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(54) **Title**: PULMONARY DRAINAGE APPARATUS

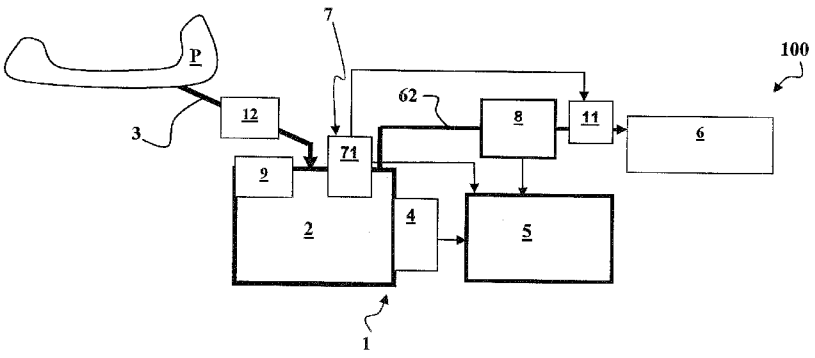

FIG. 1

(57) **Abstract**: A pleural drainage device (100), comprising: - A sealed disposable collecting container (2), connected with a drainage tube (3) having, in use, an end introduced into the pleural space, which container (2) is apt to receive the liquid and/or gaseous fluids drained by said tube (3); - A liquid level sensor (4), associated with the container (2) and apt to detect the level of drained liquid received into the latter; - a control unit (5) associated with the level sensor and further pressure (7) and flow (8) sensors; and - a suction pump (6).

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PULMONARY DRAINAGE APPARATUS

DESCRIPTION

The present invention refers to a drainage device, particularly suitable for pulmonary use but also applicable in other body districts, such as, e.g. the cardiac one, and to a related apparatus, preferably with modular components.

In the clinical field, the term “drainage” is used to indicate the surgical procedure by which just a draining effect is obtained. More specifically, focusing the attention only on thoracic applications, by "thoracic drainage" or "pleural drainage" it is meant the suction of air or liquid infiltrations present in the pleural cavity, i.e. in the space defined between the membrane of said pleura and the pulmonary alveolar parenchyma.

Evacuation of the above-mentioned infiltrations is fundamental, since in their presence the pulmonary parenchyma does not follow the pleura in the respiratory motions and therefore does not expand, partially or totally preventing gas exchange at the alveolar level. In fact, when external air at atmospheric pressure enters the pleural space, such air leads to total or partial collapse of the pulmonary parenchyma. In that case, intrapleural pressure balances itself or tends to balance itself with the atmospheric one, and such a pressure balance prevents air entering the lungs via the respiratory tract from moving around freely, thereby losing the above-mentioned gas exchange ability at the alveolar level. As it is known, in fact, normal breathing occurs only when the atmospheric and intrapulmonary pressures are different.

Therefore, drainage has the purpose of bringing pressure values in the intrapleural environment back to physiological conditions, removing air and liquid secretions from the cavity itself.

Drainage represents a fundamental surgical procedure, often indispensable for a correct treatment of some pathologies, and in particular pneumothorax, pleural empyema, neoplastic pleural effusion and post-traumatic/post-surgical hemothorax/pneumothorax (e.g. in thoracic, heart or esophageal surgery), and in some types of heart surgery.

In spite of the remarkable impact of the above-mentioned air and liquid infiltrations on post-operative hospital stay and mobility, their detection currently remains entrusted, in most cases, to empirical methods markedly affected by subjective conditions of the operator. In general, such empirical methods are based on observation “by eye” of leaks in the form of bubbles in a "water valve" chamber of collection systems connected to a pleural drainage tube. In fact, such "classic" drainage systems provide only a qualitative evaluation of the patient's condition, and their sole advantage is that of having a limited cost.

Currently, also drainage systems equipped with control sensors are known, in particular for controlling suction pressure and flow.

However, also the known devices providing the objective detection of some drainage parameters do not yet allow a complete and fully satisfactory control of the procedure, to the detriment of the reliability of the latter, and are scarcely versatile with respect to applications in different clinical fields, despite being anyhow rather expensive and of complex construction.

Therefore, the technical problem set and solved by the present invention is that of providing a drainage device, particularly suitable for pleural drainage, but also suitable for cardiac drainage, allowing to overcome the drawbacks mentioned above with reference to the known art.

Such a problem is solved by a device according to claim 1.

Preferred features of the present invention are set forth in the dependent claims thereof.

The present invention provides some relevant advantages. The main advantage lies in the fact that the device of the invention allows an optimal management of the drainage procedure, allowing a monitoring and a complete control of the latter and concomitantly being extremely versatile and of simple structure.

