(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 September 2015 (03.09.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/130705 A1

(51) International Patent Classification:
A61B 5/021 (2006.01)

(21) International Application Number:
PCT/US2015/017377

(22) International Filing Date:
24 February 2015 (24.02.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/944,408 25 February 2014 (25.02.2014) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

— *with international search report (Art. 21(3))*

(54) Title: PATIENT MONITORING SYSTEM WITH GATEKEEPER SIGNAL

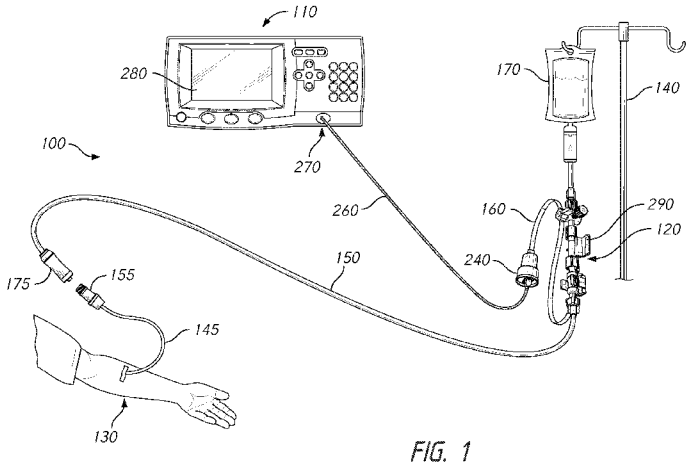

FIG. 1

(57) Abstract: A gatekeeper electronic signal can be generated by a patient sensor and/or in an intermediate device, such as an electrical cable, that is separate from a patient's physiological information electronic signal. The gatekeeper signal can be generated to indicate to a computer monitor that the sensor and/or cable is of the type that is compatible with, and/or usable with, such computer monitor, and/or that the sensor and/or cable is properly attached to the computer monitor. The gatekeeper signal can be created by an ambient temperature sensor on, or in electrical communication with, the patient monitor, and/or the gatekeeper signal can be created by a gatekeeper electronic signal generator to simulate an ambient temperature value. The gatekeeper signal can be separate from an electronic signal or plurality of signals that include patient physiological information, and the gatekeeper signal may not include any patient physiological information.

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PATIENT MONITORING SYSTEM WITH GATEKEEPER SIGNAL

RELATED APPLICATIONS

[0001] This application claims the priority benefit of U.S. Provisional Patent Application No. 61/944,408, filed on February 25, 2014, and entitled, "Patient Monitoring System with Gatekeeper Signal," the entire contents of which are hereby incorporated by reference herein and made part of this specification for all that it discloses.

BACKGROUND

Field

[0002] Certain embodiments disclosed herein relate generally to monitoring physiological parameters of a patient, and specifically to verifying that a proper sensor is in communication with a physiological monitoring system.

Description of the Related Art

[0003] In many healthcare settings, especially in the care of seriously afflicted cardiac patients, it is desirable or necessary for a healthcare practitioner to be able to obtain generally continuous information about a patient's physiology, such as a patient's cardiac performance or a patient's blood characteristics. Electronic physiological monitoring systems can include a tubular catheter inserted into a patient's blood vessel, a sensor in fluid communication with the catheter, and a computer monitor in electrical communication with the sensor. The computer monitor is typically positioned at or near a patient's bedside and typically includes a computer processor and a display of data regarding the patient's cardiac performance.

[0004] The sensor may be a disposable component, used in treating a particular patient and then discarded and replaced with a new sensor. A variety of different types of sensors are made by different sources and purchased by healthcare facilities for different physiological monitoring systems. Several of these different types of sensors may be available in a particular healthcare setting. In addition, some sensors may be connected to

the monitoring systems by one or more intermediate devices, such as one or more cables, that may be disposable or non-disposable. Some sensors and/or intermediate cables may not be validated for, or compatible with, or safe for use with, a particular physiological monitoring system. Such sensors and/or cables, if somehow connected to or placed in electrical communication with a particular physiological monitoring system, might cause damage to the monitoring system or yield false readings about a patient's current physiological condition. Moreover, even if a proper sensor and/or cable is intended to be used, but the electrical connection between the sensor and/or cable and the computer monitor is not properly connected, such as if the electrical connector is not fully inserted or includes a bent or damaged electrical contact, then an incomplete or faulty data signal may be transmitted from the sensor to the computer monitor.

SUMMARY

[0005] In some embodiments, a gatekeeper electronic signal can be generated remote from the patient monitor. In some embodiments, the gatekeeper electronic signal can be generated by a patient sensor and/or in an intermediate device, such as an electrical cable, that is separate from a patient's physiological information electronic signal. The gatekeeper signal can be generated to indicate to a computer monitor that the sensor and/or cable is of the type that is compatible with, and/or usable with, such computer monitor, and/or that the sensor and/or cable is properly attached to the computer monitor. In some embodiments, the gatekeeper signal can be created by an ambient temperature sensor on, or in electrical communication with, the patient monitor, and/or the gatekeeper signal can be created by a gatekeeper electronic signal generator to simulate an ambient temperature value. The gatekeeper signal can be separate from an electronic signal or plurality of signals that include patient physiological information, and the gatekeeper signal may not include any patient physiological information. In some embodiments, the gatekeeper signal is not configured to be used to process or evaluate any electronic signals to obtain or analyze patient physiological information.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] Figure 1 illustrates an example of a critical-care patient monitoring system;

[0007] Figure 2 illustrates an example of a schematic representation of a patient sensor that is configured to generate a gatekeeper electrical signal;

[0008] Figure 3 illustrates an example of a patient sensor with an ambient temperature sensor; and

[0009] Figure 4 illustrates an example of an algorithm or subroutine in a computer monitor for monitoring, evaluating, and/or responding to a gatekeeper electrical signal.

