



(11) **EP 3 193 713 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention  
of the grant of the patent:  
**22.05.2019 Bulletin 2019/21**

(51) Int Cl.:  
**A61B 5/087** <sup>(2006.01)</sup> **A61B 5/00** <sup>(2006.01)</sup>  
**A61M 16/00** <sup>(2006.01)</sup>

(21) Application number: **15842322.8**

(86) International application number:  
**PCT/US2015/050721**

(22) Date of filing: **17.09.2015**

(87) International publication number:  
**WO 2016/044610 (24.03.2016 Gazette 2016/12)**

(54) **BREATHING THERAPY MACHINE HAVING MEANS FOR DETECTING AN INSPIRATORY FLOW LIMITATION DURING SLEEP-DISORDERED BREATHING**

THERAPEUTISCHES ATEMGERÄT MIT MITTELN ZUR ERKENNUNG EINER  
EINATMUNGSFLUSSBEGRENZUNG BEI ATEMSTÖRUNGEN IM SCHLAF

MACHINE RESPIRATOIRE THERAPEUTIQUE AYANT DES MOYENS POUR DÉTECTER UNE  
LIMITATION DE DÉBIT INSPIRATOIRE EN CAS DE TROUBLE RESPIRATOIRE DU SOMMEIL

(84) Designated Contracting States:  
**AL AT BE BG CH CY CZ DE DK EE ES FI FR GB  
GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO  
PL PT RO RS SE SI SK SM TR**

• **LAUER, Jeffrey J.**  
**Nanty Glo, PA 15943 (US)**

(30) Priority: **18.09.2014 US 201414489552**

(74) Representative: **Barker Brettell LLP**  
**100 Hagley Road**  
**Edgbaston**  
**Birmingham B16 8QQ (GB)**

(43) Date of publication of application:  
**26.07.2017 Bulletin 2017/30**

(73) Proprietor: **DeVilbiss Healthcare LLC**  
**Somerset, PA 15501 (US)**

(56) References cited:  
**US-A- 5 335 654** **US-A- 5 483 969**  
**US-A1- 2004 123 866** **US-A1- 2004 123 866**  
**US-A1- 2006 037 614** **US-A1- 2007 215 146**  
**US-A1- 2008 082 018** **US-A1- 2012 179 061**  
**US-B1- 6 739 335**

(72) Inventors:  
• **KNEPPER, Michael B.**  
**Friedens, PA 15541 (US)**

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

**EP 3 193 713 B1**

## Description

### Field of the Invention

[0001] This invention relates generally to the field of breathing therapy machines of the type used to treat obstructive and/or central sleep disorders and specifically to the treatment of such sleep disorders when flow limited breathing patterns are detected.

### Background of the Invention

[0002] Continuous Positive Airways Pressure (CPAP) breathing therapy machines are well known in the art for use in the treatment of sleep disordered breathing by supplying a continuous positive pressure to a patient's airway while the patient sleeps. A typical CPAP apparatus is programmed with a therapy pressure, and is able to maintain the set pressure (measured either at the mask or at a base unit) during the inhalation and exhalation phases of the breathing cycle. The pressure setting is typically programmed via a control on the unit. Bi-PAP machines will typically vary the positive pressure delivered to the user during the inhalation and exhalation phases of the breathing cycle. Typically, Bi-PAP machines deliver a lower pressure during the exhalation phase of the breathing cycle, to make it easier or less uncomfortable for patients to exhale while using the machine. The Bi-PAP machine is typically programmed with a therapy pressure, which is used as the inhalation pressure, while the exhalation pressure is typically a standard difference from the inhalation pressure.

[0003] Figure 1 shows a schematic view of a typical prior art CPAP / Bi-PAP machine 30. Positive pressure is maintained by regulated blower 40, under control of motor control circuitry 38. Blower 40 supplies a pressurized flow of air to a mask connected via the flexible tube (not shown) to blower 40. Regardless of whether the device is a CPAP machine or a Bi-PAP machine, microprocessor 34, in accordance with normal operating programming stored in memory 36 produces a motor control signal which is interpreted by motor control circuitry 38. Motor control circuitry 38 translates motor control signal 37 into electrical impulses that control the speed of blower 40 to produce the desired pressure through flow element 42 and ultimately to the user of the device. The machine may be equipped with various sensors, such as pressure sensor 44 and flow sensor 46 to aid in the detection of sleep events. Control and programming of the device is accomplished via user interface 32.

[0004] The term "inspiratory flow limitation" describes a physiological condition in which the respiratory pattern is defined by constant or decreasing air flow without pressure dependence throughout significant portions of inspiration. This flow limitation is commonly caused by a narrowing of the upper airway. The pattern can be identified by a flattening of areas of the inspiratory waveform, as detected in the CPAP patient interface, resulting in an

inspiratory waveform contour having plateaus which correlate to an elevated upper airway resistance.

[0005] The ability to detect the flow limitation condition is important for several reasons. If the increased airway resistance is sufficiently high, the tidal volume will fall. If the high upper airway resistance and reduced tidal volume persist, sleep-disordered breathing events will likely occur in the form of hypopneas or even apneas. Furthermore, if sufficient inspiratory muscle effort is required to overcome the flow limitation, transient arousals from sleep may occur, which may lead to daytime somnolence. Titration studies have also shown that flow limitation may curtail periods of deep sleep, even when the patient is not aroused.

[0006] In the context of a CPAP breathing therapy device, the ability to reliably detect a flow limitation condition can be used as an aid in adjusting the therapy pressure. Typically, a breathing therapy machine will seek to deliver the lowest possible therapeutically effective pressure to the patient, such as to minimize any patient discomfort associated with the use of the device. Typically, such devices will slowly lower the therapy pressure until the patient experiences an event, then will raise the pressure to stop the events, and then will return to slowly lowering the pressure. The ability to detect flow limitations as the pressure is lowered can act as a warning mechanism that further lowering the pressure may precipitate the occurrence of events. Therefore, when the flow limitation condition is detected, the CPAP machine can stop the lowering of the pressure, or increase the pressure to alleviate the flow limitation condition.

[0007] There are many methods of detecting flow limitation extant in the literature and several have been implemented in prior art CPAP machines. However, it has been found that prior art methods are unreliable and may often miss detecting flow limitation conditions, particularly in situations where the airflow waveform does not exhibit well-defined plateau areas in the inspiratory portion of the waveform. Therefore it would be desirable to have a more reliable method of determining the flow limitation condition.

[0008] The patent document US 5,335,654 discloses a method and apparatus for adjusting the positive airway pressure of a patient to have an optimum (e.g. minimum) value, in the treatment of obstructive sleep apnea.

### Summary of the Invention.

[0009] The invention is defined by the appended claims.

[0010] The present invention presents an improved method of detecting a flow: limited breathing pattern in a CPAP device. In this method, the flow waveform for each breath is analyzed by calculating the variance in the average slope for a moving window across the data points of the waveform. The results of the calculation are then analyzed to determine if the slope at any point in the waveform is flat enough (i.e., has a low enough variance)

to warrant a determination of possible flow limitation. In a second embodiment, an analysis of the duty cycle kinetics of the airflow waveform is used to add certainty to the determination of a flow limitation condition.

