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(12) United States Patent
Al-Ali**(10) Patent No.: US 6,725,075 B2**
(45) Date of Patent: *Apr. 20, 2004**(54) RESPONSABLE PULSE OXIMETRY SENSOR****(75) Inventor: Ammar Al-Ali, Tustin, CA (US)****(73) Assignee: Masimo Corporation, Irvine, CA (US)****(*) Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 38 days.

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Related U.S. Application Data**(63)** Continuation of application No. 09/456,666, filed on Dec. 9, 1999, now Pat. No. 6,377,829.**(51) Int. Cl.⁷ A61B 5/00****(52) U.S. Cl. 600/344; 600/323****(58) Field of Search 600/309-311, 322-326, 600/344, 315-316; 356/39-41****(56) References Cited****U.S. PATENT DOCUMENTS**

4,621,643 A	11/1986	New, Jr. et al.
4,865,038 A	9/1989	Rich et al.
5,090,410 A	2/1992	Saper et al.
5,158,323 A	10/1992	Yamamoto et al.
5,170,786 A	12/1992	Thomas et al.
5,638,818 A	6/1997	Diab et al.
5,660,567 A	8/1997	Nierlich et al.
5,673,693 A	10/1997	Solenberger
5,678,544 A	10/1997	DeLonzor et al.
5,758,644 A *	6/1998	Diab et al. 600/323
5,919,133 A	7/1999	Taylor et al.

5,995,855 A	11/1999	Kiani et al.
5,999,834 A	12/1999	Wang et al.
6,014,576 A *	1/2000	Raley 600/344
6,256,523 B1	7/2001	Diab et al.
6,308,089 B1 *	10/2001	von der Ruhr et al. 600/338
6,377,829 B1 *	4/2002	Al-Ali 600/323

FOREIGN PATENT DOCUMENTS

EP	0 313 238 A2	10/1988
WO	WO 01/41634 A2	6/2001

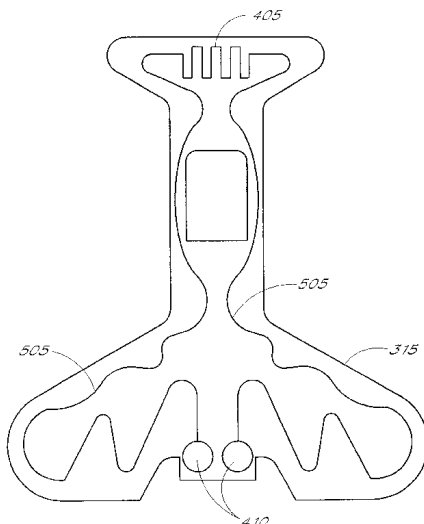
OTHER PUBLICATIONS

http://www.masimo.com/systemo.htm, "System Overview & Performance", 2 pages, reviewed on Sep. 17, 1999.

(List continued on next page.)

Primary Examiner—Eric F. Winakur*Assistant Examiner*—Matthew Kremer**(74) Attorney, Agent, or Firm**—Knobbe, Martens, Olson & Bear LLP**(57) ABSTRACT**

A pulse oximeter sensor has both a reusable and a disposable portion. The reusable portion of the sensor preserves the relatively long-lived and costly emitter, detector and connector components. The disposable portion of the sensor is the relatively inexpensive adhesive tape component that is used to secure the sensor to a measurement site, typically a patient's finger or toe. The disposable portion of the sensor is removably attached to the reusable portion in a manner that allows the disposable portion to be readily replaced when the adhesive is expended or the tape becomes soiled or excessively worn. The disposable portion may also contain an information element useful for sensor identification or for security purposes to insure patient safety. A conductive element that allows a pulse oximeter monitor to read the information element is located on the disposable portion in such a way that continuity is broken when the adhesive tape become torn, such as upon removal from the measurement site.

14 Claims, 11 Drawing Sheets

OTHER PUBLICATIONS

<http://www.masimo.com/pandt.htm>, "Products & Technology", 1 page, reviewed on Sep. 17, 1999.

<http://www.masimo.com/cables.htm>, "Patient Cables", reviewed on Sep. 17, 1999.

<http://www.masimo.com/adt.htm>, "Inop adt—Adult Disposable Digit Sensor", 1 page, reviewed on Sep. 17, 1999.

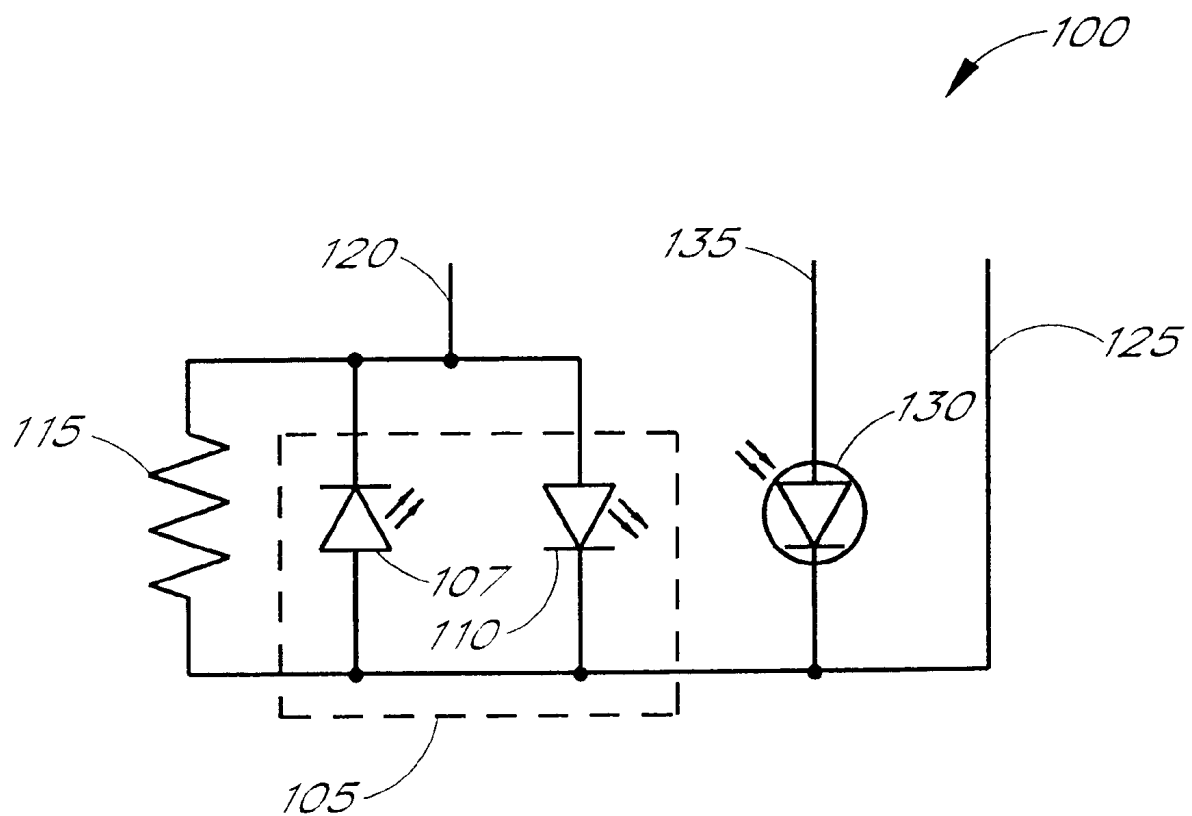
http://www.mrequipment.com/products/oximetry_patient_mntrg.htm, "MR Equipment Magnetic Resonance Equipment Corporation, MR-Compatible High-Performance Optical Fiber Sensors,, Pulse Oximetry Sensors for MRI

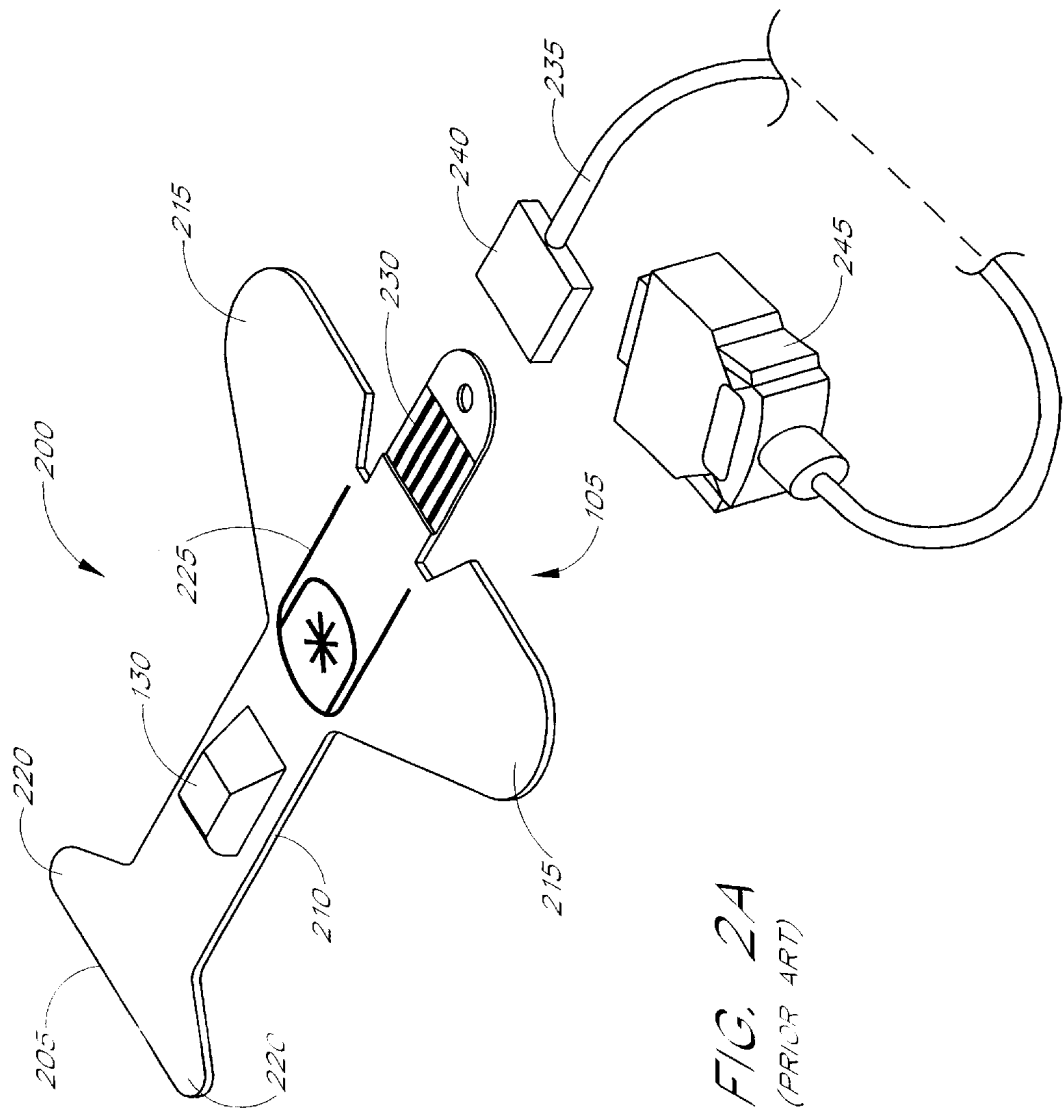
Fiber Optic Sensors for use with MR-Compatible Pulse Oximeter", 2 pages, reviewed on Sep. 17, 1999.

