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Baker, JR.

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(54) **SYSTEM AND METHOD FOR DETECTION OF UNSTABLE OXYGEN SATURATION**

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(75) Inventor: **Clark R. Baker JR.**, Castro Valley, CA (US)

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Correspondence Address:
Nellcor Puritan Bennett LLC
c/o Fletcher Yoder PC
P.O. BOX 692289
HOUSTON, TX 77269-2289 (US)

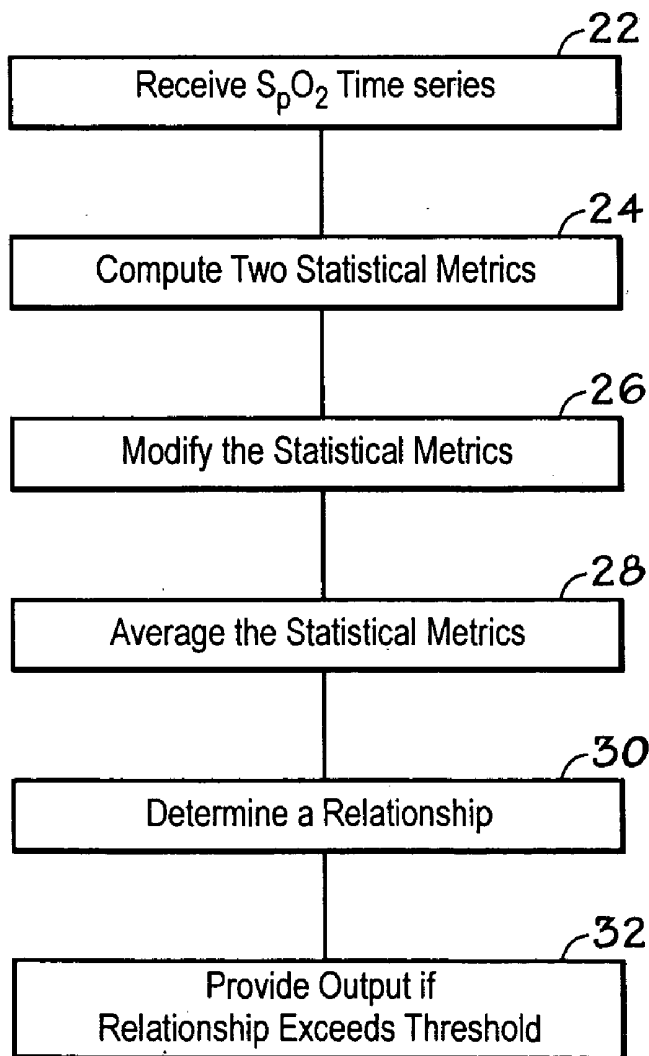
(57) **ABSTRACT**

(73) Assignee: **Nellcor Puritan Bennett Incorporated**, Pleasanton, CA

Methods and systems are described for simplified detection of unstable oxygen saturation of a patient by analysis of statistical variations in blood oxygen. One method for automatic detection of unstable oxygen saturation of a patient using a pulse oximeter comprises receiving at least a single time series input of oxygen saturation values and computing at least two metrics based on statistical properties of the single time series input of the oxygen saturation values.

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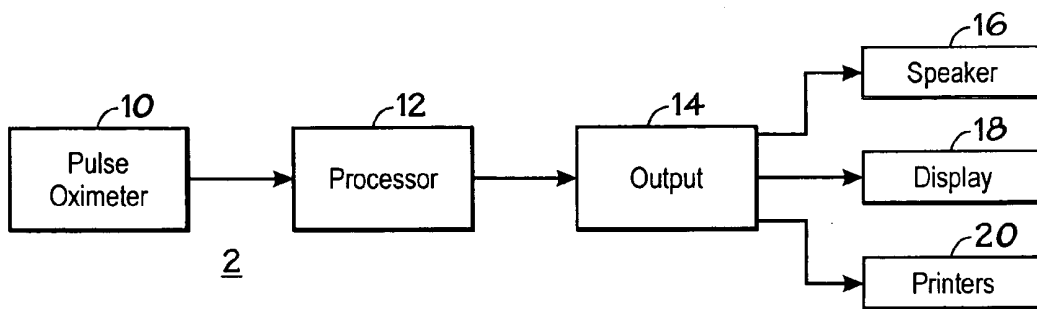