DETAILED DESCRIPTION

[0010] As illustrated in the example of Figure 1, in some embodiments, a critical-care patient monitoring system 100 can include a computer monitor 110 placed in electrical communication with a patient sensor 120, such as a cardiac-monitoring sensor and/or a blood parameter sensor, which in turn is placed in fluid communication with a blood vessel of a patient 130, such as by way of a catheter 150. Though shown as an integrated unit, the computer monitor 110 may include one or more separable components; for example, the visual display, with or without embedded processing capabilities, may be releasably attached to the base computer monitor. As a patient's heart beats, a pressure wave is transmitted through the patient's interconnected system of blood vessels (veins and arteries). The pressure wave provides information about the patient's cardiac performance, which can be electrically transmitted from the patient sensor 120 to the computer monitor 110, such as by way of a wired connection 160 or a wireless connection. The information about the patient's cardiac performance can be derived or calculated through a mathematical analysis performed by the computer monitor 110 of the shape of the pressure wave, and/or the ways in which the pressure wave changes over time, etc. As shown, the patient sensor 120 can be positioned on a suitable holding structure 140, such as a pole stand or other holder, and the patient sensor can be in fluid communication with a liquid source 170.

[0011] As shown in Figures 2 and 3, in some embodiments, a patient sensor 120 such as a cardiac monitoring sensor can comprise a transducer 180 that is configured to

transform mechanical motion into electrical energy, such as a pressure sensor that produces an electrical signal that changes over time in response to changes in fluid pressure. The patient sensor 120 can comprise a fluid-receiving region 190, such as a fluid channel, that is in communication with the transducer. The fluid channel can form part of, or be attached to, or otherwise be positioned in fluid communication with, the medical catheter 150 or other tubing or device in fluid communication with a patient's vessel. In some embodiments, the fluid-receiving region 190 is a liquid-receiving region that is configured to receive one or more liquids such as blood, water, saline, or another medical fluid. A distal end of the medical catheter can be inserted into a patient's blood vessel, in contact with the patient's blood, in a conventional manner.

[0012] The medical catheter 150 can contain a column of biocompatible fluid, such as saline and/or blood, that interfaces with the blood flowing inside of a patient's blood vessel (e.g., a vein or an artery). The column of fluid can be provided by a liquid source 170, such as an IV bag, that is pressurized or that is gravity-fed into the patient sensor 120, which can be disposed in fluid communication with the patient sensor 120 by way of one or more fluid connectors 195. A suitable valve, such as a stopcock 200 can provide a controllable connection between the liquid source 170 and the patient sensor 120. The stopcock 200 can permit fluid to flow from the liquid source 170, to the fluid-sensing region 190, and/or to or from a side port 205. As the pressure wave from the patient's beating heart is transmitted through the patient's blood vessel, the wave is communicated through fluid interaction with the blood into the column of fluid inside the medical catheter 150, and then to the fluid channel 190 at or near the transducer, where the fluid pressure wave can be converted into a cardiac monitoring electrical signal and transmitted by an electrical wire 160 or wirelessly to the computer monitor 110. The computer monitor 110 can be programmed to analyze the cardiac monitoring electrical signal to provide physiological information about the patient, such as cardiac performance information (e.g., pulse rate, blood pressure such as systolic pressure and/or diastolic pressure, and/or cardiac output, etc.).

[0013] In addition to, or instead of, providing cardiac performance information, a blood parameter sensor can be provided with a medical catheter configured to convey information about one or more blood parameters, such as one or more of: a blood gas level (e.g., oxygen and/or carbon dioxide, etc.), a pH level, a hemoglobin level, a hematocrit level,

a glucose level, and/or a blood temperature, etc. In some embodiments, one or more blood parameters can be determined by measuring characteristics of light waves that are transmitted into and/or reflected from the blood or another substance in communication with the blood, such as through a system of one or more fiber optic light-transmitting and/or light-receiving cables. In some embodiments, one or more blood parameters can be determined by placing one or more sensors in close communication with the blood, such as a temperature-sensing thermistor suspended in the blood or positioned near the blood.

[0014] The patient sensor 120, whether a cardiac-monitoring sensor and/or a blood-parameter sensor, or some other form of patient sensor, can be structured, positioned, and/or oriented in a variety of different ways. The patient sensor 120 can comprise a patient-information electrical signal generator 210. In some embodiments, a physiological sensing device such as a cardiac monitoring sensor and/or a blood parameter sensor can form part of the patient-information electrical signal generator or can be in electrical communication with the patient-information electrical signal generator.

[0015] In some embodiments, the patient sensor 120 comprises a housing 230 with one or more transducers 180 or receivers positioned on or in or near the housing 120, in combination with a medical catheter 150 and one or more electrical wires 160 and/or one or more electrical connectors 240. The patient sensor 120, including the physiological sensing device or transducer 180, the patient-information electrical signal generator 210, the gatekeeper electrical signal generator 250, the medical catheter 150, the electrical wires 160, and/or the electrical connectors 240, can be a disposable unit. A patient-information electrical signal can be produced by the patient-information electrical signal generator of the patient sensor from the patient information or data obtained by one or more sensors regarding the physiological characteristics, conditions, or status of a patient. The patient's physiological information can be conveyed to or toward the computer monitor 110 of the critical-care patient monitoring system 100 by way of a patient-information electrical signal through the one or more electrical wires 160, 260 and/or one or more electrical connectors 240. In some embodiments, the patient's physiological information can be conveyed to or toward the computer monitor 110 of the critical-care patient monitoring system 100 by way of a patient-information electrical signal that is transmitted wirelessly.

