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Asymmetrical nasal delivery elements and fittings for nasal interfaces

Abstract

A nasal interface uses asymmetrical nasal delivery elements to deliver an asymmetrical flow through the interface to both nares or to either nare, and a mouthpiece may be inserted to maintain a leak, to improve dead space clearance in the upper airways, decrease peak expiratory pressure, reduce noise, increase safety of the therapy for smaller patients and reduce resistance in the interface allowing desired flow rates to be achieved at reduced motor speeds of associated flow generating devices. Different forms of fittings, such as sleeves or inserts can be attached to nasal delivery elements to improve or optimize the therapeutic effects of nasal high flow. It may allow high pressures to be achieved at lower flow rates, reduce noise, improve patient comfort and efficiently clear anatomical dead space.

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Background/Summary

INCORPORATION BY REFERENCE TO ANY PRIORITY APPLICATIONS
(1) Any and all applications for which a foreign or domestic priority claim is identified in the Application Data Sheet as filed with the present application are hereby incorporated by reference under 37 CFR 1.57.
BACKGROUND OF THE INVENTION
Technical Field of the Invention
(2) The present invention generally relates to a nasal interface. More particularly, the present invention relates to asymmetrical nasal delivery elements for a nasal interface and other arrangements for achieving asymmetric flow or partial unidirectional flow.
Description of the Related Art
(3) Humidifiers are used to provide humidified respiratory gases to a patient. Gases are delivered to the patient via a patient interface. Examples of a patient interface include an oral mask, a nasal mask, a nasal cannula, a combination of oral and nasal mask, and the like.
(4) Nasal interfaces can be used to deliver a high flow of gases to a patient. Nasal delivery elements are inserted into the nose of a patient to deliver the required therapy. The nasal delivery elements may be required to seal or semi-seal at the nose, or may not be required to seal at the nose, to deliver the therapy. Nasal high flow typically is a non-sealing therapy that delivers relatively high-volume flow to the patient through a nasal interface, which flow may be sufficient to meet or exceed the patient's inspiratory flow rate.
SUMMARY OF THE INVENTION
(5) Although prongs for nasal interfaces exist in the prior art, an aspect of at least one of the embodiments disclosed herein includes the realization that there are problems with the insertion of these prior art prongs into the nose of a patient. Prongs in the art require high motor speeds of the flow generating device to deliver the desired flow rate to the patient. A flow generating device is a device that delivers a flow of gas to a patient.
(6) If the interface is suddenly occluded, the static pressure may increase to equal the backpressure in the system, which may potentially reach undesirable levels. The undesirably high static pressure

is intensified for child and infant prongs because the reduced prong diameter required to fit the nares of a child or infant can increase resistance to flow through the interface to the patient.
(7) Currently there are few different sized nasal delivery elements available to better fit a patient, and it can be difficult to optimize dead space clearance and delivered pressure to the patient. The current options may use supplemental oxygen, require more heating, more water and may not provide a high level of patient comfort. Undesirably high flows or excessively high flows are being provided to patients to achieve the desired pressure effects with the existing interfaces. A nasal delivery element of a nasal interface with a smaller diameter may have a high leak and as a result will deliver lower pressure to a patient. A large diameter may not be as efficient at clearing anatomical dead space from the patient airways.
(8) A system is disclosed that uses nasal high flow in combination with asymmetrical nasal delivery elements for a nasal interface to deliver respiratory gases to a patient via an asymmetrical flow. Asymmetrical nasal delivery elements can provide the patient with increased dead space clearance in the upper airways, Due to a decrease in peak expiratory pressure, noise can be reduced, and asymmetrical nasal delivery elements may provide a more desirable therapy for infant use due to mitigation of the risk of completely sealing the airways of the patient. The asymmetry of the nasal delivery elements can reduce the resistance to flow through the interface, which can achieve desired flow rates using lower backpressure and/or lower motor speeds of the flow generating device.
(9) Different embodiments disclose a system that modifies the pressure effects during nasal high flow while maintaining efficient dead space clearance, by adding fittings such as but not limited to, sleeves or inserts to the nasal interface. It may increase pressure swings generated during breathing, increase jetting effects, improve patient comfort, more efficiently clear dead space and increase expiratory pressure. The use of fittings may reduce the required operational flow, which may result in less noise, reductions in heating, oxygen and water usage, desirable or optimized therapeutic effects of nasal high flow. Thus a lower flow rate may be able to achieve a higher pressure.
(10) Accordingly, in one aspect the present invention relates to a nasal interface comprising asymmetrical nasal delivery elements, the asymmetrical nasal delivery elements comprising a first nasal delivery element that is a prong and a second nasal delivery element that is a prong or a pillow, the prong or pillow of the second nasal delivery element having a greater internal cross-sectional area on a plane perpendicular to the airflow direction than a prong of the first nasal delivery element, which causes asymmetrical flow or partial unidirectional flow of gases at the nares of a subject, to improve dead space clearance, preferably to reduce the volume of anatomical dead space within the volume of the airway of a subject, to reduce peak expiratory pressure, to reduce noise, and/or to reduce resistance to flow at the patient interface.
(11) In various embodiments the first and second nasal delivery elements may comprise (1) an orifice without a nasal prong adapted in use to rest adjacent one nare and a nasal prong or a nasal pillow adapted in use to engage the other nares, or (2) a first nasal prong having a first cross-sectional area and a second nasal prong or a nasal pillow having a second cross-sectional area, the second cross-sectional area being greater than the first cross-sectional area, or (3) a first nasal prong having a first outer circumference and a second nasal prong or a nasal pillow having a second outer circumference, the second outer circumference being greater than the first outer circumference, or (4) a first nasal prong having a first cross-sectional area and a first outer circumference and a second nasal prong or a nasal pillow having a second cross-sectional area and a second outer circumference, the second cross-sectional area and second outer circumference being greater than the first cross-sectional area and first outer circumference.
(12) In various embodiments the second cross-sectional area may be about 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5, 10, 10.5, 11, 11.5, 12, 12.5, 13, 13.5, 14, 14.5, 15, 15.5, 16, 16.5, 17, 17.5, 18, 18.5, 19, 19.5, 20, 20.5, 21, 21.5, 22, 22.5, 23, 23.5, 24, 24.5, 25, 25.5, 26, 26.5, 27, 27.5, 28, 28.5, 29, 29.5, 30, 30.5, 31, 31.5, 32, 32.5, 33, 33.5, 34, 34.5, 35, 35.5, 36, 36.5, 37, 37.5,

38, 38.5, 39, 39.5, 40, 40.5, 41, 41.5, 42.5, 43, 43.5, 44, 44.5, 45, 45.5, 46, 46.5, 47, 47.5, 48, 48.5, 49, 49.5, or 50 mm.sup.2, and useful ranges may be selected between any of these values (for example, about 1.5 to about 10, about 1.5 to about 20, about 1.5 to about 30, about 1.5 to about 40, and about 1.5 to about 50 mm.sup.2).
(13) In various embodiments the first cross-sectional area may be about 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 311 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 78, 79, or of the second cross-sectional area, and useful ranges may be selected between any of these values (for example, about 20 to about 30, about 20 to about 40, about 20 to about 50, about 20 to about 60, about 20 to about 70, and about 20 to about 80%).
(14) In various embodiments the second cross-sectional area may be about 1.5 to about 50 mm.sup.2 and the first cross-sectional area may be about 20% to about 80% of the second cross-sectional area, preferably about 50%.
(15) In various embodiments the ratio of the first cross-sectional area to the second cross-sectional area may be at least about 1:1.2, 1:1.25, 1:1.3, 1:1.35, 1:1.4, 1:1.451, 1:1.551, 1:1.6, 1:1165, 1:1.71, 1:1.75, 1:1.8, 1:1.85, 1:1.9, 1:1.95, 1:2, 1:2.05, 1:2.1, 1:2.151 1:2.21 1:2.251 1:2.31 1:2.351 1:2145, or 1:215, and useful ranges may be selected between any of these values (for example, about 1:1.2 to about 1:2.5). Preferably the ratio may be about 1:2.
(16) In various embodiments the second outer circumference may be about 7.5, 8, 8.5, 9, 9.5, 10, 10.5, 11, 11.5, 12, 12.5, 13, 13.5, 14, 14.5, 15, 15.5, 16, 16.5, 17, 17.5, 18, 18.5, 19, 19.5, 20, 20.5, 21, 21.5, 22, 22.5, 23, 23.5, 24, 24.5, 25, 25.5, 26, 26.5, 27, 27.5, 28, 28.5, 29, 29.5, or 30 mm, and useful ranges may be selected between any of these values (for example, about 7.5 to about 10, about 7.5 to about 15, about 7.5 to about 20, about 7.5 to about 25, and about 7.5 to about 30 mm).
(17) In various embodiments the first outer circumference may be about 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 501 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 641 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 78, 79, or 80% of second outer circumference, and useful ranges may be selected between any of these values (for example, about 20 to about 30, about 20 to about 40, about 20 to about 50/about 20 to about 60, about 20 to about 70, and about 20 to about 80%).
(18) In various embodiments the second outer circumference may be about 7.5 mm to about 30 mm and the first outer circumference may be about 20% to about 80% of the second outer circumference, preferably about 50%.
(19) In various embodiments the ratio of the first outer circumference to the second outer circumference may be at least about 1:1.2, 1:1.25, 1:1.3, 1:1.35, 1:1.4, 1:1.45, 1:1.55, 1:1.65, 1:1.7, 1:1.75, 1:1.8, 1:1.9, 1:1.95, 1:2, 1:2.05, 1:2.1, 1:2.15, 1:2.2, 1:2.25, 1:2.3, 1:2.35, 1:2.45, or 1:2.5, and useful ranges may be selected between any of these values (for example, about 1:1.2 to about 1:2.5). Preferably the ratio may be about 1:2.
(20) In various embodiments, the nasal interface may be adapted so that fittings may be attached to the nasal delivery elements of the interface to alter the shape or inner or outer diameters of the nasal delivery elements to efficiently clear dead space, reduce operational flow, and reduce noise.
(21) In various embodiments, one nasal delivery element may comprise a single lumen, or both nasal delivery elements may comprise a single lumen.
(22) In another aspect the present invention relates to user interface assembly comprising a nasal interface as described herein, a securement system for the user interface and/or a component associated with the user interface (e.g. such as a tube or tubing), and/or a tube connected to the user interface providing at least a part of a breathing circuit for a user of the interface.
(23) In various embodiments the securement system may comprise a two-part releasable attachment (or connection) arrangement, the arrangement comprising a dermal patch and a user interface patch, (1) the dermal patch having a patient side and an interface side, (a) the patient side of the dermal patch being attachable to the skin of a user, (e.g. by an adhesive, generally being of a

