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(54) PACIFIER PULSE OXIMETER SENSOR

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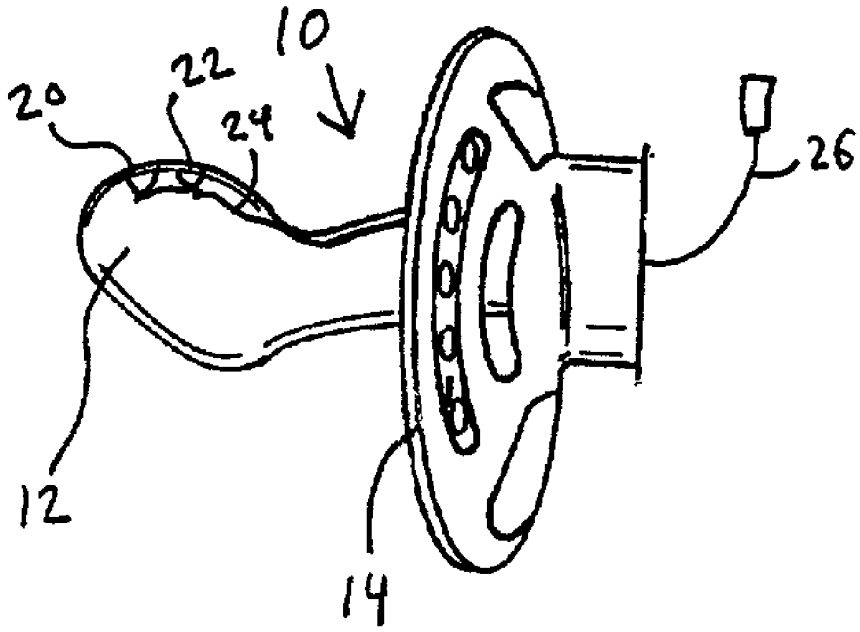
(52) **U.S. Cl.** **600/323**; 600/341

(57) **ABSTRACT**

A pacifier pulse oximeter sensor includes pulse oximeter sensor elements located within the nipple of a pacifier. The pulse oximeter sensor elements may be completely within the nipple material, embedded within the nipple material, nested within the nipple material, or adjacent to the nipple material while not being exposed to the outside environment. The pulse oximeter sensor elements include a light source and a light detector. The pulse oximeter sensor elements communicate with an oximeter through wiring, an electrical connector, and/or wirelessly. An alternative embodiment adds oximeter processing capabilities to the pacifier pulse oximeter sensor.



