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(54) **OXIMETRY PULSE INDICATOR**

OXIMETER MIT PULSANZEIGE

DISPOSITIF INDICATEUR DE PULSATIONS POUR OXYMETRIE DE POULS

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US-A- 3 875 930
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Description

Background of the Invention

[0001] 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.

[0002] 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.

[0003] 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. Patent 5,632,272 assigned to the assignee of the present invention.

[0004] U.S. Patent 4,193,393 discloses a numeric diagnostic electrocardiometer including an A/D converter for converting an EKG signal at each of the conventional electrodes employed in EKG analysis into numbers which are stored in an assigned memory as time and amplitude signals. The waveform is divided into time segments within which the basic waveshape is known. A programmed logic array stores abnormalities within a range for each segment of the EKG waveform. The stored samples are read into the programmed logic array and deviation of the waveform beyond that programmed produces a numeric output.

Summary of the Invention

[0005] The present invention is defined by the claims.

[0006] 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.

[0007] 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. Patent 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.**

[0008] 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.

[0009] An example of the determination of pulse rate in the presence of distortion is described in WO-A-98 46 126, entitled "Improved Signal Processing Apparatus and Method," which is assigned to the assignee of the current application. Another example of pulse rate determination in the presence of distortion is described in WO-A-00 38569, entitled "Plethysmograph Pulse Recognition Processor," which is assigned to the assignee of the current application.

[0010] 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.

[0011] 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. 3A, the display provides practically no information regarding the patient's pulse.

[0012] 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.

[0013] 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.

[0014] 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.

[0015] 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.

[0016] 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.

Brief Description of the Drawings

[0017]

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

FIG. **4** illustrates the inputs and outputs of the pulse indicator according to the present invention;
FIG. **5** illustrates 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; and
FIG. **14** is a display illustrating a distorted plethysmograph and a corresponding low-confidence-level visual pulse indicator.

Detailed Description of the Preferred Embodiments

[0018] 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.

[0019] 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.

[0020] 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.

[0021] 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 WO-A-98 46126 or WO-A-00 38569, both cited above.

[0022] FIG. **5A** 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.

[0023] FIG. **5B** 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. Patent No. 5,632,272 entitled "Signal Processing Apparatus,".

[0024] 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 WO-A-00 38569 cited above.

[0025] 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.

[0026] 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.

[0027] 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.

[0028] 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.

[0029] 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.

[0030] 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.**

[0031] 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:

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

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.

[0032] 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 = .2 and c_2 = .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 = .2 and c_2 = .8. If the signal is from a neonate, then c_1 = .5, c_2 = .5. Because a neonate pulse rate is typically higher than an adult, the PR density changes less quickly and, hence, less filtering is applied.

[0033] 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:

<u>Adults</u>

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

<u>Neonates</u>

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

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

[0034] 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.**

[0035] 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.**

[0036] 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:

<u>Adults</u>

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

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

Neonates

$$\text{peak output} = \prod_{i=1}^{3}(In_7 - In_{7-i} > 0) \prod_{i=3}^{9}(In_9 - In_{9+i} > -0.05) \tag{6}$$

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

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

[0037] 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

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

Neonates and No Distortion

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

Distortion (Adults or Neonates)

$$\text{edge output} = (\text{down slope value} > 0.65) \bullet \text{peak output} \tag{10}$$

[0038] 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

$$\text{symmetrical peak output} = \text{false} \tag{11}$$

Neonates and No Distortion

$$\text{symmetrical peak output} = (\text{down slope}>1)\bullet(\text{up slope}>1)\bullet(|\text{down slope - up slope}|\leq 0.5)\bullet\text{peak} \qquad (12)$$

Neonates and Distortion

$$\text{symmetrical peak output} = (\text{down slope}>0.35)\bullet(\text{up slope}>0.35)\bullet(|\text{down slope - up slope}|\leq 0.5)\bullet\text{peak} \qquad (13)$$

[0039] 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

$$\text{decline} = (3 < (\text{down slope - up slope}) < 6)\bullet\text{slope} \qquad (14)$$

Neonates and No Distortion

$$\text{decline} = (0.5 < (\text{down slope - up slope}) < 2)\bullet\text{slope} \qquad (15)$$

Distortion (Adults or Neonates)

$$\text{decline} = (0.5 < (\text{down slope - up slope}) < 8)\bullet\text{slope} \qquad (16)$$

[0040] 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.

[0041] 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 .8 times the sample frequency, 62.5 Hz., divided by the pulse rate in pulses per second, or:

$$\text{min. gap} = .8 \times (60/\text{pulse rate}) \times 62.5 = 3000/\text{pulse rate} \qquad (17)$$

[0042] 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.**

[0043] 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."

[0044] 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.

[0045] 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.

[0046] 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.

[0047] The pulse oximetry pulse 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.

Claims

1. A processing apparatus (400) having as an input a plethysmograph waveform (403), said plethysmograph waveform (403) comprising a plurality of pulses, said apparatus generating a trigger (409) synchronous with the occurrence of said pulses, said apparatus comprising:

    a waveform analyzer (630) in communication with said plethysmograph waveform (403) and responsive to the shape of said pulses, wherein the waveform analyzer (630) derives a measure of distortion (632) in said plethysmograph waveform (403) that is indicative of a quality of said plethysmograph waveform (403); and
    a decision element (640) conditionally responsive to said measure of distortion (632) derived by said waveform analyzer (630) to provide said trigger (409).

2. The processing apparatus (400) of claim 1 further comprising a pulse rate input (401), wherein said decision element (640) is conditionally responsive to said pulse rate input (401) to provide said trigger (409).

3. The processing apparatus (400) of claim 2 wherein said decision element (640) is responsive to said measure of distortion (632) when said measure of distortion (632) indicates that said plethysmograph waveform (403) is substantially undistorted and is responsive to said pulse rate input (401) when said waveform (403) is substantially distorted.

4. The processing apparatus (400) of claim 1 wherein said trigger (409) is used to generate an audible indicator of pulse occurrence.

5. The processing apparatus (400) of claim 1 wherein said trigger (409) is used to generate a visual indicator of pulse

occurrence.

6. The processing apparatus (400) of claim 5 wherein said visual indicator also incorporates an indication of data integrity.

7. The processing apparatus (400) of claim 1, wherein an indication of data integrity is used in a visual or audio indicator.

8. The processing apparatus (400) of claim 1**,** wherein the waveform analyzer (630) establishes criterion (910, 922, 930) for determining the measure of distortion in the plethysmograph waveform, determines whether said criterion (910, 922, 930) are satisfied, and generates the measure of distortion (632) based on said criterion (910, 922, 930).

