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(54) **PATIENT MONITOR CAPABLE OF MONITORING THE QUALITY OF ATTACHED PROBES AND ACCESSORIES**

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CPC ***A61B 5/14551*** (2013.01); *A61B 2560/028* (2013.01); *A61B 2560/0276* (2013.01); *A61B 2560/0285* (2013.01); *A61B 2562/08* (2013.01); *A61B 2562/226* (2013.01); *A61B 2562/227* (2013.01)

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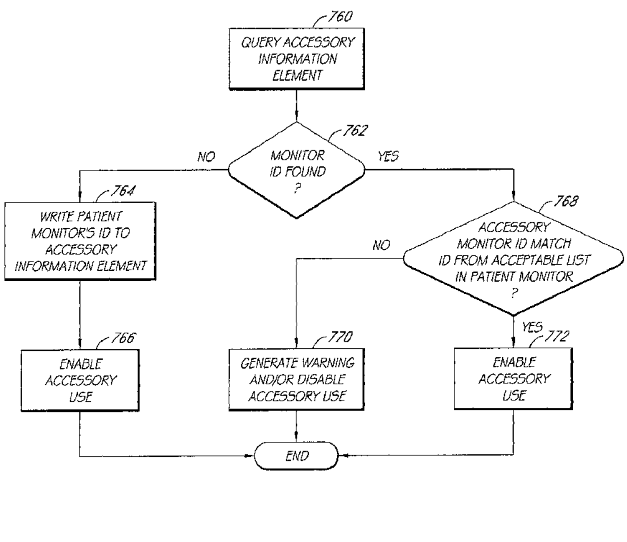
(57) **ABSTRACT**

A system and method to help maintain quality control and reduce cannibalization of accessories and attached probes in a highly sensitive patient monitor, such as a pulse oximetry system. One or more attached components may have information elements designed to designate what quality control mechanisms a patient monitor should look to find on that or another component or designate other components with which the one component may properly work. In a further embodiment, such information elements may also include data indicating the appropriate life of the component.

11 Claims, 7 Drawing Sheets



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See application file for complete search history.

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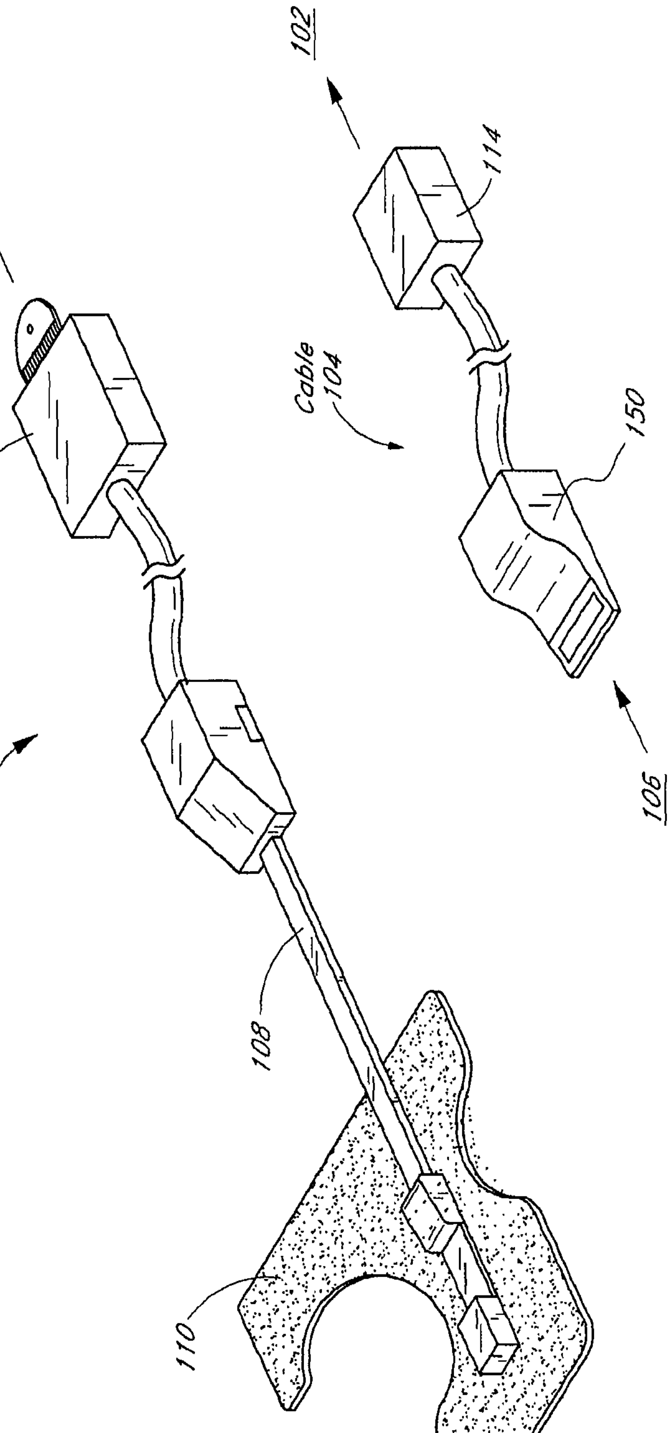
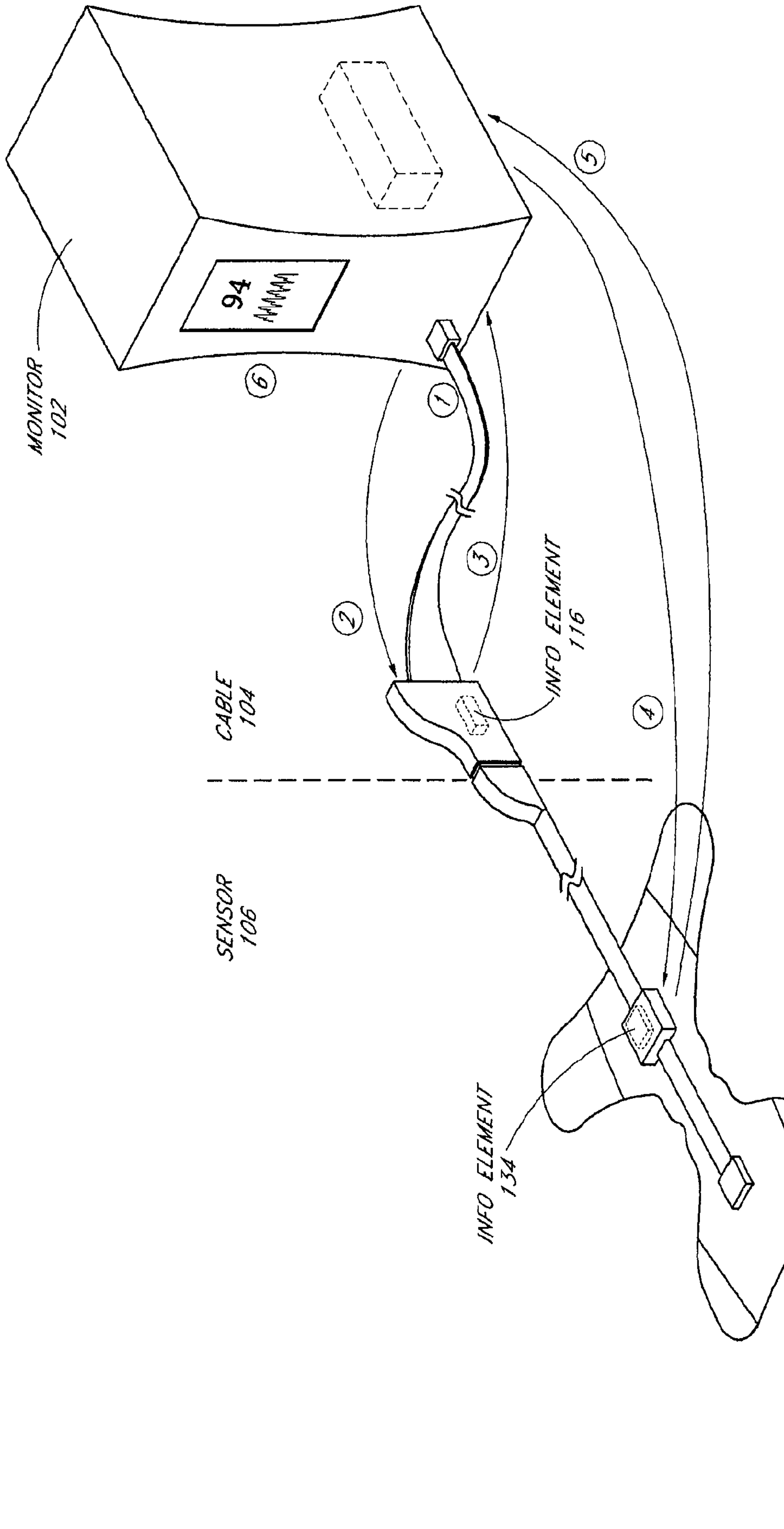


