US009724025B1

(12) **United States Patent**
Kiani et al.

(10) **Patent No.: US 9,724,025 B1**
(45) **Date of Patent: Aug. 8, 2017**

(54) **ACTIVE-PULSE BLOOD ANALYSIS SYSTEM**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **14/328,694**

(22) Filed: **Jul. 10, 2014**

Related U.S. Application Data

(63) Continuation-in-part of application No. 14/153,393, filed on Jan. 13, 2014.

(60) Provisional application No. 61/752,976, filed on Jan. 16, 2013, provisional application No. 61/844,699, filed on Jul. 10, 2013.

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

(52) **U.S. Cl.**
CPC ***A61B 5/14552*** (2013.01); ***A61B 5/6826*** (2013.01); ***A61B 5/7207*** (2013.01)

(58) **Field of Classification Search**
CPC A61B 5/1455; A61B 5/14551; A61B 5/14552; A61B 5/7278; A61B 5/6843
See application file for complete search history.

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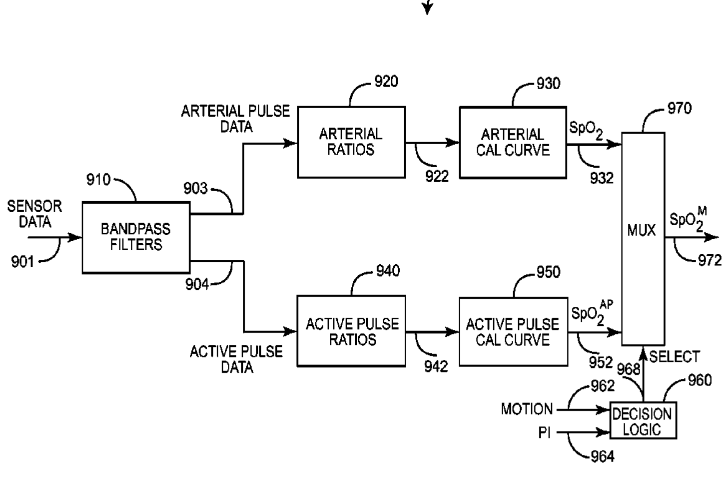
(57) **ABSTRACT**

An active-pulse blood analysis system has an optical sensor that illuminates a tissue site with multiple wavelengths of optical radiation and outputs sensor signals responsive to the optical radiation after attenuation by pulsatile blood flow within the tissue site. A monitor communicates with the sensor signals and is responsive to arterial pulses within a first bandwidth and active pulses within a second bandwidth so as to generate arterial pulse ratios and active pulse ratios according to the wavelengths. An arterial calibration curve relates the arterial pulse ratios to a first arterial oxygen saturation value and an active pulse calibration curve relates the active pulse ratios to a second arterial oxygen saturation value. Decision logic outputs one of the first and second arterial oxygen saturation values based upon perfusion and signal quality.

20 Claims, 13 Drawing Sheets



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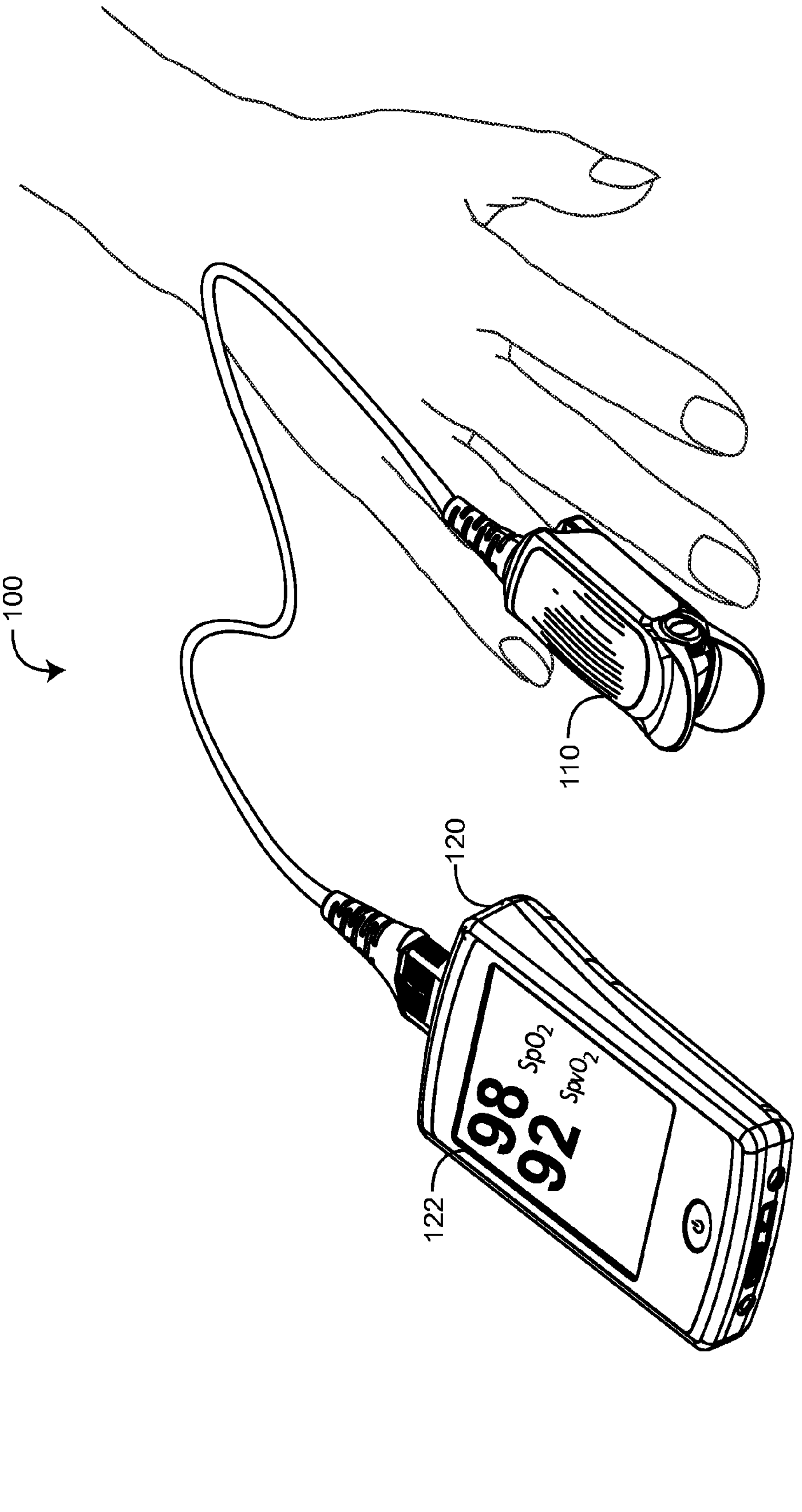

FIG. 1

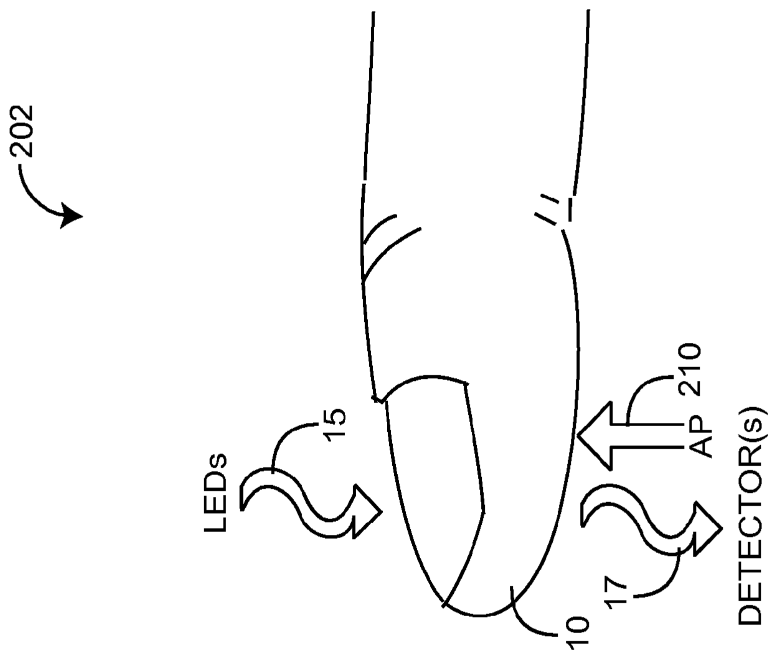

FIG. 2B

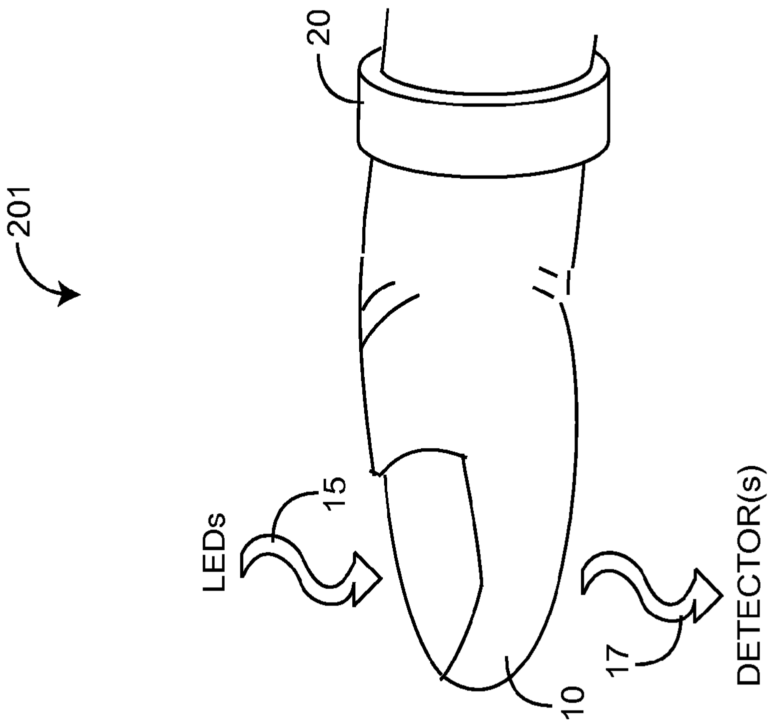

FIG. 2A (prior art)

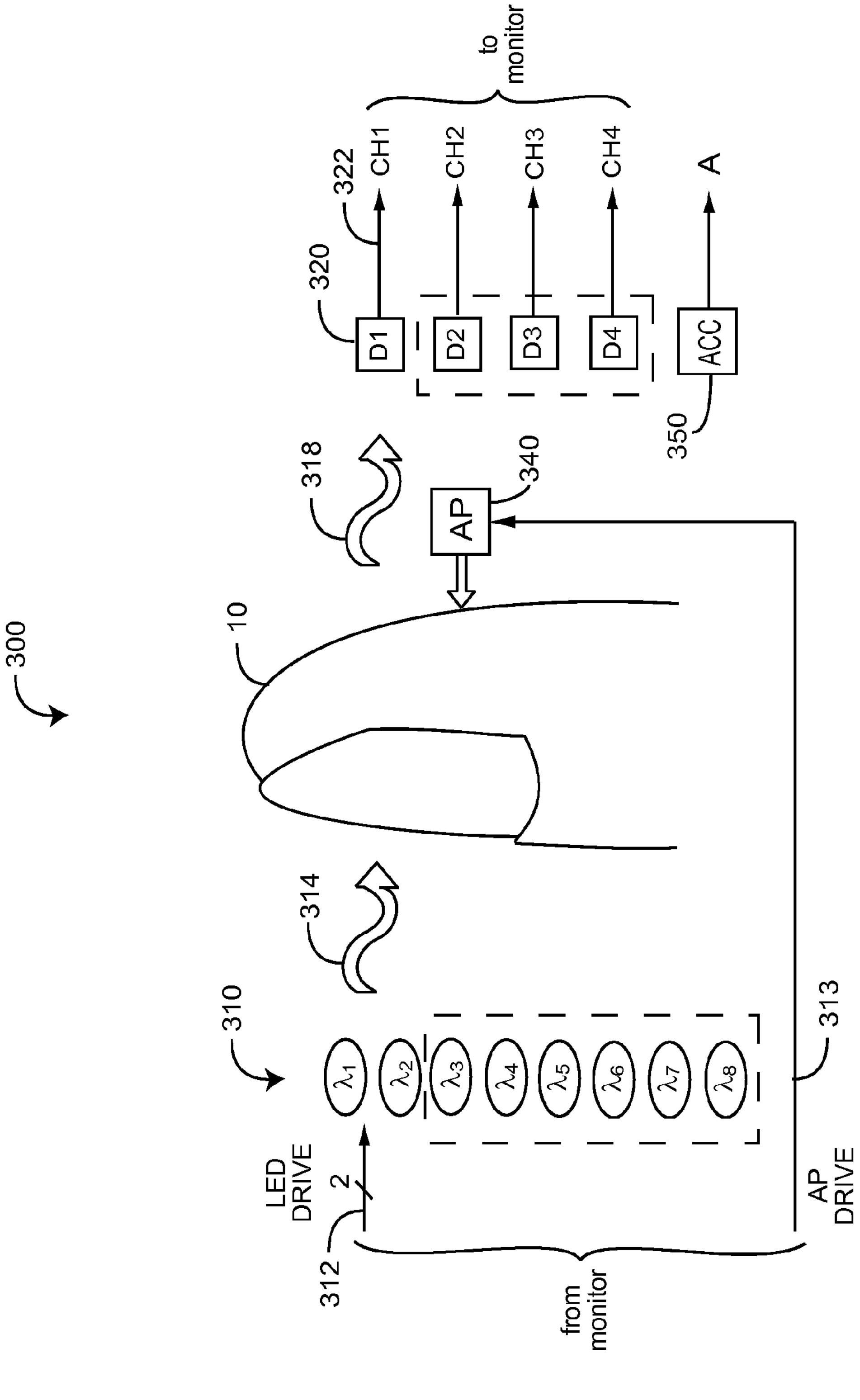
300
310
λ_1
λ_2
λ_3
λ_4
λ_5
λ_6
λ_7
λ_8
LED DRIVE
2
312
from monitor
313
AP DRIVE
314
10
318
AP
340
320
D1
D2
D3
D4
322
CH1
CH2
CH3
CH4
to monitor
ACC
350
A

