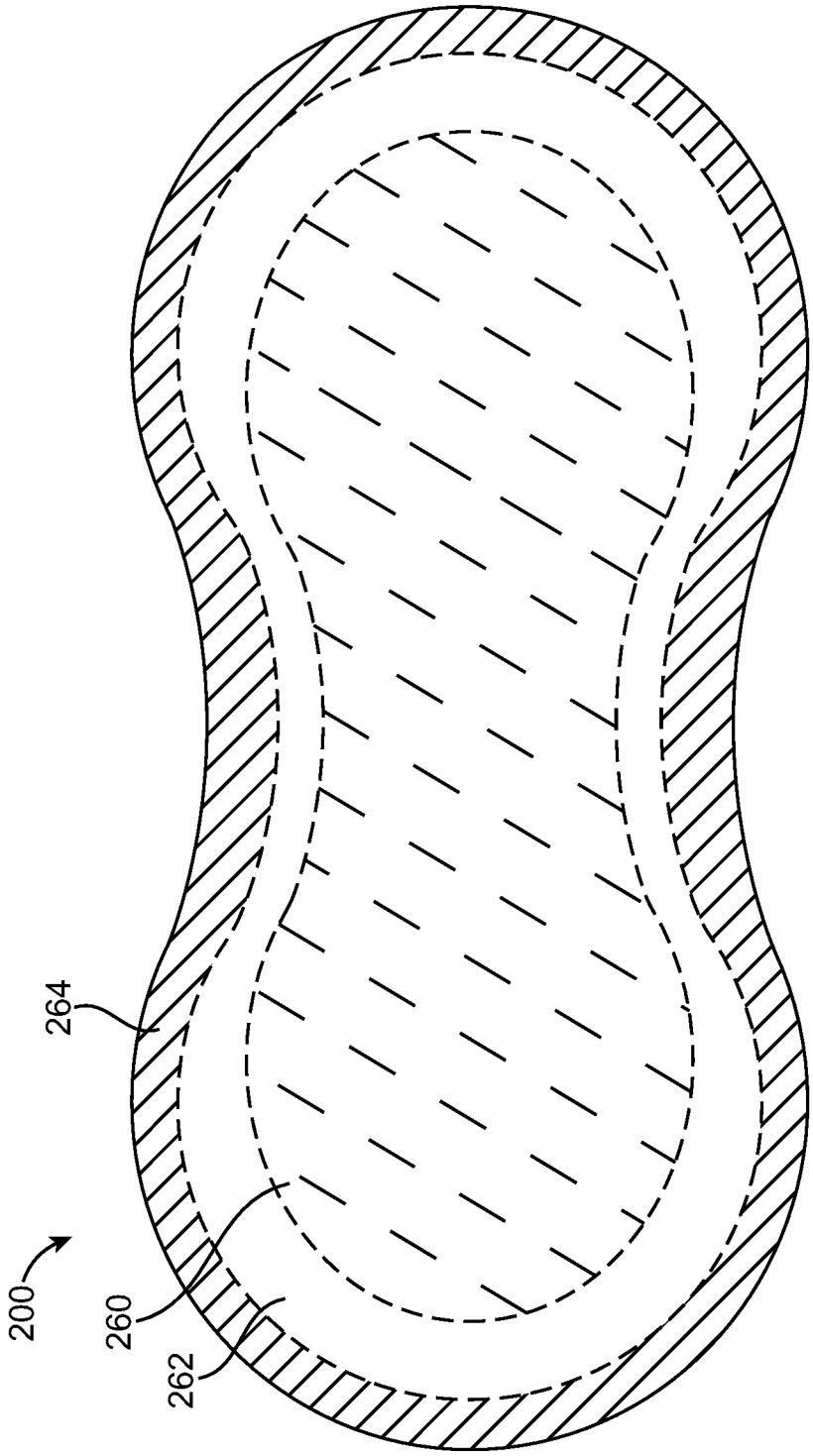


FIG. 2F

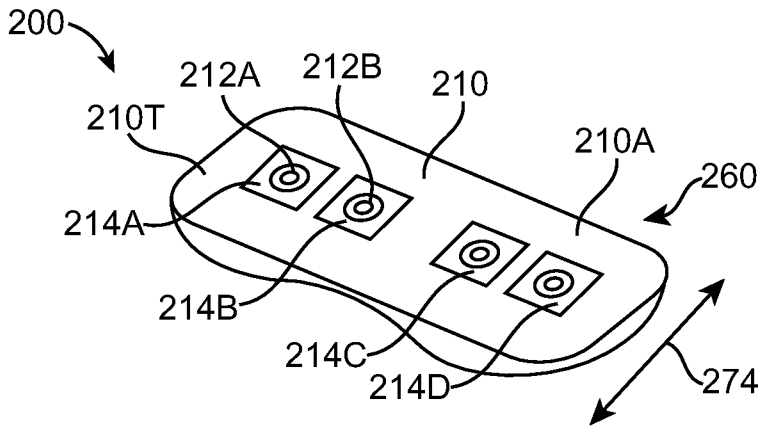

200
212A
212B
210
210T
210A
260
214A
214B
214C
214D
274

FIG. 2H

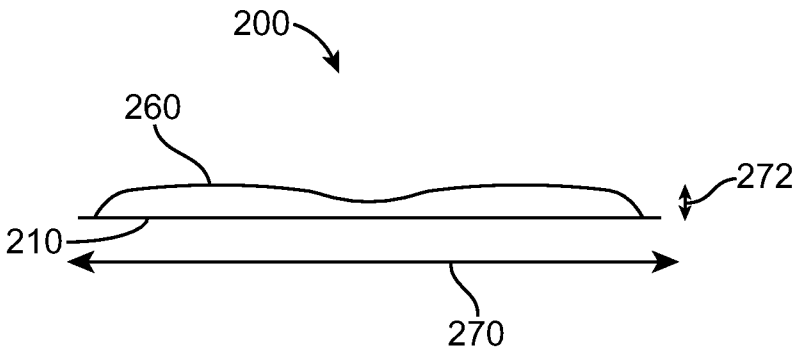

200
260
272
210
270

FIG. 2G

