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(54) **BIOLOGICAL INFORMATION MEASUREMENT DEVICE, MIXED VENOUS OXYGEN SATURATION ESTIMATION METHOD, AND PROGRAM**

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(57) **ABSTRACT**

Provided is a biological information measurement device, including: a blood index calculation unit which calculates at least part of a blood index associated with oxygen transport based on transmitted light or reflected light when a body part of a test subject is irradiated with light with a plurality of wavelengths; an oxygen consumption calculation unit which calculates an oxygen consumption based on a gas concentration in inspired air, a gas concentration in expired air, and a ventilation amount of the test subject; a cardiac output calculation unit which calculates a cardiac output based on a biological signal obtained by a noninvasive method from the test subject; and an SvO**2** estimation unit which estimates the mixed venous oxygen saturation of the test subject by substituting the blood index, the oxygen consumption, and the cardiac output in a calculation formula.

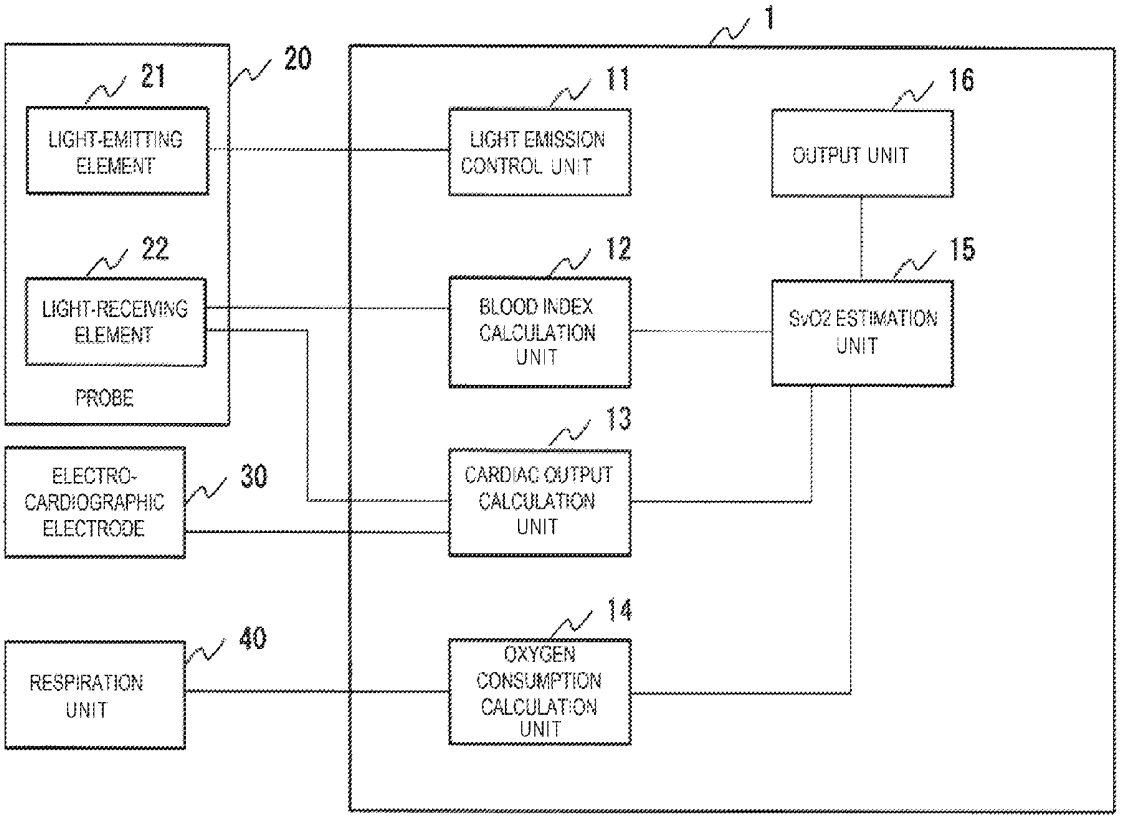


FIG. 1

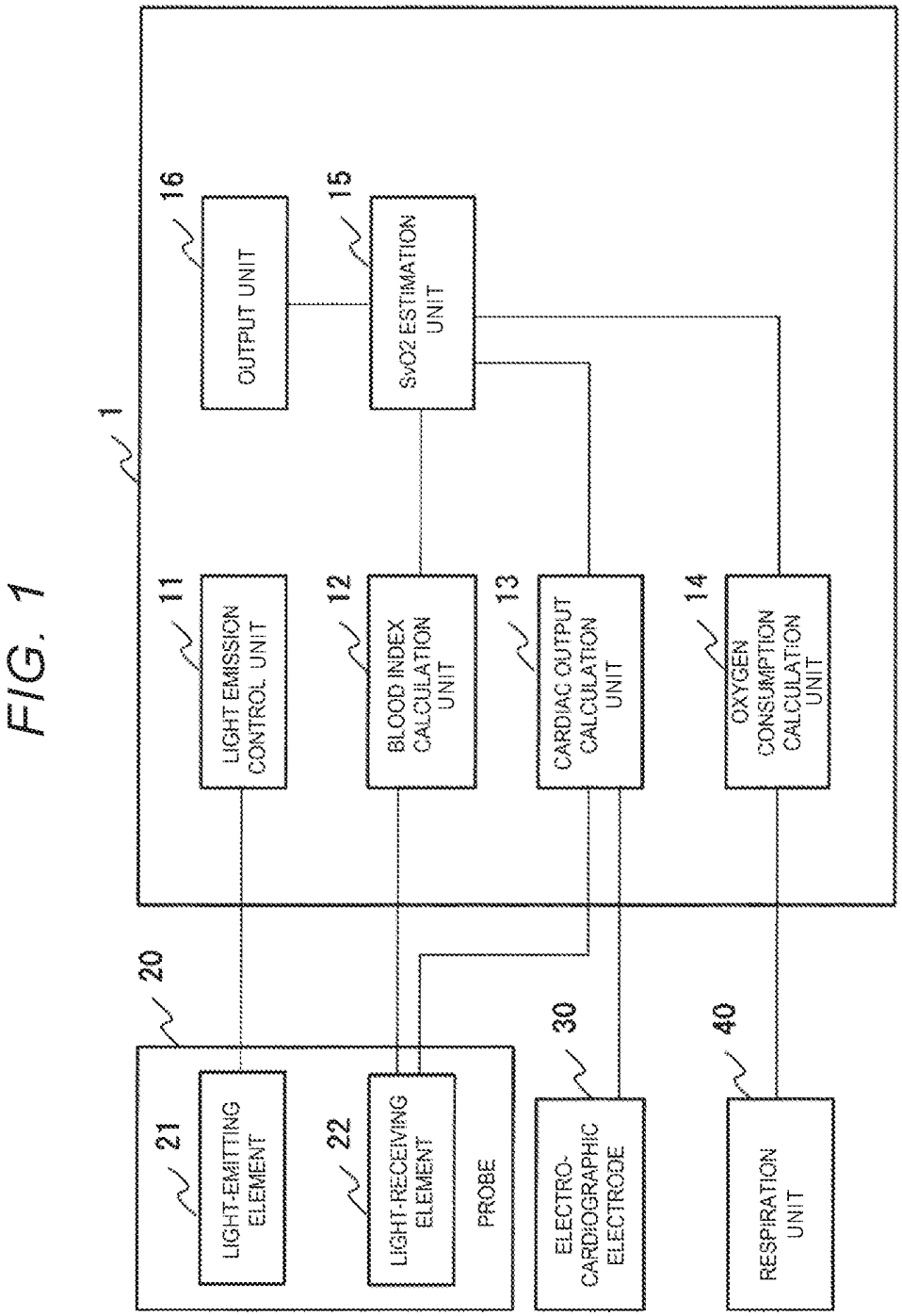
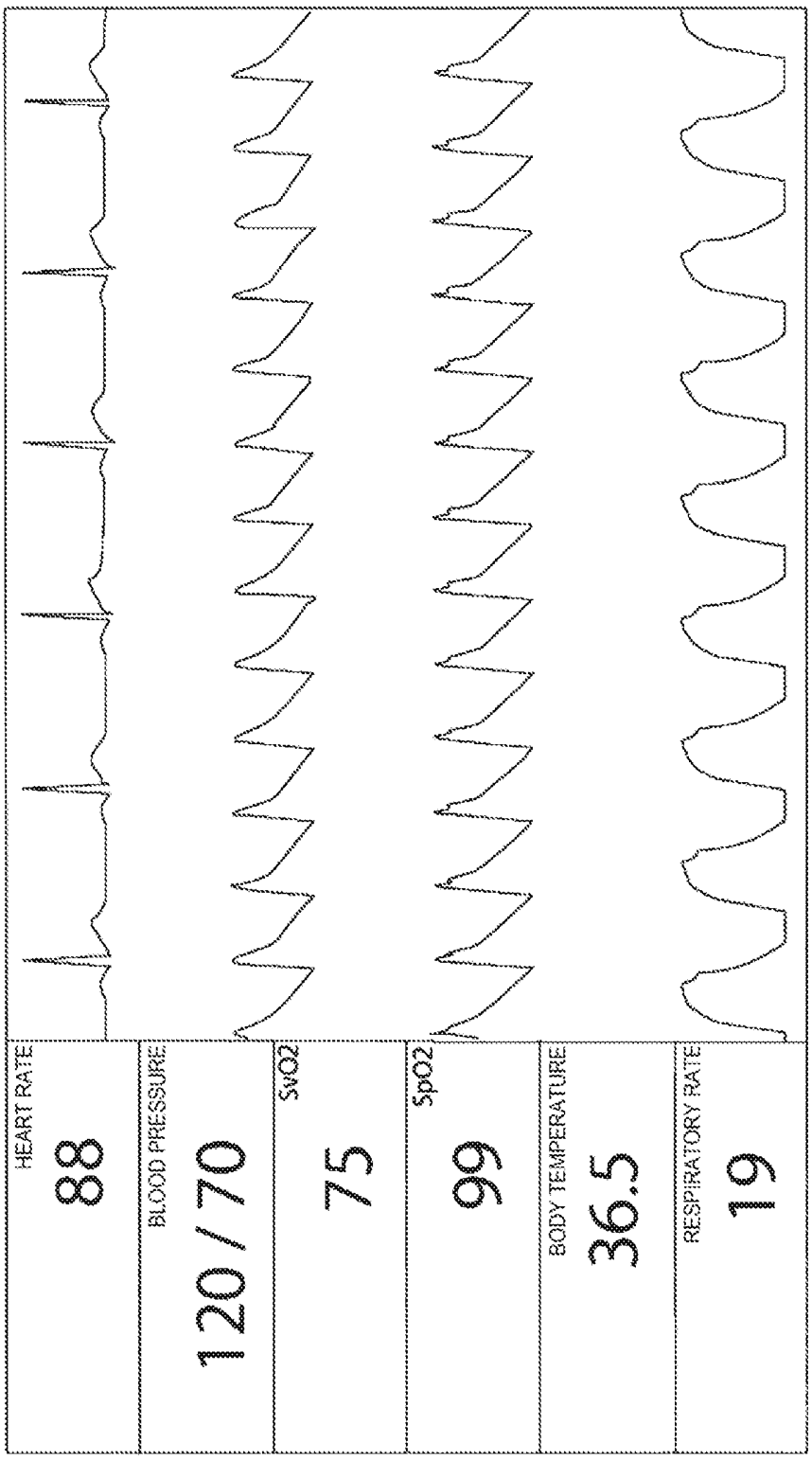

1
16
OUTPUT UNIT
15
SvO2 ESTIMATION UNIT
11
LIGHT EMISSION CONTROL UNIT
12
BLOOD INDEX CALCULATION UNIT
13
CARDIAC OUTPUT CALCULATION UNIT
14
OXYGEN CONSUMPTION CALCULATION UNIT
20
21
LIGHT-EMITTING ELEMENT
22
LIGHT-RECEIVING ELEMENT
PROBE
30
ELECTRO-CARDIOGRAPHIC ELECTRODE
40
RESPIRATION UNIT

FIG. 2


HEART RATE
88
BLOOD PRESSURE
120/70
SvO2
75
SpO2
99
BODY TEMPERATURE
36.5
RESPIRATORY RATE
19

BIOLOGICAL INFORMATION MEASUREMENT DEVICE, MIXED VENOUS OXYGEN SATURATION ESTIMATION METHOD, AND PROGRAM

[0001] CROSS-REFERENCE TO RELATED APPLICATION(S)

[0002] This application claims priority to and the benefit under 35 U.S.C. §119(a) of the earlier filing date of Japanese Application No. JP 2016-041835 filed Mar. 4, 2016, which is incorporated herein by reference, in its entirety, for any purpose.

