(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 March 2005 (10.03.2005)

PCT

(10) International Publication Number
WO 2005/020805 A1

(51) International Patent Classification^7: **A61B 5/00**

(21) International Application Number: PCT/CH2004/000552

(22) International Filing Date: 1 September 2004 (01.09.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/654,184 3 September 2003 (03.09.2003) US

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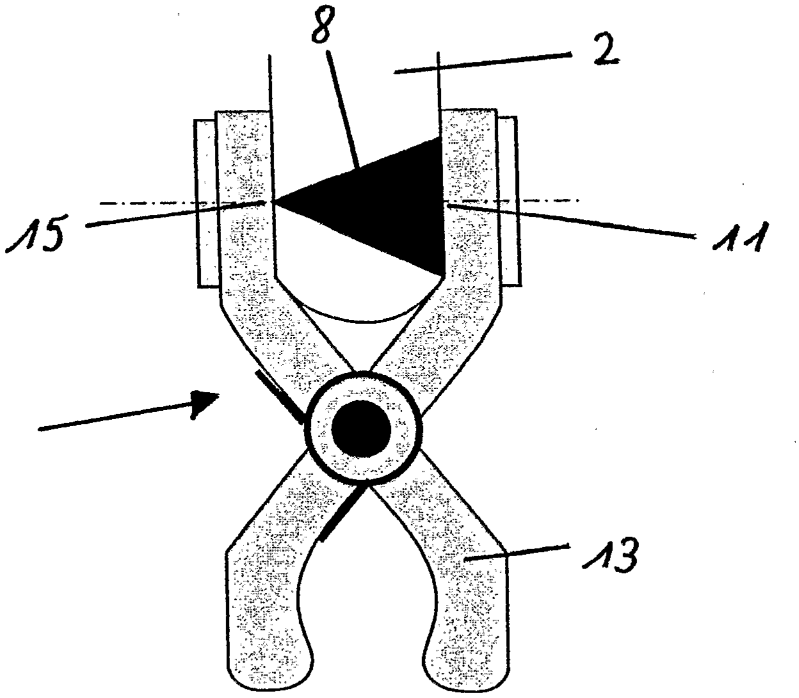
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: INCREASING THE PERFORMANCE OF AN OPTICAL PULSOXIMETER



(57) Abstract: Proposed is a configuration for the acquisition and/or monitoring of medical data, in particular the state of the cardiovascular an pulmonary system, blood values or blood composition, characterised by at least one measuring sensor for the acquisition of the medical data such as the state of the cardiovascular system, etc. of a person comprising at least one light source which can emit light at least at two wavelengths, as well as at least one light receiver for determining the light transmitted and/or reflected through a tissue portion of a person or an animal further comprising means in order to increase the optical Signal-to-Noise and/or Signal-to-Background ratio.

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Increasing the performance of an optical pulsoximeter

The present invention refers to a configuration for the acquisition and/or monitoring of medical data according to the introduction of claim 1 and a method for the acquisition and/or monitoring of the state of health or of medical data of a person or an animal.

The invention relates in particular to optical pulsoximetry used for non-invasive measurement of pulsation and oxygen saturation in arterial human or animal blood, and is particularly concerned with increasing the technical performance of pulsoximetry in terms of quality and robustness of the measurement signal versus environmental disturbances and energy consumption.

Pulsoximetry is a widely used standard optical technology for non-invasive monitoring of pulsation and oxygen saturation in arterial human or animal blood [1]. The method consists of measuring the absorption of reduced (Hb)- and oxidized (HbO_2) haemoglobin at two optical wavelengths, where the relative absorption coefficients differ significantly, e.g. 660 nm and a second wavelength in the range of 800 to 1000 nm, preferably 890 nm or 950 nm. A concise description of the measurement method and the sensor signals is given in [2].

Commercially available pulsoximeter sensors are typically used in hospitals and doctor's offices where the (optical) environment and mounting of the sensor onto the patient's skin are well defined. In the recent past pulsoximetry measuring devices and methods are also offered and used for mobile monitoring and surveying of human individuals, e.g.

suffering of diseases, such as heart problems, diabetes, respiratory diseases, insufficient oxygen blood saturation, etc. Pulsoximetry measuring devices are also used in sports for control and survey of athletes. Respective monitoring devices are described within the international patent application WO 02/089 663 which proposes in this respect to monitor in particular persons with cardio vascular disorders by means of pulsoximetry with measurements being taken by means of pulsoximetry preferably on an ear or on a finger. When using pulsoximetry in telemedicine or near patient testing applications, which means e.g. at self-controlling and self-testing of patients in non-ideal environment, standard pulsoximeter sensors suffer from signal instability and insufficient robustness versus environmental disturbances.

Critical points are:

- Human tissue scatters and transmits light in the visible and near infrared (NIR) wavelength range. Therefore, suppression of environmental optical radiation, e.g. sunlight, is difficult by geometric means of the architecture of the pulsoximeter sensor.
- The power spectrum of environmental optical radiation strongly varies as a function of time and place where the pulsoximeter is used, e.g. day versus night, indoor versus outdoor. Therefore, the background (offset) in the detected optical power varies in a large range, making difficult the analog and digital signal processing of the

primary sensor signal.

- The temporal spectrum of pulsoximeter signals varies in the range of 0.5 Hz to 5 Hz where environmental optical radiation may have significant components leading to parasitic contributions which cannot be separated from the pulsoximeter signals of interest.
- Realization of a performing electronic band pass filter in the range of 0.5 Hz to 5 Hz, in order to suppress DC offset and high frequency contribution in the pulsoximeter signal, is technically challenging. Further, optical contributions, e.g. temporally structured daylight, and electronic noise, e.g. 1/f (1/frequency-Noise), are stronger in the low frequency range 0.5 Hz to 10 Hz than in higher frequency ranges.

It is therefore an object of the present invention to define optical and/or electronic means for increasing the Signal-to-Noise ratio (S/N) and Signal-to-Background ratio (S/B) of a pulsoximeter sensor for robust application of pulsoximetry in telemedicine- and near patient testing applications in rough (optical) environmental conditions, e.g. at changing light influences, such as sunlight, shadow, artificial light, etc.

The posed problem is solved by means of a configuration/method according to the invention. Proposed is a configuration for monitoring which comprises at least one of the following components:

- at least one measuring sensor for the acquisition of the medical data, such as the state of the cardiovascular and pulmonary system, as e.g. pulsation frequency, oxygen saturation of blood, breathing frequency, etc. of a human being or an animal, comprising at least one light source which can emit light at least at two wavelengths, as well as at least one light receiver for determining the light transmitted through a tissue portion of the person or the animal; and

- at least one light baffle or light trap, respectively, and/or an optical wavelength filter which is adapted to the power spectrum of the light source and the absorption spectrum of human or animal arterial blood. The basic idea of using geometric baffles or light traps, respectively, and/or optical wavelength filters is to suppress by geometric and/or optical means the parasitic contribution of environmental radiation in order to increase or stabilize the S/B (Signal/Background) ratio vs. environmental conditions. The increase of the S/B ratio is e.g. estimated to a factor 10-100.

In addition to the above mentioned configuration, or as an alternative, a further configuration is proposed which comprises at least the following components:

- at least one measuring sensor on the person or the animal for the acquisition or the monitoring of medically relevant data, such as in particular data, which describe the cardio vascular and pulmonary function and/or contained data regarding blood values or blood composition, which sensor comprises at least one light source which can emit light at least at two wavelengths, as well as at least one light receiver for determining the light transmitted through a tissue portion of the person, and

- at least one light source frequency modulating means to frequency modulate the optical radiation of the light source at a carrier frequency in order to shift the power spectrum of the pulsoximeter signals. The basic idea of using AC-Coupling or Lock-In Amplification (synchronous detection), is to temporarily modulate the amplitude of the optical radiation of, e.g., the LED at a carrier frequency f_c in order to shift the power spectrum of the pulsoximeter signals into a higher frequency range where environmental optical radiation is unlikely and electronic band pass filtering is technologically less stringent. Thus, the pulsoximeter signals are readily discriminated from electronic and parasitic contributions of environmental optical radiation outside the frequency range of, e.g. f_c +/- 5 Hz, increasing significantly the S/N (Signal/Noise)- and S/B ratio.

Further specific designs of the configurations are described within the dependent claims.

