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(54) **Title**: HEART FAILURE DECOMPENSATION PREDICTION BASED ON CARDIAC RHYTHM

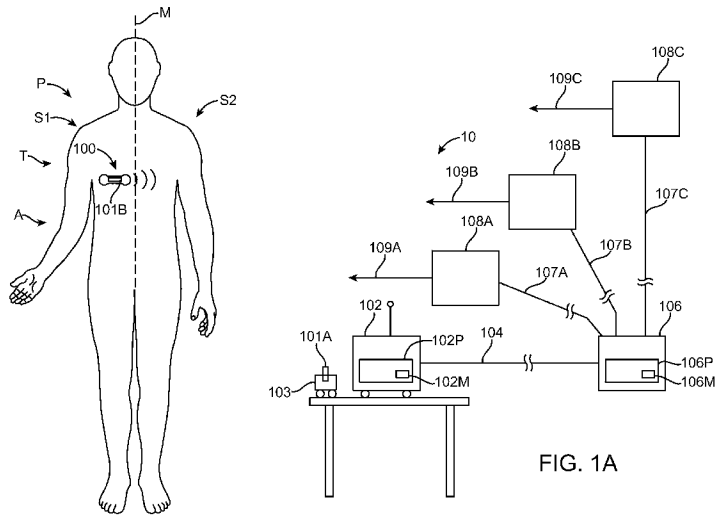


FIG. 1A

(57) **Abstract**: Systems and methods of detecting an impending cardiac decompensation of a patient measure an electrocardiogram signal of the patient. An incidence of cardiac arrhythmias is determined from the electrocardiogram signal. A risk of impending decompensation is determined in response to the incidence of cardiac arrhythmias. 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. Although embodiments make specific reference to monitoring electrocardiogram and other physiological signals with an adherent patch, the system methods and devices are applicable to many applications in which physiological monitoring is used, for example wireless physiological monitoring with implanted sensors for extended periods.

WO 2009/114548 A1

HEART FAILURE DECOMPENSATION PREDICTION BASED ON CARDIAC RHYTHM

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application claims the benefit under 35 USC 119(e) of US Provisional Application No. 61/035,970 filed March 12, 2008; the full disclosure of which is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

[0002] 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.

[0003] 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 other heart failure. 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 heart failure 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.

[0004] Patients who have cardiac decompensation may be incorrectly diagnosed initially in at least some instances, as the symptoms may make the patient appear to suffer from another ailment. For example, pulmonary congestion resulting from cardiac decompensation may appear as a lung disorder. In addition, work in relation to embodiments of the present invention suggests that measurement devices and techniques to detect an impending sudden cardiac death may not be appropriate for detecting an impending cardiac decompensation.

[0005] Many devices have been developed to monitor patients. 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 may not be sufficient to reliably detect and/or avoid an impending cardiac decompensation. 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. 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 patients are not adequately monitored.

[0006] Therefore, a need exists for improved patient monitoring and detection of impending cardiac decompensation. Ideally, such improved patient monitoring would provide reliable detection of an impending cardiac decompensation and avoid at least some of the short-comings of the present methods and devices.

BRIEF SUMMARY OF THE INVENTION

[0007] Embodiments of the present invention provide systems and methods for the detection of an impending cardiac decompensation. Decompensation is a failure of the heart to maintain adequate blood circulation, such that may pulmonary congestion. Therefore, determining the risk of impending decompensation can decrease trauma to the patient and may save the patient's life by allowing delivery of therapy in response to an elevated risk of impending 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 emergency room (hereinafter "ER") and intensive care unit (hereinafter "ICU") care can be avoided. Embodiments of the present invention can determine the risk of impending decompensation based on measurement of the electrocardiogram signal from the patient. Although embodiments make specific reference to monitoring electrocardiogram and other physiological 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 implanted sensors for extended periods.

[0008] In a first aspect, embodiments of the present invention provide a method of detecting an impending cardiac decompensation of a patient. An electrocardiogram signal of the patient is measured. An incidence of cardiac arrhythmias is determined from the electrocardiogram signal. A risk of impending decompensation is determined in response to the incidence of cardiac arrhythmias.

[0009] In many embodiments, the electrocardiogram signal is measured for at least one week and the risk of impending decompensation is determined in response to the incidence of cardiac arrhythmias measured for the at least one week. The incidence of cardiac arrhythmias can be compared to an earlier baseline incidence of cardiac arrhythmias for the patient to determine the risk of impending decompensation. In some embodiments, the incidence of cardiac arrhythmias may be compared to an earlier baseline incidence of cardiac arrhythmias for a patient population to determine the risk of impending decompensation. The electrocardiogram signal may comprise at least one of a derived signal, a time averaged signal, a filtered signal or a raw signal.

[0010] In many embodiments, the incidence of cardiac arrhythmias is combined with at least one of a heart rate, a heart rate variability, a bioimpedance, an activity or a respiration of the patient to determine the risk of impending decompensation. At least one of a weighted combination, a tiered combination or a logic gated combination, a time weighted combination or a rate of change can be used to combine the incidence of cardiac arrhythmias with the at least one of the heart rate, the heart rate variability, the bioimpedance, the activity or the respiration of the patient. The incidence of cardiac arrhythmias can be determined with an atrial arrhythmia that comprises at least one of a bradycardia, an atrial fibrillation, an atrial tachycardia, or an atrial flutter. The incidence of cardiac arrhythmias may also be determined with a ventricular arrhythmia comprising at least one of a bradycardia, a sustained ventricular tachycardia, a non-sustained ventricular tachycardia or a premature ventricular contraction.

[0011] The electrocardiogram signal can be measured in many ways. In specific embodiments, the electrocardiogram signal is measured with an adherent patch comprising electrodes, the patch continuously adhered to the patient for at least one week. The electrocardiogram signal may be measured with electrodes injected and/or implanted into the patient.

[0012] In many embodiments a therapy can be delivered to the patient in response to the risk of impending decompensation, for example cardiac rhythm management therapy.

[0013] In many embodiments, the electrocardiogram signal is measured where the patient is located and the risk of impending decompensation is determined at a remote location. This can distribute the processing of information from the electrocardiogram signal to two or more locations and result in improved handling of the information from the electrocardiogram signal, for example by permitting smaller device for the patient and increasing the rate of transmission of information from the patient to the remote site and/or decreasing bandwidth requirements of the network. The benefits of this distributed processing can be realized with many embodiments. In some embodiments, an adherent patch that supports a processor may be adhered to the patient, and the incidence of cardiac arrhythmias can be determined with the processor when the patch is adhered to the patient. The processor can transmit the incidence of arrhythmias to the remote site to determine the risk of impending decompensation. Alternatively or in combination, the electrocardiogram signal can be transmitted to an intermediate device, for example a gateway, to determine the incidence of arrhythmias, and the incidence of arrhythmias can be transmitted from the intermediate device to the remote site where the risk of the impending cardiac decompensation is determined.

[0014] In some embodiments, the electrocardiogram signal is measured where the patient is located, and the incidence of cardiac arrhythmias determined at the remote site. In specific embodiments, the electrocardiogram signal is transmitted to the remote site where the risk of the impending cardiac decompensation are determined. This transmission of the signal to the remote site may also allow further evaluation of the signal at the remote site, for example by a physician.

[0015] In many embodiments, instructions are transmitted from a remote site to a processor supported with the patient, and the incidence of cardiac arrhythmias is determined with the processor in response to the instructions. In specific embodiments, the risk of impending decompensation is determined with the processor supported by the patient in response to the instructions from the remote site.

[0016] In many embodiments, a flag status is determined in response to the risk.

[0017] In another aspect, embodiments of the present invention provide a system to detect impending cardiac decompensation of a patient. The system comprises circuitry to measure an electrocardiogram signal of the patient, and a processor system comprising a tangible medium in communication with the circuitry. The processor system is configured to determine an incidence of cardiac arrhythmias from the electrocardiogram signal and determine a risk of impending decompensation in response to the incidence of cardiac arrhythmias.

[0018] In many embodiments, the processor system is configured to receive the electrocardiogram signal for at least one week and determine the risk of impending decompensation in response to the incidence of cardiac arrhythmias over the at least one week.

[0019] In many embodiments, the processor system is configured to compare the incidence of cardiac arrhythmias to an earlier incidence of cardiac arrhythmias and determine the risk of impending decompensation. The electrocardiogram signal may comprise at least one of a derived signal, a time averaged signal, a filtered signal or a raw signal. The processor system may be configured to combine the incidence of cardiac arrhythmias with at least one of a heart rate, a heart rate variability, a bioimpedance, an activity or a respiration of the patient to determine the risk of impending decompensation.

[0020] In many embodiments the system comprises an adherent patch comprising a breathable tape, electrodes and gel to measure the electrocardiogram signal. The breathable tape, the electrodes and the gel are arranged to adhere continuously to the patient for at least one week and measure the electrocardiogram signal for the at least one week.

