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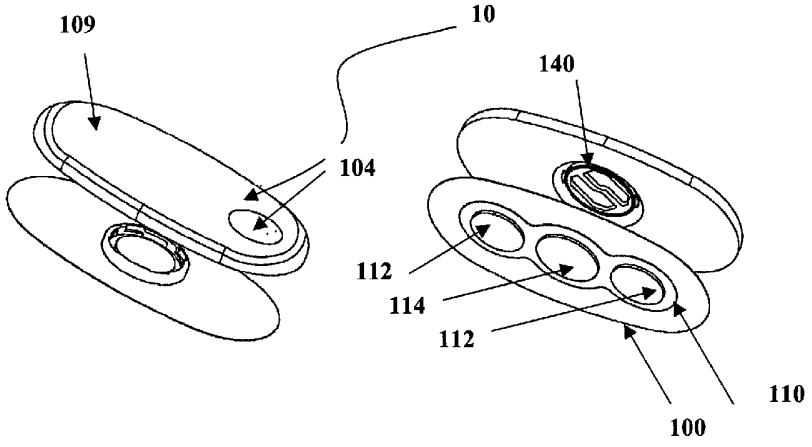
(54) Title: ADAPTIVE PHYSIOLOGICAL MONITORING SYSTEM AND METHODS OF USING THE SAME



(57) Abstract: The present invention provides methods and an apparatus for an adaptive physiological monitoring system (10). The physiological monitoring system incorporates a sensor (110) responsive to the physical activity of the monitor-wearing patient. The system monitors one or more physical parameter(s) of the user to distinguish between periods of quiet rest and normal waking activity and communicates non-urgent information regarding a system error or information about the measured physical parameter to the user or to an external system only if one or more physical parameters of the user exceed predetermined threshold criteria. The system also suppresses alerts regarding physiological states that are inconsistent with normal patient activity if one or more physical parameters of the user exceed a predetermined threshold. The physiological monitoring system (10) incorporates a sensor (110) responsive to the physical activity level of the user, for detecting directly or indirectly measuring the physical activity level of the user.

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ADAPTIVE PHYSIOLOGICAL MONITORING SYSTEM AND METHODS OF USING THE SAME

DESCRIPTION

The present invention relates generally to the field of physiological monitoring of patients, and more particularly, to methods and an apparatus for a physiological monitoring system with an adaptive alert mechanism.

Doctors often need round-the-clock measurements of a body parameter over a period of time to make an accurate diagnosis of a condition. Vasovagal syncopal events and arrhythmias of the heart are particularly challenging to diagnose because of their relative infrequency, sudden onset and short duration. Holter monitors are one type of ambulatory physiological monitoring systems (PMS) that are used to measure the electrical signals of a patient's heart over a period of time to detect abnormalities in the heart beat of the patient. Typically, these systems continuously monitor electrocardiography (ECG) signals for a finite test period of about 24-96 hours. By reviewing the collected ECG data in an external monitoring device, doctors may identify patients who have heart arrhythmias and who are at risk for ventricular tachycardia or other cardiac conditions.

In patients who have already been diagnosed with an arrhythmic heart condition, and who are at risk for potentially life-threatening cardiac events, it is often desired to monitor their condition over the long term. It is therefore desirable that the monitoring system be capable of long term monitoring for arrhythmic events and adequately capture such events when they occur. Since the device will be worn by the patient for potentially

long durations of time, it is also desirable for the device to be compact, lightweight, mechanically robust, and unobtrusive as the patient goes about his normal daily routine of activity and rest. Traditional Holter monitors are unsuitable for such long term monitoring because of their bulky profile and relatively high power consumption levels required to power the continual ECG detection and data storage.

Ambulatory ECG monitors typically include several electrodes that are attached to the patient and a processor that acquires and processes the electrical signals into data and stores the data for later analysis. If it is functioning properly, the monitoring system is able to detect and capture cardiac event data for later retrieval and analysis. In practice, however, it is often the case that the monitoring becomes interrupted because of battery-power loss, sensor detachment problems, or other system or user errors.

Existing PMS typically employ an audible or visual alarm to alert the user of any such system malfunctions or errors. Some of the malfunctions or errors that trigger the alarm require immediate user attention, such as a malfunction requiring shutdown and restart of the PMS, signal loss due to improper sensor connection(s), or electrical interference. Other errors that trigger the alarm are less urgent (e.g., low battery power). In these prior art systems, both urgent and non-urgent types of information are communicated to the user via the alarm, whether or not the user is receptive to being disturbed.

One such conventional system is described in U.S. Patent No. 6,248,067 to Causey, Kovelman, Purvis, and Mastrototaro, and assigned to MiniMed Inc., which patent is entitled "Analyte Sensor and Holter-Type Monitor System and Method of Using the Same," which is hereby incorporated by reference in its entirety. This patent describes a Holter-type recorder device equipped with a vibrator alarm or optical indicator such as a light-emitting diode (LED) that alerts the user of a system malfunction. This vibration

alarm, if it remains unanswered by the user, provides additional reminders to an audio alarm. The drawback of this system is that the audio alarm may become triggered during periods of sleep or other inopportune times when the user cannot respond promptly.

In other systems, a user of the PMS may manually change a switch setting between audible and/or silent (e.g. tactile or visual) alarm modes to prevent undesired beeping interruptions. However, manual switching represents a suboptimal solution because the burden is on the user to constantly switch between modes as he goes about his daily routine of active and inactive periods and other instances where interruptions may not be tolerated or it is necessary to conceal the presence of the PMS.

There is a need, therefore, for an improved method and apparatus for an adaptive physiological monitor that alerts the user of events indicating a system problem or malfunction when it determines that the user is in an active waking state or otherwise receptive of receiving and responding to the alarm.

In the case of PMS systems that alarm for life-threatening arrhythmia conditions, physical activity on the part of the monitored patient has some additional implications. First, physical activity may result in signal artifact that causes the monitored physiological parameter (e.g. the ECG signal) to resemble its form when some life-threatening arrhythmias (e.g. ventricular fibrillation) are present when they are in fact absent, and may generate a false positive alarm. At the same time, physical activity above a certain level may be inconsistent with the presence of the life-threatening arrhythmia or condition, because the life-threatening condition weakens the patient or renders the patient unconscious. Thus, physical activity itself, apart from its influence on the signal quality of the monitored physiological parameter, provides significant information about the patient's

cardiac status, and in combination with the ECG signals, provides a more complete assessment of the cardiac condition of a patient at a given time.

