

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
28 August 2008 (28.08.2008)

PCT

(10) International Publication Number
WO 2008/101302 A1

(51) International Patent Classification:

A61M 16/20 (2006.01) A62B 18/10 (2006.01)
A62B 7/04 (2006.01) F16K 17/34 (2006.01)
A62B 9/02 (2006.01) F24F 3/00 (2006.01)

(21) International Application Number:

PCT/AU2008/000247

(22) International Filing Date:

25 February 2008 (25.02.2008)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

2007900927 23 February 2007 (23.02.2007) AU

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

— of inventorship (Rule 4.17(iv))

Published:

— with international search report

(54) Title: DEMAND VALVE FOR BREATHING APPARATUS

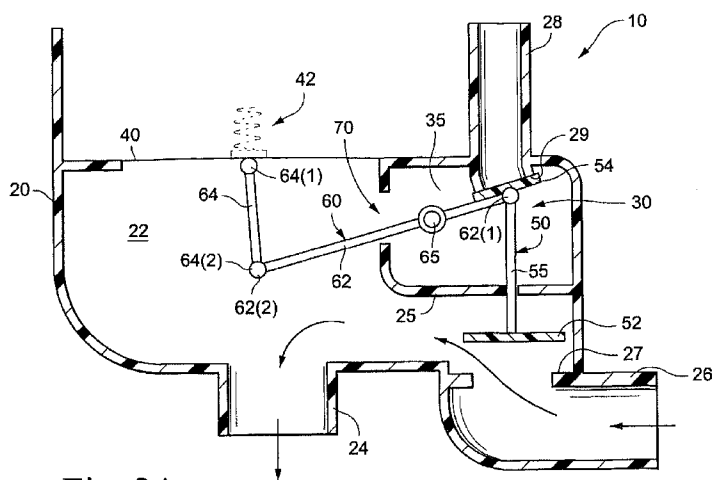


Fig. 2A

(57) Abstract: A demand valve (10) for a breathing apparatus includes a housing (20), a valve assembly (30), and a diaphragm (40) coupled to the valve assembly (30). The housing (20) defines a chamber (22) and includes a demand port (24) adapted to be in fluid communication with the entrance of a patient's airways, an inlet port (26) adapted to be in fluid communication with a supply of breathable gas at a positive pressure, and an exhaust port (28) adapted to allow gas to exit the housing (20). The valve assembly (30) includes an inlet valve (52) adapted to at least partially close the inlet port (26) and an exhaust valve (54) adapted to at least partially close the exhaust port (28). The diaphragm (40) is constructed and arranged to be responsive to pressure within the chamber (22) in order to effect movement of the valve assembly (30) to selectively close the inlet and exhaust ports (26, 28).

DEMAND VALVE FOR BREATHING APPARATUS

CROSS-REFERENCE TO APPLICATION

[0001] This application claims the benefit of Australian Provisional Application No. AU 2007900927, filed February 23, 2007, which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to a demand valve for use in a mechanical breathing apparatus. In particular, the present invention relates to apparatus that reduces the effort of breathing, particularly during exhalation.

[0003] Aspects of the invention may be used for Non-invasive Positive Pressure Ventilation (NPPV) and for continuous positive airway pressure (CPAP) therapy of sleep disordered breathing (SDB) conditions such as obstructive sleep apnea (OSA). However, aspects of the invention may have application in other fields.

BACKGROUND OF THE INVENTION

[0004] U.S. Patent No. 7,066,175 discloses a demand valve for a breathing apparatus including a supply inlet port adapted to be connected to a pressurized source of oxygen and an outlet port adapted to be connected to the inlet of a patient's breathing appliance. The demand valve includes a valve assembly for connecting/disconnecting the inlet port to and from the outlet port. However, such demand valve do not allow scavenging of exhausted gas.

SUMMARY OF THE INVENTION

[0005] One aspect of the invention relates to a demand valve for a breathing apparatus. The demand valve includes a housing, a valve assembly, and a diaphragm coupled to the valve assembly. The housing defines a chamber and includes a demand port adapted to be in fluid communication with the entrance of a patient's airways, an inlet port adapted to be in fluid communication with a supply of breathable gas at a positive pressure, and an exhaust

port adapted to allow gas to exit the housing. The valve assembly includes an inlet valve adapted to at least partially close the inlet port and an exhaust valve adapted to at least partially close the exhaust port. The diaphragm is constructed and arranged to be responsive to pressure within the chamber in order to effect movement of the valve assembly to selectively close the inlet and exhaust ports.

[0006] Another aspect of the invention relates to a breathing apparatus including a housing defining a chamber with a variable volume. The housing includes a demand port adapted to be in fluid communication with the entrance of a patient's airways, an inlet port adapted to be in fluid communication with a supply of breathable gas at a positive pressure, and an exhaust port adapted to allow gas to exit the housing. The housing is constructed and arranged to expand during an expiration phase of the patient's breathing cycle and to contract during an inspiration phase of the patient's breathing cycle to thereby forcibly vent at least a portion of exhausted gas to the exhaust port.

[0007] Another aspect of the invention relates to a method for supplying breathable gas to a patient. The method includes providing a patient interface for communication with a patient, setting a PAP device to generate a supply of breathable gas at a substantially constant positive pressure, and controlling the flow of breathable gas to be delivered to the patient interface upon patient inhalation, and at least partially stopped or impeded from proceeding to the patient interface upon patient exhalation.

[0008] Another aspect of the invention relates to a method for supplying breathable gas to a patient. The method includes providing a chamber with a variable volume between a patient interface for communication with a patient and a PAP device structured to generate a supply of breathable gas at a substantially constant positive pressure, and expanding the volume during an expiration phase of the patient's breathing cycle and contracting the volume during an inspiration phase of the patient's breathing cycle to thereby forcibly vent at least a portion of exhausted gas to atmosphere.

[0009] Other aspects, features, and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:

[0011] Fig. 1 is a schematic view of a breathing apparatus including a demand valve according to an embodiment of the present invention;

[0012] Fig. 2A illustrates a demand valve according to an embodiment of the present invention, the demand valve arranged to provide pressurized gas to a patient;

[0013] Fig. 2B illustrates the demand valve of Fig. 2A with the demand valve arranged to scavenge gas from the patient;

[0014] Fig. 3A illustrates a demand valve according to another embodiment of the present invention, the demand valve arranged to provide pressurized gas to a patient;

[0015] Fig. 3B illustrates the demand valve of Fig. 3A with the demand valve arranged to scavenge gas from the patient;

[0016] Fig. 4 illustrates a demand valve according to another embodiment of the present invention, the demand valve arranged to scavenge gas from the patient;

[0017] Fig. 5A is a graph illustrating pressure applied to the chamber of the demand valve from a supply of pressurized breathable gas during expiration and inhalation phases of the patient's breathing cycle; and

[0018] Fig. 5B is a graph illustrating pressure within a chamber during expiration and inhalation phases of the patient's breathing cycle for the demand valve and for a typical CPAP device.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0019] The following description is provided in relation to several embodiments which may share common characteristics and features. It is to be understood that one or more features of any one embodiment may be combinable with one or more features of the other embodiments. In addition, any single feature or combination of features in any of the embodiments may constitute additional embodiments.