BACKGROUND

[0003] Example of the present invention relates to a biological information measurement device, a mixed venous oxygen saturation estimation method, and a program.

[0004] Mixed venous oxygen saturation (SvO2) is oxygen saturation of pulmonary arterial blood. The mixed venous oxygen saturation is used as an index of the balance between supply and demand of oxygen in the body. For example, a decrease in mixed venous oxygen saturation means a lack of oxygen supply or an increase in oxygen consumption. The mixed venous oxygen saturation changes due to respiratory failure, circulatory failure, or hypermetabolism accompanying fever or infection. Therefore, the mixed venous oxygen saturation is particularly utilized for ascertaining the state of circulation of oxygen in the whole body in the intensive care field.

[0005] In general, the mixed venous oxygen saturation is measured by inserting a Swan-Ganz catheter into the pulmonary artery. However, this method is an invasive method in which a Swan-Ganz catheter is inserted into the body of a test subject, and therefore places a large burden on the test subject.

[0006] In light of this, a method of noninvasively measuring the mixed venous oxygen saturation has been proposed. JP-T-2010-524598 (Patent Document 1) discloses a technique in which a light-emitting element and a light-receiving element are placed in the vicinity of a target deep vascular structure (for example, the pulmonary artery), and blood flowing through the deep vascular structure is irradiated with light, whereby the oxygen saturation of the blood is measured.

[0007] WO 13/112812 (Patent Document 2) discloses a system in which the mixed venous oxygen saturation is noninvasively calculated using photoacoustic imaging. In the system, a tissue to be measured is irradiated with laser light, and the mixed venous oxygen saturation is calculated using an ultrasonic wave generated accompanying light absorption.

[0008] U.S. Patent Application Publication No 2012-0065485 (Patent Document 3) discloses a device in which pulmonary arterial blood is irradiated with light using an NIRS sensor and the mixed venous oxygen saturation is measured.

[0009] In the techniques disclosed in the above Patent Documents 1 and 2, the mixed venous oxygen saturation is noninvasively measured by applying light (including laser light) from a biological tissue immediately above the pulmonary artery. In this method, in the case where light could not be applied to the exact place (the place where a blood vessel to be measured is present), the accurate mixed venous oxygen saturation may not be able to be measured. Further, in the technique disclosed in Patent Document 3, since an MRS sensor is used, light does not reach the deep region in the body, and thus, the measurement may not be able to be performed accurately in a test subject with a large physique.

[0010] That is, in the above-mentioned techniques, the mixed venous oxygen saturation may not be able to be measured accurately and noninvasively.

SUMMARY

[0011] The invention has been made in view of the above problems, and a main object of the invention is to provide a biological information measurement device and a mixed venous oxygen saturation estimation method capable of noninvasively and accurately measuring the mixed venous oxygen saturation.

[0012] One aspect of a biological information measurement device according to the invention includes:

[0013] a blood index calculation unit which calculates at least part of a blood index associated with oxygen transport based on transmitted light or reflected light when an arbitrary body part of a test subject is irradiated with light with a plurality of wavelengths;

[0014] an oxygen consumption calculation unit which calculates an oxygen consumption based on a gas concentration in inspired air, a gas concentration in expired air, and a ventilation amount of the test subject;

[0015] a cardiac output calculation unit which calculates a cardiac output based on a biological signal obtained by a noninvasive method from the test subject; and

[0016] an SvO2 estimation unit which estimates a mixed venous oxygen saturation of the test subject by substituting the blood index, the oxygen consumption, and the cardiac output in a calculation formula derived from a principle of blood circulation and an oxygen binding amount per unit hemoglobin.

[0017] It is known that a blood index (an arterial oxygen saturation or the amount of hemoglobin in blood) associated with oxygen transport, an oxygen consumption, and a cardiac output can be noninvasively and accurately obtained by the function of a biological information monitor used in a general hospital (JP-A-8-322822 (Patent Document 4), IP-A-2005-312947 (Patent Document 5), etc.). An SvO2 estimation unit **15** estimates a mixed venous oxygen saturation (SvO2) by substituting these parameters in a calculation formula derived from the blood circulation and the oxygen transport amount per unit hemoglobin. The SvO2 estimation unit **15** uses parameters which can be noninvasively and accurately calculated in the calculation, and therefore, the mixed venous oxygen saturation (SvO2) can be continuously and accurately estimated,

[0018] The invention can provide a biological information measurement device and a mixed venous oxygen saturation estimation method capable of noninvasively and accurately measuring the mixed venous oxygen saturation.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] FIG. **1** is a block diagram showing the configuration of a biological information measurement device **1** according to an embodiment of the present disclosure.

[0020] FIG. **2** is a view showing an example of a display screen of the biological information measurement device **1** according to an embodiment of the present disclosure.

DETAILED DESCRIPTION

[0021] Hereinafter, embodiments of the invention will be described with reference to the drawings. FIG. **1** is a block diagram showing the configuration of a biological information measurement device **1** according to an embodiment of the present disclosure. The biological information measurement device **1** measures various vital signs (electrocardiogram, blood pressure, arterial oxygen saturation, heart rate, respiratory rate, body temperature, etc.) of a test subject. The biological information measurement device **1** may be a bed-side monitor which is used in a hospital room, or may be a medical telemeter (transmitter) which is always carried by a test subject (patient). That is, the biological information measurement device **1** may have any form or size as long as it is a device which measures the vital signs of a test subject.

[0022] The biological information measurement device **1** is connected to any type of probe, a cuff, an electrode, and the like. The biological information measurement device **1** shown in FIG. **1** is connected to a probe **20**, an electrocardiographic electrode **30**, and a respiration sensor **40**. Incidentally, although not shown in the drawing, the biological information measurement device **1** may be connected to a cuff (air bag) for noninvasive blood pressure measurement, a body temperature sensor, or the like.

