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(54) **DATA COLLECTION IN A MULTI-SENSOR PATIENT MONITOR**

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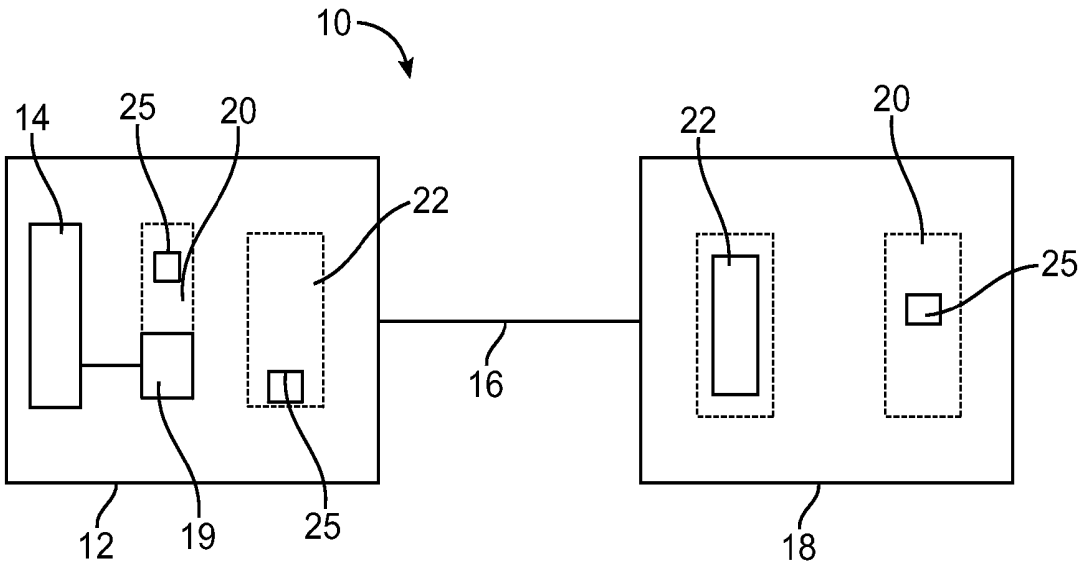
(57) **ABSTRACT**

A system for tracking a patient's physiological status and detecting and predicting negative physiological events, with a detecting system and a remote monitoring system. The detecting system includes a plurality of sensors that provide an indication of at least one physiological event of a patient, and a wireless communication device coupled to the plurality of sensors, and configured to transfer patient data from the plurality of sensors to a remote monitoring system. The a remote monitoring system coupled to the wireless communication device, wherein during a registration period, the detecting system being activated for a first time and communicating with the remote monitoring system to register the detecting system and activate data logging.



