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(54) Title: MECHANICAL VENTILATOR

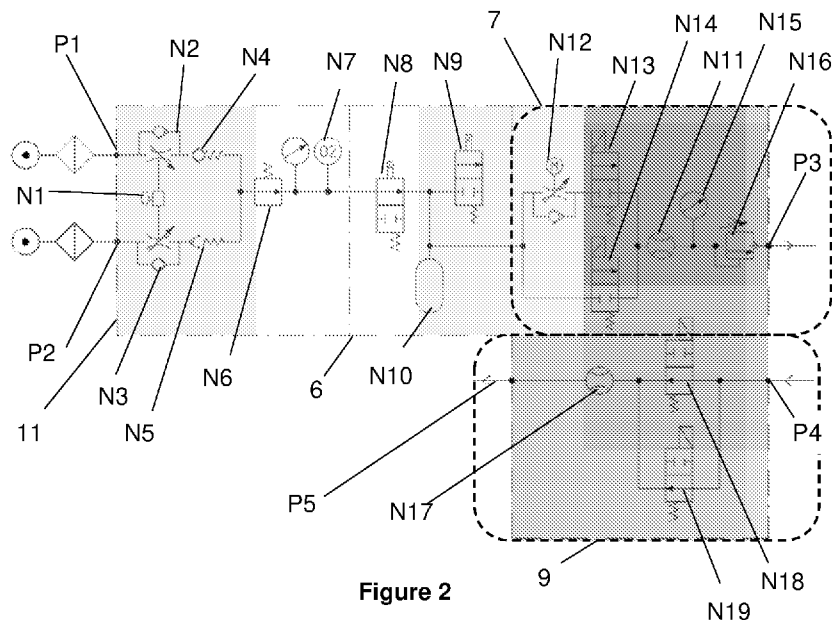


Figure 2

(57) **Abstract:** A mechanical ventilator to supply O₂-enriched air to a patient comprising: a main unit (2) comprising at least two external gas inlet ports (P1, P2) and an O₂-enriched air supply unit (6); a disposable unit (3) allowing to prevent cross-contamination from one patient to another, the disposable unit comprising gas outlet ports; an O₂-enriched air supply circuit (7) which comprises at least one inspiration valve (N13) and pneumatic components (N14, N15, N16) allowing O₂-enriched air to be supplied to the patient, wherein said inspiration valve and the pneumatic components (N15, N16) which are located downstream of said inspiration valve along the supplied air circulation stream are located in the disposable unit, wherein the pneumatic components which are located upstream of said inspiration valve are located in the main unit; and connection means (4) to allow fluidic connection between the main unit and the disposable unit.



EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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Mechanical ventilator

5 [001] The invention is related to mechanical ventilators. More particularly, the invention is related to a mechanical ventilator with a disposable part.

[002] A ventilator forces air through tubing into an endotracheal tube positioned in a patient's trachea. These ventilators may have different working modes, either volume-controlled (VC) or pressure-controlled (PC).

10 [003] Volume control (VC) means that both volume and flow are pre-set prior to inspiration. Pressure control (PC) means that inspiratory pressure is pre-set as either a constant value or it is proportional to the patient's inspiratory effort. Under these two different working modes, different ventilatory patterns may be implemented, among them, VC-CMV for Volume Controlled Ventilation with continuous Mandatory Volume sequence PC-CSV for
15 Pressure Controlled Ventilation with Continuous Spontaneous Ventilation sequence.

[004] In VC-CMV mode, gas flows to the patient until a pre-set volume is delivered to the ventilator circuit. This mode is usually used at the start of patient's treatment.

[005] In PC-CSV mode, gas is allowed to flow into the lungs until a present airway pressure limit is reached, at which time a valve opens allowing exhalation to ensue. The
20 volume delivered by the ventilator varies with changes in airway resistance, lung compliance, and integrity of the ventilatory circuit. This mode is usually used at the end of patient's treatment.

[006] In both configurations, air exhaled by the patient enters in the circuit and may potentially contaminate surfaces of the ventilators and transmit bacteria to other patients.

25 [007] In light of epidemics such as the COVID-19 epidemic, said systems may be needed for a large number of patients and thus risk of infection transmission is increasing. There is so a need for ventilator which reduces the risk of transmission of infections from one patient to another.

[008] Complex ventilator maintenance programs have been put in place in several
30 healthcare systems to reduce the transmission risks, but they are burdensome and require time to be carefully followed, time which is lacking during epidemics.