[0023] The probe **20** emits light on an arbitrary body part (for example, a fingertip, an earlobe, a forehead, or the like) of a test subject, and receives transmitted light or reflected light from the body part. The probe **20** includes a light-emitting element **21** and a light-receiving element **22**. The light-emitting element **21** emits light with a plurality of wavelengths including a wavelength of light which is absorbed by water on a body part. The light-emitting element **21** emits light with a plurality of wavelengths selected from an arbitrary wavelength between, for example, 600 nm and 1300 nm on a biological tissue. The light-emitting element **21** may be any as long as it is comprised of, for example, a light-emitting diode (LED).

[0024] The light-receiving element **22** receives transmitted light obtained by transmitting the light with a plurality of wavelengths through the body part (or reflected light obtained by reflecting the light with a plurality of wavelengths from the body part). The light-receiving element **22** converts the transmitted light (or the reflected light) into an electrical signal (biological signal) and inputs the signal to a blood index calculation unit **12** and a cardiac output calculation unit **13**. Although not shown in the drawing, the light-receiving element **22** may include an A/D (analog-digital) converter which performs A/D conversion of the electrical signal as appropriate. The light-receiving element **22** may be any as long as it is comprised of, for example, a photodiode.

[0025] The electrocardiographic electrode **30** includes a plurality of electrodes (a disposable electrode and a clip electrode) for measuring an electrocardiogram (ECG) of a test subject. The electrocardiographic electrode **30** is attached to a predetermined place of the chest or the limb of a test subject. The electrocardiographic electrode **30** and the biological information measurement device **1** are connected to each other through an electrical cable. The electrocardiographic electrode **30** inputs a biological signal obtained from the predetermined place of the test subject to the cardiac output calculation unit **13**.

[0026] The respiration sensor **40** measures a gas concentration in expired air, a gas concentration in inspired air, and a ventilation amount of a test subject. The respiration sensor **40** may be actually comprised of a plurality of sensor devices. For example, the respiration sensor **40** may be comprised of an artificial respirator which can be connected to the so-called biological information measurement device **1** and a gas sensor and a flow sensor which can be attached to the artificial respirator. A medical worker places the gas sensor and the flow sensor on an expired air-side respiratory circuit and an inspired air-side respiratory circuit or an exhaust port of the artificial respirator. The gas sensor obtained the expired air and inspired air of the test subject from the respective respiratory circuits or the exhaust port and measures a gas concentration in the expired air and a gas concentration in the inspired air. Further, the flow sensor measures a ventilation amount of the test subject.

[0027] Further, the respiration sensor **40** may measure a gas concentration in the expired air or a gas concentration in the inspired air by a so-called side-stream system. The respiration sensor **40** is comprised of, for example, an artificial nose attached to a test subject, an adapter for sampling, a sampling tube, a gas sensor, a flow sensor to be attached to the mouth, and the like. The expired air of a test subject is sucked through the sampling tube, and the sucked gas is measured by the gas sensor. By doing this, a gas concentration in the expired air and a gas concentration in the inspired air of the test subject are measured. The flow sensor attached to the mouth measures a ventilation amount of the test subject.

[0028] Further, the respiration sensor **40** may be comprised of a gas sensor and a flow sensor attached to the mouth. The gas sensor in this configuration measures a gas concentration in expired air and a gas concentration in inspired air of a test subject. The flow sensor measures a ventilation amount of the test subject.

[0029] That is, the respiration sensor **40** may have any configuration as long as it can measure a gas concentration in expired air, a gas concentration in inspired air, and a ventilation amount of a test subject. The respiration sensor **40** inputs the measured gas concentration in the expired air, gas concentration in the inspired air, and ventilation amount of the test subject to an oxygen consumption calculation unit **14**.

[0030] Subsequently, the configuration of the biological information measurement device **1** will be described. The biological information measurement device **1** includes a light emission control unit **11**, a blood index calculation unit **12**, a cardiac output calculation unit **13**, an oxygen consumption calculation unit **14**, an SvO2 estimation unit **15**, and an output unit **16**. Although not shown in the drawing, the biological information measurement device **1** includes a memory unit (including a primary memory device and a secondary memory device) which stores any type of data.

[0031] The light emission control unit **11** controls light with a plurality of wavelengths emitted on a body part of a test subject. Specifically, the light emission control unit **11** controls the wavelength, emission timing, and emission intensity of light emitted by the light-emitting element **21**. Here, it is preferred that the light emission control unit **11** controls emission of light so that light with a plurality of wavelengths including light with a wavelength which is absorbed by water is emitted in order for the below-mentioned blood index calculation unit **12** to calculate the amount of hemoglobin in blood.

[0032] The blood index calculation unit **12** calculates at least part of a blood index associated with oxygen transport based on light (transmitted light or reflected light) obtained by transmitting or reflecting the light with a plurality of wavelengths including a wavelength of light which is absorbed by water through or from an arbitrary body part of a test subject. More specifically, the blood index calculation unit **12** calculates at least an arterial oxygen saturation, and preferably also calculates the amount of hemoglobin in blood.

[0033] The blood index calculation unit **12** obtained transmitted light or reflected light when red light (for example, light with a wavelength of 660 nm) and infrared light (for example, light with a wavelength of 940 nm) are emitted on a body part, The absorbance of hemoglobin in blood for red light and infrared light varies whether or not the hemoglobin binds to oxygen. The recognition of an artery may be performed by known plethysmography. The blood index calculation unit **12** calculates the arterial oxygen saturation from the ratio of absorbed red light to absorbed infrared light (pulse spectrophotometry). Incidentally, a detailed calculation method of the arterial oxygen saturation may be basically the same as the method described in Non-Patent Document 1 ("Pulse Oximeter no Tanjo to Riron (Advent and Theory of Pulse Oximeter)", written by Takuo Aoyagi, The Journal of Japan Society for Clinical Anesthesia, vol. 10, No. 1, pp. 1-11, 1990) or Non-Patent Document 2 ("ME Hayawakari (Quick Understanding) Q&A, Sphygmomanometer, Cardiac Output Meter, Blood Flow Meter" supervised by Yasuhisa Sakurai, Nankodo Co., Ltd.).

