



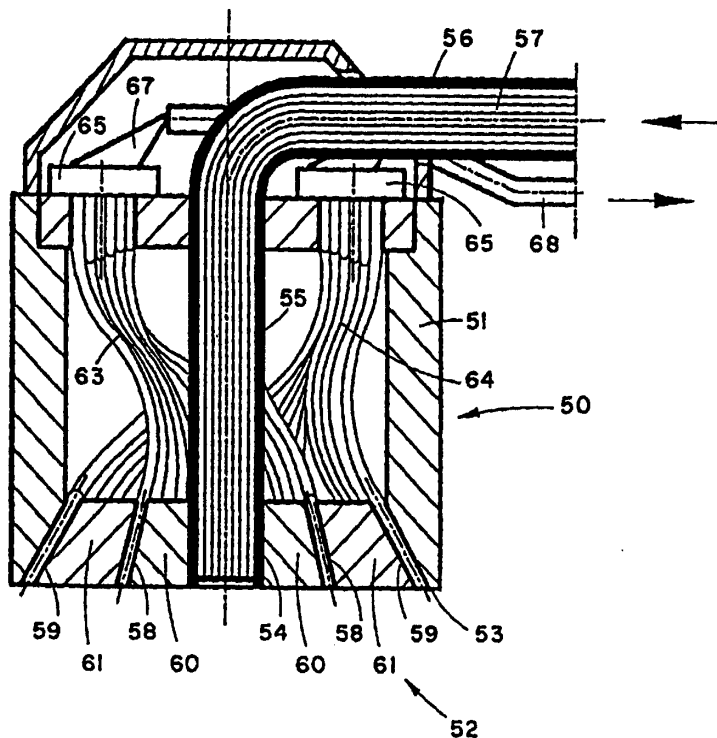
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<p>(21) International Application Number: PCT/IL96/00006 (22) International Filing Date: 6 June 1996 (06.06.96) (30) Priority Data: 114080 9 June 1995 (09.06.95) IL 114082 9 June 1995 (09.06.95) IL (71) Applicant (for all designated States except US): CYBRO MEDICAL LTD. [IL/IL]; P.O.B. 600, Matam, 31000 Haifa (IL). (72) Inventors; and (75) Inventors/Applicants (for US only): FINE, Ilya [IL/IL]; 59/6 Herzl Street, 76541 Rehovot (IL). STERNBERG, Alexander [IL/IL]; 31 Harofe Street, 34367 Haifa (IL). KATZ, Yeshayahu [IL/IL]; 45A Eder Street, 34752 Haifa (IL). GOLDINOV, Leonid [IL/IL]; 21A/9 Nativ Hen, 32243 Haifa (IL). RAPOPORT, Boris [IL/IL]; 3/12 Nativ Shomron, 28000 Kiryat Ata (IL). (74) Agent: COHN, Michael; Reinhold Cohn and Partners, P.O. Box 4060, 61040 Tel-Aviv (IL).</p>		<p>(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>Without international search report and to be republished upon receipt of that report.</i></p>

(54) Title: SENSOR, METHOD AND DEVICE FOR OPTICAL BLOOD OXIMETRY

(57) Abstract

There is described a new sensor for optical blood oximetry as well as a method and apparatus in which the new sensor is used. The new sensor includes two point-like light emitters positioned in the center of the device in close proximity to each other and at least one and preferably two annular detector terminals concentrically surrounding the light emitters. The light sources may, for example, be two laser diodes emitting each monochromatic light within the range of 670-940 nm. The detector devices are, for example, photodiodes.



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SENSOR, METHOD AND DEVICE FOR OPTICAL BLOOD OXIMETRY

FIELD OF THE INVENTION

The present invention relates to a novel sensor for non-invasive optical blood oximetry, such as blood pulse oximetry effected on a blood perfused tissue; to a method of optical oximetry; and to a device suitable
5 for performing the method.

