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(71) Applicant: **THE HOSPITAL FOR SICK CHILDREN** [CA/CA]; 555 University Avenue, Toronto, Ontario M5G 1X8 (CA).

(72) Inventors: **SOARES, Diane**; 3669 Autumnleaf Crescent, Mississauga, Ontario L5L 1K7 (CA). **TESSARO, Mark Oliver**; 279 Booth Avenue, Toronto, Ontario M4M 2M7 (CA). **KARSLI, Cengiz**; 761 Bay Street, Townhouse 3, Toronto, Ontario M5G 2R2 (CA). **GORDON, Peter Alexander**; #510-30 Charles Street West, Toronto, Ontario M4Y 1R5 (CA).

(74) Agent: **HILL & SCHUMACHER**; 264 Avenue Road, Toronto, Ontario M4V 2G7 (CA).

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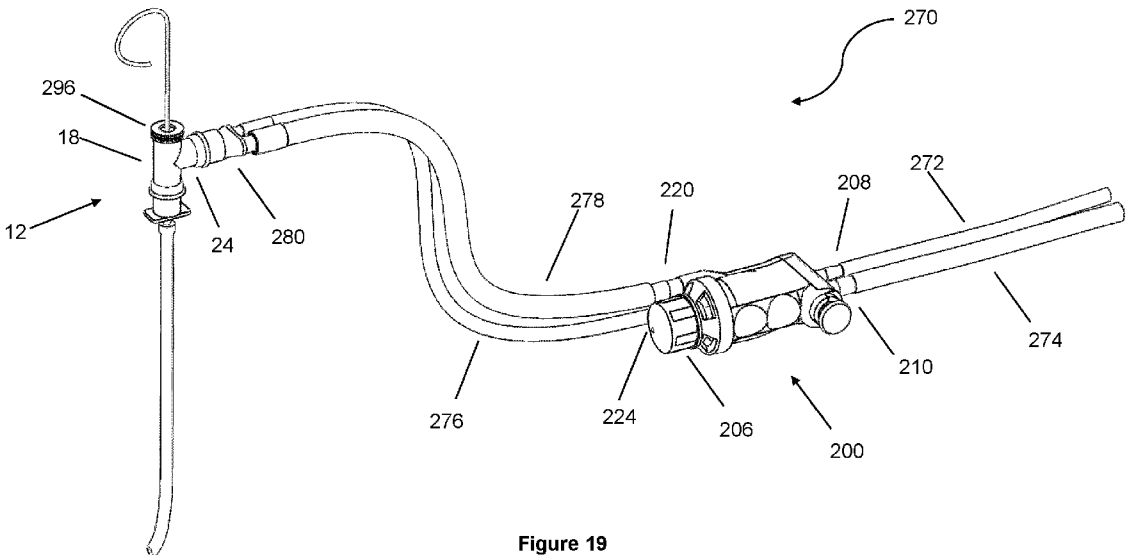

Figure 19

(57) Abstract: This disclosure discloses a tracheal intubation device designed to improve safety during intubation attempts. The device allows for the delivery of medical gas (such as oxygen) flow through the endotracheal tube itself during intubation attempts. This moves the source of apneic oxygen lower in the patient's airway to bypass anatomy that otherwise can obstruct medical gas flow. The device can also switch on-demand to generating suction through the endotracheal tube to clear away fluids that block the intubator's view and that block medical gas flow. There are currently no devices that can deliver both medical gas and on-demand suction using the endotracheal tube as the flow conduit during the process of intubation. The present device accomplishes these tasks while incorporating non-obvious elements to optimize its use and efficacy.

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TRACHEAL INTUBATION DEVICE FOR DELIVERY OF APNEIC OXYGENATION AND SUCTION

FIELD OF THE DISCLOSURE

This disclosure relates to devices for the delivery of apneic oxygenation and suction, and more specifically devices for delivery of apneic oxygenation and on-demand suction through an endotracheal tube during the process of intubation.

BACKGROUND

Airway intubation is the placement of an endotracheal tube into a patient's airway to a depth below the vocal cords. It is a procedure that can occur electively in order to protect the airway and respiration of a patient during surgery or can occur in a critical illness. It is a high-risk procedure as it occurs when patients are apneic (not breathing) either due to their illness or from medications, and a narrow time window is available to the intubator prior to a dangerous decrease in the patient's blood oxygen levels, which significantly are worsened in the presence of disease. An intubation attempt may be prolonged due to airway anatomy that either prevents good visualization of the airway or due to difficulty advancing the endotracheal tube. It may also be prolonged if fluids (secretions or blood) obscure the intubator's view of the endotracheal tube's path, requiring a suction catheter to be introduced into the patient's mouth.

Apneic oxygenation is the delivery of flowing oxygen into a patient's nares via nasal cannula tubing during intubation attempts, and provides a proven safety benefit by delaying the time to oxygen desaturation. This oxygen flow can be blocked by the same airway conditions or fluids mentioned above, negating this safety benefit. Therefore, providing a tracheal intubation device that can, while being inserted into the patient's airway, be switched by the clinician from delivering oxygen and providing suction if needed would be very advantageous and increase the safety of the insertion procedure.

SUMMARY

Provided is a tracheal intubation device designed to improve safety during intubation attempts. The device allows for the delivery of oxygen (or other medical gas) flow through the endotracheal tube (or through a laryngeal mask airway or other supraglottic device that secures a patient's airway) itself during intubation attempts. This moves the source of apneic oxygen lower in the patient's airway to bypass nasopharynx anatomy that otherwise can obstruct oxygen flow. The device can also switch on-demand to generating suction through the endotracheal tube to clear away fluids that block the intubator's view and that block oxygen flow. There are currently no devices that can deliver both oxygen and on-demand suction using the endotracheal tube as the flow conduit during the process of intubation. The present device accomplishes these tasks while incorporating non-obvious elements to optimize its use and efficacy.

The present device comprises an endotracheal tube adaptor that connects to the patient-exterior-end of the endotracheal tube, a control unit that connects to standard medical gas and suction tubing and controls medical gas and suction delivery, and a length of lightweight flexible tubing that connects the adaptor to the control unit.

During intubation, a semi-rigid stylet is placed within the endotracheal tube to make it rigid enough to allow it to advance rather than bending as it slides along airway surfaces. The distal end of this stylet sits at the airway-end of the endotracheal tube, while the proximal end of the stylet emerges from the patient-exterior-end of the endotracheal tube, and prevents the application of oxygen supply tubing to the endotracheal tube. Our device's adaptor to the patient-exterior-end of the endotracheal tube allows for a stylet using an in-line self-sealing minimal-leak port, allowing oxygen flow or suction to occur via a second off-axis adaptor conduit.

An intubation requires the clinician to use one hand to control a laryngoscope (a blade with a light source) to generate a view of the airway, and the other hand to manipulate the endotracheal tube towards the vocal cords. Our device utilizes lightweight flexible tubing to connect its endotracheal tube adaptor to a control unit. The on-demand suction control components as well as bulky tubing running from medical gas and suction sources are thus kept away

from the patient-exterior-end of the endotracheal tube. This maintains a clear visual axis for the intubator, and ensures that the endotracheal tube does not become difficult to manipulate, as it would if the mass of these components were added directly to its patient-exterior-end. It allows an assistant to activate on-demand suction at a location where their manipulation of the device will not obscure the intubator's view or create traction on the endotracheal tube that would make it more difficult to manipulate.

The application of high pressures into a patient's airway can cause airway tissue damage (barotrauma). The present control device contains a pressure-release valve that activates automatically if pressure within the flexible tubing rises above a set level, thus preventing barotrauma.

Thus disclosed herein is an airway device for delivering medical gas to a patient, comprising:

an airway access device configured to be coupled to a patient's airway;

an airway access device adaptor connected to and in flow communication with the airway access device;

a medical gas input control unit including a housing having first and second ends, the second end of said control united being connected to the airway access device adapter, the control unit including a medical gas supply coupling located at the first end of the housing connectable to a source of medical gas, a pressure limiting device located downstream of the medical gas supply coupling, and wherein the pressure limiting device is configured to limit medical gas flow upon a pressure of medical gas in the pressure limiting device exceeding a preselected threshold pressure; and

the airway access device adapter is configured to form a gas tight seal with the airway access device when coupled to said airway access device.

The device medical gas input control unit may further comprise a suction supply coupling located at the first end of the housing and being connectable to a source of suction, and the control unit may include a hand-operated control mechanism for controlling both suction and medical gas flow.

The hand-operated control mechanism may be a finger activated switch for switching between the source of suction and the source of medical gas, and the control unit may be configured such that when the finger activated mechanism is not activated, medical gas flows to the airway access device, and

when activated the medical gas flow is stopped and suction is applied to the airway access device, so that medical gas and suction cannot be provided at the same time.

The hand-operated control mechanism may be a finger activated switch for switching between the source of suction and the source of medical gas and the control unit may be configured such that when the finger activated mechanism is not activated, medical gas flows to the airway access device, and when activated the medical gas flow is reduced to a preselected flow rate and suction is simultaneously applied to the airway access device, so that medical gas and suction are provided at the same time.

The airway access device adaptor may be connected to, and in flow communication with, the airway access device by means of elongate flexible tubing.

The pressure limiting device may be any one of a pressure relief valve, a pressure regulating valve, a rupture disc, an aperture, or a breather vent.

The airway access device may be any one of an endotracheal tube, Laryngeal mask airway, tracheostomy tube, nasopharyngeal airway or tube, oropharyngeal tube, cricothyrotomy tube, and the like.

The present disclosure provides an airway device for delivering medical gas to a patient, comprising:

an airway access device configured to be coupled to a patient's airway;

an airway access device adaptor connected to and in flow communication with the airway access device;

a medical gas input control unit including a housing having first and second ends, the second end of said control united being connected to said airway access device adapter, the control unit including a medical gas supply coupling located at said first end of the housing connectable to a source of medical gas, a pressure limiting device located downstream of the medical gas supply coupling, and wherein the pressure limiting device is configured to limit medical gas flow upon a pressure of medical gas in the pressure limiting device exceeding a preselected threshold pressure;

a suction supply coupling located at the first end of the housing and being connectable to a source of suction, the control unit including a hand-

operated control mechanism for controlling both suction and medical gas flow; and

the airway access device adapter being configured to form a gas tight seal with the airway access device when coupled to the airway access device.

The hand-operated control mechanism may be a finger activated switch for switching between the source of suction and the source of medical gas, the control unit being configured such that when the finger activated mechanism is not activated, medical gas flows to the airway access device, and when activated the medical gas flow is stopped and suction is applied to the airway access device, so that medical gas and suction cannot be provided at the same time.

The hand-operated control mechanism may be a finger activated switch for switching between the source of suction and the source of medical gas, the control unit being configured such that when the finger activated mechanism is not activated, medical gas flows to the airway access device, and when activated the medical gas flow is reduced to a preselected flow rate and suction is simultaneously applied to the airway access device, so that medical gas and suction are provided at the same time.

The airway access device adaptor may be connected to, and in flow communication with, the airway access device by means of elongate flexible tubing.

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The airway access device may be any one of an endotracheal tube, Laryngeal mask airway, tracheostomy tube, nasopharyngeal airway or tube, oropharyngeal tube, cricothyrotomy tube, and the like.

The present disclosure provides an airway device for delivering medical gas to a patient, comprising:

an endotracheal tube having a first end configured to be inserted into a patient's airway and an opposed second end;

an endotracheal tube adaptor attached to the second end configured to have one end of an elongate flexible tube attached thereto; and

a hand operated medical gas input control unit including a housing having first and second opposed ends, a second end of the elongate flexible

tube being connected to the second end of said housing, the control unit including a medical gas supply coupling connectable to a source of medical gas and a pressure limiting device located downstream of the medical gas supply coupling between said medical gas supply coupling and the first end of the housing, wherein the pressure limiting device is configured to vent the medical gas out of the housing upon a pressure of medical gas in the flexible tube exceeding a preselected threshold pressure and

the endotracheal tube adapter configured to form a gas tight seal with said endotracheal tube when coupled to said airway access device.

The medical gas input control unit may further comprise a suction supply coupling located at the first end of the housing and being connectable to a source of suction, the control unit including a hand-operated control mechanism for controlling both suction and medical gas flow.

The pressure limiting device may be a pressure relief valve is located adjacent to the second end of the housing with the medical gas supply coupling being located between said pressure relief valve and said suction supply coupling.

The suction supply coupling may be located adjacent to the first end of the housing, and wherein the medical gas supply coupling is located adjacent to the second opposed end, and wherein said pressure limiting device is a pressure relief valve located between the medical gas supply coupling and the suction supply coupling.

A further understanding of the functional and advantageous aspects of the disclosure can be realized by reference to the following detailed description and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The disclosure will be more fully understood from the following detailed description thereof taken in connection with the accompanying drawings, which form part of this application, and in which:

Figure 1 is a front view of an embodiment of the tracheal intubation device showing the airway unit, endotracheal tube, tubing component, and control unit;

Figure 2 is a perspective view of the device of **Figure 1**;

Figure 3 is a perspective view of the control unit of the device of **Figure 1**;

Figure 4A is a top-down view of the control unit of **Figure 3** with a cutting plane;

Figure 4B is a section view of the control unit taken along the plane A-A of **Figure 4A**;

Figure 5 is a wire-frame view of the control unit of **Figure 3** showing gas streamlines when on-demand suction is activated;

Figure 6 is a front view of an embodiment of the tracheal intubation device where the tracheal intubation device is for medical gas delivery only;

Figure 7 is a diagram of an alternate embodiment of the control unit;

Figure 8 is a diagram of an alternate embodiment of the control unit having separate medical gas and suction chambers;

Figure 9 is a diagram of an alternate embodiment of the control unit having separate medical gas and suction sections;

Figure 10 is a top-down view of an alternate embodiment of the tracheal intubation device with the endotracheal tube adaptor and tubing component of the device of **Figure 1** and the control unit of **Figure 7**;

Figure 11 is view of the device of **Figure 10** being used with a mannequin showing the airway unit, a tubing component, and a control unit;

Figure 12 is a view of the device of **Figure 10** being used with a mannequin while suction is active;

Figure 13A is a diagram of an alternate embodiment of the tracheal intubation device as a portable unit with stand-alone medical gas and suction supplies;

Figure 13B is a perspective view of the tracheal intubation device of **Figure 13A**;

Figure 14A is an isometric view of another embodiment of a hand operated control unit for the tracheal intubation device disclosed herein;

Figure 14B is a disassembled view of the handheld unit of **Figure 14A**;

Figure 15A is a rear view of the handheld unit of **Figure 14A** looking along arrow **15A** of **Figure 14A**;

Figure 15B is a bottom view of the handheld unit of **Figure 14A** looking along arrow **15B** of **Figure 14A**;

Figure 16A is a side view of a valve forming part of the hand held control unit of **Figure 14A**;

Figure 16B is a view of the valve of Figure 16A but the input and output gas and suction connectors coupled thereto;

Figure 17A is an isometric view of a partially disassembled control unit of **Figure 14A**;

Figure 17B is a side elevation view of the control unit of **Figure 14A**;

Figures 18A is an isometric view of the hand operate control unit, showing the interior structure of the medical gas and suction flow pathways in its default state with the finger operated control button unengaged by the clinician such that in this default stated medical gas is flowing into the patient's airway;

Figure 18B is an isometric view of the control unit similar to **Figure 18A** showing suction and oxygen flow pathways through the control unit but now with the control button depressed or activated by the clinician so that the medical gas is vented to atmosphere and the suction is engaged to clear the patient's airway;

Figure 19 is an isometric view of the assembled tracheal intubation device using the hand operated control unit of **Figure 14A**;

Figure 20A is a side view of a gas and suction coupling connecting the hand operated control unit of **Figure 14A** to the tracheal intubation tube with the coupled to the adapter attached to the intubation tube;

Figure 20B is a perspective view of the coupling of **Figure 20A** connected to the tracheal intubation tube and tubes for delivering medical gas and suction from the hand operated unit of **Figure 14A** to the tracheal intubation tube;

Figure 21A is an isotropic view showing the sealing cap forming part of an airway access device adaptor forming part of the present device; and

Figure 21B is a cross-sectional view of the sealing cap of **Figure 21A**.

DETAILED DESCRIPTION

The devices described herein are directed, in general, to tracheal intubation devices and more specifically to tracheal intubation devices for delivery of apneic oxygenation (or other medical gases) and on-demand

suction. Although embodiments of the present invention are disclosed herein, the disclosed embodiments are merely exemplary and it should be understood that the invention relates to many alternative forms, including different shapes and sizes. Furthermore, the Figures are not drawn to scale and some features may be exaggerated or minimized to show details of particular features while related elements may have been eliminated to prevent obscuring novel aspects. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting but merely as a basis for the claims and as a representative basis for enabling someone skilled in the art to employ the present invention in a variety of manners.

As used herein, the terms “comprises”, “comprising”, “includes” and “including” are to be construed as being inclusive and open ended, and not exclusive. Specifically, when used in this specification including claims, the terms “comprises”, “comprising”, “includes” and “including” and variations thereof mean the specified features, steps or components are included. These terms are not to be interpreted to exclude the presence of other features, steps or components.

As used herein, the terms “about” and “approximately”, when used in conjunction with ranges of dimensions, compositions of mixtures or other physical properties or characteristics, is meant to cover slight variations that may exist in the upper and lower limits of the ranges of dimensions so as to not exclude embodiments where on average most of the dimensions are satisfied but where statistically dimensions may exist outside this region. It is not the intention to exclude embodiments such as these from the present invention.

As used herein, the coordinating conjunction “and/or” is meant to be a selection between a logical disjunction and a logical conjunction of the adjacent words, phrases, or clauses. Specifically, the phrase “X and/or Y” is meant to be interpreted as “one or both of X and Y” wherein X and Y are any word, phrase, or clause.

As used herein the phrase “airway access device” refers to any medical device used by a clinician to access a patient’s airway. Thus the airway access device may include any of, but is not limited to, an endotracheal tube, Laryngeal mask airway, tracheostomy tube, nasopharyngeal airway or tube, oropharyngeal tube, cricothyrotomy tube, and the like.