[0034] Further, the blood index calculation unit **12** calculates the amount of hemoglobin in blood using pulse spectrophotometry. The pulse spectrophotometry is a method of determining the ratios of the concentrations of substances in arterial blood by irradiating a biological tissue with light and measuring the light absorption property of arterial blood in the tissue utilizing the fact that the effective thickness of blood is pulsated by blood pulsation in the biological tissue. Various types of hemoglobin in blood (for example, oxygenated hemoglobin, deoxygenated hemoglobin, carboxyhemoglobin, and methemoglobin) and water have different light absorption properties, and therefore, by using light with a plurality of wavelengths, the ratios of the concentrations of various types of hemoglobin and water can be obtained. By calculating the ratio (CHb/Cw=Hb (g/ml)) of the sum of the ratios of the concentrations of various types of hemoglobin (CHb (g %)) with respect to the ratio of the concentration of water (Cw (g %)), the concentration of hemoglobin can be calculated. Incidentally, in this calculation, the volume of **1** g of water is assumed to be 1 ml. Therefore, in the case where the amount of hemoglobin in blood is calculated, it is necessary to irradiate a body part with light with a wavelength which is absorbed by water, Please see Patent Document 4 for a detailed calculation method of the amount of hemoglobin in blood using pulse spectrophotometry.

[0035] It is more preferred that the blood index calculation unit **12** calculates the amount of hemoglobin in blood, in which only hemoglobin capable of transferring oxygen (normal hemoglobin) is targeted (in other words, abnormal hemoglobin is excluded). That is, it is desired that the fractional oxygen saturation which is the ratio of oxygenated hemoglobin capable of transferring oxygen to the total hemoglobin is used. Alternatively, the concentration of oxygenated hemoglobin HbO2 (g/dl) may be directly calculated by calculating the ratio of the concentration of water Cw (g %) with respect to the ratio of the concentration of the above-mentioned oxygenated hemoglobin CHO2 (g %).

[0036] The abnormal hemoglobin refers to hemoglobin which does not have an ability to transfer oxygen, and is, for example, carboxyhemoglobin or methemoglobin.

[0037] In the case where the concentration of carboxyhemoglobin or the concentration of methemoglobin is calculated, it is only necessary to allow the light-emitting element **21** to irradiate a test subject with orange light (or red-orange light) in addition to near infrared light and red light as light to be irradiated onto the test subject. The transmitted light (or the reflected light) of each light changes in response to blood pulsation. The blood index calculation unit **12** determines an extinction ratio between respective wavelengths, and the concentration of carboxyhemoglobin or the concentration of methemoglobin may be calculated based on the extinction ratio. Please see JP-A-2002-228579 (Patent Document 6) which is the earlier application filed by the present inventors for a detailed calculation method of the concentration of carboxyhemoglobin. Similarly, please see JP-A-2002-315739 (Patent Document 7) which is the earlier application filed by the present inventors for a detailed calculation method of the concentration of methemoglobin. Since the concentration of abnormal hemoglobin can be calculated, the amount of normal hemoglobin can be calculated by multiplying the total amount of hemoglobin by the concentration of normal hemoglobin.

[0038] The blood index calculation unit **12** inputs the calculated arterial oxygen saturation and the calculated hemoglobin amount in blood to the SvO2 estimation unit **15**. As described above, the blood index calculation unit **12** may input the total amount of hemoglobin in blood to the SvO2 estimation unit **15** as the amount of hemoglobin in blood, however, it is more preferred that a value (the amount of normal hemoglobin) obtained by subtracting the amount of abnormal hemoglobin from the total amount of hemoglobin in blood is input to the SvO2 estimation unit **15** as the amount of hemoglobin in blood.

[0039] The cardiac output calculation unit **13** calculates a cardiac output based on the biological signal obtained from a test subject. This will be described in detail below.

[0040] The cardiac output calculation unit **13** obtained an electrocardiographic signal from the electrocardiographic electrode **30** and calculates an electrocardiogram (ECG) from the electrocardiographic signal. The cardiac output calculation unit **13** calculates a heart rate (FIR) based on the waveform of the electrocardiogram. For example, the cardiac output calculation unit **13** may calculate a heart rate from the number of detected R waves.

[0041] Further, the cardiac output calculation unit **13** obtained a photoplethysmographic signal from the probe **20**. As described above, the probe **20** performs light emission for measuring a general arterial oxygen saturation (SaO2). The cardiac output calculation unit **13** calculates a pulse wave transition time (PWTT) based on a photoplethysmographic waveform obtained from the photoplethysmographic signal and the electrocardiogram. Please see, for example, Non-Patent Document 3 (Internet <URL: http://www.nihonkohden.co.jp/iryo/techinfo/pwtt/principle.html> searched on Feb. 13, 2016) for the relationship among the photoplethysmographic waveform, the electrocardiogram, and the pulse wave transition time. Further, as for the detailed calculation method of the pulse wave transition

time, the calculation may be performed by utilizing a pulse pressure, and for example, the same method as described in Patent Document 5 may be adopted.

[0042] The cardiac output calculation unit **13** estimates a cardiac output by substituting the pulse wave transition time and the heart rate in the following formula (1).

$$CO=(\alpha L\times PWTT+\beta L)\times HR \quad \text{Formula (1)}$$

[0043] In the formula (1), CO represents a cardiac output, PWTT represents a pulse wave transition time, HR represents a heart rate, and α, β, and L each represent a coefficient intrinsic to a test subject.

[0044] The respective coefficients in the above formula (1) are coefficients intrinsic to a test subject, however, these coefficients may be calibrated using calibration values obtained by the measurement of a blood pressure for calibration. As for a detailed calibration method, a method equivalent to the method described in Patent Document 5 (for example, FIG. 12 in Patent Document 5) may be adopted.

[0045] The cardiac output calculation unit **13** inputs the calculated cardiac output to the

[0046] SvO2 estimation unit **15**. When using the above formula (1), the cardiac output can be continuously calculated. Therefore, it is preferred that the cardiac output calculation unit **13** continuously calculates the cardiac output and inputs the calculated cardiac output to the SvO2 estimation unit **15**.