FIG. 1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102
94
1
2
3
4
5
6
CABLE
104
SENSOR
106
INFO ELEMENT
116
INFO ELEMENT
134

FIG. 1B

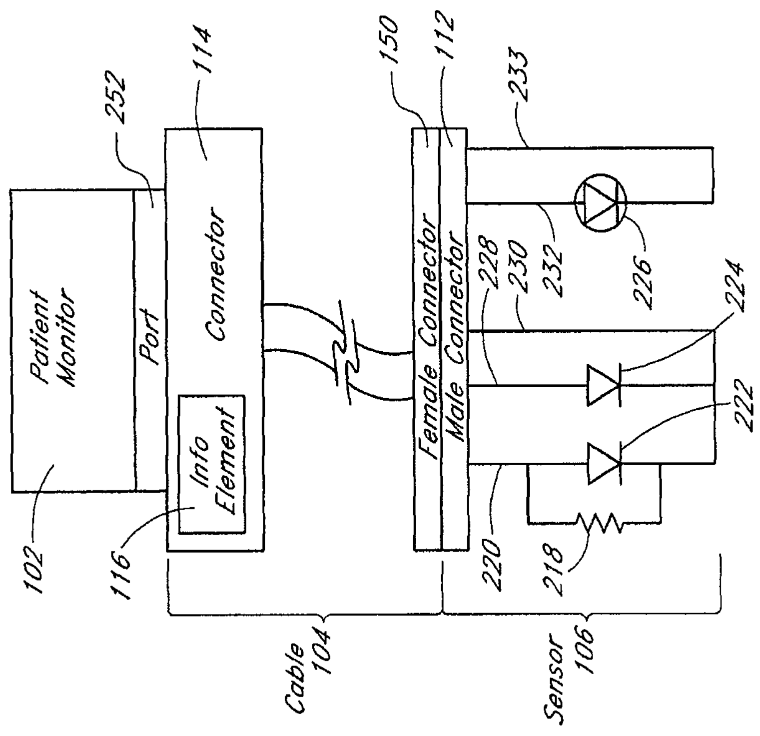

Patient Monitor
Port
Connector
Info Element
Female Connector
Male Connector
Cable 104
Sensor 106
102
116
252
114
150
112
233
232
230
228
226
224
222
220
218

FIG. 2

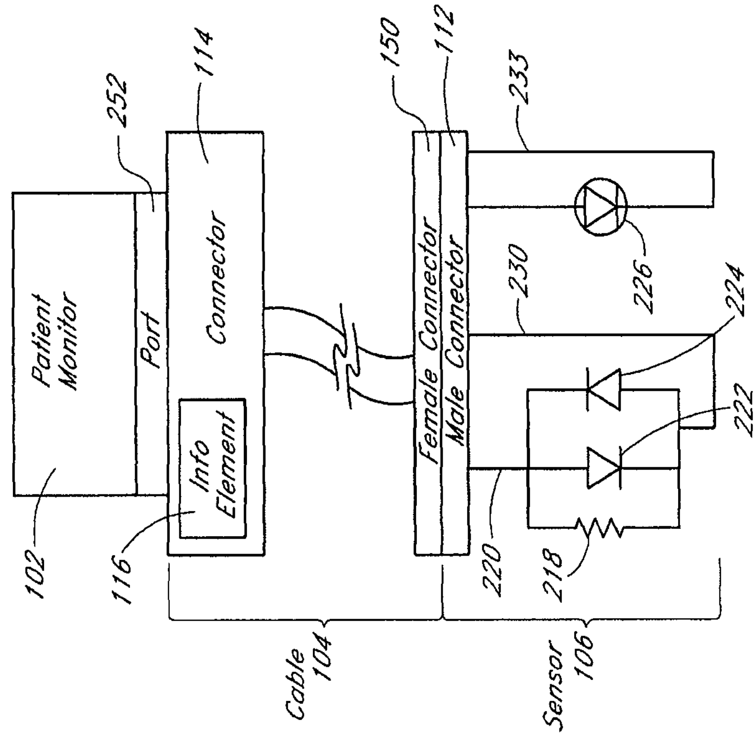
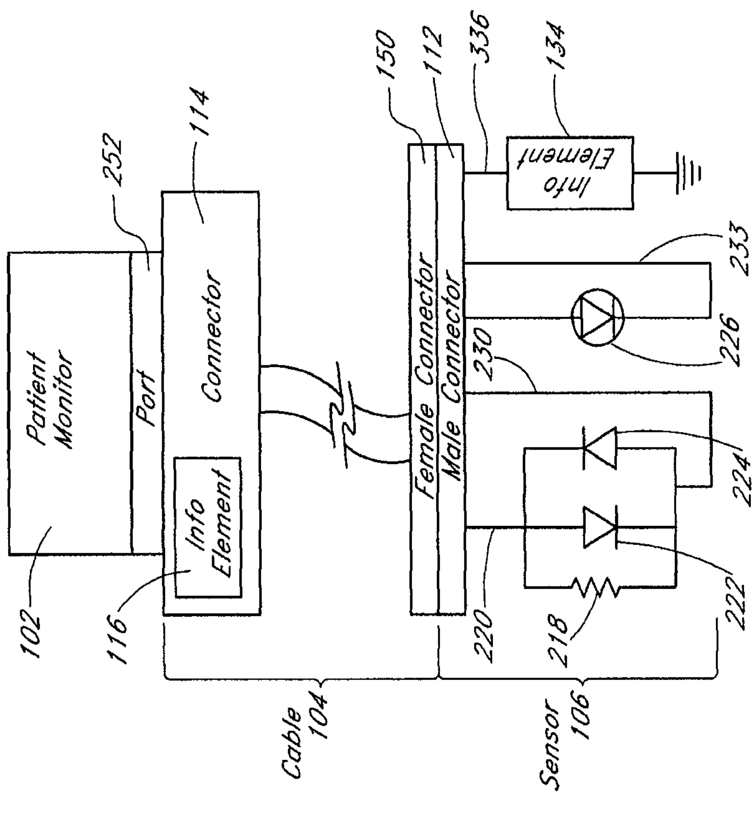

Patient Monitor
Port
Connector
Info Element
Female Connector
Male Connector
Cable 104
Sensor 106
102
116
252
114
150
112
233
230
226
224
222
220
218

FIG. 2A

FIG. 3


Patient Monitor
Port
Connector
Info Element
Female Connector
Male Connector
Info Element
Cable 104
Sensor 106
102
116
252
114
150
112
336
134
233
226
230
224
220
218
222

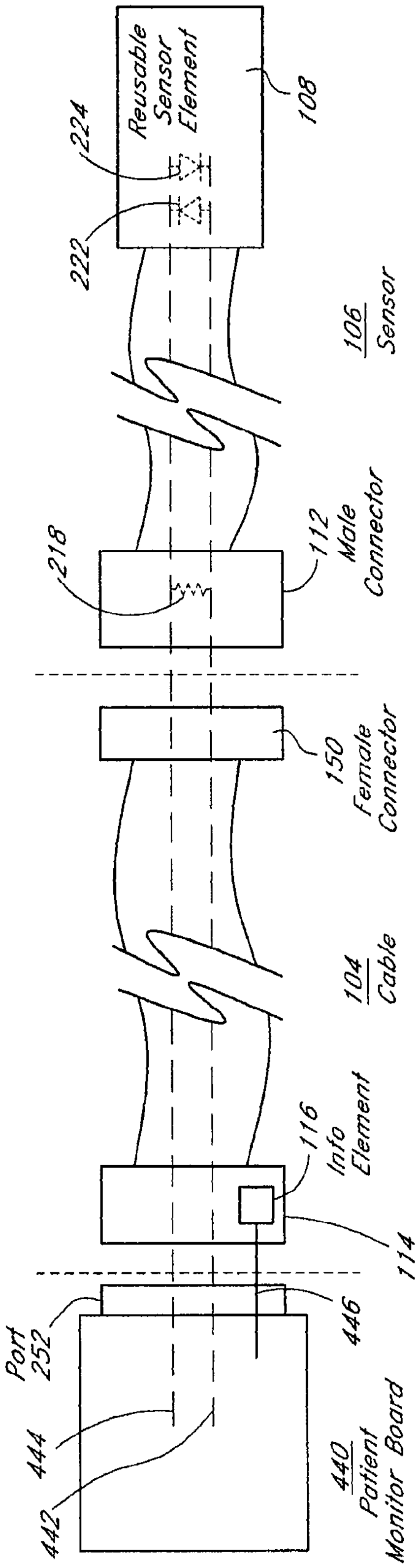

Reusable Sensor Element
108
222
224
106 Sensor
218
112 Male Connector
150 Female Connector
104 Cable
116 Info Element
114 Connector
Port 252
446
444
442
440 Patient Monitor Board

