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(54) **PHYSIOLOGICAL PARAMETER SYSTEM**

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

(72) Inventors: **Ammar Al-Ali**, San Juan Capistrano, CA (US); **John Graybeal**, Grantville, PA (US); **Massi Joe E. Kiani**, Laguna Niguel, CA (US); **Michael Petterson**, Dana Point, CA (US)

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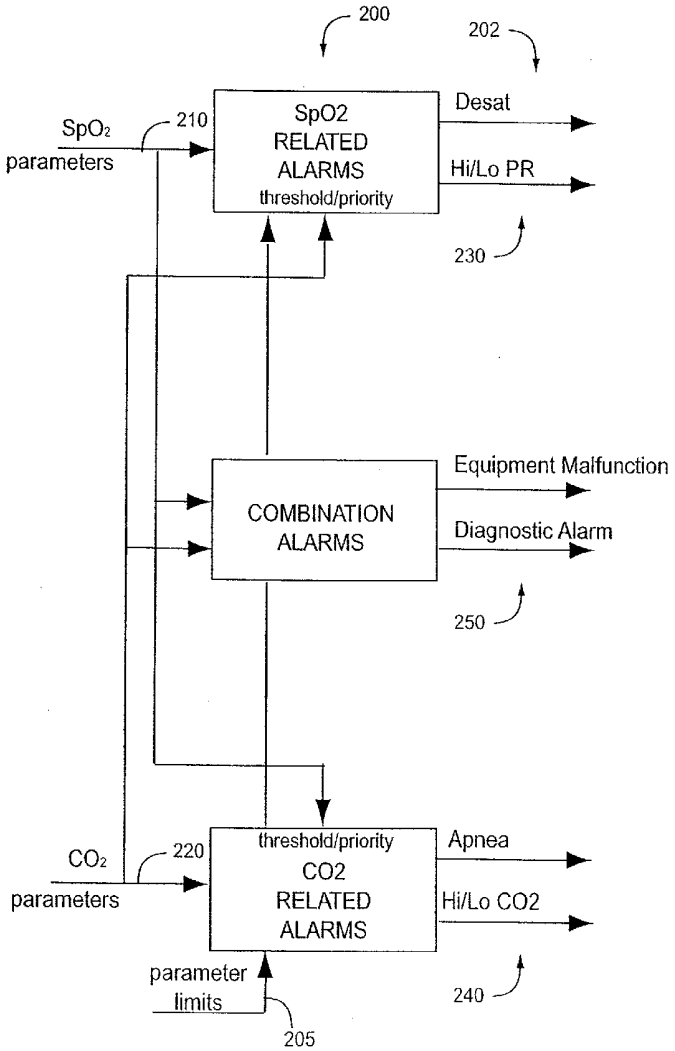
(57) **ABSTRACT**

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.



