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(54) **CONGENITAL HEART DISEASE MONITOR**

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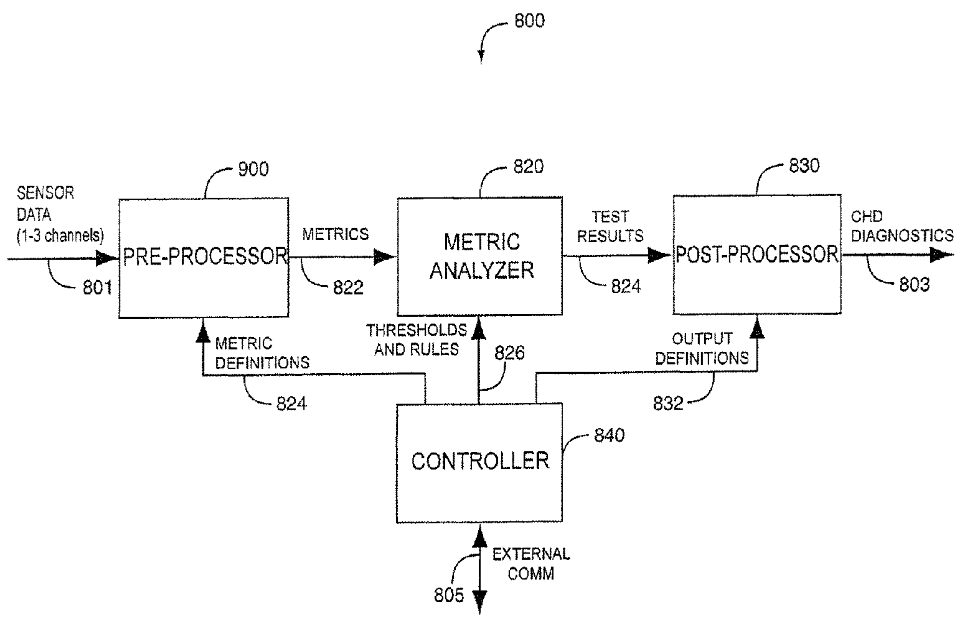
(57) **ABSTRACT**

A congenital heart disease monitor utilizes a sensor capable of emitting multiple wavelengths of optical radiation into a tissue site and detecting the optical radiation after attenuation by pulsatile blood flowing within the tissue site. A patient monitor is capable of receiving a sensor signal corresponding to the detected optical radiation and calculating at least one physiological parameter in response. The physiological parameter is measured at a baseline site and a comparison site and a difference in these measurements is calculated. A potential congenital heart disease condition in indicated according to the measured physiological parameter at each of the sites or the calculated difference in the measured physiological parameter between the sites or both.

18 Claims, 10 Drawing Sheets



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See application file for complete search history.

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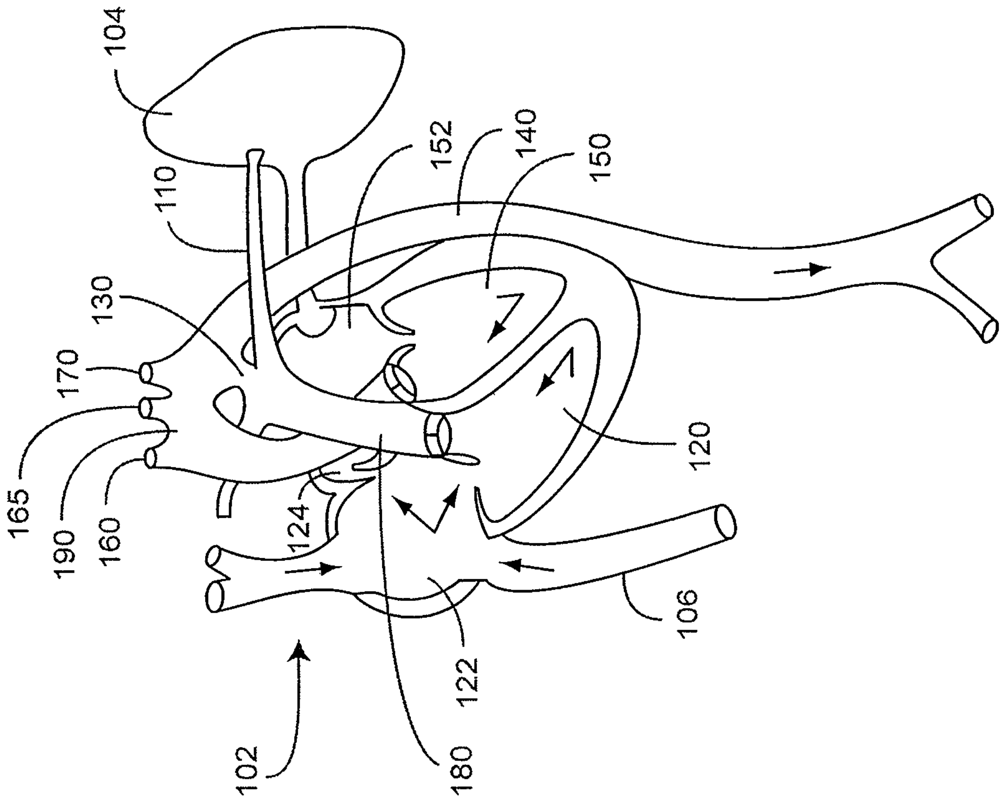