FIG. 4

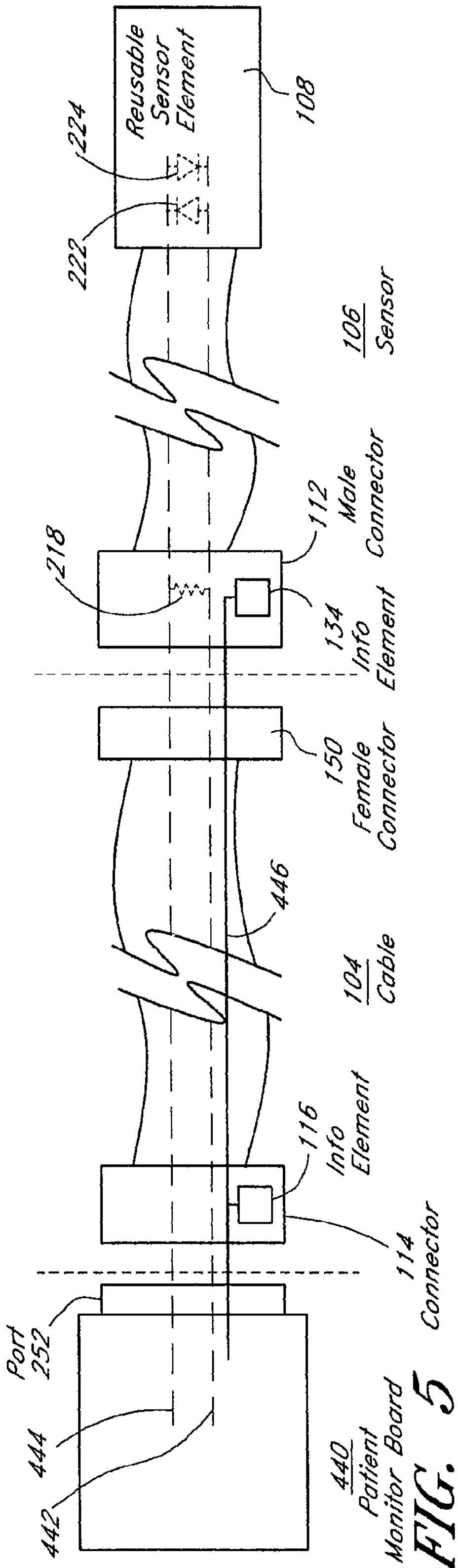

Reusable Sensor Element
108
222
224
106 Sensor
218
112 Male Connector
134 Info Element
150 Female Connector
446
104 Cable
116 Info Element
114 Connector
Port 252
444
442
440 Patient Monitor Board

FIG. 5

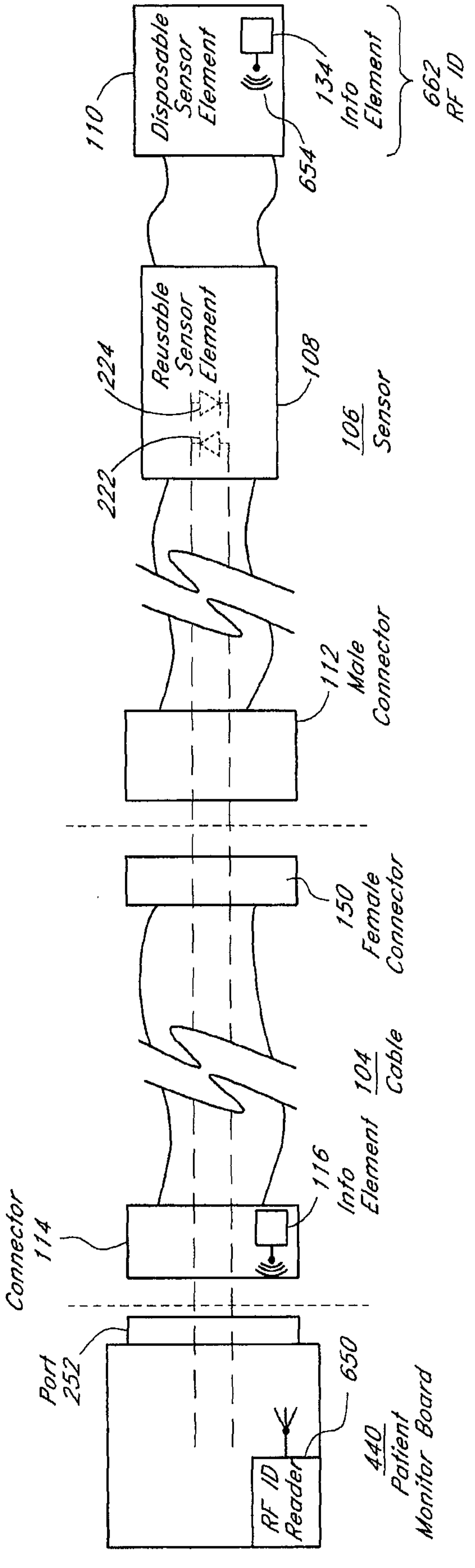

110
Disposable Sensor Element
134
Info Element
654
662
RF ID
224
Reusable Sensor Element
222
108
106
Sensor
112
Male Connector
150
Female Connector
104
Cable
116
Info Element
Connector
114
Port
252
650
RF ID Reader
440
Patient Monitor Board

FIG. 6

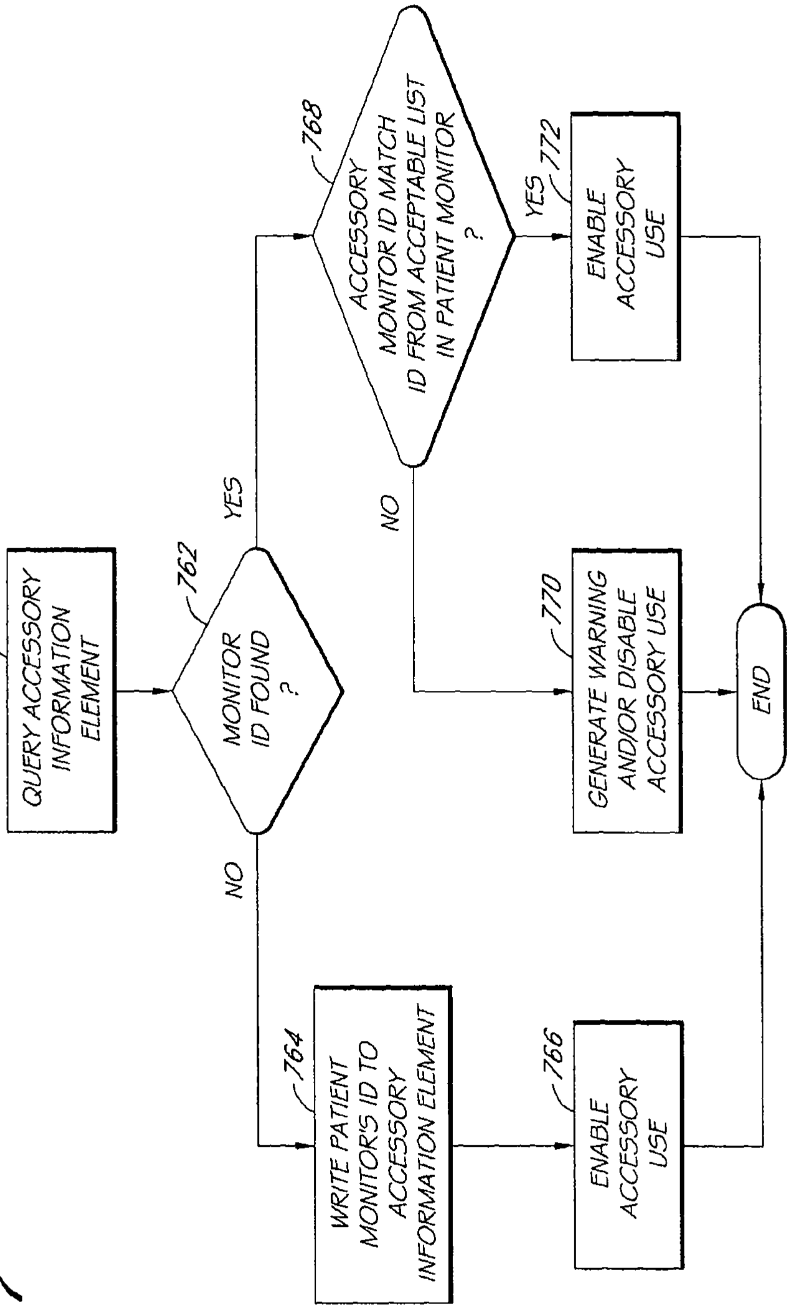

760
QUERY ACCESSORY INFORMATION ELEMENT
762
MONITOR ID FOUND ?
YES
NO
764
WRITE PATIENT MONITOR'S ID TO ACCESSORY INFORMATION ELEMENT
766
ENABLE ACCESSORY USE
768
ACCESSORY MONITOR ID MATCH ID FROM ACCEPTABLE LIST IN PATIENT MONITOR ?
YES
NO
770
GENERATE WARNING AND/OR DISABLE ACCESSORY USE
772
ENABLE ACCESSORY USE
END

FIG. 7

PATIENT MONITOR CAPABLE OF MONITORING THE QUALITY OF ATTACHED PROBES AND ACCESSORIES

PRIORITY CLAIM

This application is a continuation of U.S. application Ser. No. 11/871,817, filed Oct. 12, 2007, entitled "Patient Monitor Capable of Monitoring the Quality of Attached Probes and Accessories", which claims priority to U.S. Provisional Application No. 60/851,788, titled "Patient Monitor Capable of Monitoring the Quality of Attached Probes and Accessories" and filed on Oct. 12, 2006, the disclosure of which is incorporated herein by reference.

