ENERGY MANAGEMENT FOR ADHERENT PATIENT MONITOR

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ABSTRACT

A heart failure patient management system includes a detecting system. The detecting system includes an adherent device configured to be coupled to a patient. The adherent device includes a plurality of sensors to monitor physiological parameters of the patient to determine heart failure status. At least one ID may be coupled to the adherent device that is addressable and unique to each adherent device. A wireless communication device is coupled to the plurality of sensors and configured to transfer patient data directly or indirectly from the plurality of sensors to a remote monitoring system. The remote monitoring system is coupled to the wireless communication device. An energy management device may be coupled to the plurality of sensors.
FIG. 12

[Diagram showing a flowchart with decision points and processes related to data transmission and validation.]
ENERGY MANAGEMENT FOR ADHERENT PATIENT MONITOR
CROSS-REFERENCES TO RELATED APPLICATIONS

The present application claims the benefit under 35 USC 119(e) of U.S. Provisional Application Nos. 60/972, 336, 60/972, 537, 60/972, 340 all filed Sep. 14, 2007, 61/055, 666 filed May 23, 2008, and 61/079, 746 filed Jul. 10, 2008; the full disclosures of which are incorporated herein by reference in their entirety.

The subject matter of the present application is related to the following applications: Nos. 60/972, 512; 60/972,329; 60/972,354; 60/972,616; 60/972,363; 60/972,343; 60/972,581; 60/972,629; 60/972,316; 60/972,333; 60/972,359; all of which were filed on Sep. 14, 2007; 61/046, 196 filed Apr. 18, 2008; 61/047,875 filed Apr. 25, 2008; and 61/055,645, 61/055,656, 61/055,662 all filed May 23, 2008.


BACKGROUND OF THE INVENTION

1. Field of the Invention
2. This invention relates generally to systems and methods that use wireless physiological monitoring, and more particularly to systems and methods for heart failure patient monitoring.

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

Another area in which home-monitoring is of particular interest is in the remote monitoring of a patient param-
Another object of the present invention is to provide a remote monitoring system for HF patients where heart failure status is determined by a variance from a baseline value of sensor outputs.

[0026] Yet another object of the present invention is to provide a remote monitoring system for HF patients where baseline values are defined by a look up table.

[0027] Still a further object of the present invention is to provide a remote monitoring system for HF patients where heart failure status is determined when a first sensor output is at a high value that is greater than a baseline value, and at least one of the second sensor outputs is at a high value also sufficiently greater than a baseline value to indicate heart failure status.

[0028] Another object of the present invention is to provide a remote monitoring system for HF patients where heart failure status is determined by time weighting the outputs of at least first, second and third sensors, and the time weighting indicates a recent event that is indicative of the heart failure status.

[0029] These and other objects of the present invention can be achieved in many embodiments comprising a patient monitoring system that includes a detecting system. The detecting system has, (i) an adherent device configured to be coupled to a patient, the adherent device including a plurality of sensors that monitors physiological parameters of the patient, for example physiological parameters to determine heart failure status, (ii) at least one ID coupled to the adherent device that is addressable and unique to each adherent device, and (iii) a wireless communication device coupled to the plurality of sensors and configured to transfer patient data from the plurality of sensors to a remote monitoring system. The remote monitoring system is coupled to the wireless communication device. An energy management device may be coupled to the plurality of sensors so as to minimize power consumption when the patch is worn by the patient.

[0030] In a first aspect, embodiments of the present invention provide a system for monitoring a patient. The system comprises a patient detecting system and a remote monitoring system. The patient detecting system can measure the patient and includes an adherent device configured to be coupled to a patient. The adherent device comprises a plurality of sensors to measure physiological parameters of the patient to determine physiologic status of the patient. The patient detecting system also includes an energy management device coupled to the plurality of sensors and a wireless communication device coupled to the plurality of sensors. The remote monitoring system is coupled to the wireless communication device and configured to transfer patient data from the plurality of sensors to the remote monitoring system.

[0031] In many embodiments, an energy generation device is coupled to the energy management device.

[0032] In many embodiments, the energy management device is part of the patient detecting system. The adherent device may be configured to sample intermittently. For example, the plurality of sensors may be configured to sample no more than 30 seconds for every minute for ECG, no more than once per second for an accelerometer sensor and no more than 60 seconds for every 15 minutes for impedance.

[0033] The plurality of sensors may be configured to measure at least one of biopotential, heart rate, heart rhythm, HRV, HRT, heart sounds, respiratory sounds, blood pressure, activity, posture, wake/sleep, orthopnea, temperature, heat flux or patient activity. The plurality of sensor may be con-
figured to measure the patient activity with at least one of a ball switch, an accelerometer, minute ventilation, heart rate, bioimpedance, noise, skin temperature, heat flux, blood pressure, muscle noise or patient posture.

[0034] In many embodiments, the plurality of sensors is configured to switch between different modes. The different modes comprise a first mode and a second mode, the first mode different from the second mode.

[0035] The energy management device may be configured to deactivate selected sensors to reduce redundancy and reduce power consumption. The energy management device may be configured to use sensor cycling for energy management. The plurality of sensors may comprise a first portion of sensors and a second portion of sensors. The first portion can be configured to sample at first times and the second portion can be configured to sample at second times. The first times may be different from the second times, and the energy management device may be configured to cycle sampling between the first sensors and the second sensors.

[0036] The plurality of sensors may comprise a first core sensor and a second sensor. The first core sensor is configured to continuously monitor and detect while the second sensor is configured to verify a physiological status in response to the core sensor raising a flag. The plurality of sensors may comprise a first portion and a second portion. The first portion is different from the second portion. The first portion is configured for short term tracking and the second portion of the sensors is configured for long term tracking.

[0037] The adherent device may be configured to be activated. The adherent device may be activated by at least one of a physiological trigger, automatic impedance, a tab pull, battery insertion, a hall or reed switch, a breakable glass capsule, a dome switch, by light activation, pressure activation, body temperature activation, a connection between electronics associated with the sensors and the adherent device, exposure to air and by a capacitive skin sensor.

[0038] The energy management device may be configured to perform at least one of modulate a clock speed to optimize energy, monitor cell voltage drop—unload cell, monitor coulomb-meter or other battery monitor, battery end of life dropoff to transfer data, elective replacement indicator, call center notification, sensing windows by the sensors based on a monitored physiological parameter or sensing rate control. The energy generation device may be configured to generate energy by at least one of a thermo-electric unit, kinetics, fuel cell, through solar power, a zinc air interface, Faraday generator, internal combustion, a micro-battery and with a rechargeable device.

[0039] In many embodiments, the system further comprises a processor. The processor comprises a tangible medium coupled to the plurality of sensors and to the wireless communication device. The processor is configured to receive patient data from the plurality of sensors and process the patient data. The processor may be located at the remote monitoring system. The processor may be included in a monitoring unit, which comprises part of the patient detecting system. Logic resources may be located at the monitoring unit. These logic resources determine a physiological event of a patient.

[0040] In many embodiments, the system further comprises logic resources located at the remote monitoring system. These logic resources may determine a physiological status of the patient and detect a physiological event of a patient.

[0041] In many embodiments, the system further comprises a processor system. The processor system comprises a tangible medium and has program instructions for evaluating values received from the plurality of sensors with respect to acceptable physiological ranges for each value received by the processor.

[0042] The wireless communication device may be configured to receive instructional data from the remote monitoring system. The wireless communication device may comprise at least one of a modem, a serial interface, a LAN connection and a wireless transmitter. The wireless communication device may include a receiver and a transmitter for receiving data indicating the values of the physiological event detected by the plurality of sensors, and for communicating the data to the remote monitoring system. The wireless communication device may comprise a wireless local area network for receiving data from the plurality of sensors. The wireless communication device may include a data storage for recording the received data from the plurality of sensors. The wireless communication device may include a controller configured to control sending of the data supplied by the plurality of sensors.

[0043] In many embodiments, the system further comprises an external device coupled to the adherent device comprising the plurality of sensors. The external device may comprise at least one of a weight scale, a blood pressure cuff, a medical treatment device or a medicament dispenser.

