



(12) **EUROPEAN PATENT APPLICATION**

(43) Date of publication: **23.03.2011 Bulletin 2011/12** (51) Int Cl.: **A61B 5/00 (2006.01)**

(21) Application number: **10181436.6**

(22) Date of filing: **24.03.2000**

(84) Designated Contracting States:
DE FR GB

(30) Priority: **25.03.1999 US 126148 P**

(62) Document number(s) of the earlier application(s) in accordance with Art. 76 EPC:
06012571.3 / 1 719 449
00916663.8 / 1 171 025

(71) Applicant: **Masimo Corporation**
Irvine, CA 92618 (US)

(72) Inventors:
• **Diab, Mohamed K.**
Mission Viejo
CA 92692 (US)

• **Ali, Ammar Al**
Trustin
CA 92782 (US)

(74) Representative: **Vossius & Partner**
Siebertstrasse 4
81675 München (DE)

Remarks:

This application was filed on 28-09-2010 as a divisional application to the application mentioned under INID code 62.

(54) **Improved pulse oximeter probe-off detector**

(57) An intelligent, rule-based processor (300) provides signal quality based limits to the signal strength operating region of a pulse oximeter. These limits are superimposed on the typical gain dependent signal strength limits (314). If a sensor signal appears physiologically generated, the pulse oximeter is allowed to operate with minimal signal strength, maximizing low perfusion performance. If a sensor signal is potentially due to a signal induced by a dislodged sensor, signal strength requirements are raised. Thus, signal quality limitations

enhance probe off detection without significantly impacting low perfusion performance. One signal quality measure used is pulse rate density (354), which defines the percentage of time physiologically acceptable pulses are occurring. If the detected signal contains a significant portion of unacceptable pulses, the minimum required signal strength is raised proportionately. Another signal quality measure used in conjunction with pulse rate density is energy ratio (352), computed as the percentage of total energy contained in the pulse rate fundamental and associated harmonics.

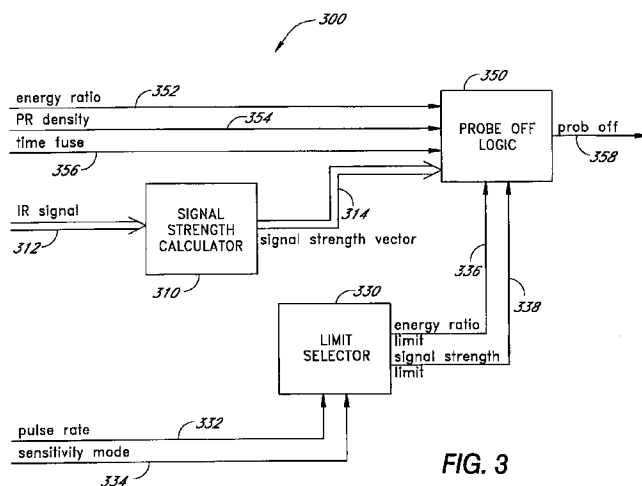


FIG. 3

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 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.

[0002] 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.

Summary of the Invention

[0003] To compute peripheral arterial oxygen saturation, denoted Sp_aO_2 , pulse oximetry relies on the differential light absorption of oxygenated hemoglobin, HbO_2 , and deoxygenated hemoglobin, Hb , to compute their respective concentrations in the arterial blood. This differential absorption is measured at the red and infrared wavelengths of the sensor. In addition, pulse oximetry relies on the pulsatile nature of arterial blood to differentiate hemoglobin absorption from absorption of other constituents in the surrounding tissues. Light absorption between systole and diastole varies due to the blood volume change from the inflow and outflow of arterial blood at a peripheral tissue site. This tissue site might also comprise skin, muscle, bone, venous blood, fat, pigment, etc., each of which absorbs light. It is assumed that the background absorption due to these surrounding tissues is invariant and can be ignored. Accordingly, blood oxygen saturation measurements are based upon a ratio of the time-varying or AC portion of the detected red and infrared signals with respect to the time-invariant or DC portion. This AC/DC ratio normalizes the signals and accounts for variations in light pathlengths through the measured tissue.

[0004] FIG. 1 illustrates the typical operating characteristics of a pulse oximeter. During a calibration phase, the pulse oximeter input gain is adjusted higher to accommodate opaque skin and lower to accommodate translucent skin at the sensor site. Variations in blood perfusion at the sensor site result in variations in input signal strength. The graph **100** shows acceptable input sensitivity as a function of gain. The y-axis **110** represents the signal strength (SS), which is the ratio of the peak-to-peak AC signal to the DC signal, expressed as a percentage. The x-axis **120** represents the gain, which is shown with decreasing values along the x-axis. The graph **100** has an unshaded region **130** representing the acceptable operating range of the pulse oximeter and a shaded region **140** representing conditions outside that operating range, which, when detected, will result in a pulse oximeter "probe off" alarm. The operating region **130** has a floor **150** at relatively low gains, representing the highest sensitivity to patients with low perfusion. Because input noise increases with gain, the operating region also has a corner point **160** below which input sensitivity is noise limited and falls off with increasing gain, i.e. increasing opacity.

[0005] A pulse oximeter with the operating characteristics shown in FIG. 1 may fail to detect a probe off condition. This problem occurs when the sensor becomes partially or completely dislodged from the patient, but continues to detect an AC signal within the operating region of the pulse oximeter. Probe off errors are serious because the pulse oximeter may display a normal saturation when, in fact, the probe is not properly attached to the patient, potentially leading to missed desaturation events.

[0006] Failure to detect a probe off condition is the result of the sensor detector receiving light directly from the emitters without transmission through the patient's tissue. The pulse oximeter is particularly vulnerable to probe off errors when operating at its highest sensitivity, where even small induced variations in light directly detected from the emitters have sufficient signal strength to be processed as a physiological signal. In a probe off condition, a detector AC signal can be induced by slight changes in the direct light path between the emitters and detector. For example, small amounts of patient motion, such as chest movement from breathing, can induce a probe off AC signal. As another example, "creep" in the sensor configuration, such as a folded sensor gradually returning to its original unfolded shape after becoming

dislodged can also induce a probe off AC signal. Further restricting the operating region **130** shown in FIG. **1** can reduce probe off errors. Such restrictions, however, would also severely limit the ability of the pulse oximeter to make saturation measurements on patients with poor perfusion.

[0007] The present invention is a monitor-based improvement to detecting the probe off condition described above. Of-course, other methods of detecting the probe-off condition could be combined with the present improvement. In particular, an intelligent, rule-based processor uses signal quality measurements to limit the operating region of the pulse oximeter without significant negative impact on low perfusion performance. These signal-quality operating limits are superimposed on those of FIG. **1** to improve probe off detection. In this manner, the pulse oximeter can reject AG signals that have sufficient signal strength to fall within the operating region **130** of FIG. **1**, but that are unlikely to be a plethysmograph signal. One signal quality measurement that is used is pulse rate density, which is the percentage of time detected pulses satisfy a physiologically acceptable model. Another signal quality measurement is energy ratio, which is the percentage of signal energy that occurs at the pulse rate and its harmonics. The operating region of the pulse oximeter is then defined in terms of signal strength versus gain, signal strength versus PR density and energy ratio versus predefined energy ratio limits.

[0008] In one aspect of the present invention, a probe-off detector has a signal input, a signal quality input and a probe off output. The signal quality input is dependent on a comparison between a sensor output and a physiological signal model. The probe off output provides an indication that the sensor may not be properly attached to a tissue site. The detector comprises a signal strength calculator, a stored relationship between signal strength and signal quality and a comparator. The signal strength calculator has an input in communications with the sensor signal and provides a signal strength output that is dependent on the time-varying component of the sensor signal. The stored relationship defines an acceptable operating region for the sensor. The comparator has signal strength and signal quality as inputs and provides the probe off output based on a comparison of the signal strength and the signal quality with the stored relationship.