FIG. 1A

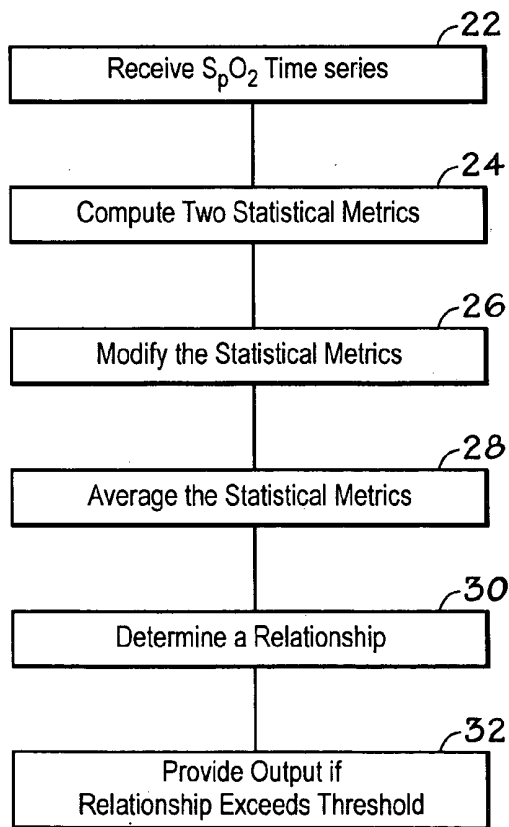


FIG. 1B

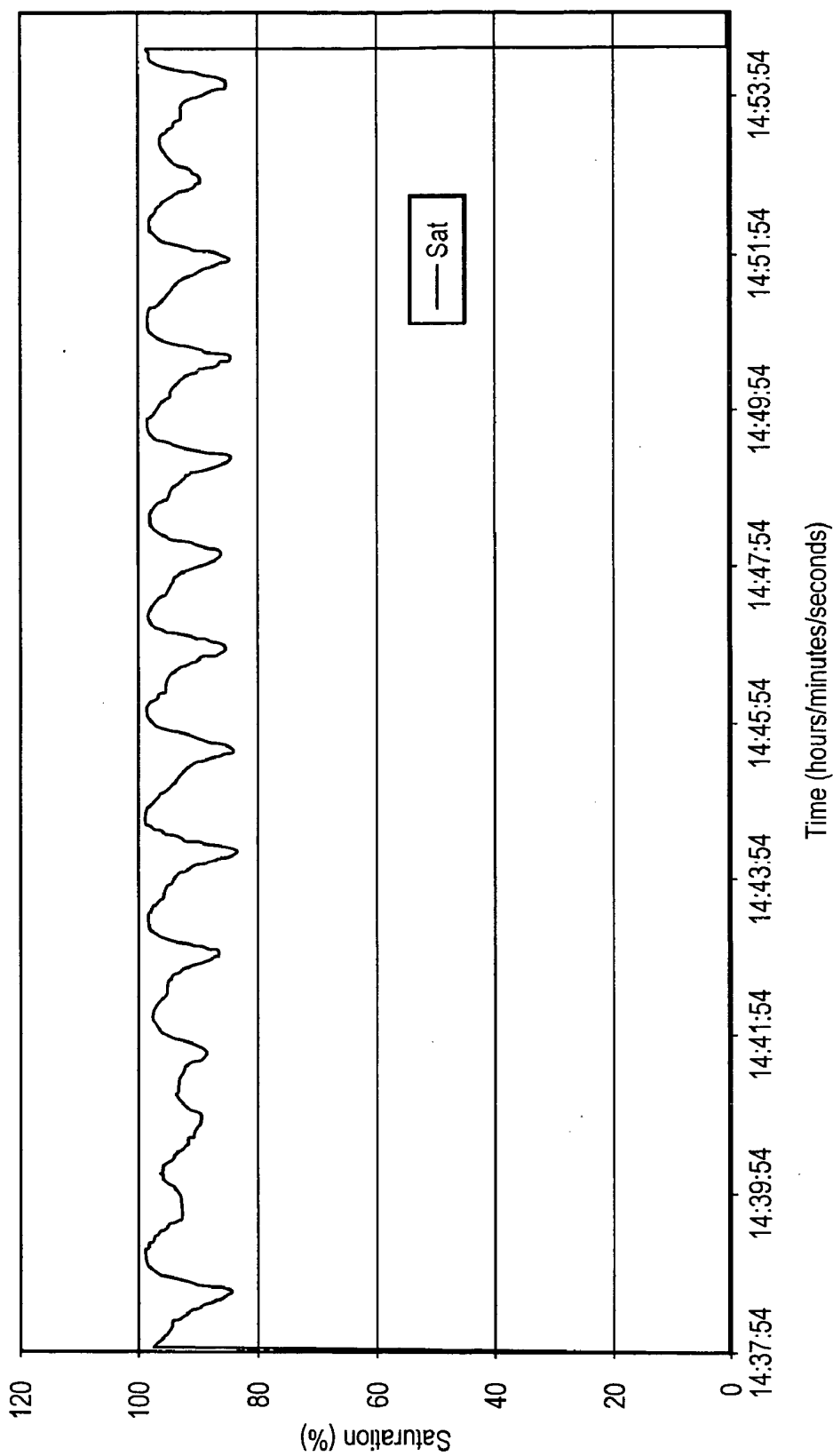


FIG. 2

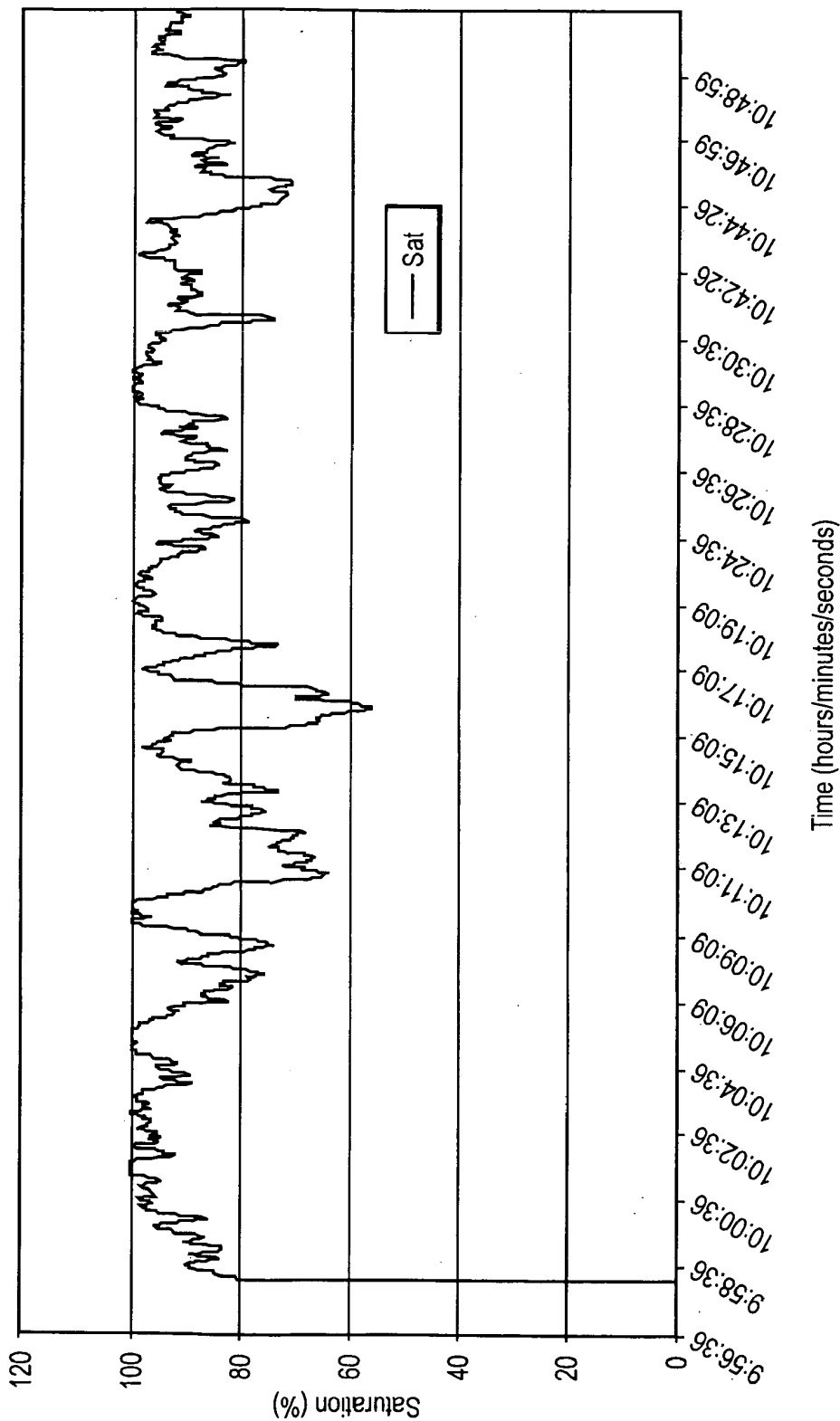


FIG. 3

