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NASAL CANNULA ASSEMBLY

FIELD OF THE INVENTION
The present disclosure relates to devices and systems for providing gases to patients for respiratory therapy. More specifically, the present disclosure relates to nasal cannula interfaces for providing gases to patients via the nasal passages.

BACKGROUND OF THE INVENTION
Medical professionals may wish to provide patients with respiratory assistance in the form of supplemental oxygen or airflow for many reasons in ICU (intensive care unit), other hospital, or home environments. Different types of interfaces for supplying gases to patients are available. For example, various nasal masks, full face masks, oral interfaces, nasal pillows, and nasal cannula interfaces exist. Nasal cannula interfaces typically include two nasal prongs that are placed in the patient’s nostrils to deliver gases to the patient.

Nasal cannula assemblies generally consist of entry tubing, either symmetric or single sided that lies across the upper lip. Protruding from this tubing are open ended prongs which extend into the nares of the patient to deliver oxygen. Nasal cannula have the advantage of being more comfortable and acceptable than a face mask to most patients. A single flow entry nasal cannula has the advantage of being unobtrusive, and may be more relevant to delivering humidity than a dual flow entry style of nasal cannula, due to the advantage of flow rates and surface area for heat loss. A single flow entry however is provided at one side of the cannula, the left or the right side. If the tube is on the left side for example, the user has difficulty in use if the flow source is on the opposite or right side of the user requiring longer lengths of tubing and causing the tube to cross the body.

When providing humidified gases to a patient it is common to use a heated breathing circuit (tubing). This circuit is heavy and can drag and pull on the patient interface. It is common to use a short flexible tube between the heated circuit and patient interface to reduce any torque or twisting. In order to stop the weight pulling on the patient interface, circuit hangers are occasionally used. This is a large extendable metal arm to take the weight. It also has been known in the art to clip part of the tubing to the
patient's clothes or bedclothes. Both of these solutions have been found to be quite unsuitable for mobile patients especially when sleeping and turning in bed.

With patient interfaces such as nasal cannula the stability of the nasal prongs on the face is very important, as movement of the prongs within the nares can cause severe irritation. Current methods employed to retain a single entry nasal cannula on the face use a simple elastic band of material around the back of the patients head. This is prone to rotating the nasal cannula relative to the patient's head especially when turning ones head on a pillow. This rotation causes the prongs move within the nares, irritating this sensitive area.

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

It is an object of the present invention to provide an improved nasal cannula assembly or patient interface headgear, or to at least provide the public with a useful choice.

**SUMMARY OF THE INVENTION**

In one aspect, the present invention broadly involves a nasal cannula assembly comprising:

a cannula part comprising a pair of tubular nasal prongs for insertion into the nares of a patient, and a manifold in fluid communication with the nasal prongs, the manifold comprising an aperture at left hand end of the manifold and an aperture at the right hand end of the manifold,

a connector adapted to receive an end of a gases flow conduit and be removably received in the aperture at left hand end of the manifold and the aperture at the right hand end of the manifold, and

a plug adapted to be removably received in the aperture at left hand end of the manifold and the aperture at the right hand end of the manifold,

in use the connector or the plug fitted to one of the apertures at the left and right sides of the manifold, and the plug fitted to the other one of the apertures at the
left and right sides of the manifold to configure the conduit to extend from either the left side or right side of the nasal cannula assembly.

Preferably the plug and connector are separate parts.

Preferably the plug and connector are coupled or attached together by a lateral member to form a clip.

Preferably the clip is an integrally formed unitary member.

Preferably the clip and cannula part are complimentary adapted so that in use the lateral member is elastically deflected to fit the clip to the cannula part.

Preferably the clip is fitted to the cannula part by pushing the clip onto the cannula part in a direction perpendicular to a lateral direction of the cannula.

Preferably the cannula part comprises a rigid member for interfacing with the clip and the prongs are formed of a resilient material attached to the rigid member.

Preferably the rigid member and the lateral member are adapted so that the lateral member is flexed to spread the plug and connector apart when attaching the clip to the cannula part.

Preferably the clip is substantially 'C' or 'U' shaped.

Preferably the plug and connector each extend into the aperture at the ends of the manifold.

Preferably the clip provides a positive force against the manifold to grip the manifold between the plug and the connector.

Preferably the cannula part comprises a recessed portion that is sized and shaped to receive the lateral member.
Preferably the cannula part comprising the manifold and nasal prongs is integrally formed.

Preferably the resilient material is over moulded to the rigid member.

Preferably the cannula part comprises side arms and the rigid member extends along the side arms.

Preferably the rigid part comprises through holes in the side arms for the resilient material to extend through by an over moulding process or assembly process.

Preferably the rigid member comprises a recessed portion that is sized and shaped to receive the lateral member.

Preferably the apertures at the ends of the manifold are formed in the rigid member.

Preferably the lateral member is length adjustable.

Preferably the clip comprises a first part and a second part, the first part comprises one of the plug and the connector and the second part comprises the other one of the plug and the connector, the first part comprises a first lateral member and the second part comprises a second lateral member, and

the first and second lateral members coupled together in a telescoping arrangement and comprising complementary features to set the lateral distance between the plug and the connector.

Preferably the complementary features comprise a projection on one of the first and second parts and a corresponding aperture in the other one of the first and second parts, the projection being received in the aperture to set the lateral distance between the plug and the connector.

Preferably one of the first and second parts comprises a plurality of corresponding apertures, the projection being received in the one of the plurality of apertures to set the lateral distance between the plug and the connector, the plurality of apertures providing for a range of cannula part sizes.
Preferably the clip is movably attached to the cannula part.

Preferably the clip is rotationally coupled to the cannula part.

Preferably the clip is rotationally coupled to the cannula part on a rotational axis on or parallel to the sagittal plane of the cannula to position the conduit to the left or right side of the nasal cannula assembly.

Preferably the manifold is formed of a relatively rigid material, and the cannula part comprises a resilient material moulded over the manifold, the nasal prongs integrally formed with the resilient material, and the cannula part comprises an axle extending from the manifold, and the clip rotationally mounted on the axle.

Preferably the axle is integrally formed with the manifold.

Preferably the clip comprises a keyway so that the clip can be removably mounted to the cannula part.

Preferably cannula part comprises a flange at the end of the axle to retain the clip on the axle in a direction along the rotational axis.

Preferably ends of the manifold are curved with a centre of curvature on the rotational axis, and the plug and the connector each have a complementary curvature so that the clip can rotate on the rotational axis to position the connector at either end of the manifold.

Preferably the over moulded resilient material covers ends of the manifold to provide a seal with the plug and connector.

In a second aspect, the present invention broadly involves a nasal cannula assembly as claimed in claim 3 wherein the clip is fitted to the cannula part by pushing the clip laterally into the manifold via one of the aperture at the left hand end and the aperture at the right hand end so that the connector is received in one of the aperture at the left hand end and the aperture at the right hand end and the plug is received in the other
one of the aperture at the left hand end and the aperture at the right hand end to configure the conduit to extend from either the left side or right side of the nasal cannula assembly.

Preferably the cannula part comprises a rigid member for interfacing with the clip and the prongs are formed of a resilient member attached to the rigid member, and the cannula part and the rigid member each comprise side arms extending laterally from the manifold.

In a third aspect, the present invention broadly involves nasal cannula assembly comprising:

a cannula part comprising a pair of tubular nasal prongs for insertion into the nares of a patient,

a connector adapted to receive an end of a gases flow conduit,

a manifold attached to or integrally formed with the connector, the connector providing an inlet to the manifold and the manifold having at least one outlet,

the cannula part movably attached to the manifold to be attached to the manifold in two orientations to configure the conduit to extend from either the left side or right side of the nasal cannula assembly.

Preferably the cannula part is rotatable relative to the manifold about a substantially vertical axis.

Preferably the manifold comprise an open top that is the manifold outlet, and the cannula part fits over the open top so that the prongs are in communication with the connector.

Preferably the manifold comprises a lip on a surface of the manifold to which the cannula part connects.

Preferably an axle extends from the manifold or the cannula part and the cannula part rotates relative to the manifold on the axle.

In a fourth aspect, the present invention broadly involves a nasal cannula assembly comprising:
a cannula part comprising a pair of tubular nasal prongs for insertion into the nares of a patient, and a left and a right lateral side arm for attaching headgear,

a first conduit for providing as flow of gas to one said nasal prong and a second conduit for providing a flow of gas to the other said nasal prong,

a first joint connecting the first conduit to one said nasal prong and a second joint connecting the second conduit to the other said nasal prong, the joints adapted to allow the first and second conduits to be routed to a left side or a right side of the nasal cannula assembly, and

a left clip on the left lateral side arm and a right clip on the right lateral side arm,

in use the first conduit being held by the left clip or the right clip to configure the first conduit to extend from either the left side or right side of the nasal cannula assembly, and the second conduit being held by the left clip or the right clip to configure the second conduit to extend from either the left side or right side of the nasal cannula assembly.

Preferably the cannula part is an integrally formed part.

Preferably each joint is a flexible tube adapted to bend at least 90 degrees in any direction without substantial occlusion.

Preferably the flexible tubes comprise circumferentially extending ribs so that bending of the flexible conduit section does not cause the flexible conduit section to collapse.

Preferably each joint is a swivel joint.

Preferably each swivel joint rotates on an axis that is at an angle to an axis of the corresponding nasal prong so that rotation of the swivel joint allows both conduits to be routed to the left side or the right side without overlapping.

Preferably each swivel joint is a swivel elbow.

Preferably each said clip comprises two channels or receptacles each for receiving one of the tubes.
Preferably each flexible tube is integrally formed with a nasal prong.

Preferably each clip is integrally formed with a said side arm.

