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FILE HISTORY US 6,771,994

PATENT:	6,771,994
INVENTORS:	KIANI MASSI E
	DIAB MOHAMED K
TITLE:	Pulse oximeter probe-off detection system
APPLICATION NO:	US2003374303A
FILED:	24 FEB 2003
ISSUED:	03 AUG 2004
COMPILED:	19 MAR 2020

11 PATENT NUMBER and ISSUE DATE 771994 AUG 8 8 2004 6 "APA U.S. UTILITY Patent Application EXAMINER 2000 APPL NUM FILING DATE CLASS SUBCLASS GAU 10374303 02/24/2003 600 3736 322 APPLICANTS: Kiani Massi; Diab Mohamed; **CONTINUING DATA VERIFIED: rigis application is a DIV of 09/595,081 06/16/2000 PAT 6,526,300 which claims benefit of 60/140,000 06/18/1999 * FOREIGN APPLICATIONS VERIFIED: RESCIND PG-PUB DO NOT PUBLISH ATTORNEY DOCKET NO □ yes ဩ'no □ yes ☑ no Foreign priority claimed 35 UNC 1/15 conditions met MASIMO 172DV1 Verified and Acknowledged Even inors's initials Mattitude TITLE : Pulse eximeter probe-off detection system U.S.DEPT. OF COMM /PAT & TM-PTO-438L(Rev. 12-94 30/00 Freedo A DANGER NOTICE OF ALLOWANCE MAILED CLAIMS ALLOWED Mittluo / Kr. Assistant Examiner Print Claim O.G / 🖌 Total Claim 13/04 18 16 ISSUE FEE 1117 DRAWING Amount Due Date Paid eels Drwg. Print Fig. Figs.Drwg. 6/22/04 15 16 5B 2 ð 9 330.0 ₿ files 4-16-04 imary Examiner A TERMINAL Application Examiner PREPARED FOR ISSUE WARNING: The information disclosed herein may be restricted. Unauthorized disclosure may be prohibited by the United States Code Title 35, DISCLAMER Sections 122, 181 and 368, Possession outside the U.S. Patent & Trademark Office is restricted to authorized employees and contractors only. ISSUE FEE IN FI DISK (CRF) CD-KCM (Attached in pocket on right inside flap) FILED WITH:

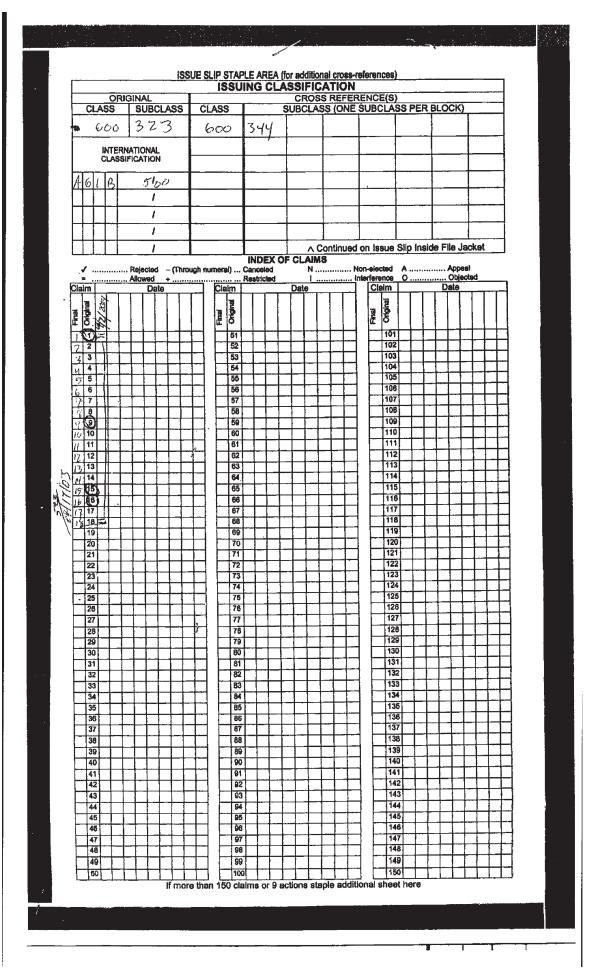
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PULSE OXIMETER PROBE-OFF DETECTION SYSTEM

Transaction History

Date	Transaction Description	
02-24-2003	Workflow - Drawings Finished	
02-24-2003	Workflow - Drawings Matched with File at Contractor	
02-24-2003	Initial Exam Team nn	
03-14-2003	IFW Scan & PACR Auto Security Review	
04-17-2003	Application Is Now Complete	
04-18-2003	Application Dispatched from OIPE	
03-09-2004	Case Docketed to Examiner in GAU	
04-05-2004	Notice of Allowance Data Verification Completed	
04-13-2004	Mail Notice of Allowance	
04-19-2004	Dispatch to Publications	
04-21-2004	Receipt into Pubs	
04-22-2004	Receipt into Pubs	
04-22-2004	Workflow - File Sent to Contractor	
05-25-2004	Receipt into Pubs	
06-22-2004	Issue Fee Payment Verified	
06-22-2004	Issue Fee Payment Received	
06-22-2004	Receipt into Pubs	
07-01-2004	Dispatch to FDC	
07-01-2004	Application Is Considered Ready for Issue	
07-06-2004	Receipt into Pubs	
07-15-2004	Issue Notification Mailed	
08-03-2004	Recordation of Patent Grant Mailed	
08-03-2004	Patent Issue Date Used in PTA Calculation	
12-08-2005	Correspondence Address Change	
06-18-2007	Post Issue Communication - Certificate of Correction	
08-02-2011	Correspondence Address Change	

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(12) United States Patent Kiani et al.

PULSE OXIMETER PROBE-OFF (54)DETECTION SYSTEM

- Inventors: Massi E. Kiani, Laguna Niguel, CA (75) (US); Mohamed K. Diab, Mission Viejo, 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 0 days.
- (21) Appl. No.: 10/374,303
- Feb. 24, 2003 (22) Filed:

(65) **Prior Publication Data**

US 2003/0139656 A1 Jul. 24, 2003

Related U.S. Application Data

- Division of application No. 09/595,081, filed on Jun. 16, 2000, now Pat. No. 6,526,300. (62)
- 2000, now rat. No. 6,526,300. Provisional application No. 60/140,000, filed on Jun. 18, 1999. (60)
- (51) Int. Cl.⁷ A61B 5/00
- (52) U.S. Cl. 600/323; 600/344
- Field of Search .. 600/309-310, (58) 600/322-324, 316, 344, 473, 476

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(10) Patent No.:

(45) Date of Patent:

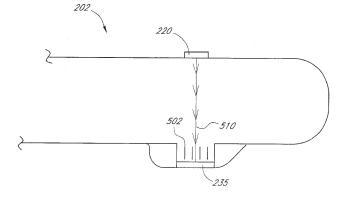
Primary Examiner-Mary Beth Jones

Assistant Examiner-Matthew Kremer (74) Attorney, Agent, or Firm-Knobbe, Martens, Olson, & Bear, LLP

ABSTRACT (57)

The present invention provides a number of improvements that can be incorporated into a pulse oximeter probe to detect when a probe has become dislodged from a patient and/or to prevent a probe-off condition. A probe-off condition occurs when the optical probe becomes partially or completely dislodged from the patient, but continues to detect an AC signal within the operating region of the pulse oximeter. In one aspect, the present invention provides electrical contacts that contact the skin of a patient when the probe is properly attached. In another aspect, the present invention provides a number of louvers placed in front of the sensor's photodetector to filter out oblique light rays that do not originate from a point in front of the detector. Accordingly, if the emitter and photodetector are not properly aligned, the photodetector will not produce a signal within the valid operating range of the pulse oximeter. In accordance with a method of the present invention the pulse oximeter can sound an alarm or display a warning if it determines that the probe is not properly attached to the patient.

18 Claims, 15 Drawing Sheets







Sheet 1 of 15

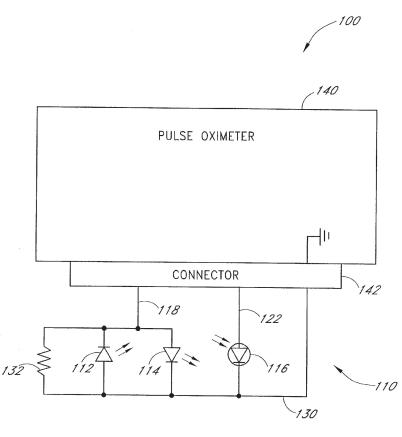
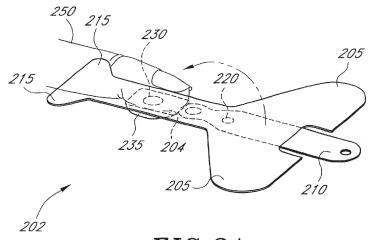
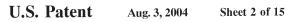


FIG.1







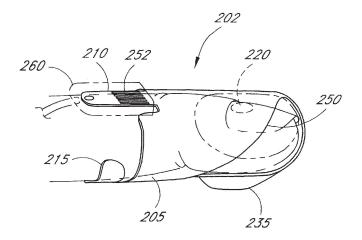


FIG.2B



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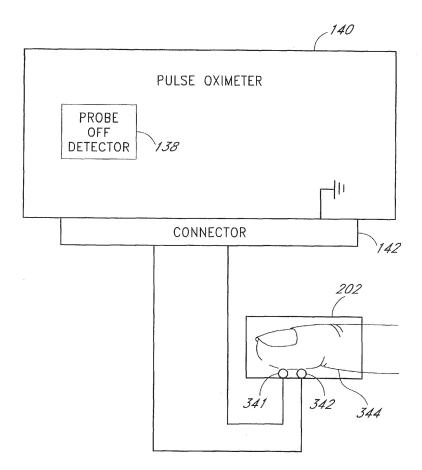
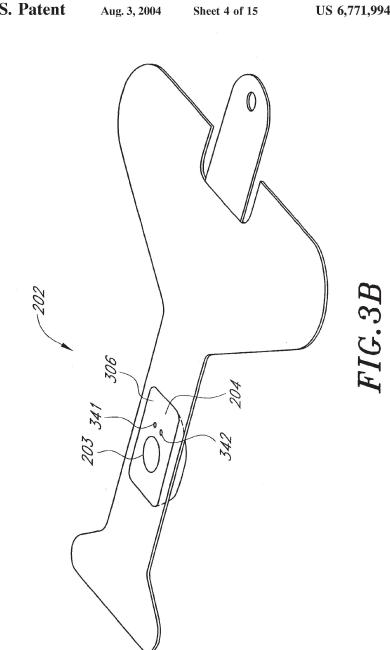


FIG.3A







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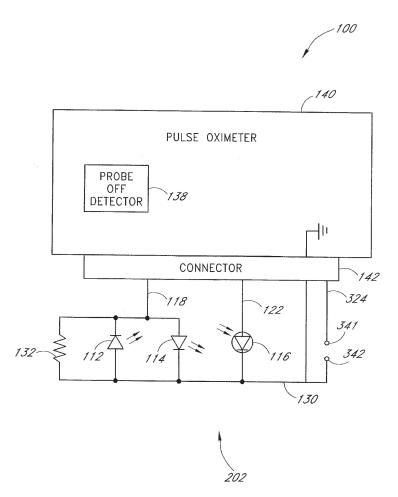


FIG.3C





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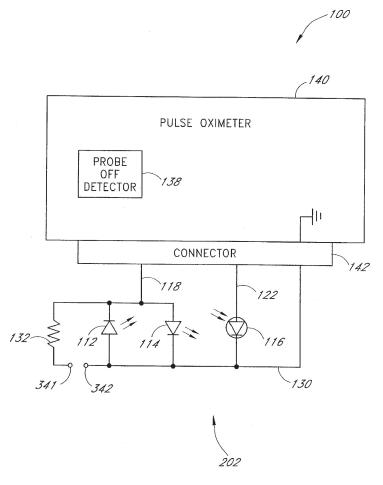


FIG.3D





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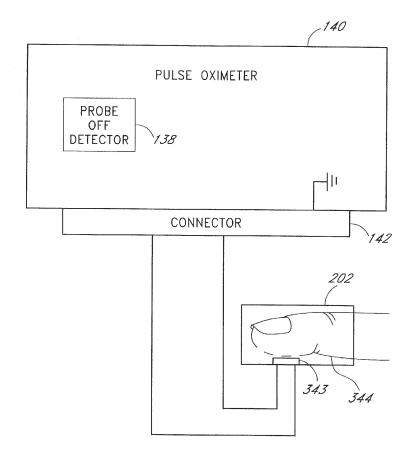
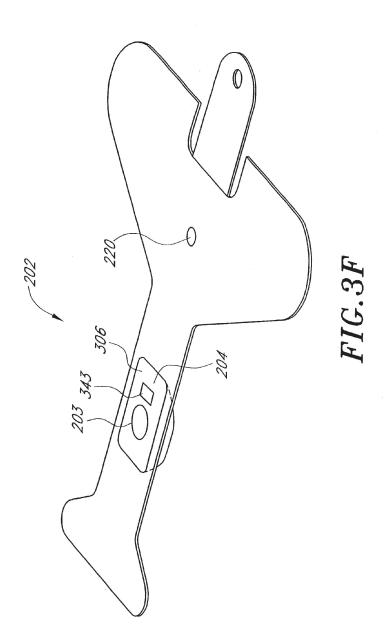


FIG.3E



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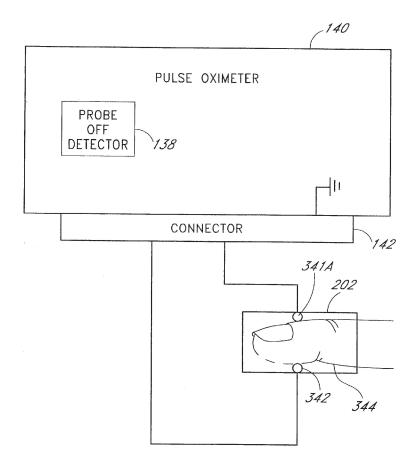
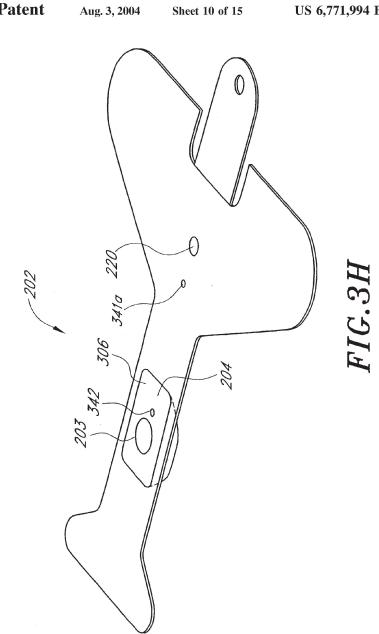


FIG.3G



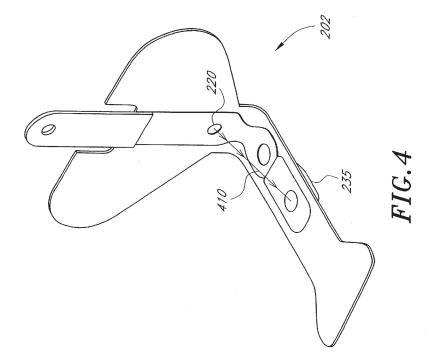
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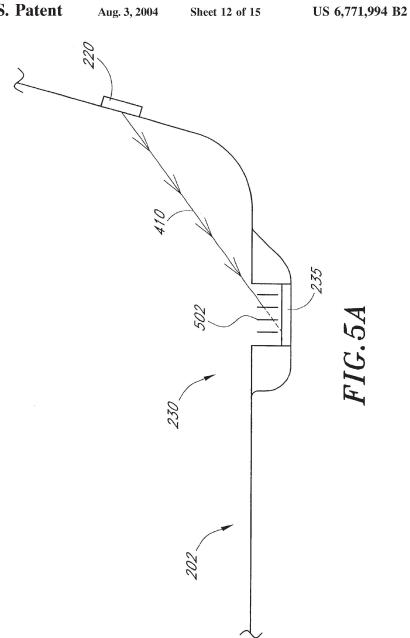
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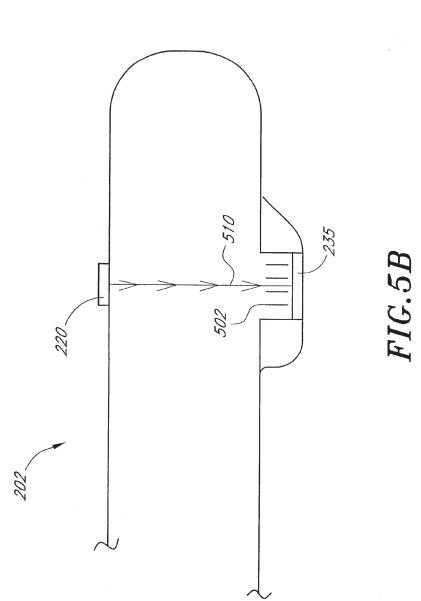
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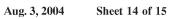


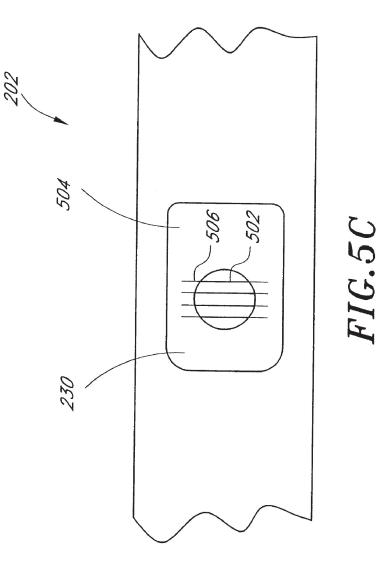
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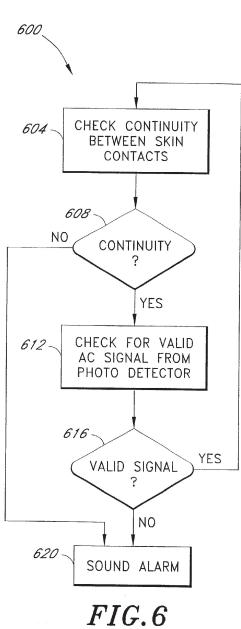
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1 PULSE OXIMETER PROBE-OFF DETECTION SYSTEM

REFERENCE TO RELATED APPLICATIONS

The present application claims priority benefit under 35 U.S.C. § 120 to, and is a divisional of, U.S. patent application Ser. No. 09/595,081, filed Jun. 16, 2000, now U.S. Pat. No. 6,526,300, entitled "Pulse Oximeter Probe-Off Detection System," which claims priority benefit under 35 U.S.C. § 119(e) from U.S. Provisional Application No. 60/140,000, filed Jun. 18, 1999, entitled "Pulse Oximeter Probe-Off Detection System." The present application also incorporates the foregoing utility disclosure herein by reference.