Accordingly, there is also a need for a knowledge-based PMS that inhibits the transmission of an alarm reflecting a life-threatening physiological event when the system detects that the patient is physically active.

The present invention solves these and other problems by providing a method and apparatus for an adaptive physiological monitoring system that differentiates between urgent and non-urgent information and then alerts the user accordingly based on a knowledge-based approach that considers the user's receptivity to responding to the information, and more generally that considers the implications of the user's level of physical activity. By transmitting information in this adaptive manner, user acceptance of the PMS is improved. The user is not disturbed during periods of rest with non-urgent information, and the incidence of false positive alarms is reduced as well.

According to one aspect of the present invention, an exemplary embodiment is a method and system for an adaptive physiological monitoring system that monitors one or more physical parameter(s) of the user to distinguish between periods of quiet rest and normal waking activity and communicates non-urgent information to the user only if one or more physical parameters of the user exceeds a predetermined threshold.

According to an embodiment of this aspect of the present invention, the physiological monitoring system incorporates a sensor responsive to the physical activity level of the user, such as an accelerometer or other mechanical, chemical, or electrical means for detecting directly or indirectly measuring the physical activity level of the user

According to another aspect of the invention, an exemplary embodiment is a method and apparatus for a lightweight, energy-saving physiological monitoring system that conserves power by delaying transmission of non-urgent information to the patient when the patient is asleep or resting.

According to one embodiment of this aspect of the present invention, the alert information is communicated to the patient by means of a device local to the monitor, such as a vibrator or speaker.

According to another embodiment of this aspect of the present invention, the alert information is communicated to the patient by means of devices in his environment, which the monitor signals wirelessly.

According to yet another aspect of the invention, an exemplary embodiment is a method and apparatus for long term, low power ECG monitoring. By limiting the transmission of information when the patient is asleep or resting, the present invention allows for considerable savings in battery power consumption, increasing the capacity for long term monitoring of the patient.

According to yet another aspect of the invention, an exemplary embodiment is a method and apparatus for long term monitoring for life-threatening physiological events. By inhibiting the transmission of alarms reflecting the appearance of a life-threatening pattern in the physiological parameter being monitored when the patient is engaged in normal waking activity inconsistent with the life-threatening phenomenon, the incidence of false alarms is reduced.

FIG 1 is a perspective view of one embodiment of the physiological monitoring system of the present invention.

FIG 2 is a pictorial view showing a physiological monitoring system (PMS) according to an embodiment of the present invention on a patient.

FIG 3 illustrates a block diagram depicting the major components of the PMS according to an exemplary embodiment of the present invention.

FIG 4 is a flow chart depicting the steps performed by the physiological monitoring system to create a feedback loop that monitors a patient's physiological parameters and alerts the patient of system errors and physiological conditions in an adaptive manner based on the detected activity level of the patient.

A more complete understanding of the method and apparatus of the present invention is available by reference to the following detailed description of the embodiments when taken in conjunction with the accompanying drawings. It is worthy to note that any reference herein to "one embodiment" or "an embodiment" means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment of the invention. The appearances of the phrase "in one embodiment" in various places in the specification are not necessarily all referring to the same embodiment. The detailed description of the embodiments which follows is intended to illustrate but not limit the invention. The scope of the invention is defined by the appended claims.

A physiological monitoring system according to the present invention comprises an adaptive system that, in addition to monitoring a particular physical characteristic of the

patient for medical purposes, communicates a variety of information to the user based on a knowledge-based approach that determines whether the user is physically active. If the system detects that the patient is asleep, resting, or otherwise in a non-active state, it defers the transmission of non-urgent information until it detects that the patient is in a normal active state. On the other hand, if the system detects that the patient is in a normal active state, it inhibits, as false alarms, transmission of any urgent information that is inconsistent with the patient being in a normal active state.

Briefly, the above-described adaptive monitoring is achieved by way of an internal microprocessor having sufficient logic and data analysis capabilities to independently perform all internal control functions, including acquisition of data from sensors, processing of that data, and providing appropriate instructions to various sensors and output devices. On-board memory (e.g., static read and write memory) performs control and analysis processes and selectively stores critical information regarding a cardiac episode.

FIG 1 illustrates a perspective view of an embodiment of the monitoring system for monitoring cardiac parameters in an ambulatory setting of daily activity. The system 10 comprises a monitor 100 and sensors 110 or other transducers that are connected to the monitor 100. A wireless transmitter 109, and optionally, an event button 104 are located on the monitor 100.

The monitor 100 is designed for use with one or more sensors or transducers such as electrodes 112. As will be appreciated by one of skill in the art, a variety of sensors may be employed in the practice of this invention. With sufficient hardware and connections to the body, numerous physiologic parameters may be sensed as is pointed out in U.S. Pat. No. 5,464,434 issued to Alt and U.S. Pat. No. 5,464,431, issued to Adams et

al., which is hereby incorporated by reference in its entirety. The physical parameters may include, but are not limited to, a patient's body movements, heartbeats, respiratory movements, snoring, and other mechanical movements and sounds detected by the sensors, respiration rate and depth (by for example, impedance plethysmography), brain waves, body temperature, and blood pressure.

A plurality of sensors 110 may be employed simultaneously to measure the same or different physiological characteristics. For instance, typically two to six electrodes 112 may be employed to measure biological rhythmic signals such as heart rate in conjunction with an activity sensor 114 such as an accelerometer that measures the physical activity level of the patient. As shown in FIG 2, in one embodiment, at least one set of sensors 110 comprises ECG electrodes 112 that measure electrocardiograms and that are placed in contact with the patient's body so as to receive signals from the patient which are transmitted to the monitor 100. As is obvious to one of skill in the art, the electrodes may be conventional electrodes comprised of silver chloride or other compositions designed to receive analog ECG input. The system 10 may also comprise a set of activity sensors 114 that detect motion, movement, acceleration, mechanical vibrations, sound, or other indicator of physical activity on the part of the human subject.

The activity sensor 114 may comprise a piezoelectric pressure transducer, a pedometer, a vibratory or motion detector, a detector that measures residual noise generated by friction between the electrode contacts and the patient's skin, strain gage or other transducer means for measuring activity. In addition to an accelerometer, other sensors which measure physiological parameters which distinguish between resting and active states may be employed.