FIG. 1

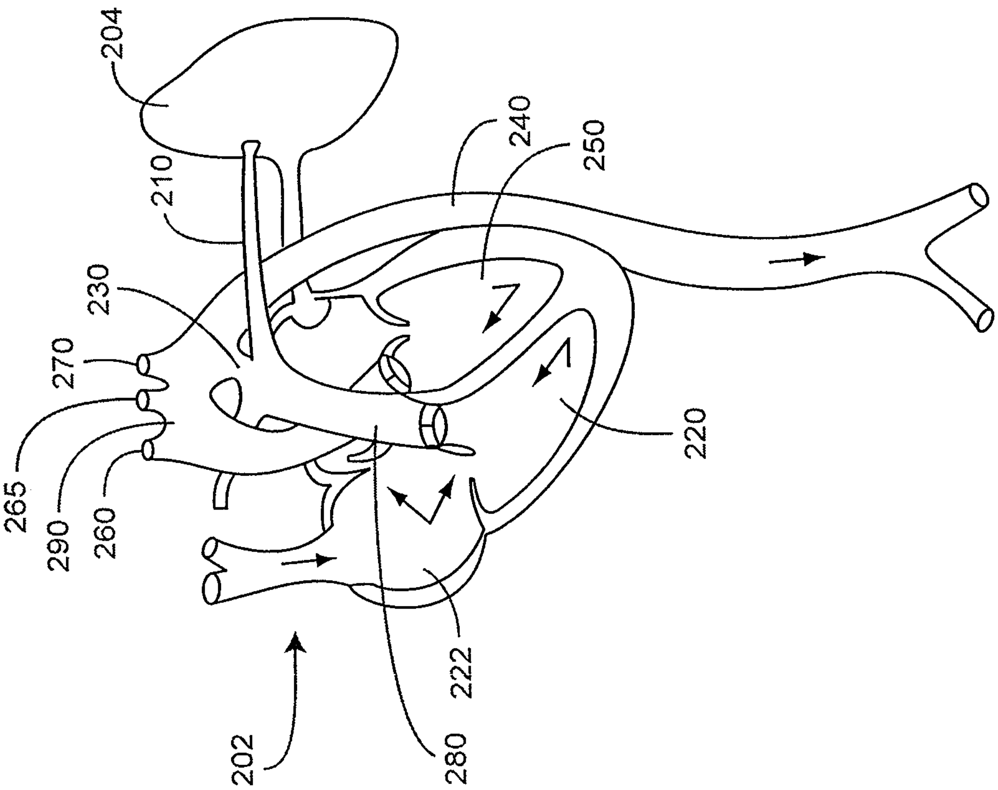


FIG. 2

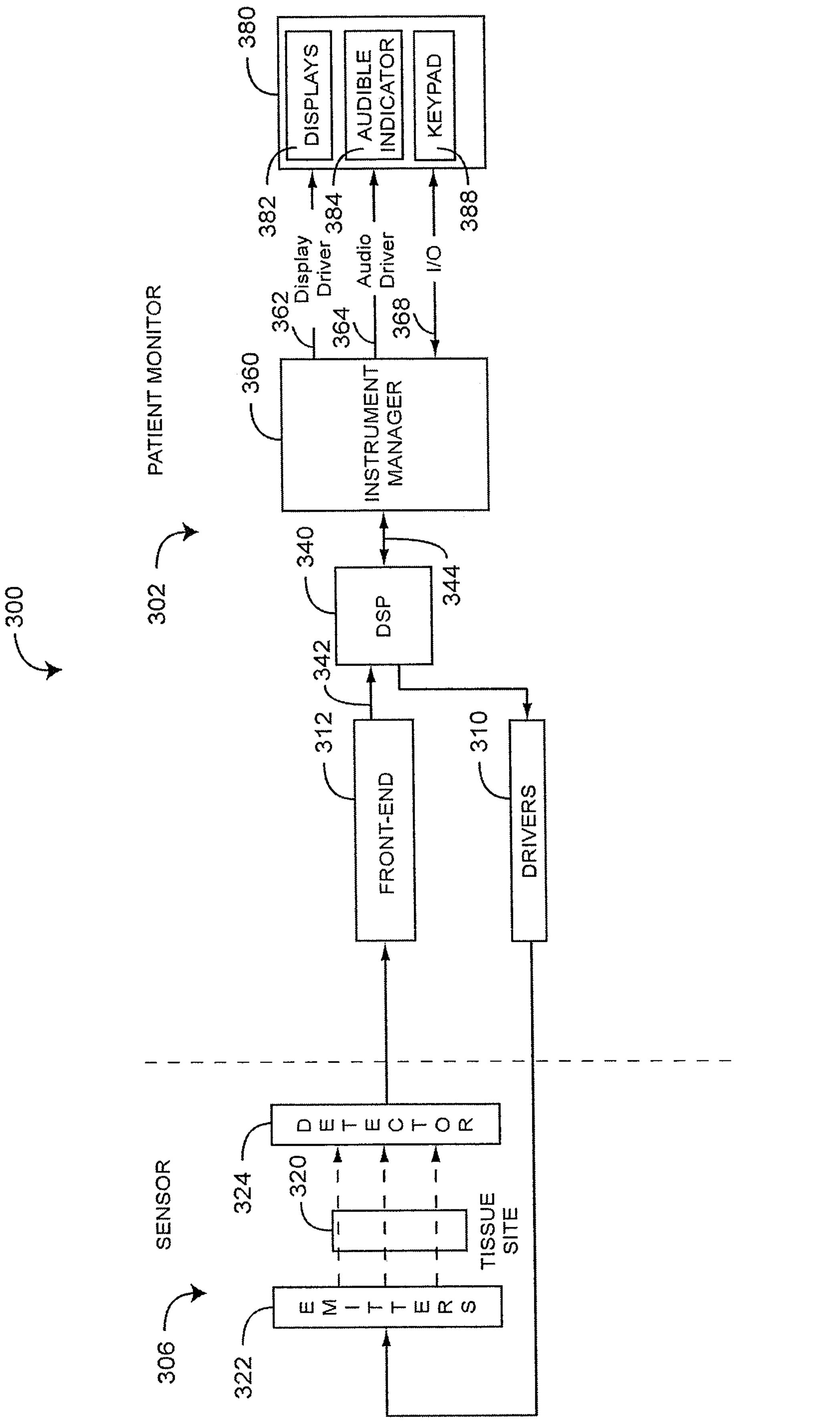

300
302
PATIENT MONITOR
306
SENSOR
322
EMITTERS
320
TISSUE SITE
324
DETECTOR
312
FRONT-END
310
DRIVERS
342
340
DSP
344
360
INSTRUMENT MANAGER
362
Display Driver
364
Audio Driver
368
I/O
380
382
DISPLAYS
384
AUDIBLE INDICATOR
388
KEYPAD