While the following disclosure and figures illustrates the present airway device for delivering medical gas and suction to a patient using an endotracheal tube as the airway access device, it will be appreciated that with minor design modifications the present device can be adapted for any airway access device, such as, but not limited, to those mentioned above.

The tracheal intubation device of the present disclosure, an embodiment of which is shown in **Figure 1** at **10** generally comprises an endotracheal tube adaptor **12**, a tubing component **14** and a control unit **16**.

The endotracheal tube adaptor **12** of the present disclosure, an embodiment of which is shown in **Figure 1**, generally comprises a body **18**, an airway connector **20** attached to the body **18**, a stylet accommodator **22** attached to the body **18** and a tubing port **24** attached to the body **18**. The body **18** has a hollow chamber **26** made of rigid material. In a preferred embodiment of the disclosure, the body **18** is cylindrical.

The airway connector **20** is shaped such that the patient-exterior end **30** of an endotracheal tube **28** can be removably attached to the airway connector **20** such that medical gas and/or suction may be conducted through the airway connector between the airway end **32** of the endotracheal tube **28** and the body chamber **26**. In a preferred embodiment, the airway connector **20** is cylindrical and is shaped such that the universal **15** mm diameter connector of an endotracheal tube or laryngeal mask airway or other supraglottic airway device can be removably attached by snug fit to the airway connector **20**. In the embodiment of the disclosure shown in **Figure 1**, the airway connector is shaped such that the patient-exterior-end **30** of the endotracheal tube **28** is secured by snug fit within the airway connector.

The stylet accommodator **22** is attached to the body **18** of the endotracheal tube adaptor **12** and allows a semi-rigid stylet **34** to be removably positioned within the endotracheal tube **28** during intubation to make the endotracheal tube **28** rigid enough to allow it to advance into the airway rather than bending on airway surfaces. The diameter of the endotracheal tube **28** is greater than the diameter of the stylet **34** allowing medical gas or suction to be delivered during intubation. The stylet accommodator **22** is a self-sealing minimal-leak port, allowing medical gas and suction flow between the tubing

component **14** and the endotracheal tube **28** via the endotracheal tube adaptor **12**.

In the embodiment of the disclosure shown in **Figure 1**, the stylet accommodator **22** is an enclosure that encloses the distal end **36** of the stylet **34** such that the stylet **34** can be inserted into the endotracheal tube **28** during intubation.

In an alternate embodiment of the disclosure, the stylet accommodator **22** is a removable plastic cap with a hole in the center of said cap so an intubation stylet can be inserted into the endotracheal tube through the hole in said cap. It will be appreciated by one skilled in the art that a cap with no hole in it can be used if the device of the present disclosure is being used without an intubation stylet.

The tubing port **24** is attached to the body **18** of the endotracheal tube adaptor **12** and is shaped such that the tubing component **14** can is removably attachable to the endotracheal tube adaptor **12**. The tubing port **24** conducts medical gas flow or suction between the body chamber **26** of the endotracheal tube adaptor **12** and the tubing component **14**. In a preferred embodiment shown in **Figure 1**, the tubing port **24** is a hollow, open-ended cylinder. The tubing component **14** is attachable to the tubing port **24** either by adhesive, a snug fit, a crimping or clamping mechanism, a banding mechanism, a riveting mechanism and/or a flange mechanism. The tubing port **24** is either shaped such that the tubing component fits around the tubing port or the tubing component fits within the patient side tubing attachment.

In the embodiment of the present disclosure shown in **Figure 1**, the airway connector **20** is attached to one end of the body **18** and the stylet accommodator **22** is attached to the other end of the body **18**. Furthermore, the stylet accommodator **22** is in line with the central axis of the airway connector **20**. The tubing port **24** is attached to the side face of the body **18** where the central axis of the tubing port is at an angle to the central axis of the airway connector **20**.

The tubing component **14**, an embodiment of which is shown in **Figure 1**, consisting of semi-rigid or flexible, lightweight tubing, attaches at one end to the tubing port **24** of the endotracheal tube adaptor **12** and attaches at the other end to a tubing component port **46** of the control unit **16**. The tubing component

14 conducts medical gas flow or suction between the endotracheal tube adaptor **12** and the control unit. The flexible nature of the tubing component **14** of the tracheal intubation device **10** is shown in **Figure 2.**

The control unit **16**, shown in **Figure 3**, generally comprises a body **38**, a control apparatus **40**, a medical gas input port **42**, a suction port **44**, a tubing component port **46** and a pressure release valve **48**.

The body **38** of the control unit **16** has a hollow main chamber **50** made of rigid material. In a preferred embodiment, the body **38** is a cylinder.

In the embodiment of the present disclosure shown in **Figure 3**, the tubing component port **46** is attached to one end of the body **38** and the suction port **44** is attached to the other end of the body **38**. The main chamber **50**, best shown in **Figure 4B** is between the tubing component port **46** and the control apparatus **40**. The medical gas input port **42** is attached to the side of the body **38** and the pressure release valve **48** is attached to the side of the body **38** between the medical gas input port **42** and the tubing component port **46**.

The control apparatus **40** enables an operator to switch from medical gas supply to on-demand suction. In the embodiment shown in **Figure 3**, the suction port **44** is separated from the main chamber **50** by the control apparatus **40**. The suction chamber **52**, best shown in **Figure 4B** is the space between the control apparatus **40** and the suction port **44**. The medical gas input port **42**, tubing component port **46**, and pressure release valve are all attached to the body **38** of the control unit. The control apparatus **40** is attached such that when it is not activated, the suction chamber **52** is separated from the main chamber **50**. When the control apparatus **40** is not activated, medical gas is delivered through the medical gas input port into the main chamber **50** and through the tubing component port **46** into the tubing component **14**. The medical gas then moves from the tubing component **14** through the tubing attachment **24** into the body chamber **26** of the endotracheal tube adaptor **12** and from the body **18** through the airway connector **20** into the endotracheal tube **28** and the medical gas flows through the endotracheal tube **28** and out of the airway end **32** of the endotracheal tube **28**. The control apparatus **40** is attached such that when it is in the activated position, a channel opens between the suction chamber **52** and the main chamber **50**, allowing for a suction force to be conducted through the tracheal intubation device **10**. When the control apparatus **40** is in the activated

position the suction force is sufficient to clear blockages that occur during intubation. Any fluids and semi-solids (such as mucous) preventing medical gas flow through the endotracheal tube or obscuring the incubator's view can be extracted when suction is activated. When suction is activated, matter is sucked into the airway end **32** of the endotracheal tube **28** and moves through the endotracheal tube into the body **18** of the endotracheal tube adaptor **12** through the airway connector **20**. From the body **18** the matter moves through the tubing attachment **24** into the tubing component **14**. From the tubing component **14** the matter moves through the tubing component port **46** into the main chamber **50** of the control unit **16**. When suction is activated medical gas flow continues from the medical gas source (not shown) into the main chamber **50** with any matter extracted from the patient through the endotracheal tube adaptor **12** and tubing component **14**, as shown in **Figure 5**. From the main chamber **50**, the medical gas and extracted matter move through the activated control apparatus **40** and through the suction port **44** into the suction tubing. In the embodiment of the control unit **16** shown in **Figures 1** through **4**, the control unit is constructed out of off the shelf components.

In the embodiment of the disclosure shown in **Figure 1**, the control apparatus **40** is an off-the shelf valve with the default state of the valve being closed. The control valve has an automatic return mechanism such that the valve is closed when no force is being applied to the button **54**. When a sufficient pushing force is applied to the button **54**, the control valve **40** opens and when said force ceases to act on the button **54**, the control valve **40** returns to the closed position.

The medical gas input port **42** attaches to the body **38** of the control unit **16** such that a medical gas supply tube is attachable to the medical gas input port **42** and medical gas is able to flow from a medical gas supply tube through the medical gas input port **42** into the main chamber **50**. In the embodiment shown in **Figure 3**, the medical gas input port is a rigid hollow tapering cone with external ridges to secure a medical gas supply tube around the rigid hollow tapering cone. The rigid hollow tapering cone is used as a male connector component for standard medical gas tubing.

The suction port **44** attaches to the body **38** of the control unit **16** such that a suction supply tube is attachable to the suction port and suction is able to

be supplied to the suction chamber **52** of the control unit **16**. The suction port enables the flow of matter and medical gas from the suction chamber **52** through the suction port **44** into the suction supply tube if the control apparatus **54** is activated. In the embodiment shown in **Figure 3**, the suction port is a rigid hollow tapering cone with external ridges to secure a suction supply tube around the rigid hollow tapering cone. The rigid hollow tapering cone is used as a male connector component for standard medical suction tubing.

The tubing component port **46** is attached to the body **38** such that the end of the tubing component **14** that is not attached to the endotracheal tube adaptor **12** is removably attached to the tubing component port **46**. The tubing component port **46** enables medical gas flow or suction to be conducted between the main chamber **50** of the control unit **16** and the tubing component **14**. In the embodiment shown in **Figure 3**, the tubing component port **46** is a rigid hollow tapering cone with external ridges to secure the tubing component **14** around the rigid hollow tapering cone.

The pressure release valve **48** is attached to the body **38** such that the valve opens if the pressure within the main chamber **50** is above a predetermined level. When the pressure release valve **48** is opened, any pressure throughout the tracheal intubation device **10** that is above the setting on the pressure release valve **48** is released. The pressure release valve **48** opens to release pressure within the tracheal intubation device **10** if the pressure within the system is at a dangerous level, decreasing the risk of barotrauma (tissue damage in the airway due to high pressure). It will be appreciated by those skilled in the art that a cap may be placed around the pressure release valve **48** to disable the pressure release valve **48**. By setting the flow of medical gas into the device at a level that leads to opening of the pressure release valve **48,** the device will also provide continuous positive airway pressure at a level determined by the setting of the pressure release valve **48**. This pressure release valve **48** may have a single pressure level at which it opens, or may be of an adjustable design to allow it to open at any selected pressure level within a range of pressures,
1 cm H_20 to 100 cm H_20, for example.

In an alternate embodiment of the endotracheal intubation device shown in **Figure 6**, there are no suction components, and the device is used only for

the delivery of medical gas flow. The endotracheal intubation device **56** consists of an endotracheal tube adaptor **58**, a tubing component **60** and a control unit **62**. The endotracheal tube adaptor **58** and the tubing component **60** of device **56** being the same as endotracheal tube adaptor **12** and tubing component **14** of the device **10** of **Figure 1**. Control unit **62** is similar to control unit **16**, however control unit **62** consists of a body **64**, a medical gas input port **66**, a tubing component port **68** and a pressure release valve **70**, and does not have any suction components or a control apparatus.

In **Figure 7** an alternate embodiment of the control unit is shown. This embodiment **72** consists of similar components to control unit **16**, the components being a body **74**, a medical gas input port **76**, a suction port **78**, a tubing component port **80** and a pressure release valve **82**. However, the control apparatus **84** of control unit **72** is a barrel and plunger mechanism. The barrel and plunger mechanism comprises a barrel **86** that is attached to the body **74** and has an opening **88** to the main chamber **90** of the control unit **72** and there is another opening **92** to the suction chamber **94** of the control unit **72**. The plunger **96** has a channel **98** running through it and the plunger is positioned within the barrel **86** with a spring **100** in one end of the barrel **86** between the barrel **86** and the plunger **96**. The plunger **96** is positioned within the barrel **86** such that the plunger cannot slide out of the barrel **86** and the spring **100** exerts a force on the plunger such that the default state of the control apparatus **84** is not activated. When a pushing force is exerted on the end of the plunger **96** without the spring **100**, the plunger **96** translates within the barrel **86** such that the channel **98** aligns with the openings **88** and **92**, giving the control apparatus **84** an activated state. If this force ceases to be exerted on the plunger **96** the spring **100** exerts a force on the plunger **96** translating the plunger **96** such that the channel **98** is not aligned with the channels **88** and **92**, returning the control apparatus **84** to a not activated state.

It will be appreciated by those skilled in the art that any other elastic object with a similar function to the spring **100** may be used so that the apparatus automatically returns to a default state. For example, sponge can be used instead of a spring. Alternatively, it will also be appreciated by those skilled in the art that the control apparatus **84** of the control unit **72** does not need an automatic return mechanism if it is not desirable.

In **Figure 8** another type of control unit is shown at **102**. This control unit **102** is comprised of similar components to control unit **16**, the components being a body **104**, a medical gas input port **106**, a suction port **108**, a tubing component port **110**, a pressure release valve **112** and a control apparatus. The control apparatus of control unit **102** is a channel selector mechanism **114**, such as but not limited to, a stopcock. The channel selector mechanism **114** allows either medical gas flow from the medical gas input port **106** through a medical gas chamber **116** or suction from the suction port **108** through a suction chamber **118** to communicate to the body chamber **120** of the control unit **102**. In unit **102**, when suction is engaged, gas flow is blocked from entering the body chamber **120** of the control unit **102**. The channel selector mechanism **114** ideally possesses a default state in which medical gas communicates to the body chamber **120** of the control unit **120**. Actively engaging the channel selector **114** allows suction to be communicated to the body chamber **120** while blocking medical gas flow. The channel selector **114** also ideally possesses an automatic return feature such that once the channel selector **114** is no longer actively engaged, the channel selector **114** returns to the default state in which medical gas is communicated to the body chamber **120** of the control unit **102**. The blockage of medical gas flow during the activation of suction prevents the medical gas flow from reducing the total suction force flowing through the body chamber of the device. If medical gas continued to flow through the body chamber simultaneously, the effective suction force, and therefore the ability to remove material, would be reduced. In a separate embodiment, the medical gas could be limited to a preselected flow rate, instead of fully blocking, to achieve a similar result.

It will be appreciated by those skilled in the art that any other channel selection feature with a similar function to a stopcock may be used so that the control apparatus automatically returns to a default state. Alternatively, it will also be appreciated by those skilled in the art that the channel selector of the control unit does not need an automatic return mechanism if it is not desirable.

In **Figure 9** an alternate embodiment of the control unit is shown. This embodiment **122** is comprised of similar components to control unit **in Figure 8**, the components being a body **124**, a medical gas input port **126**, a suction port **128**, a tubing component port, a pressure release valve **130** and a channel

selector mechanism **132**. However, in this embodiment, the body **124** houses two separate channels, one for medical gas **134** and one for suction **136**. As in **Figure 8**, the channel selector mechanism **132** allows only medical gas or suction to be engaged, but not both at once. Similar to the mechanism shown in **Figure 8**, the channel selector mechanism **132** shown in **Figure 9** ideally possesses a default state in which medical gas flow is engaged while suction is not engaged. When suction is engaged, gas flow is blocked from entering the medical gas channel **134** within the control unit **122**. Actively engaging the channel selector **132** allows suction to be communicated to the suction channel **136** within the body **122** while blocking medical gas flow to the medical gas channel **134** within the body **122**.

The channel selector **132** also preferably possesses an automatic return feature such that once the channel selector **132** is no longer actively engaged, the channel selector **132** returns to the default state in which medical gas flow is communicated to the medical gas channel **134** within the body and suction is blocked from communicating with the suction channel **136** within the body of the control unit. In this embodiment, the tubing component consists of two separate channels, one for medical gas flow **138** and one for suction **140**, and the tubing attachment **of** the endotracheal tube adaptor **is** different from tubing attachment **24**, such that it is compatible with the tubing component of the present embodiment**.** In the present embodiment, the medical gas tube and suction tube may be connected to form one dual channel tubing component**.** This dual channel tubing may consist of side-by-side channels, or one smaller diameter channel dwelling within one large diameter channel.

It will be appreciated by those skilled in the art that any other channel selection feature with a similar function to a stopcock may be used so that the apparatus automatically returns to a default state. Alternatively, it will also be appreciated by those skilled in the art that the channel selector of the control unit does not need an automatic return mechanism if it is not desirable.

In addition, it will be understood that the present tracheal intubation device may be produced without suction and the associated suction control, and instead provides only medical gas supply and its associated control unit.

Another tracheal intubation device **142** is shown in **Figure 10** in which the tracheal intubation device **142** is comprised of the endotracheal tube

adaptor **144**, the tubing component **146**, the endotracheal tube **148** and the intubation stylet **150** which are the same as the endotracheal tube adaptor **12**, the tubing component **14**, the endotracheal tube **28** and the intubation stylet **34** of the tracheal intubation device **10** shown in **Figure 1** respectively. The tracheal intubation device **142** uses a control unit **152** that is the same as control unit **72** shown in **Figure 7**.

An embodiment of the present disclosure is shown in **Figures 11** and **12** wherein the tracheal intubation device **142**. During intubation, the intubator inserts the intubation stylet **150** into the endotracheal tube **148** through the stylet accommodator **154** of the endotracheal tube adaptor **144** to make the endotracheal tube **148** sufficiently rigid such that the endotracheal tube is able to advance lower in the patient's airway instead of bending as it slides along airway surfaces. During intubation, a laryngoscope **156** is used to generate a view of the airway this occupies one of the intubator's hands. The intubator holds the endotracheal tube with stylet with his or her other hand to manipulate the endotracheal tube toward the patient's vocal cords. Suction may be operated by an assistant who is positioned with the control unit such that the intubator is able to easily manipulate the endotracheal tube, as shown in **Figure 12**.

In an alternate embodiment of the disclosure, the tracheal intubation device may be included in a portable unit **158** with stand-alone medical gas and suction supplies, as shown in **Figure 13A**. In this embodiment **158**, the medical gas supply **160** and suction supply **162** are housed in a portable case **164** with the tracheal intubation device **166** and an optional laryngoscope. This portable unit **158** enables one to perform an intubation in an area where separate medical gas and suction supplies are not otherwise available. In this portable unit **158** the endotracheal tube adaptor **168**, tubing component **170** and control unit **172** of tracheal intubation device **166** are the same as endotracheal tube adaptor **12**, tubing component **14** and control unit **16** of tracheal intubation device **10** respectively. **Figure 13B** shows the portable unit **158** closed and ready for transport.