[0021] In many embodiments, the processor system is configured to determine the incidence of cardiac arrhythmias with an atrial arrhythmia comprising at least one of a bradycardia, an atrial fibrillation, an atrial tachycardia, or an atrial flutter. The processor system may be configured to determine the incidence of cardiac arrhythmias with a ventricular arrhythmia comprising at least one of a bradycardia, a sustained ventricular tachycardia, a non-sustained ventricular tachycardia or a premature ventricular contraction.

[0022] In many embodiments, electrodes are coupled to the circuitry to measure the electrocardiogram signal, and the electrodes are configured to be implanted and/or injected into the patient.

[0023] In many embodiments, the processor system comprises a local processor and a remote processor at a remote site. The local processor is connected to an adherent patch configured to adhere to the skin of the patient, and the local processor is configured to measure the electrocardiogram signal. The remote processor is configured to determine the risk of impending decompensation.

[0024] In some embodiments, the local processor is configured to transmit the electrocardiogram signal to the remote site to determine the risk of impending decompensation.

[0025] In some embodiments, the local processor is configured to transmit the incidence of arrhythmias to the remote site and the remote processor is configured to determine the risk of impending decompensation from the incidence of arrhythmias.

[0026] In some embodiments, the local processor is configured to determine the incidence of cardiac arrhythmias in response to the electrocardiogram signal. The remote processor is configured to determine the risk of impending decompensation in response to the incidence of electrocardiogram signals determined with the local processor.

[0027] In some embodiments, the remote processor is configured to determine the incidence of cardiac arrhythmias of the patient in response to the electrocardiogram signal.

[0028] In many embodiments, the processor system comprises a local processor connected to an adherent patch configured to adhere to the skin of the patient, and the local processor is configured to determine the incidence of arrhythmias from the electrocardiogram signal and determine the risk of impending decompensation in response to the incidence of arrhythmias. The local processor may be configured to receive instructions transmitted from the remote site to configure the local processor to determine the risk of impending decompensation in response to the electrocardiogram signal.

[0029] In many embodiments, the processor system is configured to determine a flag status in response to the electrocardiogram signal.

[0030] In another aspect, embodiments provide a system to detect impending cardiac decompensation of a patient. The system comprises circuitry to measure an electrocardiogram signal of the patient. A processor system comprises a tangible medium in communication with the circuitry, in which the processor system is configured to determine an incidence of cardiac arrhythmias from the electrocardiogram signal and determine a risk of impending decompensation in response to the incidence of cardiac arrhythmias.

[0031] In another aspect, embodiments of the present invention provide a computer-readable storage medium comprising a set of instructions for a computer system to evaluate a risk of an impending cardiac decompensation of a patient. The set of instructions comprises an input routine, an output routine and a run routine. The input routine is operatively associated with a source of electrocardiogram data from the patient. The run routine is configured to determine a risk of the impending cardiac decompensation of the patient with the source of electrocardiogram data. The output routine is configured to provide the risk of the impending decompensation available for external use outside the computer system.

[0032] In many embodiments, the input routine, the run routine and the output routine are located on a server at a remote site.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] Figure 1A shows a patient and a monitoring system comprising an adherent device, according to embodiments of the present invention;

[0034] Figure 1B shows a bottom view of the adherent device as in Figure 1A comprising an adherent patch;

[0035] Figure 1C shows a top view of the adherent patch, as in Figure 1B;

[0036] Figure 1D shows a printed circuit boards and electronic components over the adherent patch, as in Figure 1C;

[0037] 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;

[0038] Figure 1E shows batteries positioned over the printed circuit board and electronic components as in Figure 1D;

[0039] Figure 1F shows a top view of an electronics housing and a breathable cover over the batteries, electronic components and printed circuit board as in Figure 1E;

[0040] Figure 1G shows a side view of the adherent device as in Figures 1A to 1F;

[0041] Figure 1H shown a bottom isometric view of the adherent device as in Figures 1A to 1G;

[0042] Figure 2A shows a method of predicting an impending cardiac decompensation, according to embodiments of the present invention; and

[0043] Figure 3A shows a simplified flow chart of a computer-readable storage medium having a set of instructions that can be read by a computer system to detect an impending decompensation, according to embodiments of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0044] Embodiments of the present invention provide systems and methods for the detection of an impending cardiac decompensation. Decompensation is a failure of the heart to maintain adequate blood circulation, such that pulmonary congestion results. Therefore, determining the risk of impending decompensation can save the patient's life by delivering therapy in response to an elevated risk of impending 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. Embodiments of the present invention can determine the risk of impending decompensation based on measurement of the electrocardiogram signal from the patient. Although embodiments make specific reference to monitoring electrocardiogram and other physiological 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 implanted sensors for extended periods. In some embodiments, implanted sensors may be used, for example as described in U.S. Pat. Nos. 6,208,894; 6,315,721; 6,185,452; and U.S. Application No. 60/972,329, entitled "Injectable Device for Physiological Monitoring" (Attorney Docket No. 00456-1004), filed on September 14, 2007, with the same assignee as the present application; the full disclosures of which patents and applications are incorporated herein by reference.

[0045] Decompensation encompasses failure of the heart to maintain adequate blood circulation, often resulting in pulmonary congestion. 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 heart failure are also at an increased risk for SCA, decompensation is primarily the result of mechanical dysfunction, and SCA is primarily an electrical dysfunction caused by inadequate and/or inappropriate electrical signals of the heart.

[0046] 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 embodiments, 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.

[0047] Monitoring system 10 includes components to transmit data to a remote center 106 at a location remote from the patient. The patient can be located in a first building and the remote center located at a second site in a second building, for example with both the first building and the second building located in the same town. The remote center and patient can be located much farther from each other, and the patient can be located on a first continent and the remote center located at a site on a second continent. 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, intermediate device 102 may comprise a gateway device connected to the Internet. In many embodiments, monitoring system 10 comprises a distributed processing system with at least one processor on device 100, at least one processor 102P on intermediate device 102, and at least one processor 106P at remote center 106, each of which processors is in electronic communication with the other processors. At least one processor 102P comprises a tangible medium 102M, and at least one processor 106P comprises a tangible medium 106M. 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 embodiments, monitoring system 10 comprises a closed loop system in which patient care can be monitored and implemented from the remote center in response to signals from the adherent device.

[0048] In many embodiments, the adherent device may continuously monitor physiological parameters, communicate wirelessly with a remote center, and provide alerts when necessary. The system may comprise an adherent patch, which attaches to the patient's thorax and contains sensing electrodes, battery, memory, logic, and wireless communication capabilities. In some embodiments, the patch can communicate with the remote center, via the intermediate device in the patient's home. In 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.

[0049] 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.

[0050] In many embodiments, 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 embodiments, 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 embodiments, 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.

[0051] In many embodiments, 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.

[0052] In many embodiments, the patch wirelessly communicates with a remote center. In some embodiments, 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.

[0053] 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 embodiments, 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 embodiments, at least four electrodes are attached to the patch, for example six electrodes. In some embodiments 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 embodiments, the electrodes can be affixed to the patch 110, for example with known methods and structures such as rivets, adhesive, stitches, etc. In many embodiments, patch 110 comprises a breathable material to permit air and/or vapor to flow to and from the surface of the skin.

[0054] 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 embodiments, 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.

[0055] 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 embodiments, 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 embodiments, 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 embodiments, electronic components 130 can be mounted on the additional PCB's.

[0056] 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 embodiments, 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.

[0057] Work in relation to embodiments of the present invention suggests that skin temperature may effect impedance and/or hydration measurements, and that skin temperature measurements may be used to correct impedance and/or hydration measurements. In some embodiments, increase in skin temperature 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.

[0058] 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 embodiments, 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 embodiments, device 100 comprise a distributed processor system, for example with multiple processors on device 100.

[0059] 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 embodiments, 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.

[0060] In some embodiments, 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 embodiments, 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.

[0061] Activity sensor and activity circuitry 134 can comprise many known activity sensors and circuitry. In many embodiments, the accelerometer comprises at least one of a piezoelectric accelerometer, capacitive accelerometer or electromechanical accelerometer. The accelerometer may 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.

[0062] Impedance circuitry 136 can generate both hydration data and respiration 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.

[0063] 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 embodiments, impedances can be measured and provide useful information over a wide range of frequencies, for example from about 0.5 kHz to about 200 KHz. Work in relation to embodiments of the present invention suggests that extracellular resistance 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 embodiments, a single frequency can be used to determine the extracellular resistance and/or fluid. As sample frequencies increase from about 10 kHz to about 20 kHz, capacitance related to cell membranes decrease the impedance, such that the intracellular fluid contributes to the impedance and/or hydration measurements. Thus, many embodiments of the present invention employ measure hydration with frequencies from about 0.5 kHz to about 20 kHz to determine patient hydration.

