US006654624B2

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

(10) **Patent No.: US 6,654,624 B2**
(45) **Date of Patent: Nov. 25, 2003**

(54) **PULSE OXIMETER PROBE-OFF DETECTOR**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 22 days.

(21) Appl. No.: **10/027,574**

(22) Filed: **Dec. 19, 2001**

(65) **Prior Publication Data**

US 2002/0072660 A1 Jun. 13, 2002

Related U.S. Application Data

(63) Continuation of application No. 09/531,820, filed on Mar. 21, 2000, now Pat. No. 6,360,114.
(60) Provisional application No. 60/126,148, filed on Mar. 25, 1999.

(51) **Int. Cl.**[7] **A61B 5/00**
(52) **U.S. Cl.** **600/336**
(58) **Field of Search** 600/336, 310, 600/322, 323, 330, 331, 481, 509, 544, 546, 547

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,295,475	A		10/1981	Torzala
4,331,161	A		5/1982	Patel
4,399,824	A		8/1983	Davidson
4,561,440	A		12/1985	Kubo et al.
4,603,700	A		8/1986	Nichols et al.
5,226,417	A		7/1993	Swedlow et al.
5,368,041	A	*	11/1994	Shambroom 600/544
5,370,114	A		12/1994	Wong et al.
5,469,845	A		11/1995	DeLonzor et al.
5,503,148	A		4/1996	Pologe et al.
5,758,644	A		6/1998	Diab et al.
5,782,757	A		7/1998	Diab et al.
5,823,950	A		10/1998	Diab et al.
6,035,223	A		3/2000	Baker, Jr.
6,360,114	B1	*	3/2002	Diab et al. 600/336

FOREIGN PATENT DOCUMENTS

DE	197 28 902 A 1	7/1997
EP	0 182 197 A2	11/1985
EP	0 315 040 A1	10/1988
GB	2 061 496 A	10/1980

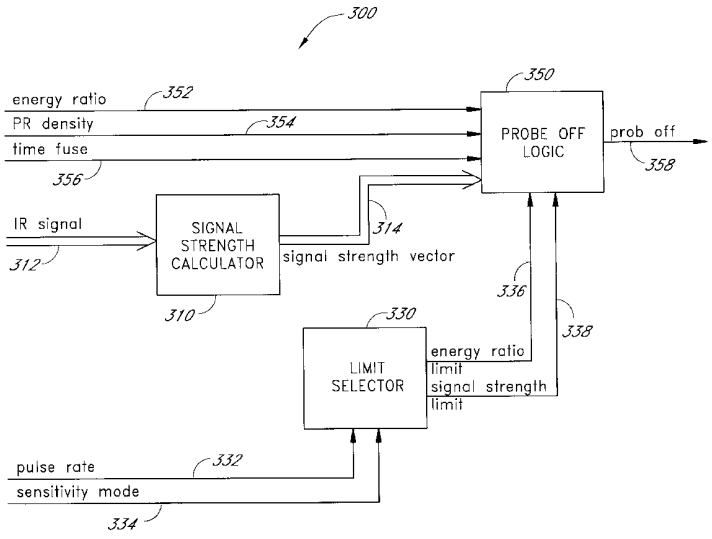
* cited by examiner

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(57) **ABSTRACT**

An intelligent, rule-based processor 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. 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, which defines the percentage of time physiologically acceptable pulses are occurring. If the detected signal contains a significant percentage 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, computed as the percentage of total energy contained in the pulse rate fundamental and associated harmonics.

