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**Al-Ali et al.**

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(54) **PHYSIOLOGICAL PARAMETER SYSTEM**

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(52) **U.S. Cl.**

CPC ..... ***A61B 5/7275*** (2013.01); ***A61B 5/14551*** (2013.01); ***A61B 5/7221*** (2013.01); ***A61B 5/746*** (2013.01); *A61B 5/0836* (2013.01); *A61B 2560/0276* (2013.01)

(58) **Field of Classification Search**

CPC combination set(s) only.

See application file for complete search history.

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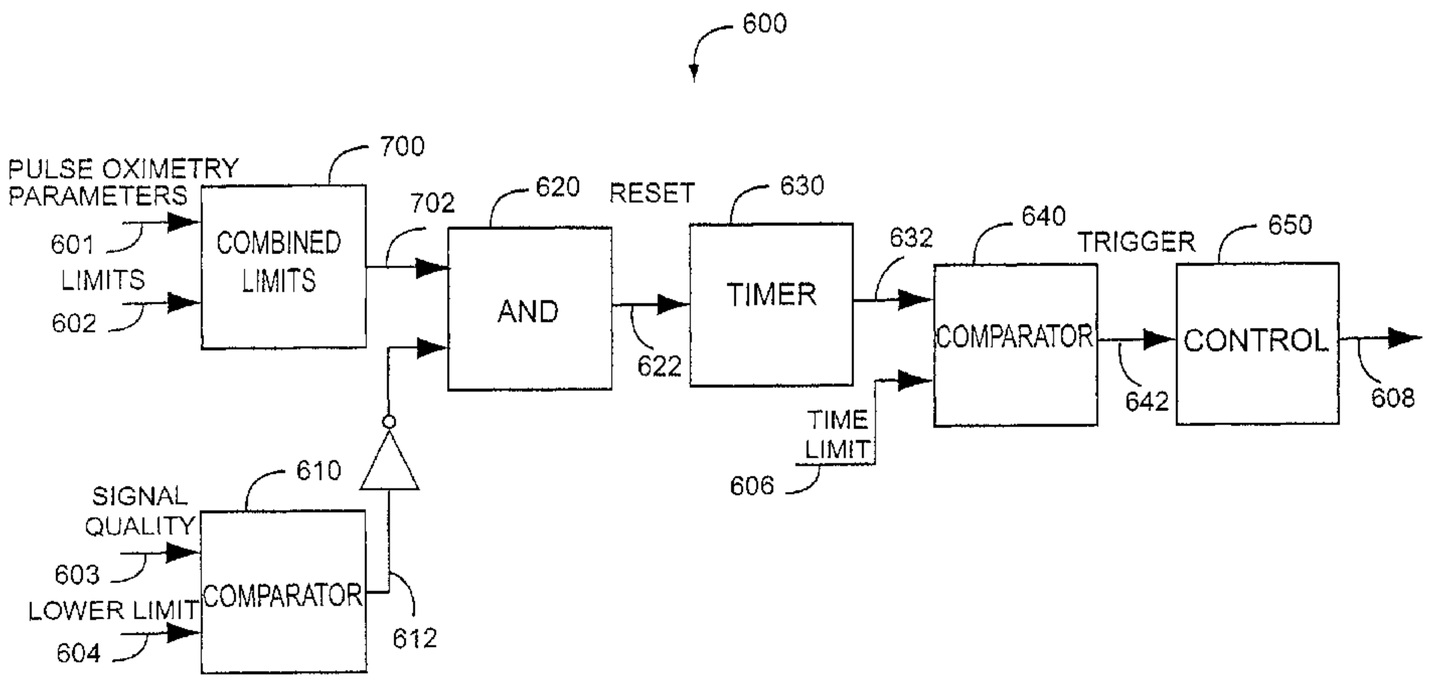
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(57) **ABSTRACT**

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.

