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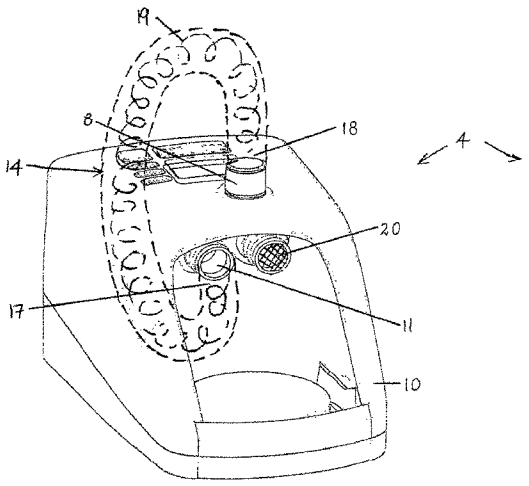

(57) Abstract: The present invention provides a breathing assistance apparatus that has a convenient and effective method of cleaning internal conduits inside the apparatus. The breathing assistance apparatus is preferably a gases supply and humidification device. The cleaning method is a method of disinfection that is automated so minimal training is required to disinfect in particular an internal elbow conduit within the device. It is therefore not necessary to dismantle the gases supply and humidification device, therefore, inadvertent damage to the internal parts of the device is avoided. The present invention also provides a method of disinfecting a heated breathing conduit and a patient interface.

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BREATHING ASSISTANCE APPARATUS

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to a gases supply and gases humidification apparatus that can be disinfected and reused for different patients. The invention also relates to a method for disinfecting apparatus parts that extend the life of these parts for use by a single patient.

Summary of the Prior Art

A number of methods are known in the art for assisting a patient's breathing. Continuous Positive Airway Pressure (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 Apnoea (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.

CPAP is also commonly used for patients with a variety of respiratory illnesses, including Chronic Obstructive Pulmonary Disease (COPD).

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 patient interface. 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 or reduce the level of pressure applied to the lungs. 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 pharmacological 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 pass-over 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.

Oxygen is the most common drug prescribed to hospitalized patients. The delivery of oxygen via nasal cannula or facemask is of benefit to a patient complaining of breathlessness. By increasing the fraction of inspired oxygen, oxygen therapy reduces the effort to breathe and can correct resulting hypoxia (a low level of oxygen in the tissues).

The duration of the therapy depends on the underlying illness. For example, postoperative patients may only receive oxygen while recovering from surgery while patients with COPD require oxygen 16 to 18 hours per day.

Currently greater than 16 million adults are afflicted with COPD, an umbrella term that describes a group of lung diseases characterized by irreversible airflow limitation that is associated mainly with emphysema and chronic bronchitis, most commonly caused by smoking over several decades. When airway limitation is moderately advanced, it manifests as perpetual breathlessness, without physical exertion. Situations such as a tracheobronchial infection, heart failure and also environmental exposure can incite an exacerbation of COPD that requires hospitalization until the acute breathlessness is under control. During an acute exacerbation of COPD, the patient experiences an increase in difficulty of breathing (dyspnea), hypoxia, and increase in sputum volume and purulence and increased coughing.

Oxygen therapy provides enormous benefit to patients with an acute exacerbation of COPD who are hypoxic, by decreasing the risk of vital organ failure and reducing dyspnea. The major complication associated with oxygen therapy is hypercapnia (an elevation in blood carbon dioxide levels) and subsequent respiratory failure. Therefore, the dose of oxygen administered can be critical and must be precisely known.

To accurately control the oxygen dose given to a patient, the oxygen-enriched gas must exceed the patient's peak inspiratory flow to prevent the entrainment of room air and dilution of the oxygen. To achieve this, flows of greater than 20 L/min are common. Such flows of dry gases cause dehydration and inflammation of the nasal passages and airways if delivered by nasal cannula. To avoid this occurrence, a heated humidifier is used.

The majority of systems that are used for oxygen therapy or merely delivery of gases to a patient consists of a gases supply, a humidifier and conduit. Interfaces include facemasks, oral mouthpieces, tracheostomy inlets and nasal cannula, the latter having the advantage of being more comfortable and acceptable than a facemask.

A group of patients who would benefit from humidification therapy are patients who have mucociliary clearance deficiencies. These patients often have purulent mucus and are susceptible to infections from pathogens.

Heated humidified air with an abundance of water particles is an ideal medium to harbour disease carrying pathogens. Consequently, considerable design expertise has been required to provide the market with active pass-over humidifiers that deliver water molecules, in gas phase only, so that it is not possible for disease pathogens to be carried in air to the patient. Water that condenses on the inner surfaces of the breathing circuit or conduit at the end of a treatment session may harbour pathogens that would be delivered to the patient next time they use the device. This is particularly the case with humidification therapies where patients are receiving body temperature fully saturated air.

In hospital environments or similar it is often not possible for gases supply devices, such as devices that deliver CPAP and include a humidifier, to be used by multiple patients. If devices were to be used in this manner all parts, from the humidification chamber to and including the patient interface, must be disposed of or cleaned to a high standard of disinfection in between use by different patients. Often CPAP devices and humidifiers are provided in an integrated unit, such as the Sleepstyle™ 600 series CPAP device of Fisher & Paykel Healthcare Limited. This CPAP device is predominantly used for home use by an individual. This device has internal tubing from the outlet of the humidification chamber that is difficult to disinfect. As these devices are difficult to disinfect they are often not used in settings such as hospitals or clinics where multiple patients will use the device.

In the home use situation when oxygen therapy and CPAP devices are used by a single patient the lifespan of the breathing tube and patient interface is determined by the mechanical lifespan of the parts and the build up of microbial pathogens on the breathing gases path of these parts. Often it is hard to lower microbial contamination on the breathing gas surfaces of these parts.

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 present invention consists in a breathing assistance apparatus adapted to deliver humidified gases to a patient comprising:

a housing,

a gases supply within said housing,

a gases outlet in said housing in fluid connection with said gases supply and adapted to make fluid connection with an inlet of a humidifier in order to supply gases to said humidifier,

an outlet in said humidifier,

a patient outlet on said housing,

a gases return in said housing, adapted to make fluid connection with said humidifier outlet in order to receive humidified gases from said humidifier and provide humidified gases to said patient outlet, said patient outlet being in fluid connection with or adapted to make fluid connection with a breathing conduit for delivery of humidified gases to a patient,

a heated gases conduit including a heating element adapted for connection between said gases outlet and said patient outlet.

Preferably said gases return has a temperature sensor within that senses the temperature of said gases flowing through said gases return.

