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Berthon-Jones et al.

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(54) **ADMINISTRATION OF CPAP TREATMENT PRESSURE IN PRESENCE OF APNEA**

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Related U.S. Application Data

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(30) **Foreign Application Priority Data**

Nov. 7, 1997 (AU) PP0269

(51) **Int. Cl.**
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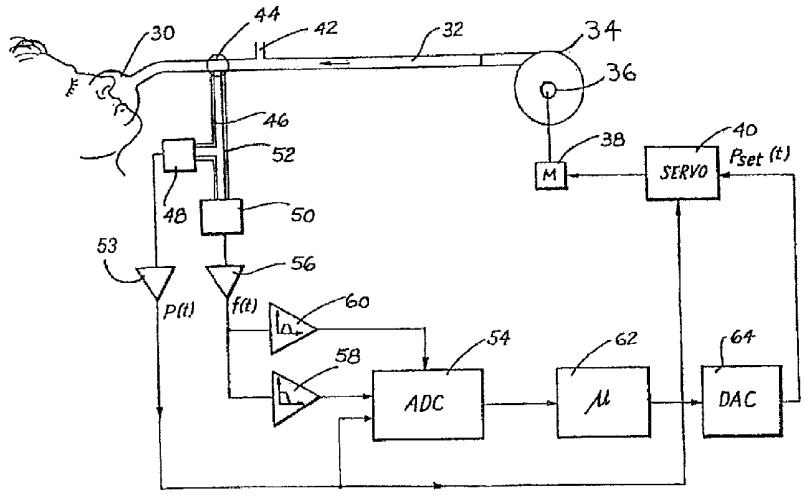
A61M 16/06 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61M 16/0069*** (2014.02); ***A61B 5/0205*** (2013.01); ***A61B 5/4818*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 2503/06; A61B 2560/0456; A61B 2562/187; A61B 5/0002; A61B 5/02028; A61B 5/0205; A61B 5/021; A61B 5/022; A61B 5/02405; A61B 5/02427; A61B 5/0245; A61B 5/02455; A61B 5/0261; A61B 5/031; A61B 5/04012; A61B 5/04017; A61B 5/0404; A61B 5/0428; A61B 5/0444; A61B 5/0484; A61B 5/0533; A61B 5/08; A61B 5/0803; A61B 5/0809; A61B 5/0816; A61B 5/0826; A61B 5/0836; A61B 5/085; A61B 5/087; A61B 5/0876; A61B 5/0878; A61B 5/091; A61B 5/097; A61B 5/11; A61B 5/1102; A61B 5/1116; A61B 5/1118; A61B 5/113; A61B 5/1135; A61B 5/14551; A61B 5/14552; A61B 5/14553; A61B 5/1459; A61B 5/16; A61B 5/4064; A61B 5/411; A61B 5/417; A61B 5/4504; A61B 5/4809; A61B 5/4818; A61B 5/4836; A61B 5/6803; A61B 5/6805; A61B 5/6814; A61B 5/6819; A61B 5/6831; A61B 5/6887; A61B 5/6897; A61B 5/6892; A61B 5/7221; A61B 5/7239; A61B 5/725; A61B 5/7257; A61B 5/7264; A61B 5/7267; A61B 5/7278; A61B 5/7282; A61B 5/7475; A61B 6/541; A61B 7/003; A61B 9/00; A61M 15/00; A61M 15/003; A61M 15/0013; A61M 15/0015; A61M 15/0016; A61M 15/0018; A61M 15/002; A61M 15/0021; A61M 15/0065; A61M 15/008; A61M 15/0083; A61M 15/0085; A61M 15/0086; A61M 15/0088; A61M 15/009; A61M 15/0091; A61M 16/00; A61M 16/0003; A61M 16/0006; A61M 16/0009; A61M 16/0051; A61M 16/0066; A61M 16/0069; A61M 16/04; A61M 16/0463; A61M 16/06; A61M 16/0633; A61M 16/0666; A61M 16/0672; A61M 16/0677; A61M 16/0683; A61M 16/08; A61M 16/0808; A61M 16/0816; A61M 16/0833; A61M 16/085; A61M 16/0866; A61M 16/0875; A61M 16/10; A61M 16/101; A61M 16/1055; A61M 16/1065; A61M 16/1075; A61M 16/12;



A61M 16/125; A61M 16/14; A61M 16/16; A61M 16/20; A61M 16/202; A61M 16/204; A61M 16/205; A61M 16/206

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(57) **ABSTRACT**

CPAP treatment apparatus is disclosed having a controllable flow generator (**34**, **38**, **40**) operable to produce breathable gas at a treatment pressure elevated above atmosphere to a patient by a delivery tube (**32**) coupled to a mask (**30**) having connection with a patient's airway. A sensor (**44**, **50**, **56**, **58**) generates a signal representative of patient respiratory flow, that is provided to a controller (**54**, **62**, **64**). The controller (**54**, **62**, **64**) is operable to determine the occurrence of an apnea from a reduction in respiratory airflow below a threshold, and if an apnea has occurred, to determine the duration of the apnea and to cause the flow generator (**34**, **38**) to increase the treatment pressure. In one preferred form the increase in pressure is zero if the treatment pressure before the apnea exceeds a pressure threshold. Below the pressure threshold the increase in pressure is an increasing of the duration of the apnea multiplied by the between the pressure threshold and the current function difference treatment pressure.

18 Claims, 6 Drawing Sheets

Related U.S. Application Data

continuation of application No. 12/250,188, filed on Oct. 13, 2008, now Pat. No. 8,220,457, which is a continuation of application No. 11/237,278, filed on Sep. 28, 2005, now Pat. No. 8,511,307, which is a continuation of application No. 10/958,854, filed on Oct. 5, 2004, now Pat. No. 6,988,498, which is a continuation of application No. 10/281,743, filed on Oct. 28, 2002, now Pat. No. 6,817,361, which is a continuation of application No. 09/531,915, filed on Mar. 21, 2000, now Pat. No. 6,502,572, which is a continuation-in-part of application No. 09/008,743, filed on Jan. 19, 1998, now Pat. No. 6,367,474.

(51) **Int. Cl.**

A61B 5/0205	(2006.01)
A61B 5/00	(2006.01)
A61M 16/08	(2006.01)

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

CPC ***A61B 5/4836*** (2013.01); ***A61M 16/00*** (2013.01); ***A61M 16/0003*** (2014.02); ***A61M 16/0051*** (2013.01); ***A61M 16/06*** (2013.01); ***A61M 16/0875*** (2013.01); *A61M 2016/0036* (2013.01)

(58) **Field of Classification Search**

USPC 128/200.24, 204.18, 204.21, 204.22,128/204.23, 204.24, 204.25, 204.26, 204.28,128/204.29, 205.11, 205.12, 205.19, 205.23,128/205.24, 205.25

See application file for complete search history.