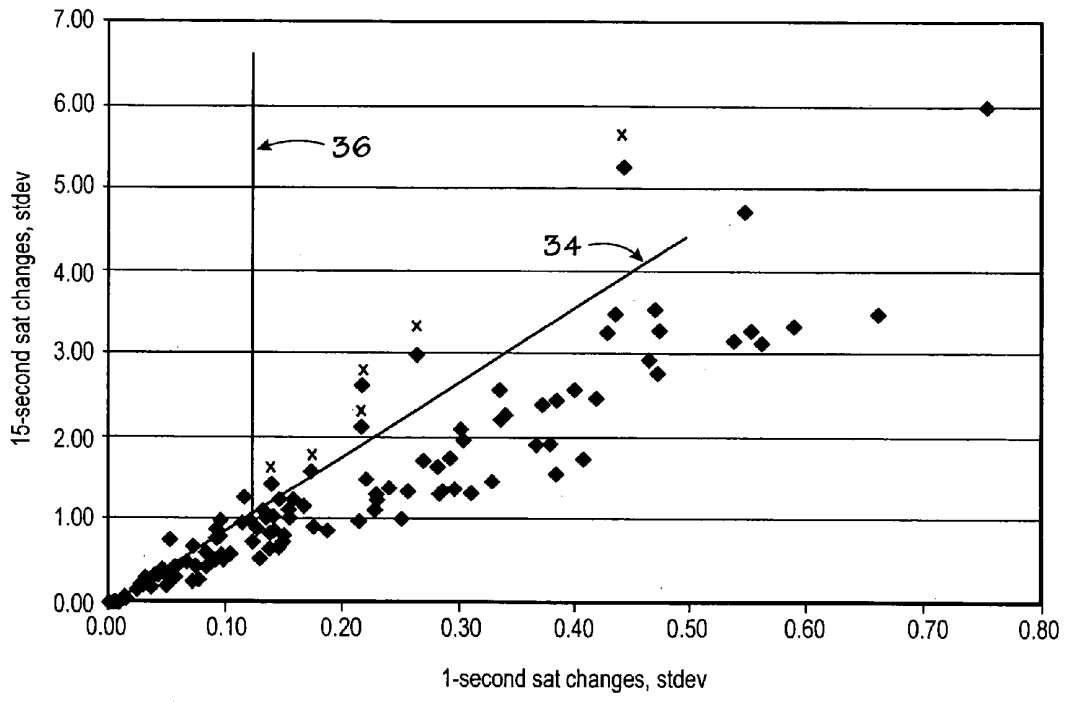


FIG. 4

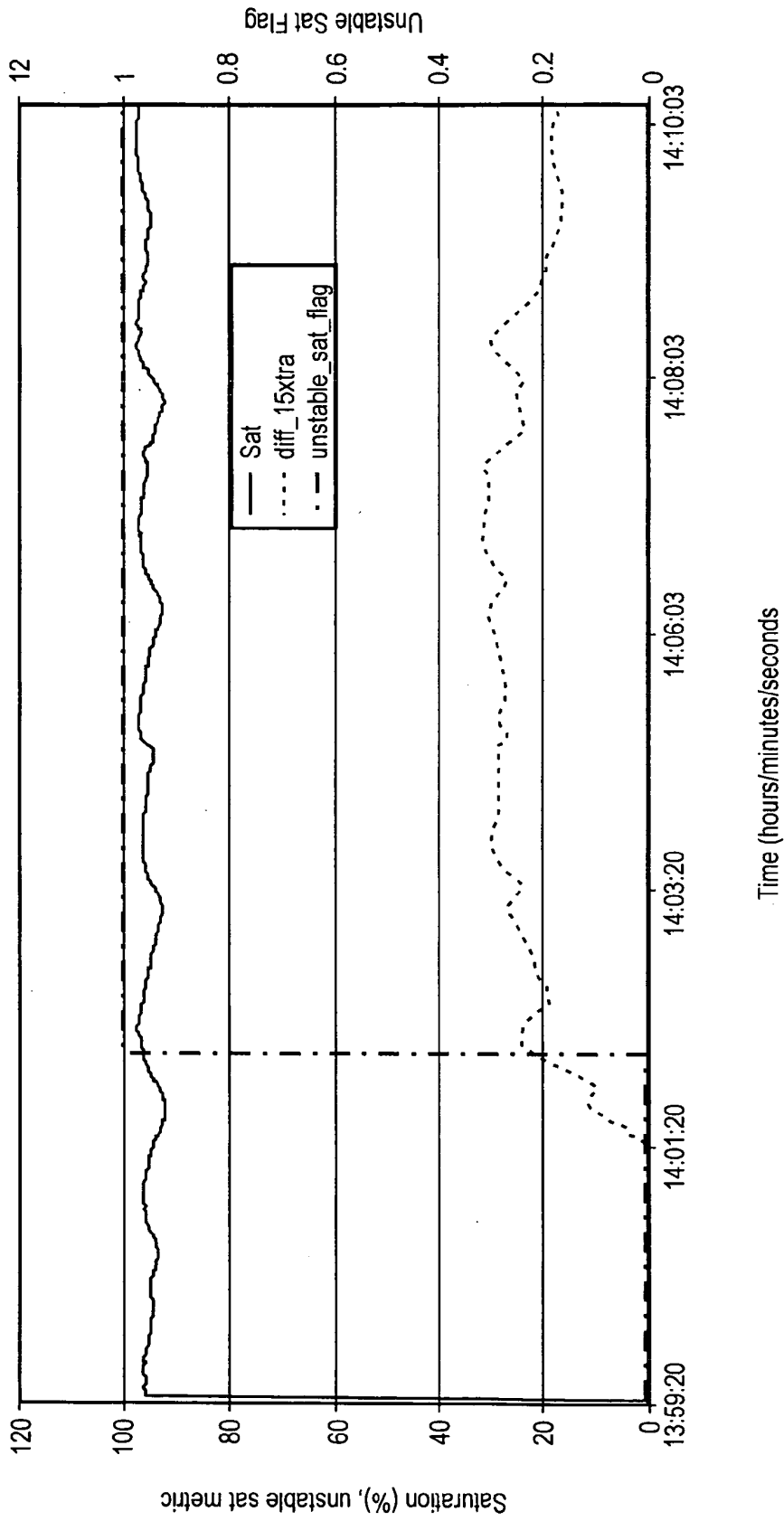
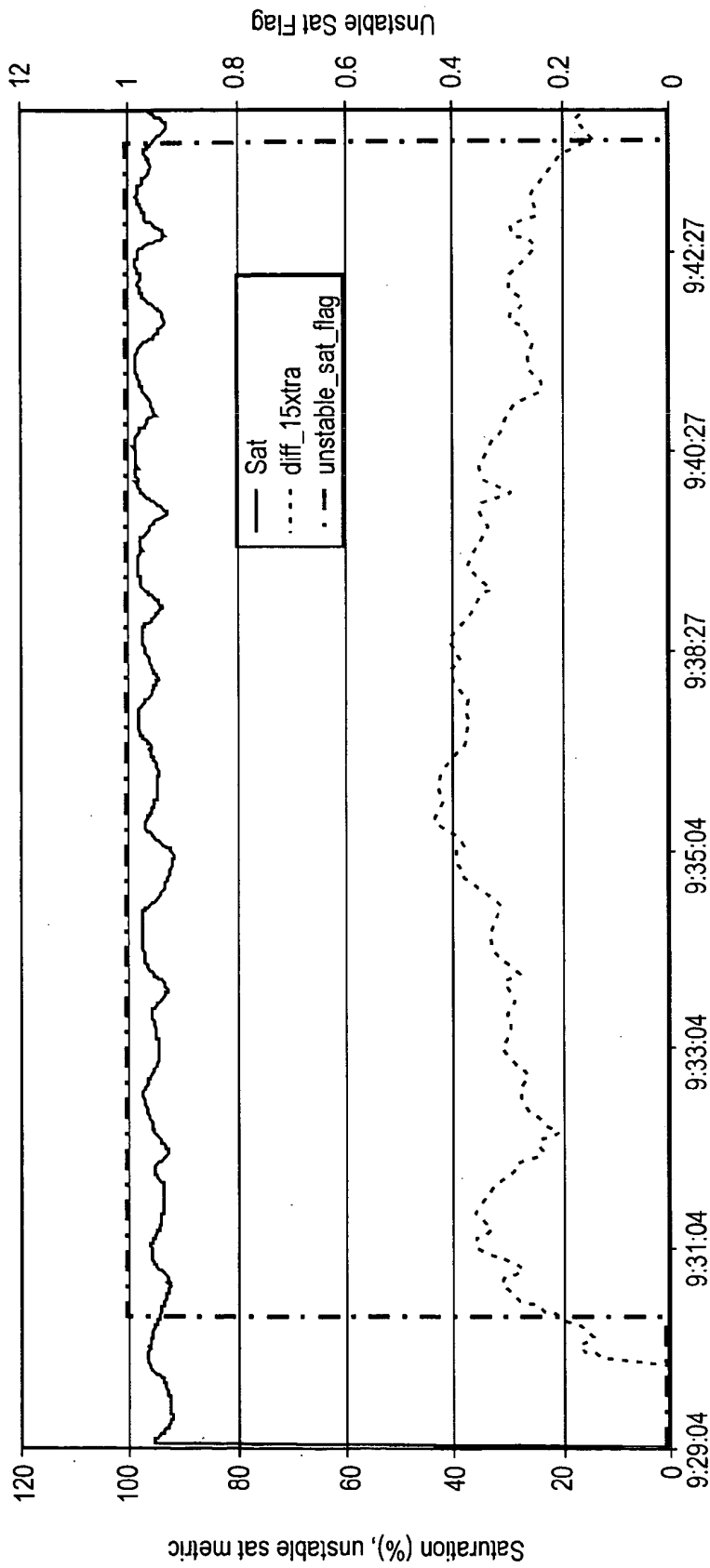


FIG. 5



Time (hours/minutes/seconds)