[0020] In this specification, the word “comprising” is to be understood in its “open” sense, that is, in the sense of “including”, and thus not limited to its “closed” sense, that is the sense of “consisting only of”. A corresponding meaning is to be attributed to the corresponding words “comprise”, “comprised” and “comprises” where they appear.

[0021] The term “air” will be taken to include breathable gases, for example air with supplemental oxygen. It is also acknowledged that the apparatus described herein may be designed for use with fluids other than air.

1. Breathing Apparatus

[0022] Fig. 1 is a schematic view of a breathing apparatus 2 including a demand valve 10 according to an embodiment of the present invention. As illustrated, the breathing apparatus 2 includes a positive airway pressure (PAP) device or flow generator 4 structured to generate a supply of air or breathable gas at a positive pressure, a patient interface 6 (e.g., full-face mask, nasal mask, etc.) structured to provide a seal with the patient's face, and a demand valve 10 between the PAP device 4 and the patient interface 6.

[0023] In an embodiment, the demand valve 10 includes an inlet in fluid communication with the outlet of the PAP device 4 (e.g., via an air delivery tube) and an outlet in fluid communication with the inlet of the patient interface (e.g., via an air delivery tube), as described below. However, it should be appreciated that the demand valve may be at least partially incorporated into the PAP device and/or the patient interface, e.g., demand valve incorporated into the housing of the PAP device.

2. Demand Valve

[0024] Figs. 2A and 2B illustrate a demand valve 10 for use in a breathing apparatus according to an embodiment of the present invention. As illustrated, the demand valve 10 includes a housing 20 defining a chamber 22, a valve assembly 30, and a diaphragm 40 coupled to the valve assembly 30 that is responsive to pressure within the chamber 22 in order to regulate a supply of pressurized breathable gas to a patient and assist with scavenging or venting exhausted gas to atmosphere.

2.1 Housing

[0025] The housing 20 includes a demand port 24, an inlet port 26, and an exhaust port 28. The demand port 24 is adapted to be connected to the entrance of a patient's airways (e.g., via an air delivery tube and some form of patient interface or mask). The inlet port 26 is adapted to be connected to a supply of air or breathable gas at a positive pressure (e.g., via an air delivery tube and a PAP device). In an embodiment, the air or breathable gas is provided at a relatively constant positive pressure, e.g., between 2-30 cmH₂O for the treatment of obstructive sleep apnea or other respiratory diseases or conditions, although other fields of use are also considered. However, the air or breathable gas may be provided at variable or bi-level pressures. The exhaust port 28 is adapted to allow air or gas (e.g., exhausted CO₂) to exit the housing 20, e.g., to atmosphere.

[0026] The chamber 22 is in constant fluid communication with the demand port 24 and is in variable fluid communication with the inlet and exhaust ports 26, 28, as described in greater detail below. A baffle wall 25 is provided between the inlet and exhaust ports 26, 28 and defines an exhaust chamber 35 adjacent the exhaust port 28.

2.2 Valve Assembly

[0027] The valve assembly 30 includes a valve 50 and a mechanical arm 60 to interconnect the valve 50 with the diaphragm 40. As shown in Figs. 2A and 2B, the valve 50 includes an inlet valve 52 engageable with an inlet valve seat 27 adjacent the inlet port 26 and an exhaust valve 54 engageable with an exhaust valve seat 29 adjacent the exhaust port 28. As illustrated, the inlet and exhaust valves 52, 54 are coupled to one another, e.g., by a mechanical link 55.

[0028] The mechanical arm 60 is responsive to movement of the diaphragm 40, which is responsive to pressure within the chamber 22 as described in greater detail below. The mechanical arm 60 is arranged to create a mechanical advantage such that movement of the diaphragm 40 moves the valve 50 relative to the inlet and exhaust ports 26, 28. Specifically, the mechanical arm 60 includes a first and second links 62, 64. The first link 62 is pivotally mounted to the housing 20 via an off-center hinge 65 (which creates the mechanical advantage) and includes a first end 62(1) pivotally mounted to the valve 50 and a second end 62(2). The second link 64 includes a first end 64(1) in communication or coupled with the

diaphragm 40 and a second end 64(2) pivotally mounted to the second end 62(2) of the first link 62.

[0029] As shown in Figs. 2A and 2B, the coupled inlet and exhaust valves 52, 54 include a generally I-shaped cross-sectional configuration, and the inlet port 26 includes an axis that is generally aligned or coaxial with an axis of the exhaust port 28. This arrangement allows the coupled valves 52, 54 to move generally linearly to open one of the inlet and exhaust ports 26, 28 while closing the other, and vice versa. While generally aligned, the baffle wall 25 prevents short circuiting of the incoming gas directly to the exhaust chamber 35 or exhaust port 28.

[0030] In an embodiment, it may be possible for the coupled valves 52, 54 to assume an intermediate position so that both the inlet and exhaust ports 26, 28 are simultaneously open. That is, the valves may not entirely open/close respective ports, but may at least partially open/close the ports to regulate flow through the inlet/exhaust ports during inhalation/exhalation phases of the patient's breathing cycle.

[0031] However, the valve and/or housing may include other suitable configurations. For example, in Figs. 3A and 3B, the valve may be in the form of a piston 250 including a plunger portion 252 and a head portion 254. In use, the plunger portion 252 is structured to open/close the inlet port 26 and the head portion 254 is structured to open/close the exhaust port 28.

[0032] The piston-type valve may include different configurations, e.g., depending on the structure of the housing and inlet/exhaust ports thereof. For example, Fig. 4 illustrates a piston-type valve 350 including a plunger portion 352 with an angled side wall.

2.3 Diaphragm

[0033] The diaphragm 40 (e.g., flexible membrane) is provided to the housing 20 and is structured to allow the volume of the chamber 22 to change responsive to pressure within the chamber 22. In its initial or relaxed position, the diaphragm assumes a generally flat configuration, as shown in Fig. 2A. When deformed or expanded (due to pressure within the chamber 22), the diaphragm balloons outwardly and assumes a generally contoured or bulbous configuration, as shown in Fig. 2B. It should be appreciated that the diaphragm may

assume other suitable configurations in its relaxed or expanded positions, e.g., diaphragm may be slightly curved (inward or outward) in its relaxed position.

[0034] In the illustrated embodiment, the diaphragm 40 may have inherent resiliency and/or may be coupled to a biasing structure (e.g., spring 42) so that the diaphragm is biased to its relaxed position. The spring rate provided by the diaphragm 40 may be adjustable.

[0035] In use, increased pressure within the chamber 22 causes the diaphragm 40 to expand from its relaxed position to its expanded position (against biasing thereof), and decreased pressure within the chamber 22 allows the diaphragm 40 to resiliently return to its relaxed position. Movement of the diaphragm 40 effects movement of the mechanical arm 60 which in turn effects movement of the valve 50 to open and close the inlet and exhaust ports 26, 28, i.e., the coupled inlet and exhaust valves 52, 54 are arranged to open and close respective inlet and exhaust ports 26, 28 responsive to pressure within the chamber 22.

2.4 Operation

[0036] The housing chamber 22 is in fluid communication with the demand port 24, which is coupled to a patient interface provided to the patient's face. The demand valve 10 is structured to supply pressurized breathable gas to the patient interface (e.g., upon patient inhalation) and allow exhausted gas to exit to atmosphere (e.g., upon patient exhalation).