[0044] In many embodiments, the system further comprises a notification device coupled to the patient detecting system and the remote monitoring system. The notification device is configured to provide a notification when values received from the plurality of sensors are outside acceptable physiological ranges. The patient measurement system may be configured to measure physiological parameters at a high-rate of sampling in response to a trigger from at least one of a medical provider, the remote monitoring system or a medical treatment device. The at least one of the medical provider, the remote monitoring system or the medical treatment device are configured to trigger the high-rate of sampling of the physiological parameters for alert verification. The notification device may be configured to communicate with the at least one of the patient, a clinician, a family member, a caregiver or a medical provider when the values received from the plurality of sensors are not within acceptable physiological ranges. The notification device may further be configured to communicate from one device to another device, thereby allowing for therapeutic intervention to prevent decompensation when the values received from the plurality of sensors are not within acceptable physiological ranges.

[0045] In many embodiments, the system further comprises a memory management device. The memory management device is configured to perform at least one of data compression, prioritizing of sensory by a sensor, monitoring at least some from at least some of the sensors, sensing by the sensors in real time, noise blanking such that sensor data is not stored when noise above a selected level is determined, low-power of battery charging or decimation of old sensor data.

[0046] The adherent device may comprise a wearable patch that includes a battery.

[0047] The physiological status of the patient may comprise a heart failure status. At least one of the patient detecting
system or the remote monitoring system may comprise a processor system configured to determine the heart failure status of the patient in response to the physiological parameters.

[0048] The plurality of sensors may comprise a combination of at least two sensors configured to detect or predict decompensation. The combination may be configured to measure at least two of an electrocardiogram signal, a hydration signal, an accelerometer signal or a respiration signal of the patient.

[0049] The remote monitoring system may include a receiver, a transmitter and a display for displaying data representative of values of at least one physiological event detected by the plurality of sensors.

[0050] The remote monitoring system may include a data storage mechanism and a comparator. The data storage mechanism has a plurality of acceptable ranges for physiological values stored therein. The comparator compares the data received from the monitoring system with the acceptable ranges stored in the data storage device.

[0051] The remote monitoring system may include a portable computer. The remote monitoring system may comprise a portable unit having a display screen and a data entry device for communicating with the wireless communication device.

[0052] In another aspect, embodiments of the invention provide a device for monitoring a patient. The device comprises an adherent device comprising a plurality of sensors, sensor circuitry coupled to the plurality of sensors, wireless circuitry and energy management circuitry. The adherent device is configured to couple to a skin of the patient. The sensor circuitry comprises electrocardiogram circuitry, bioimpedance circuitry, accelerometer circuitry, and temperature sensor circuitry. The power management device is coupled to the wireless circuitry and configured to transmit data from the sensor circuitry with a wireless circuitry duty cycle of no more than about 5%.

[0053] In many embodiments, the device is configured to monitor continuously a patient health status in response to the plurality of sensors.

[0054] In many embodiments, the patient may comprise a heart failure patient and the adherent device is configured to continuously monitor the heart failure status with the wireless circuitry duty cycle of no more than about 5%.

[0055] In many embodiments, a majority of the sensor circuitry comprises a duty cycle of no more than about 5%. For example, the electrocardiogram circuitry may comprise a duty cycle of no more than about 40%; the bioimpedance circuitry may comprise a duty cycle of no more than about 10%; the accelerometer circuitry may comprise a duty cycle of no more than about 1%; and the temperature sensor circuitry may comprise a duty cycle of no more than about 1%.

[0056] The power management device may comprise a timer coupled to the sensor circuitry to determine the duty cycle of each sensor.

[0057] In many embodiments, the device further comprises a processor. The processor comprises a tangible medium coupled to the sensor circuitry and is configured with the timer to sample data from the sensor circuitry. The adherent device is configured to support the processor, the plurality of sensors, the sensor circuitry, the wireless circuitry and the energy management circuitry with the skin of the patient.

[0058] In many embodiments, the processor is configured to determine a heart rate of the patient in response to the electrocardiogram circuitry. The processor may also be configured to determine a respiration of the patient in response to the bioimpedance circuitry.

[0059] In many embodiments, the device further comprises a processor system. The processor system comprises the processor and a second processor at a remote location. The second processor is wirelessly coupled to the processor supported with adherent device. The processor system is configured to detect decompensation of a heart failure patient in response to output from the plurality of sensors. The second processor at the remote location may be configured to combine the output from the plurality of sensors detect the decompensation of the heart failure patient. The second processor at the remote location can be configured to determine a respiration rate of the patient at the remote location in response to the bioimpedance circuitry.

[0060] In many embodiments, the device comprises at least one battery configured to power the electrocardiogram circuitry, the bioimpedance circuitry and the accelerometer circuitry and the temperature sensor circuitry for at least about one week when the adherent device is adhered to the skin of the patient. The adherent device may be configured to consume no more than about 1500 mA- Hours per day when the adherent device is adhered to the patient for an extended period of at least about one week.

[0061] In another aspect, embodiments of the present invention provide a method for monitoring a patient. The method comprises adhering an adherent device to a skin of the patient. The adherent device comprises a plurality of sensors. Patient data are measured with sensor circuitry coupled to the plurality of sensors. The sensor circuitry comprises at least one of electrocardiogram circuitry, bioimpedance circuitry, accelerometer circuitry, or temperature sensor circuitry. The patient data is transmitted with wireless transmission circuitry supported the skin of the patient to a remote monitoring system. The wireless transmission circuitry transmits the patient data intermittently with a duty cycle of no more than about 5%.

**BRIEF DESCRIPTION OF THE DRAWINGS**

[0062] FIG. 1 is a block diagram illustrating one embodiment of a patient monitoring system of the present invention;

[0063] FIG. 2A and 2B illustrate exploded view and side views of embodiments of an adherent device with sensors configured to be coupled to the skin of a patient for monitoring purposes;

[0064] FIG. 3 illustrates one embodiment of an energy management device that is coupled to the plurality of sensors of FIG. 1;

[0065] FIG. 4 illustrates one embodiment of present invention illustrating logic resources configured to receive data from the sensors and/or the processed patient for monitoring purposes, analysis and/or prediction purposes;

[0066] FIG. 5 illustrates an embodiment of the patient monitoring system of the present invention with a memory management device;

[0067] FIG. 6 illustrates an embodiment of the patient monitoring system of the present invention with an external device coupled to the sensors;

[0068] FIG. 7 illustrates an embodiment of the patient monitoring system of the present invention with a notification device;

[0069] FIG. 8 is a block diagram illustrating an embodiment of the present invention with sensor leads that convey
signals from the sensors to a monitoring unit at the detecting system, or through a wireless communication device to a remote monitoring system;

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

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

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

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

DETAILED DESCRIPTION OF THE INVENTION

Embodiments of the present invention comprise an adherent multi-sensor patient monitor capable of tracking a patient’s physiological status. The monitor can be configured for and detecting and predicting physiological events, for example negative physiological events. The device may comprise an intelligent combination of sensors to enhance detection and prediction capabilities, for example to detect cardiac decompensation.

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 dec compensation 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.

The combination of sensors can be used to detect cardiac decompensation, which can be difficult to diagnose in the early stages.

The adherent patch device may comprise an energy management device configured with a variety of energy management features. The energy management device comprises circuitry configured for energy management, for example at least one of timer circuitry, processor circuitry, or programmable array logic (PAL) circuitry. The energy management device may be configured with at least one of the following:

1. Patch activation
   a. Patch can be activated
   b. Mechanism for removing from storage mode
   i. Automatic impedance/physiological variable trigger
   ii. Tab pull (e.g. integrated into package)
   iii. Battery insertion
   iv. Hall/reed switch
   v. Breakable glass capsule
   vi. Dome switch
   vii. Light activated (storage in opaque package)
   viii. Pressure activated (storage in vacuum sealed package)
   ix. Temperature (body temperature activated)
   x. Temp/activity/physiological variable within range
   xi. Connection between electronics and patch
   xii. Exposure to air (zinc-air battery, etc.)
   xiii. Capacitive skin sensor

2. Intermittent sampling
3. Data management
   a. Data compression
   b. Prioritizing sensor data—all sensors monitored in real time—subset of sensors stored for report
   c. Noise blanking
   d. Low-power caching
   e. Decimate old data
   f. EOC dropoff to transfer data
   g. ERI: call center notification
4. Power/energy generation/storage
   a. Thermo-electric unit
   b. Kinetic
   c. Fuel cell
   d. Solar powered
   e. Zinc-air
   f. Faraday generator
   g. Internal combustion
   h. Nuclear powered
   i. Micro-battery
   j. Acoustic
   k. Inductive
   l. Rechargeable

5. Energy management
   a. Modulate clock speed to optimize energy
   b. Physiological (e.g. sleep) control of sensors—duty cycle, sample rate control (based on always-on sensor)

6. Energy monitoring
   a. Monitor cell voltage drop—unload cell
   b. Monitor coulomb-meter or other battery monitor

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

Embodiments may comprise a patient management system comprising an adherent patch that is applied to the patient, for example for monitoring heart failure patients. The patch can be configured to monitor physiological patient parameters, communicates wirelessly with a remote center, and provides alerts when necessary. The patient management system may comprise a variety of tracking and security devices.