[009] Some ventilators have been equipped with filters, but they are not selective enough and let some particles go through.

[0010] Patent US2016/0235932 suggests a mechanical ventilator comprising a mechanical
35 part with a motor and a sterile, disposable part comprising all component in air-contact with

the patient's breath. As all parts in contact with patient's breath are disposable, they may be changed from one patient to another and thus avoid contamination. However, in this device, all parts, except the motor must be changed from one patient to another, which make the use of this ventilator very onerous and prevent thus its extensive use.

[0011] There is so a need for a mechanical ventilator which allows reducing the risk of cross-contamination between patient at low-cost to be broadly used during epidemics.

[0012] This problem is solved by a mechanical ventilator according to the invention comprising a main unit comprising at least two external gas inlet ports and an O₂-enriched air supply unit. The mechanical ventilator comprises a disposable unit comprising gas outlet ports, an O₂-enriched air supply circuit which comprises at least one inspiration valve and pneumatic components allowing O₂-enriched air to be supplied to the patient, said inspiration valve and the pneumatic components located downstream of it along the supplied air circulation stream, being located in the disposable unit, the pneumatic components located upstream being located in the main unit and connexion mean allowing the fluidic connexion between the main unit and the disposable unit.

[0013] The ventilator of the invention may also comprise the following optional characteristics considered separately or according to all possible technical combinations:

- the ventilator comprises a display unit,
- the ventilator comprises an air exhaust circuit allowing to exit the air exhaled by the patient from the ventilator, said air exhaust circuit being in the disposable unit,
- the O₂-enriched air supply unit comprises a bellows,
- the O₂-enriched air supply circuit comprises at least one inspiration and one expiration flowmeters,
- the inspiration flowmeter is located upstream of the inspiration valve,
- the inspiration flowmeter is located downstream of the inspiration valve,
- the O₂-enriched air supply circuit further comprises a pressure sensor upstream of the inspiration valve and the inspiration flowmeter and the pressure sensor are a single part made by additive manufacturing,
- flowmeters are Venturi flowmeters.

[0014] Other characteristics and advantages of the invention will emerge clearly from the description of it that is given below by way of an indication and which is in no way restrictive, with reference to the appended figures in which:

- Figure 1 illustrates a ventilator according to an embodiment of the invention,

- Figure 2 is a scheme illustrating a pneumatic diagram of a ventilator according to a first embodiment of the invention
- Figure 3 is a scheme illustrating a pneumatic diagram of a ventilator according to a second embodiment of the invention
- 5 - Figure 4 illustrates a disposable unit of a ventilator according to an embodiment of the invention,
- Figure 5 illustrates an example of piping and valve for the air supply circuit
- Figure 6 illustrates an additive manufactured valve

10 [0015] Elements in the figures are illustration and may not have been drawn to scale.

[0016] As illustrated in figure 1, a ventilator 1 according to an embodiment of the invention comprises a main unit 2 and a disposable unit 3. Those two units are in fluid connexion with each other through connexion means 4. By fluidic connexion it is meant that when connected, air mixture needed for patient's breathing can circulate from the main unit 2 to the disposable unit 3 through the connexion means 4. In a preferred embodiment this
15 connexion is also electronic so that control information may be given to the main unit 2 and then sent to the disposable unit 3.

[0017] In the rest of the text, terms upstream and downstream have to be understood according to the circulation of the medical air flow from the inlet ports, through the main unit and the air supply circuit 6 to the patient and back to the disposable unit through the air exhaust circuit 9.
20

[0018] The main unit 2 comprises a power supply 8, external gas inlet ports, namely at least one medical air and one oxygen inlet (not represented on the figure), a mixing device allowing to prepare the mixing between medical air and O₂ in required proportions to produce an O₂-enriched air to be supplied to the patient. This O₂-enriched air is then sent to an air supply unit 6 able to store the O₂-enriched air and send it to the O₂-enriched air supply circuit 7. In a preferred embodiment the O₂-enriched air supply unit 6 comprises a bellow. The main unit further comprises control means allowing to control the working mode of the ventilator, between VC and PC modes previously described, and a control panel 5.
25 The control panel 5 maybe a dedicated screen integrated in the man unit 2. In a preferred embodiment it is a dedicated screen located outside of, but in connection with, the main unit 2.
30

[0019] In a preferred embodiment, as illustrated in figure 1, the O₂-enriched air supply circuit 6 is located into the disposable unit 3 but in other embodiments it could also be partly in the main unit 2. The main unit 2 comprises a first connexion mean (not represented).
35

According to the invention the disposable unit 3 comprises the O₂-enriched air exhaust circuit, which allows air exhaled by the patient to be exhausted from the ventilator. This is the part which is in contact with patient's breath and thus most prone to contamination. The disposable unit 3 comprises second connexion means designed so as to match the first connexion means of the main unit 2 and provide fluidic and electric connexion between both units. Thanks to those connexion means the disposable unit may be easily detached from the main unit and replaced by a new one, just like a cartridge in a printer.