Another embodiment of the system is shown in **Figures 14A** to **20B**. A hand operated control unit **200**, shown in **Figures 14A** and **14B**, generally

comprises a body **202**, a control apparatus **204**, and a pressure limiting device **206** (such as but not limited to an adjustable medical pressure relief valve **206).**

A medical gas input port **208** and suction input port **210** are connected to the control apparatus **204,** shown in **Figure 14B**. Internal connectors **212** are connected to the control apparatus **204** and press-fit into the body **202**. A lid **214** slides into the body **202** to contain the control apparatus **204** and a button cap **216** is press-fit to the spring-loaded button **218** of the control apparatus **204**. A pressure limiting device **206** is press-fit into the device body **202.** A suction output port **220**, exhaust port **222**, and medical gas output port **224** are integrated in the body **202** and are best shown in **Figures 15A** and **15B**. The exhaust port **222** directs either medical gas or suction to atmosphere, depending on the state of the control apparatus **204**. The exhaust port is protected from an operator with an extension **226** of the body **202,** best shown in **Figures 15A** and **15B**. Finger grip cutouts **228** enable comfortable grasping of the device body **202** by an operator. The suction output port **220,** exhaust port **222**, and medical gas output port **224** are located toward the rear and bottom of the device body **202** for the same purpose.

The control apparatus **204** is an off-the-shelf spring-return 5-way valve with two input ports **240** and **242,** and three output ports **244, 246,** and **248**, shown in **Figure 16A.** In the default state, or non-activated state, the input port **240** is directed to output port **246**, and input port **242** is directed to output port **248.** The output port **244** is idle. In the activated state, input port **240** is directed to output port **244**, and input port **242** is directed to output port **246.** The output port **248** is idle.

Shown in **Figure 16B** is a medical gas input port **208** is attached to input port **242**, and a suction input port **210** is attached to input port **240** on the control apparatus **204.** Internal pipe connectors **212** are connected to output ports **244, 246,** and **248** on the control apparatus **204**. The control apparatus **204** assembled with internal pipe connectors **212** is press-fit into the body **202,** with an airtight seal formed between the internal pipe connectors **212** and internal body channels **250, 252,** and **254** shown in **Figure 17A**.

Control apparatus **204** output port **244** is connected to internal body channel **250** via an internal pipe connector **212,** control apparatus **204** output port **246** is connected to internal body channel **252** via an internal pipe

connector **212,** and control apparatus **204** output port **248** is connected to internal body channel **254** via an internal pipe connector **212,** as shown in **Figure 17B.** The internal body channels **250, 252,** and **254** are integrated into the body of the device **202** and direct medical gas and suction flow.

Figures 18A and **18B** show the medical gas and suction flow channels internally in the device body. Separate, dedicated suction and medical gas channels within the control unit **200** allow for the connection to separate, dedicated tubing for medical gas and suction lines. Compared to a single channel for both medical gas and suction, such as the embodiment shown in **Figure 1**, this configuration avoids the requirement for suctioned material to pass through the device before medical gas is supplied to the patient; medical gas can be delivered immediately once suction is no longer required.

The control apparatus **204** enables an operator to switch from medical gas supply to on-demand suction. The device is configured to deliver medical gas when in the non-activated state. As shown in **Figure 18A**, when the control apparatus **204** is not activated, a medical gas source (not shown) is connected to medical gas input port **208** and flows via dedicated medical gas channel **254** inside the device body **202.** The medical gas enters the main chamber **260** which is directly connected to the pressure limiting device **206** via press-fit. The medical gas exits the main chamber **260** via a medical gas channel **262** to the output port **224.** If the local pressure inside the chamber **260** exceeds the current setting of the pressure limiting device **206**, excessive pressure will vent to the atmosphere via a spring-loaded vent mechanism located in the pressure limiting device **206**. In this non-activated state, a suction source (not shown) is connected to the suction input port **210** and suction is diverted to the exhaust channel **252** and to atmosphere via exhaust port **222.**

The body extension **226** protects an operator from unintentionally preventing suction flow from entering the exhaust port **222.** The dedicated suction channel **250** and suction output port **220** are idle in this non-activated configuration, and only medical gas is delivered to the patient.

In the activated configuration shown in **Figure 18B**, the control apparatus **204** is activated via the spring-loaded control unit button **218**. The activated configuration alters the internal configuration of the control apparatus **204** and diverts medical gas from the medical gas input port **208** to the exhaust channel

252, where it is vented to atmosphere at exhaust port **222**. The extension **226** protects the operator from unintentionally blocking the medical gas venting from exhaust port **222.** The suction force enters the device at suction input port **210** and flows through dedicated suction channel **250** inside the device body **202** and continues to the suction output port **220.** In a separate embodiment, the medical gas could be limited to a preselected flow rate to avoid reducing the effective suction force flowing through the endotracheal tube, without venting medical gas to atmosphere.

An embodiment of the present disclosure is shown in **Figure 19** at **270**, in which the endotracheal tube adapter **12**, the same as described by **Figure 1**, is included with a control unit **200** and tubing **272, 274, 276,** and **278**. Standard medical gas tubing **272** conducts medical gas flow between the source (not shown) and the control unit **200**. The medical gas tubing **272** is connected to the control unit **200** via medical gas input port **208**. Standard suction tubing **274** conducts suction between the source (not shown) and the control unit **200**. The suction tubing **274** is connected to the control unit **200** via suction input port **210**. Standard medical gas tubing **276** conducts medical gas between the control unit **200** medical gas output **224** and flow Y-junction **280**. Suction tubing **278** conducts suction between the control unit **200** suction output port **220** and flow Y-junction **280.**

Shown in **Figure 20A** and **20B**, the flow Y-junction **280** connects via press-fit of the flow Y-junction output **294** to the tubing port **24** of the body **18** of the endotracheal tube adapter **12.** The endotracheal tube adapter **12** functions as described in **Figure 1**. A standard medical gas connector **292** and standard suction connector **290** are integrated in the flow Y-splitter **280, best shown in Figure 20B.** Suction tubing **278** attaches at one end to the suction connector **290** of the flow Y-junction **280** attached to the endotracheal tube adaptor **12** and attaches at the other end to the suction output **220** of the control unit **200**. The oxygen tubing **276** attaches at one end to the medical gas connector **292** of the flow Y-junction **280** attached to the endotracheal tube adaptor **12.** The flow Y-junction **280** converts the single channel of the endotracheal tube adapter **12** to dedicated medical gas and suction channels.

Shown in **Figure 20A**, a sealing cap **296** is press-fit into the top portion of the body **18** of the endotracheal tube adapter **12**. The sealing cap is

comprised of a plastic housing **298** with an embedded silicon gasket **300,** best shown in **Figures 21A** and **21B.** A stylet insertion opening **302** is a small puncture in the center of the silicon gasket **300** and provides an opening for the stylet **34** to be inserted into the endotracheal tube adapter **12**. The sealing cap **296** prevents any medical gas or suction leakage from the endotracheal adapter **12** during the insertion of the stylet **34**, and seals completely to prevent medical gas or suction leakage when the stylet is fully removed.

Ventilation includes both conventional and non-conventional modalities. Non-conventional modalities including but not limited to high frequency oscillation (HFO) in which delivered medical gas is rapidly moved back and forth to provide active inspiration and active expiration. The oscillation is achieved using mechanical methods such as a piston, membrane, flow interrupter, or switching valves. Non-conventional modalities also include high or low frequency jet ventilation, in which high pressured medical gas is intermittently delivered by means of flow interruption. High frequency jet ventilation achieves flow interruption by mechanical methods such as solenoid valves, fluidic or rotating valves, and other pneumatically or electronically controlled devices. Low frequency jet ventilation is typically achieved by hand-triggered flow interruption devices. The control unit of the present airway device for delivering medical gas to a patient can be readily modified to operate in these non-conventional modalities. For example, the present control unit may be modified as disclosed above to deliver gas in any of these non-conventional modalities.

In an embodiment the present disclosure provides an airway access device configured to be coupled to a patient's airway and which comprises;

an airway access device adaptor connected to and in flow communication with the airway access device;

a medical gas input control unit including a housing having first and second ends, the second end of said control united being connected to the airway access device adapter, the control unit including a medical gas supply coupling located at the first end of the housing connectable to a source of medical gas, a pressure limiting device located downstream of the medical gas supply coupling, and wherein the pressure limiting device is configured to limit

medical gas flow upon a pressure of medical gas in the pressure limiting device exceeding a preselected threshold pressure; and

the airway access device adapter is configured to form a gas tight seal with the airway access device when coupled to said airway access device.

In an embodiment the device medical gas input control unit further comprises a suction supply coupling located at the first end of the housing and being connectable to a source of suction, and the control unit may include a hand-operated control mechanism for controlling both suction and medical gas flow.

In an embodiment the hand-operated control mechanism is a finger activated switch for switching between the source of suction and the source of medical gas, and the control unit may be configured such that when the finger activated mechanism is not activated, medical gas flows to the airway access device, and when activated the medical gas flow is stopped and suction is applied to the airway access device, so that medical gas and suction cannot be provided at the same time.

In an embodiment the hand-operated control mechanism is a finger activated switch for switching between the source of suction and the source of medical gas and the control unit may be configured such that when the finger activated mechanism is not activated, medical gas flows to the airway access device, and when activated the medical gas flow is reduced to a preselected flow rate and suction is simultaneously applied to the airway access device, so that medical gas and suction are provided at the same time.

In an embodiment the airway access device adaptor is connected to, and in flow communication with, the airway access device by means of elongate flexible tubing.

In an embodiment the pressure limiting device is any one of a pressure relief valve, a pressure regulating valve, a rupture disc, an aperture, or a breather vent.

In an embodiment the airway access device is any one of an endotracheal tube, Laryngeal mask airway, tracheostomy tube, nasopharyngeal airway or tube, oropharyngeal tube, cricothyrotomy tube, and the like.

In an embodiment the present disclosure also provides an airway device for delivering medical gas to a patient, comprising:

an airway access device configured to be coupled to a patient's airway;

an airway access device adaptor connected to and in flow communication with the airway access device;

a medical gas input control unit including a housing having first and second ends, the second end of said control united being connected to said airway access device adapter, the control unit including a medical gas supply coupling located at said first end of the housing connectable to a source of medical gas, a pressure limiting device located downstream of the medical gas supply coupling, and wherein the pressure limiting device is configured to limit medical gas flow upon a pressure of medical gas in the pressure limiting device exceeding a preselected threshold pressure;

a suction supply coupling located at the first end of the housing and being connectable to a source of suction, the control unit including a hand-operated control mechanism for controlling both suction and medical gas flow; and

the airway access device adapter being configured to form a gas tight seal with the airway access device when coupled to the airway access device.

In an embodiment the hand-operated control mechanism is a finger activated switch for switching between the source of suction and the source of medical gas, the control unit being configured such that when the finger activated mechanism is not activated, medical gas flows to the airway access device, and when activated the medical gas flow is stopped and suction is applied to the airway access device, so that medical gas and suction cannot be provided at the same time.

In an embodiment the hand-operated control mechanism is a finger activated switch for switching between the source of suction and the source of medical gas, the control unit being configured such that when the finger activated mechanism is not activated, medical gas flows to the airway access device, and when activated the medical gas flow is reduced to a preselected flow rate and suction is simultaneously applied to the airway access device, so that medical gas and suction are provided at the same time.

In an embodiment the airway access device adaptor is connected to, and in flow communication with, the airway access device by means of elongate flexible tubing.

In an embodiment the pressure limiting device is any one of a pressure relief valve, a pressure regulating valve, a rupture disc, an aperature, or a breather vent.

In an embodiment the airway access device is any one of an endotracheal tube, Laryngeal mask airway, tracheostomy tube, nasopharyngeal airway or tube, oropharyngeal tube, cricothyrotomy tube, and the like.

In an embodiment the present disclosure provides an airway device for delivering medical gas to a patient, comprising:

an endotracheal tube having a first end configured to be inserted into a patient's airway and an opposed second end;

an endotracheal tube adaptor attached to the second end configured to have one end of an elongate flexible tube attached thereto; and

a hand operated medical gas input control unit including a housing having first and second opposed ends, a second end of the elongate flexible tube being connected to the second end of said housing, the control unit including a medical gas supply coupling connectable to a source of medical gas and a pressure limiting device located downstream of the medical gas supply coupling between said medical gas supply coupling and the first end of the housing, wherein the pressure limiting device is configured to vent the medical gas out of the housing upon a pressure of medical gas in the flexible tube exceeding a preselected threshold pressure and

the endotracheal tube adapter configured to form a gas tight seal with said endotracheal tube when coupled to said airway access device.

In this embodiment the medical gas input control unit further comprises a suction supply coupling located at the first end of the housing and being connectable to a source of suction, the control unit including a hand-operated control mechanism for controlling both suction and medical gas flow.

In this embodiment the pressure limiting device is a pressure relief valve is located adjacent to the second end of the housing with the medical gas supply coupling being located between said pressure relief valve and said suction supply coupling.

In this embodiment the suction supply coupling is located adjacent to the first end of the housing, and wherein the medical gas supply coupling is located adjacent to the second opposed end, and wherein said pressure limiting device

is a pressure relief valve located between the medical gas supply coupling and the suction supply coupling.

In summary, the present disclosure provides an airway device for delivering medical gas to a patient and suction, ideally but not exclusively intended for the delivery of apneic oxygenation (or other medical gas), with a pressure relief valve for protection from high pressure. The device includes an intubation stylet and optional medical aspiration directly through an endotracheal patient tube during intubation, without need for a bendable soft catheter. The patient end allows for connection to a standard endotracheal tube connector and the devices includes a self-sealing port at the patient end which allows for the application of an intubation stylet while maintaining airflow with minimal leakage. The patient end of the device and the control unit for controlling medical gas flow and suction are separated by semi-rigid or flexible tubing. The control unit includes a port for the application of standard small bore medical gas tubing that allows for the delivery of apneic oxygenation during insertion of the endotracheal tube into the patient's airway. The control unit includes a pressure release valve that protects the patient airway from high pressures. The control unit further includes a plunger switch that can be engaged by the clinician to provide access medical aspiration directly to the endotracheal tube. The control unit also includes a port that can be connected to standard suction tubing to regulated suction.

It will be understood that while the present device has been described and illustrated as being configured for providing oxygen during the apneic portion of intubation with an endotracheal tube, this device may have other applications. It is essentially a device that allows and controls flow of medical suction and medical gas (that may or may not be oxygen) to an airway device (that may or may not be an endotracheal tube).

The foregoing description of the preferred embodiments of the disclosure has been presented to illustrate the principles of the disclosure and not to limit the disclosure to the particular embodiment illustrated. It is intended that the scope of the disclosure be defined by all of the embodiments encompassed within the following claims and their equivalents.

THEREFORE WHAT IS CLAIMED IS:

1. An airway device for delivering medical gas to a patient, comprising:

an airway access device configured to be coupled to a patient's airway;

an airway access device adaptor connected to and in flow communication with said airway access device;

a medical gas input control unit including a housing having first and second ends, said second end of said control united being connected to said airway access device adapter, said control unit including a medical gas supply coupling located at said first end of said housing connectable to a source of medical gas, a pressure limiting device located downstream of said medical gas supply coupling, and wherein said pressure limiting device is configured to limit medical gas flow upon a pressure of medical gas in the pressure limiting device exceeding a preselected threshold pressure; and

said airway access device adapter configured to form a gas tight seal with said airway access device when coupled to said airway access device.

2. The device according to claim 1 wherein said medical gas input control unit further comprises a suction supply coupling located at said first end of said housing and being connectable to a source of suction, said control unit including a hand-operated control mechanism for controlling both suction and medical gas flow.

3. The device according to claim 2 wherein said hand-operated control mechanism is a finger activated switch for switching between the source of suction and the source of medical gas, said control unit being configured such that when said finger activated mechanism is not activated, medical gas flows to the airway access device, and when activated the medical gas flow is stopped and suction is applied to the airway access device, so that medical gas and suction cannot be provided at the same time.

4. The device according to claim 2 wherein said hand-operated control mechanism is a finger activated switch for switching between the source of suction and the source of medical gas, said control unit being configured such

that when said finger activated mechanism is not activated, medical gas flows to the airway access device, and when activated the medical gas flow is reduced to a preselected flow rate and suction is simultaneously applied to the airway access device, so that medical gas and suction are provided at the same time.

5. The device according to any one of claims 1 to 4, wherein said airway access device adaptor is connected to, and in flow communication with, said airway access device by means of elongate flexible tubing.

6. The device according to any one of claims 1 to 5, wherein said pressure limiting device is any one of a pressure relief valve, a pressure regulating valve, a rupture disc, an aperture, or a breather vent.

7. The device according to any one of claims 1 to 6, wherein said airway access device is any one of an endotracheal tube, Laryngeal mask airway, tracheostomy tube, nasopharyngeal airway or tube, oropharyngeal tube, cricothyrotomy tube, and the like.

8. An airway device for delivering medical gas to a patient, comprising:

an airway access device configured to be coupled to a patient's airway;

an airway access device adaptor connected to and in flow communication with said airway access device;

a medical gas input control unit including a housing having first and second ends, said second end of said control united being connected to said airway access device adapter, said control unit including a medical gas supply coupling located at said first end of said housing connectable to a source of medical gas, a pressure limiting device located downstream of said medical gas supply coupling, and wherein said pressure limiting device is configured to limit medical gas flow upon a pressure of medical gas in the pressure limiting device exceeding a preselected threshold pressure;

a suction supply coupling located at said first end of said housing and being connectable to a source of suction, said control unit including a hand-

operated control mechanism for controlling both suction and medical gas flow; and

said airway access device adapter configured to form a gas tight seal with said airway access device when coupled to said airway access device.

9. The device according to claim 8 wherein said hand-operated control mechanism is a finger activated switch for switching between the source of suction and the source of medical gas, said control unit being configured such that when said finger activated mechanism is not activated, medical gas flows to the airway access device, and when activated the medical gas flow is stopped and suction is applied to the airway access device, so that medical gas and suction cannot be provided at the same time.

