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(54) MULTI-SENSOR PATIENT MONITOR TO DETECT IMPENDING CARDIAC DECOMPENSATION

MULTI-SENSOR-PATIENTENMONITOR ZUM NACHWEIS VON BEVORSTEHENDER HERZDEKOMPENSATION

MONITEUR MULTICAPTEURS POUR PATIENT CONÇU POUR DÉTECTER UNE DÉCOMPENSATION CARDIAQUE IMMINENTE

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(56) References cited:
WO-A2-2007/103835
US-A- 6 049 730
US-A1- 2005 113 703
US-A1- 2006 064 030
US-A1- 2006 235 316
US-A1- 2007 106 167
US-A1- 2007 129 622
US-A1- 2007 142 732
US-A1- 2007 167 850
US-A1- 2007 173 705
US-A1- 2007 208 262
US-B1- 6 491 647

- **PINNA G D ET AL: "Nocturnal periodic breathing is an independent predictor of cardiac death and multiple hospital admissions in Heart failure", COMPUTERS IN CARDIOLOGY, 2006, IEEE, PISCATAWAY, NJ, USA, 17 September 2006 (2006-09-17), pages 837-840, XP031249101, ISBN: 978-1-4244-2532-7**

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(Cont. next page)

- ELLERY S ET AL: "Predicting mortality and rehospitalization in heart failure patients with Home Monitoring-; The Home CARE pilot study", CLINICAL RESEARCH IN CARDIOLOGY, STEINKOPFF-VERLAG, DA, vol. 95, no. 3, 1 April 2006 (2006-04-01), pages iii29-iii35, XP019382870, ISSN: 1861-0692, DOI: 10.1007/S00392-006-1306-6
- PINNA ET AL: "Home telemonitoring of vital signs and cardiorespiratory signals in heart failure patients: System architecture and feasibility of the HHH model", INTERNATIONAL JOURNAL OF CARDIOLOGY, ELSEVIER SCIENCE PUBLISHERS, AMSTERDAM, NL, vol. 120, no. 3, 19 July 2007 (2007-07-19) , pages 371-379, XP022157300, ISSN: 0167-5273, DOI: 10.1016/J.IJCARD.2006.10.029
- TEN-HMS INVESTIGATORS ET AL: "Noninvasive Home Telemonitoring for Patients With Heart Failure at High Risk of Recurrent Admission and Death", JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY, ELSEVIER, NEW YORK, NY, US, vol. 45, no. 10, 17 May 2005 (2005-05-17), pages 1654-1664, XP027719672, ISSN: 0735-1097 [retrieved on 2005-05-17]

Description

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention. The present invention relates to patient monitoring, and more specifically to patient monitoring to detect and/or avoid impending cardiac decompensation. Although embodiments make specific reference to monitoring impedance and electrocardiogram signals with an adherent patch, the system methods and device described herein may be applicable to many applications in which physiological monitoring is used, for example wireless physiological monitoring with implantable devices for extended periods.

[0002] Patients are often treated for diseases and/or conditions associated with a compromised status of the patient, for example a compromised physiologic status such as heart disease. In some instances a patient may have suffered a heart attack and require care and/or monitoring after release from the hospital. While such long term care may be at least partially effective, many patients are not sufficiently monitored and eventually succumb to cardiac decompensation, or heart failure. One example of a device that may be used to monitor a patient is the Holter monitor, or ambulatory electrocardiography device. Although such a device may be effective in measuring electrocardiography, such measurements alone may not be sufficient to reliably detect and/or avoid an impending cardiac decompensation.

[0003] In addition to measuring heart signals with electrocardiograms, known physiologic measurements include impedance measurements. For example, transthoracic impedance measurements can be used to measure hydration and respiration. Although transthoracic measurements can be useful, such measurements may use electrodes that are positioned across the midline of the patient, and may be somewhat uncomfortable and/or cumbersome for the patient to wear.

[0004] Work in relation to embodiments of the present invention suggests that known methods and apparatus for long term monitoring of patients may be less than ideal to detect and/or avoid an impending cardiac decompensation. In at least some instances, cardiac decompensation can be difficult to detect, for example in the early stages. At least some of the known devices may not collect the right kinds of data to treat patients optimally. For example, although successful at detecting and storing electrocardiogram signals, devices such as the Holter monitor can be somewhat bulky and may not collect all of the kinds of data that would be ideal to diagnose and/or treat a patient, for example to detect decompensation. In at least some instances, devices that are worn by the patient may be somewhat uncomfortable, which may lead to patients not wearing the devices and not complying with direction from the health care provider, such that data collected may be less than ideal. Although implantable devices may be used in some instances, many of these devices can be invasive and/or costly, and may suffer at least some of the shortcomings of known wearable devices. As a result, at least some patient are not adequately monitored, and may go into cardiac decompensation, or even die. Work in relation to embodiments of the present invention suggests that improved monitoring may avoid patient trauma, save lives, and decrease health care costs.

[0005] Therefore, a need exists for improved patient monitoring. Ideally, such improved patient monitoring would avoid at least some of the short-comings of the present methods and devices.

[0006] Pinna, G D, et al, "Nocturnal Periodic Breathing Is an Independent Predictor of Cardiac Death and Multiple Hospital Admissions in Heart Failure", Computers in Cardiology, 2006, IEEE, Piscataway, NJ, USA, 17 September 2006 (2006-09-17), pages 837-840, XP031249101, ISBN: 978-1-4244-2532-7, discloses an assessment of the association of periodic breathing with mortality and hospital re-admissions. The study demonstrates that in mild-to-moderate heart failure patients nocturnal breathing disorders, quantified by the apnea/hypopnea index and by the duration of periodic breathing, have a prognostic value independent of known major clinical and functional predictors. A finding of the investigation is that nocturnal breathing disorders are significant and independently associated with a higher risk of multiple hospital re-admissions for heart failure patients.

[0007] WO 2007/103835 A2 discloses a wearable/disposable physiologic monitor comprising an integrated circuit including signal conditioning circuitry, a real-time clock, digital control logic, and mode-selection logic for setting an operating mode of the circuit to stand-alone or peripheral modes. In the stand-alone mode, the digital control logic periodically stores data packets including multiple sensor data types in a digital memory. In the peripheral mode, the data packets are transmitted to a microcontroller for processing. The monitor includes sensors such as electrocardiogram (ECG) electrodes, accelerometers, and a temperature sensor. Monitor and/or firmware piracy are reduced by initializing physiologic monitors in the field upon verifying user authorization.; An initialization console activates and configures the monitor by transferring an authorization code, firmware, a set of enabled sensors and sampling rates, a set of customized voice messages, and other parameters, and/or by programming a programmable logic array.

BRIEF SUMMARY OF THE INVENTION

[0008] Embodiments of the present invention, the scope of which is defined by the appended claims, provide systems for the detection of an impending cardiac decompensation. In many embodiments, the impending decompensation can

be detected early enough to avoid, or at least delay, the impending decompensation, such that patient trauma and/or expensive ICU care can be avoided.

[0009] In the invention as claimed, embodiments of the present invention provide a system to detect impending cardiac decompensation of a patient. The system comprises circuitry to measure at an electrocardiogram signal of the patient and a hydration signal of the patient. A processor system comprising a tangible medium in communication with the circuitry is configured to combine the electrocardiogram signal and the hydration signal to detect the impending cardiac decompensation.

[0010] In some embodiments, the processor system comprises a least one processor remote from the patient configured to combine two to detect the decompensation.

[0011] In some embodiments, the processor system comprises a processor supported with the patient configured to receive instructions transmitted from a remote site and combine the two in response to the instructions to detect the impending cardiac decompensation.

[0012] In other non-claimed examples, the at least two comprise at least three of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal and the at least three are measured and combined to detect the impending cardiac decompensation. In specific embodiments, the at least three comprise at least four of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal and the at least four are measured and combined to detect the impending cardiac decompensation.

[0013] In other non-claimed examples the processor system simultaneously uses the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal to determine impending cardiac decompensation. The at least two signals can be used simultaneously in many ways,

[0014] In many embodiments, combining comprises the processor system using the electrocardiogram signal and the hydration signal. to look up a value in a previously existing array. In some non-claimed examples, combining comprises at least one of adding, subtracting, multiplying, scaling or dividing the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal. In some embodiments, the at least two of the electrocardiogram signal, the hydration signal, the respiration signal, or the activity signal can be combined with at least one of a weighted combination, a tiered combination or a logic gated combination, a time weighted combination or a rate of change.

[0015] In many embodiments, the processor system determines a flag status in response to the electrocardiogram signal and the hydration signal. The processor system determines the flag status in response to a change in the the electrocardiogram signal and the hydration signal. In some embodiments, the processor system affects the circuitry to make additional signal measurements of the patient in response to the flag status.

[0016] In many embodiments, the processor system combines the electrocardiogram signal and the hydration signal in response to a time of day.

[0017] In many embodiments, the electrocardiogram signal and the hydration signal comprise at least one of a derived signal, a time averaged signal, a filtered signal or a raw signal.

[0018] In many embodiments, the processor determines baseline values of the patient for the electrocardiogram signal and the hydration signal. The electrocardiogram signal and the hydration signals may comprise changes from the baseline values.

[0019] In many embodiments, the electrocardiogram signal and the hydration signal comprise differences from baseline values of a patient population. The impending decompensation is detected in response to the differences from the baseline value of the patient population.

[0020] In many embodiments, the hydration signal comprises an impedance signal.

[0021] In a non-claimed example, the activity signal may comprise an accelerometer signal to determine a posture of the patient. In specific examples, the accelerometer signal may comprise a three dimensional inclination signal to determine a three dimensional orientation of the patient.

[0022] In non-claimed examples, the processor system combines a temperature signal with the at least two of the electrocardiogram signal, the hydration signal, a respiration signal or the activity signal to detect the impending cardiac decompensation.

[0023] In many embodiments, the processor transmits the signal to a remote site where the signal are combined to detect the impending cardiac decompensation.

[0024] In a non-claimed example, instructions are transmitted from a remote site to a processor supported with the patient. The processor combines signals in response to the instructions to detect the impending cardiac decompensation

BRIEF DESCRIPTION OF THE DRAWINGS

[0025]

Figure 1A shows a patient and a monitoring system comprising an adherent device, according to embodiments of the present invention;

Figure 1B shows a bottom view of the adherent device as in Figure 1A comprising an adherent patch;
Figure 1C shows a top view of the adherent patch, as in Figure 1B;
Figure 1D shows a printed circuit boards and electronic components over the adherent patch, as in Figure 1C;
Figure 1D-1 shows an equivalent circuit that can be used to determine optimal frequencies for determining patient hydration, according to embodiments of the present invention;
Figure 1E shows batteries positioned over the printed circuit board and electronic components as in Figure ID;
Figure IF shows a top view of an electronics housing and a breathable cover over the batteries, electronic components and printed circuit board as in Figure IE;
Figure 1G shows a side view of the adherent device as in Figures 1A to IF;
Figure 1H shown a bottom isometric view of the adherent device as in Figures 1A to 1G;
Figure 2A shows a method of predicting an impending cardiac decompensation, according to embodiments of the present invention; and
Figures 3A and 3B show clinical data measured with an adherent patch device.