33 Claims, 7 Drawing Sheets



APPLE 1015

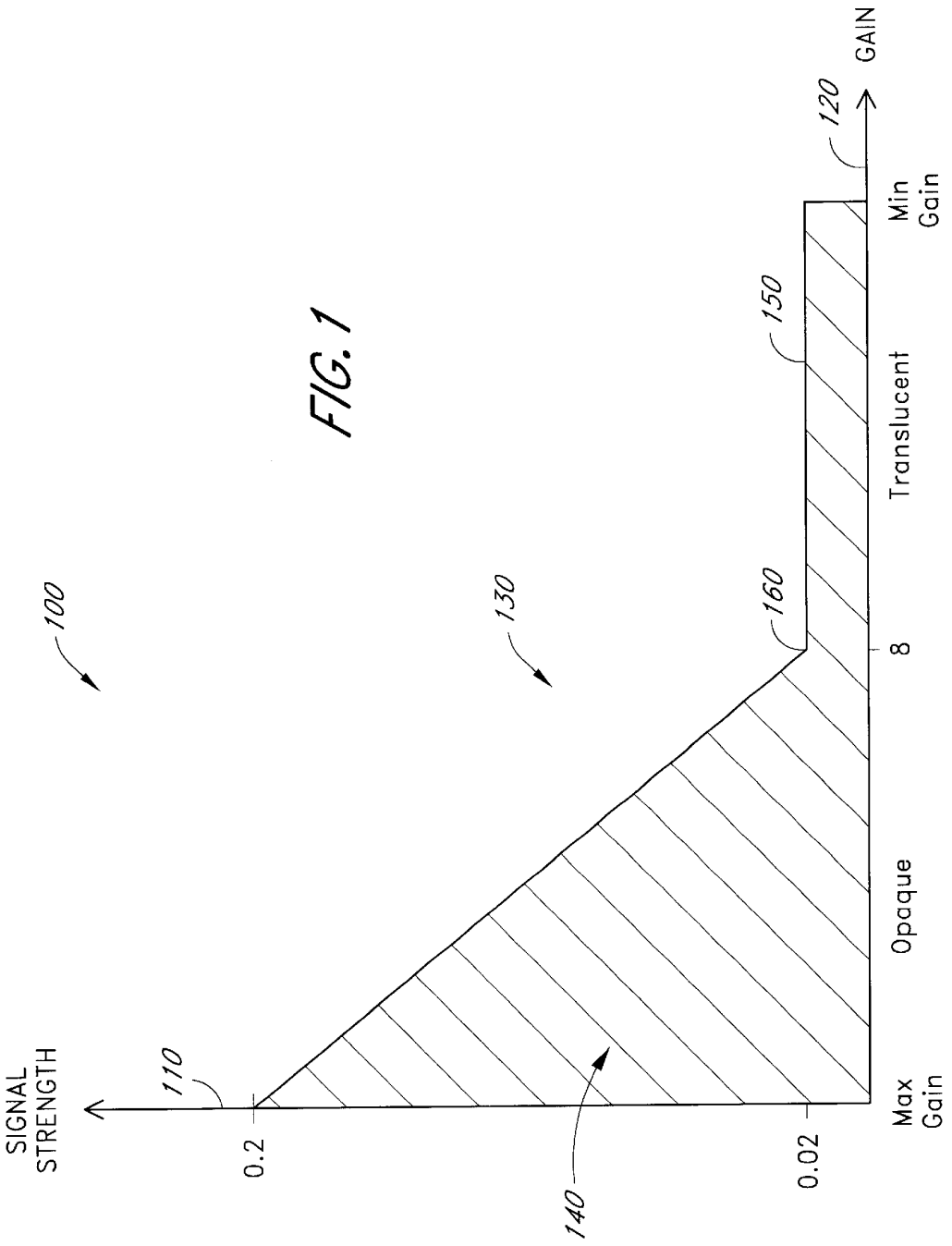

100
130
SIGNAL STRENGTH
110
0.2
0.02
140
160
8
150
120
GAIN
Max Gain
Opaque
Translucent
Min Gain