BACKGROUND OF THE INVENTION

The present invention relates to optical probes that can be attached to the finger, toe, or appendage of a patient. More particularly, the present invention relates to devices and methods for identifying when a probe has become dislodged 20 from a patient.

DESCRIPTION OF THE RELATED ART

Oximetry is the measurement of the oxygen status of 25 blood. Early detection of low blood oxygen is critical in the medical field, for example in critical care and surgical applications, because an insufficient oxygen supply can result in brain damage and death in a matter of minutes. Pulse oximetry is a widely accepted noninvasive procedure for measuring the oxygen saturation level of arterial blood, an indicator of oxygen supply. A pulse oximetry system generally consists of a probe attached to a patient, a monitor, and a cable connecting the probe and monitor. Conventionally, a pulse oximetry probe has both red and infrared (IR) light-emitting diode (LED) emitters and a photodiode detector. The probe is typically attached to a patient's finger or toe, or a very young patient's foot. For a finger, the probe is configured so that the emitters project light through the fingernail, the arteries, vessels, capillaries, tissue and bone. The photodiode is positioned opposite the LED so as to detect the LED transmitted light as it emerges from the finger tissues

The pulse oximetry monitor (pulse oximeter) determines oxygen saturation by analyzing the differential absorption by arterial blood of the two wavelengths emitted by the probe. The pulse oximeter alternately activates the probe LED emitters and reads the resulting current generated by the photodiode detector. This current is proportional to the intensity of the detected light. The pulse oximeter calculates a ratio of detected red and infrared intensities, and an arterial oxygen saturation value is empirically determined based on the ratio obtained. The pulse oximeter contains circuitry for controlling the probe, processing the probe signals and displaying the patient's oxygen saturation and pulse rate. A pulse oximeter is described in U.S. Pat. No. 5,632,272 assigned to the assignee of the present invention.

SUMMARY OF THE INVENTION

The present invention provides a number of improve- 60 ments that can be incorporated into a pulse oximeter probe to detect when a probe has become dislodged from a patient and/or to prevent a probe-off condition. A probe-off condition occurs when the optical probe becomes partially or completely dislodged from the patient, but may continue to 65 detect an AC signal within the operating region of the pulse oximeter.

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In one aspect, the present invention provides a number of electrical contacts that contact the skin of a patient when the probe is properly attached. The pulse oximeter can check the continuity through the contacts to determine whether the probe is properly attached. If the probe is not properly attached, the pulse oximeter can identify a probe-off condition even though the oximeter measures an AC signal that appears like the probe is still attached.

In another aspect, the present invention provides a number of louvers placed in front of the probe's photodetector to filter out oblique light rays that do not originate from a point in front of the detector. If the probe becomes dislodged, the emitter will not likely remain in front of the photodetector. If the emitter and photodetector are not properly aligned, the photodetector will not produce a signal within the valid operating range of the pulse oximeter. The louvers prevent light from an oblique angle from reaching the photodetector and creating a false signal that might be interpreted by the pulse oximeter as a physiological signal. Accordingly, the pulse oximeter can determine that a probe has become dislodged when the photodetector does not produce a valid signal. Furthermore, probe-off conditions can avoided since oblique light rays are not able to reach the photodetector to produce an apparently valid signal.

BRIEF DESCRIPTION OF THE DRAWINGS

Referring now to the drawings in which like reference numbers represent corresponding components throughout: FIG. 1 illustrates a schematic of one embodiment of a pulse oximeter system;

FIGS. 2A–B depict an optical probe and the attachment of the optical probe on the fingertip of an adult patient;

FIG. **3A** illustrates a schematic of a pulse oximeter system that incorporates electrical contacts to the skin of a patient, in accordance with one embodimet of the present invention;

FIG. 3B illustrates a perspective view of an optical probe incorporating electrical contacts to the skin of a patient;

FIG. **3**C illustrates a schematic of one embodiment of a pulse oximeter system that incorporates electrical contacts to the skin of a patient;

FIG. **3D** illustrates a schematic of a preferred embodiment of a pulse oximeter system that incorporates a number of electrical contacts to the skin of a patient;

FIG. **3**E depicts a generalized schematic of a pulse oximeter that incorporates another embodiment of a contact on a pulse oximeter probe;

FIG. **3**F depicts a perspective view an optical probe incorporating the embodiment of FIG. **3**E;

FIG. **3**G depicts a generalized schematic of a pulse oximeter system that incorporates another embodiment of a contact sensor in accordance with the present invention;

FIG. 3H depicts a perspective view of an optical probe incorporating the contact sensor of FIG. 3G;

FIG. 4 illustrates a probe that has become unfastened; FIG. 5A illustrates a probe wherein a number of louvers

are placed in front of the detector assembly; FIG. 5B illustrates a properly attached probe wherein a number of louvers are placed in front of the detector assembly;

FIG. **5**C illustrates a top plan view of a preferred embodiment of a probe wherein a number of louvers are placed in front of the detector assembly

FIG. $\boldsymbol{6}$ illustrates a flow chart of the method of detecting a dislodged probe.

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DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

To compute peripheral arterial oxygen saturation, denoted Sp.O2, pulse oximetry relies on the differential light absorption of oxygenated hemoglobin, HbO2, and deoxygenated hemoglobin, Hb. This differential absorption is measured at the red and infrared wavelengths of the probe. In addition, pulse oximetry relies on the pulsatile nature of arterial blood to differentiate hemoglobin absorption from absorption of other constituents in the surrounding tissues. Light absorption between systole and diastole varies due to the blood volume change from the inflow and outflow of arterial blood at a peripheral tissue site. The tissue site might also comprise skin, muscle, bone, venous blood, fat, pigment, etc., each of which absorbs light. Blood oxygen saturation measurements are based upon a ratio of the time-varying or AC portion of the detected red and infrared signals with respect to the time-invariant or DC portion. This AC/DC ratio normalizes the signals and accounts for variations in light pathlengths through the measured tissue

As reproduced in FIG. 1, a schematic of one embodiment of a pulse oximeter system 100 is disclosed in U.S. Pat. No 5,758,644 (the '644 patent), assigned to the assignee of the present application and incorporated herein by reference. The system 100 comprises a pulse oximeter 140, which is attached through a connector 142 to a probe 110. The probe 110 comprises a first LED 112, a second LED 114 and a photodetector 116. The first and second LEDs 112 and 114 are connected back-to-back and share a common electrical connection 118. The photodetector 116 has its own electrical connection 122. Each of the LEDs 112 and 114 and the photodetector 116 are connected at their outputs to a common ground electrical connection 130. The two LEDs 112 and 114 are preferably configured to produce different wavelengths of light, which pass through the flesh of a patient to be detected by the photodetector 116. The oximeter 140 can select the LED to be driven by applying either a positive or negative voltage to the connection 118. A coding resistor 132 has a resistance that can measured by the pulse oximeter 140 to determine the particular characteristics of the probe 110. The coding resistor 132 is coupled in parallel with the first LED 112 or the second LED 114. The resistor 132 can be used to indicate the operating wavelength of the first and second LEDs 112 and 114, or to indicate the type of probe. In order to read the coding resistor 132, the pulse oximeter 140 drives the first LED 112/coding resistor 132 combination at a level that is low enough that the LED draws insignificant current. At this level, significantly all of the current flows through the coding resistor 132 and the pulse oximeter 140 can determine the value of the resistor in accordance with Ohm's law. By configuring the coding resistor 132 in parallel with one of the LEDs 112, 114, the added expense of an additional lead connecting the pulse oximeter 140 to the probe 110 can be saved.

One embodiment of a disposable probe for use with pulse oximetry systems is disclosed in U.S. Pat. No. 5,782,757, assigned to the assignee of the present application and incorporated herein by reference. FIGS. 2A–B depict the optical probe 202 and the attachment of the optical probe 202 on the fingertip 250 of an adult patient. The disposable optical probe 202 is designed to fit comfortably onto a patient's fingertip. As illustrated in FIG. 2A, the probe 202 includes a central portion 204, a pair of adhesive flanges 205 extending from the central portion 204, and a pair of smaller adhesive flaps 215 extending from the central portion 204 on - 4

the end of the optical probe 202 opposite from a connector tab 210. The probe 202 further includes an emitter aperture 220 with a number of emitters (e.g., a light-emitting diodes) positioned within the central portion 204 close to the connector portion 210, and a detector aperture 230 which allows light to pass through the detector aperture 230 to a detector assembly 235. An adult fingertip 250 is shown in phantom in FIG. 2A to illustrate the position at which the fingertip 250 is placed when the probe 202 is to be fastened onto the fingertip 250 for use. Although not depicted specifically in FIGS. 2A-2B, the probe 202 is typically fabricated from multiple layers.

FIG. 2B illustrates the probe 202 fastened onto the fingertip 250. As shown in FIG. 2B, the probe 202 folds to conform to the very end of the fingertip. The adhesive flaps 205 fold downward (in the illustration of FIG. 2B) to wrap around the fingertip 250 while the adhesive flaps 215 fold upward (in the illustration of FIG. 2B) about a portion of the circumference of the fingertip 250 to provide support. As shown in FIG. 2B, when the probe 202 is folded about the fingertip 250, the emitters located within the probe are spaced opposite the detector assembly 235 such that light from the emitters passes through the emitter aperture 220, through the finger 250 and is incident upon the detector assembly 235 through the detector aperture 230.

FIG. 2B depicts a receiving connector portion 260 which engages with contacts 252 on the connector 210 to provide an electrical connection between the optical probe 202 and the pulse oximeter 140. Once the optical probe 202 is securely fastened to the fingertip 250 and the connector 210 provides an electrical connection between the optical probe 202 and digital signal processing circuitry, signals are detected from the detector 235 and transmitted to the processing circuitry via the connector 260.

A probe-off condition occurs when the optical probe becomes partially or completely dislodged from the patient, but continues to detect an AC signal within the operating region of the pulse oximeter. Probe-off errors are serious because the pulse oximeter may display a normal saturation when, in fact, the probe is not properly attached to the patient, potentially leading to missed desaturation events. Failure to detect a probe-off condition is the result of the probe detector receiving light directly from the emitters without transmission through the patient's tissue.

As illustrated in the schematic of FIG. 3A, a first aspect of the present invention involves an optical probe 202 which incorporates a number of electrical contacts 341 and 342 that make contact to the skin of the patient when the probe 202 is properly secured. In order to detect a probe-off condition, a probe-off detector module 138 of the pulse oximeter 140 periodically applies a voltage across the contacts 341 and 342 or drives a current. A non-zero current indicates that the patient's skin 344 has closed the circuit between the contacts 341 and 342 and the probe 202 is properly secured. If the probe becomes dislodged, the patient's skin 344 is no longer be in contact with the contacts 341 and 342, resulting in an open circuit.

FIG. 3B illustrates one preferred embodiment of an optical probe 202 incorporating one embodiment of the present invention. The present embodiment incorporates a first electrical contact 341 and a second electrical contact 342 in the surface 306 of the central portion 204 of the probe 202. The electrical contacts 341 and 342 are positioned in a location such that contact to a finger or flesh portion of the patient is ensured when the probe 202 is properly attached. In the illustrated embodiment, the contacts 341 and 342 are located

- 5

proximate the detector aperture 203. In another embodiment, contacts 341 and 342 are on opposite sides of the detector aperture 203. The optical probe 202 also has an emitter aperture 220 through which light of at least two wavelengths passes from LEDs.

As illustrated in the schematic diagram of FIG. 3C, the pulse oximeter system 100 of FIG. 1 can be modified to incorporate the first aspect of the present invention by extending an additional lead 324 through the connector 142 to the probe 202. The additional lead can be connected to one contact 341 while the second contact 342 can be wired to the common ground lead 130.

A schematic diagram of another embodiment of the present invention is illustrated in FIG. 3D. The contacts 341 and 342 can be installed in line within the path of the coding resistor 132. When the patient's skin 344 is in contact with the contacts 341 and 342, the circuit through the coding resistor 132 will be closed; when the patient's skin 344 is not in contact with the contacts 341 and 342, the circuit through the coding resistor 132 will be open. The skin 344 will have some finite resistance between the contacts 341 and 342 that will affect the measured resistance of the coding resistor. As the contacts 341 and 342 are installed in series with the coding resistor 132, any resistance across the contacts 341 and 342 will be added to the resistance of the coding resistor 132 when the pulse oximeter 140 attempts to measure the resistance of the coding resistor 132. The resistance of the skin 344 can effectively be ignored in the measurement of the coding resistor 132, however, by choosing the value of the coding resistor 132 to be substantially larger than the resistance of a patient's skin 344 between the contacts 341 and 342. Alternatively, the acceptable resistance for the coding resistor can be specified as in a range that includes the likely added resistance of the skin in the circuit. In the present configuration, the probe-off detector module 138 of the pulse oximeter 140 can verify that the optical probe 202 is properly secured simultaneously with checking the resistance of the coding resistor 132. An open circuit indicates that the probe has become dislodged, whereas a valid resistance of a coding resistor 132 indicates a proper attachment of the probe 202. If the probe has become dislodged, the pulse oximeter 140 can sound an alarm, display a warning message, or both.

The pulse oximeter **140** is particularly vulnerable to probe-off errors when operating at its highest sensitivity, ⁴⁵ where even small induced variations in light directly detected from the emitters have sufficient signal strength to be processed as a physiological signal. In a probe-off condition, a detector AC signal can be induced by slight changes in the direct light path between the emitters and the ⁵⁰ detector. For example, small amounts of patient motion, such as chest movement from breathing, can induce a probe-off AC signal. As another example, "creep" in the probe configuration, such as a folded probe gradually returning to its original unfolded shape after becoming dislodged ⁵⁵ can also induce a probe-off AC signal.

FIGS. 3E and 3F depict a generalized embodiment of the present invention with the same features as described in 3A and 3B, except that the electrical contacts 341, 342 are replaced with a contact sensor 343. The electrical contacts 60 341 and 342 comprise a specialized case of a contact sensor 343 where skin is involved. The contact sensor 343 may also comprise a piezoelectric sensor, a conductive contact sensor, or any other contact sensor which detect the contact of the tissue material. 65

FIGS. **3**G and **3**H depict yet another embodiment of the electrical contact based contact sensor of FIGS. **3**A and **3**B.

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FIG. 3G depicts a schematic form with a pulse oximeter 140 and a probe off detector module. FIG. 3H depicts a perspective view of the optical pulse oximeter probe haveing optical emitters and at least one detector. However, in this embodiment, electrical contact 341A and electrical contact 342 are positioned opposite each other. The electrical contact 341A is positioned near the emitter aperture 220, so as to contact the portion of the tissue material near the emitter 220. The electrical contact 342 is positioned near the detector aperture 203. Similarly, other contact sensors could be positioned, one near the emitter aperture 220 and one near the detector aperture 203.

In one embodiment the electrical contacts **341**, **342**, **341**A are metallic. In another embodiment, these contacts comprise conductive adhesive, or gel based contacts.

FIG. 4 illustrates a probe 202 that has become unfastened. The illustrated probe 202 is shown in a partially unfolded shape that provides an oblique path 410 from the emitter aperture 220 to the detector assembly 235. As a patient moves, or as the probe 202 unfolds, rays of light travelling along the oblique light path 410 may generate an AC signal that could be interpreted by the pulse oximeter 140 as a physiological signal.

As illustrated in the cross section of FIG. 5A, a number of louvers 502 are placed in front of the detector assembly 235 within the detector aperture 203 in accordance with a second aspect of the present invention. The louvers 502 block light rays travelling along an oblique path 410 (i.e., light that does not originate from in front of the detector assembly 235). As illustrated in FIG. 5B, if the probe 202 is properly attached, the emitter aperture 220 will be directly in front of the detector assembly 235 and light rays will pass directly through the louvers 502 along a direct path 510.

FIG. 5C illustrates a top plan view of a preferred embodiment of this aspect of the present invention. The detector aperture 2o3 is formed in a plastic body 504 having slots 506 to hold the louvers 502 in place across the detector aperture 203. In a preferred embodiment of the present aspect, the louvers 502 can be created from commercially available "3M Light Control Film."

The louvers 502 of the present aspect advantageously provide a separate or improved method for the pulse oxime ter 140 to determine when a probe has become dislodged through monitoring the signal produced by the photodetector 116. If the probe 202 becomes improperly secured, the emitter aperture will likely move from its proper location directly above the detector assembly 235, which will cause any oblique light rays to be blocked by the louvers 502. With no light rays reaching the detector assembly 235, the detector will produce no signal. The probe-off detector 138 of the pulse oximeter 140 can detect the lack of signal and sound an alarm. The louvers 502 also advantageously block oblique light rays that might create a false signal that could be interpreted by the pulse oximeter 140 to be a physiological signal. Accordingly, the louvers 502 reduce or eliminate the possibility of a probe-off condition. The louvers 502 may be used alone or in combination with the contacts described herein.

FIG. 6 illustrates one embodiment of a method 600 by which a pulse oximeter 140 detects a dislodged probe and/or a probe-off condition. At a step 604, the probe off detector module 138 checks for continuity between the skin contacts 341 and 342. If, at a step 608, there is continuity between the contacts 341 and 342, the oximeter 140 passes control to a step 612. If, on the other hand, there is no continuity at the step 608, the oximeter 140 passes control to a step 620. At

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step 620 the oximeter 140 sounds an alarm to alert a condition necessitating attention. At the step 612, the oximeter 140 checks for a valid AC signal from the photodetector. If, at a step 616, there is a valid signal, the oximeter 140 passes control back to the step 604 to start the cycle over again. If, on the other hand, there is no valid AC signal at the step 616 the oximeter sounds an alarm at the step 620. Accordingly, the pulse oximeter checks for and detects dislodgment of a probe and/or a probe-off condition.

While certain exemplary preferred embodiments have ¹⁰ been described and shown in the accompanying drawings, it is to be understood that such embodiments are merely illustrative of and not restrictive on the broad invention. Further, it is to be understood that this invention shall not be limited to the specific construction and arrangements shown and described since various modifications or changes may occur without departing from the spirit and scope of the invention she limited not by this detailed description but by the claims appended hereto. ²⁰

What is claimed is:

- 1. A pulse oximetry probe comprising:
- a flexible probe body configured to contact the skin of a patient on opposing surfaces of a body member of the patient when the probe body is properly affixed to the ²⁵ patient;
- light emitting diodes incorporated into the probe body;
- a light sensitive detector which detects light from a first direction originally emitted by the light emitting 30 diodes, wherein the light comprises at least first and second wavelengths and has been transmitted through body tissue carrying pulsing blood; and
- at least one structure positioned approximately parallel to the first direction and is configured to filter out light 35 from reaching the light sensitive detector from a direction substantially different from the first direction.
- 2. The pulse oximetry probe of claim 1, wherein the structure comprises one or more louvers.
- 3. The pulse oximetry probe of claim 1, wherein the 40 structure comprises a plurality of louvers.
- 4. The pulse oximetry probe of claim 1, further comprising a coding resistor.