Preferably said breathing assistance apparatus further comprises a filter connectable to said gases return to filter gases exiting said gases return.

In a second aspect the present invention consists in a method of disinfecting a breathing assistance apparatus, said breathing assistance apparatus including a gases supply capable of supplying a flow of gases at a predetermined pressure to a patient and

capable of providing power to conduits supplying gases to said patient, said method comprising the steps of:

connecting a heated gases conduit, including a heating element, between an outlet of said gases supply and an outlet to said patient,

said gases supply providing a predetermined flow of gases to said disinfection conduit over a predetermined period of time,

said gases supply including a controller to supply power to said heating element and said controller causing the heating element to heat the heated gases conduit up to a predetermined temperature.

Preferably said predetermined period of time is between 2 and 60 minutes.

Preferably said predetermined period of time is approximately 30 minutes.

Preferably said predetermined temperature is between 60 and 90 degrees Celsius.

Preferably said predetermined temperature is approximately 80 degrees Celsius.

Preferably said predetermined circulating flow is between 1 and 50 litres per minute.

Preferably said predetermined circulating flow is approximately 10 litres per minute.

In a third aspect the present invention consists in a method of disinfecting at least one of a breathing conduit and patient interface, said breathing conduit and said patient interface being connected to a breathing assistance apparatus including a gases supply capable of supplying a flow of gases at a predetermined pressure or flow to a patient and capable of providing power to said breathing conduit supplying gases to said patient, said breathing assistance apparatus including a humidifying chamber and heater capable of heating water within said chamber and said breathing conduit including a heating element, said method comprising the steps of:

removing water from said chamber,

said gases supply providing a predetermined flow of gases to said chamber and at least one of said breathing conduit and patient interface over a predetermined period of time,

said gases supply including a controller to supply power to said heater and said heating element, said controller causing the said heater and said heating element to heat said gases supplied to said at least one of said breathing conduit and patient interface to a

predetermined temperature to dry and disinfect said at least one of said breathing conduit and patient interface to prevent accumulation of bacteria in said at least one of said breathing conduit and patient interface.

Preferably said predetermined period of time is between 30 and 120 minutes.

Preferably said predetermined period of time is approximately 90 minutes.

Preferably said predetermined temperature is between 40°C and 75°C.

Preferably said predetermined temperature is 40°C.

Preferably said method includes the step of placing a cap on the distal end of said breathing conduit at a point where said patient interface is connected in normal use.

Preferably said method includes the step of placing said patient interface in an enclosure.

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.

In this specification where reference has been made to patent specifications, other external documents, or other sources of information, this is generally for the purpose of providing a context for discussing the features of the invention. Unless specifically stated otherwise, reference to such external documents is not to be construed as an admission that such documents, or such sources of information, in any jurisdiction, are prior art, or form part of the common general knowledge in the art.

BRIEF DESCRIPTION OF THE DRAWINGS

A preferred form of the present invention will now be described with reference to the accompanying drawings.

Figure 1 is an illustration of the breathing assistance apparatus that may utilise the method of disinfecting of the present invention.

Figure 2 is an exploded view of an elbow connection conduit of the breathing assistance apparatus of the present invention.

Figure 3 is a front view of a gases supply and humidifier apparatus with a hot gases tube (disinfection conduit) and a filter connection of the present invention.

Figure 4 is a front view of the gases supply and humidifier apparatus of Figure 3 without the disinfection conduit and ready for use by a patient.

Figure 5 is a perspective view of a breathing assistance apparatus with a filter over a gases return of the breathing assistance apparatus.

Figure 6 is a close up view of the gases return with the filter, in particular, the filter cover and a projection that extends within the gases return.

Figure 7 is a front view of the gases supply and humidifier apparatus showing the gases return and the temperature sensor residing within it.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides a breathing assistance apparatus that has a convenient and effective method of cleaning internal conduits inside the apparatus. As shown in Figure 1, the flow of gases passes in sequence through a gases supply means or flow driver (such as, a blower, fan or compressor), humidification chamber, heated delivery circuit and patient interface.

Further the present invention also provides a method of disinfecting a heated breathing conduit and a patient interface.

Gases are passed to the patient by way of a patient interface 2. The patient interface used with the apparatus of the present invention may be a full-face mask, nasal mask, nasal cannula, oral mouthpiece or tracheostomy connection, but the description below and figures disclose the use of a nasal cannula.

With reference to Figure 1 the breathing assistance apparatus of the present invention is shown in which a patient 1 is receiving humidified and pressurised gases through a nasal cannula 2. The cannula 2 is connected to a gases transportation pathway or inspiratory conduit 3 that in turn is connected to an integrated gases supply (blower) and humidifying device 4 (including a humidification chamber 5). In the preferred embodiment of the blower-humidifying device 4, the gases supply or blower is combined in one housing with the humidifier and humidification chamber. The humidification chamber 5 extends out from the housing 10 and is capable in use of being removed and replaced (by a slide on movement, such as that described in WO04024429 of Fisher & Paykel Healthcare Limited, the contents of which are incorporated by reference) by the patient or other user. Also, the gases supply outlet port 11 (see Figure 2) that feeds the inlet to the humidification chamber 5 is internal within the housing 10. It must be

appreciated that the embodiment described above in relation to the housing and the figures merely illustrates one form of the housing of the integrated gases supply and humidifying device.

The inspiratory conduit 3 (see Figure 1) is connected to the outlet 8 of a humidification chamber 5 that contains a volume of water 6. Inspiratory conduit 3 preferably contains heating means or heater wires 7 that heat the walls of the conduit to reduce condensation of humidified gases within the conduit and the patient interface (e.g. nasal cannula 2) such the conduit as described in WO04026382 of Fisher & Paykel Healthcare Limited, the contents of which are incorporated by reference.

The humidification chamber 5 is preferably formed from a plastics material and may have a highly heat conductive base (for example an aluminium base) that is in direct contact with a heater plate 25. The device 4 is provided with control means or an electronic controller that may comprise a microprocessor based controller executing computer software commands stored in associated memory. The controller receives input from sources such as user input means or dial (not shown) through which a user of the device 4 may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient 1.

In response to the user set humidity or temperature value input via dial (or buttons) and other possible inputs such as internal sensors that sense gases flow or temperature, or by parameters calculated in the controller, the controller determines when (or to what level) to energise heater plate to heat the water 6 within humidification chamber 5. As the volume of water 6 within humidification chamber 5 is heated, water vapour begins to fill the volume of the chamber above the water's surface and is passed out of the humidification chamber outlet 8 with the flow of gases (for example air) provided from a blower part of the device that has entered the device 4 through an inlet 9 on the back of the device 4.

