(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 October 2011 (06.10.2011)

PCT

(10) International Publication Number
WO 2011/122964 A1

(51) International Patent Classification:
A61M 16/00 (2006.01) *A61M 16/20* (2006.01)
A61M 16/04 (2006.01)

(21) International Application Number:
PCT/NZ2011/000040

(22) International Filing Date:
29 March 2011 (29.03.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/318,542 29 March 2010 (29.03.2010) US

(71) Applicant *(for all designated States except US)*: **FISHER & PAYKEL HEALTHCARE LIMITED** [NZ/NZ]; 15 Maurice Paykel Place, East Tamaki, Auckland, 2013 (NZ).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **TATKOV, Stanislav** [NZ/NZ]; 20 Gillet Place, Botany Downs, Auckland, 2014 (NZ).

(74) Agents: **ADAMS, Matthew, D** et al.; A J Park, 6th Floor Huddart Parker Building, PO Box 949, Wellington, 6015 (NZ).

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

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

Published:

— *with international search report (Art. 21(3))*

(54) **Title**: TRACHEAL COUPLINGS AND ASSOCIATED SYSTEMS AND METHODS

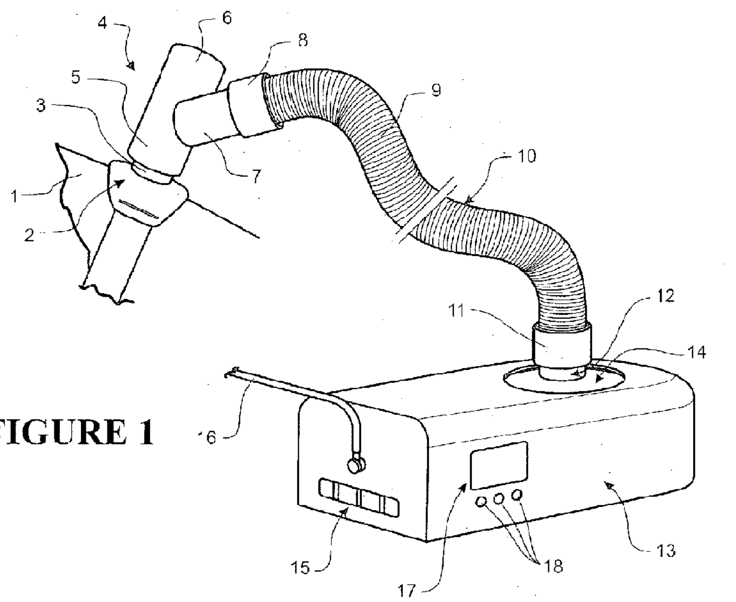


FIGURE 1

(57) **Abstract**: A tracheal coupling for interfacing between a patient and a gases source, the connector comprising a patient port (33) for connecting to the trachea interface/insert, an outlet port (36), and inlet port (31) between patient port and outlet port for receiving a flow of gases from the gases flow source, the connector restricting expiratory flow in use to produce PEEP of at least 1 cm H20 when flow to the inlet port is 50 litres per minute. A system or method for supplying gases to a patient using the connector is also disclosed. Flow restriction is implemented using an orifice that can be adjustable, jetting or turbulence induced by a directed flow nozzle (30). PEEP can also be varied by flow control of gas source.

WO 2011/122964 A1

"TRACHEAL COUPLINGS AND ASSOCIATED SYSTEMS AND METHODS"

Field of Invention

The present invention relates to tracheal couplings (e.g. connectors/interfaces) for connecting/interfacing between an intubated or tracheotomised spontaneously breathing patient and a gas supply conduit from a continuous breathing gas supply.

Summary of the Invention

An object of the invention is to provide a tracheal coupling which will at least go some way towards providing a useful choice.

In one aspect the present invention may be said to consist in a tracheal coupling for interfacing between a patient and a gases source, the connector comprising a patient port for connecting to the trachea interface/insert, an outlet port, and inlet port between patient port and outlet port for receiving a flow of gases from the gases flow source, the connector restricting expiratory flow in use to produce PEEP of at least $1cmH_20$ when flow to the inlet port is 50 litres per minute.

Preferably the coupling is a connector that can be connected to a trachea interface/insert in or on a patient to interface between a patient and a gases source.

Preferably the trachea interface/insert is one or more of:

a trachea button, a endotracheal tube, a tacheostomy tube, a laryngeal mask.

Alternatively the coupling comprises a trachea interface that can be attached to a patient to interface between a patient and a gases source.

Preferably the flow restriction includes a restriction between inlet port and outlet port or at outlet port.

Preferably the flow restriction includes an adjustable orifice.

Preferably the flow restriction is caused by turbulence from inlet flow.

Preferably the flow restriction is caused by jetting air from inlet flow.

Preferably the connector includes a nozzle extending from the inlet port toward the patient port.

Preferably the nozzle extends through the patient port.

Preferably the nozzle includes a bend in a portion between an outlet end of the nozzle and the patient port.

Preferably the coupling further comprises a pressure relief valve.

Preferably the restriction comprises a heat and moisture exchanger.

In another aspect the present invention may be said to consist in a system for supplying breathing gases to a patient comprising an airflow source including an adjustable flow control, and a tracheal coupling for receiving gases from the airflow source in excess for a patient's breathing requirements, supplying breathing gases for the patient to inhale, and releasing exhaled gases and uninhaled gases through an outlet port, the connector restricting expiratory flow to generate amount of PEEP according to flow through connector, and thereby according to the setting of the adjustable flow control of the airflow source.

Preferably the tracheal coupling is a connector that can be connected to a trachea interface/insert in or on a patient.

Preferably the trachea interface/insert is one of: a trachea button, a endotracheal tube, a tacheostomy tube, a laryngeal mask.

Preferably the coupling comprises a trachea interface that can be attached to a patient to interface between a patient and a gases source.

Preferably the flow restriction includes a restriction between an inlet port and outlet port, or at the outlet port.

Preferably the flow restriction includes an adjustable orifice.

Preferably the system further comprises a pressure relief valve.

Preferably the flow restriction is caused by turbulence from inlet flow.

Preferably the flow restriction is caused by jetting air from inlet flow.

Preferably the connector includes a nozzle extending from the inlet port toward the patient port.

Preferably the nozzle extends through the patient port.

Preferably the nozzle includes a bend in a portion between an outlet end of the nozzle and the patient port.

In another aspect the present invention may be said to consist in a tracheal coupling comprising a patient port, an outlet port, an inlet port between the patient port and the outlet port, such that flow from the inlet port can go to the patient port or direct to the outlet port, and a flow restriction between the inlet port and the outlet port, or at the outlet port.

Preferably the flow restriction includes an adjustable orifice.

Preferably the tracheal coupling further comprises a pressure relief valve.

In another aspect the present invention may be said to consist in a tracheal coupling comprising a patient port, an outlet port, an inlet port between the patient port and the outlet port, such that flow from inlet port can go to the patient port or direct to outlet port, and a jet or nozzle discharging flow from the inlet port toward the patient port in the flow path of gases flowing from the patient port to the outlet port.

Preferably the tracheal coupling further comprises a restriction between the inlet port and the outlet port, or at the outlet port.

Preferably the flow restriction includes an adjustable orifice.

Preferably the tracheal coupling further comprises a pressure relief valve.

In another aspect the present invention may be said to consist in a method of providing breathing gases to a patient comprising: a) attaching a tracheal coupling to a breathing tube of the patient, the coupling having a patient port, an outlet port, an inlet port between the patient port and the outlet port, such that flow from inlet port can go to the patient port or direct to the outlet port, and a jet or nozzle discharging flow from the inlet port toward the patient port in the flow path of gases flowing from the patient port to the outlet port, b) selecting a flow level for a supply of gases to the connector to generate a desired amount of PEEP, c) supplying the flow level of gases to the inlet port of the connector.

In another aspect the present invention may be said to consist in a method of providing breathing gases to a patient comprising: a) attaching a tracheal coupling to a breathing tube of the patient, the connector having a patient port, an outlet port, an inlet port between the patient port and the outlet port, such that flow from inlet port can go to the patient port or direct to outlet port, and a jet or nozzle discharging flow from the inlet port toward the patient port in the flow path of gases flowing from the patient port to the outlet port, b) adjusting a flow restriction for the connector according to an expected flow of gases and a desired amount of PEEP c) supplying a flow of gases to the inlet port of the connector.

