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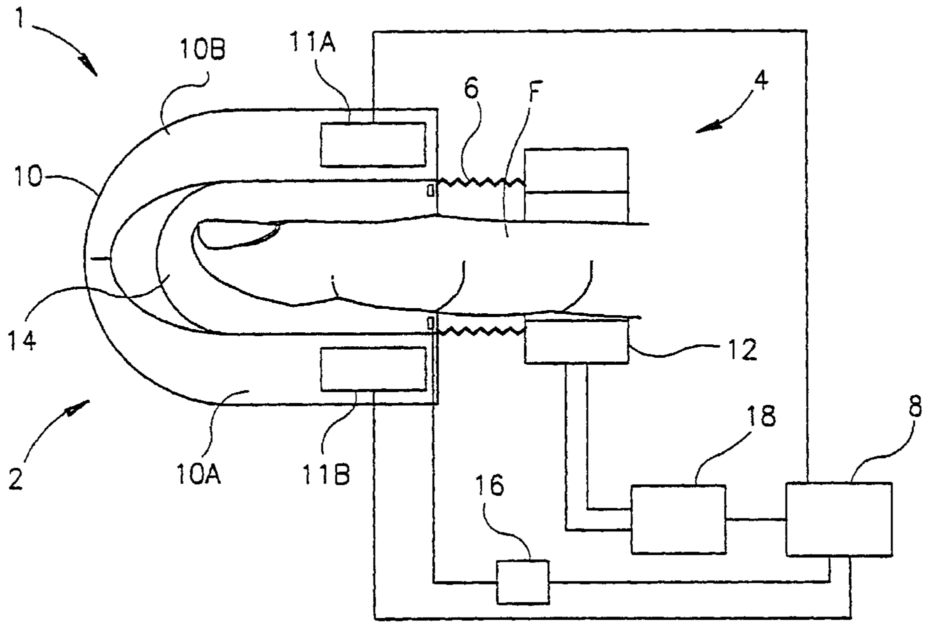
(54) Title: AN OPTICAL DEVICE FOR NON-INVASIVE MEASUREMENT OF BLOOD-RELATED SIGNALS AND A FINGER HOLDER THEREFOR



(57) Abstract: An optical measurement device is presented. The device is attachable to the patient's body by means of a support assembly and adapted for performing non-invasive measurements of blood-related signals. The support assembly comprises a heating element (14) for engaging the organ (F) at a first region, and carries a measurement unit (11A, 11B) for applying optical measurements to the first region. The heating element (14) is operable for heating the organ at the first region to a desired temperature. An occlusion assembly (12) is provided for applying over-systolic pressure to a second region on the patient's body located upstream of the first region with respect to a normal blood flow direction.

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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.

An Optical Device for Non-Invasive Measurement of Blood-related Signals and a Finger Holder Therefor

FIELD OF THE INVENTION

The present invention is in the field of non-invasive measurements of physiological parameters of patients, and relates to a device for measuring blood-related signals.

BACKGROUND OF THE INVENTION

Numerous techniques have been developed for the non-invasive measurement of blood-related signals, being aimed at determining various blood-related parameters such as blood oxygen saturation and the concentration of substances contained in the blood, e.g., glucose. These techniques typically utilize a measurement device or probe, which is designed to be attached to a patient's body (typically his finger), and includes an optical assembly for irradiating the finger with light and detecting its light response.

Most of the known devices are based on spectrometric techniques. According to these techniques, a tissue is irradiated with light of different wavelengths, and a photodetector detects light returned from the tissue. Analysis of the detected returned signal allows the determination of the required biological variable. The accuracy of the method depends on various conditions, some of which are associated with the detected signal and others with the irradiated tissue. This technique gives poor results due to a low signal-to-noise ratio, artifacts and the fact that the returned pulsatile signal might be very low.

Recently developed techniques propose various solutions directed towards overcoming the above drawbacks. US Patent 5,131,391 discloses a pulse oxymeter aimed at overcoming a problem associated with constriction of blood vessels that might occur during stress or invasive procedures such as surgery. To this end, the pulse oxymeter, in addition to a photodetector, has a warming device.

