"HUMIDITY CONTROLLER"

TECHNICAL FIELD

This invention relates to breathing assistance apparatus, particularly but not solely, for supplying optimal humidity temperature of gases to a patient to assist the patient's breathing.

BACKGROUND ART

A number of methods are known in the art for assisting a patient's breathing. Continuous Positive Airway pressure or CPAP involves the administration of air under pressure to a patient, usually by a nasal mask. It is used in the treatment of snoring and Obstructive Sleep Apnea (OSA), a condition characterised by repetitive collapse of the upper airway during inspiration. Positive pressure splints the upper airway open, preventing its collapse. Treatment of OSA with nasal CPAP has proven to be both effective and safe, but CPAP is difficult to use and the majority of patients experience significant side effects, particularly in the early stages of treatment.

Upper airway symptoms adversely affect treatment with CPAP. Mucosal drying is uncomfortable and may awaken patients during the night. Rebound nasal congestion commonly occurs during the following day, simulating a viral infection. If untreated, upper airway symptoms adversely affect rates of CPAP use.

Increases in nasal resistance may affect the level of CPAP treatment delivered to the pharynx, and reduce the effectiveness of treatment. An individual pressure is determined for each patient using CPAP and this pressure is set at the mask. Changes in nasal resistance affect pressure delivered to the pharynx and if the changes are of sufficient magnitude there may be recurrence of snoring or airway collapse.

Such symptoms can also occur in a hospital environment where a patient is on a respirator. Typically in such situations the patient is intubated. Therefore the throat tissue may become irritated and inflamed causing both distress to the patient and possible further respiratory problems.

A number of methods may be employed to treat such upper airway symptoms, including pharmacologic agents to reduce nasal disease, or heating the bedroom. One

most commonly employed method is humidification of the inspired air using an in line humidifier. Two types of humidifier are currently used. Cold passover humidifiers rely on humidifying the air through exposure to a large surface area of water. While they are cheap, the humidity output is low at high flows, typically 2 to 4 mg\L absolute humidity at flows above 25L/min. The output is insufficient to prevent mucosal drying. Heated water bath humidifiers are more efficient, and produce high levels of humidity even at high flow rates. They are effective at preventing upper airway mucosal drying, prevent increases in nasal resistance, and are the most reliable means of treating upper airway symptoms.

Any of these active systems will have, to some degree or other, condensation (or rain out) in the tubing connecting the humidifier to the patient. The degree of condensation is strongly dependent on the ambient temperature, being much greater for greater differences between the ambient temperature and the gas temperature. The formation of large quantities of water in the breathing tubing causes considerable inconvenience to the patient, may accelerate cooling of the gas, may eventually occlude the tubing, or may be expelled into the patient. Also, the patient may experience discomfort, when breathing gases are delivered at temperatures widely divergent from that of the ambient temperature. Excessive condensation also results in inefficient usage of the water in the humidifying chamber.

In a hospital environment, where the ambient temperature of the atmosphere within the hospital environment is controlled by air conditioning for example, the required temperature for the humidified gases supplied by the apparatus may be controlled within set temperature parameters that are sufficiently close to the ambient temperature to prevent condensation within the conduit. However it is still necessary to have good control over the temperature and humidity of gases as they are actually supplied to the patient.

In the home care environment in which a user requires to use humidifying apparatus at home, the range of ambient and gas temperatures may well exceed that of the hospital environment. In the home care environment, the user will usually wear a face mask which is connected to end of the conduit and such a humidifier may be used in the home environment for the treatment of breathing and sleep apnea disorders and/or

in conjunction with ventilators or CPAP devices. In addition, non active humidifiers are commonly employed utilising the known pass over humidification technique.

In US Pat. No. 5640951 issued to Fisher and Paykel a heated conduit for a humidified breathing assistance apparatus is disclosed which includes a temperature probe at the end of a heated conduit. By heating the conduit the problems relating to condensation in the conduit may be overcome. However in order to implement closed loop control over the temperature of the supplied gases (and therefore the power input to the conduit heater element), it is necessary to measure the temperature as close to the point at which it is supplied as possible. The temperature probe and its associated wiring included for this purpose make the attachment to the face mask or intubated patient bulky and therefore more uncomfortable for the patient. Therefore it would be advantageous if a heated conduit for a humidified breathing assistance apparatus could be implemented without the need for a temperature probe at the end of the conduit. It would also be advantageous to have some indication, when the conduit heater is energised, that it is operating correctly.