FIG. 3

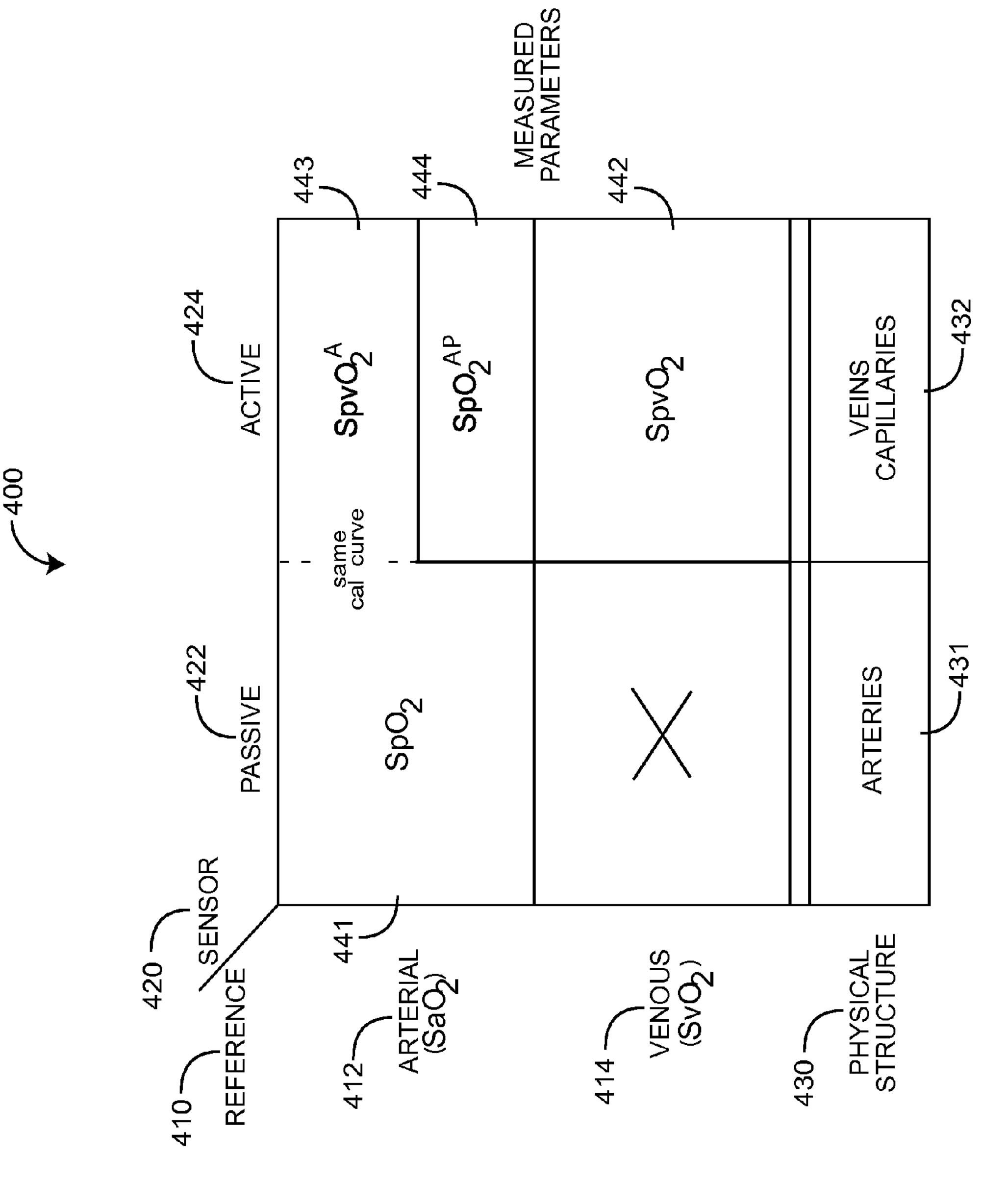
400
410
REFERENCE
420
SENSOR
422
PASSIVE
424
ACTIVE
412
ARTERIAL
(SaO_2)
414
VENOUS
(SvO_2)
430
PHYSICAL
STRUCTURE
441
SpO_2
same
cal curve
443
$SpvO_2^A$
444
SpO_2^{AP}
MEASURED
PARAMETERS
442
$SpvO_2$
431
ARTERIES
432
VEINS
CAPILLARIES

FIG. 4

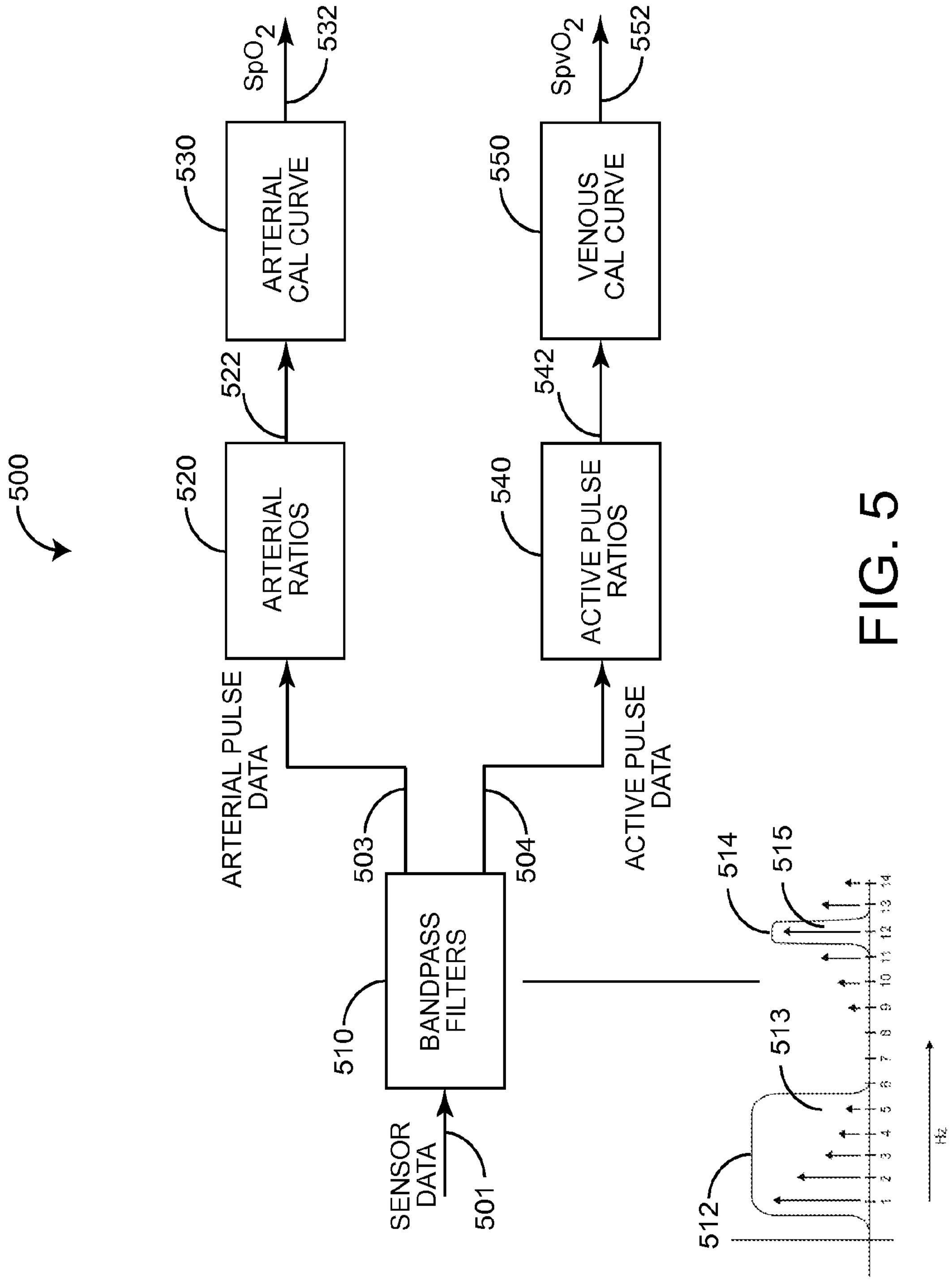
500
SENSOR DATA
501
BANDPASS FILTERS
510
503
504
ARTERIAL PULSE DATA
ACTIVE PULSE DATA
ARTERIAL RATIOS
520
522
ARTERIAL CAL CURVE
530
SpO_2
532
ACTIVE PULSE RATIOS
540
542
VENOUS CAL CURVE
550
$SpvO_2$
552
512
513
514
515
Hz

FIG. 5

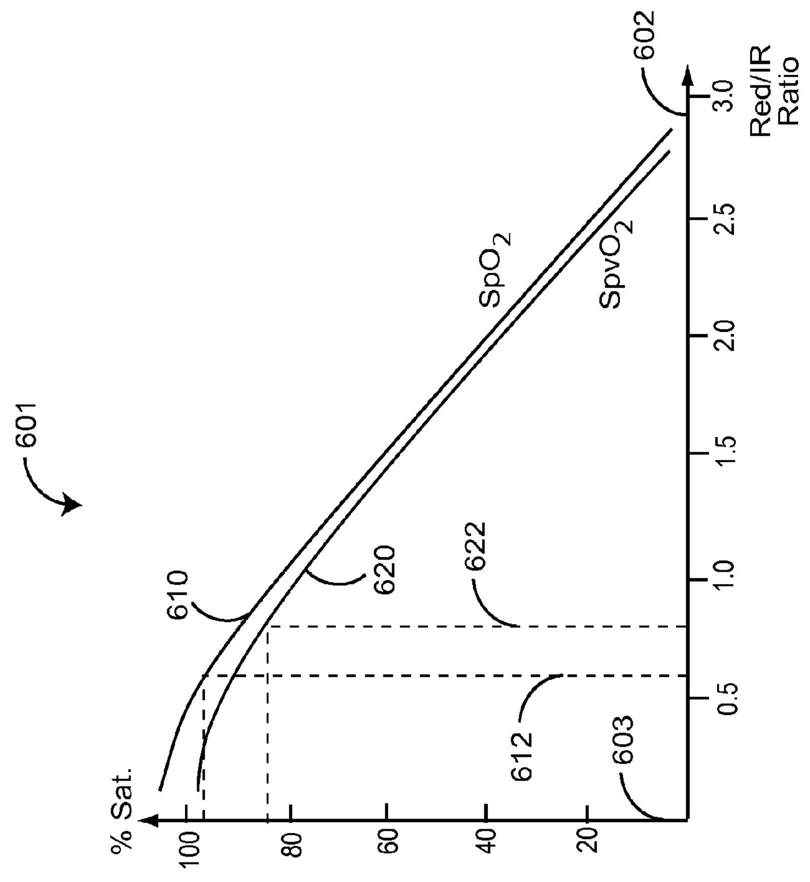
601
% Sat.
100
80
60
40
20
0.5
1.0
1.5
2.0
2.5
3.0
Red/IR Ratio
602
603
610
612
620
622
SpO2
SpvO2

