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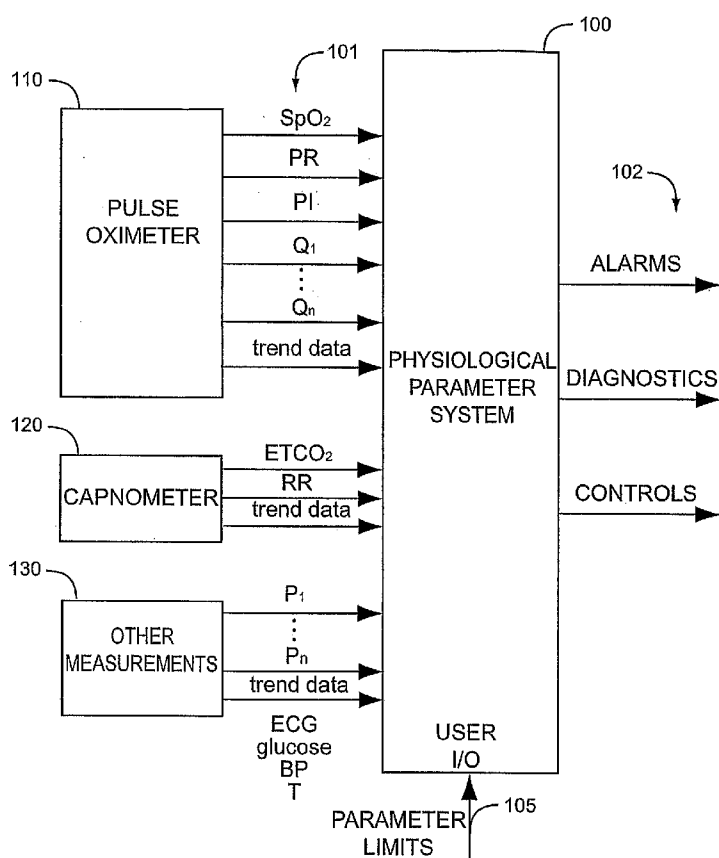
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(54) Title: PHYSIOLOGICAL PARAMETER SYSTEM



(57) Abstract: A physiological parameter system has one or more parameter inputs responsive to one or more physiological sensors. The physiological parameter system may also have quality indicators relating to confidence in the parameter inputs. A processor is adapted to combine the parameter inputs, quality indicators and predetermined limits for the parameters inputs and quality indicators so as to generate alarm outputs or control outputs or both.



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PHYSIOLOGICAL PARAMETER SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application relates to and claims the benefit of prior U.S. Provisional Applications No. 60/551,165 titled *Combined Physiological Parameter Monitor*, filed 03/08/2004 and No. 60/600,640 titled *Physiological Parameter Controller*, filed 08/11/2004, both prior applications incorporated by reference herein.

BACKGROUND OF THE INVENTION

[0002] Pulse oximetry is a widely accepted noninvasive procedure for measuring the oxygen saturation level of arterial blood, an indicator of a person's oxygen supply. Early detection of a low blood oxygen level 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. A typical pulse oximetry system utilizes a sensor applied to a patient's finger. The sensor has an emitter configured with both red and infrared LEDs that project light through the finger to a detector so as to determine the ratio of oxygenated and deoxygenated hemoglobin light absorption. In particular, the detector generates first and second intensity signals responsive to the red and IR wavelengths emitted by the LEDs after absorption by constituents of pulsatile blood flowing within a fleshy medium, such as a finger tip. A pulse oximetry sensor is described in U.S. Patent 6,088,607 titled *Low Noise Optical Probe*, which is assigned to Masimo Corporation, Irvine, CA and incorporated by reference herein.

[0003] Capnography comprises the continuous analysis and recording of carbon dioxide concentrations in the respiratory gases of patients. The device used to measure the CO₂ concentrations is referred to as a capnometer. CO₂ monitoring can be performed on both intubated and non-intubated patients. With non-intubated patients, a nasal cannula is used. Capnography helps to identify situations that can lead to hypoxia if uncorrected. Moreover, it also helps in the swift differential diagnosis of hypoxia before hypoxia can lead to irreversible brain damage. Pulse oximetry is a direct monitor of the oxygenation status of a patient. Capnography, on the other hand, is an indirect monitor that helps in the differential diagnosis of hypoxia so as to enable remedial measures to be taken expeditiously before hypoxia results in an irreversible brain damage.

SUMMARY OF THE INVENTION

[0004] Multiple physiological parameters, combined, provide a more powerful patient condition assessment tool than when any physiological parameter is used by itself. For example, a combination of parameters can provide greater confidence if an alarm condition is occurring. More importantly, such a combination can be used to give an early warning of a slowly deteriorating patient condition as compared to any single parameter threshold, which may not indicate such a condition for many minutes. Conditions such as hypovolemia, hypotension, and airway obstruction may develop slowly over time. A physiological parameter system that combines multiple parameters so as to provide an early warning could have a major effect on the morbidity and mortality outcome in such cases.

[0005] Further, a greater emphasis has been put on decreasing the pain level of patients on the ward. Accordingly, patients are often given an IV setup that enables the patient to increase the level of analgesia at will. In certain situations, however, the patient's input must be ignored so as to avoid over medication. Complications from over sedation may include hypotension, tachycardia, bradycardia, hypoventilation and apnea. A physiological parameter system that uses pulse oximetry monitoring of SpO₂ and pulse rate in conjunction with patient controlled analgesia (PCA) can aid in patient safety. Utilization of conventional pulse oximetry in conjunction with PCA, however, can result in the patient being erroneously denied pain medication. Conventional monitors are susceptible to patient motion, which is likely to increase with rising pain. Further, conventional monitors do not provide an indication of output reliability.

[0006] Advanced pulse oximetry is motion tolerant and also provides one or more indications of signal quality or data confidence. These indicators can be used as arbitrators in decision algorithms for adjusting the PCA administration and sedation monitoring. Further, advanced pulse oximetry can provide parameters in addition to oxygen saturation and pulse rate, such as perfusion index (PI). For example, hypotension can be assessed by changes in PI, which may be associated with changes in pulse rate. Motion tolerant pulse oximetry is described in U.S. Patent 6,699,194 titled *Signal Processing Apparatus and Method*; signal quality and data confidence indicators are described in U.S. Patent 6,684,090 titled *Pulse Oximetry Data Confidence Indicator*, both of which are assigned to Masimo Corporation, Irvine, CA and incorporated by reference herein.