FIG. 1

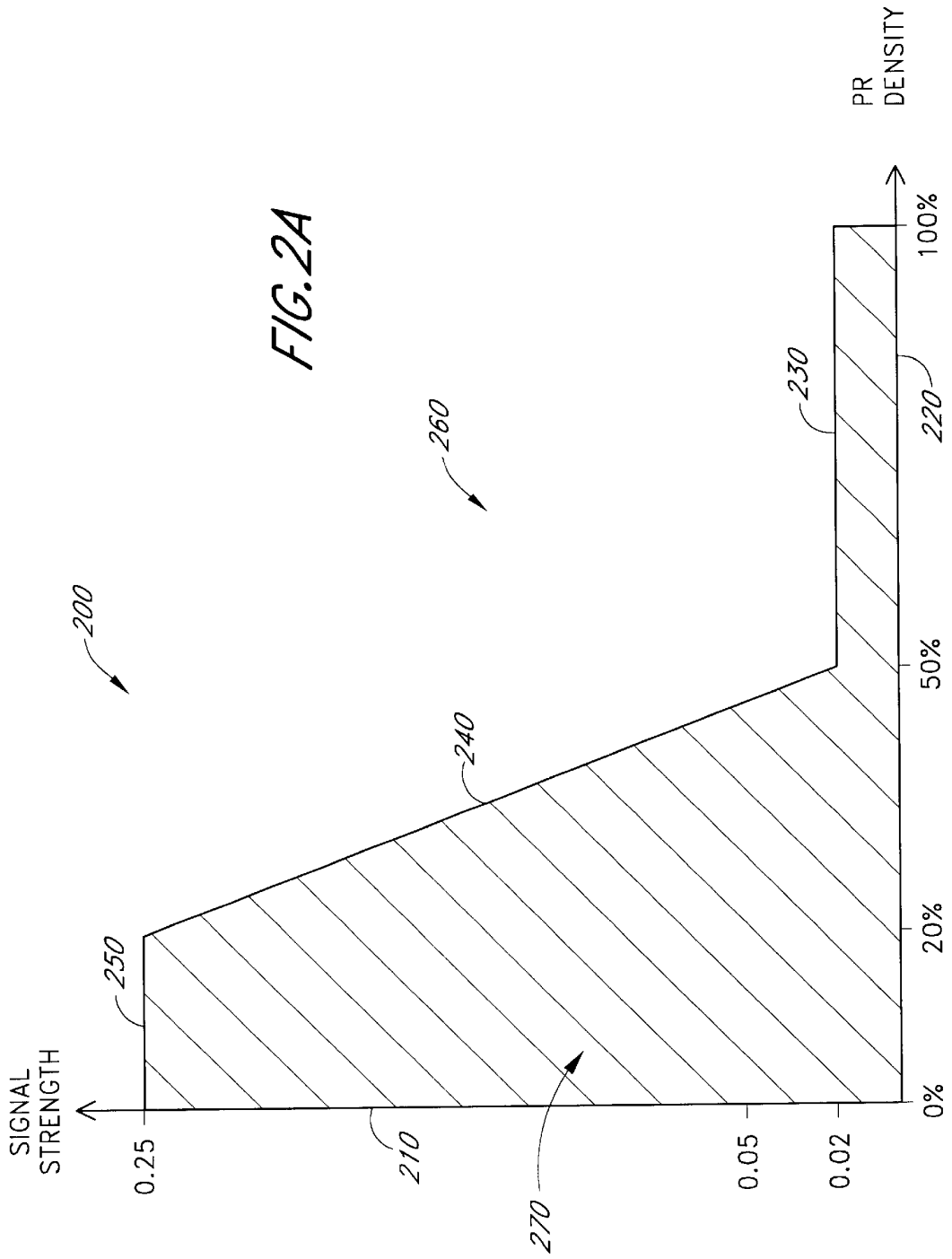

SIGNAL STRENGTH
0.25
0.05
0.02
PR DENSITY
0%
20%
50%
100%
200
210
220
230
240
250
260
270

FIG. 2A

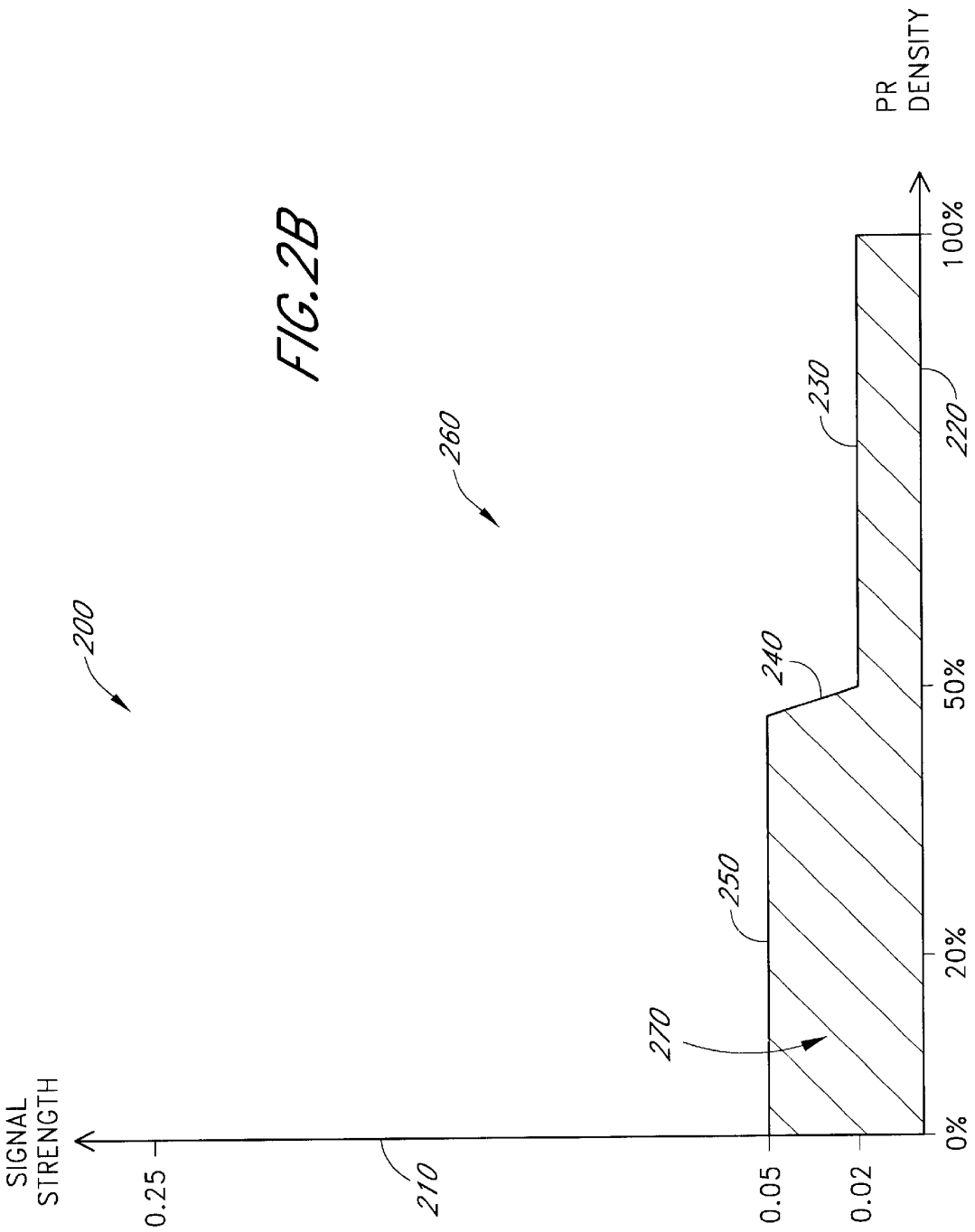

SIGNAL STRENGTH
0.25
0.05
0.02
PR DENSITY
0%
20%
50%
100%
200
210
220
230
240
250
260
270

FIG. 2B