In one mode of the invention, the activity sensor 114 is a cantilevered suspended element which constitutes a high impedance voltage generator such as a piezoelectric element. The sensors may be incorporated into the monitor module 100 itself, or placed in close proximity to the monitor. The output of the activity sensor 114 is connected to a processor 142 contained within the monitor 100. The piezoelectric element is a passive element or sensor requiring no power to cause it to be operational. The distortion of the surface of or of the element, itself, generates the appropriate signal.

The activity sensors 114 may alternatively detect chemical or electrical changes in the patient that indicate the onset of sleep. For example, in one exemplary embodiment, the activity sensor 114 is integrated within the monitor 100 unit, as shown in FIG 2, and in other embodiments, are external to the monitor 100, such as a wrist-mounted activity sensor 114 attached to a wrist with a strap that detects electromyographic (EMG) electrical impulses produced by the wearer's wrist muscles. Such electrical impulses provide measurements of the changes in the muscular activity at the wearer's wrist, which measurements are useful in detecting drowsiness. The sensors 110 are applied to the body such that the surface of the sensors makes physical and/or electrical contact with the patient.

Although the monitor 100, and thus the sensors 110 are shown applied to the chest, one of skill in the art will appreciate that various alternative sensor construction, materials, and designs are within the scope of the present invention. The information signals from these measuring devices such as the ECG electrodes 112 and activity sensors 114 are then transmitted to the monitor 100 for amplification and processing.

Referring now to FIG 3, which is a block diagram of the major elements of the monitoring system 10, the system includes the sensors 110 (sensor electrodes 112 and

activity sensor 114), an electronics module 140, a power circuit 150, which provides power to the system 10, and may include a voltage splitter and voltage regulator in addition to a battery, an alarm 160 (acoustic alarm 162 and silent alarm such as a tactile or visual/light alarm 164), a user interface module 170, a wireless transmitter 109 or other means for communicating with an external computer, device, or medical personnel (not shown). The user interface module 170 includes an event button 104 and optionally, a user display 106 which displays status messages and system error messages to the user.

Referring now to the details of the exemplary electronics module 140 shown in block form in FIG 3, the major components of the electronic module 140 include a CPU or microprocessor 142 with an internal CPU memory 144 and an internal digital input/output circuit, signal conditioners 145, analog-to-digital converters 147, an activity threshold detector 148 input with a programmable activity level 149, and a clock 146. The microprocessor 142 performs a multitude of functions, including, but not limited to, receiving and processing signals output from the sensors 110 regarding arrhythmia conditions and checking and processing system errors. The selection and design of such circuitry and various other circuit means will be obvious to one of ordinary skill upon review of this specification.

The output of the sensors 110 such as the ECG electrodes 112 is coupled to a signal conditioning circuit 145 which filters and amplifies the output. For the purposes of this example, the present invention contemplates that the ECG electrode sensors 112 and activity sensor 114 are analog signals that are communicated to an analog-to-digital (A/D) converter and communicated to the microprocessor 40 as digital signals along signal path 141. Digital sensors may be substituted, bypassing the A/D converter 147.

Communication between the microprocessor 142 and memory/storage 144 is provided by memory line 143. The data storage (memory) device 144 is optionally included for storing the ECG signal data, pre-set threshold limits for the physiological conditions being monitored, and user input received through the user interface module 170.

In the interest of keeping the monitor 100 compact and lightweight, the memory 144 may be limited to internal CPU/microprocessor memory, which for example, may be static random access memory or "flash" memory, their equivalents, or any of the above in combination with conventional magnetic storage such as a small portable disk drive unit. If the memory comprises only an internal CPU flash memory with limited data storage capacity, the ECG signal data detected by electrodes 112 may be stored into memory in a continuous overwrite mode.

In the present embodiment, flash memory (e.g., 128K of SRAM) is provided. Under normal circumstances when no arrhythmia event is occurring, the monitoring system 10 continuously overwrites the ECG data in the CPU flash memory. When an arrhythmia event does occur, the monitoring system 10 retains the data for the short time period surrounding the event (e.g. 1 minute) in the memory for later study. As will be appreciated by one of skill, the information may be stored in reserved areas of a looping memory, preferably in identifiable memory partitions and accessed in sections or in its entirety with the appropriate external device to initiate and receive such transmissions from the monitoring system 10. Event recording using such a looping memory is detailed in the prior art such as in U.S. Patent No. 5,987,352 to Klein, Warkentin, Riff, Lee, Carney, Turi, and Varrichio, and assigned to Medtronic, Inc., which patent is entitled "Minimally Invasive Implantable Device for Monitoring Physiologic Events," which is hereby incorporated by reference in its entirety.

For each physiological parameter that is being monitored by the sensors 110, an individualized baseline or threshold may be computed and stored in the RAM memory of the microprocessor 142 or an optional external memory 144. In the case of some physiological parameters, fixed threshold levels may be used. The microprocessor 142 receives status information from the memory 144 regarding these system variables. In an exemplary embodiment, information regarding the arrhythmia frequency that is pre-determined to qualify as a class 1 arrhythmia event is stored in the flash memory of the microprocessor 142. If the ECG sensors measure electrical signals that exceed the programmed arrhythmia frequency, the microprocessor 142 alerts the patient through the user interface module 170, and/or with external devices through the wireless transmitter 109. In the case of alerts reflecting states in which the patient may require assistance, or may be unresponsive, alerts may instead or additionally be directed, by means of wireless transmission to an external system, such as to an emergency responder.

The user interface 170 communicates with the microprocessor 142 of the electronics module 140 via an internal digital input/output circuit which communicates directly with the microprocessor 142 on input/output lines. For instance, when the battery power is low (e.g., depletion within 24 hours of usage), the microprocessor prompts a message on the user display 106, warning the user that the battery power needs to be recharged. The user display 106 is a visual display that may be implemented as a light-emitting diode (LED) display, a dual-colored (back to back) LED, or a conventional alpha-numeric display such as a liquid crystal display (LCD). In the single LED embodiment, the microprocessor may cause the LED to flash to indicate low battery power or a system error. In a dual-colored LED embodiment, the microprocessor 142 may cause the LED to remain unlit and flash in two different colors to indicate the status of the battery power or

other system functions. If an LCD is employed, the display may indicate the time of day as well as system status information.