[0016] In some embodiments, a non-disposable electrical cable 260 can be used to convey the patient-information electrical signal and the gatekeeper electrical signal from the electrical wires 160 in the patient sensor 120 to the computer monitor 110. In some embodiments, a gatekeeper signal-generating device 250 can be in electrical communication with such a cable or another intermediate device, or can be integrated into or embedded in such a cable or another intermediate device, instead of or in addition to being in electrical communication with or integrated into or embedded in a disposable patient sensor 120. In some healthcare settings, the distance between the transducer portion 180 of the patient sensor 120 and the computer monitor 110 can be significant, such as when the transducer 180 is positioned on a pole stand 140 or in some other location relatively close to the entry point of the medical catheter into the patient's body (such as into the patient's arm 130 or some other location) and the computer monitor 110 is located on a stand in a hospital room several feet away from the entry point. A fluid 145 catheter attached to the patient can be connected to the fluid line 150 from the sensor 120 by way of a pair of fluid connectors, such as corresponding male and female fluid connectors 155, 175.

[0017] Since the electrical wiring may be draped down from the transducer 180, across the floor, and back up to the computer monitor 110 (to avoid creating horizontal wire barriers to persons walking around the patient's vicinity), the length of electrical wiring 160, 260 between the transducer 180 and the computer monitor 110 may be in the range of about 6 feet or so (2 meters). If all of this wiring 160,260 were part of the disposable patient sensor 120, it would dramatically increase the manufacturing cost and unit price of the disposable patient sensor 120, which would be unnecessary because much of the wiring does not routinely come into contaminating contact with a patient, and need not be sterile, but is instead positioned on the floor or near the computer monitor, and can therefore be used with multiple patients. In some embodiments, the electrical connection with the patient sensor 120 is achieved by attaching an electrical connection portion 240 of the patient sensor 120 to a proximal electrical connection portion of the non-disposable cable, and then attaching a distal connection portion of the non-disposable cable 270 to an electrical connection portion of the computer monitor.

[0018] The electrical information can be conveyed in some embodiments wirelessly, such as by way of an electromagnetic short-range signal, such as over a Wi-Fi

network or by way of a Bluetooth or ZigBee signal, or by some other wireless protocol that is acceptable or utilized in a healthcare setting. Any description or illustration in this specification of an electrical wire 160, 250, or electrical connection 140 can be accomplished in a wireless manner and such descriptions or illustrations of wires or electrical connections should be understood to also refer to and encompass wireless connections. For example, any description or illustration of a patient-information electrical signal and/or a gatekeeper electrical signal being conveyed over a wired connection should be understood to also refer to and encompass a suitable wireless connection.

[0019] To help verify that a proper patient sensor 120 is attached to the computer monitor 110 and/or that a proper secondary cable 270 is attached to the computer monitor 110 and/or to ensure that the electrical connection between the sensor 120 and the computer monitor 110 is properly established, a gatekeeper electrical signal can be transmitted to the monitor 110. In some embodiments, the signal is generated by a component permanently coupled to the sensor device. In some embodiments, the signal is generated at least in part by the non-disposable cable configured to place the sensor in electrical communication with the computer monitor. In some embodiments, the signal is generated by a combination of both the components permanently coupled to the sensor device and the non-disposable cable configured to place the device in electrical communication with the computer monitor. In some embodiments, the receipt of the gatekeeper electrical signal by the computer monitor is a required condition for the computer monitor 110 to function and/or for the computer monitor 110 to display patient information on a display screen 280. In some embodiments, the monitor 110 will only calculate and display physiological information about the patient after the monitor 110 receives the gatekeeper electrical signal and/or only for so long as the gatekeeper electrical signal continues to be transmitted to the monitor (continuously or within an allowable time interval). In some embodiments, if the gatekeeper electrical signal is not received by the computer monitor as expected, an error message will be conveyed on the display screen or in some other manner. The error message can indicate that no sensor is connected, that an improper sensor is connected to the computer monitor, and/or that the user should check an electrical attachment with the computer monitor, etc.

[0020] The gatekeeper electrical signal can be generated by a signal generator in a variety of different ways and in a variety of different locations. As shown in the example

of Figure 2, in some embodiments, the signal generator for producing the gatekeeper electrical signal is located on or within or near the housing 220 of the patient sensor. In some embodiments, the gatekeeper electrical signal is produced by a signal generator comprising a temperature sensor 290, such as an ambient temperature sensor. In some embodiments, the signal generator is only an ambient temperature sensor; in some embodiments, a temperature sensor 290 is in electrical communication with a gatekeeper electrical signal generator for producing the gatekeeper electrical signal. The temperature sensor 290 can be structured, positioned, and/or oriented in a variety of different ways. For example, the temperature sensor 290 can comprise a temperature-sensitive electrical component, such as a diode or a transistor or a thermistor or another electrical component, in which the output voltage or another quality of the electrical signal or the resistivity of the component changes as a function of the temperature of the air or other material surrounding the electrical component that is in thermal communication with the temperature-sensitive electrical component.

[0021] It is expected that the critical-care patient monitoring system 100 will be used in settings in which the ambient temperature is generally about the level of a standard room temperature, such as about 70°F or about 21°C, and/or within a standard room temperature range, such as at least about 65°F and/or less than or equal to about 75°F (or at least about 18°C and/or less than or equal to about 24°C). Other temperature ranges, including other standard room temperature ranges, within or outside of these temperature ranges can be utilized. The temperature sensor 290 can be configured to generally sense the ambient temperature in the patient's room or the ambient temperature at, near, or inside of the patient sensor 120 or the housing 230 of the patient sensor 120. In some embodiments, the gatekeeper temperature sensor 290 is positioned outside of the fluid-containing portion 190 of the patient sensor 120 and/or outside of fluid communication or direct thermal communication with the fluid in the patient sensor 120. In some embodiments, the gatekeeper temperature sensor 290 is isolated or separated from, is largely unaffected by, and/or is unable to provide clinically useful information about, changes in a patient's body temperature or other physiological parameters of a patient. In some embodiments, the gatekeeper electrical signal can help ensure that the critical-care patient monitoring system is

used in an environment in which ambient temperature ranges will not affect the functioning of the electrical equipment and/or the physiological readings obtained from a patient.

