US 20080081971A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2008/0081971 A1

Ollerdessen (43) Pub. Date: Apr. 3, 2008

(54) SYSTEM AND METHOD FOR PREVENTING SENSOR MISUSE

(75) Inventor: **Albert L. Ollerdessen**, Danville, CA (US)

Correspondence Address:
Covidien
IP Counsel - Respiratory & Monitoring Solutions
60 Middletown Avenue
North Haven, CT 06473

(73) Assignee: **Nellcor Puritan Bennett Inc.**

(21) Appl. No.: **11/541,251**

(22) Filed: **Sep. 29, 2006**

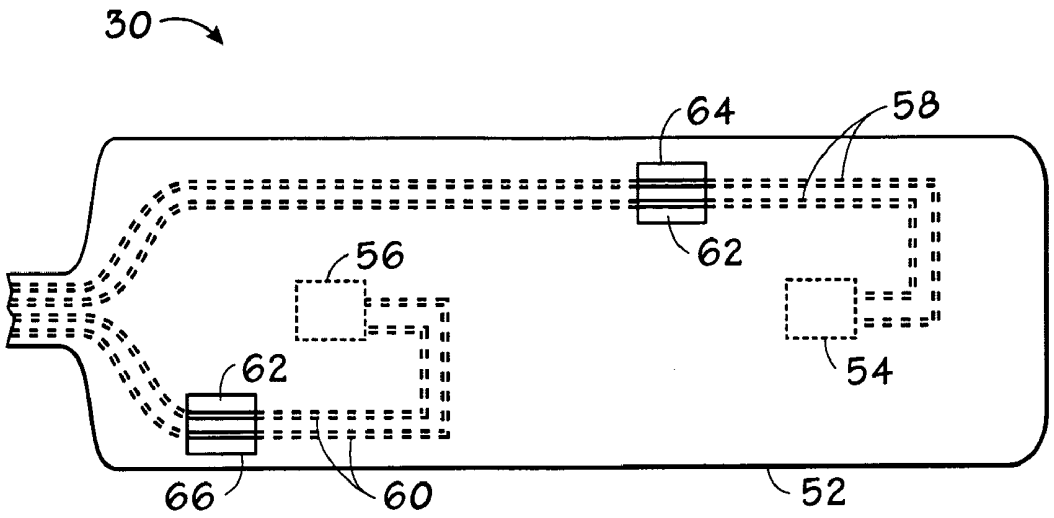
Publication Classification

(51) **Int. Cl.**
A61B 5/00 (2006.01)

(52) **U.S. Cl.** **600/323**

(57) **ABSTRACT**

Embodiments of the present invention relate to a pulse oximetry sensor. The pulse oximetry sensor may comprise an emitter configured to transmit a signal into tissue, a detector configured to detect the signal, and a quality assurance component coupled to a first sensor component and second sensor component. The quality assurance component may be configured to break and disable the sensor upon separation of the first sensor component from the second sensor component.