The heart failure patient management system can monitor physiological parameters and uses algorithms to determine heart failure status and an predict impending cardiac decompensation. The system comprises an adherent patch device with wireless communication capabilities. The
The adherent patch device may be tagged with a sensor ID, which is addressable and unique to each patch. This ID may be transmitted to the remote sensor with the data stream, and can be used to associate the data with the particular patch system. If multiple disposable patches are used by the same patient, the multiple patches may be linked as a set, and replacement patches linked to the original set. At the hospital, when the patch set is given to the patient, the nurse may register via a web site and upload patient info onto patch, for example using a hospital unit with scanner and wireless connection to patch.

The modem may be assigned to the patient, which then links to the patch set. A particular modem can be configured to only communicate with a specific patch set, which is associated with a specific patient. Registration with the remote center may occur automatically.

The patch may be associated with a patient using caller ID (to determine the source of the modem communication, using an RFID tag on the patient, for example implant or second patch, a body tattoo, a fingerprint ID, or GPS. A removable memory component, for example containing a unique tag, may be reused as the patches are replaced.

To enhance security, a tamper-proof electronics housing may be used with the adherent patch device.

The adherent patch device may also produce two different outputs, protected patient data with restricted communication and general device and/or patient information for general communication. The restricted communication may require additional security verification. The restricted communication may be encrypted, while general communication is not.

Additional security mechanism may include: skin tattoo with patch reader, modem identification, encrypted communication, encrypted data storage on the device, biometric ID, and x-ray ID tags.

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

In one specific embodiment, the system 10 is used for decompensation prediction of a heart failure patient. For example system 10 may comprise a heart failure patient management system used for decompensation prediction of a heart failure patient. System 10 comprises a detecting system, for example a patient measuring system, denoted as 12, and a remote monitoring system 18. The detecting system comprises an adherent device configured to couple to the patient, for example configured to adhere to the patient’s skin.

The adherent device comprises a plurality of sensors 14. The plurality of sensors can measure physiological parameters of the patient to monitor the patient and determine the status of the patient, for example to determine heart failure status. The physiological parameters can provide an indication of at least one physiological event, for example a cardiac decompensation or an impending cardiac decompensation. The plurality of sensors may be coupled to the patient, for example adhered to the patient’s thorax. The adherent device may be housed in a tamper proof housing prior to placement on the patient.

The logic circuitry, or resources, can be configured in many ways to detect the at least one physiological event, such as heart failure. For example, the remote monitoring system may comprise the logic circuitry, and the remote monitoring system may determine HF status when a rate of change of at least two sensor outputs comprises an abrupt change in the sensor outputs, such as an abrupt change as compared to a change in the sensor outputs over a longer period of time. The remote monitoring system may determine HF status by a tiered combination of at least a first and a second sensor output, with the first sensor output indicating a problem that is then verified by at least a second sensor output. The remote monitoring system may determine HF status in response to a variance from a baseline value of sensor outputs. In some embodiments, the baseline values may be defined by a look up table. The HF status may be determined when a first sensor output is at a high value that is greater than a baseline value, and at least one of a second or a third sensor outputs is at a high value also sufficiently greater than a baseline value to indicate heart failure status. Heart failure status may be determined by time weighting the outputs of at least first, second and third sensors, and the time weighting indicates a recent event that is indicative of the heart failure status. When the patient measuring system comprises the logic circuitry, the patient measuring system may similarly detect at the least one physiological event.

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

The plurality of sensors 14 may comprise at least one ID sensor. The at least one ID sensor may be coupled to the adherent device, addressable, and unique to each adherent device. The adherent device may comprise the ID sensor of the plurality of sensors 14.

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

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

[0139] Electrical circuitry and components 230 comprise circuitry and components to take physiologic measurements, transmit data to remote center and receive commands from remote center. In many embodiments, electronic components 230 may comprise known low power circuitry, for example complementary metal oxide semiconductor (CMOS) circuitry components. Electronic components 230 comprise an activity sensor and activity circuitry, impedance circuitry and electrocardiogram circuitry, for example ECG circuitry. In some embodiments, electrical circuitry may comprise a microphone and microphone circuitry to detect an audio signal from within the patient, and the audio signal may comprise a heart sound and/or a respiratory sound, for example an S3 heart sound and a respiratory sound with rales and/or crackles. Electronics circuitry and components 230 may comprise a temperature sensor, for example a thermometer, and temperature sensor circuitry to measure a temperature of the patient, for example a temperature of a skin of the patient. [0140] A cover 262 can extend over the batteries, electronic components and flex printed circuit board. In many embodiments, an electronics housing 260 may be disposed under cover 262 to protect the electronic components, and in some embodiments electronic housing 260 may comprise an encapsulant over the electronic components and PCB. In some embodiments, cover 262 can be adhered to the adhesive patch with an adhesive. In many embodiments, electronics housing 260 may comprise a water proof material, for example a sealant adhesive such as epoxy or silicone coated over the electronic components and/or PCB. In some embodiments, electronics housing 260 may comprise metal and/or plastic. Metal or plastic may be potted with a material such as epoxy or silicone. Cover 262 may comprise many known biocompatible cover, casing and/or housing materials, such as elastomers, for example silicone. The elastomer may be fenestrated to improve breathability. In some embodiments, cover 262 may comprise many known breathable materials, for example polyester, polyamide, and/or elastane (Spandex). The breathable fabric may be coated to make it water resistant, waterproof, and/or to aid in wicking moisture away from the patch.

[0141] Adherent device 200 comprises several layers. Gel 214A, or gel layer, is positioned on electrode 212A to provide electrical conductivity between the electrode and the skin. Electrode 212A may comprise an electrode layer. Adhesive patch 210 may comprise a layer of breathable tape 210T, for example a known breathable tape, such as tricot-knit polyester fabric. In many embodiments, a gap 269 extends from adhesive patch 210 to the electronics circuitry and components 230, such that breathable tape 210T can breath to provide patient comfort. An adhesive 216A, for example a layer of acrylate pressure sensitive adhesive, can be disposed on underside 210A of patch 210. A gel cover 280, or gel cover layer, for example a polyurethane non-woven tape, can be positioned over patch 210 comprising the breathable tape. A PCB layer, for example flex PCB 220, or flex PCB layer, can be positioned over gel cover 280 with electronic components 230 connected and/or mounted to flex PCB 220, for example mounted on flex PCB so as to comprise an electronics layer disposed on the flex PCB. In many embodiments, the adherent device may comprise a segmented inner component, for example the PCB, for limited flexibility. In many embodiments, the electronics layer may be encapsulated in electronics housing 260 which may comprise a waterproof material, for example silicone or epoxy. In many embodiments, the electrodes are connected to the PCB with a flex connection, for example trace 223A of flex PCB 220, so as to provide strain relief between the electrodes 212A, 212B, 212C and 212D and the PCB. Gel cover 280 can inhibit flow of gel 214A and liquid. In many embodiments, gel cover 280 can inhibit gel 214A from seeping through breathable tape 210T to maintain gel integrity over time. Gel cover 280 can also keep external moisture from penetrating into gel 214A. Gel cover 280 may comprise at least one aperture 280A sized to receive one of the electrodes. In many embodiments, cover 262 can encase the flex PCB and/or electronics and can be adhered to at least one of the electronics, the flex PCB or the adherent patch, so as to protect the device. In some embodiments, cover 262 attaches to adhesive patch 210 with adhesive 216B. Cover 262 can comprise many known biocompatible cover, housing and/or casing materials, for example silicone. In many embodiments, cover 262 comprises an outer polymer cover to provide smooth contour without limiting flexibility. In some embodiments, cover 262 may comprise a breathable fabric. Cover 262 may comprise many known breathable fabrics, for example breathable fabrics as described above. In some embodiments, the breathable fabric may comprise polyester, polyamide, and/or elastane (Spandex™) to allow the breathable fabric to stretch with body movement. In some embodiments, the breathable tape may contain and elute a pharmaceutical agent, such as an antibiotic, anti-inflammatory or antifungal agent, when the adherent device is placed on the patient.