[0047] To the oxygen consumption calculation unit **14**, a gas concentration in the expired air, a gas concentration in the inspired air, and a ventilation amount of a test subject are input from the respiration sensor **40**. The oxygen consumption calculation unit **14** calculates a difference between the oxygen concentration in the gas concentration in the expired air and the oxygen concentration in the gas concentration in the inspired air (difference in oxygen concentration). The oxygen consumption calculation unit **14** calculates the oxygen consumption (VO2) of the test subject by multiplying the calculated difference in oxygen concentration by the ventilation amount. The oxygen consumption calculation unit **14** inputs the calculated oxygen consumption to the SvO2 estimation unit **15**.

[0048] The SvO2 estimation unit **15** estimates the mixed venous oxygen saturation based on the amount of hemoglobin in blood, the arterial oxygen saturation, the oxygen consumption, and the cardiac output. The mechanism of this estimation will be described below.

[0049] It has been widely known that the Fick's formula (the following formula (2)) based on the law of blood circulation (the law of conservation of mass) is established (Non-Patent Document 4 (Yung GL, et.al, "Comparison of impedance cardiography to direct Fick and thermodilution cardiac output determination in pulmonary arterial hypertension."Congestive Heart Failure 2004, 10 (2, suppl. 2): 7-10), Internet <URL: http://www.ncbi.nlm.nih,gov/pubmed/15073478> searched on Feb. 13, 2016)),

$$(CaO2-CvO2)\times CO=VO2 \quad \text{Formula (2)}$$

[0050] In the formula (2), CaO2 represents an arterial oxygen content, CvO2 represents a mixed venous oxygen content, CO represents a cardiac output, and VO2 represents an oxygen consumption.

[0051] Further, it is known that the amount of oxygen binding to 1 g of hemoglobin is from about 1.3 ml to 1.4 ml (Non-Patent Document 4). When this oxygen binding amount per gram of hemoglobin is represented by K (K is a constant between 1.3 and 1.4, preferably between 1.31 and 1.36. In general, K=1.34 is adopted), a difference between the arterial oxygen content and the mixed venous oxygen content, that is, the value of (CaO2−CvO2) can be represented by the following formula (3).

$$(CaO2-CvO2)=K\times Hb\times(SaO2-SvO2) \quad \text{Formula (3)}$$

[0052] In the formula (3), K represents an oxygen binding amount per unit hemoglobin (1 g of hemoglobin), Hb represents the amount of hemoglobin in blood, SaO2 represents an arterial oxygen saturation, and SvO2 represents a mixed venous oxygen saturation. Here, SaO2 and SvO2 are each a fractional oxygen saturation. Abnormal hemoglobin (carboxyhemoglobin or methemoglobin) is hemoglobin which cannot bind to oxygen. In the case where the ratio of abnormal hemoglobin is large, when the functional oxygen saturation (the amount of oxygenated hemoglobin to the sum of the amount of oxygenated hemoglobin and the amount of deoxygenated hemoglobin) is substituted in the formula (3), CaO2 or CvO2, which is a blood oxygen content, becomes a value having an error. Due to this, in the case where the amount of abnormal hemoglobin is small, the functional oxygen saturation may be used in the formula (3), however, in the case where the amount of abnormal hemoglobin is large, it is not preferred to use the functional oxygen saturation in the formula (3).

[0053] Therefore, the mixed venous oxygen saturation can be calculated based on the formula 4) modified from the above formula (2) and formula (3). That is, the mixed venous oxygen saturation can be estimated from the calculation formula (formula (4)) based on a formula in Fick principle (a principle of blood circulation) and the oxygen binding amount per unit hemoglobin (for example, 1 g of hemoglobin).

$$SvO2=SaO2-(VO2/(K\times Hb\times CO)) \quad \text{Formula (4)}$$

[0054] In the formula (4), SvO2 represents a mixed venous oxygen saturation, SaO2 represents an arterial oxygen saturation, VO2 represents an oxygen consumption, Hb represents the amount of hemoglobin in blood, CO represents a cardiac output, and K represents an oxygen binding amount per unit hemoglobin (for example, 1 g).

[0055] The SvO2 estimation unit **15** calculates an estimation value of the mixed venous oxygen saturation by substituting the arterial oxygen saturation, the amount of hemoglobin in blood, the cardiac output, and the oxygen consumption calculated by the respective calculation units (the blood index calculation unit **12**, the cardiac output calculation unit **13**, and the oxygen consumption calculation unit **14**) in the formula 4). The SvO2 estimation unit **15** inputs the calculated estimation value of the mixed venous oxygen saturation to the output unit **16**.

[0056] The output unit **16** outputs various biological waveforms or the measurement values of various vital signs of a test subject. Here, the "output" may be a display output on a display or may be an output on a paper by printing. Further, the "output" is a concept including an output of an alarm sound when any of the vital signs is abnormal. Therefore, the output unit **16** is a display (and a peripheral circuit of the display), a printer (and a peripheral circuit thereof), a speaker (and a peripheral circuit thereof), or the like provided for the biological information measurement device **1**. The output unit **16** outputs the mixed venous oxygen saturation estimated by the SvO2 estimation unit **15**.

For example, the output unit **16** displays a measurement value or a trend graph of the mixed venous oxygen saturation on a display. The output unit **16** may also display a measurement value or a measurement waveform of a general vital sign (a blood pressure or a body temperature) on the display in addition thereto.

[0057] FIG. **2** is a view showing one example of a display screen on which the output unit **16** performs displaying. As shown in the drawing, on the display screen, an estimated value of the mixed venous oxygen saturation (SvO2) is displayed along with a heart rate and a blood pressure. The display screen shown in FIG. **2** is merely an example, and the estimated value of the mixed venous oxygen saturation may not only be displayed by a numerical value, but also may be displayed by a trend graph (a form by which a change over time is found).

[0058] Next, an effect of the biological information measurement device **1** according to this embodiment will be described. As described above, it is known that a blood index (an arterial oxygen saturation or the amount of hemoglobin in blood) associated with oxygen transport, an oxygen consumption, and a cardiac output can be noninvasively and accurately obtained by the function of a biological information monitor used in a general hospital. The SvO2 estimation unit **15** estimates a mixed venous oxygen saturation by substituting these parameters in a calculation formula derived from the blood circulation and the oxygen transport amount per unit hemoglobin. The SvO2 estimation unit **15** uses parameters which can be noninvasively and accurately calculated in the calculation, and therefore, the mixed venous oxygen saturation can be continuously and accurately estimated.