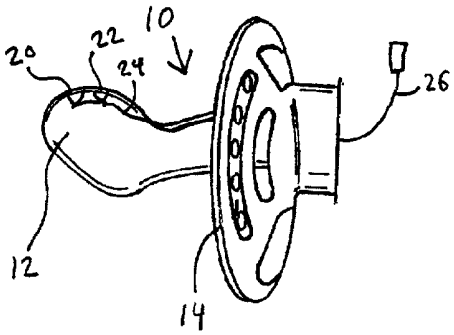


Fig. 1

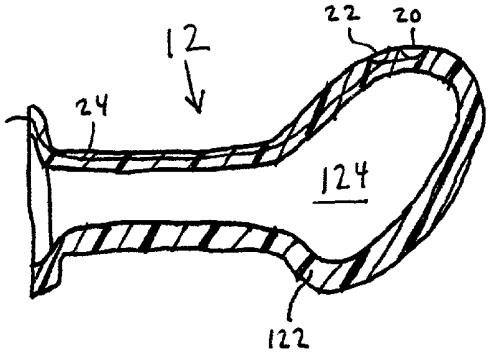


Fig. 2

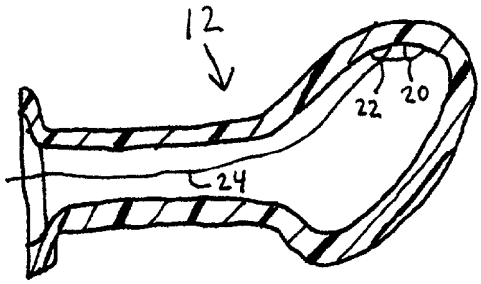


Fig. 3

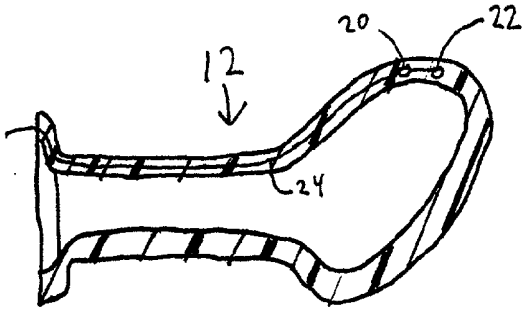


Fig. 4

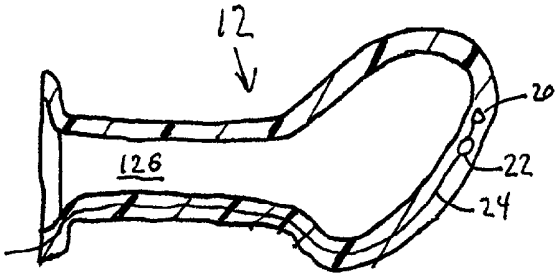


Fig. 5

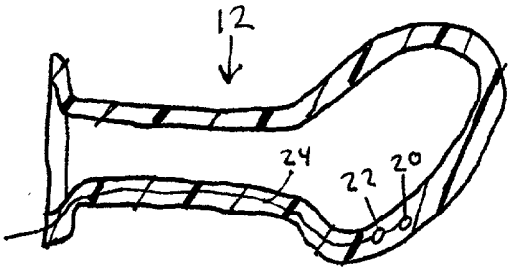


Fig. 6

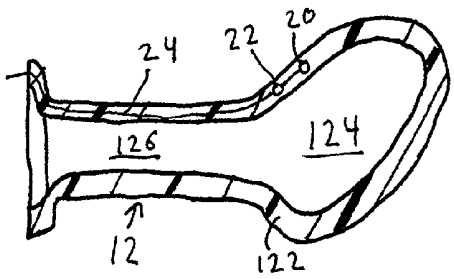


Fig. 7

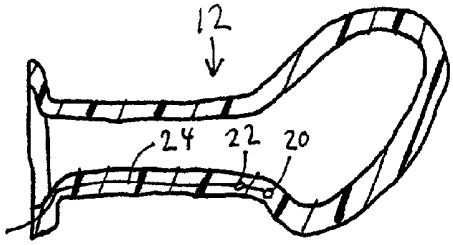


Fig. 8

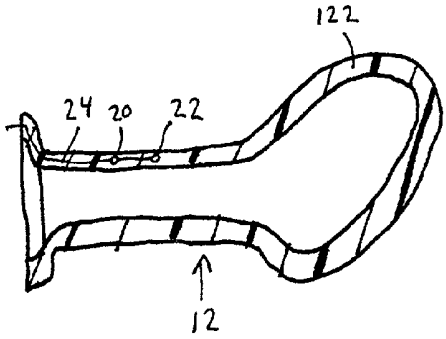


Fig. 9

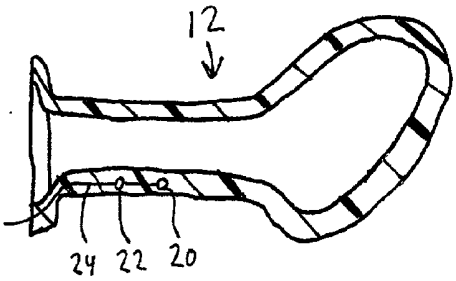


Fig. 10

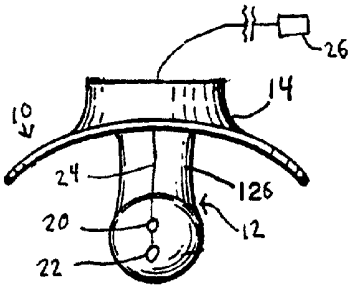


Fig. 11

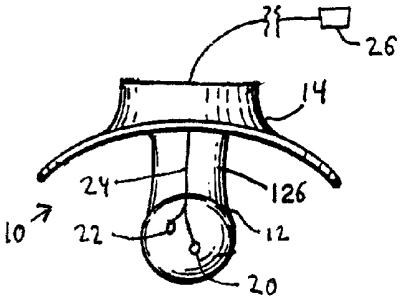


Fig. 12

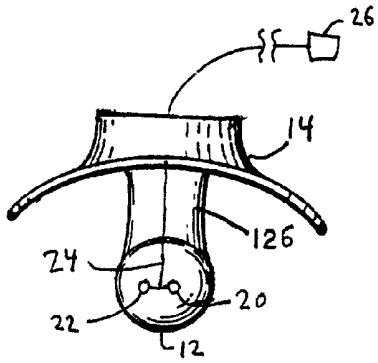


Fig. 13

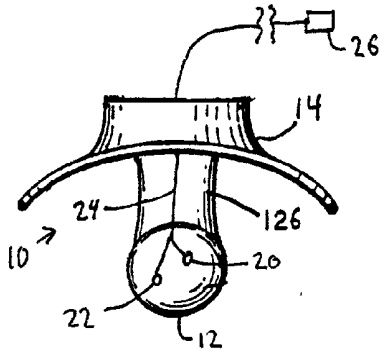


Fig. 14

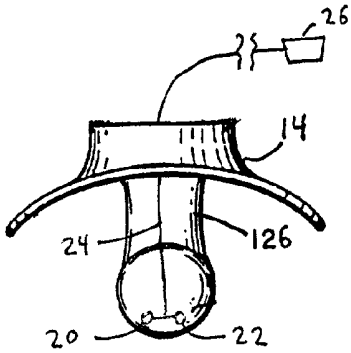