Patentansprüche

1. Verarbeitungsvorrichtung (400) mit einer Plethysmograph-Wellenform (403) als Eingabe, wobei die Plethysmograph-Wellenform (403) mehrere Pulse aufweist, wobei die Vorrichtung ein Triggersignal (409) synchron zum Auftreten der Pulse erzeugt, wobei die Vorrichtung aufweist:

   einen Wellenformanalysator (630), der in Kommunikation mit der Plethysmograph-Wellenform (403) steht und auf die Form der Pulse reagiert, wobei der Wellenformanalysator (630) ein Verzerrungsmaß (632) in der Plethysmograph-Wellenform (403) ableitet, das eine Qualität der Plethysmograph-Wellenform (403) anzeigt; und
   ein Entscheidungselement (640), das auf das durch den Wellenformanalysator (630) abgeleitete Verzerrungsmaß (632) bedingt reagiert, um das Triggersignal (409) bereitzustellen.

2. Verarbeitungsvorrichtung (400) nach Anspruch 1, ferner mit einer Pulsfrequenzeingabe (401), wobei das Entscheidungselement (640) auf die Pulsfrequenzeingabe (401) bedingt reagiert, um das Triggersignal (409) bereitzustellen.

3. Verarbeitungsvorrichtung (400) nach Anspruch 2, wobei das Entscheidungselement (640) auf das Verzerrungsmaß (632) reagiert, wenn das Verzerrungsmaß (632) anzeigt, daß die Plethysmograph-Wellenform (403) im wesentlichen unverzerrt ist, und auf die Pulsfrequenzeingabe (401) reagiert, wenn die Wellenform (403) im wesentlichen verzerrt ist.

4. Verarbeitungsvorrichtung (400) nach Anspruch 1, wobei das Triggersignal (409) verwendet wird, um eine akustische Anzeige für das Pulsauftreten zu erzeugen.

5. Verarbeitungsvorrichtung (400) nach Anspruch 1, wobei das Triggersignal (409) verwendet wird, um eine visuelle Anzeige für das Pulsauftreten zu erzeugen.

6. Verarbeitungsvorrichtung (400) nach Anspruch 5, wobei die visuelle Anzeige auch eine Datenintegritätsanzeige beinhaltet.

7. Verarbeitungsvorrichtung (400) nach Anspruch 1, wobei eine Datenintegritätsanzeige in einer visuellen oder akustischen Anzeige verwendet wird.

8. Verarbeitungsvorrichtung (400) nach Anspruch 1, wobei der Wellenformanalysator (630) Kriterien (910, 922, 930) zum Bestimmen des Verzerrungsmaßes in der Plethysmograph-Wellenform festlegt, bestimmt, ob die Kriterien (910, 922, 930) erfüllt sind, und das Verzerrungsmaß (632) auf der Grundlage der Kriterien (910, 922, 930) erzeugt.

Revendications

1. Dispositif de traitement (400) ayant comme une entrée une forme d'onde de pléthysmographe (403), ladite forme d'onde de pléthysmographe (403) comprenant une pluralité de pulsations, ledit dispositif générant un déclencheur (409) synchrone avec la survenance desdites pulsations, ledit dispositif comprenant :

   un analyseur de forme d'onde (630) en communication avec ladite forme d'onde de pléthysmographe (403) et sensible à la forme desdites pulsations, dans lequel l'analyseur de forme d'onde (630) dérive une mesure de distorsion (632) dans ladite forme d'onde de pléthysmographe (403) qui est indicative d'une qualité de ladite

forme d’onde de pléthysmographe (403); et
un élément de décision (640) sensible de manière conditionnelle à ladite mesure de distorsion (632) dérivée par ledit analyseur de forme d’onde (630) pour fournir ledit déclencheur (409).

2. Dispositif de traitement (400) selon la revendication 1 comprenant en outre une entrée de fréquence de pulsations (401), dans lequel ledit élément de décision (640) est sensible de manière conditionnelle à ladite entrée de fréquence de pulsations (401) pour fournir ledit déclencheur (409).

3. Dispositif de traitement (400) selon la revendication 2, dans lequel ledit élément de décision (640) est sensible à ladite mesure de distorsion (632) quand ladite mesure de distorsion (632) indique que ladite forme d’onde de pléthysmographe (403) est sensiblement non déformée et est sensible à ladite entrée de fréquence de pulsations (401) quand ladite forme d’onde (403) est sensiblement déformée.

4. Dispositif de traitement (400) selon la revendication 1, dans lequel ledit déclencheur (409) est utilisé pour générer un indicateur audible de survenance de pulsation.

5. Dispositif de traitement (400) selon la revendication 1, dans lequel ledit déclencheur (409) est utilisé pour générer un indicateur visuel de survenance de pulsation.

6. Dispositif de traitement (400) selon la revendication 5, dans lequel ledit indicateur visuel incorpore également une indication d’intégrité de données.

7. Dispositif de traitement (400) selon la revendication 1, dans lequel une indication d’intégrité de données est utilisée dans un indicateur visuel ou audio.

8. Dispositif de traitement (400) selon la revendication 1, dans lequel l’analyseur de forme d’onde (630) établit des critères (910, 922, 930) pour déterminer la mesure de distorsion dans la forme d’onde de pléthysmographe, détermine si lesdits critères (910, 922, 930) sont satisfaits et génère la mesure de distorsion (632) sur la base desdits critères (910, 922, 930).