Furthermore, the above mentioned problem is solved according to the invention by means of methods according to the invention. Proposed is a method for monitoring e.g. pulsation frequency, oxygen saturation in blood or breathing frequency, which comprises at least one of the following steps:

- measuring or monitoring medically relevant data of a person or an animal, such as in particular data, which describe the cardiovascular and pulmonary function and/or contain data regarding blood values or blood composition with the use of at least one measuring sensor, which sensor comprises at least one light source which can emit light at least at two wavelengths;

- receiving and detecting the emitted and shaped light with at least one light receiving element for determining the light transmitted through the tissue portion of the person or the animal.

In addition, it is further proposed to filter the emitted light by using geometrical baffles or light traps, respectively, and/or optical wavelength filters to suppress by geometric and/or optical means the parasitic contribution of environmental radiation.

In addition to the above mentioned method or as an alternative, it is further proposed to temporarily modulate the amplitude of the optical radiation of the light source by using e.g. AC-Coupling or Lock-In Amplification detection means. The basic idea of using AC-Coupling or Lock-In Amplification detection means is to temporarily modulate the optical radiation of, e.g., the LED at the carrier frequency f_c in order to shift the power spectrum of the pulsoximeter signals into a higher frequency range where an environmental optical radiation is unlikely and electronic band pass filtering is technologically less stringent.

Further preferred methods are described in the dependent claims.

Further preferred embodiment variants, in particular of an ear sensor employed for measurements by means of pulsoximeter, are found in the international patent application WO 02/089 663 which herewith is included as an integral component of the present patent application.

The invention will be explained in further detail by examples and with reference to the enclosed figures. Therein depicted:

Fig. 1	schematically the arrangement of an ear clip for oximetric measurement;
Fig. 2	schematically the ear clip of Fig. 1 in cross section view;
Fig. 3a	a diagram showing the light absorption curves of with oxygen saturated (HbO_2) and unsaturated (Hb) haemoglobin;
Fig. 3b	a diagram showing the spectrum sensitivity of a photo detecting element;
Fig. 3c	in a diagram the transmission spectrum of a double band pass filter;
Fig. 4a	in perspective view a part of an oximetric sensor with arranged baffles to avoid stray light;
Fig. 4b	the part of the sensor of Fig. 6a in longitudinal section;
Fig. 4c	an oximetric sensor in perspective view, containing optical lenses, filters and geometrical baffles;

Fig. 5a	a diagram showing power spectrum of physiological signals;
Fig. 5b	a diagram showing power spectrum of ambient light;
Fig. 5c	a diagram showing power spectrum of physiological signals and ambient light without phase shifting or modulation of the light source of a sensor;
Fig. 6	a diagram showing power spectrum of physiological signals and ambient light with phase shifting or modulation of the light source of a sensor;
Fig. 7	a principal of using band pass filtering means at a sensor with applied phase shifting or modulation of the light source at a sensor, and
Fig. 8a+b	a further fixing system for arranging a pulsoximetric sensor system as an alternative to a clip according to Figs. 1 and 2.

Fig. 1 shows schematically the arrangement of an ear sensor 1 which can be arranged in form of an ear clip. This sensor 1 can be arranged e.g. at an earlobe of ear 2. Furthermore, the sensor or ear clip is connected via a wire 3 and the connection 5 with the main unit 7 including e.g. a power source, like a battery, and measuring and/or monitoring electronics.

In Fig. 2, the ear clip 1 is shown in cross section where it can specifically be seen that the sensor is designed in form of a clip 13. The sensor or ear clip 13 furthermore includes a light source 15 which emits a light beam 8 to a light receiver 11. The light is guided or emitted through the ear skin or earlobe 2.

As already mentioned in the introduction, the sensor is working according to the oximetric principal which is known best out of the state of the art. Optical pulsoximetry is used for non-invasive measurement, e.g. for pulsation and oxygen saturation in the human body. The light source is emitting light at two wavelengths, at 660 nm and a second wavelength within the range of 800 to 1000 nm, which means in the present case at 890 nm. Therefore, it is of course also possible to have two light emitting sources arranged, which means two LEDs. The light receiver is determining the light transmitted through the earlobe, which means through the tissue portion of a person to be surveyed.

Within the main unit 7 the measured values can be compared with reference values being representative for a certain health status of the person to be surveyed.

Of course, the sensor can also be arranged at other parts of the human body, such as e.g. at a finger or a toe. In addition, the monitoring can also be executed at animals, which means that pulsoximetric sensors can also be arranged e.g. at the ear of animals, such as e.g. cows. According to an alternative design of the sensor, it could also be possible to arrange the light receiver in such a way so that the light reflected through the earlobe is determined. Again, according to a further alternative, it could even be possible by arranging at least two light receivers to determine the light transmitted through the earlobe and the light reflected by the earlobe.

To influence the sensor architecture of the pulsoximetric sensor, it is possible to use a light receiving or light sensitive element 11 with reduced light sensitivity outside the spectral range of the band limited light source as LEDs. Fig. 3a shows the light absorption curves of with oxygen saturated 22 and unsaturated 23 blood. As visible from the shown diagram, the sensor architecture, which means the spectrum sensitivity, should be in the range within approximately 500 nm to approximately 1000 nm. In addition, in Fig. 3a the two wavelengths λ_1 and λ_2 are indicated at which the pulsoximetric sensor is operated.

As a consequence, Fig. 3b shows the spectrum sensitivity of a silicon photo detecting element which is suitable for the use in a pulsoximetric sensor according to the present invention. As shown, the detection sensitivity is within a range of approximately 500 to 1000 nm. In other words, any light below or above this range would not be detected by the light receiving element with a sensitivity as shown in Fig. 5b. In addition, it is possible to arrange an optical wavelength filter or double pass filter which is e.g. light permeable at the wavelength of approximately 660 nm and in the range of approximately 850 nm to 910 nm. A corresponding transmission spectrum of such a double band pass filter will be suitably used in a pulsoximetric sensor as shown in Fig. 3c.

Preferably, the two means, as described with reference to Fig. 3b and c, are combined as wavelength filters might be also light permeable in lower wavelengths areas and higher wavelengths areas which, by using a selective light detecting element, can be eliminated.

As alternative to the described filters or in addition to the filters it is even possible to arrange a filter with a detection sensitivity in the range of approx. above 600 or preferably 630 nm. In other words, all light above 630 nm will pass the filter, while light with lower frequencies will be absorbed.

A further possibility for the better performance of a pulsoximetric sensor, is to arrange geometric means as e.g. so-called geometrical baffles (light trap). In figure 4a, a part of a pulsoximetric sensor is shown, which means the part of the sensor after the transmitted light has passed, e.g. the earlobe of a human or animal individual. Within the mentioned sensor part 31, after e.g. a double pass filter 33, circumferential extending baffles 37 are arranged to avoid stray light to reach the photo detecting element.

For any stray light which has entered the sensor e.g. before or at the area of the earlobe, will be trapped within the depressions of the baffles 37, and therefore will not substantially influence the emitted light of the LEDs.

Fig. 4b shows the part of the sensor of Fig. 4a in a longitudinal section. The stray light will be trapped substantially within the depressions of the baffles 37, while the emitted light by the LEDs will reach the optical sensor 35.

According to the preferred embodiment of the invention, the described optical and geometric means, such as the wavelength filters, the sensor architecture, and the mentioned baffles, can be combined as shown in principle and perspective view in Fig. 4c. Light is emitted from the two LEDs 15 to be guided as beams 12 through the earlobe 2. After the earlobe, the double pass filter 33 is arranged to guarantee that only light in the range of approximately 660 nm and in the range of approximately 890 nm is transmitted through the filter. After the filter, any stray light, entered the sensor e.g. trough the earlobe from the side, will be trapped within the baffles 37 which are arranged in circumferential direction. Finally, a photo detecting element 35 is arranged with specific spectrum sensitivity.

By using sensor architecture as shown in Fig. 4c, the Signal-to-Background ratio may be increased in a range of a factor 50 to 1000.

According to a further aspect of the present invention, it is furthermore possible to use a light source modulation to temporarily modulate the optical radiation of the LED.

The basic idea of using AC-Coupling or Lock-In Amplification (synchronous detection), is to temporarily modulate the optical radiation of the LED at the carrier frequency f_c in order to shift the power spectrum of the pulsoximeter signals into a higher frequency range where environmental optical radiation is unlikely and electronic band pass filtering is technologically less stringent. AC-Coupling or Lock-In Amplification is well known out of the state of the art and is described in literature 3.

Fig. 5a shows a spectrum of physiological signals, such as pulsation frequency, breathing frequency, etc. The frequency of physiological events is within the range of approximately 0.5 Hz (30 heartbeats in one minute) up to approximately 3 Hz (180 heartbeats in one minute) that can be even higher and therefore is supposed to go up to 5 Hz.