DISCLOSURE OF THE INVENTION

It is an object of the present invention to provide a breathing assistance apparatus which goes some way to overcoming the abovementioned disadvantages or which at least provides the public or industry with a useful choice.

Accordingly in a first aspect the invention consists in a breathing assistance apparatus adapted to deliver humidified gases at a desired level of humidity or at a desired temperature to a patient comprising:

humidification means having an electrical input power and capable of humidifying said gases up to a level of humidity prior to delivery to said patient, said level of humidity depending on said input power to said humidification means,

transportation pathway means for conveying said humidified gases from said humidification means to said patient, and

control means including stored instructions to:

(a) determine a parameter relating to the flow rate of said gases through said apparatus;

(b) determine based on at least said parameter the required electrical power input to said humidification means to deliver said gases to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature;

(c) supply as said input power to said humidification means a level of power substantially similar to said determined power input to said humidification means.

In a further aspect the invention consists in a breathing assistance apparatus for humidification of gases at a desired level of humidity or at a desired temperature comprising:

humidification means having an electrical input power capable of humidifying said gases up to a level of humidity, said level of humidity depending on said input power to said humidification means, and

control means including stored instructions to:

(a) determine a parameter relating to the flow rate of said gases through said apparatus;

(b) determine based on at least said parameter the required electrical power input to said humidification means to humidify said gases to a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature;

(c) supply as said input power to said humidification means a level of power substantially similar to said determined power input to said humidification means.

In a still further aspect the invention consists in a breathing assistance apparatus adapted to deliver humidified gases at a desired level of humidity or at a desired temperature to a patient comprising:

humidification means having an electrical input power capable of humidifying said gases up to a level of humidity prior to delivery to said patient, said level of humidity depending on said input power to said humidification means,

transportation pathway means for conveying said humidified gases from said

humidifcation means to said patient,and

pathway heating means having an electrical input power, and being associated with said transportation pathway means wherein the gases flowing through said transportation pathway means are heated either directly or indirectly by said pathway heating means whereby the level of heating depending on said input power to said pathway heating means;

control means which supply said input power to said humidification means and said pathway heating means, and providing a control output indicative of said pathway heating means being correctly connected to said control means and operating in according within predefined limits; and

connection means to electrically connect said control means and said pathway heating means and including an indicator in use connected to said control output, wherein when said said pathway heating means being correctly connected to said control means and operating in according within predefined limits said control means energising said indicator.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

One preferred form of the present invention will now be described with reference to the accompanying drawings in which;

Figure 1 is a illustration of a respiratory humidifier system,

Figure 2 is a illustration of the humidifier base of the respiratory humidifier system of Figure 1,

Figure 3 is a block diagram of the control system which controls the humidifier in the preferred embodiment of the present invention,

Figure 4 is a flow diagram of the algorithm used to control the heater wire within the respiratory conduit,

Figure 5 is an example of how the heater plate temperature varies over time, when the pressure is controlled constant,

Figure 6 is a graph of heater plate power against flow rate, and

Figure 7 is a graph of conduit heater element power and flow rate.

DETAILED DESCRIPTION OF THE INVENTION

Whether used in a hospital environment or in a home care environment, the present invention will generally have associated two main pieces of apparatus. Firstly an active humidifier which controls the temperature of a heater plate heating a body of water to achieve a desired temperature and humidity of the gases being humidified. Secondly a transport conduit from the humidifier to the patient is also required, which is preferably heated to reduce condensation, or "rain out".

