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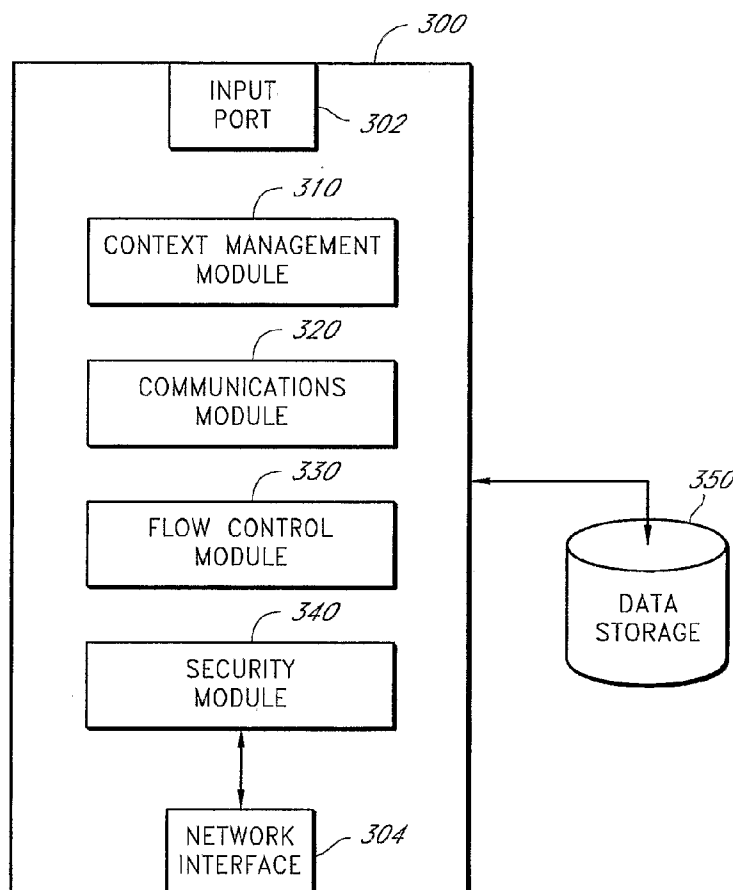
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(54) Title: PHYSIOLOGICAL ALARM NOTIFICATION SYSTEM



(57) Abstract: A method of context-based communication of physiological information over a network includes receiving physiological information, preparing a contextual data package, establishing a network connection, and communicating the contextual data package. The physiological information is received with a portable network interface module from at least one physiological monitor coupled to a single medical patient. The physiological information is related to a physiological condition of the medical patient, and the portable network interface module is exclusively assigned to the medical patient. The contextual data package is prepared with the portable network interface module. The contextual data package includes context information related to the medical patient and the physiological information. The network connection is established with a user over a network with the portable network interface module, and the portable network interface module manages the network connection with the user. The contextual data package is communicated to the user over the network with the network connection.



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PHYSIOLOGICAL ALARM NOTIFICATION SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority from U.S. Provisional Application No. 60/741,835 filed December 3, 2005, entitled "Physiologic Alarm Notification System," which is incorporated herein by reference. This application also claims priority from U.S. Provisional Application No. 60/756,241 filed January 3, 2006, entitled "Physiologic Alarm Notification System," which is also incorporated herein by reference.

BACKGROUND

Field of the Invention

[0002] This invention relates to a system, apparatus, and method for transmitting physiological information over a network. In certain embodiments, the invention relates to transmitting physiological information and patient context information to an end user over a shared network using a network interface module.

Description of the Related Art

[0003] Hospitals, nursing homes, and other patient care facilities typically include patient monitoring devices at one or more bedsides in the facility. Patient monitoring devices generally include sensors, processing equipment, and displays for obtaining and analyzing a medical patient's physiological parameters. Physiological parameters include, for example, respiratory rate, SpO₂ level, pulse, and blood pressure, among others. Clinicians, including doctors, nurses, and certain other medical personnel use the physiological parameters obtained from the medical patient to diagnose illnesses and to prescribe treatments. Clinicians also use the physiological parameters to monitor a patient during various clinical situations to determine whether to increase the level of medical care given to the patient.

[0004] Many patient monitoring devices provide an alarm function that triggers an alarm when certain physiological parameters exceed safe thresholds. Situations giving rise to an alarm might include, for example, decreased heart rate, respiratory rate, or low SpO₂ levels. Alarms enable clinicians to respond rapidly to possible life-threatening situations. Alarms may be audible, visual, or transmitted over a network to locations in a hospital where clinicians are not in direct view of a patient.

[0005] Various proprietary networks have been used in hospitals to aid clinicians in receiving alarms and other physiological information during normal (e.g., non-alarm) operation. One technique for transmitting alarms and physiological data throughout a hospital is to include a server or workstation at one or more central nurses' stations in the hospital. Physiological information from several patients may be observed at the server or workstation. However, this conventional central station paradigm does not adequately address the workflow models in hospital general care floors where nurse to patient ratios are often 1:6 or greater, where nurses have a lower skill set than ICUs, and where patients are often housed in private or semi-private rooms not in direct view of clinicians. Some systems are adapted to include clinician paging to enable secondary alarm notification to mobile health care personnel, but such systems still rely on a central station concept and therefore bear the cost for such components.

[0006] Many hospitals have their own unique proprietary network infrastructure. These networks generally include proprietary connectors, communications hardware, servers, and software. Both wired and wireless proprietary networks are used. For example, patients who are bed-ridden may be connected to a bedside device that is wired to the network. Ambulatory patients may wear a mobile monitoring device that uses radio frequency signals and telemetry techniques to transmit physiological information over the network.

[0007] There are also drawbacks to using proprietary networks for alarm notification. One drawback is that proprietary networks tend to be costly to obtain, setup, and maintain. Patient monitoring devices must be designed to interface with the proprietary network or special adaptors must be used. Specialized servers and server software must be obtained, and extensive training may be required to teach clinicians how to use unfamiliar interfaces. In addition, updating aging proprietary networks with newer, more standardized technology may require the design of new adaptors, software, and additional training. Another drawback is that proprietary networks may provide only limited amounts of data to remote devices due to physical limitations in legacy hardware and software.

[0008] Patient monitoring devices used in some proprietary networks include communications hardware within the device. Consequently, replacing or upgrading these patient monitoring devices simultaneously requires replacement of the communications hardware, which is cost-inefficient. In other systems, patient monitoring devices instead

connect to a docking station that contains communications hardware. However, these docking stations are often wired into a proprietary network and suffer the drawbacks attendant to such networks.

SUMMARY OF THE INVENTION

[0009] Various embodiments of the present invention include a method of context-based communication of physiological information over a network. The method includes receiving physiological information with a portable network interface module from at least one physiological monitor coupled to a single medical patient, wherein the physiological information is related to a physiological condition of the medical patient, and wherein the portable network interface module is exclusively assigned to the medical patient, preparing a contextual data package with the portable network interface module, wherein the contextual data package includes context information related to the medical patient and the physiological information, establishing a network connection with a user over a network with the portable network interface module, wherein the portable network interface module manages the network connection with the user, and communicating the contextual data package to the user over the network with the network connection.

[0010] In one embodiment, the network is a shared network. Communicating the contextual data package to the user over the network in one embodiment includes using communications protocols complying with open architecture communications standards.

[0011] In certain embodiments, the method also journals at least one of the following: 1) physiological information from the physiological monitor, 2) changes in the network connection, 3) changes in operation by the user, and 4) changes in system behavior. Journaling may also include operating within a transaction-based architecture.

[0012] Various implementations of the method also perform flow control. Flow control in some implementations includes storing the contextual data package in a flow control buffer with the portable network interface device, verifying with the portable network interface device that the contextual data package was received by the user, and resending the contextual data package stored in the flow control buffer with the portable network interface device, in the event that the user did not receive the contextual data package.

[0013] In one embodiment, the method receives the context information with the portable network interface module. The context information may include a portable

network interface module category, a medical patient category, a usage of the portable network interface module category, or a network connection category.

[0014] In another embodiment, a method of managing patient context in a patient monitoring system on an open communications architecture includes receiving clinical data with a portable communications module from at least one sensor coupled to a patient, wherein the clinical data is related to a physiological condition of the medical patient, and wherein the portable communications module is a bedside device, managing a patient context with the portable communications module, wherein the patient context includes context information related to the patient and the clinical data, establishing a network connection with a user over an open communications architecture with the portable communications module, wherein the portable communications module manages connectivity with the user, and communicating the patient context to the user over the open communications architecture with the network connection. In one embodiment, the context information includes patient name, patient identification number, patient location, or clinical data.