DETAILED DESCRIPTION OF THE INVENTION

[0026] Embodiments of the present invention provide systems for the detection of an impending cardiac decompensation. In many embodiments, the impending decompensation can be detected early enough to avoid, or at least delay, the impending decompensation, such that patient trauma and/or expensive ICU care can be avoided.

[0027] 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.

[0028] Figure 1A 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 100. Adherent device 100 can be adhered to a patient P at many locations, for example thorax T of patient P. In many examples, the adherent device may adhere to one side of the patient, from which data from the one side 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.

[0029] Monitoring system 10 includes components to transmit data to a remote center 106. Adherent device 100 can communicate wirelessly to an intermediate device 102, for example with a single wireless hop from the adherent device on the patient to the intermediate device. Intermediate device 102 can communicate with remote center 106 in many ways, for example with an internet connection. In many examples, monitoring system 10 comprises a distributed processing system with at least one processor on device 100, at least one processor on intermediate device 102, and at least one process at remote center 106, each of which processors is in electronic communication with the other processors. Remote center 106 can be in communication with a health care provider 108A with a communication system 107A, such as the Internet, an intranet, phone lines, wireless and/or satellite phone. Health care provider 108A, 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 109A, for example by cell phone, email, landline. Remote center 106 can be in communication with a health care professional, for example a physician 108B, with a communication system 107B, such as the Internet, an intranet, phone lines, wireless and/or satellite phone. Physician 108B can be in communication with patient P with a communication, for example with a two way communication system, as indicated by arrow 109B, for example by cell phone, email, landline. Remote center 106 can be in communication with an emergency responder 108C, for example a 911 operator and/or paramedic, with a communication system 107C, such as the Internet, an intranet, phone lines, wireless and/or satellite phone. Emergency responder 108C can travel to the patient as indicated by arrow 109C. Thus, in many examples, 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.

[0030] In many examples, the adherent device may continuously monitor physiological parameters, communicate wirelessly with a remote center, and provide alerts when necessary. The system according to the invention as claimed comprises 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 the many embodiments, the remote center receives the data and applies the prediction algorithm. When a flag is raised, the center may communicate with the patient, hospital, nurse,

and/or physician to allow for therapeutic intervention to prevent decompensation.

[0031] 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 model 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.

[0032] In many examples, the adherent device may comprise a reusable electronics module with replaceable patches (the module collects 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 examples, the device may have a rechargeable module, and may use dual battery and/or electronics modules, wherein one module 101A can be recharged using a charging station 103 while the other module 101B is placed on the adherent device. In some examples, the intermediate device 102 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.

[0033] In many examples, the system 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 (average, minimum, maximum), heart rhythm, HRV, HRT, heart sounds (e.g. S3), respiratory sounds, blood pressure, activity, posture, wake/sleep, orthopnea, temperature/heat flux, and weight. The activity sensor may be one of the following: ball switch, accelerometer, minute ventilation, HR, bioimpedance noise, skin temperature/heat flux, BP, muscle noise, posture.

[0034] In many embodiments, the patch wirelessly communicates with a remote center. In some examples, the communication may occur directly (via a cellular or Wi-Fi network), or indirectly through intermediate device 102. Intermediate device 102 may consist of multiple devices which communicate wired or wirelessly to relay data to remote center 106.

[0035] Figure 1B shows a bottom view of adherent device 100 as in Figure 1A comprising an adherent patch 110. Adherent patch 110 comprises a first side, or a lower side 110A, that is oriented toward the skin of the patient when placed on the patient. In many examples, adherent patch 110 comprises a tape 110T which is a material, preferably breathable, with an adhesive 116A. Patient side 110A comprises adhesive 116A to adhere the patch 110 and adherent device 100 to patient P. Electrodes 112A, 112B, 112C and 112D are affixed to adherent patch 110. In many examples, at least four electrodes are attached to the patch, for example six electrodes. In some examples, the patch comprises at least two electrodes, for example two electrodes to measure an electrocardiogram (ECG) of the patient. Gel 114A, gel 114B, gel 114C and gel 114D can each be positioned over electrodes 112A, 112B, 112C and 112D, respectively, to provide electrical conductivity between the electrodes and the skin of the patient. In many examples, the electrodes can be affixed to the patch 110, for example with known methods and structures such as rivets, adhesive, stitches, etc. In many examples, patch 110 comprises a breathable material to permit air and/or vapor to flow to and from the surface of the skin.

[0036] Figure 1C shows a top view of the adherent patch 100, as in Figure 1B. Adherent patch 100 comprises a second side, or upper side 110B. In many examples, electrodes 110A, 110B, 110C and 110D extend from lower side 110A through the adherent patch to upper side 110B. In some embodiments, an adhesive 116B can be applied to upper side 110B to adhere structures, for example, a cover, to the patch such that the patch can support the electronics and other structures when the patch is adhered to the patient. The printed circuit board (PCB) comprise completely flex PCB, rigid PCB combined flex PCB and/or rigid PCB boards connected by cable.

[0037] Figure 1D shows a printed circuit boards and electronic components over adherent patch 110, as in Figure 1C. A printed circuit board (PCB), for example flex PCB 120, can be positioned above 110B of patch 110. Flex PCB 120 can include traces that extends to connectors 122A, 122B, 122C and 122D on the flex PCB. Connectors 122A, 122B, 122C and 122D can be positioned on flex PCB 120 in alignment with electrodes 112A, 112B, 112C and 112D so as to electrically couple the flex PCB with the electrodes. In some examples, connectors 122A, 122B, 122C and 122D may comprise insulated wires or a flex circuit that provide strain relief between the PCB and the electrodes. In some examples, additional PCB's for example PCB 120A, 120B, 120C and 120D be connected to flex PCB 120. Electronic components 130 can be connected to flex PCB 120 and/or mounted thereon. In some examples, electronic components 130 can be mounted on the additional PCB's.

[0038] Electronic components 130 comprise components to take physiologic measurements, transmit data to remote center 106 and receive commands from remote center 106. In many embodiments, electronics components 130 may comprise known low power circuitry, for example complementary metal oxide semiconductor (CMOS) circuitry components. Electronics components 130 comprise an activity sensor and activity circuitry 134, impedance circuitry 136 and

electrocardiogram circuitry, for example ECG circuitry 136. In some non-claimed examples, electronics circuitry 130 may comprise a microphone and microphone circuitry 142 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 130 may comprise a temperature sensor, for example a thermistor, and temperature sensor circuitry 144 to measure a temperature of the patient, for example a temperature of a skin of the patient. Electronics circuitry may comprise a heat flux sensor and heat flux sensor circuitry to measure a skin heat flow of a patient.

[0039] 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 non-claimed examples, increase in skin temperature 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.

[0040] Electronics circuitry 130 may comprise a processor 146. Processor 146 comprises a tangible medium, for example read only memory (ROM), electrically erasable programmable read only memory (EEPROM) and/or random access memory (RAM). Electronic circuitry 130 may comprise real time clock and frequency generator circuitry 148. In some examples, processor 136 may comprise the frequency generator and real time clock. The processor can be configured to control a collection and transmission of data from the impedance circuitry electrocardiogram circuitry and the accelerometer. In many examples, device 100 comprise a distributed processor system, for example with multiple processors on device 100.

[0041] In many embodiments, electronics components 130 comprise wireless communications circuitry 132 to communicate with remote center 106. 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 accelerometer signal. In specific examples, wireless communication circuitry is configured to transmit the hydration signal, the electrocardiogram signal and the accelerometer signal to the remote center with a single wireless hop, for example from wireless communication circuitry 132 to intermediate device 102. 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.

[0042] In some examples, intermediate device 102 comprises 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. In many examples, the data collection system can transmit data in response to commands from remote center 106 and/or in response to commands from the adherent device.

[0043] Activity sensor and activity circuitry 134 can comprise many known activity sensors and circuitry. In many non-claimed examples, the accelerometer comprises at least one of a piezoelectric accelerometer, capacitive accelerometer or electromechanical accelerometer. The accelerometer may comprise a 3-axis accelerometer to measure at least one of an inclination, a position, an orientation or acceleration of the 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 hydration data.

[0044] Impedance circuitry 136 generates hydration data. In many embodiments, impedance circuitry 136 is electrically connected to electrodes 112A, 112B, 112C and 112D such that electrodes 112A and 112D comprise outer electrodes that are driven with a current, or force electrodes. The current delivered between electrodes 112A and 112D generates a measurable voltage between electrodes 112B and 112C, such that electrodes 112B and 112C comprise inner electrodes, or sense electrodes that measure the voltage in response to the current from the force electrodes. The voltage measured by the sense electrodes can be used to determine the hydration of the patient.

[0045] Figure 1D-1 shows an equivalent circuit 152 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 152 comprises an intracellular resistance 156, or R(ICW) in series with a capacitor 154, and an extracellular resistance 158, or R(ECW). Extracellular resistance 158 is in parallel with intracellular resistance 156 and capacitor 154 related to capacitance of cell membranes. In many examples, impedances can be measured and provide useful information over a wide range of frequencies, for example from about 0.5 kHz to about 200 KHz. Work in relation to embodiments of the present invention suggests that extracellular resistance 158 can be significantly related extracellular fluid and to cardiac decompensation, and that extracellular resistance 158 and extracellular fluid can be effectively measured with frequencies in a range from about 0.5 kHz to about 20 kHz, for example from about 1 kHz to about 10 kHz. In some examples, 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, the present invention as defined by the appended claims employs measure hydration with frequencies from about 0.5 kHz to about 20 kHz to determine patient hydration.

[0046] In many non-claimed examples, impedance circuitry 136 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.

[0047] ECG circuitry 138 generates electrocardiogram signals and data from electrodes 112A, 112B, 112C and 112D. In some examples, ECG circuitry 138 is connected to inner electrodes 12B and 122C, which may comprise sense electrodes of the impedance circuitry as described above. In some examples, the inner electrodes may be positioned near the outer electrodes to increase the voltage of the ECG signal measured by ECG circuitry 138. In some examples, the ECG circuitry can share components with the impedance circuitry.

[0048] Figure IE shows batteries 150 positioned over the flex printed circuit board and electronic components as in Figure 1D. Batteries 150 may comprise rechargeable batteries that can be removed and/or recharged. In some examples, batteries 150 can be removed from the adherent patch and recharged and/or replaced.

[0049] Figure IF shows a top view of a cover 162 over the batteries, electronic components and flex printed circuit board as in Figure IE. In many examples, an electronics housing 160 may be disposed under cover 162 to protect the electronic components, and in some examples electronics housing 160 may comprise an encapsulant over the electronic components and PCB. In many examples, electronics housing 160 may comprise a water proof material, for example a sealant adhesive such as epoxy or silicone coated over the electronics components and/or PCB. In some examples, electronics housing 160 may comprise metal and/or plastic, which may be potted with silicone, epoxy, etc.