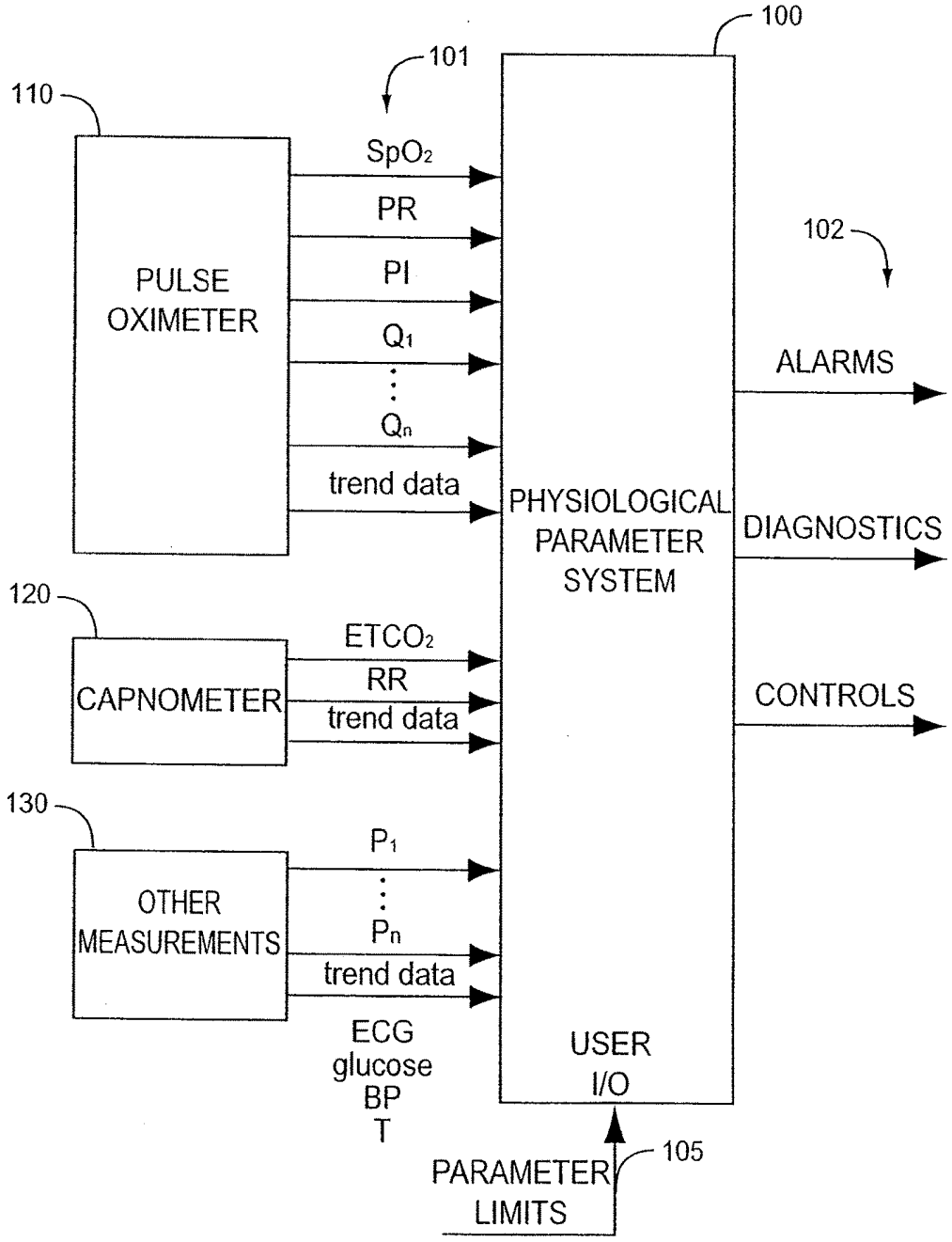

100
101
110
PULSE OXIMETER
SpO2
PR
PI
Q1
Qn
trend data
102
ALARMS
DIAGNOSTICS
CONTROLS
PHYSIOLOGICAL PARAMETER SYSTEM
120
CAPNOMETER
ETCO2
RR
trend data
130
OTHER MEASUREMENTS
P1
Pn
trend data
ECG
glucose
BP
T
USER I/O
105
PARAMETER LIMITS

