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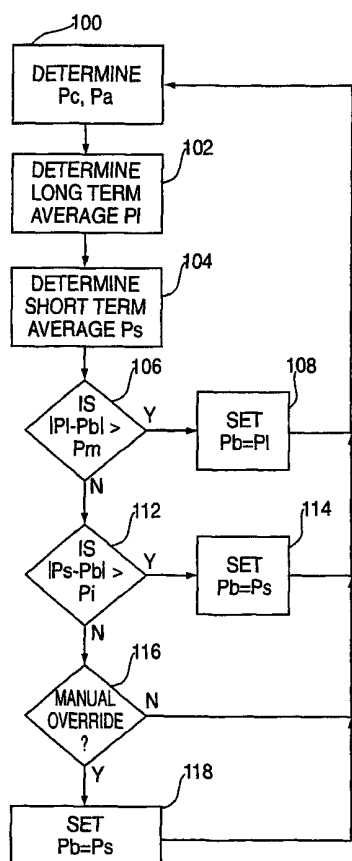
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[Continued on next page]

(54) Title: APPARATUS WITH AUTOMATIC RESPIRATION MONITORING AND DISPLAY



(57) Abstract: A respiratory device is provided with a display showing a respiration signal related to a breathing pattern of a patient. This signal is derived from the difference between a sensed signal indicative of the respiration and airflow generated by the device and a baseline signal. The parameter is adjusted so that the respiration signal is restricted to a predetermined dynamic range. A short term average of the respiration signal (taken over about 0.5 seconds) and a long term average of respiration signals (taken over about 12 seconds) are calculated based on the CPAP measure. These averages are used to monitor the dynamic change in the respiration signal. If a large variation in either average is detected, the baseline is set to a value selected to rapidly reduce the respiration signal to a lower offset.



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## APPARATUS WITH AUTOMATIC RESPIRATION MONITORING AND DISPLAY

This application claims priority to United States provisional application S.N. 60/139,516 filed June 16, 1999.

### BACKGROUND OF THE INVENTION

#### *A. Field of Invention*

The invention relates to respiratory systems such as Non-Invasive Positive Pressure Ventilation (NIPPV), nasal Continuous Positive Airway Pressure (CPAP) and other similar apparatus, used, for example, in the treatment of Sleep Disordered Breathing (SDB) or Obstructive Sleep Apnea (OSA). More particularly, this invention pertains to a respiratory apparatus which uses an automatic baseline tracking technique to monitor and display a patient's respiration, for example during a CPAP titration session of a sleep investigation.

#### *B. Description of The Prior Art*

CPAP, NIPPV and similar types of respiratory apparatus function to supply clean breathable gas (usually air, with or without supplemental oxygen) at a prescribed pressure or pressures, synchronously with a patient's respiration. A suitable CPAP apparatus in which the present invention may be incorporated is, for example, the Sullivan<sup>®</sup> V made by ResMed Ltd. of North Ryde NSW, Australia.

A respiratory apparatus typically includes a blower, an air filter, a mask or other similar patient interface, an air delivery conduit connecting the blower to the mask, and a microprocessor-based control unit. The blower generally includes a servo-controlled motor and an impeller and is used to provide a flow of pressurized air to the patient. The blower may also include a valve for discharging air. Optionally, the apparatus may include a humidifier which can apply moisture to the air supplied through the air delivery conduit. The control unit is used to control the functions of the blower, and to monitor clinical functions and other parameters associated with respiration. These parameters may be used for the diagnosis of sleep and respiratory disorders. Respiratory disorders

such as apnea, snoring, and partial airflow limitations can be inferred by a clinician from the patient's respiration, the associated breathing pattern and signals from other sensors.

A convenient, established way of monitoring respiration during the diagnosis of a sleep disorder consists of analyzing pressure fluctuations obtained from nasal oxygen cannulae inserted into the patient's nares. This provides an indication of respiration flow. If upper-airway irregularities of a significant number are recorded, a CPAP titration session may be ordered. The goal of a CPAP titration session is to determine what level of CPAP treatment is needed to abolish the bulk of the patient's upper-airway irregularities. Throughout the session the CPAP level (pressure) is manually adjusted to resolve the irregularities. During such a session, respiration may be assessed by interpreting the mask pressure signal, a complex pressure signal consisting of the following components: (a) a CPAP component related to the positive airway pressure induced by the blower and having a very low frequency (in the order of 0-0.1 Hz) and high amplitude (in the order of 2-30 cm H<sub>2</sub>O); (b) a respiration component related to the normal respiration of the patient and having a relatively low frequency (of about 0.01 Hz) and low amplitude, generally not exceeding 10 mm of H<sub>2</sub>O; and possibly (c) a component associated with snoring and having a high frequency in the range of 30-200 Hz and a low amplitude in the order of mm of H<sub>2</sub>O. For diagnostic purposes, it is desirable to generate an output signal indicative of the last two components (b) and (c) to derive the respiration sequence referred to herein as the respiration signal.

Prior art respiration monitoring systems use high-pass filtering to separate the desired components from the complex pressure signal. This technique can be unsatisfactory because: (1) if the high-pass filter excludes low-frequency components of the respiratory signal, it will compromise the integrity of the monitored signal; (2) it is slow to track changes in CPAP component, particularly fluctuations due to leaks which are often known to cause step changes in the pressure signal; and (3) if performed in software, it requires high resolution and extensive signal processing.

Another known technique for deriving and monitoring a respiration signal uses a DC-coupled response amplifier without high-pass filtering of the complex pressure signal. The disadvantage of a DC-coupled technique is that the CPAP component appears as a DC offset which must be subtracted from the complex pressure signal so that the respiration signal does not exceed the dynamic range of the measurement

system. During a titration study, each adjustment of the CPAP treatment pressure may demand an adjustment of the DC offset, if the respiration signal is to stay within the dynamic range of the monitoring system. Typically a special manual knob is provided for this purpose which allows an operator to eliminate the DC offset. Hence, using a DC-coupled response amplifier is time-consuming and requires a manual operation of the respiratory apparatus, additional training, and constant attention by an operator.