[0050] Cover 162 may comprise many known biocompatible cover, casing and/or housing materials, such as elastomers, for example silicone. The elastomer may be fenestrated to improve breathability. In some examples, cover 162 may comprise many known breathable materials, for example polyester or polyamide fabric. The breathable fabric may be coated to make it water resistant, waterproof, and/or to aid in wicking moisture away from the patch. The breathable fabric may be coated in order to make the outside hydrophobic and the inside hydrophilic.

[0051] Figure 1G shows a side view of adherent device 100 as in Figures 1A to IF. Adherent device 100 comprises a maximum dimension, for example a length 170 from about 4 to 10 inches (from about 100 mm to about 250mm), for example from about 6 to 8 inches (from about 150 mm to about 200 mm). In some examples, length 170 may be no more than about 6 inches (no more than about 150 mm). Adherent device 100 comprises a thickness 172. Thickness 172 may comprise a maximum thickness along a profile of the device. Thickness 172 can be from about 0.2 inches to about 0.4 inches (from about 5 mm to about 10 mm), for example about 0.3 inches (about 7.5 mm) .

[0052] Figure 1H shown a bottom isometric view of adherent device 100 as in Figures 1A to 1G. Adherent device 100 comprises a width 174, for example a maximum width along a width profile of adherent device 100. Width 174 can be from about 2 to about 4 inches (from about 50 mm to 100 mm), for example about 3 inches (about 75 mm).

[0053] Figure 2A shows a non-claimed method 200 of predicting an impending cardiac decompensation. A step 205 measures an ECG signal. The ECG signal may comprise a differential signal measured with at least two electrodes and may be measured in many known ways. A step 210 measures an hydration signal. The hydration signal may comprise an impedance signal, for example a four pole impedance signal, and may be measured in many known ways. A step 215 measures a respiration signal. The respiration signal may comprise an impedance signal, and may be measured in many known ways. A step 220 measures an activity signal. The activity signal may be measured in many known ways and may comprise a three dimensional accelerometer signal to determine a position of the patient, for example from a three dimensional accelerometer signal. A step 225 measures a temperature signal. The temperature signal may be measured in many ways, for example with a thermistor, a thermocouple, and known temperature measurement devices. A step 230 records a time of day of the signals, for example a local time of day such as morning, afternoon, evening, and/or nighttime.

[0054] A step 235 processes the signals. The signals may be processed in many known ways, for example to generate at least one of a derived signal, a time averaged signal, a filtered signal. In some examples, the signals may comprise raw signals. The ECG signal may comprise at least one of a heart rate signal, a heart rate variability signal, an average heart rate signal, a maximum heart rate signal or a minimum heart rate signal. The hydration signal may comprise an impedance measurement signal. The activity signal may comprise at least one of an accelerometer signal, a position signal indicating the orientation of the patient, such as standing, lying, or sitting. The respiration signal may comprise a least one of a respiration rate, a maximum respiration rate, a minimum respiration rate, an average respiration rate or respiration rate variability. The temperature may comprise an average temperature or a peak temperature.

[0055] A step 240 compares the signals with baseline values. In many embodiments, the baseline values may comprise measurements from the same patient at an earlier time. In some embodiments, the baseline values comprise values for a patient population. In some embodiments, the baseline values for a patient population may comprise empirical data from a suitable patient population size, for example at least about 144 patients, depending on the number of variables

measured, statistical confidence and power used. The measured signals may comprise changes and/or deviations from the baseline values.

[0056] A step 245 transmits the signals. In many examples, the measurement signals, which may comprise derived and/or processed measurement signals, are transmitted to the remote site for comparison. In some examples, the signals may be transmitted to a processor supported with the patient for comparison.

[0057] A step 250 combines at least two of the ECG signal and the hydration signal to detect the impending decompensation.

[0058] The signals can be combined in many ways. In some embodiments, the signals can be used simultaneously to determine the impending cardiac decompensation.

[0059] In some embodiments, the signals can be combined to look up a value in a previously existing array.

Table 1. Lookup Table for ECG and Hydration Signals

Heart Rate / Hydration	*0-49 bpm*	*50-69 bpm*	*70-90 bpm*
>60 Ohms	N	N	Y
41-59 Ohms	N	Y	Y
0-40 Ohms	Y	Y	Y

[0060] Table 1 shows combination of the electrocardiogram signal with the hydration signal to look up a value in a pre-existing array. For example at a heart rate of 89 bpm and a hydration of 35 Ohms, the value in the table may comprise Y. In specific examples, the values of the look up table can be determined in response to empirical data measured for a patient population of at least about 100 patients, for example measurements on about 1000 to 10,000 patients.

[0061] In some examples, the table may comprise a three or more dimensional look up table.

[0062] In some examples, the signals may be combined with at least one of adding, subtracting, multiplying, scaling or dividing the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal. In specific examples, the measurement signals can be combined with positive and or negative coefficients determined in response to empirical data measured for a patient population of at least about 100 patients, for example data on about 1000 to 10,000 patients.

[0063] In some examples, a weighted combination may combine at least 3 measurement signals to generate an output value according to a formula of the general form

$$\mathrm{OUTPUT} = aX + bY + cZ$$

where a, b and c comprise positive or negative coefficients determined from empirical data and X, Y and Z comprise measured signals for the patient, for example at least three of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal. While three coefficients and three variables are shown, the data may be combined with multiplication and/or division. One or more of the variables may be the inverse of a measured variable.

[0064] In some examples, the ECG signal comprises a heart rate signal that can be divided by the activity signal. Work in relation to embodiments of the present invention suggest that an increase in heart rate with a decrease in activity can indicate an impending decompensation. The signals can be combined to generate an output value with an equation of the general form

$$\mathrm{OUTPUT} = aX/Y + bZ$$

where X comprise a heart rate signal, Y comprises a hydration rate signal and Z comprises a respiration signal, with each of the coefficients determined in response to empirical data as described above.

[0065] In some examples, the data may be combined with a tiered combination. While many tiered combinations can be used a tiered combination with three measurement signals can be expressed as

$$\mathrm{OUTPUT} = (\Delta X) + (\Delta Y) + (\Delta Z)$$

where (ΔX), (ΔY), (ΔZ) may comprise change in heart rate signal from baseline, change in hydration signal from baseline and change in respiration signal from baseline, and each may have a value of zero or one, based on the values of the

signals. For example if the heart rate increase by 10%, (ΔX) can be assigned a value of 1. If hydration increases by 5%, (ΔY) can be assigned a value of 1. If activity decreases below 10% of a baseline value (ΔZ) can be assigned a value of 1. When the output signal is three, a flag may be set to trigger an alarm.

[0066] In some examples, the data may be combined with a logic gated combination. While many logic gated combinations can be used a logic gated combination with three measurement signals can be expressed as

$$\text{OUTPUT} = (\Delta X) \text{ AND } (\Delta Y) \text{ AND } (\Delta Z)$$

where (ΔX), (ΔY), (ΔZ) may comprise change in heart rate signal from baseline, change in hydration signal from baseline and change in respiration signal from baseline, and each may have a value of zero or one, based on the values of the signals. For example if the heart rate increase by 10%, (ΔX) can be assigned a value of 1. If hydration increases by 5%, (ΔY) can be assigned a value of 1. If activity decreases below 10% of a baseline value (ΔZ) can be assigned a value of 1. When each of (ΔX), (ΔY), (ΔZ) is one, the output signal is one, and a flag may be set to trigger an alarm. If any one of (ΔX), (ΔY) or (ΔZ) is zero, the output signal is zero and a flag may be set so as not to trigger an alarm. While a specific example with AND gates has been shown the data can be combined in may ways with known gates for example NAND, NOR, OR, NOT, XOR, XNOR gates. In some examples, the gated logic may be embodied in a truth table.

[0067] A step 255 sets a flag. The flag can be set in response to the output of the combined signals. In some examples, the flag may comprise a binary parameter in which a value of zero does not triggers an alarm and a value of one triggers an alarm.

[0068] A step 260 communicates with the patient and/or a health care provider. In some examples, the remote site may contact the patient to determine if he or she is okay and communicate the impending decompensation such that the patient can receive needed medical care. In some examples, the remote site contacts the health care provider to warn the provider of the impending decompensation and the need for the patient to receive medical care.

[0069] A step 265 collects additional measurements. Additional measurements may comprise additional measurements with the at least two signals, for example with greater sampling rates and or frequency of the measurements. Additional measurements may comprise measurements with a additional sensors, for example an onboard microphone to detect at least one of rales, S1 heart sounds, S2 heart sounds, S3 heart sounds, or arrhythmias. In some examples, the additional measurements, for example sounds, can be transmitted to the health care provider to diagnose the patient in real time.

[0070] The processor system, as described above, can be configured to perform the method 200, including many of the steps described above. It should be appreciated that the specific steps illustrated in Figure 2A provide a particular method of predicting an impending cardiac decompensation, according to an embodiment of the present invention.

EXPERIMENTAL CLINICAL STUDY

[0071] The protocol below has been used to measure signals from actual patients with an adherent device. These data show that an adherent patch as described above can be continuously adhered for at least one week. These data also show that 90 day continuous in home monitoring can be achieved with a set of 13 patches in which one of the patches is replaced each week. The clinical testing device used an adherent device with modifications, as described more fully below and referred to as the MS system (multi-sensor). Although the clinical device did not include wireless circuitry and processor circuitry supported with the patch adhered to the skin of the patient, these data do show that such a device, as described above, can be made by one of ordinary skill in the art based on the teachings described herein. Additional empirical studies can be conducted on a suitable number of patients.

MS Clinical System Description

[0072] The MS clinical system includes many of the structure components described above. There is a flexible connection between the electrodes and the flex PCB, for example wires or polyurethane with silver ink. The cover can stretch with the breathable tape on both the clinical device and the above described wireless device. There is generally a gap between the flex PCB and breathable tape in both clinical and above described wireless devices. The tested device used weights to at least partially simulate the weight of wireless and processor circuitry. The adherent device of the MS clinical system comprises four electrodes to measure bioimpedance and ECG signals and a 3-axis accelerometer, as described above. Bioimpedance signals were used to determine patient respiration and patient hydration, and accelerometer signals were used to determine patient activity and posture. The MS clinical adherent patch device comprising the sensors and at least some sensor circuitry were connected to a processor to record data. The processor was connected to the tested adherent device with wires and supported away from the tested adherent patch device, for example around the patient's waist. Data were collected at regular intervals and uploaded to a remote site, as described

above.

[0073] Clinical testing of the MS clinical system shows the effectiveness of the structures for continuous adherence of at least one week and data collection, and that patches can be successively removed and replaced by the patient for in-home monitoring. This effectiveness has been shown without requiring fully functional electronics circuitry such as a battery, wireless circuitry and process circuitry on the adherent device. For example, the MS system includes an insert with about 20 g of additional weight. Although an insert with a 20 gram weight was used for the MS clinical device, greater amounts of weight and circuitry can be used, for example about 30-50 g. The patch device may be modified to accommodate additional weight, for example by increasing the size of the adherent surface. The shape of the MS clinical patch is generally elongate, similar to the elongate shape shown above.

