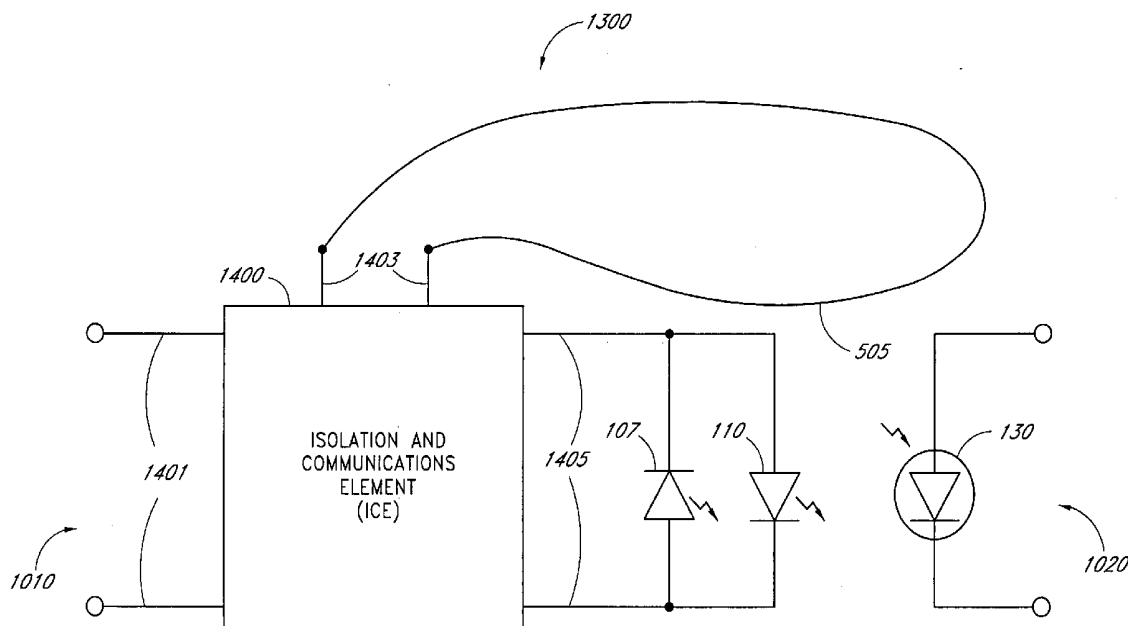




US 20060020180A1

(19) **United States**(12) **Patent Application Publication**
Al-Ali(10) **Pub. No.: US 2006/0020180 A1**(43) **Pub. Date: Jan. 26, 2006**(54) **ISOLATION AND COMMUNICATION
ELEMENT FOR A RESPONSABLE PULSE
OXIMETRY SENSOR**(60) Provisional application No. 60/351,784, filed on Jan.
25, 2002.**Publication Classification**(76) Inventor: **Ammar Al-Ali**, Tustin, CA (US)Correspondence Address:
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614 (US)(51) **Int. Cl.**
A61B 5/00 (2006.01)(52) **U.S. Cl.** **600/310; 600/344**(57) **ABSTRACT**(21) Appl. No.: **11/235,617**(22) Filed: **Sep. 26, 2005****Related U.S. Application Data**(63) Continuation of application No. 10/351,643, filed on
Jan. 24, 2003, now Pat. No. 6,950,687, which is a
continuation-in-part of application No. 10/128,721,
filed on Apr. 23, 2002, now Pat. No. 6,725,075, which
is a continuation of application No. 09/456,666, filed
on Dec. 9, 1999, now Pat. No. 6,377,829.

A sensor has a connector adapted to electrically commu-
nicate with a physiological measurement instrument. A break-
able conductor incorporated by the sensor transitions from a
continuity state to a discontinuity state as the result of sensor
wear. An isolation and communications element (ICE) has
an instrument port and an electrically isolated loop port. The
instrument port is in communications with the connector and
the loop port is in communications with the breakable
conductor. The ICE generates a control output responsive to
the discontinuity state to render the sensor inoperable.



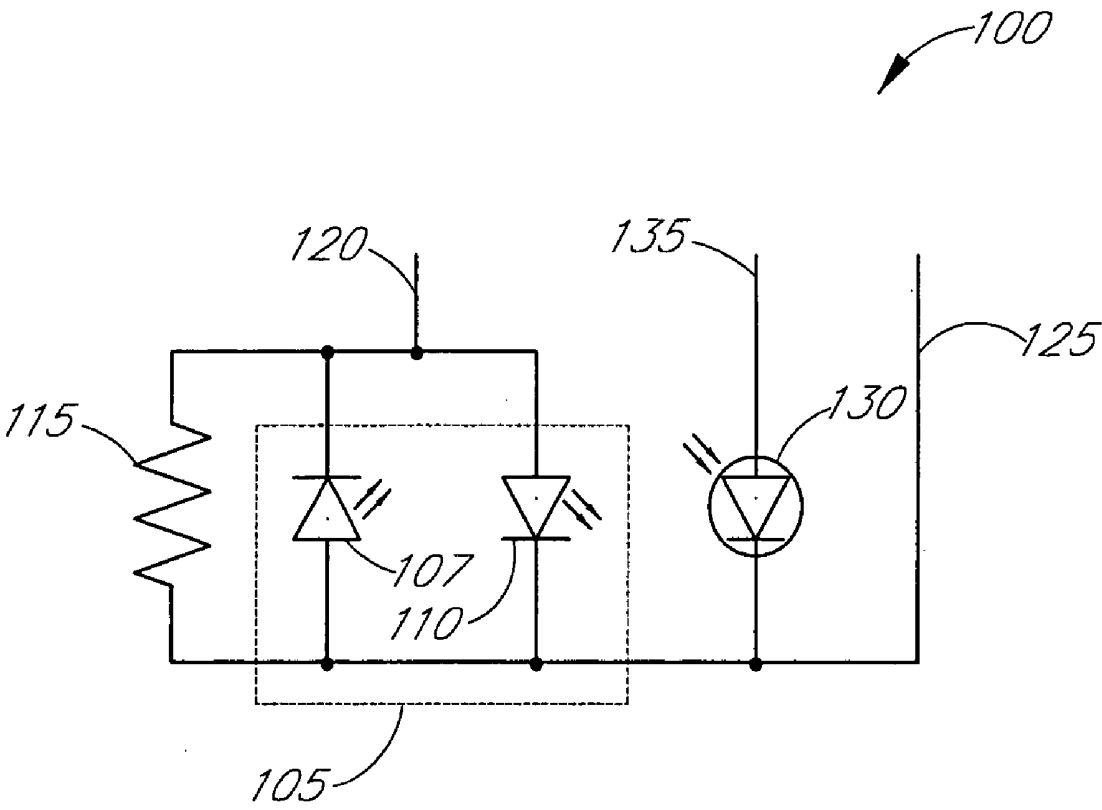
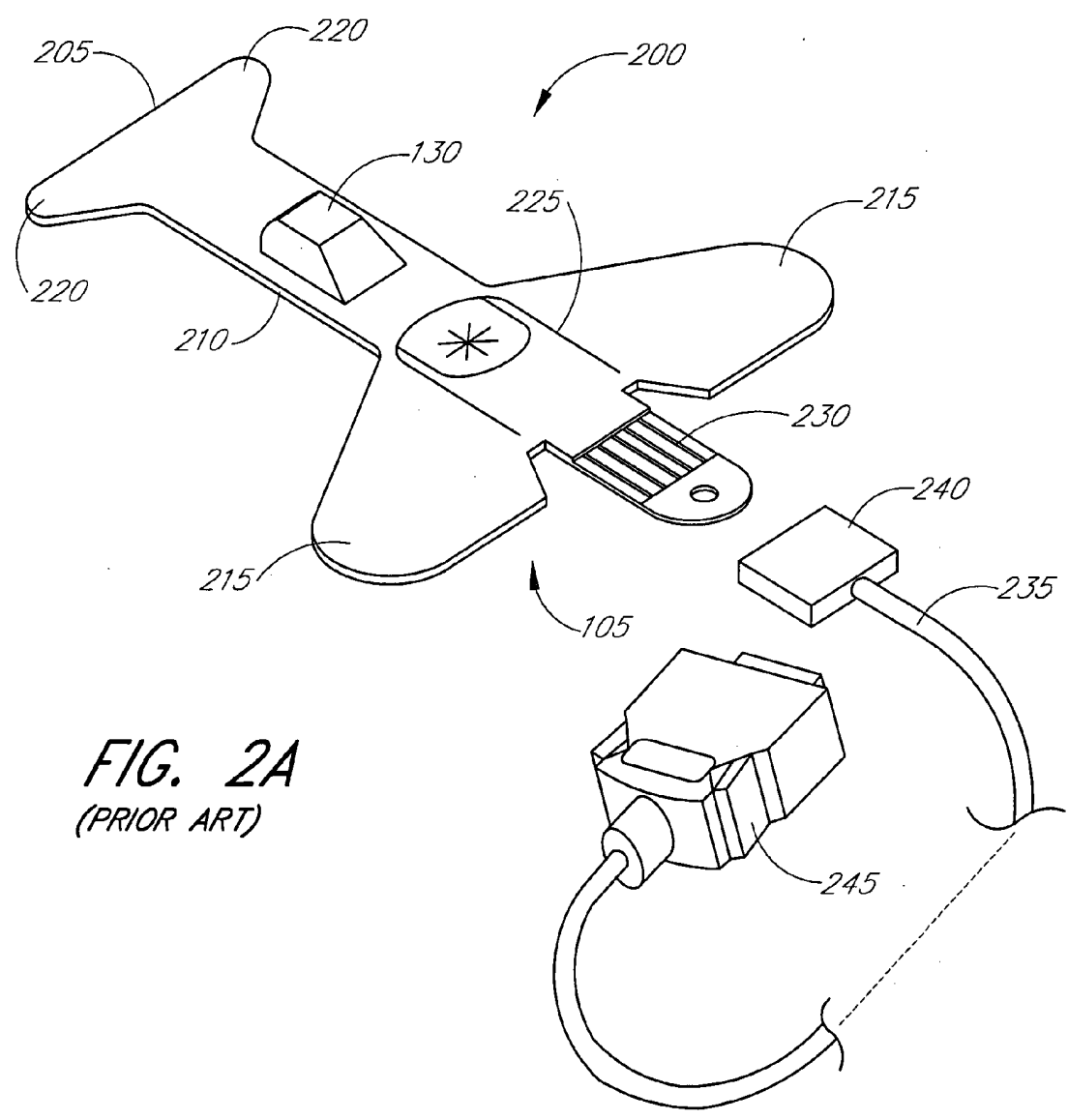