FIG. 1

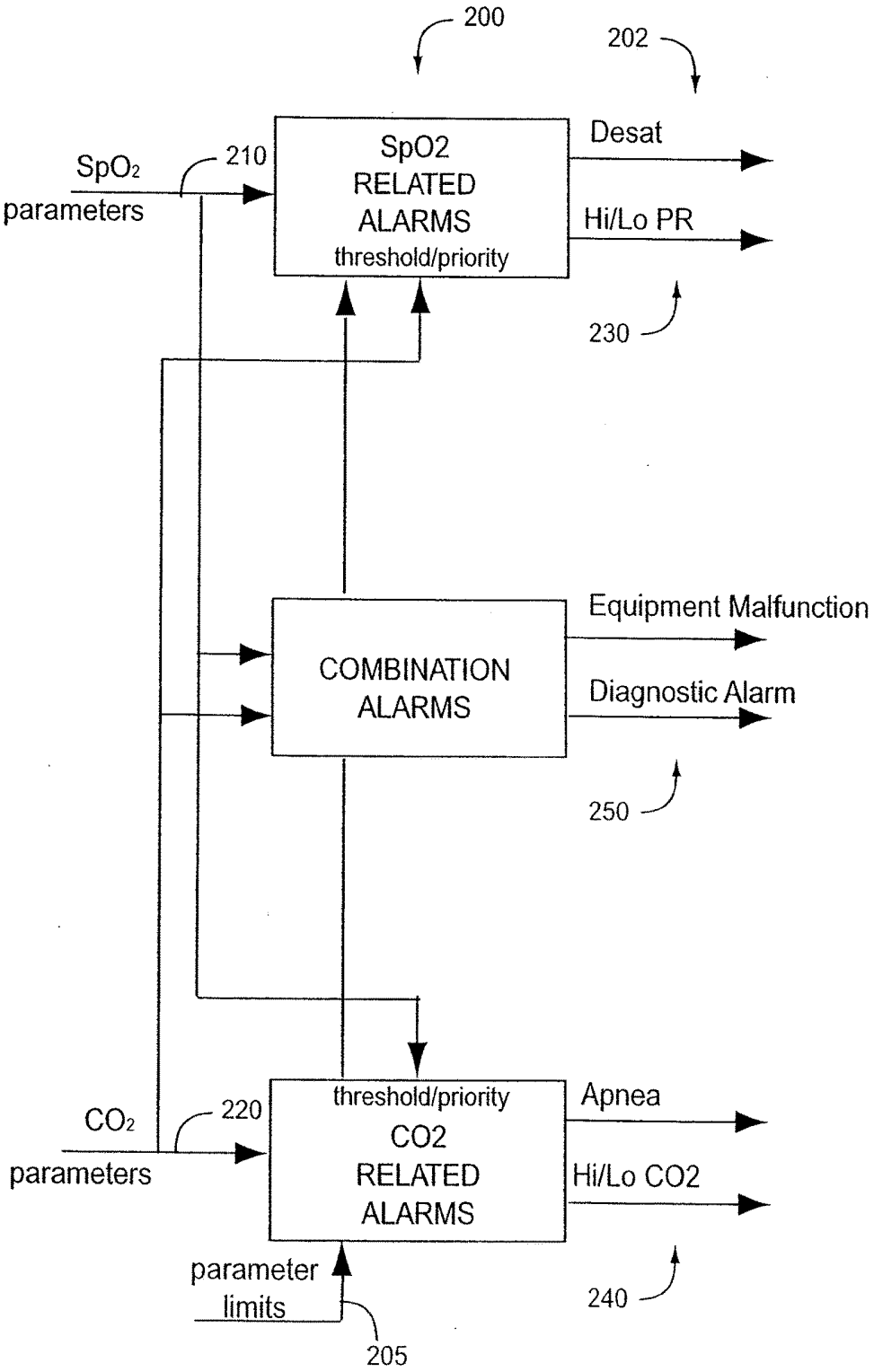

200
202
SpO2
RELATED
ALARMS
threshold/priority
SpO2
parameters
210
Desat
Hi/Lo PR
230
COMBINATION
ALARMS
Equipment Malfunction
Diagnostic Alarm
250
threshold/priority
CO2
RELATED
ALARMS
CO2
parameters
220
Apnea
Hi/Lo CO2
240
parameter
limits
205

FIG. 2

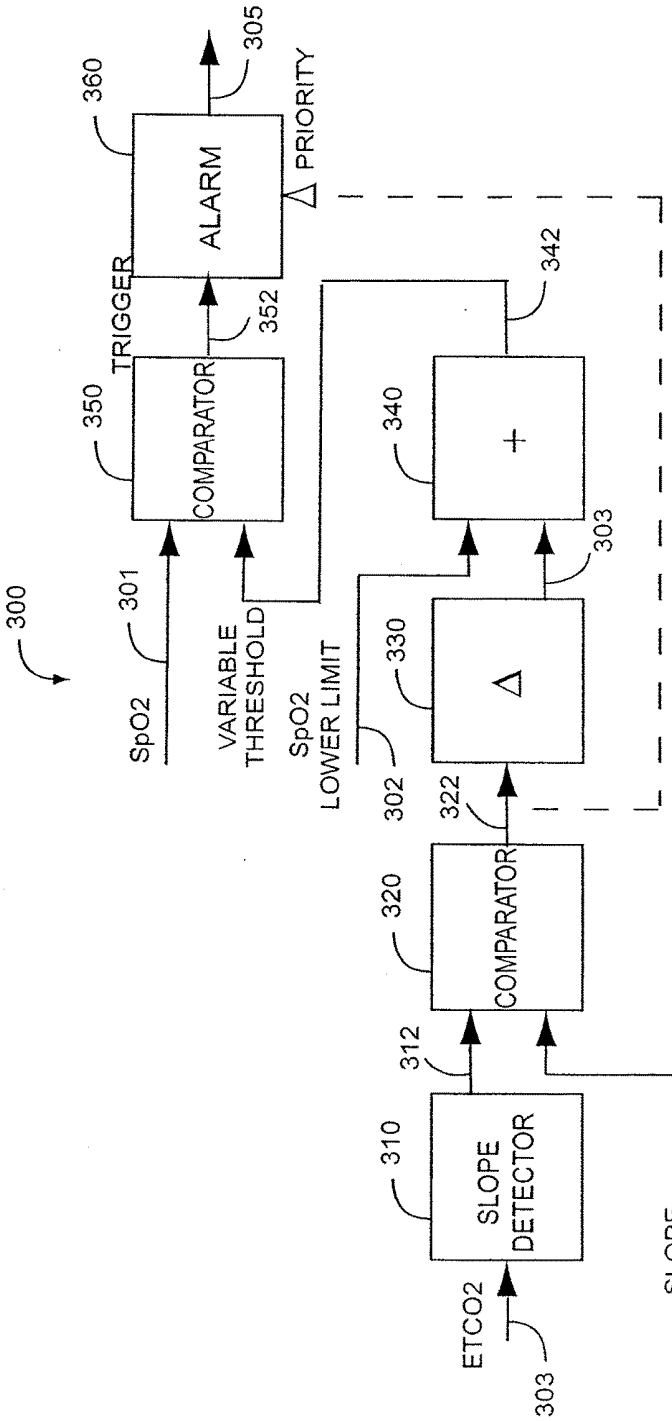

300
SpO2
301
VARIABLE THRESHOLD
SpO2 LOWER LIMIT
302
330
Δ
303
340
+
342
350
COMPARATOR
TRIGGER
352
360
ALARM
305
PRIORITY
320
COMPARATOR
322
312
310
SLOPE DETECTOR
ETCO2
303
SLOPE LIMIT
304