FIG. 3

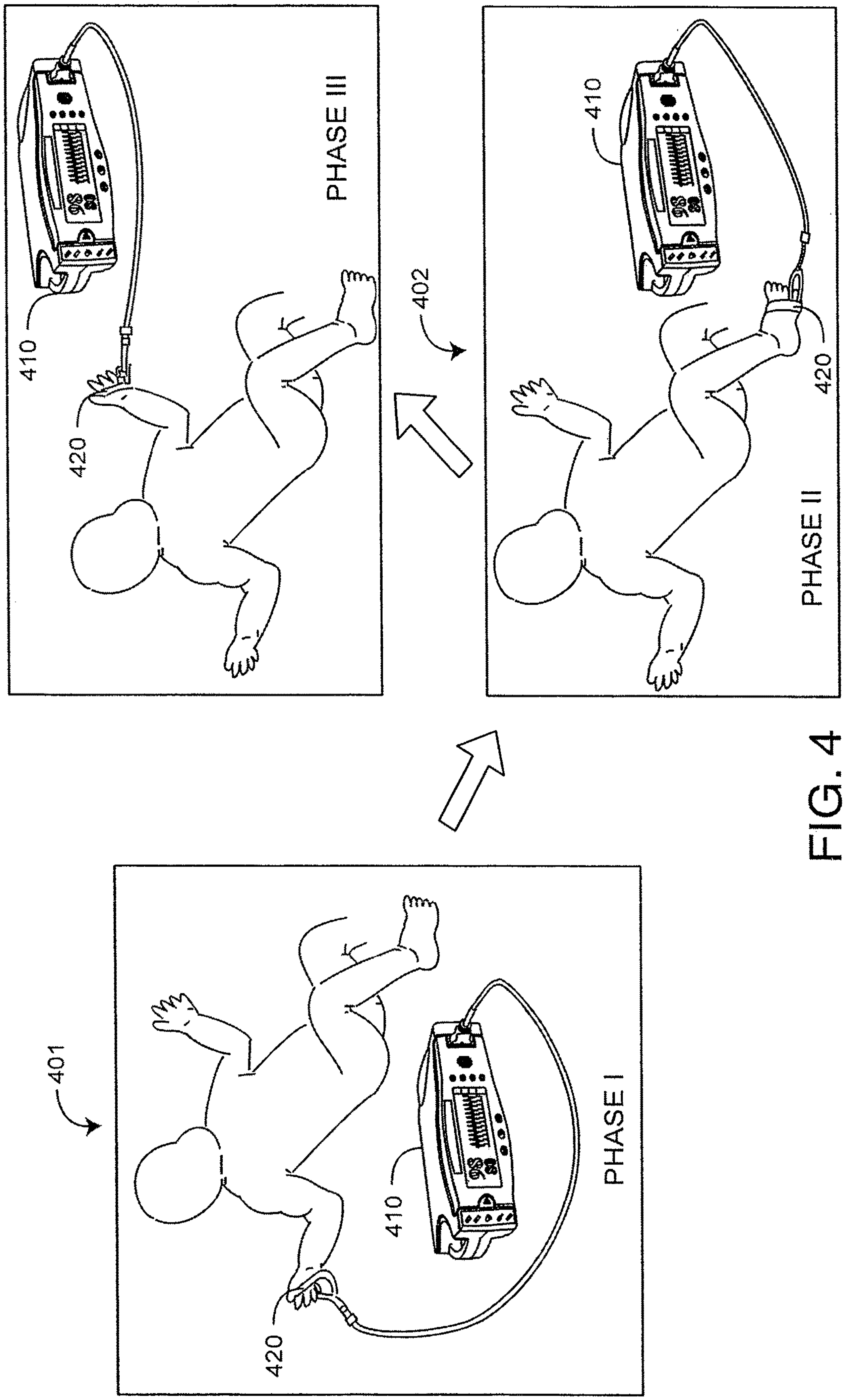


FIG. 4

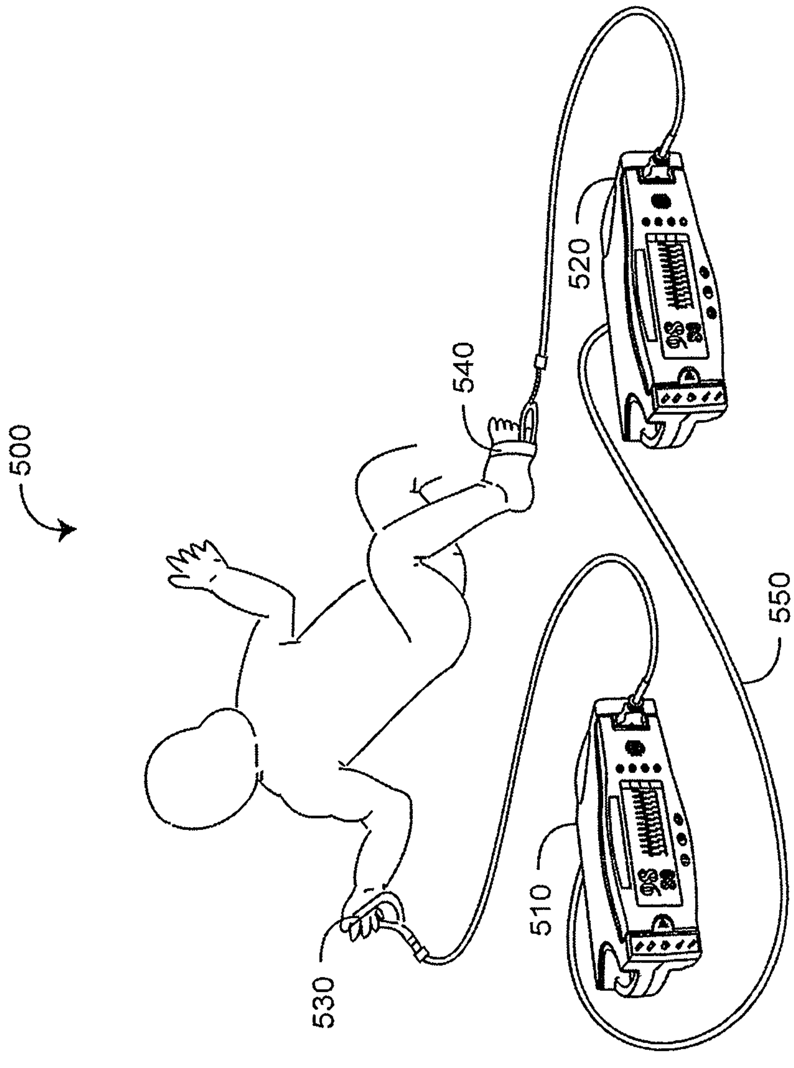


FIG. 5

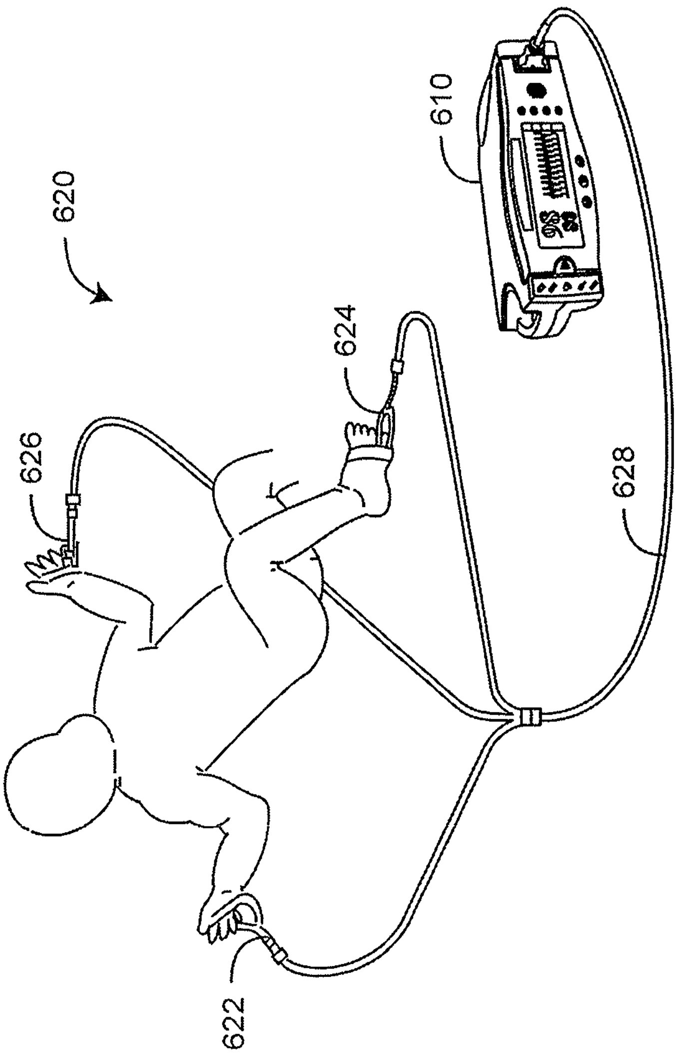


FIG. 6

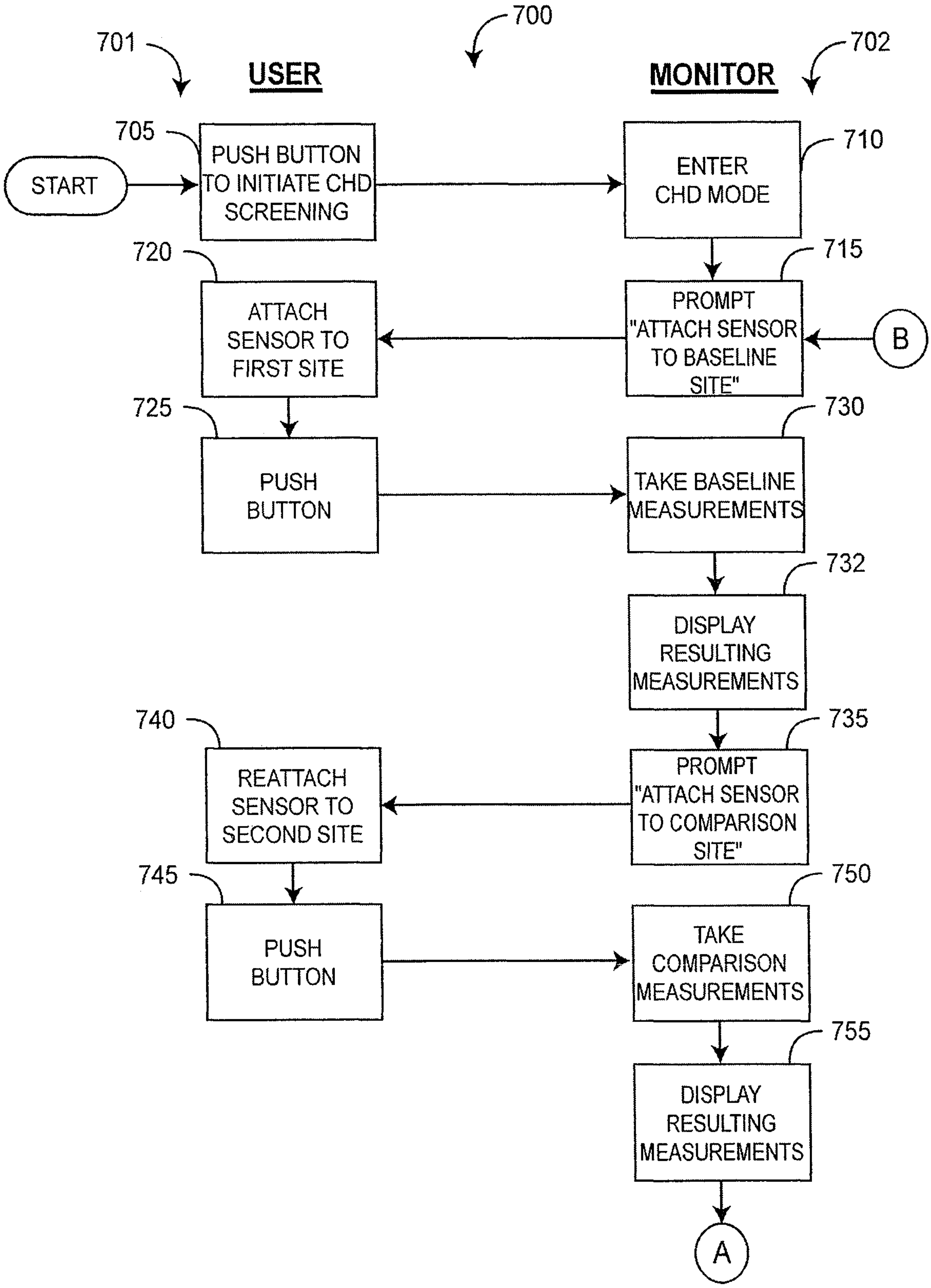
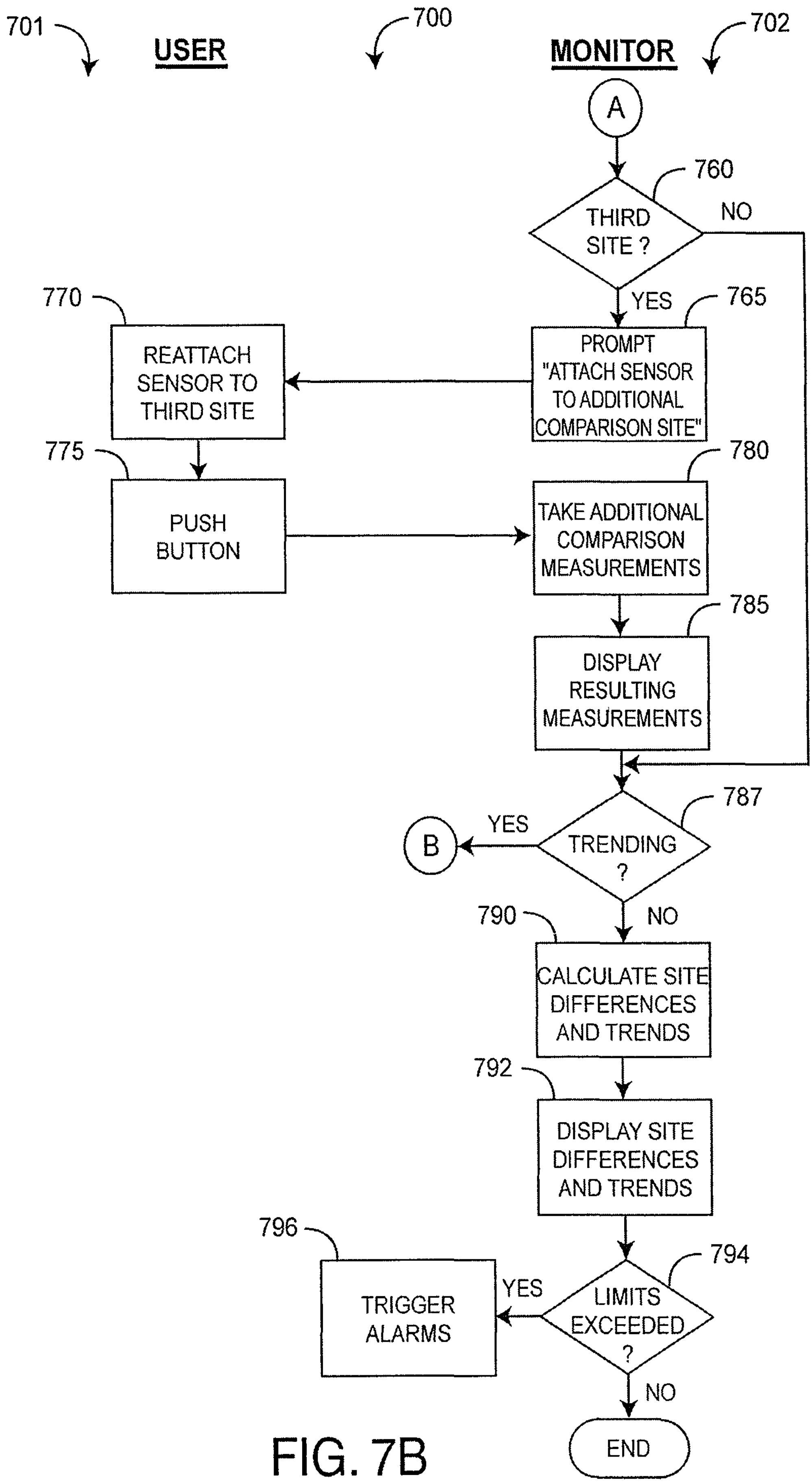

