US007024233B2

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Ali et al.

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(45) **Date of Patent: Apr. 4, 2006**

(54) **PULSE OXIMETRY DATA CONFIDENCE INDICATOR**

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(73) Assignee: **Masimo Corporation**, Irvine, CA (US)

(*) 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.: **10/942,672**

(22) Filed: **Sep. 16, 2004**

(65) **Prior Publication Data**

US 2005/0033128 A1 Feb. 10, 2005

Related U.S. Application Data

(63) Continuation of application No. 10/739,794, filed on Dec. 18, 2003, which is a continuation of application No. 09/858,114, filed on May 15, 2001, now Pat. No. 6,684,090, which is a continuation-in-part of application No. 09/478,230, filed on Jan. 6, 2000, now Pat. No. 6,606,511.

(60) Provisional application No. 60/115,289, filed on Jan. 7, 1999.

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

(52) **U.S. Cl.** **600/323**; 600/336; 600/502

(58) **Field of Classification Search** 600/322–323, 600/309–310, 336, 500, 502
See application file for complete search history.

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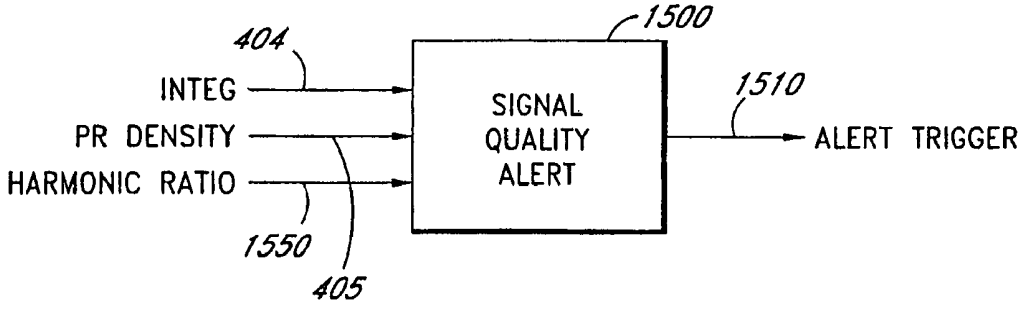
Primary Examiner—Eric F. Winakur
(74) *Attorney, Agent, or Firm*—Knobbe, Martens, Olson & Bear LLP

(57) **ABSTRACT**

According to some embodiments of the present invention, a display is used to show a signal from a physiological sensor as well as an indication of the signal's quality. While this indication of the signal's quality may be provided in a number of ways, it is preferably provided by changing a color on the display.

24 Claims, 24 Drawing Sheets



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Co-pending U.S. Appl. No. 10/739,794 entitled "Pulse Oximetry Data Confidence Indicator," filed Dec. 18, 2003 and Pending Claims filed Sep. 16, 2004.

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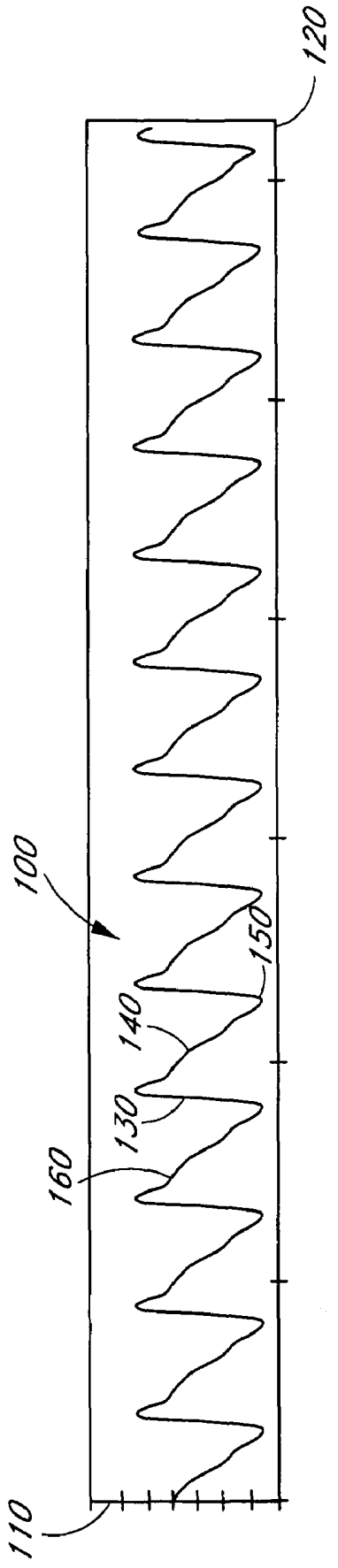


FIG. 1

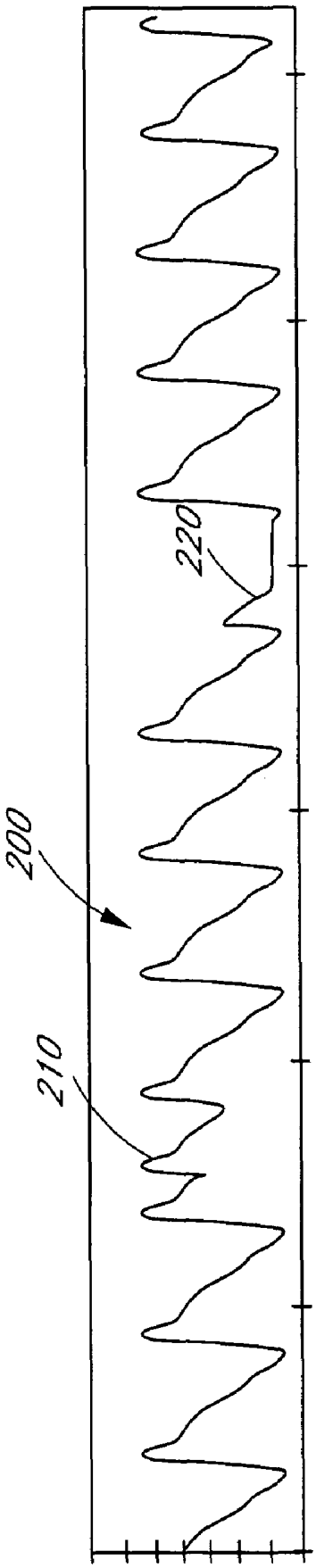


FIG. 2

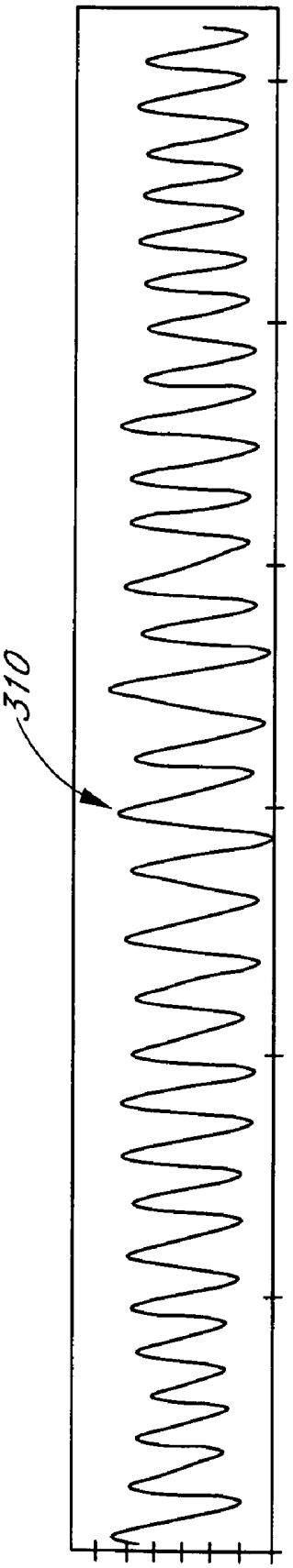


FIG. 3A

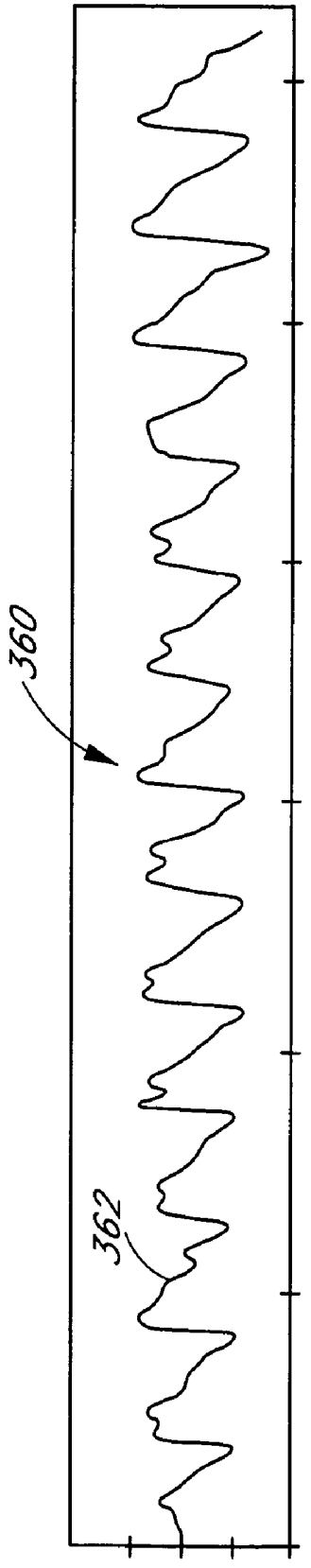


FIG. 3B

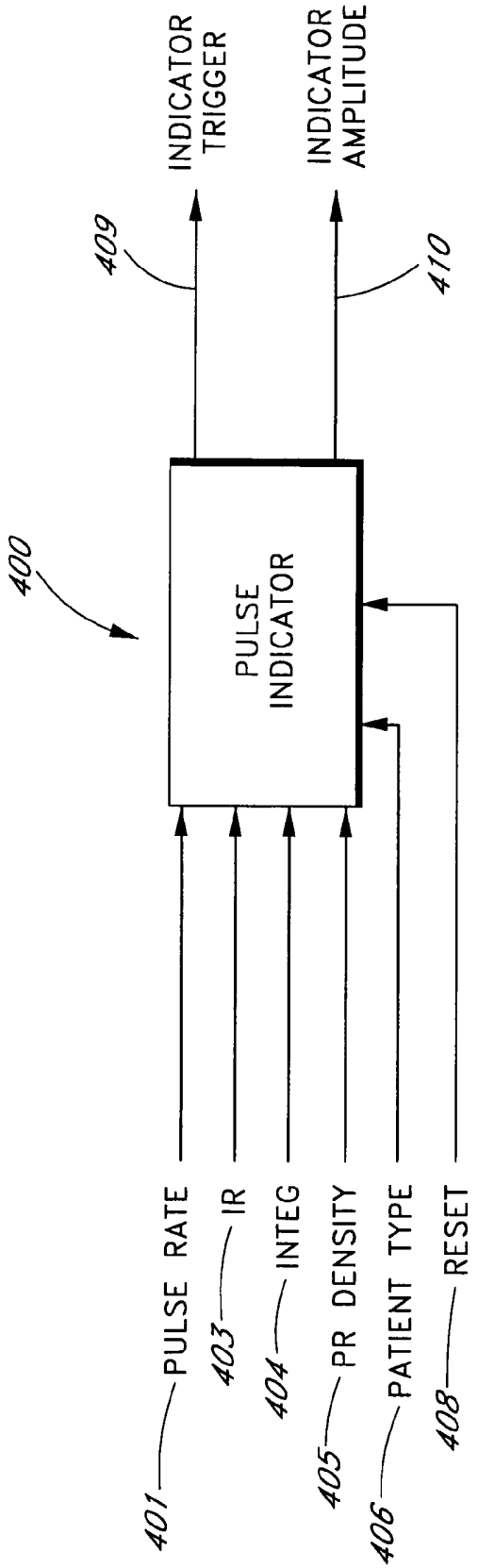

INDICATOR TRIGGER
INDICATOR AMPLITUDE
409
410
400
PULSE INDICATOR
PULSE RATE
IR
INTEG
PR DENSITY
PATIENT TYPE
RESET
401
403
404
405
406
408

