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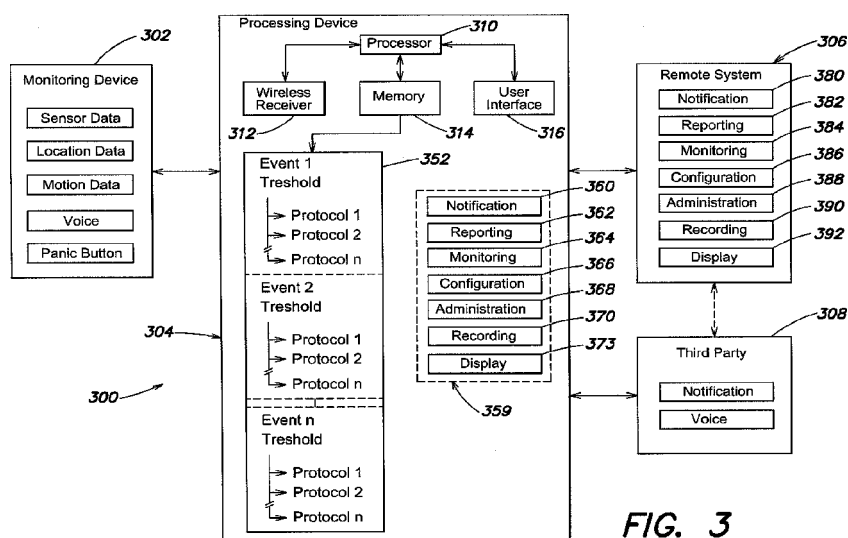


FIG. 3

(57) Abstract: A processing device includes a processor, a wireless receiver coupled to the processor, a memory coupled to the processor and a user interface where the wireless receiver is configured to receive signals transmitted by the wireless transmitter, the memory is configured to store at least one event and a plurality of protocols associated with the event where each of the at least one event and the plurality of protocols concern a threshold established for the at least one physiological parameter, and the user interface is configured to allow the user to establish at least one of the threshold, the event and the plurality of protocols.

PERSONAL MONITORING APPARATUS, SYSTEM AND METHOD**RELATED APPLICATIONS**

This application claims priority under 35 U.S.C. § 119(e) to U.S. Provisional
Application Serial No. 61/185,455, entitled "PERSONAL MONITORING DEVICE," filed on
June 9, 2009, which is herein incorporated by reference in its entirety.

BACKGROUND OF INVENTION**1. Field of Invention**

The present disclosure relates generally to personal monitoring devices, and more
specifically to mobile devices for receiving one or more physiological conditions of an
individual, and processing protocols responsive to the one or more conditions.

2. Discussion of Related Art

Improvements in sensor technology have enabled devices for monitoring physiological
attributes, such as pulse, respiration, and temperature, to become smaller, lighter, and better
adapted for the comfort of individuals being monitored. Such sensors have been integrated
into portable devices that allow individuals increased mobility. In the area of patient care, such
sensors allow patients a high quality of life while facilitating the ability of physicians, health
care providers and others to perform continuous or recurring patient monitoring.

SUMMARY

Systems and methods of monitoring one or more physiological conditions, and
processing protocols responsive to the one or more conditions, are described herein.

Regardless of whether a personal monitoring device is employed by a healthy individual or by
one under supervised medical care, local user control of the device can increase the relevance
and effectiveness of actions that are to be taken by the device and associated system in
response to any event that is triggered by one or more monitored physiological conditions.
Further, local processing of the output of the monitoring device can provide a user with
powerful local control and important information associated with modifying the user's
behavior. In some embodiments, these features are employed such that the complex decision
making required to effectively respond to a predetermined set of physiological conditions is

performed by a processing device, for example, the user's mobile phone. In these embodiments, the processing device can include a plurality of events that correspond to at least one physiological condition and a plurality of protocols that are available in response to the physiological condition, for example, the amount by which the physiological condition(s) deviate from the event threshold. For example, the event threshold can be established based on the analyses of one or a plurality of physiological parameters with respect to elapsed time and/or trends.

According to one aspect of the present disclosure, an individual to be monitored for one or more physiological conditions wears one or more monitoring devices that are in communication with a processing device, for example, using the Bluetooth™ open wireless standard. The monitoring devices, which may have integrated wireless transmitters, are designed to be easily wearable and include one or a plurality of sensors for detecting one or more physiological attributes, including, but not limited to, pulse, blood oxygen level, temperature, respiration, heart waveform, heart-rate, galvanic skin response, activity, perspiration, body fluid chemistry, and other such detectable attributes. The processing device may be responsive to data received from the monitoring devices, including values corresponding to various physiological attributes. For instance, the processor may be configured to automatically identify an event based on parameters included in the data, and to provide a notification or guidance, such as an alert, to the individual and/or others if any parameter exceeds a threshold value.

According to some embodiments, the monitoring device includes a plurality of physiological sensors. According to one embodiment, the processing device identifies a critical condition (e.g., cardiac arrest) based on data received from a plurality of sensors included in the monitoring device. For example, the processing device can be programmed to respond to an event that includes thresholds for heart-rate and respiration. These two parameters may be indicative of any number of conditions when considered alone or in combination. The conditions can include both a "normal" condition of the user and more critical conditions including life threatening conditions. The processing device can be programmed to evaluate the data received from the monitoring device and to select a protocol to be executed. The selection of the protocol depends upon the event, the event threshold (for example, the amount by which the physiological condition(s) deviate from the event

threshold), the amount of time above or below the threshold, the interaction with other monitored conditions, the characteristics of the trend approaching the threshold, and the corresponding protocol (for example, the action or actions to be taken for a given event threshold).

5 According to one embodiment, the processing device communicates a notification or alert to the user or to one or more other individuals. The notification may include information related to the condition of the individual, as well as an identification of the individual's location and/or the time at which the critical condition was identified using, for example, the Global Positioning System (GPS). According to various embodiments, the selection of events,
10 event parameters, and related protocols associated with the events can be established by the user or be dynamically altered by the user with the processing device and/or remotely by a third party, such as a physician.

 In accordance with one aspect, the system includes a monitoring device and a processing device. In accordance with some embodiments, the monitoring device includes at
15 least one physiological sensor and a wireless transmitter, where the monitoring device is configured to be coupled to a user to allow at least one physiological parameter of the user to be sensed by the at least one physiological sensor. In accordance with further embodiments, the processing device includes a processor, a wireless receiver coupled to the processor, a memory coupled to the processor and a user interface. In still further embodiments, the
20 wireless receiver is configured to receive signals transmitted by the wireless transmitter, the memory is configured to store at least one event and a plurality of protocols associated with the event where each of the at least one event and the plurality of protocols concern a threshold established for the at least one physiological parameter, and the user interface is configured to allow the user to establish at least one threshold, at least one event and at least one of the
25 plurality of protocols. In accordance with one embodiment, at least one action is selected by the user for inclusion in at least one of the plurality's protocols respectively, for each of the respective protocols the at least one action is selected by the user based on the a value of the physiological parameter relative to the threshold and the processor is configured to automatically identify and process protocols selected from the plurality of event protocols in
30 response to receipt by the processing device of a physiological parameter that meets the

threshold established by the user. According to another embodiment, at least one action is selected by the user for inclusion in each of the plurality of protocols.

In accordance with a further embodiment, the memory is configured to store a current configuration established by the user with the processing device including the at least one physiological parameter, the at least one event, the plurality of protocols associated with the event and the threshold established for the at least one physiological parameter. In accordance with yet another embodiment, the memory is configured to store a plurality of current configurations including the first configuration and a second configuration established by the user with the processing device. In one example, the at least one physiological parameter includes a first physiological parameter and the second configuration includes a second physiological parameter. In still another embodiment, the at least one event is the first event, the plurality of protocols is the first plurality of protocols and the threshold includes a threshold established for the first physiological parameter. In one embodiment, the second physiological parameter includes a different physiological parameter than the first physiological parameter and the second configuration includes a second event that differs from the first event, a second plurality of protocols including at least one protocol that differs from protocols included in the first plurality of protocols and a threshold established for this second physiological parameter.

In accordance with any of the preceding embodiments, the physiological sensor can include a chip having a biomedical device included therein, for example, the biomedical device can include a device included in the chip for analysis of bodily fluid of the user.

In accordance with another aspect, a computer readable storage medium is encoded with a computer programmer for execution on a processor included in a processing device where the processing device is in wireless communication with a monitoring device coupled to the user. In accordance with one embodiment, the program when executed on the processor performs a method of identifying an event resulting from a value of a physiological parameter of the user and initiating at least one protocol in response to the event. In accordance with some embodiments, the method includes acts of storing the decision tree in a memory included in the processing device, the decision tree including a plurality of physiological parameters, a plurality of event thresholds associated with the plurality of physiological parameters, a plurality of events each associated with at least one of the plurality of event thresholds and a

plurality of protocols each associated with at least one of the plurality of events. In accordance with a further embodiment, the method includes an act of receiving, by the processing device, a wireless transmission from the monitoring device, the wireless transmission including data concerning the value of at least one physiological parameter of the user. In a still further
5 embodiment, the method includes an act of analyzing, with the processor, the received data using the decision tree to determine whether an event threshold included in the plurality of event thresholds has occurred, and if so, associating the event threshold with the event. In a still further embodiment, the method includes an act of selecting, with the processor using the decision tree, at least one of the plurality of protocols for execution in response to the event.

10 In accordance with one embodiment, the method also includes an act of analyzing with the processor the physiological parameter for change in the values over time to determine whether the event has occurred. In yet another embodiment, the method includes an act of analyzing, with the processor, the physiological parameter for trends that occur during a period of time selected by the user to determine whether the event has occurred.

15 In yet another embodiment, the method includes an act of allowing the user to modify the plurality of physiological parameters, the plurality of physiological parameters, the plurality of event thresholds, the plurality of events, and the plurality of protocols included in the decision tree. According to one embodiment, the method includes an act of protecting the decision tree in the memory to prevent the user from modifying at least some portions of the
20 decision tree stored therein.

According to another aspect, a method employing a processing device and a monitoring device carried by a user, includes acts of monitoring, by the monitoring device, at least one physiological parameter of the user; receiving, by the processing device, data wirelessly transmitted by the monitoring device, the data including a value of the at least one
25 physiological parameter; analyzing, by the processing device, the data using a decision tree stored in the processing device to determine whether an event has occurred based on at least one event threshold concerning the at least one physiological parameter; and executing, by the processing device, at least one of a plurality of protocols in response to the event. In one embodiment, the event, the at least one event threshold, and the plurality of protocols are
30 defined in the decision tree.

According to another embodiment, the method includes analyzing, by the processing device, the received data for changes of the value of the at least one physiological parameter over time to determine whether the event has occurred based on the at least one event threshold.

5 In yet another embodiment, the method includes configuring the at least one event threshold and the at least one of the plurality of protocols in response to an input of the user to the processing device. In a further embodiment, the method includes configuring the at least one event threshold and the at least one of the plurality of protocols in response to an input of a third party to the processing device.

10 In still another embodiment, the user changes configuration to reflect changed circumstances of the user and the changed circumstances include at least one of a change in activity, a change in location, a change in health status, and a change in medication.

