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(54) **HYPOVOLEMIA DIAGNOSIS TECHNIQUE**

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See application file for complete search history.

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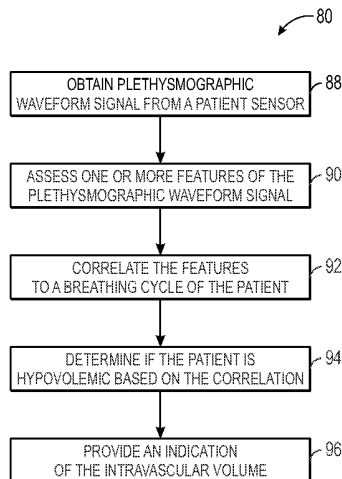
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(57) **ABSTRACT**

Embodiments of the present disclosure relate to a system and method for determining a risk, onset, or presence of hypovolemia based on one or more features of a plethysmographic waveform during a patient breathing cycle. For example, a hypovolemic patient may exhibit characteristic changes in pulse amplitude or stroke volume during inhalation and exhalation relative to a healthy patient. Further, a trend or pattern of such features may be used to assess the patient's fluid condition.

15 Claims, 8 Drawing Sheets



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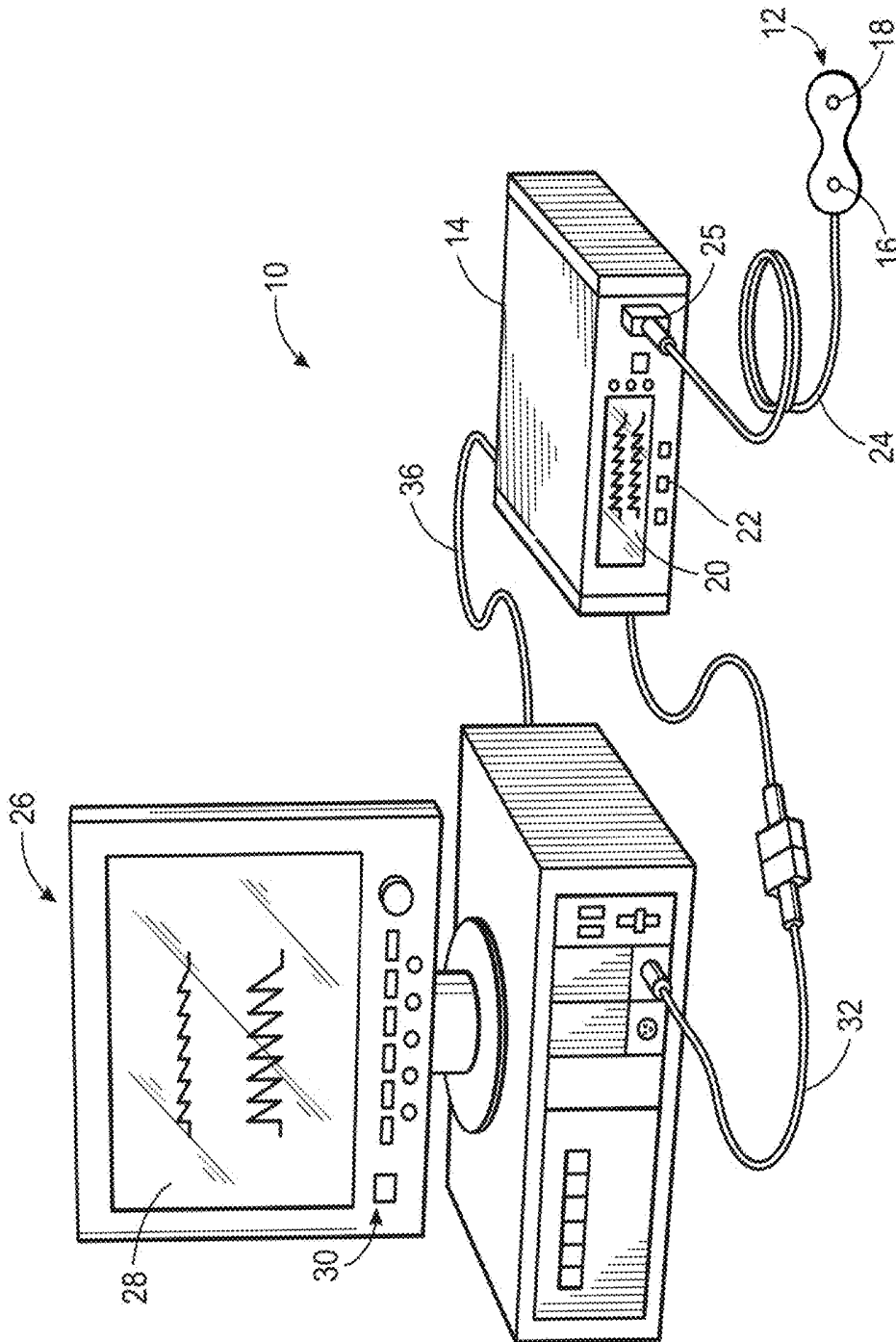


