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(54) HFCWO system

(57) A medical system for high frequency chest wall oscillation (HFCWO) treatments comprising
- A wearable body (2) being at least partially resilient
- An air supply (3) configured to send pressured air into at least part of said wearable body (2)
Characterized in that
- the air supply (3) is configured to send pressured air into at least part of said wearable body (2) in a substantially steady stream
- and in that it comprises at least one valve (10) configured to intercept and to control at least one of the frequency and the volume of pressured air flowing into at least part of said wearable body (2).

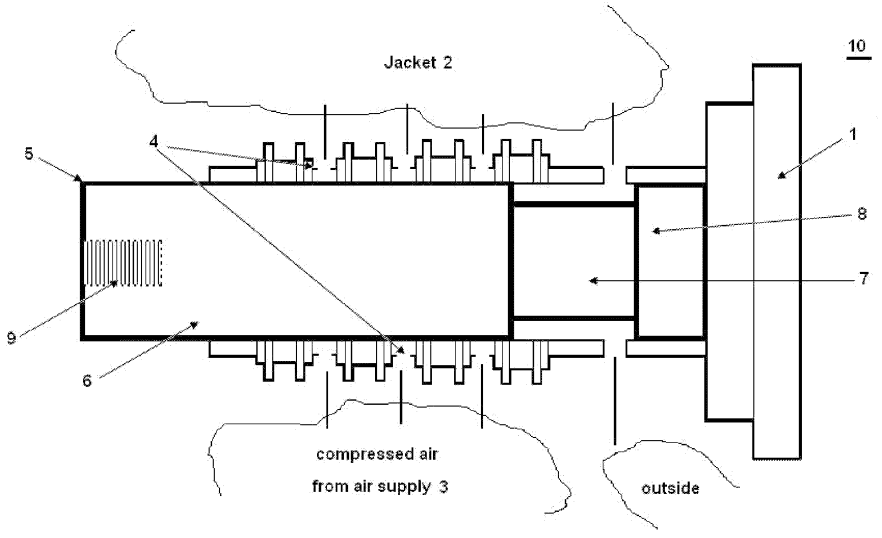

Fig 3 a

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Description

[0001] The invention relates in general to a medical device applying repetitive compressions to the body of a human helping him/her to loosen mucus from the lungs and trachea, and improve the blood circulation.

[0002] More specifically, the present invention relates to high frequency chest wall oscillation (HFCWO) therapy systems, especially but not limited to HFCWO therapy systems suitable for use in home care as well as in a hospital, or in a healthcare facility.

[0003] Under normal conditions, the human body efficiently clears mucus from the lungs and the respiratory tract by way of coughing.

[0004] Irregularities in the normal mucociliary transport system or hyper secretion of respiratory mucus results in an accumulation of mucus in the lungs causing severe medical complications such as hypoxemia, hypercapnia, chronic bronchitis and pneumonia.

[0005] Abnormal respiratory mucus clearance is a manifestation of many medical conditions such as pertussis, cystic fibrosis, atelectasis, bronchiectasis, cavitating lung disease, vitamin A deficiency, chronic obstructive pulmonary disease (COPD), asthma, and immotile cilia syndrome. Exposure to cigarette smoke, air pollutants and viral infections also affect mucociliary function negatively. Post surgical patients, paralyzed persons, and newborns with respiratory distress syndrome also exhibit reduced mucociliary transport.

[0006] Chest physiotherapy is a well-known method for treating patients with one or more of the above health conditions.

[0007] Several methods of chest physiotherapy exist.

[0008] Traditionally, care providers perform Chest Physical Therapy (CPT) one to four times per day. CPT consists of a patient lying in one of twelve positions while a caregiver "claps" or pounds on the chest and back over each lobe of the lung. To treat all areas of the lung in all twelve positions requires pounding for half to three-quarters of an hour together with inhalation therapy. CPT clears the mucus by shaking loose airway secretions through chest percussions and draining the loosened mucus toward the mouth. Active coughing is required to ultimately expectorate the loosened mucus. CPT requires the assistance of a caregiver, often a family member if a nurse or respiratory therapist is not available. It is a physically exhausting process for both the CF patient and the caregiver.

[0009] Artificial respiration devices for applying and relieving pressure on the chest of a person have been used to assist in lung breathing functions, and loosening and eliminating mucus from the lungs of persons with cystic fibrosis (CF). These devices use jackets having air accommodating bladders that surround the chest of the patient. The bladder worn around the thorax of the CF patient repeatedly compresses and releases the thorax at frequencies as high as 25 cycles per second. Each compression produces a rush of air through the lobes of the lungs that shears the secretions from the sides of the airways and propels them toward the mouth where they can be removed by normal coughing.

[0010] One of the most efficient treatments is the High Frequency Chest Wall Oscillation (HFCWO) also commonly referred to as "airway clearance jackets". Treatments using HFCWO are well-known in the art.

[0011] The document EP1932501 describes a HFCWO system that comprises an air pulse generator in communication with an inflatable garment. The air pulse generator comprises housing and an air pulse assembly coupled to the housing. The problem with this device is that the whole system is a big and heavy device, difficult for the patient to move around. Furthermore since this device is mainly used in hospitals and healthcare institutions, but also as home care, it would be an advantage to avoid the use of a clumsy, heavy and expensive system. The purpose of the present invention is to propose a device and a method to solve the above problems found with HFCWO systems according to the prior art.