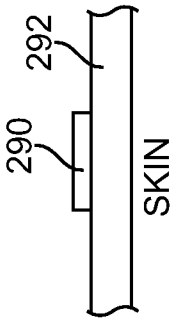

290
292
SKIN

FIG. 2K

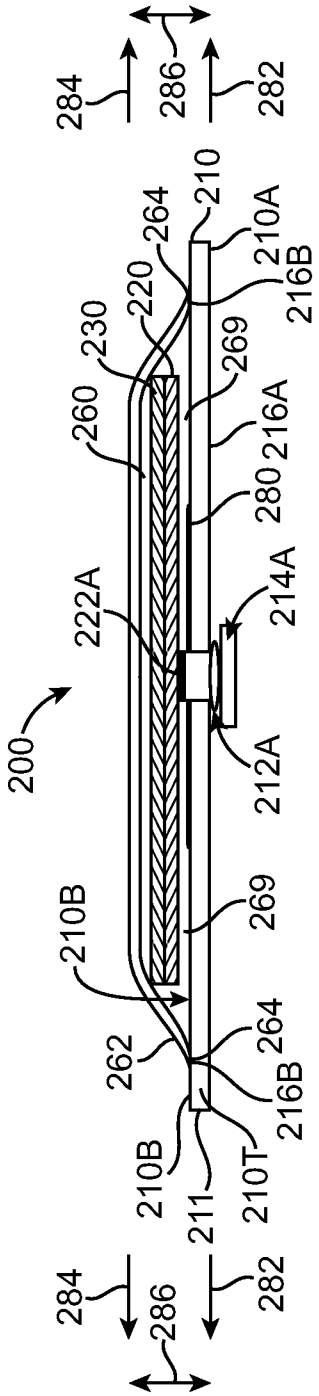

284
286
282
210
210A
264
220
216B
230
269
260
216A
280
222A
214A
200
212A
210B
269
262
264
216B
210B
211
210T
284
286
282