FIG. 1

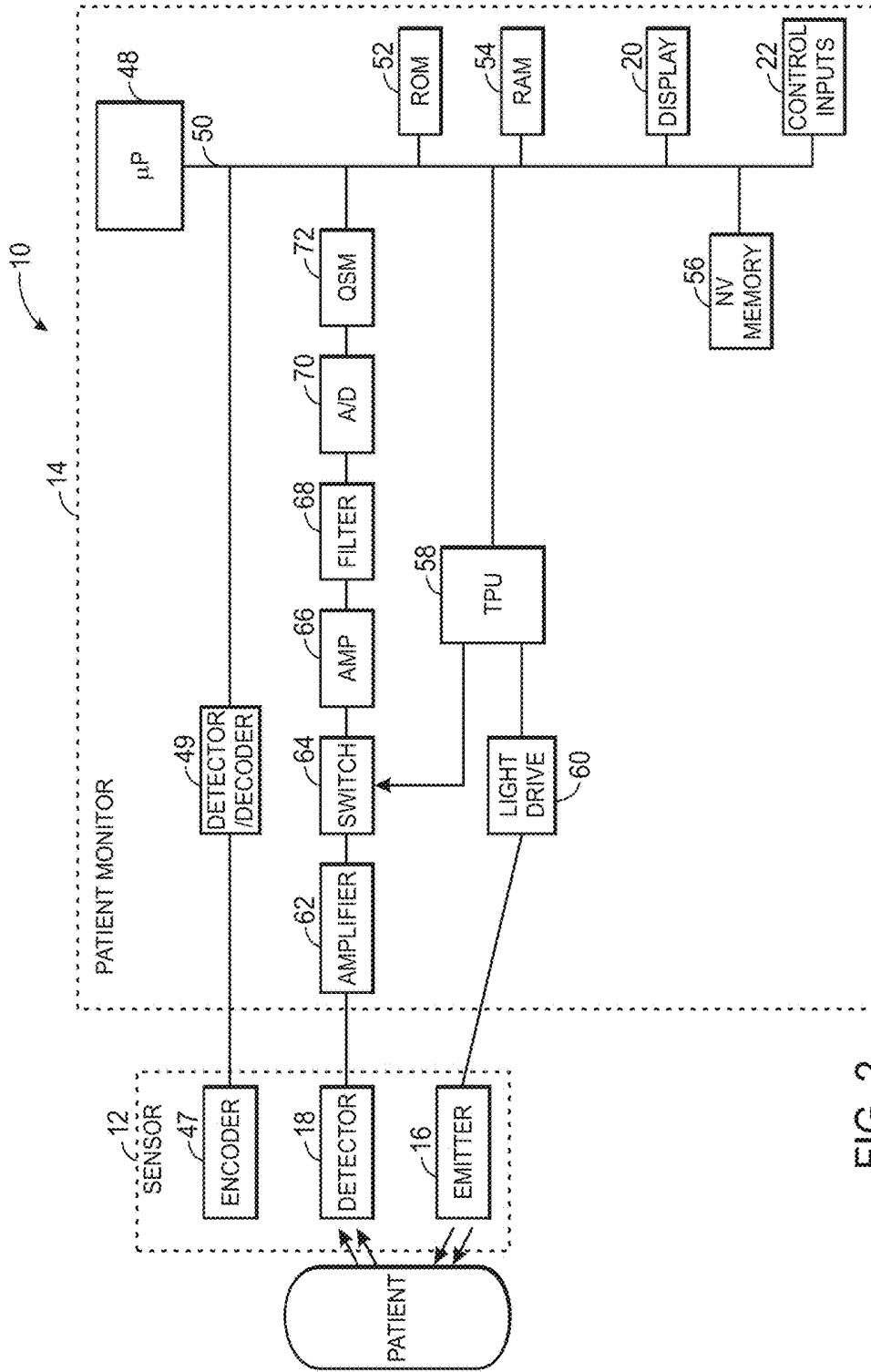


FIG. 2

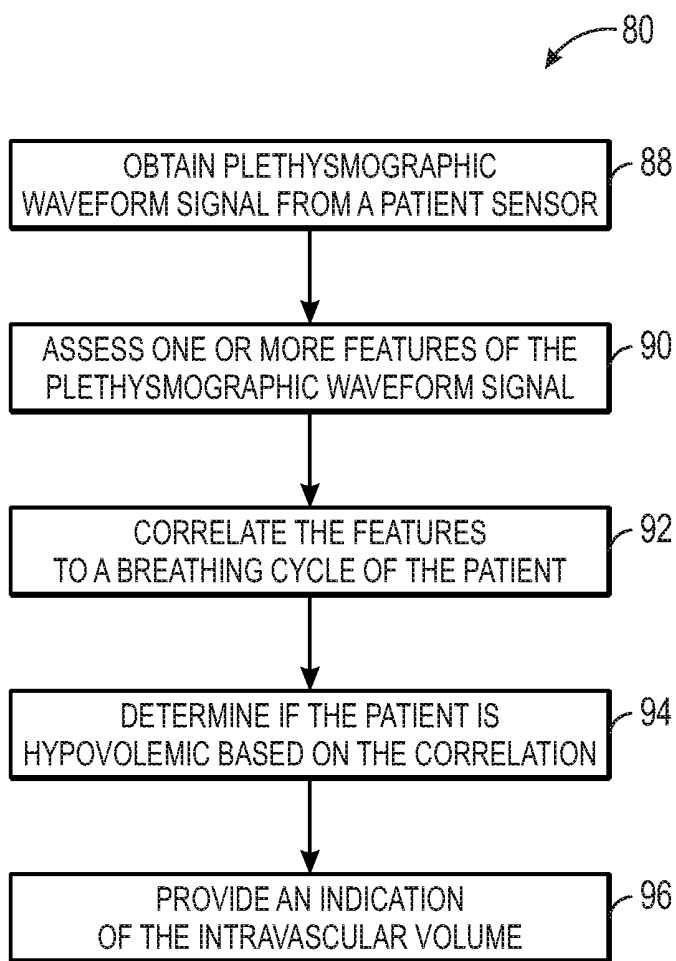


FIG. 3

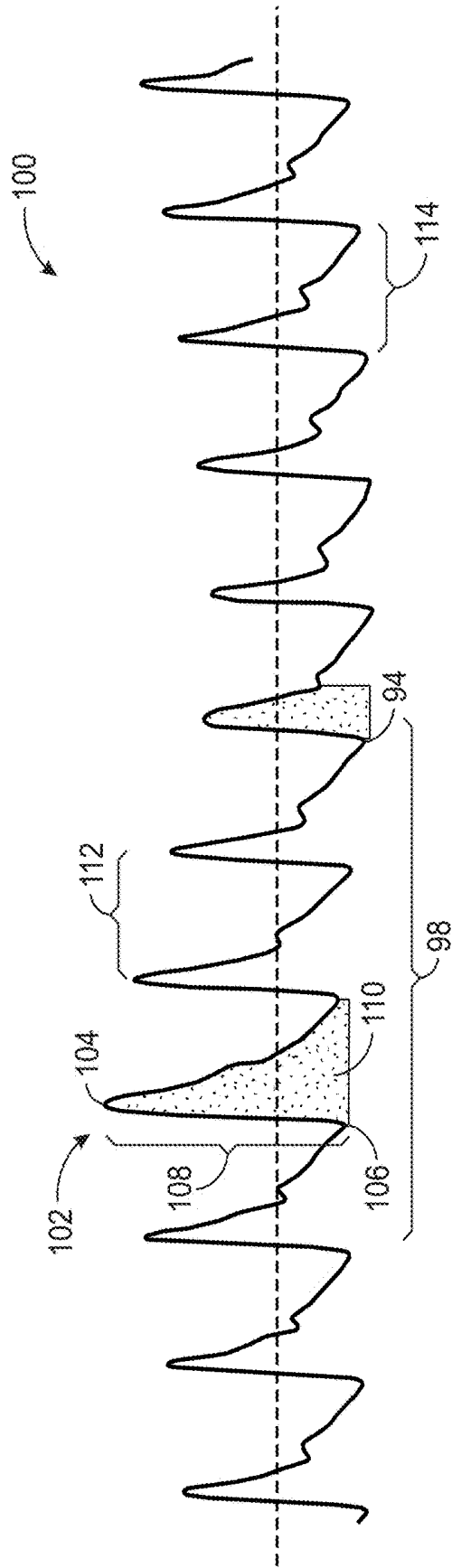


FIG. 4

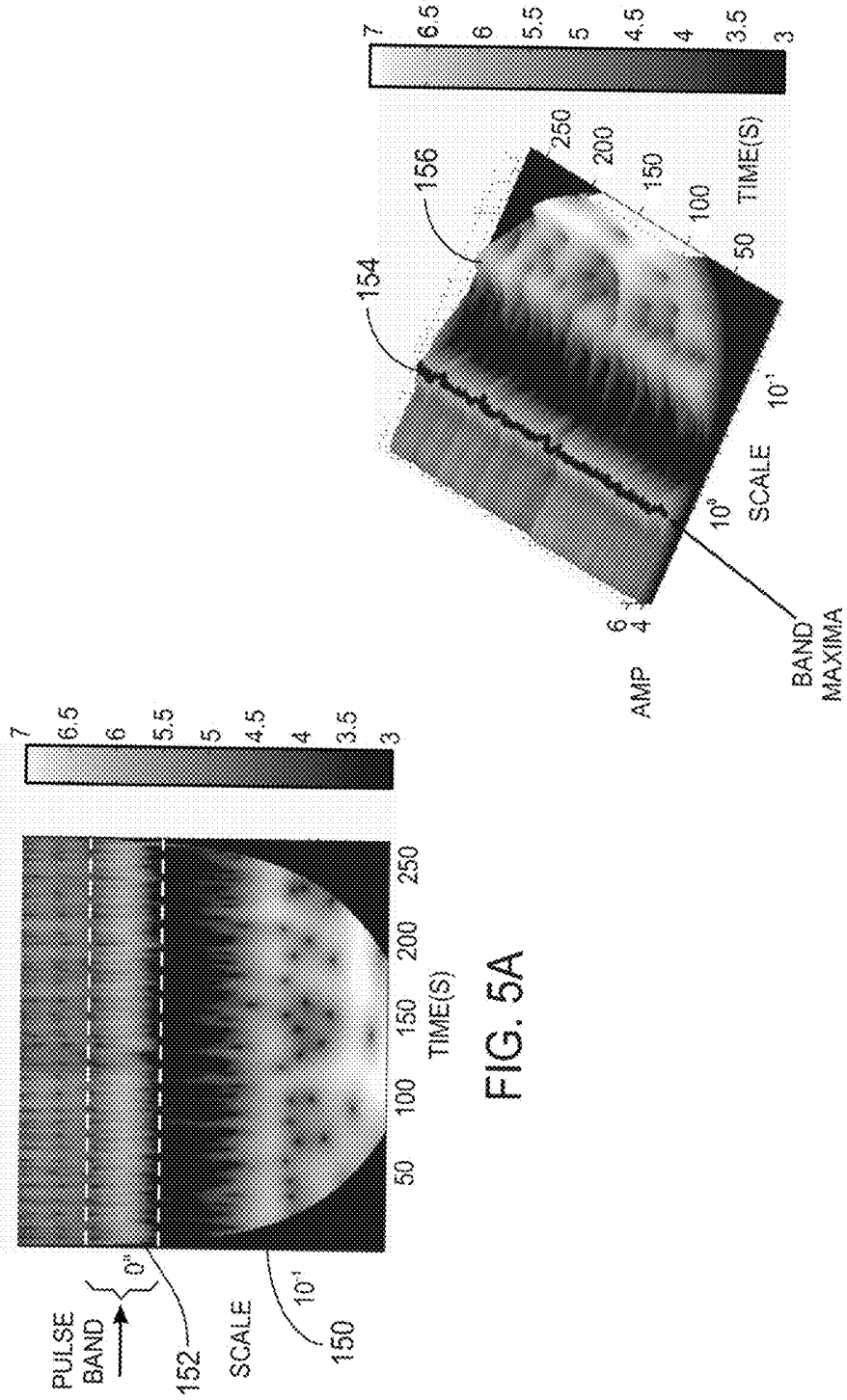


FIG. 5A

FIG. 5B

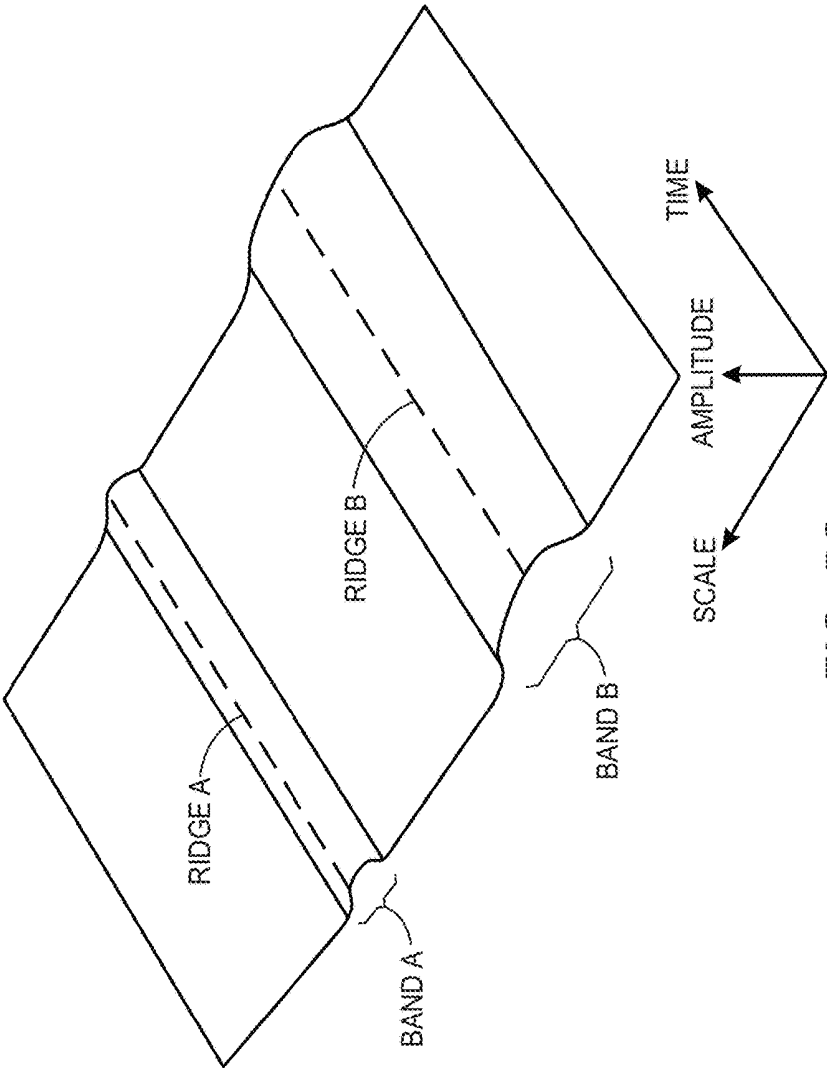


FIG. 5C

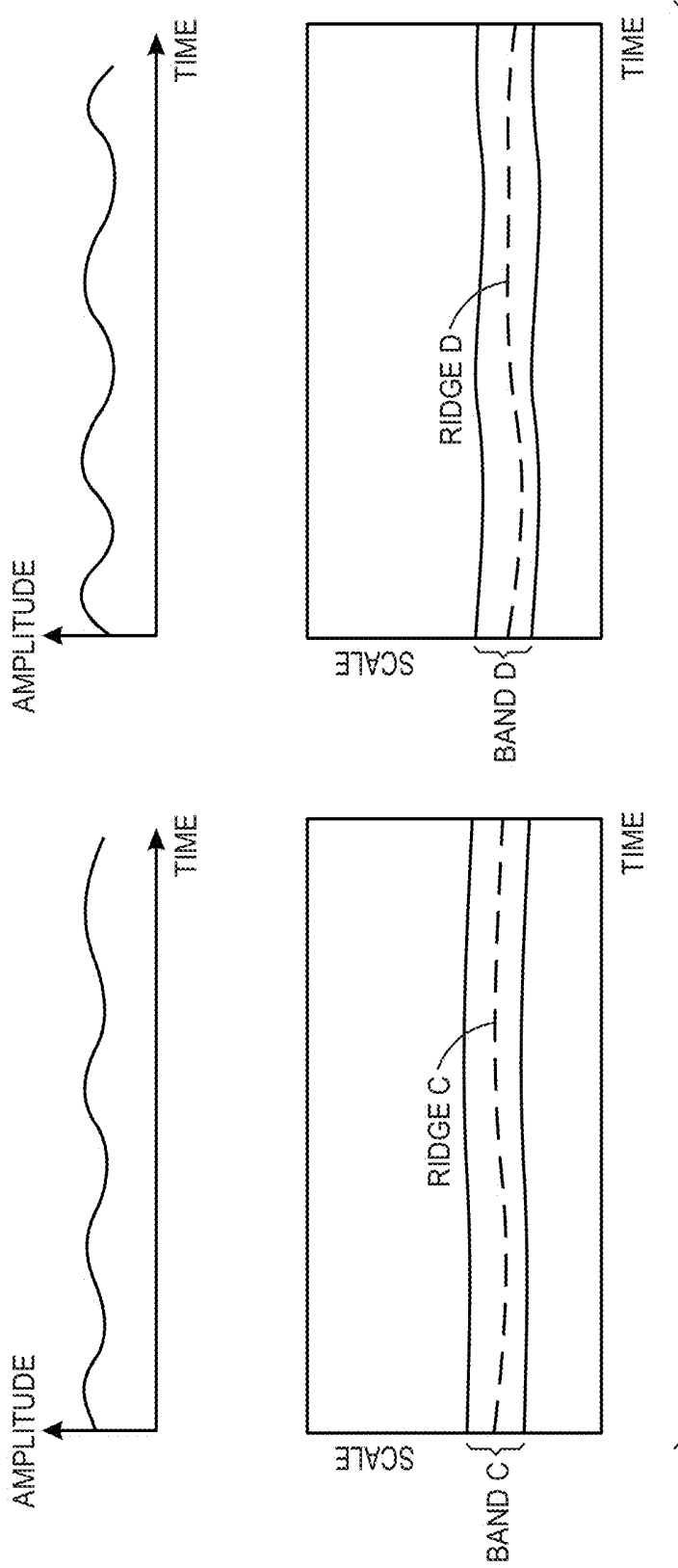


FIG. 5D

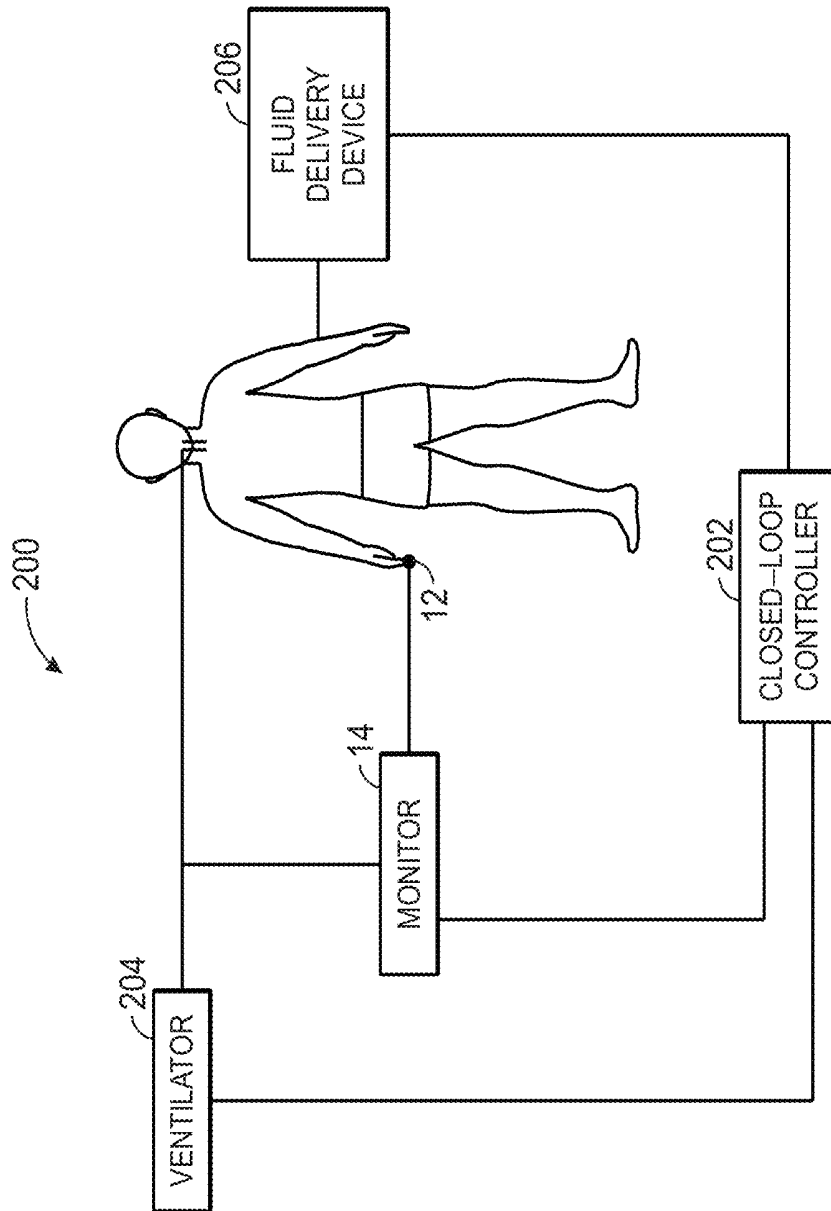


FIG. 6

HYPOVOLEMIA DIAGNOSIS TECHNIQUE**CROSS-REFERENCE TO RELATED APPLICATIONS**

This application is a continuation of U.S. application Ser. No. 13/404,402, filed Feb. 24, 2012, the disclosure of which is hereby incorporated by reference in its entirety for all purposes.

BACKGROUND

The present disclosure relates generally to techniques for monitoring physiological parameters of a patient. Specifically, embodiments of the present disclosure relate to medical devices that are capable of providing an indication of hypovolemia.

This section is intended to introduce the reader to various aspects of art that may be related to various aspects of the present disclosure, which are described and/or claimed below. This discussion is believed to be helpful in providing the reader with background information to facilitate a better understanding of the various aspects of the present disclosure. Accordingly, it should be understood that these statements are to be read in this light, and not as admissions of prior art.

One physiological parameter that physicians may wish to monitor is blood fluid volume (i.e., intravascular volume). Variations from normal fluid volume in the blood may indicate a change in clinical condition or an injury. For example, hypovolemia is a state of decreased intravascular volume that may be associated with dehydration. Correct clinical assessment of hypovolemia is complex. More specifically, intravascular volume is difficult to estimate, particularly in critically ill patients. Without an accurate assessment of a patient's intravascular volume, it is difficult to predict whether a patient will respond to fluid therapy (e.g., a blood or fluid infusion) with an improvement in clinical condition, such as an increase in stroke volume and cardiac output. Accordingly, accurate assessments of intravascular volume may assist a clinician in determining whether a patient will be responsive to fluid therapy.