In a fifth aspect, the present invention broadly involves a nasal cannula system comprising a nasal cannula assembly as defined in any one of the above aspects and a headgear attached to the nasal cannula assembly for attaching the nasal cannula assembly to a patient's head.

In a sixth aspect, the present invention broadly involves a system for providing a flow of respiratory gases to a user or patient comprising a blower, a humidifier, the conduit and a nasal cannula system as defined in the fifth aspect.

In a seventh aspect, the present invention broadly involves a headgear comprising:
   a strap, each end of the strap adapted to be attached to a patient interface and extend around a patient's head to hold the patient interface in place on a patient's face, wherein
   at least a portion of the strap is configured to bifurcate into more than one band to extend around the patient's head.

Preferably the strap comprises a longitudinal frangible section extending along a portion of the strap to be torn by a user to separate the portion of the strap into more than one band.

Preferably the frangible section comprises a relatively thin section.

Preferably the frangible section is a perforated section.

Preferably the bands are separated by the frangible section.

Preferably the strap comprises a finger hole at the frangible section to assist with separating the bands by tearing the frangible section.
Preferably the strap comprises a hole at an end of the frangible section, the hole comprising a rounded portion defining an end of the frangible section to prevent tearing the strap beyond the frangible section.

Preferably the hole is a finger hole.

Preferably at least the portion of the strap is formed from fabric forming the bands, and the fabric is coated with a polymer with the bands arranged together, the coating providing the frangible section between the bands, the coating adapted to be torn to separate the bands.

Preferably the bands are formed by a longitudinal cut in the fabric along the portion of the strap, the polymer coating bridging the cut to hold the bands together in a non-bifurcating configuration.

Preferably the fabric is a foamed fabric.

Preferably the bands are separated by a removable section of the strap comprising a lift tab, the removable section joined to the bands by the frangible section.

Preferably the headgear comprises a clasp that is slidable along at least the portion of the strap configured to bifurcate.

Preferably to bifurcate the strap to separate the bands the clasp is slidable to an end of the bands, and the clasp is slidable to a midpoint of the bands to hold the bands together as a single strap.

Preferably to bifurcate the strap to separate the bands the clasp is slidable to an end of the bands, and the clasp is slidable to an opposite end of the bands to hold the bands together as a single strap.

Preferably each band comprises a feature that interfaces with a corresponding feature on the clasp to bind the bands together when in a non-bifurcated configuration.
Preferably the bands comprise interlocking teeth that are separated or mated by sliding the clasp along the bands.

Preferably the headgear comprises a web that extends between the bands, in a non-bifurcated configuration the web is bunched up or folded into a non-expanded configuration, and in a bifurcated configuration where the bands are spaced apart the web is expanded or unfolded to cover an area between the spaced apart bands.

Preferably the headgear comprises two clasps, in a non-bifurcated configuration both clasps are slid towards a central position of the strap to hold the bands together, and in a bifurcated configuration each clasp is slid to an end of the bands so that the bands may separate between ends of the bands.

Preferably each clasp and the straps are complementary adapted so that moving each clasp to an end of the bands forces the bands apart to separate the bands into a bifurcated configuration.

Preferably each clasp comprises two spaced apart flanges and three pins extending between the spaced apart flanges, the bands extending between the flanges, one said pin positioned between the bands and the other two pins positioned on outer edges of the bands, and the bands comprises a cross over portion near ends of the bands.

Preferably one or each band may comprise a central tab or stop to limit the amount of travel of the clasps along the bands.

Preferably the portion of the strap configured to bifurcate extends around the back of the patient's head from behind the patient's ears in use.

Preferably ends of the bands are pivotally coupled together.

Preferably the bands in a non-bifurcated configuration are arranged edge-to-edge.

Preferably the bands in a non-bifurcated configuration are arranged side-by-side.
Preferably the bands in the non-bifurcated configuration are held together by one or more of tearable stitching, a clasp or clasps, buttons, clips, hook and loop fasteners or magnets.

In an eighth aspect, the present invention broadly involves headgear for securing a patient interface to a user's face comprising:

- a strap, each end of the strap adapted to be attached to a patient interface and extend around a patient's head to hold the patient interface in place on a patient's face, wherein

- the strap comprises a non-stretchable section and a stretchable section, the non-stretchable section adapted to be attached the patient interface and support a gases supply conduit coupled to the patient interface.

Preferably each end of the strap is a non-stretchable section adapted to be attached to the patient interface and the stretchable section is an intermediate section that extends between the non-stretchable sections around the back of the patient's head.

Preferably the non-stretchable section is adapted to be attached to one side of the patient interface and the stretchable section is adapted to be attached to an opposite side of the patient interface.

Preferably the non-stretchable section comprises a feature for securing the conduit.

In a ninth aspect, the present invention broadly involves a headgear for securing a patient interface to a user's face comprising:

- a strap comprising a first stretchable section adapted to be attached to one side of a patient interface and a second stretchable section adapted to be attached to an opposite side of a patient interface, and a non-stretchable intermediate section extending between each end of the stretchable sections.

Preferably the intermediate portion is an annular portion, ends of the stretchable sections attached to the annular portion.

Preferably the headgear comprises a first non-stretchable sleeve and a second non-stretchable sleeve each extending from the non-stretchable intermediate section, and

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the first stretchable section extends along an inside of the first non-stretchable sleeve and the second stretchable section extends along an inside of the second non-stretchable sleeve.

Preferably the first and second non-stretchable sleeves extend from the intermediate portion to forward of the patient's ears in use.

Preferably the first and second stretchable sections are not attached to the first and second non-stretchable sleeve along the length of the sleeve from the intermediate portion.

Preferably one or both sleeves is/are adapted to support a gas conduit for providing a gas flow to the patient interface.

Preferably the head gear comprises a lanyard connected to a said sleeve adapted to secure the gas conduit.

Preferably the lanyard is stretchable.

Preferably the non-stretchable intermediate section is bifurcated to comprise two separate bands.

Preferably the non-stretchable section is configured to bifurcate into more than one band to extend around the patient's head.

Preferably the headgear comprises a bifurcated section comprising two bands and one said band is the non-stretchable intermediate section.

Preferably the headgear comprises a first non-stretchable 'Y' connector connecting between the first stretchable section and one end of the two bands and a second non-stretchable 'Y' connector connecting between the second stretchable section and an opposite end of the two bands.

Preferably one of the two bands is a stretchable band.
Preferably an upper one of the two bands is the stretchable band and a lower one of the two bands is the non-stretchable band.

Preferably the non-stretchable band is length adjustable.

Preferably at least one of the bands is adjustable in length.

Preferably an upper one of the two bands is adjustable in length.

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

As used herein the term "and/or" means "and" or "or", or both.

As used herein "(s)" following a noun means the plural and/or singular forms of the noun.

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

The sagittal plane of a nasal cannula or other patient interface is defined as the sagittal plane of a user that extends through the cannula or patient interface when the cannula or patient interface is positioned on a user's face in use. For example, the sagittal plane of a nasal cannula comprising a nasal prong for each nostril is positioned centrally between the nasal prongs.

The lateral direction with respect to a nasal cannula is the direction extending between left and right hand ends of the cannula. The lateral direction is perpendicular to a direction extending between the front and back of the cannula. The sagittal plane of a cannula is perpendicular to the lateral direction.
The invention involves the foregoing and also envisages constructions of which the following gives examples only.

**BRIEF DESCRIPTION OF THE DRAWINGS**

**Figure 1** illustrates a respiratory humidifier system that may be used with a nasal cannula assembly according to one or more embodiments of the present invention.

**Figures 2A and 2B** illustrate a nasal cannula assembly comprising a cannula part and a separate plug and conduit connector.

**Figure 3** illustrates a nasal cannula assembly comprising cannula part and a clip comprising a plug and conduit connector for connecting a gas conduit to the cannula part.

**Figures 4A and 4B** illustrate a nasal cannula assembly comprising cannula part and a clip comprising a plug and conduit connector for connecting a gas conduit to the cannula part. The cannula part comprises a rigid member for interfacing with the clip.

**Figures 5A and 5B** illustrate a clip comprising a conduit connector and a plug, for connecting a gas conduit to a cannula part. A lateral distance between the plug and connector is adjustable. Figure 5B is an exploded view.

**Figure 6A to 6C** illustrate a nasal cannula assembly comprising a cannula part and a clip comprising a plug and conduit connector for connecting a gas conduit to the cannula part. The clip is rotationally mounted to the cannula part.

**Figures 7A and 7B** illustrate a nasal cannula assembly comprising a cannula part and a conduit connector comprising a manifold. The cannula part is rotationally mounted to the manifold.

**Figures 8A to 8C** illustrate a nasal cannula assembly comprising a cannula part and a clip comprising a plug and conduit connector for connecting a gas conduit to the cannula part. The clip is inserted laterally into a manifold of the cannula part.

**Figure 9A** illustrates a cannula assembly comprising a pair of gas supply conduits, each conduit connected to a nasal prong via a flexible tube section, and a clip at each side of the cannula assembly for configuring the conduits to extend from the left or right side of the cannula.

**Figures 9B and 9C** illustrate a nasal cannula assembly comprising a pair of gas supply conduits, each conduit connected to a nasal prong via a swivel elbow.
Figure 10A illustrates a bifurcate-able strap for a headgear comprising a frangible section to bifurcate a portion of the strap into two separate bands.

Figure 10B illustrates a bifurcate-able strap in use in a non-bifurcated configuration.

Figure 10C illustrates a bifurcate-able strap in use in a bifurcated configuration.

Figure 10D illustrates how a bifurcate-able strap comprising a frangible section is separated to form a bifurcated a portion comprising two separate bands.

Figure 10E illustrates a bifurcate-able strap in a non-bifurcated configuration.

Figure 10F illustrates a cross section of the strap of Figure 10E.

Figure 10G illustrates a cross section of the strap of Figure 10A.