[0064] In many embodiments, 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.

[0065] ECG circuitry 138 can generate electrocardiogram signals and data from electrodes 112A, 112B, 112C and 112D. In some embodiments, 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 embodiments, 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 embodiments, the ECG circuitry can share components with the impedance circuitry.

[0066] Figure 1E 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 embodiments, batteries 150 can be removed from the adherent patch and recharged and/or replaced.

[0067] Figure 1F shows a top view of a cover 162 over the batteries, electronic components and flex printed circuit board as in Figure 1E. In many embodiments, an electronics housing 160 may be disposed under cover 162 to protect the electronic components, and in some embodiments electronics housing 160 may comprise an encapsulant over the electronic components and PCB. In many embodiments, 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 embodiments, electronics housing 160 may comprise metal and/or plastic, which may be potted with silicone, epoxy, etc.

[0068] 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 embodiments, 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.

[0069] Figure 1G shows a side view of adherent device 100 as in Figures 1A to 1F. 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 embodiments, 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) .

[0070] 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).

[0071] Figure 2A shows a method 200 of predicting an impending cardiac decompensation. Method 200 can be performed with at least one processor of a processor system, as described above. 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 determines an incidence of arrhythmias from the ECG signal. The incidence of arrhythmias can be determined using known methods and apparatus to detect arrhythmias, for example as described in U.S. Pat. Nos. 3,677,260; 5,271,411; 5,301,677; and 6,480,734, the full disclosures of which are incorporated by reference. A step 215 measures an impedance signal. The impedance signal can be used determine hydration and/or respiration of the patient. The impedance signal may comprise a four pole 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.

[0072] 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 embodiments, the signals may comprise raw signals. The ECG signal may comprise at least one of a raw ECG signal, a digitally filtered ECG signal, 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 impedance signal may comprise a transthoracic impedance measurement signal. The impedance signal may be used to measure hydration of the patient. Alternatively or in combination, the impedance signal may be used to determine a respiration signal that 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 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 temperature may comprise an average temperature or a peak temperature.

[0073] A step 240 compares the incidence of arrhythmias and/or other patient data with baseline values. In many embodiments, the baseline values may comprise arrhythmia measurements and/or values from the same patient at an earlier time. In some embodiments, the baseline values comprise baseline arrhythmia 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. Additional measured signals, as described above, may be compared to baseline values to determine changes and/or deviations from the baseline values.

[0074] A step 245 transmits the signals. In many embodiments, the measurement signals, which may comprise derived and/or processed measurement signals, are transmitted to the remote site for comparison. Alternatively or in combination, at least some of the measurement signals may be transmitted to the intermediate device, for example a processor of the gateway as described above, for comparison. This distribution of the processing of the signals to various locations including the processor on the patient, the processor of the gateway, and the processor of the remote site, can optimize performance of the system. For example the patch worn by the patient may be smaller as some of the processing can be done off the patch, and the communication of the patient information and/or date from the patch to the remote site can occur quickly some processing of the data has extracted the relevant information so as to decrease the size of the transmitted signal, thereby lowering the bandwidth requirements of the system that transmits from the patch to the remote site, for example an internet connection from the gateway to the remote site.

[0075] A step 250 combines the incidence of arrhythmias with additional patient information, for example at least one of a heart rate, a heart rate variability, a bioimpedance signal, an activity, a hydration signal or a respiration of the patient to determine the risk of impending decompensation. As noted above, these signals may comprise signals derived from a common measurement, for example hydration signals and respiration signals derived from an impedance measurement. In many embodiments, at least two and sometime at least three of the signals are

combined. In some embodiments, at least four signals are combined to detect the impending decompensation.

[0076] The signals can be combined in many ways. In some embodiments, the signals can be used simultaneously to determine the impending cardiac decompensation.

[0077] In some embodiments, the signals can be combined by using a look up table, for example to look up a value in a previously existing array.

[0078] Table 1. Lookup Table for Incidence of Arrhythmias and Heart Rate Signals

Heart Rate / Incidence of Arrhythmias	*0-49 bpm*	*50-69 bpm*	*70-90 bpm*
Low	N	N	Y
Medium	N	Y	Y
High	Y	Y	Y

[0079] Table 1 shows combination of the incidence of arrhythmias with heart rate signals to look up a value in a pre-existing array. For example, at a heart rate of 89 bpm and an incidence of arrhythmias of "High," the value in the table may comprise Y. In specific embodiments, 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. The incidence of arrhythmias can be determined in many ways, for example based on the number of arrhythmias over time, for example number per day. The incidence of arrhythmias can also be determined with an index that is determined in response to the duration and/or severity of the arrhythmias, for example with calculations that include the duration of the arrhythmia and/or severity of the arrhythmias.

[0080] In some embodiments, the table may comprise a three or more dimensional look up table.

[0081] In some embodiments, the signals may be combined with at least one of adding, subtracting, multiplying, scaling or dividing. In specific embodiments, 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.

[0082] In some embodiments, a weighted combination may combine at least 3 measurement signals to generate an output value according to a formula of the general form

[0083] OUTPUT = aX + bY + cZ

[0084] 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 incidence of arrhythmias, the heart rate, the heart rate variability, the bioimpedance and/or 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.

[0085] In some embodiments, 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

[0086] OUTPUT = aX /Y + bZ

[0087] 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. The output value can be combined with other data, for example the lookup table and/or weighted combinations as described above.

[0088] In some embodiments, 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

[0089] OUTPUT = (ΔX) + (ΔY) + (ΔZ)

[0090] where (ΔX), (ΔY), (ΔZ) may comprise change in arrhythmias from baseline, change in heart rate 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 incidence of arrhythmias increase by 50% or more, (ΔX) can be assigned a value of 1. If the heart rate increases by 100%, (ΔY) can be assigned a value of 1. If respiration decreases below 50% 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.

[0091] In some embodiments, 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

[0092] OUTPUT = (ΔX) AND (ΔY) AND (ΔZ)

[0093] where (ΔX), (ΔY), (ΔZ) may comprise change in the incidence of arrhythmias from baseline, change in heart rate 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 incidence of arrhythmias increase by 50%, (ΔX) can be assigned a value of 1. If heart rate increases by 100%, (ΔY) can be assigned a value of 1. If activity decreases below 50% 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 embodiments, the gated logic may be embodied in a truth table.

[0094] One of ordinary skill in the art will recognize that the above ways of combining data can be used with known statistical techniques such as multiple regression, logistical regression and the like to fit data base on an empirical sampling of patient data. In addition, the above examples show specific combinations based on patient measurements, and other combinations and/or patient measurements can be used to determine the risk of impending decompensation.

[0095] A step 260 sets a flag. The flag can be set in response to the output of the combined signals. In some embodiments, 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. In some embodiments, a therapy, for example cardiac rhythm management therapy, can be delivered when the flag is set to one.

[0096] A step 265 communicates with the patient and/or a health care provider. In some embodiments, 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 and/or therapies. In some embodiments, 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.

[0097] A step 270 collects additional measurements. Additional measurements may comprise additional measurements with at least two signals, for example with greater sampling rates and or frequency of the measurements. In some embodiments, the additional measurements, for example the electrocardiogram signal, can be transmitted to the health care provider to diagnose the patient in real time.

[0098] 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. Other sequences of steps may also be performed according to alternative embodiments. For example, alternative embodiments of the present invention may perform the steps outlined above in a different order. Moreover, the individual steps illustrated in Figure 2A may include multiple sub-steps that may be performed in various sequences as appropriate to the individual step. Furthermore, additional steps may be added or removed depending on the particular applications. One of ordinary skill in the art would recognize many variations, modifications, and alternatives.

[0099] Figure 3A shows a simplified flow chart 315 of a computer-readable storage medium 310 having a set of instructions 315 that can be read by a computer system to detect an impending decompensation. Medium 310 can include a variety of tangible media, and medium 310 can be present in many locations, such as the processor supported with the adherent patch, the processor of the intermediate device that includes the gateway, and the processor at the remote center that may comprise several servers. In particular, the storage medium can be RAM which temporarily stores the set of instructions. This temporary storage can occur on the processor of the adherent device, the processor of the intermediate device, and/or the processor(s) of the server at the remote site and/or all three locations. The set of instructions 315 can be loaded onto the medium by any means including transferring set of instructions 315 from the Internet, the intranet, the LAN, the floppy drive, the CD ROM drive and the flash RAM such as a jump drive. The set of instructions 315 can include an input routine 320, a run routine 330, and an output routine 340. Input routine 320 can be operatively associated with a source of patient data. For example input routine 320 can cause the acquisition of patient data from the ECG signal, incidence of arrhythmia signal, impedance signal, activity signal, temperature signal and time of day signal as described with regard to steps 205, 210, 215, 220, 225 and 230 herein, and read this data into the computer RAM. Alternatively, input routine 320 can read patient information data, for example the incidence of arrhythmias, from the tangible medium, the

internet, an intranet, a LAN or the like, so as to make the data available for analysis. For example, patient information data acquired from the method 200 as shown in Fig. 2A can be input with routine 320, for example incidence of arrhythmia, heart rate and respiration data input to the server at the remote site. Run routine 330 can process the data made available to the processor with input routine 320. Run routine 330 can use the acquired data from steps 205, 210, 215, 220, 225 and 230 to determine the risk of impending decompensation as described in steps 235 to 255. After the risk of impendent decompensation has been determined, output routine 340 makes the risk of impending decompensation available for external use outside the computer. For example, with regard to step 260 the flag can be set to warn of impending decompensation and with regard to step 265 the risk of impending decompensation can be communicated with the patient and/or health care provider, for example as a number on a scale from one to ten in which ten indicates an extreme risk of impending decompensation requiring immediate intervention.