[0037] In the absence of a supply of pressurized breathable gas to the demand valve 10, the diaphragm 40 assumes its relaxed position so that the exhaust valve 54 is held in contact with the exhaust seat 29 adjacent the exhaust port 28 (e.g., see Fig. 2A). Thus, the inlet port 26 is open and the exhaust port 28 is closed to prevent any inward leakage of atmospheric air into the demand valve 10. In an alternative embodiment, the demand valve 10 be arranged so that the coupled valves 52, 54 assume an intermediate position when the diaphragm 40 is in its relaxed position so both the inlet and exhaust ports 26, 28 are simultaneously, slightly open.

[0038] When a supply of pressurized breathable gas is supplied to the demand valve 10 (e.g., from PAP device coupled to the inlet port 26), the pressurized breathable gas passes through the inlet port 26, through the chamber 22, through the demand port 24, and into the patient interface for inhalation by the patient (e.g., see Fig. 2A). As illustrated, during the inhalation phase of the patient's breathing cycle, the baffle wall 25 is provided between the

inlet and exhaust ports 26, 28 to direct the pressurized breathable gas towards the demand port 24.

[0039] When the patient stops inhaling, the incoming gas will start to pressurize the chamber 22 and begin expanding the diaphragm 40. As shown in Fig. 2B, when the patient exhales, the exhausted gas will further increase the pressure within the chamber 22 which causes the diaphragm 40 to further expand. As the diaphragm 40 reaches its expanded position, the mechanical arm 60 pivots about the off-center hinge 65 to cause the inlet valve 52 to engage the inlet valve seat 27 adjacent the inlet port 26. Due to the off-center hinge 65, the diaphragm 40 may have a relatively low spring constant, yet the desired movement of the valve 30 can still be effected (e.g., even against pressure from the inlet port 26). This movement closes to the inlet port 26 to stop or nearly stop the supply of pressurized breathable gas, while allowing the exhaust valve 54 to open the exhaust port 28 to allow the exhausted gas to exit the chamber 22.

[0040] When the patient inhales again, the pressure within the chamber 22 decreases which causes the diaphragm 40 to resiliently return to its initial position (e.g., under biasing from inherent resiliency, a biasing structure, and/or ambient pressure on the outside of the diaphragm). As the diaphragm 40 reaches its relaxed position, the mechanical arm 60 pivots about the off-center hinge 65 to cause the exhaust valve 54 to engage the exhaust valve seat 29 adjacent the exhaust port 28. This movement closes to the exhaust port 28 to prevent gas from exiting the chamber 22, while allowing the inlet valve 52 to open the inlet port 26 to allow pressurized breathable gas to enter the chamber 22 and proceed through the demand port 24 to the patient interface.

[0041] Fig. 5A includes a graph illustrating pressure (P_s) applied to the chamber from the supply of pressurized breathable gas during expiration and inhalation phases (E, I) of the patient's breathing cycle, and Fig. 5B includes a graph illustrating pressure (P_c) within the chamber during expiration and inhalation phases (E, I) of the patient's breathing cycle for the demand valve (in dashed lines) and for a typical CPAP device (in solid lines).

[0042] As shown in Fig. 5A, the supply of pressurized gas applied to the chamber is stopped or nearly stopped during the exhalation phase (E), the supply of pressurized gas is opened during the inhalation phase (I), and the supply of pressurized gas is partially opened/stopped as the inlet valve transitions between open/closed positions (e.g., both inlet

and exhaust ports open). This arrangement reduces breathing effort especially during patient exhalation as described below.

[0043] As shown in Fig. 5B, the pressure within the chamber for the demand valve (in dashed lines) increases during patient expiration and decreases during patient inspiration. The pressure in the chamber may even be a negative value, i.e., a vacuum in certain cases. As described above, this arrangement controls movement of the diaphragm which effects movement of the inlet and exhaust valves. Specifically, the higher pressure during expiration results in expansion of the diaphragm and an increase in the volume of the chamber, and the lower pressure during inspiration results in contraction of the diaphragm and a decrease in the volume of the chamber. As illustrated in dashed lines, the pressure swing between expiration and inspiration is not significant due to the variable volume of the chamber and/or the regulation of the supply of pressurized gas. In contrast, the pressure swing for a chamber of a typical CPAP device (in solid lines) has substantial pressure swings because it does not include a diaphragm to vary the chamber volume and/or it is not structured to stop or at least partially stop the supply of pressurized gas during exhalation, nor increasing venting/exhaust during exhalation.

[0044] Figs. 3A and 3B illustrate movement of the piston-type valve 250 described above between a position to provide a supply of pressurized breathable gas (Fig. 3A) and a position to allow exhausted gas to exit the chamber (Fig. 3B). As illustrated, the plunger portion 252 of the piston-type valve 250 is structured to open/close the inlet port 26 and the head portion 254 of the piston-type valve 250 is structured to open/close the exhaust port 28.

[0045] Fig. 4 illustrates the piston-type valve 350 described above in a position to close the inlet port 26 while opening the outlet port 28.

2.5 Reduced Breathing Effort

[0046] The demand valve 10 is structured to reduce breathing effort, especially during patient exhalation. Specifically, the demand valve 10 regulates the supply of pressurized gas so that pressurized gas is supplied to the patient when demanded (i.e., upon patient inhalation). When the patient exhales, the supply of pressurized gas is at least partially restricted (e.g., inlet port 26 closed) so that the patient does not have to exhale against pressurized gas, i.e., less effort to exhale. Further, the exhaust valve can be designed

significantly larger to vent higher flow to allow reduced work of exhalation to the patient. The flow generator also works with less effort as leak is not constant, especially during inhalation.

[0047] Thus, the demand valve may allow a PAP device that supplies relatively constant positive pressure to simulate bi-level type therapy to a patient, i.e., higher pressure during inhalation and lower pressure during exhalation. It may be possible for the demand valve to be used with PAP devices structured to supply VPAP or Bi-level therapy.

2.6 Scavenging

[0048] The demand valve 10 may be structured to provide forced venting or scavenging of exhausted gas (e.g., efficient washout of CO₂) to the exhaust port 28. Specifically, at the end of exhalation as the patient begins to inhale and the diaphragm 40 begins to resiliently return or contract to its initial position to open the inlet port 26, the movement of the diaphragm 40 along with the pressurized gas entering the chamber 22 creates a blast of pressure to force all the gas within the chamber 22 to exit the housing 22. That is, the blast of pressure forces gas to exit through the exhaust port 28 (until it is closed by the exhaust valve 54) as well as urge the supply of pressurized gas towards the demand port 24. In this embodiment, both the inlet and outlet valves 52, 54 may be slightly open at the same time to assist scavenging.

2.7 Exhaust Flow Restrictor

[0049] As illustrated, the housing 20 includes internal walls adjacent the exhaust port 28 that define an exhaust flow restrictor 70. The exhaust flow restrictor 70 (which may be adjustable) is structured to restrict the flow of gas to the exhaust port 28 communicated with atmosphere. As a result, pressure increase in the chamber 22 (i.e., upon exhalation) will increase the pressure drop across the exhaust flow restrictor 70 which allows gas to gradually vent to atmosphere when the exhaust port 28 is opened, i.e., exhaust flow restrictor 70 restricts flow so flow does not exceed the maximum flow rate at the exhaust port 28. In addition, the exhaust flow restrictor 70 may help control the rate at which the diaphragm 40 expands.