Fig. 15

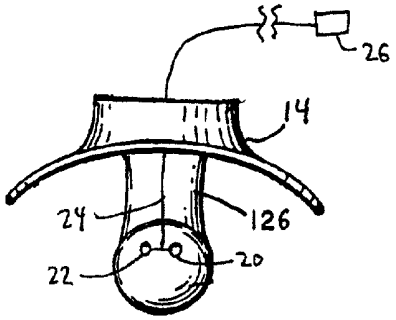


Fig. 16

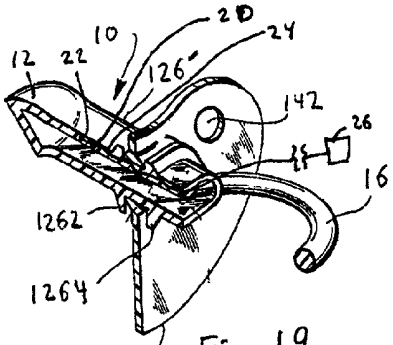


Fig. 19

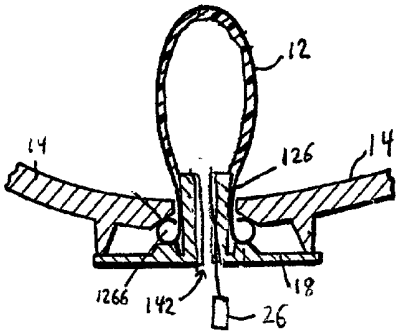


Fig. 20

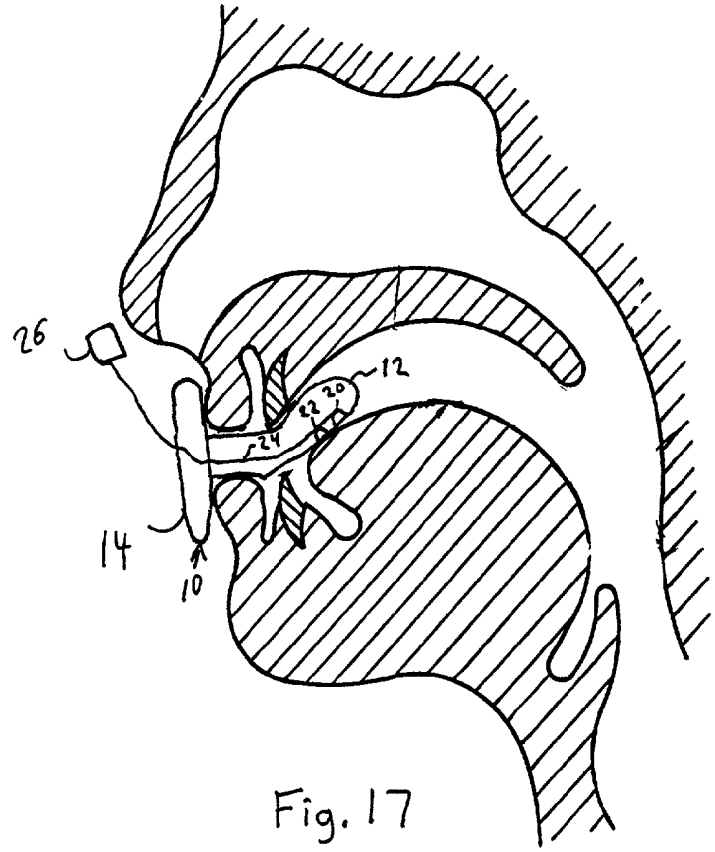


Fig. 17

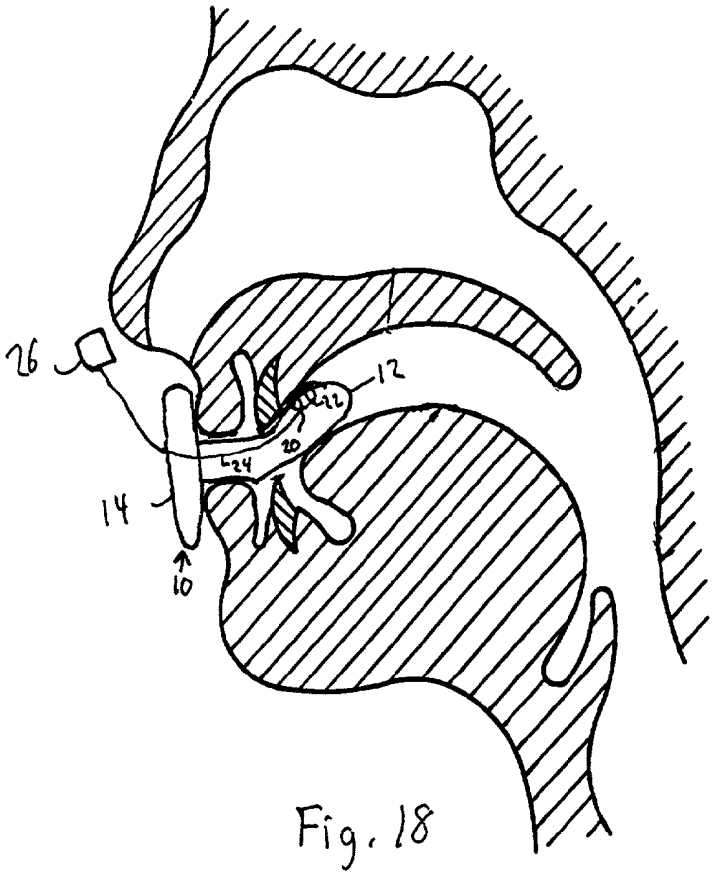


Fig. 18

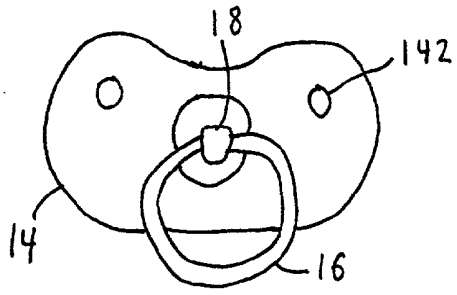


Fig. 21(a)

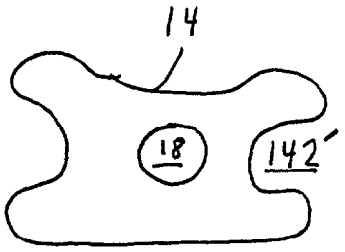


Fig. 21(b)

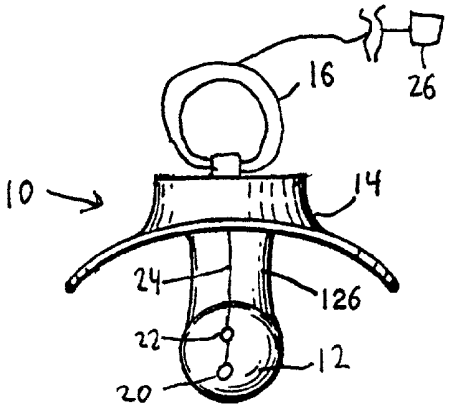


Fig. 22

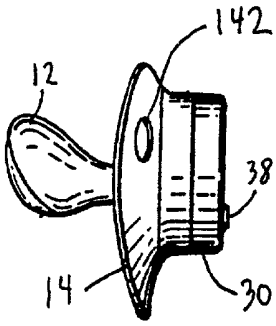


Fig. 23

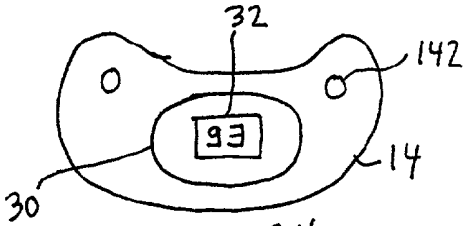


Fig. 24

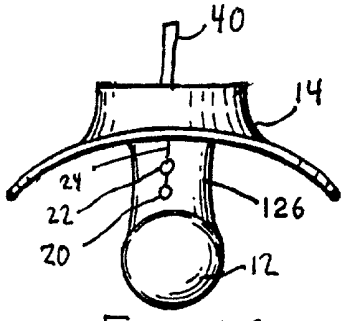


Fig. 26

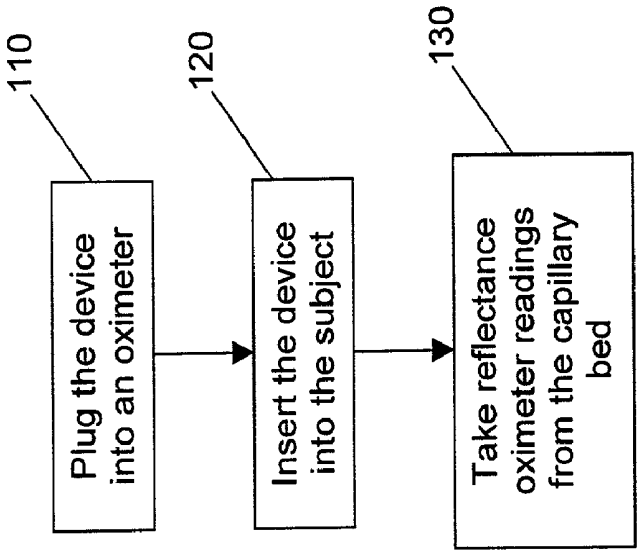

110
120
130
Plug the device into an oximeter
Insert the device into the subject
Take reflectance oximeter readings from the capillary bed