dermatologically sensitive adhesive such as a hydrocolloid), (b) the interface side of the dermal patch being provided with the first part of a two-part releasable attachment or connection system, and (2) the user interface patch having an interface side and patient side, (a) the patient side of the user interface patch being provided with the complimentary second part of the two-part releasable attachment or connection system, (b) the interface side of the user interface patch being attachable (or connectable) to the user interface and/or the component associated with the user interface (e.g. a tube or tubing).
(24) In various embodiments the tube comprises (1) a tubular body, the body defining a lumen extending between open terminal ends of the body, (2) an internal form enclosed within the lumen and supportive of the tubular body, and (3) a coating encapsulating the internal form, the coating securing the internal form to the tubular body.
(25) In various embodiments the interface comprises (1) at least one nasal prong, the prong having a gas outlet adapted to be inserted into a user's nare and a gas inlet fluidly connected to the gas outlet, (2) the at least one nasal prong comprising a backing, the backing configured to rest on a user's face, wherein a lip extends about at least a part of the perimeter of a rear surface of the backing, the rear surface configured for receiving or retaining the user interface patch, such that in use, the user interface patch may be releasably attachable or connectable to, or with, the dermal patch affixed to a user's face.
(26) In various embodiments the lip is a barrier.
(27) In various embodiments the lip extends at least about the perimeter of a region substantially adjacent to a prong associated with the backing.
(28) In various embodiments the lip is an endless lip extending about the perimeter of the rear surface of the backing.
(29) In various embodiments the lip is a series of one or more separate lips.
(30) In various embodiments the one or more separate lips are adjacent or adjoining or overlapping lip portions.
(31) In various embodiments, in use, the lip substantially forms a fluid (e.g. liquid) seal, or barrier to fluid, between the rear surface of the backing and a cannula facing surface of the user interface patch.
(32) In various embodiments the backing is substantially planar or flat or contoured (such as a pre-formed curve) backing configured to rest on a user's face.
(33) In various embodiments the backing assists as a stabilizer of the prong(s) in the nare(s) of a user.
(34) In various embodiments the at least one backing extends laterally outward from the at least one nasal prong, away from the septum of a user.
(35) In various embodiments the lip(s) is hydrophobic.
(36) In various embodiments the lip(s) comprises at least one outer perimeter lip portion and at least one inner perimeter lip portion, each of said lips provided for contacting with a user's face.
(37) In various embodiments the nasal interface may further comprise (1) a face mount part comprising a base portion and the nasal delivery elements, and (2) a gases flow manifold part having a gases inlet for receiving a flow of gas from a gas source, and a gases outlet for delivering the flow of gas to the nasal delivery elements of the face mount part, the manifold part being adapted to be received by the base portion of the face mount part to fluidly connect the outlet of the manifold with the nasal delivery elements of the face mount part, and wherein the manifold part further comprises a groove at the outlet to establish a gap between the base portion of the face mount part and the manifold part, in a region of the base portion configured to locate adjacent a user's philtrum in use to thereby eliminate or at least alleviate pressure on the user's septum from the manifold part in use.
(38) In various embodiments the face mount part may comprise at least one substantially horizontal side entry passage to the interior of the base portion for releasably receiving the outlet of the

manifold part therethrough.
(39) In various embodiments the face mount part may comprise a pair of opposed side entry passages to the interior of the base portion, each adapted to releasably receive the outlet of the manifold part therethrough.
(40) In various embodiments the gases flow manifold part may be formed from a relatively harder material than the face mount part.
(41) In various embodiments the gases flow manifold part a be formed from a substantially rigid plastics material, such as polycarbonate.
(42) In various embodiments the face mount part may be formed from a substantially soft plastics material, such as silicone.
(43) In various embodiments the nasal interface may further comprise headgear comprising a strap forming a part of the headgear for assisting in retaining or stabilizing of the nasal interface upon a user, wherein the strap, or a section of the strap, to be located upon or to be placed in contact with the face or a portion of a user's face includes a surface region for frictionally engaging with the user's face, the surface region being of a relatively higher frictional surface material than the remainder of the strap forming the or a part of the headgear.
(44) In various embodiments the strap or a respective section of the strap, includes two symmetric surface regions for frictionally engaging with two symmetric portions on either side of the user's face.
(45) In various embodiments a remainder of the strap is arranged to extend as a non-facial contacting strap or section of strap which is to extend beyond the user's face or the portion of the user's face.
(46) In various embodiments, each surface region for frictionally engaging with the user's face or a portion of the user's face including the relatively higher frictional surface material assists with retaining or stabilizing of a patient interface upon the face of a user.
(47) In various embodiments each surface region comprises a material applied to the strap or the respective section of strap.
(48) In various embodiments the material applied is in the form of a sleeve positioned about the strap or the respective section of strap.
(49) In various embodiments the sleeve is configured to removeably couple about the strap or the section of the strap.
(50) In various embodiments the strap or the respective section of the strap extends through a passage in the sleeve.
(51) In various embodiments the strap or the respective section of the strap is adapted to be threaded through the passage.
(52) In various embodiments the material applied is in the form of a material coated upon the strap or the respective section of strap.
(53) In various embodiments the material applied is over-moulded upon the strap or the respective section of strap.
(54) In various embodiments the material applied is smooth and comfortable for skin contact.
(55) In various embodiments the material applied is a thermoplastic elastomer.
(56) In various embodiments each surface region is a surface of wider surface area at an end to be located more adjacent to the patient interface than the surface area of an opposing end more distant from the patient interface.
(57) In various embodiments each surface region tapers from the relatively wider surface area to the relatively lesser surface area.
(58) In various embodiments the strap or each section of the strap including the surface region further comprises a component of the strap configured to releasably couple the patient interface.
(59) In various embodiments each portion of the user's face includes a cheek of the user.
(60) In another aspect the present invention relates to a method of delivering gas to the airway of a

subject in need thereof, improving the ventilation of a subject in need thereof, reducing the volume of anatomical dead space within the volume of the airway of a subject in need thereof, and/or treating a respiratory condition in a subject in need thereof, the method comprising delivering a continuous flow of gas to the nares of a subject through a nasal interface comprising asymmetrical nasal delivery elements to generate an asymmetrical flow or a partial unidirectional flow of gases at the nares.

(61) In various embodiments the method may comprise improving the ventilation of a subject in need thereof includes reducing peak expiratory pressure, reducing noise during expiration, and/or reducing resistance to flow at the patient interface.

(62) In various embodiments the gas may be delivered to one nare of the subject at a first flow rate of about 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, or 60 L/min, and useful ranges may be selected between any of these values (for example, about 5 to about 10, about 5 to about 20, about 5 to about 30, about 5 to about 40, about 5 to about 50, and about 5 to about 60 L/min).