**[0011]** The CPAP machine can use the detection of a flow limitation condition to alter the therapy pressure delivered to the patient. The onset of the flow limitation condition can be a signal that further lowering of the therapeutic pressure may result in events, such as hypopneas or apneas. Thus, the machine can use this information to curtail the lowering of pressure, or to increase pressure if the flow limitation condition persists.

### **Brief Description of the Drawings**

#### **[0012]**

Figure 1 shows a prior art CPAP device of the type in which the present invention may be implemented.

Figure 2 is a flow chart showing the algorithm used to detect the flow limitation condition.

Figure 3 is a graph showing an airflow waveform exhibiting the flow limitation condition, as well as a waveform showing the output of the flow limitation detection algorithm.

### **Detailed Description of the Invention**

**[0013]** The improved flow limitation detection algorithm of the present invention can be implemented in a typical prior-art device, as shown in Figure 1, as a software module stored in memory 36. In the preferred embodiment, the algorithm is essentially two algorithms working concurrently, one to determine if the pressure should be raised, and the other to determine if the pressure should be lowered. As one of skill in the art would realize, this is only one way of implementing the invention, and other implementations may be used without deviating from the spirit or scope of the invention. As would also be realized by one of skill in the art, the existence of the flow limitation condition is but one of many factors that can be used in determining the correct setting of the therapeutic pressure. As such, the output of the flow limitation algorithm, in a typical embodiment of a CPAP machine, will be used as one factor among several others to dynamically adjust the therapeutic pressure delivered to the patient.

**[0014]** In Figure 3, reference A shows an airflow waveform displaying the flow limitation condition. The inspiration portion of the breathing cycle is shown above the dotted line. Absent the flow limitation condition, the airflow waveform resembles a sine wave. Visually, the flow limitation condition is easy to detect, being indicated by flattened areas on the inspiration portion of the airflow waveform, examples of which are shown with reference number 301 in Figure 3, reference A. Note that the flat-

tened areas of the waveform indicative of the flow limitation condition may have a positive or negative slope. The algorithm of the present invention is capable of recognizing both negatively sloped plateaus, as shown by reference number 301, and positively sloped plateaus, as shown by reference number 302.

**[0015]** Figure 2 shows a flow chart of the algorithm used to analyze the airflow waveform for each breath taken by the patient. As previously discussed, only the inspiration portion of the airflow waveform is of interest in detecting the flow limitation condition.

**[0016]** The algorithm starts at Reference A in Figure 2 and, in box 202, the inspiration portion of the airflow waveform is detected and its duration is measured. The airflow waveform consists of data points sampled from the flow sensor 46 shown in Figure 1, which is typically sampled at a rate of 32 Hz. Other sampling rates will, or course, work equally as well. Depending upon the duration of the patient's breathing cycle, the inspiration portion of the airflow waveform could contain from several dozen to several hundred sampled points. In the preferred embodiment, the sampled points are retrieved and stored in an array for processing. Analysis is performed on the inspiration portion of each breathing cycle independently from other breathing cycles.

**[0017]** Once the data from the inhalation portion of the breathing cycle has been obtained and the duration measured, the data is normalized. Because not all breaths taken by the patient are the same (i.e., some breaths may be more or less shallow than others) the breathing sample is normalized in box 204 to an arbitrary standard breath. As one of skill in the art would realize, many methods of normalizing the data can be used. However, in the preferred embodiment of the invention, the average of the airflow signal is taken over the inspiration portion of the breathing cycle, that is, the amplitude of each sampled data point is summed and the sum is divided by the total number of sampled data points. A gain is then applied to each sampled data point based on the calculated average to provide the normalization to the arbitrary standard breath.

**[0018]** In box 206, filtering is applied to smooth the airflow waveform to eliminate small "bumps" in the waveform that have no impact on the overall detection of the flow limitation condition. As one of skill in the art would realize, many forms of filtering may be utilized. However, in the preferred embodiment of the invention, a moving average method is used. A window containing approximately one-ninth of the total number of samples in the inspiration portion of the airflow waveform is averaged, and the window is then shifted by one data point. In the moving average method of filtering, the number of samples contained in the moving average window may be varied without deviating from the scope of the invention.

**[0019]** The algorithm then proceeds to box 208, where, in the preferred embodiment, all of the samples in the inspiration portion of the breathing cycle are divided and placed into bins, with each bin containing an approxi-

mately equal number of samples. In the preferred embodiment of the invention the total number of samples is divided into a minimum of 7 separate "bins". So, for example, if the inspiration portion of the breathing cycle contained 175 samples, the first 25 samples would be in the first bin, the next 25 samples would be in the second bin, and so forth. Note that the number of bins chosen is arbitrary and in the preferred embodiment, is nominally 7 and maybe more, depending upon the total number of sampled data points in the inspiration portion of the breathing cycle for a particular breath. As one of skill in the art would realize, any number of bins could be utilized. Additionally, because the actual number of sampled data points may not be evenly divided between the number of bins, all bins may not have the exact number of sampled data points therein.

**[0020]** In box 210, the algorithm iterates through each bin and, in box 212, calculates the average slope over all sampled data points in the bin. Note that the average slope is the derivative of the airflow waveform. To calculate the average slope, the difference between each adjacent pair of sampled data points is taken and summed in an accumulator. When the difference between all points in the bin has been accounted for, the sum is divided by the number of sampled data points in the bin, resulting in the average slope over all sampled data points in the bin. When the average slope has been calculated for each bin, control proceeds to box 214.

**[0021]** In box 214 the bins are numerically ranked and sorted based upon the average slope calculated in box 212. In box 216, a moving window containing 3 bins is iterated over all of the bins and for each window, in box 218, the variance of the average slope of the bins in the window is calculated. As an example, if there are 7 bins, labelled 1, 2, 3, 4, 5, 6 and 7, the variance will be calculated for a moving window containing sets of bins as follows: {1,2,3}, {2,3,4}, {3,4,5}, {4,5,6}, and {5,6,7}. More or less bins may be used, and the number of points over which the variance is calculated may also be varied without departing from the scope of the invention.

**[0022]** Mathematical variance measures how far a set of numbers is spread out. Therefore, a variance of zero indicates that all the values in the calculated set are identical (i.e., they exhibit a steady slope), which would be indicative of a plateaued area of the airflow waveform. A small variance indicates that the data tends to be very close to the mean, and therefore, close to each other, which is indicative of a likelihood of a flow limitation condition, that is, the members of the calculated set where the slope is derived from the airflow waveform are nearly equal, but still show little variation from bin to bin (i.e., a flattened area on the airflow waveform). Simultaneously, the members of the calculated set may exhibit a positive or negative slope. Conversely, a high variance indicates that the data is very spread out around the mean and from each other, which is more indicative of a normal airflow waveform having a high slope variance calculation as measured from all of the calculated sets, and

therefore not exhibiting the flow limitation condition.

**[0023]** In box 220 the bin having the lowest variance is selected and is analyzed to determine if the value of the variance is indicative of a flow limitation condition.

**[0024]** In box 222 a semi-arbitrary scale is used to determine if a flow limitation condition exists and, if so, if the flow limitation is mild, moderate or severe in nature depending upon the value of the lowest variance for the inspiration portion of each breathing cycle. Control then returns to the beginning of the algorithm for the next breath.

**[0025]** In Figure 3 the output of the algorithm is shown as Reference B. The waveform in Reference B shows a determination of no flow limitation or a flow limitation characterized as mild, moderate or severe. Note that the determination in waveform B may be offset in time slightly from the airflow waveform A.