[0142] In one embodiment, the wireless communication device 16 is configured to receive instructional data from the remote monitoring system.

[0143] Referring to FIG. 3, an energy management device 19 can be coupled to the plurality of sensors. In one embodiment, the energy management device 19 is part of the detecting system. In various embodiments, the energy management device 19 performs one or more of modulate a clock speed to optimize energy, monitor cell voltage drop—unload cell, monitor coulomb-meter or other battery monitor; battery end of life droppoff to transfer data, elective replacement indicator,
call center notification, sensing windows by the sensors 14 based on a monitored physiological parameter and sensing rate control.

[0144] In one embodiment, energy management is achieved by using time as a variable. This can be achieved by intermittent sampling. Variable time courses can be used for measuring signals from the beginning and the duty cycle rates can be adjusted, for example adjusted at the remote monitoring system 18.

[0145] In one embodiment, the energy management device 19 is configured to generate energy by at least one of, a thermo-electric unit, kinetics, fuel cell, through solar power, a zinc air interface, Faraday generator, internal combustion, nuclear power, a micro-battery and with a rechargeable device.

[0146] Referring again to FIG. 1, the adherent device may include a patch set configured to be coupled to the patient. Patches in the patch set, as well as replacement patches can be linked together and coupled to hardware at the detecting system 12 or at the remote monitoring system 18. Patches of the patch set can also be linked at software at a back end at the remote monitoring system 18. Registration with the remote monitoring system 18 can occur each time a new patch is put on the patient.

[0147] When an adherent device is provided to a patient, a medical provider registers that adherent device, associated with that patient, with the remote monitoring system 18. Registration can take place a variety of different ways, including but not limited to, via a web site, and the like. Upon registration, patient data is uploaded to the adherent device. An association of the adherent patch with the patient occurs by at least one of, caller ID, an RFID tag on the patient, a body tattoo, fingerprint ID and GPS.

[0148] In one embodiment, a modem is assigned to the patient and links to the adherent device. The modem can be configured to determine which patch is sending information to the modem. The modem communicates only with the patch set of the patient, and the modem only communicates with those patches with which it is associated. The modem can be at the detecting system 12 or at the remote monitoring system 18.

[0149] In one embodiment, the ID sensor 14 has a removable memory component with a unique patient ID that is reused as patches of the patch set are replaced. In one embodiment, the ID sensor 14 produces a first output that has protected patient data with restricted communication, and a second output that has general device and patient information for general communication. Access to the protected patient data can require an additional security verification. At least a portion of the protected patient data can be encrypted. A variety of additional security verifications including but not limited to, a skin tattoo with an adherent device reader, a modem identification, an encrypted communication, an encrypted data storage on the adherent device, a biometric ID, an X-ray ID tag and the like.

[0150] The system 10 is configured to automatically detect events. The system 10 automatically detects events by at least one of, high noise states, physiological quietness, sensor continuity and compliance. In response to a detected physiological event, patient states are identified when data collection is inappropriate. In response to a detected physiological event, patient states are identified when data collection is desirable. Patient states include, physiological quietness, rest, relaxation, agitation, movement, lack of movement and a patient’s higher level of patient activity.

[0151] The system can use an intelligent combination of sensors to enhance detection and prediction capabilities, as more fully disclosed in U.S. patent application Ser. No. 60/972,537, identified as Attorney Docket No. 026843-000200US, filed Sep. 14, 2007, the full disclosure of which has been previously incorporated herein by reference, and as more fully explained below. The intelligent combination of sensors may comprise a sensor to measure at least two of an electrocardiogram signal, a hydration signal, an accelerometer signal or a respiration signal of the patient.

[0152] In one embodiment, the detecting system 12 communicates with the remote monitoring system 18 periodically or in response to a trigger event. The trigger event can include but is not limited to at least one of, time of day, if a memory is full, if an action is patient initiated, if an action is initiated from the remote monitoring system, a diagnostic event of the monitoring system, an alarm trigger, a mechanical trigger, and the like.

[0153] The adherent device be activated by a variety of different means including but not limited to, a physiological trigger, automatic impedance, a tab pull, battery insertion, a hall or reed switch, a breakable glass capsule, a dome switch, by light activation, pressure activation, body temperature activation, a connection between electronics associated with the sensors and the adherent device, exposure to air, by a capacitive skin sensor and the like.

[0154] The detecting system 12 can continuously, or non-continuously, monitor the patient, alerts are provided as necessary and medical intervention is provided when required. In one embodiment, the wireless communication device 16 is a wireless local area network for receiving data from the plurality of sensors.

[0155] A processor 20 is coupled to the plurality of sensors 14 and can also be a part of the wireless communication device 16. The processor 20 comprises at least one tangible medium and may comprise a processor system. The processor 20 receives data from the plurality of sensors 14 and creates processed patient data.

[0156] In many embodiments, the processor 20 comprises at least one of a processor of detecting system 12 comprising a tangible medium, a processor of remote monitoring system 18 comprising a tangible medium, a processor of wireless communication device 16 comprising a tangible medium or a processor of monitoring unit 22 comprising a tangible medium. In one embodiment, the processor 20 is located at the remote monitoring system. In another embodiment, the processor 20 is located at the detecting system 12.

[0157] The processor 20 can be integral with a monitoring unit 22 that is part of the detecting system 12 or part of the remote monitoring system, or both. The monitoring unit can be located at the remote monitoring system 18.

[0158] The processor 20 has program instructions for evaluating values received from the sensors 14 with respect to acceptable physiological ranges for each value received by the processor 20 and determine variances. The processor 20 can receive and store a sensed measured parameter from the sensors 14, compare the sensed measured value with a predetermined target value, determine a variance, accept and store a new predetermined target value and also store a series of questions from the remote monitoring system 18.

[0159] As shown in FIG. 4, logic resources 24 are provided that take the data from the sensors 14, and/or the processed
patient data from the processor 20, to predict an impending decompensation. The logic resources 24 can be at the remote monitoring system 18 or at the detecting system 12, such as in the monitoring unit 22.

[0160] In one embodiment, illustrated in FIG. 5, a memory management device 25 is provided. In various embodiments, the memory management device 25 performs one or more of data compression, prioritizing of sensing by a sensor 14, monitoring all or some of sensor data by all or a portion of sensors 14, sensing by the sensors 14 in real time, noise blanking to provide that sensor data is not stored if a selected noise level is determined, low-power of battery caching and decimation of old sensor data.

[0161] The sensors 14 can have associated circuitry, e.g., processor 20, which can provide a variety of different functions, including but not limited to, initiation, programming, measuring, storing, analyzing, communicating, predicting, and displaying of a physiological event of the patient. Each of sensors 14 is preferably sealed, such as housed in a hermetically sealed package. In one embodiment, at least a portion of the sealed packages include a power source, a memory, logic resources and a wireless communication device. In one embodiment, the sensors 14 can include, flex circuits, thin film resistors, organic transistors and the like. The sensors 14 can include ceramics to enclose the electronics. Additionally, the sensors 14 can include drug eluting coatings, including but not limited to, an antibiotic, anti-inflammatory agent and the like.

[0162] A wide variety of different sensors 14 can be utilized, including but not limited to, bioimpedance, heart rate, heart rhythm, HRV, HRT, heart sounds, respiration rate, respiration rate variability, respiratory sounds, SpO2, blood pressure, activity, posture, wake/sleep, orthopnea, temperature, heat flux and an accelerometer. A variety of activity sensors can be utilized, including but not limited to, a ball switch, accelerometer, minute ventilation, HR, bioimpedance noise, skin temperature/heat flux, BP, muscle noise, posture and the like.

