(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 142 097 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
09.01.2019 Bulletin 2019/02

(21) Application number: **08733446.2**

(22) Date of filing: **02.05.2008**

(51) Int Cl.:
A61B 5/00 *(2006.01)* ***A61B 5/1455*** *(2006.01)*

(86) International application number:
PCT/AU2008/000624

(87) International publication number:
WO 2008/134813 (13.11.2008 Gazette 2008/46)

(54) **NON-INVASIVE MEASUREMENT OF BLOOD OXYGEN SATURATION**

NICHTINVASIVE MESSUNG DER BLUTSAUERSTOFF-SÄTTIGUNG

MESURE NON INVASIVE DE LA SATURATION EN OXYGÈNE DU SANG

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MT NL NO PL PT RO SE SI SK TR

(30) Priority: **02.05.2007 AU 2007902315 P**
04.05.2007 US 916108 P

(43) Date of publication of application:
13.01.2010 Bulletin 2010/02

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EP 2 142 097 B1

Printed by Jouve, 75001 PARIS (FR)

Description

FIELD OF THE INVENTION

[0001] The present invention relates to a method and device of non-invasively determining oxygen saturation of blood within deep vascular structures, and in particular, but not exclusively, to a method of determining oxygen saturation of central venous, mixed venous and central arterial blood within structures such as the internal jugular vein, superior vena cava, right atrium, right ventricle, pulmonary artery, left atrium, left ventricle, carotid artery and aorta. The invention also relates to devices for use in non-invasively determining oxygen saturation of blood within deep vascular structures.

BACKGROUND OF THE INVENTION

[0002] In critically ill and unstable patients assessment of oxygen delivery to the tissues is of vital importance. If inadequate, early interventions to optimise oxygen delivery may prevent multiple organ failure and death[1]. These interventions include administration of intravenous fluids, inotropes (that stimulate heart contraction) and support of ventilation to improve oxygenation of blood.

[0003] Central venous or mixed venous blood oxygen saturations reflect the adequacy of oxygen delivery to the parts of the body from which the blood has drained. Mixed venous blood (blood in the right ventricle and central and peripheral parts of the pulmonary arteries) offers the best assessment of the adequacy of oxygen delivery to the whole body. However, central venous blood (blood in the internal jugular, subclavian, femoral and brachiocephalic veins, the inferior and superior vena cava and the right atrium) can be used as a surrogate of the adequacy of oxygen delivery to the whole body. [2]

[0004] Currently, assessment of oxygen delivery by venous saturation measurement is generally undertaken by placing a catheter in a central vein or pulmonary artery from which blood is withdrawn. Oxygen saturation of the withdrawn blood is then measured by a blood gas machine. Alternatively, a fibre-optic catheter can be placed in the central vein or pulmonary artery and the oxygen saturation can then be directly measured by optical methods. An approach such as this involving the insertion of an intravenous fibre-optic catheter and direct measurement of oxygen saturation by oximetry is discussed in US patent no. 5,673,694 to Rivers.

[0005] Both of these approaches involve significant limitations as they require a skilled doctor to insert the catheter, they involve the expense of the blood gas machine or fibre-optic catheter, there is significant risk of adverse events associated with catheter insertion (pneumothorax, infection, bleeding, arrhythmia and tamponade) and finally, there is a delay in obtaining the venous blood saturation while the catheter is inserted.

[0006] The present inventor proposes a non-invasive method to directly measure blood oxygen saturation (such as central venous and mixed venous blood oxygen saturation) by placing a light oximeter device on the skin over deep vascular structures. Pulse oximetry, using red and infrared light sources, is an established technique to measure haemoglobin oxygen saturation of blood vessels in the skin. The sensors are commonly placed on fingers, ears, nose and forehead. Pulse oximetry is routinely used in patients to determine whether oxygenation of the blood by the lungs is adequate. Standard pulse oximetry techniques do not provide information about adequacy of oxygen delivery.

[0007] Two wavelengths of light are generally used in pulse oximetry one in the red band (between about 620nm and about 750nm, but usually in the range of about 640nm - 680nm, most usually about 660nm) and the infrared band (between about 750nm and about 1mm, but usually between about 900nm and 960nm, but often 905nm, 910nm or 940nm). The light is absorbed by haemoglobin in the blood. Deoxyhaemoglobin (Hb) absorbs more of the red band while oxyhaemoglobin absorbs more of the infra-red band. In pulse oximetry light is first transmitted through the tissues and the intensity of the transmitted or reflected light is then measured by the photo-detector. The pulse oximiter determines the AC (pulsatile) component of the absorbance at each wavelength and the amount of the red and infrared AC components is determined, which is indicative of the concentration of oxyhaemoglobin and deoxyhaemoglobin molecules in the blood. The ratio of these molecules indicates the overall haemoglobin oxygen saturation.

[0008] The potential of non-invasive trans-cutaneous pulse oximetry to measure the haemoglobin oxygen saturation of blood in deep vascular structures, for example that carry central venous and mixed venous blood, has not previously been recognised. However, a recent patent (US 7,047,055, to Boas and Zourabian [3]) has suggested that light oximetry of deep tissue structures is possible. This work demonstrated a light oximetric technique to measure arterial saturation in the head of a fetus in utero.

[0009] Other techniques have been proposed to measure mixed venous oxygen saturation using pulse oximetry. These techniques are, however, invasive and require insertion of an endotracheal tube (US 6,961,600, Kohl) [4] or a transoesophageal echocardiographic probe [5]. Venous saturation of peripheral tissues may also be measured using oximetric techniques. These measurements are, however, of limited clinical utility as they only reflect the extent of oxygen delivery to the peripheral tissue assessed, such as the index finger (US 2005/0256386, Chan) or thenar eminence (US 7,072,701, Chen) (US 6,985,763 Boas).

[0010] US patent publication no. 2006/0253007 to Cheng et al describes a light oximetric technique to measure cardiac output, by determining venous blood oxygen saturation in a few deep vascular structures. Cheng et al suggests the concurrent use of ultrasound to assist the correct location of emitter and receiver probes, as well

as requiring oximetry measurements be taken simultaneously at two separate locations to distinguish the signal arising from the deep vascular structure from that of surrounding tissue. The present inventor has demonstrated that by utilising the pulsatile nature of the deep vascular structures to generate a plethysmographic trace it is possible to accurately locate the emitter and receiver elements to optimise the signal detected and to thereby do away with the need for concurrent ultrasonography and measurements from more than one location. The individuality of the plethysmography in the present technique is used to identify that the signal is arising from the vascular structure of interest and to filter out signals arising from other interfering chromophores, such as small blood vessels and surrounding tissues.

[0011] US 5,111,817 discloses a method and device for non-invasively determining arterial blood oxygenation and, simultaneously, blood pressure.

[0012] WO 01/17421 relates to a method and related apparatus for determining oxygen concentration in blood. It suggests the application of sensors to the wrist, fingers, toes or arm.

[0013] It is a preferred object of the present invention to overcome or at least ameliorate to some extent problems associated with prior art methods of determining oxygen saturation in deep vascular structures. Other objects of the present invention will become apparent from the following detailed description thereof.

SUMMARY OF THE INVENTION

[0014] According to the present invention there is provided a method for non-invasive determination of oxygen saturation of blood within a deep vascular structure of a human patient comprising locating on skin of the patient in a vicinity of the deep vascular structure of interest emitter and receiver elements of a light oximeter device, wherein optimal location of said elements is achieved through matching of a plethysmography trace obtained to known plethysmography characteristics of the deep vascular structure of interest, and wherein oxygen saturation is determined from a ratio of light absorbed at different wavelengths by haemoglobin in the blood within the vascular structure of interest.

[0015] In the invention the deep vascular structure of interest is selected from the internal jugular vein, subclavian vein, femoral vein, brachiocephalic vein, inferior vena cava, superior vena cava, right atrium, right ventricle, pulmonary artery (including both peripheral and central parts), left atrium, left ventricle, carotid artery, vertebral artery, subclavian artery, brachiocephalic artery, femoral artery and aorta.

[0016] In one embodiment the method is for non-invasive determination of central venous blood oxygen saturation. In this case the deep vascular structure of interest is preferably selected from the internal jugular vein, subclavian vein, femoral vein, brachiocephalic vein, inferior vena cava, superior vena cava and right atrium.

[0017] In another preferred embodiment the method is for non-invasive determination of mixed venous blood oxygen saturation. In this case the deep vascular structure of interest is preferably selected from the right ventricle and pulmonary artery.

[0018] In another preferred embodiment the method is for non-invasive determination of central arterial oxygen saturation. In this case the deep vascular structure of interest is preferably selected from the left atrium, left ventricle, carotid artery, vertebral artery, subclavian artery, brachiocephalic artery, femoral artery and aorta.

[0019] Preferably the emitter element emits light in both red and infra-red wavelengths. Preferably the red light has a wavelength of between about 620nm and about 750nm, more preferably between about 640nm and about 680nm and most preferably the red light has a wavelength of about 660nm.

[0020] Preferably the infra-red light has a wavelength of between about 750nm and about 1mm. More preferably the infra-red light has a wavelength of between about 900nm and about 960nm and most preferably the infra-red light has a wavelength of about 905nm, 910nm or 940nm.

[0021] According to another embodiment of the present invention there is provided an oximetry device for use in the method as outlined above.

[0022] According to the present invention there is provided an oximetry device according to claim 1.

[0023] Preferably the plethysmography characteristics of the deep vascular structure of interest can also be made available on the display.

[0024] The workable connection can be either physical or wireless.

[0025] Preferably the red light has a wavelength of between about 620nm and about 750nm, more preferably between about 640nm and about 680nm and most preferably the red light has a wavelength of about 660nm.

[0026] Preferably the infra-red light has a wavelength of between about 750nm and about 1mm. More preferably the infra-red light has a wavelength of between about 900nm and about 960nm and most preferably the infra-red light has a wavelength of about 905nm, 910nm or 940nm.

BRIEF DESCRIPTION OF THE FIGURES

[0027] The invention will be further described with reference to the figures, wherein:

Fig. 1 is a schematic diagram of the device of the invention.