**4 Claims, 8 Drawing Sheets**



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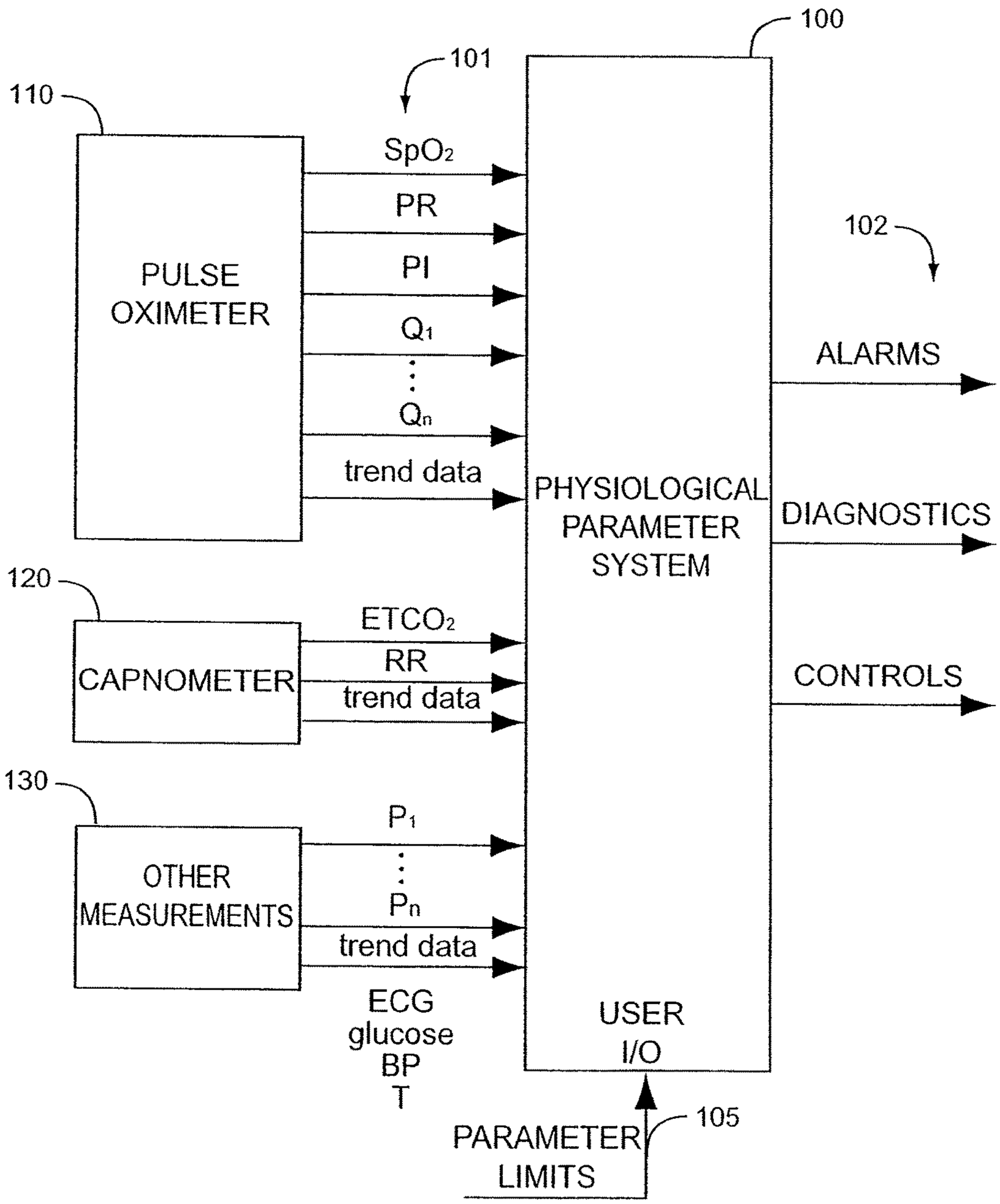

100
101
110
SpO2
PR
PI
Q1
Qn
trend data
PULSE OXIMETER
102
ALARMS
PHYSIOLOGICAL PARAMETER SYSTEM
DIAGNOSTICS
120
ETCO2
RR
trend data
CAPNOMETER
CONTROLS
130
P1
Pn
trend data
OTHER MEASUREMENTS
ECG
glucose
BP
T
USER I/O
105
PARAMETER LIMITS