FIG. 2I

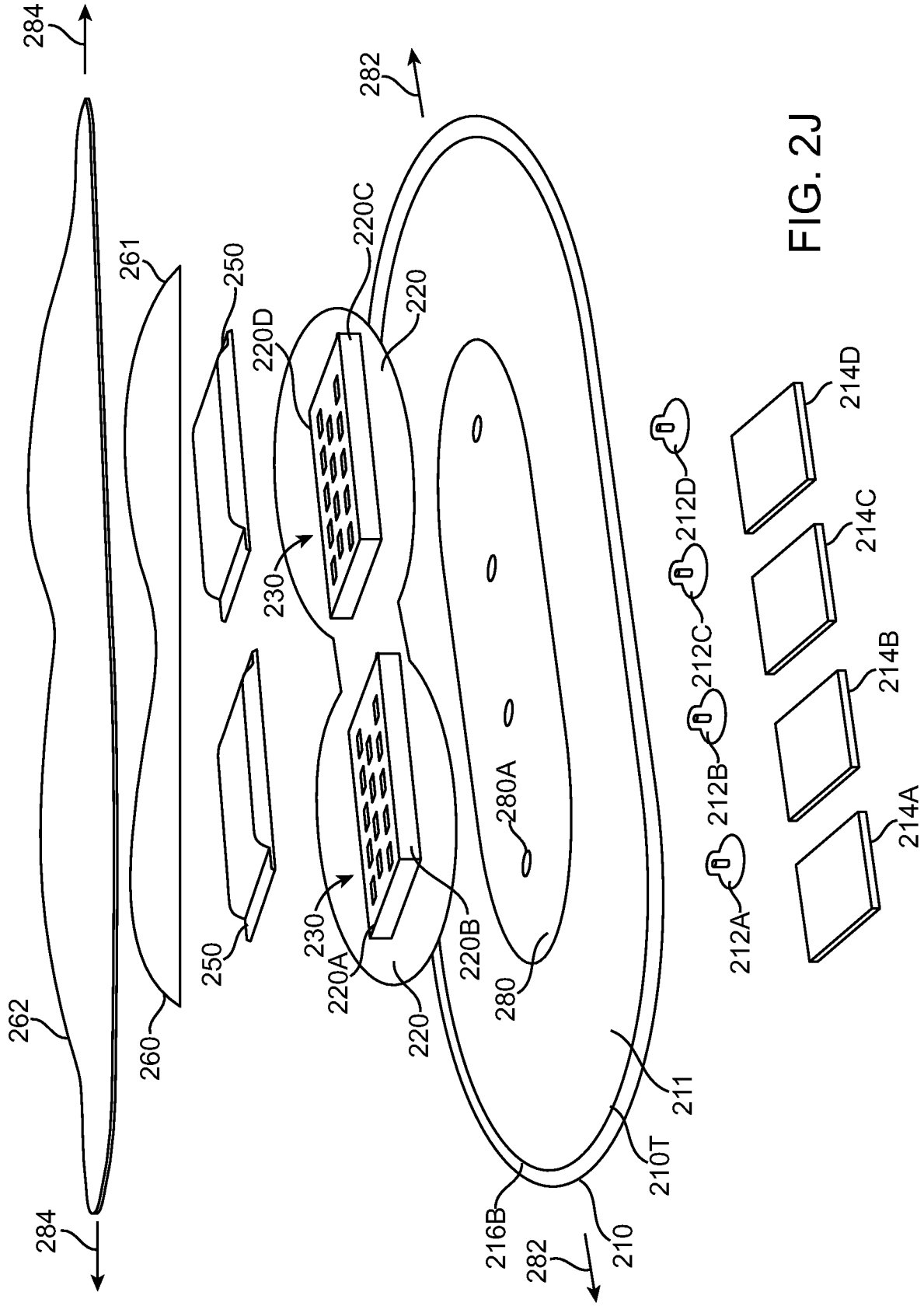

284
282
261
250
220C
220D
220
230
250
230
220A
220B
280A
280
220
262
260
284
282
216B
210
210T
211
212A
212B
212C
212D
214A
214B
214C
214D