Fig. 2 is a schematic diagram of the light emitter and receiver elements of the device of the invention when in position on the skin of a patient in the vicinity of a deep vascular structure of interest.

Fig. 3 shows a scan of relative light absorbance

against time for oximetry of the right ventricle, demonstrating in (a) the phases of right ventricle emptying (systole) and filling (diastole) and the peak in relative absorbance during diastole. In (b) the higher relative absorbance of red light is shown in the case where the blood has a lower oxygen saturation level and in (c) the lower relative absorbance of infra-red light is shown in the case where the blood has a lower oxygen saturation level.

Fig. 4 is a CT scan demonstrating the distance between the skin and the internal jugular veins and carotid arteries (where "RIJ" is the right internal jugular vein and "LIJ" is the left internal jugular vein),

Fig. 5 is a CT scan demonstrating the distance between the skin and the brachiocephalic veins (where "LBCV" is the left brachiocephalic vein and "RBCV" is the right brachiocephalic vein).

Fig. 6 is a CT scan demonstrating the distance between the skin and the aorta and superior vena cava (where "SVC" is the superior vena cava).

Fig. 7 is a CT scan demonstrating the distance between the skin and the pulmonary artery (where "PA" is the pulmonary artery).

Fig. 8 is a CT scan demonstrating the distance between the skin and the right and left ventricles (where "RV" is the right ventricle and "LV" is the left ventricle).

Fig. 9 shows (from top to bottom) the electrocardiogram (ECG), arterial blood pressure, central venous pressure, right internal jugular vein and finger plethysmography traces from one of the patients in the clinical study.

Fig. 10 shows a regression plot of internal jugular vein pulse oximetry determined oxygen saturation against superior vena cava blood gas determined oxygen saturation.

Fig. 11 shows (from top to bottom) the ECG, arterial blood pressure and finger and right ventricular plethysmography traces from one of the patients in the clinical study.

Fig. 12 shows (from top to bottom) the ECG, arterial blood pressure, central venous pressure and pulmonary artery and finger plethysmography traces from one of the patients in the clinical study

Fig. 13 shows (from top to bottom) the ECG, arterial blood pressure, aortic plethysmography trace, central venous pressure and pulmonary artery and forehead plethysmography trace from one of the patients in the clinical study

DETAILED DESCRIPTION OF THE INVENTION

[0028] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

[0029] The reference to any prior art in this specification is not, and should not be taken as, an acknowledgment or any form of suggestion that that prior art forms part of the common general knowledge in Australia.

[0030] To assist in understanding of this document definitions of a few important terms are provided below:
Central venous blood is (relatively de-oxygenated) blood located within centrally (rather than peripherally) located veins. It includes blood within the internal jugular, subclavian, femoral and brachiocephalic veins, the inferior and superior vena cava and the right atrium.

[0031] *Mixed venous blood* is (relatively de-oxygenated blood) located within the right ventricle and central and peripheral parts of the pulmonary arteries, which is being returned to the lungs for re-oxygenation. Monitoring of oxygen saturation in mixed venous blood provides the best assessment of the adequacy oxygen delivery.

[0032] *Central arterial blood* is oxygenated blood within centrally (rather than peripherally) located arteries, other than the pulmonary artery (which carries de-oxygenated blood). It includes blood within the left atrium, left ventricle and carotid, vertebral, subclavian, brachiocephalic, femoral and aortic arteries.

[0033] *Deep vascular structures* are major blood vessels (including the chambers of the heart) which are not superficially located. That is, they are generally at least 1cm, usually at least 2cm and most usually at least 3cm to 5cm, and up to about 10cm beneath the skin of normal patients, depending upon the size and anatomy of the patient concerned. Deep vascular structures include the internal jugular, subclavian, femoral and brachiocephalic veins and the inferior and superior vena cava, the right atrium, right ventricle and central and peripheral parts of the pulmonary arteries, the left atrium, left ventricle and carotid, vertebral, subclavian, brachiocephalic, femoral and aortic arteries.

[0034] *A Plethysmography trace* is the pulsatile signal arising from blood vessels and other blood containing structures, obtained by traditional pulse oximetry methods. The plethysmography trace reflects changes in blood volume and red blood cell orientation through the pulsatile cycle as well as other physical characteristics of the blood vessel or blood containing structure. These factors influence the extent of absorption of oximetry light. The nature of the plethysmography trace for a particular pulsatile vascular structure is therefore a distinguishing feature of that structure.

[0035] The present invention relates generally to methods and devices for determining blood oxygen saturation in deep vascular structures, which do not require the use of ultrasound to locate the vascular structure of interest and also do not require the taking of oximetry measurements at multiple locations. This is achieved by exploiting traditional oximetry techniques and devices, but in conjunction with using the plethysmography trace obtained to optimally locate the emitter and receiver elements of the device on the skin in the vicinity of the structure of interest. By using this approach it is also possible to filter out signals obtained from other chromophores such as those located in surrounding tissues or smaller vessels.

[0036] The methods and device of the invention are useful in a number of clinical settings. Firstly, to measure the central venous blood and mixed venous blood oxygen saturations. This allows the adequacy of oxygen delivery to the tissues throughout the body to be assessed non-invasively. Secondly, to measure the oxygen saturation of blood draining from a particular part of the body, such as the brain, by monitoring blood saturations of the internal jugular veins. This allows the adequacy of oxygen delivery to that region of the body to be assessed non-invasively. A further application is to measure the central arterial blood oxygen saturation. This allows arterial oxygen saturations to be monitored in conditions in which blood flow to superficial tissues, such as the skin, may be poor such that no reliable signal can be obtained by traditional pulse oximetry methods.

[0037] It is therefore possible using the methods and devices of the invention to assess the adequacy of oxygen delivery to the whole body of a human or animal patient, which will be of importance for example in monitoring critically ill or potentially unstable patients, monitoring before, during and after surgical procedures, monitoring during and after cardiac arrest, monitoring during exercise or in cardiac stress testing to detect cardiac or respiratory dysfunction, in exercise testing in humans or animals to document the workload at which the anaerobic threshold is reached and in self monitoring of cardiac function by athletes and high altitude climbers, pilots of non-pressurised aircraft and others exposed to low oxygen environments.

[0038] The invention also allows an assessment of the adequacy of oxygen delivery to the brain, through monitoring of oxygen saturation in one or both of the internal jugular veins. This application is indicated in patients in which blood flow to the brain may be inadequate, such as any form of acute brain injury, following neurosurgical procedures, following operations or procedures on blood vessels supplying the brain, such as the aorta, carotid, vertebral, cerebella and cerebral arteries.

[0039] In addition to measurement of central venous and mixed venous blood oxygen saturation, this transcutaneous technique can be used to measure central arterial blood oxygen saturation. In some clinical situations it is difficult to obtain a superficial pulse oximetry trace due to poor blood flow to the peripheral tissues[6]. These situations include low cardiac output (such as in cardiac arrest, shock), sepsis (resulting in peripheral shut down of blood flow), peripheral vascular disease and exposure to a cold environment. In such situations measurement of central arterial blood oxygen saturation using the present invention will offer a valuable aid to patient management. This technique allows measurement of blood oxygen saturation in central deep vascular structures containing arterial blood, such as the left atrium, left ventricle and carotid, vertebral, subclavian, brachiocephalic, femoral and aortic arteries.

[0040] An important feature of the present invention relates to reliance on the plethsymographic character of the vascular structure of interest detected by the oximetry technique. The pulsatile signal (or plethysmograph trace) of a vascular structure reflects the temporal changes in blood flow through the deep vascular structure of interest. As the blood flow through the deep vascular structures has characteristic features, the plethysmograph trace also reflects these characteristic features and can therefore be used to identify that the signal is arising from the particular deep vascular structure of interest. The characteristic features of a plethysmography trace from a particular deep vascular structure can therefore also be used to filter out other pulsatile signals arising from other interfering chromophores, such as small blood vessels in surrounding tissues. These contribution of these other interfering pulsatile signals can also be assessed through conventional pulse oximetry.

[0041] Another aspect of the invention that enables oximetry to be used to monitor blood oxygen saturation in deep vascular structures, where this had not been considered possible in the past, relates to the relative high volume of blood in deep large blood vessels that results in relatively high absorption of light compared to the blood volume in small blood vessels of the skin and surrounding tissues. This difference in blood volume provides a further means of effectively filtering out signals arising from interfering chromophores, such as small blood vessels in surrounding tissues.

[0042] The present invention allows for the determination of blood oxygen saturation in deep vascular structures in a non-invasive manner. By this it is meant that there is no need for direct sampling of blood and nor is it necessary for any form of central line or other probe to be inserted within the patient, either within or adjacent to vascular structures (such as within the gastrointestinal tract in the vicinity of a vascular structure). Indeed, the present invention can conveniently be conducted by placing the emitter and receiver elements of a light oximeter device on the skin of the patient over deep vascular structure of interest. Deep vascular structures within which blood oxygen saturation can be determined include those containing central venous blood, such as the internal jugular vein, subclavian vein, femoral vein, brachiocephalic vein, inferior vena cava, superior vena cava and right atrium, those containing mixed venous blood, such as the right ventricle and pulmonary artery (central and pe-

ripheral regions) and those containing central arterial blood, such as the left atrium, left ventricle, carotid artery, vertebral artery, subclavian artery, brachiocephalic artery, femoral artery and aorta.

[0043] The right ventricle has a number of characteristics that make it well suited for monitoring. Firstly, it is a pulsatile chamber of the heart; hence the light absorbance will vary with the cardiac cycle. Peak absorbance occurs during diastole (the point in the cardiac cycle when the right ventricle fills with blood). This characteristic provides a method to filter out absorbance by arterial and venous blood in superficial tissues and by non-pulsatile chromophores such as the skin and muscle. Secondly, the right ventricle at the end of diastole is a significant absorber of light - at this point in the cardiac cycle it contains around 100-200 ml of blood. This exceeds the volume of blood in the overlying tissues (through which the light also passes) by at least a factor of 10. The ratio of relative absorbance of the two wavelengths of light during right ventricular diastole, can then be used to derive the oxygen saturation of blood in the right ventricle.