BRIEF DESCRIPTION OF THE DRAWINGS

15 The accompanying drawings are not intended to be drawn to scale. In the drawings, each identical or nearly identical component that is illustrated in various figures is represented by a like numeral. For purposes of clarity, not every component may be labeled in every drawing. In the drawings:

20 FIG. 1 illustrates an overview of a system in accordance with one embodiment of the present disclosure;

FIG. 2 illustrates a system in accordance with one embodiment of the present disclosure;

FIG. 3 illustrates a system in accordance with another embodiment of the present disclosure;

25 FIG. 4 illustrates a system in accordance with yet another embodiment of the present disclosure;

FIG. 5 illustrates a process in accordance with an embodiment of the present disclosure; and

30 FIGS. 6A-6C illustrate block diagrams of parameters, thresholds, events and protocols in accordance with embodiments of the present disclosure.

DETAILED DESCRIPTION

Embodiments of this invention are not limited in their application to the details of construction and the arrangement of components set forth in the following description or illustrated in the drawings. Embodiments of the invention are capable of other embodiments and of being practiced or of being carried out in various ways. Also, the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. The use of “including,” “comprising,” “having,” “containing,” “involving,” and variations thereof herein is meant to encompass the items listed thereafter and equivalents thereof as well as additional items.

Figure 1 illustrates an overview of a system 100 having a monitoring device 110 including one or more sensors 112 and a wireless transmitter 114, a processing device 120 having a wireless transceiver 122 that is wirelessly coupled to the monitoring device 110, a remote system 130 coupled to the processing device 120 through a network 140 and also coupled to a remote network 138.

According to one embodiment, a user 102 carries, wears, or otherwise has on their person at least one monitoring device 110 having one or more sensors 112. The user 102, by way of non-limiting examples, may be a generally healthy person, a patient under medical care, an elderly or infirm individual, a person in the armed forces, a person having a high-risk health condition or disease (e.g., heart disease or cancer patient) or engaged in a high-risk or hazardous activity (e.g., athlete, construction worker, or police officer), a VIP (e.g., an executive officer, political official, celebrity, or wealthy individual), or research subject. Each sensor 112 can detect and measure, for example, one or a plurality of physiological attributes such as pulse, blood oxygen level, temperature, respiration, or other vital signs. According to one embodiment, the monitoring device 110 is designed to be worn by the user 102 continuously or regularly, and may be configured to be comfortable, rugged, waterproof, unobtrusive, and/or fail safe. For instance, the monitoring device 110 may be integrated into, among other objects, a bracelet, wristwatch, chest band, arm band, sweatband, headset, pendant, or article of clothing. In other instances, the monitoring device 110 may be surgically implanted in the user 102.

According to some embodiments, the monitoring device 110 can also include a wireless transmitter 114, such as a Bluetooth™ transmitter, for transmitting data acquired from one or

more of the sensors 112 to the processing device 120, which includes the wireless transceiver 122 that is compatible with the wireless transmitter 114. In one example, the user 102 wears monitoring device 110 having a sensor configured to measure the user's pulse and a wireless transmitter for transmitting pulse data to processing device 120, which may be a mobile phone, personal digital assistant (PDA), or other mobile device which is generally located nearby the user 102. It is appreciated that the processing device 120, being local to the user 102, enables the user to easily configure and interact with the system 100, and further provides the user with a system that is mobile and can function independently of any remote devices, for example, if the user is in an area where communications (e.g., telephone, mobile phone, Internet) are limited or unavailable.

Referring to Figure 1, according to one embodiment, and as discussed in further detail below, the processing device 120 is adapted to process data received from the monitoring device 110 and detect at least one event based on a threshold corresponding to a physiological condition, or combination of physiological conditions, of the user 102. Each event corresponds to one or more physiological parameters that, upon reaching a threshold value, trigger the event. According to some embodiments, the threshold value includes a range of values having upper and lower limits. Further, the processing device 120, upon detecting an event, can execute one or more event protocols 124 that, for example, generate a notification or alert for the user 102 and/or one or more third parties 132, or take other action in accordance with event protocol(s), such as recording or analyzing the data or communicating with the remote system 130. According to various embodiments, execution of the protocol results in the initiation of a plurality of actions performed by the processing device 120 and/or other elements of the system 100. For example, the processing device communicates instructions and/or actions to the remote system 130 to be performed by the remote system.

In another embodiment, one or more event protocols 124 are stored on the processing device 120. The event protocols 124, for example, define one or more actions to be taken when an event occurs. Further, one or more of the event protocols 124 may be processed based on a degree to which a plurality of physiological conditions and/or other parameters that can trigger an event deviate from a threshold value (e.g., mild, moderate, severe).

In one embodiment, the event protocols 124 are user-defined. For example, the user 102 may program the event protocols 124 into the processing device 120 using a user interface

of the processing device. In another embodiment, the event protocols 124 are configured remotely by a third party 132, such as a physician, nurse, nurse practitioner, or other individual involved with monitoring of the user 102. For example, the third party 132 may program the event protocols 124 into the processing device 120 through the remote system 130 and network 140 using a user interface of the remote system or other device.

In one embodiment, a processing device 120 is a mobile telephone or similar mobile communications device. The processing device 120 may be adapted to communicate with a remote system 130 through a network 140. The processing device 120 may also be adapted to communicate with one or more other third parties 132 each having, for example, communications devices compatible with network 140. In another embodiment, the event protocols 124 may be configured by the user 102 and/or the third party 132. In still another embodiment, a remote expert system (not shown) may also receive, manage and process the information.

In another embodiment, a network 140 may be, for example, a mobile communications network, a computer network, the Internet, a telephone network, or other wide-area or local network that is compatible with the processing device 120 and is adapted to transmit information between the processing device 120 and the remote system 130 and/or the other third parties 132. Non-limiting examples of the network 140 include GSM (global system for mobile communications), PCS (Personal Communications Service), UMTS (universal mobile telecommunication system), EDGE (enhanced data rates for GSM evolution), CDMA (code division multiple access), Telex, pager (TAP, FLEX, ReFLEX, POCSAG, Golay, ERMES and NTT), Ethernet, microwave, satellite, RS-232 serial, USB, IrDA, Wi-Fi, and Bluetooth.

According to various embodiments, third parties 132 may include health care providers, physicians, family members, emergency services providers, and/or cryonicists. Each individual 132 may further be associated with an authorization level that defines the type or amount of information received or exchanged with a processing device 120 or a remote system 130, and/or defines an authority for the individual 132 to configure, for example, event protocols 124 remotely. For example, a family member may be authorized to receive alerts when a critical physiological condition (or combination of physiological conditions) of the user 102 is detected. In another example, a physician may be authorized to configure the threshold

and/or protocol associated with an event detected by the processing device 120 or the remote system 130.

In another embodiment, an individual 132 interacts with remote system 130, for example, to receive notifications that are generated by processing device 120. For instance, remote system 130 may include a user interface configured to display a notification or alert the individual 132. In another example, remote system 130 may be configured to enable the individual 132 to receive reports related to one or more physiological attributes of user 102, or to configure event thresholds and/or event protocols on processing device 120. Further, remote system 130 may be configured to communicate with one or more third parties 132, such as those discussed above, through a remote network 138.

According to one embodiment, an event occurs when each of a plurality of physiological parameters that are sensed by the monitoring device 110 reach a respective threshold value. In some embodiments, upon occurrence of the event, at least one of a plurality of protocols associated with the event is automatically selected and processed by the processing device 120. In various embodiments, protocols can cause a notification of the event to be presented to the user 102 and/or a third party 132, such as a request for aid or an alarm, or other action to be taken, such as automatic administration of a medication or automatic defibrillation of the user. For example, if several parameters are being monitored, such as heart-rate, change in heart-rate, heart-rate regularity, and motion; an event may occur when a rapid change in each of the three heart-rate parameters is detected. The event may cause a first protocol to be processed if the user 102 is moving, which may indicate that the user is exercising, that causes a local notification of the event to the user. If the user 102 is not moving, which may indicate that the user is in medical distress, the event may cause a second protocol to be processed that alerts an emergency services provider.

According to another embodiment, the event occurs when a single physiological parameter that is sensed by the monitoring device 110 reaches a threshold value. Upon occurrence of the event, at least one of a plurality of protocols associated with the event is processed by the processing device 120. Each of the protocols may cause a notification of the event to be presented to the user 102 and/or a third party 132, such as a request for aid or an alarm, or other action to be taken, such as automatic administration of a medication or automatic defibrillation of the user. For example, an event may occur when a monitored blood

glucose level of the user 102 reaches a respective threshold value. The event may cause a first protocol to be processed that notifies the user 102 that the blood glucose level has reached the threshold value. The event may cause a second protocol to be processed when the blood glucose level deviates from the threshold value by a preset value. The second protocol may cause, for example, an automatic administration of glucose to the user 102, as well as a notification to a third party 132, such as a physician.

Referring to Figure 2, a system 200 includes a monitoring device 202 and a processing device 204. The monitoring device 202 and the processing device 204 may, in one embodiment, each be implemented by the respective devices discussed above in reference to Fig. 1. According to one embodiment, the monitoring device 202 is a wearable device having one or more physiological sensors 210 and a wireless communications interface 210, such as a Bluetooth™-compatible transmitter. The monitoring device 202 may also include a GPS receiver 212, a motion sensor 214 (e.g., accelerometer), a compass 216, and/or an altimeter 218 for detecting the location and motion of an individual wearing the device. Further, the monitoring device 202 may include a processor 220, a memory 222, a user interface 224, and/or a power supply 226. The memory 222 may be, for example, static RAM, dynamic RAM, ROM, EPROM, EEPROM, or flash memory. According to one embodiment, the processor is included in a microcontroller. According to this embodiment, the memory 222 can be included in the microcontroller or in memory external to the microcontroller.

According to one embodiment, the monitoring device 202 is worn by an individual and continuously monitors one or more of the physiological attributes of the individual. The monitoring device 202 may have a form factor that enables the device to be worn comfortably for extended periods of time and during varying activities, such as working, running, swimming, playing athletics, and/or sleeping. To facilitate such uses, the monitoring device 202 may generally be rugged, waterproof, and resistant to electro-static discharge and variations in temperature, humidity, and altitude. Further, the monitoring device 202 may include one or more physiological sensors 210 each adapted to reliably detect and measure one or more physiological attributes, such as pulse, temperature, or respiration under varying conditions commonly associated with continuous or extended use of the device.

In one embodiment, the monitoring device 202 includes a user interface 224 that may have, for example, a power switch, a configuration control (e.g., sensitivity controls for the

sensors or for controlling wireless communications interface 212), and/or a function control (e.g., panic, call, and/or reset buttons).

According to another embodiment, the monitoring device 202 is adapted to determine a location and/or a movement of the user. For example, the monitoring device 202 may be adapted to receive GPS signals for determining the location (e.g., using GPS coordinates) and/or the current time. In another example, the monitoring device 202 may include a motion sensor, such as an accelerometer, and/or a compass for determining rate and/or direction of movement of the user. Location and motion data may be used separately or in combination with one another.