FIG. 2J

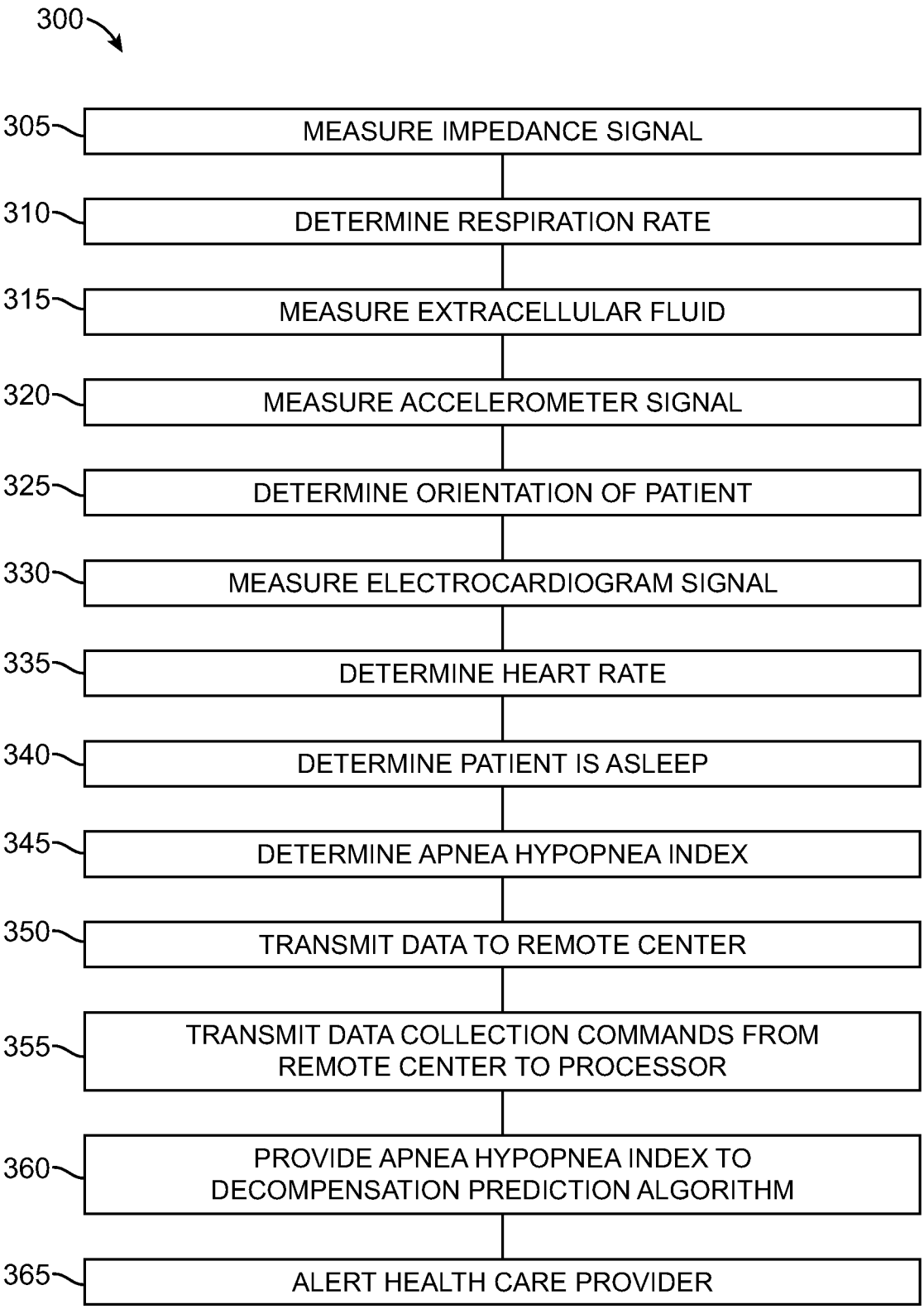

300
305
MEASURE IMPEDANCE SIGNAL
310
DETERMINE RESPIRATION RATE
315
MEASURE EXTRACELLULAR FLUID
320
MEASURE ACCELEROMETER SIGNAL
325
DETERMINE ORIENTATION OF PATIENT
330
MEASURE ELECTROCARDIOGRAM SIGNAL
335
DETERMINE HEART RATE
340
DETERMINE PATIENT IS ASLEEP
345
DETERMINE APNEA HYPOPNEA INDEX
350
TRANSMIT DATA TO REMOTE CENTER
355
TRANSMIT DATA COLLECTION COMMANDS FROM REMOTE CENTER TO PROCESSOR
360
PROVIDE APNEA HYPOPNEA INDEX TO DECOMPENSATION PREDICTION ALGORITHM
365
ALERT HEALTH CARE PROVIDER

