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(54) NONINVASIVE HYPOVOLEMIA MONITOR

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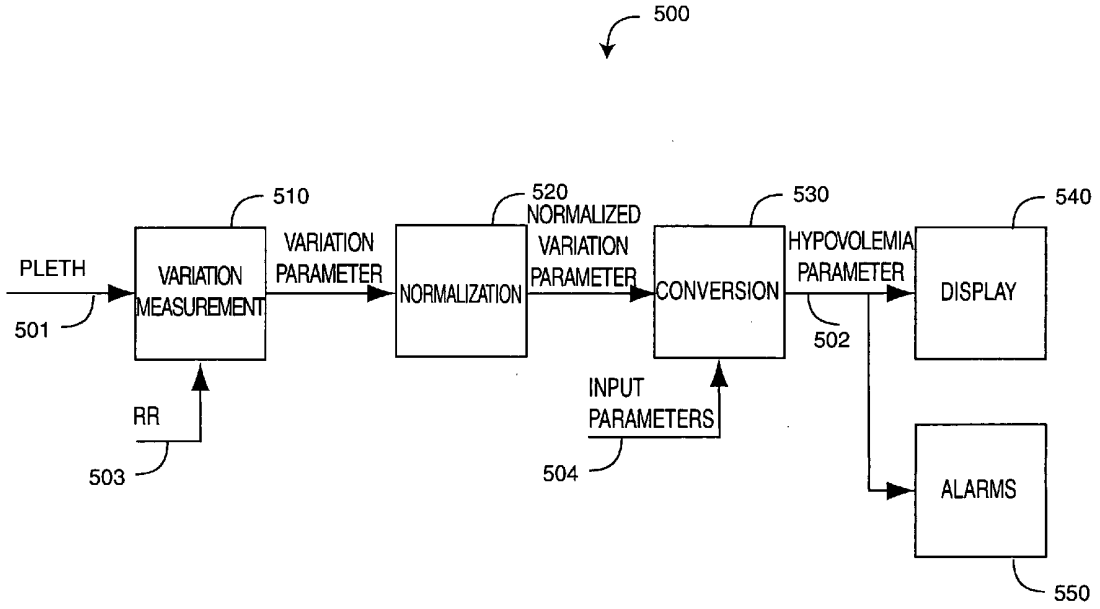
(57) ABSTRACT

A hypovolemia monitor comprises a plethysmograph input responsive to light intensity after absorption by fleshy tissue. A measurement of respiration-induced variation in the input is made. The measurement is normalized and converted into a hypovolemia parameter. An audible or visual indication of hypovolemia is provided, based upon the hypovolemia parameter.