FIG. 6

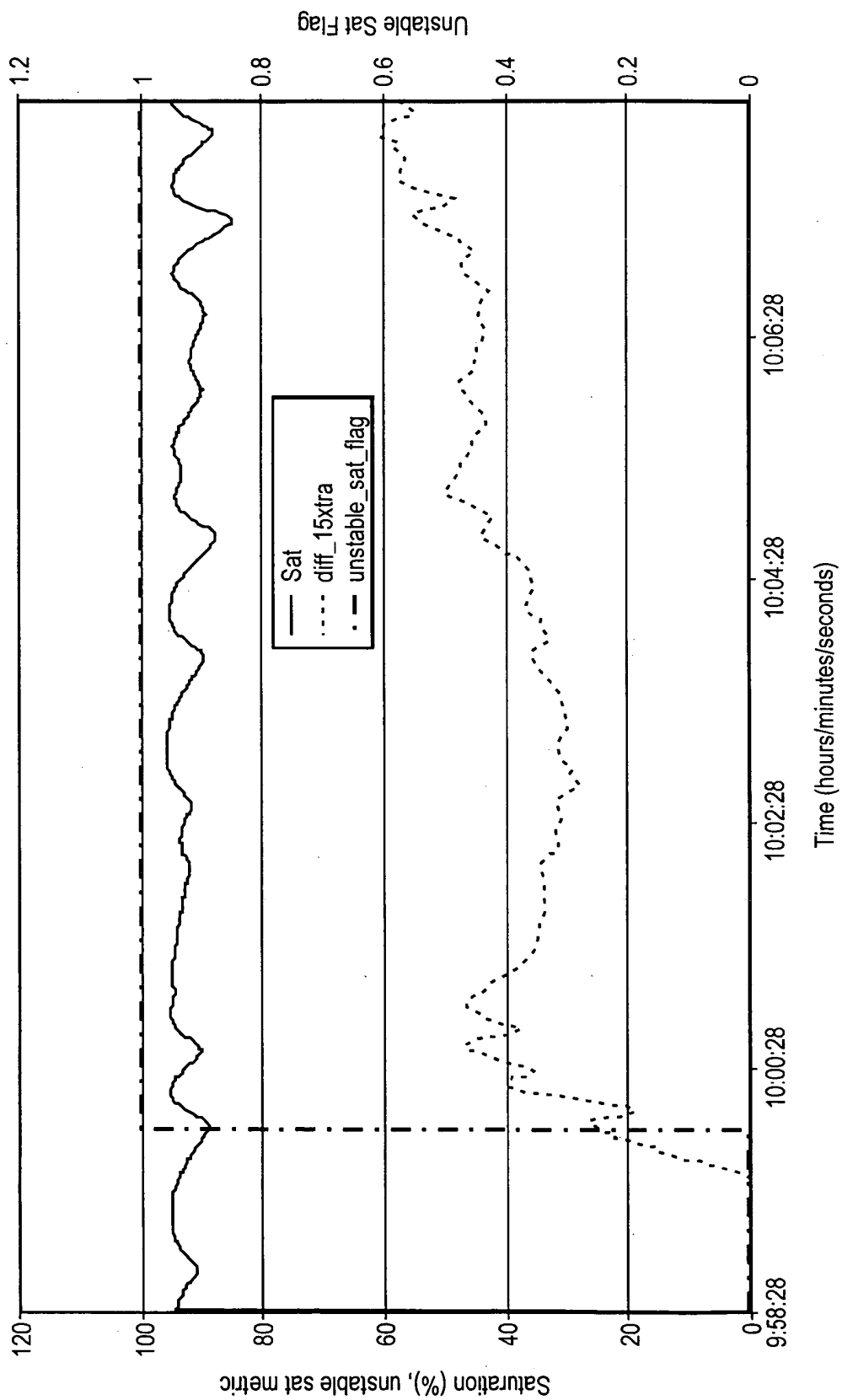


FIG. 7

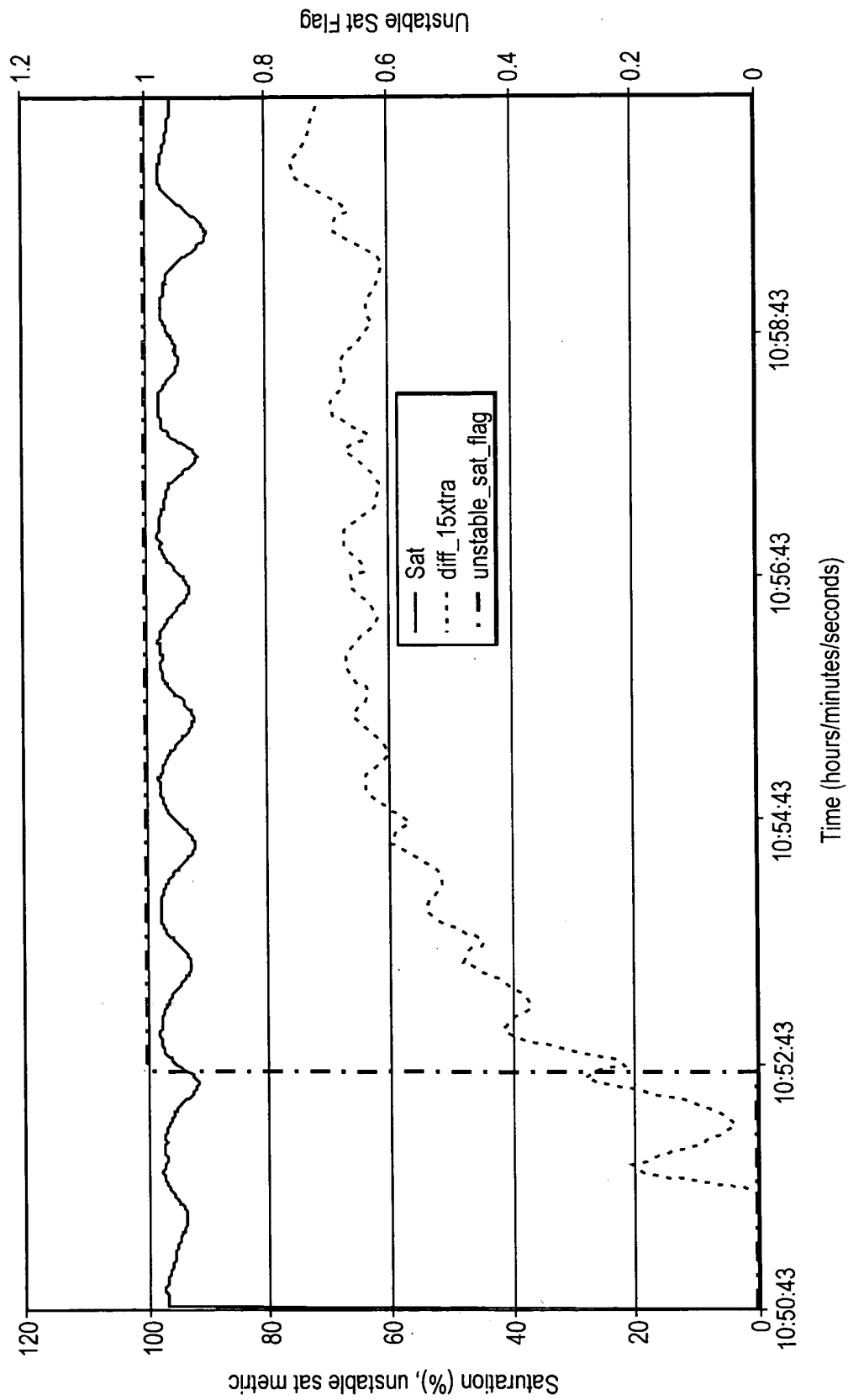


FIG. 8

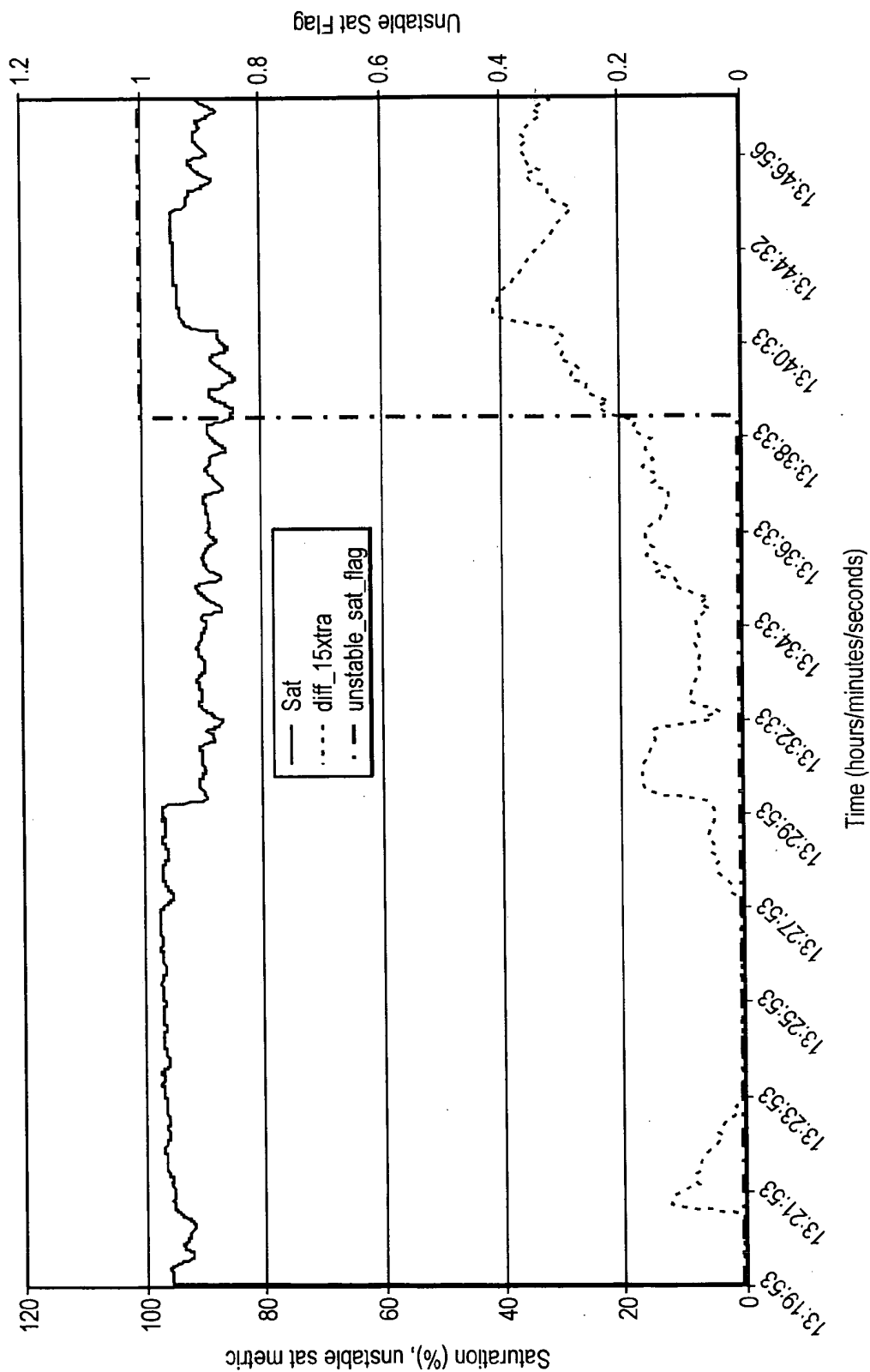
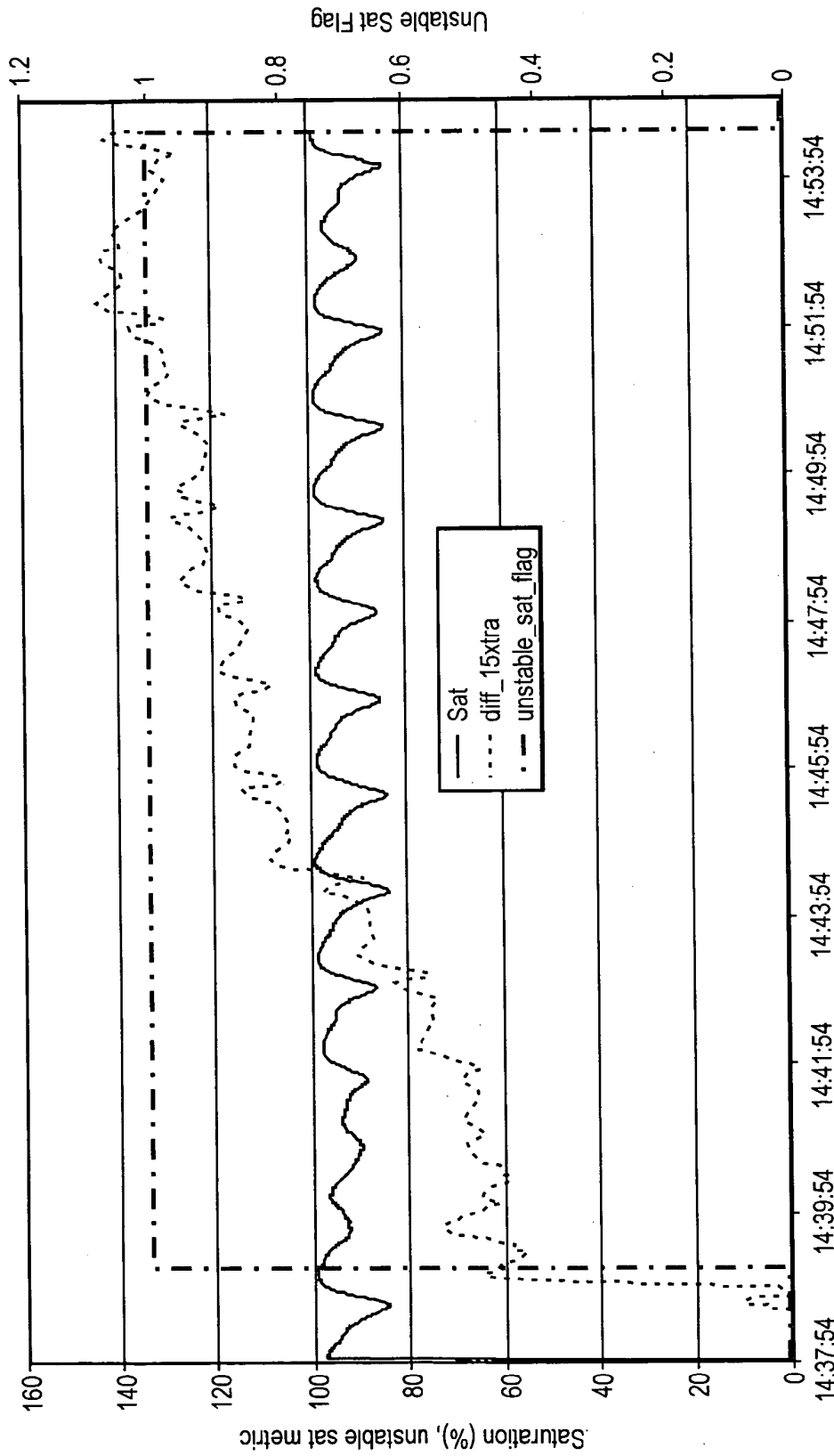


FIG. 9



Time (hours/minutes/seconds) **FIG. 10**

SYSTEM AND METHOD FOR DETECTION OF UNSTABLE OXYGEN SATURATION

BACKGROUND OF THE INVENTION

[0001] The present invention generally relates to medical methods and systems, particularly for the detection of unstable oxygen saturation of a patient.

[0002] Obstructive sleep apnea is recognized as one of the most common disorders in the United States. The lower oxygen levels associated with obstructive sleep apnea play a major role in cardiovascular morbidity including cardiac arrest and stroke. Obstructive sleep apnea causes characteristic patterns of gradual oxygen de-saturation, followed by rapid re-saturation when a sleeping patient's body manages to briefly increase muscle tone in the upper airway to sufficiently resume respiration. This pattern tends to repeat cyclically at roughly similar periods and saturation amplitudes. Millions of patients experience such characteristics of sleep apnea for years at a time without being diagnosed or treated as acute health consequences do not readily arise. Despite the fact that obstructive sleep apnea is easily treated, both the patient and the family are often completely unaware of the presence of this dangerous condition as anything more than heavy snoring.

[0003] Obstructive sleep apnea often develops as patients enter middle age and begin to snore. The major cause is an increase in fat deposition in the neck which results in narrowing of the airway. When the muscle tone of the upper airway diminishes during sleep, negative pressure associated with inspiration through this narrow airway results in collapse of the upper airway which effectively chokes off all air movement and a fall in oxygen. The fall in oxygen produces central nervous system stimulation contributing to hypertension, potential heart and blood vessel injury, and finally results in arousal of the patient. Upon arousal, increase in airway muscle tone opens the upper airway and the patient rapidly inhales and ventilates quickly to correct the low oxygen levels. Generally, the arousal is brief and the patient is not aware of the arousal.

[0004] Undiagnosed obstructive sleep apnea can lead to serious consequences, including progressive decline in heart muscle function, blood vessel damage, and even death by stroke or cardiac arrest.

[0005] Detection of such profound physiologic instability may be accomplished by conventional polysomnography. However, this approach is expensive and difficult to implement on a sufficient scale. Further diagnosis approaches for detecting obstructive sleep apnea with the use of oximetry systems are described by the following U.S. Pat. Nos. 5,398,682; 5,605,151; 5,891,023; 6,223,064; 6,342,039; 6,609,016; 6,748,252; 6,760,608 and U.S. Patent Publication Nos. 2002/0190863; 2003/0000522; 2003/0158466, the full disclosures of which are incorporated herein by reference. A number of these references are directed to analyzing waveshapes of various signals.