If the CPAP component generated by the blower is continuously known by the respiration monitoring system, an alternate technique would be to subtract this CPAP component from the complex pressure signal sensed in the mask, theoretically leaving just the respiration signal. This technique is impractical because leaks may occur, causing the pressure in the mask to deviate significantly from the pressure set for the blower and because the blower may not be in constant communication with the sensing device and, therefore, the CPAP component may not always be present.

## OBJECTIVES AND SUMMARY OF THE INVENTION

In consideration of the above, it is an objective of the present invention to provide a respiratory apparatus in which a respiration signal is generated, the signal being automatically adjusted to lie in a predetermined range.

A further objective is to provide a respiratory apparatus capable of displaying a respiration signal to a clinician by calculating a baseline correction and automatically adjusting the baseline to track long and/or short term variations of the respiration signal.

A further objective is to provide a respiratory apparatus which generates a respiration signal indicative of a patient's respiration without the need for an operator to compensate manually for pressure variations produced by the apparatus.

A key advantage of the invention to a clinician performing a sleep study is that the need for intervention during the operation of the subject respiratory apparatus is reduced or eliminated. The present invention simplifies respiration monitoring without sacrificing signal integrity.

A further advantage of the subject invention is that it provides a respiratory apparatus which displays a respiration signal as an indication of the upper airway resistance in a patient, the apparatus being reliable and easy to use.

Other objectives and advantages of the invention shall become apparent from the following description.

Briefly, a respiratory apparatus constructed in accordance with this invention includes a blower providing a flow of pressurized air to the patient, a patient interface (such as a mask receiving air from the blower), a control unit for managing the blower, and a display to show a respiration signal generated by the control unit. The control unit includes a pressure transducer for sensing the actual instantaneous pressure within the patient interface and for converting this pressure to an electrical pressure signal, and a summer which subtracts a baseline pressure signal from the pressure signal to generate a respiration signal. The baseline signal can be adjusted automatically or manually. For the automatic adjustment of the baseline signal, long term and short term averages of the respiration signal are calculated. These averages are used to adjust the baseline signal in a manner that insures that the respiration signal remains within the predetermined range. Adjusting the baseline pressure signal compensates for changes in the respiration signal caused by the operation of the blower (i.e., the CPAP component) or other factors, such as the development of a sudden leak.

## BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows the elements of a respiratory apparatus constructed in accordance with this invention;

Fig. 2 shows a block diagram for a control unit for the respiratory apparatus of Fig. 1;

Fig. 3 shows a flow chart illustrating the operation of the respiratory apparatus of Figs. 1 and 2; and

Figs. 4A-4E show time dependent graphs of a respiration signal generated by the control unit of Fig. 2 for various operating conditions.

## DETAILED DESCRIPTION OF THE INVENTION

Referring now to Fig. 1, a respiratory apparatus 10 constructed in accordance with this invention includes a blower 12 adapted to provide pressurized air, a flexible conduit 14, a mask 16 and a control unit 18. The control unit 18 is connected to the mask 16 by a flexible pressure line 20 via a pressure port 22. The control unit 18 is also connected to a display 24 and to the blower 12 by respective cables 26 and 28. The blower 12 may be a CPAP flow generator such as the one marketed under the name Sullivan®V generator made by ResMed Ltd. of North Ryde, NSW, Australia.

The mask 16 is used to represent generically any suitable patient interface such as a nasal mask or a full face mask, such as the Mirage® mask made by ResMed, or other similar devices designed to deliver air from the generator 12.

The display 24 is designed to indicate graphically the operation of the apparatus 10 and the respiration of the patient, as indicated, for example, on chart 30. The display 24 may be a chart recorder, a CRT, a PC or a similar device.

Preferably, control unit 18 is programmable and includes a screen 32 and two rocker switches 34 and 36. The first rocker switch 34 is marked with up and down arrows, as shown, and is used to select a mode of operation from a menu on screen 32. The other switch 36 is marked with + and - symbols and may be used to select and

change the values of certain programmable parameters associated with the operation of the apparatus 10. Finally, an override switch 38 is also provided on control unit 18 to override the operation of the apparatus. Control unit 18 monitors the operation of the blower 12 and generates a signal indicative of the respiration of the patient for display.

The apparatus 10 may be used to perform sleep studies and may be installed in a hospital, clinic, or patient's home. For this purpose, the control unit 18 monitors the respiration of the patient through mask 16 and configures the blower 12 to provide a controlled pressurized air into the mask 16 through conduit 14 when required, as is well known in the art.

As shown in Fig. 2, the control unit 18 includes a microprocessor 40, a pressure sensor 42, an analog-to-digital (A/D) converter 44, an amplifier 46 and a summer 48. The pressure sensor 42 is used to detect the current pressure within the mask 16 and to send a corresponding current pressure signal  $P_c$  to the A/D converter 44 and to the summer 48. The microprocessor 40 uses the current pressure  $P_c$  in the mask to derive a baseline pressure signal  $P_b$  which is summed with signal  $P_c$ .

More particularly, the summer 48 subtracts the baseline pressure signal  $P_b$  from the current pressure  $P_c$ . The resulting adjusted pressure  $P_a$  ( $P_a = P_c - P_b$ ) is fed to the amplifier 46 which amplifies it at a gain  $G$  (selected by the microprocessor) to generate a respiration signal  $R$ .

Referring to Fig. 3, during operation of the apparatus the baseline pressure signal  $P_b$  is determined as follows. In step 100, a current pressure  $P_c$  is first determined dynamically by sensor 42. Using this signal  $P_c$ , and a nominal or default value  $P_{b0}$  (selected as discussed below), the signal  $P_a$  is calculated using formula  $P_a = P_c - P_b$ . This signal  $P_a$  is then amplified at gain  $G$  to obtain respiration signal  $R$ . In step 102 a long term average parameter  $P_l$ , which is indicative of a long term average of the respiration signal  $R$ , is calculated. Parameter  $P_l$  may be a moving average of the respiration signal taken over the previous 12 seconds.