[0012] In a more specific manner, the present invention relates to a medical system for high frequency chest wall oscillation (HFCWO) treatments comprising

- A wearable body being at least partially resilient
- An air supply configured to send pressured air into at least part of said wearable body
  Characterized in that
- the air supply is configured to send pressured air into at least part of said wearable body in a substantially steady stream
- and in that it comprises at least one valve configured to intercept and to control at least one of the frequency and the volume of pressured air flowing into at least part of said wearable body.

[0013] The mentioned medical system is a HFCWO system or device. Since many hospitals have a global air distribution system that provides steady stream air, the system according to the invention can be directly connected to the global air distribution system and thereby avoiding a big and heavy compressor with pulsed air. The invention can also be used with a compressor generating a steady stream of air.

[0014] It is worth noticing that with the right frequency and settings, the system according to the invention could also be used with compressed pulsed air.

[0015] Optionally, the invention may comprise anyone of the following features.

[0016] The air supply is a pressured air distribution of a building and/or comprises means for storing pressured air under a liquid or gaseous state and/or comprises a compressor provided to deliver a stream of substantially steady air.

[0017] The valve described above may usually have an outer part and an inner part configured to cooperate with the outer part. The outer part is provided with one or more holes to create air passages.

[0018] The valve comprises at least an input hole connected to the air system and at least an output hole connected to the wearable body. The system is provided so that in a first position the inner part blocks at least one of an input hole, thereby preventing passage of air between the input and output hole; a second position, where the inner part lets the input and output hole unblocked, allowing air passage between them.

[0019] The outer part has a substantially cylindrical body and the inner part, which may be a piston configured to move inside said cylindrical body, said piston being connected to a motor. The inner part can move with a translational movement and/or a rotational movement.

[0020] The motor may be a 12V DC motor or alternatively the motor can be replaced by a magnetic system, which will reduce the wear and tear and noise.

[0021] The valve is further configured to control the amount of pressured air let through to the wearable body by movements of the piston.

[0022] The valve is further configured to release the pressured air from the wearable body to the outside of said system by movements of the piston.

[0023] The valve is also configured to alternate between letting pressured air pass through the valve to the wearable body and releasing the pressured air from the wearable body to the outside of said system.

[0024] The partially resilient body, adapted to be worn by a human patient can be but is not limited to, a vest or a jacket. It has at least two compartments configured to be independently filled with pressured air. Each of the compartments comprises a valve for controlling the frequency of the pressured air in that compartment. In another embodiment, each valve controlling the frequency of the pressured air in a compartment can be comprised within the jacket but located outside of said compartment. In a third embodiment, the same valve can be located outside the jacket.

[0025] Two distinct compartments can for example be the front side of the jacket and the back of the jacket.

[0026] The valve controls the volume of the pressured air in the corresponding compartment. In one embodiment, one valve can control the volume of the pressured air in more than one compartment at the time.

[0027] In another embodiment, valves controlling the body compartments, also referred to as local valves, can be connected to one main valve distributing the pressured air to said local valves alternately or simultaneously. These embodiments will later be described in further details.

[0028] The valve is configured to alternate between letting pressured air pass through the valve to a first compartment of the wearable body, letting pressured air pass through the valve to a second compartment of the wearable body and releasing the pressured air from the wearable body to the outside of said system.

[0029] The system further comprises a user interface allowing a user of the system to control the movements and frequency of the inner part in relation to the outer part. This way, the patient or the health caretaker can control which compartments should be active and which should be passive. By active compartments we mean compartments that inflate and deflate according to a preset frequency, and by passive compartments we mean compartments that don't let any pressured air in or out.

[0030] The wearable body is a wearable device on the upper body of a human. Namely, the wearable device is a vest or a jacket, and the system is a High Frequency Wall Chest Oscillation (HFWCO) therapy.

[0031] The invention further relates to a method of generating air pressure in a body, said body being at least partially resilient, comprising sending pressured air from an air supply into at least part of said partially resilient body

Characterized in that

- said air supply is sending pressured air in a steady stream into at least part of said partially resilient body
- and in that said steady stream of pressured air is passing through at least one valve before reaching at least part of said wearable body , and in that
- said valve intercepts and controls the frequency of pressured air flowing into at least part of said wearable body.

[0032] A preferred embodiment of the invention will now be described in further details according to the drawings.

Fig 1 shows a schematic view of the generic system according to the invention.
Fig 2a shows the valve cylinder according to the invention without the piston.
Fig 2b shows the piston of the present invention.
Fig 3a shows the assembled valve comprising the valve cylinder and the piston in a first position according to the present invention.
Fig 3a shows the assembled valve comprising the valve cylinder and the piston in a second position according to the present invention.
Fig 4 shows a schematic of another embodiment according to the present invention.
Fig 5 shows a schematic of another embodiment according to the present invention.