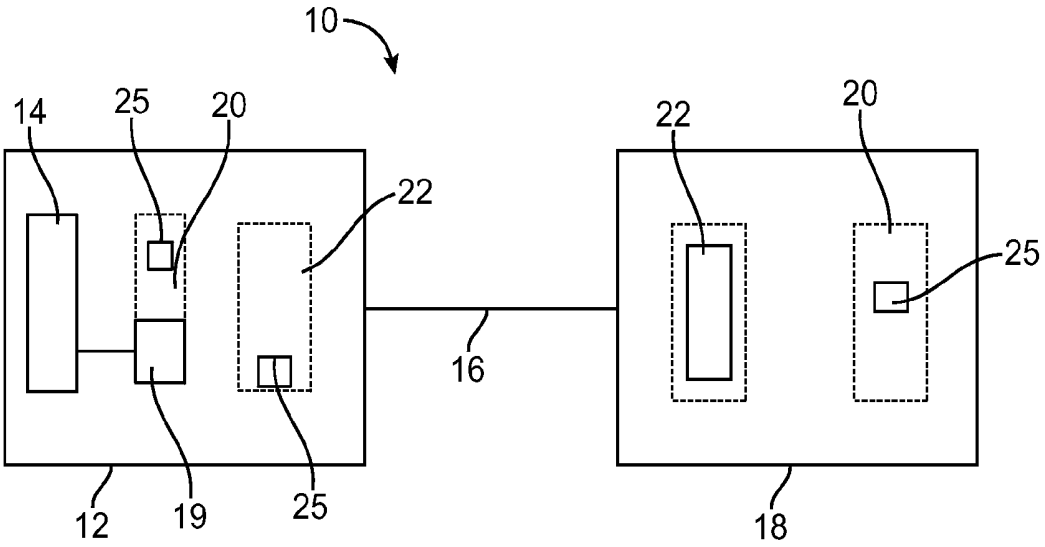


FIG. 1

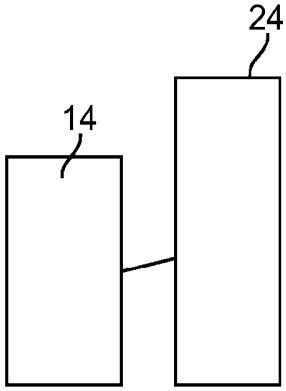


FIG. 4

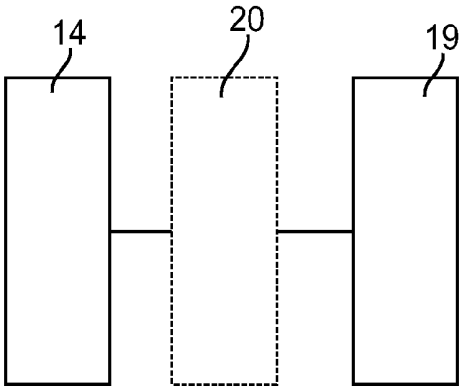


FIG. 3

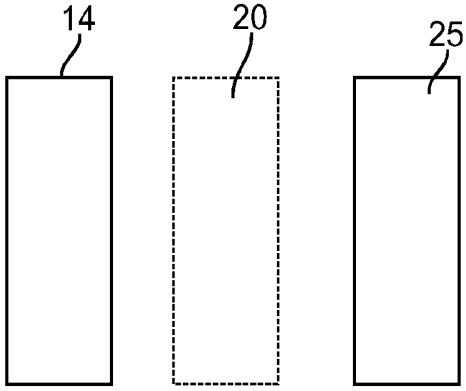


FIG. 5

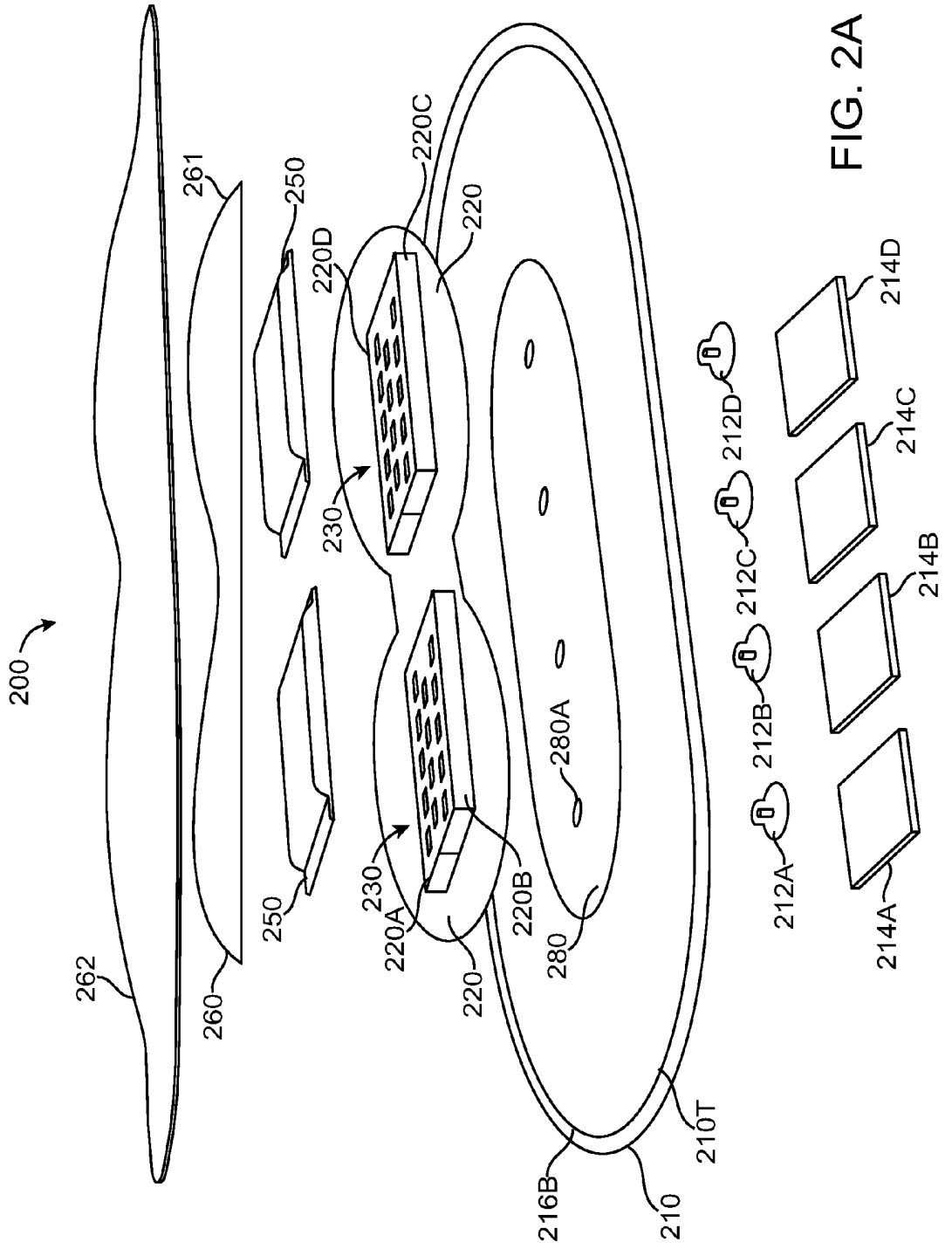

200
262
260
261
250
250
220D
220C
220
230
230
220A
220B
220
280
280A
216B
210
210T
212A
212B
212C
212D
214A
214B
214C
214D