In yet another embodiment, the monitoring device 202 communicates with a processing device 204 through, for example, a wireless communications interface 212. The processing device 204 includes a wireless transceiver 250 that is adapted to receive communications transmitted by monitoring device 202. The processing device 204 may also include a GPS receiver 252, a processor 254, a memory 256, and a power supply 260. In one example, the processing device 204 is a smartphone, such as the iPhone® smartphone by Apple, Inc. or the Blackberry® smartphone by Research in Motion Limited, although it should be understood that other mobile devices (e.g., “feature phones,” personal digital assistants or portable media players) may be used.

According to other embodiments, the processing device 204 may include a personal computer (PC) or other microcomputer, a set-top box, a cable modem, or other computing device. The processing device 204 may, according to one embodiment, include a communication interface 262 adapted to interface with a network 270. For instance, the communication interface 262 can include a GSM interface for a mobile telephone system, and the network 270 may be a GSM-compatible communication network that is coupled to one or more cellular towers 272 for communicating information to, for example, a remote system 130 or other third parties 132, as discussed above with reference to Fig. 1. According to some embodiments, the network 270 can include any one of or any combination of a computer network, a wide-area network, a local area network (for example, Wi-Fi), the Internet, or other communication network. In another embodiment, the network 270 may be coupled to a remote system 274, such as the remote system 130 as discussed above with reference to Fig. 1.

According to one embodiment, the processing device 204 receives data transmitted wirelessly by a monitoring device 202. Such data may include, but is not limited to, data or information provided by any of the sensors 210, the GPS receiver 212, the motion sensor 214, the compass 216 and/or other data associated with the physiological attributes, the location and/or activities of an individual using the monitoring device 202. For instance, the monitoring device 202 may transmit data continuously or periodically to processing device 204 if both devices are within radio frequency (RF) range of one another. In one example, the monitoring device 202 transmits data when the physiological attributes change or are detected to be within a preset range of values. In another example, if the processing device 204 is out of RF range of the monitoring device 202, the monitoring device 202 stores data collected by, for example, the physiological sensor 210, in the memory 222 until communications can be restored, at which time the stored data is transmitted to the processing device 204.

In one embodiment, the processing device 204 includes a GPS receiver 252 for determining a location of the device. In another embodiment, the processing device 204 utilizes information received from one or more cellular towers 272 to triangulate a position of the device.

In still another embodiment, the processing device 204 includes a user interface 258 that enables a user, for example, to receive notifications, alerts, or other information related to the physiological conditions and/or location of the person using a monitoring device 202. According to some embodiments, the user is the same person who is using the monitoring device 202. According to other embodiments, the user is someone other than the individual who is using the monitoring device. For example, a parent can operate the processing device where the monitoring device is being used by their child. The converse may also be true where the individual wearing the device is elderly. The user interface 258 may include a text display, a graphical display, an audible annunciator, and/or one or more input mechanisms, such as a keyboard, trackball, or function key (e.g., panic button). For example, if the processing device 204 determines that an event has occurred, a notification (or other action) generated by a corresponding event protocol may be presented to the user through the user interface 258.

Referring now to Figure 3, a system 300 includes a monitoring device 302 in communication with a processing device 304. The processing device 304 may be in further communication with a remote system 306 and/or a third party 308. In one embodiment, the

monitoring device 302 and the processing device 304 may each be implemented by the respective devices discussed above with reference to Fig. 2. In another embodiment, the monitoring device 302 communicates one or more of the following to the processing device 304: sensor data (e.g., physiological data), location data, motion data, voice, and alerts, for example, periodic alerts, a panic alert, etc.

According to another embodiment, a processing device 304 includes a processor 310, a wireless receiver 312 coupled to the processor 310, a memory 314 coupled to the processor 310, and a user interface 316 coupled to the processor 310. According to some embodiments, the processing device includes a microcontroller which includes the processor 310. The memory 314 may be, for example, static RAM, dynamic RAM, ROM, EPROM, EEPROM, or flash memory. In some embodiments, the memory 314 may be included in the microcontroller while in other embodiments the memory 314 is external to the microcontroller. The processing device 304 may include, for example within the memory 314, one or more event configurations 352. Each event configuration 352 may include a threshold and one or more event protocols. The event protocols may define one or more actions to be taken upon the triggering of the corresponding event, for example, when a value of a physiological parameter exceeds the corresponding threshold for the event. The processing device 304 may also include a local annunciator for alerting or notifying an individual of an event. For example, if a user is suffering a cardiac arrest, arrhythmia, or other heart-related condition that exceeds an event threshold associated with heart function, the processing device 304 may, upon receiving the corresponding data from the monitoring device 110, send a Short Message Service (SMS) message (or other type of message) to a local "911" emergency operator, where the message identifies the condition and/or location of the user.

In one embodiment, the wireless receiver 312 is configured to receive signals transmitted by a monitoring device 302. Such signals may include, but are not limited to including, sensor data, location data, motion data, voice, and/or panic alert.

According to another embodiment, a memory 314 may be configured to store an event configuration 352 that includes at least one event, and at least one event threshold value and at least one event protocol each associated with a respective event. An event occurs when each of one or a plurality of physiological parameters that are sensed by the monitoring device 302 reach the respective threshold value or values. Upon occurrence of the event, at least one of a

plurality of protocols associated with the event is processed by the processing device 304. Each of the protocols may cause a notification of the event to be presented to the user (not shown) and/or a third party 308, such as a request for aid or an alarm, or other action to be taken, such as automatic administration of a medication or automatic defibrillation of the user.

5 For example, an event may be configured in relation to a heart-rate of an individual using monitoring device 302 using multiple parameters, such as a heart-rate value, a respiration value, and a perspiration value. A threshold associated with the event may be configured to a heart-rate value having a lower limit of 55 beats per minute, a respiration of 12 liters of air per minute, and a body temperature of 100 degrees Fahrenheit. Accordingly, if the heart-rate of
10 the individual is 55 beats per minute or less, the respiration is 12 liters per minute or more, and the temperature is 100 degrees or more, a corresponding event protocol may be processed, for example, by annunciating an alert and/or generating a notification, which may be presented locally (e.g., by processing device 304), or remotely (e.g., by remote system 306 or at third party 308).

15 According to various embodiments, non-limiting examples of events caused by various physiological conditions include: a sudden increase in heart-rate and a decrease in heart-rate regularity with no change in respiration (indicates possible Atrial Fibrillation); a rapid proportional increase in heart-rate, respiration, activity, perspiration (GSR) (indicates possible normal exercise pattern); a sudden proportional increase in heart-rate, respiration, activity,
20 perspiration (GSR) and change in GPS position (indicates possible running), a low pulse rate with decreased blood pressure (indicates possible intrinsic cardiac arrhythmia or a vaso-vagal event); a high pulse rate with a low blood pressure and an increased respiratory rate (indicates possible shock due to sepsis or other causes); abnormalities of body temperature including abnormal trend of lowering temperature with lowering pulse rate (indicates possible trend
25 toward or onset of hypothermia); a trend toward increasing temperature with an increasing pulse rate and a lowering blood pressure (indicates trending toward onset of possible septic shock). It should be understood that other combinations of physiological conditions may cause one or more events to occur.

In another embodiment, one or more of the event thresholds and/or event protocols may
30 be configured by a user using, for example, the user interface 316 of the processing device 304. For example, the user may configure an event threshold for triggering a heart-rate event at a

lower limit of 55 beats per minute. In another example, the user may configure an event protocol to be processed when the corresponding heart-rate threshold is achieved, such as establishing a list of contacts (e.g., physician, family member, cryonicist) to be notified of the event.

5 According to one embodiment, each of the event thresholds and event protocols has one or more of the following: a privilege level and a priority level. The privilege level describes the rights of the user or a third party with respect to the corresponding event threshold and/or event protocol. For example, the privilege level may be monitor only (e.g., the ability to monitor the physiological parameters associated with the event, or the ability to receive
10 notifications associated with the event), create, modify, delete, or any combination thereof. The priority level describes the priority of the associated event threshold or event protocol with respect to other thresholds or protocols that may be created for an event. For example, a user-created event threshold may have a lower priority than a physician-created threshold, such that the physician-created threshold will be processed before the user-created threshold.

15 According to yet another embodiment, an event configuration 352 includes a plurality of protocols associated with a corresponding event having a plurality of event thresholds. According to some embodiments, the relevant protocols for a given set of parameters are automatically selected processed locally by the processing device 304. Each of the protocols may be processed, for example, when the value corresponding to a physiological attribute
20 deviates from the corresponding threshold by a predetermined degree. The predetermined degree may be configured by a user using the user interface. For example, the user may establish a threshold for triggering a heart-rate event at a lower limit of 55 beats per minute, and a first degree of deviation of 10 beats per minute. Further, the user may configure the protocol corresponding with the first degree of deviation to notify, e.g., an emergency services
25 provider of the event and, optionally, of the location of the person being monitored. Accordingly, if the person's heart-rate drops to the threshold of 55 beats per minute, a first protocol may be processed, as described in the above example, and further, if the person's heart-rate drops to 45 beats per minute, a second protocol may be processed (e.g., contact emergency services). The processor of processing device 304 may be configured to
30 automatically identify and process one or a plurality of the event protocols to generate a

notification for transmission to at least one third party when a corresponding event threshold is reached or to initiate other actions alone or in combination with the notification.

In various embodiments, the processing device 304 includes a plurality of modules 359 including a notification module 360, a reporting module 362, a monitoring module 364, a configuration 366 module, an administration module 368, a recording module 370, and a display module 372. According to some embodiments, the modules 359 are interconnected with one another, for example, via internal communication in the processing device 304. In one embodiment, the modules 359 are included in the processor 310. Further, the modules can be provided by hardware, software or by a combination of hardware and software components, for example, one or more algorithms.

According to one embodiment, the processing device 304 is configured to provide a notification of the occurrence of one or more events. The notification module 360 can operate to notify a user through text or graphical messages, audible tones, voice announcements, or other annunciations. In one embodiment, when an event occurs, the processing device 304 can emit an alarm tone, display a message, or play a recorded voice announcing the occurrence of the event, requesting aid on behalf of the user, and/or providing instructions for actions to be taken by the user or third party, for example, an individual who is to aid to the user. The event may be, for example, a threatening event such as primary cardiac arrhythmia, primary respiratory disturbance, and hemodynamic disturbance is detected, or a less severe event, for example an increase in heart-rate, respiration, activity and perspiration related to normal or strenuous activity, such as exercise.

In another embodiment, if an event occurs, the processing device 304 may communicate a message or other information to the remote system 306 and/or a third party 308, such as a physician, health care provider, cryonicist, emergency services provider, and/or family member. The message or other information may include text, graphics, voice, or other data, such as data related to the physiological condition of the user of the monitoring device 302, or data related to the event.

According to one embodiment, the processing device 304 includes a reporting module 362. Reporting may include generating and/or displaying reports such as charts, tables, figures, data plots versus time or other parameters, summaries, or other compilations of data, for example, data communicated by the monitoring device 302. The reports may include data

compiled from sensor data (e.g., physiological sensors), location data, motion data, voice data, and/or panic button data as some examples. For example, one report may include a list of historical sensor data, such as the heart-rate of a user over a period of time. The reports may, for example, be retrieved by the user through the user interface 316.