Figure 11 illustrates a bifurcate-able strap for a headgear comprising a lift out portion defined by a frangible section, for bifurcating a portion of the strap into two separate bands.

Figures 12A and 12B illustrate a bifurcate-able strap for a headgear comprising a clasp slidable along a bifurcate-able section of the strap to configure the bifurcate-able section into a bifurcated or a non-bifurcated configuration.

Figures 13A to 13C illustrate a bifurcate-able strap for a headgear comprising two clasps slidable along a bifurcate-able section of the strap to configure the bifurcate-able section into a bifurcated or a non-bifurcated configuration.

Figure 14 illustrates a bifurcate-able strap wherein ends of separate bands of the strap are pivotally coupled.

Figure 15 illustrates a headgear strap comprising a stretchable and a non-stretchable portion. The non-stretchable portion is bifurcated into two separate bands.

Figure 16 illustrates a headgear strap comprising a bifurcated portion wherein at least one band of the bifurcated portion is stretchable and ends of the bifurcated bands are joined by a non-stretchable Y connector.

Figure 17 illustrates a head gear strap comprising a stretchable portion and a non-stretchable portion. The non-stretchable portion supports a gases supply conduit.

Figure 18 illustrates a head gear strap comprising a first non-stretchable section attached to one side of a patient interface and a second non-stretchable section attached to an opposite side of the patient interface, and a stretchable intermediate section extending between the first and second non-stretchable sections.

Figure 19 illustrates a head gear strap comprising a first stretchable section attached to one side of a patient interface and a second non-stretchable section attached to an opposite side of the patient interface, and a non-stretchable annular intermediate section extending between the first and second non-stretchable sections.
Figure 20 illustrates a head gear strap comprising a bifurcated portion wherein at least one band of the bifurcated portion is adjustable in length.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Although certain embodiments and examples are described below, those of skill in the art will appreciate that the disclosure extends beyond the specifically disclosed embodiments and/or uses and obvious modifications and equivalents thereof. Thus, it is intended that the scope of the disclosure herein disclosed should not be limited by any particular embodiments described below. Various features described herein can be used individually or in various combinations and subcombinations in existing and/or improved respiratory interfaces.

Whether used in a hospital environment or in a home environment, a system for providing a flow of gases to a patient or user may comprise four main pieces of apparatus. Firstly a blower for providing a flow of pressurised gas to the patient. Secondly an active humidifier that controls the temperature of a heater plate heating a body of water to achieve a desired temperature and humidity of the flow of gas. Thirdly a transport conduit from the humidifier to the patient is also required, which may be heated to reduce condensation, or “rain out”. Fourthly a patient interface for delivering the pressurized humidified flow of gases to a patient, for example a nasal cannula designed to fit into the nasal cavity of a patient or user. In some situations a flow of pressurized gases may be provided to a patient without humidification, in which case a humidifier is not a necessary apparatus.

Referring to Figure 1 a humidifying circuit as might be used with a patient interface comprising the present invention is shown. A patient 1 is receiving humidified and pressurised gases through a nasal cannula assembly 20 connected to a humidified gases transportation pathway or inspiratory conduit 3 that in turn is connected to a humidifier 8 (including humidification chamber 5) that is supplied with gases from a blower 15 or other appropriate gases supply means. The inspiratory conduit 3 is connected to the outlet 4 of a humidification chamber 5 which contains a volume of water 6. Humidification chamber 5 is preferably formed from a plastics material and may have a highly heat conductive base (for example an aluminium base) which is in direct contact with a heater plate 7 of humidifier 8. The humidifier 8 is provided with control means or electronic controller 9 which may comprise a microprocessor based
controller executing computer software commands stored in associated memory. Gases flowing through the inspiratory conduit 3 are passed to the patient by way of the nasal cannula assembly 20.

Controller 9 receives input from sources such as user input means or dial 10 through which a user of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient 1. In response to the user set humidity or temperature value input via dial 10 and other possible inputs such as internal sensors that sense gases flow or temperature, or by parameters calculated in the controller, controller 9 determines when (or to what level) to energise heater plate 7 to heat the water 6 within humidification chamber 5. As the volume of water 6 within humidification chamber 5 is heated, water vapour begins to fill the volume of the chamber above the water’s surface and is passed out of the humidification chamber 5 outlet 4 with the flow of gases (for example air) provided from a gases supply means or blower 15 which enters the chamber through inlet 16. It should be noted that it is possible to obtain the relationship between the humidity of the gases in humidification chamber 5 and the temperature of the heater plate 7. Accordingly, it is possible to utilise the heater plate temperature in an algorithm or a look-up table to determine the humidity of the gases.

The blower 15 may be provided with a variable speed pump or fan 2 which draws air or other gases through the blower inlet 17. The speed of variable speed pump or fan 2 may be controlled by a further control means or electronic controller 18 (or alternatively the function of this controller 18 could be carried out by the other controller 9) in response to inputs from controller 9 and a user set predetermined required value (preset value) of pressure or fan speed via dial 19.

A heating element 11 may be provided within the conduit or tubing 3 to help prevent condensation of the humidified gases within the conduit. Such condensation is due to the temperature of the walls of the conduit being close to the ambient temperature, (being the temperature of the surrounding atmosphere) which is usually lower than the temperature of the humidified gases within the conduit. The heater element effectively replaces the energy lost from the gases through conduction and convection during transit through the conduit. Thus the conduit heater element ensures the gases delivered are at an optimal temperature and humidity.

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Side swapping cannula

Various cannula assemblies according to some embodiments of the present invention are described with reference to Figures 2A to 9. With reference to Figures 2A and 2B, in some embodiments a nasal cannula system comprises a cannula assembly 100, head gear straps (not shown) and a gas supply tube 3. The cannula assembly 100 comprises a cannula part or face mount part 101 for interfacing with a patient's nares. The cannula part may be formed from a thermoplastic, silicone or silicone like material and comprises a manifold 102, nasal prongs 103 and side straps or arms 104 or other connection features for connecting to headgear. In some embodiments the nasal prongs, side arms and manifold may be integrally formed. The manifold is in fluid communication with the nasal prongs and in some embodiments the manifold is open, or has an aperture 105, at each end. The aperture at each end is adapted to receive the gas tube 3 or a connector 106 connected to the gas tube. The cannula assembly also comprises a plug or cap 107. The cap is configured to be received in the aperture at each end of the manifold. The cannula is therefore configurable to have the tube extend from either the left hand end or the right hand end of the manifold. A user or patient may attach the tube via the connector 106 to one of the right hand end and the left hand end of the manifold 102, and the plug 107 to the other one of the left and right hand ends. The tube and the plug engage in the manifold to seal the apertures 105 in the ends of the manifold. In the illustrated embodiment the tube connector and plug each comprise a flange to be received in a corresponding groove in the manifold to secure the connector and plug correctly in place and to form a seal with the manifold.

In some embodiments the plug and conduit connector may be coupled or attached together. For example, as illustrated in Figure 3, the plug 207 and connector 206 are connected together by a lateral member 208. In some embodiments the plug, connector and lateral member are integrally formed to for a clip 210. The conduit or tube may be provided with the clip 210 so that the conduit 3 is a clip on supply tube. In the embodiment of Figure 3, cannula part 201 comprises a manifold 202 in communication with prongs 203 and two openings 205, one at each end of the manifold. The clip 210 may be described as a manifold receiving structure. The manifold receiving structure 210 can be assembled to the supply tube 3 at the time of manufacture or can be connectable to the supply tube 3 prior to use. In certain embodiments, the manifold receiving structure 210 can be a substantially 'C' or 'U'
shaped manifold receiving structure or clip 210 as illustrated in Figure 3 or the manifold receiving structure 210 can have any shape that allows for complimentary coupling to the manifold 202. In some embodiments, the manifold 203 has a complimentary shape or matching shape to receive the manifold receiving structure 210 which can be clipped onto, to the manifold 202 with the supply tube 3 positioned facing either way (left or right) as desired. For example, a user may seat the plug 207 end of the clip in the aperture 205 at one end of the manifold 202, and then flex or elastically bend the lateral member 208 to move the clip 210 onto the manifold to position the conduit connector 206 over the aperture 205 at the other end of the manifold. Once in position the user releases the clip 210 so that the lateral member 208 elastically unbends to seat the conduit connector in the aperture at the end of the manifold. In some embodiments the plug and connector each extend into the ends of the manifold to provide a seal and prevent the clip from being simply pulled out of the manifold without deflection of the lateral member of the clip to clear the plug or connector from the corresponding aperture 205 in the end of the manifold. In some embodiments the clip provides a positive force against the manifold to grip the manifold between the plug and the connector to ensure a seal is formed at each end of the manifold and securely retain the clip to the manifold. In some embodiments the cannula part 202 may comprise a recessed portion 209 that is sized and shaped to receive the lateral member 208. The recessed portion 209 can be located on the forward and lateral portions of the cannula part and may have a depth suitable to accommodate an entirety of the thickness of the lateral member of the manifold receiving structure 210, such that an outward-facing surface of the manifold receiving structure 210 is flush with or recessed within the outer surface of the manifold 202. Such an arrangement assists in securing the manifold receiving structure 210 to the manifold 202 and/or can inform the user how to correctly locate and secure the manifold receiving structure 210 to the manifold 202. The recessed portion assists to retain the clip in position on the manifold.