FIG. 2A

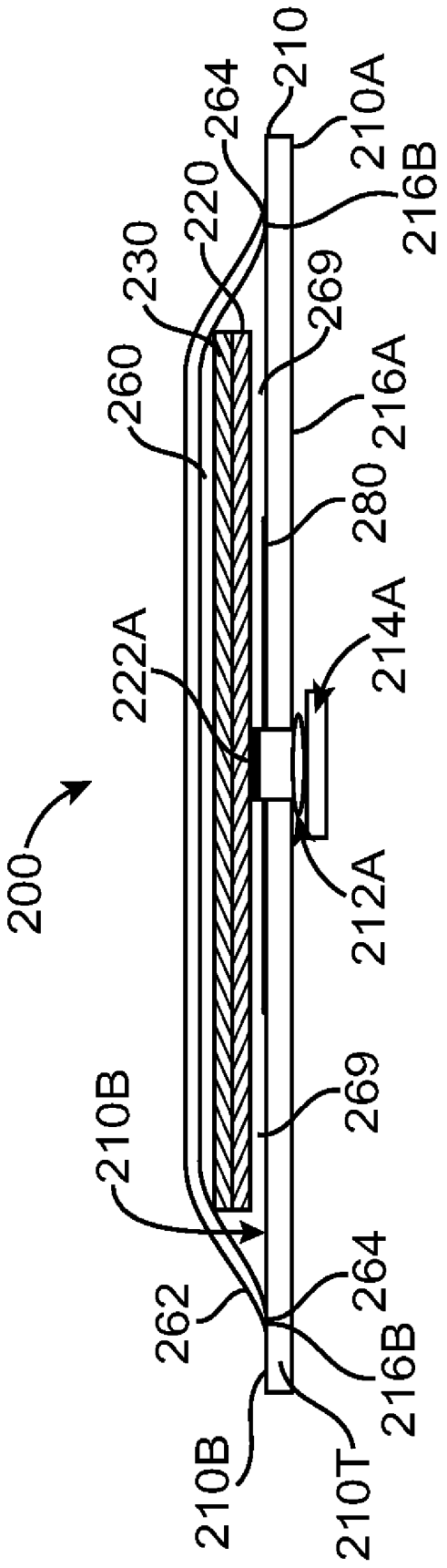

200
210
210A
216B
264
220
230
269
260
216A
280
214A
222A
212A
210B
269
264
262
216B
210B
210T

FIG. 2B

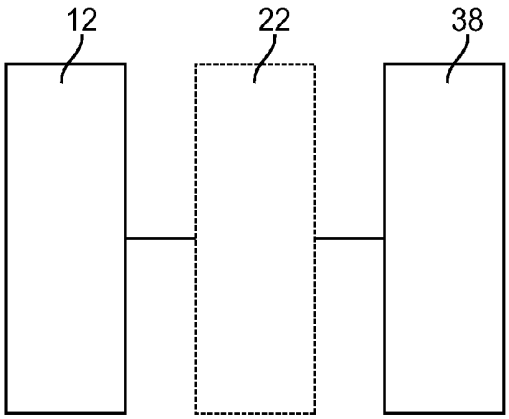


FIG. 6

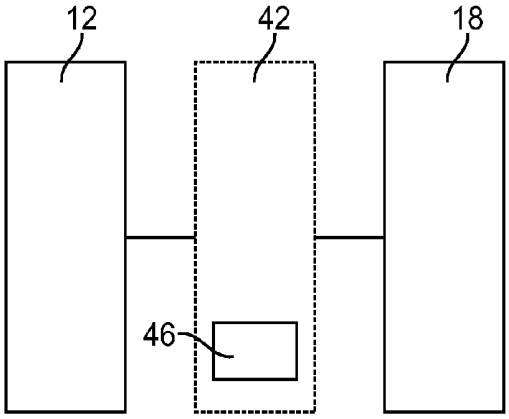


FIG. 7

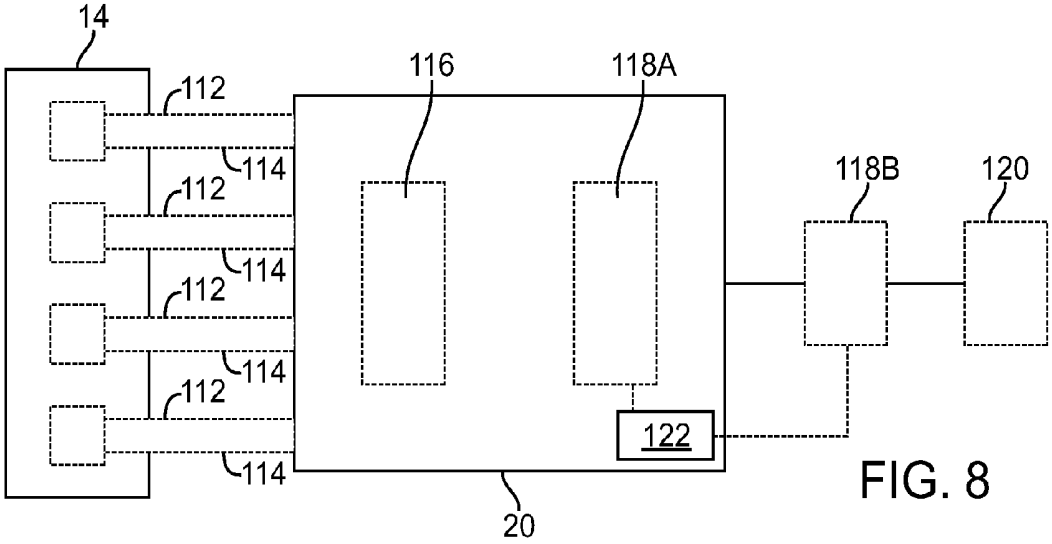


FIG. 8

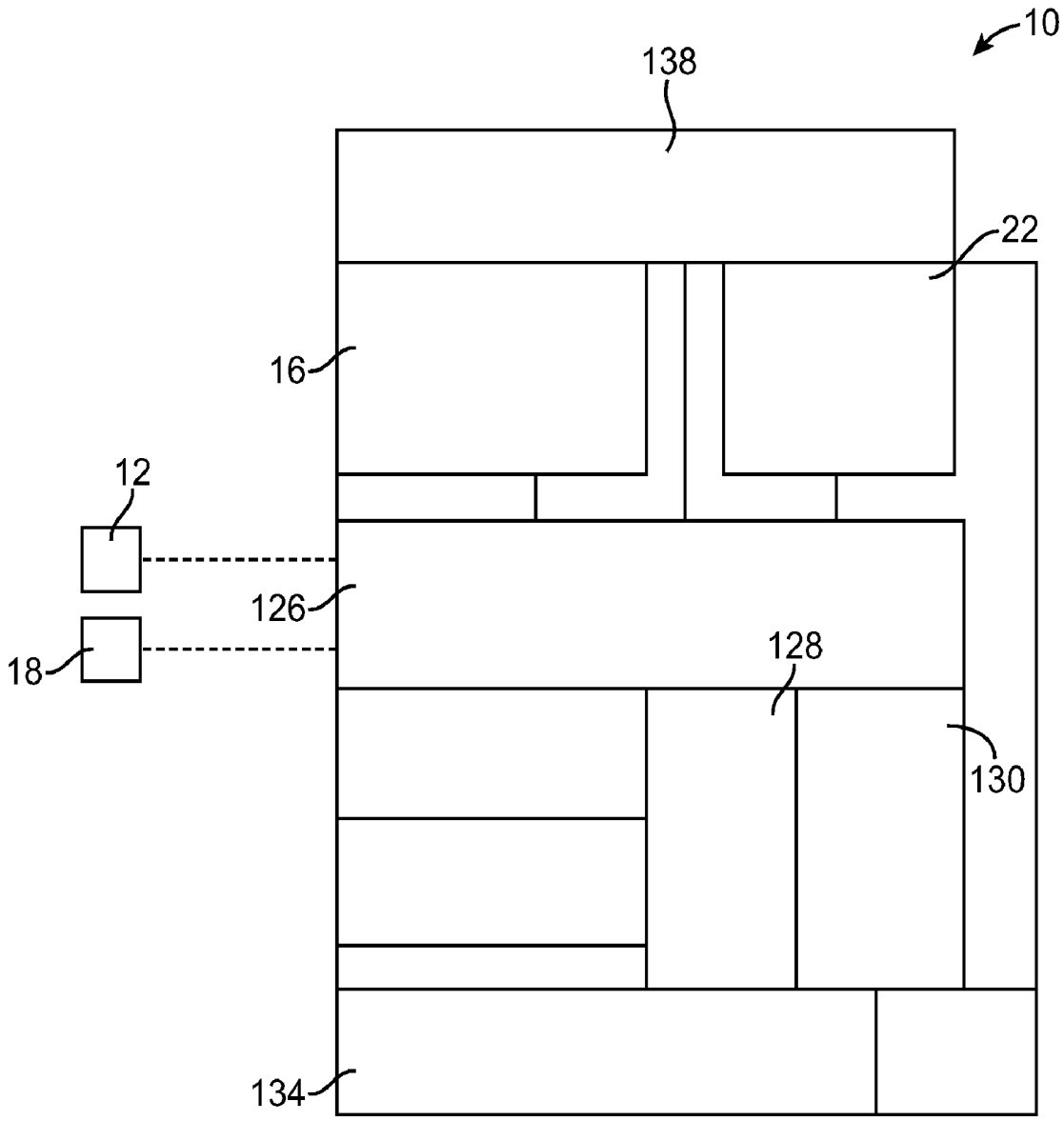


FIG. 9

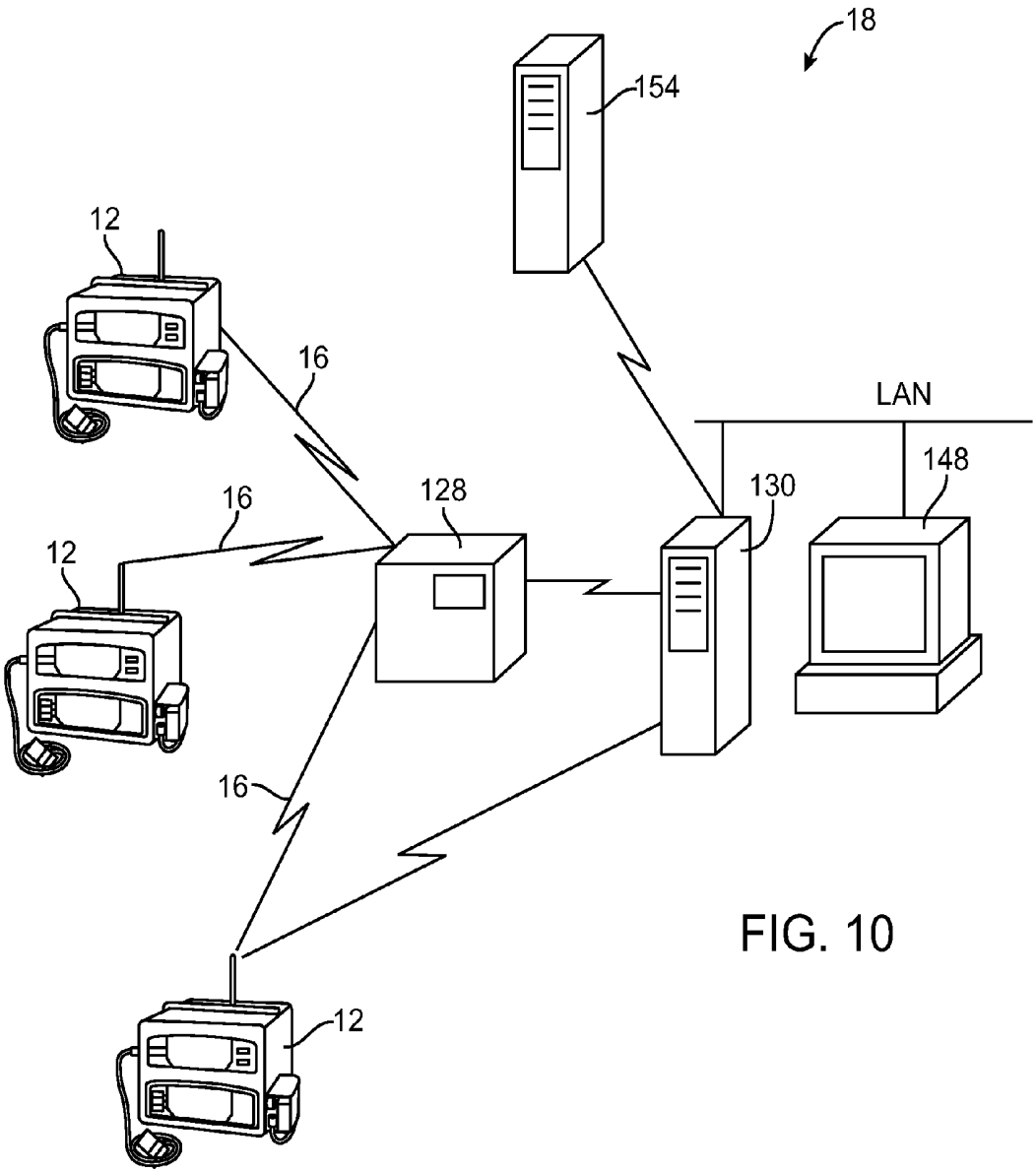
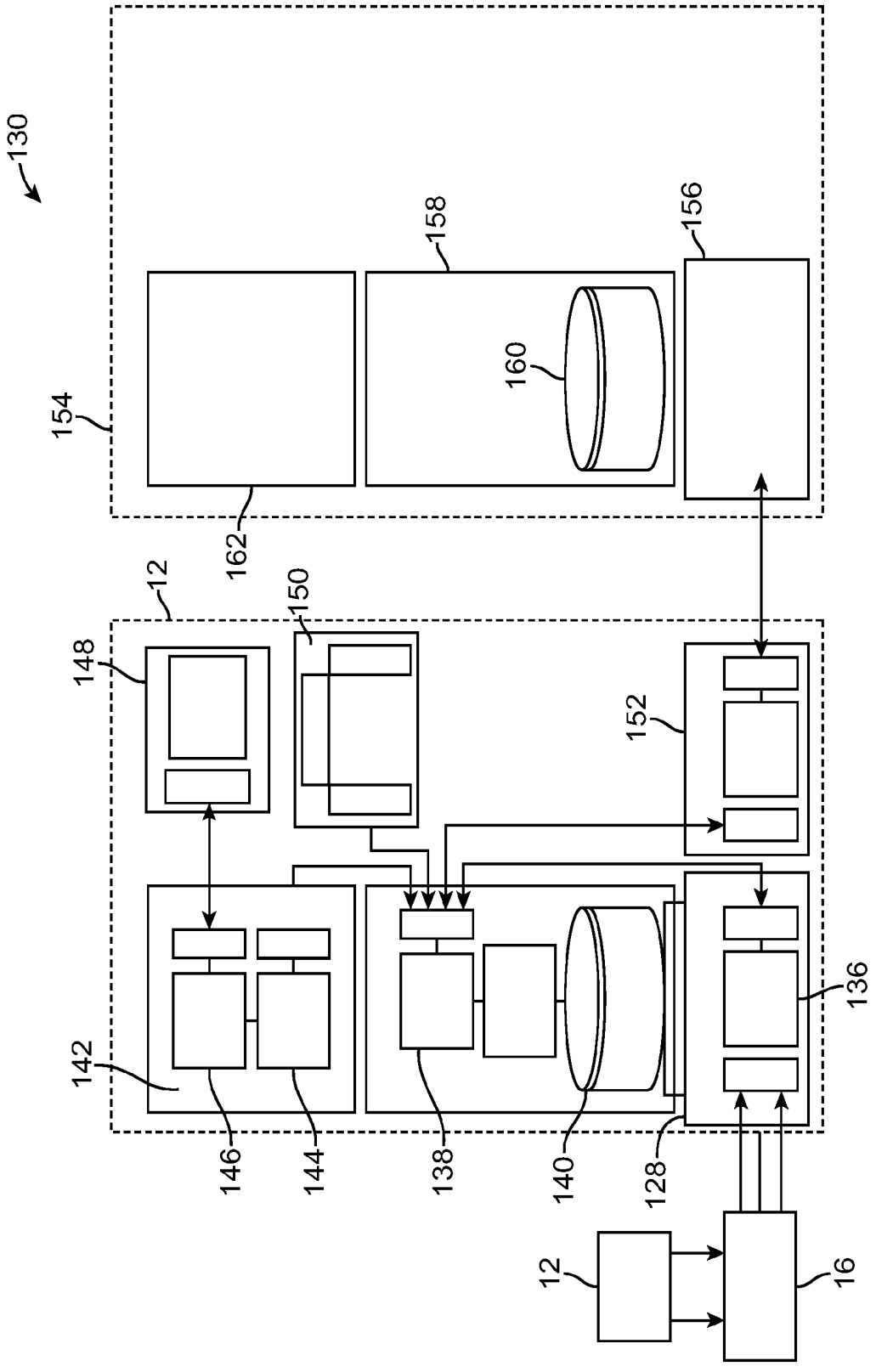


FIG. 10


130
154
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140