Referring to Figure 1 a humidifying apparatus as might be used in a hospital generally referenced 1 is shown. The apparatus comprises a body 2 containing heating means comprising a heating plate 20 having an electric heating element therein or in thermal contact therewith and control means for example electronic circuitry which may include a microprocessor for controlling the supply of energy to the heating element. The body 2 is removably engageable with a humidifying chamber 3 which contains water for humidifying gases. Referring to Figures 2 which show the humidifier apparatus in more detail, the humidifying chamber 3 has edges which engage with collar 24 on the humidifier apparatus. The gases to be humidified may be a mixture of air, oxygen and anaesthetic for example which are supplied to the chamber through a gases inlet 4. This might be connected to a ventilator, or in the case of CPAP therapy a CPAP blower. A gases outlet 5 is also provided and the gases outlet 5 is connected to the conduit 6 (Figure 1) which conveys humidified gases to a remote destination such as an intubated patient at the end 7 of the conduit. Alternatively, the end 7 of the conduit may have a gas mask attached thereto, which mask is used to cover a nose and/or mouth of a user so as to supply humidified gases to the user for breathing, as in the delivery of CPAP therapy. The humidifier heater plate 20 has a temperature transducer 8 which is in electrical connection with the electronic control circuitry in body 2 of the apparatus so that the control means monitors the temperature of the heating plate.

A heating element 10 is provided within the conduit 6 to help prevent condensation of the humidified gases within the conduit. Such condensation is due to the temperature of the walls of the conduit being close to the ambient temperature, (being the temperature of the surrounding atmosphere) which is usually lower than the temperature of the humidified gases within the conduit. The heater element is effectively replaces the energy lost from the gases through conduction and convection during transit through the conduit. Thus the conduit heater element ensures the gases delivered are at an optimal temperature and humidity.

The present invention provides a means of controlling at least the heater plate and preferably also the conduit heater element without the need for any sensors, either in the humidifier chamber or positioned in the conduit. This is achieved by estimating the rate of flow of gases through the humidifier using parameters already available to the controller. For a given humidifier an appropriate level of power can then be determined to apply to the heater plate to achieve the desired temperature of gases delivered to the patient. Additionally this may be used to provide a more appropriate level of energisation at this conduit heater element. This not only saves the cost of the extra sensors but also allows the apparatus connected to the end of the conduit to be simpler and lighter.

In the preferred embodiment of the present invention the controller 100, shown in Figure 3, uses a range of inputs to control both the power 108 supplied to the heater plate 110 as well as the power 114 supplied to the conduit heating element 116 (if present). In certain applications it may also be used to provide control instructions to auxiliary apparatus such as a blower fan. Using an internal algorithm 106 the controller 100 estimates the power 108 to supply to the humidifier heater plate 110 to achieve a given humidity and or temperature of gases at the top of the humidifier chamber alternatively (or estimates the temperature to achieve a given power). It then uses a second algorithm 102 to estimate the required power 114 to supply to the conduit heater element 116 and the humidifier heater plate 110 to achieve optimal temperature and/or humidity of the gases delivered to the patient 118.

Referring to Figure 4, when the humidifier starts up the controller executes a supervisory algorithm, which controls the heater plate and if present the conduit heater

element. Initially 128 the heater plate is controlled to a temperature of 40°C and the conduit heater element may be energised with a duty cycle of for example 50%. The heater plate temperature (or alternatively the power supplied to the heater plate) is then monitored 130 until it settles to a stabilised level. Effectively a window 132 is superimposed over the heater plate temperature profile 134 of which an example is shown in Figure 5. When the profile 134 (over the entire period of the window 132) fits within the bounds of the window 132, it is effectively considered to have stabilised. Once this has occurred the controller enters a calculation stage.

Firstly, it calculates the flow rate of the gases 136 using any one of a number of methods which will be described later.