5. The pulse oximetry probe of claim **1**, further comprising an circuit configured to contact at least a portion of the 45 body tissue.

- 6. The pulse oximetry probe of claim 1, wherein the flexible probe body comprises a reusable optical probe.
- 7. The pulse oximetry probe of claim 1, wherein the flexible probe body comprises a disposable optical probe.
- 8. The pulse oximetry probe of claim 1, wherein the flexible probe body comprises reusable and disposable portions of an optical probe.
- **9**. A pulse oximeter for processing signals received from an optical probe, the pulse oximeter comprising:
- an input for receiving at least first and second intensity signals from a light-sensitive detector which detects

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light of at least first and second wavelengths transmitted through body tissue carrying pulsing blood; and

a signal processor which determines a probe-off condition when at least one of the first and second intensity signals is substantially attenuated

10. The pulse oximeter of claim 9, wherein the attenuation is caused by improper application an optical probe to the body tissue.

1. The pulse oximeter of claim 9, further comprising an audio alarm indicating when the probe-off condition is determined.

12. The pulse oximeter of claim 9, further comprising an visual alarm indicating when the probe-off condition is determined.

13. The pulse oximeter of claim 9, further comprising a coding resistor.

14. The pulse oximeter of claim 9, further comprising an circuit configured to contact at least a portion of the body tissue.

15. A sensor which generates at least first and second intensity signals from a light-sensitive detector which detects light of at least first and second wavelengths transmitted through body tissue carrying pulsing blood; the sensor comprising:

- at least one light emission device;
- a light sensitive detector; and
- a plurality of louvers positioned over the light sensitive detector to accept light from the at least one light emission device originating from a general direction of the at least one light emission device and then transmitting through body tissue carrying pulsing blood, wherein the louvers accept the light when the sensor is properly applied to tissue of a patient.

16. A method of processing one or more signals to detect a condition of improper positioning of an optical probe, the method comprising:

- expecting to receive at least first and second intensity signals from a light-sensitive detector which detects light of at least first and second wavelengths transmitted through body tissue carrying pulsing blood;
- blocking light originating from an angle oblique to a proximate relationship between the detector and a light source; and
- receiving one of an un-interpretable signal or signal other than the expected first and second intensity signals because the light is blocked; and

indicating a probe off condition.

17. The method of claim 16, wherein the indicating

comprises at least one of an audible or visual alarm. **18.** The method of claim **16.** wherein blocking light comprises positioning a plurality of louvers between the ⁵⁵ light source and the light-sensitive detector.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

 PATENT NO.
 : 6,771,994 B2

 APPLICATION NO.
 : 10/374303

 DATED
 : August 3, 2004

 INVENTOR(S)
 : Massi E. Kiani

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:

At column 2, line 36, delete "embodimet" and insert -- embodiment --, therefore.

At column 6, line 3, delete "haveing" and insert -- having --, therefore.

Signed and Sealed this

Seventeenth Day of July, 2007

JON W. DUDAS Director of the United States Patent and Trademark Office PATENT APPLICATION SERIAL NO. 103(4/2)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE FEE RECORD SHEET

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Attorney Docket No. MASIMO.172DV1 Date: February 24, 2003 Page 1

United States Patent and Trademark Office P.O. Box 2327 Arlington, VA 22202 ATTENTION: BOX PATENT APPLICATION Sir:

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Transmitted herewith for filing is the patent application of

Inventors: Massi E. Kiani Laguna Niguel, CA

> Mohamed K. Diab Mission Viejo, CA

For:

PULSE OXIMETER PROBE-OFF DETECTION SYSTEM

This application is a divisional of U.S. Application Serial No. 09/595,081, filed on June 16, 2000, entitled

"Pulse Oximeter Probe-Off Detection System."

Enclosed are:

- (X) 15 sheets of drawing;
- a copy of the Declaration (2 pages), Recorded Assignment (3 pages), and Power of Attorney with copy of Assignment (4 pages) from parent patent application;
- (X) 14 pages of specification;
- an Information Disclosure Statement (2 pages), and PTO Form 1449 (1 pages) with 16 references, one of which is being submitted;
- (X) a check in the amount of \$834 to cover the filing fee; and
- (X) a return prepaid postcard.

FOR	NUMBER FILED	NUMBER EXTRA	RATE	FEE
Basic Fee	······································		\$750	\$750
Total Claims	18 - 20 =	0 ×	\$18	\$0
Independent Claims	4 - 3 =	1 ×	\$84	\$84
If application contains any	multiple dependent clair	ns(s), then add	\$280	\$0
		TOT/ FEE	AL FILING	\$834



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PATENT

Attorney Docket No. MASIMO.172DV1 Date: February 24, 2003 Page 2

The Commissioner is hereby authorized to charge any additional fees which may be required, now or in the future, or credit any overpayment to Account No. 11-1410.

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BOX PATENT APPLICATION United States Patent and Trademark Office P.O. Box 2327 Arlington, VA 22202

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

Attorney Docket No.:		MASIMO.172DV1
Applicants	:	Massi E. Kiani, Mohamed K. Diab
For	:	PULSE OXIMETER PROBE-OFF DETECTION SYSTEM
Attorney	:	John M. Grover
"Express Mail" Mailing Label No.	:	EV 211919815 US
Date of Deposit	:	February 24, 2003

I hereby certify that the accompanying

Transmittal Letter; Specification in 14 pages; 15 sheets of drawings; Copy of Declaration (2 pages), Copy of Recorded Assignment (3 pages), Copy of Power of Attorney Form with copy of Assignment (4 pages) from the parent patent Application; Information Disclosure Statement (2 pages); PTO Form 1449 with 16 references, one of which is being submitted; Check for Filing Fee; and Return Prepaid Postcard

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and are addressed to the United States Patent and Trademark Office, P.O. Box 2327, Arlington, VA 22202.

Los Angeles 310-551-3450

>John M. Grover

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MASIMO.172DV1

PATENT

PULSE OXIMETER PROBE-OFF DETECTION SYSTEM

REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority benefit under 35 U.S.C. § 120 to, and is a divisional of, U.S. Patent Application No. 09/595,081, filed June 16, 2000, entitled "Pulse Oximeter Probe-Off Detection System," which claims priority benefit under 35 U.S.C. § 119(e) from U.S. Provisional Application No. 60/140,000, filed June 18, 1999, entitled "Pulse Oximeter Probe-Off Detection System." The present application also incorporates the foregoing utility disclosure herein by reference.

BACKGROUND OF THE INVENTION

[0002] The present invention relates to optical probes that can be attached to the finger, toe, or appendage of a patient. More particularly, the present invention relates to devices and methods for identifying when a probe has become dislodged from a patient.

DESCRIPTION OF THE RELATED ART

[0003] Oximetry is the measurement of the oxygen status of blood. Early detection of low blood oxygen is critical in the medical field, for example in critical care and surgical applications, because an insufficient oxygen supply can result in brain damage and death in a matter of minutes. Pulse oximetry is a widely accepted noninvasive procedure for measuring the oxygen saturation level of arterial blood, an indicator of oxygen supply. A pulse oximetry system generally consists of a probe attached to a patient, a monitor, and a cable connecting the probe and monitor. Conventionally, a pulse oximetry probe has both red and infrared (IR) light-emitting diode (LED) emitters and a photodiode detector. The probe is typically attached to a patient's finger or toe, or a very young patient's foot. For a finger, the probe is configured so that the emitters project light through the fingernail, the arteries, vessels, capillaries, tissue and bone. The photodiode is positioned opposite the LED so as to detect the LED transmitted light as it emerges from the finger tissues.

[0004] The pulse oximetry monitor (pulse oximeter) determines oxygen saturation by analyzing the differential absorption by arterial blood of the two wavelengths emitted by the probe. The pulse oximeter alternately activates the probe LED emitters and reads the resulting current generated by the photodiode detector. This current is proportional to the

-1-

intensity of the detected light. The pulse oximeter calculates a ratio of detected red and infrared intensities, and an arterial oxygen saturation value is empirically determined based on the ratio obtained. The pulse oximeter contains circuitry for controlling the probe, processing the probe signals and displaying the patient's oxygen saturation and pulse rate. A pulse oximeter is described in U.S. Patent 5,632,272 assigned to the assignee of the present invention.

SUMMARY OF THE INVENTION

[0005] The present invention provides a number of improvements that can be incorporated into a pulse oximeter probe to detect when a probe has become dislodged from a patient and/or to prevent a probe-off condition. A probe-off condition occurs when the optical probe becomes partially or completely dislodged from the patient, but may continue to detect an AC signal within the operating region of the pulse oximeter.

[0006] In one aspect, the present invention provides a number of electrical contacts that contact the skin of a patient when the probe is properly attached. The pulse oximeter can check the continuity through the contacts to determine whether the probe is properly attached. If the probe is not properly attached, the pulse oximeter can identify a probe-off condition even though the oximeter measures an AC signal that appears like the probe is still attached.

[0007] In another aspect, the present invention provides a number of louvers placed in front of the probe's photodetector to filter out oblique light rays that do not originate from a point in front of the detector. If the probe becomes dislodged, the emitter will not likely remain in front of the photodetector. If the emitter and photodetector are not properly aligned, the photodetector will not produce a signal within the valid operating range of the pulse oximeter. The louvers prevent light from an oblique angle from reaching the photodetector and creating a false signal that might be interpreted by the pulse oximeter as a physiological signal. Accordingly, the pulse oximeter can determine that a probe has become dislodged when the photodetector does not produce a valid signal. Furthermore, probe-off conditions can avoided since oblique light rays are not able to reach the photodetector to produce an apparently valid signal.

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BRIEF DESCRIPTION OF THE DRAWINGS

[0008] Referring now to the drawings in which like reference numbers represent corresponding components throughout:

[0009] Figure 1 illustrates a schematic of one embodiment of a pulse oximeter system;

[0010] Figures 2A-B depict an optical probe and the attachment of the optical probe on the fingertip of an adult patient;

[0011] Figure 3A illustrates a schematic of a pulse oximeter system that incorporates electrical contacts to the skin of a patient, in accordance with one embodimet of the present invention;

[0012] Figure 3B illustrates a perspective view of an optical probe incorporating electrical contacts to the skin of a patient;

[0013] Figure 3C illustrates a schematic of one embodiment of a pulse oximeter system that incorporates electrical contacts to the skin of a patient;

[0014] Figure 3D illustrates a schematic of a preferred embodiment of a pulse oximeter system that incorporates a number of electrical contacts to the skin of a patient;

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[0015] Figure 3E depicts a generalized schematic of a pulse oximeter that incorporates another embodiment of a contact on a pulse oximeter probe;

[0016] Figure 3F depicts a perspective view an optical probe incorporating the embodiment of Figure 3E;

[0017] Figure 3G depicts a generalized schematic of a pulse oximeter system that incorporates another embodiment of a contact sensor in accordance with the present invention;

[0018] Figure 3H depicts a perspective view of an optical probe incorporating the contact sensor of Figure 3G;

[0019] Figure 4 illustrates a probe that has become unfastened;

[0020] Figure 5A illustrates a probe wherein a number of louvers are placed in front of the detector assembly;

[0021] Figure 5B illustrates a properly attached probe wherein a number of louvers are placed in front of the detector assembly;

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[0022] Figure 5C illustrates a top plan view of a preferred embodiment of a probe wherein a number of louvers are placed in front of the detector assembly

[0023] Figure 6 illustrates a flow chart of the method of detecting a dislodged probe.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0024] To compute peripheral arterial oxygen saturation, denoted Sp_4O_2 , pulse oximetry relies on the differential light absorption of oxygenated hemoglobin, HbO₂, and deoxygenated hemoglobin, Hb. This differential absorption is measured at the red and infrared wavelengths of the probe. In addition, pulse oximetry relies on the pulsatile nature of arterial blood to differentiate hemoglobin absorption from absorption of other constituents in the surrounding tissues. Light absorption between systole and diastole varies due to the blood volume change from the inflow and outflow of arterial blood at a peripheral tissue site. The tissue site might also comprise skin, muscle, bone, venous blood, fat, pigment, etc., each of which absorbs light. Blood oxygen saturation measurements are based upon a ratio of the time-varying or AC portion of the detected red and infrared signals with respect to the time-invariant or DC portion. This AC/DC ratio normalizes the signals and accounts for variations in light pathlengths through the measured tissue.

[0025] As reproduced in Figure 1, a schematic of one embodiment of a pulse oximeter system 100 is disclosed in U.S. Patent 5,758,644 (the '644 patent), assigned to the assignee of the present application and incorporated herein by reference. The system 100 comprises a pulse oximeter 140, which is attached through a connector 142 to a probe 110. The probe 110 comprises a first LED 112, a second LED 114 and a photodetector 116. The first and second LEDs 112 and 114 are connected back-to-back and share a common electrical connection 118. The photodetector 116 has its own electrical connection 122. Each of the LEDs 112 and 114 and the photodetector 116 are connected at their outputs to a common ground electrical connection 130. The two LEDs 112 and 114 are preferably configured to produce different wavelengths of light, which pass through the flesh of a patient to be detected by the photodetector 116. The oximeter 140 can select the LED to be driven by applying either a positive or negative voltage to the connection 118. A coding resistor 132 has a resistance that can measured by the pulse oximeter 140 to determine the

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particular characteristics of the probe 110. The coding resistor 132 is coupled in parallel with the first LED 112 or the second LED 114. The resistor 132 can be used to indicate the operating wavelength of the first and second LEDs 112 and 114, or to indicate the type of probe. In order to read the coding resistor 132, the pulse oximeter 140 drives the first LED 112/coding resistor 132 combination at a level that is low enough that the LED draws insignificant current. At this level, significantly all of the current flows through the coding resistor 132 and the pulse oximeter 140 can determine the value of the resistor in accordance with Ohm's law. By configuring the coding resistor 132 in parallel with one of the LEDs 112, 114, the added expense of an additional lead connecting the pulse oximeter 140 to the probe 110 can be saved.

One embodiment of a disposable probe for use with pulse oximetry [0026] systems is disclosed in U.S. Patent 5,782,757, assigned to the assignee of the present application and incorporated herein by reference. Figures 2A-B depict the optical probe 202 and the attachment of the optical probe 202 on the fingertip 250 of an adult patient. The disposable optical probe 202 is designed to fit comfortably onto a patient's fingertip. As illustrated in Figure 2A, the probe 202 includes a central portion 204, a pair of adhesive flanges 205 extending from the central portion 204, a connector portion 210 situated between the flanges 205, and a pair of smaller adhesive flaps 215 extending from the central portion 204 on the end of the optical probe 202 opposite from a connector tab 210. The probe 202 further includes an emitter aperture 220 with a number of emitters (e.g., a light-emitting diodes) positioned within the central portion 204 close to the connector portion 210, and a detector aperture 230 which allows light to pass through the detector aperture 230 to a detector assembly 235. An adult fingertip 250 is shown in phantom in Figure 2A to illustrate the position at which the fingertip 250 is placed when the probe 202 is to be fastened onto the fingertip 250 for use. Although not depicted specifically in Figures 2A-2B, the probe 202 is typically fabricated from multiple layers.

[0027] Figure 2B illustrates the probe 202 fastened onto the fingertip 250. As shown in Figure 2B, the probe 202 folds to conform to the very end of the fingertip. The adhesive flaps 205 fold downward (in the illustration of Figure 2B) to wrap around the fingertip 250 while the adhesive flaps 215 fold upward (in the illustration of Figure 2B) about

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a portion of the circumference of the fingertip 250 to provide support. As shown in Figure 2B, when the probe 202 is folded about the fingertip 250, the emitters located within the probe are spaced opposite the detector assembly 235 such that light from the emitters passes through the emitter aperture 220, through the finger 250 and is incident upon the detector assembly 235 through the detector aperture 230.

[0028] Figure 2B depicts a receiving connector portion 260 which engages with contacts 252 on the connector 210 to provide an electrical connection between the optical probe 202 and the pulse oximeter 140. Once the optical probe 202 is securely fastened to the fingertip 250 and the connector 210 provides an electrical connection between the optical probe 202 and digital signal processing circuitry, signals are detected from the detector 235 and transmitted to the processing circuitry via the connector 260.

[0029] A probe-off condition occurs when the optical probe becomes partially or completely dislodged from the patient, but continues to detect an AC signal within the operating region of the pulse oximeter. Probe-off errors are serious because the pulse oximeter may display a normal saturation when, in fact, the probe is not properly attached to the patient, potentially leading to missed desaturation events. Failure to detect a probe-off condition is the result of the probe detector receiving light directly from the emitters without transmission through the patient's tissue.

[0030] As illustrated in the schematic of Figure 3A, a first aspect of the present invention involves an optical probe 202 which incorporates a number of electrical contacts 341 and 342 that make contact to the skin of the patient when the probe 202 is properly secured. In order to detect a probe-off condition, a probe-off detector module 138 of the pulse oximeter 140 periodically applies a voltage across the contacts 341 and 342 or drives a current. A non-zero current indicates that the patient's skin 344 has closed the circuit between the contacts 341 and 342 and the probe 202 is properly secured. If the probe becomes dislodged, the patient's skin 344 is no longer be in contact with the contacts 341 and 342, resulting in an open circuit.

[0031] Figure 3B illustrates one preferred embodiment of an optical probe 202 incorporating one embodiment of the present invention. The present embodiment incorporates a first electrical contact 341 and a second electrical contact 342 in the surface

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306 of the central portion 204 of the probe 202. The electrical contacts 341 and 342 are positioned in a location such that contact to a finger or flesh portion of the patient is ensured when the probe 202 is properly attached. In the illustrated embodiment, the contacts 341 and 342 are located proximate the detector aperture 203. In another embodiment, contacts 341 and 342 are on opposite sides of the detector aperture 203. The optical probe 202 also has an emitter aperture 220 through which light of at least two wavelengths passes from LEDs.

[0032] As illustrated in the schematic diagram of Figure 3C, the pulse oximeter system 100 of Figure 1 can be modified to incorporate the first aspect of the present invention by extending an additional lead 324 through the connector 142 to the probe 202. The additional lead can be connected to one contact 341 while the second contact 342 can be wired to the common ground lead 130.

A schematic diagram of another embodiment of the present invention is [0033] illustrated in Figure 3D. The contacts 341 and 342 can be installed in line within the path of the coding resistor 132. When the patient's skin 344 is in contact with the contacts 341 and 342, the circuit through the coding resistor 132 will be closed; when the patient's skin 344 is not in contact with the contacts 341 and 342, the circuit through the coding resistor 132 will be open. The skin 344 will have some finite resistance between the contacts 341 and 342 that will affect the measured resistance of the coding resistor. As the contacts 341 and 342 are installed in series with the coding resistor 132, any resistance across the contacts 341 and 342 will be added to the resistance of the coding resistor 132 when the pulse oximeter 140 attempts to measure the resistance of the coding resistor 132. The resistance of the skin 344 can effectively be ignored in the measurement of the coding resistor 132, however, by choosing the value of the coding resistor 132 to be substantially larger than the resistance of a patient's skin 344 between the contacts 341 and 342. Alternatively, the acceptable resistance for the coding resistor can be specified as in a range that includes the likely added resistance of the skin in the circuit. In the present configuration, the probe-off detector module 138 of the pulse oximeter 140 can verify that the optical probe 202 is properly secured simultaneously with checking the resistance of the coding resistor 132. An open circuit indicates that the probe has become dislodged, whereas a valid resistance of a coding resistor

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132 indicates a proper attachment of the probe 202. If the probe has become dislodged, the pulse oximeter 140 can sound an alarm, display a warning message, or both.