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is related to U.S. patent application Ser. No. 11/640,077, filed on Dec. 12, 2006, which is a continuation of U.S. patent application Ser. No. 10/757,279, filed on Jan. 13, 2004, which is a continuation of Ser. No. 10/005,711, filed on Nov. 8, 2001, now U.S. Pat. No. 6,678,543, which is a continuation of U.S. patent application Ser. No. 09/451,151, filed on Nov. 30, 1999, now U.S. Pat. No. 6,397,091, which is a continuation of U.S. patent application Ser. No. 09/016,924, filed on Feb. 2, 1998, now U.S. Pat. No. 6,011,986, which is a continuation of U.S. patent application Ser. No. 08/478,493, filed on Jun. 7, 1995, now U.S. Pat. No. 5,758,644, as well as U.S. patent application Ser. No. 08/745,474, filed on Nov. 12, 1996, now U.S. Pat. No. 5,823,950, which is a divisional of U.S. U.S. patent application Ser. No. 08/478,493, filed on Jun. 7, 1995, now U.S. Pat. No. 5,758,644. The present application incorporates the foregoing disclosures herein by reference.

BACKGROUND OF THE DISCLOSURE

Field of the Disclosure

The present disclosure relates in general to noninvasive patient monitoring systems, including oximeters and co-oximeters, and their accessories such as sensors or cables. In particular, this disclosure relates to patient monitors capable of monitoring the quality of attached accessories.

Description of the Related Art

Patient monitoring of various physiological parameters of a patient is important to a wide range of medical applications. Oximetry is one of the techniques that has developed to accomplish the monitoring of some of these physiological characteristics. It was developed to study and to measure, among other things, the oxygen status of blood. Pulse oximetry—a noninvasive, widely accepted form of oximetry—relies on a sensor attached externally to a patient to output signals indicative of various physiological parameters, such as a patient's constituents or analytes, including for example a percent value for arterial oxygen saturation, carbon monoxide saturation, methenoglobin saturation, fractional saturations, total hematocrit, billirubins, perfusion quality, or the like

A pulse oximeter sensor generally includes one or more energy emission devices, such as specific wavelength emitting LEDs, and one or more energy detection devices. The sensor is generally attached to a measurement site such as a patient's finger, toe, ear, ankle, or the like. An attachment mechanism positions the emitters and detector proximal to the measurement site such that the emitters project energy into the tissue, blood vessels and capillaries of the measurement site, which in turn attenuate the energy. The detector then detects that attenuated energy. The detector communicates at least one signal indicative of the detected attenuated energy to a signal processing device such as an oximeter, generally through cabling attaching the sensor to the oximeter. The oximeter generally calculates, among other things, one or more physiological parameters of the measurement site. In some oximeter systems, specific-valued resistors in the attached sensor provide the signal processing device specific wavelength ("k") information for the emitters of the sensor. For example, oximeters that capture k information are disclosed in U.S. Pat. No. 4,621,643, entitled "Calibrated Optical Oximeter Probe" and awarded to New, Jr. et al. on Nov. 11, 1986, and U.S. Pat. No. 4,700,708, entitled "Calibrated Optical Oximeter Probe" and awarded to New, Jr. et al. on Oct. 20, 1987.

Patient monitors, generally, and oximeter systems specifically are often highly sensitive instruments. This is especially the case in oximeter systems capable of determining physiological parameters during patient motion, such as those commercially available from Masimo Corporation of Irvine, Calif., and disclosed generally in U.S. Pat. No. 6,263,222, entitled "Signal Processing Apparatus," and U.S. Pat. No. 6,157,850, also entitled "Signal Processing Apparatus," U.S. application Ser. No. 09/491,175, entitled "Universal/Upgrading Pulse Oximeter," and the like, each of which is incorporated herein by reference. The manufacturers of such oximeter systems incorporate into their signal processing algorithms an expectation of a certain type and quality of electronic components in the cabling and sensors. Often the results produced by the signal processing, such as, for example, the output values of various monitored physiological parameters of the patient, are at least somewhat dependent upon receipt of signals from quality electronic components. Thus, many manufacturers carefully control and manage the type and quality of their sensors and accessories.

However, when other sensor manufacturers lure caregivers into purchasing "compatible" sensors, the oximeter manufacturer loses the ability to control the type and quality of the electronic components, the accuracy of their attachment/placement mechanisms, and the like. This is especially problematic with knock-off accessories that attempt to standardize sensor components across differing manufacturers' oximeter systems. For this reason, oximeter manufactures began using the foregoing resistors also as quality control security devices. For example, some oximeter systems look for specific-valued resistors within the circuitry of their sensors, such as, for example, those resistors disclosed in patents entitled "Manual and Automatic Probe Calibration:" U.S. Pat. No. 5,758,644, awarded to Diab et al. on Jun. 2, 1998; U.S. Pat. No. 6,011,986, awarded to Diab et al. on Jan. 4, 2000; and U.S. Pat. No. 6,397,091, awarded to Diab et al. on May 28, 2002. Although such resistor mechanisms improved manufacturer's quality control, some knock off sensor manufactures unfortunately began copying or otherwise scavenging quality control devices from, for example, expired or authorized sensors, thus defeating the quality control device of the original oximeter manufacturer.

Additionally upgrades to patient monitor algorithms and specifications may be made with the expectation that accessories with different optics, higher fidelity, different specifications or the like will be used. A quality check in such an instance can help to ensure that any upgraded algorithms produce more accurate results.

SUMMARY OF THE DISCLOSURE

Based on at least the foregoing, there is a need to provide oximetry systems capable of monitoring the quality of attached optical probes and accessories, while reducing the ability of unscrupulous sensor manufacturers to defeat such quality controls. Accordingly, one aspect of the present disclosure is a patient monitoring system for maintaining quality control while reducing a likelihood of defeat of that quality control, through, for example, cannibalization of quality control devices from used and possibly damaged authorized sensors. According to an embodiment of the disclosure, an oximetry system includes an oximeter, a sensor, and a connecting cable to connect the sensor to the oximeter. In an embodiment, the cable includes an information element capable of storing information. The cable's information element could be provided through an active circuit such as a transistor network, memory chip, EEPROM (electronically erasable programmable read-only memory), EPROM (erasable programmable read-only memory), or other identification device, such as multi-contact single wire memory devices or other devices, such as those commercially available from Dallas Semiconductor or the like. In an embodiment, the oximeter accesses the information stored on the information element of the cable to determine whether the cable is an authorized cable.

In an embodiment, the oximeter may use the information stored on the cable information element to determine a type of quality control device expected on an attached sensor. For example, one type of information may advantageously instruct the oximeter to look for a quality control device comprising a sensor identifier, for example, a resistor of a specified value on the sensor. Another type of information may advantageously instruct the oximeter to look for a different quality control device comprising, for example, a sensor information element storing additional identifying information. In the event that the oximeter fails to find one or more of the information element on the cable and the quality control device(s) on the sensor, the oximeter may take one or more remedial actions, such as, for example, activating audio or visual alarms, combinations of the same, or the like. In an embodiment, the oximeter may display an alarm message such as "unrecognized sensor," "unauthorized sensor" "unrecognized cable," "unauthorized cable," or the like.

Another aspect of the present disclosure is a method for testing a sensor. The method comprises obtaining first information from a first information element, outputting a signal to the sensor based on the first information, receiving one or more responses from the sensor, and determining whether the one or more responses from the sensor indicate the sensor comprises an authorized sensor.

In yet other embodiments, encryption algorithms may advantageously encrypt information stored on one or more of the various information elements and/or encrypt the communication to and from the oximeter. A skilled artisan will recognize from the disclosure herein that a wide variety of simple or complex encryption algorithms, paradigms, methodologies, or a combination of the same could be used to further inhibit copyist sensor manufacturers attempting to produce "compatible" sensors outside the quality control of the oximeter provider. Examples can include the use of translation tables, symmetric or asymmetric key-based encryption methods, or many other encryption techniques or combinations known to an artisan of ordinary skill.

In yet a further embodiment, the oximeter may further store information regarding the useful and safe life of electrical components of, for example, the sensor, the cabling, or the like. For example, the amount of use of a particular component may advantageously be tracked to reduce overuse of that component. Monitoring of overuse is

especially advantageous in reusable technologies, and may be accomplished, for example, as disclosed in U.S. Pat. No. 6,515,273 entitled "System for Indicating the Expiration of the Useful Operating Life of a Pulse Oximetry Sensor," awarded to Al-Ali, owned by the assignee of the present disclosure and incorporated herein by reference. In such systems, the oximeter systems may advantageously be capable of identifying source-indicating elements in an attached cabling and/or sensor, and how long various sensor elements have been in use. Thus, should an unauthorized sensor manufacturer manage to scavenge some or all of the identifying parts of a used sensor according to this embodiment, the useful life measurement may advantageously significantly reduce any extended use of any cannibalized sensor. For example, in some embodiments, the useful life of electronic components of a sensor may be measured in weeks of use, thereby significantly limiting the value of scavenged components to knock-off sensor manufacturers. Reduction of scavenged value advantageously increases the ability of sensor manufacturers to control the quality of sensor components and oximeter accessories.