US Patent 5,638,818 discloses a measurement device having an improved optical probe designed so as to reduce noise in the course of measuring signals in a compressible tissue. The probe includes a base having an aperture for the finger to be inserted therein, which aperture leads to a chamber where a photodetector is placed in a manner to have no contact with the finger. A light source is affixed to the finger above the chamber. This design enables to maintain the optical path of transmitted light. A scattering medium is interposed between the light source and the finger so as to improve the signal-to-noise ratio. In a later patent of the same author (US Patent No. 5,782,757) a disposable optical probe and a reusable probe in the form of a padded clip-on bracket are disclosed. The probes are designed so as to fit comfortably onto a patient's fingertip.

WO 9843096 discloses a measurement device, where measurements are applied to a part of the body whose thickness is modulated harmonically by at least two pressure modulating frequencies. This part of the body is irradiated with at least two different wavelengths, where at least one of them lies in a range of optical absorption of the blood components to be determined.

JP 10033512 discloses a measurement device having a slot for a patient's finger to be inserted thereto. The walls of the slot are coated by an insulating material. A light source and a detector are accommodated at opposite sides of the slot so as to be at opposite sides of the finger.

DE 19629342 discloses a measurement device in the form of a holder for holding a patient's finger at its one side in a manner to apply a slight pressure thereto. The device analyzes light reflected from the finger.

The above devices deal with natural pulsatile signals. What is actually measured by these devices is an enhanced optical pulsatile signal. It is known that a regular optical pulsatile signal is typically 2-3% of the total transmission. The above devices are capable of obtaining the enhanced pulsatile signal that reach 8-10% of the total light transmission intensity. This enhancement of the natural pulsatile signal is a boundary of all conventional techniques of the kind specified.

SUMMARY OF THE INVENTION

The present invention provides a novel optical measurement device for non-invasive measurements of blood parameters utilizing an occlusion based technique disclosed in a co-pending application PCT/IL 99/00331 assigned to the assignee of the present application. According to this technique, a state of blood flow cessation is created in a medium at a measurement location, and measurements are taken during this state. The measured signals are thus not pulsatile. This enables to significantly enhance the measured light response of the medium, as compared to that of the prior art techniques dealing with the pulsatile signals.

Thus, the present invention takes advantage of the fact that measurements taken during the state of blood cessation allows for a significant increase of the blood-related signals, as compared to those taken during the state of normal blood flow. To create a state of blood flow cessation within a patient's organ at a measurement location, over-systolic pressure is applied at a location upstream of the measurement location with respect to a normal blood flow direction.

The main idea of the present invention is based on the fact that effects of heating and optionally pressuring the medium at the measurement location even more enhance the blood-related signals to be measured. The measurement device according to the invention includes a support assembly for attaching to the patient's organ that carries a measurement unit, and comprises a heating element, and an occlusion assembly. The measurements unit comprises an illumination/detection assembly, which when in the operative position of the support assembly being attached to the patient's organ applies optical measurements at a first location on the organ spaced-apart from a second, occluded location in a direction of a normal blood flow. The heating element, on the one hand, enables to heat the organ in the vicinity of the first, measurement location to a desired temperature, and, on the other hand, is capable of providing pressurization and comfortable fixation of the organ, and prevents its displacement relative to the illumination-detection assembly during measurements.

There is thus provided according to one aspect of the invention, an optical measurement device for performing non-invasive measurement of blood-related signals, the device comprising:

- a support assembly for attaching to the patient's extreme organ, the support assembly comprising a heating element for engaging the organ at a first region thereon and heating it to a desired temperature;
- a measurement unit mounted on the support assembly, the measurement unit comprising an illumination-detection assembly operable for illuminating said first region, detecting light response of the illuminated region, and generating data representative thereof;
- an occlusion assembly operable for applying substantially over-systolic pressure to a second region on the patient's body located upstream of said first region with respect to a normal blood flow direction; and
- a control unit, which is coupled to the measurement unit for selectively actuating the measurements, analyzing data indicative of the detected light response and determining at least one desired parameter of the patient's blood, and is coupled to the occlusion assembly for selectively operating this assembly.

The occlusion assembly includes a cuff associated with a pneumatic drive for applying the over-systolic pressure. The cuff is either a ring mountable onto the patient's organ at the second region, or a band with Velcro-like fasteners.

Preferably, the heating elements is substantially flexible. The support assembly may be in the form of a clip supporting the illumination-detection assembly and having the heating element attached to its inner surface.