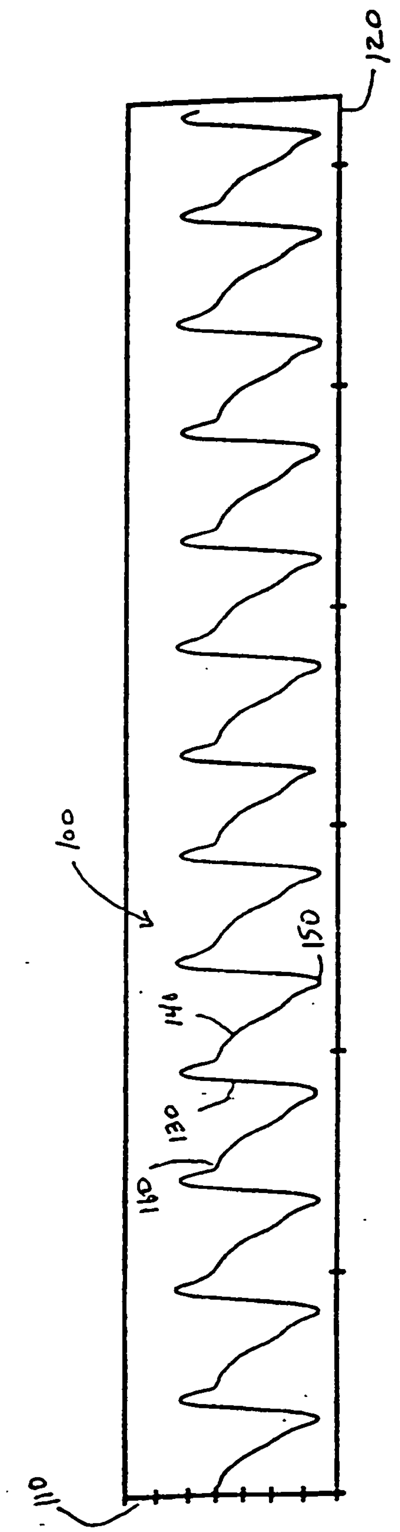


FIG. 1

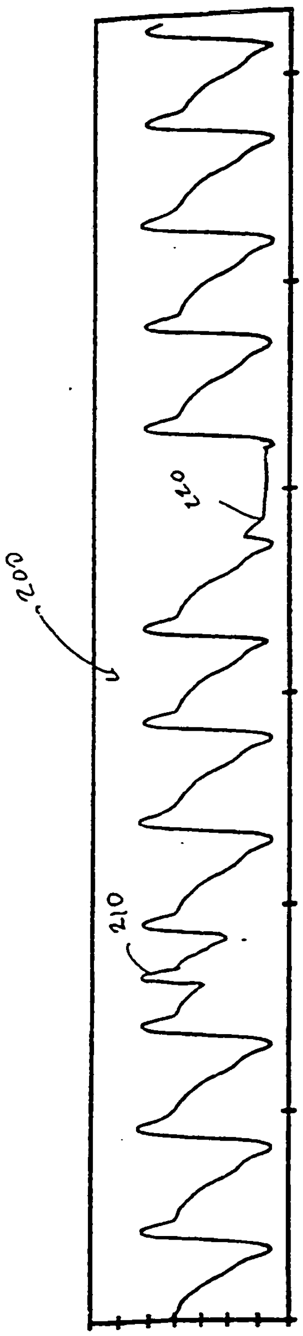


FIG. 2

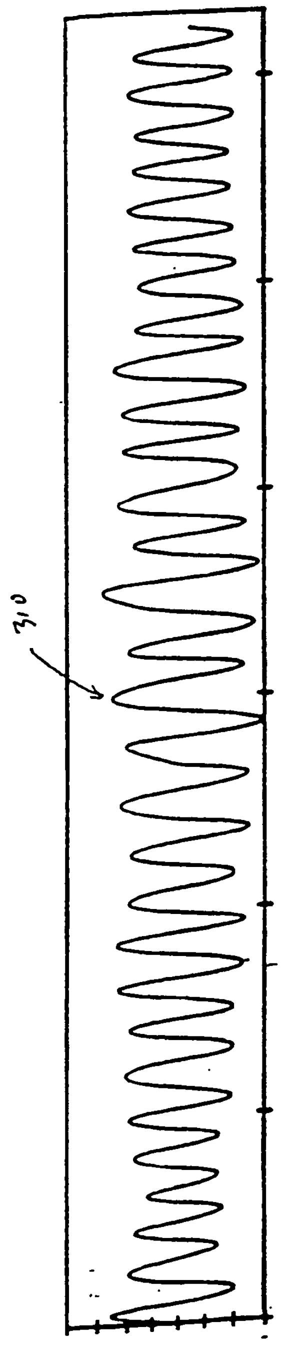


FIG. 3A

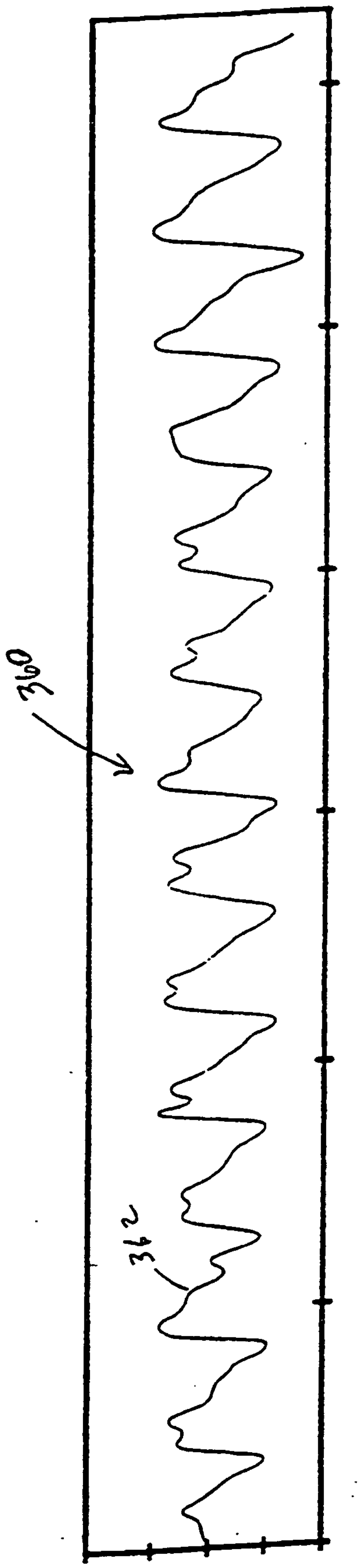


FIG. 3B

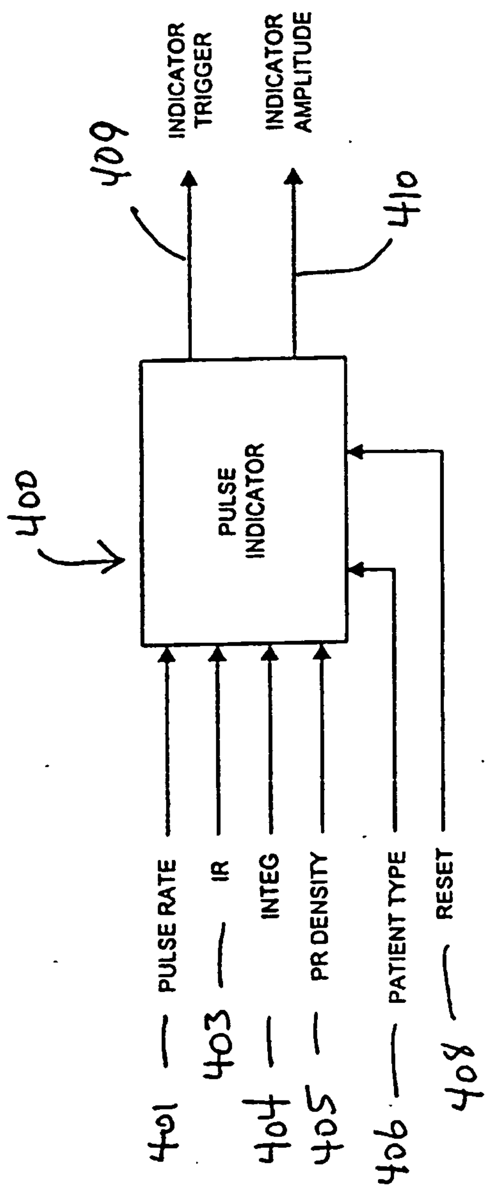

INDICATOR TRIGGER
INDICATOR AMPLITUDE
409
410
400
PULSE INDICATOR
401
PULSE RATE
403
IR
404
INTEG
405
PR DENSITY
406
PATIENT TYPE
408
RESET