[0015] In still another embodiment, an apparatus for context-based communication of physiological information over a network includes a portable network interface module that is assigned exclusively to a medical patient and that receives physiological information from a sensor coupled to the medical patient. The portable network interface module includes a context management module that prepares a contextual data package, wherein the contextual data package includes context information related to the medical patient and the physiological information, and a network management module that establishes a network connection with a user over a network, that manages the network connection with the user, and that communicates the contextual data package to the user over the network. The network of various embodiments is a shared network. The portable network interface module may also be a web server.

[0016] In one embodiment, the context management module also receives the context information from a server. The portable network interface module may further include a flow control module that stores the contextual data package in a flow control buffer, verifies that the contextual data package was received by the user, and resends the contextual data package stored in the flow control buffer in the event that the user did not receive the contextual data package.

[0017] In various embodiments, the portable network interface module further includes a security management module that manages user authentication on the shared network. The network management module also communicates the contextual data package to the user in real time. The network management module also communicates historical physiological information to the user. The context information includes patient identification information and patient location information.

[0018] In various embodiments, a system for context-based communication of physiological information over a network includes a sensor that receives physiological information related to a physiological condition of a medical patient and that generates a signal based upon the physiological information, a sensor processing module coupled with the sensor that processes the signal, and a portable network interface module exclusively assigned to the medical patient and coupled with the sensor processing module, wherein the portable network interface module receives the physiological information from the sensor processing module. The portable network interface module includes a context management module that prepares a contextual data package, wherein the contextual data package includes context information related to the medical patient and the physiological information, and a network management module that establishes a network connection with a user over a network, that manages the network connection with the user, and that communicates the contextual data package to the user over the network. In one embodiment, the network is a shared network. In addition, the context information of certain embodiments includes a portable network interface module category, a medical patient category, a usage of the portable network interface module category, or a network connection category.

[0019] In certain embodiments, the system further includes a server coupled with the network that archives the contextual data package from the portable network interface module. The server also journals at least one of the following: 1) physiological information from the physiological monitor, 2) changes in the network connection, 3) changes in operation by the user, and 4) changes in system behavior. The server also acts as an interface between the network and an electronic medical records (EMR) system.

[0020] In certain embodiments, an apparatus for context-based communication of physiological information over a network includes means for receiving physiological information with a portable network interface module from at least one physiological monitor coupled to a single medical patient, wherein the physiological information is

related to a physiological condition of the medical patient, and wherein the portable network interface module is exclusively assigned to the medical patient, means for preparing a contextual data package with the portable network interface module, wherein the contextual data package includes context information related to the medical patient and the physiological information, means for establishing a network connection with a user over a network with the portable network interface module, wherein the portable network interface module manages the network connection with the user, and means for communicating the contextual data package to the user over the network with the network connection.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] FIG. 1 is an exemplary block diagram showing a physiological monitoring system according to an embodiment of the present invention;

[0022] FIG. 2 is an exemplary block diagram showing another embodiment of a physiological monitoring system;

[0023] FIG. 3 is an exemplary block diagram showing a network interface module according to an embodiment of the present invention;

[0024] FIG. 4 is an exemplary flowchart diagram showing a process for context-based communication of physiological information according to an embodiment of the present invention; and

[0025] FIG. 5 is an exemplary block diagram showing an alarm notification system according to an embodiment of the present invention.

DETAILED DESCRIPTION

[0026] Various embodiments according to the invention will be described hereinafter with reference to the accompanying drawings. These embodiments are illustrated and described by example only, and are not intended to limit the scope of the invention.

[0027] In various embodiments, physiological monitoring systems are systems that monitor physiological signals generated by a medical patient and process the signals to determine any of a variety of physiological parameters of the patient. For example, in some cases, a physiological monitoring system can determine any of a variety of physiological parameters of a patient, including respiratory rate, inspiratory time,

expiratory time, i:e ratio (e.g., inspiration-to-expiration ratio), inspiratory flow, expiratory flow, tidal volume, minute volume, apnea duration, breath sounds, rales, rhonchi, stridor, and changes in breath sounds such as decreased volume or change in airflow. In addition, in some cases the physiological monitoring system monitors other physiological sounds, such as heart rate to help with probe-off detection, heart sounds (e.g., S1, S2, S3, S4, and murmurs), and changes in heart sounds such as normal to murmur or split heart sounds indicating fluid overload. Moreover, the physiological monitoring system may use a second probe over the chest for better heart sound detection, keep the user inputs to a minimum (for example, only input height), and use a Health Level 7 (HL7) interface to automatically input demography.

[0028] A physiological monitoring system of certain embodiments includes one or more patient monitoring devices connected to a shared network using open architecture communications standards. The patient monitoring devices of certain embodiments include a physiological monitor coupled with a network interface module. The physiological monitor includes one or more sensors and a sensor processing module for processing signals from the sensors. The network interface module receives physiological information from the sensor processing module and transmits this information over the shared network. The network interface module may connect to a variety of physiological monitors. In addition, the network interface module of various implementations is a portable bedside device assigned exclusively to one medical patient.

[0029] In certain embodiments, the network interface module facilitates establishing a network connection directly with end users over the shared network. These end users, including doctors, nurses, and other hospital staff, may receive physiological information, alarms, and alerts from the network interface module on an electronic device, such as a pager, PDA, laptop, computer, computer on wheels (COW), or the like.

[0030] Referring to FIG. 1, certain embodiments of a physiological monitoring system 100 (e.g., alarm notification system) include an open network architecture using “off-the-shelf” hardware and communication protocols. This architecture in various implementations is a shared, or open, network includes multiple patient monitoring devices 110, a network bus 120 (e.g., an Ethernet backbone), and a hospital WLAN 126. In addition, the shared network may further include a connection 122 to the Internet 150, to end user devices 152 over the Internet 150, and to end user devices 152 over the hospital WLAN 126. The physiological monitoring system 100 of

certain embodiments is therefore an enterprise system that achieves a cost-effective replacement for currently available patient monitoring systems.

[0031] The physiological monitoring system 100 includes a plurality of bedside devices, e.g., patient monitoring devices 110. The patient monitoring devices 110 of various embodiments include sensors 102, one or more sensor processing modules 104, and a communications module, e.g., network interface module 106. In the depicted embodiment, two patient monitoring devices 110 are shown. One patient monitoring device includes one set of sensors 102, one sensor processing module 104, and one network interface module 106. The other patient monitoring device 110 includes two sets of sensors 102, two sensor processing modules 106, and one network interface module 106.

[0032] In certain embodiments, each patient monitoring device 110 is used by one medical patient. The patient monitoring devices 110 form a network of patient monitoring devices 110, each of which can communicate with clinicians and other end users over a shared network, including a hospital network 126 and network interfaces to the Internet 150.

[0033] One or more sensors 102 of the patient monitoring device 110 are attached to a medical patient. These sensors 102 may include ECG sensors, acoustic sensors, pulse oximeters, and other types of sensors. The sensors 102 obtain physiological information from a medical patient and transmit this information to the sensor processing module 104 through cables 103 or through a wireless connection (not shown). In certain embodiments, the physiological information includes one or more physiological parameters or values and waveforms corresponding to the physiological parameters.

[0034] The sensor processing module 104 receives physiological information from the sensors 102. The sensor processing module 104 of certain embodiments includes a circuit having a processor, input ports for receiving the physiological information, software for processing the physiological information in the processor, an optional display, and optionally an input device (e.g., a keyboard). In addition, the sensor processing module 104 contains one or more output ports, such as serial ports. For example, an RS232, RS423, or autobaud RS232 (serial interface standard) port or a universal serial bus (USB) port may be included in the sensor processing module 104.

[0035] In certain embodiments, the sensor processing module 104 generates waveforms from signals received from the sensors 102. The sensor processing module

104 may also analyze single or multiparameter trends to provide early warning alerts to clinicians prior to an alarm event. In addition, the sensor processing module 104 in certain embodiments generates alarms in response to physiological parameters exceeding certain safe thresholds.

[0036] Example alerts include no communication with pulse oximeter, alarm silenced on pulse oximeter, instrument low battery (pulse oximeter), and transmitter low battery. Example alarms include SpO₂ levels and alarms, high and low SpO₂, high and low PR, HbCO level and alarms, HbMET level and alarms, pulse rate and alarms, no sensor, sensor off patient, sensor error, low perfusion index, low signal quality, HbCO, HbMET, PI trend alarm, and desat index alarm.

[0037] The network interface module 106 in the depicted embodiment is connected to one or more sensor processing modules 104 through one or more connectors 108, which may be serial connectors corresponding to the serial ports in the sensor processing modules 104. Dashed lines on the connector 108 indicate that the network interface module 106 of certain embodiments is not permanently attached to the sensor processing modules 104. In alternative embodiments (not shown), however, the network interface module 106 is contained within a sensor processing module 104.