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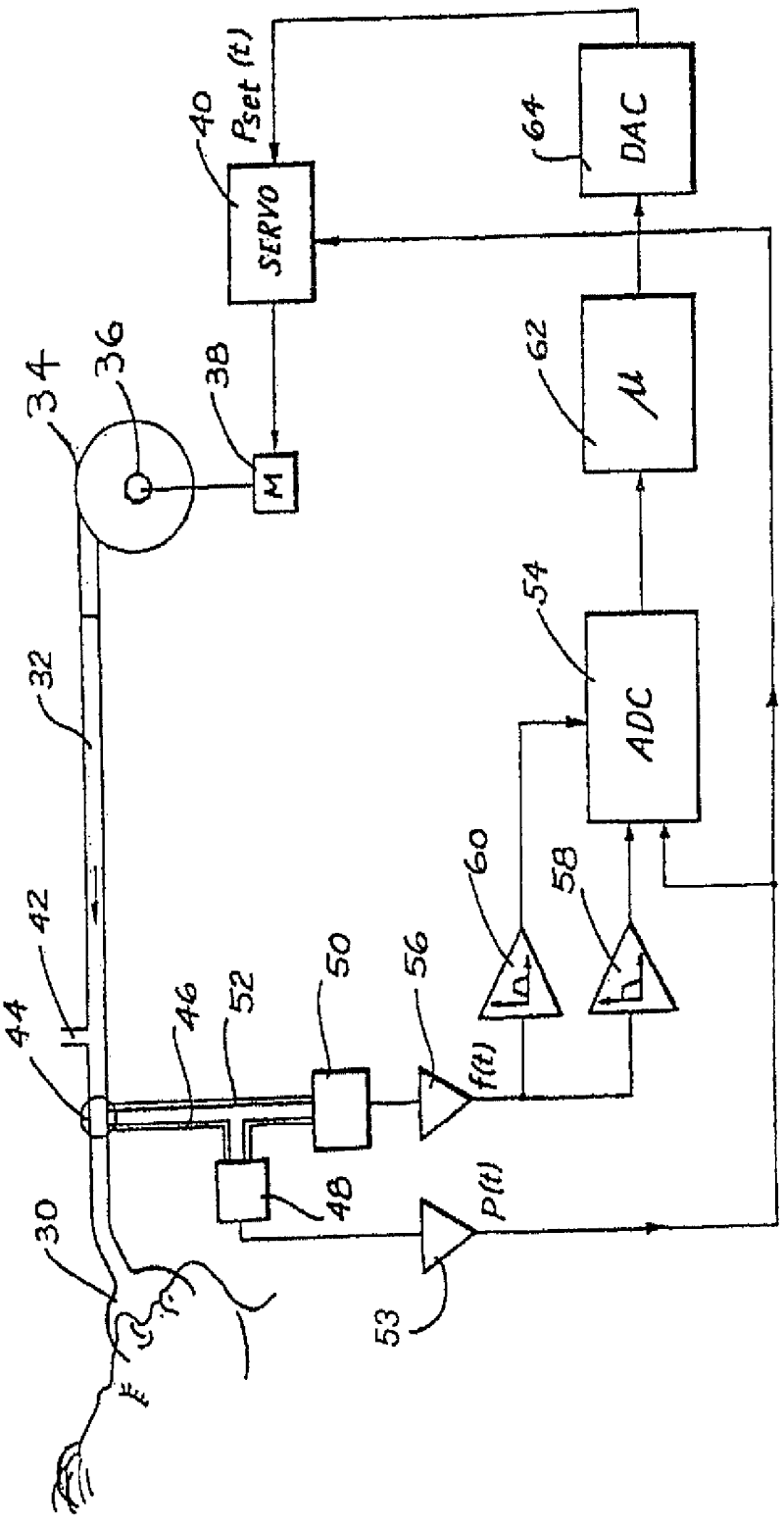
Pset (t)
40
SERVO
64
DAC
62
μ
34
36
38
M
32
54
ADC
60
58
42
44
46
52
50
56
f(t)
48
P(t)
30
53