In a preferred embodiment, the invention provides a drainage apparatus which lends itself to a modular embodiment, to the advantage of the overall inexpensiveness of the procedure.

Other advantages, features and operation steps of the present invention will be made evident in the following detailed description of some embodiments thereof, given by way of example and not for limitative purposes.

Reference will be made to Figure 1, showing a block diagram related to a preferred embodiment of the drainage device according to the present invention.

Referring to Figure 1, a drainage device, particularly suitable for pleural drainage but also suitable for cardiac drainage, and obtained according to a preferred embodiment of the invention, is generally denoted by 1.

In its basic version, the device 1 comprises a sealed collecting container 2, sealingly connected or connectible to a tubular drainage member 3. The latter has, in use, an end introduced into the pleural cavity, or other intracorporeal space to be drained, of the patient (denoted by way of example with P in Figure 1), and the container 2 is just apt to receive the liquid and/or gaseous fluids drained by suction from said space by the tubular member 3 itself.

In the present example, the container 2 is of disposable type and preferably made of plastics, e.g. by molding.

Always in the present embodiment, the container 2 is of the so-called "three-chamber" type. In particular, according to said embodiment the container 2 comprises three communicating environments, their arrangement being such that they are filled in sequence by the drained fluid.

Preferably, the container 2 is transparent or has at least one transparent portion.

The container 2 has a liquid level sensor 4, apt to detect the level of drained liquid received into the container 2 itself. Preferably, the level sensor 4 is removably associated with the container 2. In particular, according to a particularly preferred embodiment the level sensor 4 is suitable for a reading in transparency of the level of liquid, without contacting the latter. In that case, the level sensor can be removably held on the outer wall of the container, e.g. in a suitable housing thereof.

The three-environment embodiment of the container 2 entails the advantage,

with respect to a single environment, of allowing a more accurate reading of the level of liquid.

In other variant embodiments, the above-introduced level sensor may be replaced by an equivalent means for detecting the volume of liquid received into the container 2.

The drainage device 1 is intended as part of a drainage apparatus, the latter generally denoted by 100, comprising, besides the above-mentioned tubular member 3, also a control unit 5 in communication with the level sensor 4, and suction means 6. The latter is controlled by the control unit 5 and is apt to cause a negative pressure in the container 2, and therefore in the tubular member 3, to obtain the desired removal of fluid from the pleural space or other intracorporeal space.

The apparatus 100 also comprises a pressure sensor 7, apt to detect the pressure inside the container 2 and it also in communication with the control unit 5.

Preferably, the pressure sensor 7 is of probe type and therefore comprises a probe member 71 arranged within the container 2 and an actual sensor/transducer member arranged in correspondence of the control unit 5 or in communication with the latter.

The apparatus 100 further comprises a flow sensor 8, it also in communication with the control unit 5 and arranged at a communication line 62 between the container 2 and the suction means 6.

Preferably, the apparatus 100 also comprises ventilation means, in communication with the control unit 5 and apt to cause automatic ventilation of the container 2 in case of an excess of vacuum. In the present example, such means comprises a ventilation valve 9 arranged in correspondence of the container 2 and an associated pressure sensor (preferably the same sensor 7 introduced above) apt to detect the pressure inside the container 2 itself.

The above-introduced suction means 6 is preferably implemented by a portable pump of suitable head.

The suction means 6 is preferably associated with adjustment means 11, typically an electrovalve, to vary, in association with the control unit 5, the level of vacuum within a certain hysteresis range.

The suction means 6 may provide both an external power-supplying and a power-supplying by portable units, e.g. optionally rechargeable batteries.

In a variant embodiment, the apparatus 100 may be equipped with a connection to the vacuum system usually present in hospitals, to be used alternatively to the above-introduced dedicated suction means.

Preferably, in correspondence of the tubular drainage member 3 it is provided means 12 for enabling/preventing fluid communication between the container 2 and the intracorporeal space to be drained, typically implemented by a one-way safety valve. This latter means 12 may be in communication with the control unit 5 and controlled thereby, and/or be associated with a vacuum detection sensor.

Therefore, the control unit 5 is suitable for managing the drainage procedure and may be implemented by hardware and software means known *per se* and based on digital technology. The control unit 5 is of course interfaceable with suitable software installable on a PC or palmtop, by USB or wireless connection, or it can be directly incorporated in such systems.

To the control unit 5 also display means, e.g. a display, can be associated in order to immediately read, through said display, the values detected by the above-introduced sensors. In case of the above-mentioned connection to a palmtop, PC, etc., such data could (also) be displayed on such further systems.