700
701
USER
MONITOR
702
705
START
PUSH BUTTON TO INITIATE CHD SCREENING
ENTER CHD MODE
710
720
715
ATTACH SENSOR TO FIRST SITE
PROMPT "ATTACH SENSOR TO BASELINE SITE"
B
725
730
PUSH BUTTON
TAKE BASELINE MEASUREMENTS
732
DISPLAY RESULTING MEASUREMENTS
740
735
REATTACH SENSOR TO SECOND SITE
PROMPT "ATTACH SENSOR TO COMPARISON SITE"
745
750
PUSH BUTTON
TAKE COMPARISON MEASUREMENTS
755
DISPLAY RESULTING MEASUREMENTS
A

FIG. 7A



701
USER
700
MONITOR
702
A
760
THIRD SITE ?
NO
YES
770
REATTACH SENSOR TO THIRD SITE
765
PROMPT "ATTACH SENSOR TO ADDITIONAL COMPARISON SITE"
775
PUSH BUTTON
780
TAKE ADDITIONAL COMPARISON MEASUREMENTS
785
DISPLAY RESULTING MEASUREMENTS
787
B
YES
TRENDING ?
790
NO
CALCULATE SITE DIFFERENCES AND TRENDS
792
DISPLAY SITE DIFFERENCES AND TRENDS
796
794
TRIGGER ALARMS
YES
LIMITS EXCEEDED ?
NO
END

FIG. 7B

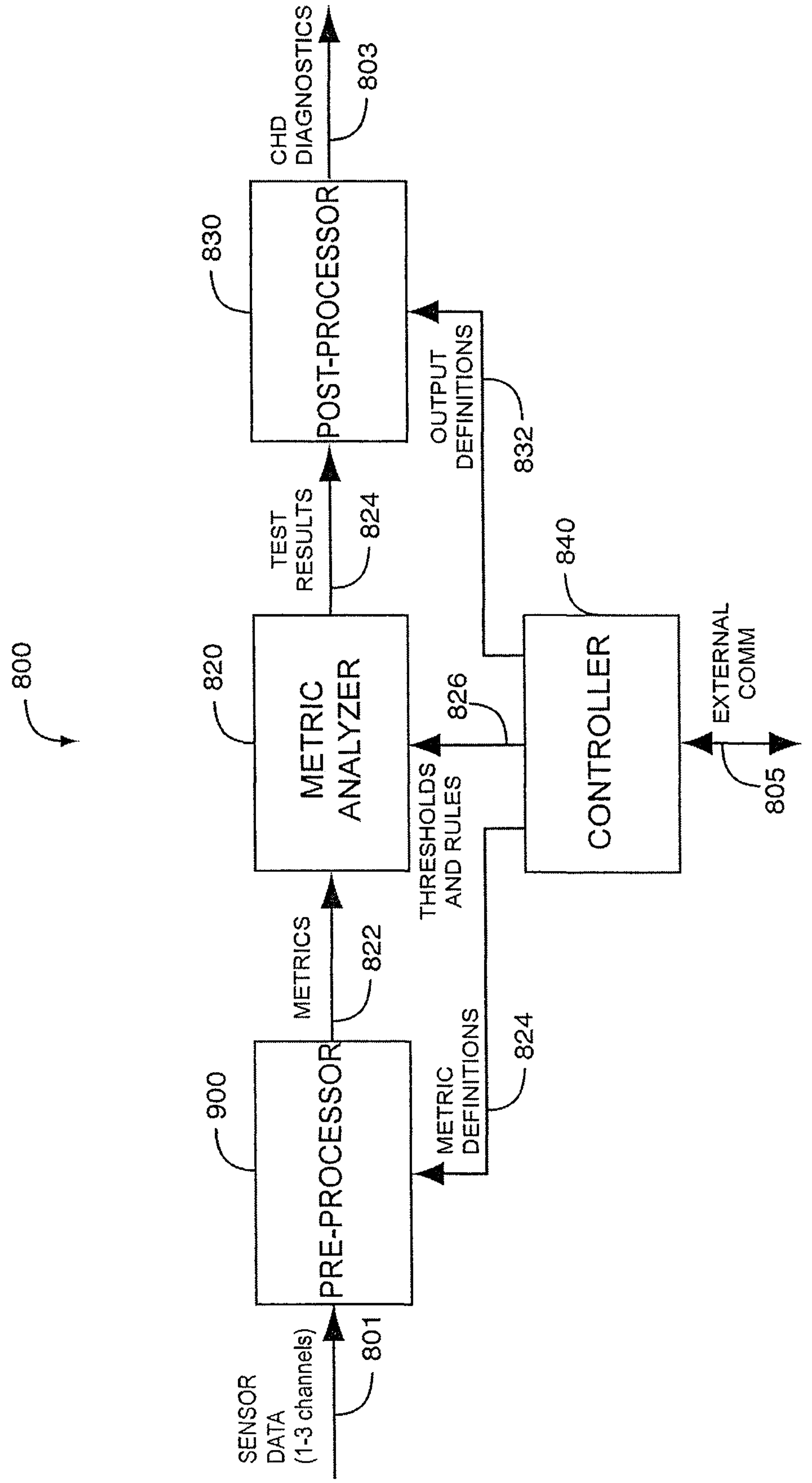

800
SENSOR DATA (1-3 channels)
801
PRE-PROCESSOR
900
METRICS
822
METRIC ANALYZER
820
TEST RESULTS
824
POST-PROCESSOR
830
CHD DIAGNOSTICS
803
METRIC DEFINITIONS
824
THRESHOLDS AND RULES
826
OUTPUT DEFINITIONS
832
CONTROLLER
840
EXTERNAL COMM
805