In another aspect the present invention may be said to consist in a connector for interfacing between an endotracheal tube or tracheostomy tube and a gases source, the connector comprising a patient port for connecting to the endotracheal or tracheostomy tube, an outlet port, and inlet port between patient port and outlet port for receiving a flow of gases from the gases flow source, the connector restricting expiratory flow in use to produce PEEP of at least $1cmH_20$ when flow to the inlet port is 50 litres per minute.

In another aspect the present invention may be said to consist in a system for supplying breathing gases to a patient fitted with an endotracheal or tracheostomy tube comprising an airflow source including an adjustable flow control, and a connector receiving gases from the airflow source in excess for a patient's breathing requirements, supplying breathing gases for the patient to inhale, and releasing exhaled gases and uninhaled gases through an outlet port, the connector restricting expiratory flow to generate amount of PEEP according to flow through connector, and thereby according to the setting of the adjustable flow control of the airflow source.

In another aspect the present invention may be said to consist in a tracheal connector comprising a patient port, an outlet port, an inlet port between the patient port and the outlet port, such that flow from the inlet port can go to the patient port or direct to the outlet port, and a flow restriction between the inlet port and the outlet port, or at the outlet port.

In another aspect the present invention may be said to consist in a tracheal connector comprising a patient port, an outlet port, an inlet port between the patient port and the outlet port, such that flow from inlet port can go to the patient port or direct to outlet port, and a jet or nozzle discharging flow from the inlet port toward the patient port in the flow path of gases flowing from the patient port to the outlet port.

As used in this specification, "trachea connector" means a connector coupling between a gases supply conduit and the open end of a tracheostomy tube or ET tube.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

The term "comprising" is used in the specification and claims, means "consisting at least in part of". When interpreting a statement in this specification and claims that includes "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.

Brief Description of the Drawings

Embodiments of the present invention will be described with reference to the accompanying drawings.

Figure 1 illustrates a system for supplying breathing gases to a tracheotomised patient.

Figures 2A and 2B illustrate a prior art trachea connector.

Figure 2A illustrates the flow through the connector during patient inhalation.

Figure 2B illustrates the flow through the connector during patient exhalation.

Figures 3A and 3B are cross sectional views of a trachea connector according to one aspect of the present invention.

Figure 3A illustrates flows through the connector during patient inhalation.

Figure 3B illustrates flows through the connector during patient exhalation.

Figures 4A and 4B are cross sectional side elevations of a trachea connector according to a second aspect of the present invention.

Figure 4A illustrates flows through the connector during patient inhalation.

Figure 4B illustrates flows through the connector during patient exhalation.

Figure 5 is a cross sectional side elevation of a trachea connector according to a further aspect of the present invention where a restriction is provided intermediately located between the inlet port and the outlet port.

Figure 6 is a cross sectional side elevation of a trachea connector according to a further aspect of the present invention including an adjustable flow restriction.

Figure 7 is a cross sectional side elevation of a trachea connector according to a further aspect of the present invention including an alternative adjustable restriction.

Figure 8 is a cross sectional side elevation of a trachea connector according to a further aspect of the present invention incorporating flow restrictions in the form of a restricted outlet and a jet-generating nozzle.

Figure 9 is a cross sectional side elevation of a trachea connector according to a further aspect of the present invention illustrating the combination of a turbulence-generating nozzle and a variable restricted outlet.

Figure 10 is a cross sectional side elevation of a trachea connector according to a further aspect of the present invention including an adjustable restricted outlet and a pressure relief valve.

Figure 11 is a plot of pressure versus time illustrating the pressure generated at the internal end of the tracheostomy by three different tracheal connectors under high flow supply conditions (50 litres per minute) used in conjunction with a lung simulator. Pressure generated at the end of the tracheostomy tube in the patient airway of the prior art tracheal connector with no supply flow is also shown.

Figure 12 is a cross sectional side elevation of a trachea connector according to a further aspect of the present invention illustrating the combination of a turbulence-generating nozzle and a sensor port.

Figure 13 shows a trachea interface (mask).

Figure 14 shows a stoma (trachea) button.

Figure 15 shows a tracheostomy tube.

Figure 16 shows an endotracheal tube.

Figure 17 shows a trachea interface comprising a body and mask.

Figures 18 to 28 show various aspects of a trachea interface with a body and mask with PEEP control.

Detailed Description

Tracheal couplings (e.g. in the form of connectors of trachea interfaces) according to the present invention are intended to be used in conjunction with the breathing gases supply system as generally depicted in Figure 1. A tracheal coupling provides for passage of breathing gases (e.g. oxygen)/interfacing between a high flow gases supply and a patient (such as a tracheotomised or intubated patient.) A tracheal coupling can take the form of a connector that couples to a trachea insert/interface in or on a tracheotomised or intubated patient, either nasally or orally or otherwise. Alternatively, it can take the form of a trachea interface which can be attached to a tracheotomised/intubated patient. The tracheal coupling can be used with other high flow gases sources, such as a supply of air from a wall outlet or ventilator. The tracheal couplings are intended for use in a high flow therapy situation (e.g., the gas supply exceeds peak inspiratory flow) where the patient is spontaneously breathing. This means that a substantial proportion of the air supplied to the connector vents directly to the room without being breathed by the patient.

Figure 1 illustrates a system into which tracheal couplings in the form of connectors according to the present invention may be incorporated. An external portion to a tracheostomy tube extends out of the neck of patient 1. A male connector 3 extends from the tracheostomy tube. A trachea connector 4 includes a patient end 5 connected to the male connector 3 of the tracheostomy tube. The connector 4 includes outlet end 6 and an inlet tube 7. The inlet tube is connected to the cuff 8 of a breathing tube 10. The breathing tube includes a flexible conduit 9 for supplying breathing gases to the patient. A cuff 11 at the other end of the breathing tube 10 is connected to outlet connector 12 of a gases flow source. The gases flow source may be a flow generator 13. The flow generator 13 may include a humidification system including humidification chamber 14. Breathing gases can be delivered to the user at, or near, optimal temperature and humidity (37°C, 44 mg/L humidity) as the gases are delivered. Emulating the conditions within healthy adult lungs (37°C, 44 mg/L humidity) can help maintain healthy mucociliary function in users with respiratory disorders affecting secretion.

The flow generator 13 typically includes a blower receiving air from an air intake 15 and optionally oxygen from oxygen supply line 16. A user interface may include a display screen 17 and user controls 18. The user controls may be in the form of buttons on the housing of the flow generator or combined with the display screen as a touch screen on the flow generator. An example flow generator for use in this application is the Fisher & Paykel Healthcare AIRVO™. The flow generator includes a flow sensor and a feedback control which monitors the delivered flow and varies the blower speed to maintain the output flow of the generator at a level set through the user controls.

The trachea connector 4 may also be used with the endotracheal tube (ET tube) of orally or nasally intubated patients. Endotracheal tubes and tracheostomy tubes are trachea inserts/interfaces. Other types of trachea inserts/interfaces that a trachea connector can be used with or connected to comprise stoma (trachea) buttons, and laryngeal masks.

Tracheal couplings in the form of trachea interfaces could also be used with the blower 17 and conduit 10 system shown in Figure 1.

A prior art trachea coupling in the form of a connector is illustrated in Figures 2A and 2B. The connector includes an inner surface 22 at end 5 for connecting over the outlet 3 of the tracheostomy tube, an outer surface 24 of inlet tube 7 for fitting inside the cuff 8 of the breathing tube and an open outlet at end 6. The connector is for use in a high flow therapy where the patient is spontaneously breathing. The connector is not for use in a controlled mechanical ventilation. The connector is illustrated in Figure 2A with typical flows during patient inhalation and in Figure 2B with typical flows during patient exhalation. During patient inhalation, a portion 28 of inlet flow 26 flows directly to outlet 20 of the connector. Another portion 29 of inlet flow 26 flows to the patient through end 5. During exhalation, a flow 26 continues to enter the connector from the flow generator and, as indicated by arrows 23 flows to the outlet 20 together with flow 27 being returned through port 5 from the patient.

A prior art tracheal coupling (in the form of a connector) shown in Figures 2A and 2B provides an outlet port of about the same cross section as the inlet port and the patient port. In the high flow environment, the connector produces a very small pressure in the patient airway. Referring to Figure 11, with a flow of 50 litres per minute, this connector produced a pressure as illustrated in section B of the pressure plot. In this section, maximum PEEP (Positive End Expiratory Pressure) was less than 1cm$H_2$0.