Alternatively, the support assembly may be in the form of the substantially flexible heating element that supports the illumination-detection assembly. To this end, the heating element is in the form of a cuff-like cushion to be wrapped around the organ within the region under measurements (i.e., the first region). This cuff-like cushion is associated with a pneumatic drive, constituting together a pressurizing assembly for supplying desired, substantially under-systolic (e.g., 10-50mmHg) pressure. This pressurizing assembly is aimed at, on the one hand, adjusting the cuff-like cushion to a specific patient, and, on the other hand, providing slightly pressurization of the patient's organ within the first region, thereby enhancing the measured signals.

Preferably, the desired temperature for heating the region under measurements is approximately 37°-38°. Heating can be carried out either continuously or by applying short thermal pulses (e.g., electrical or light energy) to accelerate heating of the measurement region to the desired temperature.

The heating element may be in the form of a film made of a thermoconductive material, or of a non-conductive flexible material with a heater implemented therein. The heating element may be a two- or three-layer structure. If the two-layer structure is used, the first layer, which is in contact with the patient's organ, is made of an insulating material, and the second layer is made of an electrically conductive (i.e., heating) material. If the three-layer structure is used, the first layer, which is in contact with the patient's organ, is made of an insulating material, the second, intermediate layer is made of a heating material, and the third layer is made of a dielectric material.

The illumination-detection assembly may be of any known kind. The assembly may be designed for detecting either light transmitted through the illuminated region or light scattered (reflected) therefrom.

Preferably, the patient's organ under measurements is his finger.

According to another aspect of the present invention, there is provided a finger holder to be used in a measurement device for non-invasive measurement of blood-related signals, the finger holder comprising:

- a support assembly for attaching to the patient's finger comprising a heating element for engaging a region of the finger, the heating element being operable for heating said region to a desired temperature.; and
- a measurement unit mounted on said support assembly, wherein the measurement unit comprises an illumination-detection assembly operable for illuminating the finger at a measurement location in the vicinity of said region, detecting light response of the illuminated location, and generating data representative thereof.

Preferably, the finger holder also comprises a pressurizing assembly operable to apply under-systolic pressure to the finger within the measurement location.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, a preferred embodiment will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

Fig. 1 illustrates a measurement device according to one embodiment of the invention, applied to the patient's finger;

Fig. 2 graphically illustrates the main principles of occlusion-based measurements carried out by the device of Fig. 1;

Fig. 3 illustrates another embodiment of the measurement device; and

Fig. 4 illustrates yet another embodiment of the invention having a different construction of the measuring unit.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

More specifically, the present invention is used with a patient's finger, and is therefore described below with respect to this application.

Referring to Fig. 1, there is illustrated a measurement device **1**, constructed according to one embodiment of the invention, being applied to a patient's finger **F**. The device **1** comprises such main constructional parts as: a measurement unit **2** located at a first location on the finger **F**, an occlusion assembly **4** located at a second location on the finger **F**, a flexible connector **6** connecting the unit **2** and assembly **4**, and a control unit **8** coupled to the unit **2** and assembly **4**. The provision of the connector **6**, which may be either flexible or rigid, is optional.

The measurement unit **2** includes a finger holder **10** in the form of a clip (constituting a support assembly) that comfortably secures the measurement unit onto the patient's finger, which is enclosed between opposite sides **10A** and **10B** of the clip **10**. These opposite parts of the clip **10** also serve for holding an illumination unit **11A** and a detection unit **11B**, respectively. The construction and operation of such an illumination-detection assembly are known *per se*, and therefore need not be specifically described, except to note the following. The illumination unit **11A** includes a suitable light source for illuminating a region of the finger with light of at least two different wavelengths, while the detection unit **11B** includes a suitable sensor means accommodated to detect light components transmitted through the illuminated region (i.e., light response of the illuminated region) and generating data representative thereof. It should be noted that the illumination-detection assembly could be designed and accommodated in a manner to detect light reflected from the finger.

The data generated by the detection unit (measured data) are indicative of the time dependence of the intensity of the detected light for each wavelength. These data are transmitted to a processing utility of the control unit **8**, which is operated by suitable software for analyzing the measured data and determining desired parameters of the patient's blood, for example the concentration of hemoglobin, glucose, cholesterol, etc. A calculation scheme suitable for the determination of these parameters is disclosed in the above-indicated co-pending application, and does not form part of the present invention.