FIG. 6A

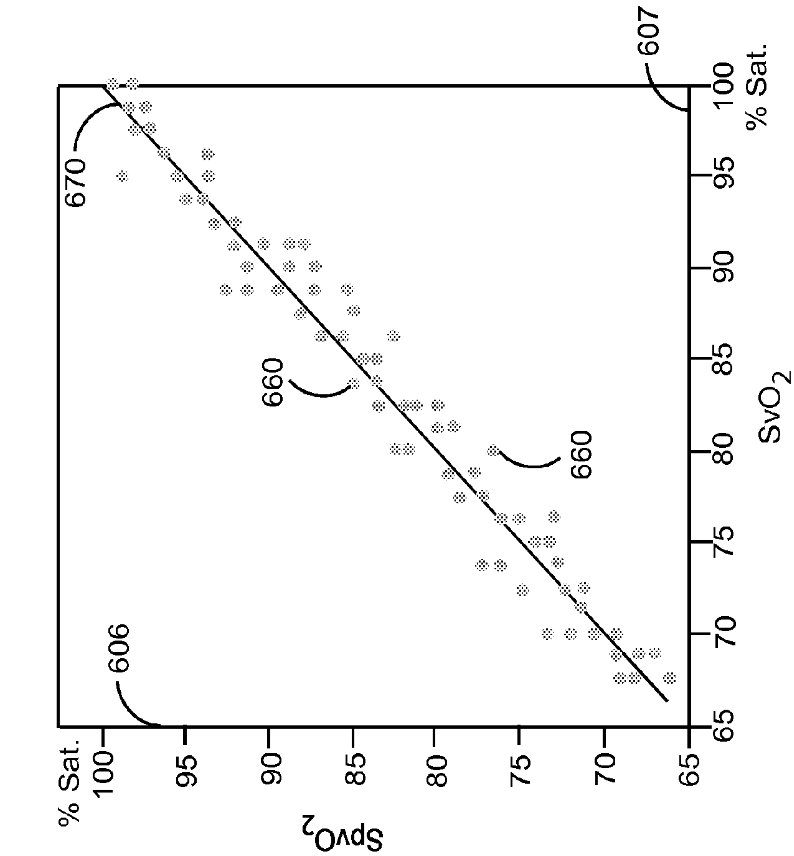
605
% Sat.
100
95
90
85
80
75
70
65
SpvO2
SvO2
606
607
660
660
670

FIG. 6B

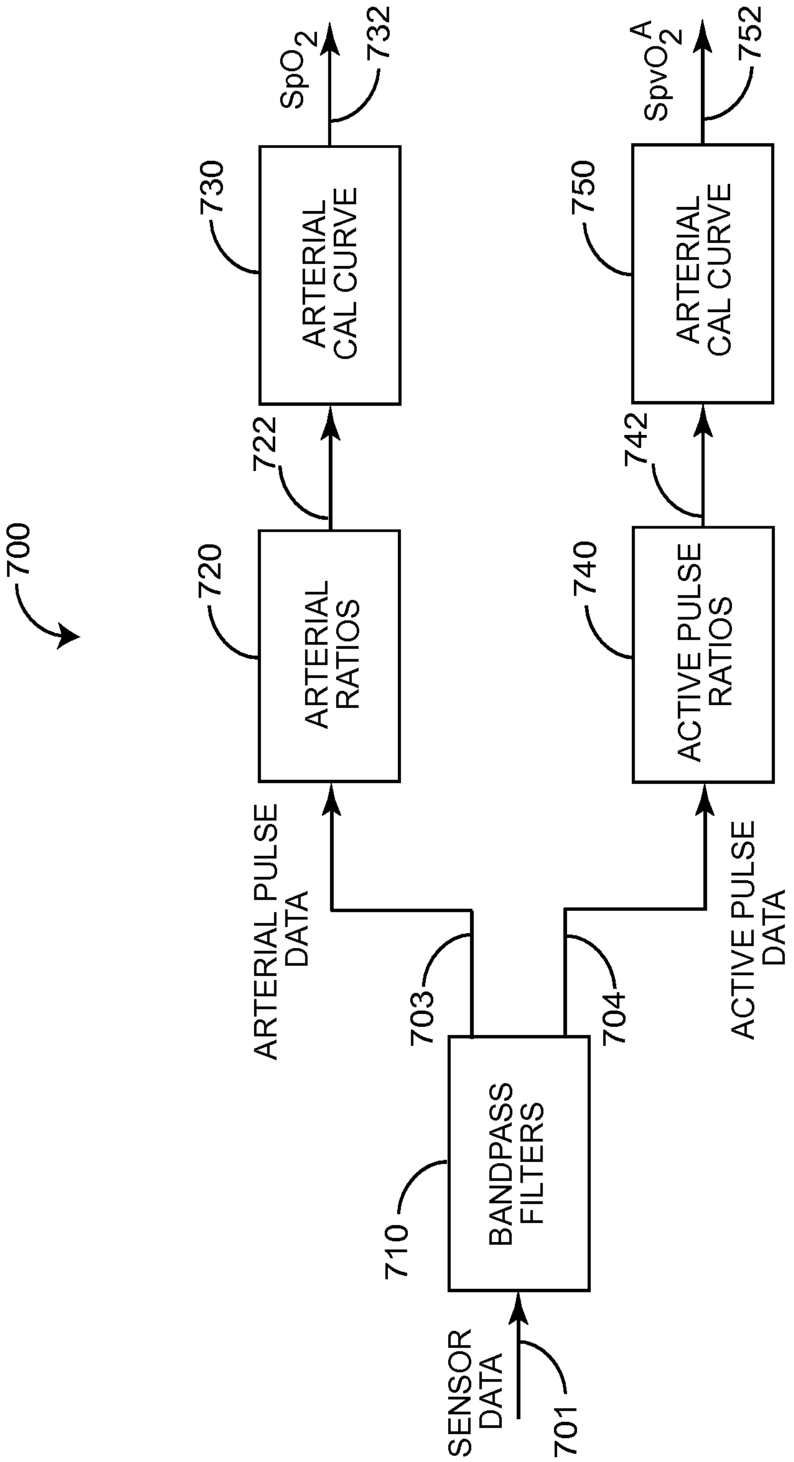
700
SENSOR DATA
701
BANDPASS FILTERS
710
703
704
ARTERIAL PULSE DATA
ACTIVE PULSE DATA
ARTERIAL RATIOS
720
722
ARTERIAL CAL CURVE
730
SpO2
732
ACTIVE PULSE RATIOS
740
742
ARTERIAL CAL CURVE
750
SpvO2A
752

FIG. 7

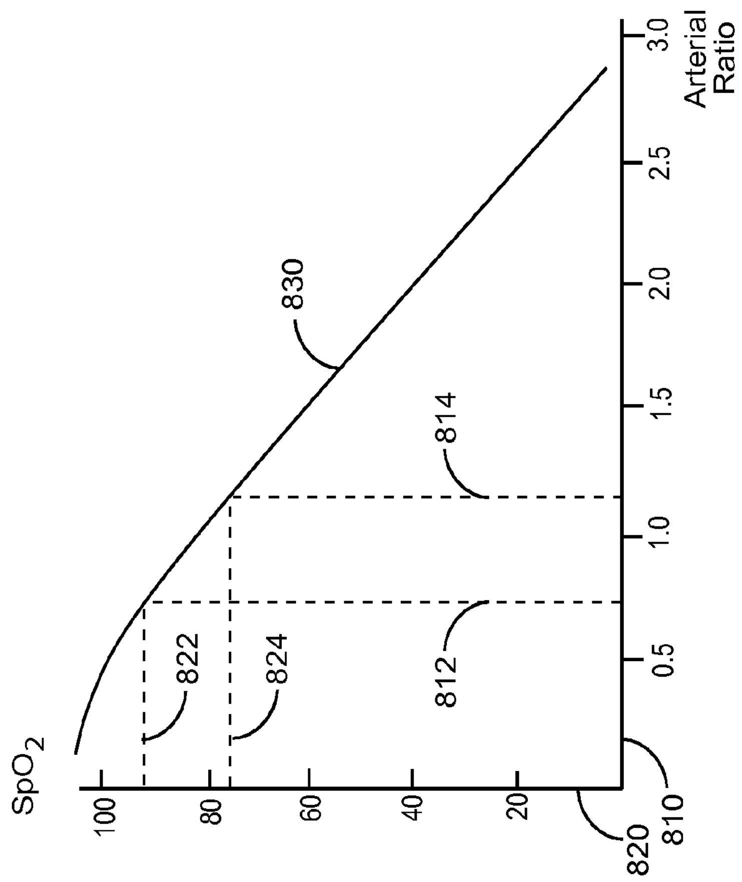
801
SpO_2
100
80
60
40
20
820
810
0.5
1.0
1.5
2.0
2.5
3.0
Arterial Ratio
822
824
812
814
830

FIG. 8A

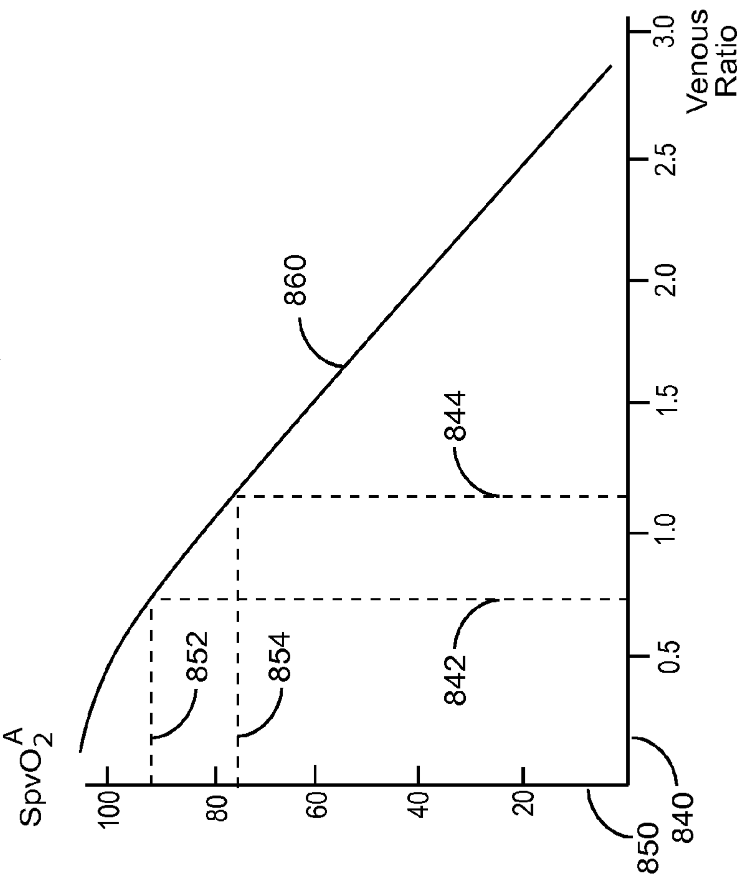
802
$SpvO_2^A$
100
80
60
40
20
850
840
0.5
1.0
1.5
2.0
2.5
3.0
Venous Ratio
852
854
842
844
860