Fig. 27

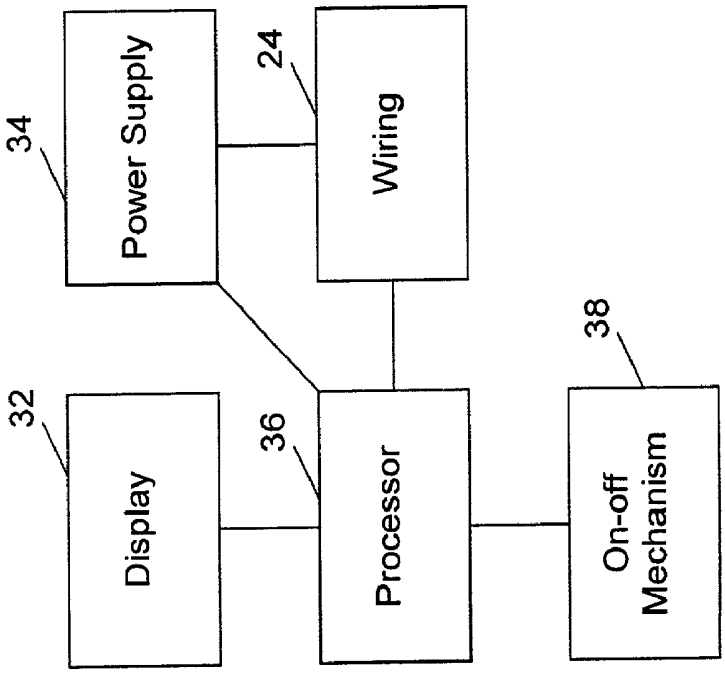

34
Power Supply
24
Wiring
32
Display
36
Processor
38
On-off Mechanism

Fig. 25

PACIFIER PULSE OXIMETER SENSOR

[0001] This application claims the benefit of U.S. provisional Application Ser. No. 60/182,018, filed Feb. 11, 2000, entitled Pacifier with Reflectance Pulse Oximetry, which is hereby incorporated by reference.

FIELD OF THE INVENTION

[0002] This invention is directed to an apparatus and a method for measuring blood oxygenation from locations within the oral cavity of a subject, for example, a small child or a small/newborn animal. More particularly, the invention relates to using pulse oximeter sensors to perform reflective pulse oximetry within the oral cavity of a subject.

BACKGROUND OF THE INVENTION

[0003] With a few exceptions, tradition and technology have favored transillumination pulse oximetry in the operating theater. The principle of operation of the pulse oximeter is fairly simple but is arguably the most important development in anesthesia monitoring in the twentieth century. Two wavelengths of light (usually 660 nm and 940 nm) are used to spectrophotometrically determine the ratio of oxidized to reduced hemoglobin noninvasively as well as to determine the pulsatility of blood plethysmographically.

[0004] However, reflectance oximetry rather than transillumination oximetry was the earliest investigative form of the technique for taking oximeter readings. Transillumination pulse oximetry, without question, is the most effective form when oximetry is obtained through skin. However, when skin is not interposed as a barrier to capillary bed access, reflectance pulse oximetry easily can be achieved with very accurate results. Indeed, it is used commonly and effectively among intrapartum and neonatal patients whose capillary beds are easily accessed through their skin. The technique has also been applied to adult and pediatric burn patients by placing the reflectance sensor in wounds or over hyperemic sites such as healed partial thickness burns. The effect is achieved by the backscattering of incident bispectral light that traverses and, on reflection from nonabsorptive collagenous tissues, retraverses formed elements in the blood back to the oximeter elements. Rather than superseding transillumination pulse oximetry, this technique broadens the scope of possible monitoring sites, adding to the clinician's armamentarium.

[0005] Presently, the most common application of this in a medical setting is via transillumination through the capillary bed of a peripheral digit. However, young patients such as babies are apt to remove or reject foreign objects such as finger oximeters or inserted tubes upon realizing their placement when recovering from anesthesia or awaking from sleep. Sick children, in particular, are more likely to be restless and easily agitated and thus will resist any attempts to have medical readings taken like temperature or oximeter readings. Additionally, it is not unusual for multitrauma and thermally injured patients to either have severe peripheral vasoconstriction or to have severely damaged (or missing due to amputation) peripheral vascular beds.

[0006] There are other often overlooked capillary beds readily accessible in most adult burn patients and young children that are as amenable to reflectance oximetry similar to the forehead of the premature infant. The buccal surface, posterior soft palate, hard palate, lingual surfaces, and gums of a burned patient and/or child are seldom compromised no matter how severe the burn, and the capillary beds are very close to the surface in those areas. Transillumination pulse oximetry of the tongue and cheek has been documented as a viable method of monitoring, but not everyone has the equipment available to place a transilluminating pulse oximeter on the tongue or cheek.

[0007] Recent studies indicate that oral pulse oximetry is a superior modality when compared to peripheral transillumination pulse oximetry. A variety of studies have shown that oral pulse oximeters are more reliably and rapidly responsive than peripheral pulse oximeters. However, these studies use oral transillumination pulse oximetry, held in place via complex devices or pieces of improvised malleable metal. Oral secretions, equipment failure, and placement difficulty often render these techniques ineffective.

[0008] Prior pulse oximeter sensors inserted through the mouth are usable only when the patient is under general anesthesia. These pulse oximeter sensors are inserted to reach the larynx area, for example, U.S. Pat. No. 5,282,464 to Brain et al. Another known method uses transillumination pulse oximetry of the posterior tongue, but this method possibly may not be used with a patient, who is awake, for example, U.S. Pat. No. 5,205,281 to Buchanan. Also, the posterior tongue is not the most accessible body part to take oximetry measurements.

[0009] Notwithstanding the usefulness of the above-described devices, and the above-identified recognized viability of transilluminating pulse oximetry, a need exists for a more convenient method for obtaining oximeter readings from a subject.

SUMMARY OF THE INVENTION

[0010] The invention while addressing the problems of the prior art obtains advantages that were not achievable with the prior art apparatuses and methods.

[0011] An object of this invention is to provide an effective method for taking pulse oximetry measurements from oral capillary beds.

[0012] Another object of the invention is the use of reflectance pulse oximetry via the oral cavity for a variety of surgical, anesthetic, or critical care procedures or situations to include patients that are awake, undergoing general anesthesia, or recovering from general anesthesia.

[0013] Another object of the invention is to allow for lingual placement of a pulse oximeter sensor for reflectance readings to provide efficient and clinically accurate pulse oximetry measurements.

[0014] Another object of the invention is to allow for buccal placement of a pulse oximeter sensor for reflectance readings to provide efficient and clinically accurate pulse oximetry measurements.