BACKGROUND OF THE INVENTION

In the prior art there is described a method of measuring the degree of oxygen saturation of blood using what is commonly known as the
10 optical pulse oximetry technology. References to that technology may be found in US 4,167,331, US 4,938,218, in the brochure "Fetal Oxygen Physiology" sponsored by NELLCOR LTD., and there are others. In accordance with this method, a blood perfused tissue is illuminated and light absorption by the tissue is determined by a suitable light sensor. Pulsatile
15 changes in the value of absorption which are caused by cardiovascular activity of the blood are then used to determine the characteristic of interest, i.e. the degree of blood oxygen saturation.

The value of oxygen saturation (SaO_2) in arterial blood is defined by the following known equation:

20

$$SaO_2 = \frac{[HbO_2]}{[HbO_2] + [Hb]} 100\% \quad (1)$$

where $[HbO_2]$ is the concentration of oxygenated hemoglobin concentration in a unit of blood volume and $[Hb]$ is the concentration of reduced hemoglobin.

In commonly used methods of pulse oximetry a tissue under investigation is illuminated by light having at least two components of different wavelengths, and the measurements are based upon the following two physical phenomena:

- (a) the light absorbance of oxygenated hemoglobin is different from that of reduced hemoglobin, at each of the two wavelengths;
- (b) the light absorbance of the blood perfused tissue at each wavelength has a pulsatile component, which results from the fluctuating volume of arterial blood passing across the tissue between the light source and the sensor.

It is therefore assumed, that the pulsatile absorbance component of a tissue layer located between the light source and the sensor characterizes the degree of oxygen saturation of arterial blood.

Various types of sensors designed for effecting measurements in the performance of optical pulse oximetry are known in the art, and among the known optical sensors those dedicated to measuring the degree of oxygen saturation of fetal arterial blood constitute a particular group of such devices.

Basically, the prior art discloses two types of optical sensors which are associated with and serve for two modes of performing optical blood oximetry: transmission pulse oximetry in which so-called transmissive sensors are used and reflection pulse oximetry in which so-called reflectance or transreflectance sensors are used. In transmission pulse oximetry one measures light passing across a blood perfused tissue such as a finger, an ear or the like by placing a light emitter and the detection of a transmissive sensor at two opposite sides of the tissue under examination, as described for example in US 4,938,213. In reflection oximetry, on the other hand, reflectance or transreflectance sensors can be used which comprise both light emitters and light detectors which are accordingly placed on one and the same side of the tissue under examination, as described, for example, in

US 5,228,440, 5,247,932, 5,099,842 and in WO 90/01293. Reference to the two types of sensors can also be found, for example, in US 5,247,932 and in "Fetal Oxygen Saturation Monitoring" sponsored by NELLCOR.

Both the transmission and the reflection modes of operation have
5 specific limitations of applicability and their accuracy in general, and in specific applications in particular is not satisfactory. Thus, for example, the transmission technology can be successfully applied only in cases where the tissue to be investigated forms a distinctive protrusion which makes it possible to apply a light emitter and a light sensor at opposite surfaces.

10 It is thus evident that the reflection technology is the one most commonly resorted to, notably in fetal oximetry. Unfortunately, however, accuracy of the conventional reflection technology is rather low in comparison with that of the transmission one, because the degree of diffusion of the emitted light in the tissue is unknown, which means that the
15 nature of the functional interdependence between a light signal received by the sensor and the degree of blood oxygen saturation is also unknown. Another disadvantage of the known reflection technology is a partial shunting of the emitted light on the surface of the tissue between the source and the sensor, and a specular reflection created by the superficial layer of
20 the tissue.

U.S. Patent No. 5,009,842 describes a sensor with means for overcoming the problem of shunting of the emitted light on the outer surface of the tissue between the light source and the detector. U.K. Patent Application No. 2 269 012 proposes to select and separate light signals
25 resulting from light reflection by a superficial layer of a blood perfused tissue such as skin or hair, essentially by choosing a particular distance between the locations of emitting and detecting optical fibers on the contacted surface of the tissue under examination.

Fetal oximeters usually comprise applicators which generally
30 include a plate with at least one substantially point-like light source and at least one substantially point-like light detector suitably spaced from the light source(s). One drawback of such applicators is that if the applicator is

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