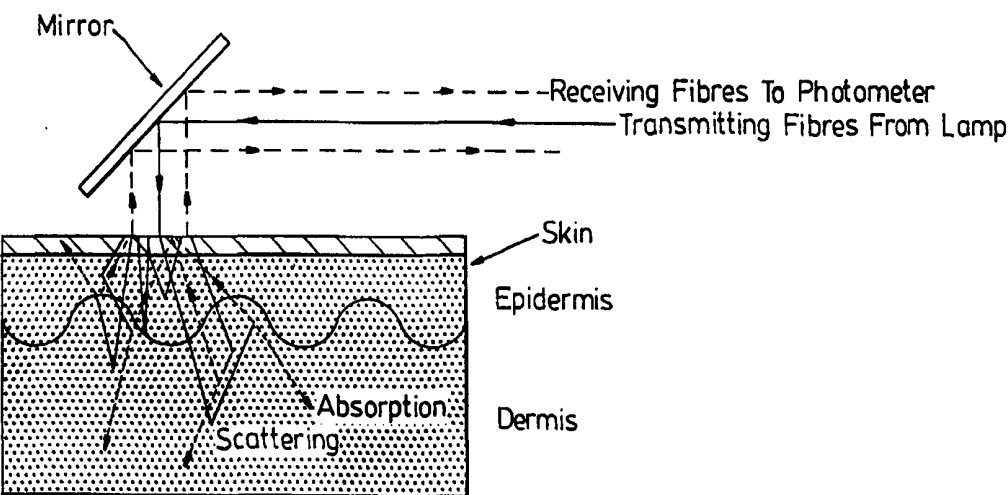




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(54) Title: OPTICAL DEVICE  The diagram illustrates an optical device for measuring blood oxygen saturation. It shows a cross-section of skin with two layers: the Epidermis and the Dermis. A mirror is positioned above the skin surface. Light from a lamp travels through transmitting fibers to the skin surface. Some light is reflected by the mirror, and some enters the skin. Inside the skin, light undergoes scattering and absorption. Receiving fibers collect the light and send it to a photometer.		
(57) Abstract There is described a sensor device which comprises light source means for emitting a light beam, photodetector means for receiving the light beam after passing through or being reflected within living tissue and arranged to provide signals corresponding to the intensities of the respective wavelength of light received by the photodetector means characterised in that the sensor device measures blood oxygen saturation. The device can be used in conjunction with a conventional pulse oximeter. There is also described a method of measuring blood oxygen saturation.		

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OPTICAL DEVICE

This invention relates to an optical device for monitoring or measuring/displaying the arterial oxygen saturation with motion artefact suppression and to a novel medical
5 technique for providing arterial oxygen saturation data.

Monitors are available which use non-invasive optical techniques to measure the arterial oxygen saturation in patients. For example, it is known, that in order to measure blood oxygen saturation, it is necessary to provide a device which passes
10 light through biological tissue, such as the human finger, and to monitor the transmitted or reflected output signal from a photodetector of this device continuously. Such devices are described, inter alia, in International Patent Application No WO94/03102.

15 As is well known in the art, these instruments suffer interference due to patient movement, i.e. motion artefact.

Movement of the subject leads to a change in the length of the path of the light through the biological tissue and hence to a variation in the intensity of light received
20 by the photodetector. This renders the device incapable of distinguishing between changes in received light intensity caused by variations in light absorption by the component being monitored (eg oxygen in the blood), and changes in received light intensity caused by variations in the light pathlength due to movement of the subject. The problem is common to all optical monitoring devices and can render these
25 devices inoperative for long periods of time. The problem is particularly severe in critical health care applications, where continuous monitoring is essential.

The device described in WO 94/03102 attempts to address the problem of the motion artefact in measuring SaO_2 by using an additional wavelength to enable the motion
30 artefact to be cancelled. Although WO 94/03102 broadly describes the use of a plurality of wavelengths (including the $n+1$ motion artefact wavelength) the device

exemplified uses three wavelengths, namely, a pulse rate wavelength, an SaO_2 wavelength and a motion artefact wavelength. However, in practice, the three wavelengths proposed in WO 94/03102 are not sufficient to overcome motion sensitivity.

5

Generally, medical practitioners desire to measure arterial oxygen saturation (SaO_2). For example, conventionally used pulse oximeters measure SaO_2 . We have now devised an optical measuring or monitoring device which is able to monitor or measure blood oxygen saturation (SO_2) and display the arterial blood oxygen saturation non-invasively and to suppress the effects of motion artefact.

10

Furthermore, existing optical devices do not take into account the variations in transmitted light with varying skin colours. Melanin is present in increasing concentrations from fair through brown to black skin. The peak of its absorption spectrum is at 500nm decreasing almost linearly with increasing wavelength. Melanin is present in the epidermis, thus, in very high concentrations as is the case in black skin, it can mask the absorption of haemoglobin in the dermis. Even in brown skin, the absorption by melanin is superimposed on that of haemoglobin so that any algorithm which uses the shape of the absorption spectrum in order to produce SO_2 value needs to compensate for this fact.

15

20

Thus, we have also devised an optical measuring or monitoring device which is capable of compensating for variations in melanin levels in the skin.

In accordance with this invention, there is provided a sensor device which comprises light source means for emitting a light beam, photodetector means for receiving the light beam after passing through or being reflected within living tissue and arranged to provide signals corresponding to the intensities of the respective wavelength of light received by the photodetector means characterised in that the sensor device measures blood oxygen saturation.

30

The sensor of the invention may use a spectral wavelength of from 526 to 586 nm.

In a preferred embodiment of the invention the light beam will emit a plurality of wavelengths, the arrangement being such that the signal levels corresponding to the
5 different wavelengths bear a predetermined relationship with each other. A particular advantage of the sensor of the invention is that it only enables a user to compare "slopes" on a graph and the use of a range of different wavelengths allows for a more accurate determination without an increase in costs. In a preferred embodiment of the invention 3 or more different wavelengths are used, the optimum number of
10 wavelengths is 5 or 6 and preferably 6.

It is also an important feature of the present invention that at least one or more of the wavelengths used are isobestic wavelengths. For the sake of clarity, by the term isobestic wavelength we mean a wavelength at which oxygenated haemoglobin and
15 deoxygenated haemoglobin absorb the same amount of light. In a preferred embodiment substantially most of the wavelengths used are isobestic wavelengths. When six wavelengths are used it is preferred that five of them are isobestic wavelengths. In this preferred embodiment the sixth wavelength is one at which there is maximum difference between the absorption of light of oxygenated
20 haemoglobin and deoxygenated haemoglobin.