[0009] In another aspect of the present invention, a pulse oximetry sensor signal is processed to determine if it is properly attached to a tissue site. The process steps involve setting a signal strength limit that is dependent on signal quality, calculating a signal strength value from the sensor signal, calculating a signal quality value from the sensor signal and indicating a probe off condition if the signal strength is below the limit for the signal quality value previously determined.

[0010] The following aspects are preferred embodiments of the invention.

1. A processor for determining when a physiological sensor may not be properly positioned with respect to a measurement site, the processor comprising:

a signal strength calculator which processes a sensor signal input expected to be representative of at least one parameter measured by the physiological sensor, to produce a signal strength output representative of a strength of the sensor signal input, wherein the sensor signal input is provided from the physiological sensor; and
a probe off logic module which indicates that the sensor signal input may not represent the parameter when a predetermined portion of the signal strength output is below a threshold value.

2. The processor of aspect 1, wherein the probe off logic module comprises comparator.

3. The processor of aspect 1, wherein the threshold comprises a ratio of a first value of a substantially alternating part of the signal strength output to a second value of a substantially non-alternating part of the signal strength output.

4. The processor of aspect 3, wherein the ratio comprises a value above which a probe-off condition does not exist for all values of the signal strength output.

5. The processor of aspect 3, wherein the ratio is 0.25.

6. The processor of aspect 3, wherein the ratio is 0.05.

7. The processor of aspect 1, wherein the probe off logic module indicates that the sensor signal input may not represent the parameter when the predetermined portion of the signal strength output is below the threshold value and a signal quality of the sensor signal input falls within a non-operative region.

8. The processor of aspect 7, wherein the non-operative region comprises a region defined by a relationship between the signal strength output and the signal quality.

9. The processor of aspect 7, wherein the signal quality comprises a comparison of the sensor signal input with one or more physiological signal, models,

10. The processor of aspect 7, further comprising a timeout input indicative of non-acceptable pulses in at least one predetermined block of the sensor signal input.

11. The processor of aspect 7 wherein the probe off logic module indicates that a probe-off condition exists when a timeout output indicates absence of acceptable pulses in at least one predetermined block of the sensor signal input, when the predetermined portion of the signal strength output is below the threshold, and the signal quality of

the sensor signal input falls within a non-operative region.

12. The processor of aspect 7, further comprising an energy ratio representative of whether a measurement of energy in the sensor signal input is above the threshold value.

13. The detector of aspect 12, wherein the probe off logic module indicates that a probe-off condition may exist when the energy ratio is above the threshold value, when the predetermined portion of the signal strength output is below the threshold, and when the signal quality of the sensor signal input falls within the non-operative region.

14. The detector of aspect 12, wherein the probe off logic module indicates that a probe-off condition may exist when the energy ratio is above the threshold value, a timeout output indicates absence of acceptable pulses in at least one predetermined block of the sensor signal input, when the predetermined portion of the signal strength output is below the threshold, and when the signal quality of the sensor signal input falls within the non-operative region.

15. The processor of aspect 1, wherein the threshold value comprises a signal strength floor below which a probe-off condition exists for all values of the signal strength output.

16. The processor of aspect 1, wherein the threshold value is dependent upon a sensitivity mode of the physiological sensor.

17. The processor of aspect 16, wherein the sensitivity mode is selectable by an operator.

18. An improved method of detecting that a pulse oximetry sensor may not be properly attached to a tissue site by processing a sensor signal, said method comprising the steps of:

setting a signal strength limit that is dependent on signal quality;
calculating a signal strength value from said sensor signal;
calculating a signal quality value from said sensor signal; and
indicating a probe off condition if said signal strength value is below said limit for said signal quality value determined in said calculating step.

19. An improvement to a probe-off detector having a signal input, a signal quality input and a probe off output, said signal quality input dependent on a comparison between a sensor output and a physiological signal model, said probe off output providing an indication that said sensor may not be properly attached to a tissue site, said improvement comprising:

a signal strength calculator having an input in communications with said signal and providing a signal strength output that is dependent on the time-varying component of said signal;
a stored relationship between said signal strength and said signal quality that defines an acceptable operating region for said sensor; and
a comparator having as inputs said signal strength and said signal quality and providing said probe off output based on a comparison of said signal strength and said signal quality with said stored relationship.

Brief Description of the Drawings

[0011]

FIG. 1 is a graph illustrating minimum signal strength operating limits for a pulse oximeter:

FIGS. **2A** and **2B** are graphs illustrating additional minimum signal strength operating limits for a pulse oximeter, based on signal quality according to the present invention;

FIG. **2A** is a graph of signal quality operating limits for a pulse oximeter in normal input sensitivity mode;

FIG. **2B** is a graph of signal quality operating limits for a pulse oximeter in high input sensitivity mode;

FIG. **3** is a top-level block diagram of a rule-based intelligent processor that provides the signal quality operating limits illustrated in FIGS. **2A-2B**;

FIG. **4** is a detailed block diagram of the signal strength calculator portion of FIG. **3**;

FIG. **5** is a detailed block diagram of the probe off logic portion of FIG. **3**; and

FIG. **6** is a detailed block diagram of the signal strength dependant checks portion of FIG. **5**.

Detailed Description of the Preferred Embodiments

[0012] FIGS. **2A** and **2B** illustrate how the operating range of a pulse oximeter is modified based on pulse rate density according to one embodiment of the present invention. Calculation of PR density is disclosed in U.S. Provisional Patent Application No. 60/114,127 filed December 30, 1998, and in U.S. Patent Application No. 09/471,510, filed December 23, 1999, entitled "Plethysmograph Pulse Recognition Processor," which is assigned to the assignee of the current

application and incorporated by reference herein. The processor described therein has a candidate pulse portion that determines a plurality of potential pulses within the input IR waveform. A physiological model portion of the processor then determines the physiologically acceptable ones of these potential pulses. The processor provides statistics regarding the acceptable pulses. One statistic is pulse density, which is the ratio of the period of acceptable pulses to the duration of a block or "snapshot" of the IR input waveform.

[0013] FIG. 2A shows a graph 200 of signal strength on the y-axis 210 versus PR density on the x-axis 220 for normal sensitivity. The operating region 260 is shown unshaded, and the probe off region 270 is shown shaded. A signal strength floor 230 of .02, below which a probe off condition exists for all values of PR density, determines one portion of the operating region 260. That is, no matter how many of the detected plethysmograph pulses are deemed physiologically acceptable, if the signal strength is less than .02, then the pulse oximeter indicates a probe off condition. A signal strength ceiling 250 of .25, above which the pulse oximeter is in a valid operating region for all values of PR density, determines another portion of the operating region 260. That is, signal quality is ignored if signal strength is above .25. Between the signal strength ceiling 250 and floor 230, acceptable signal strength is dependent on PR density. The slope of the boundary 240 defining this relationship is:

$$\text{slope} = \frac{-.25 - .02}{(.5 - .2)} = \frac{-.23}{.3} = \text{-.7667} \quad (1)$$

Thus, this boundary can be defined by the following equivalent equations:

$$SS = \text{-.7667} \bullet \text{PR density} + .4033 \quad (2)$$

$$\text{PR density} = \text{-.13043} \bullet SS + 0.5261 \quad (3)$$

[0014] FIG. 2B shows a graph 200 of signal strength on the y-axis 210 versus PR density on the x-axis 220 for high sensitivity. This graph is equivalent to that of FIG. 2A except that the signal strength ceiling 250 is set at .05. Thus, signal quality indicated by PR density is ignored as long as the signal strength is above .05.