[0015] Yet another object of the invention is to monitor oxygen levels in newborns and young children who are difficult to monitor because of their natural restlessness and young age.

[0016] Still another object of the invention is to monitor oxygen levels in severely burned ICU patients who are difficult to monitor.

[0017] An advantage of the invention is an improvement in the quality of care resulting from using a straightforward method with easily used devices to take internal oximetry measurements and readings.

[0018] Another advantage of the invention is that EMS crews and personnel will be able to use this invention easily in the field during, for example, emergency situations.

[0019] Another advantage of the invention is improved pulse oximetry readings.

[0020] Another advantage of the invention is reflectance pulse oximetry requires less power to function and thus less heat is produced than transilluminance pulse oximetry. The decrease in produced heat lowers the risk the subject will be burned.

[0021] Yet another advantage of the invention is that ambient light will not degrade the oximeter readings because the invention is within the mouth of a subject.

[0022] The apparatus and the method accomplish the above objectives and achieve the advantages. The apparatus and the method are easily adapted to a wide variety of situations.

[0023] Furthermore, intraoral buccal, palatal, or lingual placement of a pulse oximeter probe in a configuration relying upon reflected light will provide pulse oximetry measurements comparable to those obtained by peripheral pulse oximetry. Test protocols suggest that buccal and palatal reflectance pulse oximetry provides a simple, accurate means of monitoring arterial oxygen saturation in the severely burned patient where oximetric monitoring presents a challenge.

[0024] Furthermore, the apparatus to perform this method is extremely useful in cases where it is difficult at best or not even possible to attach prior art pulse oximeter sensors with clips or straps to the patient. The types of patients that this apparatus would be useful with are critically ill or injured patients including newborns, babies, young children, young animals, and burn or trauma patients without alternative sites and maxillofacial injuries.

[0025] Given the following enabling description of the drawings, the apparatus and the method should become evident to a person of ordinary skill in the art.

DESCRIPTION OF THE DRAWINGS

[0026] The use of cross-hatching within these drawings should not be interpreted as a limitation on the potential materials used for construction. Like reference numerals in the figures represent and refer to the same element or function.

[0027] **FIG. 1** depicts a side view of the preferred embodiment of the invention.

[0028] **FIG. 2** illustrates a side cross-section of a nipple of the preferred embodiment of the invention.

[0029] FIGS. **3-10** depict side cross-sections of a nipple to illustrate various alternative placements and arrangements of pulse oximeter elements according to the invention.

[0030] FIGS. **11-16** illustrate top views of various alternative placements and arrangements of the pulse oximeter elements according to the invention.

[0031] **FIGS. 17 and 18** depict the invention in use in a subject.

[0032] **FIGS. 19 and 20** illustrate cross-sections of examples of attaching the nipple to the shield for the preferred embodiment of the invention.

[0033] FIGS. **21**(*a*)-(*b*) depict an example of a shield structure for use in the preferred embodiment of the invention.

[0034] **FIG. 22** illustrates a top view of an alternative embodiment of the invention.

[0035] **FIG. 23** depicts a top cross-section of another alternative embodiment of the invention.

[0036] **FIG. 24** illustrates a rear view of the alternative embodiment of the invention illustrated in **FIG. 23**.

[0037] **FIG. 25** depicts a block diagram for an alternative embodiment of the invention illustrated in **FIGS. 23 and 24**.

[0038] **FIG. 26** illustrates a top view of another alternative embodiment of the invention.

[0039] **FIG. 27** depicts a flowchart illustrating the steps for performing the preferred embodiment.

DETAILED DESCRIPTION OF THE INVENTION

[0040] FIGS. **1-18** illustrate a preferred embodiment and alternative component arrangements of the pacifier oximeter sensor assembly. The assembly preferably includes a pacifier **10**, pulse oximeter sensor elements **20**, **22**, and wiring **24**.

[0041] The pacifier **10** preferably includes a nipple (or baglet) **12** and a shield (or guard) **14**. The nipple **12** may be a variety of shapes in addition to those shown in FIGS. **1-18** that will allow the subject to apply a suction force to the nipple **12**. Exemplary shapes for the nipple **12** include orthodontic, bottle nipple, spherical, and thumb shaped. The nipple **12** preferably is a flexible material typically used to make pacifiers and baby bottle nipples such as polypropylene, polyvinyl chloride, silicones, epoxies, polyester, thermoplastics, rubber, or similar flexible material. Preferably, the material used to make the nipple **12** will be at least partially translucent to allow light to pass through in the area of the pulse oximeter sensor elements **20**, **22**. Preferably, the nipple **12** will have an inner cavity **124** formed as a void in the nipple material **122**. However, the nipple **12** may be solid or filled with a flexible material to increase the protection of the pulse oximeter sensor elements **20**, **22** and wiring **24**.

[0042] The pulse oximeter sensor elements **20**, **22** preferably are within the material **122** making up the nipple **12** to reduce the impact of the material **122** on the transmission of light through the material **122**. However, the pulse oximeter sensor elements **20**, **22** may be nested within the nipple material **122** as shown, for example, in **FIG. 4** or the pulse oximeter sensor elements **20**, **22** may abut the nipple material **122** on the inner cavity surface as shown, for example, in **FIG. 3**. The pulse oximeter sensor elements **20**, **22** preferably will be placed in a position to transmit light and receive backscattered light from a capillary bed within the oral cavity of the subject as illustrated, for example, in **FIGS. 17 and 18**. The preferred locations are along the top of the nipple **12** (FIGS. **2-4**), at the tip of the nipple **12** (**FIG. 5**), and along the bottom of the nipple **12** (**FIG. 6**). Also, the

pulse oximeter elements **20**, **22** may be located in and/or along the nipple shank **126** as illustrated, for example, in FIGS. **7-10**.

[**0043**] Preferably, the pulse oximeter sensor elements include a light source **20** and a light detector **22**. The placement and location of the light source **20** and the light detector **22** depicted in FIGS. **1-18** may be switched with respect to each other. Furthermore, the light source **20** and the light detector **22** may be in a variety of exemplary spatial locations relative to each other as shown, for example, in **FIGS. 1116**. Although FIGS. **11-16** illustrated the pulse oximeter sensor elements **20**, **22** on the top of the nipple **12**, these elements may have similar spatial locations on other portions of the nipple **12** such as the tip, bottom, and along the shank **126**.