(63) In various embodiments the flow rate to the other nare of the subject may be at a second flow rate that may be about 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 78, 79, or 80% of the first flow rate, and useful ranges may be selected between any of these values (for example, about 20 to about 30, about 20 to about 40, about 20 to about 50, about 20 to about 60, about 20 to about 70, and about 20 to about 80%).

(64) In various embodiments the gas may be delivered to one nare of the subject at a first flow rate of about 5 L/min to about 60 L/min and to the other nare of the subject at a second flow rate that may be about 20% to about 80% of the first flow rate, preferably about 50%.

(65) In various embodiments the subject's mouth may be closed or sealed.

(66) In various embodiments the subject's mouth may be open.

(67) In various embodiments the method may further comprise inserting a mouthpiece into the mouth of the subject, to maintain a leak from the mouth of the subject into the atmosphere, a negative pressure line, or an expiratory limb, or to increase or control dead space clearance.

(68) In various embodiments sound generated by the expiration of gas through the nares' may be less than the sound generated by nasal expiration during nasal high flow therapy conducted at an equivalent flow rate using a nasal interface that comprises symmetrical nasal delivery elements.

(69) In various embodiments the gas pressure in the subject's airway may be estimated and/or measured.

(70) In various embodiments the average gas pressure in the subject's airway may be maintained at a level of less than about 4 cm H.sub.2O, preferably at a level of less than about 3.5, 3, 2.5, 5 or 1 cm H.sub.2O, preferably with the subject's mouth open or closed, preferably with the subject's mouth closed.

(71) In various embodiments the oxygen concentration of the subject's airway may be measured.

(72) In various embodiments the oxygen concentration of the subject's airway may be maintained at a substantially constant level or increased.

(73) In various embodiments the carbon dioxide concentration of the subject's airway may be measured.

(74) In various embodiments the carbon dioxide concentration of the subject's airway may be maintained at a substantially constant level or reduced.

(75) In various embodiments the molar fraction of carbon dioxide in the upper airway of the subject may be reduced, preferably by at least about 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 molar % or more, compared to the molar fraction of carbon dioxide in the upper airway of the subject when breathing without assistance.

(76) In various embodiments the molar fraction of carbon dioxide in the upper airway of the subject may be reduced, preferably by at least about 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 molar % or more, compared to nasal high flow therapy conducted at an equivalent flow rate using a nasal interface

that comprises symmetrical nasal delivery elements.
(77) In various embodiments the peripheral capillary oxygen saturation of the subject may be measured.
(78) In various embodiments the peripheral capillary oxygen saturation of the subject may be maintained at a substantially constant level or increased.
(79) In various embodiments herein the peripheral capillary oxygen saturation of the subject may be increased compared to nasal high flow therapy conducted at an equivalent flow rate using a nasal interface that comprises symmetrical nasal delivery elements.
(80) In various embodiments the subject may be hypoxic or hypoxemic before the method is carried out.
(81) In various embodiments the respiratory condition may be chronic obstructive pulmonary disease, asthma, pneumonia, bronchitis, or emphysema.
(82) In various embodiments the gas may be delivered to the airway of the subject for at least about 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 90, 120, 150, or 180 minutes or more, or for at least about 1, 2, 3, 6, 9, 12, 15, 18, 21, 24, 36, 48, 60, or 72 hours or more, or for at least about 1, 2, 3, 4, 5, 6, or 7 days or more, and useful ranges may be selected between any of these values (for example, about 15 minutes to about 7 days, about 15 minutes to about 72 hours, about 15 minutes to about 180 minutes, about 30 minutes to about 7 days, about 30 minutes to about 72 hours, and about 30 minutes to about 180 minutes).
(83) In various embodiments the method may be carried out using an interface of the invention.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
(1) These and other features, aspects, and advantages of the present invention will be described with respect to the following figures, which are intended to illustrate and not to limit the preferred embodiments.
(2) FIG. **1** is a nasal interface as known in the prior art.
(3) FIG. **2** is a nasal interface with asymmetrical nasal delivery elements.
(4) FIG. **3** is a graphical depiction of pressure and motor speed.
(5) FIGS. **4***a*-**4***n* are different embodiments of a nasal interface with asymmetrical nasal delivery elements.
(6) FIGS. **5***a*-**5***f* are different embodiments of a nasal interface with fittings.
(7) FIGS. **6***a*-**6***c* are different embodiments of a nasal interface with different flow supplies.
(8) FIG. **7** depicts carbon dioxide rebreathing for nasal delivery elements of nasal interfaces with different inner diameters.
(9) FIG. **8** depicts pressure effects for elements of nasal interfaces with different outer diameters.
(10) FIGS. **9**A-**9**I are different embodiments of an asymmetrical nasal interface, with one nasal delivery element having a greater internal cross-sectional area on a plane perpendicular to the airflow direction than the other nasal delivery element.
(11) FIG. **10** is an infrared image of a symmetric carbon dioxide gas stream at a flow rate of 25 L/min.
(12) FIG. **11** is an infrared image of an asymmetric carbon dioxide gas stream at a flow rate of 25 L/min.
(13) FIG. **12** shows a nasal cannula positioned in an operative position on the face of a user.
(14) FIG. **13** is a side view of the nasal cannula arrangement of FIG. **12**.
(15) FIG. **14** shows the constituent assembly components of the embodiment of FIGS. **12** and **13**.
(16) FIG. **15** is a front perspective view of a nasal cannula arrangement with a backing component comprising a lip.

(17) FIG. **16** is a rear perspective view of a nasal cannula arrangement with a backing component comprising a lip.
(18) FIG. **17** is a top rear perspective view of a nasal cannula arrangement with a backing component comprising a lip and a user interface patch on a rear surface of the backing component.
(19) FIG. **18** is a cross sectional view through the nasal cannula arrangement of FIG. **32** when user interface patch is in connection with a dermal patch.
(20) FIG. **19** is a side rear perspective view of the nasal cannula arrangement of FIGS. **15** to **18**.
(21) FIG. **20** is a perspective view of a face mount part of the preferred form patient interface of the invention from the outer side of the face mount part.
(22) FIG. **21** is a perspective view of a gases flow manifold part of the preferred form patient interface of the invention.
(23) FIG. **22** is a perspective view of the face mount part of FIG. **20** from an inner side of the face mount part.
(24) FIG. **23** is a perspective view of the face mount part of FIG. **20** from an underside of the face mount part.
(25) FIG. **24**A is a perspective view of a preferred patient interface and headgear in an assembled state.
(26) FIG. **24**B is a perspective view of the patient interface and headgear of FIG. **24**A in a disassembled state.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

(27) Nasal interfaces (FIG. **1**) can be used to deliver a high flow of gases to a patient. Nasal delivery elements, such as prongs or nasal pillows, are inserted into the nose of a patient to deliver the required therapy. The nasal delivery elements may be desired to seal or semi-seal at the nose, or may not be required to seal at the nose, to deliver the therapy. As used herein, prongs typically refer to nasal delivery elements designed to not seal or to only semi-seal at the nose, while nasal pillows typically refer to nasal delivery elements designed to seal at the nose. Nasal high flow (NHF) typically is a non-sealing therapy that delivers relatively high-volume flow to the patient through a patient interface, such as a nasal interface. A nasal interface as herein described may refer to, but is not limited to, a nasal cannula.
(28) Disclosed is a system to deliver gases to a patient through an asymmetrical cannula interface (FIG. **2**). An asymmetrical interface or asymmetrical nasal delivery elements, as described herein, refers to a interface where the nasal delivery elements differ in length (including the substantial or complete absence of a nasal delivery element), internal or external diameter, angle or form, or any combination of these. The system allows an asymmetrical flow to the delivered through the interface to both nares or to either nare. Asymmetrical flow as described herein refers to a flow that differs within the interface or within the nose. In this way, a different flow may be delivered by each nasal delivery element, or the flow may differ between inspiration and expiration, or the delivered flow may be a combination of the above. An asymmetrical flow may also include partial unidirectional flow. Delivery of asymmetrical flow may improve clearance of dead space in the upper airways, decrease peak expiratory pressure, increase safety of the therapy particularly for children and infants, and reduce resistance to flow in the interface. An asymmetrical interface, nasal delivery elements or interface as described herein includes interfaces or systems configured to produce such asymmetrical flow through asymmetrical nasal delivery elements or otherwise.
(29) Pressure generated by NHF depends on flow through the cannula interface, the size of the nasal delivery elements and/or nares of the patient, and the breathing cycle. If flow, leak, or a combination of flow and leak, is asymmetrical through the interface, the flow through the nose may become asymmetrical during breathing. Partial or total unidirectional flow may occur and there may be improved clearance of anatomical dead space as the air is continuously flushed from the upper airways, Total unidirectional flow may be discomforting to a subject. Partial unidirectional flow may be preferred whereby less discomfort is experienced by a subject. Total unidirectional

flow as described herein occurs if flow enters one nare by a nasal delivery element and exits via the other nare via a nasal delivery element, vents to the atmosphere, due to the absence of a nasal delivery element, or the like. Partial unidirectional flow as described herein refers to flow that may enter the nose via both nares and leave the nose from one nare, flow that may enter the nose through one nare and leave the nose via both nares, or different proportions of flow that may enter the nose through both nares and different proportions of flow that may leave the nose through both nares, and is preferably flow that may enter the nose via both nares and leave the nose from one or both nares.