FIG. 3

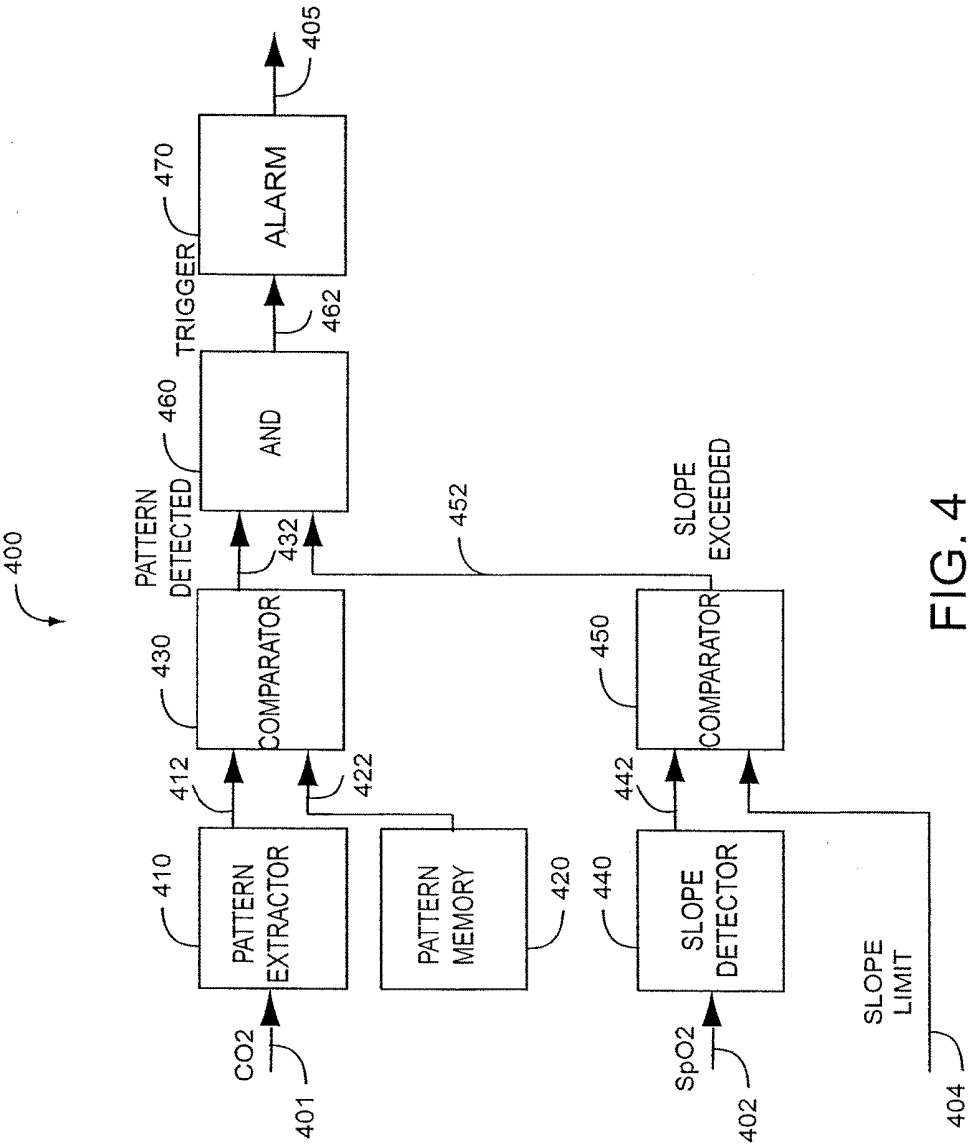

400
CO2
401
PATTERN EXTRACTOR
410
412
PATTERN MEMORY
420
422
COMPARATOR
430
PATTERN DETECTED
432
AND
460
TRIGGER
462
ALARM
470
405
SpO2
402
SLOPE DETECTOR
440
442
COMPARATOR
450
SLOPE EXCEEDED
452
SLOPE LIMIT
404