The tracheal couplings according to the present invention include adaptations to work with the high flow environment (for example with the flow generator 13 in Figure 1) to produce an elevated pressure in the patient airway and PEEP. Because a large portion of the supplied gases are exhausted direct to the room, there is a tolerance for variation in the delivered flow rate. The tracheal couplings of the present invention provide a level of pressure support that varies depending on the flow rate delivered to the connector. The clinician can use variation of the flow rate supplied to the tracheal coupling of the present invention to vary the pressure support for the patient. Exhaust gas flow rates may be regulated by fixing the restriction to gas flow through variable or non-variable adaptations. The end expiratory pressure experienced by a user can therefore be regulated. A positive end expiratory pressure (PEEP) can keep the airways and alveoli from collapsing at end-expiration and reopen airways and alveoli that have already collapsed. The therapeutic provision of PEEP can improve gas exchange (decreased intra pulmonary shunt), reduce the resistance to airflow (lung resistance), and makes the lungs less stiff (increased lung compliance). Levels of oxygen and carbon dioxide also may improve, reducing the need for supplemental oxygen and the sensation of breathlessness. PEEP may also improve cardiac performance by increasing mean intra thoracic pressure. PEEP is of special advantage to assisting in the treatment of obstructive lung diseases and heart failure, including emphysema, bronchiectasis, chronic bronchitis, cystic fibrosis and pulmonary edema.

A number of variations of tracheal couplings according to the present invention are illustrated in Figures 3A to 10, 12 and 17 to 28 and described below. Figures 3A to 10, 12 show connectors, while Figures 17 to 28 show trachea interfaces. These tracheal couplings can provide for interfacing between a patient and gases supply. These tracheal couplings include a range of features for producing an elevated internal pressure from the flow flowing through the tracheal couplings in order to provide PEEP. The invention also contemplates tracheal couplings incorporating more than one of these adaptations. Examples of tracheal couplings incorporating multiple adaptations are illustrated in Figures 6, 8 and 9 and Figures 24, 26 and 27. Nonetheless, other combinations of these features are also possible and within the scope of the invention.

Figures 3A and 3B illustrate a tracheal coupling in the form of a connector including a directed flow nozzle 30 extending from the inlet port 31. The directed flow nozzle 30 includes an outlet end 32 facing towards the patient port 33. The outlet end 32 of the nozzle 30 is smaller than the inlet port area and the inlet flow 34 accelerates through the nozzle 30. During inhalation, a portion 35 of the flow 34 flows directly to the outlet port 36. The remainder 37 flows through the patient port 33 to be inhaled by the patient. As can be seen in Figure 3B, when the patient exhales, the flow of exhaled gases 38 is opposed by the incoming gases 39. The opposed flows create a zone of turbulence adjacent the nozzle outlet 32. This turbulent flow zone resists with the patient exhalation flow 38 to create an elevated pressure at the patient port of the connector.

The flow nozzle could extend beyond patient port into tracheostomy tube or other trachea insert/interface the connector is used with. This could include a bend so that the nozzle turns the inlet flow into line with the patient airway. The nozzle would not extend further than necessary to make this turn For example, the portion in line with the patient airway would be no more than 30mm long. So it would not irritate mucosa in the trachea.

Figures 4A and 4B illustrate another connector including a flow restriction at the outlet end. The flow restrictor may be in the form of a wall partially closing the end of the connector. The wall includes an aperture 40 of a particular size, the area of the aperture 40 being smaller than the cross sectional area of the inlet port. Flow from the outlet end of the connector is restricted by the port 40, producing a back pressure in the connector that is a function of the flow rate through the aperture.

As illustrated in Figure 4A, during inhalation, a portion 41 of the incoming flow 42 flows directly to the aperture 40, while a portion 43 is inhaled by the patient. As illustrated in Figure 4B, during patient exhalation, all of the incoming air 42 and the exhaled air 44 combines, and the combined flow 45 flows through aperture 40.

This greater combined flow during exhalation leads to a greater pressure within the connector during patient exhalation. The aperture may be substituted by multiple apertures, or a screen, mesh or filter.

In practice, a range of connectors may be provided with apertures 40 of different size (cross sectional area). A clinician may select a connector from this range according to the flow and pressure support needs of their patient. For example, a connector with a certain aperture size may be rated to provide a first pressure support with a first flow level, a second (greater) pressure support at a second (greater) flow level, a third (still greater) pressure support at a third (still greater) flow level and so on. Another connector with a larger aperture may be rated to provide the first pressure support at the second flow level. Another connector with a smaller aperture may be rated to provide the second pressure support at the first flow level. The clinician, knowing the pressure support desired and the flow rated intended to be used, can select the connector with the closest matching pairing of flow and pressure. This selection could be facilitated by a chart of pressure support against flow, with each connector being represented in the chart in the form of a region or band. The clinician would select pressure support on one scale and flow on the other scale. The point on the chart indicated by these selections would fall in the region or band of a connector suitable for supplying that combination of flow and pressure support.

Figure 5 illustrates a variation of the connector of Figures 4A and 4B, including a fixed flow restricting aperture 50 at a location intermediate between the inlet port and the outlet port. This aperture 50 may be provided in a wall 51 within the connector. Alternatively the intermediate restriction could be provided by a neck in the surrounding wall 52 of the connector. The subsequent expanded portion 53 of the outlet may allow other components with a male connector to be fitted to the tracheal connector, with the portion 53 acting as a female interface.

Figure 6 illustrates a connector including an adjustable outlet aperture. The adjustable outlet aperture includes a primary aperture 60 in the wall of the connector. A cap 61 covers the outlet end 62 of the connector. The cap 61 includes a tapered slot 63 at generally the same longitudinal location as the aperture 60 when the cap 61 is fitted to the connector. Rotation of the cap 61 changes the part of slot 63 which intersects with aperture 60. More of less of the aperture

60 can be exposed to the internal portion of the connected, by rotation of the cap 61 to adjust the amount of intersection of the slot 63 and the aperture 60. Multiple apertures 60 may be provided on the outlet portion 62 of the connector and multiple slots on the cap 61.

Preferably the slot and aperture or slots and apertures are configured so that for all positions of the cap there will be some outlet aperture exposed at all times, namely at least some intersection of the slot 63 and the aperture 60 always exists.

The cap 61 may be retained on the end of the tracheal connector by any suitable arrangement. In the illustrated arrangement, an outwardly extending lip 64 at the end of the connector engages in an inwardly extending channel of the cap 61. The cap 61 might be moulded, for example, from a plastics material, or from an elastomeric material such as silicone. An elastomeric material which would allow for internal undercuts to be moulded more easily. An elastomeric material would also provide a frictional engagement on the connector to maintain the rotational position of the cap.

Figure 7 illustrates an alternative connector including an adjustable aperture. In this version, one or more primary apertures 70 are provided in the wall of the connector. A plug 71 may be adjusted into and out of the outlet end. An end portion of the plug partially overlaps the outlet apertures 70 by a degree that varies according to the longitudinal position of the plug.

In the illustrated arrangement the plug includes an external thread which engages with an internal thread in the outlet end 72 of the connectors for adjusting the longitudinal position of plug 71. Rotation of the plug in a first direction draws the plug into the connector. Rotation of the plug in a second direction (relative to the connector) progressively withdraws the plug from the connector to progressively open the outlet aperture.

Numerous alternative arrangements for providing an adjustable outlet aperture may suggest themselves and be within the scope of the present invention. Many arrangements for providing a minimum flow aperture may also suggest themselves, for example, movement of any adjusting member (such as plug 71 of cap 61) may be limited so that at all times at least part of the primary outlet aperture remains uncovered. Alternatively one or more additional by-pass outlets may be provided through the body of the connector, or through any adjusting member (such as through the end of cap 61 or through the body of plug 71).

The cap 61 of the embodiment of Figure 6 may be reconfigured to be a hollow plug on the inside of the connector. Similarly, the plug 71 of the embodiment of Figure 7 may be reconfigured to be a cap with a wall around the outside of the connector. This could for example have a threaded wall like that shown in Figure 9, or a frictional engagement portion like that shown in

Figure 6. Other arrangements for opening and closing a flow passage by adjusting the position of a covering or closing member may also be used, such as a ball cock or similar valve.

Figure 8 illustrates a connector including a turbulent flow generator and an outlet restriction. The turbulent flow generator comprises nozzle 81 extending from the inlet port 84 and directed toward the patient port 85. The outlet flow restriction comprises an aperture 82 in end wall 83 closing the outlet end of the connector. Of course, other forms of adjustable flow restriction may be provided and other forms of turbulent flow generating nozzle. According to one example the nozzle may be configured to deliver a swirling or vortex flow into the tracheostomy or ET tube or other trachea insert/interface that the connector is connected to. This might have some benefit in clearing the airway of the tube.

