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

OPTISCHE VORRICHTUNG ZUR NICHTINVASIVEN MESSUNG VON BLUTBEZÜGLICHEN SIGNALEN UND FINGERHALTER DAFÜR

DISPOSITIF OPTIQUE DE MESURE NON INVASIVE DES SIGNAUX SANGUINS ET SUPPORT DE DOIGT DESTINE A CE DISPOSITIF

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Description

FIELD OF THE INVENTION

[0001] 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

[0002] 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.

[0003] 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.

[0004] 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.

[0005] 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.

[0006] 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.

[0007] 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.

[0008] 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.

[0009] 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.

[0010] WO 98/04182 relates to non-invasive detection of a physiological state or medical condition. WO 01/22868, published after the filing date of this application, relates to a finger holder and associated optical measurement device.

SUMMARY OF THE INVENTION

[0011] 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 WO 99/65384 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.

[0012] 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.

[0013] The main idea of the present invention is based on the fact that effects of heating and optionally pres-

suring 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.

[0014] Thus there is provided according to the invention, an optical measurement device for use in non-invasive measurement of blood-related signals, the device comprising a support assembly for attaching to the patient's extreme organ, such as a finger, the support assembly comprising a heating element for heating a first region of the organ 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 of the organ, 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 and to the occlusion assembly for actuating the application of over-systolic pressure and the measurements, to thereby enable generation of the measured data indicative of the detected light response and analysis of said data for determining at least one desired parameter of the patient's blood; and in which the control unit operates the occlusion assembly to apply the over-systolic pressure to said second region to thereby create a state of blood flow cessation in said first location, and operates the measurement unit to apply the measurements during said state of the blood flow cessation in said first region, said measured data being thereby representative of time dependence of an enhanced non-pulsatile light response signal indicative of the blood-related signal; said heating element is substantially flexible for engaging said first region, the heating of said first region resulting in that said non-pulsatile light response signal is significantly enhanced, said heating element having one of the following configurations: (i) a two-layer structure with the first layer, which is to be in contact with the patient's organ, being made of an insulating material and the second layer being made of a thermoconductive material, (ii) a three-layer structure with the first layer, which is to be 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, and (iii) a cuff-like cushion associated with a pneumatic driver operated by the control unit for applying a desired substantially under-systolic pressure to the location covered by the heating element.

[0015] 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.

[0016] 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.

[0017] 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.

[0018] 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.

[0019] 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.

[0020] Preferably, the patient's organ under measurements is his finger.

[0021] Furthermore, there is provided a finger holder to be used in the optical measurement device of the invention for use in non-invasive measurement of blood-related signals by detection the enhanced non-pulsatile

light response of the first region on the finger, the finger holder comprising said support assembly for attaching to the patient's finger comprising the substantially flexible heating element for engaging said first region of the finger and heating it to a desired temperature said measurement unit mounted on said support assembly and a pressure applying assembly.

[0022] Preferably, the finger holder comprises a pressure applying assembly operable to apply under-systolic pressure to the finger within the measurement location.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] 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

[0024] More specifically, the present invention is used with a patient's finger, and is therefore described below with respect to this application.

[0025] 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.

[0026] 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.

[0027] 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.

[0028] 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.

[0029] 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.

[0030] 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.

[0031] 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 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.

[0032] 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.

[0033] Fig. 2 illustrates two graphs, G_1 and 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.

[0034] 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.

[0035] 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.

[0036] 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 2-3 W allows for using batteries that enable the measurement device to be conveniently portable.

[0037] 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.

[0038] 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.

[0039] 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.

