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(54) **PHYSIOLOGICAL TREND MONITOR**
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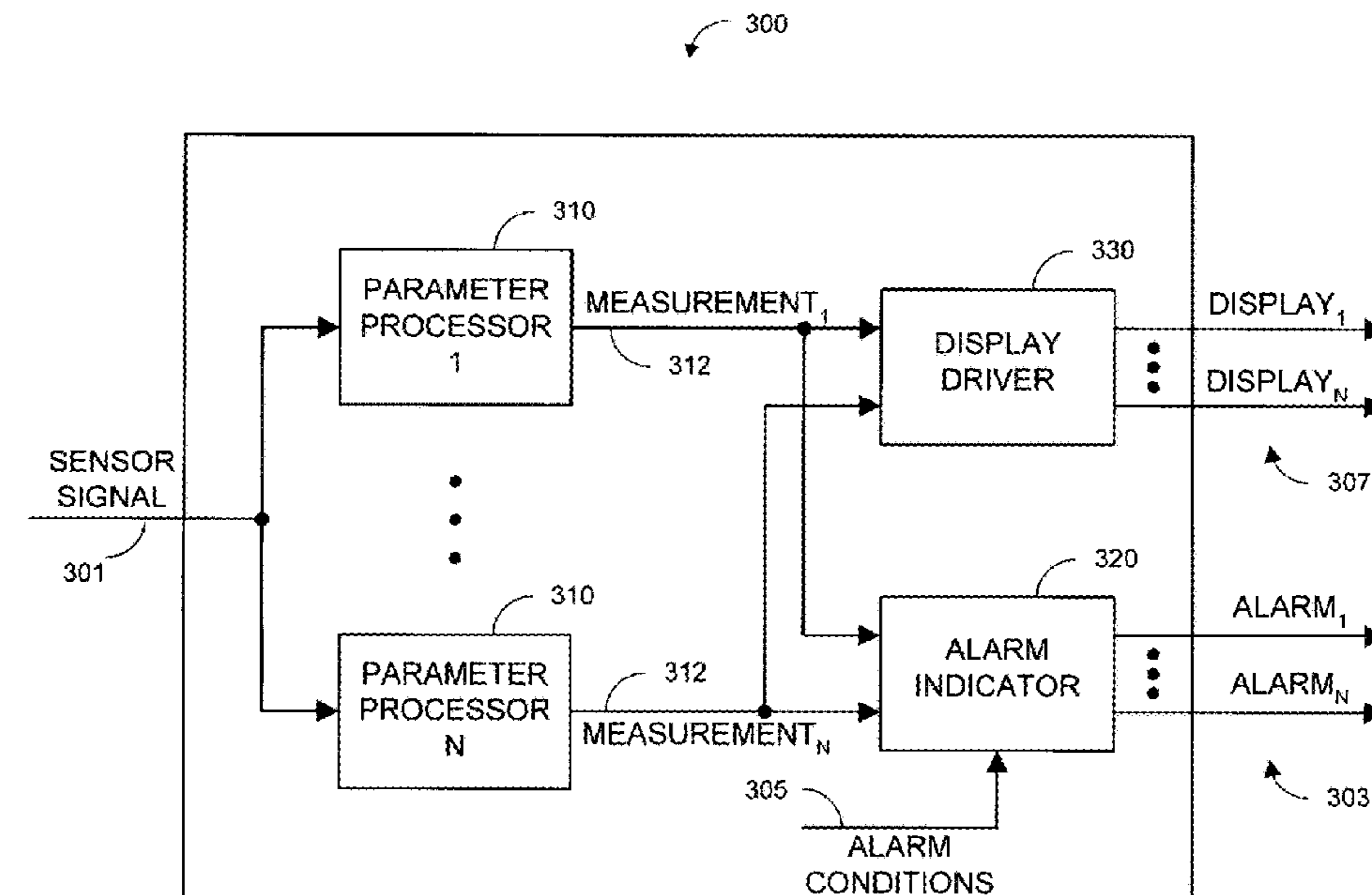
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(57) **ABSTRACT**

A physiological trend monitor has a sensor signal responsive to multiple wavelengths of light transmitted into a tissue site. The transmitted light is detected after attenuation by pulsatile blood flow within the tissue site. A processor has an input responsive to the sensor signal and a physiological parameter output. Features are extracted from the physiological parameter output. Criteria are applied to the features. An alarm output is generated when the criteria are satisfied.

10 Claims, 9 Drawing Sheets



Related U.S. Application Data

Jan. 31, 2011, now Pat. No. 8,228,181, which is a continuation of application No. 12/070,061, filed on Feb. 12, 2008, now Pat. No. 7,880,606, which is a continuation of application No. 11/717,591, filed on Mar. 13, 2007, now Pat. No. 7,355,512, which is a continuation of application No. 11/405,815, filed on Apr. 18, 2006, now Pat. No. 7,190,261, which is a continuation of application No. 10/975,860, filed on Oct. 28, 2004, now Pat. No. 7,030,749, which is a continuation of application No. 10/351,735, filed on Jan. 24, 2003, now Pat. No. 6,822,564.

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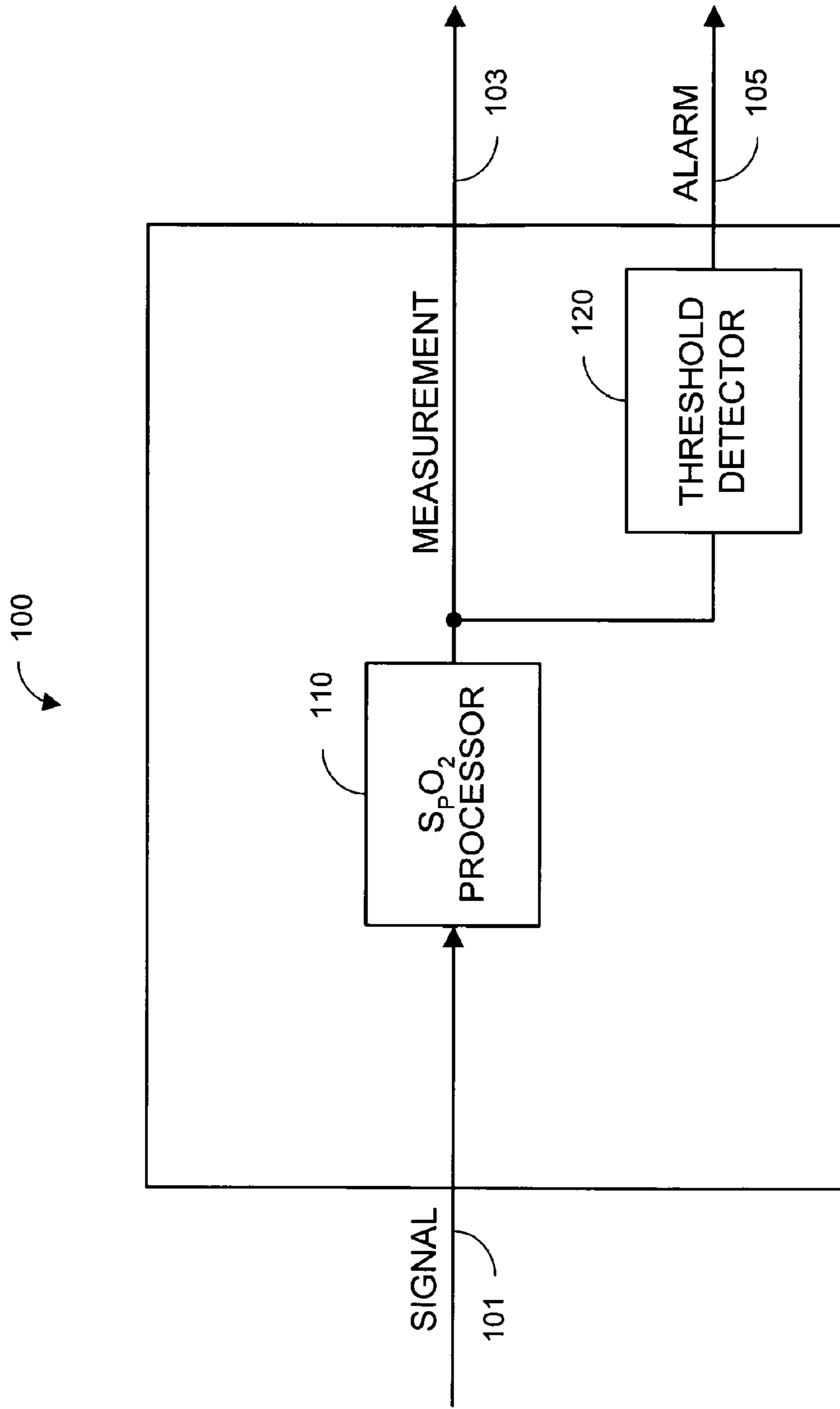