In addition, in another embodiment, attached accessories, such as cabling and/or sensors, may have an information element that can store data from an oximeter or other patient monitor. In such an embodiment, each oximeter or patient monitor has a software ID. When an accessory is attached, the monitor looks to see if any monitor has written to the accessory's information element. If not, in an embodiment, the monitor stores its software ID on the accessory. In a possible embodiment, use of an accessory which has had a monitor ID written to it may only be enabled if the accessory is attached to the monitor having the same ID or some defined set of monitors having software IDs in a specific set that includes the monitor ID written to it.

Yet another embodiment may utilize similar principles in controlling the upgrading of patient monitors. In an embodiment, a patient monitor is capable of monitoring a wide array of patient parameters, but the monitoring of individual parameters may be enabled or disabled based on the parameter monitoring licensed to the user. It will be advantageous to allow changes to the enabled parameters without returning the patient monitor to the manufacturer. In an embodiment, this may be done by connecting an upgrade tool much like any other accessory discussed herein. In an embodiment, the ability to upgrade a given patient monitor is dependent on an ID on the upgrade tool matching or corresponding to an allowed monitor ID.

For purposes of summarizing the disclosure, certain aspects, advantages and novel features of the disclosure have been described herein. Of course, it is to be understood that not necessarily all such aspects, advantages or features will be embodied in any particular embodiment of the disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings and the associated descriptions are provided to illustrate embodiments of the present disclosure and do not limit the scope of the claims.

FIG. **1** illustrates a perspective view of a typical sensor including reusable and disposable elements, and a typical cable.

FIG. **1**B illustrates the signal flow of an embodiment of a method of utilizing quality control elements to monitor authorized accessories according to this disclosure.

FIG. **2** illustrates an exemplary block diagram of an oximetry system including quality control devices, according to an embodiment of the disclosure.

FIG. 2A illustrates another exemplary block diagram of an oximetry system including quality control devices, according to an embodiment of the disclosure.

FIG. 3 illustrates another exemplary block diagram of an oximetry system including quality control devices, according to an embodiment of the disclosure.

FIG. 4 illustrates an exemplary block diagram of an oximetry system including quality control devices, according to an embodiment of the disclosure.

FIG. 5 illustrates an exemplary block diagram of an oximetry system including quality control devices, according to an embodiment of the disclosure.

FIG. 6 illustrates an exemplary block diagram of an oximetry system including quality control devices utilizing wireless identification technology.

FIG. 7 illustrates a flow chart of an embodiment of a method utilizing quality control elements to enforce a site license.

DETAILED DESCRIPTION

The present disclosure has applicability to medical probes in general and is directed toward patient monitors, cabling, sensors, and the like. As discussed above, a patient monitor comprises signal processing capable of monitoring whether a caregiver or user is attaching authorized cabling and/or sensors. Such quality control systems aid monitor manufacturers in ensuring that caregivers such as doctors obtain accurate data from patient monitors used in applications from general ward, athletic, or personal monitoring to surgical and other potentially life-threatening environments, to any other use of noninvasive monitoring of patient physiologies. Although the present disclosure is applicable to many different types of patient monitors, some of this discussion will focus on pulse oximeters, as representative embodiments only.

In general, a patient monitor may advantageously read a first information element on a first accessory to obtain first quality control information. The first information may advantageously allow the signal processor to identify the first accessory, such as a cable, as an authorized cable. In an embodiment, the patient monitor may advantageously read a second information element on a second accessory to obtain second quality control information. In an embodiment, the first information element provides an indication of what the second quality control information should be. When the first and second information correlates, the patient monitor can be more assured of the quality of the attached accessories. On the other hand, when there is a mismatch, various remedial measures may be taken, including displaying a message of one or more unauthorized accessories, actuating an indicator light on one or more of the accessories, or other audible or visual indications of the mismatch.

For example, in an embodiment, a signal processor of a patient monitor communicates with a first information element associated with a first accessory, and uses the information stored or coded therein to determine a type of information such as a resistance value, expected to be stored or coded into a second information element associated with a second accessory. Specifically, the information gained from the first accessory, such as a cable, may provide specific resistance value(s) or range of values expected on the second accessory, such as a sensor. Such resistance values may be found in parallel with one or more emitters (such as for example, those disclosed in the foregoing '644 patent) or on separate conductors (such as, for example, those disclosed in the foregoing '643 patent). In other embodiments, the information gained from the first accessory provides information usable to access the second information element. Communication with the second information element on the second accessory advantageously provides the specific resistance value(s) or range of values expected on the sensor.

In another embodiment, the patient monitor may advantageously additionally acquire information indicative of the lifespan, amount of use, or age of one or more accessories, including the cable and/or the sensor. In an embodiment, if the patient monitor determines that one or more accessories have expired, it will inform the user with an appropriate audio or visual message.

Much of this discussion utilizes pulse oximeters and oximeter cable and sensor accessories in explaining the disclosure and for ease of understanding. However, the disclosure herein is not limited thereby. Patient monitors other than oximeters may similarly utilize the ideas disclosed. Similarly, labeling the first and second accessories as a cable and sensor more clearly differentiate the two accessories; however, a skilled artisan will recognize, from the disclosure herein, a wide range of uses of cascading security devices for linked or nonlinked monitor accessories.

To facilitate a complete understanding of the disclosure, the remainder of the detailed description describes the disclosure with reference to the drawings. Corresponding numbers indicate corresponding parts, and the leading digit of any number indicates the figure in which that element is first shown.

FIG. 1 shows sensor and cable elements of an oximeter system as is generally known in the prior art. The system comprises cable **104** connecting sensor **106** to an oximeter **102** (not shown). As shown here, the sensor **106** includes a reusable portion **108**, generally including expensive electronics, and a disposable portion **110**, generally including positioning mechanisms such as tape. Male connection housing **112** at one end of sensor **106** connects sensor **106** to female cable connection **150** of cable **104**. The operation and construction of reusable and disposable sensors is disclosed in U.S. Pat. No. 6,920,345 entitled "Optical Sensor Including Disposable and Reusable Elements" awarded to Al-Ali and owned by the assignee of the present disclosure, the full disclosure of which is incorporated herein by reference. Other disclosure may be found in U.S. Application No. 60/740,541, filed Nov. 29, 2005, also entitled "Optical Sensor Including Disposable and Reusable Elements," incorporated herein by reference.

FIG. 1B illustrates a patient monitor **102** and attached accessories in accordance with an embodiment of the disclosure. Specifically, cable **104** and sensor **106** each include an information element housed within them (cable information element **116** and second sensor information element **134**, respectively). The placement of these information elements need not be as shown in the figure, as will be described in more detail below. FIG. 1B also illustrates the signal flow of an embodiment of a process for controlling the quality of attached accessories. First, the quality control process may be initiated when one or more new accessories are attached to the monitor **102**; similarly, the process may initiate when a monitor is turned on. Recognizing that an accessory is attached, the monitor searches for cable information element **116** (step **2**). The information element **116** then returns a cable authentication code, which may be used by the monitor to determine that the cable **104** is a quality, authorized cable (step **3**). Based on the cable authentication code, the monitor **102** then searches for a specific sensor information element **134** (step **4**). If the correct type of information element is found, the monitor retrieves a sensor authorization code (step **5**). The monitor can then compare the cable authorization code and the sensor authorization code to determine whether the cable **104** and sensor **106** are matching, quality accessories. If the codes do correlate, the monitor may enable the system for monitoring of a patient (step **6**).

FIGS. **2** and **2**A show a block diagram of embodiments of oximeter systems including improved security technologies. Oximeter **102** uses port **252** to connect to cable **104** at connector **114**. Cable **104** in turn uses cable connector **150** to connect to sensor **106** at connection housing **112**. Cable **104** includes an information element **116**, which may be located anywhere therein, but is pictured in the figures in port connector **114**. Cable information element **116** is preferably an EEPROM with encrypted data. In an embodiment, sensor **106** includes LEDs **222** and **224**. The first LED **222** has a first corresponding electrical connection **220**; the second LED **224** has a second corresponding electrical connection **228**; and the photodetector **226** has a corresponding electrical connection **232**. In the configuration shown in FIG. **2**, the LEDs **222**, **224** are connected at their outputs to a common ground electrical connection **230**; however, other configurations may advantageously be implemented, such as, for example back-to-back (see FIG. **2**A), anode, cathode, common anode, common cathode, or the like. The photodetector **226** is connected to an electrical connection **233**. In accordance with this aspect of the present disclosure, one of the LED electrical connections **220** can also be used for a first sensor information element **218**—placing first sensor information element **218** in parallel with one of LEDs **222**, **224**. In an embodiment, first sensor information element may comprise a coding resistor or other passive element.