Further provided in the measuring unit **2** is a cushion **14** attached to an inner surface of the clip **10** and coupled to a power source **16**. The cushion **14** is made of a flexible material so as to provide comfortable fixation of the finger **F** and prevent its displacement relative to the illumination-detection assembly during measurements. By varying the thickness of the cushion **14**, its flexibility can be desirably adjusted.

The cushion **14** is preferably made of a thermoconductive material having an electrical resistance suitable for heating the finger up to a desired temperature (e.g., 35°-39°) in response to the electric supply provided by the power source **16**. Such a flexible and thermoconductive material may be rubber, silicone, PVC, thermoplasts, and other materials containing carbon or metal fillings.

The occlusion assembly **4** includes a flexible cuff **12** coupled to a pneumatic driver **18**, which is, in turn, coupled to a corresponding utility of the control unit **8**. The control unit selectively operates the driver **18** for applying a constant, over-systolic pressure (e.g., 270-300mmHg, but, generally, adjustable for each specific patient) to the second location of the finger **F**. It should be noted, although not specifically shown, that such a ring-like cuff **12** may be replaced by a band having Velcro-like fasteners.

The main operational principles of the device **1** are based on the following. It was found by the inventors, and disclosed in the above-indicated co-pending patent application, that that the optical characteristics of a blood flow containing medium (e.g., the patient's finger) start to change in time, when causing blood flow cessation. In other words, once the blood flow cessation state is established, the optical characteristics start to change dramatically, such that they differ from those of a normal blood flow by about 25 to 45%, and sometimes even more than 60 %. Hence, the accuracy (i.e., signal-to-noise ratio) of the optical measurements can be substantially improved by conducting at least two timely separated measurement sessions each including at least two measurements with different wavelengths of incident radiation. The light responses of the finger at these two sessions essentially differ from each other. At least one of the measurement sessions during which the measurement is effected should be chosen, either during temporary blood flow cessation, or during the state of transitional blood flow. Alternatively, single blood current occlusion can be used, namely a single long occlusion measurement be taken and analyzed.

Thus, the patient's wears the device **1**, and the control unit actuates the driver **18** to create the over-systolic pressure. Upon determining the establishment of the state of blood flow cessation, the control unit **8** operates the measurement unit **2** for carrying out one or more measurement sessions as described above, and the processing utility of the control unit **8** performs the data analysis.

Fig. 2 illustrates two graphs, $\mathbf{G_1}$ and $\mathbf{G_2}$ presenting experimental results corresponding to the time dependence of the blood-related signal **R** measured with the device **1** without and with the heating effect, respectively. As shown, the application of the device **1** creates a strong optical signal, approximately 30%-40% of the total transmission intensity, which is significantly increased by the heating effect.

Reference is made to Fig. 3, illustrating a measurement device **100** constructed and operated according to another embodiment of the invention. To facilitate understanding, same reference numbers are used for identifying those components which are identical in the devices **1** and **100**. The device **100** is constructed generally similar to the device **1**, but has a finger holder designed somewhat differently, as compared to that of the device **1**. Here, the combination of the clip **10** and cushion **14** is replaced by a flexible thermoconductive cuff **110** coupled to a pneumatic drive **112** operated by the control unit **8**. The cuff **110** and the pneumatic drive **112** constitute together a pressurizing assembly. It should be noted, although not specifically shown, that this pressurizing assembly may be mounted on the clip **10** of Fig. 1. In other words, the pressurizing assembly may replace only the cushion **14**. Generally speaking, the finger holder may include both heating and pressurizing elements.

The cuff **110** supports the illumination and detection units **11A** and **11B**, and provides a required thermostabilization of electronic elements. To put the device **100** in the operation, a desired, substantially low pressure (e.g., 10-50mmHg) is applied to the cuff **110**, and suitable voltage is supplied thereto.

The cuff **110** is made from one of the above-listed flexible thermoconductive materials. These materials can be manufactured by any known suitable technique, such as press forming, injection molding, etc., and may have a wide range of electrical resistance enabling the operation with low voltage, for example, in the range 1-24V. This voltage supply is acceptable for medical devices. The low power supply of approximately 2-3W allows for using batteries that enable the measurement device to be conveniently portable.