FIG. 8

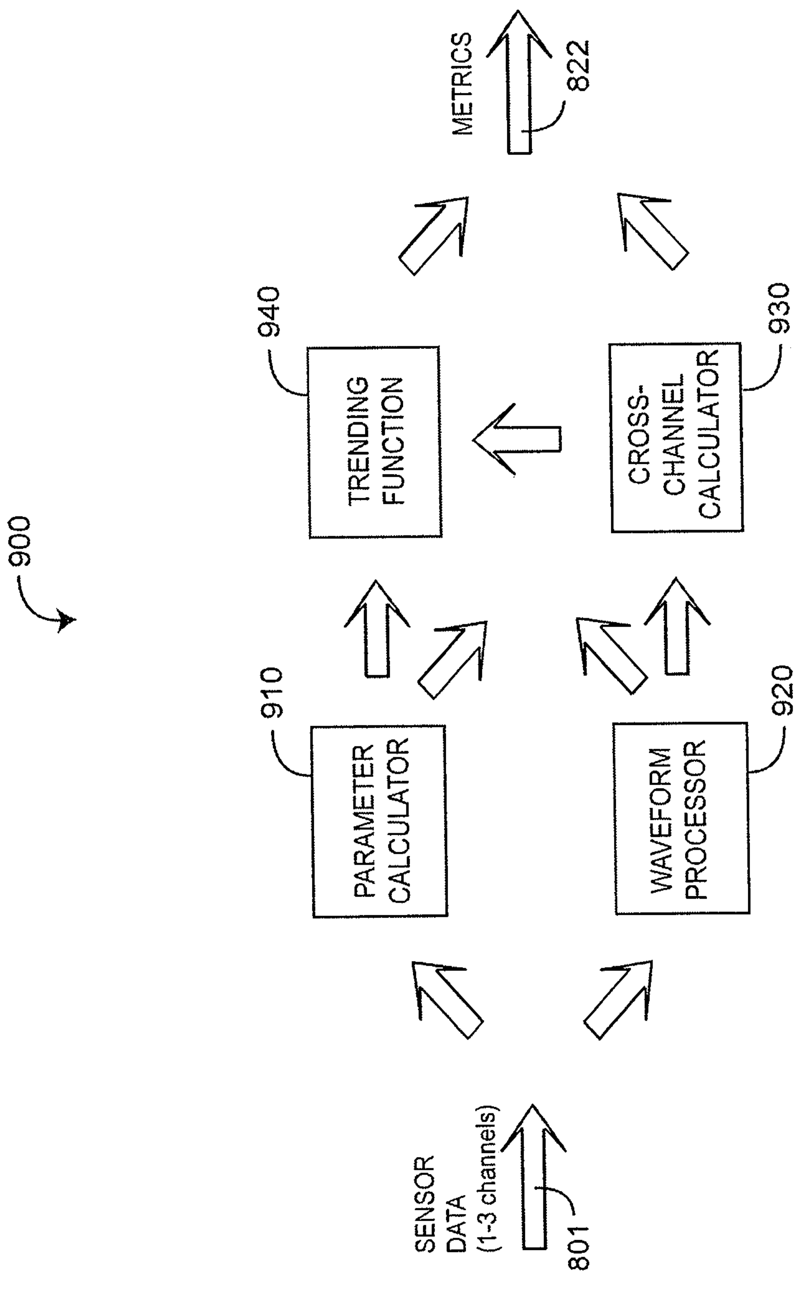

900
METRICS
822
940
TRENDING FUNCTION
930
CROSS-CHANNEL CALCULATOR
910
PARAMETER CALCULATOR
920
WAVEFORM PROCESSOR
SENSOR DATA (1-3 channels)
801

FIG. 9

CONGENITAL HEART DISEASE MONITOR

REFERENCE TO RELATED APPLICATION

The present application is a continuation of U.S. application Ser. No. 13/907,638, filed May 31, 2013, entitled "Congenital Heart Disease Monitor," which is a continuation of U.S. application Ser. No. 11/858,053, filed Sep. 19, 2007, entitled "Congenital Heart Disease Monitor," which claims priority benefit under 35 U.S.C. § 119(e) from U.S. Provisional Application No. 60/846,160, filed Sep. 20, 2006, entitled "Congenital Heart Disease Monitor," which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

Congenital heart disease (CHD) is relatively common, occurring in 5 to 10 of every 1,000 live births. Early diagnosis and treatment has improved outcomes in this population, but still a number of infants with CHD are sent home undiagnosed. Up to 30% of deaths due to CHD in the first year of life are due to such unrecognized cases. Several forms of CHD are the result of a patent ductus arteriosus (PDA).

FIG. **1** illustrates a fetal heart **102** and a portion of a fetal lung **104**. Prior to birth, the lung **104** is non-functional and fluid-filled. Instead, oxygenated blood is supplied to the fetus from gas-exchange in the placenta with the mother's blood supply. Specifically, oxygenated blood flows from the placenta, through the umbilical vein **106** and into the right atrium **122**. There, it flows via the foramen **124** into the left atrium **152**, where it is pumped into the left ventricle **150** and then into the aortic trunk **190**. Also, oxygenated blood is pumped from the right atrium **122** into the right ventricle **120** and directly into the descending aorta **140** via the main pulmonary artery **180** and the ductus arteriosus **130**. The purpose of the ductus arteriosus **130** is to shunt blood pumped by the right ventricle **120** past the constricted pulmonary circulation **110** and into the aorta **140**. Normally, the ductus arteriosus **130** is only patent (open) during fetal life and the first 12 to 24 hours of life in term infants. If the ductus arteriosus remains patent, however, it can contribute to duct-dependent congenital heart diseases, such as those described below.

Patent Ductus Arteriosus

FIG. **2** illustrates a neonatal heart **202** with a patent ductus arteriosus **230**. The ductus arteriosus frequently fails to close in premature infants, allowing left-to-right shunting, where oxygenated "red" blood flows from the aorta **240** to the now unconstricted pulmonary artery **210** and recirculates through the lungs **204**. A persistent patent ductus arteriosus (PDA) results in pulmonary hyperperfusion and an enlarged right ventricle **220**, which leads to a variety of abnormal respiratory, cardiac and genitourinary symptoms.

Persistent Pulmonary Hypertension in Neonates

As shown in FIG. **2**, persistent Pulmonary Hypertension in Neonates (PPHN) is a neonatal condition with persistent elevation of pulmonary vascular resistance and pulmonary artery pressure. The pulmonary artery **210** that normally feeds oxygen depleted "blue" blood from the right ventricle **220** to the lung **204** is constricted. The back pressure from the constricted pulmonary artery **210** results in a right-to-left shunting of this oxygen depleted blood through the ductus arteriosus **230**, causing it to mix with oxygen rich "red" blood flowing through the descending aorta **240**.

Aortic Coarctation

Also shown in FIG. **2**, coarctation of the aorta is a congenital cardiac anomaly in which obstruction or narrowing occurs in the distal aortic arch **290** or proximal descending aorta **240**. It occurs as either an isolated lesion or coexisting with a variety of other congenital cardiac anomalies, such as a PDA. If the constriction is preductal, lower-trunk blood flow is supplied predominantly by the right ventricle **220** via the ductus arteriosus **230**, and cyanosis, i.e. poorly oxygenated blood, is present distal to the coarctation. If the constriction is postductal, blood supply to the lower trunk is supplied via the ascending aorta **240**.

SUMMARY OF THE INVENTION

Once a problematic patent ductus arteriosus (PDA) is detected, closure can be effected medically with indomethacin or ibuprofen or surgically by ligation. Clinical symptoms of duct-dependent CHD, however, can vary on an hourly basis, and the required extended and inherently intermittent testing is difficult with current diagnostic techniques. These techniques include physical examination, chest x-ray, blood gas analysis, echocardiogram, or a combination of the above to detect, as an example, the soft, long, low-frequency murmur associated with a large PDA or, as another example, a retrograde flow into the main pulmonary artery.

As shown in FIG. **2**, a right hand has blood circulating from the left ventricle **250** through the innominate artery **260**, which supplies the right subclavian artery (not shown). Because the innominate artery **260** is upstream from the ductus arteriosus **230**, the oxygen saturation value and plethysmograph waveform obtained from the right hand are relatively unaffected by the shunt and serve as a baseline or reference for comparison with readings from other tissue sites. Alternatively, a reference sensor can be placed on a facial site, such as an ear, the nose or the lips. These sites provide arterial oxygen saturation and a plethysmograph for blood circulating from the left ventricle **250** to the innominate artery **260**, which supplies the right common carotid artery (not shown), or to the left common carotid artery **265**.

Also shown in FIG. **2**, either foot has blood supplied from the descending aorta **240**. A PDA **230** affects both the oxygen saturation and the blood flow in the descending aorta **240**. As stated above, the PDA **230** causes oxygen-depleted blood to be mixed with oxygen-rich blood in the descending aorta **240**. Because the descending aorta **240** supplies blood to the legs, the oxygen saturation readings at the foot will be lowered accordingly. That is, duct-dependent CHD may be manifested as a higher arterial oxygen saturation measured at a right hand tissue site (reference) and a lower oxygen saturation measured at a foot tissue site.

A PDA also allows a transitory left to right flow during systole, which distends the main pulmonary artery **280** as the result of the blood flow pressure at one end from the right ventricle and at the other end from the aortic arch **290**. A left-to-right flow through the shunt **230** into the distended artery **280** alters the flow in the descending aorta **240** and, as a result, plethysmograph features measured at either foot. Duct-dependent CHD, therefore, may also be manifested as a plethysmograph with a narrow peak and possibly a well-defined dicrotic notch at a hand baseline site and a broadened peak and possibly no notch at a foot site.