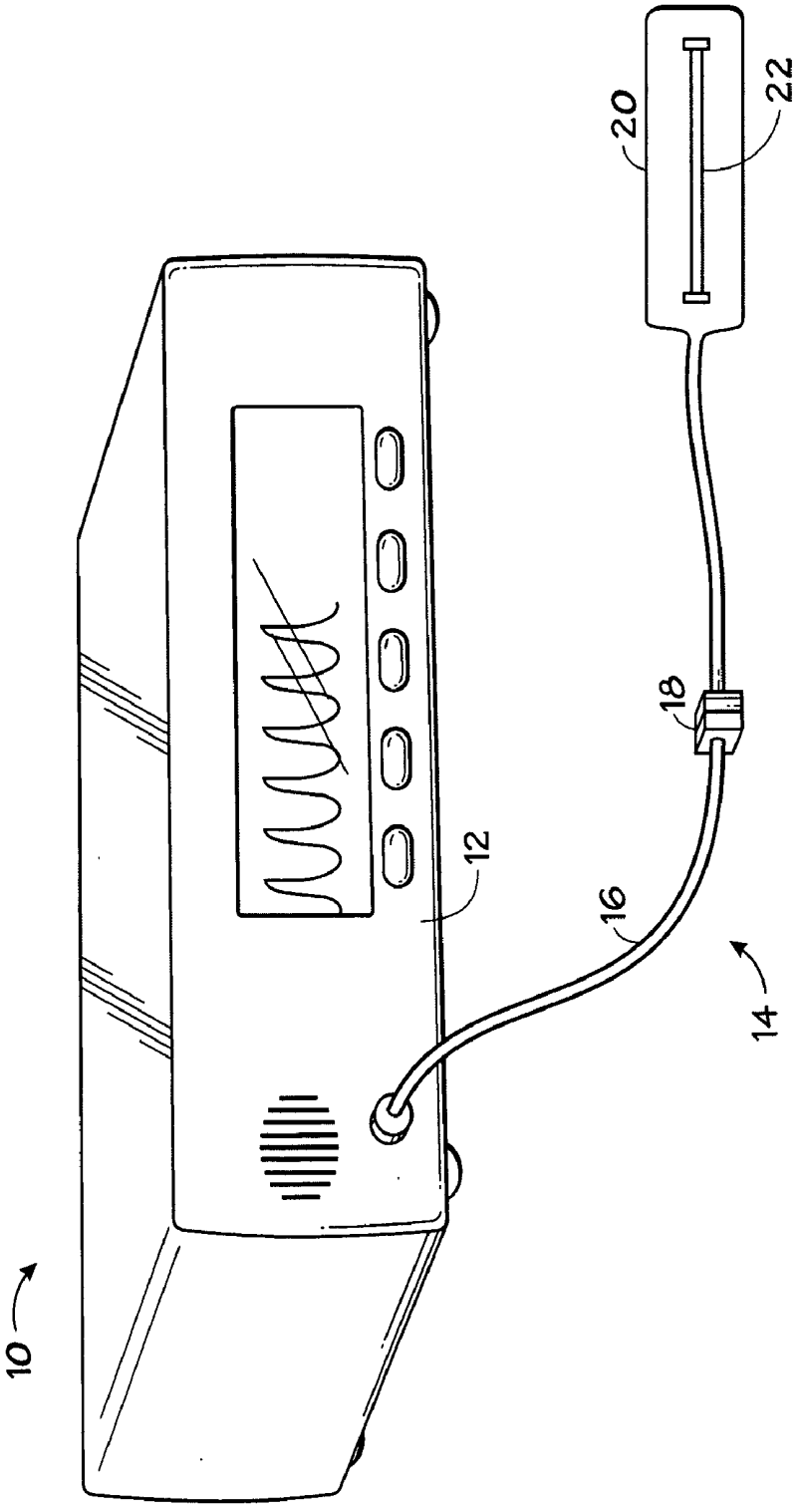


FIG. 1

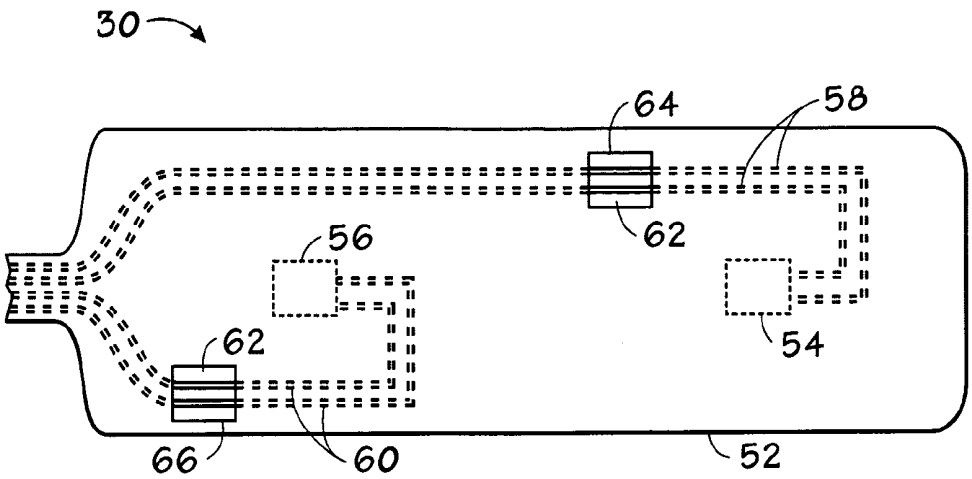


FIG. 2

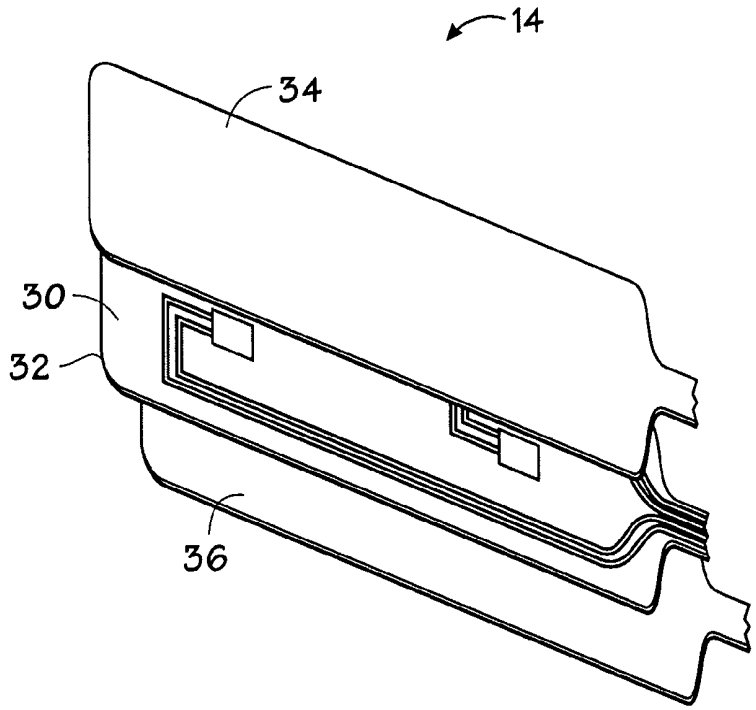


FIG. 3

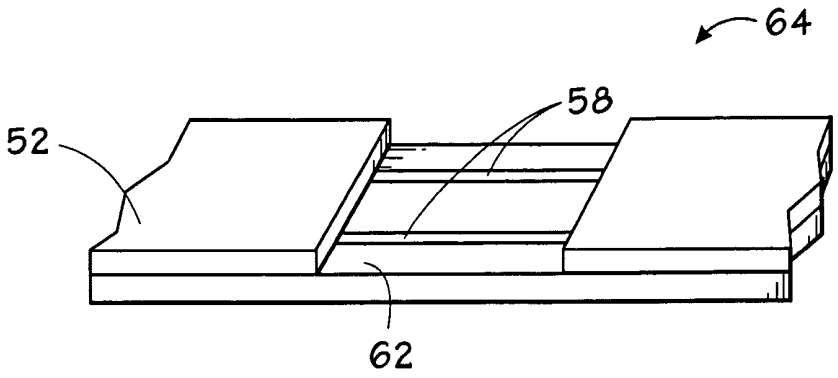


FIG. 4

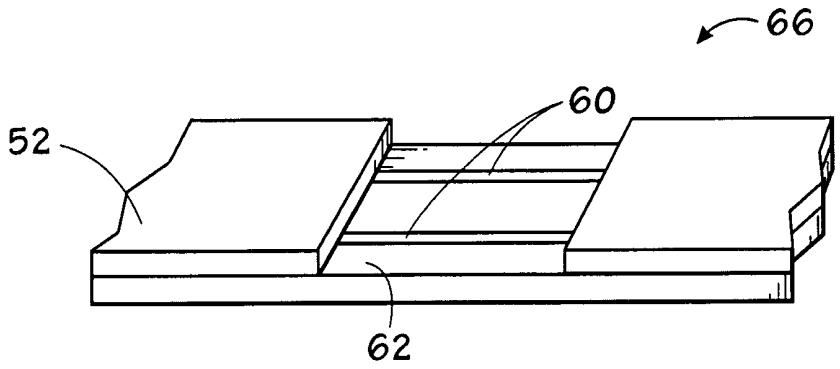


FIG. 5

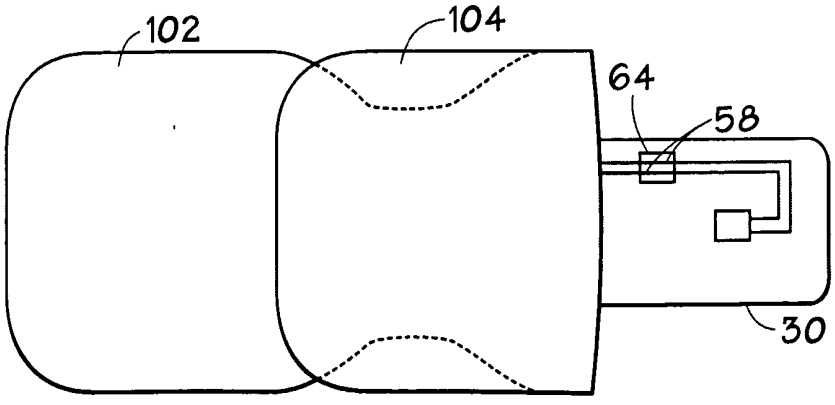