Secondly knowing the rate of flow of the gases the algorithm then calculates the required heater plate power 138 (alternatively heater plate temperature) to achieve a desired temperature/humidity of gases (alternatively heater plate power). A relationship has been empirically determined using a humidifier and a heated conduit such as that as described in US5640951, the contents of which are incorporated herein by reference. The actual relationship for any other arrangement would either have to be empirically determined by experimentation or theoretically calculated. For a desired temperature of gases exiting the humidifier of for example 37°C the relationship between the power supplied to the heater plate (P_{HP}), the rate of flow of gases (F_{gas}) and the ambient temperature (T_{amb}) is graphed in Figure 6. From this an approximate general algebraic equation has been extrapolated which the controller can use to determine an approximate level of power to apply to the heater plate:

$$P_{HP} = (-0.1239 \times T_{amb} + 5.383) \times F_{gas} + (-0.3112 \times T_{amb} + 10.738)$$

Thirdly the algorithm calculates the required power input to the conduit heater wire 140 to deliver a desired temperature of the gases to the patient. With gases flowing at a known rate of flow it is possible to calculate the resultant temperature of the gases once they have flowed through a conduit of known characteristics surrounded by the atmosphere at a known or assumed ambient temperature. Thermal characteristics of the conduit will either be known or can be calculated by experimentation. This relationship is based off empirical data using a humidifier and a heated conduit such as that as described in US5640951. The actual relationship for any other arrangement would

either have to be empirically determined by experimentation or theoretically calculated. With a conduit entry gas temperature of 37°C and a temperature of gases delivered to the patient of 40°C, the relationship between the flow rate of the gases (F_{gas}), the power input to the conduit heater element (P_c), the ambient temperature (T_{amb}) is graphed in Figure 7. This is extrapolated to a general algebraic expression:

$$P_c = (-0.0005*T_{amb} +0.0169) F_{gas}^2 - [10^{-5}*T_{amb}^3 -0.0042 *T_{amb}^2+0.2189*T_{amb} - 3.0075]F_{gas} - 1.0169*T_{amb} +38.956$$

Practically this relationship can be simplified whereby P_c is dependent only on T_{amb}. This is an acceptable approximation for the conduit heater element, as it is not as crucial as the heater plate.

Once the heater plate and conduit heater element have been appropriately energised, the controller continues to monitor 142 the system for any changes in the variables. The main reason for this is to avoid thermal overshoot ie where the flow drops suddenly, the temperature of gases can become dangerously high.

In order to monitor effectively, two methods are used. Firstly the flow rate is monitored and secondly the change in flow rate (with respect to time) is also monitored. The first 144 is to allow the system to respond to any changes in the system. The second 146 is a fast response system in order to avoid thermal overshoot. Effectively where either P_{HP} or T_{HP} is controlled constant, monitoring the other variable gives an indication of any change in flow, or any other variable which requires a recalculation.

In order to monitor the flow a variable x (defined as P_{HP}/T_{HP}), which is closely related to the flow rate, is constantly calculated and monitored . If it goes up there is a 30 minute delay before the controller initiates a recalculation, to avoid spurious readings and unnecessary calculations. If it goes down there is a 30 second delay before the controller recalculates, to avoid any possibility of the delivered gases being, even transiently, too hot.

Where large step changes occur the controller needs to react quickly. In such cases it will reset to initial conditions to wait until the system stabilises again, as any calculations in the interim would be pointless. To achieve this dx/dt is calculated and monitored. While a negative value is more dangerous, any deviation over a certain value will reset the controller.

In an alternative embodiment of the present invention the expected heater plate

temperature is calculated using

$$T_{HP} = -7.3319*Ln(F_{gas}) + 63.655$$

and if the actual heater plate temperature deviates by more than 5°C then the program recalculates the required powers.

Thus in summary controller carries out the following steps:

1) Estimates the rate of flow of gases keeping all variables constant 136.
2) Estimate the required heater plate power/temperature to achieve a specified temperature/humidity of gases in the humidification chamber 138.
3) Calculate the power input to the heater wire to achieve a desired output temperature 140.

It will be appreciated that a greater level of power will be supplied to the conduit heater element if:

i) the rate of flow of the gases reduces,
ii) the ambient temperature decreases,
iii) the differential between ambient and gases temperature increases.

It will also be appreciated that the heater plate temperature could be controlled to a set valve (using closed loop control) as opposed to power. In this case the power supplied would be monitored as a measure of system stability. Furthermore where relationships are expressed algebraically they could equally be stored in look-up tables.