FIG. 4

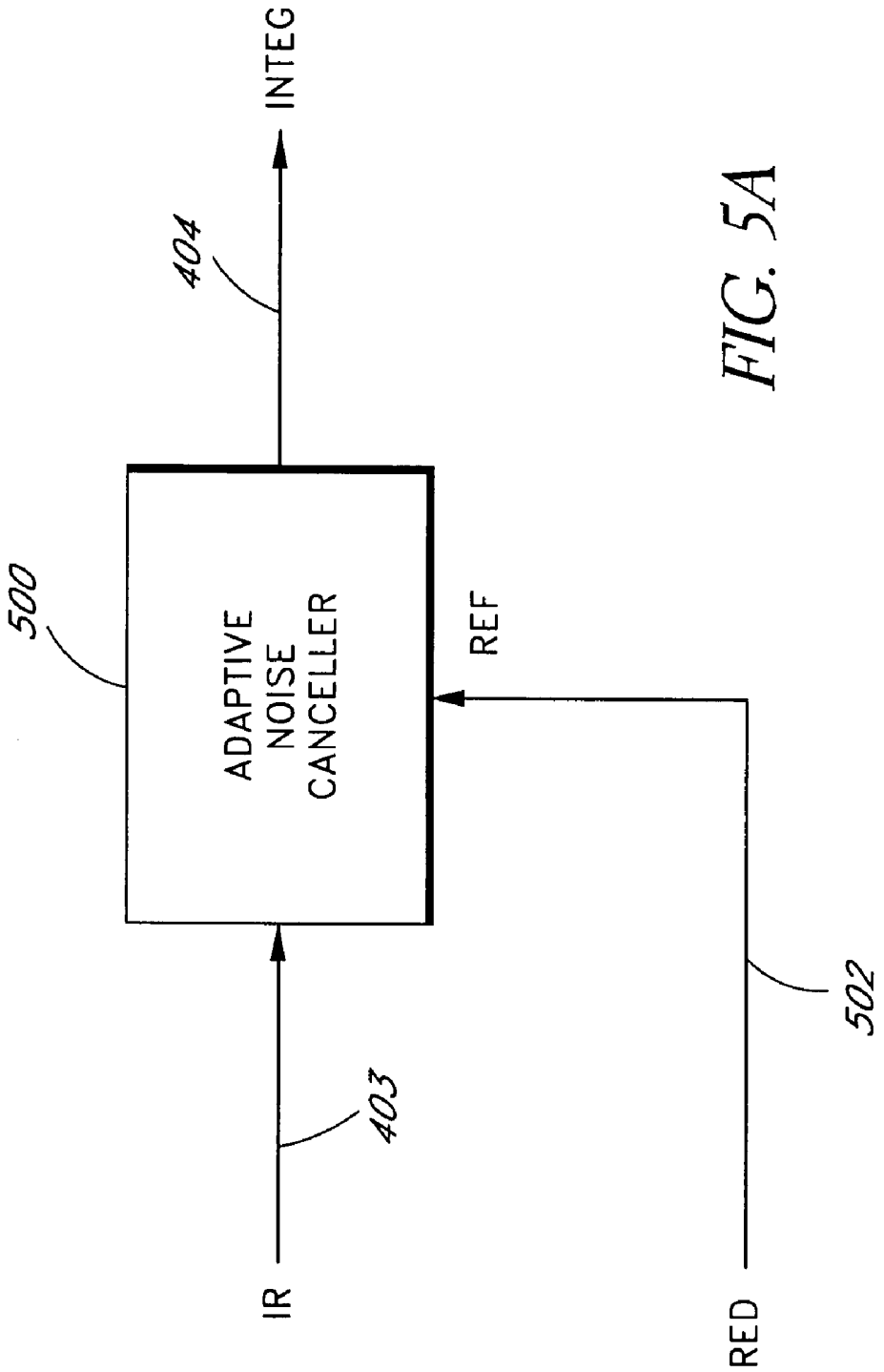


FIG. 5A

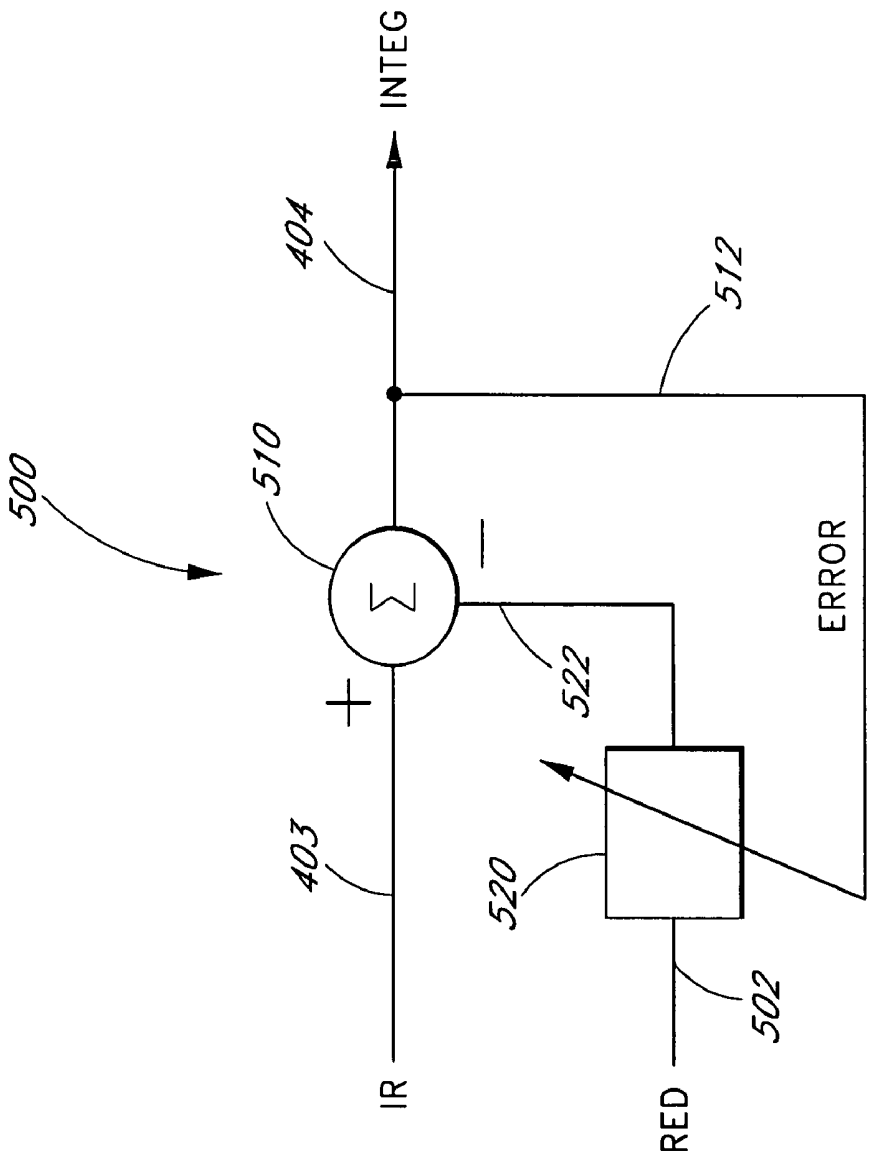


FIG. 5B

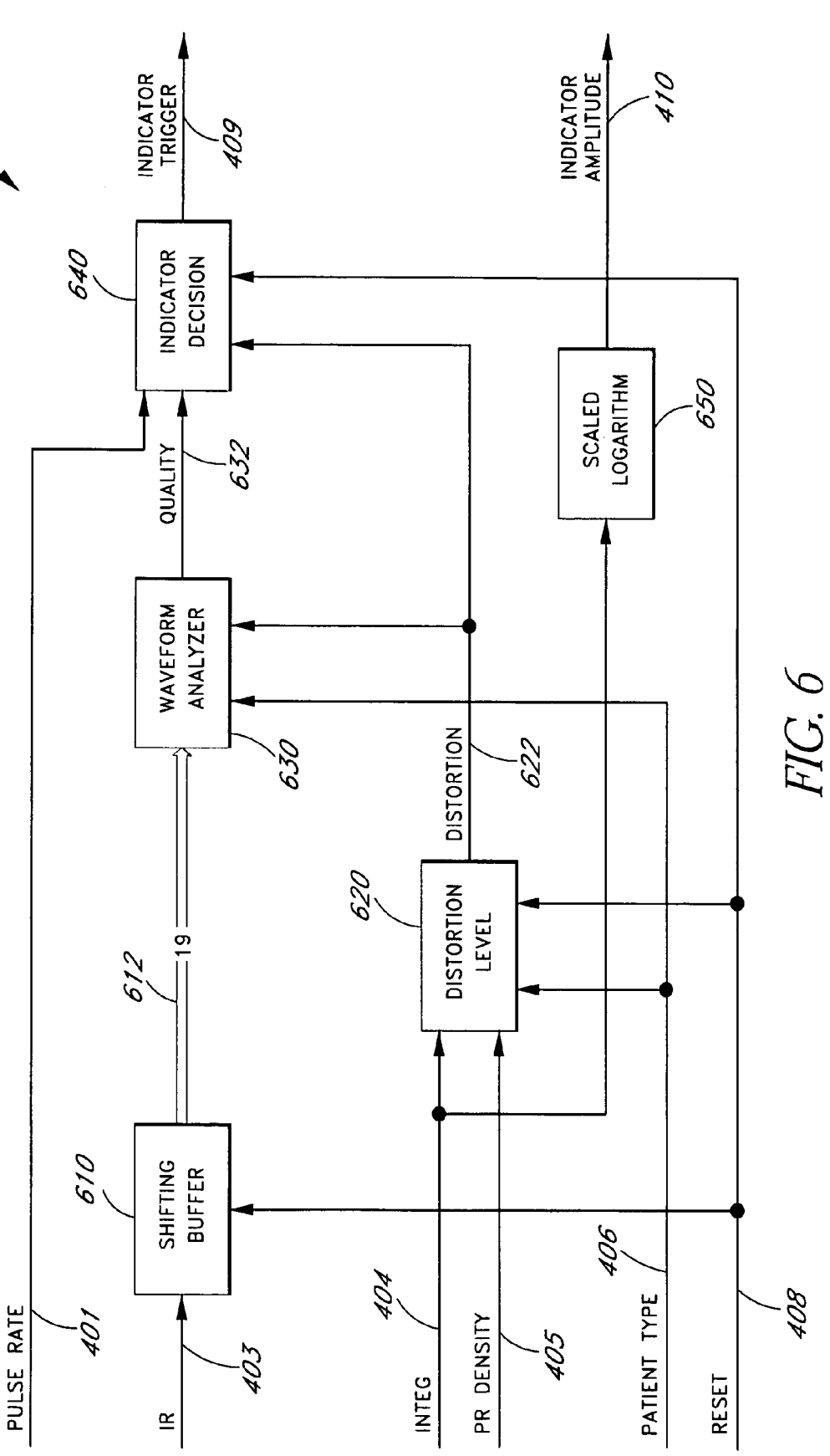

400
INDICATOR TRIGGER
409
INDICATOR AMPLITUDE
410
640
INDICATOR DECISION
SCALED LOGARITHM
650
QUALITY
632
WAVEFORM ANALYZER
630
DISTORTION
622
620
DISTORTION LEVEL
612
19
610
SHIFTING BUFFER
PULSE RATE
401
IR
403
INTEG
404
PR DENSITY
405
PATIENT TYPE
406
RESET
408

FIG. 6

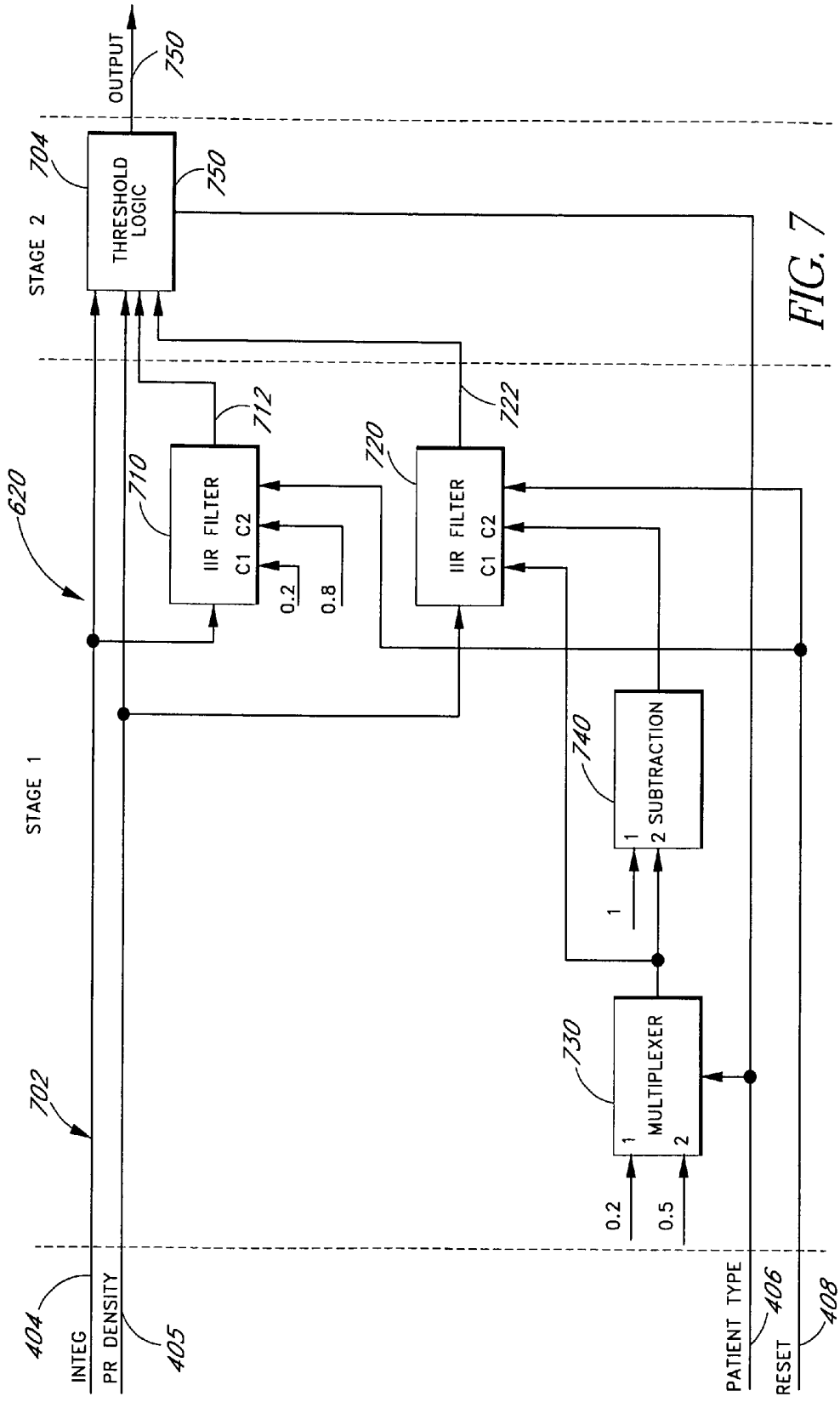

OUTPUT
750
704
THRESHOLD LOGIC
750
STAGE 2
712
722
710
720
620
IIR FILTER C1 C2
0.2
0.8
IIR FILTER C1 C2
740
1
2 SUBTRACTION
1
730
MULTIPLEXER
1
2
0.2
0.5
STAGE 1
702
404
INTEG
PR DENSITY
405
PATIENT TYPE
406
RESET
408

FIG. 7

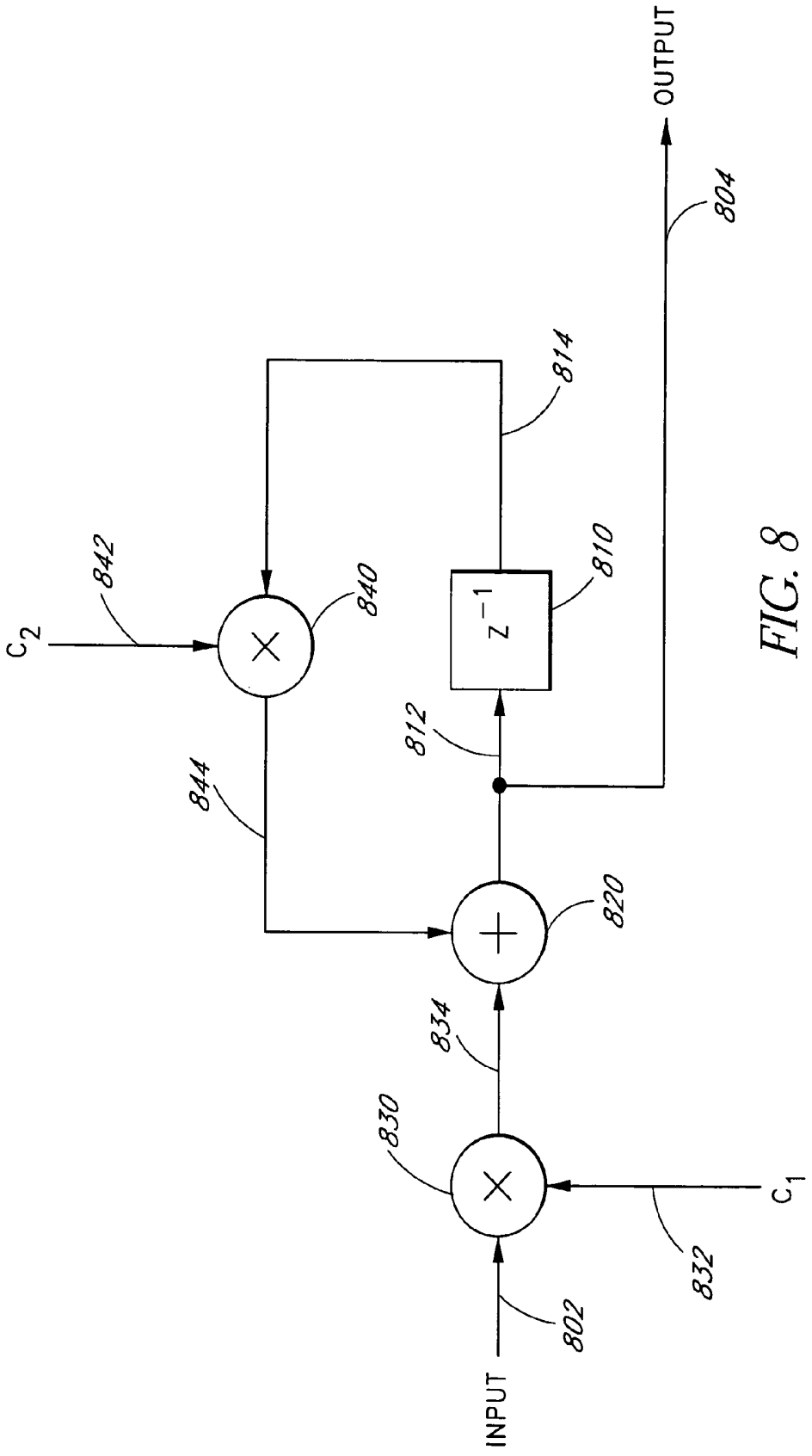

OUTPUT
804
814
842
840
C_2
Z^{-1}
810
812
844
820
834
830
C_1
832
802
INPUT

FIG. 8

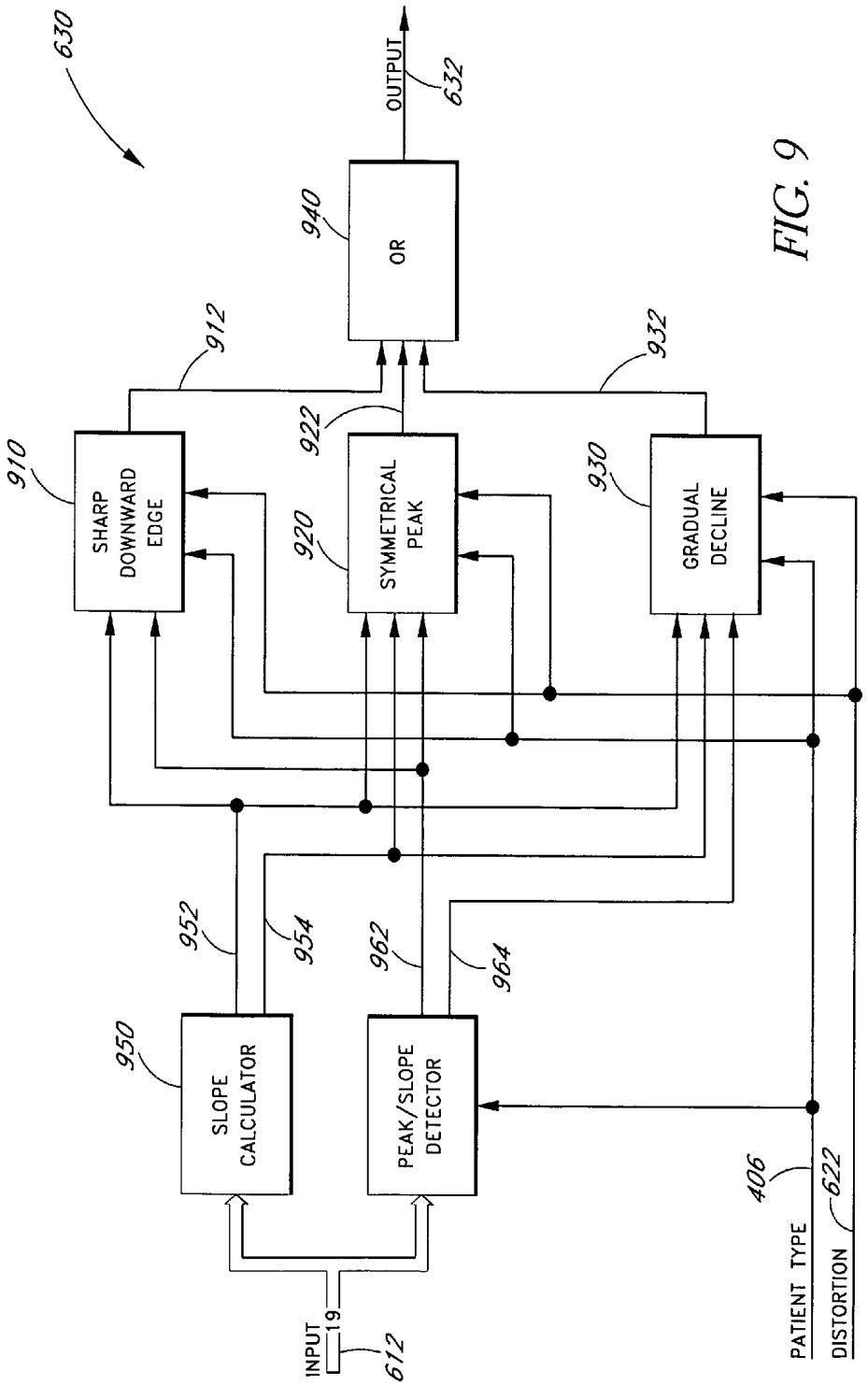

630
OUTPUT
632
940
OR
912
932
922
910
SHARP DOWNWARD EDGE
920
SYMMETRICAL PEAK
930
GRADUAL DECLINE
952
954
962
964
950
SLOPE CALCULATOR
PEAK/SLOPE DETECTOR
406
PATIENT TYPE
622
DISTORTION
INPUT
19
612