[0020] When in use, the O₂-enriched air supply unit 6 works at a higher pressure ($\geq 80\text{cmH}_2\text{O}$) than the pressure expected for patient's treatment. There will thus always be a higher pressure upstream of the O₂-enriched air supply circuit 7 and therefore by pressure difference the flow can only occur towards the patient and not towards the O₂-enriched air supply unit 6. The O₂-enriched air supply unit will thus never be in contact with patient's breath and thus won't be contaminated by potential bacteria it may contain.

[0021] Figure 2 and 3 are pneumatic diagrams of a ventilator according to two different embodiments of the invention. In both figures the components of the main unit 2 are uncoloured while the components located in the disposable unit 3 are in grey. According to the two embodiments, medical air and oxygen are supplied to the ventilator 1 through external gas inlet ports P1, P2, they are then mixed in a mixer 11 and the mixture is sent to an O₂-enriched air supply unit 6.

[0022] The mixer comprises a medical air line flow regulator N2, an oxygen check line flow regulator N3, a medical air line check valve N4, an oxygen line check valve N5 and a pressure reducer N6. The flow regulators N2, N3 are controlled by a single manual key N1, located on the main unit. They work symmetrically so that air and oxygen mixture may be accurately controlled. The check valves N4, N5 are non-return valves which prevents backflow from the other lines to the medical air / oxygen lines due to pressure difference. The pressure reducer N6 is used to limit and regulate the pressure entering the O₂-enriched air supply unit. It has a pressure gauge to display the pressure to a maintenance operator in case adjustments are needed.

[0023] The O₂-enriched air supply unit 6 comprises an oxygen sensor N7, a reservoir filling valve N8, a reservoir relief valve N9 and at least one bellow N10. The bellow N10 comprises a frame connecting the mechanical assembly, a reservoir, which may be a heat-sealed polyamide/polyethylene bag able to withstand a pressure of at least 2 bar, a compression plate that is housed in the frame and connected to it by two bearings allowing it to rotate, a set of preloaded springs, preferentially at a number of ten, which allow to maintain a constant pressure in the bellow, and a pressure adjustment tool which allows adjustment of

pressure in the bellow by regulation of springs tensions. The reservoir filling valve N8 is closes when the reservoir reaches its maximum volume. The reservoir relief valve N9 releases air form the reservoir outside of the ventilator if the filling valve N8 is deficient or when any incident leading to an overfilling of the reservoir occurs. The oxygen sensor N7
5 measures the proportion of oxygen in the mixture and displays the FiO2 value on the interface. FiO2 stands for Fraction of Inspired oxygen, which is the molar or volumetric fraction of oxygen in the inhaled gas.

[0024] The O2-enriched air supply unit 6 expulses a required quantity of air mixture towards the O2-enriched air supply circuit 7 which comprises an inspiratory flow regulator N12, an
10 inspiration valve N13, a support valve N14, an inspiration manometer N15 and an overpressure valve N16. Whatever the embodiment, all elements downstream of the valves N13 and N14, both included, are located in the disposable unit as they are elements that come into contact with the patient's breath. Upstream of these valves, the difference in pressure produced in normal operation makes flow in the opposite direction impossible.
15 This O2-enriched air supply circuit is connected to inhalation tubes (not represented) through inhalation connection port P3 and sends the air mixture towards the patient's lungs through said tubes during inhalation phases.

[0025] During exhalation phases, the patient's lungs expulses exhaust air through exhalation tubes (not represented) connected through connection port P4 to the air exhaust
20 circuit 9 which is integrally located into the disposable unit 3. The air exhaust circuit 9 comprises an exhalation valve N18, a PEEP (Positive End Exhalation Pressure) relief valve N19, an exhalation flowmeter N17 and air outlets P5.