FIG. 1

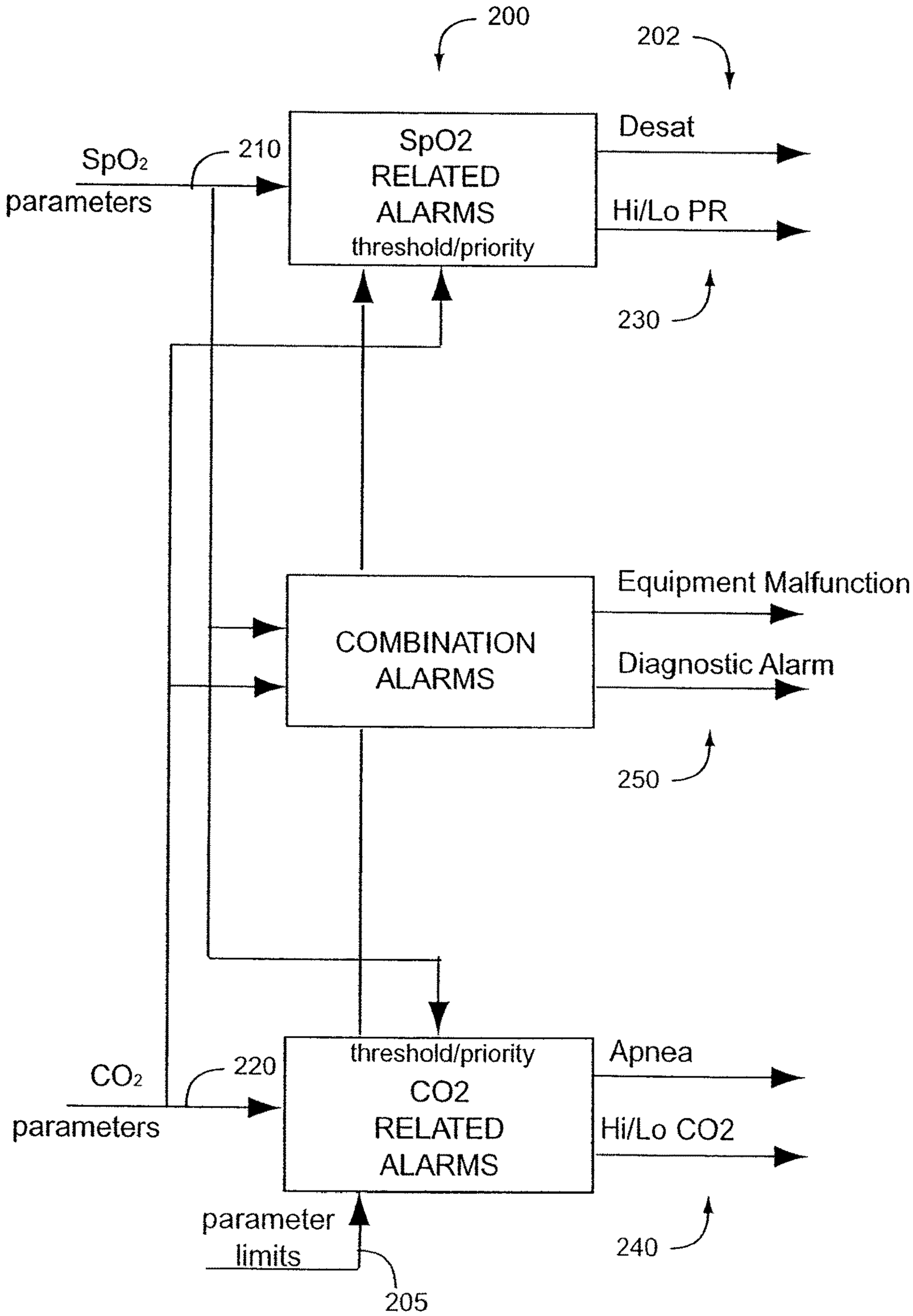

200
202
SpO2
RELATED
ALARMS
threshold/priority
SpO2
parameters
210
Desat
Hi/Lo PR
230
COMBINATION
ALARMS
Equipment Malfunction
Diagnostic Alarm
250
CO2
RELATED
ALARMS
threshold/priority
CO2
parameters
220
Apnea
Hi/Lo CO2
240
parameter
limits
205