FIG. 9

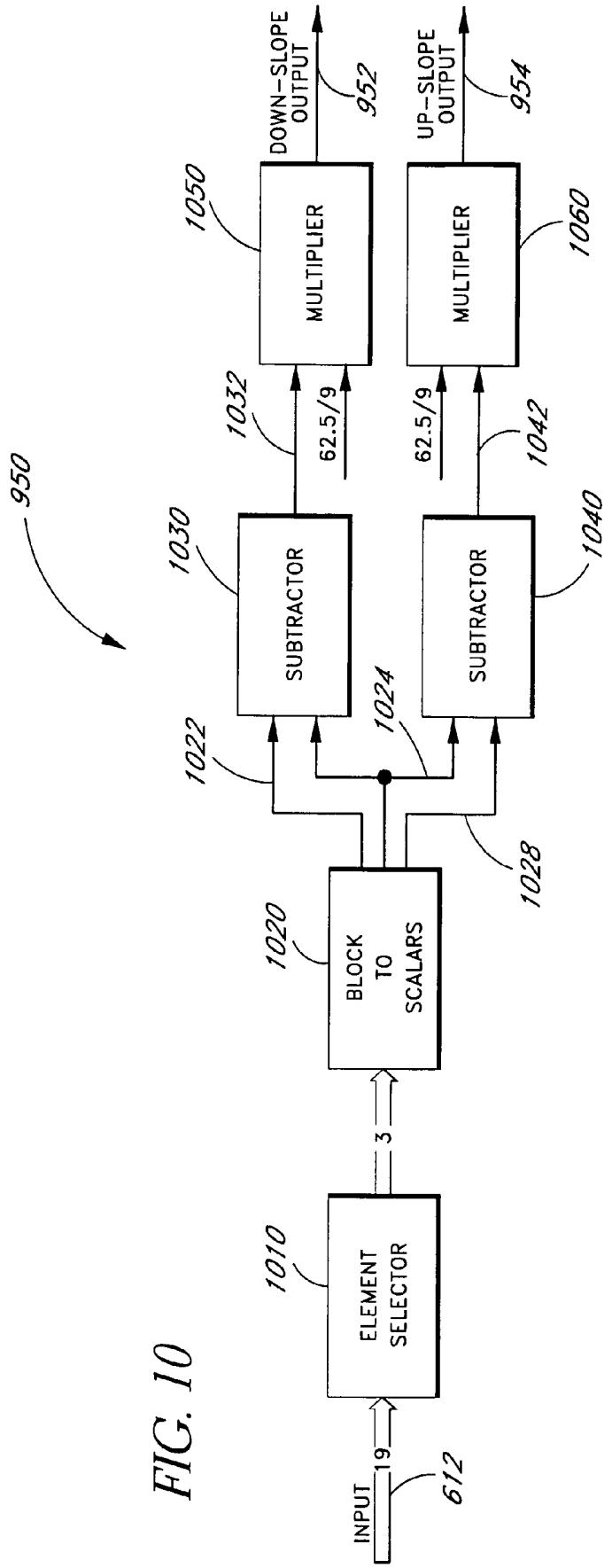

950
INPUT
19
612
ELEMENT SELECTOR
1010
3
BLOCK TO SCALARS
1020
1028
1022
1024
SUBTRACTOR
1030
SUBTRACTOR
1040
62.5/9
1032
62.5/9
1042
MULTIPLIER
1050
MULTIPLIER
1060
DOWN-SLOPE OUTPUT
952
UP-SLOPE OUTPUT
954

FIG. 10

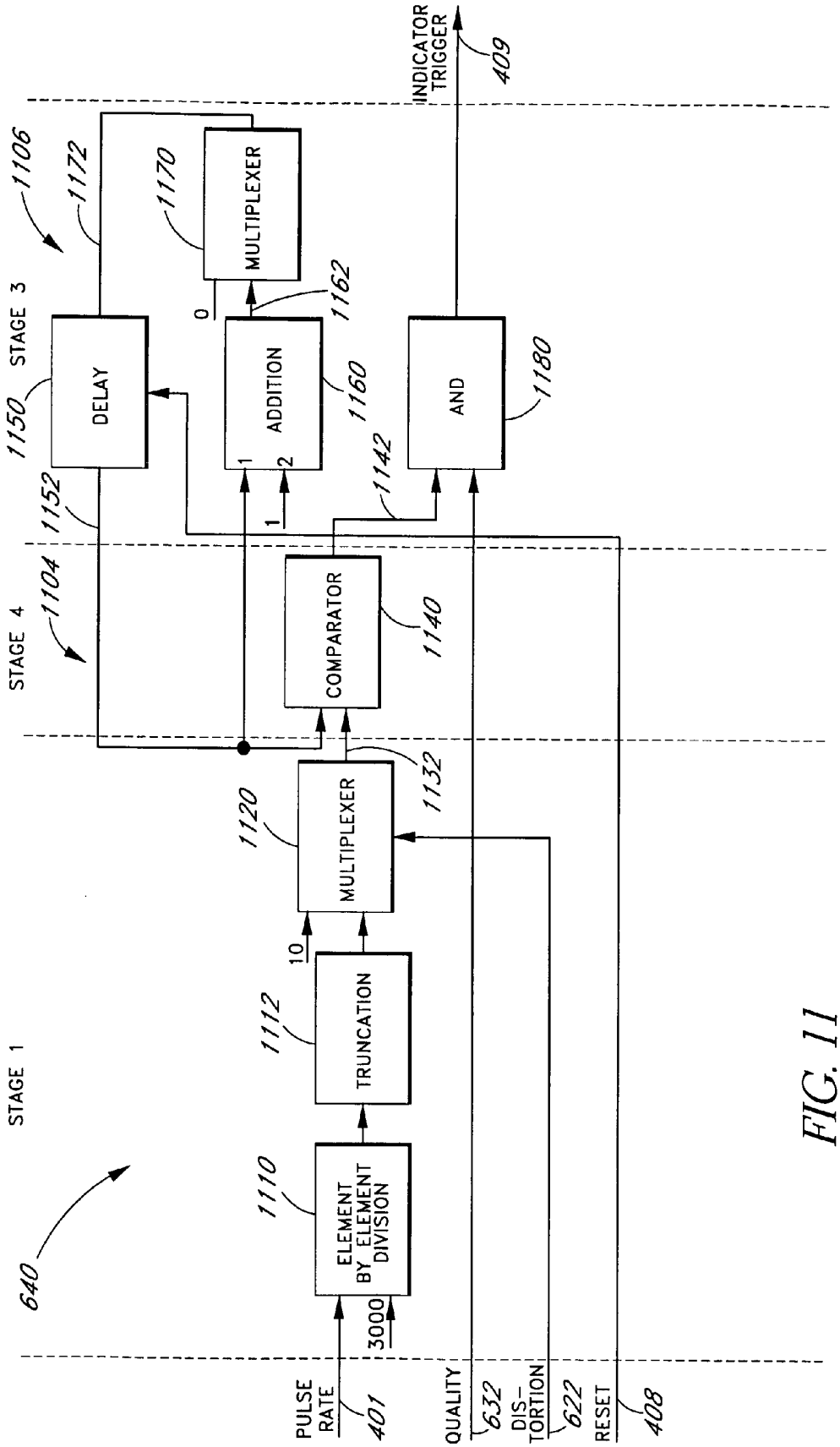

640
STAGE 1
STAGE 3
STAGE 4
1106
1172
1170
MULTIPLEXER
1162
0
INDICATOR TRIGGER
409
1150
DELAY
ADDITION
1160
1
2
AND
1180
1142
1152
1104
COMPARATOR
1140
1120
MULTIPLEXER
1132
10
1112
TRUNCATION
1110
ELEMENT BY ELEMENT DIVISION
3000
PULSE RATE
401
QUALITY
632
DIS-TORTION
622
RESET
408