[0006] Alternative diagnostic methods and systems for identifying sleep apnea that do not require evaluation of a patient by polysomnography or the analysis of a succession of specific events could be advantageous.

BRIEF SUMMARY OF THE INVENTION

[0007] A method for automatic detection of unstable saturation of a patient using a pulse oximeter is provided. At

least a single time series input of oxygen saturation values (e.g., SpO₂) is received and at least two metrics are computed based on statistical properties of the single time series input of oxygen saturation values. In one embodiment, the statistical metrics are then averaged and a relationship determined between the statistical metrics. An output is provided if the relationship exceeds a threshold value, wherein the threshold value is indicative of cyclic saturation variations. In one embodiment, the ratio of the average saturation changes over fifteen second intervals to the average saturation changes over one second intervals is calculated. Small changes are disregarded, and remaining ones with a ratio above a threshold slope indicate possible sleep apnea or hypopnea. Generally, cyclic saturation variations may be detected with a period in the range from one minute to five minutes. Some cyclic saturation variations may be detected in periods as short as 35 to 50 seconds.

[0008] Methods and systems of the present invention provide for simplified detection of unstable oxygen saturation of a patient by analysis of statistical variations in blood oxygen. In particular, the present invention provides physiologic signal processing systems and oximetry software algorithms that allow for the detection of obstructive sleep apnea, ventilation instability, airway instability, breathing arrhythmia, hypopnea, and like conditions.

[0009] The output from the methods and systems of the present invention may comprise a report, record data, or alarm generation. Alarm management may also comprise various outputs, including an audio alarm, a visual alert, or a print-out so as to inform the patient, nurse, physician, etc. of the detected unstable saturation variations and this potentially risky physiologic condition. It will further be appreciated that the metrics of the statistical properties of the single SpO₂ time series may additionally be modified based on one or more signal quality metrics internal to an oximetry algorithm so that the simplified detection methods of the present invention are not easily fooled by non-physiologic artifacts. For example, challenging conditions such as patient motion, low perfusion, or interference from other electronic devices may be screened out so as not to trigger a false alarm.