[0050] In one form of the invention, pressure from the PAP device is used to counterbalance the diaphragm 40. By controlling the pressure in the PAP device one may

control the diaphragm 40 and hence the venting through the exhaust valve 54. See for example International Patent Application PCT/IB2007/001837 the contents of which are hereby expressly incorporated by cross-reference.

[0051] In one form the exhaust valve 54 includes a conical valve plunger that allows finer control over the rate of flow through the valve.

[0052] In one form inlet valve 52 includes a piston element that allows a range of different flows through the outlet valve while the inlet valve remains closed. For example, the piston element may completely close the inlet valve in a range of different positions (part-way through, all the way through) while the exhaust valve is moving through a range of different degrees of openness.

[0053] In one form the position of the arm 60 is relayed to a flow generator, e.g. via a rotation sensor at axis 65 that would provide appropriate breath data to the machine which could enhance therapy further; e.g. reduce pressure further on exhalation.

[0054] In one form the diaphragm has an adjustable spring constant.

[0055] While the invention has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the invention. Also, the various embodiments described above may be implemented in conjunction with other embodiments, e.g., aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodiments. Further, each independent feature or component of any given assembly may constitute an additional embodiment. In addition, while the invention has particular application to patients who suffer from OSA, it is to be appreciated that patients who suffer from other illnesses (e.g., congestive heart failure, diabetes, morbid obesity, stroke, bariatric surgery, etc.) can derive benefit from the above teachings. Moreover, the above teachings have applicability with patients and non-patients alike in non-medical applications.

WHAT IS CLAIMED IS:

1. A demand valve for a breathing apparatus, comprising:
a housing defining a chamber and including a demand port adapted to be in fluid communication with the entrance of a patient's airways, an inlet port adapted to be in fluid communication with a supply of breathable gas at a positive pressure, and an exhaust port adapted to allow gas to exit the housing;
a valve assembly including an inlet valve adapted to at least partially close the inlet port and an exhaust valve adapted to at least partially close the exhaust port; and
a diaphragm coupled to the valve assembly,
wherein the diaphragm is constructed and arranged to be responsive to pressure within the chamber in order to effect movement of the valve assembly to selectively close the inlet and exhaust ports.
2. The demand valve according to claim 1, wherein the valve assembly includes a mechanical arm to interconnect the inlet and exhaust valves with the diaphragm.
3. The demand valve according to claim 2, wherein the mechanical arm is pivotable about an off-center pivot axis arranged to create a mechanical advantage such that movement of the diaphragm moves the inlet and exhaust valves relative to respective inlet and exhaust ports.
4. The demand valve according to any one of claims 1-3, wherein the inlet and exhaust valves are coupled to one another by a mechanical link.
5. The demand valve according to claim 1, wherein the inlet and outlet valves are in the form of a piston including a plunger portion adapted to close the inlet port and a head portion adapted to close the exhaust port.
6. The demand valve according to any one of claims 1-5, wherein the exhaust port is communicated to atmosphere.

7. The demand valve according to any one of claims 1-6, wherein the diaphragm is moveable between a relaxed position which causes the exhaust valve to close the exhaust port and the inlet valve to open the inlet port, and an expanded position which causes the inlet valve to close the inlet port and the exhaust valve to open the exhaust port.

8. The demand valve according to claim 7, wherein the diaphragm assumes a generally flat configuration when in the relaxed position and assumes a generally contoured or bulbous configuration when in the expanded position.

9. The demand valve according to any one of claims 7-8, wherein the diaphragm includes inherent resiliency.

10. The demand valve according to any one of claims 7-9, wherein the diaphragm is coupled to a biasing structure that biases the diaphragm into the relaxed position.

11. The demand valve according to any one of claims 7-10, wherein the diaphragm is movable to the expanded position responsive to increased pressure within the chamber.

12. The demand valve according to claim 11, wherein the diaphragm is movable to the expanded position responsive to patient exhalation or the transition from inhalation to exhalation.

13. The demand valve according to any one of claims 7-12, wherein the diaphragm is movable to the relaxed position responsive to decreased pressure within the chamber.

14. The demand valve according to claim 13, wherein the diaphragm is movable to the relaxed position responsive to patient inhalation or the transition from exhalation to inhalation.

15. The demand valve according to any one of claims 1-14, wherein the valve assembly is arranged such that the inlet port is closed while the exhaust port is open.

16. The demand valve according to any one of claims 1-15, wherein the diaphragm is constructed and arranged to forcibly vent at least a portion of exhausted gas to the exhaust port.

17. The demand valve according to any one of claims 1-16, wherein the diaphragm is constructed and arranged to move in response to patient inhalation or the transition from exhalation to inhalation to force gas within the chamber to the exhaust port.

18. The demand valve according to any one of claims 1-17, wherein the diaphragm is constructed and arranged to vary a volume of the chamber in order to force gas to the exhaust port.

19. The demand valve according to any one of claims 1-18, wherein the housing includes an exhaust flow restrictor adjacent the exhaust port.

20. A breathing apparatus, comprising:
a PAP device structured to generate a supply of breathable gas at a positive pressure in the range of 2-30 cmH₂O;
a patient interface structured to provide a seal with a patient's face; and
a demand valve according to any one of claims 1-19.

21. The breathing apparatus according to claim 20, wherein the demand port is connected to the patient interface and the inlet port is connected to the PAP device.

22. The breathing apparatus according to any one of claims 20-21, wherein the demand valve is connected between the PAP device and the patient interface.

23. The breathing apparatus according to any one of claims 20-22, wherein the PAP device is structured and configured to provide breathable gas at a relatively constant positive pressure.

24. A breathing apparatus, comprising:
a housing defining a chamber with a variable volume, the housing including a demand port adapted to be in fluid communication with the entrance of a patient's airways, an inlet port adapted to be in fluid communication with a supply of breathable gas at a positive pressure, and an exhaust port adapted to allow gas to exit the housing,
wherein the housing is constructed and arranged to expand during an expiration phase of the patient's breathing cycle and to contract during an inspiration phase of the patient's breathing cycle to thereby forcibly vent at least a portion of exhausted gas to the exhaust port.

25. The breathing apparatus according to claim 24, wherein the housing is constructed and arranged to forcibly urge the supply of breathable gas towards the demand port during the inspiration phase.

26. The breathing apparatus according to any one of claims 24-25, further comprising a diaphragm provided to the housing, the diaphragm constructed and arranged to vary the volume of the chamber responsive to pressure within the chamber.

27. The breathing apparatus according to claim 26, further comprising a valve assembly coupled to the diaphragm, the valve assembly including an inlet valve adapted to at least partially close the inlet port and an exhaust valve adapted to at least partially close the exhaust port.

28. The breathing apparatus according to claim 27, wherein the diaphragm is constructed and arranged to vary the volume of the chamber in order to effect movement of the valve assembly to selectively close the inlet and exhaust ports.