As shown in Figure 3 the cannula part comprising the manifold, nasal prongs and side arms may be integrally formed, for example from a silicone or silicone like material. In some embodiments, the cannula part may comprise a relatively rigid part for interfacing with and receiving and/or retaining the clip. For example, illustrated in Figures 4A and 4B, the cannula part 301 may comprise conduit clip receiving or retaining part 311 for receiving conduit clip 310. The silicone or silicone like material
of the resilient cannula part 301a may be over moulded to the relatively rigid retainer 311, or attached by other fastening technologies, for example bonding, mechanical snap fitting, ultrasonic welding or any other suitable fastening method known in the art. The resilient part 301a may comprise an open cavity or channel 312. The manifold apertures 305 may be provided in the clip receiving part 311. The clip receiving part and the resilient part 301a are assembled so that the clip receiving part 311 closes the open channel 312 except for the apertures 305. The clip receiving part 311 and the resilient part combine to form the manifold of the cannula part 301. The clip receiving part may comprise a recess 309 for receiving the lateral member 308 of the clip 310 as described with reference to the embodiment of Figure 3. The clip receiving part may comprise through holes 313 for resilient material of the resilient cannula part to pass to secure the resilient part to the clip receiving part, for example in an over moulding process or an assembly process. The clip receiving part may be formed from the same material as the conduit clip. The relatively rigid (compared to the soft or resilient material of the cannula) material of the clip receiving part provides for positive fitting or engagement between the conduit clip and the cannula part 301. The clip may be mated with the cannula part by pushing the clip onto the cannula part in a direction on or parallel to the sagittal plane of the cannula assembly, that is a direction perpendicular to a lateral direction of the cannula. By pushing the clip onto the cannula part, interference between the plug and conduit connector with the retainer causes the lateral member of the clip to deflect to allow the plug and connector to move over the apertures at the ends of the manifold. Once the plug and connector are aligned with the manifold apertures the lateral member elastically unbends to snap the clip in place on the cannula part.

In some embodiments the plug and conduit connector may be removably attached together, or the conduit clip may comprise an adjustment feature to adjust the relative position of the plug and conduit connector. For example, with reference to Figures 5A and 5B, the conduit clip 410 comprises two parts, a first part 414 and a second part 415. In the illustrated embodiment, the first part comprises the plug 407 and the second part comprises the conduit connector. The first part comprises a lateral member 408a and the second part comprises a lateral member 408b. In some embodiments the lateral members 408a and 408b assemble together in a telescoping arrangement, and comprise complementary features to set the lateral distance between the plug 407 and the conduit connector 406. In the illustrated embodiment the lateral
member 408a of the first part 414 is received in the lateral member 408b of the second part, however the lateral member connected with the conduit connector could be received in a corresponding lateral member connected to the plug. The first and second parts comprise complementary features to set the distance between the plug and conduit connector. For example, as illustrated the one of the first and second parts 408a and 408b may comprise a projection to be received in a corresponding aperture in the other one of the first and second parts. In the illustrated embodiment the first part 414 comprises a projection 416 on lateral member 408a, and the second part 415 comprises an aperture 417 in the lateral member to receive the projection 416 to set the lateral distance between the plug and the conduit connector. In some embodiments the clip may be provided with more than one aperture 417 to provide a range of lateral distances between the plug and conduit connector to accommodate a range of cannula sizes. In use, a user may assemble the conduit clip 410 to a cannula part (for example cannula part 201 of Figure 3 or the cannula part 301 of Figure 4A) with the plug and conduit connector initially in an extended position. Once the plug 407 and conduit connector 406 are aligned with apertures 205 of the manifold of the cannula part, the user pushes the plug and conduit connector together in a lateral direction to attach the conduit clip and conduit to the cannula part. In some embodiments the first and second parts are biased apart, for example by a spring 420 or a resilient member.

In the embodiments of Figures 3 to 5B the conduit clip is removable from the cannula part so that the cannula can be assembled with the conduit 3 extending from either the left hand side or the right hand side of the cannula assembly. In some embodiments, the conduit clip may be movably attached to the cannula assembly. For example, in some embodiments the conduit clip may be rotationally attached to the cannula part so that the conduit connector can be positioned at either the right hand or left hand end of the cannula manifold.

With reference to Figures 6A to 6C, in some embodiments the cannula assembly 500 comprises a conduit clip 510 rotationally attached to the cannula part 501 about a rotational axis 520 that is approximately on or parallel to the sagittal plane of a user (that is, an axis that is approximately horizontal in use with a user in a standing position). To position the conduit to the left or right sides of the cannula assembly the conduit clip is rotated on the axis 520, as illustrated in Figure 6B where the clip 510 is
rotated part way between the right and left sides of the assembly. As illustrated in embodiment 6C, in some embodiments the cannula part comprises a resilient material moulded or fitted over a relatively rigid manifold 502. The manifold 502 may comprise a hollow member comprising two apertures 513 to be in communication with nasal prongs 503, and an aperture 505 at each end to which the plug 507 or conduit connector 506 seals. In some embodiments, the silicone or silicone like material of the resilient cannula part 501a may be over moulded to the relatively rigid manifold 502, or attached by other fastening technologies, for example bonding, mechanical snap fitting, ultrasonic welding or any other suitable fastening method known in the art. The resilient cannula part is formed with the nasal prongs aligned with or in communication with the apertures 513 and is formed with an aperture 505 at each end to communicate with the aperture 505 of the manifold. In some embodiments, an axle 515 may be integrally formed with the rigid manifold 502. The conduit clip 510 is rotationally received on axle 515. In some embodiments the clip 510 may comprise a keyway so that the clip can be removably mounted to the cannula part 501. In some embodiments the cannula assembly 500 comprises a flange 516 at the end of the axle 515 to retain the conduit clip on the axle. Preferably the ends of the manifold are curved with a centre of curvature on the rotational axis 520. The plug and the conduit connector have a complementary curvature so that the clip 510 can rotate on the rotational axis 520 to position the conduit at either end of the cannula assembly. The resilient material of the cannula part at the ends 518 of the manifold may provide a seal with the plug and conduit connector. The rigid manifold may be formed from the same material as the conduit clip. The relatively rigid (compared to the soft or resilient material of the cannula) material of the manifold may provide for positive fitting or engagement between the conduit clip 510 and the cannula part 501.

Figures 7A and 7B illustrate an embodiment of a nasal cannula assembly 600. The cannula assembly comprises a cannula part 601 having a pair of prongs 603. The conduit 3 is attached to the cannula assembly 600 via a connector 606. The connector comprises a manifold 602. The manifold comprises an inlet and an outlet. The manifold 602 is attached to or integrally formed with the conduit connector 606. The cannula part 601 is rotatable relative to the manifold 602. The cannula part 601 is mounted on and rotatable about a vertical shaft such that the prongs rotate together. In some embodiments, the cannula part 601 is a separate component from the manifold/tubing assembly and the removable cannula part 601 can allow for the use of
different sizes of prongs for different nose sizes while using the same size manifold 602 (for example as part of a standard gas conduit). In some embodiments, the manifold 602 may comprise an open top 605 that is the manifold outlet. The cannula part fits over or covers the open top so that the prongs are in communication with the manifold inlet provided by the conduit connector. In some embodiments the manifold comprises a lip 607 on a surface of the manifold to which the cannula part 601 connects. In some embodiments the lip may extend about the open top of the manifold. The cannula part 601 can have a mating section 608 (for example an annular groove) that is complementary to the lip 607. In some embodiments that contain a lip 607 on the manifold 602, the cannula part 601 can be lifted from the surface of the manifold and rotated about a vertical shaft so that the prongs 603 can be repositioned to the appropriate direction. The cannula part 601 can be rotatable about a vertical, central axis of the manifold 602 or an axis that is centrally located relative to the prongs such that the conduit 3 switches between the left hand side or the right hand side of the cannula assembly.

Figure 8A illustrates an embodiment of a nasal cannula assembly 700 that is similar to the cannula of Figure 3. In the cannula assembly of Figure 8A, the plug 707 and conduit connector 706 are connected together by a lateral member 708. In some embodiments the plug, connector and lateral member are integrally formed to form a clip 710. The conduit or tube may be provided with the clip 710 so that the conduit 3 is a clip on supply tube. In the embodiment of Figure 8A, cannula part 701 comprises a manifold 702 in communication with prongs 703 and two openings 705, one at each end of the manifold. The clip 710 may be described as a manifold receiving structure. The manifold receiving structure 710 can be assembled to the supply tube 3 at the time of manufacture or can be connectable to the supply tube 3 prior to use. In certain embodiments, the manifold receiving structure 710 can be a substantially 'C' or 'U' shaped manifold receiving structure or clip 710 as illustrated in Figure 8A or the manifold receiving structure 710 can have any shape that allows for complimentary coupling to the manifold 702.

Unlike the embodiment of Figure 3 where the clip 210 is clipped onto the manifold 202 of the cannula part by mating the plug with the manifold from one end of the manifold and the conduit clip with the manifold from the other end, in the embodiment of Figure 8A, the clip is pushed into the manifold from one end. That is, the clip is inserted into
the manifold from either end of the manifold so that the conduit connector is positioned to the right or the left side of the manifold. The clip is inserted into the manifold via the aperture 705 at one end until the conduit connector 706 mates with that aperture and the plug 707 mates with the aperture 705 at the opposite end of the manifold 702. The clip can be pushed into the manifold from either end. The clip is not elastically deformed to mate the clip with the manifold.

In some embodiments, the cannula part 701 may be provided with a relatively rigid part for interfacing with and receiving and/or retaining the clip 710. For example, illustrated in Figures 8B, the cannula part 701 may comprise conduit clip receiving or retaining part 711 for receiving conduit clip 710. The retainer 711 is illustrated in Figure 8C. The silicone or silicone like material of the resilient cannula part 701a may be over moulded to the relatively rigid retainer 711, or attached by other fastening technologies, for example bonding, mechanical snap fitting, ultrasonic welding or any other suitable fastening method known in the art. The relatively rigid (compared to the soft or resilient material of the cannula) material of the clip receiving part provides for positive fitting or engagement between the conduit clip 711 and the cannula part 701. The clip is inserted laterally into the manifold from one end.