[0026] The inspiration and exhalation flowmeters N11, N17 are used to control the flow of both inspiration and exhalation. The flowmeters are preferentially Venturi flowmeters and
25 may be additive manufactured. The inspiratory flow regulator N12 is used to adjust the flow in each inspiratory cycle. The inspiration valve N13 delimits the total Inspiratory time (Ti) by its closing and opening. The support valve N14 is normally closed and is used exclusively in PC-CSVs mode to achieve a faster setpoint in pressure control. The overpressure valve N16 is placed before connexion port P3 to guarantee a maximum pressure of 80cmH20 in
30 the patient connection port P3 according to norm UNE EN ISO 60601-2-12. The exhalation valve N18 is a normally open valve which by means of its opening and closing delimits the exhalation time (Te). The PEEP relief valve N19 is a normally closed valve with a lower flow rate than the exhalation valve N18 which relieves the overpressure generated by the valve for more accurate control of the PEEP.

[0027] In the embodiment of figure 2, the inspiration flowmeter N11 is located downstream of the inspiratory valves N13 and N14. This allows to use a single additive manufactured part for the Venturi flow meter N11 and the pressure sensor N15, as illustrated in figure 5. Whereas, in the embodiment of figure 3, the inspiration flowmeter N11 is located upstream
5 of the inspiratory valves N13 and N14. This allows the flow meter to be reusable as it is located in the main unit and does not come into contact with the patient's breath.

[0028] Figure 4 illustrates a disposable unit 3 of a ventilator 1 according to an embodiment of the invention. It comprises the second connexion means 4B, the O₂-enriched air supply circuit comprising the inspiration and support valves N13, N14, a Venturi inspiration
10 flowmeter N11, a pressure sensor intake N15 and connexion port P3 to connect the air supply circuit to the tubes directing the air mixture to the patient's lungs during inhalation phases. It further comprises the air exhaust circuit including exhalation connection port P4 to connect the air exhaust circuit 9 to the tube exhausting patient's breath during exhalation phase, exhalation and PEEP relief valves N18, N19, an exhalation flowmeter N17 and an
15 air outlet (not represented).

[0029] Figure 5 illustrates an example of piping and valve for the O₂-enriched air supply circuit which can be used with a ventilator according to the invention. In this example, casing of the valve is additive manufactured and integrated with the venturi flowmeter N11, the pressure sensor N15 and the rest of the piping in one piece. The valve N13 as illustrated in
20 figure 5 is custom made valve, made by additive manufacturing which is disposable after use. As illustrated in figure 6, it is composed of a servomotor 31 as mechanical actuator and of a valve seat 32. In another embodiment said valve N13 could also a commercial valve such as valve referenced VXZ232GA from company SMC which after use may be returned to the manufacturer and sterilize for further re-use.

[0030] In VC-CMV's mode the current volume V_t is constant, and the pressure is variable. There is no spontaneous ventilation. The constant setpoint demanded by the parameter V_t is adjusted for each breathing cycle by the inspiratory flow regulator N12, while the inspiratory time T_i is determined by the opening duration of the inspiration valve N13. The support valve N14 does not operate in this mode, so it remains closed. PEEP relief valve
30 N19 closes after exhalation valve N18 so that the PEEP can be fine-tuned without creating an overpressure due to a sudden shutoff of the expiratory flow.

[0031] In PC-CSV's mode, the Inspiratory Pressure (IP) is constant and the volume is variable. All vents are initiated and cycled by the patient by a pressure trigger. Therefore, the respiratory rate and inspiratory time are set by the patient. In this mode, the support
35 valve N14 opens at the beginning of the inspiration to provide a higher flow rate than the

inspiration valve N13 can give, as it is limited by the regulator N12. By doing so, the pressure set-point is reached more quickly. Once the Inspiratory Pressure (IP) is reached, the support valve N14 closes and the inspiratory flow is exclusively regulated through the inspiration valve N13 by adjusting the inspiratory flow regulator N12. As in the VC-CMV mode, PEEP relief valve N19 closes after exhalation valve N18 so that the PEEP can be fine-tuned without creating an overpressure due to a sudden shutoff of the expiratory flow.

[0032] With the ventilator according to the invention the disposable unit may be easily detached from the main unit and replaced by a new one when ventilator must be used for a new patient. As the air exhaust circuit is in the disposable unit there is no risk of cross-contamination from one patient to another. Moreover, with the ventilator according to the invention, most of the air supply part is contained into the main unit and can thus be reused for different patient which reduces drastically the use cost of the ventilator.