To this end, indicators such as the systolic blood pressure variation, pulse pressure variation, or stroke volume variation may be used to estimate intravascular volume and determine whether a patient is likely to be fluid responsive. However, these measurements tend to be invasive. For example, to obtain an accurate pulse pressure waveform from which the intravascular volume can be determined, a physician may insert an invasive arterial line.

BRIEF DESCRIPTION OF THE DRAWINGS

Advantages of the disclosed techniques may become apparent upon reading the following detailed description and upon reference to the drawings in which:

FIG. 1 is an illustration of a patient monitoring system in accordance with an embodiment;

FIG. 2 is a block diagram of a patient monitor for determining hypovolemia in accordance with an embodiment;

FIG. 3 is a flow diagram of a method for determining hypovolemia shock in accordance with an embodiment;

FIG. 4 is an illustration of a plethysmographic waveform signal;

FIGS. 5A and 5B show illustrative views of a scalogram derived from a plethysmographic signal in accordance with an embodiment;

FIG. 5C shows an illustrative scalogram derived from a signal containing two pertinent components in accordance with an embodiment;

FIG. 5D shows an illustrative schematic of signals associated with a ridge in FIG. 5C and illustrative schematics of a further wavelet decomposition of these newly derived signals in accordance with an embodiment; and

FIG. 6 is a block diagram of a closed-loop ventilation system for administering a fluid therapy in accordance with an embodiment.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

One or more specific embodiments of the present techniques will be described below. In an effort to provide a concise description of these embodiments, not all features of an actual implementation are described in the specification. It should be appreciated that in the development of any such actual implementation, as in any engineering or design project, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which may vary from one implementation to another. Moreover, it should be appreciated that such a development effort might be complex and time consuming, but would nevertheless be a routine undertaking of design, fabrication, and manufacture for those of ordinary skill having the benefit of this disclosure.

Photoplethysmography is a noninvasive technique for monitoring physiological characteristics of a patient. In one example, a photoplethysmography device uses a sensor that transmits light through a patient's tissue and photoelectrically detects the absorption and/or scattering of the transmitted light in such tissue. More specifically, the light passed through the tissue is typically selected to be of one or more wavelengths that may be absorbed or scattered by the blood in an amount correlative to the amount of the blood constituent present in the blood. The amount of light absorbed and/or scattered may then be used to estimate the amount of blood constituent in the tissue or the blood oxygen saturation using various algorithms.

As provided herein, certain features of the plethysmographic waveform may be analyzed for characteristics, variations, or patterns that are linked to hypovolemia and, in certain embodiments, hypovolemic shock, e.g., loss of blood volume due to acute trauma or internal bleeding. Based on a detection of low blood volume, appropriate therapy may be administered to the patient. For example, IV or fluid therapy may be administered to a patient with hypovolemia. Additionally, the techniques provided herein may be used for monitoring surgical or post-surgical patients to detect internal bleeding or rapid blood loss.

In particular, the plethysmographic waveform includes a pulsatile AC component that may be characterized by amplitude, width, and/or an area under the curve for individual pulses. The AC component of the plethysmographic signal is representative of variations in left ventricular stroke volume during each cardiac cycle, as well as dynamic changes in the peripheral vasculature. During traumatic shock, there is a loss of blood volume that leads to reductions in left ventricular stroke volume, which in turn may be reflected as characteristic changes in the AC component of the plethysmographic waveform signal. In addition, the act of respira-

tion results in characteristic changes in the AC component of the signal. For example, the inhalation of oxygen and exhalation of carbon dioxide are accompanied by hemodynamic changes such as beat to beat interval changes, baseline shifts, and pulse amplitude variations. Detection of these changes and analysis of their magnitude may be used to monitor the onset or presence of hypovolemic shock. In one embodiment, these waveform features may be calculated using algorithms for calculating a patient respiration rate from the plethysmographic waveform.

The changes in the plethysmographic waveform signal that are associated with hypovolemia may be detected earlier than other types of changes, including heart rate and blood pressure changes. Accordingly, the present techniques allow earlier diagnosis of hypovolemia and/or associated shock. In addition, the present techniques account for the presence of arrhythmic beats. Rather than ignoring the presence of arrhythmia, the present techniques may use the number, frequency, or type of arrhythmic beats as a factor in determining the probability of shock. For example, in one embodiment, a determination of hypovolemic shock may be based on the respiration rate pulse band, respiratory sinus arrhythmia, and baseline modulation during respiration.

With this in mind, FIG. 1 depicts an embodiment of a patient monitoring system 10 that may be used in conjunction with a plethysmographic sensor 12. Although the depicted embodiments relate to photoplethysmography or pulse oximetry, the system 10 may be configured to obtain a variety of medical measurements with a suitable medical sensor. The system 10 includes the sensor 12 that is communicatively coupled to a patient monitor 14. The sensor 12 includes one or more emitters 16 and one or more detectors 18. The emitters 16 and detectors 18 of the sensor 12 are coupled to the monitor 14 via a cable 24 through a plug 25 coupled to a sensor port. Additionally, the monitor 14 includes a monitor display 20 configured to display information regarding the physiological parameters, information about the system, and/or alarm indications. The monitor 14 may include various input components 22, such as knobs, switches, keys and keypads, buttons, etc., to provide for operation and configuration of the monitor. The monitor 14 also includes a processor that may be used to execute code such as code for implementing the techniques discussed herein.

The monitor 14 may be any suitable monitor, such as a pulse oximetry monitor available from Nellcor Puritan Bennett LLC. The monitor 14 may also be capable of determining a patient's respiration rate based on the plethysmographic waveform signal. Furthermore, to upgrade conventional operation provided by the monitor 14 to provide additional functions, the monitor 14 may be coupled to a multi-parameter patient monitor 26 via a cable 32 connected to a sensor input port or via a cable 36 connected to a digital communication port, or via an RF or optical wireless link. Alternatively, the techniques provided herein may be incorporated into one or more individual modules with plug-in connectivity to the multi-parameter patient monitor 26. Such modules may include connectors that allow the calculated physiological parameters to be sent to the host multi-parameter monitor. In addition, the monitor 14, or, alternatively, the multi-parameter patient monitor 26, may be configured to calculate physiological parameters and to provide a central display 28 for the visualization of information from the monitor 14 and from other medical monitoring devices or systems. The multi-parameter monitor 26 includes a processor that may be configured to execute code. The multi-parameter monitor 26 may also include

various input components 30, such as knobs, switches, keys and keypads, buttons, etc., to provide for operation and configuration of the a multi-parameter monitor 26. In addition, the monitor 14 and/or the multi-parameter monitor 26 may be connected to a network to enable the sharing of information with servers or other workstations. In certain embodiments, the sensor 12 may be a wireless sensor 12. Accordingly, the wireless sensor 12 may establish a wireless communication with the patient monitor 14 and/or the multi-parameter patient monitor 26 using any suitable wireless standard. By way of example, the wireless module may be capable of communicating using one or more of the ZigBee standard, WirelessHART standard, Bluetooth standard, IEEE 802.11x standards, or MiWi standard. In embodiments in which the sensor 12 is configured for wireless communication, the strain relief features of the cable 24 may be housed in the sensor body 34.

As provided herein, the sensor 12 may be a sensor suitable for detection of one or more physiological parameters. The sensor 12 may include optical components (e.g., one or more emitters 16 and detectors 18). In one embodiment, the sensor 12 may be configured for photo-electric detection of blood and tissue constituents. For example, the sensor 12 may include pulse oximetry sensing functionality for determining the oxygen saturation of blood as well as other parameters (e.g., respirations rate) from the plethysmographic waveform detected by the oximetry technique. An oximetry system may include a light sensor (e.g., sensor 12) that is placed at a site on a patient, typically a fingertip, toe, forehead or earlobe, or in the case of a neonate, across a foot. The sensor 12 may pass light using the emitter 16 through blood perfused tissue and photoelectrically sense the absorption of light in the tissue. For example, the monitor 14 may measure the intensity of light that is received at the light sensor as a function of time. A signal representing light intensity versus time or a mathematical manipulation of this signal (e.g., a scaled version thereof, a log taken thereof, a scaled version of a log taken thereof, etc.) may be referred to as the photoplethysmograph (PPG) signal. The light intensity or the amount of light absorbed may then be used to calculate the amount of the blood constituent (e.g., oxyhemoglobin) being measured and other physiological parameters such as the pulse rate and when each individual pulse occurs. Generally, the light passed through the tissue is selected to be of one or more wavelengths that are absorbed by the blood in an amount representative of the amount of the blood constituent present in the blood. The amount of light passed through the tissue varies in accordance with the changing amount of blood constituent in the tissue and the related light absorption. At least two, e.g., red and infrared (IR), wavelengths may be used because it has been observed that highly oxygenated blood will absorb relatively less red light and more infrared light than blood with a lower oxygen saturation. However, it should be understood that any appropriate wavelengths, e.g., green, etc., may be used as appropriate. Further, photoplethysmography measurements may be determined based on one, two, or three or more wavelengths of light.