[0059] The techniques described in the above-mentioned Patent Documents 1 to 3 each require an exclusive sensor (in the technique described in patent Document 1, a light-emitting element for deep blood vessels, etc., in the technique described in patent Document 2, a photoacoustic imaging sensor, and in the technique described in patent Document 3, an MRS sensor). Due to this, these techniques have problems that the configuration of the device is complicated, and also the cost is high. Further, it is necessary to apply light to a blood vessel to be measured from immediately above the vessel, and therefore, more accurate measurement may not be able to be performed due to a lack of experience of a medical worker or the like.

[0060] On the other hand, the biological information measurement device **1** according to this embodiment can estimate the mixed venous oxygen saturation (SvO2) by the configuration of a biological information monitor using a common probe **20** for multiwavelength measurement, an electrocardiographic electrode **30**, and a respiration sensor **40**. That is, the mixed venous oxygen saturation can be estimated while avoiding the complication of the device or the increase in cost due to the adoption of an exclusive sensor. Further, the above-mentioned parameters can be noninvasively and accurately measured regardless of the experience or skill of a medical worker. Therefore, even if any medical worker is in charge of the test subject, the mixed venous oxygen saturation can be accurately estimated.

[0061] The transmitted light or the reflected light received by the probe **20** can also be used for the calculation of the amount of hemoglobin in blood along with the calculation of the arterial oxygen saturation. The transmitted light or the reflected light can be used in common for the calculation of a plurality of parameters, and therefore, the device can be simplified.

[0062] It is preferred that the blood index calculation unit **12** calculates a value obtained by subtracting the amount of abnormal hemoglobin from the total amount of hemoglobin in blood (in other words, only the amount of normal hemoglobin) as the amount of hemoglobin in blood. According to this, the effect of abnormal hemoglobin which cannot transport oxygen can be cancelled, and thus, the mixed venous oxygen saturation can be more accurately estimated.

[0063] Hereinabove, the invention made by the present inventors has been specifically described based on embodiments, however, the invention is not limited to the above-mentioned embodiments, and it is needless to say that various modifications can be made without departing from the gist of the invention.

[0064] The calculation methods of the respective parameters described above are merely examples, and other methods may be used. That is, the SvO2 estimation unit **15** may estimate the mixed venous oxygen saturation by substituting the measurement values of the respective parameters obtained by an arbitrary method which is noninvasive and is not affected by the experience of a medical worker in the above-mentioned calculation formula.

[0065] For example, the amount of hemoglobin in blood may be measured from blood collected in advance from a test subject. In this case, it is only necessary to adopt a configuration in which the probe **20** or the blood index calculation unit **12** calculates only the arterial oxygen saturation (that is, a general configuration in which the measurement of an arterial oxygen saturation is performed).

[0066] Further, the cardiac output calculation unit **13** may calculate the cardiac output from a blood flow signal as described in Patent Document 8 (JP-A-2003-220045) or Non-Patent Document 5 (Internet <URL: http://www.kykb.jp/manatec1.html> searched on Feb. 13, 2016). Further, the cardiac output calculation unit **13** may calculate the cardiac output noninvasively based on the value of a blood pressure measured from a finger or the like (Patent Document 9 (JP-T-2002-541961) or Non-Patent Document 6 (Internet <URL: http://www.edwards.com/jp/professionals/products/hemodynamic_monitoring/co_sv/clears ight/#> searched on Feb. 13, 2016)). The cardiac output calculation unit **13** may also calculate the cardiac output noninvasively using a method called a so-called "reactance method" (Patent Document 10 (JP-T-2014-521433) or Non-Patent Document 7 (Internet <URL: http://www.imimed.co.jp/product/monitor/detail/starling_sv.html> searched on Feb. 13, 2016)). Further, as described in Patent Document 11 (JP-A-2006-231012), an oxygen circulation time is measured, and an estimation value of the cardiac output correlated with the oxygen circulation time may be calculated using a regression equation.

[0067] That is, the cardiac output calculation unit **13** may calculate the cardiac output based on a biological signal obtained from a test subject using a noninvasive method.

[0068] At least part of the processing performed by the above-mentioned various processing units (the light emission control unit **11**, the blood index calculation unit **12**, the cardiac output calculation unit **13**, the oxygen consumption calculation unit **14**, and the SvO2 estimation unit **15**) may be realized by causing a CPU (Central Processing Unit, not

shown in FIG. **1**) provided in the biological information measurement device **1** to execute a program.

[0069] Here, the program is stored using various types of non-transitory computer readable media and can be supplied to a computer. The non-transitory computer readable media include various types of tangible storage media. Examples of the non-transitory computer readable media include magnetic recording media (such as flexible disks, magnetic tapes, and hard disk drives), magneto-optical recording media (such as magneto-optical disks), CD-ROM (Read Only Memory), CD-R, CD-R/W, semiconductor memories (such as mask ROM, PROM (Programmable ROM), EPROM (Erasable PROM), flash ROM, and RAM (random access memory). Further, the program may be supplied to a computer through any of various types of transitory computer readable media. Examples of the transitory computer readable media include electrical signals, optical signals, and electromagnetic waves. The transitory computer readable media can supply the program to a computer through a wired communication channel such as an electrical wire or an optical fiber or a wireless communication channel

What is claimed is:

1. A biological information measurement device, comprising:

a blood index calculation unit configured to calculate at least part of a blood index associated with oxygen transport based on transmitted light or reflected light when a body part of a test subject is irradiated with light with a plurality of wavelengths;

an oxygen consumption calculation unit configured to calculate an oxygen consumption based on a gas concentration in inspired air, a gas concentration in expired air, and a ventilation amount of the test subject;

a cardiac output calculation unit configured to calculate a cardiac output based on a biological signal obtained by a noninvasive method from the test subject; and

an SvO2 estimation unit configured to estimate a mixed venous oxygen saturation of the test subject by substituting the blood index, the oxygen consumption, and the cardiac output in a calculation formula derived from a principle of blood circulation and an oxygen binding amount per unit hemoglobin,

2. The biological information measurement device according to claim **1**, wherein the calculation formula is represented by the following formula:

$$SvO2=SaO2-(VO2/(K\times Hb\times CO)) \quad \text{Formula (4)}$$

wherein SvO2 represents the mixed venous oxygen saturation, SaO2 represents an arterial oxygen saturation, VO2 represents the oxygen consumption, Hb represents an amount of hemoglobin in blood, CO represents the cardiac output, and K represents the oxygen binding amount per unit hemoglobin (for example, 1 g).

