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(54) Title: DISPOSABLE ACTIVE HUMIDIFIER FOR THE MECHANICAL VENTILATION OF A PATIENT

(57) Abstract

This invention is a disposable active humidifier used in conjunction with mechanical ventilation of a patient, having a cartridge (1) which forms a humidification chamber (2) which is delimited by an inlet (3), an outlet (4), and can be interposed in the ventilation circuit (40). The cartridge (1) has an interspace (11) which is externally delimited by a heat exchange surface, and is internally delimited by a hydrophobic membrane (12) which surrounds the humidification chamber (2). A humidification fluid, e.g., water, originating from a bottle or bag, can be introduced in the interspace (11).

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DISPOSABLE ACTIVE HUMIDIFIER FOR THE MECHANICAL VENTILATION OF A PATIENT

The present invention relates to a disposable active humidifier for the mechanical ventilation of a patient.

It is known that the mechanical ventilation of a patient uses dry gases which are humidified before being inspired by the patient. Most commercially available systems are based on the principle of making the gas flow directly over the water contained in a heated container.

The conventional solution has a drawback which is constituted by the relatively high volume of the cartridge, which constitutes an additional bulk; it should be noted that it is very important to reduce bulk, since in mechanical ventilation, in which the pressure of the ventilator expands the lungs of the patient to ventilate him, an extra compressible space is certainly a negative factor.

The aim of the invention is indeed to eliminate the drawbacks mentioned above, which are typical of conventional systems (bacterial contamination and high compressible volume), by providing a disposable active humidifier for the mechanical ventilation of a patient which has a very small bulk and in particular constitutes an integrated segment in the ventilation circuit and in practice therefore does not increase the volume of compressible air.

Within the scope of this aim, a particular object of the invention is to provide a disposable active humidifier which can be prepared in a sterile package which can be connected only once to the patient without requiring further handling with the risk of bacterial contamination.

Another object of the present invention is to provide an active humidifier in which the water remains confined within the cartridge with a continuous supply which in practice forms a closed circuit with no need for connection to the outside.

Another object of the present invention is to provide a disposable active humidifier which, by virtue of its particular constructive characteristics, is capable of giving the greatest assurances of reliability and safety in use.

This aim, these objects and others which will become apparent hereinafter are achieved by a disposable active humidifier for the mechanical ventilation of a patient, according to the invention, characterized in that it comprises a cartridge which forms a humidification chamber which is delimited by an inlet and by an outlet and can be interposed in a ventilation circuit, said cartridge having an interspace which is externally delimited by a heat exchange surface and is internally delimited by a hydrophobic membrane which surrounds said humidification chamber, a humidification fluid being introducible in said interspace.

Further characteristics and advantages will become apparent from the description of a preferred but not exclusive embodiment, illustrated only by way of non-limitative example with the aid of the accompanying drawings, wherein:

Figure 1 is a schematic sectional view of a disposable active humidifier according to the invention;

Figure 2 is a schematic view of the active humidifier

included in a ventilation circuit.

With reference to the above figures, the disposable active humidifier for the mechanical ventilation of a patient comprises a cartridge, generally designated by the reference numeral 1, which internally forms a humidification chamber 2 which is delimited by an inlet 3 and by an outlet 4 which are formed on respective caps 5 and 6 which are arranged mutually opposite at the axial ends of the humidification chamber 2.

The cartridge 1 is externally provided with a heat exchange surface, advantageously constituted by a tubular aluminum casing 10, which delimits an interspace 11 formed by a hydrophobic membrane 12 which delimits the humidification chamber 2.

Inside the humidification chamber 2 there is a diffuser 20 which is meant to direct the incoming air stream so that it flows over the membrane 12, so as to facilitate the transfer of humidity through the hydrophobic membrane 12 that delimits the interspace 11, inside which water is introduced by means of an inlet 30, to which it is possible to connect a simple bag or bottle which continuously introduces the water into the interspace so that by means of the hydrophobic membrane it is possible to ensure the required degree of humidity of the air.

It should be added that the diffuser advantageously has protrusions 21 shaped like a conical inclined surface, which facilitate the conveyance of the air stream against the membrane, which provides a barrier against bacteria, so that the system can be supplied with ordinary distilled water, thus reducing the operating costs.

The cartridge 1 can be easily used in a ventilation circuit, designated schematically by the reference numeral 40 in the drawing, in which there is a heater 41 which forms the seat for accommodating the external casing of the cartridge.

From the above description it is thus evident that the invention achieves the intended aim and objects, and in particular the fact is stressed that the particular structure that has been used allows to provide a disposable active humidifier which in practice does not increase the volume of air present in the ventilation circuit, since it provides a simple segment which is interposed in the ventilation circuit itself.