FIG. 1

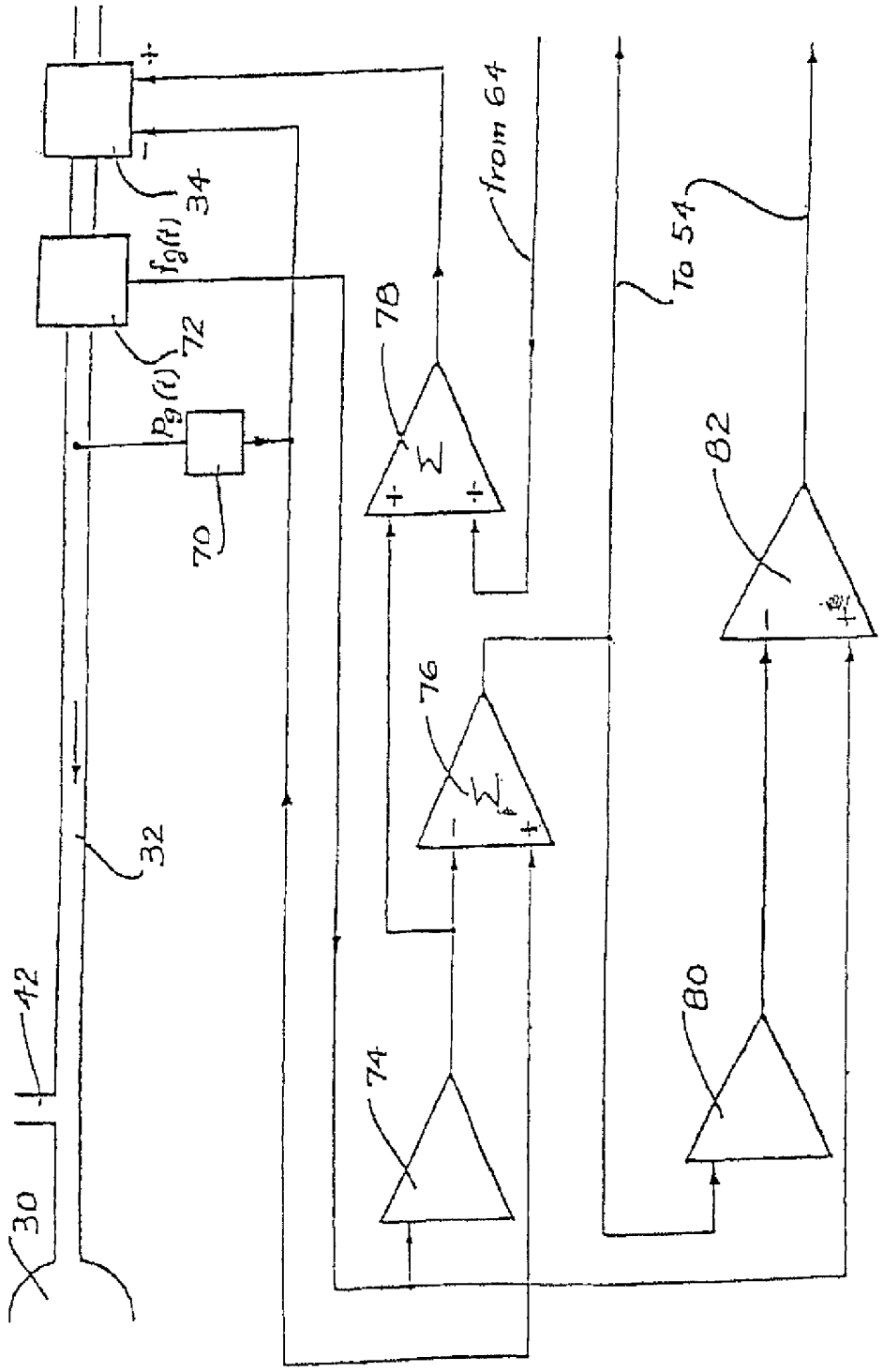

FIG. 2

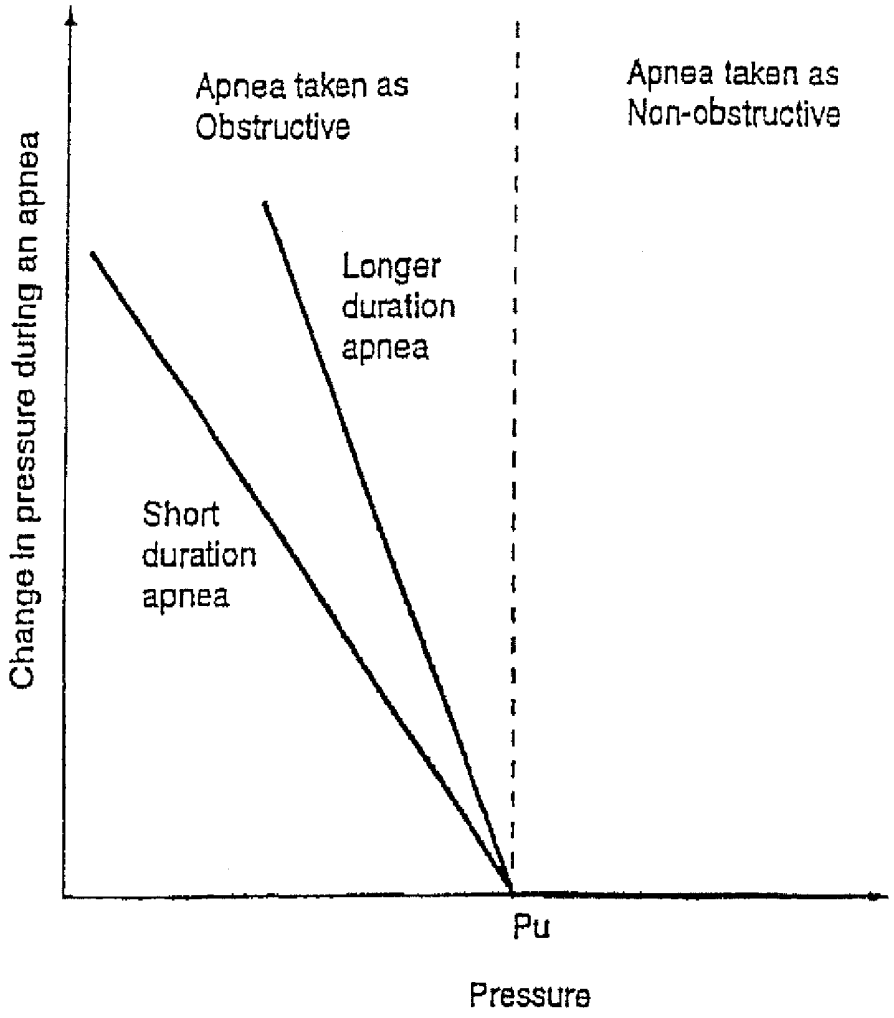
Apnea taken as
Obstructive
Apnea taken as
Non-obstructive
Longer
duration
apnea
Short
duration
apnea
Change in pressure during an apnea
Pu
Pressure