FIG. 8B

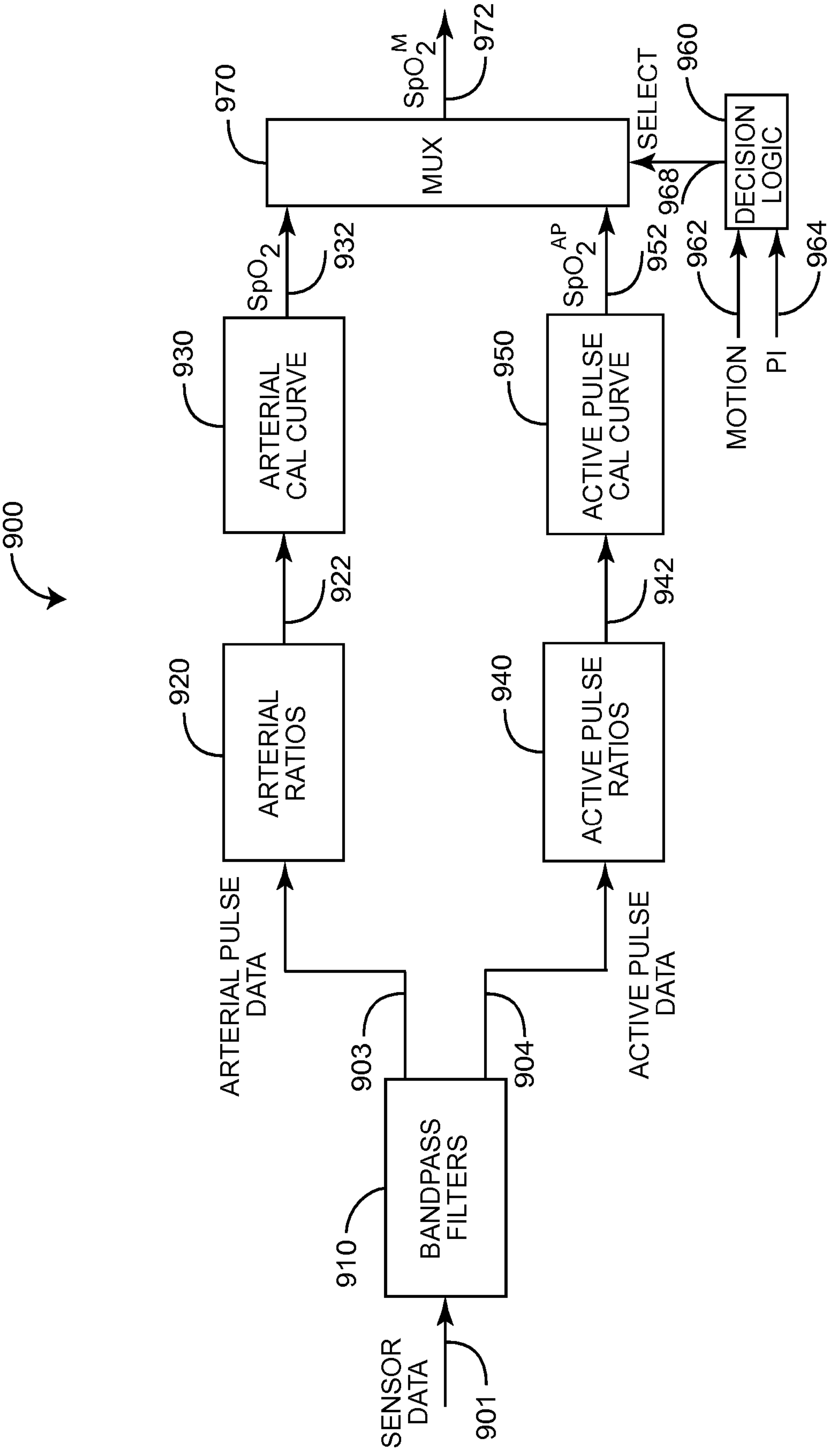
900
SENSOR DATA
901
BANDPASS FILTERS
910
903
904
ARTERIAL PULSE DATA
ACTIVE PULSE DATA
ARTERIAL RATIOS
920
922
ACTIVE PULSE RATIOS
940
942
ARTERIAL CAL CURVE
930
ACTIVE PULSE CAL CURVE
950
SpO2
932
SpO2AP
952
MUX
970
SpO2M
972
SELECT
968
DECISION LOGIC
960
MOTION
962
PI
964

FIG. 9

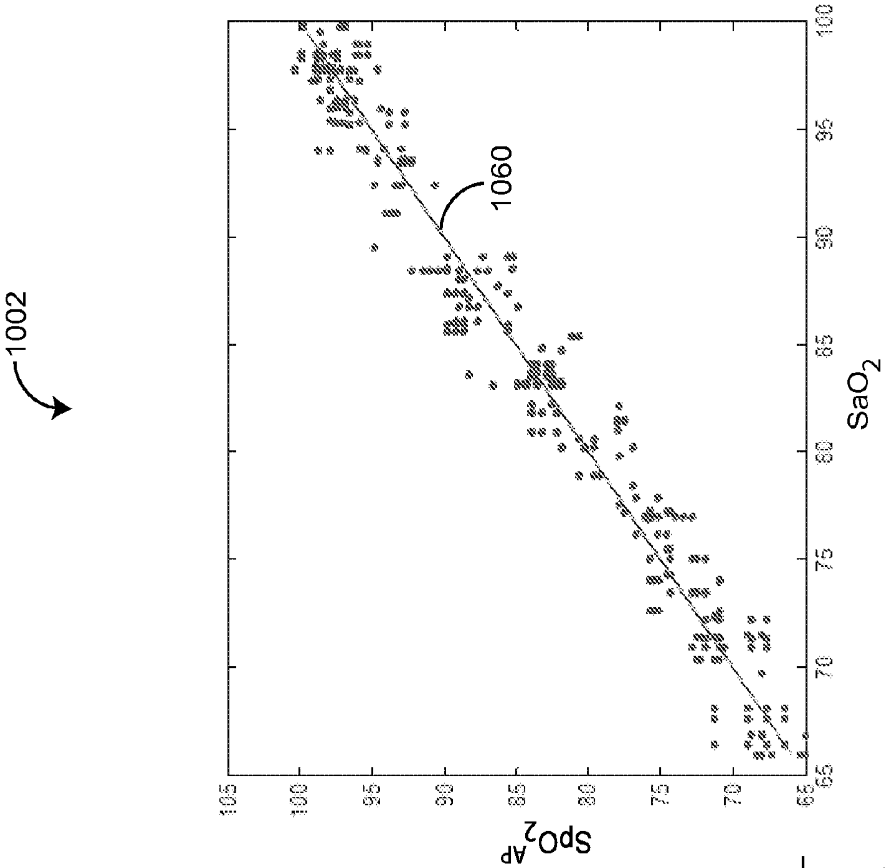

FIG. 10B

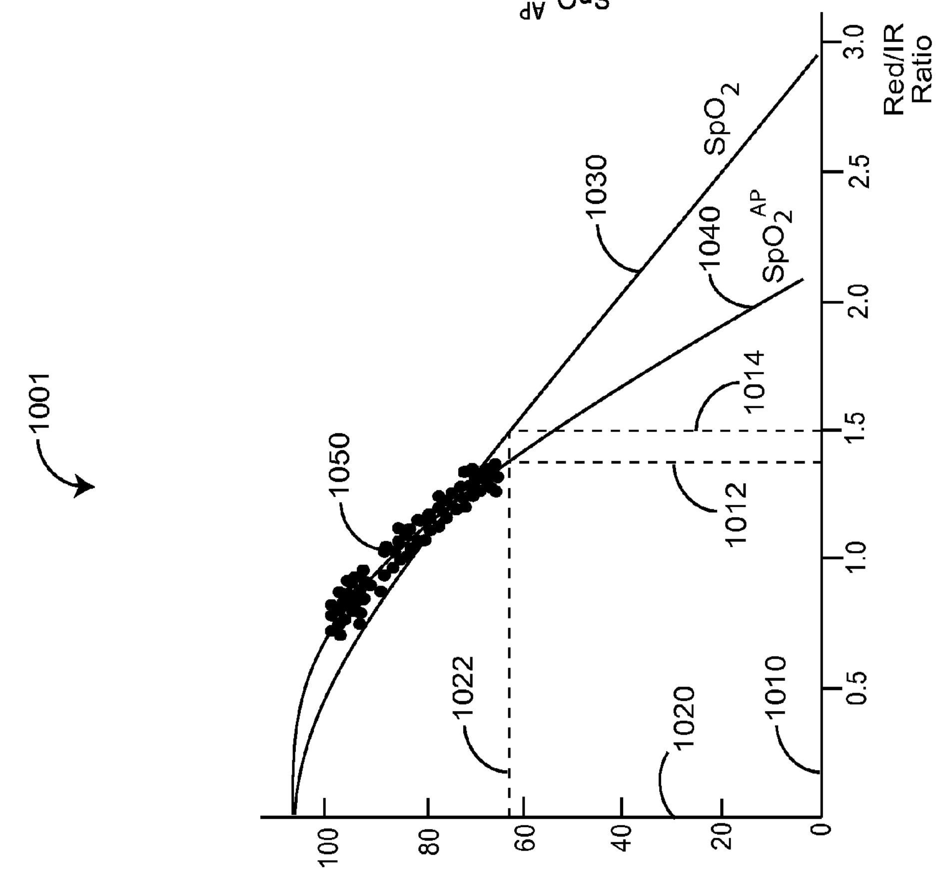

FIG. 10A

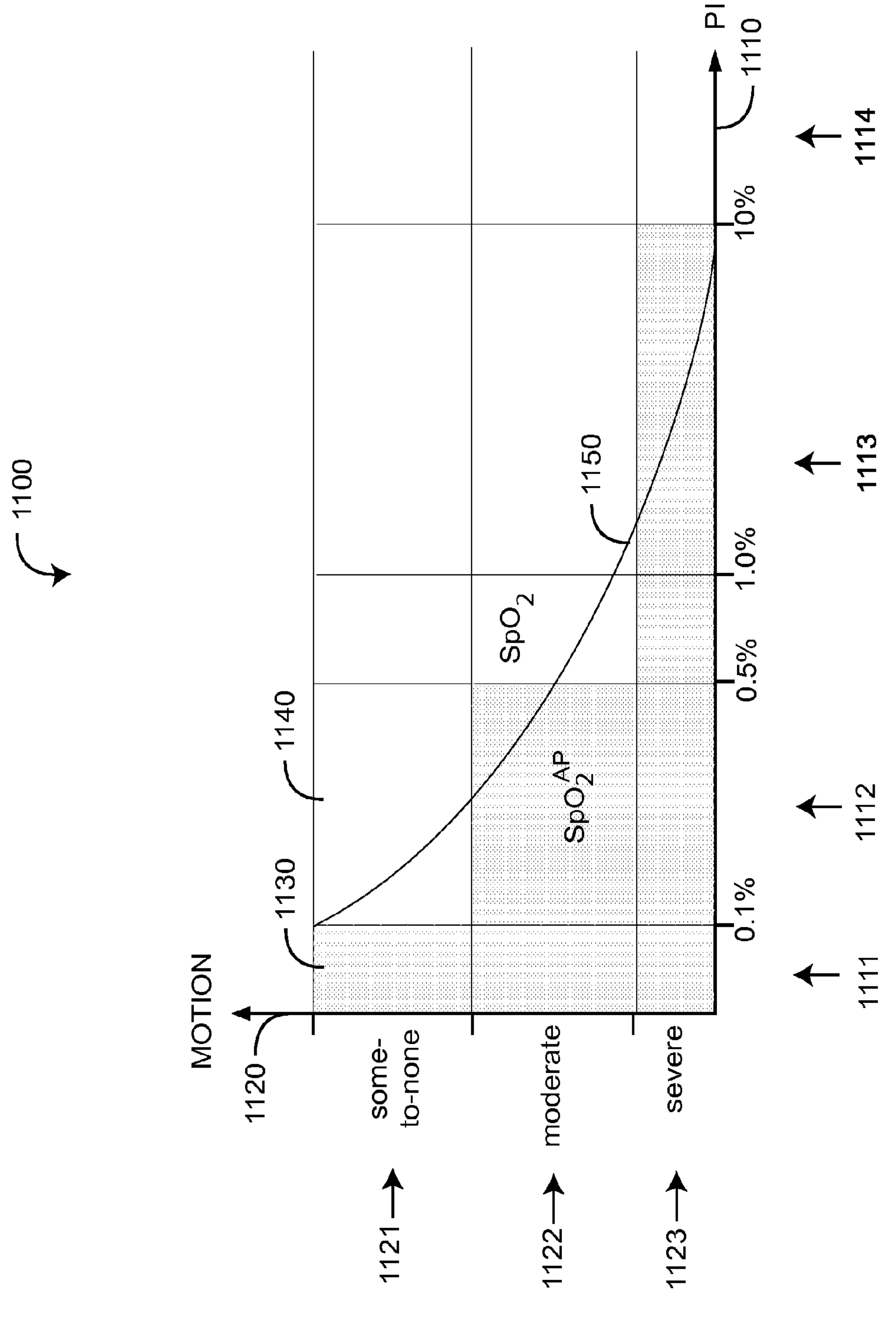
1100
MOTION
PI
1110
1111
1112
1113
1114
0.1%
0.5%
1.0%
10%
1120
1121
1122
1123
some-to-none
moderate
severe
1130
1140
1150
SpO_2
SpO_2^{AP}