Turning to FIG. 2, a simplified block diagram of the medical system 10 is illustrated in accordance with an embodiment. As noted, the sensor 12 may include optical components in the forms of emitters 16 and detectors 18. The emitter 16 and the detector 18 may be arranged in a reflectance or transmission-type configuration with respect to one another. However, in embodiments in which the sensor 12 is configured for use on a patient's forehead (e.g., either alone or in conjunction with a hat or headband), the

emitters **16** and detectors **18** may be in a reflectance configuration. Such sensors **12** may be used for pulse oximetry or regional saturation monitoring (e.g., INVOS® monitoring). An emitter **16** may also be a light emitting diode, superluminescent light emitting diode, a laser diode or a vertical cavity surface emitting laser (VCSEL). An emitter **16** and detector **18** may also include optical fiber sensing elements. An emitter **16** may include a broadband or “white light” source, in which case the detector could include any of a variety of elements for selecting specific wavelengths, such as reflective or refractive elements, absorptive filters, dielectric stack filters, or interferometers. These kinds of emitters and/or detectors would typically be coupled to the sensor **12** via fiber optics. Alternatively, a sensor assembly **12** may sense light detected from the tissue is at a different wavelength from the light emitted into the tissue. Such sensors may be adapted to sense fluorescence, phosphorescence, Raman scattering, Rayleigh scattering and multiphoton events or photoacoustic effects in conjunction with the appropriate sensing elements.

In certain embodiments, the emitter **16** and detector **18** may be configured for pulse oximetry. It should be noted that the emitter **16** may be capable of emitting at least two wavelengths of light, e.g., red and infrared (IR) light, into the tissue of a patient, where the red wavelength may be between about 600 nanometers (nm) and about 700 nm, and the IR wavelength may be between about 800 nm and about 1000 nm. The emitter **16** may include a single emitting device, for example, with two LEDs, or the emitter **16** may include a plurality of emitting devices with, for example, multiple LED's at various locations. In some embodiments, the LEDs of the emitter **16** may emit three or more different wavelengths of light. Such wavelengths may include a red wavelength of between approximately 620-700 nm (e.g., 660 nm), a far red wavelength of between approximately 690-770 nm (e.g., 730 nm), and an infrared wavelength of between approximately 860-940 nm (e.g., 900 nm). Other wavelengths may include, for example, wavelengths of between approximately 500-600 nm and/or 1000-1100 nm and/or 1200-1400 nm. Regardless of the number of emitting devices, light from the emitter **16** may be used to measure, as provided herein, a risk, onset, or presence of hypovolemia. In certain embodiments, the sensor measurements may also be used for determining oxygen saturation, respiration rate, water fraction, hematocrit, or other physiologic parameters of the patient. It should be understood that, as used herein, the term “light” may refer to one or more of ultrasound, radio, microwave, millimeter wave, infrared, visible, ultraviolet, gamma ray or X-ray electromagnetic radiation, and may also include any wavelength within the radio, microwave, infrared, visible, ultraviolet, or X-ray spectra, and that any suitable wavelength of light may be appropriate for use with the present disclosure. In another embodiment, two emitters **16** may be configured for use in a regional saturation technique. To that end, the emitters **16** may include two light emitting diodes (LEDs) that are capable of emitting at least two wavelengths of light, e.g., red or near infrared light. In one embodiment, the LEDs emit light in the range of 600 nanometers to approximately 1000 nm. In a particular embodiment, one LED is capable of emitting light at 730 nm and the other LED is capable of emitting light at 810 nm.

In any suitable configuration of the sensor **12**, the detector **18** may be an array of detector elements that may be capable of detecting light at various intensities and wavelengths. In one embodiment, light enters the detector **18** after passing through the tissue of the patient. In another embodiment,

light emitted from the emitter **16** may be reflected by elements in the patient's tissue to enter the detector **18**. The detector **18** may convert the received light at a given intensity, which may be directly related to the absorbance and/or reflectance of light in the tissue of the patient, into an electrical signal. That is, when more light at a certain wavelength is absorbed, less light of that wavelength is typically received from the tissue by the detector **18**, and when more light at a certain wavelength is reflected, more light of that wavelength is typically received from the tissue by the detector **18**. The detector **18** may receive light that has not entered the tissue to be used as a reference signal. After converting the received light to an electrical signal, the detector **18** may send the signal to the monitor **14**, where physiological characteristics may be calculated based at least in part on the absorption and/or reflection of light by the tissue of the patient.

In certain embodiments, the medical sensor **12** may also include an encoder **47** that may provide signals indicative of the wavelength of one or more light sources of the emitter **16**, which may allow for selection of appropriate calibration coefficients for calculating a physical parameter such as blood oxygen saturation. The encoder **47** may, for instance, be a coded resistor, EEPROM or other coding devices (such as a capacitor, inductor, PROM, RFID, parallel resident currents, or a colorimetric indicator) that may provide a signal to a microprocessor **48** related to the characteristics of the medical sensor **12** to enable the microprocessor **48** to determine the appropriate calibration characteristics of the medical sensor **12**. Further, the encoder **47** may include encryption coding that prevents a disposable part of the medical sensor **12** from being recognized by a microprocessor **48** unable to decode the encryption. For example, a detector/decoder **49** may translate information from the encoder **47** before it can be properly handled by the processor **48**. In some embodiments, the encoder **47** and/or the detector/decoder **48** may not be present. In some embodiments, the encrypted information held by the encoder **47** may itself be transmitted via an encrypted data protocol to the detector/decoder **49**, such that the communication between **47** and **49** is secured.

Signals from the detector **18** and/or the encoder **47** may be transmitted to the monitor **14**. The monitor **14** may include one or more processors **48** coupled to an internal bus **50**. Also connected to the bus may be a ROM memory **52**, a RAM memory **54**, non-volatile memory **56**, a display **20**, and control inputs **22**. A time processing unit (TPU) **58** may provide timing control signals to light drive circuitry **60**, which controls when the emitter **16** is activated, and if multiple light sources are used, the multiplexed timing for the different light sources. TPU **58** may also control the gating-in of signals from detector **18** through a switching circuit **64**. These signals are sampled at the proper time, depending at least in part upon which of multiple light sources is activated, if multiple light sources are used. The received signal from the detector **18** may be passed through one or more amplifiers (e.g., amplifiers **62** and **66**), a low pass filter **68**, and an analog-to-digital converter **70** for amplifying, filtering, and digitizing the electrical signals from the sensor **12**. The digital data may then be stored in a queued serial module (QSM) **72**, for later downloading to RAM **54** as QSM **72** fills up. In an embodiment, there may be multiple parallel paths for separate amplifiers, filters, and A/D converters for multiple light wavelengths or spectra received.

Based at least in part upon the received signals corresponding to the light received by optical components of the

pulse oximetry sensor **20**, microprocessor **48** may calculate a hypovolemia indicator and/or the respiration rate, oxygen saturation and/or heart rate using various algorithms, such as those employed by the Nellcor™ N-600x™ pulse oximetry monitor, which may be used in conjunction with various Nellcor™ pulse oximetry sensors, such as OxiMax™ sensors. In addition, the microprocessor **48** may calculate and/or display trend or parameter variability using various methods, such as those provided herein. These algorithms may employ certain coefficients, which may be empirically determined, and may correspond to the wavelengths of light used. The algorithms and coefficients may be stored in a ROM **52** or other suitable computer-readable storage medium and accessed and operated according to microprocessor **48** instructions. In one embodiment, the correction coefficients may be provided as a lookup table.

As provided herein, a loss or change in intravascular volume associated with hypovolemia may be determined based on changes or patterns detected in the characteristic respiratory-induced variations of the plethysmographic waveform. In particular embodiments, these changes may be assessed using algorithms for determining respiration rate and/or oxygen saturation. For example, a patient monitor **14** capable of determining a respiration rate may employ certain algorithms that assess features of the waveform including amplitude variations, baseline shifts, arrhythmic beats, and beat-to-beat variations. These features may be extracted from the algorithm calculations and used as inputs to a hypovolemia determination. In another embodiment, signal processing techniques used for processing the plethysmographic waveform signal to determine oxygen saturation may be used to assess pulse quality, changes in pulse amplitude, and/or pulse shape. Further, in particular embodiments, information about a patient's breathing cycle may also be used as an input to a hypovolemia determination.

For example, a patient's pulse amplitude may be assessed to determine if the patient is hypovolemic. For healthy patients with normal fluid status, the left ventricular stroke volume decreases as the patient breathes in. During exhalation, there is a corresponding small increase in the left ventricular stroke volume. These changes in stroke volume relate to respiratory-induced pulse amplitude variations in the plethysmographic waveform. Accordingly, changes in pulse amplitude may be used at least in part to estimate changes in stroke volume. In certain embodiments, the estimation of stroke volume may also incorporate additional factors and/or parameters, such as heart rate, vascular tone, or pulse pressure. For patients experiencing onset of hypovolemia, a relatively larger drop in stroke volume during inhalation may be observed. Similarly, a relatively larger increase in stroke volume occurs during exhalation for patients with hypovolemia. By tracking trends in pulse amplitude as correlated to a breathing cycle, early onset of hypovolemia may be detected.

FIG. **3** is a process flow diagram illustrating a method **80** in accordance with some embodiments. The method may be performed as an automated procedure by a system, such as system **10**. In addition, certain steps of the method may be performed by a processor, or a processor-based device such as a patient monitor **14** that includes instructions for implementing certain steps of the method **80**. According to an embodiment, the method **80** begins with obtaining a plethysmographic waveform signal from a pulse oximetry sensor **12** at step **88**.