[0038] The network interface module 106 in various implementations includes a processor, an input port (such as a standard RS232 serial port), a network output port such as an Ethernet port, and software which enables the network interface module 106 to act as a network-communications enabled device. In addition, the network interface module 106 includes a storage device 114, which may be included within the network interface module 106 or attached separately to the network interface module 106.

[0039] The network interface module 106 manages the connectivity overhead for initiating and maintain connectivity with end user devices over the shared network. In certain embodiments, the network interface module 106 manages connectivity by acting as a microserver or web server. In such instances, the network interface module 106 is a network connection enabled device. As a web server, the network interface module 106 establishes direct connections to the Internet 150, such that an end user may access web pages stored on the storage device 104 of the network interface module 106. In one embodiment, the network interface module 106 therefore does not require a separate server for connecting to the Internet 150. In one embodiment, the network interface module 106 connects to the Internet 150 directly through a modem, such that the

connection 122 includes a modem. In managing connectivity over the shared network, the network interface module 106 may also perform security management functions, such as user authentication.

[0040] In certain embodiments, the network interface module 106 sends data over the shared network through an access point 124 or other wireless or wired transmitter. Alternatively, the network interface module 106 may communicate physiological information directly to end users over the Internet 150. End users such as clinicians carrying notifier devices, e.g., end user devices 128, 152 connected to the hospital WLAN 126 may receive real-time viewing of physiological patient parameters and waveforms on demand or in the event of an alarm or alert. Real-time or slightly delayed transmission of physiological information in certain embodiments comports with standards for alarm latency in compliance with Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards for effective alarm response. The network interface module 106 of certain embodiments therefore adds functionality equivalent to a central nurses' station.

[0041] In certain embodiments, the network interface module 106 performs context management. In one embodiment, context management includes associating context information with physiological information to form a contextual data package. Context information may include several categories of information, including the categories of context information related to the network interface module 106, context information related to the medical patient, context information related to usage of the network interface module 106, and context information related to a network connection. Within one or more of these context categories, context information might include a patient name, a patients' unique hospital identification number, patient location, an identification number for a network interface module 106, time stamps for events occurring in the physiological monitoring system 100, environmental conditions such as changes to the state of the network and usage statistics of the network interface module 106, and identification information corresponding to the network link (e.g., whether the network connection is WiFi or Ethernet). In one embodiment, the context information in the contextual data package may include all of or any subset of context information from one or more of the context categories.

[0042] The network interface module 106 receives context information, for example, by a nurse entering the information in the network interface module 106 or from

a server 136. In one embodiment, by receiving this information (including, e.g., patient identification number and location), the network interface module 106 becomes exclusively assigned to the medical patient. The network interface module 106 transmits or communicates the contextual data package to clinicians during an alarm or alert, upon clinician request, or on a scheduled basis. In addition, the network interface module 106 may transmit a continuous stream of physiological information to clinicians.

[0043] By optionally connecting to multiple sensor processing modules 104 in certain embodiments, the network interface module 106 is able to associate patient context information and other context information with multiple sensor processing modules 104. Consequently, context can be created for one or more sensor processing modules 104 in addition to context being created for the network interface module 106.

[0044] In addition to transmitting the contextual data package, the network interface module 106 in one embodiment stores the contextual data package in the storage device 114. The storage device 114 may be a flash memory, a hard disk drive, or other form of non-volatile or volatile memory. In certain embodiments the storage device 114 acts as a flow control buffer. The network interface module 106 uses the storage device 114 acting as a flow control buffer to perform flow control during communications, as explained more fully below in connection with FIG. 3.

[0045] In some implementations, a server 136 may optionally be included in the physiological monitoring system 100. The server 136 in these implementations is generally a computing device such as a blade server or the like. In certain embodiments, the server 136 is an appliance server housed in a data closet. In other embodiments, the server 136 is a server located at a central nurses' station, such as a workstation server.

[0046] The server 136 receives contextual data packages from a plurality of network interface modules 106 and stores the contextual data package in a storage device 138. In certain embodiments, this storage device 138 therefore archives long-term patient data. This patient data may be maintained even after the patient is discharged. In storing patient data, the server 136 may act as an interface between the shared network and an external electronic medical record (EMR) system.

[0047] The server 136 may also store data concerning user interactions with the system and system performance metrics. Integrated into the server 136 of certain embodiments is a journal database that stores every alert and alarm or a subset of the alerts and alarms as well as human interaction in much the same way as an aviation "black

box” records cockpit activity. The journal is not normally accessible to the clinical end user and, without technical authorization, cannot be tampered with. In addition, the server 136 may perform internal journaling of system performance metrics such as overall system uptime.

[0048] In one embodiment, the journaling function of the server 136 constitutes a transaction-based architecture. Certain transactions of the physiological monitoring system 100 are journaled such that a timeline of recorded events may later be reconstructed to evaluate the quality of healthcare given. These transactions include state changes relating to physiological information from the patient monitoring devices 100, to the patient monitoring devices 110, to the hospital WLAN 126 connection, to user operation, and to system behavior. Journaling related to the physiological information received from a physiological monitor in one embodiment includes recording the physiological information itself, recording changes in the physiological information, or both.

[0049] The server 136 in certain embodiments provides logic and management tools to maintain connectivity between network interface modules 106, clinician notification devices such as PDAs and pagers, and external systems such as EMRs. The server 136 of certain embodiments also provides a web based interface to allow installation (provisioning) of software related to the physiological monitoring system 100, adding new devices to the system, assigning notifiers (e.g., PDAs, pagers, and the like) to individual clinicians for alarm notification at beginning and end of shift, escalation algorithms in cases where a primary caregiver does not respond to an alarm, interfaces to provide management reporting on the alarm occurrence and response time, location management, and internal journaling of system performance metrics such as overall system uptime (see, e.g., FIG. 5 and accompanying description).

[0050] The server 136 in certain embodiments also provides a platform for advanced rules engines and signal processing algorithms that provide early alerts in anticipation of a clinical alarm. The operating system on the server 136 in one embodiment is Linux-based for cost reasons, though a Microsoft-based or other operating system may also be used. Moreover, the server 136 is expandable to include data storage devices and system redundancy capabilities such as RAID (random array of independent disks) and High Availability options.

[0051] In another embodiment (not shown), end user devices 128, 152 include one way POCSAG Pagers having a 2 line display with audible and vibrate mode, of suitable size and durability for severe mechanical environments typical of hospital general floor settings. In yet another embodiment, the end user devices 128, 152 include two way paging systems, such as Motorola Flex and WLAN pagers. One advantage of two-way paging is the ability to confirm message receipt and the ability to remotely silence alarms. Wireless PDAs may also be used by end users based on ruggedness and acceptable form factors as determined by an end user. An example of such a device is the Symbol Technology MC50 PDA / Barcode Scanner.

[0052] FIG. 2 depicts another embodiment of the physiological monitoring system 200 of the present invention. The physiological monitoring system 200 includes network communications enabled devices 210. The network communications enabled devices 210 are connected directly to a hospital network 220 through a wireless connection. In certain embodiments, the network communications enabled devices 210 include sensors and sensor processing modules, similar to the sensors 102 and sensor processing modules 104 of FIG. 1. Certain of these network communications enabled devices 210 are bedside devices, and others are handheld or otherwise patient-worn devices that may be used by an ambulatory (mobile) patient.

[0053] The hospital network 220 transmits physiological information and context information to clinician notifier devices, including pagers 240, PDAs 230, and the like. In certain embodiments, the hospital network 220 utilizes a server 250 to transmit contextual data packages to a page transmitter 242, which further transmits the data to one-way wireless pagers 240. An external interface 280 may be coupled with the server 250. The external interface 280 could include one or more of the following: enterprise paging, nurse call systems, wide area paging systems, enterprise clinical and patient information systems, and third party monitoring and surveillance systems.

[0054] Certain other devices 260, such as some patient monitoring equipment, are not network communications enabled devices. That is, these other devices 260 are unable to connect to a network unaided. In the depicted physiological monitoring system 200, example devices 260 that are not network communications enabled are connected to a network interface module 270. The network interface module 270 is connected to the non-network communication enabled other devices 260 through RS232 cables 264. Such a connection is a standardized serial connection found on many devices. Because the

network interface module 270 has an RS232 port, the network interface module 270 can allow non-network communication enabled patient monitoring devices to connect directly to the hospital network 220 and also to the Internet.

[0055] Moreover, by connecting to one or more other devices 260 in some embodiments, the network interface module 270 is able to associate patient context information and other context information with one or more other devices 260. Consequently, context can be created for one or more other devices 260 in addition to context being created for the network interface module 270.