FIG. 1 (Prior Art)

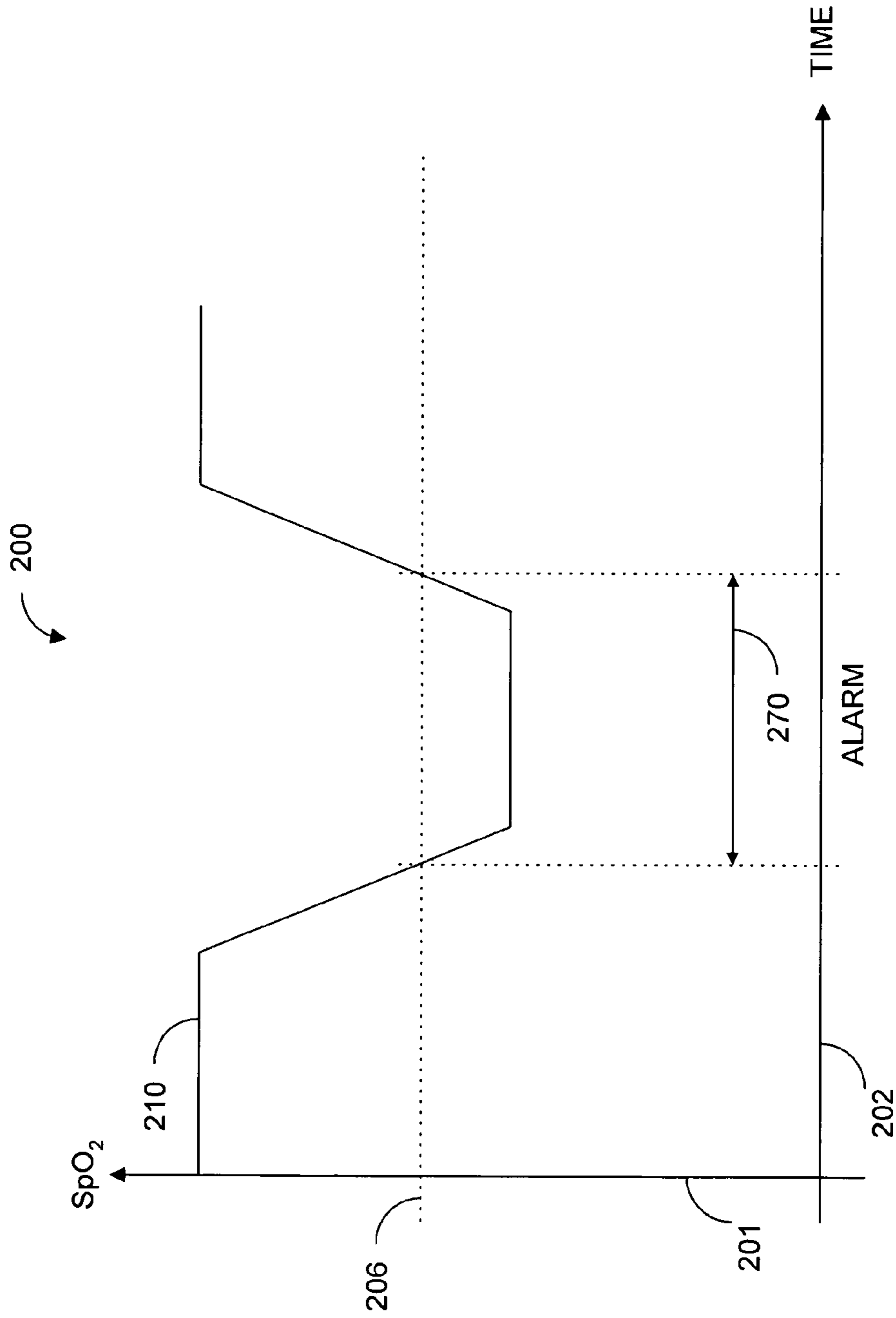


FIG. 2

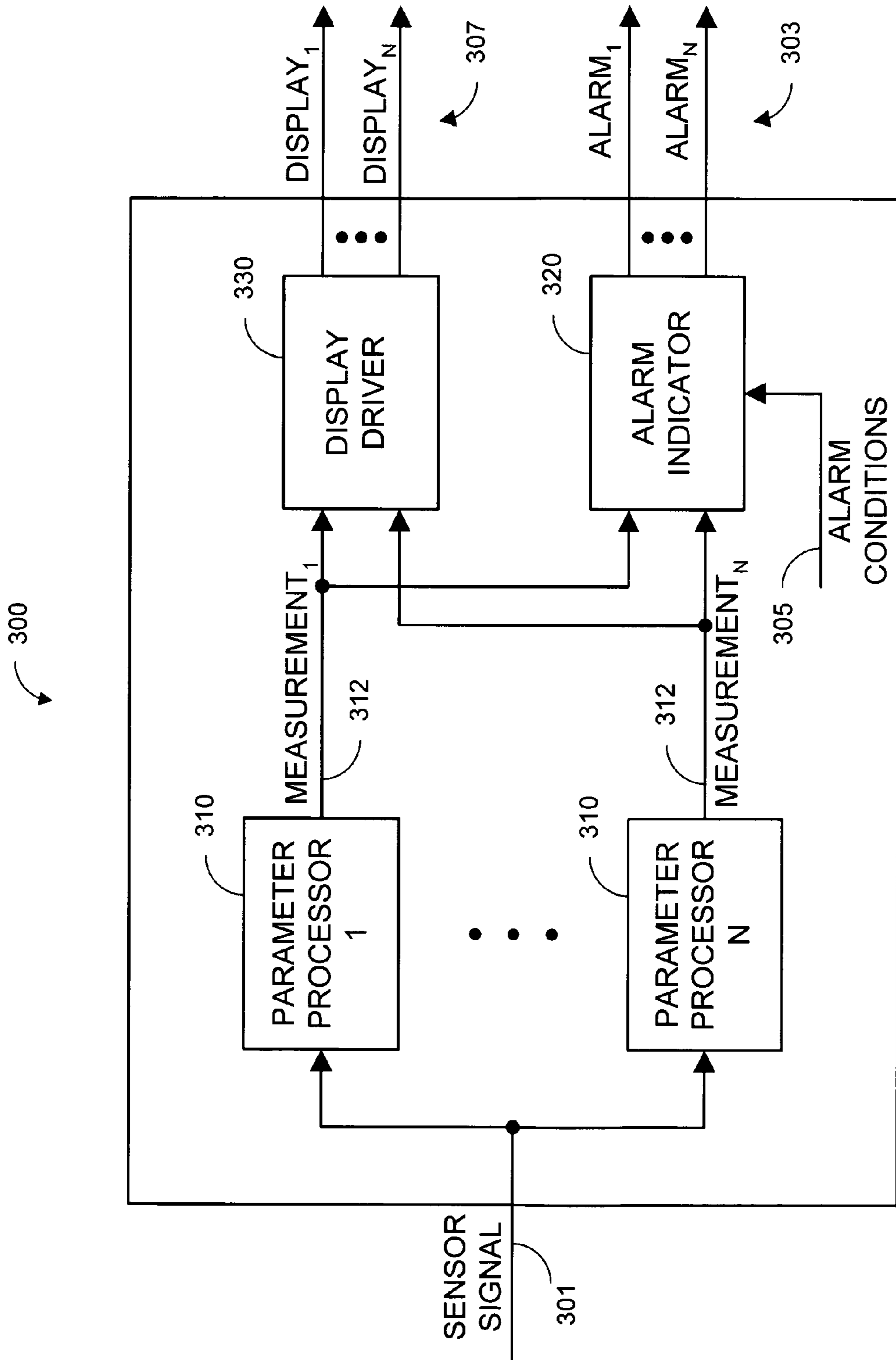


FIG. 3

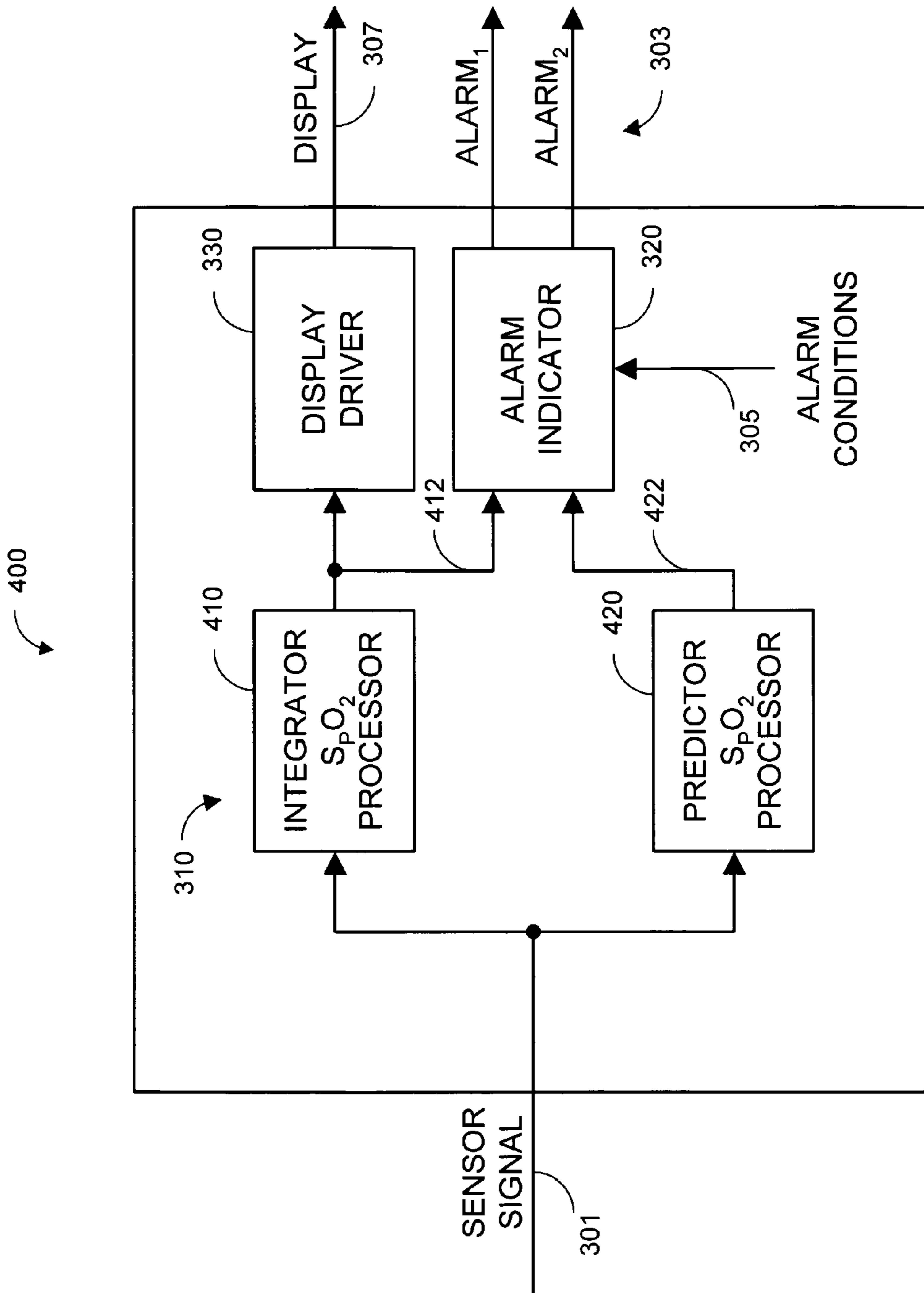


FIG. 4

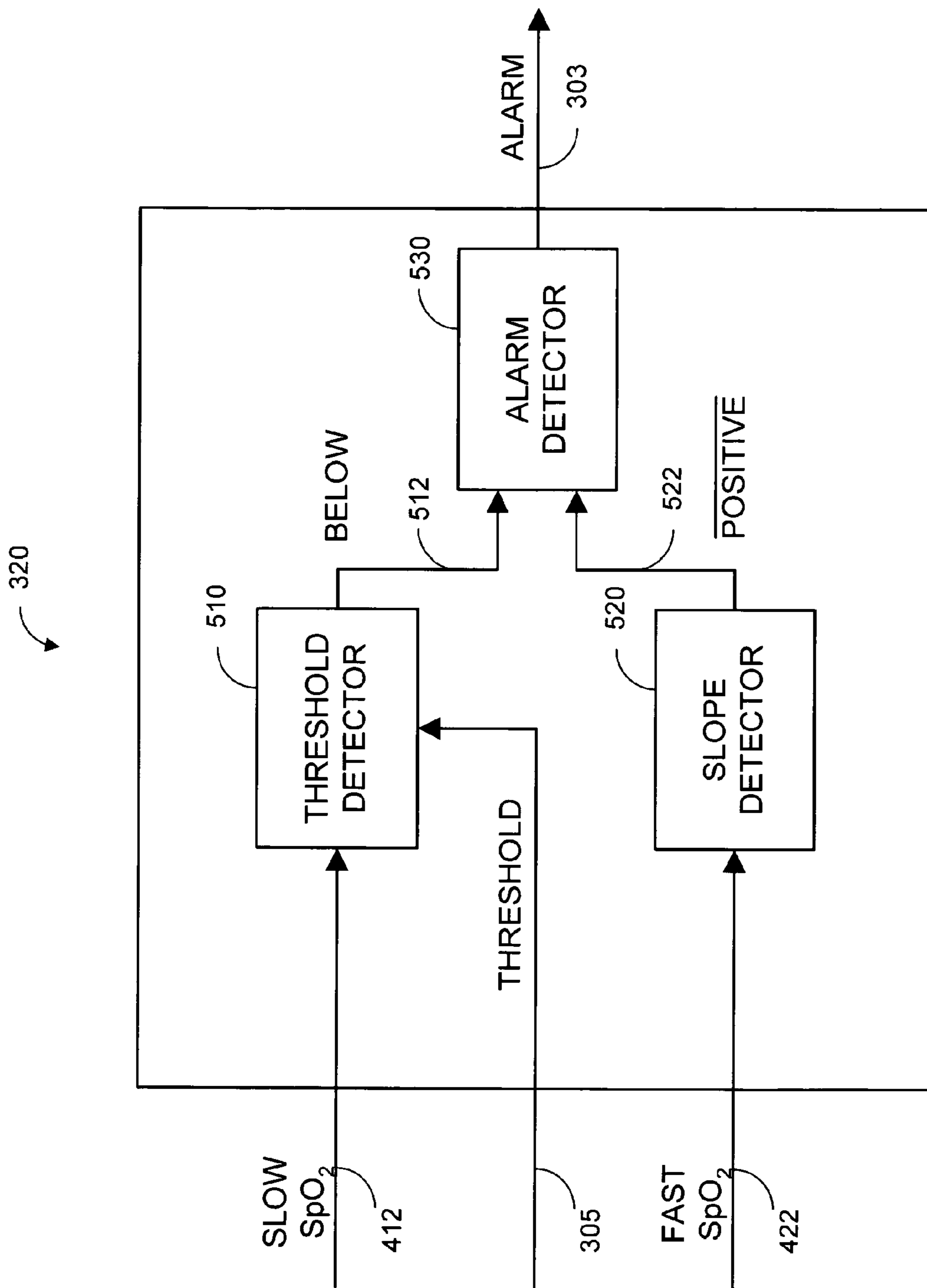


FIG. 5

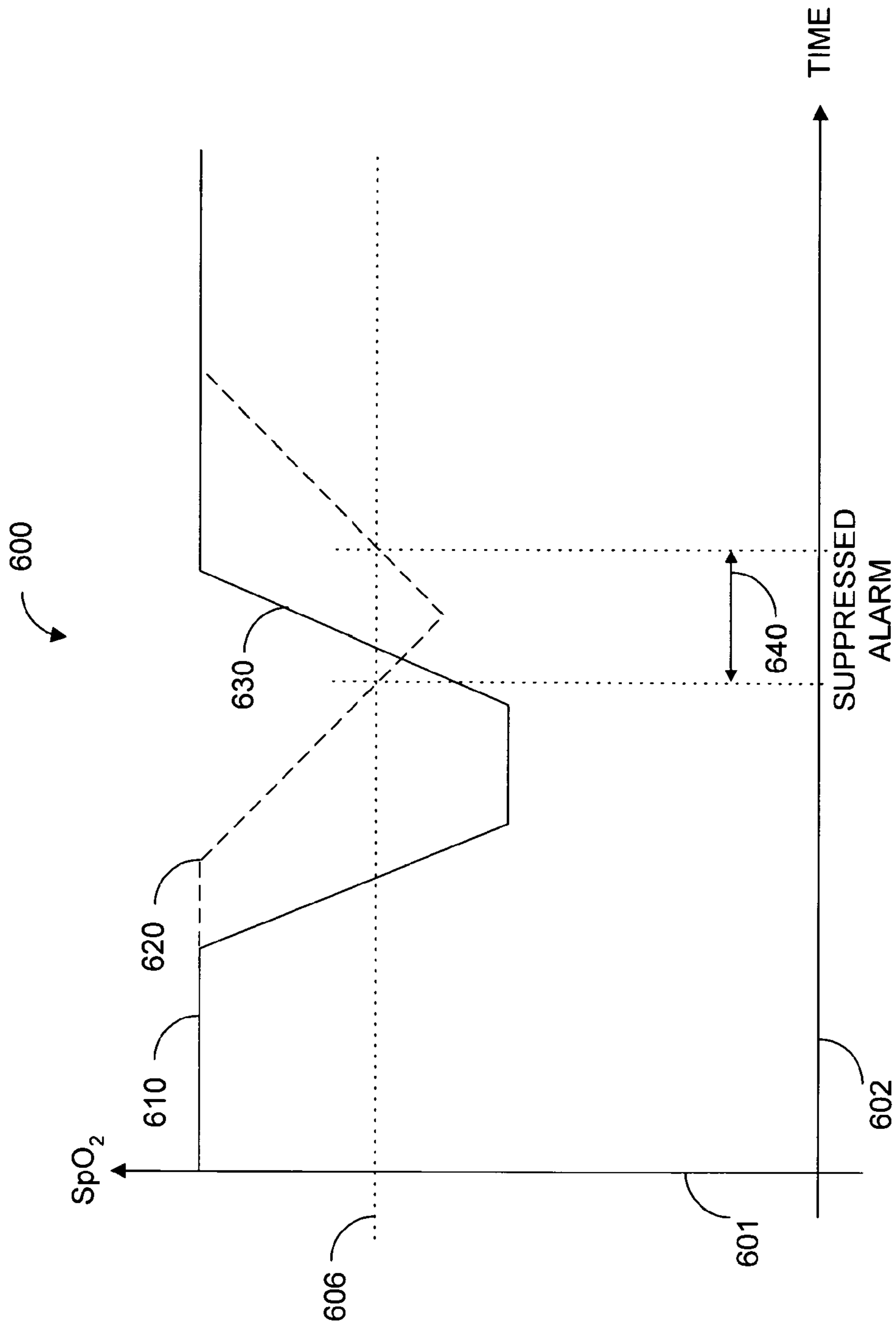


FIG. 6A

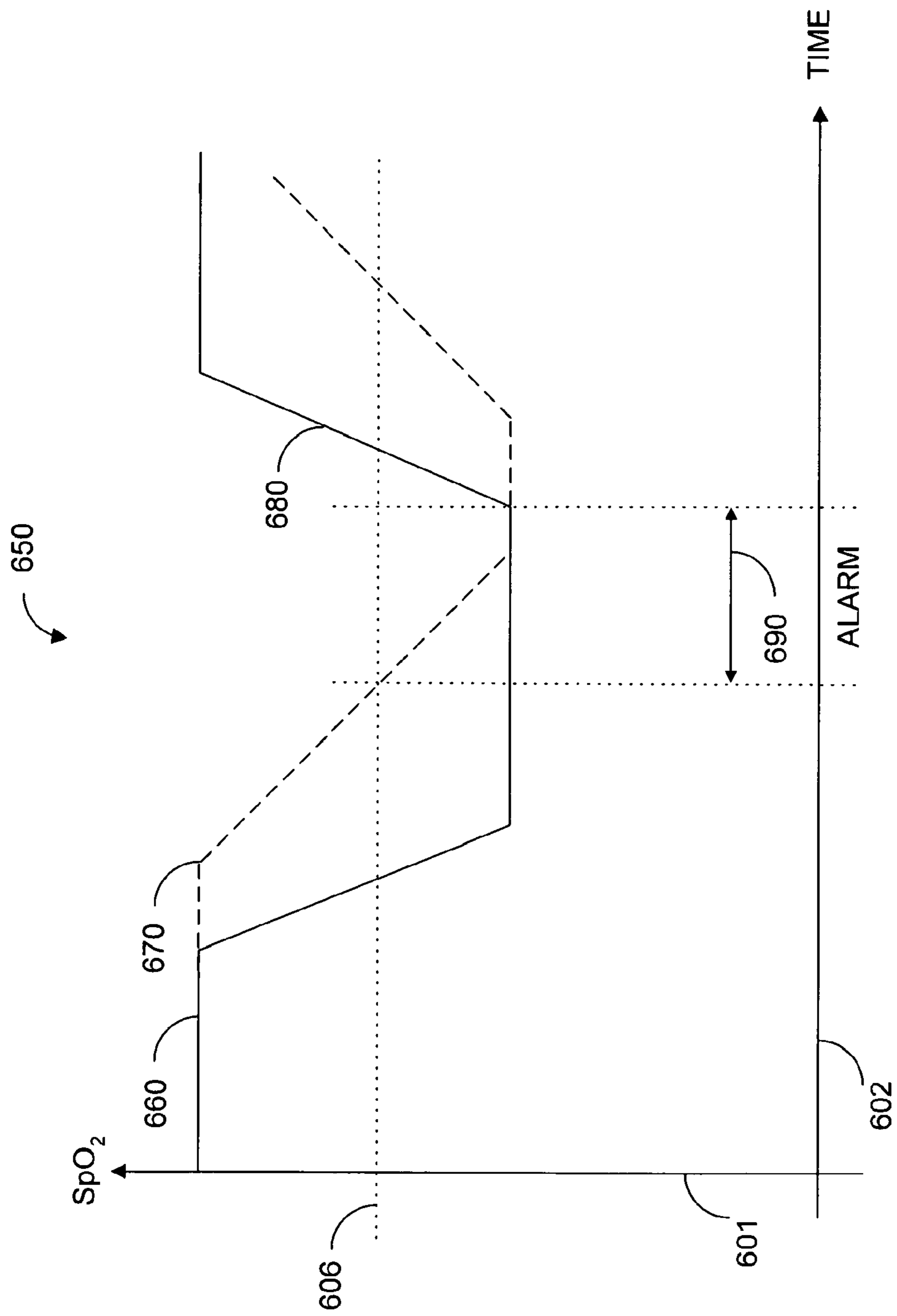


FIG. 6B

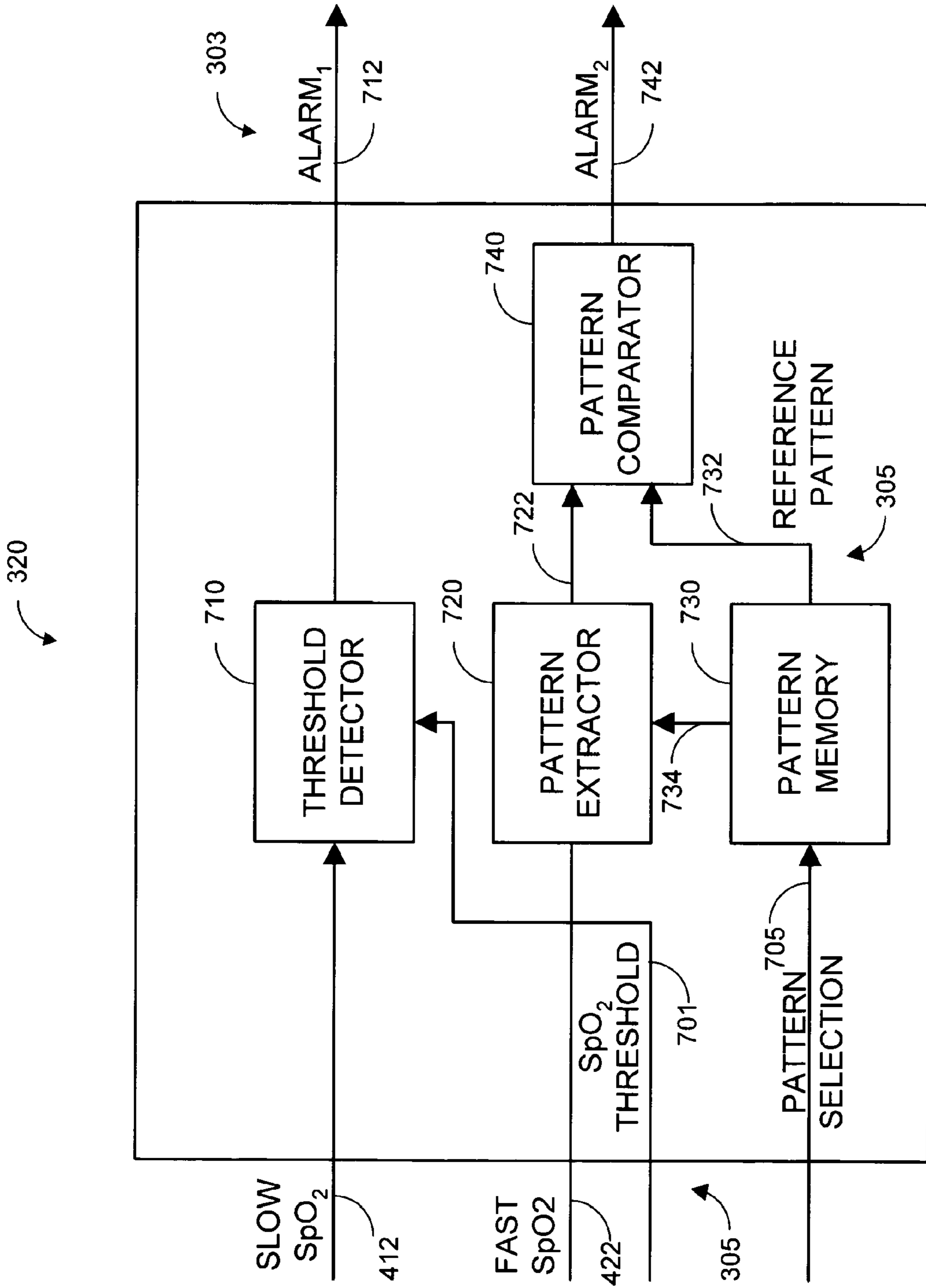


FIG. 7

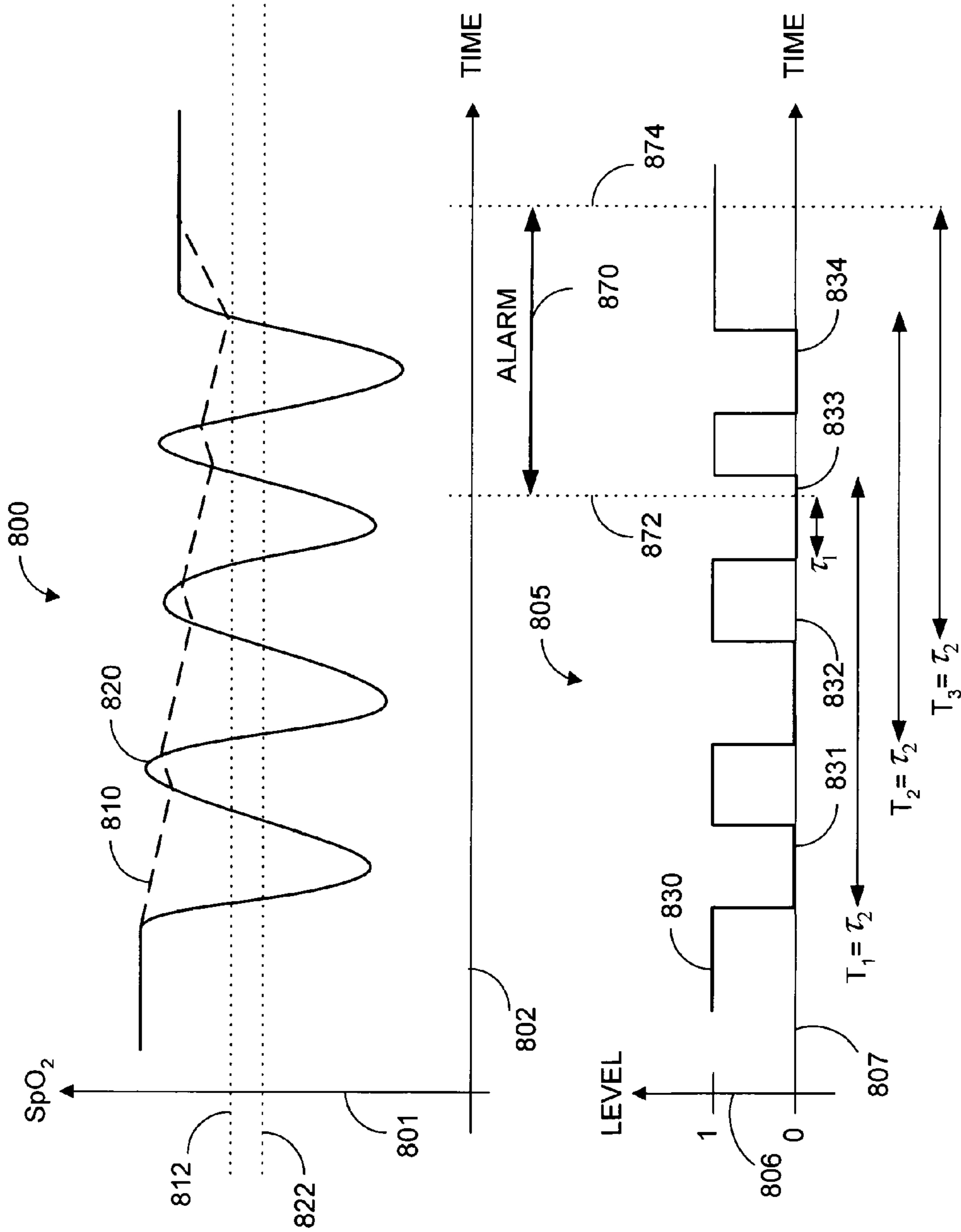


FIG. 8

PHYSIOLOGICAL TREND MONITOR

Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

INCORPORATION BY REFERENCE TO ANY PRIORITY APPLICATIONS

This application is an application for reissue of U.S. Pat. No. 9,636,056, issued on May 2, 2017 and titled "Physiological Trend Monitor,"; more than one reissue application has been filed for the reissue of U.S. Pat. No. 9,636,056, including U.S. patent application Ser. No. 16/385,846 (the present application), and U.S. patent application Ser. No. 17/665,400, which is a reissue divisional application. Any and all applications, if any, for which a foreign or domestic priority claim is identified in the Application Data Sheet of the present application are hereby incorporated by reference under 37 CFR 1.57.

BACKGROUND

Physiological measurement instruments employed in healthcare environments often feature visual and audible alarm mechanisms that alert a caregiver when a patient's vital signs are outside of predetermined limits. One example is a pulse oximeter, which measures the oxygen saturation level of arterial blood, an indicator of oxygen supply. A typical pulse