128
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12
16

FIG. 11

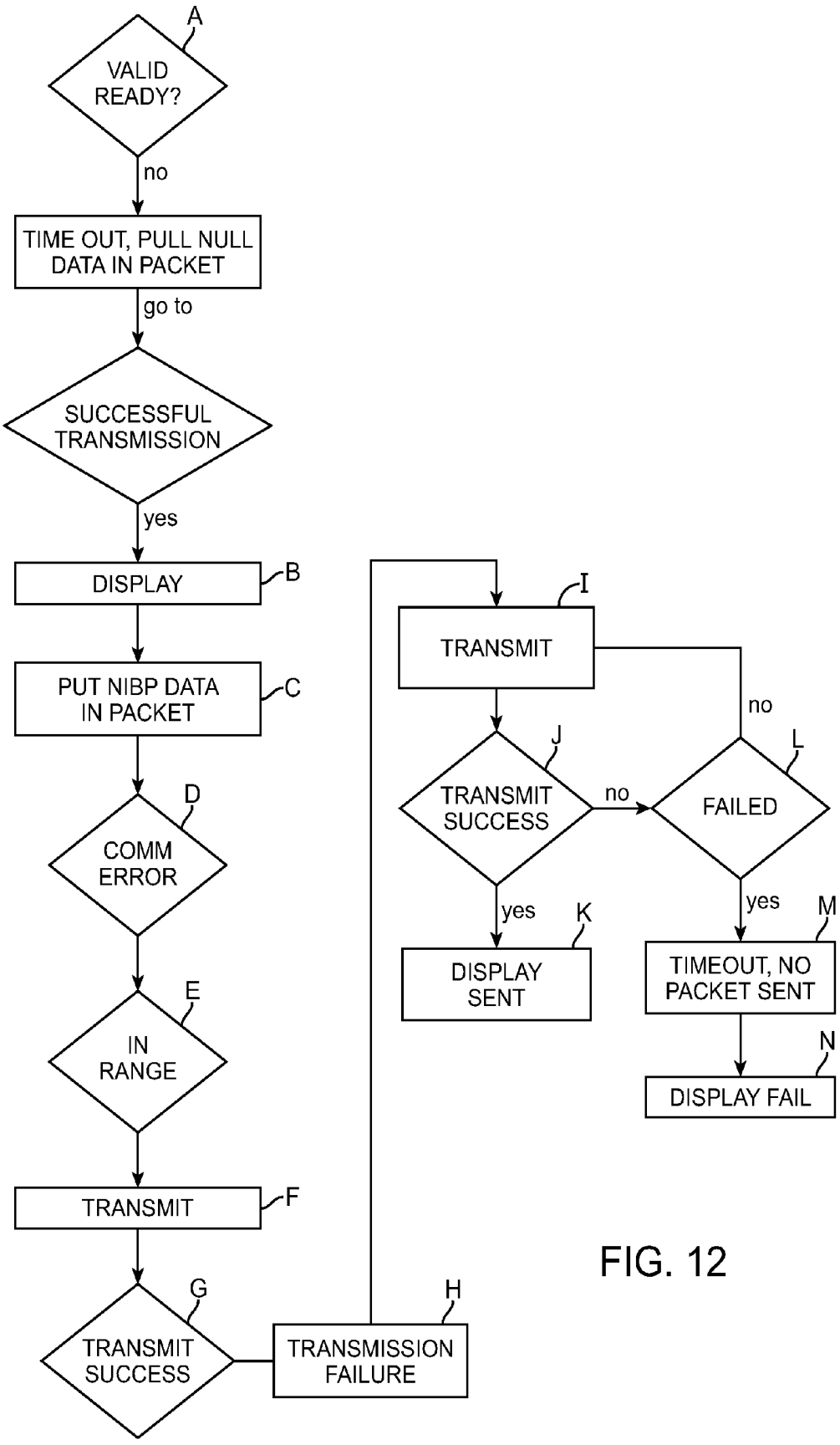
A
VALID READY?
no
TIME OUT, PULL NULL DATA IN PACKET
go to
SUCCESSFUL TRANSMISSION
yes
DISPLAY
B
PUT NIBP DATA IN PACKET
C
D
COMM ERROR
E
IN RANGE
TRANSMIT
F
G
TRANSMIT SUCCESS
H
TRANSMISSION FAILURE
I
TRANSMIT
J
TRANSMIT SUCCESS
no
L
FAILED
yes
K
DISPLAY SENT
yes
M
TIMEOUT, NO PACKET SENT
N
DISPLAY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