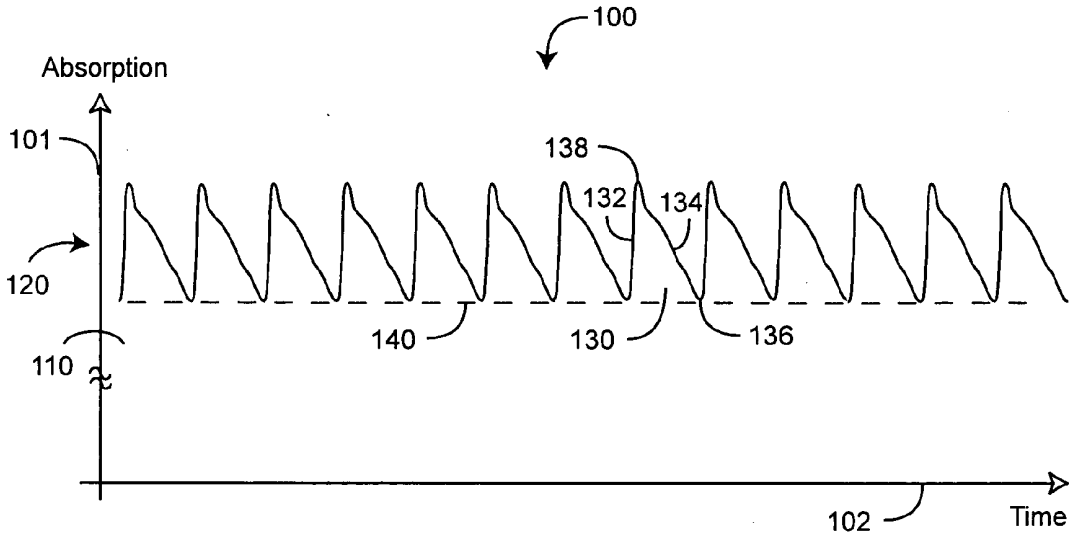

100
Absorption
101
120
110
138
132
134
140
130
136
102
Time

FIG. 1

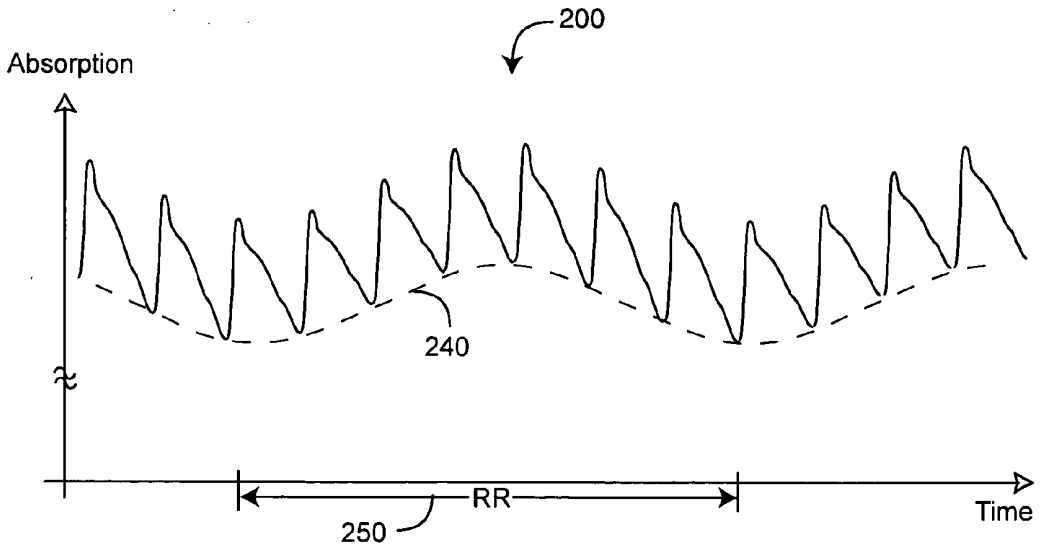

200
Absorption
240
RR
250
Time

FIG. 2

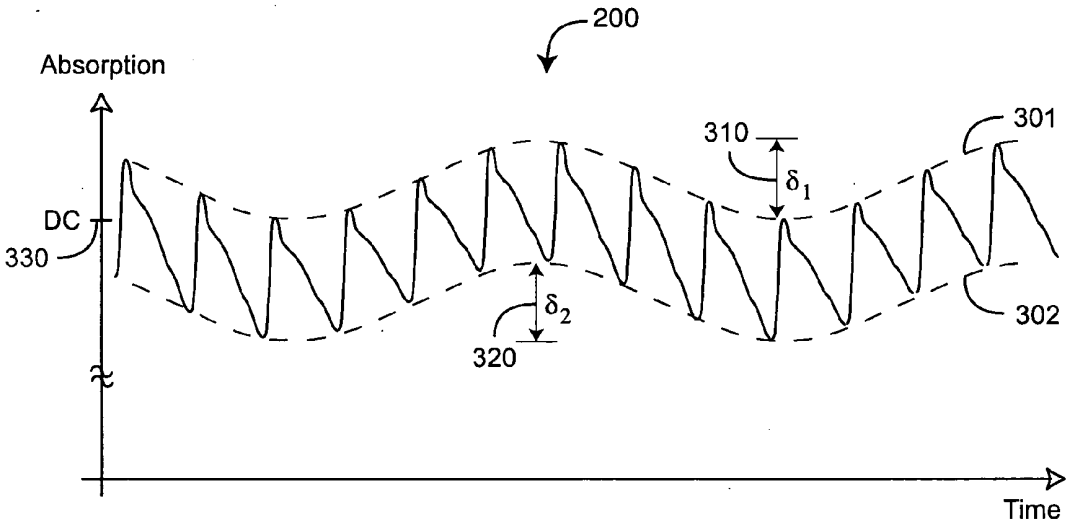

200
Absorption
310
301
δ_1
DC
330
δ_2
302
320
Time

FIG. 3

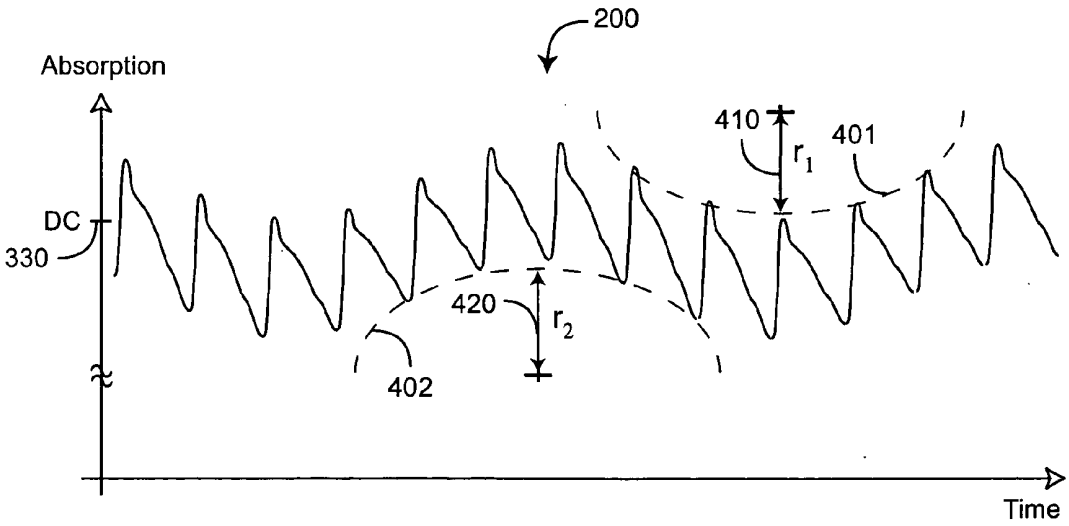

200
Absorption
410
401
r_1
DC
330
420
r_2
402
Time

FIG. 4

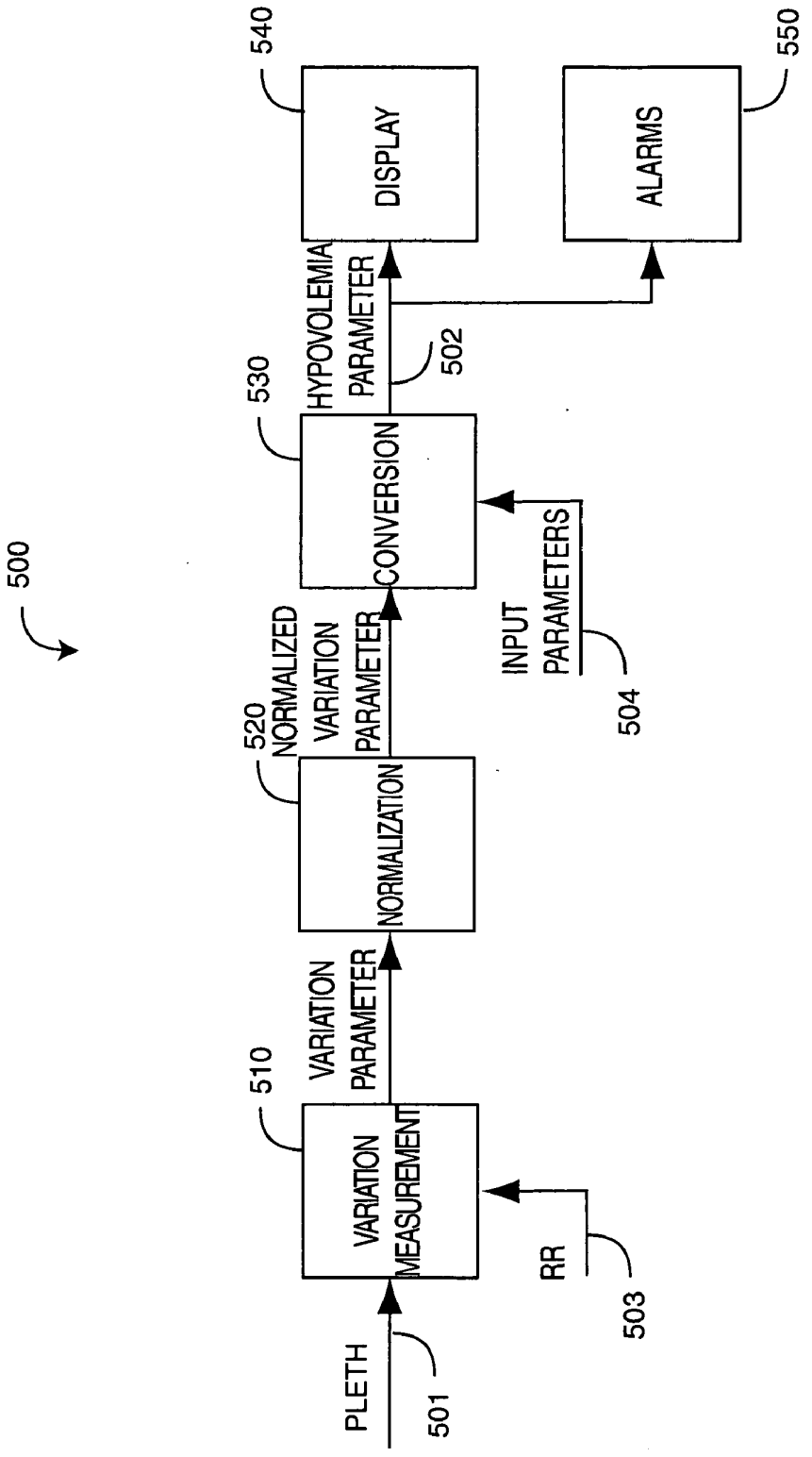

500
PLETH
501
RR
503
510
VARIATION MEASUREMENT
VARIATION PARAMETER
520
NORMALIZATION
NORMALIZED VARIATION PARAMETER
INPUT PARAMETERS
504
530
CONVERSION
HYPOVOLEMIA PARAMETER
502
540
DISPLAY
550
ALARMS

FIG. 5

NONINVASIVE HYPOVOLEMIA MONITOR

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application relates to and claims the benefit of U.S. Provisional Application No. 60/607,562 entitled Noninvasive Hypovolemia Monitor, filed Sep. 7, 2004 and incorporated by reference herein.

