



## A CONDUIT

### FIELD OF THE INVENTION

5 The present invention relates to a conduit, more particularly, though not solely, to a respiratory conduit for providing inspiratory gas to a patient interface.

### BACKGROUND TO THE INVENTION

10 Improvements in conduit for directing respiratory gas or gases to a patient or an interface for the patient (that is a patient interface) are continually sought after. Such conduit is widely used as part of those facilities available as a medical resource in providing respiratory gases to a patient.

More specialised conduit design is employed to allow for greater control of the respiratory gases being supplied to a patient or patient interface especially where accurate tidal volume control is desired for resuscitation applications. Such accuracy being even more important for neonatal applications.

15 In addition, providing continuous positive airway pressure (CPAP) can be useful depending on a patient's medical state or condition.

20 Providing an improved conduit capable of supplying both CPAP respiratory gas and accurate delivery of a respiratory gas tidal volume to a patient is advantageous as it can allow the provisioning of both in a single device. But supplying both CPAP respiratory gas and accurate delivery of a respiratory gas tidal volume to a patient has problems because the gasses are compressible and with such compressibility comes a reducing in accuracy, both in pressure and timing, particularly for tidal volume control.

25 It is therefore an object of the present invention to provide a conduit, and/or a respiratory conduit for providing inspiratory gas to a patient interface which will go at least some way towards addressing the foregoing problems or which will at least provide the industry or public or both with a useful choice.

30 In this specification where reference has been made to patent specifications, other external documents, or other sources of information, this is generally for the purpose of providing a context for discussing the features of the invention. Unless specifically stated otherwise, reference to such external documents is not to be construed as an admission that such documents, or such sources of information, in any jurisdiction, are prior art, or form part of the common general knowledge in the art.

Further aspects and advantages of the present invention will become apparent from the ensuing description which is given by way of example only.

## BRIEF DESCRIPTION OF THE INVENTION

In a first aspect, the present invention may be said to be a conduit for delivery of  
5 inspiratory gas to a patient interface, the conduit comprising:

a primary lumen having an inlet operatively connectable with a primary  
inspiratory gas supplier, and

a secondary lumen having an inlet operatively connectable with a secondary  
inspiratory gas supplier,

10 wherein respective outlets of the primary and secondary lumens terminate in a  
communal region, the outlet of the secondary lumen including a first pressure responsive  
valve,

and wherein the communal region is communicable with a patient interface via a  
second pressure response valve, such that in the second valve's closed position an  
15 exhaust port or ports to the surrounding environment become communicable with the  
patient interface.

Preferably the first valve responsively:

opens (or is open) when the pressure supplied within the secondary lumen is  
greater than the pressure within the communal region, and

20 closes (or is closed) when the pressure supplied within the secondary lumen is  
equal to or less than the pressure within the communal region.

Preferably the second valve responsively:

opens (or is open) when the pressure within the communal region is greater than  
the pressure within the patient interface, and

25 closes (or is closed) when the pressure within the communal region is equal to or  
less than the pressure at the patient interface.

Preferably the second valve, in the open position, allows for delivery of the gases  
delivered to the communal region to the patient interface.

Preferably the outlet of the primary lumen terminates directly into the communal region.

30 Preferably the outlet of the primary lumen is open-ended.

Preferably the secondary inspiratory gas supplier is capable of providing a substantially constant pressure gas.

Preferably a blower, optionally an electrically driven blower, provides the substantially constant pressure gas.

5            Preferably the secondary inspiratory gas supplier provides for a continuous positive airway pressure ("CPAP") for a patient.

Preferably the primary gas supplier can provide delivery of a controlled tidal volume of gas to a patient interface.

10           Preferably the primary inspiratory gas supplier is an electrically operable device comprising:

                 a pump including a rigid cylinder including at least one gas inlet and at least one gas outlet, a piston to travel in the cylinder, and at least one valve, the or each valve configured to allow gas to be displaced into the cylinder through the at least one gas inlet during at least one of a first stroke direction and/or a second stroke direction of the piston in the cylinder, and for allowing gas to be displaced through the at least one gas outlet for delivery to the communal region during an opposite of the at least one of the first stroke direction and/or second stroke direction of the piston in the cylinder,

15

                 a motor, selected from one of a stepper motor and feedback motor or a stepper motor with feedback and linear motor, operatively connected to the piston to move the piston in the cylinder.

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Preferably the primary inspiratory gas supplier is the electrically operable device as described by PCT/NZ2008/000128 (WO/2008/147229)

Preferably the electrically operable device further comprises of a blower for providing a CPAP source of inspiratory gas to the communal region via the at least one outlet.

25           Preferably the primary lumen is of smaller cross-sectional area than the cross sectional area of the secondary lumen.

Preferably the primary lumen is of smaller volume than the volume of the secondary lumen.

30           Preferably the primary and secondary lumens are of the same or substantially similar length from inlet to outlet and/or are preferably coextensive and/or are preferably joined together.

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Preferably the primary and secondary lumen are co-axial.

Preferably the primary and secondary lumens are side-by-side or adjacent one another.

Preferably the first and second pressure responsive valves are one-way valves.

5 Preferably the first and second pressure response valves allow inspiratory gas to be delivered to the communal region and can prevent a patient's exhalation gas from entering the lumens.

Preferably the second valve is actuatable between open and closed positions via one of an electrical or pneumatic controller or control system.

Preferably the patient interface is a face mask.

10 Preferably the communal region is defined by a manifold housing.

Preferably the primary and secondary lumens are removably engaged to the manifold housing.

In second aspect the present invention may be said to be a conduit for delivery of inspiratory gas to a patient interface, the conduit comprising:

15 a primary lumen having an inlet operatively connectable with a primary inspiratory gas supplier, and

a secondary lumen having an inlet operatively connectable with a secondary inspiratory gas supplier,

20 wherein respective outlets of the primary and secondary lumens terminate in a communal region, the outlet of the secondary lumen including a first pressure responsive valve, the first valve responsively:

opening (or is open) when the pressure within the secondary lumen is greater than the pressure within the communal region, and

25 closing (or is closed) when the pressure within the secondary lumen is equal to or less than the pressure within the communal region,

and wherein the communal region is communicable with a patient interface via a second pressure response valve, the second valve responsively:

opening (or is opens) when the pressure within the communal region is greater than the pressure at the patient interface, and

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closing (or is closed) when the pressure within the communal region is equal to or less than the pressure at the patient interface,

such that when the second valve is in the closed position, an exhaust port or ports to the surrounding environment can become communicable with the patient interface.

Preferably the second valve is in or is caused to move to the closed position when a patient exhales and the exhaust port or ports are in or are open or are caused to open, to causes the flow of gas caused by exhalation to pass out the exhaust port or ports to the surrounding environment.

Preferably when the second valve is in the open position the exhaust port or ports are closed preventing gas flow to the surrounding environment.

In a third aspect the present invention may be said to be a conduit for delivery of inspiratory gas to a communal region comprising:

a primary lumen having an inlet operatively connectable with a primary inspiratory gas supplier, and

a secondary lumen having an inlet operatively connectable with a secondary inspiratory gas supplier,

wherein respective outlets of the primary and secondary lumens terminate in a communal region, the outlet of the secondary lumen including a first pressure responsive valve, and wherein the communal region is communicable with a patient interface via a second pressure response valve, such that in the second valve's closed position an exhaust port or ports to the surrounding environment become or can become communicable with the patient interface.

In a fourth aspect the present invention may be said to be a conduit for delivery of inspiratory gas comprising:

a primary lumen having an inlet operatively connectable with a primary inspiratory gas supplier, and

a secondary lumen having an inlet operatively connectable with a secondary inspiratory gas supplier,

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wherein the secondary inspiratory gas supplier is a continuous positive airway pressure ("CPAP") supply and the primary inspiratory gas supplier provides controlled tidal volume gas delivery for a patient.

5 In a fifth aspect the present invention may be said to be a patient interface for receiving inspiratory gas from a conduit as claimed above.