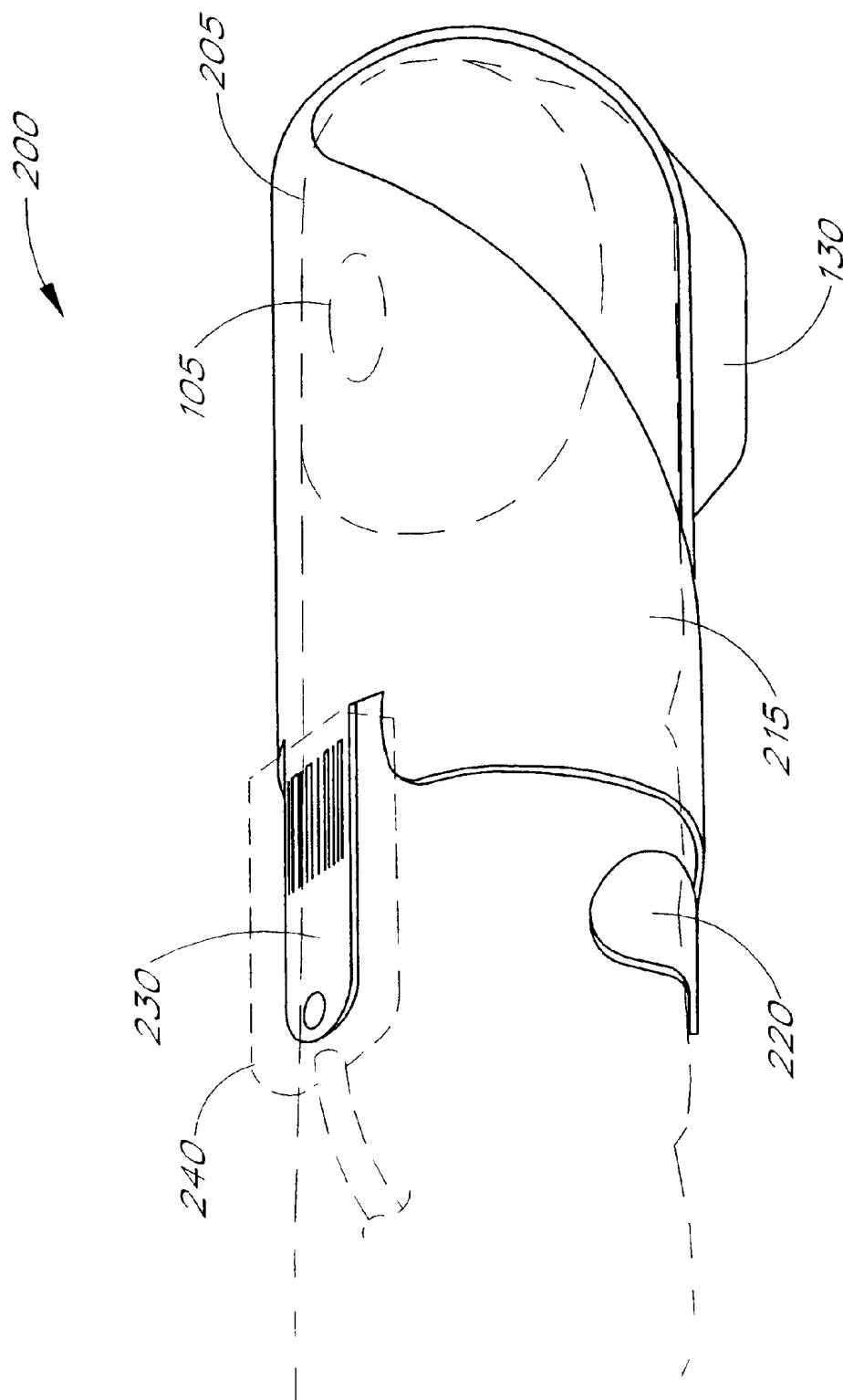
Masimo Corporation, "Discrete Saturation Transform Example", reviewed on Sep. 17, 1999.

MSP Industry Alert, "Masimo To Introduce NR7 At ASA", pp. 18, 19, and the front and back cover, vol. 3, No. 3, Fall 2001.