[0034] The pulse oximeter 140 is particularly vulnerable to probe-off errors when operating at its highest sensitivity, where even small induced variations in light directly detected from the emitters have sufficient signal strength to be processed as a physiological signal. In a probe-off condition, a detector AC signal can be induced by slight changes in the direct light path between the emitters and the detector. For example, small amounts of patient motion, such as chest movement from breathing, can induce a probe-off AC signal. As another example, "creep" in the probe configuration, such as a folded probe gradually returning to its original unfolded shape after becoming dislodged can also induce a probe-off AC signal.

[0035] Figures 3E and 3F depict a generalized embodiment of the present invention with the same features as described in 3A and 3B, except that the electrical contacts 341, 342 are replaced with a contact sensor 343. The electrical contacts 341 and 342 comprise a specialized case of a contact sensor 343 where skin is involved. The contact sensor 343 may also comprise a piezoelectric sensor, a conductive contact sensor, or any other contact sensors which detect the contact of the tissue material.

[0036] Figures 3G and 3H depict yet another embodiment of the electrical contact based contact sensor of Figures 3A and 3B. Figure 3G depicts a schematic form with a pulse oximeter 140 and a probe off detector module. Figure 3H depicts a perspective view of the optical pulse oximeter probe haveing optical emitters and at least one detector. However, in this embodiment, electrical contact 341A and electrical contact 342 are positioned opposite each other. The electrical contact 341A is positioned near the emitter aperture 220, so as to contact the portion of the tissue material near the emitter 220. The electrical contact 342 is positioned near the detector aperture 203. Similarly, other contact sensors could be positioned, one near the emitter aperture 220 and one near the detector aperture 203.

[0037] In one embodiment the electrical contacts 341, 342, 341A are metallic. In another embodiment, these contacts comprise conductive adhesive, or gel based contacts.

[0038] Figure 4 illustrates a probe 202 that has become unfastened. The illustrated probe 202 is shown in a partially unfolded shape that provides an oblique path 410

-8-

from the emitter aperture 220 to the detector assembly 235. As a patient moves, or as the probe 202 unfolds, rays of light travelling along the oblique light path 410 may generate an AC signal that could be interpreted by the pulse oximeter 140 as a physiological signal.

[0039] As illustrated in the cross section of Figure 5A, a number of louvers 502 are placed in front of the detector assembly 235 within the detector aperture 203 in accordance with a second aspect of the present invention. The louvers 502 block light rays travelling along an oblique path 410 (i.e., light that does not originate from in front of the detector assembly 235). As illustrated in Figure 5B, if the probe 202 is properly attached, the emitter aperture 220 will be directly in front of the detector assembly 235 and light rays will pass directly through the louvers 502 along a direct path 510.

[0040] Figure 5C illustrates a top plan view of a preferred embodiment of this aspect of the present invention. The detector aperture 203 is formed in a plastic body 504 having slots 506 to hold the louvers 502 in place across the detector aperture 203. In a preferred embodiment of the present aspect, the louvers 502 can be created from commercially available "3M Light Control Film."

[0041] The louvers 502 of the present aspect advantageously provide a separate or improved method for the pulse oximeter 140 to determine when a probe has become dislodged through monitoring the signal produced by the photodetector 116. If the probe 202 becomes improperly secured, the emitter aperture will likely move from its proper location directly above the detector assembly 235, which will cause any oblique light rays to be blocked by the louvers 502. With no light rays reaching the detector assembly 235, the detector will produce no signal. The probe-off detector 138 of the pulse oximeter 140 can detect the lack of signal and sound an alarm. The louvers 502 also advantageously block oblique light rays that might create a false signal that could be interpreted by the pulse oximeter 140 to be a physiological signal. Accordingly, the louvers 502 reduce or eliminate the possibility of a probe-off condition. The louvers 502 may be used alone or in combination with the contacts described herein.

[0042] Figure 6 illustrates one embodiment of a method 600 by which a pulse oximeter 140 detects a dislodged probe and/or a probe-off condition. At a step 604, the probe off detector module 138 checks for continuity between the skin contacts 341 and 342. If, at a

-9-

step 608, there is continuity between the contacts 341 and .342, the oximeter 140 passes control to a step 612. If, on the other hand, there is no continuity at the step 608, the oximeter 140 passes control to a step 620. At step 620 the oximeter 140 sounds an alarm to alert a condition necessitating attention. At the step 612, the oximeter 140 checks for a valid AC signal from the photodetector. If, at a step 616, there is a valid signal, the oximeter 140 passes control back to the step 604 to start the cycle over again. If, on the other hand, there is no valid AC signal at the step 616 the oximeter sounds an alarm at the step 620. Accordingly, the pulse oximeter checks for and detects dislodgment of a probe and/or a probe-off condition.

[0043] While certain exemplary preferred embodiments have been described and shown in the accompanying drawings, it is to be understood that such embodiments are merely illustrative of and not restrictive on the broad invention. Further, it is to be understood that this invention shall not be limited to the specific construction and arrangements shown and described since various modifications or changes may occur without departing from the spirit and scope of the invention as claimed. It is intended that the scope of the invention be limited not by this detailed description but by the claims appended hereto.



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WHAT IS CLAIMED IS:

1. A pulse oximetry probe comprising:

a flexible probe body configured to contact the skin of a patient on opposing surfaces of a body member of the patient when the probe body is properly affixed to the patient;

light emitting diodes incorporated into the probe body;

a light sensitive detector which detects light from a first direction originally emitted by the light emitting diodes, wherein the light comprises at least first and second wavelengths and has been transmitted through body tissue carrying pulsing blood; and

at least one structure positioned approximately parallel to the first direction and is configured to filter out light from reaching the light sensitive detector from a direction substantially different from the first direction.

2. The pulse oximetry probe of Claim 1, wherein the structure comprises one or more louvers.

3. The pulse oximetry probe of Claim 1, wherein the structure comprises a plurality of louvers.

4. The pulse oximetry probe of Claim 1, further comprising a coding resistor.

5. The pulse oximetry probe of Claim 1, further comprising an circuit configured to contact at least a portion of the body tissue.

6. The pulse oximetry probe of Claim 1, wherein the flexible probe body comprises a reusable optical probe.

7. The pulse oximetry probe of Claim 1, wherein the flexible probe body comprises a disposable optical probe.

8. The pulse oximetry probe of Claim 1, wherein the flexible probe body comprises reusable and disposable portions of an optical probe.

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9. A pulse oximeter for processing signals received from an optical probe, the pulse oximeter comprising:

an input for receiving at least first and second intensity signals from a lightsensitive detector which detects light of at least first and second wavelengths transmitted through body tissue carrying pulsing blood; and

a signal processor which determines a probe-off condition when at least one of the first and second intensity signals is substantially attenuated.

10. The pulse oximeter of Claim 9, wherein the attenuation is caused by improper application an optical probe to the body tissue.

11. The pulse oximeter of Claim 9, further comprising an audio alarm indicating when the probe-off condition is determined.

12. The pulse oximeter of Claim 9, further comprising an visual alarm indicating when the probe-off condition is determined.

13. The pulse oximeter of Claim 9, further comprising a coding resistor.

14. The pulse oximeter of Claim 9, further comprising an circuit configured to contact at least a portion of the body tissue.

15. A sensor which generates at least first and second intensity signals from a light-sensitive detector which detects light of at least first and second wavelengths transmitted through body tissue carrying pulsing blood; the sensor comprising:

at least one light emission device;

a light sensitive detector; and

a plurality of louvers positioned over the light sensitive detector to accept light from the at least one light emission device originating from a general direction of the at least one light emission device and then transmitting through body tissue carrying pulsing blood, wherein the louvers accept the light when the sensor is properly applied to tissue of a patient.

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16. A method of processing one or more signals to detect a condition of improper positioning of an optical probe, the method comprising:

expecting to receive at least first and second intensity signals from a lightsensitive detector which detects light of at least first and second wavelengths transmitted through body tissue carrying pulsing blood;

blocking light originating from an angle oblique to a proximate relationship between the detector and a light source; and

receiving one of an un-interpretable signal or signal other than the expected first and second intensity signals because the light is blocked; and

indicating a probe off condition.

17. The method of Claim 16, wherein the indicating comprises at least one of an audible or visual alarm.

18. The method of Claim 16, wherein blocking light comprises positioning a plurality of louvers between the light source and the light-sensitive detector.



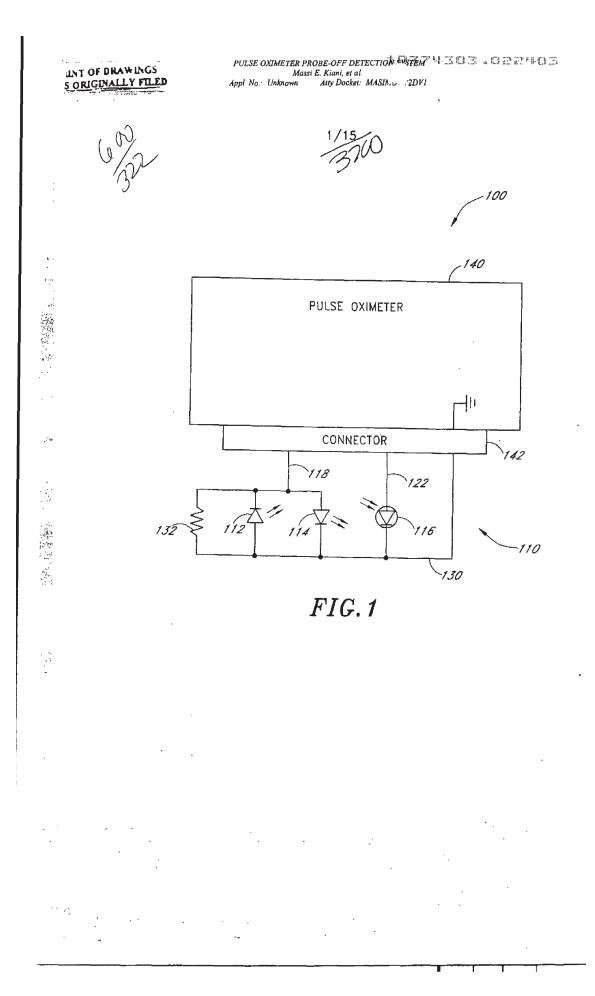
PULSE OXIMETER PROBE-OFF DETECTION SYSTEM ABSTRACT OF THE DISCLOSURE

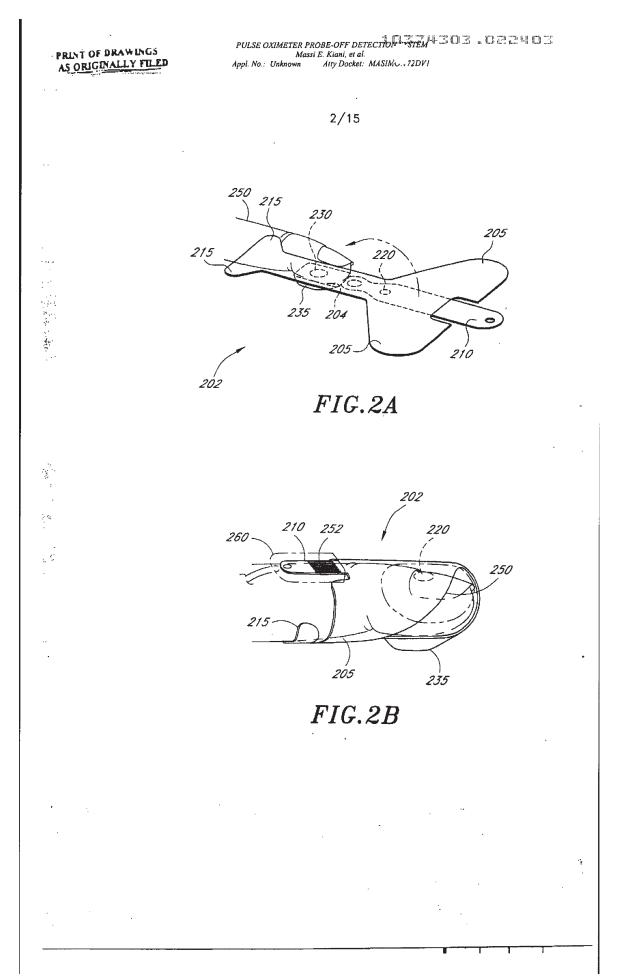
The present invention provides a number of improvements that can be incorporated into a pulse oximeter probe to detect when a probe has become dislodged from a patient and/or to prevent a probe-off condition. A probe-off condition occurs when the optical probe becomes partially or completely dislodged from the patient, but continues to detect an AC signal within the operating region of the pulse oximeter. In one aspect, the present invention provides electrical contacts that contact the skin of a patient when the probe is properly attached. In another aspect, the present invention provides a number of louvers placed in front of the sensor's photodetector to filter out oblique light rays that do not originate from a point in front of the detector. Accordingly, if the emitter and photodetector are not properly aligned, the photodetector will not produce a signal within the valid operating range of the pulse oximeter. In accordance with a method of the present invention the pulse oximeter can sound an alarm or display a warning if it determines that the probe is not properly attached to the patient.

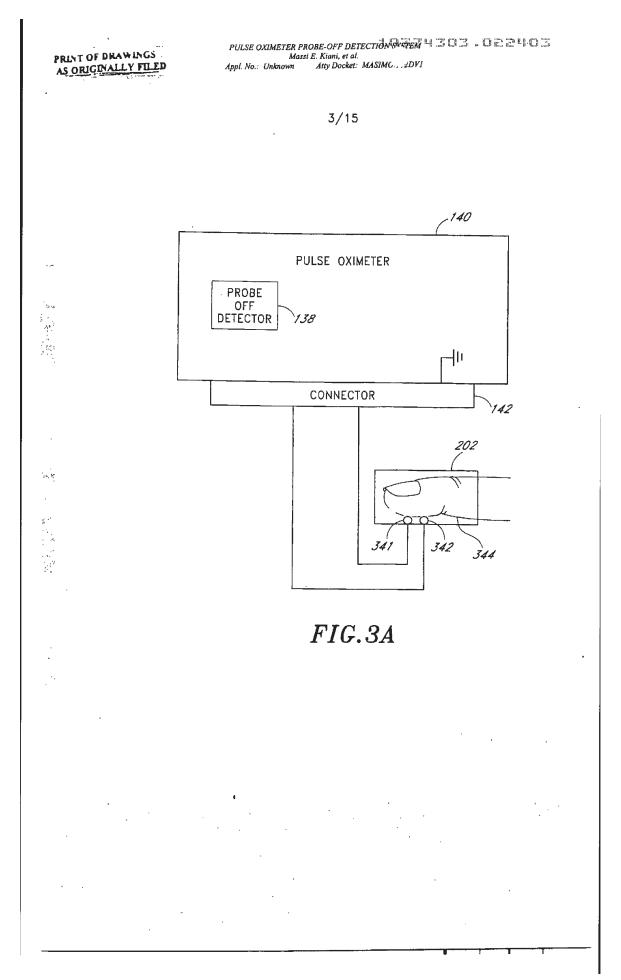
PATENT

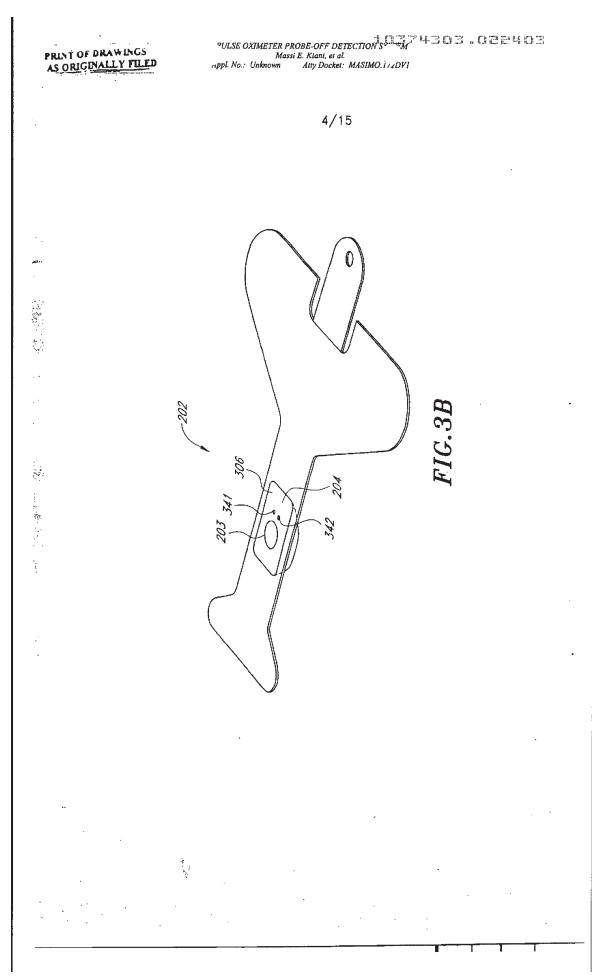
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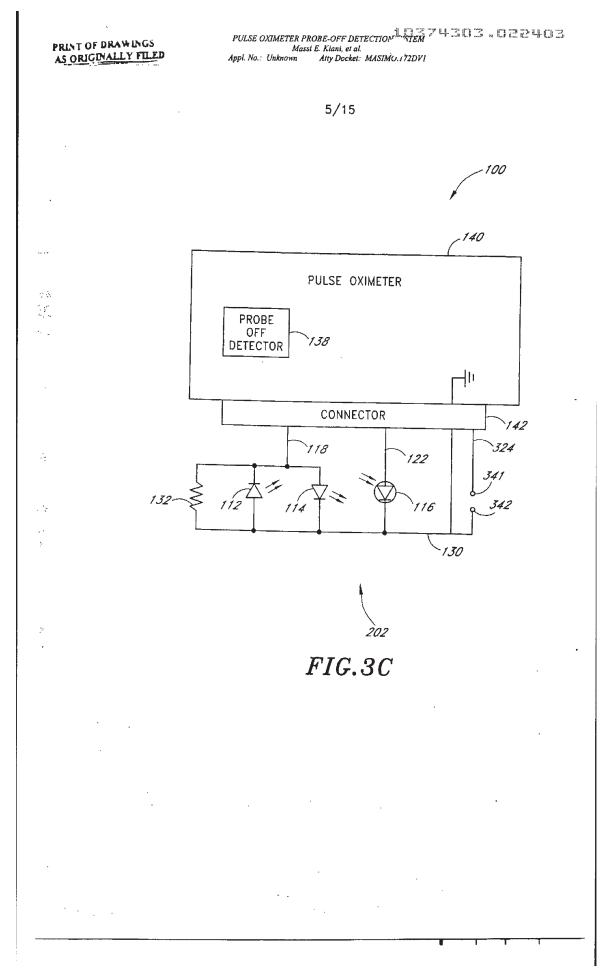


