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(54) **CYANOTIC INFANT SENSOR**

(76) Inventor: **Ammar Al-Ali**, Tustin, CA (US)

Correspondence Address:
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614 (US)

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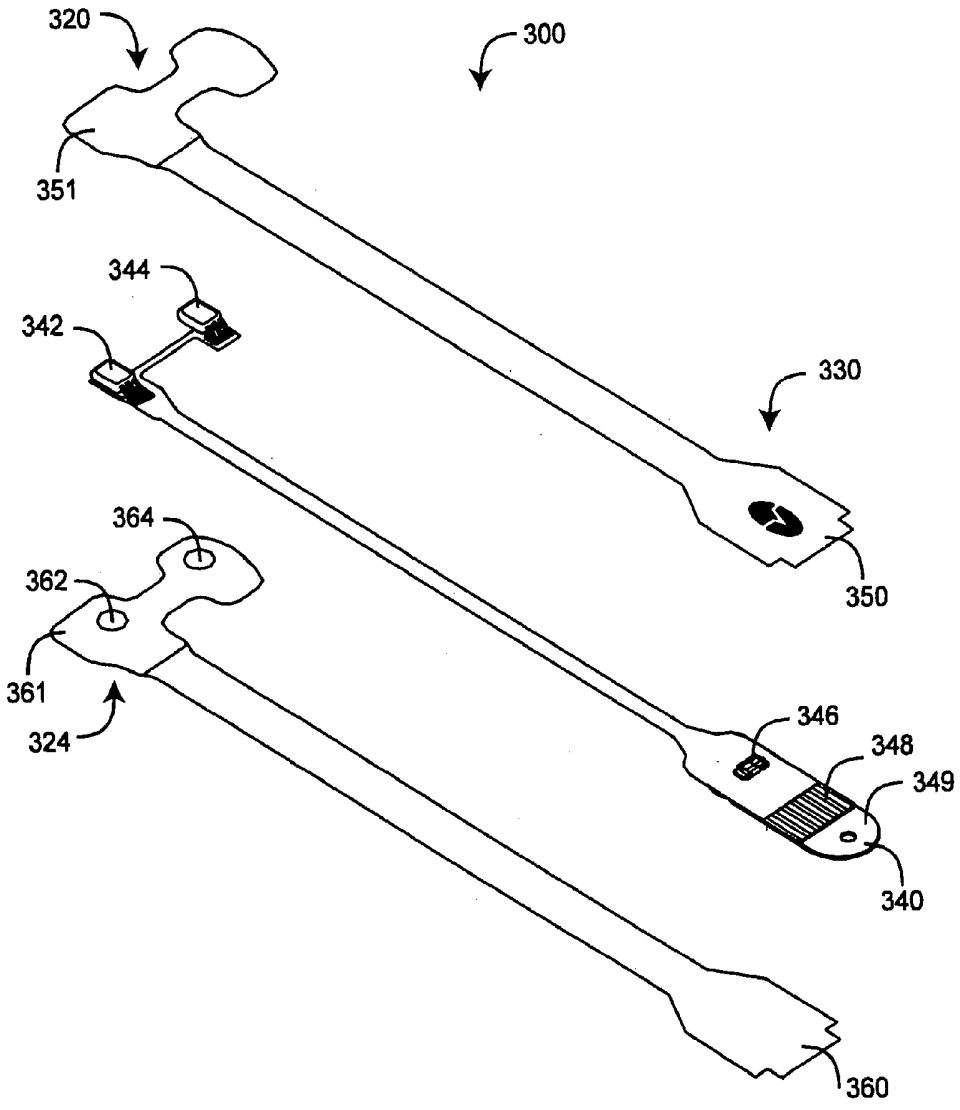
A61B 5/00 (2006.01)

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

(57) **ABSTRACT**

A pulse oximetry sensor comprises emitters configured to transmit light having a plurality of wavelengths into a fleshy medium. A detector is responsive to the emitted light after absorption by constituents of pulsatile blood flowing within the medium so as to generate intensity signals. A sensor head has a light absorbing surface adapted to be disposed proximate the medium. The emitters and the detector are disposed proximate the sensor head. A detector window is defined by the sensor head and configured so as to limit the field-of-view of the detector.