As indicated above, the cushions **14** (Fig. 1) or cuff **110** (Fig. 2) could be entirely manufactured from a thermoconductive, resistive material. It should, however, be noted that a non-conductive element may be used with heating elements implanted therein. Alternatively, the cuff could be composed of two parts or layers. In other words, the cushion may have a two- or three-layer structure. In the case of the two-layer structure, the upper layer, which is contact with the finger, is made of an insulating material such as silicone, rubber, polyethylene, etc., and the lower layer is made of a heating material, such as conductive silicone, rubber or other conductive materials. In the case of the three-layer structure, an intermediate layer is made of a heating material such as electro-conductive silicone, rubber or flexible metal materials like NiCr films, wires, etc., and the lower layer is made of a dielectric materials, such as non-conductive silicone or rubber. Electrical contacts may either be installed in the flexible cushion or cuff during the manufacturing process, or be assembled in a separate process thereafter.

Turning now to Fig. 4, there is illustrated yet another embodiment of the invention aimed at avoiding the use of additional pneumatic means associated with the application of the under-systolic pressure, thereby rendering the measurement device even more portable. To this end, a support assembly **304** comprises the flexible heating cushion **14** put on the finger **F**, and a shrinkable ring or cap **305** having a spring portion **305A**. The ring **305**, after being heated by the voltage supply (not shown), presses the cushion **14** against the tension of the spring **305**. When this pressure exceeds a maximum permissible tension of the spring, it tears off, thereby opening the electric circuit and stopping the heating.

The advantages of the present invention are thus self-evident. The measurement device according to the invention is portable and easy to operate. The device is inexpensive due to the use of low voltage supply. The provision of a support assembly of adjustable diameter, i.e., the clip **10** and flexible cushion **14** (Fig. 1), cuff **110** (Fig. 3) or cushion **14** with the ring **305** (Fig. 4), enables the comfortable fitting of the finger's position. The heating effect enhances the measured signals, and the slight pressurization of the region under measurements enhances these signals even more.

Those skilled in the art will readily appreciate that various modifications and changes may be applied to the preferred embodiment of the invention as hereinbefore exemplified without departing from its scope defined in by the appended claims.

CLAIMS:

1. An optical measurement device for performing non-invasive measurement of blood-related signals, the device comprising

- a support assembly for attaching to the patient's extreme organ, the support assembly comprising a heating element for engaging the organ at a first region thereon and heating it to a desired temperature;
- a measurement unit mounted on the support assembly, the measurement unit comprising an illumination-detection assembly operable for illuminating said first region, detecting light response of the illuminated region and generating data representative thereof;
- an occlusion assembly for applying over-systolic pressure to a second region on the patient's body located upstream of said first region with respect to a normal blood flow direction; and
- a control unit, which is coupled to the measurement unit for selectively actuating the measurements, analyzing data indicative of the detected light response and determining at least one desired parameter of the patient's blood, and is coupled to the occlusion assembly for selectively operating this assembly.

2. The device according to Claim 1, wherein said desired temperature is approximately 35°-39°.

3. The device according to Claim 1, wherein the heating element is substantially flexible.

4. The device according to Claim 1, wherein said heating element contains thermoconductive material.

5. The device according to Claim 1, wherein said heating element is made of a non-conductive material with a heater implemented therein.

6. The device according to Claim 1, wherein said heating element is composed of two layers, the first layer, which is in contact with the patient's organ, being made of an insulating material, and the second layer being made of a thermoconductive material.

7. The device according to Claim 1, wherein said heating element is composed of three layers, the first layer, which is in contact with the patient's organ, being made of an insulating material, the intermediate layer being made of a heating material, and the third layer being made of a dielectric material.

8. The device according to any one of Claims 4 to 7, wherein said thermoconductive material is electrically conductive silicone.

9. The device according to any one of Claims 4 to 7, wherein said thermoconductive material is electrically conductive rubber.

10. The device according to Claim 7, wherein said dielectric material is non-conductive silicone.

11. The device according to Claim 7, wherein said dielectric material is non-conductive rubber.

12. The device according to Claim 1, wherein said support assembly comprises a pressurizing assembly for applying a desired, substantially under-systolic pressure to the patient's organ in the vicinity of the first region.

13. The device according to Claim 12, wherein said pressurizing assembly comprises said heating element in the form of a cuff-like cushion associated with a pneumatic driver operated by the control unit for applying the desired pressure.