FIG. 11

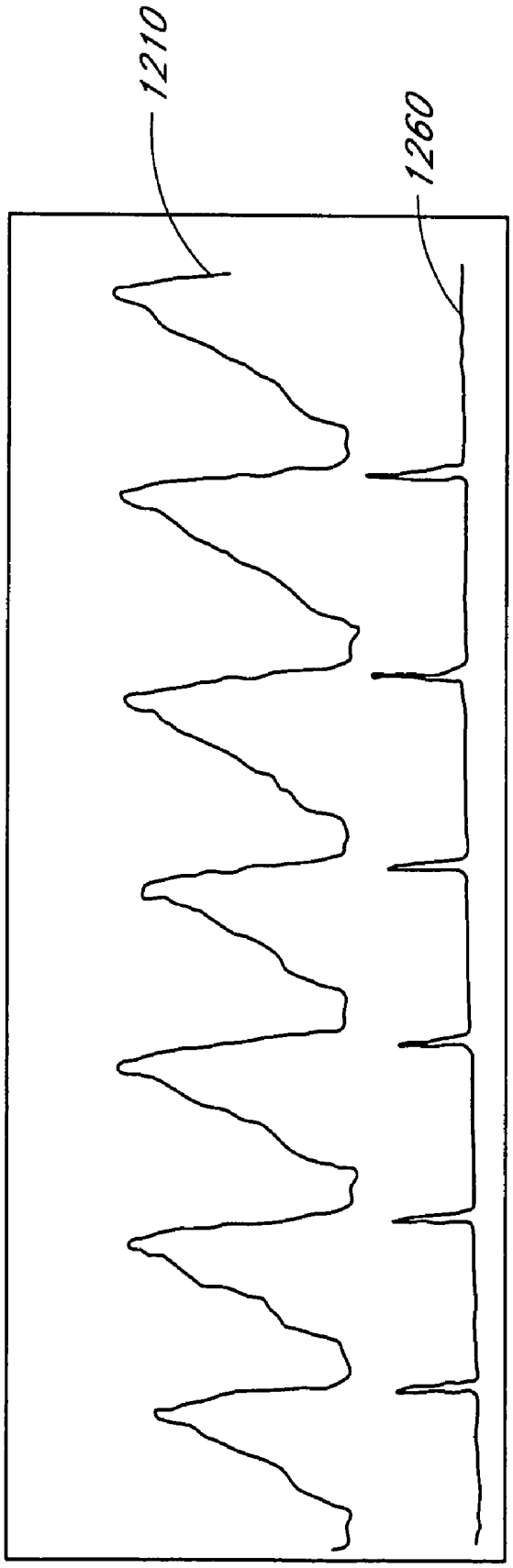


FIG. 12

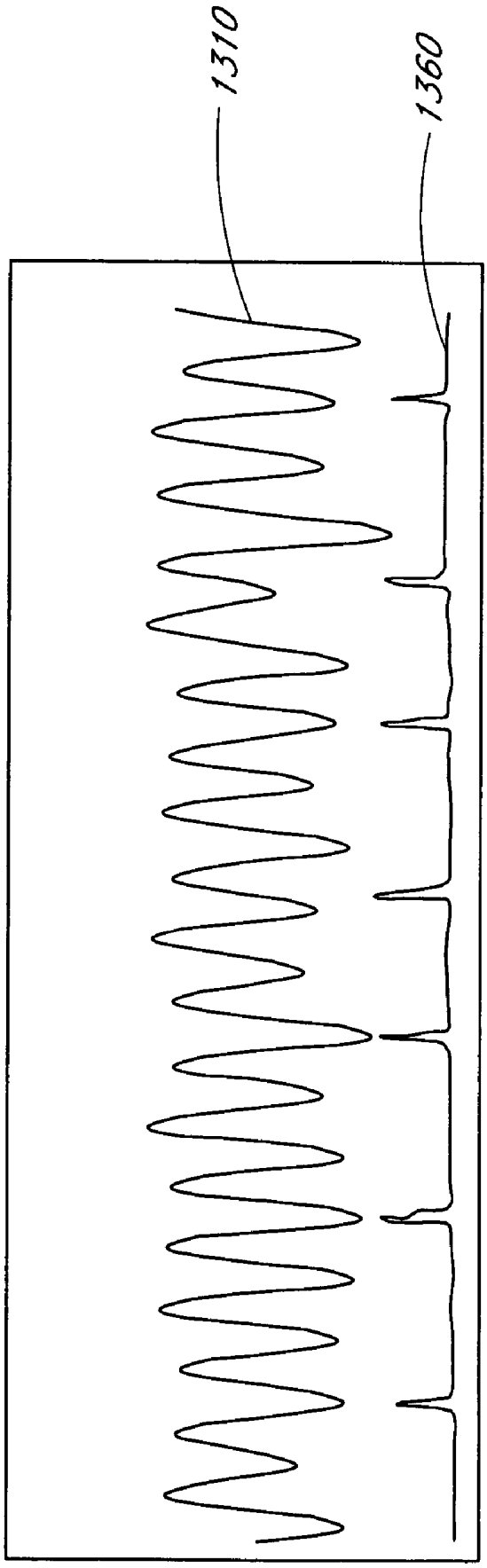


FIG. 13

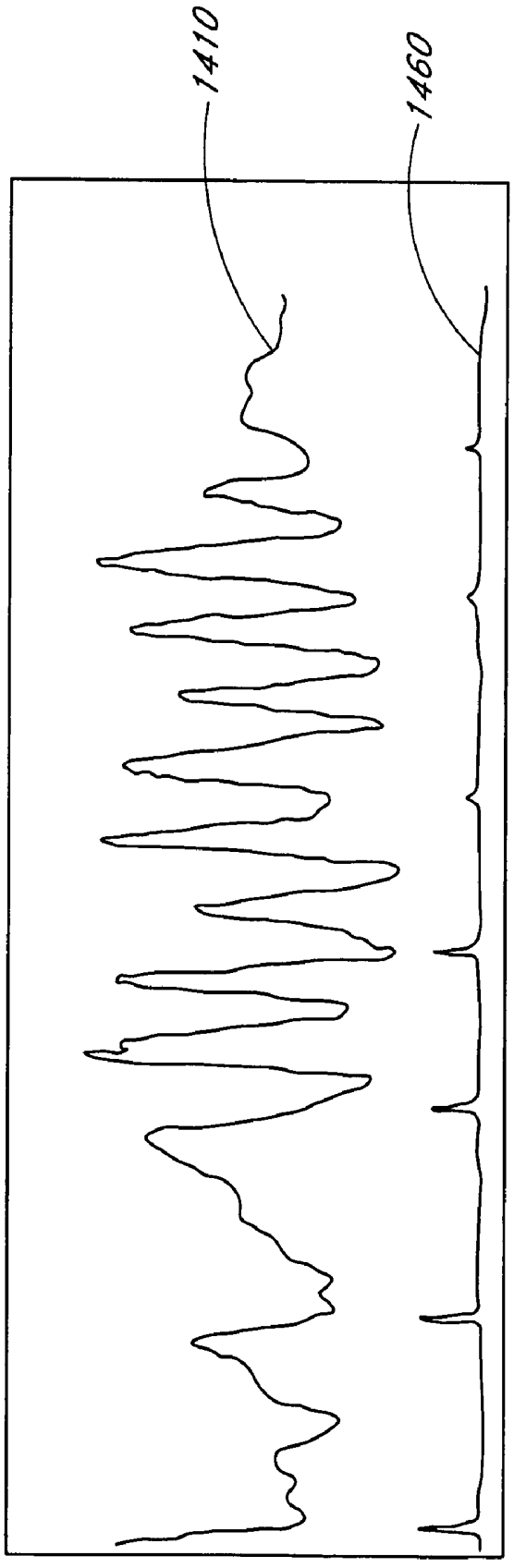


FIG. 14

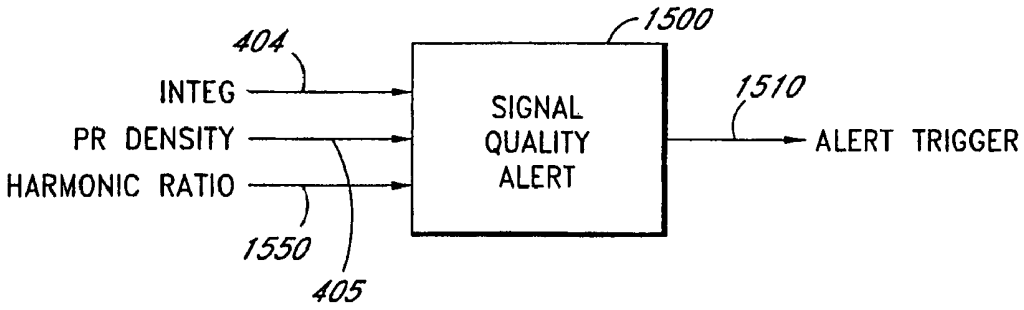

404
INTEG
PR DENSITY
HARMONIC RATIO
1550
405
1500
SIGNAL
QUALITY
ALERT
1510
ALERT TRIGGER

FIG. 15

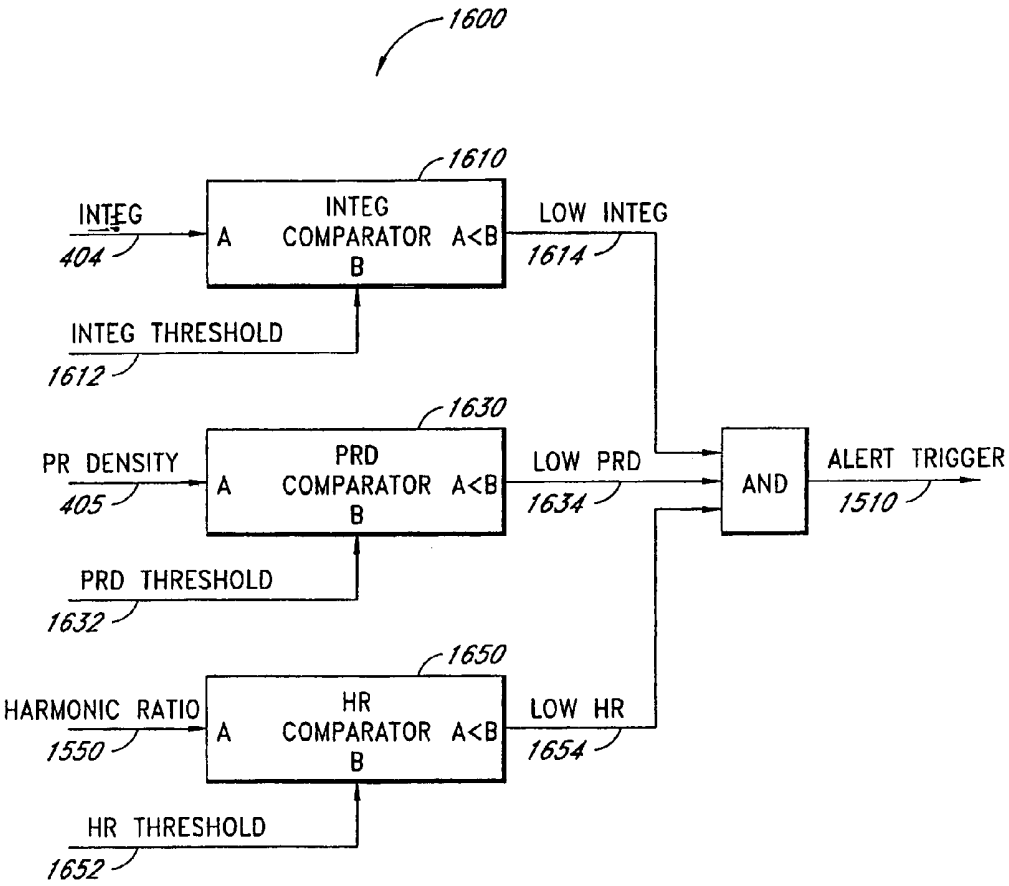

1600
1610
INTEG
404
A
INTEG COMPARATOR A<B
B
LOW INTEG
1614
INTEG THRESHOLD
1612
1630
PR DENSITY
405
A
PRD COMPARATOR A<B
B
LOW PRD
1634
AND
ALERT TRIGGER
1510
PRD THRESHOLD
1632
1650
HARMONIC RATIO
1550
A
HR COMPARATOR A<B
B
LOW HR
1654
HR THRESHOLD
1652

FIG. 16

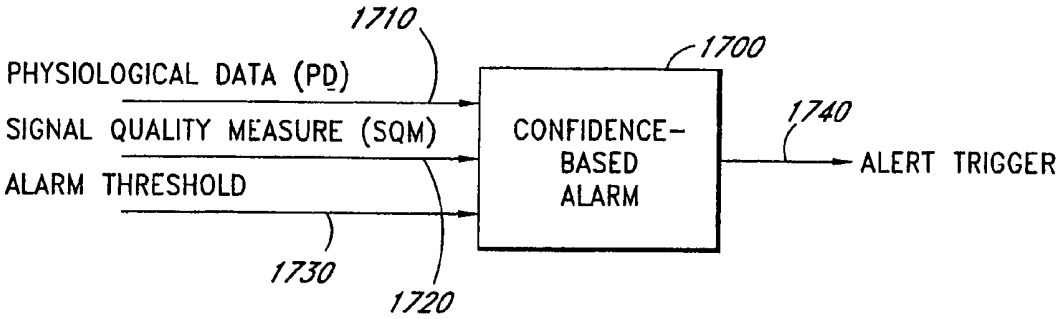

1710
1700
PHYSIOLOGICAL DATA (PD)
SIGNAL QUALITY MEASURE (SQM)
ALARM THRESHOLD
CONFIDENCE-BASED ALARM
1740
ALERT TRIGGER
1730
1720

FIG. 17

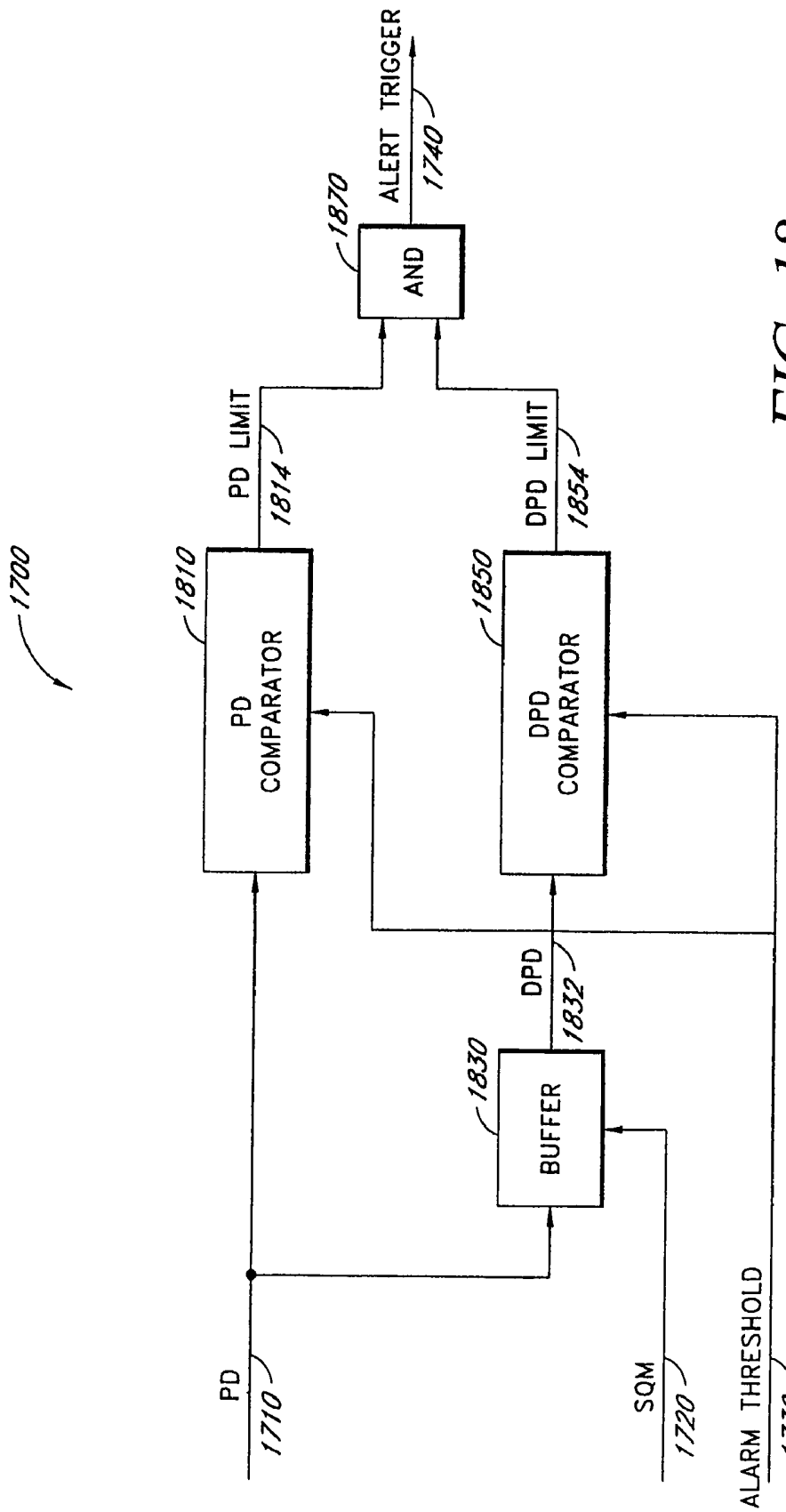

1700
PD
1710
SQM
1720
ALARM THRESHOLD
1730
BUFFER
1830
DPD
1832
PD
COMPARATOR
1810
PD LIMIT
1814
DPD
COMPARATOR
1850
DPD LIMIT
1854
AND
1870
ALERT TRIGGER
1740