FIG. 3

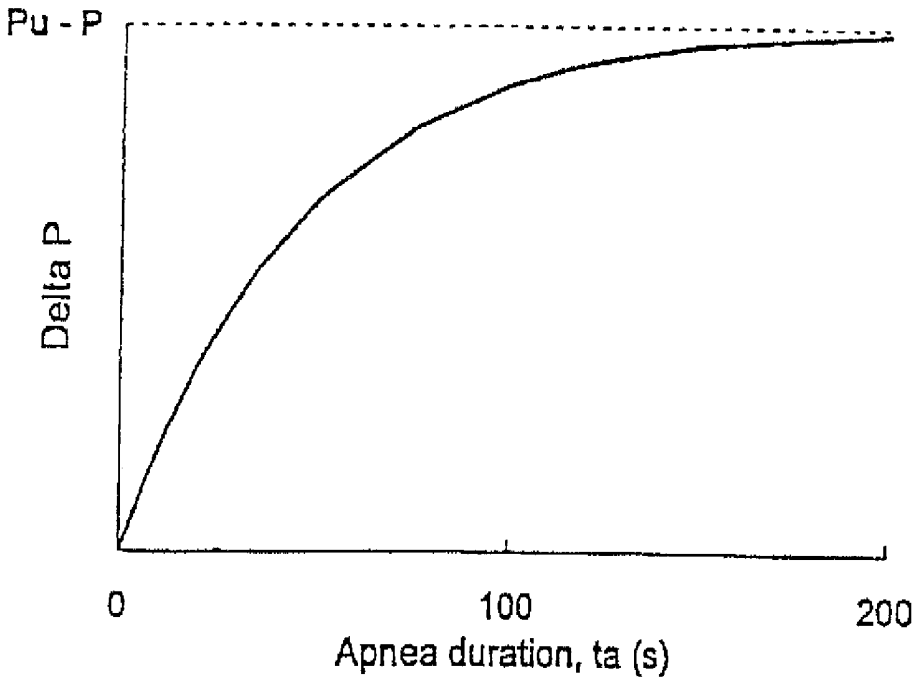

FIG. 4

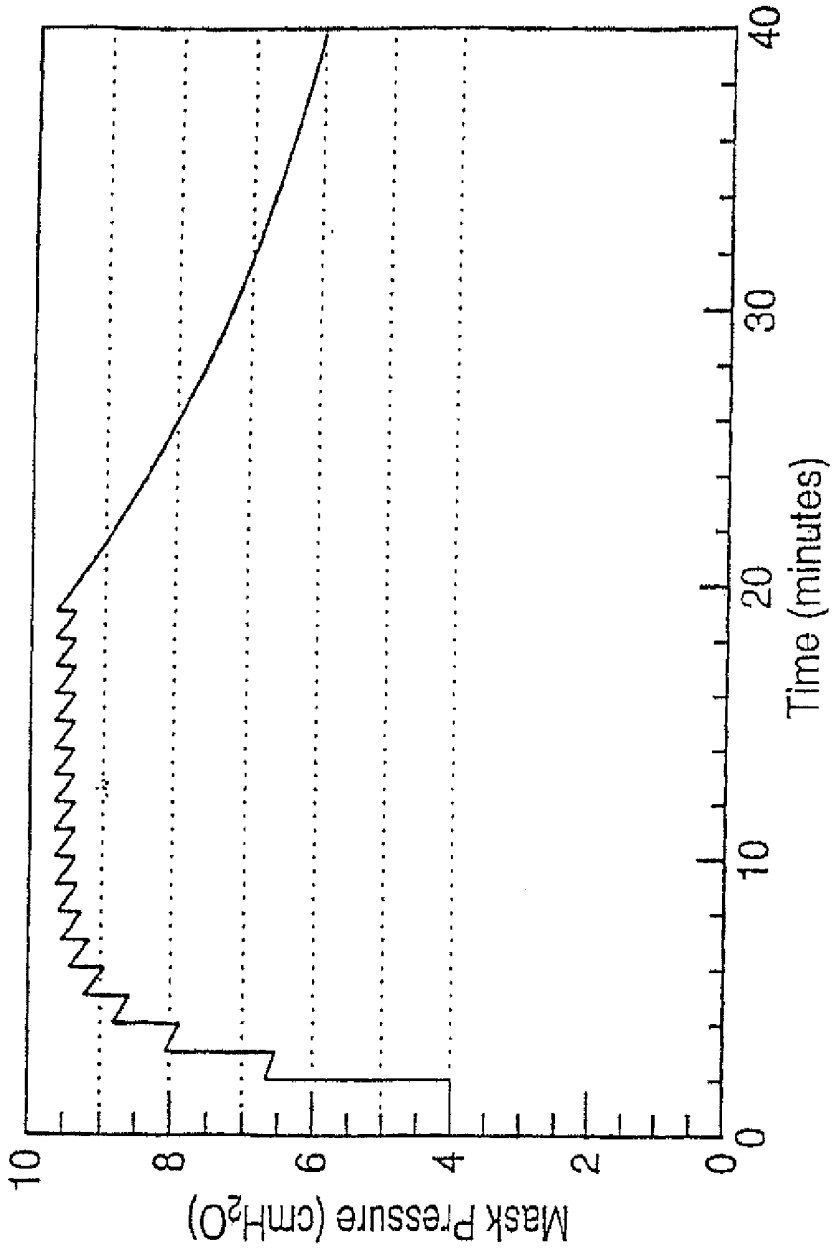

FIG. 5

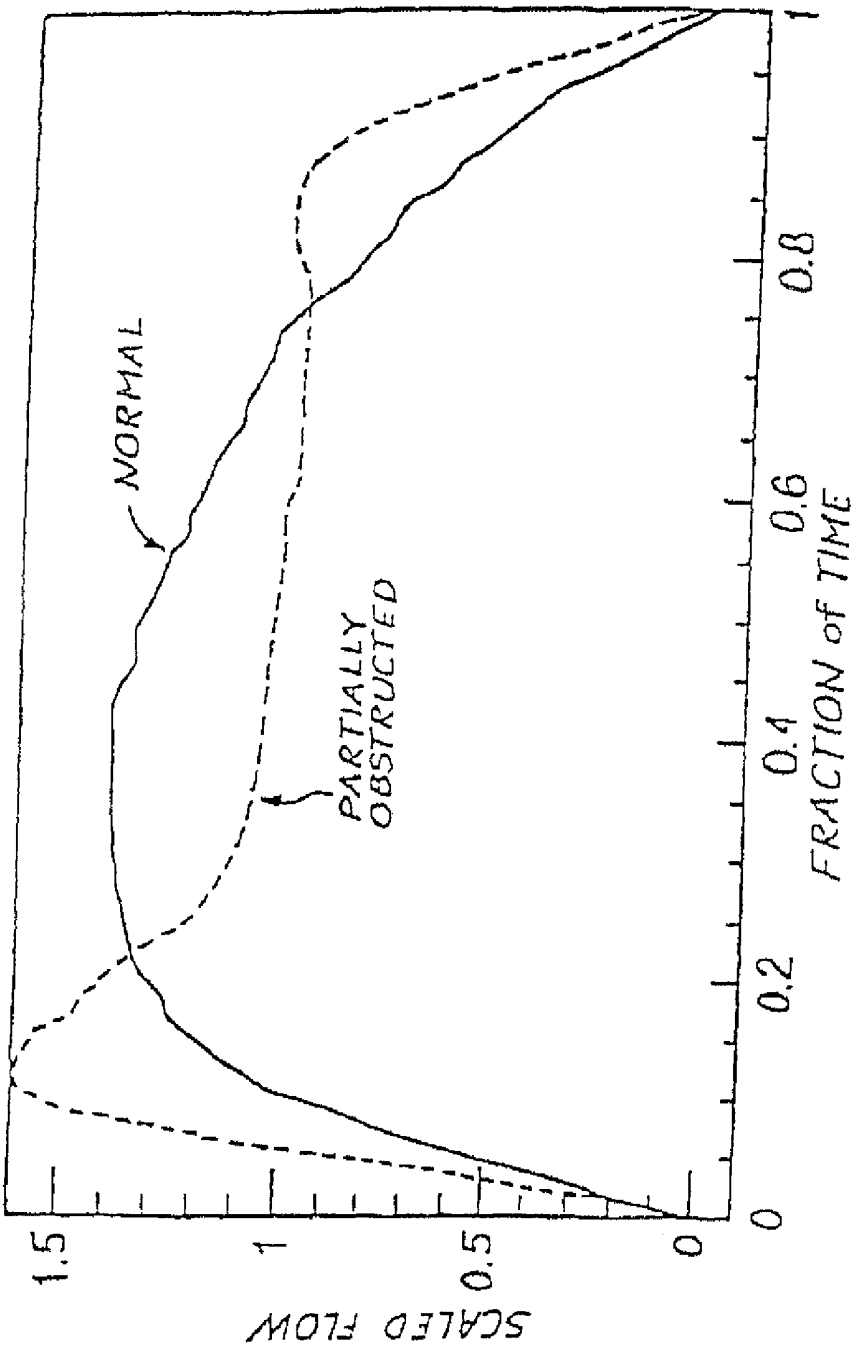
NORMAL
PARTIALLY OBSTRUCTED
SCALED FLOW
1.5
1
0.5
0
0
0.2
0.4
0.6
0.8
1
FRACTION of TIME

FIG. 6

ADMINISTRATION OF CPAP TREATMENT PRESSURE IN PRESENCE OF APNEA

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation of U.S. patent application Ser. No. 13/477,505 (now U.S. Pat. No. 8,684,000), filed May 22, 2012, which is a continuation of U.S. patent application Ser. No. 12/250,188 (now U.S. Pat. No. 8,220,457), filed Oct. 13, 2008, which is a continuation of U.S. patent application Ser. No. 11/237,278 (now U.S. Pat. No. 8,511,307), filed Sep. 28, 2005, which is a continuation of U.S. Pat. No. 6,988,498, issued Jan. 24, 2006, which is a continuation of U.S. Pat. No. 6,817,361, issued Nov. 16, 2004, which is a continuation of U.S. Pat. No. 6,502,572, issued Jan. 7, 2003, which is a continuation-in-part of U.S. Pat. No. 6,367,474, issued Apr. 9, 2002, which claims priority from Australian Application No. PP0269, filed Nov. 7, 1997, the disclosure of which is incorporated herein by reference.

FIELD OF THE INVENTION

This invention relates to the administration of continuous positive airway pressure (CPAP) treatment for partial or complete upper airway obstruction.

BACKGROUND OF THE INVENTION

In the Sleep Apnea syndrome a person stops breathing during sleep. Cessation of airflow for more than 10 seconds is called an "apnea". Apneas lead to decreased blood oxygenation and thus to disruption of sleep. Apneas are traditionally (but confusingly) categorized as either central, where there is no respiratory effort, or obstructive, where there is respiratory effort. With some central apneas, the airway is open, and the subject is merely not attempting to breathe. Conversely, with other central apneas and all obstructive apneas, the airway is closed. The occlusion is usually at the level of the tongue or soft palate. The airway may also be partially obstructed (i.e., narrowed or partially patent). This also leads to decreased ventilation (hypopnea), decreased blood oxygenation and disturbed sleep.

The common form of treatment of these syndromes is the administration of Continuous Positive Airway Pressure (CPAP). The procedure for administering CPAP treatment has been well documented in both the technical and patent literature. An early description can be found in U.S. Pat. No. 4,944,310 (Sullivan). Briefly stated. CPAP treatment acts as a pneumatic splint of the airway by the provision of a positive pressure usually in the range 4-20 cm H_2O. The air is supplied to the airway by a motor driven blower whose outlet passes via an air delivery hose to a nose (or nose and/or mouth) mask sealingly engaged to a patient's face. An exhaust port is provided in the delivery tube proximate to the mask. The mask can take the form of a nose and/or face mask or nasal prongs, pillows or cannulae.

Various techniques are known for sensing and detecting abnormal breathing patterns indicative of obstructed breathing. U.S. Pat. No. 5,245,995 (Sullivan et al.), for example, generally describes how snoring and abnormal breathing patterns can be detected by inspiration and expiration pressure measurements made while a subject is sleeping, thereby leading to early indication of preobstructive episodes or other forms of breathing disorder. Particularly, patterns of respiratory parameters are monitored, and CPAP pressure is raised on the detection of pre-defined patterns to provide increased airway pressure to, ideally, subvert the occurrence of the obstructive episodes and the other forms of breathing disorder.

Automatic detection of partial upper airway obstruction and pre-emptive adjustment of nasal CPAP pressure works to prevent frank obstructive apneas in the majority of subjects with obstructive sleep apnea syndrome. However, some subjects with severe disease progress directly from a stable open upper airway to a closed airway apnea with complete airway closure, with little or no intervening period of partial obstruction. Therefore it is useful for an automatically adjusting CPAP system to also respond to a closed airway apnea by an increase in CPAP pressure. However, it is not desirable to increase CPAP pressure in response to open airway apneas, firstly because this leads to an unnecessarily high pressure and secondly because the high pressure can reflexly cause yet further open airway apneas, leading to a vicious circle of pressure increase.

One method for distinguishing open airway apneas (requiring no increase in pressure) from closed airway apneas (requiring a pressure increase) is disclosed in commonly owned European Publication No. 0 651 971 A1 (corresponding to U.S. Pat. No. 5,704,345). During an apnea, the mask pressure is modulated at 4 Hz with an amplitude of the order of 1 cmH_2O, the induced airflow at 4 Hz is measured, and the conductance of the airway is calculated. A high conductance indicates an open airway. This 'forced oscillation method' requires the ability to modulate the mask pressure at 4 Hz, which increases the cost of the device. Furthermore, the method does not work in the presence of high leak, and can falsely report that the airway is closed if the subject has a high nasal or intrapulmonary resistance.

The present invention is directed to overcoming or at least ameliorating one or more of the foregoing disadvantages in the prior art.

BRIEF SUMMARY OF THE INVENTION

Therefore, the invention discloses a method for the administration of CPAP treatment pressure comprising the steps of:

supplying breathable gas to the patient's airway at a treatment pressure;

determining a measure of respiratory airflow; and

determining the occurrence of an apnea from a reduction in the measure of respiratory airflow below a threshold, and, if having occurred

(i) determining the duration of the apnea; and

(ii) increasing the treatment pressure by an amount which is an increasing function of the duration of the apnea, and a decreasing function of the treatment pressure immediately before the apnea.