5 According to an embodiment, the monitoring module 364 may operate to monitor parameters, thresholds, events and event protocols. In one embodiment, the monitoring module 364 operates to monitor in real-time, physiological data, location data, motion data, or other data being received or processed by the processing device 304. For example, the monitoring module 364 can be configured to monitor data from one or more sensors included
10 in the monitoring module.

 According to one embodiment, the parameters, event thresholds, and event protocols are included in a decision tree that can be configured by the user with the configuration module 366. For example, the configuration module 366 provides the user with an ability to create, modify, delete, and/or view parameters, events, event thresholds and/or event protocols. In
15 some embodiments, the user can configure the processing device 304 to create an event that occurs when various parameters or combinations of parameters reach a threshold, such as a heart-rate event where the user's heart-rate falls below 55 beats per minute and where the rate of change of the user's heart-rate exceeds 5 beats per minute. One or more protocols may also be configured by the user to initiate or take an action. For example, execution of the protocol
20 may result in the processing device sounding an audible alarm or notifying an emergency services provider. Event configurations may be stored, for example, in the memory 314 and/or at the remote system 306.

 In another embodiment, the user can employ the configuration module to modify an existing event to change, for example, the event threshold and/or event protocols. For
25 example, the user may modify a list of individuals to be contacted when a critical event, such as cardiac arrest, occurs. In another example, the user may modify the event threshold for one or more events, such as modifying the threshold for the heart-rate event discussed above.

 In yet another embodiment, the user may modify privileges and/or priorities associated with event configurations. For example, the user may assign a "monitor-only" privilege to the
30 heart-rate event discussed above, which permits third parties to receive, for example,

notifications generated by the event, but prohibits the third parties from modifying the event configuration.

In another embodiment, the user may configure events, event thresholds and/or event protocols with the configuration module 366 using the user interface 316. In various
5 embodiments, the user can employ the configuration module 366 to locally modify the configuration of the decision tree stored in the processing device 304 to reflect changed circumstances. For example, the user can modify parameters, thresholds, events and protocols as a result of changes in their physical health, mental health, activity level, geographic location and ambient conditions, as some examples. According to one embodiment, the configuration
10 module 366 can be employed by the user to configure a decision tree stored remote from the processing device, for example, at the remote system 306. In another embodiment, the user and/or a third party may configure events, event thresholds and/or event protocols through the remote system 306.

In yet another embodiment, the configuration function 366 enables configurations of
15 events, event thresholds and/or event protocols from more than one location and/or by more than one user. Further, configurations stored at the remote system 306 may be synchronized with configurations stored at the processing device.

According to an embodiment, the processing device 304 includes an administration module 368. For example, the administration module 368 can be employed by the system 300
20 for administration of, for example, a drug, other pharmaceutical compound, fluid, defibrillation, or other treatment to the user wearing a device adapted for such administration and configured to communicate with the processing device 304. For example, if a low blood sugar event occurs, the processing device 304 may command a glucose administration device worn by the user to inject a dosage of glucose.

25 According to an embodiment, the recording module 370 operates to but is not limited to, capturing and storing into, for example, the memory 314, data received from the monitoring device 302. Such data may be retrieved at a later time by, for example, the reporting function 362 discussed above, or by any other function requiring access to the stored data.

According to an embodiment, the display module 372 operates to, but is not limited to,
30 communicating and/or formatting data stored in, for example, the memory 314 for display. The data may include physiological parameters, location data, motion data, or other data

associated with the monitoring device 302. In one embodiment, the data may be displayed textually, graphically, and/or audibly (e.g., playback of a voice conference or call for assistance using the processing device 304). According to one embodiment, data received from the monitoring device is displayed in substantially real-time.

5 Referring to Figure 4, a system 400 includes a remote system 402 coupled to a network 404, such as a network 140 as described above with reference to Fig. 1. The remote system 402 may also be implemented, for example, by a remote system 130 as discussed above with reference to Fig.1. The network 404 may be, for example, a computer network, a wide-area network, a local area network, the Internet, or other communication network.

10 According to another embodiment, a remote system 402 includes a processor 412, a communications interface 412 coupled to the processor 410, a memory 414 coupled to the processor 410, and a user interface 416 coupled to the processor 410. The remote system 402 may include, for example within the memory 414, one or more event configurations 452. Remote system 402 may also include a local annunciator for altering or notifying an individual
15 of an event.

In an embodiment, a memory 414 may include an event configuration 452 having one or more events each associated with at least one event threshold and one or more event protocols. According to one embodiment, each of the event thresholds and event protocols has one or more of the following: a privilege level and a priority level. The privilege level
20 describes the rights of a third party with respect to the corresponding event threshold and/or event protocol. For example, the privilege level may be monitor only (e.g., the ability to monitor the physiological parameters associated with the event, or the ability to receive notifications associated with the event), create, modify, delete, or any combination thereof. The priority level describes the priority of the associated event threshold or event protocol with
25 respect to other thresholds or protocols that may be created for an event. For example, a family-member-created event threshold may have a lower priority than a physician-created threshold, such that the physician-created threshold will be processed before the user-created threshold.

30 According to another embodiment, the remote system 402 may perform one or more of the following functions: notification (e.g., notifying a third party of an event); reporting (e.g., providing a report of data associated with a physiological condition); monitoring (e.g.,

providing a display of data associated with a physiological condition); configuration (e.g., enabling a third party to view, create, modify, and/or delete event thresholds and/or event protocols); administration (e.g., remotely activating a device worn by the user to administer a medication); and recording (e.g., storing data associated with a physiological condition in the memory 414).

In another embodiment, one or more event configurations may be configured by a user interacting with a remote system 402 through a user interface 416. The user may define an event by entering parameters associated with one or more physiological conditions to be monitored, each having individually or in combination an event threshold and one or more event protocols. For example, an event may be defined as a cardiac arrest where the person being monitored has a heart-rate at or below 55 beat per minute in combination with a respiration of 4 liters per minute of air or less. In another example, the event may include meeting or exceeding each of the above described thresholds during a period of time, such as 1 minute. The event configurations may be communicated through network 404 to a processing device, such as the processing device 120 as discussed above with reference to Fig. 1, to be stored in the memory of the processing device.

In yet another embodiment, and as shown in Fig. 3, remote system 402 provides one or more modules, including, but not limited to, a notification module 380, a reporting module 382, a monitoring module 384, a configuration module 386, an administration module 388, a recording module 390, and a displaying module 392. In one embodiment, these modules may operate similarly to the operation of the respective function modules described above with reference to Fig. 3 where the operations primarily take place at the remote system. According to some embodiments, one or more operations provided by the modules occur at the processing device 304. In one embodiment, the configuration module 386 enables a third party to configure events, event thresholds, and/or event protocols stored in the memory 414. In another embodiment, the third party may synchronize the event configuration(s) with a processing device, such as the processing device 304 discussed above with respect to Fig. 3. Similarly, one or more of the other functions discussed above may be performed by the remote system 402 alone or in combination with the processing device.

Figure 5 illustrates a process 500 for monitoring a physiological condition of an individual. Process 500 begins at act 502. At act 504, a sensor of a monitoring device

measures a physiological attribute of the individual. The physiological attribute may be any attribute measurable by a sensor, such a pulse, blood oxygen level, temperature, respiration, brain function, location, or motion. At act 506, data including the physiological attribute is transmitted to a processing device. The data may be transmitted, for example, wirelessly using the Bluetooth™ standard. At act 508, the data is received by the processing device. The processing device may be carried by the individual or located at a further distance within radio receiving range of the monitoring device. At act 510, the data is compared with a threshold corresponding to the physiological attribute. For example, for a physiological attribute of heart-rate, the threshold may be a lower limit of 55 beats per minute. If the data includes a measured heart-rate of 55 beats per minute or less, a first protocol is processed at act 512. The first protocol, for example, may include generating a local annunciation.

In another embodiment, process 500 includes determining, at act 514, a degree to which the data deviates from the threshold corresponding to a physiological attribute. For example, if the data includes a measured heart-rate of 45 beats per minute, and the threshold is 55 beats per minute, the degree to which the data deviates is 10 beats per minute. At act 516, if the degree to which the data deviates from the threshold meets or exceeds a first user-selected deviation (e.g., 10 beats per minute), a second protocol is processed. The second protocol, for example, may include generating a request for an emergency responder. At act 518, process 500 ends.

Referring now to FIGS. 6A-6C a block diagram is illustrated in accordance with one embodiment. In accordance with the illustrated embodiment, the block diagram presents a plurality of parameters 610, a plurality of thresholds 612 and a plurality of events and associated protocols 614. In various embodiments, the elements illustrated in FIGS. 6A-6C and other elements may be included in a decision or logic tree that can be stored in the processing device, for example, processing device 304, the remote system 402 or in each of the processing device and the remote system. In accordance with some embodiments the user can add and delete parameters, for example, where they have changed the configuration and/or replaced the monitoring device. In particular the monitoring device currently employed by a user may include a different quantity or different types of sensors than a monitoring device that may have been previously worn by the user. In addition, the user can establish thresholds for each of the parameters where threshold levels correspond to generation of an event that leads to an execution of one or more protocols 614. In accordance with some embodiments, the

events and associated protocols 614 can also be added to, removed, modified and re-sequenced by the user of the processing device. That is, the user can modify the decision tree to tailor the settings and courses of action to changes in their circumstances. According to some embodiments, the user can implement these changes in substantially real time. Further, as
5 described above, the user of the processing device can be the same individual whose physiological parameters are being monitored by the monitoring device.

According to some embodiments, the plurality of parameters 610 may include physiological parameters of the user, parameters concerning the environmental conditions the user is subject to and the location and/or movement of the user. In the illustrated embodiment,
10 the plurality of parameters include heart rate 613, blood oxygen 615, respiration 617, perspiration 619, blood pressure 621, body temperature 623, body fluid 625, activity 627, location 629, altitude 631, and ambient temperature 633. Further, the thresholds illustrated in FIG 6A include a first heart rate threshold 611, a second heart rate threshold 616, a third heart rate threshold 618, a blood glucose threshold 607, a first location threshold 608 and a second
15 location threshold 609. The plurality of events and associated protocols 614 illustrated in FIG 6A include a first event 624, a first protocol associated with the first event 626, a second protocol 628 associated with the first event and a third protocol associated with the first event. In addition FIG 6A illustrates a second event (Event 2) 630, and a first protocol 632, a second protocol 634, and a third protocol 636 associated with 630 the second event.

Further, in the illustrated embodiment the plurality of thresholds 612 include a heart
20 rate value threshold 611, a heart rate rate of change threshold 616, a heart rate regularity threshold 618, a blood glucose threshold 607, a displacement threshold 608, and a rate of displacement threshold 609. FIG. 6A only illustrates some example of parameters, thresholds, and events/protocols, however, the listed parameters may be provided alone in the combination
25 shown, and alternatively, in other combinations with the parameters illustrated or other parameters. In addition, each of the parameters may include one or a plurality of thresholds that are employed by the processor to evaluate the status of the individual and trigger events and their associated protocol or protocols. According to one embodiment, each of the plurality of parameters 610 includes at least one threshold.