FIG. 1



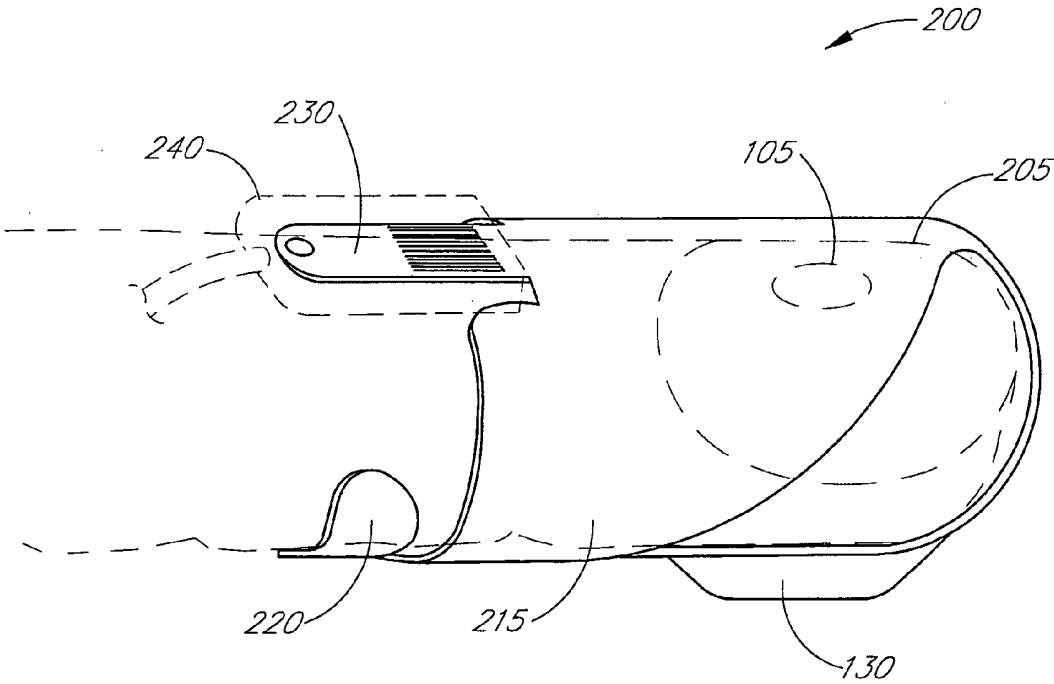


FIG. 2B
(PRIOR ART)