[0056] FIG. 3 depicts a network interface module 300 in accordance with certain embodiments of the present invention. The network interface module 300 in the depicted embodiment includes an input port 302, which in certain embodiments is a serial port for facilitating a connection to a sensor processing module. The network interface module 300 also includes a network interface 304, which may be a wired interface (e.g., Ethernet) or a wireless interface such as WiFi, Bluetooth, or the like. Alternatively, the network interface module 104 may communicate through a cable TV interface or other type of interface. Such a CTV interface provides a subcarrier bi-directional communications capability that would simultaneously co-exist with video formats.

[0057] The network interface module 300 also communicates with a storage device 350. While in the depicted embodiment the storage device 350 is shown as separate from the network interface module 300, in some implementations the storage device 350 is part of the network interface module 300. In addition, though not shown, the network interface module 300 may include a processor for implementing communications program code. Similarly, though not shown, the network interface module 300 may include an input device for a nurse to input context information and a display for receiving output from the network interface module 300.

[0058] The network interface module 300 can be integrated into handheld, portable or stationary patient monitoring platforms or instruments or contained in an accessory package with an RS 232 input for general interface to such devices. In another embodiment, (not shown) active RFID tag capabilities are included with the network interface module 106, with the clinician devices (e.g., notifier devices), or with both so that either a patient or a clinician can be located when an event occurs or on request. When operating on a shared network, the network interface module 106 is also compliant with to the open architecture communications standards of IEEE 802.1X (security and

authorization), IEEE 802.3 (Ethernet), and WiFi (IEEE 802.11 a, b, g, e, i wireless protocols).

[0059] A context management module 310 in the network interface module 300 manages context data. In one embodiment, the context management module 310 receives context information, such as the context information described in connection with FIG. 1 above. In one embodiment, a nurse or other clinician enters context information, such as patient name, identification number, and location, into the network interface module 300 via a keyboard or other input device (not shown) when the patient is admitted to the hospital or assigned a particular bed in the hospital. In other embodiments, the context management module 310 receives the context information from a server, such as the server 136 of FIG. 1.

[0060] The context management module 310 associates the context information with physiological information received from a sensor processing module. In certain embodiments, the context management module 310 performs this association when an alarm condition occurs. In such instances, the context management module 310 may create a contextual data package including a snapshot of historical physiological information together with the context information. In other embodiments, the context management module 310 performs an association continuously, and the network interface module 300 sends continuous or scheduled contextual data packages to end users. In addition, the context management module 310 or other modules in the network interface module 300 store the contextual data package in the storage device 350.

[0061] The communications module 320 uses the network interface 304 to communicate with a network. In certain embodiments, the communications module 320 possesses the functionality of a web server. As a web server, the communications module 320 enables the network interface module 300 to communicate with a hospital network and the Internet directly, without using a server. Consequently, other devices such as physiological monitoring devices that are not network connection enabled may connect with the network interface module and thereby become network enabled. The network interface module 300 manages the connectivity overhead for initiating and maintaining connectivity, manages context information (e.g., any of the context information described above in connection with FIG. 1), and provides a web server for displaying patient information on web-enabled devices. In one embodiment, a communications protocol based on XML technologies allows bedside devices to interface to a multitude of target

end user platforms including PDAs, computer on wheels (COW), Tablet PCs, IP cell phones (smartphones), and fixed PCs.

[0062] In certain embodiments, the communications module 320 uses standard communications protocols to communicate with a network. Some examples of standard communications protocols include Ethernet, WiFi (WLAN), Bluetooth, and the like. By using standard communications protocols, the communications module 320 is able to send and receive data over a shared network or open network architecture. However, the communications module 320 may also be used on a proprietary network using proprietary protocols.

[0063] In embodiments where the network interface module 300 communicates over a shared network rather than a proprietary network, the network interface module 300 shares network resources with other devices on the network. In some cases, high-volume network traffic affects the reliability of network communications. Consequently, certain implementations of the network interface module 300 include a flow control module 330. The flow control module 330 verifies that transmitted data was received by an end user. In the event that the end user did not receive the data, the flow control module 330 resends the data stored in the storage device 350. In certain embodiments, the storage device 350 therefore acts as a flow control buffer.

[0064] A security module 340 manages user access to the network interface device 300 and to data stored in the storage device 350. In certain embodiments, the security module 340 determines whether a user attempting to connect to the network interface module 300 is authorized to do so. In one implementation, the security module 340 uses the standard IEEE.802.1X network access control protocol to manage authentication. The network interface module 106 in certain embodiments provides security and encryption to meet the Health Insurance Portability and Accountability Act (HIPAA) requirements.

[0065] In certain embodiments, the network interface module 300 incorporates all or a portion of the functionality specified by the IEEE 1073 standard and the most recent update to the IEEE 1073 standard, namely the IEEE 11703 standard, both of which are hereby incorporated by reference. In certain embodiments, the context management module 310, the communications module 320, the flow control module 330, and the security module 340 also incorporate functionality specified in the IEEE 1073 and 11703

standards. By using standard protocols, the network interface module 300 may be used to enable network communication for a wide variety of physiological monitoring devices.

[0066] FIG. 4 depicts a process 400 for context-based communication of physiological information according to an embodiment of the present invention. In certain embodiments, the process 400 is performed by any of the network interface modules described above in connection with FIGs. 1-3. In addition, the process 400 in certain embodiments may be performed by any of the physiological monitoring systems described in connection with FIGs. 1, 2, and 5.

[0067] The process 400 begins by receiving context information at 402. In one embodiment, a device such as a network interface module receives the context information once, such as in an initialization step. The process 400 then receives physiological information at 404. In certain embodiments, the process 400 continues to receive physiological information throughout the remaining steps of the process 400. Alternatively, the process 400 may receive physiological information 400 for a portion of the process 400.

[0068] At 405, the process 400 determines whether an alarm condition or alert has occurred. If an alarm condition or alert has occurred, the process 400 proceeds to 406. However, if an alarm condition or alert has not occurred, the process 400 loops back to 404. In one embodiment, the looping back of the process 400 to 404 represents that a network interface module continually receives physiological information until an alarm condition or alert occurs. In certain embodiments (not shown), the process 400 may continue to receive physiological information even when an alarm condition or alert occurs.

[0069] At 406 the process 400 prepares a contextual data package. The contextual data package may include context information and a snapshot of physiological information. In one embodiment, the snapshot of physiological information includes the physiological information that gave rise to an alarm or alert. In one embodiment, the snapshot of physiological information includes information both before and after the occurrence of an alarm or alert. The contextual data package is stored in a flow control buffer at 408.

[0070] At 410, the process 400 establishes a network connection. In one embodiment, establishing a network connection at 410 includes connecting a network interface module to an end user device, such as a notifier device assigned to a nurse

during his or her work shift. The process 400 then determines at 412 whether the user of the device (e.g., the nurse) has been authenticated. If the user has not been authenticated, the process 400 proceeds to 420. On the other hand, if the user has been authenticated, the process 400 proceeds to 414.

[0071] The process 400 at 414 communicates the contextual data package to the user. At 416, the process 400 determines whether the contextual data package was received. If the contextual data package was received, the process 400 proceeds to 420. Otherwise, the process 400 proceeds to 418, where the process 400 accesses data stored in the flow control buffer. In one embodiment, the data accessed by the process 400 is equivalent to or substantially equivalent to the contextual data package communicated to the user at 414.

[0072] The process 400 then loops back to 414, where the process 400 communicates (e.g., resends) the contextual data package to the user, and then at 416 re-verifies that the package was received. The process 400 in some implementations continues to loop between steps 414, 416, and 418 until the contextual data package was received. Thus, steps 414, 416, and 418 in certain embodiments constitute flow control performed by the process 400. These flow control steps allow the process 400 to overcome network transmission errors which may occur in shared networks.

[0073] If the contextual data package was received, the process 400 evaluates whether to continue the monitoring of physiological information at 420. If the process 400 determines to continue monitoring, the process loops back to 404, where the process 400 continues to receive physiological information. If, however, the process 400 determines not to continue monitoring, the process 400 ends.

[0074] In various embodiments of the process 400, the contextual data package or the physiological information alone is transmitted to the user even in the absence of an alarm condition. In still other embodiments, fewer than all of the steps are performed, or the steps are performed in different order. For instance, the process 400 may only perform the steps of receiving physiological information at 404, preparing a contextual data package at 406, establishing a network connection at 410, and communicating the contextual data package to the user at 414.

[0075] FIG. 5 depicts an alarm notification system 500 in accordance with certain embodiments of the present invention. A clinical subsystem 510 defines the major software components of alarm notification system 500 including a clinical assignment

module 512, a bedside device initialization module 514, a notification and viewing module 516, an escalation rules module 518, a clinical report module 520, and a clinical data stores module 522. An authentication feature is built into mobile computing devices in compliance with HIPAA and hospital IT policies.