Figure 9 illustrates an embodiment of a nasal cannula assembly 800 that comprises dual gases conduits 3a, 3b, one conduit for each nasal prong. The cannula assembly 800 comprises a cannula part 801 comprising prongs 803. The cannula part may be formed from a thermoplastic, silicone or silicone like material and comprises the nasal prongs 803 and side straps or arms 804 or other connection features for connecting to headgear. In some embodiments the cannula part is an integrally formed part. Each conduit is connected to a corresponding prong via a joint adapted to allow the conduits to be routed to a left side or a right side of the nasal cannula assembly. In the embodiment of Figure 9A each conduit is connected to a corresponding prong via a flexible conduit section or tube 805. For example, the flexible conduit section may be formed from a silicone or silicone like material. The flexible conduit may comprise circumferentially extending ribs so that bending of the flexible conduit section does not cause the flexible conduit section to collapse. Preferably, bending of the flexible conduit section does not cause substantial occlusion of the internal passage of the flexible conduit section. The conduits 3a, 3b may be routed to either the right or left side of the cannula by bending each flexible conduit section, for example by 90 degrees
to either the left or right sides. To retain the conduits in place, the cannula is preferably provided with a clip 806 on each side of the cannula assembly 800. Each clip may comprise two channels or receptacles, each channel for receiving one of the tubes 3a, 3b. In some embodiments the clip comprises a channel or receptacle for receiving both conduits 3a, 3b. The clip may be formed from silicone or silicone like material, and could be integrally formed with the cannula part, or could be formed from a plastic material that is more rigid than the material of the cannula part. In some embodiments a strap may be provided at the cannula for strapping the conduits to the cannula.

In some embodiments each conduit 3a, 3b is connected to a corresponding prong via a swivel joint. The conduits 3a, 3b may be routed to either the right or left side of the cannula by rotating each swivel joint at the nasal cannula. An example nasal cannula assembly 900 is illustrated in Figures 9B and 9C. In some embodiments each swivel joint is a swivel elbow. In some embodiments each swivel joint rotates on an axis 906a, 906b that is at an angle to an axis 907a, 907b of the corresponding prong. Rotation of the swivel joint on an angle as illustrated allows both tubes 3a, 3b to be routed to the left side or the right side without overlapping. As illustrated in Figure 9B, with both tubes routed to the right hand side of the cannula assembly the tube 3a extending from the left nasal prong extends below the tube 3b extending from the right nasal prong. In an alternative configuration with both tubes routed to the left hand side of the cannula assembly, the tube 3b extending from the right nasal prong extends below the tube 3a extending from the left nasal prong.

**Bifurcating headgear**

Various headgear systems or straps according to some embodiments of the present invention are described with reference to Figures 10A to 19. A headgear or head strap is attached to a patient interface such as a cannula to hold the patient interface in position on a user's face. Headgear comprises at least one strap that extends about a user's head.

With reference to Figures 10A to 10F, in some embodiments a head gear strap comprises a portion that is configured to bifurcate into more than one band to extend around the patients head. With reference to Figures 10A to 10F, in some embodiments the head gear strap 1000 comprises a portion 1001 that is configured to bifurcate into
more than one band 1002. With the strap 1000 in a non-bifurcated or joined configuration the strap is a single band 1000, as illustrated in Figures 10A and 10B. Where the bifurcate-able portion 1001 of the strap has been bifurcated into more than one band 1002, the strap provides more than one band to extend about a user's head, as shown in Figure 10C. When bifurcated, ends of the bands 1002 are joined together at a common or non-bifurcate-able part 1003 of the strap 1000. The non-bifurcate-able parts of the strap are attached to a patient interface in use. For example, ends 1003 of the strap may be attached to a patient interface in use, directly to the interface or via other connecting straps.

In the embodiment illustrated in Figures 10A to 10F, the strap 1000 comprises a longitudinal frangible section 1004. In some embodiments the frangible section comprises a relatively thin section 1010 as shown in Figure 10F to be torn by a user to separate the portion of the strap into more than one band 1002, as shown in Figure 10D. For example, the strap may be formed from silicone or a silicone like material with a thin portion as shown in Figure 10F that can be torn by a user. In some embodiments the frangible section may be a perforated section of the strap. The frangible section is a section of the strap that is weaker than the bands 1002 of the strap so that the frangible section may be torn without tearing the bands or other sections of the strap.

Each band extends between the ends of the strap. The bands are separated by the frangible section. In some embodiments, the strap 1000 comprises a finger hole 1005 at the frangible section to assist with separating the bands by tearing the frangible section. For example, in the illustrated embodiment there is a finger hole part way along the frangible section, for example in a centre of the frangible section. In some embodiments there may be a hole at one or both ends of the frangible section. In some embodiments the hole at an end of the frangible section is a tear drop shape with a rounded portion defining an end of the frangible section. The rounded portion 1006 assists with preventing tearing of the strap beyond the frangible section so that only the frangible section tears when separating the bifurcate-able section of the strap into bands. In some embodiments the hole at the end of the frangible section may not be suited for inserting a finger and so may not be used for separating the bands but for preventing tearing of the strap beyond the frangible section. The frangible section may be described as a tear bead.
In some embodiments the frangible strap 1000 is formed from a fabric material and coated on one or both sides with coating layer. In some embodiments the frangible strap 1000 is formed from a foamed fabric material, for example a polyurethane foam, and the coating layer is a polymer, for example a silicone or other flexible polymer, for example Nylon or Spandex or natural alternatives such as latex. With reference to the cross section shown in Figure 10G, in some embodiments, the frangible section is formed by cutting the fabric 1007 to form the separate bands 1002, and coating the fabric with a coating layer 1008 on at least one side to hold the separate bands together in a single strap with faces of the cut 1009 through the fabric held together or close together. The coating bridging the cut 1009 in the fabric provides the thin section that can be torn by a user to separate the bands apart.

In some embodiments, with reference to Figure 11, the strap 1100 may comprise a lift out or removable portion or tab 1120. The removable section extends the length of the bifurcate-able section and is separated from the bands 1102 of the strap by a frangible section 1104. The frangible section extends around or defines a perimeter of the removable section. The removable section 1120 may comprise a grip tab 1121 at one end for a user to grab to tear the frangible section 1104 to remove the removable section from the strap to separate the bifurcate-able section into separate bands.

In some embodiments the bifurcate-able section of the strap may extend in use to forward of the user's ears. In some embodiments the bifurcate-able section of the strap may extend in use from behind the user's ears.

In the embodiments of Figures 10A to 11 the bands 1002 are arranged edge-to-edge when the bands are in a non-bifurcated configuration. In some embodiments, the bands 1002 may be arranged side-by-side when in a non-bifurcated configuration. For example, in the embodiment illustrated in Figure 14 (described below) the bands 1402 when arranged together in a non-bifurcated configuration are placed one on top of the other (side-by-side).

In an embodiment where the bands are arranged side-by-side when the bands are in a non-bifurcated configuration, the bands may be held together in the non-bifurcated portion by stitching between the bands. The stitching is of a sufficiently low strength
so that the stitching may be broken or torn to separate the bands into a bifurcated configuration. In some embodiments the bands are held in a side-by-side configuration by other means, for example a clasp or clasps, buttons, hook and loop fasteners or magnets.

In the embodiments illustrated in Figures 10A and 11 the strap is irreversibly bifurcable. Once the frangible section is torn, the strap comprises multiple bands. There is no means to rejoin the separate bands into a single strap. In some embodiments, the head gear strap may be reversibly bifurcable. For example, as shown in Figures 12A and 12B in some embodiments the head gear comprises a strap 1200 and a clasp 1220 that is slidable along at least the bifurcate-able section of the strap. To hold separate bands 1202 together the slidable clasp is moved to or towards a central position of the strap 1200, as shown in Figure 12B. To allow the separate bands to separate or bifurcate, the slidable clasp is moved towards an end of the bifurcate-able portion of the strap, as illustrated in Figure 12A. The clasp may be a sleeve that passes around the bands to hold the bands together. In some embodiments the bands may each comprise a feature that interfaces with a corresponding feature on the clasp to bind the bands 1202 together when in a non-bifurcated configuration. For example, the clasp and bands may comprise a zipper where the bands comprises interlocking teeth that are separated or mated by sliding the clasp along the bands from one end of the bifurcate-able section to the other end of the bifurcate-able section. Alternatively one band may comprise a channel extending along the band, the other band comprising a corresponding a projection extending along the band. The clasp is adapted to push the projection into the channel to hold the bands together, or separate the projection from the channel to bifurcate the strap. In some embodiments the head gear comprises a fabric or sheet material or web that extends between the bands. In a non-bifurcated configuration the web is bunched up or folded into a non-expanded configuration. In a bifurcated configuration where the bands 1202 are spaced apart the web 1210 is expanded or unfolded to cover an area between the spaced apart bands, as shown in Figure 12A.

In some embodiments the head gear comprises two clasps as illustrated in Figures 13A to 13C. In a non-bifurcated configuration both clasps 1320 are slid towards a central position of the strap to hold the bands together, as illustrated in Figure 13B. In a
bifurcated configuration each clasp is slid to an end of the bands 1302 so that the bands may separate between ends of the bands, as illustrated in Figures 13A and 13C.

In some embodiments the clasp comprises two spaced apart flanges 1321 as illustrated in Figure 13C. In Figure 13C, the clasp 1320 at the right hand end of the strap is drawn with one flange 1321 omitted to illustrate three posts or pins 1322 extending between the spaced apart flanges 1321. The pins are shown in hidden detail at the clasp at the left hand end of the strap 1300 as drawn. The bands 1302 extend between the flanges 1321. One pin 1322a is positioned between the bands 1302 and the other two pins are positioned on outer edges of the bands. Ends of the bands may be pivotally coupled together at pivot joints 1323. One or each band 1302 may comprise a central tab or stop to limit the amount of travel of the clasps along the bands 1302.