[0040] 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 (1) for use in non-invasive measurement of blood-related signals, the device comprising:

   - a support assembly (10) for attaching to the patient's extreme organ, such as a finger, the support assembly comprising a heating element (14) for heating a first region of the organ to a desired temperature;
   - a measurement unit (2) mounted on the support assembly (10), the measurement unit comprising an illumination-detection assembly (11A-11B) operable for illuminating said first region of the organ, detecting light response of the illuminated region and generating data representative thereof;
   - an occlusion assembly (4) 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 (8), which is coupled to the measurement unit (2) and to the occlusion assembly (4) for actuating the application of over-systolic pressure and the measurements, to thereby enable generation of the measured data indicative of the detected light response and analysis of said data for determining at least one desired parameter of the patient's blood; and in which:

     the control unit (8) operates the occlusion assembly (4) to apply the over-systolic pressure to said second region to thereby create a state of blood flow cessation in said first location, and operates the measurement unit (2) to apply the measurements during said state of the blood flow cessation in said first region, said measured data being thereby representative of time dependence of an enhanced non-pulsatile light response signal indicative of the blood-related signal;
     said heating element is substantially flexible for engaging said first region, the heating of said first region resulting in that said non-pulsatile light response signal is significantly enhanced, said heating element having one of the following configurations: (i) a two-layer structure with the first layer, which is to be in contact with the patient's organ, being made of an insulating material and the second layer being made of a thermoconductive material, (ii) a three-layer structure with the first layer, which is to be 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, and (iii) a cuff-like cushion associated with a pneumatic driver operated by the control unit for applying a desired substantially under-systolic pressure to the location covered by the heating element.

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

3. The device according to Claim 1(ii, iii), wherein said heating element contains thermoconductive material.

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

5. The device according to Claim 1(iii), 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.

6. The device according to Claim 1(iii), 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.

7. The device according to any one of Claims 1(i), 2 referring back to claim 1(i), 3 to 6, wherein said thermoconductive material is electrically conductive silicone.

8. The device according to any one of Claims 1(i), 2 referring back to claim 1(i), 3 to 6, wherein said thermoconductive material is electrically conductive rubber.

9. The device according to Claim 1(ii) or 6, wherein said dielectric material is non-conductive silicone.

10. The device according to Claim 1(ii), wherein said dielectric material is non-conductive rubber.

11. The device according to Claim 1(i) or 1(ii), 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.

12. The device according to Claim 11, 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.

13. The device according to Claim 12, wherein said desired pressure is approximately 10-50mmHg.

14. 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.

15. The device according to Claim 14, wherein said cushion cuff-like member is a ring mountable onto the patient's organ.

16. The device according to Claim 14, wherein said cushion cuff-like member is a bend having Velcro-like fasteners so as to form a ring on the patient's organ.

17. The device according to Claim 1 (i, ii), wherein said support assembly comprises a clip-like member.

18. The device according to Claim 1, wherein said over-systolic pressure is about 270-300mmHg.

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

20. The device according to Claim 19, wherein said pressure applying assembly is incorporated in said support assembly, and is operable to apply substantially under-systolic pressure to the finger in the vicinity of the first region.

21. The device according to Claim 20, wherein said heating element is incorporated in said pressure applying assembly being in the form of a cuff-like cushion associated with a pneumatic driver operable to apply the substantially under-systolic pressure.

Patentansprüche

1. Optische Meßvorrichtung (1) zur Verwendung bei der nichtangreifenden Messung von blutbezogenen Signalen, die

- eine Trägeranordnung (10) zum Befestigen an einem extremen Organ eines Patienten, wie etwa einem Finger, wobei die Trägeranordnung ein Erwärmungselement (14) zum Erhitzen eines ersten Bereiches des Organs auf eine gewünschte Temperatur hat,
- eine an der Trägeranordnung (10) befestigte Meßeinheit (2), wobei die Meßeinheit eine Beleuchtungserfassungsanordnung (11A-11B) umfaßt, die für das Ausleuchten des ersten Bereiches des Organs betrieben werden kann und die die Lichtreaktion des ausgeleuchteten Bereiches erfaßt und Daten erzeugt, welche diese wiedergeben,
- eine Okklusionsanordnung (4) für das Ausüben übersystolischen Drucks auf einen zweiten Bereich des Patientenkörpers, die sich aufstromwärts von dem ersten Bereich in Bezug auf die normale Blutflußrichtung befindet, und
- eine Kontrolleinheit (8) umfaßt, welche an die Meßeinheit (2) und die Okklusionsanordnung (4) angeschlossen ist, um die Ausübung übersystolischen Drucks und die Messungen auszulösen, um dadurch die Erzeugung der gemessenen Daten zu ermöglichen, die die erfaßte Lichtreaktion und die Analyse dieser Daten anzeigen, um wenigstens einen gewünschten Parameter des Patientenblutes zu bestimmen, und bei der