29. A method for supplying breathable gas to a patient, comprising:
providing a patient interface for communication with a patient;
setting a PAP device to generate a supply of breathable gas at a substantially constant positive pressure; and
controlling the flow of breathable gas to be delivered to the patient interface upon patient inhalation, and at least partially stopped or impeded from proceeding to the patient interface upon patient exhalation.
30. A method according to claim 29, further comprising forcibly venting at least a portion of exhausted gas to atmosphere.
31. A method according to any one of claims 29-30, wherein controlling the flow of breathable gas includes controlling a valve in communication with the flow of breathable gas.
32. A method for supplying breathable gas to a patient, comprising:
providing a chamber with a variable volume between a patient interface for communication with a patient and a PAP device structured to generate a supply of breathable gas at a substantially constant positive pressure; and
expanding the volume during an expiration phase of the patient's breathing cycle and contracting the volume during an inspiration phase of the patient's breathing cycle to thereby forcibly vent at least a portion of exhausted gas to atmosphere.
33. A method according to claim 32, further comprising forcibly urging the supply of breathable gas towards the patient interface during the inspiration phase of the patient's breathing cycle.

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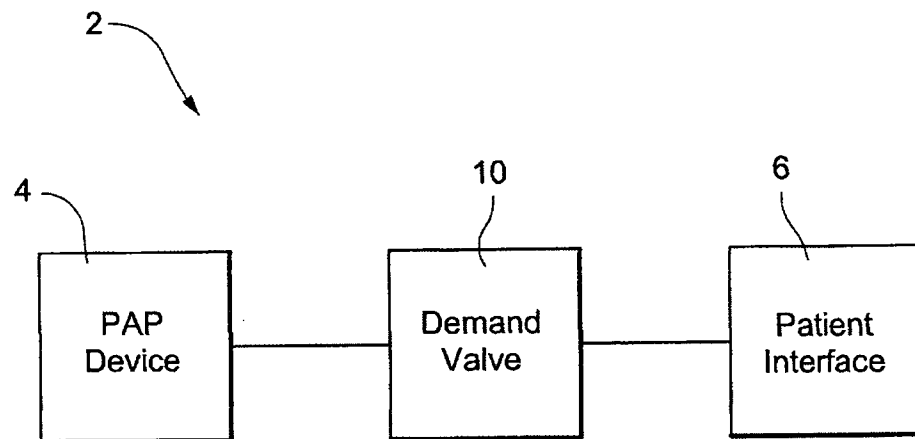