[0163] The outputs of the sensors 14 can have multiple features to enhance physiological sensing performance. These multiple features have multiple sensing vectors that can include redundant vectors. The sensors can include current delivery electrodes and sensing electrodes. Size and shape of current delivery electrodes, and the sensing electrodes, can be optimized to maximize sensing performance. The system 10 can be configured to determine an optimal sensing configuration and electronically reposition at least a portion of a sensing vector of a sensing electrode. The multiple features enhance the ability of system 10 to determine an optimal sensing configuration and electronically reposition sensing vectors. In one embodiment, the sensors 14 can be partially masked to minimize contamination of parameters sensed by the sensors 14.

[0164] The size and shape of current delivery electrodes, for bioimpedance, and sensing electrodes can be optimized to maximize sensing performance. Additionally, the outputs of the sensors 14 can be used to calculate and monitor blended indices. Examples of the blended indices include but are not limited to, heart rate (HR) or respiratory rate (RR) response to activity, HR/RR response to posture change, HR+RR, HR/RR+bioimpedance, and/or minute ventilation/accelerometer and the like.

[0165] The sensors 14 can be cycled in order to manage energy, and different sensors 14 can sample at different times. By way of illustration, and without limitation, instead of each sensor 14 being sampled at a physiologically relevant interval, e.g. every 30 seconds, one sensor 14 can be sampled at each interval, and sampling cycles between available sensors.

[0166] By way of illustration, and without limitation, the sensors 14 can sample no more than 30 seconds for every minute for ECG, no more than once a second for an accelerometer sensor, and no more than 60 seconds for every 15 minutes for bio-impedance.

[0167] In one embodiment, a first of sensors 14 comprises a core sensor that continuously monitors and detects, and a second of sensors 14 verifies a physiological status in response to the core sensor 14 raising a flag. Additionally, at least some of sensors 14 can be used for short term tracking, and other sensors of sensor 14 used for long term tracking.

[0168] Referring to FIG. 6, in one embodiment, an external device 38, which may comprise a medical treatment device, is coupled to the sensors 14. The external device 38 can be coupled to a monitoring unit 22 that is part of the detecting system 12, or in direct communication with the sensors 14. A variety of different external devices 38 can be used to monitor and/or treat the patient, the external devices 38 including but not limited to, a weight scale, blood pressure cuff, cardiac rhythm management device, a medical treatment device, medicament dispenser and the like. Suitable cardiac rhythm management devices include but are not limited to, Boston Scientific’s Latitude system, Medtronic’s CareLink system, St. Jude Medical’s HouseCall system and the like. Such communication may occur directly, or via an external translator unit.

[0169] Referring again to FIG. 6, the external device 38 can be coupled to an auxiliary input of the monitoring unit 22 at the detecting system 12 or to the monitoring system 22 at the remote monitoring system 18. Additionally, an automated reader can be coupled to an auxiliary input in order to allow a single monitoring unit 22 to be used by multiple patients. As previously mentioned above, the monitoring unit 22 can be at the remote monitoring system 18 and each patient can have a patient identifier (ID) including a distinct patient identifier. In addition, the ID identifier can also contain patient specific configuration parameters. The automated reader can scan the patient identifier ID and transmit the patient ID number with a patient data packet such that the main data collection station can identify the patient.

[0170] It will be appreciated that other medical treatment devices can also be used. The sensors 14 can communicate wirelessly with the external devices 38 in a variety of ways including but not limited to, a public or proprietary communication standard and the like. The detecting system 12 comprising sensors 14 can be configured to serve as a communication hub for multiple medical devices, coordinating sensor data and therapy delivery while transmitting and receiving data from the remote monitoring system 18.

[0171] In one embodiment, the detecting system 12 comprising sensors 14 is configured to coordinate data sharing between the external systems 38 allowing for sensor integration across devices. The coordination of the sensors 14 provides for new pacing, sensing, defibrillation vectors and the like.

[0172] In one embodiment, the processor 20 is included in the monitoring unit 22 and the external device 38 is in direct communication with the monitoring unit 22.

[0173] In another embodiment, illustrated in FIG. 7, a notification device 42 is coupled to the detecting system 12 and
the remote monitoring system 18. The notification device 42 is configured to provide notification when values received from the sensors 14 are not within acceptable physiological ranges. The notification device 42 can be at the remote monitoring system 18 or at the monitoring unit 22 that is part of the detecting system 12. A variety of notification devices 42 can be utilized, including but not limited to, a visible patient indicator, an audible alarm, an emergency medical service notification, a call center alert, direct medical provider notification and the like. The notification device 42 provides notification to a variety of different entities, including but not limited to, the patient, a caregiver, the remote monitoring system, a spouse, a family member, a medical provider, from one device to another device such as the external device 38, and the like.

[0174] Notification can be according to a preset hierarchy. By way of illustration, and without limitation, the preset hierarchy can be, patient notification first and medical provider second, patient notification second and medical provider first, and the like. Upon receipt of a notification, a medical provider, the remote monitoring system 18, or a medical treatment device can trigger a high-rate sampling of physiological parameters for alert verification.

[0175] The system 10 can also include an alarm 46, that can be coupled to the notification device 42, for generating a human perceptible signal when values received from the sensors 14 are not within acceptable physiological ranges. The alarm 46 can trigger an event to render medical assistance to the patient, provide notification as set forth above, continue to monitor, wait and see, and the like.

[0176] When the values received from the sensors 14 are not within acceptable physiological ranges the notification is with at least one of, the patient, a spouse, a family member, a caregiver, a medical provider and from one device to another device, to allow for therapeutic intervention to prevent dec complication, and the like.

[0177] In another embodiment, the sensors 14 can switch between different modes, wherein the modes are selected from at least one of, a stand alone mode with communication directly with the remote monitoring system 18, communication with an implanted device, communication with a single implanted device, coordination between different devices (external systems) coupled to the plurality of sensors and different device communication protocols.

[0178] By way of illustration, and without limitation, the patient can be a congestive heart failure patient. Heart failure status is determined by a weighted combination change in sensor outputs and be determined by a number of different means, including but not limited to, (i) when a rate of change of at least two sensor outputs is an abrupt change in the sensor outputs as compared to a change in the sensor outputs over a longer period of time, (ii) by a tiered combination of at least a first and a second sensor output, with the first sensor output indicating a problem that is then verified by at least a second sensor output, (iii) by a variance from a baseline value of sensor outputs, and the like. The baseline values can be defined in a look up table.

[0179] In another embodiment, heart failure status is determined using three or more sensors by at least one of, (i) when the first sensor output is at a value that is sufficiently different from a baseline value, and at least one of the second and third sensor outputs is at a value also sufficiently different from a baseline value to indicate heart failure status, (ii) by time weighting the outputs of the first, second and third sensors, and the time weighting indicates a recent event that is indicative of the heart failure status and the like.

[0180] In one embodiment, the wireless communication device 16 can include a modem, a controller to control data supplied by the sensors 14, serial interface, LAN or equivalent network connection and a wireless transmitter. Additionally, the wireless communication device 16 can include a receiver and a transmitter for receiving data indicating the values of the physiological event detected by the plurality of sensors, and for communicating the data to the remote monitoring system 18. Further, the wireless communication device 16 can have data storage for recording the data received from the sensors 14 and an access device for enabling access to information recording in the data storage from the remote monitoring system 18.

[0181] In various embodiments, the remote monitoring system 18 can include a receiver, a transmitter and a display for displaying data representative of values of the one physiological event detected by the sensors 14. The remote monitoring system can also include a data storage mechanism that has acceptable ranges for physiological values stored therein, a comparator for comparing the data received from the monitoring system 12 with the acceptable ranges stored in the data storage device and a portable computer. The remote monitoring system 18 can be a portable unit with a display screen and a data entry device for communicating with the wireless communication device 16.