FIG. 18

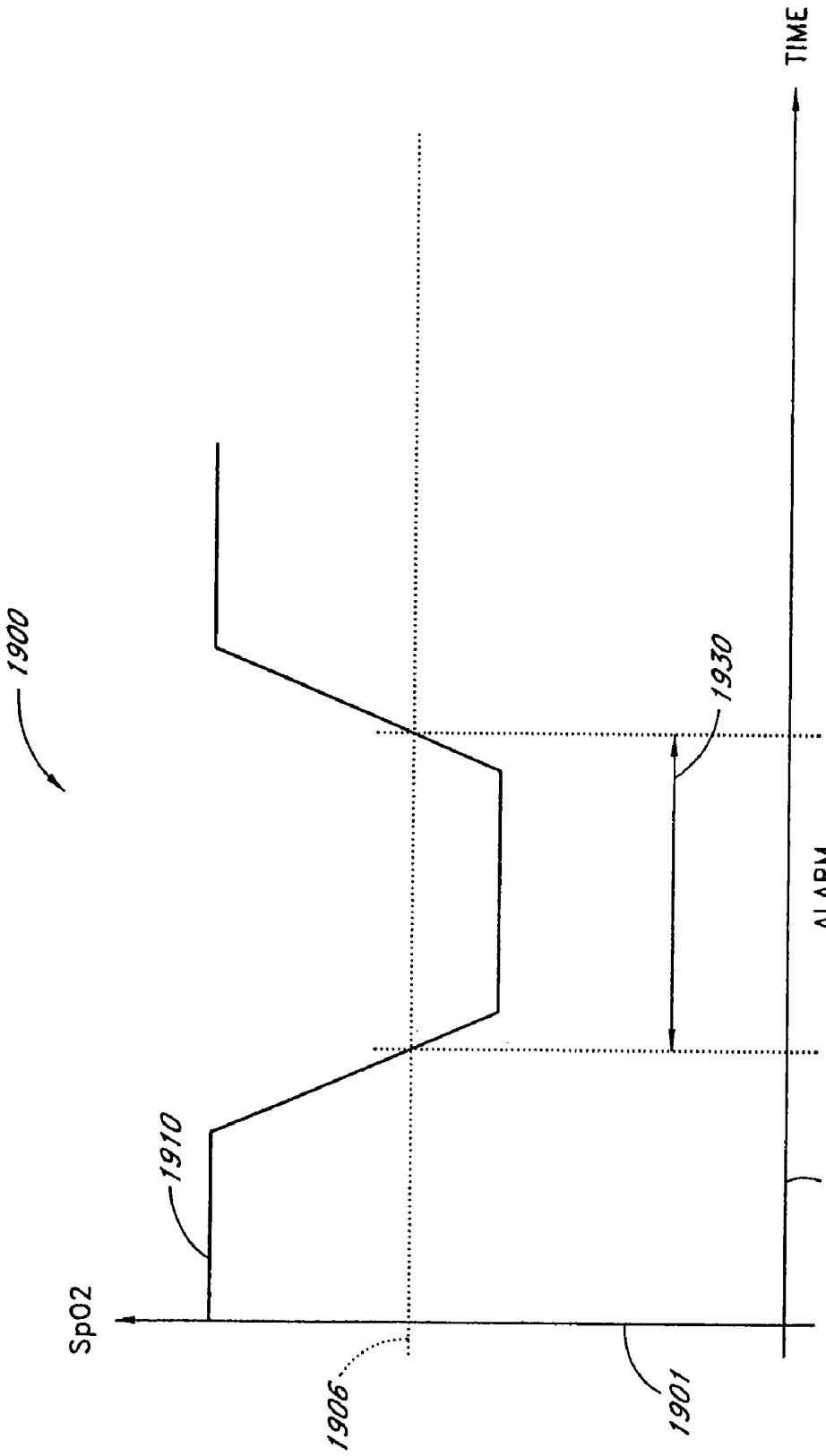


FIG. 19A

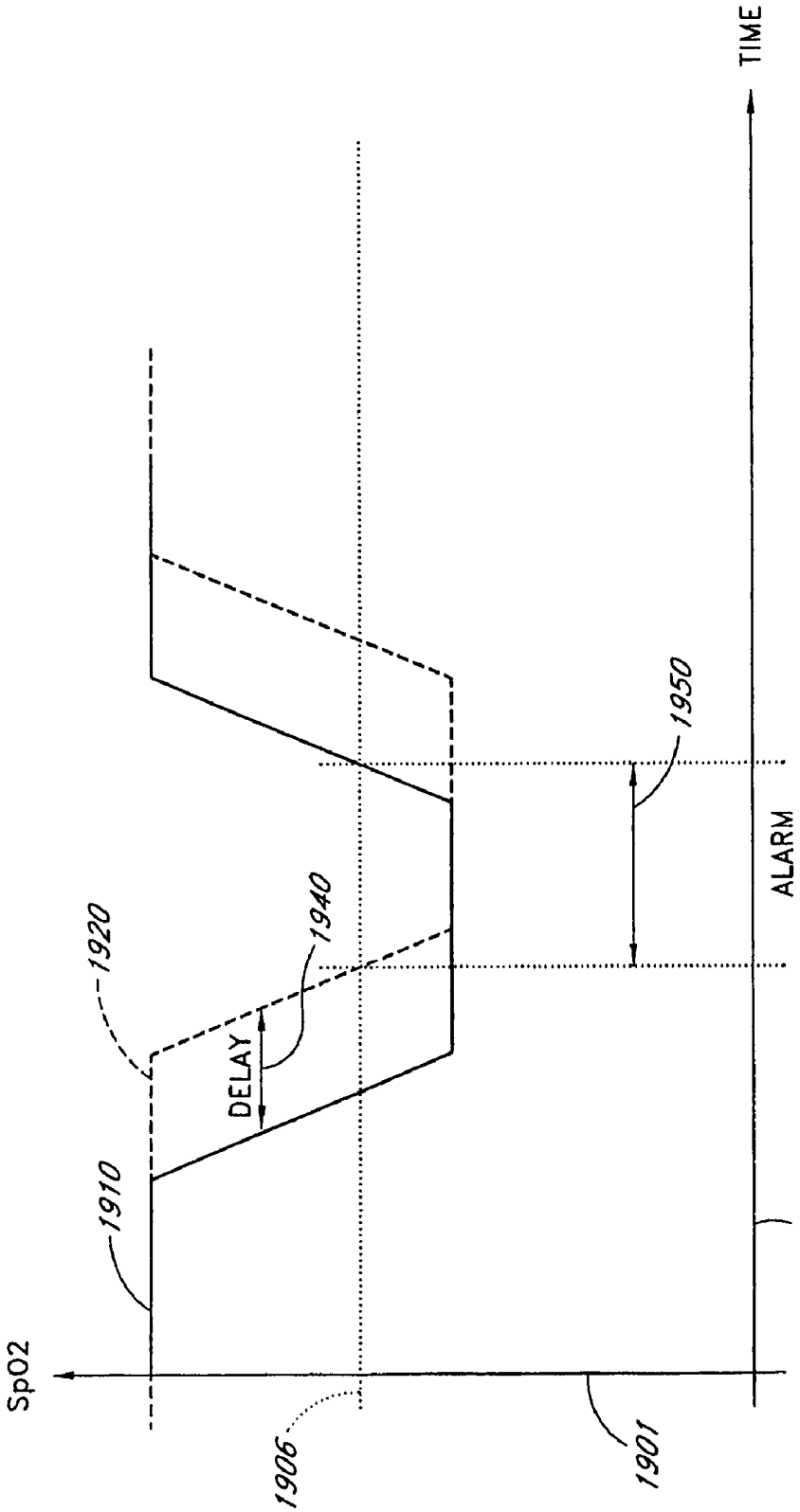

1900
1920
1940
1950
DELAY
ALARM
1910
1902
SpO2
TIME
1906
1901

FIG. 19B

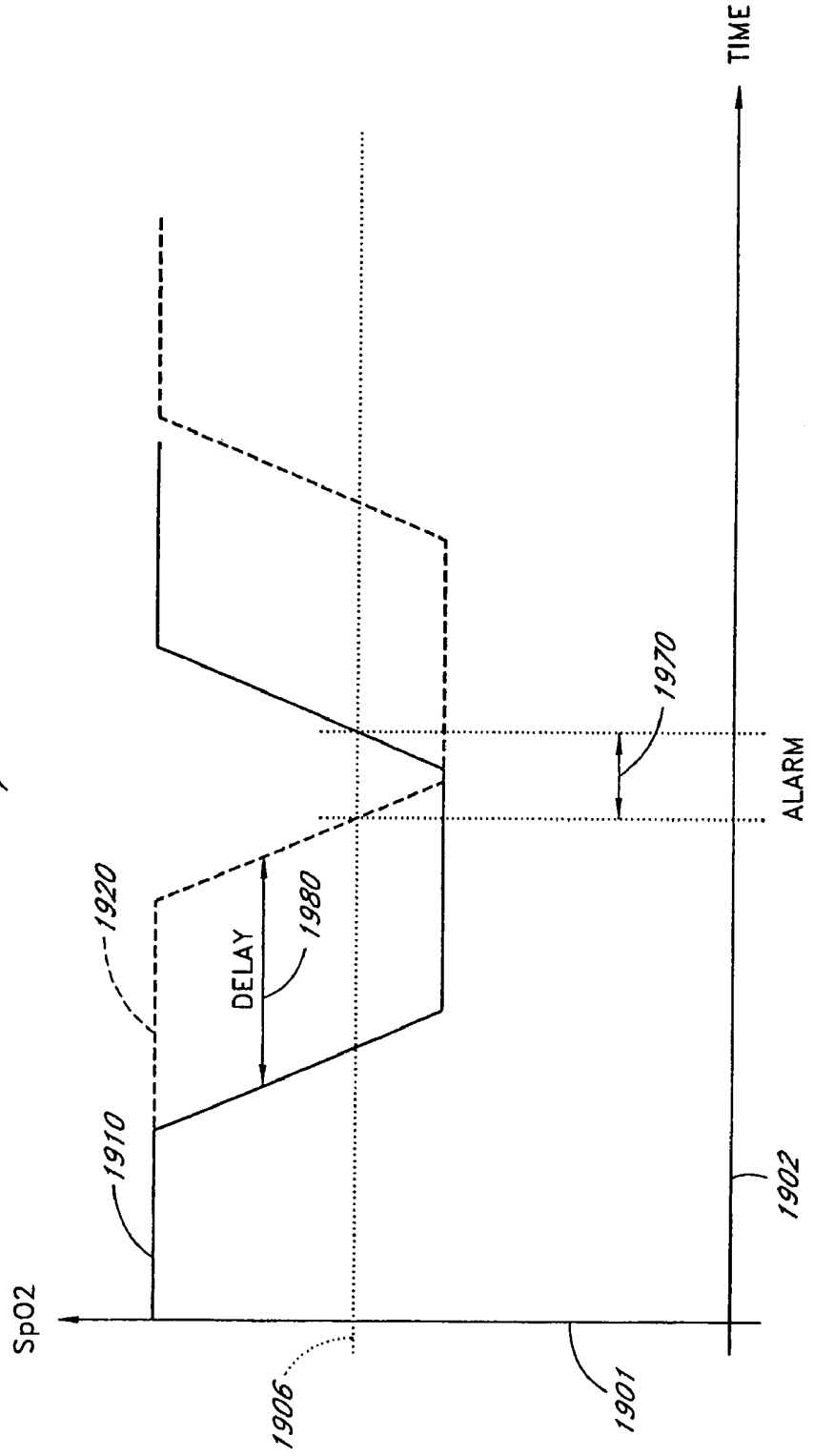

1900
TIME
1970
ALARM
1920
DELAY
1980
1910
SpO2
1902
1906
1901

FIG. 19C

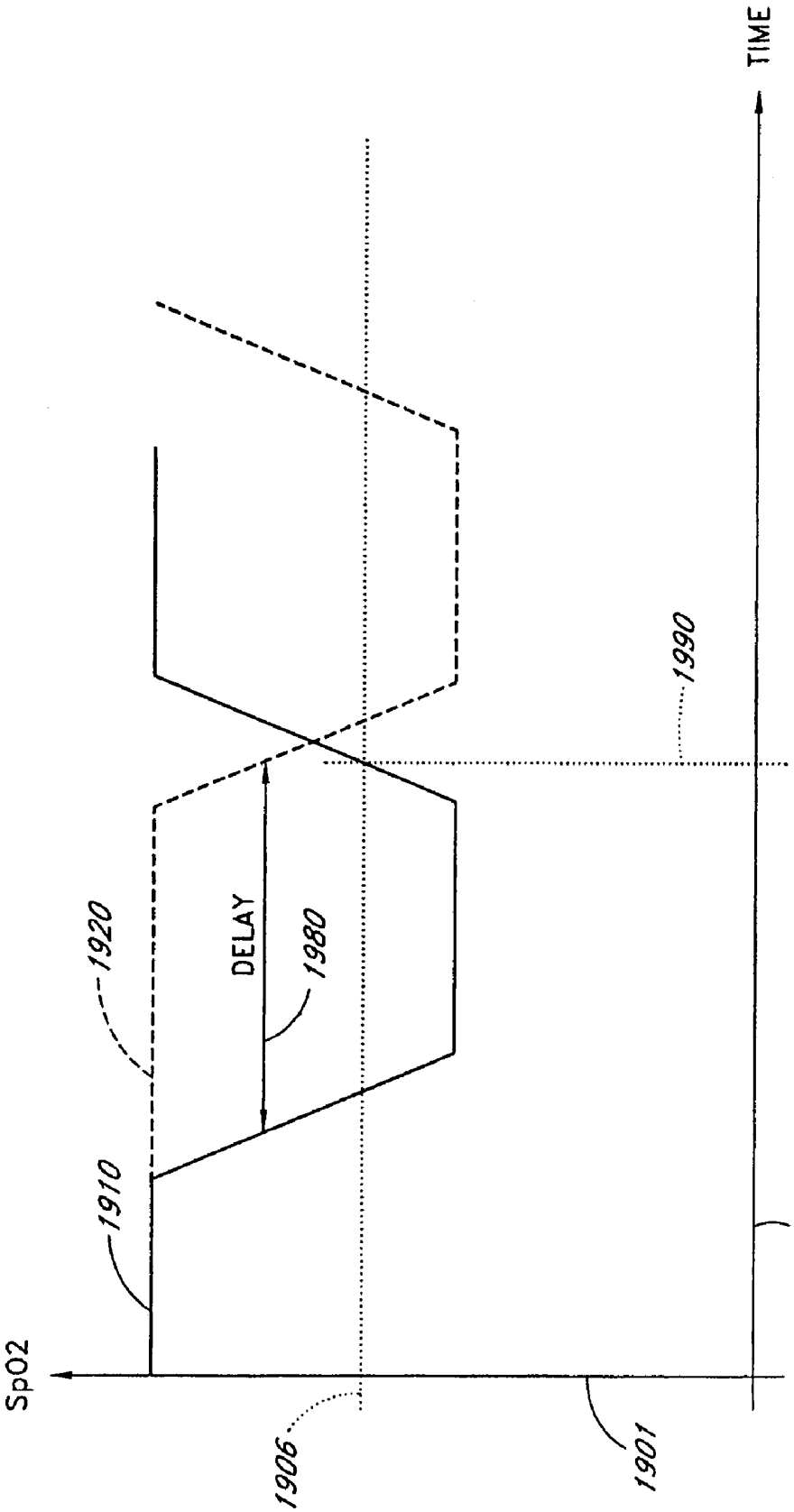

1900
TIME
1990
NO ALARM
1920
DELAY
1980
1910
1902
SpO2
1906
1901

FIG. 19D

PULSE OXIMETRY DATA CONFIDENCE INDICATOR

This application is a continuation of application Ser. No. 10/739,794, filed Dec. 18, 2003, which is a continuation of application Ser. No. 09/858,114, filed May 15, 2001 now U.S. Pat. No. 6,684,090, which is a continuation-in-part of application Ser. No. 09/478,230, filed Jan. 6, 2000 now U.S. Pat. No. 6,606,511, which claims the benefit of U.S. Provisional Application No. 60/115,289, filed Jan. 7, 1999, which applications are herein incorporated by reference in their entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This application generally relates to devices and methods for measuring physiological data, and more particularly to devices and methods of presenting this data.

2. Description of the Related Art

Oximetry is the measurement of the oxygen status of blood. Early detection of low blood oxygen is critical in the medical field, for example in critical care and surgical applications, because an insufficient supply of oxygen can result in brain damage and death in a matter of minutes. Pulse oximetry is a widely accepted noninvasive procedure for measuring the oxygen saturation level of arterial blood, an indicator of oxygen supply. A pulse oximeter typically provides a numerical readout of the patient's oxygen saturation, a numerical readout of pulse rate, and an audible indicator or "beep" that occurs in response to each pulse. In addition, a pulse oximeter may display the patient's plethysmograph waveform, which is a visualization of blood volume change in the illuminated tissue caused by pulsatile arterial blood flow over time. The plethysmograph provides a visual display that is also indicative of the patient's pulse and pulse rate.

A pulse oximetry system consists of a sensor attached to a patient, a monitor, and a cable connecting the sensor and monitor. Conventionally, a pulse oximetry sensor has both red and infrared (IR) light-emitting diode (LED) emitters and a photodiode detector. The sensor is typically attached to a patient's finger or toe, or a very young patient's patient's foot. For a finger, the sensor is configured so that the emitters project light through the fingernail and into the blood vessels and capillaries underneath. The photodiode is positioned at the fingertip opposite the fingernail so as to detect the LED transmitted light as it emerges from the finger tissues.

The pulse oximetry monitor (pulse oximeter) determines oxygen saturation by computing the differential absorption by arterial blood of the two wavelengths emitted by the sensor. The pulse oximeter alternately activates the sensor LED emitters and reads the resulting current generated by the photodiode detector. This current is proportional to the intensity of the detected light. The pulse oximeter calculates a ratio of detected red and infrared intensities, and an arterial oxygen saturation value is empirically determined based on the ratio obtained. The pulse oximeter contains circuitry for controlling the sensor, processing the sensor signals and displaying the patient's oxygen saturation and pulse rate. A pulse oximeter is described in U.S. Pat. No. 5,632,272 assigned to the assignee of the present invention.

SUMMARY OF THE INVENTION

FIG. **1** illustrates the standard plethysmograph waveform **100**, which can be derived from a pulse oximeter. The

waveform **100** is a display of blood volume, shown along the y-axis **110**, over time, shown along the x-axis **120**. The shape of the plethysmograph waveform **100** is a function of physiological conditions including heart stroke volume, pressure gradient, arterial elasticity and peripheral resistance. The ideal waveform **100** displays a broad peripheral flow curve, with a short, steep inflow phase **130** followed by a 3 to 4 times longer outflow phase **140**. The inflow phase **130** is the result of tissue distention by the rapid blood volume inflow during ventricular systole. During the outflow phase **140**, blood flow continues into the vascular bed during diastole. The end diastolic baseline **150** indicates the minimum basal tissue perfusion. During the outflow phase **140** is a dicrotic notch **160**, the nature of which is disputed. Classically, the dicrotic notch **160** is attributed to closure of the aortic valve at the end of ventricular systole. However, it may also be the result of reflection from the periphery of an initial, fast propagating, pressure pulse that occurs upon the opening of the aortic valve and that precedes the arterial flow wave. A double dicrotic notch can sometimes be observed, although its explanation is obscure, possibly the result of reflections reaching the sensor at different times.

FIGS. **2**–**4** illustrate plethysmograph waveforms **200**, **310**, **360** that display various anomalies. In FIG. **2**, the waveform **200** displays two arrhythmias **210**, **220**. In FIG. **3**, the waveform **310** illustrates distortion corrupting a conventional plethysmograph **100** (FIG. **1**). FIG. **4** shows a filtered waveform **360** after distortion has been removed through adaptive filtering, such as described in U.S. Pat. No. 5,632,272 cited above. FIG. **4** illustrates that, although the waveform **360** is filtered, the resulting pulses **362** have shapes that are distorted in comparison to the pulses illustrated in FIG. **1**.

A desirable feature of pulse oximeters is an audible "beep" tone produced to correspond to the patient's pulse. Conventionally, the beep is triggered from recognition of some aspect of the plethysmograph waveform shape. Such a waveform-triggered beep may indicate an arrhythmia, like those displayed in FIG. **2**, but may also generate false pulse indications as the result of motion-artifact or noise induced waveform distortion, as illustrated in FIGS. **3** and **4**. This characteristic results because both distortion and arrhythmias result in anomalies in the plethysmograph waveform shape on which this beep mechanism is dependent. Alternatively, the beep can be triggered from a time base set to the average pulse rate. Signal processing can generate an average pulse rate that is resistant to distortion induced error. A pulse beep based on average pulse rate is relatively insensitive to episodes of distortion, but is likewise insensitive to arrhythmias.

An example of the determination of pulse rate in the presence of distortion is described in U.S. Pat. No. 6,002,952, filed Apr. 14, 1997, entitled "Signal Processing Apparatus and Method," which is assigned to the assignee of the current application and incorporated by reference herein. Another example of pulse rate determination in the presence of distortion is described in U.S. patent application Ser. No. 09/471,510, filed Dec. 23, 1999, entitled "Plethysmograph Pulse Recognition Processor," which is assigned to the assignee of the current application and incorporated by reference herein.

One aspect of the present invention is a processor having a decision element that determines if the waveform has little or no distortion or significant distortion. If there is little distortion, the decision element provides a trigger in real-time with physiologically acceptable pulses recognized by a waveform analyzer. If there is significant distortion, then the

decision element provides the trigger based synchronized to an averaged pulse rate, provided waveform pulses are detected. The trigger can be used to generate an audible pulse beep that is insensitive to episodes of significant distortion, but is capable of responding to arrhythmia events.

Another desirable feature for pulse oximeters is a visual indication of the patient's pulse. Conventionally, this is provided by an amplitude-versus-time display of the plethysmograph waveform, such as illustrated in FIG. **1**. Some monitors are only capable of a light-bar display of the plethysmograph amplitude. Regardless, both types of displays provide a sufficient indication of the patient's pulse only when there is relatively small distortion of the plethysmograph waveform. When there is significant distortion, such as illustrated in FIG. **3**A, the display provides practically no information regarding the patient's pulse.

Yet another desirable feature for pulse oximeters is an indication of confidence in the input data. Conventionally, a visual display of a plethysmograph waveform that shows relatively small distortion would convey a high confidence level in the input data and a corresponding high confidence in the saturation and pulse rate outputs of the pulse oximeter. However, a distorted waveform does not necessarily indicate low confidence in the input data and resulting saturation and pulse rate outputs, especially if the pulse oximeter is designed to function in the presence of motion-artifact.