Fig. 1

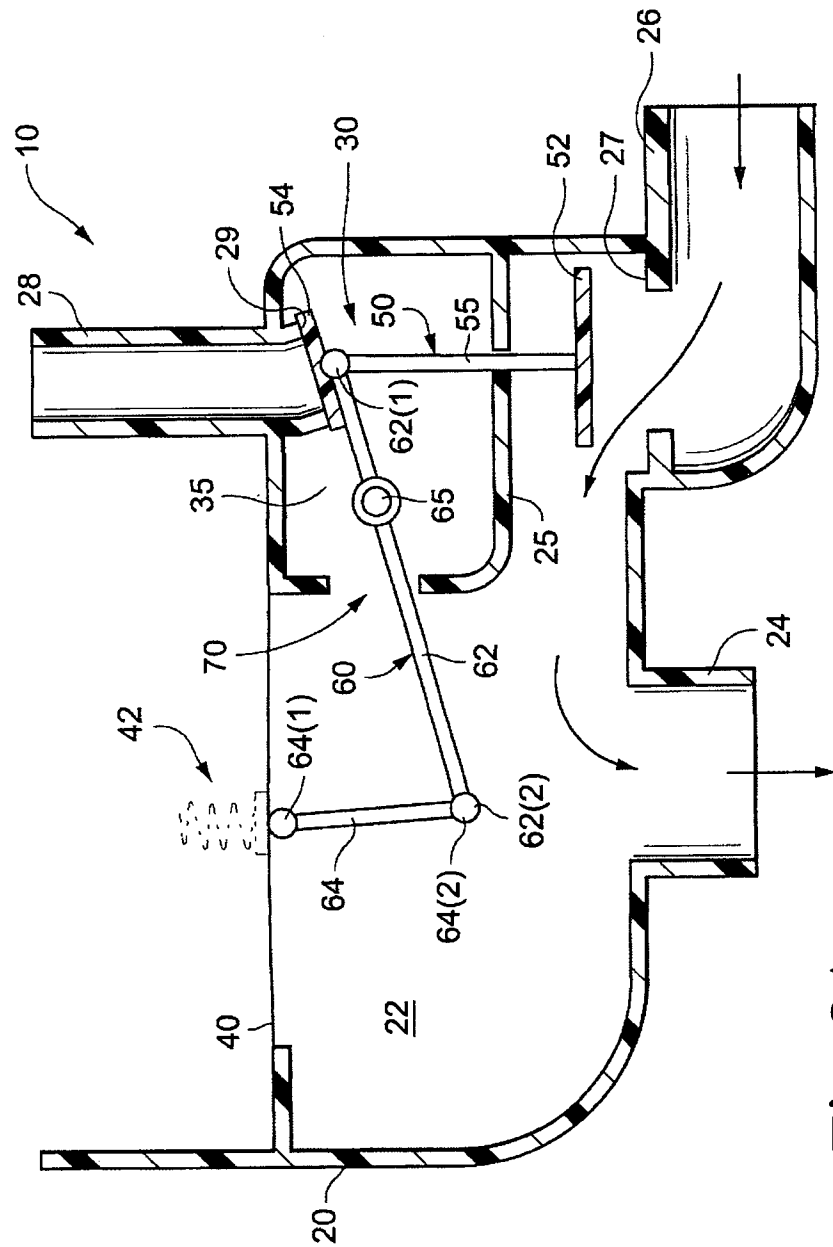


Fig. 2A

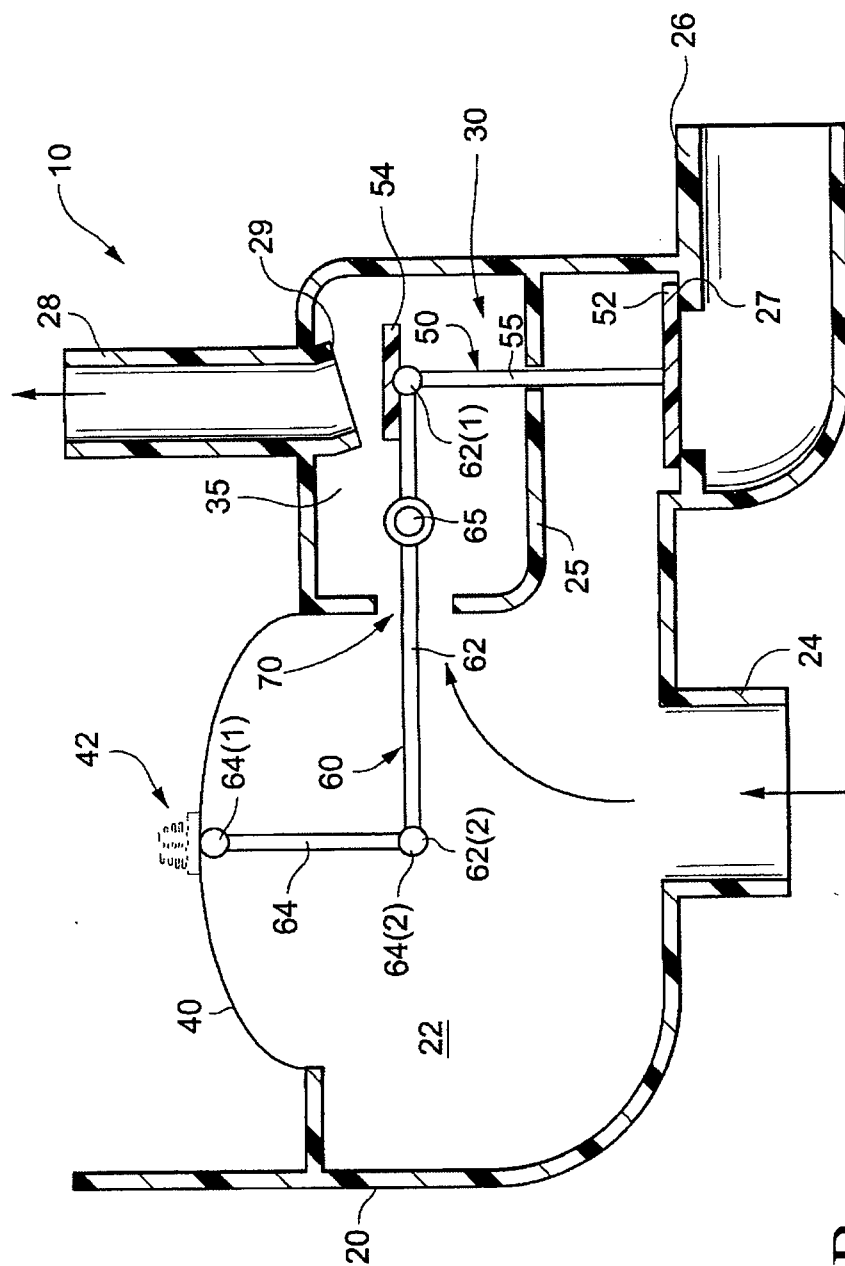


Fig. 2B

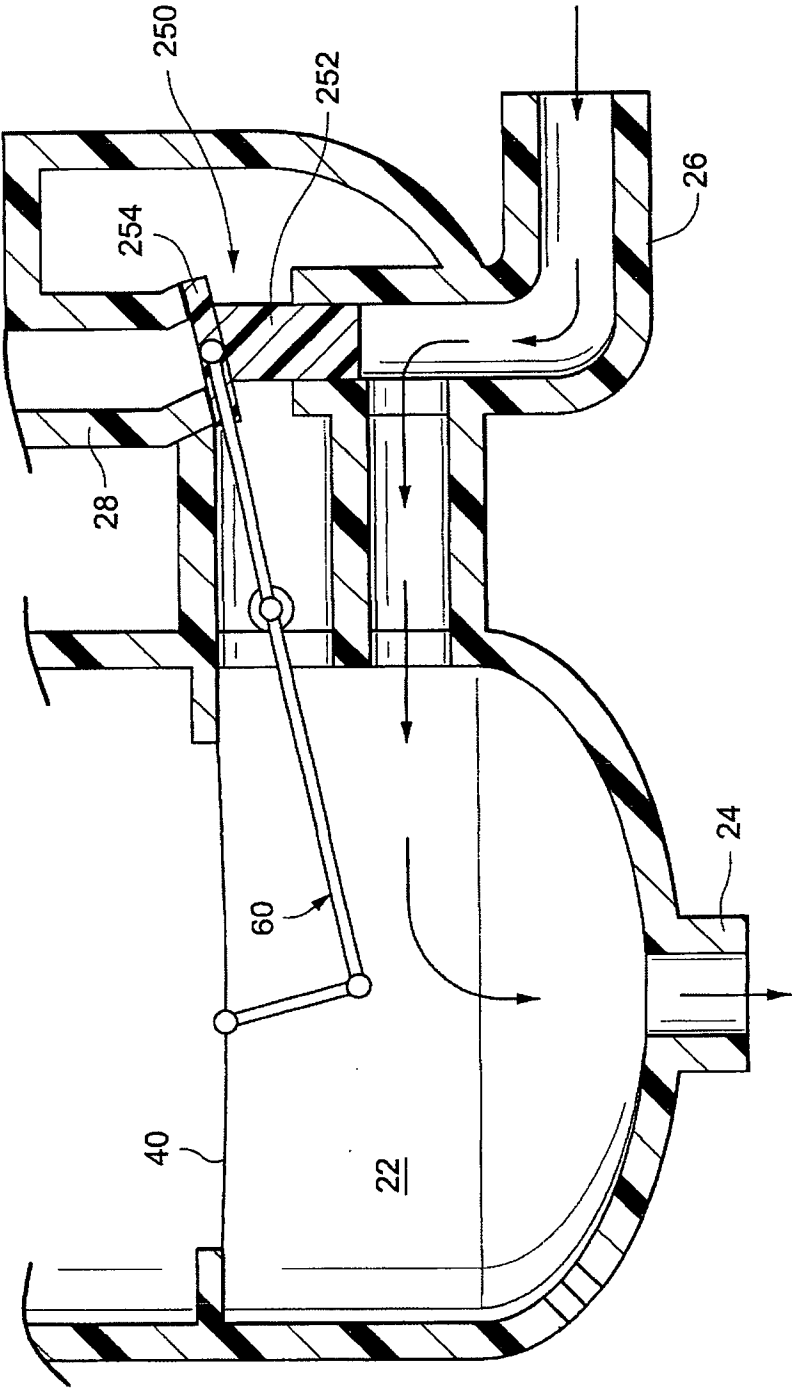


Fig. 3A

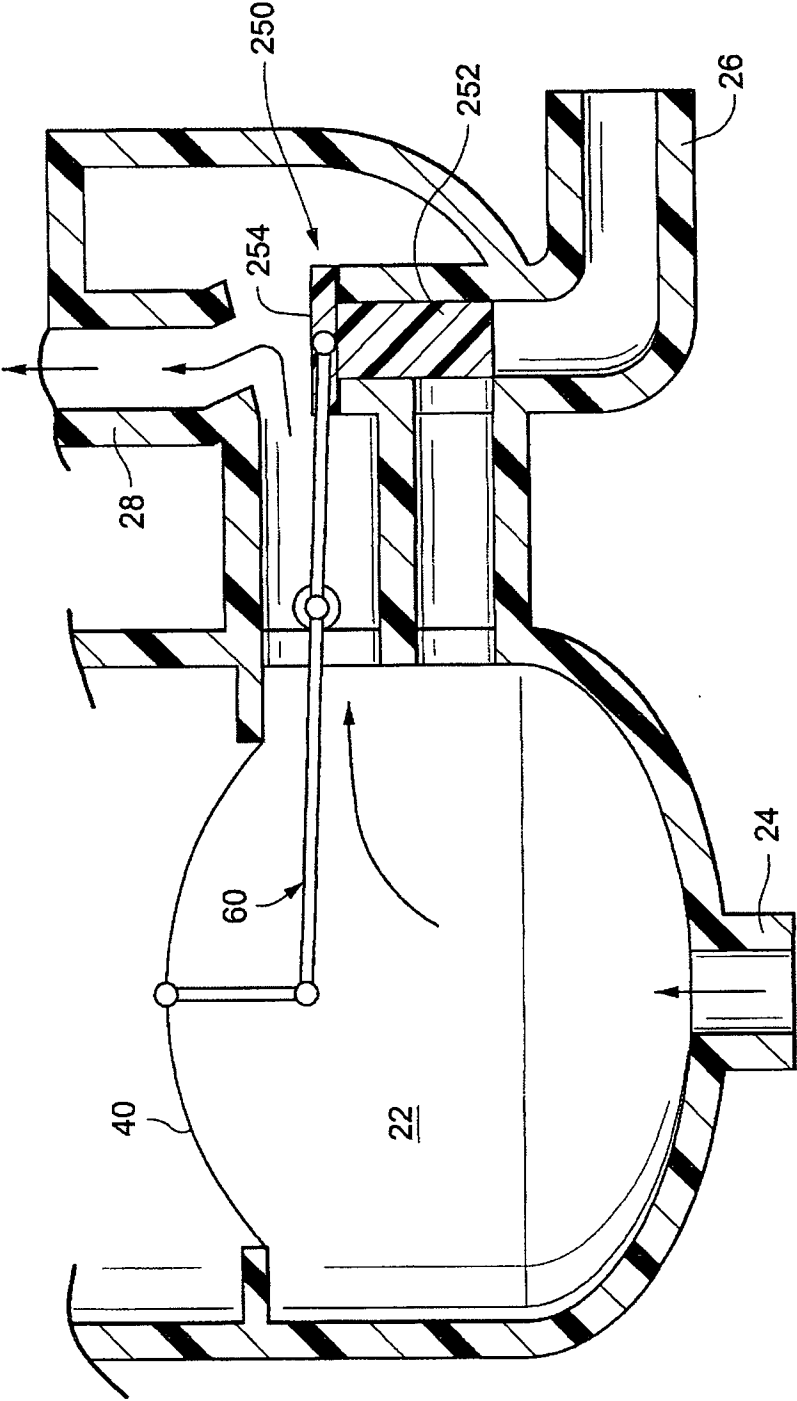