BACKGROUND OF THE INVENTION

[0002] Pulse oximetry, a widely accepted noninvasive procedure for measuring the oxygen saturation level of arterial, blood, is responsive to pulsatile blood flowing within a fleshy tissue site. **FIG. 1** illustrates the standard plethysmograph waveform **100**, which can be derived from a pulse oximeter and corresponding pulse oximetry sensor. The sensor attaches to and illuminates a peripheral tissue site, such as a finger tip. The plethysmograph waveform **100** illustrates light absorption at the tissue site, shown along the y-axis **101**, versus time, shown along the x-axis **102**. The total absorption includes static absorption **110** and variable absorption **120** components. Static absorption **110** is due to tissue, venous blood and a base volume of arterial blood. Variable absorption **120** is due to the pulse-added volume of arterial blood. That is, the plethysmograph waveform **100** is a visualization of the tissue site arterial blood volume change over time, and is a function of heart stroke volume, pressure gradient, arterial elasticity and peripheral resistance. The ideal waveform pulse **130** displays a broad peripheral flow curve, with a short, steep inflow phase **132** followed by a 3 to 4 times longer outflow phase **134**. The inflow phase **130** is the result of tissue distention by the rapid blood volume inflow during ventricular systole. During the outflow phase **130**, blood flow continues into the vascular bed during diastole. The plethysmograph baseline **140** indicates the minimum basal tissue perfusion.