The frequency spectrum of ambient light is schematically shown in diagram 5b. Sunlight is at 0 Hz, while artificial light, such as e.g. electrical in-house light, is going up to approximately 120 Hz (USA). In other words, within the range of frequencies of physiological signals, we have high influence of frequencies of sunlight and ambient light. A corresponding combined frequency spectrum is shown in Fig. 5c, which would be detected by a photo diode without the use of any means as described above in relation to Figs. 1 to 4. Fig. 5c shows a basic signal contribution due to physiological signal and additional signal contribution due to ambient light. In other words, the influence of ambient light is quite substantial, and therefore the deviations of the measured values compared to the real values can be dramatic.

Besides the high influence of ambient light, also sunlight can have a dramatic influence, e.g. if a person is walking through streets with relatively quick changing conditions between sunlight and shadow. Another serious possibility is caused by a tree avenue when driving along the trees. Sunlight then is received e.g. by the pulsoximetric sensor at a certain frequency, which means that every time when passing a tree, sunlight is attenuated and between the trees sunlight is influencing the measurement of the pulsoximetric sensor.

As a consequence, it is therefore proposed to emit light by the LEDs not as current or continuous light but as pulsed light. The frequency is chosen in such a way that it is outside the frequency spectrum of sunlight and of ambient light which, according to Fig. 5b, is in the range of above approximately 1000 Hz. Thus, the pulsoximeter signals are readily discriminated from electronic and parasitic contributions of environmental optical radiation outside the frequency f_c +/- 5 Hz increasing significantly the Signal-to-Noise and Signal-to-Background ratio. Fig. 6 shows the shift spectrum of signal to a region where there is little influence, e.g. of ambient light. F_0 is the chosen frequency of the emitted light to operate the pulsoximeter sensor and the range between f_0 - 5 Hz and f_0 + 5 Hz is the consequence of the influence of the frequency due to physiological signal. Therefore, as shown in Fig. 8, the frequency spectrum of signal at the photo diode does have a basic signal contribution due to physiological signal. The signal contribution which is shown at the top of the signal contribution due to physiological signal and which is due to ambient light, is very small and as a consequence is approximately neglectable. Any noise or sunlight within the range of 0 to 120 Hz, while the light beam for the pulsoximetric measurement is within the range of approximately f_0 - 5 Hz to f_0 + 5 Hz, will not influence the measurement of the pulsoximetric sensor. F_0 could be e.g., as mentioned, 1000 Hz which of course is a frequency far outside of any indoor light source, as e.g. halogen light, conventional light, etc. f_0 of course can be chosen at any other frequency, as e.g. 2000 Hz or even higher. By using light source modulation, it is even possible to use an additional filter removing a certain frequency spectrum. Looking e.g. at Fig. 7, it is possible to arrange a filter band pass 51 which is e.g. removing any frequencies in the range of 0 to 120 Hz. The respective filter is shown in form of the dashed line 51. As a result, we end up by a diagram according to Fig. 9b only showing any measurements in the range of f_0 - 5 Hz to f_0 + 5 Hz.

Finally, after the measurements with pulse light have been executed, of course a reversed phase shifting or modulation has to be executed to calculate the real values of the Pulsoximetric measurement. Again, this reverse face shifting on modulation according to Lock-In technique is known out of the state of the art.

Again, it is of course possible to combine the light source modulation as described with reference to Figs. 6 and 7 with any of the prior means such as the sensor architecture, as shown with respect to Fig. 3 and 4.

By using one of the proposed devices or methods, respectively, according to the present invention or a combination thereof, it is possible to use pulsoximetric measurement or monitoring to survey the health condition of a person or an animal which is mobile. In other words, pulsoximetric measurement is not restricted for use in, e.g., a hospital but can also be used, if a person is travelling, is staying at home, etc. Furthermore, it is also possible to study health conditions of animals living in nature such as e.g. cows feeding outside.

Coming back to the fixing system, which means a clip as shown in Fig. 1 and 2, it has to be mentioned that when using a clip for fixing a pulsoximetric sensor, problems could occur due to strong movements of the human or animal individual or due to swelling or contracting of the human or animal tissue during the measurement with the pulsoximetric sensor. In other words, if e.g. an earlobe of an ear 2, as shown in Fig. 2, would swell, than the distance between the LED 15 and the photo detector 11 would increase and, what is even more critical, the beam path could divert substantially from the optical axis of the LED and the photo detector. Therefore, it is preferred to further provide means for stabilizing the signal guiding and detecting and to provide means for the beam path to be co-linear with the optical axis of the LED and the photo detector. Because of that, according to Fig. 8a and 8b, it is proposed to use a frame 61 which is stable and does not change its dimensions due to strong movements of an individual carrying the pulsoximetric sensor or due to swelling or contracting of the tissue to be monitored by the pulsoximetric sensor. In this case, of course, other means have to be provided, so that the distance between the LED 15 and the photo detector 11 can be adjusted or adapted to the thickness of the tissue to be monitored. Therefore, according to Fig. 10a, it is proposed that the LED 15 is arranged within a clamping mechanism 63 and that between the clamping mechanism 63 and the LED a screw connection 65 is arranged, so that the LED 15 can be moved into the clamping mechanism or out of the clamping mechanism 63. In other words, the distance between the LED 15 and the photo detector 11 can be adjusted along the optical axis 67 which guarantees that the beam path has always been co-linear with the optical axis 67 of the LED and the photo detector.

Comparing the clip mechanism according to Fig. 1 and 2 and the frame 61 as shown in Fig. 8a, it is obvious that in using a frame it is not easy to arrange or remove the pulsoximetric sensor to or from an earlobe of an ear, if required, e.g. if a person wearing the pulsoximetric sensor is taking a bath, a shower, etc. Therefore, it is proposed, as shown schematically in Fig. 8b, to use a snap-in mechanism 71, which means that the clamp mechanism 63 holding the LED 15 can be rotated e.g. in direction ot dashed line 73 around an axis 69 and removed from the frame 61 or vice versa can be arranged at the frame 61 by arranging within the axis 69 and within the snap mechanism 71. Therefore, the LED 15 has not to be rotated within the screw connection 65 between the clamp mechanism 63 for removing the frame 61 from an earlobe of an ear.

The invention, as described with reference to Fig. 1 to 8, is of course not limited to the examples as shown in Fig. 1 to 7, but can be differently designed combined with other features, etc. E.g. pulsoximetric measurements can also be done at other parts of the body like e.g. fingers or toes. In addition, not only one light source can be used for the measurement, but also two or even more light emitting sources. It is understood that also one, two, or more light receiving detectors can be used. All the various above mentioned and proposed means for improving the pulsoximetric monitoring to survey the health condition are not restricted to the measurement of transmitted light through a human or animal tissue. All the proposed means according to the present invention can be used, of course, also by measuring reflected light or as a combination of measuring reflected and transmitted light through a human or animal tissue.

Furthermore, all the above mentioned means for improving the measurement of the oxygen saturation of blood using a light source can, of course, also be used by any further kind of measurements using a light source such as, e.g., non-invasive monitoring of arterial carbon dioxide partial tension, the content of blood sugar, etc. In other words, for any kind of measuring blood properties using light emission through a human or animal tissue, the above mentioned means for improving the measurement can be used. This means that the present invention is not at all restricted to optical pulsoximetry used for non-invasive measure of pulsation and oxygen saturation in arterial human or animal blood.

The measured values can be transmitted via a wire connection or wireless, e.g. within the range of radio frequency. Well known these days is wireless transmission using "Bluetooth" technology. According to a further embodiment, the pulsoximetric sensor could be included within a hearing aid device.

Taking prior art into consideration, the measured values can be monitored at a special unit worn by the person or patient, respectively, where e.g. a signal is generated, if the measured value is not within a predetermined range. In other words, health problems could be detected and an alarm signal could be generated which can be transmitted to a respective person, to a medical doctor, to a hospital, etc. so that help can be organised. Furthermore, it is possible to include e.g. a so-called GPS device which at any time gives the location of the person using the pulsoximetric sensor monitoring configuration.

The priority document US 10/654 184 in an integral part of this application.

Claims

1. Configuration for the acquisition and/or monitoring of medical data, in particular the state of the cardiovascular and pulmonary system, blood values or blood composition, characterised by at least one measuring sensor for the acquisition of the medical data such as the state of the cardiovascular system, etc. of a person comprising at least one light source which can emit light at least at two wavelengths, as well as at least one light receiver for determining the light transmitted and/or reflected through a tissue portion of a person or an animal further comprising means in order to increase the optical Signal-to-Noise and/or Signal-to-Background ratio.