oximeter displays a numerical readout of the patient's oxygen saturation, a numerical readout of pulse rate, and a plethysmograph, which is indicative of a patient's pulse. In addition, a pulse oximeter provides an alarm that warns of a potential desaturation event.

FIG. 1 illustrates a prior art pulse oximeter portion 100 having a signal input 101 and generating an oxygen saturation measurement output 103 and an alarm output 105. The pulse oximeter portion 100 has an oxygen saturation (SPO.sub.2) processor 110 and an associated threshold detector 120. The SPO.sub.2 processor 110 derives an oxygen saturation measurement from the signal input 101. The signal input 101 is typically an amplified, filtered, digitized and demodulated sensor signal. A sensor emits both red and infrared (IR) wavelength light, which is transmitted through a patient's tissue, detected and input to the pulse oximeter. The pulse oximeter calculates a normalized ratio (AC/DC) of the detected red and infrared intensities, and an arterial oxygen saturation value is empirically determined based on a ratio of these normalized ratios, as is well-known in the art. The oxygen saturation measurement output 103 is typically a digital signal that is then communicated to a display.

FIG. 2 illustrates the operation of a conventional threshold detector 120 (FIG. 1) utilizing a graph 200 of oxygen saturation 201 versus time 202. The graph 200 displays a particular oxygen saturation measurement 210 corresponding to the measurement output 103 (FIG. 1) and a predetermined