Figure 9 illustrates an arrangement including a turbulence generator and a flow restriction. In this case, the connector includes a turbulence generating nozzle 91 extending from the inlet port 98 toward the patient port 92. At the outlet end, the connector includes an adjustable flow restriction in a form similar to the flow restriction of Figure 7. The adjustable flow restriction includes a primary aperture 93 and a cap 94 which fits over the outlet end of the tracheal connector. The cap 94 is threaded over the end of the tracheal connector and can be advanced or retreated along the body of the connector by rotating the cap relative to the connector. Accordingly, the degree to which the cap 94 covers the primary apertures 93 can be adjusted.

Figure 10 illustrates a further embodiment of the tracheal connector. This embodiment includes a variable flow restriction of the type shown in Figure 7 with a plug 101 fitted in the outlet end 102 of the tracheal connector. The plug covers a plurality of openings / outlet apertures 103 to a degree that depends on how far the plug 101 is threaded into the body of the connector.

In the embodiment of Figure 10, the plug 101 includes a pressure relief valve, the pressure relief valve maybe in any suitable form, and could alternatively be provided through the body of the connector in any suitable location along the wall of the connector. The valve could be passively activated or actively controlled, for example, by a solenoid energisable by the flow generator or monitoring system.

In the embodiment illustrated the pressure relief valve includes a passage way 104 through the body of the plug 101. A valve member 105 is seated against a tapered surface 107 at the tracheal connector end of the passage 104. The valve member 105 is held against the seat 107 by pre-compression of a coil spring 108. The coil spring is held in its compressed state by a cap 109 clipped onto the body of pipe 101. The valve member 105 may slide along a guide member 110 extending from the cover 109. The amount of pre-compression of spring 108 controls the relief pressure at which the valve member 105 withdraws from valve seat 107.

Any other known form of pressure relief valve may be incorporated as an alternative.

Each connector shown in Figures 3A to 10 could be adapted for interfacing with a patient by connection to any type of trachea insert/interface, such as an endotracheal tube, tracheostomy tube, stoma (trachea) button, laryngeal mask or the like. Figures 13 to 16 show examples of each, which are know in the art. A trachea interface 130 is a removable interface that can be attached to the neck of a patient with a tube for insertion into the trachea, such as that shown in Figure 13. A stoma button 140 is permanently inserted into the trachea of a patient, such as that shown in Figure 14. Tracheostomy tubes 150 and endotracheal tubes 160 are inserted further into the trachea, such as that shown in Figures 15 and 16 respectively. The patient end of a connector can be coupled to a trachea insert/interface in any suitable manner, for example by a friction push fit. The term "trachea insert" or "trachea interface" can be used interchangeably to more generally refer to any of the abovementioned or other related apparatus.

Figure 11 illustrates supporting pressure that can be generated using the illustrated tracheal connectors in a high flow supply environment. Figure 11 plots internal pressure at the open end of the tracheostomy tube against time to show how the pressure varies during a patient breathing cycle. These plots were generated using sample connectors connected to a lung simulator. The sample connector is supplied with inlet gases at the inlet port, from a gas supply set to deliver 50 litres per minute.

Portion A of the trace of Figure 11 was generated by the prior art connector similar to Figures 2A and 2B when supplied without flow. The negative pressures are the result of suction from the simulated inhalations.

Portion B of the trace in Figure 11 was generated using the prior art connector with a flow of 50 litres per minute. It can be seen from this trace that the average pressure support is approximately 0.5 cmH_20 and the maximum expiratory back pressure is approximately 0.75 cmH_20.

Portion C of the trace in Figure 11was generated using a connector having a flow restricting orifice of a first size. In this connector, the flow restricting orifice was $79mm^2$ cross section area, with the body of the connector having an internal cross section of $165mm^2$. This connector produced a peak pressure support (PEEP) of approximately 2 cmH_20.

Portion D of the trace in Figure 11was generated using a connector having a flow restricting orifice of a second size. At this connector, the flow restricting orifice was $24mm^2$ cross section area, with the body of the connector having a cross section of $165mm^2$. This connector produced a peak pressure support (PEEP) of approximately 11 cmH_20.

The general form of a trachea connector according to the present invention is described above. Within that general form wide variations are possible but certain particulars are preferred.

The trachea connector preferably includes a socket at the patient port to connect with a male 15mm medical connector typical of standard tracheostomy and ET tubes. Tracheostomy tubes conforming to ISO standard 5366-1:2000 should have a permanently attached male 15mm conical connector in accordance with ISO 5356-1.

The connector should be relatively small, for example with an overall length of inlet tube of approximately 20mm and overall length of main tube of approximately 40mm. A range of length of inlet tube of 210mm to 50mm is contemplated. A range of length of main tube of 30mm to 80mm is possible with the lower end of this range preferred. The inner diameter of the main tube may be about 15mm. The inner diameter of the inlet tube may be about 10mm.

The inlet tube preferably intercepts with the main tube at an angle that forms in an obtuse angle with the patient port and an acute angle with the outlet port. An angle of about 60 degrees between the main tube and the inlet tube may be appropriate.

As shown in Figure 12, one or more additional ports 120may be included on the connector for use with sensors for monitoring properties of the gas. For example, potential sensors that could be usefully integrated with the connector include a pressure sensor or a CO_2 sensor. In a medical environment a standard luer port formed in a sidewall of the connector would be appropriate. A port for a CO_2 sensor or pressure sensor could be included anywhere along the wall of the main tube. The port 120 in Figure 12 is shown on the embodiment of Figure 3A by way of example. It could apply to any of the other embodiments in Figures 3B to 10, 12 and 17 to 28.

The connector may be made from any suitable medical plastic or polymer. The plastic may be substantially rigid (by its material and detailed shape) so that it does not deform significantly under the fluctuating pressure support generated by patient breathing.

The above describes preferred forms of the trachea connector according to the present invention. Widely differing embodiments will suggest themselves to a person skilled in the art without departing from the scope of the invention as to finding appended claims.

The tracheal coupling could also take the form of a trachea interface 172 that can be attached directly to a tracheotomised patient. Such a coupling is shown generally in Figure 17. The trachea coupling comprises an interface 170 such as that shown in Figure 17 integrated with a body portion 171 such as any of those connector embodiments shown in Figures 3A to 10. The tracheal coupling in the form of a trachea interface 172 might further comprise an additional tube/coupling connected to that patient end that inserts into the trachea of a patient. Alternatively, the patient end of the trachea interface might insert directly into the trachea.

Examples embodiments of tracheal couplings in the form of a trachea interface 172 are shown in Figures 18 to 28. The body portion any of those embodiments could take the form of any of the connectors shown in Figures 3A to 10, 12. The description for Figures 3A to 10, 12 applies to the body portion of the trachea interfaces shown in Figures 17 to 28.

As shown in Figure 2, one or more additional ports 120 may be included on the trachea interface for use with sensors for monitoring properties of the gas. For example, potential sensors that could be usefully integrated with the connector include a pressure sensor or a CO_2 sensor. In a medical environment a standard luer port formed in a sidewall of the connector would be appropriate. A port for a CO_2 sensor or pressure sensor could be included anywhere along the wall of the main tube. The port 120 in Figure 22 is shown on the embodiment 18 by way of example. It could applied to any of the other embodiments in Figures 17 to 28.

The trachea interface may be made from any suitable medical plastic or polymer. The plastic may be substantially rigid (by its material and detailed shape) so that it does not deform significantly under the fluctuating pressure support generated by patient breathing.

All the trachea couplings described herein can be used in conjunction with the blower 13 and conduit 10 system shown in Figure 1

The above describes preferred forms of the trachea connector according to the present invention. Widely differing embodiments will suggest themselves to a person skilled in the art without departing from the scope of the invention as to finding appended claims.

Claims

1. A tracheal coupling for interfacing between a patient and a gases source, the connector comprising a patient port for connecting to the trachea interface/insert, an outlet port, and inlet port between patient port and outlet port for receiving a flow of gases from the gases flow source, the connector restricting expiratory flow in use to produce PEEP of at least $1cmH_20$ when flow to the inlet port is 50 litres per minute.

2. A tracheal coupling as claimed in claim 1 wherein the coupling is a connector that can be connected to a trachea interface/insert in or on a patient to interface between a patient and a gases source.