The invention further discloses CPAP treatment apparatus comprising:

a controllable flow generator operable to produce breathable gas at a pressure elevated above atmosphere;

a gas delivery tube coupled to the flow generator;

a patient mask coupled to the tube to receive said breathable gas from the flow generator and provide said gas, at a desired treatment pressure, to the patient's airway;

a controller operable to receive input signals and to control operation of said flow generator and hence the treatment pressure; and

sensor means located to sense patient respiratory airflow and generate a signal input to the controller from which patient respiratory airflow is determined;

and wherein said controller is operable to determine the occurrence of an apnea from a reduction in said respiratory airflow below a threshold, and if having occurred, to determine the duration of said apnea and cause said flow generator to increase CPAP treatment pressure by an amount that is an increasing function of said apnea duration, and a decreasing function of the treatment pressure immediately prior to said apnea.

The invention yet further provides CPAP treatment apparatus comprising:

a controllable flow generator operable to produce breathable gas to be provided to a patient at a treatment pressure elevated above atmosphere; and

a controller operable to receive input signals representing patient respiratory airflow, and to control operation of said flow generator and hence the treatment pressure;

and wherein said controller is operable to determine the occurrence of an apnea

from a reduction in said respiratory airflow below a threshold, and, if having occurred,

to determine the duration of said apnea and cause said flow generator to increase CPAP

treatment pressure by an amount that is an increasing function of said apnea duration, and a decreasing function of the treatment pressure immediately prior to said apnea.

Preferably, the increase in treatment pressure is zero if the treatment pressure before the apnea exceeds a pressure threshold. The increase in pressure below the pressure threshold can be an increasing function of the duration of the apnea, multiplied by the difference between the pressure threshold and the current treatment pressure. Further, the increasing function of apnea duration is linear on apnea duration. Advantageously, said increasing function of apnea duration is zero for zero apnea duration, and exponentially approaches an upper limit as apnea duration goes to infinity.

The occurrence of an apnea can be determined by calculating the RMS respiratory airflow over a short time interval, calculating the RMS respiratory airflow over a longer time interval, and declaring an apnea if the RMS respiratory airflow over the short time interval is less than a predetermined fraction of the RMS respiratory airflow over the longer time interval. There also can be the further step or action of reducing the treatment pressure towards an initial treatment pressure in the absence of a further apnea.

In a preferred form, said sensor means can comprise a flow sensor, and said controller derives respiratory airflow therefrom.

In one preferred form said initial treatment pressure is 4 cmH_2O, said measure of respiratory airflow is the 25% of the RMS airflow over the preceding 5 minutes. In this preferred form no increase in pressure is made for apneas of less than 10 seconds duration, or for apneas where the treatment pressure immediately prior to the apnea is more than 10 cmH_2O, but otherwise, the lower the treatment pressure immediately prior to the apnea, and the longer the apnea, the greater the increase in treatment pressure, up to a maximum of 8 cmH_2O per minute of apnea. In this preferred form, if there is no apnea the treatment pressure is gradually reduced towards the initial minimum pressure with a time constant of 20 minutes.

The method and apparatus can advantageously be used in concert with one or more other methods for determining the occurrence of partial upper airway obstruction, such that either complete or partial upper airway obstruction can lead to an increase in pressure, but once there is no longer either complete or partial obstruction, the pressure will gradually reduce towards the initial minimum pressure.

In one particularly preferred form, partial obstruction is detected as either the presence of snoring, or the presence of characteristic changes in the shape of the inspiratory flow-vs-time curve indicative of inspiratory airflow limitation.

The method and apparatus can also advantageously be used in concert with the 'forced oscillation method' for measuring airway patency (referred to above as European Publication No. 0 651 971 A1, U.S. Pat. No. 5,704,345 whose disclosure is hereby incorporated by reference), in which the CPAP pressure is modulated with an amplitude of for example 1 cm H_2O at 4 Hz, the induced airflow at 4 Hz is measured, the conductance of the airway calculated by dividing the amplitude of the induced airflow by the pressure modulation amplitude, and the additional requirement imposed that the treatment pressure is only increased if said conductance is greater than a threshold.

Closed airway apneas are most likely to occur at low CPAP pressures, because high CPAP pressures splint the airway partially or completely open whereas pressure-induced open airway apneas are most likely to occur at high CPAP pressures, at least partially because high CPAP pressures increase lung volume and thereby stimulate the Hering-Breuer reflex, leading to inhibition of breathing. Therefore, the lower the existing CPAP pressure, the more likely an apnea is to be of the closed airway variety, and the more appropriate it is to increase the treatment pressure, whereas the higher the existing CPAP pressure, the more likely an apnea is to be of the open airway variety, and the more appropriate it is to leave the CPAP pressure unchanged. Generally apneas of less than 10 seconds duration are regarded as non-pathological, and there is no need to increase CPAP pressure, whereas very long apneas require treatment. The present invention will correctly increase the CPAP pressure for most closed airway apneas, and correctly leave the CPAP pressure unchanged for most open airway apneas.

The present invention can be combined with an independent pressure increase in response to indicators of partial upper airway obstruction such as snoring or changes in shape of the inspiratory flow-time curve. In this way it is possible in most subjects to achieve pre-emptive control of the upper airway, with pressure increases in response to partial upper airway obstruction preventing the occurrence of closed airway apneas. In the minority of subjects in whom pre-emptive control is not achieved, this combination will also correctly increase the CPAP pressure in response to those closed airway apneas that occur at low CPAP pressure without prior snoring or changes in the shape of the inspiratory flow-time curve. Furthermore, the combination will avoid falsely increasing the CPAP pressure in response to open airway apneas induced by high pressure.

Some open airway apneas can occur at low pressure. By combining the forced oscillation method with the present invention, with the additional requirement that there be no increase in pressure if the forced oscillation method detects an open airway, false increases in pressure in response to open airway apneas at low pressure will be largely avoided.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the invention will now be described with reference to the accompanying drawings, in which:

FIG. **1** shows, in diagrammatic form, apparatus embodying the invention;

FIG. **2** shows an alternative arrangement of the apparatus of FIG. **1**;

FIG. **3** shows a plot of two pressure change characteristics as a function of apnea duration;

FIG. **4** shows a plot of the apnea duration function;

FIG. **5** shows a graph of CPAP treatment pressure versus time for a preferred embodiment of the invention; and

FIG. **6** shows a graph of scaled (normalized) air flow with time for normal and partially obstructed inspiration.

DETAILED DESCRIPTION

FIG. **1** shows, in diagrammatic form, CPAP apparatus in accordance with one embodiment. A mask **30**, whether either a nose mask and/or a face mask, is sealingly fitted to a patient's face. Breathable gas in the form of fresh air, or oxygen enriched air, enters the mask **30** by flexible tubing **32** which, in turn is connected with a motor driven turbine **34** to which there is provided an air inlet **36**. The motor **38** for the turbine is controlled by a motor-servo unit **40** to commence, increase or decrease the pressure of air supplied to the mask **30** as CPAP treatment. The mask **30** also includes an exhaust port **42** that is close to the junction of the tubing **34** with the mask **30**.

Interposed between the mask **30** and the exhaust **42** is a linear flow-resistive element **44**. In practice, the distance between mask **30** and exhaust **42**, including flow resistive element **44** is very short so as to minimize deadspace volume. The mask side of the flow-resistive element **44** is connected by a small bore tube **46** to a mask pressure transducer **48** and to an input of a differential pressure transducer **50**. Pressure at the other side of the flow-resistive element **44** is conveyed to the other input of the differential pressure transducer **50** by another small bore tube **52**.

The mask pressure transducer **48** generates an electrical signal in proportion to the mask pressure, which is amplified by amplifier **53** and passed both to a multiplexer/ADC unit **54** and to the motor-servo unit **40**. The function of the signal provided to the motor-servo unit **40** is as a form of feedback to ensure that the actual mask static pressure is controlled to be closely approximate to the set point pressure.

The differential pressure sensed across the linear flow-resistive element **44** is output as an electrical signal from the differential pressure transducer **50**, and amplified by another amplifier **56**. The output signal from the amplifier **56** therefore represents a measure of the mask airflow. The linear flow-resistive element **44** can be constructed using a flexible-vaned iris. Alternatively, a fixed orifice can be used, in which case a linearization circuit is included in amplifier **52**, or a linearization step such as table lookup included in the operation of controller **62**.