[0100] It should be appreciated that the specific routines illustrated in Figure 3A provide particular flow chart embodied in a computer-readable storage medium having a particular set of instructions that can be read by a computer system to detect an impending decompensation. Other routines may also be performed according to alternative embodiments. For example, alternative embodiments may perform the steps outlined above in a different order. Moreover, the individual steps illustrated in Figure 3A may include multiple sub-steps that may be performed in various sequences as appropriate to the individual step. Furthermore, additional steps may be added or removed depending on the particular applications. One of ordinary skill in the art would recognize many variations, modifications, and alternatives.

[0101] While the exemplary embodiments have been described in some detail, by way of example and for clarity of understanding, those of skill in the art will recognize that a variety of modifications, adaptations, and changes may be employed. Hence, the scope of the present invention should be limited solely by the appended claims.

WHAT IS CLAIMED IS:

1. A method of detecting an impending cardiac decompensation of a patient, the method comprising:

measuring an electrocardiogram signal of the patient;

determining an incidence of cardiac arrhythmias from the electrocardiogram signal; and

determining a risk of impending decompensation in response to the incidence of cardiac arrhythmias.

2. The method of claim 1 wherein the electrocardiogram signal is measured for at least one week and the risk of impending decompensation is determined in response to the incidence of cardiac arrhythmias measured for the at least one week.

3. The method of claim 1 wherein the incidence of cardiac arrhythmias is compared to an earlier baseline incidence of cardiac arrhythmias for the patient to determine the risk of impending decompensation.

4. The method of claim 1 wherein the incidence of cardiac arrhythmias is compared to an earlier baseline incidence of cardiac arrhythmias for a patient population to determine the risk of impending decompensation.

5. The method of claim 1 wherein the electrocardiogram signal comprises at least one of a derived signal, a time averaged signal, a filtered signal or a raw signal.

6. The method of claim 1 wherein the incidence of cardiac arrhythmias is combined with at least one of a heart rate, a heart rate variability, a bioimpedance, an activity or a respiration of the patient to determine the risk of impending decompensation.

7. The method of claim 6 wherein at least one of a weighted combination, a tiered combination or a logic gated combination, a time weighted combination or a rate of change is used to combine the incidence of cardiac arrhythmias with the at least one of the heart rate, the heart rate variability, the bioimpedance, the activity or the respiration of the patient.

8. The method of claim 1 wherein the incidence of cardiac arrhythmias is determined with an atrial arrhythmia comprising at least one of a bradycardia, an atrial fibrillation, an atrial tachycardia, or an atrial flutter.

9. The method of claim 1 wherein the incidence of cardiac arrhythmias is determined with a ventricular arrhythmia comprising at least one of a bradycardia, a sustained ventricular tachycardia, a non-sustained ventricular tachycardia or a premature ventricular contraction.

10. The method of claim 1 wherein the electrocardiogram signal is measured with an adherent patch comprising electrodes, the patch continuously adhered to the patient for at least one week.

11. The method of claim 1 wherein the electrocardiogram signal is measured with electrodes injected and/or implanted into the patient.

12. The method of claim 1 further comprising delivering a therapy to the patient in response to the risk of impending decompensation.

13. The method of claim 12 wherein the therapy comprises cardiac rhythm management therapy.

14. The method of claim 1 wherein the electrocardiogram signal is measured where the patient is located and the risk of impending decompensation is determined at a remote location.

15. The method of claim 14 wherein an adherent patch that supports a processor is adhered to the patient and the incidence of cardiac arrhythmias is determined with the processor when the patch is adhered to the patient, and wherein processor transmits the incidence of arrhythmias to the remote site to determine the risk of impending decompensation.

16. The method of claim 14 further comprising transmitting the electrocardiogram signal to an intermediate device to determine the incidence of arrhythmias and wherein the incidence of arrhythmias is transmitted from the intermediate device to the remote site where the risk of the impending cardiac decompensation is determined.

17. The method of claim 14 wherein the electrocardiogram signal is measured where the patient is located and the incidence of cardiac arrhythmias is determined at the remote site.

18. The method of claim further comprising transmitting the electrocardiogram signal to an intermediate device to determine the incidence of arrhythmias and wherein the incidence of arrhythmias is transmitted from the intermediate device to the remote site where the risk of the impending cardiac decompensation is determined.

19. The method of claim 17 further comprising transmitting the electrocardiogram signal to the remote site where the risk of the impending cardiac decompensation is determined.

20. The method of claim 1 further comprising transmitting instructions from a remote site to a processor supported with the patient, and wherein the incidence of cardiac arrhythmias is determined with the processor in response to the instructions.

21. The method of claim 20 wherein the risk of impending decompensation is determined with the processor supported by the patient in response to the instructions from the remote site.

22. The method of claim 1 wherein a flag status is determined in response to the risk.

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

circuitry to measure an electrocardiogram signal of the patient; and

a processor system comprising a tangible medium in communication with the circuitry, the processor system configured to determine an incidence of cardiac arrhythmias from the electrocardiogram signal and determine a risk of impending decompensation in response to the incidence of cardiac arrhythmias.

24. The system of claim 23 wherein the processor system is configured to receive the electrocardiogram signal for at least one week and determine the risk of impending decompensation in response to the incidence of cardiac arrhythmias over the at least one week.

25. The system of claim 23 wherein the processor system is configured to compare the incidence of cardiac arrhythmias to an earlier incidence of cardiac arrhythmias and determine the risk of impending decompensation.

26. The system of claim 23 wherein the electrocardiogram signal comprises at least one of a derived signal, a time averaged signal, a filtered signal or a raw signal.

27. The system of claim 23 wherein the processor system is configured to combine the incidence of cardiac arrhythmias with at least one of a heart rate, a heart rate variability, a bioimpedance, an activity or a respiration of the patient to determine the risk of impending decompensation.

28. The system of claim 23 further comprising an adherent patch comprising a breathable tape, electrodes and gel to measure the electrocardiogram signal, wherein the breathable tape, the electrodes and the gel are arranged to adhere continuously to the patient for at least one week and measure the electrocardiogram signal for the at least one week.

29. The system of claim 23 wherein the processor system is configured to determine the incidence of cardiac arrhythmias with an atrial arrhythmia comprising at least one of a bradycardia, an atrial fibrillation, an atrial tachycardia, or an atrial flutter.

30. The system of claim 23 wherein the processor system is configured to determine the incidence of cardiac arrhythmias with a ventricular arrhythmia comprising at least one of a bradycardia, a sustained ventricular tachycardia, a non-sustained ventricular tachycardia or a premature ventricular contraction.

31. The system of claim 23 further comprising electrodes coupled to the circuitry to measure the electrocardiogram signal, the electrodes configured to be implanted and/or injected into the patient.

32. The system of claim 23 wherein the processor system comprises a local processor and a remote processor at a remote site, the local processor connected to an adherent patch configured to adhere to the skin of the patient, the local processor configured

to measure the electrocardiogram signal and wherein the remote processor is configured to determine the risk of impending decompensation.

33. The system of claim 32 wherein the local processor is configured to transmit the incidence of arrhythmias to the remote site and the remote processor is configured to determine the risk of impending decompensation.

34. The system of claim 32 wherein the local processor is configured to determine the incidence of cardiac arrhythmias in response to the electrocardiogram signal and wherein the remote processor is configured to determine the risk of impending decompensation in response to the incidence of electrocardiogram signals determined with the local processor.

35. The system of claim 32 wherein the remote processor is configured to determine the incidence of cardiac arrhythmias of the patient in response to the electrocardiogram signal.

36. The system of claim 35 wherein the local processor is configured to transmit the electrocardiogram signal to the remote site to determine the risk of impending decompensation.

37. The system of claim 23 wherein the processor system further comprises a local processor connected to an adherent patch configured to adhere to the skin of the patient, the local processor configured to determine the incidence of arrhythmias from the electrocardiogram signal and determine the risk of impending decompensation response to the incidence of arrhythmias.