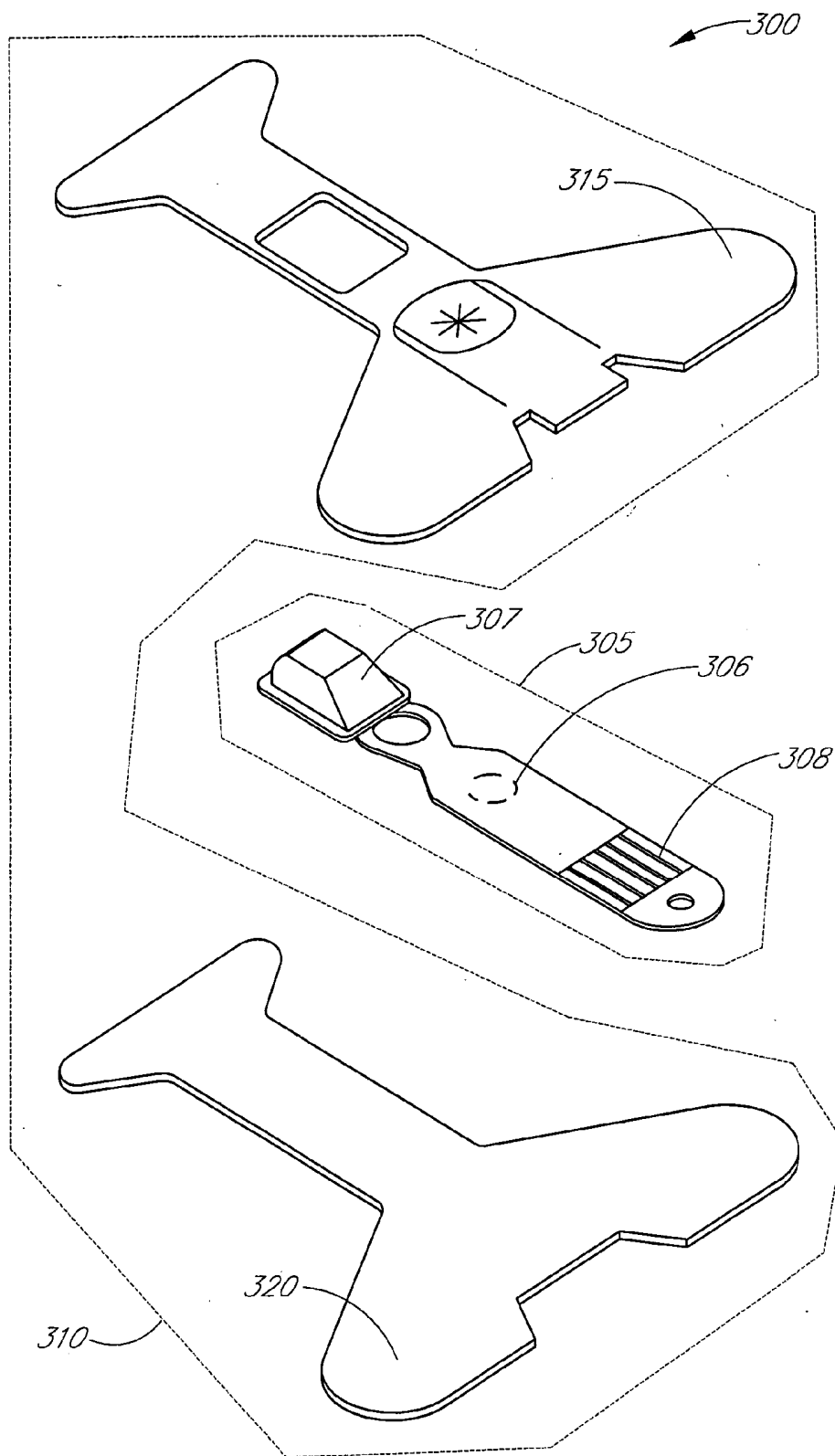


FIG. 3

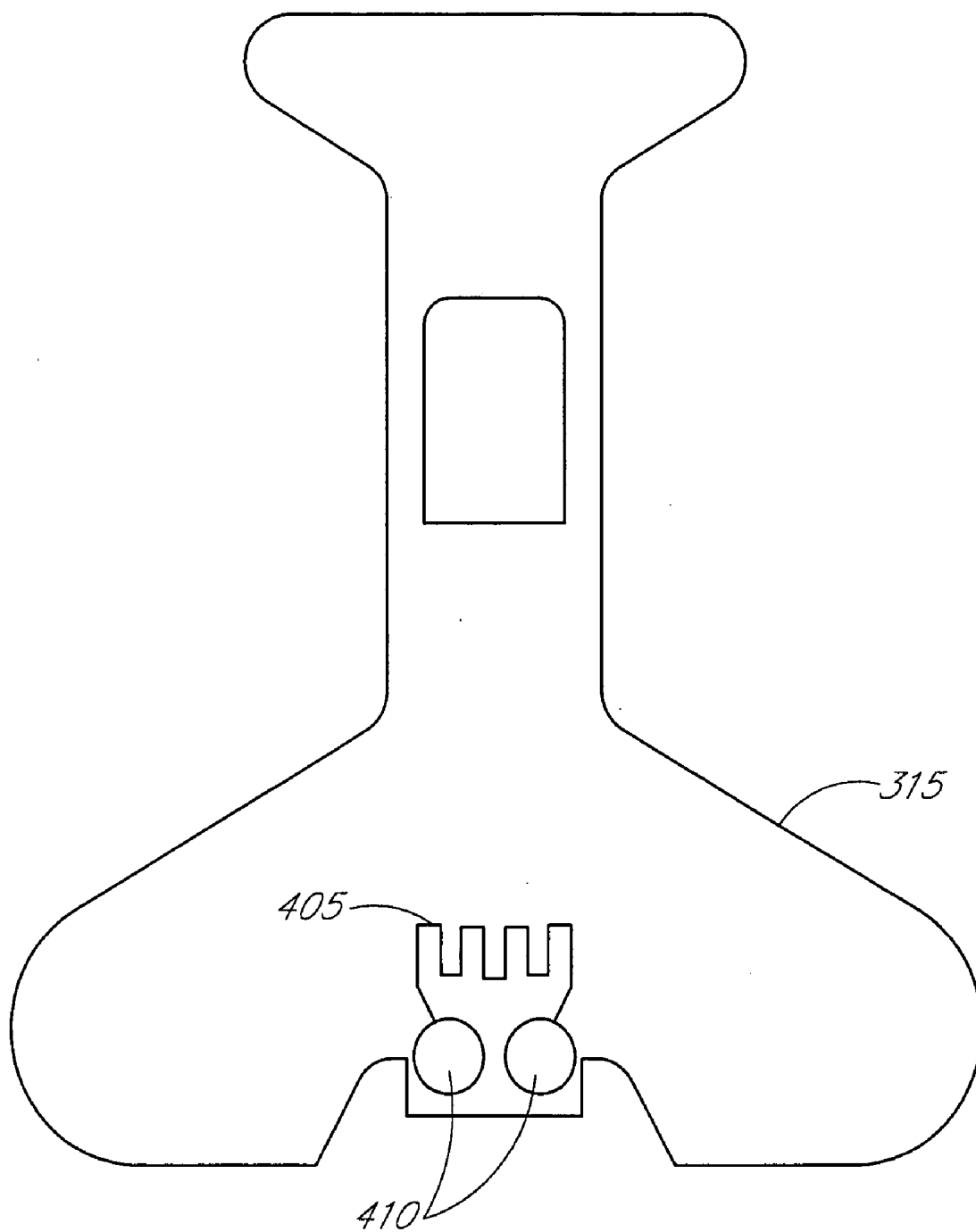


FIG. 4

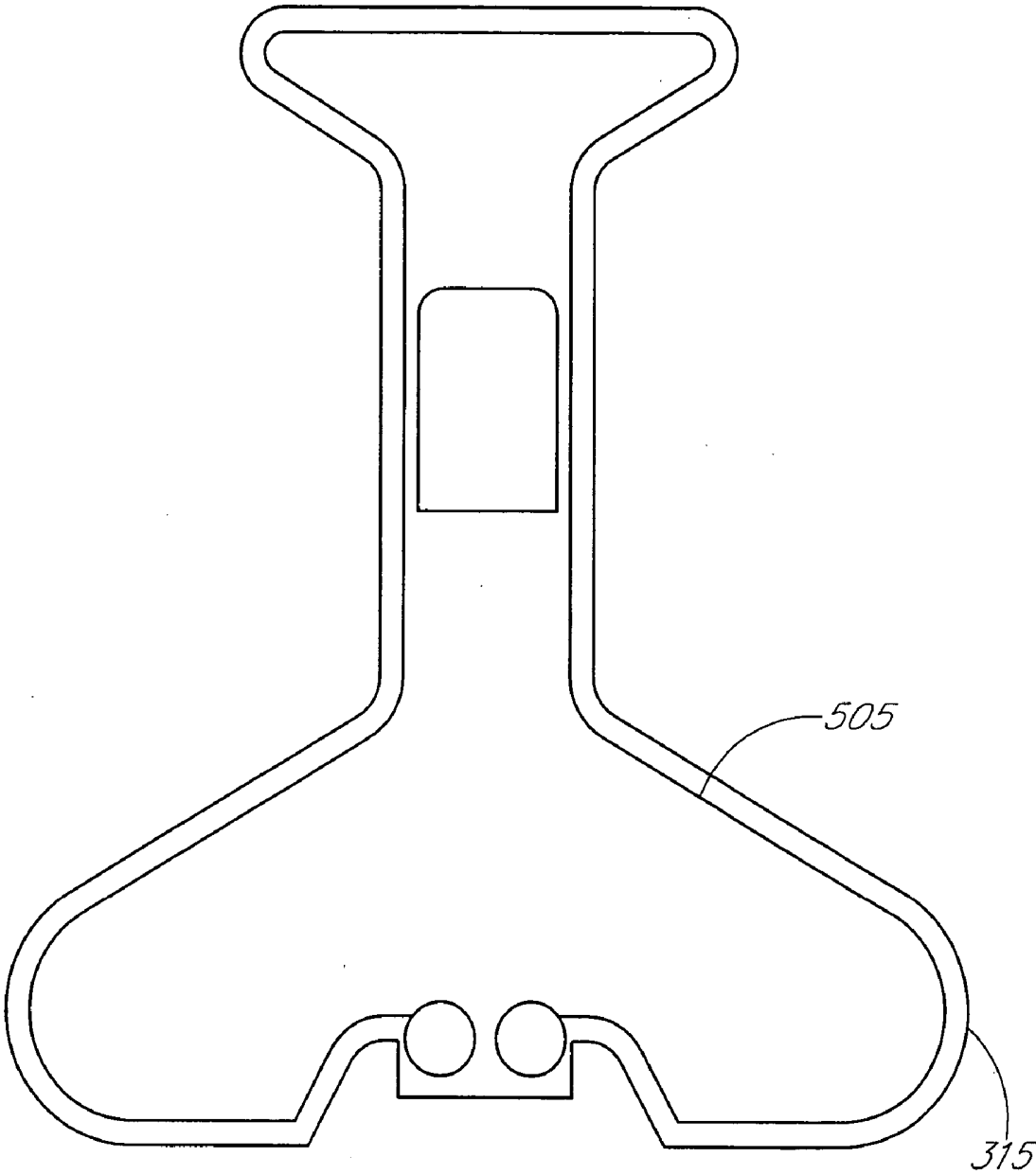


FIG. 5

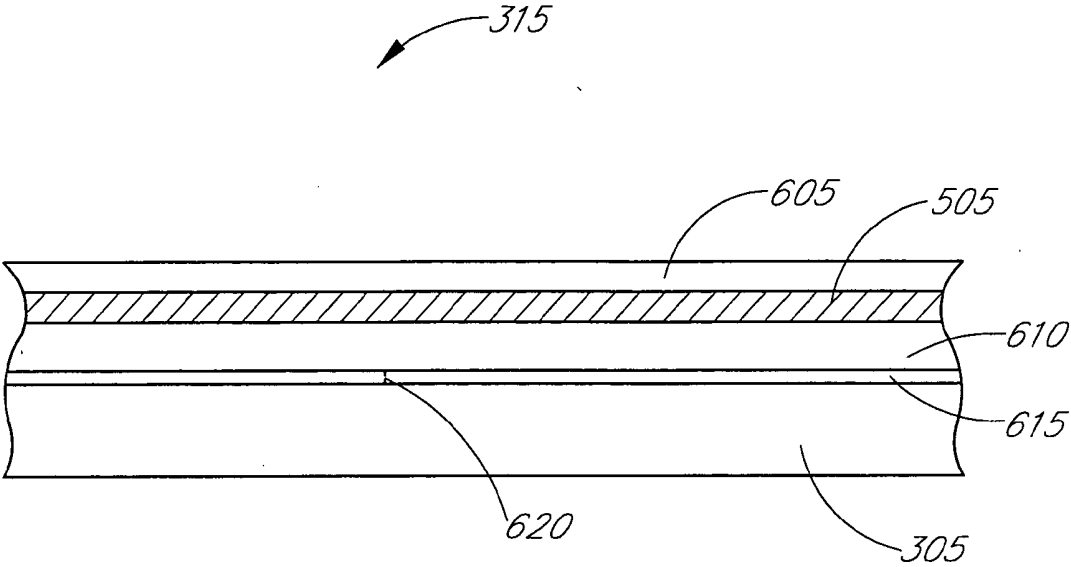


FIG. 6A