In sixth aspect the present invention may be said to be a method for delivering inspiratory gas to a patient interface comprising:

supplying a primary source of inspiratory gas to an inlet of a primary lumen,

10 supplying a secondary source of inspiratory gas to an inlet of a secondary lumen from a secondary supplier,

the inspiratory gases being delivered to a communal region at the outlets of the respective lumens, the outlet of the secondary lumen controlling delivery of the primary source of inspiratory gas to the communal region, and the communal region controlling delivery of the gases delivered to the communal region to a patient interface.

15 Preferably a primary gas supplier supplies the primary source of inspiratory gas.

Preferably a secondary gas supplier supplies the secondary source of inspiratory gas.

Preferably a first pressure responsive valve controls delivery of the secondary source of inspiratory gas to the communal region.

Preferably the first valve responsively:

20 opens (or is open) when the pressure within the secondary lumen is greater than the pressure within the communal region, and

closes (or is closed) when the pressure supplied within the secondary lumen is equal to or less than the pressure within the communal region.

25 Preferably a second pressure responsive valve controls delivery of the gases delivered to the communal region to the patient interface.

Preferably the second valve responsively:

opens (or is open) when the pressure within the communal region is greater than the pressure within the patient interface, and

30 closes (or is closed) when the pressure within the communal region is equal to or less than the pressure within the patient interface.

Preferably opening of the second valve allows for delivery of (or delivers) the gases delivered to (or residing within) the communal region to the patient interface.

Preferably the secondary gas supplier includes a third valve that prevents the flow of gases from the secondary lumen into the primary lumen.

5 In a seventh aspect the present invention may be said to be a method for delivering gases to a patient interface comprising:

ducting a flow of tidal volume of gas or gasses via a primary lumen, to a communal region of a manifold housing, and

10 ducting a flow of a continuous positive airway pressure (CPAP) of gas or gasses via a secondary lumen to the communal region of said manifold housing,

ducting of the gases in the communal region via a valve to the patient interface when the valve is open, the valve being open when the pressure in the communal region is greater than the pressure at the patient interface, and

15 preventing the flow of gas or gasses from the communal region to the patient interface by a closure or closed condition of the valve then the pressure in the communal region is less than the pressure at the patient interface.

Preferably when the flow of gas or gasses from the communal region is prevented by virtue of the closure of the valve, exhaust ports (preferably valved ports) can be presented to allow any equalisation of pressure between the ambient atmosphere and the pressure at the patient interface to occur.

20 In a further aspect the present invention may be said to be a conduit operative or to be operative between a patient interface and both (a) a tidal volume gas delivery device that can deliver controlled tidal volume gasses to a patient for the purposes of resuscitation and (b) a CPAP device for delivery of CPAP to the patient, the conduit comprising:

25 a primary lumen having an inlet operatively connectable with said tidal volume gas delivery device, and

a secondary lumen having an inlet operatively connectable with the CPAP device,

30 a manifold that, via respective outlets of the primary and secondary lumens and a manifold outlet, allows fluid communication to be established between the CPAP device and the tidal volume gas delivery device.

Preferably valves are provided that prevent the flow of tidal volume gasses from entering the secondary lumen and the flow of exhaled gasses from passing into the primary and secondary lumen.

Preferably the at least one valve is provided to allow exhaled gasses to exhaust to the atmosphere.

Preferably a valve is provided to prevent CPAP gas entering the primary lumen.

The term “comprising” as used in this specification means “consisting at least in part of”. When interpreting each statement in this specification that includes the term “comprising”, features other than that or those prefaced by the term may also be present. Related terms such as “comprise” and “comprises” are to be interpreted in the same manner.

This invention may also be said to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

The invention consists in the foregoing and also envisages constructions of which the following gives examples only.

## **BRIEF DESCRIPTION OF THE DRAWINGS**

Preferred embodiments of the invention will be described by way of example only and with reference to the drawings, in which:

Figure 1 illustrates one embodiment of a conduit according to the invention in connection with a tidal volume supplier and CPAP supplier and a patient interface,

Figure 2A illustrates the communal region and pressure responsive valves in an inhalation CPAP delivery configuration mode according to the embodiment of Figure 1,

Figure 2B illustrates the communal region and pressure responsive valves in an inhalation tidal volume delivery configuration mode according to the embodiment of Figure 1,

Figure 2C illustrates the communal region and pressure responsive valves in a configuration mode allowing exhalation of respiratory gases from a patient according to the embodiment of Figure 1,

Figure 3 illustrates a second embodiment of a conduit according to the invention in connection with a tidal volume supplier and CPAP supplier and a patient interface, including an actuator for actuating the first pressure responsive valve,

Figure 4A illustrates the communal region and pressure responsive valves in an inhalation CPAP delivery configuration mode according to the embodiment of Figure 3,

Figure 4B illustrates the communal region and pressure responsive valves in an inhalation tidal volume delivery configuration mode according to the embodiment of Figure 3,

5 Figure 4C illustrates the communal region and pressure responsive valves in a configuration mode allowing exhalation of respiratory gases from a patient according to the embodiment of Figure 3, and

Figure 5 illustrates the third valve in an alternative position to that shown in figure 1.

## 10 DETAILED DESCRIPTION OF THE INVENTION

This invention relates to accurate delivery of tidal volume to a patient interface for fluid connection with a patient that can be overlaid with and/or substituted by the delivery of a continuous positive airway pressure (CPAP) supply to the patient interface. Further, this invention provides for a valving arrangement capable of controlling the delivery of supplied tidal  
15 volume respiratory gas and CPAP respiratory gas to a patient via an interface.

The following description is provided to exemplify the invention with reference to accompanying figures 1-4C.

Figures 1 and 3 shows a patient interface such as a face mask (16) in ducted fluid communication with a primary inspiratory gas supplier (8) and a secondary inspiratory gas  
20 supplier (5). Such may be achieved via lumens (3, 6). Inlets (4, 7) of the lumens (3, 6) are suitably shaped or configured for fluid connection or attachment with the gas suppliers (5, 8). Likewise, at the other end (the patient end), the lumens (3, 6) are suitably shaped or configured for fluid connection with a further device for channelling inspiratory gas to a patient, such as a face mask (16).

25 According to a first embodiment of the invention, there is provided a conduit (1) for delivery of inspiratory gas to a patient interface such as a face mask (16), the conduit (1) comprising a primary lumen (6) having an inlet (7) operatively connectable with a primary inspiratory gas supplier (8), and a secondary lumen (3) having an inlet (4) operatively connectable with a secondary inspiratory gas supplier (5). Respective outlets (10, 9) of the primary and  
30 secondary lumens (6, 3) terminate in a communal region (11). The outlet (9) of the secondary lumen (3) includes a first pressure responsive valve (12). The communal region (11) is able to be, via a second pressure response valve (14), in fluid communication via passage (13) with a patient interface (16). When the second valve is in a closed position an exhaust port or ports (15) may

open or be open and allows for the patient interface (16) to be in fluid communication with the surrounding environment.

The communal region (11) and passage (13) in a preferred embodiment are configured within a manifold housing (30). So may the first and second valves (12, 14), the exhaust port(s) 15, be. In this preferred embodiment the primary and secondary lumen (6, 3) are detachable from the manifold housing (30). This allows different sizes or configurations of lumen (6, 3) to be used with the manifold housing (30). It also allows an alternative manifold housing (30) with configurations and/or settings of the manifold's components (such as the first and second valves (12, 14)) to be used with the primary and secondary lumen (6, 3). In this way the conduit can be adapted to suit a particular situation or patient if necessary.

Alternatively the primary and secondary lumen (6, 3) are an integral part and permanently connected to the manifold housing (30).

Figures 1, 2A, 2B and 2C illustrate a first embodiment of the invention.

Figures 3, 4A, 4B, and 4C illustrate a second embodiment of the invention in which an actuator (17) is included for actuating the second valve (14) between open and closed positions.

Arrows in the figures illustrate direction of flow of inspiratory gas through the lumens (6, 3) from the primary inspiratory gas supplier (8) and secondary inspiratory gas supplier (8), through first valve (12), through the communal region (11) and second valve (14), including any gases caused to pass out of exhaust port or ports (15) when a patient exhales and when the second valve (14) is closed.

In one embodiment the patient interface (16) is a face mask as depicted in figures 1 and 4. In alternative embodiments the patient interface (16) could be any one or more of an endotracheal tube, nasal or nasal-oral cannula or any other apparatus suitable for communicating gases to a patient.

The primary and secondary lumen (6, 3) in one embodiment are detachable from their respective suppliers of gasses.

Figures 2B and 4B shows operation of the invention in the resuscitation mode and when CPAP is not being supplied. In this mode, tidal volume is being supplied via the primary lumen (6). Figures 2C and 4C show valving configuration during the exhalation stage by a patient, the patient's exhalation gases causing gas to be exhausted via the exhaust port or ports (15) that open in response to closure of the second valve (14). Figures 2A and 4A show valving configuration during supply of CPAP gases via the secondary lumen (3) to the patient interface (16). Notably, first valve (12) and second valve (14) are in the open positions allowing CPAP gases and any tidal flow gasses to flow to the patient interface (16).

In one embodiment the primary inspiratory gas supplier (8) includes a third valve (40) that during the supply of CPAP gases only, prevents the flow of gases from the communal region (11) through the primary lumen (6) to the primary inspiratory gas supplier (8). In an alternative embodiment the third valve (40) is located at the outlet (10) of the primary lumen (6).

5 In various embodiments, the passage (13) allows a ducted fluid communication to be established with the patient interface (16) for a patient (not shown). The patient interface (16) may be removably attached to the passage (13).

According to both the first and second embodiments, the first valve (12) responsively opens or is open when the pressure (P1) supplied within the secondary lumen (3) is greater than the pressure (P11) within the communal region (11), and is closed (or closes) when the pressure (P1) supplied within the secondary lumen (3) is equal to or less than the pressure (P11) within the communal region (11). In this manner, when the first valve (12) is open inspiratory (CPAP) gas can be delivered from the secondary lumen (3) to the communal region (11). Depending on the pressure (P11) within the communal region (11), gas delivered to the communal region (11) may be further delivered to the passage (13).

Figures 2A and 4A illustrate the first pressure responsive valve (12) in an open or non-closed position. Figures 1, 2B, 2C, 3, 4B and 4C illustrate the first valve (12) in a closed or non-open position.

Further, in both the first and second embodiments, the second valve (14) is responsively open (or opens) when the pressure (P11) within the communal region (11) is greater than the pressure (P13) within the passage (13), and is closed (or closes) when the pressure (P11) within the communal region (11) is equal to or less than the pressure (P13) within the passage (13). In this manner, when the second valve (14) is open inspiratory gas can be delivered from the primary lumen (6) or secondary lumen (3) or both the primary and secondary lumens (6, 3) to the communal region (11) and from the communal region (11) to the patient interface (16). Figures 2A, 2B, 4A, 4B illustrate the second valve (14) in an open or non-closed position. Figures 1, 2C, 3 and 4C illustrate the second valve (14) in a closed or non-open position.

When the second valve (14) is in the open position the valve (14) allows for further delivery of the gases, being or already delivered to the communal region (11), to further flow to the patient interface (16). In this manner respiratory gases supplied via the primary lumen (6) or secondary lumen (3) or both lumens (6, 3) can be delivered to a patient in a controlled manner.

The outlet (10) of the primary lumen (6) may terminate directly into the communal region (11), as shown by the figures. One particular configuration provides for the outlet (10) of the primary lumen (6) to be open-ended in facilitating this arrangement.

The primary lumen's inspiratory gas supplier (8) provides delivery of a controlled tidal volume source to a patient interface (16) or to a patient, for example via the communal region (11).

The primary inspiratory gas supplier (8) may be an electrically operable device. The electrically operable device may include a pump. The pump may include a rigid cylinder including at least one gas inlet and at least one gas outlet and a piston to travel in the cylinder. At least one valve may be provided, the or each valve configured to allow gas to be displaced into the cylinder through the at least one gas inlet during at least one of a first stroke direction and/or a second stroke direction of the piston in the cylinder, and for allowing gas to be displaced through the at least one gas outlet during an opposite of the at least one of the first stroke direction and/or second stroke direction of the piston in the cylinder. A motor may power the piston. The motor may be a stepper motor or feedback motor or a stepper motor with feedback or linear motor such as a linear servo motor. Such can be operatively connected to the piston to move the piston in the cylinder.

For example, the primary inspiratory gas supplier (8) can be an electrically operable device such as that described by PCT/NZ2008/000128 (WO/2008/147229) the contents of which are hereby incorporated by reference.

The secondary inspiratory gas supplier (5) is a substantially constant pressure source. The secondary lumen's inspiratory gas supplier (5) provides delivery of a continuous positive airway pressure ("CPAP") source for a patient. For example, the supplier (5) may be a blower, such as an electrically driven blower, providing the substantially constant pressure source. One such suitable blower may be a fan, for example a single phase, 4-poles, brushless DC motor, model no. PSD1204PQBX-A, supplied by Sunonwealth Electric Machine Industry Co., Ltd.

The primary lumen (6) is of a smaller or lesser cross-sectional area than that of the secondary lumen (3). The primary lumen (6) may be of smaller or reduced volume than the volume of the secondary lumen (3). It will be appreciated the primary and secondary lumens (6, 3) may be of the same or substantially similar length, from inlet (7, 4) to outlet (10, 9).

For example, tube sizes are advantageously dissimilar because of the different requirements for tidal volume delivery and CPAP delivery. Tidal volume delivery requires that the respiratory or airway circuit has a minimum amount of dead space (small or lesser cross-sectional or volume of the primary lumen (6)) between the primary inspiratory gas supplier (8), such a pump (for example the pump described in WO/2008/147229), and the patient. Such a configuration assists to minimize the effect of compliance (compressibility of gas) to accurately deliver a predetermined volume of inspiratory gas, such as air/oxygen, to the patient interface

(15) and patient (not shown). In general, a pressure range for tidal volume delivery is about a minimum of 0 cm H<sub>2</sub>O (to ambient air pressure) for exhalation and maximum 60 cm H<sub>2</sub>O for inhalation. This is even more important for neonatal applications.

In neonatal applications the patients lungs are invariably smaller and as such, smaller tidal  
5 volumes of air are required to be delivered. Furthermore, the frequency at which the tidal  
volumes of air need to be delivered can be much higher for babies than for adult patients. The  
effects of compliance on the accuracy of the predetermined volume of inspiratory gas delivered  
are enhanced when smaller tidal volumes and higher frequencies of delivery are required. It is  
therefore important that the dead space of the respiratory or airway circuit is kept to a minimum  
10 by having a small or lesser cross-sectional or volume of the primary lumen (6).

In contrast, CPAP delivery requires that the airway circuit has a low resistance (achieve  
by providing a large cross-sectional area or diameter of the secondary lumen (3)) between the  
secondary inspiratory gas supplier (5), such as a blower, and the patient. Such a configuration  
assists to minimize the effect that resistance has to deliver a constant predetermined airway  
15 pressure to the patient. In general, a pressure range for CPAP delivery is about 0 cm H<sub>2</sub>O to  
30 cm H<sub>2</sub>O.

The primary and secondary lumens (6, 3) can be co-axial lumens, side-by-side or adjacent  
lumens. Primary and secondary lumens (6, 3) are shown in a side-by-side arrangement in the  
accompany figures 1-4C.

20 The first and second valves (12, 14) are pressure responsive. For example, the valves are  
responsive to pressure differences between pressure within the respective lumens (6, 3),  
communal region (11) and at patient interface (16) or passage (13).

The valves (12, 14) may be directional one-way valves. Desirably, the pressure response  
valves (12, 14) allow delivery of inspiratory gas or gases via the lumens (6, 3) to the communal  
25 region (11). The valves can be operated or are operable or responsive for preventing exhalation  
gas or gases from a patient from entering the communal region (11) or lumens (6, 3).

The pressure responsive valves can be of a flexible valving or membrane type, for  
example silicon, neoprene or vinyl, suitably soft or flexible to react to the changes in pressure  
between the secondary lumen (3, P3), communal region (11, P11) and patient interface (13, P13).

30 A control system (18) can be employed to monitor pressure and flow of gases being  
delivered to the patient. Such a control system or controller can include one or more pressure  
sensor(s) (19) and one or more flow sensor(s) (20). Such a control system (18) or controller  
would be used to control operation of the primary inspiratory gas supplier (8) and secondary  
inspiratory gas supplier (5). In this manner, a source of tidal volume gas and a source of CPAP

gas can be accurately delivered to the primary and secondary lumens (6, 3) for subsequent delivery to the communal region (11) and patient interface (16) and to a patient.

Suitable pressure sensors can be used to measure the airway pressure of the patient which is as close as possible to the patient end of the airway circuit. For example the pressure sensor may be at the patient interface (16) or at the passage (13). Measurements from this sensor can be used in controlling the primary inspiratory gas supplier (8) or ventilator, the secondary inspiratory gas supplier (5) or CPAP, and to open exhaust port or ports (15) (exhaust port or ports (15) and the second valve (14) being actuated by the controller in the second embodiment).

The flow sensor is used to measure the difference between inhalation (device delivered) and exhalation patient returned.

The flow sensor is preferably positioned as close as possible to the patient end of the airway circuit, i.e. at the patient interface (16) or passage (13). Such flow sensor or sensors can be used to check for leakage and the performance of the primary inspiratory gas supplier (8) and can be used to make any necessary or appropriate compensation.

As illustrated by the figures of the second embodiment of this invention (figures 3-4C), the second valve (14) may alternatively be actuatable or be actively controlled to move between open and closed positions via an actuator (17). Such may be by way of an electrical or pneumatic controller that may be operated via the control system (18).

An actuator (17) can for example be included and/or inserted into the system as shown in figures 3-4C between the outlets (10, 9) of primary and secondary lumens (6, 3) in the communal region (11) and between the second pressure valve (14) and patient interface (16) or passage (13). Operation of the conduit and valving system may be the same as the first embodiment but more active control is taken over actuation of the second valve (14). In this manner, the controller and/or operator can have greater active control of the opening and closing of the second valve (14). As the primary inspiratory gas supplier (8), delivers and controls the inhalation pressure part of a patient's breath cycle the actuator (17) and the second valve (14) work to control the exhalation part of the breath cycle of the patient.

The ability to control exhalation pressure is useful for the clinician to be able to set a predetermined shape for the exhalation part of the breath cycle. For example, a clinician may want to retain some back-pressure in the exhalation part of the breath cycle called PEEP (positive end expiratory pressure) or the clinician may want to slow or speed up the exhalation part of breath cycle. The actuator can be controlled by a controller with input from a pressure

sensor at the patient interface (16) or passage (13) end of the conduit or respiratory airway circuit.

As a further example, a clinician may want a PEEP of 10 cm H<sup>2</sup>O, in such a case the controller can be set to 10 cm H<sup>2</sup>O. When the pressure sensor reads 10 cm H<sup>2</sup>O (or less) during the exhalation part of the breath cycle the controller powers the actuator (17) to exert a force to operate the second valve (14), the controller then maintains that operation or power until the end of the patient's exhalation cycle. The required force to hold about 10 cm H<sup>2</sup>O (or other pressure) can be predetermined by the controller and suitable control systems.

In use inspiratory gas to a patient interface (16) may be supplied by supplying a primary source of inspiratory gas to an inlet (7) of a primary lumen (6), supplying a secondary source of inspiratory gas to an inlet (4) of a secondary lumen (3) from a secondary supplier (5), the inspiratory gases being delivered to a communal region (11) at the outlets (9, 10) of the respective lumens (6, 3). A first valve (12) at the outlet (9) of the secondary lumen (3) controls delivery of the secondary source of inspiratory gas to the communal region (11), and the communal region (11) facilitating delivery of the gases delivered to the communal region (11) to a patient interface (16).

In addition, a second pressure responsive valve (14) is used to control delivery of the gases delivered to the communal region (11) to the patient interface (16). In particular, the second valve (14) responsively opens or is open when the pressure (P11) within the communal region (11) is greater than the pressure (P13) within the patient interface (16), and closes or is closed when the pressure (P11) within the communal region (11) is equal to or less than the pressure (P13) within the passage (13) or patient interface (16). It will be appreciated according to the invention described, the opening of the second valve (14) allows for delivery of (or delivers) the gases delivered to (or residing within) the communal region (11) to flow through to the patient interface (16) for subsequent flow to a patient.

Preferably the first and second valves are one way valves that are responsive to pressure differential to effect their opening and/or closing.

It will be appreciated that were reference has been made to a gas or gases that any single gas element or combination of gas elements could be used. It will further be appreciated that were reference is made to a gas or gases that any fluid including liquid, gaseous or a combination of both liquid and gaseous fluids could be used.

## EXAMPLE 1

According to figures 1-2C, the following is a generalised description of operation of the invention.

**1. CPAP delivery stage: Inhalation part of patient airway cycle (Figure 2A)**

- 1.1 CPAP flow – a large diameter tube is used for delivery of a secondary inspiratory gas source (5) by an electrically operable blower.
- 1.2 Large diameter tube is being used for greater control of CPAP airway pressure delivery. This is used to assist in avoiding pressure response problems.
- 1.3 CPAP airflow pressure delivery is greater than at the end or beginning of tidal volume delivery and higher than patient airway pressure.
- 1.4 The first valve (12) (valve for CPAP) is open.
- 1.5 CPAP airflow pressure is then delivered through the first valve (12).
- 1.6 The second valve (14) is open to allow gas flow through communal region (11) via the passage (13) to the patient interface (16) for delivery to a patient.
- 1.7 Gas supply or air supplied will not flow back through the primary lumen due to response of the second valve (14) responding to the change in pressure once the patient starts to exhale and the pressure around the patient interface (16) or passage (13) becomes equal to or greater than the pressure in the communal region (11).

**2. Tidal volume delivery stage: Inhalation (Figure 2B)**

- 2.1 Tidal volume – smaller diameter tube than the CPAP tube diameter,
- 2.2 gas delivered by the secondary inspiratory gas supplier, such as an accurate gas volume delivery device. For example by the piston displacement of a secondary inspiratory gas source using the device as described by PCT/NZ2008/000128 (WO/2008/147229).
- 2.3 The smaller diameter tube is used for greater control of tidal volume delivery to overcome compliance issues.
- 2.4 Tidal volume airflow pressure is greater than CPAP pressure and patient airway pressure.

- 2.5 The first valve (12) valve for CPAP gas supply is closed.
- 2.6 Tidal volume airflow pressure is delivered through the second valve (14) to the patient interface (16).

### 3. Exhalation stage (Figure 2C)

- 5 3.1 Patient airway pressure is now greater than the tidal volume (primary inspiratory gas supplier (8)) or CPAP (secondary inspiratory gas supplier (5)) pressure.
- 3.2 The second valve (14) is closed.
- 3.3 The exhaust ports (15) are open allowing exhalation to surrounding environment.
- 3.4 Air will not flow back through tidal volume delivery tube (primary lumen (6)) because  
10 the second valve (14) is closed.

### EXAMPLE 2

According to figures 3-4C, the following is a generalised description of operation of the invention.

### 4. CPAP delivery stage: Inhalation part of patient airway cycle (Figure 4A)

- 15 4.1 CPAP pressure is set, for example, to 5 cm H<sub>2</sub>O pressure. This pressure is set at the controller, e.g. at a control panel, and pressure is sensed and checked by a pressure sensor (19).
- 4.2 CPAP pressure is then delivered through the larger tube of about 10 mm to 15 mm diameter via the CPAP blower device.
- 20 4.3 The patient airway has a lower pressure than the set CPAP pressure (P<sub>3</sub>).
- 4.4 The first valve (12) being a soft flexible valve made of, for example, silicon, opens or is open and delivers air/oxygen to the patient through the now open second valve (14). The second valve (14) is opened by actuation of an actuator (17).

### 5. Tidal volume delivery stage: Inhalation (Figure 4B)

- 18 -

5.1 The primary inspiratory gas supplier (8) is set as an example to a pressure of 20 cm H<sub>2</sub>O and a tidal volume of 25 ml at the controller via a control panel and the pressure is checked by a pressure sensor (19).

5.2 The delivery of the tidal volume is through the smaller tube of about 3 mm to 6 mm diameter.

5.3 The tidal volume pressure is now greater than the set 5 cm H<sub>2</sub>O CPAP pressure and the first valve (12) closes the outlet (9) of the larger tube (3). The ventilator continues to deliver air/oxygen through the communal region (11) and through the open second valve (14) to the patient interface (16) until the end of the inhalation delivery cycle. The second valve (14) is kept in the open position by the actuator (17).

## 6. Exhalation stage (Figure 4C)

6.1 The patient airway pressure at the patient interface (16) or passage (13) is now greater than either the outlet pressures of the large or smaller tubes (i.e. the primary or secondary lumens (6, 3)) and the pressure in the communal region (11) and greater than the set pressure of 5 cm H<sub>2</sub>O CPAP pressure.

6.2 The first valve (12) is closed.

6.3 The patient airway pressure is sensed and the actuator (17) acts to close the second valve (14). As a result of closing the second valve (14) the exhaust ports (15) are opened for release of patient exhalation gases to the surrounding environment allowing the patient to exhale.

The foregoing description of the invention includes preferred forms thereof. Modifications may be made thereto without departing from the scope of the invention.

**I/We Claim:**

1. A conduit for delivery of inspiratory gas to a patient interface, the conduit comprising:
  - a primary lumen having an inlet operatively connectable with a primary inspiratory gas supplier, and
  - 5 a secondary lumen having an inlet operatively connectable with a secondary inspiratory gas supplier,
  - wherein respective outlets of the primary and secondary lumens terminate in a communal region, the outlet of the secondary lumen including a first pressure responsive valve,
  - 10 and wherein the communal region is communicable with a patient interface via a second pressure response valve, such that in the second valve's closed position an exhaust port or ports to the surrounding environment become communicable with the patient interface.
2. A conduit as claimed in claim 1 wherein the first valve responsively:
  - 15 i. opens (or is open) when the pressure supplied within the secondary lumen is greater than the pressure within the communal region, and
  - ii. closes (or is closed) when the pressure supplied within the secondary lumen is equal to or less than the pressure within the communal region.
3. A conduit as claimed in claims 1 and 2 wherein the second valve responsively:
  - 20 i. opens (or is open) when the pressure within the communal region is greater than the pressure within the patient interface, and
  - ii. closes (or is closed) when the pressure within the communal region is equal to or less than the pressure at the patient interface.
4. A conduit as claimed in any one of claims 1 to 3 wherein the second valve, in the open position, allows for delivery of the gases delivered to the communal region to the patient interface.
5. A conduit as claimed in any one of claims 1 to 4 wherein the outlet of the primary lumen terminates directly into the communal region.
6. A conduit as claimed in any one of claims 1 to 5 wherein the outlet of the primary lumen is open-ended.
7. A conduit as claimed in any one of claims 1 to 6 wherein the secondary inspiratory gas supplier is capable of providing a substantially constant pressure gas.
8. A conduit as claimed in claim 8 wherein a blower, optionally an electrically driven blower, provides the substantially constant pressure gas.

9. A conduit as claimed in any one of claims 1 to 8 wherein the secondary inspiratory gas supplier provides for a continuous positive airway pressure ("CPAP") for a patient.
10. A conduit as claimed in any one of claims 1 to 9 wherein the primary gas supplier can provide delivery of a controlled tidal volume of gas to a patient interface.
- 5 11. A conduit as claimed in any one of claims 1 to 10 wherein the primary inspiratory gas supplier is an electrically operable device comprising:
- a pump including a rigid cylinder including at least one gas inlet and at least one gas outlet, a piston to travel in the cylinder, and at least one valve, the or each valve configured to allow gas to be displaced into the cylinder through
- 10 the at least one gas inlet during at least one of a first stroke direction and/or a second stroke direction of the piston in the cylinder, and for allowing gas to be displaced through the at least one gas outlet for delivery to the communal region during an opposite of the at least one of the first stroke direction and/or second stroke direction of the piston in the cylinder,
- a motor, selected from one of a stepper motor and feedback motor or a stepper motor with feedback and linear motor, operatively connected to the piston to move the piston in the cylinder.
12. A conduit as claimed in any one of claims 1 to 11 wherein the primary inspiratory gas supplier is the electrically operable device as described by PCT/NZ2008/000128
- 20 (WO/2008/147229)
13. A conduit as claimed in claim 11 wherein the electrically operable device further comprises of a blower for providing a CPAP source of inspiratory gas to the communal region via the at least one outlet.
14. A conduit as claimed in any one of claims 1 to 13 wherein the primary lumen is of
- 25 smaller cross-sectional area than the cross sectional area of the secondary lumen.
15. A conduit as claimed in any one of claims 1 to 14 wherein the primary lumen is of smaller volume than the volume of the secondary lumen.
16. A conduit as claimed in any one of claims 1 to 15 wherein the primary and secondary lumens are of the same or substantially similar length from inlet to outlet and/or are preferably coextensive and/or are preferably joined together.
- 30 17. A conduit as claimed in any one of claims 1 to 16 wherein the primary and secondary lumen are co-axial.
18. A conduit as claimed in any one of claims 1 to 16 wherein the primary and secondary lumens are side-by-side or adjacent one another.

19. A conduit as claimed in any one of claims 1 to 18 wherein the first and second pressure responsive valves are one-way valves.
20. A conduit as claimed in any one of claims 1 to 19 wherein the first and second pressure response valves allow inspiratory gas to be delivered to the communal region and can prevent a patient's exhalation gas from entering the lumens.
21. A conduit as claimed in any one of claims 1 to 20 wherein the second valve is actuatable between open and closed positions via one of an electrical or pneumatic controller or control system.
22. A conduit as claimed in any one of claims 1 to 21 wherein the patient interface is a face mask.
23. A conduit as claimed in anyone of claims 1 to 22 wherein the communal region is defined by a manifold housing.
24. A conduit as claimed in claim 23 wherein the primary and secondary lumens are removably engaged to the manifold housing.
25. A conduit for delivery of inspiratory gas to a patient interface, the conduit comprising:  
a primary lumen having an inlet operatively connectable with a primary inspiratory gas supplier, and  
a secondary lumen having an inlet operatively connectable with a secondary inspiratory gas supplier,  
wherein respective outlets of the primary and secondary lumens terminate in a communal region,  
the outlet of the secondary lumen including a first pressure responsive valve, the first valve responsively:  
opening (or is open) when the pressure within the secondary lumen is greater than the pressure within the communal region, and  
closing (or is closed) when the pressure within the secondary lumen is equal to or less than the pressure within the communal region,  
and wherein the communal region is communicable with a patient interface via a second pressure response valve, the second valve responsively:  
opening (or is opens) when the pressure within the communal region is greater than the pressure at the patient interface, and  
closing (or is closed) when the pressure within the communal region is equal to or less than the pressure at the patient interface,

such that when the second valve is in the closed position, an exhaust port or ports to the surrounding environment can become communicable with the patient interface.

26. A conduit as claimed in claim 25 wherein the second valve is in or is caused to move to the closed position when a patient exhales and the exhaust port or ports are in or are open or are caused to open, to causes the flow of gas caused by exhalation to pass out the exhaust port or ports to the surrounding environment.
27. A conduit as claimed in claim 25 or 26 wherein when the second valve is in the open position the exhaust port or ports are closed preventing gas flow to the surrounding environment.
28. A conduit for delivery of inspiratory gas to a communal region comprising:  
a primary lumen having an inlet operatively connectable with a primary inspiratory gas supplier, and  
a secondary lumen having an inlet operatively connectable with a secondary inspiratory gas supplier,  
wherein respective outlets of the primary and secondary lumens terminate in a communal region, the outlet of the secondary lumen including a first pressure responsive valve, and wherein the communal region is communicable with a patient interface via a second pressure response valve, such that in the second valve's closed position an exhaust port or ports to the surrounding environment become or can become communicable with the patient interface.
29. A conduit for delivery of inspiratory gas comprising:  
a primary lumen having an inlet operatively connectable with a primary inspiratory gas supplier, and  
a secondary lumen having an inlet operatively connectable with a secondary inspiratory gas supplier,  
wherein the secondary inspiratory gas supplier is a continuous positive airway pressure ("CPAP") supply and the primary inspiratory gas supplier provides controlled tidal volume gas delivery for a patient.
30. A patient interface for receiving inspiratory gas from a conduit as claimed above.
31. A method for delivering inspiratory gas to a patient interface comprising:  
i. supplying a primary source of inspiratory gas to an inlet of a primary lumen,

- ii. supplying a secondary source of inspiratory gas to an inlet of a secondary lumen from a secondary supplier,
  - iii. the inspiratory gases being delivered to a communal region at the outlets of the respective lumens, the outlet of the secondary lumen controlling delivery of the primary source of inspiratory gas to the communal region, and the communal region controlling delivery of the gases delivered to the communal region to a patient interface.
- 5
32. A method as claimed in claim 31 wherein a primary gas supplier supplies the primary source of inspiratory gas.
- 10 33. A method as claimed in claim 31 or 32 wherein a secondary gas supplier supplies the secondary source of inspiratory gas.
34. A method as claimed in any one of claims 31 to 33 wherein a first pressure responsive valve controls delivery of the secondary source of inspiratory gas to the communal region.
- 15 35. A method as claimed in claim 34 wherein the first valve responsively:
- i. opens (or is open) when the pressure within the secondary lumen is greater than the pressure within the communal region, and
  - ii. closes (or is closed) when the pressure supplied within the secondary lumen is equal to or less than the pressure within the communal region.
- 20 36. A method as claimed in any one of claims 31 to 35 wherein a second pressure responsive valve controls delivery of the gases delivered to the communal region to the patient interface.
37. A method as claimed in 36 wherein the second valve responsively:
- i. opens (or is open) when the pressure within the communal region is greater than the pressure within the patient interface, and
  - 25 ii. closes (or is closed) when the pressure within the communal region is equal to or less than the pressure within the patient interface.
38. A method as claimed in claims 36 or 37 wherein opening of the second valve allows for delivery of (or delivers) the gases delivered to (or residing within) the communal region to the patient interface.
- 30 39. A method for delivering gases to a patient interface comprising:
- i. ducting a flow of tidal volume of gas or gasses via a primary lumen, to a communal region of manifold housing, and

- ii. ducting a flow of a continuous positive airway pressure (C-pap) of gas or gasses via a secondary lumen to the communal region of said manifold housing,
  - iii. ducting of the gases in the communal region via a valve to the patient interface when the valve is open, the valve being open when the pressure in the communal region is greater than the pressure at the patient interface, and
  - iv. preventing the flow of gas or gasses from the communal region to the patient interface by a closure or closed condition of the valve then the pressure in the communal region is less than the pressure at the patient interface.
40. A method as claimed in claim 39 wherein when the flow of gas or gasses from the communal region is prevented by virtue of the closure of the valve, exhaust ports (preferably valved ports) can be presented to allow any equalisation of pressure between the ambient atmosphere and the pressure at the patient interface to occur.
41. A conduit operative or to be operative between a patient interface and both (a) a tidal volume gas delivery device that can deliver controlled tidal volume gasses to a patient for the purposes of resuscitation and (b) a CPAP device for delivery of CPAP to the patient, the conduit comprising:
- a primary lumen having an inlet operatively connectable with said tidal volume gas delivery device, and
  - a secondary lumen having an inlet operatively connectable with the CPAP device,
  - a manifold that, via respective outlets of the primary and secondary lumens and a manifold outlet, allows fluid communication to be established between a patient interface and both the CPAP device and the tidal volume gas delivery device.
42. A conduit as claimed in claim 41 wherein valves are provided that prevent the flow of tidal volume gasses from entering the secondary lumen and the flow of exhaled gasses from passing into the primary and secondary lumen.
43. A conduit as claimed in claim 41 or 42 wherein the at least one valve is provided to allow exhaled gasses to exhaust to the atmosphere.
44. A conduit as claimed in anyone of claims 41 to 43 wherein a valve is provided to prevent CPAP gas entering the primary lumen.

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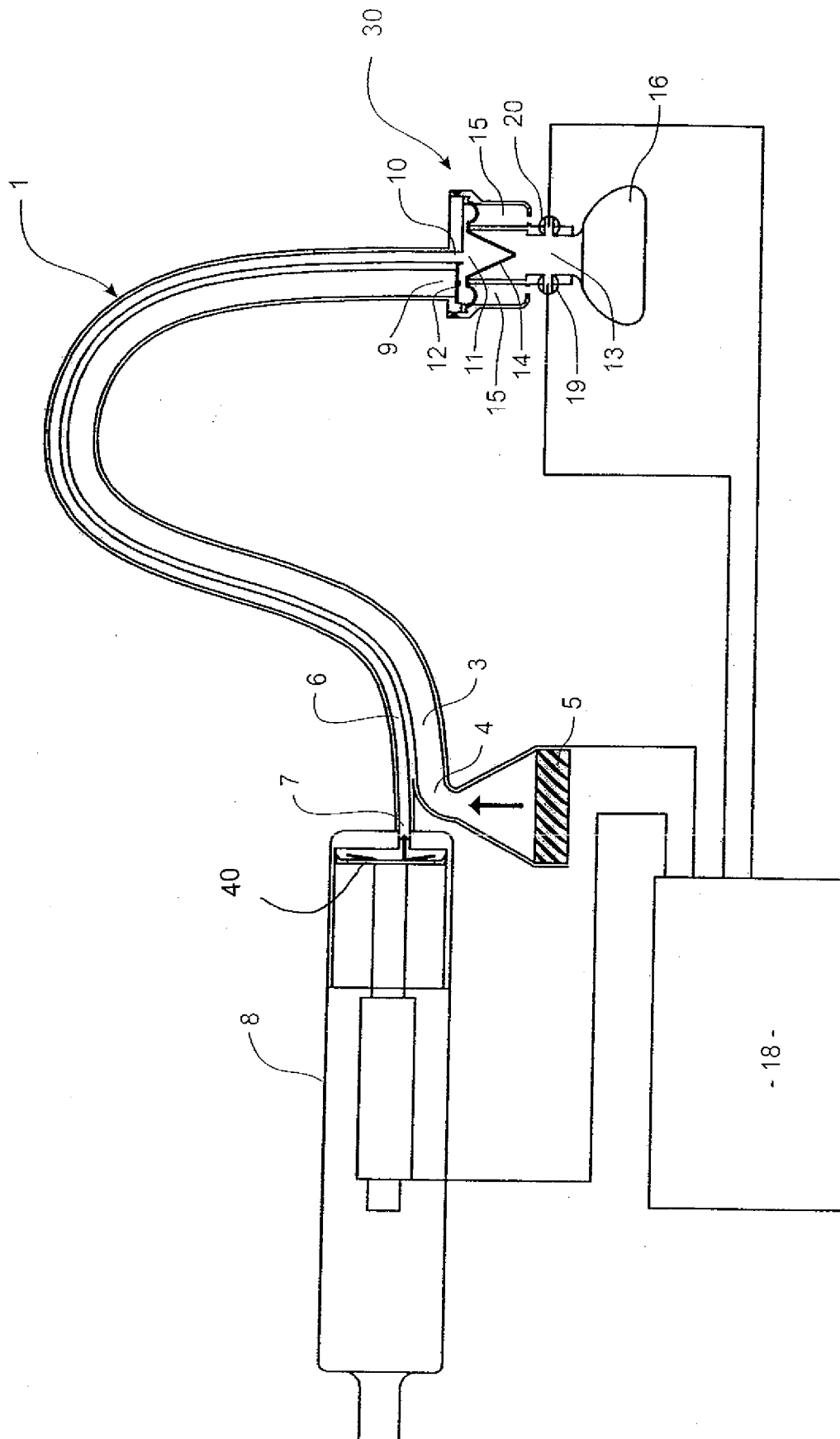


FIGURE 1

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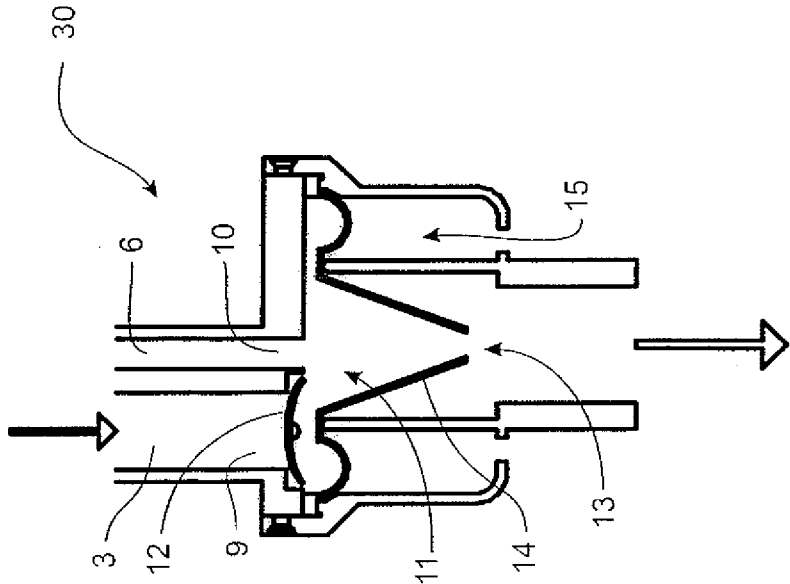


FIGURE 2A

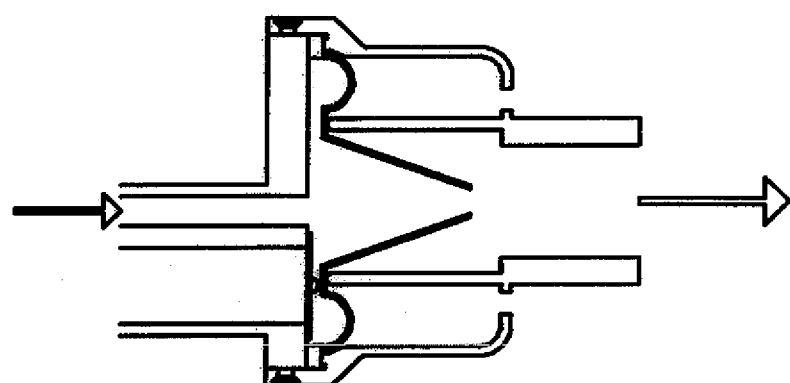


FIGURE 2B

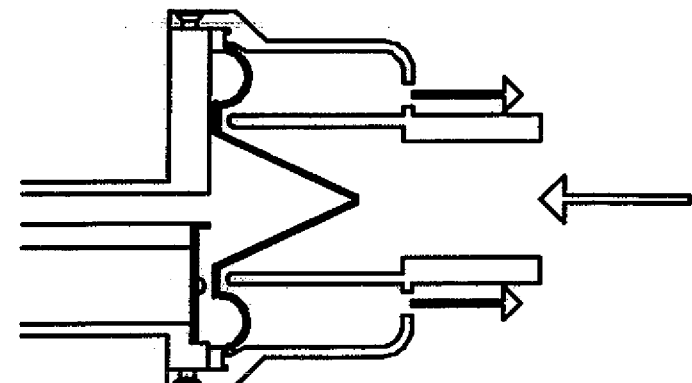


FIGURE 2C

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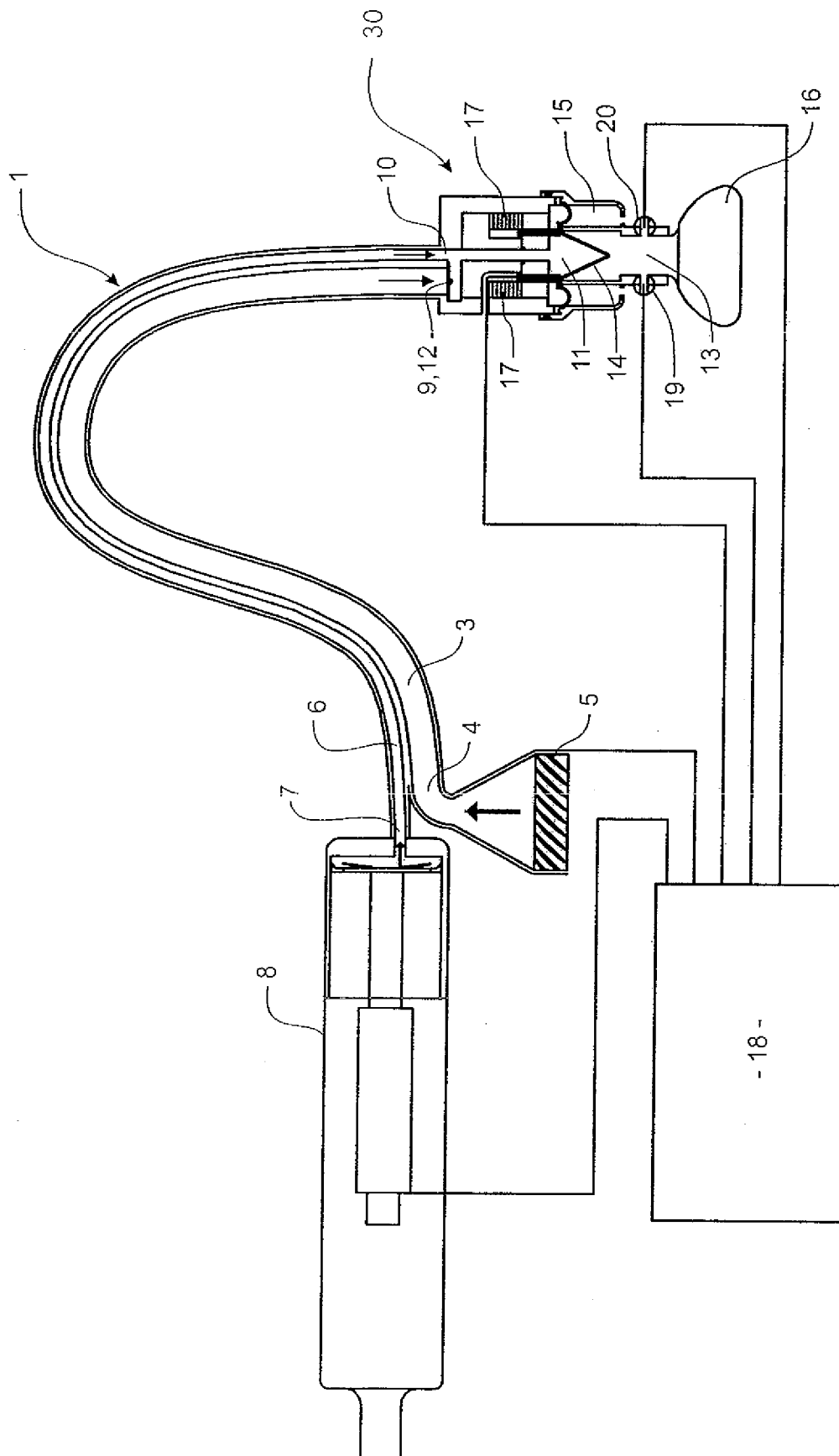


FIGURE 3

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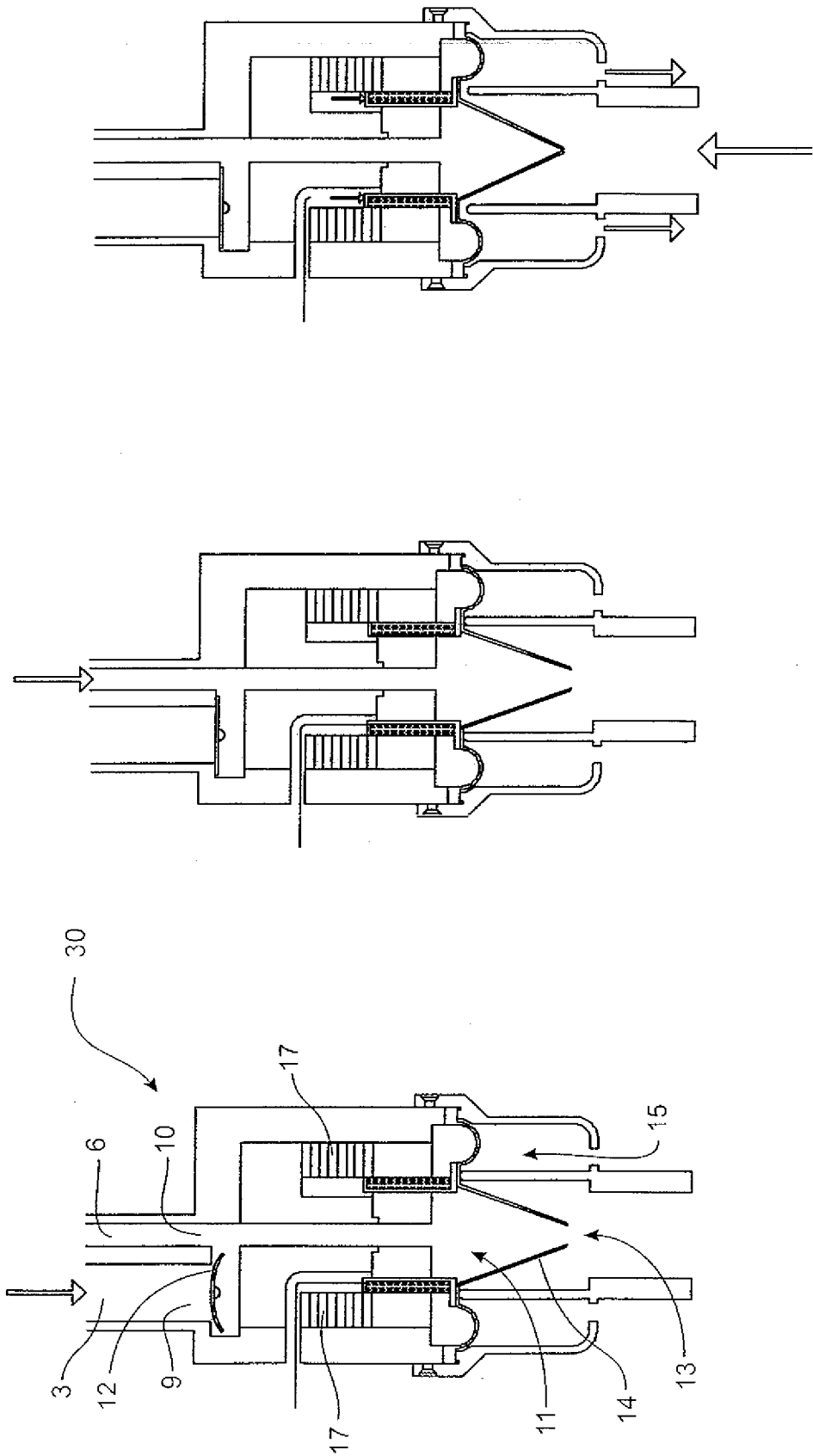


FIGURE 4C

FIGURE 4B

FIGURE 4A

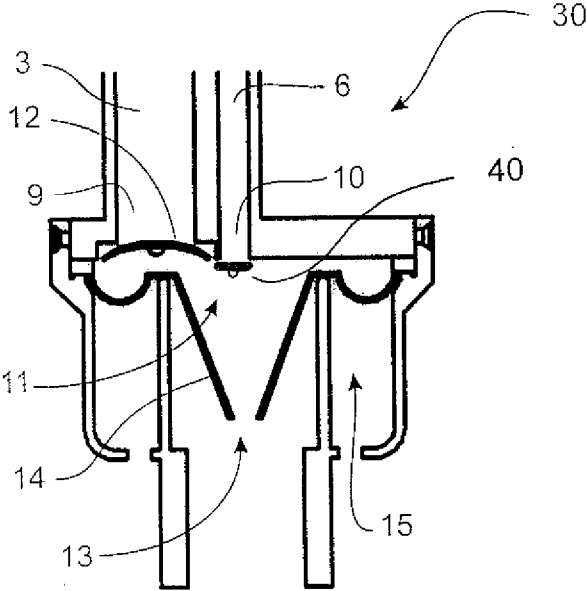


FIGURE 5

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2010/054899

## A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 16/08 (2006.01)

A62B 7/04 (2006.01)

A62B 18/10 (2006.01)

A61M 16/20 (2006.01)

A62B 9/02 (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)

EPODOC, WPI: IPC/ EC A61M16/-, A62B and keywords: conduit, tube, respiratory, inspiratory, valve, communal, common, resuscitate, analeptic, vivification, PAP, CPAP, positive airway; and like terms

GOOGLE PATENTS, PATENT LENS keywords: resuscitat, PAP, CPAP, positive airway; and like terms

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                                                                  | Relevant to claim No. |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| X         | WO 2008/147229 A1 (KUYPERS et al.) 04 December 2008<br>See page 11, line 26 – page 14, line 15; page 17, line 1 – page 18, line 14; figures 3 and 4 | 1-44                  |
| A         | US 5357951 A (RATNER) 25 October 1994<br>See column 2, line 44 – column 3, line 7; figure 2                                                         |                       |
| A         | GB 2430380 A (SIMTHS GROUP PLC) 28 March 2007<br>See page 4, line 10 – page 6, line 22; figure 2                                                    |                       |
| A         | US 2002/0020414 A1 (FUKUNAGA) 21 February 2002<br>See paragraphs [0037] – [0058]; figures 1-5                                                       |                       |



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  
20 January 2011

Date of mailing of the international search report

26 JAN 2011

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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2010/054899

**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:

See Supplemental Box I

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.:

**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 I**

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

**Continuation of Box No: III**

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1-28 and 30-44 are directed to a conduit and corresponding method for delivery of inspiratory gas to a patient interface. It is considered that *the primary and secondary lumens deliver the inspiratory gases to a communal region* comprises a first distinguishing feature.
- Claims 29 and 30 are directed to a conduit for delivery of inspiratory gas. It is considered that *the secondary gas supplier is a continuous positive airway pressure ("CPAP") supply and the primary inspiratory gas supplier provides controlled tidal volume gas delivery for a patient* comprises a second distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

Each of the abovementioned groups of claims has a different distinguishing feature and they do not share any feature which could satisfy the requirement for being a special technical feature. Because there is no common special technical feature it follows that there is no technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a priori*.

The International Searching Authority believes that a search and examination for the second invention will not involve more than negligible additional search and examination effort over that for the first invention and so no additional search fee is required in order to search and examine that invention.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.

**PCT/IB2010/054899**

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 |            |    |            |
|---------------------------------------------------------------------------------------------------------------------------|-------------|------|------------|----------------------|------------|----|------------|
| WO                                                                                                                        | 2008147229  | AU   | 2008257723 | CA                   | 2688555    | CN | 101720215  |
|                                                                                                                           |             | EP   | 2164442    | MX                   | 2009013001 | US | 2010170512 |
| US                                                                                                                        | 5357951     | NONE |            |                      |            |    |            |
| GB                                                                                                                        | 2430380     | NONE |            |                      |            |    |            |
| US                                                                                                                        | 20020020414 | NONE |            |                      |            |    |            |
| Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001. |             |      |            |                      |            |    |            |
| END OF ANNEX                                                                                                              |             |      |            |                      |            |    |            |