[0022] In some embodiments, the gatekeeper electrical signal generator 250 is in electrical communication with the gatekeeper temperature sensor 290. The gatekeeper electrical signal generator can comprise an electrical circuit configured to produce a gatekeeper electrical signal in concert with the gatekeeper temperature sensor 290. In some embodiments, the electrical signal produced by the gatekeeper electrical signal generator 250 varies as a function of the ambient temperature sensed by the temperature sensor 290. In some embodiments, the electrical signal produced by the gatekeeper electrical signal generator 250 is a generally constant value so long as the temperature sensed by the temperature sensor 290 is within a predetermine range, such as within a predetermined range of standard room temperatures.

[0023] The gatekeeper electrical signal can be conveyed from the gatekeeper electrical signal generator 250 (located on or in the patient sensor 120, in some embodiments) to the computer monitor 110 of the critical-care patient monitoring system 100 by way of an electrical wire 165 that is separate from the electrical wire or wires 167 configured to convey the patient-information electrical signal. The electrical wires 165, 167 can be separately insulated and bound together in a common wire bundle 160. In some embodiments, the gatekeeper electrical signal is independent from the patient-information signal and does not include any information about the physiological status or condition of a patient.

[0024] In some embodiments of patient sensors, the gatekeeper electrical signal is not produced from or using an actual temperature sensor or a temperature value, but instead creates a simulated temperature signal using an electrical signal generator. In Figure 2, the connection between the temperature sensor 290 and the gatekeeper electrical signal generator is represented by a dashed line to demonstrate that it need not exist in some embodiments because there may not be a temperature sensor 290 at all. A gatekeeper electrical signal derived from a simulated temperature is not based upon a temperature reading and may not vary at all, or may not vary appreciably, according to changes in temperature. The patient sensor 120 may not include a temperature sensor at all, at least not an ambient temperature sensor. The simulated temperature signal may be utilized in situations where the room or

ambient temperature is not expected to be outside of any range that would affect the proper functioning of the electronic components or the patient's physiological condition; or where there is little or no risk of sensor misattachment or a mix-up in the type of sensor to be used; or when it is desired to produce a simpler sensor with less electronic complexity. The gatekeeper electrical signal produced with a simulated temperature signal can be configured to be generally in the same range as the signal that would ordinarily be produced and transmitted by a temperature-sensing gatekeeper or verification signal generator.

[0025] A supplier can provide a disposable patient sensor 120, or an intermediate device, such as an electrical communication wire or cable, for use with a computer monitor 110, that is configured to provide a gatekeeper signal to the computer monitor 110. The supplier can provide instructions to a healthcare provider, or other user, to electrically connect the sensor and/or the intermediate device, to a computer monitor 110 that is configured to monitor an electrical gatekeeper input port for an electrical gatekeeper signal. The sensor may or may not actually provide a gatekeeper signal that is representative of a true temperature; rather, the gatekeeper signal may be a real or simulated signal. The supplier can provide instructions to the user to remove and/or discard the sensor after use by a patient, such as in a biohazard receptacle.

[0026] The computer monitor 110 of the critical-care patient monitoring system 100 can comprise a computer processor, a computer display 280 configured to display physiological information about the patient (including one or any combination of any of the physiological information that the patient sensor is configured to obtain), a power source (such as a battery or a power cord), and one or more electrical connectors, 270, 240 configured to establish an electrical connection with the patient sensor, such as by way of an attachment with one or more electrical connectors 240 that form part of the patient sensor. The computer monitor 110 can be configured to receive one or more patient-information electrical signals that convey information about a patient's physiological conditions. One or more components of the computer monitor 110 may be releasably coupled to the other components of the monitor. For example, the display 280 may be detachable from the base. The display 280 may include the computer processor and other electrical circuitry used in processing the signals, or the processor may be included in other components of the monitor 110.

[0027] The computer monitor 110 also can be configured to receive a gatekeeper electrical signal. In some embodiments, the computer monitor 110 is configured to receive, process, calculate, and/or identify an ambient temperature value from the gatekeeper electrical signal, which can be an actual ambient temperature value or a simulated ambient temperature value.

[0028] As schematically illustrated in an example in Figure 4, block 300 shows that the computer monitor 110 can monitor the gatekeeper signal or verification signal, such as on a generally continuous basis, checking periodically whether a gatekeeper signal or verification signal has been received, as shown in block 310. If some type of electrical signal has been received by the monitor 110 at the gatekeeper signal electrical connection, then the computer processor of the monitor 110 can be configured to analyze the signal, as shown in block 320, to determine whether the signal is within a particular range of values, or exhibits a particular shape or variance over time, and/or demonstrates any other particular characteristics that the computer processor of the monitor 110 is programmed to recognize as indicative of a gatekeeper signal (such as either an actual temperature signal or a simulated temperature signal), as shown in block 330.

[0029] In some embodiments, as illustrated in block 340, the computer monitor 110 can be programmed to enable receipt of the patient information signal, processing of the patient information, storage of the patient information signal in memory, transmission of the patient information signal, and/or display the patient information, only after, and/or only for so long as, the gatekeeper electrical signal is transmitted to the computer monitor. In some embodiments, the computer monitor 110 receives the gatekeeper signal from the patient sensor 120 and compares it to a predetermined range of values, thus determining whether the ambient temperature sensed by the patient monitor is within a predetermined range of ambient temperatures, such as a predetermined range of standard room temperature values. As shown in block 350, if the signal received at the gatekeeper signal electrical connection on the monitor 110 is determined not to be an actual or simulated temperature signal, then the monitor 110 can initiate an error protocol, which in some embodiments can produce one or more displays of information to the user, such as an error message, as shown in block 360, or information about the proper type of sensor 120 and/or cable to be used with critical-care patient monitoring system 100, and/or the proper way to attach a sensor 120, as shown in

block 370; and/or the error protocol can clear and/or disable the display of physiological information from the patient on the computer display 280, as shown in block 380, since such information might be incorrect or unreliable if the gatekeeper signal or verification signal is determined to be incorrect.