Furthermore, the new active humidifier is based on an innovative principle which is different from the other systems that are commercially available, since its humidification principle is based on the vaporization of water instead of on flowing over water present in a heated container.

The present system uses a humidifier cartridge which is integrated in the temperature-controlled ventilation circuit and which by vaporization charges the dry gases on the inspiratory line of the patient with humidity.

By virtue of the PVC temperature-controlled circuit in which the heating resistor is embedded in the external reinforcement spiral, the humidity released by the humidifier cartridge does not condense along the inspiratory line but is transferred in full to the patient.

The cartridge of the humidifier (see Figure 1) is constituted by an external body made of metal (aluminum)

which acts as interface with the heating element of the humidifier. Inside the cartridge there is a hydrophobic membrane which provides the interface between the liquid and the vapor phase of the inspiratory line.

The hydrophobic membrane allows the passage of the vapor that forms as a consequence of the heating of the water contained in the cartridge.

The system can be supplied with ordinary sterile/double-distilled water.

The innovation of the system is that it uses a cartridge which is integrated in the circuit (see the drawing in the accompanying Figure 2) and is preassembled to the ventilator with the connections provided.

Differently from flow-over humidification systems, the present system eliminates the contact of the supply water with the outside environment, avoiding the risk of exogenous contamination of the patient and keeping the system dry without forming condensate in the ventilation circuit.

The invention thus conceived is susceptible of numerous modifications and variations, all of which are within the scope of the inventive concept.

All the details may furthermore be replaced with other technically equivalent elements.

In practice, the materials used, as well as the contingent shapes and the dimensions, may be any according to the requirements.

CLAIMS

1. A disposable active humidifier for the mechanical ventilation of a patient, characterized in that it comprises a cartridge which forms a humidification chamber which is delimited by an inlet and by an outlet and can be interposed in a ventilation circuit, said cartridge having an interspace which is externally delimited by a heat exchange surface and is internally delimited by a hydrophobic membrane which surrounds said humidification chamber, a humidification fluid being introducible in said interspace.

2. A disposable active humidifier according to claim 1, characterized in that said humidification chamber has a substantially cylindrical shape and forms a segment of said ventilation circuit.

3. A disposable active humidifier according to the preceding claims, characterized in that said outlet and said inlet are formed by respective caps which axially delimit said interspace and said humidification chamber.

4. A disposable active humidifier according to one or more of the preceding claims, characterized in that it axially comprises, inside said humidification chamber, a diffuser which is adapted to direct the air stream of the ventilation circuit against said hydrophobic membrane.

5. A disposable active humidifier according to one or more of the preceding claims, characterized in that said interspace has an inlet for connection to a bottle or bag of fluid.

6. A disposable active humidifier according to one or more of the preceding claims, characterized in that said

diffuser has inclined rings which are adapted to divert the stream toward said hydrophobic membrane.

7. A disposable active humidifier for the mechanical ventilation of a patient, characterized in that it comprises one or more of the described and/or illustrated characteristics.

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 16/00; A62B 700, 18/08; F23D 11/00, 14/00; F24J 3/00
US CL :128/201.13, 203.26, 204.17
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)

U.S. : 128/201.13, 203.26, 204.17; 422/46

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)

APS
Search Termis: Humidifier, Hydrophobic, Membrane, HME, Heat Exchanger, Heat and Moisture Exchanger, Respirator, Ventilator

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,381,267 A (JACKSON) 26 April 1983, Figs 1-6, Summary of the Invention, and col. 5 line 62.	1-3
Y	US 5,192,499 A (SAKAI et al.) 09 March 1993, Figs 1, 3 and 5 element (1), col. 3 lines 10-36.	1-3
Y	US 3,927,981 A (VIANNAY et al.) 23 December 1975, Fig 2 element (16), Fig 3, and col. 2 line 54 to col. 3 line 50.	1-3
Y	US 4,449,992 A (YAMADA et al.) 22 May 1984, col. 5 lines 49-53.	1-3
A	US 5.435 298 A (ANTHONY) 25 July 1995, whole document..	1-3

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"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
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Date of the actual completion of the international search 23 JUNE 1999	Date of mailing of the international search report 26 JUL 1999
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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 5,035,236 A (KANEGAONKAR) 30 July 1991, whole document.	1-3

INTERNATIONAL SEARCH REPORT

International application No.
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Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 7
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

No additional aspects of the invention were set forth, it was simply a broad all encompassing statment of all the aspects of the invention set forth in the preceding claims, drawing and specification

3. ☒ Claims Nos.: 4-6
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.