[0076] The clinical assignment module 512 has an assignment function. A nursing supervisor assigns individual nurses to specific patients at the start of each shift and upon admission of new patients. Shift assignments take place at change of shift during a “report” transition exercise where individual nurses and nursing supervisor from previous shift “hand off” patients to the next shift. The report can be either formal where all nurses attend or informal dependent on hospital nursing service policies and procedures. The clinical assignment module 512 provides an intuitive interface that allows a listing of available nurses to be assigned individual patients. The major user of this module is the unit clerk as assigned by the nursing supervisor. A nurse can be assigned one or more patients or all patients. An alternative work flow is self assignment where individual nurses assign patients themselves in which case they perform functions of the unit clerk. In the self assignment model, a default is implemented where any unassigned patient is either assigned to all nurses or the nursing supervisor.

[0077] The bedside device initialization module 514 has bedside devices, such as the network interface modules described above, that are sometimes set up by an aide to the nurse. In the case where the nurse performs this task, she or he performs the functions of the nursing aide. Work flow includes delivering a device to bedside, applying sensors, initializing the device, and setting patient context, such as name, ID and location.

[0078] The notification and viewing module 516 assigns a wireless notification device, such as a one-way pager, PDA, IP telephone, COW, or Tablet to individual nurses. The device becomes associated with her or him. Alarms are routed to the notification device based on the clinical assignment module 512. Non-dedicated notifier solutions such as hospital owned paging systems issued to nurses have unknown latency characteristics. A general purpose interface is available at the server with a latency of less than 1 second upon receipt from the bedside device and is time stamped upon presentation to the server external interface and stored in a journaling system within the server. An additional interface for mobile computing platforms such as PDA, COWS, and Tablets allows viewing of current and trend data for an individual patient.

[0079] The escalation rules module 518 has a rules engine that actuates an escalation policy defined by the hospital. The escalation rules module 518 provides alternative routing of alarms to alternative and additional clinical users in the event an alarm is not responded to or persists for a predefined (e.g., by a policy) period of time. The escalation rules module 518 in certain embodiments routes alarms to an emergency response team.

[0080] The clinical report module 520 provides predefined formatted reports on the clinical data from which to determine physiologic condition and/or progress. More than one report may be dependent on end user needs. Reports are not time critical views of individual patients and may be remotely viewed by clinicians who have alarm notification system 500 privileges and have been authenticated by the alarm notification system 500. These reports are web browser views that allow clinicians to set viewing parameters such as time and parameter scales and alarm review.

[0081] The clinical data stores module 522 provides data storage and database resources to store information as known to those skilled in the art.

[0082] Further shown in FIG. 5, a technical support subsystem 530 is isolated from the clinical subsystem 510 in compliance with HIPAA and as such does not allow viewing or access to any patient information with the exception of the risk report module 538. The technical support subsystem 530 includes a provisioning module 532, an administration module, a service module 536, a risk report module 538, and a technical data store module 540.

[0083] The provisioning module 532 provides provisioning, which is the initial installation of the system and first customer use. The primary user of the provisioning module 532 is the field installer. The provisioning module 532 contains all the start up scripts and system configurations to bring the system from shipping boxes to full alarm notification system 500 functionality. Provisioning includes steps to configure individual devices, notifiers such as pagers, PDA, COW, Tables and IP telephone at the customer site, preferably by wireless means (e.g., Bluetooth).

[0084] The administrative module 534 provides a system interface for the application administrator to set up users, set policies for various actor privileges such as a nurses aide being able to set or change alarms, set up allowed device connection identifications, and other general systems administrative duties typical of IT systems.

[0085] The service module 536 provides interfaces for various technical support actors including remote service, IT Service, and Biomed Service. Each of these actors may perform each others' functions. Interfaces allow the service actors to access system performance data to access performance, for example, data traffic, device assets connected, software version management, CPU loading, network loading, etc. and execute remote technical service procedures, for example, resetting a printer queue, repartition of disk, uploading software patches, etc. The service module 536 includes a full journaling function that stores every user interaction or a portion of user actions that can be captured by the system, especially changes in default values or alarm settings.

[0086] The risk report module 538 provides summary reports on alarm occurrences, duration of alarm, clinical response time to alarms and other statistical data to determine overall effectiveness of clinical response to alarms in compliance with JCAHO, other regulatory bodies, and internal quality assurance committees.

[0087] The technical data stores module 540 has the same characteristics as the clinical data stores module 522 except that the technical data stores module 540 is used for technical data. The technical data stores module 540 may or may not share the same physical and logical entity as the clinical data stores module 522.

[0088] Additionally shown in FIG. 5, an external interface subsystem 550 provides interfaces to bedside devices and external systems such as electronic medical records, admit/discharge, transfer systems, POCSAG pager systems, middleware engines such as Emergin, and Web/XML enabled devices such as wireless PDAs, COWs and Tablet PCs. The external interface subsystem 550 has an HL7 interface 552, a pager interface 554, an XML/Web interface 556, and a device interface 558.

[0089] The HL7 interface 552 provides a bi-directional interface to electronic medical records (EMR) and supports both push and pull models. The push model is when a bedside nurse initiates data transfer. The pull model is when an EMR system polls the alarm notification system 500 server. The pager interface 554 provides output to external paging system. Message latency is identified to an end user for any user-owned paging solution. This same output can be used for middleware alarm notification systems such as Emergin. The XML/Web interface 556 provides bi-directional interface with mobile computing platforms such as wireless PDA, COWs, Tables, and Web-enabled IP phones. Mobile computing platforms support Web Browser XML applications. The device interface 558 provides a bi-directional interface to bedside devices as well as to other

devices enabled by the communications module or accessory. Application Programmer Interface (API) capability is an option for interfacing to other bedside devices.

[0090] The major end users of the alarm notification system 500 system (not shown or described for simplicity) include hospital electronic medical records, admit discharge transfer, pharmacy, clinical information, patient flow tracking and others. Actors, e.g., users of the alarm notification system 500, including clinical actors and technical support actors. The clinical actors include nursing supervisors, unit clerks, nursing aides, nurses, rapid response teams and respiratory therapists.

[0091] A nursing supervisor assigns individual nurses to specific patients at the beginning of each shift. Shift can vary according to hospital staffing policies. A unit clerk takes direction from the nursing supervisor, typically inputs assignments into system and monitors overall system. A unit clerk may not be available for all shifts. A nursing aide takes assignments from nurse or nursing supervisor, typically applies bedside device sensor, initializes the bedside device and sets alarms to default values. A nurse has primary responsibility for individual patient care and primary response to alarms. The nurse is assigned by nursing supervisor to more than one patient dependent on her/his skills and patient needs and is not always assigned the same patient. Nursing aides are not found in all hospitals.

[0092] A rapid response team responds to clinical emergencies initiated by either a bedside nurse or a nursing supervisor. The team supports more than one care unit and has one or more members depending on shift. Rapid Response Teams may not be implemented in all hospitals. A respiratory therapist has responsibilities for management of respiratory care for more than one patient and usually more than one care unit. Respiratory therapists are not found in some international settings.

[0093] Clinical actor performance substitution allows a high capability actor to assume the roles of other actors. Alarm notification system 500 allows mechanisms for such performance. For example, a nursing supervisor may perform functions of a unit clerk nursing aide, a nurse and a rapid response team. A nurse may perform functions of a unit clerk, a nursing aide and a rapid response team. In some international markets a nurse may perform the functions of a respiratory therapist.

[0094] The technical support actors include field installers, application administrators, remote services, IT engineers, biomedical engineers and risk managers. A field installer provisions the system for initial installation, installs components, and

validates that the installation and configuration meet a purchasing contract. An application administrator sets up and maintains user accounts and systems defaults. A remote service provides remote diagnostics and system maintenance over a remote link, such as dial up and VPN. An IT engineer provides network support services if the system is integrated with the hospital IT network. A biomedical engineer provides bedside and system primary service. A risk manager reviews reports for quality and risk mitigation purposes. Technical support actors may also fill in for other actors. For example, an IT engineer, a biomedical engineer, or a remote service can perform the functions of an application administrator. An IT engineer or a biomedical engineer can perform each other's functions.

[0095] Those of skill in the art will understand that information and signals can be represented using any of a variety of different technologies and techniques. For example, data, instructions, commands, information, signals, bits, symbols, and chips that can be referenced throughout the above description can be represented by voltages, currents, electromagnetic waves, magnetic fields or particles, optical fields or particles, or any combination thereof.

[0096] Those of skill will further appreciate that the various illustrative logical blocks, modules, circuits, and algorithm steps described in connection with the embodiments disclosed herein may be implemented as electronic hardware, computer software, or combinations of both. To clearly illustrate this interchangeability of hardware and software, various illustrative components, blocks, modules, circuits, and steps have been described above generally in terms of their functionality. Whether such functionality is implemented as hardware or software depends upon the particular application and design constraints imposed on the overall system. Skilled artisans can implement the described functionality in varying ways for each particular application, but such implementation decisions should not be interpreted as causing a departure from the scope of the present invention.