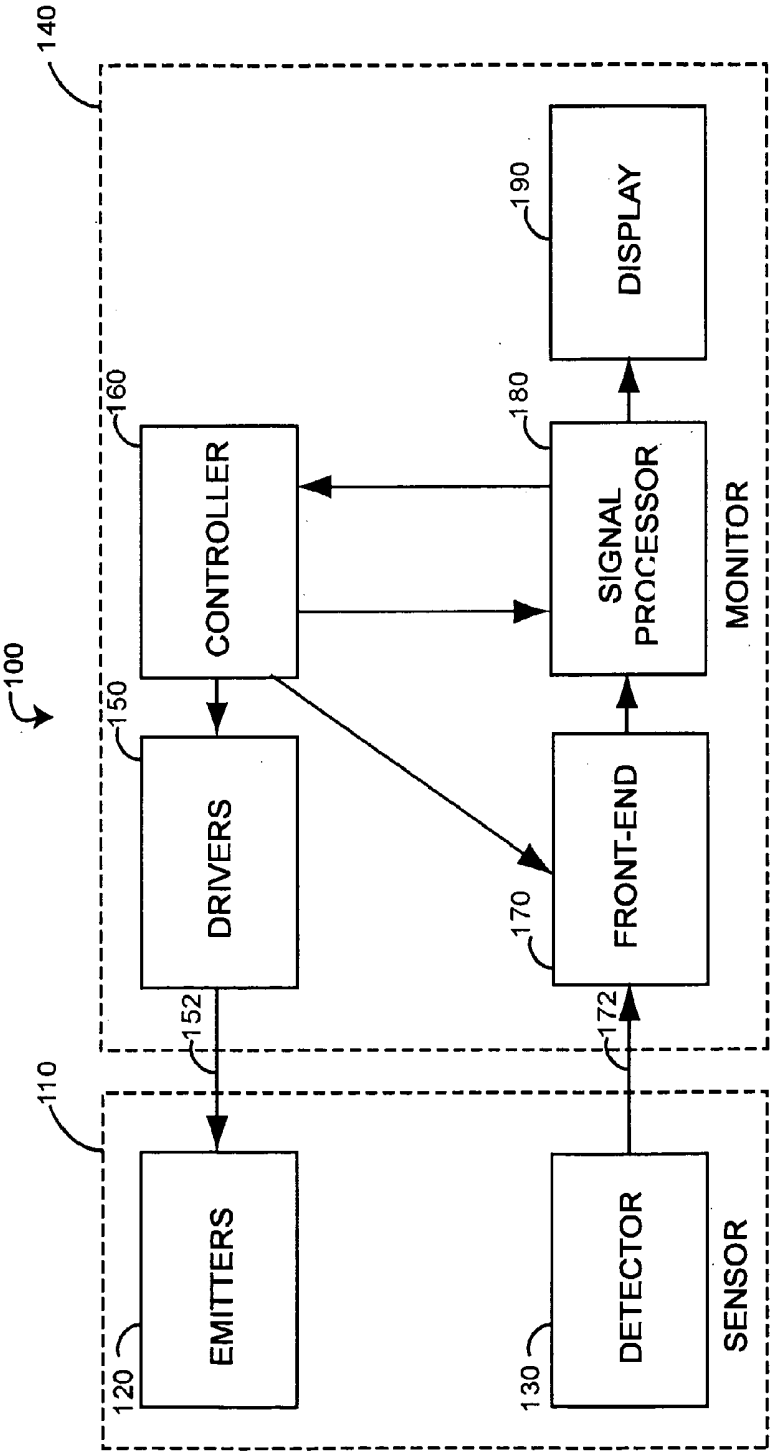


FIG. 1 (Prior Art)

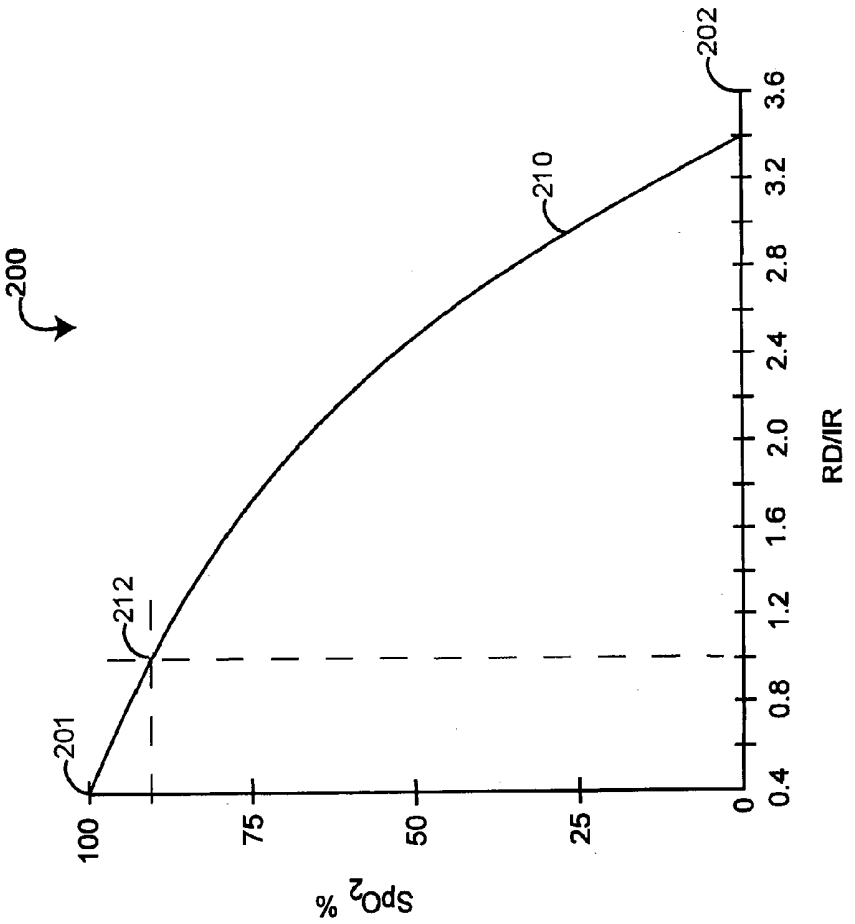


FIG. 2 (Prior Art)