According to an embodiment, Oximeter **102** may communicate with cable information element **116** which returns data to oximeter **102**. In at least an embodiment such data may be encrypted, and oximeter **102** is able to decrypt the information. In an embodiment, the information designates additional information that oximeter **102** may read from attached sensor **106**, generally from first sensor information element **218**. The value of the first sensor information element **218** and/or its placement across an LED may be used to help indicate that the probe is configured properly for the oximeter. The first sensor information element **218** may be utilized to indicate that the probe is from an authorized supplier such as a "Masimo" standard probe, "Patient Monitoring Company **1**" probe, "Patient Monitoring Company **2**" probe, etc. In another embodiment, the first sensor information element **218** may be used to indicate LED wavelengths for the sensor or other parameters of the sensor **106**.

In an embodiment, reading of the first sensor information element **218** may advantageously be accomplished according to the disclosure of U.S. Pat. No. 6,397,091, entitled "Manual and automatic probe calibration," awarded to Diab and owned by the assignees of the present disclosure, incorporated herein by reference.

In addition, it should be noted that the cable information element or first sensor information element need not be passive elements. Coding information could also be provided through an active circuit such as a transistor network, memory chip, or other identification device, for instance Dallas Semiconductor DS 1990 or DS 2401 or other automatic identification chip. It is also possible to place the first sensor information element **218** in series or in parallel with one of the LEDs **222**, **224** or with the photodetector **226** on transmission line **233** or place the first sensor information element **218** apart from all of the LEDs **222**, **224** and photodetector **226** on its own transmission lines. Other placements of the first sensor information element **218** would also be obvious to one of ordinary skill in the art, so long as the coded value or other data from first sensor information element **218** can be determined by oximeter **102**.

Another embodiment of an oximeter system having improved security technologies is shown in FIG. **3**. In embodiments such as pictured in FIG. **3**, sensor **106** of the oximeter system additionally has a second sensor information element **134**. In a preferred embodiment, second sensor information element **134** is an EEPROM with encrypted data, but it may be any of a wide variety of active or passive solutions discussed in relation to first sensor information element and/or cable information element. The second sensor information element **134** is attached to the sensor through line **336**. Line **336** may preferably be a serial cable or other type of cable that allows two-way transfer of data. In such an embodiment, cable information element **116** of the cable may provide information to oximeter **102** that indicates both a first sensor information element **218** and a second sensor information element **134** should be found and provide information to the oximeter **102**. Second sensor information element **134** may then provide data, encrypted or not, to oximeter **102**, such that the data indicates to oximeter **102** information about coding values of, or other data stored on, first sensor information element **218**. Oximeter **102** may then obtain and compare the information from first sensor information element **218** and second sensor information element **134** to determine the security and reliability of sensor **106**. If the elements do not correctly designate a single approved sensor, an audible and/or visual warning may be triggered. The addition of this second information element may serve to tie various portions of a single accessory, such as a sensor, together, thereby making it more difficult for a knock off manufacturer to scavenge parts, particularly if the parts are discarded separately. Alternatively, information from the cable information element **116** may indicate that an attached oximeter **102** should look for second sensor information element **134**. Information contained in second information element **134** may then indicate whether or not a first sensor information element **218** is present and/or what data should be included thereon to indicate an authorized sensor.

In various embodiments, second sensor information element **134** may advantageously store some or all of a wide variety of information, including, for example, sensor type designation, patient information, sensor characteristics, software such as scripts or executable code, oximeter or algorithm upgrade information, or many other types of data. In a preferred embodiment, the second sensor information element **134** may also store useful life data indicating whether some or all sensor components have expired and should be replaced. In such an embodiment, the oximeter **102** may compare the information it received from first sensor information element **218** and second sensor information element **134** as before. Further it may also help aid in determining that sensor elements have not been used longer than their useful life based on the life data retrieved from second sensor information element **134**. In such an embodiment, the oximeter **102** may also produce an audible or visual alarm if sensor life data from second sensor information element **134** indicates that some or all of sensor **106**'s components are out of date.

Similarly cable information element **116** may also include useful life data. This data can be used by oximeter **102** to help reduce the risk that cable **104** might be used longer than its safe life.

At least some embodiments including second information element **134** may include further protection against cannibalization of parts. Once a sensor including second information element **134** is attached and authorized, the LEDs should be immediately accessible for measurement by the patient monitor **102**. In an embodiment, if at any time the second information element **134** is accessible but the LEDs are not, the patient monitor **102** may trigger an alert or an alarm and/or may disable the use of the component including the second information element **134**. This may help to provide additional quality control protection because if the first and second information elements **218**, **134** are cannibalized from old sensors, they are often placed in a generic cable or generic sensor adaptor. This generic adaptor often remains connected while generic sensors are replaced.

FIG. **4** illustrates one potential general layout of the first sensor information element **218**, cable information element **116**, and LEDs **222**, **224**. In such an embodiment, oximeter board **440** is the portion of the oximeter **102** that communicates with the cable **104** and sensor **106**. In an embodiment, oximeter board **440** may preferably communicate with cable information element **116** via a serial transmission line **446**. In FIG. **4**, cable information element **116** is located in port connector **114** of the cable **104** in this embodiment. Once oximeter board **440** determines that it is connected to cable **104** providing information indicating that it should look for first sensor information element **218**, it sends and receives signals down and from transmission lines **442**, **444**. Transmission lines **442**, **444** pass the length of cable **104** into sensor **106** where first sensor information element **218** and LEDs **222**, **224** are connected in parallel as described in more detail with respect to FIG. 2A.

FIG. **4** shows a possible distribution of the first sensor information element **218** and LEDs **222**, **224** in the sensor. In the embodiment shown, first sensor information element **218** is located in the connection housing **112** where space is generally more readily available (as it is generally desirable to keep the sensor volume near the LED emitters **222**, **224** and photodetector **226** as low as possible). Other placements for the elements, such as the first sensor information element **218** and LEDs **222**, **224** on sensor **106**, are also contemplated by this disclosure. Those of ordinary skill in the art would know that first sensor information element **218**, for example, could be located anywhere in the sensor **106** or on separate transmission lines from those connecting the LEDs **222**, **224** to the oximeter board **440**.

FIG. **5** illustrates an embodiment of the layout for the cable **104** whose cable information element **116** indicates that a first sensor information element **218** and a second sensor information element **134** should be found in the sensor. In an embodiment, serial transmission line **446** connects the oximeter board **440** to the cable information element **116** as above. However, serial transmission line **446** also runs the length of cable **104** and connects to second sensor information element **134** located in sensor **106** in a multi-drop memory configuration. Oximeter board **440** may access cable information element **116** and second sensor information element **134** while running generally few transmission lines. If cable **104** is connected to a sensor **106** that does not have second sensor information element **134**, the oximeter board **440** may advantageously determine that the sensor is unauthorized and also advantageously may not enable the sensor. The rest of the circuits (i.e. transmission lines **442**, **444**; first sensor information element **218**; and LEDs **222**, **224**) are the same as in FIG. **4**.

It is to be noted that FIGS. **4** and **5** are representative embodiments only. These figures are not meant to be read as the exact or only possible locations of the elements discussed. For example, first sensor information element **218** and/or second information element **134** may or may not be located in the same portion of the sensor. One or both or neither may be placed in or near the connection housing **112**. It is also possible for them to be at other positions in the sensor. The roles of each may also be switched with either one or both containing information about data stored on the other. The numbering and discussion of the information elements is merely for ease of reference. It is also important to know that functionality of serial transmission line **446**, as well as transmission lines **442**, **444**, may be accomplished through other means, such as, for example, public or private communications networks or computing systems, or various wired or wireless communications.

Requirement Tables

In an embodiment, an information element **116** includes data allowing the connection of both types of sensors depicted in FIG. **2** and FIG. **3**. Thus, either a sensor **106** with only first information element **218** or one with both first information element **218** and second information element **134** could be connected as authorized sensors. In an embodiment, cable information element **116** may include a sensor requirement table as illustrated in Table 1 below. A sensor requirement table may list different types of attachable accessories (such as the sensors generally discussed) and designate which version of such sensors can be authorized. This may be accomplished through a single bit for each type. For example, as shown in Table 1, cable information element **116** may include a table with a list of bits designating whether or not an attached sensor must have a second information element **134**—here a 1 indicates the second information element **134** is required, while a 0 indicates an attached accessory may have either the first information element **218** or both information elements. As shown in this example, disposable sensors must include the second information element **134**, but reusable or combination sensors may include one or both sensor information elements. Any of a number of sensor or other accessories may be allowed or disallowed in such a manner. It is understood that the first sensor information element **218** must be capable of identifying the type of sensor that it is a part of for comparison to the requirement table, in such an embodiment.