FIG. 4

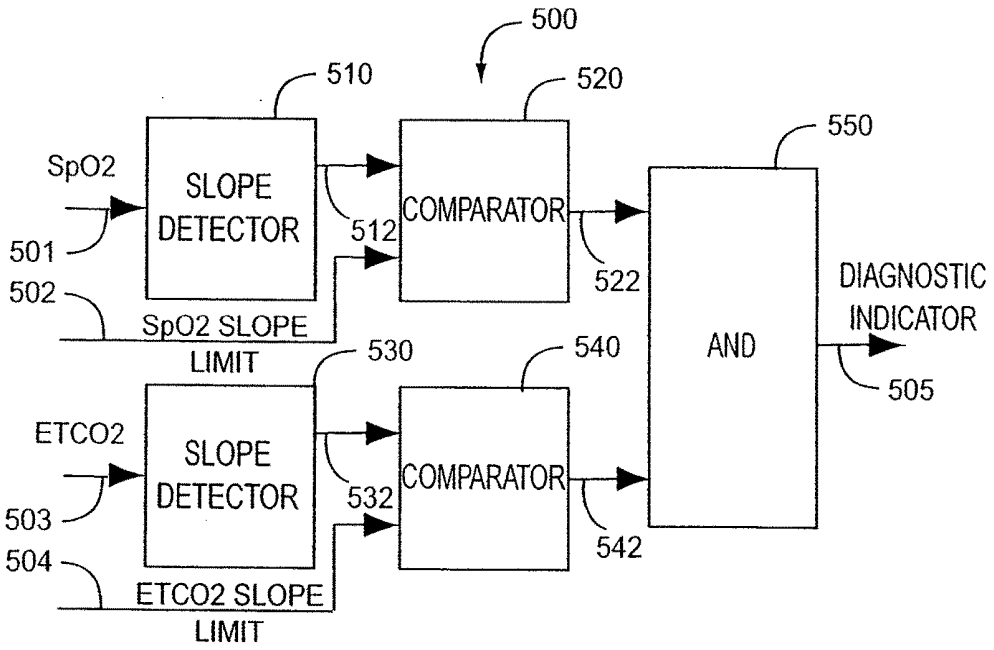

500
510
520
550
SpO2
501
SLOPE DETECTOR
512
COMPARATOR
522
502
SpO2 SLOPE LIMIT
530
540
AND
DIAGNOSTIC INDICATOR
505
ETCO2
503
SLOPE DETECTOR
532
COMPARATOR
542
504
ETCO2 SLOPE LIMIT