2. Configuration according to claim 1 comprising at least one light tray and/or optical wavelength filter.

3. Configuration according to claim 2, characterised in that the optical wavelength filter is an optical double band pass filter.

4. Configuration according to claim 2, characterised in that the light receiver has such a limited detection sensitivity that the two frequencies of the light source are within the sensitivity area of the receiver.

5. Configuration according to claims 1 to 4, characterised in that at least a wavelength filter and/or a light trap, such as geometrical baffles, are adapted to suppress, by geometric and/or optical means, the parasitic contribution of environmental radiation in order to increase and stabilise the signal/background ratio versus environmental conditions.

6. Configuration according to one of the claims 1 to 5, characterized in that at least a wavelength filter is arranged with a sensitivity such that only light with a frequency above 600 nm, preferably above 630 nm, can pass the wavelength filter.

7. Configuration according to claims 1 to 6, comprising light source amplitude modulating or light source modulating means to shift the frequency of the emitted light.

8. Configuration according to claim 7, comprising a light source amplitude modulating means to modulate the frequency of the emitted light in a frequency range substantially outside of frequency of noise and/or environmental signals.

9. Configuration according to claim 7 or 8, comprising means for light source amplitude modulation or light source modulating means to shift the frequency of the emitted light in a range where environmental disturbances are substantially neglectable.

10. Configuration according to one of the claims 7 to 9, comprising means for light source amplitude modulating or light source modulating means to shift the frequency of the emitted light in a range of above 120 Hz, preferably above 500 Hz.

11. Configuration according to one of the claims 1 to 10, comprising mechanical fixing means for arranging the configuration at a human or animal tissue as e.g. at an earlobe of an ear, the means guaranteeing that the beam path between the light emitter and the light receiver is

always co-linear with the optical axis of the light emitter and the light receiver.

12. Configuration according to claim 11, wherein the means for fixing include a rigid frame with two U- or V-like arranged arms, where in the area of the one arm end the photo detector is arranged, and at the area of the other arm end a clamping mechanism within the LED is arranged screwably connected to the clamping mechanism, so that the distance between the light receiver and the light transmitter can be varied in such a way that the beam path between the light emitter and light receiver always is co-linear with the optical axis of the light emitter and light receiver.

13. Configuration according to claim 12, wherein the arm of the frame wearing the clamp mechanism with the light emitter is removably attached to the frame, the connection between the frame and the removable arm being a snap-like mechanism to ensure that the removable arm is fixed to the frame in a constant, predetermined manner.

14. Pulsoximetric sensor, including a configuration according to one of the claims 1 to 13.

15. Method for measuring and/or monitoring of medical data, in particular the state of the cardiovascular and pulmonary system, blood values or blood composition, etc., characterised in that within a pulsoximetric sensor from at least one light source such as an LED, at least at two wavelengths, light is emitted, the light is transmitted and/or reflected through a tissue portion of a person or an animal and is received by at least one light receiver for

determining the light transmitted and/or reflected through the tissue portion, the light from the light emitting source, such as the LED or the LEDs, is directed through a light tray and/or an optical wavelength filter, wavelength filter preferably is an optical double band pass filter adapted to the power spectrum of the band limited light sources such as LEDs.

16. Method for measuring and/or monitoring of medical data, in particular the state of the cardiovascular and pulmonary system, blood values or blood composition, etc., characterised in that within a pulsoximetric sensor from at least one light source, such as an LED, at least at two wavelengths, light is emitted, the light is transmitted and/or reflected through a tissue portion of a person or an animal and is received by at least one light receiver for determining the light transmitted and/or reflected through the tissue portion, the at least one light source is pulsed operated with a phase shifting or modulation of the frequency, so that the frequency of the emitted light is in a range substantially outside of the frequency of noise and/or environmental signals, the pulsed light with the mentioned frequency is received by the, at least one, light receiver after passing through the tissue portion and finally a reversed phase shifting or modulation is executed to calculate the real values of the pulsoximetric measurement.

17. Use of the configuration according to one of the claims 1 to 13 for pulsoximetric measurements, which means for the non-invasive monitory of pulsation, oxygen saturation,

arterial carbon dioxide partial tension and/or content of blood sugar in arterial human or animal blood.