FIG. 2

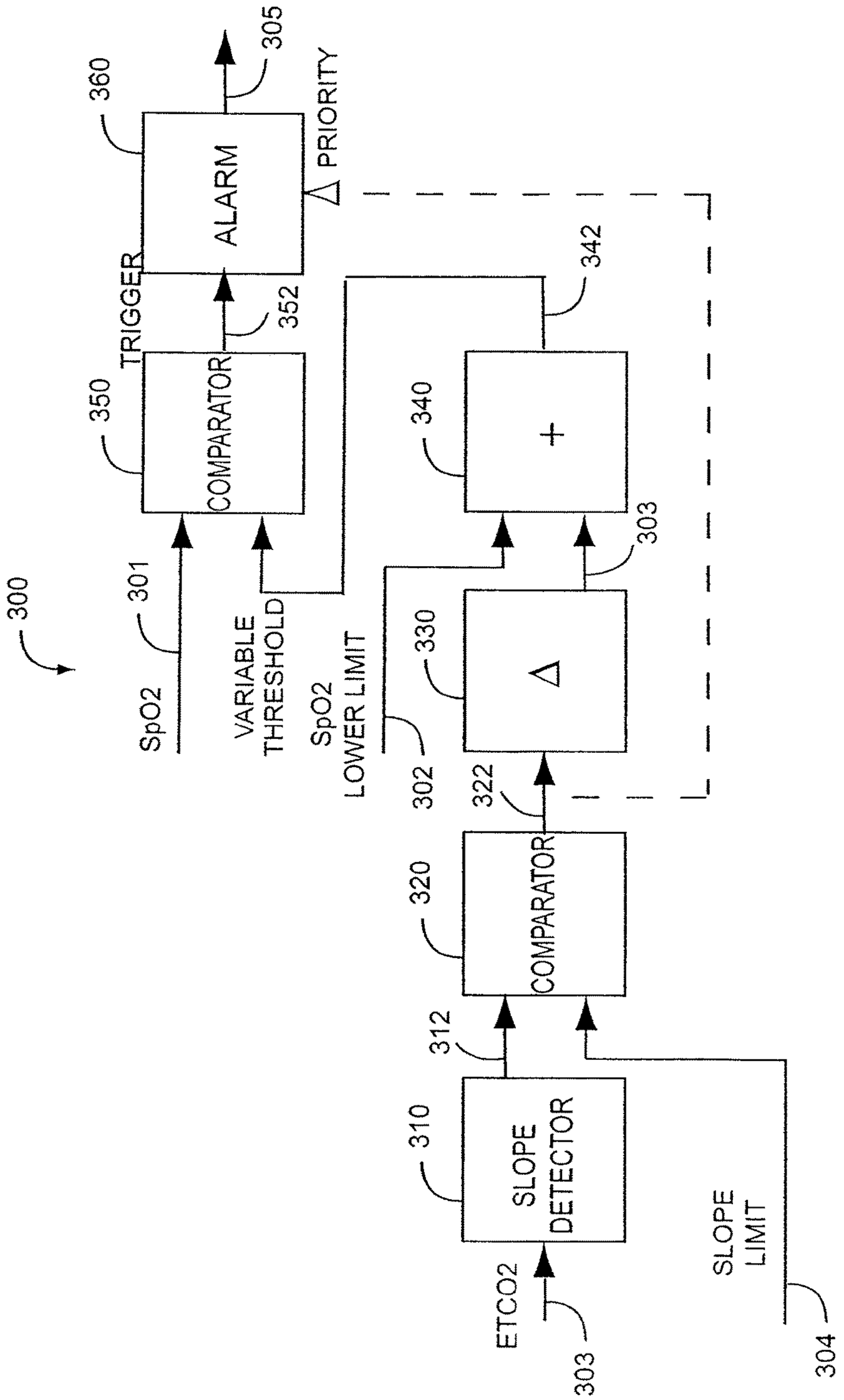

300
SpO2
301
VARIABLE THRESHOLD
SpO2 LOWER LIMIT
302
ETCO2
303
SLOPE LIMIT
304
360
TRIGGER
305
PRIORITY
350
COMPARATOR
352
340
+
342
330
Δ
320
COMPARATOR
322
310
SLOPE DETECTOR
312