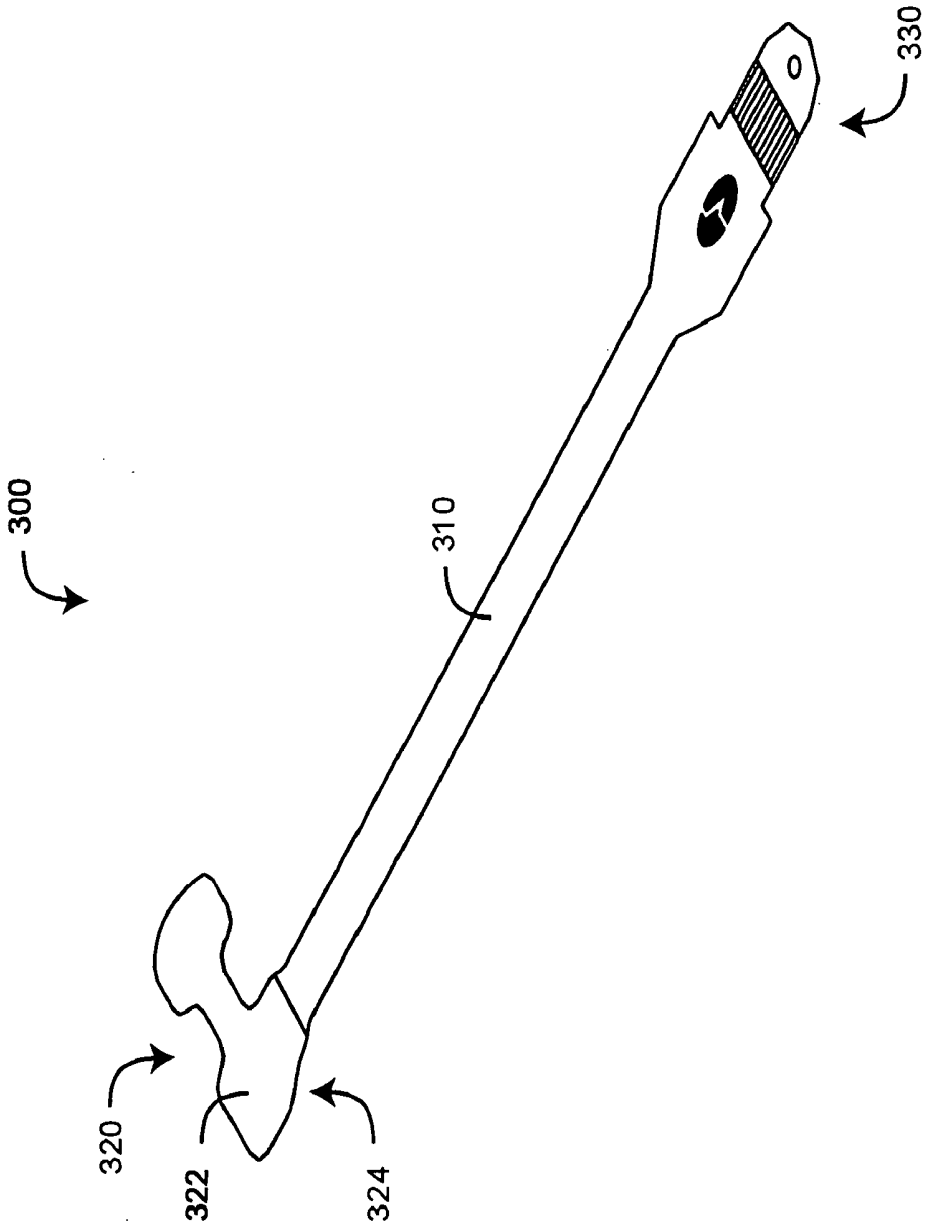


FIG. 3A

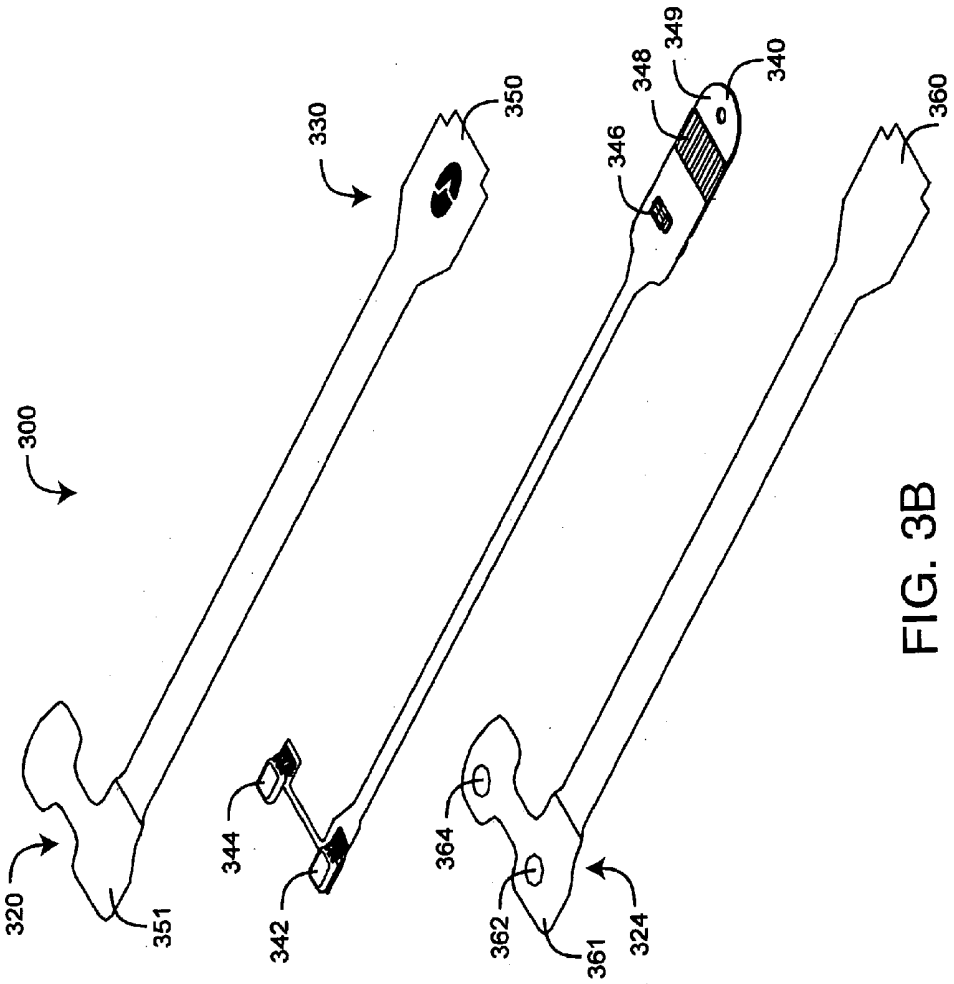


FIG. 3B

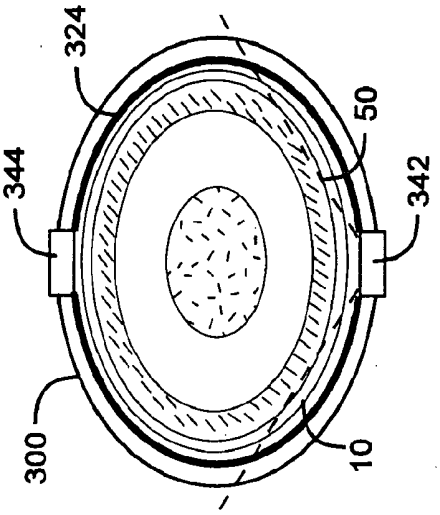


FIG. 6

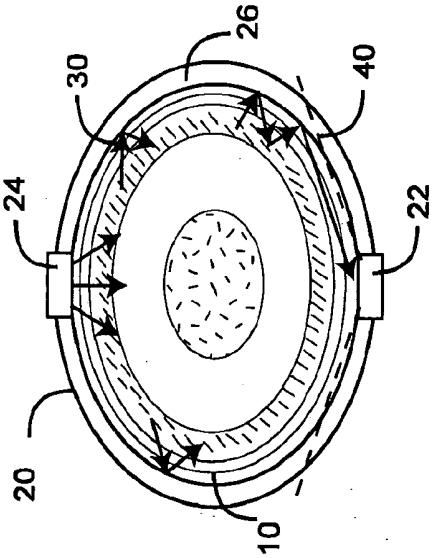


FIG. 5 (Prior Art)

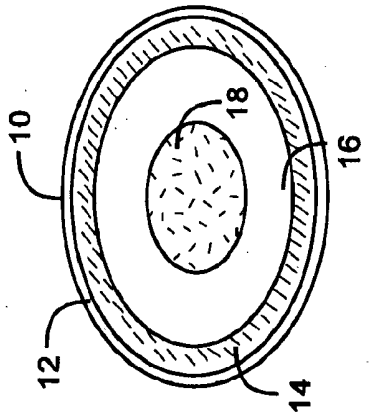


FIG. 4