The output signal from the amplifier **56** is low-pass filtered by the low-pass filter **58**, typically with an upper limit of 10 Hz, in order to remove non-respiratory noise. The amplifier **56** output signal is also bandpassed by the bandpass filter **60**, and typically in a range of 30-100 Hz to yield a snoring signal. The outputs from both the low-pass filter **58** and the bandpass filter **60** are provided to the digitizer (ADC) unit **54**. The digitized respiratory airflow (FLOW), snore, and mask pressure (P.sub.mask) signals from ADC **54** are passed to a controller **62** typically constituted by a micro-processor based device also provided with program memory and data processing storage memory.

The controller **62** outputs a pressure request signal which is converted to a voltage by DAC **64**, and passed to the motor-servo unit **40**. This signal therefore represents the set point pressure P.sub.set(t) to be supplied by the turbine **34** to the mask **30** in the administration of CPAP treatment. The controller **62** is programmed to perform a number of processing functions, as presently will be described.

As an alternative to the mask pressure transducer **48**, a direct pressure/electrical solid state transducer (not shown) can be mounted from the mask with access to the space therewithin, or to the air delivery tubing **32** proximate the point of entry to the mask **30**.

Further, it may not be convenient to mount the flow transducer **44** at or near the mask **30**, nor to measure the mask pressure at or near the mask. An alternative arrangement, where the flow and pressure transducers are mounted at or near the air pressure generator (in the embodiment being the turbine **34**) is shown in FIG. **2**.

The pressure p.sub.g(t) occurring at the pressure generator **34** outlet is measured by a pressure transducer **70**. The flow f.sub.g(t) through tubing **32** is measured with flow sensor **72** provided at the output of the turbine **34**. The pressure loss along tubing **32** is calculated in element **74** from the flow through the tube f.sub.g(t), and a knowledge of the pressure-flow characteristic of the tubing, for example by table lookup. The pressure at the mask p.sub.m is then calculated in subtraction element **76** by subtracting the tube pressure loss from p.sub.g(t).

The pressure loss along tube **32** is then added to the desired set pressure at the mask p.sub.set(t) in summation element **78** to yield the desired instantaneous pressure at the pressure generator **34**. Preferably, the controller of the pressure generator **34** has a negative feedback input from the pressure transducer **70**, so that the desired pressure from step **78** is achieved more accurately. The flow through the exhaust **42** is calculated from the pressure at the mask (calculated in element **76**) from the pressure-flow characteristic of the exhaust in element **80**, for example by table lookup. Finally, the mask flow is calculated by subtracting the flow through the exhaust **42** from the flow through the tubing **32**, in subtraction element **82**.

The methodology put into place by the controller **62** will now be described. In a first embodiment, there is a pressure response to apneas, but not to indicators of partial obstruction, and therefore snore detection bandpass filter **60** is not required.

An initial CPAP treatment pressure, typically 4 cmH.sub.2O, is supplied to the subject. The FLOW signal is processed to detect the occurrence of an apnea (as will presently be discussed) and, at the same time the P.sub.mask signal is recorded. When it is determined that an apnea has occurred its duration is recorded. At the same time P.sub.mask is compared against a pressure threshold, P.sub.u. If P.sub.mask is at or above P.sub.u the controller will act to maintain or reduce that pressure. If, on the other hand, P.sub.mask is below P.sub.u, the controller will act to increase the treatment pressure by an amount .DELTA.P.

In a preferred form, .DELTA.P is determined as follows

$$.DELTA.P=[P.sub.u-P]f(t.sub.a) \quad (1)$$

where

.DELTA.P is the change in pressure (cmH.sub.2O)

P.sub.u is the pressure threshold, which in an embodiment can be 10 cmH.sub.2O

P is the current treatment pressure immediately before the apnea (cmH.sub.20)

t.sub.a is the apnea duration(s)

f(t.sub.a) is a function that is a monotonically increasing function of t.sub.a, zero for t.sub.a=0

FIG. **3** is a graphical representation of equation (1), showing a region below P.sub.u where it is taken that an apnea is obstructive and demonstrating two cases of the

.DELTA.P characteristic as a function of apnea duration (i.e., short and longer) such that .DELTA.P is an increasing function of apnea duration and a decreasing function of the current treatment pressure. Above P.sub.u, it is taken that the apnea is non-obstructive, and .DELTA.P is held to be zero for all values of the current treatment pressure.

One form of the function f(t.sub.a) is:

$$1f(ta)=rtaP\max \quad (2)$$

In one embodiment the parameters can be:

r=0.13 cmH.sub.2O.s.sup.−1

.DELTA.P.sub.max=6 cmH.sub.2O

Another form of the function f(t.sub.a) is:

$$f(t.\mathrm{sub}.a)=1-\exp(-kt.\mathrm{sub}.a) \quad (3)$$

In one embodiment the parameter can be k=0.02 s.sup.−1

FIG. **4** is a graphical representation of equation (3) for the parameters given above.

The controller **62** implements the foregoing methodology using the following pseudo-code.

```
Set apnea duration to zero
Clear "start of breath" flag
Set initial CPAP pressure to 4 cmH.sub.2O.
Set maximum delta pressure due to apnea to 6
cmH.sub.2O.
Set top roll-off pressure to initial CPAP pressure
plus maximum delta pressure due to apnea.
REPEAT
Sample mask airflow (in L/sec) at 50 Hz.
Calculate mask leak as mask airflow low pass
filtered with a time constant of 10 seconds.
Check for presence and duration of any apnea
Check for start of breath.
IF start of breath flag set:
IF apnea duration greater than 10 seconds AND
current CPAP pressure less than top roll-off pressure:
Set delta pressure for this apnea to (top roll-off
pressure--current CPAP pressure)/maximum delta pressure due to
apnea times 8 cmH.sub.2O per minute of apnea duration.
Add delta pressure for this apnea to total delta
pressure due to apnea, and truncate to maximum delta pressure
due to apnea.
Reset apnea duration to zero.
ELSE
Reduce total delta pressure due to apnea with a time
constant of 20 minutes.
End
Set CPAP pressure to initial CPAP pressure plus
total delta pressure due to apnea.
Clear start of breath flag.
END
END
```

This implementation is suitable for subjects in whom obstructive apneas are controlled at a CPAP pressure of less than 10 cmH.sub.2O. Increasing the maximum delta pressure due to apnea from 6 cmH.sub.2O to 10 cmH.sub.2O would permit the prevention of obstructive apneas in the majority of subjects, in exchange for an increase in undesirable pressure increases due to open airway apneas.

The procedure "Check for presence and duration of any apnea" can be implemented using the following pseudocode:

```
Calculate 2 second RMS airflow as the RMS airflow
over the previous 2 seconds.
Calculate long term average RMS airflow as the 2
second RMS airflow, low pass filtered with a time constant of
300 seconds.
IF 2 second RMS airflow is less than 25% of long
term average RMS airflow:
Mark apnea detected and increment apnea duration by
{fraction (1/50)} second.
END
The procedure, "Check for start of breath" is
implemented by the following pseudocode:
IF respiratory airflow is inspiratory AND
respiratory airflow on previous sample was not inspiratory.
Set "start of breath" flag.
END
```

FIG. **5** shows the above method and apparatus in operation. The mask **30** was connected to a piston driven breathing simulator set to a normal respiratory rate and depth, and programmed to introduce a 20 second apnea once per minute from the 2nd minute to the 20th minute. In operation, the pressure remained at the initial pressure of 4 cmH.sub.20 until the first apnea, which led to a brisk increase in mask pressure. The pressure then decayed slightly during the subsequent 40 seconds of normal breathing.

Subsequent apneas produced smaller increments, and the mask pressure settled out to approximately 9.5 cmH.sub.2O. In most actual patients, the number of apneas would reduce as the pressure increased. Because the pressure due to repetitive apneas cannot exceed 10 cmH.sub.2O, and most pressure-induced open airway apneas occur at very high pressures typically above 10 cmH.sub.2O, this algorithm will not falsely or needlessly increase pressure in response to most pressure-induced open airway apneas, thus avoiding a vicious cycle of high pressure leading to open airway apneas leading to yet further pressure increase.