die Kontrolleinheit (8) die Okklusionsanordnung (4) betreibt, um den übersystolischen Druck auf den zweiten Bereich auszuüben, um dadurch einen Zustand der Blutflußunterbrechung in dem ersten Bereich zu erzeugen, und die Meßeinheit (2) betreibt, um die Messungen während dieses Zustands der Blutflußunterbrechung in dem ersten Bereich vorzunehmen, wobei die gemessenen Daten dadurch die Zeitabhängigkeit eines verstärkten nicht-pulsierenden Lichtreaktionssignals wiedergeben, das das blutbezogene Signal anzeigt,
das Erwärmungselement im wesentlichen biegsam zum Eingreifen in den ersten Bereich ist, wobei das Erwärmen des ersten Bereichs dazu führt, daß das nicht-pulsierende Lichtreaktionssignal deutlich verstärkt wird, wobei das Erwärmungselement eine der folgenden Ausgestaltungen hat, (i) einen Zwei-Schichten-Aufbau, wobei die erste Schicht, welche in Kontakt mit dem Patientenorgan kommen soll, aus einem Isoliermaterial besteht und die zweite Schicht aus einem wärmeleitenden Material besteht, (ii) einen Drei-Schichten-Aufbau, wobei die erste Schicht , welche in Kontakt mit dem Patientenorgan kommen soll, aus einem Isoliermaterial besteht und die mittlere Schicht aus einem Erwärmungsmaterial und die dritte Schicht aus einem dielektrischen Material besteht, und (iii) ein manschettenartiges Kissen, das mit einem Luftdruckantrieb verbunden ist, der durch die Kontrolleinheit betrieben wird, um einen gewünschten im wesentlichen untersystolischen Druck auf die von dem Erwärmungselement abgedeckte Stelle auszuüben.

2. Vorrichtung nach Anspruch 1, bei der die gewünschte Temperatur ungefähr 35° - 39° beträgt.

3. Vorrichtung nach Anspruch 1(ii, iii), bei der das Erwärmungselement wärmeleitendes Material enthält.

4. Vorrichtung nach Anspruch 1, bei der das Erwärmungselement aus einem nichtleitenden Material, mit einem darin implementierten Erwärmer, besteht.

5. Vorrichtung nach Anspruch 1(iii), bei der das Erwärmungselement aus zwei Schichten zusammengesetzt ist, wobei die erste Schicht, welche mit dem Patientenorgan in Kontakt steht, aus einem isolierenden Material besteht und die zweite Schicht aus einem wärmeleitfähigen Material besteht.

6. Vorrichtung nach Anspruch 1(ii, iii), bei der das Erwärmungselement aus drei Schichten zusammengesetzt ist, wobei die erste Schicht, welche mit dem Patientenorgan in Kontakt steht, aus einem isolierenden Material besteht, die mittlere Schicht aus einem erwärmenden Material besteht und die dritte Schicht aus einem dielektrischen Material besteht.

7. Vorrichtung nach einem der vorhergehenden Ansprüche 1(i), 2 unter Bezugnahme auf Anspruch 1 (i), 3 bis 6, bei der das wärmeleitfähige Material elektrisch leitendes Silikon ist.