Each of the events 624, 630 is triggered by one or a combination of parameters where
30 the parameters reach a threshold value. For example, the first event 624 and associated

protocols 626, 628 and 629 illustrated in FIG 6A concern a rapid increase in each of the heart rate 613, the respiration 617 and the perspiration 619. According to one embodiment, the first protocol 626 is initiated where each of the heart rate, the respiration, and the perspiration are rapidly increasing and the activity sensor provides an indication that activity of the user includes rapid motion. As a result, the first protocol (Protocol 1A) 626 provides for a continuing monitoring of the user's condition, in particular, the heart rate, respiration and perspiration sensed for the user, and in addition, a notification to the user to warn the user of these rapidly increasing levels. The second protocol 628 (Protocol 1B) associated with the first event 624 initiates a monitoring of the user activity to detect whether the user is running. In addition, the first event may also initiate execution of the third protocol 629 (Protocol 2) where the activity parameter 627 indicates that the user being monitored is inactive when the heart rate, respiration and perspiration are rapidly increasing. Because this combination of conditions may indicate a serious medical condition, the third protocol 629 includes notification of at least one third party of the individuals current condition.

As illustrated in FIG 6A, the second event 630 is triggered with a decrease in blood glucose below a blood glucose threshold 622. In the illustrated embodiment, the first protocol 632 can be initiated when the blood glucose level drops below a first limit but is greater than a second limit. For example, this protocol may initiate a notification provided to the individual by a local annunciation and/or receipt of a mobile phone call that their blood glucose levels are at a level that requires their attention. The second protocol 634 can be activated either initially or following the activation of the first protocol 632 when the user's blood glucose level drops below the second limit but is greater than a third limit. Here, a user equipped with an automated insulin injector may receive insulin in order to return the blood glucose levels to the desired levels for the user. In addition, the second protocol 634 can include notification of a medical service professional of the user's condition concerning blood glucose and alert them to the fact that the user may require medical assistance. The third protocol 636 associated with Event 2 is activated when the user's blood glucose drops below the third limit. This threshold can provide an indication of a hypoglycemic condition of the user to one or more third parties.

Referring now to FIG. 6B, additional thresholds are included in the plurality of threshold 612. In the illustrated embodiment, the thresholds include a first respiration threshold 656, a second respiration threshold 658, a third respiration threshold 660, a first

blood pressure threshold 662, a second blood pressure threshold 664, a third blood pressure threshold 666, a first body temperature threshold 668, and a second body temperature threshold 670. In addition, FIG. 6B also illustrates a third event 640 (Event 3) which is associated with a first protocol 642, a second protocol 644, a third protocol 646, and a fourth protocol 648. Also
5 illustrated is a fourth event (Event 4) 650 which is associated with a first protocol 652 and a second protocol 654.

According to the illustrated embodiment, the first respiration threshold is the respiration value of the individual, the second respiration threshold is a rate of change of respiration of the user, and the third respiration threshold is the regularity of respiration. Further, the first blood
10 pressure threshold includes the value of the blood pressure, the second blood pressure threshold includes a rate of change of the blood pressure and the third blood pressure threshold includes the regularity of the blood pressure. In addition, the first body temperature threshold 668 concerns the body temperature value and the second body temperature threshold is the rate of change of the body temperature.

The third event (Event 3) 640 is triggered by a rapid increase in heart rate where the respiration of the user remains unchanged. According to the illustrated embodiment, the first
15 protocol 642 is initiated when the heart rate is less than a first level and the heart rate is regular. Execution of the protocol results in notification to the user to seek immediate assistance. A third protocol 646 associated with Event 3 occurs when the value of the heart rate is less than
20 the first limit but the heart rate is irregular. Because a sudden increase in heart rate with a decrease in regularity can indicate a possible atrial fibrillation when no change in respiration has occurred, the third protocol 646 also includes notification of a third party. Further, the fourth protocol 646 initiates a notification of emergency response personnel if the heart rate is
greater than a second limit and the heart rate is rapidly increasing while respiration remains
25 unchanged.

In the illustrated embodiment, the fourth event 650 concerns a heart rate value outside the normal range with a low blood pressure. Here, heart rate in combination with low blood pressure can be used to diagnose a possible cardiac arrhythmia or a vaso-vagal event or possible shock due to sepsis and other causes. For example, the first protocol 652 associated
30 with the fourth event 650 initiates a notification of both the user and a third party if the heart rate is below a low limit when the blood pressure is low. In this example, the user notification

can make the user aware that they need to seek immediate medical assistance and can also call for aid by a third party. The second protocol 654 associated with the fourth event 650 provides that where the heart rate is greater than an upper limit and the respiration has increased at a rate above a rate of change of limit, a third party is notified because these conditions indicate that the individual being monitored may be in a state of shock.

Referring now to FIG. 6C, a fifth event 672 and corresponding protocols is illustrated in accordance with one embodiment. According to this, the associated protocols include a first protocol (Protocol 1) 674, a second protocol (Protocol 2) 676, a third protocol (Protocol 3) 678, a fourth protocol (Protocol 4) 680, and a fifth protocol (Protocol 5) 682. The fifth event addresses thresholds concerning the value of an individual's body temperature, and in particular, a body temperature that falls outside the normal range. The monitoring of body temperature can provide an indication of a possible trend toward or onset of hypothermia and a possible onset of septic shock. The first protocol 674 is initiated for circumstances where the body temperature is less than a first low limit and greater than a second low limit with the heart rate in the normal range. According to the illustrated embodiment, the first protocol initiates a start of recording body temperature data of the individual being monitored. The second protocol 676 is initiated where the body temperature is less than the first low limit, greater than the second low limit and where the heart rate is less than a first limit. When these conditions occur, the second protocol 676 initiates a notification to both the user and third parties of possible onset of hypothermia. The third protocol 678 is initiated when the body temperature is less than the second low limit. Here, because of the potential extreme decrease in temperature, execution of the third protocol initiates the contact of emergency response personnel. In addition, according to one embodiment, the location by GPS coordinates of the user can be provided to the emergency response unit. The fourth protocol 680 is initiated where the body temperature is greater than an upper limit. Here, the increase in temperature may only be indicative of a flu or other more minor conditions. Accordingly, the fourth protocol 680 initiates a notification of a third party. For example, the notification may be made in a non-emergency fashion, e.g. a lower priority communication. According to the illustrated embodiment, the fifth protocol 682 is initiated where the body temperature is greater than the upper limit, the heart rate is increasing and the blood pressure is decreasing. Because these conditions may be indicative of the onset of possible septic shock, execution of the fifth

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protocol provides a notification not only to the user of the seriousness of the condition but also to one or more third parties.

According to some embodiments, the monitoring device 110, 202, 302 and the processing device 120, 204, 304 can be included in a single integral device. In further
5 embodiments, the monitoring device and the processing device communicate over a hardwired communication link. Thus, in various embodiments, communication between the monitoring device and the processing device can employ any one of or any combination of Wi-Fi, a mobile communication network, a computer network, the Internet or other types of wide area networks or local area networks.

10 Having thus described several aspects of at least one embodiment of this invention, it is to be appreciated various alterations, modifications, and improvements will readily occur to those skilled in the art. Such alterations, modifications, and improvements are intended to be part of this disclosure, and are intended to be within the spirit and scope of the invention. Accordingly, the foregoing description and drawings are by way of example only.

15 What is claimed is:

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CLAIMS

1. A system comprising:

a monitoring device including at least one physiological sensor and a wireless
5 transmitter, the monitoring device configured to be coupled to a user to allow at least one
physiological parameter of the user to be sensed by the at least one physiological sensor; and
a processing device including:

a processor;

a wireless receiver coupled to the processor, the wireless receiver configured to
10 receive signals transmitted by the wireless transmitter;

a memory coupled to the processor and configured to store at least one event
and a plurality of protocols associated with the event where each of the at least one
event and the plurality of protocols concern a threshold established for the at least one
physiological parameter; and

15 a user interface coupled to the processor and configured to allow the user to
establish at least threshold, at least one event and at least one of the plurality of
protocols,

wherein at least one action is selected by the user for inclusion in at least one of the
plurality of protocols, respectively,

20 wherein for each of the respective protocols the at least one action is selected by the
user based on a value of the physiological parameter relative to the threshold, and

wherein the processor is configured to automatically identify and process a protocol
selected from the plurality of event protocols in response to receipt by the processing device of
a physiological parameter that meets the threshold established by the user.

25 2. The system of claim 1, further comprising a remote system in communication
with the processing device,

wherein the processing device includes a communication interface coupled to the
processor and configured to transmit a notification to the remote system during an execution of
30 the protocol.

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3. The system of claim 2, further comprising an event recording and reporting system in communication with the communication interface.

4. The system of claim 3, wherein the communication interface is configured to transmit the notification to the event recording and reporting system, and wherein the event recording and reporting system is configured to transmit the notification to a third party.

5. The system of claim 4, wherein the monitoring device includes a plurality of physiological sensors each configured to sense a different physiological condition of the user relative to others of the plurality of physiological sensors, wherein the memory is configured to store a plurality of thresholds, each threshold established for a different one or a different combination of physiological conditions relative to others of the plurality of thresholds.

6. The system of claim 5, wherein the processor is configured to automatically identify and process a first protocol of the plurality of event protocols in response to the at least one physiological parameter reaching a first value, and wherein the processor is configured to identify and process a second protocol of the plurality of protocols in response to the at least one physiological parameter reaching a second value that differs from the first value.

7. The system of claim 6, wherein the first protocol includes each of a local annunciation by the processing device to notify the user of the event sensed by the at least one physiological sensor and a communication of the notification to the third party.

8. The system of claim 7, wherein the third party includes an emergency responder.

9. The system of claim 8, wherein the second event protocol includes a request for the emergency responder to aid the user.

10. The system of claim 9, wherein the monitoring device includes a GPS, and wherein the second event protocol includes a communication of a location of the user to the emergency responder.

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11. The system of claim 7, wherein the processing device includes a mobile phone.

12. The system of claim 1, wherein the wireless transmitter and the wireless receiver employ Bluetooth communication.

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13. The system of claim 1, wherein the memory is configured to store a current configuration established by the user with the processing device including the at least one physiological parameter, the at least one event, the plurality of protocols associated with the event and the threshold established for the at least one physiological parameter.

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14. The system of claim 13, wherein the current configuration is a first configuration,
wherein the memory is configured to store a plurality of current configurations including the first configuration and a second configuration established by the user with the processing device.

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15. The system of claim 14, wherein the at least one physiological parameter includes a first physiological parameter, and
wherein the second configuration includes a second physiological parameter.

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16. The system of claim 15, wherein the at least one event is a first event, the plurality of protocols are a first plurality of protocols and the threshold includes a threshold established for the first physiological parameter,

wherein the second physiological parameter includes a different physiological parameter than the first physiological parameter; and

30

wherein the second configuration includes a second event that differs from the first event, a second plurality of protocols including at least one protocol that differs from protocols included in the first plurality of protocols and a threshold established for the second physiological parameter.

5

17. The system of claim 1, wherein the user interface includes a display configured to display the plurality of current configurations.

18. The system of claim 1, wherein the processing device includes a microcontroller
10 including the processor.

19. The system of claim 1, wherein the at least one physiological sensor includes a chip having a biomedical device included therein.