Another aspect of the current invention is the generation of a data integrity indicator that is used in conjunction with the decision element trigger referenced above to create a visual pulse indicator. The visual pulse indicator is an amplitude-versus-time display that can be provided in conjunction with the plethysmograph waveform display. The trigger is used to generate a amplitude spike synchronous to a plethysmograph pulse. The data integrity indicator varies the amplitude of the spike in proportion to confidence in the measured values.

Yet another aspect of the present invention is a processing apparatus that has as an input a plethysmograph waveform containing a plurality of pulses. The processor generates a trigger synchronous with the occurrence of the pulses. The processor includes a waveform analyzer having the waveform as an input and responsive to the shape of the pulses. The processor also includes a decision element responsive to the waveform analyzer output when the waveform is substantially undistorted and responsive to pulse rate when the waveform is substantially distorted. The trigger can be used to generate an audible or visual indicator of pulse occurrence. A measure of data integrity can also be used to vary the audible or visual indicators to provide a simultaneous indication of confidence in measured values, such as oxygen saturation and pulse rate.

A further aspect of the current invention is a method of indicating a pulse in a plethysmograph waveform. The method includes the steps of deriving a measure of distortion in the waveform, establishing a trigger criterion dependent on that measure, determining whether the trigger criterion is satisfied to provide a trigger, and generating a pulse indication upon occurrence of the trigger. The deriving step includes the sub-steps of computing a first value related to the waveform integrity, computing a second value related to the recognizable pulses in the waveform, and combining the first and second values to derive the distortion measure. The trigger criterion is based on waveform shape and possibly on an averaged pulse rate.

One more aspect of the current invention is an apparatus for indicating the occurrence of pulses in a plethysmograph waveform. This apparatus includes a waveform analyzer means for recognizing a physiological pulse in the waveform. Also included is a detector means for determining a measure of distortion in the waveform and a decision means for triggering an audible or visual pulse indicator. The decision means is based the physiological pulse and possibly the pulse rate, depending on the distortion measure.

Another aspect of the present invention is a data confidence indicator comprising a plurality of physiological data and a plurality of signal quality measures derived from a physiological sensor output. A plurality of comparator outputs are each responsive to one of the measures and a corresponding one of a plurality of thresholds. An alert trigger output combines said comparator outputs, and a low signal quality warning is generated in response to said alert trigger output. The thresholds are set so that the warning occurs during a time period when there is low confidence in the data. In one embodiment, the warning is a display message that supplements a visual pulse indicator, the display message specifies a low signal quality when the visual pulse indicator has an amplitude that is less than one-third full-scale. In another embodiment, the signal quality measures are an integrity measure, a pulse rate density measure and a harmonic ratio measure. In a particular embodiment, the thresholds may have an integrity value of less than 0.3, a pulse rate density value of less than 0.7 and a harmonic ratio value of less than 0.8.

In yet another embodiment a filter for the data generates a smoothed data output. An adjustment for the smoothed data output is a function of at least one of the signal quality measures so that smoothing at the smoothed data output increases when at least one of the signal quality measures decreases. An alarm trigger is responsive to the smoothed data output so as to generate an alarm when the smoothed data output is outside of a predetermined limit. In a particular embodiment the filter comprises a buffer having a buffer input and a delay output. The buffer input corresponds to the data and the delay output is time-shifted according to the adjustment. A first filter comparator output is responsive to the data and a data threshold, and a second filter comparator output is responsive to the delay output and a delay output threshold. The comparator outputs are combined so as to provide the alarm trigger.

A further aspect of the present invention is a data confidence indicator comprising a processor configured to derive a time-dependent physiological data set and a plurality of time-dependent signal quality measures from a physiological signal. A buffer is configured to time-shift the data set by a delay to generate a delayed data set, where the delay is a function of at least one of the signal quality measures. The indicator has a threshold setting a limit for the delayed data set. A warning is generated when the levels of the data set and the delayed data set are beyond that threshold. In one embodiment, a first comparator output is responsive to the data and the threshold, and a second comparator output is responsive to the delayed data set and the threshold. A combination of the first and second comparator outputs provides an alarm trigger for the warning. The data confidence indicator may also comprise a combination of the signal quality measures providing an alert trigger to generate warning when confidence in the data set is low.

An additional aspect of the present invention is a data confidence indication method comprising the steps of acquiring a signal from a physiological sensor, calculating a physiological data set from the signal, calculating signal quality measures from the signal, and indicating on a display the confidence in the data set based upon at least one of the signal quality measures. The indicating step may have the

substeps of utilizing the signal quality measures to detect a low signal quality period during which time the data set may be compromised, and writing an alert message on the display during at least a portion of that period. Additional utilizing substeps may include comparing each of the signal quality measures to a corresponding one of a plurality of thresholds to generate a plurality of trigger inputs and combining the trigger inputs to trigger a low signal quality warning. Additional steps may include setting an alarm limit for the data set, filtering the data set to generate an alarm trigger based upon the alarm limit and adjusting the characteristics of the filtering step according to at least one of the signal quality measures so that more filtering is applied during the low signal quality period. In one embodiment, the filtering step comprises the substeps of time-shifting the data set to create a delayed data set, comparing the data set to a threshold to generate a first trigger input, comparing the delayed data set to the threshold to generate a second trigger input, and combining the trigger inputs to generate the alarm trigger.

Yet a further aspect of the present invention is a data confidence indication method comprising the steps of acquiring a signal from a physiological sensor, calculating a physiological data set from the signal, calculating a plurality of signal quality measures from the signal, setting an alarm threshold for the data set, and delaying an alarm trigger when the data set exceeds the threshold as a function of at least one of the signal quality measures so as to reduce the probability of false alarms. In one embodiment, the delaying step comprises the substeps of time-shifting the data set by a delay to generate a delayed data set, where the delay is a function of at least one of said signal quality measures, and comparing the data set to the threshold to create a first limit output. Further substeps include comparing the delayed data set to the threshold to create a second limit output and combining the limit outputs to generate the alarm trigger. The data confidence indication method may further comprise the steps of comparing each of the signal quality measures to a corresponding one of a plurality of thresholds to generate a plurality of trigger inputs and combining the trigger inputs to trigger a low signal quality warning.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates a standard plethysmograph waveform that can be derived from a pulse oximeter;

FIG. **2** illustrates a plethysmograph waveform showing an arrhythmia;

FIG. **3**A illustrates a plethysmograph waveform corrupted by distortion;

FIG. **3**B illustrates a filtered plethysmograph corresponding to the distortion-corrupted plethysmograph of FIG. **3**A;

FIG. **4** illustrates the inputs and outputs of the pulse indicator according to the present invention;

FIGS. **5**A–B illustrate the generation of one of the pulse indicator inputs;

FIG. **6** is a top-level block diagram of the pulse indicator;

FIG. **7** is a detailed block diagram of the "distortion level" portion of the pulse indicator;

FIG. **8** is a block diagram of the infinite impulse response (IIR) filters of the "distortion level" portion illustrated in FIG. **7**;

FIG. **9** is a detailed block diagram of the "waveform analyzer" portion of the pulse indicator;

FIG. **10** is a detailed block diagram of the "slope calculator" portion of the waveform analyzer illustrated in FIG. **9**;

FIG. **11** is a detailed block diagram of the "indicator decision" portion of the pulse indicator;

FIG. **12** is a display illustrating a normal plethysmograph and a corresponding visual pulse indicator;

FIG. **13** is a display illustrating a distorted plethysmograph and a corresponding high-confidence-level visual pulse indicator;

FIG. **14** is a display illustrating a distorted plethysmograph and a corresponding low-confidence-level visual pulse indicator;

FIG. **15** is an input and output block diagram of a signal quality alert;

FIG. **16** is a functional block diagram of a signal quality alert;

FIG. **17** is an input and output block diagram of a confidence-based alarm;

FIG. **18** is a functional block diagram of a confidence-based alarm; and

FIGS. **19**A–D are saturation versus time graphs illustrating operation of a confidence-based alarm.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. **4** illustrates a pulse indicator **400**, which can be incorporated into a pulse oximeter to trigger the occurrence of a synchronous indication of each of the patient's arterial pulses. The indicator **400** operates on an IR signal input **403** and generates a trigger output **409** and an amplitude output **410**. The trigger output **409** can be connected to a tone generator within the pulse oximeter monitor to create a fixed-duration audible "beep" as a pulse indication. Alternatively, or in addition, the trigger output can be connected to a display generator within the pulse oximeter monitor to create a visual pulse indication. The visual pulse indication can be a continuous horizontal trace on a CRT, LCD display or similar display device, where vertical spikes occur in the trace synchronously with the patient's pulse, as described in more detail below. Alternatively, the visual pulse indication can be a bar display, such as a vertically- or horizontally-arranged stack of LEDs or similar display device, where the bar pulses synchronously with the patient's pulse.

The amplitude output **410** is used to vary the audible or visual indications so as to designate input data integrity and a corresponding confidence in the saturation and pulse rate outputs of the pulse oximeter. For example, the height of the vertical spike can be varied in proportion to the amplitude output **410**, where a large or small vertical spike would correspondingly designate high or low confidence. As another example, the amplitude output **410** can be used to vary the volume of the audible beep or to change the visual indication (e.g., change color or the like) to similarly designate a high or low confidence. One of ordinary skill in the art will recognize that the trigger output **409** and amplitude output **410** can be utilized to generate a variety of audible and visual indications of a patient's pulse and data integrity within the scope of this invention.

Other inputs to the pulse indicator **400** include pulse rate **401**, Integ **404**, PR density **405**, patient type **406** and reset **408**, which are described in detail below. The beep decision involves a rule-based process that advantageously responds to the pulse waveforms of the patient's plethysmograph in low-noise or no-distortion situations, but becomes dependent an averaged pulse rate during high-noise or distortion situations. This "intelligent beep" reliably indicates the patient's pulse, yet responds to patient arrhythmias, asystole conditions and similar irregular plethysmographs.

The pulse rate input **401** to the pulse indicator **400** provides the frequency of the patient's pulse rate in beats per

minute. Pulse rate can be determined as described in U.S. Pat. No. 6,002,952 "Signal Processing Apparatus and Method" or U.S. patent application Ser. No. 09/471,510 "Plethysmograph Pulse Recognition Processor," both cited above.

FIG. **5**A illustrates the generation of the Integ input **404** to the pulse indicator **400** (FIG. **4**). The IR **403** and Red **502** signals derived from a pulse oximetry sensor are input to an adaptive noise canceller **500** having Integ **404** as an output. The Integ output **404** is a measure of the integrity of the IR **403** and Red **502** input signals.

FIG. **5**B illustrates the adaptive noise canceller **500**. The reference input **502** is processed by an adaptive filter **520** that automatically adjusts its own impulse response through a least-squares algorithm. The least-squares algorithm responds to an error signal **512** that is the difference **510** between the noise canceller input **403** and the adaptive filter output **522**. The adaptive filter is adjusted through the algorithm to minimize the power at the noise canceller output **404**. If the IR **403** and Red **502** signals are relatively well-behaved with respect to the theoretical model for these signals, then the noise canceller output **404** will be relatively small. This model assumes that the same frequencies are present in the signal and noise portions of the IR and Red signals. By contrast, if a phenomenon such as scattering, hardware noise, or sensor decoupling, to name a few, affects one input signal differently than the other, then the power at the noise canceller output will be relatively large. More detail about the input signal model and the adaptive noise canceller **500** is given in U.S. Pat. No. 5,632,272 entitled "Signal Processing Apparatus," issued May 27, 1997, assigned to the assignee of the current application and incorporated by reference herein.

The PR density input **405** is a ratio of the sum of the periods of recognizable pulses within a waveform segment divided by the length of the waveform segment. This parameter represents the fraction of the waveform segment that can be classified as having physiologically acceptable pulses. In one embodiment, a segment represents a snapshot of 400 samples of a filtered input waveform, or a 6.4 second "snapshot" of the IR waveform at a 62.5 Hz sampling rate. The derivation of PR density is described in the U.S. patent application Ser. No. 09/471,510 entitled "Plethysmograph Pulse Recognition Processor," cited above.

Other inputs to the pulse indicator **400** are the IR input **403**, patient type **406** and reset **408**. The IR input **403** is the detected IR signal preprocessed by taking the natural logarithm, bandpass filtering and scaling in order to normalize the signal and remove the direct current component, as is well known in the art. Patient type **406** is a Boolean value that indicates either an adult sensor or a neonate sensor is in use. Reset **408** initializes the state of the pulse indicator **400** to known values upon power-up and during periods of recalibration, such as when a new sensor is attached or a patient cable is reconnected.

FIG. **6** is a functional block diagram of the pulse indicator **400**. The pulse indicator **400** includes a shifting buffer **610**, a distortion level function **620**, a waveform analyzer **630**, and a indicator decision **640**, which together produce the indicator trigger **409**. The pulse indicator **400** also includes a scaled logarithm function **650** that produces the indicator amplitude output **410**. The shifting buffer **610** accepts the IR input **403** and provides a vector output **612** representing a fixed-size segment of the patient's plethysmograph input to the waveform analyzer **630**. In a particular embodiment, the output vector is a 19 sample segment of the IR input **403**. This waveform segment size represents a tradeoff between reducing the delay from pulse occurrence to pulse indicator, which is equal to 0.304 seconds at the 62.5 Hz input sample rate, yet providing a sufficiently large waveform segment to analyze. This fixed-sized segment is updated with each new input sample, and a new vector is provided to the waveform analyzer **630** accordingly.

The distortion level function **620** determines the amount of distortion present in the IR input signal **403**. The inputs to the distortion level function **620** are the Integ input **404** and the PR density input **405**. The distortion output **622** is a Boolean value that is "true" when distortion in the IR input **403** is above a predetermined threshold. The distortion output **622** is input to the waveform analyzer **630** and the indicator decision **640**. The distortion output **622** determines the thresholds for the waveform analyzer **630**, as described below. The distortion output **622** also affects the window size within which a pulse indication can occur, also described below. The distortion output **622** is also a function of the patient type input **406**, which indicates whether the patient is an adult or a neonate. The reason for this dependence is also described below.

The waveform analyzer **630** determines whether a particular portion of the IR input **403** is an acceptable place for a pulse indication. The input to the waveform analyzer **630** is the vector output **612** from the shifting buffer **610**, creating a waveform segment. A waveform segment portion meets the acceptance criteria for a pulse when it satisfies one of three conditions. These conditions are a sharp downward edge, a peak in the middle with symmetry with respect to the peak, and a peak in the middle with a gradual decline. If one of these criteria is met, the waveform analyzer "quality" output **632** is "true." Different criteria are applied depending on the state of the distortion output **622**, which is also a waveform analyzer input. If the distortion output **622** indicates no distortion, strict criteria are applied to the waveform shape. If the distortion output **622** indicates distortion, looser criteria are applied to the waveform shape. Different criteria are also applied for waveforms obtained from adult and neonate patients, as indicated by the patient type **406**. The specific criteria are described in further detail below.

The indicator decision **640** determines whether to trigger a pulse indication at a particular sample point of the input waveform. Specifically, the indicator decision **640** determines if it is the right place to trigger a pulse indication on the input waveform and if the time from the last pulse indication was long enough so that it is the right time to trigger another pulse indication. The decision as to the right place to trigger a pulse indication is a function of the analyzer output **632**, which is one input to the indicator decision **640**. The decision as to the right time for an indicator trigger is a function of the state of the distortion output **622**, which is another input to the indicator decision **640**. If the distortion output **622** is "false", i.e. no distortion is detected in the input waveform, then a fixed minimum time gap from the last indicator must occur. In a particular embodiment, this minimum time gap is 10 samples. If the distortion output **622** is "true", i.e. distortion is detected in the input waveform, then the minimum time gap is a function of the pulse rate input **401**. This pulse rate dependent threshold is described in further detail below.

FIG. **7** is a detailed block diagram of the distortion level function **620**. The distortion level function has two stages. The first stage **702** filters the Integ and PR density inputs. The second stage **704** decides whether distortion is present based on both the filtered and the unfiltered Integ input **404** and PR density **405** inputs. The first stage components are a

first infinite impulse response (IIR) filter **710** for the Integ input **404** and a second IIR filter **720** for the PR density input **405**.

FIG. **8** illustrates the structure of the IIR filter **710**, **720** (FIG. **7**). Each of these filters has a delay element **810**, which provides a one sample delay from the delay element input **812** to the delay element output **814**. An adder **820** that sums a weighted input value **834** and a weighted feedback value **844** provides the delay element input **812**. A first multiplier **830** generates the weighted input value **834** from the product of the input **802** and a first constant **832**, c_1. A second multiplier **840** generates the weighted feedback value **844** from the product of the delay element output **814** and a second constant **842**, c_2. With this structure, the filter output **804** is:

$$\text{Output}_n = c_1 \cdot \text{Input}_n + c_2 \cdot \text{Output}_{n-1} \quad (1)$$

That is, the nth output **804** is the weighted average of the input and the previous output, the amount of averaging being determined by the relative values of c_1 and c_2.