[0044] In conducting the methods of the present invention it is possible to utilise modified conventional pulse oximetry devices, such as for example those described in the book Pulse Oximetry by John TB Moyle[7]. To work optimally a number of modifications are preferred. Modifications that can optimise the signal include utilisation of lasers rather than light emitting diodes to provide the light sources, increasing the distance between the light emitter and light receiving sensors, utilising the plethysmograph trace to identify the signal is arising from the deep vascular structure of interest, utilising the plethysmography trace to filter out signals arising from other interfering chromophores, utilising the signal arising from the relatively high volume of blood in the deep vascular structures (in relation to small blood vessels in superficial tissues) to filter out signals arising from small superficial blood vessels that may act as interfering chromophores, re-calibration of the absorption signals to improve accuracy of oximetry of de-oxygenated rather than traditional oxygenated blood and modification of the formula used to estimate the photon path length to reflect the photon path length required to reach deep vascular structures.

[0045] As shown in Fig. 1 devices (1) specifically useful in the present invention have a number of basic components, such as a central processing unit (2), a display (5) (for in some manner reporting plethysmographic and/or oxygen saturation information) and emitter (3) and receiver (4) elements that respectively emit and sense red and infra-red light. The display (5) may for example take the form of a printer that produces a paper scan of oxygen saturation and plethysmographic trace, a video type screen (such as cathode ray, plasma, liquid crystal) or even a device that produces an audible output of the necessary information. Naturally, in use the various components of the device (1) are connected either physically such as by wires (6) or fibre-optic cable or using conventional wireless technologies. The central processing unit (2) receives from the emitter (3) and receiver (4) elements information regarding the emitted and received light, from which it is able to match the plethysmographic character of the body being monitored with the known plethysmographic character of the deep vascular structure of interest, and is able to compute oxygen saturation from the information on emitted and received light transmitted to it, for example by utilising a clinically derived relationship for oxygen saturation in the particular structure of interest for a particular class or group of patients, as referred to further below. By matching the plethysmographic character against an ideal and giving an operator feedback via the display (5) on this the operator is able to ensure the optimal location of the emitter (3) and receiver (4) elements in the vicinity of the structure of interest (that is on the skin in the region of the structure that allows penetration of light between the emitter / receiver element and the blood within the structure of interest), as schematically depicted in Fig. 2.

[0046] In one embodiment an optical fibre is used to deliver a probe light beam (the emitter) combined from a pair of remote sources to a fitting placed in contact with the skin above, for example, the right ventricle of the patient. The fitting also contains a second optical fibre that is used to collect reflected light (the detector) from the internal tissues and blood. The optical fibres are provided with suitable collimation optics to direct the delivered beam and selectively collect the reflected light along preferred directions. The optical fibers will preferably have an adjustable mount so that the delivery and sampling directions can be modified to match different patient morphologies, to thereby meet the requirements of different patient chest size, shape, bone structure, muscle and fat content. The reflected light is spectrally analysed and converted to an electrical signal by a photodetector. Optimal light delivery and collection geometries, light sources and photodetector types can be adjusted to give optimal results. Signals from sources other than the vascular structure of interest are removed by a combination of spatial filtering, mathematical processing and computer analysis algorithms.

[0047] Two wavelengths of light are generally used in pulse oximetry one in the red band (between about 620nm and about 750nm, but usually in the range of about 640nm - 680nm, most usually about 660nm) and one in the infrared band (between about 750nm and about 1mm, but usually between about 900nm and 960nm, but often 905nm, 910nm or 940nm). The light is absorbed by haemoglobin in the blood. Deoxyhaemoglobin (Hb) absorbs more of the red band while oxyhaemoglobin absorbs more of the infra-red band. In pulse oximetry light is first transmitted through the tissues and the intensity of the transmitted (reflected) light is then measured by the photo-detector. The pulse oximiter determines the AC (pulsatile) component of the absorbance at each wavelength and the amount of the red and infrared AC components is determined, which is indicative of the concentration of oxyhaemoglobin and deoxyhaemo-

globin molecules in the blood. The ratio of these molecules indicates the overall haemoglobin oxygen saturation.

[0048] The principle of operation of the present methods are graphically represented in Fig. 3. As can be seen in Fig. 3(a) relative light absorbance in the vascular structure (in this case the right ventricle) increases as the right ventricle fills with blood during diastole. Fig 3(b) shows that relative absorbance of red light is higher when the blood in the vascular structure has lower oxygen saturation and Fig 3(c) shows that relative absorbance of infrared light is lower when the blood in the vascular structure has lower oxygen saturation. The ratio of absorbance of two or more wavelengths of light, particularly in the case of the right ventricle during diastole, is used to derive the oxygen saturation of the blood within the vascular structure. Fig. 3 also demonstrates the plethysmographic character that is particular to the right ventricle, and which is used to discriminate between the signal derived from the right ventricle and from other vascular structures to thereby optimally position the emitter and detector elements.

[0049] In the case of the use of pulse oximetry in the methods of the present invention to determine blood oxygen saturation levels within deep vascular structures clinical studies can be conducted on a patient population to determine the relationship between the apparent oxygen saturation determined by pulse oximetry for the deep vascular structure and the actual oxygen saturation in the vessel as determined by an analytical method (e.g. by use of a blood oxygen analyser). In view of this knowledge the device can be calibrated and accurate quantification of the oxygen saturation in a particular deep vessel for a particular patient can be obtained non-invasively. In determining the appropriate calibration it is be useful to take into account not only the deep vascular structure of interest, but also the age, height, weight and/or general medical condition of the patient. In this way the relationship relied upon can be specific for the structure of interest in patients of similar stature and condition.

[0050] The present invention will now be described further with reference to the following nonlimiting examples.

EXAMPLE 1

Determination of blood oxygen saturation in deep vascular structures of human patients

[0051] A non-invasive method to assess oxygen saturation of blood in central veins and mixed venous blood in the right ventricle or pulmonary artery could have great clinical utility in documenting the adequacy of oxygen delivery in potentially unstable and critically ill patients.

[0052] Previous studies have shown light can penetrate a number of centimetres into body tissues[3]. There has, however, been no previous demonstration that oximetry techniques can be used to reliably obtain oxygen saturation readings from blood in deep vascular structures. The present inventor investigated a novel non-invasive transcutaneous method to measure central venous, mixed venous and central arterial blood oxygen saturations by placing a light oximeter device on the skin over large blood vessels and cardiac chambers carrying these types of blood.

Methods

[0053] The distance in centimetres between the skin and deep vascular structures on a series of computed tomography (CT) scans of 6 supine patients was assessed.

Results

[0054] The following average distances (cm) between the skin surface and underlying deep vascular structures were determined from analysis of the CT scans;

- Pulmonary artery 4.3 ± 1.0 (mean and standard deviation)
- Right ventricle 3.5 ± 0.8
- Left ventricle 4.0 ± 1.3
- Right atrium 5.9 ± 1.5
- Left brachiocephalic vein 4.0 ± 1.0
- Superior vena cava 6.2 ± 1.5
- Right brachiocephalic vein 4.5 ± 1.6
- Right brachiocephalic artery 4.8 ±2.1
- The carotid arteries and internal jugular veins were always less than 3 cm from the skin surface.

[0055] Example CT scans are shown in Figs. 4 to 8.

Discussion

[0056] It was demonstrated that deep vascular structures in the neck and the chest lie less than 7 cm from the skin surface.

EXAMPLE 2

Character of plethysmography trace and blood oxygen saturation level.

Methods

[0057] A clinical study was undertaken in 8 critically ill ventilated patients. All patients had a central line placed in the superior vena cava. Transcutaneous pulse oximetry according to the invention was used to assess the oxygen saturation of venous blood passing through deep vascular structures including the internal jugular vein, the right ventricle and pulmonary artery. The saturation of blood in central arterial vascular structures including the aorta and left ventricle was also assessed.

[0058] The light emitter and light receiver elements of a pulse oximeter device (OxiMax adult oxygen sensor by

Nellcor attached to a pulse oximiter module of a Hewlett Packard Critical Care Monitor) were placed 2 to 8 cm apart on the skin over the vascular structure of interest.

[0059] The inventor also investigated whether the plethysmography trace obtained was consistent with the signal arising from the deep vascular structure of interest. The pulsatile nature of blood flow through each of the deep vascular structures has certain characteristics peculiar to each. The inventor hypothesised that the plethysmography trace would reflect these characteristics.

[0060] The plethysmography trace and blood oxygen saturation were documented. In patients in whom a reasonable plethysmography trace was obtained superior vena cava blood was analysed in a blood gas machine to determine the oxygen saturation In such patients example plethysmography traces were also obtained.

Results

[0061] In the internal jugular vein the inventor determined the plethysmograph trace to be consistent with the expected signal arising from the internal jugular vein in 5 of the 8 patients studied. The plethysmograph trace from these 5 patients demonstrated the characteristic "a" and "v" waves of the central venous pressure trace (Fig 9). The oxygen saturation level was low and was consistent with the level expected from blood in a central vein.

[0062] For the 5 patients in whom a reliable internal jugular vein plethysmograph trace was obtained blood was aspirated from the central line in the superior vena cava and blood gas saturations were measured. A linear relationship between the pulse oximeter and blood gas determined oxygen saturations (Fig. 10) was identified. The correlation coefficient (R^2) was 0.4.

[0063] The plethysmograph trace was consistent with the signal arising from the right ventricle in 2 of the 8 patients studied. During diastole the signal increased, this is consistent with diastolic filling of the right ventricle with blood. During systole the signal decreased, this is consistent with empting of the ventricle of blood (Fig. 11). The signal was, therefore, the inverse of the finger plethysmography trace. In addition the saturation level was low and therefore consistent with the signal arising from mixed venous blood (average value was 45%).

[0064] The plethysmography trace was consistent with the signal arising from blood in the pulmonary artery in 2 of the 8 patients studied. The systolic wave preceded the finger systolic wave (consistent with a central vascular source of the signal). In addition a dicrotic notch was evident (Fig. 12). Finally, the oxygen saturation level was low and therefore consistent with the signal arising from mixed venous blood (55%)

[0065] The plethysmography trace was consistent with the signal arising from blood in the ascending aorta in 4 of the 8 patients studied. The systolic wave preceded the forehead systolic wave (consistent with a central arterial source of the signal). In addition the waveform was narrower (Fig. 13).