[0010] The statistical metrics may comprise a magnitude of oxygen saturation changes over half second to thirty second intervals. A first metric comprises a magnitude of saturation changes over one second intervals or five second intervals. A second metric comprises a magnitude of saturation changes over ten second intervals or fifteen second intervals. Still further the statistical metrics may comprise a skewness of the single time series input of oxygen saturation values and a kurtosis of the single time series input of oxygen saturation values. The skewness of a distribution is a measure of its asymmetry in relation to a normal distribution. The kurtosis of a distribution is a measure of the shape of the distribution around the mean. The statistical metrics may be associated with ventilation or airway instability, particularly obstructive sleep apnea. It will be appreciated that the receiving, computing, modifying, averaging, determining, and providing steps of the oximetry software algorithm are carried out by a processor.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The following drawings should be read with reference to the detailed description. Like numbers in different

drawings refer to like elements. The drawings, which are not necessarily to scale, illustratively depict embodiments of the present invention and are not intended to limit the scope of the invention.

[0012] FIG. 1A is a simplified block diagram illustrating a patient monitoring apparatus in accordance with the principles of the present invention.

[0013] FIG. 1B is a simplified flow chart illustrating a method for automatically detecting unstable oxygen saturation of a patient in accordance with the principles of the present invention.

[0014] FIG. 2 graphically illustrates cyclic saturation variations characteristic of obstructive sleep apnea.

[0015] FIG. 3 graphically illustrates saturation variations due to artificial artifacts such as motion, low perfusion, or other interference.

[0016] FIG. 4 is a graph showing a relationship between two metrics computed from statistical properties of SpO₂ time series in accordance with an exemplary embodiment of the present invention; and

[0017] FIGS. 5 through 10 are graphical representations showing exemplary data output in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF THE

[0018] Exemplary embodiments of the present invention may provide patient monitoring systems and methods for automatic detection of unstable oxygen saturation of a patient using a pulse oximeter so as to diagnose obstructive sleep apnea. Exemplary embodiments of the present invention may be adapted to use single time series inputs of oxygen saturation values from non-invasive pulse oximeters (e.g., SpO₂) or data taken from invasive measurements such as measurements of arterial oxygenation saturation values (e.g., SaO₂). Moreover, data obtained by either technique allows analysis of statistical variations in blood oxygenation so as to detect unstable oxygen saturation. Pulse oximeters that may be used with exemplary systems and methods of the present invention include pulse oximeters commercially available from Nellcor Puritan Bennett Incorporated of Pleasanton, Calif., the assignee of the present application.

[0019] Referring now to FIG. 1A, a simplified block diagram illustrates a patient monitoring system 2. FIG. 1B illustrates a method for automatically detecting unstable oxygen saturation of a patient in accordance with the principles of the present invention. The system 2 includes an input device, namely a pulse oximeter 10, a processor 12 electronically coupled to the pulse oximeter 10, and output buffer 14 electronically coupled to the processor. The output buffer 14 is adapted to deliver data to at least one of a plurality of output 12. devices, such as a speaker 16, a display screen 18, or a printer 20.

[0020] The oximetry software algorithm for automatic detection of unstable saturation of a patient using a pulse oximeter is carried out by the processor 12. As shown at block 22 (FIG. 1B), at least a single time series input of oxygen saturation values is received. Examples of sources of the oxygen saturation values include the pulse oximeter 10 (FIG. 1A), as during a real-time monitoring of a patient, or from a data file created at an earlier time. As shown by block

24 (FIG. 1B), at least two metrics are computed based on statistical properties of the single time series input of oxygen saturation values. The statistical metrics are modified based on one or more signal quality metrics as indicated by block 26, averaged as indicated by block 28, and a relationship determined between the statistical metrics as indicated by block 30. For example, the relationship may be the ratio of one of the statistical metrics to another of the statistical metrics. The relationship may be defined to correspond to a known condition, such as a disordered breathing condition like obstructive sleep apnea. An output is provided if a numerical representation of the relationship exceeds a threshold value as indicated by block 32. The threshold value may be an arbitrarily chosen value indicative of a predetermined level of cyclic saturation variations. Exemplary embodiments of the present invention do not require detection of one or more specific SpO₂ events, measurement of the amplitude or period of such events, or the use of any additional physiologic monitors or parameters.

[0021] Generally, cyclic saturation variations may be detected with a period in the range from one minute to five minutes. Some cyclic saturation variations may be detected in periods as short as 35 to 50 seconds or even shorter, depending on lung capacity of the patient, for example, or other factors. Alarm management may comprise various outputs, including sounding an audio alarm through the speaker 16, displaying a visual alert on the display screen 18, or providing a print-out from the printer 20 so as to inform the patient, nurse, physician or the like of the detected unstable saturation variations.

[0022] Examples of statistical metrics that may be employed in conjunction with exemplary embodiments of the present invention include a magnitude of saturation changes over one second intervals, a magnitude of saturation changes over five second intervals, a magnitude of saturation changes over ten second intervals, or a magnitude of saturation changes over fifteen second intervals. Generally, combinations of the statistical metrics may be chosen to take into account both magnitude and frequency range of variations in a physiologic parameter of interest (i.e., oxygen saturation) to evaluate the overall repetitiveness of changes. For example, the obstructive sleep apnea may be effectively identified by taking into account the combination of a relatively short change (e.g., one second) and a relatively longer change (e.g., five, ten, or fifteen seconds). It will be appreciated however that several other statistical metrics may also be used with the to identify cyclic saturation variations characteristic of airway instability, particularly obstructive sleep apnea. Examples of other statistical metrics include processing the frequency content of the single time series input of oxygen saturation values using a Fast Fourier Transform, autocorrelation of the saturation values, or derivatives. Because re-saturation is characteristically much faster than de-saturation, the derivative of the reported saturation should have a positive skewness when measured over a period of several minutes. To the extent that these cyclic saturation variations exhibit a relatively repetitive magnitude, both the saturations and their derivatives should have a more negative kurtosis than for non-cyclic saturation variations.

[0023] The processor 12 (FIG. 1A) may include or be coupled to a memory device that contains exemplary code for an oximetry software algorithm, exemplary code for

audio alarms, exemplary code for visual alerts, or the like. The processor 12 and output devices (e.g., speaker 16, display 18, printer 20) may be disposed in a common housing with the pulse oximeter 10 to form a single integrated system. Alternatively, pulse oximeter 10, the processor 12, the output buffer 14 and various output devices 16, 18, 20 may all comprise separate independent components operatively coupled to one another. An alternative embodiment may include a subset of the pulse oximeter 10, the processor 12, the output buffer 14 and one or more of the output devices 16, 18, 20 disposed in a single housing with one or more of the remaining devices disposed externally thereto.

[0024] FIG. 2 is representative of unstable oxygen saturation behavior where the saturation changes smoothly within a period of approximately more than a minute. It will be appreciated that challenging oximetry conditions were also identified in all age groups from newborn infants to adults. Examples of such artificial artifacts include motion, low perfusion, arrhythmia, dicrotic notches, interference from other electronic devices and the like. FIG. 3 is representative of saturation variations that are primarily due to motion artifacts where the SpO₂ variations are quite irregular and often shorter in duration.

[0025] FIG. 4 is a graph that shows a plot of a plurality of datasets that have been analyzed in accordance with an exemplary embodiment of the present invention. To create the plot shown in FIG. 4, an empirical analysis was performed by post-processing a set of sample oximetry data. The sample data, which comprised empirically obtained oximetry data obtained from 113 patients over a wide range of conditions, was post-processed using an oximetry algorithm known as OSCI, which was implemented in a model N595 pulse oximeter. Each post-processed saturation output was manually examined by a skilled individual to identify datasets of patients whose oxygen saturation data exhibited cyclic de-saturations. In particular, six patients whose datasets were included in the sample database were identified as indicative of cyclic de-saturations characteristic of obstructive sleep apnea.

[0026] Referring now to FIG. 4, a relationship between two metrics computed from statistical properties of time series input of oxygenation saturation values for all 113 patients represented in the sample database is plotted. In particular, statistical metrics of saturation variations that relate both to overall magnitude and frequency were utilized. On the x-axis, the magnitude of saturation changes over one second intervals is plotted. On the y-axis, the magnitude of saturation changes over fifteen second intervals is plotted. For these metrics, magnitude may be represented by a number of methods, including either the absolute difference between two saturation values (e.g., $|S_1 - S_2|$) or the by the square root of the square of the differences (e.g., $\sqrt{(S_1 - S_2)^2}$). These two metrics and a standard deviation (i.e., the root mean square of the differences) were calculated, averaged, and plotted for each of the separate one hundred thirteen cases, as illustrated in FIG. 4.