[0007] One aspect of a physiological parameter system is a first parameter input responsive to a first physiological sensor and a second parameter input responsive to a second physiological sensor. A processor is adapted to combine the parameters and predetermined limits for the parameters so as to generate an alarm output.

[0008] Another aspect of a physiological parameter system is a parameter input responsive to a physiological sensor and a quality indicator input relating to confidence in the parameter input. A processor is adapted to combine the parameter input, the quality indicator input and predetermined limits for the parameter input and the quality indicator input so as to generate a control output.

[0009] A physiological parameter method comprises the steps of inputting a parameter responsive to a physiological sensor and inputting a quality indicator related to data confidence for the parameter. A control signal is output from the combination of the parameter and the quality indicator. The control signal is adapted to affect the operation of a medical-related device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. 1 is a general block diagram of a physiological parameter system having alarm, diagnostic and control outputs;

[0011] FIG. 2 is a block diagram of a physiological parameter system combining pulse oximetry and capnography and providing alarm outputs;

[0012] FIG. 3 is a block diagram of a saturation limit alarm enhanced by ETCO_2 measurements;

[0013] FIG. 4 is a block diagram of a CO_2 waveform alarm enhanced by SpO_2 measurements;

[0014] FIG. 5 is a block diagram of a physiological parameter system combining pulse oximetry and capnography and providing a diagnostic output; and

[0015] FIGS. 6-7 are block diagrams of a physiological parameter system utilizing pulse oximetry to control patient controlled analgesia (PCA).

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0016] FIG. 1 illustrates a physiological parameter system 100, which may comprise an expert system, a neural-network or a logic circuit, for example. The physiological parameter system 100 has as inputs 101 one or more parameters from one or more physiological measurement

devices, such as a pulse oximeter **110** and/or a capnometer **120**. Pulse oximeter parameters may include oxygen saturation (SpO_2), perfusion index (PI), pulse rate (PR), various signal quality and/or data confidence indicators (Qn) and trend data, to name a few. Capnography parameter inputs may include, for example, an exhaled carbon dioxide waveform, end tidal carbon dioxide (ETCO_2) and respiration rate (RR). Signal quality and data confidence indicators are described in U.S. Patent 6,684,090 cited above. The physiological parameter system **100** may also have parameter limits **105**, which may be user inputs, default conditions or otherwise predetermined thresholds within the system **100**.

[0017] The inputs **101** are processed in combination to generate one or more outputs **102** comprising alarms, diagnostics and controls. Alarms may be used to alert medical personnel to a deteriorating condition in a patient under their care. Diagnostics may be used to assist medical personnel in determining a patient condition. Controls may be used to affect the operation of a medical-related device. Other measurement parameters **130** that can be input to the monitor may include or relate to one or more of ECG, blood glucose, blood pressure (BP), temperature (T), HbCO and MetHb, to name a few.

[0018] FIG. 2 illustrates one embodiment of a physiological parameter system **200** combining pulse oximetry parameter inputs **210** and capnography parameter inputs **220** so as to generate alarm outputs **202**. Parameter limits **205** may be user inputs, default conditions or otherwise predetermined alarm thresholds for these parameters **210**, **220**. The alarms **202** are grouped as pulse oximetry related **230**, capnography related **240** and a combination **250**. For example, a pulse oximetry alarm **230** may be related to percent oxygen saturation and trigger when oxygen saturation falls below a predetermined percentage limit. A capnography alarm **240** may be related to ETCO_2 and trigger when ETCO_2 falls below or rises above a predetermined mm Hg pressure limit. A combination alarm **250** may indicate a particular medical condition related to both pulse oximetry and capnography or may indicate a malfunction in either instrument.

[0019] FIG. 3 illustrates a SpO_2 alarm embodiment **300** that is responsive to ETCO_2 . In particular, a SpO_2 alarm **305** may be triggered sooner and may indicate a high priority if ETCO_2 **303** is falling. That is, if ETCO_2 **303** is trending down above a certain rate, the SpO_2 alarm **305** is triggered at a higher percentage oxygen saturation threshold and alerts a caregiver to the possibility of a serious condition, e.g. a pulmonary embolism.

[0020] As shown in FIG. 3, a slope detector 310 determines the slope 312 of the ETCO₂ input 303. A slope comparator 320 compares this slope 312 to a predetermined slope limit 304. If the downward trend of ETCO₂ 303 is great enough, a delta value 303 is added 340 to the SpO₂ lower limit 302 to generate a variable threshold 342. A threshold comparator 350 compares this variable threshold 342 to the SpO₂ input 301 to generate a trigger 352 for the SpO₂ alarm 305. The alarm volume, modulation or tone may be altered to indicate priority, based upon the slope comparator output 322.

[0021] FIG. 4 illustrates a CO₂ alarm embodiment 400 that is responsive to SpO₂. In particular, morphology of the input CO₂ waveform 401 is utilized to trigger an alarm 405, and that alarm is also responsive to a falling SpO₂ 402. That is, if a pattern in the expired CO₂ waveform is detected and SpO₂ is trending down above a certain rate, then an alarm is triggered. For example, an increasing slope of the CO₂ plateau in combination with a downward trend of SpO₂ may trigger an alarm and alert a caregiver to the possibility of an airway obstruction.

[0022] As shown in FIG. 4, a pattern extractor 410 identifies salient features in the CO₂ waveform and generates a corresponding feature output 412. A pattern memory 420 stores one or more sets of predetermined waveform features to detect in the CO₂ input 401. The pattern memory 420 is accessed to provide a feature template 422. A feature comparator 430 compares the feature output 412 with the feature template 422 and generates a match output 432 indicating that a specific shape or pattern has been detected in the CO₂ waveform 401. In addition, a slope detector 440 determines the slope 442 of the SpO₂ input 402. A slope comparator 450 compares this slope 442 to a predetermined slope limit 404. If the downward trend of SpO₂ 402 is great enough, a slope exceeded output 452 is generated. If both the match output 432 and the slope exceeded output 452 are each asserted or "true," then a logical AND 460 generates a trigger output 462 to the alarm 470, which generates an alarm output 405.