As shown in FIG. **7**, the two IIR filters **710**, **720** each apply different relative weights to the input signal. In one embodiment, the weights are fixed for the Integ filter **710** and are a function of the patient type for the PR density filter **720**. In particular, for the Integ filter **710**, c_1=0.2 and c_2=0.8. For the PR density filter **720**, the combination of a multiplexer **730** and subtraction **740** set the values of c_1 and c_2 as a function of the patient type **406**. If the signal is from an adult, then c_1=0.2 and c_2=0.8. If the signal is from a neonate, then c_1=0.5, c_2=0.5. Because a neonate pulse rate is typically higher than an adult, the PR density changes less quickly and, hence, less filtering is applied.

FIG. **7** also shows the second stage **704**, which has threshold logic **750** for determining the presence of distortion. The inputs to the threshold logic **750** are Integ **404**, PR density **405**, filtered Integ **712** and filtered PR density **722**. The threshold logic **750** is also dependent on the patient type **406**. The distortion output **622** is a Boolean value that is "true" if distortion is present and "false" if no distortion is present. In one embodiment, the distortion output **622** is calculated as follows:

Adults

$$\text{distortion output} = (\text{Integ} > 0.01) + (\text{filtered Integ} > 0.0001) \cdot (\text{filtered } PR \text{ density} < 0.7) \quad (2)$$

Neonates

$$\text{distortion output} = (\text{Integ} > 0.05) + ((\text{filter Integ} > 0.005) + (PR \text{ density} = 0)) \cdot (\text{filtered } PR \text{ density} < 0.8) \quad (3)$$

where a logical "and" is designated as a multiplication "·" and a logical "inclusive or" is designated as an addition "+."

FIG. **9** is a detailed block diagram of the waveform analyzer **630**. As described above, the waveform analyzer **630** is based on three shape criteria, which are implemented with a sharp downward edge detector **910**, a symmetrical peak detector **920** and a gradual decline detector **930**. An "or" function **940** generates a waveform analyzer output **632**, which has a "true" value if any of these criteria are met. The inputs to the waveform analyzer **630** are the IR waveform samples **612** from the buffer **610** (FIG. **6**), patient type **406**, and distortion **622** output from the distortion level function **620** (FIG. **6**). The IR waveform samples **612** are a 19 sample vector representing a plethysmograph waveform segment. A slope calculator **950** and a peak/slope detector **960** provide inputs to the shape criteria components **910**, **920**, **930**.

Shown in FIG. **10**, the slope calculator **950** operates on the IR waveform samples **612** to calculate a down slope value, which is provided on a down slope output **952**, and an up slope value, which is provided on an up slope output **954**. The down slope and up slope values are defined to be, respectively, the difference between the middle point and the last and first points, scaled by a factor of 62.5/9. The scaling factor is the sampling rate, 62.5 Hz, divided by the number of samples, 9, between the middle point and end point in the 19 sample IR waveform **612**. The slope calculator **950** has an element selector **1010** that determines the center sample, the extreme left sample and the extreme right sample from the IR waveform **612**. The block-to-scalars function **1020** provides a left sample output **1022** and a center sample output **1024** to a first subtractor **1030** and the center sample output **1024** and a right sample output **1028** to a second subtractor **1040**. The first subtractor output **1032**, which is the center value minus the right sample value, is scaled by 62.5/9 by a first multiplier **1050** that generates the down slope output **952**. The second subtractor output **1042**, which is the center value minus the left sample value, is scaled by 62.5/9 by a second multiplier **1060** that generates the up slope output **954**.

Shown in FIG. **9**, the peak/slope detector **960**, like the slope calculator **950** has the IR waveform samples **612** as an input. The peak/slope detector **960** has two Boolean outputs, a peak output **962** and a slope output **964**. The peak output **962** is "true" if the input waveform contains a peak. The slope output **964** is "true" if the input waveform contains a slope. The peak output **962** and slope output **964** are also dependent on the patient type **406** to the peak/slope detector **960**. In one embodiment, the peak output **962** and slope output **964** are calculated as follows:

Adults

$$\text{peak output} = (In_9 > 0)\Pi^3_{i=1}(In_7 - In_{7-i} > 0)\Pi^9_{i=3}(In_9 - In_{9+i} > -0.05) \quad (4)$$

$$\text{slope output} = (In_9 > 0)\Pi^{18}_{i=3}(In_{i-1} - In_i > -0.005) \quad (5)$$

Neonates

$$\text{peak output} = \Pi^3_{i=1}(In_7 - In_{7-i} > 0)\Pi^9_{i=3}(In_9 - In_{9+i} > -0.05) \quad (5)$$

$$\text{slope output} = \Pi^{18}_{i=3}(In_{i-1} - In_i > -0.005) \quad (7)$$

where In_i is the ith waveform sample in the 19 sample IR waveform **612**.

FIG. **9** shows the sharp downward edge detector **910**, which is the sub-component of the waveform analyzer **630** that determines whether the shape of the input waveform segment meets the sharp downward edge criteria. To do this, the edge detector **910** determines whether the down slope value is bigger than a certain threshold and whether a peak is present. The edge detector **910** has as inputs the down slope output **952** from the slope calculator **950**, the peak output **962** from the slope/peak detector **960**, the distortion output **622** from the distortion level function **620** (FIG. **6**) and the patient type **406**. The edge detector output **912** is a Boolean value that is "true" when the waveform shape criteria is met. In one embodiment, the edge detector output **912** is calculated as follows:

Adults and No Distortion

$$\text{edge output} = (\text{down slope output} > 3) \cdot \text{peak output} \quad (8)$$

Neonates and No Distortion

$$\text{edge output} = (\text{down slope value} > 1) \cdot \text{peak output} \quad (9)$$

Distortion (Adults or Neonates)

edge output=(down slope value>0.65)·peak output (10)

FIG. **9** also shows the symmetrical peak detector **920**, which is the sub-component of the waveform analyzer **630** that determines whether the waveform contains a symmetrical peak. To do this, the symmetrical peak detector **920** checks whether the down slope and up slope values are bigger than a certain threshold, if the difference between their magnitudes is small, and if a peak is present. The symmetrical peak detector **920** has as inputs the down slope output **952** and the up slope output **954** from the slope calculator **950**, the peak output **962** from the slope/peak detector **960**, the distortion output **622** from the distortion level function **620** (FIG. **6**) and the patient type **406**. The symmetrical peak output **922** is a Boolean value that is "true" when the waveform shape criteria is met. In one embodiment, the symmetrical peak output **922** is defined as follows:

Adults

symmetrical peak output=false (11)

Neonates and No Distortion

symmetrical peak output=(down slope>1)·(up slope>1)·(|down slope−up slope|≦0.5)·peak (12)

Neonates and Distortion

symmetrical peak output=(down slope>0.35)·(up slope>0.35)·(|down slope−up slope|≦0.5)·peak (13)

FIG. **9** further shows the gradual decline detector **930**, which is the sub-component of the waveform analyzer **630** that determines whether the waveform contains a gradual decline. To do this, the decline detector **930** checks whether the difference between the down slope and the up slope values is in between two thresholds and if a slope is present. The decline detector **930** has as inputs the down slope output **952** and the up slope output **954** from the slope calculator **950**, the slope output **964** from the slope/peak detector **960**, the distortion output **622** from the distortion level function **620** (FIG. **6**) and the patient type **406**. The decline output **932** is a Boolean value that is "true" when the waveform shape criteria is met. In one embodiment, the decline output **932** is defined as follows:

Adults and No Distortion

decline=(3<(down slope−up slope)<6)·slope (14)

Neonates and No Distortion

decline=(0.5<(down slope−up slope)<2)·slope (15)

Distortion (Adults or Neonates)

decline=(0.5<(down slope−up slope)<8)·slope (16)

FIG. **11** is a detailed block diagram of the indicator decision **640** sub-component. The first stage **1102** of the indicator decision **640** determines a minimum time gap after which a pulse indicator can occur. The second stage **1104** determines whether the number of samples since the last indicator is greater than the minimum allowed pulse gap. The third stage **1106** decides whether to generate a pulse indicator trigger. If no trigger occurs, a sample count is incremented. If an indicator trigger occurs, the sample count is reset to zero.

As shown in FIG. **11**, the first stage **1102** has a divider **1110**, a truncation **1120** and a first multiplexer **1130**. These components function to set the minimum allowable gap between pulse indications. Under no distortion, the minimum gap is 10 samples. Under distortion, the gap is determined by the pulse rate. Specifically, under distortion, the minimum gap is set at 80% of the number of samples between pulses as determined by the pulse rate input **401**. This is computed as 0.8 times the sample frequency, 62.5 Hz., divided by the pulse rate in pulses per second, or:

min. gap=0.8×(60/pulse rate)×62.5=3000/pulse rate (17)

The divider **1110** computes 3000/pulse rate. The divider output **1112** is truncated **1120** to an integer value. The first multiplexer **1130** selects the minimum gap as either 10 samples if the distortion input **622** is "false" or the truncated value of 3000/pulse rate if the distortion input **622** is "true." The selected value is provided on the multiplexer output **1132**, which is fed to the second stage **1104**. The second stage **1104** is a comparator **1140**, which provides a Boolean output **1142** that is "true" if a counter output **1152** has a value that is equal to or greater than the minimum gap value provided at the first multiplexer output **1132**.

FIG. **11** also illustrates the third stage **1106**, which has a counter and an "and" function. The counter comprises a delay element **1150** providing the counter output **1152**, an adder **1160** and a second multiplexer **1170**. When the counter is initialized, the second multiplexer **1170** provides a zero value on the multiplexer output **1172**. The multiplexer output **1172** is input to the delay element, which delays the multiplexer output value by one sample period before providing this value at the counter output **1152**. The counter output **1152** is incremented by one by the adder **1160**. The adder output **1162** is input to the second multiplexer **1162**, which selects the adder output **1162** as the multiplexer output **1172** except when the counter is initialized, as described above. The counter is initialized to zero when the pulse indicator trigger **409** is "true" as determined by the output of the "and" element **1180**. The "and" **1180** generates a "true" output only when the comparator output **1142** is "true" and the quality output **632** from the waveform analyzer **630** (FIG. **6**) is also "true."

Visual Pulse Indicator

With motion, a plethysmograph displayed on a pulse oximeter is often distorted and may be obscured by artifact. With the advent of pulse oximeters that can accurately calculate saturation during motion, the plethysmograph alone is not a sufficient indicator of arterial pulses or signal quality. A visual pulse indicator according to the present invention can supplement the plethysmograph display to identify the occurrence of a patient's pulse and also indicate confidence in the computed values of saturation and pulse rate. The visual pulse indicator, shown as vertical lines coinciding with the peak of arterial pulsations, indicates a patient's pulse even when the plethysmograph is distorted or obscured by artifact. The height of the vertical line indicates data integrity. A high vertical line indicates confidence in the saturation and pulse rate measurements, whereas a small vertical bar indicates lowered confidence.

FIGS. **12**–**14** illustrate a visual pulse indicator generated in response to the indicator trigger output **409** (FIG. **4**) and indicator amplitude output **410** of the pulse indicator **400** (FIG. **4**). In FIG. **12**, the top trace **1210** is an exemplar plethysmograph waveform without significant distortion. The bottom trace **1260** is a corresponding visual pulse indication comprising a series of relatively large amplitude spikes that are generally synchronous to the falling edges of the input waveform **1210**. Because the input waveform **1210** has low distortion, the pulse indication **1260** is somewhat redundant, i.e. pulse occurrence and data confidence is

apparent from the input waveform alone. Nevertheless, FIG. **12** illustrates the visual pulse indicator according to the present invention.

In FIG. **13**, the plethysmograph waveform illustrated in the top trace **1330** displays significant distortion. In contrast to the example of FIG. **12**, pulse occurrence and data confidence is not obvious from the input waveform alone. The corresponding visual pulse indicator **1360**, however, indicates pulse occurrence at the location of the display spikes. Further, the relatively large spike amplitude indicates high data integrity and a corresponding high confidence in the computed values of pulse rate and saturation despite the waveform distortion.

In FIG. **14**, the plethysmograph waveform **1410** also displays significant distortion. In contrast to the example of FIG. **13**, the visual pulse indicator **1460** displays relatively low amplitude spikes corresponding to the latter half of the waveform sample, indicating relatively low data integrity and low confidence in the computed pulse rate and saturation.

Signal Quality Alert

FIGS. **15–16** illustrate the generation of a caregiver alert that supplements the visual pulse indicator described with respect to FIGS. **12–14**, above. When signal quality is very low, the accuracy of the computed pulse rate and saturation may be compromised and a caregiver warning is warranted. The alert may be a display message, an alarm having a unique tone or some other form of visual or audible method of drawing the attention of the caregiver.

As shown in FIG. **15**, a signal quality alert **1500** has an alert trigger output **1510** and integ **404**, PR density **405** and harmonic ratio **1550** inputs. Integ **404** and PR density **405** are described with respect to FIG. **4**, above. The harmonic ratio **1550** is derived from the ratio of the plethysmograph signal energy contained in frequency bands around the heart rate fundamental frequency and its harmonics divided by the total signal energy. The harmonic ratio provides a measure of signal quality because most of the signal energy in an uncorrupted plethysmograph is at the heart rate and harmonics. The plethysmograph spectrum and associated frequency measurements are described in U.S. Pat. No. 6,002,952, cited above.

As shown in FIG. **16**, the signal quality alert **1500** has an integrity (INTEG) comparator **1610**, a PR density (PRD) comparator **1630** and a harmonic ratio (HR) comparator **1650**. Each of the comparators **1610**, **1630**, **1650** has a Boolean output **1614**, **1634**, **1654** that is asserted when an input signal quality measure **404**, **405**, **1550** falls below a corresponding threshold **1612**, **1632**, **1652**. In particular, the INTEG comparator **1610** has a low INTEG output **1614** that is asserted when signal integrity falls below the INTEG threshold **1612**. Also, the PRD comparator **1630** has a low PRD output **1634** that is asserted when the PR density **405** falls below the PR density threshold **1632**. Further, the HR comparator **1650** has a low HR output **1654** that is asserted when the harmonic ratio **1550** falls below the HR threshold **1652**.

Also shown in FIG. **16**, the comparator outputs **1614**, **1634**, **1654** are combined with a logical AND to generate an alert trigger output **1510**. In particular, the alert trigger output **1510** is a Boolean value asserted when all of the low signal quality outputs **1614**, **1634**, **1654** are asserted. In this manner, the alert trigger **1510** is responsive to a combination of signal quality measures **404**, **405**, **1550** and is triggered when these measures all indicate a very low signal quality, as determined by the threshold inputs **1612**, **1632**, **1652**. In one embodiment, each of the signal quality measures **404**, **405**, **1550** vary between 0 and 1, and the INTEG threshold **1612** is set at 0.3; the PRD threshold **1632** is set at 0.7 and the HR threshold **1652** is set at 0.8.

Although the signal quality alert has been described with respect to a combination of the signal quality measures integrity, pulse rate density and harmonic ratio, the signal quality alert could also be triggered based upon other measures related to the level of signal distortion or corruption, motion artifact, or noise. Further, although the signal quality alert has been described with respect to a logical AND combination of these signal quality measures compared with corresponding thresholds, various other combinations of these or other measures related to the level of signal distortion or corruption, motion artifact, or noise could be used to trigger a signal quality alert. For example, an OR combination of signal quality measures each compared to a different threshold could be used to trigger an alert. As another example, an arithmetic combination of signal quality measures could be compared to a single threshold to trigger an alert. As a further example, the height of the displayed visual pulse indicator could trigger a signal quality alert if sufficiently less than full-scale, such as less than one-third full-scale.

Confidence-Based Alarm

FIGS. **17–18** illustrate a confidence-based alarm responsive to physiological data, such as oxygen saturation or pulse rate. The confidence-based alarm **1700** according to the present invention is adapted to reduce the probability of missed true alarms during high data confidence periods and to reduce the probability of false alarms during low data confidence periods. As shown in FIG. **17**, the confidence-based alarm **1700** has as inputs physiological data (PD) **1710**, signal quality measure (SQM) **1720**, and alarm threshold **1730** and an alarm trigger output **1740**. The PD input **1710** may be, for example, saturation or pulse rate data. The SQM input **1720** may be data integrity, pulse rate density, harmonic ratio, or other measures or combinations of measures related to the level of signal distortion or corruption, motion artifact, or noise. The alarm trigger **1740** initiates an audio and/or visual warning that alerts a caregiver whenever the physiological data indicates a patient's vital signs are outside of acceptable limits, as set by the alarm threshold **1730**, for example a minimum saturation or a maximum or minimum pulse rate. There may be one or more alarms **1700** in a particular pulse oximeter.