Further shown in FIG. **2**, a left hand has blood circulating from the left ventricle through the left subclavian artery **270** that supplies the left arm. Because the left subclavian artery **270** is nearer a PDA **230** than the further upstream innominate artery **260**, it may experience some mixing of deoxygenated blood and an alteration in flow due to the PDA **230**.

Duct-dependent CHD, therefore, may also be manifested as a reduced saturation and an altered plethysmograph waveform measured at a left hand tissue site as compared with the right hand baseline site, although to a lesser degree than with a foot site.

FIG. **3** illustrates a patient monitoring system **300**, which provides blood parameter measurements, such as arterial oxygen saturation, and which can be adapted as an advantageous diagnostic tool for duct-dependent CHD. The patient monitoring system **300** has a patient monitor **302** and a sensor **306**. The sensor **306** attaches to a tissue site and includes a plurality of emitters **322** capable of irradiating a tissue site **320** with differing wavelengths of light, such as the red and infrared wavelengths utilized in pulse oximeters. The sensor **306** also includes one or more detectors **324** capable of detecting the light after attenuation by the tissue **320**. A sensor is disclosed in U.S. application Ser. No. 11/367,013, filed on Mar. 1, 2006, titled Multiple Wavelength Sensor Emitters, which is incorporated by reference herein. Sensors that attach to a tissue site and include light emitters capable of irradiating a tissue site with at least red and infrared wavelengths are disclosed in one or more of U.S. Pat. Nos. 5,638,818, 5,782,757, 6,285,896, 6,377,829, 6,760,607 6,934,570 6,985,764 and 7,027,849, incorporated by reference herein. Moreover, low noise optical sensors are available from Masimo Corporation, Irvine, Calif.

As shown in FIG. **3**, the patient monitor **302** communicates with the sensor **306** to receive one or more intensity signals indicative of one or more physiological parameters and displays the parameter values. Drivers **310** convert digital control signals into analog drive signals capable of driving sensor emitters **322**. A front-end **312** converts composite analog intensity signal(s) from light sensitive detector (s) **324** into digital data **342** input to the DSP **340**. The DSP **340** may comprise a wide variety of data and/or signal processors capable of executing programs for determining physiological parameters from input data. In an embodiment, the DSP executes the CHD screening and analysis processes described with respect to FIGS. **7-9**, below.

The instrument manager **360** may comprise one or more microcontrollers controlling system management, such as monitoring the activity of the DSP **340**. The instrument manager **360** also has an input/output (I/O) port **368** that provides a user and/or device interface for communicating with the monitor **302**. In an embodiment, the I/O port **368** provides threshold settings via a user keypad, network, computer or similar device, as described below.

Also shown in FIG. **3** are one or more devices **380** including a display **382**, an audible indicator **384** and a user input **388**. The display **382** is capable of displaying indicia representative of calculated physiological parameters such as one or more of a pulse rate (PR), plethysmograph (pleth) morphology, perfusion index (PI), signal quality and values of blood constituents in body tissue, including for example, oxygen saturation (SpO_2), carboxyhemoglobin (HbCO) and methemoglobin (HbMet). The monitor **302** may also be capable of storing or displaying historical or trending data related to one or more of the measured parameters or combinations of the measured parameters. The monitor **302** may also provide a trigger for the audible indictor **384** for beeps, tones and alarms, for example. Displays **382** include for example readouts, colored lights or graphics generated by LEDs, LCDs or CRTs to name a few. Audible indicators **384** include, for example, tones, beeps or alarms generated by speakers or other audio transducers to name a few. The user input device **388** may include, for example, a keypad, touch screen, pointing device, voice recognition device, or the like.

A patient monitor is disclosed in U.S. application Ser. No. 11/367,033, filed on Mar. 1, 2006, titled Noninvasive Multi-Parameter Patient Monitor, incorporated by reference herein. Pulse oximeters capable of measuring physiological parameters including SpO_2, pleth, perfusion index and signal quality are disclosed in one or more of U.S. Pat. Nos. 6,770,028, 6,658,276, 6,157,850, 6,002,952, and 5,769,785, incorporated by reference herein. Moreover, pulse oximeters capable of reading through motion induced noise are available from Masimo Corporation, Irvine, Calif.

A congential heart disease (CHD) monitor advantageously utilizes a patient monitor capable of providing multiple-site blood parameter measurements, such as oxygen saturation, so as to detect, for example, hand-foot oxygen saturation differences associated with a PDA and related CHD.

One aspect of a CHD monitor is a sensor, a patient monitor and a DSP. The sensor is configured to emit optical radiation having a plurality of wavelengths into a tissue site and to detect the optical radiation after attenuation by pulsatile blood flowing within the tissue site. The monitor is configured to drive the sensor, receive a sensor signal corresponding to the detected optical radiation and to generate at least one of a visual output and an audio output responsive to the sensor signal. The DSP is a portion of the patient monitor and is programmed to derive a physiological parameter from sensor data responsive to the sensor signal. The physiological parameter is measured at a baseline tissue site and a comparison tissue site. The outputs indicate a potential CHD condition according to a difference between the physiological parameter measured at the baseline tissue site and the physiological parameter measured at the comparison tissue site.

Another aspect of a CHD monitor is a congenital heart disease screening method providing a patient monitor and corresponding sensor. The sensor is capable of emitting optical radiation having a plurality of wavelengths into a tissue site and detecting the optical radiation after attenuation by pulsatile blood flowing within the tissue site. The patient monitor is capable of receiving a sensor signal corresponding to the detected optical radiation and calculating a blood-related physiological parameter. The physiological parameter is measured at a baseline tissue site and a comparison tissue site. The measured physiological parameter at the baseline tissue site and at the comparison tissue site are compared. A potential CHD condition is indicated based upon the comparison.

A further aspect of a CHD monitor is a detection method determining a plurality of metrics responsive to sensor data derived from a plurality of tissue sites on an infant, testing the metrics with respect to predetermined rules and thresholds, and outputting diagnostics responsive to the test results. The metrics are at least one of a physiological parameter measurement, a cross-channel measurement and a trend. The diagnostics are responsive to the likelihood of congenital heart disease.

Yet another aspect of a CHD monitor comprises a patient monitor, a pre-processor means, an analyzer means and a post-processor means. The patient monitor is configured to receive sensor data from at least one optical sensor attached to a plurality of tissue sites on an infant. The pre-processor means is for deriving at least one metric from the sensor data. The analyzer means is for testing the at least one metric according to at least one rule. The post-processor means is for generating diagnostics based upon results of the testing The at least one rule defines when the at least one metric indicates a potential CHD condition in the infant.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an illustration of a fetal heart depicting a ductus arteriosis;

FIG. **2** is an illustration of a neonatal heart depicting a patent ductus arteriosis (PDA);

FIG. **3** is a general block diagram of a patient monitoring system adapted for congenital heart disease (CHD) detection;

FIG. **4** is an illustration of a single patient monitor utilized for CHD detection;

FIG. **5** is an illustration of multiple patient monitors utilized for CHD detection;

FIG. **6** is an illustration of a single patient monitor and multi-site sensor utilized for CHD detection;

FIGS. **7A-B** is a flow diagram of a CHD screening embodiment;

FIG. **8** is a detailed block diagram of a CHD analyzer embodiment; and

FIG. **9** is a detailed block diagram of a preprocessor embodiment for a CHD analyzer.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. **4** illustrates CHD detection utilizing a single patient monitor **410** and corresponding sensor **420**. In general, the monitor **410** provides a display or other indicator that directs a caregiver or other user to attach the sensor **420** to an initial tissue site for a first measurement and then to one or more other tissue sites for additional measurements. This procedure is described in further detail with respect to FIGS. **7A-B**, below. For example, in a Phase I configuration **401**, the sensor **420** is attached to a neonate's right hand so that the monitor **410** generates baseline site measurements. In a Phase II configuration **402**, the sensor **420** is attached to a neonate's foot so that the monitor **410** generates comparison site measurements. In an optional Phase III configuration **403**, the sensor **420** is attached to a neonate's left hand generating measurements at an additional comparison site. During each phase **401-403**, the monitor **410** takes measurements for a length of time sufficient to determine user-selected parameters, which includes SpO_2 and may include PR, PI, signal quality, pleth morphology, other blood parameters such as HbCO and HbMET, and trends over a selected time interval for any or all of these parameters. In an embodiment, baseline right-hand measurements are made first, followed by measurements at either foot, followed by optional left-hand measurements. In other embodiments, the phase-order of measurements can be user-selected and can be in any order and can include or exclude either the foot or the left-hand measurements.