10. The device according to claim 8 wherein said hand-operated control mechanism is a finger activated switch for switching between the source of suction and the source of medical gas, said control unit being configured such that when said finger activated mechanism is not activated, medical gas flows to the airway access device, and when activated the medical gas flow is reduced to a preselected flow rate and suction is simultaneously applied to the airway access device, so that medical gas and suction are provided at the same time.

11. The device according to any one of claims 8 to 10, wherein said airway access device adaptor is connected to, and in flow communication with, said airway access device by means of elongate flexible tubing.

12. The device according to any one of claims 8 to 11, wherein said pressure limiting device is any one of a pressure relief valve, a pressure regulating valve, a rupture disc, an aperature, or a breather vent.

13. The device according to any one of claims 8 to 12, wherein said airway access device is any one of an endotracheal tube, Laryngeal mask airway, tracheostomy tube, nasopharyngeal airway or tube, oropharyngeal tube, cricothyrotomy tube, and the like.

14. An airway device for delivering medical gas to a patient, comprising:

an endotracheal tube having a first end configured to be inserted into a patient's airway and an opposed second end;

an endotracheal tube adaptor attached to said second end configured to have one end of an elongate flexible tube attached thereto; and

a hand operated medical gas input control unit including a housing having first and second opposed ends, a second end of said elongate flexible tube being connected to said second end of said housing, said control unit including a medical gas supply coupling connectable to a source of medical gas and a pressure limiting device located downstream of said medical gas supply coupling between said medical gas supply coupling and said first end of said housing, wherein said pressure limiting device is configured to vent the medical gas out of said housing upon a pressure of medical gas in the flexible tube exceeding a preselected threshold pressure and

said endotracheal tube adapter configured to form a gas tight seal with said endotracheal tube when coupled to said airway access device.

15. The device according to claim 14, wherein said medical gas input control unit further comprises a suction supply coupling located at said first end of said housing and being connectable to a source of suction, said control unit including a hand-operated control mechanism for controlling both suction and medical gas flow.

16. The device according to claim 15, wherein said pressure limiting device is a pressure relief valve is located adjacent to said second end of said housing with the medical gas supply coupling being located between said pressure relief valve and said suction supply coupling.

17. The device according to claim 15 wherein said suction supply coupling is located adjacent said first end of said housing, and wherein said medical gas supply coupling is located adjacent to said second opposed end, and wherein said pressure limiting device is a pressure relief valve located between said medical gas supply coupling and said suction supply coupling.

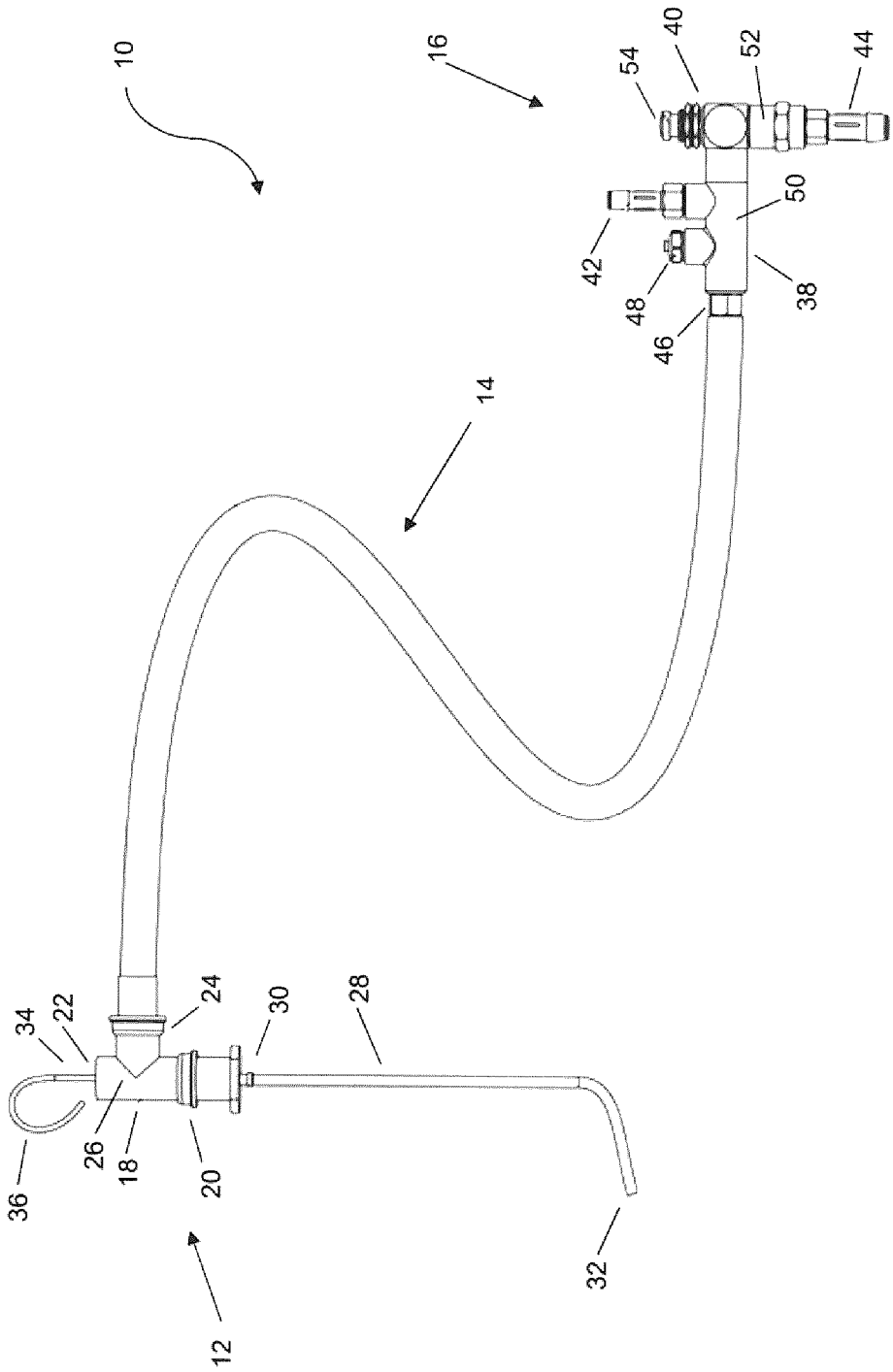


Figure 1

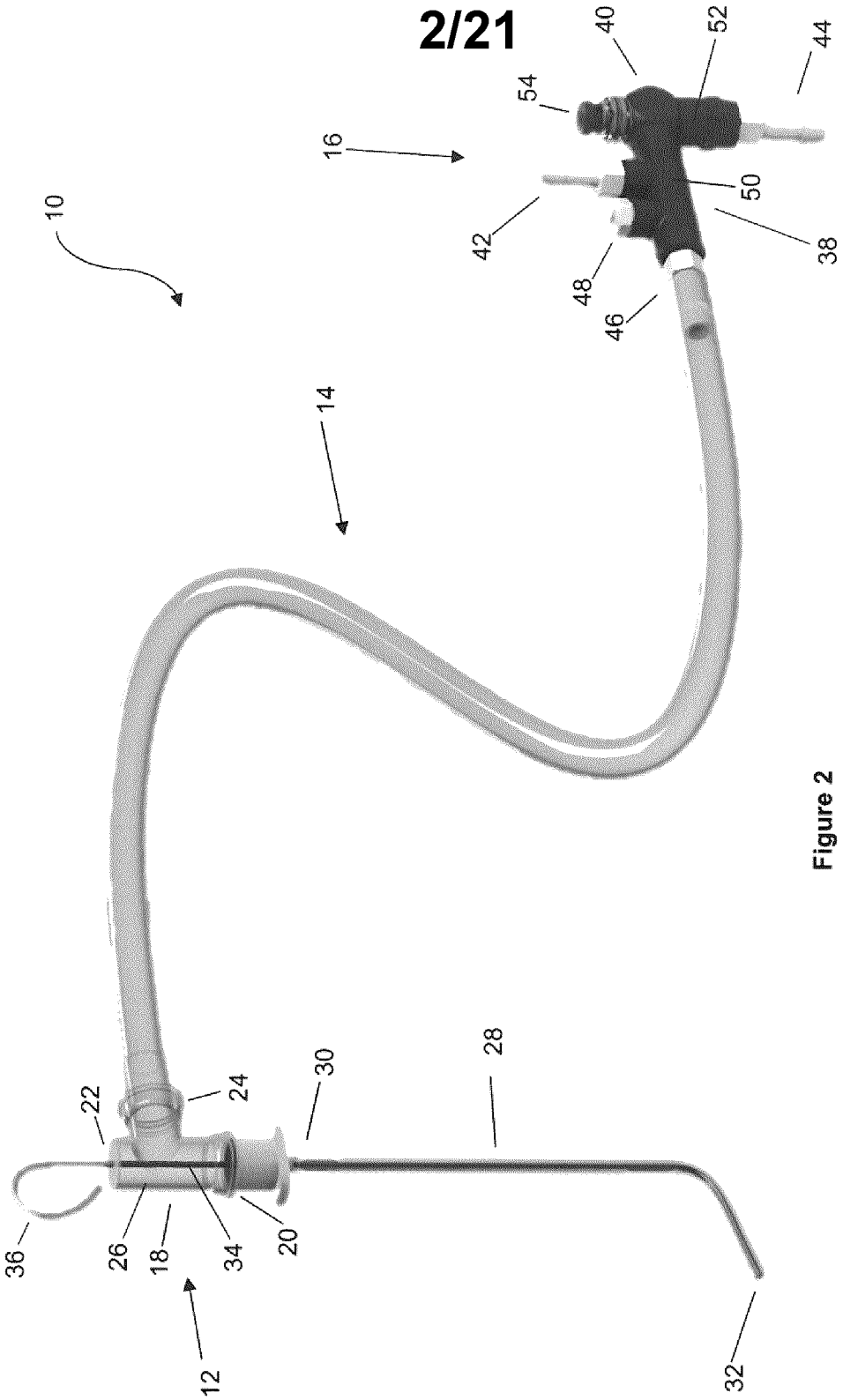
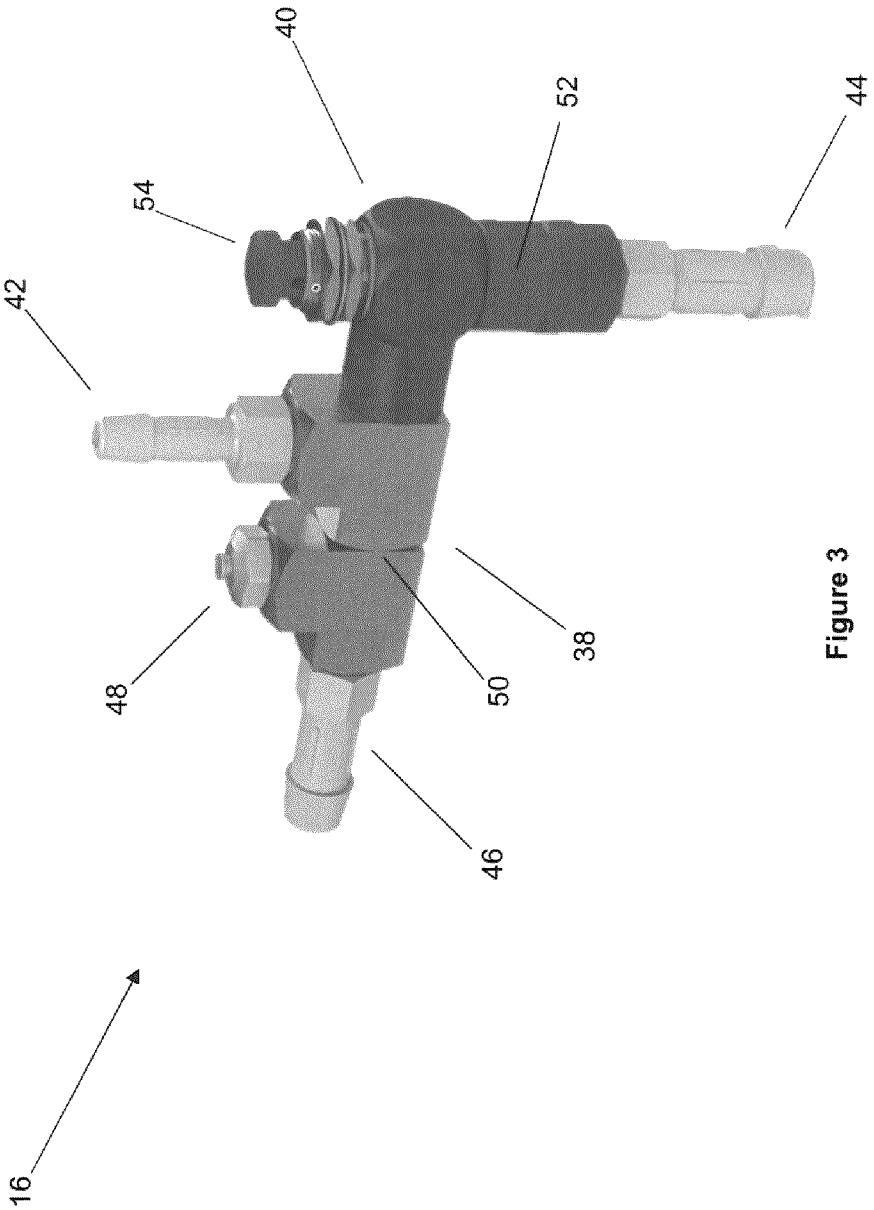


Figure 2



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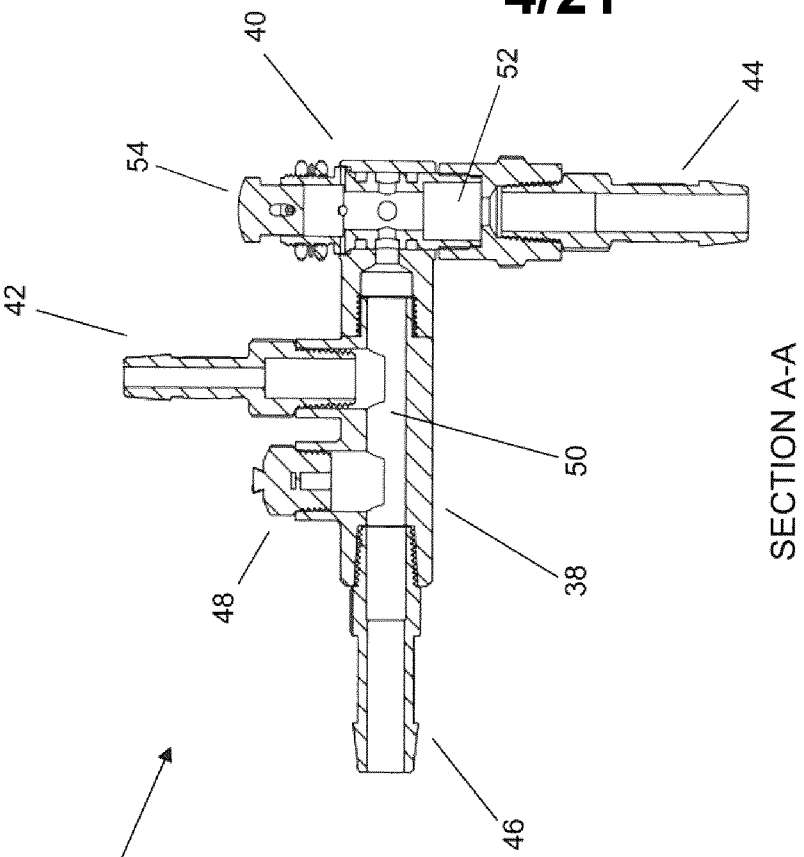