FIG. 12

DATA COLLECTION IN A MULTI-SENSOR PATIENT MONITOR

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application claims the benefit under 35 USC 119(e) of U.S. Provisional Application Nos. 60/972,316, 60/972,333, 60/972,336 and 60/972,537, all filed Sep. 14, 2007, and 61/055,666 filed May 23, 2008; the full disclosures of which are incorporated herein by reference in their entirety.

[0002] The subject matter of the present application is related to the following applications: 60/972,512; 60/972,329; 60/972,354; 60/972,616; 60/972,363; 60/972,343; 60/972,581; 60/972,629; 60/972,359; 60/972,340 all of which were filed on Sep. 14, 2007; 61/046,196 filed Apr. 18, 2008; 61/047,875 filed Apr. 25, 2008; 61/055,645, 61/055,656, 61/055,662 all filed May 23, 2008; and 61/079,746 filed Jul. 10, 2008.

[0003] The following applications are being filed concurrently with the present application, on Sep. 12, 2008: Attorney Docket Nos. 026843-000110US entitled "Multi-Sensor Patient Monitor to Detect Impending Cardiac Decompensation Prediction"; 026843-000220US entitled "Adherent Device with Multiple Physiological Sensors"; 026843-000410US entitled "Injectable Device for Physiological Monitoring"; 026843-000510US entitled "Delivery System for Injectable Physiological Monitoring System"; 026843-000620US entitled "Adherent Device for Cardiac Rhythm Management"; 026843-000710US entitled "Adherent Device for Respiratory Monitoring"; 026843-000810US entitled "Adherent Athletic Monitor"; 026843-000910US entitled "Adherent Emergency Monitor"; 026843-001320US entitled "Adherent Device with Physiological Sensors"; 026843-001410US entitled "Medical Device Automatic Start-up upon Contact to Patient Tissue"; 026843-001900US entitled "System and Methods for Wireless Body Fluid Monitoring"; 026843-002010US entitled "Adherent Cardiac Monitor with Advanced Sensing Capabilities"; 026843-002410US entitled "Adherent Device for Sleep Disordered Breathing"; 026843-002710US entitled "Dynamic Pairing of Patients to Data Collection Gateways"; 026843-003010US entitled "Adherent Multi-Sensor Device with Implantable Device Communications Capabilities"; 026843-003210US entitled "Adherent Multi-Sensor Device with Empathic Monitoring"; 026843-003310US entitled "Energy Management for Adherent Patient Monitor"; and 026843-003410US entitled "Tracking and Security for Adherent Patient Monitor."

BACKGROUND OF THE INVENTION

Field of the Invention

[0004] This invention relates generally to a patient monitoring system, and more particularly to a heart failure (HF) monitoring system.

[0005] Frequent monitoring of patients permits the patients' physician to detect worsening symptoms as they begin to occur, rather than waiting until a critical condition has been reached. As such, home monitoring of patients with chronic conditions is becoming increasingly popular in the health care industry for the array of benefits it has the potential to provide. Potential benefits of home monitoring are numerous and include: better tracking and management of chronic disease conditions, earlier detection of changes in the patient condition, and reduction of overall health care expenses associated with long term disease management. The home monitoring of a number of diverse "chronic diseases" is of interest, where such diseases include diabetes, dietary disorders such as anorexia and obesity, anxiety, depression, epilepsy, respiratory diseases, AIDS and other chronic viral conditions, conditions associated with the long term use of immunosuppressants, e.g., in transplant patients, asthma, chronic hypertension, chronic use of anticoagulants, and the like.

[0006] Of particular interest in the home monitoring sector of the health care industry is the remote monitoring of patients with heart failure (HF), also known as congestive heart failure. HF is a syndrome in which the heart is unable to efficiently pump blood to the vital organs. Most instances of HF occur because of a decreased myocardial capacity to contract (systolic dysfunction). However, HF can also result when an increased pressure-stroke-volume load is imposed on the heart, such as when the heart is unable to expand sufficiently during diastole to accommodate the ventricular volume, causing an increased pressure load (diasystolic dysfunction).

[0007] In either case, HF is characterized by diminished cardiac output and/or damming back of blood in the venous system. In HF, there is a shift in the cardiac function curve and an increase in blood volume caused in part by fluid retention by the kidneys. Indeed, many of the significant morphologic changes encountered in HF are distant from the heart and are produced by the hypoxic and congestive effects of the failing circulation upon other organs and tissues. One of the major symptoms of HF is edema, which has been defined as the excessive accumulation of interstitial fluid, either localized or generalized.

[0008] HF is the most common indication for hospitalization among adults over 65 years of age, and the rate of admission for this condition has increased progressively over the past two decades. It has been estimated that HF affects more than 3 million patients in the U.S. (O'Connell, J. B. et al., *J. Heart Lung Transpl.,* 13(4):S107-112(1993)).

[0009] In the conventional management of HF patents, where help is sought only in crisis, a cycle occurs where patients fail to recognize early symptoms and do not seek timely help from their care-givers, leading to emergency department admissions (Miller, P. Z., *Home monitoring for congestive heart failure patients,* Caring Magazine, 53-54 (August 1995)). Recently, a prospective, randomized trial of 282 patients was conducted to assess the effect of the intervention on the rate of admission, quality of life, and cost of medical care. In this study, a nurse-directed, multi-disciplinary intervention (which consisted of comprehensive education of the patient and family, diet, social-service consultation and planning, review of medications, and intensive assessment of patient condition and follow-up) resulted in fewer readmissions than the conventional treatment group and a concomitant overall decrease in the cost of care (Rich, M. W. et al., *New Engl. J. Med.,* 333:1190-95 (1995)). Similarly, comprehensive discharge planning and a home follow-up program was shown to decrease the number of readmissions and total hospital charges in an elderly population (Naylor, M. et al., *Amer. College Physicians,* 120:999-1006 (1994)). Therefore, home monitoring is of particular interest in the HF management segment of the health care industry.

[0010] Another area in which home-monitoring is of particular interest is in the remote monitoring of a patient param-

eter that provides information on the titration of a drug, particularly with drugs that have a consequential effect following administration, such as insulin, anticoagulants, ACE inhibitors, .beta-blockers, etc.

[0011] Although a number of different home monitoring systems have been developed, there is continued interest in the development of new monitoring systems. Of particular interest would be the development of a system that provides for improved patient compliance, ease of use, etc. Of more particular interest would be the development of such a system that is particularly suited for use in the remote monitoring of patients suffering from HF.

[0012] There is a need for an improved home monitoring of patients with chronic conditions. There is a further need for an improved heart failure (HF) monitoring system.