8. Vorrichtung nach einem der vorhergehenden Ansprüche 1(i), 2 unter Bezugnahme auf Anspruch 1 (i), 3 bis 6, bei der das wärmeleitfähige Material elektrisch leitendes Gummi ist.

9. Vorrichtung nach Anspruch 1(ii) oder 6, bei der das dielektrische Material nicht-leitendes Silikon ist.

10. Vorrichtung nach Anspruch 1(ii) oder 6, bei der das dielektrische Material nicht-leitender Gummi ist.

11. Vorrichtung nach Anspruch 1(i) oder (ii), bei der die Trägeranordnung eine unter Druck setzende Anordnung für die Ausübung eines gewünschten, im wesentlichen untersystolischen Drucks auf das Patientenorgan in der Umgebung der ersten Bereiches umfaßt.

12. Vorrichtung nach Anspruch 11, bei der die unter Druck setzende Anordnung das Erwärmungselement in Form eines manschettenartigen Kissens umfaßt, das mit einem Druckluftantrieb verbunden ist, der von der Kontrolleinheit zum Ausüben des gewünschten Drucks betrieben wird.

13. Vorrichtung nach Anspruch 12, bei der der gewünschte Druck ungefähr 10 - 50 mmHg beträgt.

14. Vorrichtung nach Anspruch 1, bei der die Okklusionsanordnung ein manschettenartiges Kissenteil zum Umhüllen des zweiten Bereiches und einen Druckluftantrieb umfaßt, der mit dem manschettenartigen Kissenteil derart verbunden ist, daß, wenn es durch die Kontrolleinheit betrieben wird, den im wesentlichen übersystolischen Druck auf den zweiten Bereich ausübt.

15. Vorrichtung nach Anspruch 14, bei der das manschettenartige Kissenteil ein auf dem Patientenorgan zu befestigender Ring ist.

16. Vorrichtung nach Anspruch 14, bei der das manschettenartige Kissenteil eine Schlinge mit Velcroähnlichen Befestigungseinrichtungen ist, um so einen Ring an dem Patientenorgan zu bilden.

17. Vorrichtung nach Anspruch 1(i, ii), bei der die Trägeranordnung ein klammerartiges Teil umfaßt.

18. Vorrichtung nach Anspruch 1, bei der der übersystolische Druck etwa 270 - 300 mmHg beträgt.

19. Vorrichtung nach Anspruch 1, bei der das Organ des Patienten sein Finger ist.

20. Vorrichtung nach Anspruch 19, bei der die Druck ausübende Anordnung in die Trägeranordnung eingeschlossen und betreibbar ist, um im wesentlichen untersystolischen Druck auf den Finger in der Umgebung des ersten Bereiches auszuüben.

21. Vorrichtung nach Anspruch 20, bei das Erwärmungselement in Form eines manschettenartigen Kissens in die Druck ausübende Anordnung eingeschlossen ist und mit einem Druckluftantrieb betreibbar ist, um den im wesentlichen untersystolischen Druck auszuüben.

Revendications

1. Dispositif de mesure optique (1) à utiliser lors d'une mesure non invasive de signaux relatifs au sang, le dispositif comprenant :

- un assemblage de support (10) destiné à être fixé à l'organe d'extrémité du patient, comme un doigt, l'assemblage de support comprenant un élément de chauffage (14) destiné à chauffer une première région de l'organe à une température souhaitée;
- une unité de mesure (2) montée sur l'assemblage de support (10), l'unité de mesure comprenant un assemblage de détection d'illumina-

tion (11A-11B) pouvant servir à éclairer ladite première région de l'organe, détecter la réponse lumineuse de la région éclairée et générer des données représentatives de celle-ci;

- un assemblage d'occlusion (4) destiné à appliquer une pression hyper-systolique à une deuxième région sur le corps du patient située en amont de ladite première région par rapport à une direction de flux sanguin normale, et
- une unité de commande (8) couplée à l'unité de mesure (2) et à l'assemblage d'occlusion (4) destinée à actionner l'application de la pression hyper-systolique et les mesures, pour permettre de ce fait la génération des données mesurées qui indiquent la réponse de lumière détectée et l'analyse desdites données destinées à déterminer au moins un paramètre souhaité du sang du patient,

et dans lequel :