[0003] As shown in **FIG. 1**, a pulse oximetry sensor does not directly detect absorption, and hence does not directly measure the standard plethysmograph waveform **100**. Rather, a pulse oximeter sensor generates a detected light intensity signal. However, the standard plethysmograph **100** can be derived from the detected intensity signal because detected intensity is merely an out of phase version of light absorption. That is, the peak detected intensity occurs at minimum absorption **136**, and minimum detected intensity occurs at maximum absorption **138**. Further, a rapid rise in absorption **132** during the inflow phase of the plethysmograph is reflected in a rapid decline in intensity, and the gradual decline **134** in absorption during the outflow phase of the plethysmograph is reflected in a gradual increase in detected intensity. A pulse oximetry sensor is described in U.S. Pat. No. 6,088,607 entitled Low Noise Optical Probe. A pulse oximetry monitor is described in U.S. Pat. No. 6,650,917 entitled Signal Processing Apparatus. Both of these patents are assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein.

SUMMARY OF THE INVENTION

[0004] **FIG. 2** illustrates a hypovolemic plethysmograph waveform **200**. Hypovolemia is an abnormal decrease in blood volume, often caused from blood loss during surgery or due to an injury. Under hypovolemic conditions, a respiration-induced cyclical variation occurs in a plethysmograph baseline **240**. This cyclical variation **240** is particularly evident in patients undergoing positive ventilation. The amount of cyclical variation correlates to patient blood volume, i.e. the less blood volume the greater the cyclical variation in the plethysmograph waveform. As such, gauging cyclical variation, as described in detail with respect to **FIGS. 3-5**, below, allows a hypovolemia monitor to advantageously generate a noninvasive hypovolemia indication or blood volume measure.

[0005] One aspect of a hypovolemia monitor comprises a plethysmograph input responsive to light intensity after absorption by fleshy tissue and a measurement of respiration-induced variation in the input. The measurement is normalized and converted into a hypovolemia parameter. The plethysmograph may be generated by a pulse oximeter, and an audible or visual indication of hypovolemia may be provided. In one embodiment, an envelope of the plethysmograph is detected and a magnitude of the envelope is determined in order to measure the respiration-induced variation. In an alternative embodiment, a curve-fit is made to a locus of points on the plethysmograph and the variation magnitude is determined from a characteristic of the resulting curve. In yet another embodiment, a frequency spectrum of the plethysmograph is determined and a frequency component of that spectrum proximate a respiration rate is identified. The variation magnitude is calculated from the magnitude of that frequency component.

[0006] In other embodiments of the hypovolemia monitor, the normalized measurement is calculated by dividing the variation magnitude by an average value of the plethysmograph. Conversion is accomplished by constructing a calibration curve of hypovolemia parameter versus variation magnitude and using that calibration curve to determine the hypovolemia parameter from the normalized measurement. A percentage of normal total blood volume or a percentage of total blood volume loss may be displayed based upon the hypovolemia parameter. An audible alarm or a visual alarm indicating a hypovolemia condition may also be generated.

[0007] Another aspect of a hypovolemia monitor is a variation function having a sensor input and generating a variation parameter. The sensor input is responsive to light intensity after absorption by fleshy tissue and provides a measure of respiration-induced cyclical variation in the sensor input. A normalization function is applied to the variation parameter so as to generate a normalized variation parameter responsive to an average value of the sensor input. A conversion function is applied to the normalized variation parameter so as to generate a hypovolemia parameter responsive to blood volume of a living subject. In one embodiment, the variation function comprises an envelope detector adapted to determine an envelope of the sensor input and a magnitude processor configured to calculate a magnitude of the envelope. In another embodiment, the variation function comprises a curve-fit processor adapted to determine a locus of the sensor input representative of the cyclical variation. A magnitude processor is configured to calculate a magnitude of the cyclical variation from the locus. In yet another embodiment, the variation function comprises a frequency transform processor configured to generate a frequency spectrum of the sensor input. A frequency component processor is configured to determine the

magnitude of a frequency component of the spectrum corresponding to a respiration rate of the living subject.