BRIEF SUMMARY OF THE INVENTION

[0013] In a first aspect, embodiments of the present invention provide a system for tracking a patient's physiological status and detecting and predicting negative physiological events. The system includes a detecting system and a remote monitoring system. The detecting system includes a plurality of sensors that provide an indication of at least one physiological event of a patient, and a wireless communication device coupled to the plurality of sensors, and configured to transfer patient data from the plurality of sensors to a remote monitoring system. The a remote monitoring system coupled to the wireless communication device, wherein during a registration period, the detecting system being activated for a first time and communicating with the remote monitoring system to register the detecting system and activate data logging.

[0014] In many embodiments, during the registration period the detecting system titrates a sensitivity of each of a sensor of the plurality of sensors.

[0015] In many embodiments, the system is configured to automatically detect events. The detected events may include at least one of, high noise states, low noise states, physiological quietness, sensor continuity and compliance.

[0016] In many embodiments, in response to a detected physiological event, patient states are identified. The patient states may include, physiological quietness, rest, relaxation, agitation, movement, lack of movement and a higher level of patient activity.

[0017] In many embodiments, the sensor is selected from at least one of, an accelerometer, a heart rate sensor, including ECG electrodes, a heart rate sensor, including an ECG sensor, a heart rhythm sensor, a body surface temperature sensor, an ambient temperature sensor, a bioimpedance sensor, a posture sensor, a respiration sensor, a clock, an activity sensor, an optical sensor, a blood pressure sensor and a weight sensor. The activity sensor may be selected from at least one of, ball switch, accelerometer, minute ventilation, HR, bioimpedance noise, skin temperature/heat flux, BP, muscle noise and posture.

[0018] In many embodiments, the system further comprise a sensor continuity indicator.

[0019] In many embodiments, the sensor continuity indicator is configured to test to determine if a sensor is at least one of, in contact with a skin surface, has failed and has poor performance.

[0020] In many embodiments, the system further comprise a compliance indicator.

[0021] In many embodiments, the compliance indicator determines if a sensor is coupled to a skin surface to provide a sensor output.

[0022] In many embodiments, the compliance indicator is an intermittent tester to determine that sensor continuity is intact.

[0023] In many embodiments, the compliance indicator is configured to respond to loss of sensor continuity with an alarm and notify a patient or third parry to take an action.

[0024] In many embodiments, the alarm provides a visual, auditory or electronic signal.

[0025] In many embodiments, the alarm notifies at least one of, the patient, a clinic and a health care provider.

[0026] In many embodiments, the compliance indicator detects if a patient is not using the detecting system.

[0027] In many embodiments, in response to the compliance indicator indicating that a patient is not in compliance, a signal is used to force compliance.

[0028] In many embodiments, the detecting system communicates with the remote monitoring system periodically or in response to a trigger event.

[0029] In many embodiments, the trigger event is selected from 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 on a patch and a patch replacement.

BRIEF DESCRIPTION OF THE DRAWINGS

[0030] FIG. **1** is a block diagram illustrating one embodiment of a patient monitoring system of the present invention.

[0031] FIGS. **2**A and **2**B illustrate an exploded view and side view of embodiments of an adherent device with sensors configured to be coupled to the skin of a patient for monitoring purposes;

[0032] FIG. **3** illustrates one embodiment of an energy management device that is coupled to the plurality of sensors of FIG. **1**.

[0033] FIG. **4** illustrates one embodiment of present invention illustrating logic resources configured to receive data from the sensors and/or the processed patient for monitoring purposes, analysis and/or prediction purposes.

[0034] FIG. **5** illustrates an embodiment of the patient monitoring system of the present invention with a memory management device.

[0035] FIG. **6** illustrates an embodiment of the patient monitoring system of the present invention with an external device coupled to the sensors.

[0036] FIG. **7** illustrates an embodiment of the patient monitoring system of the present invention with a notification device.

[0037] FIG. **8** is a block diagram illustrating an embodiment of the present invention with sensor leads that convey signals from the sensors to a monitoring unit at the detecting system, or through a wireless communication device to a remote monitoring system.

[0038] FIG. **9** is a block diagram illustrating an embodiment of the present invention with a control unit at the detecting system and/or the remote monitoring system.

[0039] FIG. **10** is a block diagram illustrating an embodiment of the present invention where a control unit encodes patient data and transmits it to a wireless network storage unit at the remote monitoring system.

[0040] FIG. **11** is a block diagram illustrating one embodiment of an internal structure of a main data collection station at the remote monitoring system of the present invention.

[0041] FIG. **12** is a flow chart illustrating an embodiment of the present invention with operation steps performed by the system of the present invention in transmitting information to the main data collection station.

DETAILED DESCRIPTION OF THE INVENTION

[0042] The preset invention is directed to an adherent multi-sensor patient monitor or adherent device capable of tracking a patient's physiological status and detecting and predicting negative physiological events. A variety of features related to data collection, management, and communication are disclosed.

[0043] The adherent device may have a self-registration feature. When the adherent multi-sensor patient monitor is activated for the first time, it may communicate with a remote center to register the device and activate data logging. During this registration period, the device may also titrate the sensitivity of each of its physiologic sensors.

[0044] The adherent multi-sensor patient monitor may have the capability to automatically detect events and respond appropriately:

[0045] 1. States during which data collection is inappropriate (e.g. showering)

[0046] 2. States during which data collection is particularly desirable. Such states may include physiological quietness, such as sleep, determined with one or more of the following sensors: posture, respiration, clock, activity, light, ECG, bioimpedance, blood pressure, temperature, and weight.

[0047] 3. An electrode continuity indicator. This may be an intermittent tester to determine that electrode continuity is intact. The device may respond to loss of electrode continuity with an indicator (alarm, LED, etc.) to notify the patient to take an action.

[0048] 4. A compliance indicator (e.g. detected absence of movement). If the patient is not using the device due to non-compliance, an irritating signal may be used to force compliance.

[0049] The adherent multi-sensor patient monitor may communicate with the remote center periodically, or in response to a trigger. Triggers may include time of day, memory full, patient initiated, remote center initiated, device diagnostic (e.g. low battery), alarm trigger, mechanical trigger on patch (e.g. button), and/or patch replacement.

[0050] While the present invention is intended for heart failure patient monitoring, the system may be applicable to any human application in which wireless physiological monitoring and prediction is required.

[0051] Referring to FIG. **1**, one embodiment of 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.

[0052] In one specific embodiment, the system **10** is used for decompensation prediction of a heart failure patient. A detecting system, denoted as **12**, is provided. The detecting system **12** includes an adherent device that adheres to the patient's skin with a plurality of sensors **14** that provide an indication of at least one physiological event of a patient. The plurality of sensors are coupled to the patient's thorax. 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 heart failure status and predict impending decompensation of the patient. The detecting system **12** is activated for a first time and communicating with the remote monitoring system to register the detecting system and activate data logging. During the registration period the detecting system **12** titrates a sensitivity of each sensor **14**.

[0053] FIGS. **2**A and **2**B show embodiments of the plurality of sensors **14** with supported with an adherent device **200** configured to adhere to the skin. Adherent device **200** is described in U.S. application Ser. No. 60/972,537, the full disclosure of which has been previously incorporated herein by reference. As illustrated in an exploded view of the adherent device, a cover **262**, batteries **250**, electronics **230**, including but not limited to flex circuits and the like, an adherent tape **210**T, the plurality of sensors may comprise electrodes and sensor circuitry, and hydrogels which interface the plurality of sensors **14** with the skin, are provided.