First preferred embodiment of flow estimation

Generally when used in a hospital setting a humidifier such as that described in the present invention will be used in conjunction with a respirator to supply humidified gases to an incubated patient, or possibly using a respiratory mask. As such the humidifier will operate effective independently of the respirator and therefore must make all of its control decisions based on only the sensors contained therein. In the preferred embodiment of the present invention the flow rate of the gases passing through the humidification chamber can first be estimated by comparing the power input required 108 for the humidifier heater plate to the measured temperature 112 of the heater plate. In effect the higher the rate of

flow of gases the larger the amount of power required by the heater plate in order to achieve a given heater plate temperature. Thus for a given system the relationship between power to heater plate and flow rate for a given heater plate temperature can either be determined empirically or theoretically calculated. Again using a humidifier and a heated conduit such as that as described in US5640951 the following empirically determined relationship applies:

$$F_{gas} = \frac{-(0.831 - 0.0049 * T_{amb}) + \sqrt{abs\left[(0.831 - 0.0049 * T_{amb})^2 - \left(4 * (0.00004 * T_{amb} - 0.0057) * ((14.348 - 0.25 * T_{amb}) - P_{HP})\right)\right]}}{2 * (0.0004 * T_{amb} - 0.0057)}$$

where P_{HP} is the power applied to the heater plate to achieve a given heater plate temperature in steady state of 50°C, T_{amb} is the ambient temperature and F_{gas} is the gas flow rate.

It will be appreciated this method is more appropriate in the hospital care environment where the ambient temperature can be assured with a high degree of confidence.

Second Preferred Embodiment of Flow Estimation

In the homecare environment the present invention will often be employed in conjunction with a continuous positive airway pressure (CPAP) device or such other breathing apparatus which will include a fan such as that described in US Patent No. 6050260, the contents of which are incorporated herein by reference. It will be appreciated that in such applications it may be possible to connect the controllers of the various devices together in an arrangement such that data may be readily exchanged. In such cases the rate of flow of the gases may be estimated directly from information available either from the fan or, where provided, a flow sensor.

In this embodiment of the present invention the flow is estimated based on the loading of the fan. Generally the fan will be controlled to run at a specified speed and therefore deliver a constant pressure output. The flow rate of the gases will depend on the restrictions in the flow path. In turn in order to maintain the specified speed a certain power input will be required for the fan. Therefore an algebraic relationship between the

removing external sensors making the system simpler, cheaper and lighter. Similarly it may also allow for effective control over energisation of the conduit heater element, ensuring the system as a whole operates correctly as well as being as efficient as possible.

CLAIMS:

1. A breathing assistance apparatus adapted to deliver humidified gases at a desired level of humidity or at a desired temperature to a patient comprising:

humidification means having an electrical input power and capable of humidifying said gases up to a level of humidity prior to delivery to said patient, said level of humidity depending on said input power to said humidification means,

transportation pathway means for conveying said humidified gases from said humidification means to said patient, and

control means including stored instructions to:

(a) determine a parameter relating to the flow rate of said gases through said apparatus;

(b) determine based on at least said parameter the required electrical power input to said humidification means to deliver said gases to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature;

(c) supply as said input power to said humidification means a level of power substantially similar to said determined power input to said humidification means.

2. A breathing assistance apparatus as claimed in claim 1 further comprising:

pathway heating means having an electrical input power, and being associated with said transportation pathway means wherein the gases flowing through said transportation pathway means are heated either directly or indirectly by said pathway heating means whereby the level of heating depending on said input power to said pathway heating means;

an ambient temperature sensor providing an indication of the exterior temperature;

and said instruction (b) further comprises determining based on at least said indication of the exterior temperature the required power input to said pathway heating means to deliver said gases to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature;

and said instruction (c) further comprises supplying as said input power to said pathway heating means a level of power substantially similar to said determined power



input to said pathway heating means.

3. A breathing assistance apparatus as claimed in claim 2 wherein said humidification means comprises a humidification chamber adapted to receive a volume of water and water heating means to heat said water to produce water vapour within said chamber in use, said gases passing through said water vapour in said chamber thereby being humidified, said instruction (a) further comprising:

i) energising said water heating means to heat said water towards a first condition,

ii) continuously monitoring said parameter or a variable indicative of a property of said water heating means, until said variable or said parameter indicates that said water has substantially reached said first condition,

iii) determining said parameter based on at least said variable and said indication of the external temperature.