(30) NHF delivered through an asymmetrical cannula interface can involve making an interface in which the nasal delivery elements are of different length, internal or external diameter, or a combination of these (FIG. **2**). Particularly for children or infants, nasal delivery elements will have a small internal diameter and thus higher resistance to gas flow. By using nasal delivery elements that are different lengths, each nasal delivery element may have a different internal diameter (e.g., minimum internal diameter or area). A longer nasal delivery element may have a smaller internal diameter and higher resistance to gas flow; a shorter nasal delivery element may have a larger internal diameter (e.g., larger minimum internal diameter), hence lower resistance to gas flow at the interface. A decreased resistance to flow allows the desired flow to be achieved using lower backpressure, or a lower motor speed of the gas generating device, or a combination of the two.

(31) Asymmetrical nasal delivery elements may cause the peak expiratory pressure to decrease due to the different lengths of the nasal delivery elements at the nose which may provide different internal diameters for each nasal delivery element. During exhalation a patient may be breathing against less pressure in the system as one nare may be open to the atmosphere, or a nasal delivery element may have a greater internal diameter compared to the other nasal delivery element or otherwise have less resistance to exhalation flow compared to the other nasal delivery element, which may reduce the pressure required to exhale.

(32) In an example, an asymmetrical nasal interface used with (e.g., coupled via a conduit or breathing tube) a gas generating device, such as an AIRVO™ flow generator from Fisher & Paykel Healthcare Ltd., decreases the resistance to flow. This may cause the motor speed of the AIRVO™ to drop from a range of 18,000-22,000 RPM to a range of 14,000-18,000 RPM while continuing to achieve a suitable flow for the desired therapy (e.g., NHF), such as about 8 L/min. FIG. **3** illustrates a relationship between the motor speed of the AIRVO™ flow generator and the generated backpressure in the system. The asymmetrical nasal delivery elements may cause a reduction of the backpressure generated in the system. As a result, if an interface is suddenly jammed into the nose, the maximum pressure generated will not exceed the backpressure in the system, which may improve the safety of the system during delivery of NHF.

(33) For a smaller patient, as in an infant or a child, use of asymmetrical nasal delivery elements may reduce over-insertion of both prongs into the nares, when the nares are too small with respect to the prongs, which could result in an undesired semi-seal or seal. Asymmetrical flow may be delivered to the patient even if only one prong is positioned tightly in the nose. The asymmetrical interface improves the performance of the therapy for infants as compressed gas may be used in a system without pressure control.

(34) FIGS. **4***a*-**4***n* show other embodiments that include but are not limited to: nasal delivery elements with the same internal or external diameter or nasal delivery elements with a different internal or external diameter (FIGS. **4***a* and **4***i*). The nasal delivery elements may have a different form, either different from that described above, or from each other (e.g., one prong and one nasal pillow). At least one nasal delivery element may be sealed (FIGS. **4***b* and **4***c*). At least one nasal delivery element may have at least one ventilation hole. The nasal delivery elements may be symmetrical with one or more ventilation holes in at least one nasal delivery element producing asymmetrical flow during breathing (FIGS. **4***d* and **4***n*). At least one nasal delivery element may have a narrowing at the tip, which may produce asymmetrical flow through the nasal delivery

elements in a low impedance gas delivery system as a result of a pressure difference in the nose during breathing (FIG. **4***j*). The narrowest point may be proximal to the flow source, thus the breathing cycle may not affect flow through the asymmetrical nasal delivery elements. The interface may be designed in a way that the left and right nasal delivery elements can be swapped. The interface may have an option to divert flow through either the symmetrical or asymmetrical nasal delivery elements, to an individual nasal delivery element, by varying the resistance within the interface (FIGS. **4***h* and **4***m*), or by partial over-insertion of the into nose. The nasal delivery elements may have different lengths (FIGS. **4***e* and **4***i*), or at least one nasal delivery element may extend into the nose to the nasal valves (FIG. **4***f*). More than two nasal delivery elements may be used with varying internal or external diameter or with different lengths, or a combination of these (FIGS. **4***g* and **4***k*).

(35) Pressure and flow may be measured and controlled in the nares simultaneously or separately. Flow may be continuous in one nare, while it is varied in the other nare according to the breathing cycle. Different interfaces, each delivering asymmetrical flow in the nose, may be used to continuously deliver supplemental oxygen, and to deliver continuous or variable nasal high flow. One nasal delivery element may be used to deliver oxygen, gases, aerosols or the like to the patient while another nasal delivery element may be used to deliver a higher flow of air, or a different flow of oxygen, gases, aerosols or the like to the patient. Each nasal delivery element may supply different flow rates to the patient, and may connect to different flow generating elements (FIGS. **6***a*-**6***c*).

(36) The system may improve the performance of NHF therapy, particularly in the therapy delivered to infants and children. It may reduce resistance compared to existing nasal interfaces and may extend and improve functionality of respiratory devices without modification of the hardware or software.

(37) Asymmetrical flow useful herein can be provided by a nasal interface using any form of pressure support, such as continuous positive airway pressure (CPAP) or non-invasive therapy (NIV). Anatomical dead space can be cleared by transnasal unidirectional flow during a therapy with increased airway pressure, where one nare may be sealed or may be used for inspiration from the apparatus without entrainment of room air and the other nare may be used for expiration (FIGS. **4***b* and **4***c*). In a different embodiment one of the nares may be left unobstructed, providing a more comfortable therapy that has lower noise than conventional NHF therapies.

(38) Asymmetrical flow may occur due to a pillow, cushion, divided mask or any other sealed nasal interface (FIGS. **4***b* and **4***c*). One nare may be connected to the inspiratory limb of a two-limbed ventilator circuit or to a breathing tube in a one-limbed circuit, such as a CPAP blower. The other nare may be left open (FIG. **4***l*), connected to conventional ventilation holes in the interface for biased flow, or connected to the expiratory limb in a two-limbed circuit ventilator. Connection to the expiratory limb of a ventilator may allow the use of flow variations to control the breathing in periodic breathing or Central Sleep Apnoea due to carbon dioxide clearance in the upper airway or re-breathing from the expiratory limb.

(39) Opening the mouth may decrease the pressure delivered to patient and may improve clearance of anatomical dead space. A mouthpiece may be inserted to maintain the leak, and may be further connected to a negative pressure line or the expiratory limb to increase or control clearance of dead space.

(40) To achieve comfortable asymmetrical flow, a high level of humidity, such as that delivered by the devices know as AIRVO™ or ICON™ (AIRVO™ is a humidifier with integrated flow generator device and ICON™ is a CPAP device, manufactured by Fisher & Paykel Healthcare Ltd.), may be necessary to prevent drying of the nasal epithelium. The comfort level of temperature and dew point may be determined from a ratio, and may be, but is not limited to, a range of 33° C.-37° C. and may depend on the flow rate.

(41) Different embodiments disclose a system that allows better fitting of a nasal interface into the

nares of a patient. More specifically, fittings such as, but not limited to sleeves (FIGS. **5***a*-**5***c*, **5***e*-**5***f*) and inserts (FIG. **5***d*), can be added to the nasal delivery elements of a nasal interface to optimize NHF therapy. Sleeves as described herein refer to any structure added externally to a nasal delivery element of a nasal interface. Inserts as described herein refer to any structure added internally into a nasal delivery element of a nasal interface.

(42) The NHF therapy can be improved or optimized to deliver a desired pressure profile and efficiently clear anatomical dead space. A nasal delivery element of a nasal interface with a smaller diameter may produce a jet with a higher velocity that may more efficiently clear patient dead space than a nasal delivery element with a larger diameter. Efficient clearance of dead space reduces the amount of carbon dioxide rebreathing that occurs (FIG. **7**). However a larger diameter may reduce the leak that occurs around the nasal delivery elements of the nasal interface and may result in a higher delivered pressure during both inspiration and expiration (FIG. **8**). A larger diameter may be more preferable in an acute setting, particularly when a patient is suffering from respiratory distress, as a higher expiratory pressure may decrease respiratory rate and improve ventilation.