- l'unité de commande (8) actionne l'assemblage d'occlusion (4) pour appliquer la pression hyper-systolique à ladite deuxième région pour créer de ce fait un état de cessation de flux sanguin audit premier endroit, et actionne l'unité de mesure (2) pour appliquer les mesures pendant ledit état de cessation du flux sanguin dans ladite première région, lesdites données mesurées représentant de ce fait une dépendance temporelle d'un signal optique de réponse non pulsatif amélioré représentatif du signal relatif au sang;
- ledit élément de chauffage est essentiellement souple pour mettre ladite première région en prise, le chauffage de ladite première région ayant comme conséquence la nette amélioration dudit signal optique de réponse non pulsatif, ledit élément de chauffage présentant une des configurations suivantes : (i) une structure à deux couches, la première couche, devant être en contact avec l'organe du patient, étant en matériau isolant, et la deuxième couche étant en matériau de conduction thermique, (ii) une structure en trois couches, la première couche, devant être en contact avec l'organe du patient, étant en matériau isolant, la couche intermédiaire étant en matériau chauffant, et la troisième couche étant en matériau diélectrique, et (iii) un coussin de type menotte associé à un dispositif pneumatique actionné par l'unité de commande pour appliquer un pression essentiellement hypo-systolique souhaitée à l'endroit couvert par l'élément de chauffage.

2. Dispositif selon la revendication 1, dans lequel ladite température souhaitée est d'environ 35°-39°.

3. Dispositif selon la revendication 1(ii, iii), dans lequel ledit élément de chauffage contient un matériau conducteur de la chaleur.

4. Dispositif selon la revendication 1, dans lequel ledit élément de chauffage est en matériau non conducteur avec dispositif de chauffage incorporé.

5. Dispositif selon la revendication 1(iii), dans lequel ledit élément de chauffage est composé de deux couches, la première couche, en contact avec l'organe du patient, étant en matériau isolant et la deuxième couche, en matériau conducteur de la chaleur.

6. Dispositif selon la revendication 1(iii), dans lequel ledit élément de chauffage est composé de trois couches, la première couche, étant en contact avec l'organe du patient, étant en matériau isolant, la couche intermédiaire étant en matériau chauffant et la troisième couche étant en matériau diélectrique.

7. Dispositif selon l'une quelconque des revendications 1(i), 2 se référant à la revendication 1(i), 3 à 6, dans lequel ledit matériau conducteur de la chaleur est une silicone conductrice de l'électricité.

8. Dispositif selon l'une quelconque des revendications 1(i), 2 se référant à la revendication 1(i), 3 à 6, dans lequel ledit matériau conducteur de la chaleur est un caoutchouc conducteur de l'électricité.

9. Dispositif selon la revendication 1(ii) ou 6, dans lequel le matériau diélectrique est une silicone non conductrice.

10. Dispositif selon la revendication 1(ii), dans lequel ledit matériau diélectrique est un caoutchouc non conducteur.

11. Dispositif selon la revendication 1(i) ou 1(ii), dans lequel ledit assemblage de support comprend un assemblage sous pression destiné à appliquer une pression essentiellement hypo-systolique souhaitée à l'organe du patient aux alentours de la première région.

12. Dispositif selon la revendication 11, dans lequel ledit assemblage sous pression comprend ledit élément de chauffage sous forme de coussin en menotte associé à un dispositif pneumatique actionné par l'unité de commande pour l'application de la pression souhaitée.