FIG. 3

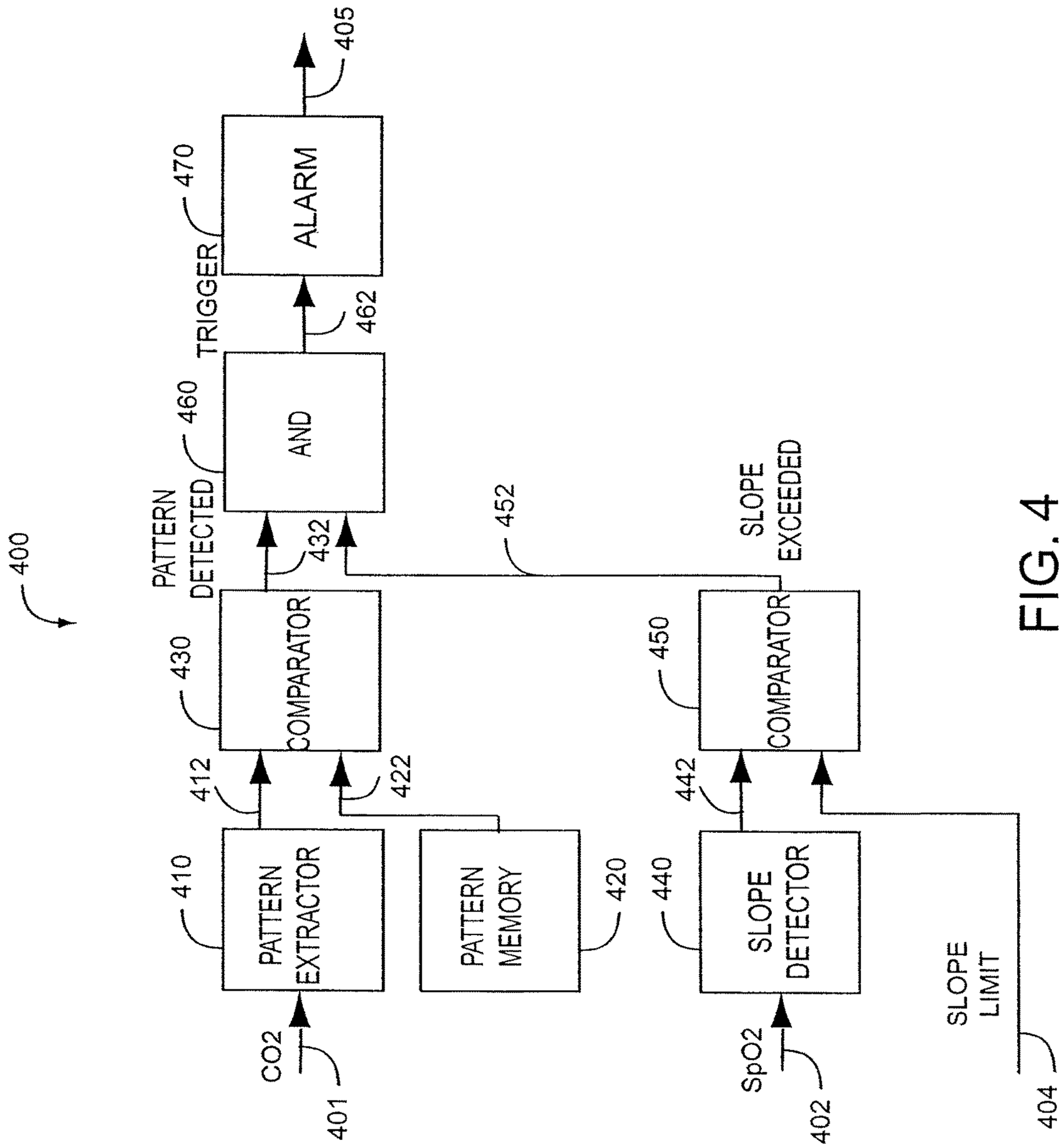

400
405
ALARM
470
TRIGGER
462
AND
460
PATTERN DETECTED
452
SLOPE EXCEEDED
COMPARATOR
430
432
COMPARATOR
450
412
422
442
PATTERN EXTRACTOR
410
PATTERN MEMORY
420
SLOPE DETECTOR
440
CO2
401
SpO2
402
SLOPE LIMIT
404

FIG. 4

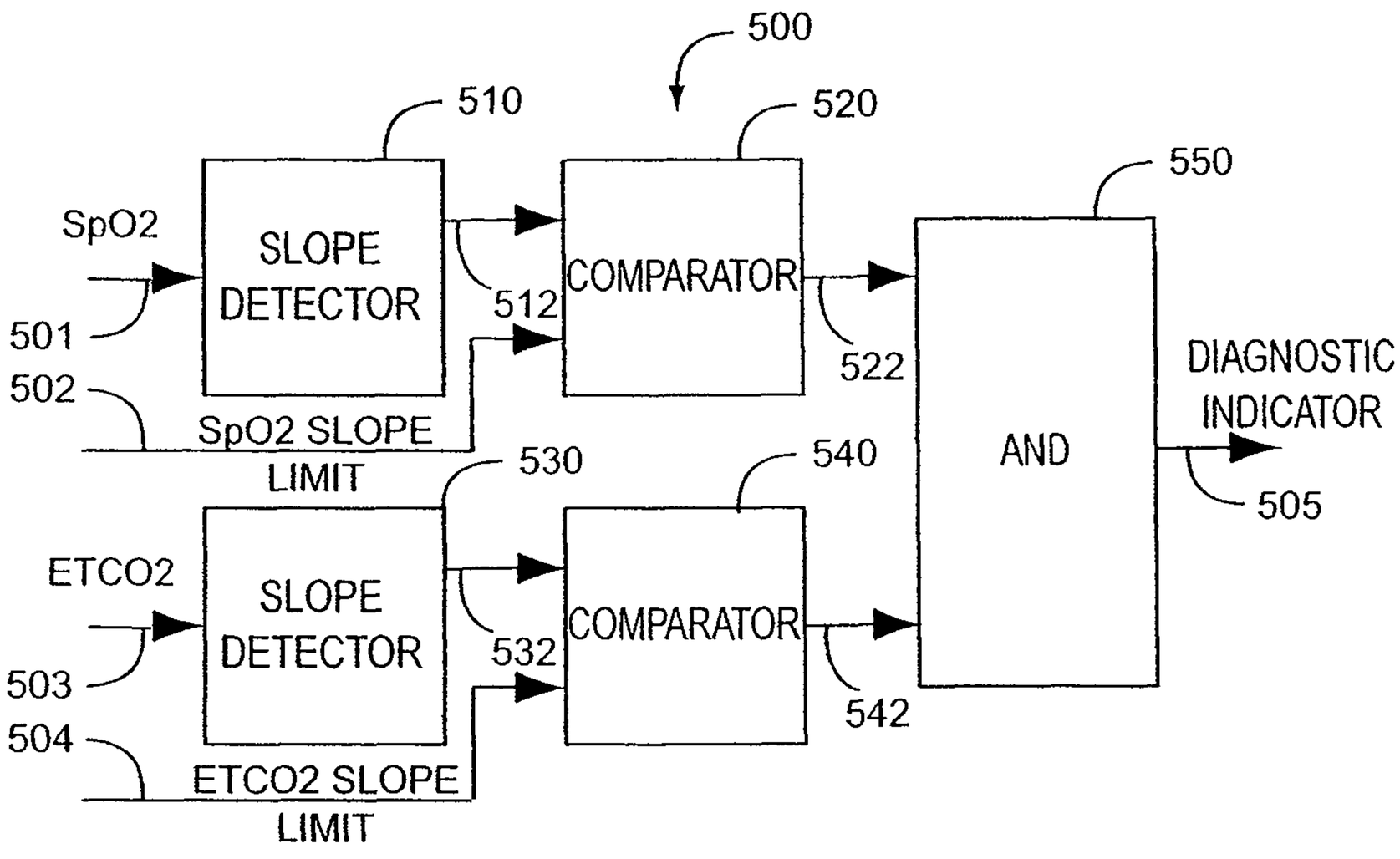

500
510
520
550
SpO2
SLOPE DETECTOR
COMPARATOR
501
512
522
502
SpO2 SLOPE LIMIT
AND
DIAGNOSTIC INDICATOR
505
530
540
ETCO2
SLOPE DETECTOR
COMPARATOR
503
532
542
504
ETCO2 SLOPE LIMIT