In some embodiments, the pressing of the optional event button 104 by the ambulatory patient causes the user interface 170 to send a signal to the microprocessor 142 to trigger the acoustic alarm 162 which emits an audible alarm and optionally transmits an alarm signal to a wired or wireless transceiver or other external communication device (not shown) for contacting appropriate medical personnel. In addition, actuation of the event button 104 may cause the microprocessor 142 to record the time an event such as the suffering of chest pains or heart flutters occurred so that the ECG data recorded at that time can be flagged for closer examination. Pressing the event button 104 also causes the microprocessor 142 to store the ECG data sequence of the event in the flash memory of the microprocessor 142 for later transmission to an external monitoring device (not shown) and later study. In the event of a false alarm, the optional event button 104 may also be used to contact and to cancel the emergency help.

The acoustic alarm 162 also emits an acoustic signal when an observed cardiovascular activity or other physiological parameter surpasses a preset limit (e.g., surpassing the maximum number of arrhythmias preset by the doctor will generate an alarm). In the case of a physiological state that is inconsistent with normal physical activity on the part of the patient, if the activity monitor threshold is exceeded, such an alert may be suppressed as a false alarm.

The output of the sensors 110 (electrode sensors 112 and activity sensor 114) is coupled to a signal conditioning circuit 145, which amplifies and filters the signals, and converted to a digital format by the analog/digital converter. The signals from the activity sensor 114, once digitally processed, are input into an activity threshold detector 148,

which is coupled to the A/D converter 147. The flow of signals and activity threshold detector 148 are set to a selected activity level by programmable activity level 149. The activity threshold detector 148 is connected to a control circuit in the microprocessor 142. The output of activity threshold detector 148 may be in binary form. For example, it may be a binary 1 if a threshold level of activity is sensed and a binary 0 if less than the threshold level of activity is sensed. The binary signal is fed to the control circuit of the microprocessor 142, which operates to power the alarm system 160. Multiple activity thresholds may be employed, establishing separate control levels for the separate adaptive functions of controlling non-urgent communication and urgent communication.

FIG 4 illustrates a flow chart of a method performed by the system 10 during adaptive monitoring of the patient according to an embodiment of the present invention. The microprocessor 142 initially sets up system variables in its memory so that the variables are proper for operation (step 200). For instance, data relating to the threshold conditions for each physiological parameter are entered into the memory of the microprocessor 142 serving the monitor 100. Thus, pre-determined baseline information regarding arrhythmia, such as the frequency and signal amplitude of electrocardiograms that would constitute a class 1 arrhythmic event are stored in the flash memory of the microprocessor 142. It is also within the scope of this invention to utilize algorithmic routines to calibrate non-static, non-preset thresholds that adapt to changing physical parameter base line information.

The system is also set so that various types of system errors, malfunctions or low power level (hereinafter collectively referred to as "errors") are categorized as either urgent or non-urgent and this information is contained in the memory. In an exemplary embodiment of the physiological monitoring system 10 of the present invention, the

microprocessor 142 runs an error routine to check for errors. Based on pre-set information, it recognizes whether an error that has occurred is "urgent" (e.g., hardware or software malfunction, system crash, corrupted data, or other error that requires the user to reinitialize the system or to obtain technical servicing of the module) or "non-urgent" (e.g., signal loss from one of the several electrode sensors due to detachment from the patient's body, warning that 24 hours of battery operating time remains, or static or electrical interference issues) that will need eventual, but not immediate patient attention.

When the monitor 100 is powered up, the microprocessor 142 executes an initialization routine to prepare the monitor unit for operation (step 210). Part of the initialization routine is for the microprocessor 142 to perform power up tests of the monitor 100 and controls of the user interface 170, including the event button 104 and user display 106. If the system fails any of the power up tests, the microprocessor 142 idles and prompts status messages on the visual display through the user interface 170.

If the system checks were successfully completed, the system enables a data acquisition mode (step 220). During the data acquisition mode, the system 10 receives and processes information from the electrode sensors 112 and continuously overwrites the ECG data in the CPU flash memory 144. Although it is within the scope of this invention to do so, to conserve memory and processing power, the activity data from the activity sensors 114 is not recorded. The data acquisition mode also includes receiving and processing information about the activity level of the patient output from the activity sensor 114. As described above, the output from the activity sensor 114 is processed through an activity threshold detector.

The monitoring continues until signals from the electrode sensors exceed a pre-set threshold, and thus indicate a "cardiac event," (step 230). The microprocessor 142

determines whether the signals indicate a cardiac event of the type that is life-threatening regardless of the physical activity level of the patient, or of another type that is life-threatening only if physical activity level is below a pre-set threshold. For cardiac events that are inconsistent with normal physical activity on the part of the patient (e.g., cardiac event is of the type that should not trigger an alarm condition if it is detected while the patient is physically active), the microprocessor 142 processes the output of the activity threshold detector 148.

If the microprocessor 142 determines that the measured signal level is above a pre-programmed activity threshold for a predetermined period of time (which may be medically and experimentally determined), indicating that the patient is in an alert state, the microprocessor 142 may suppress the cardiac event alert and return the system to the monitoring state 220. However, if in addition to exceeding the pre-set threshold for the electrode sensors, the activity level is below the set variable threshold (step 240), indicating that the patient is inactive, and has probably been rendered unconscious by the cardiac event, the microprocessor 142 does not suppress the cardiac event alert.

In certain embodiments of the invention, the PMS may be programmed with additional pre-set thresholds that recognize a variety of ECG signals and patterns that indicate a cardiac event even when physical activity is detected on the part of the patient. In such instances, when ECG signals of a pre-determined type exceed the pre-set threshold, the cardiac event alerting will remain unsuppressed regardless of the patient's activity level.

When an unsuppressed cardiac event occurs, the microprocessor 142 records the time from clock 146, turns off the ECG data overwriting routine and saves ECG data relating to the cardiac event and a buffer time period before and after the event (e.g., 30

seconds before and 30 seconds after the event) in the flash memory of the microprocessor 142 for later transmission to an external monitoring device (not shown) and later study (step 250). It also signals the alarm circuit 160 to trigger the acoustic alarm 162 and sends a distress signal through the wireless transmitter 109 (step 260). The acoustic alarm continues to sound an alarm signal until it turned off by the patient or the doctor (step 270). If neither of the above events has occurred after a pre-set time interval of monitoring has occurred, the microprocessor 142 processes error routines (step 290).

At step 290, the microprocessor 142 checks for system errors and malfunctions and conducts a test for the battery power level. If any type of system error is detected during the error routine, the microprocessor 142 determines, based on the information in the memory 144, whether the error is urgent or non-urgent (step 300). If it is urgent, the microprocessor 142 sends a signal to trigger the acoustic alarm 162 and wireless transmitter 109 (step 310). However, if a non-urgent error is detected, the microprocessor 142 processes the output of the activity threshold detector 148.