Also the communication between the control unit 5 and other components of the apparatus 100, in particular the above-mentioned sensors and valves, may be obtained with *per se* known traditional or wireless communication networks.

In use, the control unit 5 allows to set and hold the suction pressure of the means 6 (i.e., the vacuum level) substantially constant and anyhow controlled. In fact, as mentioned hereto, according to a preferred embodiment the control unit 5 allows to select a hysteresis range of the suction means 6 (i.e., a variation range of the admissible vacuum level), which in particular can be set *a priori* or variable directly by the end operator. Such a selective setting allows also compensation, to the ends of the control of the procedure, for pressure variations related to respiratory acts of the individual patient.

Moreover, the control unit 5, by its own data processing means, is capable of monitoring and assessing the air leaks drained by the intracorporeal space, leaks that are preferably calculated by difference between the total volume detected by the flow sensor 11 and the volume of liquid as associated to the detection of the level sensor 4. In particular, a difference greater than a certain predetermined threshold (within the reach of a person skilled in the art) in favor of the first value is an index of non-negligible air leaks, and therefore of the need to continue the drainage treatment.

The control unit 5, always by the above-mentioned data processing means, is capable of measuring and monitoring the level of pleural pressure as represented by the pressure into the container 2 detected by the pressure sensor 7, and of measuring and monitoring liquid pleural effusions by using the level sensor 4.

It will be appreciated that all sensors introduced hereto have at least one sensor portion not into contact with biological fluids and therefore reusable, both to reduce the costs of use and to have high-precision sensors available that may be equipped with self-controlling systems, not manageable in disposable systems. Moreover, the apparatus described lends itself to the use of sensors of commercial provenance, with no need of *ad hoc* design.

Preferably, all sensors introduced hereto, and particularly the level sensor 4, are of electronic type. It will be understood that the device and the apparatus of the invention anyhow lend themselves also to the use of sensors, both disposable and non-disposable ones, according to the specific needs.

According to a variant embodiment, the above-described apparatus also comprises alarm means (e.g. of acoustic and/or visual type), activating when the values measured by one or more of the above-introduced sensors are out of a preset range (corresponding to values acceptable for the medical course).

It will be appreciated how the described apparatus optimally lends itself to a modular embodiment. In particular, the drainage device 1 formed by the container 2 and the level sensor 4 may be used separately, as part of known drainage systems (in this case also without level sensor 4), or associated with the sole suction means 6 and/or the control unit 5.

Finally, it will be appreciated that the above-described device and

apparatus, though considered above all in connection with a plural drainage, can be used in other applications as well, in particular that for cardiac drainage, or at the level of any other body district requiring it.

The present invention has been hereto described with reference to preferred embodiments thereof. It is understood that other embodiments might exist, all falling within the concept of the same invention, as defined by the protective scope of the claims hereinafter.

CLAIMS

1. A drainage device (1), particularly suitable for pleural drainage, comprising:

- a sealed collecting container (2), connected or apt to be connected with a tubular drainage member (3) having, in use, an end introduced into the intracorporeal space to be drained, which container (2) is apt to receive the liquid and/or gaseous fluids drained by said tubular member (3); and
- means (4) for detecting the volume or level of a liquid (4), associated with said container (2) and apt to detect the volume or level of drained liquid received into the latter.

2. The device (1) according to claim 1, wherein said collecting container (2) has three communicating chambers, their arrangement being such that they are filled in sequence by the drained fluid.

3. The device (1) according to claim 1 or 2, wherein said collecting container (2) is of disposable type.

4. The device (1) according to any one of the preceding claims, wherein said volume or level detecting means (4) is removably associated with said collecting container (2).

5. The device (1) according to any one of the preceding claims, wherein said detecting means comprises a liquid level sensor (4) suitable for a reading in transparency of such a level of liquid without contacting the latter.

6. A drainage apparatus (100), comprising a drainage device (1) according to any one of the preceding claims and a control unit (5) in communication with said volume or level detecting means (4) for managing the drainage procedure.

7. The apparatus (100) according to the preceding claim, comprising a pressure sensor (7), apt to detect the pressure inside said collecting container (2) and in communication with said control unit (5).

8. The apparatus (100) according to the preceding claim, wherein said pressure sensor (7) is of probe type, comprising a probe member (71) arranged within said container (2) and a sensor/transducer member arranged in correspondence of said control unit (5) or in communication with

the latter.

9. The apparatus (100) according to any one of the claims 6 to 8, comprising suction means (6), apt to cause suction of the fluids to be drained by a negative pressure obtained in said container (2).

10. The apparatus (100) according to any one of the claims 6 to 9, comprising a flow sensor (8) in communication with said control unit (5).