In step 104, microprocessor 40 determines a short term average parameter  $P_s$  indicative of a short-term average of the respiration signal  $R$ . Parameter  $P_s$  may be a moving average of the respiration signal taken over the previous 0.5 seconds. Parameter  $P_s$  is effectively indicative of the transient pressure noise within the mask.



These calculations are made by the control unit 18 to determine pressure variations within system 10 attributable to extraneous causes, *i.e.*, variations caused by factors other than the respiration of the patient. For example, if the blower 12 is a CPAP flow generator, then the pressure variations may be due to the generated CPAP (continuous positive airway pressure) air flow. The baseline pressure signal  $P_b$  is therefore set using these pressure variations, as discussed below.

Next, the microprocessor 40 performs three checks and adjusts the baseline signal  $P_b$  (if necessary) to compensate for extraneous air pressure variations. The first check (step 106) determines the deviation between the current baseline signal  $P_b$  and the CPAP. This check comprises taking the absolute difference between the long term parameter  $P_l$  and the current baseline pressure signal  $P_b$ , and comparing this absolute difference to a predetermined threshold pressure  $P_m$ . This threshold pressure  $P_m$  may be a fraction (for example, 1/8th) of the output dynamic range of amplifier 46. If this absolute difference is larger than  $P_m$ , then in step 108 the baseline pressure  $P_b$  is set to the parameter  $P_l$ .

If no significant deviation between the current signal  $P_b$  and CPAP is found in step 106, (*i.e.*,  $|P_l - P_b| < P_m$ ) then a second check is performed in step 112. Under certain conditions, the CPAP can change rapidly. This rapid change may be due, for example, to an abrupt leak in the mask 16, or because the blower 12 is activated and starts pumping air into the mask. The purpose of this second check is to insure that the baseline signal  $P_b$  tracks the CPAP during its short-term excursion. More specifically, in step 112 a test is performed to determine whether the absolute difference between the short term average pressure parameter  $P_s$  and the baseline pressure signal  $P_b$  has exceeded a threshold pressure  $P_i$  for a period of  $T_i$ . The period  $T_i$  is defined as the maximum time period for which a healthy adult can sustain a continuous inspiration or expiration. Typically  $T_i$  is about 6 seconds and  $P_i$  is about 3 cm H<sub>2</sub>O. Alternatively, the threshold pressure  $P_i$  may also be set as a fraction of the dynamic range of the amplifier.

If in step 112 the absolute difference  $|P_b - P_s|$  is determined to be greater than  $P_i$  for the last  $T_i$  seconds, then in step 114 the baseline pressure  $P_b$  is set to the parameter  $P_s$ . The process then recycles to step 100 with the new value for  $P_b$  being used instead of  $P_{b0}$ .

The third check is performed in step 116. This step is provided as a means for a clinician to override the current value of the baseline signal  $P_b$ . For example, when the clinician activates pushbutton 38 (Fig. 1), the microprocessor 40 receives an override control signal. If this override signal is sensed, then the baseline pressure signal  $P_b$  is set to  $P_s$  (step 118). The check for an override signal is shown step 116 as following a 'NO' decision in step 112, however, it may be performed at any other time.

When in automatic mode, the control unit operates in accordance with the flow chart of Fig. 3, as described above. However, certain parameters, such as the initial value of the baseline signal  $P_b$  and the gain  $G$  may be adjusted by the clinician. For example, baseline signal  $P_b$  may be set to a nominal or default level  $P_{b0}$  in the range of 0-35 cm  $H_2O$  using switch 36. If no manual override is detected in step 116 then the process recycles to step 100.

The effects of adjusting the baseline pressure signal  $P_b$  in the manner described in Fig. 3 are best understood by reference to the waveforms of Figs. 4A- E. In each of these figures, the current pressure ( $P_c$ ) within the mask 16 is measured by pressure sensor 42 and processed by the circuit shown in Fig. 2. The respiration signal  $R$  of amplifier 46 is depicted as a function of time. Conventionally, a higher mask pressure (corresponding to exhalation) is shown as a negative signal (corresponding to a mask pressure) while inhalation is indicated in the Figures (when applicable) as a positive signal. When the respiration signal reaches the edge of the dynamic range of the amplifier it is clipped, as discussed in more detail below.

Fig. 4A shows the operation of the apparatus 10 when mask 16 is not secured to a patient and the baseline adjustment feature is disabled. As indicated in this figure, as signal  $R$  increases, it eventually reaches a maximum threshold  $M$  defined by the dynamic range of the amplifier 46. The respiration signal  $R$  is clipped at level  $M$ .

Fig. 4B is similar to Fig. 4A with the exception that the mask 16 has been secured to a patient and the respiration component is present. When signal  $R$  reaches level  $M$ , it is clipped.

Fig. 4C shows the respiration signal  $R$  and its long term average  $P_l$  when the baseline adjustment feature has been activated. As this figure depicts, prior to  $t=T_1$ , the long term average  $P_l$  is relatively stable and baseline pressure signal  $P_b$  is set to its

default value  $P_{b0}$ . At  $t=T_1$  the pressure signal increases rapidly, toward  $M$ , and stays at that level. Therefore both  $P_I$  and  $P_S$  start increasing. As soon as  $P_I$  exceeds  $P_b$  by more than the preselected threshold  $P_i$ , the baseline pressure is set to  $P_I$  (steps 106, 108). But since  $P_I$  increases relatively slowly and since  $P_a$  is very high, initially this change in  $P_b$  has no effect. After six seconds in this mode, however, the criteria of step 112 is met, and  $P_b$  is set to  $P_S$  (steps 112, 114). As a result, at  $t=T_2$  the respiration signal  $R$  is corrected automatically so that is centered around  $P_I$ .