In an embodiment, a monitor-determined time or user-selectable timer defines how long each site measurement is made, and a monitor display and/or audible indicator signals the user when to switch sensor sites. In an embodiment, a user defines time intervals or times-of-day for making repeat measurement cycles so as to obtain site difference trends. A monitor display and/or audible indicator signals the user when to begin a measurement cycle.

FIG. **5** illustrates CHD detection utilizing multiple patient monitors **510-520** and corresponding sensors **530-540**. In an embodiment, a first monitor **510** and first sensor **530** provide measurements from a right-hand tissue site. A second monitor **520** and second sensor **540** provide measurements from a foot tissue site. An interface cable **550** or wireless link provides communications between the monitors **510-520**. For example, the monitors **510-520** can communicate respective measurements via RS-232, USB, Firewire or any number of standard wired or wireless communication links. In an embodiment, one monitor, such as the baseline right-hand monitor **510** acts as the master and the comparison (e.g. foot) monitor **520** acts as a slave. The master monitor **510** generates the baseline measurements, transfers the comparison measurements from the slave monitor **520**, calculates the comparison parameters, such as oxygen saturation differences, displays the comparison parameters, calculates alarm conditions based upon the measured and comparison parameters and generates alarms accordingly.

In other embodiments, the comparison site (e.g. foot or left-hand) monitor **520** is the master and the baseline (right-hand) monitor **510** is the slave. In yet another embodiment, there are three networked monitors corresponding to right-hand, left-hand and foot sites, with one monitor acting as a master and the other monitors acting as slaves. The master monitor, in this example, calculates oxygen saturation differences for each pair of sites and generates alarms accordingly.

FIG. **6** illustrates CHD screening utilizing a single CHD patient monitor **610** and a corresponding multi-site sensor **620**. In an embodiment, the multi-site sensor **620** has two sensor heads **622-624** and a common sensor cable **628** for communication with the monitor **610**. One sensor head **622** is attached to a baseline tissue site, e.g. a right-hand and another sensor head **624** is attached to a comparison tissue site, e.g. either a foot or a left-hand. In another embodiment, a third sensor head **626** is available for attachment to a second comparison site, e.g. a left-hand. A multiple site patient monitor is disclosed in U.S. Pat. No. 6,334,065 issued Dec. 25, 2001 titled Stereo Pulse Oximeter which is assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein.

FIGS. **7A-B** illustrate a CHD screening process **700** corresponding to a single monitor CHD detection embodiment, such as described with respect to FIG. **4**, above. In general, the process **700** is described with respect to user actions **701** and monitor responses **702** and, likewise, monitor prompts **702** and user responses **701**. In particular, once the monitor enters a CHD detection mode, the monitor prompts a user to attach the sensor successively to two or more tissue sites. In this manner, the monitor can compute baseline and comparison site measurements and calculate site differences, such as in oxygen saturation, which tend to predict the likelihood or unlikelihood of CHD. In an embodiment, the monitor **702** communicates instructions to the user **701** or otherwise prompts the user with display messages. Alternatively, or in addition to display messages, the monitor **702** can prompt the user via audio messages or indicators, visual indicators such as panel lights or a combination of the above. In an embodiment, the user **701** can trigger the monitor **702** or otherwise respond to monitor **702** prompts via a panel-mounted push button. Alternatively, or in addition to a push button, the user **701** can trigger the monitor **702** or otherwise respond to the monitor **702** via touch screen, touch pad, keyboard, mouse, pointer, voice recognition technology or any similar mechanism used for accomplishing a computer-human interface.

As shown in FIG. **7A**, a user **701** initiates CHD screening **705** and the monitor **702** enters a CHD detection mode **710** in response. The monitor **702** then prompts the user **701** to attach a sensor to a baseline site **715**. In response, the user **701** attaches a sensor to a first tissue site **720**, such as a neonate's right hand, and pushes a button **725** to trigger the monitor to take baseline sensor measurements **730**. The monitor **702** displays the resulting baseline measurements **732** and prompts the user **701** to reattach the sensor to a comparison site **735**. In response, the user **701** removes the sensor and reattaches it to a second tissue site **740**, such as either of a neonate's feet, and pushes a button **745** to trigger the monitor **702** to take comparison sensor measurements **750**. The monitor **702** displays the resulting comparison site measurements **755**.

As shown in FIG. **7**B, after taking baseline site and comparison site measurements, the monitor **702** determines if a third site measurement is to be taken **760**. If so, the monitor **702** prompts the user **701** to reattach the sensor to an additional comparison site **765**. In response, the user **701** removes the sensor and reattaches it to a third tissue site **770**, such as a neonate's left-hand, and pushes a button **775** to trigger the monitor **702** to take additional comparison site measurements **780**. The monitor **702** then displays the resulting measurements **785**. The monitor **702** determines if trend measurements are being made **787**. If so, then after a predetermined delay the monitor **702** prompts the user to re-attach the sensor at the baseline site **715** (FIG. **7**A) to begin an additional series of measurements **730-785**.

Also shown in FIG. **7**B, after all site measurements are taken, the monitor **702** calculates the measurement differences between the baseline and comparison site(s) **790**, calculates trends in measurements and measurement differences **790** and displays the results **792**. The monitor **702** then determines whether any site measurements, site measurement differences or trends are outside of preset limits **794**. If limits are exceeded, the monitor generates visual and/or audio indicators of a potential CHD condition **796**. For example, an audio alert or alarm of a potential CHD condition may be a low-level intermittent beep so as to indicate a diagnostic result and not be confused with other urgent care alarms. In one embodiment, if neonatal SpO_2 measurements from both a right hand and a foot are less than about 95% or a hand-foot difference is greater than about ±3%, the monitor generates one or more indicators alerting a caregiver that a potential CHD condition exists.

FIG. **8** illustrates a CHD analyzer **800** that executes in the DSP **340** (FIG. **3**) and indicates a potential CHD or lack thereof. The CHD analyzer **800** is advantageously responsive to multiple channels of sensor data **801** so as to generate CHD diagnostics **803**. In an embodiment, the CHD analyzer **800** executes the CHD screening process described with respect to FIGS. **7**A-B, above, receiving sensor data **342** (FIG. **3**) derived from one tissue site at a time. In another embodiment, the CHD analyzer **800** receives sensor data **342** (FIG. **3**) derived from two or more sensor sites at a time, such as described with respect to FIGS. **5-6**, above. The diagnostic output **803** can be used, for example, to generate displays or indicators useful for grading a neonate with respect to a potential CHD condition and the severity of that condition. In an embodiment, an instrument manager **360** (FIG. **3**) convert CHD diagnostics **803** via a display driver **362** (FIG. **3**) and an audio driver **364** (FIG. **3**) into one or more displays **382** (FIG. **3**) and audible indicators **384** (FIG. **3**) for use by a physician, clinician, nurse or other caregiver.

In an embodiment, the CHD analyzer **800** has a pre-processor **900**, a metric analyzer **820**, a post-processor **830** and a controller **840**. The pre-processor **900** has sensor data inputs **801** from one or more sensor channels, such as described with respect to FIGS. **4-6**, above. The pre-processor **900** generates metrics **822** that may include, for example, physiological parameters, waveform features, and cross-channel comparisons and trends, as described in further detail with respect to FIG. **9**, below.

As shown in FIG. **8**, the metric analyzer **820** is configured to test metrics **822** and communicate the test results **824** to the post-processor **830** based upon various rules applied to the metrics **822** in view of various thresholds **826**. As an example, the metric analyzer **820** may communicate to the post-processor **830** when a parameter measurement increases faster than a predetermined rate, e.g. a trend metric exceeds a predetermined trend threshold.

Also shown in FIG. **8**, the post processor **830** inputs test results **824** and generates CHD diagnostic outputs **803** based upon output definitions **832**. For example, if the test result is that a trend metric exceeds a trend threshold, then the output definition corresponding to that test result may be to trigger an audible alarm. Thresholds, rules, tests and corresponding outputs are described in further detail with respect to TABLE 1, below.

Further shown in FIG. **8**, the controller **840** has an external communications port **805** that provides predetermined thresholds, which the controller **840** transmits to the metric analyzer **820**. The controller **840** may also provide metric definitions **824** to the pre-processor **900** and define outputs **832** for the post-processor **830**.

In an embodiment, CHD screening grades a neonate with respect to a likelihood of a CHD condition utilizing green, yellow and red indicators. For example, a green panel light signals that no metric indicates a potential CHD condition exists. A yellow panel light signals that one metric indicates a potential CHD condition exists. A red panel light signals that more than one metric indicates that a potential CHD condition exists. In an embodiment, the CHD analyzer **800** provides a diagnostic output **803** according to TABLE 1, below. The terms Sat_{xy}, ΔSat_{xy} and Δ_t listed in TABLE 1 are described with respect to FIG. **9**, below. Various other indicators, alarms, controls and diagnostics in response to various combinations of parameters and thresholds can be substituted for, or added to, the rule-based outputs illustrated in TABLE 1.