[0097] The various illustrative logical blocks, modules, and circuits described in connection with the embodiments disclosed herein can be implemented or performed with a general purpose processor, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field programmable gate array (FPGA) or other programmable logic device, discrete gate or transistor logic, discrete hardware components, or any combination thereof designed to perform the functions described herein. A general

purpose processor can be a microprocessor, conventional processor, controller, microcontroller, state machine, etc. A processor can also be implemented as a combination of computing devices, e.g., a combination of a DSP and a microprocessor, a plurality of microprocessors, one or more microprocessors in conjunction with a DSP core, or any other such configuration. In addition, the term "processing" is a broad term meant to encompass several meanings including, for example, implementing program code, executing instructions, manipulating signals, filtering, performing arithmetic operations, and the like.

[0098] The steps of a method or algorithm described in connection with the embodiments disclosed herein can be embodied directly in hardware, in a software module executed by a processor, or in a combination of the two. A software module can reside in RAM memory, flash memory, ROM memory, EPROM memory, EEPROM memory, registers, hard disk, a removable disk, a CD-ROM, a DVD, or any other form of storage medium known in the art. A storage medium is coupled to the processor such that the processor can read information from, and write information to, the storage medium. In the alternative, the storage medium may be integral to the processor. The processor and the storage medium can reside in an ASIC. The ASIC can reside in a user terminal. In the alternative, the processor and the storage medium can reside as discrete components in a user terminal.

[0099] The modules can include, but are not limited to, any of the following: software or hardware components such as software object-oriented software components, class components and task components, processes, methods, functions, attributes, procedures, subroutines, segments of program code, drivers, firmware, microcode, circuitry, data, databases, data structures, tables, arrays, or variables.

[0100] In addition, although this invention has been disclosed in the context of a certain preferred embodiment, it will be understood by those skilled in the art that the present invention extends beyond the specifically disclosed embodiment to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. In particular, while the present acoustic signal processing system and methods have been described in the context of a particularly preferred embodiment, the skilled artisan will appreciate, in view of the present disclosure, that certain advantages, features and aspects of the acoustic signal processing system, device, and method may be realized in a variety of other applications and software systems. Additionally, it is

contemplated that various aspects and features of the invention described can be practiced separately, combined together, or substituted for one another, and that a variety of combination and subcombinations of the features and aspects can be made and still fall within the scope of the invention. Furthermore, the systems described above need not include all of the modules and functions described in the preferred embodiments. Thus, it is intended that the scope of the present invention herein disclosed should not be limited by the particular disclosed embodiment described above, but should be determined only by a fair reading of the claims that follow.

WHAT IS CLAIMED IS:

1. A method of context-based communication of physiological information over a network, the method comprising:

receiving physiological information with a portable network interface module from at least one physiological monitor coupled to a single medical patient, wherein the physiological information is related to a physiological condition of the medical patient, and wherein the portable network interface module is exclusively assigned to the medical patient;

preparing a contextual data package with the portable network interface module, wherein the contextual data package comprises context information related to the medical patient and the physiological information;

establishing a network connection with a user over a network with the portable network interface module, wherein the portable network interface module manages the network connection with the user; and

communicating the contextual data package to the user over the network with the network connection.

2. The method of Claim 1, wherein the network is a shared network.

3. The method of Claim 1, further comprising receiving the context information with the portable network interface module.

4. The method of Claim 1, wherein communicating the contextual data package to the user over the network comprises using communications protocols complying with open architecture communications standards.

5. The method of Claim 1, further comprising journaling at least one of the following: 1) physiological information from the physiological monitor, 2) changes in the network connection, 3) changes in operation by the user, and 4) changes in system behavior.

6. The method of Claim 5, wherein journaling comprises operating within a transaction-based architecture.

7. The method of Claim 1, further comprising performing flow control, the flow control comprising:

storing the contextual data package in a flow control buffer with the portable network interface device;

verifying with the portable network interface device that the contextual data package was received by the user; and

resending the contextual data package stored in the flow control buffer with the portable network interface device, in the event that the user did not receive the contextual data package.

8. The method of Claim 1, wherein the context information comprises a category of context information selected from the group consisting of a portable network interface module category, a medical patient category, a usage of the portable network interface module category, and a network connection category.

9. A method of managing patient context in a patient monitoring system on an open communications architecture, the method comprising:

receiving clinical data with a portable communications module from at least one sensor coupled to a patient, wherein the clinical data is related to a physiological condition of the medical patient, and wherein the portable communications module is a bedside device;

managing a patient context with the portable communications module, wherein the patient context comprises context information related to the patient and the clinical data;

establishing a network connection with a user over an open communications architecture with the portable communications module, wherein the portable communications module manages connectivity with the user; and

communicating the patient context to the user over the open communications architecture with the network connection.

10. The method of Claim 9, wherein the context information comprises data selected from the group consisting of patient name, patient identification number, patient location, and clinical data.

11. An apparatus for context-based communication of physiological information over a network, the apparatus comprising:

a portable network interface module configured to be assigned exclusively to a medical patient and configured to receive physiological information from a sensor coupled to the medical patient, the portable network interface module comprising:

a context management module configured to prepare a contextual data package, wherein the contextual data package comprises context information related to the medical patient and the physiological information, and

a network management module configured to establish a network connection with a user over a network, to manage the network connection with the user, and to communicate the contextual data package to the user over the network.

12. The apparatus of Claim 11, wherein the network is a shared network.
13. The apparatus of Claim 11, wherein the portable network interface module is a web server.
14. The apparatus of Claim 11, wherein the context management module is further configured to receive the context information from a server.
15. The apparatus of Claim 11, wherein the portable network interface module further comprises a flow control module configured to store the contextual data package in a flow control buffer, to verify that the contextual data package was received by the user, and to resend the contextual data package stored in the flow control buffer in the event that the user did not receive the contextual data package.
16. The apparatus of Claim 11, wherein the portable network interface module further comprises a security management module configured to manage user authentication on the shared network.
17. The apparatus of Claim 11, wherein the network management module is further configured to communicate the contextual data package to the user in real time.
18. The apparatus of Claim 11, wherein the network management module is further configured to communicate historical physiological information to the user.
19. The apparatus of Claim 11, wherein the context information comprises patient identification information and patient location information.
20. A system for context-based communication of physiological information over a network, the system comprising:
 - a sensor configured to receive physiological information related to a physiological condition of a medical patient and to generate a signal based upon the physiological information;

a sensor processing module coupled with the sensor, the sensor processing module configured to process the signal; and

a portable network interface module exclusively assigned to the medical patient and coupled with the sensor processing module, the portable network interface module configured to receive the physiological information from the sensor processing module, the portable network interface module comprising:

a context management module configured to prepare a contextual data package, wherein the contextual data package comprises context information related to the medical patient and the physiological information, and

a network management module configured to establish a network connection with a user over a network, to manage the network connection with the user, and to communicate the contextual data package to the user over the network.

21. The system of Claim 20, wherein the network is a shared network.

22. The system of Claim 20, further comprising a server coupled with the network, the server configured to archive the contextual data package from the portable network interface module.

23. The system of Claim 22, wherein the server is further configured to journal at least one of the following: 1) physiological information from the physiological monitor, 2) changes in the network connection, 3) changes in operation by the user, and 4) changes in system behavior.

24. The system of Claim 22, wherein the server is further configured to act as an interface between the network and an electronic medical records (EMR) system.

25. The system of Claim 20, wherein the context information comprises a category of context information selected from the group consisting of a portable network interface module category, a medical patient category, a usage of the portable network interface module category, and a network connection category.

26. An apparatus for context-based communication of physiological information over a network, the apparatus comprising:

means for receiving physiological information with a portable network interface module from at least one physiological monitor coupled to a single medical patient, wherein the physiological information is related to a physiological

condition of the medical patient, and wherein the portable network interface module is exclusively assigned to the medical patient;

means for preparing a contextual data package with the portable network interface module, wherein the contextual data package comprises context information related to the medical patient and the physiological information;

means for establishing a network connection with a user over a network with the portable network interface module, wherein the portable network interface module manages the network connection with the user; and

means for communicating the contextual data package to the user over the network with the network connection.