[0033] Figure 1 shows an air supply connected to a valve according to the invention. The air supply could for example be a compressor providing compressed air. The compressed air is continuously provided in a steady stream meaning with a constant flow and volume of air. The valve connects the air supply to the jacket. In this embodiment, the valve is driven by a motor connected to a power supply. However the valve could also be driven by a magnetic system as described earlier. The valve has several options for controlling the compressed air pushed into it. In the main two, the compressed air is either blocked by a closed valve stopping the flow into

the jacket, or let through by an open valve, which will inflate the jacket connected thereto. Further options will be revealed to the reader later in this document.

[0034] The jacket in figure 1 is either fully made of a material that is flexible, or of a combination of resilient parts and rigid parts. The jacket could for example have a rigid material for the exterior part of the jacket and a flexible material for the interior part. This last embodiment is preferred to orientate the press movements, resulting from inflating the jacket, towards the body of the patient who wears it.

[0035] Figure 2a and 2b shows the valve according to the invention in further details. In figure 2a, we see a drawing of the valve cylinder 1. The cylinder 1 is hollow configured to receive a piston 5. The piston is configured to perform a sliding movement along the longitudinal axis of the valve cylinder 1. The cylinder 1 further comprises one or more holes 4 of equal or different sizes. The holes 4 are preferably aligned in two rows, each row having the same number of holes and are substantially facing each other. The cylinder 1 is preferably made of stainless steel or aluminum.

[0036] Figure 2b reveals the piston 5 configured to make translational movements along the shared longitudinal axis of the cylinder 1 and the piston 5. In one embodiment where the piston 5 is driven by a motor, an opening at one extremity is provided with internal threads to fasten the piston 5 to the mechanical countershaft of the motor (not shown in the figures). In another embodiment, the piston 5 is driven by other means that does not require a motor, and the piston 5 therefore has no opening in its extremity. The piston 5 is preferably made of PEEK (Polyether ether ketone). PEEK is a material that enables a continuous lubrication while sliding inside the cylinder 1 to give the minimum level of friction.

[0037] Physically, the piston 5 could be described as having a body 6, a neck 7 and a head 8. The body 6 and the head 8 of the piston 5 have the same diameter while the neck 7 has a diameter that is inferior to the diameter of the body 6 and head 8.

[0038] The piston 5 is preferably machined from one piece, what is also referred to as a mono-bloc.

[0039] It should be noted that the piston neck 7, can also be provided longitudinally in relation to the piston as a piston groove or recess. In that case, the piston rotates clockwise and anticlockwise instead of up and down.

[0040] Several recesses can be provided giving the possibility for inflating compartment 1 followed by compartment 2 and then compartment 3 of the vest by a clockwise movement of the piston, and then compartment 3, 2 and 1 in this order by an anticlockwise movement of the piston. Another embodiment would be to have a translational movement combined with a rotation movement including both the neck and the recess of the piston. The speed rotation of the piston can be variable as well, which makes randomness even easier to introduce when requested.

[0041] Figures 3a and 3b show the assembled valve 10 comprising the valve cylinder 1 and the piston 5. In this embodiment, a jacket 2 is connected to a first row of holes 4 provided in the valve cylinder 1. The second row of holes 4 is mainly connected to the compressed air supply 3, however with one hole reserved for an outlet connected to the exterior when releasing the compressed air from the jacket 2.

[0042] When the piston 5 is in an idle or first position, the jacket 2 is in fact in contact with the outside through the valve 10. That is the actual situation shown in figure 3a. This is achieved by aligning the neck 7 of the piston 5 with a hole connected to the jacket on one side, and the hole leading to the exterior/outside on the other side. In this way, the compressed air that might be retained in the jacket 2, will flow through the valve 10, passing around the neck 7 of the piston and out through a hole 4 in the valve cylinder 1 to the outside. The other holes 4 connected to the supply 3 of compressed air are blocked by the body 6 of the piston 5, since it fills out the diameter of the valve cylinder 1 and is thereby airtight.

[0043] In figure 3b the piston 5 is moved to a second position, thereby blocking the passageway between the jacket 2 and the outside with the piston head 8, and opening a passage between the supply 3 of compressed air and the jacket 2 by positioning the piston neck 7 between these respective holes 4 as shown on the figure. In this position the valve 10 allows the jacket 2 to be inflated by compressed air.

[0044] With the piston 5 moving forth and back between the two positions shown in figure 3a and 3b, the jacket 2 will be alternately inflated and deflated with a frequency depending on the motor connected to the piston 5 or the alternative driving mechanism used to activate the piston 5, for example a woofer. This frequency can be set by the operator of the system as shown in figure 4.

[0045] Figure 4 represents a generic flow chart of the system according to the invention. We can see that one valve 10 can be replaced by several valves working cooperatively in series. The valves can be identical but can also be different, for example, they could have a different number and different size of holes 4. The pistons 5 can move synchronously or independent of each other. The pistons 5 however move according to a predefined structure set by the operator of the system using the control panel. In a different embodiment, one predefined program may consist of moving one or more pistons 5 randomly for a certain amount of time.

[0046] In figure 5 a main valve 10 is connected to several local valves as shown. The main valve 10, being physically similar to the local valves, distribute the compressed air flowing in from the air supply 3, to these local valves either sequentially one by one or sequentially by groups.