[0182] Referring now to FIG. 8, for each of sensors 14, a sensor lead 112 and 114 conveys signals from the sensor 14 to the monitoring unit 22 at the detecting system 12, or through the wireless communication device 16 to the remote monitoring system 18, or both. In one embodiment, each signal from a sensor 14 is first passed through a filter 116, such a low-pass filter, at the detecting system 12 or at the remote monitoring system 18, to smooth the signal and reduce noise. The signal is then transmitted to an analog-to-digital converter 118A, which transforms the signals into a stream of digital data values that can be stored in a digital memory 118B. From the digital memory 118B, data values are transmitted to a data bus 120, along which they are transmitted to other components of the circuitry to be processed and archived. From the data bus 120, the digital data can be stored in a non-volatile data archive memory. The digital data can be transferred via the data bus 120 to the at least one processor 20, which processes the data based in part on algorithms and other data stored in a non-volatile program memory.

[0183] The detecting system 12 can also include a power management module 122 configured to power down certain components of the system, including but not limited to, the analog-to-digital converters 118A, digital memories 118B and the non-volatile data archive memory and the like, between times when these components are in use. This helps to conserve battery power and thereby extend the battery life. Other circuitry and signaling modes may be devised by one skilled in the art.

[0184] As can be seen in FIG. 9, a control unit 126 is included at the detecting system 12, the remote monitoring system 18 or at both locations.

[0185] In one embodiment, the control unit 126 can be a known 486 microprocessor, available from Intel, Inc., of Santa Clara, Calif. The control unit 126 can be coupled to the sensors 14 directly at the detecting system 12, indirectly at the detecting system 12 or indirectly at the remote monitoring system 18. Additionally the control unit 126 can be coupled to
a blood pressure monitor, a cardiac rhythm management device, a scale or a device that dispenses medication that can indicate the medication has been dispensed.

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

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

Referring now to FIG. 10 and FIG. 11, one embodiment of an internal structure of a main data collection station 130, at the remote monitoring system 18, is illustrated. The patient data can be transmitted to the remote monitoring system 18 by either the wireless communication device 16 or conventional modem to the wireless network storage unit 128. After receiving the patient data, the wireless network storage unit 128 can be accessed by the main data collection station 130. The main data collection station 130 allows the remote monitoring system 18 to monitor the patient data of numerous patients from a centralized location without requiring the patient or a medical provider to physically interact with each other.

The main data collection station 130 can include a communications server 136 that communicates with the wireless network storage unit 128. The wireless network storage unit 128 can be a centralized computer server that includes a unique, password-protected mailbox assigned to and accessible by the main data collection station 130. The main data collection station 130 communicates with the wireless network storage unit 128 and downloads the patient data stored in a mailbox assigned to the main data collection station 130.

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

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

The database server 138 can be accessible by an application server 142. The application server 142 can include a data adapter 144 that formats the patient data information into a form that can be viewed over a conventional web-based connection. The transformed data from the data adapter 144 can be accessible by proprietary software applications through, for example, HTTP protocol, and the like.

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

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

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

The administration server 154 can include a batch server 156 that communicates with the batch server 152 and provides the downloaded data to a database server 158. The data warehouse server 158 can include a large database 160 that records and stores the patient data.

The administration server 154 can further include an application server 162 and a maintenance workstation 148 that allow personnel from an administrator to access and monitor the data stored in the database 160.

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

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

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

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

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

A no communication error can be noted as illustrated in step E. If a communication error is noted the control unit 126 can proceed to wireless communication device 16 or to a conventional modem transmission sequence, as will be described below. However, if the communication device is working the control unit 126 can transmit the patient data information over the wireless network 16, as illustrated in step F. After the communication device has transmitted the data packet, the control unit 126 determines whether the transmission was successful, as illustrated in step G. If the transmission has been unsuccessful only once, the control unit 126 retries the transmission. However, if the communication device has failed twice, as illustrated in step H, the control unit 126 proceeds to the conventional modem process if the remote monitoring unit 22 was configured in an auto mode.

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

The processor system, as described above, can be configured to perform the method shown in FIG. 12, including many of the steps described above. It should be appreciated that the specific steps illustrated in FIG. 12 provide a particular method, according to one embodiment of the present invention. Other sequences of steps may also be performed according to alternative embodiments. For example, alternative embodiments of the present invention may perform the steps outlined above in a different order. Moreover, the individual steps illustrated in FIG. 12 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.

Referring again to FIG. 11, the patient data packets are first sent and stored in the wireless network storage unit 128. From there, the patient data packets are downloaded into the main data collection station 130. The main data collection station 130 decodes the encoded patient data packets and records the patient data in the patient database 140. The patient database 140 can be divided into individual storage locations for each patient such that the main data collection station 130 can store and compile patient data information from a plurality of individual patients.

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

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

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

[0210] Alarm Display Order Patient Status Patients can then be sorted: 1 Medical Alarm Most alarms violated to least alarms violated, then oldest to newest 2 Missing Data Alarm Oldest to newest 3 Late Oldest to newest 4 Reviewed Medical Alarms Oldest to newest 5 Reviewed Missing Data Oldest to newest Alarms 6 Reviewed Null Oldest to newest 7 NDR Oldest to newest 8 Reviewed NDR Oldest to newest.

[0211] As listed in the above, the order of patients listed on the display can be ranked based upon the seriousness and number of alarms that are registered based upon the latest patient data information. For example, if the blood pressure of a single patient exceeds the tolerance level and the patient’s heart rate also exceeds the maximum level, this patient will be placed above a patient who only has one alarm condition. In this manner, the medical provider can quickly determine which patient most urgently needs medical attention by simply identifying the patient’s name at the top of the patient list. The order which the patients are displayed can be configurable by the remote monitoring system 18 depending on various preferences.

[0212] As discussed previously, the escalation server 150 automatically generates a notification message to a specific medical provider for unacknowledged data packets based on user specified parameters.

[0213] Referring again to FIG. 9, in addition to displaying the current patient data for the numerous patients being monitored, the software of the main data collection station 130 allows the medical provider to trend the patient data over a number of prior measurements in order to monitor the progress of a particular patient. In addition, the software allows the medical provider to determine whether or not a patient has been successful in recording their patient data as well as monitor the questions being asked by the remote monitoring unit 22.

[0214] As previously mentioned, the system 10 uses an intelligent combination of sensors to enhance detection and prediction capabilities. Electrocardiogram circuitry can be coupled to the sensors 14, or electrodes, to measure an electrocardiogram signal of the patient. An accelerometer can be mechanically coupled, for example adhered or affixed, to the sensors 14, and the like, to generate an accelerometer signal in response to at least one of an activity or a position of the patient. The accelerometer signals improve patient diagnosis, and can be especially useful when used with other signals, such as electrocardiogram signals and impedance signals, including but not limited to, hydration, respiration, and the like. Mechanically coupling the accelerometer to the sensors 14, electrodes, for measuring impendence, hydration and the like can improve the quality and/or usefulness of the impedance and/or electrocardiogram signals. By way of illustration, and without limitation, mechanical coupling of the accelerometer to the sensors 14, electrodes, and to the skin of the patient can improve the reliability, quality and/or accuracy of the accelerometer measurements, as the sensor 14, electrode, signals can indicate the quality of mechanical coupling of the patch to the patient so as to indicate that the device is connected to the patient and that the accelerometer signals are valid. Other examples of sensor interaction include but are not limited to, (i) orthopnea measurement where the breathing rate is correlated with posture during sleep, and detection of orthopnea, (ii) a blended activity sensor using the respiratory rate to exclude high activity levels caused by vibration (e.g. driving on a bumpy road) rather than exercise or extreme physical activity, (iii) sharing common power, logic and memory for sensors, electrodes, and the like.

[0215] The signals from the plurality of sensors can be combined in many ways. In some embodiments, the signals can be used simultaneously to determine an impending cardiac decompensation.

[0216] In some embodiments, the signals can be combined by using the at least two of the electrocardiogram signal, the respiration signal or the activity signal to look up a value in a previously existing array.

| TABLE 1 |
|---|---|---|---|
| | Heart Rate/Respiration | A-B bpm | C-D bpm | E-F bpm |
| U-V per min | N | N | Y |
| W-X per min | N | Y | Y |
| Y-Z per min | Y | Y | Y |

[0217] Table 1 shows combination of the electrocardiogram signal with the respiration signal to look up a value in a pre-existing array. For example, at a heart rate in the range from A to B bpm and a respiration rate in the range from U to V per minute triggers a response of N. In some embodiments, the values in the table may comprise a tier or level of the response, for example fouriers. 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 look up table shown in Table 1 illustrates the use of a look up table according to one embodiment, and one will recognize that many variables can be combined with a look up table.