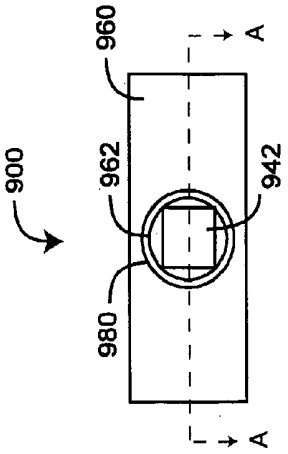


FIG. 9A

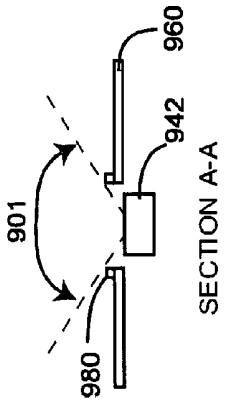


FIG. 9B

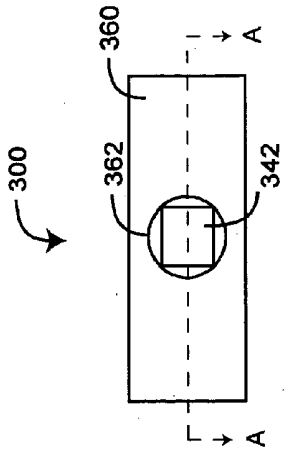


FIG. 8A

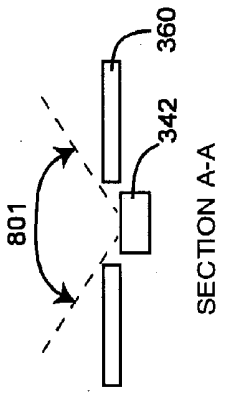


FIG. 8B

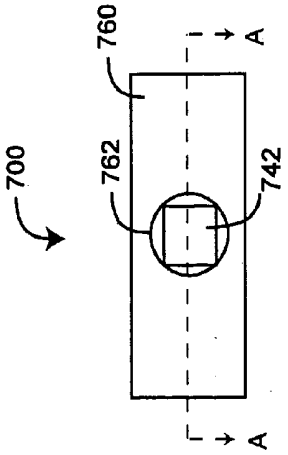


FIG. 7A (Prior Art)