FIG. 11

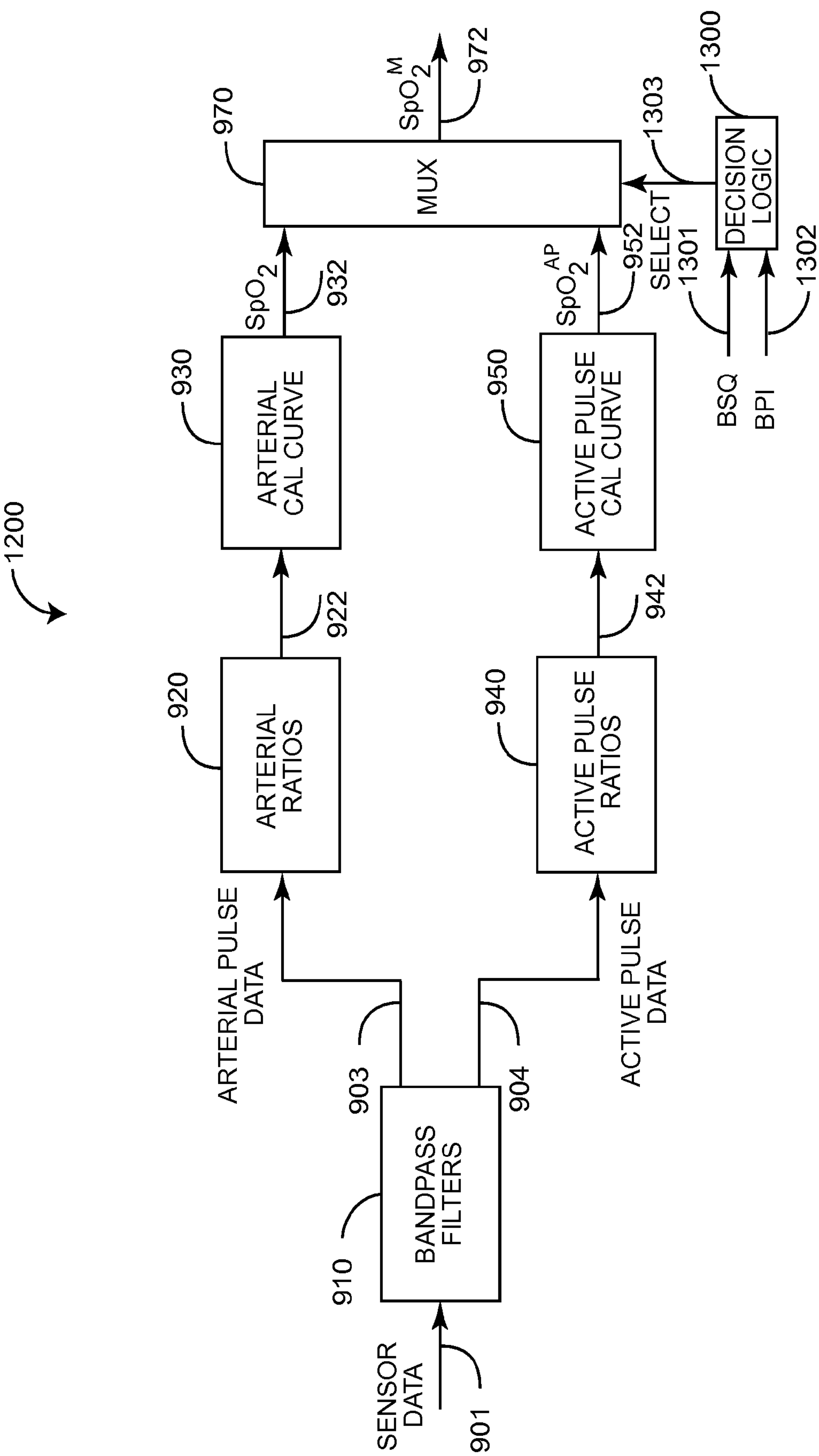
1200
SENSOR DATA
901
BANDPASS FILTERS
910
903
904
ARTERIAL PULSE DATA
ACTIVE PULSE DATA
ARTERIAL RATIOS
920
922
ACTIVE PULSE RATIOS
940
942
ARTERIAL CAL CURVE
930
932
ACTIVE PULSE CAL CURVE
950
952
SpO2
SpO2 AP
MUX
970
SpO2 M
972
SELECT
1303
DECISION LOGIC
1300
1301
1302
BSQ
BPI

FIG. 12

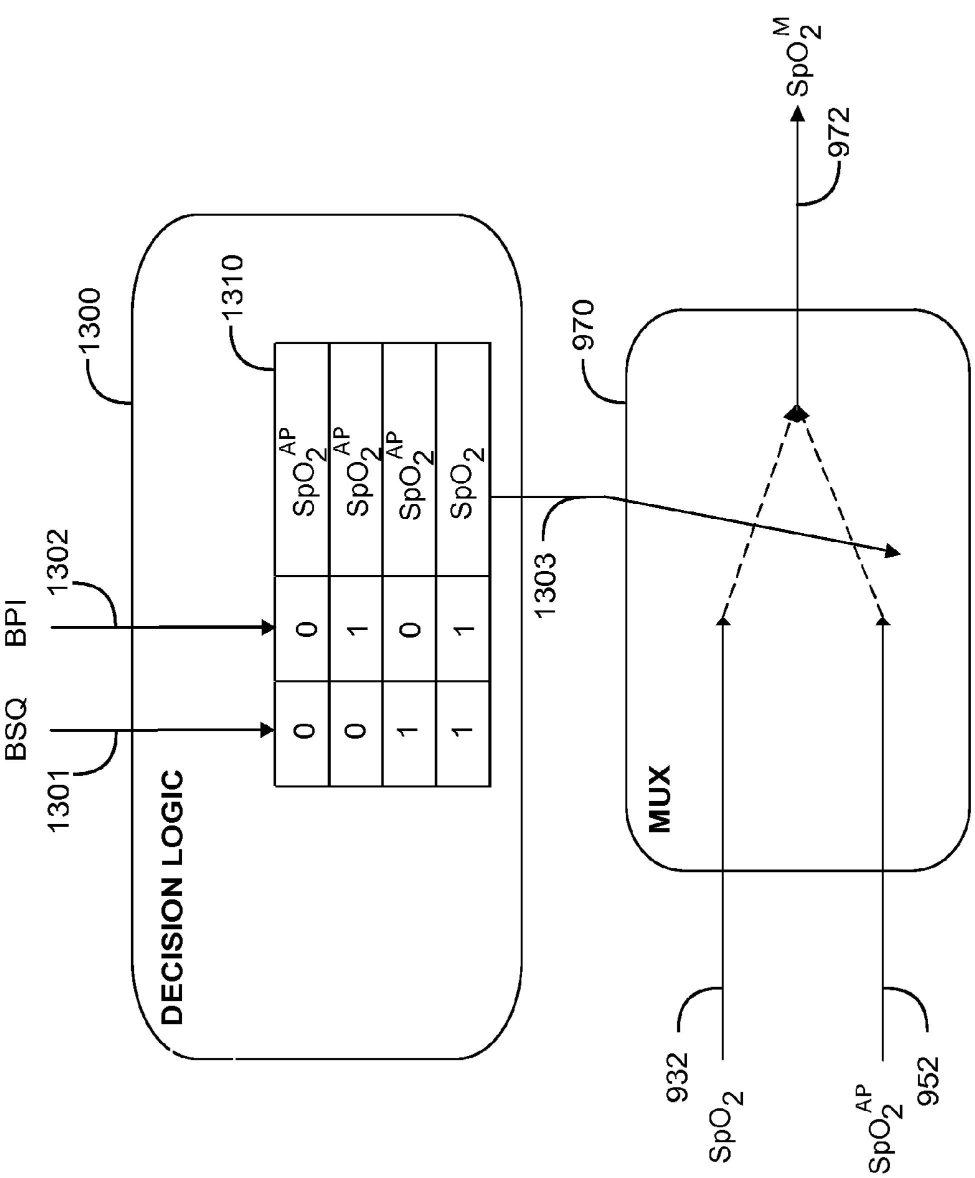
DECISION LOGIC
1300
1310
BSQ
BPI
1301
1302
1303
MUX
970
972
932
952
SpO2
SpO2 AP
SpO2 M
0 0 SpO2 AP
0 1 SpO2 AP
1 0 SpO2 AP
1 1 SpO2

FIG. 13

ACTIVE-PULSE BLOOD ANALYSIS SYSTEM

PRIORITY CLAIM AND REFERENCE TO RELATED APPLICATIONS

The present application is a continuation-in-part of U.S. patent application Ser. No. 14/153,393, filed Jan. 13, 2014, titled Active-Pulse Blood Analysis System, which claims priority benefit under 35 U.S.C. §119(e) to U.S. Provisional Patent Application Ser. No. 61/752,976, filed Jan. 16, 2013, titled Active-Pulse Blood Analysis System; the present application claims priority benefit under 35 U.S.C. §119(e) to U.S. Provisional Patent Application Ser. No. 61/844,699, filed Jul. 10, 2013, titled Active-Pulse Blood Analysis System; the above-referenced patent application and provisional patent applications are hereby incorporated in their entireties by reference herein.

BACKGROUND OF THE INVENTION

Noninvasive physiological monitoring systems for measuring constituents of circulating blood have advanced from basic pulse oximeters to monitors capable of measuring abnormal and total hemoglobin among other parameters. A basic pulse oximeter capable of measuring blood oxygen saturation typically includes an optical sensor, a monitor for processing sensor signals and displaying results and a cable electrically interconnecting the sensor and the monitor. A pulse oximetry sensor typically has a red wavelength light emitting diode (LED), an infrared (IR) wavelength LED and a photodiode detector. The LEDs and detector are attached to a patient tissue site, such as a finger. The cable transmits drive signals from the monitor to the LEDs, and the LEDs respond to the drive signals to transmit light into the tissue site. The detector generates a photoplethysmograph signal responsive to the emitted light after attenuation by pulsatile blood flow within the tissue site. The cable transmits the detector signal to the monitor, which processes the signal to provide a numerical readout of oxygen saturation (SpO_2) and pulse rate, along with an audible pulse indication of the person's pulse. The photoplethysmograph waveform may also be displayed.

SUMMARY OF THE INVENTION

Conventional pulse oximetry assumes that arterial blood is the only pulsatile blood flow in the measurement site. During patient motion, venous blood also moves, which causes errors in conventional pulse oximetry. Advanced pulse oximetry processes the venous blood signal so as to report true arterial oxygen saturation and pulse rate under conditions of patient movement. Advanced pulse oximetry also functions under conditions of low perfusion (small signal amplitude), intense ambient light (artificial or sunlight) and electrosurgical instrument interference, which are scenarios where conventional pulse oximetry tends to fail.

Advanced pulse oximetry is described in at least U.S. Pat. Nos. 6,770,028; 6,658,276; 6,157,850; 6,002,952; 5,769,785 and 5,758,644, which are assigned to Masimo Corporation ("Masimo") of Irvine, Calif. and are incorporated in their entireties by reference herein. Corresponding low noise optical sensors are disclosed in at least U.S. Pat. Nos. 6,985,764; 6,813,511; 6,792,300; 6,256,523; 6,088,607; 5,782,757 and 5,638,818, which are also assigned to Masimo and are also incorporated in their entireties by reference herein. Advanced pulse oximetry systems including Masimo SET® low noise optical sensors and read through motion pulse oximetry monitors for measuring SpO_2, pulse rate (PR) and perfusion index (PI) are available from Masimo. Optical sensors include any of Masimo LNOP®, LNCS®, SofTouch™ and Blue™ adhesive or reusable sensors. Pulse oximetry monitors include any of Masimo Rad-8®, Rad-5®, Rad®-5v or SatShare® monitors.

Advanced blood parameter measurement systems are described in at least U.S. Pat. No. 7,647,083, filed Mar. 1, 2006, titled Multiple Wavelength Sensor Equalization; U.S. Pat. No. 7,729,733, filed Mar. 1, 2006, titled Configurable Physiological Measurement System; U.S. Pat. Pub. No. 2006/0211925, filed Mar. 1, 2006, titled Physiological Parameter Confidence Measure and U.S. Pat. Pub. No. 2006/0238358, filed Mar. 1, 2006, titled Noninvasive Multi-Parameter Patient Monitor, all assigned to Cercacor Laboratories, Inc., Irvine, Calif. ("Cercacor") and all incorporated in their entireties by reference herein. An advanced parameter measurement system that includes acoustic monitoring is described in U.S. Pat. Pub. No. 2010/0274099, filed Dec. 21, 2009, titled Acoustic Sensor Assembly, assigned to Masimo and incorporated in its entirety by reference herein.

Advanced blood parameter measurement systems include Masimo Rainbow® SET, which provides measurements in addition to SpO_2, such as total hemoglobin (SpHb™), oxygen content (SpOC™), methemoglobin (SpMet®), carboxyhemoglobin (SpCO®) and PVI®. Advanced blood parameter sensors include Masimo Rainbow® adhesive, ReSposable™ and reusable sensors. Advanced blood parameter monitors include Masimo Radical-7™, Rad-87™ and Rad-57™ monitors, all available from Masimo. Advanced parameter measurement systems may also include acoustic monitoring such as acoustic respiration rate (RRa™) using a Rainbow Acoustic Sensor™ and Rad-87™ monitor, available from Masimo. Such advanced pulse oximeters, low noise sensors and advanced parameter systems have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios.