[0218] In some embodiments, the table may comprise a three or more dimensional look up table, and the look up table may comprises a tier, or level, of the response, for example an alarm.

[0219] In some embodiments, 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 respiration signal or the activity signal. 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.

[0220] In some embodiments, a weighted combination may combine at least two measurement signals to generate an output value according to a formula of the general form: OUTPUT=aw+by

[0221] where a and b comprise positive or negative coefficients determined from empirical data and X, and Z comprise measured signals for the patient, for example at least two of the electrocardiogram signal, the respiration signal or the activity signal. While two coefficients and two 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.

[0222] 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

\[
\text{OUTPUT} = aX + bY + cZ
\]

[0223] where \(X\) comprises a heart rate signal, \(Y\) comprises an activity signal and \(Z\) comprises a respiration signal, with each of the coefficients determined in response to empirical data as described above.

[0224] 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

\[
\text{OUTPUT} = (\Delta X) + (\Delta Y) + (\Delta Z)
\]

[0225] where \((\Delta X), (\Delta Y), (\Delta Z)\) may comprise change in heart rate signal from baseline, change in respiration signal from baseline and change in activity 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 increases by 10%, \((\Delta X)\) can be assigned a value of 1. If respiration increases by 5%, \((\Delta Y)\) can be assigned a value of 1. If activity decreases below 10% of a baseline value \((\Delta Z)\) can be assigned a value of 1. When the output signal is three, a flag may be set to trigger an alarm.

[0226] 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

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

[0227] where \((\Delta X), (\Delta Y), (\Delta Z)\) may comprise change in heart rate signal from baseline, change in respiration signal from baseline and change in activity 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 increases by 10%, \((\Delta X)\) can be assigned a value of 1. If respiration increases by 5%, \((\Delta Y)\) can be assigned a value of 1. If activity decreases below 10% of a baseline value \((\Delta Z)\) can be assigned a value of 1. When each of \((\Delta X), (\Delta Y), (\Delta Z)\) is one, the output signal is one, and a flag may be set to trigger an alarm. While a specific example with AND gates has been shown the data can be combined in many 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.

[0228] The adherent patch device, as described above, can be configured for continuous placement on the patient for and extended period, for example at least one week. The plurality of sensors, the wireless communication circuitry on the patch and the processor on the patch can be configured with duty cycles, such that the patient is monitored for at least one week and battery of the adherent patch will last for at least one week. Table II shows a configuration of the plurality of sensors, the wireless communication circuitry and duty cycles configured to monitor the patient for at least one week. The circuitry components shown in Table II may comprise known circuitry components, for example known ECG and HR circuitry, known Bioimpedance and Respiration Circuitry, known Accelerometer Circuitry, known Temperature Sensor Circuitry, known Flash Memory Circuitry, known Processor Circuitry and known Wireless Circuitry. The power consumption of these known circuitry components can be used to analyze the performance of the patch.

<table>
<thead>
<tr>
<th>Patch Device Component</th>
<th>Sampling Time and Interval</th>
<th>Duty Cycle %</th>
<th>Current Consumed (m.Aseconds per Day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECG Circuitry</td>
<td>20 s per minute</td>
<td>36.8</td>
<td>18,670</td>
</tr>
<tr>
<td>Bioimpedance Circuitry</td>
<td>30 s per 15 minutes</td>
<td>4.4</td>
<td>30,639</td>
</tr>
<tr>
<td>Accelerometer Circuitry</td>
<td>1 ms per 2-4 s</td>
<td>0.006</td>
<td>0.21</td>
</tr>
<tr>
<td>Temperature Sensor</td>
<td>1 ms per 1 minute</td>
<td>1.3E-05</td>
<td>0.018</td>
</tr>
<tr>
<td>Memory Circuitry</td>
<td>As needed</td>
<td>0.0034</td>
<td>21</td>
</tr>
<tr>
<td>Processor</td>
<td>500 ms per second</td>
<td>52</td>
<td>541,843</td>
</tr>
<tr>
<td>Wireless (Blate-Tooth)</td>
<td>2-3 minutes per 4</td>
<td>0.56</td>
<td>31,333</td>
</tr>
</tbody>
</table>

[0229] As shown in Table II, most of the measurement circuitry comprises a duty cycle of no more than 50%, and the processor circuitry comprises a duty cycle of about 50% and the wireless communication circuitry comprises a duty cycle of no more than about 1%. The duty cycle of the wireless communication circuitry can be increased from 0.5% to at least about 1%, for example to about 3%, without significantly effecting the total current consumed. The total energy consumed per day for the configuration shown in Table II is about 170 mA Hours. A commercially available battery having a capacity of 1500 mAh Hours will last about 8 days. This cycling of the measurement circuitry can allow the adherent device to monitor a patient, for example a heart failure patient, for at least about 1 week with the patch continuously adhered to the patient. In some embodiments, the duty cycle of the wireless communication circuitry can be increased, for example to about 5% and slightly larger battery used to provide a useful life of one week with the adherent patch continuously adhered to the patient. The data in Table II show that a heart failure patient can be continuously monitored with sensor cycling for an extended period of at least about one week and with wireless transmission of no more than about 5% when the adherent patch is adhered to the skin of the patient.

[0230] 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 system for monitoring a patient, the system comprising:
   a patient detecting system for measuring the patient including:
   an adherent device configured to be coupled to a patient, the adherent device comprising a plurality of sensors to measure physiological parameters of the patient to determine physiological status of the patient, and an energy management device coupled to the plurality of sensors;
a wireless communication device coupled to the plurality of sensors; and
a remote monitoring system coupled to the wireless communication device, wherein wireless communication device is configured to transfer patient data from the plurality of sensors to the remote monitoring system.

2. The system of claim 1, further comprising an energy generation device coupled to the energy management device.

3. The system of claim 1, wherein the energy management device is part of the patient detecting system.

4. The system of claim 1, wherein the adherent device is configured to sample intermittently.

5. The system of claim 4, wherein the plurality of sensors are configured to sample no more than 30 seconds for every minute for ECG, no more than once per second for an accelerometer sensor and no more than 60 seconds for every 15 minutes for impedance.

6. The system of claim 1, wherein the plurality of sensors is configured to measure at least one of bioimpedance, heart rate, heart rhythm, HRV, HRT, heart sounds, respiratory sounds, blood pressure, activity, posture, wake/sleep, orthopnea, temperature, heat flux or patient activity.

7. The system of claim 6, wherein the plurality of sensor is configured to measure the patient activity with at least one of a ball switch, an accelerometer, minute ventilation, heart rate, bioimpedance, noise, skin temperature, heart flux, blood pressure, muscle noise or patient posture.

8. The system of claim 1, wherein the plurality of sensors is configured to switch between different modes, the different modes comprising a first mode and a second mode, the first mode different from the second mode.

9. The system of claim 1, wherein the energy management device is configured to deactivate selected sensors to reduce redundancy and reduce power consumption.

10. The system of claim 1, wherein the energy management device is configured to use sensor cycling for energy management.

11. The system of claim 10, wherein the plurality of sensors comprises a first portion of sensors and a second portion of sensors and wherein the first portion is configured to sample at first times the second portion is configured to sample at second times.

12. The system of claim 11, wherein the first times are different from the second times, and wherein the energy management device is configured to cycle sampling between the first sensors and the second sensors.

13. The system of claim 1, wherein the plurality of sensors comprises a first core sensor and a second sensor, the first core sensor configured to continuously monitor and detect, the second sensor configured to verify a physiological status in response to the core sensor raising a flag.

14. The system of claim 1, wherein the plurality of sensors comprises a first portion and a second portion, the first portion different from the second portion, and wherein the first portion of sensor are configured for short term tracking, and the second portion of the sensors are configured for long term tracking.

15. The system of claim 1, wherein the adherent device is configured to be activated.

16. The system of claim 15, wherein the adherent device is activated by at least one of; a physiological trigger, automatic impedance, a tab pull, battery insertion, a hall or reed switch, a breakable glass capsule, a dome switch, by light activation, pressure activation, body temperature activation, a connection between electronics associated with the sensors and the adherent device, exposure to air and by a capacitive skin sensor.