[0015] Another signal quality measure, energy ratio, is also imposed on the operating region as an absolute limit. Energy ratio is the percentage of IR signal energy occurring at the pulse rate and associated harmonics compared to total IR energy. The energy ratio is computed by transforming each block of the IR signal into the frequency domain as is well known in the art. The energy ratio is computed by identifying each peak in the resulting spectrum. In one embodiment, the peaks occurring at the pulse rate and its harmonics are identified and summed. This value is divided by the sum of the magnitudes of all peaks and output as the energy ratio. Note that energy ratio computed in this manner is not a true energy calculation because the calculations are based on the peak magnitudes and not the squared magnitudes of the IR signal. In this embodiment, the minimum energy ratio must be .6 if the pulse rate is greater than or equal to 30 and .5 otherwise. That is, 60% (or 50% for low pulse rates) of the signal must be at the pulse rate frequency or its harmonics or the pulse oximeter will indicate a probe off condition. A method for calculating the pulse rate used in this calculation is disclosed in U.S. Patent No. 6,002,952, filed April 14, 1997, entitled "Improved Signal Processing Apparatus and Method," which is assigned to the assignee of the current application and incorporated by reference herein.

[0016] FIG. 3 is a block diagram illustrating one embodiment of the improved probe-off detector 300 according to the present invention. The detector has a signal strength calculator 310, a limit selector 330 and probe-off logic 350. The signal strength calculator 310 has an IR signal 312 input. This signal is the detected sensor signal after demultiplexing, amplification, filtering and digitization. In a particular embodiment, the IR signal is input to the signal strength calculator 310 at a 62.5 Hz sample rate and in overlapping "snapshots" or blocks of 390 samples, each offset from the previous block by 25 samples. The signal strength calculator 310 creates a signal strength vector output 314 consisting of a set of signal strength scalars for each of these input blocks, as described with respect to FIG. 4 below.

[0017] The limit selector 330 has pulse rate 332 and sensitivity mode 334 inputs. When the sensitivity mode input 334 has a value of 1, it indicates that the pulse oximeter is in a normal sensitivity mode, corresponding to FIG. 2A. A value of 0 indicates the pulse oximeter is in a high sensitivity mode, corresponding to FIG. 2B. The pulse oximeter operator selects the sensitivity mode. The limit selector 330 also has energy ratio limit 336 and signal strength limit 338 outputs, which are input to the probe off logic 350 as absolute minimums of energy ratio and signal strength below which a probe off condition may be indicated 350. The relationship between the pulse rate 332 and sensitivity mode 334 inputs and the energy ratio 336 and signal strength 338 outputs is specified below:

INPUT STATE	SELECTED LIMIT
pulse rate ≥ 30	minimum energy ratio - 0.6
pulse rate < 30	minimum energy ratio - 0.5
sensitivity mode - 0	minimum signal strength - 0.05
sensitivity mode - 1	minimum signal strength - 0.25

The probe off logic **350** has as inputs energy ratio **332**, PR density **334** and signal strength vector **314**. These inputs are compared to the energy ratio limit **336** and signal strength limit **338** outputs from the limit selector **330** to determine the operating region of the pulse oximeter. The probe off logic **350** also has a time fuse input **356**. The time fuse **356** is a counter that indicates the number of IR waveform blocks containing no acceptable pulses. Acceptable pulses are determined as described for the calculation of PR density **354**, above. The time fuse **356** input is 1 if there have been no acceptable pulses in a block since startup. The time fuse **356** is reset to 0 each time no acceptable pulses are detected for an input block. For each block where there are no acceptable pulses, the time fuse **356** is incremented by one. The time fuse enables the energy ratio limit and that portion of the signal strength limits above the floor **230** (FIGS. **2A-2B**). This reduces the probability of probe off alarms for transient events. In a particular embodiment, the time fuse **356** is compared to the constants -1 and 5. That is, the energy ratio and signal strength limits are enabled if there have been no acceptable pulses since startup or for more than the previous 5 IR signal blocks.

[0018] The probe off logic **350** has a Boolean probe off output **358** that is set to 1 when the probe off logic **350** detects the pulse oximeter is operating outside permissible limits. Otherwise, the probe off output **358** is 0. The probe off output can be used by the pulse oximeter to trigger a probe off alarm and error message to alert medical personnel to inspect and reattach the sensor or take other appropriate action. The probe off logic **350** is described in more detail below with respect to FIG. 5.

[0019] FIG. 4 shows further details of the signal strength calculator **310** (FIG. 3). Each **390** sample block of the IR signal **312** is initially filtered **410** remove any trends in the IR signal **312** that could cause an error in the signal strength calculations. In a particular embodiment, the filter **410** is a bandpass FIR filter with cutoff frequencies of 50 Hz and 550 Hz and a 151 tap Kaiser window having a shape parameter of 3.906. As a result, 150 samples are lost from each 390 sample input block. Thus, the filtered IR output **412** consists of **240** sample blocks.

[0020] Each 240 sample block of the filtered IR output **412** is converted **430** into multiple overlapping sub-blocks. In a particular embodiment, the sub-blocks each consist of 100 samples, and each sub-block is offset by 10 samples from the previous sub-block. Thus, the sub-block converter **430** creates 15 sub-block outputs **432** for each **240** sample filtered IR block **412**. For each sub-block, a max-min calculation **460** is performed. That is, the minimum sample magnitude in a particular sub-block is subtracted from the maximum sample magnitude in that sub-block. Each max-min output **462** is a single scalar representing the signal strength of a particular sub-block. A scalar-to-vector conversion **490** combines the max-min outputs **462** into a vector output **314** containing multiple signal strength values representing the signal strength of a particular block of the IR signal **312**.

[0021] FIG. 5 provides further detail of the probe off logic **350** (FIG. 3). The probe off logic **350** has three functional checks that each provide a Boolean output. An energy ratio check **510** compares the energy ratio **352** against the energy ratio limit **336** provided by the limit selector **330** (FIG. 3), specified in the table above. The energy ratio check **510** sets the "poor energy ratio" output **512** if the energy ratio **352** is below the energy ratio limit **336**.

[0022] A time fuse check **520** determines if the time fuse **356** indicates no acceptable pulses have occurred in the IR signal **312** (FIG. 3) for a sufficiently long time period. If so, a timeout output **522** is set. In a particular embodiment, the time fuse check **520** consists of comparators that determine if the time fuse **356** is -1 or greater than 5, indicating no acceptable pulses since startup or for a longer period than the past 5 blocks of IR signal **312**.

[0023] The signal strength dependent checks **530** determine if the pulse oximeter is within the operating limits described above with respect to FIGS. **2A** and **2B**. If the signal strength, as determined by the signal strength vector **314**, is below the floor **230** (FIGS. **2A-B**), then the signal strength failure output **534** is set. If the signal strength is above the floor **230** (FIGS. **2A-B**) but otherwise outside the operating region, i.e. within the shaded region **270** (FIGS. **2A-B**) above the floor **230** (FIGS. **2A-2B**), then the "poor signal strength" output **532** is set.

[0024] A logical AND function **540** sets a "poor signal quality" output **542** if the poor energy ratio **512**, poor signal strength **532** and timeout **522** outputs are set. A logical OR function **550** sets the probe off output **358** if the poor signal quality **542** or the signal strength failure **534** outputs are set.