Figure 4B

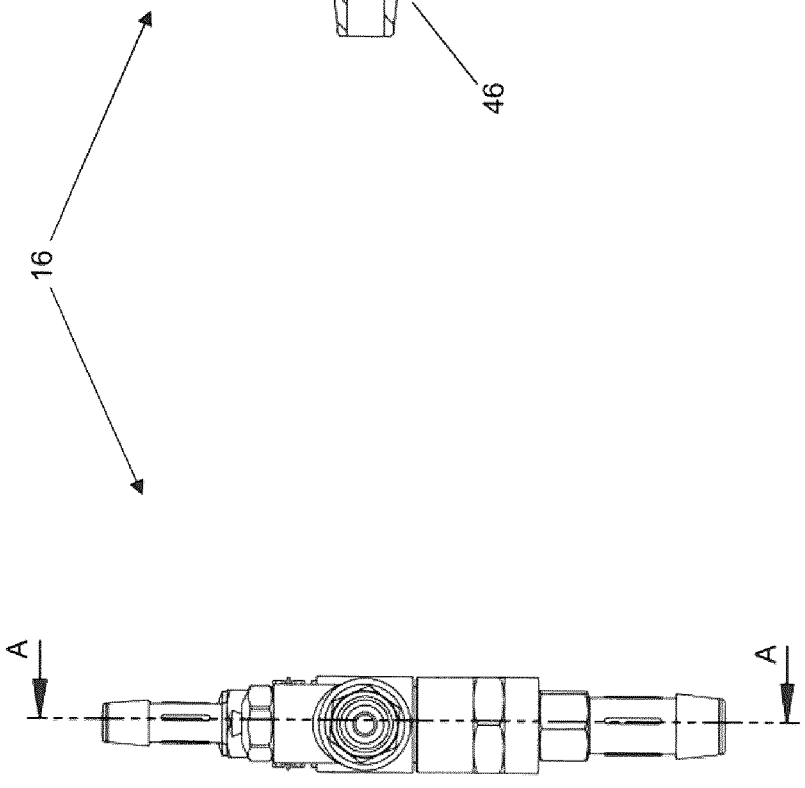


Figure 4A

5/21

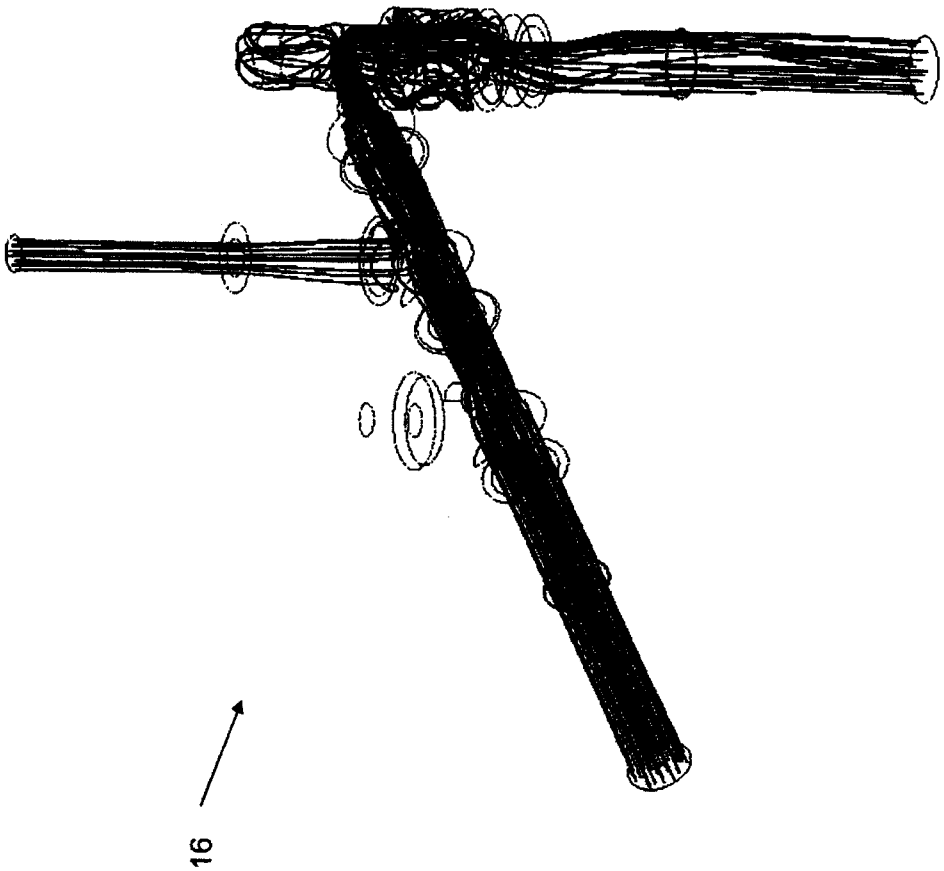
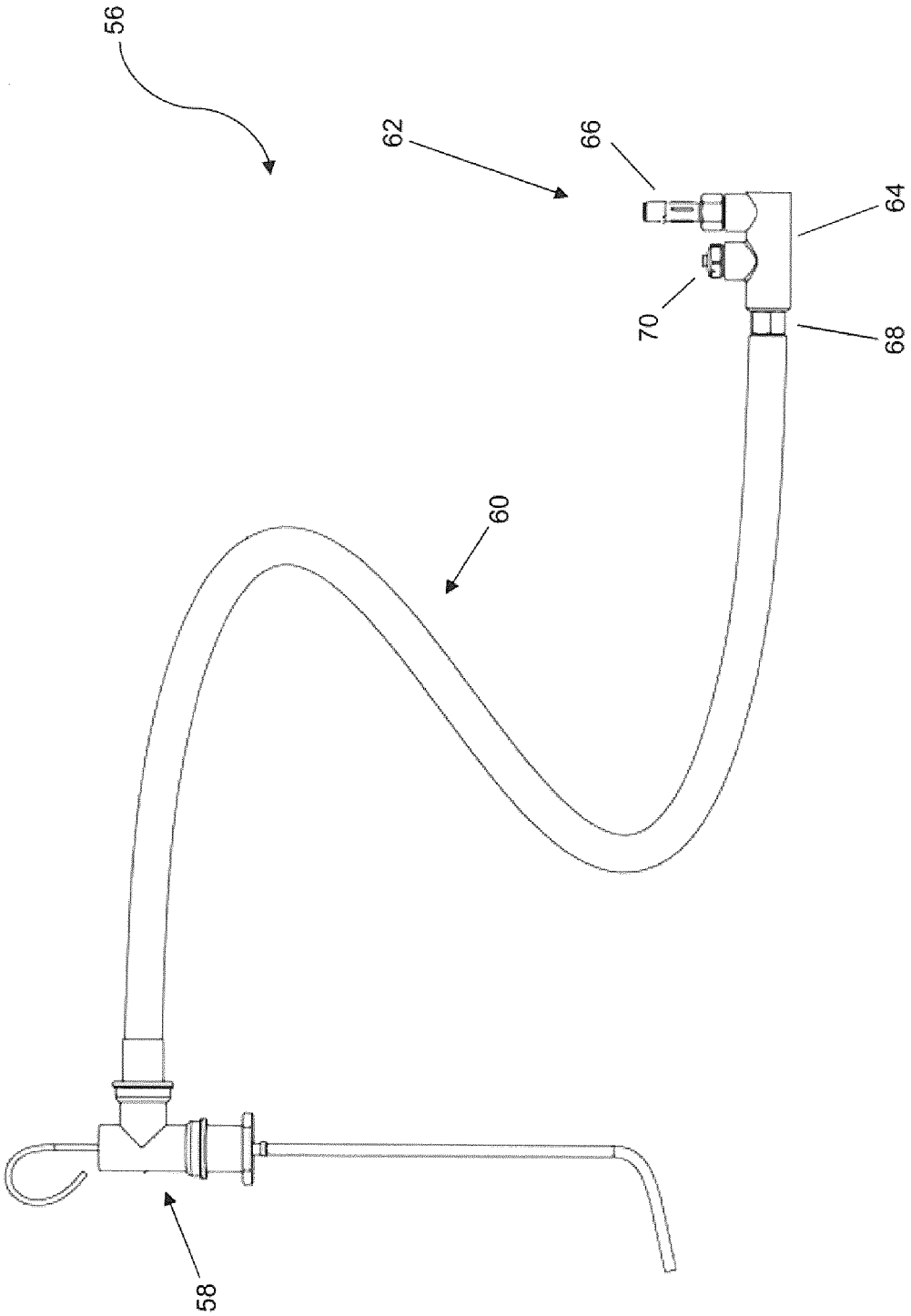


Figure 5



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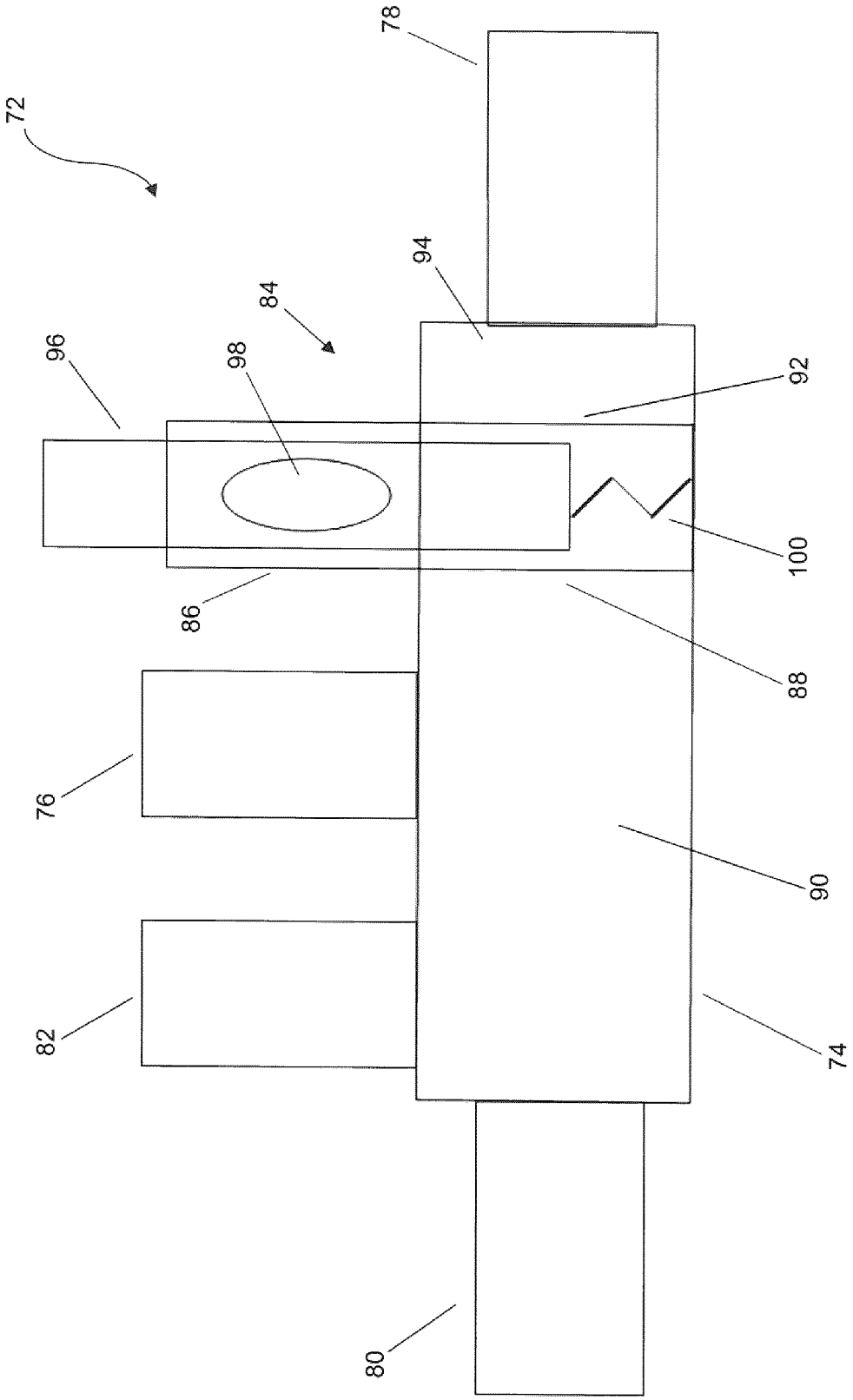

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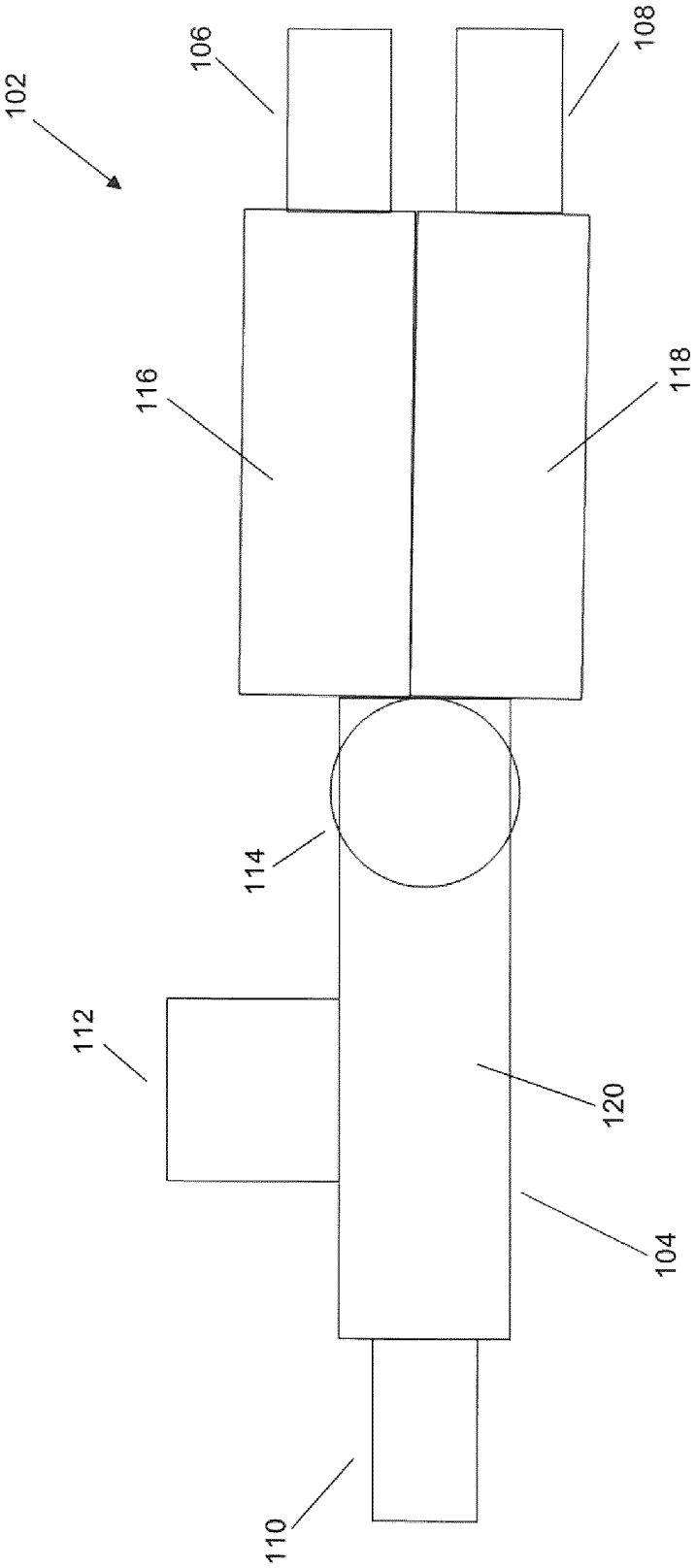