20. The system of claim 19, wherein the biomedical device includes a device for
15 analysis of bodily fluid of the user.

21. The system of claim 20, wherein the device is a non-intrusive biomedical
device.

20

22. The system of claim 19, wherein the biomedical device is included in a lab-on-a-chip.

23. A method employing a processing device and a monitoring device carried by a
25 user, the method comprising:

monitoring, by the monitoring device, at least one physiological parameter of the user;

receiving, by the processing device, data wirelessly transmitted by the monitoring device, the data including a value of the at least one physiological parameter;

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analyzing, by the processing device, the data using a decision tree stored in the processing device to determine whether an event has occurred based on at least one event threshold concerning the at least one physiological parameter; and

executing, by the processing device, at least one of a plurality of protocols in response to the event.

24. The method of claim 23, wherein the event, the at least one event threshold, and the plurality of protocols are defined in the decision tree.

25. The method of claim 23, further comprising analyzing, by the processing device, the received data for changes of the value of the at least one physiological parameter over time to determine whether the event has occurred based on the at least one event threshold.

26. The method of claim 23, further comprising configuring the at least one event threshold and the at least one of the plurality of protocols in response to an input of the user to the processing device.

27. The method of claim 26, further comprising configuring the at least one event threshold and the at least one of the plurality of protocols in response to an input of a third party to the processing device.

28. The method of claim 26, wherein the user changes configuration to reflect changed circumstances of the user.

29. The method of claim 28, wherein the changed circumstances include at least one of a change in activity, a change in location, a change in health status, and a change in medication.

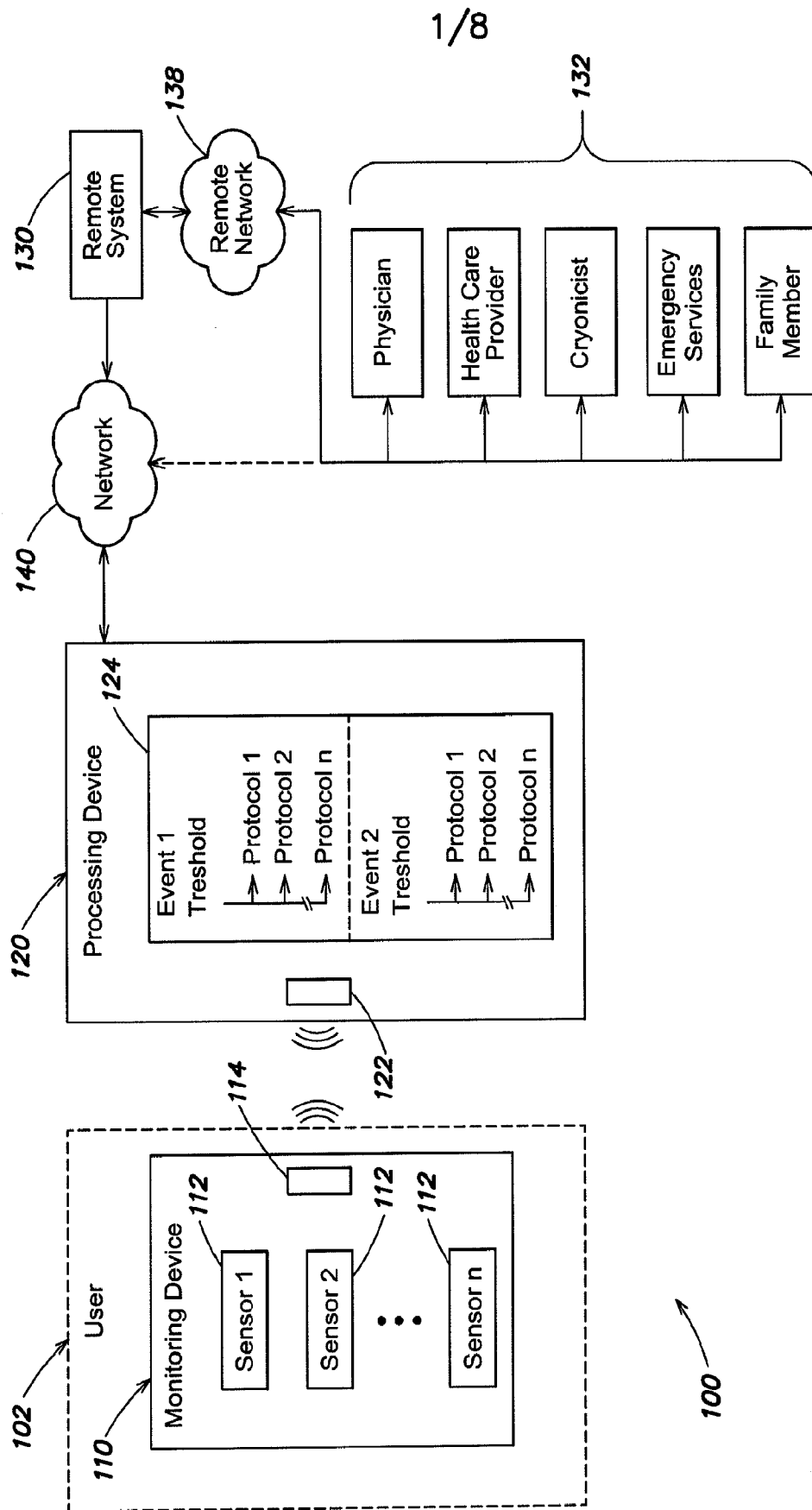


FIG. 1

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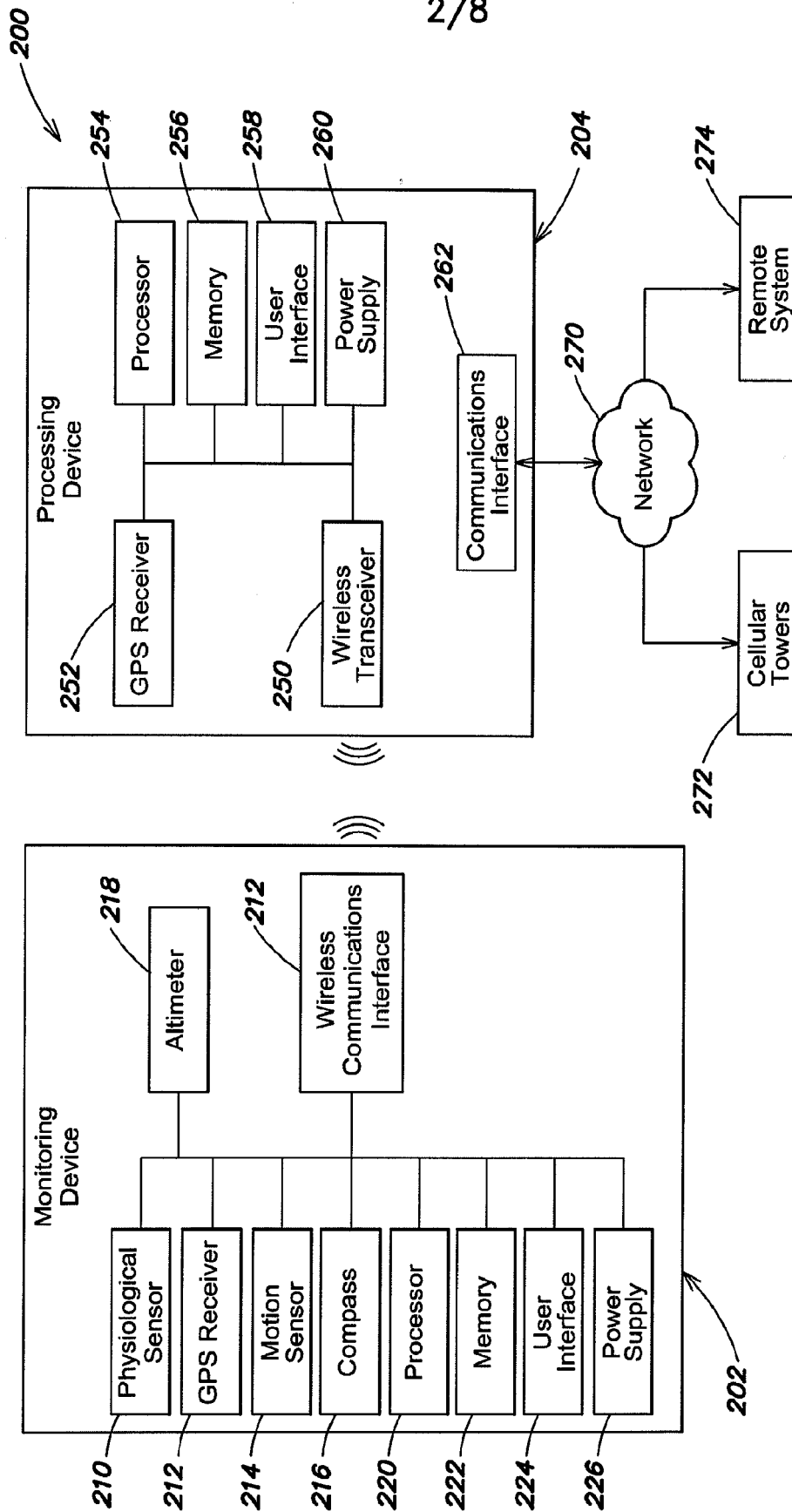