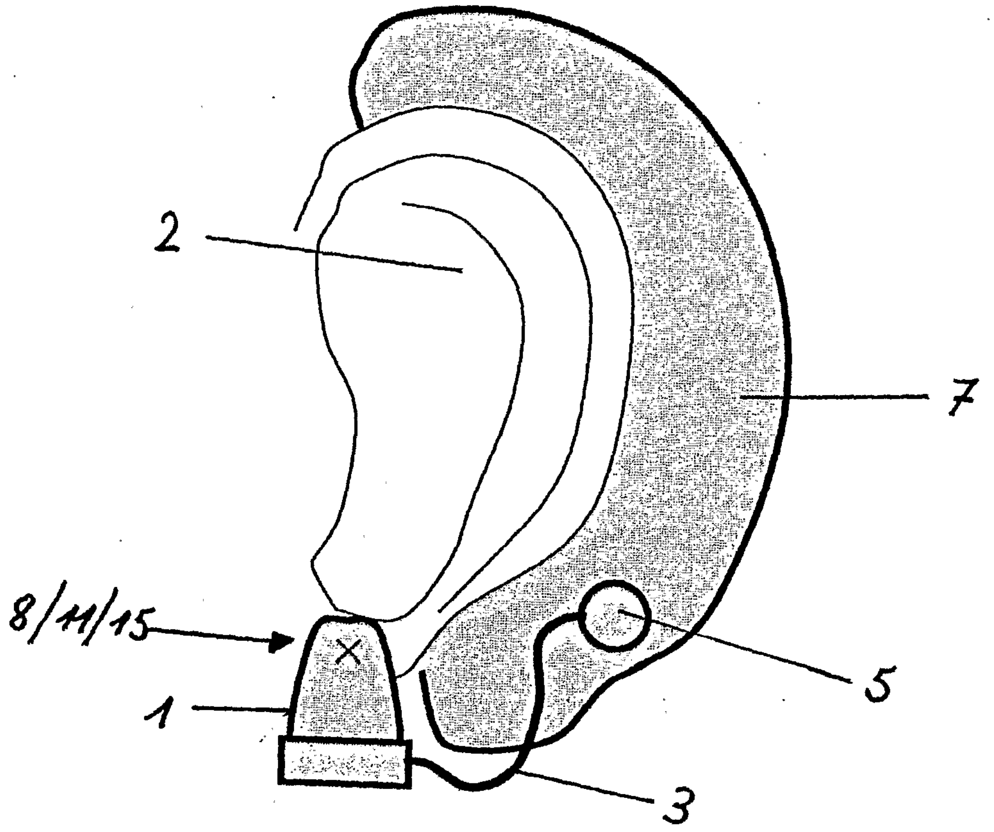


Figure 1

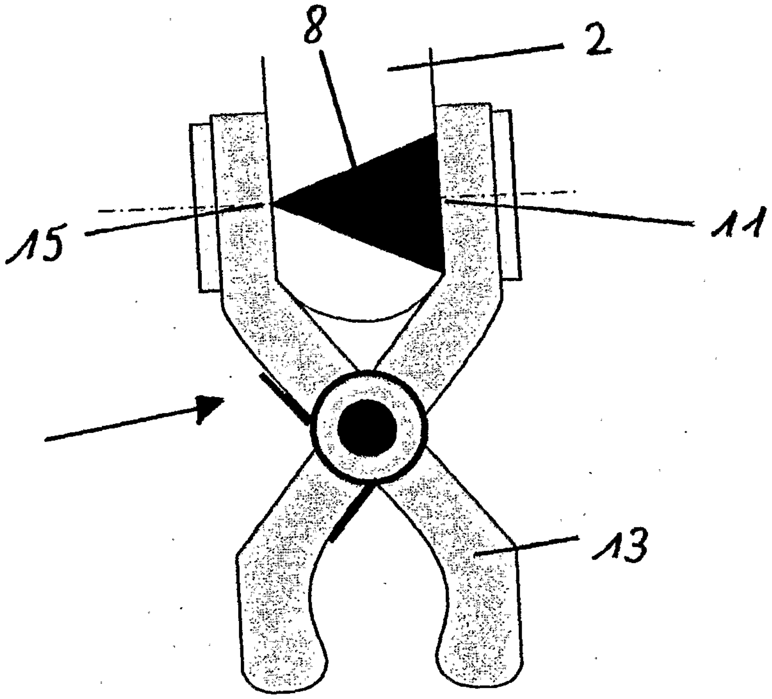


Figure 2

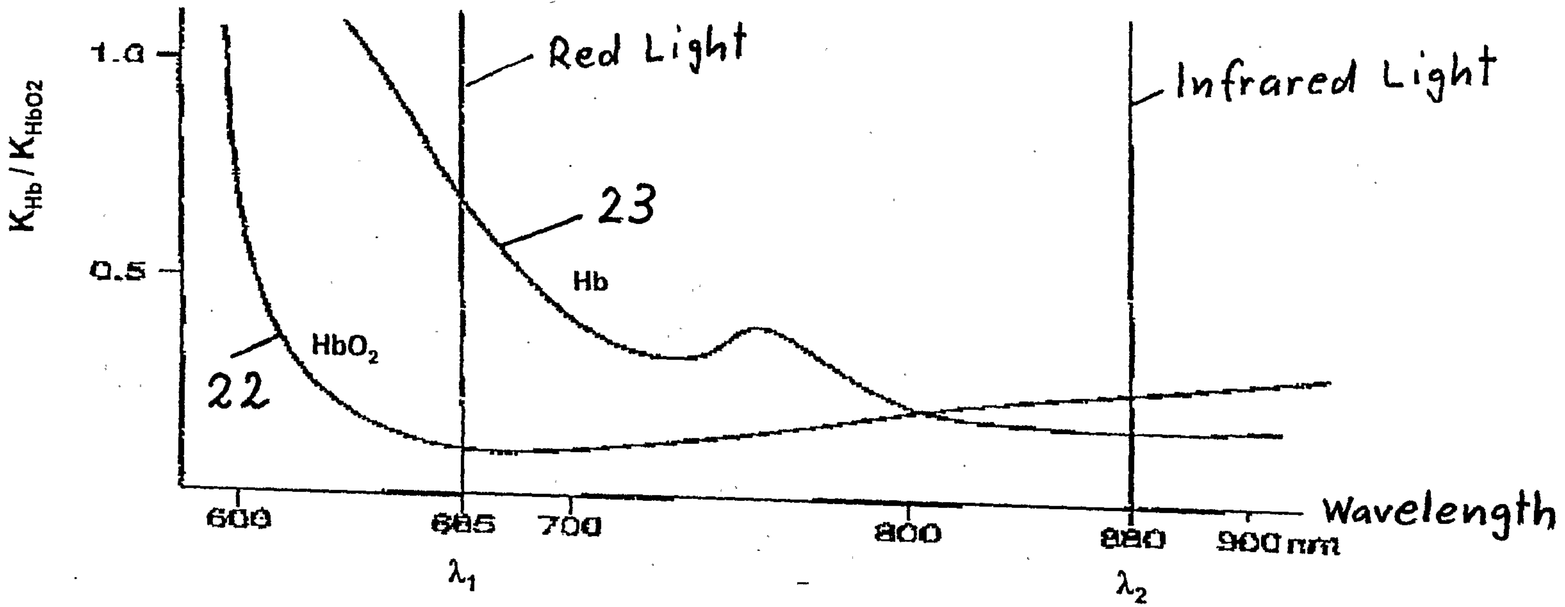

K_{Hb} / K_{HbO2}
1.0
0.5
Red Light
Infrared Light
23
Hb
22
HbO_2
600
685
700
800
880
900 nm
Wavelength
λ_1
λ_2

Figure 3a

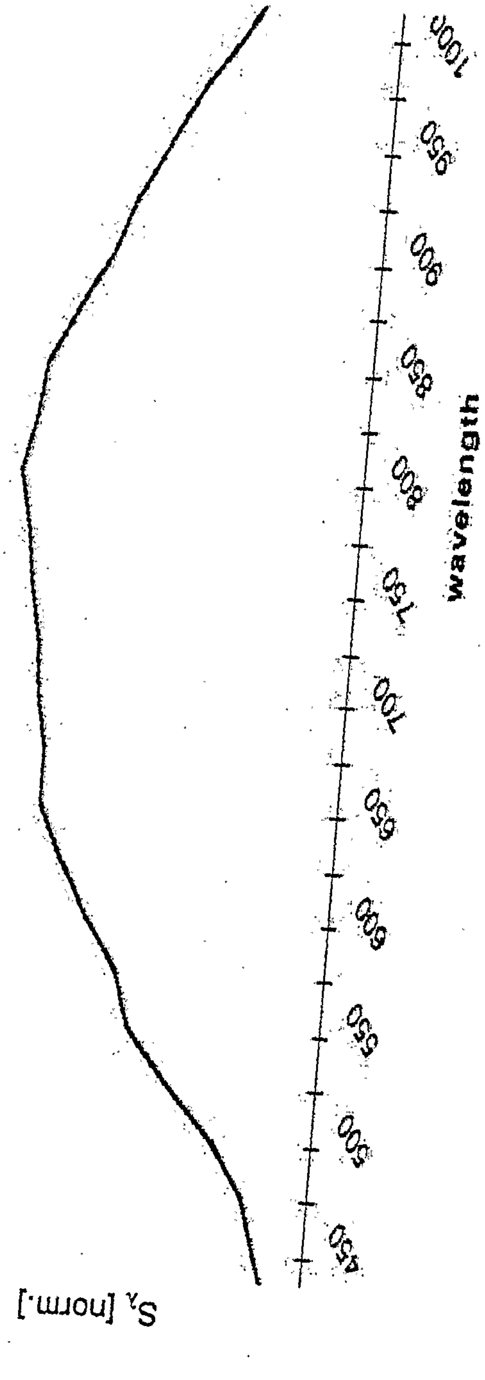

1000
950
900
850
800
750
700
650
600
550
500
450
wavelength
S_λ [norm.]

Figure 3b

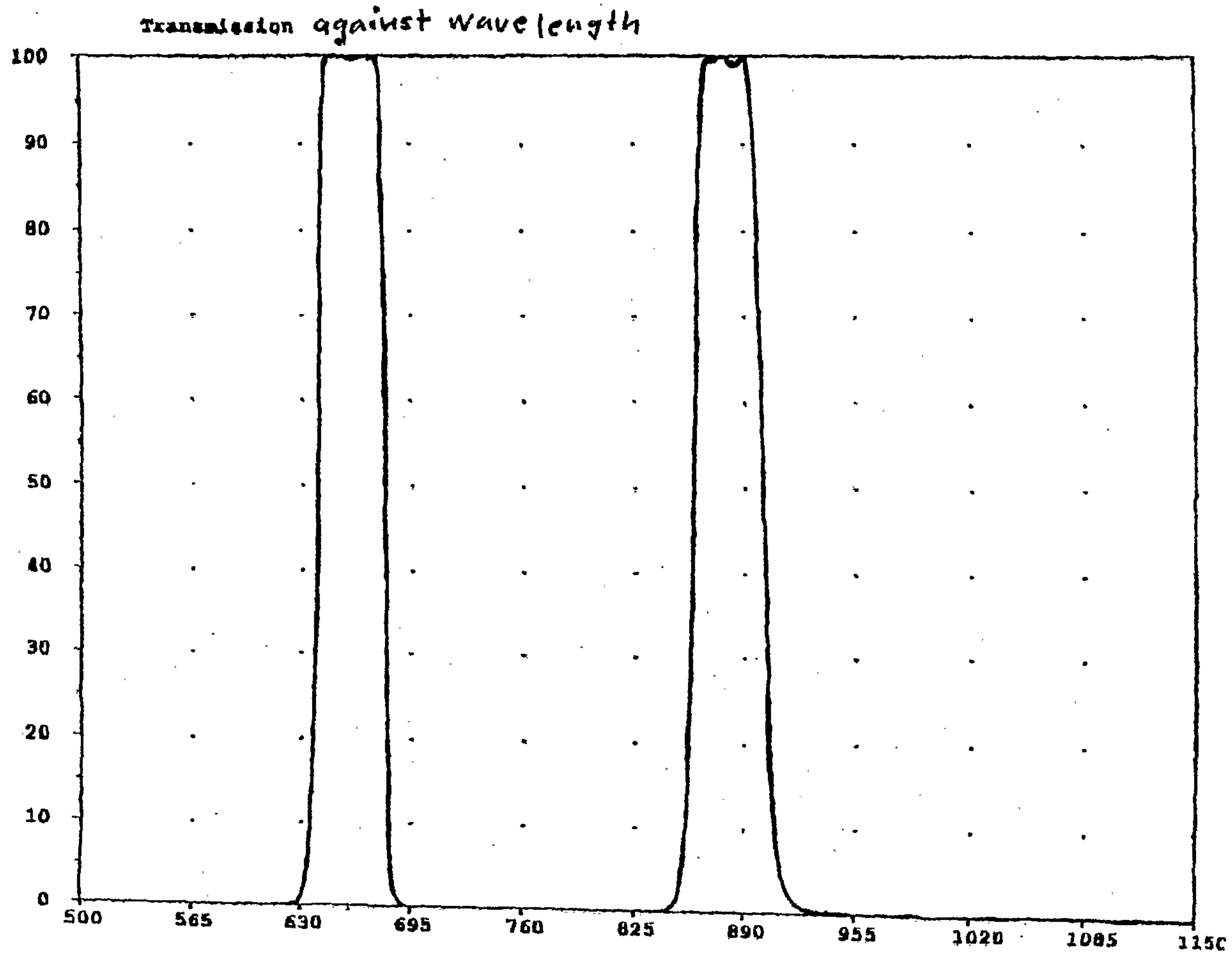

Transmission against wavelength
100
90
80
70
60
50
40
30
20
10
0
500
565
630
695
760
825
890
955
1020
1085
115C