(43) By adding fittings to the nasal delivery elements of the nasal interface, it is possible to have nasal delivery elements which combine a smaller inner and a larger outer diameter to improve or optimize dead space clearance while maintaining a high pressure at the same flow. FIG. **8** shows that a combination of a nasal delivery element with a large outer diameter and a smaller inner diameter may have similar pressure effects to a nasal delivery element with a large diameter and no insert, while a smaller inner diameter may provide less pressure. If the outer diameter is too large for a patient, the inspiratory pressure may become negative as the flow from may be lower than the peak inspiratory flow.

(44) It generally is not desirable to increase the wall thickness of a nasal delivery element as it may be stiff in the nose of the patient, which may damage the inner surface of the nares, causing patient discomfort. However by attaching the different fittings to the interface it may be possible to benefit from the combination of the inner and outer diameters, while still providing the patient with soft nasal delivery elements to be fitted into the nares, maintaining patient comfort.

(45) For example, by adding a sleeve onto a nasal delivery element of a nasal interface (FIGS. **5***a*-**5***b*, **5***e*-**5***f*), the inner diameter of the nasal delivery element remains the same and may allow jetting effects to efficiently clear the anatomical dead space, while the outer diameter has been increased to reduce the leak around the nasal delivery element and may produce higher pressure swings during breathing. The added sleeve may then be removed once the desired therapy has been delivered, or a higher pressure is no longer required. A sleeve may also function as a one-way valve which may inflate on expiration and increase expiratory pressure. To inhibit or prevent condensate accumulation a semi-permeable material may be used, a leak may be introduced, or a combination of these may be used. A sleeve may also be added to the interface to decrease the outer diameter so that it is smaller than the inner diameter (FIG. **5***c*), which may increase jetting effects, deviate or split the flow from the centre of the nasal delivery element to the periphery, or may combine these.

(46) A second example is to add an insert inside the nasal delivery element (FIG. **5***d*). This may decrease the inner diameter to reduce pressure and increase dead space clearance, while keeping the outer diameter the same. A smaller inner diameter increases jetting effects, deviates or splits the flow from the centre of the nasal delivery element to the periphery, or may combine the flow jetting effects with deviation or splitting of the flow from the centre of the nasal delivery element to the periphery.

(47) Other embodiments may include, using a fitting that may block a nasal delivery element (FIG. **5***e*), allowing NHF to be delivered through the unblocked nasal delivery element to the patient, using fittings that may cause asymmetrical flow to occur (FIG. **5***e*), or that may make an asymmetrical interface symmetrical (FIG. **5***f*). Adding sleeves that have been individually fit to a patient may reduce operational flow which may result in reduced noise, reduced supplemental

oxygen use, improved patient comfort, and the like. Reduced operational flow may also allow less heating, water use, and the like, to be required. Only one interface is needed per patient and it can be specifically fit to the patient to vary pressure or dead space clearance.

(48) FIG. **9** expands on embodiments described above of an asymmetrical nasal interface **100**, with one nasal delivery element **200** having a greater internal cross-sectional area **205** on a plane perpendicular to the airflow direction D than the cross-sectional area **305** of other nasal delivery element **300**. Referring to FIG. **9**A, a nasal interface **100** comprises nasal delivery elements in the form of nasal prongs **200**, **300** of substantially similar length but different internal cross-sectional areas **205**, **305**. Referring to FIG. **9**B, a nasal interface **100** comprises nasal delivery elements in the form of nasal prong **300** and nasal pillow **200** of substantially similar length but different internal cross-sectional areas **205**, **305**. Referring to FIG. **9**C, a nasal interface **100** comprises nasal delivery elements in the form of nasal prongs **200**, **300** of different lengths and different internal cross-sectional areas **205**, **305**. Referring to FIGS. **9**C and **9**D, a nasal interface **100** comprises nasal delivery elements in the form of nasal prongs **200**, **300** of different lengths and different internal cross-sectional areas **205**, **305**. Referring to FIG. **9**E, a nasal interface **100** comprises nasal delivery elements in the form of nasal prongs **200**, **300** of substantially similar length where nasal prong **300** narrows at its tip to have a smaller internal cross-sectional area **305** than cross-sectional area **205** of nasal prong **200**. Referring to FIG. **9**F, a nasal interface **100** comprises nasal delivery elements in the form of nasal prongs **200**, **300** of substantially similar length but different internal cross-sectional areas **205**, **305**, where prong **200** comprises a meshed tip comprising a plurality of smaller orifices rather than a single opening. Referring to FIG. **9**G, a nasal interface **100** comprises nasal delivery elements in the form of orifice **200** and nasal prong **300** of different internal cross-sectional areas **205**, **305**. It should be understood that in an alternative to the depicted embodiment, area **305** could be greater than area **205**. Orifice **200** is formed in the rests adjacent a user's nare. Referring to FIG. **9**H, a nasal interface **100** comprises nasal delivery elements in the form of nasal prongs **200**, **300** carried on separate gas delivery conduits, that may or may not be held together in a single patient interface. Prongs **200**, **300** are of substantially similar length but different internal cross-sectional areas **205**, **305**. Referring to FIG. **9***l*, a nasal interface **100** comprises nasal delivery elements in the form of nasal prongs **200**, **300** of substantially similar length but different internal cross-sectional areas **205**, **305**, where the length and area of prong **200** is determined by a fitting or sleeve.

(49) FIGS. **10** and **11** are infrared photographs depicting symmetric and asymmetric flows of carbon dioxide (25 L/min).

(50) Securement System

(51) A securement system for securing a user interface and/or user tubing to a patient that is useful herein is illustrated in FIGS. **12** to **14**, and is described in published international application WO2012/053910, which is hereby incorporated by reference in its entirety. The securement system **500** is illustrated supporting a nasal cannula on an infant's face comprising prongs **510**, a backing or harness **503** that is coupled to both prongs that retains the prongs in fixed spaced relation, and may be produced in different sizes to accommodate variations in nasal spacing. Backing **503** may also include housing **504** that generally encloses or captures at least a portion of the tube **501**. The housing **504** incorporates a coupling **505** that can be used to affix headgear for retaining the interface in position. A pair of outriggers **506** project outwardly from the backing **503** on either side of the tube **501**. The outriggers **506** increase a contact surface between the interface and a patient, which distributes the interface retention force over a greater area and reduces the pressure applied to a user's face. The user side face of the backing **503** and outriggers **506** (i.e., the side that rests against the face of a user) may be contoured to reflect anticipated anatomical structures. The backing **503** and the outriggers **506** also may be formed from a flexible material to allow the structure to adapt to a particular individual's face.

(52) Beneficially, the system provides for a generally more rapid and improved or simplified ease

of installation of a user interface into an operational position on a user. Further, these benefits may also contribute to improved or simplified ease of application of alternative user interfaces or removal of a user interface from a user when cycling a user between different therapies (such as gas treatments, e.g. CPAP or high-flow applications).

(53) Certain user interfaces may be provided specifically for interaction or accommodation with the system of the described embodiments. Alternatively, nonmodified user interfaces can be accommodated by the described embodiments and can also be positioned relatively easily and with a minimum of time involved in an installation procedure.

(54) In various embodiments provided by the securement system, such a system may provide for quick location of an interface to a user, and may provide for the secured positioning of the interface.

(55) The ease with which a user interface may be positioned for a user is particularly useful. Providing a system whereby a carer (e.g. nurse) is able to apply the securement system with a single hand or single handedly, particularly where the interface user is an infant, is particularly advantageous.

(56) In addition, in another embodiment, the securement system provides for a first level of securement of a user interface to a user. For example, such a first level of securement may be that as shown by FIGS. **12** to **14**. Where a user requires additional or heightened security of user interface positioning or securement, a secondary level of interface securement can be utilized. Such an additional level may include application of an over patch, such as that provided, for example, by patch **660**. Such a patch **660** may be an adhesive patch and can be installed over the top of the user interface and/or tubing and adhered to a portion of the dermal patch **550**.

(57) The securement system **500** comprises a two-part releasable attachment or connection arrangement **551**. The releasable connection arrangement **551** acts between a pair of patches that are affixed to the patient and the user interface respectively.

(58) The first patch is a dermal patch **550** that is adhered or otherwise attached to the patient's skin. The dermal patch has a user side that faces the user's skin and an interface side that faces the user interface. The user side of the dermal patch **550** may be attached to the skin of a user by a dermatologically sensitive adhesive, such as a hydrocolloid. The user interface side of the dermal patch is provided with the first part **553** of the two-part releasable attachment or connection system **551**.

(59) The second patch is a user interface patch **552**. The user interface patch **552** also has a patient side and an interface side. The patient side of the user interface patch **552** is disposed adjacent the dermal patch when the system **500** is engaged. The complimentary second part of the two-part releasable attachment or connection system **553** is affixed to the patient side of the user interface patch **552**, so that the respective parts of the two-part releasable attachment or connection system **551** are easily engageable when the patches **550**, **552** are brought together. The interface side of the user interface patch **552** is affixed to the user interface. The user interface patch may be integrated with or suitably adhered to the user interface.