Study Design and Rationale

[0074] The MS System is used in a clinical study of heart failure patients to gather data that can be used to develop an algorithm for diagnosing and predicting impending heart failure decompensation events. Events typically manifest as heart failure-related hospitalization, emergency room or urgent care visits leading to a change in oral or IV diuretic treatment.

[0075] The purpose of the clinical study is to correlate physiological signals recorded by the system to clinical events of acute heart failure decompensation (AHFD). Signals from the patch can be weighted and combined to determine an' index that associates physiologic parameters to impending events of decompensation. Patients who have been classified as New York Heart Association class III and IV within the last 12 months and have had a recent AHFD event can be enrolled into the study and are monitored with the MS system for approximately 90 days.

[0076] AHFD events are defined as any of the following:

1) Any heart failure related ER, Urgent Care, in-office visit or hospitalization requiring administration of IV diuretics, administration of IV inotropes, or ultrafiltration for fluid removal.

2) A change in diuretic, defined as a change in diuretic directed by the health care provider occurring inside a hospital, emergency room, or urgent care setting (i.e. no patient self-directed changes to medications not approved by a health care provider would be included), that satisfies one or more of the following: a) a change in the type of diuretic the patient is taking, b) a dose increase of an existing diuretic, or c) the addition of another diuretic.

3) A heart failure decompensation event for which death is the outcome.

[0077] Patients enrolled in the study were asked to replace the patch weekly. The study can enroll at least about 550 patients. The patient was provided with a kit comprising 13 patches for replacement. The patches were placed on alternating left and right sides of the patient's thorax, as described above, to minimize progressive irritation.

[0078] The data collected in the study can be used to develop an algorithm to at least one of detect, diagnose or predict an impending cardiac decompensation. The algorithm can be implemented on a processor system as described above. Known methods can be used to analyze the data, for example splitting the patients into two groups, one to develop parameters for the algorithm and a second group to test the algorithm developed with the first group. In many embodiments, the signal of the algorithm may comprise a simple binary output for impending cardiac decompensation of the patient. The logic output, yes or no, can be determined in response to patient data combined as described above. The logic output may comprise a signal, such as a binary Y or N signal.

[0079] The developed algorithm can be evaluated with composite sensitivity and false positive patient signal status rates. The sensitivity may be defined as the percent of true positive events out of all condition present events, and the false positive patient status signal status rate can be defined as the number of false positive patient status signals per patient-years of follow up. For example, the sensitivity can be at least 50%, for example at least 60%, at least 70%, or even at least 80%. The false positive patient signal status rate may be limited to no more than about 1.1 false positive patient status signals per patient year, for example no more than about 1.0 false positive patient status signals per patient year, no more than about 0.9 false positive patient status signals per patient year, and even no more than about 0.8 false positive patient status signals per patient year.

Clinical Results

[0080] Clinical data are available for the first 180 patients enrolled in the study.

[0081] Figures 3A and 3B show clinical data measured with an adherent patch device, in accordance with the above protocol. Figure 3A shows data from a patient with the MS patch adhered to a first patient, and the data was acquired over the 90 day period with the series of 13 patches. The signals measured included Heart Rate (beats per minute),

Heart Rate Variability (ms), Respiratory Rate (breaths per minute), Activity (m-G's) and Body Fluid (Ohms). Figure 3B shows data from a second patient similar to Fig. 3A.

[0082] Of the 180 patients who have completed the study with the MS adherent patch, as described above, all patches in all patients adhered continuously without patch failure. In all patients, the first patch adhered continuously for the first week. With the exception of a handful of patient deaths and early withdrawals that were unrelated to device failure, all patients reached the end of 90-day follow-up period having used 13 weekly patches without incident. None of the 180 patients showed skin irritation or damage that required withdrawal from the study.

[0083] The above data show that the wireless adherent patch device can be constructed for in home wireless patient monitoring for an extended period of at least 90 day, in which each patch of a set is continuously adhered to a patient for at least one week and each patch is configured to support the measurement circuitry, the processor, the wireless communication circuitry and the battery with the skin of the patient.

[0084] 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.

Claims

1. A system to detect impending cardiac decompensation of a patient, the system comprising:

circuitry (130, 134, 136, 138, 152), supported by an external patch (110) on the patient; and
a processor system (100, 102, 106, or 146) comprising a tangible medium in communication with the circuitry, **characterised in that** the circuitry (130, 134, 136,138, 152) is configured to measure an electrocardiogram signal of the patient and a hydration signal of the patient, wherein the circuitry is configured to place a voltage and/or a current at one or more electrodes having a frequency between 0.5kHz and about 20 kHz such that the measured hydration signal corresponds to an extracellular fluid of the patient;
and
that the processor system (100, 102, 106, or 146) is configured to combine the electrocardiogram signal and the hydration signal to detect the impending cardiac decompensation, wherein the electrocardiogram signal and the hydration signal are combined by a two-dimensional look-up table that relates heart a rate measured, derived from the measured electrocardiogram signal, with the measured hydration signal.

2. The system of claim 1 wherein the processor system (100, 102, 106, or 146) comprises at least one processor (102, 106) at a location remote from the patient configured to detect the decompensation.

3. The system of claim 1 wherein the processor system (100, 102, 106, or 146), supported with the patient, is configured to receive instructions transmitted from a remote site and combines the measured signals in response to the instructions to detect the impending cardiac decompensation.

4. The system of claim 1 wherein the circuitry (130, 134, 136, 138, 152) is configured to measure an activity signal of the patient and wherein the processor system (100, 102, 106, or 146) is further configured to combine the activity signal with the measured electrocardiogram signal to detect the impending cardiac decompensation.

5. The system of claim 1 wherein the processor system (100, 102, 106, or 146) is configured to simultaneously use the electrocardiogram signal and the hydration signal to determine impending cardiac decompensation.

6. The system of claim 1 wherein the processor system (100, 102, 106, or 146) is configured to determine a flag status in response to the combination of the electrocardiogram signal and the hydration signal, and preferably, determines the flag status in response to a change in the electrocardiogram signal and the hydration signal, and, more preferably, wherein the processor system (100, 102, 106, or 146) affects the circuitry (130, 134, 136, 138, 152) to make additional signal measurements of the patient in response to the flag status.

7. The system of claim 1 wherein the processor system (100, 102, 106, or 146) is configured to process by one of the following:

combining the electrocardiogram signal and the hydration signal in response to a time of day;
processing the electrocardiogram signal and the hydration signal to produce at least one of a derived signal, a time averaged signal, a filtered signal or a raw signal;

determining baseline values of the patient for the electrocardiogram signal and the hydration signal and wherein at least one, preferably both, of the electrocardiogram signal and the hydration signal comprise changes from the baseline values; and
processing differences of the electrocardiogram signal and the hydration signal from baseline values of a patient population and wherein the impending decompensation is detected in response to the differences from the baseline value of the patient population.

Patentansprüche

1. System zum Erkennen einer bevorstehenden kardialen Dekompensation eines Patienten, wobei das System Folgendes umfasst:

   Schaltung (130, 134, 136, 138, 152), die von einem externen Pflaster (110) auf dem Patienten getragen wird; und ein Prozessorsystem (100, 102, 106 oder 146), das ein materielles Medium in Kommunikation mit der Schaltung umfasst, **dadurch gekennzeichnet, dass** die Schaltung (130, 134, 136, 138, 152) konfiguriert ist, um ein Elektrokardiogrammsignal des Patienten und ein Hydratisierungssignal des Patienten zu messen, wobei die Schaltung konfiguriert ist, um eine Spannung und/oder einen Strom an einer oder an mehreren Elektroden mit einer Frequenz zwischen 0,5 kHz und etwa 20 kHz anzulegen, sodass das gemessene Hydratisierungssignal einem extrazellulären Fluid des Patienten entspricht; und
   dass das Prozessorsystem (100, 102, 106 oder 146) konfiguriert ist, um das Elektrokardiogrammsignal und das Hydratisierungssignal zu kombinieren, um die bevorstehende kardiale Dekompensation zu erkennen, wobei das Elektrokardiogrammsignal und das Hydratisierungssignal durch eine zweidimensionale Nachschlagetabelle kombiniert sind, die eine gemessene Herzfrequenz, die von dem gemessenen Elektrokardiogrammsignal abgeleitet ist, mit dem gemessenen Hydratisierungssignal in Beziehung setzt.

2. System nach Anspruch 1, wobei das Prozessorsystem (100, 102, 106 oder 146) wenigstens einen Prozessor (102, 106) an einem Ort entfernt von dem Patienten umfasst, der konfiguriert ist, die Dekompensation zu erkennen.

3. System nach Anspruch 1, wobei das Prozessorsystem (100, 102, 106 oder 146), das mit dem Patienten getragen wird, konfiguriert ist, um von einem entfernten Ort übertragene Anweisungen zu empfangen, und die gemessenen Signale als Reaktion auf die Anweisungen kombiniert, um die bevorstehende kardiale Dekompensation zu erkennen.

4. System nach Anspruch 1, wobei die Schaltung (130, 134, 136, 138, 152) konfiguriert ist, um ein Aktivitätssignal des Patienten zu messen, und wobei das Prozessorsystem (100, 102, 106 oder 146) ferner konfiguriert ist, um das Aktivitätssignal mit dem gemessenen Elektrokardiogrammsignal zu kombinieren, um die bevorstehende kardiale Dekompensation zu erkennen.

5. System nach Anspruch 1, wobei das Prozessorsystem (100, 102, 106 oder 146), das konfiguriert ist, um gleichzeitig das Elektrokardiogrammsignal und das Hydratisierungssignal zu verwenden, um eine bevorstehende kardiale Dekompensation zu bestimmen.

6. System nach Anspruch 1, wobei das Prozessorsystem (100, 102, 106 oder 146) konfiguriert ist, um einen Kennzeichenstatus als Reaktion auf die Kombination aus dem Elektrokardiogrammsignal und dem Hydratisierungssignal zu bestimmen, und bevorzugt wobei es den Kennzeichenstatus als Reaktion auf eine Änderung in dem Elektrokardiogrammsignal und in dem Hydratisierungssignal bestimmt, und stärker bevorzugt wobei das Prozessorsystem (100, 102, 106 oder 146) die Schaltung (130, 134, 136, 138, 152) beeinflusst, zusätzliche Signalmessungen des Patienten als Reaktion auf den Kennzeichenstatus durchführen.

7. System nach Anspruch 1, wobei das Prozessorsystem (100, 102, 106 oder 146) konfiguriert ist, um durch eines der Folgenden zu verarbeiten:

   Kombinieren des Elektrokardiogrammsignals und des Hydratisierungssignals als Reaktion auf eine Tageszeit;
   Verarbeiten des Elektrokardiogrammsignals und des Hydratisierungssignals, um ein abgeleitetes Signal, ein zeitgemitteltes Signal, ein gefiltertes Signal und/oder ein Rohsignal zu erzeugen;
   Bestimmen von Ausgangswerten des Patienten für das Elektrokardiogrammsignal und das Hydratisierungssignal, und wobei wenigstens ein, vorzugsweise beide, des Elektrokardiogrammsignals und des Hydratisierungssignals Änderungen gegenüber den Ausgangswerten umfassen; und

Verarbeiten von Differenzen des Elektrokardiogrammsignals und des Hydratisierungssignals von Ausgangswerten einer Patientenpopulation, und wobei die bevorstehende Dekompensation als Reaktion auf die Differenzen von dem Ausgangswert der Patientenpopulation erkannt wird.