FIG. 3A

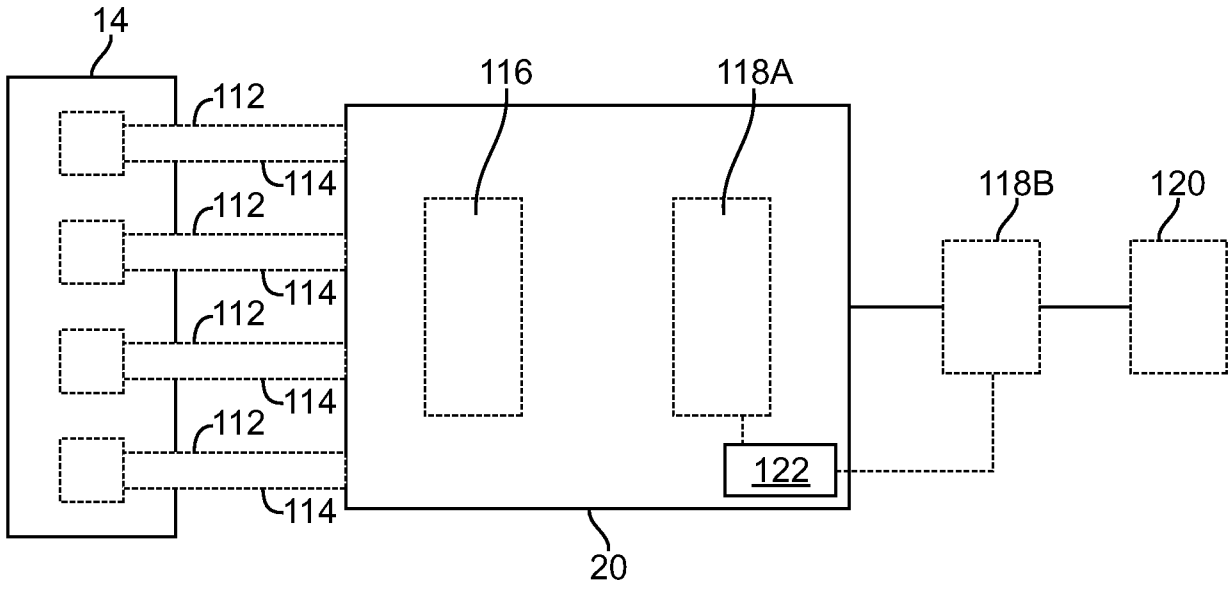


FIG. 4