FIG. 5

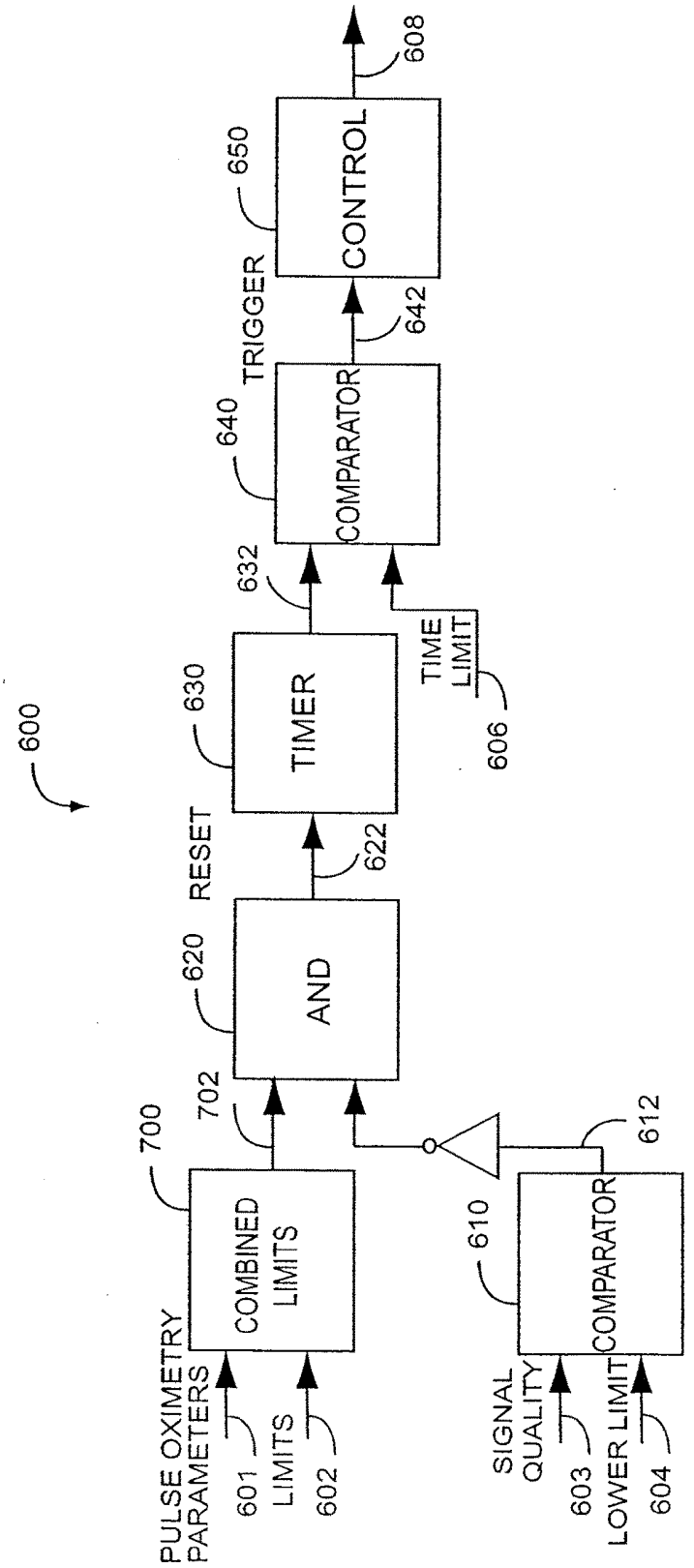

600
PULSE OXIMETRY PARAMETERS
601
LIMITS
602
SIGNAL QUALITY
603
LOWER LIMIT
604
700
COMBINED LIMITS
702
610
COMPARATOR
612
620
AND
RESET
622
630
TIMER
TIME LIMIT
606
632
640
COMPARATOR
TRIGGER
642
650
CONTROL
608

FIG. 6A

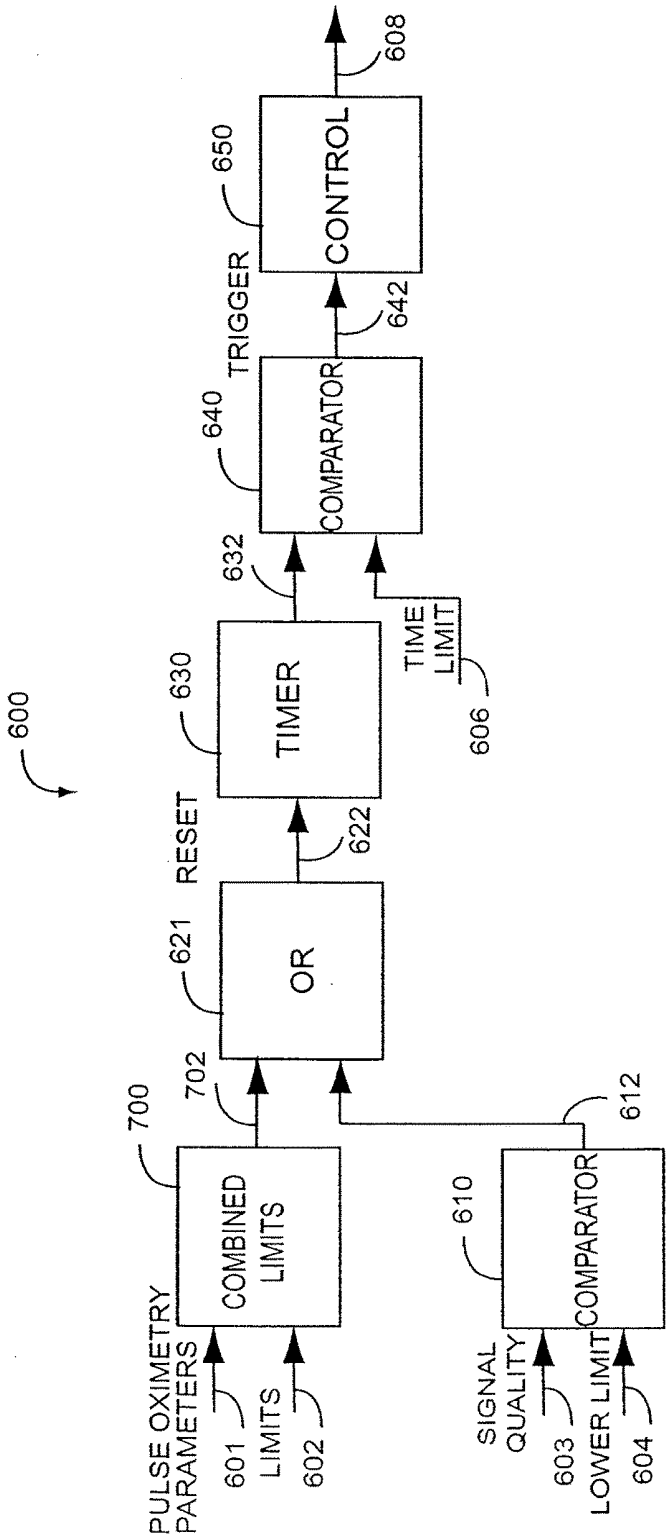

600
PULSE OXIMETRY PARAMETERS
601
LIMITS
602
700
COMBINED LIMITS
702
SIGNAL QUALITY
603
LOWER LIMIT
604
610
COMPARATOR
612
621
OR
RESET
622
630
TIMER
632
TIME LIMIT
606
640
COMPARATOR
TRIGGER
642
650
CONTROL
608