Figure 8

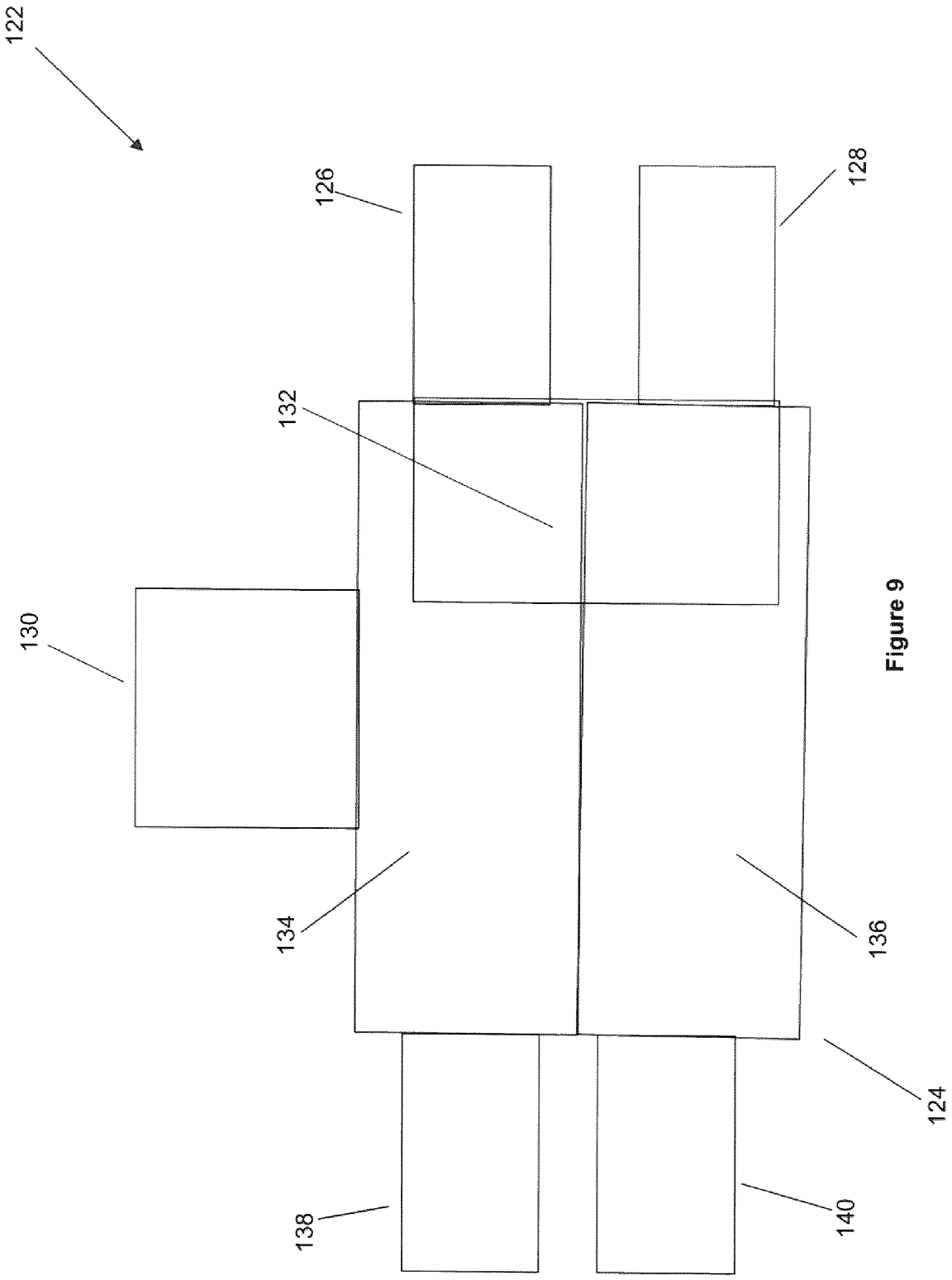


Figure 9

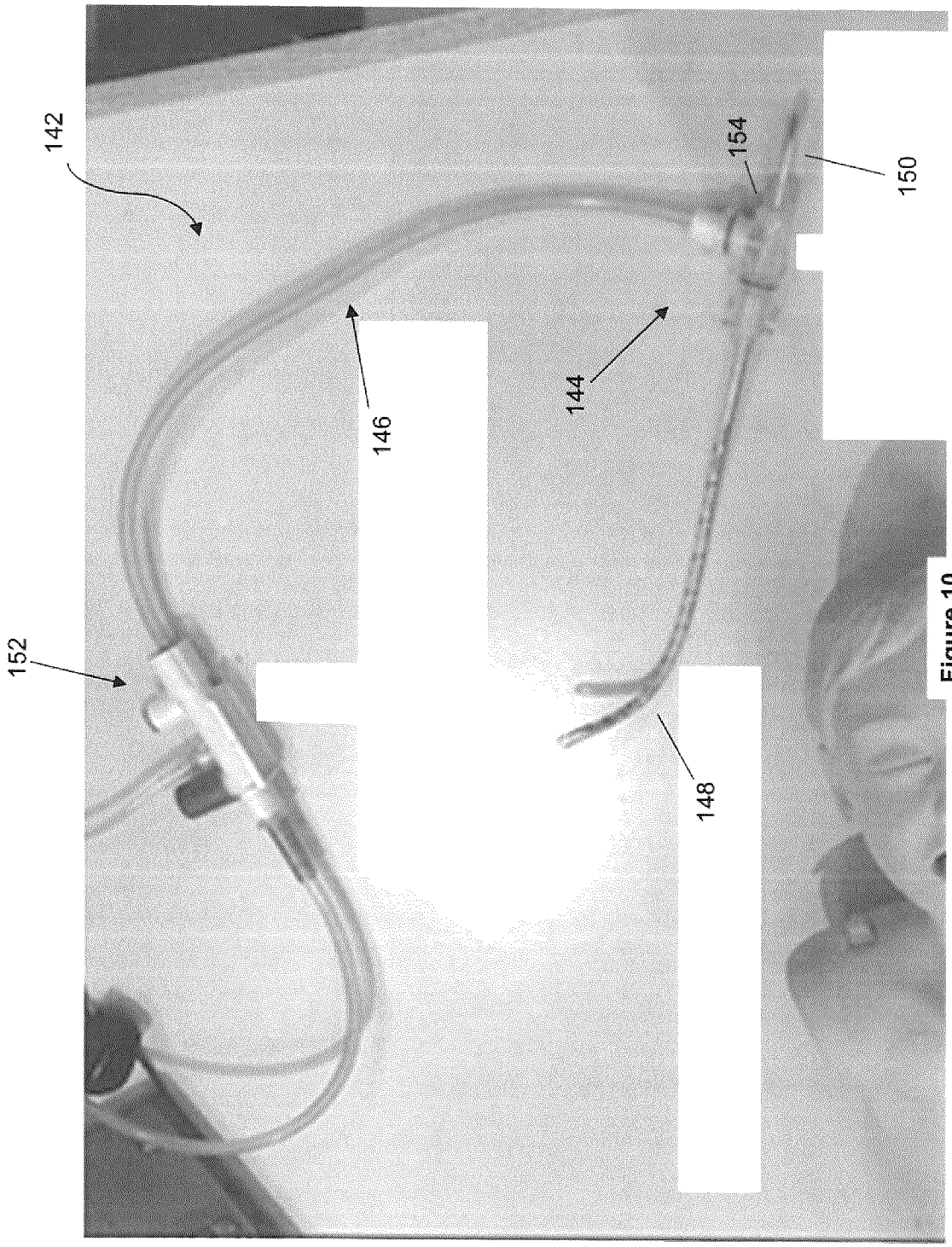


Figure 10

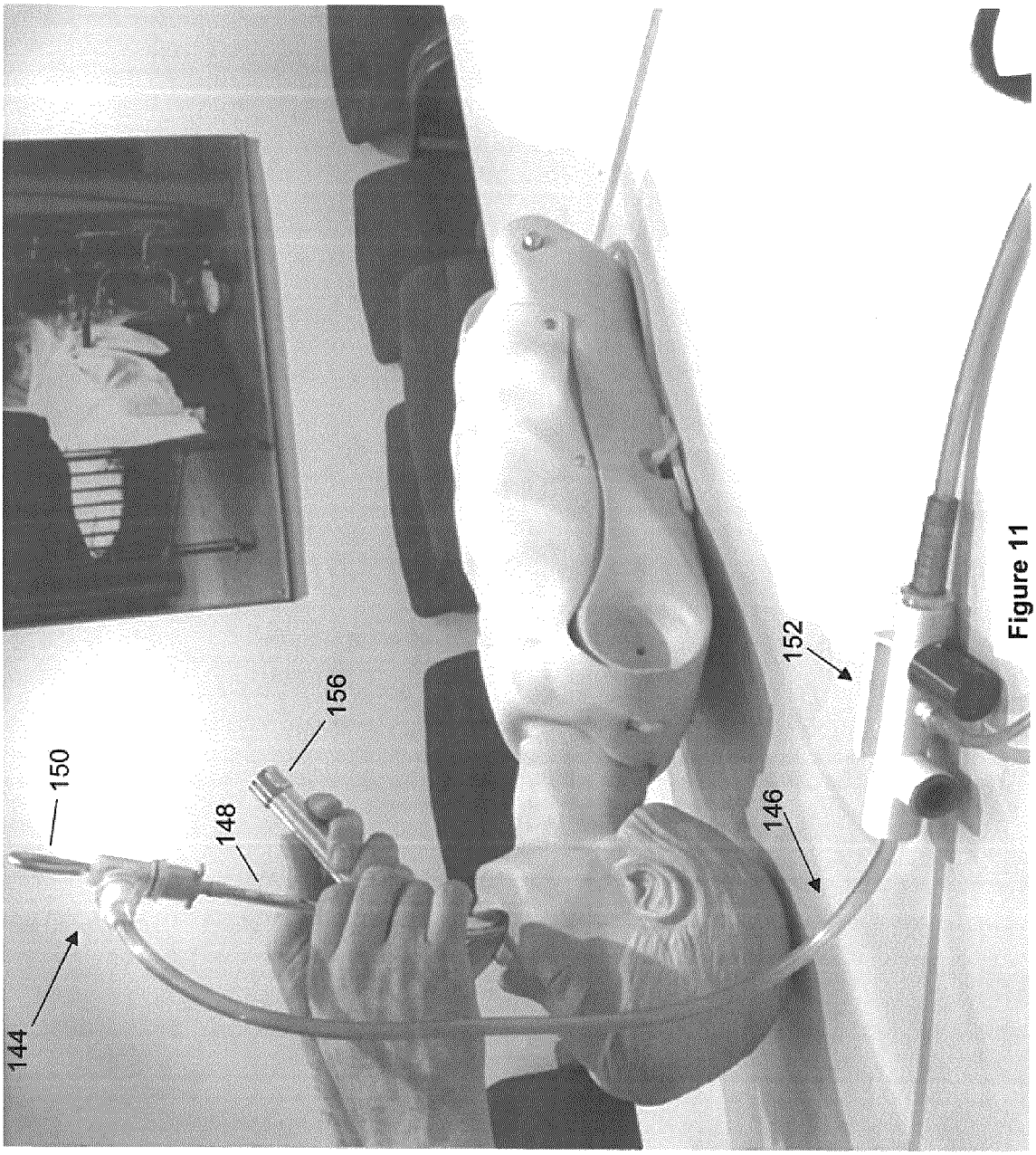


Figure 11

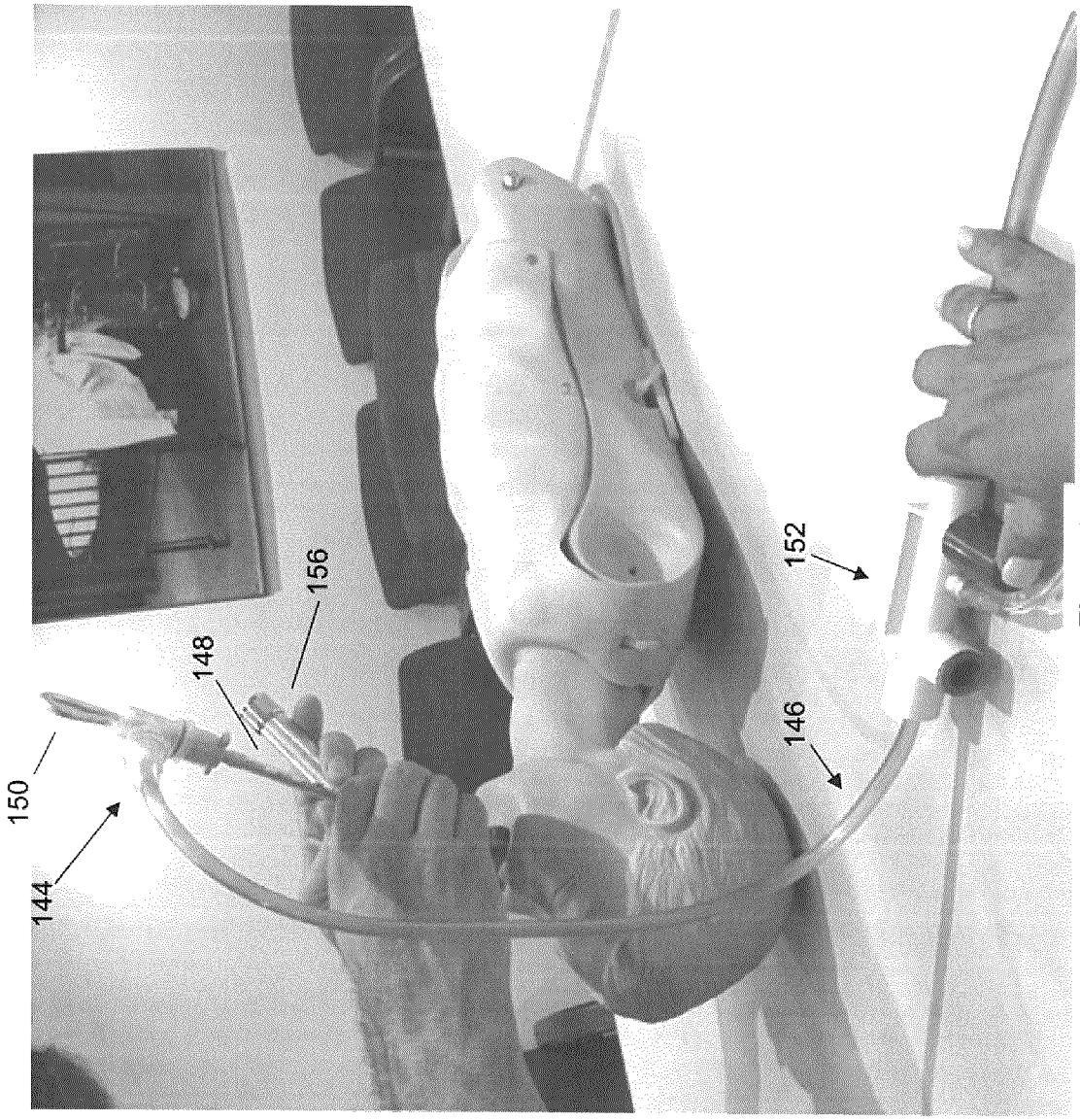


Figure 12

Figure 13B

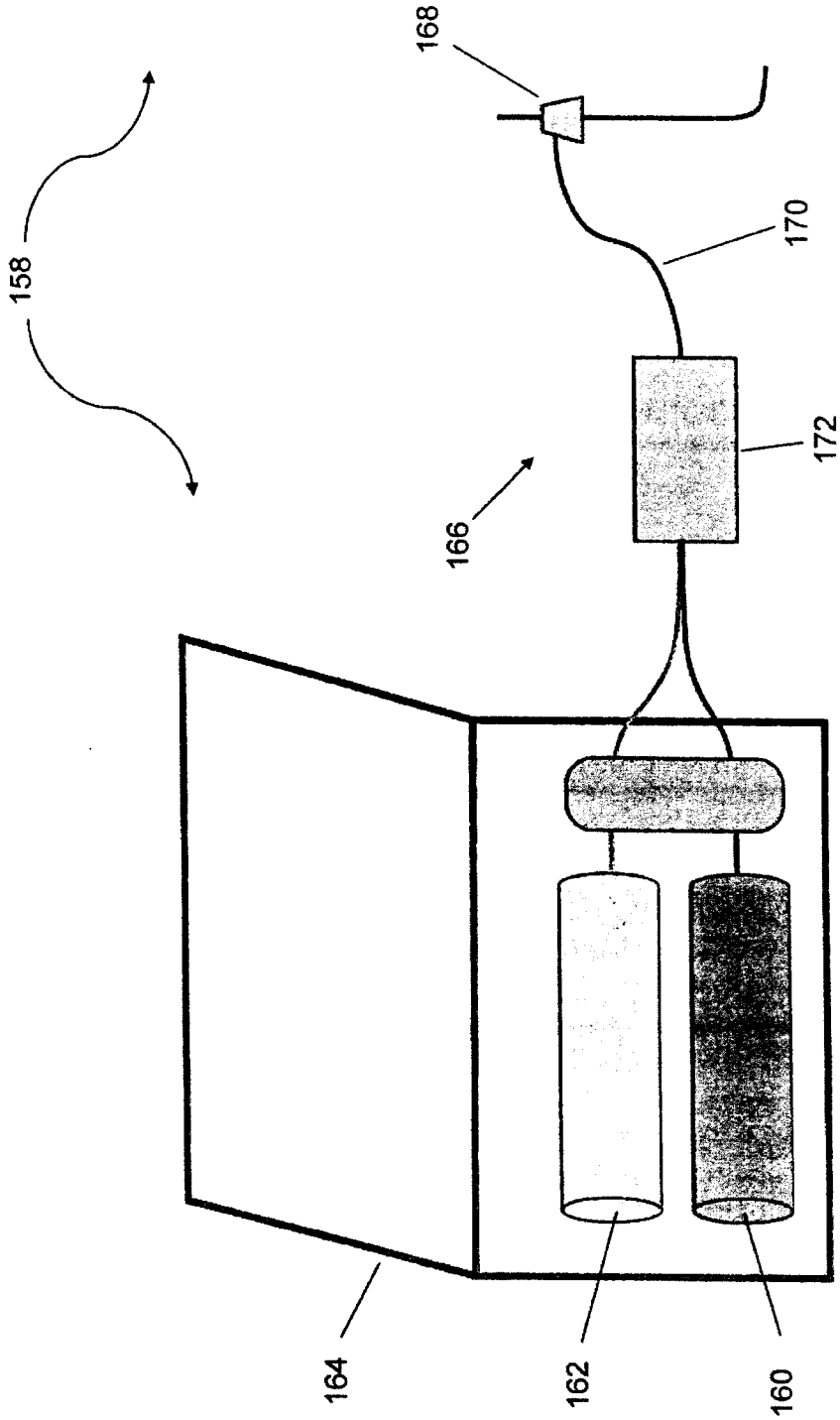


Figure 13A

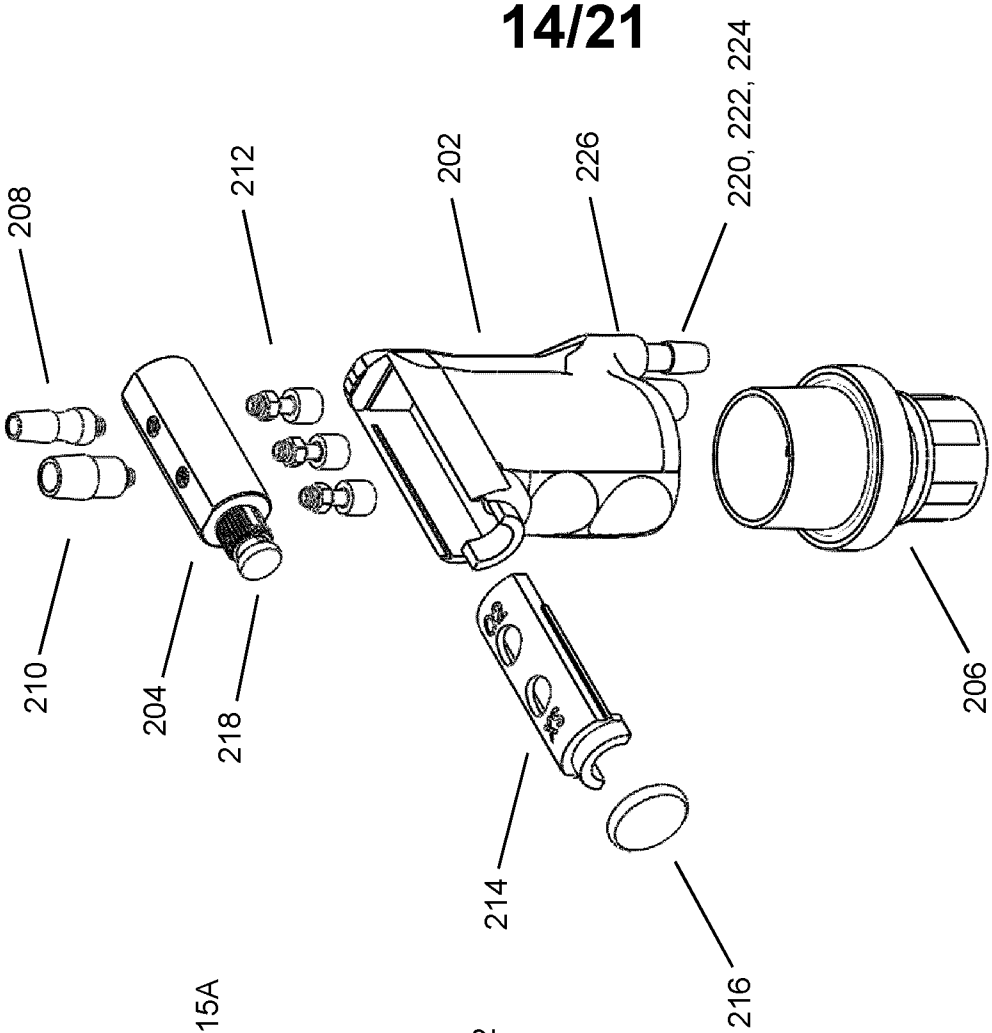


Figure 14B

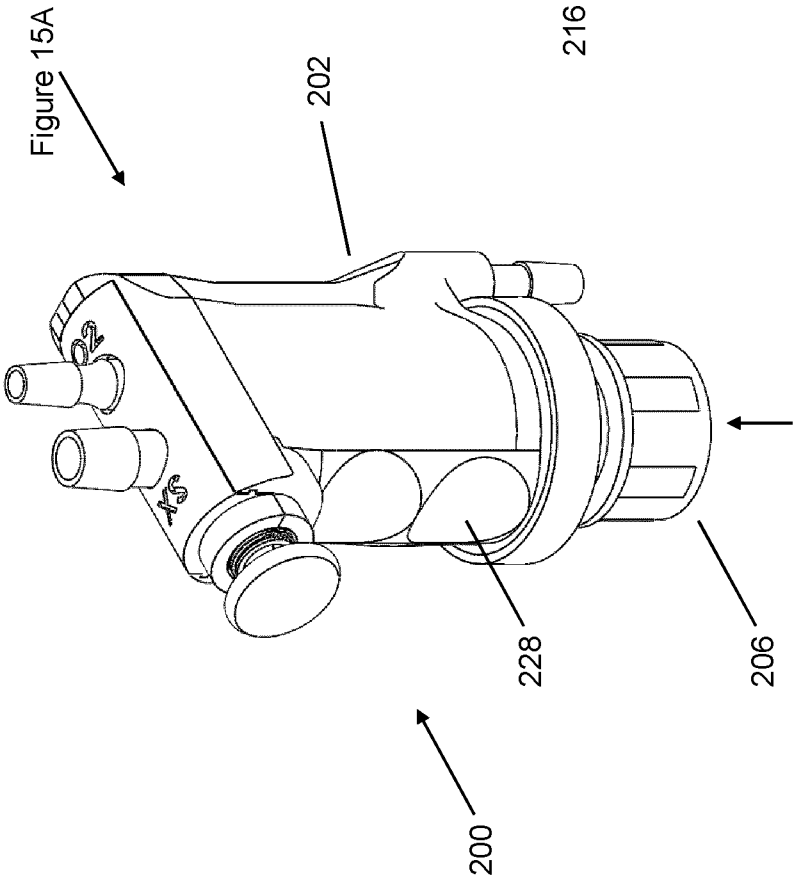
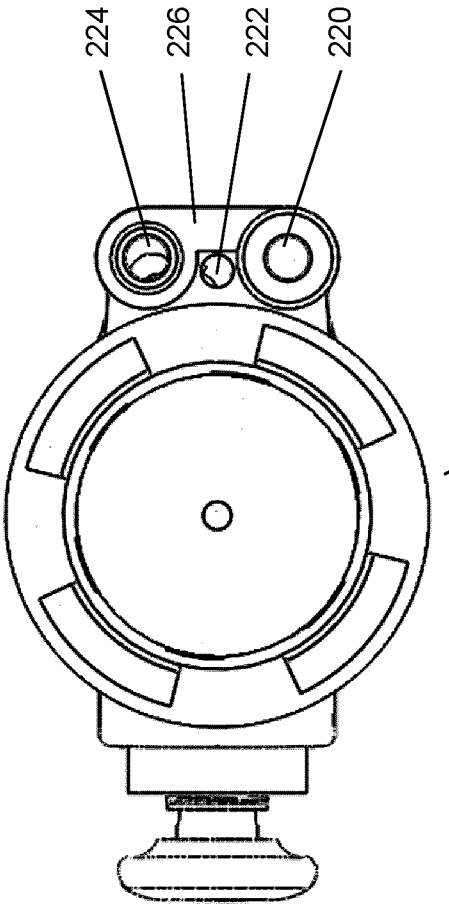
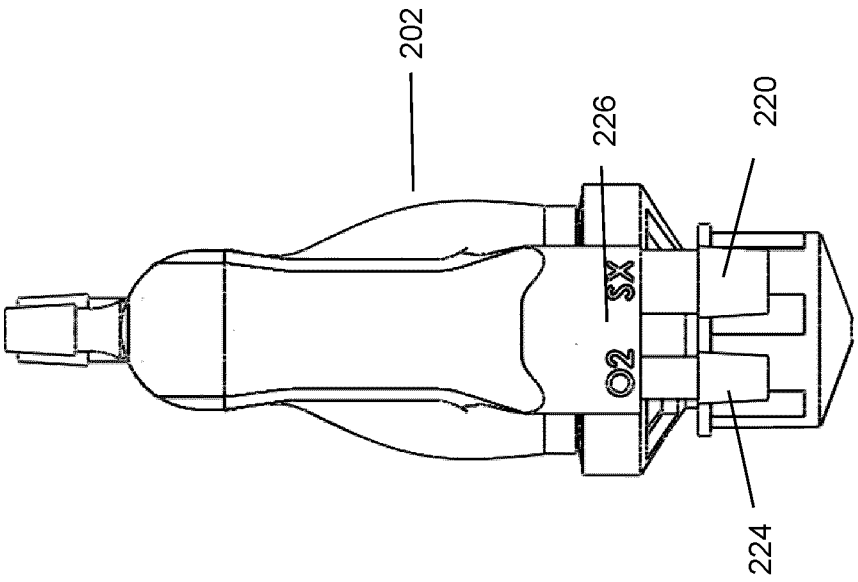