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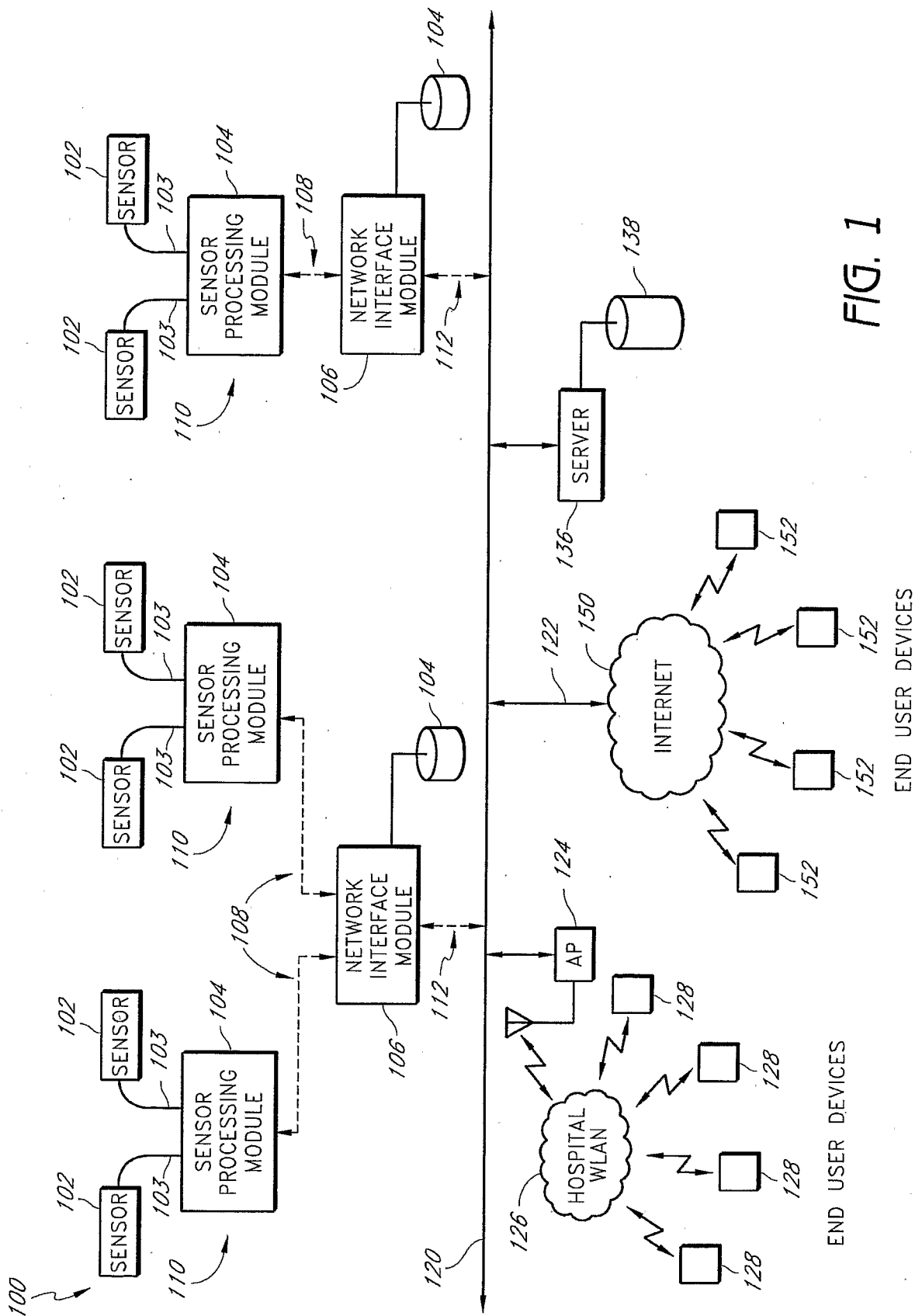
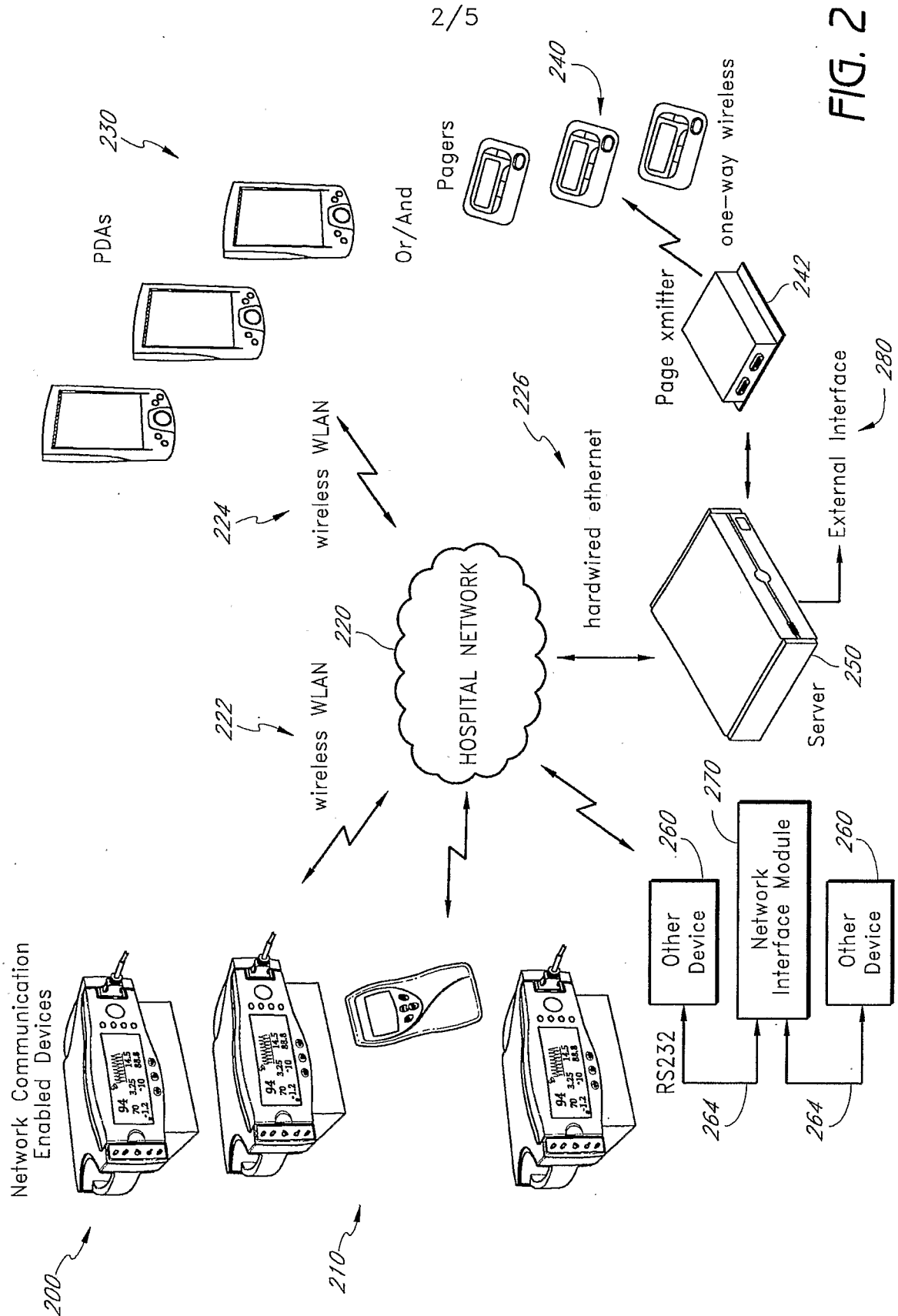


FIG. 2



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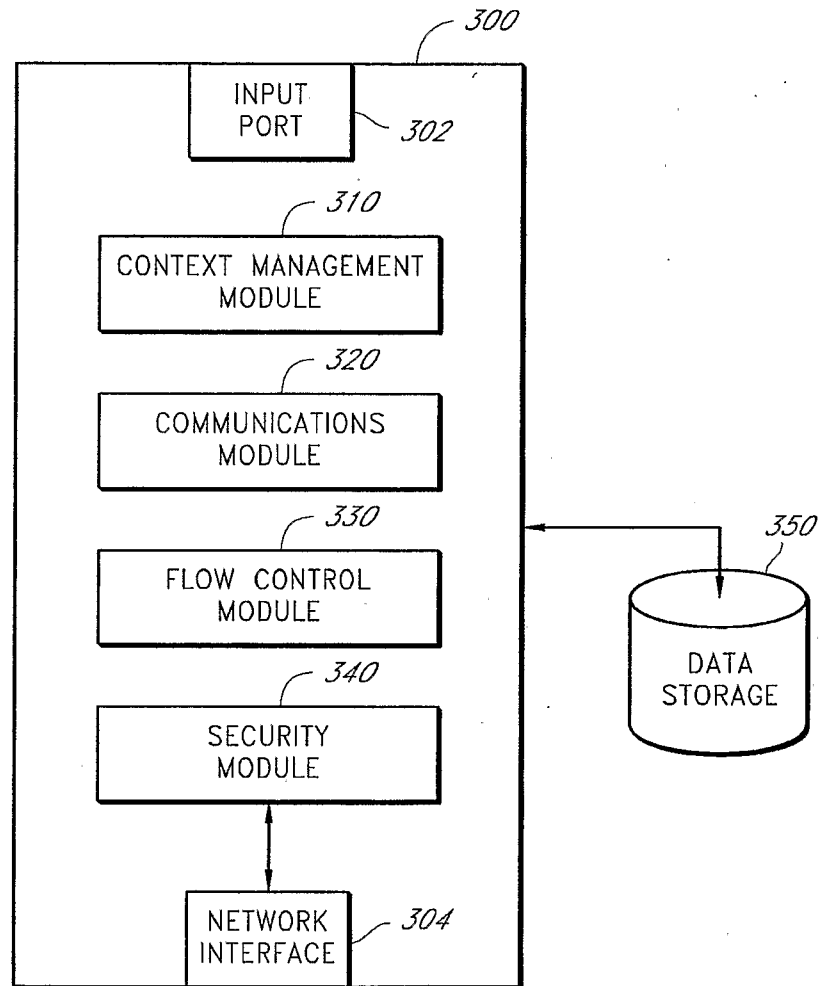