[0008] In other embodiments, the normalization function calculates the magnitude divided by the average value so as to generate a normalized magnitude. The conversion function comprises a look-up table containing a curve representing a hypovolemia parameter versus the normalized magnitude. In a particular embodiment, the hypovolemia parameter corresponds to a percentage blood volume loss of the living subject.

[0009] A further aspect of a hypovolemia monitor comprises a variation means, a normalization means and a conversion means. The variation means is for measuring a magnitude of respiration-induced cyclical variations in an input plethysmograph. The normalization means is for normalizing the magnitude relative to a DC value of the plethysmograph. The conversion means is for translating the normalized magnitude to a hypovolemia parameter responsive to blood volume loss in a living subject.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] **FIG. 1** is an absorption versus time graph of a standard pulse oximeter plethysmograph;

[0011] **FIG. 2** is an absorption versus time graph of a plethysmograph exhibiting a respiration-induced, baseline cyclical variation;

[0012] **FIG. 3** is an absorption versus time graph of a plethysmograph envelope magnitude measure of cyclical variation;

[0013] **FIG. 4** is an absorption versus time graph of a plethysmograph envelope curve fit measure of cyclical variation; and

[0014] **FIG. 5** is a block diagram of a noninvasive hypovolemia monitor.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0015] **FIG. 3** illustrates a plethysmograph envelope magnitude measure for the cyclical variation of a plethysmograph **200**. In one embodiment, an upper envelope **301** of the plethysmograph **200** is determined. For example, the upper envelope **301** may be the locus of absorption maximums (peaks) **138** (**FIG. 1**) of each pulse **130** (**FIG. 1**). A variation parameter δ_1 **310**, the magnitude of the upper envelope **301**, is determined, for example, from the delta between the highest peak and the lowest peak. The variation parameter **310** is normalized, e.g. by calculating the ratio of δ_1 **310** over the DC **330** (direct current) value or average value of the plethysmograph **200**. A hypovolemia parameter **502** (**FIG. 5**) responsive to the normalized variation parameter δ_1/DC is then advantageously derived so as to noninvasively indicate a blood volume status, as described with respect to **FIG. 5**, below.

[0016] As shown in **FIG. 3**, in another embodiment, a lower envelope **302** of the plethysmograph **200** is determined. For example, the lower envelope **301** may be the locus of absorption minimums (valleys) **136** (**FIG. 1**) of each pulse **130** (**FIG. 1**). A variation parameter δ_2 **320** of the lower envelope **302** is determined as, for example, the delta between the highest valley and the lowest valley. The variation parameter **320** is normalized as described above and a hypovolemia parameter **502** (**FIG. 5**) responsive to the normalized variation parameter δ_2/DC is then derived, as described with respect to **FIG. 5**, below.

[0017] **FIG. 4** illustrates a plethysmograph curve-fit measure for the cyclical variation of a plethysmograph **200**. In one embodiment, an upper curve-fit **401** of the plethysmograph **200** is determined. For example, the upper curve fit **401** may be a best fit of the absorption maximums (peaks) **138** (**FIG. 1**) of each pulse **130** (**FIG. 1**). In a particular embodiment, the curve **401** is an ellipse having a first axis length that is dependent on the respiration rate RR **250** (**FIG. 2**) and a variation parameter r, **410** related to a second axis length is determined by a best fit to the plethysmograph pulse peaks **138** (**FIG. 1**). The variation parameter r_1 **410** is normalized, e.g. by calculating the ratio of r_1 **410** over the DC **330** value. A hypovolemia parameter **502** (**FIG. 5**) responsive to the normalized variation parameter r_1/DC is then advantageously derived so as to noninvasively indicate a blood volume status, as described with respect to **FIG. 5**, below.

[0018] As shown in **FIG. 4**, in another embodiment, a lower curve-fit **402** of the plethysmograph **200** is determined. For example, the lower curve-fit **402** may be a best fit of the locus of absorption minimums (valleys) **136** (**FIG. 1**) of each pulse **140** (**FIG. 1**). In a particular embodiment, the curve **402** is an ellipse portion having a first axis length that is dependent on the respiration rate RR **250** (**FIG. 2**) and a variation parameter r_2 **420** related to a second axis length determined by a best fit to the plethysmograph pulse valleys **136** (**FIG. 1**). In another embodiment, the curve **402** is a portion of a circle having radius r, the variation parameter. The variation parameter r_2 **420** is normalized as described above. A hypovolemia parameter **502** (**FIG. 5**) responsive to the normalized variation parameter r_2/DC is then advantageously derived so as to noninvasively indicate a blood volume status, as described with respect to **FIG. 5**, below.