* cited by examiner

*FIG. 1*





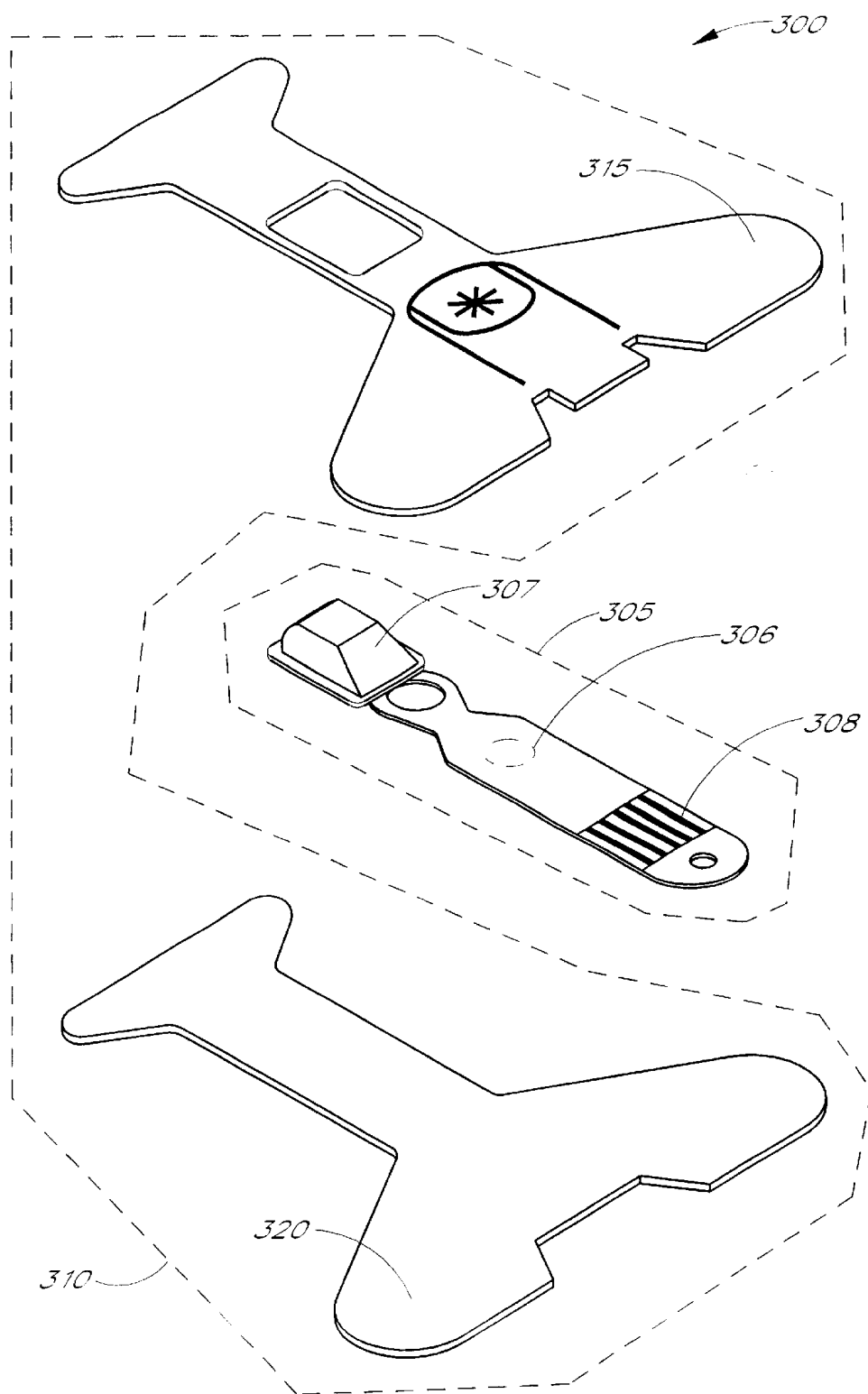


FIG. 3

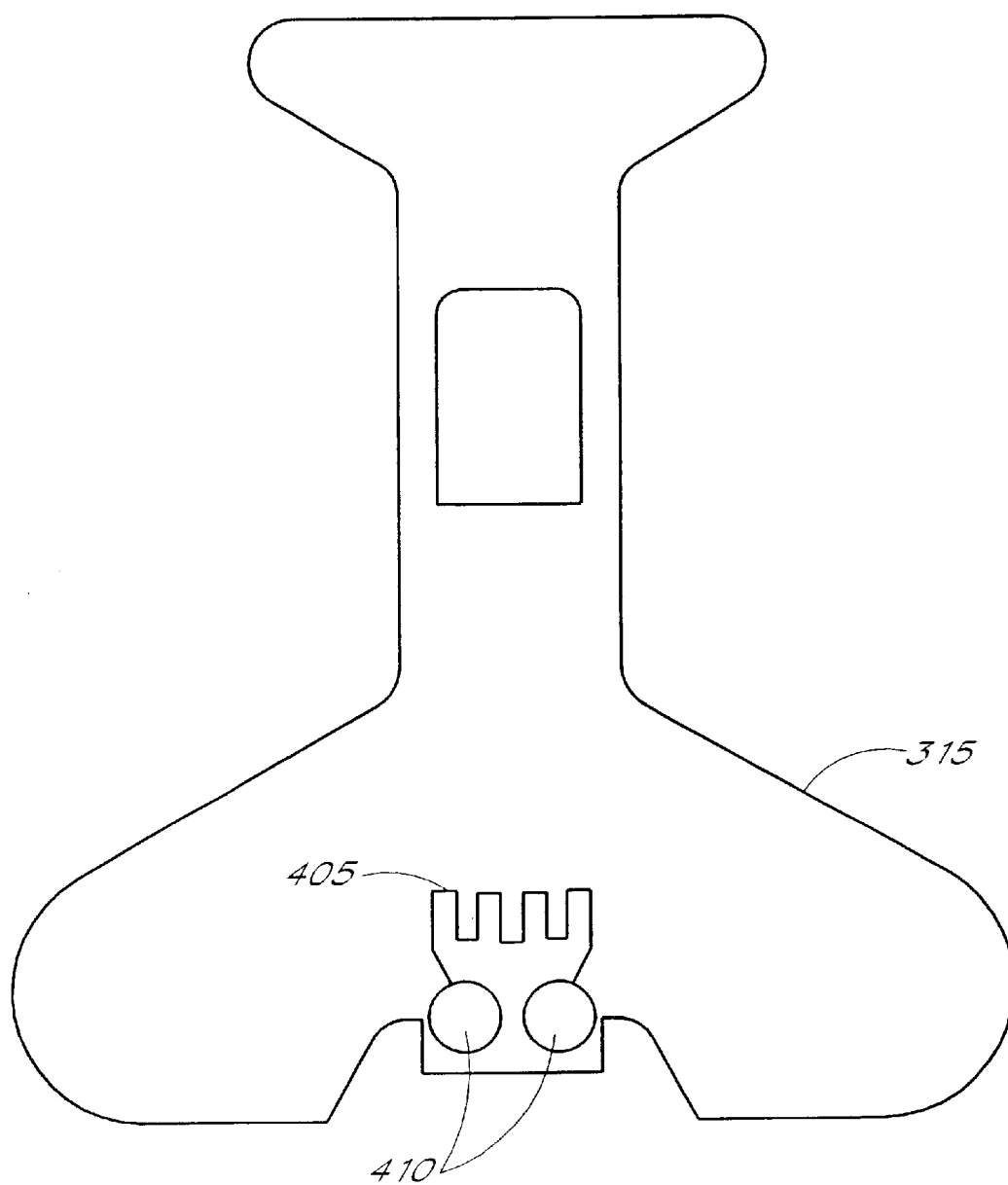


FIG. 4

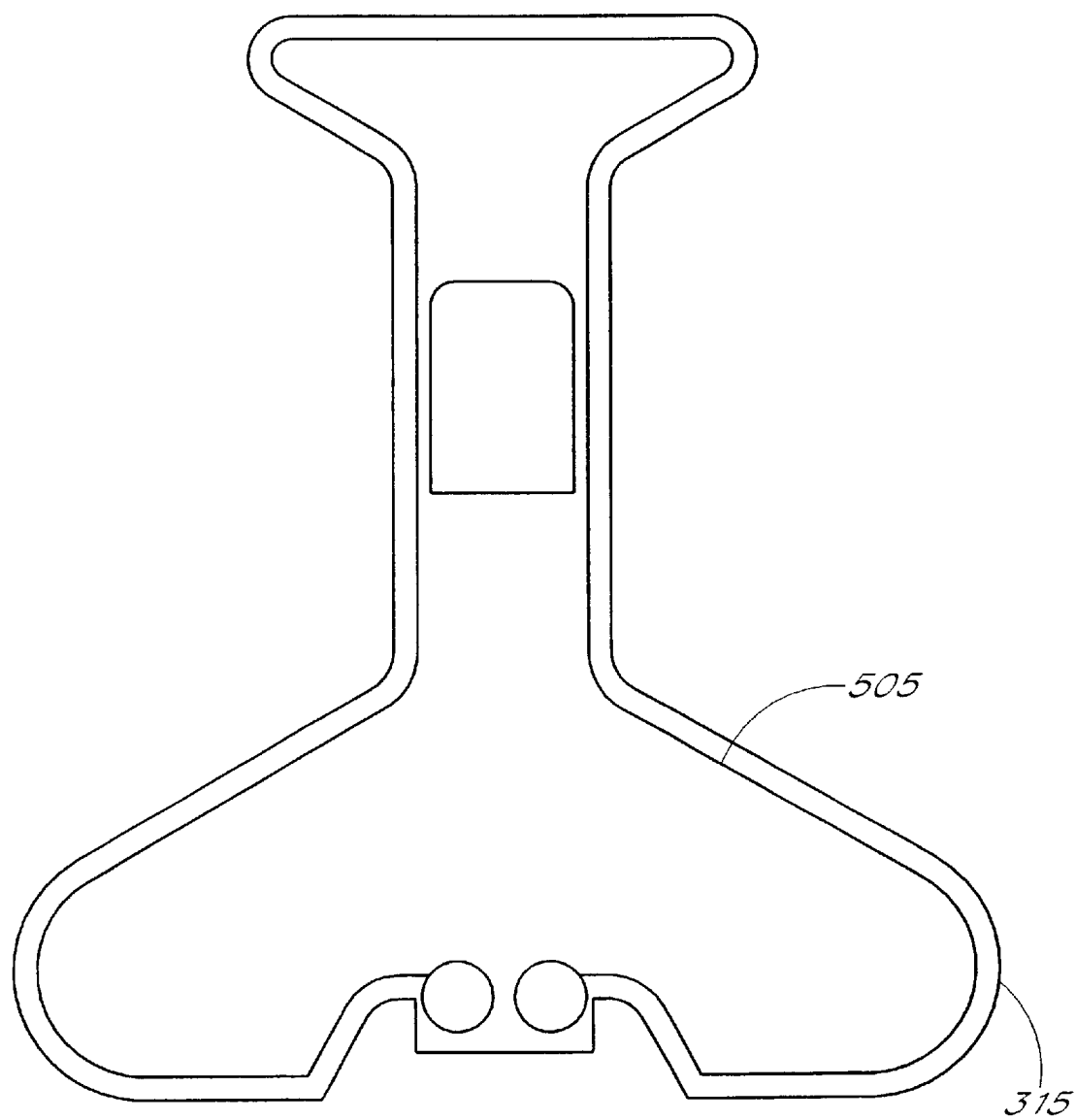