CLAIMS

1) A mechanical ventilator (1) for supplying O₂-enriched air to a patient comprising:

a. a main unit (2) comprising at least two external gas inlet ports (P1, P2) and an O₂-enriched air supply unit (6),

b. a disposable unit (3) comprising gas outlet ports (P3, P4),

c. an O₂-enriched air supply circuit (7) which comprises at least one inspiration valve (N13) and pneumatic components (N14, N15, N16) allowing O₂-enriched air to be supplied to the patient, said inspiration valve (N13) and the pneumatic components (N14, N15, N16) located downstream of said inspiration valve (13) along the supplied air circulation stream, being located in the disposable unit (3), the pneumatic components located upstream of said inspiration valve (N13) being located in the main unit (2),

d. connexion mean (4) allowing the fluidic connexion between the main unit (2) and the disposable unit (3).

2) A mechanical ventilator according to claim 1 further comprising a display unit (5).

3) A mechanical ventilator according to claim 1 or 2 further comprising an air exhaust circuit (9) allowing to exit the air exhaled by the patient from the ventilator, said air exhaust circuit (9) being in the disposable unit (3).

4) A mechanical ventilator according to anyone of the previous claims wherein the O₂-enriched air supply unit (6) comprises a bellows (N10).

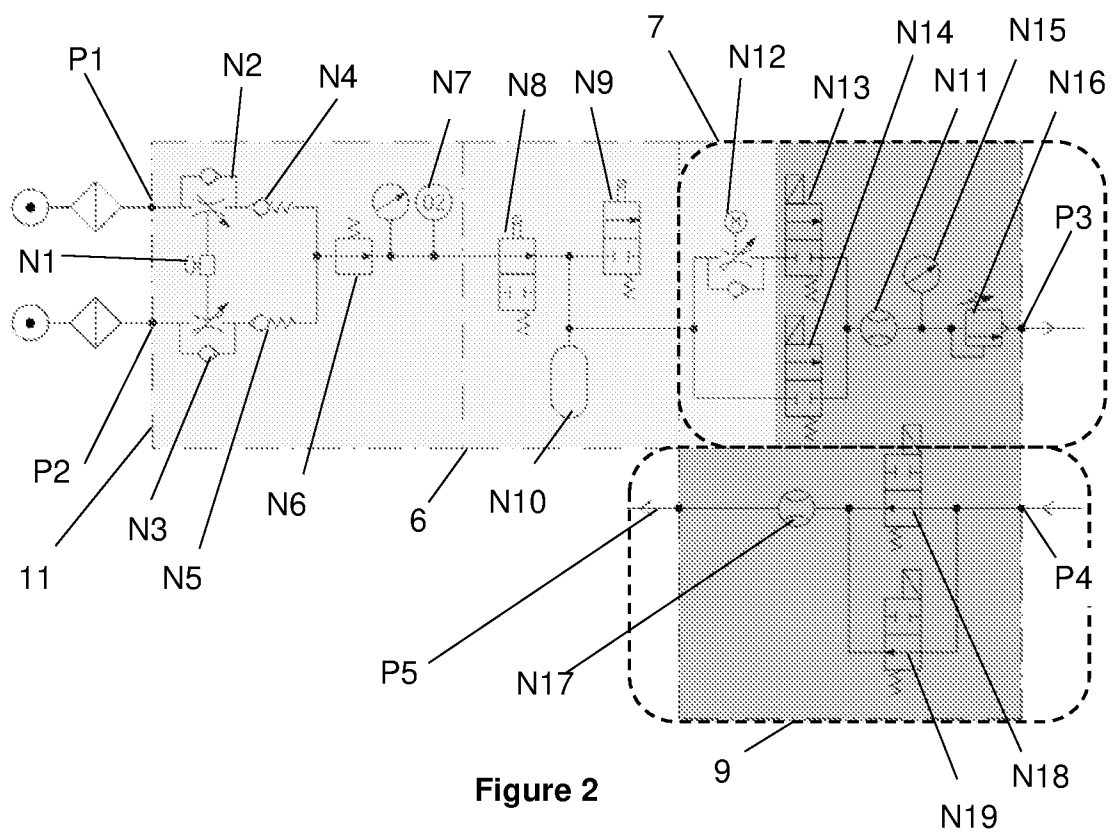
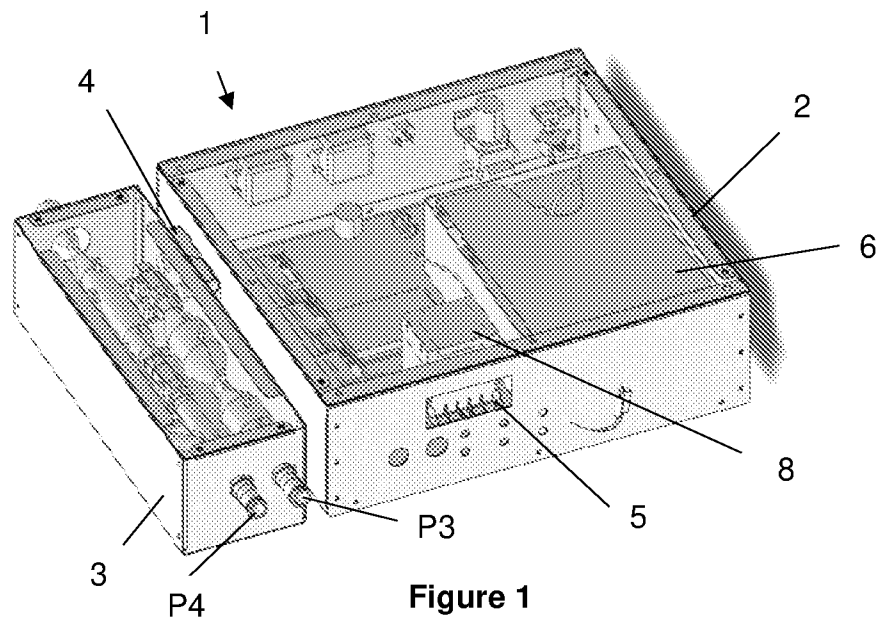
5) A mechanical ventilator according to anyone of the previous claims wherein the O₂-enriched air supply circuit (7) comprises at least one inspiration (N11) and one expiration (N17) flowmeters.