[0054] Adherent device **200** comprises a support, for example adherent patch **210**, configured to adhere the device to the patient. Adherent patch **210** comprises a first side, or a lower side **210**A, that is oriented toward the skin of the patient when placed on the patient. In many embodiments, adherent patch **210** comprises a tape **210**T which is a material, preferably breathable, with an adhesive **216**A. Patient side **210**A comprises adhesive **216**A to adhere the patch **210** and adherent device **200** to patient P. Electrodes **212**A, **212**B, **212**C and **212**D 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 **214**A, gel **214**B, gel **214**C and gel **214**D can each be positioned over electrodes **212**A, **212**B, **212**C and **212**D, respectively, to provide electrical conductivity between the electrodes and the skin of the patient. In many embodiments, the electrodes can be affixed to the patch **210**, for example with known methods and structures such as rivets, adhesive, stitches, etc. In many embodiments, patch **210** comprises a breathable material to permit air and/or vapor to flow to and from the surface of the skin. In some embodiments, a printed circuit board (PCB), for example flex PCB **220**, may be connected to upper side **200**B of patch **210** with connectors. In some embodiments, additional PCB's, for example rigid PCB's **220**A, **220**B, **220**C and **220**D, can be connected to flex PCB **220**. Electronic components **230** can be connected to flex PCB **220** and/or mounted thereon. In some embodiments, electronic components **230** can be mounted on the additional PCB's.

[0055] Electronic circuitry and components **230** comprise circuitry and components to take physiologic measurements, transmit data to remote center and receive commands from remote center. In many embodiments, electronics components **230** may comprise known low power circuitry, for example complementary metal oxide semiconductor (CMOS) circuitry components. Electronics components **230** comprise an activity sensor and activity circuitry, impedance circuitry and electrocardiogram circuitry, for example ECG circuitry. In some embodiments, electronics circuitry may comprise a microphone and microphone circuitry to detect an

audio signal from within the patient, and the audio signal may comprise a heart sound and/or a respiratory sound, for example an S3 heart sound and a respiratory sound with rales and/or crackles. Electronics circuitry and components **230** may comprise a temperature sensor, for example a thermistor, and temperature sensor circuitry to measure a temperature of the patient, for example a temperature of a skin of the patient.

[0056] A cover **262** can extend over the batteries, electronic components and flex printed circuit board. In many embodiments, an electronics housing **260** may be disposed under cover **262** to protect the electronic components, and in some embodiments electronics housing **260** may comprise an encapsulant over the electronic components and PCB. In some embodiments, cover **262** can be adhered to adhesive patch with an adhesive. In many embodiments, electronics housing **260** may comprise a water proof material, for example a sealant adhesive such as epoxy or silicone coated over the electronics components and/or PCB. In some embodiments, electronics housing **260** may comprise metal and/or plastic. Metal or plastic may be potted with a material such as epoxy or silicone.

[0057] 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.

[0058] Adherent device **200** comprises several layers. Gel **214**A, or gel layer, is positioned on electrode **212**A to provide electrical conductivity between the electrode and the skin. Electrode **212**A may comprise an electrode layer. Adhesive patch **210** may comprise a layer of breathable tape **210**T, for example a known breathable tape, such as tricot-knit polyester fabric. An adhesive **216**A, for example a layer of acrylate pressure sensitive adhesive, can be disposed on underside **210**A of patch **210**. A gel cover **280**, or gel cover layer, for example a polyurethane non-woven tape, can be positioned over patch **210** comprising the breathable tape. A PCB layer, for example flex PCB **220**, or flex PCB layer, can be positioned over gel cover **280** with electronic components **230** connected and/or mounted to flex PCB **220**, for example mounted on flex PCB so as to comprise an electronics layer disposed on the flex PCB. In many embodiments, the adherent device may comprise a segmented inner component, for example the PCB, for limited flexibility. In many embodiments, the electronics layer may be encapsulated in electronics housing **260** which may comprise a waterproof material, for example silicone or epoxy. In many embodiments, the electrodes are connected to the PCB with a flex connection, for example trace **223**A of flex PCB **220**, so as to provide strain relive between the electrodes **212**A, **212**B, **212**C and **212**D and the PCB. Gel cover **280** can inhibit flow of gel **214**A and liquid. In many embodiments, gel cover **280** can inhibit gel **214**A from seeping through breathable tape **210**T to maintain gel integrity over time. Gel cover **280** can also keep external moisture from penetrating into gel **214**A. Gel cover **280** may comprise at least one aperture **280**A sized to receive one of the electrodes. In many embodiments, cover **262** can encase the flex PCB and/or electronics and can be adhered to at least one of the electronics, the flex PCB or the adherent patch, so as to protect the device. In some embodiments, cover **262** attaches to adhesive patch **210** with adhesive **216**B. Cover **262** can comprise many known biocompatible cover, housing and/or casing materials, for example silicone. In many embodiments, cover **262** comprises an outer polymer cover to provide smooth contour without limiting flexibility. In some embodiments, cover **262** may comprise a breathable fabric. Cover **262** may comprise many known breathable fabrics, for example breathable fabrics as described above. In some embodiments, the breathable fabric may comprise polyester, polyamide, and/or elastane (Spandex™) to allow the breathable fabric to stretch with body movement. In some embodiments, the breathable tape may contain and elute a pharmaceutical agent, such as an antibiotic, anti-inflammatory or antifungal agent, when the adherent device is placed on the patient.

[0059] In one embodiment, the wireless communication device **16** is configured to receive instructional data from the remote monitoring system.

[0060] As illustrated in FIG. **3**, an energy management device **19** is 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.

[0061] In one embodiment, the energy management device **19** is configured to manage energy by at least one of, a thermoelectric 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.

[0062] The system **10** is configured to automatically detect events. The system **10** automatically detects events by at least one of, high noise states, low 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.

[0063] The system uses an intelligent combination of sensors to enhance detection and prediction capabilities, as more fully discloses in U.S. Provisional Application No. 60/972,537, filed Sep. 14, 2007, and U.S. Provisional Application No. 61/055,666, filed May 23, 2008, both entitled "Adherent Device With Multiple Physiological Sensors", the full disclosures of which is incorporated herein by reference and as more fully explained below.

[0064] 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.

[0065] 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.

[0066] 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.

[0067] 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. The monitoring unit can be at the remote monitoring system **18**.

[0068] 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**.

[0069] As shown in FIG. **4**, logic resources **24** are provided that take the data from the sensors **14**, and/or the processed patient data from the processor **20**, to predict an impending decompensation. The logic resources **24** can be at the remote monitoring system **18** or at the detecting system **12**, such as in the monitoring unit **22**.

[0070] In one embodiment, a memory management device **25** is provided as illustrated in FIG. **5**. In various embodiments, the memory management device **25** performs one or more of data compression, prioritizing of sensing by a sensor **14**, monitoring all or some of sensor data by all or a portion of the sensors **14**, sensing by the sensors **14** in real time, noise blanking to provide that sensor data is not stored if a selected noise level is determined, low-power of battery caching and decimation of old sensor data.

[0071] 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. Each sensor **14** is preferably sealed, such as housed in a hermetically sealed package. In one embodiment, at least a portion of the sealed packages include a power source, a memory, logic resources and a wireless communication device. In one embodiment, the sensors **14** can include, flex circuits, thin film resistors, organic transistors and the like. The sensors **14** can include ceramics to enclose the electronics. Additionally, the sensors **14** can include drug eluting coatings, including but not limited to, an antibiotic, anti-inflammatory agent, and the like.

[0072] 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, SpO_2, 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.

[0073] 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**.

[0074] 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.

[0075] 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.

[0076] 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.

[0077] 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.

[0078] Referring to FIG. **6**, an external device **38**, including a medical treatment device, can be 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.

[0079] 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.

[0080] 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**.

[0081] 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.

[0082] 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**.

[0083] As illustrated in FIG. **7**, in another embodiment, a notification device **42** is coupled to the detecting system **12** and the remote monitoring system **18**. The notification device **42** is configured to provide notification when values received from the sensors **14** are not within acceptable physiological ranges. The notification device **42** can be at the remote monitoring system **18** or at the monitoring unit **22** that is part of the detecting system **12**. A variety of notification devices **42** can be utilized, including but not limited to, a visible patient indicator, an audible alarm, an emergency medical service notification, a call center alert, direct medical provider notification and the like. The notification device **42** provides notification to a variety of different entities, including but not limited to, the patient, a caregiver, the remote monitoring system, a spouse, a family member, a medical provider, from one device to another device such as the external device **38**, and the like.