[0025] FIG. 6 shows a particular embodiment of the signal strength dependent checks **530** (FIG. 5). The signal strength vector **314** is converted **610** into the 15 individual signal strength scalars **612**. Relative checks **620** and absolute checks **630** are performed on each of the 15 scalars **612**. Each relative check **620** determines if signal strength is within the signal strength limit **338** relative to PR density **354**. That is, each relative check output **622** is set according to the

following, see Eq. 3 above:

INPUT STATE	RESULT
$SS \geq SS \text{ limit}$	output - 0
$PR \text{ density} > -1.3043 \bullet SS + 0.5261$	output - 0
$(SS < SS \text{ limit}) \text{ AND}$	output - 1
$PR \text{ density} < -1.3043 \bullet SS + 0.5261$	

Each absolute check **630** determines if the signal strength is above the absolute minimum floor 230 (FIGS. 2A-2B). That is, each absolute check output **632** is set according to the following:

INPUT STATE	RESULT
$SS \geq 0.02$	output-0
$SS < 0.02$	output = 1

The 15 relative check outputs **622** are processed by a sum and compare **660**, which performs an arithmetic sum of these outputs **622**. If the sum is equal or greater than 5, the poor signal strength output **532** is set. That is, poor signal strength is indicated if at least 1/3 of the scalars in the signal strength vector **314** fail their relative checks **620**. Likewise, the 15 absolute check outputs **632** are processed by a sum and compare **670**, which performs an arithmetic sum of these outputs **632**. If the sum is equal or greater than 5, the signal strength failure output **534** is set. That is, a signal strength failure is indicated if at least 1/3 of the scalars in the signal strength vector **314** fail the absolute checks **630**.

[0026] This improvement to detecting pulse oximetry probe off conditions 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 probe-off detector providing an indication that a physiological sensor may not be properly positioned proximate a tissue site, said probe-off detector comprising:

probe-off logic configured to receive a signal quality input indicative of an operating region of a sensor; and a signal strength calculator configured to receive a sensor signal from the sensor and configured to generate a signal strength output dependent on a time-varying component of the sensor signal, wherein the probe-off logic is further configured to provide a probe-off output based on a comparison of the signal strength output and the signal quality input with a stored relationship defining an acceptable operating region of the sensor relative to the signal quality input.

2. The probe-off detector of claim 1, wherein the probe-off logic comprises a comparator.
3. The probe-off detector of claim 1, wherein the probe-off logic comprises an energy ratio check.
4. The probe-off detector of claim 1, wherein the probe-off logic comprises a time check indicating that no acceptable pulses have occurred for a sufficient time period.
5. A method of detecting that a pulse oximetry sensor may not be properly attached to a tissue site by processing a sensor signal, the method comprising:

determining a signal strength limit dependent on a processor input;
calculating a signal strength value from a sensor signal of a pulse oximetry sensor;
calculating a signal quality value of the sensor signal; and
indicating a probe-off condition when the signal strength value is below the signal strength limit corresponding

with the signal quality value.

6. The method of claim 5, wherein the processor input comprises a sensitivity mode.

7. A detector for determining when a physiological sensor may not be properly positioned with respect to a measurement site, the detector comprising a signal strength calculator which processes an input signal expected to be representative of at least one parameter measured by a physiological sensor, to produce an output representative of a strength of the input signal; and logic which indicates that the input signal may not represent the parameter when a predetermined portion of the output is below a signal strength limit for a corresponding signal quality value.

8. The detector of claim 7, wherein the signal strength limit comprises a floor value below which a probe-off condition exists for all values of the output.

9. A method of determining whether a pulse oximetry sensor is properly connected to a patient, said method comprising the steps of:

receiving a signal strength vector related to a pulse oximetry sensor;
receiving at least one of a signal strength limit and a pulse rate density;
providing an indication of poor signal strength based on said signal strength vector and said at least one of a signal strength limit and a pulse rate density; and
determining whether the pulse oximetry sensor is properly connected to a patient based at least in part on the indication.

10. The method of claim 9, wherein said at least one of said signal strength limit and said pulse rate density includes said signal strength limit, and wherein said providing the indication further comprises determining a relationship between a signal strength scalar and said signal strength limit, wherein said signal strength scalar is based upon said signal strength vector.

11. The method of claim 10, wherein said determining a relationship between a signal strength scalar and said signal strength limit comprises determining whether said signal strength scalar is greater than or equal to said signal strength limit.

12. The method of claim 9, wherein said at least one of said signal strength limit and said pulse rate density includes said pulse rate density, and wherein said providing the indication further comprises determining a relationship between a signal strength scalar and said pulse rate density, wherein said signal strength scalar is based upon said signal strength vector.

13. The method of claim 12, wherein said determining a relationship between a signal strength scalar and said pulse rate density comprises determining whether said pulse rate density is greater than a function of said signal strength scalar.

14. The method of claim 13, wherein said function is of the form $y=mx+b$ and wherein b comprises said signal strength scalar.

15. The method of claim 14, wherein m is approximately -1.30.

16. The method of claim 14, wherein b is approximately 0.53.

17. The method of claim 9, further comprising providing an indication of signal strength failure based on said signal strength vector and said at least one of a signal strength limit and a pulse rate density; and wherein said determining further comprises determining whether the pulse oximetry sensor is properly connected to the patient based on at least one of the indication of poor signal strength and the indication of signal strength failure.

18. The method of claim 17, wherein said providing the indication of signal strength failure further comprises determining a relationship between a signal strength scalar and a floor value, wherein said signal strength scalar is based upon said signal strength vector.

19. The method of claim 18, wherein said determining a relationship comprises determining whether said signal strength

scalar is greater than or equal to said floor value.

20. The method of claim 19, wherein said floor value is approximately 0.02.

5 **21.** A method of determining a sensor off condition for physiological monitoring system, comprising:

receiving first and second intensity signals from a light-sensitive detector in the sensor which detects light of at least first and second wavelengths attenuated by body tissue carrying pulsing blood;
determining a plurality of signal characteristics of the first and second intensity signals originating from the
10 sensor; and
analyzing the plurality of signal characteristics to determine the sensor off condition based upon a stored relationship between signal strength of said intensity signals and at least one of said signal characteristics.

15 **22.** The method of Claim 21, wherein said analyzing comprises a rules based evaluation of the plurality of signal characteristics.

23. The method of Claim 22, wherein said plurality of signal characteristics comprises at least two of energy ratio, signal strength, pulse rate density, and a counter of the number of portions of the first or second intensity signal that contain
20 no acceptable pulse data.