[0047] Since the local valves have their own outlet to connect to the outside and thereby deflating the jacket 2 as such, the outlet of the main valve 10 connected to the outside as seen in figure 5 might not be used. Alterna-

tively, it might be used as a main outlet connecting several local outlets from local valves.

[0048] The advantage of having several valves is that each local valve can be connected to a specific compartment of the jacket 2, independent of and isolated from other compartments. In one embodiment, the jacket 2 has two compartments: one front compartment and one back compartment. By having a separate valve 10 for each compartment, it is possible to inflate the front of the jacket 2 independently of the back and vice versa. They could be inflated sequentially to create alternating but cooperative compressions. It also becomes possible to inflate only one compartment while keeping the other inactive. This allows a more controllable and focused treatment using the jacket 2.

[0049] There is no limit to the number of compartments a jacket 2 might possess. In fact, the more compartments a jacket 2 has, the more personalized and customizable the treatment will be.

[0050] It is still possible to have a high number of compartments in a jacket 2 and keeping the number of valves relatively low. Each valve can be connected to a number of jacket compartments only limited by the number of holes 4 provided in the valve.

[0051] Throughout this document, we described as an example the valves of the system as inlet valves, meaning that the valves control the air let in to the jacket. Similarly, in another embodiment, the invention can be realized by controlling the pulsations with identical exit valves. This is done by letting a steady stream of pressured air into the vest and creating the pulses by decreasing the pressure when the valve is aligned to the outside and increasing the pressure when that outlet valve is closed and the internal vest pressure goes up again.

[0052] Although illustrative embodiments of the present invention have been described in detail with reference to the accompanying drawings, it is to be understood that the invention is not limited to those precise embodiments and that changes and modifications may be effected therein by those in the art without departing from the scope and spirit of the invention.

Claims

1. A medical system for high frequency chest wall oscillation (HFCWO) treatments comprising

   - A wearable body (2) being at least partially resilient
   - An air supply (3) configured to send pressured air into at least part of said wearable body (2)

   Characterized in that

   - the air supply (3) is configured to send pressured air into at least part of said wearable body (2) in a substantially steady stream
   - and **in that** it comprises at least one valve (10) configured to intercept and to control at least one of the frequency and the volume of pressured air flowing into at least part of said wearable body (2).

2. A system according to claim 1, where said valve (10) comprises a main outer part (1) and an inner part (5) configured to move in relation to said outer part (1).

3. A system according to claim 2, where said inner part (5) performs a translational movement and/or a rotational movement in relation to said outer part (1).

4. A system according to claims 2 to 3, where said outer part (1) has a substantially cylindrical body and the inner part (5) is a piston.

5. A system according to claim 4, where said valve (10) is further configured to control the amount of pressured air let through to the wearable body (2) by movements of the piston (5).

6. A system according to claims 4 or 5, where said valve (10) is configured to release the pressured air from wearable body (2) to the outside of said system by movements of the piston (5).

7. A system according to any of the preceding claims, where said valve (10) is configured to alternate between letting pressured air pass through the valve (10) to the wearable body (2) and releasing the pressured air from the wearable body (2) to the outside of said system.

8. A system according to any of the preceding claims, where the air supply (3) is a pressured air distribution of a building and/or comprises means for storing pressured air under a liquid or gaseous state and/or comprises a compressor provided to deliver a stream of substantially steady air.

9. A system according to any of the preceding claims, where said wearable body (2) has at least two compartments configured to be independently inflated with pressured air.

10. A system according to the preceding claim, where each of said compartments is connected to at least a local valve for controlling the frequency and/or the volume of the pressured air in that compartment.

11. A system according to claim 10, where each of said local valves comprised within the compartments is connected to one main valve (10) configured to distribute pressured air to said local valves alternately or simultaneously.

12. A system according to claims 10 and 11, where said

local valves are configured to alternate between letting at least part of the pressured air pass through to a first compartment of the wearable body (2), letting pressured air pass through to at least a second compartment of the wearable body (2) and releasing the pressured air from the wearable body (2) to the outside of said system.

13. A system according to claims 2 to 5, further comprising a user interface allowing a user of the system to control the movements and frequency of the inner part (5) in relation to the outer part (1).

14. A system according to any of the preceding claims, where the wearable body (2) is worn on the upper body of a human.

15. A method of generating air pressure in a wearable body (2), said wearable body (2) being at least partially resilient, comprising

- sending pressured air from an air supply (3) into at least part of said partially resilient body (2)
Characterized in that
- said air supply (3) is sending pressured air in a steady stream into at least part of said partially resilient body (2)
- and **in that** said steady stream of pressured air is passing through at least one valve (10) before reaching at least part of said wearable body (2), and **in that**
- said valve (10) intercepts and controls the frequency of pressured air flowing into at least part of said wearable body (2).