[0030] In some embodiments, the computer processor of the computer monitor does not utilize the gatekeeper electrical signal to process, analyze, calculate, or obtain any patient information from the patient-information electrical signal or signals or from any other source; rather, the patient information contained in the patient-information electrical signal is independent from and is not required to be calibrated, adjusted, or modified by the gatekeeper electrical signal.

[0031] When the gatekeeper electrical signal represents a simulated temperature value, but not an actual temperature value, the computer monitor can in some embodiments receive such gatekeeper electrical signal as an actual temperature value and proceed to function normally and display patient data in a normal manner, as though the gatekeeper electrical signal were produced using an actual temperature value. Since the gatekeeper electrical signal is not normally utilized to calibrate, modify, normalize, or adjust the patient information in the patient-information electrical signal, the simulated temperature value of the gatekeeper electrical signal may not affect the accuracy of the patient data. Thus, the same computer monitor can be configured to function properly, in some embodiments, with a patient sensor that is configured to produce a gatekeeper electrical signal using an actual temperature measurement or a patient sensor that merely produces a signal with a simulated temperature.

THE FOLLOWING IS CLAIMED:

1. A disposable patient-monitoring device configured to be attached to tubing in fluid communication with a patient's blood vessel, and configured to be attached in electrical communication with a computer processor, the patient-monitoring device comprising:

at least one pressure sensor configured to be in fluid communication with a patient's blood vessel through a fluid-receiving region in the pressure sensor and configured to be in electrical communication with a computer processor, the pressure sensor being configured to sense a pressure wave in the patient's vasculature and being configured to transmit at least one patient-information electrical signal to the computer processor that indicates a physiological parameter of a patient;

a signal generator that is configured to send a gatekeeper electrical signal to the computer processor that indicates or simulates an ambient temperature at the disposable patient-monitoring device, outside of the fluid region, to enable the computer processor to confirm that the cardiac-monitoring device is attached in electrical communication with the computer processor, the gatekeeper electrical signal not including diagnostic or physiological information about the patient;

wherein the information conveyed by the patient-information electrical signal is not required to be calibrated or modified by the gatekeeper electrical signal.

2. A patient-monitoring system comprising the disposable patient-monitoring device of Claim 1, in combination with the computer processor.

3. The disposable patient-monitoring device of Claim 1, further comprising a housing.

4. The disposable patient-monitoring device of Claim 3, wherein the device is configured to measure an actual ambient temperature, and the ambient temperature is measured by a temperature sensor.

5. The disposable patient-monitoring device of Claim 4, wherein the ambient temperature is measured inside of the housing.

6. The disposable patient-monitoring device of Claim 4, wherein the ambient temperature is measured outside of the housing.

7. The disposable patient-monitoring device of Claim 1, wherein the gatekeeper electrical signal is generated by a simulator, not an actual temperature measurement.

8. The disposable patient-monitoring device of Claim 7, wherein the device does not include any temperature sensor.

9. A method of enabling cardiac monitoring comprising:

providing to a user a disposable cardiac-monitoring device comprising at least one pressure sensor configured to be in fluid communication with a patient's blood vessel to sense a pressure wave in the patient's blood vessel, and configured to be in electrical communication with a computer processor to transmit at least one physiologically derived electrical signal to the computer processor that indicates a cardiac parameter of a patient, and configured to generate a verification signal that indicates or simulates an ambient temperature at the disposable cardiac-monitoring device outside of the fluid region, the verification signal not being required to calibrate or otherwise modify the physiologically derived electrical signal;

instructing a user to attach the disposable cardiac-monitoring device so as to be in fluid communication with the patient's blood vessel; and

instructing a user to attach the disposable cardiac-monitoring device so as to be in electrical communication with the computer processor.

10. A method of enabling cardiac monitoring of a patient comprising:

obtaining a disposable cardiac-monitoring device; attaching the cardiac-monitoring device so as to be in fluid communication with a patient's vasculature; and attaching the cardiac-monitoring device so as to be in electrical communication

with a computer processor, thereby permitting the cardiac-monitoring device to sense a pressure wave in the patient's vasculature and transmit a pressure-wave signal to the computer processor and permitting the cardiac-monitoring device to create a second signal that indicates or simulates a temperature at the cardiac monitoring device outside of a region of the cardiac-monitoring device that contains fluid.

11. A gatekeeper signal-generating device configured to be attachable so as to be in electrical communication with a medical computer processor and a disposable patient pressure sensor having a liquid-receiving region configured to receive liquid during use, the gatekeeper signal-generating device comprising:

a signal generator configured to send a gatekeeper electrical signal to the medical computer processor that indicates or simulates an ambient temperature, outside of the liquid-receiving region, the gatekeeper electrical signal being isolated from and not configured to be used to modify or calibrate any patient-information signal;

a first electrical connector configured to attach the gatekeeper signal-generating device to the medical computer processor; and

a second electrical connector configured to attach the gatekeeper signal-generating device to the disposable patient pressure sensor.