(60) A part or corner of the user interface patch **552** may include a region that does not attach to the dermal patch **550**. The general purpose of this is to allow a region (or tab) that can be more easily gripped by a user or carer for removing or detaching the interface from the dermal patch. For example, the backing **2004** may also comprise of such a corner region.

(61) The two-part releasable attachment or connection arrangement **551** may comprise a hook and loop material (such as Velcro™ hook and loop material), a magnet or an array of magnets disposed on the respective patches with the poles suitably arranged, an adhesive arrangement that is activated when the patches are urged together or another suitable releasable suitable coupling. The interface side of the dermal patch **550** may have one of a hook or a loop material, and the patient side of the user interface patch **552** may have the other of the hook or loop material, such that the dermal and user interface patches are releasably attachable or connectable to each other.

(62) When we refer to a hook and loop material, we mean any one of a wide variety of area type mechanical fasteners. For example, the Velcro™ product range includes hook and loop product where the hook component includes upstanding nylon hooks (formed as cut loops through a woven backing web) which engage with any complimentary loop pile material. The Velcro™ range also includes extruded hook products, typically of a smaller size and which mate with “fluffy” non-woven fiber backing materials. These hook materials are designed to work with a range of loop substrates and in some cases, these hook materials act as loop substrates as well. Other similar systems include the Dual-Lock™ recloseable fastener system from 3M of St Paul, Minnesota USA. The common feature of these releasable fastening systems is that they engage at any part of the contact between the two parts of the system. Precise alignment of individual connectors is not required because a multitude of connectors are distributed across the area of the product. A wide range of releasable fastener systems within this field may be used in the releasable attachment system for providing releasable attachment between the dermal patch and the user interface.
(63) The first part of the two-part releasable attachment or connection system may be adhered to the user interface side of the dermal patch with a suitable adhesive and occupy up to 100% or less than about 90%, or about 85%, or about 75%, or about 60% or about 50% or about 40% or about 30% or about 20% or about 10% of the interface side surface area of the dermal patch.
(64) According to some embodiments, the dermal patch **550** is a generally planar pad having a thickness much less than both its width and its length. In some embodiments, the pad has an overall oval shape, but may take other shapes.
(65) The pad includes a first part **553** of the two-part releasable attachment system **551**. In some embodiments, the construction of the dermal patch is such that the first part **553** of the releasable attachment system comprises a substrate and multitude of fastener elements (with effective hooks, effective loops or other elements) provided across the area of the substrate. The substrate is secured to the body of the dermal patch. In some embodiments, the substrate is secured by adhesive or by direct bonding during forming of the dermal patch.
(66) In some embodiments, the substrate is smaller in area than the dermal patch and is located on the dermal patch so that it does not reach any edge of the dermal patch. In this way, the edge of the substrate is spread from the edge of the dermal patch all around the perimeter of the substrate.
(67) Nasal Cannula—First Embodiment
(68) FIGS. **15** to **19** show a nasal cannula **2000** useful herein in detail, which is also described in published international application WO2012/053910, which is hereby incorporated by reference in its entirety. Nasal cannula arrangement **2000** comprises at least one nasal prong **2001**, modified as described above, the or each prong **2001** having a gas outlet **2002** adapted to be inserted into a user's nare (or nares) and a gas inlet **2003** fluidly connected to the gas outlet **2001**. The at least one nasal prong **2001** comprises a backing **2004**, the backing **2004** configured to rest on a user's face, and where a lip **2005** extends about at least a part of the perimeter of a rear surface **2006** of the backing **2004**. The rear surface **2004** is configured for receiving or retaining a user interface patch **2007**. In use, the user interface patch **2007** may be releasably attachable or connectable to, or with, a dermal patch **2008** that is or can be affixed to a user's face.
(69) As shown by FIGS. **16** and **19**, the rear surface **2006** can be initially provided without a user interface patch, i.e. the surface **2006** is configured to receive or retain a user interface patch **2007**. Such a user interface patch **2007** may be connected to the rear surface **2006** by an adhesive or other suitable connection. Once the patch is then in position, it is ready to be connected to or receive a dermal patch.
(70) In one form, the user interface patch may be one part of a two-part connection system, for example the loops of a hook and loop system. In such an instance, the interface facing surface of a dermal patch **2008** would comprise of hooks that are engageable with the loops of the user interface patch. See FIG. **17** illustrating rear surface **2006** retaining a user interface patch with loops ready for connection to the hooks of a dermal patch.

(71) FIG. **18** shows a section through a cannula **2000** with the hooks **2009** of a dermal patch engaged with the loops **2010** of a user interface patch. Also shown is lumen **2011** or gas passage pathway for gas being supplied to the gas inlet of the cannula for delivery to the gas outlet **2002** of prongs **2001**.
(72) Nasal Cannula—Second Embodiment
(73) A patient interface useful herein is shown in **20** to **23**, and is described in unpublished international application PCT/NZ2014/000082, which is hereby incorporated by reference in its entirety.
(74) Referring to FIGS. **20** to **23**, the nasal prongs **111** and **112** are curved to extend into the patient's nares in use and to provide a smooth flow path for gases to flow through, and are modified to be asymmetric, as described above. The inner surfaces of the prongs **111** and **112** may be contoured to reduce noise. The bases of the prongs **111** and **112** may include curves surfaces to provide for smoother gases flow. This may reduce the noise level during operation.
(75) In some configurations, pads may be mounted around the base of the prongs to reduce noise. The pad may be a foam material or a mouldable material that generally conforms to the patient's nose anatomy. Soft cushions or pillows may alternatively be provided.
(76) The nasal prongs **111** and **112** are substantially hollow and substantially tubular in shape. The nasal prongs **111** and **112** may be consistent in outer diameter along their lengths but are preferably shaped to fit the contours of the nares. Each prong **111**/**112**, where present, has an elongate opening Illa/**112***a* at the distal end opposing a base portion **118** of the face mount part **110** to encourage a high flow of gases into the cavity. In alternative embodiments the nasal prongs **111** and **112** may have a tapered profile of a wider end at the base portion **118** and a narrower end at the openings Illa and **112***a*. The openings Illa and **112***a* may be scooped to direct the flow of gases up the patient's nares. The face mount portion **110** and in particular the nasal prongs **111** and **112** are preferably designed not to seal about the patient's nares to avoid excessive and potentially harmful build up of pressure during high flow therapy. The nasal prongs **111** and **112** are therefore sized to maintain a sufficient gap between the outer surface of the prongs **111** and **112** and the patient's skin to avoid sealing the gas path between the cannula **100** and patient. It should be understood that in the context of the present invention, the nasal prongs **111** and **112** are modified to be asymmetric, as described above.
(77) The face mount part **110** is shaped to generally follow the contours of a patient's face around the upper lip area. The face mount part **100** is moulded or preformed to be able to conform to and/or is pliable to adapt, accommodate and/or correspond with the contours of the user's face, in the region of the face where the cannula is to be located.
(78) The face mount part **110** comprises an elongate base portion **118** from which the nasal prongs **111** and **112** extend, and two wing portions **113** and **114** extending laterally from either side of the base portion **118**. The wing portions **113** and **114** are integrally formed with the base portion **118** but may alternatively be separate parts. An inner side **119** of the base portion **118** of the face mount part **110** is formed with an elongated oval recess **119***a* configured to couple a corresponding outlet of the manifold **120**. An arcuate bridge **118***a* extends from the centre of the base portion **118** to an inner wall **113***a*/**114***a* of the wings to create two horizontal side entry passages **121***a* and **121***b* for insertion of the outlet **123** of the manifold **120** from either side **121***a* or **121***b* there-through.
(79) The gases flow manifold part **120** is generally tubular in shape having a substantially annular inlet **122** at one end, and that curves around into an elongate oval outlet **123** at the opposing end. The inlet **122** is preferably removably attachable to a conduit (not shown), preferably via a threaded engagement but alternatively via a snap-fit or any other type of coupling known in the art. Alternatively, the inlet is fixedly coupled or integrally formed with a conduit. The shape of the outlet **123** corresponds with and fits into the elongate recess **119***a* of the face mount part **110** with a friction fit or snap fit engagement, such that substantial force, or at least a deliberate force applied by a user or a carer, is required to separate the manifold **120** from the face mount part **110**.