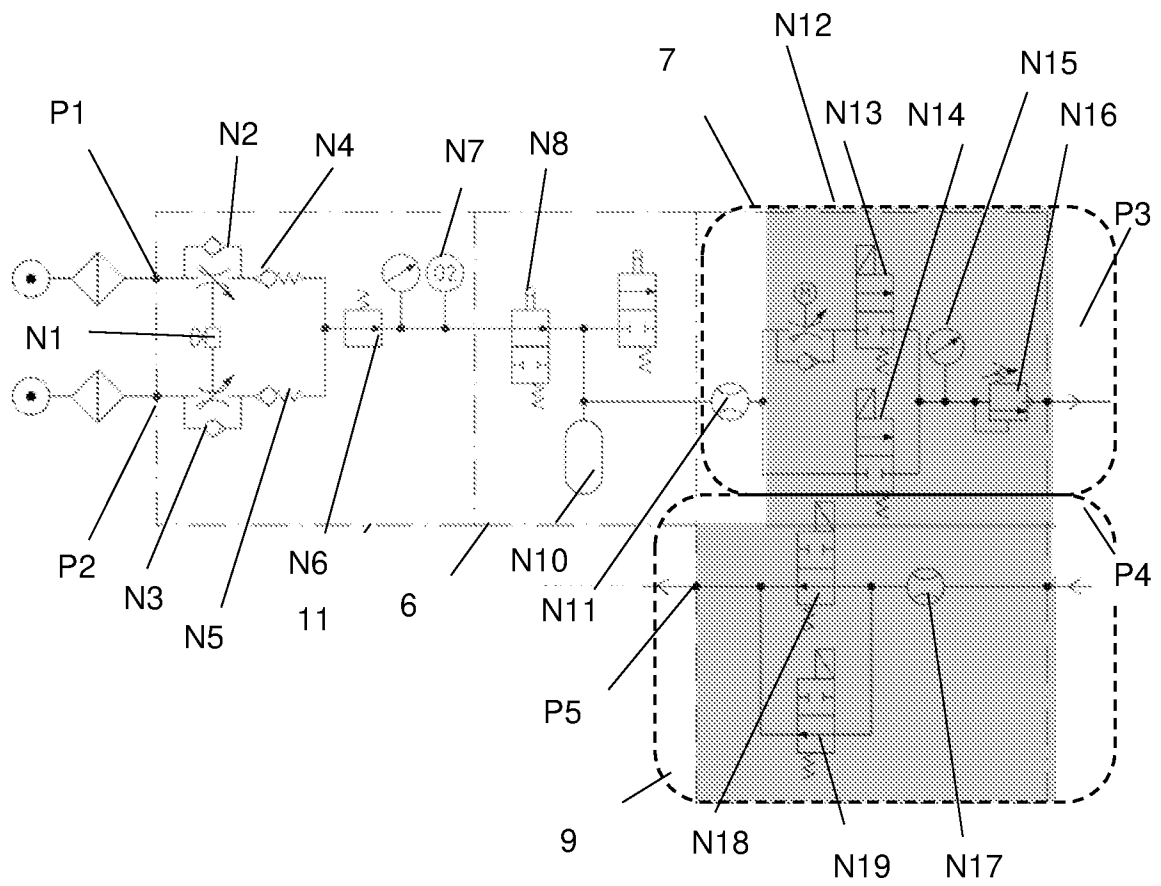
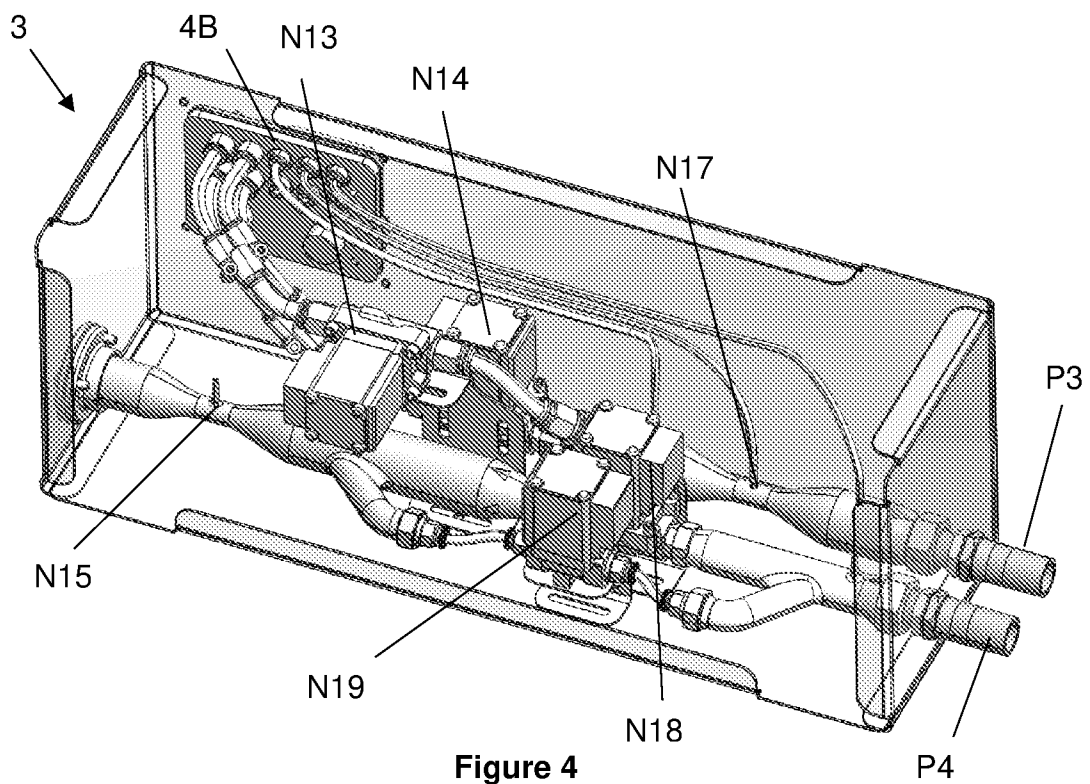
6) A mechanical ventilator according to claim 4 wherein the inspiration flowmeter (N11) is located upstream of the inspiration valve (N13).