25

30

35

40

45

50

55

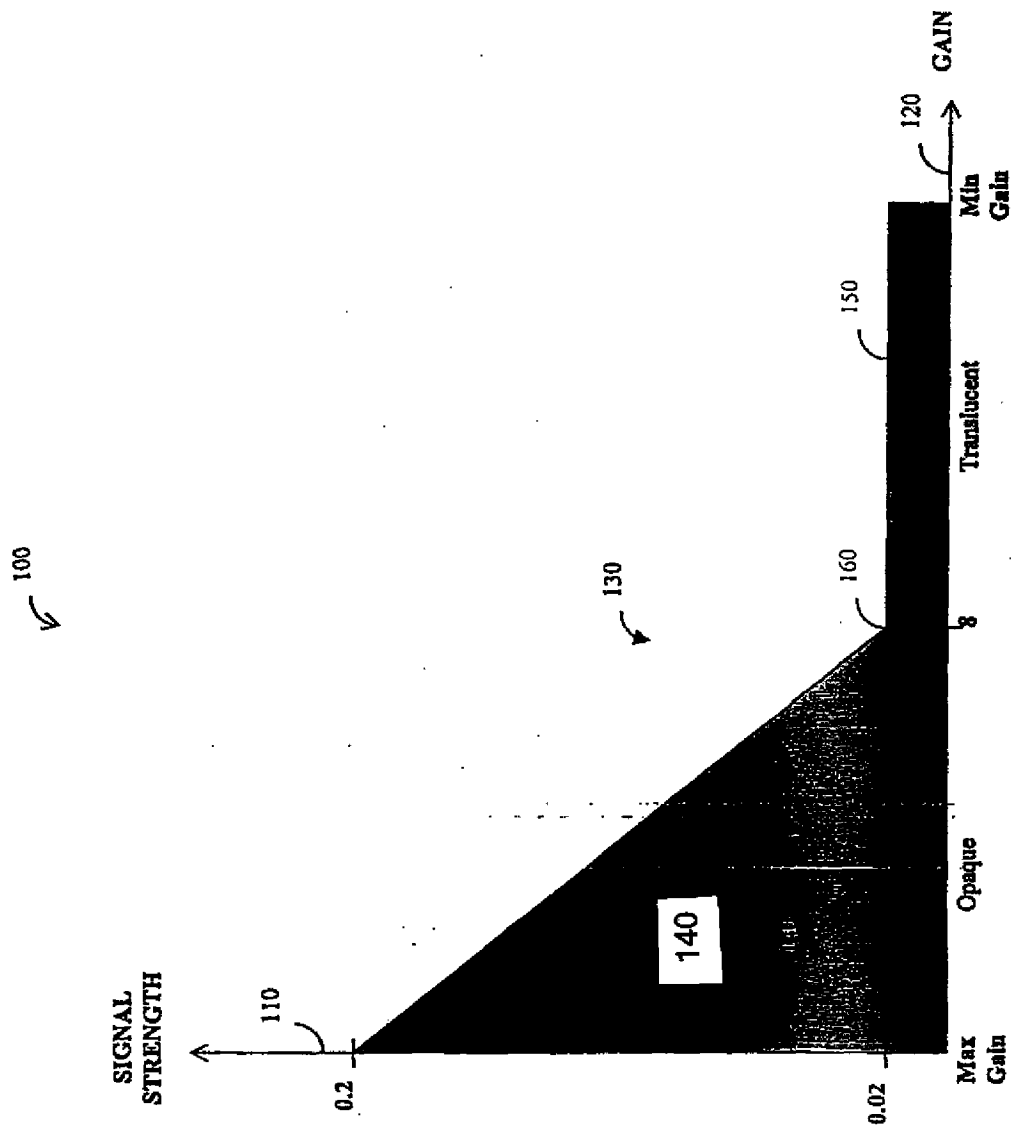


FIG. 1

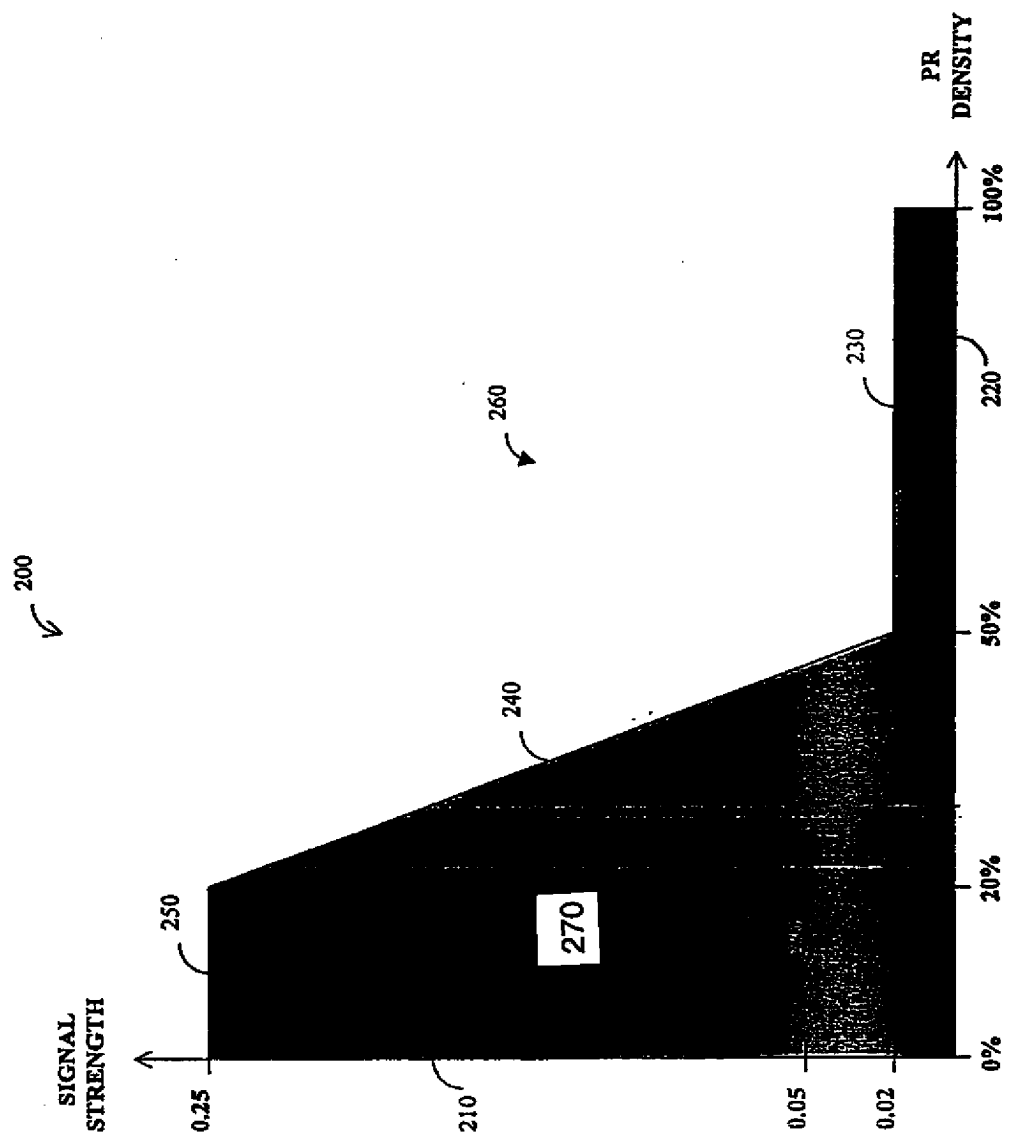


FIG. 2A

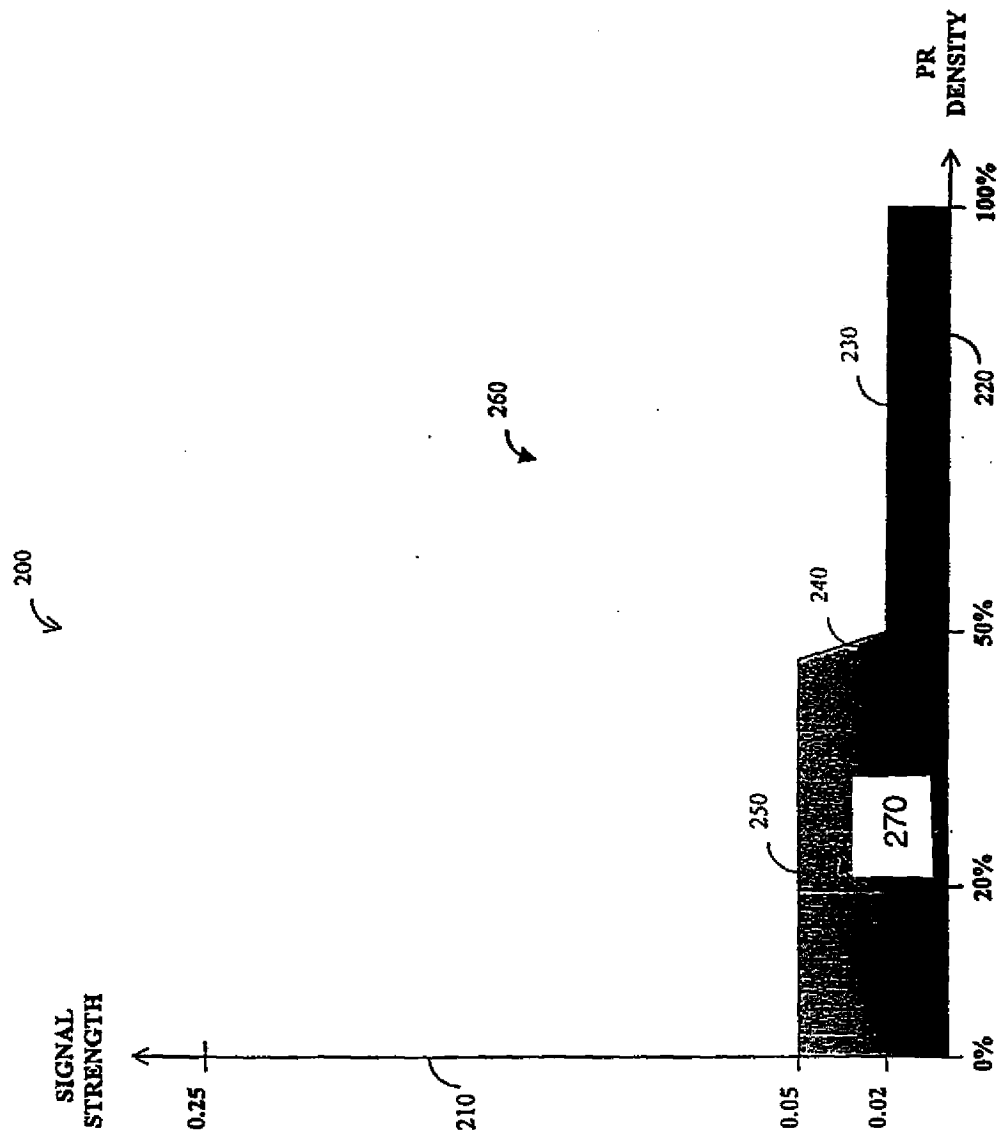


FIG. 2B

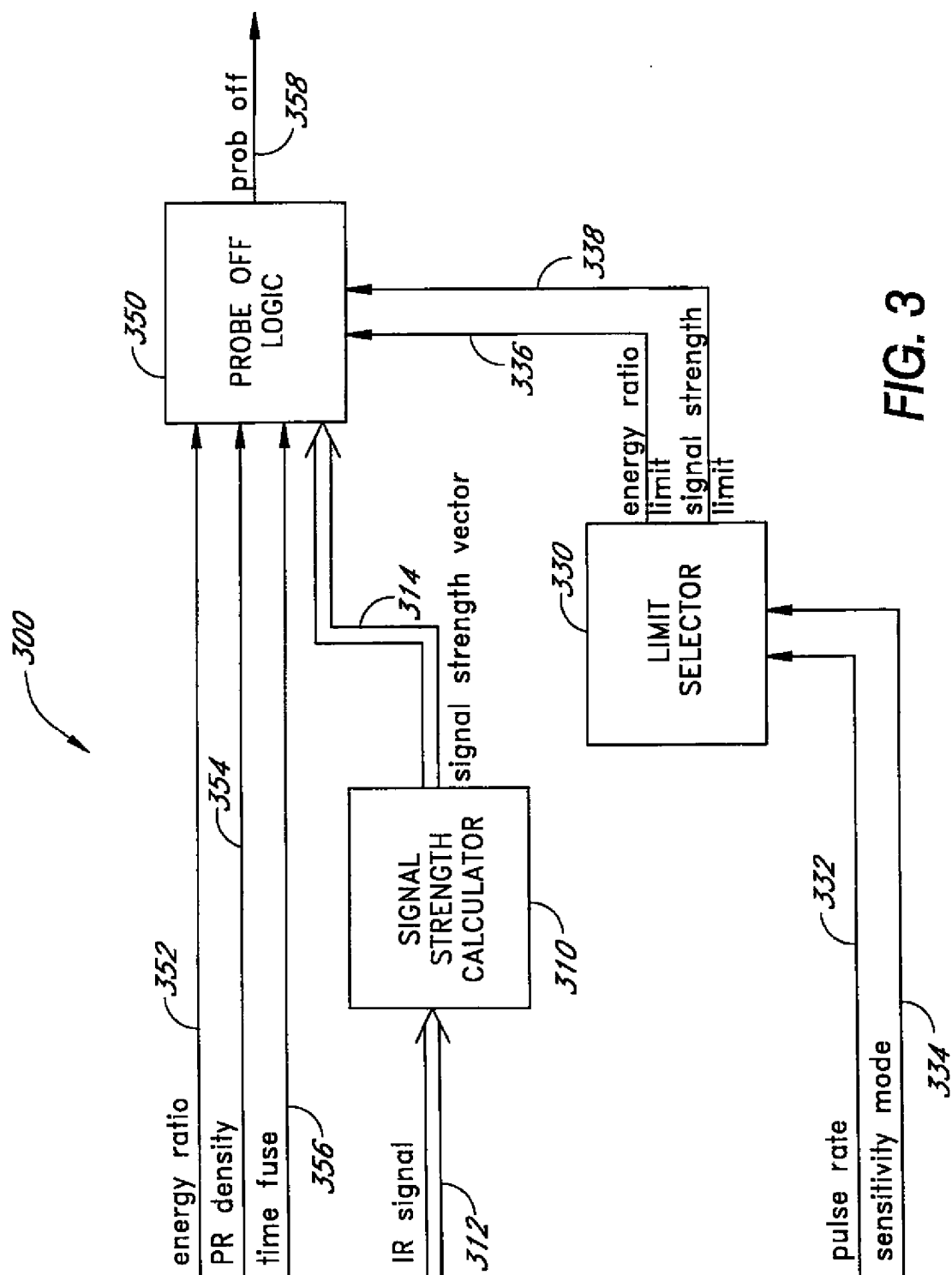


FIG. 3

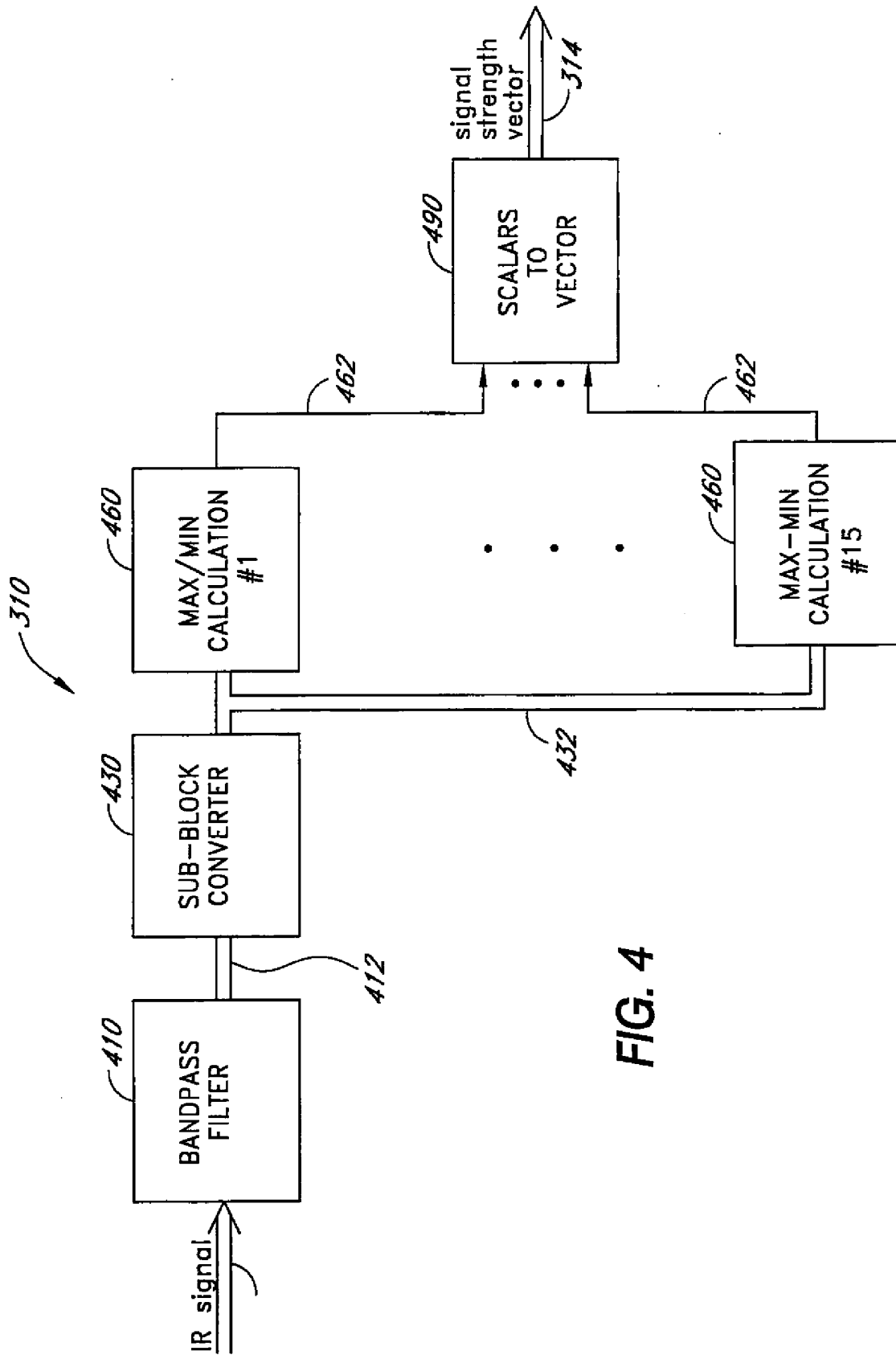


FIG. 4

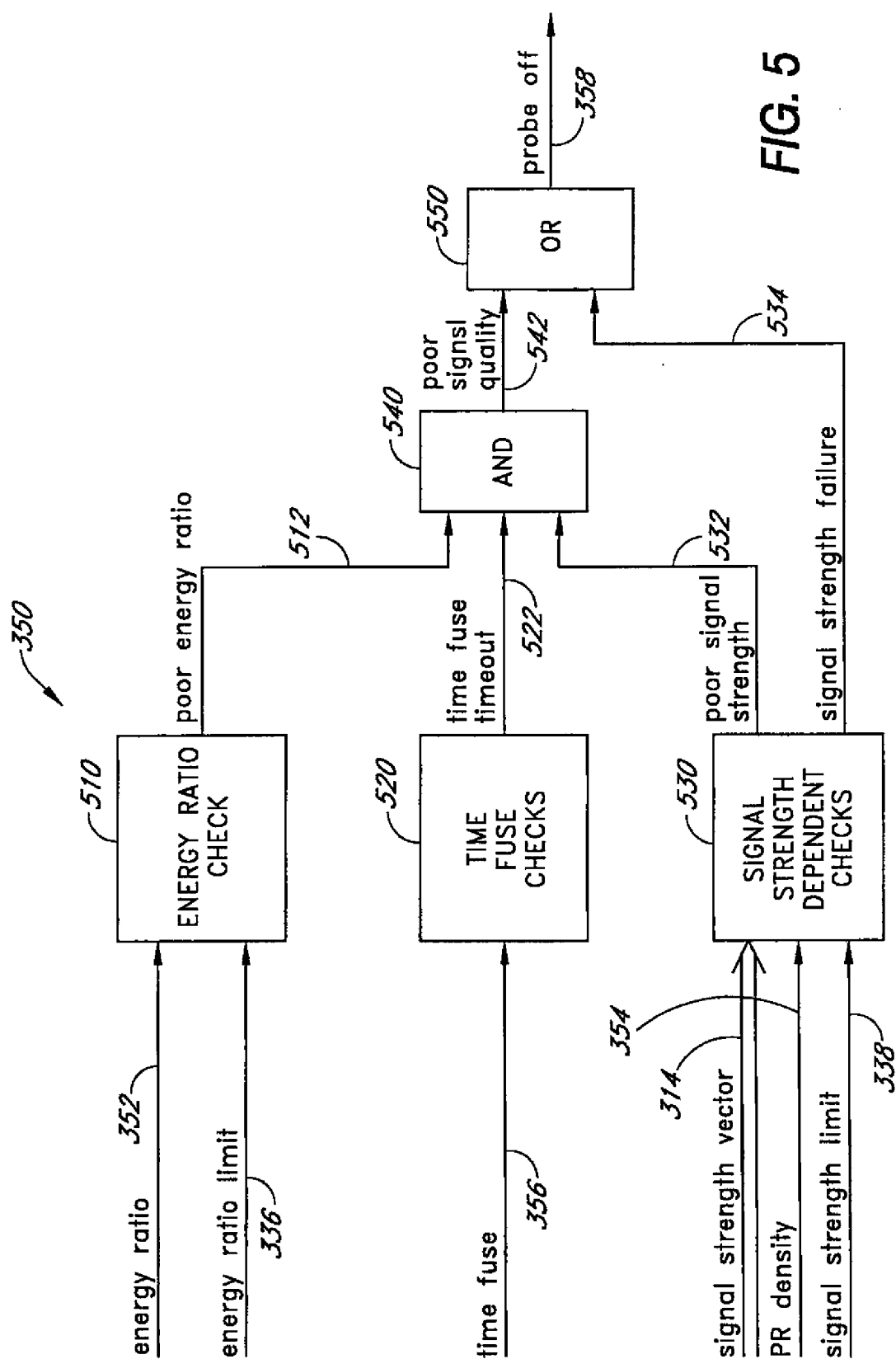


FIG. 5

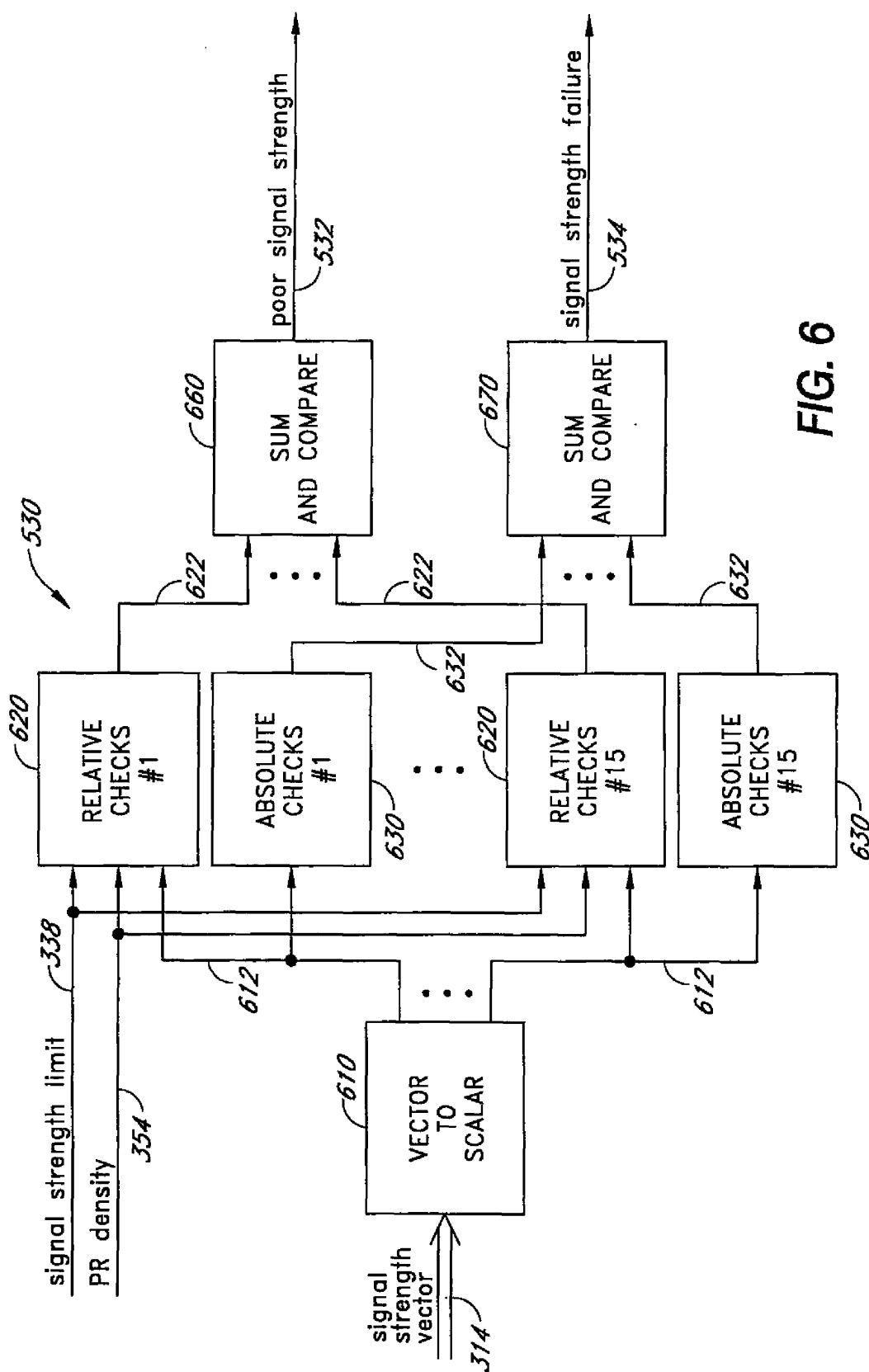


FIG. 6



EUROPEAN SEARCH REPORT

Application Number
EP 10 18 1436

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 5 846 190 A (WOHRLE DIETER [DE]) 8 December 1998 (1998-12-08) * column 2, line 65 - column 11, line 34 * * figure 1 *	1-3,5, 7-11, 17-19, 21,22	INV. A61B5/00
X	US 4 399 824 A (DAVIDSON IAN H) 23 August 1983 (1983-08-23) * column 2, line 54 - column 6, line 19; figures 1,3 *	1,2,7,8	
A	----- US 5 368 041 A (SHAMBROOM JOHN R [US]) 29 November 1994 (1994-11-29) * abstract * * column 2, line 45 - column 4, line 55 * * column 9, line 3 - line 57 * * figures 1,7 *	5,9,21	