If the microprocessor 142 determines that the measured signal level is above a pre-programmed activity threshold for a predetermined period of time (which may be medically and experimentally determined), indicating that the patient is in an alert state, the microprocessor 142 may sound an acoustic alarm 162 and wireless transmitter 109 to alert the patient to system malfunctions or errors requiring immediate attention. However, if the activity level drops below the set variable threshold (step 320), indicating that the patient is asleep or resting, the microprocessor 142 triggers a silent alarm such as a visual message on the user display 106 (step 330). The system 10 is designed to continue to monitor the patient normally until the activity level rises above the activity threshold, in which case, the system triggers the acoustic alarm (step 260).

Although various embodiments are specifically illustrated and described herein, it will be appreciated that modifications and variations of the invention are covered by the above teachings and are within the purview of the appended claims without departing from the spirit and intended scope of the invention. For example, specific electrodes for the monitoring system are depicted herein, yet other sensors are possible without departing from the scope of the present invention. Substitute sensors that detect physiological characteristics that function similarly to electrodes will be obvious to one of ordinary skill in the art. Moreover, while three electrodes are shown, other numbers of electrodes can be used without departing from the scope of the present invention. Furthermore, these examples should not be interpreted to limit the modifications and variations of the invention covered by the claims but are merely illustrative of possible variations.

CLAIMS

1. A physiological monitoring system (10) which comprises:

at least one sensor for detecting a biological signal (112), representative of a physiological characteristic of a monitor-wearing patient and generating an electrical signal representative of the biological signal;

at least one sensor for detecting the physical activity of the patient (114) and generating an electrical signal, representative of physical activity;

processing means (142), coupled to said sensors (112, 114) for processing said electrical signals;

an activity threshold detector (148) coupled to said processing means (142) for receiving said electrical signals representative of physical activity;

means for testing system functions;

a user interface (170) for communicating information about the detected biological signal and system functions to the patient;

means for controlling the communication of information (109) in response to detection of an activity threshold by said activity threshold detector (148).

2. The system of claim 1, further comprising a means for programming said physical activity sensor 114 for operational control at a selected threshold of physical activity.

3. The system of claim 1, wherein the physiological characteristic sensor (112) is adapted to sense cardiac signals.

4. The system of claim 1, wherein the physiological characteristic sensor (112) comprises electrocardiography electrodes that detect biological signals representative of the heart beats of the patient.

5. The system of claim 1, wherein the physical activity sensor (114) comprises a transducer that detects chemical, electrical or mechanical characteristics of a monitor-wearing patient, representative of physical activity, including vibrations, motion, acceleration, electromyographic impulses, or sound impulses.

6. The system of claim 1, wherein the physical activity sensor (114) comprises an accelerometer, a pedometer, an electrical noise detector, electronic capacitive sensor, an electromyographic sensor, a skin impedance sensor, or a piezoelectric sensor.

7. The system of claim 1, wherein the physical activity sensor (114) is a passive transducer including a piezeoelectric element.

8. The system of claim 1, further comprising a means for wireless transmission of information (109) about the detected biological signal or system functions to a receiver external to the system.

9. An ambulatory electrocardiography monitoring system (10) for recording electrocardiography signals from a patient, comprising:

a plurality of sensors (110) for detecting a plurality of biological signals, each biological signal representative of a physiological characteristic of a monitor-wearing patient, wherein at least one sensor (110) comprises a one or more electrocardiography

electrodes (112) that sense electrocardiography signals from a patient and at least one sensor (110) comprises a sensor that detects the activity level of the patient (114), whereby the sensors generate an electrical signal representative of each respective biological signal;

an arrhythmia threshold detector (142) coupled to the electrocardiography sensor (112) for receiving said electrical signals representative of the electrocardiography signals and determining whether the signals are below or above a preset threshold;

an activity threshold detector(148) coupled to the activity sensor (114) for receiving said electrical signals representative of the activity level of the patient and determining whether the signals are below or above a predetermined threshold;

system error detector (142) for detecting system errors, including signal loss, electrode detachment from patient, low battery power, corrupted data, or electrical interference and determining if the detected error meets pre-determined criteria;

processor (142) for controlling the communication of system and biological signal information to the patient through a user interface (170) based on the detection of an activity threshold by said activity threshold detector (148), arrhythmia threshold by said arrhythmia threshold detector (142), and/or system errors by the system error detector (142).

10. The system of claim 9, wherein the user interface (170) comprises an alarm circuit (160) comprising acoustic, tactile, or visual modes of communicating information to the patient, and mode is determined by processor (142) based on whether the signals from the respective detectors (142, 148) meet pre-determined thresholds.

11. The system of claim 9, wherein processor (142) further comprises a calibration means for setting the threshold of the arrhythmia threshold detector (142) based on

processing of electrocardiography signals from the patient to generate a baseline of electrocardiography information.

12. The system of claim 9, wherein the threshold of the arrhythmia threshold detector (142) is pre-programmed into a memory component (142, 144) of the system (10).

13. The system of claim 9, wherein the physical activity sensor (114) comprises a transducer that detects chemical, electrical or mechanical characteristics of a monitor-wearing patient, representative of physical activity, including vibrations, motion, acceleration, electromyographic impulses, or sound impulses.

14. The system of claim 9, wherein the physical activity sensor (114) comprises an accelerometer, a pedometer, an electrical noise detector, electronic capacitive sensor, an electromyographic sensor, a skin impedance sensor, or a piezoelectric sensor.

15. The system of claim 9, wherein the physical activity sensor (114) is a passive transducer including a piezeoelectric element.

16. The system of claim 9, wherein the arrhythmia threshold detector (142) is set at a pre-determined threshold to detect the occurrence of class 1 arrhythmia event.

17. The system of claim 9, further comprising means of wireless communication (109) to an external system, for communication of information about the patient and system state to the patient or to others.

18. A method for communicating information about a patient during ambulatory monitoring of a physiological condition of the patient comprising the steps of:

attaching a physiological monitoring system (10) to a patient;

sensing one or more selected physiological parameters of the patient;

sensing the physical activity of the patient;

comparing the sensed physical activity to a pre-set threshold to determine whether the physical activity exceeds the threshold;

detecting a system error to be communicated to the patient and determining whether the detected error meets pre-determined criteria;

generating an error signal based on the system error and transmitting the error signal to the patient via a user interface (170), if the physical activity of the patient exceeds the pre-set threshold.