Discussion

[0066] It was shown that light can reach deep vascular structures and the returning signal can be used to obtain a measure of the blood oxygen saturation within the structure of interest.

[0067] A linear relationship was also demonstrated between the internal jugular vein pulse oximetry and superior vena cava blood gas saturation levels, indicating that with calibration accurate quantification of oxygen saturation in the deep vascular structures can be obtained.

[0068] At least in some patients the nature of the plethysmography trace reflected the temporal changes in blood flow through these deep vascular structures. The character of the trace was therefore peculiar to each of these deep vascular structures. The distinctiveness of the plethysmography trace for each structure can therefore be used to identify that the signal is arsing from the appropriate deep vascular structure (and to thereby enable optimal location of the emitter and receiver elements in the vicinity of the structure of interest), and can also be used to filter out signals arising from other interfering chromophores, such as those in small blood vessels and other surrounding tissues.

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Claims

1. An oximetry device (1) comprising a central processing unit (2), a display (5) and emitter (3) and receiver (4) elements adapted for releasable application to human skin, all of which are workably connected in use; the emitter elements (3) being equipped to emit light of both red and infra-red wavelengths and the receiver elements (4) adapted to detect said light, with information relating to levels of emitted and received light being transmitted to said central processing unit (2); **characterised in that** said central processing unit (2) is adapted to determine the optimal positioning in use of the emitter (3) and receiver (4) elements on the skin in a vicinity of the deep vascular structure of interest by matching plethysmography characteristics derived from the information relating to levels of emitted and received light with known plethysmography characteristics of a deep vascular structure of interest that contains central venous or mixed venous blood and **in that** said central processing unit (2) is also capable of deriving from the information relating to levels of emitted and received light a measurement of blood oxygen saturation within the deep vascular structure of interest; and making said measurement available on the display (5).

2. The oximetry device according to claim 1 configured such that the plethysmography characteristics of the deep vascular structure of interest can also be made available on the display (5).

3. The oximetry device of claim 1 wherein the workable connection is physical.

4. The oximetry device of claim 1 wherein the workable connection is wireless.

5. The oximetry device of claim 1 wherein the red light has a wavelength of between about 640nm and about 680nm.

6. The oximetry device of claim 1 wherein the infra-red light has a wavelength of between about 900nm and about 960nm.

7. Use of an oximetry device according to claim 1 for non-invasive determination of oxygen saturation of central venous or mixed venous blood within a deep vascular structure of a human patient that contains central venous or mixed venous blood.

8. The use of claim 7 for non-invasive determination of central venous blood oxygen saturation.

9. The use of claim 8 wherein the deep vascular structure of interest is selected from the internal jugular vein, subclavian vein, femoral vein, brachiocephalic vein, inferior vena cava, superior vena cava and right atrium.

10. The use of claim 7 for non-invasive determination of mixed venous blood oxygen saturation.

11. The use of claim 10 wherein the deep vascular structure of interest is selected from the right ventricle and pulmonary artery.

12. A method for non-invasive determination of oxygen saturation of central venous or mixed venous blood within a deep vascular structure of a human patient that contains central venous or mixed venous blood **characterised in that** the method comprises locating on skin of the patient in a vicinity of the deep vascular structure of interest emitter (3) and receiver (4) elements of a light oximeter device (1), wherein optimal positioning of said elements on the skin in a vicinity of the deep vascular structure of interest is determined, by a central processing unit, through matching of a plethysmography trace obtained from the oximeter device (1) to known plethysmography characteristics of the deep vascular structure of interest, and wherein oxygen saturation is determined by the central processing unit from a ratio of light absorbed at different wavelengths by haemoglobin in the blood within the vascular structure of interest.

Patentansprüche

1. Oximetrie-Messgerät (1), umfassend eine Zentraleinheit (2), ein Display (5) und zur lösbaren Applikation auf menschlicher Haut ausgebildete Emitter- (3) und Receiverelemente (4), sämtlich im Gebrauch wirkverbunden, wobei die Emitterelemente (3) zur Emission sowohl roter als auch infraroter Wellenlängen ausgerüstet und die Receiverelemente (4) zur Detektion besagten Lichts ausgebildet sind und Informationen über die Lichtmengen des emittierten und des empfangenen Lichts an besagte Zentraleinheit (2) übertragen werden; **dadurch gekennzeichnet, dass** besagte Zentraleinheit (2) dazu ausgebildet ist, die optimalen Gebrauchslagen der Emitter- (3) und Receiverelemente (4) auf der Haut in der Nachbarschaft der interessierenden tiefen Gefäßstruktur durch Abgleichen der aus den Informationen über die emittierten und empfangenen Lichtmengen gewonnenen Kenngrößen mit bekannten plethysmografischen Kenngrößen einer interessierenden tiefen, zentralvenöses Blut oder gemisch-

tes venöses Blut enthaltenden Gefäßstruktur zu ermitteln, und dass besagte Zentraleinheit (2) auch dazu befähigt ist, aus den Informationen über die emittierten und empfangenen Lichtmengen eine Messung der Sauerstoffsättigung des Blutes innerhalb der interessierenden tiefen Gefäßstruktur abzuleiten und besagte Messung auf dem Display (5) verfügbar zu machen.

2. Oximetrie-Messgerät nach Anspruch 1, so ausgestaltet, dass die plethysmografischen Kenngrößen der interessierenden tiefen Gefäßstruktur auch auf dem Display (5) verfügbar sind.

3. Oximetrie-Messgerät nach Anspruch 1, wobei die Wirkverbindung körperlich ist.

4. Oximetrie-Messgerät nach Anspruch 1, wobei die Wirkverbindung drahtlos ist.

5. Oximetrie-Messgerät nach Anspruch 1, wobei das rote Licht eine Wellenlänge zwischen ca. 640 nm und ca. 680 nm aufweist.

6. Oximetrie-Messgerät nach Anspruch 1, wobei das infrarote Licht eine Wellenlänge zwischen ca. 900 nm und ca. 960 nm aufweist.

7. Verwendung eines Oximetrie-Messgeräts nach Anspruch 1 zur nichtinvasiven Ermittlung der Sauerstoffsättigung zentralvenösen oder gemischt venösen Blutes in einer tiefen, zentralvenöses oder gemischt venöses Blut enthaltenden Gefäß-struktur eines menschlichen Patienten.

8. Anwendung von Anspruch 7 zur nichtinvasiven Ermittlung der Sauerstoffsättigung zentralvenösen Blutes.

9. Anwendung von Anspruch 8, wobei die interessierende tiefe Gefäßstruktur nach Wahl die Vena jugularis interna, die Vena subclavia, die Vena femoralis, die Vena brachiocephalica, die Vena cava inferior, die Vena cava superior oder der rechte Vorhof sein kann.

10. Anwendung von Anspruch 7 zur nichtinvasiven Ermittlung der Sauerstoffsättigung gemischten venösen Blutes.

11. Anwendung von Anspruch 10, wobei die interessierende tiefe Gefäßstruktur nach Wahl die rechte Herzkammer oder die Arteria pulmonalis sein kann.

12. Verfahren zur nicht-invasiven Ermittlung der Sauerstoffsättigung zentralvenösen oder gemischt venösen Blutes in einer tiefen, zentralvenöses oder gemischt venöses Blut enthaltenden Gefäßstruktur eines menschlichen Patienten, **dadurch gekennzeichnet, dass** das Verfahren die Positionierung von Emitter- (3) und Receiverelementen (4) eines Licht-Oximetrie-Messgeräts (1) auf der Haut des Patienten in der Nachbarschaft der interessierenden tiefen Gefäßstruktur umfasst, wobei die optimale Positionierung der Elemente auf der Haut in der Nachbarschaft der interessierenden tiefen Gefäßstruktur von einer Zentraleinheit durch Abgleichen einer durch das Oximetrie-Messgerät (1) gewonnenen plethysmo-grafischen Kurve mit bekannten plethysmografischen Kenngrößen der interessierenden tiefen Gefäß-struktur ermittelt wird, und wobei die Sauerstoff-sättigung durch die Zentraleinheit ermittelt wird aus einem Verhältnis des Lichts, das bei unterschiedlichen Wellenlängen innerhalb der interessierenden Gefäßstruktur durch das im Blut befindliche Hämoglobin absorbiert wird.

Revendications

1. Dispositif d'oxymétrie (1) comprenant une unité centrale (2), un écran (5) et des éléments émetteurs (3) et récepteurs (4) adaptés pour être appliqués de façon détachable à une peau humaine, tous étant connectés de façon opérationnelle à l'usage ; les éléments émetteurs (3) étant équipés pour émettre de la lumière de longueurs d'onde à la fois dans le rouge et l'infrarouge et les éléments récepteurs (4) adaptés pour détecter ladite lumière, des informations concernant des niveaux de lumière émise et reçue étant transmises à ladite unité centrale (2) ;
caractérisé en ce que ladite unité centrale (2) est adaptée pour déterminer le positionnement optimal à l'usage des éléments émetteurs (3) et récepteurs (4) sur la peau à proximité d'une structure vasculaire profonde d'intérêt en associant des caractéristiques de pléthysmographie dérivées des informations concernant des niveaux de lumière émise et reçue avec des caractéristiques de pléthysmographie connues d'une structure vasculaire profonde d'intérêt qui contient du sang veineux central ou veineux mêlé et **en ce que** ladite unité centrale (2) peut également déduire des informations concernant des niveaux de lumière émise et reçue une mesure de saturation en oxygène du sang à l'intérieur de la structure vasculaire profonde d'intérêt ; et rendre ladite mesure disponible sur l'écran (5).

2. Dispositif d'oxymétrie selon la revendication 1 configuré de telle sorte que les caractéristiques de pléthysmographie de la structure vasculaire profonde d'intérêt peuvent également être rendues disponibles sur l'écran (5).