Generally the device and technique of the present invention measures oxygen saturation (SO_2) ie the value of oxygen saturation in venous and arterial tissue combined. Because oxygen saturation in venous tissue is usually low it is well
25 known that the value of SO_2 is less than that of SaO_2 . In the technique of the invention we call the difference the scaling factor Δ , such that

$$SaO_2 - SO_2 = \Delta$$

30 Thus the technique of the invention initially measures SaO_2 using a conventional arterial blood oxygen meter eg a pulse oximeter. SO_2 is then measured to determine

and thus subsequently SO_2 measurements made using the device of the invention are corrected by the value of Δ . Furthermore, the device and technique of the invention continually, although intermittently, allows SaO_2 and thereby Δ to be checked.

- 5 The sensor device of the invention is generally an optical measuring or monitoring device.

The sensor may be attached to the chest or abdomen of an infant. The tip of the sensor may incorporate a mirror and is provided with an optical fibre light
10 transmitting cable such that the fibre cable lies flat on the surface of the skin. White light (20 to 50W quartz halogen light bulb) is preferred and is transmitted along an optical fibre to the skin where multiple scattering occurs as photons interact with cellular and subcellular particles. Light can be absorbed by the haemoglobin present in the blood flowing in the tissue below the sensor before being scattered back along
15 receiving optical fibres. The scattered light can be transmitted along a plurality eg in the preferred embodiment 6 separate fibres to 6 photodetectors via narrow-band optical filters all in the range 500 to 600nm (green/yellow visible light) and especially between 526 and 586. Generally, the number of detectors should be the same as the number of transmitting fibres. The sensor may optionally be heated
20 above normal body temperature, to eg 40°C and up to 42°C for short periods the temperature may even reach 44°C. Alternatively, a single fibre of from 50 to 150nm in diameter may be used with one to three white LEDs.

Although the sensor of the invention may be adapted to operate with either
25 transmitted light or reflected light, it is preferred that it operates on reflectance (remittance). Thus in contrast to, eg a pulse oximeter the transmitters and the sensors are situated on the same side of the tissue when in use.

According to a further feature of the invention we provide a "hand held" sensor
30 device as hereinbefore described.

In particular, in the "hand held" sensor of the invention the optical fibre transmitting cable(s) may be replaced by a light emitting diode (LED) which significantly reduces the complexity of the sensor.

- 5 Before use, the sensor is normalised against darkness and a standard white surface, and the signal from each photodiode is measured to obtain the overall dark and "white balance" figures. Signal processing includes averaging for a period between 10 milliseconds to 10 seconds, subtracting the white balance signal, and taking a logarithm to produce a transmittance at each wavelength.

10

- In the preferred embodiments, the use of 6 wavelengths gives the technique a considerable advantage over the pulse oximetry method which uses the minimum number of wavelengths necessary to obtain the information required. The use of more wavelengths in our method gives the technique stability against spurious
15 disturbances at a particular wavelength, enables flexibility in the algorithm to cope with factors such as skin colour. Nevertheless, the sensor of the invention can utilise either oximetry or pulsed oximetry.

20

Averaging of the signal over a second or more also removes motion artefacts. It is also the case that the technique operates in the visible wavelength range. Thus, although the penetration of light into tissue is much less, the influence of poor contact with the tissue may also be considerably less thus reducing movement artefact. It is important to emphasis that our technique does not measure pulsatility as in the case in pulse oximetry.

25

SO_2 is the ratio of the oxyhaemoglobin concentration $[HbO_2]$ to the total concentration of haemoglobin ($[HbO_2] + [Hb]$, where $[Hb]$ is haemoglobin concentration) expressed as a percentage.

$$SO_2 = \frac{[HbO_2] \times 100}{[HbO_2] + [Hb]}$$

5 SO_2 is arterial oxygen saturation

The reflected absorptions (A) at six wavelengths (500, 528, 550, 560, 572 and 586 nm) are used to calculate two parameters HbI and OXI:

$$10 \quad HbI = (A_{528} - A_{520}) + (A_{550} - A_{528}) + (A_{572} - A_{550}) - (A_{586} - A_{572})$$

$$OXI = ((A_{550} - A_{500}) + (A_{572} - A_{560})) / HbI$$

SO_2 is calculated from the formula:

$$15 \quad SO_2 = 100 = (OXI - OXI_o) / (OXI_{100} - OXI_o)$$

Where OXI_o and OXI_{100} are empirically determined values for OXI at SO_2 values of 0% and 100% in skin. HbI is the haemoglobin index such that

$$20 \quad HbI \times k = [Hb]$$

where k is a constant.

The spectral range used for the algorithm is from 526 to 586nm and 22 absorption
25 values are recorded within that range. The first process is to carry out a Kubelka and Monk transformation which reduces the intrinsic effect of the scattering of light within the skin.

The following operation is carried out:

30

$$K-B \text{ Transformed spectrum} = 0.5 \times (R^2)/(1-R)$$

where R is the remitted spectrum (Reference: Kubelka, P and Munk F, Ein
 eitrag zur Optik der Farbanstriche, Zeitschrift fur technische Physik, 11a:593-
 601 (1931)).

5

In a paper presented by Wolfgang Dümmler in 1988, he describes that, according to
 the Kubelka-Munk theory (see Section II.2), the remission of an infinitely thick
 sample is dependent only on the quotients of absorption and scattering coefficients
 and is given by:

10
$$R_{\infty} = A/S + 1 - \sqrt{\{A/S (A/S + 2)\}}$$

The equation can be solved explicitly according to A/S

$$A/S = 0.5 (R_{\infty} + 1/R_{\infty}) - 1$$

15 where R is the remitted spectrum that is the spectrum of light scattered back
 from the skin.

The transformed spectra are then “straightened” by subtracting the interpolated
 straight line joining the absorption values at the isosbestic wavelengths of 526 and
 20 586nm. This, in part compensates for the melanin concentration.

The straightened spectra are normalised by division by the integral of the absorption
 values from 526 to 586nm.

25 The algorithm can make use of two reference spectra. These spectra may be from
 whole blood (measured in a cuvette) or spectra recorded in skin or the mean spectra
 recorded from several individuals. One reference spectrum is of fully oxygenated
 haemoglobin the other is of fully deoxygenated haemoglobin. The fully oxygenated
 spectrum is obtained by equilibration of whole blood in the cuvette with 95% oxygen
 30 and 5% CO₂ at 37°C or, in skin of the forefinger heated to 44°C at maximal reactive
 hyperaemia following release of the inflatable cuff after 6 minutes of brachial artery

occlusion. The fully deoxygenated spectrum is obtained by equilibration of whole blood in the cuvette with 95%N₂ and 5% CO₂ at 37°C or, in skin of the forefinger heated to 44°C at the end of a 6 minute period of brachial artery occlusion prior to release of the inflatable cuff. The reference spectra are K-M transformed,
5 “straightened” and normalised as described above.