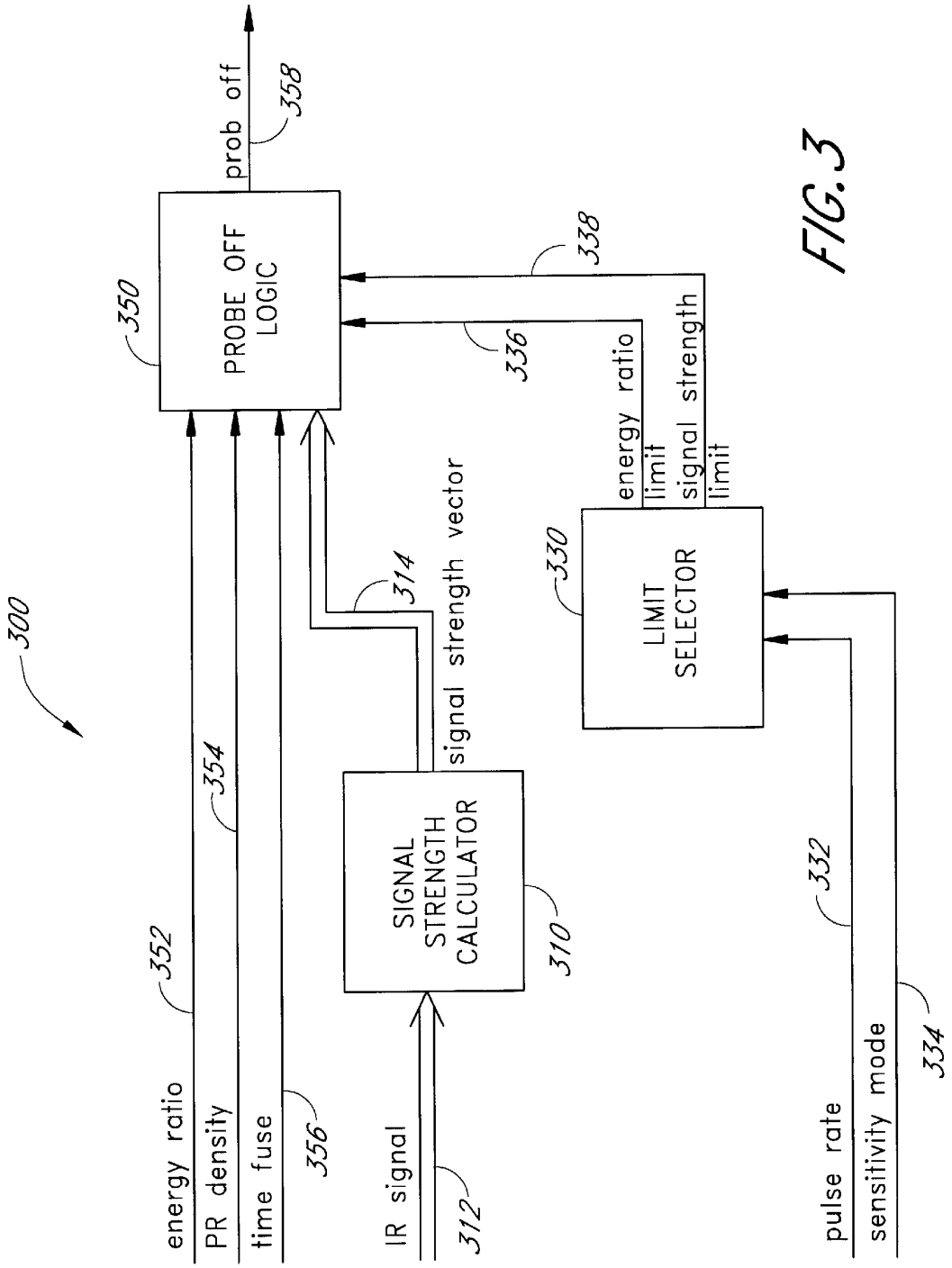

300
PROBE OFF LOGIC
350
prob off
358
338
336
energy ratio
limit
signal strength
limit
LIMIT SELECTOR
330
314
signal strength vector
SIGNAL STRENGTH CALCULATOR
310
352
354
356
energy ratio
PR density
time fuse
IR signal
312
332
334
pulse rate
sensitivity mode