3. The biological information measurement device according to claim **2**, wherein the K is a value between 1.3 and 1.4.

4. The biological information measurement device according to claim **1**, further comprising:

a light emission control unit configured to control the light with the plurality of wavelengths,

wherein the light with the plurality of wavelengths includes light which is absorbed by water, and

wherein the blood index calculation unit is configured to calculate an amount of hemoglobin in blood along with an arterial oxygen saturation based on the transmitted light or the reflected light.

5. The biological information measurement device according to claim **2**, further comprising:

a light emission control unit configured to control the light with the plurality of wavelengths,

wherein the light with the plurality of wavelengths includes light Which is absorbed by water, and

the blood index calculation unit is configured to calculate the amount of hemoglobin in blood along with the arterial oxygen saturation based on the transmitted light or the reflected light.

6. The biological information measurement device according to claim further comprising:

a light emission control unit configured to control the light with the plurality of wavelengths,

wherein the light with the plurality of wavelengths includes light which is absorbed by water, and

the blood index calculation unit is configured to calculate the amount of hemoglobin in blood along with the arterial oxygen saturation based on the transmitted light or the reflected

7. The biological information measurement device according to claim **1**,

wherein the blood index calculation unit is configured to subtract an amount of abnormal hemoglobin from a total amount of hemoglobin in the blood of the test subject as an amount of hemoglobin in blood as the at least part of the blood index.

8. The biological information measurement device according to claim **2**,

wherein the blood index calculation unit is configured to subtract an amount of abnormal hemoglobin from a total amount of hemoglobin in the blood of the test subject as the amount of hemoglobin in blood as the at least part of the blood index.

9. The biological information measurement device according to claim **3**,

wherein the blood index calculation unit is configured to subtract an amount of abnormal hemoglobin from a total amount of hemoglobin in the blood of the test subject as the amount of hemoglobin in blood as the at least part of the blood index.

10. The biological information measurement device according to claim **4**,

wherein the blood index calculation unit is configured to subtract an amount of abnormal hemoglobin from a total amount of hemoglobin in the blood of the test subject as the amount of hemoglobin in blood as the at least part of the blood index.

11. The biological information measurement device according to claim **5**,

wherein the blood index calculation unit is configured to subtract an amount of abnormal hemoglobin from a total amount of hemoglobin in the blood of the test subject as the amount of hemoglobin in blood as the at least part of the blood index.

12. The biological information measurement device according to claim **6**,

wherein the blood index calculation unit is configured to subtract an amount of abnormal hemoglobin from a total amount of hemoglobin in the blood of the test

subject as the amount of hemoglobin in blood to obtain the at least part of the blood index.

13. A mixed venous oxygen saturation estimation method, comprising:

calculating at least part of a blood index associated with oxygen transport based on transmitted light or reflected light when a body part of a test subject is irradiated with light with a plurality of wavelengths;

calculating an oxygen consumption based on a gas concentration in inspired air, a gas concentration in expired air, and a ventilation amount of the test subject;

calculating a cardiac output based on a biological signal obtained by a noninvasive method from the test subject; and

estimating the mixed venous oxygen saturation of the test subject by substituting the blood index, the oxygen consumption, and the cardiac output in a calculation formula derived from a principle of blood circulation and an oxygen binding amount per unit hemoglobin.

14. The method of claim **13**, further comprising calculating an amount of hemoglobin in blood along with an arterial oxygen saturation based on the transmitted light or the reflected light,

wherein the light with a plurality of wavelengths includes light which is absorbed by water.

15. The method of claim **13**, further comprising:

subtracting an amount of abnormal hemoglobin from a total amount of hemoglobin in the blood of the test subject as an amount of hemoglobin in blood as the at least part of the blood index,

16. A non-transitory computer readable medium comprising instructions that, when executed by one or more processing units, cause the one or more processing units to perform actions including:

calculating at least part of a blood index associated with oxygen transport based on transmitted light or reflected light when a body part of a test subject is irradiated with light with a plurality of wavelengths,

calculating an oxygen consumption based on a gas concentration in inspired air, a gas concentration in expired air, and a ventilation amount of the test subject,

calculating a cardiac output based on a biological signal obtained by a noninvasive method from the test subject, and

estimating the mixed venous oxygen saturation of the test subject by substituting the blood index, the oxygen consumption, and the cardiac output in a calculation formula derived from a principle of blood circulation and an oxygen binding amount per unit hemoglobin.

17. The non-transitory computer-readable medium of claim **10**, wherein the actions further includes calculating an amount of hemoglobin in blood along with an arterial oxygen saturation based on the transmitted light or the reflected light,

wherein the light with a plurality of wavelengths includes light which is absorbed by water.

18. The non-transitory computer-readable medium of claim **10**, wherein the actions further includes subtracting an amount of abnormal hemoglobin from a total amount of hemoglobin in the blood of the test subject as an amount of hemoglobin in blood as the at least part of the blood index.

* * * * *

专利名称(译)	生物信息测量装置，混合静脉血氧饱和度估计方法和程序		
公开(公告)号	US20170251961A1	公开(公告)日	2017-09-07
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[标]申请(专利权)人(译)	日本光电工业株式会社		
申请(专利权)人(译)	日本光电公司		
当前申请(专利权)人(译)	日本光电公司		
[标]发明人	SAEKI KOTA KOBAYASHI NAOKI		
发明人	SAEKI, KOTA KOBAYASHI, NAOKI		
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摘要(译)

提供一种生物信息测量装置，包括：血液指标计算单元，当用多个光照射测试对象的身体部分时，基于透射光或反射光计算与氧传输相关的血液指数的至少一部分。波长;氧气消耗量计算单元，其基于吸入空气中的气体浓度，呼出气体中的气体浓度和测试对象的通气量来计算氧气消耗量;心输出量计算单元，其基于通过非侵入性方法从测试对象获得的生物信号来计算心输出量;和SvO 2 估计单元，其通过在计算公式中代入血液指数，氧气消耗和心输出量来估计测试对象的混合静脉血氧饱和度。