[**0044**] The light source **20** preferably emits at least two frequencies of light in the red region, for example with a wavelength of 660 nm, and in the infrared region, for example with a wavelength of 940 nm, preferably in response to a signal from a spectrophotometer, other similar oximeter monitoring devices or multiparameter patient monitoring systems that provide oximetry readings. The light source **20** preferably is one or more of the following: two light emitters such as light emitting diodes (LED), a bispectral emitter, a dual spectral emitter, a photoemitter, or a semiconductor die. However, any light source that facilitates reflectance pulse oximetry may be employed. Typically, the two emitter arrangement will include a red LED around or at 660 nm and a near-infrared LED emitting in the range of 890 to 950 nm and more particularly at about 940 nm. The light source **20** may emit light having a bandwidth, for example, in the range of 20 to 50 nm.

[**0045**] Preferably, the light detector **22** detects light emitted by the light source **20**. Signals representing the detected light are transmitted by the light detector **22** to a spectrophotometer, an oximeter monitoring device or a multiparameter patient monitoring system that provides oximetry readings by discriminating between the relative intensity of these emissions and provides an index as to the degree of oxygen saturation of hemoglobin in blood. Preferably, the light detector **22** may be one of the following: a photoelectric receiver, a photodetector, or a semiconductor die.

[**0046**] The wiring **24** preferably includes conductive lines and contact electrodes. The wiring **24** preferably is embedded within the nipple material **122**, or passes through the nipple cavity **124**, or some combination of these two. An external cord **26** preferably is insulated and connects to the wiring **24** at a proximal end of the pacifier **126** so that the external cord **26** is outside of the oral cavity of the subject. The external cord **26** preferably includes a standard plug design to interface with a pulse oximetry spectrophotometer, a pulse monitor such as a plethysmograph, or other external device. Alternatively, the external cord **26** may be a jack to connect to a reusable cable such as the cable sold with the Nellcor® OxiCliq® systems (Mallinckrodt, Inc., St. Louis, Mo., U.S.A.).

[**0047**] The nipple **12** preferably is attached or mounted to the shield **14**. An example of one type of mounting is integrally forming the nipple **12** with the shield **14**, for example by mechanically coupling the nipple **12** to the shield **14**. Another mounting arrangement, as illustrated in **FIG. 19**, is to have the nipple **12** include a shank **126'** with two integral spaced collars **1262**, **1264** to form a channel to receive the shield **14**. Preferably, the shield **14** is at or near the proximal end of the shank **126'**. Preferably to prevent the shield **14** from being pulled off the shank **126'**, a handle **16** is looped through the shank **126'** as illustrated in **FIG. 19**.

[**0048**] Another example of attaching the nipple **12** to the shield **14** is illustrated in **FIG. 20**. The shield **14** includes an opening for the nipple shank **126** to pass through preferably such that a rim or section of rolled up material **1266** is located on the proximal side of the shield **14**. A plug **18** is inserted into the shield opening **142** to hold the nipple shank **126** in place with respect to the shield **14**. More preferably, the plug **18** will include a securing mechanism that is compressed as it travels through the shield opening **142** and then expands on the distal side of the shield **14** to secure the plug **18** in place and hold the nipple **12** securely to the shield **14**.

[**0049**] The shield **14** preferably is curved or bowed to form fit to the average baby's face. The shield **14** may be any shape that prevents it from being pulled into the subject's mouth from the suction force placed upon the nipple **12** by the subject. More preferably, the shield **14** will be shaped or include a reference indicator such that the top of the pacifier **10** can be readily determined by looking at the shield **14**. In an alternative embodiment, the shield **14** preferably includes a plurality of holes (or relief openings) **142** to allow for spit to be discharged without interference from the pacifier **10** as illustrated, for example, in FIGS. **21**(*a*), **23**, and **24**. **FIG. 21**(*b*) illustrates a relief opening **142'** that allows insertion of a catheter such as an endotracheal tube. A further alternative is for the shield to include a mesh pattern over at least a portion of it. Another alternative embodiment adds a ring (or annular or other shaped handle) **16** on the opposite side of the shield **14** from the nipple **12** as illustrated in FIGS. **21**(*a*) and **22** that may attach to either the shield **14** or the nipple **12**. Preferably, the ring is hinged, collapsible, and/or flexible.

[**0050**] An alternative embodiment of the invention is the placement of the oximeter signal processing device within a housing **30** extending from the shield **14** on the side opposite the nipple **12** as illustrated, for example, in **FIGS. 23 and 24**. The oximeter signal processing device preferably is a miniature spectrophotometer. The oximeter signal processing device preferably will include a display **32**, a power supply (such as a battery) **34**, and a processor **36** to perform calculations and to drive the display **32**, and an on-off button (or switch/mechanism) **38** as illustrated in **FIG. 25**. The display **32** preferably will show the blood oxygenation level of the subject as illustrated in **FIG. 24**. More preferably, the display **32** is a digital display. The processor **36** preferably will connect to the wiring **24** running from the pulse oximeter sensor elements **20**, **22**, calculate the blood oxygenation level, and drive both the display **32** and the light source **20**. The processor **36** preferably is a circuit that includes either an analog circuit or an integrated circuit, which is either hardwired or programmed. Preferably, the display **32**, the power supply **34**, the processor **36** will reside on a printed circuit board that includes appropriate circuitry and provides a connection to wiring **24**.

[**0051**] Another alternative embodiment of the invention is that the light source **20** and the light detector **22** may be in wireless communication with the external device instead of

connected with the external cord **26** as illustrated in **FIG. 26** as a rod (or antenna or transmitter) **40**. Alternatively, the antenna **40** may take the shape as a handle **16** similar to the one illustrated, for example, in **FIGS. 21 and 22** without the external cord **26**. Preferably, the wireless communication will occur through an antenna **40** extending away from the pacifier **10**. The transmitter may be incorporated within the antenna **40** or some other housing incorporated into the shield **14**. Preferably, the antenna **40** will be sufficiently sturdy to withstand tugging and being played with during use by the subject. This alternative embodiment also preferably includes a power source such as a battery to power all of the electrical components. The power source preferably is located within the shield, a housing, or as part of the antenna **40**.

[**0052**] A further alternative embodiment of the invention is to provide a bite block on the distal side of the shield **14** between the shield **14** and the nipple **12**. The bite block may be an extension of the shield material or a hardened nipple shank **126**. The flexible nipple **12** preferably is attached to the bite block. Preferably, the bite block will provide a passageway through which the wiring **24** may pass through. The shield **14** and nipple **12** preferably would be shaped such that multiple catheters would have space to enter the oral cavity, for example, for suction and supplying oxygen. This alternative embodiment preferably would be for use during surgery of a variety of subjects other than infants and young children.