3. Dispositif d'oxymétrie de la revendication 1 dans lequel la connexion opérationnelle est physique.

4. Dispositif d'oxymétrie de la revendication 1 dans lequel la connexion opérationnelle est sans fil.

5. Dispositif d'oxymétrie de la revendication 1 dans lequel la lumière rouge a une longueur d'onde comprise entre environ 640 nm et environ 680 nm.

6. Dispositif d'oxymétrie de la revendication 1 dans lequel la lumière infrarouge a une longueur d'onde comprise entre environ 900 nm et environ 960 nm.

7. Utilisation d'un dispositif d'oxymétrie selon la revendication 1 pour la détermination non invasive de la saturation en oxygène de sang veineux central ou veineux mêlé à l'intérieur d'une structure vasculaire profonde d'un patient humain qui contient du sang veineux central ou veineux mêlé.

8. Utilisation de la revendication 7 pour la détermination non invasive de la saturation en oxygène de sang veineux central.

9. Utilisation de la revendication 8 dans laquelle la structure vasculaire profonde d'intérêt est choisie parmi la veine jugulaire interne, la veine sous-clavière, la veine fémorale, la veine brachiocéphalique, la veine cave inférieure, la veine cave supérieure et l'atrium droit.

10. Utilisation de la revendication 7 pour la détermination non invasive de la saturation en oxygène de sang veineux mêlé.

11. Utilisation de la revendication 10 dans laquelle la structure vasculaire profonde d'intérêt est choisie parmi le ventricule droit et l'artère pulmonaire.

12. Procédé de détermination non invasive de la saturation en oxygène de sang veineux central ou veineux mêlé à l'intérieur d'une structure vasculaire profonde d'un patient humain qui contient du sang veineux central ou veineux mêlé, **caractérisé en ce que** le procédé comprend le positionnement sur la peau du patient à proximité de la structure vasculaire profonde d'intérêt d'éléments émetteurs (3) et récepteurs (4) d'un dispositif d'oxymétrie optique (1),
dans lequel un positionnement optimal desdits éléments sur la peau à proximité de la structure vasculaire profonde d'intérêt est déterminé, par une unité centrale, par association d'une trace de pléthysmographie obtenue à partir du dispositif d'oxymétrie (1) avec des caractéristiques de pléthysmographie connues de la structure vasculaire profonde d'intérêt, et dans lequel la saturation en oxygène est déterminée par l'unité centrale à partir d'un rapport de lumière absorbée à différentes longueurs d'onde par l'hémoglobine dans le sang à l'intérieur de la structure vasculaire d'intérêt.

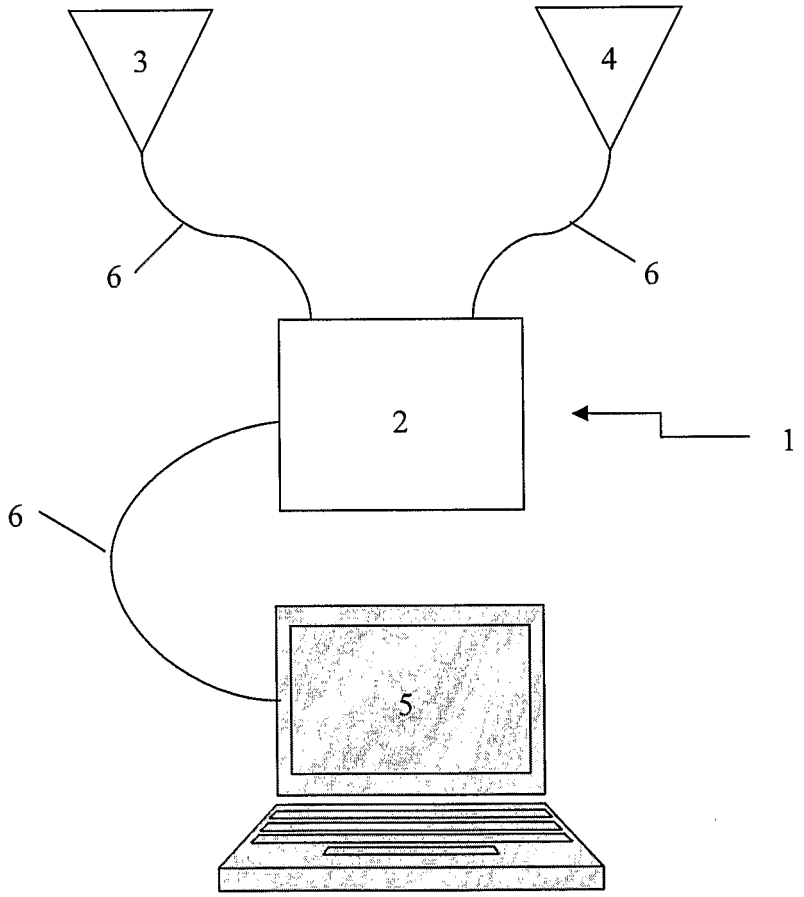


Fig. 1

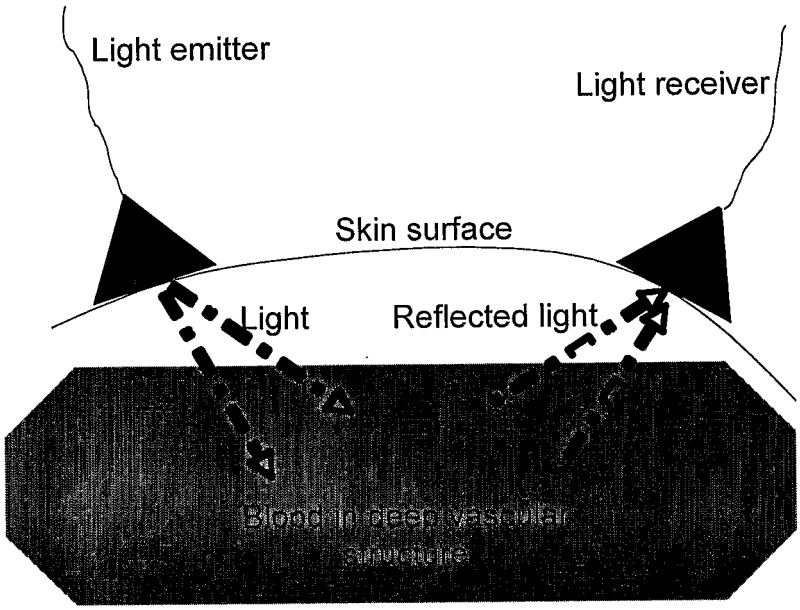

Light emitter
Light receiver
Skin surface
Light
Reflected light
Blood in deep vascular
structure

Fig. 2

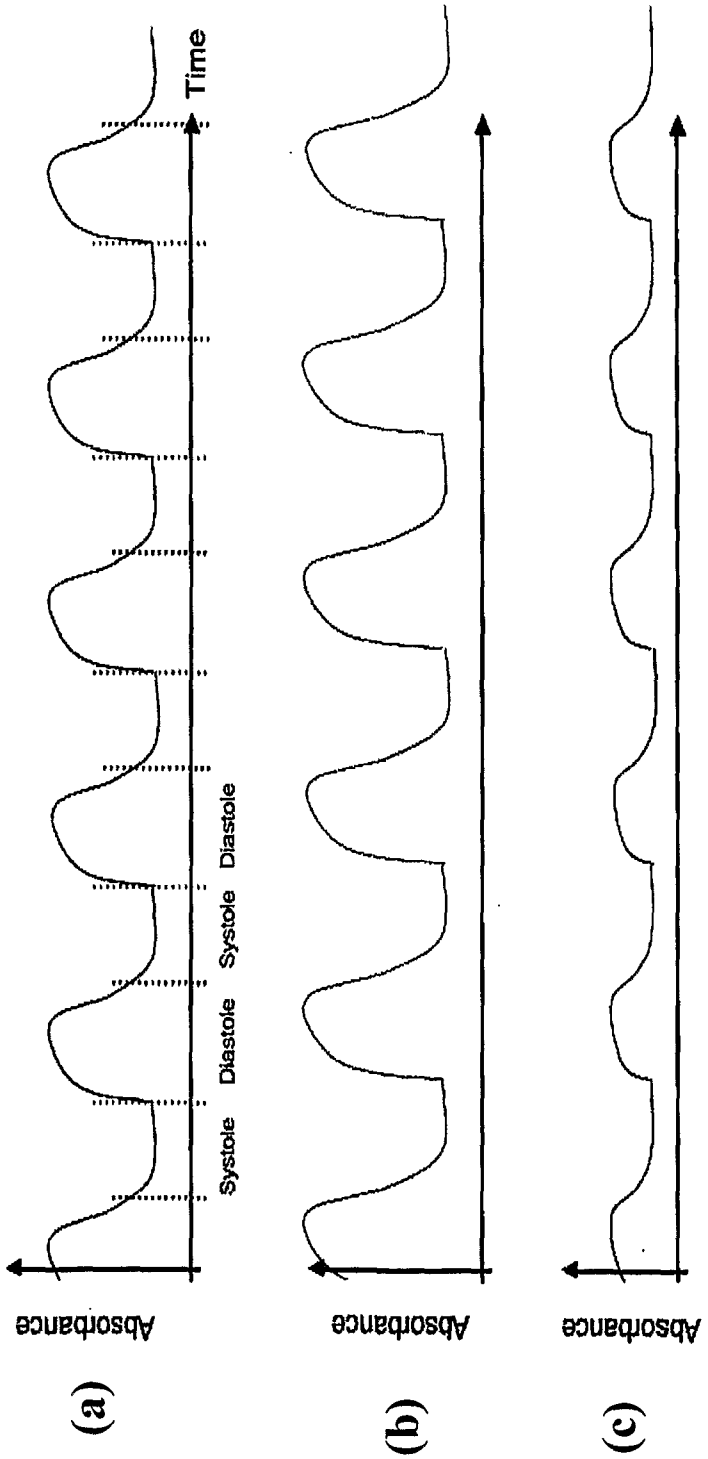

Time
Systole
Diastole
Systole
Diastole
Absorbance
Absorbance
Absorbance
(a)
(b)
(c)