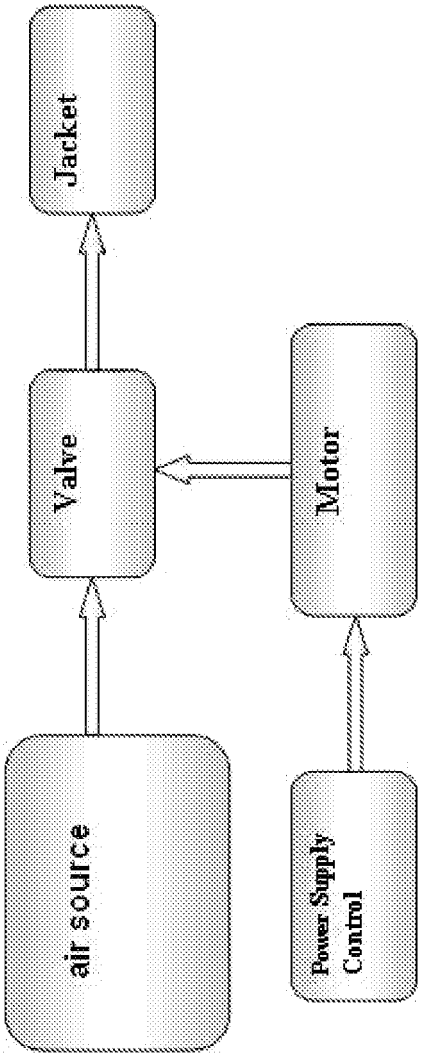

Fig 1

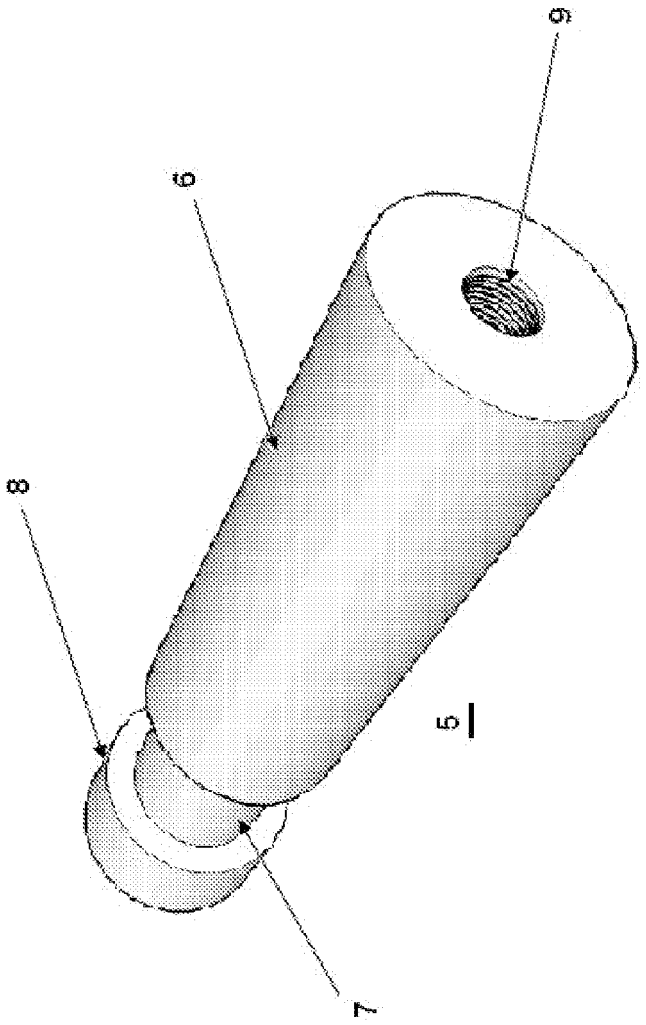

Fig 2B

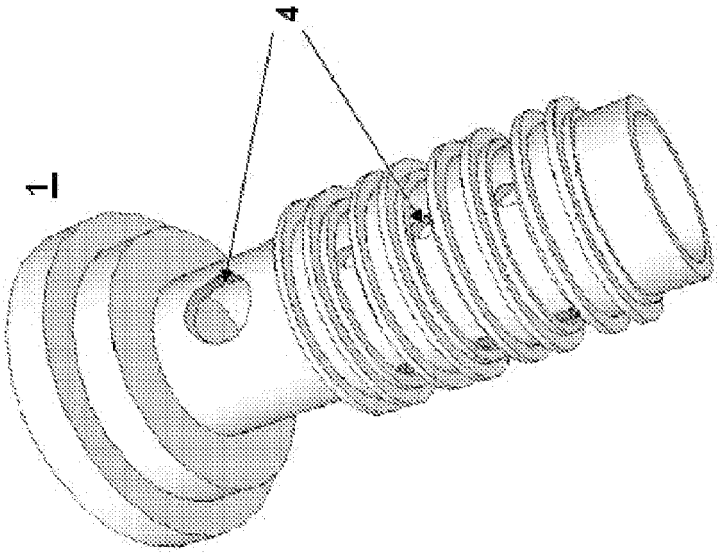