FIG. 3

FIG. 4

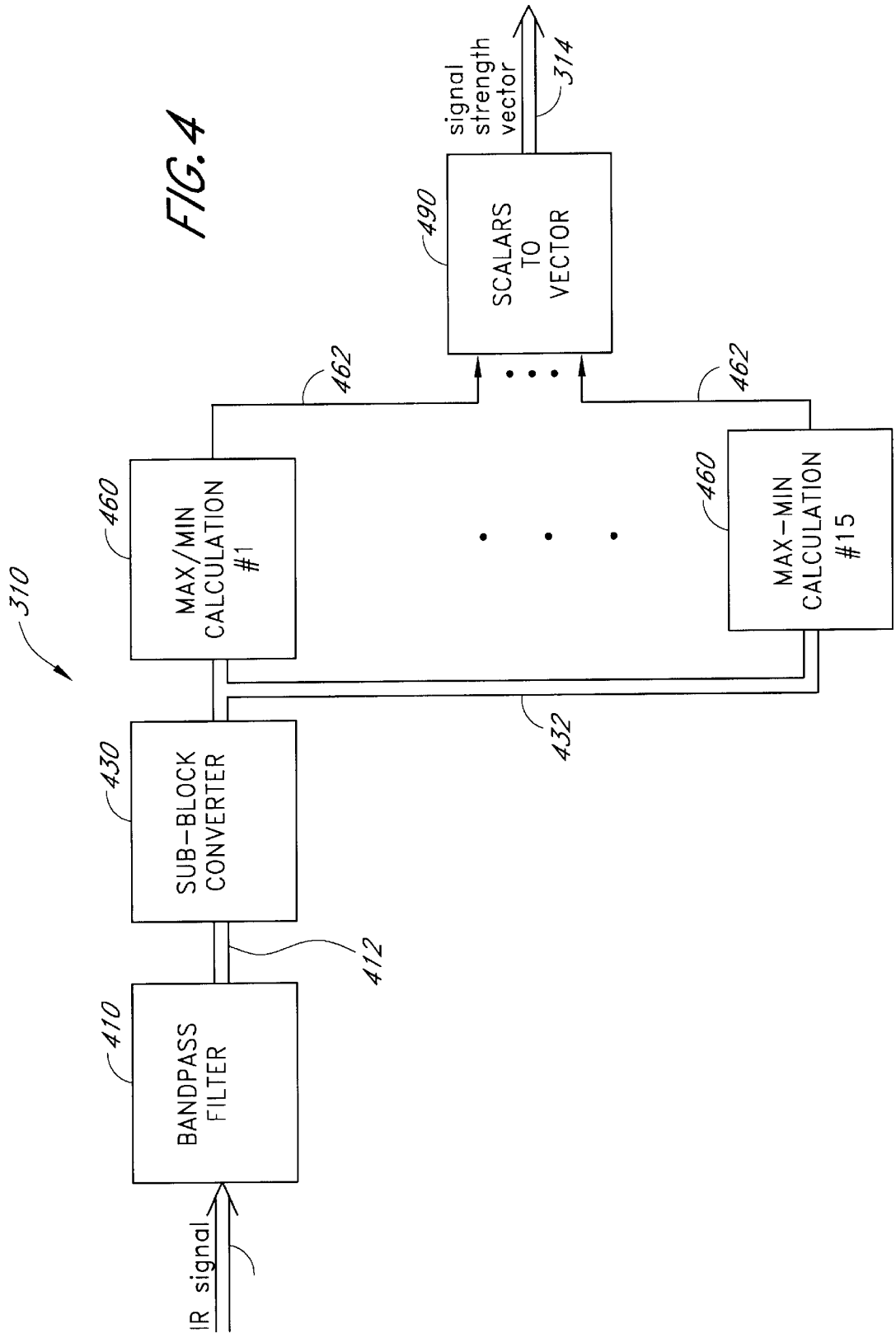

IR signal
BANDPASS FILTER
410
412
SUB-BLOCK CONVERTER
430
MAX/MIN CALCULATION #1
460
MAX-MIN CALCULATION #15
460
462
462
432
SCALARS TO VECTOR
490
signal strength vector
314
310