[**0053**] The device may be a retrofit of current pacifiers by inserting the pulse oximeter sensor elements from a disposable pulse oximeter like the Nellcor® Oxisensor® II oximeters (Mallinckrodt, Inc., St. Louis, Mo., U.S.A.) by stripping away the packaging and adhesive strip. The ring attached to must pacifiers would be removed leaving access to the interior cavity of the nipple into which the pulse oximeter sensor elements would be inserted such that they faced in the same general direction. The ring then would be reattached.

[**0054**] In accordance with the present invention, there is a method to take oximeter readings from different sites within a subject, which may be either human or animal, for the purposes of determining the amount of oxygen within the blood of the subject. The oximeter readings are accomplished using reflectance oximetry from capillary beds that are readily accessible within the subject. The capillary beds include, for example, the hard palate, the soft palate, the superior lingual surface, the inferior lingual surface, the gingivae, the mouth floor, the buccal surface, and any other surface within the oral cavity. Each of these capillary beds is accessible through the oral cavity, which extends from the lips to the oral portion of the pharynx, i.e., pars oralis.

[**0055**] **FIG. 27** illustrates a flowchart showing the steps for taking oximeter readings pursuant to the present invention. In the first step **110**, which may actually occur at a later point but no later then the initiation of taking pulse oximeter readings, the pulse oximeter sensor elements are connected to an oximeter device such as a spectrophotometer. In step **120**, the pacifier **10** is inserted into the subject through the mouth. The placement of the pacifier **10** with a pulse oximeter sensor is illustrated, for example, in **FIGS. 17 and 18**. In step **130**, reflectance pulse oximeter readings are taken from the relevant capillary bed. While taking the pulse oximeter readings, the pulse oximeter sensor elements preferably remain in contact with the relevant capillary bed to continue the flow of accurate oximeter readings.

[**0056**] The method according to the invention may be used in a variety of surgical, anesthetic, critical care procedures or situations that include patients that are awake, sedated or recovering from general anesthesia.

[**0057**] The method of taking pulse oximeter readings from different surfaces within a patient has been submitted to actual testing in the below-described population and according to the following protocols.

Reflectance Oximetry from the Buccal Surface

[**0058**] The first protocol involved taking readings from the buccal surface. Nine patients were monitored via buccal reflectance pulse oximetry over **20** consecutive surgical procedures, which procedures consisted of burn excision and grafting. Patients ranged in age from 23 to 56 years (Mean=264.8, Standard Deviation (SD)=11.2) and ranged from 17 to 75 percent total body surface area (%TBSA) burned (Mean=274.3%, SD=28.9). Each patient received from one to eight operations (Mean=4.01). Five of these nine patients arrived at the operating room intubated for all of the operations in this study. Four patients were induced and intubated in a standard fashion for all surgical procedures.

[**0059**] A Nellcor® Oxisensor® II D-25 was placed intraoraly between the lower teeth and the left or right buccal surface of the cheek and lip, with the bispectral emitter and detector facing the buccal surface. This pulse oximeter sensor orientation was used for the duration of each case. In addition, a similar disposable oximetric probe was placed on a peripheral digit in the commonly accepted transillumination configuration. At five minute intervals throughout the case, values for both oximetric probes were coded on the anesthesia record.

[**0060**] The differences between the peripheral and buccal SpO_2 (oxygen saturation of hemoglobin) values were insignificant by t-tests for correlated means. Concordance rates as percent agreements were calculated for all cases. Average percent agreement was 84% ranging from 25% to 100%. Three of the 20 samples had percent agreements less than 91%. In each of these cases, the peripheral pulse oximeter sensor appears to have failed, in two cases secondary to sepsis, and in another secondary to peripheral vasoconstriction in the face of a norepinepherine infusion. Buccal SpO_2 readings in all three cases continued to be 97% or greater.

[**0061**] This data suggests that buccal reflectance oximetry is a simple, accurate means of monitoring arterial oxygen saturation in the severely burned patient where oximetric monitoring presents a challenge. Given that central oximetry has been shown in numerous studies to be more rapidly responsive to oxygen saturation variability than peripheral oximetry, as well as more directly reflective of central oxygen saturation, there are few drawbacks and considerable benefit from this method. Indeed, in the three examples in this study where percent agreements were low, the peripheral oximetric probes were returning apparently erratic and/or generally low values while buccal oximetric readings remained at 97% or higher. All three of these patients had peripheral vascular compromise secondary to sepsis and/or a vasoconstricting agent (norepinepherine infusion).

[0062] It may appear from the study results, at first blush, that a full range of SPO_2 values was not tested and that the continuously high SpO_2 readings are spurious to the technique. On the contrary, in order to obtain a SpO_2 value greater or less than 85% a very specific set of relationships must be present relative to the bispectral emitter and light sensing oximetric elements. Thus, spuriously high values in particular do not consistently occur. High SpO_2 values require the presence of saturated hemoglobin.

Posterior Pharyngeal Reflectance Oximetry

[0063] The second protocol involved comparing posterior pharyngeal reflectance pulse oximetry to conventional peripheral transillumination pulse oximetry in difficult to monitor burn patients. Eight patients' records were reviewed over fourteen consecutive surgical procedures, all consisting of excision and grafting. Patients ranged in age from 9 to 43 years and ranged from 14.5% to 77.5% TBSA burned (Mean=30.4, SD=22.1). The number of operations per patient ranged from one to four.

[0064] A Nellcor® Oxisensor® II pulse oximeter probe was placed in the distal lumen of an appropriately sized oropharyngeal airway with sensor and emitter facing the posterior pharynx. A similar probe was placed on a peripheral digit as a transilluminating pulse oximeter. SPO_2 values were noted at five-minute intervals. Concordance statistics as well as a t-test for correlated means were calculated between the simultaneously obtained SpO_2 values.

[0065] The mean differences between pharyngeal reflectance and peripheral digital transillumination SpO_2 values were insignificant for all cases. Concordance statistics were as follows: 0.75 (n=1) and 1.0(n=12).

[0066] Given the near perfect concordance statistics in this study, this data suggests that posterior pharyngeal reflectance oximetry is a simple, highly accurate means of monitoring arterial oxygen saturation in the severely burned patient where oximetric monitoring presents a challenge.