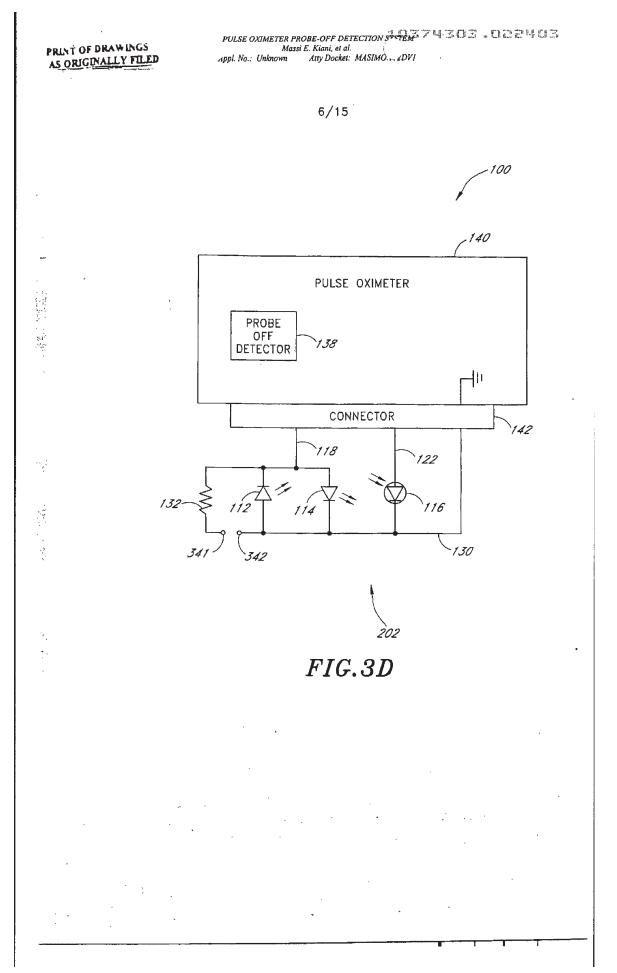


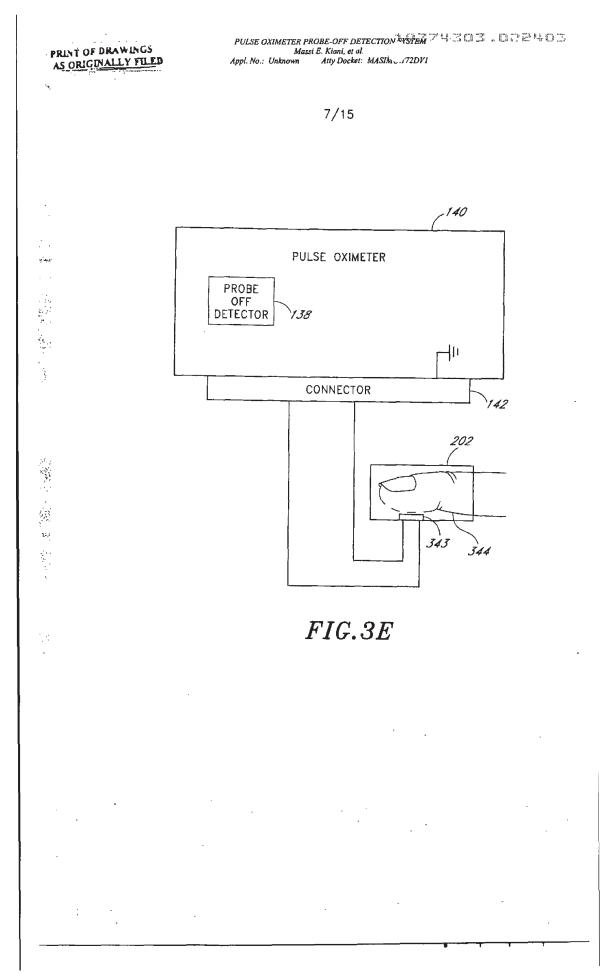


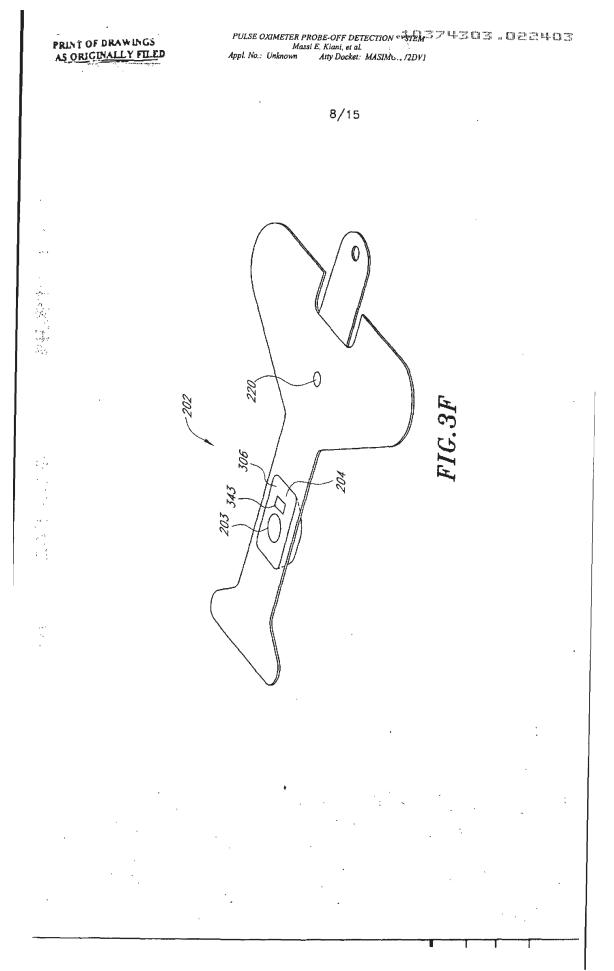


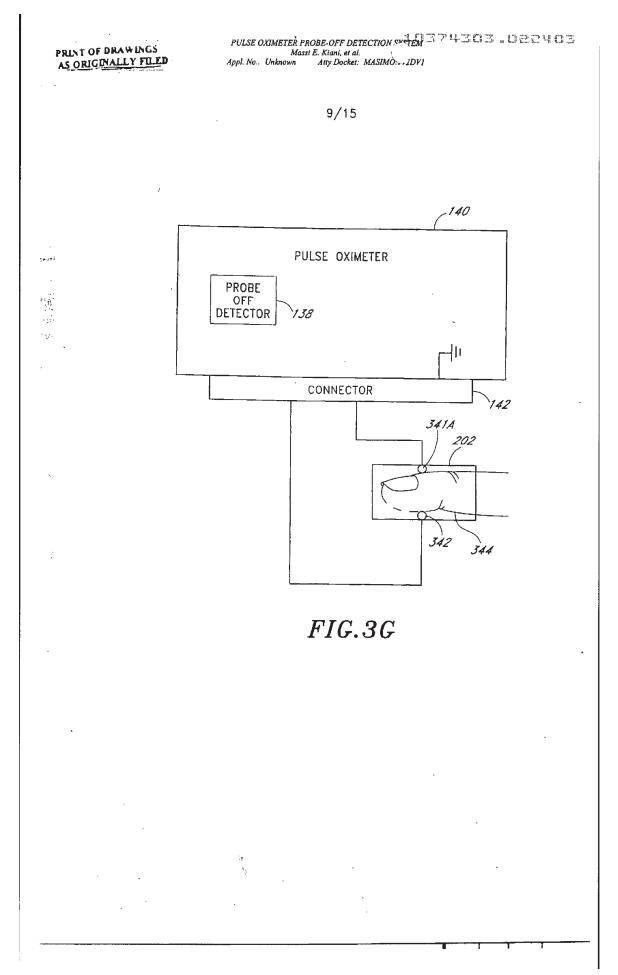


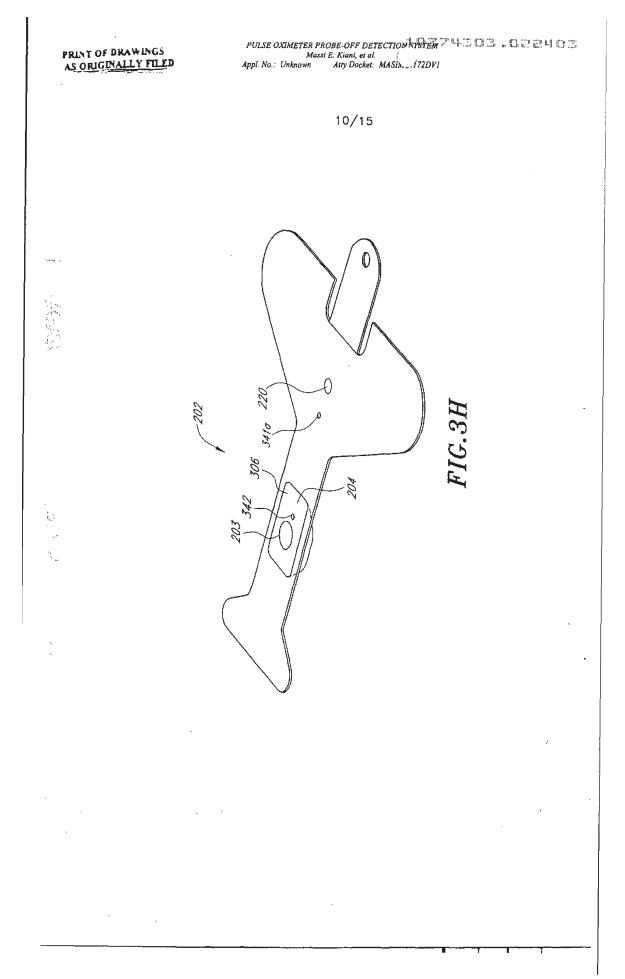


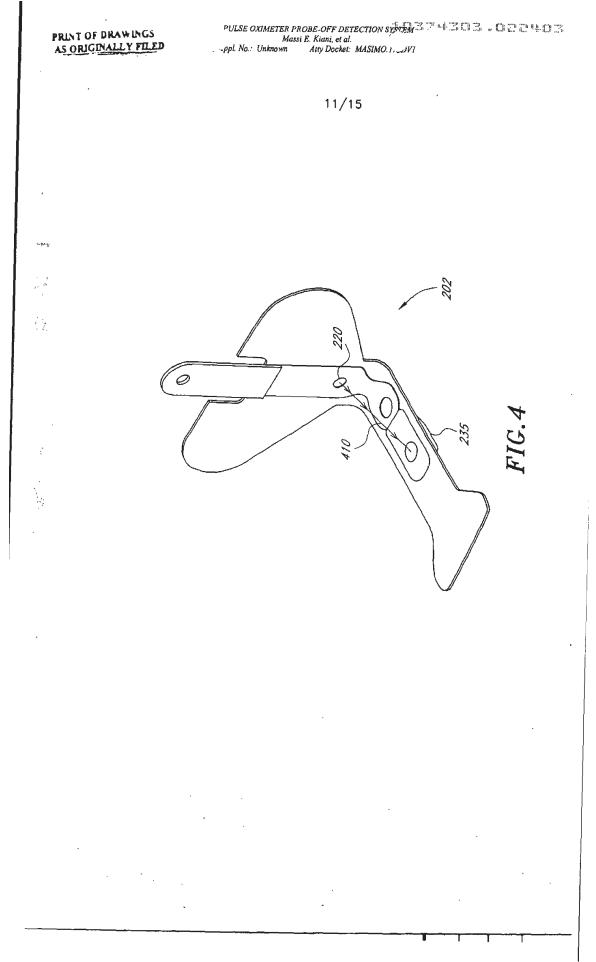


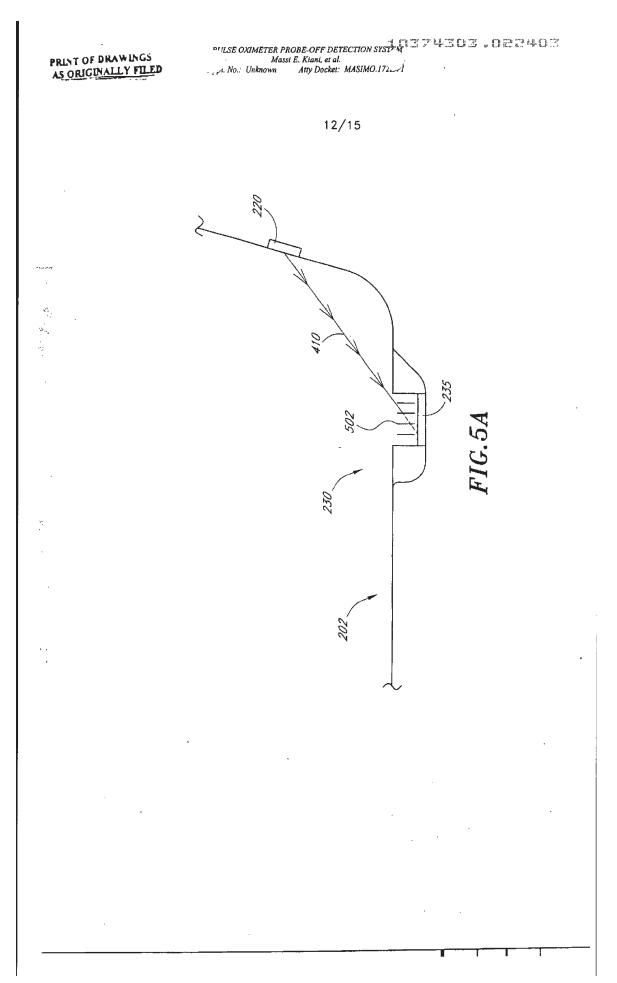


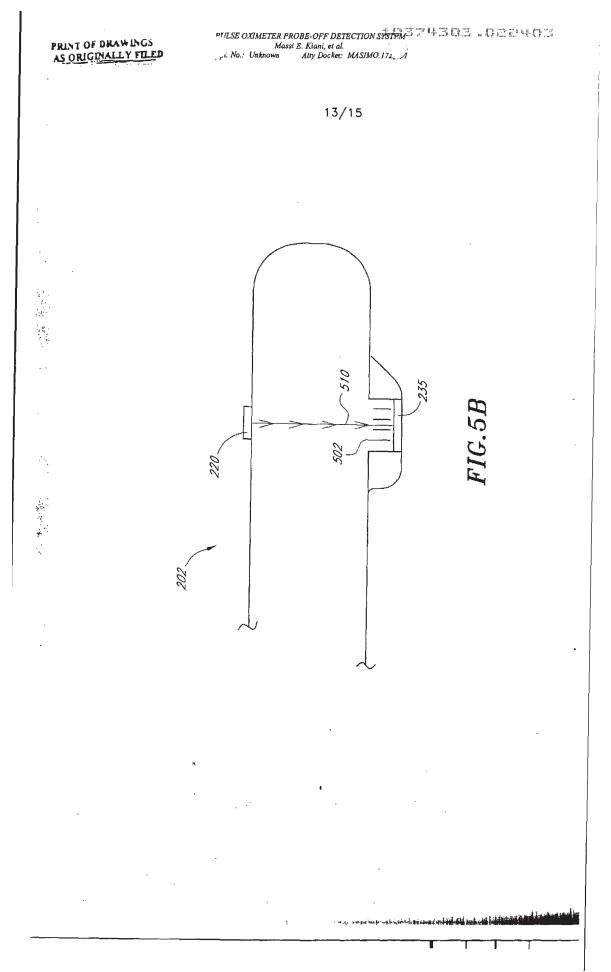


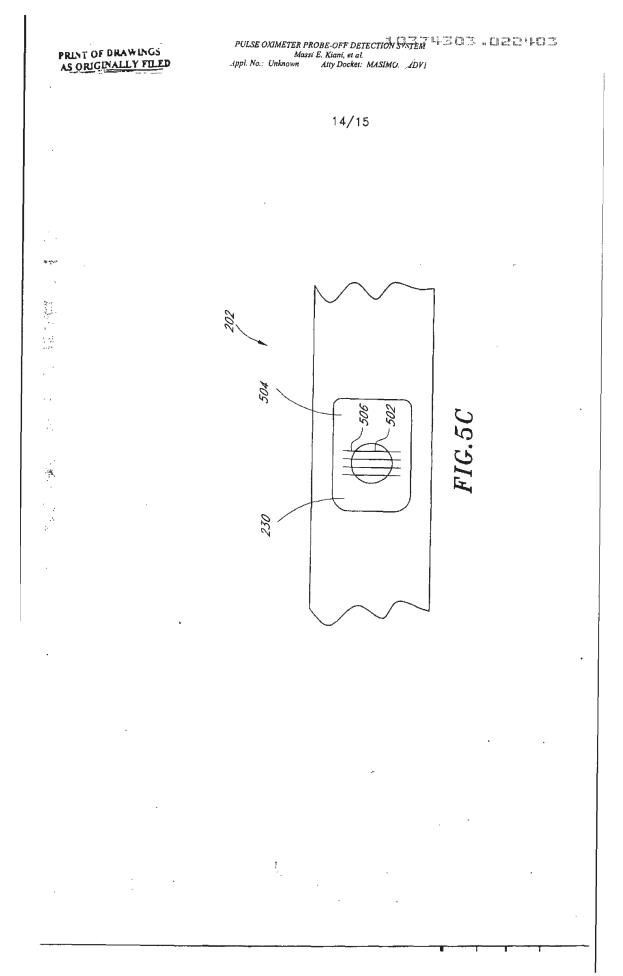


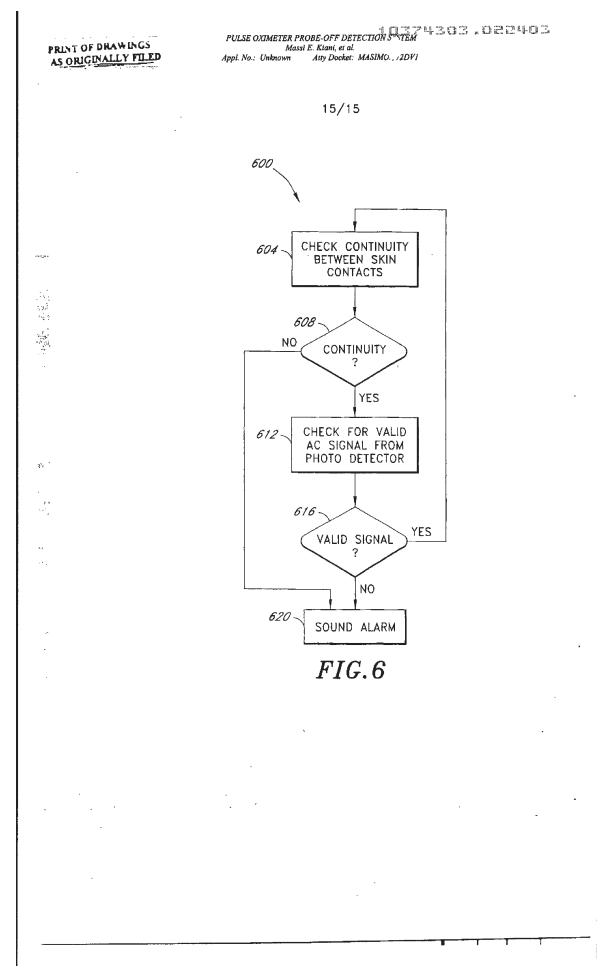