Fig. 3

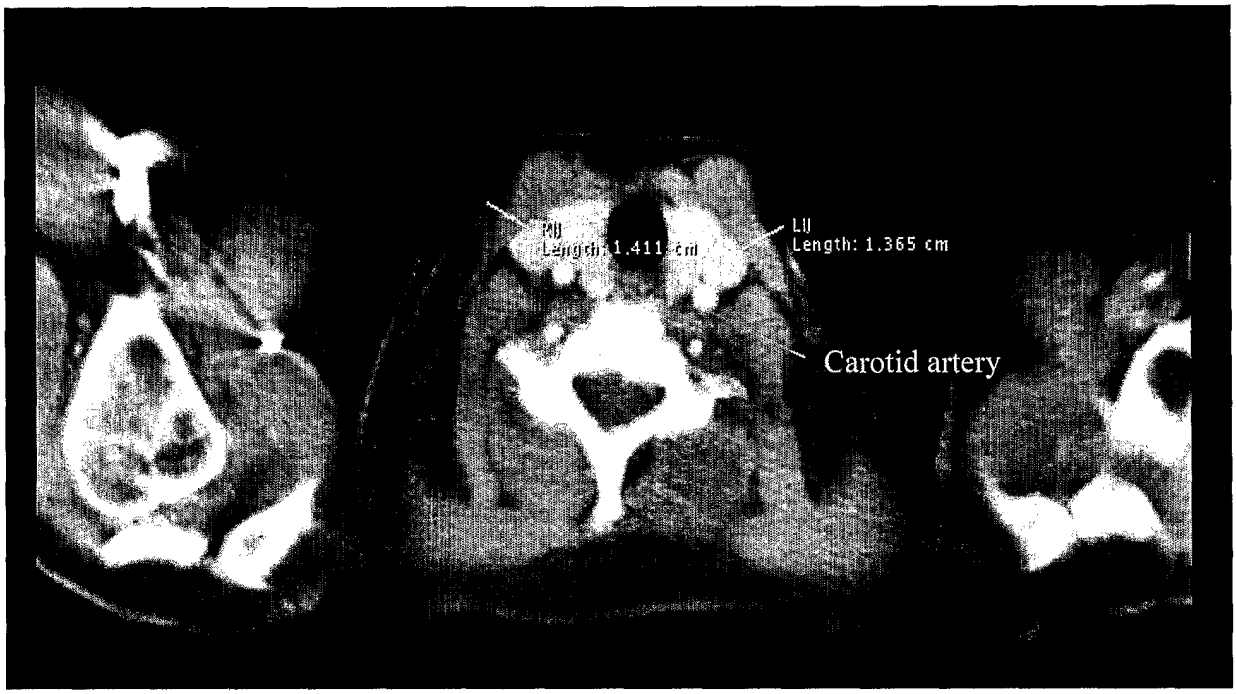


Fig. 4

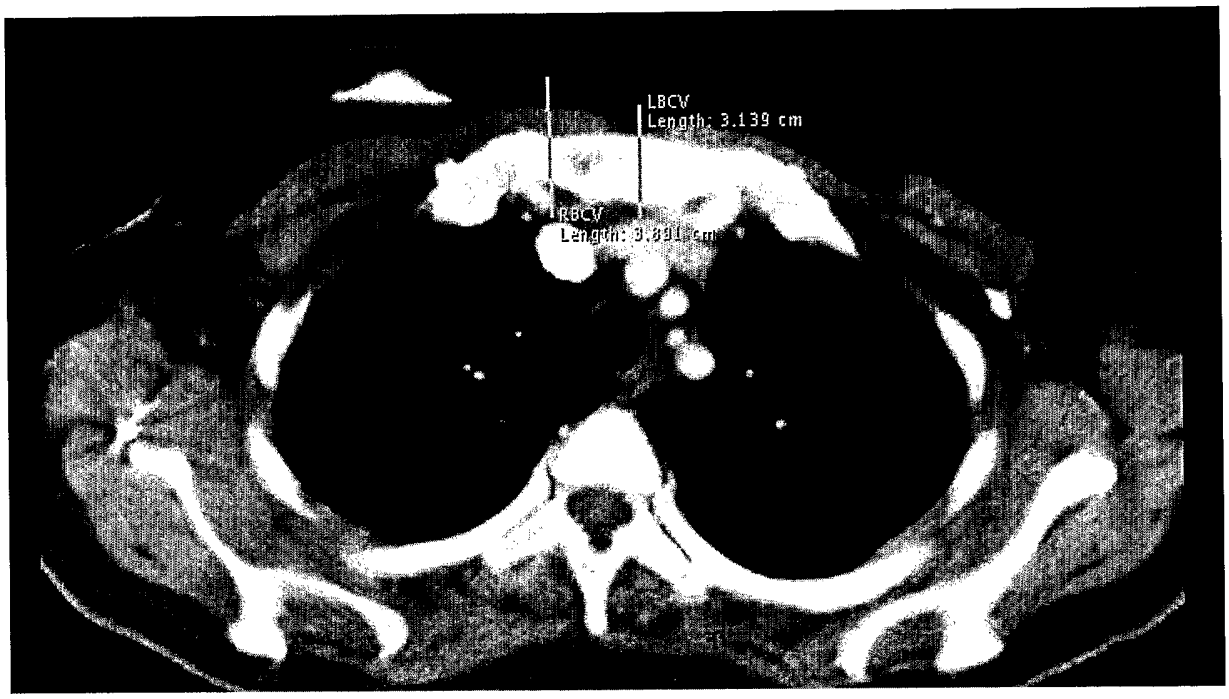


Fig. 5

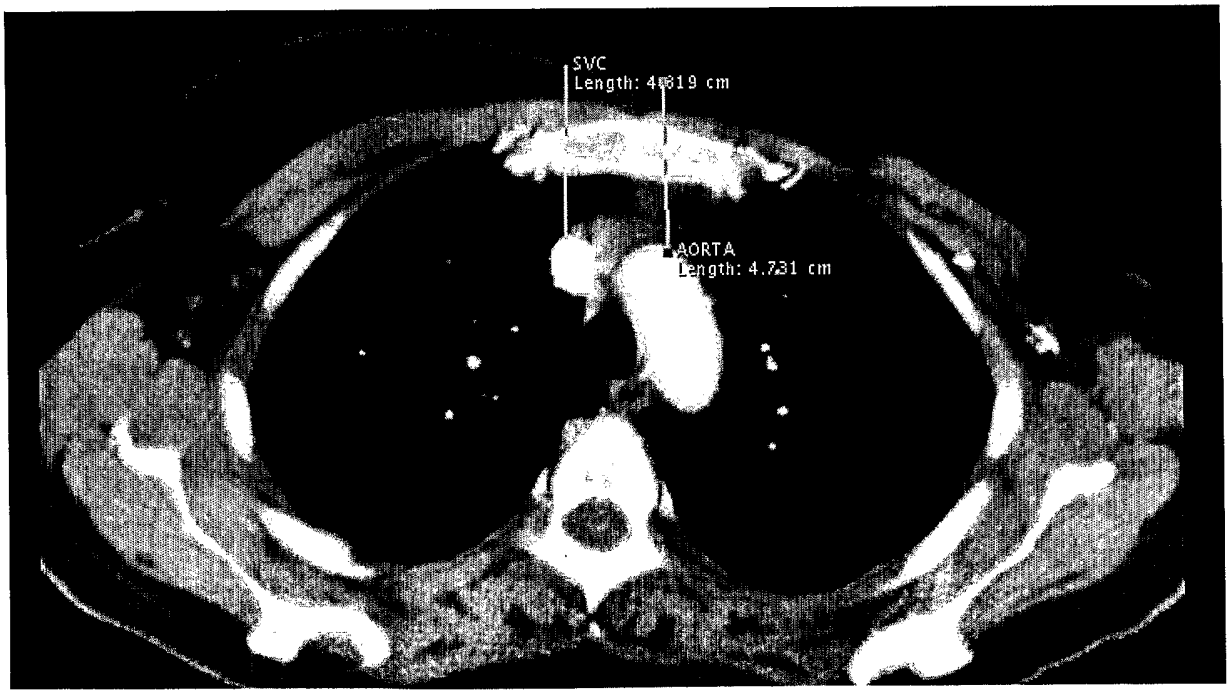


Fig. 6

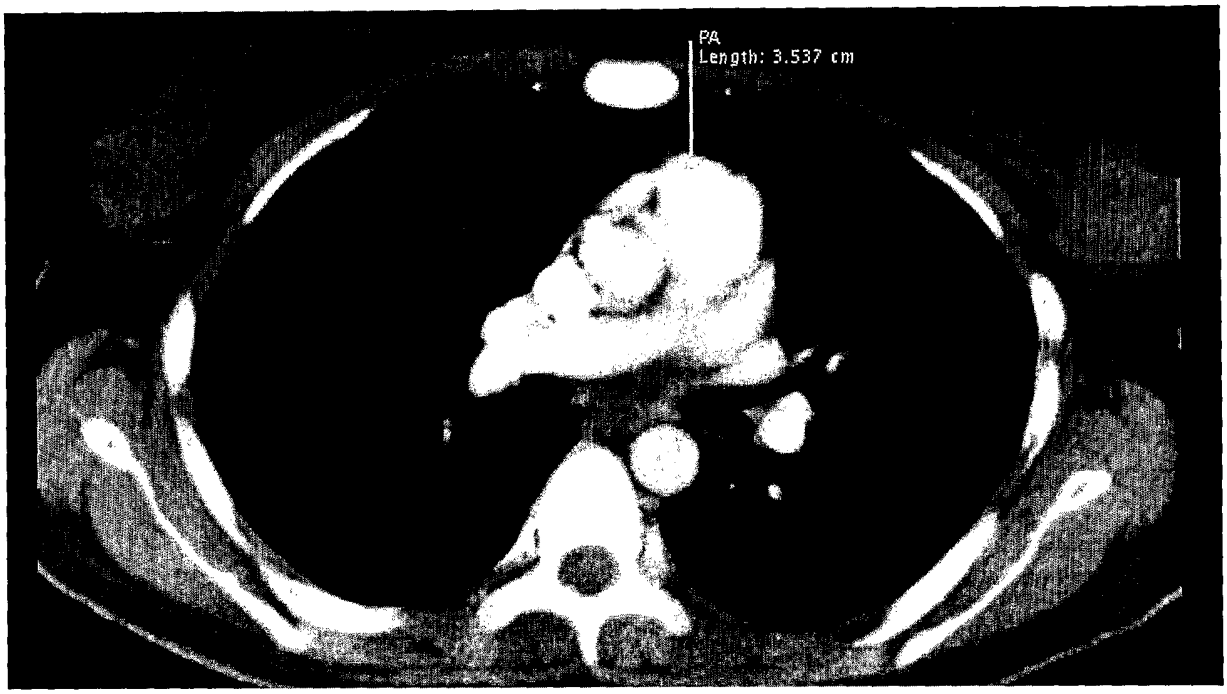


Fig. 7

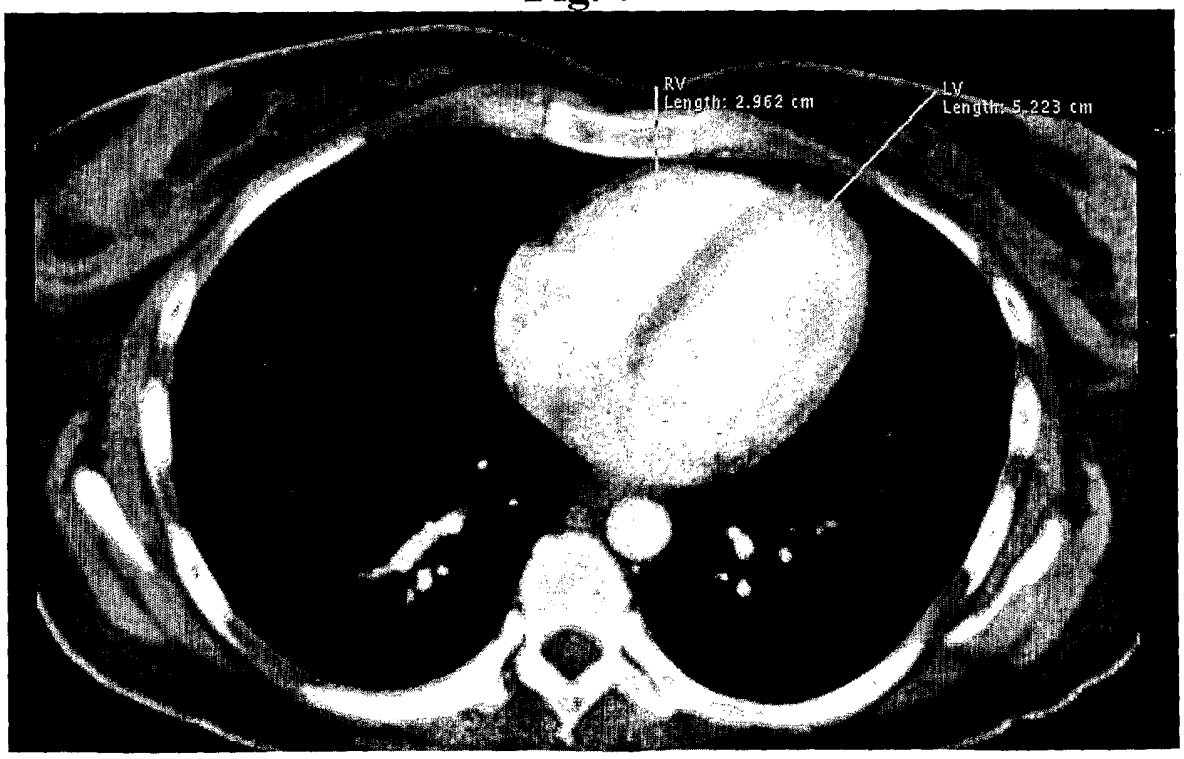


Fig. 8

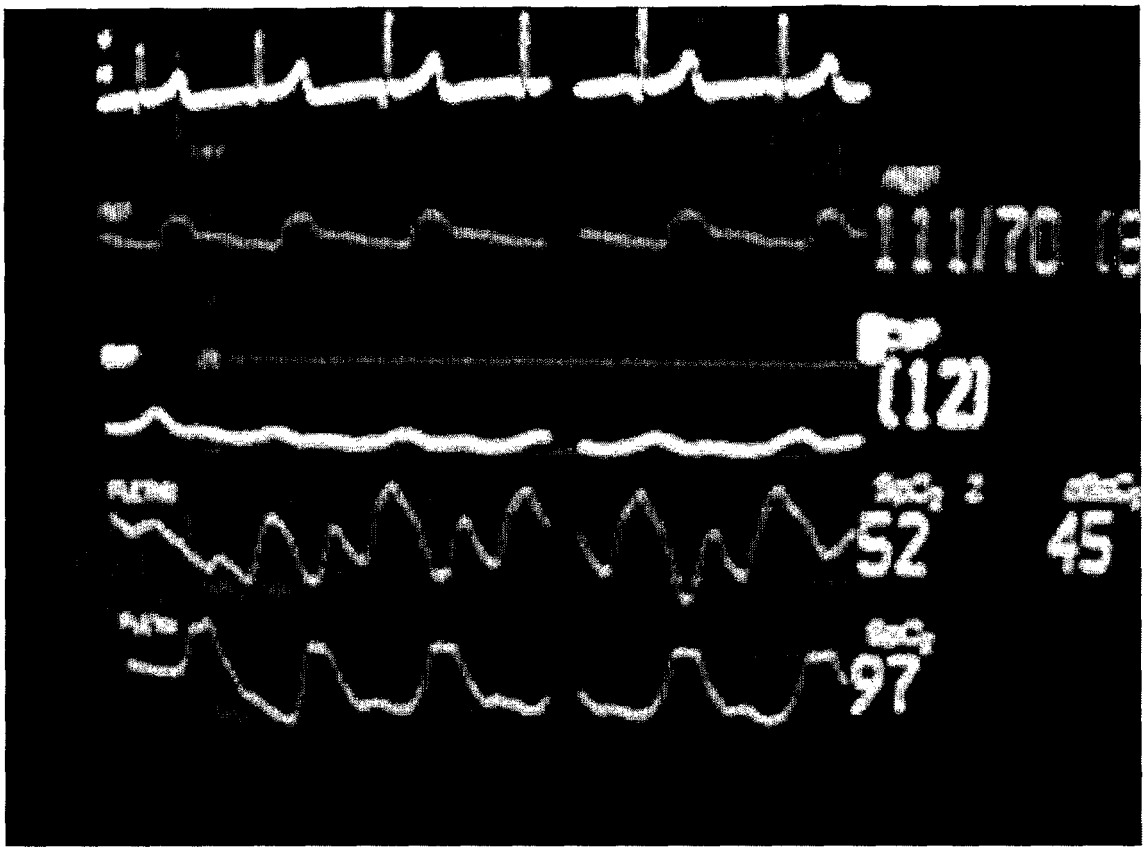

111/70
(12)
52
45
97

Fig. 9

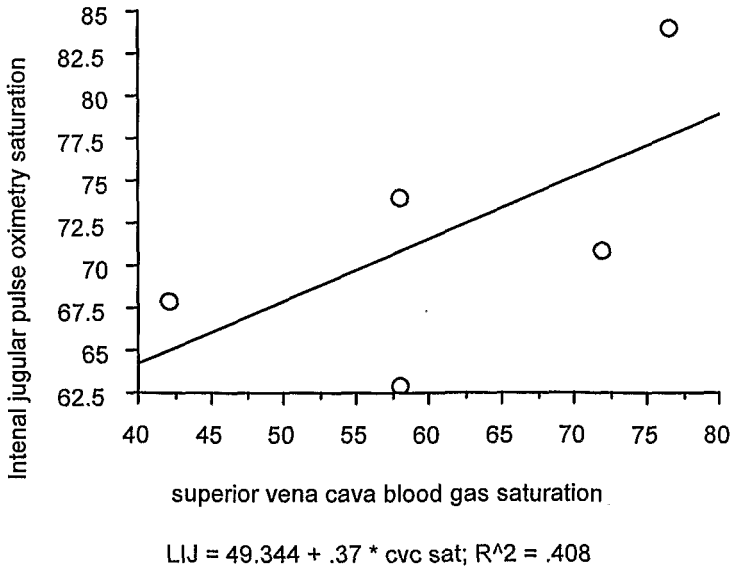
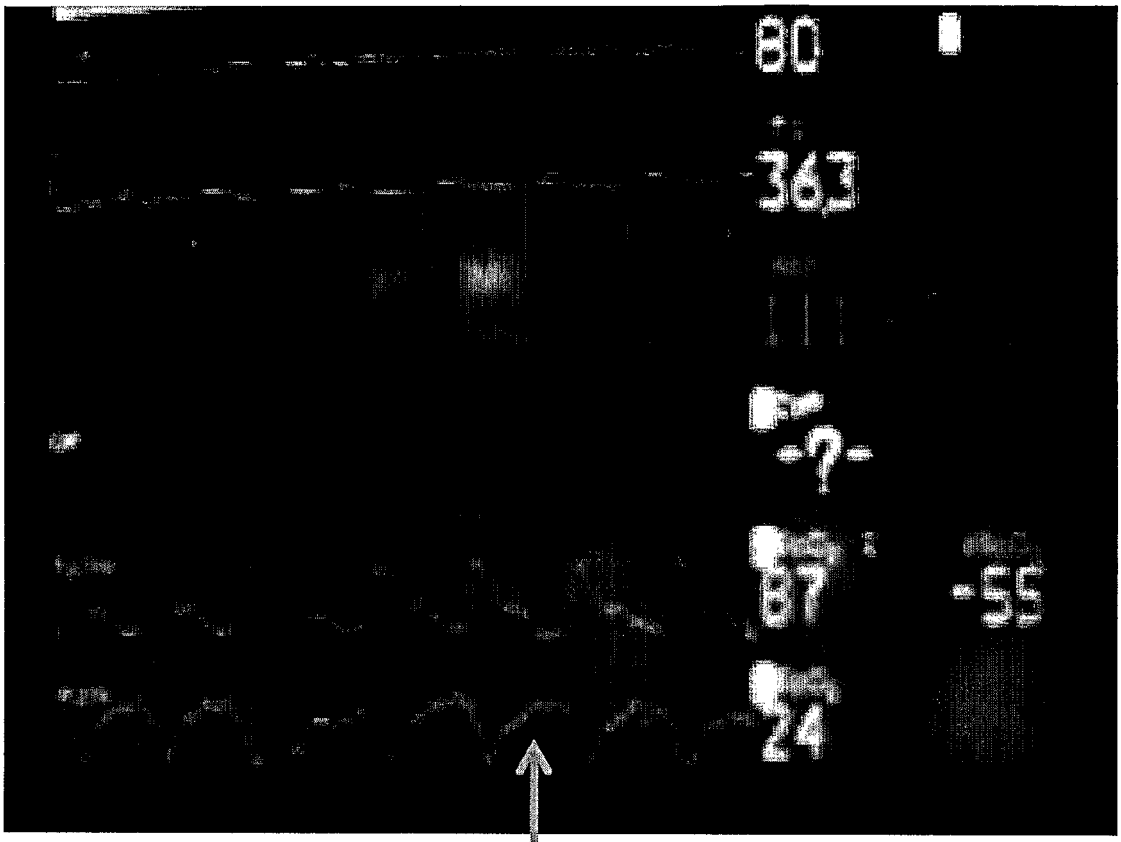
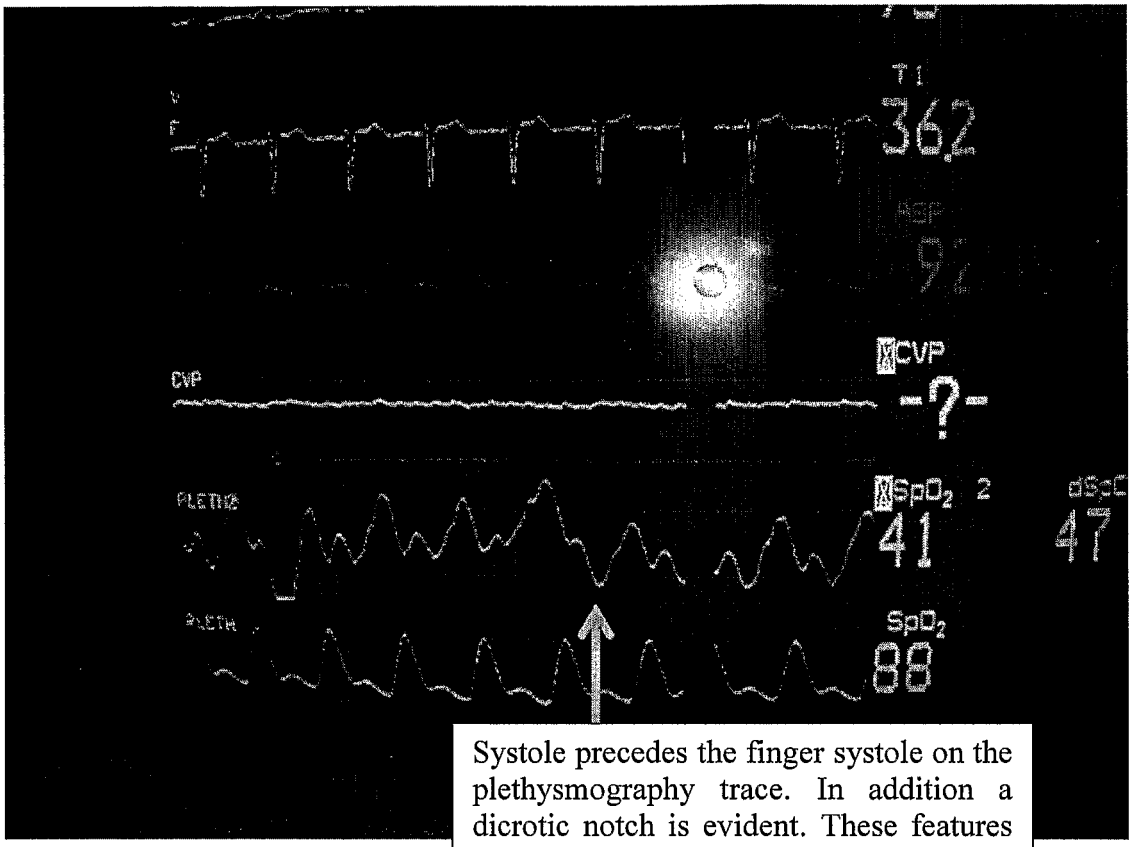

Intenal jugular pulse oximetry saturation
85
82.5
80
77.5
75
72.5
70
67.5
65
62.5
40
45
50
55
60
65
70
75
80
superior vena cava blood gas saturation
LIJ = 49.344 + .37 * cvc sat; R^2 = .408

Fig. 10