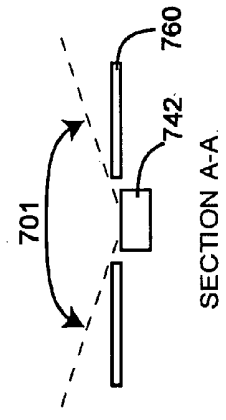


FIG. 7B (Prior Art)

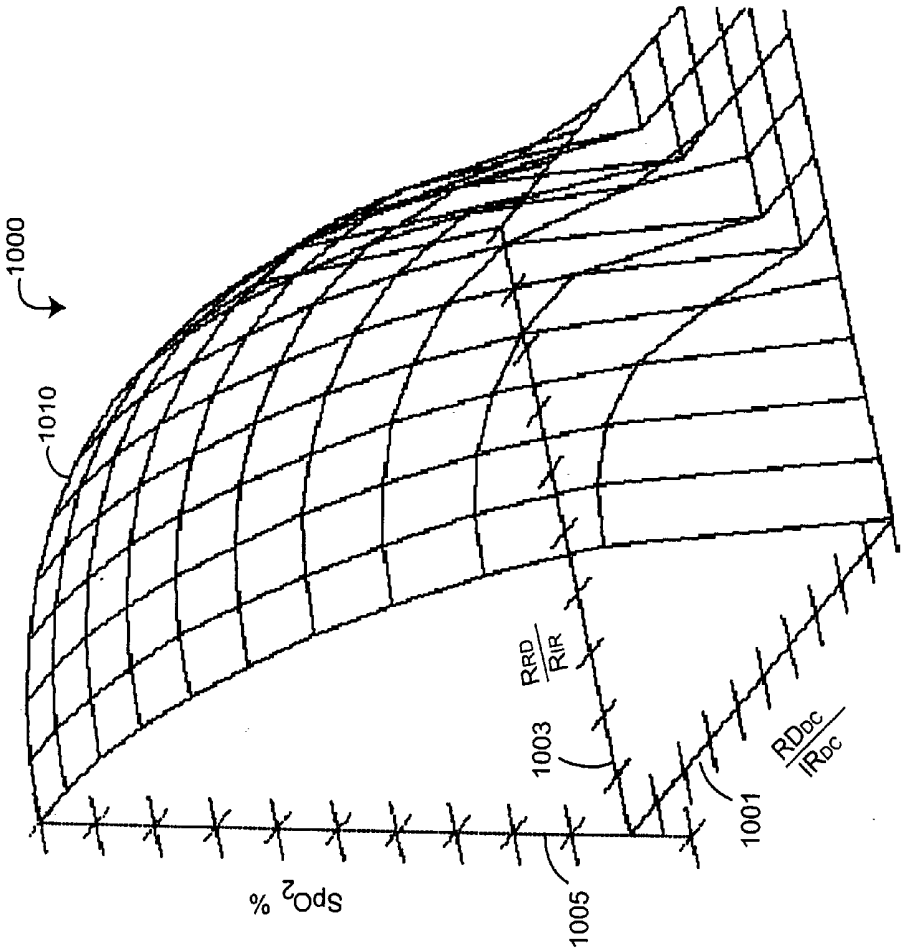


FIG. 10

CYANOTIC INFANT SENSOR

REFERENCE TO RELATED APPLICATION

[0001] The present application claims priority benefit under 35 U.S.C. §119(e) from U.S. Provisional Application No. 60/586,821, filed Jul. 9, 2004, entitled "Cyanotic Infant Sensor," which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] Cyanosis is a congenital condition in which blood pumped to the body contains less than normal amounts of oxygen, resulting in a blue discoloration of the skin. The most common cyanotic condition is tetralogy of Fallot, which is characterized by an abnormal opening, or ventricular septal defect, that allows blood to pass from the right ventricle to the left ventricle without going through the lungs; a narrowing, or stenosis, proximate the pulmonary valve, which partially blocks the flow of blood from the right side of the heart to the lungs; a right ventricle that is abnormally muscular; and an aorta that lies directly over the ventricular septal defect. Another cyanotic condition is tricuspid atresia, characterized by a lack of a tricuspid valve and resulting in a lack of blood flow from the right atrium to the right ventricle. Yet another cyanotic condition is transposition of the great arteries, i.e. the aorta originates from the right ventricle, and the pulmonary artery originates from the left ventricle. Hence, most of the blood returning to the heart from the body is pumped back out without first going to the lungs, and most of the blood returning from the lungs goes back to the lungs.

[0003] Pulse oximetry is a useful tool for diagnosing and evaluating cyanotic conditions. A pulse oximeter performs a spectral analysis of the pulsatile component of arterial blood so as to measure oxygen saturation, the relative concentration of oxygenated hemoglobin, along with pulse rate. **FIG. 1** illustrates a pulse oximetry system **100** having a sensor **110** and a monitor **140**. The sensor **110** has emitters **120** and a detector **130** and is attached to a patient at a selected fleshy tissue site, such as a thumb or toe. The emitters **120** project light through the blood vessels and capillaries of the tissue site. The detector **130** is positioned so as to detect the emitted light as it emerges from the tissue site. A pulse oximetry sensor is described in U.S. Pat. No. 6,088,607 entitled "Low Noise Optical Probe," which is assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein.