[0019] **FIG. 5** illustrates a noninvasive hypovolemia monitor **500**, which is responsive to respiration-induced cyclical variations **240** (**FIG. 2**) in a plethysmograph. The hypovolemia monitor receives a plethysmograph waveform **501** input and provides a hypovolemia parameter **502** output indicative of a patient's blood volume status. In one embodiment, the plethysmograph **501** is an IR plethysmograph generated by a pulse oximeter. In other embodiments, the plethysmograph **501** is a photoplethysmograph or a pulse oximetry red plethysmograph. The hypovolemia monitor **500** has variation measurement **510**, normalization **520** and conversion **530** functions. These functions can be performed with analog or digital circuitry or as processor-based algorithmic computations or a combination of the above.

[0020] As shown in **FIG. 5**, the variation measurement and normalization functions **510**, **520** provide a relative measure of the degree of cyclical variation in the plethysmograph **200** (**FIG. 2**). In one embodiment, the variation measurement function **510** comprises a peak detector that determines the local maxima of each pulse of the plethysmograph waveform. The magnitude **310**, **320** (**FIG. 3**), δ, of the resulting waveform envelope is then calculated. The result is normalized **520** relative to an average or DC value **330** (**FIG. 3**) or similar value of the plethysmograph. The conversion function **530** converts the normalized variation

measurement of the plethysmograph variation to a hypovolemia parameter **502**. In one embodiment, the conversion function **530** comprises a calibration curve of a hypovolemia measure versus the normalized magnitude of respiration-induced cyclical variations. The calibration curve may be derived from a patient population using a standard blood volume test, such as indocyanine green (ICG) dye injection and dissipation. In a particular embodiment, the conversion function **530** is a lookup table containing one or more of such calibration curves. The hypovolemia parameter **502** advantageously provides a numerical value relating to patient blood volume status. As one example, the hypovolemia parameter **502** is a percentage measure of blood loss. As another example, the hypovolemia parameter **502** is measure of total blood volume in liters.

[**0021**] Also shown in **FIG. 5**, input parameters **504** can be utilized by the conversion function **530**. In one embodiment, the input parameters **504** are patient type, such as adult, pediatric or neonate. In another embodiment, the input parameters include patient height and weight. In yet another embodiment, input parameters **504** are other physiological measurements, such as blood pressure.

[**0022**] Although the variation measurement and normalization functions are described above with respect to a time domain analysis, similar results can be achieved by a frequency domain analysis. For example, the variation measurement function **510** can be determined by performing a Fast Fourier Transform (FFT) or similar computation on the plethysmograph. In particular, the magnitude of the resulting spectral component at or near the respiration rate RR is determined. In one embodiment, respiration rate RR **503** is an input to the variation measurement function **510**, as provided by a ventilator, a respiration belt transducer or similar device.

[**0023**] A noninvasive hypovolemia monitor has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications.

What is claimed is:

1. A hypovolemia monitoring method comprising the steps of:

inputting a plethysmograph responsive to light intensity after absorption by fleshy tissue;

measuring a respiration-induced variation in said input;

normalizing said measurement; and

converting said normalized measurement into a hypovolemia parameter.

2. The hypovolemia monitoring method according to claim 1 comprising the further step of providing at least one of an audible indication and a visual indication of hypovolemia.

3. The hypovolemia monitoring method according to claim 2 wherein said inputting step comprises the substep of generating a pulse oximeter plethysmograph.

4. The hypovolemia monitoring method according to claim 3 wherein said measuring step comprises the substeps of:

detecting an envelope of said plethysmograph; and

determining a magnitude of said envelope.

5. The hypovolemia monitoring method according to claim 3 wherein said measuring step comprises the substeps of:

fitting a curve to a locus of points on said plethysmograph;

determining a magnitude of said variation from a characteristic of said curve.