3. A tracheal coupling as claimed in claim 2 wherein the trachea interface/insert is one or more of:

a trachea button,
a endotracheal tube,
a tacheostomy tube,
a laryngeal mask.

4. A tracheal coupling as claimed in claim 1 wherein the coupling comprises a trachea interface that can be attached to a patient to interface between a patient and a gases source.

5. A tracheal coupling as claimed in claim 1 wherein the flow restriction includes a restriction between inlet port and outlet port or at outlet port.

6. A tracheal coupling as claimed in claim 5 wherein the flow restriction includes an adjustable orifice.

7. A tracheal coupling as claimed in claim 1 wherein the flow restriction is caused by turbulence from inlet flow.

8. A tracheal coupling as claimed in claim 1 wherein the flow restriction is caused by jetting air from inlet flow.

9. A tracheal coupling as claimed in one of claims 7 or 8 wherein the connector includes a nozzle extending from the inlet port toward the patient port.

10. A tracheal coupling as claimed in claim 9 wherein the nozzle extends through the patient port.

11. A tracheal coupling as claimed in 10 wherein the nozzle includes a bend in a portion between an outlet end of the nozzle and the patient port.

12. A tracheal coupling as claimed in claim 1 further comprising a pressure relief valve.

13. A tracheal coupling as claimed in claim 1 wherein the restriction comprises a heat and moisture exchanger.

14. A system for supplying breathing gases to a patient comprising an airflow source including an adjustable flow control, and a tracheal coupling for receiving gases from the airflow source in excess for a patient's breathing requirements, supplying breathing gases for the patient to inhale, and releasing exhaled gases and uninhaled gases through an outlet port, the connector restricting expiratory flow to generate amount of PEEP according to flow through connector, and thereby according to the setting of the adjustable flow control of the airflow source.

15. A system as claimed in claim 14 wherein the tracheal coupling is a connector that can be connected to a trachea interface/insert in or on a patient.

16. A tracheal coupling as claimed in claim 15 wherein the trachea interface/insert is one of:
a trachea button,
a endotracheal tube,
a tacheostomy tube,
a laryngeal mask.

17. A tracheal coupling as claimed in claim 16 wherein the coupling comprises a trachea interface that can be attached to a patient to interface between a patient and a gases source.

18. A system for supplying breathing gases as claimed in claim 14 wherein the flow restriction includes a restriction between an inlet port and outlet port, or at the outlet port.

19. A system for supplying breathing gases as claimed in claim 14 wherein the flow restriction includes an adjustable orifice.

20. A system for supplying breathing gases as claimed in claim 14 further comprising pressure relief valve.

21. A system as claimed in claim 14 wherein the flow restriction is caused by turbulence from inlet flow.

22. A system as claimed in claim 14 wherein the flow restriction is caused by jetting air from inlet flow.

23. A system as claimed in claim 21 wherein the connector includes a nozzle extending from the inlet port toward the patient port.

24. A system as claimed in claim 23 wherein the nozzle extends through the patient port.

25. A system as claimed in 24 wherein the nozzle includes a bend in a portion between an outlet end of the nozzle and the patient port.

26. A tracheal coupling comprising a patient port, an outlet port, an inlet port between the patient port and the outlet port, such that flow from the inlet port can go to the patient port or direct to the outlet port, and a flow restriction between the inlet port and the outlet port, or at the outlet port.

27. A tracheal coupling as claimed in claim 26 wherein the flow restriction includes an adjustable orifice.

28. A tracheal coupling as claimed in either claim 26 or claim 27 further comprising a pressure relief valve.

29. A tracheal coupling comprising a patient port, an outlet port, an inlet port between the patient port and the outlet port, such that flow from inlet port can go to the patient port or direct to outlet port, and a jet or nozzle discharging flow from the inlet port toward the patient port in the flow path of gases flowing from the patient port to the outlet port.

30. A tracheal coupling as claimed in claim 29 further comprising a restriction between the inlet port and the outlet port, or at the outlet port.

31. A tracheal coupling as claimed in claim 30 wherein the flow restriction includes an adjustable orifice.

32. A tracheal coupling as claimed in either claim 29 or claim 30 further comprising a pressure relief valve.

33. A method of providing breathing gases to a patient comprising:

a) attaching a tracheal coupling to a breathing tube of the patient, the coupling having a patient port, an outlet port, an inlet port between the patient port and the outlet port, such that flow from inlet port can go to the patient port or direct to the outlet port, and a jet or nozzle discharging flow from the inlet port toward the patient port in the flow path of gases flowing from the patient port to the outlet port,

b) selecting a flow level for a supply of gases to the connector to generate a desired amount of PEEP,

c) supplying the flow level of gases to the inlet port of the connector.

34. A method of providing breathing gases to a patient comprising:

a) attaching a tracheal coupling to a breathing tube of the patient, the connector having a patient port, an outlet port, an inlet port between the patient port and the outlet port, such that flow from inlet port can go to the patient port or direct to outlet port, and a jet or nozzle discharging flow from the inlet port toward the patient port in the flow path of gases flowing from the patient port to the outlet port,

b) adjusting a flow restriction for the connector according to an expected flow of gases and a desired amount of PEEP,

c) supplying a flow of gases to the inlet port of the connector.

35. A connector for interfacing between an endotracheal tube or tracheostomy tube and a gases source, the connector comprising a patient port for connecting to the endotracheal or tracheostomy tube, an outlet port, and inlet port between patient port and outlet port for receiving a flow of gases from the gases flow source, the connector restricting expiratory flow in use to produce PEEP of at least $1cmH_20$ when flow to the inlet port is 50 litres per minute.

36. A system for supplying breathing gases to a patient fitted with an endotracheal or tracheostomy tube comprising an airflow source including an adjustable flow control, and a connector receiving gases from the airflow source in excess for a patient's breathing requirements, supplying breathing gases for the patient to inhale, and releasing exhaled gases and uninhaled gases through an outlet port, the connector restricting expiratory flow to generate amount of PEEP according to flow through connector, and thereby according to the setting of the adjustable flow control of the airflow source.

37. A tracheal connector comprising a patient port, an outlet port, an inlet port between the patient port and the outlet port, such that flow from the inlet port can go to the patient port or direct to the outlet port, and a flow restriction between the inlet port and the outlet port, or at the outlet port.

38. A tracheal connector comprising a patient port, an outlet port, an inlet port between the patient port and the outlet port, such that flow from inlet port can go to the patient port or direct to outlet port, and a jet or nozzle discharging flow from the inlet port toward the patient port in the flow path of gases flowing from the patient port to the outlet port.