FIG. 5

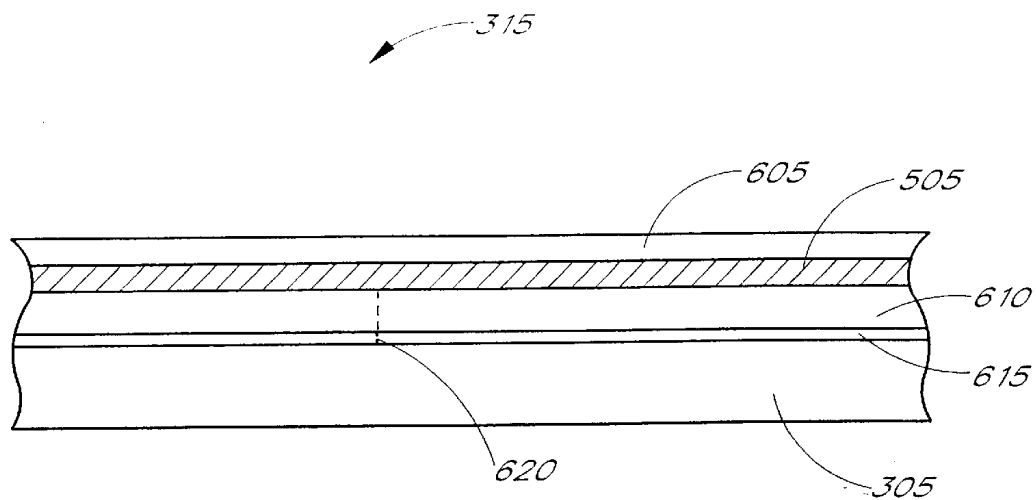


FIG. 6A

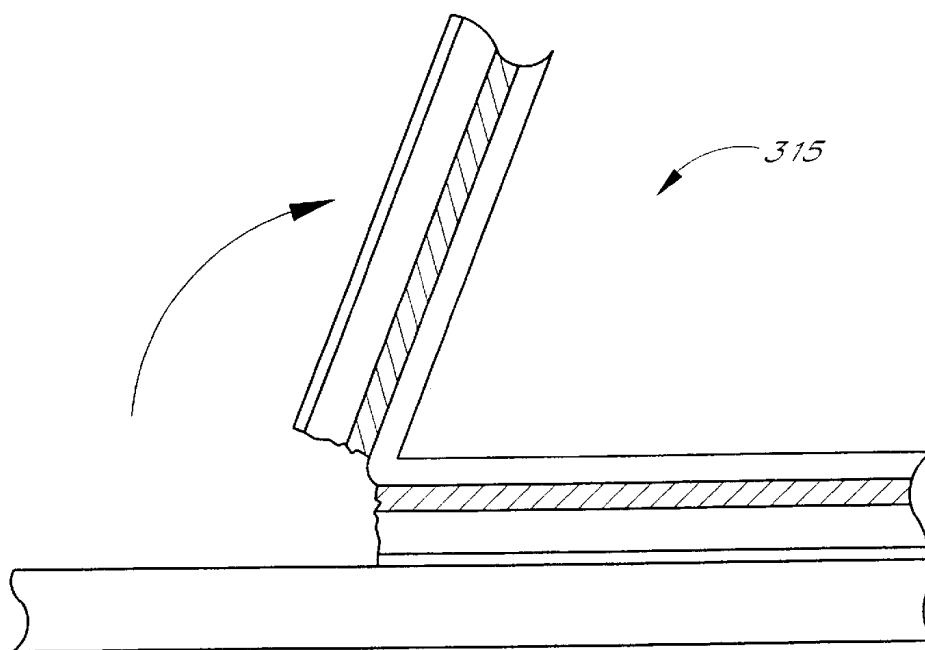
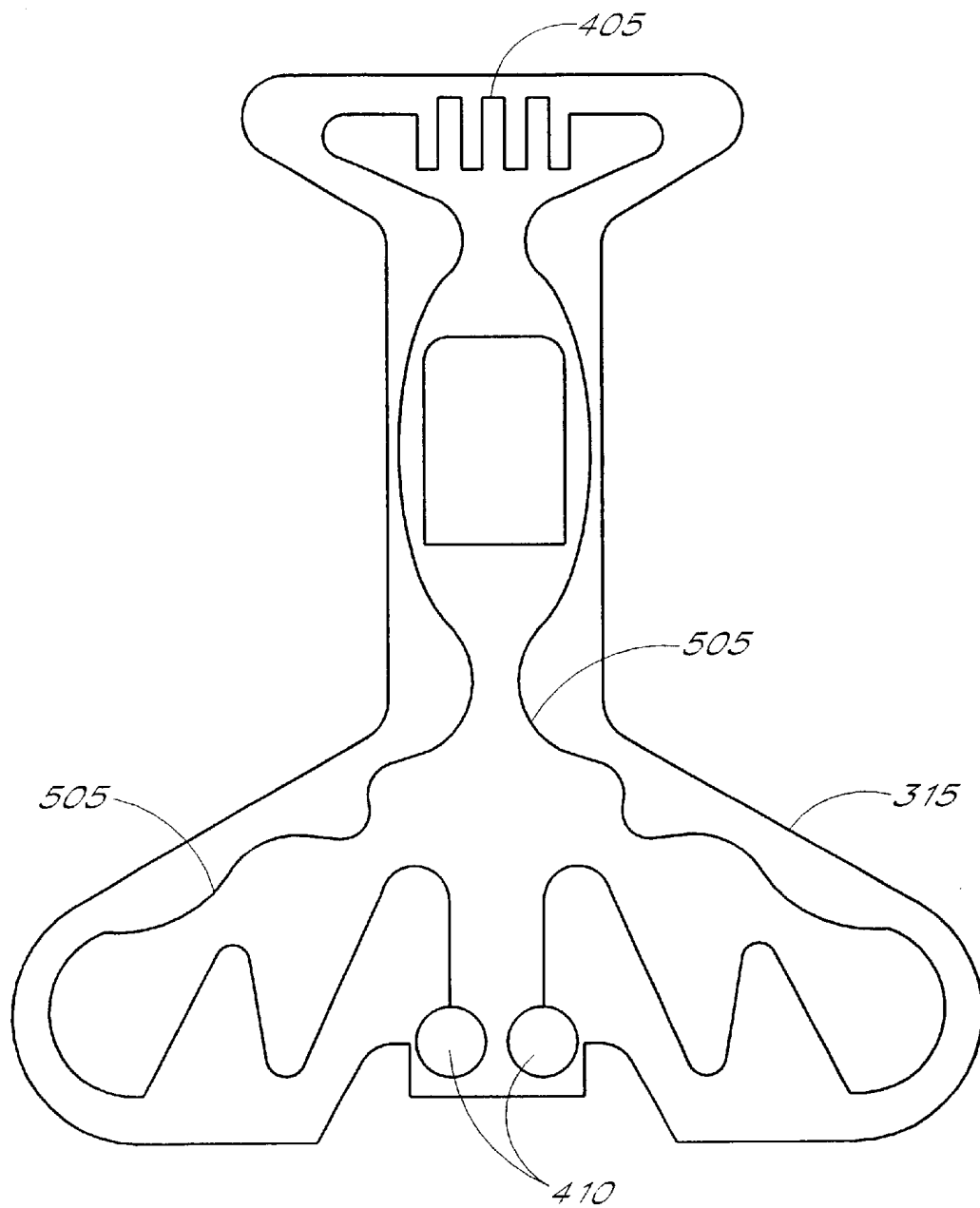