FIG. 5

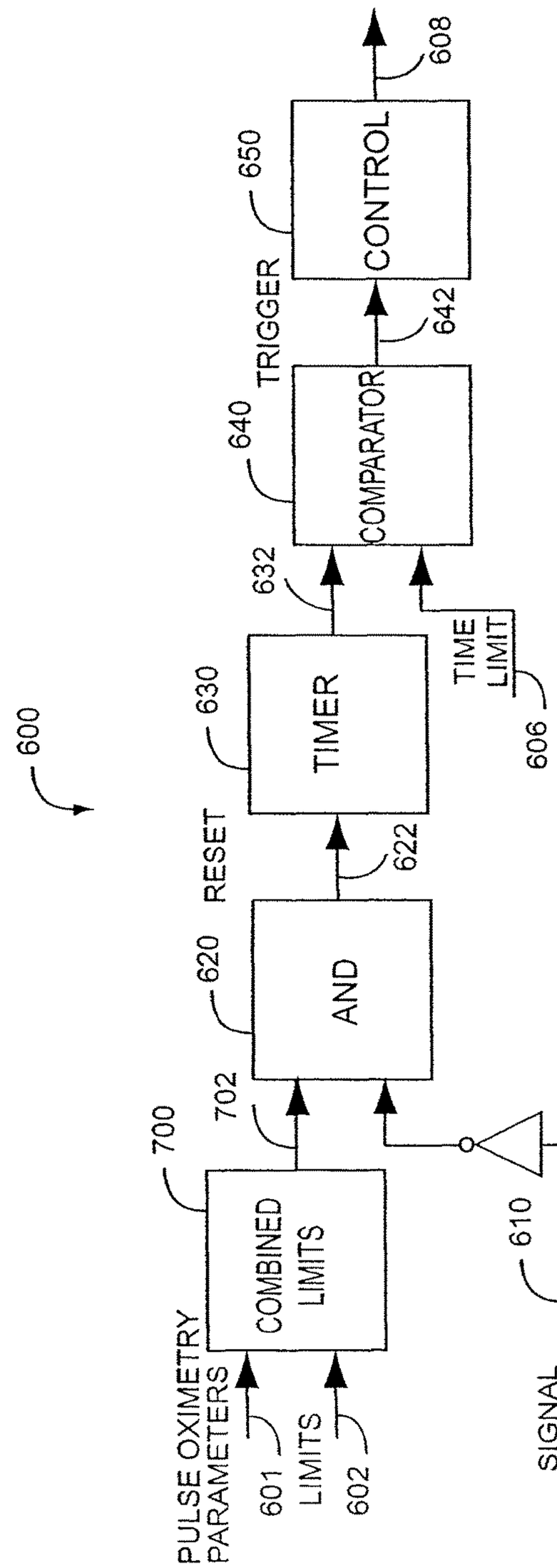

600
PULSE OXIMETRY PARAMETERS
601
LIMITS
602
700
COMBINED LIMITS
702
620
AND
RESET
622
630
TIMER
632
TIME LIMIT
606
640
COMPARATOR
TRIGGER
642
650
CONTROL
608
610
COMPARATOR
SIGNAL QUALITY
603
LOWER LIMIT
604
612