Revendications

1. Système de détection d'une décompensation cardiaque imminente chez un patient, le système comprenant :

un ensemble de circuits (130, 134, 136, 138, 152) contenus dans un timbre externe (110) sur le patient ; et un système de processeurs (100, 102, 106 ou 146) comprenant un support tangible en communication avec l'ensemble de circuits, **caractérisé en ce que** l'ensemble de circuits (130, 134, 136, 138, 152) est conçu pour mesurer un signal d'électrocardiogramme du patient et un signal d'hydratation du patient, l'ensemble de circuits étant conçu pour appliquer une tension et/ou un courant au niveau d'une ou de plusieurs électrodes ayant une fréquence comprise entre 0,5 kHz et environ 20 kHz de sorte que le signal d'hydratation mesuré corresponde à un fluide extracellulaire du patient ;
et
en ce que le système de processeurs (100, 102, 106 ou 146) est conçu pour combiner le signal d'électrocardiogramme et le signal d'hydratation afin de détecter la décompensation cardiaque imminente, le signal d'électrocardiogramme et le signal d'hydratation étant combinés au moyen d'une table de consultation bidimensionnelle qui met en rapport la fréquence cardiaque mesurée, dérivée du signal d'électrocardiogramme mesuré, avec le signal d'hydratation mesuré.

2. Système selon la revendication 1, le système de processeurs (100, 102, 106 ou 146) comprenant au moins un processeur (102, 106) situé à un emplacement distant du patient conçu pour détecter la décompensation.

3. Système selon la revendication 1 dans lequel le système de processeurs (100, 102, 106 ou 146), porté par le patient, est conçu pour recevoir des instructions transmises à partir d'un site distant et combine les signaux mesurés en réponse aux instructions pour détecter la décompensation cardiaque imminente.

4. Système selon la revendication 1 dans lequel l'ensemble de circuits (130, 134, 136, 138, 152) est conçu pour mesurer un signal d'activité du patient et dans lequel le système de processeurs (100, 102, 106 ou 146) est en outre conçu pour combiner le signal d'activité avec le signal d'électrocardiogramme mesuré pour détecter la décompensation cardiaque imminente.

5. Système selon la revendication 1 dans lequel le système de processeurs (100, 102, 106 ou 146) est conçu pour utiliser simultanément le signal d'électrocardiogramme et le signal d'hydratation afin de déterminer une décompensation cardiaque imminente.

6. Système selon la revendication 1 dans lequel le système de processeurs (100, 102, 106 ou 146) est conçu pour déterminer un état indicateur en réponse à la combinaison du signal d'électrocardiogramme et du signal d'hydratation et, de préférence, pour déterminer l'état indicateur en réponse à un changement du signal d'électrocardiogramme et du signal d'hydratation et, de manière encore plus préférable, dans lequel le système de processeurs (100, 102, 106 ou 146) affecte l'ensemble de circuits (130, 134, 136, 138, 152) pour effectuer des mesures de signal supplémentaires du patient en réponse à l'état indicateur.

7. Système selon la revendication 1 dans lequel le système de processeurs (100, 102, 106 ou 146) est conçu pour effectuer un traitement au moyen d'une des actions suivantes :

combiner le signal d'électrocardiogramme et le signal d'hydratation en réponse à une heure du jour ;
traiter le signal d'électrocardiogramme et le signal d'hydratation pour produire au moins un signal parmi un signal dérivé, un signal moyenné dans le temps, un signal filtré et un signal brut ;
déterminer des valeurs de base du patient pour le signal d'électrocardiogramme et le signal d'hydratation, au moins un signal, de préférence les deux signaux, parmi le signal d'électrocardiogramme et le signal d'hydratation comprenant des changements par rapport aux valeurs de base ; et
traiter des différences du signal d'électrocardiogramme et du signal d'hydratation par rapport aux valeurs de base d'une population de patients, la décompensation imminente étant détectée en réponse aux différences par rapport à la valeur de base de la population de patients.

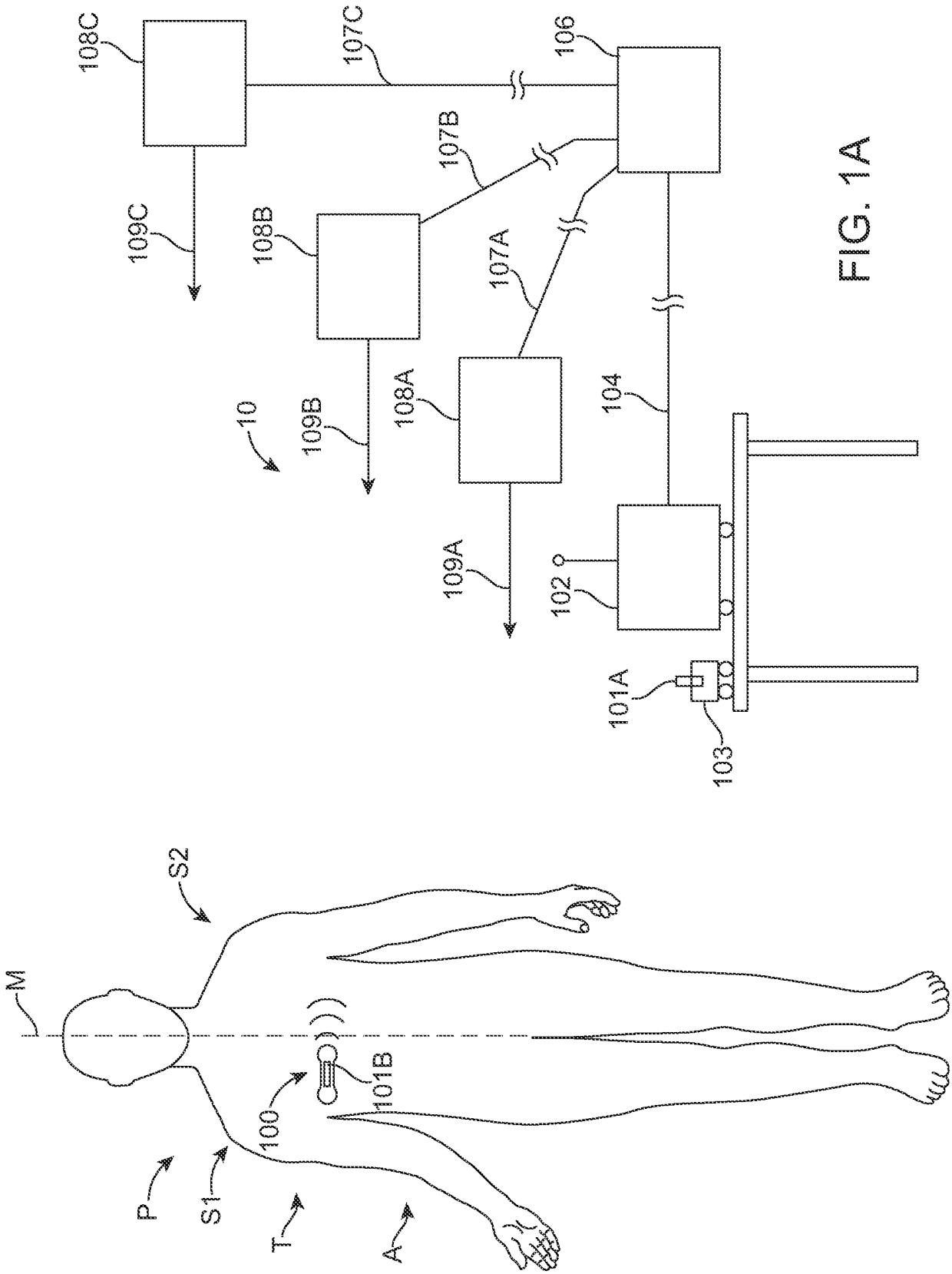
108C
107C
106
107B
109C
108B
107A
108A
104
10
109B
109A
102
101A
103
M
S2
101B
100
P
S1
T
A

FIG. 1A

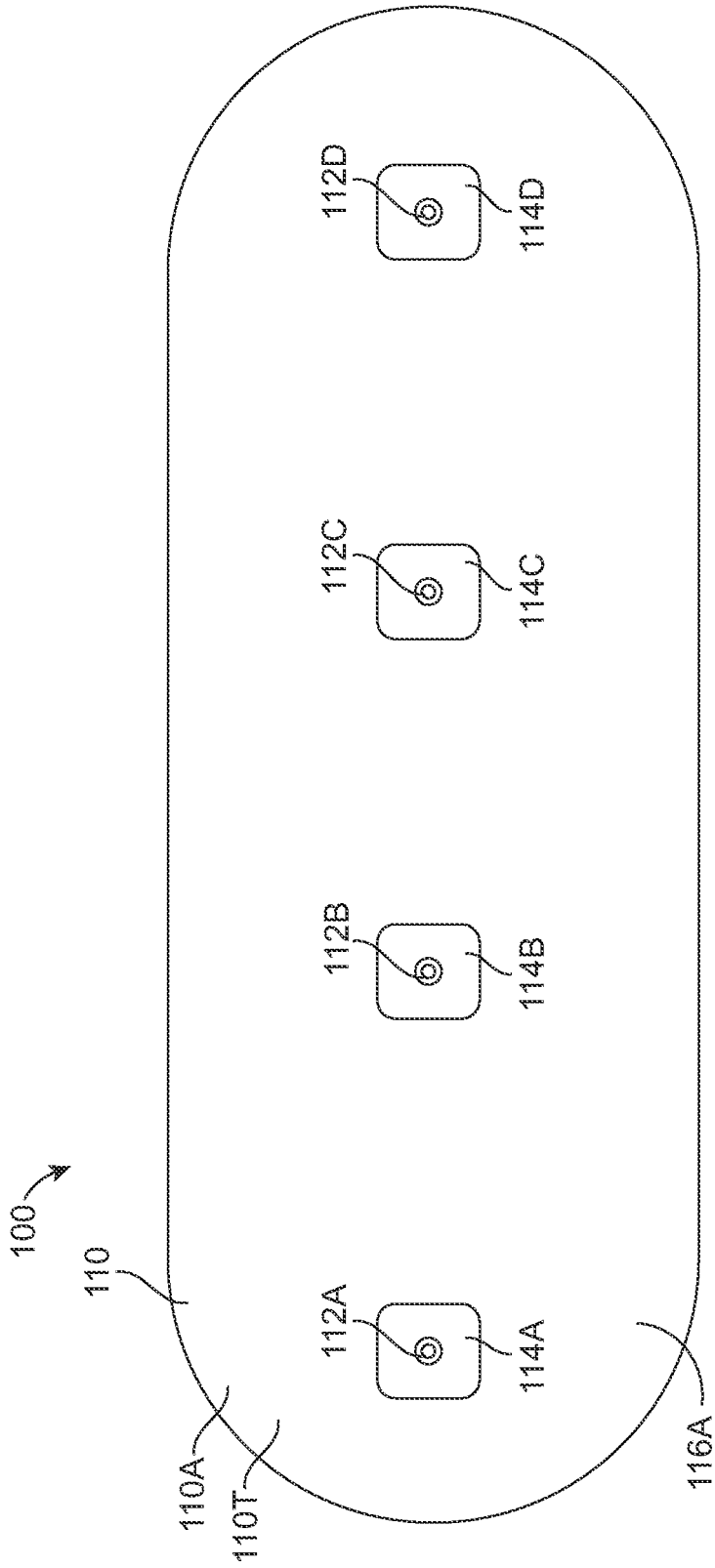
100
110
112A
114A
112B
114B
112C
114C
112D
114D
110A
110T
116A