FIG. 6

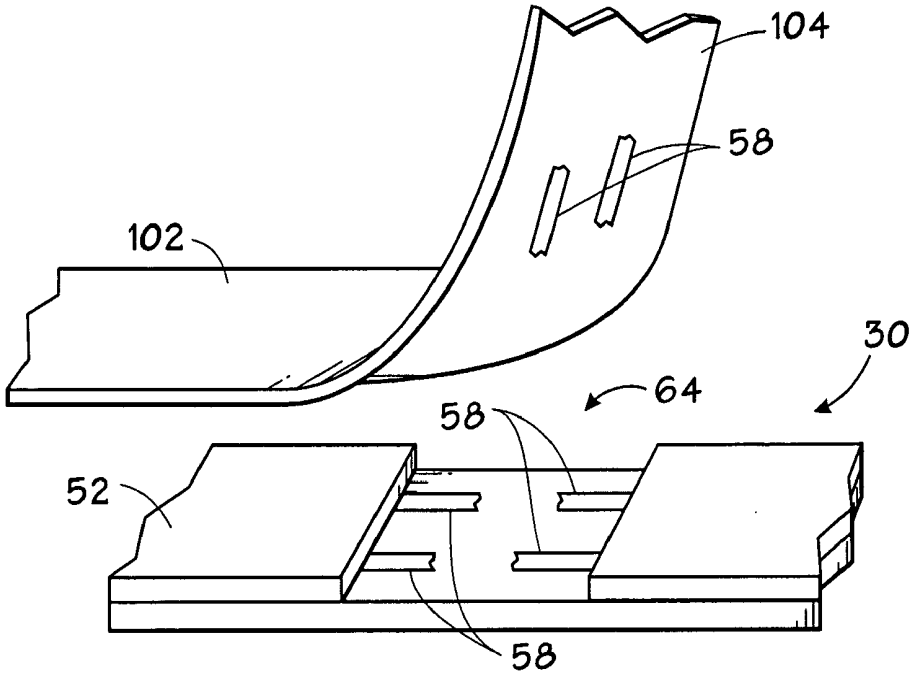


FIG. 7

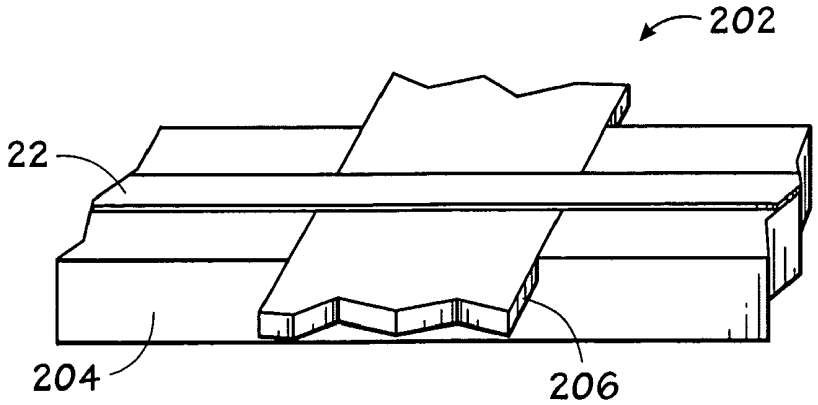


FIG. 8

SYSTEM AND METHOD FOR PREVENTING SENSOR MISUSE

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention

[0002] The present invention relates generally to a sensor for measuring patient physiological characteristics. More particularly, embodiments of the present invention relate to a sensor that measures oxygen content in a patient's blood and that limits misuse of the sensor, such as tampering with or remanufacturing of the sensor.