Figure 3c

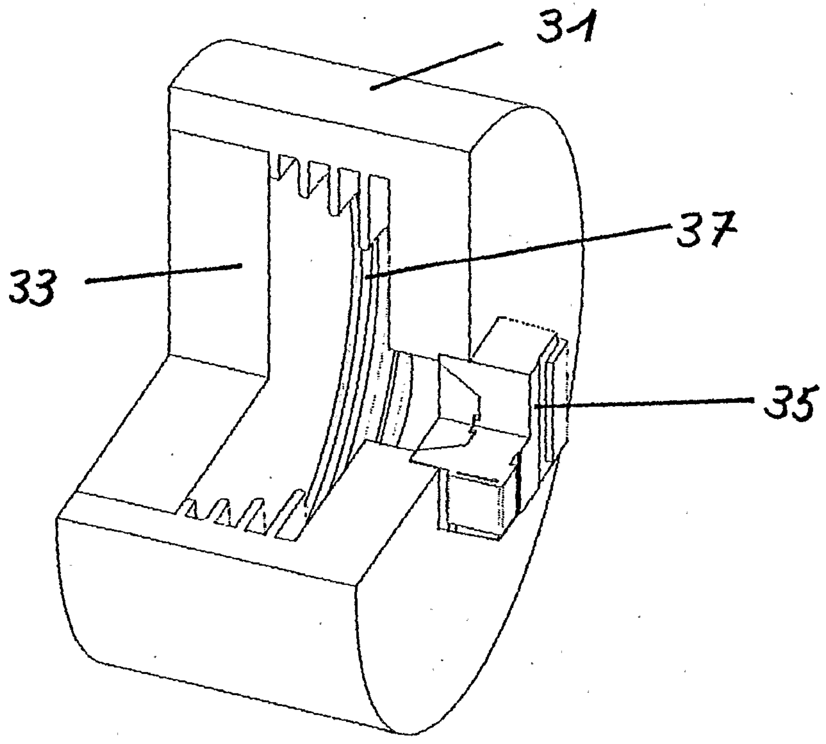


Figure 4a

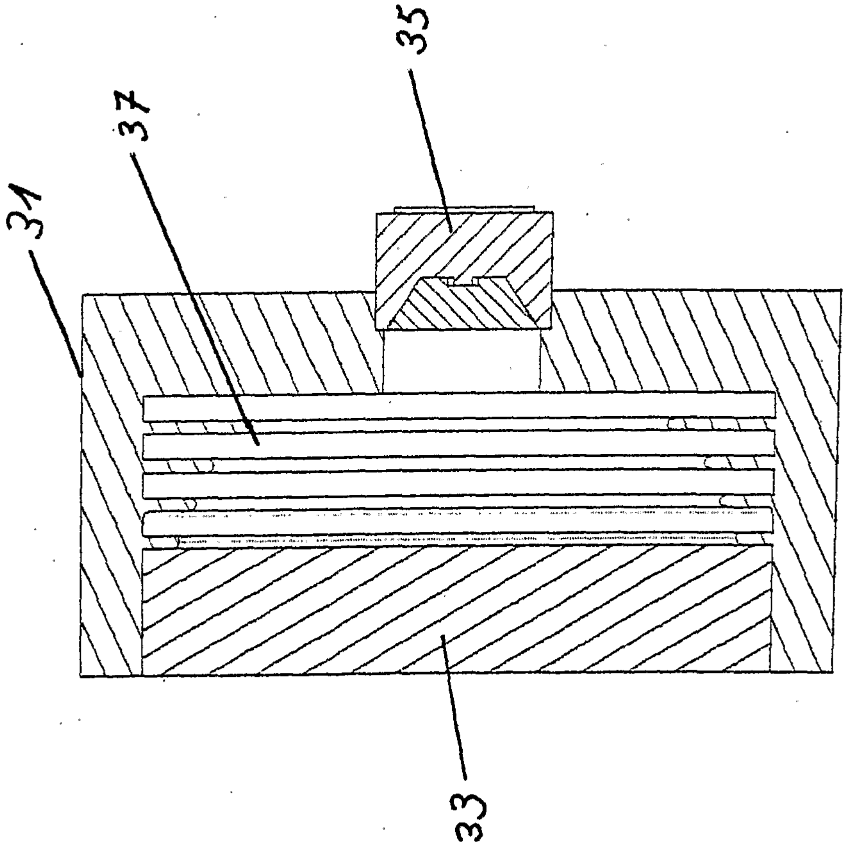


Figure 4b

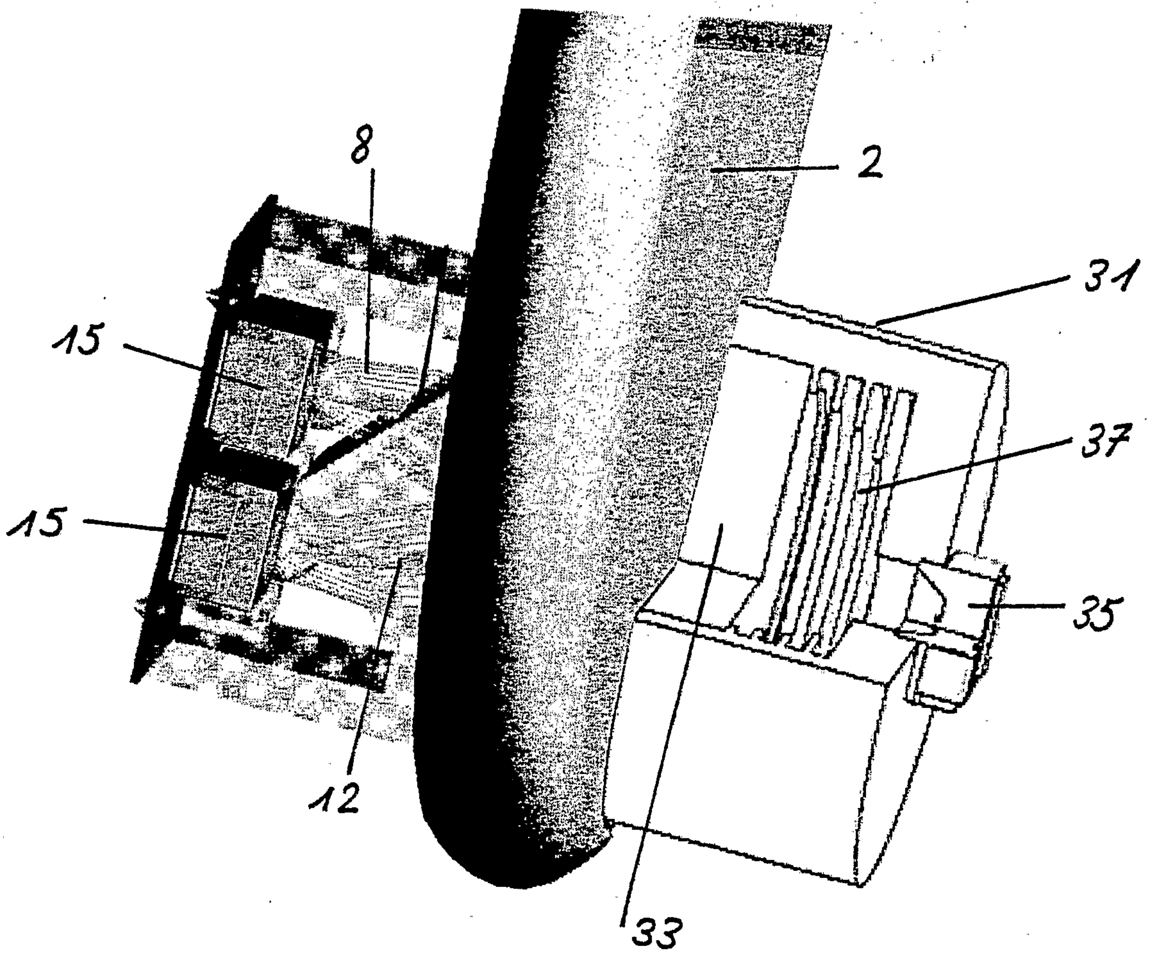


Fig. 4c

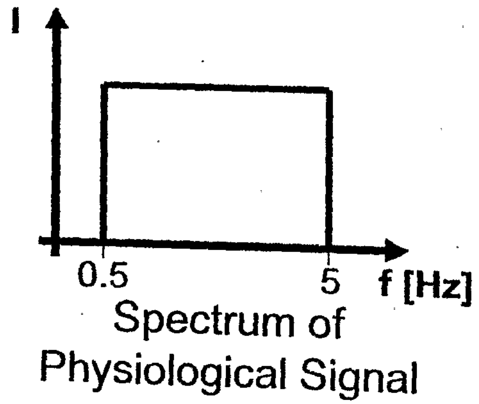


Figure 5a

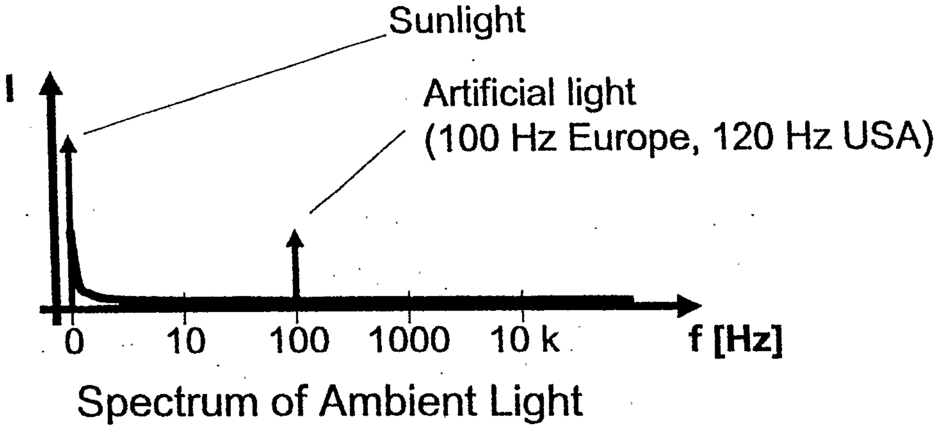

Sunlight
Artificial light
(100 Hz Europe, 120 Hz USA)
I
0
10
100
1000
10 k
f [Hz]
Spectrum of Ambient Light

Figure 5b

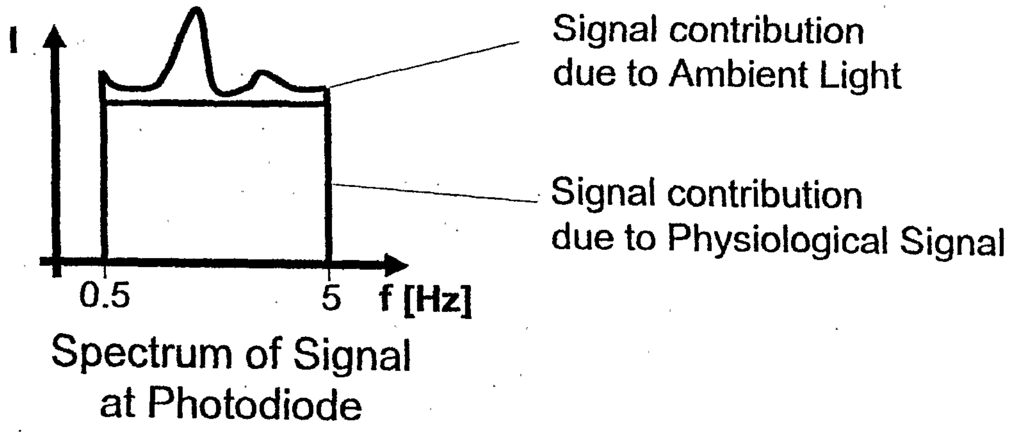

I