7) A mechanical ventilator according to claim 4 wherein the inspiration flowmeter (N11) is located downstream of the inspiration valve (N13).

8) A mechanical ventilator according to claim 6 wherein the O₂-enriched air supply circuit (7) further comprises a pressure sensor (N15) upstream of the inspiration valve (N13) and the inspiration flowmeter (N11) and the pressure sensor (N15) are
5 a single part made by additive manufacturing.

9) A mechanical ventilator according to anyone of claims 4 to 7 wherein the flowmeters are Venturi flowmeters.



**Figure 3****Figure 4**

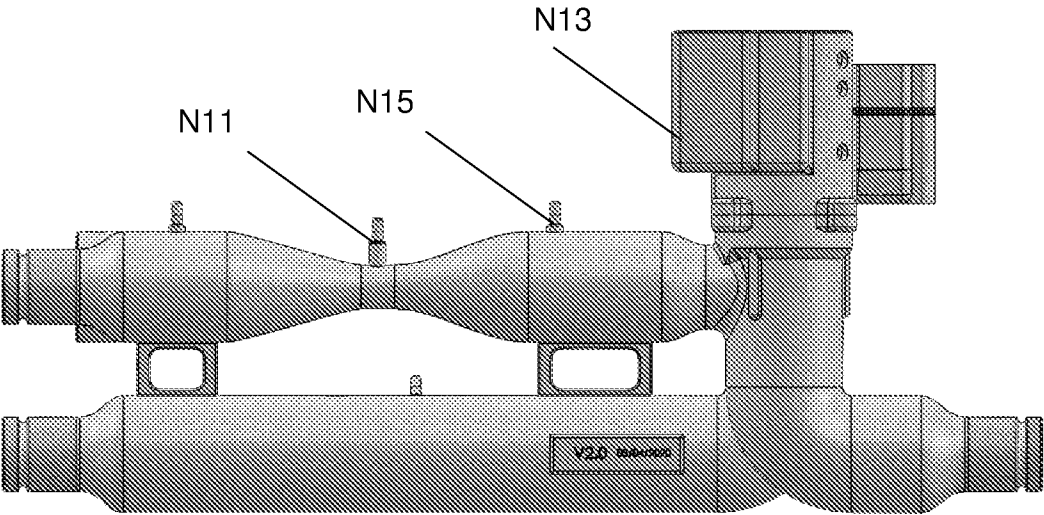


Figure 5

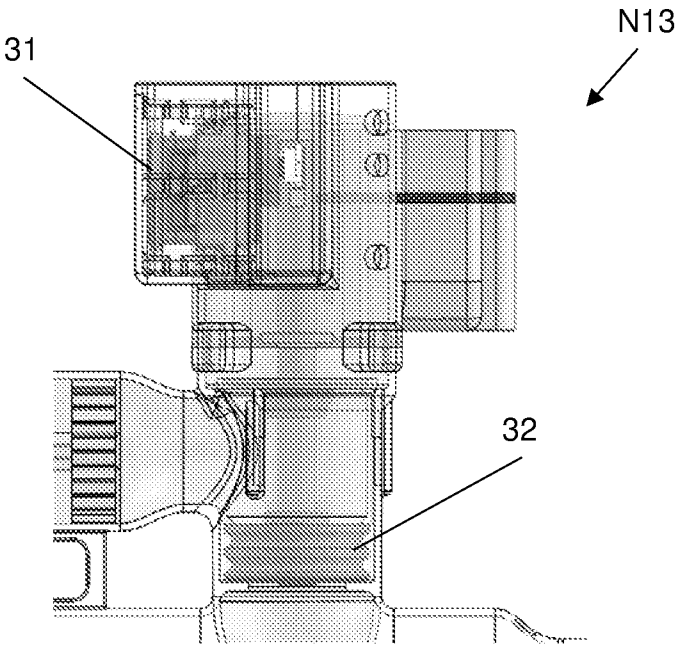


Figure 6

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2020/059743

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M16/00 A61M16/12 A61M16/20 A62B9/00
ADD. A61M16/08 A61M16/10 B33Y80/00 G01F1/36

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 A62B B33Y G01F

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)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 10 2016 122187 A1 (FRITZ STEPHAN GMBH [DE]) 24 May 2018 (2018-05-24)	1-4
Y	paragraph [0001] - paragraph [0019] paragraph [0021] - paragraph [0045] figure 1	1-5,7
X	----- WO 2008/147229 A1 (KUYPERS GILBERT JACOBUS [NZ]; MCCULLOCH RICHARD ANTHONY [NZ]) 4 December 2008 (2008-12-04)	1-4
Y	page 1, line 3 - page 10, line 5 page 11, line 26 - page 22, line 31 figures 1-11	1-4
X	----- US 2017/216549 A1 (CHANG SAMUEL M [US] ET AL) 3 August 2017 (2017-08-03)	1-6,8,9
Y	paragraph [0002] - paragraph [0011] paragraph [0028] - paragraph [0037] figures 3-9	1-7,9
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