Lingual Surface Reflectance Oximetry

[0067] The third protocol involved taking readings from the lingual surface. Data was reviewed for eight difficult to monitor patients who were monitored via lingual reflectance pulse oximetry over twenty-five consecutive surgical procedures, all consisting of burn excision and grafting. Patients ranged in age from 26 to 57 years (Mean=36.0, SD=10.3). Patients ranged from 20% to 92% TBSA burned (Mean=66.75%, SD=26.42). Number of operations per patient ranged from one to five (Mean =3.13, SD=1.55). Six of these eight patients arrived at the operating room intubated for all of the operations in this study. Two patients were induced and intubated in a standard fashion.

[0068] In each case, a Nellcor® Oxisensor® II D-25 was centered flat on the superior lingual surface with the detector and the bispectral emitter facing the lingual surface. This pulse oximeter configuration was used for the duration of each case. When clinically indicated, an arterial blood gas (ABG) sample was drawn and the SpO_2 noted for clinical monitoring and prior to transfusion in every case. All had multiple ABG's drawn and all patients were transfused. The ABG SaO_2 (oxygen saturation of arterial blood) was noted in each case.

[0069] Descriptive statistics and a concordance rate as well as a t-test for correlated means were calculated between the simultaneously obtained SpO_2 and SaO_2 values. The difference between the SpO_2 and SaO_2 values was insignificant by t-test for correlated means (t=1.25, df=24, NS). Upon inspection, the means were very close and the standard deviations were very small, as were the SEM's, all suggesting very little difference or variability between these two measures of oxygen saturation. A concordance rate of 92% was calculated (+1.5%) showing a high degree of relationship between lingual and ABG SaO_2.

[0070] This data suggests that lingual reflectance oximetry is a simple, accurate means of monitoring arterial oxygen saturation in the severely burned patient where oximetric monitoring presents a challenge. An existing disposable pulse oximeter sensor was utilized in this study saving the cost of specially designed equipment. Given that central oximetry has been shown to be more rapidly responsive to oxygen saturation variability than peripheral oximetry, there are few drawbacks and considerable benefit from this method.

INDUSTRIAL APPLICABILITY

[0071] The invention is particularly useful for monitoring the blood oxygen content of a subject, more particularity a child or infant. The invention is also useful when other sites are not available on the patient such as a patient with severe burns covering most of their body or a restless child who is prone to remove attached oximeters to fingers and other body parts. The invention may be used by hospital personnel, emergency medical crews, in-home medical personnel, laboratory and veterinary personnel and battlefield medical personnel.

[0072] Those skilled in the art will appreciate that various adaptations and modifications of the above-described devices and steps can be configured without departing from the scope and spirit of the their use in the method. Therefore, it is to be understood that, within the scope of the appended claims, the method may be practiced and arranged other than as specifically described herein. Furthermore, the above-described embodiments may be used in a variety of combinations.

We claim:

1. An oximeter sensor comprising:

a nipple,

a shield connected to said nipple, and

oximeter sensor elements in said nipple; and

wherein said oximeter sensor elements are arranged to perform reflectance pulse oximetry.

2. The device as recited in claim 1, wherein said oximeter sensor elements include:

means for transmitting light at an intraoral tissue, and

means for receiving light reflected from the intraoral tissue.

3. The device as recited in claim 2, wherein said means for transmitting and said means for receiving are embedded in said nipple.

4. The device as recited in claim 2, wherein

said nipple includes an inner cavity, and

said means for transmitting and said means for receiving are disposed in the inner cavity of said nipple.

5. The device as recited in claim 1, wherein said oximeter sensor elements include:

at least one light source, and

at least one light detector in communication with said at least one light source.

6. The device as recited in claim 5, wherein said light source includes one of at least one light emitter, a bispectral emitter, a dual spectral emitter, at least one photoemitter, at least one photodiode, at least one light emitting diode, and a semiconductor die.

7. The device as recited in claim 6, wherein said light detector includes one of a photoelectric receiver, a photodetector, a photodiode receiver, and a semiconductor die.

8. The device as recited in claim 6, wherein

said nipple includes an inner cavity, and

said light source and said light detector are disposed in the inner cavity of said nipple.

9. The device as recited in claim 7, wherein said light source and said light detector are embedded within said nipple.

10. The device as recited in claim 5, further comprising:

a transmitter,

a power source, and

wiring connecting said light source, said light detector, and said transmitter to said power source, said wiring connecting said light source and said light detector to said transmitter.

11. The device as recited in claim 5, wherein said light source and said light detector are disposed near a top of said nipple.

12. The device as recited in claim 5, wherein said light source and said light detector are disposed near a tip of said nipple.

13. The device as recited in claim 5, wherein said light source and said light detector are disposed near a bottom of said nipple.

14. The device as recited in claim 5, further comprising an oximeter device, said oximeter device includes:

a display,

a power supply connected to said display, and

a processor connected to said power supply and said display, said processor is in communication with said light source and said light detector; and

wherein said processor signals said light source to transmit light, and

said processor receives at least one signal from said light detector representing light detected by said light detector.

15. A method for using the device recited in claim 1 comprising:

connecting the device to an oximeter,

inserting the device into a mouth of a subject, and

taking reflectance pulse oximeter readings.

16. The device as recited in claim 1, further comprising a plug engaging said nipple and said shield such that at least a portion of said nipple is held in place between said plug and said shield.

17. The device as recited in claim 1, further comprising a bite block connecting said shield to said nipple.

18. An oximeter system comprising:

a spectrometer, and

a pacifier oximeter sensor having a nipple, a shield attached to said nipple, and pulse oximeter sensor elements within said nipple.

19. The oximeter system according to claim 18, wherein said pulse oximeter sensor elements include a light source and a light detector.

20. A pulse oximeter sensor comprising:

means for restricting inward suction of the pulse oximeter sensor into a subject,

means for performing reflectance pulse oximetry inside the subject, and

means for housing said oximetry means.

* * * * *

专利名称(译)	安抚奶嘴脉搏血氧仪传感器		
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摘要(译)

奶嘴脉冲血氧计传感器包括位于奶嘴的奶嘴内的脉冲血氧计传感器元件。脉冲血氧计传感器元件可以完全在乳头材料内，嵌入乳头材料内，嵌套在乳头材料内，或邻近乳头材料，同时不暴露于外部环境。脉冲血氧计传感器元件包括光源和光检测器。脉冲血氧计传感器元件通过布线，电连接器和/或无线地与血氧计通信。替代实施例将测定仪处理能力添加到安抚奶嘴脉冲血氧计传感器。