FIG. 6A

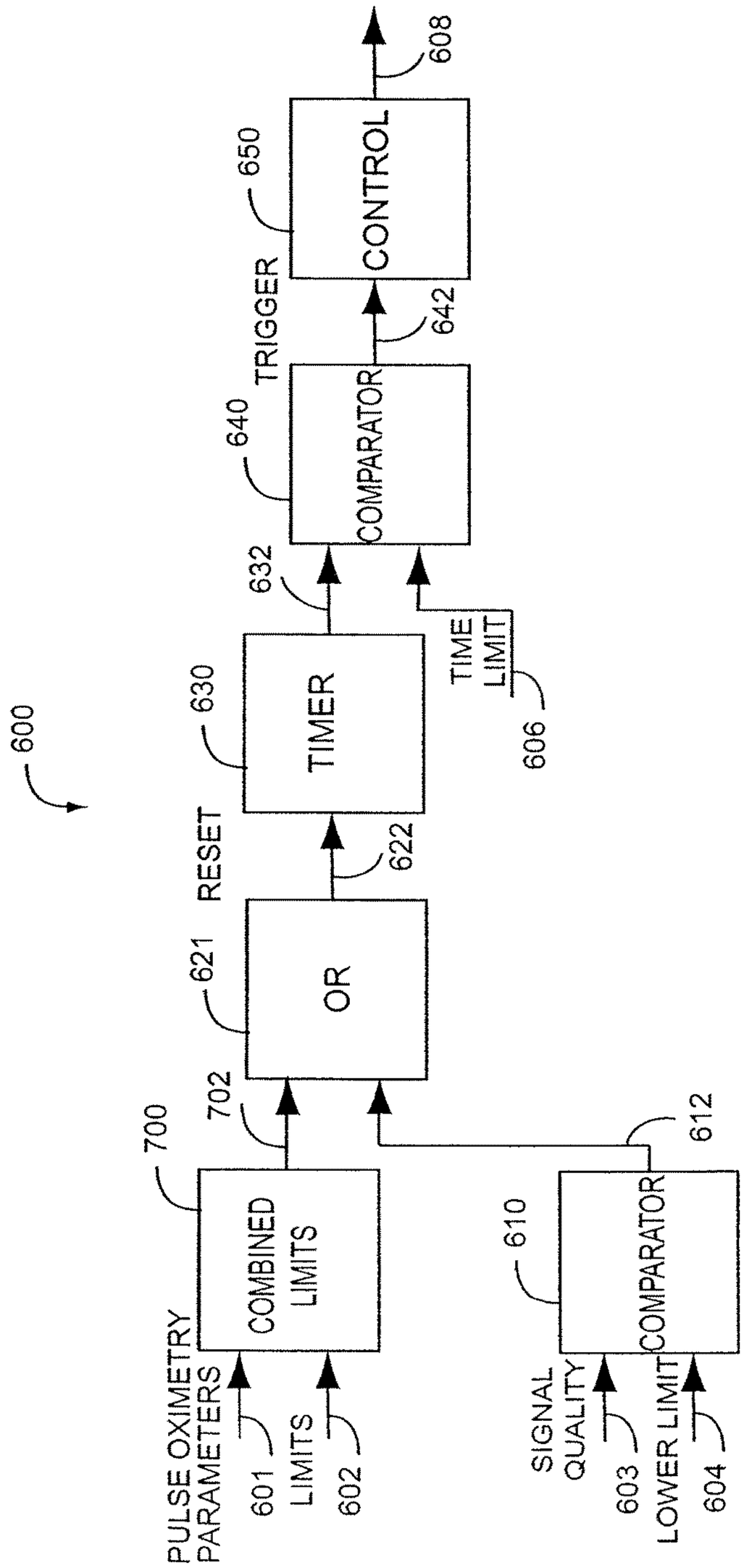

600
PULSE OXIMETRY PARAMETERS
601
LIMITS
602
700
COMBINED LIMITS
702
SIGNAL QUALITY
603
LOWER LIMIT
604
610
COMPARATOR
612
OR
621
RESET
622
TIMER
630
632
TIME LIMIT
606
COMPARATOR
640
TRIGGER
642
CONTROL
650
608