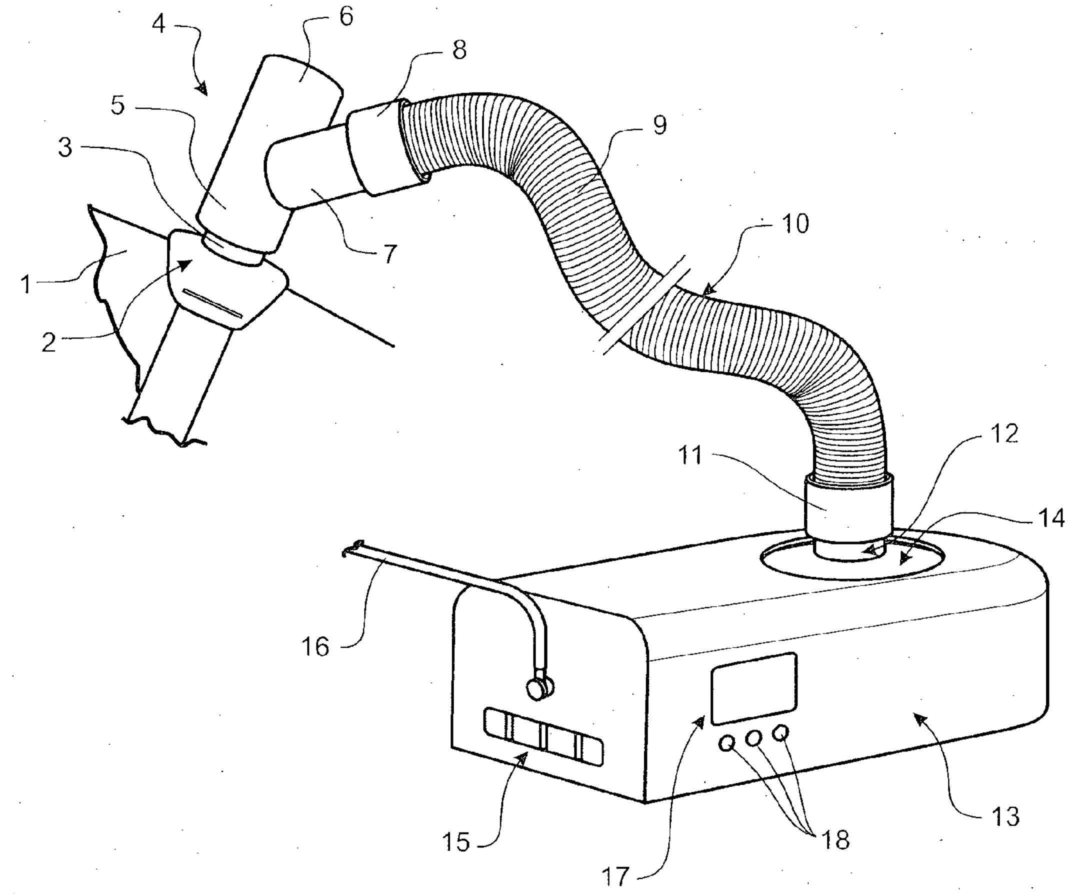


FIGURE 1

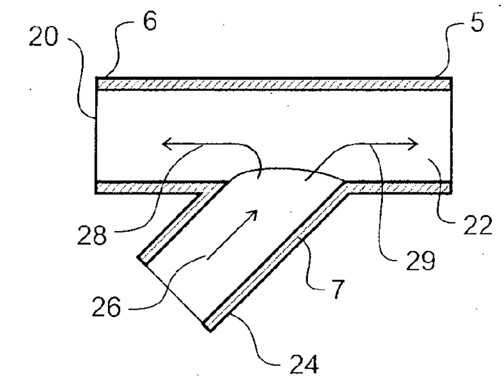


FIGURE 2A
(Prior Art))

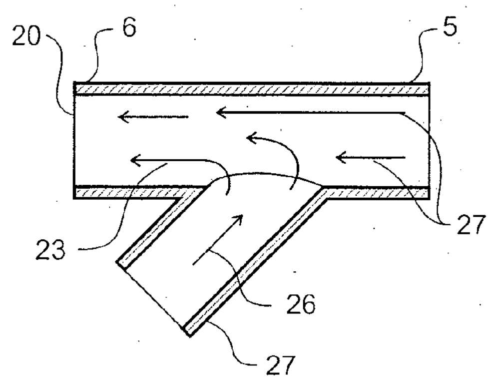


FIGURE 2B
(Prior Art))

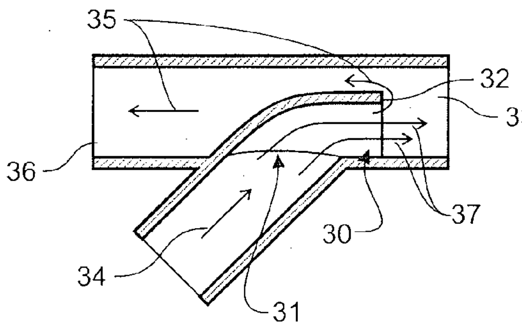


FIGURE 3A

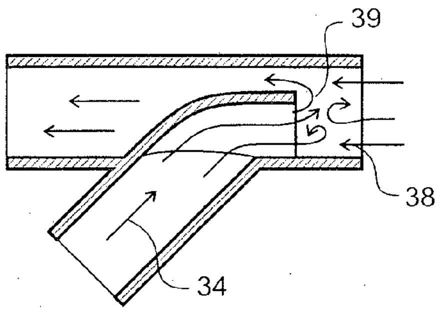


FIGURE 3B

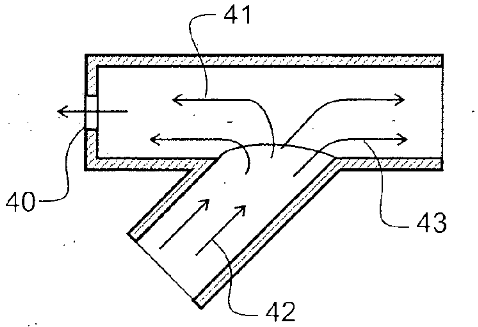


FIGURE 4A

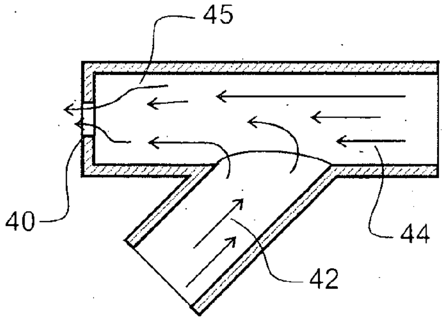


FIGURE 4B

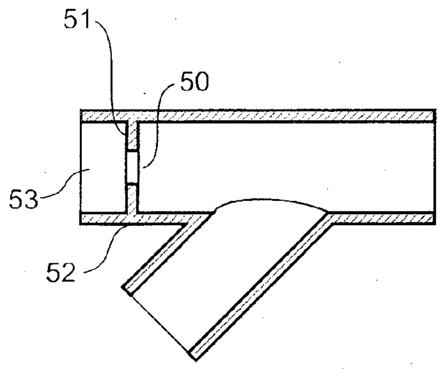


FIGURE 5

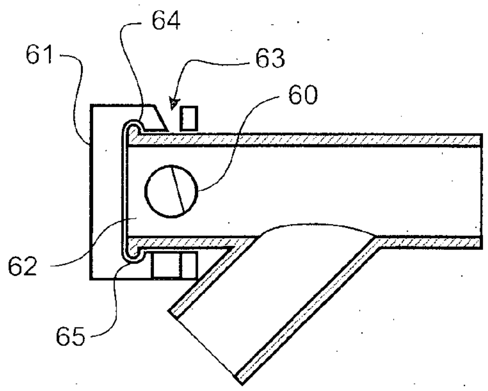


FIGURE 6

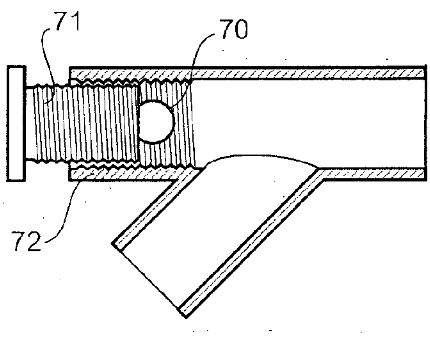


FIGURE 7

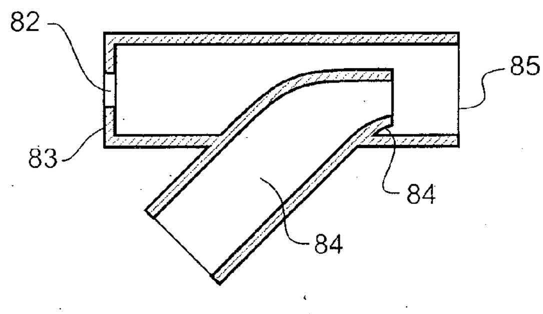


FIGURE 8

FIGURE 9

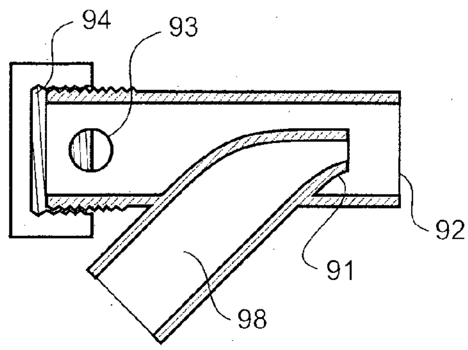


FIGURE 10

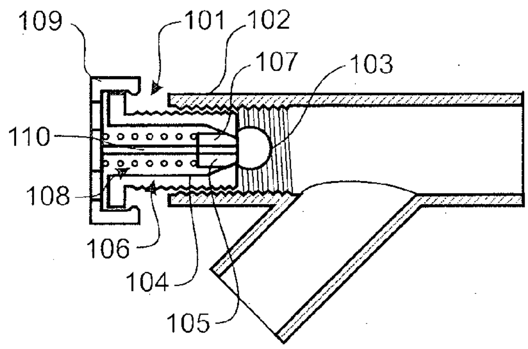
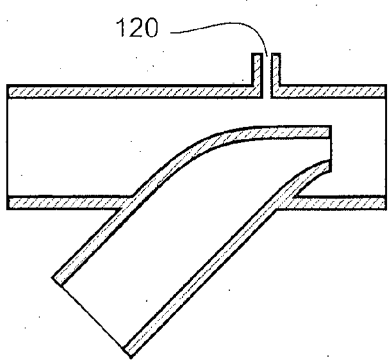