FIG. 5

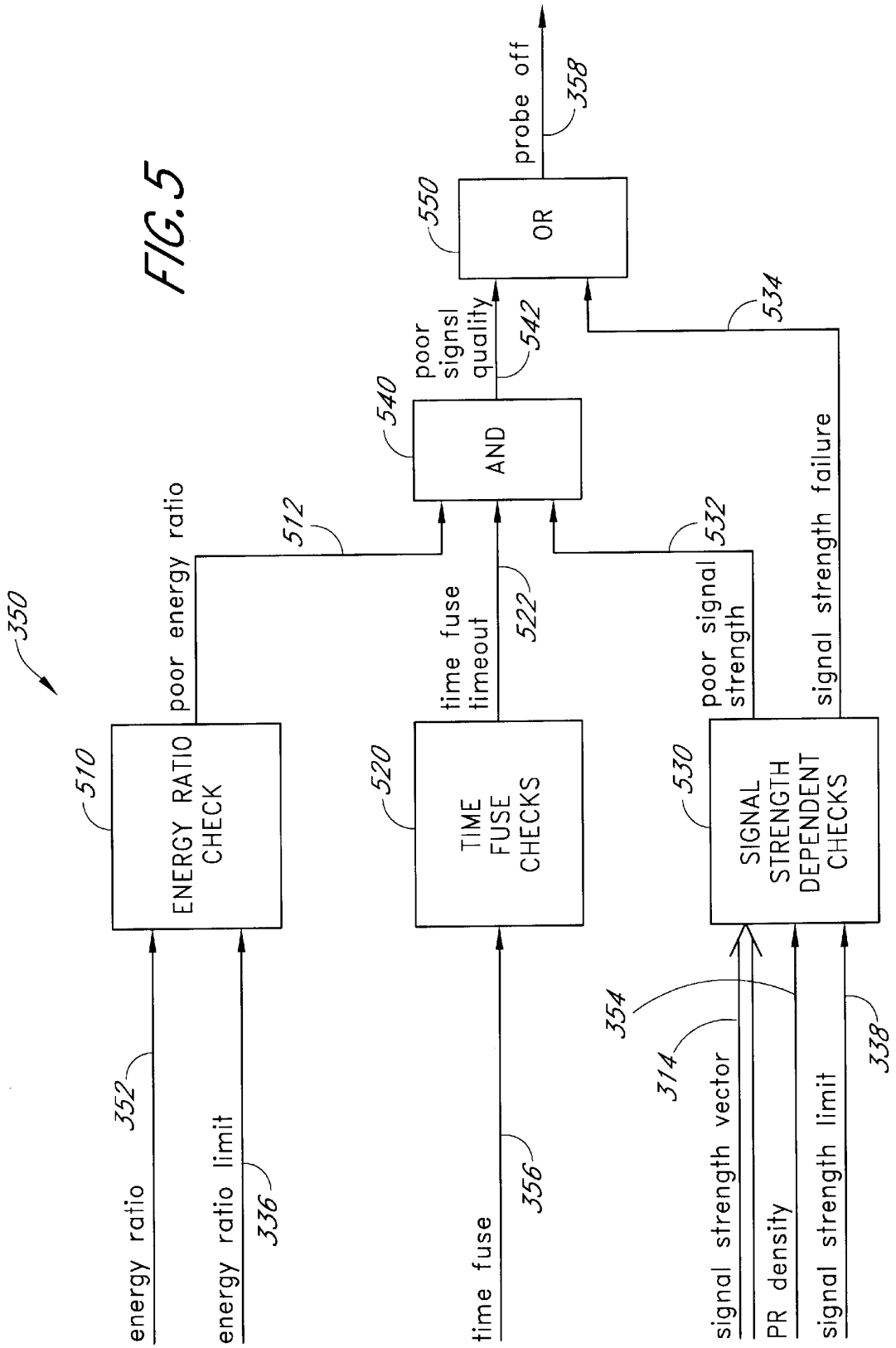
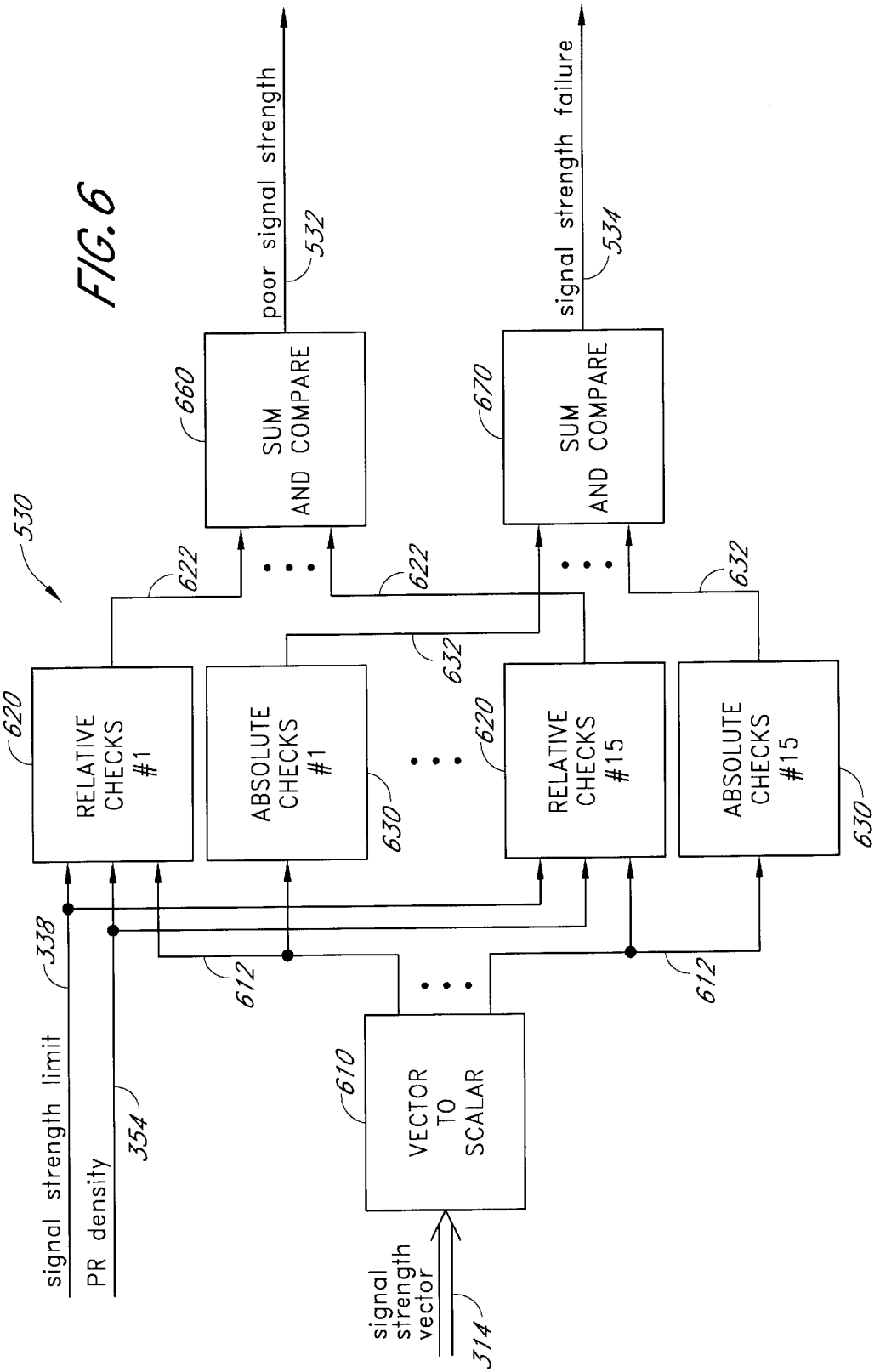

350
ENERGY RATIO CHECK
510
TIME FUSE CHECKS
520
SIGNAL STRENGTH DEPENDENT CHECKS
530
AND
540
OR
550
poor energy ratio
512
time fuse timeout
522
poor signal strength
532
poor signl quality
542
probe off
358
signal strength failure
534
energy ratio
352
energy ratio limit
336
time fuse
356
signal strength vector
314
PR density
354
signal strength limit
338

FIG. 6


530
620
RELATIVE CHECKS #1
ABSOLUTE CHECKS #1
630
620
RELATIVE CHECKS #15
ABSOLUTE CHECKS #15
630
622
622
632
632
660
SUM AND COMPARE
670
SUM AND COMPARE
poor signal strength
532
signal strength failure
534
338
signal strength limit
PR density
354
612
612
610
VECTOR TO SCALAR
signal strength vector
314

PULSE OXIMETER PROBE-OFF DETECTOR

REFERENCE TO RELATED APPLICATION

The present application is a continuation of U.S. patent application Ser. No. 09/531,820, filed Mar. 21, 2000, now U.S. Pat. No. 6,360,114, entitled "PULSE OXIMETER PROBE-OFF DETECTOR," (the parent application) and claims priority benefit under 35 U.S.C. §120 to the same. The parent application claimed a priority benefit under 35 U.S.C. §119(e) from U.S. Provisional Application No. 60/126,148, filed Mar. 25, 1999, entitled "PULSE OXIMETER PROBE-OFF DETECTOR." The present application incorporates each of the foregoing disclosures herein by reference.