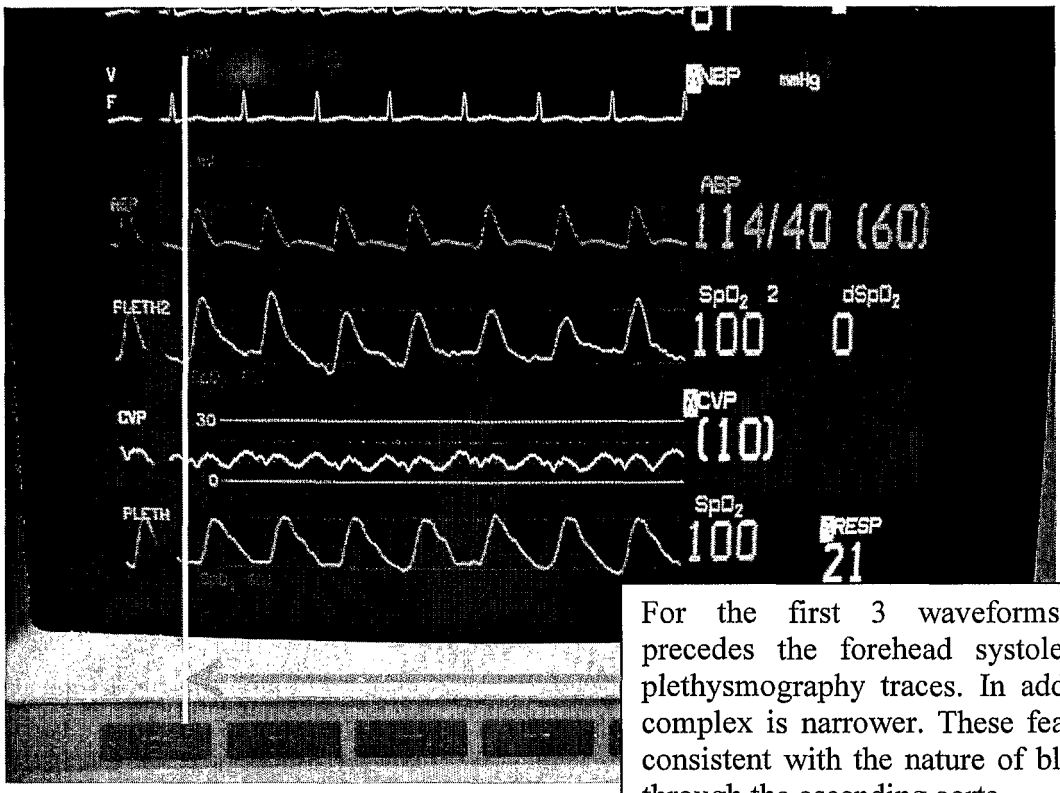
The trace increases during diastole and falls during systole. This is consistent with the nature of blood flow through the right ventricle

Fig. 11



Systole precedes the finger systole on the plethysmography trace. In addition a dicrotic notch is evident. These features are consistent with the nature of blood flow through the pulmonary artery.

Fig. 12



For the first 3 waveforms systole precedes the forehead systole on the plethysmography traces. In addition the complex is narrower. These features are consistent with the nature of blood flow through the ascending aorta.

Fig. 13

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	无创测量血氧饱和度		