12. The combination of the gatekeeper signal-generating device of Claim 11 and the medical computer processor.

13. The combination of the gatekeeper signal-generating device of Claim 11 and the disposable patient pressure sensor.

14. The gatekeeper signal-generating device of Claim 11 in electrical communication with an electrical cable.

15. The gatekeeper signal-generating device of Claim 14 embedded in an electrical cable.

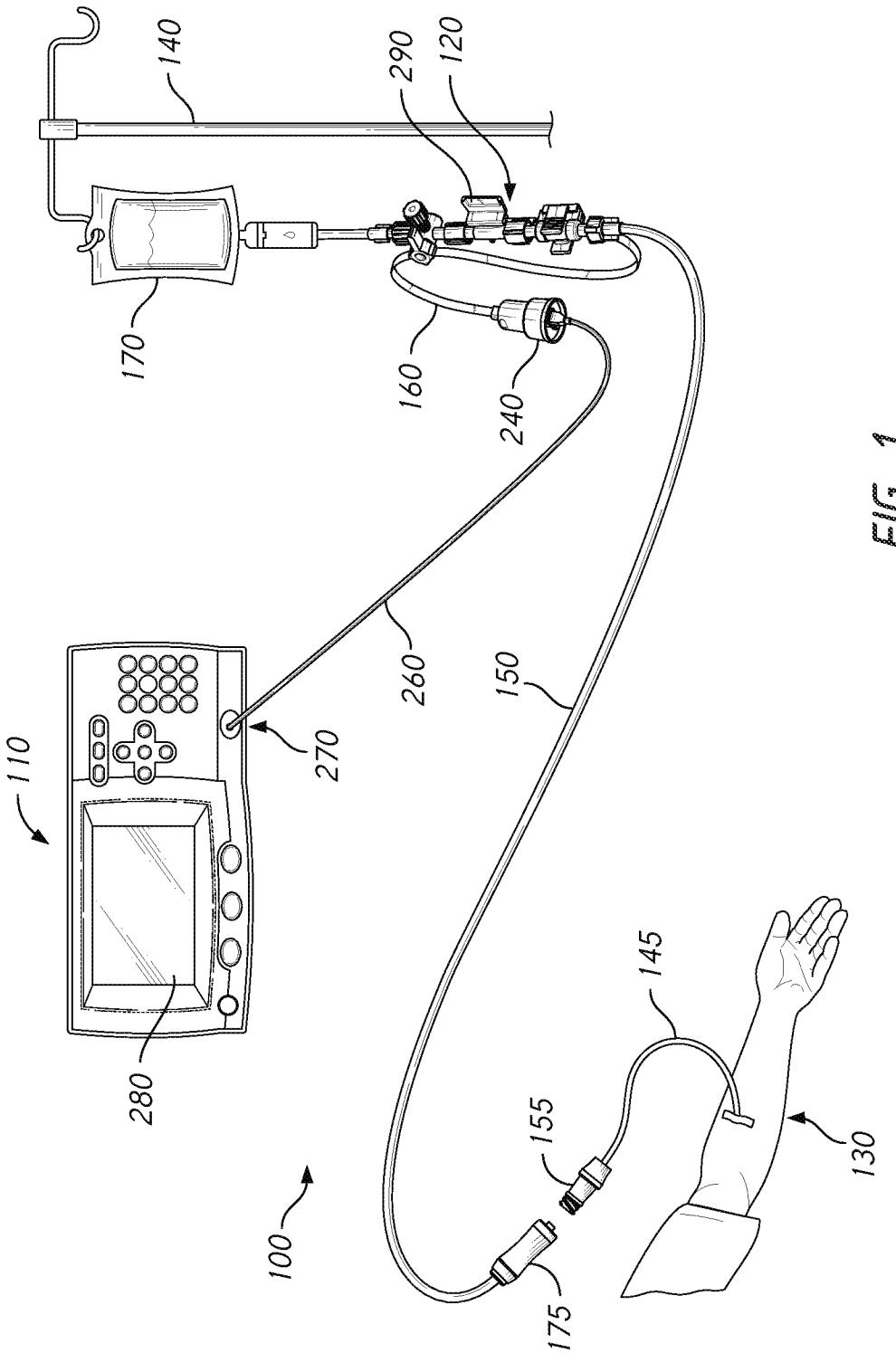

FIG. 1

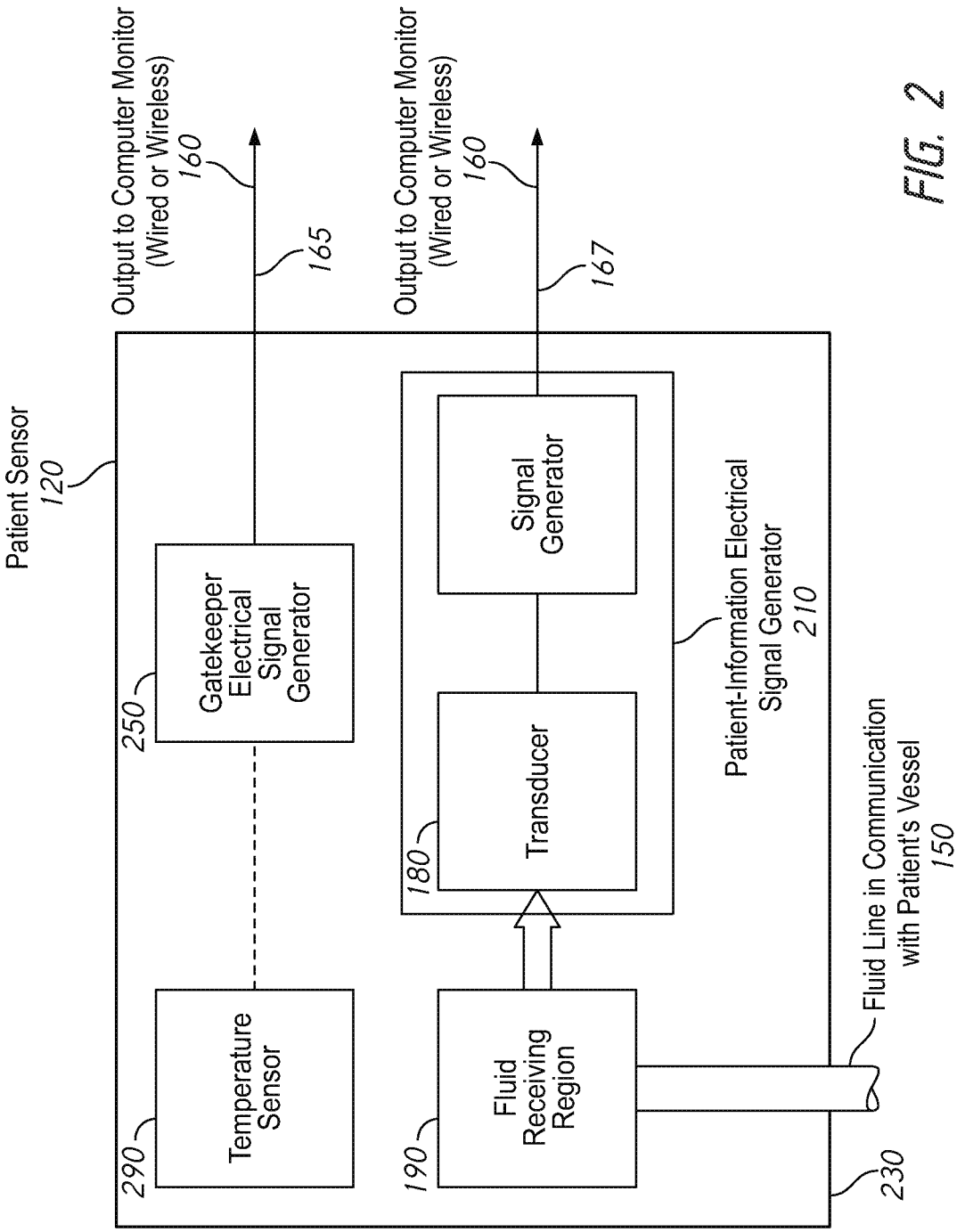
Patient Sensor
120
Output to Computer Monitor
(Wired or Wireless)
160
165
Output to Computer Monitor
(Wired or Wireless)
160
167
Gatekeeper
Electrical
Signal
Generator
250
Signal
Generator
Patient-Information Electrical
Signal Generator
210
Transducer
180
Temperature
Sensor
290
Fluid
Receiving
Region
190
Fluid Line in Communication
with Patient's Vessel
150
230