An iterative process sequentially “mixes” the two references spectra in increments of 1% until the best least squares fit is achieved with the measured spectrum using all the absorption values at the 22 wavelengths. The iteration typically starts by adding
10 100 parts of the fully oxygenated spectrum to 0 parts of the fully deoxygenated spectrum, then 99 parts of the fully oxygenated spectrum to 1 part of the fully deoxygenated spectrum and so forth until the sum of the squares of the differences between the measured absorption values and those obtained by combining the reference spectra reaches its minimum value. The resultant SO₂ value is the
15 proportion of the oxygenated reference spectrum in the best fitted spectrum (eg 80 parts of the fully oxygenated spectrum with 20 parts of the fully deoxygenated spectrum would give an SO₂ value of 80%).

A maximum limit on the least squares value is stipulated such that noise or artefacts
20 in the recorded spectra lead to the rejection of the SO₂ value.

A further important aspect of this invention is the fact that our technique measures arterial blood oxygen saturation. This is achieved in the following way: at normal skin temperature an optical measurement made on the skin of a patient would
25 measure the oxygen saturation of a mixture of venous and arterial blood in the capillaries. In our technique we heat the skin below the sensor to below 40°C. The effect of this application of heat is to cause an increase in skin blood flow, sufficient to cause the oxygen saturation of the blood in the capillaries in the skin to equilibrate with the arterial blood supply. In this way the optical device will measure the
30 equivalent of arterial blood oxygen saturation.

According to a further feature of the invention we provide a method of monitoring of SIDS in infants which comprises attaching a calibrated sensor as hereinbefore described to the skin of a patient and emitting white light, detecting and measuring the scattered light.

5

According to a further feature of the invention we provide a sensor device which measures SO_2 as hereinbefore described coupled to an oximeter eg a pulse oximeter, which is conventionally known per. The sensor device of this embodiment will measure SO_2 , while the pulse oximeter will measure SaO_2 , at least intermittently, and allowing the scaling factor Δ to be calculated and intermittently monitored. Thus the sensor device of this embodiment measures SO_2 but displays SaO_2 .

10

Thus according to a yet further feature of the invention we provide a method of SaO_2 monitoring which comprises measuring SO_2 and adding a scaling factor Δ as hereinbefore defined.

15

The method of the invention preferentially comprises the use of a sensor device of the invention. In the most preferred method, the sensor is used to continually measure SO_2 and to intermittently measure SaO_2 allowing the motion artefact to be annulled.

20

In a further embodiment, the method of the invention as hereinbefore described includes the use of the Kubelka and Monk transformation to account for melanin levels in skin.

25

The invention will now be described by way of example only and with reference to the accompanying drawings in which Figure 1 is a schematic representation of the optical measurement method of the invention;

Figures 2(a) and 2(b) are both graphs which illustrate how the SO_2 values are calculated;

30

Figure 3 is a "hand held" sensor according to the invention;

Figure 4 is a representation of the schematic layout of the optical system of the sensor of the invention;

Figure 5 is a representation of the hand held sensor of the invention in use; and

5 Figure 6a to d are graphs representing measured SO_2 values for different skin colours.

With reference to Figure 1, an optical blood saturation sensor (1) comprises transmitting fibres (2) from a lamp (not shown) which transmit light to be reflected
10 from a mirror (3) onto the skin (4) of a patient where the light in proportions is absorbed and scattered or reflected depending upon the oxygen content of the haemoglobin and the wavelengths of light used. Reflected light (5) is detected by receiving fibres (6) and transmitted to a photometer (not shown).

15 The measurement technique can best be understood by reference to Figures 2(a) and 2(b). Analysis of the data to obtain an index of haemoglobin concentration and arterial oxygen saturation (SaO_2) is carried out as follows: the gradients between 5 isobestic wavelengths (500, 520, 548, 575 and 586nm) are added to given an index which is related to the haemoglobin concentration. This index is used to normalise
20 the measured tissue spectra. The oxygen saturation (SO_2) is calculated from the gradients between the absorption peaks for de-oxygenated haemoglobin (560nm) and the two adjacent isobestic wavelengths (548 and 575nm) of the normalised spectra.

The most important factor influencing the stability of the SaO_2 lies in our 6
25 wavelength analysis technique which incorporates the 5 isobestic wavelengths and the single oxygenated/deoxygenated peak. The two accompanying Figures illustrate how the HbI and SO_2 values are obtained from the spectra. HbI is the sum of the moduli of the slopes of the lines connecting the isobestic points as shown in the first Figure 2(a): it can be seen that any change in the general level of the signal, such as
30 may occur due to small changes in the distance of the probe from the skin would not

have any significant influence on this value. The absorption spectrum may shift up or down, but the sum of the moduli of the slopes remains constant.

SO₂ values (Figure 2(b)) are calculated from the sum of the moduli of the slopes of the extinction values between the neighbouring isobestic points and the deoxygenated peak, normalised to the HbI value. We thus obtain not only an SO₂ value but, on the way, we can also obtain a measure of relative haemoglobin concentration (HbI) from our measurements.

10 With reference to Figure 3 a hand held sensor (7) may comprise a fibre optic cable (8), a prism (9), an LED (10) and a heater and temperature sensor (11). The sensor (7) is provided with insulation (12).

With reference to Figure 4, a sensor (13) is provided with 6 fibre bundles (14), a light source (15) and a thermistor (16).

CLAIMS

1. A sensor device which comprises light source means for emitting a light beam, photodetector means for receiving the light beam after passing through or
5 being reflected within living tissue and arranged to provide signals corresponding to the intensities of the respective wavelength of light received by the photodetector means characterised in that the sensor device measured blood oxygen saturation.
2. A sensor device according to Claim 1 characterised in that the sensor a
10 plurality of wavelengths.
3. A sensor device according to Claim 2 characterised in that the sensor uses a spectral wavelength of from 500 to 600 nm.
- 15 4. A sensor device according to Claim 3 characterised in that the sensor uses a spectral wavelength of from 526 to 586 nm.
5. A sensor device according to Claim 2 characterised in that the different wavelengths bear a predetermined relationship with each other
20
6. A sensor device according to Claim 2 characterised in that the sensor uses 3 or more different wavelengths.
7. A sensor device according to Claim 6 characterised in that the number of
25 wavelengths used is 5 or 6.
8. A sensor device according to Claim 2 characterised in that at least one of the wavelengths is an isobestic wavelength.
- 30 9. A sensor device according to Claim 8 characterised in that most of the wavelengths are isobestic wavelengths.