19. The method of claim 18, wherein the physical activity sensor (114) comprises a transducer that detects pre-determined chemical, electrical or mechanical characteristics of a monitor-wearing patient that are representative of physical activity, wherein the characteristics comprise vibrations, motion, acceleration, electromyographic impulses, or sound impulses.

20. The method of claim 18, wherein the physical activity sensor (114) comprises an accelerometer, a pedometer, a noise detector, electronic capacitive sensor, an electromyographic sensor, or a piezoelectric sensor.

21. The method of claim 18, wherein the selected physiological parameter of the patient is sensed by at least one sensor (110) comprising two or more electrocardiography

electrodes (112) that sense electrocardiography signals from the patient, whereby the sensor (110) generates an electrical signal representative of the selected physiological parameter.

22. The method of claim 18, wherein the physiological parameter comprises electrocardiography signals and the threshold of the selected physiological parameter of the patient is detected by an arrhythmia threshold detector (142) that determines whether the sensed electrocardiography signals are below or above a selected threshold representing an arrhythmic event.

23. A method for communicating information about a patient during ambulatory monitoring of a physiological condition of the patient comprising the steps of:

attaching a physiological monitoring system to a patient;

detecting a selected physiological parameter of the patient

sensing the physical activity of the patient;

detecting a selected threshold of the physical activity of the patient;

comparing the detected physiological parameter with pre-determined criteria to determine a physiological state of the patient reflecting an alarm condition;

generating an alert signal if the physiological condition of the patient reflects an alarm condition; and

transmitting the signal to the patient via a user interface (170), if the physical activity of the patient is below the selected threshold.