One aspect of an active-pulse blood analysis system has an optical sensor that illuminates a tissue site with multiple wavelengths of optical radiation and that outputs sensor signals responsive to the optical radiation after attenuation by pulsatile blood flow within the tissue site. A monitor communicates with the sensor signals and is responsive to arterial pulses within a first bandwidth and active pulses within a second bandwidth so as to generate arterial pulse ratios and active pulse ratios according to the wavelengths. An arterial calibration curve relates the arterial pulse ratios to a first arterial oxygen saturation, and a first active pulse calibration curve relates the active pulse ratios to a first venous oxygen saturation.

In various embodiments, the arterial calibration curve relates the active pulse ratios to a second venous oxygen saturation. A second active pulse calibration curve relates the active pulse ratios to a second arterial oxygen saturation. A multiplexer selects from the first arterial oxygen saturation and the second arterial oxygen saturation so as to output a third arterial oxygen saturation. A decision logic determines the third arterial oxygen saturation. The decision logic receives a motion input and a perfusion input. The decision logic selects the third arterial oxygen saturation when perfusion is in a lower range of perfusion values and motion is in a higher range of motion values.

Another aspect of an active-pulse blood analysis system inputs optical sensor data, filters the sensor data into arterial pulse data at a lower range of frequencies and active pulse data at a higher range of frequencies, calculates arterial pulse ratios from the arterial pulse data and active pulse ratios from the active pulse data, applies an arterial calibration curve to the arterial pulse ratios so as to generate an SpO_2 parameter and applies a second calibration curve so as to generate a second oxygen saturation parameter. In various embodiments, the second calibration curve is a venous calibration curve and the second oxygen saturation parameter is $SpvO_2$, the second calibration curve is an arterial calibration curve and the second oxygen saturation parameter is $SpvO_2^{A}$, the second calibration curve relates active pulse ratio data to SaO_2 values so as to define an arterial saturation parameter SpO_2^{AP}.

In various other embodiments, one of the SpO_2 parameter and the SpO_2^{AP} are output according to a motion and perfusion selection criterion. The selection criterion is based upon motion zones and perfusion zones. The selection criterion is based upon a boundary between a first area of relatively high perfusion combined with relatively little motion and a second area of relatively low perfusion combined with relatively large motion.

A further aspect of an active-pulse blood analysis system is an optical sensor for transmitting multiple wavelengths of light into a tissue site and detecting the transmitted light after attenuation by arterial blood flow and active pulse blood flow within the tissue site so as to generate plethysmograph data. A filter separates the detected plethysmograph data into arterial pulse data and active pulse data. A processor calculates arterial ratios from the arterial pulse data and active pulse ratios from the active pulse data. An arterial calibration curve relates the arterial pulse ratios to SpO_2 values, and a venous calibration curve relates the active pulse ratios to $SpvO_2$ values. In various embodiments, an arterial cal curve relates the active pulse ratios to $SpvO_2^{A}$ values, an active pulse cal curve relates the active pulse ratios to SpO_2^{AP} values, a multiplexor relates SpO_2 and SpO_2^{AP} values to SpO_2^{M} values, a decision logic selects SpO_2 and SpO_2^{AP} to output as SpO_2^{M} according to a combination of motion and perfusion, and a zone specifies the decision logic according to motion and perfusion.

Yet another aspect of an active-pulse blood analysis system is an optical sensor that illuminates a tissue site with multiple wavelengths of optical radiation and that outputs sensor signals responsive to the optical radiation after attenuation by pulsatile blood flow within the tissue site. A monitor communicates with the sensor signals and is responsive to arterial pulses within a first bandwidth and active pulses within a second bandwidth so as to generate arterial pulse ratios and active pulse ratios according to the wavelengths. An arterial calibration curve relates the arterial pulse ratios to a first arterial oxygen saturation (SpO_2), and an active pulse calibration curve relates the active pulse ratios to a second arterial oxygen saturation (SpO_2^{AP}).

In various embodiments, a multiplexer has a third arterial oxygen saturation (SpO_2^{M}) output selected from one of the first arterial oxygen saturation and the second arterial oxygen saturation. A decision logic determines the third arterial oxygen saturation. Signal quality and perfusion are input to the decision logic. The decision logic selects the second arterial oxygen saturation when perfusion is in a lower range of perfusion values and signal quality is in a lower range of signal quality values. The decision logic inputs a Boolean perfusion value (BPI) and a Boolean signal quality value (BSQ).

An additional aspect of an active-pulse blood analysis system is inputting optical sensor data, filtering the optical sensor data into arterial pulse data at a lower range of frequencies and active pulse data at a higher range of frequencies, calculating arterial pulse ratios from the arterial pulse data. Active pulse ratios are calculated from the active pulse data. An arterial calibration curve is applied to the arterial pulse ratios so as to generate an SpO_2 parameter indicative of arterial oxygen saturation determined from an arterial pulse. An active pulse calibration curve is applied to the active pulse ratios so as to generate an SpO_2^{AP} parameter indicative of arterial oxygen saturation determined from an active pulse.

In various embodiments, active-pulse blood analysis comprises multiplexing the SpO_2 parameter and the SpO_2^{AP} parameter so as to generate an SpO_2^{M} output parameter indicative of an arterial oxygen saturation measurement tolerate to at least one of motion, low perfusion and low signal quality. Multiplexing comprises selecting one of the SpO_2 parameter and the SpO_2^{AP} parameter as the SpO_2^{M} output parameter according to a combination of a signal quality input and a perfusion index input. Selecting comprises outputting SpO_2^{AP} as the SpO_2^{M} output parameter when the combination of signal quality and perfusion are below a threshold boundary. Selecting comprises outputting SpO_2 as the SpO_2^{M} output parameter when the combination of signal quality and perfusion are above the threshold boundary. The threshold boundary is specified by discrete zones of signal quality and perfusion. The threshold boundary is specified by a continuous curve that is a function of signal quality and perfusion.

Further aspects of an active-pulse blood analysis apparatus comprise an optical sensor means for transmitting multiple wavelengths of light into a tissue site and detecting the transmitted light after attenuation by arterial blood flow and active pulsed blood flow within the tissue site so as to generate plethysmograph data. A filter means separates the detected plethysmograph data into arterial pulse data and active pulse data. A processor means calculates arterial ratios from the arterial pulse data and active pulse ratios from the active pulse data. An arterial calibration curve means relates the arterial pulse ratios to oxygen saturation values (SpO_2). An active pulse calibration curve means relates the active pulse ratios to active pulse oxygen saturation values (SpO_2^{AP}).

In various embodiments, the active-pulse blood analysis apparatus further comprising a multiplexer means for combining the oxygen saturation values and active pulse oxygen saturation values into multiplexed oxygen saturation values (SpO_2^{M}). A decision logic means selects from SpO_2 and SpO_2^{AP} as the SpO_2^{M} output. The decision logic means is responsive to at least two of motion, perfusion and signal quality inputs.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an illustration of an active-pulse blood analysis system for concurrently determining a person's arterial oxygen saturation (SpO_2) and venous oxygen saturation ($SpvO_2$);

FIGS. **2**A-B are illustrations of active-pulse blood analysis techniques;

FIG. **2**A illustrates a prior art occlusive, off-site active-pulse technique for temporally-spaced (non-concurrent) arterial and venous oxygen saturation measurements;

FIG. **2**B illustrates a non-occlusive, on-site active-pulse technique for concurrent SpO_2 and $SpvO_2$ measurements;

FIG. **3** is an illustration of an active-pulse blood analysis sensor that allows concurrent arterial-pulse and active-pulse blood analysis;

FIG. **4** is a relational chart for various active-pulse blood analysis parameters;

FIG. **5** is a block diagram of active-pulse blood analysis for determining SpO_2 using an arterial cal curve and $SpvO_2$ using a venous cal curve;

FIGS. **6**A-B are graphs of active-pulse blood analysis calibration curves (cal curves);

FIG. **6**A is a graph of two-dimensional SpO_2 and $SpvO_2$ cal curves;

FIG. **6**B is a graph of a multi-dimensional $SpvO_2$ cal curve;

FIG. **7** is a block diagram of active-pulse blood analysis for determining SpO_2 and $SpvO_2^A$ using the same arterial calibration curve;

FIGS. **8**A-B are graphs of active-pulse blood analysis cal curves for calculating both SpO_2 and $SpvO_2^A$;

FIG. **8**A is a graph of an arterial cal curve for calculating SpO_2; and

FIG. **8**B is a graph of an identical arterial cal curve for calculating $SpvO_2^A$;

FIG. **9** is a block diagram of active-pulse blood analysis for determining SpO_2 and SpO_2^{AP} and for combining SpO_2 and SpO_2^{AP} based upon motion and perfusion index (PI) parameters so as to calculate a motion and low perfusion tolerant measure of arterial oxygen saturation (SpO_2^M);

FIGS. **10**A-B are graphs of active-pulse blood analysis cal curves for calculating SpO_2 and SpO_2^{AP};

FIG. **10**A is a two-dimensional SpO_2^{AP} cal curve shown in relation to a SpO_2 cal curve; and

FIG. **10**B is a multidimensional SpO_2^{AP} cal curve;

FIG. **11** is a motion versus perfusion decision graph for combining SpO_2 and SpO_2^{AP} so as to calculate a motion and low perfusion tolerant measure of arterial oxygen saturation (SpO_2^M);

FIG. **12** is a block diagram of active-pulse blood analysis for determining SpO_2 and SpO_2^{AP} and for combining SpO_2 and SpO_2^{AP} based upon BSQ (Boolean signal quality) and BPI (Boolean perfusion index) parameters so as to calculate a motion and low perfusion tolerant measure of arterial oxygen saturation (SpO_2^M); and

FIG. **13** is a block diagram of a decision logic embodiment for combining SpO_2 and SpO_2^{AP} based upon BSQ and BPI so as to calculate SpO_2^M.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. **1** illustrates an active-pulse blood analysis system **100** for concurrently determining a person's arterial oxygen saturation (SpO_2) and venous oxygen saturation ($SpvO_2$). The active-pulse blood analysis system **100** has an optical sensor **110** that transmits optical radiation at two or more wavelengths including red and infrared wavelengths. The active-pulse blood analysis system **100** also has a monitor **120** that determines the relative concentrations of blood constituents flowing in optically-probed pulsatile arteries and actively-pulsed capillaries and veins. A monitor display **122** is configured to readout concurrently measured oxygen saturation values including SpO_2, $SpvO_2$, $SpvO_2^A$, SpO_2^{AP} and SpO_2^M, as described below. A non-invasive blood analysis system utilizing an optical, active-pulse sensor is described in U.S. patent application Ser. No. 13/646,659 titled Noninvasive Blood Analysis System, filed Oct. 5, 2012, assigned to Cercacor and incorporated in its entirety by reference herein.

FIGS. **2**A-B illustrate active-pulse blood analysis techniques. FIG. **2**A illustrates a prior art occlusive, off-site active-pulse technique for temporally-spaced (non-concurrent) arterial and venous oxygen saturation measurements. A fingertip **10** is illuminated **15** with multiple wavelength light from, say, red and IR LEDs. Corresponding multiple wavelength light **17** emerges from the fingertip **10** after attenuation by pulsatile blood flow within the fingertip **10** and is received by detectors accordingly. The artificial pulse mechanism is a pressure cuff **20**, as shown, or a plunger or similar mechanical device located distal the fingertip **10**. An active-pulse sensor utilizing an off-site plunger or pressure cuff is described in U.S. Pat. No. 6,334,065, titled Stereo Pulse Oximeter, filed May 27, 1999, assigned to Masimo and incorporated in its entirety by reference herein. The downside to such an off-site active-pulse technique is that at least partial occlusion of the arterial blood flow occurs. As a result, accurate optical measurement of arterial blood constituents cannot be made concurrently with venous blood constituents. However, on-site active-pulse techniques present the difficulty of designing a mechanism that generates a pulse co-located with detectors, where the detected light tends to be sensitive to fingertip placement, vibration and movement. Further, conventional wisdom is that an on-site active (artificial) pulse alters or interferes with an arterial pulse such that concurrent measurement of arterial and venous blood constituents is infeasible.