Fig. 4D shows the respiration signal  $R$  staying below the threshold level  $M$  but drifting slowly. Therefore, the long term average  $P_I$  drifts as well. When  $P_I$  becomes too large,  $P_b$  is adjusted as at  $T_3$  and  $T_4$  causing the respiration signal  $R$  to approach the horizontal axis. In this manner, the respiration signal  $R$  is maintained within the dynamic range of the amplifier 46.

Fig. 4E shows a sequence wherein initially at  $t=T_5$  there is a rapid change in the current pressure  $P_c$ . This change is handled by the system in the same manner as described above regarding Fig. 4C. This rapid change is corrected at  $t=T_6$  and is followed by a gradual pressure change. The gradual pressure change is corrected at  $t=T_7, T_8, T_9$  and  $T_{10}$  as shown.

Curves similar to those of Figs. 4A-4E can be shown on display 24 so that a patient's breathing and the operation of the baseline adjustment circuit of Fig. 2 can be monitored.

At any time, the clinician may activate the override pushbutton 38 which immediately sets the baseline pressure signal  $P_b$  to the short term average  $P_S$ , thereby rapidly centering the respiration signal  $R$  to the middle of the effective dynamic range of the system.

In summary, the subject device proffers the following advantages:

- a) It utilizes a DC-coupled amplifier, thereby insuring signal spectrum that extends to 0Hz.
- b) Its automatic baseline adjustment feature can be turned off at will, leaving the clinician with the standard manual baseline adjustment.

c) Changes in the respiration signal are presented clearly to the clinician. In one embodiment, automatic adjustments are indicated by explicit markers corresponding to changes in the baseline pressure signal.

d) Adjustments of the baseline pressure signals are made only to prevent the respiration signal from moving outside the dynamic range of the amplifier.

e) Adjustments in the baseline pressure signal are preformed fast enough to track typical automatic or manual-titration without having the respiration signal R exceed the dynamic range of its amplifier.

f) Tracking does not change as a result of respiratory activity because it follows CPAP changes only.

g) For very rapidly changing CPAP pressures (*e.g.*, during the start-up period of the blower) where automatic tracking may fail to keep up, a manual baseline capture is provided to allow instantaneous baseline adjustments .

The invention has been described in conjunction with a particular type respiratory apparatus, however it may be incorporated into other kinds of devices as well. For example, in some respiratory devices respiration monitors are used which include effort sensors such as respiratory bands or suprasternal notch sensors. These effort sensors infer the effort expended by the patient during respiration and generate signals that are shown on a display. Under certain circumstances, for example when the patient moves or shifts position, the sensor signals undergo a large shift which exceeds the dynamic range of the display. The present invention may be used in such devices to cause the sensor signals to return to the dynamic range of the display.

Obviously numerous modifications may be made to this invention without departing from its scope as defined in the appended claims.

## CLAIMS:

1. A respiratory apparatus for delivering a flow of air to a patient suffering from sleep disordered breathing comprising:

a blower that generates a flow of pressurized air;

a patient interface adapted to deliver air from said blower to the patient;

a control unit coupled to said patient interface and adapted to sense a parameter characteristic of said flow of air, said control unit including an adjusting circuit adapted to operate on said parameter to generate a signal indicative of the breathing pattern of the patient; said control unit further including a first averager used to determine a first average of said signal, said adjusting circuit being adapted to restrict said signal within a predetermined range in response to said first average; and

a display adapted to show said signal.

2. The respiratory apparatus of claim 1 wherein said control unit includes a pressure sensor adapted to detect a pressure signal indicative of a pressure within said patient interface, said parameter comprising said pressure signal.

3. The respiratory apparatus of claim 1 wherein said control unit includes a baseline generator generating a baseline signal, said signal being related to said parameter and said baseline signal.

4. The respiratory apparatus of claim 3 wherein said baseline generator is coupled to said first averager and is adapted to set said baseline signal to a value related to said first average.

5. The respiratory apparatus of claim 1 wherein said first averager is adapted to generate said first average over a first time period and wherein said control unit further includes a second averager generating a second average of said signal over a second time period which is much shorter than said first time period, and wherein said adjusting

circuit adjusts said signal in a first manner dependent on said first average in one set of conditions, and adjusts said signal in a second manner dependent on said second average in another set of conditions.

6. A respiratory apparatus used to provide air under controlled conditions to a patient with a pulmonary deficiency, said respiratory apparatus comprising:
- a blower that generates a flow of pressurized air;
  - a patient interface that delivers said flow of air to the patient;
  - a control unit coupled to one of said blower and patient interface to derive a parameter indicative of said flow of air and the breathing of the patient, said control unit having a signal processing unit that processes said parameter to generate a respiration signal indicative of said breathing and an adjusting circuit adapted to determine an average value of said output signal and to adjust said respiration signal based on said average value to restrict said respiration signal to a predetermined range; and
  - a display adapted to show said respiration signal.

7. The respiratory apparatus of claim 6 wherein said adjusting circuit is adapted to determine a short term average value and a long term average value of said respiration signal based on a short and a long time period, respectively, said adjustment circuit being constructed and arranged to adjust said respiration signal in one of a first manner dependent on said short term average value and a second manner dependent on said long term average value.

8. The respiratory apparatus of claim 7 wherein said adjusting circuit is adapted to generate a baseline signal, said baseline signal being subtracted from said parameter to generate said respiration signal.

9. The respiratory apparatus of claim 8 wherein said adjusting circuit is adapted to set said baseline signal to a first value when an absolute difference between said baseline signal and said long term average value exceeds a first threshold.

10. The respiratory apparatus of claim 9 wherein said adjusting circuit is adapted to set said baseline signal to a second value when an absolute difference between said baseline signal and said short term value exceeds a second threshold.