Fig 2A

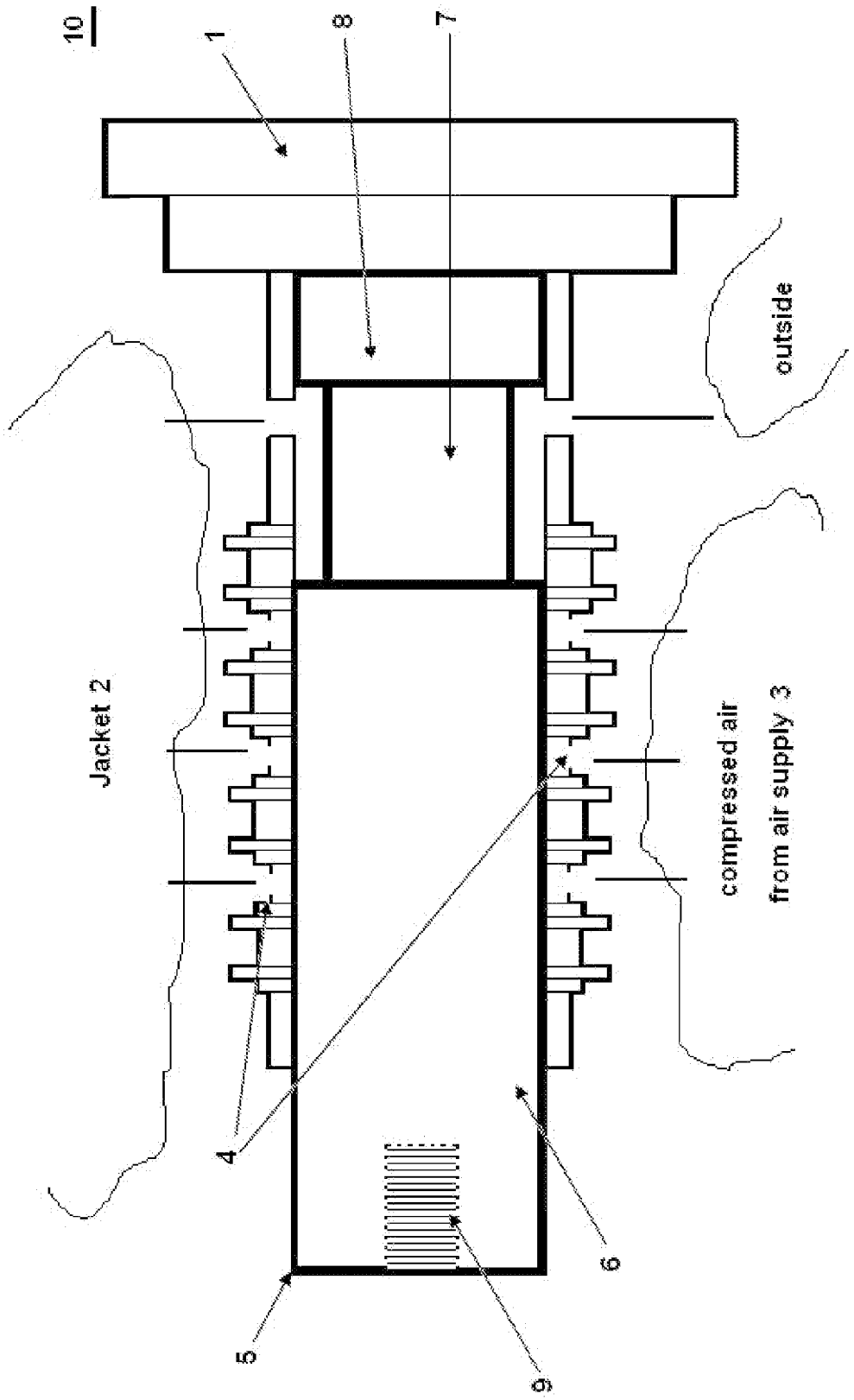
10
1
8
7
outside
Jacket 2
compressed air
from air supply 3
4
5
6
9