X	----- US 4 603 700 A (NICHOLS ROBERT A ET AL) 5 August 1986 (1986-08-05) * column 1, line 60 - column 5, line 37 *	7,8	
A	----- US 4 295 475 A (TORZALA TERENCE A) 20 October 1981 (1981-10-20) * abstract *	1,5,9,21	
A	----- US 4 603 700 A (NICHOLS ROBERT A ET AL) 5 August 1986 (1986-08-05) * column 1, line 60 - column 5, line 37 *	1,5,7,9, 21	TECHNICAL FIELDS SEARCHED (IPC) A61B
A	----- US 4 295 475 A (TORZALA TERENCE A) 20 October 1981 (1981-10-20) * abstract *	1,5,7,9, 21	
The present search report has been drawn up for all claims			
Place of search Munich		Date of completion of the search 26 November 2010	Examiner Artikis, T
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

2
EPO FORM 1503 03.82 (P04C01)

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 10 18 1436

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

26-11-2010

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
US 5846190	A	08-12-1998	DE	19537646 A1	17-04-1997
			JP	3795590 B2	12-07-2006
			JP	9108203 A	28-04-1997

US 4399824	A	23-08-1983	BR	8207911 A	13-09-1983
			DE	3280379 D1	16-01-1992
			EP	0091474 A1	19-10-1983
			JP	5058727 B	27-08-1993
			JP	58501617 T	29-09-1983
			WO	8301188 A1	14-04-1983

US 5368041	A	29-11-1994	AU	5370294 A	09-05-1994
			CA	2146979 A1	28-04-1994
			EP	0665728 A1	09-08-1995
			WO	9408507 A1	28-04-1994
			US	5381804 A	17-01-1995

US 4603700	A	05-08-1986	CA	1224642 A1	28-07-1987
			GB	2151020 A	10-07-1985
			JP	1649713 C	30-03-1992
			JP	3011772 B	18-02-1991
			JP	60174135 A	07-09-1985

US 4295475	A	20-10-1981	DE	3040204 A1	07-05-1981
			FR	2468879 A1	08-05-1981
			GB	2061496 A	13-05-1981
			JP	1184468 C	27-12-1983
			JP	56083328 A	07-07-1981
			JP	58015134 B	24-03-1983