0.5
5
f [Hz]
Signal contribution due to Ambient Light
Signal contribution due to Physiological Signal
Spectrum of Signal at Photodiode

Figure 5c

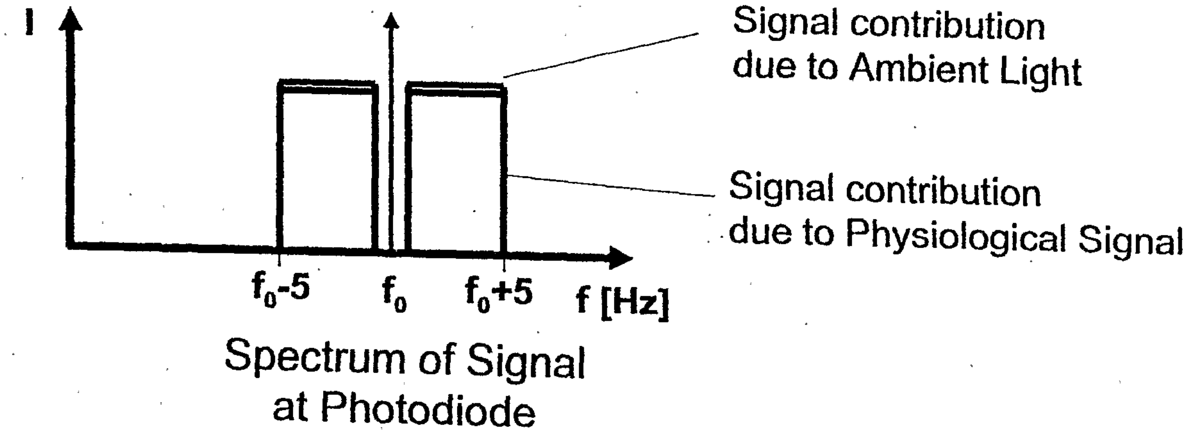

I
Signal contribution due to Ambient Light
Signal contribution due to Physiological Signal
f_0-5
f_0
f_0+5
f [Hz]
Spectrum of Signal at Photodiode

Figure 6

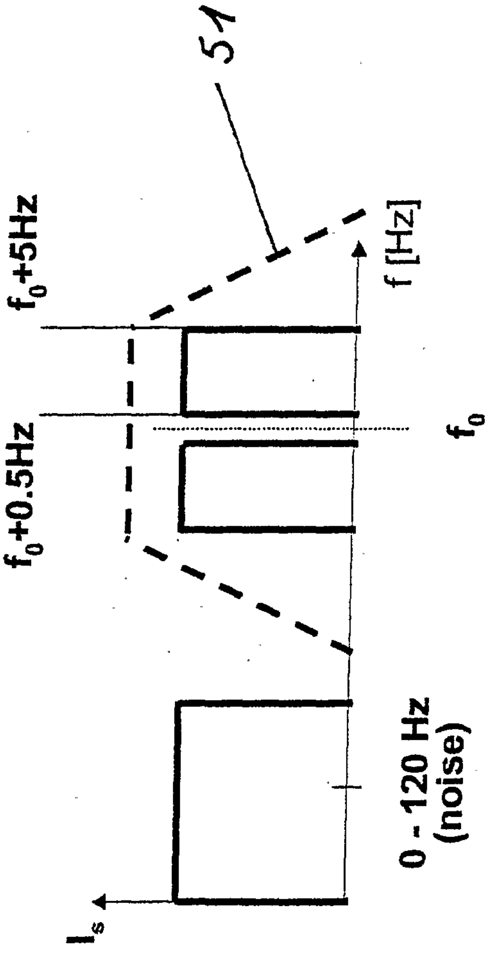
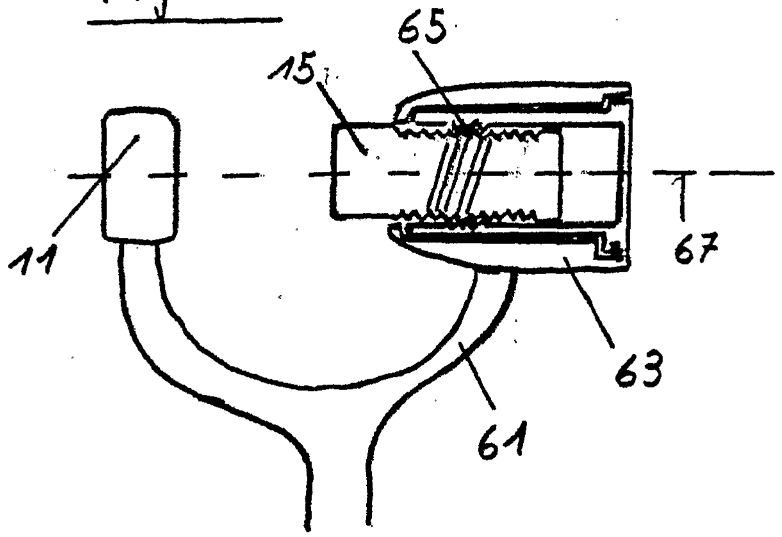