[0003] 2. Description of the Related Art

[0004] This section is intended to introduce the reader to various aspects of art that may be related to various aspects of the present invention, which are described and/or claimed below. This discussion is believed to be helpful in providing the reader with background information to facilitate a better understanding of the various aspects of the present invention. Accordingly, it should be understood that these statements are to be read in this light, and not as admissions of prior art.

[0005] Pulse oximetry may be defined as a non-invasive technique that facilitates monitoring of a patient's blood characteristics. For example, pulse oximetry may be used to measure blood oxygen saturation of hemoglobin in a patient's arterial blood and/or the patient's heart rate. Specifically, blood characteristic measurements may be acquired using a non-invasive sensor that passes light through a portion of a patient's blood perfused tissue and that photoelectrically senses the absorption and scattering of light through the blood perfused tissue. A typical signal resulting from the sensed light may be referred to as a plethysmographic waveform. Once acquired, this measurement of the absorbed and scattered light may be used with various algorithms to estimate an amount of blood constituent in the tissue, as well as other physiologic characteristics.

[0006] Conventional pulse oximeter sensors typically include emitters (e.g., a red emitter and an infrared emitter) configured to emit light waves and a photodiode detector that is arranged to detect the emitted light waves. Such sensors are typically configured to attach to a patient's finger, foot, forehead, or earlobe to facilitate measurement of blood characteristics in the associated tissue. For example, a typical oximeter sensor may be adapted to project light from the emitters through the outer tissue of a finger and into the blood vessels and capillaries inside. Such a sensor typically includes a detector that is arranged to detect the emitted light as it emerges from the outer tissue of the finger. The detector generates a signal based on the detected light and provides the signal to an oximeter, which determines blood oxygen saturation based on the signal.

[0007] Some conventional sensors also include an information element that stores information that can be read by an attached device to facilitate proper blood characteristic measurement. For example, a pulse oximeter sensor may include a memory or a resistor that can be read by an oximeter. The information stored on the information element (e.g., resistor, memory) may include parameters about the sensor. For example, the information may indicate sensor type (e.g., neonatal, pediatric, adult), the wavelengths of light produced by the emitters, and so forth. This information may be utilized in algorithms for determining values for the blood characteristic. Further, the information element may be utilized for security and quality control purposes. For example, the information element may ensure proper operation by preventing the sensor from functioning with improperly configured or unauthorized devices.

[0008] Improper remanufacturing of a sensor or tampering with the sensor can impact the quality and reliability of the sensor. For example, improper remanufacturing of a sensor may eliminate the quality assurance function of the information element or cause malfunctions by coupling incompatible sensor components together. In a specific example, an information element for a neonatal oximeter sensor may be improperly incorporated into an adult oximeter sensor during remanufacture. Such remanufacturing can cause improper operation and incorrect measurement of physiological characteristics.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Advantages of the invention may become apparent upon reading the following detailed description and upon reference to the drawings in which:

[0010] FIG. **1** is a perspective view of a patient monitor coupled to a sensor in accordance with an exemplary embodiment of the present invention;

[0011] FIG. **2** is a plan view of a sensor element in accordance with an exemplary embodiment of the present invention;

[0012] FIG. **3** is an exploded perspective view of a sensor including multiple layers in accordance with an exemplary embodiment of the present invention;

[0013] FIG. **4** is a magnified perspective view of exposed traces on a sensor element in accordance with an exemplary embodiment of the present invention;

[0014] FIG. **5** is a magnified perspective view of exposed traces on a sensor element in accordance with an exemplary embodiment of the present invention;

[0015] FIG. **6** is a plan view of a sensor with a bandage layer of the sensor partially peeled away from a sensor element in accordance with an exemplary embodiment of the present invention;

[0016] FIG. **7** is a magnified perspective view of a disassembled sensor with torn traces on separate disassembled layers of the sensor in accordance with an exemplary embodiment of the present invention; and

[0017] FIG. **8** is a magnified perspective view of a quality assurance component disposed over an intersection of a first sensor layer and a second sensor layer in accordance with an exemplary embodiment of the present invention.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

[0018] One or more specific embodiments of the present invention will be described below. In an effort to provide a concise description of these embodiments, not all features of an actual implementation are described in the specification. It should be appreciated that in the development of any such actual implementation, as in any engineering or design project, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which may vary from one implementation to another. Moreover, it should be appreciated that such a development effort might be complex and time consuming, but would nevertheless be a routine undertaking of design,

fabrication, and manufacture for those of ordinary skill having the benefit of this disclosure.