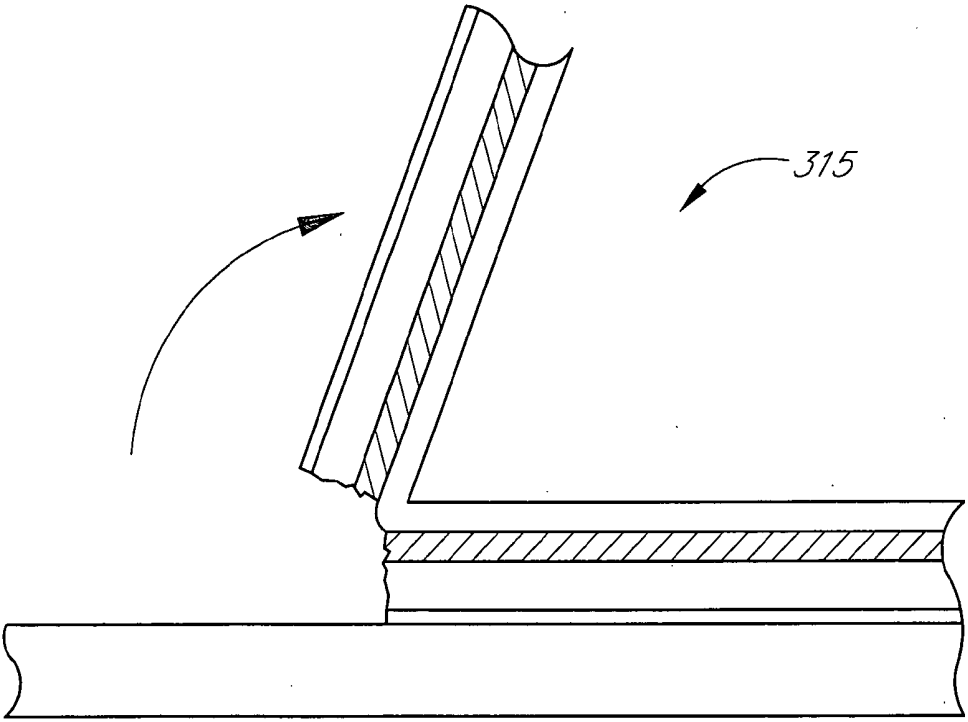


FIG. 6B

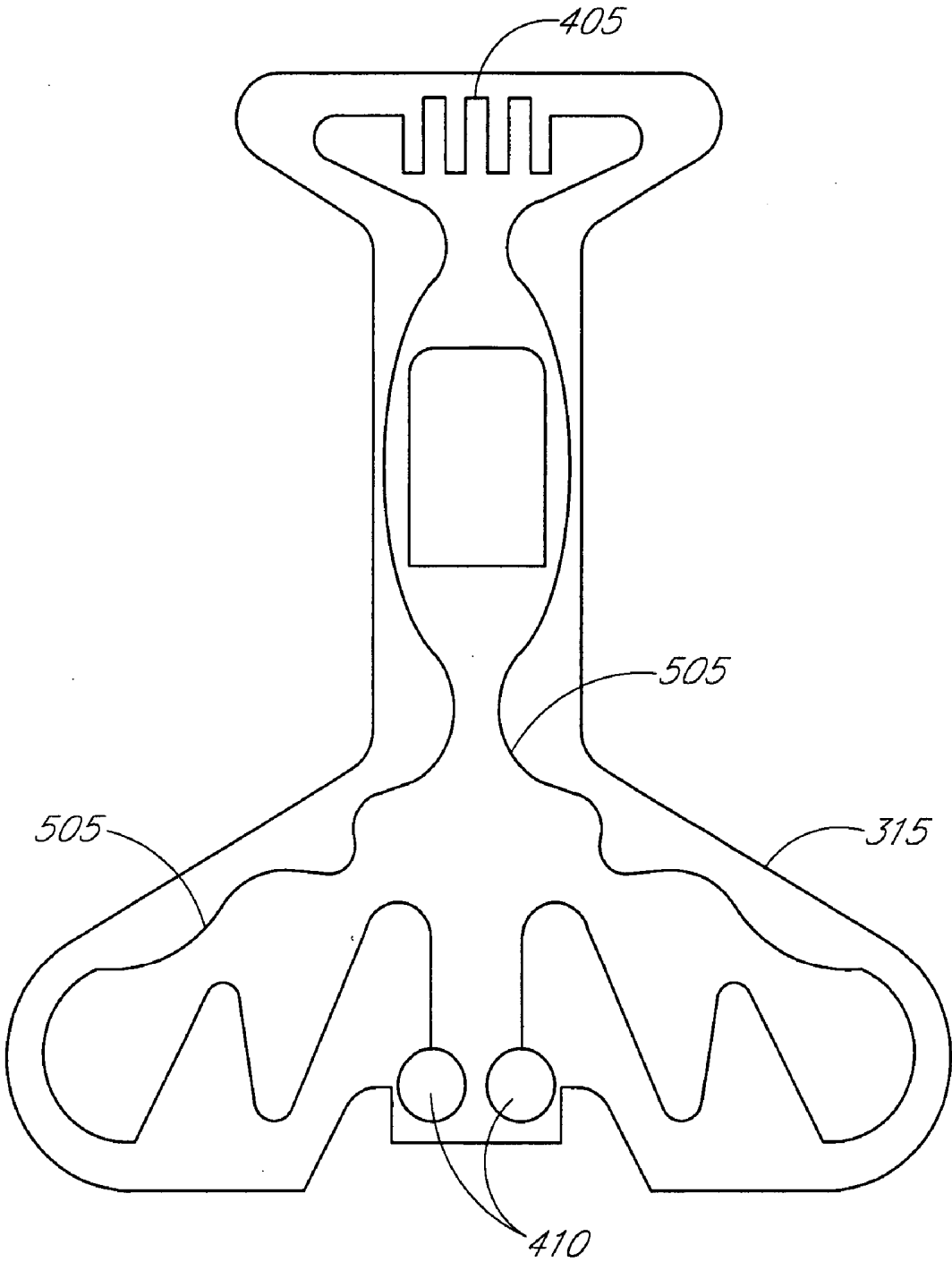


FIG. 7

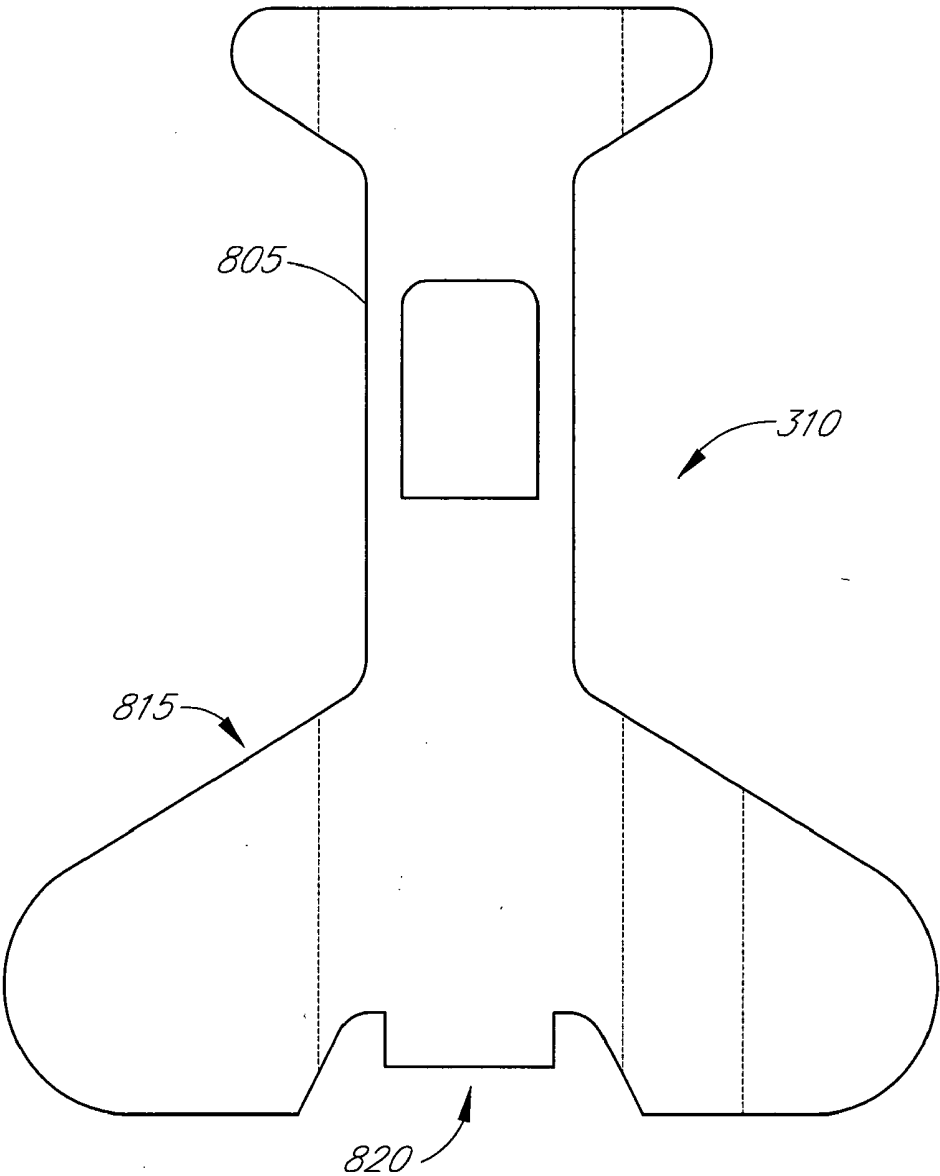


FIG. 8A

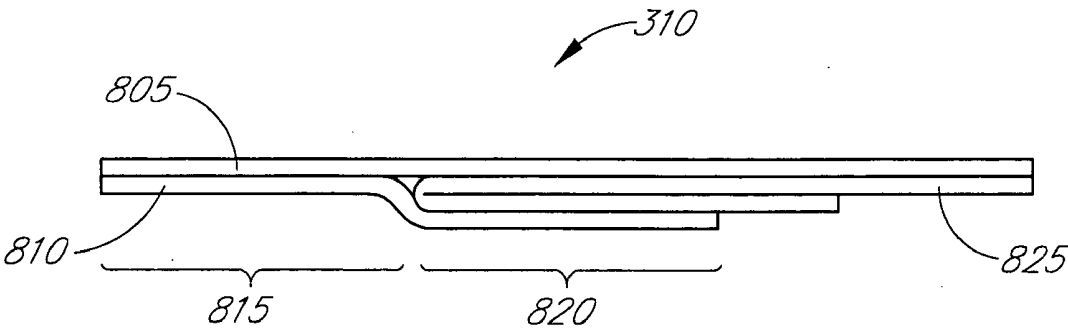
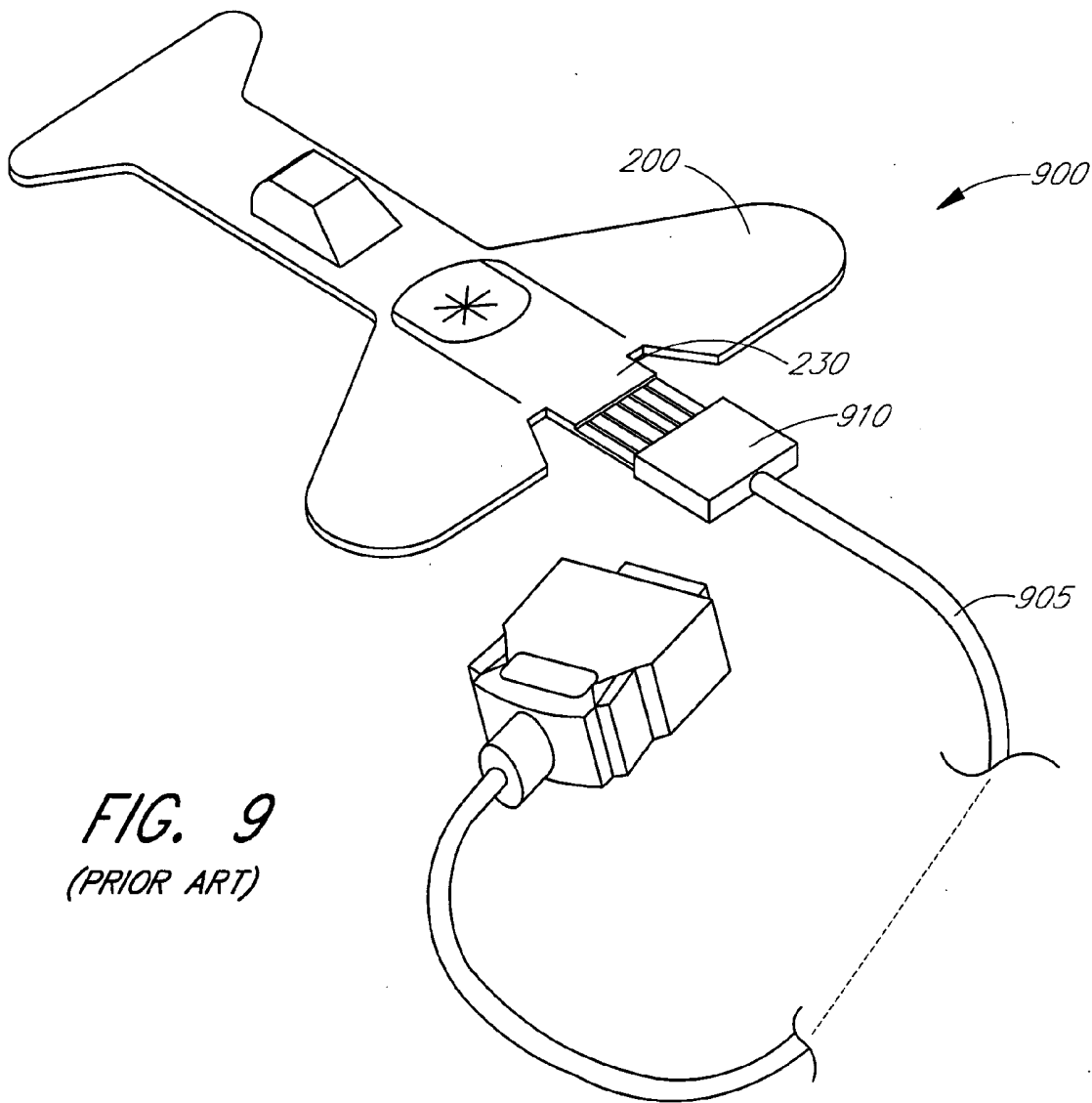