11. The respiratory apparatus of claim 10 wherein said first threshold value is related to said predetermined range.

12. The respiratory apparatus of claim 10 wherein said second threshold value is related to a pressure sustained by a healthy person during a single continuous sustained inspiration or expiration.

13. The respiratory apparatus of claim 6 wherein said adjusting circuit is adapted to determine a short term average value of said respiration signal based on a short time period, said adjustment circuit being constructed and arranged to adjust said respiration signal when the difference between said short term average value and the predetermined threshold exceeds a predetermined threshold value for at least a predetermined duration.

14. In a respiratory apparatus adapted to provide a flow of pressurized air to a patient, a method for presenting a respiration signal indicative of the patient's breathing pattern, the method comprising:

determining a parameter within the device related to the flow of pressurized air and the breathing of the patient;

adjusting said parameter based on a baseline signal to generate a respiration signal within a predetermined range based on an average value of said respiration signal; and

displaying said respiration signal.

15. The method of claim 14 further comprising, taking a difference between said baseline signal and said parameter to derive an adjusted signal.

16. The method of claim 15 further comprising determining an absolute difference between said average value and said baseline signal and if said absolute difference is not less than a first threshold, then setting said baseline signal to said average value.

17. The method of claim 16 wherein said average value is calculated over a period longer than a typical breath of a person.

18. The method of claim 17 wherein said average value is calculated over a period of about 12 seconds.

19. The method of claim 16 wherein said first threshold is related to said predetermined range.

20. The method of claim 19 wherein said first threshold is a fraction of said predetermined range.

21. The method of claim 16 wherein said average value is taken over a period which is not longer than a typical breath of a person.

22. The method of claim 21 wherein said average value is taken over a period which is much shorter than a typical breath of a person.

23. The method of claim 22 wherein said duration is about 0.5 sec.



24. The method of claim 23 wherein said first threshold is related to a minimum pressure maintained by a person during a single continuous inspiration or expiration.

25. The method of claim 14 wherein said parameter is the pressure at which air is provided to the patient.

26. A method of keeping a respiratory signal from a patient within a predetermined dynamic range of an output/display unit comprising the steps of:

determining a parameter indicative of the patient's respiration; and

automatically adjusting said parameter based on a baseline signal to generate the respiration signal within said predetermined dynamic range.

27. The method of claim 26 further comprising automatically adjusting said parameter when said parameter is outside said predetermined range for a predetermined duration,.

28. The method of claim 27 wherein said predetermined duration is long compared with the duration of a typical patient inspiration.

29. The method of claim 27 wherein said predetermined duration is long compared with the duration of a typical patient expiration