[0019] Embodiments of the present invention relate in general to a sensor for measuring patient physiological characteristics. More particularly, embodiments of the present invention relate to a sensor that measures oxygen content in a patient's blood and that includes a functional component that substantially prevents tampering with and remanufacturing of the sensor. In other words, embodiments of the present invention include a functional component that prevents efficient remanufacture of the sensor by breaking or becoming disabled when the sensor is disassembled or tampered with. For example, in one embodiment, a pulse oximeter sensor may include a conductive trace that is essential to proper operation and that breaks if the sensor is improperly disassembled. In one embodiment, the conductive trace may be required for memory operation or provide a necessary communication path for a sensor component (e.g., a light emitter or detector). In other exemplary embodiments, the sensor may include various types of functional components (e.g., memory unit, resistor) that break or stop functioning upon disassembly of the sensor, thus substantially preventing remanufacture of the sensor. For example, the sensor may include a breakable information element disposed within the sensor to facilitate measurement and ensure quality control. This information element may be arranged within the sensor to break or to become disabled upon disassembly or misuse of the sensor. For example, the information element may be a thin resistor that is coupled to multiple layers of the sensor, and when the sensor is disassembled the layers may separate causing the resistor to break.

[0020] FIG. **1** is a perspective view of a patient physiological data measurement system in accordance with an exemplary embodiment of the present invention. Specifically, FIG. **1** includes a pulse oximeter system, which is generally referred to by a reference numeral **10**. The system **10** includes an oximeter **12** (e.g., computer) that communicatively couples to a sensor **14**. The sensor **14** includes a sensor cable **16**, a connector plug **18**, and a body **20** configured to attach to a patient. The sensor **14** may be configured to couple with a patient's earlobe, finger, foot, forehead, or other locations on the patient that facilitate non-invasive measurement of desired physiological data (e.g., pulse rate, blood oxygen saturation). For example, the sensor body **20** may be configured to clip onto a patient's finger or stick on a patient's forehead. In another embodiment, the sensor **14** (e.g., an invasive brain tissue hydration sensor) may be configured for invasive operation, thus the sensor body **20** may be configured for insertion into a patient.

[0021] The sensor cable **16** and connector plug **18** may enable electronic communication from the sensor **14** to the monitor **12** and facilitate coupling and/or decoupling of the sensor **14** from the monitor **12**. In some embodiments, the sensor **14** may couple directly to the monitor **12** via the sensor cable **16**. In other embodiments, the sensor **14** may communicate with the monitor **12** wirelessly (e.g., via radio waves) and may not include the cable **16** or the connector plug **18**. Further, it should be noted that the sensor **14** may include an internal or external quality assurance component **22** (e.g., memory, resistor, trace) that prevents operation of the sensor when disabled. The quality assurance component **22** may be arranged to break when the sensor **14** is disassembled to prevent unauthorized remanufacture of the sensor **14** and, thus, ensure that quality control is maintained. For example, the quality assurance component **22** may include conductive traces, a memory device, or a resistor with an electrical break point that will disable the sensor **14** (e.g., sever communication between sensor components) if the sensor **14** is disassembled.

[0022] FIG. **2** is a plan view of a sensor element **30** in accordance with an exemplary embodiment of the present invention. The sensor element **30** may be a component part of the sensor **14** illustrated in FIG. **1**. For example, as illustrated in the exploded view of the sensor **14** in FIG. **3**, the sensor element **30** may operate as a layer of the sensor **14** that cooperates with other layers, such as a tacky connection layer **34** and a protective back covering **36**, to form the sensor **14**. The tacky connection layer **34** may facilitate coupling to a patient's forehead, and the protective back covering **36** may protect the sensor from damage or interference. While FIG. **3** illustrates an exploded view of the sensor **14** with the various layers separated, it should be noted that in some embodiments, the sensor **14** may be assembled such that the layers (e.g., layers **32**, **34**, and **36**) are substantially inseparable without damaging sensor components (e.g., quality assurance component **22**) that are essential to sensor operation. For example, in one embodiment, the layers may be interwoven with the quality assurance component **22** (e.g., a thin wire) to prevent separation of the layers without breaking the quality assurance component **22**.