FIG. 4

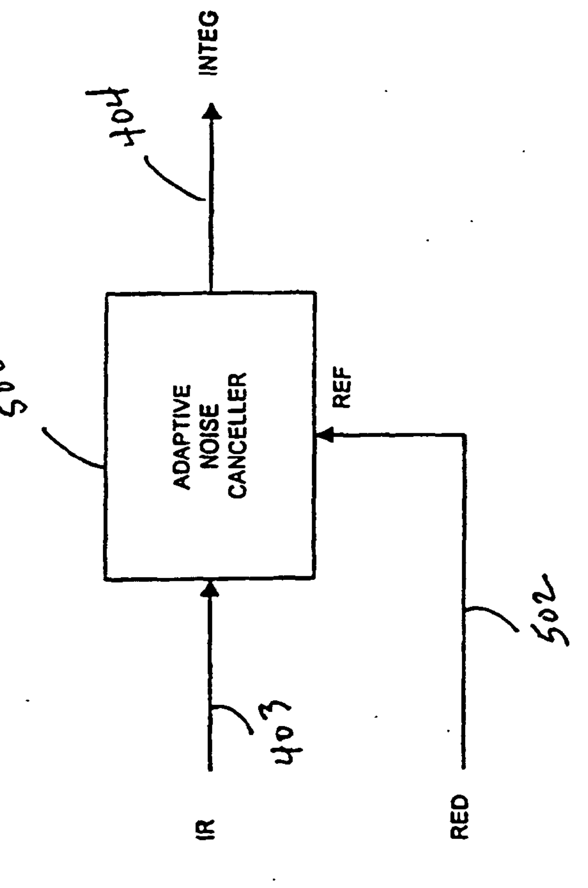


FIG. 5A

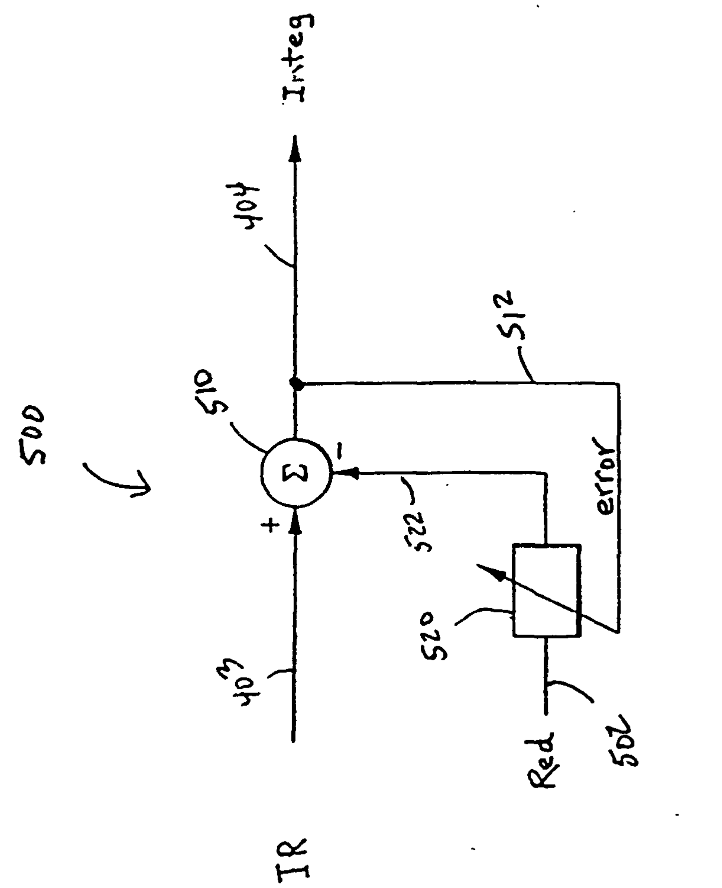
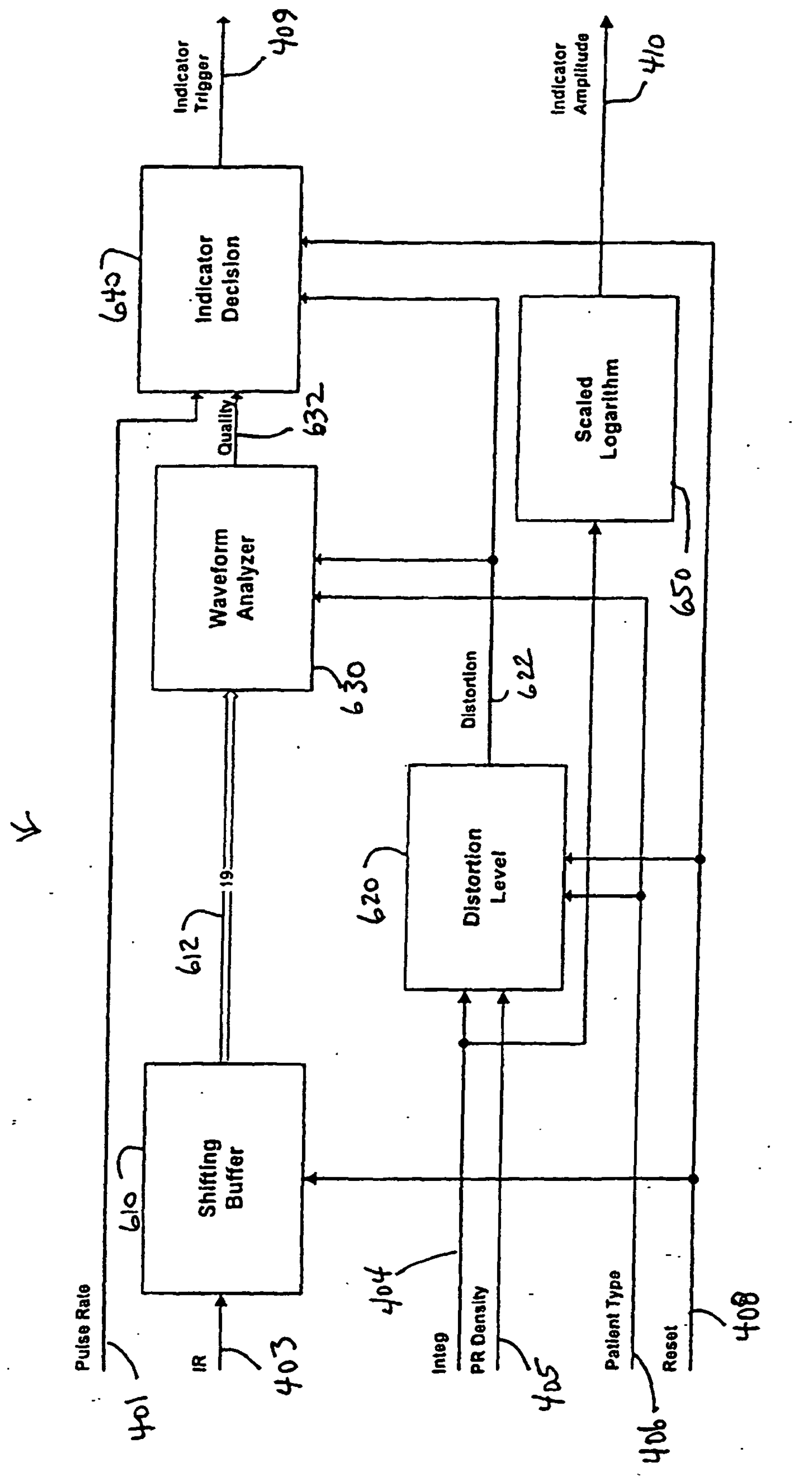