FIG. 2

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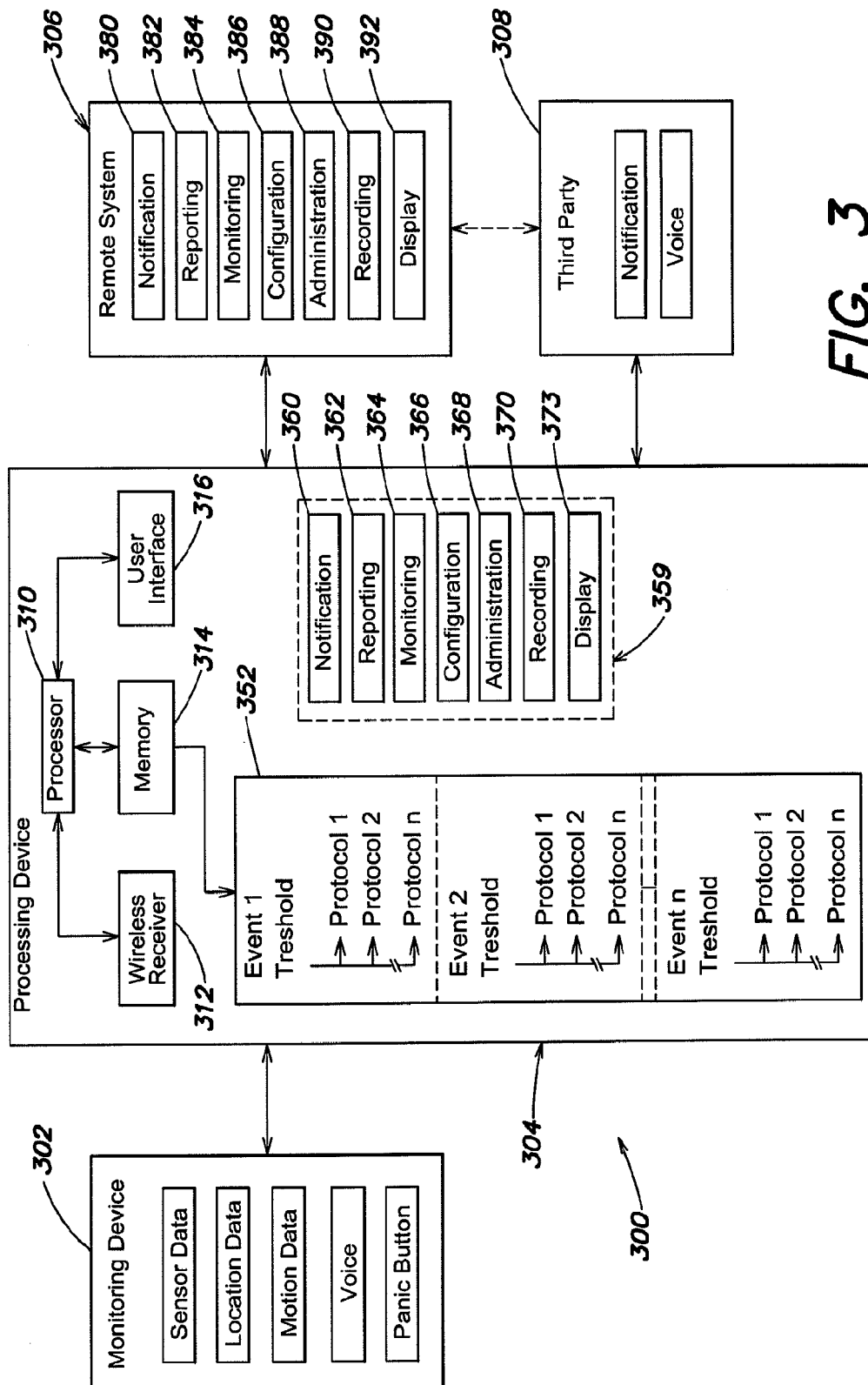


FIG. 3

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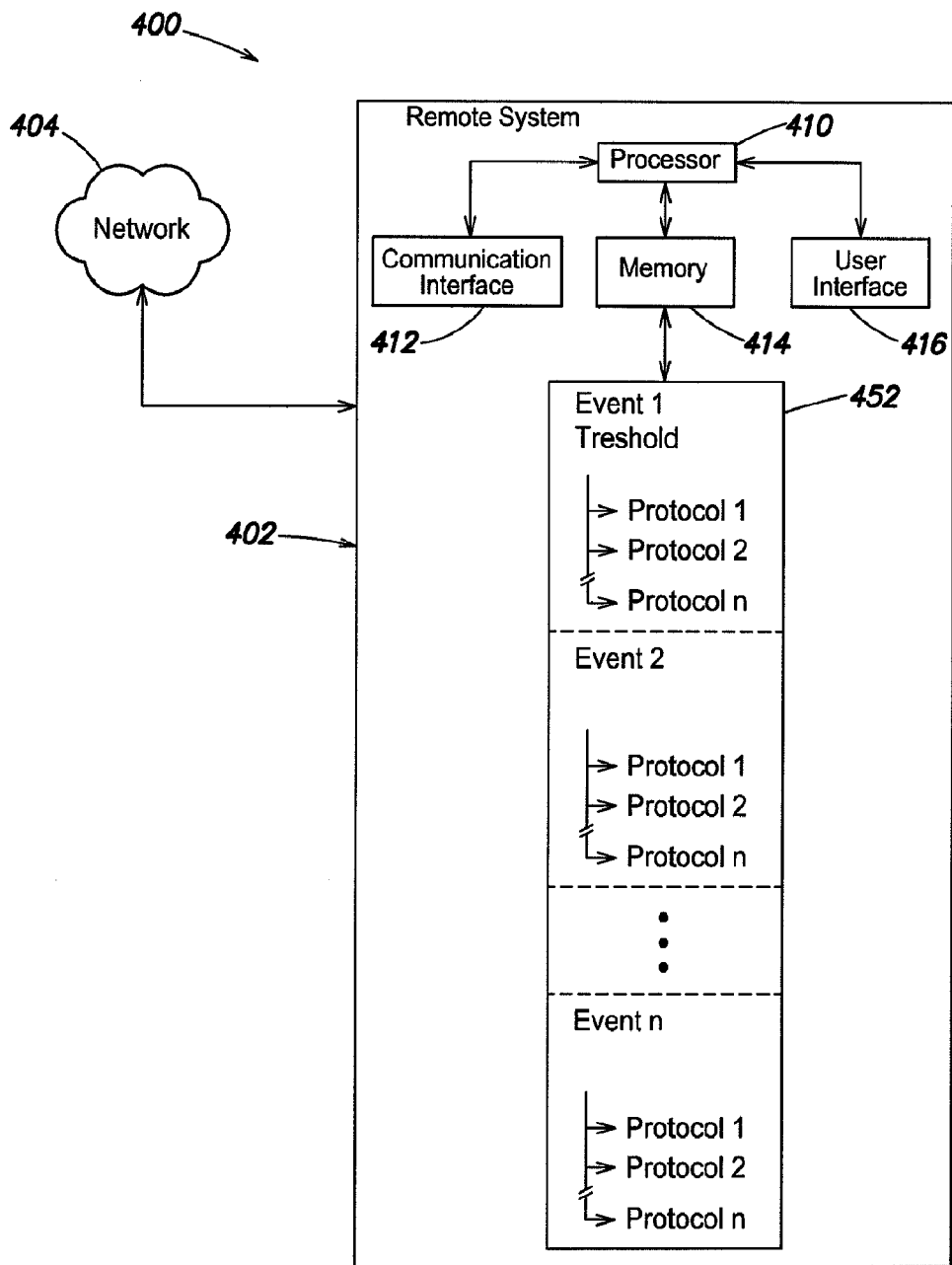
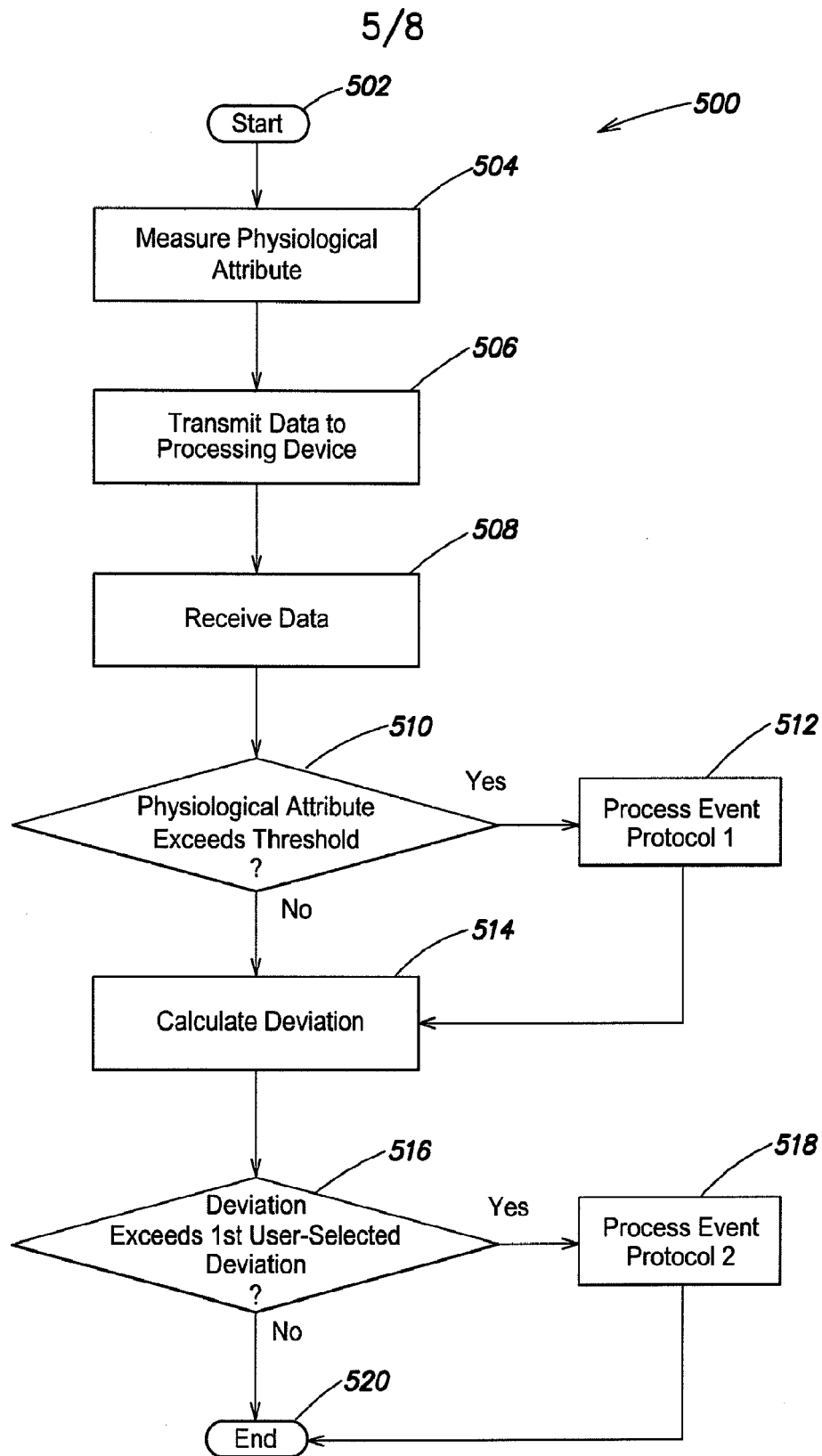