38. The system of claim 37 wherein the local processor is configured to receive instructions transmitted from the remote site to configure the local processor to determine the risk of impending decompensation in response to the electrocardiogram signal.

39. The system of claim 23 wherein the processor system is configured to determine a flag status in response to the electrocardiogram signal.

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

circuitry to measure an electrocardiogram signal of the patient; and

a processor system comprising a tangible medium in communication with the circuitry, the processor system configured to determining an incidence of cardiac arrhythmias from the electrocardiogram signal and determine a risk of impending decompensation in response to the incidence of cardiac arrhythmias.

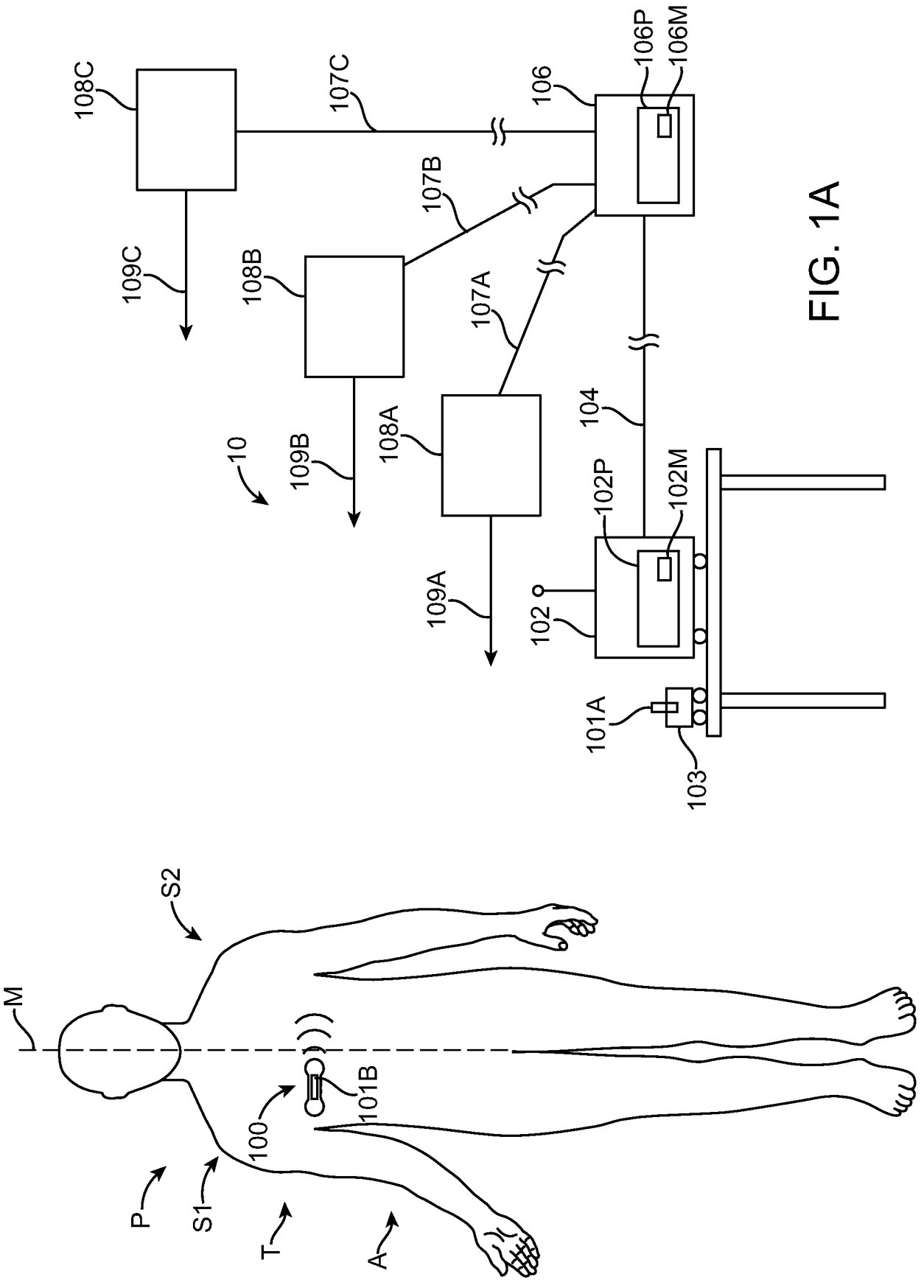
41. A computer-readable storage medium comprising a set of instructions for a computer system to evaluate a risk of an impending cardiac decompensation of a patient, the set of instructions comprising:

an input routine operatively associated with a source of electrocardiogram data from the patient;

a run routine to determine a risk of the impending cardiac decompensation of the patient with the source of electrocardiogram data; and

an output routine providing the risk of the impending decompensation available for external use outside the computer system.

42. The computer readable storage medium of claim 41 wherein the input routine, the run routine and the output routine are located on a server at a remote site.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S1
T
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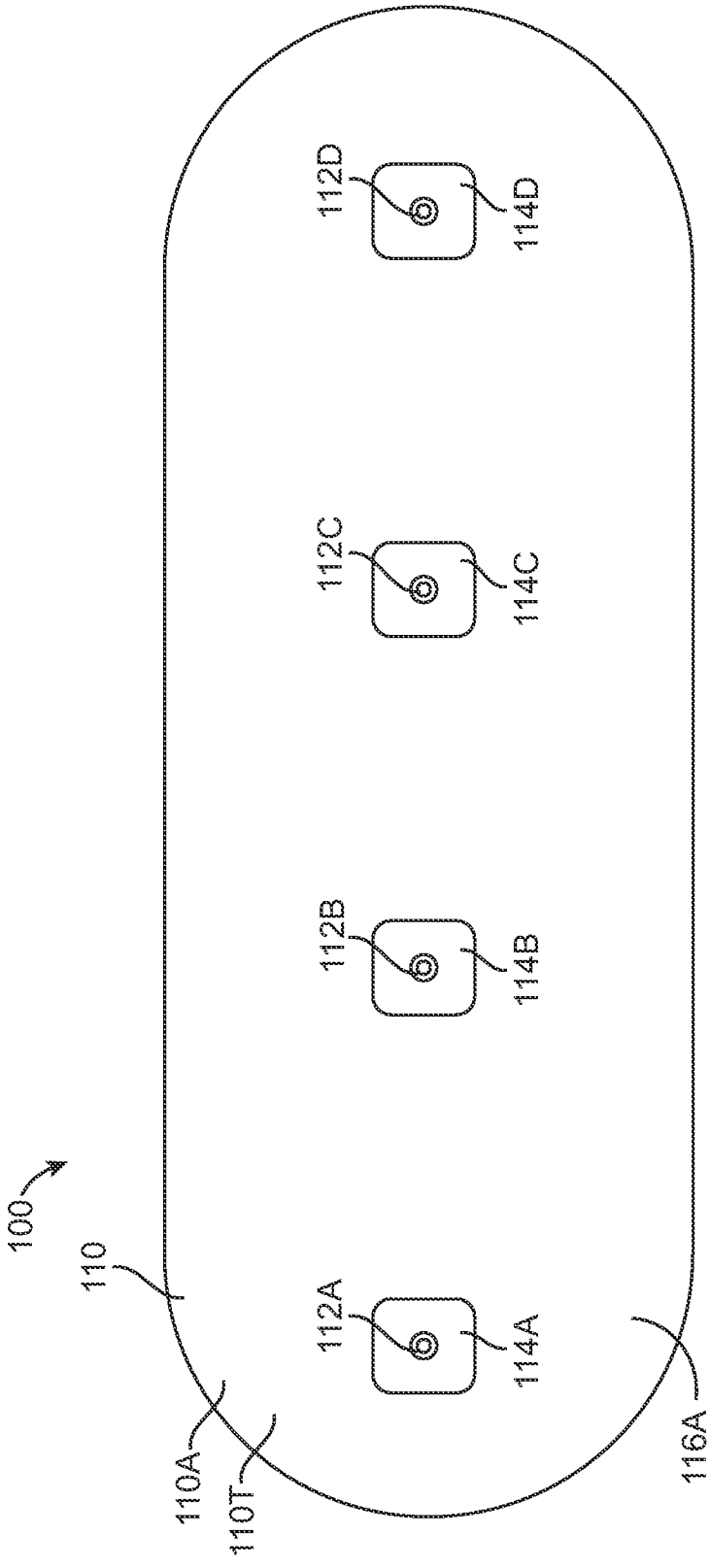
FIG. 1A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114C
112D
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110T
116A