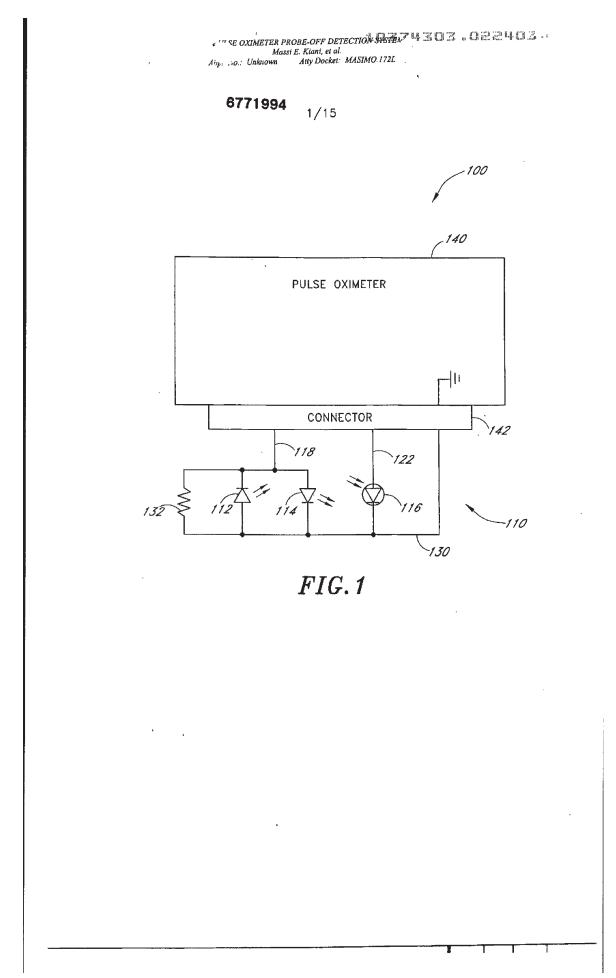












P^{***}SE OXIMETER PROBE-OFF DETECTION STSTEM⁺SOS * DC2⁺403 Massi E. Kiani, et al. App: No.: Unknown Aity Docket: MASIMO.172L.



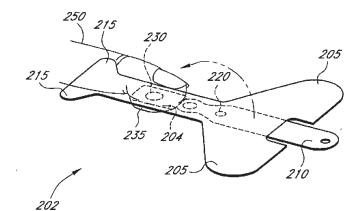


FIG.2A

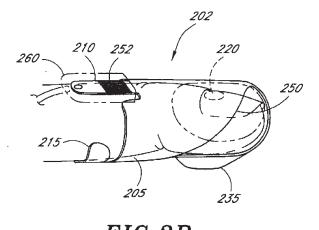
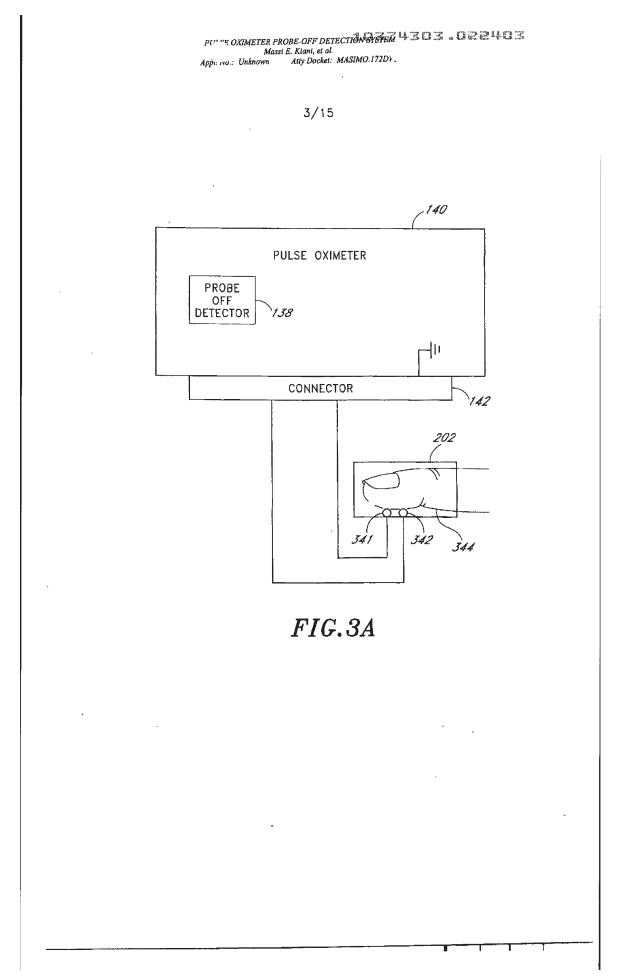
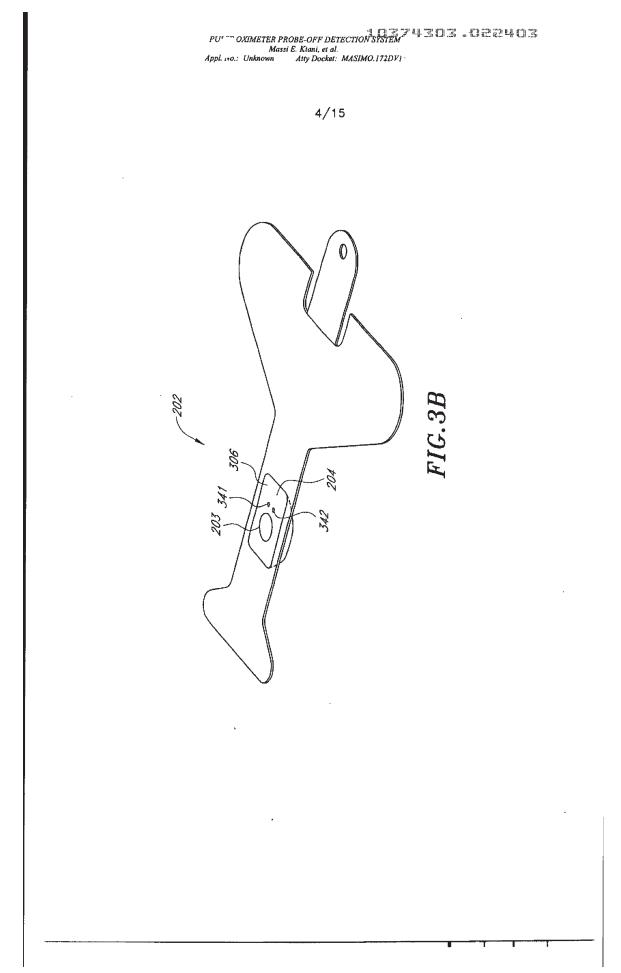
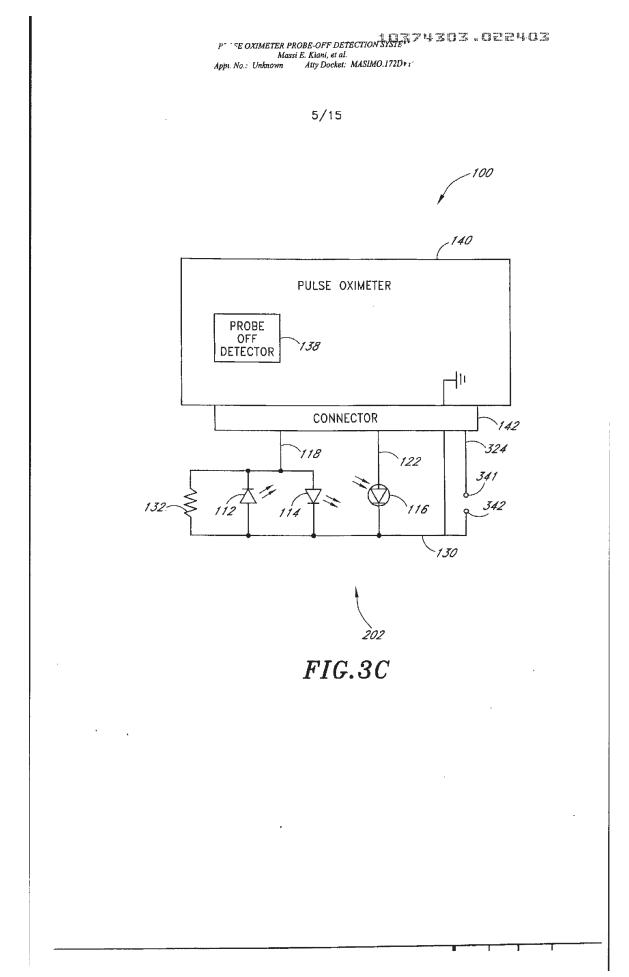
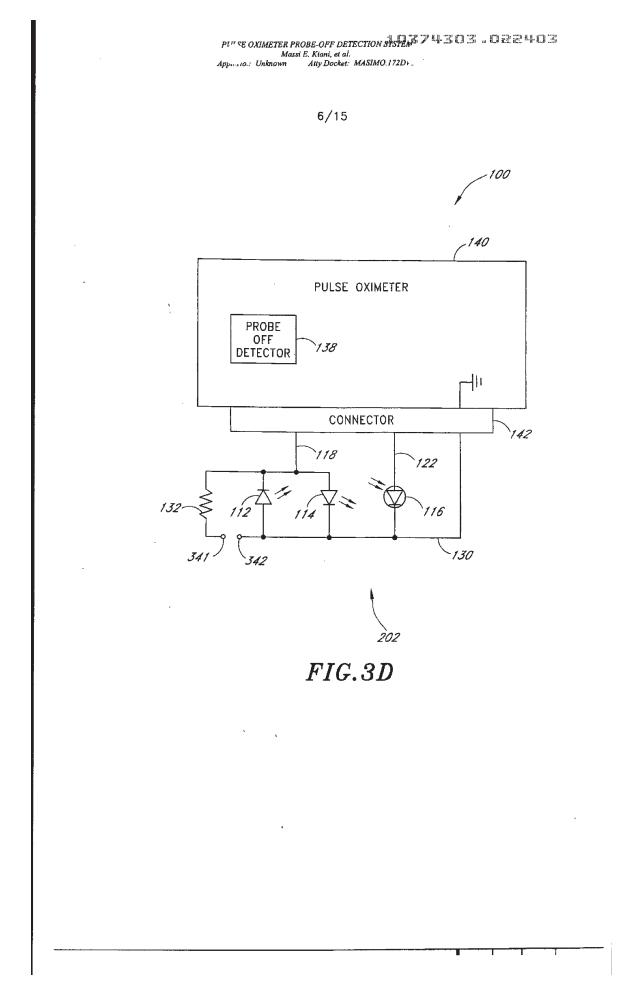