TABLE 1

Disposable	1
Reusable	0
Combination	0
Adult	1
Neonatal	0
. . .	. . .
Override	0

Furthermore, in an embodiment, the requirement table may include an override bit or entry. The override bit preferably allows the attachment of both kinds of accessories for all types, regardless of the current values listed in the rest of the table. In such an embodiment, the override bit may allow diagnostics, testing, and the like without having to separately keep track of or lose the settings for the various accessory types. Those of skill in the art will understand from this disclosure that the requirement table functionality may be implemented in a number of ways. For example, the table may be stored in an accessory information element, such as cable information element **116**, may be included in the monitor **102**, and the like. Additionally the requirement table may be implemented as a table, linked list, array, single, multi-bit variable, or the like, and each entry may comprise one or more bits to store the information. In one embodiment, the requirement table may be stored on an EPROM, which may allow the table entries to be set only once. In another embodiment, an EEPROM or other rewritable memory may allow each table entry to be altered more than once.

Site Licenses

The transfer of accessories from location to location, the sale of used accessories, and the like can also make quality control more difficult, such as by making accessory use hard to track. As such, it is also possible to help maintain quality control by recording or maintaining site licenses, so that accessories, once used, can be tracked to their first use location or maintained at a specific location.

Many patient monitors have an associated device ID, typically this is a software ID, but IDs coded into hardware are also possible. In an embodiment of the present disclosure where the monitor has such an ID, accessory use may be tracked or controlled through use of the monitor ID. A general example will be set forth before turning to a specific embodiment according to the figures. When an accessory having an information element is plugged into the monitor having a monitor ID, the monitor may check to see if a monitor ID has been written to a portion of the information element. If not, the monitor may cause its own monitor ID to be written to the information element. From this point on, any monitor connected to that accessory will be able to determine the monitor of first use. If the accessory should later fail, an accessory or patient monitor manufacturer may then be able to determine where it was first used and if it was transferred to another location. In an embodiment, accessories may be tied to specific monitors or sets of monitors, such as to aid in keeping an accessory at a particular site or location. Once an accessory is used with a specific monitor, each monitor to which it is subsequently attached can read the monitor ID and determine if the monitor with which it was first used is part of the current monitor's grouping (e.g. a site license). Monitors can be programmed to recognize monitor IDs from a specific site (such as one hospital, a health system, etc.), a geographic area (such as by country), an Original Equipment Manufacturer (OEM), combinations of the same, and the like—anywhere from a single recognized monitor (itself) to any number of monitors. In an embodiment, the information element may include at least a portion with write once capability, such as an EPROM, so that the monitor ID that is first written to the information element cannot be changed.

A specific embodiment utilizing an oximeter example will now be discussed in reference to the Figures. In looking to FIGS. **5** and **7**, oximeter board **440**, has a monitor ID (not shown). When, for example, cable **104**, having cable information element **116** is connected to oximeter board **440**, the oximeter board may query cable information element **116** (block **760**). If cable information element **116** has not been used before, in an embodiment, it will have free space to which data may be written (block **762**, branching with no monitor ID found). Oximeter board **440** will then cause monitor ID to be written to the cable information element (block **764**). (In an embodiment, a similar process may take place with sensor **106** and second sensor information element **134**.) The monitor ID written to the cable information element **116** is preferably persistent, so as to remain when the cable **104** is disconnected from oximeter board **440**. During each subsequent use of the cable **104**, oximeter board **440** will be able to read the monitor ID from cable information element **116** (blocks **760**, **762**, branching with a monitor ID found). In an embodiment, the patient monitor then compares the monitor ID found with a list accessible by the oximeter board **440** (block **768**). The oximeter board may respond according to the results of that ID comparison. For example, if the monitor ID found on the cable **104** is not acceptable, a warning may be generated or the oximeter board may not allow readings using the cable (block **770**). Alternatively, if the cable contains an acceptable monitor ID, the oximeter may perform monitoring using the cable **104** (block **772**).

For example, a hospital may have a site license that allows the cables it purchases to be used on any of its own oximeters. Each oximeter board **440** has its own monitor ID, but also has a list of monitor IDs of the other monitors the hospital owns or licenses. Once a cable is used with one of the hospital's oximeters, the cable **104** may only be able to work with that hospital's other oximeters. In one embodiment, connecting such a cable **104** to another hospital's oximeter will trigger a visual or audible warning. In another embodiment, use of the cable may be disabled. This type of quality control can help both the original hospital and the subsequent hospital in this example. If a cable fails, the first hospital can report it to the supplier who may be able to determine if the first hospital's oximeters may be the source of an underlying problem. On the other hand, the second hospital may be alerted to used accessories that may be more likely to fail.

There are numerous alternatives for such a "site license" quality control. For example, oximeters or other patient monitors may have specific lists of acceptable monitor IDs, monitor IDs may be the same for all patient monitors in a group, patient monitors may have a range of acceptable monitor IDs, patient monitors may have a specific equation or algorithm that determines acceptable monitor IDs, and the like. In some embodiments, accessories may record monitor IDs from all monitors to which they are connected, allowing manufacturers, suppliers, end users and the like to track the monitor's use.

Upgrade Tool

One specific accessory that may be utilized in a patient monitor system such as that described in the previous "Requirements Table" and "Site License" sections is an upgrade tool. Upgrade tools connect to an accessory port of a patient monitor to aid in reprogramming or updating the patient monitor without the need for an additional port, taking the patient monitor apart, returning it to the manufacturer and the like. Upgrade tools and a method for their use is generally disclosed in U.S. application Ser. No. 10/898,680, titled "Multipurpose Sensor Port" and filed on Jul. 23, 2004, incorporated herein by reference and made a part of this specification.

Often times a patient monitor or a specific control board will be made by an OEM that is capable of monitoring a host of patient parameters. Making all its boards the same can often reduce costs for an OEM. The OEM, however, may license only certain aspects of the patient monitor or control board to various users. For example, one hospital may obtain the equipment and license it to monitor SpO_2, while another may license only CO monitoring, and the like. Should a user wish to change its monitoring capabilities, the OEM does not need to sell it new equipment, instead it can just enable or disable various features of the patient monitor or control board that it has already provided to that user through use of an upgrade tool. It is important that such an upgrade tool only be enabled for specific patient monitors, however. For example, if hospital A pays for upgrades to its licenses, the OEM would like to ensure that the upgrade tool provided to A is not used to upgrade hospital B's patient monitors. The monitor ID recording discussed above is one way that this restriction can be accomplished. For example, an upgrade tool may record the monitor ID of the first monitor to which it is attached. In most instances, this will be a patient monitor from the proper upgrade group. Once this monitor ID is recorded, the upgrade tool may then only be enabled by any other patient monitor in the correct group, like any other accessory.

In other embodiments, an upgrade tool may contain an information element that stores the monitor IDs of all patient monitors for which an upgrade has been paid. The upgrade tool and patient monitor can then compare IDs to determine if the patient monitor qualifies for the upgrade. As another alternative, an upgrade tool may have a predetermined ID and all OEM patient monitors or boards that may utilize that upgrade tool may be loaded with an ID or software sufficient to match to the upgrade tool's ID during or sometime after manufacture. In other embodiments, a patient monitor may be upgraded by connection to a network, such as by telephone, cable, DSL, USB, FireWire, and the like. Additionally, in an embodiment, a patient monitor may allow a user to enter the monitor ID, such as via a keypad, keyboard, or touch screen interface.

An upgrade tool may be used to alter one or more requirements tables as well. However, it is also possible, in an embodiment, to program one or more accessories themselves to amend requirements tables or upgrade other programming. For example, a sensor information element **134** may include programming to alter a requirement table stored in a cable information element **116** once the components are connected and readied for monitoring.

Wireless Identification

Embodiments of the foregoing information elements use electrical connections to facilitate communication between the patient monitors and the information elements. This is also true in patient monitors that utilize disposable and reusable elements (such as pictured in FIG. **1**). In sensors such as FIG. **1**, it is often advantageous to control the quality of the disposable portions to reduce problems that may arise from inferior disposable portions, such as faulty attachment, improper alignment of sensor components, contamination of the measurement site through ambient light or physical contaminants, and the like. However, maintaining an electrical connection across the reusable/disposable mating point may complicate quality control efforts.

Wireless communications may offer additional advantages to help reduce reliance on electrical contacts and advantageously allow communication between disposable and other system elements. Wireless solutions include passive and active radio frequency identification (RF ID). Passive solutions get their broad ordinary meaning known to one skilled in the art, including solutions that rely on induction from surrounding electromagnetic waves, such as radio waves, to power the RF ID tag. Active solutions get their broad ordinary meaning known to one skilled in the art, including solutions that have an internal or external power source, such as a battery, photovoltaic cell, or electrical transmission lines to an exterior source of power.

A RF ID solution suitable for the purposes discussed here is generally commercially available. However, a brief discussion of the general technology is instructive. A basic RF ID tag includes an information element, such as an integrated circuit, coupled with an antenna. The antenna receives signals from a reader device capable of acquiring data from the integrated circuit of the tag. In passive RF ID, the incoming radio frequency energy from the reader device induces sufficient electrical current to power the information element and transmit a response indicative of the information stored on the information element. In active RF ID, a battery or other power source may be used to supplement or provide the power for transmitting the response.