FIG. 1B

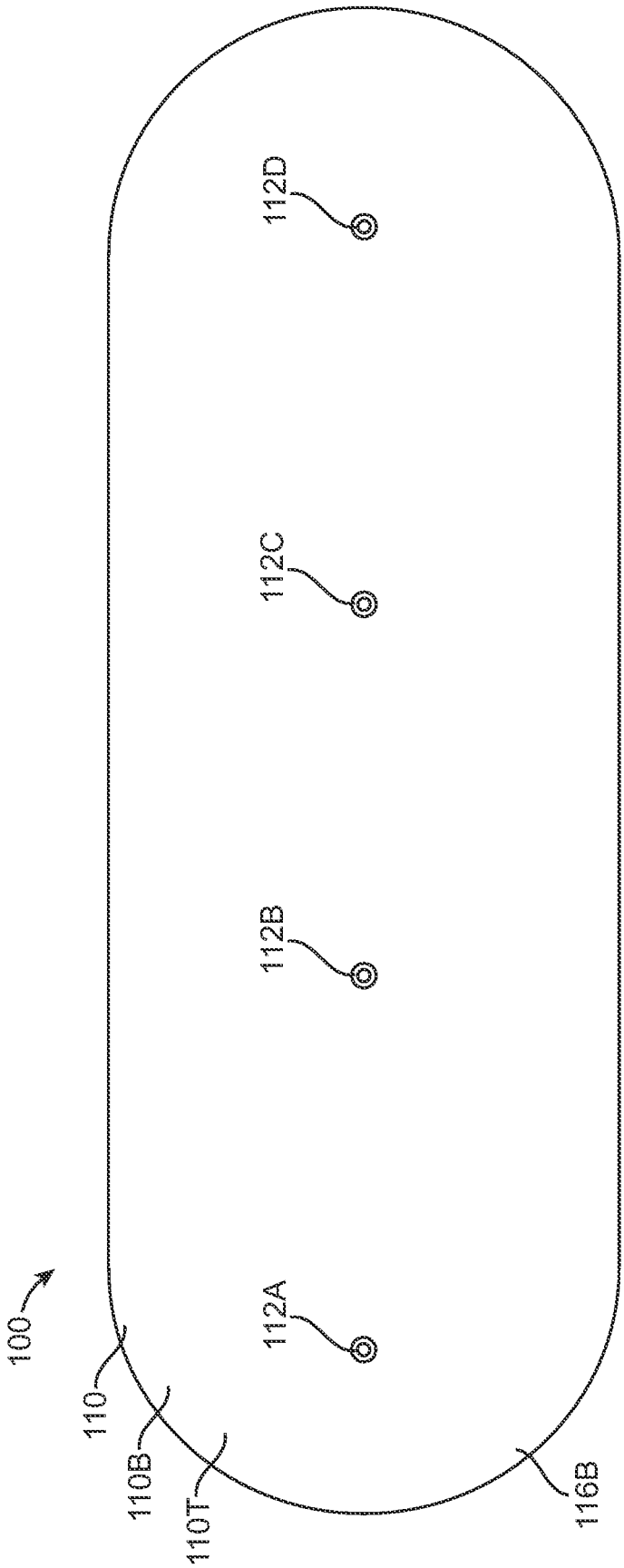

FIG. 1C

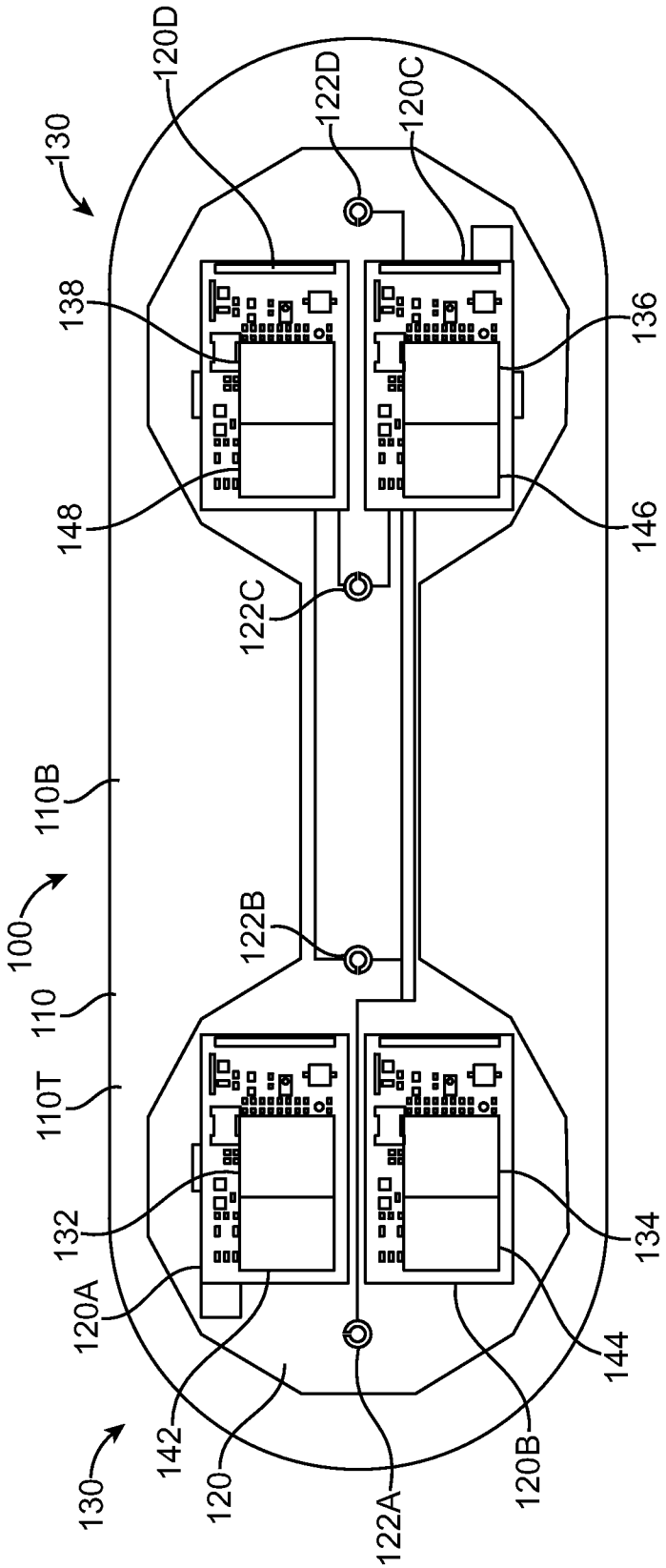

FIG. 1D

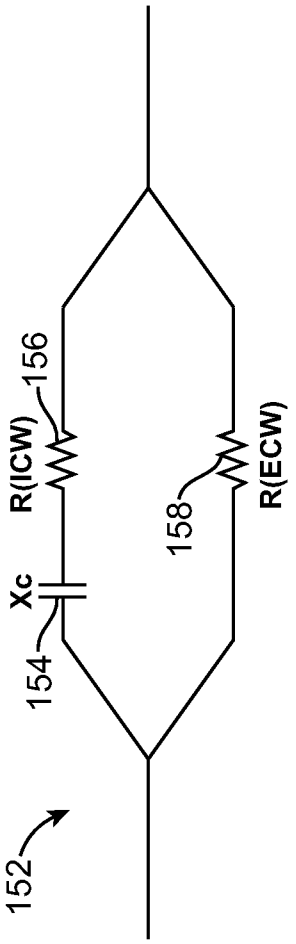

FIG. 1D-1