FIG. 1B

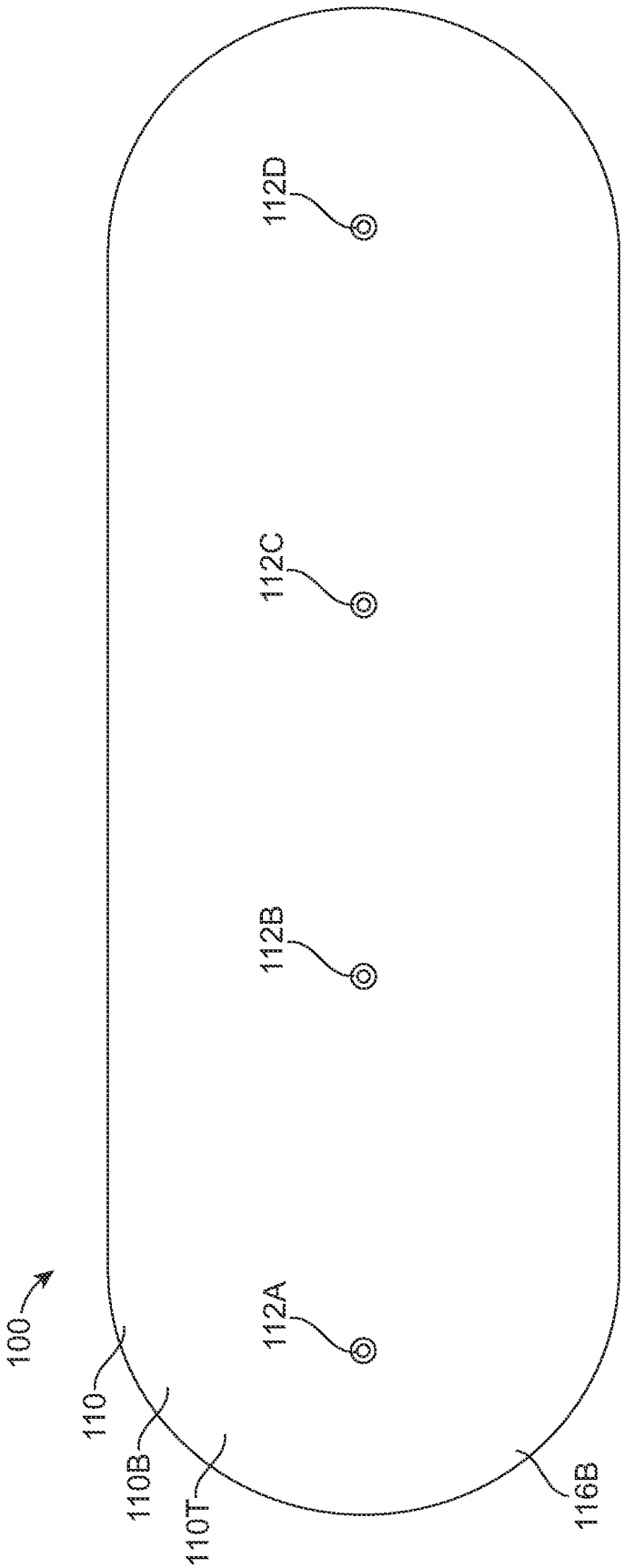

FIG. 1C

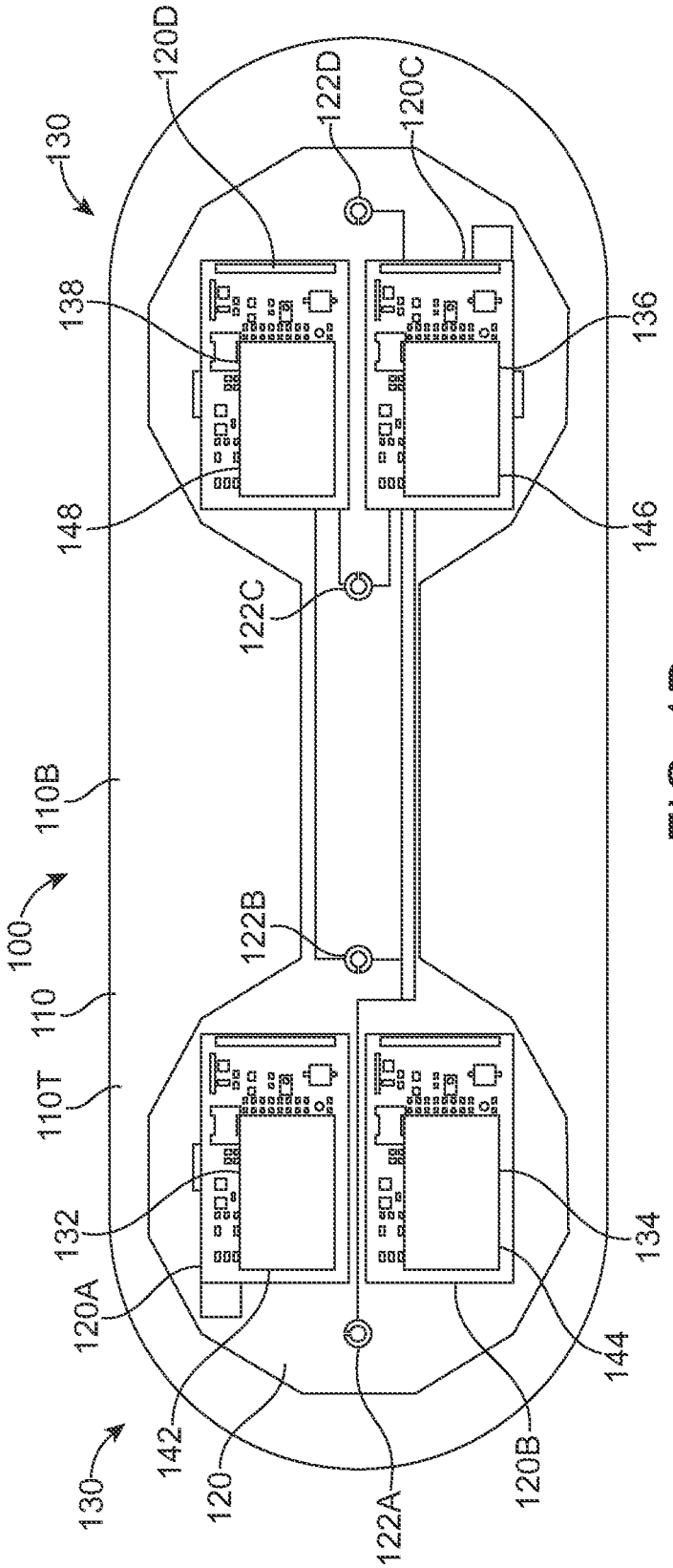

FIG. 1D

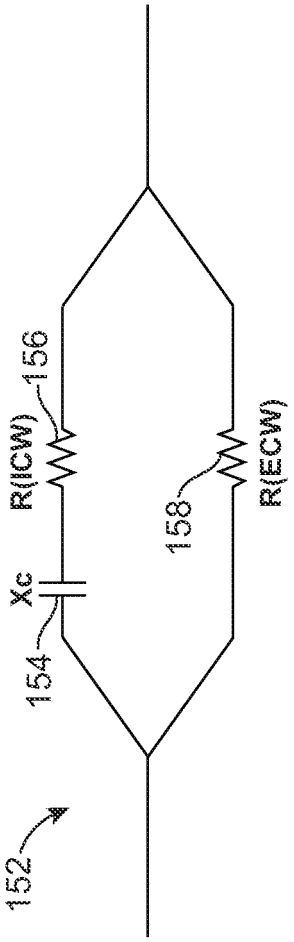

FIG. 1D-1

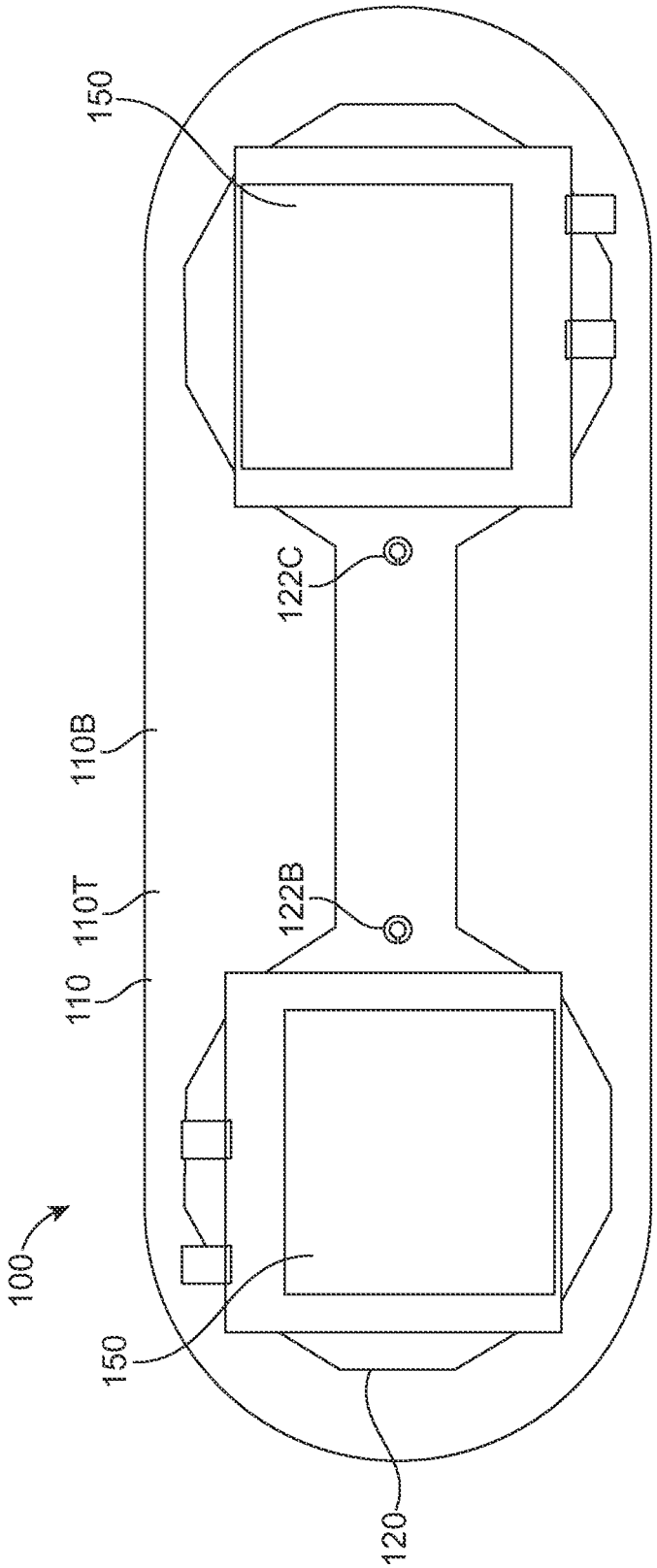

FIG. 1E

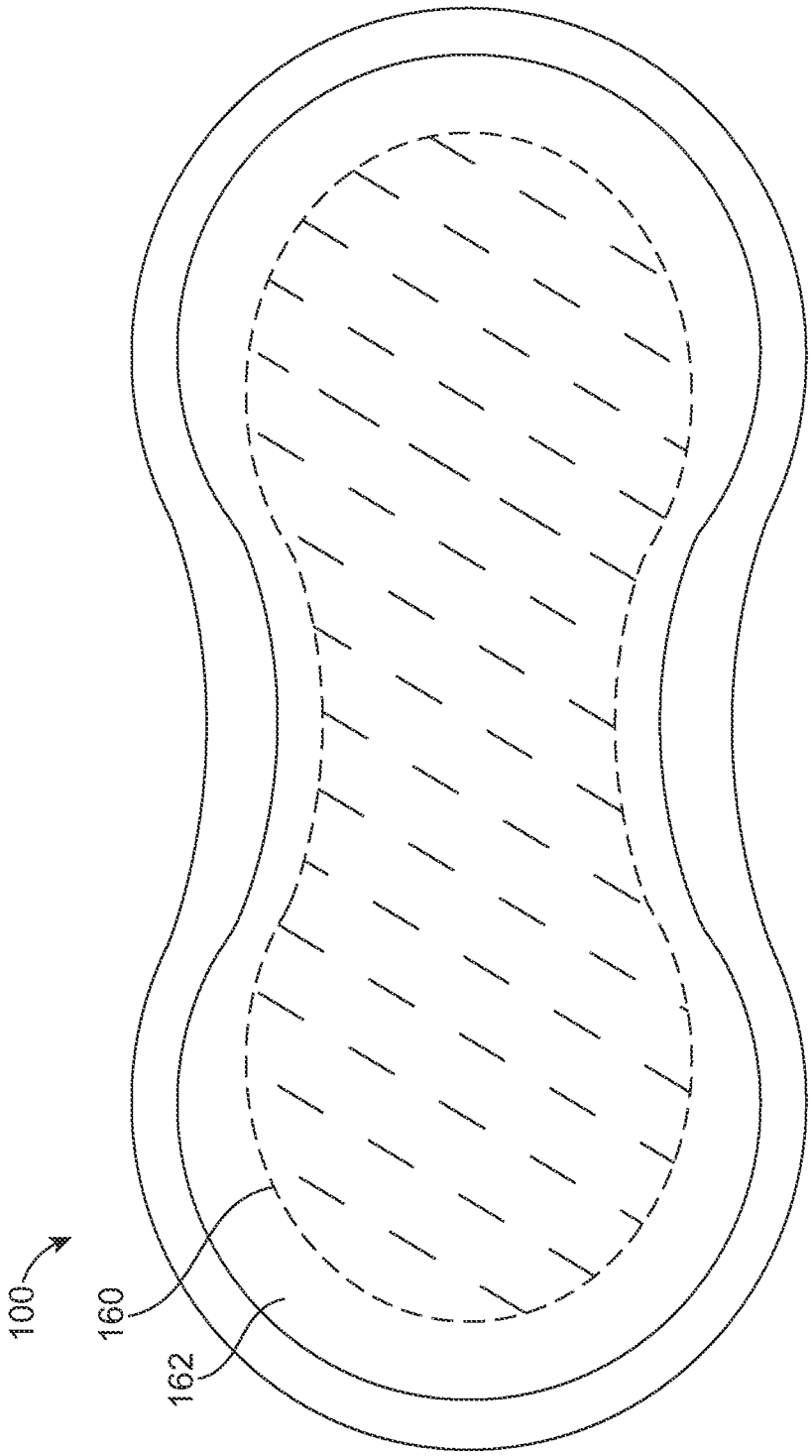

FIG. 1F

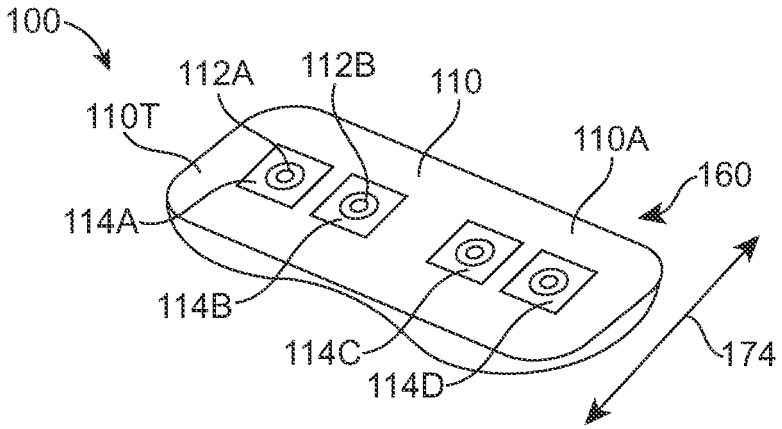
100
112A
112B
110
110T
110A
160
114A
114B
114C
114D
174

FIG. 1H

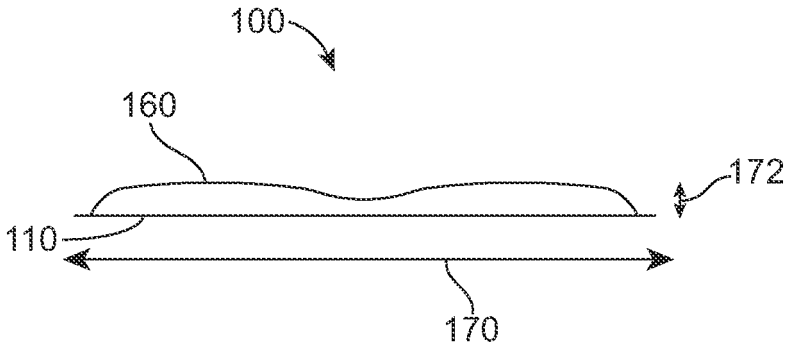
100
160
172
110
170

FIG. 1G

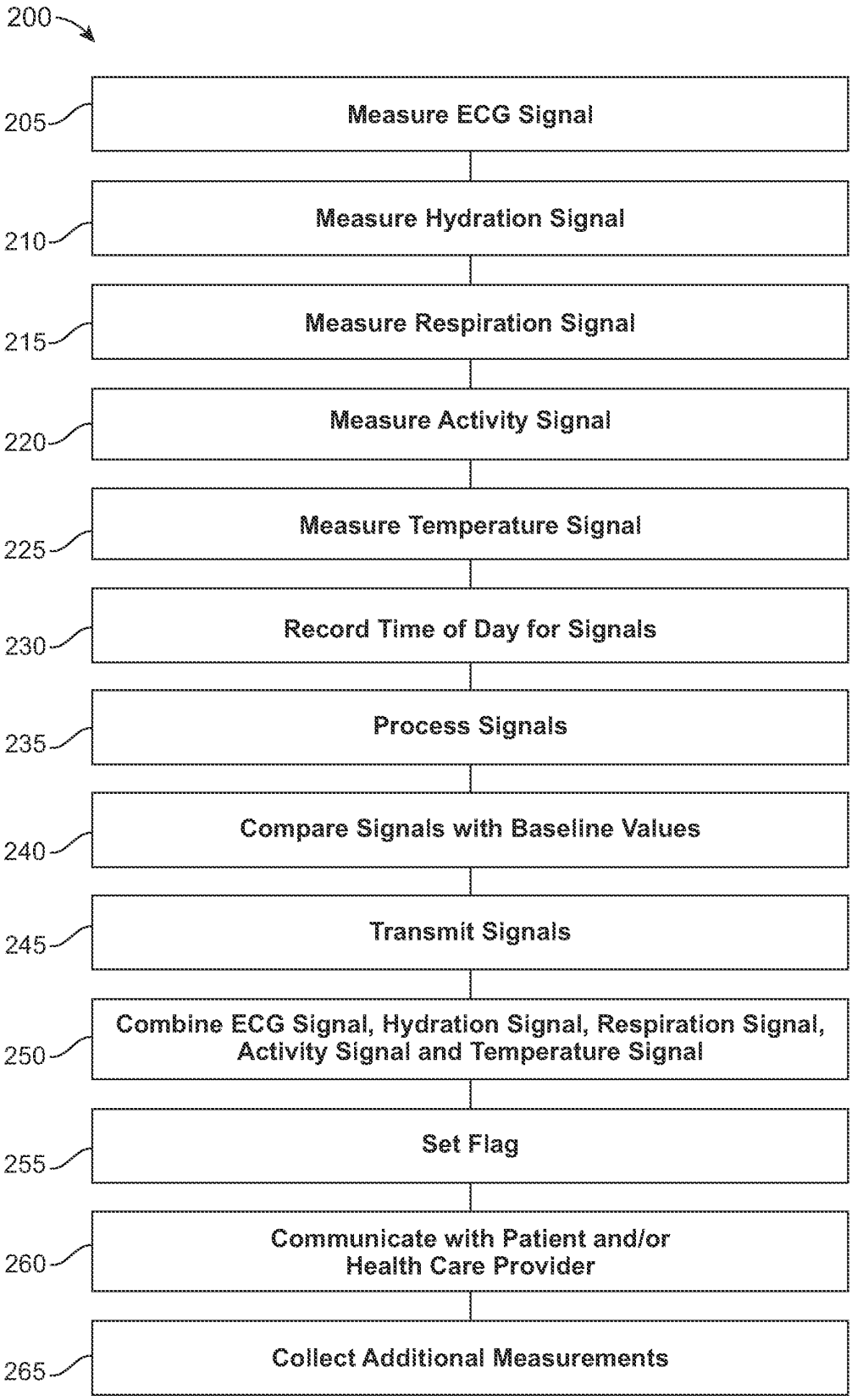
200
205
Measure ECG Signal
210
Measure Hydration Signal
215
Measure Respiration Signal
220
Measure Activity Signal
225
Measure Temperature Signal
230
Record Time of Day for Signals
235
Process Signals
240
Compare Signals with Baseline Values
245
Transmit Signals
250
Combine ECG Signal, Hydration Signal, Respiration Signal, Activity Signal and Temperature Signal
255
Set Flag
260
Communicate with Patient and/or Health Care Provider
265
Collect Additional Measurements