FIG. 6B

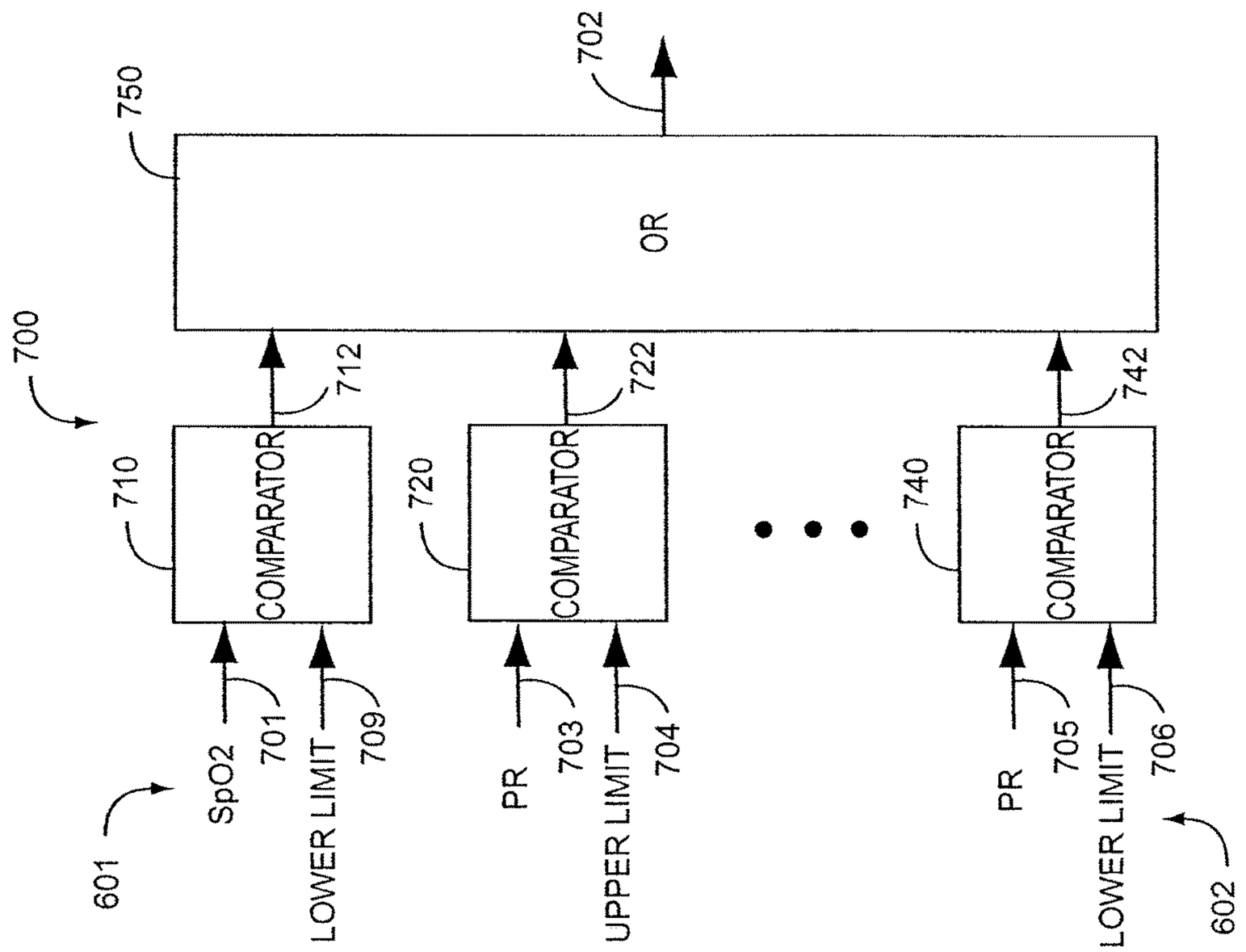

700
601
SpO2
701
LOWER LIMIT
709
710
COMPARATOR
712
PR
703
UPPER LIMIT
704
720
COMPARATOR
722
PR
705
LOWER LIMIT
706
740
COMPARATOR
742
602
750
OR
702

FIG. 7

# PHYSIOLOGICAL PARAMETER SYSTEM

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. patent application Ser. No. 12/188,154, titled Physiological Parameter System, filed Aug. 7, 2008, and 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

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.

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

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.



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.

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.

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.

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.

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

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

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

FIG. **3** is a block diagram of a saturation limit alarm enhanced by $ETCO_2$ measurements;

FIG. **4** is a block diagram of a $CO_2$ waveform alarm enhanced by $SpO_2$ measurements;

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

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

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**.

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.

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.

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.

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**.

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.

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**.

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.

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.

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 param-

eter 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.

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.

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.

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**.

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.

What is claimed is:

**1**. A physiological parameter system comprising:

one or more hardware processors configured to:

receive pulse oximetry parameters detected by a pulse oximeter, the pulse oximetry parameters including oxygen saturation and pulse rate measurements;

compare the oxygen saturation measurement with a saturation lower limit;

compare the pulse rate measurement with a pulse rate upper limit and a pulse rate lower limit;

generate a combined output based on the said comparison of the oxygen saturation and the comparison of the pulse rate measurement;

receive a quality indicator input relating to confidence in the pulse oximetry parameters;

compare the quality indicator input with a quality lower limit;

determine a lock out state of a patient controlled analgesia system based on the combined output and the comparison of the quality indicator input; and

generate a control output configured to lock out the patient controlled analgesia system based on the determination of the lock out state.

**2**. The physiological parameter system according to claim **1** wherein said control output disables the patient controlled analgesia system when confidence in the pulse oximetry parameters is low.

**3**. The physiological parameter system according to claim **2** wherein said control output prevents said the pulse oximetry parameters from disabling the patient controlled analgesia system when said quality indicator indicates confidence is low.

**4**. A physiological parameter method for automatic control of a patient controlled analgesia system using an electronic hardware processor, the method comprising:

under a control of a hardware processor:

receiving pulse oximetry parameters detected by a pulse oximeter, the pulse oximetry parameters including oxygen saturation and pulse rate;

comparing the oxygen saturation measurement with a saturation lower limit;

comparing the pulse rate measurement with a pulse rate upper limit and a pulse rate lower limit;

generating a combined output based on the said comparison of the oxygen saturation and the comparison of the pulse rate measurement;

receiving a quality indicator related to data confidence for the pulse oximetry parameters;

comparing the quality indicator input with a quality lower limit;

determining whether to lock a patient controlled analgesia system so as to disable a patient's control of the patient controlled analgesia system based on the combined output and the quality indicator;

outputting a control signal based on the said determination,

wherein said control signal is adapted to affect the operation of a the patient controlled analgesia system.

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