FIG. 8B



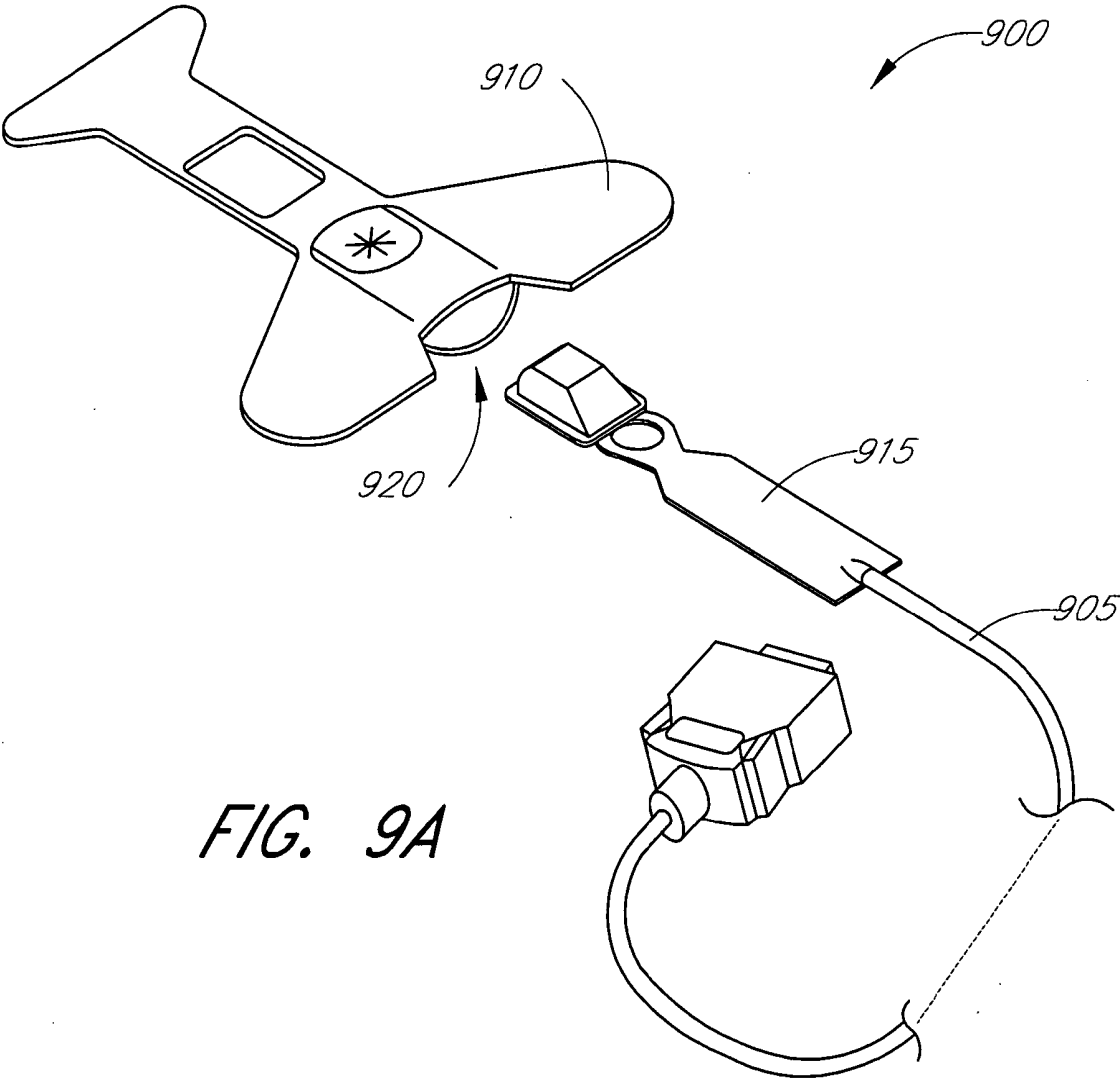
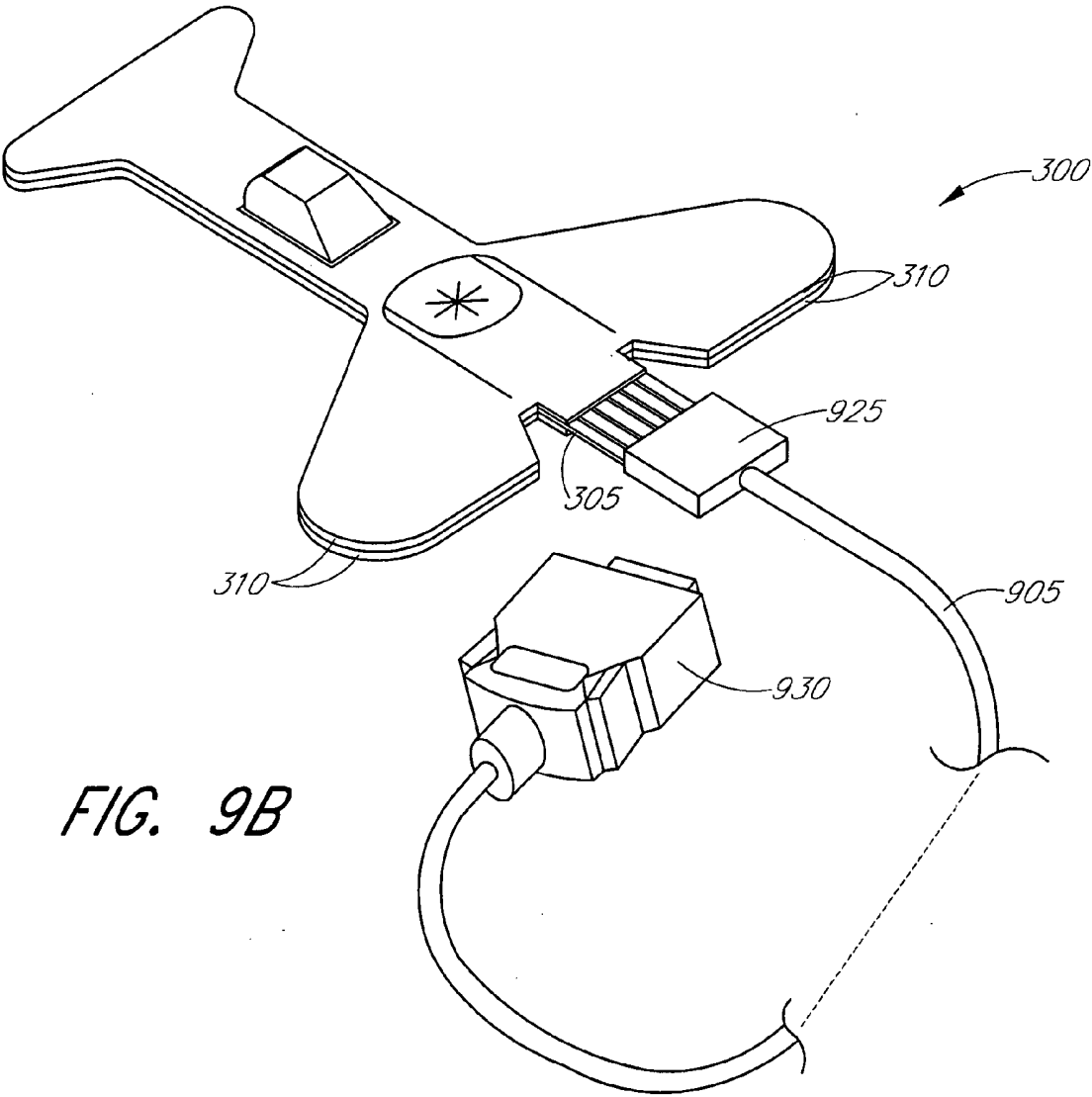