FIG. **2**B illustrates a non-occlusive, on-site active-pulse technique for concurrent SpO_2 and $SpvO_2$ measurements. In particular, a mechanical pulser **210** is co-located with sensor detectors at the fingertip **10** so that LED light **15** can be detected **17** after attenuation by pulsatile arterial, capillary and venous blood flow. An active-pulse optical sensor having mechanical, optical and electrical elements configured for concurrent probing of arterial, capillary and venous blood constituents is described in U.S. patent application Ser. No. 13/473,377, titled Personal Health Device, filed May 16, 2012, assigned to Cercacor and incorporated in its entirety by reference herein.

FIG. **3** illustrates an active-pulse blood analysis sensor **300** that allows concurrent natural pulse and active-pulse blood analysis. The sensor **300** has two or more LEDs (emitters) **310**, one or more detectors **320** and an active-pulser **340**. In other embodiments, the sensor **300** also has temperature sensors (not shown) responsive to the LEDs **310**, the detector(s) **320** and the fingertip as well as an accelerometer **350** responsive to fingertip position and movement. The LEDs **310** are individually activated by LED drives **312** so as illuminate a tissue site **10** with optical radiation **314**. The detector(s) **320** receive attenuated optical radiation **318** after absorption, reflection and diffusion by the tissue site **10** and by pulsatile blood flow within the tissue site **10**. The active-pulse **340** has a motor that controls a mechanical pulser in response to an active-pulse drive signal **313**. The motor has a "motor-on" state for starting the active-pulse and a "motor-off" state for stopping the active-pulse. Accordingly, the pulsatile blood flow may be heart-pulsed arterial blood flow or actively-pulsed venous and capillary blood flow, or both. The detector(s) **320** generates one or more channels **322** of plethysmograph and active-pulse signals to a DSP (not shown) within the blood analysis monitor **120** (FIG. **1**) for signal processing and analysis, as described in detail below.

FIG. 4 is a relational chart 400 for various active-pulse blood analysis parameters. The matrix rows 410 are invasive (blood draw) references. The matrix columns 420 are non-invasive sensor measurements. Each matrix cell 441-444 represents a blood parameter derived from an underlying calibration curve that correlates the invasive references 410 with the sensor measurements 420. FIGS. 6, 8 and 10, below, illustrate calibration curves corresponding to the cells 441-444. A "physical structure" row 430 appended at the bottom of the matrix 400 is a simple reminder that a passive sensor 422 "probes" the arteries 431, i.e. is responsive to heart-pulsed arterial blood flow, and that an active sensor 424 "probes" the capillaries and veins 432, i.e. is responsive to active-pulse induced venous blood flow. This calibration matrix 400 succinctly illustrates advantageously defined blood parameters listed within the cells 441-444, which are concurrently measured from a fingertip tissue site utilizing an active-pulse sensor 300 (FIG. 3).

As shown in FIG. 4, an $SpaO_2$ (or simply SpO_2) peripheral arterial oxygen saturation parameter 441 is a passive measurement 422 responsive to pulsatile arterial blood flow 431. An underlying SpO_2 calibration curve ("cal curve") is generated from arterial blood draws 412 correlated with the sensor-derived measurements, as described with respect to FIG. 6A, below.

Also shown in FIG. 4, an $SpvO_2$ peripheral venous oxygen saturation parameter 442 is an active-pulse measurement 424, responsive to artificially-pulsed venous and capillary blood flow 432. An underlying $SpvO_2$ cal curve is generated from venous blood draws 414 correlated with the sensor-derived measurements, as described with respect to FIGS. 6A-B, below.

Further shown in FIG. 4, an $SpvO_2^A$ peripheral venous oxygen saturation parameter 443 is an active-pulse measurement 424 responsive to artificially-pulsed venous and capillary blood flow 432. Advantageously, $SpvO_2^A$ sensor measurements utilize the same arterial ("A") cal curve 441 generated by passive sensor measurements 422 correlated with arterial blood draws 412, as cited above. $SpvO_2^A$ measurements are described with respect to FIG. 8B, below.

Additionally shown in FIG. 4, an SpO_2^{AP} peripheral arterial oxygen saturation parameter 444 is an active-pulse measurement 424 responsive to artificially-pulsed venous and capillary blood flow 432 measured with an active-pulse sensor. Advantageously, SpO_2^{AP} sensor measurements 444 utilize a unique active-pulse ("AP") cal curve generated from arterial blood draws 412 correlated with active-pulse sensor measurements, as described with respect to FIGS. 10A-B, below.

FIG. 5 illustrates an active-pulse blood analysis system 500 embodiment having a sensor data input 501, an SpO_2 532 output and an SpvO2 552 output. The sensor data 501 input has arterial pulse components 513 and active-pulse components 515. Resting heart rates range around 60 bpm (1 Hz). As such, a typical arterial pulse includes a fundamental around 1 Hz and harmonics at around 2, 3, 4 and possibly 5 Hz. In an embodiment, an active-pulse is generated at around 12 Hz. As such, a typical venous-induced pulse includes a fundamental around 12 Hz and possible spurious sidebands. Accordingly, a first bandpass filter 510 has a passband 512 so as to generate arterial pulse data 503 at heart rate and heart rate harmonic frequencies 513. Also, a second bandpass filter 510 has a passband 514 so as to generate active-pulse data 504 at the known active-pulse frequency 515.

Also shown in FIG. 5, arterial ratios 520 are calculated from the arterial pulse data 503 so as to generate arterial ratio data 522. In a two wavelength sensor embodiment, arterial ratio data 522 are red/IR ratios. Multiple (more than two) wavelength ratios are described in U.S. Pat. No. 7,343,186 titled Multi-Wavelength Physiological Monitor, assigned to Cercacor and incorporated in its entirety by reference herein. Arterial ratio data 522 are input to an arterial cal curve 530 so as to generate an SpO_2 532 output. Arterial cal curves are described with respect to FIG. 6A, below.

Further shown in FIG. 5, active-pulse ratios 540 are calculated from the active-pulse data 504 so as to generate active-pulse ratio data 542. In a two wavelength sensor embodiment, active-pulse ratio data 542 are red/IR ratios. Active-pulse ratio data 542 are input to a venous cal curve 550 so as to generate an $SpvO_2$ 552 output. Venous cal curves are described with respect to FIGS. 6A-B, below.

FIGS. 6A-B illustrate an active-pulse blood analysis system calibration curve (cal curve) 601 embodiment. FIG. 6A illustrates a two-dimensional SpO_2 (arterial) cal curve 610 and a corresponding two-dimensional $SpvO_2$ (venous) cal curve 620. The SpO_2 cal curve 610 is generated by comparing arterial-pulsed Red/IR plethysmograph ratios 602 derived by an optical sensor with corresponding percent oxygen saturation values 603 derived by arterial blood draws analyzed using a calibrated spectrometer. Similarly, the $SpvO_2$ cal curve 620 is generated by comparing active-pulse Red/IR plethysmograph ratios 602 with corresponding percent oxygen saturation values 603 derived by venous blood draws analyzed using the calibrated spectrometer. As examples, a Red/IR ratio of 0.6 yields a 96% arterial oxygen saturation value utilizing the arterial cal curve 610, and a Red/IR ratio of 0.8 yields a 84% venous oxygen saturation value utilizing the venous cal curve 620.

FIG. 6B illustrates a scatter plot 605 of $SpvO_2$ 606 versus SvO_2 607 for an active-pulse optical sensor having greater than two-wavelengths. The scatter plot values 660 compared with a unity line 670 provide a quantitative measure of how well the underlying multi-dimensional cal curve correlates with experimental results.

FIG. 7 illustrates an active-pulse blood analysis system 700 embodiment for advantageously determining SpO_2 and $SpvO_2^A$ using the same arterial calibration curve 750. The active-pulse blood analysis system 700 has a sensor data input 701, an SpO_2 output 732 and an $SpvO_2^A$ output 752. The bandpass filters 710 generate arterial pulse data 703 and active-pulse data 704 from the sensor data 701, as described with respect to FIG. 5, above. Arterial ratios 720 are calculated from the arterial data 703 so as to generate arterial ratio data 722, and an arterial cal curve 730 is applied to the arterial ratio data 722 so as to generate an SpO_2 732 output, also described with respect to FIG. 5, above and as described in further detail with respect to FIG. 8A, below.

Further shown in FIG. 7, active-pulse ratios 740 are calculated from the active-pulse data 704 so as to generate active-pulse ratio data 742, as described with respect to FIG. 5, above. Active-pulse ratio data 742 are advantageously input to an arterial cal curve 750 so as to generate an $SpvO_2^A$ 752 output, as described in further detail with respect to FIG. 8B, below. Advantageously, the arterial cal curves 730, 750 are the same, as described in further detail with respect to FIGS. 8A-B, below. As described herein, $SpvO_2^A$ denotes a venous oxygen saturation measurement utilizing an arterial oxygen saturation cal curve, as set forth with respect to FIG. 4, above.

FIGS. 8A-B illustrate active-pulse blood analysis cal curves for calculating both SpO_2 and $SpvO_2^A$. FIG. 8A illustrates an arterial cal curve for calculating SpO_2. An arterial ratio graph **801** has an arterial ratio x-axis **810**, an SpO_2 y-axis **820** and an arterial cal curve **830**. The arterial cal curve **830** is numerically-derived by correlating arterial blood draws with corresponding red/IR sensor data responsive to pulsatile arterial blood flow. The cal curve **830** data is derived across a representative patient population and stored in a look-up table. A blood parameter monitor inputs sensor data, derives ratios and calculates corresponding SpO_2 values from the look-up table accordingly. For example, a ratio of 0.75 (**812**) corresponds to roughly 92% SpO_2 (**822**); and a ratio of 1.2 (**814**) corresponds to roughly a 76% SpO_2 (**824**).

FIG. **8**B illustrates an identical arterial cal curve for calculating $SpvO_2^A$. A venous ratio graph **802** has a venous ratio x-axis **840**, a $SpvO_2^A$ y-axis **850** and the same arterial cal curve **860** stored in a monitor look-up table as described with respect to FIG. **8**A, above. However, the arterial cal curve **860** here is used to convert red/IR sensor data measured after attenuation by active-pulse venous blood into derived $SpvO_2^A$ values. The rationale for using an arterial cal curve for venous saturation calculations is that the optical characteristics of heart-pulse and active-pulse blood flow are the same. Hence, a ratio of 0.75 (**842**) corresponds to roughly 92% $SpvO_2^A$ (**852**); and a ratio of 1.2 (**844**) corresponds to roughly a 76% $SpvO_2^A$ (**854**).

FIG. **9** illustrates an active-pulse blood analysis system **900** embodiment for advantageously determining SpO_2 and SpO_2^{AP} and for combining SpO_2 and SpO_2^{AP} so as to calculate a motion tolerant measure of arterial oxygen saturation. The active-pulse blood analysis system **900** has a sensor data **901** input, an SpO_2 **932** output, an SpO_2^{AP} **952** output, and a motion-tolerant SpO_2^M oxygen saturation **972** output. The bandpass filters **910** generate arterial pulse data **903** and active-pulse data **904** from the sensor data **901**, as described with respect to FIG. **5**, above. Arterial ratios **920** are calculated from the arterial pulse data **903** so as to generate arterial ratio data **922**, and an arterial cal curve **930** is applied to the arterial ratio data **922** so as to generate an SpO_2 **932** output, as described with respect to FIG. **5**, above.

Further shown in FIG. **9**, active-pulse ratios **940** are calculated from the active-pulse data **904** so as to generate active-pulse ratio data **942**, as described with respect to FIG. **5**, above. Active-pulse ratio data **942** are advantageously input to an active-pulse cal curve **950** so as to generate an SpO_2^{AP} **952** output, as described in further detail with respect to FIGS. **10**A-B, below.

Also shown in FIG. **9**, a decision logic **960** generates a decision logic output **968**. The decision logic output **968** controls a multiplexer **970** that inputs SpO_2 **932** and SpO_2^{AP} **952** so as to generate an SpO_2^M output **972** that takes into account both. In an embodiment, a motion indicator **962** an a perfusion indicator **964** are input to the decision logic **960** so that the multiplexer **970** outputs SpO_2^{AP} **952** when a threshold amount of motion **962** and/or perfusion **964** is surpassed and so as to output SpO_2 **932** otherwise. See FIG. **11**, below. In this manner, arterial oxygen saturation is advantageously estimated from active-pulse blood flow so as to negate the effect of motion-induced venous blood flow and/or low perfusion. An optical sensor accelerometer for motion detection as well as finger position sensing is described in U.S. patent application Ser. No. 13/646,659 titled Noninvasive Blood Analysis System, cited above.