alarm threshold 206. During an alarm time period 270 when the measured oxygen saturation 210 is below the threshold 206, an alarm output 105 (FIG. 1) is generated, which triggers a caregiver alert. Adjusting the threshold 206 to a lower value of oxygen saturation 201 reduces the probability of an alarm, i.e. reduces the probability of a false

alarm and increases the probability of a missed event. Likewise, adjusting the threshold 206 to a higher value of oxygen saturation 201 increases the probability of an alarm, i.e. increases the probability of a false alarm and decreases the probability of a missed event.

SUMMARY

One aspect of a physiological trend monitor comprises transmitting light into a patient tissue site, generating a sensor signal, detecting a blood parameter trend according to the sensor signal and generating an alarm according to the blood parameter trend. The transmitted light has multiple wavelengths. The sensor signal is responsive to the light after attenuation by pulsatile arterial blood flow within the tissue site. In various embodiments, the detecting comprises deriving a curve-fitting blood parameter measurement. A blood parameter slope is calculated from the blood parameter measurement. The alarm is responsive to a negative value of the blood parameter slope. A smoothed blood parameter measurement is derived. A threshold value is set for the smoothed blood parameter measurement. The alarm is responsive to the smoothed blood parameter measurement crossing the threshold value.

Another aspect of a physiological trend monitor comprises a sensor signal responsive to multiple wavelengths of light transmitted into a tissue site and detected after attenuation by pulsatile blood flow within the tissue site. A processor has an input responsive to the sensor signal and a physiological parameter output. Features are extracted from the physiological parameter output. Criteria are applied to the features. An alarm output is generated when the criteria are satisfied. In various embodiments a pattern memory stores feature values and a comparator compares the features with the stored feature values. The criteria determine a match between the features and the stored feature values so as to trigger the alarm output. At least one of the features relate to the number of threshold crossings over a specified time period. At least one of the features relate to a duration of a threshold crossing by the physiological parameter output. At least one of the features relate to a trend in the physiological parameter and a slope of that trend over a specified time period.

A further aspect of a physiological trend monitor comprises a detector responsive to multiple wavelengths of light transmitted into a tissue site after attenuation by pulsatile blood flow within the tissue site so as to generate a sensor signal. A processor means calculates a physiological measurement in response to the sensor signal. A pattern extractor means identifies features of the physiological measurement. A pattern memory means stores a reference pattern. A pattern comparator means triggers an alarm if the identified features match the reference pattern. In various embodiments, a threshold is input to the pattern extractor. The identified features comprise at least the number of times the physiological measurement crosses the threshold within a predetermined time period. The identified features comprise at least the duration of each time the physiological measurement crosses the threshold. The physiological measurement comprises a predictive oxygen saturation measurement. A second processor means calculates an integrator oxygen saturation measurement.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram of a prior art pulse oximeter portion;

FIG. 2 is a graph of oxygen saturation versus time illustrating a conventional threshold detector alarm;

FIG. 3 is a block diagram of an alarm processor utilizing parallel measurements of a physiological parameter;

FIG. 4 is a block diagram of a pulse oximeter processor utilizing dual oxygen saturation measurements;

FIG. 5 is a block diagram of a predictive alarm indicator utilizing a threshold detector with a slow oxygen saturation measurement input and a slope detector with a fast oxygen saturation measurement input;

FIGS. 6A-B are graphs of oxygen saturation versus time illustrating operation of the alarm indicator according to FIG. 5;

FIG. 7 is a block diagram of a pattern recognition alarm indicator utilizing a threshold detector with a slow oxygen saturation measurement input and a pattern extractor with a fast oxygen saturation measurement input; and