(80) Desirably, the inadvertent disengagement of the manifold from the face mount part is to be avoided.
(81) An effective seal is also formed between the outlet **123** and the base portion **118** upon engagement of the two parts **110** and **120**. In particular, an outer rim or lip **126** is formed about the outlet **123** which corresponds with and sealably fits into an inner groove about the periphery of the inner recess **119***a* to retain the outlet of the manifold **120** within the face mount part **110**. Upon coupling the parts **110** and **120**, the upper surface of the lip **126** engages an inner surface **119***b* of the base portion **118**/surface **119***b* of the recess **119***a* to form an effective seal between the parts **110** and **120** for gases to flow there through. The nasal prongs **111** and **112** are aligned with corresponding apertures extending through the surface **119***b* of the base portion **118** to the recess **119***a* to fluidly connect the manifold outlet **123** with the nasal prongs **111** and **112** when coupled. The bridge **118***a* whilst defining the entry passages **121***a* and **121***b* for the manifold **120**, also helps to retain the manifold **120** within the base **118** of the face mount part **110**. A corresponding indent **128** is formed on the outer surface of the outlet **123** with opposed ridges **129***a* and **129***b* on either side to provide a push-fit engagement mechanism between the outlet **123** and the bridge **118***a* of the face mount part **110**.
(82) The exterior surface of the face mount portion and/or the wings **111** and **112** may comprises one or more channels to facilitate or allow air to flow between the lip and the cannula to cool the patient.
(83) Adhesive pads may be provided on each wing **111** and **112** to facilitate coupling of the cannula **100** to the patient—especially for younger children (e.g. under 5 years old).
(84) Each wing portion **113**/**114** extends laterally from the base portion **118** of the face mount part **110** and comprises an outer surface **113***b*/**114***b* configured to contact against the patient's face in use, preferably at least the upper lip region of the patient's face and slightly beyond towards the user's respective cheek. The distal ends **113***c* and **114***c* of the wings **113** and **114** are configured to releasably connect respective end portions **201** and **202** of a head strap **200**, described below, to retain the face mount portion **110** against the patient's face.
(85) In a preferred embodiment, each wing **113**/**114** comprises an integral ridge **115**/**116** extending transversely along the length of the wing **113**/**114** from the inner side of the face mount part **110** opposing the outer surface **113***b*/**114***b* of the wing **113**/**114**. In the preferred embodiment, each ridge **115**/**116** is substantially perpendicular to the outer contact surface **113***b*/**114***b* of the respective wing **113**/**114**. Each ridge **115**/**116** preferably extends from the base portion **118** of the face mount part **110** and along an upper region of the respective wing **113**/**114**. The ridge **115**/**116** acts to stabilize the face mount part **110** against the patient's face and minimize torsional stress which could otherwise cause the nasal prongs **111** and **112** to turn out and away from patient's nares. The dimensions of the ridge **115**/**116** including any combination of length, thickness and width (i.e. the extent to which the ridge extends away from the outer surface **113***b*/**114***b*), should be sufficient to improve the stabilization of the face mount part **110** upon the patient's face.
(86) The ridge **115**/**116** may be over-moulded or integrally formed with the respective wings **113**/**114** of the face mount part **110**.
(87) In a preferred embodiment, the distal or terminal end **113***c*/**114***c* of each wing **113**/**114** is accentuated or formed with a substantially greater contact surface area than a contact surface area of the wing **113**/**114** in the region adjacent the nasal prongs. This distal end portion **113***c*/**114***c* is preferably also angled relative to a general longitudinal axis of the face mount part **110** or base **118**. In particular, the distal end portion **113***c*/**114***c* extends obtusely away from the base **118**, or from a region of the respective wing **113**/**114** adjacent the base, and towards the patient's respective cheek in use. In this manner, connecting the head strap **200** to the distal end portions **113***c* and **114***c* of the wings **113** and **144** and wearing the interface **100** will create a substantially V-shaped structure that generates a force vector acting on the wings **113** and **114** and cannula **110** in the direction of the patient's cheeks. This has the effect of improving retention of the nasal prongs **111** and **112** within

the patient's nares and will cause the prongs **111** and **112** to turn into the nares when the distal ends **113***c* and **114***c* of the wings **113** and **114** are pulled by the respective ends **201** and **202** of the headgear **200**. Each distal end portion **113***c*/**114***c* may be angled smoothly or rounded or it may be angled sharply or abruptly relative to the remainder of the respective wing **113**/**114**.

(88) In the preferred embodiment, the distal end portion **113***c*/**114***c* is outwardly tapered to enlarge the contact surface area of the respective wing **113**/**114** and to also angle the distal end **113***c*/**114***c* towards the patient's cheeks.

(89) The increased surface area at the distal ends **113***c* and **114***c* provides added real estate for forming a suitable connection mechanism to couple the head strap **200**. In the preferred embodiment, clip retention formations **101** and **102** are provided at each distal end **113***c*/**114***c* to releasably couple dip components of the head strap **200** to the face mount portion **110** of the cannula **100**.

(90) A patient's septum and/or columella is generally quite a sensitive area and can be a source of discomfort when subjected to excessive contact pressure for prolonged periods. The present invention alleviates or reduces this pressure by providing a cushioned region of the cannula **100** adjacent the patient's septum/columella. In the preferred embodiment, the outlet **123** comprises a pair of opposed recesses or grooves **124**/**125** at the outer periphery for forming a dent or dip **127** in a region that locates adjacent the septum/columella in use. When coupled to the face mount portion **110**, this dip **127** creates a gap between the base portion **118** and the outlet **123** of the manifold **120**. In use, the gap cushions/softens the region of the cannula **100** directly adjacent the septum/columella. It disengages the pressure of the harder manifold part **120** from the septum/columella and allows the septum/columella to rest on the soft base of the face mount portion **110** only.

(91) The base portion **118** is preferably also formed with a hollowed outer portion and/or dipped outer profile **118***b* between the prongs **111** and **112** to alleviate pressure at the septum/columella. The hollowing should be as much as possible without (significantly) compromising the flow delivered to the patient. The dipped portion **118***b* is also preferably complementary to the periphery of the outlet **123** to maintain an effective seal between the two parts of the cannula.

(92) Headgear

(93) Generally, but also with reference to FIG. **24**, an adjustable strap **200** the adjustment mechanism is provided in the form of one or more insertable/removable strap segments or strap extensions **220**.

(94) In an alternative embodiment, a single strap may be provided with an adjustment mechanism comprising one or more adjustment buckles, as are well known in the art, located in a central region of the strap **200** that locates adjacent the rear of the patient's head in use, or located in regions of the strap **200** that locate to the side of the patient's head, such as near end portions **201**, **202**.

(95) Strap segments **220** of a fixed length can be releasably connected to the main strap **210** to extend its length. The main strap **210** in this embodiment comprises a pair of intermediate or secondary end portions **203**/**204** that are releasably connectable with one another, and that are also releasably connectable with respective ends **221** and **222** of the strap segments **220**. When the secondary end portions **203** and **204** are connected to one another, the main strap **210** is of a continuous starting length/size for the wearer. To extend the length of the strap **200** beyond this starting length, the main strap **210** can be disconnected at the secondary end portions **203**/**204** and one or more additional strap segments **220** are connected there between.

(96) A number of strap segments **220** of varying predetermined lengths may be provided to provide alternative adjustment lengths. For example, one or more strap segments **220** may be provided having a length within the range of about 1 cm to about 10 cm, or within the range of about 2 cm to about 6 cm. The strap segments **220** have lengths of, for example, about 2 cm, about 4 cm or about 6 cm. It will be appreciated that these examples are not intended to be limiting and the length of