BACKGROUND OF THE INVENTION

DESCRIPTION OF THE RELATED ART

Oximetry is the measurement of the oxygen status of blood. Early detection of low blood oxygen is critical in the medical field, for example in critical care and surgical applications, because an insufficient supply of oxygen can result in brain damage and death in a matter of minutes. Pulse oximetry is a widely accepted noninvasive procedure for measuring the oxygen saturation level of arterial blood, an indicator of oxygen supply. A pulse 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 foot. For a finger, the sensor is configured so that the emitters project light through the fingernail and into the blood vessels and capillaries underneath. The photodiode is positioned at the fingertip opposite the fingernail so as to detect the LED transmitted light as it emerges from the finger tissues.

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

SUMMARY OF THE INVENTION

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.

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.

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.

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.

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 AC 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.

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.

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.

BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

FIG. **2**B 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. **2**A–**2**B;

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 dependent checks portion of FIG. **5**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIGS. **2**A and **2**B 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 Dec. 30, 1998, and in U.S. patent application Ser. No. 09/471,510, filed Dec. 23, 1999, entitled "Plethysmograph Pulse Recognition Processor," which is assigned to the assignee of the current application and incorporated by reference herein. 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.

FIG. **2**A 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 0.02, 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 0.02, then the pulse oximeter indicates a probe off condition. A signal strength ceiling **250** of 0.25, 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 0.25. 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:

$$\text{slope}=-(0.25-0.02)/(0.5-0.2)=-0.23/0.3=-0.7667 \quad (1)$$

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

$$\text{ss}=-0.7667\cdot\text{PR density}+0.4033 \quad (2)$$

$$\text{PR density}=-1.3043\cdot\text{SS}+0.5261 \quad (3)$$

FIG. **2**B 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. **2**A except that the signal strength ceiling **250** is set at 0.05. Thus, signal quality indicated by PR density is ignored as long as the signal strength is above 0.5.

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 0.6 if the pulse rate is greater than or equal to 30 and 0.5 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. Pat. No. 6,002,952, filed Apr. 14, 1997, entitled "Improved Signal Processing Appa-

ratus and Method," which is assigned to the assignee of the current application and incorporated by reference herein.

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.

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. **2**A. A value of 0 indicates the pulse oximeter is in a high sensitivity mode, corresponding to FIG. **2**B. 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 limit **336** and signal strength limit **338** outputs is specified below:

The probe off logic **350** has as inputs energy ratio **352**, 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. **2**A–**2**B). 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.

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**.

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** to 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.

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**.

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**.

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**.

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

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.

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 ≥ SS limit	output = 0
PR density > −1.3043 · SS + 0.5261	output = 0
(SS < SS limit) AND	output = 1
PR density < −1.3043 · SS + 0.5261	

Each absolute check **630** determines if the signal strength is above the absolute minimum floor **230** (FIGS. **2**A–**2**B).

That is, each absolute check output **632** is set according to the following:

INPUT STATE	RESULT
SS ≥ 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 ⅓ 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 ⅓ of the scalars in the signal strength vector **314** fail the absolute checks **630**.

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.

What is claimed is:

1. 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 threshold value, wherein the threshold value comprises a floor value below which a probe-off condition exists for all values of the output, and wherein the floor value comprises a ratio of a first value of a substantially alternating part of the output to a second value of a substantially non-alternating part of the output.

2. The detector of claim **1**, wherein the ratio comprises about 0.02.

3. The detector of claim **1**, wherein the output comprises a group of samples, and wherein the predetermined portion of the output comprises about one-third of the group.

4. The detector of claim **3**, wherein the group of samples comprises a group of ratios, each ratio comprising a first value of a substantially alternating part of the output to a second value of a substantially non-alternating part of the output.

5. 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 signal strength of the input signal; and

logic which indicates that a probe-off condition may exist when both a predetermined portion of the output is below a signal strength threshold and a signal quality of the input signal falls within a non-operative region.

6. The detector of claim **5**, wherein the signal strength threshold is dependent upon a sensitivity mode of the physiological sensor.

7. The detector of claim **6**, wherein the sensitivity mode is set by an operator.

8. The detector of claim **5**, wherein the signal strength threshold comprises a ratio of a first value of a substantially alternating part of the output to a second value of a substantially non-alternating part of the output.

9. The detector of claim **8**, wherein the ratio comprises a value above which a probe-off condition does not exist for all values of the output.

10. The detector of claim **8**, wherein the ratio comprises a value of about 0.25.

11. The detector of claim **8**, wherein the ratio comprises a value of about 0.05.

12. The detector of claim **5**, wherein the signal quality comprises a comparison of the input signal with one or more physiological signal models.

13. The detector of claim **5**, wherein the non operative-region comprises a region defined by a relationship between the output signal and the signal quality.

14. The detector of claim **5**, further comprising a stored timeout value representative of whether the predetermined portion of the output is valid.

15. The detector of claim **5**, wherein the logic indicates that the probe-off condition may exist when all of the stored timeout value indicates the output is valid, and when both the predetermined portion of the output is below the signal strength threshold and the signal quality of the input signal falls within the non-operative region.