FIG. 9A



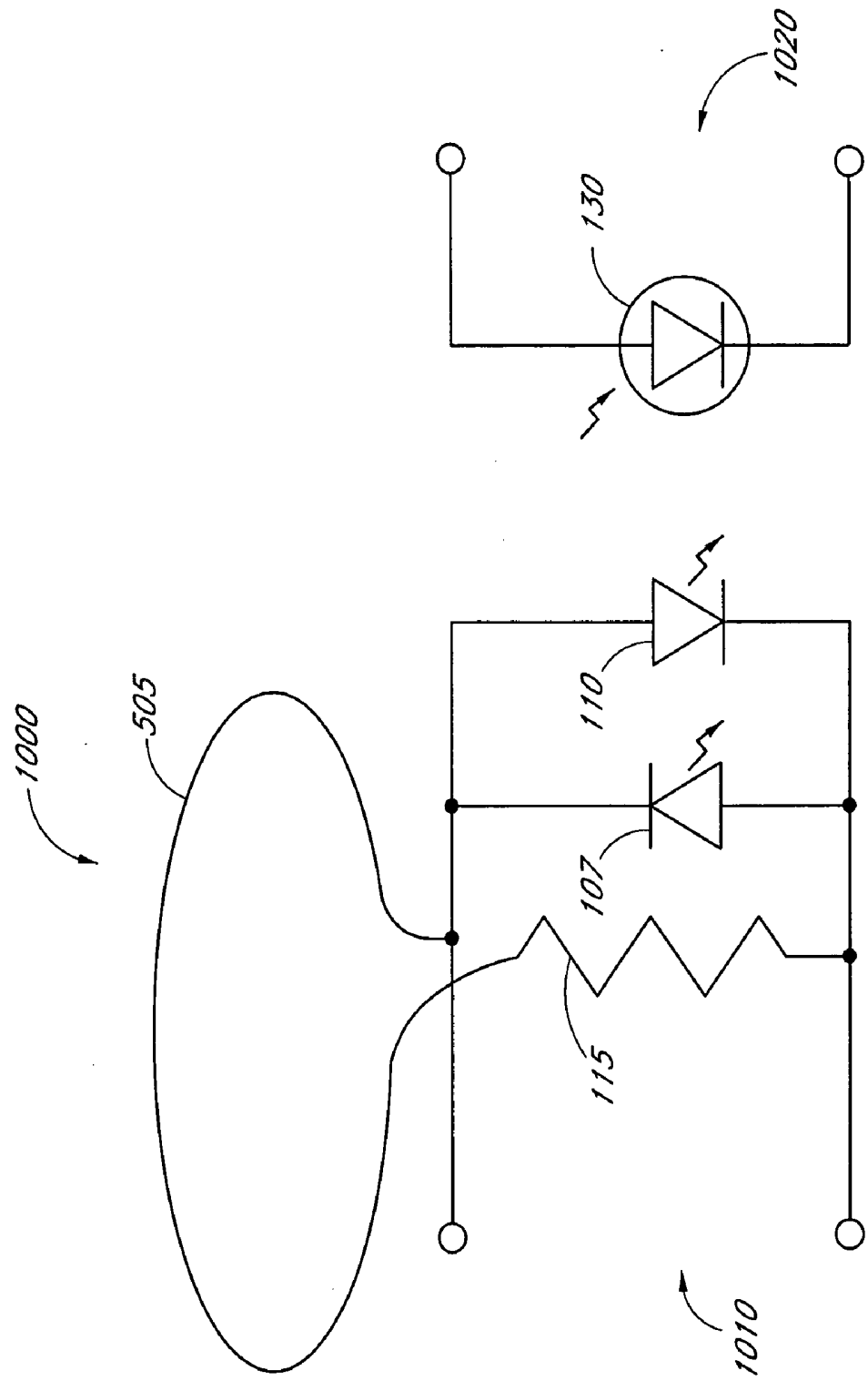


FIG. 10

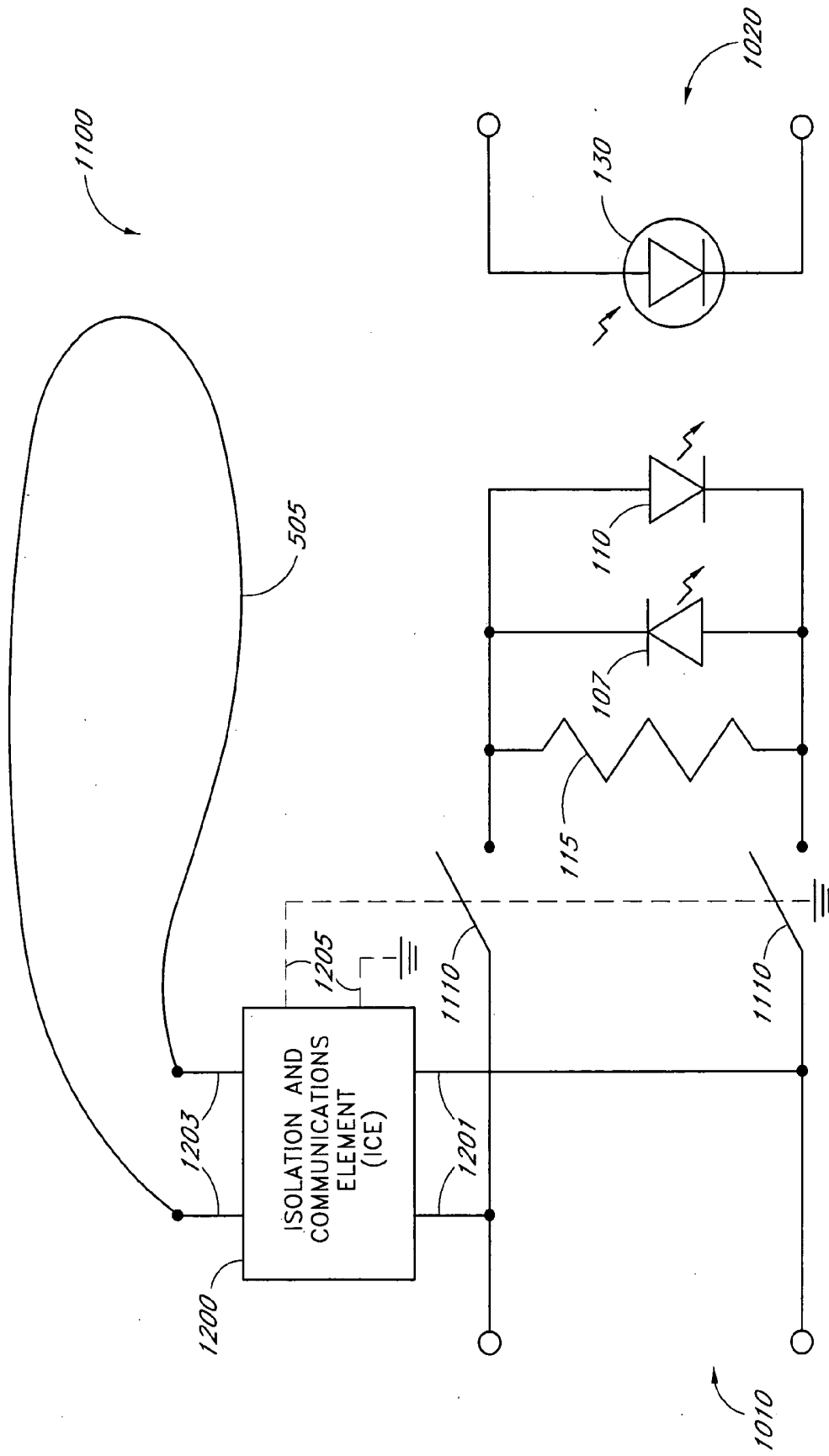


FIG. 11

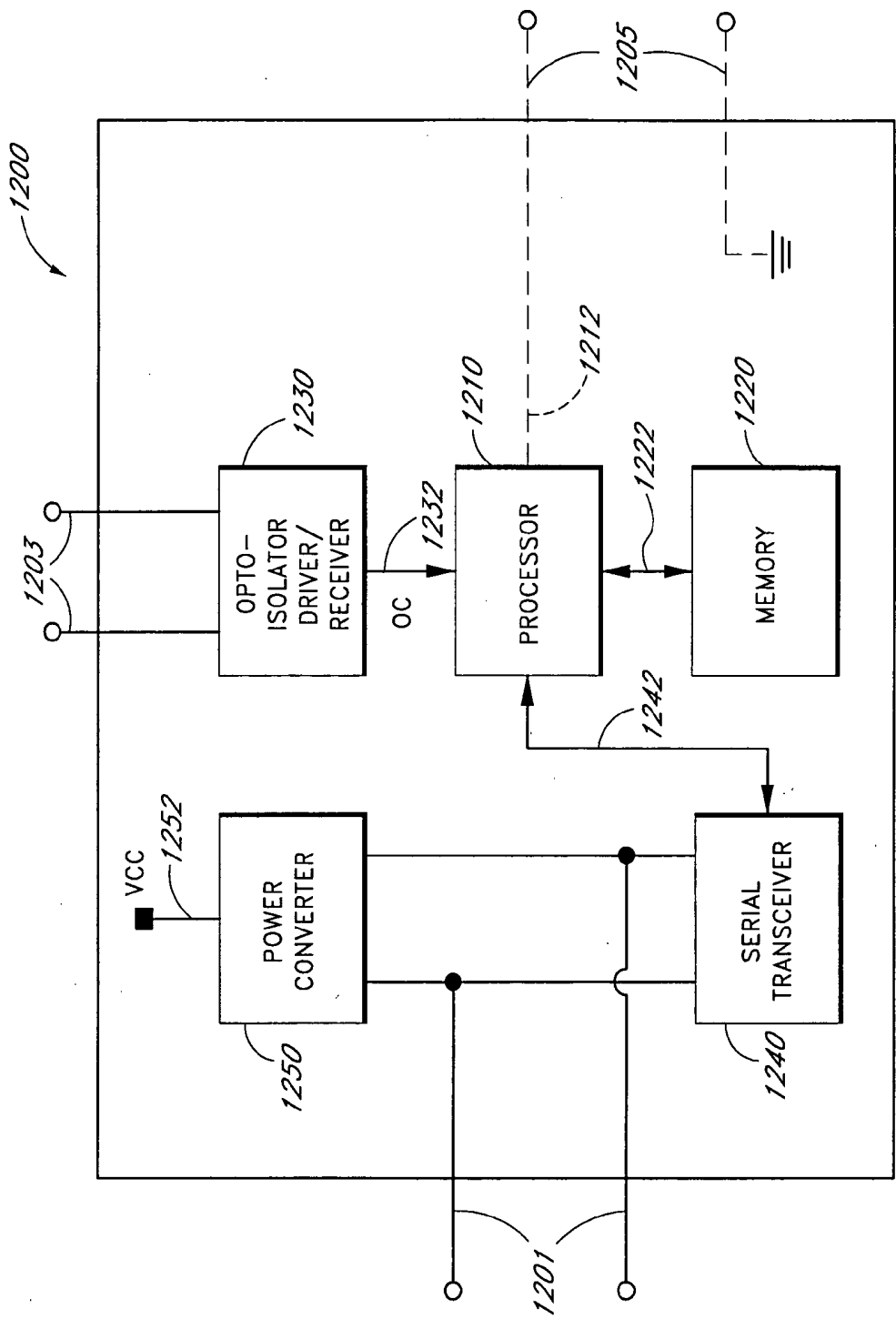


FIG. 12

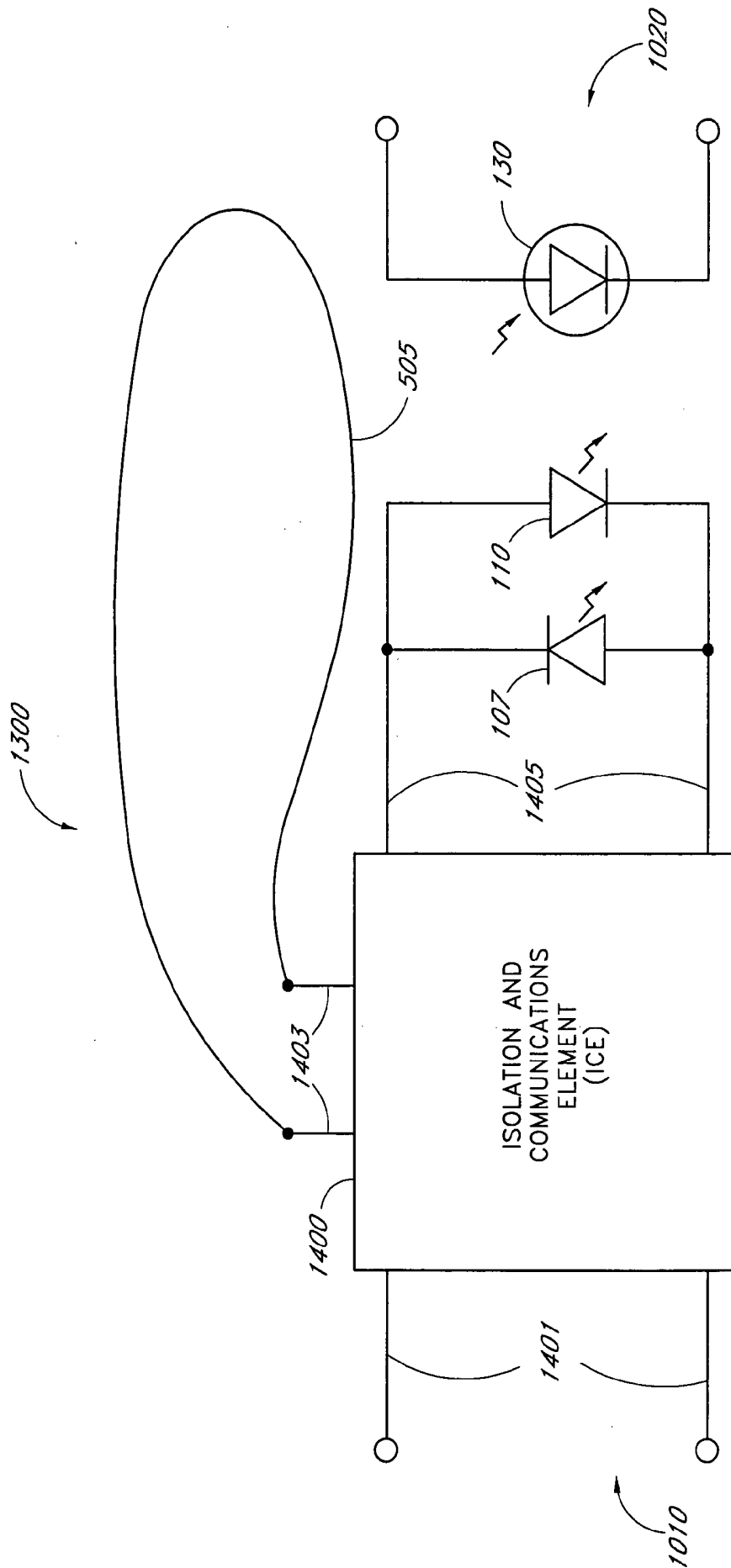


FIG. 13

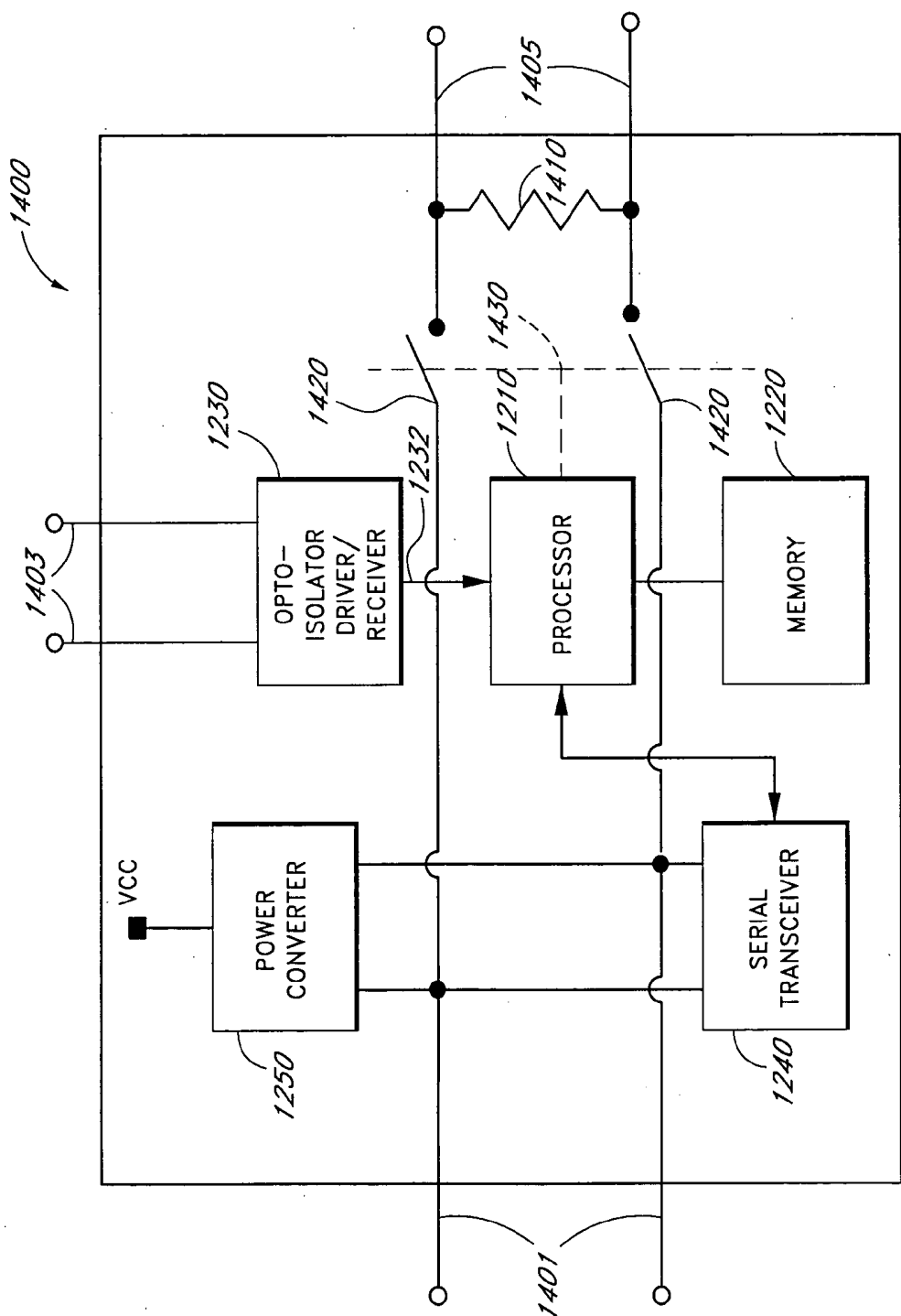


FIG. 14

ISOLATION AND COMMUNICATION ELEMENT FOR A RESPONSABLE PULSE OXIMETRY SENSOR

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application claims priority benefit under 35 U.S.C. § 120 to and is a continuation of U.S. patent application Ser. No. 10/351,643, filed Jan. 24, 2003, entitled "Isolation and Communication Element for Responsible Pulse Oximetry Sensor," which is a continuation-in-part of U.S. patent application Ser. No. 10/128,721, filed Apr. 23, 2002 (now U.S. Pat. No. 6,725,075), entitled "Responsible Pulse Oximetry Sensor," which is a continuation of U.S. patent application Ser. No. 09/456,666 filed Dec. 9, 1999 (now U.S. Pat. No. 6,377,829), entitled "Responsible Pulse Oximetry Sensor." Moreover, the present application claims priority benefit under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application Ser. No. 60/351,784, filed Jan. 25, 2002, entitled "Isolation and Communication Element for a Responsible Pulse Oximetry Sensor." The present application incorporates the foregoing disclosures herein by reference.

BACKGROUND OF THE INVENTION

[0002] 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.

[0003] 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 a pulse oximeter. The pulse 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.

[0004] 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.

[0005] 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 dispos-

able sensor must then be thrown away, wasting the long-lived emitters, photodiode and related circuitry.

[0006] 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.

[0007] 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.

[0008] Based on the foregoing, significant and costly drawbacks exist in conventional disposable and reusable oximetry sensors. Thus, a need exists for a pulse oximetry sensor that incorporates the advantages found in the disposable and reusable sensors, without the respective disadvantages.

SUMMARY OF THE INVENTION

[0009] A reusable sensor with the performance features of a disposable may incorporate a disposable adhesive tape component that can be removed from other reusable sensor components. The disposable tape may include a mechanism for the electrical connection of an information element to the emitters, where the information element provides an indication to an attached pulse oximeter of various aspects of the sensor and also insures the sensor is from an authorized supplier. The information element electrical connection mechanism may be a breakable conductor located within the disposable component such that excessive wear of the disposable component prevents connection of the information element to an attached pulse oximeter, thereby indicating that the disposable component should be replaced. There are some drawbacks to this approach, however, including patient-instrument electrical isolation and electromagnetic interference (EMI).

[0010] Electrical isolation between an electrical source and a patient needs to be 4,000V. A pulse oximeter instrument typically provides 2,500V of isolation and a pulse oximeter sensor another 1,500V. The 1,500V sensor isolation is difficult to achieve with a breakable conductor located within the tape used for patient sensor attachment. Further, a breakable conductor formed as a loop around the periphery of the disposable attachment tape, although advantageous for wear detection, creates an antenna that receives EMI, which can be conducted directly into the sensor circuitry.

[0011] A sensor incorporating an isolation and communications element (ICE) that reduces or eliminates the aforementioned drawbacks has a connector adapted to electrically communicate with a physiological measurement instrument, such as a pulse oximeter. A breakable conductor incorpo-

rated by the sensor transitions from a continuity state to a discontinuity state as the result of sensor wear. An isolation and communications element (ICE) has an instrument port and an electrically isolated loop port. The instrument port is in communications with the connector and the loop port is in communications with the breakable conductor. The ICE generates a control output responsive to the discontinuity state to render the sensor inoperable.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] **FIG. 1** illustrates a circuit diagram of a conventional disposable sensor having an information element.

[0013] **FIGS. 2A and 2B** illustrate perspective views of the conventional disposable sensor.

[0014] **FIG. 3** illustrates an exploded view of a responsible sensor having two disposable tape layers, according to one embodiment of the invention.

[0015] **FIG. 4** illustrates a top view of one of the disposable tape layers of **FIG. 3** incorporating an information element.

[0016] **FIG. 5** illustrates a top view of one of the disposable tape layers of **FIG. 3** incorporating a breakable conductor.

[0017] **FIGS. 6A and 6B** illustrate cross-sectional views of a portion of the disposable tape layer of **FIG. 5**.

[0018] **FIG. 7** illustrates a top view of one of the disposable tape layers of **FIG. 3** incorporating the information element with a breakable conductor.

[0019] **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.

[0020] **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.

[0021] **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.

[0022] **FIG. 10** is a schematic of a sensor circuit incorporating a breakable conductor.

[0023] **FIG. 11** is a schematic of a sensor circuit incorporating an embodiment of an isolation and communications element (ICE).

[0024] **FIG. 12** is a block diagram of an ICE embodiment.

[0025] **FIG. 13** is a schematic of a sensor circuit incorporating an alternative embodiment of an isolation and communications element (ICE).

[0026] **FIG. 14** is a block diagram of an alternative ICE embodiment.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Responsible Pulse Oximeter Sensor

[0027] 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 entitled "Manual And Automatic Probe Calibration," assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein. Accordingly, the configuration and the implementation of an information element will be greatly summarized as follows.

[0028] **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.

[0029] 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**.

[0030] 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.

[0031] 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.

[0032] 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.