Figure 7

Fig 8a



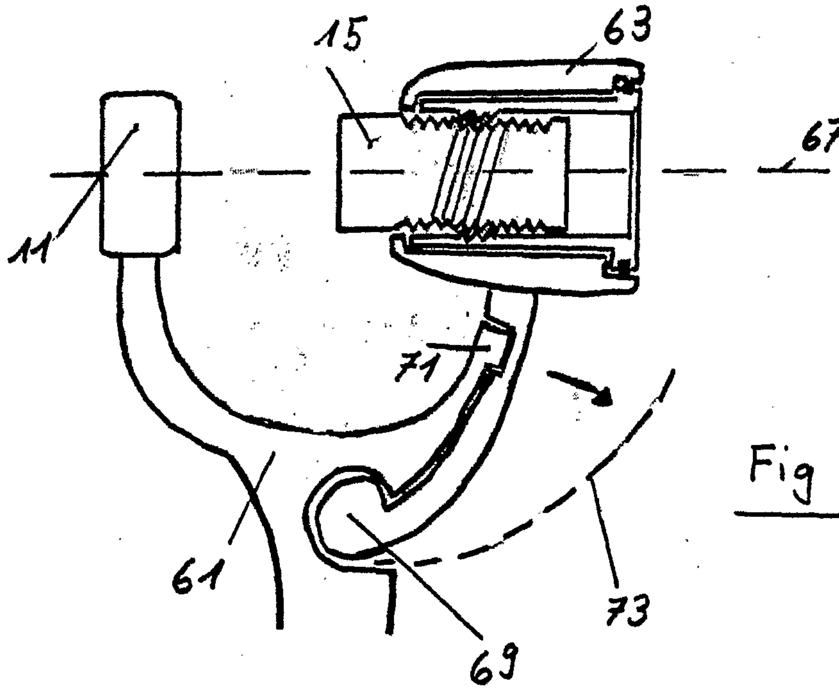


Fig 8b

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CH2004/000552

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/077536 A1 (ELFADEL IBRAHIM M ET AL) 20 June 2002 (2002-06-20) paragraph '0089!; claim 1 -----	1-3, 14-17
X	US 5 431 170 A (MATHEWS GEOFFREY R) 11 July 1995 (1995-07-11) column 2, line 52 - column 3, line 65; claim 1 -----	1,14-17
X	US 5 628 310 A (LAKOWICZ JOSEPH R ET AL) 13 May 1997 (1997-05-13) column 19, lines 12-16 -----	1,14-17
X	US 2002/062070 A1 (ROOST MATTHIAS ET AL) 23 May 2002 (2002-05-23) paragraphs '0022!, '0043! ----- -/--	1,14-17

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

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Date of the actual completion of the international search
10 November 2004

Date of mailing of the international search report
18/11/2004

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/CH2004/000552

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 167 230 A (CHANCE BRITTON) 1 December 1992 (1992-12-01) columns 3-4 -----	1-17
A	EP 0 936 762 A (SEIKO EPSON CORP) 18 August 1999 (1999-08-18) the whole document -----	1-17

INTERNATIONAL SEARCH REPORT

International Application No
[illegible]T/CH2004/000552

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002077536 A1	20-06-2002	US 6157850 A	05-12-2000
		US 5632272 A	27-05-1997
		US 5490505 A	13-02-1996
		US 5482036 A	09-01-1996
		US 2003036689 A1	20-02-2003
		US 2002128544 A1	12-09-2002
		US 2004064020 A1	01-04-2004
		US 2004068164 A1	08-04-2004
		US 2004204636 A1	14-10-2004
		US 2004210146 A1	21-10-2004
		US RE38476 E1	30-03-2004
		US 6236872 B1	22-05-2001
		US 6081735 A	27-06-2000
		AU 2125899 A	13-05-1999
		AU 699762 B2	17-12-1998
		AU 3962395 A	15-05-1996
		CA 2199016 A1	02-05-1996
		CA 2357059 A1	02-05-1996
		CN 1168624 A ,B	24-12-1997
		EP 0784448 A2	23-07-1997
		JP 10507118 T	14-07-1998
		WO 9612435 A2	02-05-1996
		US 5685299 A	11-11-1997
		US 6263222 B1	17-07-2001
		AT 184716 T	15-10-1999
		AU 658177 B2	06-04-1995
		AU 1536992 A	06-10-1992
		CA 2105682 A1	08-09-1992
		DE 69229994 D1	21-10-1999
		DE 69229994 T2	27-04-2000
		EP 1357481 A2	29-10-2003
		EP 0574509 A1	22-12-1993
		EP 0930045 A2	21-07-1999
		JP 3363150 B2	08-01-2003
		JP 6507485 T	25-08-1994
		RU 2144211 C1	10-01-2000
		WO 9215955 A1	17-09-1992
		US RE38492 E1	06-04-2004
		US 6036642 A	14-03-2000
		US 2003097049 A1	22-05-2003
		US 6206830 B1	27-03-2001
		US 5769785 A	23-06-1998
		US 2001029326 A1	11-10-2001
		US 2004204638 A1	14-10-2004
US 5431170 A	11-07-1995	AU 7973791 A	31-12-1991
		CA 2083721 A1	27-11-1991
		EP 0532572 A1	24-03-1993
		FI 925335 A	25-11-1992
		WO 9118550 A1	12-12-1991
		JP 5506802 T	07-10-1993
US 5628310 A	13-05-1997	AU 711444 B2	14-10-1999
		AU 5798896 A	29-11-1996
		CA 2218926 A1	21-11-1996
		EP 0952783 A1	03-11-1999
		JP 2001506141 T	15-05-2001
		WO 9636275 A1	21-11-1996

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
US 2002062070	A1	23-05-2002	AU	2335202	A	03-06-2002
			CA	2466105	A1	30-05-2002
			WO	0241770	A1	30-05-2002
			EP	1335666	A1	20-08-2003
			JP	2004515274	T	27-05-2004
US 5167230	A	01-12-1992	CA	1331483	C	16-08-1994
			DE	68928348	D1	30-10-1997
			DE	68928348	T2	16-04-1998
			EP	0441791	A1	21-08-1991
			JP	2603350	B2	23-04-1997
			JP	4502563	T	14-05-1992
			WO	9004941	A1	17-05-1990
			US	5779631	A	14-07-1998
			US	6134460	A	17-10-2000
EP 0936762	A	18-08-1999	EP	0936762	A1	18-08-1999
			CN	1225767	T	11-08-1999
			EP	1458122	A2	15-09-2004
			WO	9851025	A1	12-11-1998

专利名称(译)	提高光学脉冲血氧仪的性能		
公开(公告)号	EP1659930A1	公开(公告)日	2006-05-31
申请号	EP2004761892	申请日	2004-09-01
申请(专利权)人(译)	CARDIOSAFE国际公司		
当前申请(专利权)人(译)	CARDIOSAFE国际公司		
[标]发明人	CARLSON SVEN ERIK SCHNELL URBAN SCHEGG DEBORAH LIECHTI MARTIN		
发明人	CARLSON, SVEN-ERIK SCHNELL, URBAN SCHEGG, DEBORAH LIECHTI, MARTIN		
IPC分类号	A61B5/00		
CPC分类号	A61B5/14552 A61B5/6816		
优先权	10/654184 2003-09-03 US		
外部链接	Espacenet		

摘要(译)

提出了用于获取和/或监测医疗数据的配置，特别是心血管和肺部系统的状态，血液值或血液成分，其特征在于至少一个用于获取诸如州的医疗数据的测量传感器。包括至少一个可以发射至少两个波长的光的光源的人的心血管系统等，以及至少一个光接收器，用于确定通过人的组织部分透射和/或反射的光或动物，还包括用于增加光学信噪比和/或信号与背景比的装置。