FIG. 6B

*FIG. 7*

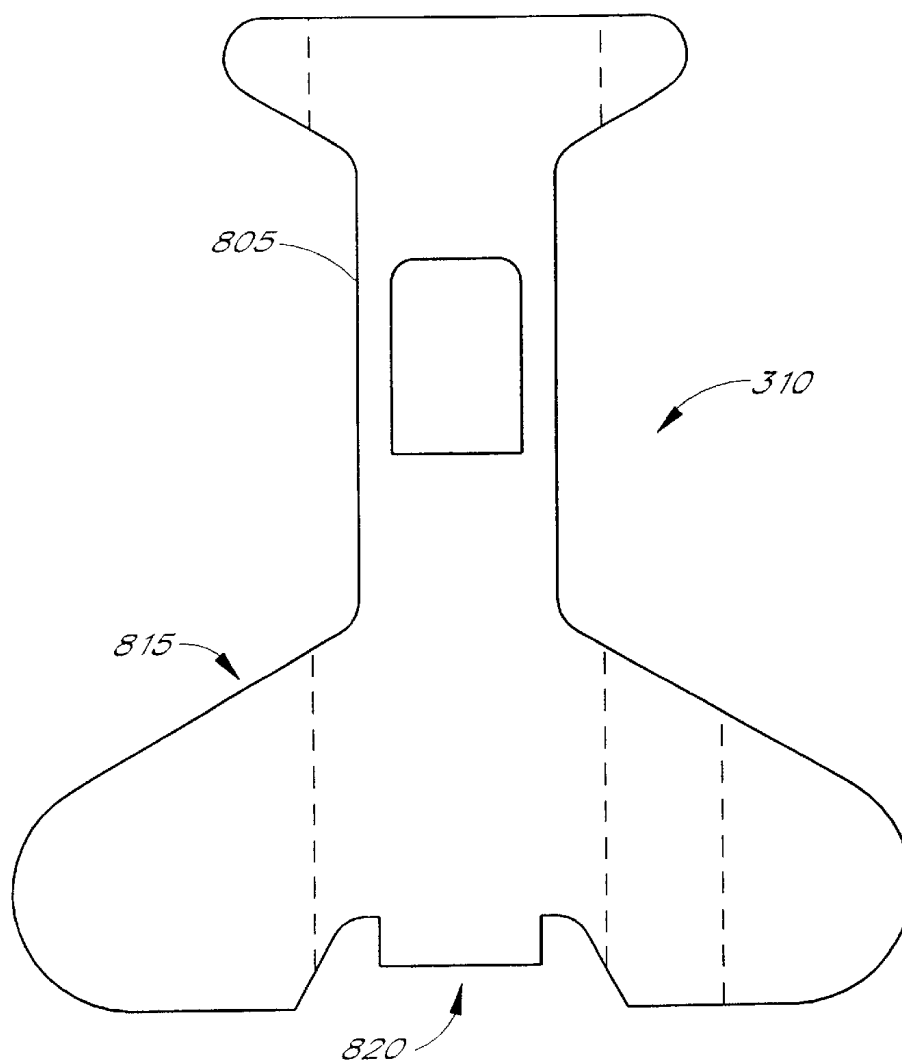


FIG. 8A

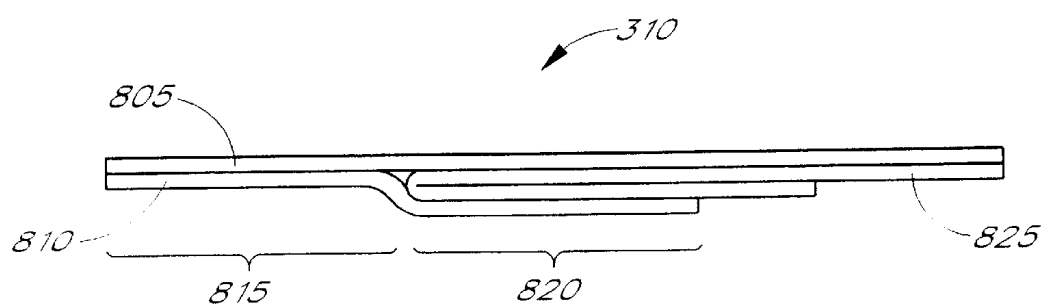
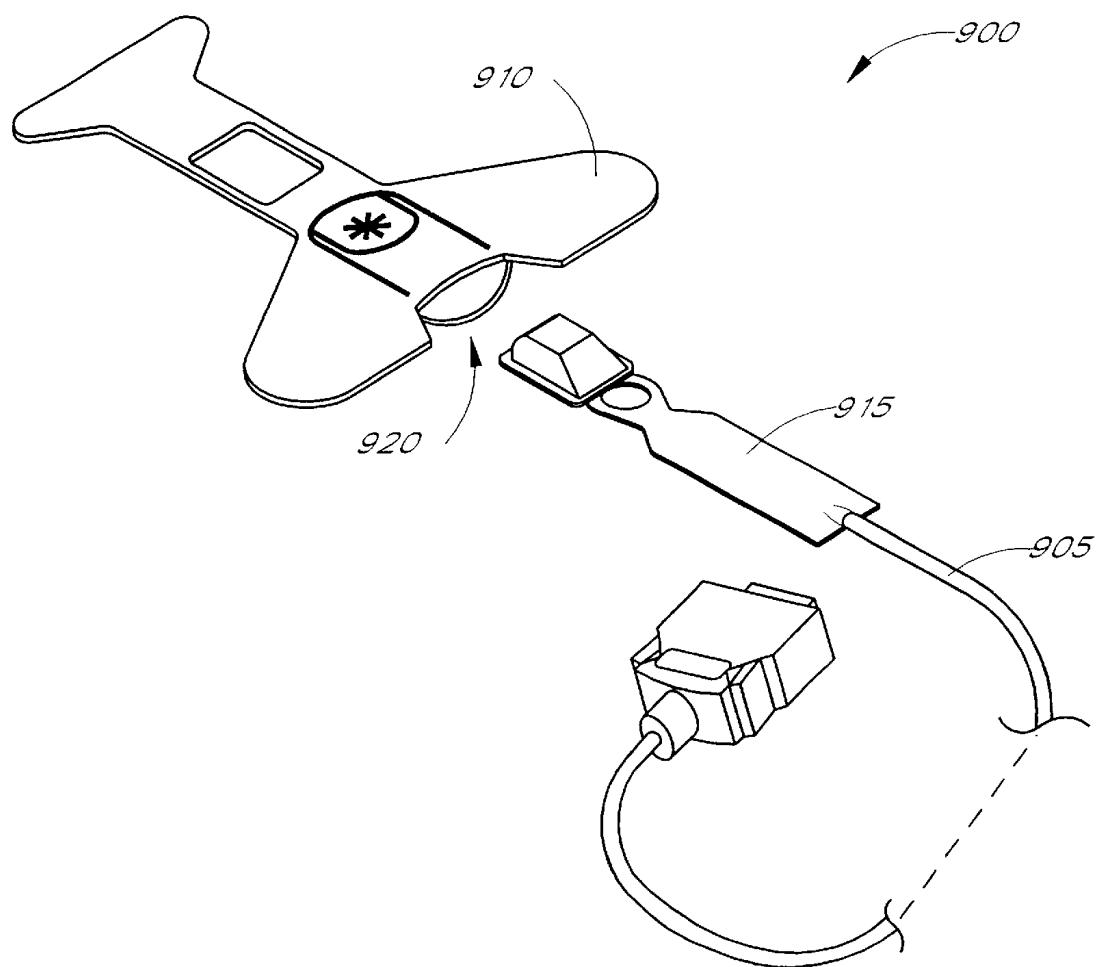


FIG. 8B

*FIG. 9A*

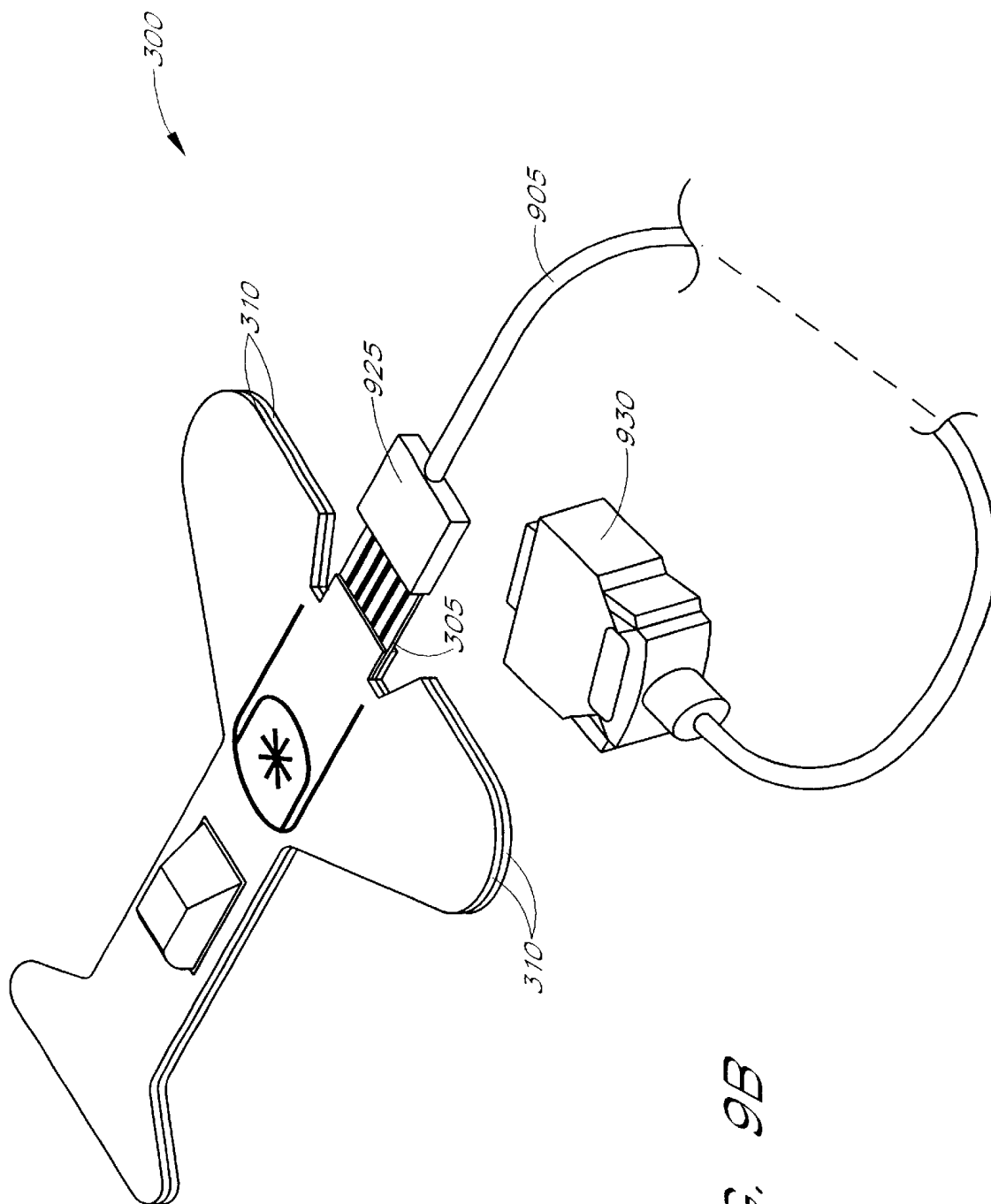


FIG. 9B

RESPONSABLE PULSE OXIMETRY SENSOR**REFERENCE TO RELATED APPLICATION**

The present application claims priority benefit under 35 U.S.C. §120 to, and is a continuation of, U.S. patent application Ser. No. 09/456,666, filed Dec. 9, 1999, entitled "Responsible Pulse Oximetry Sensor," now U.S. Pat. No. 6,377,829. The present application also incorporates the foregoing disclosure herein by reference.

FIELD OF THE INVENTION

The present invention relates in general to sensors for measuring oxygen content in the blood, and, in particular, relates to responsible (reusable/disposable) sensors having an information element contained therein.

BACKGROUND

Early detection of low blood oxygen is critical in a wide variety of medical applications. For example, when a patient receives an insufficient supply of oxygen in critical care and surgical applications, brain damage and death can result in just a matter of minutes. Because of this danger, the medical industry developed oximetry, a study and measurement of the oxygen status of blood. One particular type of oximetry, pulse oximetry, is a widely accepted noninvasive procedure for measuring the oxygen saturation level of arterial blood, an indicator of the oxygen status of the blood. A pulse oximeter relies on a sensor attached to a patient in order to measure the blood oxygen saturation.

Conventionally, a pulse oximeter sensor has a red emitter, an infrared emitter, and a photodiode detector. The sensor is typically attached to a patient's finger, earlobe, or foot. For a finger, the sensor is configured so that the emitters project light through the outer tissue of the finger and into the blood vessels and capillaries contained inside. The photodiode is positioned at the opposite side of the finger to detect the emitted light as it emerges from the outer tissues of the finger. The photodiode generates a signal based on the emitted light and relays that signal to an oximeter. The oximeter determines blood oxygen saturation by computing the differential absorption by the arterial blood of the two wavelengths (red and infrared) emitted by the sensor.