[0023] The sensor element **30** may correspond in shape to the body **20** of the sensor **14**. In the illustrated embodiment, the sensor element **30** is elongate and flexible to facilitate conformation of the sensor **14** to a patient's forehead or to facilitate wrapping the sensor **14** about the patient's finger. Further, in the illustrated embodiment of FIG. **4**, the sensor element **30** includes an insulation layer **52**, an emitter component **54**, and a detector component **56**. The emitter component **54** is coupled with a first pair of conductive traces **58**. The first pair of conductive traces facilitates communication with an external device (e.g., oximeter **12**). Similarly, the detector component **56** is coupled with a second pair of conductive traces **60** that facilitate communication with the external device. It should be noted that in some embodiments, the sensor **14** may be formed from a hard or rigid material (e.g., hard plastic).

[0024] As illustrated in FIG. **2**, a majority of the components of the sensor element **30** are covered by the insulation layer **52**. Indeed, the dashed lines indicate that the emitter component **54**, the detector component **56**, and a substantial portion of the conductive traces **58** and **60** are protectively covered by the insulation layer **52**. However, certain portions of the conductive traces **58** and **60** are not covered by the insulation layer **52** and are exposed in their location on a base layer **62**. These exposed areas are indicated by reference numerals **64** and **66**, respectively. A magnified perspective view of the exposed area **64** is provided in FIG. **4**, and a magnified perspective view of the exposed area **66** is provided in FIG. **5**. By not covering the areas **64** and **66**, the operability of the conductive traces **58** and **60**, along with the functionality of the entire sensor **14** may be made vulnerable to tampering with or disassembly of the sensor **14**. Indeed, the exposed portions of the traces **58** and **60** may

be coupled to a separate component of the sensor that will break the traces **58** and **60** if removed from the sensor element **30**.

[0025] As set forth above, the exposed areas **64** and **66** facilitate disablement of the sensor element **30** upon disassembly of the sensor **14**. For example, as illustrated in FIG. **6**, a bandage **102** may be coupled to the sensor element **30** to form the sensor **14** and to facilitate coupling of the sensor **14** to a patient. Indeed, the bandage **102** may include a tacky substance **104** on one side that is adapted to stick to a patient's skin. The bandage **102** may also couple directly to the conductive traces **58** and **60** at the exposed areas **64** and **66** (e.g., via the tacky substance **104**). When the bandage **102** becomes worn (e.g., the tacky substance **104** is substantially absent on portions of the bandage **102** that couple to the patient), an unauthorized manufacturer may wish to remanufacture the sensor **14** by removing the sensor element **30** and coupling it with a different bandage or other coupling device. It should be noted that other similar situations may also arise that encourage disassembly of the sensor **14** and reuse of the sensor element **30** or other sensor components in an unauthorized and inappropriate manner.

[0026] As set forth above, in accordance with present embodiments, disassembly of the sensor **14** (e.g., removal of the bandage **102** from the sensor element **30**), tampering with the sensor **14**, and other types of misuse may result in disabling the sensor **14** (e.g., tearing the conductive traces **58** and **60**). For example, FIG. **7** is a magnified view of the exposed area **64** after the bandage **102** has been removed from a coupling with the sensor element **30**. In the illustrated embodiment, portions of the conductive traces **58** at the exposed area **64** remain coupled to the bandage **102** when it is removed, thus tearing the traces **58**, disabling the entire sensor element **30**, and substantially preventing remanufacture. While traces **58** and **60** are used in the illustrated embodiment, in other embodiments various breakable quality assurance components (e.g., memory, resistor) may be utilized. Further, in some embodiments, the quality assurance component **22** may be disposed over an intersection **202** of a first sensor layer **204** and a second sensor layer **206**, as illustrated in FIG. **8**. By placing the quality assurance component **22** over the intersection **202** (or electrical breakpoint), severance of the quality assurance component **22** is essentially assured by separation of the two layers **204** and **206**.

[0027] While the invention may be susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and will be described in detail herein. However, it should be understood that the invention is not intended to be limited to the particular forms disclosed. Rather, the invention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the invention as defined by the following appended claims.