Figure 14A



Bottom View

Figure 15B



Rear View

Figure 15A

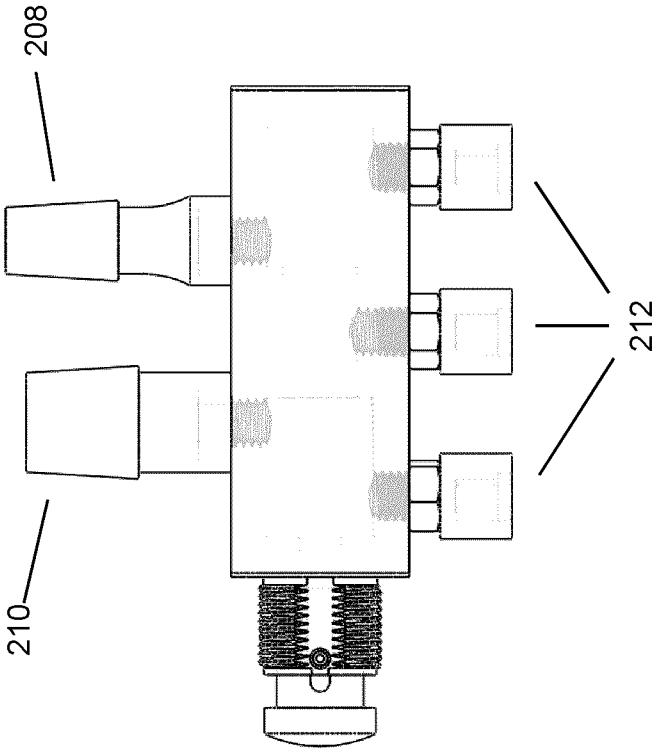


Figure 16B

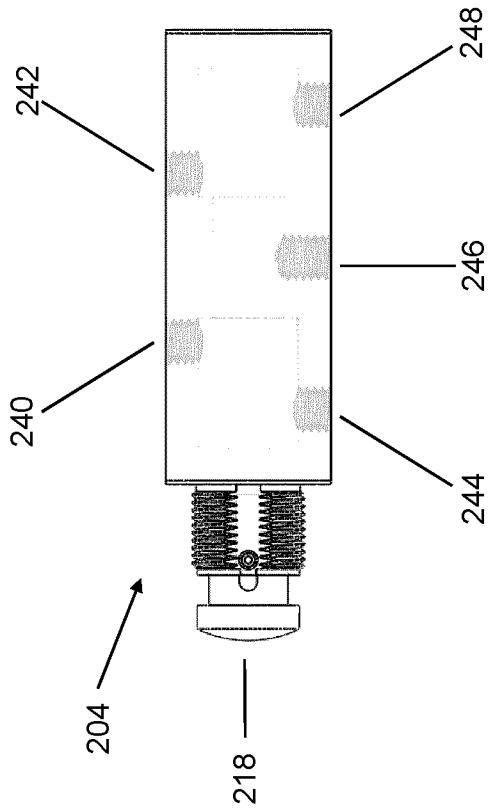


Figure 16A

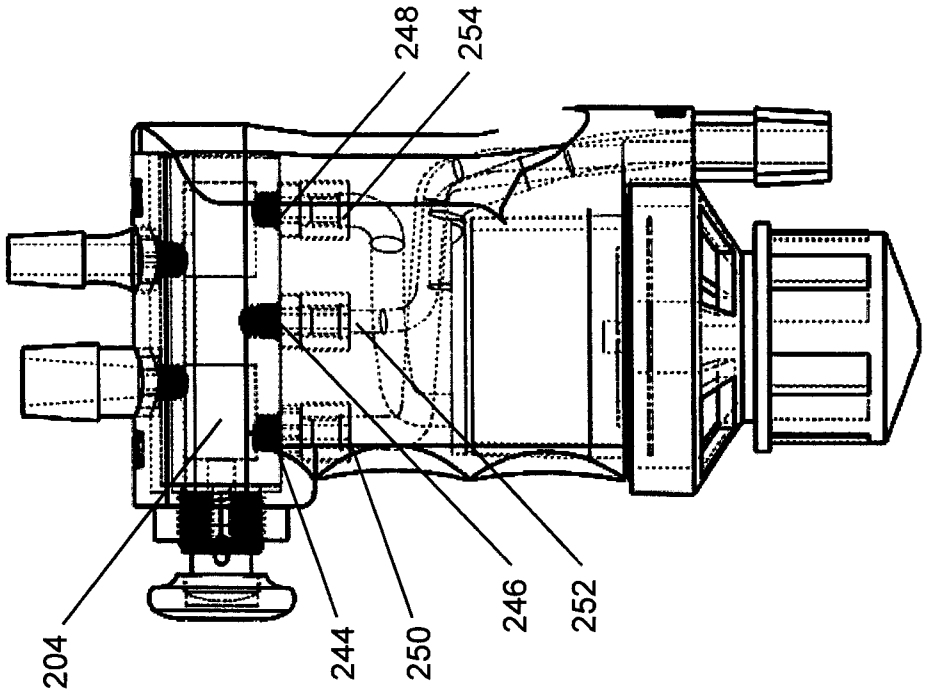


Figure 17B

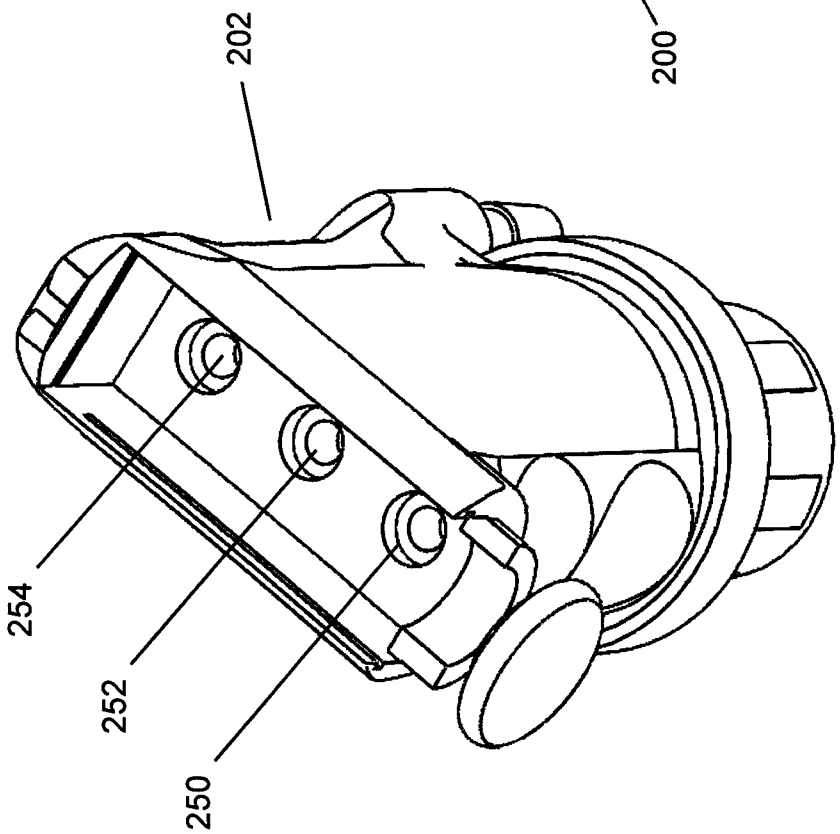


Figure 17A

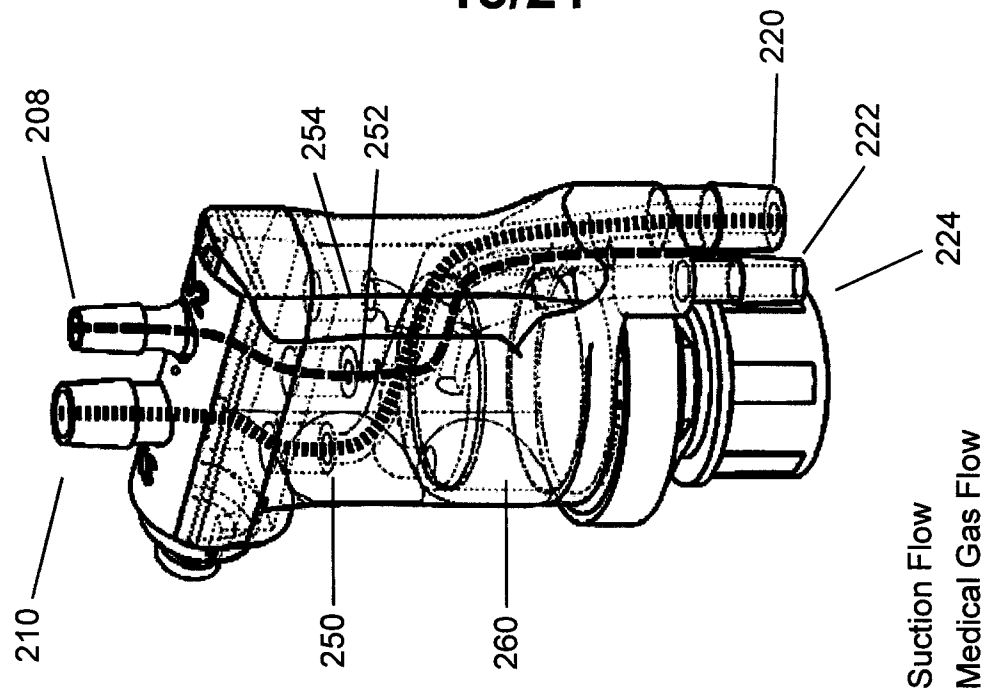


Figure 18B

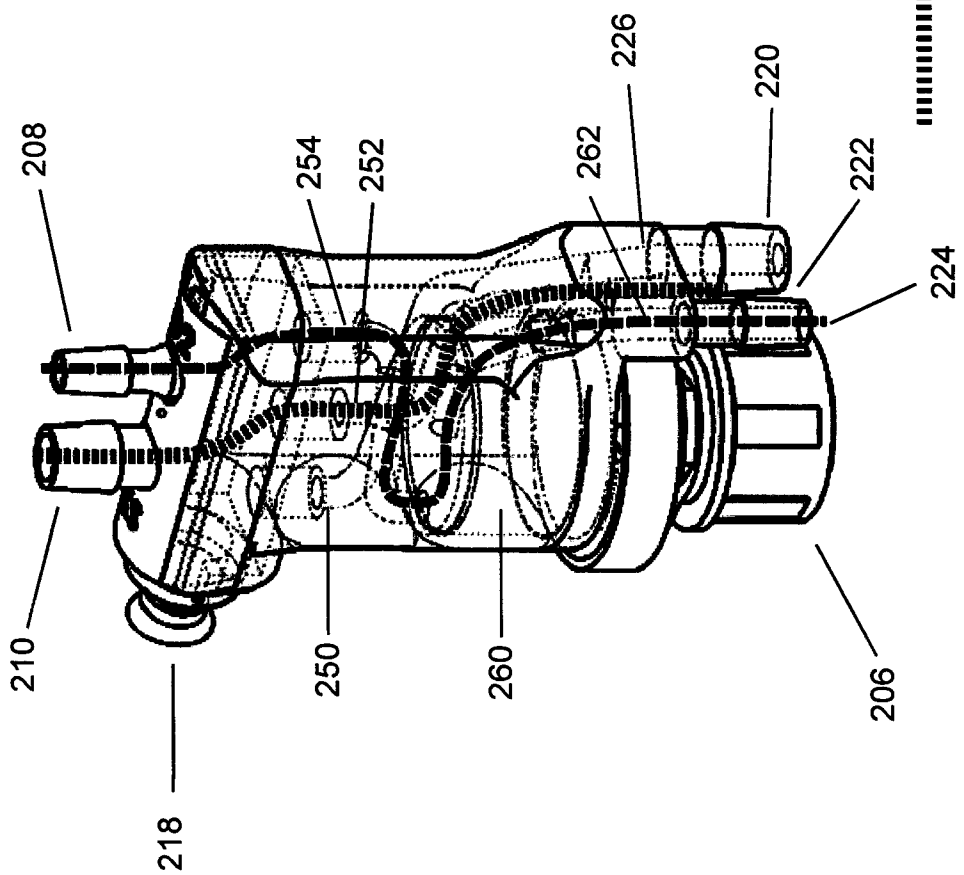


Figure 18A

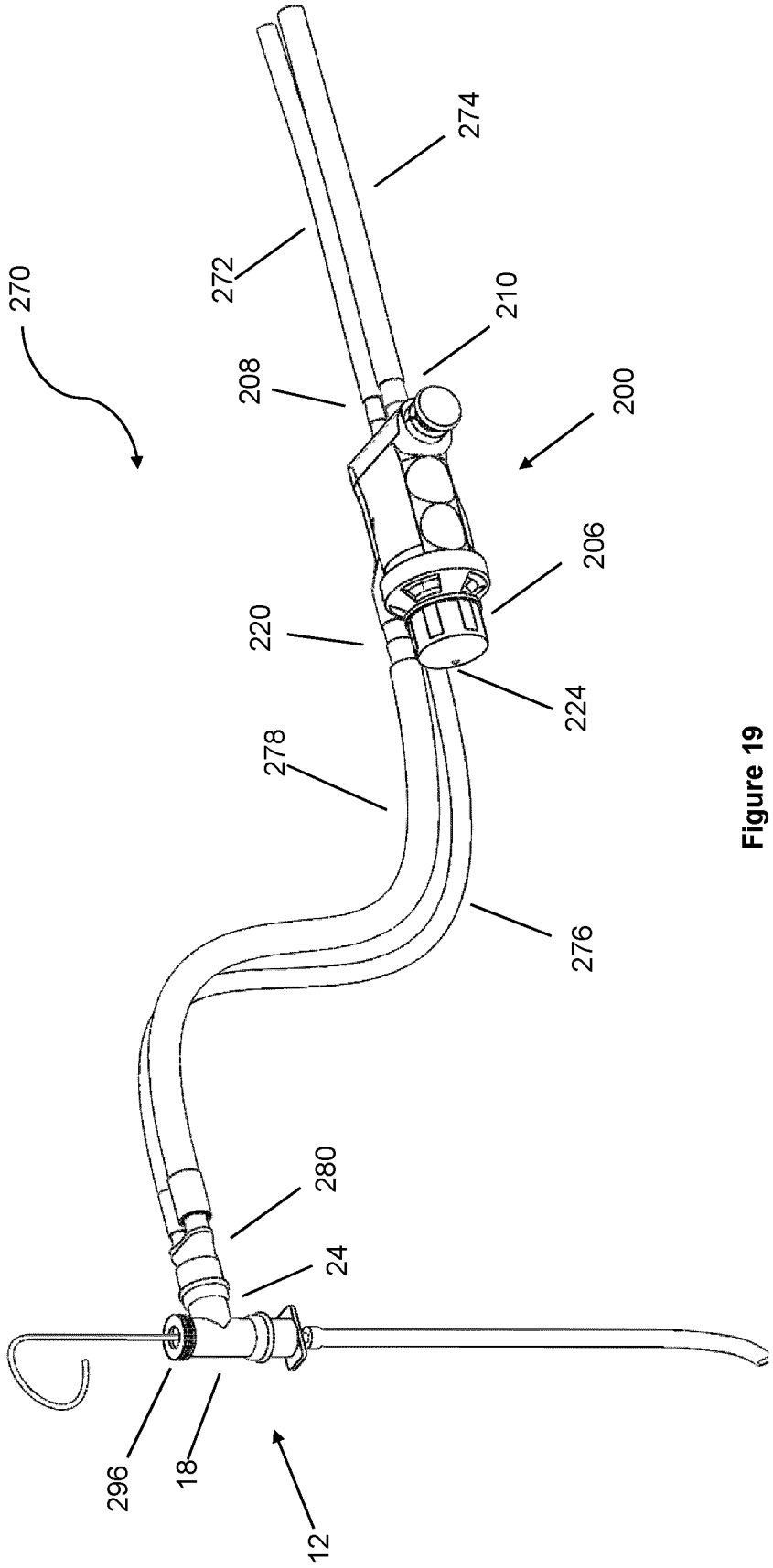


Figure 19

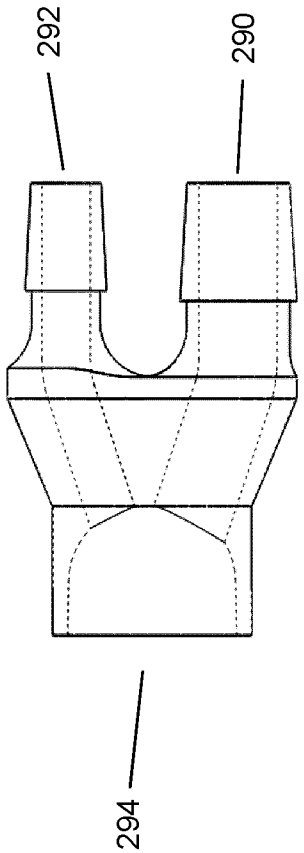


Figure 20B

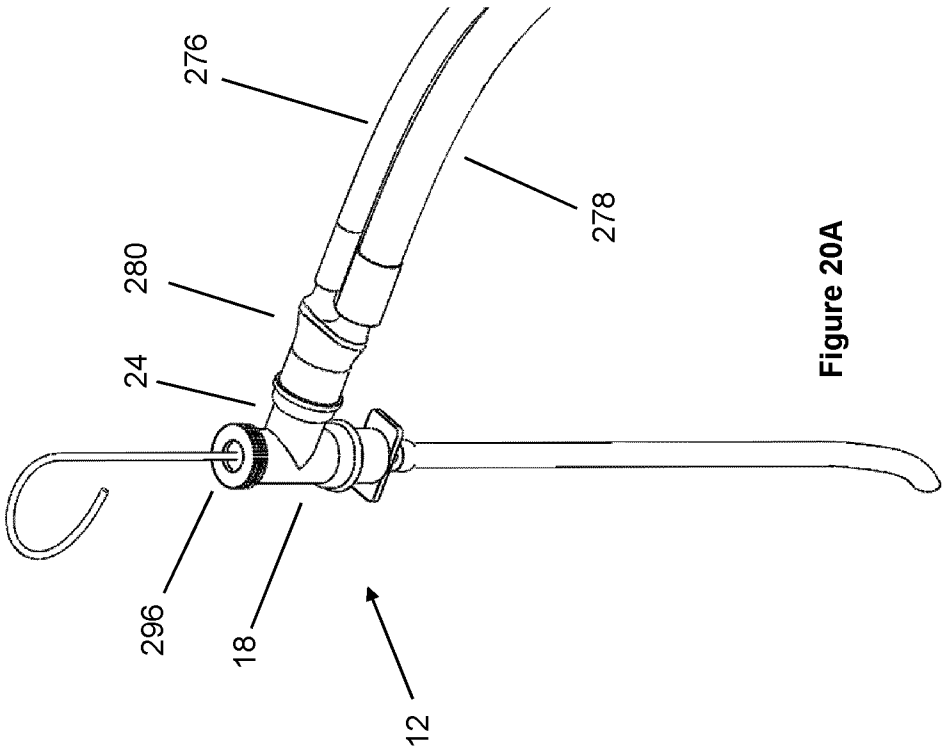


Figure 20A

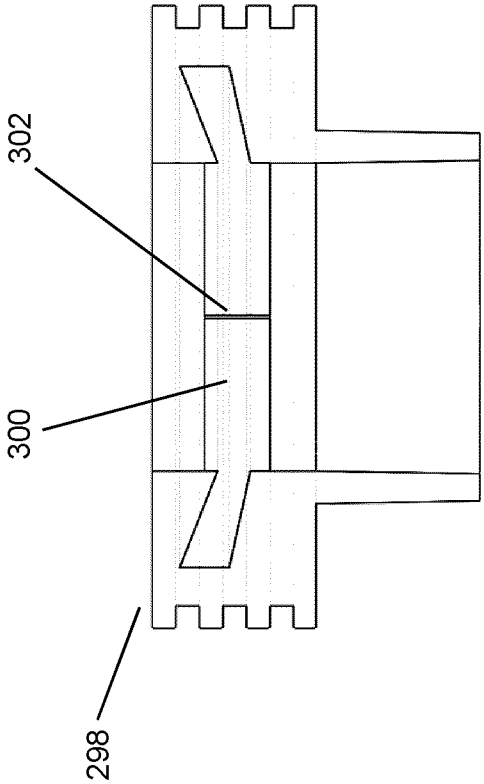


Figure 21B

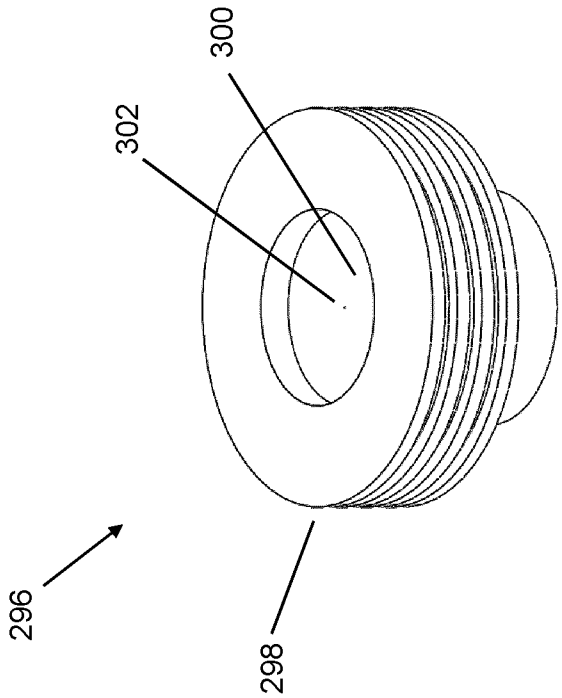


Figure 21A

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2018/050479

A. CLASSIFICATION OF SUBJECT MATTER
IPC: ***A61M 16/10*** (2006.01) , ***A61M 1/00*** (2006.01) , ***A61M 16/04*** (2006.01) , ***A61M 16/08*** (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)
IPC (2006.01): A61M 16/xx; A61M 1/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
Questel-Orbit (FAMPAT), Intellect (Canadian Patents Database)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2016/189427 A1 (PESENTI et al.) 01 December 2016 (01-12-2016) *see Abstract, Figures 1-2 and related description and claims*	1-17
X	WO 2007/066332 A2 (EFRATI, SHAI) 14 June 2007 (14-06-2007) *see Abstract, Figures 8-15 and related description and claims*	1-17
X	WO 81/02675 A (BODAI, BALAZS IMRE) 01 October 1981 (01-10-1981) *see Abstract, Figures 1-2 and related description and claims*	1-17
A	WO 99/01170 A1 (BOUSSIGNAC, GEORGES) 14 January 1999 (14-01-1999)	1-17
A	WO 99/38548 A2 (VARGAS, JAMIE) 05 August 1999 (05-08-1999)	1-17
A	WO 2013/063520 A1 (CHERSKY et al.) 02 May 2013 (02-05-2013)	1-17

☑ Further documents are listed in the continuation of Box C. ☑ See patent family annex.

*	Special categories of cited documents:	"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
"A"	document defining the general state of the art which is not considered to be of particular relevance	"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
"E"	earlier application or patent but published on or after the international filing date	"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
"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)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"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 13 July 2018 (13-07-2018)	Date of mailing of the international search report 06 August 2018 (06-08-2018)
Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 819-953-2476	Authorized officer Kristian MacKenzie (819) 639-7868

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2010/0307508 A1 (LI et al.) 09 December 2010 (09-12-2010)	1-17
A	US 2013/0104884 A1 (VAZALES et al.) 02 May 2013 (02-05-2013)	1-17
A	US 5,301,667 A (MCGRAIL et al.) 12 April 1994 (12-04-1994)	1-17
A	WO 02/089885 A2 (REISSMANN, HAJO) 14 November 2002 (14-11-2002)	1-17

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2018/050479

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
WO2016189427A1	01 December 2016 (01-12-2016)	CN107889465A	06 April 2018 (06-04-2018)
		EP3302667A1	11 April 2018 (11-04-2018)
		US2018126105A1	10 May 2018 (10-05-2018)
WO2007066332A2	14 June 2007 (14-06-2007)	WO2007066332A3	01 November 2007 (01-11-2007)
		AU2006322905A1	14 June 2007 (14-06-2007)
		AU2006322905B2	03 October 2013 (03-10-2013)
		BRPI0620592A2	16 November 2011 (16-11-2011)
		CA2631516A1	14 June 2007 (14-06-2007)
		CN101394886A	25 March 2009 (25-03-2009)
		CN101394886B	26 October 2016 (26-10-2016)
		EP1960024A2	27 August 2008 (27-08-2008)
		EP1960024B1	12 February 2014 (12-02-2014)
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		US2017113011A1	27 April 2017 (27-04-2017)
		ZA200805549B	29 April 2009 (29-04-2009)
WO8102675A1	01 October 1981 (01-10-1981)	AU7150481A	09 October 1981 (09-10-1981)
		CA1152834A	30 August 1983 (30-08-1983)
		EP0048743A1	07 April 1982 (07-04-1982)
		JPS57500418A	11 March 1982 (11-03-1982)
		US4351328A	28 September 1982 (28-09-1982)
WO9901170A1	14 January 1999 (14-01-1999)	AT264700T	15 May 2004 (15-05-2004)
		CN1236327A	24 November 1999 (24-11-1999)
		CN1152721C	09 June 2004 (09-06-2004)
		DE69823270D1	27 May 2004 (27-05-2004)