17. The system of claim 1, wherein the energy management device is configured to perform at least one of modulate a clock speed to optimize energy, monitor cell voltage drop—unload cell, monitor coulomb-meter or other battery monitor, battery end of life dropoff to transfer data, elective replacement indicator, call center notification, sensing windows by the sensors based on a monitored physiological parameter or sensing rate control.

18. The system of claim 2, wherein the energy generation device is configured to generate energy by at least one of, a thermo-electric unit, kinetics, fuel cell, through solar power, a zinc air interface, Faraday generator, internal combustion, a micro-battery and with a rechargeable device.

19. The system of claim 1, further comprising: a processor comprising a tangible medium coupled to the plurality of sensors and to the wireless communication device, the processor configured to receive patient data from the plurality of sensors and process the patient data.

20. The system of claim 19, wherein the processor is located at the remote monitoring system.

21. The system of claim 19, wherein the processor is included in a monitoring unit, the monitoring unit comprising part of the patient detecting system.

22. The system of claim 1, further comprising: logic resources located at the remote monitoring system to determine a physiological status of the patient and detect a physiological event of a patient.

23. The system of claim 21, further comprising: logic resources located at the monitoring unit that determine a physiological event of a patient.

24. The system of claim 21, further comprising a processor system comprising a tangible medium and wherein the processor system has program instructions for evaluating values received from the plurality of sensors with respect to acceptable physiological ranges for each value received by the processor.

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

26. The system of claim 1, wherein the wireless communication device comprises at least one of a modem, a serial interface, a LAN connection and a wireless transmitter.

27. The system of claim 1, wherein the wireless communication device includes a receiver and a transmitter for receiving data indicating the values of the physiological event detected by the plurality of sensors, and for communicating the data to the remote monitoring system.

28. The system of claim 1, wherein the wireless communication device comprises a wireless local area network for receiving data from the plurality of sensors.

29. The system of claim 28, wherein the wireless communication device includes a data storage for recording the data received from the plurality of sensors.

30. The system of claim 29, wherein the wireless communication device includes an access device for enabling access to information recorded in the data storage from the remote monitoring system.

31. The system of claim 1, wherein the wireless communication device includes a controller configured to control sending of the data supplied by the plurality of sensors.
32. The system of claim 1, further comprising: an external device coupled to the adherent device comprising the plurality of sensors.

33. The system of claim 32, wherein the external device comprises at least one of a weight scale, a blood pressure cuff, a medical treatment device or a medication dispenser.

34. The system of claim 1, further comprising: a notification device coupled to the patient detecting system and the remote monitoring system, the notification device configured to provide a notification when values received from the plurality of sensors are outside acceptable physiological ranges.

35. The system of claim 34, wherein the patient measurement system is configured to measure physiological parameters at a high-rate of sampling in response to a trigger from at least one of a medical provider, the remote monitoring system or a medical treatment device and wherein at least one of the medical provider, the remote monitoring system or the medical treatment device are configured to trigger the high-rate of sampling of the physiological parameters for alert verification.

36. The system of claim 34, wherein the notification device is configured to communicate with the at least one of the patient, a clinician, a spouse, a family member, a caregiver or a medical provider when the values received from the plurality of sensors are not within acceptable physiological ranges and configured to communicate from one device to another device to allow for therapeutic intervention to prevent decompensation when the values received from the plurality of sensors are not within acceptable physiological ranges.

37. The system of claim 1, further comprising: a memory management device.

38. The system of claim 37, wherein the memory management device is configured to perform at least one of data compression, prioritizing of sensing by a sensor, monitoring at least some from at least some of the sensors, sensing by the sensors in real time, noise blanking such that sensor data is not stored when noise above a selected level is determined, low-power of battery caching or decimation of old sensor data.

39. The system of claim 1, wherein the adherent device comprises a wearable patch that includes a battery.

40. The system of claim 1, wherein the physiological status of the patient comprises a heart failure status and wherein at least one of the patient detecting system or the remote monitoring system comprises a processor system configured to determine the heart failure status of the patient in response to the physiological parameters.

41. The system of claim 1, wherein the plurality of sensors comprises a combination of at least two sensors configured to detect or predict decompensation and wherein the combination comprising the at least two sensors is configured to measure at least two of an electrocardiogram signal, a hydration signal, an accelerometer signal or a respiration signal of the patient.

42. The system of claim 1, wherein the remote monitoring system includes a receiver, a transmitter and a display for displaying data representative of values of at least one physiological event detected by the plurality of sensors.

43. The system of claim 1, wherein the remote monitoring system includes a data storage mechanism having a plurality of acceptable ranges for physiological values stored therein, and a comparator for comparing the data received from the monitoring system with the acceptable ranges stored in the data storage device.

44. The system of claim 1, wherein the remote monitoring system includes a portable computer.

45. The system of claim 1, wherein the remote monitoring system comprises a portable unit having a display screen and a data entry device for communicating with the wireless communication device.

46. A device for monitoring a patient, the device comprising: an adherent device configured to adhere to a skin of the patient, the adherent device comprising a plurality of sensors, sensor circuitry coupled to the plurality of sensors, wireless circuitry and energy management circuitry, wherein the sensor circuitry comprises electrocardiogram circuitry, bioimpedance circuitry, accelerometer circuitry, and temperature sensor circuitry, wherein the power management device is coupled to the wireless circuitry and configured to transmit data from the sensor circuitry with a duty cycle of no more than about 5%.

47. The device of claim 46 wherein the device is configured to monitor a patient health status in response to the plurality of sensors.

48. The device of claim 47 wherein the patient comprises a heart failure patient and the adherent device is configured to continuously monitor the heart failure status with the wireless circuitry duty cycle of no more than about 5%.

49. The device of claim 46 wherein a majority of the sensor circuitry comprises a duty cycle of no more than about 5%.

50. The device of claim 49 wherein the electrocardiogram comprises a duty cycle of no more than about 40%, the bioimpedance circuitry comprises a duty cycle of no more than about 10%, the accelerometer circuitry comprises a duty cycle of no more than about 1%, and the temperature sensor circuitry comprises a duty cycle of no more than about 1%.

51. The device of claim 46 wherein the power management device comprises a timer coupled to the sensor circuitry to determine the duty cycle of each sensor.

52. The device of claim 51 further comprising a processor comprising a tangible medium coupled to the sensor circuitry and configured with the timer to sample data from the sensor circuitry and wherein the adherent device is configured to support the processor, the plurality of sensors, the sensor circuitry, the wireless circuitry and the energy management circuitry with the skin of the patient.

53. The device of claim 52 wherein the processor is configured to determine heart rate in response to the electrocardiogram circuitry.

54. The device of claim 53 wherein the processor is configured to determine respiration in response to the bioimpedance circuitry.

55. The device of claim 53 further comprising a processor system, the processor system comprising the processor and a second processor at a remote location, the second processor wirelessly coupled to the processor supported with adherent device, and wherein the processor system is configured to detect decompensation of a heart failure patient in response to output from the plurality of sensors.
56. The device of claim 55 wherein the second processor at the remote location is configured to combine the output from the plurality of sensors to detect the decompensation of the heart failure patient.

57. The device of claim 56 wherein the second processor at the remote location is configured to determine a respiration rate of the patient at the remote location in response to the bioimpedance circuitry.

58. The device of claim 52 comprising at least one battery configured to power the electrocardiogram circuitry, the bio-impedance circuitry and the accelerometer circuitry and the temperature sensor circuitry for at least about one week when the adherent device is adhered to the skin of the patient.

59. The device of claim 58 wherein the adherent device is configured to consume no more than about 1500 mA Hours per day when the adherent device is adhered to the patient for an extended period of at least about one week.

60. A method for monitoring a patient, the method comprising:
   adhering an adherent device to a skin of the patient, the adherent device comprising a plurality of sensors;
   measuring patient data with sensor circuitry coupled to the plurality of sensors, wherein the sensor circuitry comprises at least one of electrocardiogram circuitry, bio-impedance circuitry, accelerometer circuitry, or temperature sensor circuitry; and
   transmitting the patient data with wireless transmission circuitry supported the skin of the patient to a remote monitoring system and wherein the wireless transmission circuitry transmits the patient data intermittently with a duty cycle of no more than about 5%.

* * * * *