[0027] Significantly, as shown in FIG. 4, the results of this investigation indicate that the six datasets that were determined by empirical manual analysis to represent a cyclic pattern of unstable oxygen saturation are clearly identifiable in FIG. 4. Each of these six datasets is identified by an 'x'

in FIG. 4. Moreover, all six 'x' datasets are above a diagonal threshold line 34 in FIG. 4. The diagonal threshold 34 is an arbitrary line that is intended to correspond to a predetermined level of cyclic physiologic activity represented by a dataset under consideration. As steeper slopes are chosen for the diagonal threshold 34, fewer datasets are identified as exceeding the threshold (i.e. being above the threshold). As shallower slopes are chosen for the diagonal threshold, more datasets are identified as exceeding the threshold. For the selected set of time intervals illustrated in FIG. 4, the slope of the diagonal threshold line 34 was empirically determined to be about 9. As seen in FIG. 4, this choice of threshold values results in identification of the datasets empirically determined to represent cyclically unstable oxygen saturation. This threshold could be employed with new databases of datasets that have not been empirically evaluated, with the result that datasets having the same level of cyclic physiologic activity would be identified without the need of empirical analysis of the new data.

[0028] If the y-axis plotted magnitude of saturation changes over five or ten second intervals, the slope of the diagonal threshold line 34 will be about 4.5 to 9. Hence, a slope of the diagonal threshold line 34 will be in a range from about 60% (e.g., 9/15) to about 90% (e.g., 4.5/5) of the ratio of time intervals used for quantifying saturation changes. The diagonal threshold line indicates a preponderance of longer-term saturation variation indicative of physiologic instability.

[0029] An arbitrary vertical threshold 36 may also be employed to avoid identifying datasets that exceed the threshold line 34, but that nonetheless comprise statistical variations that are sufficiently small as to be categorized as minimal and not of interest. In FIG. 4, the vertical threshold 36 was selected so that the six datasets empirically determined to correspond to cyclic unstable variations in oxygen saturation are to the right of the vertical threshold 36 and above the threshold line 34. Thus, the results illustrated in FIG. 4 indicate a clear metric separation of the six cases empirically determined to correspond to cyclic variations indicative of obstructive sleep apnea from the other 107 datasets. This illustrates the effectiveness of the statistical metric analysis of FIG. 1B to adequately detect unstable oxygen saturation. FIG. 4 thus represents the construction of a framework of threshold values that may be employed to evaluate other datasets to identify datasets indicative of a cyclic pattern of unstable oxygen saturation. Such cyclic patterns of unstable oxygen saturation may correspond to sleep disordered breathing such as obstructive sleep apnea.

[0030] FIGS. 5-10 are graphical representations of exemplary patient data indicative of cyclically unstable oxygen saturation. One hundred thirteen sets of patient data were manually evaluated for the presence of an indication of a cyclic desaturation pattern. Of those 113 datasets, six were determined to comprise cyclic variations. Each of the graphs shown in FIGS. 5-10 each correspond to one of those six datasets. The same six datasets were subsequently identified by a computer program comprising an exemplary embodiment of the present invention. Hence, these results show the effectiveness of the statistical metric analysis set forth in FIG. 1B to effectively predict unstable oxygen saturation.

[0031] In an exemplary embodiment of the present invention, the data is identified as indicative of an instability

during all periods in which a predetermined threshold value is exceeded. This indication may comprise setting a variable to a value indicative of instability when data exceeding the threshold value is being evaluated. The variable may be set to a value indicative of no instability at other times.

[0032] As set forth above, FIGS. 5-10 each correspond to a dataset representative of cyclic saturation variations. In particular, a saturation trace from a pulse oximeter and the value of a variable (unstable_sat_flag) indicative the presence of an unstable saturation condition are shown in each of FIGS. 5-10. FIG. 5 shows cyclic variations of approximately 4% that are identified after about two and a half minutes, at which time the value of the variable unstable_sat_flag transitions from a value of zero to a value of one. FIG. 6 shows cyclic variations of approximately 5% that are identified in about one and a half minutes. FIG. 7 shows cyclic variations of approximately 2% to 6% that are identified in about one and a half minutes. FIG. 8 shows cyclic variations of approximately 6% that are identified in about two minutes. In FIG. 9, variations occur in the middle third of the dataset. These variations are believed to be attributable to a change in the oximeter sensor or sensor site. Although cyclic saturation variations are not as regular as in the other cases, cyclic variations of approximately 4% to 5% are identified after about five minutes. The dataset represented in FIG. 10 shows cyclic variations of approximately 15% that are identified in about one minute.

[0033] In simulations with synthetic data, an exemplary embodiment of the present invention detected cyclic saturation variations of approximately 2% to 3% with a period in the range from one minute to five minutes. Cyclic variations of approximately 10% were detected in periods as short as 35 to 50 seconds. An exemplary embodiment of the present invention may be adapted to detect shorter saturation cycles that may occur in the case of infants. For example, metrics for one and ten second interval saturation changes may be evaluated. The averaging response time and thresholds may also be modified to achieve more (e.g., shorter interval) or less (e.g., longer interval) sensitive detection of unstable saturation behavior depending on the desired phenomena to be detected.

[0034] The following is a listing of exemplary programming code in accordance with one embodiment of the present invention:

```
#AWK script to evaluate unstable saturation behaviour characteristic of
#obstructive sleep apnea, based on saturation and quality metrics internal
# to the oximetry algorithm.
# initialize variables
BEGIN
{
  for (i = 0; i <= 15; i++)
  {
    sat_hist[i] = 0.0;
    sat_age_hist[i] = 0.0;
    mot_hist[i] = 0;
  }
  mean_diff_15 = 0.30;
  mean_diff_1 = 0.10;
  nz_sat_cnt = 0;
  diff_15_xtra = 0.0;
  diff_15_xtra_exceeds_10_cnt = 0;
  unstable_sat_flag = 0;
}
```

-continued

```
# The following section is invoked for each ASCII input line
# which is assumed to occur once per second
{
  #read saturation, saturation age, and motion flag (columns 3, 21, 25).
  sat_hist[0] = $3 * 1.0;
  sat_age_hist[0] = $21 * 1.0;
  mot_hist[0] = $25 * 1;
  #reinitialize variables when saturation is zero
  if (sat_hist[0] == 0.0)
  {
    for (i = 0; i <= 15; i++)
    {
      sat_hist[i] = 0.0;
      sat_age_hist[i] = 0.0;
      mot_hist[i] = 0;
    }
    mean_diff_15 = 0.30;
    mean_diff_1 = 0.10;
    nz_sat_cnt = 0;
    diff_15_xtra = 0.0;
    diff_15_xtra_exceeds_10_cnt = 0;
    unstable_sat_flag = 0;
  }
  else
  {
    nz_sat_cnt++;
  }
  #update metrics when saturation has been non-zero for 15 seconds
  if ((sat_hist[0] > 0.0) && (sat_hist[15] > 0.0))
  {
    #update averaging response time (60 sec --> 5 minutes)
    fwt = 1.0 / nz_sat_cnt;
    if (nz_sat_cnt < 60)
      fwt = 1.0 / 60.0
    if (nz_sat_cnt > 300)
      fwt = 1.0 / 300.0;
    #compute and average 1-sec (short-term) saturation changes
    sat_diff_1 = 0.0;
    for (i = 0; i < 15; i++)
    {
      tmp = sat_hist[i] - sat_hist[i+1];
      if (tmp < 0.0)
      {
        tmp = 0.0 - tmp;
      }
      sat_diff_1 += tmp / 15.0;
    }
    mean_diff_1 += fwt * (sat_diff_1 - mean_diff_1)
    #compute 15-sec saturation change
    if (sat_age_hist[15] < sat_age_hist[0] + 5.0)
    {
      sat_diff_15 = sat_hist[0] - sat_hist[15];
    }
    #if saturation age has been getting younger due to
    #the cessation of artifact, then compute saturation change
    #over a slightly shorter interval
    else
    {
      sat_diff_15 = sat_hist[0] - sat_hist[14];
    }
    if (sat_diff_15 < 0.0)
    {
      sat_diff_15 = 0.0 - sat_diff_15;
    }
    #downweight saturation-change metric for very high
    #saturations.
    if (sat_hist[0] > 99.0)
    {
      sat_diff_15 -= 0.5 * (sat_hist[0] - 99.0);
    }
    #downweight saturation-change metric if motion artifact
    #was detected during the interval
    if ((mot_hist[0] > 0) || (mot_hist[7] > 0) ||
    (mot_hist[15] > 0))
      sat_diff_15 /= 2;
    #average 15-second saturation-change metric
```