**[0026]** One advantage of this invention is that it is detecting what may be perceived as "visual flatness" in the inspiratory airflow waveform, regardless of the slope of the flat portion of the inspiration waveform. It should be noted that flatness is not the equivalent of slope. The detection method of the present invention can detect a "flat" area, even if the slope of the flat area is steep.

**[0027]** One problem with the method of the present invention is that in the presence of ventilation (machines providing bi-level therapy and, in some cases, machines that adjust the pressure in response to events), the airflow waveform tends to be distorted when the pressure is switched from the inhalation pressure to the exhalation pressure, making it have more "flatness" because of the bi-level pressures. It has been found that this distortion almost always coexists with a very steep slope in the airflow waveform, but is not indicative of the flow limitation condition. As such, the present invention offers an additional embodiment wherein flattened areas of the inspiration airflow waveform having a very steep slope are dampened to reduce the sensitivity to these regions, to avoid falsely determining a flow limitation condition.

**[0028]** In box 221, a dampening factor is applied to the variance based on the average slope, such that the higher the average slope gets, the less of a factor the variance has in the determination of the flow limitation condition. To apply the dampening factor, the average slope of the three bins in the variance window is calculated. A linear or non-linear having the average slope as it's input may be applied to perform the dampening, such that the steeper the slope, the larger the dampening factor for the variance. The variance is multiplied by the dampening factor, such that a large slope will result in a large dampening factor, increasing the variance and making it less likely to be indicative of a flow limitation condition. Many such schemes are possible to make it less likely that a small variance indicates a likelihood of a flow limitation condition when a large slope is also present. All such schemes are intended to be within the scope of the invention.

**[0029]** Once it has been determined that a flow limitation exists, the CPAP machine may make decisions re-

garding the change in therapeutic pressure delivered to the patient based upon the output of the algorithm. For example, in the preferred embodiment the pressure is increased if a moderate or severe flow limitation is detected for 15 or more seconds in a one-minute period. In such cases, the pressure would rise slightly, for example by .2 cmH<sub>2</sub>O. It is also possible that the CPAP machine would ignore the output of the flow limitation algorithm. For example, if it is observed that raising the pressure several times does not alleviate the flow limitation condition, this may be considered a stable condition for the patient and the raising of the pressure is curtailed to avoid unnecessarily arousing the patient.

**[0030]** In a second embodiment of the invention, the detection of a flow limitation condition may be bolstered with a degree of certainty by applying an analysis of the duty cycle kinetics of the airflow waveform. It has been discovered that a duty cycle in which the inspiration portion is increasing compared to the expiration portion is indicative of the flow limitation condition. This occurs because when airflow is restricted during inspiration, the patient requires more time to get the required volume of air into the lungs and thus the inspiration portion of the duty cycle is increased. A trend over several breaths showing an increase in the percentage of time of the duty cycle spent in inspiration is therefore a strong indicator, especially when combined with the output of the variance-based algorithm of the present invention, that a flow limitation condition exists. As such, an analysis of the duty cycle kinetics may be utilized as a secondary indicator or as a confirmatory degree of certainty when used in conjunction with the flattening detection algorithm. In an alternative second embodiment, a flow limitation condition may only be determined when confirmed by an upwardly trending ratio of inspiration to expiration.

**[0031]** A description of the invention has been provided utilizing specific numbers and examples of calculations. As one of skill in the art would realize there may be other methods to, for example, provide filtering and/or normalization of the data that do not deviate from the intended scope of the invention, which is outlined in the claims which follow.

## Claims

1. A breathing therapy machine having an optimized auto-adjust capability comprising:
  - a. a blower, for delivering air to a user of said device at a pressure;
  - b. a processor, for controlling said blower;
  - c. non-volatile memory, accessible by said processor, said non-volatile memory containing operational programming;
  - d. an airflow sensor, electrically connected to said processor for gathering data regarding the volume of airflow to said patient, said operational

programming producing an airflow waveform from said gathered data; and

e. a flow limitation detection module, stored in said non-volatile memory as part of said operational programming, wherein said flow limitation detection module is configured to detect a flow limitation condition by:

grouping data points sampled from an inspiration portion of the airflow waveform into a plurality of bins;  
for each bin, calculating an average slope value using the data points within the bin;  
computing a plurality of variance values, wherein each variance value is computed by defining a moving window that utilizes average slope values calculated for at least three of the bins; and  
selecting and analyzing a lowest variance value of the plurality of variance values to determine if the flow limitation condition exists.

2. The breathing therapy machine of claim 1 wherein said airflow waveform consists of a series of breaths, each breath consisting of an inspiration portion and an expiration portion, and further wherein said flow limitation module performs, for each of said breaths, a series of functions consisting of:

detecting the start and end of said inspiration portion of said breath and measuring the duration of said inspiration portion; and  
selecting the lowest variance value and comparing to an absolute scale to determine if the flow limitation condition is present.

3. The breathing therapy machine of claim 2 wherein said flow limitation module performs the further function of normalizing the inspiration portion prior to computing said plurality of variance values.

4. The breathing therapy machine of claim 3 wherein said normalization function comprises:

calculating the average flow signal for said inspiration portion; and  
applying a gain to said inspiration portion based on a comparison of said average flow signal to an arbitrary standard flow signal.

5. The breathing therapy machine of claim 2 wherein said flow limitation module performs the further function of applying adaptive filtering to smooth said inspiration portion of said airflow waveform prior to computing said plurality of variance values.

6. The breathing therapy machine of claim 5 wherein

said adaptive filtering function comprises calculating a moving average of said inspiration portion.

7. The breathing therapy machine of claim 6 wherein said moving average is calculated using a window sized encompassing approximately 1/9<sup>th</sup> of said inspiration portion. 5
8. The breathing therapy machine of claim 2 wherein said flow limitation module performs the further function of ranking and sorting said plurality of bins, each of which corresponding to the data points sampled from the inspiration portion of the airflow waveform, based on said calculated average slope values prior to performing said variance calculations. 10 15
9. The breathing therapy machine of claim 2 wherein said function of selecting the lowest of said variance calculations and comparing to the absolute scale to determine if the flow limitation condition is present further comprises assigning a severity of said flow limitation condition based on the value of said lowest variance, wherein optionally said severity of said flow limitation is assigned a severity selected from a group consisting of none, mild, moderate and severe. 20 25
10. The breathing therapy machine of claim 2 wherein said flow limitation detection module performs a further function comprising: 30
  - calculating the ratio of said inspiration portion to said expiration portion for each breath over several breaths; and
  - determining if said ratio is trending toward longer inspiration times and shorter expiration times, and, if so, utilizing said trend as confirmation of the flow limitation condition. 35
11. The breathing therapy machine of claim 2 wherein said flow limitation detection module performs a further function comprising: 40
  - calculating a ratio of said inspiration portion to said expiration portion for each breath over several breaths; and
  - determining if the flow limitation condition exists only if indicated by said calculation of said variance based on the variance values and trending information associated with said ratio. 45 50
12. The breathing therapy machine of claim 1 wherein said pressure of said air is altered based on a detection of the flow limitation condition. 55
13. The breathing therapy machine of claim 12 wherein said pressure is raised if the flow limitation condition is determined to be present for at least 15 seconds

in a one minute window.