The gases supply within the device 4 is preferably a variable speed pump or fan that draws air or other gases through the blower inlet 9. The speed of variable speed pump or fan is preferably controlled by the control means or electronic controller described above in response to inputs entered into the device 4 by the user.

Disinfection of the Device

A partially exploded view of a gases supply and humidification device 4 is shown in Figure 2. The device 4 has an elbowed connection conduit 12 that has an inlet end 13, which is the gases return in the housing 4, and an outlet end 8, that is the patient outlet of the housing 4. The conduit 12 is provided to receive humidified gases from the humidification chamber 5 and as such the inlet end 13 is connected to the outlet 15 of the humidification chamber. The humidified gases are directed from the conduit's outlet end 8 into the breathing conduit 3 (see Figure 1) for delivery to a patient. It is preferred that the elbowed connection conduit 12 is permanently fixed in place in the housing 4.

There is a requirement for multiple users to use these devices as they will be used in hospitals, sleep laboratories or leased by home care companies and hospitals for short term home users.

To use such a gases supply and humidification device 4 on multiple patients the elbow conduit 12 integrated into the device must have a high level disinfection process carried out between different patients using it. For ease of use, even if the elbow conduit 12 can be removed, and to avoid dismantling and potential damage to the internal parts of the device 4 it is preferred that the elbow is disinfected in situ. This is because it is often impractical to remove the elbow, as it may have electrical connectors and the like, and clean it and reconnect it. Furthermore, the high labour content and skill level required would make removing the elbow an unreliable cleaning method and may make the device more unreliable.

Other parts of the device 4, such as the gas supply outlet 11, may also need high level disinfection between patients and could benefit from the present invention.

Currently high level disinfection is performed either by thermal or chemical process. Thermal disinfection is normally carried out by submersion in hot water or steam and chemical disinfection by submersion in instrument grade disinfectants. These processes have disadvantages for high level disinfection of devices such as the gases supply and humidification device 4 of the present invention as it cannot be submersed; steam sterilized or easily chemically disinfected.

A further option for thermal disinfection is hot dry air. The present invention is the supply of a heated gases tube (disinfection conduit) for use with a device 4 to allow in particular for disinfection of the elbow conduit 12. A disinfection conduit 14 is shown in

Figure 3. To disinfect the elbow conduit 12 a first end 17 of the disinfection conduit 14 is connected to the gases supply outlet 11 and a second end 18 to the outlet end 8 of the elbow conduit 12. The disinfection conduit 14 preferably has a heating element 19 within, through out or about the walls of the disinfection conduit 14. For example, the disinfection conduit 14 may be a section of tubing as described in WO04026382 of Fisher & Paykel Healthcare Limited with appropriate connectors on both ends of the tube to enable connection to the elbow conduit 12 and the gases supply outlet 11.

It is preferred that a removable exhaust gases filter 20 is placed on the inlet end 13 of the elbow conduit 12. This filter 20 is shown in more detail in Figures 5 and 6. In Figure 5, a filter housing 21 can be placed about the inlet end 13. The filter housing 21 is preferably made of a plastics material and can be simply removably attached to the inlet end 13, and remains on the end 13 by a friction fit. A preferably circular piece of filter material (not shown in this figure), sits inside the filter housing 21 and therefore occludes the inlet end 13, such that when in use with the disinfection conduit as described and shown with reference to Figure 3, gases exiting the inlet end 13 (patient return 13) are filtered before they exit to the ambient surroundings.

Referring to Figure 6, the filter housing 21 is shown in further detail. Preferably a projection 22 is provided with the filter 20 and housing 21. This tubular projection 22 sits within the inlet end 13 and the filter housing 21 sits about the projection 22 and over the end of the inlet 13. The projection 22 has the purpose of increasing the gases velocity at the point where heated gases are exiting the inlet end 13 (when the disinfection conduit 14 is in place as described above and in use). This has the effect of maximising the exhaust temperature of the exiting gases and minimising the temperature drop at the exit point. This ensures there is a high level of disinfection throughout the entire elbow conduit 12. In use, the heated gases flow around the spherical end 23 of the projection 22 down the sides of the tubular inlet end (in the direction of arrows A) through apertures (not shown) in the projection 22 through the filter material 20 and past the filter housing 21 into the ambient surroundings.

When the disinfection conduit 14 is connected between the gases supply outlet 11 and the patient outlet 8 as described above, the device 4 may be put into a cleaning mode whereby dry gases, such as air, are circulated through the disinfection conduit 14 and elbow conduit 12. It is preferable that the circulated gases are heated by the disinfection

conduit to a temperature of 80°C. However, a temperature between 60°C and 90°C may be suitable.

The connectors at both ends 17, 18 of the disinfection conduit 14 preferably have pneumatic fittings. Preferably the second end 18 of the disinfection conduit 14 has an electrical connection such that the heating element 19 within the conduit 14 can be supplied from the device 4 with power. In other forms of the device both ends 17, 18 may have electrical and pneumatic connections.

The device 4, and in particular, the controllers within the device 4 that control the heating of the heater plate as described above, is capable of controlling the temperature of the heating element 19.

The device 4 preferably has a setting that causes the controllers to provide a flow of gases, for example, between 1 and 50 litres per minute, to the disinfection conduit 14 and simultaneously provide power to the heating element 19, such that the gases circulating through the conduit 14 increase in temperature to 80°C. The controller then maintains the power to the heating element 19 maintaining a predetermined temperature inside the conduit 12 for a period of time, preferably 20 minutes, in order for the heated dry gases to disinfect the elbow conduit 12.

Therefore in use, after a patient has used the device 4 of the present invention, and before the next patient uses it, the patient, hospital staff or home care supplier can connect the disinfection conduit 14 to the device 4, as described above, and put the device 4 into a cleaning mode. As an example, a person might put the device into a cleaning mode by activating a button on the device that causes the controllers to provide power to the heating element and gases to the disinfection conduit at a predetermined temperature over a set period of time. In the preferred method of disinfecting the device, it is preferred that the surface temperatures inside the elbow conduit reaches a minimum of 80°C for a time period of 20 minutes and the flow provided for circulation through the elbow conduit is approximately 10 litres per minute. However, other appropriate circulating flows between 1 and 50 litres per minute and other appropriate time periods and temperatures may be used.

In the preferred form of the present invention the elbow conduit 12 preferably has a temperature sensor 24 within it, for example, as shown in Figure 7. However, in other forms of the invention, the elbow conduit may not have such a sensor.