16. The detector of claim **5**, further comprising a stored energy ratio representative of whether a measurement of energy in the input signal is above threshold value.

17. The detector of claim **16**, wherein the logic indicates that a probe-off condition may exist when all of the stored energy ratio is above the threshold value, and when both the predetermined portion of the output is below the signal strength threshold and the signal quality of the input signal falls within the non-operative region.

18. The detector of claim **16**, wherein the logic indicates that a probe-off condition may exist when all of the stored energy ratio is above the threshold value, a timeout value indicates the output includes valid data, and when both the predetermined portion of the output is below the signal strength threshold and the signal quality of the input signal falls within the non-operative region.

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

a limit selector outputting an energy ratio limit dependent upon a sensitivity mode of a physiological sensor; and

logic which indicates that a probe-off condition may exist when an energy ratio representative of an amount of energy in an input signal expected to be representative of at least one parameter measured by a physiological sensor, is below the energy ratio limit.

20. The detector of claim **19**, wherein the energy ratio comprises a ratio of signal energy in the input signal at a detected pulse rate to a total energy of the input signal.

21. The detector of claim **20**, wherein the ratio of signal energy comprises the ratio of signal energy in the input signal at a detected pulse rate and at least one harmonic of the detected pulse rate.

22. The detector of claim **19**, wherein the energy ratio limit is selected by an operator.

23. The detector of claim **19**, wherein the energy ratio limit comprises about 0.6.

24. The detector of claim **19**, wherein the energy ratio limit comprises about 0.5.

25. The detector of claim **19**, wherein the logic indicates that a probe-off condition may exist when both a timeout value indicates the input signal is valid, and when the energy ratio is below the energy radio limit.

26. The detector of claim **19**, wherein the logic indicates that a probe-off condition may exist when all of a timeout value indicates the input signal is valid, and when both a predetermined portion of an output signal representing the signal strength of the input signal is below a signal strength threshold and a signal quality of the input signal falls within the non-operative region.

27. A pulse-off detector for determining when a physiological sensor may not be properly positioned on a measurement site by monitoring characteristics of a signal expected to be representative of at least one parameter measured by the physiological sensor, the pulse-off detector comprising:

an energy ratio check which compares an energy ratio of a signal expected to be representative of at least one parameter measured by a physiological sensor, with an energy ratio limit;

a time fuse check which determines whether no acceptable values of the signal have been received;

a signal strength check which determines whether the physiological sensor is within operating limits defined by a relationship between a signal strength characteristic of the signal and a signal quality characteristic of the signal; and

logic which indicates that the physiological sensor may be in an off-probe condition based on at least one of the energy ratio check, the time fuse check and the signal strength check.

28. The pulse-off detector of claim **27**, wherein the logic indicates that the physiological sensor may be in the off-probe condition when the signal strength check indicates that the signal strength characteristic is below a signal strength threshold.

29. The pulse-off detector of claim **28**, wherein signal strength threshold comprises a value below which an off-probe condition exists for all values of the signal.

30. The pulse-off detector of claim **27**, wherein the logic indicates that the physiological sensor may be in the off-probe condition when the signal strength check indicates that the signal strength characteristic is outside the operating limits.

31. The pulse-off detector of claim **27**, wherein the logic indicates that the physiological sensor may be in the off-probe condition when the energy ratio check indicates that the energy ratio is below the energy ratio limit.

32. The pulse-off detector of claim **31**, wherein the energy ratio limit is set by an operator.

33. The pulse-off detector of claim **27**,

wherein the logic indicates that the physiological sensor may be in the off-probe condition during a first signal condition or a second signal condition,

wherein the first signal condition includes the signal strength check indicating that the signal strength characteristic is below a signal strength threshold, and

wherein the second signal condition includes all of (a) the signal strength check indicating that the signal strength characteristic is outside the operating limits, (b) the energy ratio check indicating that the energy ratio of the signal is below the energy ratio limit, and (c) the time fuse check determining that no acceptable values of the signal have been received.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,654,624 B2
APPLICATION NO. : 10/027574
DATED : November 25, 2003
INVENTOR(S) : Mohamed K. Diab et al.

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

In Column 1, Line 1, please insert -- IMPROVED -- before "PULSE".

In Column 1, Line 1, please insert -- IMPROVED -- before "PULSE".

In Column 4, Line 32, please delete "boundry" and insert -- boundary --, therefore.

In Column 5, Line 28, below "specified below:" please insert -- --.

pulse rate ≥ 30	minimum energy ratio = 0.8
pulse rate < 30	minimum energy ratio = 0.5
sensitivity mode = 0	minimum signal strength = 0.05
sensitivity mode = 1	minimum signal strength = 0.25

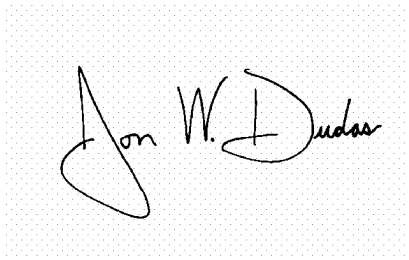
In Sheet 4 of 7, FIG. 3, Line 2, above Reference Numeral 358, please delete "prob" and insert -- probe --, therefore.

In Sheet 6 of 7, FIG. 5, Line 2, above Reference Numeral 542, please delete "signsl" and insert -- signal --, therefore.

In Column 9, Line 8, Claim 25, please delete "radio limit" and insert -- ratio limit --, therefore.

Signed and Sealed this

Nineteenth Day of June, 2007



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