In some embodiments the each clasp and the bands are complementary adapted so that moving each clasp to an end of the bands forces the bands apart to separate the bands into a bifurcated configuration. For example, as shown in Figure 13C, each clasp comprises two spaced apart flanges and three pins extending between the spaced apart flanges. The bands comprises a cross over portion 1310 near ends of the bands so that when the clasps are moved to the ends of the bands the centre pin pushes the bands apart to separate the bands into the bifurcated configuration.

In some embodiments the bifurcable strap comprises bands pivotally coupled together at the ends of the bands. For example, as shown in Figure 14, the headgear comprises bands 1402 pivotally coupled together at the ends of the bands at pivot joint 1405. In a non-bifurcated configuration one band 1402 lies over the top of the other band. Also pivotally coupled to the ends of the bands is a common strap 1406 extending between the ends of the bands 1402 and the patient interface. A gas conduit may be attached or supported by the strap 1406. In some embodiments the pivot points 1406 are forward of a user's ears in use.

**Stretch and non-stretch headgear**

In some embodiments a head gear for a patient interface comprises a strap having a non-stretchable section and a stretchable section. The stretchable section may be described as being elasticated. The stretchable section may be formed from a rubber
or silicone or silicone like material or comprise such a material. In some embodiments, the head gear strap comprises a non-stretchable section to be positioned towards the back of a user's head, and a stretchable section extending between each end of the non-stretchable section and a patient interface. As illustrated in Figure 15, in some embodiments the non-stretchable section 1501 is bifurcated. Section 1501 may be bifurcate-able from a single non-bifurcated strap as described earlier. A stretchable portion 1502 extends between each end of non-stretch portion 1501 and the patient interface.

In some embodiments, at least one of the bands of the bifurcated section is adjustable in length. For example, as illustrated in Figure 20, the non-stretchable section is bifurcated comprising two bands 2001 and is intermediate between two stretchable portions 2002. In the example embodiment, the upper one of the two bands 2001 is adjustable in length. For example, the upper band comprises two portions joined by a buckle, for example the two portions 2003 each loop through the buckle and are secured by hook and loop fasteners.

In some embodiments the head gear comprises a bifurcated portion wherein at least one band of the bifurcated portion is stretchable and ends of the bifurcated bands are joined by a non-stretchable Y connector. For example, as illustrated in Figure 16, in the head gear comprises a bifurcated portion comprising two bands 1602, 1603. Band 1602 is formed of a stretchable material. The bands 1602 and 1603 are joined at both ends by non-stretchable Y connector or Y piece 1604. A portion 1601 of the head gear strap 1600 extending between each Y connector 1604 and the patient interface on each side of the patient interface is stretchable. In some embodiments the bottom band 1603 is non-stretchable. In some embodiments non-stretchable strap 1603 has length adjustment, for example the head gear may comprise a buckle between one end of the band 1603 and a Y connector.

In some embodiments the head gear strap comprises a non-stretchable section and a stretchable section, wherein the non-stretchable section is adapted to be attached to the patient interface and support a gases supply conduit coupled to the patient interface. For example, as shown in Figure 17, the head gear strap 1700 comprises a stretchable portion 1701 and a non-stretchable portion 1702. The stretchable portion 1701 attaches to one side of the patient interface, and the non-stretchable portion
attaches to the other side of the patient interface. A gas conduit attached to the patient interface extends from the patient interface on the same side of the interface as the non-stretchable portion of the strap. The non-stretchable portion supports the gases supply conduit 3. For example the conduit is clipped or coupled to the non-stretchable strap. The weight of the conduit is taken by the strap 1702 so that the weight is not transferred to the patient interface, for example a nasal cannula.

With reference to Figure 18, in some embodiments the head gear strap 1800 comprises a first non-stretchable section 1802a adapted to be attached to one side of a patient interface and a second non-stretchable section 1802b adapted to be attached to an opposite side of the patient interface, and a stretchable intermediate section 1801 extending between the first and second non-stretchable sections. The conduit 3 may be routed to extend from either side of the patient interface, and attached or coupled to either the first or second non-stretchable portions of the strap 1800. For example a stretchable or non-stretchable lanyard may hang from the non stretchable strap 1802a or 1802b for supporting the conduit from the non stretchable strap. The non-stretchable portion 1802a or 1802b supports the gases supply conduit 3. The weight of the conduit is taken by the strap 1802a or 1802b so that the weight is not transferred to the patient interface, for example a nasal cannula. The stretchable strap may be bonded or otherwise fixed to ends of the non-stretchable straps, or releaseably attached, for example by a buckle or clip. One or both of the non-stretchable straps may be length adjustable, by for example an adjustable attachment to the patient interface.

With reference to Figure 18, in some embodiments the first and second sections 1802a and 1802b are stretchable and the intermediate portion 1801 of the strap 1800 is non-stretchable. An alternative embodiment is illustrated in Figure 19. With reference to Figure 19, in some embodiments the head gear strap 1900 comprises a first stretchable section 1902a adapted to be attached to one side of a patient interface and a second non-stretchable section 1902b (obscured from view in the Figure) adapted to be attached to an opposite side of the patient interface. A stretchable intermediate section 1901 extends between the first and second non-stretchable sections. In the illustrated embodiment the intermediate portion 1901 is an annular strap or portion that fits on the back of a user's head. Alternatively the intermediate portion may be a skull cap adapted to fit the back of a user's head. The ends of the stretchable sections
1902a and 1902b are fixed to the intermediate portion. In some embodiments, the head gear comprises a non-stretchable sleeve 1903 extending from the intermediate portion towards the patient interface. Preferably the sleeve on each side of the headgear extends from the intermediate portion to forward of the user's ear. The stretchable portion 1902a extends along an inside of the sleeve. The stretchable portion 1902a is not attached to the sleeve along the length of the sleeve from the intermediate portion 1901. The stretchable portion is therefore free to move independently of the sleeve along the length of the sleeve. Both the sleeve and the stretchable portion of the head gear strap are fixed to the intermediate portion of the strap, which in the illustrated embodiment is the annular strap 1901. In some embodiments the conduit 3 may be attached to the sleeve on either side of the head gear to support the conduit and prevent weight of the conduit being transferred to the patient interface. For example, a stretchable or non-stretchable band may extend from the sleeve 1903 to hang from the sleeve to be connected to the conduit to take the weight of the conduit.

The foregoing description of the invention includes preferred forms thereof. Modifications may be made thereto without departing from the scope of the invention as defined by the accompanying claims.
INDICATIVE CLAIMS

1a. A nasal cannula assembly comprising:

   a cannula part comprising a pair of tubular nasal prongs for insertion into the
nares of a patient, and a manifold in fluid communication with the nasal prongs, the
manifold comprising an aperture at left hand end of the manifold and an aperture at
the right hand end of the manifold,

   a connector adapted to receive an end of a gases flow conduit and be removably
received in the aperture at left hand end of the manifold and the aperture at the right
hand end of the manifold, and

   a plug adapted to be removably received in the aperture at left hand end of the
manifold and the aperture at the right hand end of the manifold,

   in use the connector or the plug fitted to one of the apertures at the left and
right sides of the manifold, and the plug fitted to the other one of the apertures at the
left and right sides of the manifold to configure the conduit to extend from either the
left side or right side of the nasal cannula assembly.

2a. A nasal cannula assembly as claimed in claim 1a wherein the plug and connector
are separate parts.

3a. A nasal cannula assembly as claimed in claim 1a wherein the plug and connector
are coupled or attached together by a lateral member to form a clip.

4a. A nasal cannula assembly as claimed in claim 3a wherein the clip is an integrally
formed unitary member.

5a. A nasal cannula assembly as claimed in claim 3a or 4a wherein the clip and
cannula part are complimentary adapted so that in use the lateral member is elastically
deflected to fit the clip to the cannula part.

6a. A nasal cannula assembly as claimed in claim 3a or 4a wherein the clip is fitted
to the cannula part by pushing the clip onto the cannula part in a direction
perpendicular to a lateral direction of the cannula.
7a. A nasal cannula assembly as claimed in any one of claims 3a to 6a wherein the cannula part comprises a rigid member for interfacing with the clip and the prongs are formed of a resilient material attached to the rigid member.

8a. A nasal cannula as claimed in claim 7a wherein the rigid member and the lateral member are adapted so that the lateral member is flexed to spread the plug and connector apart when attaching the clip to the cannula part.

9a. A nasal cannula assembly as claimed in claim 4a wherein the clip is substantially 'C' or 'U' shaped.

10a. A nasal cannula assembly as claimed in any one of claims 1a to 9a wherein the plug and connector each extend into the aperture at the ends of the manifold.

11a. A nasal cannula assembly as claimed in claim 4a wherein the clip provides a positive force against the manifold to grip the manifold between the plug and the connector.

12a. A nasal cannula assembly as claimed in claim 4a wherein the cannula part comprises a recessed portion that is sized and shaped to receive the lateral member.

13a. A nasal cannula assembly as claimed in any one of claims 1a to 12a wherein the cannula part comprising the manifold and nasal prongs is integrally formed.

14a. A nasal cannula assembly as claimed in claim 7a wherein the resilient material is over moulded to the rigid member.

15a. A nasal cannula assembly as claimed in claim 14a wherein the cannula part comprises side arms and the rigid member extends along the side arms.

16a. A nasal cannula assembly as claimed in claim 15a wherein the rigid part comprises through holes in the side arms for the resilient material to extend through by an over moulding process or assembly process.
17a. A nasal cannula assembly as claimed in claim 7a wherein the rigid member comprises a recessed portion that is sized and shaped to receive the lateral member.