FIG. 6B

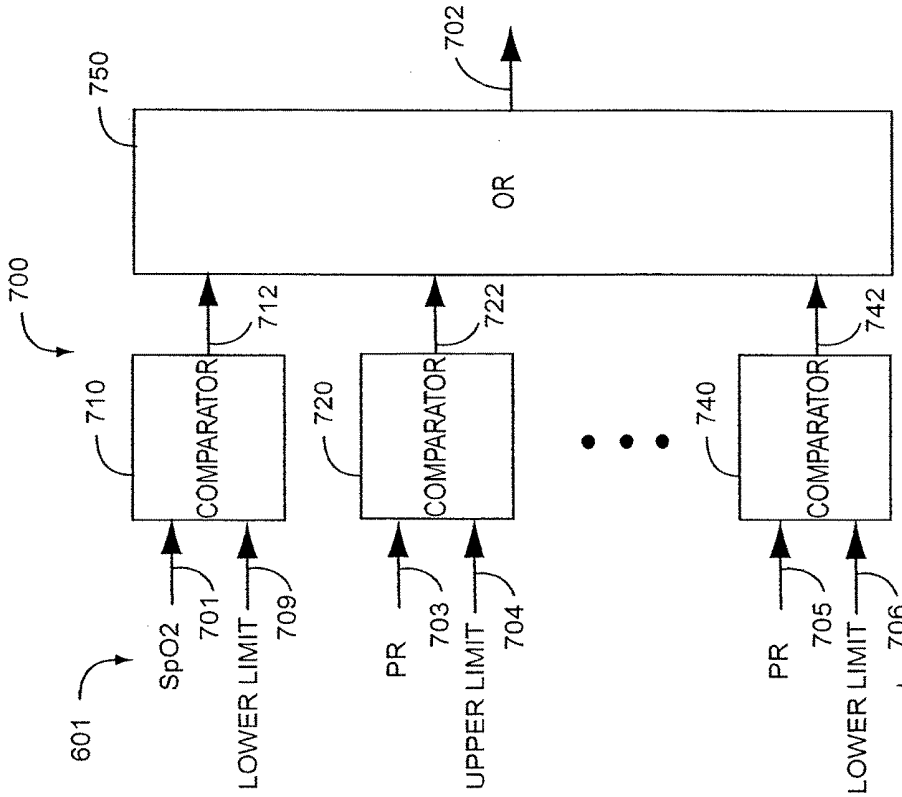

700
750
OR
702
710
COMPARATOR
712
720
COMPARATOR
722
740
COMPARATOR
742
601
SpO2
701
LOWER LIMIT
709
PR
703
UPPER LIMIT
704
PR
705
LOWER LIMIT
706
602

FIG. 7

PHYSIOLOGICAL PARAMETER SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 14/275,525, titled Physiological Parameter System, filed May 12, 2014, which is a divisional of U.S. patent application Ser. No. 12/188,154 (now U.S. Pat. No. 8,721,542), titled Physiological Parameter System, filed Aug. 7, 2008, which is a continuation of U.S. patent application Ser. No. 11/075,389 (now U.S. Pat. No. 7,415,297), titled Physiological Parameter System, filed Mar. 8, 2005, which relates to and claims the benefit of U.S. Provisional Applications No. 60/551,165, titled Combined Physiological Parameter Monitor, filed Mar. 8, 2004 and No. 60/600,640, titled Physiological Parameter Controller, filed Aug. 11, 2004. Each of the foregoing applications are 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. Pat. No. 6,088,607 titled Low Noise Optical Probe, which is assigned to Masimo Corporation, Irvine, Calif. 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 CO_2 concentrations is referred to as a capnometer. CO_2 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 SpO_2 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 of 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. Pat. No. 6,699,194 titled Signal Processing Apparatus and Method; signal quality and data confidence indicators are described in U.S. Pat. No. 6,684,090 titled Pulse Oximetry Data Confidence Indicator, both of which are assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein.