10. A sensor device according to Claims 7 or 9 characterised in that five wavelengths are isobestic and one wavelength provides the maximum absorption difference between oxygenated haemoglobin and deoxygenated haemoglobin.
- 5
11. A sensor device according to Claim 7 characterised in that the number of wavelengths used are selected from 500, 528, 550, 560, 572 and 586 nm.
12. A sensor device according to Claim 7 characterised in that the scattered light
- 10 is transmitted along 6 separate fibres to 6 photodetectors via narrow-band optical filters all in the range 500 to 600nm.
13. A sensor device according to Claim 12 characterised in that the optical filters are all in the range 526 and 586 nm.
- 15
14. A sensor device according to Claim 7 characterised in that the scattered light is transmitted along a single fibre of from 50 to 150nm in diameter used with one to three white LEDs.
- 20 15. A sensor device according to Claim 1 characterised in that it operates on reflectance (remittance).
16. A sensor device according to Claim 1 characterised in that is a "hand held" sensor device.
- 25
17. A sensor device according to Claim 1 characterised in that it is coupled to an oximeter.
18. A method of SaO_2 monitoring which comprises measuring SO_2 and adding a
- 30 scaling factor Δ .

19. A method according to Claim 18 characterised in that the method includes the use of a sensor device of claim 1.

20. A method according to Claim 18 characterised in that the sensor is used to
5 continually measure SO_2 and to intermittently measure SaO_2 .

21. A method according to Claim 18 characterised in that the Kubelka and Munk transformation is used to account for melanin levels in skin.

10 22. A method according to claim 21 characterised in that the method involves the use of an algorithm;

$$\text{K-B Transformed spectrum} = 0.5 \times (R^2)/(1-R)$$

15 where R is the remitted spectrum,

and which involves the steps of measuring the remitted spectrum from a light source measuring arterial blood flow.

20 23. A method according to claim 18 characterised in that the method the sensor is normalised against darkness and a standard white surface, and the signal from each photodiode is measured to obtain the overall dark and "white balance" figures.

24. A method according to claim 18 characterised in that signal processing
25 includes averaging for a period between 10 milliseconds to 10 seconds, subtracting the white balance signal, and taking a logarithm to produce a transmittance at each wavelength.

25. A method according to claim 18 characterised in that more than 22 absorption
30 values are recorded within that range 526 to 586nm.

26. A method according to claim 18 characterised in that one reference spectrum is of fully oxygenated haemoglobin the other is of fully deoxygenated haemoglobin.

27. A method of monitoring of SIDS in infants which comprises attaching a calibrated sensor according to claim 1 to the skin of a patient and emitting white light, detecting and measuring the scattered light.

28. A data collection, processing and display system comprising the parameters of code number protection, sampling parameters, supply air flow rates, chamber pressure, exhaust air flow rates, top timer bar, bottom set-up bar and file identification bar.

29. A computer programme product adapted for absorption data collection, processing and display of SO_2 and SaO_2 levels.

15

30. A computer programme product according to claim 26 characterised in that the processing includes the use of the algorithm:

$$SO_2 = \frac{[HbO_2] \times 100}{[HbO_2] + [Hb]}$$

SaO_2 is arterial oxygen saturation

25 wherein the reflected absorptions (A) at six wavelengths (500, 528, 550, 560, 572 and 586 nm) are used to calculate two parameters HbI and OXI:

$$HbI = (A_{528} - A_{520}) + (A_{550} - A_{528}) + (A_{572} - A_{550}) - (A_{586} - A_{572})$$

$$30 \quad OXI = ((A_{550} - A_{500}) + (A_{572} - A_{560})) / HbI$$

and

SO₂ is calculated from the formula:

$$SO_2 = 100 = (OXI - OXI_o) / (OXI_{100} - OXI_o)$$

- 5 wherein OXI_o and OXI₁₀₀ are empirically determined values for OXI at SO₂ values of 0% and 100% in skin.

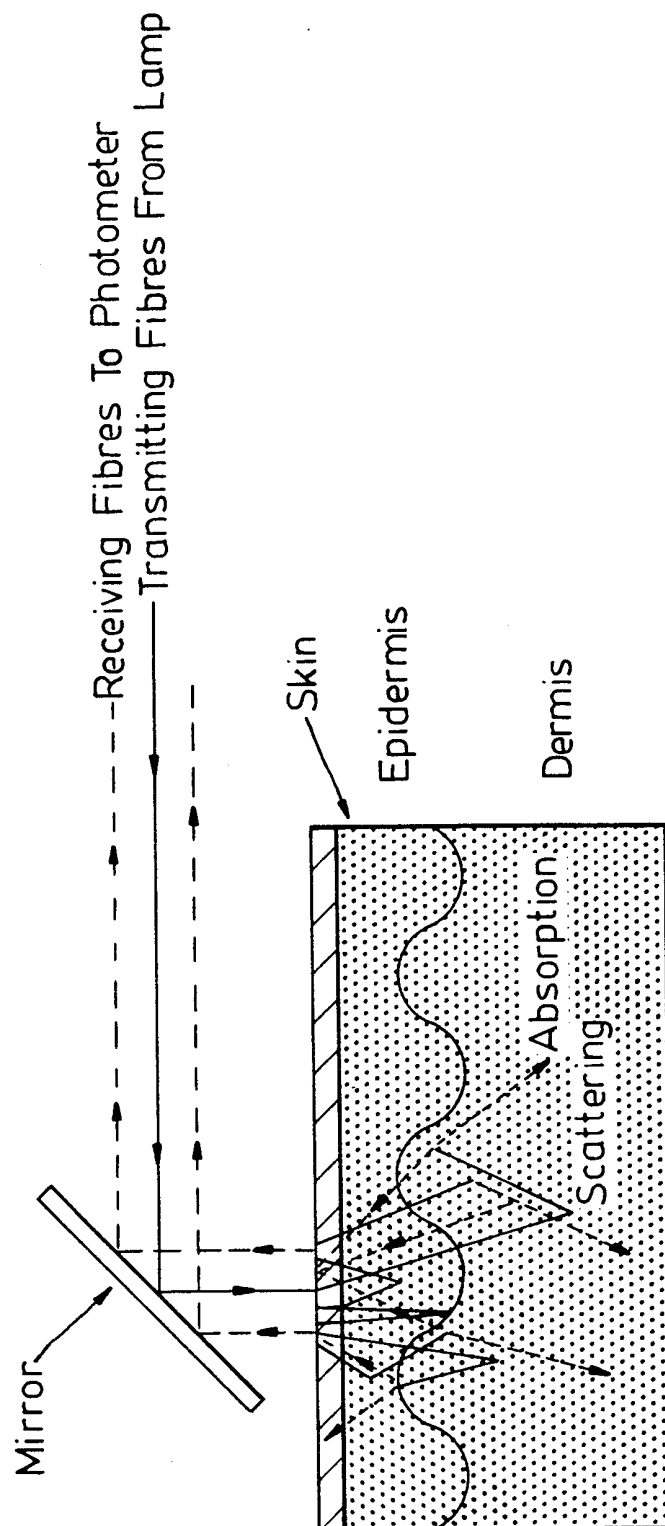
31. A sensor device programmed with a computer programme according to claim 26.