[0004] Also shown in **FIG. 1**, the monitor **140** has drivers **150**, a controller **160**, a front-end **170**, a signal processor **180**, a display **190**. The drivers **150** alternately activate the emitters **120** as determined by the controller **160**. The front-end **170** conditions and digitizes the resulting current generated by the detector **130**, which is proportional to the intensity of the detected light. The signal processor **180** inputs the conditioned detector signal and determines oxygen saturation, as described below, along with pulse rate. The display **190** provides a numerical readout of a patient's oxygen saturation and pulse rate. A pulse oximetry monitor is described in U.S. Pat. No. 5,482,036 entitled "Signal Processing Apparatus and Method," which is assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein.

SUMMARY OF THE INVENTION

[0005] The Beer-Lambert law provides a simple model that describes a tissue site response to pulse oximetry measurements. The Beer-Lambert law states that the concentration c_i of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the mean pathlength, mpl_λ, the intensity of the incident light, $I_{0,\lambda}$, and the extinction coefficient, $\epsilon_{i,\lambda}$, at a particular wavelength λ. In generalized form, the Beer-Lambert law is expressed as:

$$_\lambda = I_{0,\lambda} e^{-mpl_\lambda \cdot \mu_{a,\lambda}} \quad (1)$$

$$\mu_{a,\lambda} = \sum_{i=1}^{n} \varepsilon_{i,\lambda} \cdot c_i \quad (2)$$

where $\mu_{a,\lambda}$, is the bulk absorption coefficient and represents the probability of absorption per unit length. For conventional pulse oximetry, it is assumed that there are only two significant absorbers, oxygenated hemoglobin (HbO_2) and reduced hemoglobin (Hb). Thus, two discrete wavelengths are required to solve EQS. 1-2, e.g. red (RD) and infrared (IR).

[0006] **FIG. 2** shows a graph **200** depicting the relationship between RD/IR **202** and oxygen saturation (SpO_2) **201**, where RD/IR denotes the ratio of the DC normalized, AC detector responses to red and infrared wavelengths, as is well-known in the art and sometimes referred to as the "ratio-of-ratios." This relationship can be approximated from Beer-Lambert's Law, described above. However, it is most accurately determined by statistical regression of experimental measurements obtained from human volunteers and calibrated measurements of oxygen saturation. The result can be depicted as a curve **210**, with measured values of RD/IR shown on an x-axis **202** and corresponding saturation values shown on a y-axis **201**. In a pulse oximeter device, this empirical relationship can be stored in a read-only memory (ROM) for use as a look-up table so that SpO_2 can be directly read-out from an input RD/IR measurement. For example, an RD/IR value of 1.0 corresponding to a point **212** on the calibration curve **210** indicates a resulting SpO_2 value of approximately 85%.

[0007] Accurate and consistent pulse oximetry measurements on cyanotic infants have been difficult to obtain. An assumption inherent in the calibration curve **210 (FIG. 2)** is that the mean pathlength ratio for RD and IR is constant across the patient population. That is:

$$mpl_{RD}/mpl_{IR} = C \quad (3)$$

However, EQ. 3 may not be valid when cyanotic infants are included in that population. The reason may lie in what has been observed as abnormal tissue tone or lack of firmness associated with cyanotic defects, perhaps due to reduced tissue fiber. Such differences in tissue structure may alter the mean pathlength ratio as compared with normal infants. A cyanotic infant sensor addresses these problems by limiting variations in the RD over IR mean pathlength ratio and/or by providing a mean pathlength ratio measure so as to compensate for such variations. Alone or combined, these sensor apparatus and algorithms increase the accuracy and consistency of pulse oximetry measurements for cyanotic infants.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] **FIG. 1** is a block diagram of a prior art pulse oximetry system;

[0009] **FIG. 2** is an exemplar graph of a conventional calibration curve;

[0010] FIGS. **3**A-B are a perspective and an exploded perspective views, respectively, of a cyanotic infant sensor embodiment;

[0011] **FIGS. 4-5** depict cross-sectional views of a tissue site and an attached pulse oximeter sensor, respectively;

[0012] **FIG. 6** depicts a cross-sectional view of a tissue site and an attached cyanotic infant sensor;

[0013] FIGS. **7**A-B are plan and cross-sectional sensor head views of a conventional pulse oximeter sensor;

[0014] **FIGS. 8-9** are plan and cross-sectional sensor head views of cyanotic infant sensor embodiments; and

[0015] **FIG. 10** is an exemplar graph of a calibration surface incorporating a mean pathlength ratio measure.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0016] FIGS. **3**A-B illustrate one embodiment of a cyanotic infant sensor. The sensor has a light absorbing surface, as described with respect to **FIGS. 4-6**, below. The sensor also has a detector window configured to limit the detector field-of-view (FOV), as described with respect to **FIGS. 7-9**, below. Advantageously, these features limit mean pathlength ratio variations that are particularly manifest in cyanotic patients.