Fig. 3B

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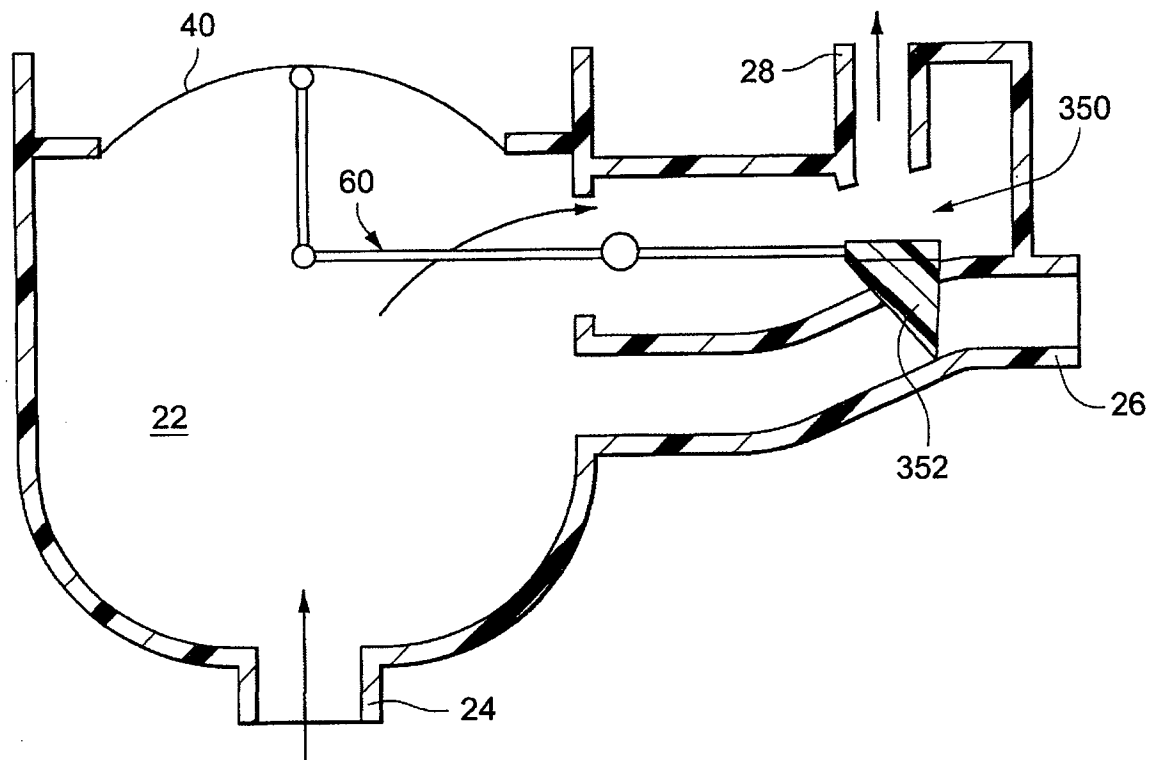


Fig. 4

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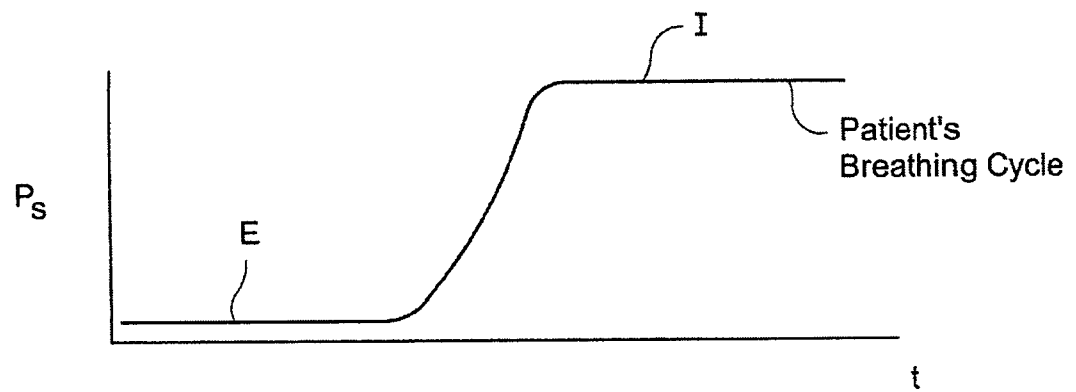