14. The breathing therapy machine of claim 12 wherein said pressure is periodically raised if the flow limitation condition is determined to be present until a certain predetermined pressure is reached, at which time the flow limitation condition is ignored.
15. The breathing therapy machine of claim 2 wherein a dampening factor is applied to each variance calculation prior to the step of selecting the lowest variance value, wherein optionally a polynomial having the average slope as an input is used to dampen the variance, and/or said dampening factor lessens the effect of said variance values as the average slope increases.

### Patentansprüche

1. Therapeutisches Atemgerät, das eine optimierte Selbstregulierungsfähigkeit aufweist, umfassend:
  - a. ein Gebläse zum Abgeben von Luft an einen Benutzer der Vorrichtung mit einem Druck;
  - b. einen Prozessor zum Steuern des Gebläses;
  - c. nicht flüchtigen Speicher, auf den der Prozessor zugreifen kann, wobei der nicht flüchtige Speicher operative Programmierung enthält;
  - d. einen Luftflusssensor, der elektrisch mit dem Prozessor verbunden ist zum Erfassen von Daten bezüglich des Luftflussvolumens zum Patienten, wobei die operative Programmierung aus den erfassten Daten eine Luftflusswellenform erzeugt; und
  - e. ein Modul zur Erkennung von Flussbegrenzung, das als Teil der operativen Programmierung im nicht flüchtigen Speicher gespeichert ist, wobei das Modul zur Erkennung von Flussbegrenzung ausgelegt ist, um einen Zustand der Flussbegrenzung zu erkennen durch:
    - Gruppieren von Datenpunkten, die an einem Einatemungsabschnitt des Luftflusswellenform gesampelt wurden, in einer Vielzahl von Zwischenspeichern;
    - für jeden Zwischenspeicher, Errechnen eines durchschnittlichen Neigungswerts unter Verwendung der Datenpunkte innerhalb des Zwischenspeichers;
    - Berechnen einer Vielzahl von Abweichungswerten, wobei jeder Abweichungswert durch Definieren eines fluktuierenden Fensters berechnet wird, das die durchschnittlichen Neigungswerte verwendet, die für mindestens drei der Zwischenspeicher errechnet wurden; und
    - Auswählen und Analysieren eines niedrigs-

- ten Abweichungswerts aus der Vielzahl von Abweichungswerten, um zu bestimmen, ob der Zustand der Flussbegrenzung vorliegt.
2. Therapeutisches Atemgerät nach Anspruch 1, wobei die Luftflusswellenform aus einer Reihe von Atemzügen besteht, wobei jeder Atemzug aus einem Einatmungsabschnitt und einem Ausatmungsabschnitt besteht, und wobei das Flussbegrenzungsmodul weiter für jeden der Atemzüge eine Reihe von Funktionen ausführt, bestehend aus:
    - Erkennen des Beginns und des Endes des Einatmungsabschnitts des Atemzugs und Messen der Dauer des Einatmungsabschnitts; und
    - Auswählen des niedrigsten Abweichungswerts und Vergleichen mit einer absoluten Skala, um zu bestimmen, ob der Zustand der Flussbegrenzung vorhanden ist.
  3. Therapeutisches Atemgerät nach Anspruch 2, wobei das Flussbegrenzungsmodul weiter die Funktion des Normalisierens des Einatmungsabschnitts vor Berechnen der Vielzahl von Abweichungswerten ausführt.
  4. Therapeutisches Atemgerät nach Anspruch 3, wobei die Normalisierungsfunktion umfasst:
    - Errechnen des durchschnittlichen Flusssignals für den Einatmungsabschnitt; und
    - Anwenden einer Verstärkung auf den Einatmungsabschnitt auf der Grundlage eines Vergleichs des durchschnittlichen Flusssignals mit einem willkürlichen Standardflusssignal.
  5. Therapeutisches Atemgerät nach Anspruch 2, wobei das Flussbegrenzungsmodul weiter die Funktion des Anwendens von adaptivem Filtern ausführt, um den Einatmungsabschnitt des Luftflusswellenformabschnitts vor Berechnen der Vielzahl von Abweichungswerten zu glätten.
  6. Therapeutisches Atemgerät nach Anspruch 5, wobei die adaptive Filterfunktion Errechnen eines fluktuierenden Durchschnitts des Einatmungsabschnitts umfasst.
  7. Therapeutisches Atemgerät nach Anspruch 6, wobei der fluktuierende Durchschnitt unter Verwendung eines Fensters errechnet wird, das so bemessen ist, dass es ungefähr 1/9 des Einatmungsabschnitt einschließt.
  8. Therapeutisches Atemgerät nach Anspruch 2, wobei das Flussbegrenzungsmodul weiter die Funktion des Ordnen und des Sortierens der Vielzahl von Zwischenspeichern ausführt, wobei jeder davon den
- Datenpunkten entspricht, die vom Einatmungsabschnitt der Luftflusswellenform gesampelt wurden, auf der Grundlage der errechneten durchschnittlichen Neigungswerte vor Ausführen der Abweichungserrechnungen.
9. Therapeutisches Atemgerät nach Anspruch 2, wobei die Funktion des Auswählens des niedrigsten der Abweichungserrechnungen und des Vergleichens mit der absoluten Skala, um zu bestimmen, ob der Zustand der Flussbegrenzung vorhanden ist, weiter Zuweisen eines Schweregrads des Zustands der Flussbegrenzung auf der Grundlage des Werts der niedrigsten Abweichung umfasst, wobei optional der Schweregrad der Flussbegrenzung einem Schweregrad zugewiesen wird, der aus einer Gruppe ausgewählt ist, die aus nicht vorhanden, mittel, mäßig und schwer besteht.
  10. Therapeutisches Atemgerät nach Anspruch 2, wobei das Modul zur Erkennung von Flussbegrenzung eine weitere Funktion ausführt, umfassend:
    - Errechnen des Verhältnisses des Einatmungsabschnitts zum Ausatmungsabschnitt für jeden Atemzug über mehrere Atemzüge; und
    - Bestimmen, ob das Verhältnis einen Trend zu längeren Einatmungszeiten und kürzeren Ausatmungszeiten aufweist, und, wenn ja, Verwenden der Trends als Bestätigung für den Zustand der Flussbegrenzung.
  11. Therapeutisches Atemgerät nach Anspruch 2, wobei das Modul zur Erkennung von Flussbegrenzung eine weitere Funktion ausführt, umfassend:
    - Errechnen eines Verhältnisses des Einatmungsabschnitts zum Ausatmungsabschnitt für jeden Atemzug über mehrere Atemzüge; und
    - Bestimmen, ob der Zustand der Flussbegrenzung vorliegt, nur wenn dies von der Errechnung der Abweichung auf der Grundlage der Abweichungswerte und der mit dem Verhältnis in Verbindung stehenden Trendinformationen angezeigt wird.
  12. Therapeutisches Atemgerät nach Anspruch 1, wobei der Druck auf die Luft auf der Grundlage einer Erkennung des Zustands der Flussbegrenzung verändert wird.
  13. Therapeutisches Atemgerät nach Anspruch 12, wobei der Druck angehoben wird, wenn der Zustand der Flussbegrenzung mindestens 15 Sekunden lang in einem einminütigen Fenster als vorhanden bestimmt ist.
  14. Therapeutisches Atemgerät nach Anspruch 12, wo-

bei der Druck regelmäßig angehoben wird, wenn der Zustand der Flussbegrenzung als vorhanden bestimmt ist, bis Erreichen eines bestimmten vorgegebenen Drucks, zu dessen Zeitpunkt der Zustand der Flussbegrenzung ignoriert wird.