FIG. 8 is a graph of oxygen saturation versus time illustrating the pattern recognition alarm indicator according to FIG. 7.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 3 illustrates a parallel measurement alarm processor 300. The alarm processor 300 has a sensor signal input 301 responsive to a physiological parameter and provides one or more alarm outputs 303 to indicate that the physiological parameter may have exceeded particular limits. The alarm processor 300 also has multiple parameter processors 310, which do not necessarily have the same or similar internal configurations. The multiple parameter processors 310 input the sensor signal 301 and provide parallel measurements 312 of the physiological parameter, each measurement having differing characteristics, such as response time or bandwidth to name a few. The alarm processor 300 further has an alarm indicator 320 that inputs the parallel parameter measurements 312 and generates the alarm outputs 303 based upon alarm conditions 305. The alarm outputs 303 change state to indicate that the parameter may have exceed one or more limits and to trigger an alarm accordingly. The alarm conditions 305 define particular limits with respect to one or more of the measurements 312. The alarm conditions 305 may be predefined, such as by user input, or determined by a separate process, such as a measurement of sensor signal quality or data confidence as described in U.S. patent application Ser. No. 09/858,114 entitled "Pulse Oximetry Data Confidence Indicator," assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein. The alarm processor 300 may also have a display driver 330 that processes one or more of the parameter measurements 312 and provides one or more display outputs 307.

FIG. 4 illustrates a pulse oximeter embodiment 400 of the alarm processor 300 (FIG. 3) described above. A pulse oximeter sensor (not shown) provides a signal input 301 that is responsive to arterial oxygen saturation, as described with respect to FIG. 1, above. The alarm processor 400 has dual oxygen saturation processors 310. An integrator oxygen saturation (SpO.sub.2) processor 410 outputs a slow SpO.sub.2 measurement 412, i.e. a measurement having a slow response time to changes in the SpO.sub.2 parameter. A predictor SpO.sub.2 processor 420 outputs a fast SPO.sub.2 measurement 422, i.e. a measurement having a fast response time that tracks changes in the SpO.sub.2 parameter. The slow SpO.sub.2 measurement 412 is input to a display driver 330, which provides an oxygen saturation display output 307. For example, the display output 307 may be input to a

digital display that provides a numerical readout of oxygen saturation to a caregiver. Both the slow SpO.sub.2 measurement 412 and the fast SpO.sub.2 measurement 422 are input to an alarm indicator 320 that generates at least one alarm output 303 based upon alarm conditions 305, as described in further detail with respect to FIGS. 5-8, below.

The integrator SpO.sub.2 processor 410, advantageously, provides a smoothed measurement of oxygen saturation suitable for threshold detection. The predictor SPO.sub.2 processor 420, advantageously, provides a curve-fitting or a predictive measurement of oxygen saturation that detects trends in oxygen saturation, as described in further detail with respect to FIG. 5 and FIGS. 6A-B, below. Further, the predictor SpO.sub.2 processor 420 advantageously tracks oxygen saturation details that may signal a critical physiological event, as described in further detail with respect to FIGS. 7-8, below. The integrator SpO.sub.2 processor 410 and predictor SpO.sub.2 processor 420 may be a pulse oximeter as described in U.S. patent application Ser. No. 09/586,845 entitled "Variable Mode Averager," assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein.

FIG. 5 illustrates a trend embodiment of an alarm indicator 320, which has a threshold detector 510, a slope detector 520 and alarm detector 530. The threshold detector 510 has a slow SpO.sub.2 measurement 412 and a threshold alarm condition 305 as inputs and a logic output BELOW 512. The slope detector 520 has a fast SpO.sub.2 measurement 422 input and a logic output POSITIVE/522. The alarm detector 530 has BELOW 512 and POSITIVE/522 logic inputs and generates an alarm output 303. The threshold detector 510 is a comparator that asserts BELOW 512 while the slow SpO.sub.2 measurement 412 is less in value than the value of the threshold 305. The slope detector 520 is a differentiator and comparator that asserts POSITIVE/522 while the slope of the fast SpO.sub.2 measurement 422 is non-positive, i.e. while the derivative of the fast SpO.sub.2 measurement 422 is zero or less than zero. The alarm detector 530 performs a logical AND function, asserts the alarm output 303 and indicates an alarm when BELOW 512 and POSITIVE/522 are both asserted. In this manner, an alarm output 303 only changes state when the slow SpO.sub.2 measurement 412 is below a threshold 305 and the fast SpO.sub.2 measurement 422 has not begun to increase in value. Advantageously, the trend recognition alarm indicator 320 reduces false alarms by suppressing a threshold-based alarm on the slow SpO.sub.2 measurement 412 when the fast SpO.sub.2 measurement 422 determines that a patient's oxygen saturation is in recovery, as described in further detail with respect to FIGS. 6A-B, below.

FIGS. 6A-B illustrate operation of the trend recognition alarm indicator 320 (FIG. 5). In FIG. 6A, a graph 600 has an SpO.sub.2 axis 601 and a time axis 602. Shown along the SPO.sub.2 axis 601 is a constant SPO.sub.2 value 606 corresponding to a threshold 305 (FIG. 5). The graph 600 shows a first plot of SPO.sub.2 versus time 610 corresponding to a fast SPO.sub.2 measurement 422 (FIG. 5). The graph 600 also shows a second plot of SpO.sub.2 versus time 620 corresponding to a slow SpO.sub.2 measurement 412 (FIG. 5). A suppressed alarm interval 640 along the time axis 602 corresponds to an alarm that would be indicated by the threshold detector 510 (FIG. 5) but is suppressed as occurring during a positive slope portion 630 of a fast SPO.sub.2 measurement 610. The alarm detector 530 (FIG. 5) would not assert an alarm output 303 (FIG. 5) during this interval.

In FIG. 6B, a graph 650 shows a first plot of SpO.sub.2 versus time 660 corresponding to a fast SpO.sub.2 measure-

ment 422 (FIG. 5). The graph 650 also shows a second plot of SpO.sub.2 versus time 670 corresponding to a slow SpO.sub.2 measurement 412 (FIG. 5). An alarm interval 690 along the time axis 602 corresponds to an alarm period triggered by the alarm output 303 (FIG. 5). This alarm interval 640 occurs while a slow SpO.sub.2 measurement 670 is below the threshold 606 and before a positive slope portion 680 of a fast SpO.sub.2 measurement 660.

FIG. 7 illustrates a pattern recognition embodiment of an alarm indicator 320, having a threshold detector 710, a pattern extractor 720, a pattern memory 730 and a pattern comparator 740. Further, the alarm indicator 320 has slow SpO.sub.2 412 and fast SpO.sub.2 422 measurement inputs in addition to threshold 701 and reference pattern 732 alarm condition inputs 305. The threshold detector 710 has a slow SPO.sub.2 measurement 412 and a SpO.sub.2 threshold 701 as inputs and a first alarm output 712. The threshold detector 710 changes the state of the first alarm output 712 when the value of the slow SpO.sub.2 measurement 412 crosses the SpO.sub.2 threshold 701. For example, the first alarm output 712 changes state to trigger an alarm when the slow SpO.sub.2 measurement 412 becomes less than the SpO.sub.2 threshold 701.