30. The method of claim 27 wherein said predetermined duration is approximately 6 seconds.

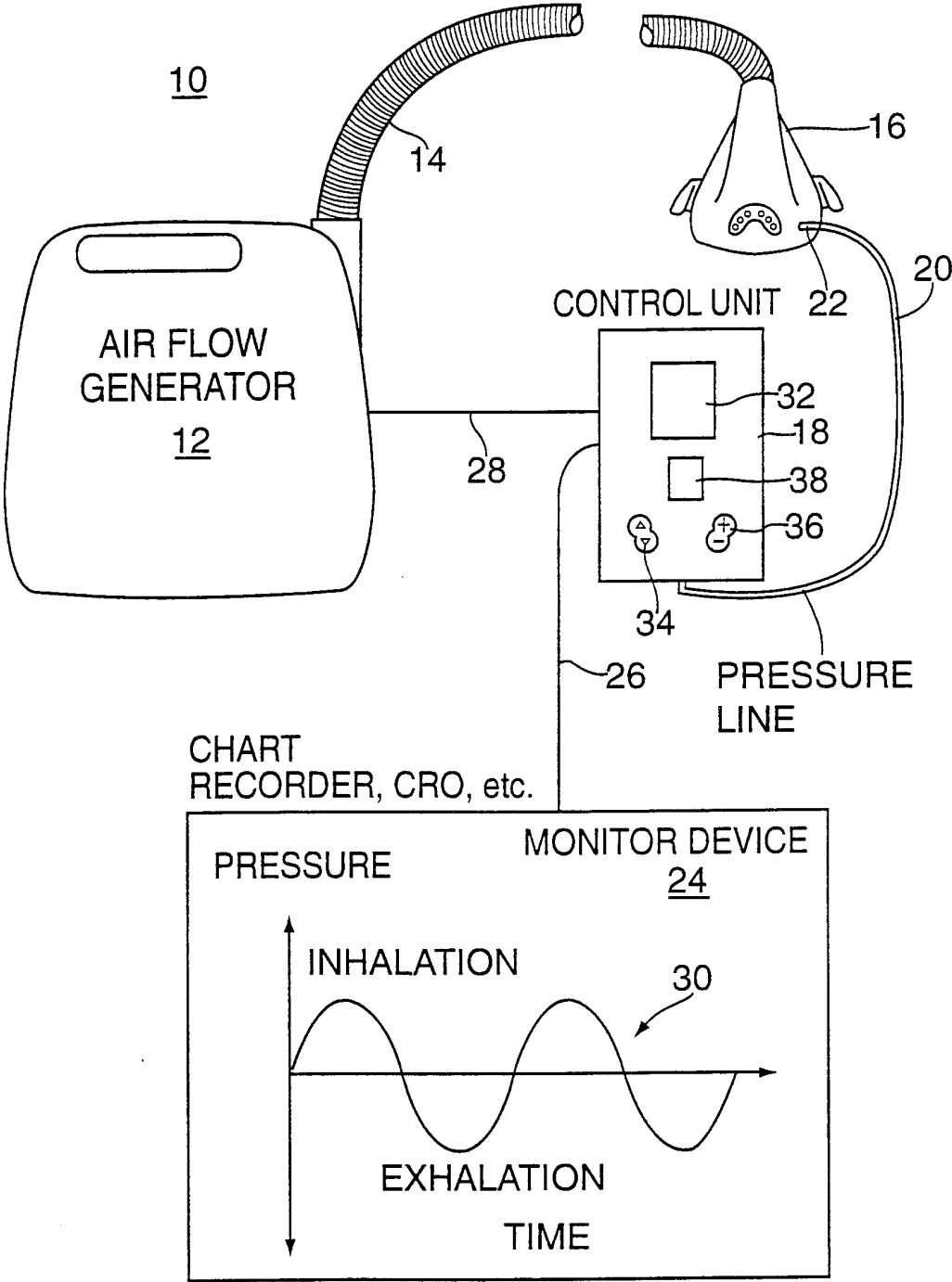
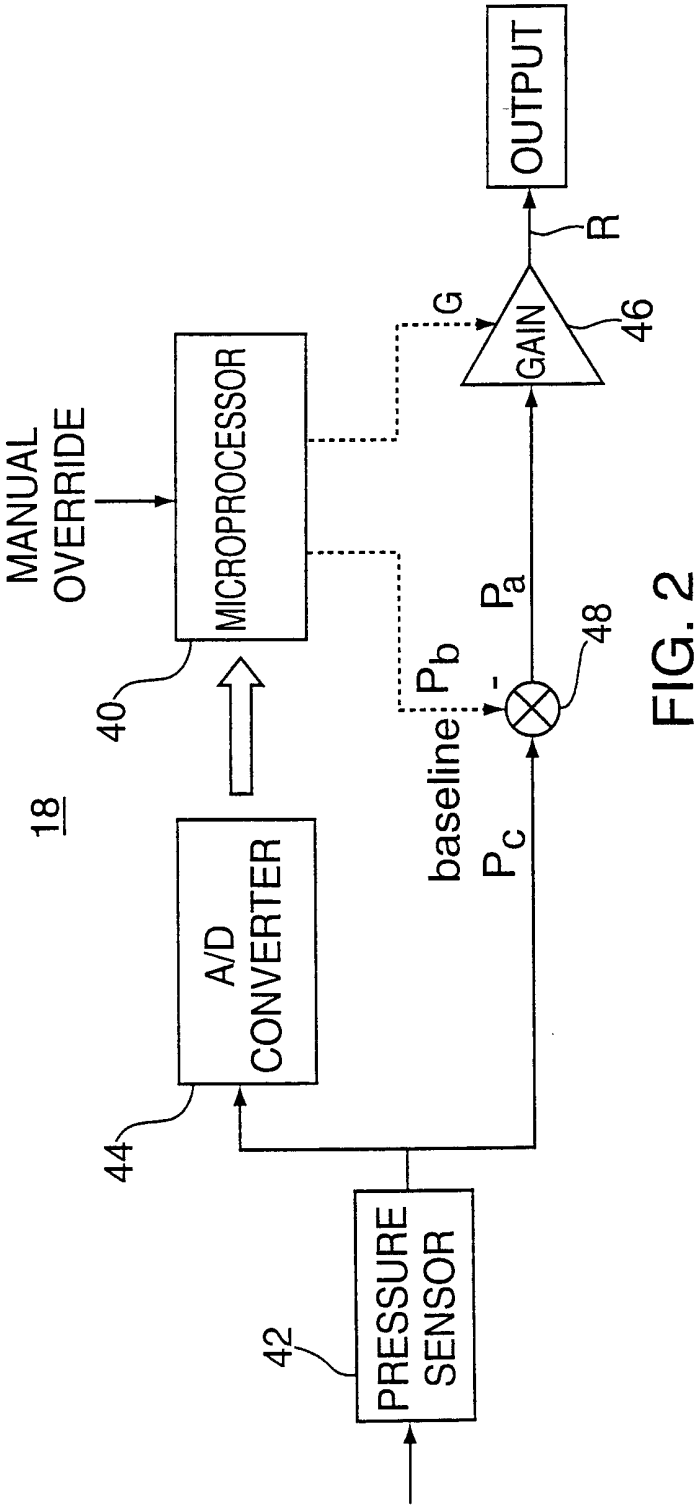


FIG. 1



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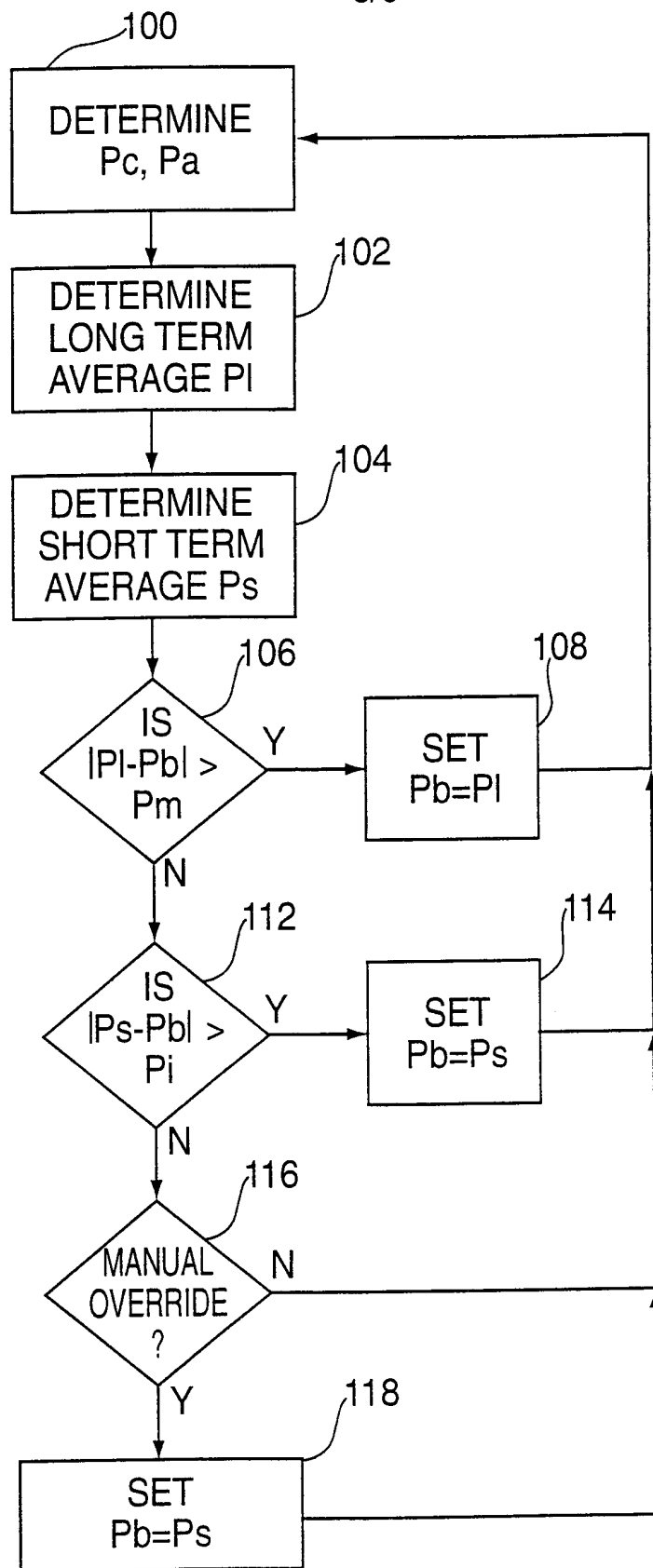