14. The device according to Claim 13, wherein said desired pressure is approximately 10-50mmHg.

15. The device according to Claim 1, wherein said occlusion assembly comprises a cushion cuff-like member for wrapping said second region, and a pneumatic driver coupled to said cushion cuff-like member so as to, when being operated by the control unit, apply said substantially over-systolic pressure to said second region.

16. The device according to Claim 15, wherein said cushion cuff-like member is a ring mountable onto the patient's organ.

17. The device according to Claim 15, wherein said cushion cuff-like member is a bend having Velcro-like fasteners so as to form a ring on the patient's organ.

18. The device according to Claim 1, wherein said support assembly comprises a clip-like member.

19. The device according to Claim 1, wherein said over-systolic pressure is such as to create a state of substantial blood flow cessation within said second region.

20. The device according to Claim 19, wherein said over-systolic pressure is about 270-300mmHg.

21. The device according to Claim 1, wherein said patient's organ is his finger.

22. A finger holder to be used in a measurement device for non-invasive measurement of blood-related signals, the finger holder comprising:

- a support assembly for attaching to the patient's finger comprising a heating element for engaging a region of the finger, the heating element being operable for heating said region to a desired temperature; and
- a measurement unit mounted on said support assembly, wherein the measurement unit comprises an illumination-detection assembly operable for illuminating the finger at a measurement location in the vicinity of said region, detecting light response of the illuminated location and generating data representative thereof.

23. The finger holder according to Claim 22, wherein said support assembly comprises a pressurizing assembly for applying a desired, substantially under-systolic pressure to the finger in the vicinity of said region.

24. The finger holder according to Claim 23, wherein said pressurizing assembly comprises the heating element in the form of a cuff-like cushion associated with a pneumatic driver operable to apply said desired, substantially under-systolic pressure.