-continued

```

mean_diff_15 += fwt * (sat_diff_15 - mean_diff_15)
}
#combine the averaged 1-second and 15-second change metrics
diff_15_xtra = 100.0 * (mean_diff_15 - 8.0 * mean_diff_1);
if (diff_15_xtra < 0.0)
  diff_15_xtra = 0.0;
if (diff_15_xtra > 10.0)
  {
  diff_15_xtra_exceeds_10_cnt++;
  }
else
  {
  diff_15_xtra_exceeds_10_cnt = 0;
  }
#update unstable saturation condition
if ((unstable_sat_flag == 1) && (diff_15_xtra < 15.0))
  {
  unstable_sat_flag = 0;
  }
if ((unstable_sat_flag == 0) && (diff_15_xtra > 20.0) &&
    (diff_15_xtra_exceeds_10_cnt > 15))
  {
  unstable_sat_flag = 1;
  }
#move old data back in the buffers. Location [1] denotes 1 second
#ago, location [15] denotes 15 seconds ago, etc.
for (i = 15; i > 0; i--)
  {
  sat_hist[i] = sat_hist[i-1];
  sat_age_hist[i] = sat_age_hist[i-1];
  mot_hist[i] = mot_hist[i-1];
  }
#print header line
if (FNR == 1)
  printf("%s\t%s\t%s\t%s\tunstable_sat_flag\tdiff_15_xtra\n",
    $1, $3, $21, $25)
#print output for each one-second ASCII input line, after line 1
else
  printf("%s\t%s\t%s\t%s\t%0.2f\n",
    $1, $3, $21, $25, unstable_sat_flag, diff_15_xtra);
}
# End of AWK script

```

[0035] The exemplary programming code may be implemented in a pulse oximetry software algorithm that allows analysis of large quantities of data in order to detect unstable oxygen saturation of a patient. Those of ordinary skill in the art will appreciate that many other programming scripts can be used and yet still perform an analysis of statistical variations in blood oxygenation so as to detect unstable oxygen saturation in accordance with embodiments of the present invention. The exemplary program code above includes artifact detection and saturation age quality metrics to reduce undesirable effects of non-physiologic artifacts of the type illustrated in FIG. 3.

[0036] An exemplary embodiment of the programming script listed above has been used to post-process oximetry data from each of the 113 cases in the sample database referred to above to evaluate unstable oxygen saturation behavior characteristic of obstructive sleep apnea. The goal of this analysis was to determine whether the manual analysis that distinguished cyclic saturation variations from other artifactual variations could be confirmed using software with an acceptable degree of reliability and response time (e.g., response time sufficiently fast to permit real-time analysis of patient data).

[0037] The outputs of the programming script listed above include the time series SpO₂ input denoted by the unbroken

saturation “Sat” trace (FIGS. 5-10), the diff_15_extra variable referred to in the exemplary program code, which quantifies the degree to which the data is above the diagonal threshold line 34 (FIG. 4). The unstable_sat_flag referred to in the example program code is set to one when the specified thresholds for the diff_15_extra variable are exceeded. Moreover, the detection of a cyclic pattern of unstable oxygen saturation may be conditioned upon exceeding a single threshold or multiple thresholds. Additionally, statistical metrics may be modified depending on a magnitude of oxygen saturation being evaluated. In the exemplary program code set forth above, the diff_15_extra variable computes and averages the absolute values of the one and fifteen second interval saturation changes, where the averaging has a response time that starts at one minute and gradually lengthens to five minutes, and determines if the threshold is exceeded.

[0038] Although certain exemplary embodiments and methods have been described in some detail, for clarity of understanding and by way of example, it will be apparent from the foregoing disclosure to those skilled in the art that variations, modifications, changes, and adaptations of such embodiments and methods may be made without departing from the true spirit and scope of the invention. For example, “exceeding a threshold” can mean being either above or below the threshold, depending on the circumstances and the parameter being measured. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

What is claimed is:

1. A method for automatic detection of unstable oxygen saturation of a patient using a pulse oximeter, the method comprising:

receiving at least a single time series input of oxygen saturation values; and

computing at least two metrics based on statistical properties of the single time series input of oxygen saturation values.

2. The method as in claim 1, further comprising averaging the statistical metrics.

3. The method as in claim 2, further comprising determining a relationship between the statistical metrics.

4. The method as in claim 3, further comprising providing an output if the relationship exceeds a threshold value.

5. The method as in claim 4, wherein exceeding the threshold value is indicative of cyclic saturation variations.

6. The method as in claim 4, wherein the output comprises sounding an audio alarm.

7. The method as in claim 4, wherein the output comprises displaying a visual alert.

8. The method as in claim 4, wherein the threshold value slope is in a range from about 60% to about 90% of a ratio of time intervals used for quantifying saturation changes.

9. The method as in claim 1, wherein the statistical metrics are associated with ventilation or airway instability.

10. The method as in claim 1, wherein the statistical metrics are associated with sleep apnea.

11. The method as in claim 1, wherein the statistical metrics in combination are sensitive to both magnitude and frequency range of oxygen saturation variations.

12. The method as in claim 1, wherein at least one statistical metric comprises a magnitude of saturation changes over 0.5 to 5 second intervals.

13. The method as in claim 12, wherein a second statistical metric comprises a magnitude of saturation changes over 10 to 30 second intervals.

14. The method as in claim 1, wherein at least one statistical metric comprises a skewness of the single time series input of oxygen saturation values.

15. The method as in claim 1, wherein at least one statistical metric comprises a kurtosis of the single time series input of oxygen saturation values.

16. The method as in claim 1, wherein cyclic saturation variations may be detected with a period of at least 35 seconds to 5 minutes.

17. The method as in claim 1, wherein receiving, computing, averaging, determining, and providing steps are carried out by a processor.

18. The method as in claim 1, further comprising modifying the statistical metrics based on one or more signal quality metrics.

19. The method as in claim 1, further comprising modifying the statistical metrics depending on a magnitude of the oxygen saturation values.

20. The method as in claim 1, further comprising determining whether the oxygen saturation values correspond to unstable oxygen saturation by comparing the oxygen saturation values to multiple thresholds.

21. A method for automatic detection of unstable oxygen saturation of a patient using a pulse oximeter, the method comprising:

receiving at least a single time series input of oxygen saturation values;

computing at least two metrics based on statistical properties of the single time series input of the oxygen saturation values;

modifying the statistical metrics based on one or more signal quality metrics;

averaging the statistical metrics;

determining a relationship between the statistical metrics; and

providing an output if the relationship exceeds a threshold value.

22. A patient monitoring system for automatically detecting unstable oxygen saturation of a patient, the system comprising:

a pulse oximeter for measuring at least a single time series input of oxygen saturation values; and

a processor programmed to compute at least two metrics based on statistical properties of the single time series input of oxygen saturation values.

23. The system as in claim 22, wherein the processor is further programmed to average the statistical metrics.

24. The system as in claim 22, wherein the processor is further programmed to determine a relationship between the statistical metrics.

25. The system as in claim 24, wherein the processor is further programmed to provide an output if the relationship exceeds a threshold value.

26. The system as in claim 25, wherein the statistical metrics are associated with one of cyclic saturation variations, ventilation or airway instability, and sleep apnea.

27. The system as in claim 22, wherein the at least two statistical metrics in combination are sensitive to both magnitude and frequency range of oxygen saturation variations.

28. The system as in claim 22, wherein at least one statistical metric comprises a skewness of the single time series input of oxygen saturation values.

29. The system as in claim 22, wherein at least one statistical metric comprises a kurtosis of the single time series input of oxygen saturation values.

30. The system as in claim 22, wherein the statistical metrics are modified depending on a magnitude of the oxygen saturation values.

31. The system as in claim 22, wherein the oxygen saturation values are determined to correspond to unstable oxygen saturation by comparing the oxygen saturation values to multiple thresholds.

32. A computer-readable storage medium having a computer-readable program embodied therein for directing operation of a computer system, the computer system including a communications system, a processor, and a memory device, wherein the computer-readable program includes instructions for operating the computer to automatically detect unstable oxygen saturation of a patient in accordance with the following:

receiving at least a single time series input of oxygen saturation values; and

computing at least two metrics based on statistical properties of the single time series input of the oxygen saturation values.

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专利名称(译)	用于检测不稳定氧饱和度的系统和方法		
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摘要(译)

描述了用于通过分析血氧的统计变化来简化检测患者的不稳定氧饱和度的方法和系统。使用脉冲血氧计自动检测患者的不稳定氧饱和度的一种方法包括接收氧饱和度值的至少单个时间序列输入并基于氧饱和度值的单个时间序列输入的统计特性计算至少两个度量。