11. The apparatus (100) according to claims 9 and 10, wherein said flow sensor (8) is arranged at a communication line (62) between said container (2) and said suction means (6).

12. The apparatus (100) according to any one of the claims 6 to 11, wherein said control unit (5) is apt to allow a selection of the variation range of the vacuum level admissible in use.

13. The apparatus (100) according to any one of the claims 6 to 12, comprising ventilation means (9) apt to cause automatic ventilation of said container (2) in case of an excess of vacuum.

14. The apparatus (100) according to the preceding claim, wherein said ventilation means comprises a ventilation valve (9) arranged in correspondence of said container (2) and an associated pressure sensor (7) apt to detect the pressure inside the container (2) itself.

15. The apparatus (100) according to any one of the claims 6 a 14, comprising a tubular drainage member (3) having, in use, an end introduced into the intracorporeal space to be drained, which tubular member (3) is connected or apt to be connected to said collecting container (2).

16. The apparatus (100) according to the preceding claim, comprising means (12) for enabling/preventing communication between said container (2) and the intracorporeal space to be drained, arranged in correspondence of said tubular member (3).

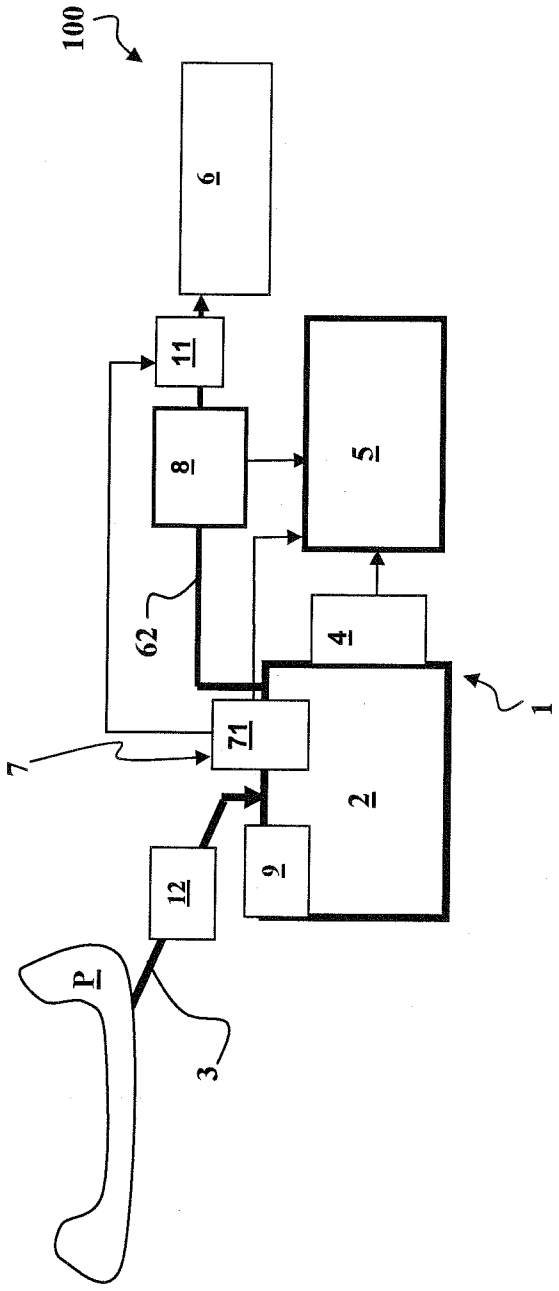

FIG. 1

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/050943

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/00
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2009/004368 A1 (SMITH & NEPHEW [GB]; HARTWELL EDWARD [GB]; SAXBY CARL [GB]) 8 January 2009 (2009-01-08) page 11, line 17 - page 14, line 5; figures 1-3	1,3-7, 9-11,15
X	GB 2 450 926 A (TALLEY GROUP LTD [GB]) 14 January 2009 (2009-01-14) page 7, line 17 - page 15, line 29; figures	1-7,9, 12-15
X	US 2002/082568 A1 (YAM JACKY [US]) 27 June 2002 (2002-06-27) paragraph [0036] - paragraph [0043]; figures	1-3,5-9, 12-16

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[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

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Date of the actual completion of the international search	Date of mailing of the international search report
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INTERNATIONAL SEARCH REPORT

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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.
X	EP 0 777 111 A1 (ALCON LAB INC [US]) 4 June 1997 (1997-06-04) column 4, line 39 - column 7, line 47; figures -----	1,3-7,9, 12,15

INTERNATIONAL SEARCH REPORT

Information on patent family members

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