In the preferred form this sensor measures the temperature of gases travelling through the conduit 12. In particular, in the preferred form of the method of disinfecting, at the start of the disinfection process, the controller or electronics within the device 4 performs some checks to ensure the disinfection conduit is correctly connected to the device 4. Firstly, a check is performed to determine that there is a heated gases flow through the elbow conduit 12. When the gas flow supplied by the device 4 and heater element 19 of the disinfection conduit 14 are both turned on, the heated gases flow is measured by the internal temperature sensor 24 inside the elbow conduit 12. After a predetermined period the heater element 19 is turned off with the gases flow of the device 4 left on. After a further predetermined period, the temperature inside the elbow conduit 12 is again measured by the temperature sensor 24. It is expected that the temperature will have dropped between measurements. This proves there is a fluid connection of gases supply connecting the flow source to the elbow conduit 12.

If a rise in temperature and a fall in temperature between measurements is not detected by the sensor 24 an error alarm will be indicated on or audibly relayed by the device, indicating the disinfection conduit 14 is not connected to the device 4 correctly.

Knowing the gases flow, ambient temperature outside the device 4 (as the device 4 has an ambient air temperature sensor incorporated within it) and the time period, in which the heating element 19 is powered, an expected temperature can be calculated for the heating and non-heating periods described above. The expected temperature can then be compared with the actual measured temperature from the temperature sensor. If these match, then the checks are complete and the disinfection conduit 14 and heating element 19 are connected and working correctly. The disinfection method, cleaning mode, as described above is then started.

In another embodiment of the present invention, the disinfection conduit may be used on a blower and humidifying device that does not have an internal temperature sensor inside the elbow conduit. In this embodiment a predetermined gases flow is caused to pass through the disinfection conduit, and a predetermined power is applied to the heating element within the disinfection conduit. The ambient conditions are known. The predetermined gases flow and predetermined power applied are determined such that the internal surface temperatures inside the elbow conduit will exceed the temperatures

required for high level disinfection for a range of ambient conditions. The predetermined temperature and power are preferably determined from testing and the like.

The method of disinfection described above has been validated by an independent laboratory, Toxikon Corporation of Bedford, MA, USA.

The method of disinfection as described above is automated so minimal training is required to disinfect the elbow conduit and it is not necessary to dismantle the gases supply and humidification device, therefore, inadvertent damage to the internal parts of the device is avoided.

Also, during the disinfection period the internal surface temperature of the elbow conduit is continuously monitored so each disinfection cycle can be validated and a disinfection completed symbol shown on the display at the completion of the process. Alternatively, if the disinfection cycle was not validated a failed disinfection symbol can be displayed to alert a user or operator.

Disinfection of Inspiratory Conduit and Patient Interface

In a second form of a blower-humidifying device 4 of the present invention a method of disinfecting an inspiratory conduit 3 and/or patient interface 2 is disclosed.

Referring to Figure 1 and as detailed above, the inspiratory conduit 3 preferably has a heating means or wires 7 within it. The wires 7 within the conduit 3 mean it can be difficult or dangerous to clean and disinfect the conduit. Therefore, prolonged use of the conduit by a patient results in high microbial contamination inside the conduit. Consequently there is a danger of infection of the patient from continual use of the conduit 3. Therefore, for home use where patients are reusing the inspiratory conduit 3 and patient interface 2 over a substantial period it is preferable to provide a method of cleaning and disinfecting the conduit 3 and patient interface 2.

As shown in Figure 1, in the standard configuration the blower and humidifying device is used with a heated breathing conduit (inspiratory conduit 3) connected to the patient outlet 8 of the device 4. The patient interface 2 is connected to the other end of the conduit 3.

The method of disinfecting is to force dry heat through the conduit and optionally the patient interface, to heat and dry the conduit and patient interface such that bacteria and microbes are killed and cannot multiply in the dry conditions. After a patient has completed their treatment (for example, each morning) the patient empties the

humidification chamber and presses a button, for example, on the device 4 thereby activating a control sequence or algorithm. The control sequence or algorithm is preferably stored in the controller (described above). A button on the device 4 may activate the control sequence but other means of activating the sequence may be provided, for example, the device may automatically activate the conduit disinfecting control sequence a predetermined time after completion of treatment (removal of the patient interface, for example) has been detected and the controller of the device has detected the humidification chamber is empty. The controller then controls the heater plate 25 to maintain heat to the humidifying chamber 5 and the blower 4 continues to supply gases to the chamber 5, such that heated dry gases pass through the chamber 5 to the conduit 3. At the same time, the power to the heating means or wires 7 is maintained to provide additional heat to the gases within the conduit 3. The heating of the gases is preferably at approximately 40°C and the exit temperature from the tube is between 40°C and 75°C. The disinfecting and heating sequence preferably continues for between 30 and 120 minutes.

More particularly, the humidification chamber heater heats the gases until the temperature of the gases in the return elbow (inlet end 13) reaches 40°C. The heating wires in the heated breathing conduit heats the air passing down the conduit until a temperature sensor at the patient end of the conduit reaches approx 50°C. In other implementations it is possible that this temperature may be raised to as high as 70°C.

In some forms of this method, a cap is placed on the patient end of the heated breathing conduit 3 (in place of the patient interface 2). The cap allows the heated gases to build up in the conduit thereby increasing the effectiveness of the disinfection process. The purpose of the cap is to ensure that a patient is not wearing the patient interface. The device 4 controller can determine this by the different pressure and flow characteristic of the gases when the cap is on the distal end of the conduit 3 compared to that characteristic when the patient interface is attached to the end of the conduit 3. With a certainty that there is no patient connected the air in the heated breathing conduit can be heated to temperatures well above safe gas breathing temperatures which improves the efficacy of the disinfection process.

In other forms of this method, the patient interface 2 is left in place at the distal end of the conduit 3 and is exposed to the heated and dry gases. In further forms the patient interface 2 during the disinfection process may be housed in a receptacle that allows

increased heat build up to occur in the patient interface, again, increasing the effectiveness of disinfection. By putting the interface in a receptacle it can be ensured that a patient cannot be using the interface for breathing, and the controlling device can detect there is no patient connected, again because of the different pressure flow characteristic. The heated breathing conduit can then be heated to temperatures well above safe gases breathing temperatures. Again this improves the efficacy of the disinfection process.

The purpose of this disinfection process is to increase the useable life of the heated breathing conduit by lowering microbial contamination on the inside surfaces the gases pass over. If the heated breathing tube is not cleaned regularly, and this is difficult with an internal heating wire, microbes can build to a level that the inside of the surfaces of the conduit become colonised with bacteria, thereby lowering the useful life of the conduit, making treatment more inconvenient for the patient.