Conventional sensors are either disposable or reusable. A disposable sensor is typically attached to the patient with an adhesive wrap, providing a secure contact between the patient's skin and the sensor components. A reusable sensor is typically a clip that is easily attached and removed, or reusable circuitry that employs a disposable attachment mechanism, such as an adhesive tape or bandage.

The disposable sensor has the advantage of superior performance due to conformance of the sensor to the skin and the rejection of ambient light. However, repeated removal and reattachment of the adhesive tape results in deterioration of the adhesive properties and tearing of the tape. Further, the tape eventually becomes soiled and is a potential source of cross-patient contamination. The disposable sensor must then be thrown away, wasting the long-lived emitters, photodiode and related circuitry.

On the other hand, the clip-type reusable sensor has the advantage of superior cost savings in that the reusable pulse sensor does not waste the long-lived and expensive sensor circuitry. However, as mentioned above, the clip-type reusable sensor does not conform as easily to differing patient skin shape, resulting in diminished sensitivity and increased ambient light.

Similar to the clip-type reusable sensor, the circuit-type reusable sensor advantageously does not waste the sensor circuitry. On the other hand, the circuit-type reusable sensor fails to provide quality control over the attachment mechanism. Much like the disposable sensors, the attachment mechanism for the circuit-type reusable sensor may become soiled or damaged, thereby leading to cross-patient contamination or improper attachment. Moreover, because the reusable circuit is severable from the attachment mechanism, operators are free to use attachment mechanisms that are either unsafe or improper with regard to a particular type of reusable circuitry.

Based on the foregoing, significant and costly drawbacks exist in conventional disposable and reusable oximetry sensors. Thus, a need exists for an oximetry sensor that incorporates the advantages found in the disposable and reusable sensors, without the respective disadvantages.

SUMMARY OF THE INVENTION

Accordingly, one aspect of the present invention is to provide a reusable/disposable (responsible) sensor having a disposable adhesive tape component that can be removed from other reusable sensor components. This hybrid sensor combines the longevity and associated cost advantages of the reusable sensor with the performance features of the disposable.

In one embodiment of the responsible sensor, the disposable tape includes an information element along with a mechanism for the electrical connection of the information element to the emitters. The information element provides an indication to an attached oximeter of various aspects of the sensor.

According to another embodiment, the information element provides an indication of the sensor type. According to yet another embodiment, the information element provides an indication of the operating characteristics of the sensor. In yet another embodiment, the information element provides security and quality control. For instance, the information element advantageously indicates that the sensor is from an authorized supplier.

According to yet another embodiment, the information element is advantageously located in the disposable portion and configured to be in communication with the reusable portion via a breakable conductor. The breakable conductor is also located within the disposable portion such that excessive wear of the disposable portion results in isolation of the information element, thereby indicating that the disposable portion should be replaced. Moreover, the information element may comprise one or more passive or active components, ranging from a single coding resistor to an active circuit, such as a transistor network, a memory device, or a central processing component.

Therefore, one aspect of the present invention is a pulse oximetry sensor including a reusable portion having an emitter configured to transmit light through tissue, a detector configured to receive light from tissue, a first contact, an external connector configured to attach to a monitor, and electrical circuitry configured to provide electrical communications to and from the external connector, the emitter, the detector and the first contact. The pulse oximetry sensor also includes a disposable portion configured to attach the reusable portion to the tissue. The disposable portion has an information element, a breakable conductor, and a second contact electrically connecting the information element and the breakable conductor, the second contact configured to create an electrical connection to the first contact when the disposable portion is combined with the reusable portion.

Another aspect of the present invention is a responsible sensor for noninvasively measuring a physiological parameter in tissue. The responsible sensor includes a reusable portion and a disposable portion. The disposable portion has at least one of an information element and a conductor electrically connected to the reusable portion. Moreover, the disposable portion is configured to secure the reusable portion to a measurement site.

Another aspect of the present invention is a method of providing disposable oximeter sensor elements. The method includes forming a disposable housing configured to receive a reusable electronic circuit. The method also includes forming at least one of an information element and a conductor associated with the disposable housing and configured to be disconnected from the reusable electronic circuit when the disposable housing is damaged, overused, or repeatedly attached.

Another aspect of the present invention is a method of providing reusable oximeter sensor elements. This includes forming a reusable electronic circuit configured to electrically connect with electronic components of a disposable housing and to employ the disposable housing for attachment to a measurement site.

Another aspect of the present invention is a method of measuring a tissue characteristic. This method includes creating a sensor through combining reusable electronic circuitry with a first disposable material such that an electrical connection is made between the reusable electronic circuitry and electronic components associated with the first disposable material. Moreover, the method includes attaching the sensor to a measurement site, removing the sensor, separating the reusable electronic circuitry from the first disposable material, and recombining the reusable electronic circuitry with a second disposable material.

Another aspect of the present invention is a pulse oximeter having a sensor including a reusable portion and a disposable portion. The disposable portion includes an information element electrically connected to the reusable portion through a breakable conductor. The breakable conductor is configured to electrically disconnect the information element from the reusable portion in the event of overuse, damage, or excessive reattachment of the disposable portion. Moreover, the pulse oximeter includes a monitor, and a cable for connecting the sensor to the monitor.

Yet another aspect of the present invention is a pulse oximeter sensor element having a disposable material that incorporates electronic components. The disposable material is configured to removably receive reusable oximeter sensor elements such that the electronic components electrically connect with the reusable oximeter sensor elements. Moreover, the disposable material is configured to secure the reusable oximeter sensor elements to a measurement site.

Another aspect of the present invention is a pulse oximeter sensor element including reusable electronic circuitry configured to electrically connect with electronic components of a disposable material and to employ the disposable material for attachment to a measurement site.

Another aspect of the present invention is a responsible sensor for measuring a tissue aspect. The responsible sensor includes a face tape, a base tape removably attached to the face tape, and reusable measurement circuitry removably secured between the face tape and the base tape. The reusable measurement circuitry is also configured to connect to an external monitor and configured to measure an aspect of tissue at a measurement site. Moreover, the face tape includes at least one of an information element and a

breakable conductor connected to the reusable measurement circuitry when the reusable measurement circuitry is secured to the face tape.

Another aspect of the present invention is a responsible sensor having a reusable emitter and detector removably connected to a patient cable. The responsible sensor also includes a replaceable envelope having electronic circuitry configured to attach to the reusable emitter and detector such that the electronic circuitry monitors at least one characteristic of the responsible sensor. Moreover, the replaceable envelope is configured to removably receive the reusable emitter and detector and configured to secure the reusable emitter and detector to a measurement site.

Yet another aspect of the present invention is a pulse oximetry sensor having an emitter, a detector and a connector. The emitter is configured to transmit light through tissue and the detector is configured to receive light from tissue to measure a physiological parameter. Further, the connector is configured to provide electrical communications between the detector and emitter and a monitor. The pulse oximetry sensor includes a reusable portion having the emitter, the detector, the connector and a first contact in communication with the connector. Moreover, the sensor includes a disposable portion having a second contact, an information element and a conductive element disposed on an adhesive substrate configured to secure the reusable portion to a measurement site. The disposable portion removably attaches to the reusable portion in a first position such that the first contact contacts the second contact. The disposable portion detaches from the reusable portion in a second position. Also, the conductive element has a continuity condition connecting the information element to the second contact so that the information element is in communication with the connector. The conductive element has a discontinuity condition isolating the information element from the second contact and the connector. The discontinuity condition results from use of the disposable portion substantially beyond a predetermined amount.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a circuit diagram of a conventional disposable sensor having an information element.

FIGS. 2A and 2B illustrate perspective views of the conventional disposable sensor.

FIG. 3 illustrates an exploded view of a responsible sensor having two disposable tape layers, according to one embodiment of the invention.

FIG. 4 illustrates a top view of one of the disposable tape layers of FIG. 3 incorporating an information element.

FIG. 5 illustrates a top view of one of the disposable tape layers of FIG. 3 incorporating a breakable conductor.

FIGS. 6A and 6B illustrate cross-sectional views of a portion of the disposable tape layer of FIG. 5.

FIG. 7 illustrates a top view of one of the disposable tape layers of FIG. 3 incorporating the information element with a breakable conductor.

FIGS. 8A and 8B illustrate a top view and a side view, respectively, of one of the disposable layers of FIG. 3 configured as a fold-over tape.

FIG. 9A illustrates a perspective view of a responsible sensor having a disposable portion configured as a tape sleeve and a reusable portion directly attached to a patient cable, according to another embodiment of the invention.

FIG. 9B illustrates a perspective view of a responsible sensor having a reusable portion removably attached to a patient cable, according to another embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The configuration of an information element for an oximeter sensor and method of reading an information element with an attached oximeter is described in U.S. Pat. No. 5,758,644, assigned to the assignee of the current application, and incorporated by reference herein. Accordingly, the configuration and the implementation of an information element will be greatly summarized as follows.

FIG. 1 illustrates a conventional oximeter sensor circuit 100. The oximeter sensor circuit 100 includes an emitter 105 comprising a first LED 107 and a second LED 110. The oximeter sensor circuit further includes an information element comprising a resistor 115. The first LED 107, the second LED 110 and the resistor 115 are connected in parallel. The parallel connection has a common input electrical connection 120 and a common return 125. The oximeter sensor circuit 100 also includes a photodetector 130 having an input electrical connection 135 connected to one end and having the common return 125 connected to the other end.