18a. A nasal cannula assembly as claimed in claim 7a wherein the apertures at the ends of the manifold are formed in the rigid member.

19a. A nasal cannula assembly as claimed in claim 3a wherein the lateral member is length adjustable.

20a. A nasal cannula assembly as claimed in claim 3a wherein the clip comprises a first part and a second part, the first part comprises one of the plug and the connector and the second part comprises the other one of the plug and the connector, the first part comprises a first lateral member and the second part comprises a second lateral member, and

the first and second lateral members coupled together in a telescoping arrangement and comprising complementary features to set the lateral distance between the plug and the connector.

21a. A nasal cannula assembly as claimed in claim 20a wherein the complementary features comprise a projection on one of the first and second parts and a corresponding aperture in the other one of the first and second parts, the projection being received in the aperture to set the lateral distance between the plug and the connector.

22a. A nasal cannula assembly as claimed in claim 21a wherein one of the first and second parts comprises a plurality of corresponding apertures, the projection being received in the one of the plurality of apertures to set the lateral distance between the plug and the connector, the plurality of apertures providing for a range of cannula part sizes.

23a. A nasal cannula assembly as claimed in claim 4a wherein the clip is movably attached to the cannula part.

24a. A nasal cannula assembly as claimed in claim 23a wherein the clip is rotationally coupled to the cannula part.
25a. A nasal cannula assembly as claimed in claim 24a wherein the clip is rotationally coupled to the cannula part on a rotational axis on or parallel to the sagittal plane of the cannula to position the conduit to the left or right side of the nasal cannula assembly.

26a. A nasal cannula assembly as claimed in claim 25a wherein the manifold is formed of a relatively rigid material, and the cannula part comprises a resilient material moulded over the manifold, the nasal prongs integrally formed with the resilient material, and the cannula part comprises an axle extending from the manifold, and the clip rotationally mounted on the axle.

27a. A nasal cannula assembly as claimed in claim 26a wherein the axle is integrally formed with the manifold.

28a. A nasal cannula assembly as claimed in claim 26a wherein the clip comprises a keyway so that the clip can be removably mounted to the cannula part.

29a. A nasal cannula assembly as claimed in any one of claims 26a to 28a wherein cannula part comprises a flange at the end of the axle to retain the clip on the axle in a direction along the rotational axis.

30a. A nasal cannula assembly as claimed in any one of claims 26a to 29a wherein ends of the manifold are curved with a centre of curvature on the rotational axis, and the plug and the connector each have a complementary curvature so that the clip can rotate on the rotational axis to position the connector at either end of the manifold.

31a. A nasal cannula assembly as claimed in claim 30a wherein the over moulded resilient material covers ends of the manifold to provide a seal with the plug and connector.

32a. A nasal cannula assembly as claimed in claim 3 wherein the clip is fitted to the cannula part by pushing the clip laterally into the manifold via one of the aperture at the left hand end and the aperture at the right hand end so that the connector is received in one of the aperture at the left hand end and the aperture at the right hand end and the plug is received in the other one of the aperture at the left hand end and
the aperture at the right hand end to configure the conduit to extend from either the left side or right side of the nasal cannula assembly.

33a. A nasal cannula assembly as claimed in claim 32a wherein the cannula part comprises a rigid member for interfacing with the clip and the prongs are formed of a resilient member attached to the rigid member, and the cannula part and the rigid member each comprise side arms extending laterally from the manifold.

1b. A nasal cannula assembly comprising:
   a cannula part comprising a pair of tubular nasal prongs for insertion into the nares of a patient,
   a connector adapted to receive an end of a gases flow conduit,
   a manifold attached to or integrally formed with the connector, the connector providing an inlet to the manifold and the manifold having at least one outlet,
   the cannula part movably attached to the manifold to be attached to the manifold in two orientations to configure the conduit to extend from either the left side or right side of the nasal cannula assembly.

2b. A nasal cannula assembly as claimed in claim 1b wherein the cannula part is rotatable relative to the manifold about a substantially vertical axis.

3b. A nasal cannula assembly as claimed in claim 2b wherein the manifold comprise an open top that is the manifold outlet, and the cannula part fits over the open top so that the prongs are in communication with the connector.

4b. A nasal cannula assembly as claimed in any one of claims 1b to 3b where the manifold comprises a lip on a surface of the manifold to which the cannula part connects.

5b. A nasal cannula assembly as claimed in any one of claims 1b to 4b wherein an axle extends from the manifold or the cannula part and the cannula part rotates relative to the manifold on the axle.

1c. A nasal cannula assembly comprising:
a cannula part comprising a pair of tubular nasal prongs for insertion into the nares of a patient, and a left and a right lateral side arm for attaching headgear,

a first conduit for providing as flow of gas to one said nasal prong and a second conduit for providing a flow of gas to the other said nasal prong,

a first joint connecting the first conduit to one said nasal prong and a second joint connecting the second conduit to the other said nasal prong, the joints adapted to allow the first and second conduits to be routed to a left side or a right side of the nasal cannula assembly, and

a left clip on the left lateral side arm and a right clip on the right lateral side arm,

in use the first conduit being held by the left clip or the right clip to configure the first conduit to extend from either the left side or right side of the nasal cannula assembly, and the second conduit being held by the left clip or the right clip to configure the second conduit to extend from either the left side or right side of the nasal cannula assembly.

2c. A nasal cannula assembly as claimed in claim 1c wherein the cannula part is an integrally formed part.

3c. A nasal cannula assembly as claimed in claim 1c or 2c wherein each joint is a flexible tube adapted to bend at least 90 degrees in any direction without substantial occlusion.

4c. A nasal cannula assembly as claimed in claim 3c wherein flexible tubes comprise circumferentially extending ribs so that bending of the flexible conduit section does not cause the flexible conduit section to collapse.

5c. A nasal cannula assembly as claimed in claim 1c or 2c wherein each joint is a swivel joint.

6c. A nasal cannula assembly as claimed in claim 5c wherein each swivel joint rotates on an axis that is at an angle to an axis of the corresponding nasal prong so that rotation of the swivel joint allows both conduits to be routed to the left side or the right side without overlapping.
7c. A nasal cannula assembly as claimed in claim 5c or 6c wherein each swivel joint is a swivel elbow.

8c. A nasal cannula assembly as claimed in any one of claims 1c to 7c wherein each said clip comprises two channels or receptacles each for receiving one of the tubes.

9c. A nasal cannula assembly as claimed in any one of claims 1c to 8c wherein each flexible tube is integrally formed with a nasal prong.

10c. A nasal cannula assembly as claimed in any one of claims 1c to 9c wherein each clip is integrally formed with a said side arm.

11c. A nasal cannula system comprising a nasal cannula assembly as claimed in any one of the preceding claims and a headgear attached to the nasal cannula assembly for attaching the nasal cannula assembly to a patient's head.

12c. A system for providing a flow of respiratory gases to a user or patient comprising a blower, a humidifier, the conduit and a nasal cannula system as claimed in claim 11c.

1d. A headgear comprising:
   a strap, each end of the strap adapted to be attached to a patient interface and extend around a patient's head to hold the patient interface in place on a patient's face, wherein
   at least a portion of the strap is configured to bifurcate into more than one band to extend around the patients head.

2d. A headgear as claimed in claim 1d wherein the strap comprises a longitudinal frangible section extending along a portion of the strap to be torn by a user to separate the portion of the strap into more than one band.

3d. A headgear as claimed in claim 2d wherein the frangible section comprises a relatively thin section.
4d. A headgear as claimed in claim 3d wherein the frangible section is a perforated section.

5d. A headgear as claimed in any one of claims 2d to 4d wherein the bands are separated by the frangible section.

6d. A headgear as claimed in any one of claims 2d to 5d wherein the strap comprises a finger hole at the frangible section to assist with separating the bands by tearing the frangible section.

7d. A headgear as claimed in any one of claims 2d to 6d wherein the strap comprises a hole at an end of the frangible section, the hole comprising a rounded portion defining an end of the frangible section to prevent tearing the strap beyond the frangible section.

8d. A headgear as claimed in claim 6d wherein the hole is a finger hole.

9d. A headgear as claimed in any one of claims 2d to 8d wherein at least the portion of the strap is formed from fabric forming the bands, and the fabric is coated with a polymer with the bands arranged together, the coating providing the frangible section between the bands, the coating adapted to be torn to separate the bands.

10d. A headgear as claimed in claim 9d wherein the bands are formed by a longitudinal cut in the fabric along the portion of the strap, the polymer coating bridging the cut to hold the bands together in a non-bifurcating configuration.

11d. A headgear as claimed in claim 9d or 10d wherein the fabric is a foamed fabric.

12d. A headgear as claimed in any one of claims 2d to 4d wherein the bands are separated by a removable section of the strap comprising a lift tab, the removable section joined to the bands by the frangible section.

13d. A headgear as claimed in claim 1d wherein the headgear comprises a clasp that is slidable along at least the portion of the strap configured to bifurcate.
14d. A headgear as claimed in claim 13d wherein to bifurcate the strap to separate the bands the clasp is slidable to an end of the bands, and the clasp is slidable to a midpoint of the bands to hold the bands together as a single strap.

15d. A headgear as claimed in claim 13d wherein to bifurcate the strap to separate the bands the clasp is slidable to an end of the bands, and the clasp is slidable to an opposite end of the bands to hold the bands together as a single strap.

16d. A headgear as claimed in claim 15d wherein each band comprises a feature that interfaces with a corresponding feature on the clasp to bind the bands together when in a non-bifurcated configuration.

17d. A headgear as claimed in claim 16d wherein the bands comprises interlocking teeth that are separated or mated by sliding the clasp along the bands.

18d. A headgear as claimed in any one of claims 13d to 17d wherein the headgear comprises a web that extends between the bands, in a non-bifurcated configuration the web is bunched up or folded into a non-expanded configuration, and in a bifurcated configuration where the bands are spaced apart the web is expanded or unfolded to cover an area between the spaced apart bands.