FIGS. **10**A-B illustrates active-pulse blood analysis system cal curve **1001**, **1002** embodiments. FIG. **10**A illustrates a two-dimensional SpO_2 (arterial) cal curve **1030** and a corresponding two-dimensional SpO_2^{AP} (active-pulse arterial) cal curve **1040**. The SpO_2 cal curve **1030** is generated by comparing arterial-pulsed Red/IR plethysmograph ratios **1010** derived by an optical sensor with corresponding percent oxygen saturation values **1020** derived by arterial blood draws analyzed using a calibrated spectrometer, as described with respect to FIG. **6**A, above. The SpO_2^{AP} cal curve **1040** is generated by comparing active-pulse Red/IR plethysmograph ratios **1010** with corresponding percent oxygen saturation values **1020** derived by arterial blood draws analyzed using the calibrated spectrometer. In particular, the SpO_2^{AP} cal curve corresponds relatively well to the SpO_2 cal curve for saturations above about 65%.

FIG. **10**B illustrates a scatter plot **1002** comparing non-invasively-derived SpO_2^{AP} values derived with an optical sensor having greater than two-wavelengths with corresponding invasively-derived SaO_2 values. A unity line **1060** provides a measure of quality for the underlying multi-dimensional SpO_2^{AP} cal curve.

FIG. **11** illustrates a motion versus perfusion decision graph **1100** for combining SpO_2 and SpO_2^{AP} so as to calculate a motion and low perfusion tolerant measure of arterial oxygen saturation SpO_2^M **972** (FIG. **9**). In particular, decision logic **960** (FIG. **9**) determines the relative amount of motion **1120** and perfusion **1110** so as to select arterial oxygen saturation SpO_2 **932** (FIG. **9**) or active-pulse arterial oxygen saturation SpO_2^{AP} **952** (FIG. **9**) as an SpO_2^M output **972** (FIG. **9**).

As shown in FIG. **11**, in a zone embodiment, relative amounts of motion **1120** and perfusion **1110** define discrete zones that determine the use of active pulse. Generally, active pulse (SpO_2^{AP}) **1130** (shaded area) is used as the measure of arterial oxygen saturation (SpO_2^M) **972** (FIG. **9**) when perfusion is relatively low and/or motion is relatively high. Arterial pulse (SpO_2) **1140** (unshaded area) is used as the measure of arterial oxygen saturation (SpO_2^M) **972** (FIG. **9**) when perfusion is relatively high and/or motion is relatively low. In a particular zone embodiment, if perfusion **1110** is less than 0.1% **1111**, then active pulse **1130** is used regardless of motion **1120**. If perfusion **1110** is between 0.1% and 0.5% **1112**, then active pulse **1130** is only used if motion is moderate **1122** to severe **1123**. If perfusion **1110** is between 0.5% and 10% **1113**, then active pulse is only used if motion is severe **1123**, and if perfusion **1110** is over 10% **1114**, active pulse is not used.

Further shown in FIG. **11**, in a boundary embodiment, relative amounts of motion **1120** and perfusion **1110** are specified by a continuous boundary **1150** that determines the use of active pulse. In a particular boundary embodiment, if perfusion **1110** is less than 0.1% **1111**, then active pulse **1130** is used regardless of motion **1120**, and if perfusion **1110** is over 10% **1114**, active pulse is not used. Otherwise, if the combination of increasing motion **1120** and decreasing perfusion **1110** falls below the boundary **1150**, then active pulse oxygen saturation **1130** is used as the arterial oxygen saturation SpO_2^M output **972** (FIG. **9**), and if the combination of decreasing motion **1120** and increasing perfusion **1110** falls above the boundary **1150**, then an arterial pulse oxygen saturation **1140** is used as the arterial oxygen saturation SpO_2^M output **972** (FIG. **9**).

FIG. **12** illustrates another active-pulse blood analysis embodiment for determining SpO_2 and SpO_2^{AP} and for combining SpO_2 and SpO_2^{AP} based upon BSQ (Boolean signal quality) and BPI (Boolean perfusion index) parameters so as to calculate a motion and low perfusion tolerant measure of arterial oxygen saturation SpO_2^M (multiplexed oxygen saturation). In particular, FIG. **12** differs from FIG. **9**, above, in that the multiplexer ("mux") select **1303** input is based upon Boolean decision logic **1300** responsive to BWQ **1301** and BPI **1302** inputs.

As shown in FIG. **12**, in an embodiment, BSQ=0 indicates low signal quality; BSQ=1 indicates high signal quality; BPI=0 indicates low perfusion; and BPI=1 indicates good perfusion. In an embodiment, BPI=0 when PI is below 1%. In an embodiment, BSQ is a direct measure of the amount of motion in the signal. In a particular embodiment, accelerometer **350** (FIG. **3**) values (x, y and z axis) are compared against a threshold and BSQ=0 when a specified percentage of the samples for any one of the three axis (x, y or z) have an accelerometer output greater than the threshold. In an embodiment, the threshold is 0.3 g and the specified percentage of samples is 50%. Decision logic **1300** is described in detail with respect to FIG. **13**, below.

FIG. **13** illustrates a decision logic **1300** embodiment for combining SpO_2 **932** and SpO_2^{AP} **952** inputs into a SpO_2^{M} **972** output. Decision logic **1300** has BSQ **1301** and BPI **1302** inputs as described with respect to FIG. **12**, above. SpO_2^{AP} **952** is selected as the SpO_2^{M} **972** output for all combinations of either BSQ=0 or BPI=0, i.e. if either the signal quality or the PI is low. SpO_2 **932** is selected as the SpO_2^{M} **972** output only if BSQ=1 and BPI=1, i.e. if both the signal quality and the PI is high.

An active-pulse blood analysis system 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 art will appreciate many variations and modifications.

What is claimed is:

1. An active-pulse blood analysis system comprising:

an optical sensor that illuminates a tissue site with multiple wavelengths of optical radiation and that outputs sensor signals responsive to the optical radiation after attenuation by pulsatile blood flow within the tissue site;

a monitor that communicates with the sensor signals and is responsive to arterial pulses within a first bandwidth and active pulses within a second bandwidth so as to generate an arterial pulse ratio and an active pulse ratio according to the wavelengths;

one or more memory devices storing an arterial calibration curve that relates arterial pulse ratios to arterial oxygen saturation values (SpO_2);

one or more memory devices storing an active pulse calibration curve that relates active pulse ratios to arterial oxygen saturation values (SpO_2^{AP});

one or more processors configured to:

select a first arterial oxygen saturation value (SpO_2) from the arterial calibration curve based on the arterial pulse ratio generated by the monitor, and

select a second arterial oxygen saturation value (SpO_2^{AP}) from the active pulse calibration curve based on the active pulse ratio generated by the monitor; and

a selection module that outputs a third arterial oxygen saturation value (SpO_2^{M}) selected from one of the first arterial oxygen saturation value (SpO_2) and the second arterial oxygen saturation value (SpO_2^{AP}) based on signal conditions.

2. The active-pulse blood analysis system according to claim **1** wherein the third arterial oxygen saturation (SpO_2^{M}) is tolerant to at least one of motion, low perfusion and low signal quality.

3. The active-pulse blood analysis system according to claim **1** wherein the signal conditions comprise a signal quality input and a perfusion index input.

4. The active-pulse blood analysis system according to claim **3** wherein the signal quality input is a Boolean signal quality input (BSQ) and the perfusion index input is a Boolean perfusion index input (BPI).

5. The active-pulse blood analysis system according to claim **4** wherein the selection module outputs the first arterial oxygen saturation only when the BSQ and the BPI are both equal to 1.

6. The active-pulse blood analysis system of claim **4** wherein the Boolean perfusion input (BPI) is zero when a measured perfusion index (PI) is below a first threshold boundary.

7. The active-pulse blood analysis system according to claim **6** wherein the first threshold boundary is a perfusion index (PI) of 1%.

8. The active-pulse blood analysis system according to claim **6** wherein the second threshold boundary is an acceleration of 0.3 g.

9. The active-pulse blood analysis system of claim **4** wherein the Boolean signal quality input (BPI) is zero when a measured acceleration of the optical sensor is greater than a second threshold boundary.

10. An active-pulse blood analysis method comprising:

inputting optical sensor data;

filtering the optical sensor data into arterial pulse data at a lower range of frequencies and active pulse data at a higher range of frequencies;

calculating arterial pulse ratios from the arterial pulse data;

calculating active pulse ratios from the active pulse data;

applying an arterial calibration curve stored in one or more memory devices to the arterial pulse ratios so as to generate an SpO_2 parameter indicative of arterial oxygen saturation determined from an arterial pulse;

applying an active pulse calibration curve stored in one or more memory devices to the arterial pulse ratios so as to generate an SpO_2^{AP} parameter indicative of arterial oxygen saturation determined from an active pulse; and

choosing between the SpO_2 parameter and the SpO_2^{AP} parameter so as to generate an SpO_2^{M} output parameter, the SpO_2^{M} output parameter comprising either the SpO_2 parameter or the SpO_2^{AP} parameter, based on signal conditions.

11. The active-pulse blood analysis method according to claim **10** wherein the SpO_2^{M} output parameter is indicative of an arterial oxygen saturation measurement tolerant to at least one of motion, low perfusion and low signal quality.

12. The active-pulse blood analysis method according to claim **11** wherein choosing comprises selecting one of the SpO_2 parameter and the SpO_2^{AP} parameter as the SpO_2^{M} output parameter according to a combination of a Boolean signal quality (BSI) and a Boolean perfusion index input (BPI).

13. The active-pulse blood analysis method according to claim **12** further comprising measuring a perfusion index (PI), and wherein the Boolean perfusion input (BPI) is zero when the perfusion index (PI) is below a first threshold boundary.

14. The active-pulse blood analysis method according to claim **13** further comprising measuring an acceleration of an optical sensor, and wherein the Boolean signal quality (BSQ) is zero when the measured acceleration is above a second threshold boundary.

15. The active-pulse blood analysis system according to claim **14** wherein the second threshold boundary is an acceleration of 0.3 g.

16. The active-pulse blood analysis method according to claim **13** wherein the first threshold boundary is a perfusion index (PI) of 1%.

17. The active-pulse blood analysis method according to claim **10** wherein the signal conditions comprise a signal quality input and a perfusion index input.

18. An active-pulse blood analysis apparatus comprising:

an optical sensor means for transmitting multiple wavelengths of light into a tissue site and detecting the transmitted light after attenuation by arterial blood flow and active pulsed blood flow within the tissue site so as to generate plethysmograph data;

a filter means for separating the detected plethysmograph data into arterial pulse data and active pulse data;

a processor means for calculating an arterial pulse ratio from the arterial pulse data and an active pulse ratio from the active pulse data;

a means for storing:

an arterial calibration curve means for relating arterial pulse ratios to oxygen saturation values (SpO_2); and

an active pulse calibration curve means for relating active pulse ratios to active pulse oxygen saturation values (SpO_2^{AP});

a means for selecting:

an oxygen saturation value (SpO_2) from the arterial calibration curve means based on the arterial pulse ratio; and

an active pulse oxygen saturation value (SpO_2^{AP}) from the active pulse calibration curve means based on the active pulse ratio; and

a means for selecting either the oxygen saturation value (SpO_2) or the active pulse oxygen saturation value (SpO_2^{AP}) as an oxygen saturation value (SpO_2^{M}) based on signal conditions.

19. The active-pulse blood analysis apparatus according to claim **18** wherein the signal conditions comprise a signal quality input and a perfusion index input.

20. The active-pulse blood analysis apparatus according to claim **19** wherein the signal quality input is a Boolean signal quality (BSQ) and the perfusion index input is a Boolean perfusion index (BPI).

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专利名称(译)	主动脉冲血液分析系统		
公开(公告)号	US9724025	公开(公告)日	2017-08-08
申请号	US14/328694	申请日	2014-07-10
[标]申请(专利权)人(译)	梅西莫股份有限公司		
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IPC分类号	A61B5/1455 A61B5/00		
CPC分类号	A61B5/14552 A61B5/7207 A61B5/6826 A61B5/721		
优先权	61/752976 2013-01-16 US 61/844699 2013-07-10 US		
外部链接	Espacenet USPTO		

摘要(译)

有源脉冲血液分析系统具有光学传感器，该光学传感器利用多个波长的光学辐射照射组织部位，并且在通过组织部位内的脉动血流衰减之后输出响应于光学辐射的传感器信号。监视器与传感器信号通信并响应第一带宽内的动脉脉冲和第二带宽内的有源脉冲，以便根据波长产生动脉脉冲比和有效脉冲比。动脉校准曲线将动脉脉搏比与第一动脉血氧饱和度值相关联，并且有效脉冲校准曲线将有效脉冲比与第二动脉血氧饱和度值相关联。判定逻辑基于灌注和信号质量输出第一和第二动脉氧饱和度值中的一个。