As mentioned, the resistor 115 is provided as an information element that can be read by an attached oximeter. In order to read the resistor 115, the oximeter drives the oximeter sensor circuit 100 at a level where the emitter 105 draws effectively insignificant current. As is well understood in the art, the emitter 105 becomes active only if driven at a voltage above a threshold level. Thus, at this low level, significantly all of the current through the input electrical connection 120 flows through the resistor 115. By reducing the drive voltage across the input electrical connection 120 and common return 125 to a low enough level to not activate the emitter 105, the emitter 105 is effectively removed from the oximeter sensor circuit 100. Thus, the oximeter can determine the value of the resistor 115.

The value of the resistor 115 can be preselected to indicate, for example, the type of sensor (e.g., adult, pediatric, or neonatal), the operating wavelength, or other parameters about the sensor. The resistor 115 may also be utilized for security and quality control purposes. For example, the resistor 115 may be used to ensure that the oximeter sensor circuit 100 is configured properly for a given oximeter. For instance, the resistor 115 may be utilized to indicate that the oximeter sensor circuit 100 is from an authorized supplier.

An information element other than the resistor 115 may also be utilized. The information element need not be a passive device. Coding information may also be provided through an active circuit, such as a transistor network, memory chip, or other identification device.

Furthermore, it will be understood by a skilled artisan that a number of different circuit configurations can be implemented that allow the oximeter sensor circuit 100 to include an information element. For example, the emitter 105 and the information element may each have individual electrical connections.

As mentioned above, the resistor 115 is preselected such that at low drive voltages, it is the only circuit element sensed by the oximeter. On the other hand, the resistor 115 can also be preselected be of a sufficiently high value that when the drive voltage rises to a level sufficient to drive the emitter 105, the resistor 115 is effectively removed from the oximeter sensor circuit 100. Thus, the resistor 115 does not affect normal operations of the emitter 105. In summary, an information element may form an integral part of the oximeter sensor circuit 100 by providing valuable information to the attached oximeter.

FIGS. 2A and 2B illustrate a conventional disposable sensor 200. The disposable sensor 200 includes an adhesive substrate 205 having an elongated center portion 210 with front and rear flaps, 215 and 220, extending outward from the elongated center portion 210. The adhesive substrate 205 may also have an image 225 superimposed on the adhesive substrate 205 so as to indicate proper use.

The elongated center portion 210 includes the oximeter sensor circuit 100 of FIG. 1. For example, the emitter 105 is housed on an underside of the elongated center portion 210 approximately beneath the superimposed image 225. Thus, as shown in FIG. 2A, the emitter 105 may be housed approximately beneath the asterisk superimposed on the image of a fingernail. On the other hand, the photodetector 130 is housed on the topside of the elongated center portion 210 in proximity with the rear flaps 220.

The elongated center portion 210 further includes an electrical connector 230 to drive the emitter 105 and to receive an output from the photodetector 130. The electrical connector 230 is preferably configured to attach to a connector cable 235 via a sensor connector 240. Also, the connector cable 235 attaches to or connects with an oximeter via an oximeter connector 245.

FIG. 2B illustrates an example of how the disposable sensor 200 wraps the front and rear flaps 215 and 220 around a finger such that the adhesive substrate 205 provides a secure contact between the patient's skin, the emitter 105 and the photodetector 130. FIG. 2B also illustrates an example of the sensor connector 240 (shown in broken lines) encompassing the electrical connector 230.

As shown in FIGS. 1-2B, the conventional disposable sensor 200 integrates the components of the conventional oximeter sensor circuit 100 such that disposal of the disposable sensor 200 includes disposal of the longer lasting, expensive circuitry found therein.

FIG. 3 illustrates an exploded view of one embodiment of a resposable (reusable/disposable) sensor 300 according to the present invention. In this embodiment, the resposable sensor 300 includes a reusable portion 305 having an emitter 306, a photodetector 307 and an electrical connector 308. The resposable sensor also includes a disposable portion 310 having a face tape layer 315 and a clear base tape layer 320. As shown in FIG. 3, the disposable portion 310 attaches to the reusable portion 305 by sandwiching the reusable portion 305 between a face tape layer 315 and a clear base tape layer 320.

According to this embodiment, conventional adhesives or other attaching methodology may be used to removably attach the face tape layer 315 to the clear base tape layer 320. Furthermore, the adhesive properties associated with the base of the conventional disposable sensor 200 may be the same as the adhesive properties on the base of the clear base tape layer 320, as both portions are provided to attach to the patient's skin.

As mentioned, the disposable portion 310 removably attaches to the reusable portion 305 in, for example, a sandwich or layered style. After removably attaching the disposable portion 310 to the reusable portion 305, the resposable sensor 300 functions similar to the disposable sensor 200, i.e., the resposable sensor 300 wraps flaps around a patient's tissue such that the emitter 306 and the photodetector 307 align on opposite sides of the tissue. However, in contrast to the disposable sensor 200, the resposable sensor 300 provides for reuse of the reusable portion 305. For example, when the disposable portion 310 becomes contaminated, worn, or defective, rather than dis-

carding the entire responsible sensor **300**, the disposable portion **310** is removed such that the reusable portion **305** may be re-removably attached to a new disposable portion **310**. The discarding of the disposable portion **310** completely avoids cross-contamination through the reuse of adhesive tapes between patients without wasting the more costly and longer lasting sensor circuitry of the responsible portion **305**. Note that optional sterilization procedures may be advantageously performed on the reusable portion **305** before reattachment to either the new disposable portion **310** or to the patient, in order to further ensure patient safety.

FIG. 4 illustrates a top view of an embodiment of the face tape layer **315** of the disposable portion **310** of the responsible sensor **300**. According to this embodiment, the face tape layer **315** further includes an information element **405** as an integral part of the face tape layer **315**. In this embodiment, the information element **405** is a resistive element made by depositing a conductive ink trace having a predetermined length and width. As is known in the art, the length, width and conductivity of the conductive ink trace determines the resistance of the resistive element. The information element **405** is deposited between contacts **410** that are also implemented with conductive ink. It will be understood by a skilled artisan that a variety of methods can be used for mating the contacts **410** with the electrical circuitry of the reusable portion **305**. For example, the contacts **410** may advantageously physically touch the leads or the electrical connector **308** such that the reusable portion **305** is electrically configured to include the information element **405**. Such a configuration employs the oximeter sensor circuit **100** of FIG. 1, having elements thereof distributed in both the reusable portion **305** and the disposable portion **310** of the responsible sensor **300**.

In the foregoing embodiment, the disposable portion **310** comprises the information element **405** along with the face tape layer **315** and the clear base layer **320**. As mentioned, the disposable portion **310** is removably attached to the reusable portion **305** and is employed in a similar manner as the disposable sensor **200**. In contrast to the disposable sensor **200**, when the disposable portion **310** of the responsible sensor **300** becomes worn, the disposable portion **310** and the information element **405** are discarded and the reusable portion **305** is saved. By discarding the information element, the attached oximeter can perform quality control. For example, if the reusable portion **305** is reattached to a patient using either a simple adhesive or any other non-authorized disposable mechanism, the responsible sensor **300** will not include the information element **405**. As mentioned above, an attached oximeter can recognize the absence of the information element **405** and create an appropriate response indicating inappropriate use of the reusable portion **305** of the responsible sensor **300**.

FIG. 5 illustrates a top view of yet another embodiment of the face tape layer **315** of the disposable portion **310** of the responsible sensor **300**. In this embodiment, the face tape layer **315** includes a breakable conductor **505** comprising a conductive ink trace located approximately along the periphery of the face tape layer **315**. This location ensures that a tear along the periphery of the face tape layer **315** results in a tear, or electrical discontinuity, in the breakable conductor **505**. For example, FIGS. 6A and 6B illustrate the face tape layer **315** in which the breakable conductor **505** is layered between a tape stock **605** and a tape base **610**. The reusable portion **305** of the responsible sensor **300** then attaches to the tape base **610** through a pressure sensitive adhesive (PSA) **615**. The PSA **615**, the conductor **505** and the tape base **610** include a score **620** such that multiple attachment and

removal of the responsible sensor **300** will result in a peripheral tear, or electrical discontinuity, in the breakable conductor **505**, as illustrated in FIG. 6B.

Thus, like the information element **405**, the breakable conductor **505** also provides security and quality control functions. In particular, repeated use of the disposable portion **305** of the responsible sensor **300** advantageously severs at least one part of the breakable conductor **505**. An attached oximeter can detect such severance and initiate an appropriate notification to, for example, monitoring medical personnel. Providing security and quality control through a breakable conductor advantageously assists in controlling problems with patient contamination or improper attachment due to weakened adhesives.

FIG. 7 illustrates yet another embodiment of the face tape layer **315**. In this embodiment, the face tape layer **315** combines the breakable conductor **505** and the information element **405**. In this embodiment, the breakable conductor **505** is printed in a serpentine pattern to further increase the probability of a discontinuity upon the tearing of any portion of the face tape layer **315**. This combination of the information element **405** and the breakable conductor **505** advantageously adds significant safety features. For example, in this embodiment, the information element **405** is connected serially with the breakable conductor **505** and in parallel with the emitter **306** of the reusable portion **305**. Therefore, any discontinuity or tear in the breakable conductor **505** separates the information element **405** from the circuitry of the reusable portion **305**.

According to the foregoing embodiment, the attached oximeter receives an indication of both overuse and misuse of the responsible sensor **300**. For example, overuse is detected through the tearing and breaking of the breakable conductor **505**, thereby removing the information element **405** from the responsible sensor **300** circuitry. In addition, misuse through employment of disposable portions **310** from unauthorized vendors is detected through the absence of the information element **405**. Moreover, misuse from purposeful shorting of the contacts **410** is detected by effectively removing the emitter **306** from the circuit, thereby rendering the responsible sensor **300** inoperative. Therefore, the responsible sensor **300** of this embodiment advantageously provides a multitude of problem indicators to the attached oximeter. By doing so, the responsible sensor **300** advantageously prevents the likelihood of contamination, adhesive failure, and misuse. The responsible sensor **300** also advantageously maintains the likelihood of quality control.