The monitor **14** may perform assess one or more features of the plethysmographic waveform at step **90** based on the plethysmographic waveform signal obtained at step **88**. At

step **92**, the plethysmographic waveform signal and its features are correlated to information related to a breathing cycle of a patient. The information about the breathing cycle may be determined based on an analysis of the plethysmographic waveform signal. That is, based on certain patterns associated with respiration and their effects on the plethysmographic waveform signal, the pulses may be correlated to a full breathing cycle including inspiration and exhalation or only certain portions of the breathing cycle (e.g., the inhalation and exhalation components of the signal may be extracted). Measuring respiration cycles may be performed using techniques such as those provided in U.S. Patent Publication No. 2010/0324827, which is incorporated by reference herein in its entirety for all purposes. Other inputs used in the correlation may be a patient's calculated heart rate and respiration rate. In a particular embodiment, if the patient is receiving breathing assistance, a ventilator may provide input to the system **10** to correlate the breathing cycle with the plethysmographic waveform. For patients breathing without assistance, a breathing cycle may be determined by a nasal thermistor, which measures the temperature changes that occur during inhalation and exhalation. Other techniques may involve indirect measurements of changes in body volume as a result of respiration, including transthoracic inductance, impedance plethysmography, or strain gauge measurement of thoracic circumference. Time-stamped inputs from such sensors or monitors may be provided to the monitor **14** and correlated to events in the plethysmographic waveform.

Based on patients associated with healthy fluid levels and/or hypovolemia, the monitor **14** may calculate an assessment of the patient's fluid condition, i.e., a risk of hypovolemia at step **94**, and provide a display or other indication to a clinician, such as a graphical, visual, or audio representation of the intravascular volume at step **96**. In one embodiment, a blood volume indicator may represent the presence of measurements, patterns, or trends in the plethysmographic waveform signal associated with normal intravascular blood volume and may include a numeric value or a green light indicated on a display or a short tone generated by a speaker associated with monitor **14**. Similarly, measurements, patterns, or trends in the plethysmographic waveform signal associated with hypovolemia may trigger an alarm, which may include one or more of an audio or visual alarm indication. Further, the monitor **14** may provide a confidence metric or indicator to provide information to the clinician relating to how many parameters may have been taken into account. For example, if the indicator is taken into account the presence of arrhythmia or arrhythmic beats, the confidence may be higher than if arrhythmia is not accounted for.

In one embodiment, the alarm may be triggered if the hypovolemia indicator is substantially greater than a predetermined value, substantially less than a predetermined value, or outside of a predetermined range. The predetermined values, thresholds, and/or ranges may be empirically determined based on clinical observations of patients with normal fluid status relative to hypovolemic patients. In a particular embodiment, a hypovolemia indicator may increase if particular trends in the plethysmographic waveform are detected. One such pattern may be a trending increase in a patient's stroke volume during exhalation. Another such trend may be a trending decrease in a patient's stroke volume during inhalation. These two trends in combination with one another may also be used to increase confidence for the hypovolemia indicator. Further, trending increases or decreases may be assessed over one or more

breathing cycles. For example, maintaining an increase or decrease in a trending value over multiple breath cycles may also increase confidence for the hypovolemia indicator. The trend values may be relative to previously assessed values in the patient or may be relative to empirically-determined cutoff values. In one embodiment, the monitor **14** may employ a truth table in which hypovolemia is indicated if both trends are present for a minimum time period. In another example, each incidence of a change in stroke volume outside of a normal threshold may be added to a counter, which may trigger an alarm when the counter reaches a minimum count.

In one embodiment, the disclosed techniques for monitoring hypovolemia may be used during a surgical procedure. In such an embodiment, a plurality of baseline measurements of the characteristics of the plethysmographic waveform may be recorded, for example over a five or ten minute period prior to the surgery. These baseline measurements may then be used to compute a baseline value of, for example, pulse amplitude during inhalation and exhalation. During and post-surgery, any trends of pulse amplitude (or any other suitable characteristic of the plethysmographic waveform) that are associated with hypovolemia may be assessed. As noted, a trend of increasing pulse amplitude during exhalation relative to a baseline or pre-surgery level may be indicative of hypovolemia. Because hypovolemia may be a precursor to hypovolemic shock, early detection may lead to timely fluid treatment and improved surgical outcomes.

FIG. 4 illustrates particular features or characteristics of a plethysmographic waveform **100** that may be assessed in determining if a patient is at risk of developing hypovolemia. An individual peak **102** may be characterized by its peak **104** and its trough **106**. In addition, the absolute distance **108** between the peak **104** and the trough **106** and the area under the curve **110** may be assessed. The plethysmographic waveform may also be assessed by its peak-to-peak variation **112**, trough-to-trough variation **114**, or a change in absolute distance **108** from beat-to-beat. In one embodiment, a pulse amplitude may be assessed as the absolute distance **108**. In addition, a time window **116** for assessing changes or trends may be selected according to the desired monitoring parameters. For example, an operator may increase the size of the window **116** from 10 seconds to 30 seconds to capture more data. The monitor **14** may provide rolling updates as the window **116** moves forward in time.

The plethysmographic waveform **100** is pulsatile and reflects hemodynamic properties, which may be used to determine a patient's blood oxygen saturation as well as heart rate. In addition, the plethysmographic waveform may be used to determine a patient's respiration rate. In one embodiment, the respiratory rate may be determined by analyzing a wavelet transformed plethysmographic signal. Information derived from the transform of the plethysmographic signal (i.e., in wavelet space) may be used to provide measurements of one or more physiological parameters.

The continuous wavelet transform of a signal $x(t)$ in accordance with the present disclosure may be defined as

$$T(a, b) = \frac{1}{\sqrt{a}} \int_{-\infty}^{+\infty} x(t) \psi^* \left(\frac{t-b}{a} \right) dt \quad (1)$$

where $\psi^*(t)$ is the complex conjugate of the wavelet function $\psi(t)$, a is the dilation parameter of the wavelet and

b is the location parameter of the wavelet. The transform given by equation (1) may be used to construct a representation of a signal on a transform surface. The transform may be regarded as a time-scale representation. Wavelets are composed of a range of frequencies, one of which may be denoted as the characteristic frequency of the wavelet, where the characteristic frequency associated with the wavelet is inversely proportional to the scale a . One example of a characteristic frequency is the dominant frequency. Each scale of a particular wavelet may have a different characteristic frequency. The underlying mathematical detail required for the implementation within a time-scale can be found, for example, in Paul S. Addison, *The Illustrated Wavelet Transform Handbook* (Taylor & Francis Group 2002), which is hereby incorporated by reference herein in its entirety.

The continuous wavelet transform decomposes a signal using wavelets, which are generally highly localized in time. The continuous wavelet transform may provide a higher resolution relative to discrete transforms, thus providing the ability to garner more information from signals than typical frequency transforms such as Fourier transforms (or any other spectral techniques) or discrete wavelet transforms. Continuous wavelet transforms allow for the use of a range of wavelets with scales spanning the scales of interest of a signal such that small scale signal components correlate well with the smaller scale wavelets and thus manifest at high energies at smaller scales in the transform. Likewise, large scale signal components correlate well with the larger scale wavelets and thus manifest at high energies at larger scales in the transform. Thus, components at different scales may be separated and extracted in the wavelet transform domain. Moreover, the use of a continuous range of wavelets in scale and time position allows for a higher resolution transform than is possible relative to discrete techniques.

In addition, transforms and operations that convert a signal or any other type of data into a spectral (i.e., frequency) domain necessarily create a series of frequency transform values in a two-dimensional coordinate system where the two dimensions may be frequency and, for example, amplitude. For example, any type of Fourier transform would generate such a two-dimensional spectrum. In contrast, wavelet transforms, such as continuous wavelet transforms, are required to be defined in a three-dimensional coordinate system and generate a surface with dimensions of time, scale and, for example, amplitude. Hence, operations performed in a spectral domain cannot be performed in the wavelet domain; instead the wavelet surface must be transformed into a spectrum (i.e., by performing an inverse wavelet transform to convert the wavelet surface into the time domain and then performing a spectral transform from the time domain). Conversely, operations performed in the wavelet domain cannot be performed in the spectral domain; instead a spectrum must first be transformed into a wavelet surface (i.e., by performing an inverse spectral transform to convert the spectral domain into the time domain and then performing a wavelet transform from the time domain). Nor does a cross-section of the three-dimensional wavelet surface along, for example, a particular point in time equate to a frequency spectrum upon which spectral-based techniques may be used. At least because wavelet space includes a time dimension, spectral techniques and wavelet techniques are not interchangeable. It will be understood that converting a system that relies on spectral domain processing to one that relies on wavelet space processing would require significant and fundamental modifications to the system in order to accommodate the wavelet space processing (e.g., to derive

a representative energy value for a signal or part of a signal requires integrating twice, across time and scale, in the wavelet domain while, conversely, one integration across frequency is required to derive a representative energy value from a spectral domain). As a further example, to reconstruct a temporal signal requires integrating twice, across time and scale, in the wavelet domain while, conversely, one integration across frequency is required to derive a temporal signal from a spectral domain. It is well known in the art that, in addition to or as an alternative to amplitude, parameters such as energy density, modulus, phase, among others may all be generated using such transforms and that these parameters have distinctly different contexts and meanings when defined in a two-dimensional frequency coordinate system rather than a three-dimensional wavelet coordinate system. For example, the phase of a Fourier system is calculated with respect to a single origin for all frequencies while the phase for a wavelet system is unfolded into two dimensions with respect to a wavelet's location (often in time) and scale.