FIGURE 12



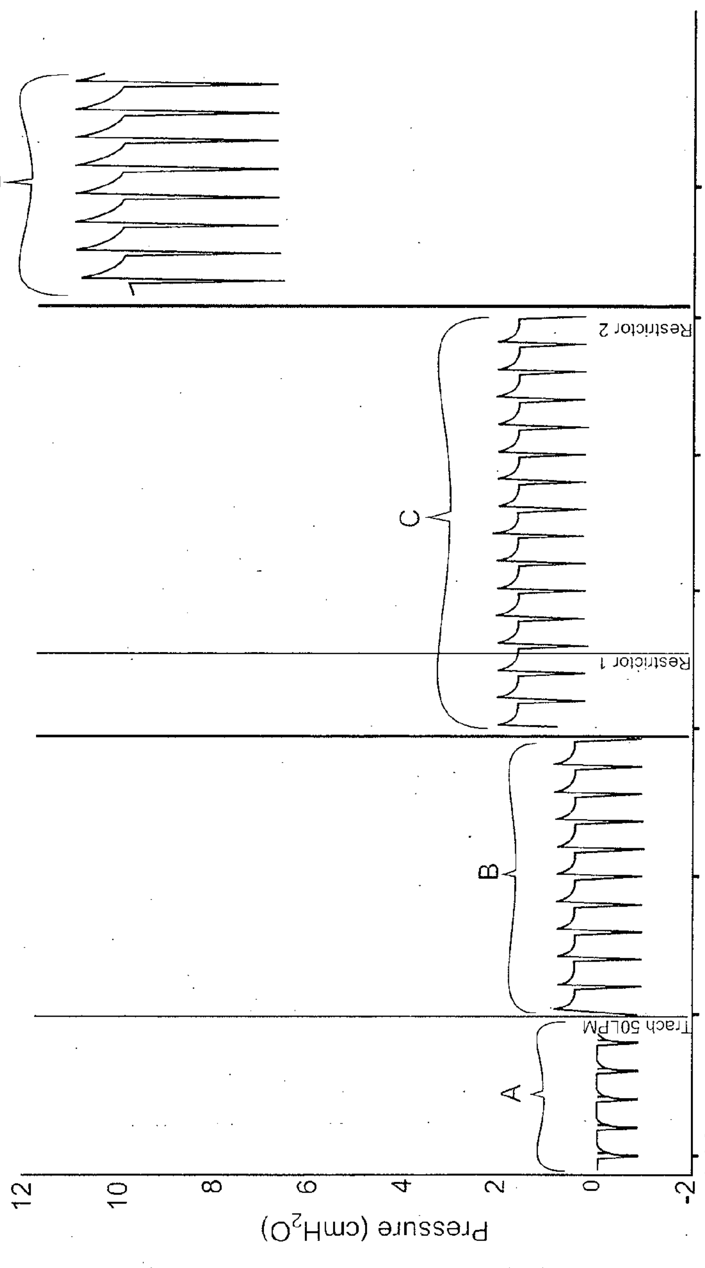

Pressure (cmH_2O)
12
10
8
6
4
2
0
-2
1:00
4
2:00
0
6
30
1:00
7
2:00
Trach 50LPM
Restrictor 1
Restrictor 2
A
B
C
D

FIGURE 11

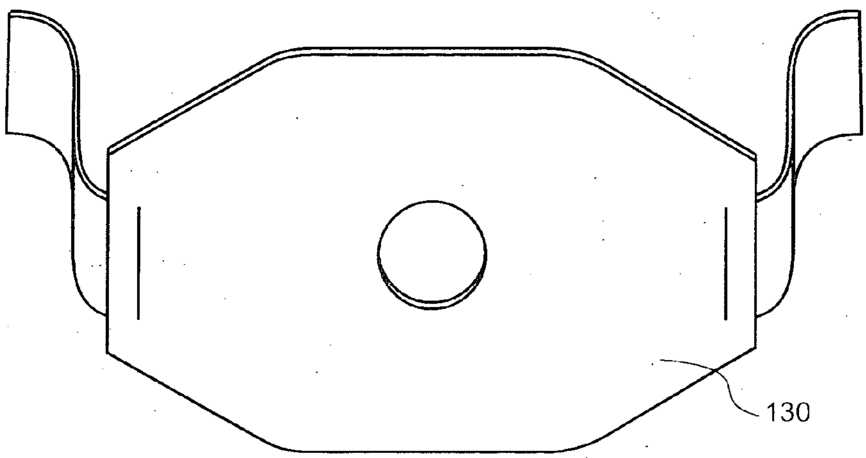
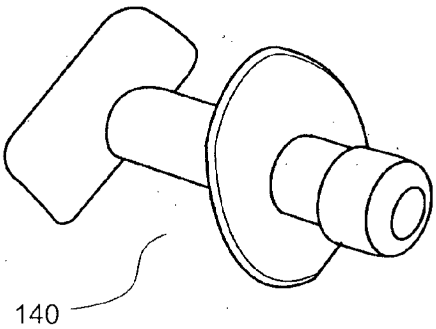


FIGURE 13



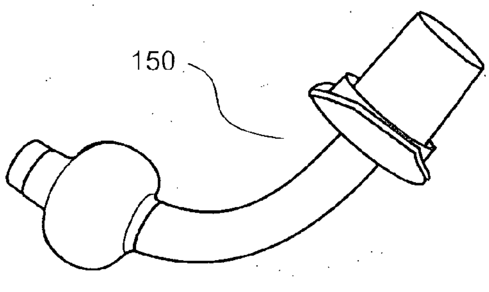
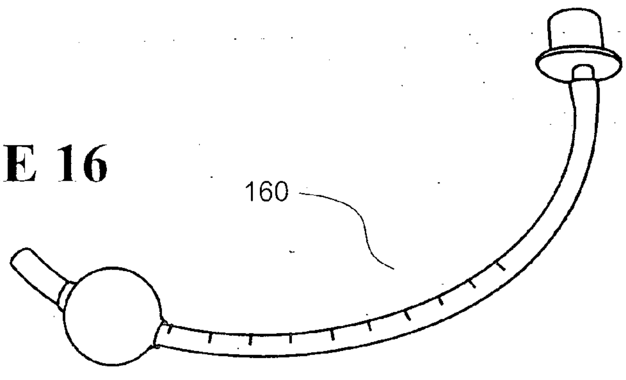