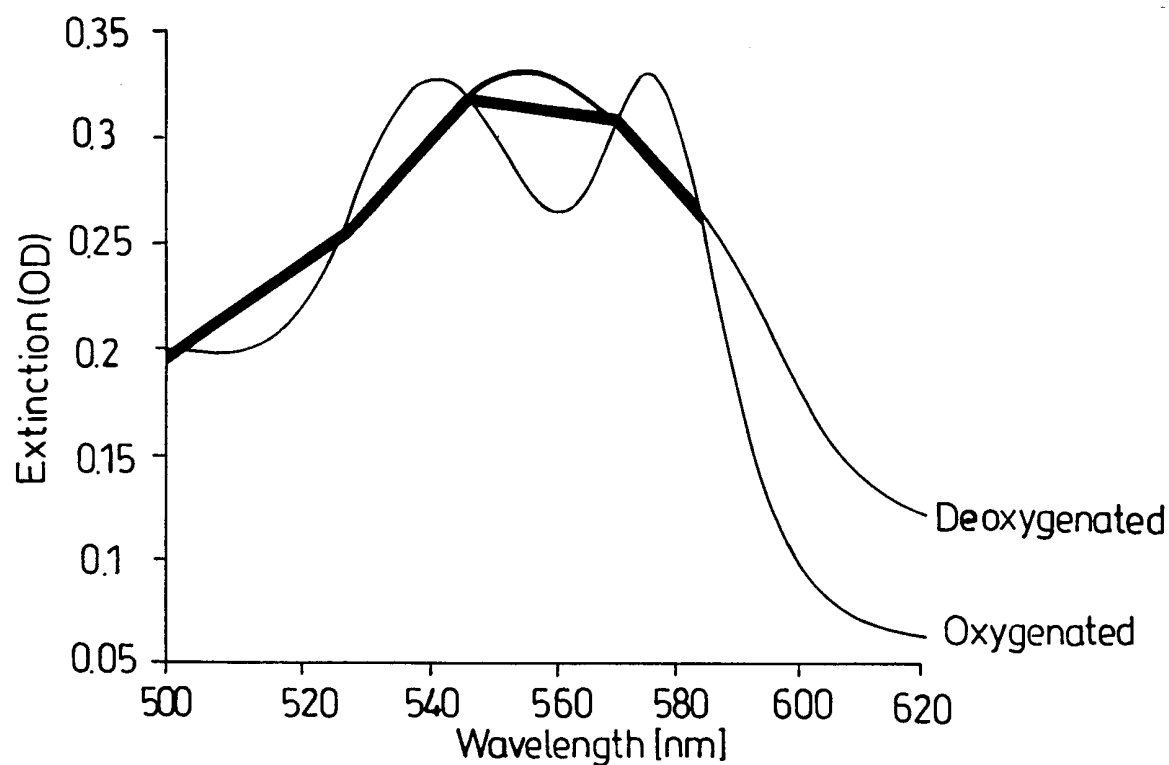
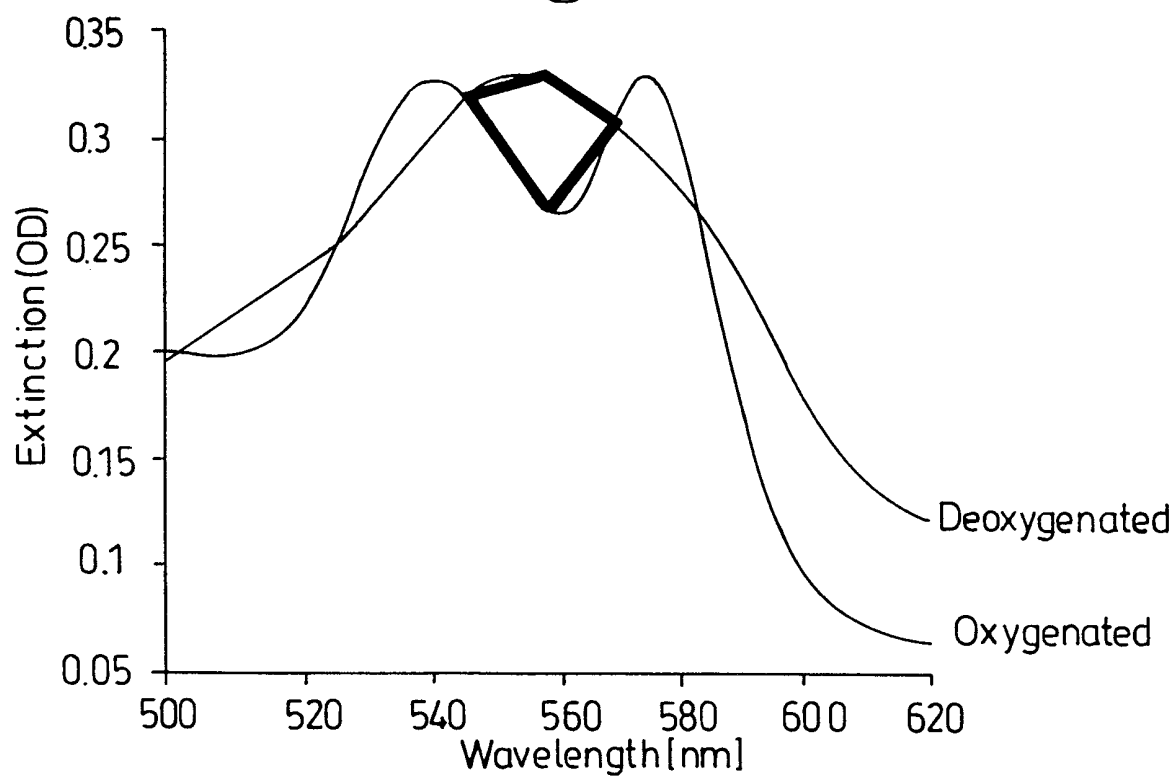
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32. A sensor device substantially as described with reference to the accompanying examples.