[0033] 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.

[0034] 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.

[0035] 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.

[0036] 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.

[0037] 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.

[0038] 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.

[0039] FIG. 3 illustrates an exploded view of one embodiment of a reusable (reusable/disposable) sensor 300. In this embodiment, the reusable sensor 300 includes a reusable portion 305 having an emitter 306, a photodetector 307 and an electrical connector 308. The reusable 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.

[0040] 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.

[0041] 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 reusable sensor 300 functions similar to the disposable sensor 200, i.e., the reusable 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 reusable sensor 300 provides for reuse of the reusable portion 305. For example, when the disposable portion 310 becomes contaminated, worn, or defective, rather than discarding the entire reusable 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 reusable 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.

[0042] FIG. 4 illustrates a top view of an embodiment of the face tape layer 315 of the disposable portion 310 of the reusable 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 reusable sensor 300.

[0043] 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 reusable 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 reusable 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 reusable sensor 300.

[0044] FIG. 5 illustrates a top view of yet another embodiment of the face tape layer 315 of the disposable portion 310 of the reusable 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.

[0045] 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.

[0046] 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.

[0047] 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.

[0048] 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.

[0049] FIGS. 8A and 8B illustrate yet another embodiment of the disposable portion 310 of the responsible sensor 300. 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 responsible 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.

[0050] 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.

[0051] 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.

[0052] FIG. 9A illustrates an embodiment of a responsible 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.

[0053] 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 responsible sensor 900 advantageously provides the security, quality control, and safety features described in the foregoing embodiments.

[0054] FIG. 9B illustrates an embodiment of a responsible sensor 300 of FIG. 3, according to another embodiment of the invention. According to this embodiment, the responsible 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 responsible 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.

[0055] 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**.

[0056] 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**. A responsible sensor is described in U.S. patent application Ser. No. 09/456,666 filed Dec. 9, 1999 entitled "Responsible Pulse Oximetry Sensor," assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein.

Isolation And Communications Element

[0057] **FIG. 10** illustrates a sensor circuit **1000** incorporating a breakable conductor, as described above. The sensor circuit **1000** has emitters **107, 110**, a corresponding detector **130**, and an information element **115**, as described with respect to **FIG. 1**. The sensor circuitry **1000** also has a breakable conductor **505**, as described with respect to **FIG. 5**. Further, the sensor circuit **1000** has an emitter input **1010** and a detector output port **1020**, which are both accessible via a connector **308** (**FIG. 3**). A pulse oximeter (not shown) attached to the connector **308** (**FIG. 3**) outputs emitter drive current to the emitter input **1010** and inputs a resulting detector current from the output port **1020**, as described with respect to **FIG. 1**. The pulse oximeter also reads the information element **115** via the emitter input **1010**, as described with respect to **FIG. 1**. Excessive wear results in a discontinuity in the breakable conductor **505**, as described above. There are drawbacks, however, to this circuit configuration. If routed within the sensor face tape layer **315** (**FIG. 5**), as described with respect to **FIGS. 5-7**, the breakable conductor **505** reduces patient electrical isolation from the pulse oximeter. Further, the breakable conductor may act as an antenna for EMI and conduct the resulting electrical noise into the sensor circuitry.

[0058] **FIG. 11** illustrates a sensor circuit **1100** incorporating one embodiment of an isolation and communications element (ICE) **1200**. In addition to the ICE **1200**, the sensor circuit **1100** has a breakable conductor **505**, an emitter input **1010**, a detector output **1020**, one or more switches **1110**, emitters **107, 110**, a detector **130** and an information element **115**. The emitters **107, 110**, detector **130** and information element **115** are described above. The ICE senses a discontinuity in the breakable conductor **505** and renders the sensor inoperable accordingly. The ICE is configured to optically isolate the breakable conductor **505** from the remainder of the sensor circuitry **1100** so as to improve electrical isolation of the patient from the pulse oximeter electrical supply and prevent electromagnetic interference (EMI) inductively coupled into the breakable conductor **505** from being conducted into the sensor circuitry **1100**. Further, the ICE provides a communication feature, described below, that allows bi-directional data transfers between a pulse oximeter and the sensor, advantageously utilizing the emitter input **1010**.

[0059] As shown in **FIG. 11**, this embodiment of the ICE **1200** is connected in parallel with the input **1010**, and the switches **1110** are external to the ICE **1200**. The ICE **1200** has a instrument port **1201**, a loop port **1203** and a control port **1205**. The instrument port **1201** connects in parallel to

the emitter input **1010**. The loop port **1203** provides a current loop that connects to the breakable conductor **505**. The control port **1205** actuates the switches **1110**, which connect the emitters **107, 110** to the emitter input **1010**. The switches **1110** may be normally open or normally closed and actuated accordingly. Further, the switches may be electromechanical or purely electrical devices.