The above embodiment can be considerably improved by the addition of independent pressure increases in response to partial upper airway obstruction indicated by the presence of snoring or changes in the shape of the inspiratory flow-vs-time curve. In the majority of subjects, in whom substantial periods of snoring or flow limitation exist prior to any closed airway apneas, the CPAP pressure will increase in response to said snoring and/or changes in the shape of the inspiratory flow-vs-time curve, to a sufficient level to largely eliminate severe partial obstruction, without any apneas of any kind occurring. In those subjects in whom closed airway apneas appear with little or no prior period of partial obstruction, the first few apneas will produce a brisk increase in CPAP pressure as previously discussed, and in general this will provide sufficient partial support to the airway to permit periods of detectable partial obstruction, preventing any further apneas from occurring.

This second embodiment is implemented using the following pseudocode.

```
Set initial CPAP pressure to 4 cmH.sub.2O.
Set apnea duration to zero
Clear "start of breath" flag
REPEAT every {fraction (1/50)} of a second
Sample mask pressure (in cmH.sub.2O), mask airflow
(in L/sec), and snore (1 unit corresponds loosely to a typical
snore).
Calculate mask leak as mask airflow low pass
filtered with a time constant of 10 seconds.
Adjust snore signal for machine noise.
Check for presence and duration of any apnea.
Check for start of breath.
IF start of breath flag set:
IF apnea duration greater than 10 seconds AND
current CPAP pressure less than 10 cmH.sub.2O:
Set delta pressure for this apnea to (10--current
CPAP pressure)/6 times 8 cmH.sub.2O per minute of apnea
duration.
```

-continued

```
    Add delta pressure for this apnea to total delta
pressure due to apnea, and truncate to 16 cmH.sub.2O
    Reset apnea duration to zero.
    ELSE
    Reduce total delta pressure due to apnea with a time
constant of 20 minutes.
    END
    Calculate flow limitation index.
    Calculate flow limitation threshold.
      IF flow limitation index is less than said
threshold:
    Set flow limitation delta pressure for this breath
to 3 cmH.sub.2O times (threshold-flow limitation index).
    Add flow limitation delta pressure for this breath
to total delta pressure due to flow limitation, and truncate
to 16 cmH.sub.2O.
    ELSE
    Reduce total delta pressure due to flow limitation
with a time constant of 10 minutes.
    END
    Calculate mean snore for breath.
    Calculate snore threshold.
      IF mean snore exceeds said threshold:
set delta pressure due to snore for this breath to 3
cmH.sub.2O times (mean snore for this breath--threshold).
    Add delta pressure due to snore for this breath to
total delta pressure due to snore, and truncate to 16
cmH.sub.2O.
    ELSE
    Reduce total delta pressure due to snore with a time
constant of 10 minutes.
END
      Set CPAP pressure to 4 cmH.sub.2O plus total delta
pressure due to apnea plus total delta pressure due to snore
plus total delta pressure due to flow limitation, and truncate
to 20 cmH.sub.2O.
    Clear start of breath flag.
    END
    END
```

In the above implementation, apneas can only cause the CPAP pressure to rise as far as 10 cmH.sub.2O, but subsequently, indicators of partial obstruction can increase the CPAP pressure to 20 cmH.sub.2O, which is sufficient to treat the vast majority of subjects.

The procedure "Adjust snore for machine noise" is described by the following pseudocode

```
    Machine noise=K1*mask pressure+K2*mask pressure
squared+K3*mask flow+K4*time derivative of mask flow+K5*time
derivative of mask pressure.
    Adjusted snore signal=raw snore signal-machine
noise.
    where the constants K1 to K5 are determined
empirically for any particular physical embodiment, and for a
particular machine may be zero.  In other embodiments, blower
fan speed measured with a tachometer or pressure at the blower
may be used instead of mask pressure.
```

The procedure "Calculate flow limitation index" is described by the following pseudocode:

```
      Identify the inspiratory portion of the preceding
breath
      Note the duration of inspiration.
      Calculate the mean inspiratory airflow.
```

For each sample point over said inspiratory portion, calculate a normalized inspiratory airflow by dividing the inspiratory airflow by the mean inspiratory airflow.

Identify a mid-portion consisting of those sample points between 25% and 75% of the duration of inspiration.

Calculate the flow limitation index as the RMS deviation over said mid-portion of (normalized inspiratory airflow−1)

The logic of the above algorithm is as follows: partial upper airway obstruction in untreated or partially treated Obstructive Sleep Apnea syndrome, and the related Upper Airway Resistance syndrome, leads to mid-inspiratory flow limitation, as shown in FIG. **6**, which shows typical inspiratory waveforms respectively for normal and partially obstructed breaths after scaling (normalizing) to equal mean amplitude and duration.

For a totally flow-limited breath, the flow amplitude vs. time curve would be a square wave and the RMS deviation would be zero. For a normal breath, the RMS deviation is approximately 0.2 units, and this deviation decreases as the flow limitation becomes more severe.

In some patients, it is not possible to prevent all upper airway obstruction, even at maximum pressure. In addition, there is a trade-off between the possible advantage of increasing the pressure in response to snoring and the disadvantage of increased side effects. This trade-off is implemented in procedure "calculate snore threshold" by looking up the snore threshold in the following table:

```
1 Pressure Threshold (cmH.sub.2O) (snore units) Description
<10 0.2 very soft 10-12 0.25 12-14 0.3 soft 14-16 0.4 16-18
0.6 moderate >18 1.8 loud
```

For similar reasons, the procedure "calculate flow limitation threshold" sets the flow limitation threshold to a lower value corresponding to more severe flow limitation, if the pressure is already high or if there is a large leak:

```
      IF mask leak is greater than 0.7 L/sec
      set leak roll-off to 0.0
      ELSE if mask leak is less than 0.3 L/sec
      set leak roll-off to 1.0
      ELSE
      set leak roll-off to (0.7-mask leak)/0.4
      END
      Set pressure roll-off to (20-mask pressure)/16
      Set flow limitation threshold to 0.15 times pressure
roll-off times leak roll-off
```

Some subjects will have occasional open airway apneas at sleep onset during stage 1 sleep and therefore at low pressure, and the above algorithm will incorrectly increase CPAP pressure in response to these events. However, such apneas are not usually repetitive, because the subject quickly becomes more deeply asleep where such events do not occur, and furthermore, the false pressure increments become smaller with repeated events. Once the subject reaches deeper sleep, any such falsely increased pressure will diminish. However, it is still advantageous to avoid falsely or needlessly increasing pressure in response to such sleep onset open airway apneas.

As previously discussed, one prior art method for avoiding unnecessary increases in pressure in response to open airway apneas is to determine the conductance of the airway during an apnea using the forced oscillation method, and only increase mask pressure if the conductance is less than a threshold. However, if the nasal airway is narrow or if the subject has lung disease, the airway conductance may be low even in the presence of an open airway and the forced oscillation method may still falsely increase pressure in response to open airway apneas. Conversely, the combination of the forced oscillation method with embodiments of