The energy density function of the wavelet transform, the scalogram, is defined as

$$S(a,b)=|T(a,b)|^2 \quad (2)$$

where $||$ is the modulus operator. The scalogram may be resealed for useful purposes. One common resealing is defined as

$$S_R(a,b) = \frac{|T(a,b)|^2}{a} \quad (3)$$

and is useful for defining ridges in wavelet space when, for example, the Morlet wavelet is used. Ridges are defined as the locus of points of local maxima in the plane. Any reasonable definition of a ridge may be employed in the method. Also included as a definition of a ridge herein are paths displaced from the locus of the local maxima. A ridge associated with only the locus of points of local maxima in the plane is labeled a "maxima ridge".

For implementations involving fast numerical computation, the wavelet transform may be expressed as an approximation using Fourier transforms. Pursuant to the convolution theorem, because the wavelet transform is the cross-correlation of the signal with the wavelet function, the wavelet transform may be approximated in terms of an inverse FFT of the product of the Fourier transform of the signal and the Fourier transform of the wavelet for each required a scale and then multiplying the result by \sqrt{a} .

In the discussion of the techniques herein, the "scalogram" may be taken to include all suitable forms of resealing including, but not limited to, the original unsealed wavelet representation, linear resealing, any power of the modulus of the wavelet transform, or any other suitable rescaling. In addition, for purposes of clarity and conciseness, the term "scalogram" shall be taken to mean the wavelet transform, $T(a,b)$ itself, or any part thereof. For example, the real part of the wavelet transform, the imaginary part of the wavelet transform, the phase of the wavelet transform, any other suitable part of the wavelet transform, or any combination thereof is intended to be conveyed by the term "scalogram".

A scale, which may be interpreted as a representative temporal period, may be converted to a characteristic frequency of the wavelet function. The characteristic frequency associated with a wavelet of arbitrary a scale is given by

$$f = \frac{f_c}{a} \quad (4)$$

where f_c the characteristic frequency of the mother wavelet (i.e., at $a=1$), becomes a scaling constant and f is the representative or characteristic frequency for the wavelet at arbitrary scale a .

Any suitable wavelet function may be used in connection with the present disclosure. One of the most commonly used complex wavelets, the Morlet wavelet, is defined as:

$$\psi(t) = \pi^{-1/4} (e^{i2\pi f_0 t} - e^{-(2\pi f_0)^2/2}) e^{-t^2/2} \quad (5)$$

where f_0 is the central frequency of the mother wavelet. The second term in the parenthesis is known as the correction term, as it corrects for the non-zero mean of the complex sinusoid within the Gaussian window. In practice, it becomes negligible for values of $f_0 \gg 0$ and can be ignored, in which case, the Morlet wavelet can be written in a simpler form as

$$\psi(t) = \frac{1}{\pi^{1/4}} e^{i2\pi f_0 t} e^{-t^2/2} \quad (6)$$

This wavelet is a complex wave within a scaled Gaussian envelope. While both definitions of the Morlet wavelet are included herein, the function of equation (6) is not strictly a wavelet as it has a non-zero mean (i.e., the zero frequency term of its corresponding energy spectrum is non-zero). However, it will be recognized by those skilled in the art that equation (6) may be used in practice with $f_0 \gg 0$ with minimal error and is included (as well as other similar near wavelet functions) in the definition of a wavelet herein. A more detailed overview of the underlying wavelet theory, including the definition of a wavelet function, can be found in the general literature. Discussed herein is how wavelet transform features may be extracted from the wavelet decomposition of signals. For example, wavelet decomposition of plethysmographic signals may be used to provide clinically useful information within a medical device.

Pertinent repeating features in a signal give rise to a time-scale band in wavelet space or a resealed wavelet space. For example, the pulse component of a plethysmographic signal produces a dominant band in wavelet space at or around the pulse frequency. FIGS. 5A and B show two views of an illustrative scalogram 150 derived from a plethysmographic signal, according to an embodiment. The figures show an example of the band 152 caused by the pulse component in such a signal. The pulse band is located between the dashed lines in the plot of FIG. 5A. The band is formed from a series of dominant coalescing features across the scalogram. This can be clearly seen as a raised band across the transform surface in FIG. 5B located within the region of scales indicated by the arrow in the plot (corresponding to 60 beats per minute). The maximum of this band with respect to scale is the ridge. The locus of the ridge is shown as a black curve on top of the band in FIG. 5B. By employing a suitable resealing of the scalogram, such as that given in equation (3), the ridges found in wavelet space may be related to the instantaneous frequency of the signal. In this way, the pulse rate may be obtained from the plethysmographic signal. Instead of resealing the scalogram, a suitable predefined relationship between the

scale obtained from the ridge on the wavelet surface and the actual pulse rate may also be used to determine the pulse rate.

By mapping the time-scale coordinates of the pulse ridge onto the wavelet phase information gained through the wavelet transform, individual pulses may be captured. In this way, both times between individual pulses and the timing of components within each pulse may be monitored and used to detect heart beat anomalies, measure arterial system compliance, or perform any other suitable calculations or diagnostics. Alternative definitions of a ridge may be employed. Alternative relationships between the ridge and the pulse frequency of occurrence may be employed.

As discussed above, pertinent repeating features in the signal give rise to a time-scale band in wavelet space or a rescaled wavelet space. For a periodic signal, this band remains at a constant scale in the time-scale plane. For many real signals, especially biological signals, the band may be non-stationary; varying in scale, amplitude, or both over time. FIG. 5C shows an illustrative schematic of a wavelet transform of a signal containing two pertinent components leading to two bands in the transform space, according to an embodiment. These bands are labeled band A and band B on the three-dimensional schematic of the wavelet surface. In this embodiment, the band ridge is defined as the locus of the peak values of these bands with respect to scale. For purposes of discussion, it may be assumed that band B contains the signal information of interest. This will be referred to as the "primary band." In addition, it may be assumed that the system from which the signal originates, and from which the transform is subsequently derived, exhibits some form of coupling between the signal components in band A and band B. When noise or other erroneous features are present in the signal with similar spectral characteristics of the features of band B then the information within band B can become ambiguous (i.e., obscured, fragmented or missing). In this case, the ridge of band A may be followed in wavelet space and extracted either as an amplitude signal or a scale signal which will be referred to as the "ridge amplitude perturbation" (RAP) signal and the "ridge scale perturbation" (RSP) signal, respectively. The RAP and RSP signals may be extracted by projecting the ridge onto the time-amplitude or time-scale planes, respectively. The top plots of FIG. 5D show a schematic of the RAP and RSP signals associated with ridge A in FIG. 5C. Below these RAP and RSP signals are schematics of a further wavelet decomposition of these newly derived signals. This secondary wavelet decomposition allows for information in the region of band B in FIG. 5C to be made available as band C and band D. The ridges of bands C and D may serve as instantaneous time-scale characteristic measures of the signal components causing bands C and D. This technique, which will be referred to herein as secondary wavelet feature decoupling (SWFD), may allow information concerning the nature of the signal components associated with the underlying physical process causing the primary band B (FIG. 5C) to be extracted when band B itself is obscured in the presence of noise or other erroneous signal features.

In some instances, an inverse continuous wavelet transform may be desired, such as when modifications to a scalogram (or modifications to the coefficients of a transformed signal) have been made in order to, for example, remove artifacts. In one embodiment, there is an inverse continuous wavelet transform which allows the original signal to be recovered from its wavelet transform by integrating over all scales and locations, a and b:

$$x(t) = \frac{1}{C_g} \int_{-\infty}^{+\infty} \int_0^{\infty} T(a, b) \frac{1}{\sqrt{a}} \psi\left(\frac{t-b}{a}\right) \frac{dadb}{a^2} \quad (7)$$

which may also be written as:

$$x(t) = \frac{1}{C_g} \int_{-\infty}^{+\infty} \int_0^{\infty} T(a, b) \psi_{a,b}(t) \frac{dadb}{a^2} \quad (8)$$

where C_g is a scalar value known as the admissibility constant. It is wavelet type dependent and may be calculated from:

$$C_g = \int_0^{\infty} \frac{|\hat{\psi}(f)|^2}{f} df \quad (9)$$

A continuous wavelet transform may be used to obtain characteristic metrics of the respiratory components in a plethysmographic signal, which are, in turn, correlated with fluid responsiveness. In an embodiment, at least one suitable region, such as a ridge or a band of the scalogram may be analyzed to determine a level of fluid responsiveness in a patient. For example, the amplitude modulation of a pulse band ridge, such as pulse band ridge 154 in FIG. 5B, of the scalogram may be analyzed to determine information related to fluid responsiveness. Changes in the amplitude modulation of the plethysmographic signal correlate with changes in the level of fluid responsiveness.

The pulse band ridge manifests itself in the scalogram generated from the wavelet transform. The amplitude modulation of the plethysmographic signal may be taken from the amplitude modulation of pulse band ridge. By measuring the amplitude variation of pulse band ridge, the local pulse modulation of the plethysmographic signal may be extracted. Thus, the level of fluid responsiveness may be captured by the relative pulse amplitude modulation (RPAM), which correlates the amplitude modulation of the plethysmographic signal to the level of fluid responsiveness. Higher values of RPAM may indicate greater levels of fluid responsiveness of a patient. The RPAM may be approximated by the properly scaled ratio A/M, where A may be peak-to-peak amplitude modulation of the pulse band ridge and M may be a baseline signal such as mean value of the pulse band ridge. The ratio A/M may be expressed as a percentage.