13. Dispositif selon la revendication 12, dans lequel ladite pression souhaitée est d'environ de 10-50 mmHg.

14. Dispositif selon la revendication 1, dans lequel ledit assemblage d'occlusion comprend un élément en type de menotte formant coussin pour envelopper ladite deuxième région, et un dispositif pneumatique couplé audit élément de type menotte formant coussin de manière à appliquer, lors de son actionnement par l'unité de commande, ladite pression essentiellement hyper-systolique à ladite deuxième région.

15. Dispositif selon la revendication 14, dans lequel ledit élément de type menotte formant coussin est un anneau pouvant être monté sur l'organe du patient.

16. Dispositif selon la revendication 14, dans lequel ledit élément de type menotte en coussin est une courbe présentant des fixateurs de type Velcro de manière à former un anneau sur l'organe du patient.

17. Dispositif selon la revendication 1(i,ii), dans lequel ledit assemblage de support comprend un élément de type pince.

18. Dispositif selon la revendication 1, dans lequel ladite pression hyper-systolique est d'environ 270-300mmHg.

19. Dispositif selon la revendication 1, dans lequel l'organe du patient est son doigt.

20. Dispositif selon la revendication 19, dans lequel ledit assemblage appliquant la pression est inclus dans ledit assemblage de support, et sert à appliquer une pression essentiellement hypo-systolique au doigt aux alentours de la première région.

21. Dispositif selon la revendication 20, dans lequel ledit élément de chauffage est inclus dans ledit assemblage appliquant la pression qui est sous forme de coussin en menotte associé à un dispositif pneumatique servant à appliquer la pression essentiellement hypo-systolique.