FIG. 3

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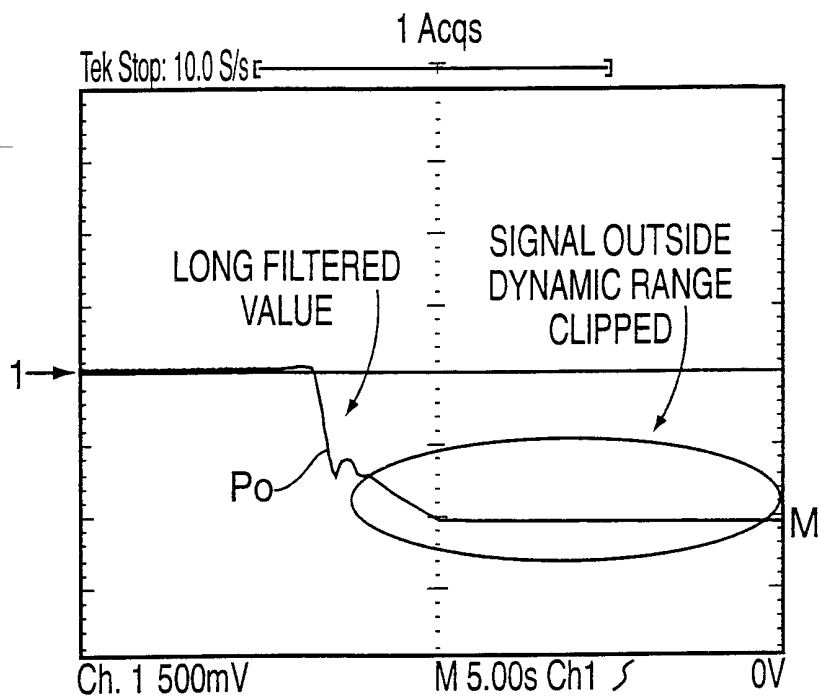