[0023] FIG. 5 illustrates a combination embodiment 500 having a diagnostic output 505 responsive to both SpO₂ 501 and ETCO₂ 503 inputs. A SpO₂ slope detector 510 determines the slope 512 of the SpO₂ input 501 and can be made responsive to a negative slope, a positive slope or a slope absolute value. A first comparator 520 compares this slope 512 to a predetermined SpO₂ slope limit 502. If the trend of SpO₂ 501 is great enough, a SpO₂ slope exceeded output 522 is asserted. Likewise, an ETCO₂ slope detector 530 determines the slope 532 of the ETCO₂ input 503. A second comparator 540 compares this slope 532 to a predetermined ETCO₂ slope limit 504.

If the downward trend of ETCO_2 501 is great enough, an ETCO_2 slope exceeded output 542 is asserted. If both slope exceeded outputs 522, 542 are asserted or "true," a diagnostic output 505 is asserted.

[0024] In one embodiment, the slope detectors 510, 530 are responsive to a negative trend in the SpO_2 501 and ETCO_2 503 inputs, respectively. Accordingly, the diagnostic output 505 indicates a potential embolism or cardiac arrest. In another embodiment, the SpO_2 slope detector 510 is responsive to negative trends in the SpO_2 501 input, and the ETCO_2 slope detector 530 is responsive to a positive trend in the ETCO_2 503 input. Accordingly, the diagnostic output 505 indicates a potential airway obstruction. The diagnostic output 505 can trigger an alarm, initiate a display, or signal a nursing station, to name a few.

[0025] FIGS. 6A-B illustrate a physiological parameter system 600 utilizing pulse oximetry to control patient controlled analgesia (PCA). In particular embodiments, a control output 608 is responsive to pulse oximetry parameters 601 only if signal quality 603 is above a predetermined threshold 604. In FIG. 6A, the control output 608 can be used to lock-out patient controlled analgesia (PCA) if pulse oximetry parameter limits have been exceeded. If signal quality is so low that those parameters are unreliable, however, PCA is advantageously allowed. That is, the pulse oximeter parameters are not allowed to lock-out PCA if those parameters are unreliable. By contrast, in FIG. 6B, the control output 608 can be used to advantageously lock-out or disable patient controlled analgesia (PCA) if pulse oximetry parameter limits have been exceeded or if signal quality is so low that those parameters are unreliable.

[0026] As shown in FIG. 6A, pulse oximetry parameters 601 and corresponding limits 602 for those parameters are one set of inputs and a signal quality measure 603 and a corresponding lower limit 604 for signal quality are another set of inputs. The parameters 601 and corresponding limits 602 generate a combined output 702 that is asserted if any of the pulse oximetry parameter limits are exceeded. A comparator 610 compares the signal quality 603 input with a lower limit 604 generating a quality output 612 that is asserted if the signal quality 603 drops below that limit 604. An AND logic 620 generates a reset 622 if the combined output 702 is asserted and the quality output 612 is not asserted. The reset 622 resets the timer 630 to zero. A comparator 640 compares the timer output 632 to a predetermined time limit 606 and generates a trigger 642 if the time limit is exceeded. The trigger 642 causes the control 650 to generate the control output 608, enabling a patient controlled analgesia (PCA), for example. In this manner, the PCA is enabled if

all monitored parameters are within set limits and signal quality is above its lower limit for a predetermined period of time.

[0027] As shown in FIG. 6B, the combined output 702, quality output 612, reset 622, timer 630, comparator 640 and control 650 are generated as described with respect to FIG. 6A, above. An OR logic 621 generates a reset 622 if either the combined output 702 or the quality output 612 is asserted. In this manner, the PCA is disabled for a predetermined period of time if any of the monitored parameters are outside of set limits or the signal quality is below its lower limit.

[0028] FIG. 7 illustrates combined limits 700 having SpO₂ parameters 601 and corresponding thresholds 602 as inputs and providing a combination output 702. In particular, if any parameter 601 exceeds its corresponding limit 602, the output of the corresponding comparator 710, 720, 740 is asserted. An OR logic 750 is responsive to any asserted output 712, 722, 742 to asserted the combined output 702. For example, the combined output 702 may be asserted if SpO₂ 701 falls below a lower limit 709, pulse rate (PR) 703 rises above an upper limit 704 or PR 703 falls below a lower limit 706.

[0029] A physiological parameter system has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications. For example, the control output 608 (FIGS. 6B) can be used to control (titrate) delivered, inspired oxygen levels to patients based upon pulse oximetry parameters, unless signal quality is so low that those parameters are unreliable. One of ordinary skill in the art will also recognize that the control output 608 (FIGS. 6B) can be used to control patient delivery of any of various pharmacological agents and/or medical gases.

WHAT IS CLAIMED IS:

1. A physiological parameter system comprising:
a first parameter input responsive to a first physiological sensor;
a second parameter input responsive to a second physiological sensor;
a plurality of predetermined limits for said parameters; and
a processor adapted to combine said parameters and said limits so as to generate an alarm output.
2. The physiological parameter system according to claim 1 further comprising:
a variable threshold responsive to said second parameter,
said alarm output responsive to said first parameter and said variable threshold.
3. The physiological parameter system according to claim 2 further comprising:
a predetermined limit related to said second parameter,
wherein said alarm output is triggered below said variable threshold, and
wherein said variable threshold is raised in response to said second parameter and said predetermined limit.
4. The physiological parameter system according to claim 3 wherein:
said first parameter is SpO₂,
said second parameter is ETCO₂, and
said variable threshold is a lower limit for SpO₂ that is raised in response to a downward trend in ETCO₂ at a rate greater than said predetermined limit.
5. The physiological parameter system according to claim 1 further comprising:
a pattern detector having a detection output responsive to said first parameter,
said alarm output responsive to said detection output.
6. The physiological parameter system according to claim 5 further comprising:
a slope detector output responsive to said second parameter; and
a predetermined slope limit responsive to said slope detector output,

wherein said alarm output is triggered only if said slope detector output exceeds said slope limit.

7. The physiological parameter system according to claim 6 wherein:
said first parameter is ETCO_2 ,
said second parameter is SpO_2 , and
said alarm output is responsive to ETCO_2 morphology only when there is a sufficient downward trend in SpO_2 .

8. A physiological parameter system comprising:
a parameter input responsive to a physiological sensor;
a quality indicator input relating to confidence in said parameter input;
a plurality of predetermined limits for said parameter input and said quality indicator input;
and
a processor adapted to combine said inputs and said limits so as to generate a control output.

9. The controller according to claim 8 wherein said control output disables patient controlled analgesia when confidence in said parameter input is low.