		DE69823270T2	24 September 2009 (24-09-2009)
		DK0888792T3	01 June 2004 (01-06-2004)
		EP0888792A1	07 January 1999 (07-01-1999)
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		ES2216255T3	16 October 2004 (16-10-2004)
		FR2765111A1	31 December 1998 (31-12-1998)
		FR2765111B1	24 September 1999 (24-09-1999)
		JP2001500048A	09 January 2001 (09-01-2001)
		PT888792E	31 August 2004 (31-08-2004)
		US2002179090A1	05 December 2002 (05-12-2002)
		US6575166B2	10 June 2003 (10-06-2003)
WO9938548A2	05 August 1999 (05-08-1999)	None	
WO2013063520A1	02 May 2013 (02-05-2013)	DK2393538T3	27 November 2017 (27-11-2017)
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		US8458844B2	11 June 2013 (11-06-2013)
		US2011023885A1	03 February 2011 (03-02-2011)
		US8468637B2	25 June 2013 (25-06-2013)
		US2011023887A1	03 February 2011 (03-02-2011)
		US8534287B2	17 September 2013 (17-09-2013)
		US2013228196A1	05 September 2013 (05-09-2013)
		US8601633B2	10 December 2013 (10-12-2013)
		US2014283875A1	25 September 2014 (25-09-2014)
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		US2014012074A1	09 January 2014 (09-01-2014)
		US9332891B2	10 May 2016 (10-05-2016)
		US2014033455A1	06 February 2014 (06-02-2014)
		US9386907B2	12 July 2016 (12-07-2016)
		US2013023729A1	24 January 2013 (24-01-2013)
		US9398837B2	26 July 2016 (26-07-2016)
		US2013104884A1	02 May 2013 (02-05-2013)
		US9445714B2	20 September 2016 (20-09-2016)
		US2013030249A1	31 January 2013 (31-01-2013)
		US9579012B2	28 February 2017 (28-02-2017)
		US2017065367A1	09 March 2017 (09-03-2017)
		US9855111B2	02 January 2018 (02-01-2018)
		US2017119494A1	04 May 2017 (04-05-2017)
		US9907624B2	06 March 2018 (06-03-2018)
		US2016193011A1	07 July 2016 (07-07-2016)
		US9962233B2	08 May 2018 (08-05-2018)
		US2017258550A1	14 September 2017 (14-09-2017)
		WO2010091309A1	12 August 2010 (12-08-2010)
		WO2011126812A1	13 October 2011 (13-10-2011)
US2010307508A1	09 December 2010 (09-12-2010)	US2010307508A1	09 December 2010 (09-12-2010)
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		EP2440275A1	18 April 2012 (18-04-2012)
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		US2014020682A1	23 January 2014 (23-01-2014)
		US9220859B2	29 December 2015 (29-12-2015)
		US2016082212A1	24 March 2016 (24-03-2016)
		US9907920B2	06 March 2018 (06-03-2018)
		WO2010144279A1	16 December 2010 (16-12-2010)
US2013104884A1	02 May 2013 (02-05-2013)	US2013104884A1	02 May 2013 (02-05-2013)
		US9445714B2	20 September 2016 (20-09-2016)
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		US8382908B2	26 February 2013 (26-02-2013)
		US2011023886A1	03 February 2011 (03-02-2011)
		US8458844B2	11 June 2013 (11-06-2013)
		US2011023885A1	03 February 2011 (03-02-2011)
		US8468637B2	25 June 2013 (25-06-2013)
		US2011023887A1	03 February 2011 (03-02-2011)

		US8534287B2	17 September 2013 (17-09-2013)
		US2013228196A1	05 September 2013 (05-09-2013)
		US8601633B2	10 December 2013 (10-12-2013)
		US2014283875A1	25 September 2014 (25-09-2014)
		US9095286B2	04 August 2015 (04-08-2015)
		US2014012074A1	09 January 2014 (09-01-2014)
		US9332891B2	10 May 2016 (10-05-2016)
		US2014033455A1	06 February 2014 (06-02-2014)
		US9386907B2	12 July 2016 (12-07-2016)
		US2013023729A1	24 January 2013 (24-01-2013)
		US9398837B2	26 July 2016 (26-07-2016)
		US2013030249A1	31 January 2013 (31-01-2013)
		US9579012B2	28 February 2017 (28-02-2017)
		US2017065367A1	09 March 2017 (09-03-2017)
		US9855111B2	02 January 2018 (02-01-2018)
		US2017119494A1	04 May 2017 (04-05-2017)
		US9907624B2	06 March 2018 (06-03-2018)
		US2016193011A1	07 July 2016 (07-07-2016)
		US9962233B2	08 May 2018 (08-05-2018)
		US2017258550A1	14 September 2017 (14-09-2017)
		WO2010091309A1	12 August 2010 (12-08-2010)
		WO2011126812A1	13 October 2011 (13-10-2011)
		WO2013063520A1	02 May 2013 (02-05-2013)
US5301667A	12 April 1994 (12-04-1994)	US5425358A	20 June 1995 (20-06-1995)
WO02089885A2	14 November 2002 (14-11-2002)	WO02089885A3	13 February 2003 (13-02-2003)
		AT531414T	15 November 2011 (15-11-2011)
		DE10123278C1	13 June 2002 (13-06-2002)
		DE20109138U1	16 August 2001 (16-08-2001)
		EP1385567A2	04 February 2004 (04-02-2004)
		EP1385567B1	02 November 2011 (02-11-2011)
		US2004231673A1	25 November 2004 (25-11-2004)
		US7481222B2	27 January 2009 (27-01-2009)