Fig 3 a

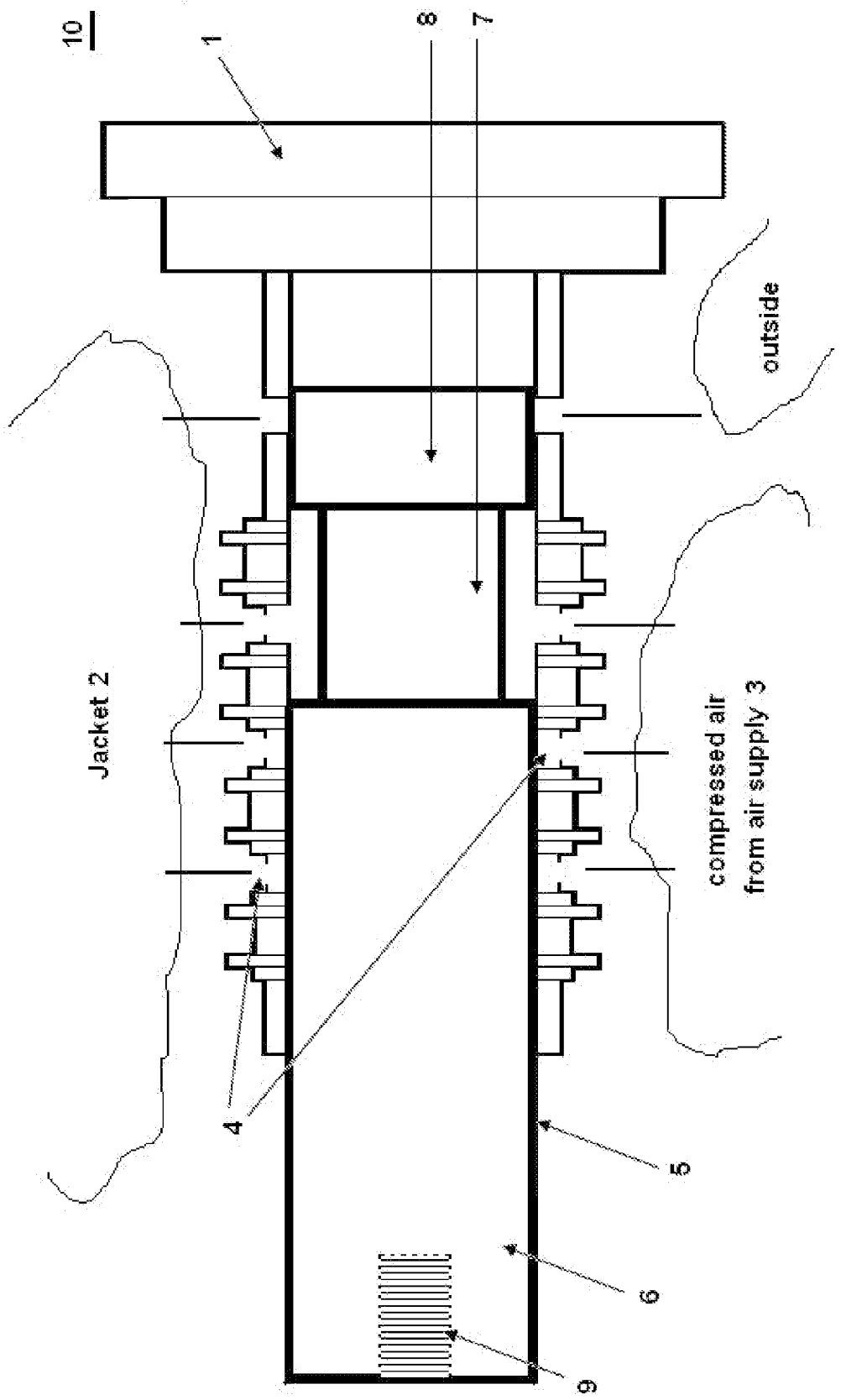
10
1
8
7
outside
Jacket 2
compressed air
from air supply 3
4
5
6
9

Fig 3b

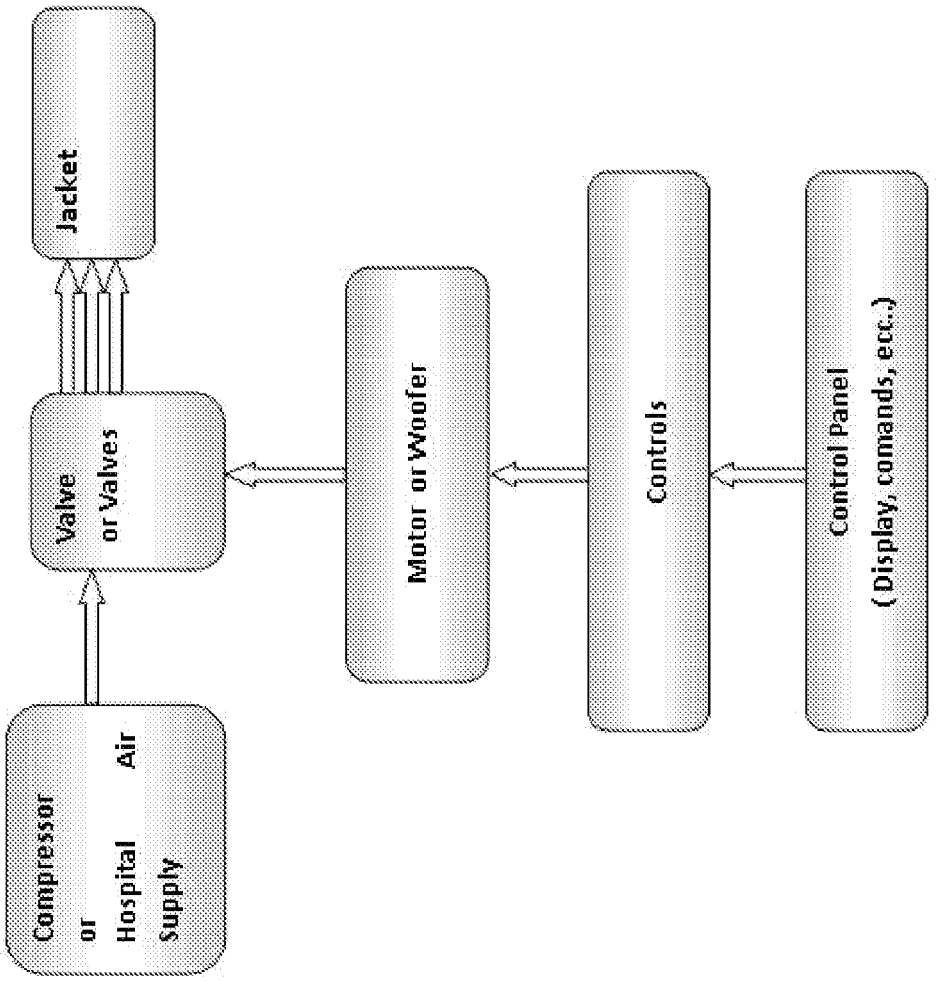
Jacket
Valve or Valves
Motor or Woofer
Controls
Control Panel (Display, comands, ecc..)
Compressor or Hospital Air Supply