10. The controller according to claim 9 wherein said control prevents said first parameter from disabling said patient controlled analgesia when confidence in said parameter is low.

11. A physiological parameter method comprising the steps of:
inputting a parameter responsive to a physiological sensor;
inputting a quality indicator related to data confidence for said parameter;
outputting a control signal from the combination of said parameter and said quality indicator,
wherein said control signal is adapted to affect the operation of a medical-related device.

12. The physiological parameter method according to claim 11 wherein said parameter and said quality indicator are derived from a pulse oximetry sensor, said outputting step comprising the substeps of:

configuring said control signal to conditionally disable said medical-related device;
regulating said control signal in response to said quality indicator.

13. The physiological parameter method according to claim 12 wherein said regulating substep comprises the substep of disabling said shut-off signal when confidence in said parameter is low.

14. The physiological parameter method according to claim 13 wherein said regulating substep comprises the substep of enabling said shut-off signal when confidence in said parameter is low.

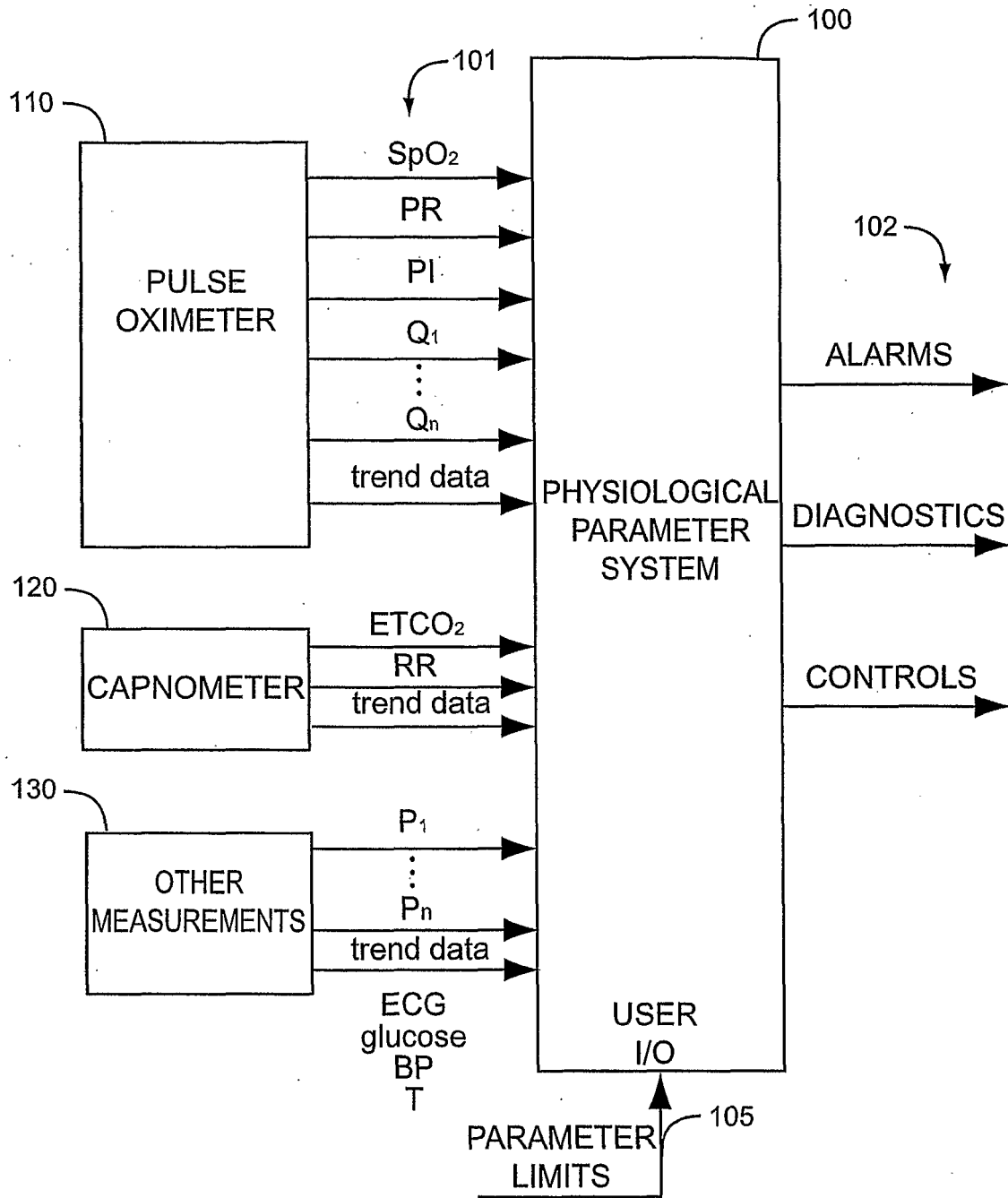


FIG. 1

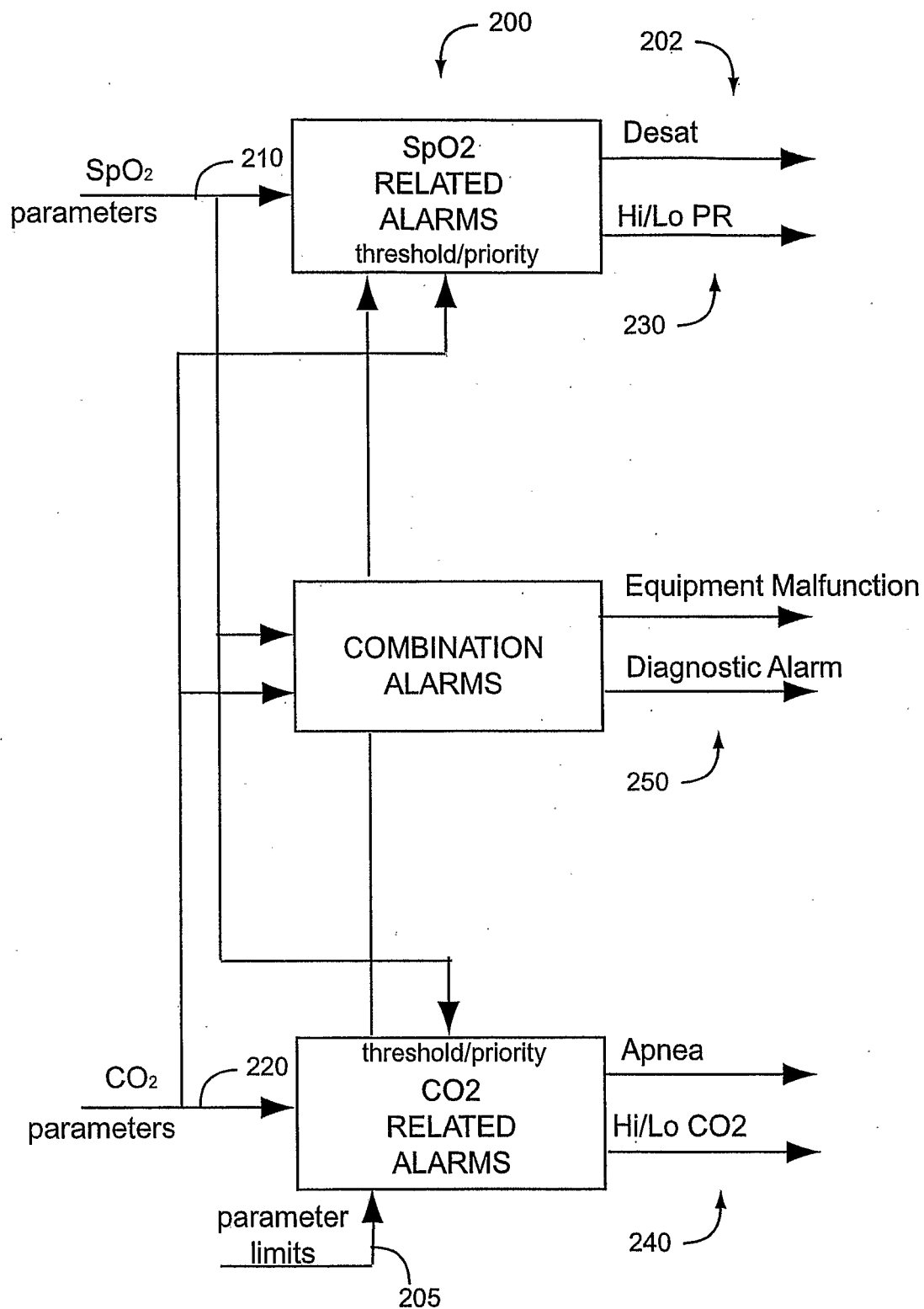


FIG. 2

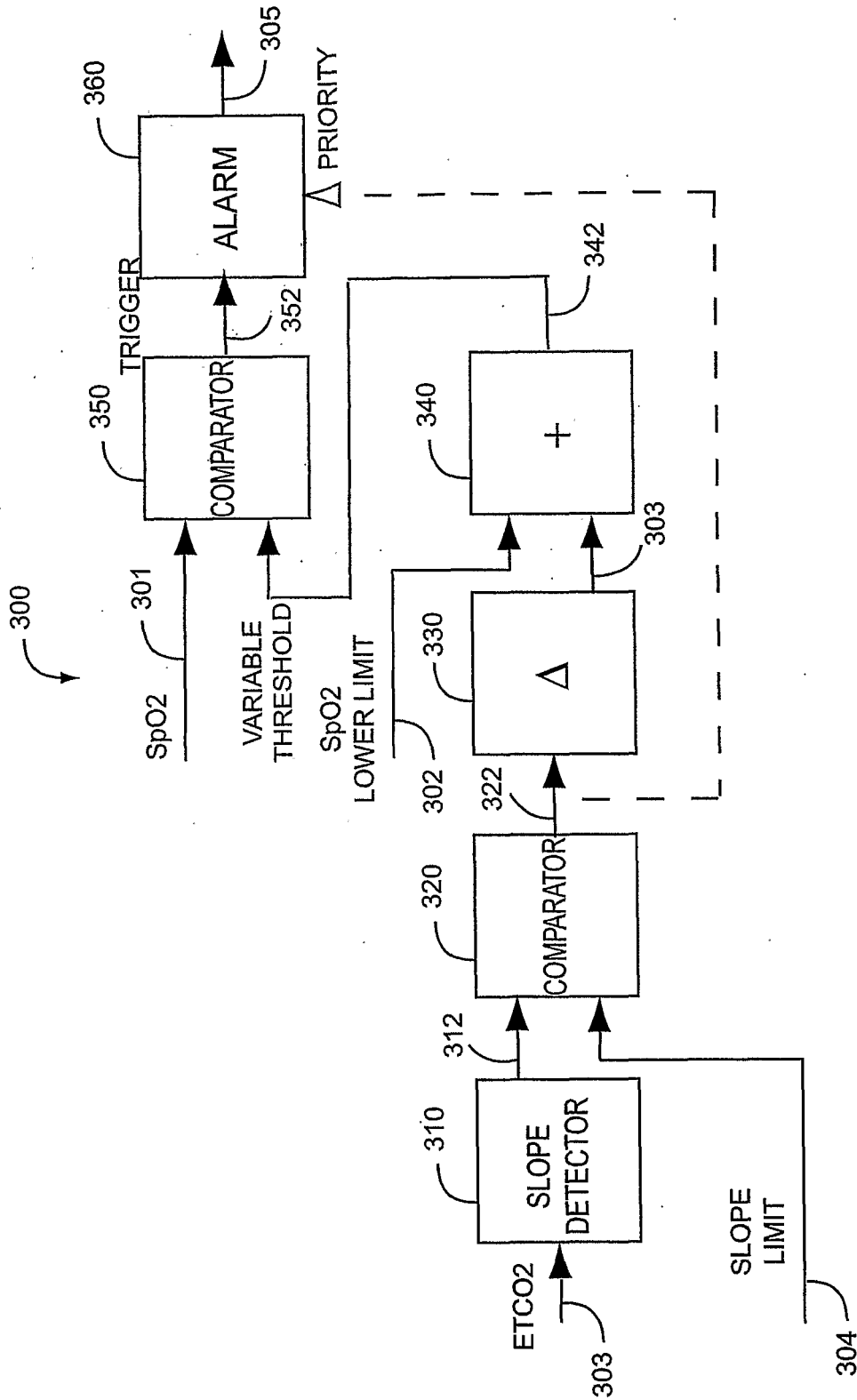


FIG. 3

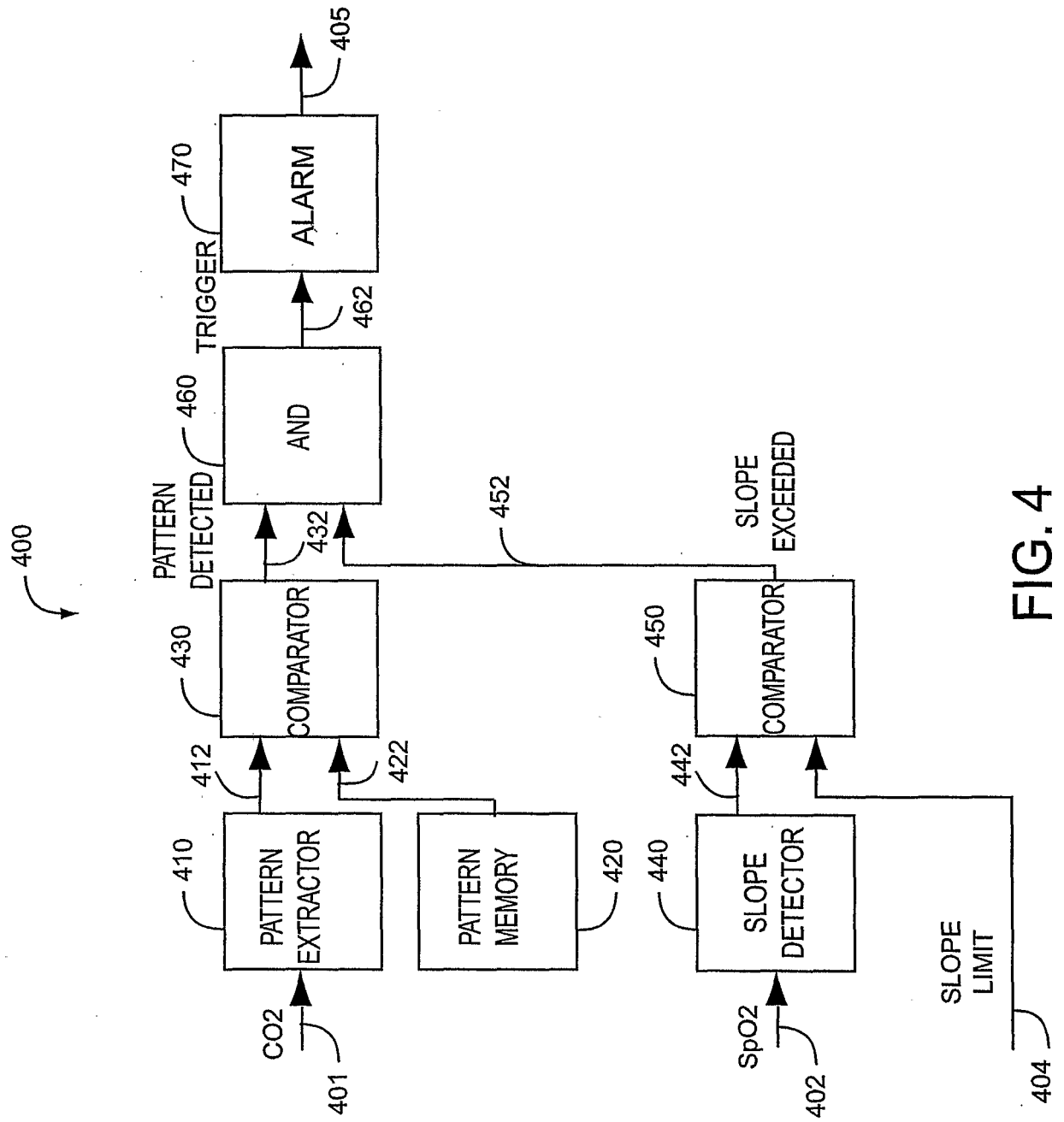


FIG. 4

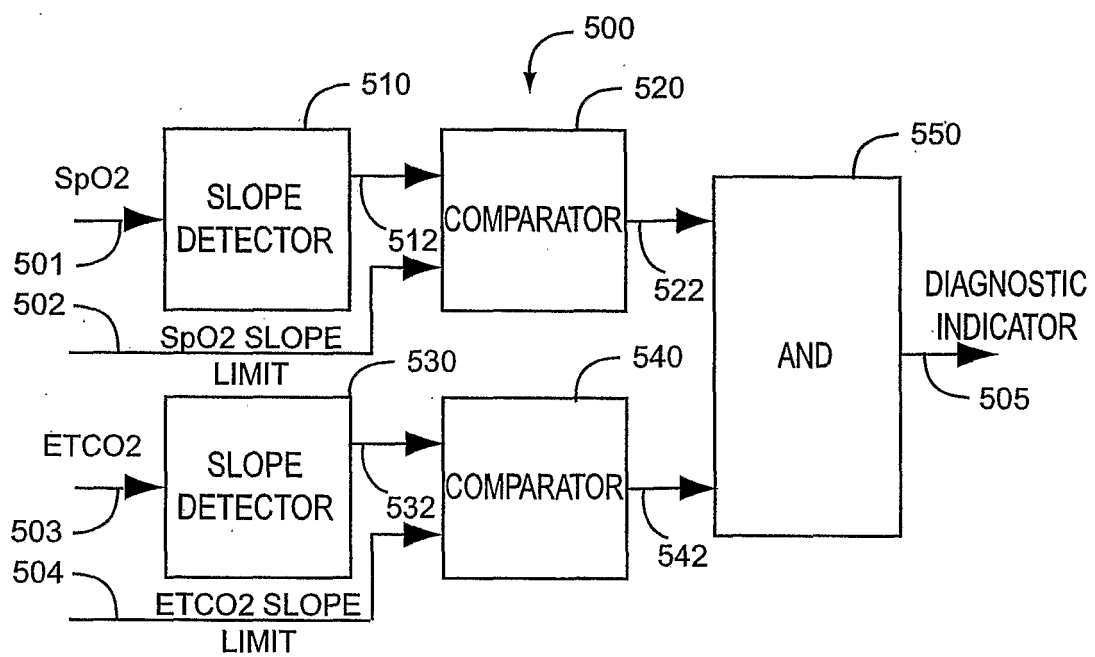


FIG. 5

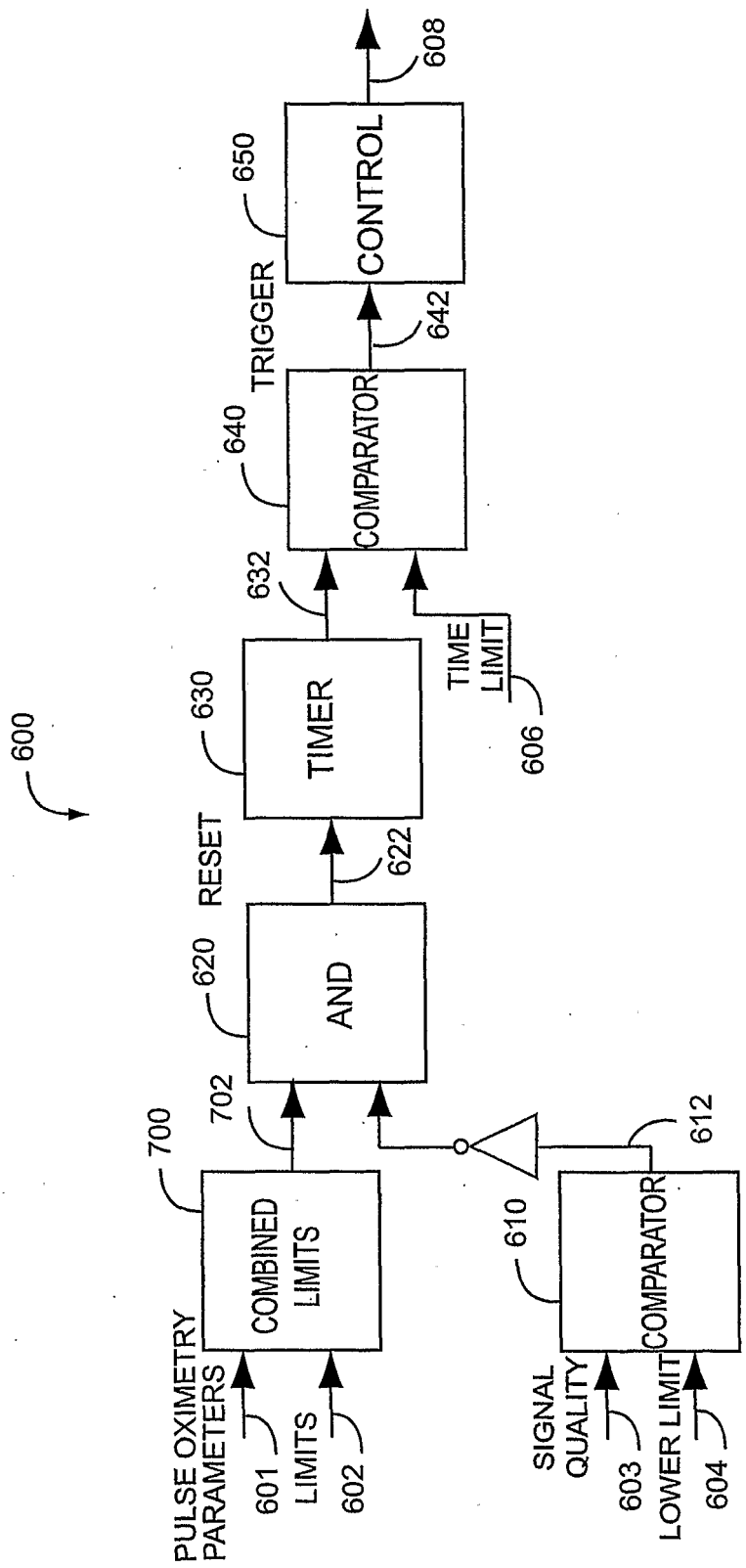


FIG. 6A

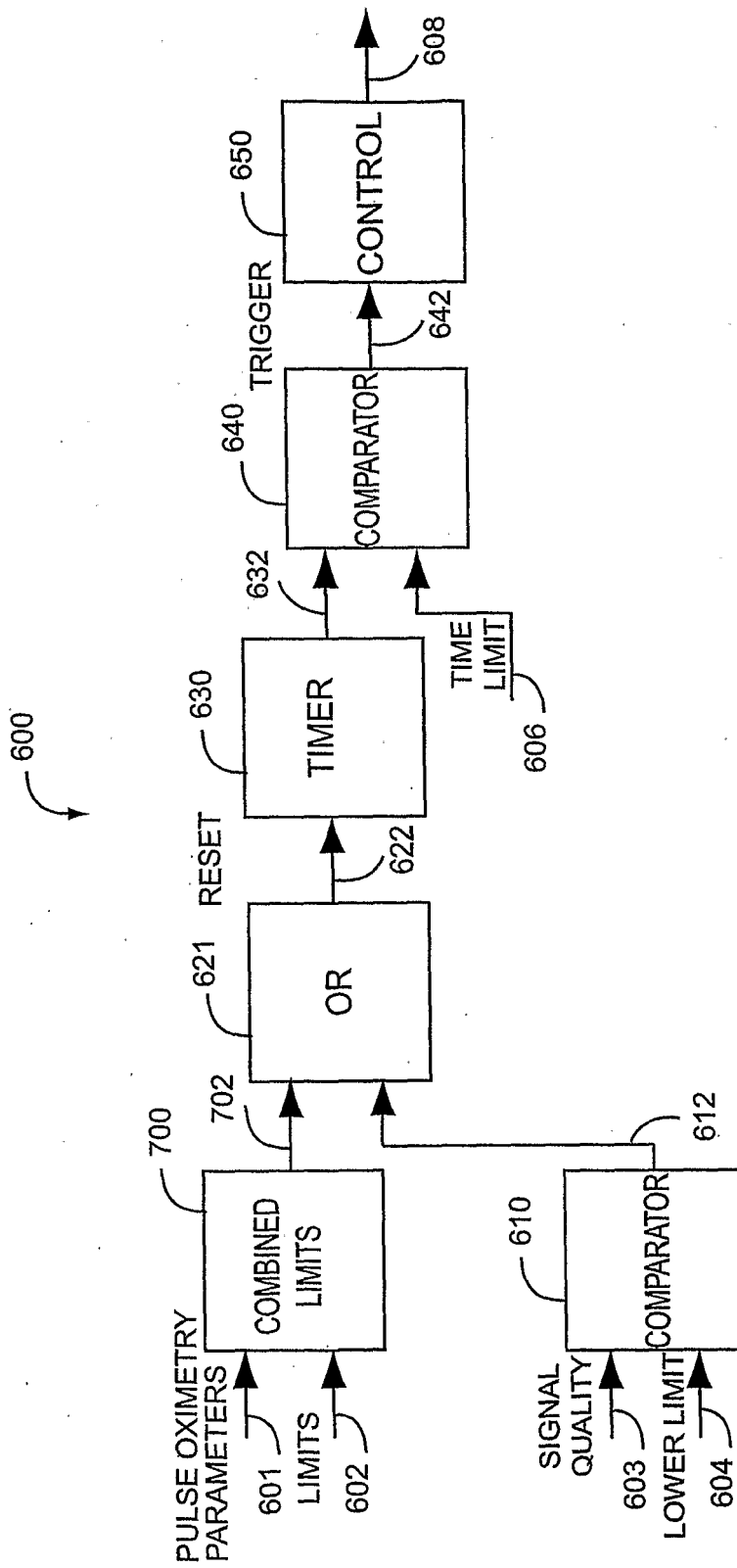


FIG. 6B

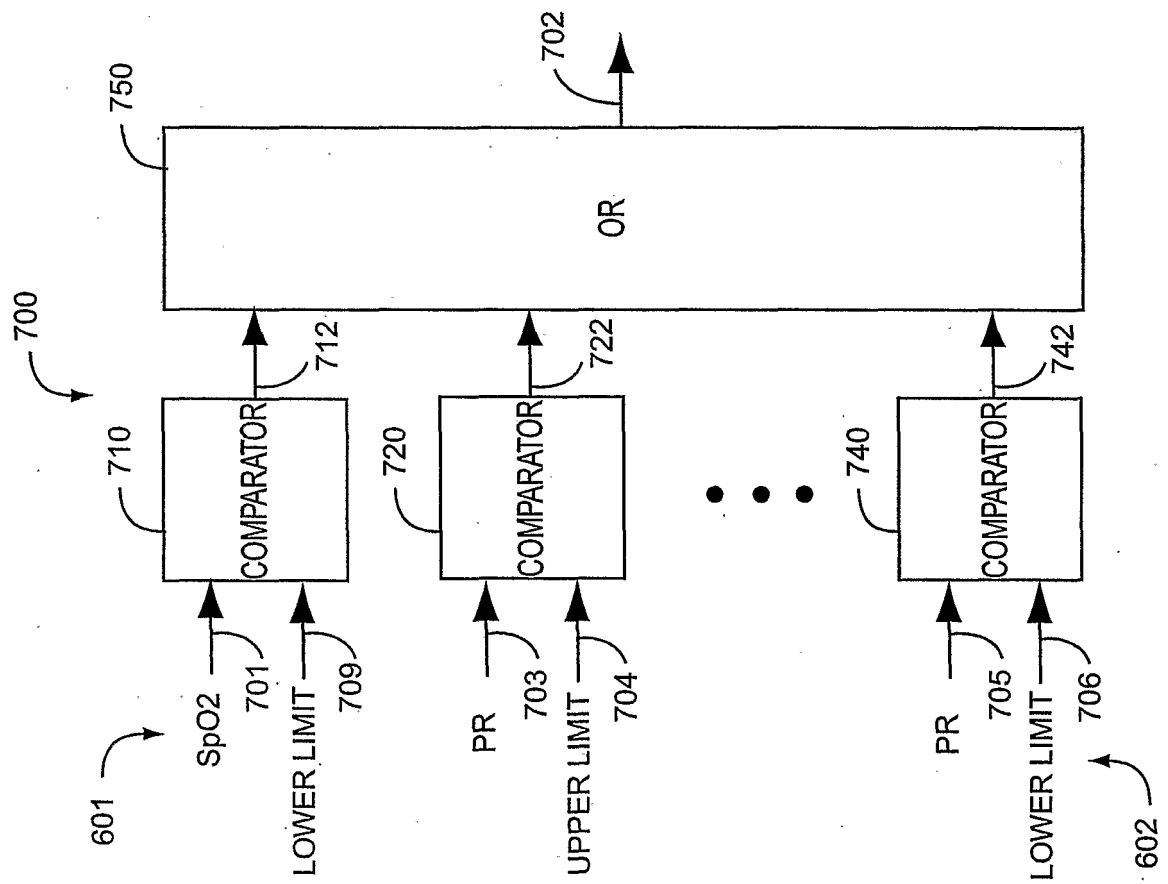


FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No

PC US2005/007580

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B5/00 A61M5/172

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 337 629 B1 (BADER GABY) 8 January 2002 (2002-01-08) column 1, line 51 - line 60 column 3, line 16 - line 26 -----	1,5,6
X	US 2002/190863 A1 (LYNN LAWRENCE A) 19 December 2002 (2002-12-19) paragraphs [0028], [0030] ----- -/--	1,5,6

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document: referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

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Date of the actual completion of the international search

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Date of mailing of the international search report

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Knüpling, M

INTERNATIONAL SEARCH REPORT

International Application No

PC~~0~~US2005/007580

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>HORN W ET AL: "Effective data validation of high-frequency data: Time-point-, time-interval-, and trend-based methods" COMPUTERS IN BIOLOGY AND MEDICINE, NEW YORK, NY, US, vol. 27, no. 5, September 1997 (1997-09), pages 389-409, XP004532359 ISSN: 0010-4825 page 391, first paragraph page 404, seventh paragraph page 407, first paragraph -----</p>	1-7
A	<p>BLOOM M J: "Techniques to identify clinical contexts during automated data analysis" INTERNATIONAL JOURNAL OF CLINICAL MONITORING AND COMPUTING NETHERLANDS, vol. 10, no. 1, February 1993 (1993-02), pages 17-22, XP008048017 ISSN: 0167-9945 page 18, second column, paragraph beginning with 'The next stage...' -----</p>	1-7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/007580

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-7

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-7

A physiological parameter system comprising variable threshold

2. claims: 8-14

A physiological parameter system comprising quality indicator; and method

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2005/007580

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			US 5891023 A	06-04-1999
			US 6609016 B1	19-08-2003
			US 6342039 B1	29-01-2002

专利名称(译)	生理参数系统		
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申请号	EP2005724991	申请日	2005-03-08
[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		
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外部链接	Espacenet		

摘要(译)

生理参数系统具有响应于一个或多个生理传感器的一个或多个参数输入。生理参数系统还可以具有与参数输入的置信度相关的质量指标。处理器适于组合参数输入，质量指示器和参数输入和质量指示器的预定限制，以便产生警报输出或控制输出或两者。