What is claimed is:

1. A pulse oximetry sensor, comprising:

an emitter configured to transmit a signal into tissue;

a detector configured to detect the signal; and

a quality assurance component coupled to a first sensor component and second sensor component, the quality assurance component configured to break and disable the sensor upon separation of the first sensor component from the second sensor component.

2. The sensor of claim **1**, wherein the quality assurance component comprises a trace.

3. The sensor of claim **1**, wherein the quality assurance component comprises an information element.

4. The sensor of claim **1**, wherein the quality assurance component comprises a memory.

5. The sensor of claim **1**, wherein the quality assurance component comprises a resistor.

6. The sensor of claim **1**, wherein the quality assurance component comprises a communication component configured to provide electrical communication with a monitor.

7. The sensor of claim **1**, wherein the first and second sensor components are first and second sensor layers and the quality assurance component is disposed across the first and second layers.

8. The sensor of claim **1**, wherein the quality assurance component is interwoven with the first sensor component and the second sensor component.

9. The sensor of claim **1**, wherein a portion of the quality assurance component couples to the second sensor component at an exposed location on the first sensor component, the exposed location defining an electrical breakpoint.

10. The sensor of claim **1**, wherein the first and second sensor components are first and second sensor layers and the quality assurance component is disposed between the first and second layers.

11. A method of assured quality operation of a pulse oximetry sensor, comprising:

transmitting a signal into tissue;

detecting the signal; and

disabling the pulse oximetry sensor upon separation of a first sensor component and a second sensor component by breaking a quality assurance component coupled to the first and second sensor components.

12. The method of claim **11**, wherein breaking the quality assurance component comprises breaking a conductive trace to disable the pulse oximetry sensor.

13. The method of claim **11**, wherein breaking the quality assurance component comprises breaking an information element to disable the pulse oximetry sensor.

14. The method of claim **11**, wherein breaking the quality assurance component comprises breaking a memory to disable the pulse oximetry sensor.

15. The method of claim **11**, wherein breaking the quality assurance component comprises breaking a resistor to disable the pulse oximetry sensor.

16. The method of claim **11**, comprising breaking the quality assurance component proximate an electrical break point.

17. The method of claim **16**, wherein breaking the quality assurance component proximate the electrical break point comprises breaking the quality assurance component proximate a junction between the first and second sensor components.

18. A method of manufacturing a quality assured pulse oximetry sensor, comprising:

providing an emitter configured to transmit a signal into tissue;

providing a detector configured to detect the signal; and

providing a quality assurance component coupled to a first sensor component and second sensor component, the

quality assurance component configured to break and disable the sensor upon separation of the first sensor component from the second sensor component.

19. The method of claim **18**, wherein the quality assurance component comprises a trace.

20. The method of claim **18**, wherein the quality assurance component comprises an information element.

21. The method of claim **18**, comprising disposing the quality assurance component across a junction between the first and second sensor components.

22. The method of claim **18**, comprising interweaving the quality assurance component with the first sensor component and the second sensor component.

23. The method of claim **18**, comprising coupling a portion of the quality assurance component to the second sensor component at an exposed location on the first sensor component, the exposed location defining an electrical breakpoint.

* * * * *

专利名称(译)	用于防止传感器误用的系统和方法		
公开(公告)号	US20080081971A1	公开(公告)日	2008-04-03
申请号	US11/541251	申请日	2006-09-29
[标]申请(专利权)人(译)	内尔科尔普里坦贝内特公司		
申请(专利权)人(译)	NELLCOR PURITAN BENNETT INC.		
当前申请(专利权)人(译)	NELLCOR PURITAN BENNETT INC.		
[标]发明人	OLLERDESSEN ALBERT L		
发明人	OLLERDESSEN, ALBERT L.		
IPC分类号	A61B5/00		
CPC分类号	A61B5/02416 A61B5/14552 A61B5/6816 A61B2560/0276 A61B5/6829 A61B5/6838 A61B5/6826		
其他公开文献	US7684842		
外部链接	Espacenet USPTO		

摘要(译)

本发明的实施例涉及脉搏血氧测定传感器。脉搏血氧饱和度传感器可包括：发射器，被配置为将信号发送到组织;检测器，被配置为检测信号;以及质量保证组件，被耦合到第一传感器组件和第二传感器组件。质量保证组件可以被配置为在第一传感器组件与第二传感器组件分离时断开和禁用传感器。