15. Therapeutisches Atemgerät nach Anspruch 2, wobei auf jede Abweichungserrechnung vor dem Schritt des Auswählens des niedrigsten Abweichungswerts ein Dämpfungsfaktor angewendet wird, wobei optional ein Polynom, das die durchschnittliche Neigung als eine Eingabe aufweist, verwendet wird, um die Abweichung zu dämpfen, und/oder der Dämpfungsfaktor die Auswirkungen der Abweichungswerte bei ansteigender durchschnittlicher Neigung verringert.

## Revendications

1. Machine de thérapie respiratoire ayant une capacité d'auto-régulation optimisée comprenant :

- a. une soufflante, pour administrer de l'air à un utilisateur dudit dispositif à une pression ;
- b. un processeur, pour commander ladite soufflante ;
- c. une mémoire non volatile, accessible par ledit processeur, ladite mémoire non volatile contenant une programmation opérationnelle ;
- d. un débitmètre d'air, relié électriquement audit processeur pour recueillir des données relatives au débit volumétrique d'air vers ledit patient, ladite programmation opérationnelle produisant une forme d'onde de flux d'air à partir desdites données recueillies ; et
- e. un module de détection de limitation de flux, stocké dans ladite mémoire non volatile dans le cadre de ladite programmation opérationnelle, dans laquelle ledit module de détection de limitation de flux est configuré pour détecter une condition de limitation de flux par :

groupement de points de données échantillonnés à partir d'une partie inspiration de la forme d'onde de flux d'air en une pluralité de compartiments ;  
pour chaque compartiment, calcul d'une valeur de pente moyenne en utilisant les points de données à l'intérieur du compartiment ;  
calcul informatisé d'une pluralité de valeurs de variance, dans laquelle chaque valeur de variance est calculée informatiquement en définissant une fenêtre glissante qui utilise les valeurs de pente moyennes calculées pour au moins trois des compartiments ; et  
sélection et analyse d'une valeur de varian-

ce la plus basse de la pluralité de valeurs de variance pour déterminer si la condition de limitation de flux existe.

2. Machine de thérapie respiratoire selon la revendication 1 dans laquelle ladite forme d'onde de flux d'air est constituée d'une série de respirations, chaque respiration étant constituée d'une partie inspiration et d'une partie expiration, et en outre dans laquelle ledit module de limitation de flux réalise, pour chacune desdites respirations, une série de fonctions constituée de :

la détection du début et de la fin de ladite partie inspiration de ladite respiration et la mesure de la durée de ladite partie inspiration ; et  
la sélection de la valeur de variance la plus basse et la comparaison à une échelle absolue pour déterminer si la condition de limitation de flux est présente.

3. Machine de thérapie respiratoire selon la revendication 2 dans laquelle ledit module de limitation de flux réalise la fonction supplémentaire de normalisation de la partie inspiration avant le calcul informatisé de ladite pluralité de valeurs de variance.

4. Machine de thérapie respiratoire selon la revendication 3 dans laquelle ladite fonction de normalisation comprend :

le calcul du signal de flux moyen pour ladite partie inspiration ; et  
l'application d'un gain à ladite partie inspiration sur la base d'une comparaison dudit signal de flux moyen à un signal de flux standard arbitraire.

5. Machine de thérapie respiratoire selon la revendication 2 dans laquelle ledit module de limitation de flux réalise la fonction supplémentaire d'application d'un filtrage adaptatif pour lisser ladite partie inspiration de ladite partie forme d'onde de flux d'air avant le calcul informatisé de ladite pluralité de valeurs de variance.

6. Machine de thérapie respiratoire selon la revendication 5 dans laquelle ladite fonction de filtrage adaptatif comprend le calcul d'une moyenne mobile de ladite partie inspiration.

7. Machine de thérapie respiratoire selon la revendication 6 dans laquelle ladite moyenne mobile est calculée en utilisant une fenêtre d'une taille représentant approximativement 1/9<sup>e</sup> de ladite partie inspiration.

8. Machine de thérapie respiratoire selon la revendica-

tion 2 dans laquelle ledit module de limitation de flux réalise la fonction supplémentaire de classement et de tri de ladite pluralité de compartiments, chacun correspondant aux points de données échantillonnés à partir de la partie inspiration de la forme d'onde de flux d'air, sur la base desdites valeurs de pente moyennes calculées avant la réalisation desdits calculs de variance.

9. Machine de thérapie respiratoire selon la revendication 2 dans laquelle ladite fonction de sélection des plus bas desdits calculs de variance et de comparaison à l'échelle absolue pour déterminer si la condition de limitation de flux est présente comprend en outre l'attribution d'une sévérité de ladite condition de limitation de flux sur la base de la valeur de ladite variance la plus basse, dans laquelle facultativement ladite sévérité de ladite limitation de flux se voit attribuer une sévérité choisie dans un groupe constitué de nulle, légère, modérée et sévère. 10
10. Machine de thérapie respiratoire selon la revendication 2 dans laquelle ledit module de détection de limitation de flux réalise une fonction supplémentaire comprenant : 25  
le calcul du rapport de ladite partie inspiration à ladite partie expiration pour chaque respiration sur plusieurs respirations ; et  
le fait de déterminer si ledit rapport tend vers des temps d'inspiration plus longs et des temps d'expiration plus courts, et, si tel est le cas, l'utilisation de ladite tendance comme confirmation de la condition de limitation de flux. 30  
35
11. Machine de thérapie respiratoire selon la revendication 2 dans laquelle ledit module de détection de limitation de flux réalise une fonction supplémentaire comprenant : 40  
le calcul d'un rapport de ladite partie inspiration à ladite partie expiration pour chaque respiration sur plusieurs respirations ; et  
le fait de déterminer si la condition de limitation de flux existe uniquement si elle est indiquée par ledit calcul de ladite variance sur la base des valeurs de variance et des informations de tendance associées audit rapport. 45
12. Machine de thérapie respiratoire selon la revendication 1 dans laquelle ladite pression dudit air est modifiée sur la base d'une détection de la condition de limitation de flux. 50
13. Machine de thérapie respiratoire selon la revendication 12 dans laquelle ladite pression est élevée si la condition de limitation de flux est déterminée comme étant présente pendant au moins 15 secondes dans 55

une fenêtre d'une minute.