[0017] The sensor emitters and detector are also matched so as to limit variations in the detector red over IR DC response, i.e. RD_{DC}/IR_{DC}, that are not attributed to variations in the mean pathlength ratio (EQ. 3). Such matching advantageously allows for measurement and calibration of the mean pathlength ratio, as described with respect to **FIG. 10**, below. In one embodiment, cyanotic infant sensors **300** are constructed so that:

$$\lambda_{RD} \approx c_1;\ \lambda_{IR} \approx c_2 \quad (4)$$

$$I_{0,RD}/I_{0,IR} \approx c_3;\ \text{for } i_{DC}(RD),\ i_{DC}(IR) \quad (5)$$

$$RD_{DC}/IR_{DC} \approx c_4 \quad (6)$$

That is, sensors **300** are constructed from red LEDs and IR LEDs that are each matched as to wavelength (EQ. 4). The LEDs are further matched as to red over IR intensity for given DC drive currents (EQ. 5). In addition, the sensors **300** are constructed from detectors that are matched as to red over IR DC response (EQ. 6).

[0018] As shown in **FIG. 3A**, the sensor **300** has a body **310** physically connecting and providing electrical communication between a sensor head **320** and a connector **330**. The sensor head **320** houses the emitters and detector and attaches to a patient tissue site. The connector mates with a patient cable so as to electrically communicate with a monitor. In one embodiment, a sensor head surface **324** is constructed of light absorbing material.

[0019] As shown in **FIG. 3B**, the sensor **300** has a face tape **330**, a flex circuit **340** and a base tape **360**, with the flex circuit **340** disposed between the face tape **330** and the base tape **360**. The flex circuit **340** has a detector **342**, an emitter **344** with at least two light emitting diodes (LEDs), an information element **346**, and contacts **348** disposed on a connector tab **349**. Neonatal sensors having a detector, LEDs, an information element, contacts and connector tab are described in U.S. Pat. No. 6,256,523 entitled "Low-Noise Optical Probes," which is assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein. In one embodiment, the face tape **350** and base tape **360** are constructed of Betham tape having attached polyethylene head tapes **351**, **361**. In a particular embodiment, the base head tape **361** is made of black polyethylene, and the face head tape **351** is made of white polyethylene. In one embodiment, a clear tape layer is disposed on the base head tape **361** tissue side over the detector window **362**. The base head tape **361** has a detector window **362** and an emitter window **364** each allowing light to pass through the base head tape **361**. In one embodiment, the base head tape **361** has a 4 mil thickness and the flex circuit has a 10 mil thickness. The combined **14** mil material thickness functions to limit the detector FOV, as described with respect to **FIGS. 6 and 8**, below.

[0020] **FIGS. 4-6** illustrate some of the pathlength control aspects of a cyanotic infant sensor **300**. **FIG. 4** depicts a fleshy tissue site **10** for sensor attachment, such as a finger or thumb **400**. The tissue **10** has an epidermis **12**, a dermis **14**, subcutaneous and other soft tissue **16** and bone **18**.

[0021] **FIG. 5** depicts a conventional pulse oximetry sensor **20** having a detector **22**, an emitter **24** and a tape **26** attached to the fleshy tissue **10**. Transmitted light **30** propagating from the emitter **24** to the detector **22** that results in a significant contribution to pulse oximetry measurements passes through and is absorbed by the pulsatile blood in the dermis **14**. A portion of the transmitted light **30** is scattered out of the epidermis **12** and reflected by the tape **26** back into the fleshy tissue **10**. The detector field-of-view (FOV) **40** is relatively wide and, as a result, the detector responds to transmitted light **30** that has propagated, at least in part, outside of the fleshy tissue **10**.

[0022] **FIG. 6** depicts a cyanotic infant sensor **300** that is configured to limit variations in the mean pathlength ratio. In particular, the sensor **300** has a light absorbing tape inner surface **324** that reduces transmitted light reflection back into the tissue site **10**, as described with respect to FIGS. **3**A-B, above. Further, the detector **342** has a limited FOV **50** so as to reduce the detection of transmitted light that has propagated outside of the tissue site **10**, as described in detail with respect to **FIGS. 7-9**, below.

[0023] **FIGS. 8-9** illustrate cyanotic infant sensor embodiments having a limited detector field-of-view (FOV). FIGS. **7**A-B illustrate a conventional sensor **700** having a tape portion **760**, a detector window **762** and a detector **742** having a relatively wide FOV **701**. In particular, the window thickness does little to restrict the FOV. FIGS. **8**A-B illustrate one embodiment of a cyanotic infant sensor **300** having a material portion **360**, a detector window **362** and a detector **342** having a restricted FOV **801**. In particular, the material thickness **360** functions to define the FOV **801**. In one embodiment, the material thickness **360** comprises a flex circuit thickness and a base head tape thickness, as described with respect to **FIG. 3B**, above. FIGS. **9**A-B illustrate another embodiment of a cyanotic infant sensor **900** having

a material portion **960**, a detector window **962** and a detector **942** having a restricted FOV **901**. In particular, an O-ring **980** deposed around the window **962** defines the FOV **901**.

[**0024**] **FIG. 10** depicts an exemplar calibration surface **1000** for a cyanotic infant sensor **300** (FIGS. **3**A-B) calculated along a DC response ratio axis **1001**, a ratio-of-ratios axis **1003** and a resulting oxygen saturation axis **1005**. Matching the emitters and detectors, as described with respect to **FIG. 3A**, above, allows for pathlength calibration. In particular, variations in the detector DC response ratio (RD_{dc}/IR_{dc}) are attributed to variations in the mean pathlength ratio (EQ. 3). As such, a calibration surface is determined by statistical regression of experimental measurements obtained from human volunteers and calibrated measurements of oxygen saturation, as is done for a conventional calibration curve (**FIG. 2**). A calculated DC response ratio **1001** in combination with a conventionally calculated ratio-of-ratios **1003** is then used to derive an oxygen saturation **1005** for the calibration surface **1000**.