15

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*Fig. 1*

2/9***Fig. 2a******Fig. 2b***

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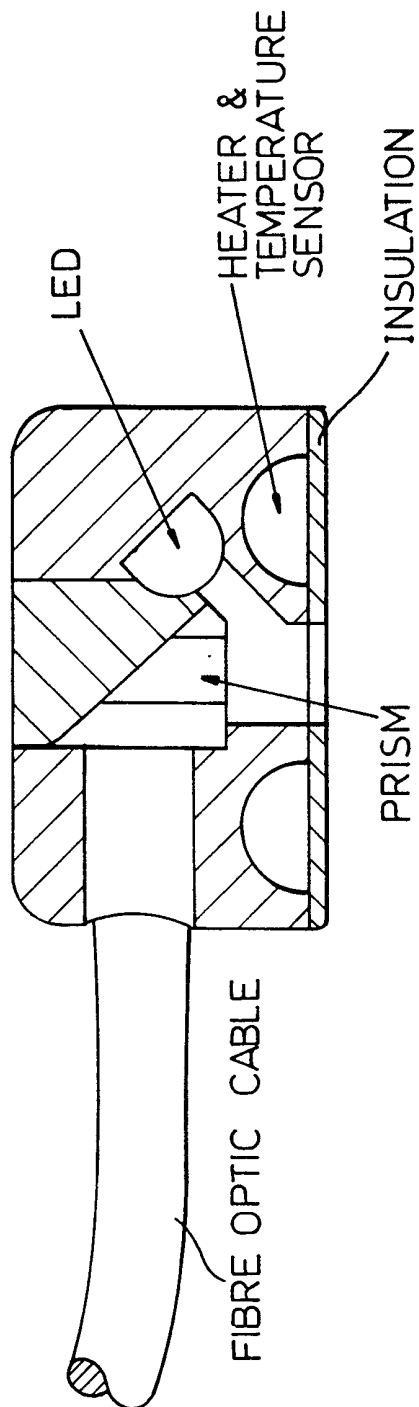
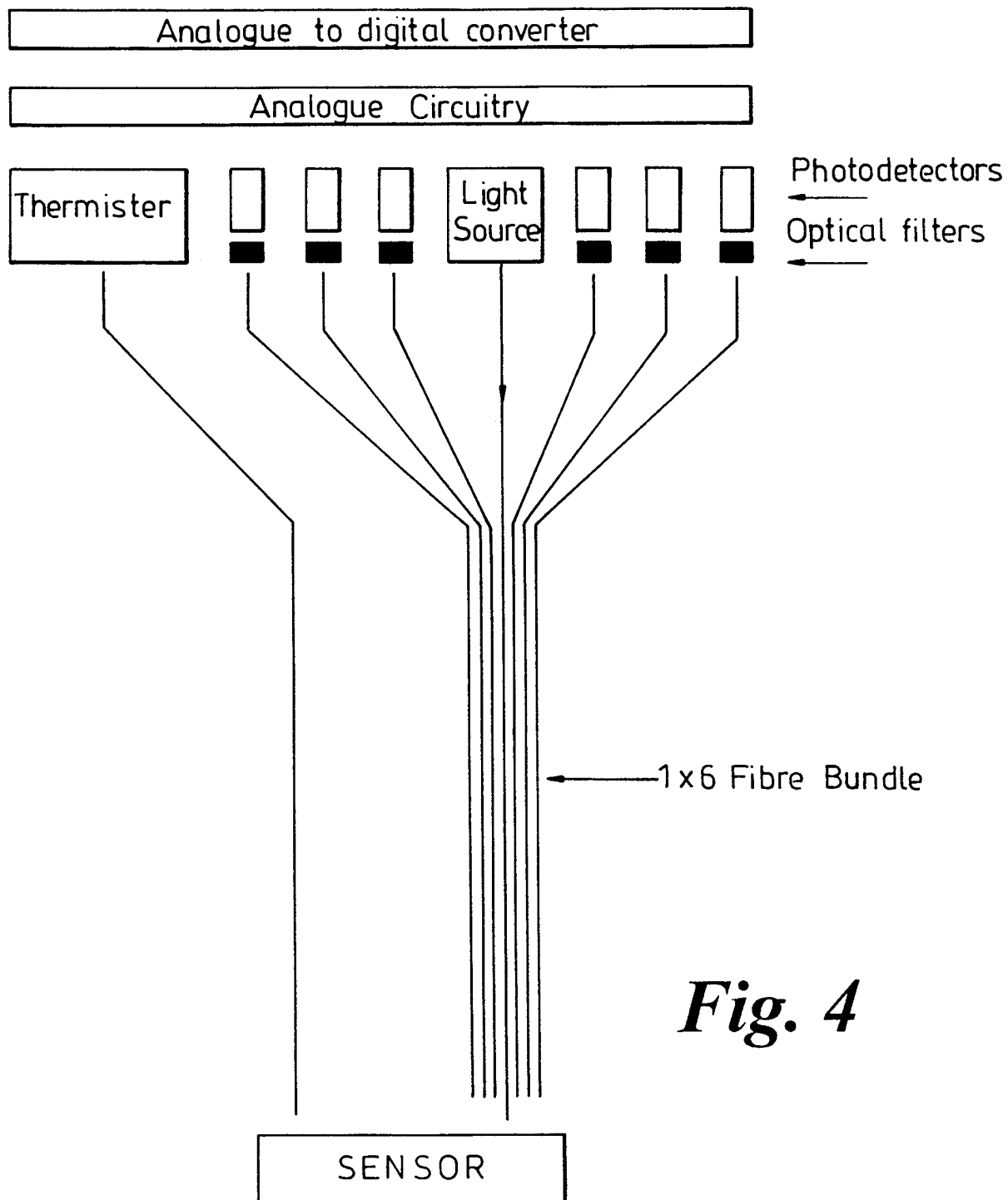
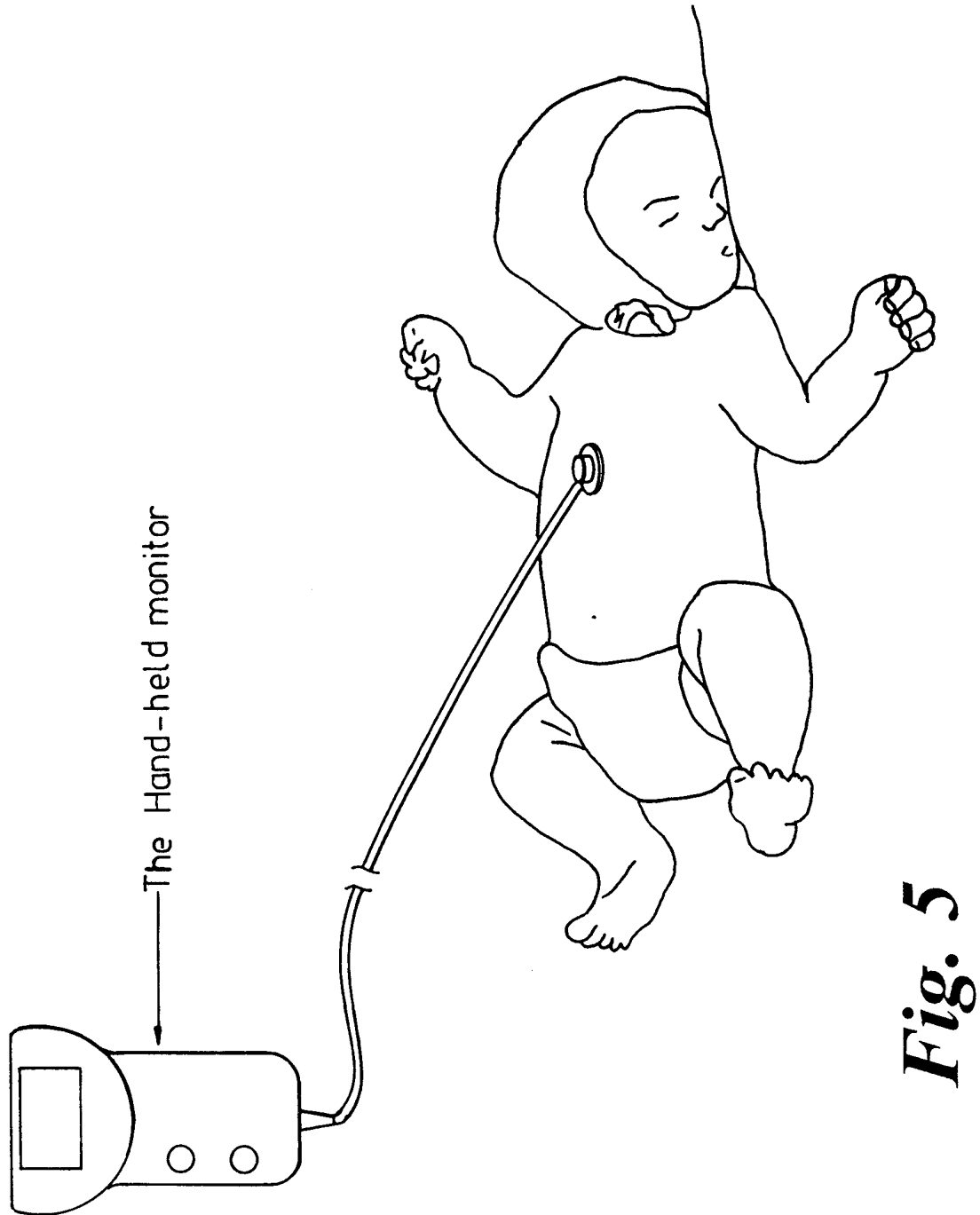