Fig 4

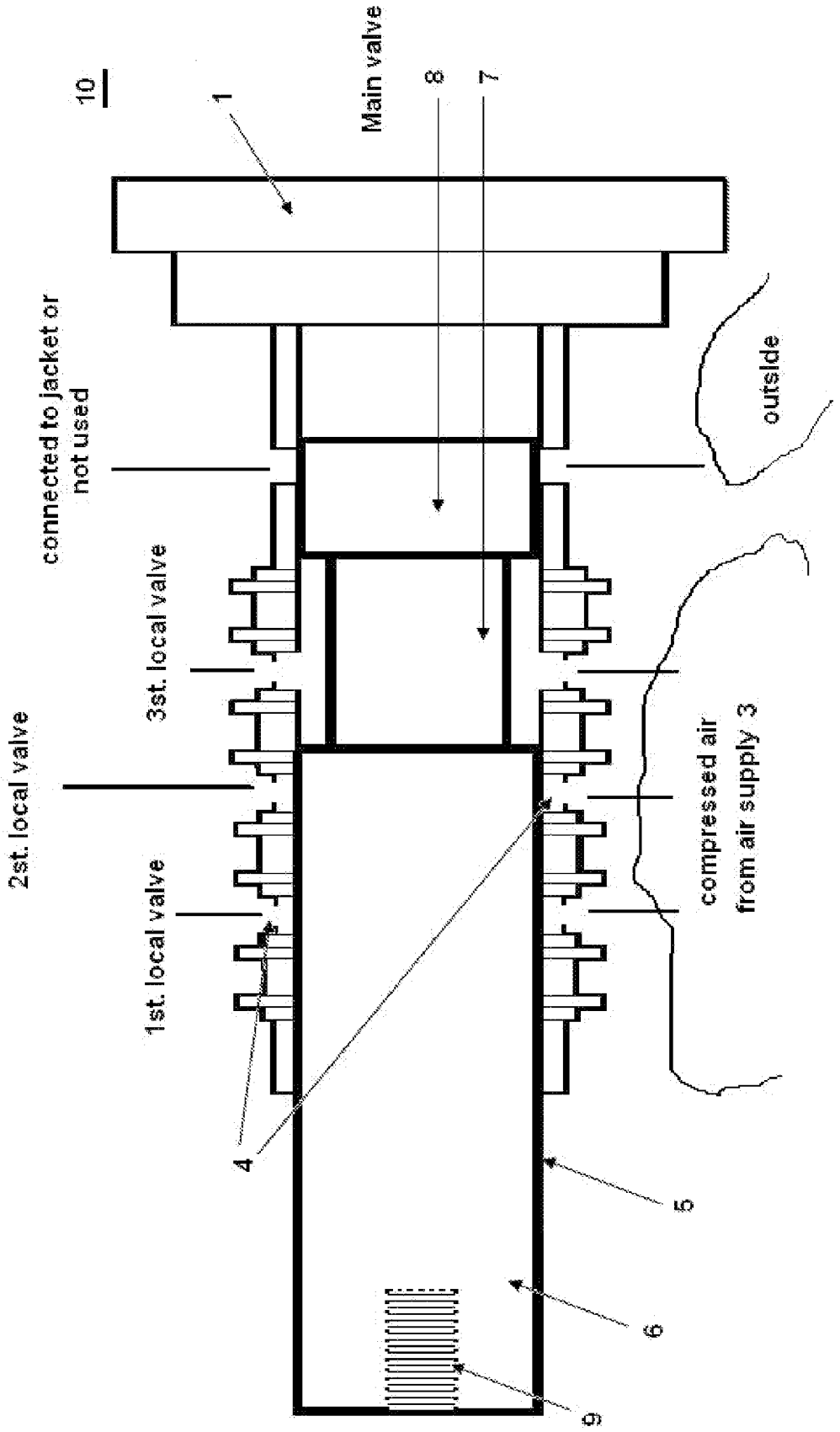
10
1
Main valve
8
7
connected to jacket or not used
outside
3st. local valve
2st. local valve
compressed air from air supply 3
1st. local valve
4
5
6
9

Fig 5

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EUROPEAN SEARCH REPORT

Application Number
EP 10 30 5050

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
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X	WO 01/93797 A2 (MIDTOWN TECHNOLOGY [US]) 13 December 2001 (2001-12-13) * page 7, line 16 - page 14, line 10; figure 3b * -----	1-3,7-15	
Y	WO 2007/106804 A2 (HUSTER KEITH A [US]; BRANSON GREGORY W [US]; O'NEAL TODD P [US]; YERMA) 20 September 2007 (2007-09-20) * paragraph [00194]; figure 31 * -----	4-6	

TECHNICAL FIELDS SEARCHED (IPC)
A61H

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	15 June 2010	Jekabsons, Armands

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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4

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ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 10 30 5050

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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15-06-2010

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EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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