FIG. 3

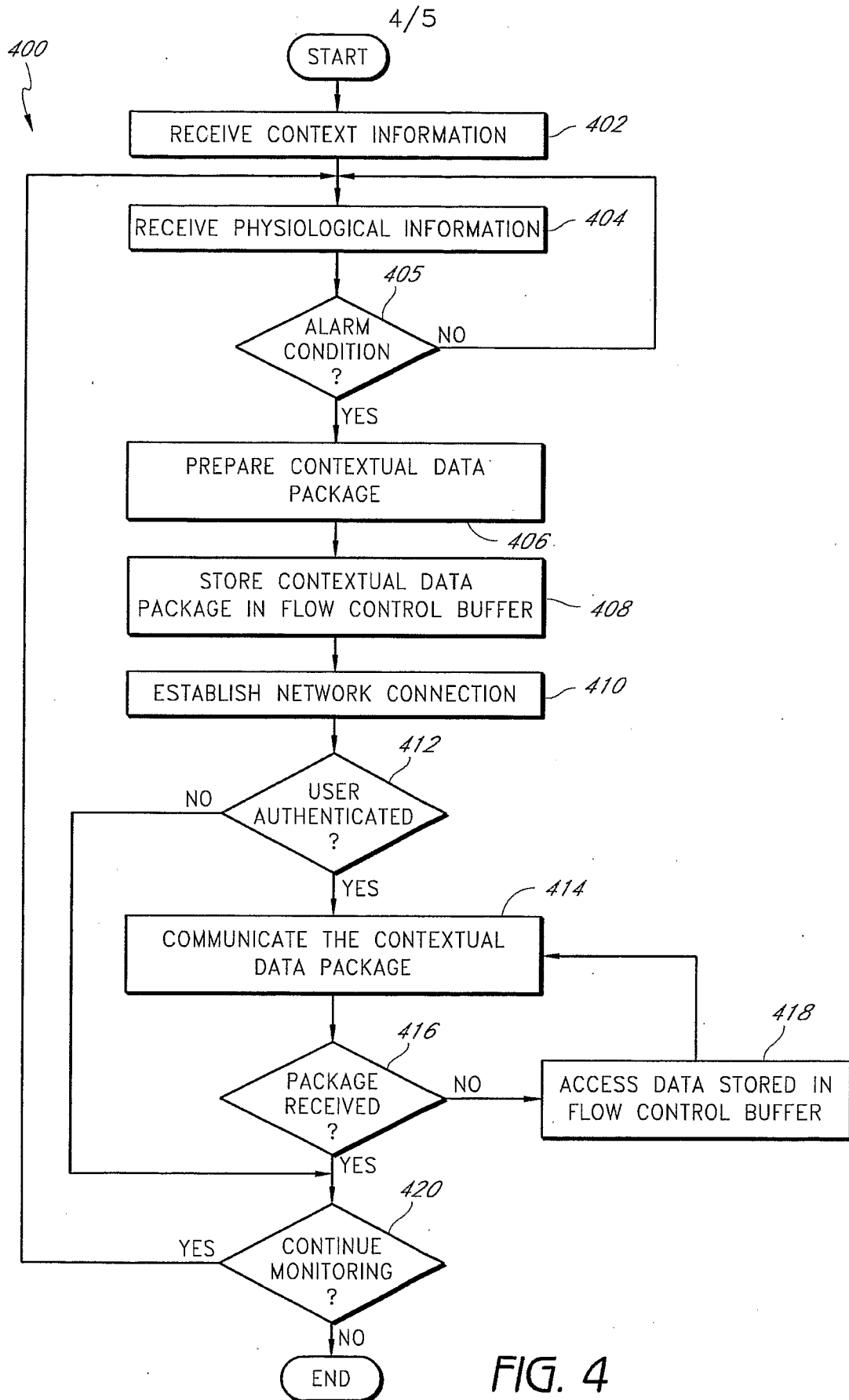


FIG. 4

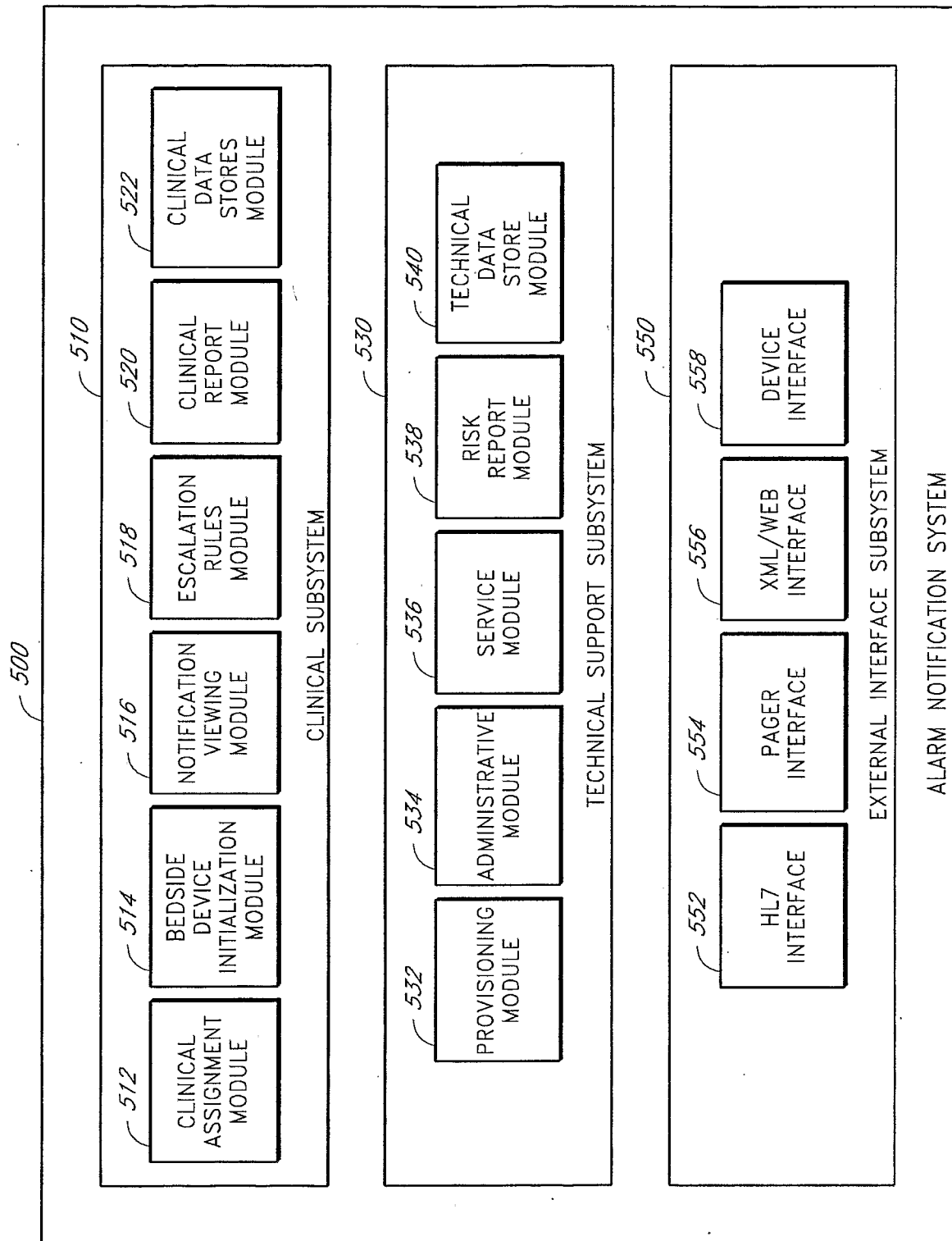


FIG. 5