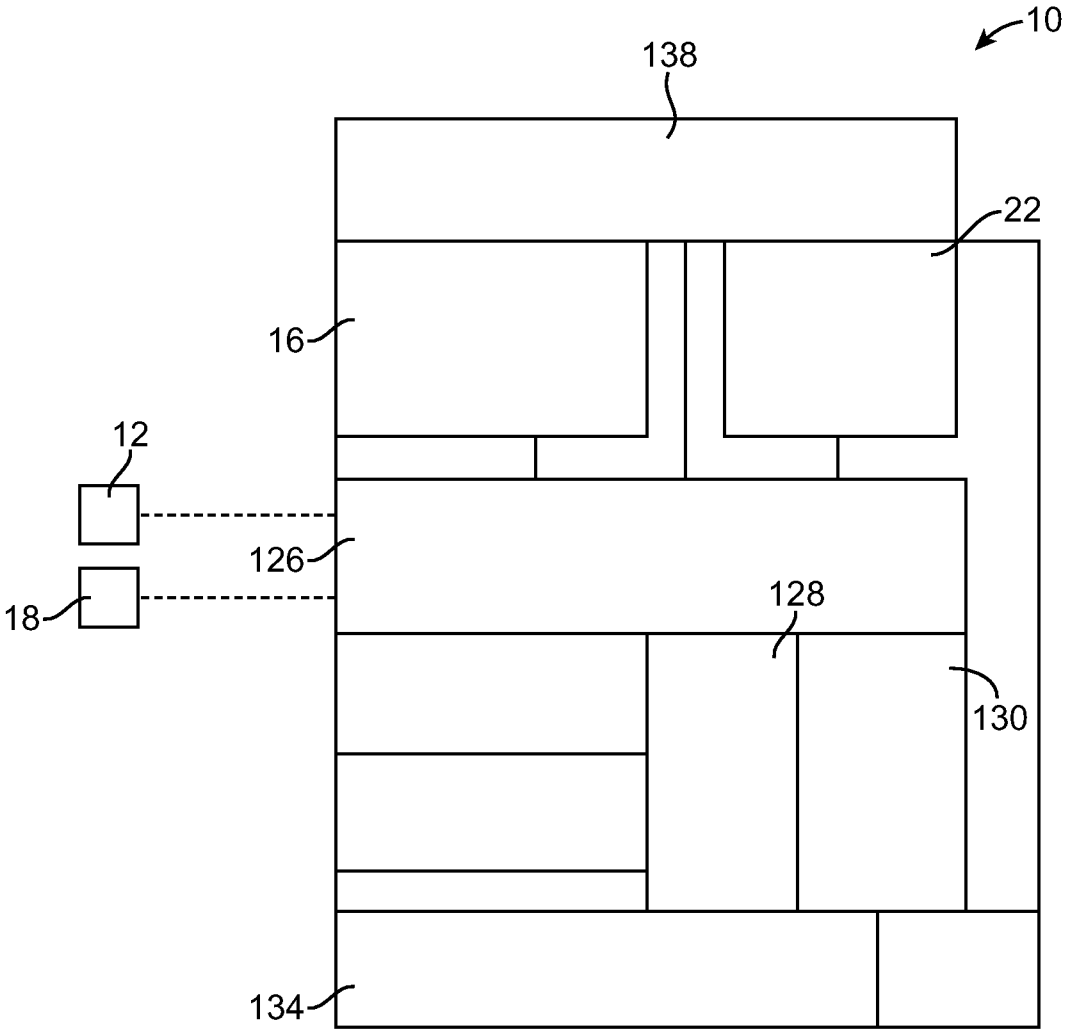


FIG. 5