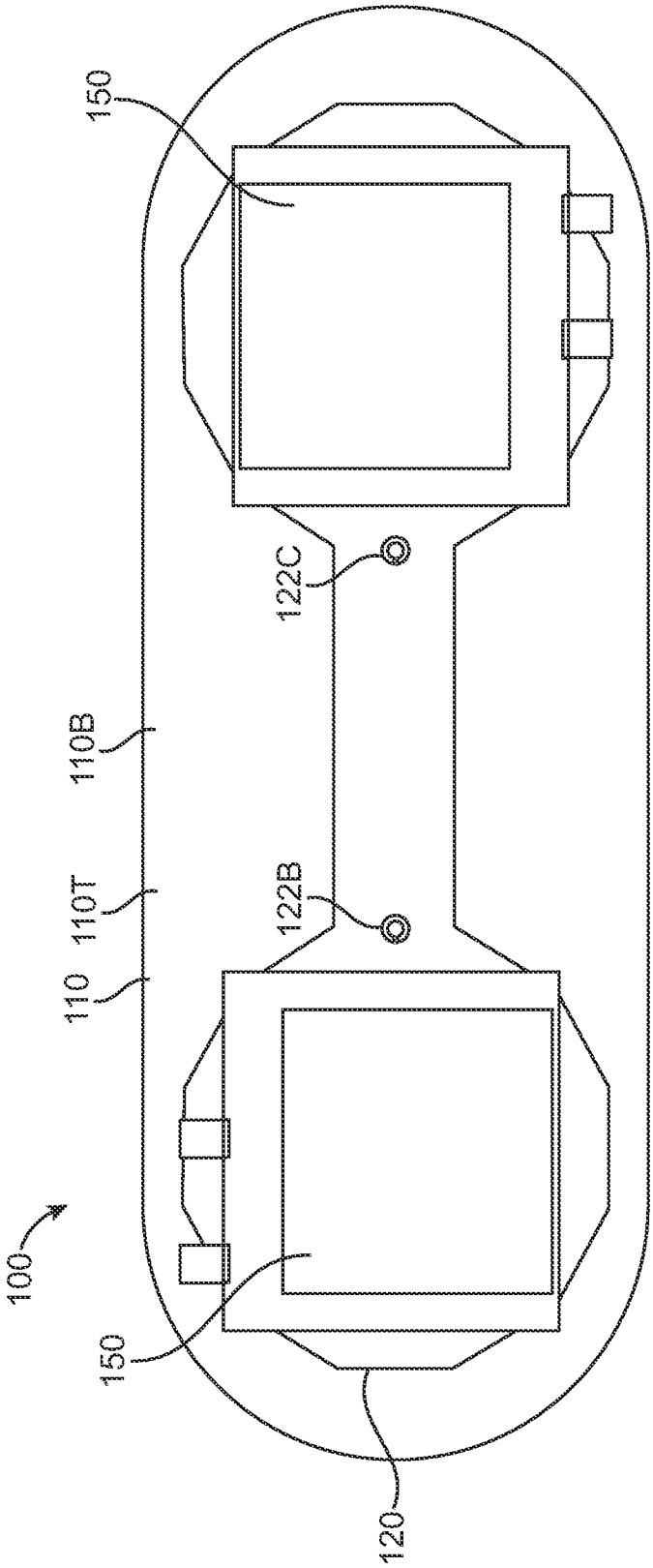

FIG. 1E

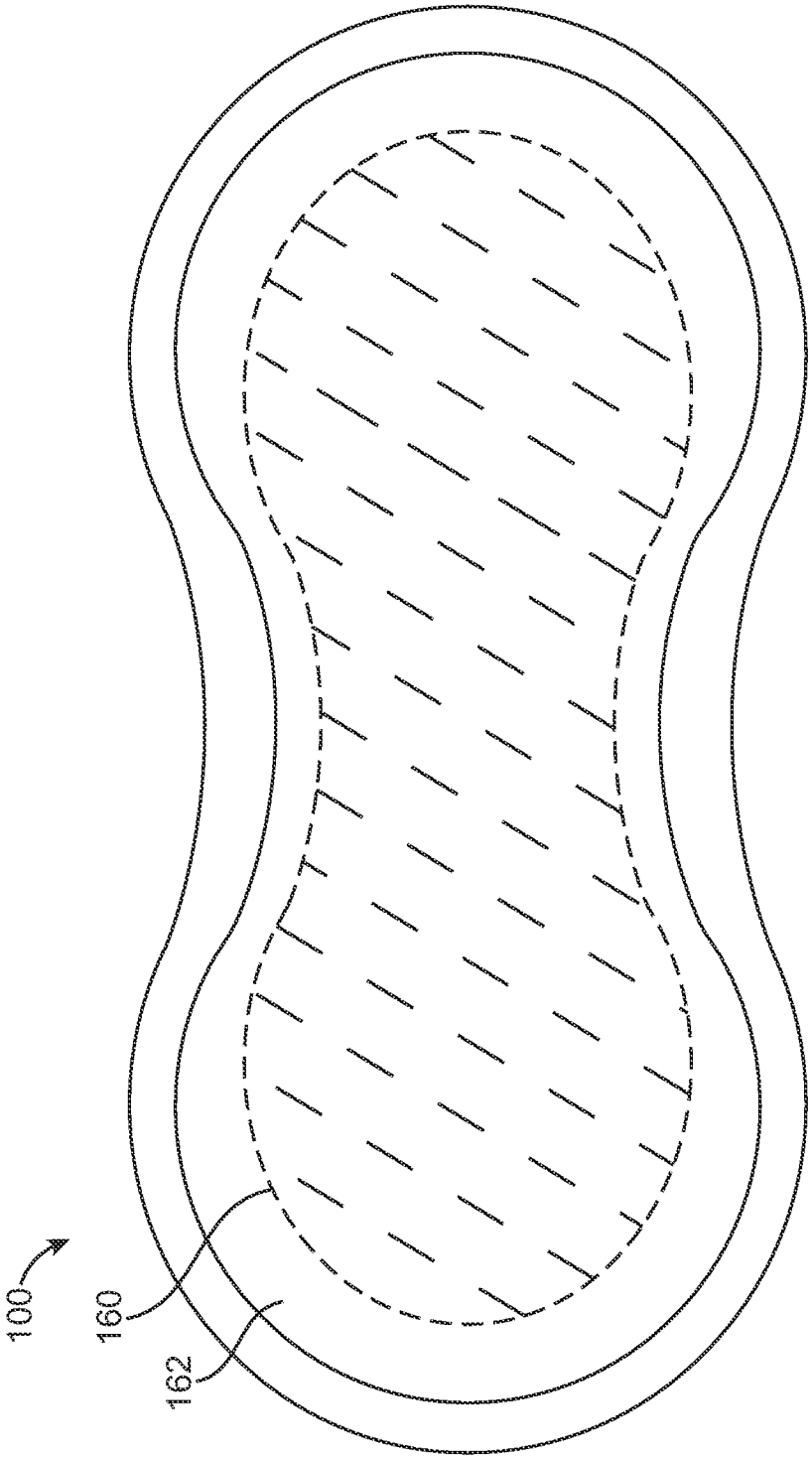

FIG. 1F

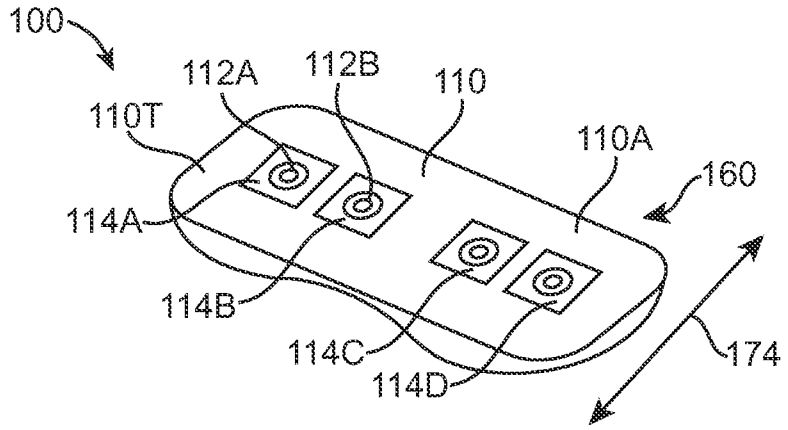
100
112A
112B
110
110T
110A
160
114A
114B
114C
114D
174