19d. A headgear as claimed in claim 13d wherein the headgear comprises two clasps, in a non-bifurcated configuration both clasps are slid towards a central position of the strap to hold the bands together, and in a bifurcated configuration each clasp is slid to an end of the bands so that the bands may separate between ends of the bands.

20d. A headgear as claimed in claim 19d wherein each clasp and the straps are complementary adapted so that moving each clasp to an end of the bands forces the bands apart to separate the bands into a bifurcated configuration.

21d. A headgear as claimed in claim 20d wherein each clasp comprises two spaced apart flanges and three pins extending between the spaced apart flanges, the bands extending between the flanges, one said pin positioned between the bands and the other two pins positioned on outer edges of the bands, and the bands comprises a cross over portion near ends of the bands.
22d. A headgear as claimed in any one of claims 13d to 21d wherein one or each band may comprise a central tab or stop to limit the amount of travel of the clasps along the bands.

23d. A headgear as claimed in any one of claims 1d to 22d wherein the portion of the strap configured to bifurcate extends around the back of the patient’s head from behind the patient’s ears in use.

24d. A headgear as claimed in claim 1d wherein ends of the bands are pivotally coupled together.

25d. A headgear as claimed in any one of claims 1d to 25d wherein the bands in a non-bifurcated configuration are arranged edge-to-edge.

26d. A headgear as claimed in any one of claims 1d to 25d wherein the bands in a non-bifurcated configuration are arranged side-by-side.

27d. A headgear as claimed in claim 26d wherein the bands in the non-bifurcated configuration are held together by one or more of tearable stitching, a clasp or clasps, buttons, clips, hook and loop fasteners or magnets.

1e. A headgear for securing a patient interface to a user’s face comprising:

   a strap, each end of the strap adapted to be attached to a patient interface and extend around a patient’s head to hold the patient interface in place on a patient’s face, wherein

   the strap comprises a non-stretchable section and a stretchable section, the non-stretchable section adapted to be attached the patient interface and support a gases supply conduit coupled to the patient interface.

2e. A headgear as claimed in claim 1e wherein each end of the strap is a non-stretchable section adapted to be attached to the patient interface and the stretchable section is an intermediate section that extends between the non-stretchable sections around the back of the patient’s head.
3e. A headgear as claimed in claim 1e wherein the non-stretchable section is adapted to be attached to one side of the patient interface and the stretchable section is adapted to be attached to an opposite side of the patient interface.

4e. A headgear as claimed in claim 1e or 2e wherein the non-stretchable section comprises a feature for securing the conduit.

1f. A headgear for securing a patient interface to a user's face comprising:
   a strap comprising a first stretchable section adapted to be attached to one side of a patient interface and a second stretchable section adapted to be attached to an opposite side of a patient interface, and a non-stretchable intermediate section extending between each end of the stretchable sections.

2f. A headgear as claimed in claim 1f wherein the intermediate portion is an annular portion, ends of the stretchable sections attached to the annular portion.

3f. A headgear as claimed in claim 1f or 2f wherein the headgear comprises a first non-stretchable sleeve and a second non-stretchable sleeve each extending from the non-stretchable intermediate section, and the first stretchable section extends along an inside of the first non-stretchable sleeve and the second stretchable section extends along an inside of the second non-stretchable sleeve.

4f. A headgear as claimed in claim 3f wherein the first and second non-stretchable sleeves extend from the intermediate portion to forward of the patient's ears in use.

5f. A headgear as claimed in 3f wherein the first and second stretchable sections are not attached to the first and second non-stretchable sleeve along the length of the sleeve from the intermediate portion.

6f. A headgear as claimed in any one of claims 3f to 5f wherein one or both sleeves is adapted to support a gas conduit for providing a gas flow to the patient interface.

7f. A headgear as claimed in claim 6f wherein the head gear comprises a lanyard connected to a said sleeve adapted to secure the gas conduit.
8f. A headgear as claimed in claim 7f wherein the lanyard is stretchable.

9f. A headgear as claimed in claim 1f wherein the non-stretchable intermediate section is bifurcated to comprise two separate bands.

10f. A headgear as claimed in claim 1f wherein the non-stretchable section is configured to bifurcate into more than one band to extend around the patients head.

11f. A headgear as claimed in claim 1f wherein the headgear comprises a bifurcated section comprising two bands and one said band is the non-stretchable intermediate section.

12f. A headgear as claimed in claim 11f wherein the headgear comprises a first non-stretchable 'Y' connector connecting between the first stretchable section and one end of the two bands and a second non-stretchable 'Y' connector connecting between the second stretchable section and an opposite end of the two bands.

13f. A headgear as claimed in claim 11f or 12f wherein one of the two bands is a stretchable band.

14f. A headgear as claimed in claim 13f wherein an upper one of the two bands is the stretchable band and a lower one of the two bands is the non-stretchable band.

15f. A headgear as claimed in claim 13f or 14f wherein the non-stretchable band is length adjustable.

16f. A headgear as claimed in claim 9f wherein at least one of the bands is adjustable in length.

17f. A headgear as claimed in claim 16f wherein an upper one of the two bands is adjustable in length.
**Application Data Sheet 37 CFR 1.76**

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<th>Title of Invention</th>
<th>NASAL CANNULA ASSEMBLY</th>
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The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

### Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

### Inventor Information:

#### Inventor 1

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#### Inventor 2

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<th>15 Maurice Paykel Place</th>
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#### Inventor 3

**Legal Name**

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**Residence Information (Select One)**

- [ ] US Residency
- [ ] Non US Residency
- [ ] Active US Military Service

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**Mailing Address of Inventor:**

| Address 1 | 15 Maurice Paykel Place |
| Address 2 | East Tamaki |
| City | Auckland | State/Province |
| Postal Code | 2013 | Country | NZ |
| **Inventor** | 4 | Remove |

**Legal Name**

| Prefix | Given Name | Middle Name | Family Name | Suffix |
| Jason | Allan | Klenner | |
| **Residence Information (Select One)** | US Residency | Non US Residency | Active US Military Service |
| **City** | Auckland | Country of Residence | NZ |

**Mailing Address of Inventor:**

| Address 1 | 15 Maurice Paykel Place |
| Address 2 | East Tamaki |
| City | Auckland | State/Province |
| Postal Code | 2013 | Country | NZ |
| **Inventor** | 5 | Remove |

**Legal Name**

| Prefix | Given Name | Middle Name | Family Name | Suffix |
| Brent | Ian | Laing | |
| **Residence Information (Select One)** | US Residency | Non US Residency | Active US Military Service |
| **City** | Auckland | Country of Residence | NZ |

**Mailing Address of Inventor:**

| Address 1 | 15 Maurice Paykel Place |
| Address 2 | East Tamaki |
| City | Auckland | State/Province |
| Postal Code | 2013 | Country | NZ |
| **Inventor** | 5 | Remove |
Application Data Sheet 37 CFR 1.76

Title of Invention: NASAL CANNULA ASSEMBLY

Inventor 6
Legal Name

Prefix  Mark
Given Name  Thomas
Middle Name
Family Name  O'Connor
Suffix

Residence Information (Select One)
☐ US Residency  ☐ Non US Residency  ☐ Active US Military Service

City  Auckland  Country of Residence  NZ

Mailing Address of Inventor:

Address 1  15 Maurice Paykel Place
Address 2  East Tamaki

City  Auckland  State/Province
Postal Code  2013  Country  NZ

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).

☐ An Address is being provided for the correspondence information of this application.

Customer Number  20995
Email Address  efiling@knobbe.com

Add Email Remove Email

Application Information:

Title of the Invention  NASAL CANNULA ASSEMBLY
Attorney Docket Number  FPHCR.341PR4  Small Entity Status Claimed
Application Type  Provisional
Subject Matter  Utility
Total Number of Drawing Sheets (if any)  21  Suggested Figure for Publication (if any)

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

Request Not to Publish. I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

EFS Web 2.2.9
**Application Data Sheet 37 CFR 1.76**

<table>
<thead>
<tr>
<th>Title of Invention</th>
<th>NASAL CANNULA ASSEMBLY</th>
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</table>

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:  
- [ ] Customer Number  
- [ ] US Patent Practitioner  
- [ ] Limited Recognition (37 CFR 11.9)

Customer Number: 20995

**Domestic Benefit/National Stage Information:**

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the application number blank.

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Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.

**Foreign Priority Information:**

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX), the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

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Additional Foreign Priority Data may be generated within this form by selecting the Add button.
Application Data Sheet 37 CFR 1.76

| Title of Invention | NASAL CANNULA ASSEMBLY |

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.

NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Authorization to Permit Access:

Authorization to Permit Access to the Instant Application by the Participating Offices

☑ Authorization to Permit Access to the Instant Application by the Participating Offices

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.
**Application Data Sheet 37 CFR 1.76**

<table>
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<tr>
<th>Application Data Sheet 37 CFR 1.76</th>
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<tr>
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**Applicant 1**

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an assignee under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

- Assignee  
- Legal Representative under 35 U.S.C. 117  
- Joint Inventor  
- Person to whom the inventor is obligated to assign  
- Person who shows sufficient proprietary interest

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. **X**

Organization Name: FISHER & PAYKEL HEALTHCARE LIMITED

**Mailing Address Information:**

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**Assignee Information including Non-Applicant Assignee Information:**

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

**Assignee 1**

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Assignee Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here.  

EFS Web 2.2.9
**Application Data Sheet 37 CFR 1.76**

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**Title of Invention**

NASAL CANNULA ASSEMBLY

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**Email Address**

**Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.**

**Signature:**

**NOTE:** This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications

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**Additional Signature may be generated within this form by selecting the Add button.**

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.