Fig. 3

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Iterative process using real blood to produce discrete spectra between 0% and 100%

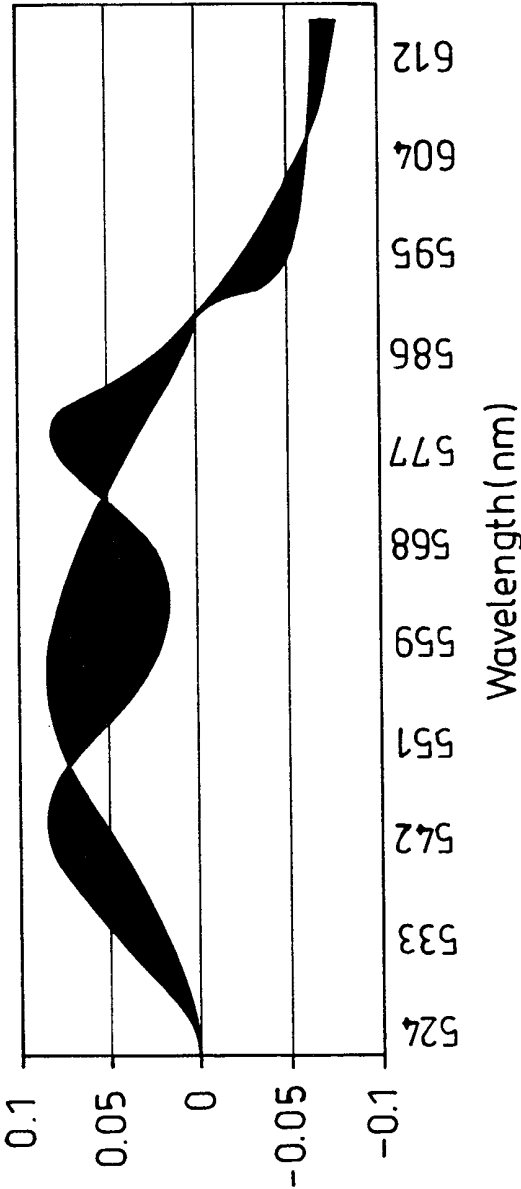


Fig. 6a

Dsat3 Indian skin Pulse oximeter against Least Squares
Fit and 6 wavelength method

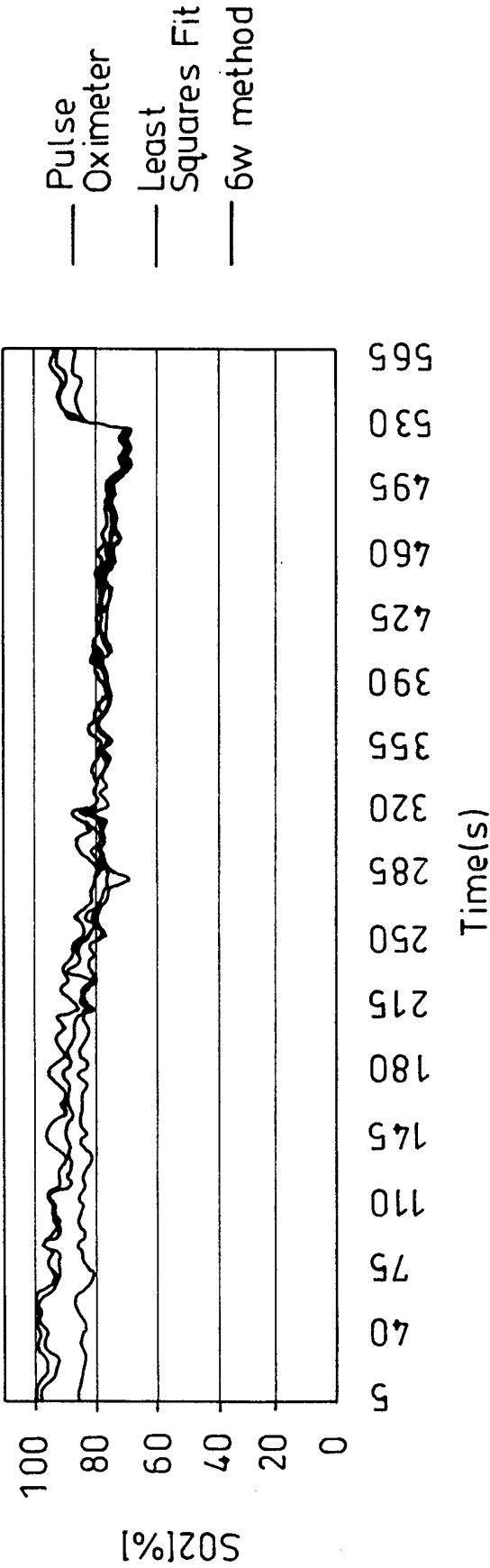


Fig. 6b

DSat4 His panic skin Pulse oximeter against Least
Squares Fit and 6 wavelength method