FIG. 1H

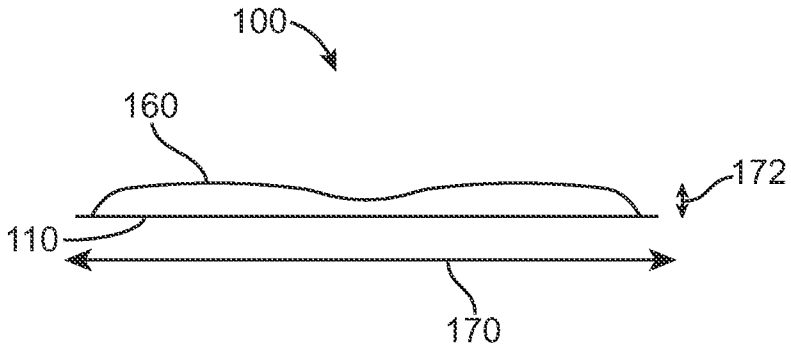
100
160
172
110
170

FIG. 1G

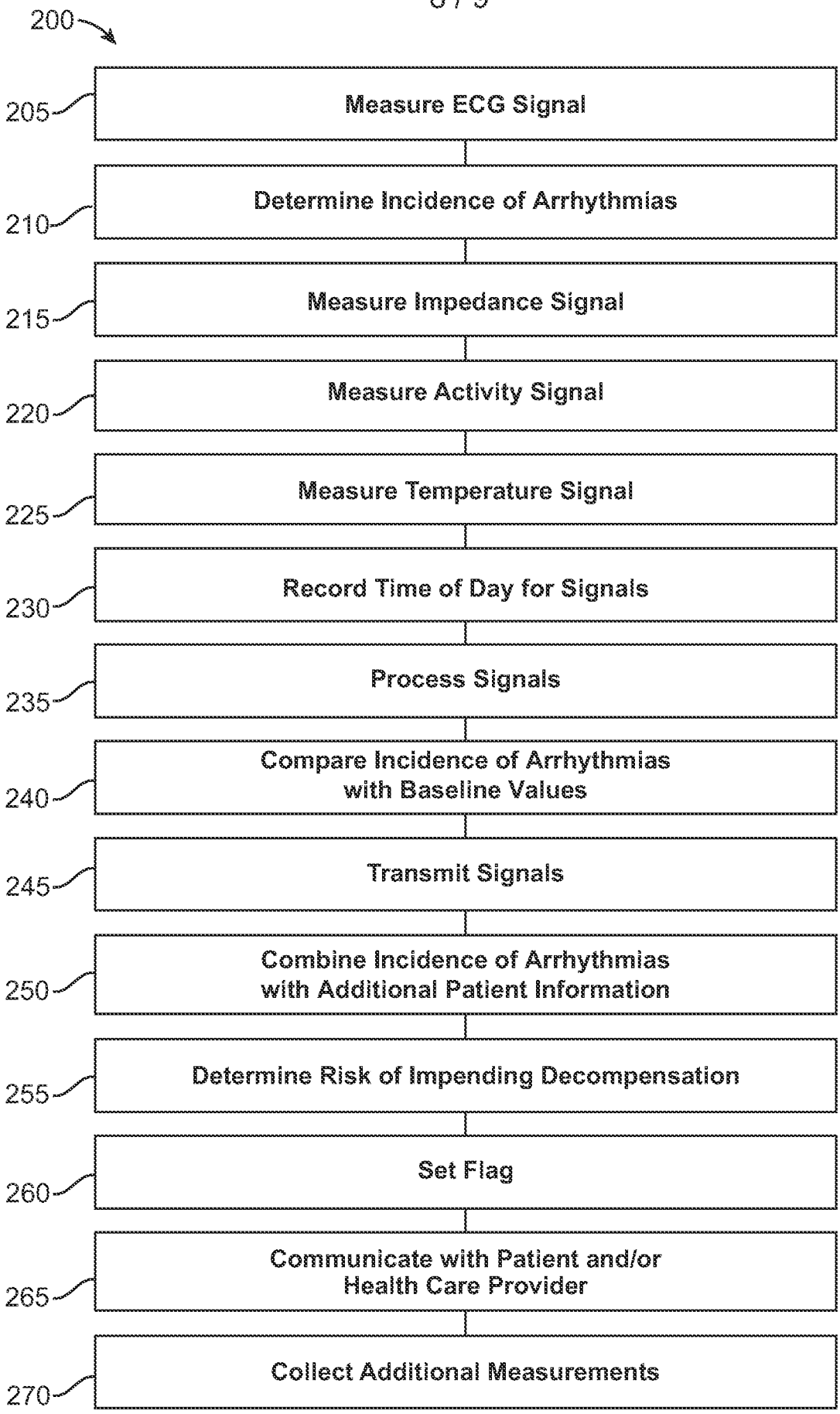
200
205
Measure ECG Signal
210
Determine Incidence of Arrhythmias
215
Measure Impedance Signal
220
Measure Activity Signal
225
Measure Temperature Signal
230
Record Time of Day for Signals
235
Process Signals
240
Compare Incidence of Arrhythmias with Baseline Values
245
Transmit Signals
250
Combine Incidence of Arrhythmias with Additional Patient Information
255
Determine Risk of Impending Decompensation
260
Set Flag
265
Communicate with Patient and/or Health Care Provider
270
Collect Additional Measurements

FIG. 2A

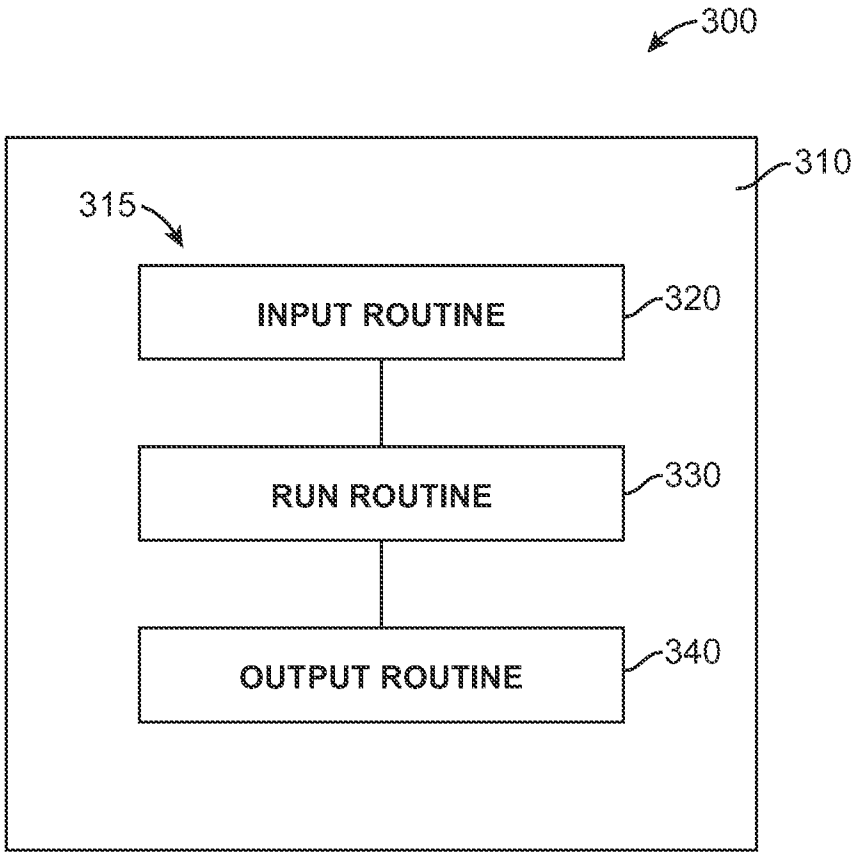
300
310
315
INPUT ROUTINE
320
RUN ROUTINE
330
OUTPUT ROUTINE
340

FIG. 3A

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/036690

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/02 (2009.01)
USPC - 600/509
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 5/00, 5/02, 5/021, 5/024, 5/0245, 5/029, 5/04, 5/0402, 5/0404, 5/0408, 5/042, 5/0452, 5/0488, 5/05, 5/053; etc. (2009.01)
USPC - 128/204.23, 903; 600/300, 301, 481, 484, 485, 486, 508, 509, 513, 526, 528; 607/6, 9, 17, 18, 28

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2005/0085734 A1 (TEHRANI) 21 April 2005 (21.04.2005) entire document	1-3, 5-9, 11-14, 16-21, 23-27, 29-31, 40, 41 --- 4, 10, 15, 22, 28, 32-39, 42
Y	US 2004/0220639 A1 (MULLIGAN et al) 04 November 2004 (04.11.2004) entire document	4
Y	US 7,206,630 B1 (TARLER) 17 April 2007 (17.04.2007) entire document	10, 15, 28, 32-38
Y	US 2007/0191723 A1 (PRYSTOWSKY et al) 16 August 2007 (16.08.2007) entire document	22, 39
Y	US 2003/0083581 A1 (TAHA et al) 01 May 2003 (01.05.2003) entire document	42

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 April 2009	12 MAY 2009
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

专利名称(译)	基于心律的心力衰竭失代偿预测		
公开(公告)号	EP2257216A4	公开(公告)日	2013-01-16
申请号	EP2009719430	申请日	2009-03-10
[标]申请(专利权)人(译)	科文迪斯有限公司		
申请(专利权)人(译)	CORVENTIS INC.		
当前申请(专利权)人(译)	CORVENTIS INC.		
[标]发明人	LIBBUS IMAD MAZAR SCOTT T MANICKA YATHEENDHAR D AMURTHUR BADRI		
发明人	LIBBUS, IMAD MAZAR, SCOTT, T. MANICKA, YATHEENDHAR, D. AMURTHUR, BADRI		
IPC分类号	A61B5/02 A61B5/0205 A61B5/00 A61B5/0408 A61B5/053 A61B7/04		
CPC分类号	A61B5/7275 A61B5/0006 A61B5/0022 A61B5/0031 A61B5/0205 A61B5/02055 A61B5/04085 A61B5/046 A61B5/0464 A61B5/053 A61B5/6833 A61B5/7246 A61B7/04 A61B2560/0412 G16H50/20 G16H50/30		
优先权	61/035970 2008-03-12 US		
其他公开文献	EP2257216A1		
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。从心电图信号确定心律失常的发生率。根据心律失常的发生率确定即将失代偿的风险。在许多实施例中，可以足够早地检测即将发生的失代偿，以避免或至少延迟即将发生的失代偿，从而可以避免患者创伤和/或昂贵的ICU护理。尽管实施例具体参考用贴附贴片监测心电图和其他生理信号，但系统方法和装置适用于使用生理监测的许多应用，例如使用植入传感器进行长时间的无线生理监测。