公开(公告)号	EP2142097B1	公开(公告)日	2019-01-09
申请号	EP2008733446	申请日	2008-05-02
[标]申请(专利权)人(译)	ST文森医院MELBOURNE		
申请(专利权)人(译)	ST.文森医院（墨尔本）有限公司		
[标]发明人	DIXON BARRY		
发明人	DIXON, BARRY		
IPC分类号	A61B5/00 A61B5/1455		
CPC分类号	A61B5/14551 A61B5/4064 A61B5/412		
代理机构(译)	GIBSON，MARK		
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其他公开文献	EP2142097A1 EP2142097A4		
外部链接	Espacenet		

摘要(译)

本发明涉及一种用于非侵入性地确定人类患者的深血管结构内的血液的氧饱和度的方法，该方法包括在所述感兴趣的深血管结构附近的患者的皮肤上定位光学血氧计的发射器和接收器元件。装置，其中所述元件的最佳位置是通过将从血氧计装置获得的体积描记迹线与感兴趣的深血管结构的已知体积描记特征相匹配来实现的，并且其中氧饱和度由血红蛋白在不同波长下吸收的光的比率确定。在感兴趣的血管结构内的血液中。本发明还涉及能够实施该方法的改进的血氧测定装置。

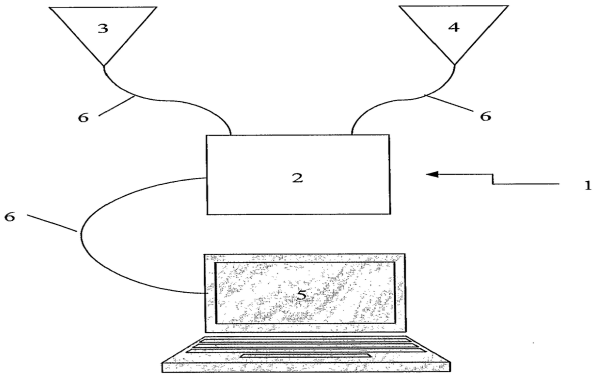

Fig. 1