As shown in FIG. **18**, the confidence-based alarm **1700** has an PD comparator **1810**, a data buffer **1830** and a delayed PD (DPD) comparator **1850**. The PD comparator **1810** has PD **1710** and alarm threshold **1730** inputs and a PD limit **1814** output. The PD limit **1814** is a Boolean value that is asserted when the PD input **1710** exceeds, either above or below depending on the physiological measure, the alarm threshold **1730**. The data buffer **1830** acts as a delay line, time shifting the PD data **1710** by a value that is a function of the SQM input **1720** to generate the delayed PD (DPD) data **1832**. The DPD comparator has DPD **1832** and alarm threshold **1730** inputs and a DPD limit **1854** output. The DPD limit **1854** is a Boolean value that is asserted when the DPD input **1832** exceeds the alarm threshold input **1730**, similar to the PD limit **1814**. In an alternative embodiment, the threshold inputs to the PD comparator **1810** and the DPD comparator **1850** are set to different levels. The confidence-based alarm **1700** also has a logical AND that combines the PD limit **1814** and DPD limit **1854** outputs to generate the

alarm trigger **1740**. The alarm trigger **1740** is a Boolean value that is asserted when both the PD limit **1814** and the DPD limit **1854** are asserted.

Also shown in FIG. **18**, the confidence-based alarm **1700** rejects those features of the physiological data PD **1710** that are below the alarm limit for less duration than the data buffer **1830** delay, so as to reduce false alarms. The probably of false alarms is reduced with increasing data buffer **1830** delay. Generally, reducing the probability of false alarms increases the probability of missed true alarms. Advantageously, the buffer delay is a function of a signal quality measure **1720**, so that the probability of false alarms is reduced when signal quality is low and the probability of missed true alarms is reduced when signal quality is high.

FIGS. **19**A–D illustrate the operation of one embodiment of a confidence-based alarm according to the present invention. FIG. **19**A illustrates an alarm with zero delay. FIGS. **19**B–D illustrate an alarm with increasing amounts of delay. FIG. **19**A is a chart **1900** having a vertical axis **1901** of saturation (SpO_2) and a horizontal axis **1902** of time. An alarm threshold **1906** is shown along the vertical axis **1901**, corresponding to the alarm threshold input **1730** (FIG. **17**). Depicted is saturation data **1910** corresponding to the PD **1710** (FIG. **17**). An alarm is immediately triggered when saturation data **1910** falls below the alarm threshold **1906**, and the duration of the alarm is the period of time the saturation data is below the threshold **1906**.

FIG. **19**B is an identical chart **1900** as described above, but depicting delayed saturation data **1920** corresponding to DPD **1832** (FIG. **18**) that is time-shifted from the saturation data **1910** by a short delay **1940**. In this example, both the saturation **1910** and the delayed saturation **1920** are below the alarm threshold **1906** during a time period **1950**. During this time period **1950**, the alarm trigger **1740** (FIG. **17**) is asserted to generate an audio and/or visual warning that a desaturation event is occurring. The onset of the alarm is delayed **1940**, as compared with FIG. **19**A. The alarm functions similarly to a low pass filter that smoothes the saturation data **1910**, preventing desaturation events that are less than the delay **1940** from triggering an alarm, as described with respect to FIG. **19**D, below.

FIG. **19**C is an identical chart **1900** as described above, but with the delayed saturation data **1920** time-shifted from the saturation data **1910** by a medium delay **1960**. In this example, during the entire time period **1970** when the saturation data **1910** is below the alarm threshold **1906**, the delayed saturation data **1920** is also below the threshold **1906**. Thus, the alarm trigger **1740** (FIG. **17**) would be asserted and a warning would be generated.

FIG. **19**D is an identical chart **1900** as described above, but with the delayed saturation data **1920** time-shifted from the saturation data **1910** by a long delay **1980**. In this example, at the time point **1990** when the saturation **1910** rises above the alarm threshold **1906**, the delayed saturation **1920** has yet to fall below the threshold **1906**. Thus, the alarm trigger **1740** (FIG. **17**) would not be asserted and no warning would be generated. FIGS. **19**A–D illustrate that the effect of an increasing data buffer delay is to increasingly delay the onset of the alarm trigger **1740** (FIG. **17**) and to increasingly filter-out or smooth a relatively short drop in saturation **1910**, which may be a false alarm during low signal quality conditions. Although the confidence-based alarm **1700** (FIG. **17**) is described above in terms of an alarm delay to reduce false alarms, where the delay is a function of signal quality, one of ordinary skill in the art will recognize that the scope of present invention encompasses other mechanisms for reducing false alarms that are a function of physiological data confidence.

A pulse oximetry data confidence indicator has been disclosed in detail in connection with various embodiments of the present invention. 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 modifications within the scope of this invention.

What is claimed is:

1. A method of providing a caregiver with a visual evaluation tool helpful in determining an indication of signal quality, the method comprising:

acquiring a physiological signal from a physiological sensor capable of detecting light attenuated by body tissue carrying blood;

measuring a signal quality of said physiological signal;

generating a trace indicative of a physiological parameter and responsive to said physiological signal on a display; and

varying a color of said trace so as to indicate said signal quality of the physiological signal.

2. The method of claim **1**, wherein the trace includes a visual indication of a pulse of the blood in the body tissue.

3. The method of claim **1**, further comprising generating a bar graph so as to indicate the signal quality.

4. The method of claim **3**, wherein the step of generating the bar graph further comprises pulsing the bar graph with a pulse of the patient.

5. The method of claim **3**, wherein the step of generating the bar graph further comprises varying a height of the bar graph to indicate the signal quality.

6. The method of claim **5**, wherein the step of varying the height of the bar graph further comprises raising the height of the bar graph as the signal quality becomes more positive and lowering the height of the bar graph as the signal quality becomes less positive.

7. The method of claim **1**, further comprising generating an audible alert in response to the signal quality.

8. The method of claim **7**, wherein the step of generating an audible alert further comprises varying a volume of the audible alert in response to the signal quality.

9. The method of claim **7**, wherein the audible alert comprises a plurality of beeps.

10. A method of providing a caregiver with a visual evaluation tool helpful in determining an indication of signal quality, the method comprising:

acquiring a signal from a physiological sensor capable of detecting light attenuated by body tissue carrying blood;

measuring a signal quality of said signal;

generating a trace responsive to said signal on a display;

varying a color of said trace so as to indicate said signal quality;

generating an audible alert in response to the signal quality,

wherein the step of generating an audible alert further comprises varying a volume of the audible alert in response to the signal quality, and wherein the step of varying the volume of the audible alert further comprises raising the volume of the audible alert as the signal quality becomes more positive and lowering the volume of the audible alert as the signal quality becomes less positive.

11. A method of altering display elements indicative of one or more parameters monitored by a patient monitoring device, the method comprising:

acquiring a physiological signal from a physiological sensor;

generating display elements, including a plethysmograph trace, in response to said physiological signal;

calculating a signal quality of said physiological signal; and

altering a color of at least the plethysmograph trace in response to the signal quality.

12. The method of claim **11**, wherein the patient monitoring device includes a pulse oximeter, and the physiological sensor includes a light sensitive detector capable of detecting light attenuated by body tissue carrying blood.

13. The method of claim **11**, further comprising: pulsing the at least one of the display elements with a pulse of a patient.

14. The method of claim **11**, wherein the step of generating display elements further includes generating a bar display.

15. The method of claim **14**, wherein the step of generating the bar display further comprises varying a height of the bar display to indicate the signal quality.

16. The method of claim **15**, wherein the step of varying the height of the bar display further comprises raising the height of the bar display as the signal quality becomes more positive and lowering the height of the bar display as the signal quality becomes less positive.

17. The method of claim **11**, further comprising generating an audible alarm in response to the signal quality.

18. A physiological monitoring device that provides a visual indication of signal quality, the device comprising:

a light sensitive detector capable of detecting light attenuated by body tissue carrying blood;

a display capable of providing a trace indicative of a physiological parameter; and

a microprocessor configured to receive a physiological signal from the light sensitive detector and generate the trace on the display in response to said physiological signal, said microprocessor also configured to measure a signal quality of the physiological signal and vary a color of the trace so as to indicate the signal quality.

19. The device of claim **18**, wherein the trace pulses with a pulse of the blood in the body tissue.

20. The device of claim **18**, wherein the display further includes a bar graph.

21. The device of claim **20**, wherein the microprocessor is configured to vary a height of the bar graph to indicate the signal quality.

22. The device of claim **21**, wherein the microprocessor raises the height of the bar graph to indicate greater signal quality and lowers the height of the bar graph to indicate lower signal quality.

23. The device of claim **18**, further comprising an audible transducer for generating an audible alert.

24. The device of claim **23**, wherein the microprocessor instructs the audible transducer to generate an audible alert in response to the signal quality.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,024,233 B2
APPLICATION NO. : 10/942672
DATED : April 4, 2006
INVENTOR(S) : Ammar Al-Ali et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 1, Line 6, after "2001" please insert -- , --.

In Column 1, Line 8, after "2000" please insert -- , --.

In Column 1, Line 43, after "young" please delete "patient's".

In Column 3, Line 33, after "generate" please delete "a" and insert -- an --, therefore.

In Column 6, Line 21, please delete "EMBODIMENT" and insert -- EMBODIMENTS --, therefore.

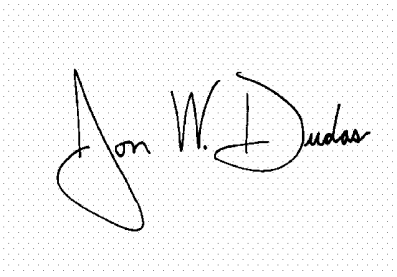
In Column 9, Line 4, please delete "filter" and insert -- filters --, therefore.

In Column 10, Line 37, please delete "i>-0.05)" and insert -- $_{i}$>0.005) --, therefore.

In Column 12, Line 5, please delete "Hz.," and insert -- Hz, --, therefore.

Signed and Sealed this

Nineteenth Day of June, 2007



JON W. DUDAS
Director of the United States Patent and Trademark Office

US007024233C1

(12) EX PARTE REEXAMINATION CERTIFICATE (9822nd)

United States Patent

Ali et al.

(10) Number: US 7,024,233 C1

(45) Certificate Issued: Sep. 3, 2013

(54) **PULSE OXIMETRY DATA CONFIDENCE INDICATOR**

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(73) Assignee: **Masimo Corporation**, Irvine, CA (US)

Reexamination Request:
No. 90/012,553, Sep. 13, 2012

Reexamination Certificate for:

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Issued:	**Apr. 4, 2006**
Appl. No.:	**10/942,672**
Filed:	**Sep. 16, 2004**

Certificate of Correction issued Jun. 19, 2007

Related U.S. Application Data

(63) Continuation of application No. 10/739,794, filed on Dec. 18, 2003, now Pat. No. 6,996,427, which is a continuation of application No. 09/858,114, filed on May 15, 2001, now Pat. No. 6,684,090, which is a continuation-in-part of application No. 09/478,230, filed on Jan. 6, 2000, now Pat. No. 6,606,511.

(60) Provisional application No. 60/115,289, filed on Jan. 7, 1999.

(51) **Int. Cl.**
A61B 5/00 (2006.01)
A61B 5/04 (2006.01)

(52) **U.S. Cl.**
USPC **600/323**; 600/336; 600/502

(58) **Field of Classification Search**
None
See application file for complete search history.

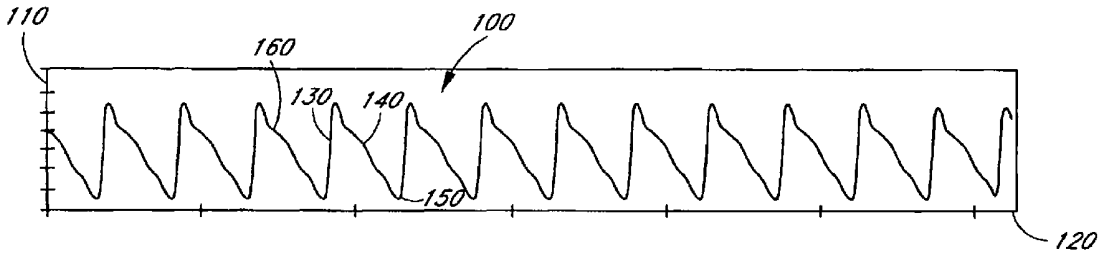
(56) **References Cited**

To view the complete listing of prior art documents cited during the proceeding for Reexamination Control Number 90/012,553, please refer to the USPTO's public Patent Application Information Retrieval (PAIR) system under the Display References tab.

Primary Examiner — Robert Nasser

(57) **ABSTRACT**

According to some embodiments of the present invention, a display is used to show a signal from a physiological sensor as well as an indication of the signal's quality. While this indication of the signal's quality may be provided in a number of ways, it is preferably provided by changing a color on the display.



EX PARTE REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

Claims **2-4**, **11-17**, **19** and **20** are cancelled.

Claims **1**, **5**, **6**, **10**, **18**, **21** and **22** are determined to be patentable as amended.

Claims **7-9** and **23-24**, dependent on an amended claim, are determined to be patentable.

New claims **25** and **26** are added and determined to be patentable.

1. A method of providing a caregiver with a visual evaluation tool helpful in determining an indication of signal quality *and a pulse during signal distortion*, the method comprising:

acquiring a physiological signal from a physiological sensor capable of detecting light attenuated by body tissue carrying blood;

measuring a signal quality of said physiological signal;

generating a continuous first trace of a blood volume change caused by pulsatile arterial blood flow over time, said first trace displaying distortion when said physiological signal includes distortion;

generating a *continuous second* trace indicative of a physiological parameter and responsive to said physiological signal on a display, *said second trace also positioned to indicate locations of pulse occurrences in said first trace at least when said first trace is displaying distortion*; and

varying a color of said *second* trace so as to indicate said signal quality of the physiological signal.

5. The method of claim **[3]** *1*, wherein the step of generating the **[**bar graph further**]** *second trace* comprises varying a height of the **[**bar graph**]** *second trace* to indicate the signal quality.

6. The method of claim **5**, wherein the step of varying the height of the **[**bar graph**]** *second trace* further comprises raising the height of the **[**bar graph**]** *second trace* as the signal quality becomes more positive and lowering the height of the **[**bar graph**]** *second trace* as the signal quality becomes less positive.

10. A method of providing a caregiver with a visual evaluation tool helpful in determining an indication of signal quality *and a pulse during signal distortion*, the method comprising:

acquiring a signal from a physiological sensor capable of detecting light attenuated by body tissue carrying blood;

measuring a signal quality of said signal;

generating a *plethysmograph* trace responsive to said signal on a display, *said plethysmograph trace displaying distortion when said signal includes distortion*;

generating a visual pulse indicator trace responsive to said signal on said display;

varying a color of said *visual pulse indicator* trace so as to indicate said signal quality;

positioning said visual pulse indicator trace on said display to identify pulse locations in said plethysmograph trace at least when said plethysmograph trace is displaying distortion; and

generating an audible alert in response to the signal quality,

wherein the step of generating an audible alert further comprises varying a volume of the audible alert in response to the signal quality, and wherein the step of varying the volume of the audible alert further comprises raising the volume of the audible alert as the signal quality becomes more positive and lowering the volume of the audible alert as the signal quality becomes less positive.

18. A physiological monitoring device that provides a visual indication of signal quality *and pulse location during signal distortion*, the device comprising:

a light sensitive detector capable of detecting light attenuated by body tissue carrying blood;

a display capable of providing a *continuous first trace and a continuous second* trace, *said first trace* indicative of a physiological parameter *and said second trace indicative of a pulse, said second trace providing a location of said pulse within said first trace at least during the presence of signal distortion*; and

a microprocessor configured to receive a physiological signal from the light sensitive detector and generate the **[**trace**]** *first and second traces* on the display in response to said physiological signal, said microprocessor also configured to measure a signal quality of the physiological signal and vary a color of the *second* trace so as to indicate the signal quality.

21. The device of claim **[20]** *18*, wherein the microprocessor is configured to vary a height of the **[**bar graph**]** *second trace* to indicate the signal quality.

22. The device of claim **21**, wherein the microprocessor raises the height of the **[**bar graph**]** *second trace* to indicate greater signal quality and lowers the height of the **[**bar graph**]** *second trace* to indicate lower signal quality.

25. The method of claim 10, wherein said plethysmograph trace comprises a continuous trace.

26. The method of claim 10, wherein said visual pulse indicator trace comprises a continuous trace.

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摘要(译)

根据本发明的一些实施例，显示器用于显示来自生理传感器的信号以及信号质量的指示。虽然可以以多种方式提供信号质量的这种指示，但优选地通过改变显示器上的颜色来提供。