the present invention has the added advantage that in most cases open airway apneas are correctly detected by the 'forced oscillation method', but in those cases where the forced oscillation method falsely reports a closed airway, the mask pressure will not increase above 10 cmH.sub.2O, thus preventing run-away increases in pressure. This is demonstrated in a third embodiment using the following pseudocode:

```
Set apnea duration to zero
Clear "start of breath" flag
REPEAT every {fraction (1/50)} of a second
Sample mask pressure (in cmH20), mask airflow (in
L/sec), and snore (1 unit corresponds loosely to a typical
snore).
Calculate mask leak as mask airflow low pass
filtered with a time constant of 10 seconds.
Adjust snore signal for machine noise.
Check for presence and duration of any apnea.
IF apnea in progress:
measure conductance of airway using forced oscillation
method.
END
Check for start of breath.
IF start of breath flag set:
IF apnea duration greater than 10 seconds AND
current CPAP pressure less than 10 cmH.sub.2O AND airway
conductance measured using forced oscillation method is less
than 0.05 cmH.sub.2O/L/sec:
Set delta pressure for this apnea to (10--current
CPAP pressure)/6 times 8 cmH.sub.2O per minute of apnea
duration.
Add delta pressure for this apnea to total delta
pressure due to apnea, and truncate to 16 cmH.sub.9O
Reset apnea duration to zero.
ELSE
Reduce total delta pressure due to apnea with a time
constant of 20 minutes.
END
Calculate flow limitation index.
Calculate flow limitation threshold.
IF flow limitation index is less than said
threshold:
Set flow limitation delta pressure for this breath
to 3 cmH.sub.2O times (threshold-flow limitation index).
Add flow limitation delta pressure for this breath
to total delta pressure due to flow limitation, and truncate
to 16 cmH.sub.2O.
ELSE
Reduce total delta pressure due to flow limitation
with a time constant of 10 minutes.
END
Calculate mean snore for breath.
Calculate snore threshold.
IF mean snore exceeds said threshold:
set delta pressure due to snore for this breath to 3
cmH.sub.2O times (mean snore for this breath--threshold).
Add delta pressure due to snore for this breath to
total delta pressure due to snore, and truncate to 16
cmH.sub.2O.
ELSE
Reduce total delta pressure due to snore with a time
constant of 10 minutes.
END
Set CPAP pressure to 4 cmH.sub.2O plus total delta
pressure due to apnea plus total delta pressure due to snore
plus total delta pressure due to flow limitation, and truncate
to 20 cmH.sub.2O.
Clear start of breath flag.
END
END
```

The procedure, "measure airway conductance using the forced oscillation method" can be implemented using the following pseudocode:

```
Modulate airway pressure with an amplitude of 1
cmH.sub.2O peak to peak at 4 Hz.
Measure amplitude of airflow signal at 4 Hz.
Measure component of mask pressure signal at 4 Hz.
Set conductance equal to said airflow amplitude
divided by said mask pressure amplitude.
An alternate expression of the combination of an
embodiment of the invention and the forced oscillation method
is:
IF
(a) the current pressure is low AND (b) the
alternative method scores the airway as closed, THEN score the
airway as closed.
ELSE IF
(a) the current pressure is high AND (b) the
alternative method scores the airway as open, THEN score the
airway as open.
ELSE
score the apnea as of unknown type.
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A further possible arrangement is to substitute the 'cardiogenic method' for determining airway patency for the 'forced oscillation method', also disclosed in European Publication No. 0 651 971 A1 (and U.S. Pat. No. 5,704,345).

More complex variants of CPAP therapy, such as bi-level CPAP therapy or therapy in which the mask pressure is modulated within a breath, can also be monitored and/or controlled using the methods described herein.

Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present invention as defined by the appended claims.

The invention claimed is:

1. A control method for a processor in the administration of CPAP treatment pressure, comprising:

controlling a flow generator for supplying breathable gas to a patient's airway at a first treatment pressure;

controlling a determination of a measure of airflow;

controlling a detection of a reduction in the measure of airflow indicative of the presence of an apnea;

controlling a detection of a flow limitation in the measure of airflow;

in response to the detected indication of the presence of an apnea, dynamically adjusting a delta pressure amount due to apnea based at least in part on a comparison between the first treatment pressure and a top roll-off pressure value;

in response to the detected flow limitation, dynamically adjusting a delta pressure amount due to flow limitation independently of the top roll-off pressure value; and

controlling the flow generator for supplying breathable gas to the patient's airway at a second treatment pressure based on the delta pressure amount due to apnea and the delta pressure amount due to flow limitation.

2. The method of claim **1**, wherein the delta pressure amount due to apnea is determined based at least in part on a monotonically decreasing function.

3. The method of claim **2**, wherein the monotonically decreasing function is a function of the first treatment pressure.

4. The method of claim **1**, wherein the delta pressure amount due to apnea is unchanged if the first treatment pressure is at or above the top roll-off pressure value.

5. The method of claim 4, wherein the top roll-off pressure value is 10 cmH_2O.

6. The method of claim 1, wherein the delta pressure amount due to apnea is determined based at least in part on a monotonically increasing function.

7. The method of claim 1, further comprising determining a duration of the indicated apnea based at least in part on the detected reduction in the measure of airflow, wherein the adjustment to the delta pressure amount due to apnea is determined based at least in part on a function of the duration.

8. The method of claim 7, wherein the function of the duration is a monotonically increasing function.

9. The method of claim 8, wherein the function of the duration is a linearly increasing function.

10. The method of claim 8, wherein the function of the duration is an exponentially increasing function.

11. The method of claim 7, wherein the adjustment to the delta pressure amount due to apnea is determined based at least in part on both a function of the duration and a function of the first treatment pressure.

12. A CPAP treatment apparatus, comprising:

a flow generator operable to supply breathable gas to a mask at a first mask pressure;

a tube coupled to the flow generator and adapted to deliver the breathable gas from the flow generator to the mask;

a controller coupled to the flow generator and configured to control the mask pressure; and

one or more sensors operable to provide a signal to the controller from which a measure of airflow is determined,

wherein the controller is operable to:

in response to a detected reduction in the measure of airflow that is indicative of an apnea, dynamically adjust a delta pressure amount due to apnea based at least in part on a comparison between the first mask pressure and a top roll-off pressure value;

in response to a detected flow limitation in the measure of airflow, dynamically adjust a delta pressure amount due to flow limitation independently of the top roll-off pressure value; and

control the mask pressure to a second mask pressure based on the delta pressure amount due to apnea and the delta pressure amount due to flow limitation.

13. The CPAP treatment apparatus of claim 12, wherein the delta pressure amount due to apnea is based at least in part on a function of the first mask pressure.

14. The CPAP treatment apparatus of claim 12, wherein the controller is operable to determine the duration of the apnea based at least in part on the determined measure of airflow.

15. The CPAP treatment apparatus of claim 12, wherein the one or more sensors comprises a pressure sensor and a flow sensor, and wherein the controller is operable to calculate a mask pressure level based on input signals from the pressure sensor and flow sensor.

16. The CPAP treatment apparatus of claim 15, wherein the one or more sensors are mounted at or near the flow generator.

17. The CPAP treatment apparatus of claim 15, wherein the controller is configured to perform a table lookup in order to calculate the mask pressure level based on the input signals from the pressure sensor and flow sensor.

18. The CPAP treatment apparatus of claim 15, wherein the controller is configured to compare the first mask pressure to the top roll-off pressure value and, if the first mask pressure is lower than the top roll-off pressure value, to adjust the delta pressure amount due to apnea.

* * * * *

专利名称(译)	在呼吸暂停的情况下施用CPAP治疗压力		
公开(公告)号	US9526855	公开(公告)日	2016-12-27
申请号	US14/187919	申请日	2014-02-24
[标]申请(专利权)人(译)	雷斯梅德有限公司		
申请(专利权)人(译)	瑞思迈有限公司		
当前申请(专利权)人(译)	瑞思迈有限公司		
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IPC分类号	A61M16/00 A61M16/06 A61B5/0205 A61M16/08 A61B5/00		
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优先权	1997PP0269 1997-11-07 AU 12/250188 2012-07-17 US 11/237278 2013-08-20 US 10/958854 2006-01-24 US 10/281743 2004-11-16 US 09/531915 2003-01-07 US 09/008743 2002-04-09 US		
其他公开文献	US20140166014A1		
外部链接	Espacenet USPTO		

摘要(译)

公开了CPAP治疗装置，其具有可控制的流量发生器（ 32 耦合到与患者气道连接的面罩（ 30 ）。传感器（ 44,50,56,58 ）产生代表患者呼吸流量的信号，该信号被提供给控制器（ 54,62,64 ）。控制器（ 54,62,64 ）可用于确定呼吸气流减少低于阈值的呼吸暂停的发生，并且如果已经发生呼吸暂停，则确定呼吸暂停的持续时间和使流量发生器（ 34,38 ）增加处理压力。在一种优选形式中，如果呼吸暂停之前的治疗压力超过压力阈值，则压力的增加为零。低于压力阈值，压力的增加是呼吸暂停持续时间的增加乘以压力阈值和当前功能差异治疗压力之间的增加。