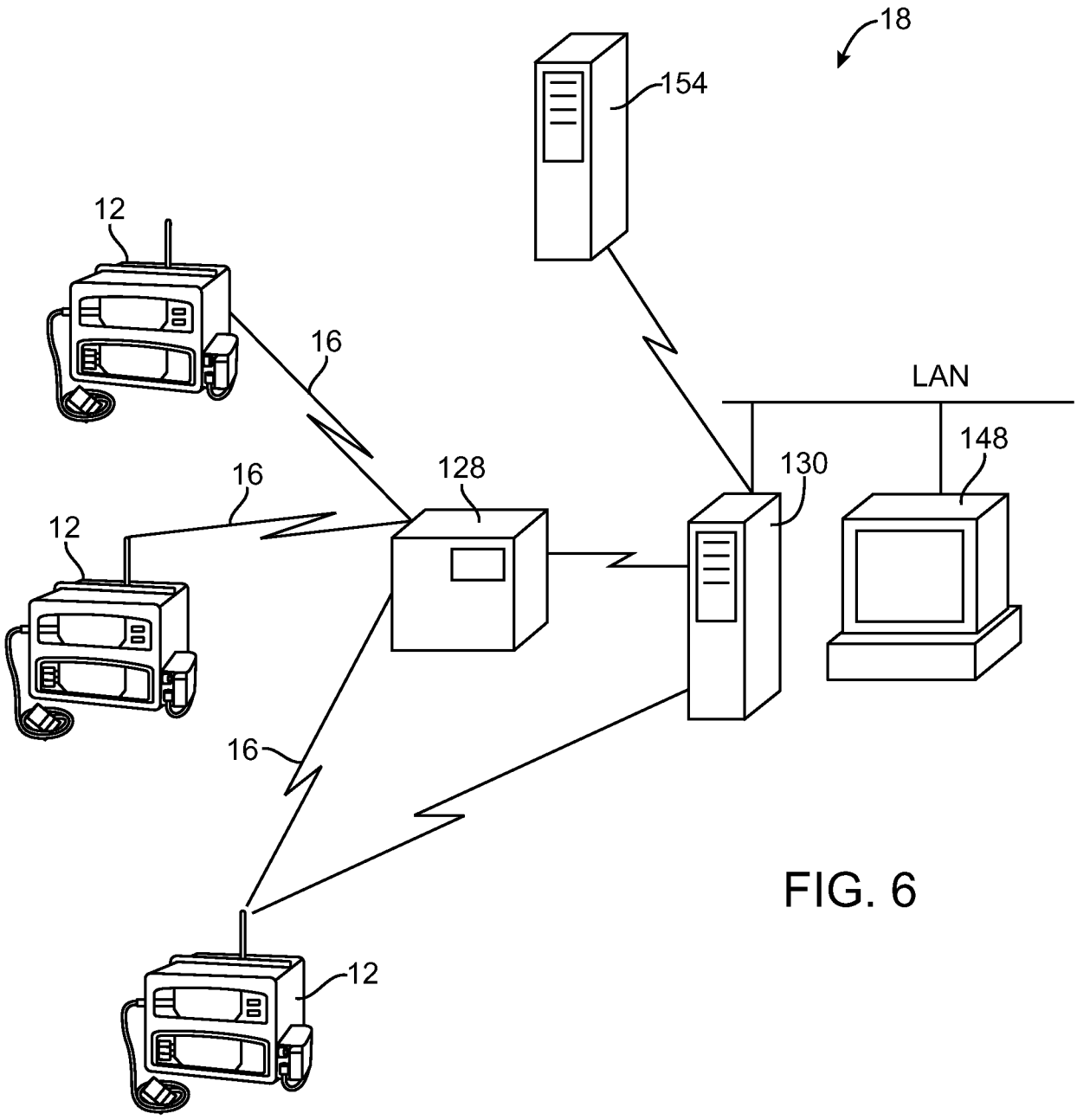
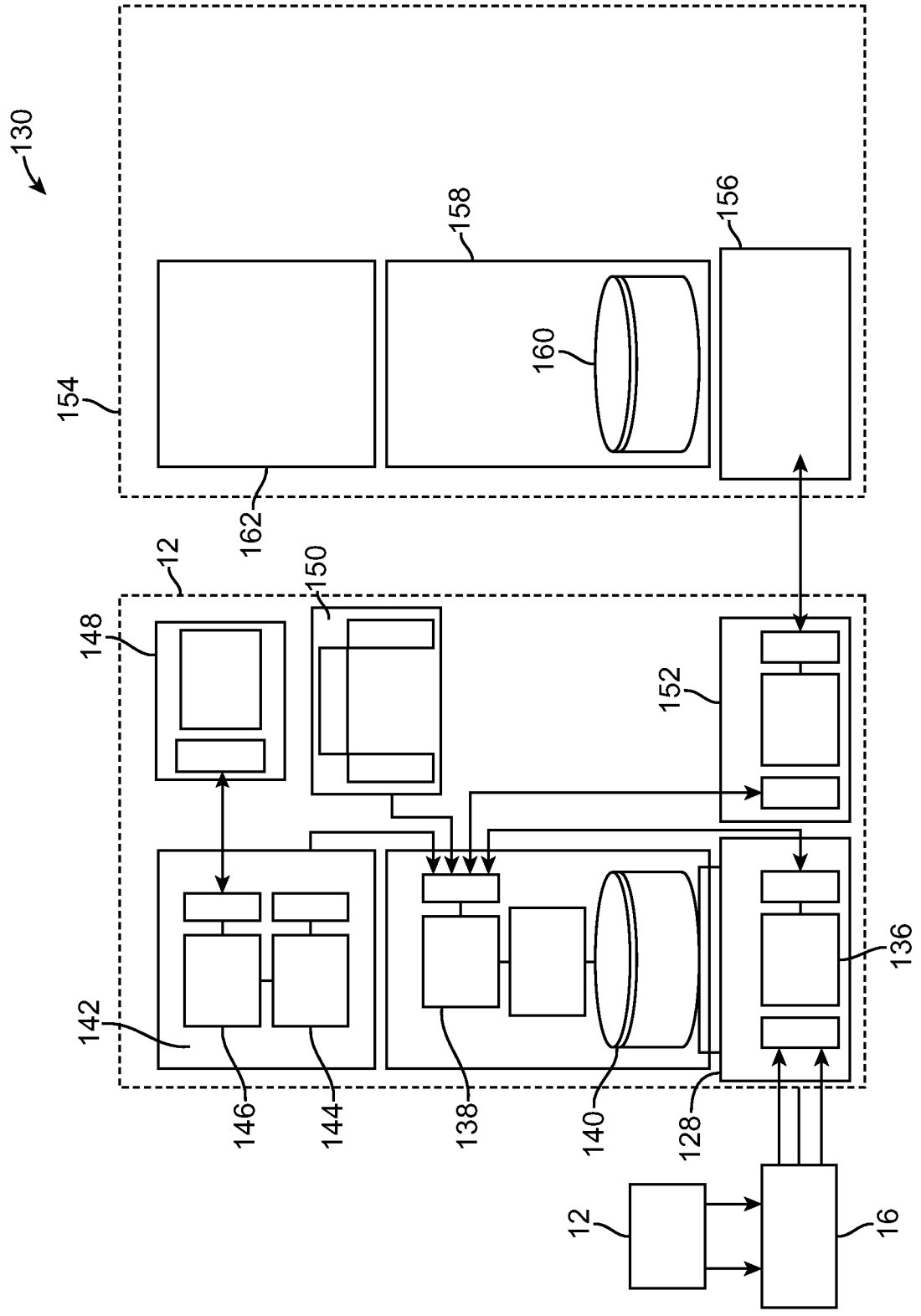