FIG. 5B



Indicator Trigger
409
Indicator Amplitude
410
640
Indicator Decision
Quality
632
Scaled Logarithm
650
Waveform Analyzer
630
Distortion
622
Distortion Level
620
19
612
Shifting Buffer
610
Pulse Rate
401
IR
403
Integ
404
PR Density
405
Patient Type
406
Reset
408

FIG. 6

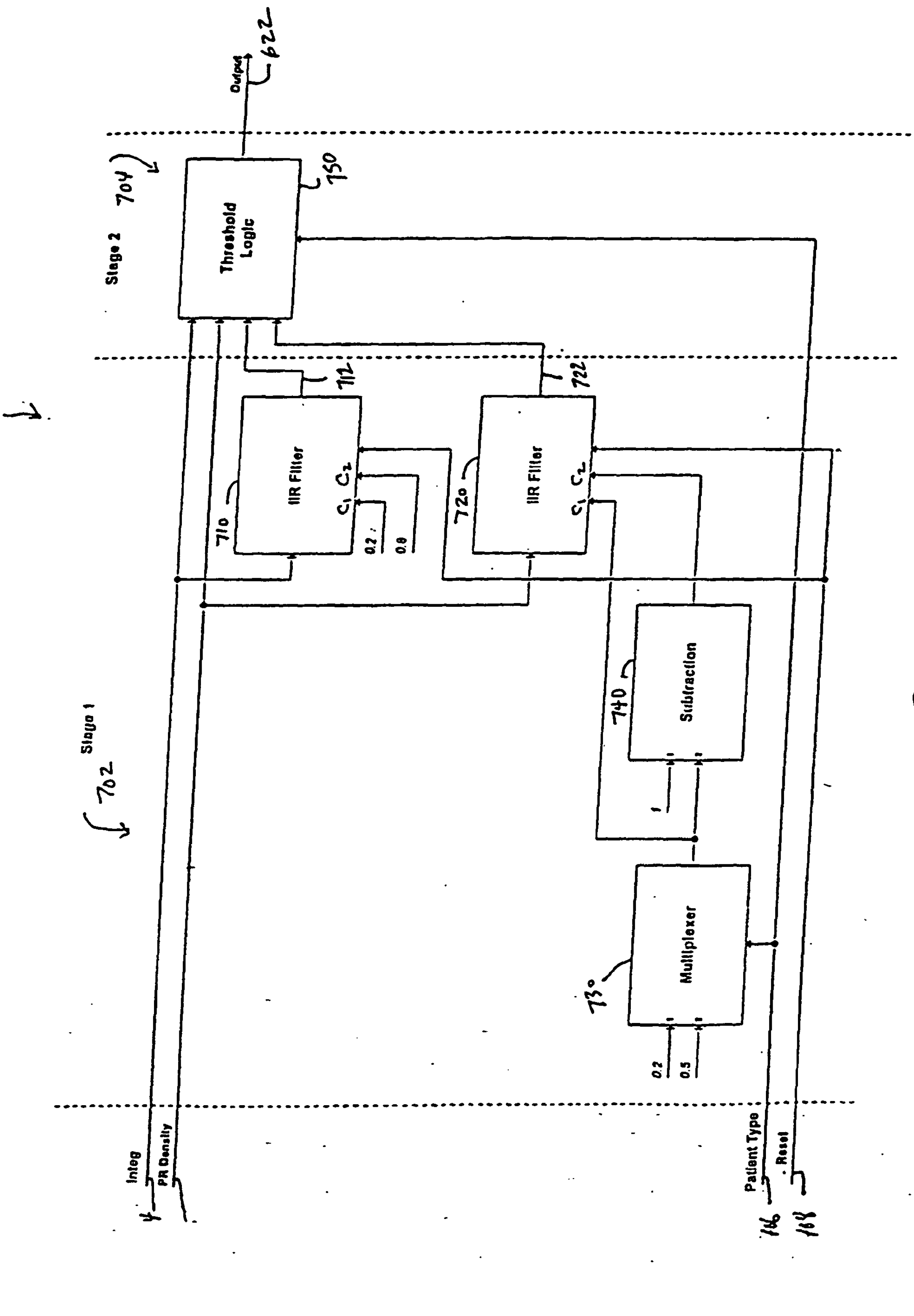

Output
622
Stage 2
704
Threshold Logic
750
712
722
IIR Filter
710
IIR Filter
720
C_1
C_2
0.2
0.8
Stage 1
702
Subtraction
740
Multiplexer
730
0.2
0.5
Integ
PR Density
Patient Type
Reset
166
168