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 5632272 A [0002]
- US 11412798 P [0012]
- US 47151099 A [0012]
- US 6002952 A [0015]

专利名称(译)	改进的脉搏血氧仪探测器		
公开(公告)号	EP2298159A1	公开(公告)日	2011-03-23
申请号	EP2010181436	申请日	2000-03-24
[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	DIAB MOHAMED K ALI AMMAR AL		
发明人	DIAB, MOHAMED K. ALI, AMMAR AL		
IPC分类号	A61B5/00 G01N21/35 A61B5/145 A61B5/1455		
CPC分类号	A61B5/7221 A61B5/14551 A61B5/6843 A61B2560/0276		
代理机构(译)	法思博事务所		
优先权	60/126148 1999-03-25 US		
其他公开文献	EP2298159B1		
外部链接	Espacenet		

摘要(译)

基于规则的智能处理器 (300) 为脉冲血氧计的信号强度操作区域提供基于信号质量的限制。这些限制叠加在典型的增益相关信号强度限制上 (314)。如果生理学上产生传感器信号, 则允许脉搏血氧仪以最小信号强度操作, 从而最大化低灌注性能。如果传感器信号可能是由移位的传感器引起的信号引起的, 则会提高信号强度要求。因此, 信号质量限制增强了探针关闭检测, 而不会显著影响低灌注性能。使用的一种信号质量测量是脉冲速率密度 (354), 其定义了生理学上可接受的脉冲发生的时间百分比。如果检测到的信号包含很大一部分不可接受的脉冲, 则所需的最小信号强度成比例地增加。与脉率密度结合使用的另一种信号质量测量是能量比 (352), 计算为脉冲率基波和相关谐波中包含的总能量的百分比。