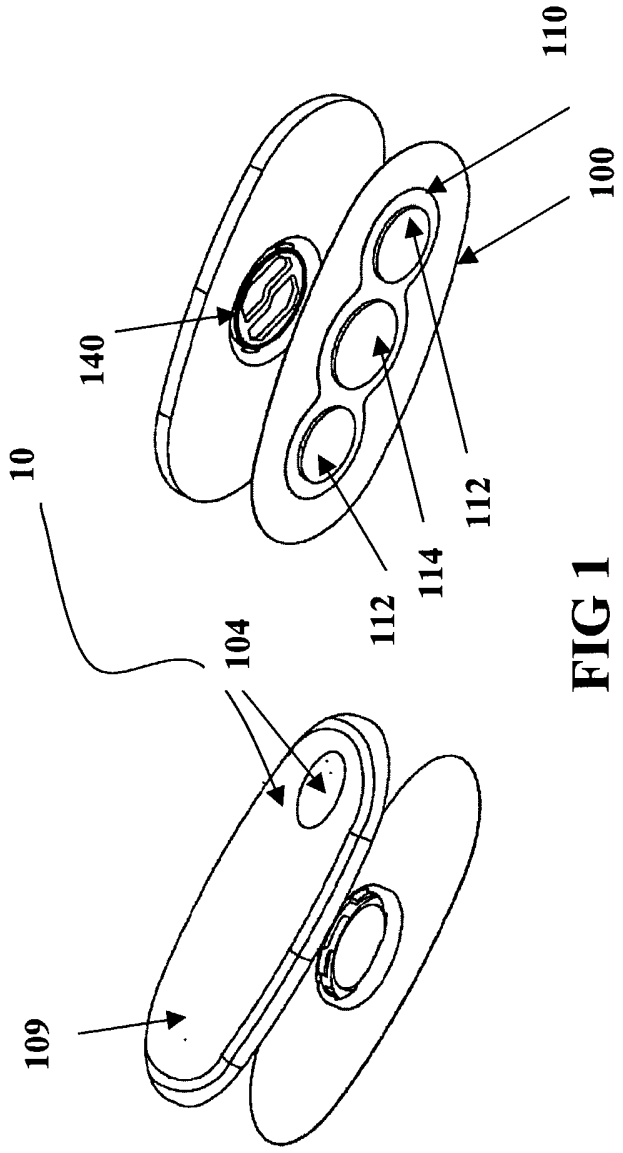

FIG 1

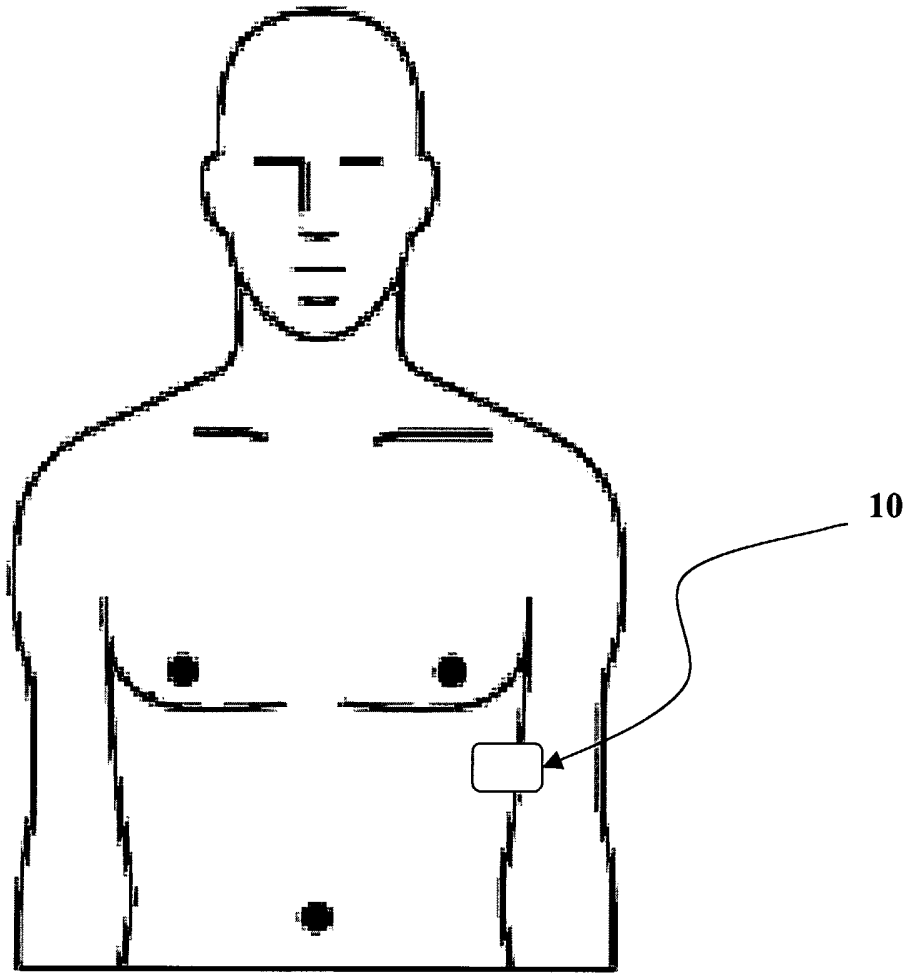

FIG 2

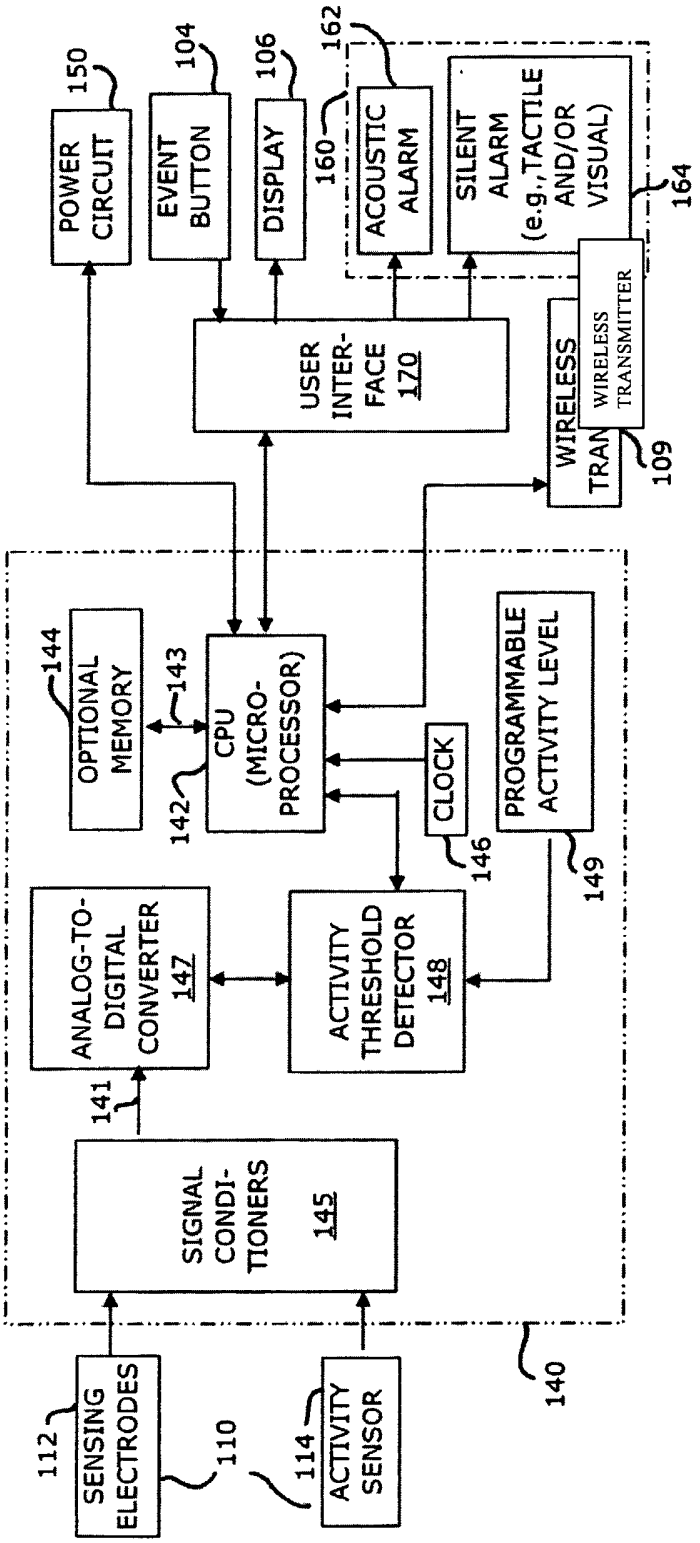
POWER CIRCUIT
150
EVENT BUTTON
104
DISPLAY
106
ACOUSTIC ALARM
160
162
SILENT ALARM (e.g.,TACTILE AND/OR VISUAL)
164
USER INTER-FACE 170
WIRELESS TRANSMITTER
WIRELESS TRAN
109
OPTIONAL MEMORY
144
143
CPU (MICRO-PROCESSOR)
142
CLOCK
146
PROGRAMMABLE ACTIVITY LEVEL
149
ANALOG-TO-DIGITAL CONVERTER 147
ACTIVITY THRESHOLD DETECTOR 148
141
SIGNAL CONDI-TIONERS 145
SENSING ELECTRODES
112
110
ACTIVITY SENSOR
114
140