FIG. 7

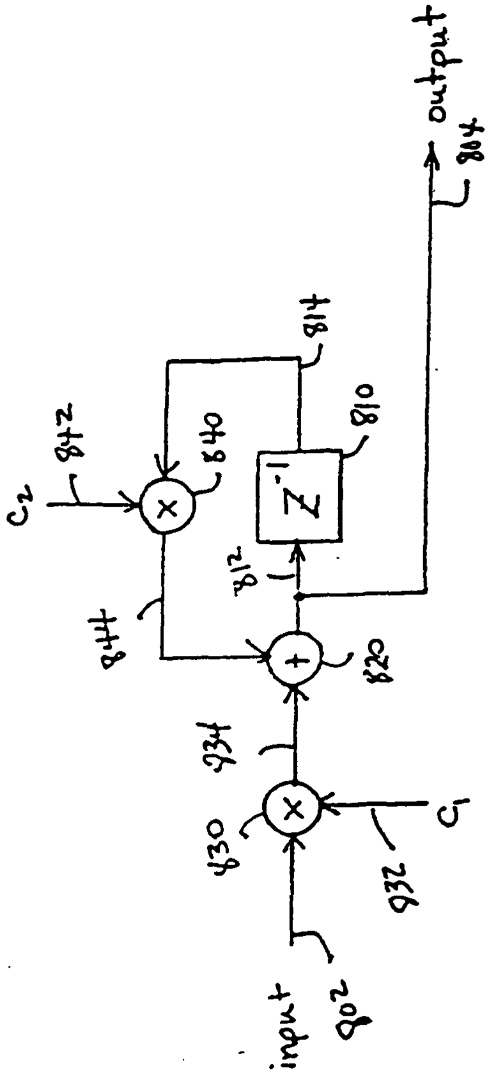

input
902
930
932
c_1
934
820
844
c_2
842
840
Z^{-1}
810
812
814
804
output

FIG. 8

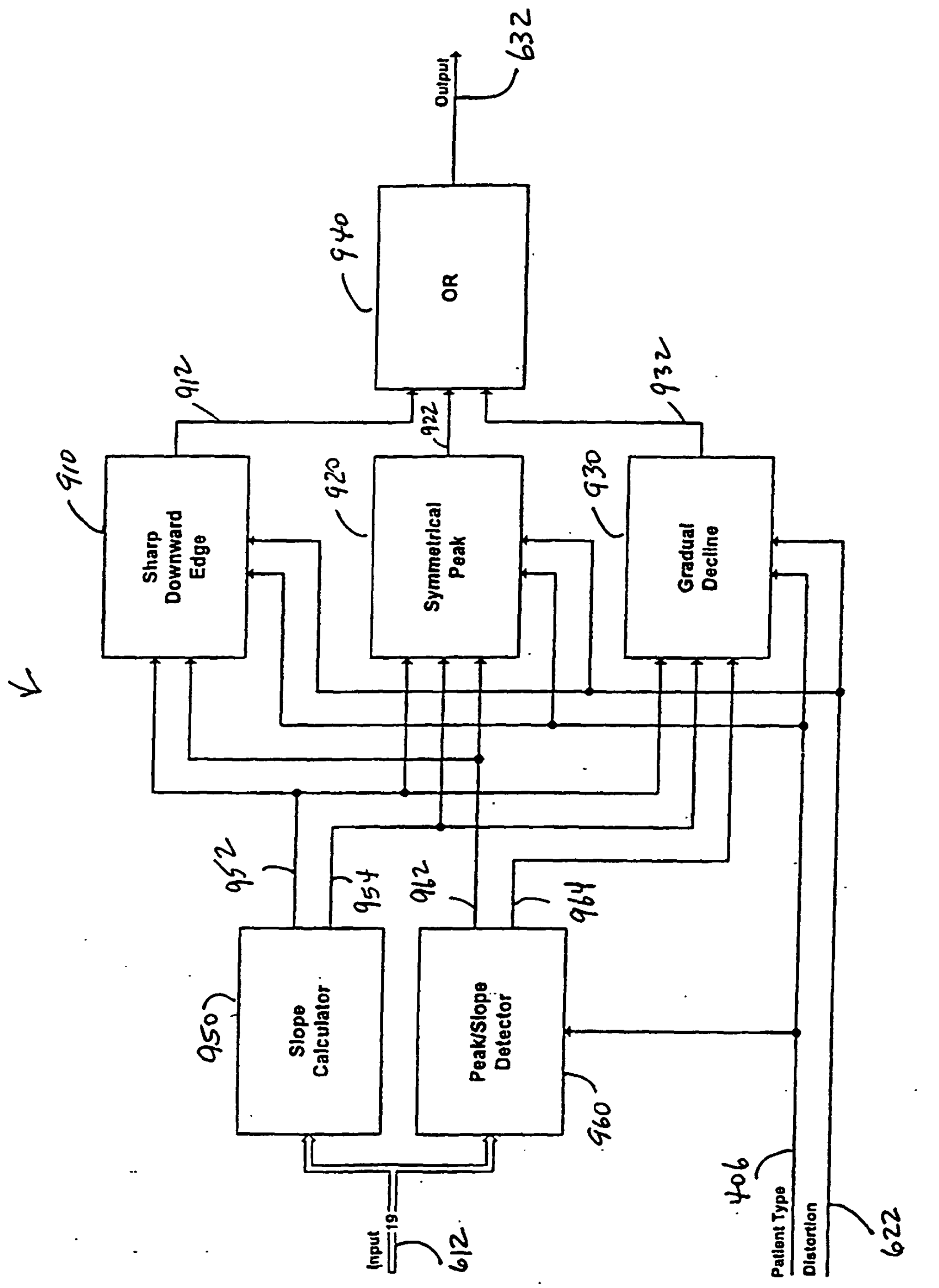

Sharp Downward Edge
Symmetrical Peak
Gradual Decline
OR
Slope Calculator
Peak/Slope Detector
Input
Output
Patient Type
Distortion
910
912
920
922
930
932
940
950
952
954
960
962
964
612
632
406
622
19