4. A breathing assistance apparatus as claimed in claim 3 wherein the determination of said power to said humidification means in said instruction (b) is also based on said indication of the external temperature.

5. A breathing assistance apparatus as claimed in claim 3 wherein said control means storing a further instruction :

(d) continuously monitor said parameter or said variable, and when a change in said parameter or said variable is greater than a first threshold said control means reverts to said instruction (b) and when a change in said parameter or said variable is greater than a second threshold said control means reverts to instruction (a).

6. A breathing assistance apparatus as claimed in claim 5 wherein if said change in said parameter of said variable indicates a decrease in flow a relatively short delay is caused before said control means reverts to said instruction (b) and if said change indicates an increase in flow a relatively long delay is caused before said control means reverts to said instruction (b).

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7. A breathing assistance apparatus as claimed in claim 5 wherein said second threshold is based on the rate of change of said parameter or said variable with respect to time, wherein when said rate of change goes over said second threshold said control means reverts to said instruction (a).

8. A breathing assistance apparatus as claimed in claims 1 or 2 further comprising a gases supply means adapted to supply gases to said humidification means at a required pressure and resulting flow rate.

9. A breathing assistance apparatus as claimed in claim 8 wherein said gases supply means provides an output signal representative the level of electrical output to said gases supply means, said signal being supplied to said control means from which the flow rate of said humidified gases is determined.

10. A breathing assistance apparatus as claimed in claim 8 or claim 9 wherein said gases supply means comprise a fan driven by a variable speed electric motor.

11. A breathing assistance apparatus as claimed in claim 10 wherein said estimate of the flow rate of said humidified gases is based on the current drawn by said variable speed motor.

12. A breathing assistance apparatus as claimed in claims 1 or 2 further comprising a gases flow rate sensor from which said estimate of the flow rate of said humidified gases is determined directly.

13. A breathing assistance apparatus as claimed in any one of claims 3 to 7 further comprising:

chamber sensing means providing an indication of the temperature of said water heating means and providing an indication of the electrical power drawn by said water heating means,

wherein said variable is indicative of said indicator of the temperature of said water

heating means or said indication of the power drawn by said water heating means.

14. A breathing assistance apparatus as claimed in claim 13 wherein said parameter is defined as the value of said power drawn by said water heating means divided by said temperature of said water heating means.

15. A breathing assistance apparatus for humidification of gases at a desired level of humidity or at a desired temperature comprising:

humidification means having an electrical input power capable of humidifying said gases up to a level of humidity, said level of humidity depending on said input power to said humidification means, and

control means including stored instructions to:

(a) determine a parameter relating to the flow rate of said gases through said apparatus;

(b) determine based on at least said parameter the required electrical power input to said humidification means to humidify said gases to a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature;

(c) supply as said input power to said humidification means a level of power substantially similar to said determined power input to said humidification means.

16. A breathing assistance apparatus adapted to deliver humidified gases at a desired level of humidity or at a desired temperature to a patient comprising:

humidification means having an electrical input power capable of humidifying said gases up to a level of humidity prior to delivery to said patient, said level of humidity depending on said input power to said humidification means,

transportation pathway means for conveying said humidified gases from said humidifcation means to said patient,and

pathway heating means having an electrical input power, and being associated with said transportation pathway means wherein the gases flowing through said transportation pathway means are heated either directly or indirectly by said pathway heating means



whereby the level of heating depending on said input power to said pathway heating means;

control means which supply said input power to said humidification means and said pathway heating means, and providing a control output indicative of said pathway heating means being correctly connected to said control means and operating in according within predefined limits; and

connection means to electrically connect said control means and said pathway heating means and including an indicator in use connected to said control output, wherein when said said pathway heating means being correctly connected to said control means and operating in according within predefined limits said control means energisng said indicator.

17. A breathing assistance apparatus substantially as herein described with reference to and as illustrated by the accompanying drawings.

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