[0060] Also shown in **FIG. 11**, the instrument port **1201** taps current from the modulated signal which drives the emitters **107, 110**, in order to supply power to the ICE **1200**. The instrument port **1201** also provides bi-directional communications between the ICE **1200** and a pulse oximeter attached to the sensor connector **308** (**FIG. 3**). Advantageously, this bi-directional communications is conducted via the emitter input **1010**, eliminating the need for additional connector pinouts. The loop port **1203** provides a current loop so as to detect discontinuities in the attached breakable conductor **505**. In response to a breakable conductor discontinuity, the control port **1205** actuates one or more of the switches **1110** to an open position so as to disconnect the information element **115** or emitters **107, 110** from the emitter input **1010**. In this manner, an attached pulse oximeter is unable to read the information element **115** and/or the sensor is otherwise rendered inoperable when the breakable conductor is broken.

[0061] **FIG. 12** illustrates one embodiment of an isolation and communications element **1200**. The ICE **1200** has a processor **1210**, a memory **1220**, an opto-isolator driver/receiver **1230**, a serial transceiver **1240**, and a power converter **1250**. The opto-isolator **1230** detects an open circuit at the loop port **1203** and asserts a logic output OC **1232** in response, indicating a discontinuity in the breakable conductor. The opto-isolator **1230** electrically isolates the loop port **1203** utilizing LED and photodiode pairs (not shown), as is well-known in the art. One pair drives the current loop created by the breakable conductor **505** (**FIG. 11**). Another pair detects an open-circuit, for example by measuring the voltage across a sampling resistor in series with the breakable conductor **505** (**FIG. 11**) and generating the OC logic output **1232** accordingly. The processor **1210** reads the OC output **1232** and, in response, generates a control output **1212** to the control port **1205**, which actuates the switches **1110** (**FIG. 11**).

[0062] The power converter **1250** is an AC-to-DC converter that taps a portion of the modulated emitter drive current at the emitter input **1201** and provides one or more DC voltage outputs **1252** to power the remainder of the ICE **1200**. The memory **1220** is connected to the processor **1210** with a bi-directional bus **1222** for transferring instructions and data. The memory **1220** may be volatile RAM or nonvolatile programmable ROM or a combination of RAM and PROM. The memory **1220** stores a variety of sensor information downloaded at the time of manufacture or during communications with a pulse oximeter, as described below.

[0063] As shown in **FIG. 11**, a modulated waveform applied to the emitter input **1201** for driving the emitters **107, 110** is described in U.S. Pat. No. 6,229,856 entitled "Method and Apparatus for Demodulating Signals in a Pulse Oximetry System" assigned to the assignee of the present application and incorporated by reference herein. In particular, a current is first applied in a forward direction with

respect to one LED **107** during a first time interval. Thereafter, no current is applied to either LED **107**, **110** during a second time interval. Then, current is applied in a forward direction with respect to the other LED **110** during a third time interval. Then, no current is applied to either LED **107**, **110** during a fourth time interval. Thereafter, the current is again applied in the forward direction for one LED **107** during a fifth time interval that corresponds to the first time interval. Typically, each emitter **107**, **110** is active for a duty cycle of 25%, and an inactive period having a 25% duty cycle separates each active period.

[0064] As shown in **FIG. 12**, the serial transceiver **1240** is connected to the emitter input **1201** and provides a bi-directional data bus **1242** to the processor **1210**. During a start-up, calibration, initialization or re-initialization period, an attached instrument, such as a pulse oximeter or testing device, may alter the modulated waveform described above for the purpose of transmitting information to the sensor processor **1210**. That is, the emitter drive current applied to the emitter input **1201** may be modulated in a manner other than a constant 25% on and 25% off cycle so as to convey information. For example, the current waveform may be pulse position modulated (PPM) or pulse width modulated (PWM) with a bit pattern, as is well known in the art. Transmitted bit patterns may contain information such as calibration data, emitter specifications, and/or manufacturing data to name a few. The serial transceiver **1240** demodulates this data, which is then transferred over the data bus **1242** to the processor **1210**, either as serial or parallel data. The processor **1210** may in turn store this information in memory **1220**.

[0065] Further, the serial transceiver **1240** may also transfer data from the processor **1210** to an attached instrument. A data upload may occur during emitter "off" periods, described above, which may be the 25% duty off-cycles or specifically designated off periods timed so that the power converter **1250** is still operational. The upload may be at a voltage that is less than the turn-on voltage of either emitter **107**, **110** so as to limit the required output power from the ICE **1200**. Alternatively, the emitters may be disconnected during data uploads by the switches **1110** (**FIG. 11**). The data upload may be accomplished by any of a number of conventional serial data transfer waveforms, such as PPM or PWM to name a few.

[0066] **FIG. 13** illustrates a sensor circuit **1300** incorporating an alternative embodiment of an isolation and communications element **1400**. The sensor circuit **1300** has a breakable conductor **505**, an emitter input **1010**, a detector output port **1020**, emitters **107**, **110** and a detector **130** as described with respect to **FIG. 11**, above. In this embodiment, the ICE **1400** is connected in series between the emitter input **1010** and the emitters **107**, **110** and utilizes internal switches **1420** (**FIG. 14**). The ICE **1400** has a instrument port **1401** and a loop port **1403**, also as described with respect to **FIG. 11**, above. Further, the ICE **1400** has a component port **1405** that connects to the emitters **107**, **110**. The ICE **1400** decouples the breakable conductor **505** from the emitter input **1010** and other portions of the sensor circuit **1300**, such as the detector **130**, as described with respect to **FIG. 11**, above. The instrument port **1401** taps power from the modulated drive signal on the emitter input **1010** and provides bi-directional communications between

the ICE **1400** and an attached pulse oximeter, also as described with respect to **FIG. 11**, above.

[0067] **FIG. 14** illustrates a block diagram of an alternative embodiment of an isolation and communications element **1400**. The ICE **1400** has a processor **1210**, a memory **1220**, an opto-isolator driver/receiver **1230**, a serial transceiver **1240**, and a power converter **1250**, as described with respect to **FIG. 12**, above. The ICE also has an internal information element **1410** and one or more internal switches **1420**. In response to a breakable conductor discontinuity as signaled by the OC logic output **1232** of the opto-isolator **1230**, the processor **1210** generates a control output **1430** that activates the switches **1420**. When activated, the switches **1420** disconnect the component port **1405** from the emitter input **1010**. In this manner, the information element **1410** cannot be read by an attached pulse oximeter and/or the sensor is rendered otherwise inoperable when the breakable conductor is broken.

[0068] Other combinations, omissions, substitutions and modifications of the ICE embodiments and the ICE-sensor circuit configurations will be apparent to the skilled artisan in view of the disclosure herein. For example, the sensor circuit was described as having back-to-back emitters and a parallel connected information element all sharing a pair of connector pinouts. The ICE, however, can also be configured with a sensor circuit having emitters and an information element with only partially shared pinouts, such as common cathode or common anode configurations, or with unshared pinouts. As another example, the sensor circuit was described with switches actuated to disconnect sensor components from the sensor connector. Other devices that can be actuated to decouple one or more sensor components from the sensor connector may be used, such as high impedance capable series devices or low impedance capable parallel devices. Further, the isolation and communications element (ICE) is described in the conjunctive, it is understood that a sensor may be configured with either an isolation function or a communications element or both.

What is claimed is:

1. An optical sensor configured to noninvasively monitor one or more physiological parameters of a wearer of the optical sensor, the optical sensor comprising:

- a plurality of emitters;
- a detector configured to detect light attenuated by body tissue of a wearer of the optical sensor;
- an emitter input configured to supply an emitter drive signal to the plurality of emitters;
- a memory device; and
- a communication device configured to receive sensor data to be stored in the memory device.

2. The optical sensor of claim 1, wherein the sensor data comprises calibration data.

3. The optical sensor of claim 1, wherein the sensor data comprises data indicative of parameters of the plurality of emitters.

4. The optical sensor of claim 1, wherein the sensor data comprises data indicative of a manufacturer of the optical sensor.

5. The optical sensor of claim 1, wherein the communication device is configured to receive the sensor data from an attached oximeter.

6. The optical sensor of claim 1, wherein the communication device is configured to receive the sensor data over the emitter input.

7. The optical sensor of claim 1, wherein the communication device is configured to receive the sensor data at least during a startup process.

8. The optical sensor of claim 1, wherein the communication device is configured to receive the sensor data at least during a calibration process.

9. The optical sensor of claim 1, wherein the communication device is configured to receive the sensor data at least during an initialization process.

10. The optical sensor of claim 1, wherein the communication device is configured to receive the sensor data at least during a re-initialization process.

11. The optical sensor of claim 1, wherein the communication device is configured to receive the sensor data at least during testing.

12. The optical sensor of claim 1, wherein the testing occurs at the manufacturer.

13. A method of providing accurate data about an attached sensor to an oximeter system, the method comprising:

accessing a memory on a noninvasive optical sensor capable of detecting light attenuated by body tissue, the optical sensor including a plurality of emitters and the memory capable of storing accurate data indicative of one or more characteristics of the optical sensor; and

storing said accurate data on said memory.

14. The method of claim 13, further comprising reading said accurate data from said memory.

15. The method of claim 14, wherein said reading comprises accessing said memory through an input to the plurality of emitters.

16. The method of claim 14, wherein said storing comprises accessing said memory through an input to the plurality of emitters.

17. The method of claim 13, wherein the accurate data comprises calibration data.

18. The method of claim 13, wherein the accurate data comprises data indicative of parameters of the plurality of emitters.

19. The method of claim 13, wherein the accurate data comprises data indicative of a manufacturer of the noninvasive optical sensor.

20. The method of claim 13, wherein the storing occurs during an initialization process.

21. The method of claim 13, wherein the storing occurs during sensor testing.

22. The method of claim 13, wherein the testing occurs at the manufacturer.

23. An optical sensor comprising:

means for storing data pertaining to specifications of an optical sensor capable of noninvasively outputting a signal indicative of one or more parameters of a wearer of the optical sensor; and

means for accessing said stored data to determine said specifications.

24. The optical sensor of claim 23, wherein said data comprises calibration data.

25. The optical sensor of claim 23, wherein said data comprises data indicative of parameters of the plurality of emitters.

26. The optical sensor of claim 23, wherein said data comprises data indicative of a manufacturer of the noninvasive optical sensor.

* * * * *

专利名称(译)	用于可重复使用的脉搏血氧饱和度传感器的隔离和通信元件		
公开(公告)号	US20060020180A1	公开(公告)日	2006-01-26
申请号	US11/235617	申请日	2005-09-26
[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		
CPC分类号	A61B5/14552 A61B5/6826 A61B2562/182 A61B2560/0276 A61B5/6838		
优先权	60/351784 2002-01-25 US		
其他公开文献	US7272425		
外部链接	Espacenet USPTO		

摘要(译)

传感器具有适于与生理测量仪器电连通的连接器。由传感器磨损导致由传感器结合的可破坏导体从连续状态转变为不连续状态。隔离和通信元件 (ICE) 具有仪器端口和电隔离环路端口。仪器端口与连接器通信，并且环路端口与可断裂导体通信。ICE响应于不连续状态产生控制输出，以使传感器不可操作。