FIG. 2A

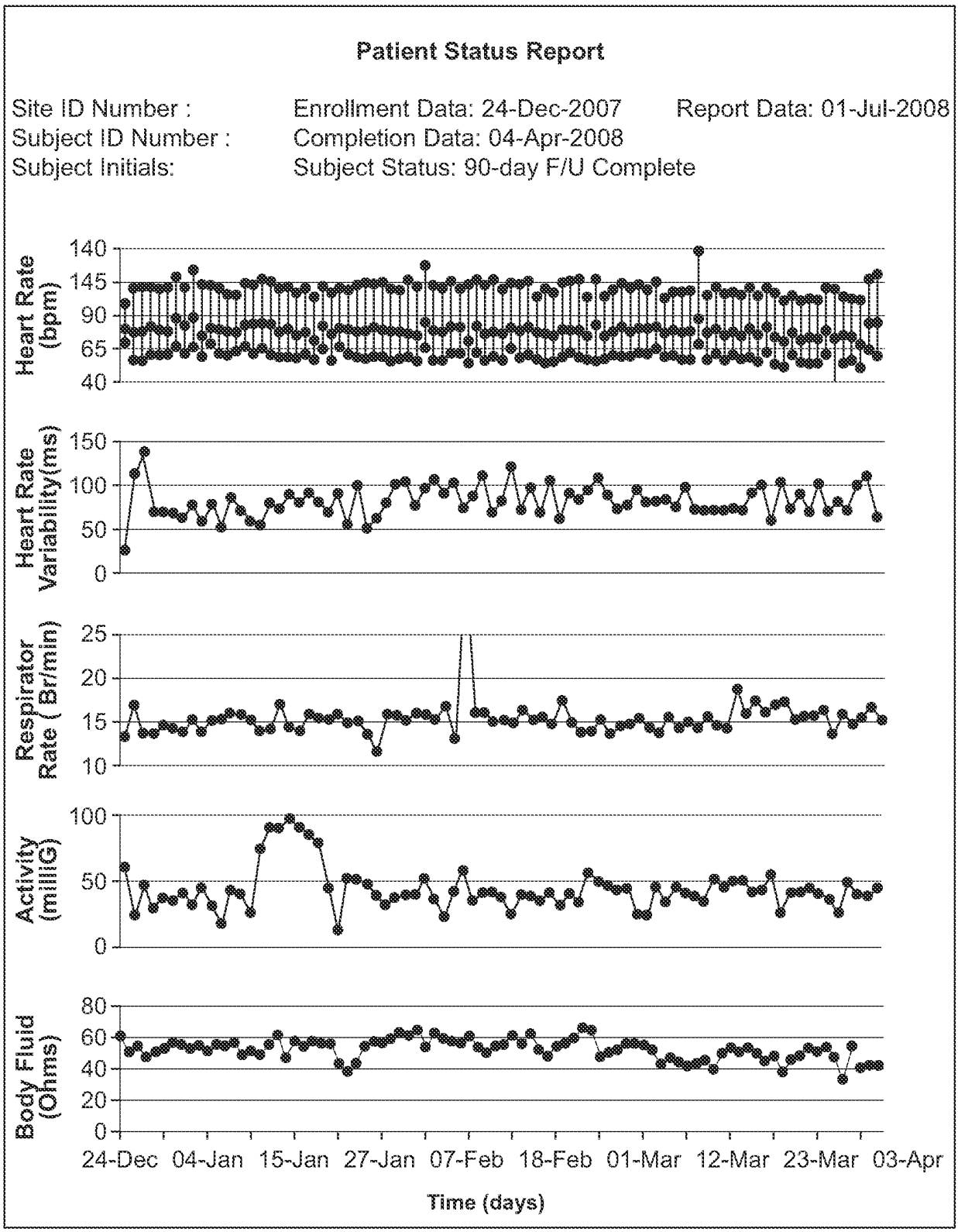
Patient Status Report
Site ID Number :
Subject ID Number :
Subject Initials:
Enrollment Data: 24-Dec-2007
Completion Data: 04-Apr-2008
Subject Status: 90-day F/U Complete
Report Data: 01-Jul-2008
Heart Rate (bpm)
140
145
90
65
40
Heart Rate Variability(ms)
150
100
50
0
Respirator Rate (Br/min)
25
20
15
10
Activity (milliG)
100
50
0
Body Fluid (Ohms)
80
60
40
20
0
24-Dec
04-Jan
15-Jan
27-Jan
07-Feb
18-Feb
01-Mar
12-Mar
23-Mar
03-Apr
Time (days)

FIG. 3A

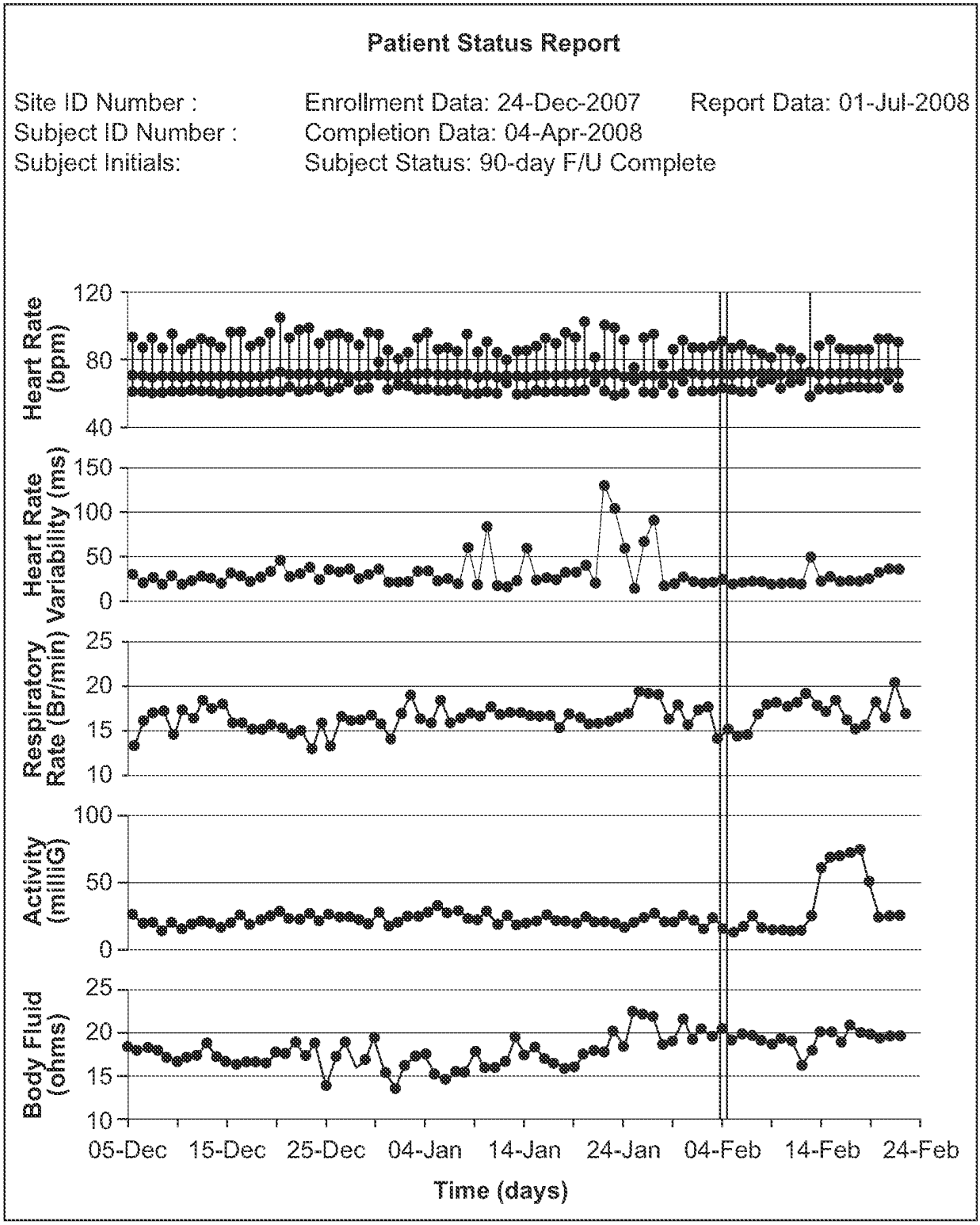
Patient Status Report
Site ID Number :
Subject ID Number :
Subject Initials:
Enrollment Data: 24-Dec-2007
Completion Data: 04-Apr-2008
Subject Status: 90-day F/U Complete
Report Data: 01-Jul-2008
Heart Rate (bpm)
120
80
40
Heart Rate Variability (ms)
150
100
50
0
Respiratory Rate (Br/min)
25
20
15
10
Activity (milliG)
100
50
0
Body Fluid (ohms)
25
20
15
10
05-Dec
15-Dec
25-Dec
04-Jan
14-Jan
24-Jan
04-Feb
14-Feb
24-Feb
Time (days)

FIG. 3B

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- WO 2007103835 A2 **[0007]**

Non-patent literature cited in the description

- Nocturnal Periodic Breathing Is an Independent Predictor of Cardiac Death and Multiple Hospital Admissions in Heart Failure. **PINNA, G D et al.** Computers in Cardiology. IEEE, 17 September 2006, 837-840 **[0006]**

专利名称(译)	多传感器患者监护仪，用于检测即将发生的心脏代偿失调		
公开(公告)号	EP2200499A1	公开(公告)日	2010-06-30
申请号	EP2008830067	申请日	2008-09-12
[标]申请(专利权)人(译)	科文迪斯有限公司		
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当前申请(专利权)人(译)	CORVENTIS INC.		
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发明人	LIBBUS, IMAD BLY, MARK, J. JAMES, KRISTOFER, J. MAZAR, SCOTT, T. WANG, JERRY, S.		
IPC分类号	A61B5/00 A61B5/0205 A61B5/024 A61B5/0404 A61B5/0408 A61B5/0452 A61B5/053 A61B5/08 G06F19/00		
CPC分类号	A61B5/04085 A61B5/04087 A61B5/0537 A61B5/443 A61B5/6833 A61B5/6843 A61B2560/0412 A61B2562/0215 A61B2562/043 G06F19/3418 G16H40/67 G16H50/30 A61B5/01 A61B5/0245		
优先权	60/972537 2007-09-14 US 60/972512 2007-09-14 US 61/055666 2008-05-23 US		
其他公开文献	EP2200499B1 EP2200499A4		
外部链接	Espacenet		

摘要(译)

检测患者即将发生的心脏代偿失调的系统和方法测量患者的心电图信号，患者的水合信号，患者的呼吸信号或患者的活动信号中的至少两个。将心电图信号，水合信号，呼吸信号或活动信号中的至少两个与算法组合以检测即将发生的心脏代偿失调。