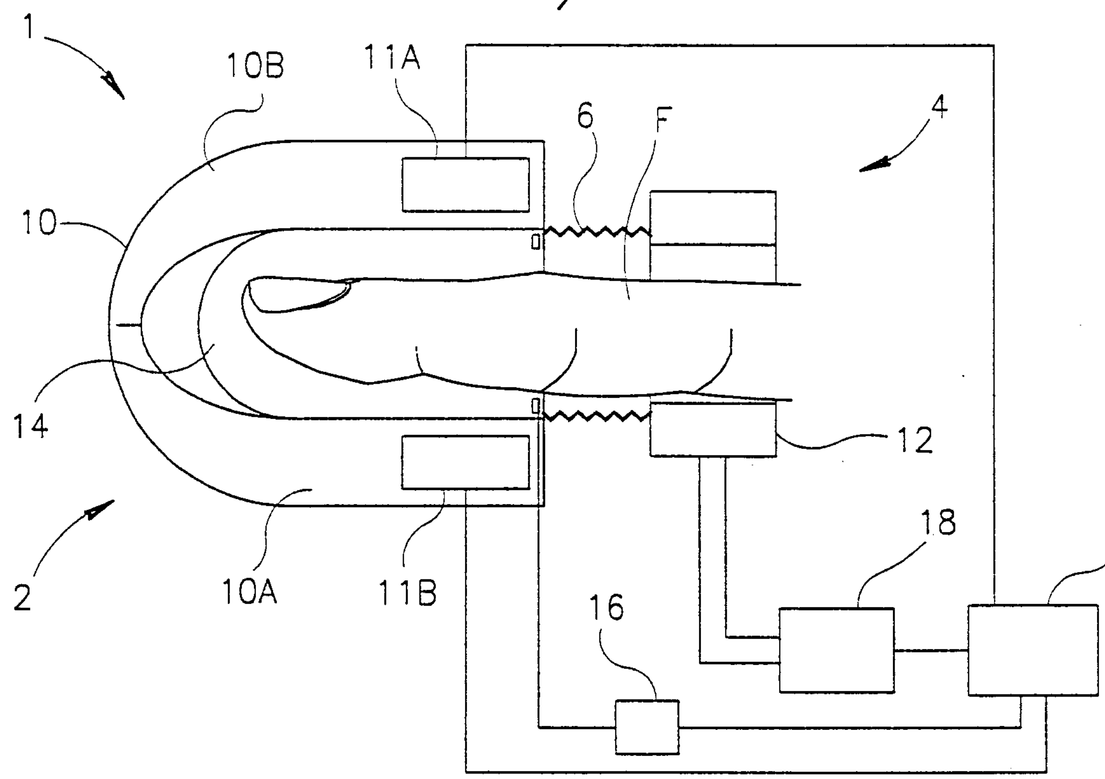

FIG.1

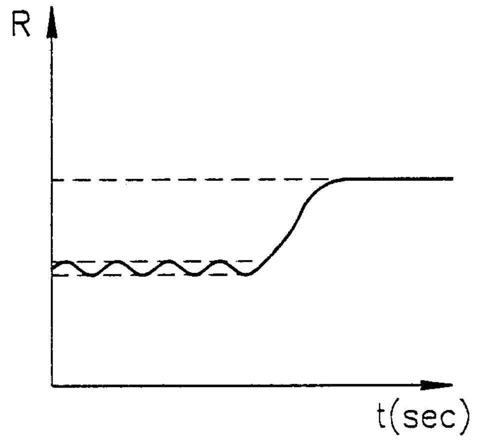

FIG.2A

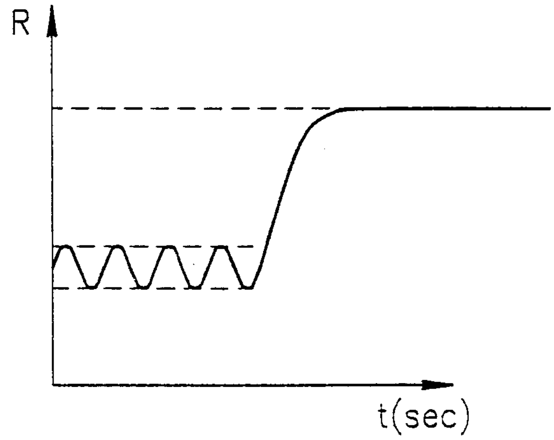

FIG.2B

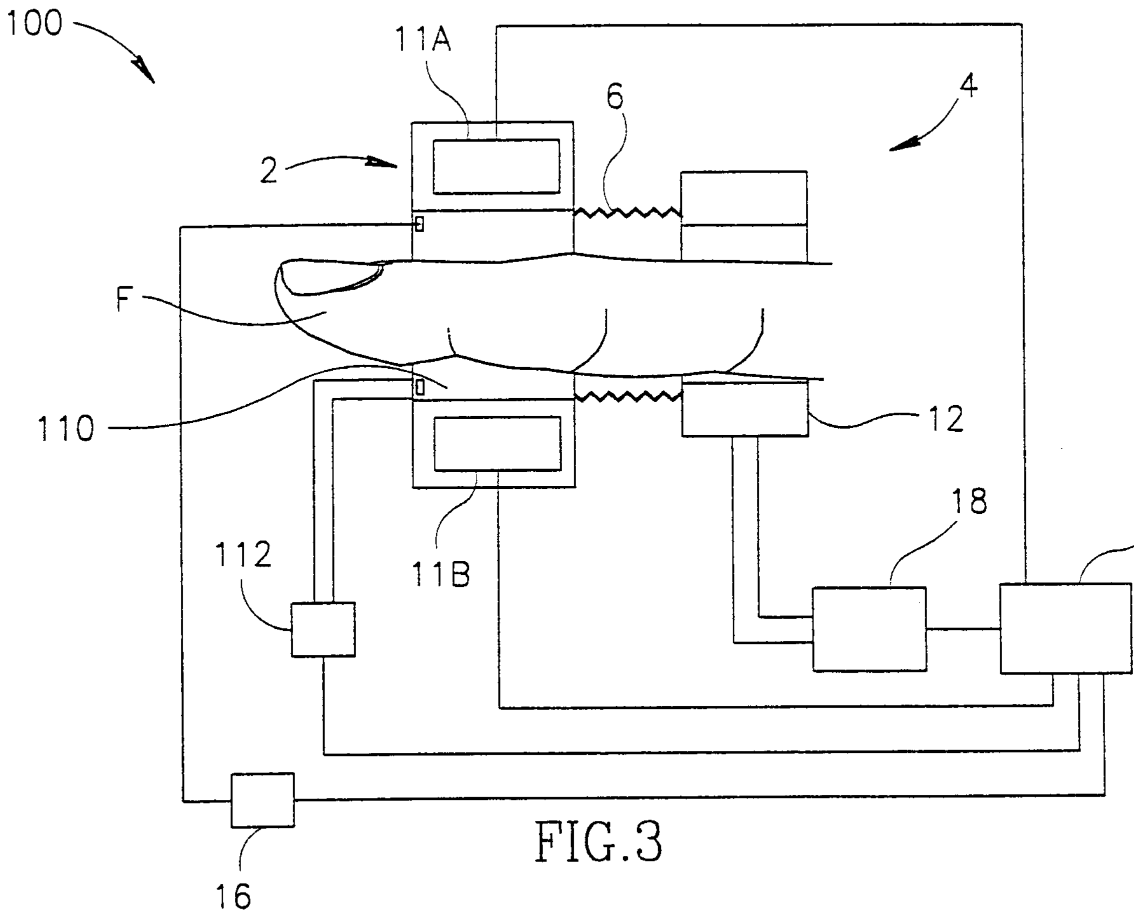

FIG.3

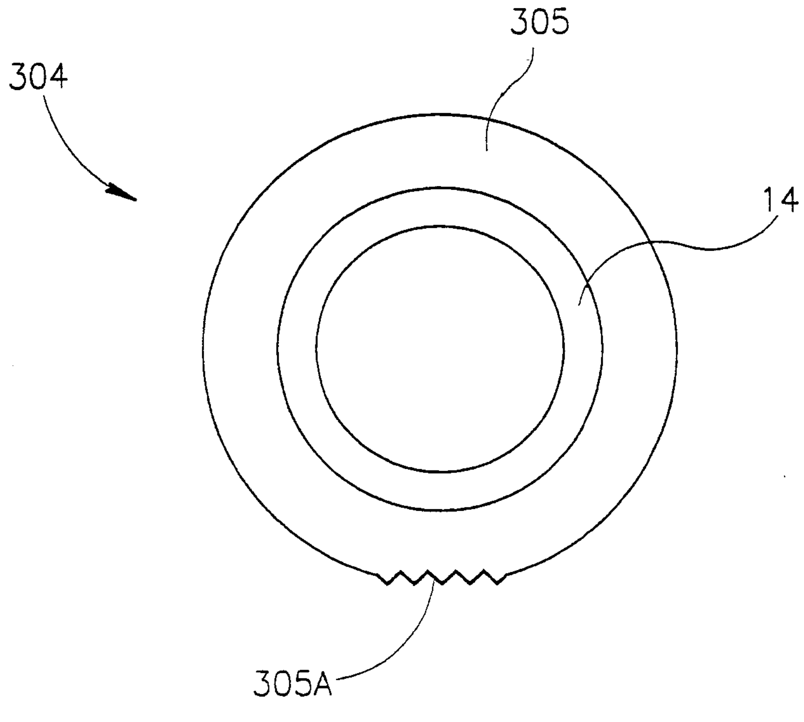

FIG.4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL 00/00629

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00 A61B5/022

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.
A,P	WO 99 63884 A (ITAMAR) 16 December 1999 (1999-12-16) page 6, last paragraph -page 21, paragraph 2	1,3,7, 12,15-24
A	WO 98 04182 A (ITAMAR) 5 February 1998 (1998-02-05) page 26, line 19 -page 59, line 4	1-3, 12-16, 19-24
A	US 4 437 470 A (PROST) 20 March 1984 (1984-03-20) column 3, line 43 - line 60 column 5, line 23 -column 6, line 4	1,14-16, 19-23
A	US 5 860 919 A (MASIMO) 19 January 1999 (1999-01-19) column 18, line 37 -column 19, line 1	1,15,16, 19-22

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search	Date of mailing of the international search report
29 January 2001	06/02/2001

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 444 934 A (HEWLETT-PACKARD) 4 September 1991 (1991-09-04) column 4, line 1 -column 6, line 9 -----	1,12,15, 16,22

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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

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专利名称(译)	一种用于血液相关信号的非侵入式测量的光学装置及其手指支架		
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摘要(译)

提出了一种光学测量装置。该装置借助于支撑组件可附接到患者身体并且适于执行血液相关信号的非侵入性测量。支撑组件包括用于在第一区域处接合器官（F）的加热元件（14），并且承载用于将光学测量施加到第一区域的测量单元（11A，11B）。加热元件（14）可操作用于将第一区域的器官加热到所需温度。提供了一种闭塞组件（12），用于将过度收缩压施加到相对于正常血流方向位于第一区域上游的患者身体上的第二区域。