FIG. 9

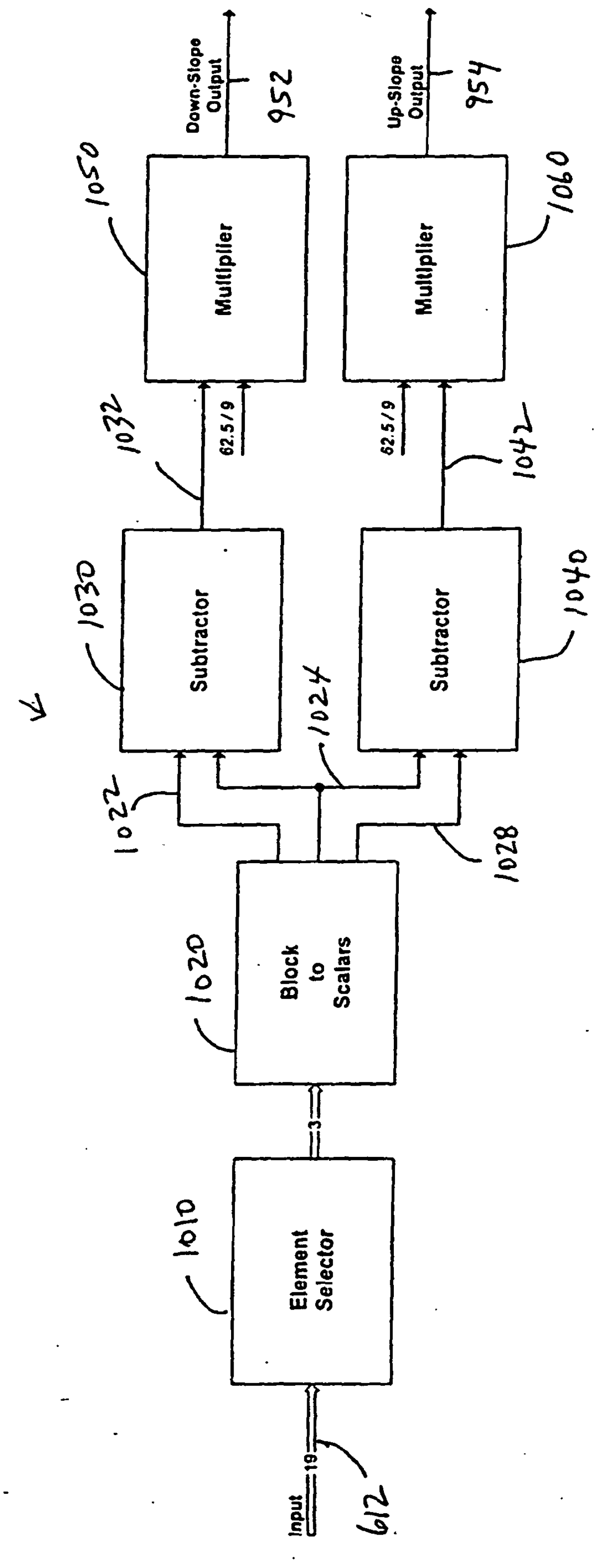

Input
19
612
Element Selector
1010
3
Block to Scalars
1020
1022
1024
1028
Subtractor
1030
Subtractor
1040
1032
1042
62.5 / 9
62.5 / 9
Multiplier
1050
Multiplier
1060
Down-Slope Output
952
Up-Slope Output
954

FIG. 10

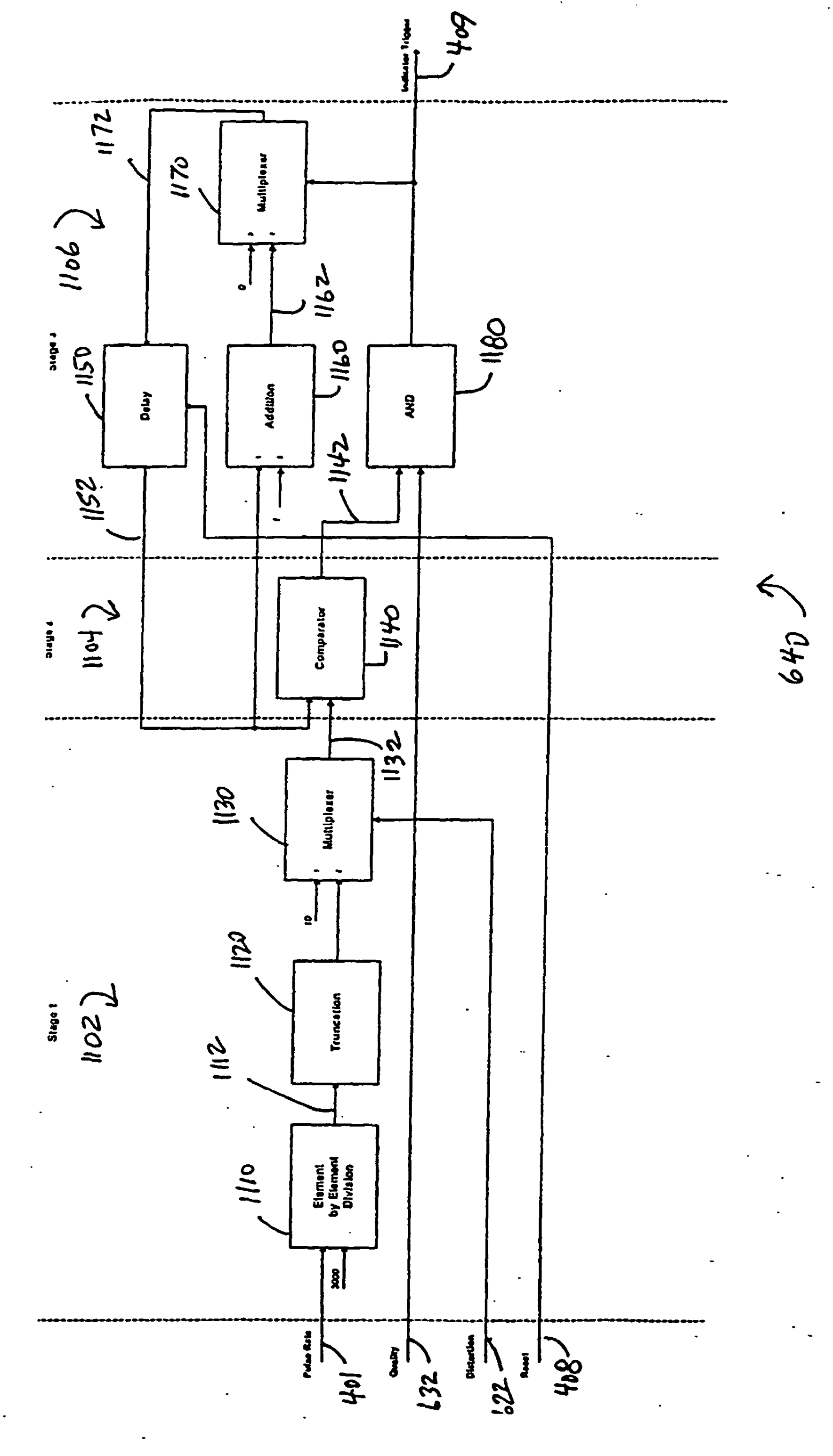

Element by Element Division
Truncation
Multiplexer
Comparator
Delay
Addition
AND
Multiplexer
Stage 1
1102
1104
1106
1110
1112
1120
1130
1132
1140
1142
1150
1152
1160
1162
1170
1172
1180
401
632
622
408
409
640