6. The hypovolemia monitoring method according to claim 3 wherein said measuring step comprises the substeps of:

determining a frequency spectrum of said plethysmograph;

identifying a frequency component of said frequency spectrum proximate a respiration rate; and

calculating a magnitude of said frequency component.

7. The hypovolemia monitoring method according to claim 4 wherein said normalizing step comprises the substeps of:

calculating an average value of said plethysmograph; and

dividing said magnitude by said average value.

8. The hypovolemia monitoring method according to claim 7 wherein said converting step comprises the substep of:

constructing a calibration curve of said hypovolemia parameter versus variation magnitude;

utilizing said calibration curve to determine said hypovolemia parameter from said normalized measurement.

9. The hypovolemia monitoring method according to claim 8 wherein said providing step comprises the substep of displaying at least one of a percentage of normal total blood volume and a percentage of total blood volume loss based upon said hypovolemia parameter.

10. The hypovolemia monitoring method according to claim 8 wherein said providing step comprises the substep of generating at least one of an audible alarm and a visual alarm indicating a hypovolemia condition.

11. A hypovolemia monitor comprising:

a variation function having a sensor input and generating a variation parameter, said sensor input responsive to light intensity after absorption by fleshy tissue, said variation parameter providing a measure of respiration-induced cyclical variation in said sensor input;

a normalization function applied to said variation parameter so as to generate a normalized variation parameter responsive to an average value of said sensor input; and

a conversion function applied to said normalized variation parameter so as to generate a hypovolemia parameter responsive to blood volume of a living subject.

12. The hypovolemia monitor according to claim 11 wherein said variation function comprises:

an envelope detector adapted to determine an envelope of said sensor input; and

a magnitude processor configured to calculate a magnitude of said envelope.

13. The hypovolemia monitor according to claim 11 wherein said variation function comprises:

a curve-fit processor adapted to determine a locus of said sensor input representative of said cyclical variation; and

a magnitude processor configured to calculate a magnitude of said cyclical variation from said locus.

14. The hypovolemia monitor according to claim 11 wherein said variation function comprises:

a frequency transform processor configured to generate a frequency spectrum of said sensor input; and

a frequency component processor configured to determine the magnitude of a frequency component of said spectrum corresponding to a respiration rate of said living subject.

15. The hypovolemia monitor according to claim 12 wherein said normalization function calculates said magnitude divided by said average value so as to generate a normalized magnitude.

16. The hypovolemia monitor according to claim 15 wherein said conversion function comprises a look-up table containing a curve representing a hypovolemia parameter versus said normalized magnitude.

17. The hypovolemia monitor according to claim 16 wherein said hypovolemia parameter corresponds to a percentage blood volume loss of said living subject.

18. A hypovolemia monitor comprising:

a variation means for measuring a magnitude of respiration-induced cyclical variations in an input plethysmograph;

a normalization means for normalizing said magnitude relative to a DC value of said plethysmograph; and

a conversion means for translating said normalized magnitude to a hypovolemia parameter responsive to blood volume loss in a living subject.

* * * * *

专利名称(译)	无创性血容量不足监测仪		
公开(公告)号	US20060058691A1	公开(公告)日	2006-03-16
申请号	US11/221411	申请日	2005-09-06
[标]申请(专利权)人(译)	Kiani曾MASSIê		
申请(专利权)人(译)	Kiani曾MASSIê		
当前申请(专利权)人(译)	摩根大通银行，NATIONAL ASSOCIATION		
[标]发明人	KIANI MASSI E		
发明人	KIANI, MASSI E.		
IPC分类号	A61B5/02 A61B5/00		
CPC分类号	A61B5/0059 A61B5/02416 A61B5/02042 A61B5/1455 A61B5/0816		
优先权	60/607562 2004-09-07 US		
其他公开文献	US7976472		
外部链接	Espacenet USPTO		

摘要(译)

血容量不足监测器包括在肉质组织吸收后响应光强度的体积描记器输入。测量呼吸引起的输入变化。将测量标准化并转换为血容量不足参数。基于血容量不足参数，提供血容量不足的听觉或视觉指示。