[0007] One aspect of a physiological parameter system in 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**A, **6**B, and **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 oximetry **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. Pat. No. 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 $ETCO_2$ input **303**. A slope comparator **320** compares this slope **312** to a predetermined slope limit **304**. If the downward trend of $ETCO_2$ **303** is great enough, a delta value **303** is added 340 to the SpO_2 lower limit **302** to generate a variable threshold **342**. A threshold comparator **350** compares this variable threshold **342** to the SpO_2 input **301** to generate a trigger **352** for the SpO_2 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 CO_2 alarm embodiment **400** that is responsive to SpO_2. In particular, morphology of the input CO_2 waveform **401** is utilized to trigger an alarm **405**, and that alarm is also responsive to a falling SpO_2 **402**. That is, if a pattern in the expired CO_2 waveform is detected and SpO_2 is trending down above a certain rate, then an alarm is triggered. For example, an increasing slope of the CO_2 plateau in combination with a downward trend of SpO_2 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 CO_2 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 CO_2 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 CO_2 waveform **401**. In addition, a slope detector **400** determines the slope **442** of the SpO_2 input **402**. A slope comparator **450** compares this slope **442** to a predetermined slope limit **404**. If the downward trend of SpO_2 **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 SpO_2 **501** and $ETCO_2$ **503** inputs. A SpO_2 slope detector **510** determines the slope **512** of the SpO_2 input **501** and can be made responsive to a negative slope, a positive slope or s slope absolute value. A first comparator **520** compares this slope **512** to a predetermined SpO_2 slope limit **502**. If the trend of SpO_2 **501** is great enough, a SpO_2 slope exceeded output **522** is asserted. Likewise, an $ETCO_2$ slope detector **530** determines the slope **532** of the $ETCO_2$ input **503**. A second comparator **540** compares this slope **532** to a predetermined $ETCO_2$ 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. **6**A-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. **6**A, 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 oximetry parameters are not allowed to lock-out PCA if those parameters are unreliable. By contrast, in FIG. **6**B, 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. **6**A, pulse oximetry parameters **601** and corresponding limits **602** for those parameters are one set of inputs and a signal quality measures **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 **703** 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. **6**B, the combined output **702**, quality output **612**, reset **622**, timer **630**, comparator **640** and control **650** are generated as described with respect to FIG. **6**A, above. An OR logic **621** generates a rest **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 SpO_2 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 SpO_2 **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** (FIG. **6**B) 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** (FIG. **6**B) can be used to control patient delivery of any of various pharmacological agents and/or medical gases.

1.-**10**. (canceled)

11. A physiological diagnosis decision system responsive to medical data received from independent medical device systems, the physiological decision system comprising one or more hardware processors configured to:

receive at least one pulse oximetry parameter responsive to irradiation of a tissue site with an optical sensor;

receive a secondary parameter responsive to measurement from a second sensor that is different from the optical sensor;

determine a first trend property of the at least one pulse oximetry parameter;

compare the first trend property with stored trending parameters corresponding to physiological condition of a patient; and

generate a diagnosis decision based on the comparison of the first trend property and the secondary parameter.

12. The physiological diagnosis decision system of claim **11**, wherein the secondary parameter is $ETCO_2$.

13. The physiological diagnosis decision system of claim **11**, wherein the secondary parameter is respiration rate.

14. The physiological diagnosis decision system of claim **11**, wherein the secondary parameter is blood pressure.

15. The physiological diagnosis decision system of claim **11**, wherein the secondary parameter is respiration rate.

16. The physiological diagnosis decision system of claim **11**, wherein the secondary parameter is temperature.

17. The physiological diagnosis decision system of claim **11**, wherein the one or more hardware processors are further configured to control a medical device based on the generated diagnosis.

18. A physiological diagnosis decision method responsive to medical data received from independent medical device systems, the physiological diagnosis decision method comprising:

receiving at least one pulse oximetry parameter responsive to irradiation of a tissue site with an optical sensor;

receiving a secondary parameter responsive to measurement from a second sensor that is different from the optical sensor;

determining a first trend property of the at least one pulse oximetry parameter;

comparing the first trend property with stored trending parameters corresponding to physiological condition of a patient; and

generating a diagnosis decision based on the comparison of the first trend property and the secondary parameter.

19. The physiological diagnosis decision method of claim **18**, wherein the secondary parameter is $ETCO_2$.

20. The physiological diagnosis decision method of claim **18**, wherein the secondary parameter is respiration rate.

21. The physiological diagnosis decision method of claim **18**, wherein the secondary parameter is blood pressure.

22. The physiological diagnosis decision method of claim **18**, wherein the secondary parameter is respiration rate.

23. The physiological diagnosis decision method of claim **18**, wherein the secondary parameter is temperature.

24. The physiological diagnosis decision method of claim **18**, wherein the one or more hardware processors are further configured to control a medical device based on the generated diagnosis.

* * * * *

专利名称(译)	生理参数系统		
公开(公告)号	US20190269370A1	公开(公告)日	2019-09-05
申请号	US16/159278	申请日	2018-10-12
[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	AL ALI AMMAR GRAYBEAL JOHN KIANI MASSI JOE E PETTERSON MICHAEL		
发明人	AL-ALI, AMMAR GRAYBEAL, JOHN KIANI, MASSI JOE E. PETTERSON, MICHAEL		
IPC分类号	A61B5/00 A61B5/1455 A61B5/083 A61M5/14 A61M5/172		
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优先权	60/551165 2004-03-08 US 60/600640 2004-08-11 US		
外部链接	Espacenet USPTO		

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。