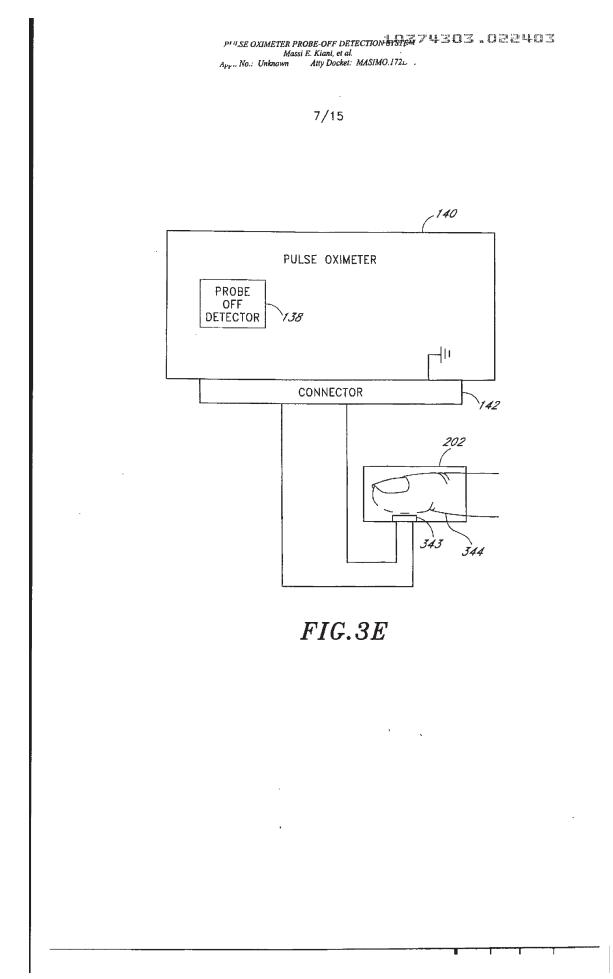
FIG.2B

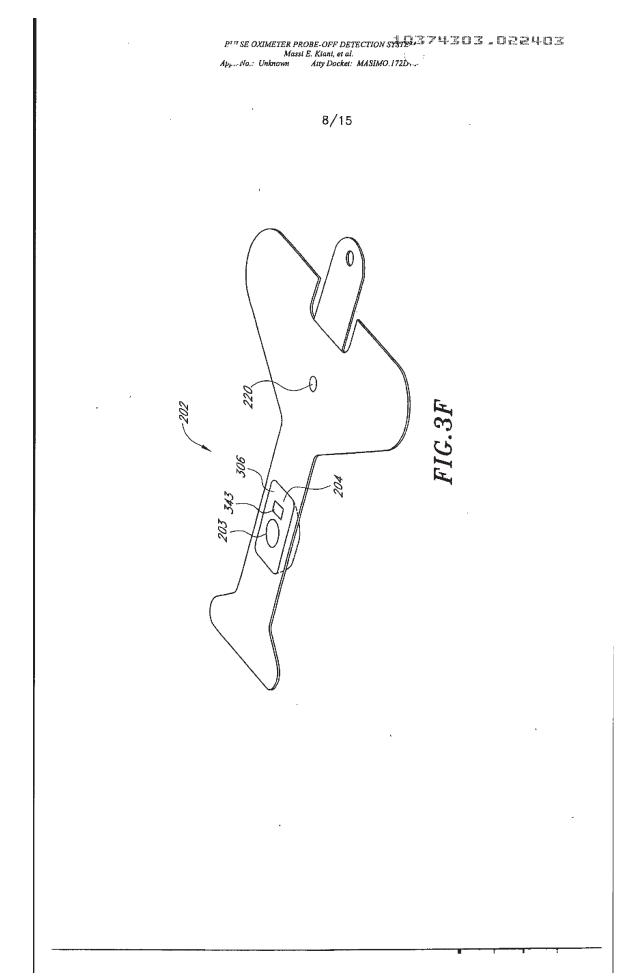


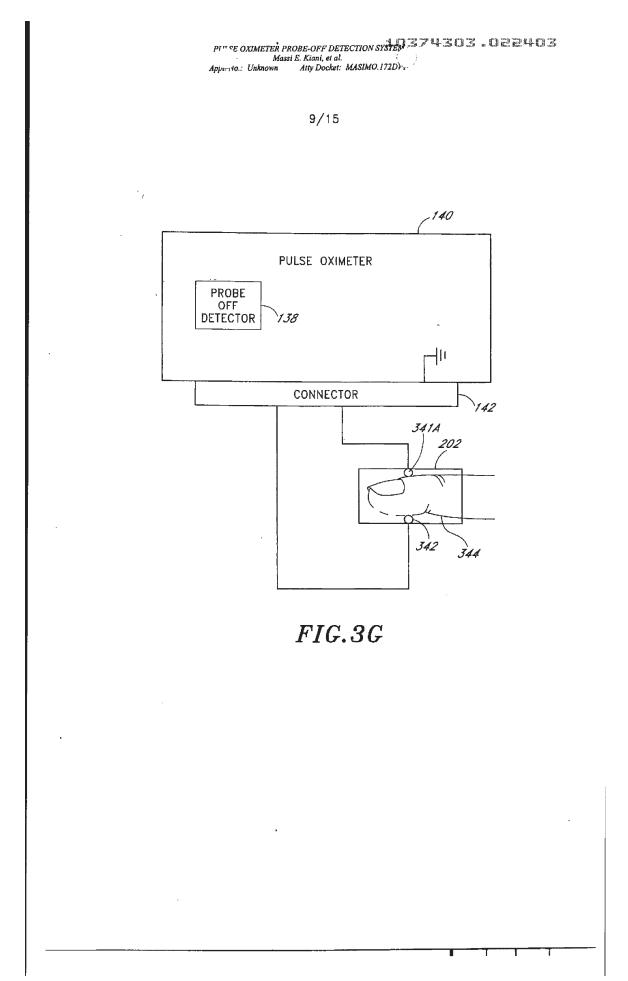


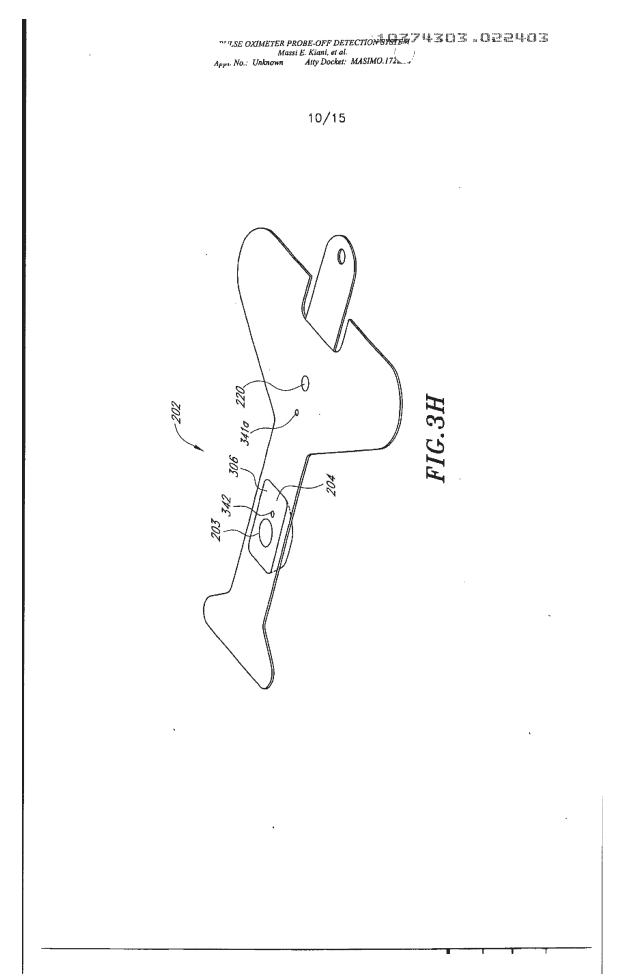


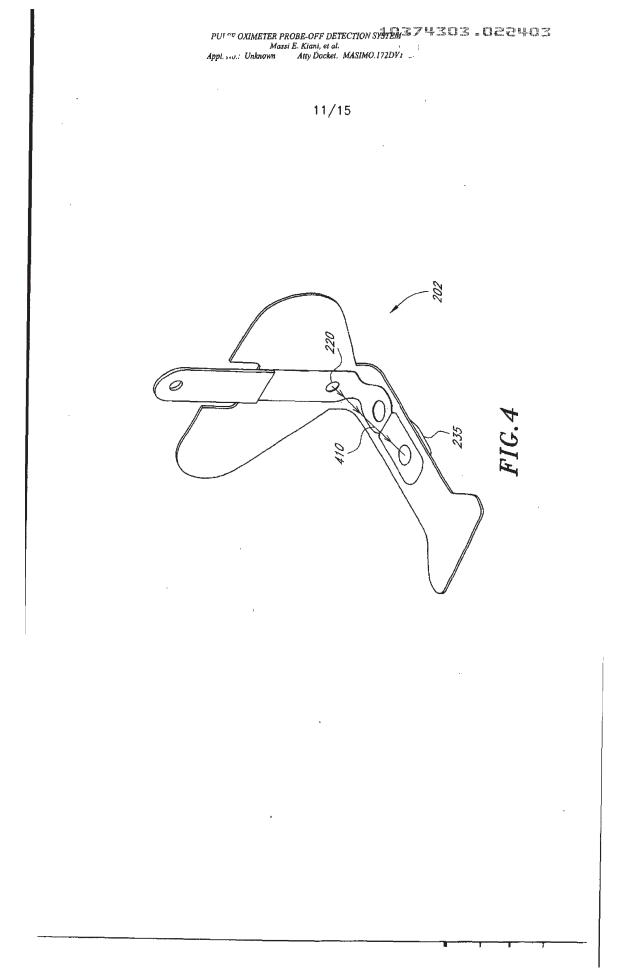


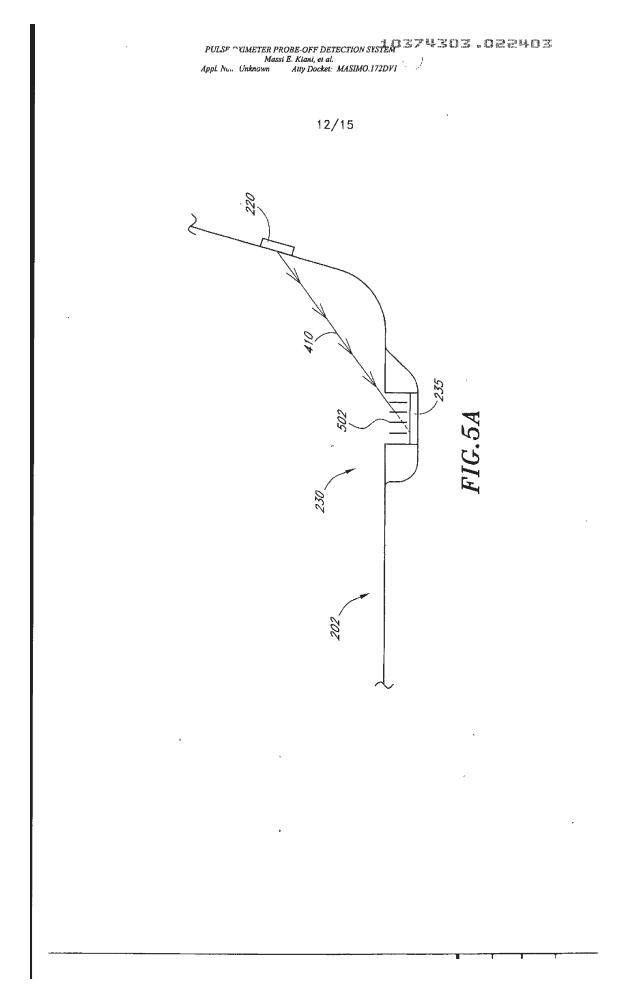


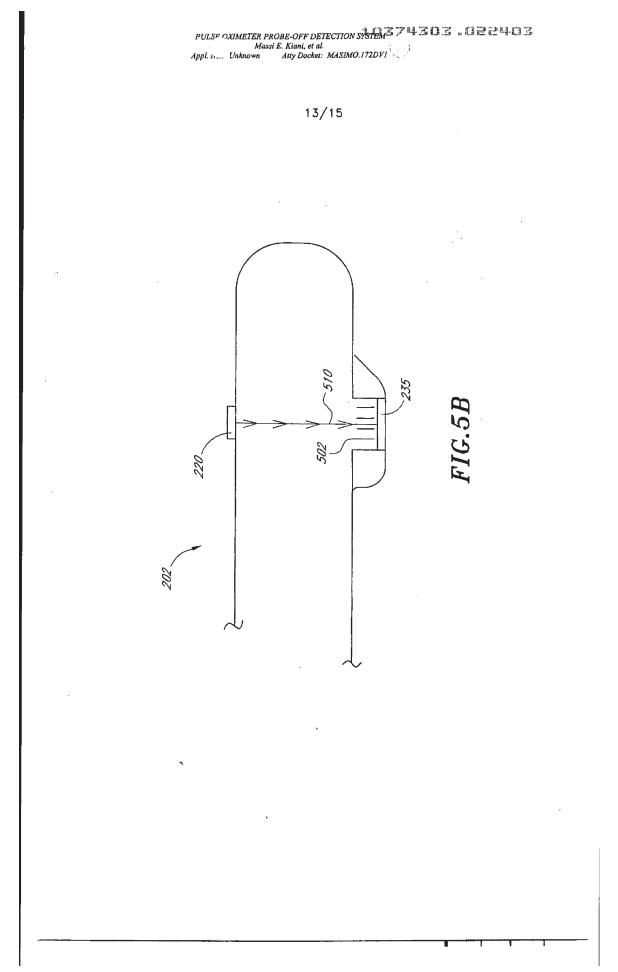


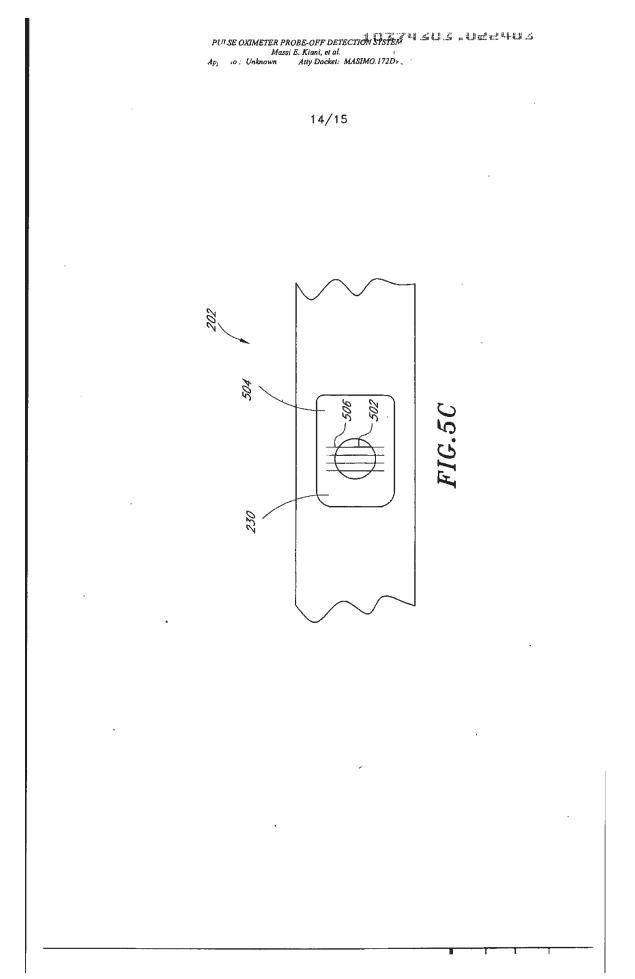


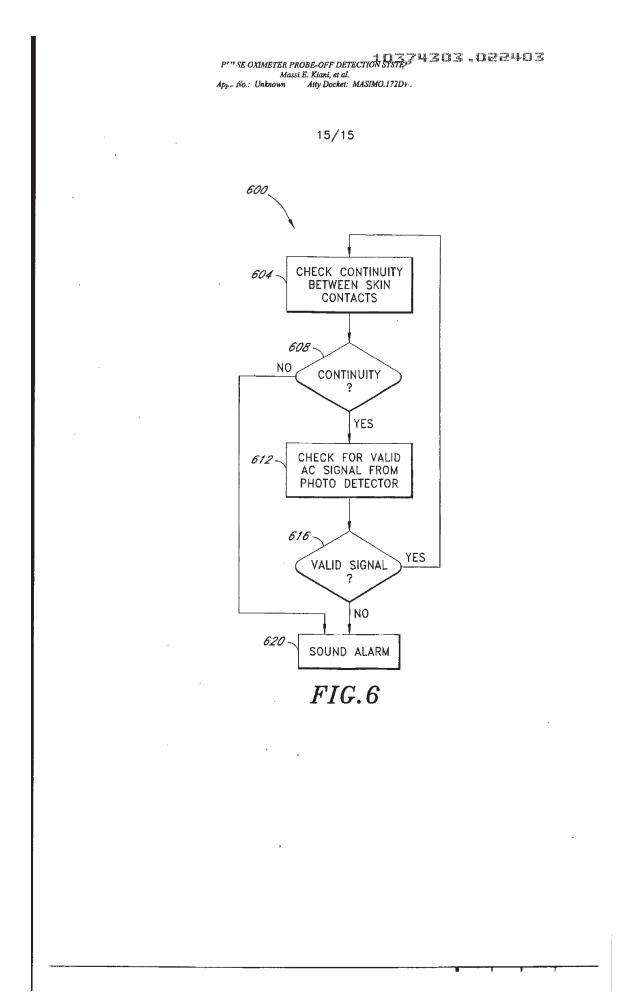












Page 1

DECLARATION - USA PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled PULSE OXIMETER PROBE OFF DETECTION SYSTEM; the specification of which was filed on June 16, 2000 as Application No. 09/595,081.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above;

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, $\S 1.56$;

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below, and insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56, which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Prior U.S.A. Application(s)

Application No.: 60/140,000

Filing Date: June 18, 1999 Status: Pending

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of	of first	inventor:	Massi E.	Kiani

Inventor's signature ______

Date 8-31-00

Page 2

Residence: 35 Brindisi, Laguna Niguel, CA 92677

Citizenship: US

Post Office Address:

Full name of second inventor: Mohamed K. Diab

Date 8-31-2000

Residence: 25075 White Spring, Mission Viejo, CA 92692

Citizenship: US

Post Office Address:

Send Correspondence To: KNOBBE, MARTENS, OLSON & BEAR, LLP Customer No. 20,995

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Le ORDATION PATE	INTS ONLY
TO THE ASSISTANT COMMISSIONER FOR PATENTS: Please	record the attached original documents or copy thereof.
 Name of conveying party(ies): (If multiple assignors, list numerically) 	2. Name and address of receiving party(ies):
1. Massi B. Kiam	 Name: Masimo Corporation Internal Address:
2. Mohamed K. Diab	Street Address: 2852 Kelvin Avenue
Additional name(s) of conveying party(ics) attached?	City: Irvine State: CA ZIP: 92614
() Yes (X) No	Additional name(s) of receiving party(ies) attached? () Yes (X) No
3. Nature of conveyance:	4. Application number(s) or Patent number(s):
(X) Assignment	() Application(s) filed herewith Execution Date(s):
() Merger () Security Agreement	(X) Patent Application No.: 09/595,081
() Change of Name	Filing Date: June 16, 2000
() Other:	() Patent No.:
Execution Date: (If multiple assignors, list execution	Issue Date:
dates in numerical order corresponding to numbers indicated in 1 above) August 31, 2000	Additional numbers attached? () Yes (X) No
5. Name and address of party to whom correspondence	7. Total fee (37 CFR 3.41): \$40
concerning document should be mailed:	(X) Enclosed
Name: Stephen C. Jensen	(X) Authorized to be charged to deposit account if any
KNOBBE, MARTENS, OLSON & BEAR, LLP Customer No. 20,995	additional fees are required, or to credit any overpayment
Internal Address: Sixteenth Floor	n Dan eit energet
Street Address: 620 Newport Center Drive City: Newport Beach State: CA ZIP: 92660	8. Deposit account number: 11-1410
Attorney's Docket No.: MASIMO.172A	Please charge this account for any additional fees which may be required, or credit any overpayment to this account.
6. Total number of applications and patents involved: one	
9. Statement and signature.	
	ation is true and correct, and any attached copy is a true copy of the
original document.	
LI'I	1 elaste
Stephen C. Jensen	un 9/26/2000
Name of Person Signing Signature	1/26/2000 Date
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Application No.: 09/595,081 Filing Date: June 16, 2000

ASSIGNMENT

WHEREAS, We, Massi E. Kiani, a United States citizen, residing at 35 Brindisi, Laguna Niguel, California 92677, and Mohamed K. Diab, a United States citizen, residing at 25075 White Spring, Mission Viejo, California 92692, have invented certain new and useful improvements in a PULSE OXIMETER PROBE OFF DETECTION SYSTEM for which we have filed an application for Letters Patent in the United States, 09/595,081, June 16, 2000;

AND WHEREAS, MASIMO CORPORATION (hereinafter "ASSIGNEE"), a Delaware Corporation, with its principal place of business at 2852 Kelvin Avenue, Irvine, California 92614, desires to acquire the entire right, title, and interest in and to the said improvements and the said Application:

NOW, THEREFORE, in consideration of the sum of One Dollar (\$1.00) to us in hand paid, and other good and valuable consideration, the receipt of which is hereby acknowledged, we, the said inventors, do hereby acknowledge that we have sold, assigned, transferred and set over, and by these presents do hereby sell, assign, transfer and set over, unto the said ASSIGNEE, its successors, legal representatives and assigns, the entire right, title, and interest throughout the world in, to and under the said improvements, and the said application and all divisions, renewals and continuations thereof, and all Letters Patent of the United States which may be granted thereon and all reissues and extensions thereof, and all rights of priority under International Conventions and applications for Letters Patent which may hereafter be filed for said improvements in any country or countries foreign to the United States, and all Letters Patent which may be granted for said improvements in any country or countries foreign to the United States and all extensions, renewals and reissues thereof; and we hereby authorize and request the Commissioner of Patents of the United States, and any Official of any country or countries foreign to the United States, whose duty it is to issue patents on applications as aforesaid, to issue all Letters Patent for said improvements to the said ASSIGNEE, its successors, legal representatives and assigns, in accordance with the terms of this instrument.

AND WE HEREBY covenant and agree that we will communicate to the said ASSIGNEE, its successors, legal representatives and assigns, any facts known to us respecting said improvements, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing and reissue applications, make all rightful oaths and generally do everything possible to aid the said ASSIGNEE, its successors, legal representatives and assigns, to obtain and enforce proper patent protection for said improvements in all countries.

Mysit -

STATE OF CALL FORMA COUNTY OF OVANJE

On August 31, 200-, before me, Gunnum B. Bannon, personally appeared personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name(s) is/are subscribed to the within instrument, and acknowledged to me that executed the same in authorized capacity(ies), and that by signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

SS.



Denue B. Saita Notary Signature

10374303.022403 PATENT Patent No.: Client Code: Issue Date: Page 2 IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 3/11 day of Hugus , 20<u>10</u>.0 med STATE OF CALIFORNA ss. COUNTY OF Orange On <u>Augul 31 7 200</u>, before me, <u>Genecutus Blan 200</u>, personally appeared personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name(s) is/are subscribed to the within instrument, and acknowledged to me that executed the same in authorized capacity(ies), and that by signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument. WITNESS my hand and official seal. enun Bactor [SEAL] GENEVIEVE B. BARTON Commission # 1110977 Notary Public — California Orange County My Comm. Expine Sep 11, 2000 Notary Signature H'\DOC\$\\$CJ\\$CJ-3261.DOC:YC\$ 082200

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MASIMO.172A

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Masimo Corporation)
App. No.	:	09/595,081))
Filed	:	June 16, 2000)
For	:	PULSE OXIMETER PROBE OFF DETECTION SYSTEM)
Examiner	:	Unknown))

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ESTABLISHMENT OF RIGHT OF ASSIGNEE TO TAKE ACTION AND REVOCATION AND POWER OF ATTORNEY

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

The undersigned is empowered to act on behalf of the assignee below (the "Assignee"). A true copy of the original Assignment of the above-captioned application from the inventor(s) to the Assignee is attached hereto. This Assignment represents the entire chain of title of this invention from the Inventor(s) to the Assignee.

I declare that all statements made herein are true, and that all statements made upon information and belief are believed to be true, and further, that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that willful, false statements may jeopardize the validity of the application, or any patent issuing thereon.

The undersigned hereby revokes any previous powers of attorney in the subject application, and hereby appoints the registrants of Knobbe, Martens, Olson & Bear, LLP, 620 Newport Center Drive, Sixteenth Floor, Newport Beach, California 92660, Telephone (949) 760-0404, Customer No. 20,995, as its attorneys with full power of substitution and App. No. : 09/ 0001 Filed : June 0, 2000

revocation to prosecute this application and to transact all business in the U.S. Patent and Trademark Office connected herewith. This appointment is to be to the exclusion of the inventor(s) and his attorney(s) in accordance with the provisions of 37 C.F.R. § 3.71.

Please use Customer No. 20,995 for all communications.

Masimo Corporation

9-5-00 Dated:

By: Joe/E. Kiani

Title: President and C.E.O.

Address: 2852 Kelvin Avenue Irvine, CA 92614

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MASIMO.172DV1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Massi E. Kiani, et al.
Ann Ma		

Group Art Unit Unknown



App. No. : Unknown

Filed : Herewith

For : PULSE OXIMETER PROBE-OFF DETECTION SYSTEM

Examiner : Unknown

INFORMATION DISCLOSURE STATEMENT

United States Patent and Trademark Office P.O. Box 2327 Arlington, VA 22202

Dear Sir:

Enclosed is form PTO-1449 listing sixteen (16) references, one of which is enclosed. Fifteen (15) of the references are of record in parent U.S. Patent Application No. 09/595,081, filed June 16, 2000, entitled "Pulse Oximeter Probe-Off Detection System." Because the 15 references are of record in the parent application, copies are not being submitted herewith. If the Examiner has difficulty accessing the application or the Examiner otherwise needs additional copies of the cited references, the Applicants will provide the same upon receipt of specific request in subsequent Office correspondences. The Applicants respectfully request consideration of cited references and that the appropriate indication of consideration be made on the enclosed form PTO-1449.