FIG. **6** illustrates an exemplary patient monitoring system incorporating wireless authentication utilizing radio frequency identification in relation to cable information element **116** and sensor information element **134**. In one embodiment of this disclosure the RF ID configuration is passive, thereby simplifying a disposable portion of a sensor according to this disclosure. In another embodiment of this disclosure, the RF ID configuration may be active. While this creates a slightly more complicated cable, sensor or other accessory, there are advantages that may offset the complications. For example, active RF ID tags typically allow for greater memory and the ability to store data received from the reader. An active RF ID tag may also provide greater transmission distances.

Specifically looking to the differences in FIG. **6**, oximeter board **440** further comprises or is in communication with a reader **650** capable of sending and receiving radio frequency signals to attached accessories. In the cable **104**, information element **116** is now connected to a radio frequency antenna **652** to form a cable RF ID tag **660**. Similarly, in the sensor **106**, second information element **134** is also connected to a radio frequency antenna **654** to form a sensor RF ID tag **662**. Because cable information element **116** and information element **134** may now communicate with each other and/or with oximeter board **440** (via reader **650**) through radio frequency signals, there is no need to have serial transmission line **446** as was previously connecting these elements.

To enable attached accessories in an embodiment utilizing this technology, oximeter board **440** directs reader **650** to send out a radio frequency signal. In the cable **104**, antenna **652** receives this signal, and redirects the energy to reply with a signal indicative of the information stored on cable information element **116**. Incoming radio frequency signals induce a current in cable information element **116** and provide the power to transmit a response. Often this is done through back scattering the carrier signal from the reader **650**. Oximeter board **440**'s reader **650** may also send out a radio frequency signal received by antenna **654** in sensor **106**. Antenna **654** likewise redirects the energy received in accepting the signal to reply with a signal indicative of the information stored on information element **134**. Reader **650** receives each of the signals generated by cable RF ID tag **660** and sensor RF ID tag **662** and communicates them to oximeter board **440**. Oximeter board **440** compares the received information and enables usage of cable **104** and sensor **106** for patient monitoring if it recognizes each as approved accessories.

It is notable that the workings of the RF ID system as in FIG. **6** have been discussed in relation to passive RF ID elements. It would be straightforward for one of ordinary skill to modify either or both of cable RF ID tag **660** and sensor RF ID tag **662** to work as active RF ID tags by addition of a power source such as a battery or electrical transmission lines from the oximeter's power source. This may be necessary if the RF ID element needs to transmit more than an identification code or other small amount of data.

It should also be understood that the site license and upgrade tool concepts may also utilize wireless technology as described herein to read and write monitor IDs. In an embodiment, this may allow a patient monitor to update associated accessories without need of attaching the accessory to the patient monitor.

Although the patient monitor capable of maintaining quality control in an optical sensor is disclosed with reference to its preferred embodiments, the disclosure is not intended to be limited thereby. Rather, a skilled artisan will recognize from the disclosure herein a wide number of alternatives for such a patient monitor. For example, the elements used to code and identify the sensor may be passive or active such as resistors, transistor networks, memory chips, or other identification devices like Dallas Semiconductor DS 1990 or DS 2401 or other automatic identification chips. As described above, first and second sensor information elements may be switched in various embodiments, and one or the other may be included. Additionally, RF ID solutions are not the only wireless solutions available; other passive or active wireless communications may also be used such as those conforming to IEEE or Bluetooth® standards. It is also possible to alter the connections between various accessories; for example, the sensor's **106** male connection housing **112** and the cable's **104** female connection housing **150** may be reversed or may each have a male and female component. Furthermore, any of a number of accessories may include elements as described herein. Such accessories may be disposable or reusable or may have portions that are disposable and others that are reusable. Accessories may include, for example, cables, sensors, battery packs, data storage such as hard drives, flash drives, and the like, computer boards, and the like.

It is also noted that the disclosure herein discusses only a two LED, one photodetector configuration for straightforwardness of the disclosure. One skilled in the art would know that more complex or varied data may be retrieved through the addition of more LEDs or other emitting devices and/or more photodetectors or other detecting devices. Such devices may continue to utilize a single first sensor information element **218** or multiple information elements, corresponding to various sensor components, with or without a second sensor information element **134**. Additionally, other combinations, omissions, substitutions and modifications will be apparent to the skilled artisan in view of the disclosure herein. Accordingly, the present disclosure is not intended to be limited by the reaction of the preferred embodiments, but is to be defined by reference to the appended claims.

Additionally, all publications, patents, and patent applications mentioned in this specification are herein incorporated by reference and made a part of the specification hereof to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

What is claimed is:

1. A method which determines if a physiological sensor is an approved sensor to be used with a patient monitoring system, the method comprising:

communicating, using a current patient monitoring system, with a sensor memory device of a physiological sensor attached to the current patient monitoring system, the sensor memory device having at least a persistent portion with write-once capability such that information written to the persistent portion cannot be changed;

when the physiological sensor has not previously communicated with any patient monitoring system, storing an identification of the current patient monitoring system in the persistent portion of the sensor memory device;

when the physiological sensor has previously been connected to and communicated with a previous patient monitoring system and an identification of the previous patient monitoring system has been stored in the persistent portion of the sensor memory device:

reading from the persistent portion of the sensor memory device the identification of the previous patient monitoring system;

accessing a memory associated with the current patient monitoring system which stores a list of identifications of approved patient monitoring systems associated with the current patient monitoring system; and

determining whether the physiological sensor is approved for use with the current patient monitoring system by comparing the identification of the previous patient monitoring system stored in the persistent portion of the sensor memory device and the identifications of approved monitoring systems, wherein the physiological sensor is determined to be approved if the identification of the previous patient monitoring system stored on the persistent sensor memory device is found among the list of identifications of approved patient monitoring systems; and

receiving and using information indicative of a physiological condition from the physiological sensor only when the physiological sensor is an approved sensor.

2. The method of claim **1**, wherein the list of identifications of patient monitoring systems comprises patient monitoring systems associated with a site license.

3. The method of claim **2**, wherein the site license is associated with a hospital.

4. The method of claim **1**, wherein the persistent portion of the sensor memory device of a physiological sensor comprises an EPROM.

5. The method of claim **1**, wherein communicating with the sensor memory device of a physiological sensor comprises communicating with a single wire memory device.

6. The method of claim **1**, further comprising disabling the use of the physiological sensor when the physiological sensor is not approved for use.

7. The method of claim **1**, further comprising generating an alarm when the physiological sensor is not approved for use.

8. A patient monitor configured to communicate with physiological sensors of different types and receive and use information indicative of a physiological condition from the physiological sensors after verification of the sensor, the patient monitor comprising:

a monitor memory configured to store a list of identifications of additional patient monitors which are associated with the patient monitor; and

a processor configured to:

communicate with a sensor memory device of a physiological sensor, the sensor memory device having at least a persistent portion with write-once capability such that information written to the persistent portion cannot be changed,

receive identification information from the persistent portion of the sensor memory device of the physiological sensor, the identification information including an identification of any previous monitoring systems which have previously communicated with the physiological sensor, and

access the monitor memory to determine whether the physiological sensor is an approved sensor by comparing the identification of any previous patient monitoring systems stored in the persistent portion of the sensor memory device with the identifications of patient monitors stored in the monitor memory, wherein the physiological sensor is determined to be approved if the identification of any previous patient monitoring system stored on the persistent portion of the sensor memory device is found among the identifications of patient monitors systems stored on the monitor memory;

wherein the patient monitor is configured to receive and use information indicative of a physiological condition of a patient only when the physiological sensor is determined to be approved, and wherein when the physiological sensor has not communicated with any previous patient monitors and no identification information is stored in the persistent portion of the sensor memory device, the processor is further configured to alter the persistent portion of the sensor memory device of the physiological sensor to include an identification of the patient monitor.

9. The patient monitor of claim **8**, wherein the sensor is an approved sensor if the sensor has not communicated with any previous patient monitor.

10. The patient monitor of claim **8**, wherein the list of patient monitors includes identifications of patient monitors associated with a site license.

11. The patient monitor of claim **10**, wherein the site license is associated with a hospital.

* * * * *

专利名称(译)	病人监护仪能够监测所附探头和附件的质量		
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[标]申请(专利权)人(译)	梅西莫股份有限公司		
申请(专利权)人(译)	Masimo公司		
当前申请(专利权)人(译)	Masimo公司		
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摘要(译)

一种系统和方法，有助于保持质量控制，并减少在高度敏感的患者监护仪（如脉搏血氧仪系统）中附件和附属探头的拆分。一个或多个附加组件可以具有设计用于指定病人监视器应当看起来在该组件或另一组件上找到什么质量控制机制的信息元素，或者指定一个组件可以正常工作的其他组件。在另一个实施例中，这样的信息元素还可以包括指示组件的适当寿命的数据。