TABLE 1

CHD Analyzer Rules and Outputs

RULE	OUTPUT
If Sat > Sat limit threshold (all channels); Sat_{xy} < Sat_{xy} limit threshold (all cross-channels); and $\Delta Sat_{xy}/\Delta t$ < Sat_{xy} trend threshold (all cross-channels).	Then illuminate green indicator.
If Sat < Sat limit threshold (any channel); Sat_{xy} > Sat_{xy} limit threshold (any cross-channel); or $\Delta Sat_{xy}/\Delta t$ > Sat_{xy} trend threshold (any cross-channel).	Then illuminate yellow indicator

TABLE 1-continued

CHD Analyzer Rules and Outputs

RULE	OUTPUT
If Sat < Sat limit threshold (any channel); and Sat_{xy} > Sat_{xy} limit threshold (any cross-channel).	Then illuminate red indicator
If Sat < Sat limit threshold (any channel); and $\Delta Sat_{xy}/\Delta t$ > Sat_{xy} trend threshold (any cross-channel).	Then illuminate red indicator

FIG. **9** illustrates a preprocessor embodiment **900** that inputs sensor data **801** derived from one or more tissue sites and outputs metrics **822**. The preprocessor **900** has a parameter calculator **910**, a waveform processor **920**, a cross-channel calculator **930** and a trending function **940**. The parameter calculator **910** outputs one or more physiological parameters derived from pulsatile blood flow at a tissue site. These parameters may include, as examples, arterial oxygen saturation ($SpaO_2$), venous oxygen saturation ($SpvO_2$), PR and PI to name a few. In an embodiment, the parameter calculator **910** generates one or more of these parameters for each sensor data channel. The waveform processor **920** extracts various plethysmograph features for each data channel. These features may include, for example, the area under the peripheral flow curve, the slope of the inflow phase, the slope of the outflow phase, the value of the end diastolic baseline and the size and location of the dicrotic notch. The cross-channel calculator **930** generates cross-channel values, such as Sxy=SpO_2 (baseline site)−SpO_2 (comparison site). In an embodiment, the calculator **930** can also generate same-channel values, such as $SpaO_2$−$SpvO_2$ from the same sensor site. The trending function **940** calculates trends from the parameter calculator **910**, the waveform processor **920** or the cross-channel calculator **930**. The trending function **940** stores historical values and compares these with present values. This comparison may include $\Delta p/\Delta t$, the change in a parameter over a specified time interval, which may also be expressed as a percentage change over that interval. An example is $\Delta Sat_{xy}/\Delta_t$, the change in the oxygen saturation difference between two tissue sites over a specified time interval.

Although described above with respect to optical sensor inputs responsive to pulsatile blood flow, in an embodiment, the CHD monitor may include sensor inputs and corresponding algorithms and processes for other parameters such as ECG, EEG, $ETCO_2$, respiration rate and temperature to name a few. Although a CHD analyzer is described above as a program executed by a patient monitor DSP, the CHD analyzer can be, in whole or in part, hardware, firmware or software or a combination functioning in conjunction with or separate from the DSP. Further, the CHD analyzer can be configured, in whole or in part, as logic circuits, gate arrays, neural networks or an expert system, as examples. In an embodiment, a CHD monitor, such as described above, for example, as incorporating a patient monitor, CHD analyzer and corresponding CHD screening process, is marketed with instructions on grading a neonate, infant or patient with respect to the likelihood of a CHD condition.

A congential heart disease monitor has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the present invention, which is defined by the claims that follow. One of ordinary skill in the art will appreciate many variations and modification.

What is claimed is:

1. An electronic monitor for detection of congenital heart disease, the electronic monitor comprising one or more hardware processors configured to:

determine a first oxygen saturation corresponding to a first measurement site on a patient;

determine a second oxygen saturation corresponding to a second measurement site on the patient;

determine a difference between the first oxygen saturation and the second oxygen saturation;

determine a rate of change of the difference between the first oxygen saturation and the second oxygen saturation; and

generate an indicator for display, wherein the indicator is generated based on an application of:

same channel rules on the first saturation value at the first measurement site or the second saturation value at the second measurement site, and

cross-channel rules on the difference and the rate of change of the difference, and

wherein the indicator corresponds to the detection of congenital heart disease.

2. The electronic monitor of claim **1**, further comprising a display to display the indicator.

3. The electronic monitor of claim **1**, further comprising a sensor configured to emit optical radiation having a plurality of wavelengths into measurement sites and to detect the optical radiation after attenuation by pulsatile blood flowing within the measurement sites.

4. The electronic monitor of claim **1**, wherein the indicator comprises a first indicator and a second indicator, wherein the first indicator represents a higher risk of congenital heart disease than the second indicator.

5. The electronic monitor of claim **4**, wherein a first color of the first indicator is different than a second color of the second indicator.

6. The electronic monitor of claim **1**, wherein the one or more hardware processors are further configured to compare the first oxygen saturation corresponding to the first channel with a saturation limit threshold.

7. The electronic monitor of claim **1**, wherein the one or more hardware processors are further configured to compare the second oxygen saturation corresponding to the second channel with the saturation limit threshold.

8. The electronic monitor of claim **1**, wherein the one or more hardware processors are further configured to compare the difference of oxygen saturation with a cross channel saturation limit threshold.

9. The electronic monitor of claim **1**, wherein the one or more hardware processors are further configured to compare the rate of change of the difference of oxygen saturation over time between the first channel and the second channel with a cross channel saturation trend threshold.

10. An electronic monitoring method for detection of congenital heart disease, the electronic monitoring method comprising:

determining a first oxygen saturation corresponding to a first measurement site on a patient;

determining a second oxygen saturation corresponding to a second measurement site on the patient;

determining a difference between the first oxygen saturation and the second oxygen saturation;

determining a rate of change of the difference between the first oxygen saturation and the second oxygen saturation; and

generating an indicator for display, wherein the indicator is generated based on an application of:

same channel rules on the first saturation value at the first measurement site or the second saturation value at the second measurement site; and

cross-channel rules on the difference and the rate of change of the difference, and

wherein the indicator corresponds to the detection of congenital heart disease.

11. The electronic monitoring method of claim **10**, further comprising displaying the indicator.

12. The electronic monitoring method of claim **10**, further comprising emitting optical radiation having a plurality of wavelengths into measurement sites and detecting the optical radiation after attenuation by pulsatile blood flowing within the measurement sites.

13. The electronic monitoring method of claim **10**, wherein the indicator comprises a first indicator and a second indicator, wherein the first indicator represents a higher risk of congenital heart disease than the second indicator.

14. The electronic monitoring method of claim **13**, wherein a first color of the first indicator is different than a second color of the second indicator.

15. The electronic monitoring method of claim **10**, further comprising comparing the first oxygen saturation corresponding to the first channel with a saturation limit threshold.

16. The electronic monitoring method of claim **10**, further comprising comparing the second oxygen saturation corresponding to the second channel with the saturation limit threshold.

17. The electronic monitoring method of claim **10**, further comprising comparing the difference of oxygen saturation with a cross channel saturation limit threshold.

18. The electronic monitoring method of claim **10**, further comprising comparing the rate of change of the difference of oxygen saturation over time between the first channel and the second channel with a cross channel saturation trend threshold.

* * * * *

patsnap

专利名称(译)	先天性心脏病监测仪		
公开(公告)号	US10588518	公开(公告)日	2020-03-17
申请号	US15/634502	申请日	2017-06-27
[标]申请(专利权)人(译)	梅西莫股份有限公司		
申请(专利权)人(译)	Masimo公司		
当前申请(专利权)人(译)	Masimo公司		
[标]发明人	KIANI MASSI JOE E		
发明人	KIANI, MASSI JOE E.		
IPC分类号	A61B5/00 A61B5/0205 A61B5/1455 A61B5/024 G16H50/30		
CPC分类号	A61B5/14551 A61B5/6838 A61B5/7278 A61B5/742 A61B5/6829 A61B5/6826 A61B5/7282 A61B5/0205 A61B5/7275 A61B5/02416 A61B2560/0276 A61B5/02055 G16H50/30 G16H50/20		
优先权	60/846160 2006-09-20 US		
其他公开文献	US20170360310A1		
外部链接	Espacenet		

摘要(译)

先天性心脏病监测器利用一种传感器，该传感器能够向组织部位发射多种波长的光辐射，并在组织部位内流动的搏动性血液衰减后检测光辐射。 患者监视器能够接收与检测到的光辐射相对应的传感器信号，并作为响应来计算至少一个生理参数。 在基线部位和比较部位处测量生理参数，并计算这些测量值之间的差异。 根据在每个部位的测量的生理参数或在部位之间或两者之间的测量的生理参数的计算出的差异，指示潜在的先天性心脏病状况。