FIGURE 14

FIGURE 15

FIGURE 16



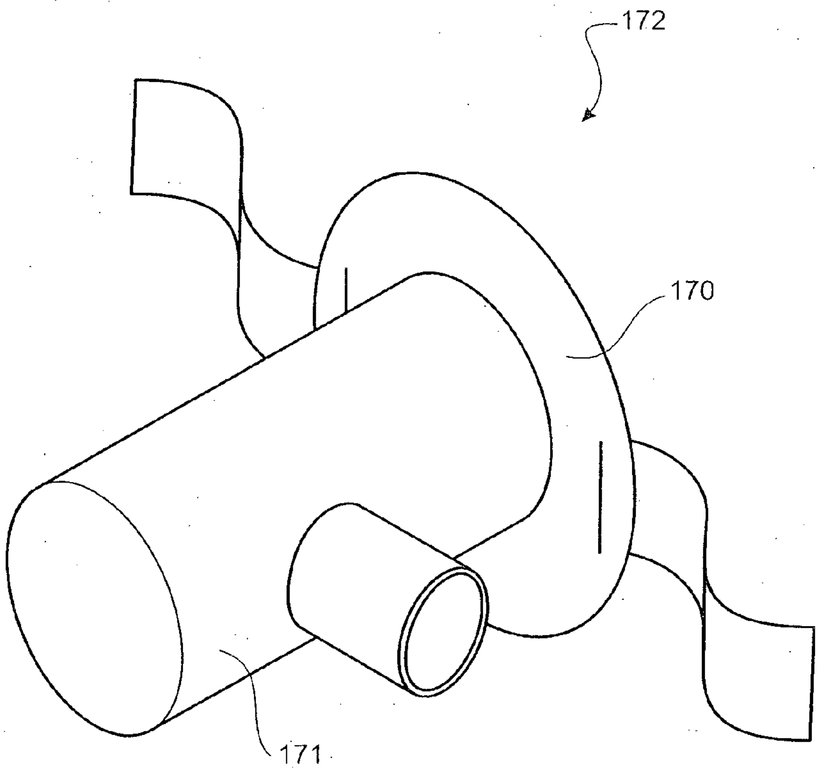


FIGURE 17

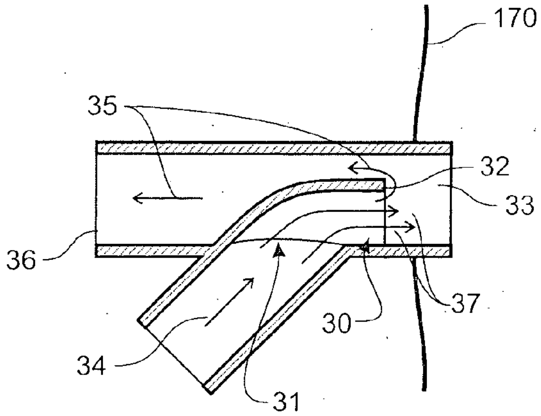


FIGURE 18

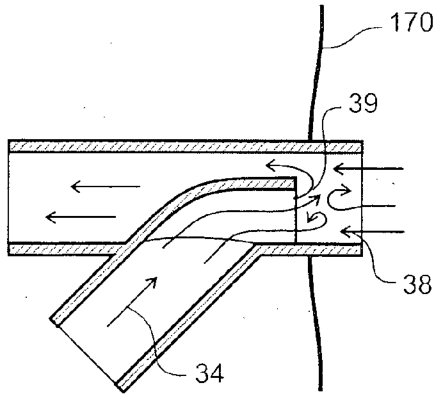


FIGURE 19

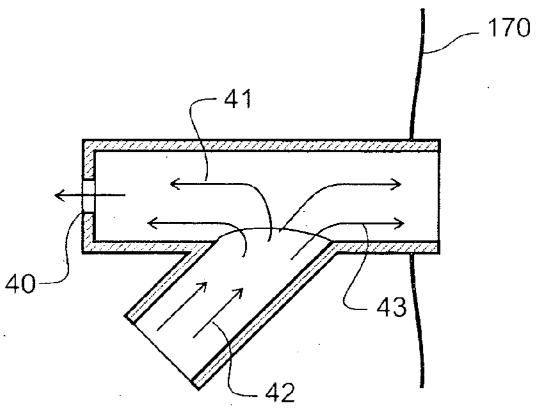


FIGURE 20

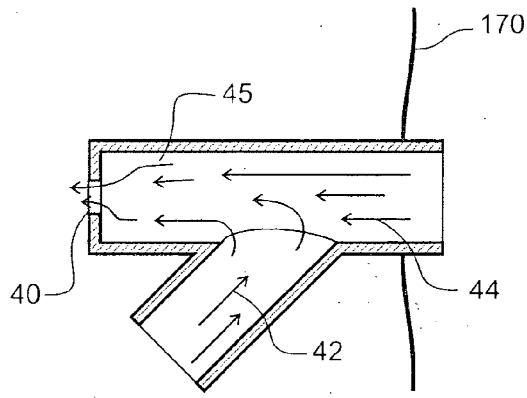
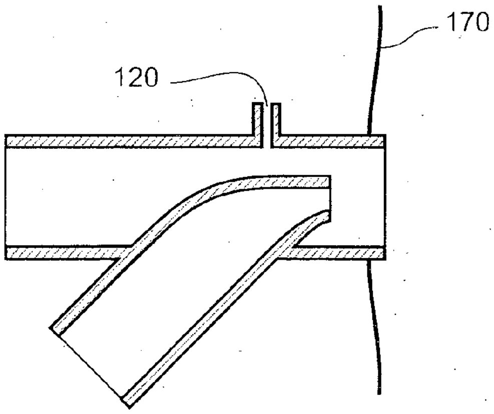


FIGURE 21

FIGURE 22



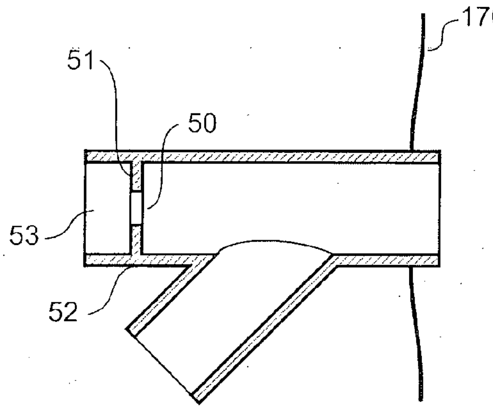


FIGURE 23

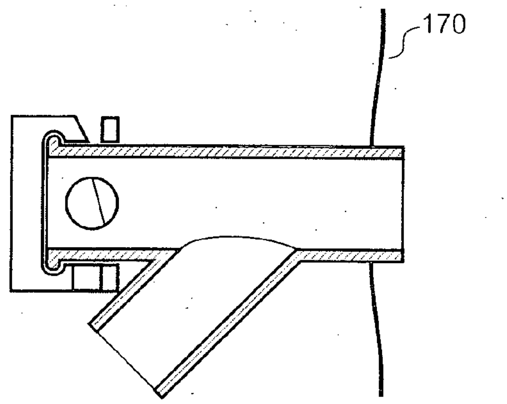


FIGURE 24

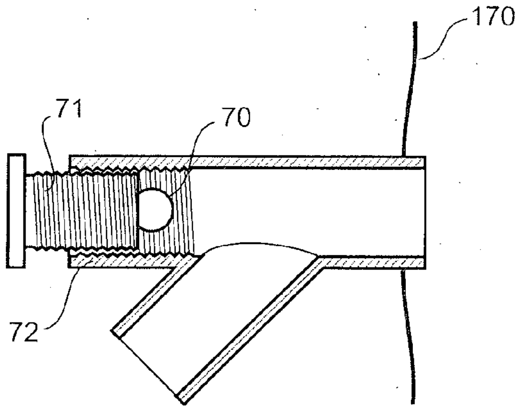


FIGURE 25

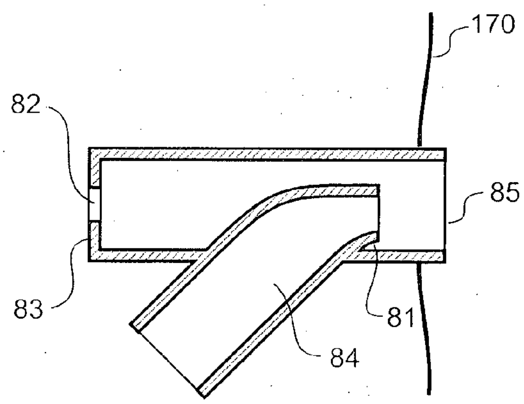


FIGURE 26

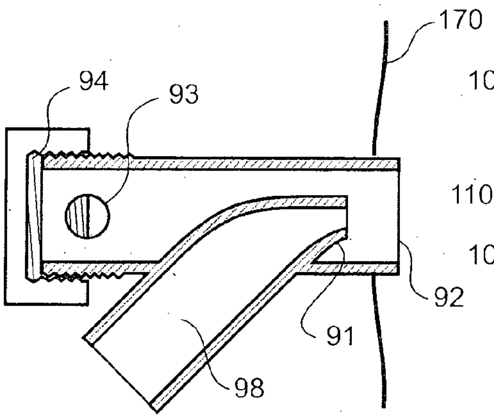


FIGURE 27

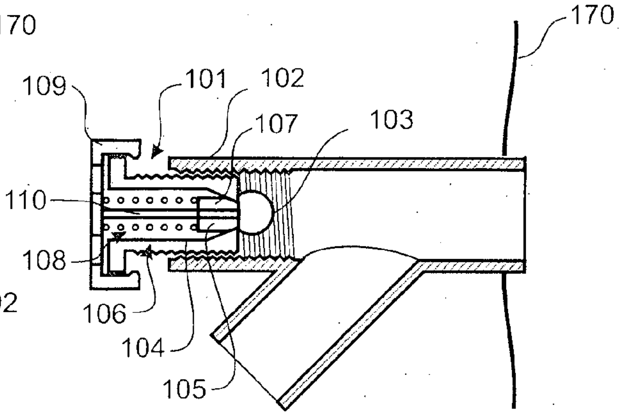


FIGURE 28