14. Machine de thérapie respiratoire selon la revendication 12 dans laquelle ladite pression est périodiquement élevée si la condition de limitation de flux est déterminée comme étant présente jusqu'à ce qu'une certaine pression prédéterminée soit atteinte, auquel moment la condition de limitation de flux est ignorée. 5
15. Machine de thérapie respiratoire selon la revendication 2 dans laquelle un facteur d'amortissement est appliqué à chaque calcul de variance avant l'étape de sélection de la valeur de variance la plus basse, dans laquelle facultativement un polynôme ayant la pente moyenne en tant qu'une entrée est utilisé pour amortir la variance, et/ou ledit facteur d'amortissement atténue l'effet desdites valeurs de variance lorsque la pente moyenne augmente. 10  
15  
20

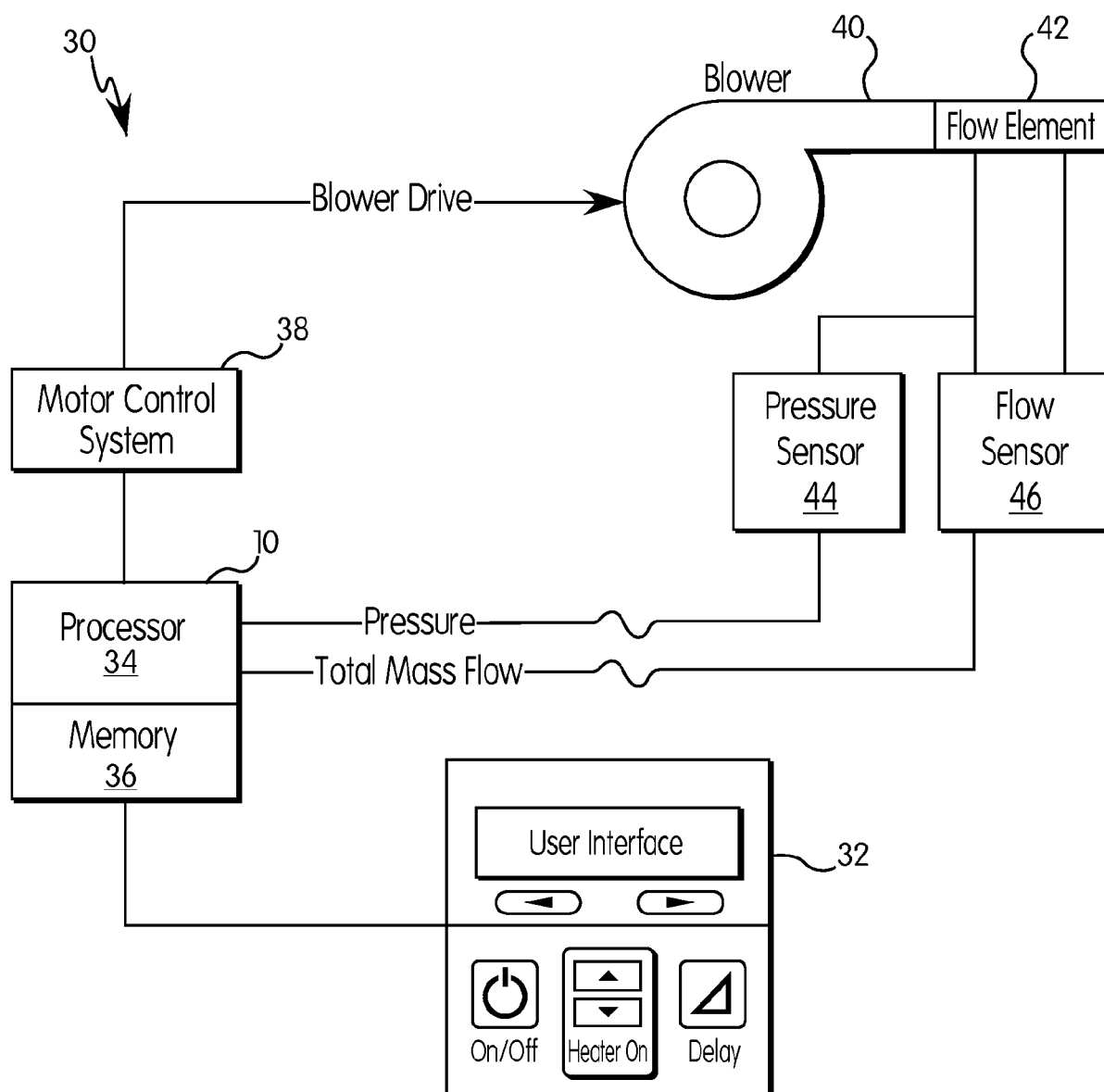


FIG. 1  
(Prior Art)