Tests were carried out on a heated breathing conduit in normal use for 2 months at home by patients with no disinfection process. The conduits were then tested for contamination. The results were that contamination within the conduits had reached a level of bacterial contamination that made the conduits unsafe for use.

Further tests were also carried out with identical heated breathing conduits used under the same conditions for 2 months as described above. The conduits were then processed with the dry heat disinfection method described above. The result was that bacterial contamination was lowered (compared to the conduits that had not been treated) to a level that the conduits could continue to be used safely.

This disinfection method by dry heat shows that bacterial contamination can be effectively lowered to a level that the conduits could continue to be used by patients.

CLAIMS:

1. A breathing assistance apparatus adapted to deliver humidified gases to a patient comprising:

a housing,

a gases supply within said housing,

a gases outlet in said housing in fluid connection with said gases supply and adapted to make fluid connection with an inlet of a humidifier in order to supply gases to said humidifier,

an outlet in said humidifier,

a patient outlet on said housing,

a gases return in said housing, adapted to make fluid connection with said humidifier outlet in order to receive humidified gases from said humidifier and provide humidified gases to said patient outlet, said patient outlet being in fluid connection with or adapted to make fluid connection with a breathing conduit for delivery of humidified gases to a patient,

a heated gases conduit including a heating element adapted for connection between said gases outlet and said patient outlet.

2. A breathing assistance apparatus according to claim 1 wherein said gases return has a temperature sensor within that senses the temperature of said gases flowing through said gases return.

3. A breathing assistance apparatus according to claim 1 or 2 further comprising a filter connectable to said gases return to filter gases exiting said gases return.

4. A method of disinfecting a breathing assistance apparatus, said breathing assistance apparatus including a gases supply capable of supplying a flow of gases at a predetermined pressure to a patient and capable of providing power to conduits supplying gases to said patient, said method comprising the steps of:

connecting a heated gases conduit, including a heating element, between an outlet of said gases supply and an outlet to said patient,

said gases supply providing a predetermined flow of gases to said disinfection conduit over a predetermined period of time,

said gases supply including a controller to supply power to said heating element and said controller causing the heating element to heat the heated gases conduit up to a predetermined temperature.

5. A method of disinfecting a breathing assistance apparatus according to claim 4 wherein said predetermined period of time is between 2 and 60 minutes.

6. A method of disinfecting a breathing assistance apparatus according to claim 4 wherein said predetermined period of time is approximately 30 minutes.

7. A method of disinfecting a breathing assistance apparatus according to any one of claims 4 to 6 wherein said predetermined temperature is between 60 and 90 degrees Celsius.

8. A method of disinfecting a breathing assistance apparatus according to any one of claims 4 to 6 wherein said predetermined temperature is approximately 80 degrees Celsius.

9. A method of disinfecting a breathing assistance apparatus according to any one of claims 4 to 8 wherein said predetermined circulating flow is between 1 and 50 litres per minute.

10. A method of disinfecting a breathing assistance apparatus according to any one of claims 4 to 8 said predetermined circulating flow is approximately 10 litres per minute.

11. A method of disinfecting at least one of a breathing conduit and patient interface, said breathing conduit and said patient interface being connected to a breathing assistance apparatus including a gases supply capable of supplying a flow of gases at a predetermined pressure or flow to a patient and capable of providing power to said breathing conduit supplying gases to said patient, said breathing assistance apparatus including a humidifying chamber and heater capable of heating water within said chamber and said breathing conduit including a heating element, said method comprising the steps of:

removing water from said chamber,

said gases supply providing a predetermined flow of gases to said chamber and at least one of said breathing conduit and patient interface over a predetermined period of time,

said gases supply including a controller to supply power to said heater and said heating element, said controller causing the said heater and said heating element to heat said gases supplied to said at least one of said breathing conduit and patient interface to a predetermined temperature to dry and disinfect said at least one of said breathing conduit

and patient interface to prevent accumulation of bacteria in said at least one of said breathing conduit and patient interface.

12. A method of disinfecting at least one of a breathing conduit and patient interface according to claim 11 wherein said predetermined period of time is between 30 and 120 minutes.

13. A method of disinfecting at least one of a breathing conduit and patient interface according to claim 11 wherein said predetermined period of time is approximately 90 minutes.

14. A method of disinfecting at least one of a breathing conduit and patient interface according to any one of claims 11 to 13 wherein said predetermined temperature is between 40°C and 75°C.

15. A method of disinfecting at least one of a breathing conduit and patient interface according to any one of claims 11 to 13 wherein said predetermined temperature is 40°C.

16. A method of disinfecting at least one of a breathing conduit and patient interface according to any one of claims 11 to 15 said method including the step of placing a cap on said breathing conduit before said heated gases are caused to flow in said breathing conduit.

17. A method of disinfecting at least one of a breathing conduit and patient interface according to any one of claims 11 to 16 said method including the step of placing said patient interface in an enclosure.

18. A breathing assistance apparatus as herein described with reference to the accompanying drawings.

19. A method of disinfecting a breathing assistance apparatus as herein described with reference to the accompanying drawings.

20. A method of disinfecting one of a heated breathing conduit and patient interface as herein described with reference to accompanying drawings.