[**0025**] A cyanotic infant sensor has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in art will appreciate many variations and modifications.

What is claimed is:

1. A pulse oximetry sensor comprising:

a plurality of emitters configured to transmit light having a plurality of wavelengths into a fleshy medium;

at least one detector responsive to said light after absorption by constituents of pulsatile blood flowing within said medium so as to generate a plurality of intensity signals;

a sensor head having a light absorbing surface adapted to be disposed proximate said medium,

said emitters and said at least one detector disposed proximate said sensor head; and

a detector window defined by said sensor head, said window configured so as to limit the field-of-view of said at least one detector.

2. The pulse oximetry sensor according to claim 1 wherein said sensor head is configured to attach to a human digit with said light absorbing surface disposed around the periphery of the digit so as to at least partially absorb emitter transmitted light that is scattered out of said digit.

3. The pulse oximetry sensor according to claim 2 wherein a material thickness of said sensor head proximate said detector window limits the field-of-view of said at least one detector.

4. The pulse oximetry sensor according to claim 2 further comprising an O-ring disposed around the periphery of said detector window so as to limit the field-of-view of said at least one detector.

5. The pulse oximetry sensor according to claim 1 wherein said emitters are selected from a plurality of matched emitters having a first wavelength intensity over a second wavelength intensity ratio for at least one predetermined DC drive current that varies less than a predetermined amount.

6. The pulse oximetry sensor according to claim 1 wherein said at least one detector is selected from a plurality of matched detectors each having a first wavelength response over a second wavelength response ratio for at least one predetermined DC incident intensity that varies less than a predetermined amount.

7. A pulse oximetry sensor comprising:

a plurality of emitters configured to transmit light having a plurality of wavelengths into a fleshy medium; and

a detector responsive to said light after absorption by constituents of pulsatile blood flowing within said medium so as to generate a plurality of intensity signals,

wherein said emitters and said detector selected from a plurality of matched emitters and matched detectors so that variations in a DC detector response ratio at said wavelengths can be generally attributed to variations in a mean pathlength ratio at said wavelengths.

8. The pulse oximetry sensor according to claim 7 wherein each of said emitters are matched according to a predetermined tolerance for a corresponding one of said wavelengths.

9. The pulse oximetry sensor according to claim 8 wherein said emitters are matched according to a DC intensity ratio tolerance at said wavelengths.

10. The pulse oximetry sensor according to claim 7 wherein said detector is matched according to a DC response ratio at said wavelengths.

11. The pulse oximetry sensor according to claim 7 further comprising:

a sensor head for mounting said emitters and said at least one detector, said sensor head adapted to be disposed around the periphery of a human digit so that a light absorbing surface of said sensor head at least partially prevents emitter transmitted light from being reflected from said surface back into said digit.

12. The pulse oximetry sensor according to claim 7 further comprising a detector window configured so as to limit the field-of-view of said detector.

13. A pulse oximetry method comprising the steps of:

transmitting light having a plurality wavelengths into a fleshy medium;

detecting said transmitted light after absorption by constituents of pulsatile blood flowing within said medium so as to generate a corresponding plurality of intensity signals; and

calculating a DC response ratio from said intensity signals as an indicator of a ratio of mean pathlengths of said transmitted light through said fleshy medium.

14. The pulse oximetry method according to claim 13 comprising the further step of deriving a calibration surface for calculating oxygen saturation as a function of said DC response ratio.

15. The pulse oximetry method according to claim 14 comprising the further step of matching emitters for said transmitted light according to a DC intensity ratio tolerance at said wavelengths.

16. The pulse oximetry method according to claim 15 comprising the further step of matching detectors for said

detecting step according to a DC intensity ratio tolerance at said wavelengths.

17. The pulse oximetry method according to claim 13 comprising the further step of absorbing at least portions of said transmitted light that are scattered out of said fleshy medium.

18. The pulse oximetry method according to claim 13 comprising the further step of limiting a detector field-of-view so as to substantially limit said detected light to portions of said transmitted light that propagate entirely through said fleshy medium.

* * * * *

专利名称(译)	Cyanotic婴儿传感器		
公开(公告)号	US20060020185A1	公开(公告)日	2006-01-26
申请号	US11/171632	申请日	2005-06-30
[标]申请(专利权)人(译)	AL ALI AMMAR		
申请(专利权)人(译)	AL-ALI AMMAR		
当前申请(专利权)人(译)	摩根大通银行，NATIONAL ASSOCIATION		
[标]发明人	AL ALI AMMAR		
发明人	AL-ALI, AMMAR		
IPC分类号	A61B5/00		
CPC分类号	A61B5/0059 A61B5/14551 A61B2503/04 A61B5/14552 A61B5/7271		
优先权	60/586821 2004-07-09 US		
其他公开文献	US7937128		
外部链接	Espacenet USPTO		

摘要(译)

脉搏血氧饱和度传感器包括发射器，其配置成将具有多个波长的光传输到肉质介质中。检测器在被介质内流动的脉动血液的成分吸收后响应于发射的光，以产生强度信号。传感器头具有光吸收表面，适于靠近介质设置。发射器和检测器靠近传感器头设置。检测器窗口由传感器头限定并配置成限制检测器的视场。