A skilled artisan will recognize that the concepts of FIGS. 3-7 may be combined in total or in part in a wide variety of devices. For example, either or both of the breakable conductor **505** and the information element **405** may advantageously be traced into the clear base tape layer **320** rather than into the face tape layer **315**.

FIGS. 8A and 8B illustrate yet another embodiment of the disposable portion **310** of the responsible sensor **300** according to the present invention. As shown in this embodiment, the disposable portion **310** includes a face tape layer **805** and a clear base tape layer **810**. According to this embodiment, the clear base tape layer **810** includes a preattached section **815** and a fold over section **820**. The preattached section **815** attaches approximately one third of the face tape layer **805** to the clear base tape layer **810**. On the other hand, the fold over section **820** forms a flap configured to create a cavity between the face tape layer **805** and the clear base tape layer **810**. The cavity is configured to receive the reusable portion

305 of the resposable sensor **300**. According to one embodiment, a release liner **825** fills the cavity and separates the face tape layer **805** from the clear base tape layer **810**. When the release liner **825** is removed, newly exposed adhesive on the fold over section **820** and the face tape layer **805** removably attaches the reusable portion **305** between the face tape layer **805** and fold over section **820** of the clear base tape layer **810**.

According to another embodiment, the cavity is so formed that adhesive is not needed. For example, the fold over section **820** may comprise resilient material that can form a friction fit relationship so as to fix the reusable portion **305** in an appropriate position relative to the disposable portion **310**. On the other hand, the fold over section **820** may also comprise material having other than resilient or adhesive properties, but still allow for proper placement of the reusable portion **305** and disposable portion **310** on the patient. For example, hook-and-loop type materials like VELCRO® may be used.

It will be understood that a skilled artisan would recognize that the fold over embodiment of the responsible sensor **300** may employ the properties discussed in relation to FIGS. 3–7, such as the information element **405** and the breakable wire **505**.

FIG. 9A illustrates an embodiment of a resposable sensor **900** integrated with an attached patient cable **905**, according to another embodiment of the invention. In this embodiment, a disposable portion **910** is attached to a reusable portion **915** by removably inserting the reusable portion **915** into a tape envelope **920** formed in the disposable portion **910**.

A skilled artisan will recognize that the disposable portion **910** may include the information element **405**, the breakable wire **505**, or both. Inclusion of one or both of these electronic components in the resposable sensor **900** advantageously provides the security, quality control, and safety features described in the foregoing embodiments.

FIG. 9B illustrates an embodiment of a resposable sensor **300** of FIG. 3, according to another embodiment of the invention. According to this embodiment, the resposable sensor **300** removably attaches to the patient cable **905** via a sensor connector **925**. The patient cable **905** then attaches to an oximeter via an oximeter connector **930**. Use of the sensor connector **925** enables the replacement of both the reusable portion **305** of the resposable sensor **300** without replacement of the sensor connector **925** or patient cable **905**. In such an embodiment, the disposable portion **310** would follow a different, more frequent, replacement schedule than that of the reusable portion **305**.

A skilled artisan will recognize that the variety of configurations described above that include the information element **405**, the breakable wire **505**, or both, may be incorporated into the embodiment of FIG. 9B.

Although the foregoing invention has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art. For example, select aspects of FIGS. 3–9B may be combined. For example, the envelope configured disposable portion **910** of FIG. 9A may be combined with the reusable portion **305** of FIG. 3.

Additionally, other combinations, omissions, substitutions and modifications will be apparent to the skilled artisan in view of the disclosure herein. Accordingly, the present invention is not intended to be limited by the reaction of the preferred embodiments, but is to be defined by reference to the appended claims.

What is claimed is:

1. A disposable substrate for substantially securing reusable components of a pulse oximetry sensor to a measurement site of a patient, the disposable substrate comprising:

a substrate;
an information element and a breakable conductor disposed within or on the substrate and electrically connected to one another, wherein the breakable conductor comprises a purposeful structural weakness; and

an electrical contact portion electrically connected to the information element and the breakable conductor, and configured to electrically connect to a reusable portion of a pulse oximetry sensor including an emitter and a detector, when the substrate is combined with the reusable portion,

wherein the substrate is also configured to substantially secure the reusable portion in proximity to a measurement site.

2. The disposable substrate of claim 1, wherein the purposeful structural weakness comprises a score.

3. Reusable circuitry usable to form a pulse oximetry sensor, the reusable circuitry comprising:

an emitter configured to irradiate a measurement site with light;

a detector configured to detect the irradiated light;

an electrical contact portion configured to be in electrical communication with a breakable conductor having a purposefully weakened portion and information element housed within or on an attachment mechanism for substantially positioning the reusable circuitry in proximity to the measurement site; and

a sensor connector configured to provide communication between the electrical contact portion and a pulse oximeter, wherein the communication provides information on a type of the reusable circuitry and whether one of the reusable circuitry and the attachment mechanism has been overused.

4. The reusable circuitry of claim 3, further comprising a patient cable, wherein the communication between the electrical contact portion and the pulse oximeter occurs over through at least the patient cable and the sensor connector

5. The reusable circuitry of claim 3, wherein the purposefully weakened portion comprises a score.

6. A method of determining a duration of use and a type of pulse oximetry sensor, the method comprising:

combining components including a reusable emitter, a reusable detector, a breakable conductor including a purposefully weakened portion, an information element, and a securing mechanism, to form a pulse oximetry sensor, wherein two or more of the components form an electrical circuit; and

determining from characteristics of the electrical circuit a type of one or more of the components and whether at least one of the components has been overused.

7. The method of claim 6, wherein the two or more of the components comprise the breakable conductor and the information element.

8. The method of claim 6, wherein the purposefully weakened portion comprises a score.

9. A pulse oximetry sensor comprising;

reusable means for determining a characteristic of a measurement site, including a means for emitting light through tissue of the measurement site, means for receiving the light from the tissue, and means for completing an electrical circuit; and

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disposable means for substantially securing the reusable means to the measurement site, including means for determining overuse of the disposable means and means for determining a type of the pulse oximetry sensor, wherein the means for determining overuse and the means for determining the type are in electrical communication with the means for completing the electrical circuit.

10. The pulse oximetry sensor of claim **9**, wherein the means for determining overuse comprises a purposefully weakened conductor.

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11. The pulse oximetry sensor of claim **10**, wherein the purposefully weakened conductor comprises a score.

12. The pulse oximetry sensor of claim **9**, wherein the means for determining overuse comprises a means for tracking time.

13. The pulse oximetry sensor of claim **12**, wherein the means for tracking time tracks the time of use.

14. The pulse oximetry sensor of claim **9**, wherein the means for determining overuse comprises a means for tracking a number of uses.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,725,075 B2
APPLICATION NO. : 10/128721
DATED : April 20, 2004
INVENTOR(S) : Al-Ali

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Page 2, column 1 (Other Publications), line 3, after "Cables"," insert -- 1 page, --.

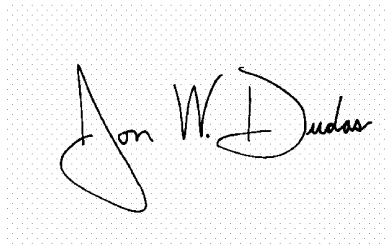
Page 2, column 1 (Other Publications), line 10, after "Sensors" delete " , " and insert -- , --, therefore.

At column 10, line 43 (Approx.), in Claim 4, after "connector" insert -- . --.

At column 10, line 62 (Approx.), in Claim 9, after "comprising" delete " ; " and insert -- : --, therefore.

Signed and Sealed this

Nineteenth Day of June, 2007

A handwritten signature in black ink on a light gray dotted background. The signature reads "Jon W. Dudas" in a cursive, stylized script. The "J" is large and loops around the "on". The "W" and "D" are also stylized.

JON W. DUDAS

Director of the United States Patent and Trademark Office

专利名称(译)	一次性脉搏血氧饱和度传感器		
公开(公告)号	US6725075	公开(公告)日	2004-04-20
申请号	US10/128721	申请日	2002-04-23
[标]申请(专利权)人(译)	AL ALI AMMAR		
申请(专利权)人(译)	AL-ALI AMMAR		
当前申请(专利权)人(译)	摩根大通银行，NATIONAL ASSOCIATION		
[标]发明人	AL ALI AMMAR		
发明人	AL-ALI, AMMAR		
IPC分类号	A61B5/00 A61B5/145 A61B5/1455		
CPC分类号	A61B5/14552 A61B5/6826 A61B5/6838 Y10T137/4478		
助理审查员(译)	克里默MATTHEW		
其他公开文献	US20020115919A1		
外部链接	Espacenet USPTO		

摘要(译)

脉冲血氧计传感器具有可重复使用部分和一次性部分。传感器的可重复使用部分保留了相对长寿命且昂贵的发射器，探测器和连接器组件。传感器的一次性部分是相对便宜的胶带组件，其用于将传感器固定到测量部位，通常是患者的手指或脚趾。传感器的一次性部分可拆卸地连接到可再用部分上，使得当粘合剂消耗或者带弄脏或过度磨损时，一次性部分可以容易地更换。一次性部分还可以包含用于传感器识别或用于安全目的的信息元件，以确保患者安全。允许脉搏血氧计监视器读取信息元件的导电元件位于一次性部分上，使得当胶带撕裂时，例如在从测量部位移除时，连续性被破坏。