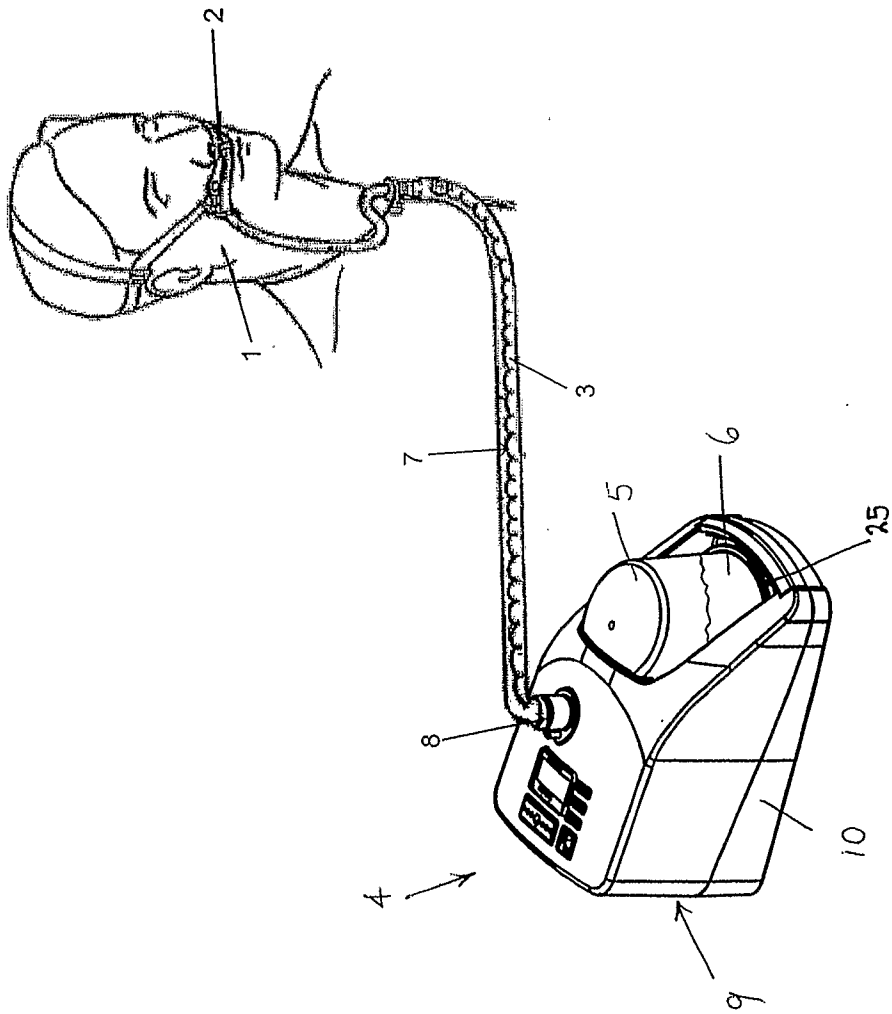

Figure 1

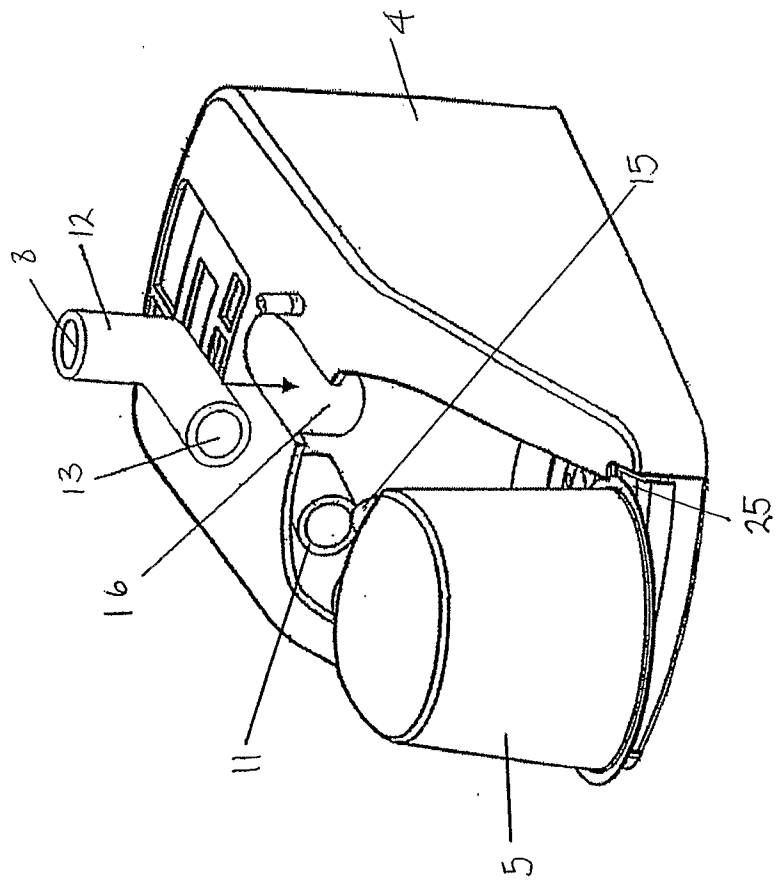

Figure 2

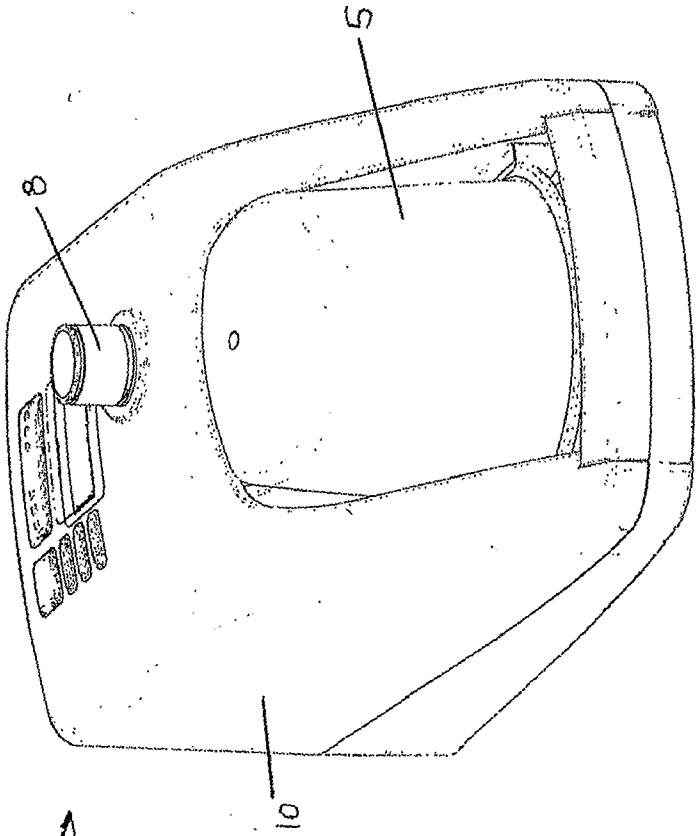

Figure 4

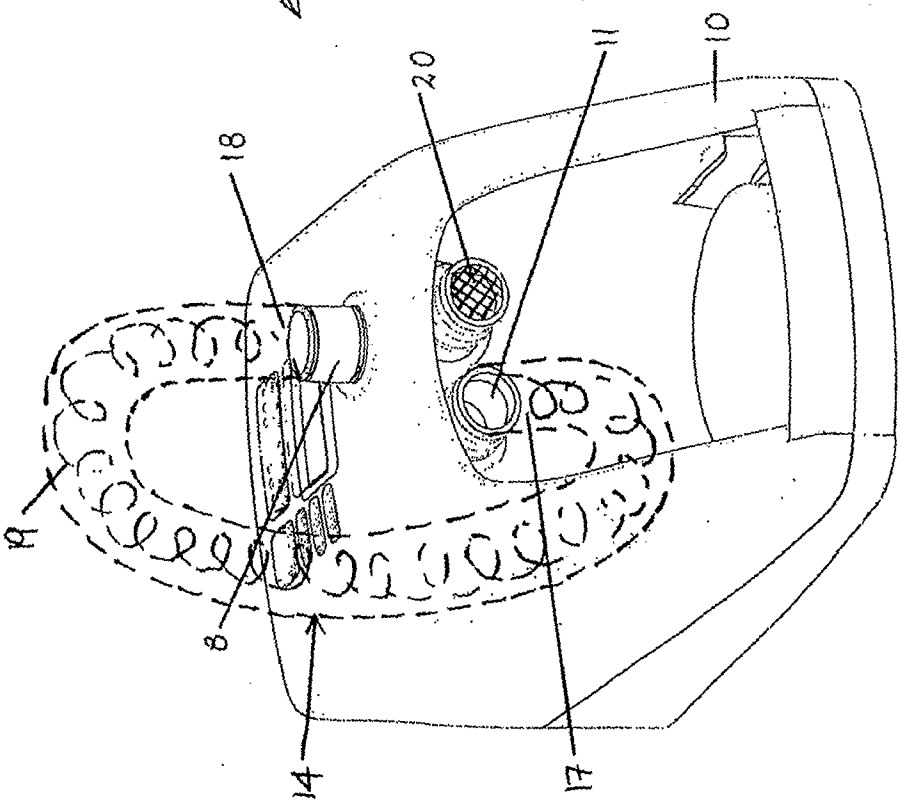

Figure 3

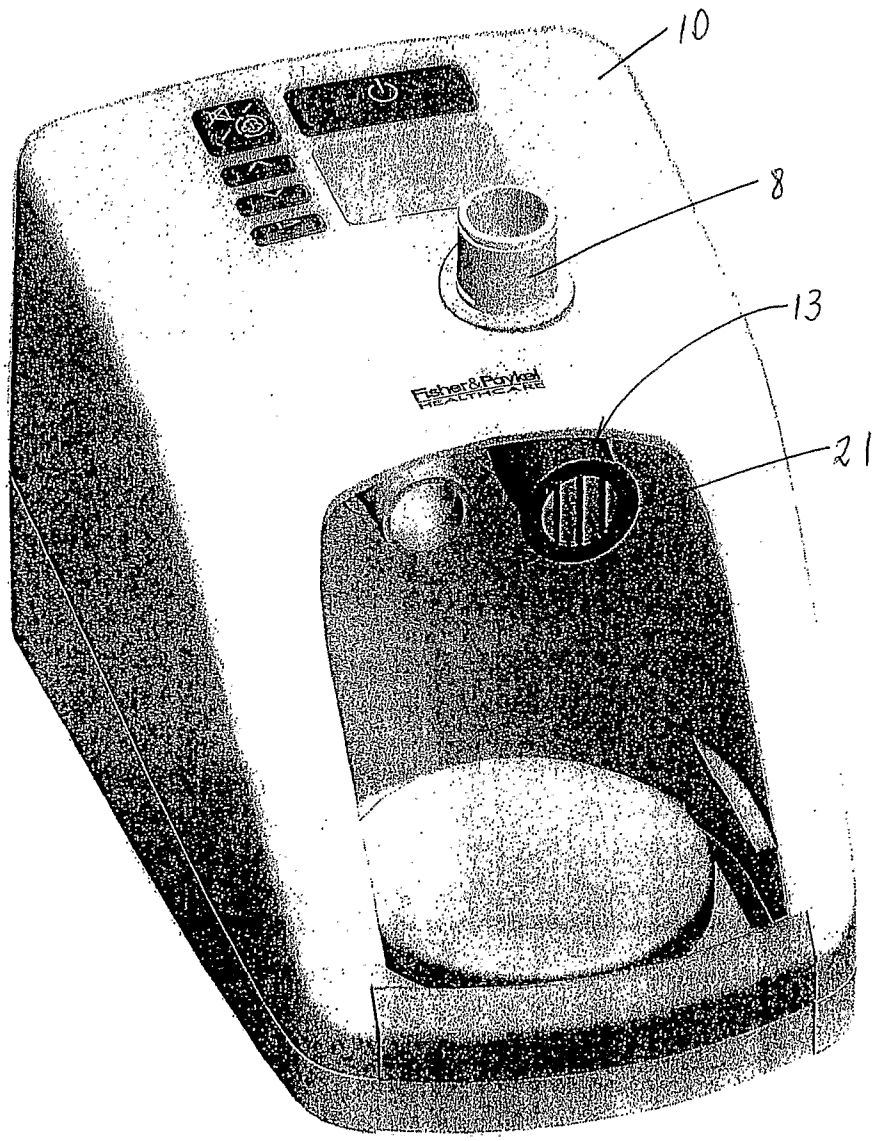

Figure 5

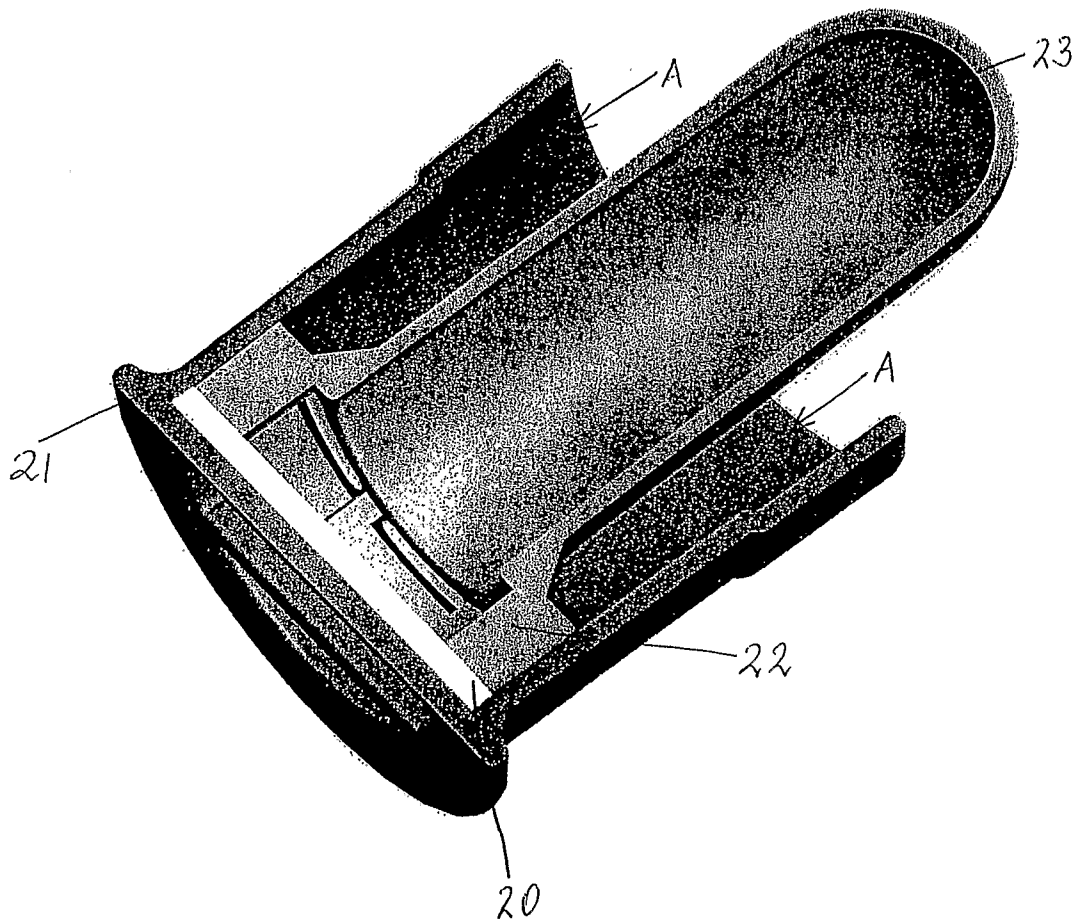

Figure 6

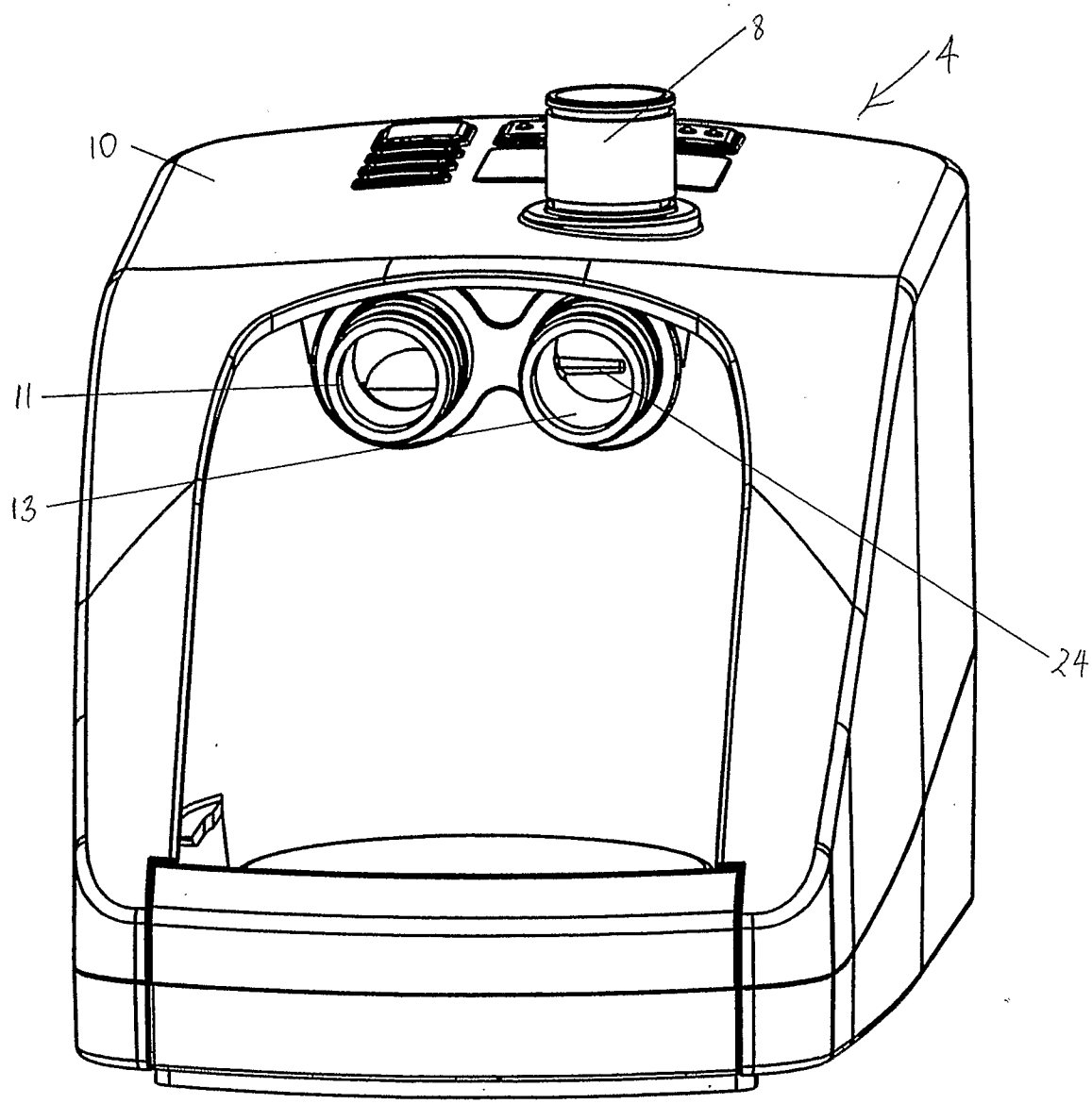

Figure 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ2006/000330

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61L 2/06 (2006.01) ***A61M 16/00*** (2006.01)

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)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI and IPC marks A61M 16/-, A61L 2/- and keywords: sterilize and heat and conduit and similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 2006/126900 A1 (FISHER & PAYKEL HEALTHCARE) 30 November 2006 Page 12 line 21 to page 13 line 20	4-10
A	WO 2005/021076 A2 (E.M.E. LIMITED) 10 March 2005 Whole document	
A	JP 4352965 A (AKOMA IKA KOGYO KK) 8 December 1992 Whole document	
A	US 6523538 B1 (WIKEFELDT) 25 February 2003 Whole document	

[X] Further documents are listed in the continuation of Box C [X] 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

"E" earlier application or patent but published on or after the international filing date

"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)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"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

"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

"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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 February 2007	- 1 MAR 2007
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer **DAVID MELHUISH** Telephone No : (02) 6283 2426

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ2006/000330

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6283132 B1 (STEPHENS et al.) 4 September 2001 Whole document	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/NZ2006/000330

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	2006126900	NIL					
WO	2005021076	NIL					
JP	4352965	NIL					
US	6523538	AU	18796/01	EP	1181070	WO	0149351
US	6283132	NIL					

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX