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(56) Documents Cited:
WO 2009/040783 A2 **US 5937858 A**
US 5400781 A **US 5101834 A**
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(54) Title of the Invention: **Oxygen therapy apparatus**
Abstract Title: **Oxygen therapy apparatus**

(57) An oxygen therapy apparatus, suitable for capnography use, comprises a connector (1) having first and second openings in fluid communication with one another, the first opening (3) being arranged to be positioned at the mouth region of a patient such that expired respiratory gasses pass through into the connector and the second opening (5) being arranged to be coupled to an oxygen supply, wherein the connector further comprises a port (21) suitable to be coupled to a CO_2 sampling tube for receiving expired respiratory gasses from within the connector.

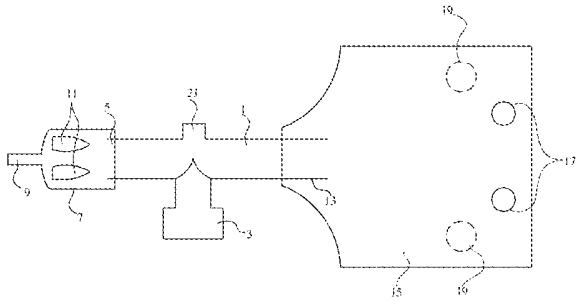

FIG. 1

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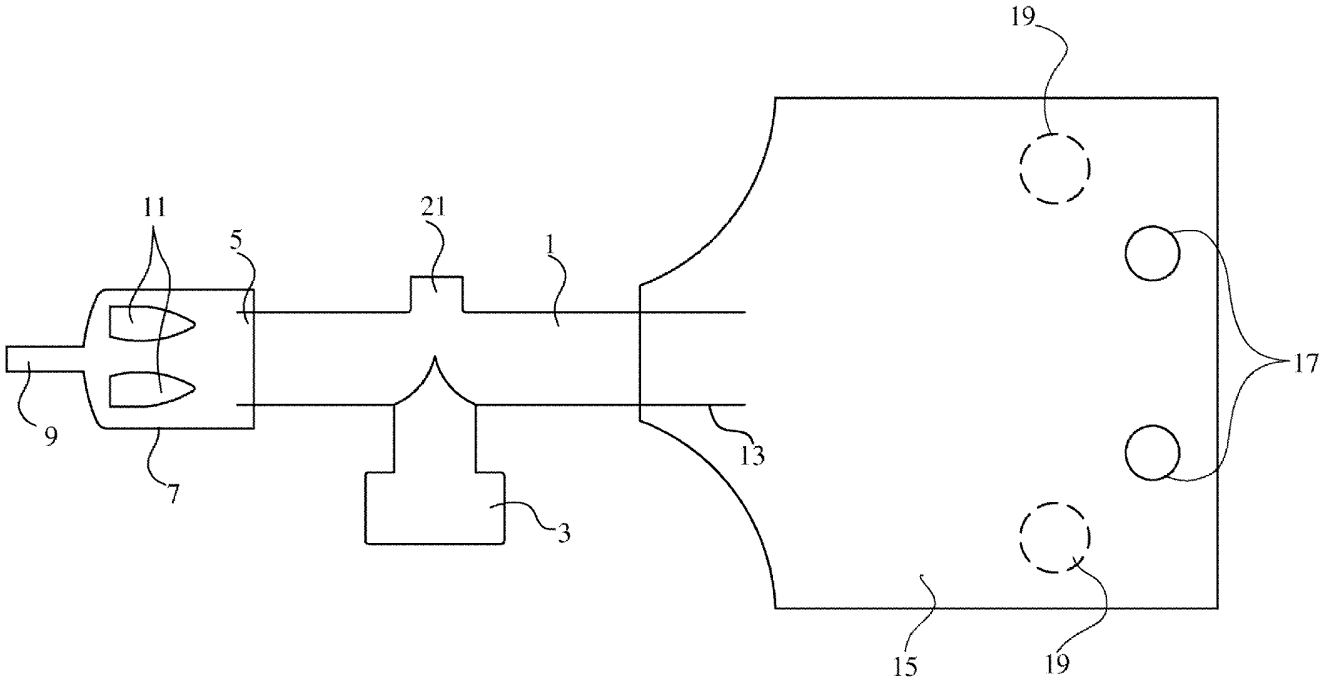

FIG. 1

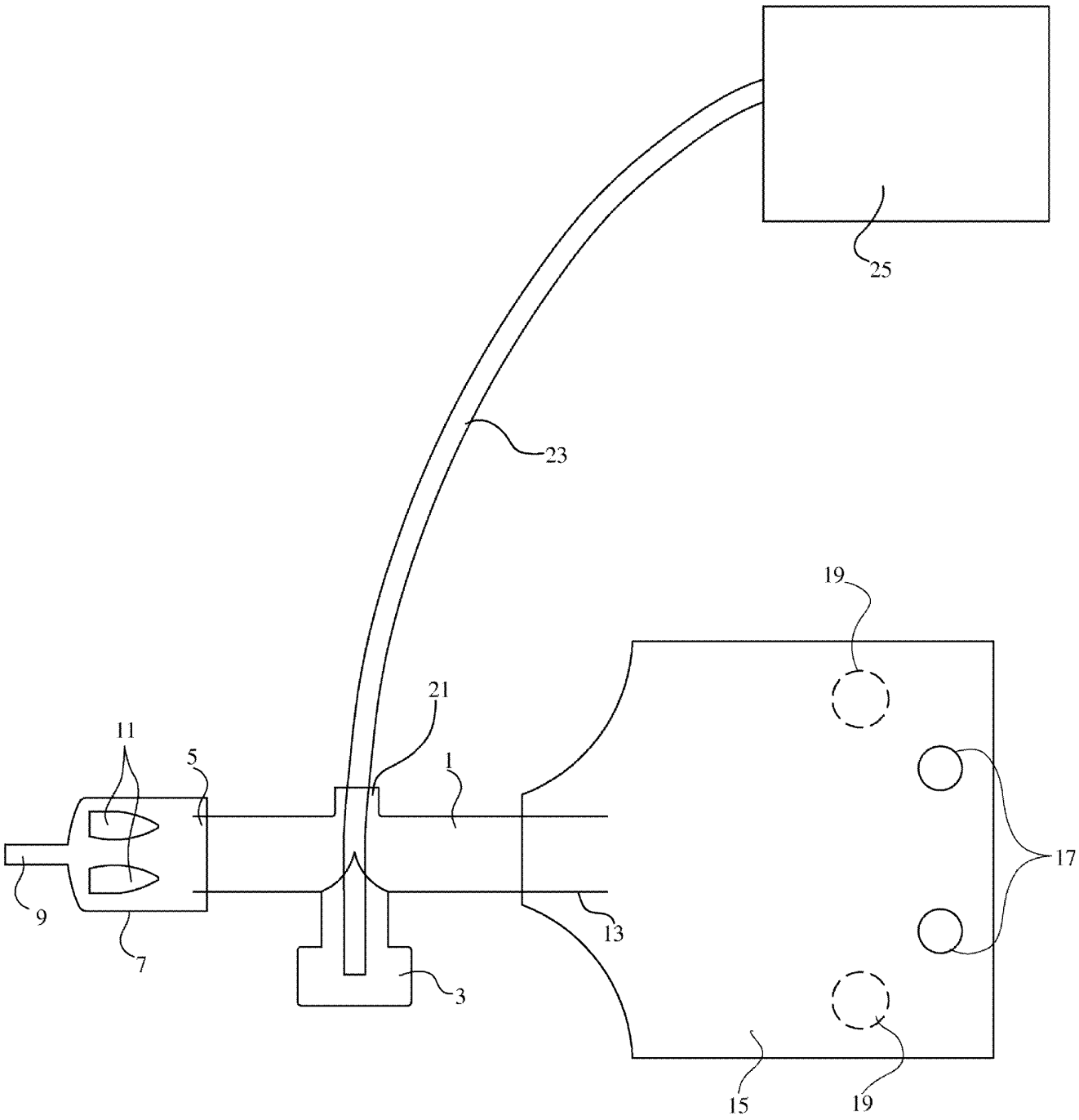

FIG. 2

OXYGEN THERAPY APPARATUS

Oxygen is essential for normal respiration in aerobic organisms, such as humans and animals. Upon entering the lungs, oxygen molecules dissolve into the lung tissues and pass into the blood stream. Following the transport of the oxygen molecules (bound to the haemoglobin in the blood) to various tissues, the oxygen diffuses into those tissues for metabolism. Oxygen therapy is administered to patients when they have low blood oxygen levels. Oxygen therapy benefits the patient by increasing the supply of oxygen to the lungs and thereby increasing the availability of oxygen to the body tissues.

A primary concern for anaesthesiologists is the prevention of hypoxia (oxygen deficiency in a patient) because hypoxia can lead to irreversible brain damage if not addressed quickly. Capnography can be used to identify situations that can lead to hypoxia if uncorrected. Capnography provides information about numerous bodily conditions, including CO_2 production. In expired respiratory gases, capnography directly reflects the expiration of CO_2 by the lungs, which can be used to determine the amount of oxygen being absorbed by a patient. Capnograph systems can be categorised as main stream or side stream. A mainstream capnograph system generally includes a CO_2 sensor located between the endotracheal tube and the breathing circuit. A side stream capnograph system, on the other hand, generally includes a CO_2 sensor located remote from the patient (within a meter to a few metres) and being aspirated via a CO_2 sampling tube. The inlet end of the CO_2 sampling tube is generally located adjacent the nasal passage of a patient. A nasal cannula is sometimes used hold the input end of the CO_2 sampling tube in position.

The applicant has identified a number of problems with known apparatus used in side stream capnograph systems. Firstly, it is generally the case that a patient will be provided with a nasal cannula, to locate the CO_2 sampling tube, in addition to other devices, such as a fixed-concentration oxygen therapy device for delivering oxygen to the patient. For example, following an operation a patient will in some cases have a laryngeal mask in situ and a post operative oxygen therapy device may be connected to the laryngeal mask to provide a controlled supply of oxygen to the patient as they recover. In such scenarios, medical staff responsible for the patient will have to apply, monitor and subsequently

remove a plurality of devices from the patient, which can be time consuming, mentally challenging and/or can increase the likelihood of user error. Furthermore, many devices are single use devices and thus the cost of each device contributes to the total cost of a particular treatment. Secondly, it is common for such oxygen delivery devices to be located at the mouth region of a patient, which in conjunction with a nasal cannula may cause the patient discomfort in some circumstances.

According to a first aspect of the present invention there is provided an oxygen therapy apparatus comprising a connector having first and second openings in fluid communication with one another, the first opening being arranged to be positioned at the mouth region of a patient such that expired respiratory gasses pass therethrough into the connector and the second opening being arranged to be coupled to an oxygen supply, wherein the connector further comprises a port arranged to be coupled to a CO_2 sampling tube for receiving expired respiratory gasses from within the connector.

Thus, apparatus according to this aspect of the present invention provides a convenient way of monitoring the CO_2 levels in expired respiratory gasses of a patient wearing an oxygen therapy device.

The port may include a cap or valve arranged or operable to inhibit gas from leaving the inside of the connector via the port.

The valve may be a non-return valve arranged to permit fluid to exit the connector therethrough but inhibit fluid from entering the connector therethrough.

The port may be substantially aligned with the second opening.

The port and first opening may be substantially coaxial.

The apparatus may further comprise a third opening in fluid communication with the first and second openings and being arranged for expired respiratory gasses to leave the connector.

The third opening may be coupled to an exhaust bag having an exhaust port formed therein, the exhaust bag being formed of a flexible material such that the exhaust bag collapses on itself and seals the exhaust port when negative pressure is present at the third opening.

The exhaust bag may include one or more further exhaust ports.

The or each exhaust port may comprise a hole formed in the exhaust bag located distally from the third opening.

The exhaust bag may be formed from a substantially transparent material.

The first opening may include a venturi barrel in fluid communication with the atmosphere.

The venturi barrel may be detachable from the connector.

The connector may comprise a T-piece.

The port may be arranged to receive a portion of the sampling tube, such that an inlet of the tube may be located within the connector.

The port may be arranged to couple with the sampling tube substantially without the sampling tube entering the port.

The oxygen therapy apparatus may further comprise a guide tube provided within the tube, the guide tube having a first end sealingly coupled to the port and a second end located in the fluid flow path of expired respiratory gases within the connector.

The first opening may be arranged to be coupled to a patient airway device.

Embodiments of the present invention will now be described below, by way of non-limiting illustrative example only, with reference to the accompanying figure, of which:

Figure 1 schematically illustrates an oxygen therapy apparatus according to an embodiment of the present invention; and

Figure 2 schematically illustrates the oxygen therapy apparatus of Figure 1 in conjunction with a CO_2 sampling tube.

An embodiment of the present invention is schematically illustrated in Figures 1 and 2. A connector 1 is provided with a plurality of interconnected openings in fluid communication with one another. In the illustrated embodiment the connector is provided with three interconnected openings. However, any suitable number may be provided. In a preferred embodiment the connector is a T-piece.

A first opening 3 is arranged to be attached to a variety of known airway devices such as an endotracheal tube or laryngeal mask. In other embodiments the first opening may be of any suitable configuration to enable it to be located at the mouth region of a patient so as to provide a passageway for respiratory gasses expired from the mouth of the patient.

A second opening 5 is attached to a venturi barrel 7 that is in turn provided with an inlet 9 arranged to be connected to a supply of 100% oxygen. The venturi barrel 7 has one or more venturi openings 11 formed in its side wall and in fluid communication with the connector 1. When connected to a 100% oxygen supply the venturi openings 11 draw in a predefined and controlled percentage of fresh air creating a mix of air and oxygen with a known percentage of oxygen. The venturi barrel may be of the kind that can be rotated so as to deliver different fixed oxygen concentration. Such venturi barrels are known. In other embodiments, the second opening may be of any configuration to enable a suitable supply of oxygen to a patient.

At the opposite end of the connector to the second opening 5 is a third opening 13. However, it should be noted that the oxygen therapy apparatus according to some embodiments of the present invention may not provided with a third opening. In embodiments where the connector comprises a T-piece, the second and third openings of the connector are longitudinally aligned along a common axis, whilst the first opening 3 as a longitudinal axis substantially at 90^{o} to that of the second and third openings. The third

opening 13 of the connector is coupled in a fluid tight manner to an exhaust bag 15 that has one or more exhaust ports 17 formed therein. In preferred embodiments the exhaust bag 15 is formed from a thin flexible material, such as HDPE (High Density Polyethylene), LDPE (Low Density Polyethylene) or PVC (Poly-Vinyl Chloride).

A port 21 is provided in fluid communication with the connector 1. The port 21 is arranged to accommodate a CO_2 sampling tube 23, as shown in Figure 2. The port 21 is of suitable dimension to enable a portion of a CO_2 sampling tube 23 to pass through it and into the connector 1. The CO_2 sampling tube 23 is in fluid communication with monitoring apparatus 25 arranged to generate a signal should the CO_2 level of a patients expired respiratory gases go above and/or below a threshold. The port 21 is arranged such that an input end of a CO_2 sampling tube 23 can be positioned in the passageway of expired respiratory gasses. In the illustrated embodiment the bore of the port 21 is coaxial with the bore of the first opening 3 as this may enable simple insertion of a sampling tube 23 in situ. However, the port 21 may be located at any suitable position and may take any suitable configuration. In some embodiments the port 21 may be located adjacent the first opening 3. The port 21 in this embodiment includes a valve (not shown) arranged to inhibit gas from entering or leaving the connector 1 via the port 21. In some embodiments, the valve may be a non-return valve arranged to permit gas to exit the connector 1 via the port 21 but inhibit gas from entering the connector 1. In the absence of a CO_2 sampling tube 23 the valve thus inhibits gas to enter the connector 1 via the port. The valve is arranged to permit the CO_2 sampling tube 23 to pass through it to enter the connector 1 and in some embodiments substantially seal the connection between the valve and the CO_2 sampling tube 23. A seal may be provided to seal the gap between the port 21 and sampling tube 23.

In another embodiment the port 21 may be arranged such that a CO_2 sampling tube 23 can be coupled thereto by fitting around a protruding part of the port 21 or interface with an axial face thereof (i.e. the port 21 and CO_2 sampling tube 23 are arranged to couple without the CO_2 sampling tube 23 passing through the port 21 and into the connector 1). Consequently, a non-return valve in fluid communication with the port 21 may function normally during CO_2 sampling in that it can inhibit gas entering the connector 1 via the port irrespective of whether a CO_2 sampling tube 23 is coupled to the port or otherwise. In such embodiments the port may be in fluid communication with a guide tube provided

inside the connector 1, the guide tube having a first end coupled to the port 21 and a second end located at a suitable space within the connector to enable ingress of uncontaminated expired respiratory gasses, for example being at or adjacent the first opening 3, or in some embodiment closer to the first opening 3 than the second opening 5. However, the port may take any suitable configuration that enables a CO_2 sampling tube 23 coupled to the port 21 to sample the expired respiratory gasses of a patient

In another embodiment of the present invention the port 21 may include a cap to seal it when not in use, in place of or in addition to a valve.

In use, when a patient exhales into the connector 1 via the second opening 5, a percentage of the expired gases enter the CO_2 sampling tube 23 and pass to the monitoring apparatus 25. The monitoring apparatus 25 is conventional apparatus arranged to generate an alarm should the CO_2 sample provided to it fall outside a predetermined threshold. Consequently the apparatus 25 need not be described in more detail. The expired gases entering the CO_2 sampling tube 23 are shielded from contamination by environmental gases due to the connector 1. The location of the inlet of the CO_2 sampling tube 23 should be suitable to prevent the air/oxygen mixture provided by the venturi barrel 7 from entering it.

A mixture of the remaining expired gases (i.e. expired gas that is not directed to the CO_2 sampling tube 23) and the air/oxygen mixture provided by the venturi barrel 7 flows into the exhaust bag 15 via the third opening 13 of the T-piece and subsequently is exhausted from the exhaust bag 15 through the exhaust port 17 due to the positive pressure induced within the exhaust bag. During exhalation the flexible exhaust bag 15 is fully or partially inflated. When the patient inhales the low pressure formed in the first opening 3 of the T-piece 1 causes the air/oxygen mixture provided by the venturi barrel 7 to flow through the first opening 3, and thus to the patient, rather than through the third opening 13 connected to the exhaust bag 15. The resulting drop in pressure at the third opening 13 of the T-piece passageway causes the flexible exhaust bag 15 to collapse in on itself, thus substantially sealing the exhaust port 17 and preventing any ingress of ambient air to the patient via the exhaust bag. Although in theory the contents of the partially inflated exhaust bag 15 could be inhaled by the patient before the bag collapses and seals the exhaust port 17, the flow of air/oxygen from the venturi barrel 7 through the exhaust bag 15 during the patient's

exhalation and pause phases causes the expired gases to be flushed from the exhaust bag 15 through the exhaust port 17 such that the contents of the partially inflated bag 15 after exhalation and during the pause phase of the patient is flushed and the exhaust bag is filled with fresh air/oxygen mixture from the venturi barrel. Whilst the volume of the exhaust bag is not critical to the correct functioning of embodiments of the present invention, it is preferred to use a small bag (relative to the expected average volume of expired gases) to ensure the exhaust bag inflates easily and does not obstruct the patient in any way.

In preferred embodiments the exhaust bag of the present invention is formed from two flat sheets of flexible material cut to the desired outline of the bag and sealed around their edges, with the exception of the opening through which the T-piece passage enters into the exhaust bag. The exhaust port(s) are formed by punching one or more holes in the distal section of the sealed exhaust bag, or in an alternative embodiment (not shown) be formed by leaving a portion of the distal seam of the exhaust bag unsealed. In any embodiment the total surface area of the exhaust port(s) 17 is arranged to be larger than that of the third opening of the connector 1 to prevent any back pressure within the connector. The flexible material is preferably substantially clear such that the formation of any mist arising from moisture in the patient's expired breath can easily be seen, the advantage being that the formation of such mist is used as evidence of the breathing function of the patient. In further embodiments the exhaust bag 15 may be formed with one or more additional exhaust ports 19 provided for safety purposes, such that should one of the exhaust ports become blocked the expired gases can still be vented through the remaining exhaust ports.

An advantage of the use of oxygen therapy apparatus according to embodiments of the present invention over conventional apparatus is that both oxygen supply to the mouth of a patient and CO_2 monitoring of expired respiratory gasses can be achieved using a single device, suitably connected to monitoring apparatus 25 or the like. This enables hospital staff to quickly fit the apparatus to a patient, for example following surgery, and reduces the number of separate devices required to couple to the patient and thereafter monitor and subsequently remove. Oxygen therapy apparatus according to embodiments of the present invention may also be cheaper to manufacture than the plurality of discrete devices that it provides the functionality of, i.e. replaces. The provision, in some embodiments of the present invention, of a connector having a port in fluid communication with the internal

space thereof enables a CO_2 sampling tube to be coupled thereto to receive a quantity of expired respiratory gases whist the connector walls inhibit contamination of the expired respiratory gases from external sources, such as environmental gases or a third party such as a nurse breathing adjacent the apparatus.

An advantage of the use of an exhaust bag according to embodiments of the present invention over a conventional one-way valve is that the inflation of the exhaust bag by the expired gases provides an easy indication both that the patient is breathing and that the device is functioning properly. If a conventional one-way valve were to become stuck closed it may not be easily or quickly spotted by a carer, thus potentially putting the patient at risk. The exhaust bag may therefore be used to provide a visual indication that a patient is breathing, whilst the CO_2 monitoring provides a breath by breath indication of the level of oxygen being absorbed by the lungs of the patient.

Thus, an oxygen therapy device according to embodiments of the present invention provides side stream CO_2 monitoring in conjunction with a fixed performance oxygen therapy devices that in some embodiments prevent patient rebreathing and which can be attached to existing airway devices. It should be noted that, whilst the port 21 has been described in conjunction with a fixed performance oxygen therapy device, the port 21 may in other embodiments be provided in conjunction with any suitable oxygen therapy device arranged to be located at the mouth region of a patient.

CLAIMS

1. Oxygen therapy apparatus comprising a connector having first and second openings in fluid communication with one another, the first opening being arranged to be positioned at the mouth region of a patient such that expired respiratory gasses pass therethrough into the connector and the second opening being suitable to be coupled to an oxygen supply, wherein the connector further comprises a port arranged to be coupled to a CO_2 sampling tube for receiving expired respiratory gasses from within the connector.

2. The oxygen therapy apparatus of claim 1, wherein the port includes a valve arranged to inhibit gas from leaving the inside of the connector via the port.

3. The oxygen therapy apparatus of claim 2, wherein the valve is a non-return valve arranged to permit fluid to exit the connector therethrough but inhibit fluid from entering the connector therethrough.

4. The oxygen therapy apparatus according to any preceding claim, wherein the port is substantially aligned with the second opening.

5. The oxygen therapy apparatus according to any preceding claim, wherein the port and first opening are substantially coaxial.

6. The oxygen therapy apparatus of any preceding claim, the apparatus further comprising a third opening in fluid communication with the first and second openings and being arranged for expired respiratory gasses to leave the connector

7. The oxygen therapy apparatus according to claim 6, wherein the third opening is coupled to an exhaust bag having an exhaust port formed therein, the exhaust bag being formed of a flexible material such that the exhaust bag collapses on itself and seals the exhaust port when negative pressure is present at the third opening.

8. The oxygen therapy apparatus of claim 7, wherein the exhaust bag includes one or more further exhaust ports.

9. The oxygen therapy apparatus of claim 7 or 8, wherein the or each exhaust port comprises a hole formed in the exhaust bag located distally from the third opening.

10. The oxygen therapy apparatus of any of claims 7 to 9, wherein the exhaust bag is formed from a substantially transparent material.

11. The oxygen therapy apparatus of any preceding claim further comprising a cap to removably seal the port.

12. The oxygen therapy apparatus of any preceding claim, wherein the port is arranged to receive a portion of the sampling tube, such that an inlet of the tube may be located within the connector.

13. The oxygen therapy apparatus of any of claims 1 to 11, wherein the port is arranged to couple with the sampling tube substantially without the sampling tube entering the port.

14. The oxygen therapy apparatus of claim 13, further comprising a guide tube provided within the tube, the guide tube having a first end sealingly coupled to the port and a second end located in the fluid flow path of expired respiratory gases within the connector.

15. The oxygen therapy apparatus according to any preceding claim, wherein the first opening is arranged to be coupled to a patient airway device.

16. Oxygen therapy apparatus substantially as herein described with reference to the accompanying drawings.

Application No:	GB0915765.2	**Examiner:**	Joanna Manning
Claims searched:	1-16	**Date of search:**	11 January 2010

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1-6, 11, 13-15	US5937858 A (CONNELL) Whole document relevant, see especially Figure 3 and column 4, lines 40 to 54
X	1-6, 12, 15	US 5101834 A (WALLACE) Whole document relevant, see especially Figures 1 and 2
X	1-3, 11, 12, 15	US 4677987 A (CHOKSI) Whole document relevant, see especially Figures 1, 5 and 7
X	1-3, 15	US 2005/022828 A1 (FUKUNAGA) Whole document relevant, see especially Figures 3a and 3b
X	1-3, 15	WO 2009/040783 A2 (COLMAN) Whole document relevant, see especially Figures 1 to 5
A	-	US 5400781 A (DAVENPORT) See Figures 3 and 4

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^{X} :

Worldwide search of patent documents classified in the following areas of the IPC

A61B; A61M

The following online and other databases have been used in the preparation of this search report

EPODOC, WPI

International Classification:

Subclass	Subgroup	Valid From
A61B	0005/097	01/01/2006
A61B	0005/083	01/01/2006