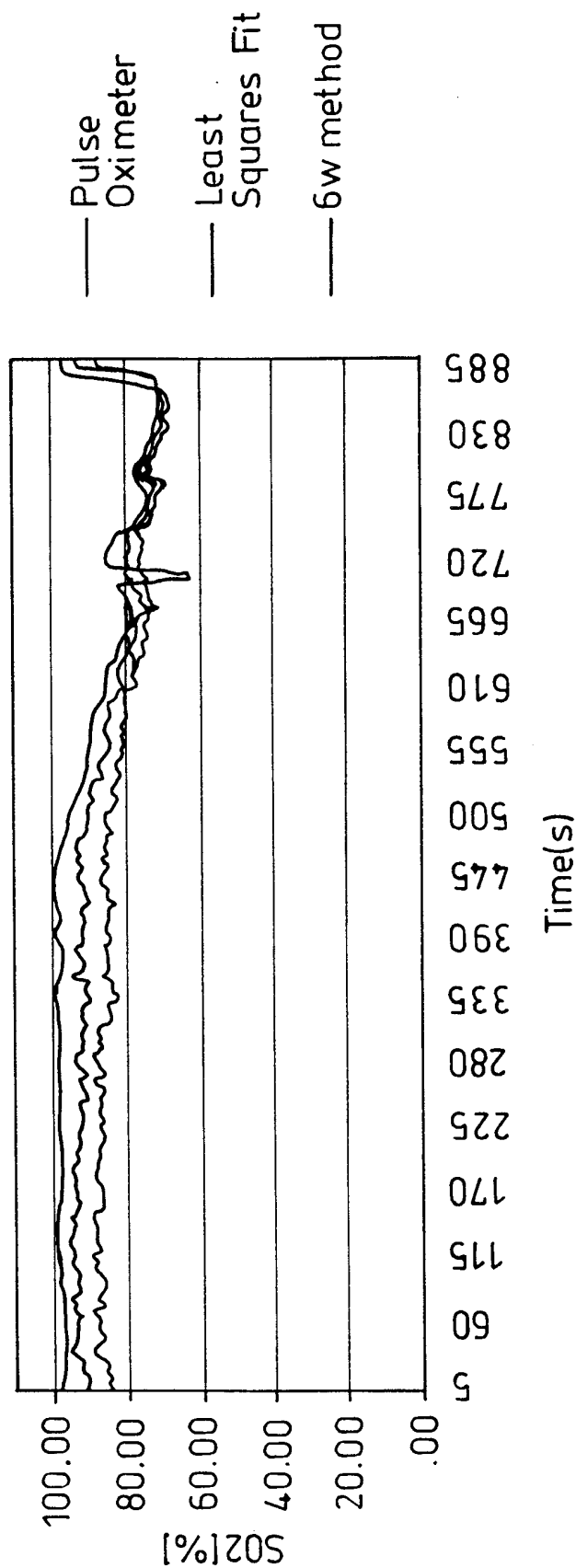


Fig. 6c

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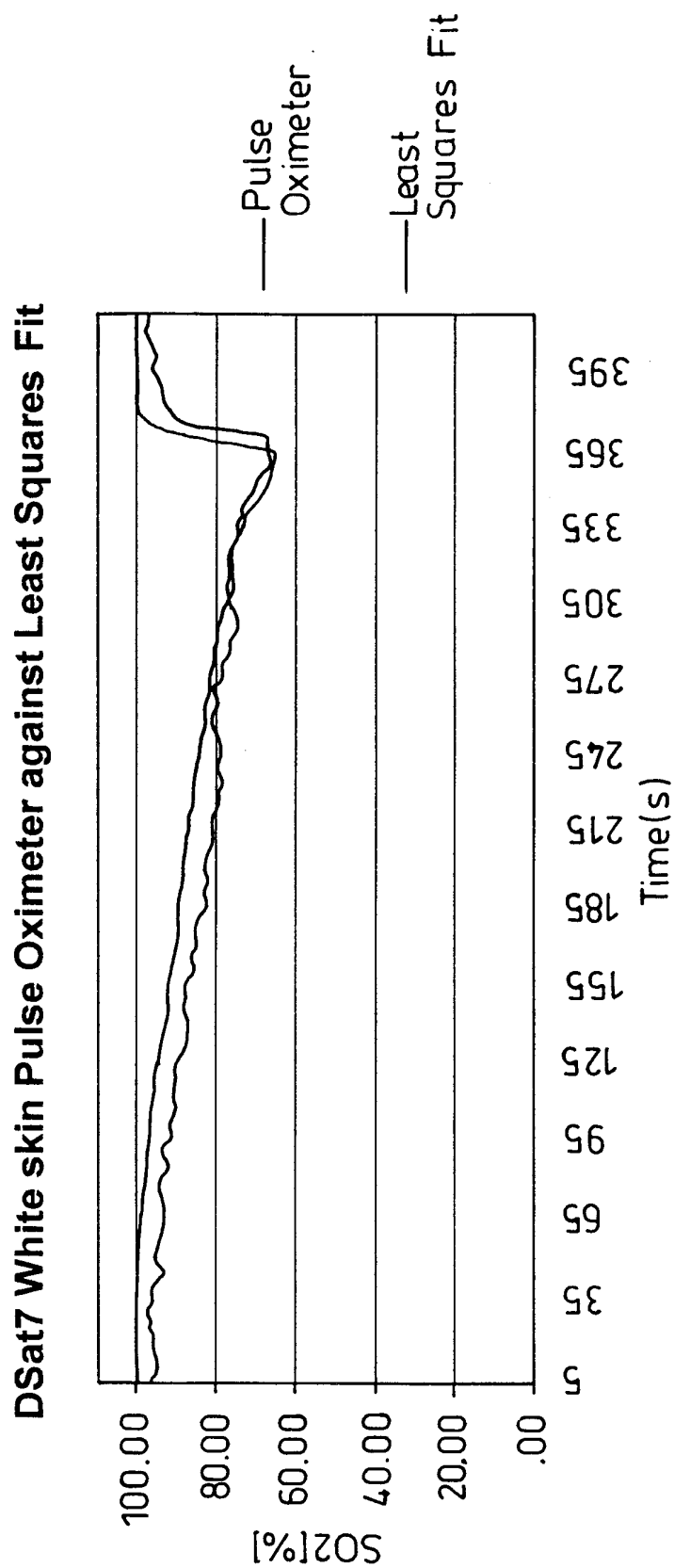


Fig. 6d