FIG. 11

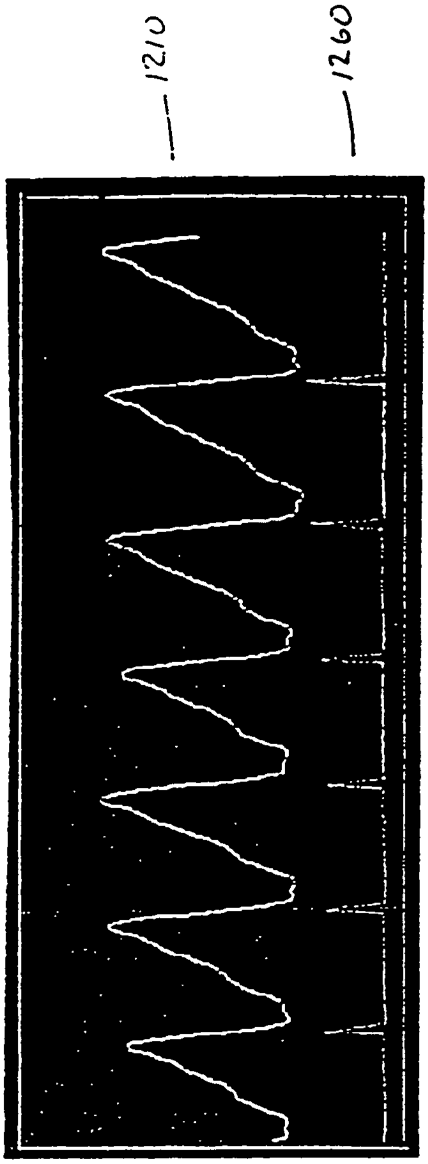


FIG. 12

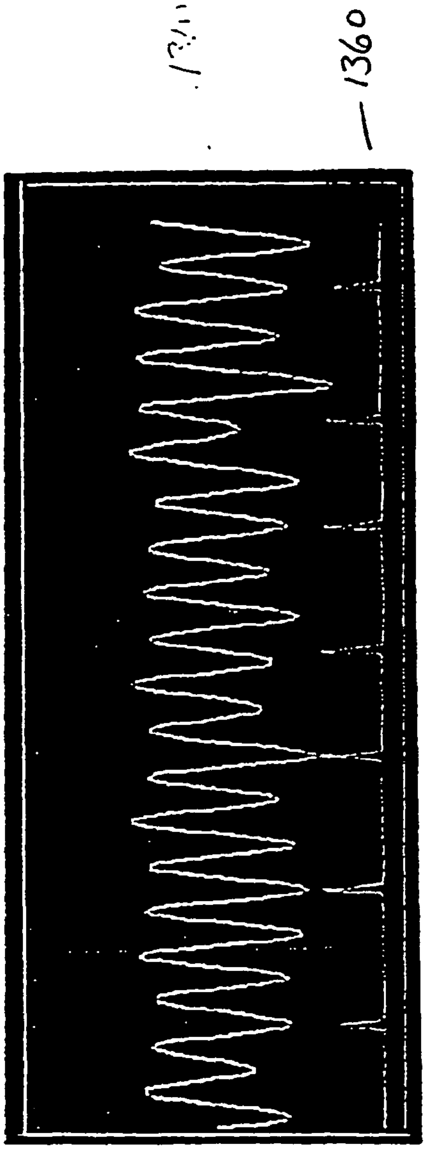


FIG. 13

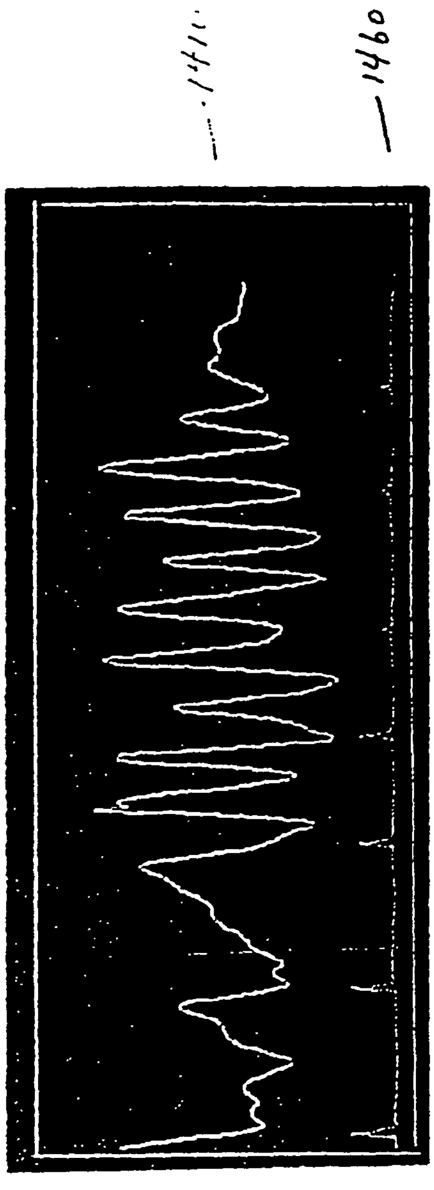


FIG. 14

专利名称(译)	血氧测量脉冲指示器		
公开(公告)号	EP1139858B1	公开(公告)日	2007-04-18
申请号	EP2000903166	申请日	2000-01-07
[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	BREED DIVYA SRINIVASAN NOVAK JEROME JOSEPH JR ALI AMMAR AL		
发明人	BREED, DIVYA, SRINIVASAN NOVAK, JEROME, JOSEPH, JR. ALI, AMMAR, AL		
IPC分类号	A61B5/00 A61B5/0245 A61B5/024 A61B5/145 A61B5/1455		
CPC分类号	A61B5/14551 A61B5/02416 A61B5/7214		
代理机构(译)	法思博事务所		
优先权	60/115289 1999-01-07 US		
其他公开文献	EP1139858A1		
外部链接	Espacenet		

摘要(译)

基于规则的智能处理器提供脉冲指示器，指示脉冲血氧计衍生的光 - 体积描记器波形中每个脉冲的发生。当相对没有损坏体积描记器信号的失真时，处理器分析波形中脉冲的形状以确定波形中产生脉冲指示的位置。当存在失真时，使用更宽松的波形标准来确定是否存在脉冲。如果存在脉冲，则脉冲指示基于平均脉冲速率。如果不存在脉冲，则不会发生任何指示。脉冲指示器提供触发和幅度输出。触发输出用于在显示器上启动可听音“嘟嘟”或视觉脉冲指示，例如水平迹线上的垂直尖峰或条形显示器上的相应指示。幅度输出用于指示数据完整性以及计算的饱和度和脉冲率值的相应置信度。幅度输出可以改变脉冲指示器的特性，例如嘟嘟声音量或频率或视觉显示器尖峰的高度。