each strap segments can be of any size as it is dependent on the user and/or application.
(97) The additional strap segments are preferably formed from a soft and stretchable/elastic material such as an elastic, textile material/fabric that are comfortable to the wearer. For example, a tubular knitted type head strap or sections of the head straps **210** may be utilized, particular for comfort over a user's ears.
(98) It will be appreciated, particular comfort may be achieved from a head strap which is able to provide suitable locating of the patient interface in a preferred relatively stable position on a user's face, yet simultaneously provide for a relatively loose fit or low tension fit about the user's head.
(99) Alternatively, the additional strap segments may be formed from a substantially rigid material such as a hard plastics material.
(100) A strap connector **230** is provided at each of the secondary end portions **203**/**204** of the main strap **210** and the respective end portions **203**/**204** of the strap segments **220**.
(101) Each connector **230** is provided with a strap connection mechanism at one end to couple to the strap material, and a coupling mechanism at an opposing end to releasably couple the respective end of a similar connector **230**.
(102) In an alternative, the connector **230** may be various different forms of adjustable buckles suitable for adjusting the length or tension of the head strap sections **210** which hold the patient interface in position about a user's head.
(103) It will also be appreciated that the connector **230** may be located so as to be off-set from a mid-point from the rear of a user's head, or may be offset to one side of a user's head. This may be advantageous so as to avoid impinging upon a part of a user's head which may otherwise be, in some positions such as sleeping, uncomfortable for the user.
(104) In yet a further embodiment, the strap segments may be of different lengths, so as to be asymmetrically provided or to help be operational with an off-set connector **230** position. Further, it may be that of the two strap segments **210**, one of those straps may be adjustable in length while the other is not. For example, one strap segment **210** may be of a permanent length or permanently connected to the connector **230**.
(105) In a preferred embodiment, the strap connection mechanism may comprise of a series of internal teeth located within the body of the connector for establishing a friction fit engagement with the respective end of the strap. A hinged jaw of the body is provided and closes upon the teeth to securely retain the end of the strap upon the teeth. The releasable coupling mechanism at the other end comprises a pair of male and female members, such as a protrusion and aperture respectively, both adapted to connect to corresponding male and female members of a similar connector **230**. A lug on the protrusion may couple a recess in the female member to provide a snap-fit engagement between the members. It will be appreciated that in alternative embodiments, any other suitable connector configuration may be used to releasably connect the secondary end portions of the strap to one another, and to the end portions of the additional strap segments.
(106) Cannula connectors **240** are provided at the primary end portions **201** and **202** of the main strap **210**. These connectors **240** have a similar strap connection mechanism to the strap connectors **230** of the secondary end portions **203** and **204**, but include a clip member, such as a push fit clip **241**, at an end of the connector **240** opposing the strap ends, The clip **241** is configured to releasably couple the respective formation **101**/**102** at the side of the cannula **110**. The clip member **241** is preferably a bendable part, such as a plastic part, that forms a hinged portion relative to the strap. The clip **241** is preferably preformed to have a curved shape along its length, such as one with an angle between flat and 20 degrees for example. This curve allows the clip **241** to fit the contour of the patient's face in the region of the clip **241**.
(107) Sleeve **270** may be preformed to have a curved shape along its length, such as one with an angle between flat and 20 degrees for example. The curve allows the sleeve to fit the contour of the patient's face or cheek in the region of the sleeve in use. Alternatively the sleeve **270** may take on the shape of a curved sleeve upon engagement with the primary end portion **201**/**202** or connector

240 of the head strap **200**.
(108) The sleeve **270** provides a surface region of relatively higher frictional surface material for frictionally engaging with the user's face or facial skin. This surface region is to be positioned for frictional engagement with the facial cheek skin of a user. The surface region is at least localized to the strap or the section of strap which is to be positioned upon the cheeks of a user. The surface region provided with the relatively higher frictional surface material is preferably of a material that is smooth and comfortable on the skin of the patient. The sleeve **270** or at least the surface region **271** is therefore formed from a relatively softer material than the connector **240**.
(109) In one preferred embodiment, the surface region **271** or the sleeve **270** is formed from a soft Thermoplastic Elastomer (TPE), but may alternatively be formed from another plastics material such as Silicone, or any other biocompatible materials.
(110) The surface region **271** may be a surface of wider surface area more adjacent to the patient interface than the surface area more distant from the patient interface. In the preferred embodiment, the sleeve **270** tapers from a relatively wider surface area **273** to a relatively lesser surface area **274** in a direction extending away from a connection point between the connector **240** and the patient interface **100**. The width of the sleeve at the end **273** is preferably the same or similar to the width of the tapered distal end **113***c*/**114***c* of the corresponding wing portion **113**/**114** of the face mount part **110**. This provides a smooth transition between the patient interface **100** and the headgear **200** for improving aesthetics and achieving a visually appealing effect.
(111) Headgear for other forms of interface in addition to nasal cannula may comprise cheek supports **270** as described or similar, at or adjacent either side end of straps of headgear of the interface, which connect to the mask, for frictionally engaging with the user's face to stabilize the mask on the face at the cheeks, and particularly for example direct nasal masks comprising nozzles or pillows which enter or engage the nares of the wearer. Such headgear may again comprise a single head strap adapted to extend in use along the patient's cheeks, above the ears and about the back of the head, with ends comprising clips in any suitable form which couple to the mask on either side (or are permanently attached to the mask).
(112) Patient interfaces according to the embodiments described above may be employed in a method a method of delivering gas to the airway of a subject in need thereof, improving the ventilation of a subject in need thereof, reducing the volume of anatomical dead space within the volume of the airway of a subject in need thereof, and/or treating a respiratory condition in a subject in need thereof, as described above.
(113) Unless the context clearly requires otherwise, throughout the description and the claims, the words “comprise comprising”, and the like, are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense, that is to say, in the sense of “including, but not limited to”.
(114) Reference to any prior art in this specification is not, and should not be taken as, an acknowledgment or any form of suggestion that that prior art forms part of the common general knowledge in the field of endeavour in any country in the world.
(115) The 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, in any or all combinations of two or more of said parts, elements or features.
(116) Where, in the foregoing description reference has been made to integers or components having known equivalents thereof, those integers are herein incorporated as if individually set forth.
(117) It should be noted that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications may be made without departing from the spirit and scope of the invention and without diminishing its attendant advantages. For instance, various components may be repositioned as desired. It is therefore intended that such changes and modifications be included within the scope of the invention. Moreover, not all of the features, aspects and advantages are

necessarily required to practice the present invention. Accordingly, the scope of the present invention is intended to be defined only by the claims that follow.

Claims

1. A nasal interface for providing a gas flow to a patient's nares, the nasal interface comprising: a first nasal delivery element and a second nasal delivery element, wherein the first nasal delivery element and the second nasal delivery element are structurally different from each other to provide an asymmetric flow of gas at the patient's nares; and wherein the first nasal delivery element and the second nasal delivery element are both configured to deliver a flow of gas to the patient's nares.
2. The nasal interface of claim 1, wherein at least one of the first nasal delivery element and the second nasal delivery element is shaped to fit contours of the patient's nares.
3. The nasal interface of claim 1, wherein at least one of the first nasal delivery element and the second nasal delivery element are sized to maintain a gap between an outer surface of each of the first nasal delivery element and the second nasal delivery element and a surface of each of the patient's nares to avoid sealing a gas path between the nasal interface and a patient.
4. The nasal interface of claim 1, wherein at least one of the first nasal delivery element and the second nasal delivery element has an elongate opening to encourage a high flow of gas into the patient's nares and/or wherein at least one of the first nasal delivery element and the second nasal delivery element has a scooped opening to direct the gas flow up the patient's nares.
5. The nasal interface of claim 1, wherein the gas flow enters a patient's nose via both nares and leaves the patient's nares from one nare.
6. The nasal interface of claim 1, wherein the gas flow enters a patient's nose through one nare and leaves the patient's nose via both nares.
7. The nasal interface of claim 1, wherein different proportions of flow enter a patient's nose through both nares and different proportions of flow leave the patient's nose through both nares.
8. The nasal interface of claim 1, wherein different proportions of flow enters a patient's nose via both nares and leaves the patient's nose from one or both nares.
9. The nasal interface of claim 1, wherein at least one of the first nasal delivery element and the second nasal delivery element comprises a sleeve or nasal pillow.
10. The nasal interface of claim 1, wherein at least one of the first nasal delivery element and the second nasal delivery element delivers gas at a flow rate of about 5 L/min to about 60 L/min.
11. The nasal interface of claim 1, wherein the gas flow is continuous or variable and/or wherein a temperature of the gas flow is between 33° C.-37° C.
12. The nasal interface of claim 1, further comprising a headgear comprising an adjustable strap.
13. The nasal interface of claim 12, wherein the adjustable strap comprises one or more insertable or removable strap segments or strap extensions.
14. The nasal interface of claim 12, wherein the adjustable strap comprises one or more adjustment buckles located in a central region of the adjustable strap.
15. The nasal interface of claim 1, wherein a first gas flow rate out of the first nasal delivery element is between 20% to 80% of a second gas flow rate out of the second nasal delivery element.
16. The nasal interface of claim 1, further comprising a face mount part comprising a base portion and the first nasal delivery element and the second nasal delivery element, the face mount part comprising at least one substantially horizontal side entry passage to an interior of the base portion.
17. The nasal interface of claim 16, further comprising a manifold part for the gas flow within the interior of the base portion, the manifold part including an outlet, the at least one substantially horizontal side entry passage having the outlet of the manifold part inserted from either side or there-through.
18. The nasal interface of claim 17, wherein the face mount part comprises one or more wing portions configured to stabilize a patient interface upon a patient's face.

19. A method of delivering gas to a patient's airway, the method comprising: delivering a flow of gas to a patient's nares through a nasal interface comprising asymmetrical nasal delivery elements to generate an asymmetrical flow of gases at the patient's nares; wherein the nasal interface comprises a first nasal delivery element and a second nasal delivery element, wherein the first nasal delivery element and the second nasal delivery element are structurally different from each other to provide an asymmetric flow of gas at the patient's nares; and wherein the first nasal delivery element and the second nasal delivery element are both configured to deliver a flow of gas to the patient's nares.