FIG. 4

**FIG. 5**

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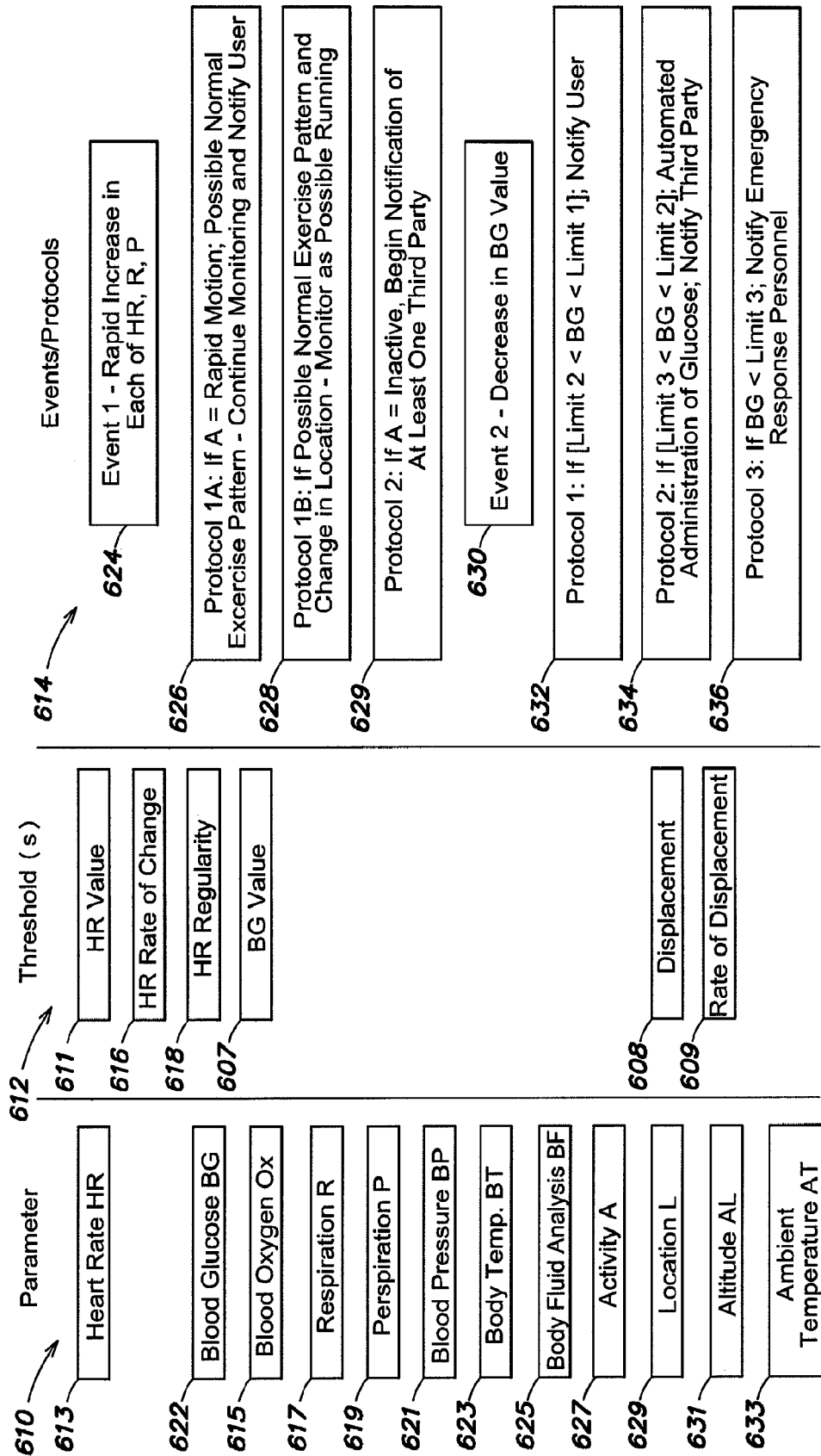


FIG. 6A

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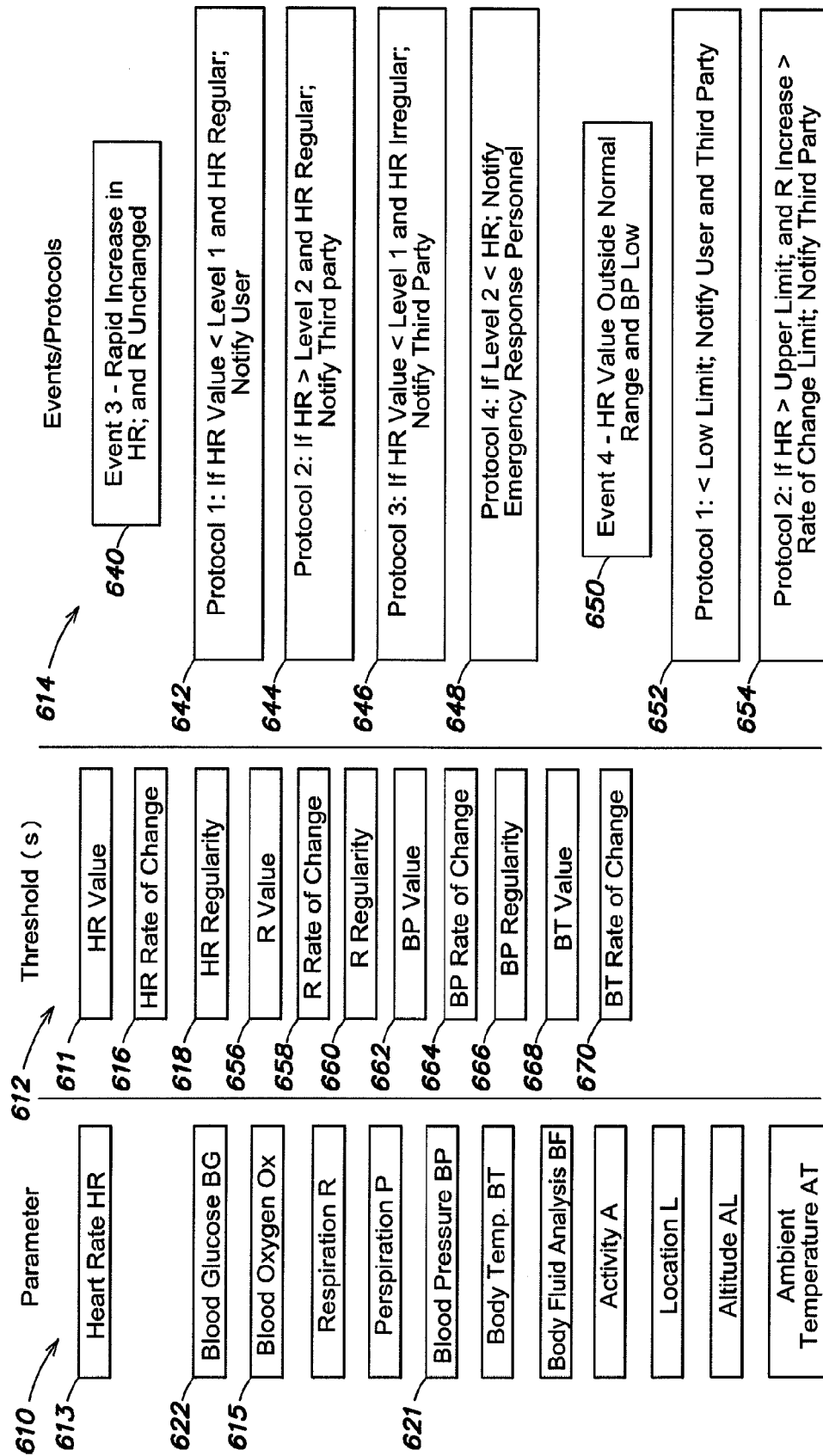


FIG. 6B

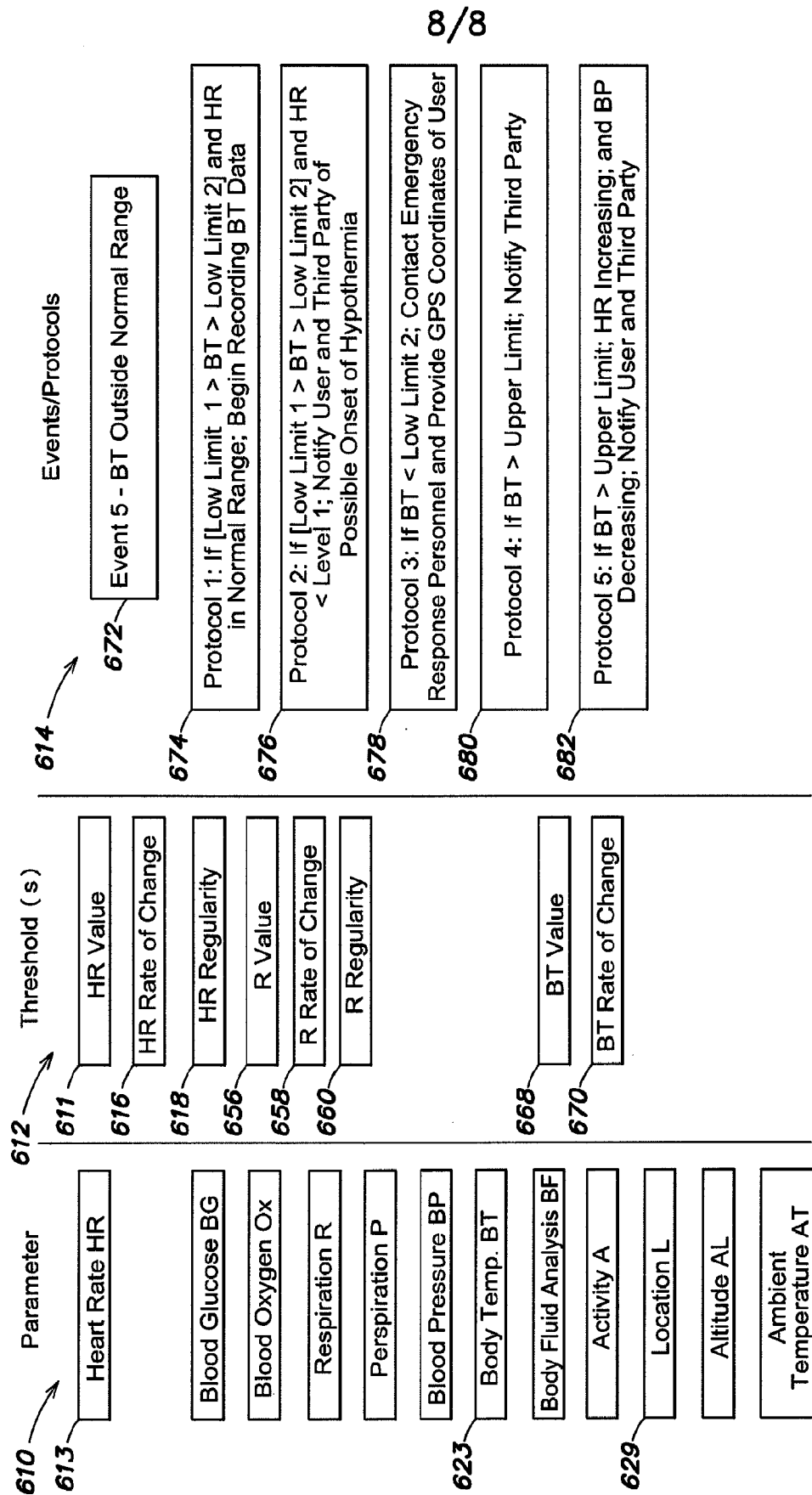


FIG. 6C

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/038043

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/00
ADD.

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)
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)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/300572 A1 (RANKERS ULRICH [US] ET AL) 4 December 2008 (2008-12-04) paragraphs [0005], [0037], [0038], [0040], [0044], [0048], [0069], [0085], [0147], [0149] figures 1-6,8-11,15,16,20	1-9, 11-29
X	WO 02/067122 A1 (MEDIK INC I [US]) 29 August 2002 (2002-08-29) page 7, lines 18-21 page 16, lines 19-25, 28-32 page 22, lines 10-13 page 23, line 6 page 24, lines 14-20 page 26, line 15 page 35, lines 7-12 figures 1-5 claims 5,6,82	1-29
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☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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Date of the actual completion of the international search

10 September 2010

Date of mailing of the international search report

29/09/2010

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	US 2005/250995 A1 (QUY ROGER J [US]) 10 November 2005 (2005-11-10) figures 1-8 -----	1-29
A	US 2008/318624 A1 (HEDTKE PAUL [US] ET AL) 25 December 2008 (2008-12-25) figures 1-11 -----	1-29

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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