As shown in FIG. 7, the pattern extractor 720 has a fast SpO.sub.2 measurement 422 and a pattern threshold 734 as inputs and an extracted pattern output 722. The pattern extractor 720 identifies features of the fast SpO.sub.2 measurement 422 that may be used for pattern matching. Features may be, for example, the number of times the fast SpO.sub.2 measurement 422 crosses the pattern threshold 734 within a certain time period, or the duration of each time period that the fast SpO.sub.2 measurement 422 is less than the pattern threshold 734, to name a few. The pattern memory 730 has a pattern selection input 705 and a reference pattern output 732. The pattern memory 730 stores values for particular features that are identified by the pattern extractor 720. The reference pattern output 732 transfers these stored values to the pattern comparator 740. The pattern memory 730 may be nonvolatile and one or more patterns may be stored at the time of manufacture or downloaded subsequently via a data input (not shown). One of multiple patterns may be determined via the pattern selection input 705, by a user or by a separate process, for example. The pattern threshold 734 may be generated in response to the pattern selection input 705 or in conjunction with a selected reference pattern 732.

Also shown in FIG. 7, the pattern comparator 740 has the extracted pattern 722 and the reference pattern 732 as inputs and generates a second alarm output 742. That is, the pattern comparator 740 matches extracted measurement features provided by the pattern extractor 720 with selected features retrieved from pattern memory 730, changing the state of the second alarm output 742 accordingly. For example, the second alarm output 742 changes state to trigger an alarm when features of the fast SpO.sub.2 measurement 422 match the reference pattern output 732. Advantageously, the pattern recognition alarm indicator 320 reduces missed events by supplementing the threshold-based first alarm output 712 responsive to the slow SpO.sub.2 measurement 412 with a pattern-based second alarm output 742 responsive to detail in the fast SpO.sub.2 measurement 422. In this manner, if a patient's oxygen saturation is, for example, irregular or intermittent, the second alarm output 742 may trigger a caregiver alert when the first alarm output 712 does not, as described in further detail with respect to FIG. 8, below.

FIG. 8 illustrates operation of a pattern recognition alarm indicator 320 (FIG. 7), as described above. A graph 800 has

a SpO.sub.2 axis 801 and a time axis 802. The graph 800 shows a SpO.sub.2 plot versus time 810 corresponding to the slow SPO.sub.2 measurement 412 (FIG. 7). Shown along the time axis 802 is a constant SPO.sub.2 value 812 corresponding to the SPO.sub.2 threshold 701 (FIG. 7). Due to the short duration of irregular and intermittent drops in SpO.sub.2, the slow SpO.sub.2 measurement 810 does not fall below the SpO.sub.2 threshold 812. Thus, the first alarm output 712 (FIG. 7) does not trigger an alarm in this example.

Also shown in FIG. 8, the graph 800 shows a SpO.sub.2 plot versus time 820 corresponding to the fast SpO.sub.2 measurement 422 (FIG. 7). Shown along the time axis 802 is a constant SPO.sub.2 value 822 corresponding to the pattern threshold 734 (FIG. 7). A corresponding graph 805 has a logic level axis 806 and a time axis 807. The graph 805 shows a logic level plot versus time 830 corresponding to the extracted pattern output 722 (FIG. 7). The logic level plot 830 has a "1" level when the fast SpO.sub.2 plot 820 is above the pattern threshold 822 and a "0" level when the fast SpO.sub.2 plot 820 is below the pattern threshold 822. In this manner, the logic level plot 830 indicates the number and duration of times the fast SpO.sub.2 plot 820 falls below a threshold value 822.

Further shown in FIG. 8, an alarm interval 870 along the time axis 802 corresponds to an alarm period indicated by the pattern comparator 740 (FIG. 7). This alarm interval 870 occurs after a reference pattern 732 (FIG. 7) is detected as matching an extracted pattern 722 (FIG. 7) and ends, correspondingly, when there is no longer a match. For example, assume that the reference pattern output 732 (FIG. 7) has the alarm criteria that at least three below threshold periods of minimum duration T.sub.1 must occur during a maximum period T.sub.2, where the value of T.sub.1 and T.sub.2 are illustrated along the time axis 807. The below threshold time periods 831-834 are each greater in duration than T.sub.2 and a first set of three, below-threshold time periods 831-833 occurs within a time period T.sub.1=T.sub.2, as illustrated. Thus, the alarm interval beginning 872 is triggered by the second alarm output 742 (FIG. 7). A second set of three, below-threshold time periods 832-834 also occurs within a time period T.sub.2=T.sub.2, as illustrated. Thus, the alarm interval 870 continues. There is no third set of three, below-threshold time periods. Thus, after the end of the time interval T.sub.3=T.sub.2, the alarm interval end 874 is triggered. This example illustrates how the pattern recognition alarm indicator 320 (FIG. 7) can trigger an alarm on an event, such as a period of irregular heartbeats, that might be missed by a threshold-based alarm responsive to the slow SpO.sub.2 measurement 412.

Although some alarm processor embodiments were described above in terms of pulse oximetry and oxygen saturation measurements, one of ordinary skill in the art will recognize that an alarm processor as disclosed herein is also applicable to the measurement and monitoring of other blood constituents, for example blood glucose and total hemoglobin concentration to name a few, and other physiological parameters such as blood pressure, pulse rate, respiration rate, and EKG to name a few.

In an embodiment, multiple pattern processors, each including a pattern extractor, pattern memory and pattern comparator, such as described with respect to FIG. 7, above, have as inputs one or more of fast SpO.sub.2 measurements, a pulse oximeter plethysmograph and pulse rate measurements. An arrhythmia alarm is generated based upon irregular heartbeat patterns being matched or otherwise detected in

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one or more combinations of SpO.sub.2 measurements, a pulse oximeter plethysmograph and pulse rate measurements.

A physiological trend monitor 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.

What is claimed is:

1. A system for non-invasively monitoring physiological trends, the system comprising:

a processor *comprising a sensor signal input and a display driver, wherein the processor is configured to:* receive, *at the sensor signal input,* a sensor signal from an optical sensor coupled with a patient, the sensor signal responsive to light attenuated by body tissue of the patient;
calculate a physiological parameter and a physiological parameter trend based on the sensor signal;
output, *by the display driver,* a value of the physiological parameter for presentation on a display; and
output an audible alarm once the physiological parameter reaches a threshold if the physiological parameter trend is not trending upward.

2. The system of claim 1, wherein the processor is further configured to suppress the audible alarm once the smoothed physiological parameter rises above the threshold, even if the physiological parameter trend is flat or trending downward.

3. The system of claim 1, wherein the processor is further configured to suppress the audible alarm once the physiological parameter trend begins to trend upward, even if the physiological parameter is under the threshold.

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4. The system of claim 1, wherein the processor is further configured to calculate the physiological parameter by smoothing physiological parameter values.

5. The system of claim 1, wherein the processor is further configured to calculate the physiological parameter by integrating physiological parameter values.

6. The system of claim 1, wherein the processor is further configured to calculate the physiological parameter trend using a curve-fitting technique.

7. The system of claim 1, wherein the processor is further configured to output the audible alarm responsive to the physiological parameter trend being negative.

8. The system of claim 1, wherein the processor is further configured to output the audible alarm responsive to the physiological parameter trend being zero.

9. The system of claim 1, wherein the physiological parameter is selected from the group consisting of oxygen saturation, blood glucose, total hemoglobin concentration, blood pressure, pulse rate, and respiration rate.

10. *A system for non-invasively monitoring physiological trends, the system comprising:*

a processor comprising a sensor signal input and a display driver, wherein the processor is configured to: receive, *at the sensor signal input,* a sensor signal from an optical sensor coupled with a patient, the sensor signal responsive to light attenuated by body tissue of the patient;
calculate a physiological parameter based on the sensor signal;
output, by the display driver, a value of the physiological parameter for presentation on a display; and
output an audible alarm once the physiological parameter reaches a threshold if a physiological parameter trend of physiological parameter values is not trending upward.

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