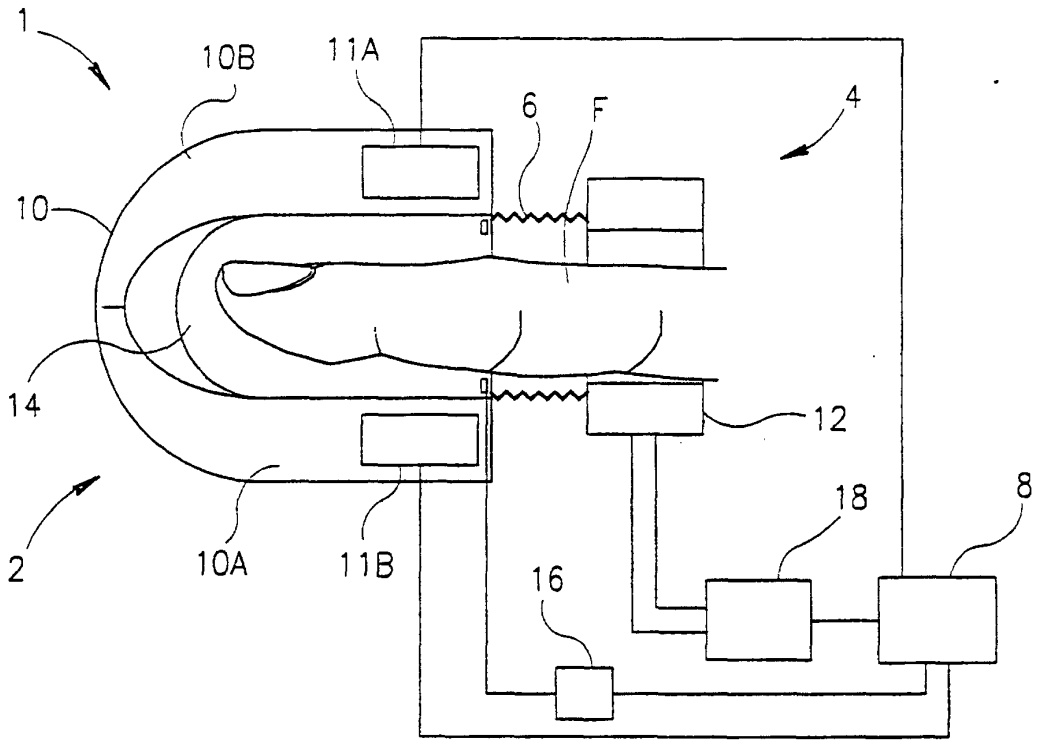

FIG.1

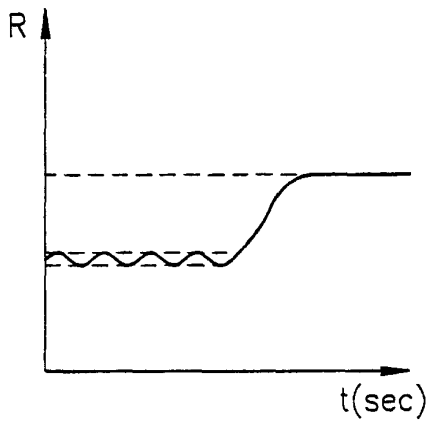

FIG.2A

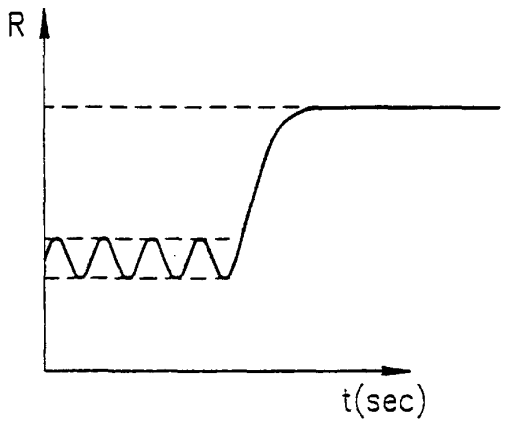

FIG.2B

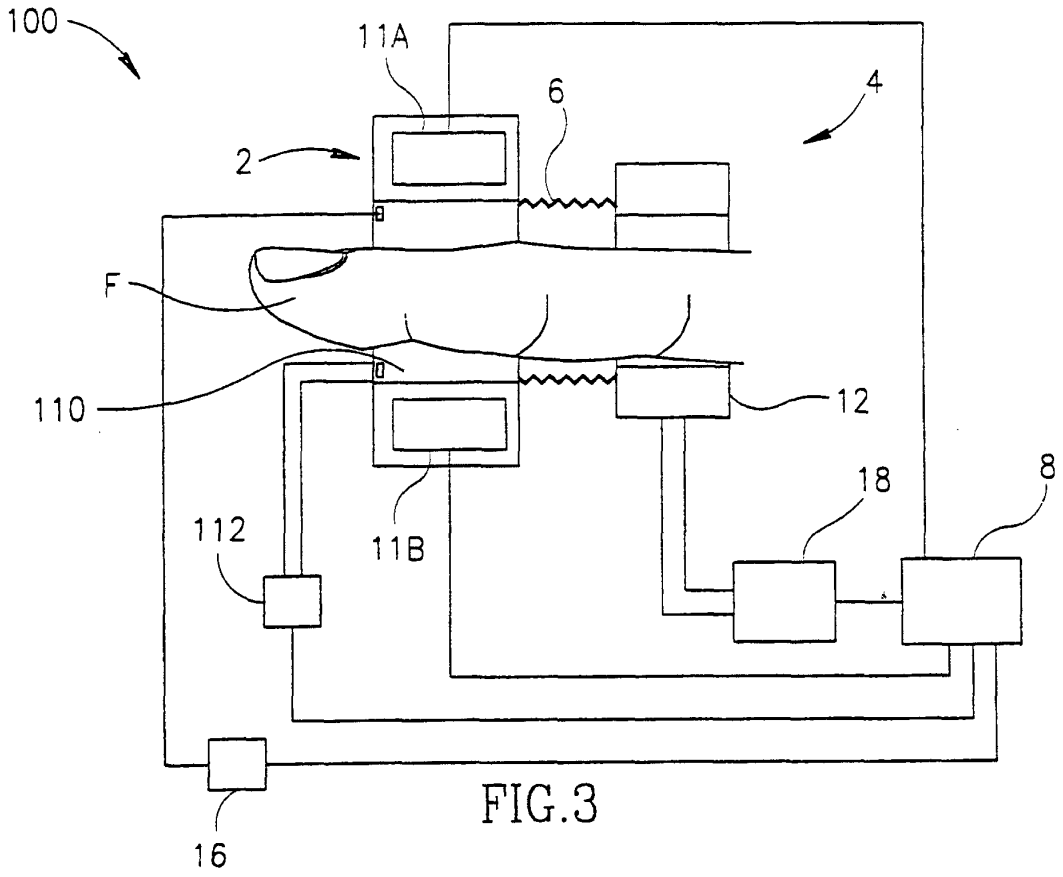

FIG.3

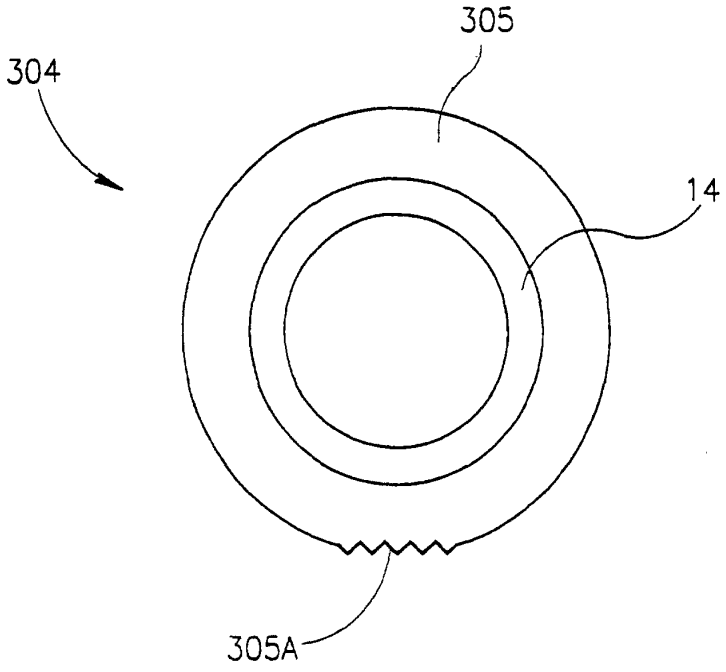

FIG.4

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		
公开(公告)号	EP1223851B1	公开(公告)日	2004-01-28
申请号	EP2000966397	申请日	2000-10-06
申请(专利权)人(译)	ORSENSE LTD.		
当前申请(专利权)人(译)	ORSENSE LTD.		
[标]发明人	FINAROV ALEXANDER KLEINMAN YOSSIE FINE ILYA		
发明人	FINAROV, ALEXANDER KLEINMAN, YOSSIE FINE, ILYA		
IPC分类号	G01N21/01 A61B5/00 A61B5/022 A61B5/145 A61B5/1455		
CPC分类号	A61B5/6826 A61B5/02241 A61B5/14552 A61B5/6838		
优先权	09/416360 1999-10-12 US		
其他公开文献	EP1223851A1		
外部链接	Espacenet		

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。

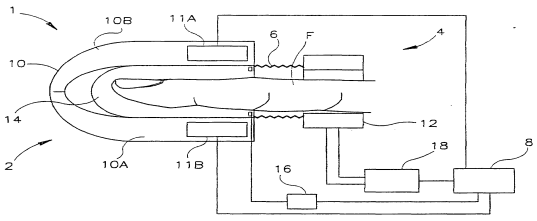

FIG.1

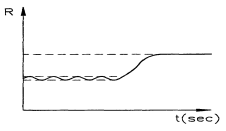

FIG.2A

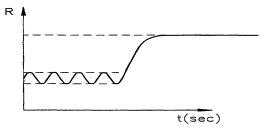

FIG.2B