[0084] 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.

[0085] 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.

[0086] 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.

[0087] 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.

[0088] By way of illustration, and without limitation, the patient can be a congestive heart failure patient. Heart failure status is 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.

[0089] In another embodiment, heart failure 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 heart failure 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 heart failure status, and the like.

[0090] 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**.

[0091] 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**.

[0092] Referring now to FIG. **8**, for each sensor **14**, a sensor lead **112** and **114** conveys signals from the sensor **14** to the monitoring unit **22** at the detecting system **12**, or through the wireless communication device **16** to the remote monitoring system **18**. In one embodiment, each signal from a sensor **14** is first passed through a low-pass filter **116**, at the detecting system **12** or at the remote monitoring system **18**, to smooth

the signal and reduce noise. The signal is then transmitted to an analog-to-digital converter **118**A, which transforms the signals into a stream of digital data values, that can be stored in a digital memory **118**B. From the digital memory **118**B, 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.

[0093] 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 **118**A, digital memories **118**B 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.

[0094] As can be seen in FIG. **9**, a control unit **126** is included at the detecting system **12**, the remote monitoring system **18** or at both locations.

[0095] In one embodiment, the control unit **126** can be a 486 microprocessor. 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, cardiac rhythm management device, scale, a device that dispenses medication that can indicate the medication has been dispensed.

[0096] The control unit **126** can be powered by AC inputs which are coupled to internal AC/DC converters **134** that generate multiple DC voltage levels. After the control unit **126** has collected the patient data from the sensors **14**, the control unit **126** encodes the recorded patient data and transmits the patient data through the wireless communication device **16** to transmit the encoded patient data to a wireless network storage unit **128** at the remote monitoring system **18** as shown in FIG. **10**. In another embodiment, wireless communication device **16** transmits the patient data from the sensors **14** to the control unit **126** when it is at the remote monitoring system **18**.

[0097] 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.

[0098] Referring now to FIG. **11**, one embodiment of an internal structure of a main data collection station **130** at the remote monitoring system **18**, is illustrated. The patient data can be transmitted by the remote monitoring system **18** by either the wireless communication device **16** or conventional modem to the wireless network storage unit **128**. After receiving the patient data, the wireless network storage unit **128** can be accessed by the main data collection station **130**. The main data collection station **130** allows the remote monitoring system **18** to monitor the patient data of numerous patients from a centralized location without requiring the patient or a medical provider to physically interact with each other.

[0099] 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**.

[0100] 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.

[0101] 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 cannot be breached.

[0102] 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.

[0103] 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 in the event that an alert is required. 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.

[0104] 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.

[0105] 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.

[0106] 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.

[0107] 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**.

[0108] 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**.

[0109] Referring now to the flow chart of FIG. **12**, if an external device **38** fails to generate a valid reading, as illustrated in step A, the control unit **126** fills the portion of the patient data packet associated with the external device **38** with a null indicator. The null indicator can be the lack of any characters between commas in the patient data packet. The lack of characters in the patient data packet can indicate that the patient was not available for the patient data recording. The null indicator in the patient data packet can be interpreted by the main data collection station **130** at the remote monitoring system **18** as a failed attempt to record the patient data due to the unavailability of the patient, a malfunction in one or more of the sensors **14**, or a malfunction in one of the external devices **38**. The null indicator received by the main data collection station **130** can indicate that the transmission from the detecting system **12** to the remote monitoring system **18** was successful. In one embodiment, the integrity of the data packet received by the main data collection station **130** can be determined using a cyclic redundancy code, CRC-16, check sum algorithm. The check sum algorithm can be applied to the data when the message can be sent and then again to the received message.

[0110] 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.

[0111] 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.

[0112] 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.

[0113] 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.

[0114] 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.

[0115] 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.

[0116] 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.

[0117] 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 sys-

tem **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:

[0118] 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.

[0119] 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.

[0120] 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.

[0121] 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**.

[0122] 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.

[0123] While the invention is susceptible to various modifications and alternative constructions, certain illustrated embodiments thereof are shown in the drawings and have been described above in detail. It should be understood, however, that there is no intention to limit the invention to the specific form or forms disclosed, but on the contrary, the intention is to cover all modifications, alternative constructions, and equivalents falling within the spirit and scope of the invention.

What is claimed is:

1. A system for tracking a patient's physiological status and detecting and predicting negative physiological events, comprising:

a detecting system, including:

a plurality of sensors that provide an indication of at least one physiological event of a patient,

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

a remote monitoring system coupled to the wireless communication device, wherein during a registration period, the detecting system being activated for a first time and communicating with the remote monitoring system to register the detecting system and activate data logging.

2. The system of claim **1**, wherein during the registration period the detecting system titrates a sensitivity of each of a sensor of the plurality of sensors.

3. The system of claim **1**, wherein the system is configured to automatically detect events.

4. The system of claim **3**, wherein the system automatically detects events by at least one of, high noise states, low noise states, physiological quietness, sensor continuity and compliance.

5. The system of claim **1**, wherein in response to a detected physiological event, patient states are identified.

6. The system of claim **5**, wherein patient states include, physiological quietness, rest, relaxation, agitation, movement, lack of movement and a higher level of patient activity.

7. The system of claim **1**, wherein each of a sensor is selected from at least one of, an accelerometer, a heart rate sensor, including ECG electrodes, a heart rate sensor, including an ECG sensor, a heart rhythm sensor, a body surface temperature sensor, an ambient temperature sensor, a bioimpedance sensor, a posture sensor, a respiration sensor, a clock, an activity sensor, an optical sensor, a blood pressure sensor and a weight sensor.

8. The system of claim **7**, wherein the activity sensor is selected from at least one of, ball switch, accelerometer, minute ventilation, HR, bioimpedance noise, skin temperature/heat flux, BP, muscle noise and posture.

9. The system of claim **1**, further comprising:
a sensor continuity indicator.

10. The system of claim **9**, wherein the sensor continuity indicator is configured to test to determine if a sensor is at least one of, in contact with a skin surface, has failed and has poor performance.

11. The system of claim **1**, further comprising:
a compliance indicator.

12. The system of claim **11**, wherein the compliance indicator determines if a sensor is coupled to a skin surface to provide a sensor output.

13. The system of claim **11**, wherein the compliance indicator is an intermittent tester to determine that sensor continuity is intact.

14. The system of claim **11**, wherein the compliance indicator is configured to respond to loss of sensor continuity with an alarm and notify a patient or third parry to take an action.

15. The system of claim **14**, wherein the alarm provides a visual, auditory or electronic signal.

16. The system of claim **14**, wherein the alarm notifies at least one of, the patient, a clinic and a health care provider.

17. The system of claim **11**, wherein the compliance indicator detects if a patient is not using the detecting system.

18. The system of claim **17**, wherein in response to the compliance indicator indicating that a patient is not in compliance, a signal is used to force compliance.

19. The system of claim **1**, wherein the detecting system communicates with the remote monitoring system periodically or in response to a trigger event.

20. The system of claim **19**, wherein the trigger event is selected from 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 on a patch and a patch replacement.

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摘要(译)

一种用于跟踪患者的生理状态并检测和预测负面生理事件的系统，具有检测系统和远程监控系统。检测系统包括：多个传感器，其提供患者的至少一个生理事件的指示;以及无线通信设备，其耦合到多个传感器，并且被配置为将患者数据从多个传感器传输到远程监控系统。。一种耦合到无线通信设备的远程监控系统，其中在注册期间，检测系统第一次被激活并与远程监控系统通信以注册检测系统并激活数据记录。