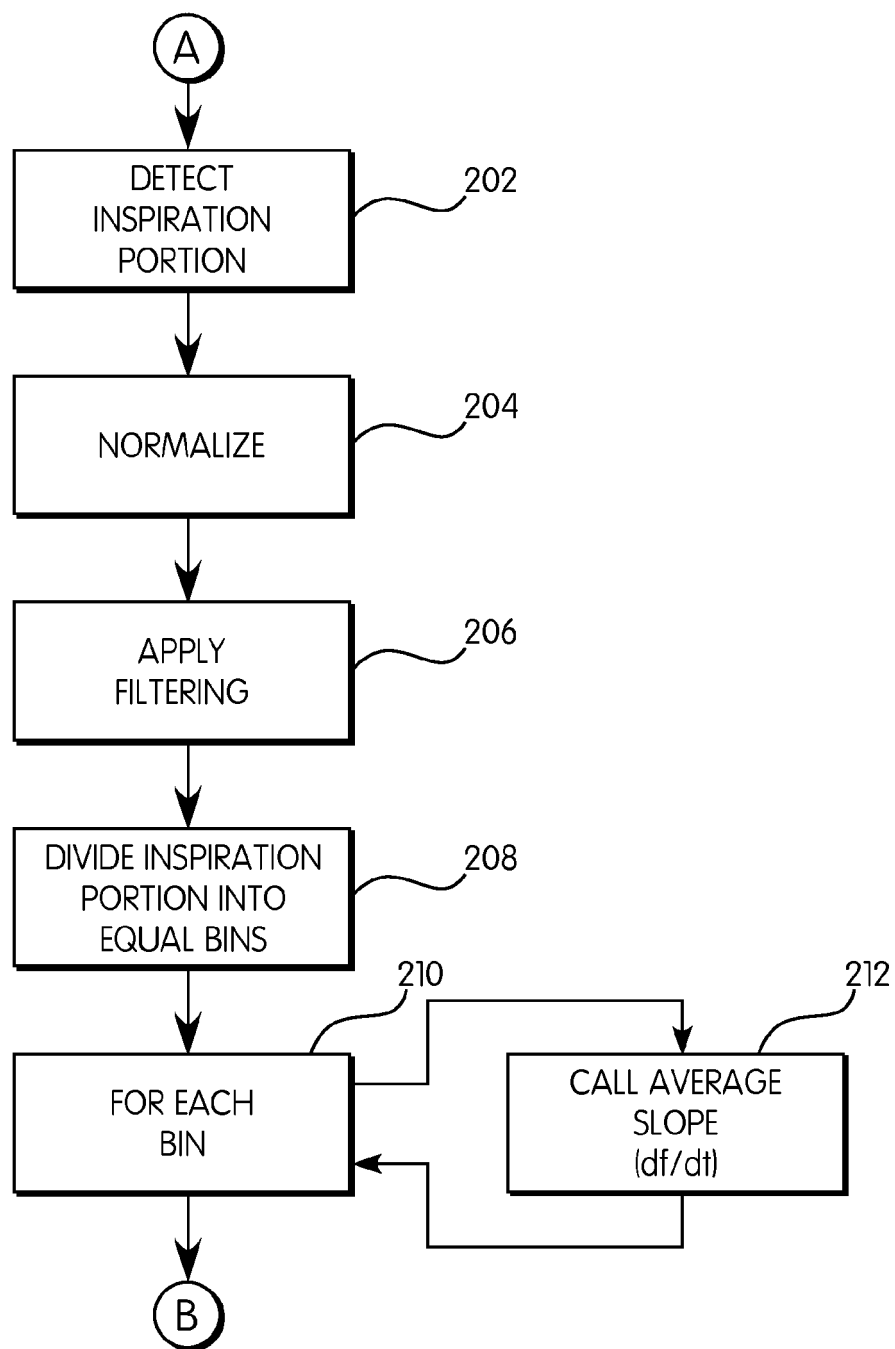


FIG. 2

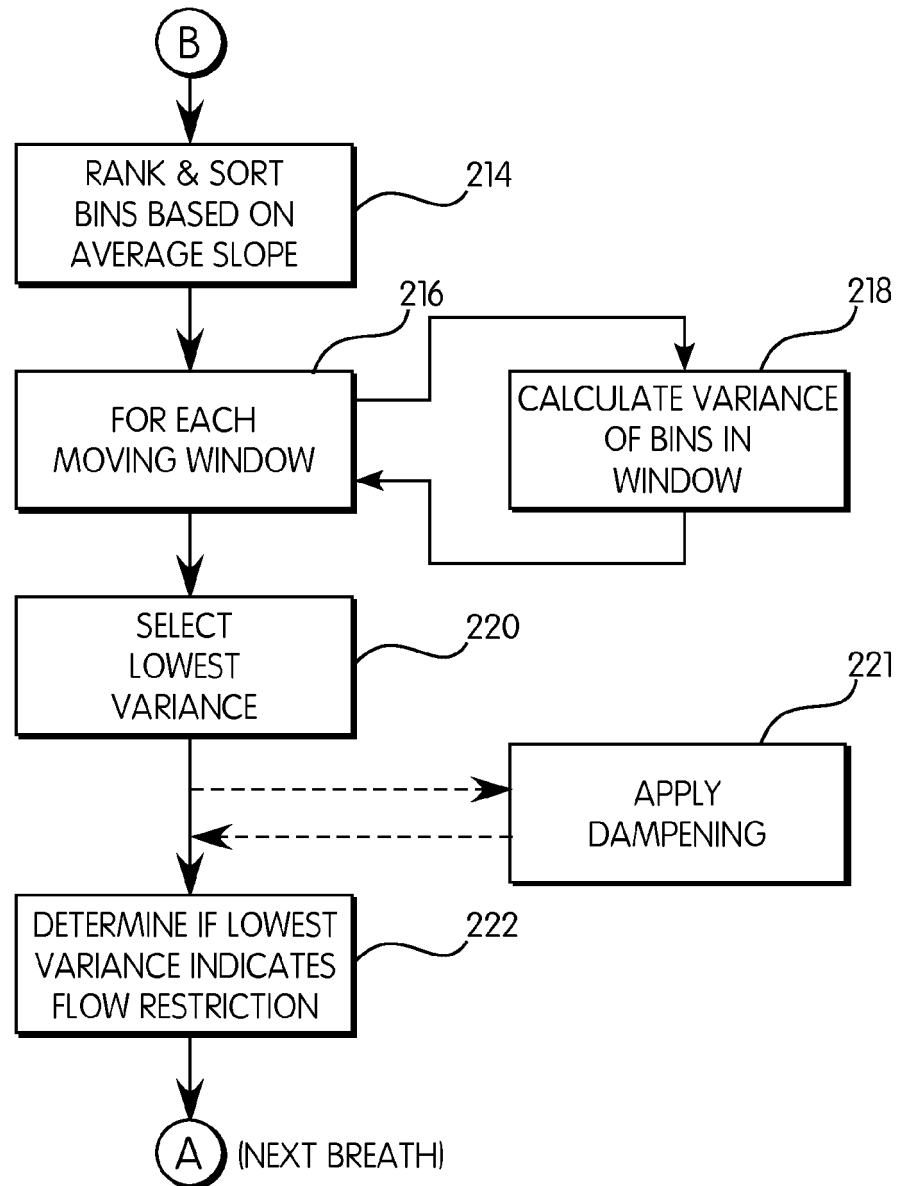


FIG. 2 (continued)