Appl. No.:UnknownFiled:Herewith

This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required in accordance with 37 C.F.R. § 1.97(b)(3).

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 24, 2003

By:

John M: Grever Registration No. 42,610 Attorney of Record Customer No. 20,995 (949) 760-0404

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ME	3	5,782,757	07/1998	Diab, et al.		-/		
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MC-	6	5,469,845	11/1995	DeLonzor, et al.		\leftarrow		
W/C	7	5,370,114	12/1994	Wong, et al.	<u> </u>			
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The MAILING DATE of this communication appears or NI claims being allowable, PROSECUTION ON THE MERITS IS (OR R erewith (or previously mailed), a Notice of Allowance (PTOL-85) or oth NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS of the Office or upon petition by the applicant. See 37 CFR 1.313 and M	EMAINS) CLOSED in this er appropriate communicate This application is suble	application. If not included tion will be mailed in due course. TH
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. X The drawings filed on <u>24 February 2003</u> are accepted by the Exa	miner.	
Acknowledgment is made of a claim for foreign priority under 38 a) □ All b) □ Some* c) □ None of the: 1. □ Certified copies of the priority documents have been 2. □ Certified copies of the priority documents have been 3. □ Copies of the certified copies of the priority document	received. received in Application No	۰ ــــــــــــــــــــــــــــــــــــ
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A SUBSTITUTE OATH OR DECLARATION must be submitted. I INFORMAL PATENT APPLICATION (PTO-152) which gives reast	Note the attached EXAMIN son(s) why the oath or dec	ER'S AMENDMENT or NOTICE OF laration is deficient.
 CORRECTED DRAWINGS (as "replacement sheets") must be s (a) Including changes required by the Notice of Draftsperson's F 1) hereto or 2) to Paper No./Mail Date (b) Including changes required by the attached Examiner's Ame Paper No./Mail Date Identifying indicts such as the application number (see 37 CFR 1.84(c)) each sheet. Replacement sheet(s) should be labeled as such in the heat DEPOSIT OF and/or INFORMATION about the deposit of attached Examiner's comment regarding REQUIREMENT FOR 	Patent Drawing Review (P endment / Comment or in the should be written on the dr eder according to 37 CFR 1, BIOLOGICAL MATERI/	ne Office action of awings in the front (not the back) of I21(d). AL must be submitted. Note the
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Application/Control Number: 10/374,303 Art Unit: 3736

REASONS FOR ALLOWANCE

Page 2

1. The following is an examiner's statement of reasons for allowance.

In regard to claim 1, U.S. Patent 5,761,540 to White teaches an illumination device, a light sensitive detector (a camera), and a microlouver filter. White does not teach a pulse oximeter probe that includes a flexible body but teaches a device for illuminating an object to be observed by a machine vision camera. In regard to claim 9, U.S. Patent 6,035,223 to Baker, Jr. teaches an oximeter that determines whether a probe is off the patient by determining if the detected intensity is greatly increased. The prior art does not teach or suggest a pulse oximeter that determines whether a probe is off the patient by determining if the detected intensity is substantially attenuated. In regard to claim 15, U.S. Patent 5,923,021 to Dvorkis et al. teaches a sensor that includes a light source and a plurality of louvers. (Abstract and Fig. 3 of Dvorkis). Dvorkis teaches the use of a detector (Abstract of Dvorkis) but does not teach the particulars of the detector. One with skill in the art would know that a suitable detector would detect a range of wavelengths. (column 2, lines 20-23 of U.S. Patent 5,635,700 to Fazekas). However, even when the teachings of Fazekas are combined with the teachings of Dvorkis, the combination does not teach all the elements of the invention of claim 15. The Dvorkis/Fazekas combination teaches a detector that detects a wavelength range, which inherently includes first and second wavelengths; the use of a light source (Abstract of Dvorkis); and a plurality of louvers positions over the detector (Fig. 3 of Dvorkis). The Dvorkis/Fazekas combination does not teach that the plurality of louvers is positioned to accept light from the at least one light emission device

Application/Control Number: 10/374,303 Art Unit: 3736

originating from a general direction of the at least one light emission device wherein the louvers accept the light when the sensor is properly applied to tissue of a patient. In regard to claim 15, U.S. Patent 4,945,239 to Wist et al. teaches a sensor that includes a light source, a light detector, and a pinhole box in front of the detector but does not teach or suggest a sensor that includes a plurality of louvers. In regard to claim 16, Wist teaches blocking light originating from an angle oblique to a proximate relationship between the detector and a light source but does not teach or suggest the step of indicating a probe off condition.

Page 3

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on 703-308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Application/Control Number: 10/374,303 Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Matthew Kremer Assistant Examiner Art Unit 3736

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A	US-5,635,700 A	06-1997	Fazeka	as, Peter			-	235/462.06
B	US-5,923,021 A	07-1999	Dvorkis					235/455
C		03-2000		Jr., Clark R.				600/323
	US-6,035,223 A	05-2000		Timothy P.				396/4
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NOTICE OF ALLOWANCE AND FEE(S) DUE

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10/374,303	02/24/2003	Massi B	l. Kiani	MASIMO.172DVI	5982
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			PATENT
804 () EURA			Case Docket No. MASIMO.172DV Date: June 22, 2004
DEM	N TH	E UNITED STATES PATENT AN	ND TRADEMARK OFFICE
Applicants	:	Massi E. Kiani et al.	CERTIFICATE OF MAILING
Appl. No.	:	10/374,303	I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service "Express Mail Post Office to Addresses"
Filed	:	February 24, 2003	service under 37 CFR 1.10 on the date indicated below and are addressed to: Mail Stop Issue Fee, Commissioner for Patents, United States Patent and Trademark Office.
For	:	PULSE OXIMETER PROBE- OFF DETECTION SYSTEM	P.O. Box 1460, Alexandria, VA 22313-1460, on
Group Art Unit	:	3736	June 22, 2004
Class/Sub-Clas	s:	600/322000	John M. Gaver, Reg. No. 42,610
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TRANSMITTAL LETTER

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Dear Sir:

Enclosed for filing is the Issue Fee for the above-identified application:

- (X) a Form PTOL-85;
- (X) a check in the amount of \$1,630 to cover the issue fee; and
- (X) a return prepaid postcard.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.

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Join M. Grover Registration No. 42,610 Attorney of Record Customer No. 20,995 (949) 760-0404

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Applicants : For : For : Attorney : "Express Mail" Mailing Label No. : : Date of Deposit : I hereby certify that the accompanying Transmittal Letter; Form PTOL-85; C Postcard are being deposited with the United States Addressee" service under 37 CFR 1.10 on t to the Commissioner for Patents, P.O. Box 1 Mail HabocSumgume-6215.00C	MASIMO.172DV1 Massi E. Kiani et al. PULSE OXIMETER PRC DETECTION SYSTEM John M. Grover EV 307990841 US June 22, 2004 Check for Filing Fee; Re Postal Service "Express he date indicated above	DBE-OFF turn Prepaid Mail Post Office and are address
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Applicants : I For : I Attorney : I Attorney : I Express Mail" Mailing Label No. : I Date of Deposit : I I hereby certify that the accompanying Transmittal Letter; Form PTOL-85; C Postcard are being deposited with the United States Addressee" service under 37 CFR 1.10 on t to the Commissioner for Patents, P.O. Box 1 Mail	Massi E. Kiani et al. PULSE OXIMETER PRO DETECTION SYSTEM John M. Grover EV 307990841 US June 22, 2004 Check for Filing Fee; Re Postal Service "Express he date indicated above 450, Alexandria, VA 223	turn Prepaid Mail Post Office and are address
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<u>21</u> INSTRUCTIONS/This form should be used for trans propriate, all further correspondence including the P Generativities corrected below or succeed otherwise methodshow free notifications.	or Fax mitting the ISSUE FEE and PUBL stant, advance orders and potificatio	(703) 740-4800 ICATION FEE (If required). Blocks of maintenance fees will be mailed	i through 4 should be completed where to the current correspondence address as
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APPLICATION NO. FILINO DATE 10/374,303 02/24/2003	FIRST NAMED DIV		O. 172DV1 5982
TITLE OF INVENTION: PULSE OXIMETER PROBE	OFF DETECTION SYSTEM		
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PLEASE NOTE: Unless so assignee is identified be been previously submitted to the USPTO or is being (A) NAME OF ASSIGNEE	ow, no mangane data wis appear so submitted under separate cover. Com (B) RESIDENCE: (*	the patent, inclusion of any or data pletion of this form is NOT a substitute CITY and STATE OR COUNTRY)	for filing an assignment.
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File History Content Report

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Document Date - 2004-08-03

Document Title - USPTO Grant

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File History Content Report

The following content is missing from the original file history record obtained from the United States Patent and Trademark Office. No additional information is available.

Document Date - 2007-06-18

Document Title - Certificate of Correction - Post Issue Communication

This page is not part of the official USPTO record. It has been determined that content identified on this document is missing from the original file history record.

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

 PATENT NO.
 : 6,771,994 B2

 APPLICATION NO.
 : 10/374303

 DATED
 : August 3, 2004

 INVENTOR(S)
 : Massi E. Kiani

Page 1 of 1

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

At column 2, line 36, delete "embodimet" and insert -- embodiment --, therefore.

At column 6, line 3, delete "haveing" and insert -- having --, therefore.

Signed and Sealed this

Seventeenth Day of July, 2007

JON W. DUDAS Director of the United States Patent and Trademark Office

File History Content Report

The following content is missing from the original file history record obtained from the United States Patent and Trademark Office. No additional information is available.

Document Date - 2011-08-02

Document Title - USPTO Communication Re: Change of Address

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UNITED STATES PATENT AND TRADEMARK	OFFICE
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 PATENT NO.
 : 6,771,994

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 INVENTOR(S)
 : Massi E. Kiani

Page 1 of 1

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At column 2, line 36, delete "embodimet" and insert - - embodiment - -, therefore. At column 6, line 3, delete "haveing" and insert - - having - -, therefore.

MAILING ADDRESS OF SENDER:

John M. Grover KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 Main Street, 14th Floor Irvine, California 92614

PTO/SB/44 Equivalent 3739967:jmo 050807 DOCKET NO. MASIMO.172DV1

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Search results for: pns=(US6771994);

Collections searched: DWPI, US Granted, Australian Innovation, Canadian Applications, US Applications, Australian Granted, French Granted, French Applications, European Granted, Australian Applications, German Utility Models, European Applications, British Applications, British Granted, German Granted, WIPO Applications, Canadian Granted, German Applications, Russian Utility Models, Russian Applications, Chinese Utility Models, Indonesian Simple, Korean Utility Models, Singaporean Applications, Chinese Granted, Indonesian Applications, Korean Granted/Examined, Thai Granted/Examined, Chinese Applications, Japanese Utility Models, Korean Applications, Vietnamese Granted, Indian Granted, Japanese Granted, Malaysian Granted, Vietnamese Applications, Indian Applications, Japanese Applications, Singaporean Granted, Argentinean Utility Models, Argentinean Applications, Mexican Granted, Brazilian Utility Models, Mexican Applications, Brazilian Granted, Brazilian Applications, Other Authorities

Table of Contents

1. US6771994B2 Pulse oximeter probe-off detection system

Family 1/1 1 record(s) per family

Record 1/1 US6771994B2 Pulse oximeter probe-off detection system

Publication Number: US6771994B2 20040803

Title: Pulse oximeter probe-off detection system Title - DWPI: Pulse oximeter probe off detection system determines improper fixation of probe if open condition exists across two electrical contacts contacting skin of patient Priority Number: US1999140000P | US2000595081A | CA2382319A Priority Date: 1999-06-18 | 2000-06-16 | 2001-11-09 Application Number: US2003374303A Application Date: 2003-02-24 Publication Date: 2004-08-03 IPC Class Table:

IPC	Section	Class	Subclass	Class Group	Subgroup
A61B0005145	А	A61	A61B	A61B0005	A61B0005145
A61B000500	A	A61	A61B	A61B0005	A61B000500
A61B00051455	A	A61	A61B	A61B0005	A61B00051455

IPC Class Table - DWPI:

IPC - DWPI	Section - DWPI	Class - DWPI	Subclass - DWPI	Class Group - DWPI	Subgroup - DWPI
A61B000500 (IPC 1-7)	А	A61	A61B	A61B0005	A61B000500 (IPC 1-7)
A61B0005145 (IPC 1-7)	A	A61	A61B	A61B0005	A61B0005145 (IPC 1-7)
A61B00050424 (IPC 1-7)	A	A61	A61B	A61B0005	A61B00050424 (IPC 1-7)
A61B000500	А	A61	A61B	A61B0005	A61B000500
A61B0005145	A	A61	A61B	A61B0005	A61B0005145
A61B00051455	А	A61	A61B	A61B0005	A61B00051455

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Assignee/Applicant: Masimo Corporation, Irvine, CA

JP F Terms:

JP FI Codes:

Assignee - Original: Masimo Corporation

Any CPC Table:

Туре	Invention	Additional	Version	Office
Current	A61B 5/6843	-	20130101	EP
Current	A61B 5/14552		20130101	EP

ECLA: A61B000568B5 | A61B00051455N2

Abstract:

The present invention provides a number of improvements that can be incorporated into a pulse oximeter probe to detect when a probe has become dislodged from a patient and/or to prevent a probe-off condition. A probe-off condition occurs when the optical probe becomes partially or completely dislodged from the patient, but continues to detect an AC signal within the operating region of the pulse oximeter. In one aspect, the present invention provides electrical contacts that contact the skin of a patient when the probe is properly attached. In another aspect, the present invention provides a number of louvers placed in front of the sensor's photodetector to filter out oblique light rays that do not originate from a point in front of the detector. Accordingly, if the emitter and photodetector are not properly aligned, the photodetector will not produce a signal within the valid operating range of the pulse oximeter. In accordance with a method of the present invention the pulse oximeter can sound an alarm or display a warning if it determines that the probe is not properly attached to the patient.

Language of Publication: EN

INPADOC Legal Status Table:

Gazette Date	Code	INPADOC Legal Status Impact				
2019-08-15	AS	-				
Description: ASSIGNMENT MASIMO CORPORATION, CALIFORNIA ASSIGNMENT OF ASSIGNORS INTEREST; ASSIGNORS:KIANI, MASSI E.; DIAB, MOHAMED K.; REEL/FRAME:050068/0744 2000-08-31						
2018-11-07	AS	-				
Description: ASSIGNMENT MASIMO AMERICAS, INC., CALIFORNIA RELEASE BY SECURED PARTY; ASSIGNOR: JPMORGAN CHASE BANK, NATIONAL ASSOCIATION; REEL/FRAME:047443/0109 2018-04-05						

2018-11-07	AS	-
	CORPORATION, CALIFORNIA RELEASE NATIONAL ASSOCIATION; REEL/FRAME	
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2016-02-05	SULP	+
Description: SURCHARGE FOR LATE	PAYMENT FEE PAYMENT YEAR 11	
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2016-02-05	FPAY	+
Description: FEE PAYMENT FEE PAY	MENT YEAR 12	
2014-05-27	AS	-
ASSIGNMENT TO CORRECT THE NAT	AN CHASE BANK, NATIONAL ASSOCIATI JRE OF CONVEYANCE PREVIOUSLY RE AS THE SECURITY AGREEMENT; ASSIG E:033032/0426 2014-04-23	CORDED AT REEL: 032784 FRAME:
2014-05-27	AS	-
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2014-04-29	AS	-
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Description: CERTIFICATE OF CORRE	ECTION	

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Description: INFORMATION ON STATU	JS: PATENT GRANT PATENTED CASE	

Post-Issuance (US): CORR-CERT Certificate of Correction 2007-07-17 2007 2007-08-07 2007 a

Certificate of Correction was issued for this patent

Reassignment (US) Table:

Assignee	Assignor	Date Signed	Reel/Frame	Date
MASIMO CORPORATION,IRVINE,CA, US	JPMORGAN CHASE BANK, NATIONAL ASSOCIATION	2018-04-05	047443/0109	2018-11-07
MASIMO AMERICAS INC.,IRVINE,CA,US	-	-	-	-
Conveyance: RELEASE BY S (SEE DOCUMENT FOR DETA	SECURED PARTY (SEE DOCU ILS).	MENT FOR DETAILS). RELEASE BY SE	CURED PARTY
	NGS LLP 4747 EXECUTIVE DR TH FLOOR SAN DIEGO, CA 92		DIEGO, CA 92121 I	PAUL HASTINGS
JPMORGAN CHASE BANK	MASIMO AMERICAS, INC.	2014-04-23	033032/0426	2014-05-27
NATIONAL ASSOCIATION,CHICAGO,IL, US	MASIMO CORPORATION	2014-04-23	-	-
	ASSIGNMENT TO CORRECT 1 64. ASSIGNOR(S) HEREBY CC			USLY RECORDED
Corresponent: PATRICK TIE	RNEY PO BOX 2828 CHICAGC), IL 60690-2828		
JPMORGAN CHASE BANK	MASIMO CORPORATION	2014-04-23	032784/0864	2014-04-29
NATIONAL ASSOCIATION,CHICAGO,IL, US	MASIMO AMERICAS, INC.	2014-04-23	-	-
Conveyance: ASSIGNMENT	OF ASSIGNORS INTEREST (S	EE DOCUMENT FOR	DETAILS).	
Corresponent: PATRICK TIE	RNEY PO BOX 2828 CHICAGC), IL 60690-2828		
MASIMO	KIANI, MASSI E.	2000-08-31	050068/0744	2019-08-15
CORPORATION,IRVINE,CA, US	DIAB, MOHAMED K.	2000-08-31	-	-
Conveyance: ASSIGNMENT	OF ASSIGNORS INTEREST (S	EE DOCUMENT FOR	DETAILS).	

Maintenance Status (US): CC

Litigation (US): 2020-01-09 2020 Masimo Corporation Cercacor Laboratories, Inc. Apple Inc.

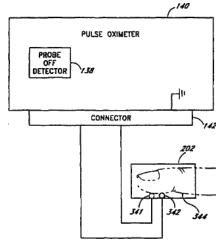
C.D. California 8:20cv00048

Opposition (EP):

License (EP):

EPO Procedural Status:

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PULSE OXIMETER PROBE-OFF DETECTION SYSTEM

PATENT # 6771994

APPLICATION # 10374303

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WINDOW		STATUS		FEES		No maintenance fees are due.
11.5 Year		Closed		Paid		
Window	First Day to Pay	Surcharge Starts	Last Day to Pay	Status	Fees	
3.5 Year	08/03/2007	02/05/2008	08/04/2008	Closed	Paid	
7.5 Year	08/03/2011	02/04/2012	08/03/2012	Closed	Paid	
11.5 Year	08/03/2015	02/04/2016	08/03/2016	Closed	Paid	

Patent Holder Information

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