FIG. 6


130
154
158
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160
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12
150
148
152
142
146
144
138
140
128
136
12
16

FIG. 7

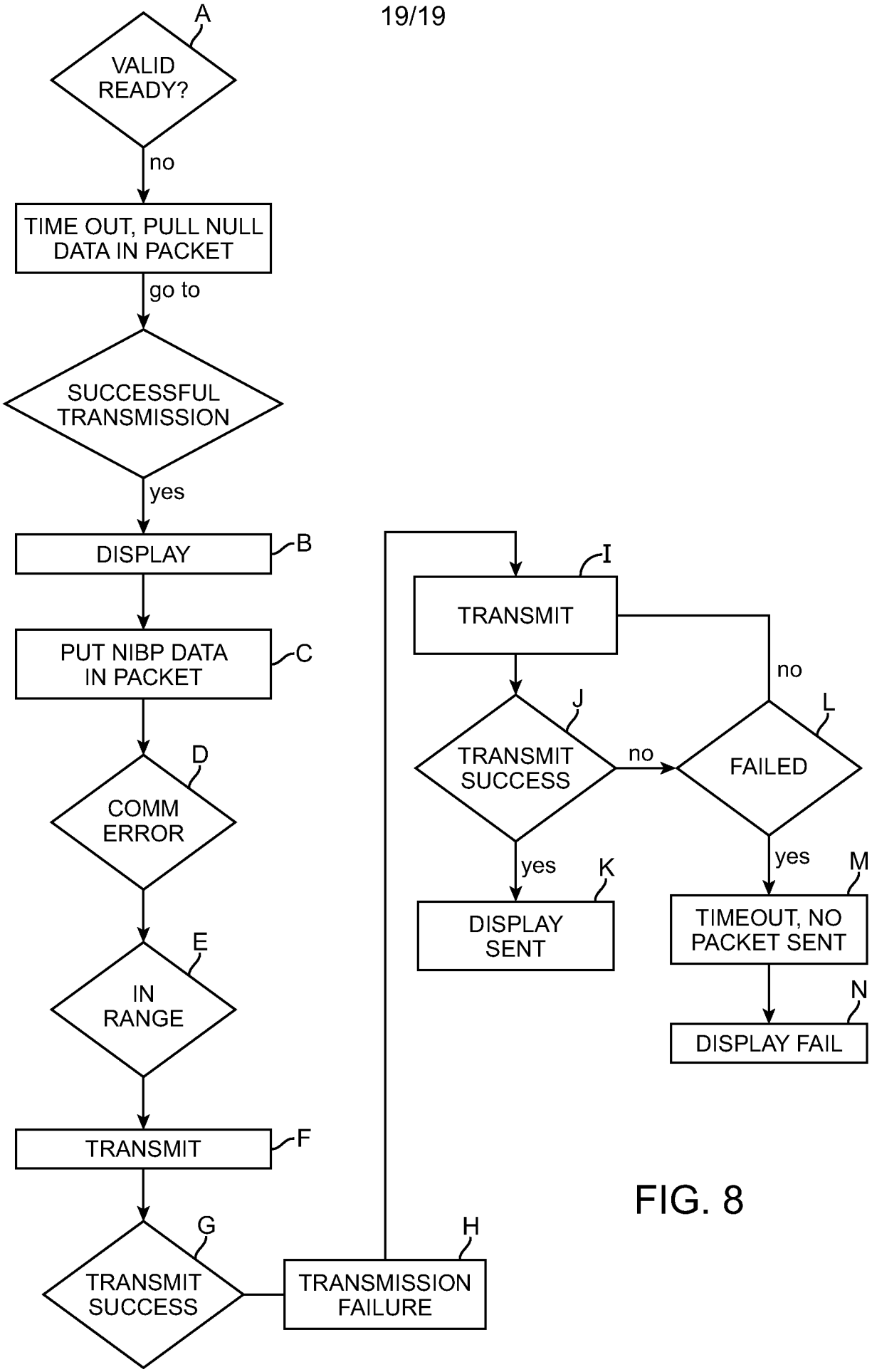
A
VALID READY?
no
TIME OUT, PULL NULL DATA IN PACKET
go to
SUCCESSFUL TRANSMISSION
yes
DISPLAY
B
PUT NIBP DATA IN PACKET
C
D
COMM ERROR
E
IN RANGE
TRANSMIT
F
G
TRANSMIT SUCCESS
H
TRANSMISSION FAILURE
I
TRANSMIT
no
J
TRANSMIT SUCCESS
no
L
FAILED
yes
K
DISPLAY SENT
yes
M
TIMEOUT, NO PACKET SENT
N
DISPLAY FAIL

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/076241

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 05/08 (2008.04)
USPC - 600/529
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 05/08 (2008.04)
USPC - 600/529

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/0027207 A1 (WESTBROOK et al) 03 February 2005 (03.02.2005) entire document	1-77
A	US 2007/0015976 A1 (MIESEL et al) 18 January 2007 (18.01.2007) entire document	1-77

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"O" document referring to an oral disclosure, use, exhibition or other means
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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 November 2008	21 NOV 2008
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774