FIG. 2

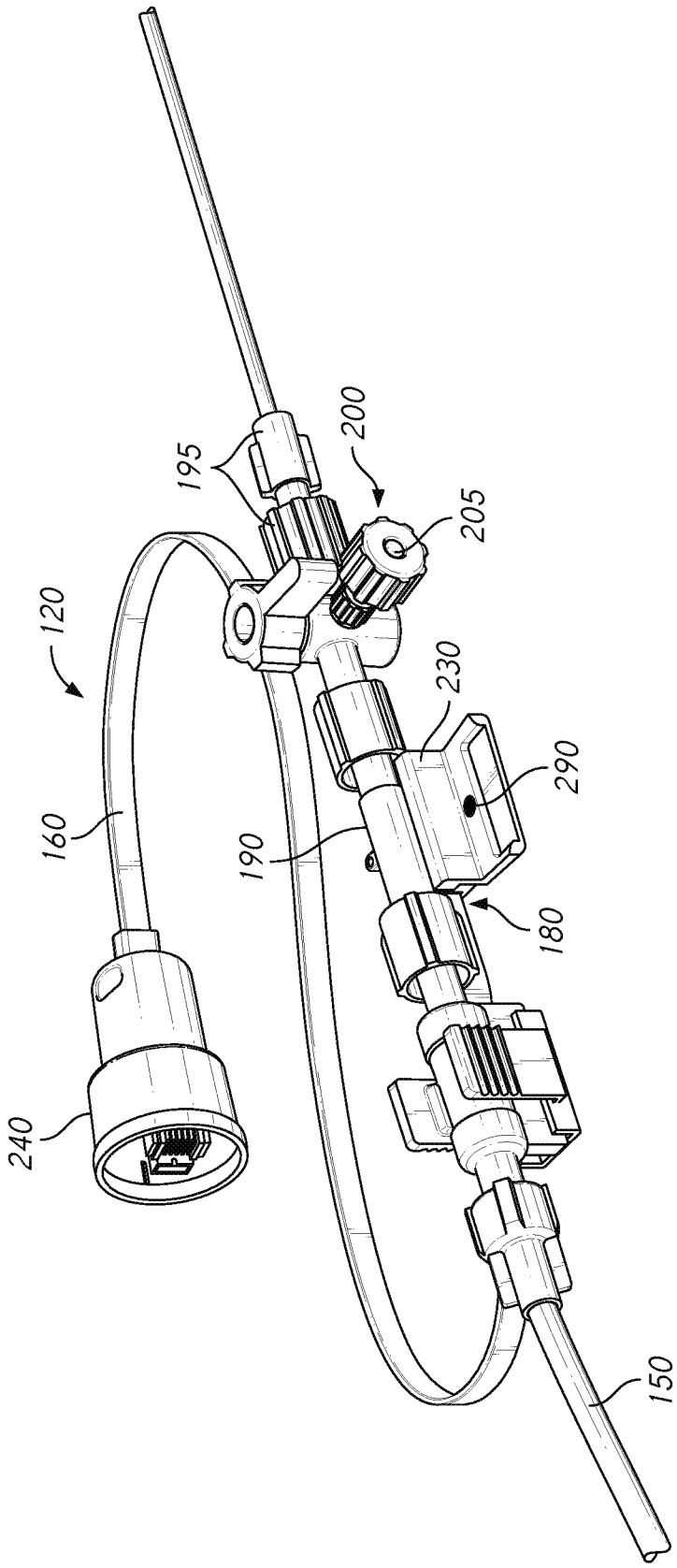

FIG. 3

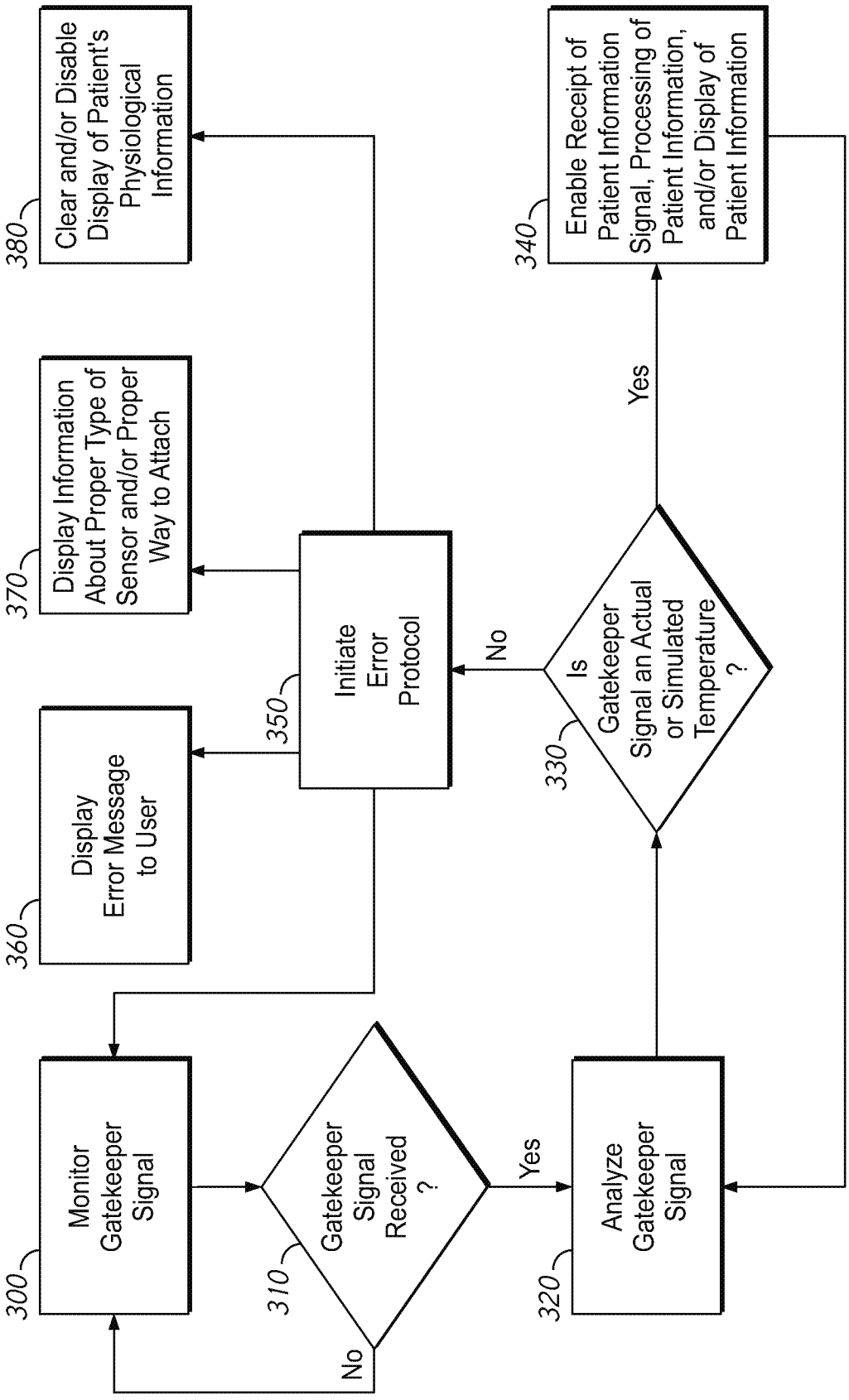
300
Monitor Gatekeeper Signal
310
Gatekeeper Signal Received ?
No
Yes
320
Analyze Gatekeeper Signal
330
Is Gatekeeper Signal an Actual or Simulated Temperature ?
No
Yes
340
Enable Receipt of Patient Information Signal, Processing of Patient Information, and/or Display of Patient Information
350
Initiate Error Protocol
360
Display Error Message to User
370
Display Information About Proper Type of Sensor and/or Proper Way to Attach
380
Clear and/or Disable Display of Patient's Physiological Information

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/017377

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/021 (2015.01)
CPC - A61B 5/021 (2015.04)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 5/00, 5/02, 5/021; A61M 5/00, 5/44; G06Q 50/00 (2015.01)
CPC - A61B 5/00, 5/02, 5/021; A61M 5/00, 5/44; G06Q 50/00 (2015.04) (keyword delimited)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 600/485; 604/113; 705/3

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

Orbit, Google Patents, Google Scholar
Search terms used: monitor, physiological monitor, blood vessel, pressure, pressure wave, sensor, temperature, processor, gatekeeper signal, attachment signal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2008/0221461 A1 (ZHOU et al) 11 September 2008 (11.09.2008) entire document	1-15
A	US 2012/0277673 A1 (LEVIN et al) 01 November 2012 (01.11.2012) entire document	1-15
A	US 2008/0235058 A1 (FRIEDMAN et al) 25 September 2008 (25.09.2008) entire document	1-15
A	US 2011/0208066 A1 (GNADINGER) 25 August 2011 (25.08.2011) entire document	1-15
A	US 2012/0203076 A1 (FATTA et al) 09 August 2012 (09.08.2012) entire document	1-15

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
28 April 2015	03 JUN 2015

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)