FIG 3

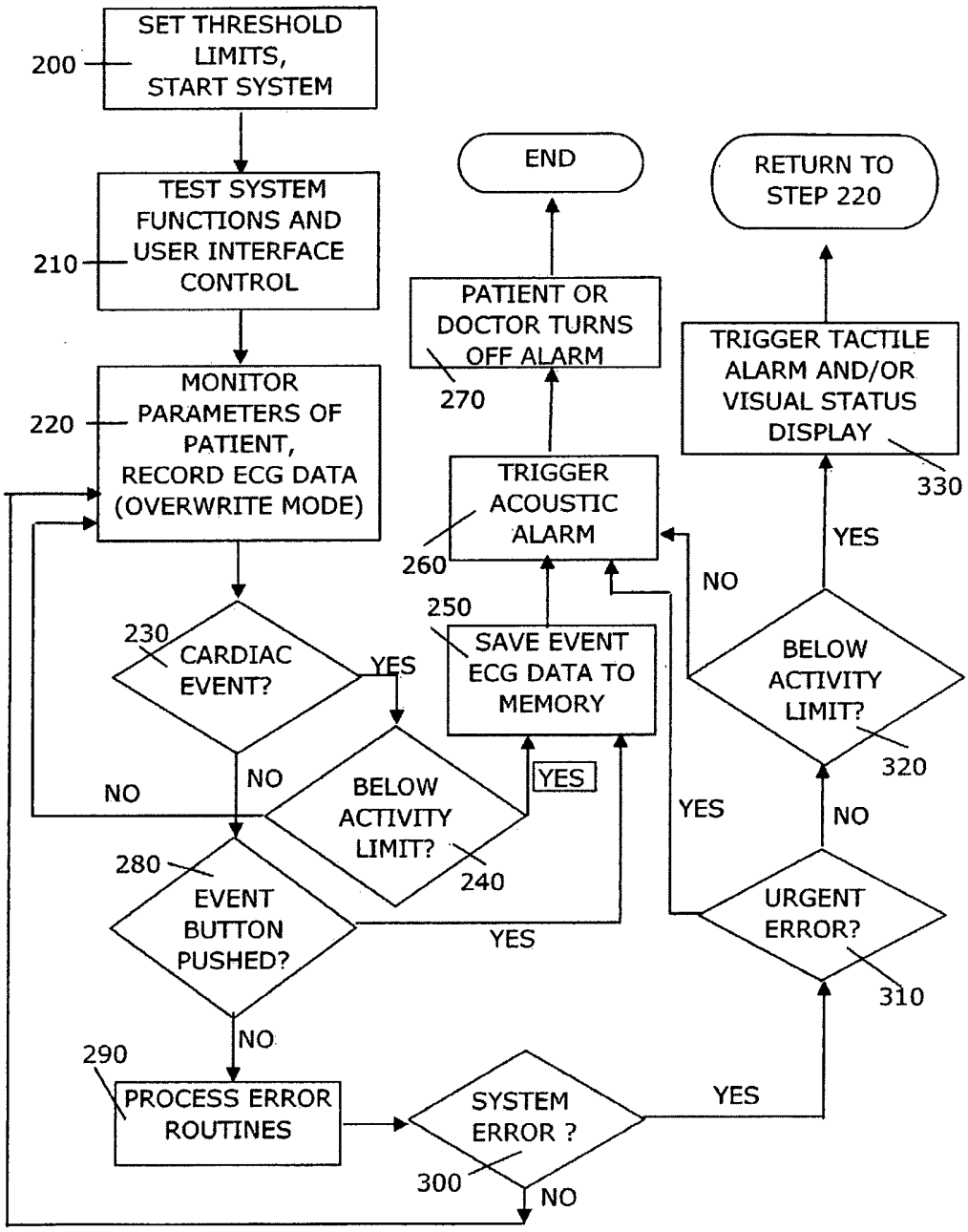
SET THRESHOLD LIMITS, START SYSTEM
200
TEST SYSTEM FUNCTIONS AND USER INTERFACE CONTROL
210
MONITOR PARAMETERS OF PATIENT, RECORD ECG DATA (OVERWRITE MODE)
220
CARDIAC EVENT?
230
YES
NO
BELOW ACTIVITY LIMIT?
240
YES
NO
SAVE EVENT ECG DATA TO MEMORY
250
TRIGGER ACOUSTIC ALARM
260
PATIENT OR DOCTOR TURNS OFF ALARM
270
END
EVENT BUTTON PUSHED?
280
YES
NO
PROCESS ERROR ROUTINES
290
SYSTEM ERROR ?
300
YES
NO
URGENT ERROR?
310
YES
NO
BELOW ACTIVITY LIMIT?
320
YES
NO
TRIGGER TACTILE ALARM AND/OR VISUAL STATUS DISPLAY
330
RETURN TO STEP 220

FIG 4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB2005/050056

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

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

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

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 404 877 A (NOLAN ET AL) 11 April 1995 (1995-04-11) column 1, line 7 - column 9, line 22	1-17
X	US 6 662 032 B1 (GAVISH BENJAMIN ET AL) 9 December 2003 (2003-12-09) paragraphs '0002!, '0175!, '0253!, '0312! - '0326!, '0335!, '0388! - '0390!	1-8
A	US 6 280 409 B1 (STONE KAREN A ET AL) 28 August 2001 (2001-08-28) the whole document	1-17
A	US 6 527 729 B1 (TURCOTT ROBERT) 4 March 2003 (2003-03-04) the whole document	1-17

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 March 2005	31/03/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Aronsson, F

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB2005/050056

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 160 478 A (JACOBSEN ET AL) 12 December 2000 (2000-12-12) the whole document -----	1-17
A	US 5 987 352 A (KLEIN ET AL) 16 November 1999 (1999-11-16) cited in the application the whole document -----	1-17

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 18-23

Rule 39.1(iv) PCT - Diagnostic method practised on the human or animal body
The subject-matter of claims 18-21 does not explicitly refers to diagnostic methods, but can still be interpreted as such for the following reasons:
Since the dependent claim 23 explicitly refers to a diagnostic method, it is considered to be embraced by the scope of its independent claim (18) and thus implicitly comprised in the subject-matter of claim 18.
Further, the steps of:
sensing the physical activity of the patient and
comparing the sensed physical activity to a pre-set threshold to determine whether the physical activity exceeds the threshold,
can also be interpreted as a diagnostic method, because physical activity could refer to for example heart activity.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2005/050056

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 18-23
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IB2005/050056

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5404877	A	11-04-1995	EP	0627194 A2	07-12-1994
US 6662032	B1	09-12-2003	AU	5842000 A	22-01-2001
			CA	2343537 A1	11-01-2001
			EP	1178751 A2	13-02-2002
			WO	0102049 A2	11-01-2001
			US	2004077934 A1	22-04-2004
US 6280409	B1	28-08-2001	US	6045513 A	04-04-2000
			CA	2331500 A1	18-11-1999
			EP	1079733 A1	07-03-2001
			JP	2002514454 T	21-05-2002
			WO	9958056 A1	18-11-1999
			US	6102874 A	15-08-2000
US 6527729	B1	04-03-2003	US	6477406 B1	05-11-2002
			US	6480733 B1	12-11-2002
			US	6409675 B1	25-06-2002
			US	6491639 B1	10-12-2002
			US	6600949 B1	29-07-2003
US 6160478	A	12-12-2000	FR	2785073 A1	28-04-2000
			US	2001004234 A1	21-06-2001
US 5987352	A	16-11-1999	US	6412490 B1	02-07-2002
			US	6496715 B1	17-12-2002
			AU	721854 B2	13-07-2000
			AU	3668097 A	09-02-1998
			CA	2260209 A1	22-01-1998
			CA	2466742 A1	22-01-1998
			EP	0944414 A2	29-09-1999
			JP	2000514682 T	07-11-2000
			WO	9802209 A2	22-01-1998