Fig. 5A

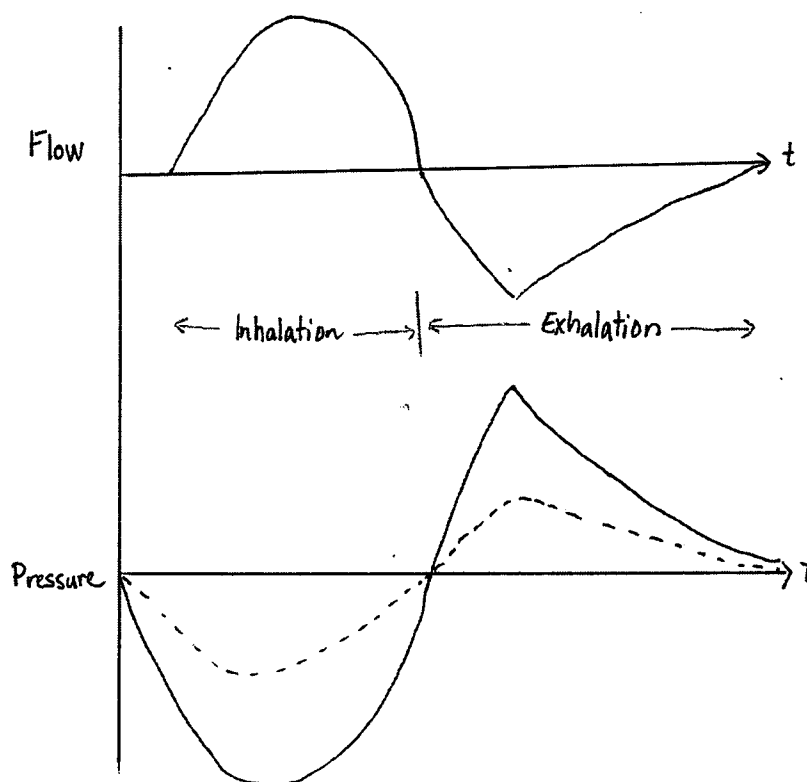


Fig. 5B

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2008/000247

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 16/20 (2006.01) *A62B 9/02* (2006.01) *F16K 17/34* (2006.01)
A62B 7/04 (2006.01) *A62B 18/10* (2006.01) *F24F 03/00* (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):

DPWI and IPC A61M 16/-, A62B 18/-, A 61B 9/- and F24F 3/- and keywords and phrases (valve, gate, one-way, ventilation supply, inlet, exhaust, air, gas, airway, demand, request, response, diaphragm, membrane, disk, thin plate, bladder, assembly, exhalation, expiration, breath, air intake, CPAP, EPAP, IPAP, OSA, PAP, housing, connector, arm, link, flexible, resilient) and like terms.

Search engine 'Google patents' with similar terms.

ESP@cenet and F16K 17/- and keywords such as valve, pressure, diaphragm.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2282213 A (RACAL HEALTH & SAFETY LIMITED) 29 March 1995 Abstract; Figure 2 elements (2), (14)-(15), (20)-(26), (16) (6A), (13) and related text, esp. page 4, lines 1- page 5, line 18; see also Figure 1 and pages 1-2.	1-4, 6-7, 9-15, 16-18, 20

☒ Further documents are listed in the continuation of Box C☒ 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	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"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
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 21 April 2008	Date of mailing of the international search report 29 APR 2008
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. +61 2 6283 7999	Authorized officer Viara Van Raad AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No : (02) 6222 3643

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2008/000247

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2174304 A (SIEBE GORMAN & COMPANY LIMITED) 05 November 1986 Abstract; Figure 4, page 4, lines 24-page 5, line 9; elements (60), (42) to (43), (73) to (75), (61), (55), (42), (57) and related text.	1-4, 7, 9-10, 17-18, 20
X	GB 2190001 A (JACKSON) 11 November 1987 Abstract; Figures 2, 3 and 5 elements (1) to (7), page 1, lines 1-32; page 2, lines 1-35, lines 90-129; Figures 7-8.	1, 6, 15-16
X	GB 2402458 A (INTERNATIONAL SAFETY INSTRUMENTS INC.) 08 December 2004 Abstract, Figure 1 and elements (1)-(8), (17)-(18), (33)-(34) and related text – see page 9, line 4 – page 12, line 17, especially elements such as inlet stem (7), diaphragm (33), pivot level (26) biasing spring (36).	1-2, 4-9, 11- 16, 17-19
X	US 7066175 B2 (HAMILTON) 27 June 2006 Abstract, Figures 7-8, 13-18 and related text; elements (14), (54a), (46), (54c), (54f), (52a) and related text; see column 5, lines 33-60; column 7.	1-2, 4, 15, 17- 18
X	EP 0449532 A2 (F.X.K. PATENTS LIMITED) 02 October 1991 Abstract, Figure 1 and related text; elements (1), (2), (4), (5), (14), (18), (11) and related text; see column 3, lines 17- column 4, line 45.	1-2, 4-8, 11- 15, 17-19
A	US 4850345 A (JACKSON) 25 July 1989 Entire document.	1-23
[P,X]	GB 2432123 A (FOSS) 16 May 2007 Abstract; Figures 1-2; pages 2-8.	1-19

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2008/000247

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search 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.:
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:

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

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

- Claims 1-23 directed to a demand valve for breathing apparatus comprising: a housing defining a chamber and including (a) a demand port *adapted* to be in fluid communication with the entrance of a patient's airways (b) an inlet port *adapted* to be in fluid communication with supply with breathable gas at a positive pressure and exhaust port *adapted* to allow gas to exit the housing (c) a valve assembly included an inlet
(Text continues...)

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 additional fees, this Authority did not invite payment of additional fees.
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.:1-23.

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

Supplemental Box

(To be used when the space in any of Boxes I to IV is not sufficient)

Continuation of Box No III:

- valve adapted to at least partially close the inlet port (d) a diaphragm coupled to the valve assembly (e) where the diaphragm is constructed and arranged to be responsive to pressure within the chamber in order to effect movements of the valve assembly to *selectively* close the inlet and the exhaust ports. It is considered that the demand valve with features (a) - (e), especially the valve assembly and the diaphragm that effects the movements of the valve assembly comprises a first distinguishing feature.
- Claims 24-28 and 32-33 directed to a breathing apparatus comprising: (i) a housing defining a chamber with variable volume the housing including (ii) a demand port *adapted* to be in fluid communication with the entrance of a patient's airways (iii) an inlet port *adapted* to be in fluid communication with supply with breathable gas at a positive pressure (iv) and exhaust port *adapted* to allow gas to exit the housing, where the housing is constructed and arranged to expand during an expiration phase of the patient breathing cycle and to contract during an inspiration phase of the patient's breathing cycle to thereby forcibly vent at least a portion of exhausted gas to the exhaust port. It is considered that the breathing apparatus with expandable housing that is contracting and expanding correspondingly during an inspiration and expiration phases of breathing comprises a second distinguishing feature.
- Claims 29-31 directed to a method for supplying breathable gas to a patient comprising: providing a patient interface for communication with patient setting a PAP device to generate a supply of breathable gas at a substantially constant positive pressure and controlling the flow of the breathable gas do be delivered to the patient interface upon patient inhalation and at least partially stopped or impeded from proceeding to the patient interface upon patient exhalation. It is considered that the method for supplying breathable gas to a patient using a flow control connected to a patient interface comprises a third distinguishing feature.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2008/000247

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			
GB	2190001	AU	72104/87	EP	0249322	IN	169998
		IN	173148	US	4821767	ZA	8703132
GB	2402458	US	7111625	US	2004244797		
GB	2282213	AU	74165/94	EP	0645163	EP	0884069
		EP	0885631	EP	1506794	GB	2315116
		GB	2315117	US	5501213		
GB	2174304	AU	54381/86	AU	54382/86	CA	1247495
		EP	0194145	EP	0214222	GB	2172507
		GB	2174305	GB	2174913	HU	43262
		HU	43263	IN	167090	JP	61268272
		US	4696295	WO	8605105	ZA	8601670
		ZA	8601671	ZA	8601676	ZM	1886
		ZW	5486	ZW	5586		
US	7066175	AU	2002340765	CA	2446614	EP	1385579
		MX	PA03010124	US	2002162553	US	2006243278
		WO	02089873				
EP	0449532	AU	73876/91	JP	6039050	NO	911085
		US	5275153				
GB	2432123	NONE					
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.							
END OF ANNEX							