Other ratios or mathematical expressions may be used to define the RPAM. For example, A may be the standard deviation of the amplitude modulation of pulse band ridge, the median absolute value of the amplitude modulation of pulse band ridge, any other suitable metric that expresses the amplitude modulation of pulse band ridge to define the RPAM, or any combination thereof. In addition, other characteristic baseline signals or features may be used for M when defining the RPAM. For example, M may be the lower bound of the signal interpolated from the troughs of pulse band ridge, the upper bound of the signal interpolated from the peaks of pulse band ridge, any other suitable characteristic baseline signal, or any combination thereof.

In an embodiment, the carrier wave amplitude of the plethysmographic signal may be analyzed to determine information related to fluid responsiveness. Changes in the amplitude of the carrier wave during a breathing cycle

correlate with changes in the level of fluid responsiveness. For example, the carrier wave amplitude may be extracted from the amplitude of the breathing band, such as breathing band **156** in FIG. **5B**, of the scalogram. The carrier wave may be indicative of venous return, and the breathing band manifests itself in the scalogram generated from the wavelet transform.

In another embodiment, the amplitude of the respiratory sinus arrhythmia (RSA) component of the plethysmographic signal may be analyzed to determine information related to fluid responsiveness. Changes in the amplitude of the RSA component correlate with changes in the level of fluid responsiveness. For example, the RSA component may be derived from the pulse band ridge, such as pulse band ridge **154** in FIG. **5(b)**, of the scalogram. Further, any band in the transform space indicative of pulse period may provide information for measuring RSA, such as a band at a scale above that of the pulse band, which, though of lower amplitude, may clearly indicate RSA. The amplitude modulation of the RSA may correlate with the amplitude modulation of the pulse band ridge. By measuring the amplitude variation of the pulse band ridge, the local modulation of the RSA waveform may be extracted. The RSA occurs naturally in the variation in the periodicity of the heart beat timing over the respiration cycle. The amplitude modulation of other components of the scalogram indicative of pulse period may be used to measure RSA in place of or in addition to the amplitude modulation of the pulse band ridge.

In other embodiments, a patient respiratory system **200** may operate under closed-loop control to provide to delivery of a fluid therapy (e.g., saline, blood, or other fluid) to a patient. FIG. **6** shows a system **200** under control of a primary controller **202** that may include a closed-loop controller that cooperates with a monitor **14** to control delivery of fluid therapy to the patient. The primary controller **202** may receive input from the monitor **14**. The controller may also receive input from a ventilator **204** or other device for determining a breathing cycle of a patient. Based on the plethysmographic waveform signal from the sensor **12**, the monitor **14** may determine a hypovolemia risk, such as a numeric indicator, based on one or more features of the plethysmographic waveform. The assessment of hypovolemia risk may be used by the controller **202** to control the fluid delivery device **206**. It should be understood that while FIG. **6** depicts the controller **202** and the monitor **14** as separate devices, the monitoring functions of monitor **14** and the controller functions of controller **202** may be incorporated into a single device in embodiments.

For example, the controller **202** may receive a request for increased fluid from the monitor **14** when the monitor determines that the patient is at risk for hypovolemia. The fluid delivery device **206** may include a peristaltic pump or other type of pump attached to an automatic intravenous line to achieve the desired delivery rate of the fluid to the patient. To control the rate at which the pump infuses the fluid, the speed of the pump may be controlled by the closed-loop controller **202**. The monitor **14** may continue to assess the patient's fluid condition during the fluid therapy. For example, if the plethysmographic waveform features show a change in trend or absolute value that indicates that the risk of hypovolemia is reduced, the controller **202** may slow or stop delivery of fluid from the fluid delivery device **206**. If the monitor **14** determines that the patient has not responded to fluid therapy, i.e., the analyzed plethysmographic wave-

form features are consistent with hypovolemia, the controller **202** may generate a signal notifying a caregiver of prolonged hypovolemia.

While the disclosure may be susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and will be described in detail herein. However, it should be understood that the disclosure is not intended to be limited to the particular forms disclosed. Rather, the disclosure is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the disclosure as defined by the following appended claims. Further, it should be understood that elements of the disclosed embodiments may be combined or exchanged with one another.

What is claimed is:

1. A method, comprising:

using a processor for:

receiving a plethysmographic waveform signal from a sensor applied to a patient;

determining one or more features of the plethysmographic waveform over time;

correlating in time the one or more features of the plethysmographic waveform to an exhalation portion and an inhalation portion of a respiratory cycle of the patient; and

determining an indication of the patient's blood volume based on a change in the one or more features of the plethysmographic waveform correlated in time with the respiratory cycle during the exhalation portion or the inhalation portion of the respiratory cycle, wherein the one or more features comprise a pulse amplitude, wherein the change comprises an increase in pulse amplitude relative to a baseline pulse amplitude value during the exhalation portion of the respiratory cycle that is greater than a range or threshold and a decrease in pulse amplitude relative to the baseline pulse amplitude value during the inhalation portion of the respiratory cycle that is greater than a second range or threshold, and wherein the indication comprises a risk of hypovolemia.

2. The method of claim 1, comprising analyzing the one or more features of the plethysmographic waveform over time after fluid therapy has been administered to the patient; and

determining if the patient's blood volume has changed after administration of fluid therapy.

3. The method of claim 1, wherein determining the one or more features of the plethysmographic waveform over time comprises extracting the one or more features from a wavelet transform of the plethysmographic waveform signal.

4. The method of claim 3, comprising eliminating arrhythmic beats from the plethysmographic waveform signal before determining the one or more features of the plethysmographic waveform over time.

5. The method of claim 3, wherein the one or more features of the plethysmographic waveform over time comprise a number of arrhythmic beats.

6. The method of claim 1, comprising determining a trend of the one or more features of the plethysmographic waveform during the inhalation portion or the exhalation portion of the respiratory cycle and determining the risk of hypovolemia based on the trend.

7. The method of claim 6, wherein determining the trend comprises determining the decrease in pulse amplitude during the inhalation portion of the respiratory cycle.

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8. The method of claim 6, wherein determining the trend comprises determining the increase in pulse amplitude during the exhalation portion of the respiratory cycle.

9. The method of claim 1, wherein a trend of the increase in pulse amplitude during the exhalation portion of the respiratory cycle and a trend of the decrease in pulse amplitude during the inhalation portion of the respiratory cycle are indicative of hypovolemia.

10. The method of claim 1, comprising displaying an indicator related to the risk of hypovolemia on a display.

11. The method of claim 1, wherein determining the one or more features of the plethysmographic waveform over time comprises determining the one or more features of the plethysmographic waveform over time in a time window.

12. The method of claim 11, wherein the time window advances with respect to time.

13. A method, comprising:
using a processor for:

- receiving a plethysmographic waveform signal from a sensor applied to a patient;
- determining one or more features of the plethysmographic waveform over time;
- correlating in time the one or more features of the plethysmographic waveform to an exhalation portion of a respiratory cycle of the patient;

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extracting one or more portions of the plethysmographic waveform correlated in time with the exhalation portion of the respiratory cycle;

determining a baseline value for the one or more features of the plethysmographic waveform over a period of time;

determining a trend of the one or more features of the plethysmographic waveform during the exhalation portion of the respiratory cycle, wherein the trend is indicative of a trending change in the one or more features of the plethysmographic waveform relative to the baseline value, wherein the one or more features comprise a pulse amplitude, and wherein the trending change comprises an increase in pulse amplitude relative to the baseline value during the exhalation portion of the respiratory cycle that is greater than a range or threshold; and

determining a risk of hypovolemia based on a comparison of the trend to the baseline value.

14. The method of claim 13, comprising triggering an alarm if the risk of hypovolemia is determined.

15. The method of claim 13, wherein determining the trend comprises determining an increased risk based on the trend of the increase in the pulse amplitude during the exhalation portion of the respiratory cycle.

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专利名称(译)	低血容量诊断技术		
公开(公告)号	US10092193	公开(公告)日	2018-10-09
申请号	US14/509302	申请日	2014-10-08
[标]申请(专利权)人(译)	柯惠有限合伙公司		
申请(专利权)人(译)	COVIDIEN LP		
当前申请(专利权)人(译)	COVIDIEN LP		
[标]发明人	MESTEK MICHAEL LISOGURSKI DANIEL		
发明人	MESTEK, MICHAEL LISOGURSKI, DANIEL		
IPC分类号	A61B6/00 A61B5/1455 A61B5/0205 A61B5/02 A61B5/026 A61B5/00 A61B5/029 A61B5/0295 A61B5/024 A61B5/08		
CPC分类号	A61B5/02042 A61B5/029 A61B5/0261 A61B5/0295 A61B5/14551 A61B5/4848 A61B5/7203 A61B5/726 A61B5/7246 A61B5/7275 A61B5/7278 A61B5/7282 A61B5/742 A61B5/746 A61B5/0205 A61B5/0816 A61B5/02405 A61B5/02427		
其他公开文献	US20150025336A1		
外部链接	Espacenet		

摘要(译)

本公开的实施例涉及用于基于患者呼吸循环期间的体积描记波形的一个或多个特征来确定血容量不足的风险，发作或存在的系统和方法。例如，相对于健康患者，血容量不足的患者可在吸气和呼气期间表现出脉搏振幅或每搏输出量的特征变化。此外，这些特征的趋势或模式可用于评估患者的流体状况。