FIG. 4A

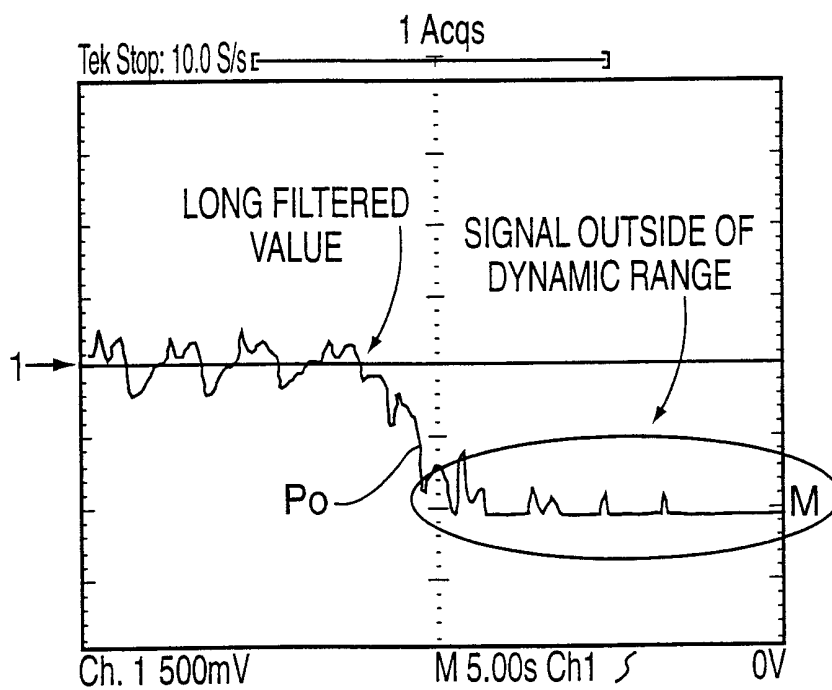


FIG. 4B

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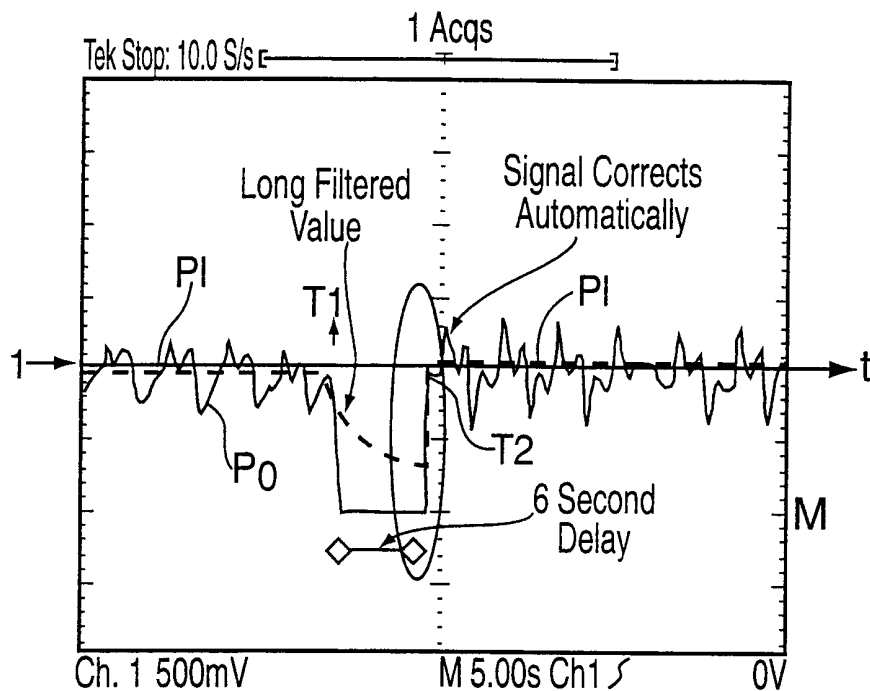


FIG. 4C

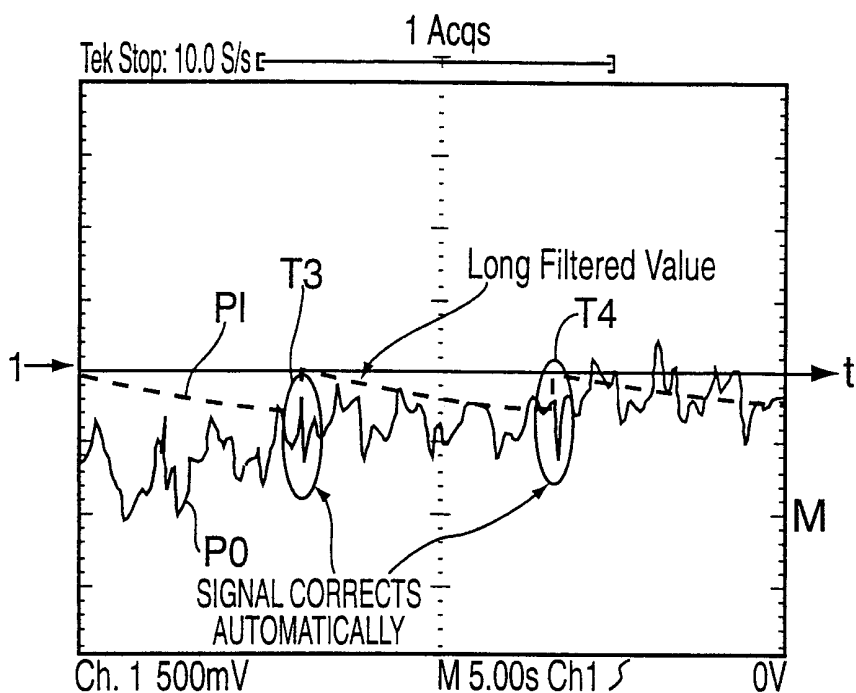


FIG. 4D

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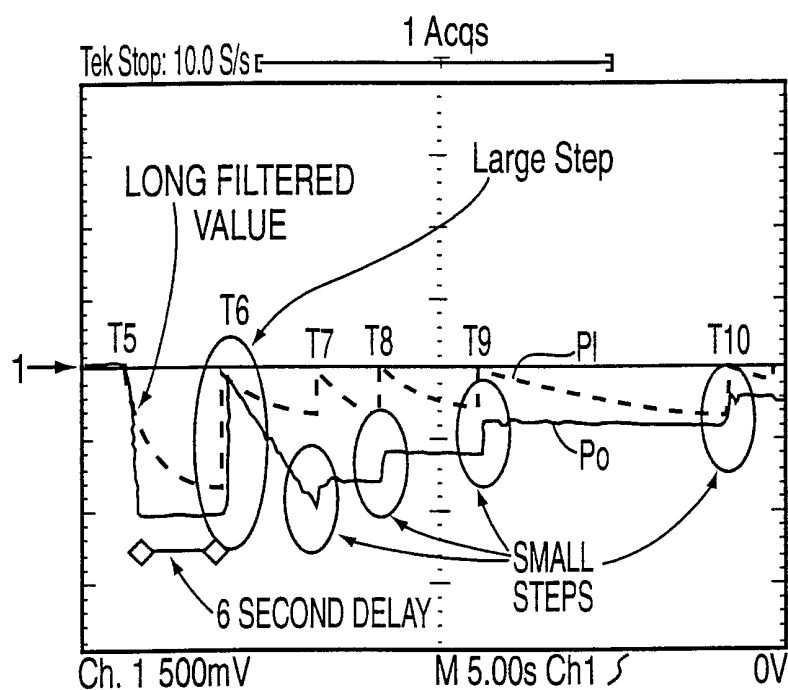


FIG. 4E

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/AU00/00678

## A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. <sup>7</sup>: A61M 16/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
A61M 16/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
AU: IPC AS ABOVE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
DWPI, IBM + keywords

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 84/02641 A1 (Porges) 19 July 1984 ✓	All
A	US 5483969 A (Medtronic, Inc.) 16 January 1996 ✓	All
P,A	WO 99/61088 A1 (Resmed Ltd) 2 December 1999 ✓	All
A	US 4630614 A (Atlas) 23 December 1986 ✓	All
A	WO 98/12965 A1 (Resmed Ltd) 2 April 1998 ✓	All

☐ Further documents are listed in the continuation of Box C ☐ See patent family annex

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 6 September 2000	Date of mailing of the international search report 11 SEP 2000
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