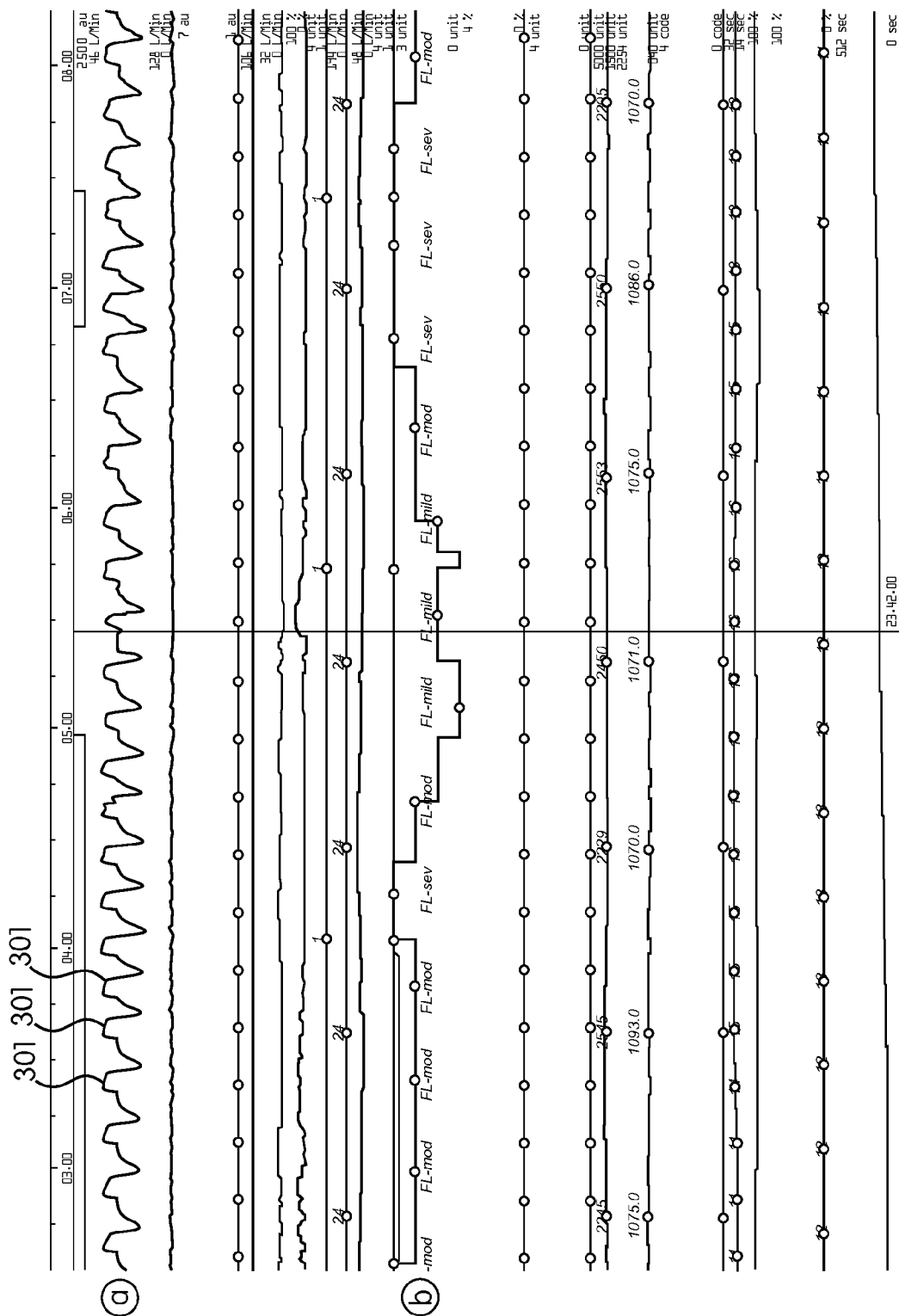


FIG. 3

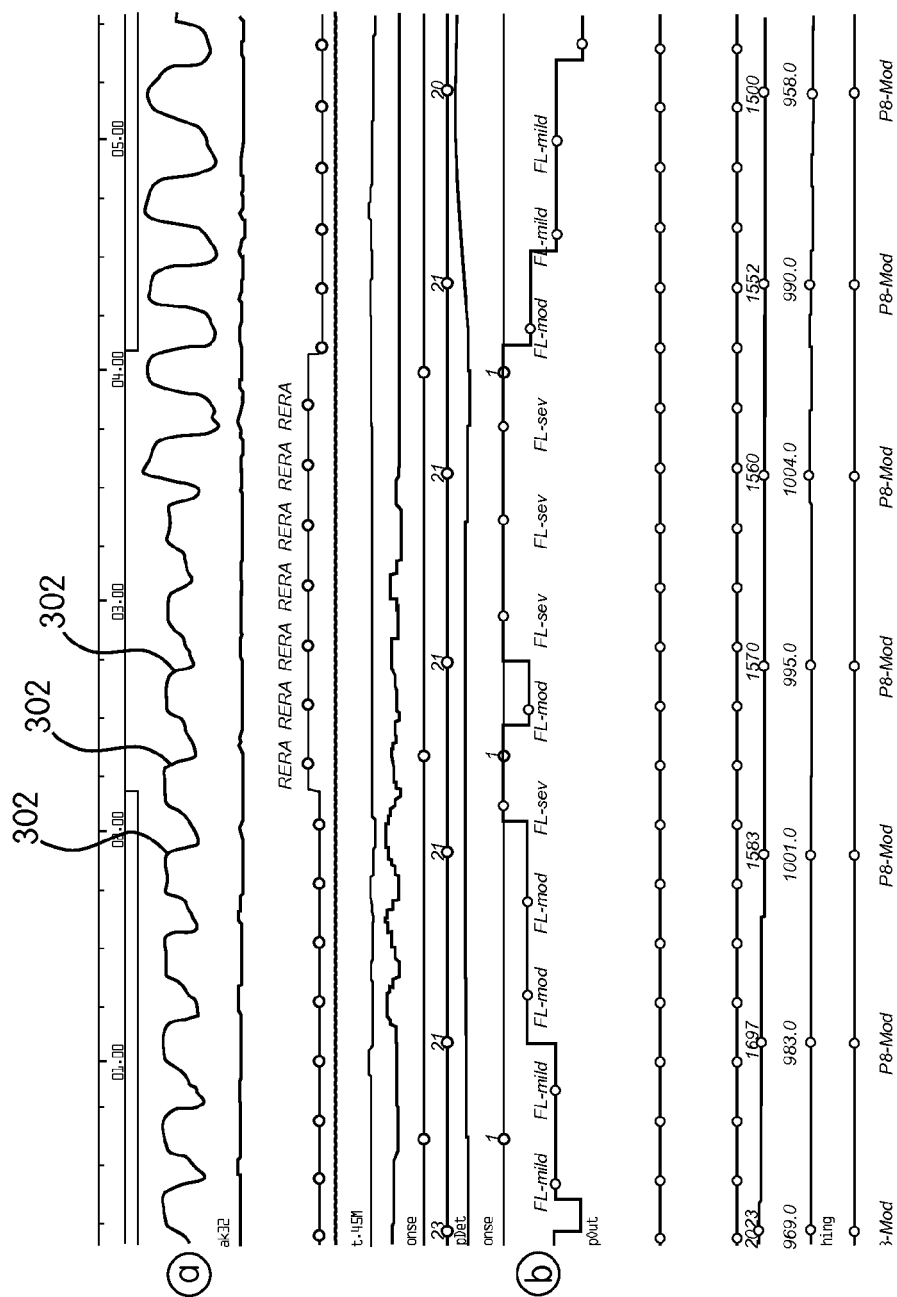


FIG. 3 (continued)

**REFERENCES CITED IN THE DESCRIPTION**

*This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.*

**Patent documents cited in the description**

- US 5335654 A [0008]

|                |                                                                                                    |         |            |
|----------------|----------------------------------------------------------------------------------------------------|---------|------------|
| 专利名称(译)        | 呼吸治疗机具有用于在睡眠呼吸紊乱期间检测吸气流量限制的装置                                                                      |         |            |
| 公开(公告)号        | <a href="#">EP3193713B1</a>                                                                        | 公开(公告)日 | 2019-05-22 |
| 申请号            | EP2015842322                                                                                       | 申请日     | 2015-09-17 |
| [标]申请(专利权)人(译) | 德维尔比斯保健有限责任公司                                                                                      |         |            |
| 申请(专利权)人(译)    | DEVILBISS HEALTHCARE LLC                                                                           |         |            |
| 当前申请(专利权)人(译)  | DEVILBISS HEALTHCARE LLC                                                                           |         |            |
| [标]发明人         | KNEPPER MICHAEL B<br>LAUER JEFFREY J                                                               |         |            |
| 发明人            | KNEPPER, MICHAEL B.<br>LAUER, JEFFREY J.                                                           |         |            |
| IPC分类号         | A61B5/087 A61B5/00 A61M16/00                                                                       |         |            |
| CPC分类号         | A61B5/087 A61B5/4836 A61M16/0069 A61M16/024 A61M2016/0027 A61M2016/0036 A61M2205/52<br>A61M2230/46 |         |            |
| 代理机构(译)        | BARKER BRETTELL LLP                                                                                |         |            |
| 优先权            | 14/489552 2014-09-18 US                                                                            |         |            |
| 其他公开文献         | EP3193713A4<br>EP3193713A1                                                                         |         |            |
| 外部链接           | <a href="#">Espacenet</a>                                                                          |         |            |

# 摘要(译)

在CPAP呼吸治疗机中实现的特征，以确定患者是否患有流量限制条件，如果是，则改变CPAP机器的操作以试图缓解该状况。

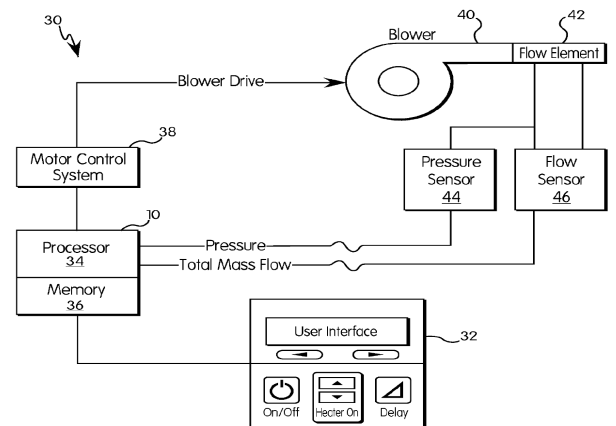


FIG. 1  
(Prior Art)